

Boehringer Ingelheim policy paper on HIV/AIDS

Preface

The HIV/AIDS pandemic is destroying lives and deteriorating living conditions all over the globe. More than 95% of people infected by HIV/AIDS are living in the developing world with limited access to life saving anti-retroviral drugs. In 2007, 55 countries reported that fewer than 25% of adults and children in need of anti-retroviral therapies received them. Also, only 34% of mothers received services to prevent the transmission of HIV to their children during birth.

Boehringer Ingelheim fully supports and is committed to the international efforts to combat HIV/AIDS in an integrated manner as expressed in the “Bremen Declaration” of the European Ministers of Health of March 2007 and the G8 Summit Declaration “Growth and Responsibility in Africa” of June 2007. Boehringer Ingelheim shares the view that access to medicines saving human lives cannot be limited to those who can afford them. A multi-sectoral response by national governments, health care systems, private industry, NGOs and civil society is required with all partners contributing to the best of their abilities and expertise. Boehringer Ingelheim has demonstrated its corporate social responsibility for developing countries through the Viramune® Donation Programme, implemented in 2000 for the prevention of mother-to-child-transmission, preferential pricing, voluntary licensing and various health care development supporting activities.

In continuation of the policy to ensure broad supply of life saving drugs to poor patients in need, Boehringer Ingelheim in 2006 implemented substantial improvements in access and in preferential pricing of anti-retroviral drugs for the developing world. This document describes the policy and the benefit for the patients.

Expanded Access - Patent Policy for the developing world

Viramune® (nevirapine)

In the past Boehringer Ingelheim granted Voluntary Licenses to several companies in Africa enabling them to produce generic nevirapine for low income countries as per World Bank classification. In order to further improve and facilitate access to nevirapine, Boehringer Ingelheim will not enforce its patents and offers interested manufactures listed on the WHO prequalification list non-assert declarations allowing them to supply nevirapine-containing medicines for Eligible Countries.

These Eligible Countries are defined as all low income countries according to the World Bank classification of economies, all countries classified as Least Developed Country (LDC) according to the United Nations and all African states which are not classified as low income of LDC like South Africa, Botswana.

Aptivus® (tipranavir)

A policy in equivalent terms shall apply to Aptivus®. At the moment, wherever there is a medical need with patients who are highly treatment experienced with virus resistance to multiple protease inhibitors, the product is available for those patients in form of a Compassionate Use Programme.

Expanded Access - Preferential Pricing policy for anti-retroviral drugs

The company offers a tiered preferential price with a total of 141 countries benefiting from the scheme. The prices do not reflect any costs for research and development or distribution which are born by the company.

Viramune® can now be supplied:

At lowest price of US\$0.60 per daily treatment for tablets is offered to all Eligible Countries, in total 78 countries (*see Annex*). The price for the 240ml bottle of suspension of Viramune is US \$12.50.

At reduced price of 1.20 US\$ daily treatment is offered to all middle income countries not benefiting from the lowest price (63 countries; *see Annex*). The price for the 240 ml bottle of suspension of Viramune is US \$17.50.

The preferential prices apply to the supply of the public sector in the countries.

Prevention of Mother-to-Child-Transmission Viramune® Donation Programme

The Viramune Donation Programme was inaugurated in 2000 as Boehringer Ingelheim's contribution to pMTCT in developing countries. It serves as a catalyst for building health care infrastructure and has the potential to reach out to more remote sites. The programme provides single-dose nevirapine for mother and baby free of charge for pMTCT. Where available, it should be administered with additional anti-retroviral medicine as recommended by WHO. Recent studies suggest that in women and infants previously treated with single-dose nevirapine for prevention of mother-to-child-transmission of HIV-1, the efficacy of subsequent Viramune® combination therapy may be reduced. Interested institutions may apply under <http://www.pmtctdonations.org>

We Care- Health Care Development supporting activities

Boehringer Ingelheim regards capacity building and human resources development as the most crucial objective in any health care development policy in emerging economies. This is the genuine obligation of committed Governments, supported by the civil sector, Non-governmental Organisations and bilateral or international assistance programmes.

Status of nevirapine non-assert declarations (July 2009)

Boehringer Ingelheim has provided the following companies with non-assert declarations: Aspen (South Africa), Aurobindo (India), Cipla (India), Emcure (India), Ranbaxy (India) and Strides (India).

Further non-assert-declarations are in process. In addition, Boehringer Ingelheim is willing to grant and has offered a royalty-free licence for production of nevirapine in Canada and export to Rwanda as part of a triple combination to Apotex in Canada.

ANNEX

List of countries qualifying for lowest price

Afghanistan, Algeria, Angola, Bangladesh, Benin, Bhutan, Botswana, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Central African Republic, Chad, Comores, Congo, Congo DR, Cote d'Ivoire, Djibouti, Equatorial Guinea, Egypt, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Haiti, India, Kenya, Kiribati, Korea DR, Kyrgyz Republic, Lao PDR, Lesotho, Liberia, Libya, Madagascar, Malawi, Maldives, Mali, Mauritania, Mauritius, Mongolia, Morocco, Mozambique, Myanmar, Namibia, Nepal, Niger, Nigeria, Pakistan, Papua New Guinea, Rwanda, Samoa, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Africa, Sudan, Swaziland, Tajikistan, Tanzania, Timor-Leste, Togo, Tunisia, Tuvalu, Uganda, Uzbekistan, Vanuatu, Vietnam, Yemen, Zambia, Zimbabwe.

List of countries for reduced price

Albania, Argentina, Armenia, Azerbaijan, Belarus, Belize, Bolivia, Bosnia and Herzegovina, Brazil, Chile, China, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Fiji, Georgia, Grenada, Guatemala, Guyana, Honduras, Indonesia, Iran, Iraq, Jamaica, Jordan, Kazakhstan, Lebanon, Macedonia FYR, Malaysia, Marshall Islands, Mayotte, Mexico, Micronesia, Moldova, Montenegro, Nicaragua, Oman, Palau, Panama, Paraguay, Peru, Philippines, Russian Federation, Samoa, Serbia, Sri Lanka, St Kitts and Nevis, St Lucia, St Vincent and the Grenadines, Suriname, Syrian Arab Republic, Thailand, Tonga, Turkey, Turkmenistan, Ukraine, Uruguay, Venezuela, West Bank and Gaza.