



**THE SUPREME COURT OF APPEAL
OF SOUTH AFRICA**

Reportable
Case Nos 542/04
543/04

In the matter between:

**PHARMACEUTICAL SOCIETY OF SOUTH AFRICA
AND OTHERS**

Appellants

and

THE MINISTER OF HEALTH AND ANOTHER

Respondents

NEW CLICKS SOUTH AFRICA (PTY) LIMITED

Appellant

and

**DR MANTO TSHABALALA-MSIMANG NO
AND ANOTHER**

Respondents

Coram: HARMS, NAVSA, MTHIYANE, BRAND and CLOETE JJA

Heard: 30 November and 1 December 2004

Delivered: 20 December 2004

Subject: Medicines and Related Substances Act – Regulations relating to a Transparent Pricing System for Medicines and Scheduled Substances – validity – legality (*ultra vires*) – Leave to appeal – failure of court of first instance to make order within reasonable time – effect.

J U D G M E N T

HARMS JA/

HARMS JA

INTRODUCTION

[1] The applicants are applying for leave to appeal. In issue is the validity of the ‘Regulations relating to a Transparent Pricing System for Medicines and Scheduled Substances’.¹ They were promulgated on 30 April 2004 by the Minister of Health in terms of s 22G of the Medicines and Related Substances Act 101 of 1965 (‘the Medicines Act’). The section permits the minister to make regulations on the recommendation of a pricing committee established by the section. The regulations may, essentially, provide for a transparent pricing system for manufacturers of medicines and may prescribe a dispensing fee. Manufacturers are obliged to charge the same price to all; discounts are prohibited; manufacturers must publish their ‘single exit price’; no one in the supply chain may charge more than the single exit price; pharmacists and other licensed health professionals may, however, add the prescribed ‘appropriate dispensing fee’, but no more. The regulations under attack provide for a pricing system that defines and controls the single exit price for manufacturers and importers and for a dispensing fee, which, for pharmacists amounts to either 16% of the exit price (if it is less than R100) or R16 (if more than R100) without a medical prescription. If there is a prescription the figures are 26% (if it is less than

¹ GN R553 GG 26304 of 30 April 2004. The date of commencement was 2 May.

R100) and R26 (if more than R100, whether R100 or R1000). The major issues are whether these fees are ‘appropriate’ and whether the regulation of the single exit price is legal.

[2] There are two applications. In one the first applicant is the Pharmaceutical Society of South Africa (‘PSSA’), joined by six other entities that own pharmacies. The other is by New Clicks SA (Pty) Ltd, the owner of 86 pharmacies. The respondents in both applications are first, the Minister of Health and second, Prof D McIntyre, cited in the court below under uniform rule 53 in her capacity as chairperson of the pricing committee. At the appeal stage the Treatment Action Campaign joined the proceedings as *amicus curiae*.

HISTORY OF THE PROCEEDINGS

[3] The applicants, in separate review applications, applied in the Cape High Court for the setting aside of the regulations. Due to the urgency of the matters, the court granted interim relief by agreement on 1 June.² In terms of the order the regulations were suspended pending the final determination of the reviews and the parties placed on terms for filing papers. At the behest of the respondents early hearing dates were allocated, namely 17 and 18 June. The matters were heard by a full bench as a court of first instance. Judgment

² All dates are 2004 unless otherwise indicated.

was delivered on 27 August and the applications were dismissed (per Yekiso J, Hlophe JP concurring; Traverso DJP dissenting).

[4] Alleging that the dismissal of their review applications (which brought the suspension of the regulations to an end) did not remove the urgency, the applicants immediately sought leave to appeal from the court below by filing their applications on the next court day, 30 August. These notices did not raise any issues not covered by the two judgments. The applicants then requested an early hearing date but the court ruled that the date had to suit respondents' counsel. The applications were eventually heard on 20 September but instead of making an *ex tempore* order, as is the practice in matters of this kind, the court reserved judgment.

[5] Some five weeks later, on 20 October, the applicants in the PSSA application wrote to the registrar of the court below, with a request to establish whether the judge president, who had intimated at the hearing that he would write the judgment, would indicate when a ruling might be expected (even if reasons were to follow). Neither the registrar nor the judge president responded. The applicants thereafter decided to file the present applications with this court. They intended as a gesture of courtesy to meet with the judge president to inform him in advance but he was unable – for

unknown reasons – to meet them. On 11 November the present applications were filed.

[6] The next day the judge president became available for the courtesy call and, according to the state attorney, he told those present that the second draft of the judgment was in the process of being typed. He enquired of them whether, in the light of the applications, he was expected to stop the process and dispense with the need to finalise the judgment. No one responded and he then said that he would continue to finalise the judgment. Once again, no indication of when judgment was to be delivered was given and no explanation for the delay provided. If there were compelling reasons for the delay, one would have expected some explanation.³

[7] In the meantime and pursuant to the filing of the present applications I had invited the parties to a conference in chambers to enable me under delegated powers to issue the necessary directions in terms of SCA rule 11 as to the manner in which the applications were to be dealt with. At the request of the respondents the meeting took place on 17 November, two days later than intended, and the ruling was issued early the next morning after consultation with the head of court and the members of the panel to whom the applications were allocated. The ruling was in the customary form:⁴ the

³ *Rolled Steel Products (Holdings) Ltd v British Steel Corp* [1986] 1 Ch 246 (CA) 310C-E.

⁴ Eg *National Union of Metalworkers of SA v Jumbo Products CC* 1996 (4) SA 735 (A) 738E-G.

hearing of the applications was consolidated, the applications were referred for oral argument on 30 November and 1 December in terms of s 21(3)(c)(ii) of the Supreme Court Act 59 of 1959, the parties were to be prepared (if called upon to do so) to address the court on the merits, and the respondents were to file any affidavits and heads of argument if and when convenient.⁵

[8] On 29 November, the eve of the hearing before this court, the judge president gave notice to the parties that judgment would be delivered on 3 December. In the event it was. Hlophe JP (Yekiso J concurring) refused leave whilst Traverso DJP would have done otherwise. Why it took three weeks to type or check a second draft of a judgment that ultimately ran to thirteen well-spaced typed pages we have not been told. As this court once said:⁶

‘Much more than a matter of mere courtesy is involved. By such conduct the administration of justice is hampered, and may be seriously hampered, by an arbiter of justice himself, whose responsibility it is to render it effective and not add judicial remissness to its already irksome delays.’

[9] Three issues arise from the present applications: (a) should they be dealt with as a matter of urgency; (b) were the applicants entitled to approach this court for leave to appeal where the court of first instance had not yet ruled on their applications (the so-called jurisdiction point) and (c) if

⁵ Which they did at close of the registrar’s office on 29 November.

⁶ *S v Lifele* 1962 (2) SA 527 (A) 531F. The context was different.

so, do the applicants have reasonable prospects of success on appeal? The respondents raised a further procedural issue, namely whether the first two issues should be separated from the third, insisting that this court should deal with the application piecemeal, and not as a whole.

URGENCY

[10] In the court below (as mentioned) the case was dealt with by agreement between the parties and by the court as one of urgency until judgment on 27 August. Nothing has since changed except that the respondents were successful. The only point made by the respondents of any consequence is that the matter is no longer urgent; had it been urgent, the applicants would have applied for leave to appeal to the Constitutional Court; instead they applied for leave to this court.⁷ One gained the impression that the respondents believe (a view shared by the court below as will appear later) that since there are constitutional issues only the Constitutional Court should deal with the matter. The choice of forum was that of the applicants alone. If properly engaged, this court has a constitutional duty to deal with a matter and deal with it expeditiously. This court does not have the power to divert cases to the Constitutional Court. In any event, and this the applicants allege is their dilemma, the Constitutional

⁷ There was a rather lame attempt in the respondents' answering affidavits in the present applications to show that the regulations did not threaten the viability of the dispensing profession but respondents' counsel thought it best not to deal with the allegations during argument.

Court is entitled to refuse to hear appeals directly and may require that they first be heard by this court. Therefore, they say, it was prudent for them to take the present route.

[11] Although not raised with reference to any facts in the affidavits opposing the applications before us, respondents' counsel objected to the present proceedings and submitted that they were procedurally unfair because of the limited time allowed to enable them to prepare on the merits; eight court days were allegedly insufficient.⁸

[12] In the court below the respondents were able to deal with both cases within exceptionally short periods, most of their own choosing. They prepared lengthy answering affidavits by 31 May (amplified by 9 June), taking into account the applications were only served on 24 and 27 May, and were in court on 1 June for the preliminary hearing. And they were ready to argue on 17 June, three ordinary days after the replying and eight ordinary days after the answering affidavits had been filed. They were also in a position to file heads of argument, so full that the court below was able to dispose of argument by four sets of counsel within a day and a half, despite the fact that the combined record ran to about 4000 pages.

⁸ The members of this court were, without any background, able to prepare the appeal within the allotted time during the busiest part of term.

