

Committed to Making a Difference

*Roche progress in global efforts to increase
access to HIV/AIDS healthcare*





Preparing beans at the market in Kampala, Uganda.

F. Hoffmann-La Roche Ltd
4070 Basel, Switzerland

- Roche Corporate website – www.roche.com
- Roche in HIV – www.roche-hiv.com
- World Health Organization (WHO) – www.who.int/en
- United Nations – www.un.org
- Joint United Nations Programme on HIV/AIDS (UNAIDS) – www.unaids.org
- World Bank – www.worldbank.org
- Global Fund – www.theglobalfund.org
- PharmAccess International – www.pharmaccess.org
- The European Coalition of Positive People (ECPP) – www.ecpp.co.uk
- International AIDS Economics Network – www.iaen.org
- Care International – www.careinternational.org.uk
- Oxfam – www.oxfam.com
- International HIV/AIDS Alliance – www.aidsalliance.org
- Global Health Council – www.globalhealth.org



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Front cover visual: Southern Malawi.

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Introduction



William M. Burns
CEO of Roche Pharmaceuticals.

“This report outlines Roche’s continued commitment to helping increase access to medicines, and where we, as a company, are focusing our efforts”

Improving and delivering healthcare globally brings many challenges. The needs of people in different countries and communities are hugely varied and cannot be delivered through the creation of a single solution or approach. It is only by assessing the healthcare needs of individuals and communities, and creating solutions that are able to fulfil these needs that we can hope to make a difference.

This report focuses on improving healthcare in the developing world and aims to provide a concise update on Roche’s latest activities and policies to increase access to medicines, particularly in the area of HIV/AIDS. Having been at the pioneering forefront of HIV/AIDS treatment since 1986, Roche has focused much of its efforts on increasing access to medicines in this area, as this is where we believe our resources and expertise will have the greatest impact.

At the end of 2004, 39.4 million people worldwide were living with HIV/AIDS¹. This shocking statistic highlights the enormity of the challenge of tackling this disease.

Until a cure for HIV/AIDS is discovered, prevention, care and treatment remain the key global priorities. Whilst at Roche our primary role is our scientific contribution to improve and discover medicines for HIV/AIDS, we have also implemented programmes on the ground to help people living in the poorest and hardest hit countries.

Roche has also developed innovative and transparent patent and pricing policies, which have been widely acknowledged by international organisations as offering greatest clarity. We have removed patents and profits as barriers to our HIV protease inhibitor medicines in the Least Developed Countries and sub-Saharan Africa.

Our employees have also chosen to engage and play a personal role in the global fight against HIV/AIDS, and each year we hold a Global Employee AIDS Walk to raise funds for children in Malawi, Africa and people across the world affected by HIV/AIDS.

However, no individual, country, government or organisation can tackle the HIV/AIDS pandemic alone; it is only through the formation of partnerships amongst organisations working towards the same goals that real and sustainable solutions can be delivered. For example, the Global Business Coalition is an organisation with over 200 companies as members, with whom Roche has worked, which aims to meet the challenges of the AIDS pandemic through access to

the business sector's unique skills and expertise.

Roche continues to work with international organisations, such as the WHO, UNAIDS, the World Bank and UNICEF, as well as governments, NGOs and academic organisations, to exchange information and share learnings that can be used in the future to improve the health of people living in resource-limited settings. By forging public / private partnerships, Roche is able to combine its specific skills and resources with those of other organisations, and deliver outputs that could not have been achieved by working in isolation.

One global initiative in which Roche is involved is the Accelerating Access Initiative (AAI), which, through the collaborative efforts of the seven research-based pharmaceutical industry members and five UN agencies, is resulting in ever-increasing numbers of HIV/AIDS patients receiving treatment in developing countries. In June 2005, the World Health Organization (WHO) reported that the AAI had shipped enough medicine to treat 427,000 people living with HIV/AIDS in developing countries – this is estimated to represent half of the reported million people currently on therapy in developing countries. Whilst we know this number is still small in the context of the global need, our efforts and the efforts of others are beginning to deliver meaningful results. We are only too aware we cannot

In Africa, 216,000 patients are being treated with medicines supplied by the AAI companies. With an increase in excess of 121% on the previous year, there has been a 23-fold increase in Africa since the establishment of the AAI in May 2000.

Data: Axios International, Q1 2005

tackle HIV/AIDS as we would other diseases; this is not “business as usual”. As a leading pharmaceutical company we make every effort to balance scientific progress with compassion, and we believe that our efforts and finite resources must continue to be concentrated to benefit those in greatest need and the actions we take must create significant and lasting improvements for health.

This report hopes to demonstrate that, at Roche, we are committed to making a difference to people whose lives have, and continue to be, devastated by HIV/AIDS. Guided by the core principle of helping people today so that they can help themselves tomorrow, we

believe we are having an impact on increasing global access to healthcare in a responsible and ethical manner.

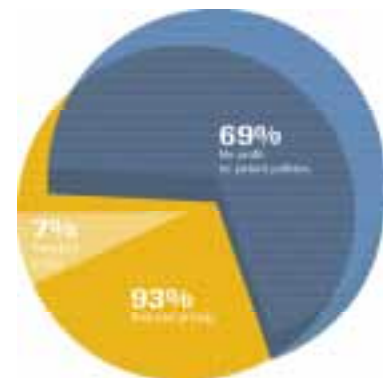
This report would not have been possible without the valuable help and insight of key stakeholders, including academics, physicians, representatives from community groups, international agencies and Roche employees.

