CONSTITUTIONAL COURT OF SOUTH AFRICA

Case CCT 59/04

MINISTER OF HEALTH	First Applicant
PROFESSOR D McINTYRE NO	Second Applicant
versus	
NEW CLICKS SOUTH AFRICA (PTY) LTD	First Respondent
PHARMACEUTICAL SOCIETY OF SOUTH AFRICA	Second Respondent
UNITED SOUTH AFRICAN PHARMACIES	Third Respondent
LA TANDT AND ASSOCIATES (PTY) LTD	Fourth Respondent
IRVINE AND MILLER (PTY) LTD	Fifth Respondent
MEDICROSS HEALTH CARE HOLDINGS LTD	Sixth Respondent
NETWORK HEALTH CARE HOLDINGS LTD	Seventh Respondent
I M DAVIS NO 2 CC	Eighth Respondent
together with	
TREATMENT ACTION CAMPAIGN	First Amicus Curiae
INNOVATIVE MEDICINES SOUTH AFRICA	Second Amicus Curiae

Heard on : 15-16 March 2005

Decided on : 30 September 2005

JUDGMENT

INDEX

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THE COURT:

[1] The Medicines Act was first enacted in 1965.[1] It has been amended on no less than fifteen different occasions since then. From 1965 until 1997 the main focus of

[1] The Medicines and Related Substances Control Act, 101 of 1965. The short title of the Act is now the Medicines and Related Substances Act, 1965. We shall refer to it as "the Medicines Act" throughout.

the Act was quality control.[2] In 1997 measures were introduced into the legislation directed towards making medicines more affordable.[3] This, to give effect to the state's constitutional obligation to provide everyone with access to health care services.[4]

[2] The newly introduced measures, especially those contained in sections15 A – C, sections 18A – C and sections 22B – H, do not fit comfortably into an Act designed to serve other purposes. They pose new problems for those who have to implement them, for those who are directly affected by them as well as for those who have to adjudicate them. The grafted sections make provision for controls to be introduced in respect of the production, importation, distribution and sales of medicines,[5] the relaxation of certain patent restrictions, the promotion where possible of generic substitution of medicines, and the establishment of a Pricing Committee to make recommendations for the introduction of a pricing system for all medicines sold in the Republic.

[3] The new measures provoked strong opposition from within the pharmaceutical industry, including litigation challenging the validity of certain of the provisions of the amending legislation. The 1997 Act was meant to be brought into force by

[2] See in this regard the remarks of Kriegler AJA in *Administrator, Cape v Raats Röntgen and Vermeulen (Pty) Ltd* 1992 (1) SA 245 (A) at 254B-E, and Sachs J in *Mistry v Interim Medical and Dental Council of South Africa and Others* 1998 (4) SA 1127 (CC) at paras 17-20; 1998 (7) BCLR 880 (CC) at paras 10-13.

[3] Medicines and Related Substances Control Amendment Act, 90 of 1997.

[4] Sections 27(1)(a) and 27(2) of the Constitution.

[5] The Medicines Act regulates both medicines and other Scheduled substances. In this judgment, when we refer to medicines, we are also referring to other Scheduled substances.

proclamation. However, from 1997 until 2002 the amending legislation remained dormant.[6] In 2002 the dormant provisions were amended by the Medicines and Related Substances Amendment Act, 59 of 2002, and the sections as amended were brought into force on 2 May 2003.[7]

[4] The present litigation arises out of regulations made to give effect to the pricing system for the sale of medicines by the Minister of Health (the Minister) on the recommendation of the Pricing Committee. The validity of these regulations has been challenged, and the challenges have been the subject of contrary decisions in the Cape High Court (the High Court) and the Supreme Court of Appeal (SCA). The proceedings aroused extensive public interest and a great deal of emotion.

In the High Court

[5] In May 2004 two applications challenging the regulations on various grounds were instituted in the High Court by, in the one case, New Clicks and, in the other, the Pharmaceutical Society of South Africa (PSSA) and others (for ease, the applicants in both cases are referred to as "the Pharmacies"). The challenges included an attack on the functioning of the Pricing Committee, the procedures used by the Pricing

[6] Subsequent to the passing of the amending legislation of 1997, but before it was brought into force, the legislature passed a new piece of legislation, the South African Medicines and Medical Devices Regulatory Authority Act, 132 of 1998, which repealed all but a few provisions of the Medicines Act. This new legislation was promulgated on 11 December 1998 and was to come into force on a date to be determined by the President. Proclamation R49 of 1999 purported to bring the legislation into force on 30 April 1999, but that proclamation was set aside. See *Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex parte President of the Republic of South Africa and Others* 2000 (2) SA 674 (CC); 2000 (3) BCLR 241 (CC) at paras 1-4. The legislation was thus never brought into force and was repealed by the Medicines and Related Substances Amendment Act, 59 of 2002.

[7] By Proclamation R23 of 28 March 2003 published in Government Gazette No 24627.

Committee and the substance of the regulations promulgated by the Minister on the Pricing Committee's recommendation. The Pricing Committee chose to abide the decision of the High Court.

[6] The matters were consolidated and heard by a full bench of three judges. Judgment was handed down on 27 August 2004. A majority dismissed the challenges to the regulations while a minority judgment held that the regulations should be set aside on various grounds.[8] The applicants sought leave to appeal against the order of the High Court, and the application for leave to appeal was by agreement heard in the High Court on 20 September 2004. Judgment was reserved.

In the SCA

[7] There was a delay in delivering judgment on the application for leave to appeal, and the Pharmacies decided to approach the SCA directly for leave to appeal. On 10 and 11 November 2004 they lodged applications in the SCA for leave to appeal. The SCA set the matter down for argument on 30 November and 1 December. Counsel for the Minister contended that the SCA did not have jurisdiction to hear the appeal, as no decision had yet been given on the Pharmacies' application for leave to appeal, and asked for argument on the issue of jurisdiction to be separated from argument on the other issues raised in the application. The SCA, however, directed that both the question of jurisdiction and that of the merits be dealt with at a single hearing. At the hearing counsel for the Minister persisted in the position that only the question of

[8] *New Clicks South Africa (Pty) Ltd v Tshabalala-Msimang and Another NNO; Pharmaceutical Society of South Africa and Others v Minister of Health and Others* 2005 (2) SA 530 (C).

jurisdiction be entertained at that stage. When the hearing went ahead on both aspects, counsel for the Minister declined to present any argument on the merits.

[8] On 3 December, after the hearing but before the SCA had given its judgment, the High Court delivered a judgment in which it ordered by a majority that leave to appeal be refused.[9] On 20 December the SCA handed down a unanimous judgment holding that it had jurisdiction to hear the matter, granting leave to appeal and holding the regulations to be invalid.[10] The Minister and the Pricing Committee then applied for leave to appeal to this Court against the decision of the SCA. They later made a separate application to this Court for a declaration to the effect that the lodging of the application for leave to appeal automatically suspended the order of the SCA. A separate judgment refusing that application is to be handed down at the same time as this judgment. The applications were heard together in this Court on 15 and 16 March.[11]

In this Court

[9] The application for leave to appeal to this Court was brought on behalf of the Minister and the Pricing Committee. The Pharmacies contended that the Pricing Committee, having elected to abide the judgment of the High Court, was not entitled

[9] *New Clicks South Africa (Pty) Ltd v Tshabalala-Msimang and Another NNO; Pharmaceutical Society of South Africa and Others v Minister of Health and Another* 2005 (3) SA 231 (C).

[10] *Pharmaceutical Society of South Africa v Tshabalala-Msimang and Another NNO; New Clicks South Africa (Pty) Ltd v Minister of Health and Another* 2005 (3) SA 238 (SCA); 2005 (6) BCLR 576 (SCA).

[11] The Court granted applications by the Treatment Action Campaign and Innovative Medicines South Africa to present argument as amici curiae. The Treatment Action Campaign provided both written and oral submissions, while Innovative Medicines South Africa provided only written submissions, and did not seek leave to address the Court orally.

to appeal against the decision of the SCA. This Court will not ordinarily grant leave to a party who has abided the decision of the lower court to appeal to this Court against the decision given by that court. There may be special circumstances where that would be permissible. This is not an issue, however, that needs be decided in this judgment. The application for leave to appeal to this Court is against the order made by the SCA. It appears from the record of the proceedings in the SCA that the Pricing Committee lodged an affidavit opposing the application for leave to appeal to that court. The SCA judgment refers to the argument being addressed to them, and the appeal being opposed by, "the respondents". There is nothing, however, to indicate whether objection was taken to the standing of the Pricing Committee to oppose the application or whether this issue was considered by the SCA.

[10] In this Court the Minister and the Pricing Committee were both represented by the same attorneys and counsel and relied on the same record, the same application and the same arguments. Nothing turns on whether the arguments must be dealt with as having been addressed to us on behalf of them both, or on behalf of the Minister alone. In particular, there is no prejudice to the Pharmacies in so doing. In the circumstances, and since it appears that the Pricing Committee opposed the application for leave to appeal to the SCA and was party to those proceedings, we have decided that it should be allowed standing to participate in the appeal to this Court as well.

[11] The Minister and the Pricing Committee argued that the SCA had not had jurisdiction to hear the appeal on the merits and that the appeal should succeed on that

ground alone. They contended further that the Minister had complied with the terms of the Medicines Act when making the regulations.[12] The Pharmacies argued that the SCA had been entitled to hear the appeal and that both in terms of the process followed and in regard to their substance, the regulations had failed to comply with the requirements of the Medicines Act. More particularly, they claimed that the fee the pharmacists were allowed to charge was not "appropriate" as required by the Medicines Act.

[12] Although the Court was aware of the need to bring to an end the uncertainty that reigned in the pharmacy sector, it was obliged to give full and appropriate consideration to the many questions raised. On most matters the Court is unanimous. On certain issues, including the question whether the dispensing fee to be charged by the pharmacists is appropriate, members of the Court adopt different positions. There are five separate judgments dealing with the merits, and three short judgments indicating concurrences. Taken together the judgments deal with a wide-ranging number of complex legal and factual issues. The summary that follows reflects the key issues raised, the positions taken by each member of the Court on those issues and the order made by the Court.

The issues raised and the conclusions reached

[13] A list of the principal issues and conclusions follows:

[12] Full details of the arguments appear in the judgment of Chaskalson CJ below at paras 59-82.

1. *Did the SCA have jurisdiction to hear the appeal by the pharmacies?* The Court holds unanimously that it did.[13]

2. *Was the SCA entitled to hear argument on the merits of the appeal and to deliver a judgment on the merits in the absence of any argument on the merits by the Minister?* The Court holds unanimously that it was.[14]

3. *Despite the decision not to argue the merits of the case before the SCA, are the Minister and the Pricing Committee entitled to appeal to this Court?* The Court holds unanimously that, given the circumstances of this case, they are.[15]

4. *Does the Promotion of Administrative Justice Act, 3 of 2000 (PAJA) apply to the recommendations of the Pricing Committee and the subsequent making of regulations by the Minister?* Five members of the Court hold that PAJA is applicable.[16] One member of the Court holds that PAJA is applicable to the fixing of the dispensing fee only;[17] and five other members of the Court hold that it is not necessary to decide whether PAJA is applicable, since on the

[13] See paras 76-77 of the judgment of Chaskalson CJ.

[14] See paras 52-58 of the judgment of Chaskalson CJ.

[15] See paras 83-84 of the judgment of Chaskalson CJ.

[16] Chaskalson CJ, Langa DCJ, Ngcobo, O'Regan and Van der Westhuizen JJ. The reasoning of Chaskalson CJ and Ngcobo J differs in that Chaskalson CJ holds that PAJA applies to the making of all regulations, whereas Ngcobo J decides the matter narrowly in respect of the powers in issue in this case, and leaves the question whether PAJA applies to all regulation-making open.

[17] Sachs J who holds that the general regulatory scheme is governed by the principles of legality.

assumption in favour of the Pharmacies that it is, they find the procedure followed to have been fair.[18]

5. *Did the fact that not all members of the Pricing Committee were present at all its meetings, including the oral representations by interested parties in April 2004, render the proceedings of the Pricing Committee unfair or unlawful?* The Court unanimously holds that it did not.

6. *Does the Medicines Act permit the regulations to provide for price control in the manner in which they have?* The Court unanimously holds that it does.[19]

7. *Do regulations 10 and 11 fix an "appropriate" dispensing fee as contemplated by the Medicines Act?* Six members of the Court hold that they do not.[20] The five remaining members of the Court hold that the dispensing fees set are in the main "appropriate". However they also hold that the dispensing fees are not appropriate in so far as rural and courier pharmacies are concerned.[21]

8. The Court holds unanimously that the challenge to the regulations overall must fail and that the SCA was accordingly wrong in setting aside the regulations as a whole. However, it considered a wide range of challenges to individual

[18] Moseneke, Madala, Mokgoro, Skweyiya and Yacoob JJ. See the reasoning in the judgment of Moseneke J at para 671.

[19] See the judgments of Chaskalson CJ (at paras 208-210); Moseneke J (at para 727-734).

[20] Chaskalson CJ, Langa DCJ, Ngcobo, O'Regan, Sachs and Van der Westhuizen JJ. The reasoning of Chaskalson CJ and Ngcobo J is slightly different, but they both reach the same conclusion.

[21] Moseneke, Madala, Mokgoro, Skweyiya and Yacoob JJ. See the reasoning in the judgment of Moseneke J at paras 779-781, and at paras 767-772.

regulations. The most important conclusions on these challenges are the following:

(a) The Court unanimously holds that regulation 5(1) is invalid in that it omits the words "and VAT" and that the invalidity can be cured by reading the words "and VAT" into the regulation after "logistics fee".[22]

(b) By a majority,[23] the Court holds that regulation 5(2)(c) is not void for vagueness but that the words "single exit" must be severed from Appendix A of the regulations wherever they appear.[24]

(c) The Court unanimously holds regulation 5(2)(e) to be invalid on the ground that it constitutes an improper delegation to the Director-General of the powers of the Pricing Committee and the Minister. The Court holds unanimously that this can be cured by severing the words "Director-General" from the relevant regulation, and reading into the regulation in their place, the words "Minister on the recommendation of the Pricing Committee".[25]

[22] See para 263 of the main judgment by Chaskalson CJ.

[23] Langa DCJ, Moseneke, Yacoob, Madala, Mokgoro, Sachs, Skweyiya and Van der Westhuizen JJ. The reasons appear from the judgment of Yacoob J at paras 804-811.

[24] Chaskalson CJ holds regulation 5(2)(c) which refers to Appendix A to be void for vagueness. See para 277 of the judgment of Chaskalson CJ. Ngcobo J (with whom O'Regan J concurs) also holds the regulation to be void for vagueness, though for somewhat different reasons.

[25] See para 281 of the main judgment by Chaskalson CJ.

(d) The Court unanimously holds that regulation 5(2)(g) dealing with the determination of a maximum logistics fee is invalid because it permits the Minister to make such determination without reference to the Pricing Committee. This is an improper delegation. The Court unanimously holds that it can be cured by reading in after the word "Minister" the words "on the recommendation of the Pricing Committee".[26]

(e) The Court unanimously holds that regulation 8(1) is invalid because it provides that the Minister may make annual determinations of price increases "after consultation" with the Pricing Committee. This is an improper delegation. The Court unanimously holds that the invalidity can be cured by severing the words "after consultation with" and replacing them with the words "on the recommendation of".[27]

(f) By a majority,[28] the court holds that regulation 8(3), which deals with increases of the single exit price during the year, is not void for vagueness.[29]

[26] See para 300 of the judgment of Chaskalson CJ.

[27] See para 286 of the judgment of Chaskalson CJ.

[28] Moseneke, Yacoob, Madala, Mokgoro, Skweyiya and Van der Westhuizen JJ. The reasons appear from the judgment of Yacoob J at paras 822-835.

[29] Chaskalson CJ, with whom Langa DCJ, O'Regan and Sachs JJ concur, concludes that regulation 8(3) is void for vagueness. See para 292 of Chaskalson CJ's judgment. Ngcobo J concludes that regulation 8(3)(iv) is invalid; and that regulation 8(3)(i) is invalid, but can be saved by an appropriate severance and reading in. See paras 492-496, and 498 of his judgment.

(g) The Court holds unanimously that the failure of the regulations to make any provision for the publication of the logistics fee is inconsistent with the requirement of transparency in the Medicines Act. The Court holds that this omission can be cured by reading in the words "and in the case of the information referred to in regulation 21(2)(d) must" before the words "publish or otherwise communicate, or require" in regulation 21.[30]

(h) The Court unanimously holds that regulation 13 dealing with the appropriate fee for the sale of Schedule 0 medicines is invalid.[31]

(i) By a majority,[32] the court dismisses the objection to regulations 22 and 23, which confer a power on the Director-General to determine whether a specific single exit price is reasonable.[33]

Remedy

[14] It will be seen from the above summary that the Court has unanimously accepted the validity of a single exit price being established for medicines sold in South Africa, and the validity of the regulatory structure put in place for its realisation

[30] See the judgment of Chaskalson CJ at para 304.

[31] See the judgment of Chaskalson CJ at para 406; see also the judgment of Moseneke J at para 677.

[32] Langa DCJ, Moseneke, Madala, Mokgoro, Ngcobo, O'Regan, Sachs, Skweyiya, Van der Westhuizen and Yacoob JJ. See the reasoning in paras 836-841 of the judgment of Yacoob J.

[33] Chaskalson CJ disagrees. He holds that the regulations do not require the single exit price to be set at an amount that the Director-General considers to be reasonable, and that his views as to the reasonableness of the single exit price are accordingly irrelevant. In the circumstances the regulations are not authorised by section 22G of the Medicines Act and are invalid. See paras 418-419 of his judgment.

by the Minister on the recommendation of the Pricing Committee. Although the regulatory scheme as a whole passes muster, there are a number of detailed provisions that fall short of the requirements of the Medicines Act. In most cases the Court has decided that the defects in the regulations can be cured by severance of certain words and/or reading in other words. In other cases the defects relate to relatively unimportant aspects of the scheme, which could continue to function while the defects are being corrected. Special attention, however, needs to be given to the invalidation of regulations 10 and 11 on the ground that the dispensing fee arrived at is not appropriate.

[15] It is necessary to consider whether because of the defects in regulations 10 and 11 the entire scheme fails, or whether the remainder of the regulations can stand without a dispensing fee for pharmacists. Whilst recognising that severability in constitutional cases may often require special treatment, this Court has applied[34] the conventional test for severance laid down in *Johannesburg City Council v Chesterfield House (Pty) Ltd*[35]

> "where it is possible to separate the good from the bad in a Statute and the good is not dependent on the bad, then that part of the Statute which is good must be given effect to, provided that what remains carries out the main object of the Statute."

[34] *Coetzee v Government of the Republic of South Africa; Matiso and Others v Commanding Officer, Port Elizabeth Prison, and Others* 1995 (4) SA 631 (CC); 1995 (10) BCLR 1382 (CC) at para 16; *Chief Lesapo v North West Agricultural Bank and Another* 2000 (1) SA 409 (CC); 1999 (12) BCLR 1420 (CC) at para 31.

[35] 1952 (3) SA 809 (A) at 822C-E

[16] Bearing in mind the important constitutional purpose served by the pricing system, we are satisfied that the correct remedy in the present case is to preserve as much of the scheme as is possible, as long as this can be done in a manner that serves the main object of section 22G of the Medicines Act. The main object of section 22G is to make medicines more accessible and more affordable by means of a transparent pricing system. Regulations 10 and 11 deal with the dispensing fee which is an important part of the pricing system, but what remains if these regulations are declared to be invalid, will not be inconsistent with the main object of the legislation. What remains will be a system which makes provision for a single exit price for each medicine and Scheduled substance, which must be the only price at which manufacturers may sell that medicine. Wholesalers, distributors and retailers may not sell medicine at a price higher than the single exit price. Wholesalers and distributors may charge only an agreed logistics fee subject to the controls imposed by the regulations. That is a coherent system, consistent with the Medicines Act, that gives effect to the main object of section 22G.

[17] There is great public interest in achieving finality in this important matter. This Court overturns the SCA's conclusion that the regulatory scheme as a whole is invalid. However, it holds that certain individual regulations are invalid. Considerable work has already been done by the Pricing Committee, and it would not be in the public interest for the Pricing Committee to have to start its determination of the dispensing fee or the other invalid regulations from the beginning again. In terms of section 8(1) of PAJA, a court or tribunal in judicial review proceedings may grant

any order that is just and equitable, including orders setting aside the administrative action and remitting the matter for reconsideration by the administrator with or without directions.[36] In the circumstances of this case, the proper course is to remit the matter to the Pricing Committee and the Minister for reconsideration in the light of this judgment.

[18] The Pricing Committee as a whole must take appropriate account of the oral representations already made to it. It will be able to determine its own procedure for hearing further representations by any interested parties, who should be given a reasonable opportunity to update or add to information already given to the Pricing Committee. In this regard, it should be emphasised that the regulations seek to introduce a new scheme with the purpose of enhancing access to affordable medicines, a goal to which all the parties to this dispute subscribe and which is in the interest of all consumers of medicines. For this goal to be achieved, the co-operation of all interested parties in both its establishment and implementation is required. Interested parties should therefore provide any information required by the Pricing Committee or the Minister as fully and timeously as possible.

[19] In its reconsideration of the issue of the appropriate dispensing fee, the Pricing Committee should look at new information that has become available in the intervening year since it made its recommendation.[37] Because single exit prices have

[36] Section 8(1)(c) of PAJA.

[37] As Lord Macnaghten reasoned in a somewhat different context but in a memorable formulation that is applicable here:

been set for most if not all medicines during the last year, the process of establishing the viability of pharmacies on the basis of a particular dispensing fee can now be undertaken on a more certain basis than during the Pricing Committee's previous deliberations. Moreover, the conduct of this litigation has made it plain that particular attention needs to be paid to the circumstances at least of rural and courier pharmacies to ensure that the right of access to health care is not prejudiced by driving such pharmacies out of the market. Section 172(1)(b) of the Constitution entitles a court deciding a constitutional matter to make any order that is just and equitable. It would not be just and equitable for pharmacists not to be entitled to charge a dispensing fee in the interim before the appropriate fee is determined by regulation. Section 22G(3)(b) and (c) of the Medicines Act must not be construed as precluding this, and we will make an order to that effect. There is no reason to believe that pharmacists, who are members of an ethical profession, will seek to exploit the situation by charging excessive dispensing fees. Should any pharmacist attempt to do so, that would constitute misconduct in terms of section 42 of the Pharmacy Act, 53 of 1974.

[20] One further point needs to be made. The effect of this Court's ruling is that portions of the published regulations no longer accurately reflect the legally valid content of the regulations as the Court orders that certain words be severed, and in

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> "In order to enable him to come to a just and true conclusion it is his duty, I think, to avail himself of all information at hand at the time of making his award which may be laid before him. Why should he listen to conjecture on a matter which has become an accomplished fact? Why should he guess when he can calculate? With the light before him, why should he shut his eyes and grope in the dark?"

The Bwllfa and Merthyr Dare Steam Collieries (1891) Limited v The Pontypridd Waterworks Company 1903 AC 426 (HL) at 431. This case involved the estimation of loss of profits. Similar reasoning has been applied in South African courts, see *Devland Investment Co v Administrator, Transvaal* 1979 (1) SA 321 (T) at 327-8.

some cases, that other words be read into the regulations. In our view, in order to promote the transparency required by the Act and the foundational value of the rule of law, it is necessary to make an order requiring the Minister to republish the regulations as a whole so that they reflect the correct legal position as set out in this Court's order. That publication should take place soon and this should be done within 60 days of the date of this judgment. If the process of determining the appropriate dispensing fee is not complete by that date, the regulations will have to be published without containing an appropriate dispensing fee which will then have to be published as soon as that process is complete. It need hardly be said, however, that given the great public interest in resolving this matter, it would be desirable for that process to be complete within 60 days and for the regulations to be republished then in their entirety. It is for this reason that the period we have set is longer than we would otherwise have determined.

Costs

[21] The appeal by the Minister and the Pricing Committee is upheld in part and dismissed in part. The result is that the Pharmacies have succeeded in their challenge to the appropriateness of the dispensing fee, a central feature of the dispute. On the other hand the Minister and the Pricing Committee have succeeded in overturning the declaration of invalidity in relation to the regulations as a whole. They have therefore both been partially successful in this Court. A further relevant fact in considering the costs in this Court is that the Minister failed to present either written or oral argument to the SCA which may have changed the course of the proceedings. In our view, it is

appropriate in the light of these considerations for the Minister to pay half the costs of the Pharmacies in this Court. As to the proceedings before the SCA, it is our view that it is just to reflect disapproval of the Minister's failure to present argument on the merits in that court, to require the Minister to bear the costs of the Pharmacies in full in that court. The costs in the High Court proceedings should follow the costs in this Court and the Minister should pay half the costs of the Pharmacies in the High Court.

Order

[22] In the light of all the separate judgments delivered in this matter, the following order is made:

1. The applicants are granted leave to appeal.
2. The appeal is upheld in part.
3. The orders of the Supreme Court of Appeal and the Cape High Court are set aside and replaced with the following order:

(a) (i) The omission from regulation 5(1) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 of the words "and VAT" after the words "logistics fee" is declared to be inconsistent with the requirements of the Medicines and Related Substances Act, 101 of 1965, as amended, and accordingly with the Constitution.

(ii) Regulation 5(1) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government

Notice No R553 of 30 April 2004 is to be read as though the words "and VAT" appear therein after the words "logistics fee".

(b) The words "single exit" contained in Appendix A to the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 are declared to be inconsistent with the requirements of the Medicines and Related Substances Act, 101 of 1965, as amended, and accordingly with the Constitution and are to be severed wherever they appear before the word "price" in Appendix A.

(c) (i) Regulation 5(2)(e) in the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 is declared to be inconsistent with the Medicines and Related Substances Act, 101 of 1965, as amended, and accordingly with the Constitution to the extent that it refers to the "Director-General" and not to the "Minister on the recommendation of the Pricing Committee".

(ii) It is declared that the words "Director-General" in regulation 5(2)(e) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 are to be severed from the regulations and the regulations are to be read as if the words "Minister on the recommendation of the Pricing Committee" appear wherever the words "Director-General" appeared.

(d) (i) The omission from regulation 5(2)(g) in the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances

contained in Government Notice No R553 of 30 April 2004 of the words "on the recommendation of the Pricing Committee" is declared to be inconsistent with the Medicines and Related Substances Act, 101 of 1965, as amended, and accordingly with the Constitution.

(ii) Regulation 5(2)(g) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 is to be read as if the words "on the recommendation of the Pricing Committee" appear after the words "the Minister".

(e) (i) Regulation 8(1) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 is declared to be inconsistent with the Medicines and Related Substances Act, 101 of 1965, as amended, and accordingly with the Constitution to the extent that it contains the phrase "after consultation with" and not the phrase "on the recommendation of".

(ii) It is declared that the words "after consultation with" in regulation 8(1) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 are to be severed from the regulations and the regulations are to be read as if the words "on the recommendation of" appear where the words "after consultation with" appeared.

(f) (i) Regulations 10 and 11 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government

Notice No R553 of 30 April 2004 are declared to be inconsistent with the Medicines and Related Substances Act, 101 of 1965, as amended, and accordingly with the Constitution and invalid.

(ii) Regulations 10 and 11 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 are remitted to the Pricing Committee and the Minister for reconsideration in the light of this judgment.

(iii) Until the Minister makes regulations in terms of section 22G(2)(b) of the Medicines and Related Substances Act, 101 of 1965, as amended, pharmacies may charge a dispensing fee.

(g) (i) Regulation 13 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 is declared to be inconsistent with the Medicines and Related Substances Act, 101 of 1965, as amended, and accordingly with the Constitution and invalid.

(ii) Regulation 13 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 are remitted to the Pricing Committee and the Minister for reconsideration in the light of this judgment.

(h) (i) The omission from regulation 21 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 of the words "and in the case of the information referred to in regulation 21(2)(d) must"

before the words "publish or otherwise communicate, or require" is declared to be inconsistent with the Medicines and Related Substances Act, 101 of 1965, as amended, and accordingly with the Constitution.

(ii) Regulation 21 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 is to be read as though the words "and in the case of the information referred to in regulation 21(2)(d) must" appear before the words "publish or otherwise communicate, or require".

(i) The Minister of Health is ordered to republish the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances contained in Government Notice No R553 of 30 April 2004 duly amended in compliance with this order within sixty days of the date of this judgment.

(j) The Minister of Health is ordered to pay half the respondents' costs incurred in the proceedings in this Court and the High Court including the costs of two counsel, as well as all the respondents' costs in the Supreme Court of Appeal including the costs of two counsel.

Chaskalson CJ, Langa DCJ, Madala, Mokgoro, Moseneke, Ngcobo, O'Regan, Sachs, Skweyiya, Van der Westhuizen and Yacoob JJ.

CHASKALSON CJ

Introduction

[23] This is an application for leave to appeal against a decision of the Supreme Court of Appeal (SCA) holding that the regulations introducing a transparent pricing system for medicines and Scheduled substances published by the Minister of Health[38] are invalid and of no force and effect.

[24] The regulations were promulgated on 30 April 2004 by the Minister of Health, purportedly in terms of section 22G of the Medicines and Related Substances Act, 101 of 1965 (the Medicines Act).[39] The operative provisions of the regulations were to come into force at the beginning of June 2004. Towards the end of May 2004 two urgent applications were brought in the Cape High Court by parties adversely affected by the regulations. In the one, the applicants were the Pharmaceutical Society of South Africa (PSSA), which is a society representing a number of companies owning and operating different types of pharmacies, the United South African Pharmacies, an association representing approximately 60% of all retail pharmacies, and five others, all companies conducting business as operators of pharmacies. I refer to this application as the PSSA application and to the applicants as PSSA. In the other, the applicant, New Clicks South Africa (New Clicks), is the owner of a chain of retail

[38] Government Gazette 26304 GN R553, 30 April 2004.

[39] See para 193 below for the provisions of section 22G.

pharmacies. I refer to this as the New Clicks application. I refer to the applicants in both applications jointly as "the Pharmacies". In both applications the Minister of Health and the chairperson of the Pricing Committee on whose recommendation the regulations were made were cited as respondents. The chairperson of the Pricing Committee did not participate in the hearing. She filed an affidavit indicating that the Pricing Committee abided the decision of the court.[40]

[25] Initially the Pharmacies sought interim relief in the form of a suspension of the regulations or some of them pending the determination of an application to be brought by them for an order declaring such regulations to be unlawful and of no force and effect.

[26] Agreement was reached between the parties that the operation of the regulations would be suspended pending the determination of the application to be brought in the High Court. This was made an order of court in the following terms:

> "IT IS ORDERED:
>
> 1. That the applications for final relief are postponed for hearing on 17 and 18 JUNE 2004.
> 2. That the Respondents shall file the record of the proceedings before the Pricing Committee by close of business on 8 JUNE 2004, and such further answering affidavits as they require by close of business on 9 JUNE 2004.
> 3. That the Applicants shall file their replying affidavits by close of business on 14 JUNE 2004.
> 4. That the parties shall exchange their heads of argument by 15 JUNE 2004.

[40] The issue concerning the standing of the Pricing Committee is dealt with in the judgment of the Court where it is held that in the circumstances of this case the Pricing Committee has standing to join in the application for leave to appeal.

> 5. That pending determination of the applications by this court, wholesalers, distributors and retailers shall not be obliged to sell medicines and scheduled substances or charge dispensing fees in accordance with the regulations published in Government Notice R553 of the Government Gazette of 30 APRIL 2004.
> 6. That all issues of costs are reserved."

[27] The sequence of events after that was as follows. The application was heard in the High Court on 17 and 18 June 2004 by a bench of three judges, Hlophe JP, Traverso DJP and Yekiso J. Judgment was given on 27 August 2004. Yekiso J, with whom Hlophe JP concurred, dismissed the application. Traverso DJP dissented and would have made an order setting aside the regulations as being unlawful.

[28] I will deal with these events and what followed in more detail later in the judgment. It is sufficient now to say that the Pharmacies applied immediately to the High Court for leave to appeal to the SCA. Judgment of the High Court on the application for leave to appeal was delayed. The Pharmacies then applied urgently to the SCA for leave to appeal against the order of the High Court. The application was lodged with the SCA before the High Court had given its judgment on the application for leave to appeal. The SCA set down the application for leave to appeal, and directed that the merits be dealt with at the same time. After argument, but before the SCA had given judgment, the High Court delivered its judgment and by a majority refused leave to appeal. On 20 December 2004 the SCA delivered its judgment. A unanimous court of five judges granted the Pharmacies leave to appeal to it and upheld the appeal. The regulations were declared to be invalid and of no force and effect.

[29] The Minister and the chairperson of the Pricing Committee then applied to this Court for leave to appeal against the judgment and order of the SCA. The application was set down for hearing during March 2005 and the parties were directed to address the merits of the appeal during their arguments so that the matter could be disposed of without hearing further arguments, should leave to appeal be granted.

The hearing of the application

[30] I pause to comment on the circumstances in which argument was heard by this Court. The disputed regulations form the core of government policy designed to reduce the costs of medicines. The Minister contends that the regulations are sanctioned by the Constitution and the Medicines Act. The Pharmacies allege that the regulations would destroy the pharmaceutical industry and retard access to health care.

[31] This seems to have created the impression in some minds that the issues were "political" and not "legal", and led to comments in the media that the decision of the Court will be a test of its independence, implying that if it finds against the government it will be independent, but not if it finds for it.

What the case is about

[32] It is necessary to put this case in its proper context and to say first what the case is not about. This case is not about the wisdom of government policy. Government is entitled to adopt, as part of its policy to provide access to health care, measures

designed to make medicines more affordable than they presently are. That has not been disputed by any of the litigants nor by any of the courts that have previously dealt with the matter.

[33] What courts are concerned with, and what this case is about, is whether the regulations have been made in accordance with the requirements of the Constitution and the law. The challenges to the validity of the regulations, and the responses to the various challenges, are based on detailed legal submissions dealing with the Constitution and the requirements of laws which make provision for just administrative action. There is nothing unusual about this. Our courts have frequently been called on to deal with similar questions in the past and will no doubt be called upon to do so in the future. This is the role of courts in a democracy.

[34] The question then is: were the regulations made in accordance with the Constitution and the law? This was what the High Court had to decide when the proceedings commenced before it. Broadly speaking there were four matters that had to be addressed in order to answer this question.

(a) Are the regulations subject to review under the provisions of the Promotion of Administrative Justice Act, 3 of 2000 (PAJA)? If not, are they subject to review under the Constitution or the common law? If they are subject to review:

(b) Did the Pricing Committee, on whose recommendation the regulations were made, conduct its affairs properly?

(c) Are the regulations consistent with the Medicines Act?

(d) Are the regulations too vague to be enforced?

[35] The majority in the High Court held that the regulations were not subject to review under PAJA but were subject to review under the Constitution and the common law. They conducted the review under the Constitution and dismissed the application.

[36] When the matter reached the SCA there was an additional question. Did the SCA have jurisdiction to entertain the application before the High Court had given judgment on the application for leave to appeal? The SCA directed that this issue be addressed in argument to it, and that the merits of the dispute concerning the validity of the regulations be addressed as well. The SCA heard argument on these issues before the High Court had delivered its judgment. Shortly afterwards, the High Court delivered its judgment in which, by a majority, it refused the application for leave to appeal. Subsequently the SCA gave its judgment. A unanimous court of five judges held that leave to appeal should be granted and that the appeal should be upheld.

[37] In its judgment on the merits the SCA held that the regulations went beyond what was permitted by section 22G of the Medicines Act and were accordingly invalid. It found it unnecessary in the circumstances to decide whether PAJA was applicable.

Procedural issues

[38] In the application for leave to appeal to this Court, the Minister and the Pricing Committee dispute that the SCA had jurisdiction to entertain the application when it did, and to make the order declaring the regulations to be invalid. They contend that the SCA's judgment is accordingly void. The Pharmacies have raised certain procedural points relating to the application for leave to appeal. Before the SCA, counsel for the Minister and the Pricing Committee refused to address the court on the merits, arguing that the question of the SCA's jurisdiction ought to be argued separately. The Pharmacies argue that the Minister should not be permitted to reopen the debate on the merits in this Court having refused to address the SCA on the merits. An additional procedural point taken by the Pharmacies relates to supplementary written submissions filed by the Minister shortly before the hearing. The Pharmacies argued at the hearing that those submissions were not lodged timeously and were therefore inadmissible. At the hearing we ruled that reference could be made to the arguments raised in the additional heads.

[39] The question whether the regulations are invalid is a constitutional matter. The other issues raised are all issues connected with the decision on a constitutional matter and are within the jurisdiction of this Court.[41]

[40] It is convenient to begin by addressing the challenge to the SCA's jurisdiction and the other procedural points that have been raised.

[41] *S v Basson* 2005 (1) SA 171 (CC); 2004 (6) BCLR 620 (CC) at para 22.

The jurisdiction of the Supreme Court of Appeal

[41] The judgment of the High Court was delivered on 27 August 2004. The Pharmacies applied immediately to the High Court for leave to appeal to the SCA against the order that had been made. As was the case with the applications on the merits, the applications for leave to appeal were brought on an urgent basis. The applications were heard on 20 September 2004 before the same full bench of the Cape High Court and judgment was reserved.

[42] Earlier, on 2 September 2004, the attorney for New Clicks had written to the registrar of the SCA asking her to approach the Deputy President of that Court with a view to having the matter enrolled during the November term, in the event of leave to appeal being granted. The registrar responded on behalf of the Deputy President as follows:

> "Subject to cases and other commitments that have already to be accommodated during the November term and others that may yet arise, and subject to the present matter becoming timeously justiciable by this Court, and subject also to the length of the record, bearing in mind that November is a short term, consideration is being given to making court time in November available for it."

[43] The State Attorney objected to the approach taken by the attorneys for New Clicks. She wrote to the registrar voicing that objection, saying that there could be little doubt that the matter involved only constitutional issues, and would be likely to finish in the Constitutional Court. She contended that if the matter was indeed urgent, an appeal to the SCA would delay the outcome. The respondents had been asked to agree that if any appeal be brought the appeal should be directly to the Constitutional

Court, but had refused to do so. In the circumstances they could not contend that the matter was urgent.

[44] On 16 September 2004 the State Attorney wrote to the Registrar of the Constitutional Court enquiring whether this Court would be able to hear an appeal in November or during the first term of 2005, if leave to appeal directly to it were granted. The response was to the effect that if proper arrangements were made in September, the matter could be heard during the November term.

[45] On 22 September 2004 the registrar of the SCA responded to the letter from the State Attorney as follows:

> "Your objection to the request is noted, but it is thought that where a party has been granted leave to appeal to this Court and thereafter approaches this Court for an accelerated hearing on good grounds (urgency being the obvious) nothing prevents this Court from considering such a request. Agreement between the parties is obviously preferable, but each case will depend on the circumstances prevailing at that particular time. A party can certainly not expect a definite 'yes' when leave has as yet not been granted and informing the applicants in this case that their request will be considered did not necessarily mean that the appeal will be heard during the November term. It will depend on the circumstances as just mentioned. If the matter does appear to be urgent, however, it is the duty of this Court to give consideration to a request to accelerate the hearing of it. The fact that there may be constitutional issues involved in an appeal does not affect that position."

[46] By 22 October 2004 judgment on the application to the High Court for leave to appeal had not yet been delivered. On that day attorneys for PSSA wrote to the

registrar of the High Court referring to the application that had been made, and the urgency of the matter, and said that in the circumstances

> "it would be appreciated if you could establish whether His Lordship the Judge President – who indicated on reserving the ruling five weeks ago that he would be writing it for the Court – would indicate when the ruling (even if reasons are to follow) may be expected."

There was no response to this letter.

[47] On 10 November 2004, a decision on the application for leave to appeal had still not been given. The Pharmacies then applied to the SCA as a matter of urgency for leave to appeal to be granted against the whole of the judgment and order made by the majority of the High Court. In their application they alleged that the matter was urgent and that there was a need for clarity to be obtained as to the lawfulness of the regulations, contending that the applicants and other industry participants and the public were being adversely affected on a continuing basis by the lack of finality regarding the validity of the regulations.

[48] They submitted that a failure to grant leave to appeal for so long a time in the "urgent circumstances" that existed had the effect of a refusal to grant the leave sought. They mentioned that a record of the proceedings in the High Court had been prepared and could be lodged immediately if required. They attached to the application for leave to appeal heads of argument, a practice note and a list of

authorities, saying that the heads of argument and list of authorities had been tendered two weeks previously to the State Attorney who had refused to accept them.

[49] On 12 November 2004, the attorneys for the parties met the Judge President of the High Court to enable the attorneys for the Pharmacies, as a matter of courtesy, to inform him of the steps that had been taken. An attempt to arrange an earlier meeting before the application to the SCA was launched had not been successful. The Judge President informed the attorneys that he was working on the second draft of the judgment dealing with the application for leave to appeal, and after enquiring whether it was still necessary to do so, went on to say that he would in fact complete and deliver the judgment.

[50] It is not necessary to deal in any detail with what took place after that. Harms JA, who had been assigned by the Deputy President of the SCA to preside in the application for leave to appeal, asked to see counsel to discuss the matter with them and a meeting was arranged for that purpose. At that meeting, which was held on 17 November, counsel for the Minister and the Pricing Committee made it clear that they objected to the procedure that had been followed, and would contend that the SCA had no jurisdiction to deal with the matter as an order had not yet been made on the application for leave to appeal.

[51] On 18 November the SCA issued a direction in the following terms:

> "1. The hearing of the applications is consolidated.

2. The applications for leave to appeal are referred for oral argument in terms of s 21(3)(c)(ii) of the Supreme Court Act on 30 November and 1 December 2004.
3. The parties must be prepared, if called upon to do so, to address the court on the merits in terms of s 21(3)(c)(ii) of the Act.
4. The respondents may file any affidavits required and heads of argument if and when convenient."

Separation of the issues

[52] On 22 November the State Attorney wrote to the registrar of the SCA acknowledging the directions. She mentioned that at the meeting with Harms JA counsel representing the Minister had placed on record that they were not briefed to deal with the appeal itself, but only with the question of jurisdiction. She asked that the directions be amended to limit the hearing on 30 November to the issue of jurisdiction. She said that the applicants would be able to file written submissions on that issue before 30 November. The registrar of the SCA responded on behalf of the Deputy President of the Court as follows:

"It must be remembered that what is before this court is an application for leave to appeal which the court is bound to consider. It is not unusual for this court, when dealing with an application for leave to appeal (petition) in which it considers that argument should be presented to it, to direct that parties be prepared to argue the merits should they be required to do so.

Obviously the question of jurisdiction will be considered as it is an integral part of the application for leave to appeal. It is, I should think, open to a party or parties to apply to the court at the hearing that the hearing of a particular issue be postponed until another issue has been decided.

The entire record has been lodged with the Registrar of this court precisely because no agreement could be reached, between the parties, on what parts of the record should be omitted.

> The Acting President is accordingly unable to amend or have amended the direction as requested in the last paragraph of your letter."

[53] It was against this background that the application for leave to appeal was heard by the SCA on 30 November and 1 December. The Minister and the Pricing Committee were represented at that hearing by counsel, who indicated to the court that they had been briefed on the issue of jurisdiction only. They contended that the SCA did not have jurisdiction to hear the appeal, as no decision had yet been given on the Pharmacies' application for leave to appeal, and asked for argument on the issue of jurisdiction to be separated from argument on the other issues raised in the application. They contended that they had a right to a ruling on the preliminary issue and a right to appeal against an unfavourable ruling. The SCA declined to order that the issue of jurisdiction be separated from the other issues and required the parties to address it on all the issues including the merits of the appeal. The Minister and the Pricing Committee contend that this ruling was wrong and raise this as one of the grounds of appeal.

[54] In its judgment the SCA explained its ruling. It referred to its decision in *S v Malinde and Others*[42] where a separation of issues had been granted at the request of an appellant. Quoting from the judgment in that case it reaffirmed its approach to the separation of issues, holding that it applied both to appeals and applications:

[42] 1990 (1) SA 57 (A).

> "This Court is in principle strongly opposed to the hearing of appeals in piecemeal fashion. . . . An exception may be made, however, where unusual circumstances call for such procedure . . . .
>
> . . . .
>
> Substantial grounds should exist for the exercise of the power. The basis of the jurisdiction is convenience – the convenience not only of the parties but also of the Court. The advantages and disadvantages likely to follow upon the granting of an order must be weighed. If overall, and with due regard to the divergent interests and considerations of convenience affecting the parties, it appears that the advantages would outweigh the disadvantages, the Court would normally grant the application."[43]

[55] The SCA held that the present matter was urgent, that it raised issues of national importance and that it was imperative that the litigation be brought to an early conclusion. The request for the issue of jurisdiction to be separated from the merits would have added to the delay, and the reasons given for the request did not meet the requirements laid down in *S v Malinde*.

[56] The SCA had taken the view that it was necessary to have regard to the merits in order to decide the application for leave to appeal and, that being so, it was appropriate to require the parties to address argument on the merits so that judgment could be given without hearing further argument should leave to appeal be granted. This is a common practice in the SCA and in this Court as well. Its purpose is to avoid unnecessary delays and costs as well as to conserve court time. Indeed, a direction to that effect was given by this Court in the present matter and without any objection having been made to this procedure, argument was addressed to us by the

[43] Id at 67F-G, 68C-D; *Pharmaceutical Society of South Africa and Others v Tshabalala-Msimang and Another NNO; New Clicks South Africa (Pty) Ltd v Minister of Health and Another* 2005 (3) SA 238 (SCA); 2005 (6) BCLR 576 (SCA) at para 15.

parties on the merits of the case, to enable us to dispose of the matter should leave to appeal be granted.

[57] The application to the SCA had been set down on short notice. The merits were complex and raised difficult legal issues. They had, however, been the subject of argument in the High Court by the same counsel some four months previously. It appears from the SCA judgment that counsel for the Minister declined the court's request to address it on the merits. The SCA was conscious of the potential prejudice to the Minister by requiring argument from counsel who might not have been properly prepared to do so. However, counsel for the Minister who had been briefed on the issue of jurisdiction only, declined an invitation from the court to request a postponement to a date convenient to them to prepare for argument on the merits. They also declined a request from the court to furnish it with a copy of their heads of argument in the High Court.

[58] The SCA is entitled to regulate its own procedure and I cannot say that the directions given by it as to how the matter should be dealt with were wrong.[44] The contention that the SCA erred in refusing to separate the issue of jurisdiction from the application for leave to appeal, and in requiring the matter to be dealt with in accordance with the directions given on 18 November 2004, must therefore be rejected.

[44] See *Mabaso v Law Society, Northern Provinces, and Another* 2005 (2) SA 117 (CC); 2005 (2) BCLR 129 (CC) at para 23 where this Court confirmed, in a different context, that the SCA is entitled to regulate its own process. See also *Universal City Studios Inc and Others v Network Video (Pty) Ltd* 1986 (2) SA 734 (A) at 754G and the authorities there cited.

Section 20(4) of the Supreme Court Act

[59] I deal now with the contention that the decision of the SCA was a nullity, and for that reason alone should be set aside by this Court. This contention is based on the provisions of section 20(4) of the Supreme Court Act, 59 of 1959, which the applicants contend are mandatory and were not complied with.

[60] Section 20(4) provides:

> "(4) No appeal shall lie against a judgment or order of the court of a provincial or local division in any civil proceedings or against any judgment or order of that court given on appeal to it except—
>
> (a) in the case of a judgment or order given in any civil proceedings by the full court of such a division on appeal to it in terms of subsection (3), with the special leave of the appellate division;
>
> (b) in any other case, with the leave of the court against whose judgment or order the appeal is to be made or, where such leave has been refused, with the leave of the appellate division."

This section of the Supreme Court Act must now be read as referring to a High Court in place of a Provincial or Local Division, and to the Supreme Court of Appeal, in place of the Appellate Division.

[61] There is a line of cases in the Appellate Division going back to *Blaauwbosch Diamonds Ltd v Union Government (Minister of Finance)*,[45] where matters had come before the court in circumstances where the necessary leave to appeal had not been

[45] 1915 AD 599.

obtained from the Provincial Division before approaching the Appellate Division.[46] In those cases the Appellate Division heard argument and deferred giving judgment on the merits until the statutory requirements had been complied with. The facts in those cases were different to the facts in the present case, but what the judgments show is that the launching of an appeal without first having complied with the statutory requirements relating to leave to appeal is not a nullity.

[62] Whilst it is necessary for the statutory requirements for leave to appeal to be complied with before a decision is given on the appeal, in a proper case the court has a discretion to defer giving judgment until those requirements have been satisfied. In *Gentiruco A.G. v Firestone SA (Pty) Ltd*[47] the Appellate Division, referring to these decisions, said:

> "Where the necessary leave to appeal is lacking this Court may, in appropriate circumstances, defer the hearing or determination of the appeal to enable the appellant to obtain such leave – see *Sita's* case, *supra*, 1967 (2) SA 442 (AD) at p. 450F-H, and authorities there cited."[48]

It held, however, that on the facts of that case it was not appropriate to adopt the "extraordinary course of deferment".

[46] See *Gentiruco A.G. v Firestone SA (Pty) Ltd* 1972 (1) SA 589 (A); *Sita and Another v Olivier NO and Another* 1967 (2) SA 442 (A); *Oliff v Minnie* 1952 (4) SA 369 (A).

[47] Id.

[48] Id at 608E-F.

[63] Counsel for the Minister and the Pricing Committee in their argument to the SCA, which they repeated in their argument to this Court, relied strongly on the judgment of the Appellate Division in *National Union of Metalworkers of South Africa v Jumbo Products CC*[49] where Corbett CJ held that it was clear from section 20(4)(b) that:

> "[T]his Court's jurisdiction to grant leave itself is dependent on the Court a quo having refused such leave. The proper procedure, as imperatively laid down by s 20(4)(b), is for the would-be appellant to apply for leave first to the Court against whose judgment the appeal is to be made. If that Court grants leave, then this Court may entertain the appeal. If that Court refuses leave, then (but only then) may this Court consider an application for leave to appeal. Thus s 20(4)(b) not only prescribes the proper procedure, but it also defines the jurisdiction of this Court to entertain an application for leave to appeal. (Compare *S v Cassidy* 1978 (1) SA 687 (A) at 690H; *Windhoek Munisipaliteit v Ministersraad van SWA/Namibia en 'n Ander* 1985 (1) SA 287 (A) at 293H-294B.)"[50]

[64] The facts in that case were quite different to the facts of the present case. The applicant had been the unsuccessful party in a case in which judgment had been given by the Witwatersrand Local Division (WLD) on 21 December 1993. On 17 and 18 March 1994, approximately two months after the time prescribed for lodging an application for leave to appeal had expired, the applicant applied to the WLD for condonation of its failure to lodge its application timeously, and for leave to appeal to the Appellate Division against the judgment and order that had been made. The application for condonation was refused. The applicant then applied to the Appellate

[49] 1996 (4) SA 735 (A).

[50] Id at 740B-D.

Division for leave to appeal against the judgment and order made by the WLD on the merits. It did so without having applied to the High Court for leave to appeal against the order refusing condonation. Moreover, it appears from the judgment that the applicant sought leave to appeal to the SCA on the merits without an application for leave to appeal on the merits having been considered by the WLD. The complex procedures that would be necessary to resolve these problems are referred to in the judgment, and the order made by the Appellate Division was that the application be struck off the roll. There is nothing in the judgment which suggests that the court intended to depart from what had been said in *Gentiruco*.

[65] In his judgment Corbett CJ refers to two cases, *S v Cassidy*[51] and *Windhoek Munisipaliteit v Ministersraad van SWA/Namibia en 'n Ander*,[52] to support his decision. The facts in those cases are also materially different to the facts in the present case.

[66] In the *Windhoek Munisipaliteit* case the appellant had not applied to the court a quo for leave to appeal. The court heard argument only on the issue of jurisdiction. It held that leave to appeal was necessary and struck the appeal off the roll.[53] In *S v Cassidy* the accused had applied for leave to appeal against sentence only. In error the order of the Appellate Division had granted leave to appeal against conviction as well

[51] 1978 (1) SA 687 (A).

[52] 1985 (1) SA 287 (A).

[53] Id at 294B.

as sentence. Attention was drawn to this error during argument and it was pointed out that the court had no power to make such an order because leave to appeal against the conviction had not been sought. It appears from the judgment that counsel for the accused chose not to ask for a postponement to enable him to approach the court a quo for leave to appeal on that issue.[54] In the result the appeal was confined to the issue of sentence only. Once again there is nothing to suggest that the court intended to depart from what had been said in *Gentiruco*.

[67] The SCA deals in its judgment with the cases to which I have referred in paragraphs 61 and 62 of this judgment and comes to the conclusion that it could and should grant leave to appeal.[55] There were unusual circumstances which justified the making of such an order. First, there was before it a substantive application for leave to appeal based on a contention that the delay by the High Court amounted in the circumstances of the case to a refusal to grant leave to appeal. It was necessary to have regard to the merits of the appeal in dealing with that issue. Secondly, the issues before the court were clearly of considerable importance affecting not only the respondents, but all participants in the pharmaceutical trade, as well as the general public which has an interest in the pricing of medicines.[56] Thirdly, it was known when the application was heard that the decision on the application for leave to appeal would be given within two days of the hearing. In those circumstances, little purpose

[54] Above n 51 at 691C.

[55] Above n 43 at paras 25, 26, 28 and 96.

[56] Id at para 14.

would have been served by dismissing the application and requiring the respondents to start all over again. That would have resulted in further delays and considerable unnecessary expense.

Constructive refusal of an application for leave to appeal

[68] An application to the SCA to grant leave to appeal on the ground that there has been a constructive refusal of leave to appeal by the High Court is a legitimate cause of action. An unreasonable delay in dealing with an application for leave to appeal interferes with a litigant's constitutional right to have access to court.[57] This is of particular concern where the issues are urgent and the delay may cause substantial prejudice. A case in point is where an accused person has been convicted and sentenced to imprisonment. A long delay in dealing with an application for leave to appeal against the conviction and sentence may result in a miscarriage of justice if the appeal is ultimately successful. The SCA gives an example of such a case in its judgment.[58]

[69] I have no doubt that a court of appeal is entitled in appropriate circumstances to treat an unreasonable delay on the part of a lower court in deciding whether or not to grant leave to appeal as a constructive refusal of the application. The delay need not

[57] Section 34 of the Constitution provides:

> "Everyone has the right to have any dispute that can be resolved by the application of law decided in a fair public hearing before a court or, where appropriate, another independent and impartial tribunal or forum."

[58] *S v Venter* 1999 (2) SACR 231 (SCA). Above n 43 at para 31 n 30.

be deliberate. The fact that there has been an unreasonable delay is sufficient in itself to entitle an appeal court to make such a finding.

[70] The granting of leave to appeal by an appeal court in such circumstances does not cause any prejudice. If the application for leave had been dismissed by the lower court the litigant would have been entitled as of right to apply to the appeal court for leave. The only prejudice caused is to the appeal court which will have been burdened with an unnecessary application in cases where the lower court would have given leave in any event.

[71] An application to an appeal court for leave to appeal based on an alleged constructive refusal of leave to appeal by a lower court should be a last resort. It must be accepted, however, that there may come a time when a delay in resolving an application for leave to appeal amounts to a constructive refusal of the application, entitling the aggrieved litigant to apply to the appeal court to grant leave itself. What constitutes an unreasonable delay will depend on the circumstances of the case.

[72] Superior courts have an inherent right to regulate and protect their own process.[59] In the exercise of this power they can decide whether or not to grant an application based on a constructive refusal of leave to appeal, and to penalise a litigant by a costs order where such an application is wrongly brought.

[59] Section 173 of the Constitution provides:

> "The Constitutional Court, Supreme Court of Appeal and High Courts have the inherent power to protect and regulate their own process, and to develop the common law, taking into account the interests of justice."

[73] The application to the SCA in the present case was clearly not frivolous. The case was of great public importance and raised issues that were complex and difficult to resolve. The SCA had heard argument and formed its own impression on the merits and whether the case was one in which leave to appeal should be granted. It was fully entitled to require argument to be addressed to it on all aspects relevant to the application to it for leave to appeal.

Leave to appeal to the SCA

[74] The High Court, which had been divided on the outcome of the main application, was also divided on the question whether leave to appeal should be granted. In their judgment dealing with the application for leave to appeal[60] the majority accepted that the case raised issues of great constitutional importance "which needed to be finalised sooner rather than later" and would be likely to end up in the Constitutional Court.[61] It is difficult to understand why, in such circumstances, they should have refused leave to appeal, and have taken so long to do so.

[75] The majority concluded that there was no reasonable prospect of another court coming to a conclusion different to that arrived at by them. In that, as subsequent events have shown, they were clearly wrong. Having regard to the importance of the

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[60] *New Clicks South Africa (Pty) Ltd v Tshabalala-Msimang and Another NNO; Pharmaceutical Society of South Africa and Others v Minister of Health and Another* 2005 (3) SA 231 (C).

[61] Id at 236F-G.

case, the difficult issues it raised, and the different views on outcome within the High Court itself, this was a case in which leave to appeal should clearly have been granted. I do not consider it necessary, however, to decide whether the delay in dealing with the application for leave to appeal in such circumstances amounted to a constructive refusal of leave to appeal.

[76] The SCA has the inherent right to regulate its own process. In the present case it had before it a valid application based on an alleged constructive refusal of leave to appeal. It knew that a decision by the High Court on the application for leave to appeal would be given within two days of the conclusion of the argument. Whatever the decision of the High Court might have been, it would have had jurisdiction to deal with the matter when it came to deliver its own judgment. After considering the relevant authorities it said:

> "In this case the applicants . . . took all the prescribed steps; they did apply to the Court below; they did apply to this Court. All that was missing was the ruling of the Court below. That came less than 48 hours after conclusion of argument, but, as is apparent from the body of authority cited, that is not fatal. The procedural condition for the determination of the applications for leave has now been fulfilled."[62]

[77] The alleged constructive refusal had proved to be an actual refusal of leave before the SCA gave its judgment. It had jurisdiction at that time to deal with the application to it for leave to appeal and to decide the appeal. The contention of the

[62] Above n 43 at para 28.

Minister and the Pricing Committee that the SCA had no jurisdiction to deal with the matter, and that its judgment is a nullity, must therefore be dismissed.

[78] The SCA had given directions that the parties must be prepared, if called upon to do so, to address the court on the merits of the case. When called upon to deal with the merits, counsel for the Minister declined to do so. They had been briefed to deal only with the issue of the court's jurisdiction and had no brief to argue the merits.

[79] What happened is recorded in the judgment of Harms JA as follows:[63]

> "Already at the meeting on 17 November with me, the respondents' counsel insisted emphatically on a separation of issues and stated that their clients would not instruct counsel to deal with the merits. During oral argument before us, the respondents' lead counsel was specifically and repeatedly asked whether they required a postponement in order to prepare argument on the merits. The questions did not elicit a response. When asked whether the respondents could provide a date convenient to them for argument on the merits, the question failed to extract a reaction. When asked whether they needed an adjournment to consider a request for a postponement, yet again, counsel did not reply and simply proceeded to argue another point.
>
> This is consistent with the attitude from the outset that the jurisdictional issue should be dealt with separately. They had a right, they said, to a separate hearing. And they wished to exercise that right in order that, if we dismiss their argument, they could appeal. That is why they decided in advance not to instruct counsel, why they refused – in spite of a request on 17 November – to provide copies of the heads of argument used in the Court below to assist us in preparing for the hearing, and why they were generally obstructive in relation to each suggestion relating to an expedited hearing." (footnote omitted)

[63] Id at paras 13 and 14.

[80] In these circumstances, and having ruled against the Minister on the separation of issues, the SCA proceeded to deal with the application for leave to appeal. The consequence of this, as the SCA points out in its judgment,[64] is that it was deprived of the benefit of argument on behalf of the Minister on the merits of the case.

[81] Commenting on this and its decision to deal with the matter without having the benefit of such argument, the SCA said:[65]

> "Cowed by the respondents' refusal to be of any assistance we cannot be. Organs of State, which have a constitutional duty to, inter alia, assist courts to ensure their effectiveness, have always treated courts with respect and we assume that the refusal to argue is not indicative of a change of heart but rather of inappropriate legal advice based on overconfidence." (footnote omitted)

[82] I would add to this only two comments. First, a further consequence of what happened has been that this Court has been deprived of the SCA's evaluation of the arguments addressed to us on behalf of the Minister and the Pricing Committee. Secondly, courts are entitled to expect assistance and not obstruction from litigants in the discharge of their difficult duties. What happened in the present case not only failed to meet this requirement, but also evinced a deplorable lack of respect for the SCA, which is the highest court in this country in respect of all matters other than constitutional matters.

[64] Id at para 40.

[65] Id.

Leave to appeal to the Constitutional Court

[83] It was contended by the Pharmacies that since the Minister had deliberately refused to address argument to the SCA on the merits of the appeal, despite having been called upon to do so, she should not be granted leave to appeal to this Court on the merits. Ultimately the question whether leave to appeal should be granted depends on whether or not it is in the interests of justice to do so. In the present case though deploring what happened in the SCA, I have come to the conclusion that it is not in the interest of justice to refuse leave to appeal on that ground.

[84] If the Minister is refused leave to appeal the decision of the SCA will become final and the regulations will be set aside. If there is substance to the appeal it would mean that government's constitutional duty to take reasonable measures to provide access to health care[66] would be defeated by an incorrect view taken concerning the jurisdiction of the SCA. It is not in the interest of justice to permit so important an issue affecting the rights of the general public and the constitutional obligations of government to be determined in this way. It is in the public interest that this Court deals with the matter, and determines the questions that have been raised as to the validity of the regulations.

The approach of the High Court to the application for review

[66] Section 27 of the Constitution reads:

> "(1) Everyone has the right to have access to—
> (a) health care services, including reproductive health care;
> . . . .
> (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights."

[85] In the High Court the Pharmacies claimed:

> "[A]n order reviewing and setting aside the recommendation purportedly made by the Pricing Committee to the First Respondent in terms of section 22G(2) of the Medicines and Related Substances Act 101 of 1965 and pursuant to which the Regulations were published . . . and/or an order declaring the Regulations . . . to be invalid and of no force or effect".[67]

[86] The form in which the relief was claimed led to arguments being addressed to the High Court, and again to this Court, which treated the recommendations of the Pricing Committee, and the decision of the Minister to accept them and to promulgate the regulations, as being separate decisions, each subject to review either under PAJA, or under the Constitution.

[87] In the High Court the majority dealt separately with the challenges to the recommendations of the Pricing Committee to the Minister and the subsequent making of the regulations by the Minister. They held that the recommendations could not be construed as having had a direct, external legal effect, which is a requirement for administrative action under PAJA.[68] They would only have had external legal effect if and when they were accepted by the Minister and promulgated. The recommendations as such were accordingly not subject to review under PAJA.

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[67] This is the order sought in the Notice of Motion lodged on behalf of the PSSA. For all practical purposes the Notice of Motion in the New Clicks application was the same.

[68] *New Clicks South Africa (Pty) Ltd v Tshabalala-Msimang and Another NNO; Pharmaceutical Society of South Africa and Others v Tshabalala-Msimang and Another NNO* 2005 (2) SA 530 (C) at paras 41-43. See below, paras 127-135 where the definition of "decision" in PAJA is addressed.

[88] However, they went on to hold that, notwithstanding this, the "activities and functions of the Pricing Committee" were subject to review under the constitutional principle of legality, the provisions of section 33(1) of the Constitution, and the provisions of the common law.[69] They concluded that the functions of the Pricing Committee constituted administrative action in terms of section 33(1) of the Constitution.[70] They accordingly conducted a review for compliance with that section, holding that:

> "[T]he term 'lawfulness' in s 33(1) is an all embracing and an umbrella concept that encapsulates all the requirements for administrative legality including all those requirements and grounds for invalidity set out in s 6 of the Promotion of Administrative Justice Act."[71]

[89] In dealing with the regulations they concluded that they too were not subject to review under PAJA because the definition of administrative action in PAJA does not include "rule-making".[72] But consistent with their approach to the recommendations of the Pricing Committee they held that

> "the fact that rule-making does not constitute administrative action, does not render the regulations themselves to be beyond judicial scrutiny. The regulations are subject to review on the basis of the principle of legality, the principles of common law to the extent such common-law principles are not inconsistent with the Constitution, the

[69] Id at para 45.

[70] Id.

[71] Id at para 61.

[72] Id at para 49. See below at paras 120-126 where the definition of "administrative action" in PAJA is addressed.

> provisions of s 33(1) of the Constitution and other relevant provisions of the Constitution."[73]

In the result they reviewed both the Pricing Committee's recommendations and the regulations for compliance with section 33 of the Constitution.

[90] The minority judgment held that the recommendations of the Pricing Committee had an external legal effect because it was a jurisdictional fact on which the making of valid regulations depended.[74] The judgment accordingly dealt with the issues in terms of the provisions of PAJA, but held that if PAJA was not applicable, the same result would follow from the application of the principle of legality.[75]

The approach of the SCA

[91] The SCA found it unnecessary to deal with PAJA. It approached the matter on the basis that the Minister's power to make regulations is dependent on the recommendations of the Pricing Committee. The Pricing Committee's recommendation

> "has to be in accordance with the provisions of s 22G – ie it must be a lawful administrative action as provided for by s 33(1) of the Constitution – since the committee has no power beyond that given to it by this section. And it follows from the principle of legality that the Minister cannot accept a recommendation or promulgate a regulation that does not fall squarely within the section."[76]

[73] Id at para 50.

[74] Id at paras 32 and 36 (Traverso DJP).

[75] Id at para 40.

[76] Above n 43 at para 49.

The Constitution and PAJA

[92] It is correct – and this was accepted by the majority and the dissent in the High Court as well as by the SCA – that the regulations have to comply with the provisions of section 22G of the Medicines Act.[77] This is required by section 33 of the Constitution and is given effect to in PAJA.

[93] However, I do not agree with the approach adopted both by the majority of the High Court, and later by the SCA, that notwithstanding the provisions of PAJA, the regulations were subject to an independent review for lawfulness under section 33 of the Constitution.

[94] Section 33 entrenches the right to administrative action that is "lawful, reasonable and procedurally fair".[78] It goes on to provide, however, that

> "National legislation must be enacted to give effect to these rights, and must—
>
> (a) provide for the review of administrative action by a court or, where appropriate, an independent and impartial tribunal;
>
> (b) impose a duty on the state to give effect to the rights in subsections (1) and (2); and
>
> (c) promote an efficient administration."[79]

[77] The relevant provisions of section 22G are provided in para 193 below.

[78] Section 33(1).

[79] Section 33(3).

[95] PAJA is the national legislation that was passed to give effect to the rights contained in section 33. It was clearly intended to be, and in substance is, a codification of these rights.[80] It was required to cover the field and purports to do so.

[96] A litigant cannot avoid the provisions of PAJA by going behind it, and seeking to rely on section 33(1) of the Constitution or the common law. That would defeat the purpose of the Constitution in requiring the rights contained in section 33 to be given effect by means of national legislation.

[97] Professor Hoexter sums up the relationship between PAJA, the Constitution and the common law, as follows:

> "The principle of legality clearly provides a much-needed safety net when the PAJA does not apply. However, the Act cannot simply be circumvented by resorting directly to the constitutional rights in s 33. This follows logically from the fact that the PAJA gives effect to the constitutional rights. (The PAJA itself can of course be measured against the constitutional rights, but that is not the same thing.) Nor is it possible to sidestep the Act by resorting to the common law. This, too, is logical, since statutes inevitably displace the common law. The common law may be used to inform the meaning of the constitutional rights and of the Act, but it cannot be regarded as an alternative to the Act."[81] (footnotes and emphasis omitted)

I agree.

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[80] *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Others* 2004 (4) SA 490 (CC); 2004 (7) BCLR 687 (CC) at para 25.

[81] This is an extract from "'Administrative Action' in the courts" a paper delivered by Professor C Hoexter for a comparative administrative justice workshop held at Cape Town from 20-22 March 2005. The paper has not yet been published.

Can the application be decided without reference to PAJA?

[98] In *Minister of Home Affairs v Eisenberg & Associates: In re Eisenberg & Associates v Minister of Home Affairs and Others*,[82] this Court left open the question whether the making of regulations by a Minister in terms of an empowering statute constitutes administrative action for the purposes of PAJA.[83] In that case it was alleged that the Minister had failed to comply with the provisions of section 4(1) of PAJA prior to making regulations. Section 4(1) addresses the question of procedural fairness required where administrative action materially and adversely affects the rights of the public.[84] Section 4(4) provides, however, that the provisions of section 4(1) may be departed from "[i]f it is reasonable and justifiable in the circumstances" to do so. It was assumed for the purposes of the judgment that PAJA was applicable. It was held, however, that in the circumstances of that case it was reasonable and justifiable for the Minister to depart from the provisions of section 4(1).

[99] It is necessary in the present case to consider whether the making of the regulations on the recommendations of the Pricing Committee, whether seen as one transaction, or as two, constituted administrative action within the meaning of PAJA. If it does, then the decision of this Court in *Bato Star*[85] must be followed, and the

[82] 2003 (5) SA 281 (CC); 2003 (8) BCLR 838 (CC) at paras 52-53.

[83] It said, at para 53 n 30, that this "raises complex issues including the question whether a construction of PAJA that excludes the making of regulations from the ambit of administrative action would be consistent with the Constitution."

[84] See para 130 below for the full text of section 4.

[85] Above n 80. In *Bato Star*, the Court held that since PAJA was applicable, that case could not be decided without reference to its provisions.

validity of the regulations will depend upon the provisions of PAJA, construed in the light of the provisions of the Constitution pursuant to which it was enacted.

Is PAJA applicable?

[100] Counsel for the applicants contended that the majority were correct in holding that PAJA was not applicable to the making of the disputed regulations. They sought to develop their argument by analysing the definitions of "administrative action" and "decision" in section 1 of PAJA. These definitions must, however, be construed consistently with section 33 of the Constitution.[86] The starting point of the enquiry, therefore, is what constitutes administrative action for the purposes of section 33.

