



25 November 2005

Chairperson: Pricing Committee  
Pricing Committee Secretariat  
c/o Directorate: Pharmaceutical Economic Evaluations  
National Department of Health  
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Dear Sir/Madam

**SUBMISSION ON AN APPROPRIATE DISPENSING FEE AS ENVISAGED BY SECTION 22G OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965**

In an advertisement placed in the Sunday Times (dated 23 October 2005 and entitled "Call for Submissions"), the Pricing Committee invited "interested parties to provide input on an appropriate dispensing fee as envisaged in terms of section 22G of the Medicines and Related Substances Act, Act No. 101 of 1965" (the Medicines Act). In particular, the advertisement called for interested parties to "provide input on all issues that are relevant to the determination of an appropriate dispensing fee."

This joint AIDS Law Project/Treatment Action Campaign submission does not consider the matters raised in the document entitled "Issues to be addressed in submissions to the Pricing Committee", as these lie outside our areas of expertise. Instead, our submission is limited to a consideration of key legal issues raised in the Constitutional Court's decision of 30 September 2005 in *Minister of Health v New Clicks South Africa (Pty) Ltd*,<sup>1</sup> being structured into three main parts:<sup>2</sup>

- First, it summarises the three key opinions of the majority regarding the unreasonableness of the dispensing fee. At least insofar as the fixing of the fee is concerned, all of these opinions are based on the finding that the provisions of the Promotion of Administrative Justice Act, 3 of 2000 (PAJA) are applicable.<sup>3</sup>
- Second, it explores the implications of these three decisions, particularly insofar as the deliberations and recommendations of the Pricing Committee in respect of a revised dispensing fee are concerned.

<sup>1</sup> As yet unreported decision in Case CCT 59/04, available online at <http://www.constitutionalcourt.org.za/site/pharm.html>

<sup>2</sup> The submission also deals briefly with the issue of rural and courier pharmacies.

<sup>3</sup> Of the majority, three judges held that "PAJA applies to the specific power to make regulations conferred by section 22G(2)(a)-(c)" of the Medicines Act (paragraph 422), two held that "PAJA applies to the making of all regulations" and one that "PAJA is applicable to the fixing of the dispensing fee only" (paragraph 13, footnote 16).

- Third, it makes short recommendations regarding the process that we believe the Pricing Committee and Minister of Health should follow in developing, adopting and publishing a revised dispensing fee.

### **Summarising the majority decision on the dispensing fee**

In *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs*, the Constitutional Court held that section 6(2)(h) of PAJA (dealing with reasonableness review) means that “an administrative decision will be reviewable if ... it is one that a reasonable decision-maker could not reach.”<sup>4</sup> In his judgment in *New Clicks*, then Chief Justice Chaskalson held that if the dispensing fee is not “appropriate” (as required by section 22G(2)(b) of the Medicines Act), it would “be inconsistent with section 6(2)(a) of PAJA.”<sup>5</sup> Or put differently, a dispensing fee will be considered as appropriate if it satisfies the PAJA requirement of reasonableness.

But what is a reasonable dispensing fee? According to *Bato Star*, which was cited with approval by the former Chief Justice,<sup>6</sup> the following factors are relevant in determining the reasonableness of any decision, in this case the fixing of the dispensing fee:

- “the nature of the decision”;
- “the identity and expertise of the decision-maker”;
- “the range of factors relevant to the decision”;
- “the *reasons given for the decision*”;
- “the nature of the competing interests involved”; and
- “the impact of the decision on the lives and well-being of those affected.”<sup>7</sup>

Implicit in this finding is that the decision-maker must be able to justify his or her position, and in so doing, must address the various relevant factors identified in *Bato Star*. According to Chaskalson, this did not happen in respect of a dispensing fee that had been shown by the evidence to pose a real threat to the viability of pharmacies and therefore the supply of medicines. He explains:

“The Pricing Committee has provided no models or other evidence to demonstrate how the dispensing fee was calculated or how the members of the Pricing Committee satisfied themselves that it was appropriate. It has not told us what assumptions it made ... or how it assessed the dispensing fee ...

An allegation has been made by professional organisations representing pharmacists that the dispensing fee will destroy the viability of pharmacies, and impair access to health care. That allegation is supported by a *sufficient body of evidence to show that this is a real possibility*. In the circumstances the applicants were under an obligation to explain how they satisfied themselves that this would not be the result

<sup>4</sup> 2004 (4) SA 490 (CC) at paragraph 44

<sup>5</sup> *New Clicks*, above note 1 at paragraph 188

<sup>6</sup> *Ibid* at paragraph 187

<sup>7</sup> *Bato Star*, above note 4 at paragraph 45 (emphasis added and footnote omitted)

of the dispensing fee prescribed in the regulations. They were the only persons who could provide this information. They did not, however, do so. Absent such explanation, there is sufficient evidence on record to show that the dispensing fee is not appropriate.”<sup>8</sup>

In a separate judgment, which places emphasis on the basis for the decision rather than the rebutting of evidence placed on record by the respondents, Justice Ngcobo similarly focused on the need for the Pricing Committee properly “to take into consideration the viability of the [dispensing] fees for pharmacies”. “If a decision maker fails to take into account a factor that he or she is bound to take into consideration,” he argued, “the resulting decision can hardly be said to be that of a reasonable decision maker.”<sup>9</sup>

Ngcobo’s line of reasoning places significant emphasis on the lack of an explanation to justify the quantum of the dispensing fee. He explains:

“What is singularly lacking in the record is an explanation of how the dispensing fees were arrived at. There is no explanation as to why the Pricing Committee chose the figures that it chose. ... It was this lack of explanation for quantum of the dispensing fees that led the SCA to conclude that there was no rational explanation for the quantum of fees and that therefore the fees were not appropriate. ...

