



JOINT SUBMISSION ON THE DRAFT MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, 2008



INTRODUCTION

Essence of this submission

The Treatment Action Campaign (TAC) and the AIDS Law Project (ALP) recognise the need for, and strongly support, legislative reform to ensure that the Medicines Control Council (MCC) is able effectively and efficiently to regulate medicines and other health products. This, we are told, is the ostensible purpose of the draft Medicines and Related Substances Amendment Bill, 2008 (“the draft Bill”)¹.

But if the draft Bill were ever to become law, this would not be achieved. Instead, its enactment would signal the final death knell of the scientific governance of medicines and clinical trials in South Africa. In our view, this is the latest attack on the evidence-based regulation of medicines and clinical trials, which began in early 1997 when the then independent and internationally respected MCC intervened to stop unauthorised and unethical trials on the industrial solvent Virodene.

This latest development, made in the name of improving effectiveness and efficiency, seeks to destroy what to date has only been weakened. It does so by proposing an amendment to the Medicines and Related Substances Act 101 of 1965 (“the Medicines Act”) that will effectively allow the Minister of Health (“the Minister”) to block the registration of medicines of proven quality, safety and efficacy, as well as to allow the sale and provision of untested “treatments” and “cures”.

The TAC and ALP are concerned that the current Minister is pursuing a dangerous agenda that, if successful, will severely undermine the work of the next Minister, Cabinet and Parliament. With this understanding, we submit that the draft Bill is irredeemably flawed and should be withdrawn. In addition to its problematic substance, it has been developed² – and is likely to be processed by the Department of Health (DoH)³ – in an unaccountable and

¹ *Government Gazette* 30985, 18 April 2008

² We are aware that Prof. Green-Thompson, special adviser to the current Minister, conducted an investigation and produced a report (“the Green-Thompson report”) on the basis of which the draft Bill was ostensibly prepared. To date, it is not known who was consulted as part of this process. In addition, the Green-Thompson report has yet to be made public, making it very difficult to understand the basis for the significant amendments proposed by the draft Bill. In the result, we have no option but to make a formal request for access to a copy of the report. That request – which will be made in terms of the promotion of Access to Information Act 2 of 2000 – will be lodged with the DoH in the near future.

³ In refusing our request to be granted an extension of two weeks for making this and another submission, the DoH explained – on 7 May 2008 – as follows:

non-transparent manner that makes a mockery of public consultation.

Instead of rushing to table draft legislation in Parliament, the DoH should embark on a process of open and accountable engagement with all domestic stakeholders – and not just the pharmaceutical industry – on how and in what way the MCC’s statutory mandate can and should be amended to ensure that it is indeed in a position appropriately to regulate the development, registration and use of safe and effective medicines of good quality free from political interference.

Structure of this submission

In this submission we explain why the draft Bill should be withdrawn. We begin by placing our concerns in context by –

- ! Tracing legislative developments since 1997 that have stripped the MCC of much of its independence;
- ! Highlighting key events in the past decade that show how the Minister and key officials in her department have misused the MCC and/or the Medicines Act to further a divisive political agenda; and
- ! Identifying substantive issues that are not – but should be – addressed by any bill that seeks to amend or replace the Medicines Act.

The submission then considers the appropriateness of locating the proposed South African Health Products Regulatory Authority (“the proposed Authority”) squarely within the DoH, reporting directly to the Minister in the absence of any governance structure of its own. In this regard, the submission briefly compares the structure of the proposed Authority with those of other statutory councils. In addition, the submission addresses the proposed Authority’s lack of a governance structure and the requirement that it report directly to the Minister.

Thereafter, the submission addresses the text of the draft Bill in some detail, focusing on four substantive areas:

- ! Powers of the Minister;
- ! Structure and mandate of the proposed Authority;
- ! Appeal and review processes; and
- ! Definitions.

CONTEXTUALISING OUR CONCERNS

As we have already indicated, our concerns regarding the draft Bill are properly understood within a particular historical context. In our view, the

“Please note that the Department is not in a position to extend the comments period as the Department itself is required to have the Bills tabled in Parliament by not later than 2 June 2008 for the Bills to be considered by Parliament this year. As stated in the said notice, it is the Department’s intention that the Bills be considered by Parliament this year.”

In other words, the DoH will read, process and address comments – as well as seek and receive Cabinet approval – within a two-week period so that what is effectively a self-imposed deadline of 2 June 2008 is met. In our view, this is simply not possible. In addition, the DoH has not made out a case why the Bills must be processed this year.

executive and legislative developments that have taken place since early 1997 underpin the overtly political nature of what might otherwise appear as mere technical amendments to the Medicines Act.

Legislative developments since 1997

Virodene

The Virodene scandal marked the beginning of the current era in which the scientific governance of medicine has been systematically undermined. The scandal – meticulously documented⁴ using public sources – involved Cabinet’s interventions in the wake of a presentation it received in January 1997 on an untested “cure” for AIDS. It is disturbing that Cabinet applauded the presentation, despite the Virodene researchers having undertaken a clinical trial – in which they had enrolled 11 patients – without receiving MCC authorisation and thus in violation of research ethics and the law.

