Draft Medicines Amendment Bill is incompatible with the scientific governance of medicine

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The AIDS Law Project (ALP) and the TAC have made a submission to the Department of Health on the Draft Medicines and Related Substances Amendment Bill, 2008. Unless our substantive concerns are addressed, we will take steps to stop this bill from being enacted. As we state in the submission:

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 With this understanding, we submit that the draft Bill is irredeemably flawed and should be withdrawn.

Read the full written submission on the Draft Medicines and Related Substances Amendment Bill, 2008.

We have also made a submission on the Draft National Health Amendment Bill. We support the bill's intention of ensuring that private health-care services and products are appropriately priced, but it is the proposed manner of regulation this that also makes this bill problematic. Our submission lists the following concerns about the bill:

- the lack of consultation in the process of developing the draft bill;
- the lack of independence of the proposed regulatory mechanism;
- the delegation of authority; and
- the ambiguities and gaps in the draft bill.

The result of the deficiencies in the Bill will be to render it ineffective, and to delay any reasonable regulation of private health care services and products.

Read the full submission on the Draft National Health Amendment Bill, 2008.

- Submissions to Parliament or Government

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