equality for all

aidslaw project

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AIDS LAW PROJECT AND TREATMENT ACTION CAMPAIGN:

SUBMISSION ON THE MEDICINES AND RELATED SUBSTANCES

AMENDMENT BILL, 2002

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Background

On 19 April 2001, the Pharmaceutical Manufacturers' Association of South Africa (PMA) and numerous multinational brand-name pharmaceutical companies abandoned their legal challenge to the Medicines and Related Substances Control Amendment Act, 90 of 1997 (the Medicines Amendment Act). This came a little over six weeks after the Pretoria High Court had admitted the Treatment Action Campaign (TAC) as amicus curiae in support of the legislation then under attack. It is widely recognised that TAC's

intervention—which included significant local and international mobilisation—was central to the abandonment of the case.

Speaking at a press conference shortly after the abandonment of the case, the Minister of Health stated as follows:

> "We regard today's settlement as a victory in the sense that it unfreezes our law and restores to us the power to pursue policies that we believe are critical to securing medicines at affordable rates and exercising wise control over them….
>
> Government will now go ahead and promulgate the law and within a few weeks draft regulations relating to various aspects of the Act will be published for public comment.
>
> Certain aspects of the Act … will kick in automatically with promulgation. In addition, we will move speedily to:
> - Set up the Pricing Committee whose job will include the gathering of pharmaceutical intelligence and advising the Minister on a transparent pricing system for medicines.
> - Activate the system of generic substitution, which will have major benefits for consumers in the private health care sector - and especially medical schemes."[1]

Despite the Minister's stated commitment to speedy implementation, the legislation has yet to be promulgated and regulations have yet to be issued. Instead, Cabinet decided on 15 May 2002 to approve the Medicines and Related Substances Amendment Bill (the Bill), which amends both the Medicines and Related Substances Control Act, 101 of 1965 (the principal Act) and the Medicines Amendment Act. The Bill was thereafter published for comment on 22 May 2002, the Minister's intention being to table the Bill in Parliament this year.[2]

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[1] Dr Manto Tshabalala-Msimang, "Drug Companies Withdraw Case Against SA Government", online: Unwembi's Resource of South African Government Information <http://www.polity.org.za/govdocs/pr/2001/pr0419a.html> (date accesed: 11 April 2002).
[2] *Government G*azette 23438 (vol. 443), GN 763 (22 May 2002).

Procedural irregularities

We are concerned that Cabinet's approval of the Bill—accompanied by the President's failure to promulgate the Medicines Amendment Act—has not only resulted in a further (and largely avoidable) delay in implementation of the Medicines Amendment Act, but has also resulted in probable unconstitutional conduct in the form of a breach of the separation of powers doctrine. In this regard, the Constitutional Court's recent judgment in *S v Walters and Another* is instructive:

> "This power conferred on the President [to bring the Act into force] ... is a public power and has to be exercised lawfully for the purpose for which it was given in the enactment. It could not lawfully be used to veto or otherwise block its implementation. The new section ... remains in abeyance for reasons that Parliament did not contemplate when the power to implement was given to the President. Resolution of the objections to the new section is the exclusive prerogative of Parliament."[3]

While *Walters* dealt with another statute, the principle nevertheless remains applicable. In that case, the Constitutional Court made it plain that promulgation of legislation may only be delayed for good reason. Thus, for example, if legislation requires regulations before it can be promulgated, it would make good sense to delay promulgation pending the finalisation of the regulations. This does not, however, provide license to delay unnecessarily the regulation drafting process.

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[3] Unreported decision of 21 May 2002 in case no: CCT28/01, available online at http://www.concourt.gov.za/judgments/2002/khumalo.pdf at paragraph 73.

What is also clear from *Walters* is that Parliament's will—that the legislation be brought into effect when it is appropriate to do so—cannot be undermined because the person tasked with implementing the act believes it to be bad or inappropriate. If that person is the President, he or she may only refer legislation back to Parliament if there are "reservations about the constitutionality of the Bill",[4] and then only prior to assenting to the Bill.

In the case of the Medicines Amendment Act, former President Mandela raised no constitutional concerns and duly assented to and signed the legislation before him. In the result, the matters dealt with by the Bill do not provide a lawful basis in terms of which President Mbeki may delay the promulgation of the Medicines Amendment Act.

