

## **Access to Healthcare**

*Roche's global commitment*



# Access to Healthcare

**Our role** is to deliver medical solutions that significantly improve people's lives now, even as we develop innovations for the future.

**Our approach** is to develop local solutions, in partnership with local stakeholders, tailored to local needs, to provide sustainable improvements in health and in healthcare.

**Our aim** is for every person who needs our products to be able to access and benefit from them.

## The global healthcare challenge

Healthcare resources and demands on those resources vary widely from country to country. In some regions, the most sophisticated new medicines and diagnostic tests are readily available, while in others the healthcare infrastructure is so limited that even basic medical care is a luxury.

Additionally, intense budget pressures and growing demand for sustainable healthcare solutions are driving the need for ever more innovative ways to bring effective and affordable medicines to patients.

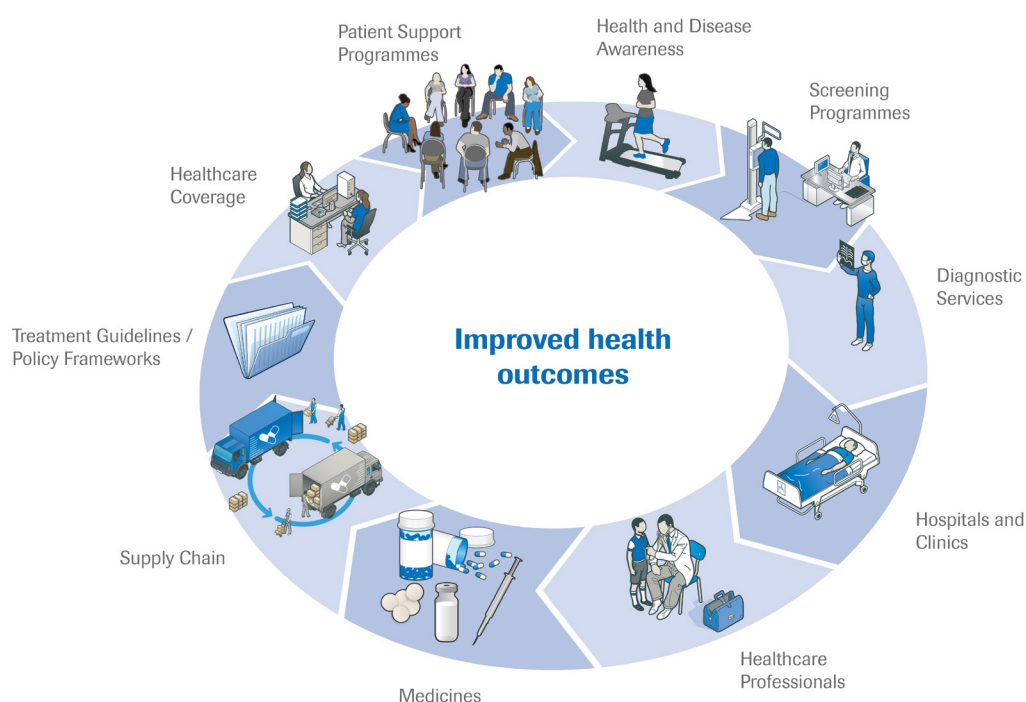
These challenges cannot be addressed effectively with a single approach or by a single entity. Rather, access to good medical care depends on many different factors, including:

- functional services, including clinics, laboratories and healthcare professionals
- a level of disease awareness by people and training among healthcare providers

- reliable supply, storage and distribution channels for medicines
- commitment from government and society to prioritise healthcare

Whilst governments have primary responsibility for establishing and maintaining healthcare systems, the healthcare industry plays an important role in improving health. As a global healthcare company, Roche shares a joint responsibility with governments, international organisations and the rest of our industry to tackle the challenges of improving access to quality healthcare.

Addressing disparities in global healthcare provision can only be achieved through sustained commitment and action by multiple stakeholders. We cannot achieve it alone.



# Our approach

Our products are only of benefit to people if they can access them. To achieve this, we work with many different partners to continuously and sustainably reduce barriers that may prevent people from being diagnosed or being treated with our medicines and achieving improved health outcomes.

Rather than adopting a single global approach, we pursue tailored solutions to address local healthcare needs. In doing so, we consider income levels, disease patterns and causes, political commitment to healthcare, healthcare infrastructure and other factors impacting

the quality and deliverability of healthcare so that we can develop comprehensive solutions, together.

We aim to do this in a way that delivers improvements to healthcare today while allowing us to continue to invest in new medical innovations that can transform patients' lives tomorrow. The objective is to generate a sustainable business model that balances the needs of all stakeholders with our commitment to improve access. In this way we create sustainable value for all stakeholders.

## Delivering innovation

Our primary contribution to the challenge of improving global healthcare has always been the research and development of new medicines and diagnostic tests that deliver significantly better treatment than those currently available in serious diseases such as cancer and CNS disorders. We focus on developing products and services that deliver sustainable value, improving patients' lives and bringing clear medical and economic benefit to healthcare systems and society.

## Improving affordability

As affordability can be a barrier for patients and healthcare systems, we work closely with payers and other stakeholders to demonstrate the value of our products and determine reimbursement. We are additionally exploring various initiatives, such as differential pricing and patient assistance programmes, which help public and private payers, as well as self-pay patients afford treatment.

**Improved  
health  
outcomes**

## Strengthening healthcare infrastructure

Functional healthcare systems, availability of facilities and trained healthcare professionals are critical for the effective use of tests and medicines and delivery of quality care. We provide a number of programmes to address healthcare infrastructure issues and support health screening, treatment, education and training. These activities range from educating healthcare professionals and helping establish clinics and laboratories, to strengthening local manufacturing capabilities and supply chains.

## Increasing awareness and patient support

Health education and support is as important to a patient's long term outcome as proper medical diagnosis and treatment. We help increase public health awareness and advance the prevention, early detection and monitoring of diseases. Our activities range from disease awareness days and screening programmes, to funding counselling and other support programmes for patients and their families.

## Delivering innovation

The success of our business hinges on our ability to create value through new innovative medicines and diagnostics that transform patients' lives. For physicians to prescribe, and for people to use and pay for our medicines and diagnostics, they must deliver benefits above and beyond currently available alternatives.

Our products deliver value through therapeutic as well as economic benefits. For example, many of our products can make healthcare delivery more efficient through improving the mode of administration, or reducing the

time patients spend in hospital. In addition, advances in science have led to Personalised Healthcare (PHC), where an accompanying diagnostics test is used to identify patients most likely to respond. This helps us to optimise the benefit for patients and ensure more efficient use of healthcare resources.

Only by continuing to create value through innovation can we continue to redefine the standard of care and continue to improve health outcomes.

## Focused on areas of high medical need

Our research and development efforts focus on five disease areas which are of epidemic concern globally. As life expectancies rise and lifestyles change, we expect that these disease areas will remain among the greatest burdens in future, continuing to affect millions of people worldwide.