To find out more about Roche's activities to deliver sustainable healthcare and innovate and improve global access to care and treatment, visit: www.roche.com



At a Glance

- Roche no profit & patent policies apply to more than 26 million people living with HIV/AIDS - 69% of all people living with HIV/AIDS worldwide
- Reduced prices for Roche HIV protease inhibitor medicines apply to 93% of all people living with HIV/AIDS in the world
- In 2003 the standard prices from Roche for its HIV protease inhibitor medicines applied to an estimated 15% of people living with HIV/AIDS globally. In 2005, standard prices for these medicines apply to just 7% of people globally.



Developing innovative medicines and delivering access

Why patents are registered

Patents and copyrights are society's way to create an environment that promotes innovation and encourages progress in all industries.

Creating innovative healthcare solutions through research and development is fundamental to the business of Roche. Conducting research is a costly and lengthy process, at an estimated USD\$500 - 800 million per drug and an average development time of 12 - 15 years^{2,3}. With this amount of resources required, and given that only five in every 5000 compounds make it to the final testing stage, developing new medicines is a high-risk business².

As a result, pharmaceutical companies register patents on new drugs to protect their intellectual property and prevent other manufacturers producing copies, known as generics. By being the sole manufacturer of a medicine for a limited period, pharmaceutical companies are able to generate

revenue from sales and recoup some of the substantial cost of development over a given period of time (patents can last up to 20 years). However, patents do not start when a medicine is approved or available, but are normally registered when a molecule is in early development, which may be many years before a drug reaches a patient. As a result, the time when development costs can be recouped, known as the effective patent life (EPL) can vary. The average time from approval that a drug can be sold under patent is approximately 12 years, although it can be less than 10 years³.

During the effective patent life, pharmaceutical companies monitor the safety and continue clinical profiling of the medicine. The aim is to achieve a return for stakeholders on the development risk during this defined period while operating in a highly competitive environment.

For further information visit:
www.phrma.org (US)
www.ifpma.org (international)

Patents and impact on access to medicines

The existence of patents on medicines has been perceived as a potential barrier to treatment for those living in the developing world. Many believe that the existence of patents results in artificially high prices on medicines that, whilst necessary to fund ongoing development, are restrictive and can prevent those in need of life-saving medicines living in resource-poor countries from receiving treatment.

In 2003, Roche introduced the following policy in an effort to ensure that patents do not prevent access to its medicines for those living in the poorest countries of the world:

Patent policy for all Roche medicines

- **To file no new patents on ANY Roche medicines – across all disease areas – in the Least Developed Countries as defined by the United Nations. Nor will Roche enforce existing patents it holds in these countries.**

Roche's patent policy focuses on the areas of the world that are both the poorest and hardest hit by HIV/AIDS. In the developed world accessibility of treatment has resulted in HIV/AIDS being classed as a manageable chronic illness. However for people living in developing countries where access to treatment is still scarce, HIV/AIDS remains a major cause of death. With as many as 2.3 million people in sub-Saharan Africa having died from HIV/AIDS in 2004, expanding access to treatment for the 25 million people living with the disease in this region remains a priority^{4,5}.

By committing not to enforce existing patents or file new patents in the Least Developed Countries Roche provides generic manufacturers with simple and clear parameters on what is legally permitted. As a result, generic versions of any Roche medicine can be produced without consultation or the need to apply for a voluntary or compulsory licence to grant permission.

Applying for such licences can be a lengthy process, which can be highly restrictive for local manufacturers and prevent generic production.

Roche HIV/AIDS medicines and patents

As HIV/AIDS is a pandemic of such prevalence and devastating impact, Roche has developed a specific patent policy for its HIV/AIDS 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 antiretrovirals where it holds the patents in these countries.

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

By enabling generic manufacturers to produce 'copy' ARV medicines for supply to sub-Saharan Africa and the Least Developed Countries without prior consent, Roche hopes to encourage those with the necessary



Roche focuses its activities on helping people living the Least Developed Countries and sub-Saharan Africa, the continent hardest hit by HIV/AIDS.

skills and resources to produce competitively priced HIV treatments.

By allowing production of generic versions of ARV medicines within these regions, Roche hopes that overall production will increase, helping ensure that there is sufficient supply of these essential medicines to respond to the growing numbers of people accessing treatment as a result of scale-up efforts.

However, ensuring that patents do not restrict the production of generic versions of Roche medicines in the Least Developed Countries is only a small part of a much more complex problem. Past experience has shown that in some therapy areas, such as

malaria and tuberculosis, where the most commonly used drugs are no longer under patent, many millions of people in the poorest regions still do not have access to these medicines. For this reason, Roche also focuses on the development of local programmes and appropriate price discounting to help increase access to HIV medicines.

Detailed information regarding the status on all Roche held patents for medicines to treat HIV/AIDS is provided to the WHO. For further information visit: www.who.int

For further information on Roche's patent policy and full details on where it applies visit: www.roche-hiv.com

“We are encouraged that Roche has recently committed itself not to take action against bioequivalent generic versions of its HIV drugs in sub-Saharan Africa.”

