

Roche Position on R&D for Neglected Tropical Disease

Roche is conscious of the health needs in Least Developed Countries and has a long-standing role in the provision of treatment for some neglected diseases.

We focus our R&D expertise on the search for differentiated and innovative new medicines into serious and life-threatening diseases where we can make the greatest difference to addressing unmet medical need globally.

Our contributions towards diseases considered “neglected” and primarily affecting Least Developed Countries includes a collaboration for diarrhoeal diseases, medicine and diagnostics for paediatric HIV plus our active virology research programme

Roche’s contribution towards global health is our investment in the development & commercialisation of medically differentiated medicines to help treat serious and life-threatening diseases where there is unmet medical need and where we have expertise and experience.

Our R&D investments currently focus across five disease areas. All are of epidemic proportions globally and in areas where we can demonstrate success and where we believe we can make the greatest difference. The disease areas include the viral diseases hepatitis B, hepatitis C and human papillomavirus and oncology. It is important to note that as many people are infected with the hepatitis C virus as are with HIV and it is estimated that more than 2 billion people worldwide are currently or have been previously infected with the hepatitis B virus¹.

We are constantly on the lookout for ways to improve health. If in the course of our research, discoveries are made which could have application in tropical disease, we would consider offering the molecule to a non profit organisation for the benefit of society.

Significantly-neglected diseases: a long-standing role

We have a long-standing role in the provision of treatment for significantly-neglected diseasesⁱ, where the majority of those affected do not have access to safe and affordable diagnostics or medicines:

- Roche developed the anti-malarial therapies Lariam and Fansidar, which are now off-patent and therefore publicly available for local production
- Roche donated 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 OZ277
- In 2003, we donated all rights and the technology to manufacture Benzonidazole, for the treatment of Chagas disease to the Brazilian government, to assist in its efforts to reduce the impact of this neglected disease
- 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 – an area which has long been cited by non-governmental organisations as significantly neglected
- Roche has worked in collaboration with the WHO to establish rapid response stockpiles and regional stockpiles of the influenza antiviral Tamiflu for use in the management of bird flu

¹ <http://www.epidemic.org/theFacts/theEpidemic/worldPrevalence/>

outbreaks in the worlds developing countries and as a first line of defense in the event of a pandemic. This work is being augmented by ongoing technical and clinical work including the recent development and approval of child-sized Tamiflu capsules, and investigations to further understand and optimize Tamiflu treatment for people infected with H5N1 avianj influenza

- In April 2008, we entered into a collaboration with the Institute of 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 yearⁱⁱ

Roche has a specific clinical trials policy to protect patients in low income countries. Roche will not conduct clinical studies in such countries solely for the purposes of registering the drug in another country. Roche commits to apply for marketing authorisations of medicines in countries in which trials are conducted.

Similarly, where possible, we utilise our current initiatives to support other organisations' efforts to investigate potential solutions towards neglected tropical diseases. Through our Employee Secondment Programme, we facilitate and fund employees to contribute their skills and expertise to health related projects of Least Developed Countries for up to 18 months. This includes tropical disease research institutes.

It remains important and relevant that society acknowledges the eradication of diseases such as malaria in Europe. Such tropical disease can be controlled more easily by investment in environmental changes than attempting to discover, develop and deliver a new medicine to all those in need. New building materials and environmental interventions facilitated the eradication of malaria from the entire European continent by 1975.² Without environmental change - the only route to long term and sustained health improvement - medicine becomes a temporary "sticking plaster" on this immense human need.

In order to be able to continue delivering new medicines in the years to come, Roche is committed to sustain our responsibility to our stakeholders to provide long-term value through the research, development and commercialisation of medicines which add medical value to patients, payers and society in general. Wherever possible, we will continue to seek ways to contribute towards health improvements in Least Developed Countries.

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 August 18, 2008

ⁱ Medicens Sans Frontieres MSF and Neglected Diseases <http://www.accessmed-msf.org/main/other-diseases/msf-and-neglected-diseases/> (Accessed 18 April 2008)

ⁱⁱ Awane 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>

² <http://www.cdc.gov/Ncidod/eid/vol6no1/reiter.htm>