TAC Electronic Newsletter

By *moderator*
Created *2006/01/30 - 12:00am*
30 January, 2006 - 00:00 ? moderator

Contents

TAC and allies demand better anti-retro-viral roll-out in Mpumalanga

By Sydney Masinga with additional reporting by Doron Isaacs

Themba Hospital was the first accredited antiretroviral (ARV) clinic in Mpumalanga Province following the publication of the Operational Plan on 19 November 2003. In August 2005 TAC met clinic-head Dr Mavuso who said that 80 people were on ARV treatment with about 3,000 on the waiting list. Later in 2005 Dr Mavuso told TAC that the waiting list had dropped to 1,850 and he assumed the rest (1,150) had died while on the list. In December 2005 an NGO analysed Themba Hospitals antiretroviral programmed and informed the Joint Civil Society Monitoring Forum (JCSMF) that the number of people on the waiting list was approximately 1,150.

In an interview on Ligwalagwala FM on 19 January 2006, Provincial Health Department spokesperson Mpho Gabashane said that Themba hospital had 200 people on ARV treatment. The JSCMF put the number at 197 in December 2005, but hospital staff have informed TAC that only 88 people are currently receiving treatment.

Dr Mavuso has attributed Themba Hospital's slow ARV rollout to a lack of pharmacists. But this does not seem to be the whole story. At present Themba Hospital has two qualified pharmacists and four pharmaceutical interns. Kwa Mhlanga Hospital, which only began its rollout in September 2005, has no doctor in the ARV clinic and only one pharmacist but approximately 300 people on treatment. Rob Ferreira Hospital has only one pharmacist (one having

been transferred to Themba Hospital), three doctors and, according to the JCSMF, 820 patients on ARV treatment. A source at Rob Ferreira puts this figure higher at 1,900 on ARV treatment. The difficulty in attaining exact figures emphasises the need for the National Department of Health to implement proper monitoring and evaluation of the ARV rollout.

Themba Hospital had a larger number of pharmacists at the start of 2005, however some resigned allegedly due to poor living conditions and inadequate transport. The hospital advertised eight pharmacist posts in mid 2005, none of which have been filled.

Some patients told the TAC that they were given prescriptions at Themba Hospital to buy ARVs from a commercial pharmacy for R460 per month, although the hospital is stocked with ARVs. Healthcare workers have expressed concern that the ARVs at Themba hospital may expire.

On 26 January 2006 the Department of Health held a community imbizo at Themba hospital. Health MEC Mr Pogisho Pasha was not present, but Dr. Keith Michaels spoke, fielded questions and accepted a TAC memorandum from the 150 members present. Questions about the unavailability of ARVs dominated the meeting. Dr. Michaels, who was receptive to the grievances expressed, suggested that a TAC member sit on the hospital board. Sydney Masinga has been nominated for this purpose, while board hospital chairperson Mrs M. Malapane has said she is open to the idea. The National Health Act makes provision for community members to sit on hospital boards.

[END OF MPUMALANGA STORY]

Letter from Physicians for Human Rights to President Mbeki

23 January 2006

Physicians for Human Rights has written to President Mbeki (see full text below), calling upon the South African Government to "repudiate Dr. Matthias Rath's false AIDS treatment assertions".

Physicians for Human Rights is a respected human rights organisation based in the United States.

From their website:
"Using medical and scientific methods, we investigate and expose violations of human rights worldwide and we work to stop them. We support institutions that hold perpetrators of human rights abuses, including health professionals, accountable for their actions."

Contact details of Physicians for Human Rights: http://www.phrusa.org
For comment, please speak to Eric Friedman on 091-202-728-5335 ext. 303.

