

Patients

Our 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.

Our primary role is to develop products with clear medical benefits. We also have a responsibility to help improve global access to our products, supply safe medicines and reliable tests that give value for money, provide factual information about our products, and carry out clinical trials ethically. Importantly, we must also understand and respond to patients' views.

The value of medicines and diagnostics

Our unique approach to personalised healthcare (PHC) helps us develop novel products that patients need and governments and regulators demand. PHC means tailoring 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.

We understand the tough decisions healthcare providers have to make. We employ experienced health economists that work in partnership with local health authorities to address their specific needs regarding access to medicines. These teams are involved in the development process right up to a new drug reaching the market. They liaise with local sales and marketing teams, payers, clinicians and patients, perform market research to incorporate patient and payer perspectives into development, and ensure that clinical trials are designed to demonstrate economic as well as health benefits. The information generated during clinical trials, along with evidence from research activities and economic modeling, is used to demonstrate the total value of a product during its lifecycle.

Global access to healthcare

We are committed to improving access to our products through a long-term strategy that includes improving reimbursement systems and advocating greater patient access. The majority of healthcare systems recognise the clear medical and economic value of our products as a result of our engagement with them. For example, cancer drugs such as Herceptin and Xeloda can ease pressure on healthcare budgets by delaying, reducing or preventing hospital visits, surgery and the need for palliative care. In many cases, they help patients return to work more quickly.

Patients can access our products through doctors, hospitals, laboratories and pharmacies in roughly 180 countries, although the majority of our business is in developed countries as they have more advanced healthcare systems. Public health policy and standards of healthcare vary greatly, as does public awareness of the causes, prevention and treatment of disease. The healthcare industry has an important role to play in helping to raise standards, but we are just part of a much bigger picture; there are many other systemic problems that prevent equal access to healthcare globally.

We work with governments, non-governmental organisations (NGOs), patient groups and healthcare providers to tackle health inequalities, increase access to our products and provide sustainable healthcare.

In 2008 we issued a position statement on access to medicines and diagnostics. This was developed with input from a broad range of employees from both divisions and is designed to provide the information our stakeholders seek.

Access for those most in need | The world's least developed countries (LDCs) are hardest hit by disease and have the poorest healthcare systems to deal with this burden. There are too few hospitals, laboratories and healthcare professionals to meet demand, and international aid focuses on AIDS,

tuberculosis and malaria. Public health policy has limited local investment.

Our aim is to provide sustainable access to healthcare in poor countries through:

- Fair patent and pricing policies
- Research and development
- Partnerships with governments, NGOs and others
- Education, training and knowledge-transfer

We do not file or enforce any patents in the least developed countries defined by the United Nations. In addition, we do not file or enforce patents on our antiretroviral drugs in any sub-Saharan African country, as this is the region most affected by HIV/AIDS.

In 2008 we updated our position statement on pricing to include six guiding principles that apply to both divisions. As a result of this review, we are assessing the structure and feasibility of special pricing schemes to improve access to our products and services, especially in less affluent economies. We continue to supply our antiretroviral therapies for HIV/AIDS at no-profit prices in all LDCs and sub-Saharan Africa. This pricing policy covers 70% of people with HIV globally.

We also updated our position on R&D for neglected tropical disease in 2008. We focus our R&D on our area of expertise – the search for differentiated and innovative medicines for life-threatening diseases in areas of unmet medical need – as this is where we can make the most difference. These diseases include oncology, viral diseases such as hepatitis B and C, diseases of the central nervous system like Alzheimer's, and diabetes, which is reaching epidemic proportions in developed and developing countries.

We have a long-standing commitment to addressing the diagnosis and treatment of neglected diseases:

- We developed the antimalaria drugs Lariam and Fansidar, which are now off-patent and available for local generic production

- We provide the Drugs for Neglected Diseases initiative free access to our compounds and knowledge for treating Chagas disease and sleeping sickness
- We developed HIV testing and drug formulations for infants, a significantly neglected area identified by NGOs
- We provide diagnostics for the early detection and monitoring of HIV and tuberculosis

In 2008 we began a research collaboration with the Institute of OneWorld Health to increase R&D into neglected diseases. OneWorld Health will 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.

