



Pharmaceuticals

# Removing Barriers, Increasing Access

*Roche's commitment to increase access to  
HIV medicines in resource-limited countries*



Updated August 2006

*At the end of 2005, an estimated 38.6 million people were living with HIV/AIDS, a disease which has claimed the lives of 2.8 million people globally in 2005 alone.<sup>1</sup> At present, at least 80% of people in need of antiretroviral therapy are currently not receiving treatment.<sup>1</sup>*

As efforts to scale up treatment in the developing world become more successful, and the number of people receiving first-line therapy increases, there will inevitably be an increased need for second-line treatment options. People failing on their initial treatment regimens will need to switch to alternative regimens, generally including a protease inhibitor as recommended in the World Health Organization Guidelines for antiretroviral therapy in resource-limited settings,<sup>2</sup> such as Roche's Invirase® (saquinavir).

As part of its commitment to increase access to its HIV medicines, Roche has developed innovative and transparent policies to remove barriers to its HIV protease inhibitor medicines in countries where resources are fewest and the need for treatment is greatest.

<sup>1</sup> UNAIDS. 2006 Report on the global AIDS epidemic. May 2006

<sup>2</sup> World Health Organization. 'Scaling up antiretroviral therapy in resource-limited settings: Treatment Guidelines for a Public Health Approach'. 2003 Revision



# Roche's HIV/AIDS Patent Policy

Roche has developed a specific patent policy for its HIV antiretroviral medicines, which commits that:

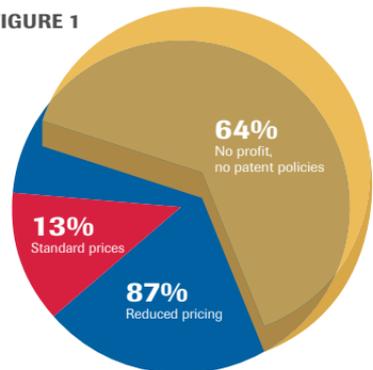
- In addition to not filing or enforcing patents on any Roche medicines in the Least Developed Countries\*, Roche will not file patents on new antiretrovirals (ARVs) in sub-Saharan Africa, the poorest and hardest hit region
- Roche will not take any action against generic manufacturers of its ARVs where it holds the patents in these countries

Roche provides letters granting immunity from suit, upon request, to generic manufacturers interested in producing generic versions of antiretroviral medicines for which Roche holds patents for Least Developed Countries and sub-Saharan Africa.

This policy enables local manufacturers to produce generic antiretroviral medicines for supply to sub-Saharan Africa and the Least Developed Countries without prior consent. To help strengthen the manufacturing capability and capacity within these countries, Roche also launched a new initiative in January 2006 – the AIDS Technology Transfer Initiative – to provide local manufacturers with the technical expertise to produce their own generic version of Invirase.

*Roche's patent and no profit pricing policies apply to more than 24 million people and close to two thirds of all people living with HIV/AIDS globally.<sup>1</sup>*

FIGURE 1



\* United Nations (UN) list of Least Developed Countries can be found inside this leaflet

# HIV Protease Inhibitors Pricing Policy

**Roche offers its HIV protease inhibitors, Invirase and Viracept<sup>®</sup>, at no profit prices for direct supplies from the headquarters in Basel to Least Developed Countries and sub-Saharan Africa.**

The no profit prices do not reflect research or development costs, marketing costs, distribution costs or company overheads. Roche reviews its no profit prices on an annual basis, and will continue to do so for as long as the company supplies these medicines.

Following a cost analysis by Médecins Sans Frontières, the no profit prices available from Roche for Invirase and Viracept have been calculated to be similar or lower than the generic versions of these medicines\*.<sup>3</sup> These prices apply to all presentations of Roche protease inhibitors, including Viracept paediatric powder and the recently EU and US approved Invirase 500 mg.

Summary of prices available for direct purchase from Roche Basel. <sup>4</sup> Available to all countries in sub-Saharan Africa and all UN-defined Least Developed Countries. <sup>5</sup> These are no profit prices.			
Invirase 200	Invirase 500	Viracept	Viracept
Price per pack (270 x 200mg capsules) / CHF	Price per pack (120 x 500mg tablets) / CHF	Price per pack (270 x 250mg tablets) / CHF	Paediatric powder Price per 144g pack / CHF
<b>95.30</b>	<b>97.70</b>	<b>97.30</b>	<b>38.90</b>

Roche also offers significantly reduced pricing for direct supplies of Invirase and Viracept from the headquarters in Basel to low and lower middle income countries, where there is a need for access to HIV/AIDS treatments, but where local governments are able to play a greater role and make a more significant contribution towards the provision of public healthcare and treatment.<sup>5</sup>