According to the World Health Organisation (WHO), the greatest threat to health in low- and middle- income countries will be posed by 'non-communicable' or

non-infectious diseases such as cancer, cardiovascular disease, and diabetes. Roche is helping drive the global effort in addressing the burden caused by these diseases.

For further information see:

[www.roche.com/research\\_and\\_development](http://www.roche.com/research_and_development)

**Cancer.** The WHO estimates that 12.7 million people worldwide are diagnosed with cancer.<sup>1</sup> Cancer is a leading cause of death worldwide, accounting for 7.6 million deaths in 2008 (around 15% of all deaths). The WHO estimates that the number of people dying from cancer will rise to 13.1 million by 2030.<sup>1</sup>

**Infectious diseases.** The WHO estimates that 130-170 million people worldwide are infected with the hepatitis C virus and an additional 3-4 million people each year are newly infected.<sup>2</sup> About 350 million people are estimated to have the hepatitis B virus, which is highly prevalent in China and other countries in Asia and Africa.<sup>3</sup>

**Inflammation and autoimmune disorders.** Rheumatoid arthritis is estimated to affect over 21 million people worldwide; 1% of the population.<sup>4</sup> The exact cause of rheumatoid arthritis is unknown and there is no cure, but achieving remission has become an objective.

### **Cardiovascular and metabolic disorders.**

Cardiovascular disease is the number one cause of death globally, accounting for 17.3 million deaths in 2008 (around 30% of all deaths). Metabolic disorders like diabetes are also significant world health challenges, with an estimated 370 million people worldwide suffering from diabetes; a number which is expected to double by 2030.<sup>5</sup>

**Central nervous system disorders.** Alzheimer's disease, the most common form of dementia, is one of the biggest threats facing ageing industrial societies. There is currently no cure, only the possibility of slowing the progression of the disease.<sup>6</sup> It is estimated that there were 36 million people living with dementia worldwide in 2010; this number will increase to 66 million by 2030 and 115 million by 2050.<sup>6</sup>

## Personalised Healthcare

Personalised Healthcare aims to provide therapies which are tailored to different subgroups of patients. For some diseases, our diagnostic tests can identify those patients most likely to respond to a specific treatment – that means physicians are better able to decide whom, how and when to treat their patients. Increasingly, tests can also identify patients at risk of side effects from specific drug interventions, which further helps physicians by identifying safer and more efficient treatment alternatives.

Diagnostics play a key role in developing targeted medicines and combining drugs with specific diagnostic tests that assess whether a patient is likely to respond to treatment. All our new compounds are developed in conjunction with a diagnostic programme.

For further information see:

[www.roche.com/personalised\\_healthcare](http://www.roche.com/personalised_healthcare)

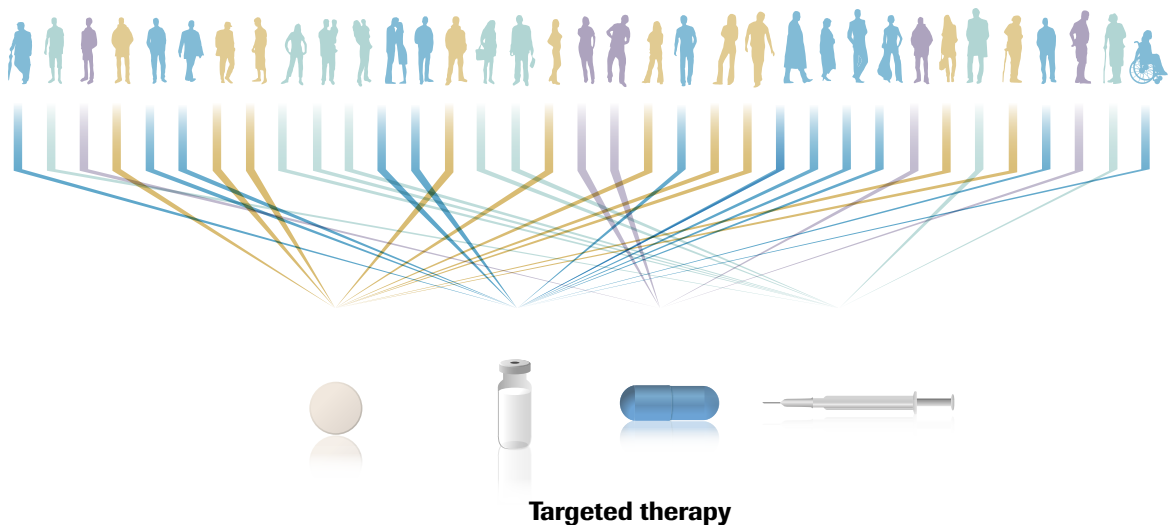
*“The immediate combination of diagnosis, therapy and monitoring of treatment success in hepatitis B infection is a major step forward. This increases the benefits for our patients enormously.”*

**Prof. Henry Lik-Yuen Chan**

Director, Cheng Suen Man Shook Centre for Hepatitis Research;  
Director, Centre for Liver Health, The Chinese University of Hong Kong, Hong Kong, China.



### Patients with the same syndrome may not have the same disease





## Helping patients access new medicines

Our focus is on enrolling patients in clinical trials to obtain the data required to enable regulatory and reimbursement authorities to review and decide on whether these new medicines should be marketed and reimbursed. Approval by regulatory authorities is the only way to make medicines broadly available to patients for the use under the supervision of a qualified healthcare professional or doctor.

Each of our medicines must undergo a series of robust clinical trials to determine its safety and effectiveness before receiving approval by regulatory authorities. Around 320,000 people worldwide participate in our clinical trials each year, where they receive standard of care treatment and potential access to our investigational medicines.

It may not be possible, however, for all patients who might receive benefit from the new medicine to enrol in the on-going clinical trials, and nor is it possible to have clinical trials for all potential disease settings available.

Roche understands the concerns that people living with serious or life-threatening conditions, for which no satisfactory alternate treatments are available, have about accessing new medicines as soon as possible. Under specific circumstances and in compliance with applicable laws, Roche provides patients with pre-approval access to medicines outside of clinical trials and before regulatory approval, through an expanded access programme, a pre-approval safety study, or through compassionate use.

For further information see:

[www.roche.com/clinical\\_trials](http://www.roche.com/clinical_trials)

### In 2012...

18,000,000

people received treatment with one of Roche's 25 **top medicines**

326,000

patients received access to the **latest treatments** through Roche's Diagnostic and Pharmaceutical clinical trials

72

promising **new molecules** were in clinical development, to treat over 40 different diseases

67

percent of our molecules in clinical development had a **personalised healthcare approach**

55

**diagnostic products** launched in key markets

3

**new cancer medicines** were brought to market

## A sustainable approach to sharing intellectual property

For innovation to continue to drive medical breakthrough, investment in research and development has to be compensated and new drugs must be adequately protected, which is where patents come in. Patents temporarily confer an exclusive right to market the products they protect, ensuring that innovation is rewarded and the search for new treatments continues. Then, once the patents for our products expire, the information needed to manufacture them becomes freely available for others to use.

