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TAC Electronic Newsletter

By *moderator*
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- Tenofovir Campaign details and memo
- Response to City Press poor reporting on microbicide trial by Mark Heywood (AIDS Law Project and TAC) and Francois Venter (Southern African HIV Clinicians Society) as published in City Press

TAC mobilises over tenofovir

Tomorrow, 22 February, TAC will be holding demonstrations around the country demanding the registration of tenofovir (see TAC newsletter of 6 February for a fact sheet on tenofovir). All welcome.

Details

Pretoria: Meet at Union Buildings, 10am. March to MCC and Department of Health. (Ph: 011 339 8421) Durban: Meet at the Park in Armstrong Ave, La Lucia Ridge, 10am. March to Aspen. (Ph: 031 304 3673) Cape Town: Picket at Aspen offices, Waverley Business Park, Observatory, 10am. (Ph: 021 447 2593) East London: Picket at Aspen, Robbie De Lange Road, Wilsonia, 10am. (Ph: 043 722 2645)

Here is the memo we will be handing over to the Department of Health, MCC, Aspen and Gilead tomorrow:

MEMORANDUM

Register tenofovir and combination medicines that include tenofovir

Include tenofovir in the antiretroviral treatment guidelines.

To:
Professor Peter Eagles, Chairperson, Medicines Control Council
Ms. Mandisa Hela, Registrar of Medicines, Medicines Control Council
Dr. Manto Tshabalala-Msimang, Minister of Health
Mr. Thamsanqa Mseleku, Director-General of Health
Mr. Stephen Saad, Group Chief Executive, Aspen Pharmacare
Dr. John C. Martin, President and Chief Executive Officer, Gilead Sciences

22 February 2007

TAC members are demonstrating today at the offices of the Department of Health, Medicines Control Council and Aspen Pharmacare. We hold you and also Gilead Sciences collectively responsible for the slow registration of tenofovir. Making tenofovir available in the public health system will improve HIV patient outcomes and save lives.

As you are aware, tenofovir is an antiretroviral that we need to have registered in South Africa, so it can become part of first-line antiretroviral therapy (ART) as an option to stavudine (d4T). Tenofovir has a better side-effect and resistance profile than most other antiretroviral medicines, particularly d4T. It is only taken once daily and it is available in combination pills with other antiretrovirals in other countries. At least one clinical trial has shown that an ART regimen that includes tenofovir has better patient outcomes than a commonly used regimen in South Africa. HIV clinicians have called for tenofovir to be included in the antiretroviral treatment protocol.

This essential medicine has been available in the United States since 2001, yet it is February 2007, more than five years later, and tenofovir is still not registered in South Africa, the country with probably more HIV-positive people than any other in the world. This is a travesty. Tenofovir remains unregistered because of bureaucratic delays by both the Medicines Control Council (MCC) and Gilead Sciences, as well as insufficient political will. Furthermore, the drug registration process is opaque and shrouded in an unnecessary level of confidentiality.

Some patients access tenofovir via the MCC's time-consuming administratively complex Section 21 authorisation. But the vast majority of people who need this medicine, especially poor people using public sector facilities, cannot access it.

TO MCC CHAIRPERSON PROFESSOR PETER EAGLES AND REGISTRAR OF MEDICINES MS. MANDISA HELA

We understand that the original application for the registration of tenofovir was sent to the MCC by Gilead Sciences in early 2004. We further understand that Aspen Pharmacare restarted the process and applied for fast-track registration in 2005. More than two years since the original application, tenofovir remains unregistered.
We call on the MCC to take all necessary steps to register tenofovir by the end of February 2007.

You have refused to divulge information on the status of the tenofovir registration, offering the excuse that you are protecting the confidentiality of the applicants. But the MCC's responsibility is to the public, not to pharmaceutical companies.
We also call on the MCC to make its registration process transparent.

The MCC is under-resourced. It is unresponsive to public enquiries and takes too long to register most new essential medicines. The delayed registration of tenofovir is not unique. The registration of the 600mg efavirenz pill and atazanavir are examples of other medicines whose registrations took too long. Public confidence in life-saving medicines depends on the effective functioning of this essential institution.
We call on the MCC to demand the resources it needs to do its job.

We are also concerned that the MCC must be independent of political influence. For example, the MCC, correctly, registered oseltamivir phosphate (Tamiflu) in a short time. Yet this drug has not yet been needed in South Africa and its efficacy against avian Influenza is unclear. By contrast, tenofovir has been proven effective in clinical trials and has been in use across the world since 2001. We hope that the MCC's slow registration of tenofovir has not been due to the irrational negative political climate surrounding antiretrovirals.
We call on the MCC to act in the public interest only.

TO MINISTER OF HEALTH DR. MANTO TSHABALALA-MSIMANG AND DIRECTOR-GENERAL OF HEALTH MR. THAMSANQA MSELEKU

You have both expressed concerns about the side-effects of antiretroviral medicines. Many people with HIV could have avoided lactic acidosis and other side-effects of d4T if tenofovir had already been registered. While it would be

inappropriate for the Department of Health to tell the MCC whether or not to register a medicine, the Department certainly has a duty to ask the MCC to speed up its decision-making processes.
We call on you to urge the MCC to complete its registration decision on tenofovir by end of February 2007.

