

## Merck's efavirenz - a story of broken promises

### Broken promises

In October 2002, Merck announced its "new 600mg tablet formulation of Stocrin (efavirenz) at a price of US\$0.95 per day [US\$346.75/patient/year] in least developed countries of the world and those hardest hit by the HIV/AIDS epidemic".<sup>1</sup> This formulation allows patients to take one tablet (600mg) instead of three capsules (200mg) per day.<sup>2</sup>

However, 16 months later this offer has failed to materialise. It appears that this announcement was a calculated attempt to gain media attention for Merck and its marketing partner Bristol-Myers Squibb for the launch of the new 600mg formulation of EFV in North America, Europe and other wealthy markets. At the time, the drug was registered in the US but registration dossiers hadn't even been filed in developing countries.

Since October 2002, patients and those supporting AIDS programs in developing countries have been paying a significant surcharge. If Merck had followed through on their offer, the new formulation would have meant a yearly saving of US\$153.25 per patient. Today the daily dose of efavirenz (EFV) is not US\$0.95 but rather US\$1.37 (three 200mg capsules).

**To make good on its promise Médecins Sans Frontières urges Merck to immediately:**

1. lower the price of the 200mg capsule of Stocrin to US\$0.32, so that the real price of the drug will be, as advertised, US\$0.95 per day [US\$346.75/patient/year] "in least developed countries of the world and those hardest hit by the HIV/AIDS epidemic".
2. take whatever steps are necessary to register the 600mg formulation in developing countries and publicly report on the status of registration.

### Background

Efavirenz (EFV), a crucial element in first-line AIDS treatment, is a non-nucleoside reverse transcriptase inhibitor indicated in antiretroviral combination treatment of HIV-1 infected adults, adolescents and children of three years of age or older. It is sold as Sustiva® by Bristol-Myers Squibb in the US, Canada, Italy, France, Germany, Spain and the UK, and as Stocrin® by Merck everywhere else in the world, in five dosage forms: : 600mg film coated tablets, 200mg hard capsules, 100mg hard capsules, 50mg hard capsules and 30mg/1ml oral solution. The dosage is 600mg once daily for adults and 200 to 400mg per day for children over three from 13 to 40kg.

EFV is part of the WHO recommended first-line regimens in the WHO guidelines published on 1<sup>st</sup> December 2003, and is a critical component of ARV combination therapy, particularly for patients co-infected with HIV/TB.

<sup>1</sup> Merck press release 23.10.02 "Merck Offers HIV Antiretroviral in New Formulation at Less Than One Dollar Per Day to Least Developed Countries and Those Hardest Hit by the Epidemic"

<sup>2</sup> The 200mg capsule continues to be useful for children and HIV/TB co-infected patients.

Since 2001, Merck has offered a differential price for its 200mg formulation of US\$500/patient/year<sup>3</sup> for low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence of 1% or greater, for Governments, international organizations, NGOs and private sector organisations (e.g. employers, hospitals and insurers). For medium HDI countries with adult HIV prevalence of less than 1%, the price is US\$920/patient/year.

In October 2002, under the same conditions as mentioned above, Merck announced a price reduction for the 600mg formulation of EFV at US\$346.75/patient/year (US\$0.950/unit), for low HDI countries plus medium HDI countries with adult HIV prevalence of 1% or greater. For medium HDI countries with adult HIV prevalence less than 1%, the price of the 600mg was announced as US\$767/patient/year (US\$2.10/unit).

“By making this new formulation of Stocrin available,” Merck Chairman, President and Chief Executive Officer Raymond V. Gilmartin said, “Merck is continuing its efforts to expand access to HIV care and treatment in Africa and other regions of the developing world.”<sup>4</sup>

However, due to lack of registration/distribution, the 600mg has not been available in most countries where MSF is working. The spirit of the offer could have been immediately put into practise by lowering the price of the 200mg formulation but Merck has so far refused to take this step. In Europe, a precedent for equivalency pricing between the 200mg and 600mg has already been set. A European patient would pay the same price for treatment whether they were taking 3 x EFV 200mg or 1 x 600mg.

