Removing Barriers
Increasing Access

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

Updated July 2004

F. Hoffmann-La Roche Ltd.
4070 Basel, Switzerland
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.
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® (sulfadoxine/pyrimethamine) or Lariam® (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® (saquinavir) and Viracept® (nelfinavir)²

- HIV protease inhibitors (Invirase and Viracept) supplied at no profit for direct supplies from Basel to Least Developed Countries³ and sub-Saharan Africa
- Roche no profit prices for Invirase and Viracept available to Least Developed Countries³ and sub-Saharan Africa are lower than the price of generic versions of these medicines⁴
- Further reduced pricing for direct supplies of Invirase and Viracept available from Basel to low and lower middle income countries¹

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 Countries³ and sub-Saharan Africa.

Summary of prices available for direct purchase from Roche Basel.⁴
Available to all countries in sub-Saharan Africa and all UN defined Least Developed Countries.³ These are “no profit” prices

<table>
<thead>
<tr>
<th>Invirase</th>
<th>Viracept</th>
<th>Viracept</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price per pack</td>
<td>Price per pack</td>
<td>Paediatric powder</td>
</tr>
<tr>
<td>(270 x 200mg capsules) / CHF</td>
<td>(270 x 250mg tablets) / CHF</td>
<td>Price per 144g pack / CHF</td>
</tr>
<tr>
<td>89.60</td>
<td>88.40</td>
<td>39.50</td>
</tr>
</tbody>
</table>

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 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.**

**Available to all low income and lower middle income countries**

<table>
<thead>
<tr>
<th></th>
<th>Invirase</th>
<th>Viracept</th>
<th>Viracept</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price per pack (270 x 200mg capsules) / CHF</td>
<td>200</td>
<td>200</td>
<td>45</td>
</tr>
<tr>
<td>Price per pack (270 x 250mg tablets) / CHF</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

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.7

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

<table>
<thead>
<tr>
<th>For failure on:</th>
<th>Change to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>d4T or ZDV</td>
<td>TDF or ABC</td>
</tr>
<tr>
<td>+ 3TC</td>
<td>+ ddi³</td>
</tr>
<tr>
<td>+ NVP or EFV</td>
<td>+ LPV/r or SQV/r³</td>
</tr>
</tbody>
</table>

a Dose of ddi 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. 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.

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
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

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

Production No: 1004492
July 2004.

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