Médecins Sans Frontières (MSF). Campaign for Access to Essential Medicines

2 PHRMA, 2005

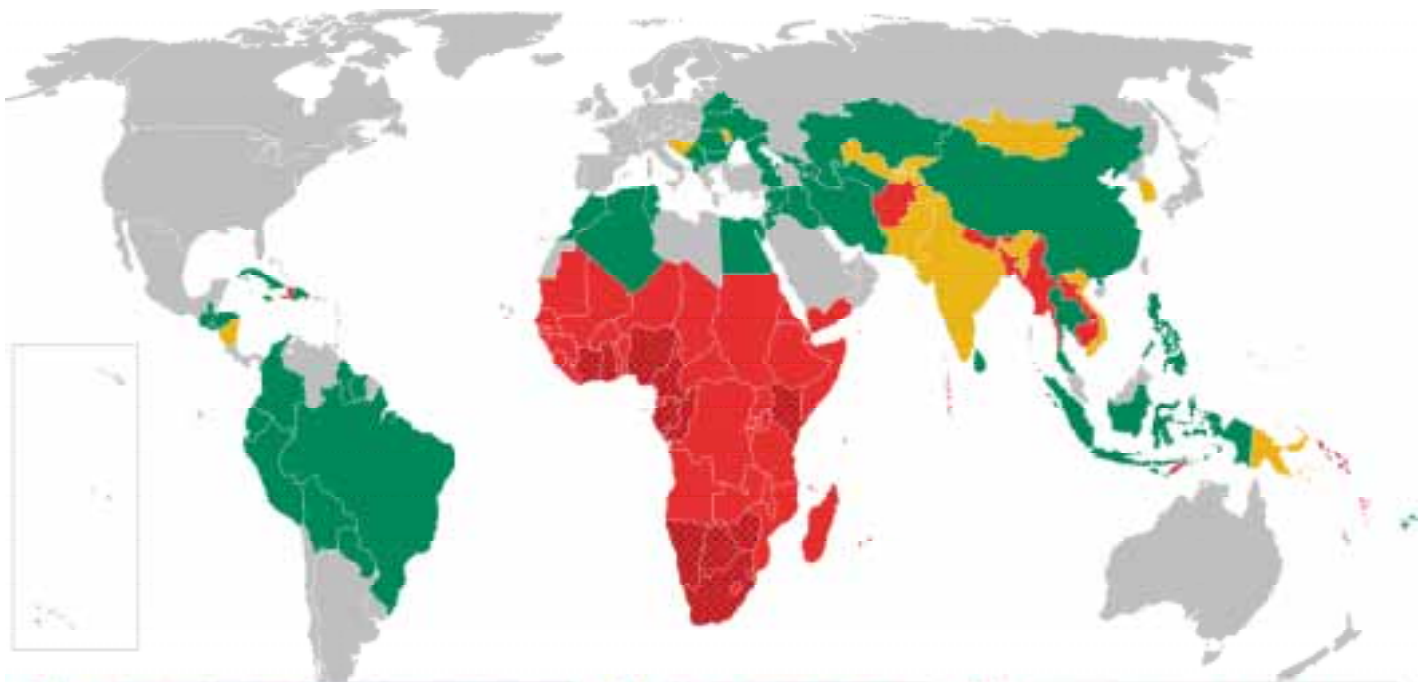
3 Grabowski, H G. Patents and new product development in the pharmaceutical and biotechnology industry <http://www.dallasfed.org/research/pubs/science/grabowski.pdf>

4 Palella FJ, Deloria-Knoll M, Chmiel JS, et al. Survival benefit of initiating antiretroviral therapy in HIV-infected persons in different CD4+ cell strata. *Ann Intern Med* 2003; 138(8):620-626

5 World Health Organization. Ten leading causes of death, developed and developing regions, 2000

Country Classifications

Countries eligible to purchase Roche no profit (red) and reduced price (green/yellow) HIV protease inhibitor medicines November 2005



Least Developed Countries (as defined by the United Nations) as of November 2005

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

Additional countries in sub-Saharan Africa not covered by the UN list of Least Developed

Botswana	Mauritius
Cameroon	Namibia
Congo, Rep	Nigeria
Cote d'Ivoire	Seychelles
Gabon	South Africa
Ghana	Swaziland
Kenya	Zimbabwe

Countries designated by the World Bank classification of economies as low income economies (those not otherwise classified as "Least Developed" by the UN) as of November 2005

India	Pakistan
Korea, Dem. Rep.	Papua New Guinea
Kyrgyz Republic	Tajikistan
Moldova	Uzbekistan
Mongolia	Vietnam
Nicaragua	

Countries designated by the World Bank classification of economies as lower middle income (those not otherwise classified as "Least Developed" by the UN or within sub-Saharan Africa) as of November 2005

Albania	Iraq
Algeria	Jamaica
Armenia	Jordan
Azerbaijan	Kazakhstan
Belarus	Macedonia, FYR
Bolivia	Marshall Islands
Bosnia and Herzegovina	Micronesia, Fed. Sts
Brazil	Morocco
Bulgaria	Paraguay
China	Peru
Colombia	Philippines
Cuba	Romania
Dominican Republic	Serbia and Montenegro
Ecuador	Sri Lanka
Egypt, Arab Rep.	Suriname
El Salvador	Syrian Arab Republic
Fiji	Thailand
Georgia	Tonga
Guatemala	Tunisia
Guyana	Turkmenistan
Honduras	Ukraine
Indonesia	West Bank and Gaza
Iran, Islamic Rep.	

