

SOUTH AFRICA - Delayed drug registrations hard to swallow

JOHANNESBURG, 4 March 2010 (PlusNews)



Photo: [UNAIDS](#) 

Patient-friendly but unapproved

Delays in registering antiretroviral (ARV) medication may keep cheaper, more patient-friendly drugs out of reach as South Africa prepares to launch the world's largest tender for medicines.

In a [letter](#) to Dr Aaron Motsoaledi, the Minister of Health, the South African HIV Clinicians Society called on the country's drug registration body, the Medicines Control Council (MCC), to fast-track the approval of certain ARVs, the generic versions of others, and fixed-dose ARV combinations that combine multiple ARVs into a single pill.

The new [ARV tender](#) will allow pharmaceutical companies to bid for supplying the biggest HIV treatment programme in the world, but drugs without MCC approval are unlikely to be included in the tender process. Many activists have said that excluding these as yet unapproved drugs will lead less companies to apply for the tender and [push up prices](#), while also depriving patients of fixed-dose combination therapy.

"My biggest concern is that the MCC is just not functioning well - they're trying to repair the system but they're not giving priority to these drugs," said Dr Francois Venter, president of the Clinicians Society, who noted that some drugs had been awaiting approval for more than two years due a backlog in the MCC.

"These drugs need to be pushed to the front of the queue; these are not experimental drugs we are talking about here, these drugs have been registered in Europe for more than a year," Venter told [IRIN/PlusNews](#).

According to the [HIV Clinicians Society's](#) letter, all fixed-dose combinations, some of which are likely to form part of first-line regimens, and new, heat-stable paediatric formulations are among the drugs awaiting registration.

"I cannot think of another drug that is more important drug than ARVs," Venter said. "If the [MCC](#) can't fulfil its role as a registering body then, frankly, it must get out of the way."

South Africa has an HIV prevalence of about 18 percent, and its national ARV programme reaches an estimated 1.7 million people, according to UNAIDS.

Dealing with the backlog

The MCC has taken steps to address the backlog, but the organization remains understaffed said Jonathan Berger, a senior researcher at the [AIDS Law Project](#) and a member of the MCC, who spoke to IRIN/PlusNews in his personal capacity.

Long delays in registering new drugs have prompted calls by the Joint Civil Society Monitoring Forum (JCSMF) - a civil society body that monitors implementation of the government's National Strategic Plan for HIV and AIDS - for the government to waive the registration process for drugs already approved by stringent regulatory bodies such as the US Food and Drug Administration and the World Health Organization.

South African law prohibits this, but Berger said the health department might not have ruled out switching to an

abbreviated review process for some drugs that have already been approved overseas.

What it means

[*Andy Gray*](#), a pharmacist at the Centre for the AIDS Programme of Research in South Africa (CAPRISA) at the University of KwaZulu-Natal, said adherence and provision were a lot harder without fixed-dose combinations.

"If these [fixed combinations] aren't registered, we won't be able to take advantage of them as we increase the number of patients on treatment, and as we increase the number of sites providing ARVs, and as we increase the use of nurses to provide treatment," he told IRIN/PlusNews.

"There are great advantages to using fixed-dose combinations - they reduce errors with prescribing them, they're quicker for pharmacies to dispense, and they're easier for patients to comply with."