Over 100 million people each year are treated with our medicines that are now off-patent and we continue to manufacture. Many millions more receive generic versions other manufacturers have produced. This legacy is another way that healthcare companies are providing a lasting contribution to world health.

Off-patent Roche medicines that have changed treatment paradigms and continue to contribute to

global health long after patent expiry include Lariam (mefloquine) and Fansidar (sulfadoxine/pyrimethamine) for malaria, Rimifon for the treatment of tuberculosis, benznidazole for Chagas disease and the antibiotics Bactrim and Rocephin.

We recognise that flexibility around patents in some of the poorest countries can help broaden access to medicines. For that reason, we do not file for new patents on any Roche medicines in least developed or low income countries. We also do not file or enforce patents for any antiretroviral HIV medicines in sub-Saharan African countries, where HIV/AIDS affects over 22.5 million people.<sup>7</sup> In this way, generic versions of any of our medicines can be produced and distributed in these markets without applying for a licence.

For more information see:

[www.roche.com/patents](http://www.roche.com/patents) and

[www.roche.com/sustainable\\_patent\\_pricing\\_policies](http://www.roche.com/sustainable_patent_pricing_policies)

## Life-savers for millions

### Rimifon

In 1952 Roche developed the first effective drug for pulmonary tuberculosis: Rimifon. Even now, its active ingredient, isoniazid, remains an indispensable component of tuberculosis treatment.



1952

### Bactrim

In 1969, Roche introduced Bactrim for the treatment of bacterial infections. Its active ingredient, co-trimoxazole, has since been administered in about two billion doses. Bactrim and its generic forms have become a standard treatment for infection, particularly in developing countries.



1969

### Rocephin

In 1982 Roche brought Rocephin to the market, an injectable antibiotic used to treat a wide range of infectious diseases. The patents expired between 1997 and 2005; by 1999 there were 2,012 ceftriaxone generics on the market, produced in 38 different countries. To date Rocephin has benefited over 140 million patients.



1982

## Addressing neglected diseases

Roche has a longstanding role in the diagnosis and treatment of neglected tropical diseases in some of the poorest countries. For example, our antimalarial drugs Lariam (mefloquine) and Fansidar (sulfadoxine/pyrimethamine) are off-patent and available for local generic production. We have donated compounds and expertise in malaria drug development to the Medicines for Malaria Venture. We also donated all the rights and technology to manufacture benznidazole, for the treatment of Chagas disease, to the Brazilian government in 2003.

In the area of neglected diseases, rather than having our own R&D centres we have formed innovation networks with some of the world's leading academic institutions and innovators. This 'virtual R&D hub' approach enables Roche to help support new discoveries in diagnostics and drug development, in areas such as TB and dengue, through cost effective and flexible approaches, and increases our relationships with world-class organisations.

## WHO Model Lists of Essential Medicines

Twenty-four medicines developed by Roche are included on the World Health Organisation (WHO) Model Lists of Essential Medicines. Twenty-two of these medicines are patent free and include life-saving antibiotics, anti-malarials and chemotherapy.

Essential medicines are selected with regard to disease prevalence, evidence on efficacy and safety, feasibility of routine use in such settings and comparative cost-effectiveness. The WHO core list contains medicines

believed to be required for a basic healthcare system, including the most efficacious, safe and cost effective medicines for priority conditions.<sup>8</sup>

The WHO Model Lists of Essential Medicines serves as a guide for the development of national and institutional essential medicine lists.

For more information see:  
[www.who.int/medicines/publications/essentialmedicines/en](http://www.who.int/medicines/publications/essentialmedicines/en)

### Roche products deemed essential medicines by the WHO

Product	Treatment area
amitriptylin	Anti-depressant
ascorbic acid (Redoxon)	Vitamin C deficiency
benznidazole (Radanil, Rochagan)	American trypanosomiasis (Chagas disease)
ceftriaxon (Rocephin)	Broad-spectrum cephalosporin antibiotic
cycloserine (D-Cycloserine)	Pulmonary TB
diazepam (Valium)	Tranquilizer
flucytosine (Ancotil)	Antifungal medicine
fluorouracil (Fluorouracil)	Chemotherapeutic agent
heparin sodium (Liquemin)	Anti-coagulation agent
isoniazid (Rimifon)	TB
levodopa + benserazide (Madopa)	Parkinson's disease
mefloquine (Lariam)	Malaria

Product	Treatment area
midazolam (Dormicum)	Sedation/ palliative care
neostigmine (Prostigmin)	Myasthenia gravis/ anaesthesia
oseltamivir (Tamiflu)	Anti-viral/ Influenza
pegylated interferon alpha (Pegasys)	Anti-viral/ Hepatitis C
procarbazine (Natulan)	Hodgkin's lymphoma
protamine hydrochloride (Protamin)	Heparin antagonist
pyridostigmin (Mestinon)	Myasthenia gravis
retinol (Arovit)	Vitamin A deficiency
saquinavir (Invirase)	HIV/AIDS
sulfadoxin + pyrimethamine (Fansidar)	Malaria
sulfamethoxazole + trimethoprim / co-trimoxazole (Bactrim)	Anti-bacterial agent
thiamine (Berolase)	Heart failure/ Vitamin B1 deficiency

## Improving affordability

Our approach to establishing the prices of our products is to reflect the value that they bring to patients, their families, healthcare professionals, payers and societies. When defining this value, we take into account how well the medicine or diagnostic works, what other medicines or diagnostics are available to treat or test the same disease, how to ensure our products get to the people who need them and the ability of healthcare systems and individuals to afford them. This means that the price of medicines and diagnostic tests varies between countries as public healthcare systems and product reimbursement are organised differently. When bringing a product to market, we work closely with healthcare authorities, insurers and other payers to gain appropriate reimbursement, taking into account the value provided in that specific local setting and purchasing power in that country.

We also recognise that the value of our products can vary across different geographies, along with the ability of healthcare systems and individuals to pay for them; therefore we take a tailored approach to the pricing of our medicines. Part of this tailored approach is to develop reimbursement arrangements around value, rather than a uniform pricing structure. We employ multiple

approaches for improving affordability, including:

- Securing reimbursement through commercial arrangements and/or differential pricing
- Assisting out-of-pocket paying patients through patient assistance programmes
- Contributing to the development of private health insurance coverage

Our aim is to develop solutions that deliver improvements to healthcare systems while allowing us to continue to invest in research and development of innovative diagnostics and medicines that can transform patients' lives tomorrow. The objective is to generate a sustainable business model that balances the needs of all stakeholders with our commitment to improve access.

We are open to discussing new approaches to pricing our medicines with payers in settings where regulatory conditions permit, such as for combinations of biologic treatments or linking prices to treatment outcomes. These new ways of pricing drugs are complex and require governments, insurers and industry to work closely together in developing new reimbursement models.

### No-profit pricing in the poorest countries

We supply our second-line protease inhibitor Invirase (saquinavir) for HIV/AIDS at no-profit prices to the world's Least Developed Countries (LDCs) and all of sub-Saharan Africa (SSA), which covers 63 countries and is home to 64% of all people living with HIV/AIDS.