\* Calculations based on exchange rate as of 14/07/06. These are subject to fluctuations over time  
3 Médecins Sans Frontières (MSF). Eighth edition of "Untangling the web of price reductions: A pricing guide for the purchase of ARVs for developing countries". June 2005  
4 For individual dosing see prescribing information in the 'Pharmaceutical products' section at: [www.roche-hiv.com](http://www.roche-hiv.com)  
5 UN list of Least Developed Countries and World Bank list of low income and lower middle income countries are detailed within and are current as of July 2006. For further information visit [www.un.org](http://www.un.org) / [www.worldbank.org](http://www.worldbank.org)

Summary of prices available for direct purchase from Roche Basel.<sup>4</sup> Available to all low income and lower middle income countries.<sup>5</sup>

<b>Invirase 200</b>	<b>Invirase 500</b>	<b>Viracept</b>	<b>Viracept</b>
Price per pack (270 x 200mg capsules) / CHF	Price per pack (120 x 500mg tablets) / CHF	Price per pack (270 x 250mg tablets) / CHF	Paediatric powder Price per 144g pack / CHF
<b>200.00</b>	<b>222.00</b>	<b>200.00</b>	<b>45.00</b>

For further information on Roche's HIV/AIDS patent and pricing policies, and on the policies applicable for all Roche medicines, please visit: [www.roche-hiv.com](http://www.roche-hiv.com).

*The no profit prices for Least Developed Countries and sub-Saharan Africa, together with the further reduced prices for low and lower middle income countries, apply to more than 33 million people, representing over 87% of all people living with HIV/AIDS worldwide [Fig 1].<sup>1</sup>*

Roche prioritises the UN-defined Least Developed Countries.<sup>5</sup> These are countries that fulfil the following criteria:

- Low-income (based on three-year average estimate of the gross domestic product per capita between \$750 and \$900)
- Human resource weakness (based on a quality of life index including nutrition, health, education and adult literacy)
- Economic vulnerability (based on a composite economic vulnerability index)

Roche reduced prices are applicable to countries defined by the World Bank as low income (\$825 or less) and lower middle income (\$826-\$3,255) based on their gross national income (GNI) per capita.<sup>5</sup>



# Ongoing efforts to develop innovative new therapies

## *Invirase 500 mg*

As part of its ongoing efforts to develop innovative new therapies for people living with HIV/AIDS, Roche continues to research and develop HIV treatments that meet the evolving needs of patients.

To help improve patient adherence, Roche developed a 500 mg formulation of Invirase\*, which aims to provide patients with a simplified dosing regimen by significantly decreasing their daily Invirase pill burden by more than half to two pills twice daily.

This formulation of Invirase is also available at no profit and reduced profit prices, and no patents have been registered in Least Developed Countries and sub-Saharan Africa.

## *Paediatric formulations*

The need to increase access to antiretroviral therapy for the millions of children living worldwide with HIV/AIDS is vital.<sup>6</sup> Currently, nine out of ten children needing antiretroviral treatment worldwide live in sub-Saharan Africa.<sup>7</sup>

A paediatric formulation of Viracept has been developed for children aged three years above and is available at no profit within Least Developed Countries and sub-Saharan Africa. Roche continues to research and develop new and improved formulations of its HIV medicines for paediatric use.

\* 1000 mg of Invirase is taken with 100 mg of ritonavir twice daily and in combination with other antiretrovirals

<sup>6</sup> UNAIDS Country data. July 2004

<sup>7</sup> World Health Organization. Progress on Global Access to HIV antiretroviral therapy – a report on '3 by 5' and beyond. March 2006

## **Roche Pricing Policy Terms and Conditions**

- The prices available direct from Roche HQ exclude costs for freight, import, duty, taxes, distribution and inventory, which may be added at a local level
- A comprehensive list of prices, countries and conditions are available on the website [www.roche-hiv.com](http://www.roche-hiv.com)
- As company overheads are excluded, minimum order quantity of 10,000 CHF is required to ensure effective use of resources and allow the lowest possible prices to be offered
- The prices are ex-factory prices from Roche's headquarters in Basel Switzerland. Under circumstances where Roche is requested to provide delivery, distribution costs as well as import taxes and duties must be added. Local retail prices are therefore higher than these ex-Roche Basel prices
- These prices are provided subject to the conditions that the drug will not be diverted or re-exported to other countries not qualifying for the specified price as defined on [www.roche-hiv.com](http://www.roche-hiv.com)
- All purchasers placing orders from Roche Basel will be required to provide a recipient name and final delivery destination in order to enable tracking and monitoring of product supply

Viracept is supplied by Roche outside of the US, Canada, Japan and Korea.

