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# TAC complains to the Competition Commission about the anti-competitive conduct of the world's largest pharmaceutical company

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- TAC lodges complaint against MSD and Merck over failure to license key antiretroviral drug, efavirenz, on reasonable terms.
- Full complaint is available at: http://www.tac.org.za/documents/TACvMSDFinalCompCompapersFinalOf041107.zip

## Summary

64 cents in every rand of the South African government?s first line regimen for the treatment of HIV/AIDS is spent on one drug, *efavirenz*. It is made by the world?s largest drug company Merck.

The refusal by Merck ?and its South African subsidiary, MSD? to allow sufficient generic competition contributes significantly to the high price of the drug. The AIDS Law Project (ALP) acting on behalf of the Treatment Action Campaign (TAC) has asked the Competition Commission to investigate. MSD holds a twenty-year patent on efavirenz that expires in 2013. TAC expects the Competition Commission to recommend that Merck and MSD be compelled to issue multiple licences on reasonable terms.

TAC is doing this to ensure that the government and ordinary people have access to the lowest priced efavirenz products of proven quality, safety and efficacy. We also wish to ensure that patients have access to a wider range of medicines containing efavirenz and a regular, uninterrupted supply of this essential life-saving medicine.

Access to efavirenz is essential to save lives. Lower efavirenz prices will mean that the government can treat substantially more people. Compelling Merck and MSD to give an adequate number of licences on reasonable terms will give effect to the rights to dignity, life, equality and access to health services.

The TAC will mobilize a local and international campaign to support the appropriate licensing of generic efavirenz and our complaint at the Competition Commission.

*A special thanks to Jonathan Berger of the AIDS Law Project for his persistent and diligent work on this matter. Geoff Budlender, Gregg Gonsalves, Nathan Geffen, Fatima Hassan, Nonkosi Khumalo, Doron Isaacs, Nick Friedman, Sean Flynn, Brian Honerman and Alison Dyer did great work on this.*

Once again, thanks to Adila Hassim and her team at the ALP.

# Background to complaint

Nearly 400,000 people with HIV are on life-saving highly active antiretroviral therapy (HAART) in South Africa in the public and private sectors. HAART means having to take at least three antiretroviral medicines daily. Two thirds of people initiating HAART take efavirenz. Yet it costs both the state far more than the combined price of the other two drugs. Even though several companies across the world manufacture cheaper and a wider range of efavirenz than produced by MSD and Merck, these are not available in South Africa. Furthermore, there have been at least three stockouts of efavirenz in Southern Africa.

The main reason for these three problems is that one company, the world's largest pharmaceutical manufacturer Merck, effectively has a monopoly on the sale of efavirenz in South Africa. Merck and its South African subsidiary, MSD, have refused licenses to at least two generic manufacturers. Licenses have been given to two local companies, but the terms of the licenses are unreasonable and neither company has to date been able to bring generic efavirenz products to market. The two companies who have been refused licenses have registered generic efavirenz with the Medicines Control Council and could bring their medicines to market immediately if licensed.

Therefore, acting on behalf of the Treatment Action Campaign (TAC), the AIDS Law Project (ALP) filed a complaint at the Competition Commission of South Africa on Tuesday, 6 November 2007. The complaint alleges that MSD and Merck are violating the Competition Act 89 of 1998. The complaint argues that their refusal to license efavirenz to a sufficient number of generic companies on reasonable terms threatens access to comprehensive treatment for HIV/AIDS by

- preventing cheaper generic efavirenz products from being brought to market;
- preventing co-formulated and co-packaged antiretroviral products containing efavirenz and at least one other antiretroviral medicine from being brought to market; and
- placing the sustainability of supply of efavirenz products in South Africa under threat because of the risk of stockouts.

