

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

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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 sections 15 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 applied³⁴ 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

"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 “the 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”.

[3]

THE COURT

- (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.