Oxfam Briefing Paper

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Investing for life

Meeting poor people's needs for access to medicines through responsible business practices

There are major shortcomings in the pharmaceutical industry's current initiatives to ensure that poor people have access to medicines. To shore up its own flagging economic performance, the industry is increasingly looking to the potentially huge markets within emerging economies. Yet, poor people who live in these countries still desperately lack affordable and appropriate medicines. The time is ripe for a bold new approach. The industry must put access to medicines at the heart of its decision-making and practices. This is both a more sustainable long-term business strategy and would allow the industry to better play its role in achieving the universal right to health.

Oxfam International

Executive summary

Access to medicines is fundamental for people to achieve their right to health. While governments have the primary responsibility for ensuring access to health care for all their citizens, the role of the pharmaceutical industry in providing a vital element – medicines – carries its own responsibilities.

In 2002, Save the Children, VSO (Voluntary Service Overseas), and Oxfam published 'Beyond Philanthropy',[1] a report that called for the pharmaceutical industry to contribute to addressing the health crisis in developing countries. The report challenged the industry to adopt policies in five areas: pricing, patents, joint public–private initiatives, research and development, and the appropriate use of medicines. Since the publication of the report, the industry has made halting progress in some of these areas, mainly by adopting limited policies to promote access to medicines for high-profile diseases such as HIV and AIDS, TB, and malaria.

However, the challenge to ensure that millions of poor people can get the medicines they need remains huge, given the appearance of new diseases; the re-emergence of 'old' diseases; the threat of pandemics; and the growing burden of non-communicable diseases in developing countries. Malaria claims the lives of one million people every year – mostly children and pregnant women.[2] Two million people die annually from TB. Half of the global cancer deaths are in developing countries. The World Health Organisation (WHO) estimates that the occurrence of asthma is increasing on average by 50 per cent every ten years in cities in the developing world.[3] Currently 85 per cent of the world's population is being priced out of the industry's market.[4]

Current industry approaches do not address the problem sufficiently. Major shortcomings include:

- a failure to implement systematic and transparent tiered-pricing mechanisms for medicines of therapeutic value to poor people in developing countries, where prices are set according to a standard formula which reflects ability to pay and the price of generic versions where they exist;
- the lack of research and development (R&D) to address the dearth of dedicated products for diseases that predominantly affect poor people in developing countries. This includes drug formulations that are applicable and usable in the developing world. Between 1999 and 2004, there were only three new drugs for neglected diseases out of 163 new chemical entities (NCEs);[5]
- persistent inflexibility on intellectual property protection, and in some cases, active lobbying for stricter patent rules and legal challenges to governments' use of TRIPS public-health safeguards, thereby preventing poor people from accessing inexpensive generic versions of essential medicines; and

- too heavy a focus on donations, which by their nature are unpredictable and have been found to cause chaos in the market for low-cost medicines as well as undermining generic competition.

Oxfam believes that the potential for pharmaceutical companies to contribute more substantially and effectively towards increasing access to medicines for poor people in developing countries is not being met, and that there are three factors that have prevented companies from moving forward.

First, companies' pursuit of strategies that address access to medicines merely as a reputational problem has resulted in patchy, ad-hoc approaches which have failed to deliver sustainable solutions.

Second, the industry's responses to flagging financial performance – hiking up prices, aggressively defending patents and prolonging existing ones through 'ever-greening' rather than investing in research and development of new medicines – have undermined needs for lower prices, flexible approaches to patenting, and R&D investment into diseases relevant to the developing world.

Third, the industry's failure to comprehend access to medicines as a fundamental human right enshrined in international law, and to recognise that pharmaceutical companies have responsibilities in this context, has prevented the adoption of appropriate strategies.

It is clear that there are pressures on the pharmaceutical industry to change course. Increased financial burdens on health systems due to ageing populations and changing disease burdens are stimulating calls for lower prices from both North and South. The industry is now challenged to be more transparent about its price rationale so that governments and public-health advocates can request greater alignment between the prices set and purchasing power. The intellectual property regime and the market-driven model of drug development are criticised for not delivering real innovation required to relieve the global public-health crisis.

At the same time, investors are clearly concerned that this industry is not delivering the profits that it used to. Emerging market economies are being identified as the possible panacea to this flagging growth. There are enormous opportunities in these markets, including lower costs to conduct R&D and clinical trials, and low-cost manufacturing. These economies also offer substantial market potential. However, for this to be realised, the industry will have to recognise that serving these markets requires a vastly different approach: one which reflects the significance of massive income disparities, the impacts of high prices on increasing vulnerability and insecurity, and the need for medicines that are relevant and adaptable to poor settings.