We supply Invirase at significantly reduced prices in countries defined by the World Bank as Low- or Lower Middle-Income Countries (LMICs), where HIV/AIDS is a growing problem. Valcyte (valganciclovir hydrochloride), our medicine for AIDS-related cytomegalovirus retinitis, is also available at reduced prices for NGO-led AIDS treatment programmes in LDCs, Low Income countries, SSA, and LMICs.

In total, 87% of people living with HIV/AIDS reside in countries eligible for no-profit or reduced-priced Roche HIV medicines. We review our no-profit



prices for HIV medicines annually and adjust them when necessary to ensure they remain no-profit. In this way, we are able to offer prices similar to or below those of generic medicines. Additionally, through our AmpliCare initiative, we offer our diagnostic HIV tests at substantially reduced prices, increasing early detection of HIV infection in infants and reliable monitoring of HIV treatment efficacy.

For prices of our HIV medicines see:

[www.roche.com/sustainable\\_patent\\_pricing\\_policies](http://www.roche.com/sustainable_patent_pricing_policies)

## AmpliCare: Combating HIV/AIDS in developing countries

Our response to the enormous challenge of combating HIV/AIDS was to form the AmpliCare programme, which provides affordable, quality diagnostic tests to resource-limited countries. Since its inception in 2002, AmpliCare has increased access to HIV diagnostic and monitoring tests in sub-Saharan Africa and other countries where the disease burden is the highest, with over 1,250,000 infants tested for HIV and over 2,100,000 patients on HIV/AIDS therapy monitored for viral levels.

The success of the programme lies in our approach. We used our R&D capabilities to re-design tests and the delivery of test results to suit local conditions; we developed differential pricing programmes in partnership with international health organisations and we trained healthcare workers to ensure reliable testing.

For infants, we re-designed our tests and developed a novel method for gathering and transporting blood samples that overcame some of the barriers to diagnosis. For example, by using dried blood spots (DBS) instead of standard blood samples from infants, HIV early infant diagnosis (EID) is now more accessible in many developing countries. We also introduced SMS technology, making it easier to send test results to rural healthcare facilities, while

also engaging the care-giver. This improved patient follow-up by reducing logistical bottlenecks, socio-economic constraints and technological limitations.



For adults, our viral load test, which measures the amount of the virus in the blood stream, is necessary to monitor the efficacy of HIV treatment. Recent advances have enabled Roche to transfer lessons learned in the EID programme to the use of DBS to viral load testing.

Working in partnership with local communities and hospitals and international agencies such as UNICEF, the Clinton Health Access Initiative, Inc., AmpliCare is building and equipping laboratories, training healthcare workers, and diagnosing and monitoring patients. More than 100 laboratory technicians across sub-Saharan Africa are trained annually at our PCR Academy and partner training facilities in South Africa. This training has been augmented by programmes at the recently established Roche Scientific Campus, which will train healthcare workers in all facets of laboratory medicine.

Through the AmpliCare initiative, Roche is helping to develop effective local solutions for resource-limited countries and providing more affordable diagnostic tests without compromising quality.



## Differential pricing

In emerging and developing markets, economic growth is not necessarily matched by improvements in healthcare infrastructure and funding: people may have access to quality healthcare in the higher income private sector but in the public health system the situation can be very different. In countries with little private insurance or public reimbursement, people have to pay the majority of costs themselves. We therefore use differential pricing which aims to tailor prices to the needs of patients and healthcare providers across countries and population segments, based on ability to pay.

We are piloting several differential pricing models, including local manufacturing and second brands, in partnership with local companies and governmental organisations. These programmes include reduced prices to governments to facilitate reimbursement and may also incorporate diagnostic tests and education of healthcare professionals and general awareness programmes as part of a packaged solution geared to local needs.

We are in the process of establishing differential pricing programmes in a number of countries for some of our therapies, including Pegasys (Hepatitis C and B), MabThera (non-Hodgkin lymphoma and chronic lymphocytic leukaemia) and Herceptin (HER2-positive breast cancer and gastric cancer).

Whilst differential pricing improves access to healthcare in many regions of the world, there are still many challenges around its implementation. A global solidarity is needed to ensure that lower prices granted to low- and middle-income countries are not taken advantage of by high-income countries. This way, countries contribute to investing in future innovation in line with their economic ability. We welcome inter-governmental action to ensure that price referencing and parallel trade are not used beyond country groups of similar economic development levels; this would facilitate the increased use of differential pricing in resource-limited countries and therefore, access to innovative medicines.

## Linking pricing to a patient's ability to pay

In the Philippines, healthcare coverage is available through the government owned Philippine Healthcare Insurance Corporation (PhilHealth) which offers basic coverage but does not cover treatment with biologics. This meant that less than 10% of patients with HER2-positive disease received targeted treatment.



Together with health authorities, Roche developed differential pricing options for medicines such as Herceptin, with discount levels patients receive based on their ability to pay, as assessed by an independent third party. Now, through these programmes, barriers such as cost of the medication and testing quality, which prevented physicians from prescribing treatment, have been addressed. This has increased the number of people that can now access our targeted treatment.

## Differential pricing approaches: second brands

One way to help affordability is through the use of second brands. Second brand products are the same as the original brand, except that they have been packaged and commercialised under a different brand name. As they are manufactured in the same production sites as the original, this means that the second brand is the same Roche product and is subject to the same quality control procedures as the product sold in other markets.

Second brands are produced for use within that country and are provided at a reduced price in return for reimbursement into public healthcare segments. We

are working with a number of governments and local partners to enable the introduction of second brands, where local regulatory and legal requirements allow.

Additionally, in a number of countries we are partnering with local manufacturers on end-stage manufacturing of our second brands. This additionally helps strengthen local manufacturing capabilities, increases local skills and provides employment (*see strengthening infrastructure*).

### Second-brand enables differential pricing in Egypt



Hepatitis C virus (HCV) prevalence in Egypt is amongst the highest in the world, with a ten percent prevalence of chronic infection among persons aged 15–59 years. Health-care-associated transmission is a major contributor to HCV transmission.<sup>9</sup> Due to budget considerations, the Egyptian government was unable to treat all their patients with Pegasys (pegferon), Roche's treatment for HCV.

Starting in 2006, Roche worked with the Egyptian government to initiate the National Ministry of Health Project for Treating Chronic Hepatitis C which included a proposal to package Pegasys locally. To differentiate the locally manufactured Pegasys, it carries the trade name Pegferon, and is packaged in a vial form rather than the pre-filled syringe form sold in the private sector.

This second brand approach allows differential pricing, with the local brand available at a



significantly reduced price to the government, enabling greater access to the public sector. Over 110,000 patients who otherwise may not have received treatment have been treated with Pegferon since the programme launched in 2006. In addition, this has generated greater confidence in Pegasys which led to increased usage in the private-payor market as well. It also positioned Roche as a key partner of the Ministry of Health, in both public and medical societies. This project has become a model that Roche is evaluating for application in other countries and therapeutic areas.