The letter to President Mbeki

January 13, 2005

President Thabo Mbeki
Private Bag X1000
Union Buildings, West Wing, 2nd Floor
Government Avenue
Pretoria, South Africa

Dear President Mbeki:

Physicians for Human Rights calls upon the South African Government to repudiate Dr. Matthias Rath's false AIDS treatment assertions, which incorrectly promote vitamin therapy as a treatment for AIDS and undermine the importance of life-saving antiretroviral therapy. After much delay, the South African Government has begun to take important steps to provide antiretroviral therapy to people living with AIDS, including the release of a comprehensive care and treatment plan in late 2003. While more than 70,000 people with AIDS are now being treated in the public sector thanks to this plan, implementation has been behind schedule, with lower than the targeted number of people in urgent need of antiretroviral therapy now on treatment.

One impediment to treatment has been the mixed messages the government has sent on the value of AIDS medication, due in large part to the South African Department of Health's tolerance of the pharmaceutical proprietor, Matthias Rath. In recent months, Dr. Rath has been distributing untested medicines (primarily composed of high-dosage vitamins) to people with HIV in South Africa, claiming inaccurately that these medicines reverse the course of AIDS. He has also admitted to conducting an experiment on people in the Khayelitsha township without the approval of the Medicines Control Council. Furthermore, Dr. Rath has wrongly attacked organizations and individuals devoted to alleviating the HIV epidemic, such as the Treatment Action Campaign (TAC). For example, Dr. Rath's Foundation has distributed a poster that accuses TAC of promoting AIDS drugs that "make people even more sick," and claims that "TAC forces the government to spread disease and death among the people of our country and at the same time ruin our economy."

Dr. Rath has used his South African experiments to market his products in the United States and Europe, by placing advertisements in the New York Times, the International Herald Tribune and on numerous websites. The South African Government has been regrettably tolerant of Dr. Rath's views even though they are clearly contrary to overwhelming scientific evidence. Dr. Rath has met with Minister of Health Dr. Manto Tshabalala-Msimang, who has made statements that appear to support Dr. Rath. The Minister allowed Dr. Rath's associates to present their "findings" to the National Health Council, a body consisting of the heads of health in all South Africa's provinces. This peddling of pseudoscience leads to increased confusion among patients, who then may delay seeking assistance from South Africa's extensive public health care system.

Dr. Rath's views and efforts have been condemned by the South African Medical Association, the Southern African HIV Clinicians Society, the South African Council of Churches, major trade unions in South Africa (including the largest one, the Congress of South African Trade Unions, COSATU), and the United Nations.

Organizations in South Africa, including the Treatment Action Campaign, Medecins Sans Frontieres, and others lodged complaints with the South African authorities earlier this year to stop Dr. Rath's activities ? such as making false claims about medicines, distributing medicines for the purpose of treating HIV/AIDS that are not registered for this purpose, and conducting an unauthorized experiment on human subjects ? but nothing substantive has been done. On the contrary, the Minister of Health has gone on record in South Africa's Parliament stating "I will only distance myself from Dr. Rath if it can be demonstrated that the vitamin supplements that he is prescribing are poisonous for people infected with HIV." The primary danger is not the supplements themselves, however, although very high doses of vitamins do have serious potential dangers for people with HIV/AIDS. The danger is that people will listen to Dr. Rath's claims that the vitamins will cure AIDS, while believing antiretrovirals to be toxic and potentially deadly, and so will take the supplements instead of life-saving antiretrovirals. Earlier this year, for example, Dr. Rath's foundation issued a press release claiming, falsely, that "with micronutrients alone, the AIDS patients could reverse the symptoms of AIDS and lead almost normal lives again."

In reality, the only medicines shown to be effective in reversing the course of AIDS are antiretrovirals. Although antiretrovirals produce side-effects in many patients and have to be taken daily for life, numerous scientific studies have demonstrated beyond reasonable doubt that their benefits significantly outweigh their risks. For more than 8 out of every 10 people who take them, they substantially extend life and reduce illness.