Pricing of Roche HIV and AIDS-related medicines and global pricing policy

Whilst on-going efforts to improve access to antiretroviral (ARV) medicines for people living with HIV/AIDS in the developing world are having an impact, statistics show that as many as nine out of ten people remain in need of treatment, the majority of whom live in sub-Saharan Africa. Scaling up access to care and treatment remains a priority without which, in as little as two years, as many as five or six million people could die⁶.

Treatment recommendations

To co-ordinate the scale-up of HIV/AIDS care and treatment, in 2003, the WHO updated its guidelines for provision within resource-poor countries. The guidelines outline some of the challenges faced in delivering treatment within these regions, such as cost, need for refrigeration of some medicines and simplicity of regimen. These considerations were used to create treatment recommendations.

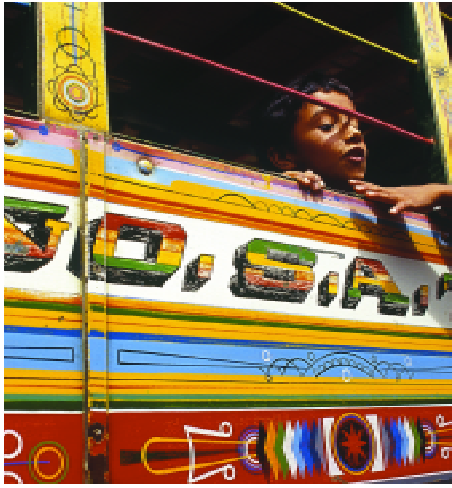
The WHO recommends that the priority for HIV/AIDS treatment is individuals with clinically advanced disease or CD4 cell counts less than 200, who should immediately commence treatment with an initial non-nucleoside reverse transcriptase inhibitor (NNRTI) based combination treatment composing of two

nucleosides and an NNRTI. Due to the possibility of side-effects, greater number of tablets, higher price of production and difficulty in delivering treatment, the use of protease inhibitor based regimens is recommended as second-line treatment to be used by people who cannot tolerate an NNRTI-based regimen or for whom these medicines have failed and become ineffective.

Roche does not manufacture any of the medicines recommended by the WHO as first-line treatments for HIV/AIDS. However, Roche manufactures Invirase (saquinavir), listed as a second-line treatment option, and Viracept (nelfinavir) which is listed as a second-line option for children. In 2002, Roche established policies that would remove barriers and increase access to these treatments for people living in low and lower middle income developing countries.

Roche recognised that as efforts to scale up the number of people on first-line therapy became successful and greater numbers of people received treatment, the need for second-line treatment options would also become increasingly important.

For a full copy of the guidelines visit: www.who.int/hiv/pub



Challenge of treating children with HIV/AIDS

Treating children with HIV/AIDS can bring additional challenges. Ensuring that they receive medicines in a formulation that can be taken by those who may find it difficult to swallow capsules or tablets, and dispensed by any healthcare professional in a standardised dose according to body surface area or weight, is essential. The two protease inhibitor formulations produced by Roche, nelfinavir and saquinavir, are both recommended by the WHO as second-line treatment options for children*. Viracept, which is included in the Roche pricing policy, is available in a powder formulation specifically designed for children.

* saquinavir (children >25kg). Invirase in combination with other ARVs is indicated for the treatment of HIV-1 infected adults. Viracept is indicated for the treatment of adults, adolescents and children of 3 years of age and older.

HIV protease inhibitors: Invirase (saquinavir) and Viracept* (nelfinavir)

In 2002, Roche committed to supply its protease inhibitor medicines, Invirase and Viracept, at no profit prices for people living in the Least Developed Countries and sub-Saharan Africa. These prices are the lowest prices at which these medicines can be produced in a long-term and sustained manner, and have been shown to be less than that of generic versions of the medicines⁷. The prices do not reflect research or development costs, marketing costs, distribution costs or company overheads. As company overheads are not included within the no profit price, Roche requires a minimum order quantity to ensure that resources are used effectively and the lowest possible price can be offered and sustained.

Roche also committed to 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 treatment⁸.

A comprehensive list of prices, countries and conditions are available on the website www.roche-hiv.com

The prices available direct from Roche exclude costs for freight, import, duty, taxes, distribution and inventory, which may be added at a local level. The minimum order is 10,000 CHF. The prices are ex-factory prices from the 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 the 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. The packs are marked "Supplied under the Accelerating Access Initiative. Exportation prohibited".

The pricing policy for Invirase and Viracept forms part of Roche's ongoing commitment to increase access to HIV healthcare and treatment. The no profit prices for Least Developed Countries and sub-Saharan Africa, together with the reduced prices for low and lower middle income countries, apply to an estimated 35 million people, representing over 93% of all people living with HIV/AIDS worldwide⁹.