The meaning of administrative action in section 33 of the Constitution

[101] Prior to the adoption of the interim Constitution in 1994 administrative action was subject to review by the superior courts. There were two overarching principles which formed the basis of judicial review. First, that the functionaries or bodies exercising delegated powers are confined to the powers vested in them by the empowering legislation. Should they exceed such powers, their actions are illegal, and invalid. Secondly, the exercise of delegated powers by such persons or bodies must ordinarily be carried out in accordance with fair procedures.

[86] *Bato Star*, id at para 25; *Investigating Directorate: Serious Economic Offences and Others v Hyundai Motor Distributors (Pty) Ltd and Others: In re Hyundai Motor Distributors (Pty) Ltd and Others v Smit NO and Others* 2001 (1) SA 545 (CC); 2000 (10) BCLR 1079 (CC) at para 21.

[102] An extensive body of law, initially influenced strongly by English law, was built up around these two principles, which developed into the well known doctrines of ultra vires and procedural fairness. In developing this body of administrative law, courts were careful to distinguish between their powers on appeal, which ordinarily included a power to consider the merits of the decision appealed against, and their power on review, which was ordinarily directed to consideration of issues of legality and procedural fairness. The merits of the decision were not relevant save in certain limited circumstances. In that regard, our courts followed the approach of Lord Russell CJ in *Kruse v Johnson*[87] where he stated:

> "I do not mean to say that there may not be cases in which it would be the duty of the Court to condemn by-laws . . . as invalid because unreasonable. But unreasonable in what sense? If, for instance, they were found to be partial and unequal in their operation as between different classes; if they were manifestly unjust; if they disclosed bad faith; if they involved such oppressive or gratuitous interference with the rights of those subject to them as could find no justification in the minds of reasonable men, the Court might well say, 'Parliament never intended to give authority to make such rules; they are unreasonable and ultra vires.'"[88]

[103] Unreasonableness in this sense was treated as part of the ultra vires doctrine "because Parliament did not intend to give authority to make such a regulation."[89] Under the doctrine of parliamentary supremacy Parliament was entitled to make inroads into this principle, and frequently did so prior to 1994. But subject to this,

[87] [1898] 2 QB 91.

[88] Id at 99-100.

[89] *R v Abdurahman* 1950 (3) SA 136 (A) at 150D.

unreasonableness in this "specialised sense of that word"[90] was a ground on which delegated legislation could be reviewed.

[104] There was accordingly only limited scope for reviewing the exercise of delegated powers on the grounds of "unreasonableness". Our courts were reluctant even to exercise this limited power.[91] They tended to follow the approach of the English Court of Appeal in *Associated Provincial Picture Houses Limited v Wednesbury Corporation*,[92] which was that

> "It is true to say that, if a decision on a competent matter is so unreasonable that no reasonable authority could ever have come to it, then the courts can interfere . . . but to prove a case of that kind would require something overwhelming".[93]

[105] Thus, for instance, in *National Transport Commission and Another v Chetty's Motor Transport (Pty) Ltd*[94] the Appellate Division held that a claimant relying on this ground of review had to show that

> "the . . . decision was grossly unreasonable to so striking a degree as to warrant the inference of a failure to apply its mind (to the issues) – a formidable onus."[95]

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[90] Id at 143F.

[91] See the discussion of this topic by Jansen JA in *Theron en Andere v Ring van Wellington van die NG Sendingkerk in Suid-Afrika en Andere* 1976 (2) SA 1 (A). Jansen JA suggested that a distinction should be drawn between what he termed the "formal test" and the "material/extended formal standard test". In the case of the former, the courts will not interfere with the merits of the decision and are concerned only with the manner in which the decision was exercised (at 13F-G). In the case of the latter, which Jansen JA held to apply in the case of judicial bodies created by statute or contract, a decision could be set aside on the basis that it was not reasonably supported by the evidence (at 20D-21C).

[92] [1948] 1 KB 223 (CA).

[93] Id at 230.

[94] 1972 (3) SA 726 (A).

[106] Although the applicability of the *Wednesbury* test strictly to all types of review has been the subject of academic criticism,[96] review of delegated legislation on the ground of "unreasonableness" was previously of limited scope.

The impact of the Constitution

[107] The adoption of the interim Constitution in 1994 had a material impact upon the existing body of administrative law. The Bill of Rights contained a provision entitling every person to—

> "(a) lawful administrative action where any of his or her rights or interests is affected or threatened;
> (b) procedurally fair administrative action where any of his or her rights or legitimate expectations is affected or threatened;
> (c) be furnished with reasons in writing for administrative action which affects any of his or her rights or interests unless the reasons for such action have been made public; and
> (d) administrative action which is justifiable in relation to the reasons given for it where any of his or her rights is affected or threatened."[97]

In effect these provisions entrenched in the interim Constitution as part of the right to administrative justice, the doctrines of legality and procedural fairness and to a limited extent made provision for review on the ground of "reasonableness": the decision had

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[95] Id at 735G.

[96] See *Bato Star* above n 80 at paras 44 and 45; Jowell and Lester, "Beyond *Wednesbury*: Substantive Principles of Administrative Law", [1987] *Public Law* 368, at 372; Cane *An Introduction to Administrative Law* 3ed (Clarendon Press, Oxford 1996) ch 9; Hoexter *The New Constitutional and Administrative Law: Volume II – Administrative Law* (Juta, Lansdowne 2002) at 186-7.

[97] Section 24 of the interim Constitution.

to be "justifiable in relation to the reasons given for it". This right was, however, subject to limitation under section 33 of the interim Constitution.[98] This meant that the government could limit the general powers of a court to review administrative action, but no longer had the unlimited power which previously existed to insulate such decisions against judicial review. Moreover, the scope for judicial review was broadened by other provisions of the interim Constitution, in particular the anti-discrimination provisions of the equality right,[99] the right to access to information,[100] property rights,[101] and the right to have justiciable disputes settled by a court of law.[102]

[108] The provisions of section 33 of the Constitution are similar to those contained in section 24 of the interim Constitution. There is, however, a material difference. Under the interim Constitution a requirement for just administrative action was that a decision must be justifiable in relation to the reasons given. That in substance set

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[98] Section 33(1) of the interim Constitution read as follows:

> "The rights entrenched in this Chapter may be limited by law of general application, provided that such limitation—
>
> (a) shall be permissible only to the extent that it is—
>
> (i) reasonable; and
>
> (ii) justifiable in an open and democratic society based on freedom and equality; and
>
> (b) shall not negate the essential content of the right in question,
>
> and provided further that any limitation to—
>
> (aa) a right entrenched in section 10, 11, 12, 14(1), 21, 25 or 30(1)(d) or (e) or (2); or
>
> (bb) a right entrenched in section 15, 16, 17, 18, 23 or 24, in so far as such right relates to free and fair political activity,
>
> shall, in addition to being reasonable as required in paragraph (a)(i), also be necessary."

[99] Section 8.

[100] Section 23.

[101] Section 28.

[102] Section 22.

rationality as the review standard.[103] Under section 33 administrative decisions can now be reviewed for reasonableness. That is a variable but higher standard, which in many cases will call for a more intensive scrutiny of administrative decisions than would have been competent under the interim Constitution.

[109] When the interim Constitution was adopted the making of delegated legislation was regarded as administrative action subject to judicial review. There is nothing to suggest that the interim Constitution, or the Constitution which took its place, intended to exclude delegated legislation from what had previously been understood as being administrative action. On the contrary, the Constitutions point in the opposite direction.

Open and transparent government

[110] The interim Constitution established a constitutional state in which the Constitution was supreme and binding upon the legislature, the executive and all organs of state. The 1996 Constitution continued and strengthened this commitment making clear that the constitutional state would be one in which there would be open and transparent government.

[111] The preamble of the Constitution sets as a goal the establishment of "a society based on democratic values, social justice and fundamental human rights" and declares that the Constitution lays "the foundation for a democratic and open society".

[103] *Bel Porto School Governing Body and Others v Premier, Western Cape, and Another* 2002 (3) SA 265 (CC); 2002 (9) BCLR 891 (CC) at paras 86-90.

Section 1 of the Constitution which establishes the founding values of the state, includes as part of those values "a multi-party system of democratic government, to ensure accountability, responsiveness and openness."[104] It is apparent from section 57(1)(b) that the democratic government that is contemplated is a participatory democracy, which is accountable, transparent and makes provision for public involvement.[105] Consistently with this, section 59(1) of the Constitution provides:

> "The National Assembly must—
>
> (a) facilitate public involvement in the legislative and other processes of the Assembly and its committees; and
>
> (b) conduct its business in an open manner, and hold its sittings, and those of its committees, in public".

Similar provisions are also made in respect of the National Council of Provinces,[106] provincial legislatures[107] and local government.[108]

[112] Chapter 10 of the Constitution, which deals with public administration, provides in section 195:

> "(1) Public administration must be governed by the democratic values and principles enshrined in the Constitution, including the following principles:

[104] Section 1(d).

[105] Section 57(1)(b) provides that:

> "The National Assembly may make rules and orders concerning its business, with due regard to representative and participatory democracy, accountability, transparency and public involvement."

[106] Section 72 of the Constitution.

[107] Sections 116(1)(b) and 118(1)(a) of the Constitution.

[108] Sections 152(1)(a) and (e), section 154(2) and 160(4)(b) of the Constitution.

> . . . .
>
> (e) People's needs must be responded to, and the public must be encouraged to participate in policy-making.
>
> (f) Public administration must be accountable.
>
> (g) Transparency must be fostered by providing the public with timely, accessible and accurate information.
>
> . . . .
>
> (2) The above principles apply to—
>
> (a) administration in every sphere of government;
>
> (b) organs of state; and
>
> (c) public enterprises.
>
> (3) National legislation must ensure the promotion of the values and principles listed in subsection (1)."

Functionaries who make regulations in terms of empowering legislation are "organs of state".[109]

[113] The making of delegated legislation by members of the executive is an essential part of public administration. It gives effect to the policies set by the legislature and provides the detailed infrastructure according to which this is to be done. The Constitution calls for open and transparent government, and requires public participation in the making of laws by Parliament and deliberative legislative assemblies. To hold that the making of delegated legislation is not part of the right to just administrative action would be contrary to the Constitution's commitment to open and transparent government.

The meaning of administrative action in section 33(1) of the Constitution

[109] See n 115 where the definition of "organ of state" appears.

[114] In *Fedsure Life Assurance Ltd and Others v Greater Johannesburg Transitional Metropolitan Council and Others*[110] this Court had to consider the meaning of administrative action under section 24 of the interim Constitution. It said that:

> "In addressing this question it is important to distinguish between the different processes by which laws are made. Laws are frequently made by functionaries in whom the power to do so has been vested by a competent legislature. Although the result of the action taken in such circumstances may be 'legislation', the process by which the legislation is made is in substance 'administrative'. The process by which such legislation is made is different in character to the process by which laws are made by deliberative legislative bodies such as elected municipal councils. Laws made by functionaries may well be classified as administrative; laws made by deliberative legislative bodies can seldom be so described."[111]

[115] I am not unmindful of the fact that an unqualified right to demand that delegated legislation must be "reasonable and procedurally fair" may subject such legislation to a more intense review by the courts than was the case in the pre-constitutional era. An obligation to provide written reasons for the delegated legislation, to persons whose rights have been adversely affected by it, would add to the burden.

[116] Significantly, however, the transitional provisions of Schedule 6 to the Constitution suspended the operation of sections 33(1) and (2) pending the enactment of the legislation contemplated in section 33(3). That legislation had to be enacted

[110] 1999 (1) SA 374 (CC); 1998 (12) BCLR 1458 (CC).

[111] Id at para 27 in the judgment of Chaskalson P, Goldstone and O'Regan JJ. Although this was not a unanimous judgment, Kriegler J and other members of the Court who expressed contrary views on certain of the issues in the case, did not dissent from this proposition. See para 117 in the judgment of Kriegler J.

within 3 years and pending that being done, the provisions of section 24 of the interim Constitution would remain in place.[112]

[117] This addressed a concern that might otherwise have existed that a general and unqualified right to "lawful, reasonable and procedurally fair" administrative action might place too heavy a burden on government. The legislation to be enacted had to take into account the need to "promote an efficient administration". Until the mandated legislation had been enacted, the provisions of section 24 of the interim Constitution, and not those of sections 33(1) and (2) of the 1996 Constitution, would be applicable. The enactment of the mandated legislation, and the limitations permissible under section 36,[113] would enable Parliament to address these concerns.

[118] It would no doubt be possible to give a narrow construction to "administrative action" in section 33 and to have two systems of review, one under the common law for delegated legislation, and the other under the Constitution for administrative action construed narrowly. But that would not be consistent with the purpose of section 33 which is to establish a coherent and overarching system for the review of all

[112] Item 23(1) and (3) of Schedule 6 to the Constitution.

[113] Section 36 of the Constitution reads as follows:

> "Limitation of rights.—(1) The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including—
>
> (a) the nature of the right;
> (b) the importance of the purpose of the limitation;
> (c) the nature and extent of the limitation;
> (d) the relation between the limitation and its purpose; and
> (e) less restrictive means to achieve the purpose.
>
> (2) Except as provided in subsection (1) or in any other provision of the Constitution, no law may limit any right entrenched in the Bill of Rights."

administrative action; nor would it be consistent with the values of the Constitution itself.[114] Properly construed, therefore, "administrative action" in section 33(1) of the Constitution, includes legislative administrative action.

[119] If, then, administrative action in section 33 of the Constitution must be construed as including legislative administrative action, how should PAJA be construed?

Is regulation-making subject to PAJA?

[120] "Administrative action" is defined in section 1 of PAJA as meaning

> "any decision taken, or any failure to take a decision, by—
>
> (a) an organ of state, when—
>
> (i) exercising a power in terms of the Constitution or a provincial constitution; or
>
> (ii) exercising a public power or performing a public function in terms of any legislation; or
>
> (b) a natural or juristic person, other than an organ of state, when exercising a public power or performing a public function in terms of an empowering provision,
>
> which adversely affects the rights of any person and which has a direct, external legal effect, but does not include [actions listed in subparagraphs (aa) to (ii) of this definition]".

I deal later with the exclusions listed in subparagraphs (aa) and (ii).

[114] *Bato Star* above n 80 at para 22.

[121] The Minister and the Pricing Committee are both organs of state.[115] The regulation of prices in the disputed regulations adversely affect the rights of pharmacists and other persons in the pharmaceutical industry. The regulations will therefore be "administrative action" within the meaning of PAJA, if the making of the regulations constituted a "decision", and if they are not excluded by subparagraph (aa) to (ii) of the definition of administrative action.

The exclusions

[122] The exclusions from the definition of "administrative action" are:

> "(aa) the executive powers or functions of the National Executive, including the powers or functions referred to in sections 79(1) and (4), 84(2)(a), (b), (c), (d), (f), (g), (h), (i) and (k), 85(2)(b), (c), (d) and (e), 91(2), (3), (4) and (5), 92(3), 93, 97, 98, 99 and 100 of the Constitution;
>
> (bb) the executive powers or functions of the Provincial Executive, including the powers or functions referred to in sections 121(1) and (2), 125(2)(d), (e) and (f), 126, 127(2), 132(2), 133(3)(b), 137, 138, 139 and 145(1) of the Constitution;
>
> (cc) the executive powers or functions of a municipal council;
>
> (dd) the legislative functions of Parliament, a provincial legislature or a municipal council;
>
> (ee) the judicial functions of a judicial officer of a court referred to in section 166 of the Constitution or of a Special Tribunal established under section 2 of the Special Investigating Units and Special Tribunals Act, 1996 (Act No. 74 of

[115] Section 1 of PAJA defines "organ of state" as having "the meaning assigned to it in section 239 of the Constitution". According to section 239 of the Constitution an "organ of state" means

> "(a) any department of state or administration in the national, provincial or local sphere of government; or
>
> (b) any other functionary or institution—
>
> (i) exercising a power or performing a function in terms of the Constitution or a provincial constitution; or
>
> (ii) exercising a public power or performing a public function in terms of any legislation,
>
> but does not include a court or a judicial officer".

1996), and the judicial functions of a traditional leader under customary law or any other law;

(ff) a decision to institute or continue a prosecution;

(gg) a decision relating to any aspect regarding the appointment of a judicial officer, by the Judicial Service Commission;

(hh) any decision taken, or failure to take a decision, in terms of any provision of the Promotion of Access to Information Act, 2000; or

(ii) any decision taken, or failure to take a decision, in terms of section 4(1)".

[123] Subparagraph (aa) deals with the executive powers and functions of the National Executive. It refers to sections 79, 84, 85, 91, 92, 93, 97, 98, 99 and 100 of the Constitution. Sections 79 and 84 of the Constitution deal with powers vested in the President alone. They are not relevant to the present case. Nor are sections 92, 93, 97, 98, and 99. Section 85 is, however, relevant and of importance.

[124] Section 85 deals with the President and Cabinet. If it had stood alone there would have been greater force in the finding that the making of regulations by a minister is excluded from the definition of "administrative action". But it does not stand alone. Subparagraph (aa) of the definition goes on to refer to specific subparagraphs of section 85(2), including sections 85(2)(b), (c), (d), and (e), but excludes from the list section 85(2)(a). The provisions of section 85(2)(a) to (e) are as follows:

"(2) The President exercises the executive authority, together with the other members of the Cabinet, by—

(a) implementing national legislation except where the Constitution or an Act of Parliament provides otherwise;

(b) developing and implementing national policy;

(c) co-ordinating the functions of state departments and administrations;

> (d) preparing and initiating legislation; and
> (e) performing any other executive function provided for in the Constitution or in national legislation."

[125] The omission of subparagraph (2)(a) from the specified list of exclusions is significant. Subparagraph (bb) of the definition of administrative action deals with the powers of the provincial executive. Various provisions of section 125 of the Constitution are listed, but again significantly, sections 125(2)(a), (b) and (c), which refer to the implementation of legislation, are omitted from the list.

[126] In *President of the Republic of South Africa and Others v South African Rugby Football Union and Others (SARFU)*[116] this Court said that

> "one of the constitutional responsibilities of the President and Cabinet Members in the national sphere (and premiers and members of executive councils in the provincial sphere) is to ensure the implementation of legislation. This responsibility is an administrative one, which is justiciable, and will ordinarily constitute 'administrative action' within the meaning of s 33."

If sections 85(2)(a) and 125(2)(a), (b) and (c) had not been omitted from the list of exclusions, the core of administrative action would have been excluded from PAJA, and the Act mandated by the Constitution to give effect to sections 33(1) and (2) would not have served its intended purpose. The omission of sections 85(2)(a) and 125(2)(a), (b) and (c) from the list of exclusions was clearly deliberate. To have excluded the implementation of legislation from PAJA would have been inconsistent

[116] 2000 (1) SA 1 (CC); 1999 (10) BCLR 1059 (CC) at para 142.

with the Constitution. The implementation of legislation, which includes the making of regulations in terms of an empowering provision, is therefore not excluded from the definition of administrative action.

Does the making of regulations constitute a "decision"?

[127] PAJA defines "decision" as follows:

> "'decision' means any decision of an administrative nature made, proposed to be made, or required to be made, as the case may be, under an empowering provision, including a decision relating to—
>
> (a) making, suspending, revoking or refusing to make an order, award or determination;
>
> (b) giving, suspending, revoking or refusing to give a certificate, direction, approval, consent or permission;
>
> (c) issuing, suspending, revoking or refusing to issue a licence, authority or other instrument;
>
> (d) imposing a condition or restriction;
>
> (e) making a declaration, demand or requirement;
>
> (f) retaining, or refusing to deliver up, an article; or
>
> (g) doing or refusing to do any other act or thing of an administrative nature, and a reference to a failure to take a decision must be construed accordingly".

[128] It is true that the making of regulations is not referred to in subparagraphs (a) to (f). But the reference in the main part of the definition to "*any* decision of an administrative nature" and in the general provision of subparagraph (g) to "doing or refusing to do *any* other act or thing of an administrative nature" brings the making of

regulations within the scope of the definition.[117] This seems to me to be the clear meaning of the definition. But if there is any doubt on this score, the definition of administrative action must be construed consistently with section 33 of the Constitution.[118] All the judges in the High Court considered that the making of regulations falls within the scope of "administrative action" in section 33 of the Constitution. I have already indicated why I agree with this conclusion.

[129] The majority in the High Court considered that the failure to refer specifically to legislative administrative action in the definition of "decision" in section 1 of PAJA was deliberate, and indicated an intention to exclude such action from being reviewed under PAJA. I have already dealt with why I take a different view. It is necessary, however, to deal briefly with reasons given by the majority of the High Court for their decision on this issue.

[130] They attached weight to the specific exclusion from the definition of administrative action in PAJA, of "any decision taken, or failure to take a decision, in terms of section 4(1)."[119] Section 4 of PAJA provides:

> "Administrative action affecting public.—(1) In cases where an administrative action materially and adversely affects the rights of the public, an administrator, in order to

[117] "Any" is a word of wide import. See *Commissioner for Inland Revenue v NST Ferrochrome (Pty) Ltd* 1999 (2) SA 228 (T) at 232D-E and the authorities there cited.

[118] *Bato Star* above n 80 at para 44; *Daniels v Campbell NO and Others* 2004 (5) SA 331 (CC); 2004 (7) BCLR 735 (CC) at paras 43-44; *National Director of Public Prosecutions and Another v Mohamed NO and Others* 2002 (4) SA 843 (CC); 2002 (9) BCLR 970 (CC) at para 33; *Hyundai* above n 86 at paras 21-22.

[119] Subparagraph (ii) of subparagraph (b) of the definition of administrative action.

give effect to the right to procedurally fair administrative action, must decide whether—

(a) to hold a public inquiry in terms of subsection (2);

(b) to follow a notice and comment procedure in terms of subsection (3);

(c) to follow the procedures in both subsections (2) and (3);

(d) where the administrator is empowered by any empowering provision to follow a procedure which is fair but different, to follow that procedure; or

(e) to follow another appropriate procedure which gives effect to section 3.

(2) If an administrator decides to hold a public inquiry—

(a) the administrator must conduct the public inquiry or appoint a suitably qualified person or panel of persons to do so; and

(b) the administrator or the person or panel referred to in paragraph (a) must—

(i) determine the procedure for the public inquiry, which must—

(aa) include a public hearing; and

(bb) comply with the procedures to be followed in connection with public inquiries, as prescribed;

(ii) conduct the inquiry in accordance with that procedure;

(iii) compile a written report on the inquiry and give reasons for any administrative action taken or recommended; and

(iv) as soon as possible thereafter—

(aa) publish in English and in at least one of the other official languages in the Gazette or relevant provincial Gazette a notice containing a concise summary of any report and the particulars of the places and times at which the report may be inspected and copied; and

(bb) convey by such other means of communication which the administrator considers effective, the information referred to in item (aa) to the public concerned.

(3) If an administrator decides to follow a notice and comment procedure, the administrator must—

(a) take appropriate steps to communicate the administrative action to those likely to be materially and adversely affected by it and call for comments from them;

(b) consider any comments received;

> (c) decide whether or not to take the administrative action, with or without changes; and
>
> (d) comply with the procedures to be followed in connection with notice and comment procedures, as prescribed.
>
> (4)(a) If it is reasonable and justifiable in the circumstances, an administrator may depart from the requirements referred to in subsections (1)(a) to (e), (2) and (3).
>
> (b) In determining whether a departure as contemplated in paragraph (a) is reasonable and justifiable, an administrator must take into account all relevant factors, including—
>
> (i) the objects of the empowering provision;
>
> (ii) the nature and purpose of, and the need to take, the administrative action;
>
> (iii) the likely effect of the administrative action;
>
> (iv) the urgency of taking the administrative action or the urgency of the matter; and
>
> (v) the need to promote an efficient administration and good governance."

I refer more fully to its provisions later when I deal with arguments directed to the issue of procedural fairness.

[131] Section 4(1) imposes an obligation on an administrator concerned with decisions that affect the public to comply with the requirement of procedural fairness, but authorises him or her to decide how to give effect to this requirement. As long as the procedure followed meets the requirements of one of subparagraphs (a) to (d), the provisions of section 4(1) will have been complied with.

[132] What is or is not administrative action for the purposes of PAJA is determined by the definition in section 1. It is only if the action taken falls within the definition that section 4 comes into play. The fact that the choice of a particular procedure to be

followed in terms of section 4(1) is not itself subject to review, does not provide any help in deciding what is or is not "administrative action". All that it means is that an administrator's choice of procedure is final. Consistently with this the implementation of the choice in a manner consistent with sections 4(2), (3) or (4) remains subject to review.

[133] I cannot agree, therefore, that section 4(1) points to a decision to exclude legislative administrative action from the definition of administrative action. To the contrary, the provisions of section 4, which contemplate that administrative action that materially affects the rights of "the public" will be subject to review, suggest that regulations, the most common form of administrative action affecting the rights of the public, are indeed subject to review under PAJA. If they were to be excluded one would have expected this to have been done directly in specific terms in the exclusions listed in the definition of "administrative action", rather than indirectly through the provisions of subparagraph (ii). But if that had been done it could well have given rise to a constitutional challenge that PAJA does not comply with section 33(1) of the Constitution. Instead, the legislature has chosen the route of allowing for procedural fairness in respect of action affecting the public, and providing a safety valve in section 4(4) for cases where compliance with such a requirement would impede efficient administration.

[134] The majority in the High Court appreciated that the omission of section 85(2)(a) of the Constitution from the list of exclusions in subparagraphs (aa) to (ii) had to be addressed.[120] Section 85(2)(a) provides that:

> "The President exercises the executive authority, together with the other members of the Cabinet, by implementing national legislation except where the Constitution or an Act of Parliament provides otherwise".

They held that the omission of section 85(2)(a) from the exclusions could be explained on the grounds that PAJA is an Act of Parliament which provides otherwise. I do not agree. PAJA does not deal with who exercises executive authority in respect of rule-making. It deals with the circumstances in which the exercise of the executive authority is subject to review.

[135] It follows that the making of the regulations in the present case by the Minister on the recommendation of the Pricing Committee was "a decision of an administrative nature". The regulations were made "under an empowering provision".[121] They had a "direct, external legal effect" and they "adversely" affected the rights of pharmacists and persons in the pharmaceutical industry. They accordingly constitute administrative action within the meaning of PAJA.

The Minister and the Pricing Committee

[120] Above n 68 at para 49.

[121] Section 22G of the Medicines Act. See para 193 below where the relevant provisions of section 22G are provided.

[136] The making of regulations in terms of section 22G of the Medicines Act involves a two-stage process. First, a recommendation by the Pricing Committee, and second a decision by the Minister as to whether or not to accept the recommendation. Counsel for the Minister contended that this called for two separate decisions, one by the Pricing Committee, and one by the Minister. They submitted that the Pricing Committee's decision was not administrative action because it had no direct, external legal effect. The Minister's decision had direct, external legal effect but it was not administrative action within the meaning of PAJA. Thus, the regulations were not open to being reviewed in terms of PAJA. They accepted, however, that the regulations could be reviewed for "legality" under the Constitution in terms of this Court's decision in *Fedsure*.[122]

[137] In the circumstances of the present case, to view the two stages of the process as unrelated, separate and independent decisions, each on its own having to be subject to PAJA, would be to put form above substance.

[138] The Minister was not obliged to act on the Pricing Committee's recommendations. She had a discretion whether to do so.[123] But ultimately there had to be one decision to which both the Pricing Committee and the Minister agreed. Neither had the power to take a binding decision without the concurrence of the other. It was only if and when agreement was reached, that regulations could be made.

[122] Above n 110.

[123] It was not suggested by either party that "may" in section 22G should be construed as "must".

[139] In such circumstances debate between the Pricing Committee and the Minister concerning the regulations to be made would not be inappropriate. Such debate would further the purpose of the legislation and facilitate the reaching of agreement. This is recognised in the General Regulations made in terms of section 35 of the Medicines Act (the General Regulations) which deal with the composition of the Pricing Committee.[124] Regulation 38 provides:

> "(1) The pricing committee contemplated in section 22G of the Act shall consist of no more than eighteen members, but shall include—
>
> (a) one person nominated by the Minister of Finance;
> (b) one person nominated by the Minister of Trade and Industry;
> (c) one or more persons representing the Department of Health;
> (d) at least one person with background in pharmacology;
> (e) at least one person with background in the law;
> (f) at least one person with background in academic medical research;
> (g) at least two persons with economics background, one of whom must be a health economist; and
> (h) at least one person representing independent patient or consumer groups."

The regulation contemplates that the Pricing Committee will have members "*representing* the Department of Health" (my emphasis). This would facilitate an exchange of ideas between the National Department of Health (the Department) and the Pricing Committee during the process of information gathering and deliberations which would be necessary before a recommendation could be made to the Minister. It

[124] General Regulations made in terms of the Medicines and Related Substances Act, 101 of 1965 as amended in Government Gazette 24727 R510, 10 April 2003.

would also avoid the need for two separate investigations to be undertaken each being conducted independently of the other at different times.

[140] In the arguments addressed to us it was suggested that there had been an inappropriate relationship between the Department and the Pricing Committee and that members of the Department should not have been present at meetings of the Pricing Committee at which deliberations were conducted and decisions taken. The Departmental officials were not, however, "strangers". Some were members of the Pricing Committee. Others also had to attend meetings because in terms of the General Regulations [125] the Secretariat of the Pricing Committee consisted of employees designated by the Director-General. The presence of Departmental representatives at meetings of the Pricing Committee was therefore necessary. There is no evidence to suggest that the presence at meetings of the Pricing Committee of officials who were not members of the Pricing Committee was not for a proper purpose, or that their presence could have inhibited the discussions or the expression of views. Their presence at meetings of the Pricing Committee is not in my view a ground for setting aside the recommendations of the Pricing Committee.

[141] The Pricing Committee's work on the regulations was continuing and ongoing until the Minister agreed. In substance the decision to make the regulations was, and had to be, a joint decision of the Minister and the Pricing Committee. In such circumstances it cannot be said that the Pricing Committee's role in the joint decision-

[125] Regulation 38(4).

making process, had no "direct external legal effect". If the Pricing Committee's role in the joint decision-making process was flawed, the entire process would have been tainted. This is relevant to the question of procedural fairness and the challenge to the way in which the Pricing Committee carried out its work, which is dealt with later. However, as far as lawfulness and vagueness of the regulations are concerned, it makes no difference to the analysis.

[142] Before leaving this part of the judgment one further comment is necessary. In the academic writings on PAJA reference is made to the fact that certain of its provisions have been borrowed from German and Australian law.[126] PAJA must, however, be interpreted by our courts in the context of our law, and not in the context of the legal systems from which provisions may have been borrowed. In neither of the countries is there a defined constitutional right to just administrative action. Transplanting provisions from such countries into our legal and constitutional framework may produce results different from those obtained in the countries from which they have been taken.

Review under PAJA

[143] PAJA addresses the four requirements of the Constitution relating to just administrative action: lawfulness, reasonableness, procedural fairness and the provision of reasons.

[126] Hoexter *The New Constitutional and Administrative Law* above n 96 at 107-10 and references there cited.

[144] Lawfulness is relevant to the exercise of all public power, whether or not the exercise of the power constitutes administrative action.[127] Where the making of regulations is challenged on this ground, lawfulness depends on the terms of the empowering statute. If the regulations are not sanctioned by the empowering statute they will be unlawful and invalid. This is an issue raised in the present case and I will deal with it later.

[145] Reasonableness and procedural fairness are context specific. What is reasonable and procedurally fair in one context, is not necessarily reasonable or procedurally fair in a different context.[128] In *R v Secretary of State for the Home Department, ex parte Daly*[129] Steyn LJ referred to an observation by Laws LJ[130] emphasising that "the intensity of review in a public law case will depend on the subject matter in hand". Steyn LJ went on to say "[t]hat is so even in cases involving convention rights. In law context is everything". In *First National Bank of SA Ltd t/a Wesbank v Commissioner, South African Revenue Service and Another; First National Bank of SA Ltd t/a Wesbank v Minister of Finance*[131] Ackermann J referred with approval to this passage.

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[127] *Affordable Medicines Trust and Others v Minister of Health of RSA and Another* 2005 (6) BCLR 529 (CC) at para 49; *Pharmaceutical Manufacturers Association of SA and Another: In re Ex parte President of the Republic of South Africa and Others* 2000 (2) SA 674 (CC); 2000 (3) BCLR 241 (CC) at para 20; *Fedsure* above n 110 at para 58.

[128] *Bato Star* above n 80 at para 45.

[129] [2001] 3 All ER 433 (HL) at 447A.

[130] In *R (Mahmood) v Secretary of State for the Home Department* [2001] 1 WLR 840 at para 18.

[131] 2002 (4) SA 768 (CC); 2002 (7) BCLR 702 (CC) at para 63.

[146] Legislative administrative action is a special category of administrative action. It involves the making of laws and the taking of policy decisions for that purpose. Under our Constitution these are decisions which are within the domain of the executive to whom Parliament has delegated its law-making power. Whilst the exercise of this power is subject to constitutional control, it is important that the special role of the executive in exercising this power be acknowledged, and that courts "take care not to usurp"[132] it.

Procedural fairness

[147] In *Bato Star*[133] this Court made clear that context is relevant both to procedural fairness and reasonableness. In the case of regulations the subject matter will be of particular importance. I would add that sensitivity to the special role of the executive in making regulations is also called for in regard to the other grounds for review prescribed by PAJA.

[148] Bearing this in mind, I turn now to deal with challenges to the validity of the regulations made by the Pharmacies. These challenges are brought on the grounds that the regulations failed to comply with provisions of PAJA relating to procedural fairness, reasonableness and lawfulness. I will deal first with procedural fairness, and then with reasonableness and lawfulness.

[132] *Bato Star* above n 80 at para 45.

[133] Id.

[149] The procedural fairness challenge is complicated by the fact that the regulations were made, as they had to be, by the Minister on the recommendation of the Pricing Committee. It was contended, as I have previously mentioned, that this involved the taking of two decisions, one by the Pricing Committee, and one by the Minister, and that procedural fairness had to be observed in relation to each decision.

[150] I have explained why I consider that the making of the regulations should be seen as one process involving at different times both the Minister and the Pricing Committee.[134] Section 22G does not require the Minister and the Pricing Committee to follow any particular procedure in making the regulations. The relevant requirements are therefore those prescribed by section 4(1) of PAJA.[135] They call in the first instance for a decision to be taken as to whether to hold a public enquiry, to follow a notice and comment procedure, to do both, or to follow another appropriate procedure which gives effect to section 3 of PAJA.[136]

[151] What section 3 of PAJA requires is that administrative action must be procedurally fair. It refers specifically to the giving of adequate notice and providing a reasonable opportunity to make representations, and makes it clear that what is necessary for this purpose will depend on the circumstances of each case.

[134] See paras 136-141 above.

[135] See para 130 above for the text of section 4.

[136] Id.

[152] In *Du Preez and Another v Truth and Reconciliation Commission*[137] Corbett CJ sought guidance from the remarks of Lord Mustill in *Doody v Secretary of State for the Home Department and other appeals*[138] as to what is required of a public official or body who has to meet the requirements of procedural fairness.[139] Lord Mustill's remarks were as follows:

> "What does fairness require in the present case? My Lords, I think it unnecessary to refer by name or to quote from, any of the often-cited authorities in which the courts have explained what is essentially an intuitive judgment. They are far too well known. From them, I derive the following. (1) Where an Act of Parliament confers an administrative power there is a presumption that it will be exercised in a manner which is fair in all the circumstances. (2) The standards of fairness are not immutable. They may change with the passage of time, both in the general and in their application to decisions of a particular type. (3) The principles of fairness are not to be applied by rote identically in every situation. What fairness demands is dependent on the context of the decision, and this is to be taken into account in all its aspects. (4) An essential feature of the context is the statute which creates the discretion, as regards both its language and the shape of the legal and administrative system within which the decision is taken. (5) Fairness will very often require that a person who may be adversely affected by the decision will have an opportunity to make representations on his own behalf either before the decision is taken with a view to producing a favourable result, or after it is taken, with a view to procuring its modification, or both. (6) Since the person affected usually cannot make worthwhile representations without knowing what factors may weigh against his interests fairness will very often require that he is informed of the gist of the case which he has to answer."

[137] 1997 (3) SA 204 (A) at 231I-232D; 1997 (4) BCLR 531 (A) at 542F-543A.

[138] [1993] 3 All ER 92 (HL) at 106D-H.

[139] See also *Premier, Mpumalanga, and Another v Executive Committee, Association of State-Aided Schools, Eastern Transvaal* 1999 (2) SA 91 (CC); 1999 (2) BCLR 151 (CC) at para 39.

[153] Standards of fairness called for in respect of law-making by legislative administrative action are different to standards of fairness called for in cases involving adjudication or administrative decisions such as licensing enquiries and the like where individual interests are at stake and decisions affecting particular individuals have to be taken. An individual needs to know the concerns of the administrator and to be given an opportunity of answering those concerns. The decisions may depend on particular facts and may sometimes involve disputes of fact that have to be resolved.

[154] When it comes to the making of regulations the context is different. Regulations affect the general public and that means that diverse and often conflicting interests have to be taken into account in deciding what the laws will be. The decision of the law-maker on how to resolve these conflicting interests is ultimately a question of policy.

[155] As Lord Mustill points out "[t]he principles of fairness are not to be applied by rote identically in every situation." It cannot be expected of the law-maker that a personal hearing will be given to every individual who claims to be affected by regulations that are being made. What is necessary is that the nature of the concerns of different sectors of the public should be communicated to the law-maker and taken into account in formulating the regulations.

[156] In Parliament this is done through the publication of a Bill containing the provisions of the proposed legislation, hearings before Parliamentary committees, and

debates in Parliament where matters of principle raised by sectors of the public affected by the law can be contested.

[157] Where laws are made through legislative administrative action, the procedure of publishing draft regulations for comment serves this purpose. It enables people who will be affected by the proposals to make representations to the law-maker, so that those concerns can be taken into account in deciding whether or not changes need to be made to the draft.

[158] This does not mean that the Minister who makes the regulations has to study thousands of pages received from the general public and respond to them. The analysis of these responses can be left to officials whose responsibility it is to consider the comments received and to report to the Minister on them.

[159] In deciding whether the requirements of procedural fairness have been met in the present case, which is concerned with legislative administrative action, decided cases dealing with different situations are not of particular assistance. What has to be decided is whether the procedures followed by the Minister and the Pricing Committee in the process of making the regulations were in all the circumstances fair.

[160] Professor McIntyre, the chairperson of the Pricing Committee, deals with the procedures followed by the Pricing Committee in carrying out its work. Preliminary investigations were made into the pricing structure of the pharmaceutical industry in

South Africa and comparative research in that regard was undertaken, looking at how other countries have dealt with similar problems.

[161] The research included studying information gathered previously by a Pricing Committee working group that had been established by the Department to consider pricing policies. During this period there had been "on-going engagement with major stakeholders" in the pharmaceutical industry, and written submissions had been received from them over a period of years.

[162] While the work of the Pricing Committee was progressing, some members were tasked to secure more information from stakeholders on certain issues. They would then report to the Pricing Committee what had been obtained. As a result, the views of the Pricing Committee were updated on a continuous basis.

[163] The Pricing Committee decided at an early stage of the process that it would recommend to the Minister that draft regulations be prepared and published for general comment so that comment received should be considered before the regulations were finalised. Draft regulations were accordingly submitted to the Minister and published by her for general comment on 16 January 2004. The notice in the Government Gazette in which the draft regulations were published stated:

> "The Minister of Health intends to make the regulations in the Schedule. Interested persons are invited to submit written comments or representations on the proposed Regulations to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for

> attention of the Cluster Manager: Pharmaceutical Policy and Planning), within three months of the date of publication of this Notice."

During the period of three months allowed for comment, written representations were in fact received, and considered both by the Department and the Pricing Committee.

[164] A decision was taken at a meeting of the Pricing Committee that an opportunity be given to interested parties who had made written representations, to make oral representations as well. This invitation was communicated to interested parties in letters from the Department of Health written on behalf of the Director-General.

[165] The invitation was to make oral presentations on the written comments they had made on the draft regulations. It said that:

> "The Department has decided that it would be beneficial to invite stakeholders to make oral presentations on their written comments on these proposed regulations."

[166] Conditions were attached to the invitation. They prescribed that a supporting written document on the comments to be given should be supplied to the Department in advance of the oral presentation. Each presenter would be limited to one hour. The invitation contained the following comments which are relevant to the arguments advanced on behalf of the Pharmacies:

> "The Pricing Committee is a technical committee whose task is to make recommendations to the Minister of Health. You are therefore advised to prepare your written and oral inputs in as much detail as possible and with a view to supplying accurate and substantiated information to the Department and the Pricing

> Committee on how the proposed regulations may affect your interests. Where the regulations raise more than one possibility, you are advised to include all possible impacts in your presentations.
>
> The object of these sessions is not to provide further clarification by departmental officials or members of the Pricing Committee on the proposed regulations. Consequently no questions for clarification will be answered. The Department and the Pricing Committee would like to hear your comments on, and interpretation of, the regulations as opposed to their own views. This said, you may by all means indicate areas that are not clear to you and in what way they lack such clarity.
>
> Due to the fact that trade secrets or other sensitive information may be contained in your presentations, no other stakeholders or members of the public will be present at any session. Only members of the Pricing Committee and officials from the Department of Health will be attending. Not all members of the Pricing Committee may be able to attend every session due to other commitments." (emphasis omitted)

[167] This invitation, and what followed at the oral presentations, was the basis of the contentions by the Pharmacies that procedural fairness had not been observed. In particular, it was contended that the procedure was flawed from the beginning because the hearing was to be attended by some, and not all, of the members of the Pricing Committee. It was also contended that when the oral presentations were made, those members of the Pricing Committee who attended did not remain throughout the hearings, but walked in and out of the hearings while they were taking place. This, however, is disputed, and no finding in that regard can be made on the papers.

[168] One of the issues was whether the hearings were called by the Department or the Pricing Committee. It is clear from the evidence that the decision to arrange for oral presentations to be made was taken at a meeting of the Pricing Committee at

which representatives of the Department were present, that it was contemplated that the invitation would be issued by the Department, and that members of the Pricing Committee as well as representatives of the Department would be present during the oral presentations.

[169] Although the invitation was issued by the Department of Health, it was done with the concurrence of the Pricing Committee, which arranged for some of its members to be present during the presentations. The letter of invitation mentioned that the oral presentations would provide clarification for the Department and the Pricing Committee of the concerns of the objectors.

[170] Counsel for New Clicks, relying on *Schierhout v The Union Government*[140] and cases that have followed it,[141] contended that this procedure did not meet the procedural fairness requirements of PAJA because all members of the Pricing Committee did not attend the oral presentations.

[171] The *Schierhout* line of cases was concerned with adjudication. Whilst it is ordinarily necessary for bodies appointed to deal with such matters to be properly constituted at all times throughout the adjudication process,[142] the same does not

[140] 1919 AD 30 at 44.

[141] See for instance, *Yates v University of Bophuthatswana and Others* 1994 (3) SA 815 (B) at 847I-849B; *Schoultz v Voorsitter, Personeel-Advieskomitee van die Munisipale Raad van George, en 'n Ander* 1983 (4) 689 (C) at 707F-H.

[142] *R v Price* 1955 (1) SA 219 (A) at 223E-G. Section 147 of the Criminal Procedure Act, 51 of 1977 now makes provision for cases to continue if a quorum is broken due to death or incapacity. See *S v Malinde*, above n 42, for a discussion of these provisions.

necessarily apply to a committee such as the Pricing Committee whose work would involve research, the gathering of information and the making of enquiries before making its recommendations. In this regard I agree with the following comment of Corbett JA in *S v Naudé*:[143]

> "[I]t must be conceded that a commission is, in general, the master of its own procedures. Within the bare framework provided by the Act and such modifications and regulations as may have been made by the State President in terms of sec 1(1) of the Act, it is free to determine how it shall function. There is no doubt that a commission, particularly where it consists of a substantial number of persons, may operate without every member participating personally in every activity. Were it otherwise, a commission would be hamstrung from the start." [144]

In each case what will be required will depend on the interpretation of the empowering legislation and relevant regulations, prescribing how a commission should function.

[172] Section 22G of the Medicines Act does not deal with how the Pricing Committee is to be composed or how it is to function, save to say that members of the Pricing Committee were to be appointed for a period of not more than five years. The composition and functioning of the Pricing Committee is dealt with in regulations made by the Minister under her power to make the General Regulations.[145] The regulations provide that the Pricing Committee shall consist of not more than eighteen members. They do not make provision for a quorum and authorise the Pricing

[143] 1975 (1) SA 681 (A).

[144] Id at 704G-H.

[145] See regulation 38 of the General Regulations above at para 139.

Committee to determine the procedure for the conduct of its business. They had to address a difficult and contentious issue which would call for ongoing work over an extended period. It could not have been contemplated that all its members would have to attend all meetings or to participate personally in all decisions of the Pricing Committee. Neither the Medicines Act nor the regulations can be construed as imposing such a requirement. The Pricing Committee was therefore entitled to determine its own methods of work, including the manner in which material relevant to its mandate should be gathered.[146]

[173] The General Regulations make provision for only four matters affecting the Pricing Committee. The composition of the Pricing Committee, the provision to which I have referred concerning the conduct of the Pricing Committee's business, the authority to the Director-General to designate employees of the Department to serve as the secretariat of the Pricing Committee, and a provision that:

> "The Committee may appoint, subject to the approval of the Minister, subcommittees as it may deem necessary, to investigate and report to it any matter within the purview of the Committee in terms of the Act."

It was contended that if the Pricing Committee wished some but not all of its members to be present when the oral presentations were being made, it should have secured the Minister's consent to that, and appointed a sub-committee for that purpose.

[146] *S v Naudé* above n 143 at 699B-C.

[174] I do not agree. This was not an investigation of a discrete issue in which other members of the Pricing Committee would not participate. It was part of the process of evaluating the draft regulations which included, but was not limited to, a consideration of responses to the publication of the draft regulations.

[175] The draft regulations were published for comment on 16 January 2004. The responses called for had to be in writing and sent to the Department. When the written responses were received they were sent by the Department to the members of the Pricing Committee to allow them to consider the representations over an extended period. All the members of the Pricing Committee were involved in this process.

[176] The invitations from the Department brought to the attention of those who were to make representations that all members of the Pricing Committee would not necessarily be present. Knowing that, they accepted the invitation.

[177] The Minister and the Pricing Committee were not engaged in a process of adjudication in which disputes of fact had to be resolved. They were engaged in a law-making process in which those who would be affected by their decisions were given details of their proposals and an opportunity of stating their objections. The process was highly public, there were public forums, meetings with stakeholders, lobbying, media reports and an opportunity to make written representations.

[178] PSSA's written objections lodged with the Pricing Committee focussed on the issues raised in this litigation, as did the representations by New Clicks, and others. It was made clear by them, and others who supported them, that they contended that the dispensing fee in the draft regulations, set at 24% for medicine under R100 and R24 for medicine costing R100 or above, would cause pharmacists to trade at a loss. The written objections set out details in support of this contention.

[179] For instance, the written objection by PSSA sought to establish by actuarial evidence that the proposed fee structure would cause pharmacists to trade at a loss. It made various proposals directed to the draft pricing scheme, including a proposal that pharmacists would be able to trade at a reasonable profit at a fixed dispensing fee of R25 per prescription item, plus 25% of cost for medicine costing R50 or less and 12,5% of cost for medicine costing more than R50. An additional proposal was that there should be a rural supplementation for community pharmacies in rural areas. New Clicks also submitted detailed representations contending that pharmacists would trade at a loss if the dispensing fee proposed in the regulations were adopted, as did others in the pharmaceutical industry. They all had a fair opportunity of making their views known.

[180] The regulations that were ultimately adopted and made after considering the objections increased the proposed dispensing fee from R24 to R26 for medicine costing R100 or more, and from 24% to 26% for medicine costing less than R100.

The proposal as to the manner in which the single exit price should be calculated was materially changed. Other material changes were also made to the regulations.

[181] The arrangement made for some members of the Pricing Committee to attend the oral presentations must be seen against this background. The objectors had been given an opportunity to formulate detailed written objections to the draft regulations. Only those who did so were invited to make oral presentations. The purpose of this procedure was to enable the presenters to clarify the existing representations in so far as that might be necessary. The proceedings were electronically recorded on tape and video and that would make it possible to refer to them in detail if that should prove to be necessary later in the process.

[182] The decision to invite oral representations to be made after written representations had been lodged was an addition to the notice and comment procedure which in itself would have been sufficient to meet the requirements of PAJA. I am not persuaded that by providing this additional opportunity to the objectors in which some but not all of the members of the Pricing Committee participated, a fair procedure was converted into an unfair procedure.

[183] Whether the dispensing fee will result in pharmacists trading at a loss is a dispute relevant to the question whether it is an appropriate fee within the meaning of section 22G of the Medicines Act. The Pharmacies dispute that it is. But that is a separate issue and is one of the issues raised in the contention that material provisions

of the regulations contravene the lawfulness requirement of PAJA. A question relevant to that issue is whether the Pricing Committee had regard to the submissions made to it by the Pharmacies at the oral hearings. I deal with this when I consider the challenge that the dispensing fee is not "appropriate".[147]

[184] Before dealing with that issue, it is necessary to address an argument that the Minister should have conducted a further enquiry after the Pricing Committee had made its final recommendation.

[185] In my view there is no substance in this submission. I have previously explained why the process of making regulations should be seen as a single process involving both the Minister and the Pricing Committee. The Minister had representatives on the Pricing Committee, and the Department was kept informed of developments as they occurred. The invitation to make written representations on the draft regulations came from the Minister. The invitation to supplement the representations by oral presentations came from the Department. The written representations were submitted to the Department, and Department officials conducted the proceedings at which the oral presentations were made. The process involved both the Minister and the Pricing Committee. This was compatible with their responsibilities in terms of section 22G of the Medicines Act. The contention that the Minister was obliged to engage in a further process after the Pricing Committee had made its recommendations must therefore be dismissed.

[147] See below from para 311.

Reasonableness

[186] Section 6(2)(h) of PAJA provides that:

> "A court or tribunal has the power to judicially review an administrative action if the exercise of the power or the performance of the function authorised by the empowering provision, in pursuance of which the administrative action was purportedly taken, is so unreasonable that no reasonable person could have so exercised the power or performed the function".

[187] In *Bato Star*[148] this Court held that section 6(2)(h) of PAJA should be construed consistently with the Constitution to mean that

> "[A]n administrative decision will be reviewable if . . . it is one that a reasonable decision-maker could not reach.
>
> What will constitute a reasonable decision will depend on the circumstances of each case, much as what will constitute a fair procedure will depend on the circumstances of each case. Factors relevant to determining whether a decision is reasonable or not will include the nature of the decision, the identity and expertise of the decision-maker, the range of factors relevant to the decision, the reasons given for the decision, the nature of the competing interests involved and the impact of the decision on the lives and well-being of those affected." (footnote omitted)

[188] It is not necessary in the present case to consider how this should be applied to the making of the regulations. The dispensing fee is required by section 22G(2)(b) to be "appropriate". If it is, then it will not be unreasonable within the meaning of

[148] Above n 80 at paras 44-45

section 6(2)(h) of PAJA. If it is not appropriate, it will not comply with the empowering statute, and will be inconsistent with section 6(2)(a) of PAJA.[149]

Lawfulness

[189] Section 6(2)(f)(i) of PAJA provides:

> "A court or tribunal has the power to judicially review an administrative action if the action itself contravenes a law or is not authorised by the empowering provision".

The Pharmacies have challenged the pricing system prescribed by the regulations on the grounds that it contains material provisions that are not authorised by the empowering legislation, or which fail to comply with what the empowering legislation requires. In this regard it is contended that the following provisions of the pricing system are not authorised by section 22G of the Medicines Act, which is the provision under which the Minister and the Pricing Committee acted:

(a) The imposition of price control measures.

(b) The definition of the single exit price.

(c) The delegation of certain powers to the Director-General.

(d) The power of the Minister to determine annual increases in the single exit price and to place a cap on the logistics fee.

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[149] Section 6(2)(a) of PAJA reads:

> "A court or tribunal has the power to judicially review an administrative action if—
> (a) the administrator who took it—
> (i) was not authorised to do so by the empowering provision;
> (ii) acted under a delegation of power which was not authorised by the empowering provision; or
> (iii) was biased or reasonably suspected of bias".

(e) A pricing system that is not transparent.

(f) A dispensing fee that is not appropriate.

I will deal with these contentions in turn.

The pricing system

[190] The pricing system contemplated by the regulations is as follows. A "single exit price" (SEP) will be set for the sale of each medicine that is sold by a manufacturer or importer.[150] This must not be higher than a maximum price, which has to be calculated on the basis of sales during 2003.[151] Provision is made for how the SEP is to be calculated in respect of products sold for the first time after January 2004.[152]

[191] The SEP thus established becomes a fixed price at which the manufacturer or importer must sell the product.[153] Wholesalers who buy the medicine for onward sale must sell at a price not higher than the SEP;[154] and the same applies to pharmacists whether they buy the medicine from the manufacturer, importer, wholesaler or distributor. The wholesalers and distributors are entitled to a logistics fee for their

[150] Regulation 2 of the regulations.

[151] Regulation 5(2)(c)(ii).

[152] Id.

[153] See regulation 2 and regulation 5(1).

[154] Regulation 6.

services[155] and the pharmacists are entitled to an "appropriate" dispensing fee for their services.[156] Provision is made for price increases and for bringing manufacturers' prices into line with international standards by a system of international benchmarking.[157] I deal later with the details of these provisions which are relevant to other challenges to the regulations.

[192] In effect the system contemplates that the medicine and Scheduled substances will move along the distribution chain at a price not higher than the SEP, which is the price at which the medicine or Scheduled substance must enter the distribution chain. Wholesalers, distributors and pharmacists cannot put up the price of the medicine, and are limited to the fees they are entitled to charge in terms of the regulations. The result is that medicines will become available to all consumers, other than the state, wherever they are, and whoever they may be, and from whatever source they are supplied, at the SEP or a lower price. It is contemplated that the price of medicines will be transparent, and over time will be brought into line with prices in other countries where the price of medicines is regulated.

Price control

[193] The Pharmacies contend that the regulations introduce a system of price control which is not authorised by section 22G or any other provision of the Medicines Act

[155] See the definition of "logistics fee" in regulation 2 and regulation 5(2)(f) and (g).

[156] Regulation 10.

[157] Regulation 5(2)(e).

and is therefore unlawful. It is convenient to refer here to the relevant provisions of section 22G.

> "(2) The Minister may, on the recommendation of the pricing committee, make regulations—
>
> (a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;
>
> (b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a);
>
> (c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines.
>
> (3)(a) The transparent pricing system contemplated in subsection (2)(a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.
>
> (b) No pharmacist or person licensed in terms of section 22C(1)(a) or a wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).
>
> (c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2)(b)."

[194] The section not only permits, but in fact requires price control measures to be made, that affect all parties in the distribution chain. Section 22G(3)(a) prescribes that the price at which the manufacturer or importer must sell to persons other than the state, is the SEP. That is a mandatory price control measure that must be reflected in the regulations. So too is the requirement of section 22G(3)(b), that a pharmacist, or other person licensed to sell medicines, may not sell them at a price higher than the SEP. There is accordingly no substance in the submission that section 22G does not contemplate price control measures.

[195] There is, however, a narrower issue that has to be considered for it is one of the reasons given by the SCA for holding the regulations to be invalid. It concerns the setting of the SEP. Section 22G does not specify how or by whom the SEP should be determined. It is argued that the provisions in the regulations which place procedural or substantive limits on the setting of the SEP are ultra vires the Medicines Act. The phrase "single exit price" is not a term of art. It must be construed in the context of the Medicines Act and in particular of section 22G(3). In that context it seems to me that the Pharmacies are correct in contending that it is the price at which a medicine enters the distribution chain. But does that mean that the regulations cannot prescribe how that price is to be determined or controlled?

[196] The SCA held that this was indeed so. They considered the purpose of the pricing system for which section 22G makes provision to be the elimination of the discounts and subsequent mark-ups which had previously distorted the market.[158] But this is achieved by sections 18A and B which specifically prohibit such schemes.

[197] Section 22G adds to this the element of transparency. The SCA referred to the importance of transparency in these terms:

> "[S]ince dispensers are entitled only to add a prescribed fee, a member of the public would be able to assess whether the price paid is the correct one. Because

[158] Above n 43 at para 57.

> manufacturers would know what the prices charged by their competitors are, they will have to reduce their prices and publish the reduced prices in order to compete."[159]

But transparency is only one of the mandatory requirements of the pricing system. Other mandatory requirements are referred to in section 22G(3). There must be a SEP and an obligation that medicines may not be sold at a higher price than the SEP. These mandatory requirements do not, however, limit the general power to establish a pricing system for all medicines.

[198] Counsel for the Pharmacies submitted that "the mischief" at which section 22G is directed is the elimination of the system of discounting and subsequent marking up of the prices of pharmaceutical products that characterised the sale of such products in the past. But that is prohibited by sections 18A and B of the Medicines Act, and is not directly addressed in the regulations.

Legislative history

[199] The Pharmacies refer to the explanatory memorandum which accompanied the Medicines and Related Substances Control Amendment Bill, 72 of 1997, when it was introduced into Parliament, which says that the primary purpose of the Bill was to bring the Medicines Act into line with the National Drug Policy of the Department of Health.

[159] Id at para 58.

[200] In *S v Makwanyane and Another*[160] I had occasion to consider whether background material is admissible for the purpose of interpreting the Constitution. I concluded that

> "where the background material is clear, is not in dispute, and is relevant to showing why particular provisions were or were not included in the Constitution, it can be taken into account by a Court in interpreting the Constitution."[161]

[201] Although it is not entirely clear whether the majority of the Court concurred in this finding, none dissented from it. I have no reason to depart from that finding and in my view it is applicable to ascertaining "the mischief" that a statute is aimed at where that would be relevant to its interpretation. This would be consistent with the decisions of the Appellate Division in *Attorney-General, Eastern Cape v Blom and Others*,[162] and *Westinghouse Brake & Equipment (Pty) Ltd v Bilger Engineering (Pty) Ltd*[163] and the cases from other jurisdictions referred to in *Makwanyane's* case.[164]

[202] The National Drug Policy is set out in a comprehensive document which addresses health objectives, economic objectives and national development objectives. The economic objectives are as follows:

> "(a) to lower the cost of drugs in both the private and public sectors

[160] 1995 (3) SA 391 (CC); 1995 (6) BCLR 665 (CC).

[161] Id at para 19.

[162] 1988 (4) SA 645 (A) at 668H-669D.

[163] 1986 (2) SA 555 (A) at 562H-563A.

[164] Above n 160 at paras 14-16.

(b) to promote the cost-effective and rational use of drugs
(c) to establish a complementary partnership between Government bodies and private providers in the pharmaceutical sector
(d) to optimize the use of scarce resources through cooperation with international and regional agencies."[165]

[203] The drug pricing policy is dealt with in a separate chapter. Its aim is said to be: "To promote the availability of safe and effective drugs at the lowest possible cost".[166] The mischief, therefore, to which section 22G is directed is the lowering of the high cost of drugs. The price control provisions of the regulations are a means, though not the only means, of addressing this mischief.

[204] The document goes on to describe how the stated aim of this policy is to be achieved. It is not necessary to decide whether it is permissible to have regard to this for the purpose of interpreting section 22G. Even if I were to assume in favour of the Pharmacies that it is a relevant consideration,[167] the methods described include establishing a "Pricing Committee with clearly defined functions to monitor and *regulate* drug prices", the development of a "data base . . . to monitor the cost of drugs in the country in comparison with prices in developing and developed countries" and that "[p]rice increases will be regulated."[168] The policy for implementation also refers to "total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services, such as dispensers of drugs, as well as private

[165] Paragraph 2.2 of the National Drug Policy for South Africa.

[166] Chapter 4 of the National Drug Policy.

[167] I have considerable doubt whether it is.

[168] Paragraph 4.1 of the National Drug Policy (my emphasis).

clinics and hospitals", the introduction of a "non-discriminatory pricing system" which will if necessary be enforced, and the replacement of the "wholesale and retail percentage mark-up system" with "a pricing system based on a fixed professional fee."[169] The regulations seem to me to be broadly in line with these policies. The question, however, is not whether the regulations are consistent with policy statements, but whether they are sanctioned by the empowering legislation.

[205] PSSA rely on evidence given by the former Director-General of Health as to the meaning of section 22G and on his opinion that the SEP was to be set by manufacturers. The opinion of the former Director-General as to the meaning of section 22G is not admissible for this purpose. It is the Court's duty, and not that of the former or present Director-General, to interpret the statute.

[206] No doubt the prohibition of discounts and bonuses and the mandated element of transparency to which the SCA refers are likely to create market conditions more conducive to competition than those that previously existed. But these are not the only measures by which the price of medicines can be lowered. Sections 15C,[170]

[169] Id.

[170] Section 15C provides:

> "Measures to ensure supply of more affordable medicines.—The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may—
>
> (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
>
> (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the

18A,[171] 22F,[172] 22G, and 22H,[173] read together, contain a regulatory framework, partly in the Medicines Act and partly in regulations to be made under section 22G, designed to contribute to the lowering of the cost of medicines. It is within this context that section 22G must be read and construed.

Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;

(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b)."

[171] Section 18A reads as follows:

"Bonusing.—No person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme."

[172] Section 22F provides:

"Generic substitution.—(1) Subject to subsections (2), (3) and (4), a pharmacist or a person licensed in terms of section 22C(1)(a) shall—

(a) inform all members of the public who visit the pharmacy or any other place where dispensing takes place, as the case may be, with a prescription for dispensing, of the benefits of the substitution for a branded medicine by an interchangeable multi-source medicine, and shall, in the case of a substitution, take reasonable steps to inform the person who prescribed the medicine of such substitution; and

(b) dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so.

(2) If a pharmacist is forbidden as contemplated in subsection (1)(b), that fact shall be noted by the pharmacist on the prescription.

(3) When an interchangeable multi-source medicine is dispensed by a pharmacist he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.

(4) A pharmacist shall not sell an interchangeable multi-source medicine—

(a) if the person prescribing the medicine has written in his or her own hand on the prescription the words 'no substitution' next to the item prescribed;

(b) if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or

(c) where the product has been declared not substitutable by the council."

[173] Section 22H reads as follows:

"Purchase and sale of medicines by wholesalers.—(1)(a) No wholesaler shall purchase medicines from any source other than from the original manufacturer or from the primary importer of the finished product.

(b) A wholesaler shall sell medicines only into the retail sector.

(2) Subsection (1) shall not be construed as preventing the return of medicines for credit purposes only, to the manufacturer or wholesaler from which that medicine was initially obtained.

(3) Any wholesaler may in the prescribed manner and on the prescribed conditions be exempted by the Director-General from the provisions of subsection (1)."

[207] It is apparent from various provisions of the Medicines Act that the pharmaceutical industry is tightly regulated. Controls are imposed over the manufacture, sale and distribution of medicines.[174] Section 22H requires a wholesaler to purchase medicines only from the original manufacturer or from the primary importer of the finished product, and to sell only into the retail sector. In terms of section 22F pharmacists may not sell medicines that have been prescribed, if there is a generic substitution available at a lower price, unless a person prescribing the medicine "has written in his or her own hand on the prescription the words 'no substitution' next to the item prescribed".[175] Section 15C of the Medicines Act makes provision for the Minister to prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular to make provision for the relaxation of certain provisions of the Patents Act, 57 of 1978 to facilitate parallel importation of medicines still under patent protection. Section 18A provides that "[n]o person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme." Section 18B prohibits the provision of free samples to persons in the distribution chain.

Controlling the price of medicines

[208] Does the fact that the Medicines Act imposes these various controls in specific terms and provides that the fees of pharmacists, wholesalers and distributors are to be

[174] Sections 15C, 18A, 18B, 18C, 22A, 22C, 22F and 22H.

[175] See above n 172 for the full text of section 22F(4).

prescribed in the regulations, but says no more about the SEP than that it is the only price at which the manufacturer may sell medicine, mean that the regulations may not deal with how the SEP is to be set or controlled in the future?

[209] A statutorily mandated pricing system, which is to be fleshed out by regulations, inevitably contemplates a system with inbuilt controls. Reverting to section 22G, which is the section under which the regulations were made, a thread that runs through it is that the pricing system must contain measures that will enable control to be exercised over the price of medicines. Section 22G prescribes certain essential measures to be included in the system but does not say that they are the only measures that are competent. There seems to be no reason why the "pricing system" referred to in section 22G, which contemplates price controls throughout the distribution chain, should be construed as excluding controls over how the SEP should be set and increased.

[210] I am accordingly unable to agree with the SCA, or with the submissions made to us in this regard by counsel for the Pharmacies. In my view the regulations are not invalid simply because they include price control measures affecting the SEP.

Single exit price: section 22G of the Medicines Act

[211] The SCA held that the provisions of the regulations dealing with the SEP are inconsistent with the Medicines Act. Regulations must where possible be construed

consistently with the empowering Act under which they are made.[176] It is necessary, therefore, in dealing with the appeal against this decision to begin by considering the provisions of the Medicines Act that are relevant to the appeal.

[212] The sale and distribution of medicines and Scheduled substances is strictly controlled by the Medicines Act, which regulates the manufacture, quality, importing, distribution and sale of such products.

[213] The Medicines Act and regulations contemplate that the marketing of medicines will be along a distribution chain leading from the manufacturer to the public in ways which may involve a number of different actors.

[214] In the public sector in South Africa the chain begins with the manufacturer or importer and ends with a state institution which provides medicine to patients treated by the state in public hospitals and clinics, or by district surgeons. The state buys its supplies through tender processes at costs that are usually less than that for which the same medicines can be bought in the private sector. In the private sector the chain begins with the manufacturer or importer and ends with a retailer, or medical practitioner, dentist, veterinarian, or health professional, who deals directly with the public. A distinction is made between Schedule 0 medicines on the one hand and all other scheduled medicines on the other. The former may be sold by any retailer,[177]

[176] See Du Plessis "Statute Law and Interpretation" in Joubert et al (eds) *The Law of South Africa*, First Reissue vol 25 (Butterworths, Durban 2001) at para 285.

[177] Section 22A(3).

while the latter may be sold only by medical practitioners, dentists, veterinarians, licensed health professionals, manufacturers of and wholesale dealers in pharmaceutical products, and retailers who are pharmacists.[178] The Medicines Act also makes a distinction between prescription and non-prescription medicines. The latter are those medicines contained in Schedules 0, 1 and 2 which can be sold without a doctor's prescription, and the former are those contained in Schedules 3 to 6, which require a doctor's prescription.[179]

Wholesalers and distributors

[215] The Medicines Act recognises that in addition to manufacturers there are intermediaries who have a role to play in the distribution of medicines earmarked for sale to the public. They are distributors and wholesalers. They must be licensed in terms of the Medicines Act to carry out these functions.[180] The Medicines Act does not define "distributor" or "wholesaler" but if the words are given their ordinary meaning, a distributor would be an agent or representative of the manufacturer or wholesaler, and a wholesaler would be a person who trades in bulk for his or her own account. This seems to have been accepted by the parties, and as appears from the affidavits lodged in this matter, to be consistent with the way the trade operates in practice. According to the PSSA founding affidavit made by Ms Davis, manufacturers generally supply their products through a wholesaler, who buys in bulk,

[178] See section 22A(4) and (5) of the Act. In terms of section 22A(9)(a)(i) of the Act, no one may supply Schedule 7 and 8 medicines without a permit issued by the Director-General.

[179] Section 22A(4) and (5)(a).

[180] Section 22C(1)(b) of the Medicines Act.

and sells to retailers in smaller quantities, or through a distributor, who acts as the manufacturer's agent, and as such deals either with retailers or wholesalers. Manufacturers also sell products directly to retailers.

[216] Section 22A of the Medicines Act controls the possession and sale of medicines and Scheduled substances and identifies the persons who are entitled to do so. Sections 22A(4) and (5) of the Medicines Act do not include distributors amongst those entitled to sell medicines listed in Schedules 1 to 6. Yet section 22G(3), which is a provision of the framework provided by the Medicines Act for the pricing system, refers in subparagraph (a) to selling by manufacturers, and in subparagraph (b) to selling by pharmacists, wholesalers and distributors.[181] This seems prima facie to contemplate that distributors may sell medicines for their own account – which would be prohibited by sections 22A(4) and (5). A breach of these sections is a criminal offence.[182]

[217] But if sections 22G(3)(b) is construed in the light of section 22A(4) and (5), and the meaning to be given to "wholesaler" and "distributor" in the context of the Medicines Act, it must be understood as referring to sales by distributors on behalf of manufacturers and not on their own behalf. If they were to sell on their own behalf they would, in respect of such sales, cease to be a distributor, would become a

[181] See para 193 above where the text of section 22G is provided.

[182] Section 29(k).

wholesaler, and would require a wholesaler's licence to do so. Construed thus, section 22G(3)(b) can be reconciled with sections 22A(4) and (5).[183]

The regulation of participants in the making and distribution of medicines and Scheduled substances

[218] The Medicines Act requires persons engaged in the making and distribution of medicines and Scheduled substances to be licensed to do so. This is dealt with in section 22C of the Medicines Act[184] and in the General Regulations. In terms of sections 22C(1)(b) and 22C(6) manufacturers, distributors or wholesalers licensed to do so may import medicines.[185] With the exception of section 15C, which deals with parallel importing of patented medicines, no other section of the Medicines Act authorises anyone other than a manufacturer, wholesaler or distributor to import medicines or Scheduled substances. It is not clear from section 15C whether persons

[183] This is consistent with the definition of "distributor" in the pricing regulations: see para 242 below.

[184] It is not necessary here to deal with the special power vested in the Minister to sanction the importing of medicine protected by the patent in terms of section 15C.

[185] Section 22C(1)(b) reads as follows:

> "Licensing.—(1) Subject to the provisions of this section—
>
> . . . .
>
> (b) the council may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine."

Section 22C(6) reads as follows:

> "No manufacturer, wholesaler or distributor referred to in subsection (1)(b) shall manufacture, import, export, act as a wholesaler of or distribute, as the case may be, any medicine unless he or she is the holder of a licence contemplated in the said subsection."

engaged in parallel importing in terms of that section also require to be licensed under section 22C, but that need not be decided in this case.

