

Roche Position on Access to Medicines and Diagnostics

MISSION

Our primary role in improving access to medicines and diagnostics is through the research, development & commercialisation of innovative medicines and diagnostics to help treat serious and life-threatening diseases where there is unmet medical need. We constantly seek sustainable and ethical ways to create partnerships, policies and programmes that increase access to medicine and diagnostics

Roche works with various stakeholder groups, from shareholders and payers to patients, physicians and employees, and we are taking their different interests, needs and views into consideration. Given the many barriers that limit access to healthcare for people throughout the world, we are often asked about our commitment and responsibility regarding access to our medicines and diagnostics.

At Roche, we believe that access to medicines and diagnostics is essential but cannot be taken for granted throughout the world. There is an immense difference in the level of resources available in different countries to meet healthcare needs, with almost half (42%) of the world's population receiving total healthcare funding of less than 50 US\$ per year.^{i,ii,iii} While society and governments have the ultimate responsibility for providing healthcare to their people, we believe that as a leading research-based pharmaceutical and diagnostics company, we can help make a difference within our sphere of influence, by focusing on the delivery of medicines and diagnostic tools that help address unmet medical need and by encouraging governments and other stakeholders to use their best efforts within the sphere of their responsibility, to provide locally the highest attainable health support for their people.

Our approach to pricing strives to balance business imperatives and our commitment to improving access to our treatments and services. Further principles on our pricing will be made available via a separate Roche position paper on pricing.

Roche's approach to access to medicines and diagnostics is based on:

1. Research and development
2. Partnerships
3. Sustainable and ethical programmes
4. Business sustainability

1. **Roche's primary role in improving access to medicines is through the discovery, development & commercialisation of medically differentiated medicines and diagnostics to help diagnose, monitor and treat serious and life-threatening diseases where there is unmet medical need**
 - Roche's focus is the search for innovative new medicines and diagnostics by funding and conducting R&D into serious and life-threatening diseases, investing 9.8 bn Swiss francs in 2009^{vi}
 - Over 269,000 people took part in our clinical trials globally in 2009^{vi}, receiving access to the latest treatments for cancer, arthritis and other diseases
 - Roche is a pioneer in developing cancer medicines and diagnostics. With cancer continuing to grow as one of the leading causes of death worldwide, Roche's investment in the development of new, innovative medicines and diagnostics will play a significant role in reducing this rapidly increasing global disease burden
 - For medicines, Roche's pipeline contains new molecules which are developed to fight diseases like cancer, autoimmune diseases, diabetes, hepatitis and diseases that affect the central nervous system like Alzheimer's or schizophrenia; where there is still high unmet medical need and where we have expertise. For diagnostics, Roche's pipeline contains innovative diagnostics for predisposition, diagnosis and disease classification, therapy prediction, disease prognosis and disease monitoring, mainly for cancer, virology and metabolic diseases as well as for blood screening. And for cancer, there are ongoing collaborations between Roche Pharmaceuticals and Roche Diagnostics to develop companion diagnostics, with the goal to achieve most efficacious and safe treatment options for selected patient groups.
 - Roche has had a long-standing track record in the provision of diagnostics and treatment for diseases such as HIV/AIDS, Hepatitis C, Chagas and malaria, prevalent where the majority of those affected throughout the world do not have access to safe and affordable healthcare, diagnostics, drugs or vaccines^{iv}
 - Roche developed the anti-malarial therapies Lariam and Fansidar, which are now off-patent and therefore publicly available for local production
 - Roche Diagnostics has developed paediatric (infant) testing for HIV, in response to the need for effective diagnostic testing for children with HIV/AIDS in developing countries, which has long been cited by non-governmental organisations as an area of significant neglect by the pharmaceutical industry
 - Roche Diagnostics produces diagnostic solutions that allow for the early identification and / or monitoring of neglected diseases including HIV and Tuberculosis. Roche continues to invest in the research and development of new diagnostic modalities focusing on newer and more relevant tools for these diseases

- Roche has entered into collaboration with the Institute for OneWorld Health, enabling the screening of compounds from the Roche library to identify a potential new drug for the treatment of diarrhoeal diseases, which kill approximately 2 million children in developing countries each year^v
- Eighteen medicines developed by Roche are deemed Essential Medicines by the WHO. 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 remains long after patent expiry.¹³

2. Roche forges partnerships with governments & other healthcare providers because medicines and diagnostics are only one component of the healthcare puzzle