TAC's action is aimed at helping to implement the *The HIV & AIDS and STIs Strategic Plan for South Africa 2007-2011* (National Strategic Plan), which states:

?The cost implications of the NSP are large, in some options exceeding 20% of the health budget without considering the costs arising from the effect of the epidemic on hospital and primary care services. In attempting to increase the feasibility of this plan ? **[a]ttention should be placed on increasing the affordability of medicines.**? [our emphasis]

This is the not the first time that the TAC has approached the Competition Commission. In addition to a July 2000 submission regarding the proposed merger between pharmaceutical companies Glaxo Wellcome and SmithKline Beecham ? which subsequently formed the company GlaxoSmithKline (GSK) ? the TAC has submitted two complaints: the first in 2002 regarding allegations of excessively priced antiretroviral medicines marketed and sold by GSK and Boehringer Ingelheim (BI); and the second in 2004 primarily regarding allegations of price-fixing by members of the National Pathology Group (NPG).

The latter complaint resulted in significant changes in the way the NPG?s members conduct their businesses, as well as a further complaint instituted by the Commissioner into various practices in the pathology sector. The Commission?s

investigation into the pricing of key antiretroviral medicines (zidovudine, lamivudine and nevirapine) sold by GSK and BI revealed that the two companies had indeed abused their dominant positions in the relevant markets. The matter was settled between the parties, thus obviating any need for a Competition Tribunal hearing.

## What is efavirenz?

Like nevirapine, efavirenz belongs to the class of antiretroviral medicines known as non-nucleoside reverse transcriptase inhibitors (NNRTIs). All antiretroviral medicines target either a particular step in the life cycle of HIV or its interaction with host cells. As NNRTIs, both nevirapine and efavirenz inhibit a key viral enzyme ? reverse transcriptase ? required for the completion of the early stages of HIV replication.

Reverse transcription is a process whereby single strands of viral RNA are converted into double-stranded DNA by the reverse transcriptase enzyme. This enables HIV genetic material to combine with the host cell?s DNA, a process central to the replication of HIV. NNRTIs work by binding directly to the reverse transcriptase enzyme thereby interfering with its ability to function.

## Why is access to efavirenz important?

Efavirenz is one of a limited number of antiretroviral medicines that are provided as part of HAART in the public sector. All adults initiating HAART in the public sector are prescribed a treatment regimen containing stavudine, lamivudine and either efavirenz or nevirapine (depending on a number of medical and other factors). Currently the majority of people are using efavirenz instead of nevirapine. All children on treatment will need to have access to efavirenz or nevirapine, either as part of an initial (first-line) or a second-line regimen.

Efavirenz is also one of the most widely prescribed antiretroviral medicines in the private sector, accounting (for the six month period of January to June 2007) for over 80% of all NNRTI sales (in terms of volume). In the USA, for example, the most widely prescribed standard treatment regimen for the initiation of HAART ? and recommended by the relevant antiretroviral treatment guidelines ? is Atripla, a combination of the antiretroviral medicines tenofovir disoproxil fumarate, emtricitabine (better known as FTC) and efavirenz. Patients taking Atripla only have to swallow a single pill once a day. While Atripla is not yet registered for use in South Africa, the combination of tenofovir and FTC (known as Truvada) is available, as is efavirenz.

## So what is the complaint trying to achieve?

In essence, the complaint is trying to ensure access to a sustainable supply of a range of affordable efavirenz products, including:

- Stand-alone efavirenz in a range of strengths (50mg for children; 200mg and 600mg for adults);
- Co-formulated products (combinations in a single pill) such as tenofovir/FTC/efavirenz and tenofovir/lamivudine/efavirenz; and
- Co-packaged products (combinations in a blister pack) such as stavudine/lamivudine+ efavirenz, stavudine+ lamivudine + efavirenz, tenofovir/FTC + efavirenz, tenofovir/lamivudine + efavirenz and tenfovovir +

lamivudine + efavirenz.

Affordability and sustainability of supply are clearly linked, with the best way to ensure both being to license a sufficient number of generic companies to manufacture and import efavirenz products. The evidence shows that real competition ? necessary to drive prices down as far as is reasonably possible ? is only reached when there are at least five competitors: the original patent holder (in this case Merck) and four generic competitors.

