Access to medicines and diagnostics

focused on developing countries
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This report outlines the approach we have taken to improve healthcare in the poorest countries of the world. Medicines and diagnostics are the cornerstone of our business, but we believe that they are just one part of the solution to improving healthcare for those people in the greatest need.

Almost all medicines that are marked as essential by the World Health Organization (WHO) are off patent, which means that the majority of treatments that are urgently needed to address health priorities in the world’s poorest countries could be met with generic medicines. The fact that this does not universally happen highlights the real issues affecting access to medicines in these countries.

This is why we have evolved our approach to improving access to healthcare in a different way, going beyond our medicines and diagnostic tools to look at ways that we can use our strengths as a business to address the health needs in those countries.

With researching, developing and manufacturing life-saving medicines and diagnostics being the mainstay of our business, we are uniquely equipped to share our expertise on the ground with local manufacturers in poor countries to help improve the quality of manufacturing medicines and set-up the necessary infrastructure to provide diagnostic services.

We also use our expertise in working in partnerships with clinicians, governments, non-governmental organisations (NGOs), patient groups and healthcare providers to strengthen our approach in developing countries – building public-private partnerships through which we can establish sustainable programmes that deliver healthcare to patients and facilitate experience exchange and education for physicians.

We build on the strengths of our colleagues and our extensive research programmes to help address the treatment and diagnosis of diseases that are highly prevalent in developing countries. We encourage our employees to share their skills directly with established healthcare projects in the poorest countries of the world through our unique Secondment Policy. We have also shared our compounds library with a non-profit organisation to develop medicines for neglected disease. In the course of our research, if discoveries are made which could have application in tropical disease, we will share that knowledge with a non-profit organisation or other interested stakeholder to benefit patients in need.

Our approach to increasing access to our medicines and diagnostics in developing countries reflects our overall approach as a business. We believe we can make a difference in many therapeutic areas through our capacity to innovate while keeping the patient at the heart of everything we do. We have made personalised healthcare a cornerstone of our innovation strategy because we can use our pharmaceuticals and diagnostics expertise to tailor treatments more closely to patients’ needs. In the same way, in developing countries we have focussed on using our strengths in ways that directly reach patients in need and improve the quality of healthcare in local communities in a sustainable way.

We are proud of what we have done and we will continue to strive to find new ways to bring sustainable healthcare to patients throughout the world.

Severin Schwan
CEO, Roche Group
Introduction

Global access to healthcare
Nearly half of our world’s population live with under US$50 per person per year of total healthcare funding. While governments are responsible for setting up healthcare systems in individual countries, Roche believes it has a responsibility to help improve global access to its products, to supply safe medicines and reliable tests that give value for money, to provide factual information about its products, and to conduct clinical trials ethically.

Roche is working on a long-term strategy for access to medicines and diagnostics that includes working with healthcare authorities and advocating greater patient access. The majority of healthcare systems recognise the clear medical and economic value of our medicines and diagnostic tools as a result of our engagement with them. Patients can access them through doctors, hospitals, laboratories and pharmacies in roughly 180 countries.

Public health policy and standards of healthcare vary greatly, as does public awareness of the causes, prevention and treatment of disease. There are many barriers that limit access to healthcare for people throughout the world. The difference in the level of resources available in different countries to meet healthcare needs is immense, and thus not everyone has equal access to healthcare. Some patients are able to live longer, healthier lives than others with the same disease because the same level of medical care is not available in all countries. The development and improvement of the provision of healthcare is the responsibility of many stakeholders, including governments, industry, the private healthcare sector, and healthcare providers. Healthcare resources and needs vary widely from country to country and cannot be addressed with a single approach.

Roche’s approach to improving access for those most in need
Roche has developed different strategies and programmes for improving access globally, which reflect the needs of different regions.

Given their more advanced healthcare systems, the majority of our business is in developed countries, where we work closely with local payers to demonstrate the value of our medicines and diagnostic tests and agree upon a level of reimbursement that enables access. [See page 6 for further information on our approach to access to medicines and diagnostics in developed countries]

Middle-income countries, however, may require a different business model to developed markets, as often they have healthcare systems which are in the early stage of development, and rely heavily on the private payer system. [See page 6 for further information on our approach to access to medicines and diagnostics in emerging markets]

In the poorest countries of the world, we believe that increasing access to medicines and diagnostics necessitates yet another approach.

The world’s Least Developed Countries (as defined by the United Nations) are hardest hit by infectious diseases such as HIV and have the poorest healthcare systems to deal with this burden. Limited access to medicines and diagnostics is just one part of the problem; there is a critical lack of even the most basic healthcare. There are too few hospitals, laboratories and healthcare professionals to meet demand, and international aid focuses primarily on HIV/AIDS, tuberculosis and malaria. Public health has limited local investment.

Roche’s approach in these countries is therefore driven by the need to create sustainable solutions to help facilitate better access not only to our medicines and diagnostics – which are just one part of the solution – but to healthcare as a whole. Roche sees this as its ethical responsibility and concentrates on using its strengths and resources to help improve medical care overall in these countries.

To Roche, sustainability means that rather than giving away our medicines and diagnostic tools, our expertise and resources are used to support improvements to healthcare that will bring lasting and continued benefit to the people that need them. As part of this approach, Roche works in partnership with governments, international and local organisations to provide sustainable healthcare for the people most affected by disease, by increasing awareness, screening, education, knowledge and technical expertise.

Roche is committed to continually reviewing its approach to increasing access to medicines and diagnostics in the poorest countries of the world, and creating new ways to use its strengths and resources to bring sustainable health benefits to people in need.
An overview of our approach in developing countries

This report provides a summary of the policies, partnerships and initiatives that Roche, as a company, has undertaken as part of its responsibility to increase access to its medicines and diagnostics in developing countries.

We have structured the report around the four core principles that underpin our approach:
- Research and development
- Fair pricing policies
- Partnerships
- Sustainable and ethical programmes

These principles aim to allow Roche to carry out its responsibility to increase access to healthcare in developing countries in a way that is sustainable as a business. As a research-based healthcare company, we ultimately have a responsibility to be around for years to come, producing new and innovative medicines which add medical value to patients, payers and society in general.

Access in emerging markets

Middle-income countries often require a different business model to developed markets. Each country’s healthcare system is at a different stage of development and has specific needs.

Roche works in partnership with governments to help establish processes, education and clinical trial programmes. We have established a dedicated Medical Affairs Group to develop specific programmes targeted to individual emerging countries. We also supply our products to private healthcare systems in these countries.

To provide just one example, in Egypt, a lower-middle-income country, hepatitis C prevalence is amongst the highest in the world, affecting up to 12% of the country’s population. Roche has worked with the Egyptian government to initiate the National Ministry of Health (MOH) Project for Treating Chronic Hepatitis C (CHC), resulting in a vast increase of patients who now have access to treatment.

Access to medicines in developed countries

Even in the developed world, access for patients to innovative medicines varies between countries. This is due to many factors, such as lack of reimbursement of products, public health funding failing to keep pace with the burden of the disease, lack of payment by insurance companies, through to lack of medical insurance in general.

Roche works closely with local payers to demonstrate the value of its products and agree a level of reimbursement that enables access. However, there are still many people in developed countries who have limited or no access to healthcare or health insurance.

Roche therefore supports a number of initiatives in developed countries to help provide healthcare to those in need.