[13] The respondents' submissions in this regard, sadly, were but a smokescreen. 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.⁹

[14] 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

⁹ In answer to a complaint about my ruling, addressed to the Acting President of the court, he pointed out that the respondents were entitled to apply at the hearing for a postponement of the 'merits', which they never did.

were generally obstructive in relation to each suggestion relating to an expedited hearing.¹⁰ As will become apparent from the discussion on the merits, the issues are of national importance. Because of uncertainty and confusion created and the frustration of what was intended, namely access to health care, it is imperative that the litigation should be brought to an early conclusion. There is accordingly no merit in the respondents' submission that the applications are not urgent or that they were prejudiced procedurally by an urgent hearing.

SEPARATION OF ISSUES¹¹

[15] In *S v Malinde* 1990 (1) SA 57 (A) 67F-G it was said:

‘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 . . . or in “enkele gevalle van 'n besondere aard” . . .’

The same applies to applications. Nicholas AJA proceeded to state (at 68C-E):

‘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

¹⁰ Of the seven counsel who appeared on behalf of the respondents in the court below, three appeared before us. One of these was a member of the pricing committee, which was responsible for the draft regulations.

¹¹ Uniform rule 33(4) does not apply to the SCA.

convenience affecting the parties, it appears that the advantages would outweigh the disadvantages, the Court would normally grant the application.’

He concluded (at 86E) by saying that the court should not grant an application for a separate hearing unless there appeared to be a reasonable degree of likelihood that the alleged advantages would in fact result.

[16] The respondents have not sought to justify a separation of issues by filing an application therefor. Instead, they claim a right thereto and in this regard they cited *Chevron Engineering (Pty) Ltd v Nkambule* 2003 (5) SA 206 (SCA) and *American Natural Soda Corporation v Competition Commission* 2003 (5) SA 655 (SCA). They submitted that the separation of jurisdiction from other issues is the normal procedure of this court. They are wrong. Sometimes the issue is dealt with separately but that usually depends on the nature of the application. For instance, in *American Natural Soda* the application was for an order declaring, inter alia, that the applicants were entitled to note an appeal while in *Chevron* the applicant not only asked for leave to appeal but also for directions in regard to the further prosecution and conduct of the appeal.¹² In neither case was the record before court nor did the question of separation of issues arise.

[17] As said, the only reason the respondents advanced in support of a separation was that they wished to appeal any unfavourable ruling first,

¹² See *Chevron Engineering (Pty) Ltd v Nkambule* para 20; and *American Natural Soda Corporation v Competition Commission* para 1.

which would have added to the delay. That reason is insufficient and does not fulfil the requirements laid down in *S v Malinde*. In addition, there are the considerations alluded to in para 14 above, which militate against a separation.

JURISDICTION

[18] The facts recited have a material bearing on the next issue, namely, whether this court was entitled to entertain the applications for leave to appeal considering the fact that they were launched before the court below had ruled on the applications before it. The respondents submit not. The basis of their submission is that this court does not have any jurisdiction in the absence of a ruling by the lower court.

[19] As a starting point, this court does not have any original jurisdiction.¹³ Its jurisdiction is derived from the Constitution and is principally limited to decide appeals and issues connected with appeals (which includes applications for leave to appeal).¹⁴ Although this court, like the Constitutional Court and High Courts, has the inherent power to protect and regulate its own process, that ‘does not extend to the assumption of jurisdiction not conferred upon it by statute.’¹⁵

¹³ *Moch v Nedtravel (Pty) Ltd t/a American Express Travel Service* 1996 3 SA 1 (A) 7F-G.

¹⁴ Constitution s 168(3); *S v Basson* 2004 (6) BCLR 620 (CC) para 103.

¹⁵ *Moch v Nedtravel (Pty) Ltd t/a American Express Travel Service* 1996 3 SA 1 (A) 7F-G. See also *Sefatsa v Attorney-General, Transvaal* 1989 (1) SA 821 (A) 834E.

[20] This principle requires some elucidation, which can be done with reference to the cases just cited. In *Moch* the facts were these: s 150 of the Insolvency Act 24 of 1936 does not permit an appeal against a provisional order of sequestration. The applicant in that matter argued that this court could bypass the prohibition by the exercise of its inherent jurisdiction. It was in answer to that submission that this court said that the inherent power to regulate its process does not extend to the assumption of jurisdiction not conferred upon it by statute. In *S v Basson*¹⁶ the issue was similar. The question was whether the Criminal Procedure Act 51 of 1977 gave the state a right to appeal the discharge of an accused on the merits. If the Constitution or a statute does not provide for such a right that is the end of the matter and this court cannot assume the power. Neither case was concerned with the instance where there is a right of appeal subject to procedural preconditions.

[21] Appeal jurisdiction of this court in civil proceedings is derived from s 20(1) of the Supreme Court Act. This court has jurisdiction to hear appeals against judgments or orders in any civil proceeding.¹⁷ Section 20(4)(b) contains certain conditions that apply to the present cases:

¹⁶ 2004 (6) BCLR 620 (CC).

¹⁷ The only exclusion is in s 20(7) which deals with certain matrimonial disputes.

‘No appeal shall lie against a judgment or order of the court of a provincial or local division [read: high court] in any civil proceedings . . . except—

(a) . . . ;

(b) . . . 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 [read: Supreme Court of Appeal].’

The purpose of para (b) is to protect this court against baseless appeals and it does so by limiting appeals to those that have reasonable prospects of success.¹⁸ Prior to its amendment in 1982, the section gave a party in the position of the applicants an untrammelled right of appeal to this court.¹⁹

[22] Although couched in the negative, these provisions mean that in civil proceedings emanating from high courts, everyone has a right of appeal against judgments or orders. The right is not absolute since leave to appeal is required. Leave is a condition for exercising the right or, put differently, it is a jurisdictional fact for an appeal. The court whose judgment is sought to be appealed must first be approached for leave.²⁰ If that is granted, the condition is fulfilled. If it is refused, the party wishing to appeal has a right to petition this court for leave. That much is clear from *National Union of*

¹⁸ *S v Rens* 1996 (1) SA 1218 (CC) para 7; *Cronshaw v Coin Security Group (Pty) Ltd* 1996 (3) SA 686 (A) 689B.

¹⁹ The amendment was introduced by the Appeals Amendment Act 105 of 1982.

²⁰ That court must also consider whether the appeal should be to the full court or this court. Since these matters were heard in the first instance by a full bench of three members, an appeal to the full court was not possible.

Metalworkers of SA v Jumbo Products CC 1996 (4) SA 735 (A) 740A-D

where Corbett CJ said that –

‘no appeal lies to this Court against the judgment on the merits or the judgment refusing condonation of the late filing of the application to the Court *a quo* for leave to appeal *except* either where the Court *a quo* has itself granted leave to appeal or where, the Court *a quo* having refused such leave, such leave has been granted by this Court. Thus, as is clear from the subsection, this 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 section 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 section 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.’

[23] In view of the considerable emphasis placed by the respondents on this passage, some aspects should be emphasised about the judgment. The first is that the applicant for leave did not apply for leave from the court of first instance and thus failed to take the first step. (The same is true of most, if not all, the cases where this court has said that an application to the court *a quo* and its subsequent order are jurisdictional facts.)²¹ Second, the judgment did not deal with the case where a litigant, following the correct procedure, is unable to obtain a decision from that court within a reasonable time

²¹ Eg *Middelberg v Prokureursorde, Transvaal* 2001 (2) SA 865 (SCA) para 5.

(relative to the circumstances). Third, the effect of the (interim) Constitution on the interpretation of the provision did not arise.

[24] Although a ruling by the court below is a jurisdictional fact, this does not mean that the filing of an appeal or an application for leave with this court is a nullity simply because the court below has not yet given its ruling. That is apparent from a series of judgments dating back to *Gabriel v Natal Law Society* 1913 AD 327. There the appellant required leave to appeal. The court below did not grant or refuse leave, wrongly believing that it was unnecessary to make a ruling. At the hearing the appellant argued that leave was not required but this court disagreed. It then granted leave *nunc pro tunc*, as though proper application had been made timeously, but warned that such procedure should not generally be adopted.

[25] In terms of the then applicable statute, no interlocutory order was subject to appeal save by leave of the court or judge making the order.²² In other words, this court could not grant leave, even if leave had been refused by the court of first instance. The appellant in *Blaauwbosch Diamonds Ltd v Union Government (Minister of Finance)* 1915 AD 599 failed to apply for leave. Although this court had no jurisdiction to hear the matter, it did not strike the appeal from the roll as being a nullity; instead it allowed the case to stand down to enable the appellant to obtain the necessary leave. It did not

²² Appellate Division Further Jurisdiction Act 1 of 1911 s 3(b).

hear argument on the merits and postpone the judgment pending the grant of leave because the court of first instance was the final arbiter of whether leave should be granted or not. The hearing continued eleven days later, leave having been obtained in the interim from the court of first instance.²³

The facts in *Oloff v Minnie* 1952 (4) SA 369 (A) were virtually identical. The same provision applied and the appellant failed to apply for leave to appeal from the court of first instance. This court noted that it had no jurisdiction to dispose of the case but nevertheless heard argument on the merits and let the case stand over. It said (at 376B-C):

‘This matter must, therefore, stand over to enable the plaintiff to apply within twenty-one days of this judgment to the Court *a quo* for leave to appeal. If that Court grants such leave and the order granting leave is lodged with the Registrar of this Court, we, having heard argument on the merits, will be in a position to deliver a judgment on the merits and to make an appropriate order as to costs. If the Court *a quo* refuses leave to appeal and the order refusing such leave is lodged with the Registrar of this Court, this matter will, without any further order of this Court, be deemed to have been struck off the roll with costs.’