To evaluate the number of people receiving ARV treatments in the developing world, Roche provides data to an independent monitoring agency, which calculates the estimated number of people receiving treatment from the research-based pharmaceutical manufacturers of the AAI. This information is then provided to the WHO for inclusion in the overall statistics regarding the scale of access to ARV treatments.

Cymevene (ganciclovir) and Valcyte (valganciclovir)

Cytomegalovirus (CMV) is a common infection normally dormant in people with healthy immune systems. In those who have a weakened immune system, such as people with AIDS, the virus can become active. Pneumonia retinitis (infection in the eyes), which can result in blindness, and gastrointestinal disease are the most common problems associated with CMV. In developed countries, where there has been widespread introduction of HIV treatment, the number of people with HIV who progress to AIDS has been reduced and therefore the incidence of CMV infections decreased. For people living in the Least Developed Countries and sub-

* Viracept is supplied by Roche outside the USA, Canada, Japan and Korea

⁷ Seventh edition of 'Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries', Médecins Sans Frontières (MSF), February 2005

⁸ World Bank list of low and lower middle income countries can be found on www.worldbank.org

⁹ UNAIDS

Saharan Africa, where access to ARVs is limited, CMV remains a problem. Roche has two medicines to treat CMV infections, Cymevene vials and Valcyte. As there is no patent on Cymevene, manufacturers can and do produce generic versions of this medicine.

Roche's patent policy for HIV/AIDS medicines in Least Developed Countries and sub-Saharan African countries also applies to Valcyte, which can be used to treat CMV but globally is primarily used in organ transplantation.

Global pricing policy

In 2003, Roche committed to establish its prices for new prescription products in the Least Developed Countries, low income and lower middle income countries at price levels which would not generate higher income than for similar products in Switzerland. The price level is based on the Roche price at the first transaction in Switzerland and is subject to the influences and factors of export markets, including but not limited to import duties and taxes, exchange rates, national price regulations and local distribution and retail margins.

As a result, the local price from Roche for new medicines available in these countries will be set no higher than the equivalent ex-Roche price in Switzerland at launch. Local retail prices will fluctuate over time with currency exchange rates when compared to the Swiss price and will be higher due to local mark ups over which Roche has no control.

This means generic versions of both Roche CMV treatments can be produced and used in Least Developed Countries and sub-Saharan Africa without the need for a voluntary or compulsory licence.

FUZEON (enfuvirtide)

FUZE ON, the innovative HIV therapy, was developed to respond to the growing incidence of resistance to HIV medicines, which is prevalent in developed countries in patients who have received treatment for their HIV/AIDS.

As a consequence of the scaling up of access to ARV treatment and the small number of people in developing countries who have become resistant to other available HIV therapies, there may be a need for treatments beyond second-line. In accordance with Roche's patent policy, there are no patents on FUZEON in the Least Developed Countries or sub-Saharan Africa. In addition, Roche also reviews and grants special applications for marketing authorisation or special license sales of FUZEON on a country-by-country basis.

However, whilst the WHO recognises that FUZEON is an advance in the treatment of HIV/AIDS, it is not recommended within the treatment guidelines for resource-limited settings because, 'the need for parenteral administration and the cost of the drug make it impractical for use in resource-limited settings'.

Focussing on the big picture

Price cuts alone are not enough to solve the problem of HIV/AIDS. Making medicines more affordable is only one of the many hurdles that have to be overcome to increase access to medicines in resource-limited countries.

With as many as three billion people living on USD\$2 per day or less, poverty has a huge negative impact on efforts to tackle HIV/AIDS. With many people having scarcely enough food or clean water to survive, the struggle to attain these basics of life are prioritised over healthcare and medicines. It is important that communities are offered assistance to develop skills and utilise local resources so that they can eradicate poverty in the long-term, and that efforts to prevent HIV/AIDS are prioritised to ensure that countries have an able workforce to assist in future development.

The lack of functioning healthcare systems and shortage of healthcare professionals in resource-limited countries is also a barrier to delivering effective care and treatment for HIV/AIDS. One example of the problems faced by developing countries is the migration of desperately needed doctors and nurses to developed countries, particularly those from English-speaking countries in sub-Saharan Africa, which have been most severely affected.

Additional funding is also required to ensure that new and established HIV prevention, care and treatment programmes being undertaken in developing countries can be sustained long-term. In September 2005, the Global Fund to Fight AIDS, Tuberculosis and Malaria announced that the total amount of USD\$3.7 billion pledged in funding to-date is not sufficient to finance existing and new projects, the cost of which has been estimated at about USD\$7 billion. The Global Fund has suggested that donors and also recipient countries will need to increase their contribution and resources allocated to fighting HIV/AIDS, tuberculosis and malaria.

For further information visit:

www.theglobalfund.org

Supporting the development of healthcare systems



Kenyatta Hospital, Nairobi. Site of one of the original CARE treatment centres in Africa supported by Roche.

To support the development of healthcare systems that are sustainable in the longer-term, Roche has developed relationships with local governments, academic centres, non-governmental organisations (NGOs), intergovernmental organisations and independent not-for-profit organisations, with the aim of directly

benefitting local communities in poor countries.