Our AIDS Technology Transfer Initiative (TTI) is another example of working with others to provide sustainable healthcare. Since 2006 we have shared the knowledge required to produce our HIV treatment saquinavir with local manufacturers in the LDCs and sub-Saharan Africa, free of charge. Because we don't enforce patents in these countries, the manufacturers can freely produce a generic version of the drug, increasing local supply. In early 2008, we signed agreements with four manufacturers, bringing the total to ten. We also expanded the TTI to include training seminars on good manufacturing practices, with the aim of improving the quality of all locally-produced essential medicines. The first two seminars took place in Tanzania and South Africa and were attended by 56 delegates from 21 organisations. A participant from Bangladesh commented: 'As far as I am aware, Roche is the only company offering training seminars such as these.'

We announced an agreement with the Clinton Foundation HIV/AIDS Initiative (CHAI) in February 2008. We are providing dry blood spot tests, which are easily administered, stored and transported, at substantially reduced prices. These are used to diagnose HIV in children younger than 18 months. 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.

Since early 2007 we have offered Valcyte at a substantially reduced price to the international NGOs treating AIDS-related CMV (cytomegalovirus). This discount is for exclusive use in AIDS patients in least developed countries and sub-Saharan Africa. It has recently been extended to all low and lower middle income countries, covering 88% of all people living with HIV/AIDS worldwide.

In 2008 we facilitated an information exchange symposium in partnership with the PharmAccess Foundation. This was attended by 129 healthcare professionals from 26 African and Asian countries, who shared insights and best practices for HIV/AIDS management in lower-income countries. We also partnered with physicians from the Albert Einstein College of Medicine to train over 200 Ethiopian doctors, nurses, clinical officers and final-year medical students.

Our unique employee secondment policy enables Roche employees to use their skills and expertise, primarily in the LDCs. Interested employees partner with organisations that aim to prevent or manage disease in the world's poorest countries. In 2008 we approved two new secondments. A communications manager from Roche Sweden was seconded to a project focused on the mental health of children traumatised by the AIDS crisis in Swaziland. An information systems specialist from Roche Canada began work with World Vision Canada on IT systems to help improve health and nutrition in Africa, Asia and South America.

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 spec-

ific needs. We often work in partnership with governments to help establish processes, education and clinical trial programs. For example, 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.

We continue to supply our HIV medicines at reduced prices in the low and lower-to-middle income countries defined by the World Bank.

Access in the developed world | We work closely with local payers to demonstrate the value of our products and agree a level of reimbursement that enables access. However, there are still many people in developed countries who cannot afford healthcare or the insurance to pay for it. In the USA, where there is currently no universal healthcare system, we provide drugs at no charge to those in need through the Roche Patient Assistance Program (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 1 billion US dollars. In 2008, 22,000 patients benefited from the PAP. We also support the industry's efforts to raise awareness of assistance programs 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 1.3 billion U.S. Dollars 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.

Examples of access programmes

	2008	2007
% of HIV-infected patients living in countries eligible for no-profit medicines	71%	63%
% of HIV-infected patients living in countries eligible for reduced-price medicines	88%	86%
Patients benefiting from USA patient assistance programmes	38,000+	34,482

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 and access to the latest treatments for cancer, arthritis and other serious diseases.

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

We do not perform clinical trials in countries where we will not seek marketing approval.

Patients benefiting from clinical trials

	2008	2007
Number of clinical trials	890+	1,000+
Number of healthcare centres involved	13,600+	17,000+
Number of patients in phase I–IV clinical trials	235,420	201,752

Patients seeking new clinical trials to participate in and people wishing to learn from the results of completed trials can access this information on www.roche-trials.com. The trial registry and results database are hosted by a third party to ensure independence.

As of 31 December 2008 the site contained details of 574 pharmaceutical protocols, 27 diagnostic protocols and 216 trial results. These studies cover more than 70 conditions including Alzheimer's disease, asthma, around 25 cancers, cardiovascular disease, depres-

sion, diabetes, hepatitis, HIV/AIDS, influenza and obesity. The website had more than 440,000 page visits in 2008.