The reason for the ruling in the ultimate sentence was that, as mentioned, the court of first instance could refuse leave, which would put an end to the right of appeal. The appeal was later upheld without further argument.²⁴ A similar course was taken in *Sita v Olivier NO* 1967 (2) SA 442 (A) 450E-H under a

²³ But see *De Beer v Minister of Posts and Telegraphs* 1922 AD 175.

²⁴ *Oloff v Minnie* 1953 (1) SA 1 (A).

statutory provision which, for all intents and purposes was identical to that contained in s 20(4)(b) of the Supreme Court Act.²⁵

[26] In *Gentiruco AG v Firestone SA (Pty) Ltd* 1972 (1) SA 589 (A) 608E-G, Trollip JA summed up the position when he said that –

‘Where the necessary leave to appeal is lacking this Court may, in appropriate circumstances, defer the hearing or determination of the appeal to enable to appellant to obtain such leave . . .’²⁶

It should be emphasised that either the hearing or the determination (judgment) can be deferred and, secondly, that the circumstances should be appropriate before this extraordinary procedure may be adopted.

[27] Instructive is *Holt v Brook* 1959 (3) SA 803 (N). Under the applicable statute the appellant, in order to appeal, had to give a prescribed notice (referred to as a s 61 notice) to the other party of its intention to appeal and had to obtain the leave of the court of first instance. In issue was the question whether or not the notice could precede the grant of leave. Broome JP, speaking on behalf of a full bench, said (at 805C-F):

‘A litigant may surely form and notify an intention to appeal before he has taken all the procedural steps which lie before him. These must be taken before his appeal can be heard, but the order in which they are taken does not appear to me to be of any importance, provided that each is taken within the time, if any, specifically prescribed

²⁵ The ultimate decision was reported as *Sita v Olivier NO* 1967 (3) SA 597 (A).

²⁶ *Gentiruco AG v Firestone SA (Pty) Ltd* 1972 (1) SA 589 (A) 608E-G.

therefor. When a person desires to institute action in any Court he will invariably find that the law prescribes an initial step which he must take to set his litigation on foot. Usually it is a summons. Similarly a litigant against whom judgment has been given who desires to appeal will find that an initial step is laid down which he must take to set his appeal on foot. Normally this step is the notice of appeal. In the present case it is the notice under sec. 61. When that notice is given his appeal is on foot. It may be, as here, that he requires leave to appeal, but the obtaining of such leave is not the initial step which sets his appeal on foot and without which there is no appeal on foot at all. It is a step which he must take before his appeal can be entertained by the Court of Appeal.’

[28] In all the cases cited, the would-be appellant failed to apply for leave to appeal from the court of first instance. Notwithstanding the absence of this jurisdictional fact, this court accepted that it could hear and decide the matter provided the condition was fulfilled before judgment was delivered. In this case the applicants are in a better position. They 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.

[29] There is another reason why s 20(4)(b) of the Supreme Court Act does not prevent a consideration of the application. All statutes must be read in the light of the Constitution. More particularly, s 39 enjoins courts, when

interpreting the Bill of Rights to promote the values that underlie an open and democratic society based on human dignity, equality and freedom; and when interpreting any legislation, to promote the spirit, purport and objects of the Bill of Rights.

[30] Although the Constitution does not guarantee a right of appeal in civil proceedings explicitly,²⁷ a general right to a ‘fair’ hearing is entrenched in s 34.²⁸ Applied to the provisions of the Supreme Court Act, this means that the proceedings there described must, procedurally, be ‘fair’. In *Boodhoo & Ors v. Attorney General of Trinidad and Tobago (Trinidad and Tobago)* [2004] UKPC 17 (PC) the Privy Council had to consider the effect of a basic right to ‘the protection of the law’ contained in the constitution of Trinidad and Tobago on a delay in appeal proceedings, and it quoted with approval the following statement of de la Bastide CJ in the Court of Appeal of Trinidad and Tobago (at para 9):

‘It seems to me that this is the right that can most appropriately be invoked by persons who complain of delay by a court in delivering judgment or for that matter failure to deliver judgment. Surely, if the protection of the law means anything, it must mean that persons are entitled to have recourse to the appropriate court or tribunal prescribed by law for the purpose of enforcing or defending their rights against others or resolving disputes of one kind or another. It is axiomatic that such a right is meaningless

²⁷ Whether the right is implicit does not arise. Cf s 35(3)(c).

²⁸ Cf *Besserglik v Minister of Trade, Industry and Tourism (Minister of Justice intervening)* 1996 (4) SA 331 (CC) para 9-10.

without a decision by the court or tribunal to which the claim or dispute is referred for adjudication.’

The Privy Council concluded by holding that

‘delay in producing a judgment would be capable of depriving an individual of his right to the protection of the law, as provided for in section 4(b) of the Constitution of Trinidad and Tobago, but only in circumstances where by reason thereof the judge could no longer produce a proper judgment *or the parties were unable to obtain from the decision the benefit which they should.*’

(Para 12, emphasis added.) The same must apply to the right to a ‘fair hearing’ in respect of an application for leave to appeal.²⁹

[31] The Supreme Court Act assumes that the judicial system will operate properly and that a ruling of either aye or nay will follow within a reasonable time. The Act – not surprisingly – does not deal with the situation where there is neither and a party’s right to litigate further is frustrated or obstructed. The failure of a lower court to give a ruling within a reasonable time interferes with the process of this court and frustrates the right of an applicant to apply to this court for leave. Inexplicable inaction makes the

²⁹ Cf s 35(3)(d) and (o) of the Constitution. The European Convention on Human Rights provides in art 6(1) that ‘In the determination of his civil rights and obligations ..., everyone is entitled to a ... hearing within a reasonable time by [a] tribunal’ There are many judgments on the article and reasonableness is assessed particularly in the light of the circumstances of the case, having regard in particular to the complexity of the case and the conduct of the parties to the dispute and the relevant authorities. *Terranova v Italy* (ECHR) 4 December 1995, Series A no. 337-B para. 20).

right to apply for leave from this court illusory.³⁰ This court has a constitutional duty to protect its processes and to ensure that parties, who in principle have the right to approach it, should not be prevented by an unreasonable delay by a lower court.³¹ In appropriate circumstances, where there is deliberate obstructionism on the part of a court of first instance or sheer laxity or unjustifiable or inexplicable inaction, or some ulterior motive, this court may be compelled, in the spirit of the Constitution and the obligation to do justice, to entertain an application of the kind presently before us.

[32] In *Montsisi v Minister van Polisie* 1984 (1) SA 619 (A) the court dealt with s 32(1) of the since repealed Police Act 7 of 1958. It proscribed the institution of legal proceedings against the police more than six months after the cause of action had arisen. According to jurisprudence the six months period was a ‘vervaltermyn’, which meant that it could not have been suspended under the provisions of a prescription statute. The allegations were that the appellant had been detained by the SA Police on 10 June 1977 under the provisions of the Terrorism Act 83 of 1976 and that he was assaulted while in detention on 13 June and 27 October 1977. He was only released from detention on 28 July 1978, after the lapse of the six month

³⁰ In *S v Venter* 1999 (2) SACR 231 (SCA) the trial court took eight months to enroll the application for leave to appeal. The applicant had been sentenced to 4 years effective imprisonment. He was in prison and on appeal his sentence was reduced to six months. A clear failure of justice due to judicial delay.

³¹ See s 173 of the Constitution, which deals with this court’s inherent power to regulate and protect its own process.

period. It was common cause that, by virtue of the provisions of s 6 of the Terrorism Act, the appellant was not able to institute any legal proceedings during the period of his detention. This court found that his claim was not out of time applying the general principle of *lex non cogit ad impossibilia* (at 635A-H). This principle, which is really one of the law of contract, has general application. Applied to the issues in this case, if an applicant finds it impossible to obtain a ruling within a reasonable period from a court below, its absence cannot be held against it. (By parity of reasoning one could apply the principle of fictional fulfilment of a condition.)

