=== COVER PAGE ===

TO: _____

FROM: COMMITTEE SECTION

FAX: 021-403-2854

TEL: 021-403-3746

COMMENT:

ORAL SUBMISSION TO THE SELECT COMMITTEE ON SOCIAL SERVICES: MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL [B 44B—2008] PARLIAMENT, CAPE TOWN, 21 OCTOBER 2008

BACKGROUND AND INTRODUCTION

1. The Treatment Action Campaign (TAC) and the AIDS Law Project (ALP) once again welcome the opportunity to make submissions on the Medicines and Related Substances Amendment Bill [B 44B—2008] ("the Bill"). In particular, we extend our thanks to Chairperson Masilo for giving us this opportunity to address the Select Committee on Social Services today.

2. From the outset, we wish to restate that we unequivocally accept the need for, and strongly support, legislative reform aimed at strengthening the regulatory framework for medicines, medical devices and other health products in this country.

3. We have therefore made ourselves available at every step of this process to work with and assist both the Department of Health (DoH) and Parliament to ensure that the Medicines Control Council (MCC) – or any comparable health product regulatory authority – is appropriately empowered efficiently and effectively to fulfil its mandate, free from political and commercial interference and in accordance with the principles of scientific governance.

4. Accordingly, we have made oral and written submissions on earlier versions of the Bill, including the original departmental draft and the version tabled in Parliament in June of this year. All of our submissions have sought to address a number of concerns relating both to the content of the Bill as well as the consultation process which preceded its tabling in Parliament.

5. In essence, the substantive concerns which we and others raised during the Portfolio Committee's deliberations concerned the following shortcomings in the Bill as tabled:

    5.1. The inappropriate – and arguably unconstitutional – allocation of broad unchecked powers over the regulation of medicines and other health products to the Minister of Health ("the Minister");

5.2. The replacement of an independent MCC with a health products regulatory authority that was initially designed to operate as a line function within the DoH rather than as an independent government agency; and

5.3. The Bill's failure to provide Parliament with appropriate oversight over the new body tasked with the registration of medicines and other health products ("the Authority").

6. While we are pleased that the Portfolio Committee has made a number of key amendments to the Bill that address some of the concerns raised in our earlier submissions, we are of the view that the Bill still falls short of ensuring that the Authority is able to function as an independent government agency. To do so, the Bill needs to provide much greater detail on the structure and nature of the Authority, deal appropriately with the appointment of the Authority's chief executive officer (CEO), and provide Parliament with a much stronger oversight role.

7. Equally important, the Bill fails to address our concerns regarding the Minister's power to exclude medicines and other health products from the operation of all or part of the Act. Currently, this power can only be exercised on the unanimous recommendation of the MCC. The Bill would have the Authority make that recommendation instead. And for as long as the Authority's independence is not guaranteed in law and in practice, regardless of who occupies the office of Minister of Health, concerns will remain that the power to exclude could be used inappropriately to advance a political or commercial – instead of a public – interest.

8. As an accompaniment to our presentation today, you have before you copies of our latest written submission, which speaks to our outstanding concerns with the Bill. It proposes a number of amendments to the text of the Bill that, as explained in its introduction, "seek to ensure that the new South African Health Products Authority ... is able to function efficiently and effectively and in accordance with the Constitution". Our submission draws from recommendations made in our previous submissions and includes both our proposed amendments to the text of the Bill as well as the rationale behind these suggested amendments.

9. Given our limited time before you today we will not attempt to go through our proposed amendments line by line. Instead, for the remainder of this presentation

we will give a brief overview of what our amendments are seeking to achieve and our justification for having submitted them to this Committee for its consideration.

10. In short, our proposed amendments cover three substantive issues:

10.1. The structure and mandate of the Authority (**Clause 2** of the Bill);

10.2. Criteria and processes for the appointment of the Chief Executive Officer and other Authority staff (**Clause 3**); and

10.3. The power of the Minister to exclude medicines or other health products from certain or all aspects of regulation (**Clause 41**).

11. In addition, we also propose the inclusion of two additional clauses to the Bill (in accordance with recommendations made in our previous submissions) concerning:

11.1. The recognition of other stringent regulatory authorities in certain limited circumstances (proposed new **section 14(5)** of the Act); and

11.2. Access to information in accordance with the Constitution (proposed amendment to **section 34** of the Act).

STRUCTURE AND MANDATE OF THE AUTHORITY (CLAUSE 2)

13. Although it is much improved, the Bill in its current form still proposes the establishment of an authority that is neither truly independent nor directly accountable to Parliament. Neither of these characteristics is, in our view, justifiable.

14. Our proposed amendments to Clause 2 of the Bill therefore seek to:

14.1. Strengthen and guarantee the Authority's independence; and,

14.2. Ensure that Parliament retains primary oversight over the Authority.

15. What do we mean by independence? By *independence* we refer here to the institutional conditions under which the Authority executes its statutory mandate. In order for it to function efficiently, effectively and impartially, we contend that, as

far as is reasonably possible, the institutional and structural conditions under which the Authority operates must protect it from undue external influence.