To provide just one example, in the United States, where there is no universal healthcare system, Roche provides drugs at no charge to those in need through the Roche Patient Assistance Programme (PAP):
- Roche set the standard for assisting patients in need in the 1960s, becoming one of the first companies in the USA to establish a PAP
- Since 2000, the programme has provided free drugs worth over US$1 billion
- In 2008, 22,000 patients benefited from the PAP
- Roche also supports the industry’s efforts to raise awareness of assistance programmes available via the Partnership for Prescription Assistance

Through its Genentech Access Solutions programme, the company provides patients and healthcare providers with coverage and reimbursement support, patient assistance and informational resources. Patient assistance support is for eligible patients in the United States who do not have insurance coverage or who cannot afford their out-of-pocket co-pay costs. Since 1985, when its first product was approved, Genentech has donated approximately US$1.3 billion in free medicine to uninsured patients through its Genentech Access to Care Foundation (GATCF) and other charitable programmes. In 2008 GATCF helped approximately 16,000 new patients.

For further information please visit: www.gene.com/gene/products/access

Further information on Roche’s patient access programmes in developed countries can be found on the country-specific company websites, which can be accessed through the Roche Worldwide menu here: www.roche.com/index

More on the web:
For a complete overview of the activities Roche undertakes to help increase global access to our medicines and diagnostics, position documents on key subjects, as well as the latest information on the initiatives included in this report – please visit our responsibility web pages: www.roche.com/corporate_responsibility

If you would like to contact Roche with feedback or questions about information within this report, please find the details on: www.roche.com/contact_form
First collaboration phase completed with the Institute for OneWorld Health to support R&D into neglected diseases.

Established collaboration with Novo Nordisk and the World Diabetes Foundation to help children with type-1 diabetes in Africa.

Secured five new technology transfer agreements with local manufacturers in Africa and Asia.

Held three Pan-African training seminars to improve local production of essential medicines, attended by 56 delegates from 21 organisations.

Partnered with physicians from Albert Einstein College of Medicine to train over 200 Ethiopian healthcare professionals.

Approved two new employee secondments in the world’s poorest countries to share skills on local projects to improve healthcare.

Extended annual employee fundraising event to support more vulnerable children.

Reduced price for cytomegalovirus (CMV) medicine Valcyte (valgancyclovir) for AIDS patients extended to NGO AIDS treatment programmes in all low- and lower-middle-income countries.

Partnered with Clinton Foundation HIV/AIDS Initiative (CHAI) to improve access to HIV testing for infants in 35 countries in Sub-Saharan Africa.

Launched the Tamiflu Reserves Programme to produce and store Tamiflu (oseltamivir) for pandemic stockpiling in specified developing countries at a significantly reduced price.

Renewed contracts with sub-license holders who are producing oseltamivir in China and India.

Announced a donation of 5.65 million treatment courses of Tamiflu to the WHO to replenish their pandemic stockpiles, including 650,000 treatment courses of Tamiflu small (30mg and 45mg) capsules for children. This donation replaces a previous donation by Roche to the WHO of 5.125 million treatment courses.

Cancer education and screening process enhanced on Phelophepa Health Care Train in South Africa.
Roche’s products and services provide vital benefits to society and to patients across the healthcare spectrum. Our diagnostic tests are used to screen for, detect, diagnose, select treatment for and monitor disease. Our medicines can prevent and cure disease, alleviate symptoms and hasten recovery.

In 2008, Roche invested almost 9 billion Swiss francs into the discovery and development of new diagnostic testing and treatments. Our R&D investments currently focus across five disease areas – oncology, inflammation, metabolism, virology and central nervous system (CNS). All are of epidemic proportions globally, are in areas where we can demonstrate success and where we believe we can make the greatest difference. For diagnostics, our pipeline contains innovative diagnostics for early detection (screening), diagnosis and disease classification, disease prognosis and disease monitoring, mainly for cancer, virology, diabetes and metabolic diseases, as well as for blood screening. Further information on Roche R&D can be accessed at: www.roche.com/r_d_overview

The value of our medicines and diagnostics
With our expertise in molecular biology across diagnostics and pharmaceuticals, Roche is uniquely positioned to create value for patients and the healthcare system.

Roche’s unique approach to personalised healthcare (PHC) helps us develop novel medicines and diagnostic tools that patients need and governments and regulators demand. PHC means fitting treatments to patients to improve clinical outcomes. Our expertise in diagnostics gives us a great competitive advantage, as we can use diagnostics to deepen our understanding of a disease, how medicines work, and differences between patients.

This helps us develop better, safer drugs targeted at the patients who will benefit most. This is not only good for the patient, but will also appeal to payers and regulators due to their greater efficacy and, hence, cost-effectiveness.

At Roche, we focus our research and development on our areas of expertise to search for differentiated and innovative medicines for life-threatening diseases in areas of unmet medical need. This is where we can make the most difference. Roche’s contributions towards diseases considered neglected and primarily affecting Least Developed Countries includes a collaboration for diarrheal diseases, medicine and diagnostics for pediatric HIV plus our active virology research programme.

Access to medicines and diagnostics | Research and development
Clinical trials

Clinical trials of new medicines not only demonstrate the safety and efficacy of a drug, but also provide educational, financial and medical support for participating hospitals, as well as access to the latest treatments for cancer, arthritis, diabetes and other serious diseases.

Patients taking part in trials receive free medical treatment during and often after the trial until the drug is available on prescription.

More than 235,000 people took part in our clinical trial programmes during 2008, receiving access to our latest treatments.

**Patients benefitting from clinical trials**

<table>
<thead>
<tr>
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<th>2008</th>
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<tbody>
<tr>
<td>Number of clinical trials</td>
<td>890+</td>
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<tr>
<td>Number of healthcare centres involved</td>
<td>13,600</td>
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<tr>
<td>Number of patients in ph I-IV clinical trials</td>
<td>235,420</td>
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 Patients seeking new clinical trials in which to participate, and people wishing to learn from the results of completed trials, can access this information on: www.roche-trials.com

Patients globally can also access details of our trials in patients through the IFPMA clinical trials portal at www.ifpma.org/clinical trials, and on the USA National Institute of Health’s global registry at: www.clinicaltrials.gov

**Global disease burden**

The diseases covered under the global disease burden definition are those that contribute to 1% or more of total deaths in the world according to the Disease Control Priorities Project.

The global disease burden includes the following conditions – Roche is active in many of these areas (marked with *):

- Tuberculosis (TB)*
- HIV/AIDS*
- Diarrheal diseases
- Measles
- Malaria
- Lower respiratory infections*
- Perinatal conditions*
- Stomach cancers*
- Colon, rectum and liver cancer*
- Trachea, bronchus, and lung cancers*
- Diabetes mellitus*
- Hypertensive and ischemic heart disease*
- Cerebrovascular diseases*
- Chronic obstructive pulmonary diseases*
- Cirrhosis of the liver*
- Nephritis and nephrosis

With a broad portfolio of tumour markers for prostate, colorectal, liver, ovarian, breast, stomach, pancreatic and lung cancer, as well as a range of molecular oncology tests, Roche will continue to be a leader in providing cancer-focussed treatments and diagnostics.

Planned regulatory filings over the next few years aim to provide treatment to patients for pancreatic, gastric, non-small cell lung, and prostate cancers, as well as Ewing’s sarcoma.

**Ethical approach to R&D**

Roche’s global position on clinical research commits us to high ethical standards and makes clear our position on specific areas of concern. We have a specific clinical trials policy for low- and middle-income developing countries to further protect patients. For example, we will not conduct clinical studies in such countries solely for the purposes of registering the drug in another country, meaning we do not perform clinical trials in countries where we will not seek marketing approval.

To view our clinical trials policy in full, visit: www.roche.com/clinical_trials
Access to medicines and diagnostics | Research and development

Roche has a long-standing commitment to addressing the diagnosis and treatment of diseases highly prevalent in the developing world.