[33] That brings me to a consideration of whether, on the facts of this case, there was an undue delay in issuing a ruling, which entitled the applicants to approach this court for leave. In this regard it is well to remember that by its very nature the judicial process is slow, judges have other cases to attend to, they have to consider their verdicts and give reasoned judgments, due allowance must be made for the speed with which individual judges work, and that –

‘citizens who are engaged in litigation have to face a number of possible hazards. The members of a court consisting of an even number of judges may divide evenly, so giving rise to the need for a rehearing. A jury may have to be discharged or a judge to recuse himself at an advanced stage of a trial, without anyone having been at fault. A judge may

die or take ill before concluding the hearing of a case or before judgment is given. These constitute the ordinary risks inseparable from litigation . . .³²

[34] The present matters began as urgent applications and, since the parties were agreed that they were urgent, the court below properly dealt with them on that basis. Two compendious judgments (in all about 180 typed pages) were delivered within two months. The applications for leave raised no new points that had to be covered by any further judgment. Applications for leave are ordinarily dealt with by courts expeditiously and leave is either granted or refused instantly, sometimes accompanied by an *ex tempore* judgment of a page or two.³³ The validity of regulations that have a profound effect on many would usually provide compelling reasons to have the issue determined as soon as possible.³⁴

[35] The respondents did not submit that the delay was reasonable or justifiable. Their counsel was not prepared to deal with the question of what the case would have been if a court refuses because of an ulterior motive to give a ruling, saying it was hypothetical. Instead, he submitted that the court all along intended to deliver a ruling, relying on the meeting with the judge president on 12 November. It really misses the point. One is supposed to

³² *Boodhoo & Ors v. Attorney General of Trinidad and Tobago (Trinidad and Tobago)* [2004] UKPC 17 (PC) para 14.

³³ This court as a rule disposes of applications for leave without oral argument and without providing any reasons: *Mphahlele v First National Bank of South Africa Ltd* 1999 (3) BCLR 253 (CC).

³⁴ Cf *Minister of Public Works v Kyalami Ridge Environmental Association* 2001 (3) SA 1151 (CC) para 27.

adjudge the matter as it stood when the applications were filed, and objectively.

[36] It is necessary to have regard to the terms of Hlophe JP's judgment to see whether it contains any clues as to why it had to be delayed. The first seven pages of the judgment deal with the reason why the application for leave was not dealt with in chambers but in open court. Those reasons are academic and have nothing to do with the question whether or not leave should have been granted. During the course of this discussion Hlophe JP took umbrage to the applicants' direct approach to the head of this court to determine the availability of dates before the application had been determined, as if it amounted to some kind of lese-majesty.³⁵ Apparently he did not appreciate fully that the applicants were entitled to approach this court either by way of an appeal or an application for leave to appeal, irrespective of the outcome of their applications before the court below.

[37] Hlophe JP, when dealing with the merits of the application, himself said that –

‘there was absolutely nothing new that came out in argument when we heard the application for leave to appeal. All the issues raised were fully canvassed in a long judgment which was carefully written.’

³⁵ He did not comment, maybe because he was unaware that the respondents had approached the Acting Chief Justice to determine what dates were available there.

Why then, one may fairly ask, did it take longer to dispose of the application for leave than the application itself? He said that the fact that there was a minority judgment did not mean that another court might reasonably agree with the minority. (As Antoine de Saint-Exupéry said, it is harder to judge oneself – and, one may add, the fruits of one’s labours – than to judge others.) He proceeded to find (so it would appear) that since the case raises constitutional issues, leave to this court should not be granted, apparently assuming that a court of first instance does have the right to choose the appeal forum while all it can decide is whether there were reasonable prospects of success.

[38] Ineluctably, in the light of the nature and scope of the issues, the period of the delay, the lack of explanation, the urgency of the case, the content of Hlophe JP’s judgment and the other factors mentioned, the only conclusion can be that the delay was not only regrettable, it was unreasonable – so unreasonable in fact that it could only be interpreted as a refusal of leave.

[39] The judgment of Hlophe JP concluded with a reference to the spirit of *ubuntu* in interpreting statutes. The word appeared in an endnote of the interim Constitution where it dealt with national unity and reconciliation:

‘These can now be addressed on the basis that there is a need for understanding but not for vengeance, a need for reparation but not for retaliation, a need for *ubuntu* but not for victimisation.’

It does, however, not appear in the Constitution in express terms. *Ubuntu* has many dimensions but its application to statutory interpretation is novel.³⁶ It ought to apply to the relationship between courts and the respect required of organs of state and courts towards citizens and towards each other. One does sense that the court below was irritated because the applicants had the temerity to ask for a quick disposition of the applications for leave. There are some who believe that requests for ‘hurried justice’ should not only be met with judicial displeasure and castigation but the severest censure and that any demand for quick rendition of reserved judgments is tantamount to interference with the independence of judicial office and disrespect for the judge concerned.³⁷ They are seriously mistaken on both counts. First, parties are entitled to enquire about the progress of their cases and, if they do not receive an answer or if the answer is unsatisfactory, they are entitled to complain.³⁸ The judicial cloak is not an impregnable shield providing

³⁶ *S v Makwanyane* 1995 (6) BCLR 665, 1995 (3) SA 391 (CC) para 225: ‘Respect for the dignity of every person is integral to this concept.’ Para 237: ‘The concept carries in it the ideas of humaneness, social justice and fairness.’ Para 263: “‘The need for *ubuntu*’ expresses the ethos of an instinctive capacity for and enjoyment of love towards our fellow men and women; the joy and the fulfilment involved in recognizing their innate humanity; the reciprocity this generates in interaction within the collective community; the richness of the creative emotions which it engenders and the moral energies which it releases both in the givers and the society which they serve and are served by.’ Para 308: ‘Generally, *ubuntu* translates as “humaneness”. ... in its fundamental sense it denotes humanity and morality.’

³⁷ *Botha v White* 2004 (3) SA 184; [2003] 2 All SA 362 (T) para 55.

³⁸ The protocol issued in 2003 by the Chief Justice and Judges of the Supreme Court of Tasmania out what the local position has been since time immemorial:

immunity against criticism or reproach. Delays are frustrating and disillusioning and create the impression that judges are imperious. Secondly, it is judicial delay rather than complaints about it that is a threat to judicial independence because delays destroy the public confidence in the judiciary. There rests an ethical duty on judges to give judgment or any ruling in a case promptly and without undue delay and litigants are entitled to judgment as soon as reasonably possible.³⁹ Otherwise the most quoted legal aphorism, namely that ‘justice delayed is justice denied’, will become a mere platitude. Lord Carswell recently said:

‘The law's delays have been the subject of complaint from litigants for many centuries, and it behoves all courts to make proper efforts to ensure that the quality of justice is not adversely affected by delay in dealing with the cases which are brought

‘1. The policy of the Court is that judgment should be delivered as expeditiously as possible. However, given (inter alia) the constantly changing and often unpredictable demands on judicial time, the differences in the priorities for the delivery of judgments in different cases and the difference in the time required for the writing of judgment in different cases, the judges do not regard it as appropriate or useful to settle a time-table governing the delivery of reserved judgments.

2. It is the Court's view that it is highly desirable that the Court is always informed if there is some special reason why judgment should be delivered quickly in a particular case and the Court has never seen any objection to solicitors for the parties making an enquiry in appropriate cases as to when a reserved judgment might be expected to be delivered.

3. In the event that the solicitors for one or more of the parties are concerned at the delay in any given case, an enquiry in writing may be made to the Judge in question or to his Associate as to when judgment may be expected.

4. If the enquiry is not answered to the satisfaction of the solicitor or the client, the enquiry should be directed to the Chief Justice, who will then consult with the Judge who has reserved judgment.

5. If the delay is that of the Chief Justice, the enquiry should be made to the Senior Puisne Judge.

6. If any solicitor is reluctant to make a direct approach as set out above, he or she should write to the President of the Tasmanian Bar Association in confidence advising details of the proceeding number, the parties, the name of the Judge and the date of reservation. The President will then write to the Chief Justice (or Senior Puisne Judge) without identifying the solicitor on whose behalf the enquiry is made and the Chief Justice (or Senior Puisne Judge) will then consult with the Judge who has reserved judgment.

7. After consultation with the Judge who has reserved judgment, the Chief Justice (or Senior Puisne Judge) will respond to the President's enquiry for forwarding to the solicitor making the original enquiry.

8. This Protocol is similar to one operating in Victoria, which is said to have operated satisfactorily from its inception. It is made in response to a request from the Tasmanian Bar Association.’

³⁹ ‘Ethical guidelines for judges’ para 17 published at 117 (2000) *SALJ* 406. These guidelines were adopted by the heads of court and apply to all judges.

before them, whether in bringing them on for hearing or in issuing decisions when they have been heard.’⁴⁰

In *Goose v Wilson Sandford and Co*⁴¹ the Court of Appeal censured a judge for his delay in delivering a reserved judgment and said:

‘Compelling parties to await judgment for an indefinitely extended period . . . weakened public confidence in the whole judicial process.

Left unchecked it would be ultimately subversive of the rule of law.’

THE MERITS

[40] In order to succeed, the applicants have to persuade us that there is a reasonable prospect of success in the appeal. Once an application of this kind is referred to oral argument there is no reason to have two hearings, one to ascertain whether there are reasonable prospects and a second to determine the merits of the appeal. The respondents, forewarned that this established procedure may be followed, decided, as mentioned, not to address these issues.⁴² Although we have been deprived of the privilege of their argument, we are fortunate to have a full judgment of the majority of the court below which dealt favourably with most of the points raised by the respondents in their papers. One can also glean from the affidavits, which contain much by way of argument, and the minority judgment what the

⁴⁰ *Boodhoo & Ors v. Attorney General of Trinidad and Tobago (Trinidad and Tobago)* [2004] UKPC 17 (PC).

⁴¹ The Law Times Reports (Feb 19, 1998) 85 at 86.