Thereafter, the MCC analysed Virodene itself and took a considered decision – wholly within its statutory powers and mandate – to block continued human trials. The analysis showed that the active ingredient of Virodene is a toxic industrial solvent.⁵ This action brought the head of the MCC – Professor Peter Folb – into conflict with then former Deputy President Mbeki, who asserted that “[t]he cruel games of those who do not care should not be allowed to set the national agenda”. Folb was consequently pressured to – and in fact did – resign.

The 1997 amendment

The Virodene scandal was followed by certain legislative developments. The Medicines and Related Substances Control Amendment Act 90 of 1997 (“Act 90 of 1997”), which introduced a range of access-friendly provisions that we strongly supported,⁶ unfortunately also amended the provisions dealing with appointments to the MCC. Prior to the amendment, section 3(1) of the Medicines Act gave the Minister the power to appoint up to 24 members of council. Section 3(2) set out, in much detail, the qualifications of people to be

⁴ See James Myburgh, “The Virodene Affair” (2007), available online at <http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71619?oid=83156&sn=Detail> (last accessed 14 May 2008). In response to the presentation, then Deputy-President Mbeki is reported to have commented as follows:

“The AIDS victims described what had happened to them as a result of the treatment. They were in the cabinet room, walking about, perfectly all right. It was a worthy thing to see because the general assumption is that if you get to a particular point with AIDS it really is a matter of time before you die.”

⁵ No evidence meeting basic scientific standards ever indicated that Virodene could be an effective treatment. By 2002, there was conclusive evidence that it was unfit for human consumption. Yet links between the Virodene researchers and the Presidency continued until at least 2001, as has recently been admitted by the President’s spokesperson.

⁶ The TAC’s *amicus curiae* intervention in support of Act 90 of 1997 – combined with domestic and international advocacy and mobilisation spearheaded by the TAC – is widely credited with forcing the Pharmaceutical Manufacturers Association of South Africa and its co-applicants to abandon their high court challenge to the legislation. In this regard, see Mark Heywood, “Debunking Conglomo-talk: A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation” (2001) 5 *Law, Democracy and Development* 133

appointed as members of council.⁷

Act 90 of 1997 removed these statutory requirements. Instead, detail on the qualifications necessary for membership of the MCC was to be contained in the regulations, with section 3 now stating that the MCC “shall consist of so many members, but not more than 24, as the Minister may from time to time determine and appoint”. While regulation 35 of the General Regulations⁸ – which were promulgated only on 10 April 2003 – retains much of the detail previously contained in section 3, its relocation from the statute to subordinate legislation reduced Parliament’s oversight role and invested overly broad discretionary powers in the Minister.⁹

Prior to Act 90 of 1997, the MCC was empowered to appoint its own executive committee, a majority of whom had to be persons appointed from the following two categories: medical practitioners with a speciality in medicine; and persons with “a special knowledge of the action and application of medicines for human use”. Act 90 of 1997 removed the qualification requirements for the majority, meaning that any council member could be on the executive committee, with no specific expertise needed. In addition, the executive committee had to be appointed “subject to the approval of the Minister”. This was in addition to the Minister’s already broad powers to appoint the MCC and its chair and deputy chair.

The new 1998 Act

In fairness, the former Minister’s initial policy response to the Virodene scandal was somewhat short-lived. In late 1998, Parliament approved the South African Medicines and Medical Devices Regulatory Authority Act 132 of 1998 (“the SAMMDRA Act”), which was assented to by former President Mandela on 11 December 1998. Amongst other things, the SAMMDRA Act established a drug regulatory authority (DRA)¹⁰ that was intended to “be independent and impartial in the performance of its functions.”¹¹ Section 5 of the SAMMDRA Act, which dealt with the objects and functions of the independent DRA, provided as follows:

“The primary object of the South African Medicines and Medical Devices Regulatory Authority is, subject to the provisions of this Act, to provide for the monitoring, evaluation, regulation, investigation,

⁷ For example, the MCC had to include at least two medical practitioners with a speciality in medicine, at least one general practitioner and at least one person with “a special knowledge of the action and application of medicines for human use”.

⁸ *Government Gazette* 24727, Notice R510

⁹ Linked to the composition of the MCC were a range of amendments in Act 90 of 1997 dealing with period of office, reappointments, disqualifications, vacation of office and the filling of vacancies. While most of these changes were somewhat benign, a couple introduced much needed reform. These relate to a bar on persons employed in the pharmaceutical industry being appointed to the MCC (section 6(1)(d) of the Medicines Act) and requirement regarding the disclosure of commercial interests in the pharmaceutical or health care industry (section 6(4) of the Medicines Act).

¹⁰ The viability of such an independent DRA was confirmed in a KPMG report entitled “SAMMDRA: Operational and Financial Review – Discussion Draft” (2 December 1998). A copy of this report can be made available upon request.

¹¹ Section 2(3)

inspection, registration and control of medicines, complementary medicines, veterinary medicines, clinical trials and medical devices and related matters in the public interest, and for that purpose it must –

- (a) ensure the efficient, effective and ethical evaluation and registration of medicines, complementary medicines, veterinary medicines and devices that meet defined standards of quality, safety and efficacy;
- (b) ensure that the process of evaluating and registering medicines, complementary medicines, veterinary medicines and devices is, subject to this Act, transparent, fair, objective and concluded timeously;
- (c) ensure the periodic re-assessment and monitoring of medicines, complementary medicines, veterinary medicines and devices;
- (d) ensure that evidence of existing and new adverse events, interactions, information about pharmaco-vigilance is being monitored globally, analysed and acted upon;
- (e) ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation; and
- (f) ensure that clinical trial protocols are being assessed according to prescribed ethical and professional criteria and defined standards.”