- We have developed partnerships with many organisations with the aim of supporting initiatives to benefit the health of local communities including:
 - The Cambodian Treatment Access Programme which in partnership with the Ministry of Health and academia established a clinic and provided treatment to over 1,000 Cambodian HIV/AIDS patients
 - The CARE programme which in partnership with PharmAccess Foundation established HIV treatment programmes across Africa and educational events reaching over 600 healthcare professionals in 29 countries across Africa and Asia
 - We have established partnerships with international public health organisations to help increase access to laboratory services. Together with the Clinton Foundation HIV/AIDS initiative, we are providing diagnostic solutions for early infant diagnosis in 35 resource-limited countries with set targets in mind thereby extending our global physical reach into some of the most remote countries in the world
 - The Phelophepa Health Care Train is a mobile clinic bringing medical care to rural South Africa. With support from Roche, the train has reached out to over 13 million people – including women and children who would otherwise have no access to basic medical services
 - We support US patient assistance programmes that provide free medicines for people with inadequate or no health insurance. In 2009, 40,000 patients in the US benefited from Roche and Genentech Patient Assistance Programmes^{vi}
 - We are contributing to the “Changing Diabetes in Children” programme with the World Diabetes Foundation and Novo Nordisk to help children with type-1-diabetes in Africa. The goal is to partner with governments to develop a structured diabetes care model, solutions for healthcare professionals for optimal diabetes care and patient education and training for diabetes self-management. We will also provide blood glucose monitoring supplies to the programme.

- We are committed to continually reviewing our approach to increasing access to medicines and diagnostics in the poorest countries of the world and creating new ways to use our strengths and resources to bring sustainable health benefits to people in need. For example, one current key focus is to find ways to share our heritage and expertise in oncology with local healthcare workers to help improve cancer management in low income countries.

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

- To Roche, thinking about access to medicines and diagnostics means more than just giving money or products. Our approach is to work in partnership with others to find the most feasible ways of removing barriers within the ethical, legal, regulatory and commercial constraints that determine the delivery of healthcare in that country
- We have established transparent patent policies for all our medicines so intellectual property is not a barrier to any of our medicines in the world's Least Developed Countries^{vii}. In addition, we have targeted policies for medicines that require enhanced manufacture and supply to help address access in developing countries with the greatest need:
 - We will not file or enforce patents on antiretrovirals in sub-Saharan Africa, the poorest and hardest hit region by HIV/AIDS
 - We have provided manufacturing sub-licenses to generic manufacturers in China and India allowing them to produce generic versions of Tamiflu (oseltamivir) in order to further increase the global availability of the drug for pandemic use. In addition, we have also signed an agreement with a South African manufacturer to produce a generic version for the African continent
- Outside of these policies, however, Roche believes that the existing laws and processes for patents need to be followed, upheld and protected to allow new medicines to be developed and made available. Roche does not file or enforce existing patents on medicines in Least Developed Countries
- AIDS Technology Transfer Initiative, launched in 2006 as part of our efforts to further identify ways to increase access to HIV treatment
 - Shares, free of charge, the knowledge Roche has developed to manufacture saquinavir with local manufacturers in sub-Saharan Africa and Least Developed Countries
 - Ten agreements signed and expressions of interest received from 40 manufacturers in 17 eligible countries, as of 2009

- Programme expanded in 2008 to include training seminars for local manufacturers in these countries, focusing on the development of good manufacturing practices to improve locally produced essential medicines beyond HIV
- Drug donations do not form a central component of our activities to increase sustainable access to medicines globally. The life-long provision of treatment for chronic diseases such as HIV cannot be guaranteed by a commercial company and we therefore consider such one-off donations of medicines for chronic diseases unethical. There are acute emergency situations where we provide medicines to recognised organisations with the expertise to effectively reach those in need.
 - In 2004, we donated 220,000 packs of antibiotic medicines to help approximately 80,000 people affected by the Tsunami disaster^{viii,ix}
 - In 2008, when the Sichuan region in China was hit hard by a devastating earthquake, Roche's local affiliates in China reacted immediately and provided 53'000 ampoules of its anti-infection medicine Rocephin and made a monetary donation to the Red Cross

During discussions with the World Health Organization (WHO), it became clear that developing countries need additional attention regarding pandemic preparedness. As a result, we have donated over 5 million Tamiflu treatment courses to the WHO; 3 million packs for used as a “fire blanket” to help contain the pandemic in the area it breaks out and 2 million are for distribution by WHO to countries in need.^xFollowing the WHO declaration of pandemic alert phase 5, an additional donation was made to them of 5.65 million courses of treatment to replenish the Regional Stockpile and the Rapid Response Stockpile plus establish a new pediatric stockpile of 650,000 treatment courses of Tamiflu small capsules