[219] The General Regulations require importers to have a licence[186] and make provision for licences to be issued only to manufacturers, wholesalers and distributors.[187] A contravention of these regulations is a criminal offence.

[220] Section 22H of the Medicines Act provides that a wholesaler may only purchase medicine from the "original manufacturer" or the "primary importer" and may only sell to the retail sector.[188] In terms of section 22H(3) the Director-General may exempt a wholesaler from these restrictions.

[221] There is no definition of "primary importer" and these words are not used in any other section of the Medicines Act. It is not clear from this or other provisions of the Medicines Act who a primary importer is. It is, however, not necessary for the purposes of the decision in this case to answer that question.

[222] In terms of the Medicines Act, the importing, distribution and sale of medicines must therefore take place within the following framework. Only manufacturers,

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[186] Regulation 12(2)(a) provides: "A person can only import a medicine or scheduled substance if such person is licensed in terms of the Act to import medicines".

[187] Regulation 19 deals with the procedures to be followed in applying for such licences. Only persons referred to in section 22C(1)(b) are competent in terms of the regulations to make such applications.

[188] See above n 173 for the text of section 22H.

wholesalers and distributors, licensed to do so, may import medicines. Only manufacturers, wholesalers and distributors, licensed to do so, may sell medicines. Manufacturers and wholesalers sell medicines for their own account, distributors sell medicines as agent or representative of the manufacturer, or possibly on behalf of a wholesaler. If medicines are imported by a person other than the manufacturer, an importer who becomes the owner of the medicines bought, and sells them for its own account, acts as a wholesaler for the purposes of the Medicines Act, and must have a wholesaler's licence authorising it to import and carry on business as a wholesaler. In that event the wholesaler, unless exempted under section 22H, must sell the imported medicine to the retail trade. If medicines are imported by an importer as representative of the manufacturer on whose behalf the importer sells the medicine, that importer is a distributor for the purposes of the Medicines Act. In that event, the distributor may sell the medicine on behalf of the manufacturer, either to a wholesaler or directly to retailers.

Remuneration of wholesalers and distributors

[223] Sections 22G(2) and (3) of the Medicines Act provide:

> "(2) The Minister may, on the recommendation of the pricing committee, make regulations—
>
> (a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;
>
> (b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a);
>
> (c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines.

> (3)(a) The transparent pricing system contemplated in subsection (2)(a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.
>
> (b) No pharmacist or person licensed in terms of section 22C(1)(a) or wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a)."

[224] The pricing system contemplated by section 22G of the Medicines Act requires that there be a SEP, and stipulates that the SEP is the only price at which the manufacturer may sell medicines to persons other than the state.[189] Distributors, wholesalers, and pharmacists may not sell the medicine at a price higher than the SEP.[190]

[225] The Medicines Act contemplates that wholesalers and distributors will be engaged in the marketing of medicines. They are prohibited by section 22G from being recompensed for doing so through a mark-up on the price, and indirect rewards through bonuses, rebates and the provision of samples are prohibited by sections 18A and B.[191] The only way they can be rewarded is by payment through means other than the mark-up on the price.

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[189] Section 22G(3)(a).

[190] Section 22G(3)(b).

[191] See above n 171 where the text of section 18A is produced. Section 18B reads as follows:

> "Sampling of medicines.—(1) No person shall sample any medicine.
> (2) For the purposes of this section 'sample' means the free supply of medicines by a manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, but does not include the free supply of medicines for the purposes of clinical trials, donations of medicines to the State, tendering to the State and quality control by inspectors.

[226] The Medicines Act makes provision for them to be rewarded through "fees" payable to them for their services. Hence sections 22G(2)(b) and (c) make provision for the regulations to include "an appropriate dispensing fee" to be charged by a pharmacist and "an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines."

[227] It was contended by New Clicks, but not by PSSA, that the reference in section 22G(2)(c) to "any other person selling Schedule 0 medicines" demonstrates that section 22G(2)(c) applies only to the sale of Schedule 0 medicines, and that no provision is made for wholesalers or distributors to receive remuneration for their role in the sale of prescription medicines. In this regard it drew attention to section 22G(3)(c) which makes clear that a pharmacist may charge a dispensing fee in addition to the SEP, but says nothing about a wholesaler.

[228] As initially formulated in Act 90 of 1997 sections 22G(2) and (3) provided:

> "(2) The Minister may, on the recommendation of the pricing committee, make regulations—
>
> (a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;
>
> (b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a).
>
> (3)(a) The transparent pricing system contemplated in subsection (2)(a) shall include a single exit price which shall be published as prescribed, and such price shall

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> (3) The use of medicines or Scheduled substances for exhibition purposes shall be as prescribed."

> be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.
>
> (b) No pharmacist or person licensed in terms of section 22C(1)(a) shall sell a medicine at a price greater than the price contemplated in paragraph (a).
>
> (c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2)(b)."

[229] As initially formulated, therefore, section 22G made no provision for sales by wholesalers. It dealt only with manufacturers, pharmacists, and licensed health professionals. It was in this context that section 22G(3)(c) made it clear that the requirement that pharmacists and licensed health professionals shall not sell at a price higher than the SEP, did not preclude them from charging a dispensing fee.

[230] Act 90 of 1997 introduced the present sections 22A and 22H. Section 22A authorises a "wholesale dealer" to sell Scheduled substances (which would have included medicines). Section 22H provides that no wholesaler shall purchase medicines from any source other than from the original manufacturer or from the primary importer of the finished product, and required the wholesaler to sell medicine to the retail sector. There was an obvious problem. If the manufacturer had to sell at the SEP and the wholesaler (who sells for its own account) may only buy from the manufacturer and sell to the retail trade, which had to sell at no more than the SEP, how was the wholesaler to make a living? It was presumably for this reason that

section 22G was amended by Act 59 of 2002 which introduced section 22G(2)(c), making provision for an appropriate fee to be charged by wholesalers.[192]

[231] When it did so, however, it failed to make a consequential amendment to section 22G(3)(c), which states that the prohibition against selling at a price higher than the SEP does not preclude the charging of a dispensing fee by the pharmacist. The absence of a similar provision in respect of a wholesaler or distributor cannot preclude them from making such a charge, otherwise section 22G(2)(c) would not serve the purpose it was clearly intended to serve. It would also, if so construed, effectively prevent the wholesaler from carrying on the business contemplated by section 22H.

[232] Unless the Medicines Act is construed as making provision for a fee to be charged by wholesalers or distributors for their services in marketing prescription medicines, it would be impossible for them to conduct their businesses. It seems to me that if regard is had to this, section 22G(2)(c), construed purposively in the context of its history and the Medicines Act as a whole, means that the regulations may make provision for appropriate fees to be charged by distributors and wholesalers (who may sell all categories of medicines), and also for persons who may only sell Schedule 0 medicines. If this were not the proper construction of the language construed in the context of the Medicines Act, I would in any event adopt it, in accordance with the

[192] Act 90 of 1997 and Act 59 of 2002 were both brought into force on 2 May 2003.

principle in *Venter v R*[193] which allows a court to depart from the clear language of a statute where that would otherwise lead

> "to absurdity so glaring that it could never have been contemplated by the legislature, or where it would lead to a result contrary to the intention of the legislature, as shown by the context or by such other considerations as the Court is justified in taking into account".[194]

The regulations dealing with the pricing system

[233] Since its first enactment in 1965 the Medicines Act has been amended on no less than fifteen different occasions. Some of the amendments are complex and do not fit easily with earlier provisions of the Medicines Act. The process of drafting the regulations was also rushed. Draft regulations were published for comment on 16 January 2004. Comments had to be made within three months. Many representations were made during this period as a result of which decisions were taken to amend the regulations in material respects. Some of these decisions were only taken during March 2004. Draft regulations were submitted to the Minister for her approval on 19 April 2004. After discussions with the Minister, amended regulations were submitted to her for approval on 21 April and were published in the Gazette on 30 April 2004. Against this background it is not surprising that there are a number of problems in interpreting the regulations and attempting to reconcile them with one another and with the provisions of the Medicines Act.

[193] 1907 TS 910.

[194] Id at 915.

[234] From a reading of the regulations against the background of the Medicines Act it seems that the pricing system contemplated by the Minister and the Pricing Committee is as follows. A SEP must be set for every medicine to be sold in South Africa. The SEP must be sufficient to allow for payment of a logistics fee by manufacturers to wholesalers/distributors and VAT. At the commencement of the regulations the SEP must be calculated according to a formula prescribed in the regulations, subject to adjustment by a process of comparative international benchmarking, and annual reviews. Provision is made for a dispensing fee for the remuneration of pharmacists and for an annual review of such fee. Consistently with section 22G of the Medicines Act, the manufacturer has to sell at the SEP and wholesalers/distributors and pharmacists are not entitled to remuneration other than the logistics fee and the dispensing fee.

[235] Section 29(k) of the Medicines Act provides that it is an offence to contravene any provision of sections 22A, 22C(5) and (6), 22F, 22G, or 22H, or to contravene or fail to comply with "any condition imposed thereunder". The pricing system in the regulations made under section 22G imposes conditions of sale which have to be complied with by various participants in the distribution chain.[195] A breach of those regulations is therefore a criminal offence in terms of section 29(k) of the Medicines Act.

[195] Regulation 1 provides: "The sale of medicines and Scheduled substances in the Republic of South Africa is subject to the conditions stipulated in these regulations."

[236] This, in broad outline, is the scheme. The scheme is criticised by the Pharmacies on the ground that regulation of prices is less effective than market forces. The choice of price regulation, if not inconsistent with the Medicines Act,[196] was a policy decision within the domain of the legislature and the executive with which this Court will not interfere. This Court is concerned with whether the scheme meets the requirements of the Medicines Act and was adopted in accordance with the provisions of the Constitution and PAJA, and not with whether there may be better ways of achieving the same purpose. I am satisfied that, in broad outline, the scheme is consistent with the Medicines Act. The devil, however, lies in the detail.

The supply chain

[237] To begin with, the regulations are structured with a particular "supply chain" in mind. The "supply chain" is defined in regulation 2 to include:

> "any two or more of the following—
> (a) a manufacturer;
> (b) an importer;
> (c) an exporter;
> (d) a wholesaler;
> (e) a distributor;
> (f) a retailer;
> (g) a person licensed in terms of section 22C(1)(a) of the Act;
> (h) the user of a medicine".[197]

[238] The regulations define an importer as

[196] This is dealt with above in paras 208-210.

[197] See the definitions in regulation 2.

> "a person importing medicines for the purpose of sale in the Republic from a manufacturer or other person outside of the Republic and includes a parallel importer as defined in the Act".

There is no definition of "parallel importer" in the Medicines Act. Presumably the reference was intended to be to a person importing medicine in terms of section 15C of the Medicines Act,[198] and this is how the words are defined in the General Regulations.[199]

[239] When they refer to an importer in the "supply chain" the regulations may be understood as referring to a person other than a manufacturer, distributor or wholesaler. This is also what may be inferred from the way the definitions of logistics fee,[200] logistical services,[201] single exit price,[202] retailer,[203] and user[204] are formulated in the regulations, and also from regulations 6, 14, 21, 22(1), and 24.

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[198] Section 15C is discussed above in paras 206-207.

[199] The General Regulations define "parallel importer" as "a person who parallel imports a medicine into the Republic on the authority of a permit issued in terms of regulation 7(3)".

[200] According to regulation 2, "'logistics fee' means the fee that is payable in respect of logistical services".

[201] "'[L]ogistical services' means those services provided by distributors and wholesalers in relation to a medicine or Scheduled substance including but not limited to warehousing, inventory or stock control management, order and batch order processing, delivery, batching, tracking and tracing, cold chain storage and distribution".

[202] "'[S]ingle exit price' means the price set by the manufacturer or importer of a medicine or Scheduled substance in terms of these regulations combined with the logistics fee and VAT and is the price of the lowest unit of the medicine or Scheduled substance within a pack multiplied by the number of units in the pack".

[203] "'[R]etailer' means a person who is not a wholesaler, importer, exporter, manufacturer or distributor who sells a medicine or Scheduled substance to a user and includes a person licensed in terms of section 22C(1)(a) of the Act".

[204] "'[U]ser' means a natural person to whom a medicine or Scheduled substance is sold for use and excludes a manufacturer, importer, exporter, wholesaler, distributor, retailer and any other person selling medicines or Scheduled substances in the Republic".

[240] The definition of importer in the pricing regulations also contemplates that importers will be engaged in selling medicines. Regulation 24(4) says as much. It provides that:

> "Manufacturers and importers must, with effect from the date one month after the date of commencement of these regulations, sell medicines and Scheduled substances only in accordance with the provisions of these regulations."

[241] In this context the regulations must be construed as referring to lawful importers.[205] To act lawfully, importers must be licensed in terms of the Medicines Act. And the Medicines Act only makes provision for such licences to be issued to manufacturers, distributors and wholesalers.[206]

~~[242]~~ The regulations define "distributor" as meaning:

> "a person, other than a manufacturer, wholesaler or retailer, who supplies a medicine or Scheduled Substance to a retailer or wholesaler".

The definition refers to "supply" and not to "sell". This is consistent with the Medicines Act which does not permit distributors to sell medicines or Scheduled substances for their own account. They may, however, import the medicine on behalf of the manufacturer, and if licensed to do so, they become importers as well.

[205] *S v Le Grange* 1962 (3) SA 498 (A) at 502-3.

[206] Section 22C(1)(b) and 22C(6).

~~[243]~~ "Wholesaler" is defined as meaning:

> "a dealer who purchases medicines or Scheduled substances from a manufacturer and sells them to a retailer and includes a wholesale pharmacy".

This is also consistent with the Medicines Act which requires wholesalers to buy from manufacturers. If they do so they may in the process become "importers".

~~[244]~~ With this explanation of the participants in the supply chain and the roles assigned to them under the Medicines Act and the regulations, I turn to consider the arguments addressed to us on behalf of the Pharmacies in support of the finding by the SCA that the regulations are inconsistent with the Medicines Act and are accordingly invalid.

[245] The Pharmacies contend that the regulations dealing with the setting of and increases in the SEP are incoherent, in parts contradictory, and are inconsistent with section 22G of the Medicines Act. They also contend that the regulations are vague and uncertain in other respects and that the dispensing fee prescribed by the regulations for pharmacists is not an "appropriate fee".

Vagueness

[246] It seems to have been assumed by the parties, and in my view correctly so, that vagueness is a ground for review under PAJA. Although vagueness is not specifically mentioned in PAJA as a ground for review, it is within the purview of section 6(2)(i) which includes as a ground for review, administrative action that is otherwise

"unconstitutional or unlawful". This Court has held that the doctrine of vagueness is based on the rule of law which is a foundational value of our Constitution.[207] In *Affordable Medicines*[208] this Court explained the doctrine in the following terms:

> "[L]aws must be written in a clear and accessible manner. What is required is reasonable certainty and not perfect lucidity. The doctrine of vagueness does not require absolute certainty of laws. The law must indicate with reasonable certainty to those who are bound by it what is required of them so that they may regulate their conduct accordingly. The doctrine of vagueness must recognise the role of government to further legitimate social and economic objectives. And should not be used unduly to impede or prevent the furtherance of such objectives."[209] (footnotes omitted)

Related to this is a requirement implicit in all empowering legislation that regulations must be consistent with, and not contradict, one another. Regulations which fail to comply with these requirements would therefore contravene section 6(2)(i) of PAJA.

The SEP

[247] "Single exit price" is defined in regulation 2 as meaning

> "the price set by the manufacturer or importer of a medicine or Scheduled substance in terms of these regulations combined with the logistics fee and VAT and is the price of the lowest unit of the medicine or Scheduled substance within a pack multiplied by the number of units in the pack".

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[207] *Dawood and Another v Minister of Home Affairs and Others; Shalabi and Another v Minister of Home Affairs and Others; Thomas and Another v Minister of Home Affairs and Others* 2000 (3) SA 936 (CC); 2000 (8) BCLR 837 (CC) at para 47; *Affordable Medicines* above n 127 at para 108.

[208] Id.

[209] Id.

[248] Regulation 5(1) provides that:

> "Upon commencement of these regulations the price of a medicine or Scheduled substance must be set by the manufacturer, or where the medicine or Scheduled substance is imported by a person other than the manufacturer, the importer of the relevant medicine or Scheduled substance, and combined with the logistics fee in order to arrive at a single exit price for the relevant medicine or Scheduled substance."

Manufacturers, wholesalers, distributors, and importers

~~[249]~~ The definition of SEP in regulation 2 and the provisions of regulation 5 which deal with how the SEP is to be calculated, require it to be set by the manufacturer or importer.[210] Referring to this the SCA held that "[t]he Act itself draws a clear distinction between a 'manufacturer', an 'importer', a 'wholesaler' and a 'distributor'."[211] The judgment goes on to say that

> "The Act, in this form, must have raised immediate problems for the committee. The first would have been that it does not take account of the fact that manufacturers of medicines may be foreign concerns and that their products may be imported by third parties. (As mentioned, the Act requires importers to be licensed.) The committee, one assumes, recognised the problem of prescribing to foreign manufacturers that they have to publish a single exit price and that they may not sell for more than that price. The committee was also faced with the problem that it could hardly be fair to deny importers the right to charge more than the manufacturer's price. No doubt in order to overcome these defects in the Act, the committee's proposal was to recognise that an 'importer' purchases medicines from a manufacturer abroad and to define the single exit price as the price set not only by the manufacturer, but, alternatively, by the importer. This could not be done. The Act is clear. It requires manufacturers (and only manufacturers) to set their single exit prices, and importers are a genus

[210] The definition of SEP in regulation 2 and regulation 5(1).

[211] Above n 43 at para 51(c).

> different from manufacturers and cannot by any stretch of the imagination be equated with them. It follows that, to this extent, the regulations are ultra vires the Act: the committee was not entitled to make the proposal and the Minister was not entitled to accept it."[212]

~~[250]~~ I do not agree that the Medicines Act "requires manufacturers (and only manufacturers) to set their single exit prices". The Medicines Act requires the pricing system to make provision for a SEP. Section 22G does not, however, deal with how or by whom the SEP must be set. It merely says that the SEP must "be published as prescribed" and that the manufacturer must sell at the SEP. How the SEP is to be set is a matter that can legitimately be determined by the pricing system itself. I can see no reason why the pricing system should not impose an obligation on importers, who introduce medicines into the country, to ensure that the regulations are complied with in respect of those medicines, and that the SEP is set in accordance with such requirements.

[251] I also do not agree that the Medicines Act draws a clear distinction between manufacturers, wholesalers and distributors on the one hand and importers on the other. It does draw a distinction between manufacturers, wholesalers and distributors, but it recognises that each may import medicine and Scheduled substances and, with the possible exception of importing in terms of section 15C, does not permit anyone else to import such products. It is possible that a particular manufacturer, wholesaler or distributor may not be licensed to import medicine, and to that extent there may be

[212] Id at para 52. Footnotes to this paragraph of the judgment have been omitted from the quotation. They refer to the definition of importer and the definition of the SEP with the words "or importer" in that definition emphasised.

a distinction between those who are licensed to import and those who are not. But importers are not "a genus different from manufacturers"; manufacturers licensed to do so may import.

Foreign manufacturers

[252] The Medicines Act requires manufacturers to sell medicine and Scheduled substances at the SEP. Section 22G(3)(a) of the Medicines Act[213] provides that the SEP is the only price at which the manufacturer may sell medicines and Scheduled substances, and section 22G(3)(b) provides that the price "contemplated in paragraph (a)" is the maximum price at which wholesalers, distributors and pharmacists may sell the medicine.

[253] If a foreign manufacturer sells medicine in South Africa directly or through a distributor there is no reason why section 22G(3)(a) should not be applicable to that transaction. The position may, however, be different if the foreign manufacturer sells to a South African wholesaler abroad, as could be the case if the medicine were sold free on board in a foreign port. For the purposes of this judgment I am prepared to assume that this would be so, and that section 22G(3)(a) would not apply to such a transaction.

[254] This does not mean, however, that the pricing system established under section 22G cannot regulate the price at which such medicines are sold in South Africa.

[213] The text of the section and its relevance to this case has been referred to in para 193.

Section 22G(2)(a) contemplates a transparent pricing system for all medicines and Scheduled substances. The language is general and applies to *"all* medicines and Scheduled substances sold in the Republic". That includes foreign-made medicines as well as South African-made medicines.

[255] According to the evidence in this case over 50% of the medicines sold in the Republic are imported. Wholesalers who buy medicine from foreign manufacturers are not the manufacturers of such medicines, and thus do not fall within the ambit of the provisions of section 22G(3)(a) that apply to manufacturers. If the price at which they buy the medicine is not the price contemplated in section 22G(3)(a), section 22G(3)(b) will not apply to them, and absent any provision in the pricing system regulating the price at which such medicine may be sold in South Africa, they would be free to sell the medicine to retailers without any restriction. This would fundamentally undermine what the Medicines Act sets out to achieve.

[256] If, as I have assumed, section 22G(3)(a) is construed as having no application to medicines purchased abroad by wholesalers from foreign manufacturers, there is no reason why the regulations made in terms of section 22G(2)(a) should not fill that gap and make provision for the regulation of the price at which such medicines may be sold in South Africa. A failure to do so would leave a gaping hole in the pricing system.

[257] Construed purposively, therefore, section 22G(2)(a) must be understood as authorising a pricing system that applies to all medicine, whether manufactured locally or in a foreign country, and whether sold in South Africa by the manufacturer, or on its behalf by a distributor, or by a wholesaler who has purchased the medicine abroad.

The inclusion of the logistics fee in the SEP

[258] The SCA also finds fault with the inclusion of a logistics fee in the calculation of the SEP. The judgment says:

> "The regulations define the single exit price as 'the price set by the manufacturer or importer . . . combined with the logistics fee', which is something greater than the manufacturer's price, since it includes both the manufacturer's price and the logistics fee."[214]

And concludes that

> "[a]ll this, with the best of motives, circumvents s 22G which states expressly that the 'single exit price' is the manufacturer's selling price. Wholesalers, as the Act and the regulations recognise, purchase from manufacturers or importers. To deem their mark-up as part of the manufacturer's price is an impermissible simulation."[215] (footnotes omitted)

[259] The Medicines Act requires wholesalers to sell medicine to retailers and precludes them from selling medicine at a higher price than the SEP. They cannot, therefore, mark-up the price at which they bought the medicine. The only

[214] Above n 43 at para 54.

[215] Id at para 55.

remuneration to which they are entitled for selling the medicine to retailers (which the Medicines Act requires them to do) is the "appropriate fee" contemplated by section 22G(2)(c).

[260] The regulations make provision for this. They do so by prescribing a logistics fee. This is defined as meaning "the fee that is payable in respect of logistical services".[216] And those are defined, also in regulation 2, as "services provided by distributors and wholesalers in relation to a medicine or Scheduled substance including but not limited to" certain services identified in the definition.[217]

[261] The problem arises not in relation to the wholesaler or distributor being remunerated by a "logistics fee" but in the way the regulations deal with this and with the fixing of the SEP. As appears from what follows some of the regulations are difficult to interpret and in parts are vague and contradictory.

The calculation of the SEP

[262] According to the definition in regulation 2 the SEP is "the price set by the manufacturer or importer . . . combined with the logistics fee and VAT".[218] Construed literally this is a contradiction in terms. The ordinary meaning of price in a contract of sale is the money or other consideration for which goods or property are sold. In

[216] Regulation 2. The definition of "logistics fee" appears above at n 200.

[217] Regulation 2. The definition of "logistical services" appears above at n 201.

[218] The full text of the definition is set out at para 247.

terms of the Medicines Act, however, the manufacturer or importer has to sell at the SEP. So the reference in the definition of the SEP to the "price set by the manufacturer or importer" cannot be to the manufacturer's selling price. It can only be to a price set for the purpose of calculating the SEP. I refer to this price as "the core price". However, the definition goes on to provide that the "price" after this calculation has been made "is the price of the lowest unit of the medicine or Scheduled substance within a pack multiplied by the number of units in the pack". Here, "price" can only mean the SEP of a unit of the medicine.

[263] The definition contemplates, therefore, that the starting SEP will be the result of a calculation which may depend upon agreement between the manufacturer or importer on the one part and the wholesaler or distributor on the other. The former sets a "core price" for the purpose of the calculation to which a logistics fee agreed with the latter will be added, with the total being the SEP. This is affirmed in regulation 5(1) which provides:

> "Upon commencement of these regulations the price of a medicine or Scheduled substance must be set by the manufacturer, or where the medicine or Scheduled substance is imported by a person other than the manufacturer, the importer of the relevant medicine or Scheduled substance, and combined with the logistics fee in order to arrive at a single exit price for the relevant medicine or Scheduled substance."

The "price set" is again the "core price" and not the SEP. There is, however, no reference in regulation 5(1) to VAT. To be consistent with the definition and with the pricing scheme contemplated by the regulations, the words "and VAT" would have to

be read into regulation 5(1) after "logistics fee". Construed thus, the regulations are internally consistent; which is required by the Medicines Act. It is necessary, however, to go further and to apply this conclusion to the regulations dealing with the calculation of a maximum SEP.

The maximum price for the first SEP

[264] Regulation 5(2)(c) provides that "the price of each medicine or Scheduled substance to be set upon the date of commencement of these regulations by the manufacturer or importer must not be higher . . . than the weighted average net selling price" of the medicine or Schedule substance during the calendar year 2003. It is not clear whether the reference here to "the price" and the "weighted average net selling price" is to the manufacturer's 2003 price or the price at which the medicine was sold to the retail trade in 2003.

[265] A formula for determining the "weighted average net selling price" of a particular medicine is prescribed in regulation 5(2)(c)(ii). It is:

> "'S divided by the total number of lowest units (eg a tablet) for all of the packs of the same dosage strength of the medicine sold in the year 2003'
>
> Where S = the total rand value of net sales (being sales less discounts) for all packs of the same dosage strength of the medicine sold in the year".

At the foot of regulation 5(2)(c) there is a note in brackets which reads as follows: "(Note: Examples of the manner in which the weighted average net selling price must be calculated are cited in Appendix A of these regulations.)" Presumably this is

meant to clarify how the calculation of the maximum SEP for a particular medicine is to be made.

[266] Appendix A contains the following heading: "Examples of the manner in which the weighted average net selling price must be calculated". Immediately below this heading is an example dealing with solid dosages. The sub-heading reads as follows: "Calculation of single exit price for solid dosage form where this is available in different pack sizes". The first example is then given. Before the second example, which deals with liquid dosages, there is a similar sub-heading which says "Calculation of single exit price for liquid dosage form where this is available in different pack sizes". Each example concludes with the statement as to what "the single exit price" of the tablet pack and bottle of medicine is. Appendix A therefore treats the "weighted average net selling price" as the maximum SEP per unit, and not as a maximum "price" to be set by the manufacturer/importer, to which must be added a logistics fee and VAT, in order to calculate the maximum SEP.

[267] If the calculation in Appendix A is based on sales to the retail sector it would produce an accurate average "exit" price inclusive of VAT for the medicine in 2003. It would include all sales to the retail sector whether by manufacturers, distributors or wholesalers at a time when wholesalers charged a mark-up and not a logistics fee. This would provide an accurate model for determining the 2003 exit prices which, in terms of the regulations were to become a marker for a price freeze.

[268] If the maximum SEP is the "weighted average net selling price" as calculated in Appendix A, the reference in regulation 5(2)(c) to the price "to be set", is to the SEP and not, as in the definition and regulation 5(1), to the core price. If this is not so, there will be a contradiction between regulation 5(2)(c) and Appendix A.

[269] However, "discounts" is defined in regulation 2 in great detail as including, but not being limited to, a variety of benefits that might be given by "manufacturers" or "importers" to persons "selling medicines".[219] That points to the manufacturer's or importer's price in 2003 being the relevant price. So too does regulation 24(1) which calls for information to be submitted to the Director-General by manufacturers and importers concerning sales, discounts and volumes of medicines sold during 2003. No such obligation is imposed on wholesalers who are not importers. Such information would not be necessary for the calculation if the relevant price is the price to retailers and not the manufacturer's price. Practical considerations may also favour a construction based on the manufacturer's net price, for this would avoid difficulties that might arise if there had been a change in the "importer" between 2003 and the coming into force of the regulations.

[270] It is now more than a year since the regulations were gazetted. The determination of the first SEP and the calculation of the maximum permissible price at which it may be set, called for cooperation between the manufacturers, and the wholesalers and distributors. A manufacturer had to set "the price" at which it was

[219] Persons selling medicines include wholesalers and pharmacists. But wholesalers can also be importers who sell to pharmacists.

willing to deal. Both had to agree on the logistics fee. And this was so whether or not the wholesalers and distributors were the importers of the medicine.

[271] The setting of the maximum SEP depended on information to be obtained from manufacturers and wholesalers. In a tightly controlled trade like the pharmaceutical trade this ought not to have presented insuperable difficulties. Any problems that might have existed at the time seem to have been resolved. Indeed, according to the evidence SEPs have by now been set in respect of most if not all medicines, and dealings between manufacturers and wholesalers are taking place on that basis.

[272] If regard is had to Appendix A as drafted, and if the reference in regulation 5(2)(c) to "the price" is construed as being to the SEP, there will be no contradiction between Appendix A and regulation 5(2)(c). Ordinarily I would favour this construction as being consistent with the validity of the regulations. There are, however, other issues raised in relation to regulation 5(2)(c) which need to be considered before deciding whether or not the regulation is too vague and uncertain to be enforced.

[273] According to regulation 5(2)(c) the calculation of the maximum SEP is to be made on the basis of the "total rand value of net sales" without indicating whether such sales include or exclude sales to the state. It is contended that this omission gives rise to an uncertainty that materially affects the calculations. It appears from the evidence that the price of medicines sold to the state is ordinarily determined by

tender, and not through prices fixed for sales to the private sector. Section 22G(3)(a) provides that the SEP does not apply to medicines sold to the state. Since the regulations are concerned only with sales to the private sector I would construe regulation 5(2)(c) as referring to sales, other than sales to the state.

Medicines sold for the first time after January 2004

[274] The formula in regulation 5(2)(c) and Appendix A for setting the maximum SEP cannot be applied to medicines that were not sold in South Africa during 2003. If the sale of a medicine or Scheduled substance commenced only on or after 1 January 2004, regulation 5(2)(c)(ii) requires the "price" of the medicine (in this context the "price" in my view is the maximum SEP), to be calculated

> "using the average of the total rand value of sales less the total rand value of the discounts for the period for which the medicine was sold and with reference to the price of that medicine in other countries in which prices of medicines and Scheduled substances are regulated and published."

Regulation 5(2)(c)(i) deals in the same way with Scheduled substances. It is not possible from these provisions to determine how the maximum SEP should be calculated. Assuming that it can be established what countries are referred to and what the prices are (presumably the manufacturer knows this) there is no indication of how this formula is to be applied if the prices differ. The words "with reference to" are insufficient to provide a basis for the calculation to be made.

[275] The only purpose served by regulation 5(2)(c) is to fix a maximum SEP for medicines at the commencement of the regulations. Since the formula used for determining this maximum was based on 2003 sales, it could have no application to medicines that were not sold during 2003. Hence the provisos, which are directed to determining the maximum SEPs for medicines that came onto the market between 1 January 2004 and the date of commencement of the regulations. The formula for doing so must be sufficiently precise to enable that to be done.

[276] Since preparing this judgment I have had the benefit of reading the judgment of Yacoob J who suggests that the provisos were adopted to allow for a more flexible method of calculating SEPs for medicines which had only recently come onto the market. I regret that I cannot agree with this proposition. That would have applied equally to medicines that came onto the market during the last month or two of 2003. The provisos were necessary, not for this reason, but because the prescribed formula has no application to products that were not sold during 2003. It was therefore necessary to have a different formula for such products. For the reasons that I have given I consider that the method for determining the maximum SEP for these products prescribed by the provisos is too vague and uncertain to enable persons affected by the regulation to calculate the maximum that was permissible.

[277] In these circumstances, and considering all the problems and uncertainties that there are in construing regulation 5(2)(c) as a whole I would hold that the regulation is too uncertain to be enforced.

International benchmarking

[278] The SEP set initially is later required to be brought into line with international benchmarks. This is dealt with in regulation 5(2)(e) which provides:

> "The Director-General must determine and publish in the Gazette a methodology for conforming with international benchmarks, taking into account the price, and factors that influence price, at which the medicine or Scheduled substance, or a medicine or Scheduled substance that is deemed equivalent by the Director-General, is sold in other countries in which prices of medicines and Scheduled substances are regulated and published and the single exit price of each medicine or Scheduled substance must, within 3 months of publication of such methodology in the Gazette conform with international benchmarks in accordance with such methodology."

Objection is taken to this provision on the ground that the regulation delegates to the Director-General a discretion not permitted by section 22G(2)(a) of the Medicines Act.

[279] The methodology is an essential part of the pricing system, and is the basis for the determination of the maximum SEP. No objective criteria are set for establishing the methodology. In effect, the regulations vest a broad subjective discretion in the Director-General to determine a crucial part of the pricing system.

[280] It may well be legitimate for the Minister and the Pricing Committee to make provision for a system which will require the prices of medicines in South Africa to be brought into line with international benchmarks, and to delegate to the Director-General the responsibility for making the calculations necessary to give effect to that

methodology. But the regulations go much further than that. They delegate to the Director-General the power to determine the methodology itself. The Director-General has to decide what factors that influence price are relevant and have to be taken into account, what medicines are deemed to be equivalent for the purpose of the benchmarking, what countries are to be used for the purpose of the benchmarking, and what methodology is to be applied in determining whether or not the SEP is in conformity with "international benchmarks".

[281] The methodology will ultimately determine the SEP of every medicine or Scheduled substance. That was pre-eminently a task for the Minister and the Pricing Committee. The Pricing Committee was appointed because of its special expertise. Policy considerations require the Minister's involvement as well. They must determine the pricing system themselves, and not delegate this function to the Director-General. I would therefore hold that regulation 5(2)(e) constitutes an unauthorised delegation of power and for that reason is invalid. This defect in the regulation can be remedied by reading words into the regulation. I would do so by reading into the regulation the words: "the Minister on the recommendation of the Pricing Committee" in place of "the Director-General".

Increases in the SEP

[282] We live in times when inflation and volatile exchange rates have an impact on prices. Prices are continually changing in relation to these factors and other market

considerations. It could never have been contemplated that the regulations would require the SEP to be firm, and not subject to increase from time to time.

[283] Having made provision for a maximum SEP it was necessary for that determination to be subject to review from time to time. The regulations address this issue by making provision for an annual review,[220] and for reviews at other times to be made in exceptional circumstances.[221] Here too objection has been taken to the delegation of powers to the Minister, and to the vagueness of the relevant regulations.

[284] Regulation 8 deals with annual increases. Regulation 8(1) provides:

> "The extent to which the single exit price of a medicine or Scheduled substance may be increased will be determined annually by the Minister, after consultation with the Pricing Committee, by notice in the Gazette with regard to—
>
> (a) the average CPI for the preceding year;
> (b) the average PPI for the preceding year;
> (c) changes in the rates of foreign exchange and purchasing power parity;
> (d) international pricing information relating to medicines and Scheduled substances;
> (e) comments received from interested persons in terms of regulation 8(2); and
> (f) the need to ensure the availability, affordability and quality of medicines and Scheduled substances in the Republic."

[220] Regulation 7 subject to regulations 5, 8 and 9.

[221] Regulation 9.

Interested parties are given an opportunity to make representations to the Minister before such determination is made and the procedure to be followed in that regard is set out in regulation 8(2).

[285] Because of the different factors which may affect the determination of a maximum price for a particular SEP, it would have been difficult for the regulations to prescribe a formula for this to be done. Had the regulations made provision for the Pricing Committee and the Minister to exercise control over the process that would have been consistent with section 22G(2). The regulations do not, however, do this. They provide that the determination shall be made by the Minister "after consultation with the Pricing Committee". This would require the Minister to give serious consideration to the views of the Pricing Committee, but would leave her free to disagree with them.[222] This is in contrast with the Medicines Act, which requires agreement between the Minister and the Pricing Committee on the pricing system.

[286] The annual review is an important component of the pricing system. It involves a consideration of factors in which expertise in the pricing of medicines is required. Since the Pricing Committee has to be involved in the process there is no practical necessity for delegating this function to the Minister alone. What the regulation does is to leave to the Minister alone, a task which is the joint responsibility of the Minister and the Pricing Committee, without there being any practical necessity for this to be done, or any obvious reason why the Pricing Committee's power should be

[222] *Ex parte Chairperson of the Constitutional Assembly: In re Certification of the Constitution of the Republic of South Africa, 1996* 1996 (4) SA 744 (CC); 1996 (10) BCLR 1253 (CC) at para 131.

subordinated to that of the Minister. In my view the delegation of the decision-making power to the Minister alone is an improper delegation of a power vested jointly in the Minister and the Pricing Committee by the Medicines Act. I would hold regulation 8(1) to be invalid for this reason. I would, however, correct this defect by reading into the regulations the words: "the Minister on the recommendation of the Pricing Committee" in place of the words: "the Minister after consultation with the Pricing Committee".

[287] There is, however, another problem concerning price increases. Regulation 7 provides:

> "Subject to the provisions of regulations 5, 8 and 9, the single exit price of a medicine or Scheduled substance may only be increased once a year."

Regulation 5 deals with the setting of the first SEP and provides in sub-regulations (2)(a) and (b):

> "The single exit price must be set in accordance with the following provisions—
>
> (a) for a period of one year after commencement of these regulations the single exit price shall not be increased;
>
> (b) subject to sub-regulation 5(2)(a) the single exit price may be increased in terms of regulation 8 of these regulations".

This means that SEPs established at the date of the commencement of the regulations must not be increased during the first year following that date. After the first year they may be increased in accordance with regulation 8.

[288] Regulation 8(3) provides:

> "Subject to the provisions of regulation 8(1), a manufacturer or importer may no more than once a quarter increase the single exit price of a medicine or Scheduled substance within a year provided that—
>
> (i) such increase does not exceed the single exit price of the medicine or scheduled substance as first published in respect of that year;
>
> (ii) the increase in the single exit price is applied to all sales of the medicine or Scheduled substance and not the selected categories of purchasers;
>
> (iii) the manufacturer or importer notifies the Director-General of the increase in the single exit price at least 48 hours prior to the implementation of such increase;
>
> (iv) the single exit price may not be increased as contemplated in terms of this regulation 8(3) within the period of six months beginning from the date of commencement of these regulations."

[289] Apparent contradictions between regulations 5, 7 and 8 are:

(a) Regulation 7 provides that the SEP may be increased once a year.

(b) Regulation 8(3) provides that the SEP may be increased no more than once a quarter.

(c) Regulation 5(2)(a) provides that for a period of one year after the commencement of the regulations the SEP shall not be increased.

(d) Regulation 8(3)(iv) provides that increases in terms of regulation 8(3) may not be made within the period of six months from the date of commencement of the regulations.

[290] Yacoob J has suggested a means of reconciling these provisions. In his view regulation 7 allows a manufacturer or importer to increase the SEP if the Minister fails to publish a notice and make a determination timeously in accordance with regulation 8(1). I am unable to agree with this. It seems to me to be contrary to the policy of the Medicines Act and the regulations to hold that a failure by the Minister to act timeously would result in there being no constraints upon manufacturers and importers in relation to price increases. I am also not persuaded that the language of the regulations is reasonably capable of the construction he has placed on it.

[291] It seems to me to be more likely that the purpose of regulation 8 is to establish a system in which a maximum permissible increase of the SEP would be determined on an annual basis, but space would be left for manufacturers and importers to fix the SEP at a price below the maximum. Manufacturers and importers who do so would then be allowed to increase prices on a quarterly basis as long as they do not exceed the maximum allowed. This would also be consistent with the Pricing Committee's final report to the Minister on 21 April 2004 under cover of which the final regulations were submitted to the Minister. It indicated that

> "manufacturers may reduce and increase their prices in response to competitive imperatives, as long as the price at no time exceeds the SEP that has been established for that year and that these price increases do not occur more than once a quarter."

[292] Regulation 8(3) is confusing, badly worded, and if regard is had to regulations 5, 7 and 8(1), too vague to be understood by those bound by it. I would hold it to be invalid on those grounds. It needs to be harmonised with regulations 5 and 7, and

redrafted to indicate with sufficient clarity what is meant, and what is permissible concerning price reductions and price increases. When the regulations are reformulated attention also needs to be given as to how reductions in the SEP, and increases in the SEP made in terms of regulations 8 and 9, are to be published.[223]

Exceptional circumstances

[293] Regulation 9(1) provides:

> "The Minister may, in exceptional circumstances, authorise a manufacturer or importer, on written application by such manufacturer or importer, to increase the price of a medicine or Scheduled substance by a specified amount greater than that permitted in terms of regulation 8."

This is also objected to as an invalid delegation.

[294] The criteria to be taken into account by the Minister are set out in regulation 9(2).[224] These provide sufficient guidance for determining whether or not

[223] The issue of publication is dealt with in paras 295-296 below.

[224] Regulation 9(2):

> "In considering an application as contemplated in regulation 9(1) the Minister must take into account—
>
> (a) the nature and extent of any adverse financial, operational and other circumstances for the manufacturer or importer if the application made in terms of regulation 9(1) is not approved;
>
> (b) the effect, if any, on the availability of the medicine or Scheduled substance within the Republic if the application made in terms of regulation 9(1) is not approved;
>
> (c) the nature of the health condition for which the medicine or Scheduled substance is a registered indication within the Republic and the extent to which public health would be adversely affected should the medicine or Scheduled substance become unavailable or unaffordable within the Republic;
>
> (d) the extent to which the rights contemplated in section 27(1)(a) and 27(3) of the Constitution may be adversely affected or limited—

"exceptional circumstances" exist. This is a decision that may have to be taken urgently, and will be relevant for a limited period until the next annual review. Any increase allowed under regulation 9(1) will be taken into account at the time of such review. In the circumstances it seems to me to be legitimate for the regulations to leave these "exceptional" measures to the Minister to decide.

Publication of the SEP

[295] Section 22G(3)(a) of the Medicines Act requires the SEP to be "published as prescribed". It is contended by New Clicks that this requirement has not been complied with because regulation 3 provides for publication of the SEP in a manner to be determined by the Director-General from time to time "by notice in the Gazette". This leaves it to the Director-General to determine when and how the publication should take place.

[296] This contention overlooks the requirements of regulations 24 and 4. Regulation 24(1) requires manufacturers and importers within one month of the date of commencement of the regulations to submit to the Director-General "a schedule reflecting the single exit price of a pack of each medicine or Scheduled substance sold by them, including the pack size, dosage form and strength of the medicine or Scheduled substance". Regulation 4 requires the single exit price to "be clearly and legibly reflected on the package or the immediate container within which a medicine

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(i) should the single exit price not be increased by the amount requested in the application; and
(ii) should the medicine or Scheduled substance become unavailable or unaffordable within the Republic."

or Scheduled substance is sold to a user." These provisions ensure that the SEP will be published to the Director-General, to participants in the distribution chain and to persons who buy from the pharmacists. The Medicines Act requires only that the SEP should be published as prescribed. Regulations 4 and 24 meet that requirement in so far as the first SEPs are concerned. Regulation 19 contemplates that applicants for the registration of new medicines will determine the first SEP for that medicine and inform the Director-General of that. The SEP will also have to be marked on the packaging in accordance with regulation 4. In the circumstances the objection must be rejected.

The logistics fee

[297] Section 22G(2)(c) of the Medicines Act authorises the Minister on the recommendation of the Pricing Committee to make regulations "on an appropriate fee to be charged by wholesalers or distributors". Regulations 5(2)(f) and 5(2)(g) do this by making provision for a logistics fee. They provide:

> "5(2) The single exit price must be set in accordance with the following provisions—
>
> . . . .
>
> (f) Subject to regulation 5(2)(g), the logistics fee must be determined by agreement between the provider of the logistical services and the manufacturer or importer.
>
> (g) The Minister must determine a maximum logistics fee where, in the opinion of the Minister, such a determination is necessary to promote or protect the interests of the public in—
>
> (i) ensuring reasonable access to affordable medicines;
>
> (ii) the realisation of the constitutional right of access to health care services contemplated in section 27 of the Constitution;

> (iii) the efficient and effective distribution of medicines and Scheduled substances throughout the Republic."

It is contended by the Pharmacies that an agreed fee is not appropriate and that it is not transparent.

[298] A logistics fee determined by agreement between the parties to the transaction is a fee determined by market conditions between parties free to bargain with one another, and whose interests do not coincide in all material respects. That is an appropriate fee, bearing in mind the provision for the fee to be capped if that should be necessary in the public interest.

[299] The power to determine a maximum fee is, however, vested in the Minister if in her "opinion" such a determination is necessary. Although the "capped" fee must be "appropriate", and to that extent is subject to objective criteria, regulation 5(2)(g) in effect leaves it to the Minister to determine the "appropriateness" of the fee, instead of setting a maximum itself. The regulations could possibly have done so by fixing a maximum fee in the form of a charge based on a percentage of the cost of the medicine (a reasonable wholesaler's mark-up), as was done in the case of the dispensing fee, or in some other way that would have enabled the determination of the maximum fee to be calculated from the terms of the regulations themselves. If this had been done the parties would have been free to bargain for appropriate fees less than the maximum, depending on the services to be rendered. However, because of

the different services that may be provided by different wholesalers and distributors there may have been good reasons for not adopting this approach.

[300] The regulations do not, however, address what the cap for an appropriate fee will be, or how it is to be determined. They leave that to the Minister to determine if "in her opinion" it is necessary to do so. The maximum logistics fee, like the maximum SEP, is an important part of the pricing system. If it was considered necessary to have greater flexibility than is possible by prescribing a maximum fee in the regulations, or a formula for determining it, the fixing of the fee should have been delegated to the Pricing Committee and the Minister, and not to the Minister alone. I would therefore hold that the provision vesting in the Minister the power to determine a cap for the logistics fee constitutes an impermissible delegation. I would, however, remedy that defect by reading into regulation 5(2)(g) after the word "the Minister", the words "on the recommendation of the Pricing Committee".

Transparency and publication of the logistics fee

[301] The SCA held that the logistics fee was not "transparent" because it was a fee to be "determined by agreement between the provider of logistical services and the manufacturer or importer".[225] This seems to contemplate that the regulations should have fixed a basis for the determination of the fee, and not have left it to the parties to determine themselves.

[225] Regulation 5(2)(f). Above n 43 at para 56.

[302] However, the services provided by a wholesaler or distributor will vary depending upon the agreement they have with the manufacturer, and the choice to leave the determination of the logistics fee in the first instance to agreement between the parties to the contract is not inappropriate. For instance, a fee payable to a wholesaler who imports the medicines or Scheduled substances is likely to be more than a fee payable to a wholesaler who purchases the products in South Africa from the manufacturer or the distributor. And the same applies to differences in volumes, geographical areas, and other services that may have a bearing on the particular fee to be paid to a particular wholesaler or retailer.

[303] The logistics fee is an expense that manufacturers may now have to incur if they wish to deal in the South African market. In this respect it is no different to other expenses which the manufacturer has to carry in order to produce and distribute its products. All those expenses are the result of agreements between the manufacturer and its suppliers or service providers. All have to be taken into account by the manufacturer in setting a price to be the basis of the calculation of the first SEP. What is important is that the amount of the "logistics fee" should be made known in a way that meets the requirement of transparency.

[304] There is no provision of the regulations (other possibly than their inclusion in the SEP) that requires the logistics fee to be made public. Regulation 21(2)(d) makes provision for a method of informing the public of the fees charged by wholesalers, distributors, retailers and other persons selling medicines and Scheduled substances,

but it is left to the discretion of the Director-General to decide whether or not to require this to be done. This does not meet the transparency called for by the Medicines Act. The omission is not sufficiently material to justify the regulations being set aside for this reason alone. The defect must, however, be remedied and I would do so by reading into regulation 21 the words "and in the case of the information referred to in regulation 21(2)(d) must" before the words "publish or otherwise communicate, or require". This will not preclude the Minister on the recommendation of the Pricing Committee from amending the regulations to make provision for a different method of publication consistent with the Medicines Act.

Is there certainty as to the SEP?

[305] It was also contended that the inclusion of the logistics fee in the calculation of the SEP gives rise to uncertainty and contradictions. There are three related arguments that were raised. First, that the inclusion of the logistics fee as a component of the SEP, is inconsistent with regulation 5(2)(f) which requires the fee to be determined by agreement between the manufacturer and the wholesaler or distributor. This, it was argued, could not be complied with where a manufacturer uses more than one wholesaler or distributor to market its medicines. In that event, if there are different agreements between the manufacturer and the different intermediaries, there may be more than one SEP for the same product which would be inconsistent with section 22G(3)(a) of the Medicines Act.

[306] Regulation 5 deals with the setting of the SEP at the commencement of the regulations. What the regulation requires is that there should be agreement between the manufacturer on the one hand and the relevant wholesaler or distributor on the other, as to the SEP at which the medicine would be sold at the commencement of the regulations. The logistics fee had therefore to be determined in advance and built into the SEP. If there was more than one wholesaler or distributor all would have had to be party to the agreement. Construing regulation 5 in this way avoids any contradiction between regulation 5(2)(f) and section 22G(3)(a). There would be only one logistics fee and that fee would have been taken into account in determining the SEP.

[307] It is not permissible for a manufacturer to fix different SEPs for different wholesalers and distributors. It follows that once the SEP has been set, it controls all sales by the manufacturer unless and until the SEP is changed in accordance with the provisions of the regulations. If wholesalers and distributors who were not party to the original agreement are subsequently used to market the medicine, they must agree to do so on the basis of the existing logistics fee.

[308] It was also contended that if the logistics fee is included in the SEP then, instead of selling at the SEP which is what section 22G(3)(a) requires, the manufacturer will in truth be selling at the core price. This is not so. Sales must be at the SEP. The fact that the "logistics fee" is taken into account in calculating the SEP is not inconsistent with this. The sale must be at the SEP subject to a provision that

the manufacturer will pay the wholesaler or distributor the agreed logistics fee. The manner and time of payment of that fee will depend on the terms of their agreement.

[309] Finally, it was contended that payment of a logistics fee cannot be reconciled with regulation 6 which provides:

> "A manufacturer, importer, distributor or wholesaler may not charge any fee or amount other than the single exit price in respect of the sale of a medicine or Scheduled substance to a person other than the State."

[310] In the context of the Medicines Act and the regulations as a whole, regulation 6 must be read as referring to a fee other than the logistics fee. Otherwise it would be contrary to the Medicines Act which makes provision for wholesalers and distributors to charge an "appropriate" fee for selling medicines. Construed thus there is no contradiction between regulations 5 and 6.

Appropriate dispensing fee for pharmacists: regulations 10 and 11

[311] Section 22G(2)(b) authorises the Minister on the recommendation of the Pricing Committee to make regulations "on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a)" of the Medicines Act. Regulations 10, 11 and 12 deal with the dispensing fee for medicines and Scheduled substances in Schedules 1 to 8 of the Medicines Act. Regulation 13 deals with Schedule 0 medicines. It is contended by the Pharmacies that the

dispensing fees thus prescribed are not "appropriate" and that these regulations are accordingly invalid.[226]

[312] The SCA held that there is no absolute standard for determining what is "appropriate", and that reasonable persons may well disagree about this.[227] It held, however, that "appropriate" is a justiciable standard, requiring a balance to be struck between the needs of the public to have access to affordable medicine and the interests of pharmacists who are an essential link in the supply chain. It said that a fee that is unjust or unfair could not be regarded as an "appropriate" fee.[228]

[313] Counsel for the applicants submitted that the SCA erred in adopting this approach. They contended that courts are ill equipped to deal with economic matters and ought not to sit in judgment on what are essentially political decisions taken by the executive in making regulations. I do not agree that a court should refrain from examining the lawfulness of the dispensing fee simply because the decision as to what it should be involves economic and political considerations. The exercise of all public power is subject to constitutional control[229] and it is the duty of courts if called upon to do so to determine whether or not power has been exercised consistently with the requirements of the Constitution and the law. In the present case it is contended that

[226] This is a challenge to the lawfulness of the regulation concerned. See section 6(2)(f)(i) of PAJA and para 189 above where lawfulness is discussed.

[227] Above n 43 at para 79.

[228] Id at para 77.

[229] *Affordable Medicines* above n 127 at para 48; *Pharmaceutical Manufacturers Association* above n 127 at para 20.

the dispensing fee prescribed in the regulations is not an "appropriate" fee within the meaning of section 22G(2) of the Medicines Act. It was the duty of the courts which have dealt with this matter, including this Court, to decide whether this contention is correct.

[314] The purpose of section 22G of the Medicines Act read in the context of the Medicines Act as a whole is to enhance the accessibility and affordability of medicines. This is an obligation of the state which in terms of section 27 of the Constitution is obliged to take reasonable measures to enhance access to health care.

[315] Section 22G requires the measures taken to achieve this end to be "appropriate". The cost of medicine is relevant to accessibility, but it is not the only factor. The medicine must be available to those who require it. Pharmacies are an essential component of the distribution chain. If pharmacies go out of business the accessibility of medicines will be impaired. An appropriate fee is thus one which at least strikes a balance between these requirements of cost and availability.

[316] This does not mean, as the SCA pointed out, that there is only one appropriate fee, or that courts are entitled to substitute their decision for that of the Pricing Committee and the Minister, because they consider it to be better than theirs. Unless a court is satisfied that the dispensing fee is in fact inappropriate it is not entitled to interfere with the decision of the Minister and the Pricing Committee, even if it disagrees with it.

[317] According to Professor McIntyre the dispensing fee should be a professional fee for services rendered by pharmacists in connection with the sale of medicines. It should be sufficient to enable a well-run pharmacy to make a reasonable profit. This is not disputed. What is disputed is whether the prescribed dispensing fee is sufficient for this purpose.

[318] The SCA held that the dispensing fee was not "appropriate" because "the unassailed factual material on record" showed that the fee will not provide pharmacists with sufficient revenue to cover their operating costs.[230] The "factual material" referred to consisted in the main of reports made by experts concerning the impact that the prescribed dispensing fee will have on the viability of pharmacies, and the material on which such reports are based.

The introduction of a professional dispensing fee

[319] Before the regulations came into force pharmacists sold medicines to clients at a mark-up over the purchase price. In addition there was a small dispensing fee of R1,30 per item and other small charges for containers and broken bulk when part but not all of a package of medicine was sold. The Medicines Act shifts revenue from a mark-up on the sale of medicine, to a prescribed dispensing fee.

[230] Above n 43 at para 89.

[320] Professor McIntyre says that the approach adopted by the Pricing Committee was that the dispensing fee should provide an appropriate remuneration for the pharmacist's professional services, taking into account not only the time and expertise involved in dispensing, but also the costs associated with that service. In making these calculations regard should be had to income that can be derived from professional services other than dispensing, for which charges can be made. A fee that gives effect to these considerations should also be as simple as possible and clear and understandable to the consumer. A flat fee for medicine in the more expensive range serves this purpose. A percentage fee for medicine in the lower cost range is necessary to ensure that such costs are not "overburdened".

[321] Her response to the allegation that the fee is not appropriate is that the Pricing Committee conducted a thorough investigation, considered all the information put before it, and applying these principles concluded that the prescribed dispensing fee would enable well-run pharmacies to make a reasonable profit.

Different types of pharmacies

[322] PSSA contend that there are four different types of pharmacies whose operations will be affected in different ways by the dispensing fee. They are community pharmacies, courier pharmacies, pharmacies in medical centres and hospital pharmacies. There are also different considerations relevant to community pharmacies in urban areas and those in rural areas. The Pharmacies argue that the dispensing fee is not sufficient to enable any of these types of pharmacies to trade

profitably. In support of this contention they rely on the evidence of three experts, Mr Jordaan, Dr Stillman and Mr Kellerman. I deal later with this evidence.[231]

Community pharmacies

[323] Community pharmacies are retail pharmacists that operate shops. They have a dispensary (the back shop) from which medicine is sold, and a front shop which deals in consumer goods. According to Professor McIntyre the Pricing Committee asked PSSA and other associations representing pharmacists to provide them with information to show the actual costs of dispensing medicines, but none of the associations did so. Instead, they provided information showing the revenue and expenditure of pharmacies as one business, without the breakdown necessary to separate dispensing from other activities including the running of the front shop. Similar averments are made by Dr Pillay and Dr Zokufa.

[324] This is disputed in the replying affidavit by Mr Honeysett, who is the principal deponent to affidavits on behalf of New Clicks. He says in response to this allegation:

> "[I]t is now suggested that the applicant has only in this application made available information which it was previously invited to produce. This is simply untrue and it is striking that the information given now is not properly addressed. The applicant in fact made a full presentation at the oral hearing to which it was invited. What Dr Zokufa does not disclose is that at the end of that hearing it was complimented by representatives of the Department and Pricing Committee for the completeness of its representations and its helpfulness. It was only after the regulations were already

[231] Below at paras 344-358 and 359-371.

> published and after I complained about its content to Dr Pillay, that he invited further information."

[325] This is not a dispute that can be resolved on the papers. What is relevant and of importance, however, is that whether it asked for this information or not, the Pricing Committee appear to have dealt with the dispensing fee without having such information. In doing so it made assumptions that, on the papers before us, cannot be sustained.

The back shop and the front shop

[326] First, it is assumed that the dispensaries of community pharmacies subsidise the front shops. In this regard Dr Zokufa says that "[e]ffectively, mark-ups on medicines have heavily cross-subsidised expenses related to front shop activities" to date. He goes on to say that it is not appropriate, as implied by New Clicks and PSSA, that the dispensing fee "should be increased in order to address the threat to financial viability imposed by inefficient front shop operations." Professor McIntyre's evidence is to the same effect, and she says that consumers ought not to bear such costs.

[327] Neither Dr Zokufa nor Professor McIntyre provide any evidence in support of the assertion that the dispensaries subsidise the front shops, nor do they indicate the source of this allegation. The Pharmacies dispute this assertion and the averment that this can be implied from their opposition to the dispensing fee. They contend that it is not a logical proposition for, if this were so, pharmacists would confine their operations to dispensing and rid themselves of loss-making activities.

Revenue from compounding

[328] The Pricing Committee and the Minister say that in addition to revenue from the dispensing fee, regard must be had to additional revenue streams that pharmacists can earn from compounding medicines, primary care drug therapy, and from other services such as tests and taking blood pressure for which the pharmacist can charge separately. They do not say how they calculated the revenue stream from these "additional sources of revenue" or what weight was given to it in their calculations. It seems, however, to have been treated as a significant factor, on which much emphasis is placed in their affidavits. It also seems clear from their evidence that in formulating the final regulations the Pricing Committee did not take "compounding" and "admixing" into account in determining the dispensing fee.

[329] The Pharmacies dispute the contention that there are material revenue streams apart from dispensing that are available to pharmacists. They say that on a proper construction of the Medicines Act and the regulations, compounding is part of dispensing and that revenue from other sources is negligible. Dr Stillman says that in his calculations all revenue was taken into account including revenue that may have been earned from compounding and other sources.

[330] There is a dispute on the papers as to whether dispensing includes compounding. In the definition of compounding contained in the regulations made in terms of the Pharmacy Act, 53 of 1974[232]

> "'dispensing' means the interpretation and evaluation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container according to the Medicines Act and the provision of information and instructions by a pharmacist to ensure the safe and effective use of medicine by the patient and 'dispense' has a corresponding meaning".

[331] In the Pricing Committee's report to the Minister on the draft regulations submitted by it on 18 December 2003, it is said that the dispensing fee

> "would cover all of the following services: the interpretation and evaluation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container and the provision of information and instructions by a pharmacist to ensure the safe and effective use of medicine by the patient. It should also be noted that this fee will also cover both the professional remuneration and the pharmacy's operating costs."

This fee would cover all services outlined in the definition of dispensing above. This in substance is the definition of dispensing in the Pharmacy Act regulations.

[332] Although this is not repeated in the report on the final regulations – there is no reference there to what dispensing includes – neither Professor McIntyre nor Dr Zokufa offers any explanation for the comment in the first report as to what dispensing includes. Nor do they say why the Pricing Committee subsequently

[232] Regulations Relating to the Practice of Pharmacy, Government Gazette 21754 GN R1158, 20 November 2000.

changed its mind. The first mention of the view that compounding is not included in the dispensing fee was in the High Court proceedings where the Minister and the Pricing Committee contended that compounding is not part of dispensing.

[333] The authority of pharmacists to supply medicines comes from the Pharmacy Act and its regulations,[233] which define dispensing as including compounding. Dr Thiede refers in his affidavit to "dispensing in the sense contemplated by the regulations". He does not explain why the regulations contemplate a distinction being made between the meaning of "dispensing" in the Pharmacy Act regulations, and its meaning in the Medicines Act, nor does he say why the Pricing Committee took a different view when it made its report to the Minister on the draft regulations where the basic fee structure was set.

[334] It hardly seems to be practical for a medicine compounded or admixed pursuant to a doctor's prescription for a particular patient to be subjected to the requirements for setting and publishing the SEP for medicines. Nor would I construe section 22G(3)(a) as requiring that. In my view "manufacturer" in section 22G(3)(a) must be construed as being a person other than a pharmacist or a licensed health professional. If that is so, the section does not apply to medicine "made" by them for particular patients through compounding or admixing.

[233] Id.

[335] This does not mean, however, that the regulations do not have to deal with compounding and admixing. Sections 22C(1)(a) and 22C(5) of the Medicines Act require persons other than pharmacists to be licensed to "compound and dispense". Section 22G(2)(a) requires the pricing system to be for "*all* medicines and Scheduled substances" sold in the Republic. That would include compounded and admixed medicines sold by pharmacists and licensed health professionals.

[336] Section 22G(2)(b) contemplates that the regulations will make provision for an appropriate dispensing fee to be charged by a pharmacist or licensed health professional. The General Regulations made in terms of the Medicines Act in 2003 define "compound" as meaning to prepare, mix, combine, package and label a medicine for dispensing, and define "dispense" in the case of a pharmacist, as meaning "dispense" as defined in the regulations under the Pharmacy Act. Those regulations define dispensing as including compounding.

[337] The Medicines Act defines "sell" as meaning "sell by wholesale or retail . . . or prepare or possess for purposes of sale". A pharmacist who compounds or admixes medicines for a customer pursuant to a doctor's prescription and "sells" the compounded or admixed product, dispenses it.

[338] "Compounding" and "admixing" involve the preparation by a pharmacist of medicine for sale to the public, and are components of dispensing. Section 22G(2)(b) requires provision to be made for an appropriate dispensing fee to be charged by

pharmacists and licensed health professionals. That fee should therefore deal with compounding and admixing.

[339] Professor McIntyre concedes that pharmacists may spend a considerable amount of time compounding and admixing medication. It is, however, clear from the regulations and the Pricing Committee's own evidence that the dispensing fee has been set in a way which makes no provision for this. It is not clear what the implications of this will be for the average pharmacist or licensed doctor, though the Minister and the Pricing Committee contend that compounding constitutes a significant revenue stream additional to dispensing, which will supplement the revenue stream of the pharmacy. What is clear, however, from the evidence is that compounding of oncology medicine is a highly specialised time consuming task, requiring a significant capital investment, and special skills. If no allowance is made for this activity in the regulations, the "one size fits all" dispensing fee will impact more severely on those specialists, than the "average" pharmacist.

[340] The Minister and the Pricing Committee do not indicate how compounded and admixed medicines are to be dealt with in terms of the Medicines Act and regulations if they are not included within the concept of dispensing. Counsel for the Minister and the Pricing Committee could offer no answer to this conundrum other than to suggest that there is no limit on the prices pharmacists can charge for the preparation and sale of such medicines. But that does not fit the structure and purpose of the Medicines Act and regulations.

[341] In my view the only way that compounding and admixing can be dealt with, if regard is had to the provisions and purpose of the Medicines Act, is to treat these functions as being an aspect of the dispensing function for which special provision has to be made in addition to the basic "dispensing fee". And this, the regulations fail to do. This omission is a factor relevant to the issue of the appropriateness of the dispensing fee.

Calculating the profitability of the dispensary

[342] Professor McIntyre deals with the approach adopted by the Pricing Committee to the calculation of the dispensing fee. She says that the Pricing Committee requested PSSA and other associations representing pharmacists to provide information that demonstrated the actual costs of dispensing, but none of these associations did so. The information provided apparently dealt with the shop as a whole without a breakdown of the separate activities of the front shop and the back shop. According to Dr Thiede, who is a member of the Pricing Committee, the dispensing fee was calculated "on the basis of the dispensing activity and the operational costs relating to dispensing." Yet nowhere in the minutes or the affidavits is any reference made to the source of such information, or how the calculation was made in the absence of the information from pharmacists that was considered by the Pricing Committee to be essential for this purpose.

[343] The Pharmacies offer expert evidence to demonstrate that pharmacies will not be viable if the pricing system in the regulations is applied. The evidence of Mr Jordaan, Dr Stillman and Mr Kellerman is relied on to support this contention. In response, the Minister and the Pricing Committee rely on the evidence of Dr Pillay, Dr Thiede, Professor Henry, Professor Mossialos and Professor Mooney. Of these, only Dr Thiede and Dr Pillay deal directly with the calculations made by the Pharmacies' experts.

Mr Jordaan's evidence

[344] Mr Jordaan was employed as head of professional services at Purchase, Milton and Associates from whom New Clicks had acquired their chain of pharmacies. He addresses the question whether the dispensaries in this chain of pharmacies, treated as separate entities, will be profitable if operated in terms of the prescribed dispensing fee. He submits a report in which he concludes that the overall impact of the dispensing fee will be to place the continued viability of the New Clicks pharmacies seriously at risk.

[345] The community pharmacies whose records were used by Mr Jordaan were acquired by New Clicks during 2003. There were 80 pharmacies in the chain. This was before the regulations came into force. Mr Jordaan's calculations are made on the basis of unaudited records of sales of medicines during 39 days between August 2003 and January 2004, said to have been selected randomly.

[346] He analyses the information in these records and calculates the contribution that different aspects of the business of the chain make to the chain's gross profit. His calculations, which are not always easy to follow, lead him to conclude that the gross profit of the back shop expressed in rand terms would have been reduced by 57,35% if the dispensing fee prescribed in the regulations had been applicable at that time.

[347] His evidence is disputed on three grounds – that he is not an expert, that his sample is too small to be reliable and that he has not had regard to revenue streams for professional services other than dispensing, for which pharmacists are entitled to charge. In addition the calculations are also criticised.

[348] Mr Jordaan is a pharmacist with an auditing diploma and experience in the operation of pharmacies. His evidence on the impact of the dispensing fee on profits involved the extraction and analysis of data from the New Clicks records. There is no reason to doubt his qualifications to undertake such a task.

[349] He prepared four tables dealing with the turnover in New Clicks stores and the gross profit rates on sales in the various sectors of these stores. The first three tables deal with large, medium and small stores. The fourth is a model of a "typical" pharmacy prepared from the information in the first three tables. He uses this model for the calculations in his report.

[350] The information is derived from computer records of sales in the various stores which are exported on a daily basis to a central data base that New Clicks maintains and which is under Mr Jordaan's control.

[351] The tables show the contribution to total sales made by each of six departments in the stores and the rates of gross profits on the sales from such departments. The departments are described as Beauty, Clinic, Fast Moving Consumer Goods, Prescription, OTC, Vitamins and Health. OTC are over the counter sales. Prescriptions and OTC are from the "back shop" and the others from the "front shop".

[352] The fourth table, which is the model on which he works, is as follows:

	Category Contribution to Total Sales	Gross Profit%
Beauty	0.85%	32.20%
Clinic	0.42%	
Fast Moving Consumer Goods	2.35%	24.12%
Prescription	61.18%	27.36%
OTC	22.11%	30.87%
Vitamins & Health	13.08%	27.95%

There is no gross profit percentage shown for the Clinic which contributes only 0,42% to turnover and has apparently been ignored in the calculations.

[353] The back shop contributes approximately 83,29% to the shop's turnover and the front shop 16,7%. The tables dealing with large, medium and small stores reveal a

similar pattern. As Dr Stillman points out in his report the gross profit rates in the different departments do not differ materially. The back shop is clearly responsible for most of the store's "gross profit". There is, however, what seems to be a patent error in Mr Jordaan's report where he says that the back shop contributes 27,9% of the gross profit. This is inconsistent with the comment he makes in the same paragraph of the report that the front shop makes a minimal contribution to gross profit and sales. The figures speak for themselves that the back shop's contribution to gross profit is close to 84% of the total gross profit.

[354] This patent error does not seem to me to be of particular relevance to the conclusions reached by Mr Jordaan. It is not commented on by any of the experts. If correct, it may possibly have been relevant to the allocation of expenses between the back shop and the front shop, though that has not been done on the basis of contributions to gross profit. A more nuanced approach has been adopted allocating particular expenses according to their relevance to the activities of the front shop and the back shop. That allocation is not seriously disputed by Dr Thiede who describes it as a "defensible approach".

[355] Dr Thiede does, however, question the reliability of Mr Jordaan's conclusions. He says that calculations were made on the basis of records taken at random over 39 days in a period of six or seven months (some calculations were done on six months, others on seven) from 80 pharmacies in one chain, and that this is not a representative sample from which inferences can be drawn concerning the industry as a whole.

[356] The calculations involved an analysis of 651 966 transactions for the sale of medicines. It is no doubt a small sample of the total industry, but the conclusion that the dispensing fee will convert profit-making pharmacies in the New Clicks group into loss-making businesses is consistent with the analysis of the impact of the dispensing fee on courier pharmacies, pharmacies in medical centres and hospital pharmacies dealt with by Dr Stillman.

[357] Dr Thiede also criticises Mr Jordaan's report in so far as it deals with an income statement of a typical pharmacy. He says that in some respects the calculations made are unclear, and incorrectly modelled, but he does not point specifically to items other than those to which Mr Jordaan responded and has given satisfactory explanations, nor does he offer an alternative model of a typical pharmacy.

[358] There is a further criticism that the report was prepared on the basis of estimates of what the SEPs would be. But that must also have been the case as far as the dispensing fee is concerned because the SEPs were not known at that time. Mr Jordaan says that he assumed that the SEPs would on average be 20% less than the manufacturer's pre-regulation price list which was the "industry perception" at that time. This is not disputed in the evidence nor is it suggested that the SEPs would prove to be higher than that. As Mr Jordaan points out, if the SEPs prove to be lower than he assumed for the purpose of his report, this would aggravate the adverse impact of the dispensing fee on a pharmacy's business.