Patients globally can also access details of our trials in patients through the IFPMA clinical trials portal at www.ifpma.org/clinicaltrials, and on the USA National Institutes of Health's global registry at www.clinicaltrials.gov. We are committed to publishing our clinical trial data – good or bad – in reputable, peer-reviewed journals.

We collect the information gained through clinical trials and post-marketing surveillance and feed this back into the development program. We also provide this information to regulatory authorities as required.

We apply strict data protection principles to all personal medical data collected during clinical trials, in line with our directive on the protection of personal data. These principles apply equally to data about our customers, suppliers and employees.

Patient safety

Almost all medicines have side effects in some patients. Our priority is to make certain that the benefits of taking the drug outweigh any undesirable effects. We do all we can to reduce the likelihood of adverse events. We rigorously test, monitor and analyse the effects of our products in all relevant patient groups during development, and continue to monitor them after launch.

We investigate all reported adverse events to ascertain if they are related to our products. If there is a link, we re-evaluate whether the benefits of the drug still outweigh the risks. We also have robust procedures in place to promptly inform patients, physicians, healthcare providers and regulators of any new product safety information.

In 2007 we reported the recall of our HIV drug Viracept following evidence of contamination with

the chemical ethyl methansulphonate. We began the process of establishing registers of patients who took the drug during the affected time period so we could monitor and support those who may have taken contaminated drugs. However, research confirmed that there are no ill effects from taking affected batches of Viracept, and so the relevant health authorities have told us that the registries are an unnecessary precaution. We made efforts to keep all those affected informed throughout the process.

Patient advocacy

Patient groups are important partners for Roche. We share an interest in helping patients understand and manage their disease and gain access to the information and treatment they need. We only work with patient groups on activities that benefit the patients the group represents. Our policy is to be transparent about our activities and to respect the independence of the patient organisation.

In 2008 we revised our position statement and guidelines for working with patient groups to adapt them to the recently approved EFPIA Code. One major change is that we must publicly list all patient groups we support financially, whereas we previously only disclosed those receiving 30,000 Swiss francs or more. We will list all patient groups receiving financial sponsorship by March 2009. Patient groups we give non-financial support to must be publicly listed if the support is significant or meaningful, as guided by EFPIA member associations.

Also in 2008 we launched an internal database to track patient group partnerships with Roche affiliates in Western Europe. The database contains details of the patient groups we work with, the funding given each year, and individual projects worked on with each group. It will provide a clearer understanding of our partnerships with patient groups and help us share learning and experience. Once the database is fully up and running in Western Europe, we plan to roll it out to all regions.

Also in 2008 we worked with the European Genetic Alliances Network (EGAN) to produce a patient FAQ and glossary on clinical trials. Patient representatives provided questions that patients often ask, and we supplied answers to address them. The documents aim to provide clear, straightforward information about enrolling in a clinical trial, for example. EGAN has published the documents on its website, as has the Genetics Interest Group, which has 140 member organisations.

A number of Roche companies have launched local initiatives to support patients and patient groups in their country. For example, Roche Austria launched the Lebens Hilfe (life rescue) fund to provide financial aid to cancer patients returning to regular life after beating their disease.

More on the web

- Personalised Healthcare:
www.roche.com/phc_in_r_d
- Roche position statements on access to medicines and diagnostics, pricing, neglected diseases, and working with patient groups:
www.roche.com/access_to_healthcare
www.roche.com/medical_value_patents_and_pricing
www.roche.com/roche_access_healthcare.pdf
- Programmes in LDCs: www.roche.com/programmes_in_least_developed_and_developed_countries
- Programmes in developed countries:
www.pparx.org
www.GenentechAccessSolutions.com
- Roche trials and patient safety:
www.roche-trials.com
www.roche.com/clinical_trials
www.roche.com/managing_medication_safety
- Working with patients:
www.roche.com/patient-groups
- EGAN website:
www.egan.eu/publications/publications_and_presentations.htm