## Patient assistance programmes

In many markets our products are not reimbursed or are only partially reimbursed, and patients have to pay out-of-pocket. In these markets we offer a variety of patient assistance programmes which range from providing medicines free of charge, to co-pay support for patients in financial difficulties as a way to ensure treatment is initiated or continued.

Even in countries with advanced healthcare systems, many people cannot afford treatment, including those with personal insurance plans, which may not fully cover treatments. To help patients overcome this barrier, Roche has a number of programmes that assist both the underinsured and the uninsured with access to our medicines.

### Improving access to breast cancer care in China

In China there is limited access to biologic medicines in the public sector and the majority of patients have to pay out-of-pocket. To help these patients, we launched a patient assistance programme in collaboration with the Cancer Foundation in China (CFC) and the Ministry of Health. Through the CFC, Roche donates eight cycles of treatment to a patient after the patient has taken the first six cycles to complete the full course of treatment.

In addition, we support patient education programs by the Chinese Anti-Cancer Association and collaborate with the local pathologist's association to improve HER2 testing quality. Before this programme, less than 15% of women in China with HER2-positive breast cancer received targeted treatment. Today, our integrated approach of HER2 testing and affordability assistance has doubled the number of women receiving targeted treatment for breast cancer.



## Genentech Access Solutions

In the US there is no universal public healthcare system. While many people have health insurance through private or government-sponsored plans, a significant number of people are still underinsured or completely uninsured. For those with insurance, patients may be expected to pay a co-payment associated with the cost of their medicines.

Genentech, a member of the Roche Group, runs several programmes in the US to help with patient access once a Genentech medicine is prescribed. More than 350 employees in Genentech Access Solutions help more than 100,000 fully insured, underinsured and uninsured patients with access issues each year.

Genentech Access Solutions helps insured patients navigate the complexities of health insurance coverage by explaining what their policy covers and what they need to pay for, and by helping them to find payment support programmes where possible. Genentech Access Solutions also assists eligible patients who cannot afford their out-of-pocket co-payments through either a Genentech co-pay card

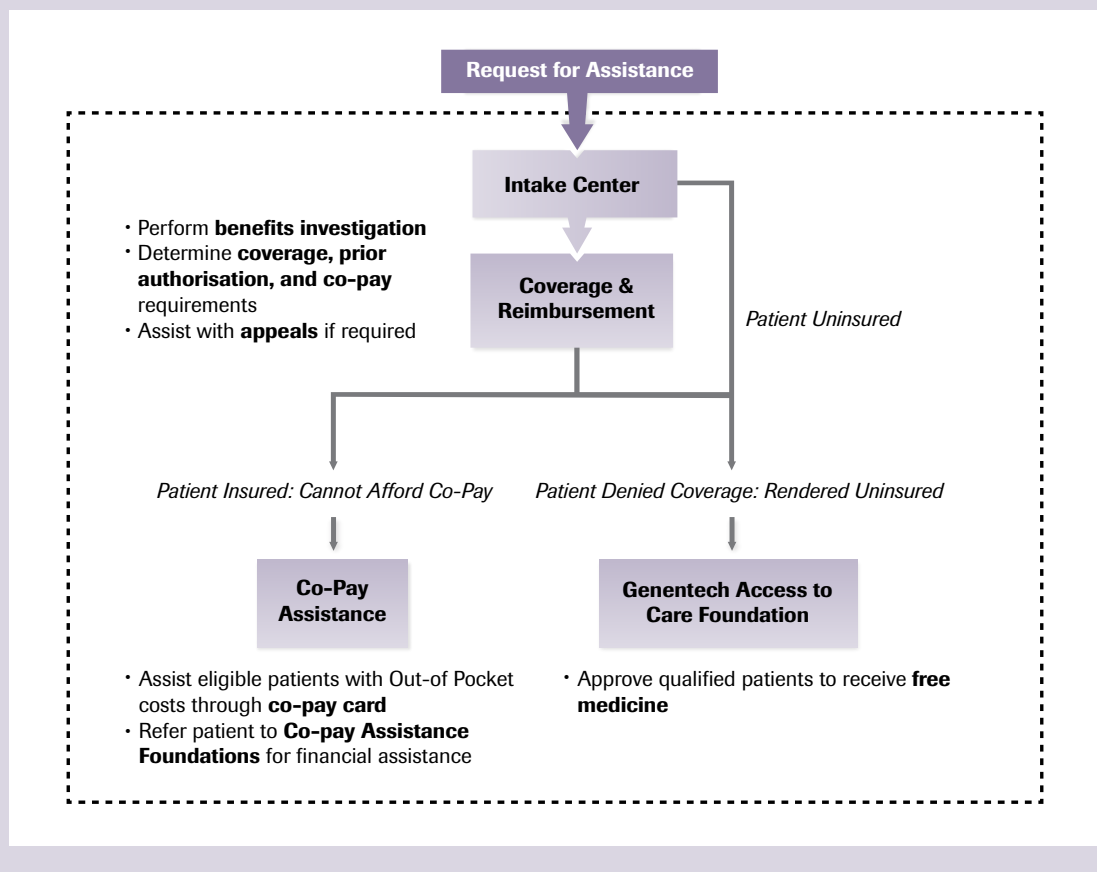
or through referral to a co-pay assistance foundation for financial assistance. Genentech has supported a number of independent, non-profit co-pay assistance foundations with more than \$930 million in donations since 2005.

The Genentech Access to Care Foundation (GATCF) was established to provide free medicines to patients without insurance or who are rendered underinsured by payer denial. Patients must meet certain financial and medical criteria to receive their medicine free of charge. In addition, the Foundation makes free drugs available to eligible patients who have private insurance and have met or exceeded their lifetime maximum benefits. The Foundation provides support to around 40,000 uninsured patients every year.

Since 1985, when its first product was approved, Genentech has donated more than \$3.5 billion in free medicine through GATCF and other product donation programs.

For further information see:

[www.gene.com/patients/patient-access](http://www.gene.com/patients/patient-access)



## Improving health insurance coverage

A system of broad private or public health insurance is essential to improve access to medicines and diagnostics. Indeed, health insurance is one reason that modern medicine is available in many countries to help people live longer and in better health. In past decades, economic growth has enabled emerging countries to begin establishing their own systems of health insurance.

While healthcare policy is a government responsibility, businesses can support the degree of available coverage in many ways. Roche, for instance, is working closely with leading insurers and reinsurers, along with local insurance companies in Brazil, China, the Philippines, Hong Kong, Mexico, Peru and Russia to help broaden health insurance policies to cover comprehensive cancer care.

*“What our customers need most once they are diagnosed with cancer are the following: First, a way of paying for cancer treatment, which is where our insurance money comes in. Second, a treatment plan, which is very important and an area where we, as an insurance company, lack knowledge. With Roche on board, we will have exactly the help we need.”*

**Ryan Bi**

Taikang Life Insurance Co., Ltd.



