# ORAL SUBMISSION TO THE PORTFOLIO COMMITTEE ON HEALTH ON THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL [B 44—2008] PARLIAMENT, CAPE TOWN, 5 AUGUST 2008

## INTRODUCTION

1. The AIDS Law Project (ALP) and the Treatment Action Campaign (TAC) once again welcome the opportunity to make submissions on the Medicines and Related Substances Amendment Bill [B 44—2008] ("the Bill").

2. At the outset, we would like to restate that we unequivocally recognise the need for, and strongly support, legislative reform to ensure that the Medicines Control Council (MCC) – or any comparable regulatory and oversight body – is able to ensure the effective and efficient regulation of medicines and other health products. In our view, this is not only demanded by good public health policy but is also constitutionally mandated.

3. We recognise, however, that the MCC has for some time struggled to discharge its statutory mandate effectively and efficiently. Not only has its independence been under threat in recent years, as is described in our first written submission, but it has also lacked the requisite financial and human resources necessary for the appropriate regulation of medicines. Simply put, it has often lacked both the willingness and capacity to do its job.

4. Unfortunately, there is very little in the Bill currently before you that suggests a proper recognition of the MCC's challenges. Of greater concern, however, is that whether considered on its own or when compared to the report of the *Ministerial Task Team on the Restructuring of the Medicines Regulatory Affairs and Medicines Control Council* ("the Task Team report"), the Bill seeks to introduce amendments that are likely to make matters worse.

5. These issues are addressed in detail in our two written submissions. In particular, those documents make it plain that we have come to the conclusion that –

5.1 Contrary to its stated purpose, the Bill – if enacted into law – will not ensure the effective and efficient regulation of medicines and other health products in South Africa;

5.2 The Bill has the potential to undermine the scientific governance of medicines and other health products by –

5.2.1 Inappropriately – and arguably unconstitutionally – allocating broad powers to the Minister; and

5.2.2 Replacing a semi-independent MCC with a health products regulatory authority that is effectively to operate as a line function within the Department of Health ("the DoH"); and

5.3 In large part, the Bill is not supported by the Task Team report, with many of the Bill's provisions in fact undermining the report's recommendations.

**KEY SUBSTANTIVE CONCERNS**

6. Before proposing a way forward in terms of process, we would like to address two of the substantive issues raised in our first submission: the powers of the Minister, and the structure and mandate of the proposed Authority. We will not repeat but nevertheless stand by our previous submissions on other substantive provisions of the Bill and are willing to answer relevant questions should it be deemed necessary.

**Powers of the Minister**

7. The Bill is replete with the allocation of inappropriate and unduly broad powers to the Minister. As was the case with our first written submission, we retain our focus today on three of these:[1]

7.1 Registration of certified medicines;

7.2 Authorisation to use uncertified and/or unregistered medicines; and

7.3 Exclusion of products from the operation of all or part of the Medicines Act and appropriate safeguards in this respect.

[1] The Minister also appears to have been granted inappropriately broad regulation drafting powers, over and above the already overly broad powers as set out in section 35 of the Medicines Act.

Registration of certified medicines

8. Of greatest concern is the Bill's proposal that the current registration process – which only considers issues of quality, safety and efficacy in line with drug regulatory authorities (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 such registration is "in the public interest".[2]

9. In this regard, clause 7 of the Bill sets out factors – some of which are particularly vague and unclear – that must be taken into account in making this determination:

> (i) Public health interests including national epidemiological trends;
> (ii) economic interests in relation to health policies;
> (iii) whether the product is supportive of national health policy and goals in the long term;
> (iv) whether the product is likely to significantly improve access to health care for vulnerable groups within society;
> (v) the experience of other countries concerning the marketing, distribution and use of the product; and
> (vi) generally, whether the public would be best served by such registration.

10. In our view, such concerns are indeed appropriate for consideration by health care funders insofar as their actual provision and/or reimbursement is concerned. In particular, we believe that it would be appropriate for a revised set of such factors to form the statutory basis upon which medicines are included on the Essential Drugs List (EDL). Once so included, their provision would be guaranteed – as a matter of law – in the public sector and that part of the private sector funded by medical schemes.[3]

11. Having said that, however, we submit that there is no reasonable basis for excluding products from the market that satisfy the internationally accepted three-pronged test of quality, safety and efficacy. Such a broad power will create uncertainty and delays, is likely to result in fewer products being submitted for certification and registration, and will undoubtedly result in litigation should certified products be prevented from reaching the market.