For example, we have an established track record in the provision of diagnostics and treatment for diseases such as HIV/AIDS, hepatitis C, Chagas, tuberculosis (TB) and malaria. [See page 11 for further information]

Wherever possible, we utilise our current initiatives to support other organisations’ efforts to investigate potential solutions towards diseases that are highly prevalent in the developing world, which include neglected tropical diseases. For example, through our employee Secondment Policy, some Roche employees have worked on secondment with tropical disease research institutes, where they have been able to share their invaluable skills and expertise to help contribute to global research and management of such diseases. [For more information on Roche’s employee Secondment Policy, please see page 30]

Roche is constantly on the lookout for ways to improve health that support its approach to provide hands-on guidance that can make a sustainable difference in the areas where we have expertise. If in the course of our research, discoveries are made which could have application in tropical disease, Roche would consider offering the molecule to a non-profit organisation for the benefit of society.

R&D for diseases highly prevalent in the developing world
Roche has a long-standing commitment to addressing the diagnosis and treatment of diseases that are highly prevalent in the developing world

- Roche developed the antimalaria drugs Lariam (mefloquine) and Fansidar (sulfadoxine / pyrimethamine), which are off-patent and available for local generic production
- We have donated our expertise in both industrial drug development and specifically in malaria drug development to the Medicines for Malaria Venture in support of the molecule known as OZ7
- In 2003, Roche donated all rights and the technology to manufacture benznidazole, for the treatment of Chagas disease, to the Brazilian government to assist in its efforts to reduce the impact of this neglected disease
- We developed HIV testing and drug formulations for infants, a significantly neglected area identified by NGOs
- Roche provides diagnostics for the early detection and monitoring of HIV and TB
  - We have developed a dry blood spot methodology to help national HIV/AIDS programmes overcome some of the logistic challenges involved in utilising HIV molecular-based diagnostic detection and monitoring tests
  - Further investment has also been made in developing a new-generation HIV viral load assay to meet the needs of an environment faced with a constantly mutating HIV virus
  - We are committed to finding a workable diagnostics solution that improves on current tools being utilised in resource-poor settings to screen and diagnose TB, an infectious disease that is a leading killer of people with HIV. We are currently exploring the role of molecular biology for this purpose, with new tools being evaluated in developing countries with a high HIV burden
- As part of Roche’s commitment to improving rates of TB detection, we are developing a new diagnostic test for TB, the LightCycler® system. The new test offers a number of advantages over traditional testing, including improved patient management and a reduction in the rate of smear negative results. We are currently evaluating which countries will be suitable candidates for the test
- Roche has partnered with Google.org by donating our medical research and sequencing expertise to support a multidisciplinary surveillance, research and response system for emerging infectious diseases in East Africa. [For more information see page 13]

“We are proud of our contribution in the battle against tuberculosis, which is really a plague in African countries. Every patient should get exactly what he needs to be cured – this is Roche’s basic idea of Personalised Healthcare. A fast, safe and reliable test result is the backbone of this concept.”

Manfred Baier
Head of Roche Applied Science
Access to treatment and diagnostic testing specifically designed and suitable for children has long been cited by NGOs as an area of neglect.

Roche has used its expertise to help address the need for pediatric formulations and diagnostics solutions for children in the following areas:

**HIV/AIDS**

In the area of HIV/AIDS, children under one year old are dying of AIDS-related illnesses without ever being diagnosed.9 There are also a limited number of HIV medicines available to treat HIV in children.10 The United Nations Children’s Fund (UNICEF) estimates that survival rates among HIV-positive infants can improve by up to 75% when diagnosis and treatment is initiated within their first 12 weeks.11

Roche has developed HIV drug formulations and testing for infants:

- The HIV medicine Viracept (nelfinavir) – one of the WHO’s listed second-line treatment options for children in resource-limited countries – is available in a powder formulation specifically designed for children
- Roche has developed infant testing for HIV, in response to the need for effective diagnostic testing for children with HIV/AIDS in developing countries
- Roche announced an agreement with the Clinton Foundation HIV/AIDS Initiative (CHAI) in 2008. We are providing molecular-based HIV infant diagnostic tests in combination with dry blood spot methodology, which are easily administered, stored and transported, at substantially reduced prices. These are used to diagnose HIV in children younger than 18 months [For more information on this partnership, see page 25]

**Pandemic influenza**

As part of their pandemic planning, governments and other agencies are recognizing the particular vulnerability of children and the special role they play in amplifying the spread of influenza. Children have been significantly impacted by previous pandemics and they appear to be disproportionately affected by the 2009 pandemic.

In addition to an existing syrup formulation, Roche has developed pediatric Tamiflu capsules (30mg and 45mg) to provide a convenient option for the treatment and prevention of influenza for children one year and older; this formulation makes stockpiling easier.

**Diarrheal diseases**

In 2008, Roche opened its compound library to the Institute of OneWorld Health to screen compounds from the Roche library to identify new drugs for treating acute diarrhea. Diarrhea kills approximately two million children in developing countries each year and there are currently no effective drugs widely available.12 [For more information see page 14]
Predicting and preventing emerging infectious diseases in East Africa

Emerging infectious diseases are a significant burden to public health systems and the East African region is known to be one of the major hot beds for the emergence of novel viruses and new strains of known viruses.

In 2009, Roche entered into a collaboration with Google.org, the philanthropic arm of Google.com, to launch a joint initiative to monitor the circulation, transmission and maintenance of arboviruses – a large group of viruses transmitted by blood-sucking insects and other arthropods such as ticks. Our ultra high-throughput sequencing capabilities, powered by the Genome Sequencer FLX System, will be used by dedicated research organisations in Kenya to advance the understanding of how these viruses work and evolve, linking these findings to improve the treatment and management of infectious diseases. The initiative’s first priority is to tackle Rift Valley Fever – a potentially lethal disease for both people and livestock which is transmitted by mosquitoes.

“We are proud to work with our partners to bring this technology to a region of the world where novel viruses frequently emerge. We are confident that access to this system will improve monitoring of infectious diseases and enable faster discovery in case of a novel outbreak.”

Christopher McLeod
CEO of 454 Life Sciences, a Roche Company
“Our work with Roche is an example of the different kinds of partnerships required to make the goal of reducing childhood deaths from diarrheal diseases in the developing world a reality. The world has shown its resolve to fight pediatric diarrheal diseases by committing to the United Nations Millennium Development Goal of reducing the child mortality rate by two-thirds by 2015.”

Richard Chin, M.D.
Chief Executive Officer for the Institute of OneWorld Health

Research collaboration with the Institute for OneWorld Health

Through our partnership with the Institute for OneWorld Health (iOWH), the first US non-profit pharmaceutical company, we have enabled the institute to have access to compounds in our library, with the goal of finding a potential medicine to treat childhood diarrhea in developing countries.

The partnership supports the activities of iOWH to assemble a portfolio of product candidates to address various aspects of diarrheal diseases, with a special focus on treatments for infants and young children.

The iOWH successfully completed its first screening campaign of our proprietary compound library in May 2009. The iOWH will select up to 40 new drug leads for further study intended to identify a new treatment for childhood diarrhea.

Diarrheal diseases kill approximately two million children under the age of five in developing countries each year, a child mortality rate that is greater than AIDS, TB, and malaria combined. By bringing together skills and resources from both Roche and iOWH, we believe that there is a much greater chance of finding a new, more effective treatment for life-threatening childhood secretory diarrhea.
Employee special assignment at the Institute for OneWorld Health, San Francisco, US

Roche employee Paul Nakagaki, from Group Research Strategy at Roche headquarters in Basel, undertook a special assignment at the iOWH to share his skills to support research into neglected diseases primarily affecting developing countries.