The visuals enclosed in this leaflet are for illustrative purposes only and there is no suggestion that the individuals portrayed have any of the diseases discussed.

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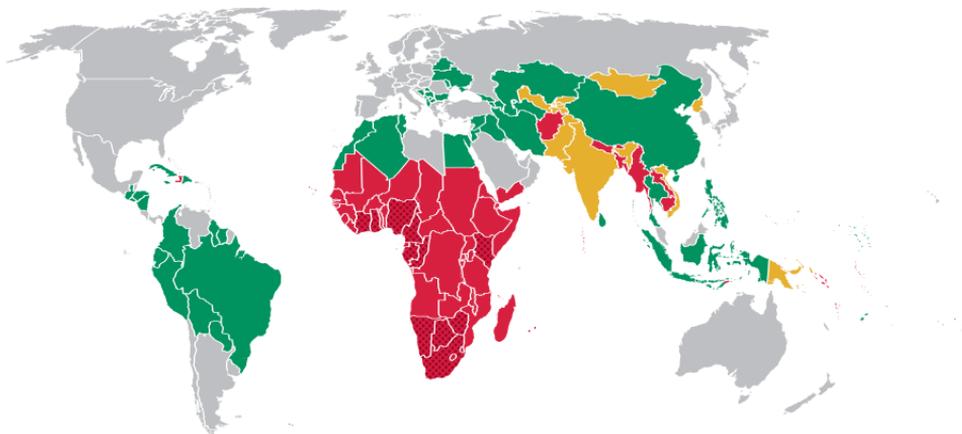
Made from recycled fibre and Forestry Stewardship Council pulp.



For further information on the terms and conditions of Roche's policies and activities, please visit:

**[www.roche-hiv.com](http://www.roche-hiv.com)**

If you would like to contact Roche with feedback or questions, please e-mail: [info.makingadifference@roche.com](mailto:info.makingadifference@roche.com)



**The following countries are designated by the UN as Least Developed (as of July 2006):<sup>5</sup>**

Afghanistan • Angola • Bangladesh • Benin • Bhutan • Burkina Faso • Burundi • Cambodia • Cape Verde • Central African Republic • Chad • Comoros • Democratic Republic of Congo • Djibouti • Equatorial Guinea • Eritrea • Ethiopia • Gambia • Guinea • Guinea-Bissau • Haiti • Kiribati • Lao People's Democratic Republic • Lesotho • Liberia • Madagascar • Malawi • Maldives • Mali • Mauritania • Mozambique • Myanmar • Nepal • Niger • Rwanda • Samoa • Sao Tome and Principe • Senegal • Sierra Leone • Solomon Islands • Somalia • Sudan • Timor-Leste • United Republic of Tanzania • Togo • Tuvalu • Uganda • Vanuatu • Yemen • Zambia

**Additional countries in sub-Saharan Africa not covered by the UN list of Least Developed Countries for which the lowest level no profit prices apply:**

Botswana • Cameroon • Congo • Côte d'Ivoire • Gabon • Ghana • Kenya • Mauritius • Namibia • Nigeria • Seychelles • South Africa • Swaziland • Zimbabwe

**The following countries are designated by the World Bank classification of economies as low income economies\*† (as of July 2006):<sup>5</sup>**

India • Democratic Republic of Korea • Kyrgyz Republic • Mongolia • Pakistan • Papua New Guinea • Tajikistan • Uzbekistan • Vietnam

**The following countries are designated by the World Bank classification of economies as lower middle income economies\*† (as of July 2006):<sup>5</sup>**

Albania • Algeria • Armenia • Azerbaijan • Belarus • Bolivia • Bosnia and Herzegovina • Brazil • Bulgaria • China • Colombia • Cuba • Dominican Republic • Ecuador • Egypt • El Salvador • Fiji • Georgia • Guatemala • Guyana • Honduras • Indonesia • Iran • Iraq • Jamaica • Jordan • Kazakhstan • Republic of Macedonia • Marshall Islands • Micronesia Federal States • Moldova • Morocco • Nicaragua • Paraguay • Peru • Philippines • Serbia and Montenegro • Sri Lanka • Suriname • Syrian Arab Republic • Thailand • Tonga • Tunisia • Turkmenistan • Ukraine • West Bank and Gaza

\* Those not otherwise classified as "Least Developed" by the UN

† Excluding those countries included in the list of sub-Saharan countries where no profit prices apply