Purpose of the submission

Notwithstanding these concerns, our submission on the Bill is focused primarily on two substantive areas of concern. The first, dealing with the independence of the Medicines Control Council (MCC), considers the composition of the MCC as well as processes in terms of which decisions of the MCC are to be reviewed. The second area of concern deals with the regulation of marketing practices of pharmaceutical manufacturers.

In addition, this submission provides support for several of the new amendments proposed. In particular, we consider certain provisions dealing

[4] Section 79(1) of the Constitution.

with generic substitution, the pricing committee and search and seizure operations.

Independence of the MCC

The combined effect of the provisions in the Bill dealing with the MCC's composition and appeals against its decisions will be the undermining of its operational independence and the efficacy of the drug regulatory process. Together, the amendments will allow for political considerations to be placed above the broader public interest, with the health and safety of people—as well as constitutional rights to life and access to health care services—potentially being put at risk.

Parliament has an obligation to ensure that this does not happen. Writing for a unanimous Constitutional Court in *Dawood and Another v Minister of Home Affairs and Others; Shalabi and Another v Minister of Home Affairs and Others; Thomas and Another v Minister of Home Affairs and Others*, Justice O'Regan held that "[i]n a constitutional democracy such as ours the responsibility to protect constitutional rights in practice is imposed both on the Legislature and on the Executive and its officials."[5]

Composition of the MCC

While section 3 of the principal Act—which sets out the qualifications necessary for appointment to the MCC—was amended by section 3 of the Medicines Amendment Act so as to remove any reference to necessary

[5] 2000 (3) SA 936 (CC) at para 48.

qualifications, implicit in section 6(2)(b) of the principal Act is that the Minister's discretion to make appointments to the MCC in terms of section 3 is somewhat restricted. Section 6(2)(b), as amended, reads as follows: "A member of the council shall vacate his or her office … if he or she ceases to hold any qualification necessary for his or her appointment."

While the Minister's discretion to appoint council members would be somewhat broader upon promulgation of the Medicines Amendment Act (given that he or she would no longer be required to appoint people with particular qualifications), implicit in section 6(2)(b) is the principle that appropriate qualifications—although not expressly defined—are nevertheless a prerequisite for appointment to the MCC.

In terms of section 2(a) of the Bill, section 6(2)(b) of the principal Act is to be deleted. While suggesting that appropriate qualifications are no longer a prerequisite for appointment to the MCC—indicating that expert knowledge on matters of medicine and pharmaceutics is no longer required before being entrusted with making decisions on the safety, quality and efficacy of medicines—the proposed amendment makes it plain that even if council members were appointed because of particular qualifications, that loss of such qualifications would not necessitate vacation of office.

In addition, section 2(b) of the Bill—by deleting the words "subject to the provisions of section 3" from section 6(3) of the principal Act—makes it plain that temporary appointments to fill vacancies for the unexpired portions of

periods of office are not dependant on any particular qualifications. Thus, for example, the temporary replacement for a person with special knowledge of pharmaceutics does not have to be a person with such knowledge. In this way, the Bill removes the last remaining reference to qualifications necessary for appointment.

It is the responsibility of the legislature to ensure that when it confers discretionary powers—such as the power to make appointments to the MCC—that the empowering legislation is drafted in such a way as to limit the risk of an unconstitutional exercise of such powers.[6] To remedy the unconstitutionality caused by a broad discretionary power granted in the absence of statutory guidance circumscribing its use, the Constitutional Court in *Dawood* referred the legislation back to Parliament to determine what guidance should be given to the decision-makers.[7]

Appeals against decisions of the MCC

As the MCC exercises control over a very lucrative and powerful industry, as well as regulating the safety, quality and efficacy of medicines and medical products, the public interest demands that its decisions be protected from undue influence. The mechanism chosen by the Medicines Amendment Act to ensure fair play is by allowing any person who is aggrieved by a decision of the MCC to refer that decision to an appeal committee comprised of both legal and medical experts. The appeal committee's decision, in turn, would be subject to a further appeal to the High Court.

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[6] Ibid.
[7] See ibid at paragraph 63.

In this way, the Medicines Amendment Act seeks to guarantee the independence of the MCC from partisan interests. Although currently regulated somewhat differently under the principal Act, the essential principle regarding independence is nevertheless still maintained. In essence, independent legal and medical experts are tasked with hearing appeals against decisions of the MCC.