"Taking an assignment at iOWH provided me with an invaluable opportunity to contribute my expertise to help make a difference in an organisation with the mission to save lives in the most neglected diseases and neglected populations. My role focussed on the development of iOWH's long-term R&D strategy and on helping them to implement a sustainable long-term business plan.

iOWH focusses on driving drug development for neglected diseases from initial screening of molecules to approval. They also work to increase local capabilities to ensure the medicines are not just approved, but can reach patients. The organisation has done some excellent work building scientific expertise and building and managing difficult and complex partnerships. As would be expected in a grant-based R&D model, retention of staff is a major challenge due to limited or non-sustainable funding.

Like other Product Development Partnerships (PDPs), iOWH runs virtual discovery and R&D which enables them to identify outcomes that are mutually beneficial for them, biotechs, NGOs, contract manufacturing organisations, other pharmaceutical companies and governments. This is an extremely complex process, but one which could be the model for the whole industry in the future.

My time at iOWH has given me first-hand experience of this approach and given that I am already familiar with the other R&D models, I am now better suited to evaluate such proposals on behalf of Roche. In addition, I have learned a tremendous amount about the challenges of global health and the approaches to address them.

It is my sincere hope that Roche now gains a better rounded leader after returning to the company following my sabbatical."

"This new partnership is an important next step in our plans to expand our diarrheal disease programme and ensure that a robust pipeline of new treatments is under development."

Dr. David Brown
Portfolio Head and interim Chair of the Board of Directors for iOWH
As one of the world’s leading healthcare providers, at Roche we carry out our business activities in close collaboration with numerous stakeholders. Stakeholders ranging across the investment and financial community, shareholders, healthcare providers and payers, NGOs, patients and patient organisations, as well as employees, require sustainable performance, transparency and social responsibility from pharmaceutical companies.

Our approach to pricing strives to balance our business imperatives with our commitment to improving access to our treatments and services.

Our pricing policies are designed to provide sustainable access to medicines around the globe.

The cost of medicines and diagnostics is just one of the many barriers to treatment in the world’s poorest countries. Pharmaceutical companies are often criticised for the prices they charge compared with generic versions. Research-based healthcare companies like Roche have to cover the costs of discovering and developing the products, plus the costs of the many research projects that fail. Without recovering these costs through our pricing, we cannot fund research into new drugs and continue the fight against disease.

Pricing policy for our HIV/AIDS medicines

Roche continues to supply two antiretroviral therapies for HIV/AIDS at no-profit prices in all Least Developed Countries and sub-Saharan Africa. This pricing policy covers 63 countries representing more than 68% of people with HIV globally. These are the lowest prices at which the medicines can viably be sold and do not reflect research or development costs, marketing costs, distribution costs or company overheads. Roche supplies these medicines at reduced prices in countries defined by the World Bank as low- or lower-middle-income. In total, 83% of people living with HIV/AIDS live in countries eligible for reduced priced Roche HIV medicines. We review our no-profit prices for HIV medicines regularly and adjust them when necessary to ensure they remain without profit to Roche.

We will consider preferential pricing schemes in low- and lower-middle-income countries (as defined by the World Bank), for diseases that are deemed key priorities by appropriate supranational institutions, after thorough evaluation of the products, markets and potential collaborations at a country level.

For example:

- Roche provides differentiated pricing of Tamiflu for pandemic use in developed and developing countries, with significant and consistent reduced pricing to governments in developing countries available through the Tamiflu Reserves Programme [See page 18 for further information]

- The Roche AmpliCare programme provides flexible pricing for HIV diagnostic tools to support programmes initiated by supranational and governmental organisations. This is being extended to include other neglected diseases wherein Roche may have applicable diagnostic solutions [See page 18 for further information]
Reduced price for Valcyte for AIDS patients

Cytomegalovirus (CMV) is a common virus normally dormant in people with healthy immune systems. In those who have a weakened immune system, such as people with AIDS or transplant patients, the virus can become active. The most common problems associated with CMV include pneumonia, retinitis (infection in the eyes), which can result in blindness, and gastrointestinal disease.

Valcyte is indicated for CMV retinitis in AIDS patients and prevention of CMV disease in solid organ transplant patients. Given its important role in the treatment of CMV for AIDS patients, we have been faced with a difficult challenge that balances our commitment to help increase access to Valcyte for AIDS patients in the poorest countries of the world, while ensuring our long-term commitment to the global transplant market.

To address this need, since 2007 Roche has offered Valcyte at a substantially reduced price to the international NGOs treating AIDS-related CMV infection. This discount was for exclusive use in their AIDS patients in Least Developed Countries and sub-Saharan Africa, and was subsequently extended to their programmes in low- and lower-middle-income countries.
Increasing access to HIV viral load monitoring

As one of the world’s leading providers of diagnostics, Roche has a social responsibility to give access to care in areas where this is limited – precisely where HIV/AIDS is taking its greatest toll. We take this responsibility very seriously and this is why we are committed to expanding our AmpliCare Initiative in the world’s poorest countries.

AmpliCare is Roche Diagnostics’ proactive response to this enormous humanitarian challenge of HIV/AIDS. Since its initiation in 2002, the programme has been supplying HIV viral load tests at substantially reduced prices to sub-Saharan Africa, South Africa and countries defined by the United Nations as Least Developed.

AmpliCare focusses on the complete continuum of care – from testing to monitoring to education – and works to optimise efforts on a region-by-region basis. It includes flexible pricing and support of major government and private programmes. In addition, the AmpliCare Initiative offers an education programme to ensure that local doctors and nurses are fully informed on the latest advances in HIV/AIDS care and diagnosis.

Tamiflu Reserves Programme

Under the Tamiflu Reserves Programme, launched in July 2009 for developing economies, Roche will produce and store Tamiflu pandemic stockpiles for specified developing countries at a significantly reduced price with the cost spread over a number of years.

We will then ship the stockpile to the governments of countries concerned when an influenza pandemic has been announced, or in the event of a public health emergency, upon request from the governments concerned. The countries can exercise their option to purchase the product at any time. The countries who would qualify for this programme are those countries who are members of the Global Alliance for Vaccines and Immunization (GAVI).4,5

“The Tamiflu Reserves Programme enables these countries to reserve Tamiflu for pandemic preparedness for their citizens at a significantly reduced price with the cost of purchase spread over the shelf life of the product, thus trying to offer access with affordability. The programme also addresses issues of controlled storage and security for developing nations where this may otherwise be an issue.”

David Reddy
Global Pandemic Preparedness Task Force leader
Roche’s pricing principles

In 2008, we prepared our position statement on pricing to include six guiding principles that apply to both our Pharma and Diagnostics divisions:

1. Roche’s approach to pricing strives to balance business imperatives and our commitment to improving access to our treatments and services.

2. Roche assumes a holistic approach when setting the price of a new product and services; a number of elements are considered, among which – most importantly – the clinical and economic value of the product as compared to available treatment alternatives, the size and disease condition of the target population, the fit of the product in the treatment algorithm, the level of unmet medical need addressed, as well as past and future development and manufacturing investments.

3. In order to ensure a sustainable business model to Roche, product prices must allow us to generate financial returns on extensive investments in innovation.

4. When bringing a product to market, Roche determines the price in negotiations with payers and providers, taking into account the value provided in that specific local setting.

5. Roche is committed to collaborate under best efforts with payers and providers to expedite the product launch process of its products and services.

6. In order to respond to the social responsibility of providing and improving access to products and services especially in less affluent economies, Roche is assessing structure and feasibility of special pricing schemes.
Partnerships

Roche forges partnerships with governments and other healthcare providers because medicines and diagnostics are only one part of the solution to improve health.

