AIDS law project
info@alp.org.za
www.alp.org.za

Johannesburg
+27 (0)11 356-4100 (tel)
+27 (0)11 339-4311 (fax)
PO Box 32361
Braamfontein 2017

6th Floor, Unit 6/002,
Braamfontein Centre
23 Jorissen Street,
Braamfontein

CapeTown
+27 (0)21 422-1490 (tel)
+27 (0)21 422-1551 (fax)
122 Longmarket Street,
Westminster Hse, CapeTown 8000

30 June 2008

Mr. L. V. J. Ngculu, MP
Chairperson, Portfolio Committee on Health
c/o Ms. Vuyokazi Majalamba
Committee Secretary, Portfolio Committee on Health
3rd Floor, 90 Plein Street
Cape Town 8000

Per fax: 086 694 3279 and per e-mail: vmajalamba@parliament.gov.za

Dear Mr. Ngculu

AIDS LAW PROJECT (ALP) AND TREATMENT ACTION CAMPAIGN (TAC) SUBMISSION TO THE PORTFOLIO COMMITTEE ON HEALTH ON THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL [B 44—2008]

The ALP and TAC welcome this opportunity to make a written submission on the Medicines and Related Substances Amendment Bill [B 44—2008] ("the Bill"). Our joint submission is comprised of this cover letter and the following two attached documents:

- Our original written submission to the Department of Health (DoH) on the draft Medicines and Related Substances Amendment Bill, 2008 ("first submission");[1] and
- A new document entitled "Analysis of the Task Team Report and Comparison with the Medicines and Related Substances Amendment Bill, 2008" ("second submission").

These two documents have been developed as part of engaging the DoH and its legislative proposals regarding the regulation of medicines and other health products. As an integral part of our interactions, representatives from the ALP and

[1] Our submission, which was sent to the DoH on 16 May 2008, is attached hereto entitled "Joint Submission on the Draft Medicines and Related Substances Amendment Bill, 2008". On 16 May 2008, we also made a joint submission on the draft National Health Amendment Bill, 2008.

TAC met with senior DoH officials to discuss the first submission.[2] At that meeting – held at the DoH on 20 May 2008 – we called for the public release of the report of the *Ministerial Task Team on the Restructuring of the Medicines Regulatory Affairs and Medicines Control Council* ("the MTT report"), which was posted online later that week.

Unfortunately, our written and oral submissions appear to have had no impact whatsoever on the DoH's deliberations. A slightly revised version of the draft legislation was published on 2 June 2008[3] and formally introduced to Parliament on 17 June 2008. In form and substance, the Bill is largely indistinguishable from the earlier departmental version. As such, it treats our carefully considered submissions as irrelevant. We continue to stand by these earlier submissions.

In particular, we remain steadfast in the view that the Bill should be withdrawn. This conclusion is further strengthened by our second submission that shows the extent to which the Bill departs from the recommendations contained in the MTT report. As such, the Bill is the embodiment of a fundamentally flawed consultation process – where consultation appears to have treated with significant contempt.

Amongst other things, the two documents that comprise this submission show that –

- 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;

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

  - Inappropriately – and arguably unconstitutionally – allocating broad powers to the Minister; and
  - Replacing a semi-independent Medicines Control Council with a health products regulatory authority that is effectively to operate as a line function within the DoH; and

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

[2] We also discussed our submission on the draft National Health Amendment Bill, 2008.
[3] Government Notice No. 611, *Government Gazette* No. 31114

We will advance these submissions in greater detail at the public hearings on 5 and 6 August 2008. In particular, we will argue that the Bill is so deeply flawed that nothing short of a complete rewrite is necessary. Simply put, we will explain why it should be returned to the DoH so that the recommendations of the MTT report – as well as the submissions originally received by the department – can be seriously addressed and given effect. Only then would it be appropriate for draft legislation to be considered and processed by your committee.

One final matter requires your attention. In our original submission to the DoH, we drew attention to its failure to act on detailed information provided by the TAC to investigate the unlawful activities of vitamin salesman Matthias Rath. Since then, judgment in the case of *Treatment Action Campaign and Another v Matthias Rath and Others* has been delivered.[4] Amongst other things, Justice Zondi's decision finds that the Minister of Health and her director-general had failed to take reasonable measures – as required by law – to prevent Rath from conducting unauthorised clinical trials and publishing advertisements concerning the medicinal effects of one of his products on people living with AIDS.

Justice Zondi's findings are instructive. They underline the importance of the scientific governance of medicines, the vulnerability of state officials to undue commercial pressure and the need to ensure oversight of the executive. Importantly, they provide significant support for our call for the establishment of an independent government agency to regulate the development, use and registration of all health products, something quite different from that which the Bill seeks to establish.

Once again, we thank you for the opportunity to make this submission and look forward to engaging you and your committee at the public hearings on 5 and 6 August 2008.

Yours sincerely

Mr. Mark Heywood
Executive Director, ALP

Ms. Vuyiseka Dubula
General Secretary, TAC

[4] Case no 12156/05, High Court of South Africa (Cape of Good Hope Provincial Division), 13 June 2008, available online at http://www.tac.org.za/community/rath.