At the moment, there are theoretically two generic competitors in respect of stand-alone efavirenz products. But while one of them has only recently managed to gets its 600mg tablet registered by the Medicines Control Council (MCC), neither has brought efavirenz products to market. Two generic companies that have managed to get their 600mg tablets registered could bring their products to market today, but for the fact that they have not been licensed by MSD to do so.

Further, there will be no competitors in respect of the combination tenofovir/FTC/efavirenz, given that the two licences already granted are only in respect of stand-alone products. In addition, none of the other combinations or co-packaged products discussed above can ever come to market in the absence of generic companies being licensed. This is because MSD is not able to bring any product containing lamivudine to market (as it does not hold the patent and has not been licensed to bring lamivudine products to market).

## Could government not have taken action against MSD?

According to section 4 of the Patents Act 57 of 1978, a Minister of State (in this case the Minister of Health or the Minister of Trade and Industry) may ?

?use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner [of patents] on application by or on behalf of such Minister and after hearing the patentee.?

In a constitutional democracy that recognises a right to have access to medicines (an integral part of the right to have access to health care services), the concept of a ?public purpose? clearly includes ensuring access to a sustainable supply of a range of affordable efavirenz products, particularly when such products are necessary for implementing existing government policy regarding the treatment of HIV infection. Unfortunately, neither Minister has seen fit to use this crucial public power, despite being urged to do so. In the result, an organisation such as TAC has had to assume the responsibility itself. To its credit, government has provided TAC with the legal space within which to operate, primarily by enacting the Competition Act and establishing and resourcing the Competition Commission.

## What happens now?

The Competition Commission has up to a year to conduct and conclude its investigation into the complaint. If it agrees with the TAC that MSD and/or Merck have violated the Competition Act, it must refer the matter to the Competition Tribunal within the year for adjudication and prosecute it on behalf of the TAC and the broader public. If it does not refer the matter, the TAC is free to refer the matter itself. If it agrees with the TAC that the matter requires a more speedy investigation, it may approach the Competition Tribunal much earlier, as the year period is only an upper limit.

During the investigation, the Competition Commission will seek a response from MSD and Merck to the TAC?s papers. We have also asked the Competition Commission to afford TAC an opportunity to comment on this response. The Competition Commission is also entitled to use powers of search, seizure and/or subpoena to obtain relevant information and/or documents, should the relevant parties not cooperate. In addition, it may speak to any experts that it deems appropriate, and may receive relevant information from other stakeholders and/or interested parties.

## What relief does TAC seek?

TAC has asked the Competition Commission to compel Merck to issue licences on reasonable terms for producing and/or importing generic efavirenz products, including co-packaged and co-formulated ones, to any company that is able to satisfy certain objective and reasonable criteria.

## Has TAC tried to negotiate with MSD?

Acting on behalf of the TAC, the ALP has been in discussions with MSD for almost six years regarding the need for it to grant multiple licences ? on reasonable and non-discriminatory terms ? for the local production and/or importation of a range of generic efavirenz products. Progress over the years was agonizingly slow:

- MSD first licensed Thembalami Pharmaceuticals to produce stand-alone efavirenz products in April 2004. Thembalami, a joint venture between South Africa?s Adcock Ingram and the South African subsidiary of India?s Ranbaxy Laboratories, did not survive long enough to bring any efavirenz products to market.

- Some time after Thembalami?s collapse, MSD licensed Aspen Pharmacare ? in July 2005 ? on substantially similar terms. To date, Aspen has not managed to have any efavirenz products registered by the MCC, meaning its generic efavirenz products are not yet on the shelves

- In late August 2007, three months after the ALP sent a final letter of demand to MSD (dated 21 May 2007), a second generic company ? Adcock Ingram ? was licensed. While this move was welcomed by the TAC, it did not address all of its concerns, necessitating the filing of the complaint.

However, the TAC remains open to further discussions with MSD. It has no interest in protracted litigation and would prefer for the parties to negotiate a settlement in the public interest. If such a settlement could be reached, as was the case in 2003 with GSK and BI, the TAC would be prepared to withdraw its complaint.

For further information contact:

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