

# Removing Barriers Increasing Access

Roche's Commitment to Increase Access to Medicines for HIV/AIDS and Malaria



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Roche's policies are focused on countries hardest hit by the AIDS pandemic with the fewest resources. Roche's patent and no profit pricing policies apply to an estimated 26 million people and two thirds of all people living with HIV/AIDS globally<sup>1</sup>

### Roche's Global Patent Policy

Roche has pledged:

- Not to file patents for any medicines across all disease areas in the Least Developed Countries of the world, as defined by the United Nations (UN)\*
- *Not* to file patents on new or investigational HIV medicines in Least Developed Countries and sub-Saharan Africa
- *Not* to take action in Least Developed Countries and sub-Saharan Africa against the sale or manufacture of generic versions of HIV medicines
- No patents for its treatments for malaria Fansidar<sup>®</sup> (sulfadoxine/ pyrimethamine) or Lariam<sup>®</sup> (mefloquine) – in Least Developed Countries and sub-Saharan Africa

As a result of Roche's patent policy, generic versions of saquinavir can be produced in Least Developed Countries and sub-Saharan Africa without the need for a voluntary or compulsory licence.

\* UN list of Least Developed Countries can be found on the following page.



### HIV Protease Inhibitors Pricing Policy

# Roche's pricing policy aims to further increase access to its HIV protease inhibitors, Invirase<sup>®</sup> (saquinavir) and Viracept<sup>®</sup> (nelfinavir)<sup>2</sup>

- HIV protease inhibitors (Invirase and Viracept) supplied at *no profit* for direct supplies from Basel to Least Developed Countries<sup>3</sup> and sub-Saharan Africa
- Roche no profit prices for Invirase and Viracept available to Least Developed Countries<sup>3</sup> and sub-Saharan Africa are lower than the price of generic versions of these medicines<sup>4</sup>
- Further *reduced pricing* for direct supplies of Invirase and Viracept available from Basel to low and lower middle income countries<sup>3</sup>

Roche has committed, as part of its pricing policy, to review the no profit prices on an annual basis. As a result, in 2004 Roche decreased the no profit prices of Invirase and Viracept for the Least Developed Countries<sup>3</sup> and sub-Saharan Africa.

#### Summary of prices available for direct purchase from Roche Basel.<sup>5</sup> Available to all countries in sub-Saharan Africa and all UN defined Least Developed Coutries.<sup>3</sup> These are "no profit" prices

Invirase	Viracept	Viracept
Price per pack	Price per pack	Paediatric powder
(270 x 200mg capsules) / CHF	(270 x 250mg tablets) / CHF	Price per 144g pack / CHF
89.60	88.40	39.50

## The following countries are designated by the United Nations (UN) as Least Developed:

Afghanistan • Angola • Bangladesh • Benin • Bhutan • Burkina Faso • Burundi • Cambodia • Cape Verde • Central African Republic • Chad • Comoros • Democratic Republic of Congo (formerly Zaire) • 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 • Tanzania • Timor-Leste • 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 In addition, Roche also further reduced the prices of Invirase and Viracept offered to low and lower middle income countries<sup>3</sup> by as much as a third in 2004, in recognition of future increased need for second-line therapies.

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

Invirase	Viracept	Viracept
Price per pack	Price per pack	Paediatric powder
(270 x 200mg capsules) /	(270 x 250mg tablets) /	144g / CHF
CHF	CHF	
200	200	45

The no profit prices – available to Least Developed Countries and sub-Saharan Africa – together with the further reduced prices for low and lower middle income countries, apply to an estimated 36 million people, representing as many as 85% of all people living with HIV/AIDS worldwide.<sup>6</sup>

For procurement details, please visit www.roche-hiv.com

#### Low income economies - source World Bank classification of economies\*:

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

#### Lower middle income economies\*\*:

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 • Morocco • Paraguay • Peru • Philippines • Romania • Russian Federation • Serbia and Montenegro • Sri Lanka • Suriname • Syrian Arab Republic • Thailand • Tonga • Tunisia • Turkey • 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.



Committed to improving healthcare globally with expertise across two of the three priority diseases of the developing world identified by the World Health Organization (WHO): **HIV/AIDS and MALARIA** 

HIV/AIDS is a worldwide pandemic that has resulted in the deaths of over 30 million people globally. At the end of 2003, an estimated 40 million people were living with HIV/AIDS. It is estimated that there are 6 million people in immediate need of antiretroviral therapy, however, less than 7% are currently receiving treatment.<sup>7</sup>

The WHO has recognised the importance of scaling up treatment in resource-poor settings and has issued guidelines for the provision of treatment within these regions. The guidelines include the protease inhibitor, saquinavir (SQV), within second-line treatment options for those failing on first-line therapy.

# Fig 1. Recommended second-line regimens in adults and adolescents in the event of treatment failure of first-line ARV regimens



a Dose of ddl should be reduced from 400 mg to 250 mg when coadministered with TDF. b LPV/r and SQV/r require secure cold chain. NFV can be considered as an alternative in resource-limited settings without cold chain.

# Malaria kills one child every 30 seconds in Africa

At least 300 million acute cases of malaria exist globally, causing more than a million deaths every year. Around 90% of these deaths occur in Africa, mostly amongst young children.<sup>8</sup>

Although there are currently a number of treatment options available for those infected with malaria, limited availability of treatment makes disease management difficult. Improving access to these medicines would greatly reduce the impact of the disease, which accounts for 40% of public health expenditure in Africa.<sup>8</sup>

Roche has developed a number of strategies aimed at increasing access to its anti-malarial therapies, Fansidar (sulfadoxine/pyrimethamine) and Lariam (mefloquine), for people living in the Least Developed Countries and sub-Saharan Africa:

- Publicising the patent status in Least Developed Countries and sub-Saharan Africa
- *Making technical information on its anti-malarial therapies available to the WHO* as part of on-going efforts to share knowledge and facilitate research and development to discover new, affordable anti-malarial therapies and treatment strategies
- Collaborations with the Medicines for Malaria Venture (MMV) to provide a generic company with a new anti-malarial molecule, plus the expertise and rights to develop and deliver this as a new anti-malarial therapy, without compensation to Roche. This activity is on-going



- 1 UNAIDS / WHO, Dec 03. AIDS epidemic update
- 2 For individual dosing see prescribing information in the 'Pharmaceutical products' section at: www.roche-hiv.com
- 3 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 04. For further information visit www.un.org / www.worldbank.org
- 4 Sixth edition of 'Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries', Médecins Sans Frontières (MSF), April 2004
- 5 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. The no profit prices direct from Roche Basel are the lowest prices at which the products can be provided in a viable, long term and sustained manner. They do not reflect research or development costs, marketing costs, distribution costs or company overheads. A comprehensive list of prices, countries and conditions are available on the website www.roche-hiv.com. The minimum order remains of 10,000 CHF. 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
- 6 UNAIDS. www.unaids.org/html/pub/Global-Reports/Barcelona/TableEstimatesEnd2001\_en\_xls.xls
- 7 AAI, March 2004
- 8 WHO Roll Back Malaria infosheet 1

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.

For further information on Roche policies and activities, please visit: www.roche-hiv.com or www.roche.com/home/sustain/sus\_med.htm



#### Innovating HIV Care Working Towards a Brighter Future

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

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