⁴² They are not the first to do so: *Letterstedt v Morgan* (1849) 5 Searle 373.

respondents' contentions would have been. Cowed by the respondents' refusal to be of any assistance we cannot be. Organs of state, who have a constitutional duty to, *inter alia*, assist courts to ensure their effectiveness,⁴³ 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.

LEGALITY

[41] In *Gerber v MEC of the Gauteng Provincial Government, Development Planning & Local Government* [2002] 4 All SA 518, 2003 (2) SA 244 (SCA) at para 35 it was pointed out that –

‘The Republic of South Africa is a constitutional State. Local authorities and other State institutions may act only in accordance with powers conferred on them by law. This is the principle of legality, an incident of the rule of law.’

This brings me to the main thrust of the attack on the validity of the regulations, which is that they lack legality or, in pre-Constitutional parlance, that they are *ultra vires*. As was said by Chaskalson P,

‘What would have been *ultra vires* under the common law by reason of a functionary exceeding a statutory power is invalid under the Constitution according to the doctrine of

⁴³ Constitution s 165(4).

legality. In this respect, at least, constitutional law and common law are intertwined and there can be no difference between them.’⁴⁴

The learned President further pointed out that the doctrine of legality, as an incident of the rule of law, was an implied provision of the interim Constitution; that it is 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; and that the Constitution in specific terms now declares that the rule of law is one of its foundational values.⁴⁵ In this regard it is well to remember that it is not the function of the judiciary

‘to “second guess” the executive or legislative branches of government or interfere with affairs that are properly their concern’

but that

‘[a]dherence to the prescribed forms and procedures and insistence upon the executive not exceeding its powers are important safeguards in the Constitution’⁴⁶

and that questions of legality cannot be decided on the basis that the minister or the committee acted in good faith.⁴⁷

⁴⁴ *Pharmaceutical Manufacturers Association of SA: In re Ex parte President of the RSA* 2000 (3) BCLR 241; 2000 (2) SA 674 (CC) para 50.

⁴⁵ Para 17. He referred to *Fedsure Life Assurance Ltd v Greater Johannesburg Transitional Metropolitan Council* 1998 (12) BCLR 1458; 1999 (1) SA 374 (CC) para 56-59 and *President of the Republic of South Africa and Others v South African Rugby Football Union and Others* 2000 (1) SA 1; 1999 (10) BCLR 1059 (CC). See also *Minister of Home Affairs v Eisenberg* 2003 (8) BCLR 838; 2003 (5) SA 281 (CC) para 39.

⁴⁶ *Executive Council of the Western Cape Legislature v President of the RSA* 1995 (10) BCLR 1289; 1995 (4) SA 877 (CC) para 99.

⁴⁷ At para 100.

[42] In order to determine the scope of the minister's powers in promulgating the regulations in contention the logical starting point is an interpretation of the Medicines Act. The Act must be read in the light of s 27(1) of the Bill of Rights, which provides that everyone has the right to have access to health care services, including reproductive health care and that the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this right. One has to agree that the right of access to health care includes the right of access to medicines although this right is not without limitations.⁴⁸ It is also correct that the prohibitive pricing of medicines may be tantamount to a denial of the right of access to health care. All that is really common cause. What is not, is how parliament has sought to achieve the progressive realisation of this right through the provisions of the Act.

[43] There is another dimension of the right in issue, namely the negative obligation resting on the state to desist from preventing or impairing the right of access to health care services.⁴⁹

[44] As initially promulgated, the Medicines Act was called the Drugs Act and provided for the registration of drugs for human use, the establishment of a Drugs Control Council and matters incidental thereto. It has been the

⁴⁸ *Soobramoney v Minister of Health, KwaZulu-Natal* 1998 (1) SA 765, 1997 (12) BCLR 1696 (CC).

⁴⁹ *Minister of Health v Treatment Action Campaign (2)* 2002 (10) BCLR 1033; 2002 (5) SA 721 (CC) para 46.

subject of repeated amendments, including one in 1974 when a name change to the Medicines and Related Substances Control Act took place.⁵⁰ The word ‘control’ was removed from the name by s 28 of the Medicines and Related Substances Control Amendment Act 90 of 1997. When courts have said⁵¹ that the purpose of the Medicines Act was directed at the control of medicines and so-called related substances, to regulate the manner in which scheduled substances were made available to members of the public, to control the quality and supply of medicines generally and to protect the citizenry at large, they were not dealing with the provisions introduced by the amending Act. Some are of particular significance to this case, namely sections 15C, 18A, 18B and 22G. In order to determine the purpose and meaning of the provisions introduced by amending Act one has to delve deeper.

[45] It needs to be mentioned in parenthesis that the Medicines Act was supposed to have been repealed – save for some provisions including those just mentioned – by the South African Medicines and Medical Devices Regulatory Authority Act 132 of 1998. Because of certain problems, the

⁵⁰ Drugs Control Amendment Act 65 of 1974 s 35.

⁵¹ *Administrator, Cape v Raats Röntgen and Vermeulen (Pty) Ltd* 1992 (1) SA 245 (A) 254B-G; *Mistry v Interim Medical and Dental Council of SA* 1998 (7) BCLR 880; 1998 (4) SA 1127 (CC) para 10-11.

promulgation by the President of this Act was set aside.⁵² Since then the repealing Act itself has been repealed.⁵³

[46] The Medicines Act has no preamble and its long title is singularly uninformative. It provides for the registration of medicines and states that only registered medicines may be sold (s 14(1)). They, and related substances,⁵⁴ are classified. In general terms, schedule 0 drugs may be sold in an open shop; schedule 1 drugs may be sold by pharmacists without a prescription; schedule 2 drugs may also be sold by pharmacists without a prescription but only under stricter conditions; schedule 3, 4, 5 and 6 substances may be sold by a pharmacist but only with a prescription; whereas schedule 7 and 8 substances are prohibited substances (s 22A). Persons other than pharmacists who are registered under the Health Professions Act 56 of 1974 may be licensed to dispense medicines (s 22C(1)(a)). The Act also recognises the existence of a chain of supply for medicines, and manufacturers, importers, wholesalers and distributors must all be licensed (s 22C(1)(b), s 22H). It follows from this that dispensers of pharmaceuticals are considered essential to the provision of medicines to the public, especially since the number of dispensing doctors is subject to regulation (s 22C(1)(a)). It also follows that the viability of the dispensing

⁵² *Pharmaceutical Manufacturers Association of SA: In re Ex parte President of the RSA* 2000 (3) BCLR 241; 2000 (2) SA 674 (CC).

⁵³ Medicines and Related Substances Act 59 of 2002 s 14.

⁵⁴ For purposes of this judgment reference will not be made to 'related substances'.

profession is a matter of public interest and was a matter of concern to the legislature. I shall deal in more detail with this aspect later.

[47] It is common cause that s 22G is concerned with the provision of more affordable medicines. There are hardly any contextual guidelines available to determine its meaning. (In due course I shall refer to its history because that throws some light on its scope.) One contextual pointer, however, is s 15C, which provides that the minister may prescribe conditions for the

‘supply of more affordable medicines in certain conditions for the supply of more affordable medicines to protect the health of the public’.

The ‘conditions’ are carefully circumscribed: they deal with parallel importation of patented medicines and the importation of medicines identical to others already registered, ie, to obviate or limit the registration procedures for new suppliers of medicines already on the market. The present regulations, it needs to be emphasised, do not purport to and could not have been promulgated under this section.

[48] Instead the regulations were, as mentioned, made under s 22G, which in its present form provides as follows:

‘22G ‘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.

(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 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.’

[49] It is clear that the minister’s powers to make regulations is dependent on the recommendation of the pricing committee, in other words, such a recommendation is a jurisdictional fact. The 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.

TRANSPARENT PRICING SYSTEM

[50] Section 22G permits regulations that introduce a ‘transparent pricing system’. The concept is not defined and must therefore be given its ordinary meaning unless there are reasons for not doing so. The only qualifier for the pricing system is that it must be ‘transparent’, ie, open to public scrutiny. This is explained further in para (3)(a), which provides that the system must include a single exit price that has to be published in a prescribed manner.

[51] Some aspects need to be emphasised:

- (a) The ‘single exit price’ is the price charged by the ‘manufacturer’.
- (b) The manufacturer may sell at that price only to persons other than the state.
- (c) The Act itself draws a clear distinction between a ‘manufacturer’, an ‘importer’, a ‘wholesaler’ and a ‘distributor’.
- (d) An importer, wholesaler or distributor may not sell medicines at a price higher than the manufacturer’s single exit price.

- (e) The only exception may be schedule 0 medicines: wholesalers, distributors and other vendors may charge a prescribed 'appropriate' fee in addition to the manufacturer's single exit price.
- (f) A dispenser may also not sell at a higher price than the manufacturer's exit price.
- (g) However, a dispenser may charge a prescribed 'appropriate dispensing fee'.
- (h) These provisions must be read in the light of s 18A and 18B: section 18A prohibits the supply of medicines according to a bonus system, rebate system or other incentive system while s 18B prohibits the supply of free samples.