## Improving health insurance for cancer treatment in China

Like many other countries, China is facing a sharp increase in cancer rates. Cancer is now the number one killer in urban areas and the second leading cause of death in the country as a whole.<sup>10</sup> An ageing population, pollution, heavy smoking and the adoption of a Western lifestyle mean that cancer will remain a major health issue in China for the foreseeable future.

Currently, cancer patients in China pay for their own cancer treatment, as there is limited public reimbursement for these treatments and insurance policy pay-outs do not fund adequate medical care.

In recent years, Roche has worked with local insurers in China to improve health insurance coverage. Through our worldwide contacts with hospitals, labs and healthcare networks, we provide local and global data on cancer treatment options and cost analysis, based on incidence and mortality rates, to local insurance companies. We also provide general cancer awareness and prevention programmes. Our efforts have enabled insurance companies to



determine an appropriate pay-out for treatment and to launch affordable cancer insurance policies that cover the best available treatment, access to hospitals and doctors, and cancer education and support.

In 2012, close to 10 million oncology insurance policies were sold in China thanks to the collaborations between Roche and seven major insurance companies.

## Strengthening healthcare infrastructure

Limited functioning healthcare systems and trained healthcare professionals is still a major barrier to people accessing medicines and diagnostics in some of the world's poorest countries. Roche has therefore established a number of programmes to help overcome these barriers and thereby increase the provision of screening, treatment, education and training. These programmes range from training healthcare professionals and helping to establish clinics and laboratories, to strengthening local manufacturing capabilities and supply chains.

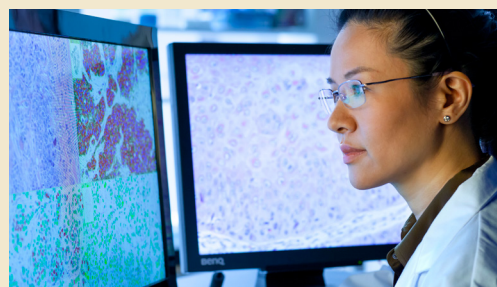
Our focus is on increasing local capabilities as we believe this provides a more sustainable way to address health needs and develop healthcare systems for the future.

## Educating and training healthcare professionals

Roche offers programmes that improve knowledge in disease and product areas where we have particular expertise. Our activities range from publishing education and training materials to hosting or supporting medical congresses. We focus on increasing understanding in areas such as disease pathways, different treatment options and appropriate use, product safety and general healthcare.

Additionally, Roche is involved in establishing quality control programmes and training laboratory technicians in areas such as laboratory medicine and pathology, which enables them to carry out accurate diagnostic testing. Laboratory tests provide the basis for a majority of healthcare decisions, so it is critical that the test results be reliable.

## Scientific Partnership for HER2 testing Excellence (SPHERE)



Roche launched the SPHERE programme in Asia Pacific to help improve the quality of testing for HER2-positive breast cancer in the region. To date, SPHERE operates in China, Korea, Taiwan, Hong Kong, Indonesia, Philippines, Thailand, Vietnam and Malaysia.

Breast and gastric cancers are both highly prevalent in Asia Pacific, accounting for over 20% of all cases of cancer-related mortality in 2008 alone.<sup>11,12</sup> HER2-positive breast cancer affects around 1 in 5 people with breast cancer<sup>13</sup> and can be treated with Herceptin (trastuzumab). As Herceptin is a personalised treatment, it only works in people with HER2-positive disease and therefore the HER2 status of a patient's tumours needs to be tested before they potentially start Herceptin treatment.

The SPHERE programme aims to help train surgeons on how to take a good tissue biopsy, establish training and quality control procedures for lab technicians, to strengthen pathologists' ability to interpret diagnostic tests and to promote enhanced collaboration between pathologists, technicians, surgeons and oncologists involved in breast and gastric cancer diagnosis. The capabilities learned by healthcare professionals in the SPHERE programme are also applicable to other types of diagnostic testing. In 2012 alone, more than 9,000 healthcare professionals have been involved in SPHERE.



## Supporting healthcare skills and diagnostic training capacity in Africa

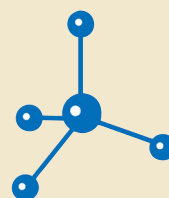
The Roche Scientific Campus was opened in Johannesburg in 2012 to help increase capacity of laboratory diagnostics services and accredited laboratories and address the lack of trained diagnostics workers in Africa. Training is conducted by internal and external certified trainers and experts in collaboration with local and international organisations.

This purpose-built training centre provides:

- hands-on, certified training courses for laboratory technologists and engineers
- general laboratory management trainings for managers and policy makers
- relevant education on specific health and scientific topics for HCPs and scientists

Additionally, in 2012 Roche Diagnostics and the US President's Emergency Plan for AIDS Relief (PEPFAR) formed a five-year, public-private partnership to strengthen training for diagnostics workers in Africa. The goals are specifically to improve laboratory services - including certification courses for pathologist, molecular diagnostics and quality management. The partnership also includes collaboration with the African Society for Laboratory Medicine, thereby increasing the sustainability of the partnership.

## Roche Scientific Campus



*"Strengthening laboratory systems is a priority for PEPFAR because 50-70% of clinical decisions depend on accurate laboratory diagnosis. The dramatic scale-up of anti-retroviral treatment requires strengthening partner countries' laboratory systems, molecular diagnostics and monitoring, and human resources. PEPFAR is pleased to partner with Roche to strengthen targeted laboratory systems and thereby advance HIV/AIDS prevention, treatment, and care outcomes,"*

said Ambassador Eric Goosby,  
U.S. Global AIDS Coordinator.



## Transferring skills and know-how

To improve access to our medicines in a number of countries, we have partnered with local manufacturers for end-stage manufacturing and distribution. This approach helps support local infrastructure and increases skills, provides employment and strengthens our relationship with the government.

To make local packaging possible, we work with governments, healthcare systems and local manufacturers to share our manufacturing techniques and supply chain management practices through skills

training and technology transfer. These collaborations help support emerging countries in acquiring the expertise needed to build or expand their healthcare manufacturing sector, as well as providing local employment.

Our aim is to help governments and our manufacturing and distribution partners develop locally appropriate capabilities to ensure safe, reliable delivery of high-quality and cost-effective medicines to people who need them.

### Technology Transfer Initiative



HIV/AIDS affects over 22.5 million people in sub-Saharan Africa. Increasing manufacturing knowledge and capacity, and reducing African manufacturers' reliance on the West are crucial steps to building sustainable access to HIV/AIDS therapies.

We launched the AIDS Technology Transfer Initiative in 2006. The aim of the initiative was to share our expertise in manufacturing our HIV protease inhibitor saquinavir and to provide hands-on guidance to local manufacturers from Least Developed Countries and



those within sub-Saharan Africa so that they could increase their manufacturing capabilities to global standards.

During the four year initiative, a dedicated Roche team visited 39 local production facilities and we signed Technology Transfer agreements with 13 organisations in six countries. These organisations are now capable of manufacturing their own generic versions of saquinavir.

