Medicines Control Council must stop dragging its heels on life-saving drugs

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In 1997, Judge Edwin Cameron nearly died of AIDS. Last year, at over 50, he cycled the Argus race. Cameron is alive and healthy today because of the science of medicine. His story is not unusual. Today, most people with AIDS who can access antiretroviral treatment can live almost normal lives. Scientifically proven medicines have changed HIV's prognosis from a painful and slow early death to a manageable chronic disease.

Modern medicine is very imperfect, but it has greatly improved quality of life. With success, however, has come the huge health industry and its numerous exaggerated and false claims. Drug companies are heavily regulated to deter them from selling untested products. But even with regulation, there are many unproven remedies for sale offering cures for every conceivable ailment from bad luck to fatal diseases.

The Medicines Control Council (MCC) is the body responsible for determining which medicines can be sold in South Africa. It is one of those seldom heard from technical institutions that is nevertheless very important at some time or another to most people's lives. We rely on the MCC to maintain our confidence in medicine, especially prescription ones for serious diseases. Its job is to consider the safety and efficacy of medicines. It has to register those whose probable benefits outweigh their risks and reject all others. For new medicines for deadly diseases, it should act swiftly. It must be influenced only by what is in the public interest.

Over 70% of people in South Africa depend primarily on the public health system for their essential medicines. The quality of the medicines available in public facilities is dependent on what the MCC registers, as well as national treatment protocols approved by the Department of Health. The antiretroviral programme in the public health system is an example of this. It has prolonged and improved many thousands of lives.

The Western Cape government, which keeps good records of its programme, released a report in June 2006 that stated "by four years duration on [antiretrovirals], 7 out of 10 ... adult patients are still in care. Without treatment almost all of these patients would have died in this time period." However one of the drugs used in the programme, called d4T, can cause side-effects that in rare cases are fatal. The evidence is beyond doubt that d4T's advantages outweigh its risks but many patients, especially overweight women, would benefit from replacing it with a better drug called tenofovir. It has fewer side-effects than d4T and only needs to be taken once a day. It has several other technical advantages which lead to better patient outcomes. HIV clinicians are calling for the antiretroviral treatment protocol to be changed to include tenofovir. Yet, even though tenofovir was registered in the US in 2001, it is still not registered here.

The delayed registration of tenofovir is partly the fault of the US patent-holder, Gilead, because it only applied for the drug to be registered in 2004. Then Gilead entered a deal with South African pharmaceutical maker Aspen to market and distribute the drug. Aspen took over the registration application and this caused further delays. Aspen applied for

what is known as fast track registration but more than two years since the original application, tenofovir remains unregistered. Only some patients can access the medicine - via a time-consuming special authorisation process administered by the MCC. Public sector patients have very little chance of accessing it.

It is absurd that a ground-breaking medicine has been unavailable for so long to most people with HIV in the country which probably has the world's largest number of infections.

The MCC is letting down people with AIDS. For one thing, it together with the Department of Health bears responsibility for the failure to crack down on unproven remedies. But it is the MCC who must take much of the blame for the slow registration of tenofovir. True, it is under-resourced, but this is not an acceptable excuse. It is a critical institution and it is government's job to make sure it has the budget allocation it needs. Despite the concerns raised by government about antiretroviral side-effects it has taken no steps to give the MCC the resources it needs to register a better antiretroviral with fewer side-effects.

TAC is therefore demonstrating outside the MCC, Department of Health and Aspen offices on 22 February. But activists cannot be expected to protest whenever a drug's registration is delayed. Rather, the MCC must do its job competently. Today it is tenofovir, but in future there will be other drugs for other diseases that will need to be registered without delays.

Most of us will at some point need a scientifically proven medicine to alleviate pain, cure a disease or prolong life. It is in our interests to have an effective MCC so that we can be confident that the best life-saving medicines are available in the country when we need them.

- Quackery

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