Creating initiatives that can provide medical care and treatment within the existing healthcare structure represents a challenge to all the groups involved in dealing with HIV/AIDS and demands an active commitment from everyone;

There are 50 countries currently defined by the United Nations (UN) as least developed. In these countries there is an inadequate standard of living and a significant lack of resources, including health, education, nutrition, and human literacy^{10,11}.

The gross annual income per person of a Least Developed Country is less than USD\$750, and the economies are highly vulnerable to external factors or natural disasters, which can have a devastating, long-lasting impact. At present there are over 700 million people who live in the Least Developed Countries and battle daily against poverty and deprivation. In sub-Saharan Africa for example, nearly half the population, more than 300 million people, lives on one dollar or less a day^{12,13}.

¹⁰ UN list of Least Developed Countries (LDCs) can be found on www.un.org

¹¹ <http://r0.unctad.org/conference/>

¹² United Nations
<http://www.un.org/News/Press/docs/2004/ecosoc6118.doc.htm>

¹³ United Nations. Progress towards the Millennium Development Goals, 1990-2003
http://www.un.org/special-rep/ohrls/lde/MDGs/Goal_1-final.pdf

from those directly affected, their relatives, their community and local aid organisations, all the way to the regional or national authorities and the international community with its numerous specialist institutions and organisations.

As a research-based pharmaceutical company, and in the interests of targeting assistance to maximise benefit, Roche focuses its efforts on helping people living in the Least Developed Countries; the most resource-limited settings around the world where the need is greatest and the most basic forms of medical care are not available.

In light of the devastating scale of the HIV/AIDS pandemic, Roche has developed relationships with groups that possess local knowledge of the treatment and management of HIV in resource-poor regions and have similar goals – to deliver comprehensive and sustainable HIV healthcare where it is most needed.

In order to find effective solutions, Roche believes that public-private partnerships provide the best possible approach to achieve consistent progress.

Cambodian Treatment Access Programme

Cambodia has scarce economic resources and infrastructure and is

*Cambodian Treatment Access Programme
The Cambodian Treatment Access Programme, known as CTAP, was established in September 2003 as a unique three-way partnership between the Cambodian Ministry of Health, the National Centre in HIV Epidemiology and Clinical Research at the University of New South Wales in Australia and Roche.*



Opening of the CTAP centre in Cambodia.

defined by the United Nations as least developed, with a gross national income of USD\$320 per capita¹⁴. It has one of the highest recorded prevalence rates of HIV/AIDS in Asia, with over 157,000 people currently living with the disease¹⁵.

The initial aim of CTAP was to establish and launch a local treatment centre by November 2004, which could provide a range of services including counselling, clinical care and HIV treatment. It was also designed to provide a framework for a comprehensive education programme for healthcare professionals, which would provide them with an international standard of training and

would be beneficial in the long-term for people living with HIV/AIDS.

In addition to meeting these initial aims, Cambodian and expatriate staff supported by CTAP played a role in the development and publication of Cambodian National HIV Treatment Guidelines and Policies and National HIV Care Training Programme to help further expand access to quality HIV care throughout the country.

Cambodia has taken major steps in both the prevention and care of HIV/AIDS, which have seen reductions in transmission rates and expanding uptake of treatment. Nevertheless, an ongoing and substantial effort will be required in Cambodia and elsewhere in the Asia-Pacific region, if countries are to avoid the devastating effects that the HIV/AIDS epidemic has had in other parts of the world, particularly Africa.

¹⁴ The World Bank
<http://www.worldbank.org/data/databytopic/GNIPC.pdf>

¹⁵ The World Health Organization
http://www.who.int/3by5/en/cp_khm.pdf, end of 2004

CARE, the Cohort to evaluate Access to antiRetroviral treatment and Education, was established by Roche and PharmAccess Initiative in 2001. The programme was set-up in four major urban treatment centres across Africa: Côte d'Ivoire, Kenya, Senegal and Uganda.

CARE, the Cohort to evaluate Access to antiRetroviral treatment and Education

The aim of CARE was to provide a structured programme through which antiretroviral medicines could be provided to those infected with HIV/AIDS, and from which the learnings and results could be used as a model for providing HIV healthcare in any resource-limited country across the world.

To date CARE has generated positive results. Data from the four sites have shown that HIV treatment success rates for people living with HIV/AIDS in Africa can be as high as those achieved in Western settings, something that had never previously



Healthcare professionals at the 2004 CARE training event in Dakar, Senegal.

been proved and which many thought would not be possible due to the numerous challenges faced in delivering treatment.

In addition, as a result of the educational forums that have been held as part of the CARE programme, hundreds of healthcare professionals from more than 14 African countries, as well as delegates from the USA and Europe, have met to discuss HIV/AIDS and shared knowledge with the aim of helping to improve the care and

treatment offered in each of these countries and to develop strategies to overcome some of the challenges. An educational DVD was also produced in multiple languages to extend the reach of this educational forum and share the learnings with a much wider audience.

To view more information and data from CARE visit: www.roche-hiv.com

“At the time, Roche and PharmAccess were the only ones investing in the kind of programme that CARE represented. CARE is a very important project because we learnt how to implement treatment scale-up programmes and so could immediately expand when the funds became available. JCRC is now the largest treater of HIV/AIDS in Uganda.”