The Minister’s powers in relation to the independent DRA were somewhat limited and reasonably well defined. For example, section 2(4)(a) of the SAMMDRA Act empowered the Minister to “issue policy consistent with the objects mentioned in section 5”. But before doing so, section 2(4)(b) required the Minister to consult the independent DRA and publish the text of the proposed policy for public comment “in order to obtain a view of interested persons”. In other words, policy could only be issued if it were consistent with a detailed set of statutory objects and had been developed in a consultative manner.

The SAMMDRA Act, which was promulgated on 18 December 1998, stated that it was to come into operation on a date to be determined by the President. On 30 April 1999, former President Mandela issued a proclamation purporting to bring the SAMMDRA Act into operation.¹² Unfortunately, however, this resulted in the Medicines Act – including its schedules and regulations – being largely repealed and an insufficient regulatory framework put in its place. This is because the SAMMDRA Act was brought into force in the absence of the necessary replacement schedules and regulations.

A somewhat lengthy legal process ensued, resulting – amongst other things – in the President’s proclamation being declared unconstitutional. The effect of the Constitutional Court’s order in *Pharmaceutical Manufacturers Association of South Africa, In re: Ex Parte President of the Republic of South Africa*,¹³ a

¹² *Government Gazette* 20024, Proclamation R49

¹³ 2000 (2) SA 674 (CC)

landmark decision that recognised the justiciable principle of rationality, was the reinstatement of the Medicines Act and its schedules and regulations. The SAMMDRA Act remained on the statute books, but effectively on ice.

The 2002 amendment

In addition to repealing the SAMMDRA Act, the Medicines and Related Substances Amendment Act 59 of 2002 (“Act 59 of 2002”) brought two problematic sets of changes into our law. First, it removed the two remaining references to qualifications necessary for appointment to the MCC: section 6(2)(b), which provided for the vacation of office of an MCC member if he or she ceased “to hold any qualification necessary for his appointment”, was deleted; and section 6(3), which dealt with appointments to fill vacancies for the unexpired portion of any previous MCC member’s term, was amended to remove any reference to section 3.¹⁴

Of greater concern were the amendments dealing with appeal and review procedures. Prior to Act 90 of 1997, appeals against decisions of the MCC were dealt with as follows:

- ! Any appeal lay to an appeal committee appointed by the Minister for the particular dispute in question;
- ! The appeal committee was to be composed of a retired judge or advocate with at least five years’ experience (as the committee’s chairperson), a pharmacologist and a third person (a homeopath if in relation to a homeopathic medicine, or a medical practitioner with a speciality in medicine if in relation to a medicine); and
- ! The procedures to be followed by the appeal committee were expressly set out in the legislation.

Act 90 of 1997 changed this somewhat, first by also allowing for internal appeals against decisions of the Director-General of Health (“the DG”) – and not just decisions of the MCC – to the appeal committee. In addition, it introduced the following benign changes:

- ! The chairperson did not have to be a retired judge or advocate, but rather a person with at least 10 years’ legal experience;
- ! The requirement of a pharmacologist was dropped; and
- ! The other two members of the appeal committee were required to possess skills relevant to the case.

Interestingly, section 24(6) of the Medicines Act, which was introduced by Act 90 of 1997, allowed for a further appeal to a high court – and not just a review, as would have been the case before. A full appeal allows for an overturning of the decision if, in the opinion of the high court, the decision was not the decision that the high court would have made. This provision was, however,

¹⁴ As Act 90 of 1997 had already removed the substance of section 3 in respect of qualifications for appointment, this provision was technically meaningless. However, it could have been amended to ensure that the replacement person could only be appointed if he or she possessed comparable skills and/or expertise to the person he or she was replacing on the MCC.

to be short-lived – Act 59 of 2002 removed it in its entirety. Because the two amendments were promulgated together, the provision dealing with appeals to the high court never came into operation.

In addition, Act 59 of 2002 brought in the following problematic amendments:

- ! Appeals against decisions of the DG have been removed from the jurisdiction of appeal committees, and are now to be adjudicated by the Minister solely on the basis of written submissions; and
- ! The legal expertise of the chairperson of the appeal committee has been downgraded from a particular period of experience to simply having “knowledge of the law”.

To date, there has been no public explanation as to why the SAMMDRA Act was repealed. Nor has the Minister or her department offered any justifiable basis for the manner in which Act 59 of 2002 further undermined an already weakened MCC. However, as the following section of this submission shows, the legislative agenda pursued by the Minister is wholly consistent with her department’s problematic – and arguably unlawful – conduct.

Misusing the MCC and/or the Medicines Act

Over the last decade, the MCC's independence has been eroded and its actions have often been influenced by considerations other than those solely relating to the quality, safety and efficacy of medicines.¹⁵ In particular, the following two examples stand out:

- ! The MCC’s conduct during the TAC’s court challenge regarding the provision of the ARV medicine nevirapine for the prevention of mother-to-child transmission of HIV (“PMTCT”);¹⁶ and
- ! The MCC’s role in dealing with vitamin salesman Matthias Rath and his unregistered medicines.

