



## Access to Medicines

### The Pharmaceutical Companies' Response

#### Introduction

The availability of medicines for the poor in developing, middle-income and developed countries is an area that represents a big risk to pharmaceutical companies' reputations. Governments, non-governmental organisations and pharmaceutical companies have been working on this issue, both individually and together in recent years, and have achieved a lot.

Nonetheless, according to the World Health Organisation (WHO), one third of the world's population lacks regular access to essential drugs. This estimate rises to over 40% in low income countries and over 50% in the poorest countries of Asia and Africa, where infectious diseases such as tuberculosis, malaria and AIDS are the leading cause of death.

Responsibility for increasing access to essential medicines does not fall to one single organisation. It is the responsibility of the whole international community. Developing countries need to build new health systems, financing needs to be increased, medicines need to be affordable and new medicines need to be developed for diseases affecting developing countries.

#### Developing World

Developing countries' health systems are very often the weak link in making essential drugs available to their people. The problem of access to medicines will not be solved until these countries have properly managed health systems with adequate resources and funding.

Despite unprecedented resources being made available for public health, many governments are unable to fund the clinics and staff needed to deliver basic healthcare.

The World Bank estimates that \$14 per person per year is needed to provide the most basic health services. Yet the average spend in sub-Saharan Africa is just \$6. The African region of the World Health Organisation suffers more than 24% of the global burden of disease, but has only 3% of the world's health workers. Migration of African health workers to wealthier markets is exacerbating the situation. There is a global shortage of health workers, and the AIDS epidemic is making the situation worse.

Tackling this crisis is a complex challenge. Significant political will and resources are needed to aid development and build healthcare infrastructure.

It is the responsibility of governments and intergovernmental agencies, often supplemented by work of the NGOs, to deliver the necessary healthcare in these countries. Also, the pharmaceutical industry can play a significant role in supporting their efforts.

#### Middle Income countries

These are more economically developed than developing countries, but often have healthcare demands that outstrip their available resources. These challenges are often exacerbated by the HIV/AIDS epidemic. In these countries, pharmaceutical companies will negotiate preferential pricing arrangements on a case-by-case basis. This is done through dialogue and negotiation with the governments. The goal is to combine viable and sustained commercial return for the company with improved affordability for the healthcare systems concerned.

#### Pharmaceutical Companies' Role

Most large pharmaceutical companies are already involved in increasing access to essential medicines in developing countries in a number of ways. The most obvious is through reduced pricing on their drugs and allowing generic manufacture of particular medicines. However, pharmaceutical companies are also engaging in research and development activities on diseases afflicting the developing world, and are working to help strengthen health systems in developing countries.

It is not sustainable for companies to give away their products indefinitely in significant quantities. In their policy paper on access to medicines, the UK Government says that it favours approaches by pharmaceutical companies based on differential pricing, although acute disease eradication programmes can be supported with donated products.

Differential pricing raises the risk of diversion, with lower priced products diverted from legitimate purchasers back to richer markets. This is of particular concern for single-source products that command high prices in developed markets. This then threatens the sustainability of differential pricing. Companies are taking steps to minimise this through the use of differential packaging and formulation. The G8 committed to work to tackle diversion, and the EU has introduced regulation to combat it too.

Many pharmaceutical companies have joined Public Private Partnerships (PPPs). These attempt to overcome the obstacles to tackling the lack of commercial incentive of many health problems afflicting the poor. They involve international agencies, such as the World Health Organisation, pharmaceutical companies and national governments working together on particular health issues, such as HIV/AIDS.

It should be noted that there is no common standard for evaluating the efforts of pharmaceutical companies on the issue of access to medicines.

## Intellectual Property

Patents are important incentives for the continued innovation that drives progress in pharmaceuticals. The path to a new medicine is a long, complex, expensive and risky process. It can take between 8-12 years and typically over \$800m of investment before the first returns are realised. Drugs normally reach the market with 8-15 years of patent protection left before generic competition is allowed. Therefore they must generate the necessary revenue during this period to earn a return on the investment and generate funds for future drug development.

## What the major European companies do:-

### GlaxoSmithKline

GSK contributes to the developing world through research, preferential pricing, partnerships, voluntary licenses, and community investment in public health initiatives. They also have special pricing arrangements for middle income countries and Patient Assistance Programs to help uninsured patients in the US.

They believe that their response is not only the right thing to do, but that it makes good business sense to adapt their practices to address such challenges. It gives them leadership in developing markets and also helps attract and retain the best employees.