Principal CARE Investigator, Kampala

Supporting local communities directly

Alongside its partnership initiatives and access programmes, Roche has also provided support directly to local communities ravaged by the HIV/AIDS pandemic. An annual, company-wide, employee driven fundraising initiative raised over a million Swiss francs in 2004 for orphan centres and HIV/AIDS community groups worldwide. Most recently, funding raised by Roche employees and matched by the

company has enabled resources to be provided to children in Malawi who have been orphaned primarily as a result of AIDS – a disease that has left over 500,000 Malawian children without one or both parents¹⁶. Working in partnership with the European Coalition of Positive People



A group of children at one of the orphan centres in Malawi, supported by the Roche Global Employee AIDS Walk.

(ECPP), a London-based international HIV/AIDS patient organisation, the Roche Employee AIDS Walk has supported work being undertaken in seven orphan centres in Malawi and Mozambique. Resources such as food, clean water and shelter are provided, as is help to develop infrastructure that will benefit the children in the long-term, such as education and skill development, which will help them become self-sufficient as adults.

The resources allocated to orphans in Malawi not only assist the children, but also offer relief to extended family members who may be trying to care for many orphaned children as well as their own in extreme poverty.

For further information about ECPP visit: www.ecpp.co.uk

¹⁶ UNAIDS/WHO/Epidemiological fact sheets – 2004 update – Malawi
http://www.who.int/GlobalAtlas/PDFFactory/HIV/EFS_PDFs/EFS2004_MW.pdf

Medicines to treat people in developing countries

Clinical trials

Undertaking clinical trials is integral to the development of any new medicine that has the potential to have a significant medical or scientific benefit, and ensuring that all trials are conducted in a manner that is ethically sound and meets local regulatory requirements is of paramount importance to Roche.

In 2003, Roche established a specific policy for company sponsored HIV

clinical trials in developing countries. This was revised and extended in 2005 to incorporate criteria for third party supported HIV clinical trials in developing countries. At this time an additional policy covering clinical trials for all Roche medicines in developing countries was also created.

To view a full copy of both of these clinical trials policies visit:
www.roche-hiv.com

Key considerations from the HIV clinical trials policy include:

- **A standard of care for people with HIV/AIDS aligned with the accepted standards of therapy as defined by the WHO for resource-poor settings**
- **Supply of the Roche medicine following termination of the trial assured for all the participants for as long as they receive medical benefit from that medication, provided that the benefit-risk ratio for the product continues to support such use.**

Roche will only consider providing support to third party sponsored clinical trials in low and middle income countries where:

- **The standard of care is according to accepted standards of therapy for the treatment of the disease**
- **There is a written agreement describing how post trial treatment will be assured for as long as the participants continue to benefit from that treatment**
- **The ethical standards are demonstrably equivalent to those of a high income country**
- **There is commitment to publish information about the trial on a public Clinical Trials Registry and post the results and outcomes of that trial on a public repository.**

Drug donations

Whilst there are emergency situations where Roche will provide medicines to recognised organisations possessing both the expertise and proven ability to effectively reach those in need, drug donations do not form a central component of Roche activities to increase access to medicines globally. The provision of treatment for diseases, such as HIV/AIDS, that require life-long therapy and for which medicine needs to be taken for an indefinite period of time cannot be provided by a commercial company, and therefore makes donations of such medicines unethical.

All requests that Roche receives from charitable organisations seeking drug donations are evaluated on an individual basis and a decision is made based on a number of key criteria being met, as outlined by the WHO guidelines. Key considerations include:

- **Donor recipients** - Requests will only be evaluated if they are from a recognised professional organisation or institution that possesses both the

expertise and a proven ability to effectively reach the people in need.

- **Ethics** - Providing therapy for chronic diseases, such as HIV/AIDS, is totally different to delivering emergency aid such as food, painkillers or antibiotics. As HIV therapy is lifelong, it would be unethical for Roche to make a donation of its HIV medicines without the guarantee of continuous supply for each recipient's entire life. This is equally applicable for other medicines used in chronic conditions.
- **Disaster relief** - When a disaster occurs, Roche will review the situation and provide assistance where it can.

For further information regarding drug donations visit: www.who.int

If you would like to contact Roche with feedback or questions about any information within this report, please email: info.makingadifference@roche.com

In December 2004, Roche donated 220,000 packs of antibacterial and antibiotic medicines to help as many as 80,000 people affected by the tsunami disaster.

The medicines were made available to an international aid organisation to support emergency healthcare delivery in the affected countries in Asia.

Additional Roche policies



Market-seller testing quality of produce at the market in Kampala, Uganda.

Human Resources: Secondment Policy

Roche is committed to offering employees opportunities for personal development while contributing full-time to a humanitarian cause through its secondment policy.

The objectives of the policy include identification of meaningful projects where consistently high performing Roche employees can make a sustainable contribution. Roche allows appropriate employees to make themselves available for healthcare projects. This is possible as long as the local authorities and any other partners are actively committed to providing the essential infrastructure and support necessary for the employee(s) activities. Seconded employees continue to receive their salary and benefits from Roche for the secondment duration, which may be between 3 and 18 months.

Performance and commitment

Roche remains committed to improving global access to healthcare and will continue to develop its relationships with existing stakeholders and public partners. Roche's involvement in access programmes and stakeholder activities is continuously evaluated on sustainability and benefit. Activities are undertaken in a responsible and ethical manner and reviewed on a case-by-case basis to ensure optimum, long-term impact.