The PMTCT case

Despite having registered nevirapine for PMTCT, thus considering it safe and effective for this purpose,¹⁷ the MCC equivocated on emphasising the safety and efficacy of nevirapine on several occasions. For example –

- ! A member of the MCC, acting in his capacity as such, deposed to an affidavit in support of the Minister's policy not to provide nevirapine – or any other ARV medicine – for PMTCT;¹⁸

¹⁵ See TAC, “Submission to African Peer Review Mechanism – The HIV Epidemic: A discussion of the response of the South African Government” (February 2006), available online at <http://www.tac.org.za/Documents/AfricanPeerReviewMechanismReportFinal-20060217.pdf> (last accessed: 15 May 2008)

¹⁶ *Minister of Health v Treatment Action Campaign (No 2)* 2002 (5) SA 721 (CC)

¹⁷ The MCC later amended its registration of nevirapine by removing the indication for PMTCT. It did this by excluding the critical HIVNET012 study from consideration, a decision that has never been properly clarified but which was apparently politically influenced.

¹⁸ See affidavit of Philip Chukwuka Onyebujoh, available online at http://www.tac.org.za/Documents/MTCTCourtCase/affidavit/Philip_Chukwuka_Onyebujoh.txt (last accessed: 13 May 2008)

- ! Statements questioning the safety and efficacy of nevirapine were released by the MCC shortly in advance of critical court dates; and
- ! In a radio interview on SAfm at that time, the MCC's chairperson – Professor Peter Eagles – implied that research on nevirapine had not been tested in an African setting, ignoring both the HIVNET012 (Uganda) and SAINT (South Africa) trials of nevirapine for PMTCT.

Matthias Rath

Although the Law Enforcement Unit (LEU) – which is tasked with enforcing the Medicines Act – is located within the DoH, it serves the MCC (as do other parts of the DoH's directorate of medicines regulatory affairs). But despite the TAC and others having lodged complaints with the DoH and MCC regarding Matthias Rath's unlawful activities, the LEU has failed properly to investigate Rath's activities or even to provide a report of the limited investigation it undertook. Attempts by the TAC to get the LEU and MCC to take action against Rath have so far failed. Their failure to act is the subject of an application in the Cape High Court in respect of which judgment was recently reserved.¹⁹

Another example that reflects the collective failure of the DoH and the MCC to enforce the Medicines Act relates to the DG's instruction to Port Health authorities in Cape Town to release a shipment of Rath's unregistered medicines. In attempting to justify the MCC's failure to act in this case, Eagles is reported to have stated as follows:

"If the law enforcement personnel of the department are asked by the DG or the health minister to set aside their concerns around imported medicines, then the DG takes full responsibility when something goes wrong. The health minister has the overall say and she can delegate that authority to the DG. Whoever makes the decision, they are responsible for that decision."²⁰

Unaddressed substantive issues

In addition to the legislative and executive history outlined above, the context is also informed by the Minister's failure in the draft Bill to address a range of substantive issues that have for some time required attention, including –

- ! Insofar as medicines (as defined) are concerned, an outdated phased registration process ("the call-up procedure")²¹ – which allows for certain categories of medicines to remain exempt from registration requirements – that may have made sense when the Medicines Act was first introduced more than 40 years ago in 1965;

¹⁹ *Treatment Action Campaign and Another v Matthias Rath and Others*, case no 12156/05, High Court of South Africa (Cape of Good Hope Provincial Division). TAC's papers in this case are available online at <http://www.tac.org.za/community/rath> (last accessed: 15 May 2008)

²⁰ See Pearlie Joubert, "Health department DG frees seized Rath drugs" (7 July 2006), available online at <http://www.aegis.com/news/dmg/2006/MG060702.html> (last accessed 13 May 2008) and TAC, "The Wrongs of Rath", available online at <http://www.tac.org.za/community/rath> (last accessed 13 May 2008)

²¹ This is discussed below.

- ! The need, pending registration in South Africa, to permit the use of priority products already registered by stringent DRAs such as the US Food and Drug Administration the European Medicines Agency; and
- ! Provisions in the Medicines Act that permit the MCC to operate in secrecy and non-transparently.

Failure to consider these and other similar issues indicates that the Minister is not attuned to many of the real barriers that prevent the MCC from operating effectively and efficiently. For example, there is no detail in the draft Bill regarding the allocation of resources to the proposed Authority to enable it to function efficiently and effectively.²² Similarly, although much noise has been made by the DoH about timelines for ensuring speedy drug registration, the draft Bill is glaringly silent on this issue, presumably leaving the detail to draft regulations that have yet to be published. This reinforces the perception that the draft Bill is less about the appropriate regulation of medicines than it is about ensuring total executive control over the statutory body.

The call-up procedure

When the Medicines Act was first introduced, it was well understood that it was not appropriate or even possible to require the immediate registration of all medicines (as defined). This resulted in a provision that allowed the MCC, from time to time, to issue “call-up” notices in terms of which new categories of medicines would be required to be registered. Now, more than 40 years later, all medicines (as defined) should be subject to registration. The very reason for a staggered approval process in this regard no longer exists.²³

Recognition of other stringent regulatory authorities

Section 21 of the Medicines Act allows for the MCC to authorise the use of unregistered medicines. This is an important power that is necessary for a number of purposes, such as –

- ! Conducting clinical research necessary for establishing the evidence on the basis of which new medicines may be registered;
- ! Authorising the use of experimental treatments on compassionate grounds for those who have exhausted their treatment options; and
- ! Authorising the use of medicines registered elsewhere that are likely to be registered here in the future.