South Africa has the potential to lead the developing world in the response to the HIV pandemic. Already it has made substantial progress. But hundreds of thousands of people in immediate need of antiretroviral treatment still do not have

access, many mistakenly believe they do not need the drugs to stay alive, and the country continues to experience large numbers of new infections. A multi-pronged strategy is needed to significantly accelerate treatment scale-up. One of the simplest yet most urgent steps that the South African Government can take is to affirm that it stands firmly behind science, including the proven value of antiretroviral therapy. We call on the South African government to distance itself from Dr. Rath's positions and activities, clearly and consistently state that his AIDS treatment assertions are contrary to the firm consensus of the medical and scientific community, including that within the South African government, and unequivocally endorse the use of antiretroviral medication to save lives.

Sincerely,

Holly G. Atkinson, MD
President

CC: Dr. Manto Tshabalala Msimang
Minister of Health, South Africa

[END OF PHYSICIANS FOR HUMAN RIGHTS LETTER]

Bristol-Myers Squibb fails to supply life-saving medicine

Amphotericin B is a life-saving medication used to treat cryptococcal meningitis. Following pressure from various organisations in 2005, Bristol-Myers Squibb (BMS) dropped the price of this medicine. But now BMS is failing to supply sufficient quantities of the medicine to meet demand. BMS has apparently committed to restoring supply by end of February, but this is an unacceptably long delay that will result in avoidable deaths.

Below is a letter from BMS obtained by TAC, followed by a letter from TAC to BMS. Please note that BMS refers to amphotericin B by its commercial name Fungizone I.V.

Below the letter from BMS is a letter from TAC demanding that BMS address the situation by 2 February.

Letter sent by Bristol-Myers Squibb to GF Jooste Hospital

23 December 2005

Bristol-Myers Squibb (Pty) Ltd

47 Van Buuren Road

Bedfordview

PO Box 1408

Bedfordview 2008

South Africa

(011) 456-6400

Fungizone I.V. (Registration Number A/20.1.7/724

Information regarding stock shortages

It is with regret that we inform you of shortages we are currently experiencing on Fungizone I.V. The reason for the stock shortage is that demand has exceeded expectation.

Bristol-Myers Squibb sincerely regrets the inconvenience caused to our customers and assure you of our commitment to resolving the situation as speedily as we possibly can.

Yours sincerely

Bristol Myers Squibb (Pty) Ltd

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Planning Manager

Letter sent by TAC to BMS

27 January 2006

Mr Michael Berry

CEO Bristol-Myers Squibb (Pty) Ltd (South Africa)

PO Box 1408

Bedfordview

2008

South Africa

Per registered mail and per fax: (011 456 6584)

Dear Mr Berry,

URGENT: SHORTAGE OF AMPHOTERICIN B IN GF JOOSTE HOSPITAL, CAPE TOWN, SOUTH AFRICA

It has come to our attention that GF Jooste Hospital is experiencing a shortage of amphotericin B.

As you are aware, amphotericin B is indicated for the treatment of cryptococcal meningitis, an AIDS-defining illness with a high mortality rate. We have been informed that some patients with this condition at GF Jooste have not been able to access this essential medicine, which Bristol-Myers Squibb (BMS) distributes in South Africa.

Our legal representatives, the AIDS Law Project, corresponded extensively with BMS during 2005. The purpose of this correspondence was to ensure an affordable and sustainable supply of amphotericin B. Consequently BMS agreed to offer amphotericin B at the significantly reduced price of R26 per vial (down from R145). You are therefore also aware from this previous correspondence that we are concerned that amphotericin B should be consistently accessible in the South African public sector.

We have in our possession correspondence from BMS which acknowledges that your company is responsible for the current amphotericin B shortage due to underestimating demand. We are disappointed that you have not been more vigilant in ensuring a sufficient supply of this medication and have consequently endangered lives.

The present shortage of Amphotericin B is more than an ?inconvenience to ? customers? as stated in your letter; it is a life-threatening problem for patients with cryptococcal meningitis.