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[2] For discussion on the legal meaning of the term "public interest", see *Rail Commuters Action Group and Others v Transnet Ltd t/a Metrorail and Others* 2005 (2) SA 359 (CC)

[3] Once included on the EDL, a medicine would automatically form part of the prescribed minimum benefits in terms of the Medical Schemes Act 131 of 1998 and its regulations.

12. In addition, the Minister 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 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

13. The Bill proposes that the Authority may only issue “section 21” authorisations for the use of uncertified and/or unregistered medicines “in consultation with the Minister". This is problematic on two accounts. First, the sheer volume of section 21 applications requires a much simpler administrative 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.

14. 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. In the result, access to certain essential medicines and/or the authorisation of clinical trials may be severely compromised, arguably in violation of the guarantee in section 27 of the Constitution of access to health care services.

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

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

    12.1 The Minister can only act if he or she receives a recommendation from the MCC in this regard; and

    12.2 All MCC members present at the relevant council meeting must support the recommendation.

16. The new proposal simply refers to an Authority recommendation, which

effectively removes all checks and balances. In other words, the Chief Executive Officer (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.

17. 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 the case of *Dawood v Minister of Home Affairs*; *Shalabi v Minister of Home Affairs; Thomas v Minister of Home Affairs*. These principles and their relevance for the regulation of medicines and other health products are discussed in some detail in our first written submission.

**Structure and mandate of the proposed Authority**

18. In our first written submission, we considered numerous issues relating to the structure and mandate of the proposed Authority. While we stand by those submissions, we would like to focus today on two of our original concerns:

    15.1 Locating the proposed authority within the DoH; and

    15.2 Lack of governance structure and direct reporting to the Minister.

<u>Locating the proposed authority within the DoH</u>

19. 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, this is the model 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.

20. 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.

21. 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 structures.

Lack of governance structure and direct reporting to the Minister

22. As already indicated, the Bill not only locates the proposed Authority within the DoH, but also removes all references to any governance structure (such as the actual council of the MCC). Instead, the proposed Authority – to be headed by a 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.[4] 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.

23. 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.

**CONCLUSION**

24. We remain steadfast in the view that the Bill is so deeply flawed that nothing short of a complete rewrite is necessary. This is not only because of the substantive changes that it seeks to introduce, but also because the Bill is the

[4] In contrast, the US Senate must confirm the President's appointment of the Commissioner of the Food and Drug Administration after a rigorous public vetting procedure.

embodiment of a fundamentally flawed departmental consultation process. As is evident from our written submissions, the DoH appears to have treated this process with significant contempt. In addition, it has not done justice to the findings and recommendations of the Task Team report.

25. As recognised by the Bill, the Task Team report should indeed provide the starting point in the development of legislative reform. However, as discussed in some detail in our second written submission, that report raises numerous concerns such as the Task Team's composition, the manner in and the extent to which it consulted and complied with its terms of reference, and its failure to address the Constitution. In particular, the Task Team report fails to recognise and address the state's constitutional obligations regarding the regulation of health products.

26. In our view, these concerns can be addressed by a process that seeks first to engage stakeholders and build consensus on the development and finalisation of policy before embarking on legislative reform. As alluded to in our first written submission, this is nothing new for some government departments. In that submission, we described the manner in which the Intellectual Property Rights from Publicly Financed Research and Development Bill [B 46—2008] – which is currently being considered by the Portfolio Committee on Science and Technology – was developed, having its genesis in a draft policy framework that was approved by Cabinet as far back as December 2005.[5]

27. We submit that the Bill should be returned to the DoH so that the concerns relating to the work of the Task Team, as well as the findings and recommendations contained in its report, can be addressed at the level of policy. This may require a call for public submissions on the Task Team report or a policy document based on its findings and recommendations. Only then would it be appropriate for draft legislation to be formulated and thereafter considered and processed by this committee.

**Zackie Achmat**
**Deputy General Secretary, TAC**

**Jonathan Berger**
**Senior researcher, ALP**

[5] See footnote 41