To enhance future activities undertaken, Roche commits that it will establish Key Performance Indicators (KPIs). These KPIs will be agreed in advance and be reviewed on an ongoing basis to ascertain to what extent these have been achieved and how these can be used by internal and external audiences for the greatest impact in the future.

These KPIs will be published annually in the Roche Sustainability Report.

For further information and updates on Roche's performance visit:

www.roche.com/home/sustainability.htm

Reviewing and progressing

Roche believes it is important to constantly review its own activities and allow others to review our performance so that we can not only ensure that we are meeting our commitment, but also receive feedback that may help us adapt and improve our future activities.

We consult with external stakeholders who provide feedback on activities undertaken and who helped in the development of this report.

If you would like to contact Roche with feedback or questions about any information within this report, please email:

info.makingadifference@roche.com

Frequently asked questions

Q: Why did Roche develop a pricing policy for its HIV protease inhibitor medicines?

In 2002, Roche developed both pricing and patent policies in an effort to increase access to its medicines for people living in the poorest countries of the world. Tiered pricing was developed for Roche's HIV protease inhibitor medicines, which are considered by the World Health Organization (WHO) as essential medicines. We developed this policy to ensure clear, consistent and transparent pricing on our HIV protease inhibitor medicines.

By developing such policies, Roche has provided clear guidance to those wishing to purchase its medicines. The policies enable Roche to define publicly where it focuses its efforts and resources and why it has taken this approach.

Q: Where do Roche's pricing policies apply?

The no profit pricing for Roche HIV protease inhibitor medicines applies to countries in sub-Saharan Africa and those defined as Least Developed. The reduced tiered prices apply to all countries defined by the World Bank as low and lower middle income countries.

Q: Why doesn't Roche extend its no profit price to all developing countries?

"Developing countries" is a term that encompasses countries with a very broad range of economic development. Upper middle income developing countries have far greater resources and wealth than the Least Developed Countries of the world.

With almost 40 million people globally living with HIV/AIDS, Roche has focused its efforts on helping the people who have fewest resources and have been hardest hit by HIV/AIDS. Roche extends its no profit prices for its HIV protease inhibitor medicines, Invirase and Viracept, beyond Least Developed Countries to include all of sub-Saharan Africa, as this is the continent where over 65% of all people with HIV/AIDS live, many of who will die without access to ARV treatment.

Reduced prices are offered to low and lower middle income countries, where HIV/AIDS may be a significant health issue, but local governments have more resources to enable them to provide and make HIV/AIDS treatment a priority. Roche will further review prices should low and lower middle income countries wish to purchase on a large volume, fixed contract basis.

Roche understands that increasing access to ARV medicines is essential and has implemented policies to help achieve this, and also has a responsibility to ensure that commitments are sustainable by the company in the long-term.

Q: How many people are benefitting from Roche pricing policies?

The Roche no profit prices for HIV protease inhibitors are available to over 26 million people living in the Least Developed Countries and sub-Saharan Africa. This is almost 70% of all people living with HIV/AIDS.

In addition, when the Roche reduced pricing is included, which applies to those in low and lower middle income countries, the number of people to whom Roche's access pricing policies apply is in excess of 35 million people – this is over 93% of the total number living with HIV/AIDS globally.

Q: How often does Roche review its no profit prices for its HIV/AIDS protease inhibitors?

Roche reviews its no profit prices at least once a year. This review helps ensure that the no profit prices direct from Basel remain truly without profit as production costs vary – both

increase and decrease - over time. They do not reflect research or development costs, marketing costs, distribution costs or company overheads.

Q: Why does Roche have a minimum order?

The Roche no profit prices do not reflect research or development costs, marketing costs, distribution costs or company overheads. As company overheads have not been included, Roche requires a minimum order quantity to ensure that resources are being used effectively and the lowest possible price can be offered.

The minimum order value is CHF10,000. The number of doses this value of purchase covers varies depending on the product purchased. For example, those purchasing Invirase at no profit would be required to buy a minimum order of approximately 110 packs (270 x 200mg) which is equivalent to treating nine people for one year. As a Swiss company Roche invoices in Swiss francs and supplies these medicines from its headquarters in Switzerland.

Q: Are the Roche no profit protease inhibitors different?

Roche medicines are produced to exactly the same high quality standards across the world. The only



Women's co-operative community meeting in Cameroon.

noticeable difference in the no profit medicines is that the packs are marked "Supplied under the Accelerating Access Initiative. Exportation prohibited" to help ensure that these essential medicines get to the people for whom they are intended and are not diverted and resold outside that country.

Q: Who is eligible to buy Roche protease inhibitors, Invirase or Viracept, at reduced prices?

Roche reduced prices for Invirase and Viracept are available to both public and not for profit private purchasers directly from Roche Basel.

Q: Where do Roche's patent policy apply?

Roche's patent policy enables the generic production of all Roche drugs,

across all diseases, for supply to any country defined by the United Nations as Least Developed. Additionally, it allows generic production of HIV medicines for which Roche holds patents for all countries in sub-Saharan Africa.

For further information about the terms and conditions of purchase please visit: www.roche-hiv.com

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