[52] 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’⁵⁵ purchases medicines from a manufacturer abroad and to define the single exit price as the price not only set by the manufacturer, but, alternatively, by the importer.⁵⁶ 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 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.

[53] An associated problem the committee obviously had was that the Act does not allow wholesalers or distributors to charge more than the manufacturer’s single exit price. However, the Act does not prohibit wholesaling or distributing by third parties (because that would have amounted to a breach of the constitutional obligation not to make medicines inaccessible) and since it requires them to be licensed, one has to accept that the Act regards them as a link in the supply chain. The only limitation the

⁵⁵ “‘Importer’ means 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.”

⁵⁶ The full definition reads: “‘Single 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.” [Emphasis added.]

Act places on wholesalers is to oblige them to purchase from the original manufacturer or the primary importer of the finished product (s 22H).

[54] In order to solve the problem the committee devised the idea of a logistics fee, which is payable in respect of ‘logistical services’. These are defined to mean –

‘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.’

The manufacturer or the importer has to agree with the wholesaler or distributor on this fee. 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.

[55] All 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.⁵⁷ To deem their mark-up as part of the manufacturer's price is an impermissible simulation.⁵⁸

[56] There is another problem that goes to the root of this regulation. Providing for a 'transparent' pricing system was the whole object of the exercise. The Act says so in terms but the logistics fee is not transparent precisely because it is a fee negotiated privately between the manufacturer and wholesaler. Although the minister may prescribe a maximum (probably impermissibly, as an improper delegation), that in itself does not make the fee transparent.

[57] Next to consider is whether s 22G permits, through the pricing system, price control by the state and, if not, whether the regulations provide for price control. As Yekiso J correctly pointed out, the legislative history of the enactment shows that its purpose is 'the elimination of the system of discounts and subsequent mark-ups which had the effect of rendering medicine unaffordable, particularly to the poor section of our population' because

⁵⁷ The regulations define 'wholesaler' as 'a dealer who purchases medicines or Scheduled substances from a manufacturer and sells them to a retailer and includes a wholesale pharmacy.' [Underlining added.]

⁵⁸ The second respondent, according to her affidavit, thought that the transparent pricing system as contemplated by the Act included a logistics fee. She may have been confusing the regulations with the Act.

‘the discounting and the subsequent marking-up of pharmaceutical products that characterised the sale of such products in the past, had the effect of negating the right to healthcare enshrined in section 27(1) of the Constitution.’

Therefore –

‘Section 22G was enacted to address the mischief of the system of discounting and the subsequent marking-up of pharmaceutical products in circumstances where it was not known how the price, which the end user or consumer or patient had to pay, was arrived at.’

[58] In other words, since manufacturers are obliged to sell to all and sundry at a single exit price that is transparent and may not give discounts, the public will be able to know what the true price of the goods are. And since dispensers are only entitled to add a prescribed fee, a member of the public would be able to assess whether the price paid is the correct one. Because 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.

[59] That is the price reduction mechanism envisaged by the section. It does not contemplate a system whereby the committee, the state or the regulations can fix or limit the manufacturer’s exit price. Although this is clear from the section as a whole it is comforting to know that the

department⁵⁹ agreed with this interpretation as did the court below⁶⁰ although the second respondent did not in her affidavit.

[60] The majority found that ‘the State does not play a role in the determination of the single exit price.’ The problem with this finding is that it was made without any regard to the specifics of the regulations. Although reg 5(1) provides that the manufacturer must set the single exit price upon the commencement of the regulations, reg 5(2) immediately set a cap on that price: it could have been no more than a price calculated with reference to a formula based on prices that prevailed during the year 2003. It becomes more intricate when the regulations deal with new medicines. Then the price of the medicine 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 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.’⁶¹

(The other countries are not specified, but that is a discrete problem.)

[61] The next phase is the determination and publication by the director-general of –

⁵⁹ Per the director-general, Mr Ntsaluba, in previous litigation under oath.

⁶⁰ Per Yekiso J: ‘It is worth repeating that the single exit price referred to in the Act and the Regulations is set by the manufacturer or the importer of the relevant medicine or Scheduled substance. The single exit price has to be set by the manufacturer or the importer concerned.’

⁶¹ Reg 5(2)(c) proviso.

‘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 the prices of medicines and Scheduled substances are regulated and published’.⁶²

Within three months thereafter the single exit price must –

‘conform with international benchmarks in accordance with such methodology.’⁶³

[62] Finally, for a period of one year the single exit price may not be increased; it may not be increased more than once a year and the extent to which it may be increased is to be determined by the minister after consultation with the committee.⁶⁴

[63] In the light of this elementary analysis of the pricing system contained in the regulations it is impossible to subscribe to the finding of Yekiso J that ‘the applicants’ concern as regards the Regulations complained of, namely, that they restrict the manufacturers’ and the importers’ right to determine a single exit price, has no merit.’⁶⁵

While the Act contemplates the imposition of a downward pressure on the prices of medicines through the introduction of a transparent pricing system, the committee thought that it contemplates direct price control. In its submission to the minister, which accompanied the draft regulations, it

⁶² Reg 5(2)(e).

⁶³ Reg 5(2)(e).

⁶⁴ Regs 5(2)(a) and (b), 7 and 8.

⁶⁵ At para 53.

explained that ‘the regulation of medicine prices is both justifiable and necessary’ and proceeded to set out how manufacturers’ prices would be ‘reduced’ and ‘managed’ in the way set out above. Yekiso J quoted a number of extracts from the minutes of the committee which are consistent with the contents of the memorandum. He found, however, that these references were selective and that, having regard to the record as a whole, the inference that the committee had regard to irrelevant considerations was unjustified. Unfortunately, he did not provide any references from which a contrary conclusion can be drawn and I could not find any. Whether the regulation of medicine prices is justifiable or necessary and how it should be done are matters for parliament to decide. It chose the limited option contained in s 15C. It was not for the committee to pursue its own agenda, irrespective of how commendable its motives may have been, and the minister was not entitled to accept a recommendation that did not fall within the parameters of the Act.⁶⁶ In a country struggling with limited resources to meet the needs of the poor it is laudable and noble to strive to reduce the costs of medicines. We are, however, a nation that subscribes to the primacy of the rule of law and all measure to that end must comply the principle of legality.

⁶⁶ Cf *Goldberg v Minister of Prisons* 1979 (1) SA 14 (A) 48E.

[64] Another problem with the regulations in this regard is the fact that while the Act requires that the regulations should prescribe the method of publication of the single exit price, the regulations have delegated the function to the director-general.⁶⁷ This the Act does not permit.

[65] The regulations, insofar as they deal with a transparent pricing system, consequently fail the legality test on many fundamental aspects.

SCHEDULE 0 MEDICINES

[66] It is convenient to deal now with the regulations where they purport to prescribe, in the words of s 22G

‘an appropriate fee to be charged by wholesalers or distributors or by any other person selling Schedule 0 medicines.’⁶⁸

It will be recalled that sch 0 medicines are those that can be sold in an open shop.

[67] There is once again a problem with the Act. While it allows for the setting of fees to be charged by vendors of sch 0 medicines, it simultaneously prohibits the sale of sch 0 medicines at a price higher than the single exit price. The only add-on permitted is the fee of the dispenser

⁶⁷ Reg 3: ‘In order to promote transparency in the pricing of medicines . . . a manufacturer or . . . the importer of a medicine . . . shall publish, where applicable, the following information in such manner and format, at such time intervals, upon such conditions and in such media as may *be determined by the Director-General from time to time by notice in the Gazette.*’ [Emphasis added.]

⁶⁸ This is the result of a 2002 amendment.

and, unless one indulges in hermeneutical gymnastics, the fee of the wholesaler or distributor, though prescribed, cannot be added to the 'single exit price'. But that has nothing to do with the validity of the regulations and I shall approach the matter on the basis that there is no prohibition on the addition of the fee to the single exit price.

[68] In its final recommendation to the minister, the committee noted that in its view substantial competition prevails in the sch 0 market. It therefore recommended that all retailers be allowed to sell these medicines with a percentage mark-up as they have done in the past, save that the mark-up may not exceed what it was at the time of the introduction of the regulations. Regulation 13 accordingly 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.'

[69] Because sch 0 medicines are subject to a single exit price and that price does not allow for any mark-up or fee for wholesalers or distributors, by excluding them from reg 13, the regulation in effect determines that wholesalers and distributors are not entitled to any fee, let alone an appropriate fee.

[70] The mark-up of each individual retailer on each individual product, which it had on the shelf on 2 May, cannot be considered to be a ‘fee’. A ‘fee’ is in ordinary parlance a payment made to a professional or para-professional in exchange for advice or services. It is not the same as a gross profit or a mark-up on goods. There must in the light of the regulations be tens of thousands of ‘fees’ in the market place. The Act insists that the ‘fee’ must be ‘appropriate’. There is no basis for the assumption that the mark-up on a particular medicine on a particular day by a particular retailer can ever amount to an appropriate fee. For instance, the item could have been sold as a loss leader on the relevant date, in which event the product must be sold at a loss in perpetuity. On the other side of the coin, if the item was then sold at an excessive price, the retailer will be able to carry on selling at that price.