GSK still strongly believes that intellectual property rights are essential to the pharmaceutical industry, as without them they would not be able to invest in research and development for new medicines. However, by finding innovative ways to help poor people in developed and developing countries to access their medicines, they can address ethical, reputational and commercial imperatives. It is for these reasons that management consider access to medicines a business driver of GSK.

### R&D

Research and Development of new drugs and vaccines is an essential element in improving health in the developing world. There are still no effective treatments for some widespread life-threatening diseases. Also, many existing treatments for diseases such as malaria are becoming less effective due to drug resistance.

For HIV/AIDS which affects both developed and developing countries, there is a commercial market for new treatments. This encourages investment in the required R&D. However, for many diseases that disproportionately affect the developing world, the lack of resources for healthcare means there is often no viable commercial market for new treatments. PPPs are helping to address this problem.

GSK collaborates with several PPPs including the Medicines for Malaria Venture, the Global Alliance for TB Drug Development, the Aeras Global TB Vaccine Foundation and the International AIDS Vaccine Initiative.

They have created a dedicated group in their R&D function to focus on diseases of the developing world (DDW). This includes a bespoke DDW discovery centre in Spain, employing 100 scientists, and clinical development experts in the UK and US. DDW projects are prioritised according to their social and public health benefits rather than their commercial returns.

In total GSK is conducting R&D into 11 diseases of particular relevance to the developing world (Malaria, leishmaniasis, dengue fever, hep C, hep E, HIV/AIDS, N. meningitis, cervical cancer, TB, Chlamydia and pneumococcal disease).

### Preferential Pricing

GSK blames poverty, lack of political will and insufficient medical infrastructure as the main barriers to accessing healthcare in developing countries. They do agree that affordability of medicines is also an important factor, that needs to be tackled by both pharmaceutical companies and governments. Taxes, tariffs and distributor mark ups can significantly increase the price of medicines, and it is these factors that need to be addressed by governments.

For their part, GSK make anti-retrovirals available at not-for-profit prices to the worlds poorest countries, and at discounted prices for middle income countries. Vaccines are also available at preferential prices. GSK use a tiered pricing structure for vaccines, with prices for the developing world around a tenth of those for developed countries. They work with UNICEF, the WHO and the Pan American Health Organisation in addition to governments and NGOs, to provide affordable vaccines for developing countries. Vaccines include basic polio as well as specially developed combination vaccines which target several diseases.

### Anti Diversion

Product diversion, where not-for-profit medicines are illegally shipped back for sale in wealthier countries is a problem. GSK have taken action by producing distinctive looking versions of their drugs for not-for-profit markets. For example they produce red rather than white tablets for Combivir, Eпивir, Trizivir and Retrovir anti-retroviral therapies.

### Patient Assistance Programs

Even in developed countries some patients cannot afford the medicines they need. This is a particular problem for the US where many people do not have health insurance. GSK has developed Patient Assistance Programs and a discount savings card to help these patients to obtain prescription medicines at discount prices. Patient Assistance Programs provide prescription medicines to low-income, uninsured patients free or at minimal cost. These apply to medicines ranging from cancer treatments to outpatient treatments.

### AstraZeneca

AZ state that as a publicly owned company they have a duty to ensure that they continue to deliver a return on investment for their shareholders. They balance many different factors including ensuring appropriate patient access in their global pricing policy, which provides the framework for them to optimise the profitability of their products in a sustainable way.

### Pricing

For medicines that are critical to meeting healthcare needs, either because they treat diseases prevalent in developing countries, or address an unmet need against a life threatening condition, AZ aim to provide patient access through charitable donation or expanded patient access programmes. They also support the concept of differential pricing in this context, whilst putting safeguards in place to prevent diversion from the intended patients.

### Developing World

AZ says it is committed to making a contribution to improving health in the developing world. However, the AZ portfolio of drugs is not particularly relevant to the treatment of the most significant healthcare problems of the developing world. They believe that they can best help by applying global skills, resources and experience to meeting the challenge in other ways.

As a result, they have set up a dedicated resource on finding a new treatment for tuberculosis.

Existing TB therapies are effective but treatment regimes are complicated and prolonged which can lead to patients giving up once the symptoms are no longer apparent, but before the infection is fully treated. This may lead to a relapse and makes drug resistance more likely. New drugs need to be compatible with HIV/AIDS therapies because TB is the biggest killer of those infected with HIV. AZ opened a purpose built research centre in 2003, dedicated to TB research based in Bangalore. 80 scientists are employed there, focusing on finding new therapies that will act on drug-resistant strains, shorten the duration of treatment and be compatible with HIV therapies.