Importantly, section 21 is limited in its application and is ordinarily granted on an individual named-patient basis or for use by or within a particular institution. It has never been – and arguably is not suitable to be – used more broadly, such as for authorising the widespread use of unregistered medicines in a public health programme. Similarly, it has not been used to authorise the sale of unregistered medicines through private retail pharmacies. Ordinarily, this is not a problem.

²² In contrast, consider sections 16 and 17 of the SAMMDRA Act, which deal with the DRA’s staffing and financing in some detail.

²³ We have been advised that a phased approach to the registration of complementary medicines and medical devices may still be required.

But there is sufficient evidence to show why a broader authorisation for the use of unregistered medicines may be required in certain circumstances, such as the prevention and/or treatment of priority diseases such as HIV and TB. Importantly, this was recognised by the Global Steering Committee (GSC) that was convened by the Joint United Nations (UN) Programme on HIV/AIDS (UNAIDS) in the run-up to the 2006 UN General Assembly Special Session on HIV/AIDS (UNGASS) “to identify global-level actions, to provide insights and inspiration and to act as a political sounding board.” The current Minister was a member of the GSC.

In his note to UNGASS entitled “Follow-up to the outcome of the twenty-sixth special session: implementation of the Declaration of Commitment on HIV/AIDS – Scaling up HIV prevention, treatment, care and support”, the former UN Secretary-General explained as follows:

“The Global Steering Committee identified delays in the regulatory approval of new products as a major obstacle in making HIV treatment and prevention technologies rapidly available to users. Countries are not yet taking full advantage of the WHO pre-qualification process, or qualification by other stringent drug regulatory authorities, to expedite the availability of HIV-related medicines and commodities on a provisional basis prior to full approval by the respective country regulatory authorities.”²⁴

In our view, there is no reasonable basis for refusing to follow the GSC’s advice on this issue. To the contrary, the evidence points in the other direction. In addition to delays occasioned by an inefficient DRA, another reality that must be addressed is the regular practice followed by many pharmaceutical companies of initiating the registration process in developing countries only once products have been registered for use in the United States (US) and other developed countries. One such example is the ARV medicine tenofovir disoproxil fumarate (TDF), which was first registered in the US in 2001. TDF was only registered by the MCC some 5½ years later in April 2007, following delays by all relevant parties.

Secrecy and section 34

In numerous interactions with the MCC regarding the registration of ARV medicines such as TDF, the ALP has repeatedly been referred to the provisions of section 34 of the Medicines Act – apparently in attempts to explain why we were not entitled to the information we sought. In each case, the ALP had sought information regarding what appeared to be inordinate and unjustifiable delays in the registration process.

In correspondence with the MCC, the ALP has twice pointed out that –

“section 34 provides a convenient – albeit potentially unconstitutional – shield behind which the MCC appears to conduct its statutory

²⁴ At paragraph 42, available at <http://www.unaids.org/en/Conferences/2006HLM/default.asp> (last accessed: 13 May 2008)

responsibilities in secrecy, seemingly without regard to the constitutional value of accountability.”²⁵

The ALP also argued that on a proper interpretation of the provision, section 34 does not prevent the MCC from acceding to many of our requests. In addition, the ALP has argued that “to the extent that section 34 may be understood to prevent the disclosure of the requested information ... it is particularly vulnerable to constitutional challenge.” We stand by these concerns and submit that now is the time to amend section 34 in such a way that it no longer provides the MCC with a shield to act unconstitutionally.²⁶

STRUCTURAL CONCERNS

Locating the proposed authority within the DoH

In principle, we would not have a strong objection to the mere location of a DRA within a department of health that is able and has demonstrated the willingness to operate independently. In fact, the departmental model is the one that has been adopted in countries such as the US and Canada. Where such a placement becomes problematic is when the DRA’s independence of operation is compromised, such as what happens where mandates are unduly limited, oversight structures are weak (or non-existent) and the political head of the department has unduly broad and inappropriate discretionary powers. South Africa is a case in point.

There are at least two further concerns to address in the South African context. First, regulatory and oversight institutions are established and operate within the broad legal framework provided by the Constitution, which differs markedly from the foundational documents of other countries. Unlike ours, the US and Canadian Constitutions do not recognise a right to have access to health care services. They also do not recognise the principle of state accountability as does ours. Further, the US Constitution does not recognise positive obligations on the state in respect of fundamental rights.

Second, the South African context is one in which a variety of regulatory and oversight institutions already exist in one or other particular form. Of the collection, none is structured in a manner vaguely similar to that of the proposed Authority. The question to be answered is what – if anything – differs from the medicines regulation environment that requires such a radical departure from largely established practice in relation to the structures, mandates and lines of accountability of statutory councils. In our view, concerns regarding efficiency and effectiveness of operation are common to all such bodies and can be addressed within existing or similar structures.