Roche has developed partnerships with a wide variety of organisations with the aim of supporting initiatives to benefit the healthcare structures of local communities. By forging public/private partnerships, we are able to combine our specific skills and resources with those of other organisations to deliver outputs that could not have been achieved by working in isolation.

We 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.

Establishing a mobile clinic in rural South Africa

Roche has provided funding for the Phelophepa Health Care Train since it began over 15 years ago. Each year, this mobile clinic delivers healthcare to more than 45,000 rural South Africans in some of the country’s most remote areas, where there is just one doctor for every 4,000 patients.

The name Phelophepa is derived from two different South African languages and means ‘good, clean health,’ although patients frequently call it the ‘train of hope.’

Phelophepa, which is a project of the South African Transnet Foundation, has 16 coaches and is equipped to supply general, dental, eye and psychiatric care. The train provides primary care only – as it covers such a large area, it visits each place just once every two years.

With support from Roche and Transnet, Phelophepa has reached those who would otherwise have no access to basic medical services. One of the things that makes the service so effective is that it provides much needed basic health education to people in the community, including traditional healers.

We have increased our financial commitment to the project over the years, enabling the provision of several new services such as cancer screening and diabetes prevention. Recent studies predict a sharp rise in the number of people with type-2 diabetes in South Africa, making this a valuable addition to the train’s services. Cancer screening is also important, as African women are often unaware that breast lumps can be malignant.

Roche employees within our South African affiliate team regularly volunteer to support the mobile clinic.
“We are committed to improving the situation of people with diabetes and their caregivers. And we are especially dedicated to projects in the developing countries where structured and high-quality diabetes care is not yet established. Together with our partners, the World Diabetes Foundation and Novo Nordisk, we want to change the diabetes care landscape to prepare healthcare systems for the future.”

Burkhard G. Piper
Head of Roche Diabetes Care

Changing diabetes in children

Roche has entered into a collaboration with Novo Nordisk and the World Diabetes Foundation (WDF) to help children with type-1 diabetes in Africa through Novo Nordisk’s five-year programme “Changing Diabetes in Children.” Roche Diabetes Care is actively endorsing and supporting humanitarian activities in this project, starting in Tanzania, Uganda, Cameroon, Guinea-Conakry and the Democratic Republic of Congo.

We are contributing to this programme by supporting efforts to develop a structured diabetes care model, assisting with solutions for healthcare professionals for optimal diabetes care as well as providing specific patient education and training programmes for comprehensive diabetes self-management. This will also include donation of blood glucose monitoring supplies. In order to better understand and deliver tailored diabetes education and care in these developing countries, we will involve our own resources to make this project a pilot to several delivery care models in developing and emerging countries to achieve improved medical and economic outcomes and to avoid costly diabetes complications.

Together with Novo Nordisk and the WDF, our intention is to work on a sustainable approach by partnering with the governments to provide care for these children with type-1 diabetes until they reach the age of 18, and by building the infrastructure to eventually support all people with diabetes.

By working with and involving local and national government health officials, this programme is designed to build long-term solutions for sustainable diabetes care for all people with diabetes in the selected countries. We aim to use our extensive experience from the last 35 years in diabetes management and education to help change the lives of children in this programme. We will work closely with both Novo Nordisk and WDF through local clinics and summer camps to educate and train healthcare professionals, patients and their families on comprehensive and effective diabetes management.

Diabetes: no longer a rare chronic disease in Africa

In Africa, the number of people with diabetes in 2007 was 10.4 million, and it is expected to increase to 18.7 million in 2025. The International Diabetes Federation (IDF) estimates that 38,000 children in Africa have type-1 diabetes.

The majority of cases of diabetes in Africa go undetected; the undiagnosed cases are estimated to be as high as 60 to 80% in Cameroon, Ghana and Tanzania. Undiagnosed diabetes evolves silently into complications such as renal failure, retinopathy, cardiovascular disease and lower limb amputation. Between 1.4% and 6.7% of diabetic foot cases result in amputation.

Annual mortality linked to diabetes worldwide is estimated at more than one million. In some countries in Africa, the mortality rate is very high – more than 40 per 10,000 inhabitants. It is estimated that a child in sub-Saharan Africa that is newly diagnosed with type-1 diabetes has the life expectancy of as short as one year.
Supporting basic healthcare training in Ethiopia

For three years, Roche has supported physicians from the Albert Einstein College of Medicine to train over 200 Ethiopian doctors, nurses, clinical officers and final-year medical students. The broad programme is tailored to address the greatest educational needs of local health workers, such as caring for victims of traffic accidents, complications in pregnancy and childbirth, as well as treatment of infectious diseases.

Providing training in molecular biology techniques in Southern Africa

In order to address the skills shortage in molecular biology laboratories in Southern Africa, Roche Diagnostics has formed a partnership with the National Institute for Communicable Diseases (NICD) in South Africa to establish the PCR Academy. The Academy provides accredited training programmes for laboratory staff in molecular biology techniques, as well as broader skills including safety in the laboratory, quality control, and the management and presentation of data.

Roche's HIV/AIDS access partnerships

Roche has a long-standing heritage of innovation in HIV, initiated with the introduction of Hivid (zalcitabine), the first nucleoside reverse transcriptase inhibitor in 1992. Our work has resulted in major contributions in this field, among them the development of PCR diagnostic and viral load technology, the introduction of the first protease inhibitor, Invirase (saquinavir) for patients in 1995, and the launch of the first fusion inhibitor, Fuzeon (enfuvirtide) in 2003, despite the considerable technical challenges we faced in producing this very complex molecule on a large scale.

We have also conducted pre-clinical studies in investigational compounds targeting the CCR5 entry pathway and the reverse transcriptase enzyme. In 2008 we acknowledged that challenges in our antiretroviral programmes meant these molecules would not offer patients sufficient improvement over currently available options, therefore leading us to conclude that none warranted further progression. Since our goal is to focus where we believe we can deliver significant improvements over existing medicines, this means that we will no longer have an active research programme in HIV medicine.

Following this development, Roche's resources within Virology have been re-focused on diseases in which we believe we can deliver substantial improvements over existing medicines, such as hepatitis B and C as well as human papillomavirus (HPV). While Roche no longer has active antiretroviral research activity, we are proud of our significant contribution to the treatment of HIV/AIDS and the initiatives we have implemented to increase access to our HIV medicines. We continue to make available our medicines for the treatment of HIV/AIDS (Fuzeon, Invirase and Viracept) and our pricing and patent policies remain unchanged for people living with HIV in poor countries.

Roche's HIV access programmes in resource-limited countries have focussed on providing long-term sustainable benefits for local communities. This has involved establishing local HIV clinical centres of excellence for patients and educational training programmes for healthcare professionals across Africa and Asia.

To ensure that these programmes were able to make a sustainable difference to benefit local communities, they were designed with two key factors in mind: the provision of expertise and resources required for centres to be able to secure international funding from supranational institutions, such as the Global Fund; and the capacity to transition patients into national treatment programmes to continue their care long term at a local level.
The Cambodian Treatment Access Programme (CTAP)

CTAP was launched in 2003 through a unique three-way partnership with Roche, the Cambodian Ministry of Health’s HIV/AIDS programme, NCHADS, and the National Centre in HIV Epidemiology and Clinical Research at the University of New South Wales (NCHECR) in Sydney, Australia.

The aim of CTAP was to establish a local treatment centre and clinic to 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 Cambodians living with HIV/AIDS.