- Employee Secondment Policy, to enable our employees to contribute their skills and transfer their expertise to health related projects primarily in the world's Least Developed Countries
 - Each secondment lasts 3-18 months and participating employees continue to receive their salary from Roche during this period
 - The policy includes the potential for our staff to contribute to neglected tropical disease research projects

4. Roche is a business and needs to make a reasonable return for its key stakeholders.

- We will consider preferential pricing schemes in non-OECD developing countries, 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
 - Since 2002, we have supplied our antiretroviral medicines, Invirase and Viracept, at no profit prices for people living in Least Developed Countries and sub-Saharan Africa. Our no

profit, no patent policies for these HIV medicines apply to 70% of all people with HIV/AIDS worldwide^{xi,xii}

- 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
 - Roche has the Amplicare program for providing access to HIV monitoring diagnostic tools to supranational and governmental organisations. This program is currently being extended to include other neglected diseases wherein Roche may have applicable diagnostic solutions
- We take our role of improving access to medicines and diagnostics very seriously. We have a responsibility to our stakeholders to provide long-term sustainable value through the research, development and commercialisation of our medicines and diagnostics which add medical value to patients, payers and society in general. We are committed to working with our key stakeholders to enable access to our medicines and diagnostics globally and reporting on progress.

This paper was proposed by the Corporate Sustainability Committee and approved by the Pharma Executive Committee and the Diagnostics Executive Committee; it became effective on May 14, 2009. Statistics were updated in 2010.

ⁱWHO Measured Levels of Per capita Expenditure on Health 2000-2004. <http://www.who.int/nha/country/Annex%202.pdf>. (Accessed 8 February 2008)

ⁱⁱUNAIDS Population Statistics. <http://www.unaids.org/en/CountryResponses/Countries/default.asp>. (Accessed 8 February 2008) (FYI each individual country must be selected to provide population data)

ⁱⁱⁱUN World Population Statistics. www.un.org/esa/population/publications/wpp2006/English.pdf (Accessed 8 February 2008)

^{iv}Medicins Sans Frontieres MSF and Neglected Diseases <http://www.accessmed-msf.org/main/other-diseases/msf-and-neglected-diseases/> (Accessed 18 April 2008)

^vAwane AP, Kremer M. What Works in Fighting Diarrheal Diseases in Developing Countries? A Critical Review. The World Bank Research Observer 2007 22(1):1-24 <http://wbro.oxfordjournals.org/cgi/content/abstract/22/1/1>

^{vi}Roche Annual Report 2009

^{vii}UN list of Least Developed Countries (LDCs) can be found on <http://www.un.org/special-rep/ohrlls/lhc/list.htm> (Accessed 29 February 2008)

^{viii}Roche press release 30 December 2004 <http://www.roche.com/med-cor-2004-12-30> (Accessed 8 April 2008)

^{ix}Roche Annual Report 2005 <http://www.roche.com/gb05e.pdf>

^xRoche press release <http://www.roche.com/inv-update-2007-07-23b> (Accessed 8 April 2008)

^{xi}UNAIDS. 2007 report on the global AIDS epidemic. November 2007

<http://www.unaids.org/en/KnowledgeCentre/HIVData/EpiUpdate/EpiUpdArchive/2007/> (Accessed 8 February 2008)

^{xii}UNAIDS HIV/AIDS prevalence by country. <http://www.unaids.org/en/CountryResponses/Countries/default.asp>

¹³WHO Model List of Essential Medicines http://www.who.int/medicines/publications/08_ENGLISH_indexFINAL_EML15.pdf

Alcuronium (Alloferin), Amitriptylin (Laroxyl), Ceftriaxon (Rocephin), Cycloserin (D-Cycloserin Roche), Diazepam (Valium Roche), Fluorouracil, Isoniazid (Rimifon), Levodopa (Larodopa Roche, resp. Madopar), Mefloquin (Lariam), Neostigmin (Prostigmin), Procarbazin (Natulan), Pyridostigmin (Mestinon), Saquinavir (Invirase), Sulfadoxin (Fansil), Sulfadoxin+Pyrimethamin (Fansidar), Sulfamethoxazol (Gantano), Sulfamethoxazol+Trimethoprim (Bactrim), Thiamin (Berolase)