²⁵ In addition to recognising accountability as a foundational value, the Constitution also provides for public administration to be governed by a range of basic values and principles. In particular, section 195(1)(f) expressly requires that public administration be accountable. In addition, section 195(1)(g) provides as follows:

“Transparency must be fostered by providing the public with timely, accessible and accurate information.”

²⁶ As it reads, section 34 of the Medicines Act is most likely in conflict with the right of access to information that is entrenched in section 32 of the Constitution.

Lack of governance structure and direct reporting to the Minister

As already indicated, the draft Bill not only locates the proposed Authority within the DoH, but also removes all references to any governance structure (such as the council of the MCC). Instead, the proposed Authority – to be headed by a Chief Executive Officer (CEO) appointed directly by the Minister in the absence of any statutory guidance regarding his or her appropriateness for this crucial position – is accountable and reports directly to the Minister. Requiring the proposed Authority to report in this way removes the direct links that currently exist between Parliament, its oversight committees and the MCC. While Parliament may still exercise a degree of oversight, its powers will be limited.

Not only is this an inappropriate allocation of power, but it also leaves the proposed Authority without any governance and internal structure at all. One can only assume that this detail will either be included in future regulations, or that the Authority will somehow be slotted into the DoH directorate dealing with medicines regulatory affairs. Either way, it is inappropriate for such broad discretions to be allocated to the Minister, particularly in the absence of any guidance regarding their exercise.

ANALYSIS OF THE TEXT

Notwithstanding our submission that the draft Bill should be abandoned in its entirety, we nevertheless believe that it is important to provide input on particular provisions of the proposed amendment in respect of which we have substantive concerns. In this section of the submission, we therefore focus on the following four substantive areas:

- ! Powers of the Minister;
- ! Structure and mandate of the proposed Authority;
- ! Appeal and review processes; and
- ! Definitions.

Powers of the Minister

The draft Bill is replete with the allocation of inappropriate and unduly broad powers to the Minister. In this section, we focus on three of these:²⁷

- ! Registration of certified medicines;
- ! Authorisation to use uncertified and/or unregistered medicines; and
- ! Exclusion of products from the operation of all or part of the Medicines Act and appropriate safeguards in this respect.

Registration of certified medicines

Of greatest concern is the draft Bill's proposal that the current registration process – which only considers issues of quality, safety and efficacy in line with DRAs across the world – be replaced by a two-stage process: certification by the proposed Authority on the basis of quality, safety and efficacy; followed by registration by the Minister if he or she is satisfied that

²⁷ In addition, the Minister appears to have been granted inappropriately broad regulation drafting powers, over and above the already overly broad powers set out in section 35 of the Medicines Act.

such registration is “in the public interest”. In this regard, the draft Bill sets out vague and unclear factors that must be taken into account in making this determination:²⁸

- ! Public health interests;
- ! Economic interests in relation to health policies;
- ! Strategic interests in relation to health policies;
- ! The need and desirability for such products; and
- ! Generally whether the public would be best served by such registration.

While some of these concerns may in fact be appropriate for consideration by health care funders (such as the state and medical schemes) insofar as their actual provision and/or reimbursement is concerned, there is no reasonable basis for excluding products from the market that satisfy the well-established and internationally accepted three-pronged test of quality, safety and efficacy. Such a broad power will create uncertainty, is likely to result in fewer products being submitted for registration, and will undoubtedly result in litigation should certified products be prevented from reaching the market. In other words, the Minister will likely face ongoing legal action in respect of every certified product he or she refuses to register.

One of the reasons why the registration of medicines by the MCC is often unduly delayed is the current requirement that the full council – and not its committees – be involved in the decision regarding the actual registration of each medicine. The draft Bill seemingly compounds this problem by requiring the Minister to apply his or her mind to the registration of every health product that has been certified by the proposed Authority. This is an unduly bureaucratic process that is likely to result in significant delays, possibly even greater than those currently experienced, even in such cases where the Minister’s decisions are not challenged in court.

In addition, the Minister is a political appointment who is unlikely to have the necessary qualifications, knowledge and experience to determine whether a medicine should indeed be registered. Instead, that determination should be made by suitably qualified experts free from political interference. It is one thing for the draft Bill to require that the Minister be responsible for ensuring that the registration of medicines is done effectively and efficiently. It is quite another for him or her to be tasked with direct responsibility for registration itself.

Authorisation to use uncertified and/or unregistered medicines

The draft Bill proposes that the Authority may only issue authorisations in terms of section 21 – already discussed in this submission – “in consultation with the Minister”. This is problematic on two accounts. First, the sheer volume of section 21 applications requires a much simpler administrative

²⁸ Not only may the Minister refuse to register products, but in respect of those that he or she does register, he or she may impose registration conditions that may well be over and above the certification conditions already imposed by the Authority.

process that should wholly be located within the Authority. Second, the decision on whether to issue such an authorisation is not a political decision, but rather a technical decision based on simple compliance with well-established criteria. On both counts, the Minister is not an appropriate person to be tasked with making such decisions. He or she will have neither the time nor the expertise to apply his or her mind appropriately.

Exclusion of products from the operation of all or part of the Medicines Act

The draft Bill proposes that the Minister be given much greater powers to exclude products from the operation of all or part of the Medicines Act. As it currently operates, section 36 allows for the Minister to exclude medicines, but puts in place the following appropriate checks and balances:

- ! The Minister can only act if he or she receives a recommendation from the MCC in this regard; and
- ! All MCC members present at the relevant council meeting agree with the recommendation.