Dr Stillman's report

[359] Dr Stillman is an economist specialising in the economics of competition policy and regulatory issues. He considers the position of the four categories of pharmacies to which I have referred and concludes that the dispensing fee will not provide any of them with sufficient revenue to make them viable. He prepared two reports to deal with this issue: the first to support the contention made by the Pharmacies that the regulations will destroy the viability of pharmacies; and the second to reply to criticisms of his report made in the answering affidavits.

[360] His qualifications to give this evidence were also challenged. Whilst Dr Stillman's expertise is not directly concerned with the pharmaceutical industry, he is a highly qualified economist well able to undertake an analysis of the accounting records.

[361] Dr Stillman was provided with information of the net sales, gross profit and operating profit of each of 75 New Clicks pharmacies during a period of six months from July to December 2003. Information concerning the other five stores was considered by New Clicks not to be reliable. Six of the remaining 75 pharmacies were excluded by Dr Stillman from his analysis because they were start-up stores or were going through a process of refurbishment that disrupted their operations.

[362] Mr Jordaan's analysis in respect of the New Clicks pharmacies is relied on by Dr Stillman to calculate whether the 69 pharmacies in the chain would be profitable if revenue had come from the dispensing fee. He analyses the data, using Mr Jordaan's estimate that the dispensing fee will result in a 57,35% reduction in gross profit expressed in rand terms. Applying this factor to the 69 shops in the chain, 14 of which were already operating at a loss, he concludes that all but two of the shops would have operated at a loss. The other two would have made a small net profit, but not enough to warrant an investment being made in them.

[363] Dr Stillman's conclusions concerning the New Clicks pharmacies depend on the reliability of Mr Jordaan's report. That report was based on an analysis of 80 pharmacies, 11 of which were rejected by Dr Stillman as not being sufficiently reliable for his purposes. None of the applicants' witnesses comment on this and it is not possible from the evidence to say whether this affects the reliability of either or both reports.

[364] Whilst some of Dr Thiede's criticisms of Mr Jordaan's report are not without substance, he does not analyse the model produced by Mr Jordaan in any detail. He offers no positive evidence of the model on which the Pricing Committee worked to satisfy itself that the dispensing fee is appropriate and that pharmacies will be viable if it is applied. In the result the only evidence we have on the operating profit of a dispensary of a community pharmacy taken in isolation, apart from assertions unsupported by evidence, is that provided by Mr Jordaan.

Courier pharmacies

[365] Courier pharmacies, as their name suggests, deliver medicine to their clients. They operate dispensaries but do not have front shops. Their services are of particular importance to people who because of illness or other reasons cannot easily access community pharmacies. They serve chronically ill patients providing them with medication (often expensive) at their homes and process claims for refunds from medical aid schemes.

[366] In considering the profitability of courier pharmacies Dr Stillman relies on data from Chronic Medical Dispensary (CMD), which is owned by the fourth respondent in this appeal. CMD is one of the three largest courier pharmacies in South Africa. These pharmacies deal in high volumes of sales and have a low profit margin. In April 2004 CMD had an operating profit margin of 1,1%. The calculations provided to Dr Stillman show that if revenue had been based on the dispensing fee, CMD would have had a negative operating profit margin of 5,1%.

Medical centres

[367] Medical centres offer a range of health services provided by doctors, dentists, and other health professionals including pharmacists. These pharmacies are similar in most respects to community pharmacies, but are said to have front shops that are much smaller than those of community pharmacies. Dr Stillman relies on information provided by Medicross, the operator of 44 pharmacies in these centres, and Mr

Kellerman, a consultant to Medicross. According to this information, if the revenue of these pharmacies had been based on the dispensing fee the gross profit of the pharmacies would have been reduced by 68% and the pharmacies would have had operating losses equal to 33% of revenue. In his second report Dr Stillman corrects these figures. In the interim SEPs had been published and Mr Kellerman could now rely on that information instead of estimates on which his first assessment had been based. As a result he reduced the figures to a gross profit loss of 59% and an operating loss of 20%.

Hospitals

[368] Hospitals are required to have pharmacies to serve their patients. Some of these pharmacies have small "front shops" as well. Dr Stillman was provided with data on actual revenue and expenses of pharmacies in the Netcare group in 2003, and with estimates by Mr Kellerman of the impact on the revenue if that had been based on dispensing fees under the regulations. This indicated that the gross profit of the pharmacies would have been reduced by 63% and that this would have resulted in an operating loss equal to 8,7% of revenue.

[369] The estimates of the impact that the dispensing fee will have both on the operations of pharmacies in medical centres and on hospitals were thus made by Mr Kellerman and not by Dr Stillman. Mr Kellerman says that the data was provided to him by the operator of the medical centre pharmacies and included details of 4,5 million transactions. He analysed the 4,5 million transactions to determine the

weighted average net cost of sales which he estimated to be close to the future SEP for such sales. He does not say, however, how he used this information to calculate the total of the dispensing fees which would have been received for the 4,5 million transactions.

[370] His analysis of data from hospital pharmacies was on 12 million transactions in 2003 and was done to enable Dr Stillman to compare the financial results that were actually obtained in 2003 with the results that would have been obtained if the new regulations had been in effect. He confirms that estimates were made and provided to Dr Stillman. The estimates appear from Dr Stillman's report, but not the details of how they were made.

[371] Dr Stillman's evidence as far as medical centres and hospital pharmacies are concerned is based on Mr Kellerman's analysis of relevant data, which is not set out in any detail in Mr Kellerman's affidavit, nor commented on by any of the applicants' experts. The accuracy of the data is, however, not challenged. Although the basic information is stated baldly, it has been verified by Mr Kellerman on oath, and there is no reason to reject it.

[372] The response of the Minister and the Pricing Committee to the charge that the dispensing fee will destroy the viability of pharmacies is two-pronged. First, they rely on experts to support their determination of the dispensing fee, and to criticise the correctness of the conclusions reached by Mr Jordaan, Dr Theron and Dr Stillman.

Secondly, they contend that the evidence relied on by the Pharmacies is based on a static model which assumes that there will be no change in market conditions. That assumption, they contend, cannot be made. There are presently too many pharmacies for the population served by them, and the pricing scheme is premised on the assumption that when it comes into force the market will become more rational and pharmacies that are not viable will close down. The volume of business of those pharmacies that remain will increase, and will be sufficient to enable them to trade profitably.

[373] The experts on whom the Minister and the Pricing Committee rely are Dr Pillay, Professor Henry, Professor Mossialos, Professor Mooney and Dr Thiede. Of these five, only Dr Pillay and Dr Thiede comment on the Jordaan and Stillman reports.

[374] Dr Pillay's comments are directed to Mr Jordaan's conclusions concerning the impact of the dispensing fee on gross profit margins. He joins issue with Mr Jordaan on the relevance of gross profit, saying that the negative gross profit margin on which he relies is not an indicator of viability. He asserts that to determine viability regard should be had to the revenue and operational expenses of the dispensary only, saying:

> "One should bear in mind that the regulations only affect the dispensary within a retail pharmacy. None of the data that has been supplied to date addresses the income and expenditure of the dispensary which is directly relevant to the regulations. Providing information on the income and expenditure of the entire pharmacy or store is irrelevant since the regulations only relate to the dispensary."

[375] He also says that the dispensing fees prescribed by the regulations do not differ materially from fees offered in other countries where prices are regulated. He gives no details, however, of the countries he has in mind or of the way dispensing fees are controlled there.

[376] Whilst gross profit may not in itself be an indicator of the viability of a particular store – a well-run store with high volumes will fare better than a badly run store with low volumes – gross profit is a factor relevant to viability. There must be a margin at which a pharmacy will not be viable, and that is the focus of Dr Stillman's evidence.

[377] I have already referred to Dr Thiede's evidence concerning Mr Jordaan's report. He also criticises Dr Stillman, challenging his qualifications and his approach to the problem. He says that the methodology utilised is not explained in detail and that it does not conform to standards applicable to rigorous scientific studies, but does not identify where it is said to fall short of what may be required to address the issues in the present case. He criticises Dr Stillman for looking at the store as a whole instead of the dispensary in isolation, and for a failure to have regard to other revenue streams apart from dispensing and the front shop. These arguments are echoed in the affidavits of Professor McIntyre and Dr Zokufa and have already been addressed.

[378] Dr Thiede's criticisms are negative. He offers no positive evidence of the model on which the Pricing Committee worked to satisfy itself that the dispensing fee is appropriate and that pharmacies will be viable if it is applied.

[379] Professor Henry, a member of the Pricing Committee, deals with the Australian model. He does not, however, address directly any of the expert or other evidence relied on by the Pharmacies concerning viability, or say how the fees prescribed in the regulations were calculated.

[380] According to Professor Henry the Australian scheme is based on the subsidisation of medicines sold. It allows for a two-tier system, in which there is a dispensing fee of AU$4,66 and a retail margin of 10% on prescription items up to AU$180. Using an exchange rate of AU$1 = R5 (the rate he adopts) this works out at approximately R23 per prescription plus 10% of the retail price. Nothing is said about whether discounts or other incentives are permissible, how compounding and admixing is dealt with in Australia, nor how rural pharmacies or specialist pharmacies such as hospital pharmacies are dealt with under the scheme.

[381] Professor Henry does not say how medicines costing more than AU$180 are dealt with. Dr Theron in a report attached to her affidavit deals with this, saying that the retail margin is AU$18 for medicines costing AU$180 or more up to AU$360, and 5% for medicines costing AU$360 or more. This allegation is not denied.

[382] The Australian dispensing fee is higher than the dispensing fee prescribed by the regulations, but in Professor Henry's view this is accounted for by the difference between the purchasing power of the Rand and the Australian Dollar. He also says that the dispensing fee prescribed by the regulations compares favourably with dispensing fees allowed in developing countries. He does not give any information, however, of what the provisions of those schemes are or how they compare with the Pricing Committee's proposals.

[383] The Australian system described by Professor Henry has features similar to the system adopted by the Pricing Committee, but differs from the latter in material respects. It does not have a SEP (which is apparently unique to South Africa) and makes provision for other charges to be made by pharmacists, though these are not explained or dealt with in his evidence. The most important distinction, however, is that the Australian dispensing fee has no cap. There is a 10% surcharge on the retail price of all medicines, reducing to 5% as the retail price gets higher. The South African model is quite different.

[384] Professor Mossialos deals with pricing systems in other countries but does not give sufficient detail to enable reliable comparisons to be made. He deals only cursorily with the dispensing fee, saying that it is "very reasonable" within the context of the current framework of South Africa's pharmaceutical system. He does not, however, engage in the debate concerning the impact of the regulations on the

viability of pharmacies in the South African context, or deal in any way with the expert reports relied upon by the Pharmacies.

[385] Professor Mooney deals only with the question whether regulation or free market principles should have been followed as a matter of policy in the formulation of the pricing system. This is in response to Professor Kantor's affidavit criticising regulated prices. Professor Mooney's evidence is not relevant to the question whether the dispensing fee is or is not an "appropriate" fee.

Changing conditions

[386] The assumption that market conditions will change is a reasonable assumption. It appears from Dr Stillman's report that 14 of the community pharmacies acquired by New Clicks were trading at a loss in 2003. According to PSSA's written submissions made in response to the draft regulations, an actuarial analysis based on a survey of 176 community pharmacies conducted by PSSA showed that 24% of these pharmacies operated at a loss during the 2003 financial year. Of this group of loss-making pharmacies, 39% had an annual turnover of less than R2,47 million, 27% a turnover of between R2,47 million and R3,82 million, 23% a turnover of between R3,82 million and R6,28 million, and 9% a turnover in excess of R6,28 million.

[387] Dr Zokufa says that a critical factor in setting the dispensing fee was the present dispensing workload which was considered to be too low. He goes on to say that pharmacists must find a way of addressing this issue and also ways of supplementing

their income by finding sources of revenue other than dispensing fees. He seems to accept that on current volumes the dispensing fee may not be adequate.

[388] It is reasonable to assume that once the impact of the more stringent market conditions demanded by the regulations is felt, the number of pharmacies will be reduced and the volume of business available to those who survive will increase. There is, however, no evidence to show what the impact of this is likely to be on the profitability of pharmacies, or on the accessibility of medicines, particularly in rural areas, where it is acknowledged by Professor McIntyre that trading conditions are difficult.

Evaluation of the evidence

[389] The Pharmacies rely on section 6(2)(e)(iii) of PAJA, which provides that a ground for reviewing administrative action is that "irrelevant considerations were taken into account or relevant considerations were not considered". They also contend that the prescribed dispensing fee is not authorised by the Medicines Act because it is not an "appropriate" fee.

[390] I have previously mentioned that courts must be sensitive to the special role of the executive in making regulations. This, and the special expertise of the Pricing Committee, are factors to which due regard must be paid in the present case. What is or is not relevant, and what is appropriate, were in the first instance matters for the

Pricing Committee and the Minister to decide. But, as pointed out in *Bato Star*,[234] a court should not "rubber-stamp" a decision simply because of the identity of the decision maker.[235]

[391] The Pricing Committee seems to have calculated the dispensing fee without any evidence of the breakdown of the income and expenditure of the dispensaries, information they considered to be important for the proper determination of the dispensing fee. They assumed that dispensing subsidises the operations of the front shops of community pharmacies. They have not, however, provided any evidence to support this assertion, which is denied by the Pharmacies. As Dr Stillman points out, it is unlikely that front shops would be operated if they were indeed loss-making ventures. The Pricing Committee does not say what weight was attached to this assumption in the calculation of the dispensing fee.

[392] The Minister and the Pricing Committee allege that pharmacists can add to their income by charging for professional services that are presently rendered without charges being made. They do not say, however, what weight was attached to this consideration in fixing the dispensing fee. If that had been done the assumption could have been interrogated. The evidence of the Pharmacies is that this would be negligible, and there is no evidence to contradict this.

[234] Above n 80.

[235] Id at para 48.

[393] The Minister and the Pricing Committee do not deal with the impact of the dispensing fee on rural pharmacies. Professor McIntyre says that the Pricing Committee considered the predicament of rural pharmacies which are "economically disadvantaged, primarily because of a comparatively low turnover and also unfavourable payment conditions from wholesalers." They concluded, however, that this is the result of "distortions in the health sector" and that "an appropriate dispensing fee should be as neutral as possible in respect of such distortions." No mention is made of what those distortions (if any) are other than low turnover and adverse payment conditions. Moreover, they do not suggest how these distortions could be overcome, what the impact of the dispensing fee will be on the economically disadvantaged rural pharmacies, and how that will affect access to medicines in rural areas.

[394] Against this background the attitude of Professor McIntyre and Dr Zokufa to the hearings at which oral representations were made by the Pharmacies and others affected by the draft regulations is relevant. They are both at pains to distance the Pricing Committee from these hearings, saying that they were hearings called by the Department and were not meetings of the Pricing Committee.

[395] It is correct that the "hearings" were not meetings of the Pricing Committee. The decision to convene the hearings was, however, taken at a meeting of the Pricing Committee on 27 January 2004 and is recorded in the amended minutes of that meeting. According to these minutes the oral representations would be organised and

led by the "Directorate" and Pricing Committee members would also be invited. The minutes record that:

> "The Directorate should finalise dates for the stakeholder representations and inform the Committee members by 6 February 2004. The draft programme should be circulated to the Committee members."

It is also recorded that:

> "A standard invitation for the representations to be drawn up by the Department's Legal Unit. In this invitation, it should be clarified that the presentations sessions will only be for presentation and not clarification. Also indicated should be the fact that only stakeholders who have submitted written comments can sit in for oral representations."

[396] The invitations to make oral representations were sent out near the beginning of February. The minutes of the Pricing Committee's meeting on 20 February record the following under the heading: "Update on plans for stakeholder representations discussion":

> "The Directorate presented the draft stakeholder presentation schedule and informed the committee on the way forward. After a lengthy discussion the following decisions were taken".

The decisions are then listed and include the following:

> "• As associations present the general views it would be helpful to the committee to hear the views of the individuals belonging to such an association. It would give the committee an opportunity to weigh the different data. It was suggested that individual groupings should however be

> told to give different information than what would be provided by the association.
>
> . . . .
>
> - All committee members should indicate the dates on which they would be able to attend stakeholder presentations between 8 and 26 March 2004.
>
> . . . .
>
> - All members of the Pricing Committee should commit to attend the stakeholder presentations.
> - The key purpose of the presentations is to listen and not engage in discussions. The Pricing Committee and the Department will have an opportunity to ask questions but no questions of clarification will be allowed from the stakeholders.
> - A list of key questions should be developed and the data being presented should be interrogated very carefully."

[397] Pointedly Professor McIntyre and Dr Zokufa both say that the Pricing Committee took into account what was contained in the written representations made concerning the draft regulations but do not say the same about the oral representations. All that is said is that the hearings were recorded both on videotape and audiotape and the tapes were available for those members of the Pricing Committee "who so wished, to access what was said". Professor McIntyre says she watched some of the videotapes of some of the hearings – she does not say which – but no suggestion is made that any other members of the Pricing Committee did so, or that any report on the oral hearings was compiled and considered by the Pricing Committee.

[398] I have previously referred to the invitation that was addressed to "stakeholders".[236] That invitation stresses the importance of the hearings and the need

[236] At paras 164-166 above.

to supply "accurate and substantiated information to the Department and the Pricing Committee on how the proposed regulations may affect your interests." Professor McIntyre attached a copy of the invitation to her affidavit. She does not suggest that any statement in the invitation concerning the participation of the Pricing Committee was incorrect or made without the authority of the Pricing Committee.

[399] Although it was not necessary to invite oral representations in addition to the written representations that had been made, and although it was not necessary for all the members of the Pricing Committee to attend the stakeholder meetings, once the invitation had been issued the information furnished at the meetings could not be ignored. Information as to how the regulations would affect the interests of pharmacists was material to the work of the Pricing Committee. Arrangements should have been made for those who attended the oral hearings to report to the Pricing Committee on the representations that were made. This, however, was not done and it seems that in deciding upon the recommendation to be made to the Minister on an appropriate dispensing fee, regard was had only to the written representations. There is nothing to show that the concerns expressed by the Pharmacies at the oral hearings or the information provided by them at the hearings was taken into account by the Pricing Committee.

[400] The Pricing Committee was the only body able to explain how they arrived at the dispensing fee and how they satisfied themselves that it would be sufficient to meet the concerns raised in the many representations made to them by pharmacists

and pharmacists' organisations that the dispensing fee will cause pharmacies to operate at a loss and destroy the viability of the profession. If this had been done the information may have been sufficient to rebut these averments.

[401] Their response was, however, negative. It comes down to this. There are too many pharmacies and their workload is too low. Ways must be found to address this, and to develop additional sources of revenue other than dispensing. The evidence tendered by the Pharmacies that, on the basis of the prescribed dispensing fees, pharmacies will cease to be viable is flawed. All relevant factors were taken into account by the Pricing Committee and given careful consideration. The dispensing fee is appropriate and compares favourably with fees in foreign countries where prices of medicines are regulated.

[402] The only direct evidence of the impact of the dispensing fee on the viability of pharmacies is that contained in the written representations made to the Pricing Committee which form part of the record, and in the expert evidence relied on by the Pharmacies. Although there are criticisms of it, there is a substantial body of evidence which called for an answer by the Pricing Committee and the Minister. This, however, was not forthcoming.

[403] The Pricing Committee has provided no models or other evidence to demonstrate how the dispensing fee was calculated or how the members of the Pricing Committee satisfied themselves that it was appropriate. It has not told us what

assumptions it made about the probable SEPs in calculating the dispensing fee, or how it assessed the dispensing fee when it seems to have had no data dealing with dispensary revenue and expenses which it considered to be essential for that purpose. It has not addressed in any meaningful way the contention that the dispensing fee will lead to pharmacy closures that will impair accessibility to health care particularly in rural areas. The assertions made by Professor McIntyre and Dr Zokufa about additional revenue sources and the subsidisation of the front shop by the back shop, are at best flimsy. The failure to make provision for compounding in the dispensing fee is a material misdirection.

[404] "Accountability, responsiveness and openness" on the part of government are foundational values of our Constitution. An allegation has been made by professional organisations representing pharmacists that the dispensing fee will destroy the viability of pharmacies, and impair access to health care. That allegation is supported by a sufficient body of evidence to show that this is a real possibility. In the circumstances the applicants were under an obligation to explain how they satisfied themselves that this would not be the result of the dispensing fee prescribed in the regulations. They were the only persons who could provide this information. They did not, however, do so. Absent such explanation, there is sufficient evidence on record to show that the dispensing fee is not appropriate.

Appropriate dispensing fee for doctors and other health professionals: regulation 12

[405] Both New Clicks and PSSA challenge the validity of the regulations as a whole. In their Notice of Motion PSSA claim in the alternative that certain regulations should be set aside as being invalid. In this alternative prayer, the validity of regulation 12 is not challenged. New Clicks did not raise any challenges in the alternative to their main prayer claiming that the regulations as a whole are invalid. In argument, however, they contended that if their argument on the other regulations challenged by them succeeds, regulation 12 should also be declared invalid, because it cannot be severed from the other regulations. No argument was addressed to us as to whether or not the fees prescribed in regulation 12 are appropriate and I express no opinion on that. As far as severance is concerned, that is dealt with in the judgment of the Court and need not be addressed here.

Schedule 0 medicines

[406] Regulation 13 provides that the "appropriate fee" to be charged by any person, other than a wholesaler or distributor, in respect of Schedule 0 medicines "shall not exceed the percentage mark-up in respect of that medicine or Scheduled substance that was applied at the date of commencement of these regulations." No attempt was made in either the written or oral arguments to justify this regulation. The "fee" is clearly not appropriate. It differentiates between those whose mark-ups were not the same at the prescribed date. Those selling at a substantial profit are entitled to continue to do so. Those selling at a small profit or even at a loss to attract customers are obliged to continue doing so. It was contended that the challenge to the regulation is moot because Schedule 0 medicines have been excluded from the operation of the

Medicines Act in terms of section 36.[237] This, however, was only done on 19 November 2004, some five months after the regulations were promulgated, and four months after the applications were launched in the High Court. During that period, retailers who failed to comply with regulation 13 will have been liable to be prosecuted if the regulation stands. Moreover, the exclusion in terms of section 36 may be withdrawn or amended, and as long as that is the case, it cannot be said that the regulation will be "moot" in the future. Regulation 13 must therefore be declared to be invalid.

Regulation 14(5)

[407] This regulation requires a manufacturer, importer, exporter, wholesaler, distributor, pharmacist, person licensed in terms of section 22C(1)(a), or any other person selling a medicine or Scheduled substance in the Republic, if requested to do so by the Director-General, to provide information relating to particular medicines and Scheduled substances. PSSA contends that the information called for by the regulation is not sanctioned by section 22G of the Medicines Act which makes provision only for regulations to be made for the "introduction of a transparent pricing system".

[408] Regulation 14(5) entitles the Director-General to request information concerning

[237] Section 36 provides:

> "The Minister may, on the unanimous recommendation of the members present at any meeting of the council, by notice in the Gazette exclude, subject to such conditions as he may determine, any medicine from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice."

> "the comparative efficacy, safety and cost effectiveness of the medicine or Scheduled substance relative to that of other medicines or Scheduled Substances in the same therapeutic class compiled in a manner consistent with guidelines published by the Director-General in the Gazette from time to time."

PSSA contends that this has no intelligible meaning and is void for vagueness. Also, that it does not deal with the introduction of a transparent pricing system for medicines and is therefore ultra vires.

[409] Information as to costs, quality and risks of medicine being sold is relevant to a transparent pricing system. So too is comparative information about such matters which may help consumers to know whether the price of a particular medicine is in line with that of other medicines which might be taken for the same complaint. Although the regulation is in broad and general terms, the power is not unlimited and is constrained by the requirement that it must be exercised reasonably to give effect to the purpose of the legislation.[238]

[410] The regulation empowers the Director-General to seek information relevant to pricing. How he does so, should he elect to call for information, will determine whether the information sought is relevant to a pricing system and whether it meets the requirements of certainty that are called for. The power itself, however, construed in the context of the Medicines Act and the regulations, is sufficiently clear to

[238] *Affordable Medicines* above n 127 at para 126.

determine its boundaries. The objection to regulation 14(5) must therefore be dismissed.

Regulations 21(a) and (c)

[411] Regulation 21 empowers the Director-General to

> "publish or otherwise communicate, or require manufacturers, importers, wholesalers, distributors, pharmacists or persons licensed in terms of section 22C(1)(a) of the Act to publish or otherwise communicate in such manner and format as he or she may by notice in the Gazette determine, information in relation to a particular medicine or Scheduled substance or class or category of medicines or Scheduled substances or the sale of a medicine or Scheduled substance for the purpose of—
> (1) informing the public of—
>
> (a) the therapeutic value of a medicine or Scheduled substance relative to the single exit price set by the manufacturer;
> (b) the single exit price, strength, dosage form and pack size of a medicine or Scheduled substance;
> (c) the risks associated with a particular medicine or Scheduled substance relative to the single exit price of that medicine or Scheduled substance".

[412] PSSA objects to this regulation for the same reasons that it objects to regulation 14(5), contending that it is not related to a transparent pricing system and that it is void for vagueness. The price, therapeutic value and risks associated with a medicine are relevant to price and transparency. However, the therapeutic value of and risks associated with a particular medicine are objective standards which remain the same whatever the SEP might be. How such factors can be described in relation to the SEP, other than by stating the SEP which is dealt with in subsection (b), is not clear to me.

[413] The regulation must be construed as being limited to empowering the Director-General to publish or require others to publish or communicate information concerning the therapeutic value, risks and single exit price of medicines that is reasonably related to a transparent pricing system.

[414] The regulation does not require any person or persons to do anything unless and until the Director-General publishes a notice requiring them to do so. If a notice is published that simply requires publication of details of the therapeutic value, risks and single exit price of the medicine it would be relevant and could not be objected to as being vague. If a notice should require that information, and in addition require the therapeutic value and risks to be dealt with "relative to the single exit price" it would in my view be too vague to be complied with. More than that would be required from the direction. What that might possibly be is beyond me now. Greater certainty would have to be given to it in the Director-General's notice should the occasion arise for such a notice to be issued.

[415] If, for that purpose, the Director-General requires information to be published "relative to the single exit price" the notice must indicate what, in addition to the SEP, is required. The notice will be valid only if the "additional" information is relevant to a transparent pricing system and is called for in terms that are sufficiently clear to enable the persons affected to know what is required. Construed in this way, the regulation is neither ultra vires nor too vague to be enforced. I would therefore dismiss the objection to the regulation.

The Director-General's power to declare that the SEP is unreasonable: regulations 22 and 23

[416] Regulation 22 vests in the Director-General a power to determine that the SEP of a medicine or Scheduled substance is unreasonable. The factors to which the Director-General must have regard in making such a determination are listed in regulation 23.

[417] Regulation 22 makes provision for a hearing to be given to the person who will be affected by such a determination,[239] and goes on to provide[240] that if the Director-General "is not convinced" after such enquiry that the SEP is reasonable,

> "he or she may publish a notice in the Gazette to the effect that in the opinion of the Director-General, the single exit price is unreasonable and must state the reasons for such opinion."

If this is done, reasons have to be given by the Director-General for such a determination. The publication appears to be the only sanction attaching to the determination. There is no requirement in the Medicines Act or in the regulations dealing with the setting of the SEP, that the SEP must "be reasonable"; the only requirement is that the SEP must not exceed the 2003 benchmark set in regulation 5(2)(c) or the international benchmarks contemplated by regulation 5(2)(e). As long as the SEP meets those requirements it is valid.

[239] Regulation 22(2).

[240] Regulation 22(3).

[418] It may be that regulations 22 and 23 were intended to provide a mechanism for addressing differences that might arise in relation to the determination of the maximum SEP or to the application of the contemplated international benchmarking standards. If that had been done it would have provided a mechanism for addressing such issues. The regulations are, however, not directed to that end. They empower the Director-General to act if he or she is not *convinced* that a SEP is reasonable, whether or not that SEP has been fixed in accordance with the regulations.

[419] A public declaration by the Director-General that he is not convinced that a SEP that meets the requirements of the regulations is reasonable, is unrelated to a pricing system which does not require prices to be set at amounts that the Director-General is convinced are reasonable. Indeed, such a requirement would be of doubtful validity, and other criteria are set for the determination of the SEP. As long as the SEP complies with the requirements of the pricing system, the views of the Director-General as to the reasonableness of the price are irrelevant. In the circumstances regulations 22 and 23 are not authorised by section 22G of the Medicines Act and are accordingly invalid.

Conclusion

[420] The conclusions to which I have come on the challenges on the regulations, and those reached by the other members of the Court, are summarised in the judgment of

the Court. I agree that the appropriate order to be made in this case is the order made in that judgment.

NGCOBO J:

Introduction

[421] Although the High Court (both the majority and the minority judgments) considered the question whether the Promotion of Administrative Justice Act[241] (PAJA) applied to the regulations which are the subject matter of these proceedings and reached different conclusions, the Supreme Court of Appeal (SCA) found it unnecessary to consider that question. In this Court, as in the courts below, both PSSA and New Clicks (together referred to as "the pharmacies") contended that PAJA was applicable in these proceedings. The Minister and the Pricing Committee (together referred to as "the applicants") contended otherwise. The threshold question that must be decided in this case is therefore whether PAJA is applicable as contended by the pharmacies.

[422] The Chief Justice has concluded that PAJA applies. Moseneke J, for reasons advanced in his judgment, has found it unnecessary to consider the question of the applicability of PAJA. He prefers instead to assume without deciding that the administrative justice standards of lawfulness, reasonableness and procedural fairness

[241] Act 3 of 2000.

as given effect in PAJA apply in this case. I am unable to agree with this approach. In concluding that PAJA governs this case, the Chief Justice holds that PAJA, in general, applies to regulation-making. I prefer to answer the narrow question, namely, whether PAJA applies to the specific power to make regulations conferred by section 22G(2)(a)-(c) of the Medicines and Related Substances Act[242] (Medicines Act). For reasons advanced by the Chief Justice, I agree that PAJA is applicable to this narrow question. But there are additional reasons why PAJA is applicable.

[423] The approach adopted by the SCA to the question whether PAJA governs these proceedings raises the question whether the SCA was obliged to consider the applicability of PAJA. In particular, this raises the question whether where, as here, the parties have expressly relied upon PAJA, a statute that was enacted to give effect to section 33(1) of the Constitution and to codify the principles of administrative justice, it is permissible for a court to decide the matter on the basis of section 33(1) of the Constitution without a prior finding that the provisions of PAJA are deficient in the remedy that they provide. This issue has been raised in this Court before albeit in different contexts.[243] On each occasion, this Court has found that a decision on this issue was not required for the resolution of those cases. This occasion is different. And as I shall show, a decision on this issue is necessary in this case.

[242] Act 101 of 1965. I should emphasise that I refrain from deciding whether PAJA is applicable to regulation-making in general.

[243] *National Education Health and Allied Workers Union (NEHAWU) v University of Cape Town and Others* 2003 (3) SA 1 (CC); 2003 (2) BCLR 154 (CC) and *Ingledew v Financial Services Board: In re Financial Services Board v Van der Merwe and Another* 2003 (4) SA 584 (CC); 2003 (8) BCLR 825 (CC).

[424] In addition, there is a difference of opinion between the Chief Justice and Moseneke J on the question whether the dispensing fees adopted in the regulations are appropriate. The Chief Justice has concluded that they are not. Moseneke J concludes that they are, save in relation to courier and rural pharmacies. He finds that the dispensing fees do not take into account the unique circumstances of these pharmacies. For reasons set out below, I agree with this finding. However, I am unable to agree with the conclusion that Moseneke J reaches on the issue of the appropriateness of the dispensing fees. Nor do I agree with the remedy that he proposes in relation to courier and rural pharmacies. While I agree with the Chief Justice that the dispensing fees are not appropriate, my reasons for reaching that conclusion differ somewhat from those relied upon by him.

[425] I write separately therefore to: (a) consider the question whether the SCA was obliged to determine whether PAJA is applicable in these proceedings; (b) provide additional reasons why I hold that PAJA governs these proceedings; and (c) provide my reasons for concluding that the dispensing fees adopted by the regulations are not appropriate as required by section 22G(2)(b) of the Medicines Act.

Is it necessary to decide the question of the applicability of PAJA?

[426] In their respective notices of motion, both PSSA and New Clicks sought orders reviewing and setting aside the recommendation of the Pricing Committee. In addition, they sought orders declaring invalid the Regulations made pursuant to section 22G(2) of the Medicines Act. In seeking these orders, the pharmacies relied

upon the provisions of section 6 of PAJA. In particular, New Clicks submitted that the Regulations are unlawful because "they have been adopted in a manner which is in conflict with the requirements of section 6 of PAJA . . .". Section 6 of PAJA substantially codifies the grounds of review.[244]

[427] In argument, both in this Court and in the courts below, the pharmacies submitted that the review of the recommendation of the Pricing Committee is governed by PAJA. In this Court, PSSA devoted a chapter in its written argument contending that PAJA governed these proceedings. For their submissions, the pharmacies relied on the grounds of review set out in PAJA. They submitted that the making of regulations by the Minister constitutes administrative action and is therefore subject to review under PAJA.

[428] In their supplementary argument in this Court, the applicants contended that neither the recommendation nor the Regulations made pursuant to such recommendation are subject to review under PAJA. They submitted that neither amounts to administrative action as defined in PAJA. In the alternative they submitted that given the decision by the majority of the High Court that the conduct of the Pricing Committee and the Regulations were reviewable in terms of the common law and the Constitution, it is not necessary to determine in this case whether or not PAJA applied.

[244] *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Others* 2004 (4) SA 490 (CC); 2004 (7) BCLR 687 (CC) at para 25.

[429] Both judgments in the High Court considered the question of the applicability of PAJA and reached different conclusions. The majority held that both the recommendation of the Pricing Committee and the ministerial regulation-making authority were not subject to PAJA. It held that they were subject to review under the constitutional doctrine of legality, section 33(1) of the Constitution and the common law. For its part, the minority held that PAJA was applicable.

[430] On appeal, the SCA approached the matter on the basis of the doctrine of legality. Relying on this doctrine, the SCA held that the Minister cannot accept recommendations or promulgate regulations that do not fall squarely within section 22G of the Medicines Act.[245] The SCA accordingly refrained from considering the question of the applicability of PAJA after concluding that it had no bearing on its judgment.

[245] Section 22G of the Medicines Act provides:

> "(1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.
> (2) The Minister may, on the recommendation of the pricing committee, make regulations—
> (a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;
> (b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a);
> (c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines.
> (3) (a) The transparent pricing system contemplated in subsection (2)(a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.
> (b) No pharmacist or person licensed in terms of section 22C(1)(a) or a wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).
> (c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2)(b).
> (4) To the members of the pricing committee who are not in the full-time employment of the State may be paid such remuneration and allowances as the Minister, with the concurrence of the Minister of Finance, may determine."

[431] Now there can be no question that the pharmacies sought judicial review of the recommendation of the Pricing Committee and the Regulations based on that recommendation. For their causes of action, they expressly relied upon the provisions of section 6 of PAJA. They were right. In *Bato Star* this Court held that "the cause of action for the judicial review of administrative action now ordinarily arises from PAJA, not from the common law as in the past."[246] And it went on to hold that "the authority of PAJA to ground such causes of action rests squarely on the Constitution."[247]

[432] The rationale for the holding in *Bato Star* appears from the following passage:

> "In *Pharmaceutical Manufacturers Association of SA and Another: In re Ex parte President of the Republic of South Africa and Others*, the question of the relationship between the common-law grounds of review and the Constitution was considered by this Court. A unanimous Court held that under our new constitutional order the control of public power is always a constitutional matter. There are not two systems of law regulating administrative action — the common law and the Constitution — but only one system of law grounded in the Constitution. The Courts' power to review administrative action no longer flows directly from the common law but from PAJA and the Constitution itself. The grundnorm of administrative law is now to be found in the first place not in the doctrine of ultra vires, nor in the doctrine of parliamentary sovereignty, nor in the common law itself, but in the principles of our Constitution. The common law informs the provisions of PAJA and the Constitution, and derives its force from the latter. The extent to which the common law remains relevant to administrative review will have to be developed on a case-by-case basis as

[246] *Bato Star* above n 244 at para 25; *Zondi v Member of the Executive Council for Traditional and Local Government Affairs and Others* 2005 (3) SA 589 (CC); 2005 (4) BCLR 347 (CC) at para 99.

[247] *Bato Star* id.

> the Courts interpret and apply the provisions of PAJA and the Constitution."[248] (Footnotes omitted.)

[433] PAJA is national legislation contemplated in section 33(3) of the Constitution, which the legislature was required to enact to give effect to the rights guaranteed in section 33. As its long title proclaims, the purpose of PAJA is:

> "To give effect to the right to administrative action that is lawful, reasonable and procedurally fair and to the right to written reasons for administrative action as contemplated in section 33 of the Constitution".

[434] In *NAPTOSA*,[249] the Cape of Good Hope High Court had occasion to consider whether in the context of the Labour Relations Act,[250] (LRA) it is appropriate to grant relief directly under section 23(1) of the Constitution without a complaint that the LRA was constitutionally deficient in the remedies that it provides. The court held that it could not conceive that it is permissible for an applicant, save by attacking the constitutionality of the LRA, to go beyond the regulatory framework which it establishes.[251] In reaching this conclusion, the High Court was concerned that were the practice to be permitted, it would encourage the development of two parallel

[248] *Bato Star* above n 244 at para 22.

[249] *NAPTOSA and Others v Minister of Education, Western Cape, and Others* 2001 (2) SA 112 (C). Section 23(1) of the Constitution provides that: "Everyone has the right to fair labour practices". The Labour Relations Act, 1995, was enacted to give effect to the right to labour relations guaranteed by section 23 of the Constitution.

[250] Act 66 of 1995.

[251] *NAPTOSA* above n 249 at 123I.

streams of labour law jurisprudence, one under the LRA and the other under section 23(1). It considered this to "be singularly inappropriate".[252]

[435] In *NEHAWU*,[253] this Court considered *NAPTOSA* but refrained from expressing any opinion on it as it found that it had no application in that case. In *Ingledew*,[254] again this Court referred to *NAPTOSA* and observed, that together with other cases referred to in *Ingledew*, it "cast doubt on the correctness of the proposition that a litigant can rely upon the Constitution, where there is a statutory provision dealing with the matter without challenging the constitutionality of the provision concerned."[255]

[436] In my view, there is considerable force in the view expressed in *NAPTOSA*. Our Constitution contemplates a single system of law which is shaped by the Constitution. To rely directly on section 33(1) of the Constitution and on common

[252] Id at 123B.

[253] *NEHAWU* above n 243 at para 17.

[254] *Ingledew* above n 243.

[255] These cases are discussed in *Ingledew*. The cases that were referred to in *Ingledew* were largely concerned the question whether in an action against the state, a litigant may, in addition to the right to require discovery in terms of Rule 35 of the Uniform Rules of Court, seek relief in terms of section 32 of the Constitution (the right of access to information). One line of cases suggests that a litigant may in addition to the rules rely on section 32. These cases include *Swissborough Diamond Mines (Pty) Ltd and Others v Government of the Republic of South Africa and Others* 1999 (2) SA 279 (T) at 320C-D; *Phato v Attorney-General, Eastern Cape, and Another; Commissioner of the South African Police Services v Attorney-General, Eastern Cape, and Others* 1995 (1) SA 799 (E) at 815G; *Khala v Minister of Safety and Security* 1994 (4) SA 218 (W) at 225 F and 226 G; *Van Niekerk v Pretoria City Council* 1997 (3) SA 839 (T) at 850B. The other line of cases cast doubt on the correctness of the proposition that a litigant can in an action against the state, in addition to the right to require discovery in terms of Rule 35, seek relief in terms of section 32. These cases are *Inkatha Freedom Party and Another v Truth and Reconciliation Commission and Others* 2000 (3) SA 119 (C) at 135J-137C; and *Alliance Cash and Carry (Pty) Ltd v Commissioner, South African Revenue Service* 2002 (1) SA 789 (T). These cases must be understood in the context of the rules relating to discovery. However, to the extent that the *Swissborough* line of cases suggest that a litigant can rely upon the Constitution where there is a statutory provision dealing with the matter without challenging the constitutionality of the provision concerned, I am unable to agree with their reasoning.

law when PAJA, which was enacted to give effect to section 33 is applicable, is in my view inappropriate. It will encourage the development of two parallel systems of law, one under PAJA and another under section 33 and the common law. Yet this Court has held that there are not two systems of law regulating administrative action – the common law and the Constitution – "but only one system of law grounded in the Constitution."[256] And in *Bato Star* we underscored this, holding that "[t]he Courts' power to review administrative action no longer flows directly from the common law but from PAJA and the Constitution itself."[257]

[437] Where, as here, the Constitution requires Parliament to enact legislation to give effect to the constitutional rights guaranteed in the Constitution, and Parliament enacts such legislation, it will ordinarily be impermissible for a litigant to found a cause of action directly on the Constitution without alleging that the statute in question is deficient in the remedies that it provides.[258] Legislation enacted by Parliament to give effect to a constitutional right ought not to be ignored. And where a litigant founds a cause of action on such legislation, it is equally impermissible for a court to bypass the legislation and to decide the matter on the basis of the constitutional provision that is being given effect to by the legislation in question. Thus in *Bato Star* this Court held that "[t]o the extent, therefore, that neither the High Court nor the SCA considered the

[256] *Bato Star* above n 244 at para 22; *Pharmaceutical Manufacturers Association of SA and Another: In re Ex parte President of the Republic of South Africa and Others* 2000 (2) SA 674 (CC); 2000 (3) BCLR 241 (CC) at paras 33 – 45.

[257] *Bato Star* id.

[258] *NAPTOSA* above n 249 and *Ingledew* above n 243.

claims made by the applicant in the context of PAJA, they erred."[259] *A fortiori* here where the cause of action is expressly founded on PAJA.

[438] It follows that the SCA, as we held in *Bato Star*, erred in failing to consider whether PAJA was applicable. The question whether PAJA governs these proceedings cannot be avoided in these proceedings. That question formed a large part of the judgments in the High Court. Both the majority and the minority considered the question and gave reasoned judgments for their respective views, but were divided on the issue. In deciding this question, this Court is therefore not sitting both as a court of first and last instance. We have the benefit of the reasoned judgments of the High Court. In my view our decision in *Bato Star* compels us to confront the question of the applicability of PAJA in these proceedings. It is to that question that I now turn. But before considering the applicability of PAJA it is necessary to consider first, the nature of the powers and functions conferred by section 22G(2) of the Medicines Act upon the Pricing Committee and the Minister.

The nature of the process involved in making regulations under section 22G(2)

[439] Section 22G(2) provides:

> "(2) The Minister may, on the recommendation of the pricing committee, make regulations—
>
> (a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;

[259] *Bato Star* above n 244 at para 26.

(b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a);

(c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines."

[440] In this case we are not concerned with the general regulation-making power given to the Minister by section 35 of the Medicines Act. That section requires the Minister to make General Regulations "in consultation with the council."[260] We are concerned here with the specific powers and functions conferred on the Pricing Committee and the Minister to introduce a transparent pricing system for all medicines and Scheduled substances, to determine an appropriate dispensing fee to be charged by pharmacists and other health care professionals, and an appropriate fee to be charged by wholesalers and distributors. In order to carry out the objectives of the section, both the Minister and the Pricing Committee must act together.

[441] Section 22G(2) provides for a unique process. It is unique in the sense that it requires the Minister to make regulations "on the recommendation of the Pricing Committee." The recommendation of the Pricing Committee is therefore a jurisdictional fact for the exercise by the Minister of her power to make regulations. Section 22G(2) contemplates that the Minister will only make regulations if the Pricing Committee recommends them. Neither the Minister nor the Pricing Committee can act alone. They must act together. Section 22G(2) therefore contemplates a single process commencing with an investigation of the matters set out in paragraphs (a) to (c) of section 22G(2) by the Pricing Committee, followed by a

[260] The Medicines Control Council established under section 2 of the Medicines Act.

recommendation on appropriate regulations, then a consideration of the draft regulations by the Minister, culminating in a decision to make the regulations.

[442] The process conducted by the Pricing Committee and the making of the regulations based on the recommendation of the Pricing Committee are interlinked. The one is incomplete without the other. Once the process is complete, in the sense that the regulations are made, they become inseparable. Thus the recommendation of the Pricing Committee represents part of the process of regulation-making. The process of making regulations on the specific matters set out in section 22G(2)(a) to (c) must therefore be seen as a single process involving both the recommendation of the Pricing Committee and the making of regulations by the Minister based on that recommendation. If the process followed by the Pricing Committee is flawed, the ensuing recommendation is similarly flawed, so are the regulations based on such recommendation. It is this process that we are concerned with in these proceedings. And the question is whether PAJA applies to this process.

Does PAJA apply to section 22G(2)?

[443] The majority in the High Court found that both the activities of the Pricing Committee and regulation-making by the Minister do not amount to administrative action. However, they held that both "are subject to review on the principles of common law, the principle of legality as contemplated in section 1 of the Constitution and section 33(1) of the Constitution." But section 33(1) of the Constitution applies to "administrative action" within the meaning of section 33(1) of the Constitution. It is

not clear from the judgment of the majority whether the finding that the conduct of the Pricing Committee and the Minister in exercising the powers conferred by section 22G(2) are subject to review under section 33(1) of the Constitution, was intended to be a finding that the exercise of such power amounts to administrative action under section 33(1). What is clear is that the majority held that the conduct of the Pricing Committee in making a recommendation to the Minister and the regulation-making do not constitute administrative action contemplated in section 1 of PAJA.[261]

[444] The minority found that: (a) the recommendation of the Pricing Committee is a jurisdictional prerequisite for the making of regulations by the Minister and could adversely affect "the rights of the pharmaceutical industry and the public in general"[262]; and (b) has a "direct external legal effect" because the regulations can only be made upon the recommendation of the Pricing Committee. As the minority put it, "the recommendations are upon promulgation transformed into the regulations." It therefore held that the conduct of the Pricing Committee in making a recommendation amounts to administrative action within PAJA.[263] It also concluded that regulation-making also amounted to administrative action within the meaning of PAJA.[264]

[261] *New Clicks South Africa (Pty) Ltd v Tshabalala-Msimang and Another NNO; Pharmaceutical Society of South Africa and Others v Tshabalala-Msimang and Another NNO* 2005 (2) SA 530 (C) at paras 40-5 and 49-50.

[262] Id at para 31.

[263] Id at paras 30-2 and 41.

[264] Id at para 58.

[445] For its part the SCA found that the recommendation of the Pricing Committee is a jurisdictional fact for the exercise of the power to make regulations by the Minister. It held that the recommendation of the Pricing Committee "has to be in accordance with the provisions of section 22G i.e. it must be a lawful administrative action as provided for by section 33(1) of the Constitution."[265] It went on to hold that this "flows from the principle of legality that the Minister cannot accept a recommendation or promulgate a regulation that does not fall squarely within the section [22G]."[266] It took the view that "the regulations had to withstand the test of legality."[267] Given this approach, the SCA concluded that the question whether ministerial regulations and the conduct of the Pricing Committee were reviewable under PAJA, has no bearing on its judgment.[268]

Administrative action in the Constitution

[446] The starting point in determining whether PAJA is applicable to the exercise of the power conferred by section 22G is section 33(1) of the Constitution. The meaning of administrative action must be determined by reference to section 33 of the Constitution and not PAJA. Once it is determined that the exercise of the executive power authorised by section 22G(2)(a) to (c) is administrative action within the meaning of section 33, the next question to consider is whether PAJA nevertheless

[265] *Pharmaceutical Society of South Africa and Others v Tshabalala-Msimang and Another NNO; New Clicks South Africa (Pty) Ltd v Minister of Health and Another* 2005 (3) SA 238 (SCA); 2005 (6) BCLR 576 (SCA) at para 49.

[266] Id.

[267] Id at para 93.

[268] Id at para 94.

excludes it. The answer to this question must be sought, in the first place, in the exclusionary provisions of PAJA. Reference to these provisions of PAJA is not for the purposes of determining whether the process involved here is administrative action, but whether PAJA excludes the exercise of this specific power from its ambit. It follows therefore that the provisions of PAJA cannot be used as an aid to determining the meaning of administrative action in the Constitution. At best they can be used to fortify the inference that PAJA excludes the exercise of this specific power from its ambit. The first question that must be answered therefore is whether the exercise of the power conferred by section 22G(2) constitutes administrative action under section 33 of the Constitution.

[447] The meaning of administrative action within the meaning of the Constitution was first considered by this Court, in *Fedsure Life Assurance v Greater Johannesburg TMC*. There the Court held:

> "In addressing this question it is important to distinguish between the different processes by which laws are made. Laws are frequently made by functionaries in whom the power to do so has been vested by a competent legislature. Although the result of the action taken in such circumstances may be 'legislation', the process by which the legislation is made is in substance 'administrative'. The process by which such legislation is made is different in character to the process by which laws are made by deliberative legislative bodies such as elected municipal councils. Laws made by functionaries may well be classified as administrative; laws made by deliberative legislative bodies can seldom be so described."[269]

[269] *Fedsure Life Assurance Ltd and Others v Greater Johannesburg Transitional Metropolitan Council and Others* 1999 (1) SA 374 (CC); 1998 (12) BCLR 1458 (CC) at para 27.

[448] And in *President of the Republic of South Africa v South African Rugby Football Union (SARFU 3)*, this Court articulated the test for determining whether conduct constitutes administrative action as follows:

> "In s 33 the adjective 'administrative' not 'executive' is used to qualify 'action'. This suggests that the test for determining whether conduct constitutes 'administrative action' is not the question whether the action concerned is performed by a member of the executive arm of government. What matters is not so much the functionary as the function. The question is whether the task itself is administrative or not. It may well be, as contemplated in *Fedsure*, that some acts of a legislature may constitute 'administrative action'. Similarly, judicial officers may, from time to time, carry out administrative tasks. The focus of the enquiry as to whether conduct is 'administrative action' is not on the arm of government to which the relevant actor belongs, but on the nature of the power he or she is exercising."[270] (Footnotes omitted.)

The Court went on and said:

> "As we have seen, one of the constitutional responsibilities of the President and Cabinet Members in the national sphere (and premiers and members of executive councils in the provincial sphere) is to ensure the implementation of legislation. This responsibility is an administrative one, which is justiciable, and will ordinarily constitute 'administrative action' within the meaning of s 33. Cabinet Members have other constitutional responsibilities as well. In particular, they have constitutional responsibilities to develop policy and to initiate legislation. Action taken in carrying out these responsibilities cannot be construed as being administrative action for the purposes of s 33. It follows that some acts of members of the executive, in both the national and provincial spheres of government will constitute 'administrative action' as contemplated by s 33, but not all acts by such members will do so."[271] (Footnotes omitted.)

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[270] *President of the Republic of South Africa and Others v South African Rugby Football Union and Others* 2000 (1) SA 1 (CC); 1999 (10) BCLR 1059 (CC) at para 141.

[271] Id at para 142.

[449] It is clear from the last mentioned passage that the implementation of legislation is "an administrative [responsibility], which is justiciable, and will ordinarily constitute 'administrative action' within the meaning of s[ection] 33." In *SARFU 3* the Court noted that it is not always easy to determine whether the exercise of executive power amounts to formulation of policy or implementation of legislation. However, it held that the question whether the exercise of executive power amounts to implementation of legislation depends primarily upon the nature of the power. The source of the power and its subject matter, are also relevant in deciding whether the action concerned amounts to administrative action. In this regard it held:

> "Determining whether an action should be characterised as the implementation of legislation or the formulation of policy may be difficult. It will, as we have said above, depend primarily upon the nature of the power. A series of considerations may be relevant to deciding on which side of the line a particular action falls. The source of the power, though not necessarily decisive, is a relevant factor. So, too, is the nature of the power, its subject-matter, whether it involves the exercise of a public duty and how closely it is related on the one hand to policy matters, which are not administrative, and on the other to the implementation of legislation, which is. While the subject-matter of a power is not relevant to determine whether constitutional review is appropriate, it is relevant to determine whether the exercise of the power constitutes administrative action for the purposes of s 33. Difficult boundaries may have to be drawn in deciding what should and what should not be characterised as administrative action for the purposes of s 33. These will need to be drawn carefully in the light of the provisions of the Constitution and the overall constitutional purpose of an efficient, equitable and ethical public administration. This can best be done on a case by case basis."[272] (Footnotes omitted.)

[272] *SARFU 3* above n 270 at para 143.

[450] The conduct of the Pricing Committee and the Minister in exercising the power conferred on them by section 22G(2) involves the performance of functions that the legislation prescribes. It requires the introduction of a transparent pricing system, the fixing of an appropriate dispensing fee to be charged by those who dispense medicines and fixing an appropriate fee to be charged by wholesalers and distributors, by the Minister acting on the recommendation of the Pricing Committee. The nature of the power as well as its subject matter is concerned with the implementation of legislation. The exercise of this power can readily be subjected to section 33. The exercise of the power conferred by section 22G(2) therefore constitutes administrative action within the meaning of section 33. To suggest that the performance of these functions does not amount to implementation of legislation and therefore administrative action, because the Minister performs these functions through regulations, seems to me, to put form above substance. As pointed out earlier, in *Fedsure* this Court held that although laws made by functionaries in whom the powers to do so have been vested amount to legislation, the process by which such legislation is made is in substance administrative action.[273]

[451] Once it is determined that the exercise of powers given to the Minister and the Pricing Committee under section 22G(2) amounts to administrative action within the meaning of section 33, the exercise of those powers is governed by PAJA unless PAJA excludes the exercise of such powers from its scope.[274] The question that falls

[273] *Fedsure* above n 269 at para 9.

[274] Were it to be found that on its face PAJA excludes such powers, then the question of the constitutionality of PAJA would arise. In the view I take of the matter this question does not arise.

to be considered next therefore is whether the powers and functions performed by the Minister and the Pricing Committee under section 22G(2) fall within the definition of administrative action within the meaning of PAJA. Put differently, the question is whether PAJA excludes from its ambit the exercise of such powers and functions. Like any statute, PAJA must, where possible, be construed in a manner that is consistent with the Constitution.[275]

Does PAJA exclude from its ambit the powers conferred by section 22G(2)?

[452] Section 1 of PAJA defines administrative action to mean:

> "any decision taken, or any failure to take a decision, by—
>
> (a) an organ of state, when—
>
> (i) exercising a power in terms of the Constitution or a provincial constitution; or
>
> (ii) exercising a public power or performing a public function in terms of any legislation; or
>
> (b) a natural or juristic person, other than an organ of state, when exercising a public power or performing a public function in terms of an empowering provision,
>
> which adversely affects the rights of any person and which has a direct, external legal effect, but does not include—
>
> (aa) the executive powers or functions of the National Executive, including the powers or functions referred to in sections 79(1) and (4), 84(2)(a), (b), (c), (d), (f), (g), (h), (i) and (k), 85(2)(b), (c), (d) and (e), 91(2), (3), (4) and (5), 92(3), 93, 97, 98, 99 and 100 of the Constitution;

[275] *Bernstein and Others v Bester and Others NNO* 1996 (2) SA 751 (CC); 1996 (4) BCLR 449 (CC) at para 59; *De Lange v Smuts NO and Others* 1998 (3) SA 785 (CC); 1998 (7) BCLR 779 (CC) at para 85; *S v Dzukuda and Others; S v Tshilo* 2000 (4) SA 1078 (CC); 2000 (11) BCLR 1252 (CC) at para 37(a); *Investigating Directorate: Serious Economic Offences and Others v Hyundai Motor Distributors (Pty) Ltd and Others: In re Hyundai Motor Distributors (Pty) Ltd and Others v Smit NO and Others* 2001 (1) SA 545 (CC); 2000 (10) BCLR 1079 (CC) at paras 21-26; *National Director of Public Prosecutions and Another v Mohamed NO and Others* 2003 (4) SA 1 (CC); 2003 (5) BCLR 476 (CC) at para 35; *Zondi* above n 246 at para 102; and *Affordable Medicines Trust and Others v Minister of Health of RSA and Another* 2005 (6) BCLR 529 (CC) at para 36.

(bb) the executive powers or functions of the Provincial Executive, including the powers or functions referred to in sections 121(1) and (2), 125(2)(d), (e) and (f), 126, 127(2), 132(2), 133(3)(b), 137, 138, 139 and 145(1) of the Constitution;

(cc) the executive powers or functions of a municipal council;

(dd) the legislative functions of Parliament, a provincial legislature or a municipal council;

(ee) the judicial functions of a judicial officer of a court referred to in section 166 of the Constitution or of a Special Tribunal established under section 2 of the Special Investigating Units and Special Tribunals Act, 1996 (Act No. 74 of 1996), and the judicial functions of a traditional leader under customary law or any other law;

(ff) a decision to institute or continue a prosecution;

(gg) a decision relating to any aspect regarding the appointment of a judicial officer, by the Judicial Service Commission;

(hh) any decision taken, or failure to take a decision, in terms of any provision of the Promotion of Access to Information Act, 2000; or

(ii) any decision taken, or failure to take a decision, in terms of section 4(1)".

[453] Subparagraphs (aa), (bb) and (cc) exclude from the scope of PAJA executive powers and functions of the National Executive, Provincial Executives and Municipal Councils. However, subparagraphs (aa) and (bb) proceed to list specific executive powers and functions that are excluded. These subparagraphs introduce this list by using the phrase "including the powers or functions referred to" and proceed to refer to specific provisions of the Constitution which are then listed in the subparagraphs. The provisions of the Constitution that deal with the implementation of legislation at both national and provincial levels are omitted from the list.

[454] The question is whether the omission of the power to implement legislation was intended to bring the exercise of those functions within the ambit of PAJA. Put

differently, the question is whether the list of executive functions or powers listed in subparagraphs (aa) and (bb) were intended to be the only powers excluded from PAJA or whether the functions and the powers listed in the subparagraphs were listed merely to provide examples of powers or functions that are excluded from the scope of PAJA without seeking to limit the list to those powers specifically referred to in the subparagraphs. This is essentially a matter of construction, in particular, the meaning to be given to the word "including" in the context in which it occurs.

[455] As a general rule, the terms "including" or "includes" are not terms of exhaustive definition but terms of extension.[276] However, they may, depending on the context, be used as terms of exhaustive definition.[277] As the court put it in *Dilworth v Commissioner of Stamps*:

> "The word 'include' is very generally used in interpretation clauses in order to enlarge the meaning of words or phrases occurring in the body of the statute; and when it is so used these words or phrases must be construed as comprehending, not only such things as they signify according to their natural import, but also those things which the interpretation clause declares that they shall include. But the word 'include' is susceptible of another construction, which may become imperative, if the context of the Act is sufficient to shew that it was not merely employed for the purpose of adding to the natural significance of the words or expressions defined. It may be equivalent to 'mean and include', and in that case it may afford an exhaustive explanation of the meaning which, for the purposes of the Act, must invariably be attached to these words or expressions."[278]

[276] *Ndlovu v Ngcobo; Bekker and Another v Jika* 2003 (1) SA 113 (SCA) at para 20; *R v Louw and Another* 1934 CPD 365 at 367-8; *Jones & Co v Commissioner for Inland Revenue* 1926 CPD 1 at 5.

[277] *R v Debele* 1956 (4) SA 570 (A) at 575A-576E.

[278] *Dilworth and Others v Commissioner of Stamps* [1899] A.C. 99 at 105-6.

[456] The sense in which the term "including" is used must be ascertained from the context in which it is used.[279] In *De Reuck v Director of Public Prosecutions, WLD*, this Court referred to "useful guidelines for this determination" and said:

> "The correct sense of 'includes' in a statute must be ascertained from the context in which it is used. *Debele* provides useful guidelines for this determination. If the primary meaning of the term is well known and not in need of definition and the items in the list introduced by 'includes' go beyond that primary meaning, the purpose of that list is then usually taken to be to add to the primary meaning so that 'includes' is non-exhaustive. If, as in this case, the primary meaning already encompasses all the items in the list, then the purpose of the list is to make the definition more precise. In such a case 'includes' is used exhaustively. Between these two situations there is a third, where the drafters have for convenience grouped together several things in the definition of one term, whose primary meaning - if it is a word in ordinary, non-legal usage - fits some of them better than others. Such a list may also be intended as exhaustive, if only to avoid what was referred to in *Debele* as 'n moeras van onsekerheid' (a quagmire of uncertainty) in the application of the term."[280] (Footnotes omitted.)

[457] As pointed out earlier, section 1 of PAJA excludes from the definition of administrative action, amongst other powers, "the executive powers or functions of the National Executive". However subparagraph (aa) of section 1 proceeds to list specific provisions of the Constitution which are excluded from the definition of administrative action. Among these provisions listed are the provisions of subsections 85(2)(b) to (e) of the Constitution. Subsection 85(2)(a) which provides for the power

[279] *De Reuck v Director of Public Prosecutions, Witwatersrand Local Division and Others* 2004 (1) SA 406 (CC); 2003 (12) BCLR 1333 (CC) at para 18.

[280] Id.

to implement legislation is conspicuous by its omission from this list. The question is whether failure to mention subsection 85(2)(a) which refers to the implementation of national legislation, was intended to bring the implementation of legislation within the definition of administrative action in PAJA.

[458] All the powers or functions that are listed in subparagraph (aa) are clearly executive powers or functions. In particular, the powers and functions set out in subparagraphs (b) to (e) of subsection 85(2) and subparagraphs (d) to (g) of subsection 125(2) of the Constitution are manifestly executive powers. Subsection 85(2) provides:

> "(2) The President exercises the executive authority, together with the other members of the Cabinet, by—
>
> (a) implementing national legislation except where the Constitution or an Act of Parliament provides otherwise;
> (b) developing and implementing national policy;
> (c) co-ordinating the functions of state departments and administrations;
> (d) preparing and initiating legislation; and
> (e) performing any other executive function provided for in the Constitution or in national legislation."

While section 125(2) provides:

> "(2) The Premier exercises the executive authority, together with the other members of the Executive Council, by—
>
> (a) implementing provincial legislation in the province;
> (b) implementing all national legislation within the functional areas listed in Schedule 4 or 5 except where the Constitution or an Act of Parliament provides otherwise;

> (c) administering in the province, national legislation outside the functional areas listed in Schedules 4 and 5, the administration of which has been assigned to the provincial executive in terms of an Act of Parliament;
> (d) developing and implementing provincial policy;
> (e) co-ordinating the functions of the provincial administration and its departments;
> (f) preparing and initiating provincial legislation; and
> (g) performing any other function assigned to the provincial executive in terms of the Constitution or an Act of Parliament."

[459] None of the powers or functions listed in subparagraphs (aa) or (bb) go beyond what is generally understood to be the executive powers or functions. In other words the powers or functions introduced by the term "including" do not go beyond the meaning of executive power or function. The purpose of the list is not therefore to extend the meaning of executive powers or functions.[281] On the contrary the ordinary meaning of executive power or function "already encompasses all the items in the list".[282] In these circumstances the purpose of listing the powers or functions in subparagraphs (aa) and (bb) is to make the definition of executive function or power more precise. It seems to me that in the context in which it occurs, the term "including" is used to limit the executive powers or functions to those listed in subparagraphs (aa) or (bb).

[460] Nor can it be said that the implementation of legislation was omitted from the list of what amounts to executive power or function because implementing legislation

[281] Id.

[282] Id.

is so obviously an executive function that it required no mention.[283] But the same can be said of all the other powers or functions listed in subparagraph (aa), in particular, those set out in subparagraphs (b) to (e). They are so manifestly executive functions that they would not need any mention. Yet the legislature in PAJA decided to mention them specifically but omit implementation of legislation. It is also true that the phrase "any other executive function" found in subparagraph 85(2)(e) of the Constitution is very wide indeed. But it cannot be said to include implementation of legislation which is deliberately excluded from the list. That phrase must be construed to refer to functions that are not set out in subparagraphs (a) to (d) of subsection 85(2).

[461] The conclusion that the deliberate exclusion of implementing legislation from the list of executive powers or functions that do not fall within the ambit of PAJA was intended to bring the exercise of those powers or functions within the ambit of PAJA, is irresistible. Indeed it would have been an easy matter for the legislature to have excluded expressly implementation of legislation from the scope of PAJA. I agree with the observation by the Chief Justice that in doing so the legislature would have excluded from the scope of PAJA the very core of administrative action which is implementation of legislation. I also agree with the observation of the SCA that it is unlikely that PAJA, which was enacted to give effect to section 33 of the Constitution and to codify the principles of administrative justice would have "reduced the level of

[283] *SARFU 3* above n 270 at para 142*; Fedsure* above n 269 at para 27; *Permanent Secretary, Department of Education and Welfare, Eastern Cape, and Another v Ed-U-College (PE) (Section 21) Inc* 2001 (2) SA 1 (CC); 2001 (2) BCLR 118 (CC) at para 18. Compare *Union Government v Rosenburg (Pty) Ltd* 1945 AD 120 at 126-7.

administrative justice".[284] There are further considerations which fortify this conclusion.

[462] There can be little doubt that the implementation of national legislation is the exercise of an executive power or function. Section 85(1) of the Constitution expressly provides that "the executive authority of the Republic is vested in the President". Section 85(2)(a) expressly provides that "the President exercises the executive authority together with other members of the cabinet by . . . " among other things, "implementing national legislation . . . ". What is significant is that in relation to the executive powers or functions of the Provincial Executives, PAJA omits from the list of excluded powers those dealing with the implementation of legislation whether national or provincial or the administration of national legislation assigned to a Provincial Executive.[285]

[463] It is not without significance that the omission of implementation of legislation from the list of executive powers or functions excluded from the scope of PAJA comes after this Court in *Fedsure* and in *SARFU 3* had authoritatively laid down the definition of administrative action within the meaning of section 33(1) of the Constitution. In *Fedsure* this Court held that although laws made by functionaries in whom the powers to do so has been vested by a competent legislature, amount to legislation, the process by which such legislation is made is in substance

[284] Above n 265 at para 94.

[285] Subparagraph (bb) of section 1 of PAJA.

administrative. And such laws are to be classified as administrative action.[286] And in *SARFU 3* this Court held that the implementation of legislation whether it is at provincial or national level by the relevant executive authority will ordinarily amount to administrative action.[287]

[464] Nor is it a coincidence that in its definition of administrative action, PAJA omits from its list of excluded executive powers those dealing with implementation of legislation, which this Court held amounts to administrative action within the meaning of section 33 of the Constitution. And significantly PAJA excludes from its ambit those powers which this Court held do not amount to administrative action such as developing policy and initiating legislation.[288] PAJA defines administrative action in line with the decisions of this Court in *Fedsure* and *SARFU 3*.

[465] It seems to me that where, as here, this Court has given a construction to a concept used in the Constitution, and Parliament in subsequent legislation giving effect to a provision of the Constitution which embodies such a concept, it is safe to assume that the legislature when using the concept in question intended it to be given the meaning which has been given to it by this Court.[289] Here this Court has

[286] *Fedsure* above n 269 at para 27.

[287] *SARFU 3* above n 270. See also *Ed-U-College* above n 283 at para 18.

[288] *SARFU 3* id at para 142.

[289] Compare the rule of construction that where the legislature uses words which have received judicial construction, in the absence of anything to the contrary, Parliament must be presumed to have intended the words to bear the same meaning that courts have attributed to them. *Ex parte Minister of Justice; In re R v Bolon* 1941 AD 345 at 359; *S v Zemura* 1974 (1) 584 (RAD) at 589D-E; *Webb v Outrim* 1907 A.C. 81 at 89; *Barlow and Another v Teal* 1885 Q.B.D. 403 at 405.

construed administrative action within the meaning of section 33 of the Constitution to include the exercise of the power to implement legislation but to exclude the exercise of the power to develop policy or initiate legislation.[290]

[466] Given this construction of the concept of administrative action as used in the Constitution, it is safe to assume that in PAJA, which was promulgated subsequently, the legislature intended administrative action to bear the same meaning that it bears under section 33(1) of the Constitution as authoritatively defined by this Court. The omission of the power to implement legislation in the list of executive powers excluded from the ambit of PAJA, and the inclusion of the power to develop policy or initiate legislation in the list of powers excluded from the ambit of PAJA, is consistent with the construction of the concept of administrative action by this Court. As pointed out earlier, PAJA must, when possible be construed consistently with the Constitution.[291]

[467] I agree with the Chief Justice that the definition of "decision" in PAJA does not exclude regulation-making.[292] The reference in the main part of the definition to "any

[290] *SARFU 3* above n 270 at para 142; *Ed-U-College* above n 283 at para 18; *Pharmaceutical Manufacturers Association* above n 256 at para 45.

[291] Above n 275.

[292] Section 1 of PAJA defines decision as follows:

> "any decision of an administrative nature made, proposed to be made, or required to be made, as the case may be, under an empowering provision, including a decision relating to—
>
> (a) making, suspending, revoking or refusing to make an order, award or determination;
>
> (b) giving, suspending, revoking or refusing to give a certificate, direction, approval, consent or permission;
>
> (c) issuing, suspending, revoking or refusing to issue a licence, authority or other instrument;
>
> (d) imposing a condition or restriction;

decision of an administrative nature" and the general provision of subparagraph (g) to "doing or refusing to do any other act or thing of an administrative nature", brings the making of regulations contemplated in section 22G(2)(a) to (c) within the ambit of the definition of a "decision".

[468] Nor does the exclusion of a decision in terms of section 4(1) of PAJA indicate an intention to exclude regulation-making from the definition of administrative action in PAJA.[293] Section 4(1) contemplates "administrative action [which] materially and

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(e) making a declaration, demand or requirement;
(f) retaining, or refusing to deliver up, an article; or
(g) doing or refusing to do any other act or thing of an administrative nature, and a reference to a failure to take a decision must be construed accordingly".