Roche’s support has enabled drugs, diagnostics and training to be supplied, which resulted in CTAP successfully providing care and treatment free of charge to more than 2,000 adults and 150 children infected with HIV/AIDS at the clinic. In addition to providing the funding, HIV therapy and viral load tests, our support has also facilitated the documentation of the outputs to support advocacy for international resources for antiretroviral provision.

Through the programme, we have supported the organisation of several training events in Cambodia, giving local healthcare providers the opportunity to expand their knowledge and share their experience of treating HIV/AIDS. The training has involved 400 Cambodian clinicians, reinforcing the aim of the CTAP training programme to facilitate the national expansion of HIV care.

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

“This partnership was active during a critical period of scaling up of HIV treatment and care in Cambodia and enabled the establishment of the Social Health Clinic, which provides high quality care to over 2,000 patients. In addition, staff at the clinic continue to play key roles in training, research and provision of technical support to the National HIV programme which provides access to antiretroviral therapy to over 30,000 patients across Cambodia.”

Dr Mean Chhi Vun
Director of National Centre for HIV/AIDS, Dermatology and STDs, Ministry of Health, Cambodia
CARE – the seven year Roche HIV/AIDS partnership in Africa

In 2001, the CARE programme (Cohort to evaluate Access to antiRetroviral treatment and Education), began as a pilot study in partnership with Roche and PharmAccess Foundation to assess the efficacy of HIV treatment when used in routine clinical practice in the African setting. Although HIV treatment had become a standard treatment for HIV/AIDS patients in the West, at that time it was recognised that the majority of available data focussed on studies conducted in Europe and the United States.

Through the CARE programme, Roche has provided funding, antiretroviral treatment, diagnostic and monitoring tests, as well as support for training of healthcare professionals and education for patients, in four African countries: Côte d’Ivoire, Kenya, Senegal and Uganda. In addition to assessing the clinical effectiveness of treatment in resource-limited countries, a further aim of the initiative was to identify the key challenges and necessary solutions to provide treatment effectively, in order to establish a model for sustainable treatment programmes in any resource-limited country across the world.

CARE generated positive results demonstrating that, despite operational challenges, treatment can be used successfully and safely in Africa, and that the effectiveness of treatment can be comparable to Western settings.

CARE HIV/AIDS experience exchange meetings

Since the initial treatment programme, CARE expanded to a much larger programme of HIV/AIDS education across Africa through a series of biennial HIV experience exchange events. Originally conceived as a training forum for the lead investigators and their staff, the aim of these meetings evolved to provide a platform to share findings and key learnings from the clinical programme, relating to barriers to the delivery of effective HIV/AIDS treatment in resource-limited settings, with a wider clinical audience.

As a result of these educational forums, over 600 healthcare professionals from more than 29 countries in Africa and (in 2008) Asia have met to share insights and best practices for HIV/AIDS management in low-income countries, with the aim of helping to improve the care and treatment offered in each of these countries and to develop local strategies to overcome some of these challenges. Particular focus was on dedicated workshops for nurses and counsellors.

To access the full report on the CARE programme, visit: www.roche.com/care_brochure_08.pdf

“...The most valuable benefit – and the reason why we do medicine – is that this project has saved many lives. People would have died if the CARE project had not come into place.”

Dr Cissy Kityo
Deputy Director of Research, Joint Clinical Research Centre, Kampala, Uganda
Working with the Clinton Foundation HIV/AIDS Initiative

Roche has established partnerships with international public health organisations to help increase access to laboratory services.

For example, together with the Clinton Foundation HIV/AIDS Initiative (CHAI), we are providing diagnostic solutions for early infant diagnosis in 35 resource-limited countries to extend our global physical reach into some of the most remote countries in the world. Fast, reliable testing in infants is essential in the fight against HIV/AIDS, as children are more susceptible to disease and must start treatment as soon as possible. This agreement aims to improve access to testing in sub-Saharan Africa, where roughly 90% of HIV-infected children live.

Through the agreement, we can deliver state-of-the-art equipment including laboratory apparatus for the collection of dry blood samples, a method that has proved advantageous, as transportation and storage will not be a problem in resource-limited locations. Through our commitment to providing a fully integrated laboratory solution we have also trained laboratory personnel and developed educational and support materials to enable the implementation of a sustainable programme that strengthens the rollout of national testing.
**Why patents are registered**

Patents are society’s way of promoting innovation and encouraging progress in all industries. Creating innovative healthcare solutions through research and development is fundamental to our business. Clinical research is a highly regulated, costly and lengthy process, at an estimated one billion Swiss francs per drug and an average development time of 10 years. With so much investment required, and only one in every 10,000 compounds making it to the final testing stage, developing new medicines is a high-risk business.

As a result, pharmaceutical companies register patents on new drugs to protect their intellectual property. By being the sole manufacturer of a medicine for a limited period, companies can generate revenue from sales and recoup some of the substantial cost of development, enabling them to continue to finance R&D investment. However, patents 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 length of time from approval when development costs can be recouped is around 8-12 years.

After the patent expires, the intellectual property related to the drug is publicly available and the drug can freely be produced by any interested manufacturer. This is another way that innovative healthcare companies are creating value for society.

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**Roche continues to work on sustainable programmes to remove barriers and increase access to healthcare.**

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**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.

While intellectual property rights have been equated with higher prices and inhibited access by some, at Roche, we believe that patents are not an obstacle to access to medicines and form only a small component in a much larger, more complex challenge. While approximately 95% of the medicines on the WHO’s Essential Drug List are off-patent,20 generic versions of these medicines fail to reach the millions of people in the poorest countries in need.

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**Roche patent policies**

To allow maximum access, in 2003 Roche established transparent patent policies for all our medicines in an effort to ensure that patents do not prevent access to our medicines for those living in the poorest countries of the world:

- Roche does not file or enforce any patents on our medicines in the Least Developed Countries defined by the United Nations

- In addition, Roche does not enforce patents for antiretrovirals in sub-Saharan Africa, the region poorest and hardest hit by HIV/AIDS

**Our position on patent pools**

Roche is prepared to join a mutual voluntary patent pool, but cannot support a non-voluntary non-mutual “pool” which is, in essence, compulsory licensing. Eroding intellectual property is likely to do more to harm to patients by removing incentives for R&D of next-generation drugs and, subsequently, generic alternatives.
Producing essential medicines

Nineteen medicines developed by Roche are deemed essential medicines by the WHO — meaning that they satisfy the priority healthcare needs of the population. All these medicines are no longer under patent protection and include life-saving antibiotics, antimalarials and chemotherapy. They demonstrate our substantial and sustained contribution to global health which remains long after patent expiry.