We therefore request answers to the following questions:

? What steps is BMS taking to ensure that the shortfall of amphotericin B at GF Jooste and any other health facilities is addressed immediately?

? What steps will BMS take to ensure this does not occur again?

? By what date will the shortage be resolved?

Because of the life-threatening nature of this problem, we request your urgent and satisfactory answer by or before 2 February 2006.

Yours sincerely,

Rukia Cornelius

TAC NATIONAL MANAGER

CC: Bristol-Myers Squibb Company c/o Peter R. Dolan (CEO) by fax

[END OF AMPHOTERICIN B SHORTAGE STORY - BACK TO CONTENTS]

TAC letter to MCC regarding registration of tenofovir

27 January 2006

Ms Joey Gouws

Acting Registrar of Medicines

Medicines Control Council

Private Bag X828

Pretoria 0001

Per registered mail and per fax: (012) 312-3105

Dear Ms Gouws,

URGENT: REGISTRATION OF TENOFOVIR IN SOUTH AFRICA

It has come to our attention that tenofovir disoproxil fumarate (TDF), an essential antiretroviral (ARV) medicine widely used in the treatment of HIV infection abroad, has not yet been registered for use in South Africa. Despite this, a limited number of people on ARV treatment are accessing the medicine in terms of section 21 of the Medicines and Related Substances Act, 101 of 1965 (the Medicines Act), and there are strong indications that its widespread usage in South Africa is likely, both in the public and private sectors.

Available evidence indicates that stavudine (d4T), an ARV medicine that is widely used in South Africa and forms an essential part of the standard first-line regimen in the Department of Health's HIV treatment guidelines, should be replaced by TDF. According to specialists in the field, d4T-related toxicity is the main reason for stopping and/or changing the first-line regimen, with d4T accounting for almost all long-term side effects. TDF, on the other hand, is potent, safe and well tolerated, having a significantly better side-effect profile than d4T. In our view, the widespread availability of tenofovir in South Africa would lead to better ARV treatment outcomes.

While the TAC does not wish to be understood to suggest that the Medicines Control Council (MCC) should relax its standards regarding proven safety, efficacy and quality, we nevertheless call for the MCC to expedite the registration of TDF and request the following information, based on information that we have received regarding the registration process to date:

1. The original application for registration by Gilead Sciences, Inc. (Gilead):

a. The date on which Gilead submitted its original application for the registration of TDF; and

b. A summary of the process leading to the return of the original dossier and the MCC?s request that it be resubmitted in another form; and

2. The application for registration by Aspen Pharmacare (Aspen):

a. The date on which Aspen submitted the revised application for the registration of TDF;

b. If, at the time of application, Aspen requested fast track review status;

c. If fast track review status was requested, when it was granted;

d. If fast track review status was not granted immediately, the reason for the delay;

e. If fast track review status was not granted at all, the reason for the refusal to grant such status;

f. Given that the Medicines Act now requires fast track procedures to be completed within nine months, the date by which TDF is expected to be registered; and

g. Any other information that, in your opinion, is necessary to explain why this essential medicine has not yet been registered by the MCC.

We believe that it is in the public interest to release this information as a matter of urgency. We therefore look forward to hearing from your offices by no later than 10 February 2006.

Yours sincerely

Rukia Cornelius

TAC NATIONAL MANAGER

CC: Aspen pharmacare c/o Stephen Saad (Group Chief Executive) by fax 031 580 8647

Gilead Sciences, Inc. c/o Joseph Steele (Vice-President Commercial Development) by fax +1 650 522 5870

Stephen Saad

Group Chief Executive

Aspen Pharmacare

PO Box 1593

Gallo Manor

2052

Joseph Steele

Vice-President, Commercial Development

Gilead Sciences, Inc.

333 Lakeside Drive

Foster City

CA 94404

United States of America

[END OF TENOFOVIR STORY]

- AIDS Denialism
- Medicine Access
- Pharmaceutical Companies
- Quackery

- Thabo Mbeki
- Treatment Plan

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