[293] Section 4 of PAJA provides:

"(1) In cases where an administrative action materially and adversely affects the rights of the public, an administrator, in order to give effect to the right to procedurally fair administrative action, must decide whether—
(a) to hold a public inquiry in terms of subsection (2);
(b) to follow a notice and comment procedure in terms of subsection (3);
(c) to follow the procedures in both subsections (2) and (3);
(d) where the administrator is empowered by any empowering provision to follow a procedure which is fair but different, to follow that procedure; or
(e) to follow another appropriate procedure which gives effect to section 3.
(2) If an administrator decides to hold a public inquiry—
(a) the administrator must conduct the public inquiry or appoint a suitably qualified person or panel of persons to do so; and
(b) the administrator or the person or panel referred to in paragraph (a) must—
(i) determine the procedure for the public inquiry, which must—
(aa) include a public hearing; and
(bb) comply with the procedures to be followed in connection with public inquiries, as prescribed;
(ii) conduct the inquiry in accordance with that procedure;
(iii) compile a written report on the inquiry and give reasons for any administrative action taken or recommended; and
(iv) as soon as possible thereafter—
(aa) publish in English and in at least one of the other official languages in the Gazette or relevant provincial Gazette a notice containing a concise summary of any report and the particulars of the places and times at which the report may be inspected and copied; and
(bb) convey by such other means of communication which the administrator considers effective, the information referred to in item (aa) to the public concerned.

adversely affects the rights of the public . . . " and that the administrator will give effect to the right to procedurally fair administrative action. However, it leaves it to the administrator to decide on how to give effect to the right to procedurally fair administrative action. It is the decision of the administrator in this regard which is excluded from the definition of administrative action.

[469] Sachs J holds that "PAJA is not generally applicable to this case, but only [applies] in respect of the regulations fixing the dispensing fee." He draws attention to certain provisions of PAJA, which he holds indicate that PAJA is not generally applicable to regulation-making in these proceedings. As pointed out earlier, the provisions of PAJA cannot be used to determine whether action constitutes administrative action within the meaning of section 33 of the Constitution. They may only be used to support the inference that PAJA excludes from its ambit the exercise of the power in question. Sachs J accepts this.

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(3) If an administrator decides to follow a notice and comment procedure, the administrator must—

(a) take appropriate steps to communicate the administrative action to those likely to be materially and adversely affected by it and call for comments from them;

(b) consider any comments received;

(c) decide whether or not to take the administrative action, with or without changes; and

(d) comply with the procedures to be followed in connection with notice and comment procedures, as prescribed.

(4) (a) If it is reasonable and justifiable in the circumstances, an administrator may depart from the requirements referred to in subsections (1)(a) to (e), (2) and (3).

(b) In determining whether a departure as contemplated in paragraph (a) is reasonable and justifiable, an administrator must take into account all relevant factors, including—

(i) the objects of the empowering provision;

(ii) the nature and purpose of, and the need to take, the administrative action;

(iii) the likely effect of the administrative action;

(iv) the urgency of taking the administrative action or the urgency of the matter; and

(v) the need to promote an efficient administration and good governance."

[470] The point that needs to be stressed here is that we are not concerned here with a general regulation-making power. We are concerned with a unique process which involves the recommendation by the Pricing Committee and a decision by the Minister to make regulations based on the recommendation of the Pricing Committee. It is a process which requires both the Pricing Committee and the Minister to act together in implementing the provisions of section 22G(2). The question is whether PAJA applies to this specific process, in particular, whether the nature and the effect of the power granted by section 22G(2)(a) to (c) amounts to administrative action within the meaning of section 33 of the Constitution.

[471] Viewed in isolation regulation-making authority may be said to be a legislative act. However, as pointed out previously, it is incorrect to view individually the component parts of what is essentially a single process. The regulation-making is as much part of the entire process as the recommendation of the Pricing Committee itself. One cannot excise this step from the rest of the process for the purposes of the operation of PAJA. The making of the recommendation by the Pricing Committee and the making of the regulations by the Minister are part of a process which, when viewed in its entirety, is, in my view, administrative. One is dealing here with a dual stage administrative action – first, the recommendation of the Pricing Committee and second, the decision of the Minister to make regulations based on such recommendation. The regulation-making is an integral part of a process which when

viewed as a whole is administrative. The character of the parts is governed by the nature of the whole.

[472] Sachs J finds that "the notion of procedural fairness and the right to be given reasons fit in closely with adjudicative justice for individuals." But section 4 of PAJA suggests otherwise. It contemplates that administrative action may affect the rights of the public in general and that the administrator will give effect to the right to procedurally fair administrative action even in such a case. This could be done either by holding a public enquiry or following a "notice and comment procedure" or following some other procedure that gives effect to the right to procedurally fair administrative action.[294]

[473] Subsection 4(2) describes the procedure to be followed where the administrator decides to hold an enquiry. Such procedure includes the appointment of a suitably qualified panel to hold public enquiries. At the conclusion of the enquiry the panel must "compile a written report on the enquiry and give reasons for any administrative decision . . . recommended." In addition, it must publish a summary of the report in a government gazette. If the administrator decides to follow a notice and comment procedure, the administrator must call for comments and consider comments received before making a decision. PAJA therefore contemplates administrative action that affects not only an individual but also affects the public in general and prescribes how the right to procedurally fair administrative action is to be given effect in such a case.

[294] Section 4 of PAJA.

[474] Section 4 contemplates a dual stage process, one commencing with a panel holding public hearings and making a recommendation to an administrator and the second stage involving the decision by the administrator based on such a recommendation. The process contemplated in section 22G(2)(a) to (c) fits in with the dual stage process envisaged in section 4 of PAJA. The Medicines Act makes provision for the appointment of the Pricing Committee by the Minister. The function of the Pricing Committee is to investigate a transparent pricing system and fees to be charged by health care professionals, wholesalers and distributors. It may do this by calling for submissions from interested persons and considering these representations. Thereafter the Pricing Committee prepares a report that is accompanied by draft regulations on the issues that it is required to investigate.

[475] And, as happened in this case, the Minister accepted the draft regulations and published them in the government gazette for public comment. The Pricing Committee subsequently considered the submissions and public hearings were held on the draft regulations. The Pricing Committee thereafter made its final recommendation to the Minister on the determination of the single exit price, dispensing fees and fees to be charged by wholesalers and distributors. The Minister accepted this recommendation which was in the form of draft regulations and promulgated the regulations. The procedure that was followed by the Pricing Committee and the Minister fits in, and is consistent with that envisaged in section 4.

In my view the difficulty referred to by Sachs J does not therefore arise in relation to the specific process envisaged by section 22G(2)(a) to (c).

[476] Nor am I persuaded that categorisation of the exercise of public power as adjudicative or legislative provides the criterion as to whether the exercise of the power in question amounts to administrative action. The trend in modern administrative law has been to move away from formal classification as a criterion.[295] It is clear from the decisions of this Court in *Fedsure* and *SARFU 3* that the use of labels in order to determine whether the action in question is administrative or legislative is not helpful. Thus in *Fedsure* this Court held that the process may in form be legislative but yet administrative in substance.[296] Similarly in *SARFU 3* the Court held that what matters is not the functionary who is performing the function in question but the function that is being performed.[297] It seems to me that the fruitful enquiry is to look at the nature and effect of the power that is being exercised. This would provide a more rational foundation for determining what is administrative action.

[295] *Administrator, Transvaal, and Others v Traub and* Others 1989 (4) SA 731 (A) at 759A-C; *South African Roads Board v Johannesburg City Council* 1991 (4) SA 1 (A) at 12E-15I. In the *Traub* case at 762F-763I, the SCA rejected the distinction between quasi-judicial and purely administrative as a basis for determining whether the *audi* principle applies.

[296] *Fedsure* above n 269 at para 27.

[297] *SARFU 3* above n 270 at para 141.

[477] There is commonwealth jurisprudence that is consistent with this approach. In *Homex Realty & Development Co Ltd v Village of Wyoming*,[298] the Supreme Court of Canada said the following:

> "It seems to me that a similar analysis should be employed in the present case. That is, it is not particularly important whether the function of the municipality be classified as 'legislative' or as 'quasi-judicial'. Such an approach would only return us to the conundrums of an earlier era. One must look to the nature of the function and to the facts of each case. I would adopt what was said by Judson J. in the *Wiswell* case. Although Judson J. dissented in *Wiswell*, being of opinion that adequate notice had been given, he did say :
>
> > 'I do not think that it helps one towards a solution of this case to put a label on the form of activity in which the Metropolitan Council was engaged when it passed this amending by-law. Counsel for the municipality wants to call it legislative and from that he argues that they could act without notice. The majority of the Judges prefer the term quasi-judicial. However one may characterize the function, it was one which involved private rights in addition to those of the applicant and I prefer to say that the municipality could not act without notice to those affected.'"[299] (References omitted.)

[478] In *CREEDNZ Inc v Governor-General*[300] the New Zealand Court of Appeal said the following:

> "The next matter for consideration is the nature of the power exercised by the Governor-General in Council. The mere fact that the decision is embodied in an instrument, an Order in Council, that is legislative in form does not necessarily preclude the imposition by implication of an opportunity to be heard. Again, it is well settled in this country that a body which is exercising functions that are legislative in form and substance may be subject to an implied duty to observe the

[298] 116 DLR (3d) 1.

[299] Id at 10-11.

[300] [1981] 1 NZLR 172 at 188-9.

> requirements of natural justice. Furthermore, the dividing line between 'adjudication' (or 'administration') on the one hand and 'legislation' on the other, is not always easy to draw and the attempt may be an arid exercise for in the twilight area the conceptual foundations for a distinction are not self-evident. It is more profitable to focus on the nature and effect of the decision under the statutory scheme than to search for labels to characterise the Executive Council's functions under s 3(3)". (References omitted.)

[479] It follows therefore in my judgment, that the categorisation of action as being adjudicative is not determinative of whether the action in question is administrative or not. What matters is the nature and the effect of the power conferred.

[480] For all these reasons, I conclude that, upon a proper construction of PAJA, the implementation of the provisions of section 22G(2) by the Pricing Committee and the Minister fall within the ambit of PAJA. The exercise of that power or function by the Pricing Committee and the Minister amounts to administrative action within the meaning of section 1 of PAJA.

[481] In the event I agree with the Chief Justice that PAJA generally addresses the four requirements of section 33(1) of the Constitution relating to just administrative action, namely, lawfulness (section 6(2)(f)(i) and 6(2)(i)),[301] reasonableness (section 6(2)(h)), procedural fairness (section 6(2)(c)), and the provision of reasons (section 5).

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[301] Section 6(2)(f)(i) and (i) of PAJA provides:

> "(2) A court or tribunal has the power to judicially review an administrative action if —
> . . . .
> (f) the action itself —
> (i) contravenes a law or is not authorised by the empowering provision;
> (i) the action is otherwise unconstitutional or unlawful."

I also agree that in relation to the procedural challenge the question to be decided is whether the procedures followed by the Minister and the Pricing Committee in the process of making regulations were in all the circumstances of the case fair.

Procedural fairness

[482] In *Zondi* this Court had occasion to consider the content of procedural fairness, albeit in a different context. On that occasion we said:

> "Procedural fairness, by its very nature, imports the element of fairness. And fairness is a relative concept which is informed by the circumstances of each particular case. In each case the question is whether fairness demands that steps be taken to trace the identity of the person against whom a decision is to be made. It is therefore neither possible nor desirable to attempt to define the circumstances where the dictates of fairness will require the decision-maker to take steps to ascertain the identity of the livestock owner."
>
> . . . .
>
> "The overriding consideration will always be what does fairness demand in the circumstances of a particular case."[302]

[483] The ultimate objective is to afford persons who may be adversely affected by the decision an opportunity to make representations before the decision is made.

[484] I agree with the Chief Justice that the process that was followed by the Pricing Committee and the Minister was substantially consistent with the requirements of procedural fairness in PAJA. The pharmacies and other interested persons were

[302] *Zondi* above n 246 at paras 113-4; *Minister of Public Works and Others v Kyalami Ridge Environmental Association and Another (Mukhwevho Intervening)* 2001 (3) SA 1151 (CC); 2001 (7) BCLR 652 (CC) at para 109; *Premier, Mpumulanga, and Another v Executive Committee, Association of State-Aided Schools, Eastern Transvaal* 1999 (2) SA 91 (CC); 1999 (2) BCLR 151 (CC) at para 39.

afforded the opportunity to make written and oral representations on the draft regulations. The fact that some members of the Pricing Committee were not present at some of the hearings, does not, in itself, affect the fairness of the process. Oral representations were made in addition to written representations. And, as Professor McIntyre points out, "to give members of the Committee a full picture of everything that happened [at the oral hearings], the presentations were audio and video-taped and made available to members of the Committee." The record of the oral representations was therefore accessible to members of the Pricing Committee. All that was required was for the members of the Pricing Committee who were not present at the oral hearings to avail themselves of the opportunity to watch the video tapes of the oral representations.

[485] New Clicks submitted that on the applicants' own version, the Pricing Committee did not consider the oral representations. It is clear from the evidence of Dr Zokufa and Professor McIntyre that the Pricing Committee considered the written representations at its meetings. What is less clear is whether the oral representations were considered by the Pricing Committee. Professor McIntyre says that she "watched **some** of the video tapes of **some** of the presentations." Whether other members of the Pricing Committee did so is not apparent from the record. If the other members of the Pricing Committee had watched the video tapes, they would have said so. Nor is there any indication on the evidence of Professor McIntyre and Dr Zokufa whether oral representations were considered by the Pricing Committee. On the contrary there are indications that the members of the Pricing Committee did not

consider the oral representations because the oral hearings were not meetings of the Pricing Committee. In their evidence both Dr Zokufa and Professor McIntyre emphasised the oral hearings were not the meetings of the Pricing Committee but that of the Department. In addition, they emphasised that the Pricing Committee considered written representations but said nothing about oral representations.

[486] In the view I take of the matter I do not consider it necessary to decide whether failure by the Pricing Committee to consider oral representations affected the fairness of the process. It seems to me that if the Pricing Committee was bound to consider oral representations, and they failed to do so, such failure amounts to a failure to take into account a relevant consideration. This aspect is dealt with more fully later in this judgment.

The Regulations

Regulation 5(2)(c)

[487] Regulation 5(2)(c) was challenged on the grounds that it is contradictory and vague. There is merit in this challenge. This regulation purports to provide a formula for the calculation of the manufacturer's component of the price of a medicine or Scheduled substance before determining the SEP. Its provisions and the formula set out therein cannot therefore be construed as referring to the SEP. They make reference to the sales before the SEP was in existence. Regulation 5(2)(c) does not purport to provide for the manner of the calculating the single exit price. Yet Appendix A which purports to give examples of how to calculate the manufacturer's

price, purports to provide a manner for the "calculation of single exit price . . . ". Appendix A plainly contradicts regulation 5(2)(c). It is inconsistent with regulation 5(2)(c). I agree with Yacoob J in this regard.

[488] However, it is quite clear that the reference to "single exit price" in Appendix A should be the reference to "weighted average net selling price". Ordinarily one would replace "single exit price" with "weighted average net selling price" in the appendix. However, there is another problem with regulation 5(2)(c).

[489] The manufacturers are told to calculate their prices of medicines or Scheduled substances "with reference to the price of that Scheduled substance in other countries in which the prices of medicines and Scheduled substances are regulated and published". Identifying those countries may not be a problem. The problem is what are the manufacturers supposed to do with the prices of those countries? What impact must these prices have on the determination of the price to be set by the manufacturers in this country? And what if there are different prices.

[490] Recently, this Court had occasion to consider the doctrine of vagueness. The occasion was in *Affordable Medicines* where we said:

> "The doctrine of vagueness is founded on the rule of law, which, as pointed out earlier, is the foundational value of our constitutional democracy. It requires that laws must be written in a clear and accessible manner. What is required is reasonable certainty not perfect lucidity. The doctrine of vagueness does not require absolute certainty of laws. The law must indicate with reasonable certainty to those who are bound by it what is required of them so that they may regulate their conduct

> accordingly. The doctrine of vagueness must recognise the role of Government to further legitimate social and economic objectives. And should not be used unduly to impede or prevent the furtherance of such objectives."[303]

[491] It is clear from the regulation that the manufacturers are required to have regard to the prices of medicines in other countries where medicines are regulated and published. The question is whether regulation 5(2)(c), so construed, indicates with reasonable certainty to the manufacturers what they are required to do with the foreign prices, in particular, what impact these prices should have on determining prices in South Africa. The regulation gives no guidance at all. In its report to the Minister dated 19 April 2004 the Pricing Committee acknowledged that there are "wide variations between manufacturers in South Africa and in countries with effective price regulation across products." The regulation offers no guidance to the manufacturers as to how they are required to deal with different prices for the same product in different countries. The matter is left entirely in the hands of the manufacturers. The failure of regulation 5(2)(c) to give such guidance must be viewed against the obligation to introduce a transparent pricing system. The failure to provide guidance leaves the manufacturers at large to select any price they choose. This can hardly be said to be consistent with the policy objectives of section 22G(2). I conclude therefore that regulation 5(2)(c) is invalid for vagueness.

Regulation 8(3)

[303] *Affordable Medicines* above n 275 at para 108.

[492] The increase in the SEP is governed by regulations 5(2)(a), 5(2)(b), 7, 8 and 9. Regulation 5(2)(a) tells us when any increase in the SEP may commence. It may not be increased "for a period of one year after the commencement of [the] regulations . . . ". Regulation 5(2)(b) directs us to the provision in terms of which an increase may be made. An increase may be made in terms of the provisions of regulation 8. Regulation 7 tells us how often the SEP may be increased. It may only be increased once a year. And regulation 8(1) in turn permits the Minister to increase the SEP, while regulation 8(3) permits the manufacturers to do so. However, the provisions of regulation 8 are subject to the provisions of regulation 5(2)(a). Regulation 5(2)(b) says so:"[s]ubject to sub-regulation 5(2)(a) the single exit price may be increased in terms of regulation 8 of these regulations".

[493] The effective date of any increase in the SEP is therefore governed by regulation 5(2)(a). And it follows therefore that the SEP may not be increased within a year after the commencement of the regulations. The problem is how to reconcile regulation 8(3)(iv) which purports to permit an increase in the SEP within a year of the date of the commencement of the regulations. It does so because it prevents the increase of the SEP "within the period of six months beginning from the date of commencement of [the] regulations", thereby implying that an increase may be effected after six months but within a year of the date of the commencement of the regulations. Regulation 8(3)(iv) is clearly inconsistent with regulation 5(2)(a) to which it is subject.

[494] Regulation 8 contemplates two instances in which there may be an increase in the SEP. One is by the Minister in terms of regulation 8(1). This regulation contemplates that there will be an annual increase in the SEP and that such an increase will be determined by the Minister. It is also clear that what the Minister determines under regulation 8(1), is the extent to which the SEP may be increased. However, manufacturers are not obliged to increase their SEP by the extent determined by the Minister. They may charge less to enable them to compete with their competitors. But if they decide not to increase their SEP by the percentage determined by the Minister, they may nevertheless still increase it during that particular year. They may only do this four times a year. However, such an increase may not exceed the amount of increase determined by the Minister in terms of regulation 8(1).

[495] The scheme that emerges from regulation 8 is this: the increase contemplated in regulation 8(3) is an increase by the manufacturer that is subsequent to the annual increase determined by the Minister in terms of regulation 8(1). This is so because the increase contemplated in regulation 8(3) is subject to regulation 8(1). The manufacturers need not increase their SEP by the amount determined by the Minister. However, should they decide to increase the SEP, such increase may not exceed the increase determined by the Minister. And if they require to effect an increase that goes beyond that determined by the Minister in terms of regulation 8(1), then the provisions of regulation 9(1) apply. That regulation provides that the "Minister may, in exceptional circumstances, authorise a manufacturer . . . to increase the price of a

medicine or Scheduled substance by a specified amount greater than that permitted in terms of regulation 8".

[496] Thus construed there is no room for regulation 8(3)(iv) which contemplates an increase in the SEP not only within six months of the commencement of the regulations, but even before the Minister has determined any increase to the original SEP. This regulation cannot be reconciled with regulation 5(2)(a) to which it is subject. It follows that it must be invalid.

[497] The problem relates to the reference to "single exit price" and "first published in respect of that year" in regulation 8(3)(i). The Minister does not determine what the single exit price for the year is. What the Minister does is to determine "the extent to which the single exit price" may be increased. In the second place the Minister does not publish the single exit price. That is the function of the manufacturers. The reference to the "single exit price" and "first published in respect of that year" is therefore vague. What the scheme of regulation 8 has in mind is that whatever increase that is made by manufacturers, such increase should not go beyond the increase determined by the Minister in terms of regulation 8(1), unless such increase is authorised by the Minister in terms of regulation 9(1).

[498] I conclude therefore that regulation 8(3)(i) is void for vagueness. However, this can be cured by deleting the words "as first published" and inserting the words "amount of increase determined by the Minister in terms of regulation 8(1) as being

the extent to which", in front of the words "single exit price of the medicine or Scheduled substance", and inserting the words "may be increased" in front of the words "in that year". Regulation 8(3)(i) will therefore read: "such increase does not exceed **the amount of increase determined by the Minister as being the extent to which** the single exit price of the medicine or Scheduled substance **may be increased** in respect of that year."

The remaining regulations

[499] Save for the above, and in relation to regulation 22 and 23, I concur in the judgment of the Chief Justice. In relation to regulations 22 and 23, I concur in the judgment of Yacoob J.

[500] It now remains to consider the challenge to the appropriate dispensing fee.

The appropriate dispensing fee

[501] Section 22G(2)(b) deals with the determination of an appropriate dispensing fee to be charged by pharmacists or other health care professionals who may dispense medicines under the Medicines Act.[304] Its relevant part provides:

> "The Minister may, on the recommendation of the pricing committee, make regulations—
>
> . . . .
>
> (b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a)."

[304] Dispensing fees apply to both medicines and Scheduled substances falling into schedule 1 to 8. The reference to medicines in this judgment will include a reference to scheduled substances.

[502] In terms of section 22G(3)(b) pharmacists and other dispensers of medicines may not sell medicines at a price higher than the SEP.[305] However section 22G(3)(c) provides that the provisions of section 22G(3)(b) "shall not be construed as preventing a pharmacist or person licensed [to dispense medicine under the Medicines Act] to charge a dispensing fee as contemplated in subsection (2)(b)".[306] Section 22G(3)(c) therefore constitutes an exception to the prohibition against the sale of medicines at a price higher than the SEP. Section 22G contemplates that a dispensing fee is a fee that may be charged in addition to the SEP.

[503] All the parties as well as the courts below approached the matter on the footing that the subsection authorises the Minister, on the recommendation of the Pricing Committee, to fix an appropriate dispensing fee. Following the recommendation of the Pricing Committee, the Minister promulgated regulations 10, 11, 12 and 13, which fix dispensing fees. Broadly speaking, the regulations distinguish between medicines that are dispensed without a prescription and those dispensed on the basis of a prescription. In addition, they fix a different fee for other dispensers of medicines such as medical practitioners, dentists and professional nurses. And since a dispensing fee is a fee that may be charged in addition to the SEP, the regulations fix a dispensing fee by reference to the SEP.

[305] Section 22G(3)(b).

[306] Section 22G(3)(c).

[504] The dispensing fee in respect of medicines dispensed without a prescription is 16% of the price where the SEP is less than R100, and R16 where the SEP is R100 or more.[307] In the case of medicines that are dispensed on the basis of a prescription, the dispensing fee is 26% of the SEP where the SEP is less than R100, and R26 where the SEP is R100 or more.[308] Other dispensers such as medical practitioners, dentists and professional nurses may charge a dispensing fee of 16% of the SEP where the SEP is less than R100, and R16 where the SEP is more than R100.[309] In addition, the

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[307] Regulation 10(1) provides:

> "The appropriate dispensing fee as contemplated in section 22G(2)(b) of the Act to be charged by pharmacists must be calculated as follows:
> (1) With regard to medicines and scheduled substances falling into Schedules 1 and 2 of the Act, in the absence of a prescription the dispensing fee, exclusive of VAT, must not exceed -
> (a) 16% of the single exit price of a medicine or Scheduled substance where the single exit price of that medicine or Scheduled substance is less than one hundred rands;
> (b) sixteen rands in respect of a medicine or Scheduled substance where the single exit price of that medicine or Scheduled substance is greater than or equal to one hundred rands."

[308] Regulation 10(2) provides:

> "(2) With regard to medicines and scheduled substances falling into Schedules 3, 4, 5, 6, 7, and 8 of the Act, and medicines and Schedules substances falling into Schedules 1 and 2 of the Act in respect of which a prescription has been written, the dispensing fee, exclusive of VAT, must not exceed -
> (a) 26% of the single exit price in respect of a medicine or Scheduled substance where the single exit price of that medicine or Scheduled substance is less than one hundred rands;
> (b) twenty six rands in respect of a medicine or Scheduled substance where the single exit price of that medicine or Scheduled substance is greater than or equal to one hundred rands."

[309] Regulation 12 provides:

> "The appropriate dispensing fee as contemplated in section 22G(2)(b) of the Act to be charged by persons licensed in terms of section 22C(1)(a) of the Act must be calculated, exclusive of VAT, as follows:
> (1) Where the single exit price of a medicine or Scheduled substance is less than one hundred rands, the dispensing fee must not exceed 16 % percent of the single exit price in respect of that medicine or Scheduled substance.
> (2) Where the single exit price of a medicine or Scheduled substance is one hundred rands or more, the dispensing fee must not exceed sixteen rands in respect of that medicines or Scheduled substance.
> (3) The provisions of this regulation 12 must be reviewed annually by the Minister with regard to the CPI, the PPI, and the need to ensure the

regulations deal with the manner of calculating dispensing fees to be charged in respect of a person admitted as an inpatient [310] and in respect of Schedule 0 medicines.[311] The dispensing fee is subject to review annually in order to keep up with the CPI[312], PPI[313] and "the need to ensure the availability, affordability and quality of medicines . . .".[314]

The challenge

[505] The main ground of attack on the dispensing fees is that they are not appropriate as required by section 22G(2)(b). The pharmacies contended that the dispensing fees are not economically viable for pharmacies and would result

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availability, affordability and quality of medicines and Scheduled substances in the Republic."

[310] Regulation 11 provides:

> "Where a medicine or Scheduled substance is dispensed in terms of a prescription written for a person who has been admitted as an inpatient the dispensing fee shall be calculated in terms of regulation 10 in respect of the entire quantity of the medicine or Scheduled substance reflected on such prescription, irrespective of whether the medicine or Scheduled substance is issued from the stock of the pharmacy or from ward or theatre stock."

[311] Regulation 13 provides:

> "The appropriate fee to be charged by any person, other than a wholesaler or distributor, in respect of Schedule 0 medicines shall not exceed the percentage mark-up in respect of that medicine or Scheduled substance that was applied at the date of commencement of these regulations."

[312] CPI is defined in regulation 2 as:

> "the Consumer Price Index as determined and published by Statistics South Africa from time to time".

[313] PPI is defined in regulation 2 as:

> "the Production Price Index for pharmaceutical products as determined and published by Statistics South Africa from time to time".

[314] Regulation 10(3) provides:

> "The provisions of this regulation 10 must be reviewed annually by the Minister with regard to the CPI, the PPI, and the need to ensure the availability, affordability and quality of medicines and Scheduled substances in the Republic."

ultimately in the demise of retail pharmacies. New Clicks submitted that in fixing the dispensing fees, the Minister ignored certain relevant considerations such as the profit margin required for pharmacies to survive, the different circumstances and thus different cost structures which pharmacists may operate in different areas, the working capital cost borne by pharmacists in conducting their businesses, the cost of storing medicines and the time spent by pharmacists in providing dispensing services.

[506] In effect, the main contention by New Clicks is that in fixing the dispensing fees, the Pricing Committee failed to have proper regard to the viability of pharmacies, which is a relevant consideration in determining an appropriate dispensing fee. This much appears from the submission by New Clicks that the issue of the viability of pharmacies is an issue which "seems to have singularly passed by the Pricing Committee, which ultimately made a recommendation without any regard to the viability thereof for pharmacists." It seems to me therefore that the ground of review urged by New Clicks is that relevant matters were not given proper consideration by the Pricing Committee, a ground comprehended in section 6(2)(e)(iii) of PAJA.

[507] For its part, PSSA challenged the dispensing fees on three broad grounds. First, it submitted that the fees are not appropriate because they: (a) will drive pharmacies out of business; (b) fail to take account of the different types of pharmacies; and (c) will reduce access to medicines. Second, and for substantially the same reasons as in the first ground, PSSA contended that the fees are unreasonable and arbitrary. Third,

it submitted that the dispensing fees violate section 22 of the Constitution in that they impermissibly regulate the choice of profession and they will drive pharmacists out of the profession.

[508] The first ground of attack by PSSA raises substantially the same issue as New Clicks, namely, whether the Pricing Committee ignored relevant considerations in determining the dispensing fees. The second ground of attack, namely, that the dispensing fees are unreasonable, is closely related to the first ground. If the Pricing Committee ignored relevant considerations referred to by PSSA so that the ultimate fees determined will result in the demise of pharmacists, such fees can hardly be said to be fees that a reasonable Pricing Committee could have fixed. The third ground of attack, namely, the alleged violation of section 22 of the Constitution, stands on a different footing. It raises the question of the permissible scope of regulation of a trade.[315]

The findings of the SCA

[509] The SCA held that the evidence on the record "establishes that the fees are not appropriate and that the respondents, within whose peculiar knowledge the calculation [of the dispensing fee] fell, were unable to give any rational explanation for the quantum of the fees."[316] It found that "on the unassailed factual material on record" access to medicines will be seriously threatened because the quantum of fees fixed by

[315] *Affordable Medicines* above n 275 at paras 57 to 67 and paras 73 to 95.

[316] Above n 265 at para 89.

the regulations is insufficient to cover the costs of dispensing medicine.[317] In effect the SCA upheld the contention by the pharmacies that the quantum of fees was fixed without regard to the viability of pharmacies. It is apparent from the judgment of the SCA that its conclusion was influenced by the lack of explanation from the Pricing Committee and the Minister as to how the fees were calculated.

Issues presented

[510] What lies at the heart of the challenge to the dispensing fees is the contention that the dispensing fees as determined in the regulations are not viable for pharmacies and will drive them out of business. In effect the pharmacies contend that, in determining the dispensing fees, the Pricing Committee did not have due regard to the viability of the dispensing fees for pharmacies, as they were bound to do. This contention was upheld by the SCA, which in effect concluded that the fees were not viable for pharmacies. Failure by a decision maker to take into account a relevant consideration in the making of an administrative decision is an instance of an abuse of discretion.[318] As pointed out earlier, this is a ground of review which is expressed in section 6(2)(e)(iii) of PAJA.[319]

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[317] Id.

[318] *Affordable Medicines* above n 275 at para 35.

[319] Section 6(2)(e)(iii) of PAJA provides:

> "(2) A court or tribunal has the power to judicially review an administrative action if—
> (e) the action was taken—
> (iii) because irrelevant considerations were taken into account or relevant considerations were not considered".

[511] There is obviously an overlap between the ground of review based on failure to take into consideration a relevant factor and one based on the unreasonableness of the decision. A consideration of the factors that a decision maker is bound to take into account is essential to a reasonable decision. If a decision maker fails to take into account a factor that he or she is bound to take into consideration, the resulting decision can hardly be said to be that of a reasonable decision maker. It seems to me to follow that if, in determining the dispensing fees, the Pricing Committee was bound to take into consideration the viability of the fees for pharmacies, but failed to do so properly, the resulting fees can hardly be said to be one that a reasonable Pricing Committee could fix.

[512] As I see it therefore the central question in this case reduces to whether the Pricing Committee gave proper consideration to the viability of pharmacies in fixing the dispensing fees. This question raises two separate, but related, questions. The first is whether the Pricing Committee was bound, in fixing an appropriate dispensing fee pursuant to section 22G(2)(b), to have regard to the viability of pharmacies so that failure to do so amounted to failure to take into account a consideration relevant to the determination of an appropriate fee. The second question, which only arises if the first question is answered in the affirmative, is whether the Pricing Committee gave due regard to the viability of pharmacies.

[513] Factors that a decision maker is bound to consider in making a decision must be determined by construing the statute conferring the discretion. Where, as here, the

statute in question does not expressly state what factors are to be considered, these factors must be determined by implication from the subject matter, scope and purpose of the empowering statute including the policy objectives of the empowering statute.[320] Considerations that are relevant to the determination of an appropriate dispensing fee must therefore be sought in the purpose of section 22G(2)(b) read in the context of the Medicines Act and its underlying policy objectives. What then is the purpose of section 22G(2)(b)?

The purpose of section 22G(2)(b)

[514] The purpose of the subsection is clearly to give effect to the right of access to health care services comprehended in section 27(1)(a) and (2) of the Constitution.[321] This section guarantees the right of access to health care services and enjoins the state to "take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of [this right]." The right to health care services includes the right of access to medicines that are affordable. The state has an obligation to promote access to medicines that are affordable.

[515] Consistent with its obligation, the state has developed the National Drug Policy (NDP). This is a comprehensive policy document which sets out health, economic

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[320] Compare *Affordable Medicines* above n 275 at paras 34, 38 and 39.

[321] Section 27(1)(a) and (2) of the Constitution provides:

> "(1) Everyone has the right to have access to—
> (a) health care services, including reproductive health care;
> . . . .
> (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights."

and national development objectives of the state. What is immediately relevant for present purposes is chapter four of the NDP which deals with drug pricing. The aim of the drug pricing policy is "[t]o promote the availability of safe and effective drugs at the lowest possible cost". This is to be achieved by, amongst other things, "negotiating drug prices and by rationalising the drug pricing system in the public and private sectors". To this extent the policy proposes the establishment of a Pricing Committee to monitor and regulate drug prices; the regulation of price increases; introduction of transparency in the pricing structure of pharmaceutical manufacturers, wholesalers and those who dispense drugs; the introduction and enforcement of non-discriminatory pricing systems; and the replacement of the wholesale and retail percentage mark up system with a pricing system based on a fixed professional fee.

[516] With these policy objectives in mind, the legislature introduced an amendment to the Medicines Act in the form of section 22G.[322] As the preamble to the Medicines and Related Substances Control Amendment Act of 1997 declares, the purpose of the amendment was among others, "to provide for measures for the supply of more affordable medicines in certain circumstances", "to provide for the establishment of a pricing committee" and "to regulate the purchase and sale of medicines by wholesalers". And in its amended form, the preamble to the Medicines Act now declares as one of its purposes, "to provide for measures for the supply of more affordable medicines in certain circumstances" and "to provide for the establishment

[322] This amendment was part of a package of amendments that were largely aimed at giving effect to the National Drug Policy. It was brought about by two separate amendments: the first amendment by section 14 of the Medicines and Related Substances Control Amendment Act, 90 of 1997, and the second by sections 6, 7 and 8 of the Medicines and Related Substances Control Amendment Act, 59 of 2002.

of a pricing committee; to regulate the purchase and sale of medicines by manufacturers, distributors, wholesalers, pharmacists and persons licensed to dispense medicines".

[517] The manifest purpose of section 22G(2)(b) is to enhance accessibility and affordability of medicines.[323] It is in the light of this purpose that the factors relevant to the determination of an appropriate fee must be determined. An appropriate fee illuminates factors relevant to its determination. It is therefore necessary to consider first the meaning of an appropriate dispensing fee. The Medicines Act does not define appropriate dispensing fee. However the term appropriate dispensing fee must be construed in the light of the purpose of section 22G(2)(b), namely, to promote the availability of medicines at the lowest possible cost.

The meaning of "appropriate dispensing fee"

[518] As the SCA held, an appropriate dispensing fee must be fair and just. Indeed it can hardly be argued that a dispensing fee that is unjust or unfair is appropriate.[324] The dispensing fee must be fair not only to the public, but also to pharmacies. The fee must not be such that it will render medicines inaccessible to the general public. Nor must it be such that it drives pharmacies out of business. Its determination requires a consideration of conflicting interests of the public who are entitled to access to affordable medicines, on the one hand, and the interests of dispensers who, in terms of

[323] See para 516 above.

[324] Above n 265 at paras 76-77.

the Act, are essential to the public for the supply of medicines and whose economic viability is implicitly recognised by the Act and is of "national importance", on the other hand.[325]

[519] That said, one should not lose sight of the primary objective of section 22G(2)(b). Its primary objective is to promote access to medicines at the lowest cost possible. This objective is consistent with the constitutional right of access to health care services and the constitutional obligation of the state to take measures in order to ensure the progressive realisation of this right.[326] No doubt the interests of the pharmacists is a factor to be taken into consideration. However, they must yield to the interests of the general public. This of course does not mean that the interests of the pharmacists are to be overlooked.

[520] In fixing an appropriate dispensing fee, the Pricing Committee and the Minister have a duty to strike a balance between the need to make medicines available and accessible to the public at the lowest possible cost and the need to keep pharmacies in business. If in serving the interests of the public the price of medicines is to be reduced, this would not be sufficient to render inappropriate the fee determined by the Pricing Committee. But the reduction should not be such that it will result in the closure of the pharmaceutical industry. For the need for the continued existence of pharmacies, is implicit, if not explicit, from the objective to enhance the accessibility

[325] Above n 265 at para 77.

[326] Section 27 of the Constitution.

and affordability of medicines. Pharmacies are crucial to the public for the supply of medicines. The applicants acknowledge this, for, Professor McIntyre in her affidavit admits that "the survival of the retail pharmacy sector is essential for medicine delivery". Without that supply, access to medicines would be compromised. And this would undermine the objective of the Medicines Act to make medicines accessible to the general public. This is common cause on the record.

[521] But appropriateness is not a precise criterion. There may well be a range of dispensing fees which may be said to be appropriate. What must be prescribed must be within that range. It follows that the Pricing Committee and the Minister exercise some discretion in the determination of the appropriate dispensing fee. But they must remain within the range of what is appropriate and observe the limits for the exercise of discretion. What must constantly be borne in mind is that courts have a limited role in reviewing the exercise of an administrative discretion. They should guard against substituting their views on what is appropriate for that of the Pricing Committee and the Minister. Their role is to ensure that administrative action is lawful, reasonable and procedurally fair.

[522] There is a further consideration that is equally important in the context of this case. The determination of an appropriate dispensing fee is informed by both economic and other policy considerations. And as the Chief Justice observes, the task of the Pricing Committee calls for expertise and understanding of a complex market in which medicines are traded. The Pricing Committee possesses such expertise and it

consists of individuals with diverse backgrounds and experience in these matters. Courts have no expertise in these matters. As a general matter, they should only interfere with a fee fixed by the Pricing Committee if the fee is one that is beyond the range of what is appropriate. Such a fee would have to be challenged on the ground that it is one that a reasonable decision maker could not fix.[327]

[523] It follows that the submission by the government that courts have no business to review the appropriateness of the dispensing fee must be rejected.

[524] It is against this background that the question whether the Pricing Committee was bound to consider the viability of the dispensing fees for pharmacies in fixing dispensing fees must be determined.

Was the Pricing Committee bound to consider the viability of pharmacies?

[525] It is implicit, if not explicit from the objective to promote access to medicines by all at the lowest possible cost that there must be a supply of medicines. Access to medicines presupposes the availability of medicines. And the availability of medicines presupposes the existence of a supply of medicines. Without the supply of medicines there can be no access to medicines. The pharmaceutical industry is the source of that supply and thus the availability of medicines. Without pharmacies, access to medicines would be compromised. The pharmaceutical industry is therefore essential to the public for the supply of medicines. The importance of pharmacies is

[327] *Bato Star* above n 244 at para 44.

recognised by the NDP whose national development objectives include "support[ing] the development of the local pharmaceutical industry and the local production of essential drugs."

[526] Once it is accepted, as it must be, that pharmacists are crucial to the objectives of the Medicines Act, it must also be accepted that there is a need for them to survive. But those who are involved in the pharmaceutical industry do so for profit. An appropriate dispensing fee must be rationally related to the cost of doing business. It must be such that it makes it worthwhile for pharmacies to remain in business. And the economic viability of pharmacies is implicitly recognised by the Medicines Act. As the Australian Federal Court observed in the context of price fixing for pharmaceuticals in that country:

> "Pharmacies, like nursing homes, members of the medical profession and some hospitals are the creatures of the private sector. Those who operate them, no matter how much professional dedication they bring to their task, do so for profit. If it were not feasible to operate them profitably, pharmacy businesses would not exist any more than would nursing homes or medical practices. The legislature must be taken to understand this and to have intended prices to be fixed which would enable pharmacies to continue to operate profitably. In saying what I have, I do not mean that it follows that the prices must be such as to enable all pharmacies to operate profitably or that the prices might not be such as would make some pharmacies uneconomical perhaps because of an over concentration of them in one area, the existence of them in sparsely populated areas, inefficient operation or for other reasons. But fundamentally, so it seems to me, the legislature must have intended that the price to be fixed would be one which would enable properly run pharmacies in appropriate geographical areas to operate with a reasonable margin of profit. I emphasise the word 'reasonable'."[328]

[328] *Commonwealth of Australia v Pharmacy Guild of Australia and Another* 91 ALR 65 at 86.

[527] A dispensing fee that has the effect of driving pharmacies out of business, has the potential to cut the supply of pharmaceutical products, and thus undermines access to drugs and, ultimately, runs counter to the objectives of the Medicines Act. An appropriate dispensing fee must consider the need for pharmacies to receive, in addition to the cost to them of the drugs, some recompense for the trouble and expense of supplying the product. In addition, there is a need for such income to amount to a sufficient consideration to induce a sufficient number of pharmacists to continue to operate as approved pharmacies under the provisions of the Medicines Act.

[528] The viability of the dispensing fee for pharmacies is therefore a relevant factor which the Pricing Committee is bound to take into account when determining an appropriate dispensing fee. Also relevant in this regard are the different types of pharmacies that exist in practice such as community pharmacies, hospital pharmacies and courier pharmacies; different circumstances and thus different cost structures which pharmacies may operate in different areas such as all the inherent differences between provinces, between small and large pharmacies, between pharmacies situated in major cities and those in small rural towns; and those located in areas where doctors are also dispensing medicines; and so on. All these are matters that the Pricing Committee and the Minister were bound to take into consideration in determining the appropriate dispensing fee.

[529] The Pricing Committee and the Minister did not suggest otherwise. On the contrary they maintained that these matters were taken into consideration. While New Clicks in its written argument accepted that the deliberations of the Pricing Committee show that it was conscious of the fact that it had to fix a dispensing fee that was viable for pharmacies, New Clicks nevertheless contended that the dispensing fee was fixed without proper regard being paid to the viability of pharmacies. Before determining the question whether relevant considerations were properly taken into account by the Pricing Committee, it will be convenient to investigate first the nature and scope of the obligation of a decision maker to consider relevant factors.

The nature and scope of the obligation to consider relevant factors

[530] The Pricing Committee and the Minister must apply their minds to all relevant and material information placed before them. They must properly evaluate such information and attach such weight to it as the degree of its importance requires. They should not pay lip service to this obligation.[329] In *Bangtoo Bros. v National Transport Commission*, the court considered the meaning of the expression "apply its mind to the matter" and said:

> "It is clear from the cases that a body constituted by statute is obliged 'honestly to apply its mind to the matter' for decision. I am for the moment concerned with what is meant by the expression 'apply its mind to the matter', certain aspects of which have already been covered by this judgment. It seems to me essential that the tribunal is essentially obliged to consider all relevant and material information placed before it. To pay mere lip-service to this obligation is not sufficient, just as it would be a

[329] *Bangtoo Bros. and Others v National Transport Commission and Others* 1973 (4) SA 667 (N) at 685A-D; *Bato Star* above n 244 at para 99.

> dereliction of duty to hear representations which are pertinent, and then to ignore them. The problem arises whether the Court is concerned with the degree of importance which the tribunal attaches, in the exercise of an honest judgment, to the relevant considerations. Take a case, for example, where a factor which is obviously of paramount importance is relegated to one of insignificance, and another factor, though relevant, is given weight far in excess of its true value. Accepting that the tribunal is the sole judge of the facts, can it be said that it has in the circumstances postulated properly applied its mind to the matter in the sense required by law? After much anxious consideration I have come to the conclusion that the answer must be in the negative."[330] (Footnotes omitted.)

[531] The Pricing Committee and the Minister must therefore do more than pay lip service to the viability of pharmacies. They must address the need for pharmacies to exist in a meaningful way when fixing the appropriate fee, and be able to demonstrate that they have done so. This could be done by explaining the manner in which the viability of pharmacies was given effect. They must give an explanation of how the appropriate fee was calculated. This explanation is crucial to the process of determining an appropriate fee. It explains to the public and the pharmaceutical industry the manner in which the fee was arrived at. It discloses the reasoning process of the Pricing Committee. And it enables those who have an interest in the fee to assess whether the Pricing Committee has properly discharged its statutory duty. This explanation should generally be contained in the report of the Pricing Committee making a recommendation to the Minister.

[532] In *Bato Star* we had occasion to consider the meaning of the phrases "have regard to" and "have particular regard to" in the context of the need to take

[330] *Bangtoo Bros*. id at 685A-D.

transformation into consideration in awarding fishing quotas. On that occasion we said:

> "All these considerations point inexorably to the conclusion that the words 'have regard to' and 'have particular regard to' in the constitutional and statutory context, require a decision-maker to do more than give lip service to s 2(j). The decision must address the need for transformation in a meaningful way when decisions are made, and be able to demonstrate that this has been done. A failure to do so is unlawful, and the ensuing decision is open to attack."[331]

And we continued and said:

> "It follows that, if the Minister were to fail to heed this injunction, he would be acting unlawfully and his decision would be open to attack. It is incumbent upon the Minister to put forward facts from which it will appear that he has indeed paid due regard to the need to promote transformation. A Court reviewing the decision of the Minister has an obligation to ensure that the section has been complied with. Where there is a dispute as to whether the Minister has complied with s 2(j), the Court considering the matter must examine the facts relied upon by the Minister as establishing compliance with s 2(j), and satisfy itself that there has been compliance with this provision."[332]

[533] It now remains to consider whether the Pricing Committee and the Minister in fixing the dispensing fees properly applied their minds to matters that they were bound to consider such as the viability of pharmacies.

[534] The record shows that the Pricing Committee and the Minister were conscious of the need to consider the viability of pharmacies in fixing an appropriate fee. Indeed

[331] *Bato Star* above n 244 at para 99.

[332] Id at para 103.

in the minutes of the meeting of the Pricing Committee held on 20 and 21 November 2003 the Pricing Committee is recorded as having concluded that the "pharmacy outlets play an important role and it is therefore imperative that this market is not jeopardised by the committee's recommendation". They were also conscious of the varying circumstances in which different types of pharmacies operate. They were mindful of the fact that an appropriate fee should cover both the professional remuneration and the operating costs. In short, the Pricing Committee was alive to the factors that were relevant to the determination of an appropriate fee.

[535] What is singularly lacking in the record is an explanation of how the dispensing fees were arrived at. There is no explanation as to why the Pricing Committee chose the figures that it chose. While the Pricing Committee indicated that the fee covers both the professional remuneration and operating costs, it does not explain what was allocated to each of these component parts of the fee. As the SCA observed, "except for a general statement that all factors were taken into account, there is no evidence or document that shows what those factors were, what weight they bore, whether any calculations were made and, more particularly, whether any regard was given to the viability of the dispensing profession." It was this lack of explanation for quantum of the dispensing fees that led the SCA to conclude that there was no rational explanation for the quantum of fees and that therefore the fees were not appropriate.[333]

[333] Above n 265 at para 89.

[536] As pointed out previously, the Pricing Committee and the Minister were obliged to address the viability of the fees for pharmacies in a meaningful way, and demonstrate that they have done this. It was incumbent upon them to put forward facts from which it would appear that they had paid due regard to the viability of pharmacies so that a court considering a dispute relating to the viability of the fees could examine those facts and satisfy itself that they have properly discharged their statutory duty. In particular, they had to explain how they arrived at the figures that they adopted. In the absence of such explanation it is difficult to assess whether they had due regard to the viability of pharmacies. The mere statement by the applicants that they have done so is insufficient.

[537] Dr Zokufa states that "the regulations were modelled on the principles underpinning the Australian system although they have been adapted to the circumstances prevailing in the Republic". The Australian jurisprudence on the need to furnish an explanation for the quantum of dispensing fees is instructive. It is true, the Australian cases were decided under the Australian statute which requires a decision maker to furnish reasons for its decision. In the second place under the Australian legislation, the fees are determined by a tribunal which hears submissions from the interested parties. In principle, the obligation of the Pricing Committee to furnish an explanation for the fees adopted is no different from that of the Australian tribunal. Therefore I consider the rationale for the furnishing of reasons articulated by the Australian cases applicable in our context.

[538] In *In re: the Commonwealth of Australia and the Pharmacy Guild of Australia and Another*, Sheppard J said:

> "The provision of reasons is an important aspect of the tribunal's overall task. Reasons are required to inform the public and parties with an immediate interest in the outcome of the proceedings of the manner in which the tribunal's conclusions were arrived at. A purpose of requiring reasons is to enable the question whether legal error has been made by the tribunal to be more readily perceived than otherwise might be the case. But that is not the only important purpose which the furnishing of reasons has. A prime purpose is the disclosure of the tribunal's reasoning process to the public and the parties. The provision of reasons engenders confidence in the community that the tribunal has gone about its task appropriately and fairly. The statement of bare conclusions without the statement of reasons will always expose the tribunal to the suggestion that it has not given the matter close enough attention or that it has allowed extraneous matters to cloud its consideration. There is yet a further purpose to be served in the giving of reasons. An obligation to give reasons imposes upon the decision-maker an intellectual discipline. The tribunal is required to state publicly what its reasoning process is. This is a sound administrative safeguard tending to ensure that a tribunal such as this properly discharges the important statutory function which it has."[334]

[539] In *Dornan and Others v Riordan and Others*[335] the appeal court expressed similar concerns in the context of failure by the tribunal to explain why it had adopted a base figure of Aus $3.50 for each ready prepared item as an amount to be charged by the pharmacists. In that case even though the tribunal had disclosed the material that it had taken into consideration, the court held that this was not sufficient. The tribunal had to disclose the reasoning process that led to its determination. In this regard the court said:

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[334] Above n 328 at 88.

[335] 95 ALR 451.

> "It is, however, impossible to understand from the reasons given by the tribunal why it was that the tribunal adopted the precise base that it did. Although the interim report of the tribunal was 239 pages in length and had many lengthy appendices, including Deloittes' report, and although the report of 28 August 1989 was itself 178 pages in length, the reasons do not make it clear why the base figure of $3.50 for each ready prepared item was adopted. It seems from the interim and the final reports that the tribunal was substantially influenced by what was contained in the Deloittes' study. But even so, while the reasons disclose the material which the tribunal took into account, it is impossible to glean from the tribunal's reasons what was the reasoning process that let it to its determination."[336]

And later the court remarked:

> "These two statements are too general to make it clear what it was the $3.50 was considered to represent. Was the $3.50 thought to be fair return to pharmacists having regard to their labour and their capital invested, was it thought to be a break-even fee for an average pharmacy, was it thought to be the most that the Commonwealth could reasonably be expected to pay or was it something else? The reasons do not disclose".[337]

[540] The *Dornan* case also illustrates the difficulties that may result from a failure to furnish reasons for the fees adopted. Failure to explain how the fees have been calculated makes it impossible for the court to properly evaluate the challenge to the fees adopted. As we pointed out in *Bato Star*, the decision maker must put forward facts from which it will appear that they have considered the matter. This is essential because the court must evaluate those facts in order to satisfy itself that the empowering statutory provision has been complied with. In the *Dornan* case the

[336] Id at 455.

[337] Id at 456.

determination of the tribunal was also challenged on the grounds that (a) it failed to have regard to relevant considerations; and (b) its determination was unreasonable. In dealing with these further grounds of challenge, the court remarked as follows:

> "We do not think it useful to discuss these further grounds of challenge which were shortly argued in the appeal. Counsel for both sides submitted that, by reference to the tribunal's final report, to its interim report, to Deloittes' study and to other material, it could be ascertained that the tribunal took such and such into account or relied on this and that. The grounds were argued accordingly, reference being made to relevant legal authorities and to factors to which the tribunal may or may not have given weight. In our opinion, as the tribunal did not explain its course of reasoning, the basis for the grounds tended to fail, for the argument could find no foothold on any firm ground. For example, not having been informed why the $3.50 was adopted, it is difficult to hold that there was not a basis upon which a reasonable decision-maker could have come to that result. But this is simply to say that the reasons for the decision are so elusive that it was impossible for the pharmacists to establish those grounds of challenge — unreasonableness, material and immaterial considerations etc — upon which they relied. The major flaw in the tribunal's decision was that the tribunal did not state reasons adequate to enable the court to determine whether or not any other error had occurred in the reasoning process."[338]

[541] The failure by the Pricing Committee to explain how it arrived at the figures it adopted made it difficult to evaluate the appropriateness of the dispensing fees adopted, and thus to determine whether the Pricing Committee has properly applied its mind to the viability of pharmacies. Not having been told why the figures were adopted, it is difficult to determine whether the Pricing Committee properly applied its mind to the viability of pharmacies, and ultimately whether there was a basis upon which a reasonable decision maker could have fixed the fees in dispute. It is true and

[338] Id at 462.

the record indicates that the Pricing Committee was always conscious of the need to fix a fee that would be viable for pharmacies. This is not enough. The reasons are elusive. The Pricing Committee had to demonstrate that they had done so.

[542] The need to furnish an explanation for the quantum of fees adopted is especially important in the context of section 22G(2). The Minister is required to make regulations based on the recommendation of the Pricing Committee. The Minister does not merely rubber stamp the recommendation of the Pricing Committee. She is required to apply her mind to the recommendation and make a decision whether to accept such recommendation. She cannot therefore accept the fees proposed by the Pricing Committee simply because they have been proposed by the Pricing Committee. She must satisfy herself that the fees proposed by the Pricing Committee are appropriate within the meaning of section 22G(2). She can only do this if she is furnished with an explanation as to how the fees were arrived at. Without such information, the Minister cannot properly evaluate the appropriateness or otherwise of the fees proposed by the Pricing Committee.

[543] There is much to be said for the conclusion reached by the SCA that the record "establishes that the fees are not appropriate and that the [applicants], within whose peculiar knowledge the calculation [of the fees are], were unable to give any rational explanation for the quantum of the fees."[339] Ordinarily failure to provide an explanation would lead to the inference that there is no rational explanation for the

[339] Above n 265 at para 89.

fees determined and that the fees are therefore arbitrary.[340] This is more so here, where the fees have been challenged on the ground that they are not appropriate. However, it is not necessary to reach that conclusion here because there are considerations which suggest that the Pricing Committee did not properly apply its mind to factors which it was bound to consider. It is sufficient for the purposes of this judgment to refer only to a few of these to illustrate the point. These matters concern facts that are either common cause or not in dispute or appear from the evidence on behalf of the applicants. They relate to the viability of the dispensing fees for pharmacies; the special situation of rural pharmacies and courier pharmacies; the problem of compounding; and the failure to consider oral representations.

The viability of the dispensing fees for pharmacies

[544] In a briefing by the Department to the Parliamentary Portfolio Committee on Health on 17 February 2004, Dr Zokufa is reported to have said the following in response to a question from a member of the Portfolio Committee to the effect that pharmacists were concerned that they would not be able to sustain their business if they charged the 24% dispensing fee:

> "With regard to the concern around dispensing fees, the presenter said that South Africa has 2500 retail pharmacists and they are not enough to cover the whole country. There is a need to increase this number. The 24% and R24.00 dispensing fee is a minimal figure. The Department was interested in seeing what pharmacists would say about it. Their survival would be influenced by volumes of prescriptions that they get. The more prescriptions they get and the more items they dispense, the

[340] *Pretoria North Town Council v A.1.Electric Ice-Cream Factory (Pty) Ltd* 1953 (3) SA 1 (A) at 16F-G; *Livestock & Meat Industry Control Board v Robert S. Williams (Pty) Ltd* 1963 (4) SA 592 (T) at 598C; *Minister of National Revenue v Wright's Canadian Ropes Ltd* 1947 A.C. 109.

> more they would get the 24% or R24.00 dispensing fee. The Department felt that the dispensing of medicines should be left to the pharmacists and not medical practitioners. This would ensure an increase in the volume and number of items that the pharmacies dispense. If the Department were not strict about how it gave licences to people who are not pharmacists, the 24% or R24.00 dispensing fee would not make the sector viable. This is because the pharmacists would not be seeing big volumes, as these would have been dispensed by persons who were not pharmacists."

Later in the same briefing session, Dr Zokufa is reported as having further said:

> "The assumption is that the current volume of medicines distributed from pharmacies is far less than what it should be because there are doctors who are also dispensing medicines. If this is changed around and doctors no longer dispense medicines, that pharmacist would see an increase in the volume of medicines dispensed. With a 24% profit margin, this small pharmacist's business should be able to succeed . . . Dr Zokufa said that these Regulations were putting a huge challenge to every sector in the health industry. For the first time, the retail pharmacists were challenged to show how they would come out with 24% or R24 from the medicines they sell . . . Pharmacies do not only make their living out of prescription medicine, they make profits from their front shops too. The big discount pharmacies were not worried about the regulations because they received high volumes of prescriptions, and they make most of their money from the front shops which were not affected by these Regulations."

[545] Dr Zokufa admitted these allegations "[i]nsofar as [they] correctly reflect the statements made to [the] parliamentary portfolio committee on Health". Apart from saying that "[t]he statements . . . must be read as a whole and must be seen in their proper context", he did not dispute the accuracy of the allegations. Nor did he suggest what that proper context is. These allegations must therefore be accepted as an accurate reflection of what he said in the Portfolio Committee on Health. This

statement must be taken as further amplification of the reasons for the dispensing fees adopted.

[546] What emerges from the statement by Dr Zokufa is this: "the current volume of medicines that is distributed by pharmacies is far less than what it should be" because of competition from other dispensers of medicines such as medical practitioners. Unless there is an increase in the volume of medicines dispensed by pharmacies, the dispensing fees adopted would not be viable for pharmacies. This is so "because the pharmacists would not be seeing big volumes, as these would have been dispensed by persons who were not pharmacists." The solution to this low volume lies in leaving the dispensing of medicines to pharmacists and not medical practitioners. And therefore, unless the Department is strict about how it issued licences to other people who wish to dispense medicines, "the 24% or R24.00 dispensing fee would not make the sector viable." Implicit in the statement is the acceptance that without an increase in the current volume of medicines that are dispensed by pharmacies, the dispensing fees adopted would not be viable for pharmacies.

[547] Of course this statement by Dr Zokufa must be read in the light of his evidence in the High Court. He accepts that workload is an important variable in determining an appropriate dispensing fee. He accepts too that the current workload of community pharmacies is too low. He makes much of the admission by representatives of PSSA that if there is an increase in the workload of pharmacies, they would be prepared to accept a lower dispensing fee and the R24 would be tolerable if there is an increase in

the workload. Significantly, he does not challenge the suggestion implicit in the statement by PSSA that unless there is an increase in the volume of medicines dispensed by pharmacies, 24% or R24 is not viable for pharmacies. Instead he says that "the key issue is that retail pharmacies with a very low workload will face financial viability constraints", and adds that the solution does not lie in increasing the dispensing fee but in "seek[ing] ways of increasing the dispensing workload".

[548] Now the dispensing fees were adopted with full knowledge that they would not be viable unless there was an increase in the volume of medicines dispensed by pharmacies. On the applicants' own version, it is therefore clear that without an increase in such volume, the dispensing fees adopted are not appropriate. There is no evidence that such increase has occurred. Nor is there any explanation from the applicants as to why dispensing fees whose viability is admittedly dependent upon an increase in the volume of medicines that are dispensed by pharmacies, has suddenly become viable without such an increase. It is true, the figures of 24% or R24 were increased to 26% or R26 respectively. There is no suggestion that this increase was to compensate pharmacies for the fact that the volume of medicines that they dispense was unlikely to increase.[341]

[341] It should be recalled that when the draft regulations were published for comment in December 2003, the fees were fixed at R24/24% for retail pharmacies and R14/14% for others. Subsequent to the oral hearings, the Pricing Committee again discussed this issue which resulted in the draft regulations being published on 19 April 2004. Those regulations fixed the fees at R24/24% plus a 1.5% mark-up on the cost of the medicine dispensed. On 20 April 2004 the Pricing Committee held a meeting with the Minister and this resulted in the review of the dispensing fee which was then R26/26%, the mark-up was dropped. It seems clear that the 1.5% mark-up would have resulted in greater remuneration to pharmacies where the drugs were expensive. It is also clear that the Pricing Committee suggested the 1.5% to cover stock costs and not to deal with issues relating to a number of scripts dispensed by pharmacies.

[549] The Pricing Committee was bound to consider, among other factors, the viability of dispensing fees for rural pharmacies given the low volume of medicines dispensed by them, and the slight likelihood of their increasing that volume as well, and those pharmacies with a very low workload which were admittedly bound to "face financial viability constraints." Notwithstanding the suggestion that the solution to the low volume "is to seek ways of increasing the dispensing workload", there is nothing in the deliberations of the Committee to suggest that it ever applied its mind to the question of how the workload was to be increased to meet the concern.

[550] In the Portfolio Committee Dr Zokufa suggested that the increase of the workload could be achieved by leaving the dispensing of medicines to pharmacies and not medical practitioners. But to do so would have run counter to section 22G(2)(b) read with section 22C(1)(a) of the Medicines Act which expressly recognises that medical practitioners would dispense medicines. Indeed regulation 12 permits medical practitioners to charge a dispensing fee that is less than that fixed for pharmacies. Therefore the course suggested was manifestly not open to them. The regulations were made on the footing that medical practitioners will continue to dispense medicines and therefore that the volume of medicines dispensed by pharmacies will continue to be low because medical practitioners are also dispensing medicines.

[551] There was also a suggestion that the Department would have to be strict about how it issues licences to persons who are not pharmacists. Perhaps Dr Zokufa had in mind the licensing policy as contained in the NDP which says:

> "Medical practitioners and nurses will not be permitted to dispense drugs, except where separate pharmaceutical services are not available. In such instances/situations where dispensing by doctors and nurses has to take place, such persons will be in possession of a dispensing licence issued by the Medical Control Council. Criteria for the granting of such licence will include *inter alia*, the application of geographical limits."

[552] But that course too was not open to them. In *Affordable Medicines* we had occasion to consider a constitutional challenge to sub-regulation 18(5)(a), (c), (d) and (e) dealing with the issuing of licences to dispense medicines under the Medicines Act.[342] The medical practitioners feared that the government would use the regulations to deny them licences to dispense medicines where there were pharmacists in the area, consistent with this policy. In that case, the government denied that it had a policy of denying licences to dispense medicines to medical practitioners where there were pharmacists in the vicinity. Nevertheless we found that the purpose of sub-regulation 18(5) (a), (c), (d) and (e) was "manifestly to protect pharmacies against competition from medical practitioners and nurses" and that the sub-regulation was not authorised by the Medicines Act.[343] In addition, in that case, the Department of Health not only denied that it had a policy of denying licensing to medical practitioners where there were pharmacists in the vicinity but also expressly

[342] *Affordable Medicines* above n 275.

[343] Id at para 119.

disavowed any intention of using the impugned regulations to deny licences to medical practitioners.[344]

[553] The Pricing Committee seems to have been mindful of the fact that an increase in the volume of medicines dispensed by pharmacies was crucial to their viability. However, it is clear that what was perceived to be a solution to the low volume problem could not be implemented as this would have been inconsistent with the Medicines Act. The problem of low volume is a matter to which the Pricing Committee was bound to apply its mind. What if there was no increase? What was to become of those pharmacies whose financial viability was admittedly threatened, were they to close shop, and if they do, what impact would this have on the promotion of access to affordable medicines? The Pricing Committee does not seem to have properly applied its mind to these matters.

[554] In any event, on the applicants' own admission, the present dispensing fees are not viable for pharmacists unless there is an increase in the volume of medicines that they dispense. Both logic and common sense suggest that in the absence of evidence of the increase in such volume, the dispensing fees adopted cannot be said to be viable for pharmacies. Nor can the dispensing fees adopted be said to be the fees that a reasonable Pricing Committee could adopt. It follows that while the Pricing Committee was conscious of the need to take into consideration the viability of pharmacists, it did not give proper attention to this requirement.

[344] Id at para 113.

Rural pharmacies

[555] The other consideration relates to the treatment of rural pharmacies. Professor McIntyre accepts that "these pharmacies are generally in a difficult economic position." They are, according to her, economically disadvantaged by "a comparatively low turn-over and also unfavourable payment conditions from wholesalers." But this factor did not influence the Pricing Committee to treat rural pharmacies differently. The Pricing Committee took the view that because the disadvantage results from "distortions in the health sectors . . . an appropriate dispensing fee should be as neutral as possible in respect of such distortions." In effect therefore the Pricing Committee, while mindful of the plight of rural pharmacies, did not give proper regard to it in determining the appropriate dispensing fees.

[556] Most people who live in the rural areas are comparatively disadvantaged. Many do not have the basic facilities that are taken for granted in the urban areas. Some have to walk long distances to get health care services. For some, indeed by far the majority, access to health care services is still a distant dream. What is more they are comparatively poor. One needs no evidence to establish this. Those who live in this country know this. They witness these conditions daily. Both the print and the electronic media tell the story of rural communities. Pharmacies who operate in rural areas have to contend with these problems. But they have problems of their own. They are, as Professor McIntyre tells us, economically disadvantaged by amongst

other factors, "a comparatively low turn-over and also unfavourable payment conditions from wholesalers." The legislature must be taken to understand all of this and to have intended that fees to be fixed would enable pharmacies in the rural areas to operate profitably and not to close shop.

[557] Rural communities are entitled to have access to affordable medicine, just like those who live in urban areas. As pointed out earlier, pharmacies who operate in these areas provide an essential service – they are crucial for the supply of medicine and thus access to affordable medicine. There are about 350 pharmacies in the rural areas. According to the evidence, a rural pharmacist plays a dual role, namely, that of a health care advisor and that of a dispenser of medicine. But these pharmacies are also entitled to make a reasonable profit. Otherwise they will close their businesses. And this will result in the rural communities being deprived of access to affordable medicine. This could hardly be the purpose of section 22G(2)(b). A dispensing fee that does not take into account the fact that rural pharmacies are economically disadvantaged cannot be said to be fair and just.

[558] The Pricing Committee has not given adequate reasons for ignoring their plight. The bold statement that distortions in the health sector should not affect dispensing fees fixed, is simply not adequate. It simply begs the question. Why should their plight be ignored? What consequences will the dispensing fees have to the viability of these pharmacies, and ultimately, to the promotion of access to affordable medicines? These questions do not appear to have been addressed by the Pricing Committee. The

question which the Pricing Committee had to consider is not whether distortions in the health sector should affect the dispensing fees, but whether given the admitted economic disadvantages suffered by rural pharmacies, were the dispensing fees viable for them. In any event the disadvantages suffered by rural pharmacies do not stem only from distortions in the health sector, but they also stem from the very circumstances under which they operate such as poverty of the communities they service.

[559] While the Pricing Committee adopted the "principle of neutrality" in relation to rural pharmacies, it did not apply this principle to the differences between wholesalers and distributors. In relation to wholesalers, it took the view that the differences between wholesalers and distributors should be recognised, because "it is not the role of the Committee to remove wholesalers from the market." Why should the same consideration not apply to rural pharmacies, who are admittedly economically disadvantaged? This is not to suggest that rural pharmacies must necessarily be allowed to charge higher dispensing fees. Whether that should be so is not for courts to decide. The point here is that the Pricing Committee was bound to apply its mind properly to the situation of rural pharmacies and thereafter give cogent reasons for its decision. Instead it focused on wrong questions, namely, whether distortions of the health sector should be allowed to affect the dispensing fee. In doing so, it erred.

[560] All of this must be viewed against the admission by Professor McIntyre that rural pharmacies have a low turnover and the statement by Dr Zokufa that community

pharmacies with a very low workload will face financial viability constraints as a result of the dispensing fees. Yet the Pricing Committee did not consider whether the dispensing fees would remove rural pharmacies from the market. In my view the Pricing Committee erred in focusing on whether the distortions in the health sector should affect the dispensing fee. What the Committee was bound to consider was whether given the economic disadvantage suffered by rural pharmacies, was the dispensing fee viable for them.

Courier pharmacies

[561] Then there are courier pharmacies. Two factors are said to set courier pharmacies apart from community pharmacies and which cumulatively render them more vulnerable to a capped fee. In the first place these pharmacies supply mainly high cost medicines such as drugs for HIV patients, medicines used for renal dialysis and oncology drugs for cancer patients. According to the evidence, this means that the R26 ceiling is likely to have a larger effect on their gross profit than on the profits of a typical community pharmacy. The other factor is that these pharmacies do not have front shop operations to absorb any pharmacy losses. Any regulation that has the effect of reducing their gross profits is likely to have an adverse impact on them. The courier pharmacy business model focuses on dispensing drugs and essentially only drugs.

[562] The Pricing Committee considered the position of courier pharmacies in the context of wholesalers and, in particular, where they fit in the supply chain. It took

the view that its recommendation could not be based on efficiency or on protecting business models based purely on the level of risk that they involve. The attitude of the Pricing Committee towards courier pharmacies is summed up in the affidavit of Dr Zokufa who says that these pharmacies represent "a business model selected by the owner of the pharmacy" and that business models "are flexible and can be adjusted to the changing needs and circumstances of a business". In short, the message to courier pharmacies is adapt or die.

[563] I agree with Moseneke J that the question which the Pricing Committee was bound to consider is whether the dispensing fees would be viable for courier pharmacies. It was not called upon to consider whether the various business models should be protected. These pharmacies provide an essential service to the chronically ill – the most vulnerable. The record indicates that they dispense at least 12% of the prescription medicines by channel measured by value. It is therefore clear from the record that these pharmacies are differently situated than the other pharmacies. And it is not without significance, as pointed out earlier, that the Pricing Committee considered it necessary to recognise the differences between distributors and wholesalers because it did not want to remove wholesalers from the market. It is difficult to understand why the same considerations were not applied in relation to courier pharmacies. It seems to me that by focusing on the question whether the various business models should be protected, the Pricing Committee failed to apply its mind properly to the question of the viability of the dispensing fees for courier

pharmacies, a question which it was bound to consider. In doing so, the Pricing Committee erred.