[71] The regulations, insofar as they deal with sch 0 medicines, once again do not pass muster. Yekiso J, while holding the contrary gave no reasons for his conclusions – except that retailers would have known what their mark-ups were – and did not deal with the issues raised in the preceding paragraphs.

‘APPROPRIATE DISPENSING FEE’

[72] While s 22G permits the minister, on the recommendation of the committee, to make regulations on an ‘appropriate dispensing fee’ to be

charged by a pharmacist or a person licensed in terms of section 22C(1)(a), the Pharmacy Act 53 of 1974 (in s 49(1)(a)) allows the minister, in consultation with the Pharmacy Council, to make regulations relating to ‘the practice of pharmacy, the conduct of the business of a pharmacist, the tariff of fees payable to a pharmacist in respect of professional services rendered by him and the trading activities of a pharmacist’.

[73] This apparent contradiction gave rise to different interpretations in the court below. Traverso DJP sought to solve the problem by holding that s 22G did not permit the making of regulations that fix professional fees but only to prohibit the giving of rebates on dispensing fees or require their publication by pharmacists. I cannot agree because the attempt to harmonise the two provisions appears to me to be forced. The correct way to approach the matter is to consider that s 22G is a narrow provision while s 49(1)(a) is a general provision. The general provision must yield to the specific. Consequently, the minister may make regulations relating to the quantum of dispensing fees under s 22G and under the Pharmacy Act the tariff of all other fees, excepting dispensing fees, may be prescribed. If no regulations are made under s 22G, dispensing fees may be set under the Pharmacy Act.

[74] The Medicines Act, in requiring dispensing fees, gives recognition to the fact that dispensers are first and foremost professionals and not traders in medicines. Although the advisability of the new scheme was debated at

some length by some deponents, this is not open to question because parliament has made a policy decision in this regard and the constitutionality of s 22G is not in issue. Even though dispensers perform a professional function, their fee cannot be based on a simple time-related basis because, in order to provide their service they have to incur business related operating costs like labour, stock management, capital costs, the financing of stock and debtors (including medical aid schemes) and the like. Hospital pharmacies, for instance, are required by law to have certain medicines in stock and, while the average pharmacy may keep 2000 stock items, they generally stock between 10 000 and 12 000 line items.

[75] The next issue is the justiciability of the regulations in relation to the quantum of the dispensing fees. The section requires the dispensing fee to be ‘appropriate’. What is appropriate was not left to the discretion of the minister, and also not to that of the committee. In this regard there is a clear break from the approach adopted in matters such as security legislation during the pre-Constitutional era. There, the jurisdictional fact was quite often the opinion of one or other functionary and, provided the functionary held the opinion, courts were rather hamstrung. Here the jurisdictional fact is not someone’s opinion but an objective fact, namely a dispensing fee that must be ‘appropriate’. Whether it is appropriate, can be tested judicially. If

the fee does not pass this threshold requirement, the regulation is *pro tanto* void because it has no legal basis or justification.⁶⁹

[76] The word ‘appropriate’ means ‘specially suitable’ or ‘proper’.⁷⁰ In *Hoffmann v South African Airways* 2000 (11) BCLR 1211; 2001 (1) SA 1 (CC) paras 42-43 the court had to determine its meaning in the context of ‘appropriate relief’ as contemplated by section 38 of the Constitution.

Ngcobo J said that

“‘appropriate relief’ must be construed purposively, and in the light of section 172(1)(b), which empowers the Court, in constitutional matters, to make “any order that is just and equitable.” Thus construed, appropriate relief must be fair and just in the circumstances of the particular case. Indeed, it can hardly be said that relief that is unfair or unjust is appropriate. As Ackermann J remarked, in the context of a comparable provision in the interim Constitution, “[i]t can hardly be argued, in my view, that relief which was unjust to others could, where other available relief meeting the complainant’s needs did not suffer from this defect, be classified as appropriate.” Appropriateness, therefore, in the context of our Constitution, imports the elements of justice and fairness.’

‘Fairness requires a consideration of the interests of all those who might be affected by the order. In the context of employment, this will require a consideration not only of the interests of the prospective employee but also the interests of the employer.’

[77] In the present context, I believe, the word has a similar connotation. It can hardly be argued that a dispensing fee, which is unjust or unfair, can be

⁶⁹ *SA Defence and Aid Fund v Minister of Justice* 1967 (1) SA 31 (C) 34H-35D; *President of the Republic of South Africa v South African Rugby Football Union* 2000 (1) SA 1 (CC) para 168 footnote 132.

⁷⁰ Shorter OED.

‘appropriate’. One has to assume that the legislature did not intend unjust or unfair fees. In determining what is appropriate one must consider the conflicting interests of all those involved and affected. On the one hand there is the public, which is entitled to access to health care including affordable medicines. On the other hand there are the interests of dispensers who, in terms of 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. As the minister herself once said:

‘The pharmacy profession with its various specialities is a crucial role-player in this regard. It embodies the knowledge spectrum of formulating, manufacturing, quality control, efficacy, safety, appropriate usage, and drug supply management of drug products.’⁷¹

One is really dealing with the balancing act implicit in the right of access which, as mentioned, encompasses positive and negative obligations on the state. Affordability is not the only dimension; access is just as important. Cheap medicines available at two hypermarkets provide cold comfort to the poor living in a township or on the platteland. This means that, in order to be appropriate, the fee must be such that affordable medicines do not become inaccessible.

[78] To avoid any misapprehension about the scope of s 22G, it must be emphasised that it deals with the private sector only. Medicines sold to the

⁷¹ The text of her speech forms part of the papers.

state or dispensed by the state are excluded from its operation. Those who are dependent on the state for access to health care receive no benefit from the regulations, nor does the state.⁷²

[79] There is not an absolute standard for being appropriate and more than one fee can be appropriate. The word carries with it a measure of elasticity and reasonable persons may within reason disagree on what is and what is not appropriate. A fee structure may, for instance, be appropriate within the meaning of s 22G even if it leads to the closure of some pharmacies because the prescribed fee need not keep all pharmacies afloat or provide all pharmacists with gainful employment. The fee, also, should not cross-subsidise the unprofitable parts of a pharmacist's business. But the fee should not be such that only a few large dispensers located in relatively affluent areas with huge turnovers can survive.

[80] The Act does not define 'dispensing'. Ordinarily it means to make up medicine or to supply it according to a doctor's prescription. In this case the question arose whether it included formulation or compounding and whether a dispenser is entitled to charge, under the Act, additionally for compounding. It arose in the context of the appropriateness of a fee of R104,00 for reconstituting and preparing a set of chemotherapy drugs, which

⁷² The applicants estimate that the private sector's expenditure on medicines accounts for 70% and the state's for 30% of all funds spent. On the other hand, the private sector consumes 30% and the state 70% by volume. This indicates the great discrepancy between the two systems, something the Competition Commission is concerned about. The respondents deny these estimates but do not explain their denial.

may take an hour and a half to prepare, which requires special equipment and procedures, and where the cost to the pharmacist of the medicines amounts to R2 146,62 or, in another instance, a fee of R26,00 for compounding, taking two and a half hours, of medicine costing R8 715,00. In the answering affidavits the respondents attempted to justify the fee by stating that compounding can be charged for separately. The deponent on behalf of the minister (who was a member of the committee) and the second respondent (its chair) were not in agreement as to exactly what can be charged extra. But all that is really of no consequence. Section 22G is clear. It prohibits any add-ons except the prescribed dispensing fee. Whatever one understands under the term, it is all that can be added to the single exit price. Any other interpretation would defeat the object of the Act. This illustrates that the committee misunderstood the Act and that impacts materially on whether the prescribed fee is indeed appropriate.

[81] The fee prescribed to be charged by pharmacists has to be calculated as follows (reg 10):

‘(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.

(2) With regard to medicines and scheduled substances falling into Schedules 3, 4, 5, 6, 7, and 8 of the Act, and medicines and Scheduled 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.’

[82] The simplest way of determining whether these figures, which appear to have been calculated since they are not round figures, represent fees that are appropriate would have been to have regard to the record of the committee’s meetings or to the respondents’ evidence as to how they were calculated. 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.⁷³ Yekiso J surmised that the committee's recommendation 'was obviously preceded by some factual background' but if it were, the committee's deafening silence is not understood. Assuming that it took, in the learned judge's words, 'a conscious decision' that these fees are 'appropriate' (of which there is no evidence) that is of no assistance in the absence of an explanation as to how or why it took the decision.

[83] Bereft of an explanation from those in the know, it is necessary to deal with the expert evidence filed by the applicants. Dr Robert Stillman, a highly qualified economist, who runs an international consultancy specialising in the economics of competition policy and regulation called Lexecon, did a financial analysis to assess the likely impact of these fees on the future economic viability of different segments of the pharmacy profession. He concluded that the fees will not provide pharmacists in any of the sectors analysed with sufficient revenues to cover their operating costs.

