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Delays in Registration of ARVs: Letter by the HIV Clinicians Society

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The Southern African HIV Clinicians Society has written the following letter to the Minister of Health about the delay in the registration of antiretrovirals by the Medicines Control Council. TAC endorses it.

(PDF version of letter)

The Hon. Dr Pakishe Aaron Motsoaledi
The Minister: National Department of Health
Private Bag X399, Pretoria, 0001
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Email: masukm@health.gov.za

2 March 2010

Dear Minister Motsoaledi

RE: DELAY IN REGISTRATION OF ANTIRETROVIRALS BY MEDICINES CONTROL COUNCIL

The Southern African HIV Clinicians Society (the Society) is an association of over 16 000 health care workers in the field of HIV, most of whom reside in South Africa. The Society has been instrumental in developing independent HIV treatment guidelines that inform the care of the vast majority of patients in South Africa, as well as advising on the Department of Health guidelines.

As President of the Society, I have been approached several times in the last few weeks by concerned stakeholders, including HIV researchers, government health officials, international aid agencies, donors, pharmaceutical companies and activists, expressing intense frustration with the with the Medicines Control Council?s (MCC) slow registration process of antiretrovirals. Several of these individuals have indicated to me that they are considering resorting to legal action, as all other remedies, including repeated correspondence, have failed to draw a response or an explanation from the MCC.

HIV remains an absolute public health emergency for South Africa, with almost half of all deaths due to the disease. South Africa has over a million patients on antiretrovirals in the state and public sector, by far the largest in the world. The new Department of Health HIV treatment guidelines strive to improve the selection of antiretrovirals and the tender process, and the private sector is seeking to expand access to drugs for people with resistance. In both these cases, the single obstacle to getting affordable access to medicines appears to be the MCC registration process, as some dossiers have been before the MCC for years. We ask that the MCC prioritise the following drugs immediately:

For adults:
? All fixed dose combinations, especially the combination of tenofovir, emtricitabine (or lamivudine) and efavirenz, which will be the state first line antiretroviral and the most popular initial antiretroviral combination in private practice
? Generic versions of antiretrovirals, especially of tenofovir and paediatric abacavir

? Darunavir
? Raltegravir
? Etravirine
? All variations of existing registered antiretrovirals that require simple dossier changes

For children:
? Fixed dose combinations, as above, including abacavir/lamivudine and lopinavir/ritonavir (including the newer heat stable formulations)
? Generic abacavir

In addition, drugs to treat tuberculosis and other common opportunistic infections should be fast-tracked. If the above is not done immediately, the government will be unable to issue a competitive tender for fixed dose combinations in April, further delaying patient access to drugs which are easier to take and require less pharmacy time. In addition, competition between pharmaceutical companies is compromised, with managed care organisations, medical aids and private patients having to pay more than they should.

I am aware that the MCC is dealing with a backlog, but the fact that it appears to be blocking access to lifesaving medication is unacceptable. I suggest you instruct your acting DG to place this issue on the next MCC meeting?s agenda, scheduled for 19 March 2010, for immediate attention and action. I would appreciate a formal and urgent response from the MCC after that meeting.

Regards
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President: Southern African HIV Clinicians Society

Cc:
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Chairperson: Medicines Control Council
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