In terms of the draft Bill, however, this is no longer the case. Section 12(b) of the Bill replaces section 24(1) of the principal Act (dealing with appeals against decisions of the MCC) so that it reads as follows:

> "Any person aggrieved by the decision of the Director-General, the department or the council, as the case may be, may, within the prescribed manner and upon payment of the prescribed fee, appeal against such decision to the Minister for the purposes of the appeal concerned."

Thus instead of the expert appeal committee deliberating on contested MCC decisions, the Bill allocates the power to the Minister while simultaneously removing the further right of appeal to the High Court. In essence, the decisions of a regulatory authority dealing with technical matters are now made subject to appeal to a political office-bearer, without the benefit of that decision being subject to a full appeal to an independent judiciary.

The provisions dealing with the Minister's effective control over the decision-making powers of the MCC cannot be read in isolation, but have to be seen as part of a package of amendments that also broadens the Minister's

discretion regarding the MCC's composition. In short, the Bill not only grants to the Minister greater powers to control the composition of the MCC but also the power to overrule decisions of the very council whose composition he or she to a large extent determines. This calls into question the very purpose underpinning the need for an independent regulator.

Marketing practices of pharmaceutical companies

In terms of section 18C of the principal Act (as inserted by section 12 of the Medicines Amendment Act), the Minister of Health would be obliged to "prescribe a code of ethics relating to the marketing policies of pharmaceutical companies". In terms of section 4 of the Bill, however, the Minister will now merely be obliged to make regulations relating to a "Marketing Code".

The change in terminology, as well as process by which the code is to be formulated, reflects a significant shift towards self-regulation. This is difficult to understand. If the pharmaceutical industry is understood to be able to regulate itself adequately, how then does it become necessary to make regulations pertaining to the enforcement of a self-imposed code? Indeed, it is difficult to see how such a code could be effective. Simply put, self-regulation undermines the very mischief that the Medicines Amendment Act sought to remedy.

There are, however, certain aspects of the marketing code proposals that are to be welcomed. In particular, we recognise that the code will no longer be drafted in the complete absence of guidance from Parliament, although the

guidance provided does not deal with substantive content. While the composition of the body tasked with the drafting of the code—including not only representatives of both brand-name and generic pharmaceutical companies but also consumers and health care providers—should go some way towards ensuring that the code has value, we remain of the view that the very purpose to be achieved by the introduction of the code will be significantly undermined by the shift towards self-regulation.

Other provisions

Generic substitution

We welcome the amendment to section 22F of the principal Act regarding the obligation on pharmacists to inform prescription holders of the benefits of generic substitution. In terms of section 9 of the Bill, this obligation is not only applicable within pharmacies but also extends to "any other place where dispensing takes place". This amendment simply recognises that the dispensing of prescription drugs is not limited to pharmacies.

Pricing Committee

The Bill limits appointments to the pricing committee to terms of a maximum of five years. This is to be welcomed. In addition, the Bill extends the powers of the Minister, on the recommendation of the committee, to make regulations "on an appropriate fee to be charged by wholesalers or distributors." In terms of the Medicines Amendment Act, wholesalers and distributors were not affected by price controls. As this had the potential to undermine the

objectives of increasing access to medicines, the proposed amendment in this regard is therefore welcomed.

Search and seizure

The provisions in section 14 of the Bill dealing with search and seizure are reasonable and justifiable, carefully balancing the right to privacy with the need to ensure effective enforcement of the principal Act. This represents a significant break with the past and a commitment to law enforcement within the bounds of constitutionalism and basic human rights norms. This is also welcomed.

In particular, we welcome the requirement that a warrant from a magistrate or judge is ordinarily required before a search and seizure operation can take place, with the warrant being to search for medicines, documents or other "things" that may afford evidence of non-compliance. That the warrant can only be issued if there are reasonable grounds for believing that there has been non-compliance and that such medicines, documents or things are likely to be found on the particular premises specified in the warrant is also welcomed, as is the requirement that the warrant "be reasonably specific as to any medicines, documents or things to be searched for and seized". Further, the limited and circumscribed circumstances within which the Bill allows warrantless searches to take place sufficiently balances the constitutional rights in question.

Conclusion

While the TAC and ALP welcome the opportunity to make representations on the Bill, we nevertheless remain of the view that this process should in no way contribute to further delays in the implementation of the Medicines Amendment Act. Our support for the Medicines Amendment Act is based on recognition of the statute as a reasonable legislative measure taken by the state to increase access to health care services and to promote the achievement of equality. In our view, nothing in the Bill justifies any further delays. In the result, we trust that government will perform its constitutional obligations diligently and without delay.