A number of new antiretroviral combination pills have been developed. For example, there are now at least two manufacturers of tenofovir/FTC/efavirenz. It should also be possible to make combination pills of tenofovir/lamivudine/efavirenz and tenofovir/lamivudine/nevirapine. These combination pills would only need to be taken once, or at most twice, a day. A study conducted in South Africa has shown that reduced pill count is the most important factor in patient adherence, an issue that concerns all of us.
We call on you you to negotiate with and pressurise drug manufacturers, including generic suppliers, to produce and apply for registration of combination pills.

Once tenofovir is registered it must become part of the antiretroviral treatment protocol. Last year the Department postponed an antiretroviral treatment protocol review meeting. This meeting must take place soon.
We call on you to convene a meeting to update the antiretroviral treatment protocol.

TO ASPEN GROUP CHIEF EXECUTIVE MR STEPHEN SAAD AND GILEAD CHIEF EXECUTIVE OFFICE DR JOHN C. MARTIN

At the time that Gilead's announced its access programme for tenofovir, it apparently showed you were more responsible than other drug companies manufacturing AIDS drugs. Yet your actions did not match your public relations. It was unacceptable that Gilead only applied for registration of tenofovir, according to our information, in November 2004, three years after it was registered in the US. The same mistake should not be repeated for combination pills that include tenofovir. We call on you to apply immediately for fast-track registration of the tenofovir/FTC combination pill. We call on you to work with the other patent-holders to apply immediately for fast-track registration of tenofovir/FTC/efavirenz.

Aspen has informed us that it is not responsible for the delayed registration of tenofovir. That might be the case, but the registration process is opaque. We need access to all information relevant to the registration of tenofovir to understand what is causing the delay.
We call on you to allow the MCC to make public all relevant information on the registration of tenofovir. We also call on you to make this information public.

We are concerned that the price of tenofovir will remain too high unless there is competition between multiple manufacturers. Competition will also ensure a sustainable supply.
We call on you to not take any steps that will hamper the manufacture of generic tenofovir or combination pills that include tenofovir or FTC.

[END OF TENOFOVIR MEMO]

?Guinea pig? story on HIV prevention worrying

City Press, 10/02/2007 18:53 - (SA) http://www.news24.com/City_Press/Columnists/0,7515,186-1695_2067467,00.html

MARK HEYWOOD and FRANCOIS VENTER

Print article
email story

The article in City Press last Sunday (Women used as Aids guinea pigs) and the subsequent controversy around the ending of the Ushercell microbicide trial requires a response from South Africans concerned with preventing infectious

disease and developing scientifically proven interventions.

In recent years, South Africa has been the victim of a large number of fraudsters who ignore scientific process, marketing unproven and potentially dangerous ?cures? and interventions. People with chronic illnesses, especially serious ones such as HIV, are very vulnerable to claims about ?miracle? treatments.

Recognising this, we support scientific research that strives to obtain answers in the most rigorous way possible, observing national and local ethics oversight committee guidance.

South Africa has a grave Aids epidemic. Consequently, we desperately need HIV-prevention technologies that work for vulnerable populations. Microbicides are theoretically very exciting as women are able to control their use. Indeed, even if a woman chooses to disclose the use of a microbicide to her partner, she would initiate the application (unlike a condom).

Obviously, HIV prevention trials require enrolment of people at risk for HIV, and we know that women and girls are disproportionately at risk. But in addition it is essential that trials are conducted in the communities where these products are most needed.

Internationally, we have learnt that communities that participate in HIV prevention trials, including trials for a vaginal microbicide, experience a decreasing HIV incidence. This is due to vigorous condom promotion, counselling on HIV risk reduction and HIV voluntary counselling and testing offered during the process when volunteers are recruited to these trials.

In this regard the City Press article is worrying. By characterising people as ?guinea pigs?, it suggests that the women recruited for the study had no say in, and were ignorant about, their participation. Later in the article it is implied that payment for travel costs (at a rate set by the Medicines Control Council) is a dishonest method of persuading people in poverty to participate. The reference to ?US funded? research suggests that external researchers are forcing their research agendas onto developing populations.

However, the facts are different:

. The department of health was consulted on the study, and supports the development of a microbicide for HIV prevention.

. The study is run by a respected local researcher, part of a South African research unit that is internationally renowned for quality and integrity.

. The researcher advised international leaders of the study on the study design.

. The study was conducted using a microbicides product that had already been tested extensively.

. The study was vetted by a very credible local ethics committee.

. Women participating were offered levels of care, counselling and treatment beyond those generally available in the public sector.

. The study is regularly evaluated by independent safety boards for the safety and ethical treatment of participants. Such an independent board recommended its termination.

. There are no reports to suggest the study was run poorly or unethically.

The fact that the product failed to protect women from HIV and, may possibly have made HIV transmission rates higher, is a tragedy. However, there is no other way of evaluating potentially valuable microbicides.

Heywood is the director of the Aids Law Project and Dr Venter is president of The Southern African HIV Clinicians Society

[END OF MICROBICIDE ARTICLE]

- Antiretrovirals
- Microbicides
- Quackery

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