



333 Seventh Avenue, 2nd Flo
New York, NY 10001-5004

Tel: 212.679.6800
Fax: 212.679.7016

doctors@newyork.msf.org

February 26, 2004

Raymond V. Gilmartin, Chairman, President and Chief Executive Officer

Merck & Co., Inc.
One Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889-0100

Dear Mr. Gilmartin,

I am writing on behalf of Doctors Without Borders/Médecins Sans Frontières (MSF) to demand immediate action on both the price of 200mg efavirenz (EFV) and the registration status of the 600mg formulation of EFV in developing countries.

In October 2002, Merck announced a price reduction for the 600mg formulation of EFV, bringing the price down to \$346.75 per person per year (\$0.95 per unit). The Merck communication at the time claimed that this price would be valid for low Human Development Index (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 \$767 per person per year (\$2.10 per unit).

However, 16 months after the announcement, this offer has not materialized. By delaying registration of EFV 600mg and refusing to reduce the price of EFV 200mg, Merck has failed to make good on its promise. More importantly, Merck's failure to deliver on this promise may have lead to needless suffering and perhaps death. In order to address the barriers to access to EFV in developing countries outlined below, MSF is demanding that Merck immediately:

1. Take all necessary steps to register the 600mg formulation of EFV in developing countries and publicly report on the status of registration on a monthly basis.
2. Lower the price of the 200mg capsule of EFV to \$0.32, so that the real price of the drug will be, as advertised, \$0.95 per day (\$346.75 per person per year).

Registration/Distribution

Due to lack of registration/distribution, the 600mg formulation has not been available in most countries where MSF is working. According to information provided by Merck, EFV 600mg has been fully registered in eight developing countries as of today. Merck has also told MSF that registration is pending in a number of other countries because of delays caused by national drug regulatory authorities, but information from our field programs often contradicts this.

- In countries where MSF is working such as South Africa, the Democratic Republic of Congo, Malawi, Nigeria, Indonesia, Zimbabwe and Kenya, EFV 600mg is not registered. Today the 600mg formulation is available in few countries such as Mozambique and Kenya, through a special authorization, but this benefits only a small number of patients. In most cases, the 600mg formulation is not available and patients are obliged to take 3 X 200mg, which is 44 percent more expensive, and is cumbersome for both patients and clinicians.
- In Nigeria, where MSF is starting an ARV treatment program and adult HIV prevalence is 5.8%, Merck had still not applied for registration for the 600mg formulation as of December 2003, 14 months after your company announced the price reduction for EFV 600mg.¹
- In the case of Malawi, where MSF is currently treating more than 2,000 patients, Merck claims to have applied to register EFV 600mg in December 2002, but the Merck distributor in the country says that the company never in fact applied for registration.
- In Indonesia, Merck claims to have applied for registration of EFV 600mg in February 2003, but information from our field programs indicates that this is not true. No registrations have been filed and so far only one local NGO has a special authorization to import EFV.

The justifications given by Merck for the lack of registration remain unclear and contradictory.

Registration is not the only hurdle that Merck needs to overcome in order for the company to make good on its promise. In Mozambique, due to the lack of proper distribution channels, EFV 600mg costs 30% more than the announced price.

Price of EFV 200mg

Had Merck been serious about making EFV more widely available in developing countries, it would have not only begun registering EFV 600mg as a matter of urgency, but also immediately lowered the price of the 200mg formulation. However, despite repeated requests from MSF, 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.

Since October 2002, people living with HIV/AIDS and providers of AIDS treatment in developing countries have been paying a significant surcharge for EFV. If Merck had followed through on its offer, the new formulation would have yielded yearly savings of \$153.25 per patient. However, today, in low-income countries and middle-income countries with HIV prevalence of 1% or greater, the daily dose of EFV is not \$0.95, as advertised by Merck, but rather \$1.37 (three 200mg capsules).

