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TAC complaint increases access to efavirenz: MSD finally agrees to grant licenses on reasonable terms

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Acting on behalf of TAC, the AIDS Law Project (ALP) lodged a complaint with the Competition Commission of South Africa in late 2007 alleging that MSD (Pty) Ltd ? the South African subsidiary of multinational drug company Merck ? was unlawfully refusing to license the antiretroviral (ARV) medicine efavirenz (EFV) on reasonable terms. (?TAC complains to the Competition Commission about the anti-competitive conduct of the world's largest pharmaceutical company? at http://www.tac.org.za/community/node/2127.) Today, TAC is pleased to announce that MSD is no longer acting in an anticompetitive way, paving the way for the market entry of a wide range of affordable EFV products.

According to the ALP?s records and recent correspondence from the Commission, MSD has ?

- Licensed four generic drug companies ? two local producers and two locally-based importers ? to bring stand-alone EFV products to market;
- Agreed that all four licensees are entitled to bring co-packaged products containing EFV to market;
- Agreed that all four licensees will not unreasonably be refused consent to bring co-formulated products containing EFV to market;
- Agreed that all licensed products can be sold to both public and private sectors in South Africa and 10 other southern African countries (Angola, Botswana, DRC, Lesotho, Madagascar, Mauritius, Namibia, Seychelles, Swaziland and Zimbabwe); and
- Waived any right to a royalty.
- On the basis of these significant developments, the Commission believes that there is no reason to refer the complaint to the Competition Tribunal for adjudication. TAC agrees. Because MSD has agreed to grant multiple licences on reasonable terms, which was always the central demand, TAC has decided that it too will not refer the matter to the Tribunal. It is of the view that there is no compelling purpose served by referring what is now largely a historical complaint. Instead, TAC will focus on ensuring that the reasonable terms of the licensing agreements are appropriately implemented.

What are stand-alone, co-packaged and co-formulated products?

Stand-alone products include various dosages of EFV tablets sold separately. Co-packaged products include EFV sold in the same single pack ? often in the form of a blister ? with other ARV medicines that are ordinarily prescribed with EFV. Co-formulated products include EFV sold as part of a fixed-dose combination (FDC) product, which may combine two or more different ARV medicines in a single tablet. FDCs (and co-packaged products to a lesser extent) are widely recognised to improve adherence to ARV and other chronic treatments.

What are the implications of the developments?

In practical terms, this means that there are now a sufficient number of competitors to ensure that EFV prices are kept as low as is reasonably possible. It also means that the public sector, which until relatively recently was paying 64 cents in every rand spent on first-line ARV treatments for EFV alone, can now choose to procure from up to five suppliers.

This fact also means that we no longer have concerns regarding the sustainability of ex-manufacturer supply.

Importantly, the generic licensees are now in a position to sell the following forms of EFV if and when they are registered:

- Stand-alone products:
    - 30mg/ml paediatric suspension;
    - 50mg, 100mg and 200mg capsules; and
    - 600mg tablets;
- Co-packaged products (EFV with either two separate ARV products or a double FDC):
    - EFV + zidovudine (AZT) + lamivudine (3TC);
    - EFV + stavudine (d4T) + 3TC;
    - EFV + tenofovir (TDF) + 3TC;
    - EFV + TDF + emtricitabine (FTC);
    - EFV + didanosine (ddI) + 3TC;
    - EFV + AZT/3TC;
    - EFV + d4T/3TC;
    - EFV + TDF/3TC; and
    - EFV + TDF/FTC; and
- Co-formulated products:
    - TDF/3TC/EFV; and
    - TDF/FTC/EFV.

To date, the Medicines Control Council (MCC) has registered a number of stand-alone generic EFV products. The ALP has been advised, however, that a number of co-packaged products containing EFV are already in the registration queue, and that generic FDC products are likely to be brought to market in the foreseeable future.

Why are licensees needed to bring (almost all) combination products to market?

With the single exception of the TDF/FTC/EFV combination (MSD?s Atripla, which is still pending registration in South Africa), none of the co-packaged and co-formulated products would have been able to be placed on the South African market. This is for the following three reasons:

- In the absence of licensing agreements, the EFV patent does not allow any company other than MSD to bring EFV products to market;
- MSD?s agreement with Gilead, which holds the rights globally to TDF and FTC, is limited to a single FDC (Atripla); and
- MSD does not have the right, nor has it indicated the intention, to bring 3TC products to the South African market.

In contrast, three of the four licensees have secured licensing agreements to bring generic 3TC products to market. (?Competition Commission Settlement Agreements Secure Access to Affordable Life-Saving Antiretroviral Medicines? at http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm.) AZT is no longer under patent protection in South Africa, whereas TDF was never patented in this country. In addition, the patents on d4T, ddI, and FTC are not enforced in the country. In short, EFV was the only ARV amongst those already discussed in respect of which a patent barrier prevented much-needed combination products from being sold in South Africa.

What price reductions have we already seen?

When TAC and the ALP first started to engage MSD on this issue as far back as May 2002, the company sold a year?s supply of EFV for one adult for US$500. That price has dropped significantly. Today, MSD?s best international price

for a year?s supply is US$237.25. In contrast, the best international price for a generic equivalent of proven quality, safety and efficacy is US$150. In the South African private sector, MSD?s EFV sells for R166.90 (VAT inclusive) for a 30 days? supply. In contrast, the cheapest registered generic equivalent sells for R136.80. These prices are expected to drop even further.

Price differentials in respect of FDCs are even greater. MSD has committed to sell Atripla at US$613.20 per patient per year. In contrast, the Clinton Foundation HIV/AIDS Initiative (CHAI) has managed to secure a commitment from a reputable Indian company to bring generic TDF/FTC/EFV to market for only US$349 per patient per year. The same company has also committed to bringing generic TDF/3TC/EFV ? which is considered as therapeutically equivalent to the FTC version of the FDC ? for US$299 per patient per year. South Africa is entitled to purchase drugs through CHAI.

We have updated our fact sheet on the complaint.

- TAC complaint against MSD

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