In addition, AZ have formed a partnership with the British Red Cross to help combat TB in Central Asia through education, diagnosis and improving patient compliance with drug regimens. They have also formed a partnership with the African Medical and Research Foundation, focusing on strengthening healthcare systems and integrating delivery of TB, HIV, and malaria programmes in Uganda, a country where there is a high burden of all three diseases.

## Roche

Roche says that it works with governments and competent, locally based partners who are willing to do their part to make a difference. They believe this is the only way to develop sustainable solutions for unmet healthcare needs of the world's poorest populations.

They identify malaria, AIDS and TB as the most important diseases affecting these regions. Infrastructure is an essential requirement for any medical therapy, no matter how simple. Medicines are just one element in a highly complex system involving diagnosis, treatment and treatment monitoring.

Roche is prepared to make an active contribution to the solution, but say that government authorities and other local partners also need to play their part in such a public-private partnership – particularly in the provision of education and infrastructure.

## HIV/AIDS

Roche sees its primary role as a discoverer and developer of drugs for HIV/AIDS, but in addition the company seeks to meet its corporate citizenship responsibilities by implementing policies and programmes that are designed to help people living with the disease in the poorest parts of the world.

They have removed both patents and profits as obstacles to the use of their HIV protease inhibitors in the world's 50 least developed countries (as defined by the UN) and in all the sub-Saharan countries. They also offer discounted prices in low and middle income countries.

Roche is a founder member of the Accelerating Access Initiative (AAI) that combines the collaborative efforts of 7 research based industry members and five UN agencies. As a result of the AAI, increasing numbers of HIV/AIDS patients are receiving treatment in developing countries.

## Novartis

Novartis says it has been a leader in improving access to medicines through programmes supporting anti malaria treatment Coartem and the Glivec International Patient Assistance Programme. Novartis also makes the point that sustainable access to medicines in poor countries will require sufficient healthcare infrastructure, distribution and financing and that governments must play a principle role in addressing these problems. They also acknowledge that public-private partnerships can help secure domestic and international funding to purchase medicines and develop critical health system infrastructure.

Novartis has worked on PPPs on malaria, tuberculosis and leprosy. Since 2000 Novartis has provided free treatment for leprosy patients worldwide in collaboration with the WHO. More than 4.3 million people have been treated through multi-drug therapy supplied by Novartis. They also provide their anti-malarial drug Coartem without profit for public sector use in malaria-endemic countries.

In the developed world, they offer programmes to patients who lack medical insurance or cannot afford treatment. The most far reaching patient assistance programme ever implemented on a global scale was for Glivec their CML cancer therapy.

## Sanofi Aventis

A whole department is devoted to access to medicines. The Sanofi Aventis approach is based primarily on differential pricing, working on developing a two-layer anti malarial tablet and providing information, education and communication.

Actions are concentrated on 5 diseases where Sanofi Aventis have expertise: malaria, tuberculosis, sleeping sickness, leishmaniasis and epilepsy. These initiatives are often based on partnerships, so new programs can easily be established for developing countries.

On Malaria they have a without profits policy on their drug and are undertaking R&D on new treatments; in TB, they are working on developing an existing medicine, rifapentine, to reduce treatment duration and dosage; and in sleeping sickness, they have been working with the WHO since 2001 and produce sufficient drug quantities to cover the needs in endemic countries.

## Novo Nordisk

Novo Nordisk is almost exclusively focused on the treatment of diabetes, and as such their access to medicines efforts are limited to the one disease.

The World Diabetes foundation was established by Novo Nordisk in 2002. It is dedicated to supporting the prevention and treatment of diabetes in the developing world through the funding of sustainable projects. To date it has funded over 100 projects focusing on diabetes awareness, education and capacity building at local, regional and global levels. A projection of the impact of the WDF's work shows that the funded projects will positively impact 55 million people in the developing world.

## Conclusion

Access to medicines is a pressing issue, but it is being addressed in many areas. This is particularly evident in the very poorest countries, which have their own specific challenges in terms of disease type. The major pharmaceutical companies have all demonstrated commitment to putting resources into tackling the big developing world diseases, in particular Malaria, TB and HIV/AIDS.

Partnerships have grown over the last 6 years or so to make intervention more effective, linking global organisations such as the World Health Organisation to governments and pharmaceutical companies. Not only has this helped to create some organisation and infrastructure for the aid given to developing countries, but also helped engender confidence amongst pharmaceutical businesses that they will be afforded some protection from loss of intellectual property or diversion of product from its intended market. It has also encouraged R&D resource to be put into developing world diseases.

There is still much to do, but it will still require the will of all the parties involved, especially the governments of the afflicted countries. Pharmaceutical companies are showing willing, in varying degrees, to play their part and this can only grow as infrastructure improves.