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 over the past year:

¹ 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 **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 EFV 200mg in South Africa, as well as Malawi and Kenya.
- In **April 2003**, MSF approached Merck to get special importation authorization 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 at that time reiterated its request for a list of countries where EFV 600mg is registered.
- In **January 2004**, MSF contacted Merck to find a solution to the stock-out of EFV 50 mg in South Africa. Merck acknowledged the stock out a re-stocked a week later. MSF also wrote to MSD Indonesia to address supply problems and shortages of EFV in Indonesia.

Conclusion

We urge Merck in the strongest possible terms to immediately respond to the demands in this letter. Please feel free to contact Rachel Cohen at (212) 655-3762 or rachel.cohen@newyork.msf.org, Daniel Berman at (+ 33 1) 4021-2764 or daniel.berman@geneva.msf.org, with any questions or concerns you may have.

We look forward to hearing from you promptly.

Sincerely,

Ellen 't Hoen
Interim Director, MSF Campaign for Access to Essential Medicines

cc: Jeffrey Sturchio, Merck
Peter Piot, UNAIDS
Jack Chow, WHO
Paulo Teixeira, WHO
Steering Committee of the Pan-African HIV/AIDS Treatment Access Movement
Lobna El tabei (Egypt)
Othoman Mellouk (Morocco)
(Mo)Rolake Nwagwu (Nigeria)
Cyriaque Ako (Cote D'Ivoire)
James Kamau (Kenya)
Grace Muro (Tanzania)
Delme Cupido (Namibia)
Matilda Moyo (Zimbabwe)

Ambroise Mamona (Congo Brazaville)
Djneche Sylvania Laure (Cameroon)
Zackie Achmat, Treatment Action Campaign (South Africa)
David Ananiashvili, Georgian Plus Group, Georgia
Augustine Chella, Network of African People Living with HIV/AIDS (Zambia)
Ben Cheng, Forum for Collaborative HIV Research (USA)
Lei Chou, AIDS Treatment Activist Coalition (USA)
Polly Clayden, HIV i-Base (UK)
Simon Collins, HIV i-Base (UK)
Delme Cupido, Legal Assistance Centre, AIDS Law Unit/PATAM (Namibia)
Paul Davis, Health GAP /ACT UP Philadelphia (USA)
John Daye, National Association of People With AIDS (Australia)
Linda Dee, AIDS Action Baltimore (USA)
Anne Donnelly, Project Inform (USA)
Roman Dudnik, AIDS Foundation East-West (Russia)
Olive Edwards, Jamaican Network of Seropositives (Jamaica)
Gregg Gonsalves, Gay Men's Health Crisis (USA)
Chris Green, Spiritia Foundation (Indonesia)
Mauro Guarinieri, European AIDS Treatment Group (Italy)
Mark Harrington, Treatment Action Group (USA)
Bob Huff, Gay Men's Health Crisis (USA)
Anastasia Kamlyk, Positive Movement Belarus (Belarus)
Karyn Kaplan, Thai AIDS Treatment Action Group (Thailand)
Hanna Khodas, All-Ukrainian Network of PLWH (Ukraine)
Svilen Kolev Konov, Plus and Minus' Foundation (Bulgaria)
Sharonann Lynch, Health GAP (USA)
Njogu Morgan, PATAM/TAC (South Africa)
Guillermo Murillo, Agua Buena Human Rights Association (Costa Rica)
Germán Humberto Rincón Perfetti, Asociación Líderes en Acción (Colombia)
Subhasree Sai Raghavan, Solidarity and Action Against the HIV Infection in India (India)
Asia Russell, Health GAP/ACT UP Philadelphia (USA)
Richard Stern, Agua Buena Human Rights Association (Costa Rica)
Paisan Suwannawong, Thai AIDS Treatment Action Group (Thailand)
Vladimir Zhovtyak, All-Ukrainian Network of PLWH (Ukraine)