## Educating healthcare workers in rural Saudi Arabia



Saudi Arabia is a vast country, with around 80 percent of the population of 27 million living in urban areas where most of the specialised oncology centres are located. However, in rural areas covering some 2.5 million square kilometres, health services are provided by general practitioners, family advice and gynaecology-obstetrics units, and there is a general lack of expertise in oncology.

It is estimated that many cancer patients outside of the major cities die without being diagnosed or are referred to the cancer centres with late stage disease.

Project Outreach was started in 2013 and consists of a dedicated team of eight medical educators who travel remote areas of Saudi Arabia. Their role is to raise awareness of cancer and to improve screening. They also provide referral information for patients diagnosed with cancer to the treating physicians in the main cities. The aim is to ensure that people living in remote areas are properly diagnosed and referred to specialists early on.

Activities include organising a breast cancer symposium for primary care physicians in Madinah, where physicians were briefed on the fundamentals of cancer diagnosis, surgical treatment and chemotherapy by specialists from the country's leading hospitals. In Bisha, the project helped support the opening of a new breast cancer clinic in Bisha's Main Hospital.

The Outreach Project is an initiative between Roche, the Ministry of Health, key opinion leaders and national cancer associations, such as the Saudi Cancer Society.



## Supporting construction of a cancer centre in Turkey



Since 2004, the Turkish Ministry of Health's Cancer Control Department has been driving awareness of cancer prevention and early diagnosis, to create new models in cancer control and reduce mortality rates. One of the most important initiatives of this vision was to establish "KETEM" centres (Cancer Early Diagnosis Screening and Training Centres) throughout Turkey. These centres conduct screening programs for breast, cervical and colorectal cancers and are equipped with the latest cancer screening diagnostic equipment and systems.

In 2009, Roche supported the construction of the KETEM centre in the capital city of Turkey, Ankara. As of today, there is one centre in each of the 81 cities in Turkey (82 centres). A total of 280 KETEM centres will be established throughout Turkey before 2015, amounting to one centre per 250,000 people.



KETEMs also serve to drive awareness of the importance of prevention and early diagnosis in cancer. In line with that, Roche also supports the awareness campaign "The Blue Bicycle, hit the road for cancer early diagnosis", in cooperation with the Turkish Bicycle Federation. The Blue Bicycle completed 6 laps passing through 26 cities with the involvement of more than 10,000 people. Roche made a donation to local KETEMs in all cities visited on behalf of each participant. In addition, in each city local medical doctors organised breast cancer seminars for the public.

The Blue Bicycle campaign, running between 2006 and 2011, has helped increase public awareness on how detecting cancer early could increase the chances of survival.



## **Increasing awareness and patient support**

Helping to ensure access to medicines and diagnostics is vital, but still not enough to improve global healthcare. Roche adopts a holistic approach to healthcare, where education and support is as important to a patient's long term outcome as proper medical diagnosis and treatment. Specifically, we know that the emotional and social pressures of living with disease on top of the physical challenges are often overwhelming – a recent report showed that 45% of cancer patients found the emotional challenges of the disease harder to deal with than the practical or physical ones.<sup>14</sup> Supporting patients throughout their treatment journey can be as important as supplying them with the right medicines.

We believe we can contribute beyond our products through supporting local partners who run screening, awareness and counselling programmes for their local communities. In turn, we also hope to empower people worldwide with the knowledge to safeguard and manage their own health and the health of their families for the future.

## **Health education and awareness**

In many areas of the world we work with patient groups, hospitals and health organisations to increase awareness of diseases such as cancer, rheumatoid arthritis, hepatitis, osteoporosis and diabetes and to conduct screening programmes for the early detection of these diseases. We also publish newsletters, magazines and other publications aimed at helping people make healthy choices and changing behaviours to prevent disease. We produce information for patients, families and caregivers operate counselling services to help them understand diseases and proper use of our products; we also develop websites that provide the latest information on diagnostic tests and treatment options.

## **The “Changing Diabetes in Children” programme**



In order to address the growing problem of diabetes in the world's poorest countries, Roche joined Novo Nordisk, the World Diabetes Foundation and the International Society for Paediatric and Adolescent Diabetes to provide sustainable diabetes care for children with Type-1 diabetes through Novo Nordisk's five-year programme “Changing Diabetes in Children”.

Diabetes is no longer a rare chronic disease in Africa. In 2007, the estimated number of people with diabetes in Africa was 10.4 million,<sup>15</sup> with over 38,000 children affected. A child in Sub Saharan Africa that is newly diagnosed with type-1 diabetes has the life expectancy of only one year.

The “Changing Diabetes in Children” programme includes provision of insulin and blood glucose monitoring supplies, together with specific educational materials for children and their families to support better diabetes self-management. The programme also includes diabetes training for healthcare professionals, with the aim to help build the infrastructure to eventually support all people with diabetes.

Activities so far have been focused in Tanzania, Uganda, Cameroon, Guinea-Conakry, the Democratic Republic of Congo, India, Ethiopia and Kenya where children up to the age of 18 with type-1 diabetes are offered free treatment. To date, nearly 7,300 children are enrolled in the programme, 70 clinics have been established and 1,600 healthcare professionals trained.

## Mission “Mammobile”: to screen one million women in Algeria

In Algeria the incidence of breast cancer has increased dramatically in the past two decades. More than 70% of all cancers are diagnosed in a late stage and five year survival is very low. Algeria launched its first mobile breast cancer screening facility in February 2013 to bring much needed facilities to far-flung desert areas in the country. Roche partnered with patient advocacy group El Amel (Hope) and mobile phone operator Mobilis to combine awareness drives in rural areas with screening facilities to drive early detection and treatment. Roche supports the training of local radiologists, nurses and other professionals and also equips the Mammobile with all necessary software for performing mammograms.

*“Algeria is the biggest country in Africa. Sparsely populated towns in the interior area are far away from each other, making it difficult for the health authorities to build the necessary healthcare infrastructure to fight cancer.”*

Nora Bouzida, Communications Manager in Roche Algeria.



*“Roche is ready to be a full partner in such projects with patient advocacy groups and the government with the aim to raise awareness and provide early diagnosis for women with breast cancer. We are proud to be the first pharmaceutical company in Algeria to get involved in such a project.”*

Roche Algeria Country Manager Lynda Boucherat stresses Roche’s commitment to the programme.



## 'Design a Schoolbag' to raise awareness of arthritis in children in the UK

Arthritis affects one in 1,000 schoolchildren, and those affected have painful, stiff joints, which makes it difficult for them to carry heavy items such as schoolbags.

To help youngsters who suffer from arthritis, Roche teamed up with Arthritis Care, the UK's leading arthritis charity, on a competition to raise awareness of sJIA and of the unmet need in musculoskeletal disease in the UK. Juvenile idiopathic arthritis (JIA), which affects over 2,000 children in the UK, is the most common form of arthritis in children and adolescents, and differs significantly from arthritis commonly seen in adults (osteoarthritis, rheumatoid arthritis).