The failure by the Pricing Committee to explain how it arrived at the figures it adopted made it difficult to evaluate the appropriateness of the dispensing fees adopted, and thus to determine whether the Pricing Committee has properly applied its mind to the viability of pharmacies. Not having been told why the figures were adopted, it is difficult to determine whether the Pricing Committee properly applied its mind to the viability of pharmacies, and ultimately whether there was a basis upon which a reasonable decision maker could have fixed the fees in dispute.”<sup>10</sup>

Justice Sachs was similarly concerned about the basis for the fixing of the dispensing fee. According to him, the dispensing fee failed to meet the test of reasonableness because the Pricing Committee had failed to establish the basis for the setting of the quantum. While he was “not satisfied that the evidence proves that the impact of the limit of the dispensing fee will be such as to drive a disproportionate number of chemists out of business”, he was similarly unconvinced “that it will not have that effect.” Simply put, Sachs found himself “unpersuaded that the Pricing Committee and the Minister basically did not get it wrong.”<sup>11</sup>

Justice Sachs’ opinion sets out the basis for his finding – consistent with the views of other members of the majority on the issue of the dispensing fee – that it is for the state (and implicitly not those who are subject to the regulation) to justify the quantum of the dispensing fee:

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<sup>8</sup> *New Clicks*, above note 1 at paragraphs 403 and 404 (emphasis added)

<sup>9</sup> *Ibid* at paragraph 511

<sup>10</sup> *Ibid* at paragraphs 535 and 541

<sup>11</sup> *Ibid* at paragraph 666

“I believe that the principle of accountability imposes on ... [the state] a special responsibility in the particular circumstances to show that it has taken all reasonable steps to assess, take account of and justify the potential knock-on effects on the pharmacy profession of its new intervention. The more the risk, the greater the precaution. ...

There are circumstances, such as in the present case, where the nature of the matter, including its novelty and the uncertainty of its potential impact, requires persuasive evidence to indicate that the measure falls within the bounds of what is reasonable.”<sup>12</sup>

### **Implications of the judgment for the revision of the dispensing fee**

Read together, the opinions that collectively form the majority on the issue of the dispensing fee make it plain that the Pricing Committee must be able to justify the basis upon which it decides on the quantum of the dispensing fee, regardless of the information that is placed at its disposal. Whilst the co-operation of all interested parties is essential to the smooth and efficient functioning of the regulation drafting process, it is not for them to explain why a particular fee is or is not appropriate. Rather, the onus lies squarely on the state to justify the cap that it places on the dispensing fees that pharmacists may charge.<sup>13</sup>

### **Recommendations on the development, adoption and publication of a revised dispensing fee**

The judgment of the Court states that “in order to promote the transparency required by the Act and the foundational value of the rule of law, it is necessary to make an order requiring the Minister to republish the regulations as a whole so that they reflect the correct legal position as set out in ... [the] Court’s order.”<sup>14</sup> The same line of reasoning applies with equal force to the redrafting of regulations 10 and 11.

We therefore recommend that the Pricing Committee and the Minister of Health take great care in ensuring that when they comply with the order in *New Clicks*, they work openly and accountably by taking the following steps:

- In its recommendation to the Minister (on the basis of which she will revise the dispensing fees), the Pricing Committee should identify the concerns raised by interested parties and explain the basis for accepting or rejecting the concerns raised. In addition, it should explain the basis upon and the methodology in terms of which the new recommendation was adopted.
- In promulgating new dispensing fee regulations in the *Government Gazette*, the Minister should publish the Pricing Committee’s recommendation and explain why the recommendation was accepted.

In so doing, they would also help to avert the potential for any further litigation on this matter of national importance.

<sup>12</sup> Ibid at paragraphs 663 and 664

<sup>13</sup> The opinions also draw attention to a range of other matters that must be taken into account. These include the original written and oral submissions advanced by interested parties prior to the litigation, as well as any new information that may have been put forward or come to light at any time thereafter.

<sup>14</sup> *New Clicks*, above note 1 at paragraph 20

In addition, the Court held “that particular attention needs to be paid to the circumstances at least of rural and courier pharmacies to ensure that the right of access to health care is not prejudiced by driving such pharmacies out of the market.”<sup>15</sup> Whilst the case of rural and courier pharmacies might seem to justify a higher fee, we would caution against any differential fee that has the effect of forcing those who rely on the services of such pharmacies to pay more for their medicines than is the case in chain stores in the urban centres, for example.

In our view, this would run contrary to the spirit and purpose of the legislation. The dispensing fee itself should not be used as a tool for encouraging the establishment and/or supporting rural and courier pharmacies. There are other regulatory tools, such as tax rebates, that should be considered for this purpose instead.

We trust that these submissions will assist in the finalisation of the redrafted regulations. Should you have any enquiries regarding this submission, please do not hesitate to contact me on (011) 717-8627 or [bergerj@law.wits.ac.za](mailto:bergerj@law.wits.ac.za).

Yours sincerely

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<sup>15</sup> Ibid at paragraph 19