Compounding of medicines

[564] In its report of 18 December 2003 to the Minister, the Pricing Committee made it quite clear that dispensing fees for pharmacists covered the professional services provided by pharmacists, including the compounding of medicines. The report also stated that the dispensing fees covered both the professional remuneration and the pharmacy's operating costs. Again in the same report, the Pricing Committee, which considered what the dispensing fees covered in the light of the definition of "dispensing fee" as contained in the Regulations Relating to the Practice of Pharmacy,[345] confirmed that the dispensing fee included compounding. However, in the High Court both Professor McIntyre and Dr Zokufa averred that the dispensing fees did not include compounding. Their assertion is neither borne out by the regulations nor the record. There is no explanation for this apparent inconsistency.

[565] These statements were apparently made to refute the contention by pharmacies that the dispensing fee is the primary source of professional income for pharmacies. The pharmacies were basing their contention on the reports of the Pricing Committee

[345] Regulations Relating to the Practice of Pharmacy published in Government Gazette No 21754, Government Notice R1158 on 20 November 2000. Regulation 1 of these regulations defines "dispensing" to mean:

> "the interpretation and evaluation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container according to the Medicines Act and the provision of information and instructions by a pharmacist to ensure the safe and effective use of medicine by the patient and 'dispense' has a corresponding meaning".

which stated more than once that the dispensing fees included compounding. The applicants now allege that in addition to dispensing fees, pharmacies are free to charge for other services such as compounding. But if this is so, this would mean that pharmacies may charge whatever they want for the other services including compounding. This can hardly be said to be consistent with the primary object of the Medicines Act to promote access to medicines at the lowest cost possible.

[566] If the contention now made by Dr Zokufa and Professor McIntyre is to be accepted, then it means the Pricing Committee did not apply its mind to compounding, a matter that they were bound to consider. This flows from their admission that "a pharmacist may spend a considerable amount of time in regard to compounding and admixing of medication". And compounding is one of the professional services rendered by pharmacists. Pharmacists sell compounded medicines, which consist of a mixture of medicines that they may have purchased either from wholesalers or manufacturers. Now section 22G(3)(b) expressly prohibits the pharmacists from selling medicines at a price higher than the single exit price. The only exception allowed is for pharmacists to charge a dispensing fee contemplated in section 22G(2)(b). The obvious question that arises is at what price are the pharmacists to sell compounded medicines. This is a matter which the Pricing Committee and the Minister had to consider. On their own admission therefore, the Pricing Committee did not consider this matter. Here too, they erred.

Ignoring oral representations

[567] The final instance of failure to have regard to a relevant matter to which reference should be made is that relating to oral representations. New Clicks submitted that it is plain on the evidence of Professor McIntyre and Dr Zokufa that the Pricing Committee ignored oral representations. Both Professor McIntyre and Dr Zokufa distanced the Pricing Committee from the oral hearings. They maintained that oral hearings were held at the instance of the Department of Health and that the meetings at which oral representations were made were not meetings of the Pricing Committee but meetings of the Department. Both were at pains to emphasise that the Pricing Committee considered written representations at its meetings. They said nothing about oral representations.

[568] Other than Professor McIntyre there is no suggestion that any member of the Pricing Committee reviewed the recordings of the oral representations. Nor is there any indication that the Pricing Committee ever considered the oral representations. It is therefore plain from the evidence of Professor McIntyre and Dr Zokufa that the Pricing Committee did not consider oral representations that were made on the draft regulations. In the light of this evidence it must be accepted that the Pricing Committee made its recommendation to the Minister without regard to the information that was presented at the oral hearings on the very issues that the Pricing Committee had to consider. The question is whether the Pricing Committee was bound to consider oral representations.

[569] It is clear from the minutes of the Pricing Committee meeting held on 27 January 2004 that the Pricing Committee took a decision to hold oral hearings. It was also decided at that meeting that the Directorate of the Department of Health would initiate this process by, among other things, arranging dates of hearings, issuing letters of invitation and leading the discussion at the hearings. It was also decided that each stakeholder would be allocated one hour to make a presentation. The draft programme had to be circulated to members of the Pricing Committee. I should point out here that the process of convening and managing oral hearings had to be led by the Directorate which serves as the secretariat for the Pricing Committee.[346] Indeed in its report to the Minister dated 19 April 2004, the Chairperson of the Pricing Committee expressed "gratitude to Dr Humphrey Zokufa and the Department of Health secretariat who have provided such effective support and inputs to their work . . . ".

[570] It is equally clear that the Pricing Committee considered oral representations to be vital to its task. The importance attached to oral representations by the Pricing Committee appears from the decisions it took at its meeting of 20 February 2004 where it considered, among other issues, "Update on plans for stakeholder representations discussions". While accepting that not all members of the Pricing Committee would be able to attend the hearings, it was decided that "all members of the Pricing Committee should commit to attend the stakeholder presentations" and that to this extent "all committee members should indicate the dates on which they

[346] Regulation 38(4) of the General Regulations Made in Terms of the Medicines and Related Substances Act published in Government Gazette 24727, Government Notice R510 on 10 April 2003, provides:

> "The Director-General may designate employees of the Department to serve as the secretariat of the Committee."

would be able to attend stakeholder presentations between 8 and 26 March 2004". The minutes of that meeting also reflect the following decisions taken which demonstrate the importance that the Pricing Committee attached to oral representations:

> - "It is not possible for members of the committee to participate in all representations;
> - as associations present the general views it would be helpful to the committee to hear the views of the individuals belonging to such an association. It would give the committee an opportunity to weigh the different data;
> - the Directorate should forward copies of the written comments to the committee members as the comments are received;
> - the Pricing Committee and the Department will have an opportunity to ask questions but no questions of clarification will be allowed from the stakeholders; and
> - a list of key questions should be developed and data being presented should be interrogated very carefully."

[571] In addition, the letter of 12 February 2004 by the Director-General of Health inviting the stakeholders "to make oral representations on [their] written comments on the proposed regulations on the pricing of medicines" underscores the importance of the oral hearings not only to the Department but also to the Pricing Committee. That letter outlined the purpose of oral hearings as follows:

> "The purpose of these sessions is to hear oral presentations from stakeholders and to give them an opportunity to fully canvass their concerns and comments regarding the proposed regulations. There will be no negotiation or debates between the Department or the Committee on the one hand and yourselves on the other concerning the proposed regulations.

> The Pricing Committee is a technical committee whose task is to make recommendations to the Minister of Health. You are therefore advised to prepare your written and oral inputs in as much detail as possible and with a view to supplying accurate and substantiated information to the Department and the Pricing Committee on how the proposed regulations may affect your interests. Where the regulations raise more than one possibility, you are advised to include all possible impacts in your presentations.
>
> The object of these sessions is not to provide further clarification by departmental officials or members of the Pricing Committee on the proposed regulations. Consequently **no questions for clarification will be answered**. The Department and the Pricing Committee would like to hear your comments on, and interpretation of, the regulations as opposed to their own views. This said, you may by all means indicate areas that are not clear to you and in what way they lack such clarity."

[572] In the light of the above, it is difficult to accept that the oral hearings were meetings of the Department only. It is difficult to reconcile that assertion with the decisions taken by the Pricing Committee as reflected in its minutes and the letter inviting oral representations. The fact that the meetings were called by the Department does not in itself make those meetings to be meetings of the Department. When the draft regulations were published on 16 January 2004, for example, interested persons were invited to submit representations to the Director-General and this invitation was issued at the instance of the Minister. The applicants do not suggest that the Pricing Committee did not consider such representations because they had been requested by the Minister and had to be forwarded to the Director-General. On the contrary they repeatedly emphasised that they considered written representations. This must be so because the Directorate provides secretariat support to the Pricing Committee. It was for that reason that the Directorate was responsible

for organising oral hearings. It is not clear why the applicants should now seek to distance the Pricing Committee from the oral representations which were invited to benefit both the Pricing Committee and the Department.

[573] Be that as it may, it is clear from the record that the Pricing Committee considered it not only necessary, but also important to hold oral hearings. Indeed the importance of the oral hearings to the task of the Pricing Committee cannot be gainsaid. The purpose of oral representations was "to give [the stakeholders] an opportunity to fully canvass their concerns and comments regarding the proposed regulations." To this extent the stakeholders were "advised to prepare [their] written and oral input in as much detail as possible with the view to supplying accurate and substantiated information to the Department and the Pricing Committee on how the proposed regulations may affect [the stakeholders] interests." And in the letter inviting oral representations, the stakeholders were told that "[t]he Department and the Pricing Committee would like to hear [their] comments on, and interpretation of, the regulations as opposed to their own views." Oral representations therefore had to address matters that were relevant to the recommendation of the Pricing Committee. They were to address a matter that lies at the very heart of this litigation, namely, the viability of the dispensing fees for pharmacies. In these circumstances the Pricing Committee was bound to consider matters addressed during the oral hearings.

[574] In *Bangtoo Bros.* the Court held that it would be "a dereliction of duty to hear representations which are pertinent and then to ignore them."[347] It seems to me that having decided that oral representations are pertinent to its recommendation, the Pricing Committee was bound to properly apply its mind to such representations. Representations were available on audio and video tapes. They were therefore easily accessible to all members of the Pricing Committee. I consider it to be equally a dereliction of duty to call for oral representations which are pertinent and then to ignore them. By ignoring oral representations, the Pricing Committee deprived itself of information that it had committed itself to achieve during the oral hearings. That information was not only vital, but was manifestly relevant to its recommendation as demonstrated by the decisions taken by the Pricing Committee in relation to oral hearings. In ignoring the oral representations, the Pricing Committee ignored relevant matters which it was bound to take into account. The duty of the Pricing Committee was to apply its mind properly to all materials before it including matters raised at the oral hearings. It failed to do so when it ignored oral representations. In doing so it erred.

Conclusion

[575] It is necessary to stress two points by way of conclusion. The first is that the determination of dispensing fees is a matter that belongs to the discretion of the Pricing Committee and the Minister. The point here is that the manner in which the discretion was exercised violated PAJA. Discretion must be exercised in accordance

[347] *Bangtoo Bros*. above n 329 at 685.

with the principles of administrative justice as codified in PAJA. The role of the courts is to police the exercise of that discretion. Where it is exercised in a manner that is inconsistent with PAJA, the courts will, and must intervene. Failure by a decision maker to take into account matters that the decision maker is bound to take into consideration, is an instance of an abuse of that discretion. The enquiry in this case is therefore whether the Pricing Committee and the Minister properly applied their minds to the matters that they were bound to take into consideration. If they did not, the resulting fees can hardly be said to be ones determined in accordance with the behest of section 22G(2)(b) and thus appropriate.

[576] The other is that the fact that the fees fixed will result in the demise of some pharmacies is not necessarily indicative of the inappropriateness of the fees. This may result from many factors including inefficiency. To reach that conclusion, the pharmacies would have to put up facts which show that but for the dispensing fees pharmacies would be viable. Nor does the reduction in the profits necessarily suggest that the fees are inappropriate. On this record I am unable to reach that conclusion. In my view the record is simply inadequate for that conclusion to be reached. But the conclusion I reach is that the dispensing fees adopted are inappropriate because in the exercise of their discretion, the Pricing Committee and the Minister ignored certain relevant factors which they were bound to take into consideration.

[577] The considerations referred to above, individually and cumulatively, lead to the conclusion that the Minister and the Pricing Committee failed to properly apply their minds to the matters which they were bound to consider. The resulting dispensing fees cannot be said to be appropriate. In the result, regulations 10 and 11 are invalid in that they adopt dispensing fees that are not appropriate. And for reasons given by the Chief Justice, I agree that regulation 13 is also invalid. For these reasons, I agree with the conclusion reached by the Chief Justice that the fees adopted are not appropriate. In view of this conclusion, it becomes entirely unnecessary to consider the challenge based on section 22 of the Constitution.

[578] In view of the judgment of the Court dealing with the remedy, it is not necessary to deal with the remedy in this judgment.

SACHS J:

[579] I have had the pleasure of reading the careful and comprehensive judgment of Chaskalson CJ. Its reach is prodigious and its line of reasoning clear and persuasive. I am happy to concur in it, subject to a qualification which I make below. I have also had the benefit of reading the judgment of Ngcobo J and wish to express my agreement in broad terms with the forceful additional arguments he advances, subject to a similar qualification. In reaching the same conclusions as they do, I follow a different route in one significant respect. Chaskalson CJ holds that subordinate

legislation in general should be controlled by the Promotion of Administrative Justice Act[348] (PAJA), and Ngcobo J holds that PAJA is applicable to the facts of this case. I believe, on the other hand, that control of subordinate legislation in general should be accomplished by employing a constitutionally embedded principle of legality, and that PAJA is not generally applicable to the regulatory scheme at issue in this case, but only to the particular regulations fixing an appropriate dispensing fee. As will be seen, the differences in our respective approaches do not relate either to philosophy about constitutional control of public power, or to the outcome on the facts of the case. They concern the appropriate constitutional pathway to be followed.

The applicability of PAJA

[580] While the Constitution, like nature, abhors a vacuum, it does have what may appear to be lacunas. One of the tasks of the judiciary is, when called upon, to fill in these apparent gaps. It does so not by a process of invention but by one of completion. The courts use what is there as the foundation for discerning what is not manifest; they render explicit what is implicit. They plumb the overall structure and design of the Constitution, and let themselves be guided by the values that the Constitution articulates. Memory of past abuses, sensitivity to social context and appreciation of the goals which the Constitution sets for our society, also serve as pointers.

[348] Act 3 of 2000.

[581] With these considerations in mind, I will deal with what appears to me to be a notable lacuna in the Constitution, one which is replicated, I believe, in PAJA. It concerns the status and reviewability of subordinate or delegated legislation, which appears to have fallen between the constitutional cracks. The answer is not to leave it in obscurity, but to rescue it from the awkward void in which it finds itself. The issue then is simultaneously to imagine[349] and give substance to constitutional concepts into which subordinate legislation can be assimilated without losing its specific texture. In legal terms many questions arise: How should subordinate legislation be classified? Where in the constitutional scheme of things does it belong? Is it essentially an extension of the legislative process, or should it be seen basically as an aspect of administration?

[582] In my view it is clearly both. Thus to say that the making of subordinate legislation involves the implementation of primary legislation and is therefore part of administrative *law*, is to state the question, not to resolve it. The question that remains is: is it a form of implementation which falls under the concept of administrative

[349] The legal imagination does not invent materials that do not exist. Rather, it reconfigures already acknowledged legal materials according to a new underlying or organising principle. Such a principle derives its force from the fact that it is recognisable, incontrovertible and possessed of great and immediate explanatory power. It produces a fresh way of looking at and appreciating the significance of the materials as a whole. The whole is made up of the parts, but is greater than the parts, and solidifies their interrelationship. Central to my analysis is the concept, drawn expressly and implicitly from the text of the Constitution, that South Africa is a constitutional democracy. This basic understanding is more than an aid to the interpretation of a particular text. It serves as an independent structural element in the analysis. In the celebrated words of the American constitutional scholar Charles Black what is involved is a move from:

> ". . . the method of purported explication or exegesis of the particular textual passage considered as a directive action . . . to the method of inference from the structures and relationships created by the constitution in all its parts or in some principal part". (In *Structure and Relationship in Constitutional Law* (Ox Bow Press, Woodbridge 1985) at 7)

He points out that this involves shifting constitutional reasoning from interpretation of isolated texts to analysis based on structure and relation as created by the Constitution. (At 31-35).

action as envisaged in section 33 of the Bill of Rights, or is it in essence an extension of the legislative process that happens to be undertaken by the administration, thereby falling to be considered under a different constitutional rubric? And if the latter, what constitutional and legal principles govern it?

[583] The judgment of Chaskalson CJ contends that subordinate legislation does indeed fall within the notion of administrative action as governed by section 33. As such, the constitutional control which would apply to subordinate legislation is to be found in section 33 of the Constitution, as embodied in PAJA. In my view, however, the source of constitutional control of subordinate legislation is located rather in an expanded notion of legality in a constitutional democracy, as applied to law-making that affects the public in a general way. I believe that section 33 and PAJA are together designed to control the exercise of public power in a special and focused manner, with the object of protecting individuals or small groups in their dealings with the public administration from unfair processes or unreasonable decisions. This function should not be diffused. It involves the micro-management of public power, and is all the more effective because of its intense and coherent focus. The principles of legality in a constitutional democracy, on the other hand, operate more at the macro level. Their function is not so much to avoid individual injustice as to ensure that the processes of rule-making are consistent with the way public power should be articulated in the open and democratic society envisaged by the Constitution. These principles, for their turn, should have a larger and more context-driven sweep.

[584] Judicial review is an aspect of administrative law that covers both the micro and the macro dimensions of the exercise of public power. The duality of judicial review has long been acknowledged. As this Court said in *Fedsure:*[350]

> "Prior to the enactment of the interim Constitution, our superior Courts asserted a power *to review subordinate legislation as well as administrative and executive action.* The jurisdiction to do so was said to lie in the inherent jurisdiction of the Courts. The legal principles and the body of law developed by the Courts in the application of this power were often referred to as 'administrative law'."[351] (Footnote omitted) (My emphasis.)

[585] Taken together the micro and the macro dimensions of administrative law are complementary. Each attends to a different aspect of the same public power, and each is governed by the same foundational principles of accountability, responsiveness and openness.[352] Furthermore, whether the administration is involved in the narrow task of dealing with the rights of individuals or in fulfilling the wider function of creating subordinate legislation, it must act according to the same broad democratic values and principles enshrined in the Constitution, including those expressly set out in Chapter

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[350] *Fedsure Life Assurance Ltd and Others v Greater Johannesburg Transitional Metropolitan Council and Others* 1999 (1) SA 374 (CC); 1998 (12) BCLR 1458 (CC).

[351] Id at para 23.

[352] Section 1 of the Constitution provides:

> "The Republic of South Africa is one, sovereign, democratic state founded on the following values:
>
> (a) Human dignity, the achievement of equality and the advancement of human rights and freedoms.
> (b) Non-racialism and non-sexism.
> (c) Supremacy of the constitution and the rule of law.
> (d) Universal adult suffrage, a national common voters roll, regular elections and a multi-party system of democratic government, to ensure accountability, responsiveness and openness."

10 of the Constitution.[353] Against this background whether judicial review of delegated legislation is conducted through the lens of legality, as I believe it should be, or through the prism of section 33 and PAJA, as the Chief Justice holds, the consequences should be at least roughly the same. In both cases judicial review should be animated by the same constitutional philosophy. The question to be asked in both instances should be: what expectations are individuals and the public entitled to have of governmental conduct in the open and democratic society envisaged by the Constitution? If I choose the path of legality, I do so because I believe that it corresponds more directly with the reality of the national polity, fits in better with the overall constitutional scheme, and provides a sounder foundation for future

[353] Section 195 of the Constitution provides for the basic values and principles governing public administration as follows:

> "(1) Public administration must be governed by the democratic values and principles enshrined in the Constitution, including the following principles:
>
> (a) A high standard of professional ethics must be promoted and maintained.
> (b) Efficient, economic and effective use of resources must be promoted.
> (c) Public administration must be development-oriented.
> (d) Services must be provided impartially, fairly, equitably and without bias.
> (e) People's needs must be responded to, and the public must be encouraged to participate in policy-making.
> (f) Public administration must be accountable.
> (g) Transparency must be fostered by providing the public with timely, accessible and accurate information.
> (h) Good human-resource management and career-development practices, to maximise human potential, must be cultivated.
> (i) Public administration must be broadly representative of the South African people, with employment and personnel management practices based on ability, objectivity, fairness, and the need to redress the imbalances of the past to achieve broad representation.
>
> (2) The above principles apply to—
>
> (a) administration in every sphere of government;
> (b) organs of state; and
> (c) public enterprises.
>
> (3) National legislation must ensure the promotion of the values and principles listed in subsection (1)." (My emphasis.)

development.[354] Conversely, I believe that the "shoe" of section 33 is simply too tight to serve the function of providing appropriate constitutional control of subordinate legislation, and that PAJA recognises this.

[586] I accordingly agree with the two judgments to the extent that they hold that if PAJA is applicable, there is no scope for bypassing it. Yet I do not accept that PAJA is in fact applicable (except in the specific respect of fixing the precise amount chargeable as a dispensing fee.) The point of departure for the enquiry cannot be PAJA itself. The statute may refine the constitutional provision; it cannot define it.[355] It follows that the list of items which PAJA expressly excludes from its ambit at most indicates what the legislators thought that section 33 contemplated and then, only in a negative way by means of exclusion. It cannot serve as a guide to what section 33 in fact envisages. The starting point of the enquiry must rather be an analysis of section 33 itself. This in turn must be located within the overall manner in which the Constitution deals with the functioning of the public administration.

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[354] See Black above n 2 at 46-47 Discussing the famous *New York Times v Sullivan* case 376 U.S.254 (1964) he argues that it is idle to pretend that the First Amendment and Equal Protection clauses in the Bill of Rights dictated the decision, which was really based on the concept that no judge or jury could penalise free expression in a matter of such high national importance as the right to criticise a racist public official. He concludes (at 49) "[n]othing but possible gain in predictability could come from selection of a ground which forces one to talk about, realistic factors of national political involvement."

[355] Thus any obscurity in the rather convoluted test for reasonableness contained in section 6(2)(h) of PAJA must be resolved in favour of and not against the broad, unqualified sweep of section 33(1). See the discussion in *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Others* 2004 (4) SA 490 (CC); 2004 (7) BCLR 687 (CC) at paras 44-45. Echoes of the *Wednesbury* test which confines judicial review concerning the substance of administrative decisions to irrationality rather than reasonableness (see Chaskalson CJ at para 108) should have no place in the open and democratic society envisaged by the Constitution.

[587] The first point to note in this respect is that section 33 does not stand alone as a solitary bulwark against arbitrary or unfair exercise of public power. Administrative justice in itself has less work to do than it had in the pre-democratic era. The courts are no longer constrained by the doctrine of parliamentary supremacy, when the courts had to "claim space and push boundaries to find means of controlling public power."[356]

[588] As this Court said in *SARFU (3)* in the era of constitutional democracy, public administration, which is part of the executive arm of government, is subject to a variety of constitutional controls.[357] The Constitution is committed to establishing and maintaining an efficient, equitable and ethical public administration which respects fundamental rights and is accountable to the broader public. The importance of ensuring that the administration observes fundamental rights and acts both ethically and accountably should not be understated. In the past, the lives of the majority of South Africans were almost entirely governed by labyrinthine administrative regulations which, amongst other things, prohibited freedom of movement, controlled access to housing, education and jobs and which were implemented by a bureaucracy hostile to fundamental rights and accountability. The new Constitution envisages the role and obligations of government quite differently.[358]

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[356] Chaskalson P in *Pharmaceutical Manufacturers Association of SA and Another: In re Ex parte President of the Republic of South Africa and Others* 2000 (2) SA 674 (CC); 2000 (3) BCLR 241 (CC) at para 45. *(Pharmaceuticals)*

[357] *South African Rugby and Football Union v President of the Republic of South Africa* 2000 (1) SA 1 (CC); 1999 (10) BCLR 1059 (CC) at para 133. (*SARFU (3)*)

[358] Id.

[589] The constitutional goal is supported by a range of provisions in the Constitution.[359] First, in the Bill of Rights there is the right of access to information[360] and the right to just administrative action.[361] Secondly, all the provisions of the Bill of Rights are binding upon the Executive and all organs of state.[362] The Bill of Rights, therefore, imposes considerable substantive obligations upon the administration. Thirdly, Chapter 10 of the Constitution, titled Public Administration, sets the values and principles that must govern public administration and states that these principles apply to administration in every sphere of government, organs of state and public enterprises.[363] This Chapter also establishes a Public Service Commission to promote the values of public administration.[364] Fourthly, Chapter 9 of the Constitution establishes the office of the Public Protector whose primary task is to investigate and report on conduct in the public administration which is alleged to be improper.[365] Fifthly, the Constitution establishes the office of the Auditor-General whose responsibility is to audit and report on the financial affairs of national and provincial state departments and administrations as well as municipalities.[366]

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[359] Id at para 134.

[360] Section 32(1).

[361] Section 33.

[362] Section 7(2) and section 8(1).

[363] Section 195(2).

[364] Section 196.

[365] Section 182(1)(a) and (b).

[366] Section 188(1)(a) and (c).

[590] Section 33 fits neatly into this new and expansive constitutional framework. As this Court said further in *SARFU (3)*:

> "The principal function of s 33 is to regulate conduct of the public administration and, in particular, *to ensure that where action taken by the administration affects or threatens individuals*, the procedures followed comply with the constitutional standards of administrative justice."[367] (My emphasis.)

[591] This brings me to the second point to be noted, namely, that the right to just administrative action is contained in the Bill of Rights, which focuses on the fundamental rights of all individuals in our country. Thus, almost every section of the Bill of Rights starts with the words "everyone has the right . . .". Section 33 follows that format and states:

> "Just administrative action.—
> (1) Everyone has the right to administrative action that is lawful, reasonable and procedurally fair.
> (2) Everyone whose rights have been adversely affected by administrative action has the right to be given written reasons.
> (3) National legislation must be enacted to give effect to these rights, and must—
> (a) provide for the review of administrative action by a court or, where appropriate, an independent and impartial tribunal;
> (b) impose a duty on the state to give effect to the rights in subsections (1) and (2); and
> (c) promote an efficient administration."

[592] On the face of it, these provisions envisage the rights of individuals, ("everyone"), to be treated in a just manner by the public administration. They fit

[367] *SARFU (3)* above n 10 at para 136.

well with what Hoexter calls "administrative acts".[368] She writes that an administrative act is probably best defined as an act that implements or gives effect to a policy, a piece of legislation or an adjudicative decision. This is the operational side of the state: since policies, laws and judgments are not self-executing, they have to be put into operation by public authorities responsible for administering them. She points out that administrative acts include every conceivable aspect of government activity – granting a licence, promoting a clerk, stamping a passport, arresting a suspect, paying out a pension.

[593] By way of contrast subordinate legislation refers to law-making of a generalised character. As Chaskalson P said in *Executive Council, Western Cape*:[369]

> "In a modern State detailed provisions are often required for the purpose of implementing and regulating laws, and Parliament cannot be expected to deal with all such matters itself. There is nothing in the Constitution which prohibits Parliament from delegating subordinate regulatory authority to other bodies. The power to do so is necessary for effective law-making. It is implicit in the power to make laws for the country and I have no doubt that under our Constitution Parliament can pass legislation delegating such legislative functions to other bodies."[370]

[368] Hoexter *The New Constitutional and Administrative Law Vol II Administrative Law* (Juta, Cape Town 2002) 28-31, with assistance from Rosemary Lyster, general editor Iain Currie (Hoexter). She distinguishes between administrative acts and administrative action. In her view administrative action is wide enough to include subordinate legislation. In this respect her approach is in line with that of Chaskalson CJ in the present matter. While I agree with the underlying objective and much of the end result, I differ over the modalities.

[369] *Executive Council, Western Cape Legislature, and Others v President of the Republic of South Africa and Others* 1995 (4) SA 877 (CC); 1995 (10) BCLR 1289 (CC). (*Executive Council Western Cape*)

[370] Id at para 51.

[594] In South Africa, as in most countries, the bulk of legislation is in fact produced not by original law-making authorities but by administrative authorities. An array of terms is used for different types of delegated legislation: regulations, proclamations, rules, orders, declarations, directives, decrees and schemes are some of the most common.[371]

[595] As Hoexter points out, delegated legislation is probably the easiest of the acts by the administration to identify, partly because of the form in which it typically appears published in the Gazette, with a title, numbered clauses and so on.[372] Formal appearance, however, is not always conclusive, and other characteristics of legislation are also important: Legislation usually contains rules of general application which apply impersonally to the whole society, or to a specific community within it, rather than to individuals.

- Unlike adjudication, legislation is usually concerned not with resolving individual disputes but with implementing social policies that are intended to advance the public interest.
- Legislation usually operates prospectively. This means that it has consequences only for events that occur after the legislation has come into operation.
- Legislation is usually intended to remain in force for an indefinite period.

[371] See Hoexter above n 21 at 29.

[372] Id.

- Legislation requires publicity in an official publication in order to become valid.[373]

[596] Section 33 is directed towards administrative acts of an adjudicative kind, and not to legislative functions carried out by the administration. The notions of procedural fairness and the right to be given written reasons fit in closely with adjudicative justice for individuals. They are not, without undue interpretative strain consonant with subordinate legislation. The concept of procedural fairness has come to occupy a central place in controlling adjudicative (decision-making) administrative acts. In administrative law procedural fairness based on natural justice is a well defined concept which comprises two fundamental rules of fair procedure: that a person may not be a judge in his or her own cause; and that a person must always be fairly heard.[374] It is easy to understand how this principle operates in relation to applications for planning permission or liquor licences.

[597] It is difficult to see how it applies in relation to regulations of general application affecting thousands of suppliers of medicines and tens of millions of purchasers. As Baxter points out:

> "*Audi alteram partem*, as a doctrine, does not contemplate the kind of 'mass access' that is required for such decisions, nor does it provide an assurance that the public

[373] Id at 29-30.

[374] Wade and Forsyth *Administrative Law* 8 ed (Oxford University Press, New York 2000) at 436. (Wade and Forsyth)

> authority will or can hear the range and diversity of views all those affected by the decisions involved. More tailored procedures have to be employed."[375]

Similarly, the right of everyone who has been adversely affected by subordinate legislation to be given written reasons, while completely appropriate for individuals negatively affected by an administrative act (decision), seems highly inapposite for the millions of people affected, or potentially affected, by a new law.

[598] Thus I believe a distinction may, and should be drawn between legislative and administrative functions, or between rule-making and adjudication.[376] An integrated system of rules and institutions should be developed to enhance the effectiveness, fairness and accountability of administrative rule-making. Preferably the legislature should provide expressly for these rules and institutions. In the absence of such legislation, however, the void has to be filled by constitutionally-based principles of judicial review. While section 33 undoubtedly reflects a broad constitutional philosophy of fair dealing between citizens and the state it does not in itself provide an adequate format for judicial review of law-making as opposed to law-implementation. It is geared towards protecting the individual in his or her dealings with the public administration, and is not focused on the way laws of general application are made.

[375] See Baxter "Rule-making and the Policy Formulation in South African Administrative–Law Reform" in *Corder and others Administrative Law Reform* (Juta and Co Ltd., Cape Town 1993) at 186. This article was later republished in (1993) *Acta Juridica*. (Baxter in Corder)

[376] See O'Regan J "Rules for Rule-making: Administrative Law and Subordinate legislation" in Corder id at 160-162. (O'Regan in Corder)

[599] This brings me to the third basis for contending that PAJA does not apply to subordinate legislation, namely, the text of PAJA itself. Section 1 states:

> "'administrative action' means any *decision* taken, or any failure to take a decision, by—
>
> (a) an organ of state, when—
>
> (i) exercising a power in terms of the Constitution or a provincial constitution; or
>
> (ii) exercising a public power or performing a public function in terms of any legislation; or
>
> (b) a natural or juristic person, other than an organ of state, when exercising a public power or performing a public function in terms of an empowering provision, which adversely affects the rights of any person and which has a direct, external legal effect". (My emphasis.)

It appears that the use of the word "decision" had its origins in an equivalent Australian statute, which does not apply to delegated legislation.[377] In England, too, the courts have developed different principles of judicial review in relation to subordinate legislation and administrative acts, respectively.[378] Thus Wade and Forsyth point out:

> "In the case of rules and orders which are clearly legislative as opposed to administrative, there is normally no room for the principle of natural justice which

[377] Hoexter above n 21 at 102. She goes on to say that a narrow interpretation of the word "decision" must be resisted stoutly, since it perpetuates a discredited separation of administrative function between "legislative" and "purely administrative". She observes that it is true that a number of provisions and one ground of review relating particularly to delegated legislation were left out of the Act and deliberately so, but contends that other provisions, notably those allowing for notice and comment procedures, would apply to delegated legislation. She adds that the South African Law Commission (SALC) draft Bill included a duty on the State Law Adviser to publish protocols for rule-making, a duty on administrators to communicate their rules and standards in an appropriate way to those likely to be affected by them, and provisions relating to the keeping of registers and indexes of rules and standards, but that they were intentionally omitted from PAJA. The ground of review for vagueness also appeared in the draft Bill. All of these were left out of the final version. (Hoexter at 102 fn 203).

[378] Wade and Forsyth above n 27 at 875.

> entitles persons affected to a fair hearing in advance. But where regulations, though general in form, bear particularly hardly on one person or group, an exception may be made. Orders for such things as housing and planning schemes, although they may affect numerous people, are for this purpose treated by Parliament, and also by the courts, as matters of administration and not of legislation."[379]

It seems that in Germany, as well, a distinction is made between delegated legislation and administrative acts.[380] Even though the borderline between the two is not always easy to determine, and there will be examples of administrative functioning that takes the form of legislation but in reality amounts to an administrative act,[381] the distinction is, in my view, both philosophically sound, practically useful and jurisprudentially valuable.

[600] "Decision" in turn is defined in section 1 as meaning:

> "any decision of an administrative nature made, proposed to be made, or required to be made, as the case may be, under an empowering provision, including a decision relating to—
>
> (a) making, suspending, revoking or refusing to make an order, award or determination;
>
> (b) giving, suspending, revoking or refusing to give a certificate, direction, approval, consent or permission;
>
> (c) issuing, suspending, revoking or refusing to issue a licence, authority or other instrument;
>
> (d) imposing a condition or restriction;
>
> (e) making a declaration, demand or requirement;
>
> (f) retaining, or refusing to deliver up, an article; or

[379] Id.

[380] Hoexter above n 21 at 112.

[381] See for example *South African Roads Board v Johannesburg City Council* 1991 (4) SA 1 (A). (*South African Roads Board*)

> doing or refusing to do any other act or thing of an administrative nature, and a reference to a failure to take a decision must be construed accordingly".

The emphasis here is clearly on administrative (adjudicative) acts concerning such matters as orders, permissions and licences. There is nothing to suggest that law-making is to be covered. Indeed, the very word "decision" points away from the idea of a generalised norm applicable in an open-ended way to the public at large. A decision to adopt a law merely initiates the process of law-making, it does not constitute it.

[601] The provision dealing with PAJA that goes on to deal with the right to fair administrative action has a similar focus. Section 3 provides:

> "Procedurally fair administrative action affecting any person.—(1) Administrative action which materially and adversely affects the rights or legitimate expectations of *any person* must be procedurally fair.
>
> (2)(a) A fair administrative procedure depends on the circumstances of each case.
>
> (b) In order to give effect to the right to procedurally fair administrative action, an administrator, subject to subsection (4), must give *a person* referred to in subsection (1)—
>
> (i) adequate notice of the nature and purpose of the proposed administrative action;
>
> (ii) a reasonable opportunity to make representations;
>
> (iii) a clear statement of the administrative action;
>
> (iv) adequate notice of any right of review or internal appeal, where applicable; and adequate notice of the right to request reasons in terms of section 5." (My emphasis.)

Once more the emphasis is on the rights of "any person".

[602] The only section in PAJA which shifts the focus from 'any person' to the public, is section 4, which reads:

> "Administrative action affecting public.—(1) In cases where an administrative action materially and adversely affects the rights of the public, an administrator, in order to give effect to the right to procedurally fair administrative action, must decide whether—
>
> (a) to hold a public inquiry in terms of subsection (2);[382]
>
> (b) to follow a notice and comment procedure in terms of subsection (3);[383]
>
> (c) to follow the procedures in both subsections (2) and (3);
>
> (d) where the administrator is empowered by any empowering provision to follow a procedure which is fair but different, to follow that procedure; or

[382] Subsection 2 goes on to state:

> "If an administrator decides to hold a public inquiry—
> (a) the administrator must conduct the public inquiry or appoint a suitably qualified person or panel of persons to do so; and
> (b) the administrator or the person or panel referred to in paragraph (a) must —
> (i) determine the procedure for the public inquiry, which must—
> (aa) include a public hearing; and
> (bb) comply with the procedures to be followed in connection with inquires, as prescribed;
> (ii) conduct the inquiry in accordance with that procedure;
> (iii) compile a written report on the inquiry and give reasons for any administrative action taken or recommended; and
> (iv) as soon as possible thereafter—
> (aa) publish in English and in at least one of the other official languages in the Gazette or relevant provincial Gazette a notice containing a concise summary of any report and the particulars of the places and times at which the report may be inspected and copied; and
> (bb) convey by such other means of communication which the administrator considers effective, the information referred to in item (aa) to the public concerned."

[383] Subsection 3 provides:

> "If an administrator decides to follow a notice and comment procedure, the administrator must—
> (a) take appropriate steps to communicate the administrative action to those likely to be materially and adversely affected by it and call for comments from them;
> (b) consider any comments received;
> (c) decide whether or not to take the administrative action, with or without changes; and
> (d) comply with the procedures to be followed in connection with notice and comment procedures, as prescribed."

(e) to follow another appropriate procedure which gives effect to section 3."

This section is clearly capable of encompassing subordinate legislation. Yet there is nothing in the language to suggest that it compels the inclusion of subordinate legislation. On the contrary, the text is consistent with a requirement that special processes be followed when a planned administrative act is likely to have a significant impact on the rights of the public. Thus a decision to build a road or a railway line or to proclaim a housing or planning scheme could have a major public impact bearing heavily on those affected. Similarly, the declaration of large tracts of land as national parks or fire-controlled zones could affect a large number of landowners. As will be seen, it is my view that unlike the general regulatory scheme at issue in this matter, the determination of the fee by the Pricing Committee and the Minister of Health constitutes administrative action materially and adversely affecting the rights of the public. In these circumstances, giving a specific hearing to each and every one of the individuals affected might be quite impractical. What is envisaged is a collective process both of granting a hearing and of communicating an outcome. While the requirement of such a special process is indicative of a philosophy of government favouring openness, it does not, in my view, achieve indirectly what the rest of PAJA does not do directly, namely extend its scope to subordinate legislation generally.

[603] Section 5, on the other hand, returns the focus firmly to complaints by individuals. Dealing with the furnishing of reasons for adverse administrative action, it provides:

> "Reasons for administrative action.—(1) *Any person* whose rights *have been materially and adversely affected* by administrative action and who has not been given reasons for the action may, within 90 days after the date on which that person became aware of the action or might reasonably have been expected to have become aware of the action, request that the administrator concerned furnish written reasons for the action." (My emphasis.)

Here again the focus is on the rights of "any person" to receive written reasons. Furthermore, it applies to administrative action that has already been completed, and not to the making of laws that will operate into the future. Reasonable and justifiable departures from the giving of reasons are permitted, but the administrator must forthwith inform the person making the request of such departure.[384] This is just not the stuff of delegated legislation. The requesting and giving of written reasons accords well with the rights of someone aggrieved by the refusal of planning permission or rejection of an application for a liquor licence. It seems quite inappropriate as a mechanism to protect the rights of people who have not as yet been affected by any decision (administrative act), but who fear their rights in the future may be jeopardised when subordinate legislation comes to be implemented. Explanation of the purposes intended to be served by subordinate legislation might be an important means of ensuring public accountability. It is quite different in character from furnishing an aggrieved individual with reasons for action undertaken by the administration.

[384] Section 5(4).

[604] Section 6, which deals with judicial review of administrative action, and which is accordingly specially relevant to the present enquiry, manifests the same orientation towards administrative acts. It uses language such as "*an* administrative action", speaks about the administrator who *took it,* repeatedly refers to *the* action. Thus the crucial paragraph dealing with reasonableness, reads as follows:

> "6(2) A court or tribunal has the power to judicially review an administrative action if—
>
> . . . .
>
> (h) *the exercise of the power or the performance of the function* authorised by the empowering provision . . . is so unreasonable that no reasonable person could have so exercised the power or performed the function . . . " (My emphasis.)

I do not suggest that the language used is so precise and restrictive as absolutely to exclude subordinate legislation. Yet its whole tenor is to subject to judicial review specific acts taken in the past by an administrator, and not to contemplate review of regulation-making of a general kind intended to apply in the future. Certainly there is no express power granted to review subordinate legislation, a glaring omission in a statute that has been criticised for suffering more from over rather than under–elaboration.[385]

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[385] See Hoexter above n 21 at 112, where she points out:

> "[T]he Act perpetuates the heavy-handed all-or-nothing style of 'old' administrative law by placing the focus on *concepts* such as 'decision', 'rights' and 'direct, external legal effect'. . . . A reliance on concepts, to supply answers to fundamental questions of application
>
> > 'encourages judges and lawyers to spend their time working out the content of these concepts, instead of working out the factors relevant to judicial intervention and non-intervention.'"

[605] Finally it is necessary to refer to the remedies which PAJA provides. Section 8 reads:

> "Remedies in proceedings for judicial review.—(1) The court or tribunal, in proceedings for judicial review in terms of section 6(1), may grant any order that is just and equitable, including orders—
>
> (a) directing the administrator—
>
> (i) to give reasons; or
>
> (ii) to act in the manner the court or tribunal requires;
>
> (b) prohibiting the administrator from acting in a particular manner;
>
> (c) setting aside the administrative action and—
>
> (i) remitting the matter for reconsideration by the administrator, with or without directions; or
>
> (ii) in exceptional cases—
>
> (aa) substituting or varying the administrative action or correcting a defect resulting from the administrative action; or
>
> (bb) directing the administrator or any other party to the proceedings to pay compensation;
>
> (d) declaring the rights of the parties in respect of any matter to which the administrative action relates;
>
> (e) granting a temporary interdict or other temporary relief; or
>
> (f) as to costs."

[606] Once more, strikingly absent from this list is an express power which in terms permits setting aside of subordinate legislation, either wholly or in part. The omission of such an express power was not fortuitous but followed on the deliberate omission, lamented by Hoexter, of the power to review subordinate legislation.[386] The fact is that the power to declare delegated legislation to be ultra vires, historically such a

[386] See above n 30.

significant part of judicial review in administrative law, is not mentioned at all. It seems to me to be both inappropriate to 'read in' that power when it was manifestly not contemplated, and unnecessary when the constitutional objective can be achieved with more constitutional comfort and greater practical efficiency by other means.

[607] The absence of any direct reference in PAJA to subordinate legislation is not in itself conclusive, but rather section 33 of the Constitution that establishes the limits of PAJA not the other way round. The question that has to be resolved is whether the absence of express reference in PAJA to subordinate legislation contradicts the required reach of the principles of section 33, or accurately reflects their limits.

[608] In responding to this question I start with the assumption that in our constitutional democracy subordinate legislation cannot exist in a review-free limbo, but must be subject to judicial review directed towards ensuring accountability, responsiveness and openness. There appear to be three possible responses to the apparent lacuna in PAJA. The first would be to give section 33 the more expansive meaning attributed to it by Chaskalson CJ, and then stretch the language in PAJA to include subordinate legislation. The second would be to treat PAJA as unconstitutional to the extent that, without apparent justification, it excludes review of subordinate legislation. The third is to see no incongruency at all between section 33 and PAJA, but rather to view them both as being directed towards the well-focused objective of protecting the rights of individuals or relatively discrete groups in their dealings with the public authorities. The function of section 33 and PAJA would

accordingly not extend to controlling subordinate legislation, which would be subject to other forms of constitutional control. Given this interpretation, section 33 and PAJA would accord with one another rather than be in conflict. I believe that the third approach is the one most consistent with the structure and values of the Constitution. Support for this approach comes not from eagerness to promote symmetry for its own sake – over-tidiness of the law in an untidy world may not be a virtue – but from an acknowledgment of a significant difference in character between the making of regulations of general impact, on the one hand, and their specific implementation in particular cases, on the other.

[609] As indicated above, section 33 and PAJA do not stand alone as bulwarks against arbitrary or inappropriate use of public power. The work they do will benefit from being focused on the rights of the individual man and woman in the street, or of relatively small groups, who find themselves adversely affected by administrative decisions touching directly on their lives. Conversely, judicial review of subordinate legislation can be more effectively and robustly done if not forced to tip-toe on the narrow pedestal appropriate for reviewing administrative acts.[387] For these reasons,

[387] Black asks why should one not explicitly base constitutional holdings

> "not on Humpty-Dumpty textual manipulation, but on the sort of political inference which not only underlies the textual manipulation but is, in a well constructed opinion, usually invoked to support the interpretation of cryptic text?"

The manipulation he decried related to a case concerning a state law under which a man was prosecuted for bringing his indigent brother into the state. Five judges held the state law to be unconstitutional under the commerce-clause theory, four, under the privileges and immunities clause. The real principle, he pointed out, had nothing to do with texts concerning inter-state commerce or privileges and immunities, but was that the USA was a unitary state in which, because of its nationhood, internal barriers to travel were unthinkable.

There is, of course, no question of Humpty-Dumpty manipulation in the present matter. I believe, however, that the real principle governing review of subordinate legislation stems from the way law-making should be

therefore, I would hold that section 33 of the Constitution, as embodied in the provisions of PAJA, is not the mechanism for providing judicial review of a general regulatory scheme such as the one under consideration in the present case.

[610] Before dealing with what I consider the appropriate constitutional matrix within which to review subordinate legislation, I must stress that the non-applicability of PAJA in this area does not leave the law-making bodies free to operate in secrecy without paying heed to those affected by the laws. The era of the top-down diktat (decree from above), based on the notion that "we in government know best what is good for you" are gone. There can be no return to the days when regulation-makers regarded themselves as being at large to make new regulations in any way they chose, and with whatever content they liked, provided that they had appropriate authority to make the rules and that the regulations were not wholly irrational and bore some resemblance to or had some connection with the enabling statute. The absence of control through PAJA does not signify the existence of a void. Rather, it acknowledges space for other more effectively grounded processes of controlling subordinate law-making.

Applicability of the principle of legality in an open and democratic society

[611] Administrative bodies are not only concerned with making decisions in individual situations; they are also and more principally engaged in discharging a

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controlled in a constitutional democracy, and not from loading on to a provision in the Bill of Rights to carry more than it was designed to bear. (Above n 2 at 29)

broad network of statutory responsibilities.[388] Baxter points out that because they have a host of statutory mandates, public authorities are much more likely to be preoccupied with attaining certain overall goals than with ensuring that fairness and justice is attained in specific situations. To attain these overall goals (and sometimes merely for the purpose of maintaining internal co-ordination), public authorities develop sets of generalised standards which provide a framework within which their officers exercise the statutory powers entrusted to them. Baxter explains further that these standards take various forms, ranging in formality from published regulations having the force of law to "policies", "guidelines", and "manuals".[389] The analysis that follows will focus only on published regulations having the force of law. Different considerations might apply to other administrative rules and standards.

[612] If the result of excluding such law-making from the purview of section 33 and PAJA would effectively be to immunise subordinate legislation from judicial review, save for limited grounds such as bad faith or outright irrationality, the outcome would be constitutionally unacceptable. A strained reading of PAJA would in these circumstances have much to commend itself. I feel, however, that there is an alternative and better way of securing constitutional supervision of subordinate legislation. The approach I propose shares the philosophy underlying section 33, but is not founded on that section, nor is it constrained by the format of PAJA. In my view the basis for judicial review of subordinate legislation lies in an expansive notion

[388] Baxter in Corder above n 28 at 177.

[389] Id.

of legality derived from both express provisions and implied principles of the Constitution. It flows from the notion of constitutional legality, the foundational and organising principle which binds together the text of the Constitution in a unified and coherent whole. Legality in this sense draws its life-blood from multiple texts of the Constitution and lies at the structural heart of our constitutional democracy.[390]

[613] At the very least, as Hoexter points out, it has to be acknowledged that legality is a controlling principle for all exercises of public power. The constitutional principle of legality is of application even when the action in question is an exercise of public power that does not qualify as "administrative action":

> "Legality is thus capable of coming to the rescue when the action in question does *not* qualify for review in terms of the Promotion of Administration Justice Act or in terms of s 33, but is nevertheless action taken in pursuance of public power . . . [T]he content of the constitutional principle of legality is surprisingly far-reaching and . . . overlaps to a considerable extent with the requirements of legality imposed by s 33 and by the Act."[391]

[614] Legality is an evolving concept in our jurisprudence, whose full creative potential will be developed in a context-driven and incremental manner.[392] In the leading case of *Pharmaceutical* Chaskalson P stated:

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[390] As Black at above n 2 at 31 states, there is

> " . . . a close and perpetual interworking between the textual and the relational and structural modes of reasoning, for the structure and relations concerned are themselves created by the text, and inference drawn from them must surely be controlled by the text."

[391] Hoexter above n 21 at 84.

[392] See the discussion on constitutional control of public power by O' Regan J in *Rail Commuters Action Group and Others v Transnet Ltd t/a Metrorail and Others* 2005(2) SA 359; 2005 (4) BCLR 301 (CC) at paras 85-86. (*Metrorail*)

"In *Fedsure* this Court held that the doctrine of legality, an incident of the rule of law, was an implied provision of the interim Constitution. It stated:

> 'It seems central to the conception of our constitutional order that the Legislature and Executive in every sphere are constrained by the principle that they may exercise no power and perform no function beyond that conferred upon them by law. At least in this sense, then, the principle of legality is implied within the terms of the interim Constitution.'

This was reaffirmed in *President of the Republic of South Africa and Others v South African Rugby Football Union and Others (Sarfu 3),* where this Court outlined different ways in which the exercise of public power is regulated by the Constitution. One of the constitutional controls referred to is that flowing from the doctrine of legality. Although *Fedsure* was decided under the interim Constitution, the decision is applicable to the exercise of public power under the 1996 Constitution, which in specific terms now declares that the rule of law is one of the foundational values of the Constitution.

. . . .

Section 2 of the Constitution lays the foundation for the control of public power. It provides:

> 'This Constitution is the supreme law of the Republic; law or conduct inconsistent with it is invalid, and the obligations imposed by it must be fulfilled.'

. . . .

The exercise of all public power must comply with the Constitution, which is the supreme law, and the doctrine of legality, which is part of that law.

[A]dministrative law, which forms the core of public law, occupies a special place in our jurisprudence. It is an incident of the separation of powers under which courts regulate and control the exercise of public power by the other branches of government. It is built on constitutional principles which define the authority of each branch of government, their interrelationship and the boundaries between them.

. . . .

The written Constitution articulates and gives effect to the governing principles of constitutional law. Even if the common-law constitutional principles continue to

> have application in matters not expressly dealt with by the Constitution, (and that need not be decided in this case) the Constitution is the supreme law and the common law, in so far as it has any application, must be developed consistently with it, and subject to constitutional control."[393] (Footnotes omitted.)

[615] This approach was further developed in *Metrorail*,[394] where O'Regan J emphasised that our Constitution both constructs and restrains the exercise of public power in our democracy. She pointed out that determining the scope of public power, therefore, and any duties attached to it requires an analysis not only of the statutory provisions conferring the power, but also of the social, political and economic context within which the power is to be exercised and a consideration of the relevant provisions of the Constitution. If this approach is followed, she stated, the ambit of public duties of organs of state will be drawn in an incremental and context-driven manner.[395]

[616] I believe that the present case requires us to consider the ambit of the public duties of those responsible for drafting and adopting subordinate legislation. These duties can be summed up in the notion of legality as it operates in relation to delegated legislation. I believe that in this context legality must have both a procedural and a substantive dimension. I will deal with each in turn.

Constitutional control of subordinate law-making: the procedural dimension

[393] *Pharmaceutical* above n 9 at paras 17, 19, 20 and 45.

[394] Above n 45 at para 85.

[395] Id.

[617] In the pre-democratic South African administrative law tradition, little attention was given to the process by which administrative rules or standards were formulated by public authorities. Writing shortly before the interim Constitution was adopted, Baxter suggested that an administrative process analogous (though by no means identical) to what American administrative lawyers term 'rule-making' would greatly improve the existing situation and would lay a foundation for a modern system of administrative law under the new Constitution.[396]

[618] Wade and Forsyth point out that in the United States the Federal Administrative Procedure Act of 1946 gives a right to 'interested persons' to 'participate in the rule-making through submission of written data, views or arguments' and in some cases Congress has prescribed a formal hearing.[397] Hearings preliminary to rule-making have thus become an important part of the administrative process in the United States. But there is often no right to an oral hearing and there is a wide exception where the authority finds "for good cause" "that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest."[398]

[619] English law, they observe, appears to have moved in the opposite direction. Yet in reality the practice counts for more than the law.[399] Consultation with the interests and organisations likely to be affected by rules and regulations is a firmly

[396] Baxter in Corder above n 28 at 178.

[397] Wade and Forsyth above n 27 at 876.

[398] Id.

[399] Id.

established convention, so much so that it is unusual to hear complaints. They conclude that "[i]t may be that consultation which is not subject to statutory procedure is more effective than formal hearing, which may produce legalism and artificiality."[400]

[620] Historically administrative law in South Africa has paid little attention to the American approach and has in fact been strongly influenced by principles of judicial review first developed in England. Central to these principles was the acceptance of the notion of the supremacy of Parliament. Judicial review of subordinate legislation accordingly based itself on presumptions as to the intent of Parliament when it enacted the primary legislation. These related to substantive matters concerning the content of the delegated legislation, a question which will be dealt with later. They did not touch the procedures to be followed in the making of subordinate legislation. Thus there was no principle that persons who stood to be affected by subordinate legislation had a right to be heard.[401] Provided the person or body that produced the subordinate legislation was duly authorised by the primary legislation to do so, and provided that any procedural formalities required by the enabling statute had been complied with, no requirement of public involvement in the process would be presumed or required.

[621] By way of contrast, in our present era the principle that government, and organs of state, are accountable for their conduct is an important principle that bears on the

[400] Id.

[401] Id.

construction of constitutional and statutory obligations.[402] Secret law-making, whether at the level of original or subordinate legislation is anathema to the notion of constitutional democracy. The degree of public involvement may vary. Thus, deliberative bodies will normally deliberate in public, while non-deliberative bodies will find other means of facilitating public involvement. The new philosophy is illustrated by numerous provisions in the Constitution devoted to encouraging public involvement in the processes of adopting national and provincial legislation, as well as municipal laws.

[622] Thus section 57 empowers the National Assembly to:

> "make rules and orders concerning its business, with due regard to representative and participatory democracy, accountability, transparency and public involvement."[403]

Section 59 of the Constitution goes on to require that:

> "(1) The National Assembly must—
>
> (a) facilitate public involvement in the legislative and other processes of the Assembly and its committees; and
>
> (b) conduct its business in an open manner, and hold its sittings, and those of its committees, in public . . .
>
> (2) The National Assembly may not exclude the public, including the media, from a sitting of a committee unless it is reasonable and justifiable to do so in an open and democratic society."

[402] *Metrorail* above n 45 at para 76.

[403] Section 57(1)(b).

The provisions governing public participation in the National Assembly are mirrored in the provisions governing the National Council of Provinces.[404] There are similar provisions relating to provincial legislatures and municipalities.[405]

[623] Another provision of the Constitution that embodies the foundational principle of accountability, responsiveness and openness is section 32. It states:

> "Access to information.—(1) Everyone has the right of access to—
>
> (a) any information held by the state; and
>
> (b) any information that is held by another person and that is required for the exercise or protection of any rights.
>
> (2) National legislation must be enacted to give effect to this right, and may provide for reasonable measures to alleviate the administrative and financial burden on the state."

[624] The Preamble to the Promotion of Access to Information Act[406] (PAIA) establishes the new approach to the exercise of public power which has followed the achievement of constitutional democracy:

> "Preamble.—RECOGNISING THAT—
>
> * the system of government in South Africa before 27 April 1994, amongst others, resulted in a secretive and unresponsive culture in public and private bodies which often led to an abuse of power and human rights violations
>
> . . . .
>
> AND IN ORDER TO—

[404] Sections 70(1)(b) and 72.

[405] Sections 116(1)(b), 118, 152(1)(e) and 160(7).

[406] Act 2 of 2000.

> * foster a culture of transparency and accountability in public and private bodies by giving effect to the right of access to information;
> * actively promote a society in which the people of South Africa have effective access to information to enable them to more fully exercise and protect all of their rights".

It is also instructive to refer to the objects of PAIA, which include:

> "generally, to promote transparency, accountability and effective governance of all public and private bodies by, including, but not limited to, empowering and educating everyone—
>
> (i) to understand their rights in terms of this Act in order to exercise their rights in relation to public and private bodies;
> (ii) to understand the functions and operation of public bodies; and
> (iii) to effectively scrutinise, and participate in, decision-making by public bodies that affects their rights."[407]

[625] What all these provisions, both constitutional and statutory, have in common is a commitment to accountability, responsiveness and openness in government. They presuppose a democracy that is not only representative but participatory. Indeed the Constitution itself was a product of national dialogue, first outside of then inside Parliament. We have developed a culture of imbizo, lekgotla, bosberaad and indaba.[408] Hardly a day goes by without the holding of consultations and public participation involving all stake-holders, role-players and interested parties, whether in the public or the private sector. The principle of consultation and involvement has become a distinctive part of our national ethos.

[407] Section 9(e).

[408] To mention a few of the popular names given to the widespread practice of organising consultations.

[626] It would be strange indeed if the principles of participatory democracy and consultation operated when the chain of public power began with the enactment of the original legislation, then vanished at the crucial stage when the general principles of the original statute were being converted into operational standards and procedures, only to re-surface at the stage of the implementation of provisions impacting on specific individuals. The principle at stake at the intermediate regulation-making process would relate not so much to securing fair procedures, as to ensuring openness, responsiveness and accountability. The need to secure fairness would, however, increase in intensity to the degree that the interests of individuals came directly to be affected.

[627] Because transparency and responsiveness relate more to the broad character of the workings of our democracy than to doing justice to an individual, all interested parties, not only those whose rights stand to be adversely affected, are entitled to know what government is doing, and as concerned citizens, to have an appropriate say. Indeed, those whose rights stand to be beneficially affected by an ameliorative measure have no less an interest than those who stand to lose something. The right to speak and be listened to is part of the right to be a citizen in the full sense of the word. In a constitutional democracy dialogue and the right to have a voice on public affairs is constitutive of dignity. Indeed, in a society like ours where the majority were for centuries denied the right to influence those who ruled over them, the right "to be present" when laws are being made has deep significance.

[628] The problem, then, is not *whether* the values of accountability, responsiveness and openness should apply to the adoption of subordinate legislation, but *how*. In particular, what does the Constitution looked at as an organic and principled whole, and not as a patchwork of discrete injunctive texts, require in terms of procedures that will meet constitutional standards? How can one ensure that the processes are manageable and efficient? This is an area that cries out for express legislative guidance. Experience in this country and abroad, both positive and negative, needs to be weighed. A decade of constitutional democracy provides invaluable insight into the problems involved. Yet the fact is that such legislation is not there. The proposal by the South African Law Reform Commission that it be included in PAJA was not accepted.[409] In the absence of such legislation it will therefore be incumbent on the courts, oriented by the foundational constitutional principles of accountability, responsiveness and openness, and cognisant of the fact that we are living in a constitutional democracy, to ensure that proper procedures are followed when subordinate legislation is being made.

[629] At this stage it is neither necessary nor advisable to attempt to lay down specific rules as to what processes would meet those standards. As in the case of procedurally fair administrative action concerning individuals, much will depend on the setting in which the subordinate legislation is being adopted, the nature of the

[409] Hoexter points out that the draft Administrative Justice Bill that was appended to the South African Law Commission's *Report on Administrative Justice* (1999) included a duty on the State Law Advisor to publish protocols for rule-making, a duty on administrators to communicate their rules and standards in an appropriate way to those likely to be affected by them and, provisions relating to the keeping of registers and indexes of rules and standards, but that these were left out of the final version. (Above n 21 at 102 at fn 203)

power being exercised, the purpose of the rules being made, the people who stand most directly to be affected and the social and economic context in which the measure will function. An appropriate balance will need to be struck between facilitating meaningful public access to the process and achieving economic use of time and resources. Indeed, it should be borne in mind that endless consultation can be as paralysing to democratic decision-making as insufficient consultation.[410]

[630] In this respect section 4 of PAJA offers interesting examples of procedures which Parliament has already adopted in relation to decisions affecting the public. They include the holding of public enquiries and the use of notice and comment procedures.[411] In particular, the enabling statute itself might indicate directly which procedures should be followed. The forms of facilitating an appropriate degree of participation in the law-making process are indeed capable of infinite variation. What matters is that at the end of the day a reasonable opportunity is offered to members of the public and all interested parties to know about the issues and to have an adequate say. What amounts to a reasonable opportunity will depend on the circumstances of each case. Prudence allied to principle indicates that this is an area where the law should develop in a fact-sensitive and incremental way.

Constitutional control of subordinate law-making: the substantive dimension

[410] O'Regan in Corder quotes the classic work of Schwartz on Administrative Law (1984) as stating that a statute in the United States which required a public inquiry resulted in a hearing with a nearly 8000 page record to determine whether peanut butter should consist of 87.5 or 90 per cent peanuts. (Above n 29 at 174 at fn 87)

[411] See section 4 (3) of PAJA.

[631] In the pre-democratic era, the doctrine of ultra vires[412] was used to strike down subordinate legislation that did not meet certain judicially-established criteria. In the well-known case of *Kruse v Johnson*[413] Lord Russell laid down limited grounds for unreasonableness, as determined by the courts exercising common law powers of judicial review, in the context of subordinate legislation adopted by public representative bodies. After stating that in general the courts should not interfere with subordinate legislation as adopted by duly authorised bodies, he went on to observe:

> ". . . I do not mean to say that there may not be cases in which it would be the duty of the court to condemn byelaws made under such authority as these were made as invalid because unreasonable. But unreasonable in what sense? If, for instance, they were found to be partial and unequal in their operation as between different classes, if they were manifestly unjust, if they disclosed bad faith, if they involved such oppressive or gratuitous interference with the rights of those subject to them as could find no justification in the minds of reasonable men, the court might well say Parliament never intended to give authority to make such rules, and they are unreasonable and ultra vires."[414]

[632] The principles of reasonableness were accordingly rooted in presumptions about the intention of Parliament. Today the power and the constraint come not only from the empowering statute, but from the Constitution, which governs the manner in which the statute must be applied. This is not to say that the intentions of the Legislature, as expressed or implied, fall out of the picture. On the contrary, they will

[412] According to Hoexter the courts still use the term 'ultra vires' as before to indicate that an action is outside of its lawful parameters, illegal and of no force or effect. However, the meaning of the term has changed. Hoexter states that the '*vires'* in question are now those of the Constitution, and not simply those of Parliament. Above n 21 at 81.

[413] [1898] 2 QB 91 (Div Court).

[414] Id at 99-100.

provide the point of departure for the enquiry. The framework for the investigation will continue to be the objectives sought to be achieved by the enabling law. What is new, I believe, is the constitutional requirement of legality, in this connection in relation to the substantive character of the measure concerned. In this context legality requires compliance not only with the empowering statute, but with general constraints on the exercise of public power flowing from the nature of our constitutional democracy, in particular the requirement that government be open, responsive and accountable.

[633] In my view, if rationality is required as the minimum for the legality of primary legislation,[415] something more than mere rationality will be needed to ensure the legality of subordinate legislation. The functionaries who are responsible for drafting subordinate legislation are exercising a public power of great significance, but with no overt checks and balances. It is they who are responsible for translating the general precepts of the statute into operational standards and processes. Even if they choose to consult widely and actively, their ultimate deliberations will ordinarily take place behind closed doors. The principles of accountability and responsiveness require that the procedures for public involvement they establish in each case be reasonably related to the material they have to consider. If challenged, they should be able to account for the regulations they have adopted, and to do so in a manner that shows a reasonable fit between the requirements of the empowering statute, the material at their command and the final text.

[415] See *Pharmaceutical* above n 9 at paras 84-85.

[634] In more general terms, they have weighty statutory and constitutional obligations to fulfil. Writing in the context of the constitutional obligations of the providers of rail services to protect the safety of commuters, O'Regan J in *Metrorail,*[416] observed:

> "[T]he Court requires the bearer of constitutional obligations to perform them in a manner which is reasonable. This standard strikes an appropriate balance between the need to ensure that constitutional obligations are met, on the one hand, and recognition for the fact that the bearers of those obligations should be given appropriate leeway to determine the best way to meet the obligations in all the circumstances. As this Court reasoned in *Minister of Health and Others v Treatment Action Campaign and Others (No 2)* [2002 (5) SA 721 (CC); 2002 (10) BCLR 1033 (CC) at para 38]:
>
> > 'Courts are ill-suited to adjudicate upon issues where Court orders could have multiple social and economic consequences for the community. The Constitution contemplates rather a restrained and focused role for the Courts, namely, to require the State to take measures to meet its constitutional obligations and to subject the reasonableness of these measures to evaluation.'"

[635] I think the same principles of reasonableness must govern the exercise of powers to translate the original law into operational regulations. The situation is quite different from one where courts arrogate to themselves the right to declare that Parliament has not acted reasonably in adopting a certain piece of legislation. For the courts to do so would be to make a political judgment that would be both institutionally and constitutionally inappropriate. A court can require that Parliament

[416] Above n 45 at para 87-88.

act rationally,[417] follow due manner and form,[418] stay within its sphere of law-making competence,[419] and does not violate the Bill of Rights[420] or any other provisions of the Constitution. The case of subordinate law-making is different, however. What is in issue here is not the reasonableness of the original legislation, but the reasonableness of the manner in which it is being given effect to. To say that the drafters must fulfil their functions and craft regulations in a reasonable way is in this respect a legal not a political judgment. To hold the opposite would be to assume that Parliament and the Constitution would be satisfied if the functionaries concerned carried out their mandate in an unreasonable manner. Indeed, it would be odd if public officials could be held to the standard of reasonableness required by section 33 in their dealings with individual persons, but not be so held when drafting rules which stand to affect scores and perhaps millions of individuals.

[636] What is required, then, is a reasonable fit between the enabling law and the subordinate law. For the purposes of the present matter it is not necessary to provide precise and exhaustive details of how the reasonableness of the fit would be tested. Clearly, the drafters of the regulations must have great leeway in deciding how best to achieve the objectives of the enabling law; policy-making belongs to them, not the courts. Furthermore, when exercising judicial review the courts will give appropriate weight to the fact that the Parliamentary system promotes political accountability and

[417] *Pharmaceuticals* above n 9 at para 84.

[418] *Executive Council Western Cape* above n 22 at para 47.

[419] As provided for in sections 43 and 44 of the Constitution.

[420] Section 8(1) of the Constitution.

that we live in an open society in which all are free to criticise acts of government. Nevertheless, a constitutional democracy requires more than the right to criticise the public authorities after the event. All public power must be exercised in a way that meets constitutional standards. Accountability is not just a hallmark of good government in a political sense. It is a requirement of constitutional government in a legal sense. Accountability implies that justification be given where necessary for exercises of public power, establishing that they meet constitutional and statutory standards.

[637] The standard of reasonableness is used as a measure throughout the Constitution, notably in regard to the fulfilment of positive obligations to realise social and economic rights,[421] and with respect to permissible limitations of protected rights.[422] I see no reason why the standard should not be used as the overall principle for measuring whether or not subordinate legislation fits appropriately with the scheme of its empowering law. Reasonableness is capable of being determined objectively. It is sometimes easier to illustrate in the negative than in the positive: viewed in the context of its objectives and the situation in which it is due to be implemented, the terms of subordinate legislation must not be so wide in their reach or so disproportionate in their impact as to place them beyond the limits of what a reasonable law-maker would have considered appropriate. Proportionality will always be a significant element of reasonableness. What the concept of proportionality loses

[421] Sections 25, 26 and 27.

[422] Section 36.

in terms of predictability, it more than makes up for by being congruent with context and responsive to the intensity with which the relevant constitutional values are triggered. In my view, the logic of our new constitutional dispensation requires that the common law's one-time ultra-technical preoccupation with categories and classifications as the basis for judicial review, now be replaced by the adoption of the generalised, principled and flexible standard of review embodied in the notion of reasonableness.

[638] It needs to be observed that in the pre-democratic era the distinction drawn between legislative and adjudicative (quasi-judicial) acts was all-important for administrative law. This was because the need to grant an opportunity for a hearing would only be accepted by the courts in the case of adjudicative acts. If the act was classified as legislative, no right to a hearing would have been recognised. The artificiality of the distinction being drawn by the courts was convincingly criticised by Milne JA in *South African Roads Board.* He pointed out that he was

> ". . . not persuaded that the categorisation of statutory powers of action or decision into executive (or administrative) and legislative should in all cases provide the criterion as to whether the repository of the power is obliged in exercising it to observe the dictates of natural justice. It seems to me rather that a distinction should be drawn between (a) statutory powers which, when exercised, affect equally members of the community at large and (b) those which, while possibly also having a general impact, are calculated to cause particular prejudice to an individual or particular group of individuals."[423]

[423] Above n 34 at 12E-G.

[639] Today the situation is quite different. The right to notice and public involvement arises under the principle of legality in a constitutional democracy. It is not restricted to the natural justice principle embodied in the audi alteram partem rule. In this respect labelling an act as either legislative (rule-making) or adjudicative (rule-application) ceases to be of vital significance. The remedy in relation to both is roughly the same.

[640] One may thus envisage a continuum ranging from pure law-making acts at one end, to pure administrative (adjudicative) acts at the other. All will be subject to constitutional control that is of both a procedural and a substantive kind. There will be a difference of emphasis rather than of kind, to take account of the different constitutional and public law values implicated at each end of the spectrum. Hybrid regulatory systems involving both generality (regulatory scheme) and specificity (adjudicative act) could then be comfortably accommodated at appropriate places along the spectrum. The precise form of the hearing required in each case and the manner in which substantive reasonableness will be determined, will accordingly depend more on the nature of the interests at stake in each particular instance than on the label or labels to be attached. In this way administrative law emerges from its constitutional chrysalis as an integrated body of law. Shed of the remnants of its one-time fragmented and particularistic form, it has been metamorphosed into a comprehensive, principled, operational and elegant new legal figure.

Application to the facts of this case

[641] I turn to the facts of the present case. The fundamental feature governing the making of regulations by the Pricing Committee and the Minister was that the task be accomplished in a manner that was open, responsive and accountable. These constitutional considerations applied whether the steps taken were characterised as legislative or as representing administrative action. The more general the regulations were in effect and the more indefinite in outcome, the more they fall now to be reviewed according to the broad principles of legality in a constitutional democracy. Conversely, the more specific in their adverse impact and the more immediate the moment of their application, the more readily do they come within the provisions of section 33 and PAJA. It should be stressed, however, that the fact that the borderline between making subordinate legislation, on the one hand, and taking a decision in respect of administrative action on the other, could have been porous, would not have been of special constitutional moment. In the open and democratic society envisaged by the Constitution, the same broad expectations of how government should function must straddle the conceptual frontier. What matters is not the classification, but the character of the power being exercised.