16. In addition, as explained by the Constitutional Court in the *New National Party* case,[1] independence includes both financial and administrative independence. According to that decision, financial independence "implies the ability to have access to funds reasonably required to enable the ... [Authority] to discharge the functions it is obliged to perform under the Constitution and the ... [Medicines] Act." Further, administrative independence "implies that there will be control over those matters directly connected with the functions which the ... [Authority] has to perform under the Constitution and the Act.[2]

17. Our amendments here therefore seek to ensure that the Authority is appropriately shielded from political as well as commercial interference whilst remaining an integral, appropriately resourced and accountable part of the public administration. Clearly, to say that the Authority should be independent does not mean to suggest that the Authority should exist in what Mr. Ramasala described during last week's briefing as "a vacuum". Quite the opposite: as far as public institutions are concerned, greater independence demands greater accountability. In public administration, independence and accountability are, in effect, two sides of the same coin.

18. The Bill before you makes no mention whatsoever of a governance structure for the Authority which Parliament can hold accountable such as the board of the South African Broadcasting Corporation (SABC). Instead the body is simply required to report and account directly to the Minister of Health, the very same person to whom it reports and who is also tasked with the hiring and firing of its CEO. Requiring the proposed Authority to account in this manner removes the direct links that currently exist between Parliament and its committees on the one hand and the MCC on the other. Although Parliament will still exercise a degree of oversight through the provisions of the Public Finance Management Act 1 of 1999, its powers will be somewhat limited.

19. 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's directorate dealing with Medicines Regulatory Affairs. Either way, it is inappropriate for such broad

[1] *New National Party of South Africa v Government of the Republic of South Africa* 1999 (3) SA 191
[2] Paragraph 98

23/10/2008 11:58 021-403-2854 COMMITTEE SECTION PAGE 04/07

discretions to be allocated to the Minister, particularly in the absence of any guidance regarding their exercise.

20. We maintain that, as a public institution charged with the critical duty of safeguarding the safety and quality of medicines and other health products in the country, the Authority's activities and functions must be subject to appropriate oversight. Thus we assert that while the Authority should liaise with the DoH and report to the office of the Minister, it must account directly to Parliament. Parliamentary oversight is critical both to ensure the Authority's accountability as well as its independence.

CRITERIA AND PROCESSES FOR THE APPOINTMENT OF THE CHIEF EXECUTIVE OFFICER AND OTHER AUTHORITY STAFF (CLAUSE 3)

21. Most of our suggested revisions to the text of Clause 3 of the Bill follow on from the concerns we raised in reference to Clause 2. We will therefore not address them in any great detail. Suffice it to say that Clause 3 seeks to protect the independence and integrity of the Authority largely by:

    21.1. Placing additional checks and balances on the powers of the Minister over the appointment, management and supervision of Authority staff and committees, including its CEO;

    21.2. Establishing a central role for the National Assembly in the appointment of the CEO and ensuring that he or she is also accountable to Parliament while nevertheless reporting directly to the Minister;

    21.3. Adding further disqualifications from the office of CEO as well as further details on the qualifications of appointment for certain key members of the Authority's staff; and

    21.4. Ensuring Parliamentary oversight in relation to the adoption of key regulations dealing with the structure of the Authority, focusing on the establishment of its committees.

POWER OF THE MINISTER TO EXCLUDE MEDICINES OR OTHER HEALTH PRODUCTS FROM REGULATION (CLAUSE 41)

22. Clause 41 of the Bill, which grants powers to the Minister of Health – on the recommendation of the Authority – to exclude medicines or other health products from certain or all aspects of regulation is largely a restatement of section 36 of the principal Act but without certain important safeguards.

23. As it currently operates, section 36 of the Act allows for the Minister to exclude medicines from some or all aspects of regulation, but puts in place certain checks and balances:

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

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

24. The new proposal simply refers to an Authority recommendation, which effectively removes all checks and balances. Instead of an independent body making the recommendation, the CEO – who according to the Bill reports and accounts directly to the Minister – must make a recommendation to his or her boss. In addition, the 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*. These principles and their relevance for the regulation of medicines and other health products are discussed in detail in our first written submission.

25. To address our concerns with this clause, we have proposed amendments that require regulations – approved by Parliament – to guide the exercise of this exemption provision.

NEW CLAUSES TO BE ADDED

26. Further to the amendments noted above and in line with recommendations made in our previous submissions, we propose that two new clauses be inserted into the Bill: the first dealing with the recognition of other stringent drug regulatory authorities, including the World Health Organisation (WHO), insofar as certain priority products are concerned for use in urgent and emergency situations; and the second dealing with access to information. If adopted, the first provision would allow for increasing access to products of proven quality, safety and efficacy. The second provision is designed to ensure greater transparency in and the accountability of the Authority.

CONCLUSION

27. In conclusion, we would like to thank the Committee once again for the opportunity to speak today. We wish you well in your deliberations and offer our ongoing support. Our aim is to ensure that the Bill is as good as is reasonably possible. Should our assistance be deemed necessary and appropriate, please do not hesitate to let us know how we can help.

[ENDS]