Products developed by Roche which are deemed essential medicines by the WHO

<table>
<thead>
<tr>
<th>Product</th>
<th>Treatment area</th>
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</thead>
<tbody>
<tr>
<td>Alcuronium (Alloferin)</td>
<td>Muscle relaxant</td>
</tr>
<tr>
<td>Amitriptylin</td>
<td>Anti-depressant</td>
</tr>
<tr>
<td>Benznidazole</td>
<td>American trypanosomiasis (Chagas disease)</td>
</tr>
<tr>
<td>Ceftriaxon (Rocephin)</td>
<td>Broad-spectrum cephalosporin antibiotic</td>
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<tr>
<td>Cycloserine (D-Cycloserine)</td>
<td>Pulmonary TB</td>
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<tr>
<td>Diazepam (Valium)</td>
<td>Tranquilizer</td>
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<tr>
<td>Fluorouracil (Fluorouracil)</td>
<td>Chemotherapeutic agent</td>
</tr>
<tr>
<td>Isoniazid (Rimifon)</td>
<td>TB</td>
</tr>
<tr>
<td>Levodopa (Larodopa)</td>
<td>Parkinson's disease</td>
</tr>
<tr>
<td>Mefloquine (Lariam)</td>
<td>Malaria</td>
</tr>
<tr>
<td>Prostigmin</td>
<td>Myasthenia gravis/anaesthesia</td>
</tr>
<tr>
<td>Procarbazine (Natulan)</td>
<td>Hodgkin's lymphoma</td>
</tr>
<tr>
<td>Pyridostigmin (Mestinon)</td>
<td>Myasthenia gravis</td>
</tr>
<tr>
<td>Saquinavir (Invirase)</td>
<td>HIV/AIDS</td>
</tr>
<tr>
<td>Sulfadoxin (Fansil)</td>
<td>Anti-infective agent/Cholera</td>
</tr>
<tr>
<td>Sulfadoxin + Pyrimethamine (Fansidar)</td>
<td>Malaria</td>
</tr>
<tr>
<td>Sulfamethoxazole (Gantanol)</td>
<td>Anti-infective agent</td>
</tr>
<tr>
<td>Sulfamethoxazole + Trimethoprim / Co-trimoxazole (Bactrim)</td>
<td>Anti-bacterial agent</td>
</tr>
<tr>
<td>Thiamine (Berolase)</td>
<td>Heart failure/Thiamine (Vitamin B1) deficiency</td>
</tr>
</tbody>
</table>

Co-trimoxazole is a widely used antibiotic and also recommended by the WHO as a simple, well-tolerated and cost-effective preventative treatment for opportunistic infections in adults and children living with HIV in resource-limited settings.

Our innovation now means the whole world, including the poorest countries, have wide access to locally produced versions.

Protecting innovation

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for many forms of intellectual property rights.

A formal amendment to the TRIPS Agreement, agreed in December 2005, allows for a balance between compulsory licensing for export and respect for intellectual property. However, compulsory licensing is not a solution to improve access to medicines. As the former WHO Director General, JW Lee, commented: “If all the money and all the drugs are available today, that will not solve the problem because it cannot be delivered. There are simply not enough doctors, nurses and infrastructure.”

Our responsibility to our stakeholders means that where necessary, we must protect our intellectual property and take action against those that threaten our ability to innovate, research and develop new medicines. For example, the steps taken by two generic companies in India regarding our cancer treatment Tarceva (erlotinib) have led us to take action to protect our patent, so that in the long-term we can remain committed to developing new and innovative cancer treatments that will extend survival and improve the quality of life for cancer patients in the future.

We believe that by ignoring valid patents, all research into finding new drugs to fight severe diseases in the future is at stake. Progress can only be achieved when there is an incentive to conduct research and the results of research are protected.

For more information on TRIPS and intellectual property, visit: www.wto.org/english/tratop_e/trips_e/trips_e.htm
"We welcome the commitment from local companies to produce their own quality generic versions of saquinavir. The technical assistance from Roche should help strengthen and extend their manufacturing abilities for quality medicines. It is both encouraging and heartening that local African manufacturers are taking steps to increase their capacity to produce and provide HIV medicines locally."

Lembit Rägo
Coordinator of Quality Assurance and Safety of Medicines, World Health Organization

AIDS Technology Transfer Initiative

As part of our commitment to increase access to HIV treatment and to address the need for second-line therapy options, in 2006 Roche commenced an ‘AIDS Technology Transfer Initiative.’

The aim of the initiative was to share the knowledge we have developed to manufacture our HIV protease inhibitor saquinavir, and provide hands-on guidance to local manufacturers from Least Developed Countries and those within sub-Saharan Africa.

Local manufacturers wishing to produce generic saquinavir for use in these countries were not required to apply for a voluntary licence, as we have already committed not to file or enforce patents on our antiretrovirals within these countries.

The initiative has been well received and a total of 13 agreements have been signed with local manufacturers and institutions from eligible countries:23

- In 2006, Cosmos and Universal Corporation in Kenya and South Africa’s Aspen
- In 2007, Addis Pharmaceutical Factory in Ethiopia and Varichem Pharmaceuticals in Zimbabwe
- In 2008, Regal Pharmaceuticals in Kenya, CAPS Pharmaceuticals Ltd in Zimbabwe, Shelys Pharmaceuticals and Zenufa Laboratories in Tanzania, and Beximco Pharmaceuticals in Bangladesh
- In 2009, Radiant Pharmaceuticals in Bangladesh, Adcock Ingram in South Africa and the Muhimbili University of Health and Allied Sciences in Tanzania

Since the launch of the initiative, we have received expressions of interest from 41 manufacturers and institutions in 17 eligible countries. We have also conducted assessment visits with 39 companies to determine timing and delivery of technical expertise.

The AIDS Technology Transfer Initiative was anticipated to require approximately three years of support. It has resulted in agreements with all interested, eligible companies who could benefit from our knowledge and experience in manufacturing saquinavir and is, therefore, on track to conclude in the 2009/10 timeframe.

Sub-licensing to increase access to Tamiflu

Roche has granted sub-licenses to three manufacturers to produce generic Tamiflu for pandemic use in China, India and specified developing countries, to ensure that local populations in these areas have access to the medication. [See page 32 for further information]
Drug donations do not form a central component of Roche’s activities to increase sustainable access to medicines globally.

There are, however, acute emergency situations where we provide medicines to recognised organisations with the expertise to effectively reach those in need. For example:

- In 2008, when China was hit hard by a devastating earthquake, local Roche affiliates reacted immediately and provided 53,000 vials of the anti-infection medicine Rocephin and made a monetary donation to the Red Cross.
- From 2004 – 2006, we donated 5.125 million Tamiflu treatment courses to the WHO to support global influenza pandemic preparedness. Roche announced a further donation of 5.65 million treatment courses in 2009 to the WHO to replenish their pandemic stockpiles, including 650,000 treatment courses of Tamiflu small (30mg and 45mg) capsules for children [See page 32 for further information].
Roche employee Secondment Policy

Our unique employee Secondment Policy enables Roche employees to use their skills and expertise in health-related projects across low-income countries. Interested employees partner with organisations that aim to prevent or manage disease in the world’s poorest countries. Each secondment lasts 3-18 months and participating employees continue to receive their salary from Roche during this period.

Examples of employee secondments include a communications manager from Roche Sweden, who was seconded to a project focussed on the mental health of children traumatised by the AIDS crisis in Swaziland, and an information systems specialist from Roche Canada, who worked with a humanitarian organisation on IT systems to help improve health and nutrition in Africa and Asia.

“My secondment provided me with an invaluable understanding of the complexity of patient care in developing countries, caused by a lack of resources, stringent regulation and fundamental public health needs, such as access to clean water and sanitation. Even in this environment, my focus was always on patient need – which is ultimately our overall goal at Roche. Since returning to Roche I have benefitted from approaching my work with a more considered pace, meaning I have greater clarity of my objectives. Many people have remarked on how amazing it is that my employer has the foresight to share the skills and experience of their staff in this unique way – I think it demonstrates the real long-term vision of Roche.”

Elizabeth Simonetti
Continuous Improvement Leader at Roche Nutley, worked as a pharmacist in an outpatient clinic in Agoe, Togo.
“My over-riding and everlasting impression has to be of the abject poverty that each unfortunate family has to endure every day. And yet, despite this, there is optimism, positivity, a hope for the future, a dream that tomorrow will be better, that next year may bring more volunteers and that in some small way life may indeed be better in the new Millennium. I hope I have convinced at least some of my colleagues and friends that their presence in Mekele would be a great asset. I am extremely grateful for having been granted the opportunity to come and live and work among the wonderful people of Tigray and I hope it is the first of many visits to Ethiopia.”