[642] I will deal first with the general regulatory scheme. The overall scheme produced by the Pricing Committee and the Minister affects the public at large and applies indefinitely into the future. It is law-making in its fullest sense. Its broad objective in terms of the Medicines Act is to introduce transparency into the whole process of manufacturing, distributing and selling medicines. It is also designed to bring prices down to more affordable levels. The public in general was entitled to

know how the Pricing Committee planned to conduct its operations, what the essential subject-matter of its work would be and how the public could be involved in making representations to it. These requirements flow not from section 33 and PAJA, but from the broad principle of legality as expressly envisaged in various texts of the Constitution and implicit in its very structure and design.

[643] Interested members of the public were also entitled to expect that the regulations as eventually published would fit reasonably within the framework established by the Medicines Act, interpreted in the light of the Constitution. Not only were they entitled to have their say, they could expect that attention would be given to their representations. At the same time, they would have had to accept that however strongly they felt on a particular topic, ultimately it lay with the Pricing Committee and the Minister to make policy choices, provided the options selected fell within the bounds of what was reasonable. Furthermore, they would have had to accept that within the constraints of what was reasonable, the Pricing Committee and the Minister had a wide discretion as how best to realise the objectives of the Act.

[644] These principles of legality in a constitutional democracy, then, are applicable to judicial review of the regulatory scheme as a whole, including those laying down the need for a single exit price. They would also include the regulations establishing the principles of price control, price increases, benchmarking and publication. Taken together these and other regulations establish the overall normative structure controlling the cost of medicines. At the stage, however, when the scheme is in place

and detailed implementation of its rules as they directly affect individuals and groups happens, the decisions on implementation could well come to be subject to the provisions of section 33 and PAJA. This is a matter that need not be decided now.

[645] Whereas Chaskalson CJ and Ngcobo J apply section 33 and PAJA to their analyses of the regulatory scheme as a whole, I follow the pathway of legality as understood in a constitutional democracy. Accepting in broad terms as I do their respective evaluations of the evidence before us, but basing myself on the principles of legality rather than of section 33 and PAJA, I agree that the overall regulatory scheme passes constitutional muster, both in terms of the procedures followed and in respect of the reasonableness of its outcome.

The fixing of the dispensing fee

[646] Both their judgments, as well as that by Moseneke J, dealt separately and in some detail with the question of the fixing of an appropriate dispensing fee. The remaining part of this judgment will be concerned with that question. In my view the determination of the maximum dispensing fee which pharmacists may charge represents a discrete aspect of the work of the Pricing Committee and the Minister. The objective here is not so much to establish a general normative structure, but to determine a precise figure for a particular activity of a directly identified group of persons. The price tag put on the activity of the pharmacists affects their interests materially, adversely and in an immediately operative way. It follows that the fixing of the dispensing fee is sufficiently specific to constitute action of an adjudicative

rather than a law-making kind. As such, it falls to be reviewed under the provisions of section 33 and PAJA. This does not, however, require any dramatic change to the character of the review. The effect of invoking section 33 and PAJA is simply to highlight a twofold and very specific responsibility on those who have the task of determining the fee. Firstly, they are required to show particular concern to hear the views of those who stand to lose out, namely, the pharmacists, and secondly they must ensure, that in relation to the very specific competing interests at stake, the fee ultimately arrived at is a reasonable one. The difference is one of intensity and degree, not one of kind.

[647] The result of this analysis is that no less than four constitutional and statutory considerations require that the fixing of the dispensing fee be reasonable: first, to meet the test of legality for subordinate legislation in general; second, to meet the specific requirements of section 33 and PAJA in relation to this particular determination as a form of administrative action; third, to comply with the statutory duty of fixing a fee that is "appropriate"; and, finally to be part of a "reasonable" measure to realise the constitutional right of everyone to access to health care, to which I will refer later.

[648] It is unnecessary for me to repeat the facts of this case, which have been thoroughly analysed by my colleagues. I accept in broad terms the evaluations made by Chaskalson CJ and Ngcobo J, focusing as each does on different features of the way the Pricing Committee dealt with the evidence. Section 33 and PAJA necessitated that special attention be given to eliciting and listening to the several

voices of the pharmacists. The evidence suggests that although there were aspects of the process that could and should have been better managed, they did not affect the process as a whole in sufficiently material a manner as to vitiate it. I accordingly agree that the procedures followed in determining the dispensing fee were not constitutionally flawed.

[649] Finally I turn to the substantive reasonableness of the dispensing fee, which counsel for New Clicks acknowledged lay at the heart of the dispute ("ultimately it was about numbers"). In broad terms I adopt the evaluations in this respect made by Chaskalson CJ and Ngcobo J. I would, however, give more centrality than their judgments do to certain constitutional principles. I believe these principles should be given special weight in determining whether the Pricing Committee and Minister's approach to the appropriateness of the fee was reasonable.

[650] Thus a major element informing the reasonableness of the work of the Pricing Committee was section 27 of the Constitution, which reads:

> "Health care, food, water and social security.—(1) Everyone has the right to have access to—
>
> (a) health care services, including reproductive health care;
>
> . . . .
>
> (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
>
> (3) No one may be refused emergency medical treatment."

The determination of the appropriate dispensing fee had accordingly to be evaluated as a measure undertaken to achieve the realisation of access to health care services.

[651] The importance of this objective cannot be overestimated. Though illness strikes the rich and the poor alike, its impact on the poor is aggravated by harsh living conditions and what is frequently the extreme difficulty of getting access to health care and medication. Hence the duty on the state to take special measures to assist those who are the most vulnerable to disease and, simultaneously the most lacking in resources. The question, however, is not simply whether the objective of the regulation is worthy, which it clearly is, but whether it is reasonable. Put another way, the mere fact that it serves a rational purpose in pursuing a legitimate government aim, would not in itself be enough. It would have to pass the test of being reasonable.

[652] What is reasonable depends very much on the social, economic and historical context. Considerable discretion must be accorded to those entrusted with responsibility for drafting regulations. As Yacoob J said in *Grootboom*,[424]

> "A court considering reasonableness will not enquire whether other more desirable or favourable measures could have been adopted, or whether public money could have been better spent. The question would be whether the measures that have been adopted are reasonable. It is necessary to recognise that a wide range of possible measures could be adopted by the State to meet its obligations. Many of these would meet the requirement of reasonableness. Once it is shown that the measures do so, this requirement is met."[425]

[424] *Government of the Republic of South Africa and Others v Grootboom and Others* 2001 (1) SA 46 (CC); 2000 (11) BCLR 1169 (CC). (*Grootboom*)

[425] Id at para 41.

[653] When reasonableness is considered it becomes particularly important to ensure that vulnerable sections of the population are protected. The discretion of the rule-makers becomes attenuated to the degree that the fundamental rights of the people who are most disadvantaged are affected. In this regard our Court has frequently pointed to the extremely uneven development of our country.[426] It is a matter of common knowledge that people living in deeply impoverished rural areas have access to far fewer pharmacies than those living in the more affluent areas of the towns. It was accepted by the Pricing Committee that rural pharmacies do not have the turnover of scripts that enable many urban pharmacies to stay afloat. Similarly, we are informed that courier pharmacies which provide a service of special value to those who are vulnerable through infirmity and have difficulty getting to the chemist, work on particularly tight margins.

[654] Thus, though the principle of 'one-size-fits-all' has the great administrative virtue of being easy to understand and simple to apply, it becomes highly problematic where rural and courier pharmacies are concerned. In a setting where health needs are vastly different, the very uniformity that establishes operational strength becomes the source of constitutional infirmity. As Yacoob J pointed out in *Grootboom*:

[426] *Soobramoney v Minister of Health, KwaZulu-Natal* 1998 (1) SA 765 (CC); 1997 (12) BCLR 1696 (CC), City *Council of Pretoria v Walker* 1998 (2) SA 363 (CC); 1998 (3) BCLR 257 (CC), *Grootboom* above n 77, *Western Cape Provincial Government and Others: In re DVB Behuising (Pty) Ltd v North West Provincial Government and Another* 2001 (1) SA 500 (CC); 2000 (4) BCLR 347 (CC), *Port Elizabeth Municipality v Various Occupiers* 2005 (1) SA 217 (CC); 2004 (12) BCLR 1268 (CC), *President of RSA and Another v Modderklip Boerdery (Pty) Ltd and Others* 2005 (8) BCLR 786 (CC).

> "Reasonableness must also be understood in the context of the Bill of Rights as a whole. . . . To be reasonable, measures cannot leave out of account the degree and extent of the denial of the right they endeavour to realise. Those whose needs are the most urgent and whose ability to enjoy all rights therefore is most in peril, must not be ignored by the measures aimed at achieving realisation of the right. It may not be sufficient to meet the test of reasonableness to show that the measures are capable of achieving a statistical advance in the realisation of the right. Furthermore, the Constitution requires that everyone must be treated with care and concern. If the measures, though statistically successful, fail to respond to the needs of those most desperate, they may not pass the test."[427]

[655] For these reasons I agree that adoption of the 'one-size-fits-all' approach to the dispensing fee in relation to rural pharmacies and courier chemists, fails to meet the constitutionally enjoined standard of reasonableness. Accordingly I agree that the regulation is invalid to this extent.

[656] I have more difficulty in relation to the impact of the measures on the other pharmacists, more particularly as concerns the economic viability of their activities. Here another constitutional right comes into play. In *Affordable Medicines*[428] this Court was called upon to consider the impact on the viability of medical practice of a measure which required doctors to apply for a licence to dispense medicines from their approved premises. This necessitated an evaluation by the Court of section 22 of the Constitution, which reads:

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[427] Above n 76 at paras 43-44.

[428] *Affordable Medicines Trust and Others v Minister of Health of the RSA and Others* 2005 (6) BCLR 529. (*Affordable Medicines*)

> "22. Freedom of trade, occupation and profession.—Every citizen has the right to choose their trade, occupation or profession freely. The practice of a trade, occupation or profession may be regulated by law."

[657] Ngcobo J said that the inclusion of the above section in the Constitution is not only because of past discriminatory patterns which excluded persons from applying certain trades or taking up certain professions because of their race or gender. He pointed out that:

> "What is at stake is more than one's right to earn a living, important though that is. Freedom to choose a vocation is intrinsic to the nature of a society based on human dignity as contemplated by the Constitution. One's work is part of one's identity and is constitutive of one's dignity. Every individual has a right to take up any activity which he or she believes himself or herself prepared to undertake as a profession and to make that activity the very basis of his or her life. And there is a relationship between work and the human personality as a whole. 'It is a relationship that shapes and completes the individual over a lifetime of devoted activity; it is the foundation of a person's existence'.
>
> Though economic necessity or cultural barriers may unfortunately limit the capacity of individuals to exercise such choice, legal impediments are not to be countenanced unless clearly justified in terms of the broad public interest. Limitations on the right to freely choose a profession are not to be lightly tolerated."[429]

[658] It is not difficult to recognise that standing behind these generalised words are the familiar figures of the township or Main Road chemist or the hospital pharmacist or the white-coated person behind the medicines counter at the far end of the chain store. These men and women are by vocation dedicated people who express themselves through their work and are publicly identified by the concern they show in

[429] Id at paras 59-60.

their relationships with their customers. With their professional skill and human concern, they calm anxieties and turn their places of work into important ports of call for wide sectors of the community. A responsive government accordingly takes account of the need not only to have prices of medicines accessible, but to have outlets for medicines that are accessible, staffed by people who are accessible, in location and in manner.

[659] At the same time as there is a need to acknowledge the position of the pharmacists it is necessary, as Ngcobo J pointed out in *Affordable Medicines*, to recognise that

> ". . . we live in a modern and industrial world of human interdependence and mutual responsibility. Indeed we are caught in an inescapable network of mutuality. Provided it is in the public interest and not arbitrary or capricious, regulation of vocational activity for the protection both of the persons involved in it and of the community at large affected by it, is to be both expected and welcomed."[430]

Regulation of prices of medicines is a wholly legitimate form of regulating the profession. Indeed, preventing excessive profit-taking from the manufacturing distribution and sale of medicines is more than an option for government. It is a constitutional obligation flowing from its duties under section 27(2).

[660] In this respect I would tend to agree with Moseneke J that the mere fact that a government measure could result in service-providers losing their competitive edge so

[430] Id at para 60.

as to face being driven out of business, would not in itself be enough to make a measure legally inappropriate (unreasonable). The maintenance of "business as usual" is not a constitutional principle, and the concept of reasonableness should not be used as an apparently neutral instrument which, regarding the status quo as the settled norm, serves to block transformation and freeze challengeable aspects of our public life.[431]

[661] Counsel for the state in fact argued that the pharmacy industry would have to change its mindset so as to ensure that medicines would be available at more affordable prices. These may be policy considerations of which government has to take account, and to which a court would defer. The constitutional dimension will only arise when the impact of implementing such a policy is disproportionately severe in relation to the viability of pharmacies. The extent of the potential impact in the present matter becomes highly relevant because, as this Court has recognised, it is not always possible to draw a clear line of distinction between regulation that affects the

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[431] See Sunstein, *The Partial Constitution*, (Harvard University Press, Cambridge 1993) at 3-4. Discussing the dangers of what he refers to as status quo neutrality, he writes that neutrality takes

> "as a given and as a baseline for decision, the status quo, or what various people and groups now have: existing distributions of property, income, legal entitlements, wealth, so-called natural assets and preferences. A departure from the status quo signals partisanship; respect for the status quo signals neutrality. When government does not interfere with existing distributions, it is adhering to the neutrality requirement, and it rarely needs to justify its decision at all. When it disrupts existing arrangements, it is behaving partially, and is thus subject to constitutional doubt.
>
> . . . .
>
> In constitutional law, then, we should understand the prevailing conception of neutrality to be one that treats as legally uncontroversial any decision to respect existing distributions, and as legally suspect any decision to disrupt them."

In South Africa the apparent objectivity of the notion of status quo neutrality could frequently result in unconscious partiality in favour of protecting systemic mal-distribution. In a society where distributions are manifestly unequal and unjust, it is a defence of the status quo and the failure to make corrective intervention, rather than a re-distributive initiative, that could be open to a charge of unreasonableness.

practice of a profession on the one hand, and one that affects choice on the other.[432] Where, objectively viewed, the regulation of the practice of a profession impacts negatively on choice, such regulation must be tested under section 36(1), the limitations clause in the Bill of Rights. As such it must meet, amongst other requirements, the standard of reasonableness, of which proportionality analysis is an important component. This means it will always be a matter of context, impact and degree and ultimately, a question of balance and proportionality to be worked out on the facts of the case.

[662] The problem in the present matter is that the evidence concerning potential impact on the economic sustainability of the pharmacies, appears to be inconclusive. The regulations as a whole make for a drastic (though constitutionally propitious) intervention by the Ministry of Health in respect of lowering the price of medicines. The issue that remains unresolved on the evidence is whether the dispensing fee is fixed at a price calculated to drive a disproportionate number of pharmacists out of business.

[663] This is a new measure that has caused trauma to members of a legitimate and respected profession, who play an important social role in providing access to health care. It may be unclear whether the distress of the pharmacists arises from self-induced and self-serving panic, or is based on objective fact. Yet the problem is that there is no base-line or norm from which to judge the potential impact of the measure.

[432] *Affordable Medicines* above n 81 at para 93.

This is not a case where a system is in place and government decides on an incremental shift one way or the other. The state is in fact embarking upon an important new regulatory enterprise. I believe that the principle of accountability imposes on it a special responsibility in the particular circumstances to show that it has taken all reasonable steps to assess, take account of and justify the potential knock-on effects on the pharmacy profession of its new intervention. The more the risk, the greater the precaution.

[664] In this respect, when the reasonableness of the measure is put in issue by evidence that is more than lightweight, an element of persuasiveness or justification is required from the Ministry. It needs to go beyond reliance on placing itself inside the ordinary parameters within which a court would habitually give the nod to official discretion. There are circumstances, such as in the present case, where the nature of the matter, including its novelty and the uncertainty of its potential impact, requires persuasive evidence to indicate that the measure falls within the bounds of what is reasonable. There will be other more stable and predictable circumstances where the weighing of different elements should be left to the administrative body itself, with the court being obliged on the facts to adopt a far more deferential posture. In the long run the Ministry, the profession and the public will be better served by calculations that are manifestly reasonable, than by assertions that might or might not be true but lack convincing substantiation.

[665] Many years have been spent by the Ministry on the project. The Pricing Committee, with well qualified persons in its ranks, has worked diligently and expended a great degree of effort in fulfilling its statutory responsibilities. That in itself, however, does not suffice. It is important that the evidence be such as to show to all those affected and to the public in general, that the Pricing Committee has, after diligent enquiry into the basic issues involved and with a reasonably high degree of likelihood in relation to the material before it, "got it right", or, at the very least, not got it wrong.

[666] In the present case, I am not satisfied that the evidence proves that the impact of the limit on the dispensing fee will be such as to drive a disproportionate number of chemists out of business. Nor, however, am I convinced that it will not have that effect. Because this is a new measure, and because there is a real and not purely speculative possibility of pharmacists in large numbers being rendered insolvent, (and, I should add, because on all the evidence it is not clear that responsibility for the high price of medicines is not being unduly attributed to the retailers rather than to those higher up in the chain), I find myself unpersuaded that the Pricing Committee and the Minister basically did not get it wrong. It follows that I do not find the evidence firm enough to support a finding that the newly introduced dispensing fee meets the test of being reasonable ("appropriate").

MOSENEKE J

Introduction

[667] I have had the benefit of reading the separate judgments of Chaskalson CJ and Ngcobo J. In part my views diverge from theirs. In order to identify properly the differences it is necessary to draw attention to the five broad issues to be decided. The first collection of issues relates to procedural contentions. The second issue probes whether the impugned regulations by the Minister of Health (the Minister) and the recommendations of the Pricing Committee constitute administrative action within the meaning of the Promotion of Administrative Justice Act (PAJA).[433] The third set of issues raises the question whether the process of making the regulations satisfied the procedural fairness required by PAJA. The fourth and fifth issues relate to the validity of regulations, which govern the single exit price and the appropriate dispensing fee respectively.

[668] I start with procedural matters. I am in respectful agreement with the findings of the Chief Justice in this regard. In particular, I agree that the Supreme Court of Appeal (SCA) is entitled to regulate its procedure and that it was well within its power in directing that the objection to its jurisdiction should be heard together with the merits of the application for leave to appeal. Nothing justified the piecemeal hearing the Minister contended for or the decision not to advance any argument on the merits before that court. I have no hesitation in holding that, in the circumstances of the case, the SCA adopted the correct procedural course.

[433] Act 3 of 2000.

[669] I also cannot uphold the contention by the Minister and the Pricing Committee that the decision of the SCA is a nullity and ought to be set aside by reason only of the provisions of section 20(4)[434] of the Supreme Court Act 59 of 1959. It will be remembered that the provisions require that no appeal shall lie to the SCA except with leave of the court below, or if refused, of the SCA itself. For the reasons advanced by the Chief Justice, I agree that in a proper case, a court of appeal may hear and decide a case premised on a constructive refusal of leave to appeal. However, in the case before the SCA it was unnecessary to decide the claim of constructive refusal because the decision of the High Court refusing leave to appeal came to hand ahead of the decision of the SCA.

[670] New Clicks, the Pharmaceutical Society of South Africa (PSSA) and other respondents (the Pharmacies) took the procedural point, that because the Minister had refused to argue the merits before the SCA, she should be refused leave to do so in this Court. The Chief Justice rejects this contention. I agree. The Minister's stance before the SCA is open to criticism but it would not be in the interest of justice for an issue of such great public moment to be decided by default and without hearing the Minister responsible for making the impugned regulations.

[671] The Chief Justice and Ngcobo J take the view that it is necessary to decide whether the conduct of the Minister and of the Pricing Committee is reviewable as

[434] The full text is cited in paragraph 60 of the judgment of the Chief Justice.

administrative action under section 33 of the Constitution and PAJA. They conclude that the recommendations of the Pricing Committee and ministerial regulation-making are so reviewable. For reasons that I advance later in the judgment, I find it unnecessary to decide whether the tenets of administrative justice under the Constitution and PAJA apply to ministerial regulation-making. However, for the purposes of this case I do assume, in favour of the Pharmacies, that PAJA does apply to the making of the recommendations and the regulations under section 22G of the Medicines and Related Substances Act (the Medicines Act).[435]

[672] As did the Chief Justice and Ngcobo J, I consider the making of regulations under section 22G(2)(b) one continuous process involving at different times the Pricing Committee and the Minister up to the point of promulgation. The Pharmacies are unhappy with the deliberations of the Pricing Committee that led to the making of the regulations. Having carefully weighed their contentions, I also find that on the facts, it cannot be said that the process of making recommendations and regulations was procedurally unfair. I think that the procedure followed in making the regulations does pass muster under the procedural fairness requirements of section 4(1) read with section 3 of PAJA.

[673] I turn to the regulations governing a single exit price which are under attack on several grounds. Let me at the outset observe that it is beyond debate that the overall legislative scheme which introduces a single exit price is constitutionally authorised

[435] Act 101 of 1965.

under section 27(1)(a) and (2) of the Constitution. I further take the view that except as qualified in the judgment of Yacoob J, the regulations on a single exit price made under the legislative scheme advance access to quality and affordable medicine for "everyone" in a lawful and reasonable manner and without undue oppression to any of the interested parties. Regrettably, I have to part ways with several of the findings of the Chief Justice on the validity or otherwise of the regulations on the single exit price. I need say no more because the differences are admirably canvassed in the reasoning and outcome proposed in the judgment of Yacoob J, in which I concur.

[674] With regard to the validity of the regulations, which introduced an appropriate dispensing fee, I have concluded that on the evidence it has not been shown that the dispensing fee set by the Minister will render pharmacies economically unviable. Nor does the evidence tendered by the Pharmacies establish the quantum or level of the dispensing fee at which any class of pharmacy would be commercially viable or at which the regulations ought to have fixed the dispensing fee. At best the evidence on the commercial impact of the set dispensing fee on pharmacies, taken as a whole, is inconclusive, speculative and open to a multitude of business variables beyond the proper reach of judicial censure. I hold that the dispensing fee set by regulations 10, 11 and 12 is appropriate and does pass muster save as specifically qualified below.

[675] It is so that, for reasons they advance, the Minister and the Pricing Committee opted for a uniform dispensing fee for all pharmacies throughout our country. However, the facts tend to suggest that marginalised patients in far-flung rural areas or

consumers of vital and chronic medicines ordinarily rely on the services of rural pharmacies and courier pharmacies respectively. Though obliged to do so, there is no evidence that the Minister or the Pricing Committee, in formulating the dispensing fee, have applied their minds properly or at all to issues of access and affordability of medicines in relation to rural and courier pharmacies.

[676] In my view, to this extent only is the dispensing fee set by regulations 10 and 11 "inappropriate" and invalid. The remedy indicated by this finding is that the Pricing Committee and the Minister are required to apply their minds to the condition of rural pharmacies and courier pharmacies and those they ordinarily serve and thereafter to determine an appropriate dispensing fee in the light of the socio-economic constitutional obligations which underpin and inform the empowering legislation and regulations made under it.

[677] Lastly, the Minister and the Pricing Committee have conceded that regulation 13 does not fix an appropriate dispensing fee for the selling of Schedule 0 medicines as required by section 22G(2)(c). The concession is well made. The Minister, however, sought to persuade us that the validity of regulation 13 need not be decided as it has since become moot. I do not agree. Regulation 13 is conspicuously inconsistent with its empowering provision and falls to be set aside as invalid in these proceedings.

[678] I turn now to furnishing fuller reasons for the conclusions I have reached.

Appropriate dispensing fee

[679] Shorn of verbiage, the claim of the Pharmacies is that the prescribed dispensing fee for pharmacies is unlawful and falls to be set aside because it will lead to the demise of most pharmacies. The Cape High Court[436] (High Court) dismissed this claim and found the dispensing fee appropriate within the meaning of the impugned regulations. However, on appeal the SCA[437] upheld the Pharmacies contention and declared the regulations invalid and of no force or effect. Before this Court, the Minister urged upon us to reverse the decision of the SCA and to find that the dispensing fee does pass muster.

[680] The impugned regulations are required to introduce a transparent pricing system for medicines and Scheduled substances sold in this country. The regulations were published by the Minister in Government Notice R553 of 30 April 2004 acting in terms of powers conferred on her by section 22G(2)(b)[438] of the Medicines Act. In

[436] *New Clicks South Africa (Pty) Ltd v Tshabalala-Msimang and Another NNO; Pharmaceutical Society of South Africa and Others v Tshabalala-Msimang and Another NNO* 2005 (2) SA 530 (C).

[437] *Pharmaceutical Society of South Africa and Others v Tshabalala-Msimang and Another NNO; New Clicks South Africa (Pty) Ltd v Minister of Health and Another* 2005 (3) SA 238 (SCA); 2005 (6) BCLR 576 (SCA).

[438] Section 22G of the Medicines and Related Substances Act states:

> "(1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.
> (2) The Minister may, on the recommendation of the pricing committee, make regulations—
> (a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;
> (b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a);
> (c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule O medicines.
> (3)(a) The transparent pricing system contemplated in subsection (2)(a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price

particular, regulations 10, 11, 12 and 13 set the maximum dispensing fees pharmacists and other health care professionals may charge a user who is a natural person.[439] These operative regulations came into force at the beginning of August 2004.[440]

[681] Under regulation 10 the starting point for the calculation of a dispensing fee is the single exit price. The first class of dispensing fees relates to medicines and Scheduled substances falling into Schedules 1 and 2 of the Medicines Act and which are supplied to the user without a prescription. The dispensing fee must not exceed 16% of the single exit price where the single exit price is less than R100 and R16 where the price is equal to or greater than R100. The second class covers medicines and Scheduled substances falling into Schedules 3, 4, 5, 6, 7 and 8 of the Medicines Act and also falling into Schedules 1 and 2 of the Medicines Act in respect of which a prescription has been written. The dispensing fee must not exceed 26% of the single exit price of the medicine or substance where the single exit price is less than R100 and R26 where the single exit price is equal to or greater than R100.

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at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.
(b) No pharmacist or person licensed in terms of section 22C(1)(a) or a wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).
(c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2)(b).
(4) To the members of the pricing committee who are not in the full-time employment of the State may be paid such remuneration and allowances as the Minister, with the concurrence of the Minister of Finance, may determine."

[439] The definition of user appears in regulation 2.

[440] Regulation 24(5) read with regulation 2 sets the effective date at three months after the commencement date of 2 May 2004.

[682] Regulation 11 makes it clear that where a medicine or Scheduled substance is dispensed on prescription for a person who has been admitted as an inpatient, the fee to be charged shall be calculated as required by regulation 10 and on the entire quantity of the medicine or Scheduled substance on the prescription, even if the medicine or Scheduled substance is drawn from the stock of a pharmacy, ward or theatre.

[683] Expectedly, regulation 12 recognises that medical practitioners, dentists, nurses or other licensed persons do compound and dispense medicines. However, in terms of the regulation, they may not charge a dispensing fee of more than 16% of the single exit price where the price of the medicine is less than R100 and R16 where the price is equal to or greater than R100.

[684] The final category of fees may be levied by any person, other than a wholesaler and distributor, in respect of Schedule 0 medicines.[441] In that regard regulation 13 stipulates that the fee shall not exceed the percentage mark-up in respect of that medicine or Scheduled substance that was applied at the date when the regulations took effect.

[685] It is not without importance that the dispensing fee scheme brought to life by regulations 10, 11 and 12 prescribes a compulsory annual review. Every year the Minister is obliged to reconsider the appropriate fee provisions keeping in mind the

[441] Schedule 0 medicines include all substances that are subject to registration in terms of the Medicines Act and which are not listed in any of the other schedules.

consumer price index, the producer price index and more importantly "the need to ensure the availability, affordability and quality of medicines and Scheduled substances in the Republic."[442]

Grounds of attack against the validity of the dispensing fee

[686] In submissions before this Court, the Pharmacies contend that the process of making recommendations by the Pricing Committee and regulations by the Minister is administrative action governed by the review standard of PAJA. In the alternative they argue that the regulations are nevertheless vitiated on the basis that they are unreasonable under the common law read with section 33 of the Constitution. To demonstrate this broad submission both sets of respondents have put up separate but related legal argument and expert evidence.

[687] There are three common themes running through the complaints of the Pharmacies. The first is that the prescribed dispensing fee threatens the economic viability of most pharmacies. This contention in effect raises the substantive issue of the reasonableness or otherwise of the fee. It posits the question whether, on the facts, the maximum dispensing fee set is likely to lead to the demise of most pharmacies and in that way undermine the availability of medicines to the public. The second theme is that the fee was set without due regard to all the relevant considerations. Facially this contention questions the manner in which the quantum of the dispensing fee was reached. Yet in effect it raises the issue whether in its deliberations the Minister,

[442] See regulations 10(3) and 12(3).

acting on the advice of the Pricing Committee, acted arbitrarily and capriciously. The third theme is whether on the papers before this Court the Minister and the Pricing Committee disclose or account adequately for how they have arrived at the quantum of the dispensing fee.

[688] I start with a brief account of the contentions specific to New Clicks. Its primary attack is that the dispensing fee is not appropriate because it is not economically viable. The set fee for dispensing would result ultimately in the demise of smaller retail pharmacies whilst larger organisations, such as New Clicks, would not be able to operate their pharmacies in a sustainable manner. The viability argument is advanced in two interrelated and sometimes inseparable senses. First, it is contended that the dispensing fee cannot yield a sustainable return on capital invested in the pharmacies owned by New Clicks but instead will yield a return on capital between 5% and negative 28%, and second, it would lead to an overall reduction in the gross profit of New Clicks pharmacies from 28,96% to 14,93%. The compromised gross profit, they say, does not translate to a viable or economic return on capital. For this contention New Clicks relies on the expert evidence of Professor Kantor, Mr Jordaan and Dr Theron. I examine the expert evidence later in this judgment.[443]

[689] In a further submission, New Clicks argues that the Pricing Committee failed to give due consideration to its contentions on the appropriate profit margin for the

[443] Below paras 726-782.

viability of pharmacies. This it says because, in its submissions to the Pricing Committee, it made the point that a gross profit margin of 25% to 26% is a reasonable minimum threshold for the economic viability of pharmacies. In its minutes the Pricing Committee seems to acknowledge the threshold yet it has set a dispensing fee which, in the view of New Clicks, falls well short of the minimum profit margin required for pharmacies to be viable.

[690] New Clicks argues that the dispensing fee is bad also because there is no indication that regard has been had to economic factors that emphasise different commercial circumstances of pharmacies such as working capital, finance costs, operating and other variable costs and time spent by pharmacies in providing dispensing services.

[691] In the last instance, New Clicks urges that we find, as the SCA did, that regulation 13 is invalid because it does not determine an appropriate fee for the selling of Schedule 0 medicines as required by section 22G(2)(c)[444] of the Medicines Act but rather prescribes a percentage mark-up. It points to other difficulties including the fact that the regulation does not allege that the mark-up is appropriate and assumes that there is a single and uniform mark-up to be applied at the date of commencement of the regulations.

[444] Above n 435.

[692] In order to meet the attack, in this Court, the Minister says the SCA was wrong in deciding the dispute on the validity of regulation 13 because it has become moot. She draws attention to two notices published in the Government Gazette, which in effect exclude Schedule 0 medicines from the provisions of sections 18A and 22G of the Medicines Act and from the regulations for a period of 3 years. On the other hand, New Clicks persists that even though regulation 13 has been presently excluded from operation, it remains part of the dispensing fee scheme and thus its validity falls for determination in these proceedings. It seems to me that we are now seized with the dispute on whether the validity of the regulation is moot and if not whether it has fixed a fee for the sale of Schedule 0 medicines, which is appropriate within the meaning of section 22G. To this matter too, I return later in this judgment.[445]

Main submissions of PSSA

[693] PSSA respondents say the prescribed dispensing fee condemns pharmacies to provide their services at a loss and will force most pharmacies ultimately to go out of business. They claim that even if non-professional front shop sales were taken into account, most pharmacies will operate at a loss. They observe that not all pharmacies have front shops. For instance, a courier pharmacy would not have a front shop. In any event, they say, an appropriate fee is one that allows pharmacists to remain professionally viable through the provision of professional services, quite aside from any front shop activities, in which they chose to engage.

[445] Below para 788.

[694] Second, the PSSA submit that the uniform dispensing fee is bad because it does not differentiate between different categories of pharmacies. The Minister and the Pricing Committee omitted to take account of the different types of pharmacies. The effect of regulations 10 and 11 is to prescribe a single dispensing fee that applies to all sales of pharmaceutical products by retail pharmacies. On this argument, there are different types of pharmacies stocking a divergent range of products and with differing overhead costs, yet the dispensing fee does not make adequate provision for the differences amongst, for example, hospital pharmacies, courier pharmacies, community pharmacies and other types of pharmacies.

[695] Third, the PSSA say that the dispensing fee will undermine or reduce access to pharmaceutical products for all citizens, an outcome which is at odds with the objectives of the national health policy and the right to health care envisaged in section 27(1)(a)[446] of the Constitution. This contention rests on the viability concern and is good only if the regulations objectively speaking are likely to lead to the demise of most pharmacies.

[696] Fourth, in an argument which is also predicated on the cogency of the issue of the viability of pharmacies, the PSSA contend that regulation 10 which sets the dispensing fee, unjustifiably limits the right of pharmacists as a class to "choose a

[446] Sections 27(1) and (2) of the Constitution states:

> "(1) Everyone has the right to have access to–
>
> (a) health care services, including reproductive health care;
>
> (b) sufficient food and water; and
>
> (c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
>
> (2) The state must take reasonable legislative and other measures, within its available resources, to achieve progressive realisation of each of these rights."

trade, occupation or profession" as permitted by section 22[447] of the Constitution because pharmacies that are not economically viable will have the effect of discouraging people from choosing to pursue or remain in the profession. They submit further that regulation 10 "regulates the profession" within the meaning of section 22 of the Constitution and constitutes an arbitrary form of regulation because its unintended consequence is to destroy the pharmacy profession.

Submissions of the Minister and the Pricing Committee

[697] The Minister and the Pricing Committee urge us to hold that the dispensing fee is "appropriate" within the meaning of section 22G and therefore is lawful. The Minister draws attention to the purpose of the enabling legislation and the regulations. She argues that they promote a legitimate and pressing object of progressively achieving access to health care services, which embraces the right of everyone to have access to quality, but affordable medicines. The Minister asserts that the dispensing fee she has determined on the recommendation of the Pricing Committee is an outcome of due and proper consideration of all relevant factors by a committee of experts in the field including a proper evaluation of the operational costs of dispensaries, the viability of pharmacies and the circumstances of different classes of pharmacies.

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[447] Section 22 of the Constitution states:

> "Every citizen has the right to choose their trade, occupation or profession freely. The practice of a trade, occupation or profession may be regulated by law."

[698] The Minister contests most vigorously the suggestion that the fee is unreasonable in the sense that it will lead to the demise of pharmacies. She says there is ample evidence of the factors the Pricing Committee took into account when setting the fees that should be charged for dispensing. Attention is drawn to the minutes of the deliberations of the Pricing Committee and of its Working Group, affidavits deposed to by Pricing Committee members, other depositions filed on behalf of the Minister, proposals and representations to the Pricing Committee by stakeholders and the testimony of several experts put up by the Minister and the Pricing Committee.[448] In her written argument, the Minister analyses the evidence and thereafter asserts that there is

> "ample evidence on record . . . that shows what factors were taken into account, what weight they were given, that calculations were made and that the viability of the pharmacy profession was taken into account by the Committee in the formulation of its recommendations."

In effect the Minister and the Pricing Committee deny that they acted arbitrarily and contend that the dispensing fee is reasonable and well-suited to the objects of the empowering legislation.

SCA on dispensing fee

[699] Before I turn to the findings of the SCA on the dispensing fee it is apposite to record that the SCA had the benefit of argument on behalf of the Pharmacies only. Counsel for the Minister declined the repeated invitations of the SCA to make

[448] Professor McIntyre, Dr Pillay, Professor Mossialos, Professor Henry and Dr Thiede.

submissions on the merits of the application before that court on the ground that their brief was limited to contesting the jurisdiction of the SCA and did not extend to the case on the merits. The Chief Justice deals with this matter in greater detail and I respectfully agree with his observations. To say the very least the election of the Minister not to address the merits before the SCA is open to severe criticism and borders on outright disrespect for the court. Moreover, in a proper case such an election may constitute a bar to a litigant to raise the same issues on appeal. For reasons of public interest advanced earlier it would be inappropriate to exclude the Minister's submissions in this Court.

[700] The SCA held that what is an appropriate fee under section 22G has not been left to the discretion of the Minister but is an objective prerequisite that can be tested judicially. Absent that jurisdictional requirement of "appropriateness", the fee fails at a threshold level and the regulations that prescribe it would be void for lack of a legal basis. Relying on the reasoning of Ngcobo J in *Hoffmann v South African Airways*[449] on the meaning of the words "appropriate relief" found in section 38 of the Constitution, the Court construed "appropriate" to refer to a fee that is not unfair or unjust.

[701] On the facts the SCA found that the dispensing fee was not appropriate because

> "[e]xcept for a general statement that all factors were taken into account, there is no evidence or document that shows what those factors were, what weight they bore,

[449] 2001 (1) SA 1 (CC); 2000 (11) BCLR 1211 (CC) at paras 42-45.

> whether any calculations were made and, more particularly, whether any regard was given to the viability of the dispensing profession".[450]

The SCA found that the evidence tendered by the Minister and the Pricing Committee is "[b]ereft of an explanation"[451] and that the Pricing Committee opted for an inexplicable "deafening silence"[452] and therefore that on a "brief analysis of the evidence" there was no bona fide dispute of fact.[453] The SCA clearly preferred the expert evidence of Dr Stillman and Mr Jordaan tendered on behalf of the Pharmacies and rejected the evidence of the experts of the applicants, Professor McIntyre, Professor, Mossialos, Dr Thiede, Professor Henry, Professor Mooney and Dr Pillay.[454] The SCA concluded that on the evidence access to medicine is seriously threatened because the quantum of fees for dispensing is insufficient to cover the cost of dispensing.[455]

[702] Suffice it to observe that, before this Court, the Minister and the Pricing Committee contested most strenuously the correctness of the evidentiary finding and conclusion of the SCA. As will appear more fully later, the Minister also urges that the dispensing fee set is not open to judicial review except on the ground of rationality. The Minister does not concede that the making of recommendations by

[450] Above n 437 at para 82.

[451] Id at para 83.

[452] Id at para 82.

[453] Id at para 89.

[454] Id at para 86-88.

[455] Id at para 89.

the Pricing Committee followed by ministerial regulation-making is administrative action reviewable under PAJA. In supplementary written argument, she contends that ministerial regulation-making is not susceptible to the review standard prescribed by PAJA.

[703] Ineluctably we are called upon to consider (a) whether the determination of an "appropriate fee" envisaged by the legislature in section 22G of the Medicines Act is susceptible to judicial review and if so whether the regulation-making process is governed by PAJA; (b) whether on the facts it has been shown that the dispensing fee is inappropriate because it will lead to the demise of most pharmacies; (c) whether the Minister had proper regard to all considerations relevant to the determination of the dispensing fee and (d) whether there is an adequate account of how the decision on the dispensing fee was arrived at. Ahead of these considerations, I sketch the constitutional and legislative backdrop to the impugned regulations. Although not contested, it furnishes an invaluable context.

Constitutional and legislative background

[704] There is no dispute amongst the parties, nor can there be, that our Constitution imposes an obligation on the state to take reasonable legislative and other measures, within available resources in order to achieve the progressive realisation of everyone's right to have access to health care services.[456] Properly so, the right of access to health care services embraces the right to access quality and affordable medicines. Of

[456] Section 27(1) and (2) of the Constitution above n 446.

course, the right of access to health care services forms part of a cluster of justiciable socio-economic rights under our Constitution. In *Soobramoney v Minister of Health, KwaZulu-Natal,*[457] Chaskalson P restated the context in which socio-economic rights have to be comprehended:

> "Millions of people are living in deplorable conditions and in great poverty. There is a high level of unemployment, inadequate social security, and many do not have access to clean water or to adequate health services. These conditions already existed when the Constitution was adopted".[458]

[705] I venture to add that a little more than a decade has elapsed since the inception of the obligation of the state to respect, protect, promote and fulfil socio-economic rights. Much has been done to reduce deplorable living circumstances spawned on many of our people by our blighted past. But I fear that even more has to be done. The state remains obliged to root out poverty and want. It must accelerate reasonable and progressive schemes to ameliorate vast areas of deprivation afflicting millions of our people and in particular inadequate health care.[459] The well-earned and lofty thrust of our Constitution is at strenuous odds with demeaning deprivation. Abject poverty wrenches dignity out of any life. Access to affordable medicines is an important component of any scheme directed at poverty reduction and the physical well-being of all our people.

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[457] 1998 (1) SA 765 (CC); 1997 (12) BCLR 1696 (CC) at para 8.

[458] See also the unanimous judgment of the Court in *Government of the Republic of South Africa and Others v Grootboom and Others* 2001 (1) SA 46 (CC); 2000 (11) BCLR 1169 (CC) at para 25.

[459] *Minister of Health and Others v Treatment Action Campaign and Others (No 2)* 2002 (5) SA 721 (CC); 2002 (10) BCLR 1033 (CC) at para 36.

[706] It seems self-evident that there can be no adequate access to medicines if they are not within one's means. Prohibitive pricing of medicine, the SCA correctly found, would in effect equate to a denial of the right of access to health care. Equally true is that the state bears the obligation to everyone to facilitate equity in the access to essential drugs which in turn affect the quality of care. Ordinarily, in the private sector availability of essential drugs would occur through licensed dispensers. Pharmacies form an important but not exclusive part of the group of dispensers of pharmaceutical products. The legislature correctly recognises the importance of dispensers in making medicines accessible and to that end provides for their licensing by virtue of their respective professions.[460]

[707] With a view to meeting its obligation of providing access to health care to everyone, the state has developed and is implementing a national drug policy as part

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[460] Section 22C(1)(a) states:

> "(1) Subject to the provisions of this section–
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> a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions".

On section 22C(1)(a), Ngcobo J in *Affordable Medicines Trust and Others v Minister of Health of RSA and Another* 2005 (6) BCLR 529 (CC) stated at paras 33 and 38:

> "Nor is there anything that prevents Parliament from conferring upon the Director-General the discretion to determine those conditions. Discretion has an important role to play in decision-making. And its scope may vary.
>
> . . . .
>
> The power of the Director-General to prescribe conditions under subsection is limited by the context in which these powers are to be exercised. Thus the power to prescribe conditions must be exercised in the light of, amongst other considerations, the government purpose to increase access to medicines that are safe for consumption, the purpose for which the discretionary powers are given, and the obligations of medical practitioners who have been issued with dispensing licenses. All this provides sufficient constraint on the exercise of the discretionary powers conferred by the subsection."

of the National Health Policy. The drug policy document decries the lack of equity in access to essential drugs in the pharmaceutical sector, the rising drug prices, already high in international terms, evidence of irrational use of drugs and ineffective procurement and logistics practices. The goal of the drug policy is said to be

> "to ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa and the rational use of drugs by prescribers, dispensers and consumers".[461]

[708] Chapter 4 of the policy document calls for a new and transparent pricing structure of medicines in which the retail mark-up system would give way to a fixed professional fee and price increases would be regulated. Rightly so, none of the parties or experts in the field was heard to contest the legitimacy of these state policy objectives. In fact experts on both sides of the divide attest to the intractable tension in this country and elsewhere between the quest for affordable medicines and spiralling retail prices of essential drugs.

[709] The Medicines and Related Substances Control Amendment Act of 1997[462] and the Medicines and Related Substances Amendment Act of 2002[463] are in part the sequel to the drug policy. The legislation introduced a variety of measures, which may be seen as pointed at the reduction of prices of essential drugs. Seen collectively the new measures are intended to exert downward pressure on the cost of medicines to

[461] Preamble to the national drug policy document.

[462] Act 90 of 1997.

[463] Act 59 of 2002.

the public. The measures include the introduction of generic substitution;[464] a prohibition of bonuses, rebates and other unacceptable incentive schemes;[465] allowing parallel importation of medicines;[466] a ban on sampling of medicines;[467] requiring licensing of manufacturers, wholesalers, distributors and dispensers of medicines.[468] In turn, section 22G introduces the requirement of a transparent pricing system stipulating a single exit price for all medicines and Scheduled substances sold in the country. It permits the Minister to make regulations on an appropriate dispensing fee to be charged by a pharmacist or by any other licensed dispenser such as a doctor, dentist or nurse.

[710] In *Mistry v Interim Medical and Dental Council of South Africa and Others*,[469] Sachs J, writing for the Court, also concluded that the purpose of the Medicines Act

> "was not merely to regulate the manner in which Scheduled substances were made available to the members of the public, but to control the quality and supply of medicines generally".[470]

[464] Section 22F of the Medicines Act, above n 435.

[465] Id at section 18A.

[466] Id at section 15C.

[467] Id at section 18B.

[468] Id at section 22C.

[469] 1998 (4) SA 1127 (CC) at para 17; 1998 (7) BCLR 880 (CC) para 10.

[470] Id. It is clear that the judgment cites with approval the dicta of Kriegler AJA in Administrator, *Cape v Raats Röntgen and Vermeulen (Pty) Ltd* 1992 (1) SA 245 (A) at 254B-E. See also *Pharmaceutical Manufacturers Association of SA and Another: In re Ex parte President of the Republic of South Africa and Others* 2000 (2) SA 674 (CC); 2000 (3) BCLR 241 (CC) at para 61.

Keeping in mind the constitutional imperative on access to health care for everyone, section 22G of the Medicines Act is directed at enhancing in a transparent manner the accessibility and affordability of quality medicines to the public at large.

[711] The Pharmacies say the Pricing Committee thought that their primary function was to reduce the price of medicines. They submit that "the purpose of section 22G is not to reduce the prices of medicines by statutory price control". They concede that the purpose of the empowering provision is the reduction of prices but, in their view, it should occur through only transparency and "consistency in the determination of medicine prices". In that way, they argue, the Minister and the Pricing Committee had an ulterior purpose;[471] acted for a reason not authorised by the empowering provision;[472] took account of irrelevant considerations[473]and acted in a manner that was not rationally connected to the purpose of the empowering provision.[474]

What is an appropriate dispensing fee?

[712] It is so that "appropriate" is not a word of precise connotation. Yet one must agree that the qualification "appropriate" must mean, as found by the SCA, a fee "specially suitable" or "proper" to the purpose of the statute. Naturally, to be appropriate the fee must be just and fair to all affected by its determination.[475] What

[471] Section 6(2)(e)(ii) of PAJA.

[472] Within the meaning of section 6(2)(e)(i) of PAJA.

[473] Within the meaning of section 6(2)(e)(iii) of PAJA.

[474] Within the meaning of section 6(2)(f)(ii)(bb) of PAJA.

[475] See remarks of Ngcobo J in *Hoffmann* above n 449 at paras 42-43.

is or is not an appropriate fee can be objectively determined by reference to the purpose of the enabling legislation and the lawful boundaries for the exercise of the public power conferred. In other words the exercise of the power must be lawful, and properly related to the governmental purpose pursued.[476]

[713] It does not however mean that the term "appropriate" in itself lays down an absolute or immutable standard. It is correct that people well informed of the subject matter, might very well take different views on what is appropriate. The ultimate question must be whether the determination of appropriateness falls within a range of what may be reasonably regarded as proper, well-suited and fair. That determination falls to be made by balancing out the relevant but often competing factors and thereafter striking equilibrium amongst all factors. The competing factors would include the factual context, the purpose of the power, the nature of the measures impugned and its impact on affected parties and on the public interest.

[714] In the present matter an appropriate dispensing fee, at the very least, must reflect a suitable balance between the availability and affordability of quality medicines. Availability points to continued supply of medicines to ensure ready access. For that purpose dispensers of medicines are vital. As we have seen earlier, affordability is an incident of access to essential drugs. Implicit in the requirement of

[476] *S v Lawrence; S v Negal; S v Solberg* 1997 (4) SA 1176 (CC); 1997 (10) BCLR 1348 (CC); *Pharmaceuticals* above n 470; *Fedsure Life Assurance Ltd and Others v Greater Johannesburg Transitional Metropolitan Council and Others* 1999 (1) SA 374 (CC); 1998 (12) BCLR 1458 (CC); *President of the Republic of South Africa and Others v South African Rugby Football Union and Others (SARFU 3)* 2000 (1) SA 1 (CC); 1999 (10) BCLR 1059 (CC); *Bel Porto School Governing Body and Others v Premier, Western Cape, and Another* 2002 (3) SA 265 (CC); 2002 (9) BCLR 891 (CC); *Affordable Medicines* above n 460.

affordable medicines is a pricing regime that does not render medicines out of the reach of most users and thereby frustrate access to quality health care.

Is the determination of an appropriate fee reviewable by the courts?

[715] In this Court, the Minister contended that the determination of an appropriate dispensing fee is a matter that the legislature has left to the discretion of the Minister acting on recommendation of the Pricing Committee. She contends that what constitutes the equilibrium amongst all relevant factors is left to the Minister to strike. On this argument the appropriateness of the fee is not a jurisdictional fact because it is not capable of a single objective standard. At most, the Minister argues, courts are permitted to determine whether there is a rational basis upon which the dispensing fee was set in the regulations.

[716] It is now well settled that in our constitutional democracy the exercise of all public power must occur lawfully and is susceptible to judicial scrutiny.[477] It is so that the enabling statute empowers the Minister to set the fee on the advice of the Pricing Committee. But that does not mean the legislature has left the determination of what is an appropriate dispensing fee within the subjective discretion of the Minister. Clearly, section 22G does not immunise the regulation-making power of the Minister

[477] *S v Makwanyane and Another* 1995 (3) SA 391 (CC); 1995 (6) BCLR 665 (CC) at para 156; *Prinsloo v Van der Linde and Another* 1997 (3) SA 1012 (CC); 1997 (6) BCLR 759 (CC) at para 25; *President of the Republic of South Africa v Hugo* 1997 (4) SA 1 (CC); 1997 (6) BCLR 708 (CC) at para 13; *Fedsure* above id at para 58; *New National Party of South Africa v Government of the Republic of South Africa and Others* 1999 (3) SA 191 (CC); 1999 (5) BCLR 489 (CC) at para 19; *Pharmaceuticals* above n 470 at paras 17 and 20; *Bel Porto* id at para 87; *Minister of Health and Others v Treatment Action Campaign and Others (No 2)* above n 459; *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Others* 2004 (4) SA 490 (CC); 2004 (7) BCLR 687 (CC) at para 22; *Affordable Medicines* n 460 at para 49.

from judicial scrutiny. It is trite that a wielder of public power must exercise the power lawfully. That means the authority must be exercised within the bounds set by the empowering legislation, in a rational manner and within the constraints of the Constitution.[478] It must follow that competent courts may enquire into the lawfulness or otherwise of the determination of an appropriate dispensing fee by the Minister under section 22G(2)(b) by virtue of the principle of legality.[479]

[717] What then is the proper standard for judicial review in relation, first to the recommendations of the Pricing Committee and second to the ministerial regulations prescribing the dispensing fee? The answer clearly lies in whether the deliberations of the Pricing Committee, or the ministerial regulation-making or both, constitute administrative action within the meaning of section 33 of the Constitution.[480] After much deliberation, the majority judgment in the High Court concluded that the deliberations of the Pricing Committee and the ministerial regulations do not constitute administrative action under PAJA. The SCA found it unnecessary to decide whether PAJA is implicated. It invalidated the regulations on the ground that they had

[478] *Bel Porto* above n 44 at para 87, *Bato Star* above n 45 at para 22.

[479] *Bato Star* id.

[480] Section 33 reads as follows:

> "Just administrative action.
> (1) Everyone has the right to administrative action that is lawful, reasonable and procedurally fair.
> (2) Everyone whose rights have been adversely affected by administrative action has the right to be given written reasons.
> (3) National legislation must be enacted to give effect to these rights, and must
> (a) provide for the review of administrative action by a court or, where appropriate, an independent and impartial tribunal;
> (b) impose a duty on the state to give effect to the rights in subsections (1) and (2); and
> (c) promote an efficient administration."

failed the legality test. In this Court the Pharmacies resuscitated their reliance on the administrative justice dictates of PAJA. In supplementary written argument, the Minister advanced the opposite view that neither the recommendation nor the regulations constitute administrative action.

[718] In *Bato Star*[481] this Court made it clear that:

> "There are not two systems of law regulating administrative action - the common law and the Constitution - but only one system of law grounded in the Constitution. The Courts' power to review administrative action no longer flows directly from the common law but from PAJA and the Constitution itself. The grundnorm of administrative law is now to be found in the first place not in the doctrine of *ultra vires*, nor in the doctrine of parliamentary sovereignty, nor in the common law itself, but in the principles of our Constitution." (Footnotes omitted.)

In regard to the applicability of PAJA to a cause of action based on administrative review, O'Regan J observed that:

> "The provisions of s 6 divulge a clear purpose to codify the grounds of judicial review of administrative action as defined in PAJA. The cause of action for the judicial review of administrative action now ordinarily arises from PAJA, not from the common law as in the past. And the authority of PAJA to ground such causes of action rests squarely on the Constitution. It is not necessary to consider here causes of action for judicial review of administrative action that do not fall within the scope of PAJA. As PAJA gives effect to s 33 of the Constitution, matters relating to the interpretation and application of PAJA will of course be constitutional matters."[482] (Footnotes omitted.)

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[481] Above n 477 at para 22.

[482] Id at para 25.

[719] In *Bato Star* this Court applied PAJA. It was, however, common cause that the decision under review amounted to administrative action. For that reason the proper scope of the definition of administrative action in section 1 read with section 6 of PAJA did not concern us.[483] It does concern us now. The parties have locked horns on whether ministerial regulation-making and recommendation of the Pricing Committee are governed by the standard of administrative justice envisaged in section 33 of the Constitution and PAJA.

[720] Whether or not the exercise of public power constitutes administrative action under the Constitution is a matter of considerable complexity. In *SARFU (3)* this Court observed that what matters in the enquiry is the nature of power exercised and not the arm of government wielding the power.[484] It remarked that the mere fact that an executive arm of government exercises the power does not make the action "administrative". It made a distinction between implementation of legislation that would constitute administrative action and policy making that would not. About this distinction the Court elaborated:

> "Determining whether an action should be characterised as the implementation of legislation or the formulation of policy may be difficult. It will, as we have said above, depend primarily upon the nature of the power. A series of considerations may be relevant to deciding on which side of the line a particular action falls. The source of the power, though not necessarily decisive, is a relevant factor. So, too, is

[483] Id at para 24.

[484] Above n 476 at para 141; also see *Permanent Secretary, Department of Education and Welfare, Eastern Cape, and Another v Ed-U-College (PE) (Section 21) Inc* 2001 (2) SA 1 (CC); 2001 (2) BCLR 118 (CC) at para 18; *Zondi v MEC for Transitional and Local Government Affairs and Others* 2005 (3) SA 589 (CC); 2005 (4) BCLR 347 (CC) at para 104.

> the nature of the power, its subject-matter, whether it involves the exercise of a public duty, and how closely it is related on the one hand to policy matters, which are not administrative, and on the other to the implementation of legislation, which is. While the subject-matter of a power is not relevant to determine whether constitutional review is appropriate, it is relevant to determine whether the exercise of the power constitutes administrative action for the purposes of s 33. Difficult boundaries may have to be drawn in deciding what should and what should not be characterised as administrative action for the purposes of s 33. These will need to be drawn carefully in the light of the provisions of the Constitution and the overall constitutional purpose of an efficient, equitable and ethical public administration. This can best be done on a case by case basis."[485] (Footnotes omitted.)

[721] In *Minister of Home Affairs v Eisenberg and Associates: In re Eisenberg and Associates v Minister of Home Affairs and Others*[486] ministerial regulations were impugned also on the ground that they constituted administrative action within the meaning of section 33 of the Constitution and the provisions of PAJA. Writing for a unanimous Court, Chaskalson CJ considered the definition of "administrative action" in section 1 of PAJA which refers to "any decision taken, or a failure to take a decision in terms of section 4(1)" and said:

> "The definition of 'decision' does not refer to the making of regulations and it is not clear whether this constitutes administrative action for the purposes of PAJA. Moreover, the definition of 'administrative action' specifically excludes 'any decision taken, or a failure to take a decision, in terms of section 4(1)'. It may be open to doubt, therefore, whether reliance could be placed on PAJA in the circumstances of this case."[487] (Footnote omitted.)

[485] *SARFU 3* above n 44 at para 143.

[486] 2003 (5) SA 281 (CC); 2003 (8) BCLR 838 (CC).

[487] Id at para 52.

In that case the Court considered it unnecessary to decide whether ministerial regulation-making is administrative action stating that it

> "raises complex issues including the question whether a construction of PAJA that excludes the making of regulations from the ambit of administrative action would be consistent with the Constitution."[488]

Several legal writings draw attention to the interpretive minefield surrounding the definition of administrative action in PAJA and whether it implicates ministerial regulations.[489]

[722] I consider it neither prudent nor necessary to decide, in this case, the complex and contested issue of the proper standard of review of ministerial law-making. Having disposed of the case on the ground of legality, the SCA declined to decide the issue. As was to be expected, review under PAJA is not one of the grounds on which the Minister felt aggrieved and approached this Court. That fact is borne out by the Minister's main heads of argument that do not deal with the level of review set by PAJA at all. Only in belated supplementary heads of argument does the Minister seek to reply to the respondents' contentions based on PAJA. In any event, at the hearing, her application for the admission of late and an additional set of heads of argument

[488] Id at para 53 n 30.

[489] Joubert *The Law of South Africa (LAWSA)* 2 ed vol 1 (LexisNexis Butterworths, Durban 2003) at paras 79-81; Joubert, *LAWSA* First Reissue vol 10 Part 1 (Butterworths, Durban, 1998) at para 6; Boulle, Harris and Hoexter *Constitutional and Administrative Law* (Juta, Cape Town 1989) at 88-90; De Waal, Currie and Erasmus *The Bill of Rights Handbook* 4 ed (Juta, Lansdowne 2001) 504-505; Klaaren "Administrative Justice" in Chaskalson et al *Constitutional Law of South Africa* (Juta, Cape Town, 1996) at 25.1-25.2; De Ville *Judicial Review of Administrative Action in South Africa* (LexisNexis Butterworths, Durban 2003) at 39-40; Henderson "The Meaning of Administrative Action" (1998) 115 *SA Law Journal* 634 at 634-635; Hoexter *The New Constitutional and Administrative Law* 1 ed vol 2 (Juta, Lansdowne 2001) at 102; Burns *Administrative Law under the 1996 Constitution* 2 ed (LexisNexis Butterworths, Durban 2003) at 21-22; Currie and Klaaren *The Promotion of Administrative Justice Act Benchbook* (Siberlink, Cape Town 2001) at 83-84 para 2.38.

was contested by the Pharmacies. Moreover, although the Pharmacies do rely on the standard of administrative justice envisaged in PAJA they also rely on alternative grounds of review.

[723] I am well aware that there may be compelling reasons for holding ministerial regulation-making reviewable under PAJA. The difficulty is that there are at the very least equally persuasive considerations that ministerial legislation is not administrative action and does not fall within PAJA but is controlled and limited by the Constitution and legislation that confers the power to the minister concerned. Perhaps the immaculately reasoned judgment of Sachs J is a telling example of the depth and intricacy of the debate on administrative justice and subordinate law-making. Shortly put, I do not consider myself to have had the benefit of full argument on a matter of much, much importance for the proper development of our administrative law which hopefully will pay due regard to prudent considerations which inform the separation of powers required by our Constitution.

[724] Given the conclusion I have arrived at on the facts I need not decide the issue. I shall, however, assume without deciding that the administrative justice standard of lawfulness, reasonableness and procedural fairness espoused by the Constitution is given legislative effect in PAJA[490] and that it applies to the recommendation of the Pricing Committee and to ministerial regulation-making. On this approach, I am now called upon to evaluate the conduct of the Minister and the Pricing Committee, where

[490] Above n433; *Bato Star* n 477 at paras 23 and 25; *Zondi* above n 484 at para 99; *Affordable Medicines* above n 460 at para 49.

appropriate, against the review standard of reasonableness. The litmus test would be whether the decision impugned is "so unreasonable that no reasonable person"[491] could have arrived at it.

[725] In *Bato Star* O'Regan J says the following about the review standard of reasonableness:[492]

> "What will constitute a reasonable decision will depend on the circumstances of each case, much as what will constitute a fair procedure will depend on the circumstances of each case. Factors relevant to determining whether a decision is reasonable or not will include the nature of the decision, the identity and expertise of the decision-maker, the range of factors relevant to the decision, the reasons given for the decision, the nature of the competing interests involved and the impact of the decision on the lives and well-being of those affected. Although the review functions of the Court now have a substantive as well as a procedural ingredient, the distinction between appeals and reviews continues to be significant. The Court should take care not to usurp the functions of administrative agencies. Its task is to ensure that the decisions taken by administrative agencies fall within the bounds of reasonableness as required by the Constitution." (Footnotes omitted).

Will the dispensing fee cause the demise of pharmacies?

[726] New Clicks respondents say the dispensing fee will in time lead to the closing down of most pharmacies. They owe this conclusion to the expert evidence of

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[491] See section 6(2)(h) of PAJA which reads:

> "(2) A court or tribunal has the power to judicially review an administrative action if–
> (h) the exercise of the power or the performance of the function authorised by the empowering provision, in pursuance of which the administrative action was purportedly taken, is so unreasonable that no reasonable person could have so exercised the power or performed the function".

[492] Above n 477 at para 45.

Professor Kantor, a university professor of economics, Mr Jordaan, a pharmacist and economist and Dr Theron, a university lecturer in economics.

[727] Professor Kantor starts his affidavit by recognising that the stated purpose of the regulations is to ensure availability, affordability and quality of medicines. He accepts that South Africa is a mixed economy in which the market functions subject to regulatory control by law consistent with the Constitution; that in principle the regulation of the sale of pharmaceutical products is to be expected and that the regulation should strike a fair balance between access to health care and viability of services providing health care. He recognises that the increase of medical expenses is a global phenomenon as societies spend increased proportions of their available income on medical expenses. However, as a matter of economic principle, he is opposed to "price control systems" because in practice they become "cost plus systems". He says that in effect price control means higher prices because the industry affected normally negotiates with its regulator for costs levels that are fed back into the pricing system at the expense of the consumer. In his opinion, the government would have done best by securing best prices from manufacturers of drugs while leaving distribution to be regulated efficiently by normal market forces.

[728] Much should not be made of Professor Kantor's aversion for "price control systems" because New Clicks in whose favour his opinion was proffered does not agree with Professor Kantor's sentiment. Mr Honeysett, on behalf of New Clicks, says he "accepts the desirability of and need to regulate medicines (and particularly

the price thereof) in order to make medicines affordable to the public". This view is echoed in the expert opinion of both sides. Dr Theron, for New Clicks, and also the Minister's expert witnesses, Professor McIntyre and Professor Mooney hold that for many good reasons the price of medicines must be regulated in order to realise access to affordable medicines.

[729] Professor McIntyre who is an associate professor of health economics and an expert in that field refutes the evidence of Professor Kantor. She draws attention to the fact that Professor Kantor is an expert in monetary economics and not in economics of pharmaceuticals or of the health sector. She refutes the notion that the market for health care is highly competitive and "free" because it exhibits a wide range of material imperfections. She says therefore that it would have been inappropriate to design medicine pricing regulations without taking into reckoning these market distortions.

[730] Her affidavit sets out a catalogue of what she calls "pervasive . . . imperfections" of the health care market. I recite only a few. She testifies that the theory of perfect competition assumes that consumers have perfect knowledge about the goods and services that they consume. However, in the health sector there is an asymmetry or an imbalance of information between the health professional and the patient, or if you will, between the consumer and the supplier. The patient does not demand the medicine but the health professional operates in effect as the agent of the patient and makes decisions in regard to the use of medicines. The phenomenon is

known as "supplier induced demand". This prescription or pharmacist-initiated consumption, often relates to ill health, long-term disability or death. This imperfect agency relationship translates into sellers charging high prices without negatively influencing demand for health care products. In other words, the market allows retailers to operate inefficiently and still survive, something which an open "free" market would not tolerate.

[731] Another distortion of the market is the existence of significant barriers to entry and exit in the market for health care at the level of entering pharmacy and other health related professions and at the level of patenting of pharmaceutical products, which effectively create a monopoly and result in high prices of new medicines. Professor McIntyre also mentions that the existence of economies of scale in health care services, particularly in production, tends to create an oligopoly that translates into higher prices. She also cites the existence of risk and uncertainty as the need and demand for health care is irregular and unpredictable and tends to lead to high costs.

[732] Professor Mooney, a professor of health economics from Perth, Australia and an expert in the field of health economics, also rejects Professor Kantor's clamour for "free market forces" in the pharmaceutical sector and makes out a case for the need for regulation of the pharmaceutical sector. He makes the point that in nearly all countries, including South Africa, the pharmaceutical market distorts normal supply and demand and does not allow value for money or efficiency in the sector. He says a patient presenting at a pharmacy is not well placed to assess the reasonableness of the

price proposed; she is not in a good position to bargain, in part because she needs the medicine and because she has an unequal power relation with the health professional. Both are aware of the imbalance. In an imperfect market, regulation is indispensable because suppliers of pharmaceutical goods might charge higher prices than they would in a competitive market. In his words either the patient's wallet or the patient's health suffers.

[733] The SCA also found the regulations bad because section 22G does not authorise "statutory price control" of medicines. Whatever the precise import of statutory price control it has not been shown to be ousted by the empowering statute or impermissible under our Constitution. Moreover, as we have seen, expert evidence other than Professor Kantor's supports an urgent need for regulation of essential medicines. I do not agree that by devising a scheme to make medicines affordable through regulation 10, which sets the dispensing fee for pharmacies, the Minister's conduct is ulterior, irrelevant or irrational to the purpose of section 22G(2) and (3).

[734] The overt and, might I add, legitimate purpose of the legislation is to increase access to medicines and Scheduled substances by, amongst other measures, exerting downward pressure on their prices. The legislation seeks to achieve that purpose through a "pricing system". That must mean an organised scheme or method, which implicates prices of medicines. The scheme must be transparent. It must include a single exit price, which shall be the only price at which manufacturers shall sell medicines and an appropriate fee to be charged by retailers, distributors and

wholesalers of medicines. In my view, the Minister and the Pricing Committee were not only right but were obliged to consider and pursue the object of price reduction of essential medicines in order to advance greater access to affordable medicines.

[735] Returning to Professor Kantor's evidence, he concludes that the prescribed dispensing fee is inappropriate because pharmacies require an adequate return on capital invested "with due regard for the structures and risk inherent in the market in question". The dispensing fee does not allow an adequate return on capital without which in time pharmacies will decline and close down. He readily admits that this conclusion is derived from the evidence of both Dr Theron and Mr Jordaan pertaining to the economics and finances of retail pharmacies in South Africa.

[736] The evidence of Professor Kantor does not quantify what is an adequate return on capital for pharmacies; it does not say what the structures of the industry are; nor what the risk inherent in the pharmacy market is. He does not give an account of what gross sales margins would ensure the survival of the industry nor does he tell us whether he has critically examined the evidence of Dr Theron and Mr Jordaan and which facts or opinion in their evidence fortify his extravagant conclusion.

[737] Professor McIntyre agrees that the survival of the retail pharmacy sector is essential for medicine delivery but denies that the regulations threaten the survival of the sector and that the dispensing fee is inappropriate. She says the regulations have been designed with due caution and consideration of financial viability issues. She

notes that Professor Kantor's opinion is dependent on that of Dr Theron and Mr Jordaan but disputes the appropriateness of their assessment of adequate return on capital. She says that their assessment fails to recognise that the dispensing fee is only one source of income for retail pharmacies. The Pharmacy Council recognises other professional services that pharmacists may legitimately provide as additional sources of revenue. She says that their calculation of what is an adequate return on capital is flawed because it is not limited to costs related to dispensing activity.

[738] Professor McIntyre disputes that there is a causal link between the regulations and the survival of the pharmacy sector. She says Mr Jordaan and Dr Theron ought to have recognised that recent studies in the sector show that 24% of the community pharmacies are currently operating at a loss for reasons unrelated to the regulations. She says the move from a mark-up on the manufacturer's price of medicine to a professional fee based on pharmacy practice creates an opportunity for that profession and the rest of the health care sector to adjust their business practices and to achieve efficiency gains that will accrue to the benefit of all South Africans. She rejects the assertion that the regulations will not achieve their objectives of accessibility to affordable medicines and says if applied they certainly will.

Expert evidence of Dr Theron

[739] At the outset, Dr Theron observes that in the last decade both in South Africa and elsewhere health care and pharmaceutical costs have risen sharply and have driven governments to implement cost containment measures in various forms.

Where health care is primarily a public function, as in Australia and the European Union (EU), the state uses its power to implement cost reduction in a variety of ways. She cites examples of EU countries, which have experimented extensively with price controls including profit controls.[493] She observes that international experience has shown that market responses alone will be insufficient to bring down costs of pharmaceutical products and that some regulation is necessary, even if it is for a limited period of time. She concludes that in determining an appropriate pricing structure regime, regard should be paid to the specific structure of the health care market in the country in question.

[740] Dr Theron turns to the structure of the pharmaceutical sector in South Africa and observes that the supply side is characterised by more than 100 manufacturers in an oligopolistic market. Annual turnover of pharmaceutical companies is estimated at R10,7 billion. Manufacturers are said to wield "market power". In the private sector medicines are dispensed through retailers who are supplied by manufacturers through wholesalers and distributors. Some products go directly to dispensaries in hospitals, clinics and commercial pharmacies. Dr Theron says rationalisation in the industry may eliminate the traditional role of full line wholesalers and that may be detrimental to retail pharmacies in rural and under serviced areas which the pricing regulations are designed to protect.