The new proposal simply refers to an Authority recommendation, which effectively removes all checks and balances. In other words, the CEO – who reports directly to the Minister – must now make the recommendation to his or her boss. An independent structure, which reports directly to another branch of government, will no longer provide any check over the exercise of a particularly important power.

In addition, the draft Bill provides no guidance on the exercise of this power, arguably in violation of the principles enunciated by the Constitutional Court in *Dawood v Minister of Home Affairs; Shalabi v Minister of Home Affairs; Thomas v Minister of Home Affairs* (“the *Dawood* judgment”).²⁹ Writing for a unanimous Court in that case, 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.”³⁰

According to Justice O’Regan, it is the responsibility of the legislature to ensure that when it confers discretionary powers, the empowering legislation is drafted in such a way as to limit the risk of an unconstitutional exercise of such powers.³¹ In addition, despite the availability of legal recourse following any unconstitutional exercise of discretionary powers, the granting of such powers in the absence of guidelines is nevertheless problematic. “The fact ... that the exercise of a discretionary power may subsequently be successfully challenged on administrative grounds”, Justice O’Regan held in the *Dawood* judgment, “does not relieve the Legislature of its constitutional obligations to

²⁹ 2000 (3) SA 936 (CC)

³⁰ At paragraph 48

³¹ *Ibid.* 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 (at paragraph 63).

promote, protect and fulfil the rights entrenched in the Bill of Rights.”³²

Our primary concern regarding the proposed amendment to section 36 of the Medicines Act is that it appears to have been drafted with the express purpose of enabling the Minister to allow, amongst other things, the widespread use of unproven medicines for the treatment of HIV infection. Our well-founded suspicion is based on the Cabinet's actions during the Virodene scandal, the inappropriate actions of the current Minister and DG regarding the conduct of Matthias Rath and the provision of his untested products, and the Ministry of Health's support for other untested AIDS “treatments” and “cures” sold by people such as Zebulon Gwala and Tine van der Maas.

In this regard, we draw to your attention the following:

- ! Press statements lending support to Gwala's product uBhejane – “DA Undermines Indigenous Knowledge” (13 February 2006) and “Traditional Medicine is Here to Stay” (18 February 2006),³³ and
- ! A video produced by van der Maas entitled “Power to the People”, which features scenes of the Minister lending her support.³⁴

Structure and mandate of the proposed Authority

In addition to the issues relating to the structure and mandate of the proposed Authority that we have already discussed in this submission, we are concerned about –

- ! The removal of the MCC's advisory powers;
- ! The removal of fast-track approval processes; and
- ! Enforcement of the Medicines Act and the location of the DoH's LEU.

Removal of advisory powers

In line with the statutory mandates of other regulatory authorities, such as the Council for Medical Schemes, section 2(2) of the Medicines Act empowers the MCC to “advise the Minister or furnish a report to the Minister on any matter referred to the council by the Minister for consideration *and arising from the application of this Act*.”³⁵ This much needed power, which ensures that the expert body tasked with the registration of medicines is able to devote resources for this purpose, has been removed from the proposed Authority's mandate. Instead, the proposed Authority is simply seen as an implementer, which is not expected to participate in ongoing policy reform processes.

Removal of fast-track approval processes

In a press release entitled “Two Bills to improve access to affordable

³² Ibid

³³ These statements are available online at <http://www.doh.gov.za/docs/pr-f.html> and <http://www.tac.org.za/community/files/DOHOnTraditionalMedicineAndUbhejane-20060218.txt> (last accessed: 13 May 2008) respectively.

³⁴ Since the Minister has shown this video in a number of forums, a copy is most likely already in the DoH's custody.

³⁵ Emphasis added

healthcare”,³⁶ the Minister notes that the proposed Authority “will have specific timescales within which it will register health products and approve clinical trials.” She continues: “It is proposed that new clinical entities should be registered within 12 months and generics within six months while clinical trials will be considered within 30-60 days.” None of this is contained in the draft Bill. One can only assume that it will be included in future regulations. This, as already explained in relation to other aspects of the proposed regulatory framework, is problematic.

In addition, not only is the draft Bill silent on these issues but it also removes all current references to fast-track approval processes. In other words, the Authority is given less direction regarding timelines – a significant source of conflict between the MCC and those who want and need medicines to be registered in a timely manner – than is currently the case with the MCC. In our view, there is no place in our constitutional democracy for such retrogressive steps.

Enforcement and the location of the LEU

In theory, it is appropriate for the LEU – which is tasked with enforcing the Medicines Act – to be located within the DRA itself, and not as part of a broader DoH. But given that the proposed Authority is planned to report directly to the Minister, not much will be gained. In addition, the draft Bill is silent on the need for the LEU to be appropriately resourced, both finances and in terms of human capacity. Until now, criminally few resources have been allocated to the LEU, which – as an integral part of the DoH – has been subject to undue and overt political interference in the discharge of its statutory mandate.³⁷ Any amendment to the Medicines Act should address these legitimate concerns.