John O’Callaghan
Senior Chemist at Roche Ireland, undertook a three-month secondment in Ethiopia, teaching English, supporting recreational activities for children orphaned by AIDS and working on HIV/AIDS awareness programmes for local people.

Secondments to share our expertise to support health in Least Developed Countries
Bart Vanhauwere, Lifecycle Leader at Roche’s headquarters in Basel, spent 15 months working as a Local Fund Agent (LFA) for the Global Fund to Fight AIDS, Tuberculosis, and Malaria in Niger.

“The working conditions in Niger are very challenging – the temperature reaches frequently 45°C. In addition, infrastructure is very poor – the few roads that exist are in very poor condition so a short trip to a rural site is more like a full-blown expedition. Internet connection is very slow and there are often power cuts, with no one sure when power will resume. I soon realised that miracles cannot be achieved overnight!

My supervisory role as an LFA involved ensuring that money provided by the Global Fund to local health programmes was being spent correctly and producing results. Approximately half of my time was spent working in the field, visiting different projects around Niger, whilst the remainder was spent on project management, including budgeting, forecasting and producing progress reports. I specifically chose to work for the Global Fund because I wanted to work within a public-private partnership. My experience of working in a private organisation, which is performance-based and results-driven, created a healthy confrontation between my approach and that of those who have always worked within the public sector. Neither sector has the perfect solution to health problems in the developing world, but through working together a lot can be achieved.

My experience taught me a great deal about the priorities in treating neglected diseases in developing countries. Access to medicines is a complex issue and requires a multi-factorial approach. Issues such as a lack of appropriate personnel, limited tools and resources, and poor infrastructure are genuine barriers to access. I strongly believe that whatever contribution agencies and donors make should be targeted at supporting and strengthening local infrastructure. Accountability and responsibility for the success of programmes have to remain with the local people. Unless they take ownership, there will be no sustainable improvement in the long term.”
Preventing an influenza pandemic

Roche, as the manufacturer of the oral antiviral Tamiflu, has been working for many years with all the stakeholders involved in influenza pandemic planning, to put in place initiatives to meet global demand in the event of a pandemic.

Until recently, global preparedness focussed on the H5N1 avian influenza virus in Asia, which was widely believed to be the trigger for the next pandemic. The emergence of the new pandemic (H1N1) 2009 virus, however, created an urgent and important signal for the international community to ramp up global pandemic preparedness and response.

Our role to support pandemic preparedness in developing countries
Roche is committed to working as a collaborative and responsible partner with governments and the WHO to help them prepare for a pandemic.

In July 2009, we launched the Tamiflu Reserves Programme for developing economies. The programme will serve to ensure that Tamiflu is available to many governments and patients in developing nations for use during an officially declared influenza pandemic. [See page 18 for further information]

To further increase the global availability of Tamiflu for pandemic use, in 2006 we provided manufacturing sub-licences to generic manufacturers (Hetero, Shanghai Pharmaceutical Group and HEC Group) to produce generic versions of Tamiflu for pandemic use by governments in China, India and specified developing countries. We also granted a knowledge transfer to a South African manufacturer (Aspen Pharmaceuticals) for the provision of generic Tamiflu for pandemic use on the African sub-continent.

Emergency donation in practice
From 2004-2005, Roche made a donation of 5.125 million packs of Tamiflu to the WHO – including 3 million courses for a rapid response stockpile, intended for use as a ‘fire-blanket’ to contain or slow a pandemic at its site of outbreak and 2 million treatments to be used for regional stockpiles in those developing countries that are unable to purchase the drug for economic reasons. These packs are now being distributed to developing countries determined by the WHO to be most in need.

In May 2009, Roche announced a further donation of 5.65 million treatment courses of Tamiflu to replenish the WHO rapid response and regional pandemic stockpiles, including 650,000 treatment courses of Tamiflu small (30mg and 45mg) capsules for children.

For more information on Roche’s roles, responsibilities and contributions for global pandemic preparedness, visit: www.roche.com/roles_responsibilities_influenza.pdf.
Roche Children’s Walk

In response to the desire of employees to personally support children orphaned as a result of AIDS in Africa, in 2003 Roche launched an annual employee fundraising walk. In 2008, we extended the scope of this fundraising initiative to include the support of vulnerable children beyond AIDS.

Each participating employee gains sponsorship to raise funds – and we match the amount of money raised by employees to double the final total.

Funds raised by our employees are used to implement and support projects run by the European Coalition of Positive People (ECPP) and UNICEF in Malawi. ECPP has used the funds to establish seven orphan centres where children orphaned by AIDS are given food, day care, clothing, the chance of a secondary school education and vocational training. The funds have also enabled ECPP to employ a nurse who is specifically dedicated to monitoring the children’s health.

A further share of the funds raised is donated to UNICEF Switzerland to be invested in primary education in Malawi by building classrooms, improving facilities, buying learning materials and supporting teachers’ training at schools attended by children from the orphan centres.

Affiliate Roche sites also choose whether to donate up to half of their funds to assist local vulnerable children in their own countries.

The event has grown year on year, with numbers of employees from 1,300 in 2003 to 14,000 in 2008, raising a cumulative total of over 6,000,000 Swiss francs.

All of the funds raised are channelled through the Roche Employee Action and Charity Trust (Re&Act). Re&Act provides a structured and efficient means of pooling collective donations from employees and affiliates around the globe. Designed to facilitate employee involvement and collaboration, Re&Act manages, transfers and monitors resources provided for long-term humanitarian projects mainly in developing or low-income countries.

Further information can be accessed at: www.react.roche.com

Why Malawi?
Malawi is a country with more than 13 million people, almost one million of whom are HIV-positive. Over 500,000 children have lost one or both parents because of AIDS. Although Malawi is one of the world’s least developed and poorest countries – people live on an average of less than US$0.50 per day – it is a peaceful and stable country. This makes it a viable setting for long term, sustainable projects that can make a real difference.
We remain committed to maintaining an open dialogue with all our stakeholders and would welcome your feedback on this report.

If you would like to contact us with feedback or questions about any information within this report, please contact us via the details provided at: www.roche.com/contact_form.htm

### Useful Links

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#### Our partners

| Clinton Foundation HIV/AIDS Initiative (CHAI) | www.clintonfoundation.org |
| The European Coalition of Positive People (ECPP) | www.ecpp.co.uk |
| Institute for OneWorld Health (iOWH) | www.oneworldhealth.org |
| PharmAccess Foundation | www.pharmaccess.org |
| Transnet-Phelophepa Healthcare Train | www.transnetfoundation.co.za/Health.aspx |
| UNICEF | www.unicef.org |
| World Diabetes Foundation (WDF) | www.worlddiabetesfoundation.org |

#### Other resources

| Access to Medicine Index | www.atmindex.org |
| Drugs for Neglected Diseases Initiative | www.dndi.org |
| International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) | www.ifpma.org |
| Médecins Sans Frontières | www.msf.org |
| Oxfam | www.oxfam.org |
| The Pharmaceutical Research and Manufacturers of America (PhRMA) | www.phma.org |
| United Nations | www.un.org |
| The United States President’s Emergency Plan for AIDS Relief (PEPFAR) | www.pepfar.gov |
| World Bank | www.worldbank.org |
| World Health Organization (WHO) | www.who.int/en |
References

4 Please note that India is not included in the eligible list of countries for this programme as a sub-licence for the production of generic oseltamivir was granted to the Indian company Hetero by Roche in 2005.
18 As of 2008
20 Roche does not enforce patents on saquinavir in sub-Saharan Africa and other Least Developed Countries as part of our patent policy for antiretrovirals in this region
21 Data as of August 2009