[493] Dr Theron says that for example the UK once targeted a return on capital of between 17% and 21%.

[741] She points to a significant change on the retailing side of the market, which is still dominated by a large number of small retailers. Corporates are now permitted to enter the market and this has led to the formation of large pharmacy chains with significant buying and distribution power, all of which should augur well for retail prices.

[742] Dr Theron concludes that the pharmaceutical sector in South Africa is an industry in transition from a small-scale expensive market to a modern retailing market. She is of the view that although in the past it was characterised by high costs and high margins, increasing competitive pressure has reduced the margins and profit levels. She says it is accepted that price regulation is probably necessary to "achieve a more rapid reduction in pharmaceutical prices". She urges that these developments should be taken into consideration in designing and implementing a price regulation framework.

[743] Dr Theron suggests that in any price regulation environment, "international convention and practice"[494] requires observance of three principles: that the enterprise should be permitted to make an adequate return on capital; that the price regimes should be subject to periodic review; and that price regulations should reflect the cost structures of the industry. Dr Theron then tests two of the requirements against what she sees as the impact of the pricing regulations. She correctly records that the regulations in their final form do provide for periodic review.

[494] Dr Theron does not explain the source of the international convention and practice she relies upon and whether it is subject to any contextual variation.

[744] First, she sets a benchmark of an average gross profit of 26% as representing an economic rate of return for retail pharmacies in South Africa "based on cost structures". The source of or justification for the benchmark is not stated. Relying on the calculations by Mr Jordaan, she concludes that "operating costs" (excluding advertising costs) amount to 26,19%. She says the effect of the "[r]egulations will be an overall reduction in the gross profit percentage to a level of 14,93%". In her view, this clearly does not represent a fair rate of return. She emphasises that the potential gross profit margin of 49% earned by pharmacies in practice is reduced to 25,98% after taking into account "patient costs, medical aid costs, discounts, administration fees and write-offs".

[745] Next, Dr Theron discusses her requirement that pricing regulations must reflect the cost structure of the industry. She again stresses that for this exercise the "true retail margin" of 25,98% should be used as opposed to the perceived retail margin of 49%. She explains again that the higher gross profit of the two is whittled down to 25,98% by "discounts to medical aids and the like". Dr Theron again relies on calculations by Mr Jordaan that "pharmacies achieve a gross profit margin of 25,98% but bear total direct expenses of 26,19%". She continues, "[a]ccordingly, a significant reduction in the current gross profit levels will materially affect profit margins." Dr Theron concludes, in an unintelligible statement that, "the greatest reduction which the industry could bear is a reduction of the gross profit level from *25,98% to 26%*

particularly having regard to the present total direct expenses of 26,19%". (My emphasis.)

[746] Dr Pillay disputes the opinion evidence of Dr Theron. The SCA dismissed the evidence of Dr Pillay as having nothing to do with the issue to be decided.[495] I have found no reason to discard his evidence summarily and as irrelevant. Dr Pillay points out that Dr Theron argues that a gross profit of 26% is required to maintain viability. He denies this assertion. He testifies that he examined the financial statements of 176 pharmacies supplied to the National Department of Health by PSSA through its consultant, Mr Boyce. He found that there are pharmacies that showed a gross profit of 26% that are not viable and there are pharmacies achieving a gross profit margin of 26% that are viable. Dr Pillay concludes that these facts tell that there is no relationship between viability and gross profit. Gross profit percentage, he argues, is not a predictor of the viability of retail pharmacy. Dr Pillay says that in order to predict whether a retail pharmacy is viable or not one needs to assess the income and the expenditure of the dispensary. He says the pricing regulations affect only the dispensary within the retail pharmacy. He makes the point that none of the data put up by the Pharmacies "addresses the income and expenditure of the dispensary which is relevant to the regulations". He says putting up information on the income and expenditure of the entire pharmacy or store is irrelevant since the pricing regulations relate only to the dispensary.

[495] Above n 437 at para 86.

[747] Dr Pillay says he does not agree with Dr Theron's reliance on the calculations of Mr Jordaan because there are a number of uncertainties with his analysis. He does not however specify the uncertainties he relies upon. He says it is unclear how she arrived at the proposed model of a dispensing fee and that her conclusion that retail pharmacies will be unviable is speculative.

[748] Lastly, Dr Pillay makes the interesting point that the reckoning of 14,93% gross profit may be open to inaccuracies also because the calculation would have to predict the single exit price of manufacturers. At the time of the calculation of the gross profit of 14,93% single exit prices had not been set. Dr Pillay says the internal estimates by the National Department of Health of gross profit of retail pharmacy would be in the order of 20% and not as low as Dr Theron suggests.

[749] The opinion evidence of Dr Theron is useful in many respects. Her treatment of aspects of comparative international approaches to rising health care costs, the structure of the South African pharmaceutical market and principles of price regulation is instructive. The same cannot be said of her discussion of the impact of the pricing regulations on the adequacy of return on capital invested in pharmacies and on the cost structure of the industry. I have chosen to render her vital conclusions on adequacy of capital and costs in her own words and sadly as recorded they make little or no sense at all. Moreover, the cogency of her conclusions on return on capital and operating costs depends on the calculations of Mr Jordaan.

[750] First, she sets herself the task of telling why under the pricing regulations the return on capital is inadequate and therefore threatening to the viability of retail pharmacy. But she does not tell us, even once, what is the prudent rate of return on capital for retail pharmacies. What she tells us is that a pharmacy should achieve a gross profit on sales of 26%. But why? She does not tell us why that gross margin will achieve an adequate return on capital and which cost structure must be maintained to yield a prudent or fair rate of return. The cardinal error she makes is that she equates gross profit with pharmacy viability. The equation is obviously wrong because it is not a reliable predictor of viability of retail pharmacy.

[751] Second, Dr Theron observes, and I agree as a matter of common sense, that the adequacy of return on capital is a function of the costs structure of the industry. It seems plain that the higher the costs of an enterprise or industry the lower its return on capital and the lower the costs the higher is the return. What she tells us, without pointing to any evidence, is that pharmacies do achieve a "perceived" 49% gross profit on sales but the gross margin is reduced to a "real" 25,98% by a long list of costs, which she does *not* attribute to the pricing regulations. Dr Theron is in effect making the startling statement that for pharmacists to reach the viable margin of 26% they must at the outset make a gross profit of 49%.

[752] Third, Dr Theron says the impact of the pricing regulation is to reduce the gross profit further to a level of 14,93%. This figure is derived from Mr Jordaan's calculations. The sufficiency of a gross return of 14,93% or of any positive gross

return depends on the ideal rate of return on capital. Dr Theron does not suggest one. Simply put a gross profit margin of 14,93% of a dispensary is not a reliable predictor that it will not be viable. Therefore a reliable and accurate apportionment of operating costs to the dispensary within a pharmacy business is cardinal. Mr Jordaan's calculations are directed mainly at that task.

The evidence of Mr Jordaan

[753] Mr Jordaan is an important witness for the case of New Clicks. It will be remembered that all the other expert testimony of New Clicks is predicated on his calculations. The SCA accepted what it called "a detailed exercise" of separating the operating costs of the dispensing business from the costs of the front shop and that the pricing regulations will cause an operating net loss of R5,33 per line item.[496] The SCA dismissed the opinion of five experts put up to meet these calculations on the basis that it was irrelevant or did not deal with viability of pharmacies or amounted only to criticism of Mr Jordaan's report.[497]

[754] Mr Jordaan is a qualified pharmacist and has completed an auditing diploma in cost accounting and internal auditing. He is currently studying for a Masters degree in pharmaceutical economics. He works for a business group that owns 80 pharmacies and is about to merge with New Clicks, which has been licensed to operate and own 57 of the 80 pharmacies. It is expected that all 80 pharmacies will be taken over by

[496] Above n 437 at para 85.

[497] Above n 437 at paras 85-87.

New Clicks shortly. Mr Jordaan is head of professional services and his responsibilities include managing the health care business, implementing good pharmacy practices and refining the financial discipline of the business. He has access to the central database of the group.

[755] He explains that he has undertaken a financial analysis of the business activities of all 80 pharmacies in order to determine the impact of the pricing regulations on the business. He says that an average retail pharmacy business ordinarily has two components. The back shop dispenses prescriptions and sells medicines and Scheduled substances over the counter (OTC). The front shop conducts normal trade including the sales of vitamins and health products, beauty products and fast moving goods such as toiletries. The pharmacies may be classified as large, medium and small outlets and are located over a broad geographical spread. From raw data accessible to him Mr Jordaan prepared three tables depicting the contributions to total sales and to gross profit by the front shops and the dispensaries in each of the categories of small, medium and large. In a fourth table he depicts totals or averages of the three earlier tables. He claims that the pattern of averages found in the fourth table represents a typical pharmacy in the sector. From the tables, Mr Jordaan makes the first but important conclusion that "the OTC and dispensary portion . . . contributes 27,9% of the gross profit and sales of 83,29%." The difficulty is that the vital figure of 27,9% that represents the average gross profit contribution by the dispensary does not feature on any of the four tables. In any event, what is

noteworthy is that the dispensary businesses seem to make very high sales contributions but yield very low gross profits to the businesses as a whole.

[756] On a schedule Mr Jordaan sets out monthly operating expenses of both the front shop and back shop over seven months ending March 2004. The costs are made up of direct costs attributable only to the back shop business such as pharmacists' salaries and indirect costs, which cover the entire pharmacy business. First he allocates 100% of direct salary costs of pharmacists and assistants to the back shop and 20% of the salary costs of the front shop staff to the back shop. The rest of the costs, known as the indirect costs, are apportioned between the front shop and back shop on a ratio of 16,71/ 83,29. The ratio is informed by the respective contribution to turnover of the two sub-businesses. An extension of this reasoning is that the back shop must bear 83,29% of the monthly operating costs and the front shop must carry 16,71% of the monthly operating expenses. This apportionment is used to determine an average cost per line item. This Mr Jordaan does by dividing the number (651 966 OTC and dispensary transactions) of line items sold by the dispensaries in the New Clicks dispensary businesses during August 2003 to January 2004 into monthly operational expenses attributable to the back shop in accordance with the 17/83 apportionment formula. The result of this calculation, Mr Jordaan calls an average cost per line.

[757] The next step in the calculation is an attempt to determine the impact of the pricing regulations on the gross profit per rand value of each of the 651 966 items dispensed by New Clicks pharmacies over six months. The dispensed items were

sorted into three groups in accordance with the dispensing fee envisaged in pricing regulations 10(1), 10(2) and 13. However, in order to determine the impact of the pricing regulations on gross profit per rand value of each item dispensed, it was necessary to make an assumption on the level of the single exit price. Expectedly, Mr Jordaan does so and in that regard he relies on the industry perception. He says:

> "By applying the position prior to the introduction of the pricing regulations, the average cost per line item amounted to blue book[498] cost less 19.54%. Given that it is the industry perception that the single exit price to be introduced in accordance with the Regulations will amount to a cost of blue book less 20%, it appears from a financial perspective that the single exit price will have little bearing on the cost of the product in our calculation. Of course, if the single exit price is less than blue book less 20%, the adverse effects on the operation of a pharmaceutical enterprise will be compounded."

Mr Jordaan says that he then "notionally" applied the prescribed dispensing fee on the 651 966 items in their respective categories and found that there would be an overall reduction in gross profit percentage from 28,96% to 14,93%.

[758] Mr Jordaan makes two further conclusions from his workings. First, using the apportionment formula of 17/83 he arrives at a total cost per line item of R19,20, which after implementing the new pricing regime under the regulations is reduced to R13,87 per line item. The result is a net loss per line item of R5,33. Second, he says the overall effect of the regulations is to place at risk the continued viability of the

[498] Mr Jordaan explains that

> "[t]he blue book, is the reference price list compiled and published by the Pharmaceutical Publishers from data obtained from pharmaceutical manufacturers, which is used as a basis to calculate the suggested dispensing price of medicine."

New Clicks pharmacy business. In his words, the "back-shop transactions account for the overwhelming majority of transactions and contribute the greatest portion of the profit in a pharmaceutical enterprise".

[759] The Minister and the Pricing Committee have put up the affidavits of several experts[499] who criticise and contest the reliability and usefulness of the methodology used by Mr Jordaan and have denied and challenged the validity of the conclusions on viability of pharmacies. I shall incorporate their critique where it coincides with mine. There are three fundamental difficulties with Mr Jordaan's reckonings and conclusions.

[760] The first relates to the fairness and accuracy of the apportionment of operating costs between the front shop and the pharmacy. He attributes 83% of the costs to the pharmacy and only 17% to the front shop. But he tells us that the pharmacy business generates 83% of turnover but only 27,9% of gross profit of the combined business. In his final conclusion Mr Jordaan appears to contradict this statement when he says that the back shop contributes "the greatest portion of the profit". It appears to me inequitable that the front shop, which generates nearly 72,1% of the gross profit of the whole enterprise, should shoulder only 17% of the operating costs while the back shop is lumbered with a grossly disproportionate burden of costs. Of course this disproportionate allocation taints the calculation of the total cost per line item and the resultant net loss per line item of R5,33. It will be remembered that the SCA relied on

[499] Dr Thiede, Dr Pillay, Professor Henry and Professor Mossialos.

this net loss per line item for its conclusion that pharmacies will not be viable under the new pricing regime.

[761] The Chief Justice suggests that the criticism of Mr Jordaan's cost apportionment method is unjustified because Mr Jordaan made a "patent error" in stating that the pharmacy business generates 83% of the turnover but only 27,9% of the gross profit of the front shop and back shop combined. This may be so. Yet the apportionment is open to more fundamental criticism, which is that it assumes that but for the new dispensing fee the operating costs of New Clicks are efficient, optimal and representative of the industry. Moreover further criticism of his calculations is set out in the paragraphs to follow.

[762] The second difficulty arises from the assessment of the impact of the dispensing fee imposed by the pricing regulations. The complex but necessary process of determining the single exit price of each line of medicine or Scheduled substance was yet to be accomplished. Mr Jordaan chose to hazard an informed guess of the likely single exit price. He readily admits that this indispensable portion of the calculations is based on speculation fuelled by "industry perception" and his own "financial perspective".

[763] The next collection of issues relates to the integrity of the process. Professor Thiede draws attention to the fact that the raw internal management data used covers only approximately six months of trading; is unaudited and has not been attached for

external verification. Dr Pillay has deposed to the fact that before the litigation New Clicks was requested several times to disclose data but to no avail. Raising another issue, Professor Thiede says that a sample of 80 pharmacies is small and is not randomly drawn from a totality of pharmacies in South Africa. It constitutes only 3% of all pharmacies in the country and cannot be said to depict the average pharmaceutical enterprise in the country.

[764] I am satisfied that the evidence advanced by New Clicks does not establish its primary line of attack against the regulations, namely that the impact of the dispensing fee imposed by the regulations is to endanger the viability of the retail dispensing business conducted by New Clicks.

The expert testimony of Dr Stillman

[765] It is convenient to examine the expert evidence advanced on behalf of PSSA respondents on the viability of retail pharmacies. Dr Stillman, PhD and applied macroeconomist, explains that the goal of the financial analysis contained in his report (Lexecon 1) is to assess the impact that the new regulations are likely to have on the future economic viability of different segments of the pharmacy industry in South Africa. The segments covered by the financial analysis are courier pharmacies, community or retail pharmacies, hospital pharmacies and pharmacies in medical centres. The basic methodology entails comparing, in each segment, the operating profits that a pharmacy has realised in a specified recent past with the operating profits that the pharmacy would have realised if the same medicines had been sold during the

same period but under the dispensing fee imposed by the pricing regulations. By operating profit he means gross profit less operating expenses and, in turn, gross profit equals revenues less costs of the goods. He correctly observes that a positive operating profit is not necessarily enough to keep business open because it does not always allow for interest expense and return on capital. In my view, equally true is that a positive operating profit alone is inconclusive, it may be a sign of a viable business or of an unhealthy business. Dr Stillman is also right that negative operating profits are a strong indication that the pharmacy is not likely to be viable.

[766] Dr Stillman correctly observes that compensating pharmacists through a capped dispensing fee signals a drastic change for them. One must however remember that in its submissions to the Pricing Committee, the PSSA supported the migration from a mark-up on the costs of medicines to a system of professional dispensing fees. In the past pharmacists bought medicines from wholesalers and distributors at a cost specified by manufacturers (blue book) less a discount and then dispensed the product to the customer at a mark-up over cost. The historical mark-up on sales to consumers is 50%. Dr Stillman says in recent years medical aid schemes have reduced the pharmacists' net mark-up to the region of 20%. Dr Theron and Mr Jordaan set the same net mark-up at 26%. Be that as it may, I agree that the predictable impact of the capped dispensing fee will take two forms. First, the capped dispensing fee will reduce the current gross profit margins that pharmacies realise from selling medicines on the historical mark-up basis. Second, the more expensive the medicine sold by a

retail pharmacy the more adverse the impact of the capped fee on the gross profit of the pharmacy.

Courier pharmacies

[767] Courier pharmacies specialise in the provision of chronic and repeat prescription medicines. As their name suggests, they deliver medicines to a customer's address of choice. They utilise extensively information technology to manage remote delivery from centralised storage and distribution centres. They do not need retail front shops. Their service includes managing prescription cycles for patients to encourage compliance with their prescriptions; assisting in lodging of medical aid claims and advising patients on special requirements like HIV management programmes and delivery of high costs drugs such as antiretrovirals, medicines used for renal dialysis and oncology treatment. On the evidence, mainly three firms namely Medicines Pharmacy, Medipost and CMD use this business model. It is suggested that due to competition amongst the three firms to obtain medical aid business and to better community pharmacies, profit margins have become thin.

[768] Dr Stillman analyses the financial data of the operations of CMD for April 2004. CMD processed 30 000 prescriptions for stated revenues of R10,6 million, realising a gross margin of 17% and an operating profit margin of 1,1%. The same financial data for April 2004 was subjected to the 26%/R26 dispensing fee regime. By mid May 2004 certain manufacturers had implemented single exit prices, which cover about 46% of the prescriptions filled during April 2004. The dispensing fee's

for the balance of the prescriptions was based on actual purchase costs for April 2004 in lieu of missing single exit prices. This exercise, Dr Stillman reports, led to a gross profit margin of 10,8% and an operating profit margin of negative 5,1%. He concedes that the analysis is based on one month's data and that the majority of single exit prices were not available and actual purchase costs were used as proxies. He concludes that this result reinforces the view that given the structural challenges of the courier pharmacy, which include low margins, high cost products and no front shop, it is highly unlikely that the courier pharmacy can remain an economically viable business.

[769] It is unclear why the workings of Dr Stillman were limited to data for one month and why the financial data for the same or other months of the two older and larger operators in the business of courier pharmacies was not processed for greater statistical reach and reliability. It must be remembered that CMD did show a gross profit margin of 10,8% for the month. Single exit prices will eliminate discounts to pharmacies but will also apply downward pressure on the manufacturers' prices. The actual impact of single exit prices on highly priced medicines remains unknown. I am not persuaded that the evidence adequately establishes that the entire courier segment, on the probabilities, will not be viable under the regulations.

[770] That, however, is not the end of the matter. The report of Dr Stillman raises squarely the structural challenges facing courier pharmacies. As a segment of retail pharmacy, courier pharmacies do not have front shops to absorb pharmacy losses, if

any. We are told, and it has not been shown otherwise, that they focus mainly on delivery of high cost medicines to patients who have succumbed to chronic ailments. This class of medicines renders their business disproportionately vulnerable to a pricing regime that imposes an inflexible cap on the dispensing fee and reduces their gross profit. The evidence suggests that apart from the impact of the pricing regulations, their operating margins are thin. In the rigid cap of R26 on high cost drugs lurks the seed of destruction, albeit later, of the courier pharmacy. The vast expanse of our country and its dotted and sparse rural and semi-urban settlements must bring home the value of the service courier pharmacies render. The real question is not whether now courier pharmacies are likely to be viable, but rather whether the Pricing Committee and ultimately the Minister brought their minds properly to bear on these distinguishing features and therefore on the appropriateness of the uniform dispensing fee in relation to courier pharmacies.

[771] I could find only one reference to courier pharmacies in the deliberations of the Pricing Committee. A minute of one of its meetings records a presentation to the Pricing Committee on the logistics function in the industry followed by a discussion on courier pharmacies. The Pricing Committee noted that courier pharmacies fit into the supply chain and are registered as wholesalers. They concluded that the Pricing Committee's recommendations should be based on efficiency and they should "be careful of making legislation in order to protect business models purely on the basis of the levels of risk they involve." The Pricing Committee considered but refused to adapt the dispensing fee cap to the circumstances of courier pharmacies and by

regarding them as wholesalers, in effect required them to negotiate for a logistics fee alongside wholesalers under the single exit price regime.

[772] Courier pharmacies occupy an important space in ensuring access to medicines for a class of principally marginalised consumers. They dispense 12% of prescription medicines by channel and measured by value.[500] The Pricing Committee and the Minister took the view that courier pharmacies do not deserve separate consideration and treatment. In my view, they misdirected themselves. Their "one size fits all" solution to dispensing fees courier pharmacies may charge, in time, will frustrate access to essential drugs by those who may be bedridden or cannot readily reach community pharmacies and have to endure chronic and often life threatening afflictions. Arguably they need the medicines most and tend to survive on expensive drugs. In my view, the Pricing Committee and the Minister made irrelevant considerations or failed to pay regard to what matters in relation to the legislative objects of access to quality medicines. The issue is not whether the business model of courier pharmacies should be protected but whether the capped dispensing fee will devastate the access to essential medicines for the class of consumers they serve. The dispensing fee cannot be said to be appropriate for courier pharmacies.

Retail or community pharmacies

[500] Of the four channels of distribution described in Dr Stillman's report, being retail pharmacies, hospital pharmacies, courier pharmacies and dispensing doctors, the courier pharmacies have a 12% share in the dispensing of prescription medicines measured by value.

[773] Lexecon Report 1 characterises retail pharmacies as the backbone of the pharmacy industry in South Africa. Together they dispense approximately 56% of all prescription medicines to the public. To complete the picture, hospital pharmacies, courier pharmacies and dispensing doctors dispense 19%, 12% and 13% of medicines measured by value, respectively. The report makes the point that from a structural point of view community pharmacies are not quite as vulnerable to the new regulations on dispensing fees as courier pharmacies. Dr Stillman advances two reasons to support the conclusion. The first is that the interdependence between the back and front shop operations dictates a composite evaluation of the impact of the pricing regulation on "a total store basis". The second reason is that retail pharmacies tend to carry fewer high cost drugs than courier pharmacies. The impact of the R26 cap on gross profit is directly related to the cost of medicines that a pharmacy supplies.

[774] Simply put the owner of a pharmacy will assess the profitability of the front shop before closing down the dispensary and in turn she will look at the viability of the dispensary before closing down the front shop. Dr Stillman argues that

> "the front shop operations of community pharmacies to some extent act as a buffer that, all else equal, reduce the likelihood that the new regulations on dispensing fees will force the closure of community pharmacies."

Dr Stillman however warns that the buffer is smaller than casual observers of the industry may imagine because of competition from other retailers of front shop

products and the average net profit for community pharmacies is already low, ranging between 3% and 4% depending on the size of the pharmacy.

[775] However not all appreciated the importance of evaluating the impact of the pricing regulations on a "total store basis". On behalf of the PSSA it was argued that the financial viability of the dispensary should be evaluated alone and to the exclusion of the front shop. For New Clicks Mr Jordaan also tried to evaluate the profitability of the dispensary separately from the front shop. To that end he tried to strip the operating costs of the pharmacy from the costs of the front shop only ultimately to lumber the dispensary with 83% of all costs. On behalf of the Minister and the Pricing Committee it was also asserted that the viability of the financial operations of the dispensary should be assessed alone and that dispensaries should not subsidise front shops.

[776] This approach is correctly criticised by Lexecon Report 2. The better approach to the viability of the pharmacy enterprise is to assess the profitability of the dispensary and front shop pharmacy as one store. A front shop is optional. Therefore, one must accept that a pharmacy owner would not operate a front shop unless it makes a positive contribution to the total profit of the store. A complaint of cross-subsidisation between the two ends of the enterprise or an exercise to disentangle their respective financial performances runs contrary to the reality of the business structure of a retail pharmacy.

[777] The report then undertakes an analysis of the impact of the pricing regulations on the operating profits of New Clicks pharmacies. It concludes that under the new dispensing fee "it is likely that most community pharmacies will be put under severe financial pressure and that many will be forced to close." The conclusion is derived from the calculations presented by Mr Jordaan. I have already set out[501] the severe difficulties which are evident in the workings of Mr Jordaan on the relationship between revenues and gross profit contributions of the front shop and the back shop, on the inequitable allocation of operating costs between the two ends of the business and on the speculative use of estimates of single exit prices for the calculations. In my view these bases of calculations supplied by Mr Jordaan's evidence undermine considerably the usefulness of the impact analysis advanced in Lexecon Report 1. Moreover, the conclusion that many pharmacies will be forced to close stands in sharp contrast to Dr Stillman's preference for a "total store basis" evaluation of viability. On the latter basis, he says, it is unlikely that pharmacy enterprises will close.

[778] In my view, the expert testimony advanced in the report on retail or community pharmacies does not properly show that the pricing regulations are inappropriate because they will render "most" or "many" or "some" community pharmacies unviable.

Pharmacies in rural areas

[501] Above paras 753-759.

[779] South Africa currently has 2569 registered retail pharmacies. Of these 350 or 14% are located in rural areas. There, often the pharmacist is the important and the only source of health care advice and a sole dispenser of medicine. There is, however, a striking dearth of information on rural retail pharmacies on the papers. The minutes of the Pricing Committee identify as "key points" the principle of not distinguishing between rural and urban pharmacies and between branded and generic medicines. One senses a determination not to permit exceptions that will undermine the pricing regime.

[780] Dr Zokufa suggests that the workload of prescriptions in private pharmacies is too low for viability in the long run. He provides details of prescription workload in private sector pharmacies of 40 scripts per day in 2002, which now reportedly stand at 70 according to the PSSA. He compares this with a workload norm of 100 prescriptions per day per pharmacy in the public sector. Statistically each community pharmacy serves, on average, around 3000 people virtually all of whom are members of medical aid schemes. He makes the point that retail pharmacies with a very low workload will face financial viability constraints. He provides a table which shows the number of pharmacies in relation to the population per 100 000 and a relative oversupply of private pharmacies in Gauteng, Kwa-Zulu Natal and Western Cape. The difficulty is that the table does not tell us much about private pharmacies in rural areas.

[781] The question is whether the regulations are bad for this reason. There is no evidence to help evaluate the financial fate of rural pharmacies. None of the parties before us have nailed their colours to the mast of pharmacies in rural areas. There is, however, an eerie stillness on the papers about the structure, operations and financial well-being of this class of pharmacies. Put otherwise, one cannot from the papers develop a sense of the nature of accessibility of medicines through private sector pharmacies in rural outskirts. Given the accessibility purpose of the empowering legislation, the lot of rural pharmacies ought to be one of the centrepieces of the regulated dispensing fee. The very silence on the plight of rural pharmacies and their customers in the deliberations of the Pricing Committee and the Minister speaks loudly of a failure to have regard to a relevant and important consideration of access to affordable medicine by often marginalised rural dwellers. The dispensing fee cannot be said to be appropriate in relation to pharmacies serving in rural areas.

Hospital pharmacies

[782] The Pricing Committee and the Minister are adamant that they have considered carefully the operating costs and revenues of private hospital pharmacies and are satisfied that the regulated dispensing fee would not lead to their closure. Dr Stillman disagrees but concedes that a private hospital is legally compelled to have a pharmacy on site and that the regulated dispensing fee would cause a hospital pharmacy to close "only if the pharmacy losses were so large that it made economic sense to close the entire hospital". Dr Zokufa makes the point that private hospitals generate significant profits, particularly from high cost medicines, through the contractual relationship

with pharmacists on site. They will now have to ensure adequate recovery from main line services such as admission and theatre fees.

Conclusions

[783] I have come to the conclusion that the pivotal attack on the pricing regulations on the ground that they are likely to lead to the closure of most or many or some pharmacies cannot be upheld. The evidence seen as a whole does not establish the contention advanced by the Pharmacies. At best for the Pharmacies the evidence raises the ever-present possibility that the new dispensing fee will exert downward pressure on the profitability of pharmacies and that some whose profit margins are already low may be forced to close.

[784] It is not surprising that the expert evidence falls short of resolving several intractable issues associated with the assessment of the viability of a business. It is trite that an enterprise must realise an adequate return on capital. The challenge is fixing an appropriate level of return. The evidence does not venture to fix one. The evidence rightly notes that an adequate return is always relative to the market structure and its inherent risks. The Pharmacies submitted to the Pricing Committee and in evidence that a 26% gross profit margin on sales will lead to an adequate return on capital. But the evidence does not show that there is a fixed equation between financial viability and gross profit. Even if there is such an equation in one financial period or sector of the industry, it may not be so in another. Again the evidence tells us that the reliability of this prediction depends on the structure of the market. The

variable elements of the structure are too many to list. They are canvassed in the evidence of both sides. These include the chosen business model, the size and location of the enterprise; the operating costs and related efficiency gains of the pharmacy; the prescription workload, which in turn is conditioned by external factors such as the ratio of pharmacies to population and the level of national expenditure on health care.

[785] The Lexecon Reports do much to capture, albeit cryptically, the structure and risks in each category of pharmacy enterprise. Rightly so the reports do not pretend to be definitive because it can only flesh out what may happen on the basis of a static model. In the dynamic hustle of adapting to a new pricing regime within the pharmaceutical sector possibilities, as always, are endless. That explains why the Minister is obliged to review the impact of the regulations every year that the regulations are in force. The extravagant conclusion that the regulated dispensing fee will force pharmacies to go to the wall is in my view premature and is not adequately predicted by the evidence. What is more, I do not think the economic viability of an entire sector in the economy is as readily and uniformly predictable as the Pharmacies would have us believe.

[786] Subject to the qualification that will follow in relation to courier pharmacies and pharmacies located in rural areas, I take the view that the dispensing regulations are "appropriate" within the meaning of section 22G of the Medicines Act. They are lawful inasmuch as they are rationally connected to the admittedly legitimate purpose

of rendering medicines and Scheduled substances affordable and accessible to the public. Finally, keeping in mind the reasonableness test articulated in *Bato Star*, I am unable to find that the decision of the Pricing Committee and of the Minister is one that no reasonable person could have arrived at.

[787] The PSSA sought to persuade us that regulation 10 which sets the dispensing fee, unjustifiably limits the right of pharmacists as a class to "choose their trade, occupation or profession" as permitted by section 22 of the Constitution because pharmacies that are not economically viable will have the effect of discouraging people from choosing to pursue or remain in the profession. They submit further that regulation 10 "regulates the . . . profession" within the meaning of section 22 of the Constitution and in an arbitrary manner because its unintended consequence is to destroy the profession of pharmacy. This line of argument may hold water if the evidence shows that the new pricing regulations threaten the continued existence of pharmacies. I have found that it has not been shown that regulation 10 renders pharmacies unviable. In my view, save to the extent described earlier, the pricing regulations are reasonable, lawful and properly advance the socio-economic goal of access to affordable medicines set by the empowering statute and our Constitution. This line of argument must also fail.

[788] The SCA is quite correct that regulation 13 is ultra vires the power conferred by section 22G(2)(c) and falls to be set aside as invalid. The Minister says the SCA was wrong in deciding the dispute on the validity of regulation 13 because it has become

moot. As we saw earlier, two Government Notices exclude Schedule 0 medicines from the provisions of section 18A and 22G of the Medicines Act and from the regulations for a period of 3 years. I agree with the Pharmacies and hold that regulation 13 remains part of the dispensing fee scheme and its validity is open to determination in these proceedings.

[789] Finally, I have found that the dispensing fee is not appropriate for purposes of courier pharmacies and pharmacies in rural areas. The Minister, acting on the recommendation of the Pricing Committee is obliged to consider afresh the appropriateness of the dispensing fee set in relation to both categories.

Remedy

[790] The appeal must succeed save as stated below. Regulation 13 is unlawful and must be set aside. No case has been made out for the suspension of the declaration of invalidity of regulation 13. As we have seen, for some time now the application of regulation 13 has been suspended. The declaration of invalidity must take immediate effect.

[791] Second, in my view appropriate relief in relation to regulation 10 should take the form of an exemption for courier pharmacies from the operation of the regulated dispensing fee until the defect is corrected within a specified period rather declaring invalid the whole of regulation 10 with the resultant prejudice to the public at large. In its written argument the Treatment Action Campaign amicus delineates the adverse

impact of striking down the dispensing regulations without ordering suspension of invalidity as an interim holding position. They advocate an order directing the parties to negotiate an appropriate fee. The latter course is not open to us if the appeal substantially succeeds, as I have found.

Madala, Mokgoro, Skweyiya and Yacoob JJ concur in the judgment of Moseneke J.

YACOOB J:

[792] I have had the privilege of reading the careful, detailed and clear judgment by the Chief Justice (the main judgment). I read the judgment with considerable admiration and agree gratefully with most of it.[502] There are however three areas concerning the interpretation and constitutional validity of the regulations in relation to which I find myself in disagreement with the main judgment. Hence the need for this short judgment.

[793] I have also read the judgment of Moseneke J and agree with all of the reasoning and its conclusion. I agree with Moseneke J that it is unnecessary to decide whether

[502] Main judgment paras 23-84, 190-263, 278-286 and 293-415.

the Promotion of Administrative Justice Act[503] is applicable to the regulations at issue here, and with his conclusions concerning the appropriateness of the dispensing fee. It follows that I cannot endorse the reasoning and conclusions in these respects in the main judgment or in the judgments of Ngcobo J and Sachs J which I have read with considerable interest. I also cannot agree with the judgment of Ngcobo J concerning the regulations where its terms are inconsistent with this judgment.

[794] The three conclusions in the main judgment in relation to which my reasoning and conclusions differ are:

(a) Regulation 5(2)(c) is void for vagueness.[504]

(b) Regulation 8(3) is void for vagueness.[505]

(c) The powers vested in the Director-General by regulations 22 and 23 are invalid.[506]

Perspectives on section 22G

[795] It is appropriate to set out some perspectives on section 22G of the Act[507] before considering each of the issues listed in the previous paragraph. Section 22G to the extent relevant provides:

[503] Act 3 of 2000.

[504] Main judgment paras 264 – 277.

[505] Main judgment paras 287 – 292.

[506] Main judgment paras 416 – 420.

[507] Medicines and Related Substances Act 101 of 1965.

"Pricing committee.—(1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.

[Sub-s. (1) substituted by s. 8(a) of Act No. 59 of 2002.]

(2) The Minister may, on the recommendation of the pricing committee, make regulations—

(a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;

(b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a);

(c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines.

[Para. (c) added by s. 8(b) of Act No. 59 of 2002.]

(3)(a) The transparent pricing system contemplated in subsection (2)(a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.

(b) No pharmacist or person licensed in terms of section 22C(1)(a) or a wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).

[Para. (b) substituted by s. 8(c) of Act No. 59 of 2002.]

(c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2)(b)."

[796] The object of section 22G is to introduce a transparent pricing system. This is to be done by the Minister of Health (the Minister) on the recommendation of the Pricing Committee. The regulations may provide for an appropriate dispensing fee,[508] and an appropriate fee to be charged by wholesalers and distributors.[509] The Act prescribes several imperatives for the pricing system. The pricing system that is

[508] Section 22G(2)(b).

[509] Section 22G(2)(c).

introduced pursuant to the section must include a single exit price that must be published as prescribed. The only express prohibitions contained in the section are that a manufacturer may not sell at a price other than the single exit price to anyone except the state[510] and that no other person in the supply chain may sell at a price higher than the single exit price.[511] A pharmacist licensed to charge a dispensing fee is, by implication, prohibited from selling medicine at a price higher than the single exit price and the dispensing fee combined.

[797] I agree with the analysis in the main judgment to the effect that the aim of the section is to provide affordable medicine and that the section authorises a measure of price control. However, it must be emphasised that the section does not oblige the Minister and the Pricing Committee to come up with a regime in which the maximum prices of all medicines and Scheduled substances are fixed in terms of a formula which is mathematically calculable. There is nothing in the section which expressly or by necessary implication says that the single exit price must be contained within certain defined limits.

[798] There would accordingly have been no problem with the regulations in relation to the single exit price if they had simply:

(a) allowed the manufacturer to set the price and agree the logistics fee at all times and in relation to all medicines;

[510] Section 22G(3)(a).

[511] Section 22G(3)(b).

(b) provided that the manufacturer may increase prices only once a year; and

(c) given the Director-General the power to declare prices to be unreasonable and publish that declaration in the Government Gazette.

[799] It must have been understood by all involved in the process that the introduction of a transparent pricing system that exerted a downward pressure on the prices of medicines and Scheduled substances would be a complex endeavour. All would have realised that a system of this kind could be perfected only after a painstaking, careful and sensitive process and that the reduction of these prices to acceptable levels would take time. The ideal of a transparent pricing system that renders medicines and Scheduled substances available to all at affordable prices is as difficult to achieve as it is vital to our democracy. I regard these regulations to be the first step in the development of the pricing system and this is the context in which I consider the validity of those regulations about which there is a regrettable difference.

[800] It was suggested that there was some incongruity because section 22G does not refer to an "importer" while the regulations do. That omission is, in my view, of no moment. Section 22C makes it abundantly clear that manufacturers, wholesalers or distributors can also "import" medicine provided they have a licence to do so.[512] Importers as a category, although not expressly defined as such, are those manufacturers, wholesalers or distributors who are licensed to import medicine in terms of the Act. It would have been better if the definition in the regulations said so

[512] Section 22C(2).

but the fact that they define importer in a different way cannot detract from the inescapable conclusion as to what the term means in the Act. That is the only meaning that can be ascribed to the term.

Regulation 5(2)(c)

[801] I have already pointed out that section 22G(3)(a) requires the pricing system to include a single exit price. Most of the regulations are concerned with the single exit price and regulation 5(2)(c) is part of the mechanism by which the single exit price is set by the manufacturer or importer for all medicines and Scheduled substances that were being sold in South Africa as at the date of the commencement of the regulations.[513] The meaning and effect of regulation 5(2)(c) must be determined in its context.

[802] The single exit price is defined in regulation 2 as meaning:

> "the price set by the manufacturer or importer of a medicine or Scheduled substance in terms of these regulations combined with the logistics fee and VAT and is the price of the lowest unit of the medicine or Scheduled substance within a pack multiplied by the number of units in the pack".

[803] Some point was made about the fact that the word "price" is used twice in the definition and that the definition can make sense only if the word "price" means something different in each of its uses. I do not see how it matters if the word "price" does have a different meaning in each of its uses in the definition provided that the

[513] 2 May 2004.

different meaning is clear and provided further that the fact that the word has a different meaning in each of its uses does not confuse. The essence of the definition of the single exit price is that it is "the price set by a manufacturer or importer of a medicine or Scheduled substance in terms of these regulations combined with the logistics fee and VAT". The definition adds that the single exit price "is the price of the lowest unit . . . within a pack multiplied by the number of units in the pack". This clarifies that it is necessary to establish a single exit price in respect of the lowest unit and work from there. In other words the single exit is the price set by the manufacturer or importer together with the logistics fee and VAT in relation to the lowest unit in the pack.

[804] There is nothing vague about this definition. It makes a distinction between what may be referred to as the core price which is "the price set by a manufacturer or importer . . . in terms of these regulations" on the one hand, and the single exit price on the other. The single exit price is the core price "combined with the logistics fee and VAT". The distinction between the price set in terms of these regulations in the process of determining the single exit price on the one hand, and the single exit price itself which is a combination of the price initially set, the logistics fee and VAT must not be lost.

[805] Regulation 5(1) is consistent with this definition. It provides for the setting of a price by the manufacturer or importer and its combination with the logistics fee to arrive at the single exit price.[514] It provides:

> "5(1) Upon commencement of these regulations the price of a medicine or Scheduled substance must be set by the manufacturer, or where the medicine or Scheduled substance is imported by a person other than the manufacturer, the importer of the relevant medicine or Scheduled substance, and combined with the logistics fee in order to arrive at a single exit price for the relevant medicine or Scheduled substance."

[806] Regulation 5(2)(c) must be construed with this distinction in mind. It is appropriate at this stage to set out the regulation without the proviso:

> "5(2) The single exit price must be set in accordance with the following provisions—
>
> . . . .
>
> (c) the price of each medicine or Scheduled substance to be set upon the date of commencement of these regulations by the manufacturer or importer must not be higher—
>
> (i) in respect of a Scheduled substance that is not a medicine, than the weighted average net selling price per unit of each Scheduled substance for the calendar year 2003. . . ;
>
> (ii) in respect of a medicine, than the weighted average net selling price of the medicine which must be calculated using the formula:
>
> 'S divided by the total number of lowest units (eg a tablet) for all of the packs of the same dosage strength of the medicine sold in the year 2003'
>
> Where S = the total rand value of net sales (being sales less discounts) for all packs of the same dosage strength of the medicine sold in the year. . . .

[514] The fact that regulation 5(1) does not refer to VAT is, in my view, neither here nor there.

> (Note: Examples of the manner in which the weighted average net selling price must be calculated are cited in Appendix A of these regulations.)"

[807] The first issue to be decided is the meaning of the word "price" in the introductory words of regulation 5(2)(c). Does "price" refer to single exit price or to the core price that is the price set by the manufacturer or importer before the logistics fee and VAT are added? Textually, there is little reason to suppose that the price to be set in regulation 5(2)(c) is a reference to the single exit price. Regulation 5(1) requires the manufacturer or importer to set a price upon the commencement of the regulations in a context which makes it quite clear that it is a price set without reference to a logistics fee or to VAT. Regulation 5(2)(c), when speaking about the "price" that is "to be set upon the date of commencement of these regulations by the manufacturer or importer" can be nothing else but a reference to the "price" that "must be set by the manufacturer, or . . . the importer" in terms of regulation 5(1).

[808] It has been suggested that the fact that Appendix A to the regulations refers to the calculation of the single exit price in the process of providing examples of the way in which certain calculations are to be made, is sufficient to justify the conclusion that the price to be set by the manufacturer or importer in terms of regulation 5(2)(c) is the single exit price despite the fact that regulation 5(2)(c) does not use this phrase. It is therefore necessary to examine the relevant aspects of regulation 5(2)(c) in order to determine the purpose and meaning of Appendix A to the regulations.

[809] It is apparent that regulation 5(2)(c) requires that the price to be set by the manufacturer or importer not be higher than the "weighted average net selling price" of both a Scheduled substance and a medicine. We also see that, unlike the position in relation to Scheduled substances, the "weighted average net selling price" of medicine in the year 2003 is to be calculated using the formula provided, which in effect refers to sales less discounts. The note at the end of regulation 5(2)(c) expressly states that Appendix A cites "[e]xamples of the manner in which the weighted average net selling price must be calculated". Consistently with this Appendix A is headed:

> "EXAMPLES OF THE MANNER IN WHICH THE WEIGHTED AVERAGE NET SELLING PRICE MUST BE CALCULATED".

There is a fundamental difference between the weighted average net selling price on the one hand and the single exit price on the other. The single exit price is the core price plus the logistics fee and VAT. The weighted average net selling price during the year 2003 is an amount that must not be exceeded by the price set at the commencement of the regulations.

[810] Appendix A gives two examples. Unfortunately, each example has a sub-heading beginning with the words "[c]alculation of single exit price for . . ." and ends with a conclusion that "the single exit price" of the medicine has been determined. Yet, as has been pointed out, the appendix was concerned with the determination of the weighted average net selling price during the year 2003. There was no single exit price in the year 2003. The calculation understandably does not refer to any logistics fee. I conclude therefore that Appendix A is concerned with providing examples of

the calculation of the weighted average net selling price in the year 2003 and not the single exit price of the medicine concerned. Appendix A therefore does not provide enough justification for the conclusion that the word "price" in the introductory words of regulation 5(2)(c) is a reference to the single exit price.

[811] It follows that there is a difference between regulation 5(2)(c) which refers to the core price and not the single exit price, and those parts of Appendix A which refers to "the" single exit price. The analysis of regulation 5(2)(c) in relation to Appendix A shows that the words "single exit" are wholly inconsistent with the scheme of the regulations in relation to the single exit price. I would therefore hold that the words "single exit" wherever they appear in Appendix A must be severed from the appendix so that the appendix reads "price".

[812] A related problem is concerned with the way in which the weighted average net selling price for sales during 2003 is to be calculated. Is the calculation to be based on sales by manufacturers to wholesalers and retailers, or sales by wholesalers to pharmacists, or sales by retailers and practitioners to the general public? I take the view that the relevant price to be taken into account in the determination of the weighted average net selling price is the price at which the medicine or Scheduled substance was sold by the manufacturer or importer. After all, it is the manufacturer or importer who is required to set the price in terms of regulations 5(1) and 5(2)(c). The price to be set is exclusive of the logistics fee and VAT. The weighted average net selling price of the wholesaler to the retailer would, in the ordinary course, have

included the wholesaler's profit. To provide that the price set by the manufacturer or importer excluding the logistics fee or VAT must not exceed the weighted average net selling price in sales by wholesalers to retailers would be incongruous. It would furthermore have been unreasonable to expect the manufacturer or importer in setting the price in terms of regulation 5(2)(c), to make extensive investigations concerned with the prices at which the wholesaler had sold to retailers and the discounts that had been given.

[813] The point was also taken that there was uncertainty whether the weighted average net selling price had to be calculated taking into account sales to the state or whether all sales to the state had to be ignored for the purpose of this calculation. In my view the provision is sufficiently certain. The single exit price is the price at which medicine is to be sold to parties other than the state. The calculation of the weighted average net selling price must therefore exclude sales to the state. It was not necessary for the regulations to say so in so many words.

The provisos to regulation 5(2)(c); medicines sold for the first time after 1 January 2004

[814] The main judgment holds that the proviso to regulation 5(2)(c) which sets out the way in which the price of medicine that came to be sold in South Africa after 1 January 2004 must be calculated is vague. I suggest that the methodology is clear enough. The proviso is set out in identical terms as a qualification of regulations

5(2)(c)(i) and 5(2)(c)(ii) except that the former refers to a Scheduled substance and the latter to medicines. It reads as follows:

> "provided that where sales of the Scheduled substance or medicine[515] commenced at the beginning of January 2004 or thereafter, the price of such substance or . . . medicine[516] must be calculated using the average of the total rand value of sales less the total rand value of the discounts for the period for which the Scheduled substance or medicine[517] was sold and with reference to the price of that Scheduled substance or medicine[518] in other countries in which the prices of medicines and Scheduled substances are regulated and published." (footnotes inserted)

[815] I have already found that according to the main body of regulations 5(2)(c)(i) and 5(2)(c)(ii) the price of each medicine or Scheduled substance (excluding the logistics fee and VAT) to be set upon the date of commencement of the regulations by the manufacturer or importer must not be higher than the weighted average net selling price of that medicine or Scheduled substance during the year 2003. The proviso tells the manufacturer or importer how to calculate the price (excluding the logistics fee and VAT) of a medicine or Scheduled substance not sold in this country during the year 2003. In other words a medicine or Scheduled substance that was sold in South Africa for the first time on or after January 2004. The price in relation to these medicines or Scheduled substances could not be pegged at a level higher than the 2003 weighted average net selling price. The regulation therefore provides that the

[515] The proviso to regulation 5(2)(c)(i) refers to a Scheduled substance while the proviso to regulation 5(2)(c)(ii) refers to medicine.

[516] Id.

[517] Id.

[518] Id.

price of a medicine or Scheduled substance which began to be sold in South Africa on 1 January 2004 or thereafter

> "must be calculated using the average of the total rand value of sales less the total rand value of discounts for the period for which the Scheduled substance or medicine[519] was sold and with reference to the price of that Scheduled substance or medicine[520] in other countries in which the prices of medicines and Scheduled substances are regulated and published." (footnotes inserted)

[816] The body of regulations 5(2)(c)(i) and 5(2)(c)(ii) provide a mechanical calculation for determining the maximum price at which a medicine already selling in this country before January 2004 may be sold. The aim of providing for this level of calculability is to avoid the wholesale rise in the prices of medicines or Scheduled substances. This would have been an obviously unfortunate negative consequence of the introduction of a pricing system aimed at lowering the prices of medicines and Scheduled substances.

[817] The problem in relation to medicines and Scheduled substances that began to be sold in this country less than five months before the regulations came into effect would have been the unfairness of pegging maximum prices at the level of introductory prices. It is generally understood in the commercial sector that introductory prices in relation to medicines could be lower even than their cost as a legitimate marketing exercise.

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[519] Id.

[520] Id.

[818] The regulators therefore decided that, in the setting of the price for this limited category of medicines and Scheduled substances:

(a) the formula set out in regulation 5(2)(c)(ii) would be used as a starting point in the calculation of the price; and

(b) the setting of the price would further be informed by the price at which the medicine or Scheduled substances concerned is sold in other countries in which the prices of medicines and Scheduled substances are regulated and published.

[819] I cannot agree with the main judgment that the proviso, like the body of regulation 5(2)(c), sets an upper limit. I do not read it in this way. The body of regulation 5(2)(c) says that the price set by the manufacturer or importer must not be higher than the weighted average net selling price. The proviso, in each case, provides a method by which the price is to be calculated.

[820] This method of setting the price in each of the provisos undoubtedly gives to the manufacturer or importer wider leeway than the method by which the prices are to be set in terms of the body of regulations 5(2)(c)(i) and 5(2)(c)(ii). The Chief Justice finds this pricing mechanism to be vague. I do not agree. My understanding of the way in which the Minister and the Pricing Committee approached the single exit price is that it provided a calculable method for determining the maximum price at which medicine that had been selling in the country for a relatively long time would be sold,

to ensure a more flexible method of calculation for medicine which began to be sold here only recently, and to leave it to the manufacturer or importer to determine the single exit price in relation to medicine that comes to be sold here in the future as is implied by regulation 19.

[821] In the nature of things, prices of commodities are not precisely calculable. It is true that, in relation to medicine that came to be sold in this country after January 2004, the manufacturer or importer have more scope to determine the single exit price than they had in relation to medicines and Scheduled substances sold in South Africa before January 2004. It may also be that in relation to this latter category the manufacturer or importer is not permitted to go beyond the highest price at which the medicine is sold in any other country. I need not however decide this point. The manufacturer or importer of a medicine to be registered for sale after the coming into operation of the regulations could theoretically set a price even higher than the highest price at which that medicine is sold in any other country. But all pricing by the manufacturer or importer is subject to international benchmarking.

Regulation 8 is not vague

[822] The main judgment holds that regulations 5(2)(a), 5(2)(b), 7 and 8 are contradictory and regulation 8 is void for being vague. I do not agree. It is undoubtedly the duty of drafters of regulations to ensure that they are not difficult to interpret and that they are clearly set out. Some difficulty and lack of clarity however does not excuse us from the obligation to try to make sense of them.

[823] The major concerns in the main judgment arise out of the provisions of regulations 5(2)(a), 5(2)(b), 7 and 8. I set these out below.

Regulations 5(2)(a) and 5(2)(b) provide:

> "(2) The single exit price must be set in accordance with the following provisions—
>
> (a) for a period of one year after commencement of these regulations the single exit price shall not be increased;
>
> (b) subject to sub-regulation 5(2)(a) the single exit price may be increased in terms of regulation 8 of these regulations. . . ."

Regulation 7 reads:

> "7. Subject to the provisions of regulations 5, 8 and 9, the single exit price of a medicine or Scheduled substance may only be increased once a year."

Regulation 8 provides:

> "8(1) The extent to which the single exit price of a medicine or Scheduled substance may be increased will be determined annually by the Minister, after consultation with the Pricing Committee, by notice in the Gazette with regard to—
>
> (a) the average CPI for the preceding year;
>
> (b) the average PPI for the preceding year;
>
> (c) changes in the rates of foreign exchange and purchasing power parity;
>
> (d) international pricing information relating to medicines and Scheduled substances;
>
> (e) comments received from interested persons in terms of regulation 8(2); and
>
> (f) the need to ensure the availability, affordability and quality of medicines and Scheduled substances in the Republic.

> (2) Not less than three months before making a determination in terms of regulation 8(1), the Minister must publish a notice in the Gazette declaring his or her intention to make that determination and inviting interested persons to furnish him or her in writing with any comments thereon or any representations they may wish to make in regard thereto.
>
> (3) Subject to the provisions of regulation 8(1), a manufacturer or importer may no more than once a quarter increase the single exit price of a medicine or Scheduled substance within a year provided that—
>
> (i) such increase does not exceed the single exit price of the medicine or Scheduled substance as first published in respect of that year;
>
> (ii) the increase in the single exit price is applied to all sales of the medicine or Scheduled substance and not to selected categories of purchasers;
>
> (iii) the manufacturer or importer notifies the Director-General of the increase in the single exit price at least 48 hours prior to the implementation of such increase;
>
> (iv) the single exit price may not be increased as contemplated in terms of this regulation 8(3) within the period of six months beginning from the date of commencement of these regulations."

[824] Regulation 7 is central to the regulations which define the regime for the increase of the single exit price. It permits the increase of the single exit price of a medicine or Scheduled substance once a year and provides further that the increases in terms of regulation 7 may not take place more than once a year. It seems clear that any increase in the single exit price must be published. This follows from the definition of the single exit price. The word "year" is defined as "the period of 12 months beginning on 02 May". Every single exit price can therefore be increased in terms of regulation 7 only once during the period 2 May of one year until 1 May of the next year.

[825] Regulation 7 is however subject to regulations 5, 8 and 9. The qualification in regulation 5(2)(a) is to the effect that the single exit price set at the commencement of the regulations cannot be increased for a period of one year after it has been set. The price would have been set as at 2 May 2004 which is the date of commencement of the regulations. In the absence of the qualification rendering regulation 7 subject to regulation 5(2)(a), the manufacturer or importer would have had the right to increase the single exit price during the first year of the operation of the regulations. The object of the qualification is to prevent this. Regulation 5(2)(a) therefore qualifies regulation 7 to the extent that there can be no regulation 7 increase in the first year.

[826] Regulation 5(2)(b) is to the effect that subject to the provisions of regulation 5(2)(a), the single exit price may be increased in terms of regulation 8. Both regulations 5(2)(a) and 5(2)(b) read together make it plain that there may be no regulation 7 annual increase in the first year of the single exit price but that a regulation 8 increase is nevertheless permissible.

[827] But regulation 7 is also subject to regulation 8. In broad terms, regulation 8 allows a manufacturer or importer to increase the single exit price once a quarter provided, amongst other things, that the increased price does not exceed the maximum price determined by the Minister in terms of regulation 8(1). There is, on the face of it, a contradiction between regulations 7 and 8. Regulation 7 allows an unqualified right to increase the single exit price, but only once a year. Regulation 8(3) allows an

increase once a quarter provided that the increase does not result in a price higher than that determined by the Minister.

[828] I am driven to the conclusion that the regulations provide for two increase mechanisms: an increase by the manufacturer or importer in terms of regulation 7 once during every year after the expiry of the first year of their coming into operation, whether or not there has been a ministerial determination of the maximum increase to be permitted in terms of regulation 8(1); and single exit price increases that manufacturers or importers may make once a quarter of each year in terms of regulation 8(3) provided amongst other things that these increases do not take the single exit price beyond the upper limit determined by the Minister.

[829] The affidavit of Professor McIntyre confirms on behalf of the Pricing Committee that regulation 7 allows a manufacturer or importer to increase the single exit price once every year. In relation to regulation 8(3), however, Professor McIntyre's evidence is to the effect that increases once a quarter were contemplated by the regulations to cater for price fluctuations and that manufacturers or importers who had decreased prices to below the single exit price established for that year could thereafter increase the single exit price once a quarter up to the maximum established for that year. This is consistent with what I have found. The affidavit by Professor McIntyre omits to mention that the quarterly increases are permissible only if there is a regulation 8(1) ministerial notice and only if they do not take the increase beyond that permissible in terms of that notice. A manufacturer or importer who has

decreased or kept a single exit price below that permissible by reason of the increase allowed in terms of regulation 8(1) may increase the single exit price every quarter provided that the increase allowed in terms of regulation 8(1) is not exceeded. A manufacturer or importer who had increased the single exit price to a level beyond that permissible in terms of the subsequently published regulation 8(1) notice cannot make any regulation 8(3) quarterly increase.

[830] The other conditions set in regulation 8 for the increase are also instructive. The minority in the High Court found regulation 8(3)(i) to be incomprehensible. It provides that the increase of the single exit price allowed by regulation 8(3) must not exceed "the single exit price of the medicine or Scheduled substance as first published in respect of that year". The reference to the single exit price first published in respect of any year must be a reference to an increase that was published by a manufacturer or importer before the Minister made any determination in terms of regulation 8(1). It will have been noted that the Minister is not obliged to make any determination of the maximum allowable increase before 2 May of a particular year. Nor is there a provision that prohibits manufacturers or importers from making an increase before any determination by the Minister or otherwise than in terms of that determination.

[831] I accordingly interpret regulations 7 and 8 as follows:

(a) The manufacturer or importer have the right to increase the single exit price once a year during each year (as defined) after 2 May 2005.

(b) This right exists whether or not the Minister has made a determination before 2 May 2005.

(c) The Minister may make a determination as to the maximum allowable increase annually. There is no provision as to precisely when the determination must be made.

(d) A manufacturer or importer who makes an increase before the determination by the Minister is not bound by any limit.

(e) A manufacturer or importer who has not made any increase before the determination of the maximum by the Minister can, after the determination, make and publish an increase provided that the conditions in regulations 8(3)(ii) and 8(3)(iii) are fulfilled.

[832] The position of the manufacturer or importer who has made and published an increase in terms of regulation 7 before any determination by the Minister in terms of regulation 8(1) is in effect determined by regulation 8(3)(i) to which reference has just been made. The increase permitted to a person in this category must not exceed "the single exit price . . . as first published in respect of that year". I have already said that a manufacturer or importer who increases the price in terms of regulation 7 will be obliged to publish the increase in the price. In the circumstances, the only plausible meaning to be ascribed to regulation 8(3)(i) is that the increase must not exceed the increase in the single exit price of a medicine or Scheduled substance as first published by the manufacturer or importer in respect of that year in terms of regulation 7.

[833] I am of the view that the regime is subtle and creative. A manufacturer or importer may increase the single exit price once a year. If, however, it transpires that the Minister's determined maximum is higher than the increased price published before the determination, the manufacturer or importer takes the risk. They cannot increase the single exit price beyond the increase they first published without waiting for the Minister's publication.

[834] One more point must be made in relation to the price increase regime. There was a suggestion that regulation 8(3)(iv) adds to the confusion and contradiction created by the section. The regulation prohibits a regulation 8(3) increase within a period of six months from the date of commencement of the regulations. Regulation 5(2)(a), on the other hand, prohibits an increase for a period of one year after the commencement of the regulations. It must be remembered that the regulation 8(3) increase is permissible only if there is a regulation 8(1) determination. Regulation 8(3)(iv) simply means that even if there is a ministerial determination in terms of regulation 8(1) no manufacturer or importer may make a regulation 8(3) increase in the first six months of the operation of the provisions. Regulation 5(2)(a) prohibits an increase for a year after the commencement of these regulations absent a regulation 8(1) determination. Once there is a regulation 8(1) determination, however, a regulation 8(3) increase is permissible upon the expiry of six months of the date of commencement of the regulations.

[835] The regulations concerning the single exit price are complex but understandable. They do mean that the manufacturer or importer of a medicine might sell at a price higher than that allowed by the ministerial determination and that the manufacturer or importer of another medicine might be obliged to limit increases to the maximum determined by the Minister. This consequence is in my view of no moment. It does not detract from the Act which requires a single exit price in relation to each substance. Manufacturers or importers can choose whether they wish to pre-empt the ministerial determination and face the consequence that their price turns out to be lower than that determined by the Minister, or wait for the Minister's determination only to find that they would have increased the price to an amount beyond the maximum allowed by the ministerial determination.

Regulations 22 and 23 comply with the Constitution

[836] Finally, the main judgment holds that the provisions of regulations 22 and 23 are not sanctioned by section 22G of the Act and are therefore invalid. Again, regrettably, I cannot agree. Regulations 22 and 23 provide:

> "22.(1) The Director-General may determine that the single exit price of a medicine or Scheduled substance is unreasonable and communicate to the relevant manufacturer, importer, wholesaler or distributor, in a manner which he or she deems appropriate, such determination together with the basis upon which the determination has been made.
>
> (2) With regard to the determination contemplated in regulation 22(1), the Director-General must consult with the relevant member of the supply chain and consider any representations made by that member concerning the reasonableness of the single exit price.

(3) Where the Director-General is not convinced, after the consultation and representations contemplated in regulation 22(2), that the single exit price is reasonable, he or she may publish a notice in the Gazette to the effect that in the opinion of the Director-General, the single exit price is unreasonable and must state the reasons for such opinion.

23. In determining whether the price of a medicine or Scheduled substance is unreasonable as contemplated in regulation 22, the Director-General must have regard to—

(1) the single exit price at which the medicine or Scheduled substance is being sold in the relevant market;

(2) the single exit prices at which other medicines or Scheduled substances in the same therapeutic class are being sold in the relevant market;

(3) the prices at which the medicine or Scheduled substance and other medicines or Scheduled substances in the same therapeutic class are being sold in countries other than the Republic;

(4) changes in the CPI, the PPI and the relevant rates of foreign exchange;

(5) purchasing power parity with reference to the Republic and any other country in which the medicine or Scheduled substance is sold;

(6) the relative availability within the Republic of medicines or Scheduled substances in the same therapeutic class as the medicine or Scheduled substance and the safety and efficacy of the medicine or Scheduled substance relative to other medicines or Scheduled substances in the same therapeutic class;

(7) the nature of any indication in respect of which the medicine or Scheduled substance has been registered in the Republic;

(8) the size of the market for the medicine or Scheduled substance in the Republic relative to that in other countries;

(9) any relevant information provided by the Council for Medical Schemes established in terms of the Medical Schemes Act, 1998 (Act No 131 of 1998);

(10) the size of the obstacle, represented by the single exit price, to access to the medicine or Scheduled substance relative to the public interest in having widespread and general access to the medicine or Scheduled substance;

> (11) such other factors which in the view of the Director-General are relevant to the pricing, or the costs of manufacture or sale, of the medicine or Scheduled substance."

[837] The regulations have nothing to do with the subjective views of the Director-General. A prerequisite for the coming into operation of regulations 22 and 23 is a determination by the Director-General that the single exit price of a medicine or Scheduled substance is unreasonable. This is an objective determination subject to judicial control and must be made with due regard to the factors listed in regulation 23.

[838] The next stage in the process is that the Director-General communicate that determination to the manufacturer, importer, wholesaler or distributor.[521] The Director-General is thereafter obliged to consult with "the relevant member of the supply chain" and consider any representations made concerning the reasonableness of the single exit price. If the Director-General is not convinced by the representations made that the single exit price is reasonable, there may be a publication in the Government Gazette to the effect that the single exit price is unreasonable. The Director-General is obliged to give the reasons for this opinion.

[839] Regulations 22 and 23 read together represent, in my view, a creative and imaginative approach to the way in which downward pressure may be exerted on the price of medicines and Scheduled substances. I have already said that an important

[521] Regulation 22(1).

object of section 22G is to render medicine affordable. The process of doing so is complex to say the least. The publication of a notice in the Government Gazette to the effect that the single exit price is unreasonably high constitutes a limited sanction. It could result in the reduction of the sale of the medicine and it is this real possibility that the manufacturer, importer or wholesaler would take into account in determining the single exit price, in making increases and in considering whether or not to make an increase before the ministerial maximum is published in terms of regulation 8(1).

[840] Reference has been made to the fact that the single exit price cannot be unreasonable if it complies with regulations 5 and 19, and in particular, conforms with international benchmarks. This is undoubtedly so. The single exit price can be said to be unreasonably high only if it is palpably higher than the price allowed by the other regulations.

[841] Section 22G of the Act contemplates a pricing system with the object of ensuring a downward pressure on the price of any medicine or Scheduled substance. Regulations 22 and 23 are consistent with this objective and sanctioned by the Act.

Madala, Mokgoro, Moseneke and Skweyiya JJ concur in the judgment of Yacoob J.

LANGA DCJ:

[842] I have had the privilege of reading the separate judgments in this matter prepared by Chaskalson CJ, Moseneke J, Ngcobo J, Sachs J and Yacoob J, as well as the judgment of the Court. I agree with the order made in the judgment of the Court. Save in the respects indicated below, I concur in the judgments of Chaskalson CJ and Ngcobo J.

[843] One of the issues to be resolved in this case concerns the applicability of the Promotion of Administrative Justice Act, 3 of 2000 (PAJA). Both the Chief Justice and Ngcobo J hold that PAJA applies to the power to make the relevant regulations in terms of the Medicines and Related Substances Act, 101 of 1965 (the Medicines Act). Although the Chief Justice holds that in general PAJA applies to regulation-making, I prefer to confine my agreement to the narrow question as framed by Ngcobo J in paragraph 422 of the judgment. Subject to this qualification, I am in respectful agreement with paragraphs 23 to 263 and 278 to 410 in the judgment of Chaskalson CJ and am also in substantial agreement with the judgment of Ngcobo J.

[844] I agree with the reasoning and findings of both the Chief Justice and Ngcobo J that the dispensing fees set by the regulations are not "appropriate" as envisaged by section 22G of the Medicines Act.

[845] For the reasons given by Yacoob J, with whom I agree on this aspect, I am unable to agree with both the Chief Justice and Ngcobo J that regulation 5(2)(c) is void for vagueness. I also agree with Yacoob J's conclusion that the objection to regulations 22 and 23 should be dismissed.

O'REGAN J:

[846] I have had the opportunity of reading the judgments prepared in this matter by Chaskalson CJ, Moseneke J, Ngcobo J, Sachs J and Yacoob J. I concur, in large part, with Chaskalson CJ's judgment, in particular with paragraphs 23-181; paragraphs 183-264; paragraphs 278-416 and paragraph 420.

[847] I have only three differences which I wish to record: first, in my view, no sharp line can be drawn between the requirements of procedural fairness and reasonableness when it comes to assessing the failure by a decision-making body to consider representations made to it.[522] In my view, such a failure raises issues of both process and substance. To the extent, therefore, that members of the pricing committee failed to consider properly, or at all, the oral representations made at the hearings during April 2004, it constituted a procedural flaw as well as a flaw going to substance. I concur with Chaskalson CJ that the dispensing fees set by the regulations are not appropriate and should therefore be set aside. To the extent that the proceedings of

[522] See paragraphs 181-183 of his judgment.

the pricing committee were not fair in that they failed to take into account the representations made by the Pharmacies in respect of the dispensing fee, no other or further relief would have been granted to the applicants in this case in this respect and nothing further therefore turns on it. I also endorse the reasoning of Ngcobo J in this respect at paragraphs 567 – 574 of his judgment.

[848] Secondly, I agree that regulation 5(2)(c) is void for vagueness, but my reasons for doing so coincide with those given by Ngcobo J at paragraphs 487-491 of his judgment, rather than those given by Chaskalson CJ. Thirdly, I agree for the reasons given by Yacoob J that the challenge to regulations 22 and 23 should fail.[523]

[849] I wish to add that although Ngcobo J decides the question of the applicability of the Promotion of Administrative Justice Act, 3 of 2000, on a narrower basis than Chaskalson CJ, much of the reasoning he employs in doing so seems equally applicable to me to the wider question and I support it. I also support much of the reasoning he provides in concluding that the dispensing fees set in the regulations are not "appropriate" within the contemplation of section 22G of the Medicines Act.

[523] See paragraphs 836-841 of his judgment.

VAN DER WESTHUIZEN J:

[850] I have read the detailed and thoroughly reasoned judgments prepared in this matter by my colleagues. For the sake of clarity, I very briefly state my position on some of the issues dealt with in their judgments.

[851] I agree with the conclusion of Ngcobo J that the Promotion of Administrative Justice Act, 3 of 2000 (PAJA) applies to the power to make regulations conferred by section 22G(2)(a)-(c) of the Medicines and Related Substances Act 101 of 1965 (the Medicines Act). Much of the reasoning of Ngcobo J may be equally valid as to the wider question regarding the applicability of PAJA to regulation-making in general. In this regard I also find the reasoning of Chaskalson CJ persuasive. However, like Ngcobo J, I wish to refrain from answering the wider question. I do not regard it as necessary to do so in this case.

[852] On the validity of the regulations I agree with Yacoob J, for the reasons advanced in his judgment. I am therefore specifically of the view that regulations 5(2)(c) and 8(3) are not void for vagueness and that regulations 22 and 23 are valid. I reach this conclusion even though I do not find the regulations easy to understand and interpret.

[853] I agree with the conclusion reached by Chaskalson CJ and Ngcobo J that the dispensing fees set in the regulations are not "appropriate" within the contemplation of section 22G of the Medicines Act, and with much of the reasoning advanced in their

judgments. Amongst the factors leading me to this conclusion are the unsatisfactory explanations offered on behalf of the Pricing Committee on the relationship between the dispensary and the front shop of community pharmacies and on the question whether compounding and admixing are included in the dispensing fee, as well as the apparent failure to consider the oral representations of April 2004, pointed out in the judgments of Chaskalson CJ and Ngcobo J. I am not necessarily persuaded by the Pharmacies that the regulations would result in the demise of a significant number of pharmacies. However, as pointed out by Ngcobo J, the failure by the Pricing Committee to explain how it arrived at the figures it adopted made it impossible to determine whether the Pricing Committee has properly applied its mind to the viability of pharmacies. I agree with Moseneke J that the Minister and the Pricing Committee misdirected themselves in taking the view that courier pharmacies do not deserve separate consideration and treatment. I also agree that the dispensing fee cannot be said to be appropriate in relation to pharmacies in rural areas. I am unable to hold that the regulations regarding the dispensing fee are otherwise valid. The incorrect "one size fits all" approach, viewed together with the other troublesome aspects of the Minister and the Pricing Committee's case on the dispensing fee, has to result in the conclusion that the fee cannot be regarded as "appropriate".

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