Appeal and review processes

As is the case at present, the distinction between internal appeals and high court reviews remains. However, the draft Bill proposes that much of the detail in this regard be changed, arguably in a manner that does not accord with “the right to have any dispute that can be resolved by the application of law decided in a fair public hearing before a court or, where appropriate, another independent and impartial tribunal or forum.”³⁸

Internal appeals against decisions of the proposed Authority

While we have no major opposition to the proposals regarding the procedures for appeals of the proposed Authority’s decisions, which sees the CEO setting up an appeal committee in the event that the parties – in the absence of lawyers – are unable to resolve the dispute amicably, we do not understand why the current procedure must be abandoned. In our view, the only reasonable basis for a change would be if the appeal structure were to be formalised and no longer operate as and when required – in other words, a

³⁶ Press release dated 18 April 2008, available at <http://www.doh.gov.za/docs/pr-f.html> (last accessed: 9 May 2008)

³⁷ This includes, for example, the DG’s conduct in respect of Matthias Rath (discussed above).

³⁸ Section 34 of the Constitution

standing body.

High court reviews of appeal decisions

In contrast, we are particularly concerned about the proposed amendments in respect of high court reviews. These seem designed to address the implications of the judgment of Hartzenberg J in *The University of KwaZulu-Natal v The Medicines Control Council*,³⁹ in which the MCC was ordered to abide by a decision of an internal appeal committee pending the outcome of a high court review of that decision. That case addressed the MCC's initial refusal – subsequently overturned by the appeal committee – to authorise a clinical trial involving the use of the ARV nevirapine amongst breastfeeding mothers with HIV to reduce the risk of transmission to their nursed babies.

In this regard, the draft Bill proposes that any party to a dispute – including the proposed Authority itself – should be able to take an appeal committee decision on review,⁴⁰ and that the high court should be limited in its powers to confirming or setting aside decisions of appeal committees. In short, the draft Bill proposes that the high court not be entitled to impose its own decision on the substance, arguably in violation of sections 34 and 38 of the Constitution. Instead, it proposes that the high court should only be able to refer a matter back to the relevant appeal committee for a final decision.

Definitions

In particular, we are concerned about two proposed amendments to the definitions section of the Medicines Act:

- ! Distinction between medicines, on the one hand, and foodstuffs and cosmetics, on the other; and
- ! The concept of "public interest" in the registration of medicines.

Distinction between medicines and foodstuffs and cosmetics

The draft Bill seems intent on blurring the distinction between medicines, foodstuffs and cosmetics. It proposes that foodstuffs and cosmetics "in respect of which medicinal claims are made" be considered as "products" that may be subject to certification and registration. But the current definition of medicines, as interpreted and explained in a range of high court cases, already includes all products in respect of which medicinal claims are made. This is supported by the definitions of foodstuffs and cosmetics in the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 ("the Foodstuffs Act"), which expressly exclude products defined as medicines in the Medicines Act.

In other words, there is no need to refer to foodstuffs and cosmetics in the Medicines Act at all. Any reference to a medicine, such as in the definition of a product, includes all products that may ordinarily be understood to be foodstuffs or cosmetics but in respect of which medicinal claims are made. In contrast, a reference in the Medicines Act to a definition from the Foodstuffs Act seems to complicate matters unnecessarily – as well as to undermine the

³⁹ Unreported decision of 3 July 2007 in case no. 24595/06 before the High Court of South Africa (Transvaal Provincial Division)

⁴⁰ This seems to undermine the very basis for setting up internal appeal processes.

already established principle that the first port of call in determining whether a substance is a medicine is the Medicines Act.

"Public interest" in the registration of medicines

The term "public interest" – for the purposes of the current Medicines Act – is limited to considerations of quality, safety and efficacy. The draft bill proposes that this definition be removed. Instead, the concept of public interest in the context of the registration of medicines is to be broadened, seemingly to take into account a range of vague and uncertain factors. As already explained, this will have dire consequences for the scientific regulation of medicines in this country.

RECOMMENDATIONS ON THE WAY FORWARD

The draft Bill should be abandoned. In its place, we submit that a new and inclusive process of consultation be initiated. Amongst other things, this process should result in the development, adoption and publication of a DoH policy, a new draft Bill and a Cabinet-approved Bill that is subsequently tabled in Parliament. At each stage of the process, adequate time should be provided for full stakeholder consultation.⁴¹ We commit ourselves to taking such an inclusive and consultative process seriously, and will provide whatever support we can to ensure that the Medicines Act is amended or replaced in a manner that supports the appropriate regulation of medicines and other health products.

**Johannesburg and Cape Town
Friday, 16 May 2008**

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⁴¹ A good example of such a comprehensive stakeholder consultation process is that which has been followed by the Department of Science and Technology in relation to the Intellectual Property Rights from Publicly Financed Research Bill. Approved by Cabinet on 14 May 2008 for submission to Parliament (see "Statement on the Cabinet meeting of 14 May 2008", available online at <http://www.info.gov.za/speeches/2008/08051511451001.htm> (last accessed: 15 May 2008)), the relevant bill has its genesis in a draft policy framework that was approved by Cabinet as far back as December 2005. After engaging in a series of consultative workshops, a revised policy framework – including a draft bill – was submitted to Cabinet for approval, which was granted in June 2007. Further consultation on the draft bill took place before the final bill was submitted to Cabinet for approval before being tabled in Parliament.