Using a variety of social media tools, Roche partnered with Arthritis Care, a national charity that supports people and young children, invited children aged between 12 and 16 to help design a schoolbag that kids with arthritis would find easy to use and carry. The winning design was selected by a panel of cross-functional judges, and made into a bag that

was presented to the winner by Kelly Anne-Lyons, a young UK TV star who also suffered from sJIA as a child.

The competition itself, and the winning entry, generated over 5.7 million opportunities to see across the UK, including articles in a number of print and online magazines, with over 1,000 followers of tweets from Kelly-Anne Lyons and Arthritis Care. This helped raise awareness of this unique condition and how it affects children across the UK.



## Providing patient support

We sponsor many programmes to provide counselling and other forms of support to patients, their family, friends and caregivers to help them understand and manage their disease, their treatment and any side effects, and help return them to an active lifestyle and/or work.

Many of these activities are focused on educating people about the importance of taking their medicines exactly as prescribed and therefore these activities also tie into our mission to improve health awareness and prevent wastage of healthcare resources through suboptimal use of medicines.

We help healthcare professionals demonstrate the need for, and assist patients with, adhering to treatment regimens through patient support programmes, reminder text messages, treatment diaries and 24-hour call lines, amongst other activities. We have product websites that offer the possibility of reminding patients to take their medication, as well as provide access to trained nurses and information on how to live with a disease and medical side effects.

In addition, we operate counselling centres and telephone help lines and coordinate services to improve treatment compliance and rehabilitation.

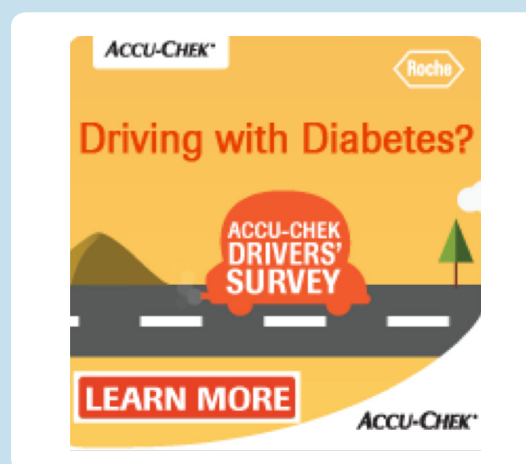
### Accu-Chek drivers' survey

For many people, driving is a central part of daily life. The ability to drive provides personal freedom for leisure activities, allows people to get to schools and stores more easily, and/or may be essential for a job. However, driving a motor vehicle is a complex task involving perception, appropriate judgement, adequate response time and reasonable physical capability.

For people with diabetes, the ability to drive safely can be affected by certain conditions such as hypoglycaemia (low blood glucose levels) or hyperglycaemia (high blood glucose levels). Having diabetes does not mean that you have to give up driving, but you do need to plan in advance before you get behind the wheel.

In 2011 Roche UK launched a campaign to raise awareness of the potential for hypoglycaemia of people with diabetes and how driving conditions can influence stress levels which may have an effect on blood glucose levels.

To check whether people were aware of the risks of driving with hypoglycaemia Roche UK carried out a survey to investigate whether they checked their blood glucose levels before driving and how people with diabetes manage their blood glucose levels. In the UK there are 2.9 million people living with diabetes, an estimated 650,000 are insulin users – over 65% of whom hold a driving license.



Over 18,000 drivers with diabetes took part and over 10,000 drivers answered the survey. One in five drivers who used insulin were unaware of the legal implication of having an accident due to hypoglycaemia and more than a quarter of drivers on insulin were not fully aware that there were national driving guidelines which recommended monitoring of blood glucose levels before driving.

As part of the campaign Roche UK also provided websites and downloadable resources with further information on diabetes and driving: <https://www.accu-chek.co.uk/gb/lifestyle/driving.html> and updated driving regulations: [https://www.accu-chek.co.uk/gb/lifestyle/Driving\\_and\\_diabetes\\_resources.html](https://www.accu-chek.co.uk/gb/lifestyle/Driving_and_diabetes_resources.html).

# Additional information

UN Country Definitions	<a href="http://www.un.org/special-rep/ohrls/ldc/list.htm">http://www.un.org/special-rep/ohrls/ldc/list.htm</a>
World Bank Country Definitions	<a href="http://data.worldbank.org/country">http://data.worldbank.org/country</a>
WHO Essential Medicines List	<a href="http://www.who.int/medicines/publications/essentialmedicines/en/">http://www.who.int/medicines/publications/essentialmedicines/en/</a>

## References

1. World Health Organisation: Cancer - Fact sheet N°297 <http://www.who.int/mediacentre/factsheets/fs297/en/> Last accessed 29 May 2013.
2. World Health Organisation: Hepatitis C - Fact sheet N°164 <http://www.who.int/mediacentre/factsheets/fs164/en/> Last accessed 29 May 2013.
3. World Health Organisation: Hepatitis B. <http://www.who.int/csr/disease/hepatitis/whocdscsrlyo20022/en/index1.html>
4. Markenson, J. Worldwide trends in the socioeconomic impact and long-term prognosis of rheumatoid arthritis. *Seminars in Arthritis and Rheumatism*, Vol 21, 1991, p 4–12.
5. International Diabetes Federation. Diabetes Atlas Update 2012. <http://www.idf.org/diabetesatlas/5e/Update2012> Last accessed 29 May 2013.
6. Alzheimer's Disease International. World Alzheimer Report 2012. London : Alzheimer's Disease International, 2012. Last accessed 29 May 2013.
7. Global report: UNAIDS report on the global AIDS epidemic 2010. Regional HIV and AIDS statistics, 2001 and 2009; page 20.
8. World Health Organisation Essential Medicines. Available at [http://www.who.int/topics/essential\\_medicines/en/](http://www.who.int/topics/essential_medicines/en/) Last accessed 29 May 2013.
9. El-Zanaty F, Way A. Egypt demographic and health survey 2008. Cairo, Egypt: Ministry of Health, El-Zanaty and Associates, and Macro International; 2009. Available at <http://www.measuredhs.com/pubs/pdf/fr220/fr220.pdf>
10. Zhao, P et al. Cancer Trends in China. *Jpn J Clin Oncol* 2010; 40: 281–5. <http://jco.oxfordjournals.org/content/40/4/281.full>
11. World Health Organisation Breast Cancer - Fact sheet <http://globocan.iarc.fr/factsheets/cancers/breast.asp>
12. World Health Organisation Gastric Cancer - Fact sheet <http://globocan.iarc.fr/factsheets/cancers/stomach.asp>
13. Wolff A.C et al. *Arch Pathol Lab Med*-Vol 131, January 2007.
14. MacMillan Cancer Support - Facts and figures: Survivorship. From: 'Macmillan Cancer Support, Worried Sick: The emotional impact of cancer'. <http://www.macmillan.org.uk/Documents/AboutUs/Newsroom/Factsheets2011/Survivorshipfactsheet.pdf>. Last accessed 29 May 2013.
15. International Diabetes Federation: Diabetes Atlas – African Region. <http://da3.diabetesatlas.org/index747c.html>. Last accessed 29 May 2013.