[84] His conclusion was based on a careful and detailed analysis of factual data and cannot be dismissed as 'sheer speculation' as Yekiso J did without any analysis of the facts. There is a difference between speculation on the one hand and prediction on the other. Stillman took as his starting point the actual figures of a number of pharmacies for April 2004. He recalculated

⁷³ It is possible that the committee had worked on the fact that the average gross profit of pharmacies was about 25% and then conflated gross profit with mark-up.

their operating profit or loss on the assumption that the regulations had been in force during that month. For example, in relation to courier pharmacies, which provide an indispensable service to those who are bedridden or housebound, he analysed the operations of one of the three largest companies, CMD, and concluded that for the month tested, its gross profit margin would have been reduced by 37% which would have eliminated its operating profits and would have left it with an operating loss equal to 5,1% of sales.⁷⁴ He did a similar exercise in relation to the New Clicks pharmacies, which are community pharmacies, and found that the operating profit margins would have been negative in 67 of the 69 stores covered. His analysis of the impact on pharmacies in medical centres was that they would have suffered an operating loss equal to 20% of revenue. Hospital pharmacies would have suffered an operating loss of 8,7% of revenue.

[85] Mr Willem Jordaan, a pharmacist with a master's degree in pharmaceutical economics, did a detailed exercise in relation to the New Clicks pharmacies. In this he excised the front shop activities in order to isolate the effect of the fees on the dispensing business and to exclude the effect of cross-subsidisation. He calculated the net loss per line item to be R5,33.

⁷⁴ Yekiso J found that since the regulations under the Pharmacy Act do not recognize courier pharmacies as a separate category for registration purposes, the pricing regulations could not cater for them. I disagree. These regulations could easily have categorized pharmacies for its own purposes and the committee was not bound by another classification for other purposes.

[86] The answer on behalf of the first respondent was one of a denial which was to be demonstrated by expert evidence. Prof Mooney, an Australian expert, gave an exposition why the free market system does not work for pharmaceuticals and why regulation is required, none of which was ultimately helpful in determining the answers to the questions before us. Mr Pillay, the director of pharmaceutical economic development in the department, who one would have expected knew how the fees were calculated, limited his evidence to the question whether a gross profit of 26% is required to maintain a viable pharmacy and said that he had found that some pharmacies with a higher gross profit were not viable and others with a lower one were. (This has nothing to do with the present question.) He did not deal at all with the Lexecon report and as far as Jordaan is concerned, he simply said that there were uncertainties with the analysis without identifying them. He added, without substantiating the allegation, that the prescribed dispensing fees do not differ significantly from those in other countries. Prof Mossialos expressed a similar opinion, namely that the fee is 'quite reasonable by international standards' but he also gave no factual basis for his opinion. Prof Henry, also from Australia, let the proverbial cat out of the bag when he said that the committee (of which he was a member) was 'concerned primarily about the affordability'. He gave no indication that the viability of the dispensing profession was ever

considered. He conceded that it is difficult to make a judgment of the appropriate level for a dispensing fee and he then made some international comparisons.⁷⁵ Australia, for instance, allows a dispensing fee equal to R23,00 but then it allows an additional retail margin. Because the result of the comparison did not suit him, he made adjustments, taking into account the purchasing power of the two currencies.

[87] The last witness for the respondents on this aspect was Dr Thiede, the deputy director of the Health Economics Unit at the University of Cape Town. He was also a member of the committee and he, too, in spite of his expertise, chose to keep everyone in the dark as to how the fees were calculated. He questioned Jordaan's evidence because the sample was not random, the allocation between back-shop and front-shop could only have been approximate and he could not on the facts provided make a recalculation.

[88] In a separate affidavit he took brief issue with the Lexecon report.

Basic to his evidence is that he believed

‘that the dispensing fee is only one fee in a catalogue of fees the pharmacist may charge, such as for example for compounding.’

(I have already pointed out that this assumption is flawed.) What other fees he had in mind, is unclear, unless he thought that functions like taking blood

⁷⁵ Whether the fee is lower in, say, Botswana, does not indicate whether the public there has reasonable access to dispensers or whether the bulk of medicines is supplied by the state.

pressure (which have always been done free of charge) could provide an income stream. He also did not attempt to quantify that kind of income which, on the evidence, is negligible (less than 1%). He further, blandly, attacked the expertise of Stillman, and stated without motivation that the methodology did not conform to rigorous scientific studies and that the sample was not a random one. The reply indicated that he was misinformed. It is significant that he nowhere gave any factual data to dispel the applicants' evidence.

[89] This brief analysis of the evidence on record shows that there is no bona fide dispute of fact. It establishes that the fees are not appropriate and that the respondents, within whose peculiar knowledge the calculation fell, were unable to give any rational explanation for the quantum of the fees. The access to medicines is seriously threatened because they are insufficient to cover the cost of dispensing. This conclusion is not based on the opinion of pharmacists but on the unassailed factual material on record. It is not without significance that the Congress of SA Trade Unions, the Consumer Goods Council and the *amicus curiae* came to the same conclusion.

[90] There appears to be an explanation for the inability of the respondents to justify the fees. It flows from the fact that the different functions of the department and those of the committee were not kept in mind, and the

working methods of the committee. According to the Act, the committee has to make the recommendations. The only function the department has until a report is presented to the minister is that of the committee's secretariat.

[91] After the draft regulations were published, the committee decided that oral representations by stakeholders should be organised by the department. These were to be led by the department, 'but the Pricing Committee members will also be invited.' In consequence of the decision the director-general invited stakeholders to make oral presentations. The terms of the letter are revealing (I quote selectively):

'The purpose of these sessions is to hear oral representations 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 regulation.'

'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.'

'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 added.]

[92] Days were set aside for this purpose. Sometimes committee members attended, sometimes not, sometimes haphazardly. Many stakeholders made detailed oral presentations (with visuals) on the effect of the proposed fees. Was this a presentation to the department or to the committee? The second respondent, justifying the fact that the committee did not consider the oral representations, said it was to the department. For what purpose, she did not say because, as mentioned, the department had no function except a secretarial one. Dr Zofuka, on behalf of the minister, unflinchingly said that the committee considered ‘all the submissions and comments’ but elsewhere admitted that they considered the written ones only. Yekiso J found no fault with these perplexing events, holding that there was nothing to show that the meetings were ‘formal meetings of the committee’ or that the committee was under a duty to afford stakeholders an opportunity to make oral representations. To my mind the facts speak for themselves. There was no reason to mislead stakeholders by inviting them to participate in a futile exercise or to ignore relevant and available material during the committee’s deliberations. It is not necessary for me to deal further with this aspect of the case because of the finding that the regulations do not prescribe a dispensing fee that is appropriate.

CONCLUSION

[93] Thus far the findings are that the regulations have, on many material aspects, failed the test of legality. Sometimes problems arose as a result of the enabling Act, sometimes it was because of a misunderstanding of the scope of the Act. The applicants allege in addition that some of the provisions are vague and void for that reason and they submit that there are instances of impermissible delegation of powers where matters, which should have been prescribed, have been left for the minister or the director-general. Some of these arguments cannot as be dismissed as easily as the majority below was able to do and some cannot be accepted as the dissenter did, but for present purposes it is not necessary to deal with them.

[94] The question whether ministerial regulations and the recommendations of the committee could have been the subject of scrutiny under the Promotion of Administrative Justice Act 2 of 2000 formed a large part of the judgments below. The majority held that they could not and the minority held otherwise. Notwithstanding they were agreed that the regulations had to withstand the test of legality. The debate, consequently, has no bearing on this judgment and I prefer to refrain from commenting save for saying that I find it unlikely that this Act, written in the light of the

Constitution and supposedly written to codify administrative justice principles, reduced the level of administrative justice.

[95] The *amicus curiae*, while submitting that the regulations, at least as far as the dispensing fee is concerned, are void, requested that any declaration of invalidity should be suspended to enable the committee to prepare a new set. There are a number of problems in this regard. As mentioned, s 22G save for minor amendments, has been since 1997 on the statute book and was only brought into effect in 2004. That may give an indication of the ability of the respondents to formulate regulations within a reasonable period. As found, the regulations are fatally defective. It will be extremely difficult, if not impossible, to draft sensible regulations unless the Act is amended. The respondents did not, in their papers, raise the possibility of a suspension and did not place any facts before the court below on which a decision to suspend can be made; neither did the *amicus curiae*. The regulations have been in effect during May and then after the judgment below, for less than four months. It is not as if a long existing pricing regime is being upset or that existing rights are affected. In short, the request does not satisfy the guidelines laid down for a suspension.⁷⁶

⁷⁶ *Mistry v Interim Medical and Dental Council of SA* 1998 (4) SA 1127 (CC) para 37.

ORDER

[96] The following order is made:

1. Leave to appeal is granted in both applications.
2. The appeals are upheld.
3. The first respondent is ordered to pay the costs, including the costs of two counsel in each matter.
4. The order of the court below is set aside and replaced with the following order in each application:

(a) The ‘Regulations relating to a Transparent Pricing System for Medicines and Scheduled Substances’ as published in GN R553 on 30 April 2004 are declared invalid and of no force and effect.

(b) The first respondent is ordered to pay the costs of the applicant(s), including the costs relating to the interim application, such costs to include the costs of two counsel.

L T C HARMS
JUDGE OF APPEAL

CONCUR:

NAVSA JA
MTHIYANE JA
BRAND JA
CLOETE JA