Pressures on the industry to meet society's expectations of access to medicines will continue for a number of reasons:

First, a growing number of developing-country governments are making serious commitments towards achieving viable health services and equity of access. Without a solution to the problem of access to medicines, they cannot meet their goals and obligations to their populations. In the developing world, where the majority of people live in poverty and are highly sensitive to price rises, companies will have to respond by implementing

sophisticated differential pricing policies correlated to different income levels or by instituting flexible patent policies to ensure the desirable low price is achieved.

Second, the epidemiology of public health is changing, with a more diverse range of diseases that require appropriate products. For developing countries particularly, their specific contextual realities need to be taken seriously: new products are needed, formulations need to be usable, and drug information and labelling should be comprehensible. R&D will have to be tailored to end-use realities.

Third, demands from civil society for the industry to deliver their end of the social contract are likely to grow and become more exacting. As the current models and incentives for delivering medicines that are suitable, usable, and affordable for poor people come under increasing scrutiny, this will add to the growing pressure upon the pharmaceutical industry to adopt different strategies that better meet global health needs.

If companies continue a slow evolution of the existing approach without addressing society's expectations, they are likely to fall seriously short of meeting the challenges of access to medicines.

Now is the time for companies to take a bold look at new ways of doing business, incorporating a social equity bottom line into their thinking, working more flexibly, transparently, and practically with a wide range of stakeholders. The current inertia on access to medicines can be overcome by placing concerns about affordability and availability at the core of business decision-making processes and operations. To do so will require strong leadership and long-term vision.

Oxfam also believes that integrating access to medicines into the core business model will institutionalise a framework for the industry to predict, respond to, and satisfy the needs of people in developing-country markets. Investors who are encouraging pharmaceutical companies to enter emerging market economies identify the need to adapt prices, to have more flexible distribution systems, and to make products that are relevant to the markets being served, as necessary elements of a business strategy.

Oxfam recognises that the fact that a social good is being provided through the market is always going to pose challenges and is susceptible to the problems of market failure. Collective action to overcome this is an imperative.

In this context, society expects pharmaceutical companies – with their privileged access to a global market – to develop necessary products at prices that are affordable, in presentations that are usable, and to market them ethically. The pharmaceutical industry is expected to fulfil these requirements reliably and sustainably, and by so doing, play its part in the wider responsibilities to improve the health of all.

1 Introduction

In 2001, Oxfam launched the 'Cut the Cost' campaign in response to the drastic impacts on poor peoples' access to medicines due to the global intellectual property regime created by the TRIPS Agreement. As part of that campaign, Oxfam considered the role played by the pharmaceutical industry in pushing through the agreement, and looked at how companies' use of 20-year monopolies to set high prices was putting medicines out of reach for poor people. A subsequent report, 'Beyond Philanthropy'[6] (published by Oxfam in collaboration with VSO and Save the Children UK), reviewed companies' responses to the challenge of access to medicines and set a number of benchmarks to measure progress.

This paper seeks to establish how far companies have gone in demonstrating their commitments in the five years since that report. It also attempts to advance some ideas as to why companies may be resisting the challenge to meet their responsibilities more effectively. Finally, it considers factors that could encourage companies towards a more progressive approach and outlines the key areas that they need to focus on.

In the last year, there have been a number of initiatives[7] that have analysed the industry's response to the access to medicines challenge.[8] We hope to have contributed to the agenda by providing a development perspective on the issues and by maintaining the momentum on progressing change.

Information for this paper was gathered through interviews with the top 12 pharmaceutical companies[9] in terms of market capitalisation, as well as one biotechnology company, Gilead (because of its portfolio of HIV and AIDS medicines). We also made use of publicly available materials relating to the companies as well as country-specific information gathered by Oxfam programme staff.

2 Access to medicines: the challenge continues

The first part of this century witnessed major strides forward in meeting the health needs of poor people. While HIV and AIDS, malaria, and TB have posed some of the biggest challenges to global health, their levels of seriousness have attracted the political will and some financial commitments. New health threats such as severe acute respiratory syndrome (SARS) and Avian flu have also stimulated collective action and continue to keep health officials on high alert, given their ability to spread rapidly, kill quickly, and potentially cause global economic meltdown.

The disproportionate impact of these diseases on poor people in developing countries has gained critical attention. Overseas development aid for health from countries in the Organisation for Economic Co-operation and Development (OECD) has risen. Some developing countries have increased their health spend. Donor funding and aid for high-profile diseases, as well as private giving, have boosted national health budgets. Multi-stakeholder initiatives have made major contributions. For example, The Global Fund to fight AIDS, TB and Malaria estimates that it provides 20 per cent of all global support for HIV and AIDS programmes and 66 per cent of funding for efforts to combat TB and malaria.[10]

Activists' campaigns have highlighted the responsibilities of pharmaceutical companies to promote public health in developing countries. Under public pressure, companies have responded through some price cuts, donations, and other initiatives to increase access to medicines for poor people in developing countries.