## **The difference between Merck’s actions and Merck’s words**

### ***Registration***

According to information provided by Merck, EFV 600mg has been fully registered in seven developing countries. Merck has also told MSF that registration is pending in a number of other countries, mainly due to the slowness of Drug Regulatory Authorities, but information from our field programmes sometimes contradicts this.

In countries where MSF is working such as South Africa, the Democratic Republic of Congo, Malawi, Nigeria, Indonesia, Zimbabwe or Kenya, EFV 600mg is not registered. Today the 600mg formulation is available in only a few countries such as Mozambique and Kenya, through a special authorisation, which limits access. In most cases the 600mg formulation is not available and patients are obliged to take 3 X 200mg, which is 44% more expensive.

In Nigeria, where MSF is starting an ARV treatment programme and adult HIV prevalence is 5.8%, Merck had still not applied for registration for the 600mg formulation.<sup>5</sup>

In the case of Malawi, where MSF is currently treating more than 2000 patients, Merck claims to have applied to register EFV 600mg on December 2002, while the Merck distributor in the country says that the company never in fact applied for registration.

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<sup>3</sup> All Merck differential price offers are Carriage and Insurance Paid (CIP).

<sup>4</sup> Merck press release 23.10.02 “*Merck Offers HIV Antiretroviral in New Formulation at Less Than One Dollar Per Day to Least Developed Countries and Those Hardest Hit by the Epidemic*”

<sup>5</sup> Merck correspondence from December 2003: “Our files for Nigeria are ready to be sent to APP (Merck distributor in Nigeria) which has to submit them to NAFDAC (National Agency for Food and Drug Administration and Control in Nigeria)”.

In Indonesia, Merck claims to have applied for registration of Stocrin 600mg in February 2003, but information obtained by our field staff tells us that this is not true. None of the dosages is registered and only a local NGO has a special authorisation to import EFV.

The reasons given by Merck to justify the lack of registration remain unclear and contradictory. MSF urges Merck to make information on the registration status of EFV 600mg public.

### ***Distribution***

Registration is not the only hurdle. In Mozambique, due to the lack of proper distribution channels, EFV 600mg costs 30% more than the announced price.

In Indonesia, Merck Indonesia has supply problems and the availability of the drug in the country is very limited.

### **Efforts to address the problem frustrated**

MSF has, in good faith, brought these issues to the attention of Merck in a series of written and face-to-face communications on this issue.

In **January 2003**, MSF met with Merck in Geneva to raise the issue of registration in countries eligible for a differential price. A list of countries where Merck had applied for or registered EFV 600mg was received in October 2003. MSF also requested that Merck lower the price of 200mg in those countries where there was no access to EFV 600mg.

In **February and March 2003**, MSF contacted Merck concerning an increase in price of EFV 50mg and 200mg in South Africa, as well as Malawi and Kenya.

In **April 2003**, MSF approached Merck to get special importation authorisation for EFV 600mg in Mozambique and South Africa.

During the Paris International AIDS Society meeting in **July 2003**, MSF met with Merck to re-discuss registration problems and reiterated its request for a list of countries where EFV 600mg is registered.

In **January 2004**, MSF contacted Merck to find a solution to resolve the stock out of EFV 50mg in South Africa. Merck acknowledged the stock out and re-stocked a week later.

Also in **January 2004**, MSF wrote to MSD Indonesia to address supply problems and shortages of EFV in Indonesia.

Merck has steadfastly refused to make good on their promise to lower the price of the 200mg formulation.

#### **Related documents:**

- 7<sup>th</sup> March, 2001 Merck & Co., Inc Announces Significant Reductions in Prices of HIV Medicines to Help Speed Access in Developing World*
- 23<sup>rd</sup> October, 2002 Merck Offers HIV Antiretroviral in New Formulation at Less Than One Dollar Per Day to Least Developed Countries and Those Hardest Hit by the Epidemic*
- 23<sup>rd</sup> October, 2002 Wall Street Journal: Merck to cut Stocrin price in the poorest countries by Rachel Zimmerman and Mark Schoofs*