The 'triple disease burden'

Against this backdrop of initiatives however, serious challenges exist. The changing disease pattern is resulting in a 'triple disease burden': new and re-emerging infectious diseases, 'old' diseases like respiratory-tract infections and diarrhoea, and non-communicable diseases (NCDs).

Infectious diseases remain the main cause of death in Africa. Malaria claims the lives of one million people every year globally – mostly children and pregnant women.[11] Two million people die annually from TB. Half a million cases of multi-drug resistant TB (MDR-TB) occurred in 2004.[12] Treatment for MDR-TB is a hundred times more expensive than standard treatment.[13] A 2006 survey found anti-TB

drug resistance in all of the 79 countries surveyed, with China, India, and the Russian Federation accounting for more than half of all MDR-TB cases worldwide.[14] Rising drug resistance is a problem for other infections too, including pneumonia (still the main cause of infant mortality[15]) and gonorrhoea (an important co-factor in the transmission and spread of HIV[16]). There is not enough research and development (R&D) into new antibiotics for these diseases, because R&D-based pharmaceutical companies do not see them as lucrative.[17]

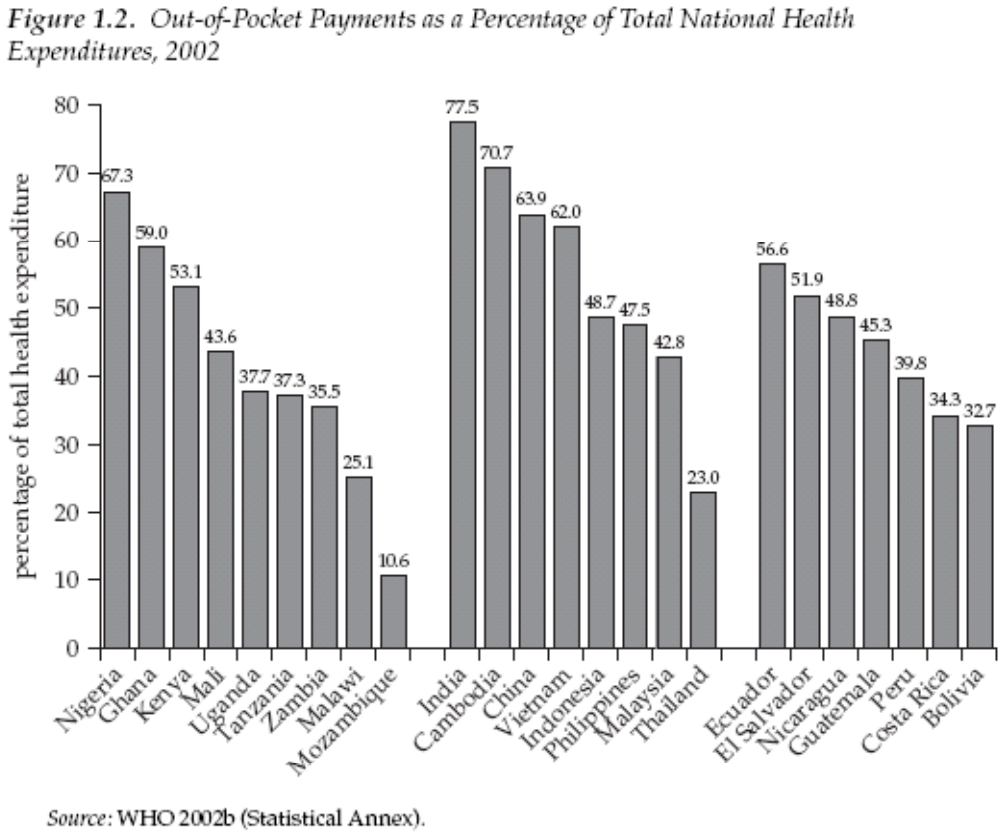
There are still 39.5 million people living with HIV – 2.6 million more than in 2004. Two-thirds of all adults and children living with HIV live in sub-Saharan Africa. As the virus becomes resistant to first-line and second-line therapies, new therapies are needed.

The growing incidence in developing countries of NCDs[18] – such as cancer, diabetes, asthma, hypertension, and cardiovascular-related illnesses – puts a severe strain on health systems and economic growth. NCDs account for at least 40 per cent of all deaths in developing countries.[19] Half of all global cancer deaths are in developing countries. The World Health Organisation (WHO) estimates that the occurrence of asthma is increasing on average by 50 per cent every ten years in cities in the developing world.[20] Cardiovascular diseases account for 25 per cent of all deaths in developing countries.[21] Changing diets, pollution in urban slums, growing consumption of tobacco by the young, and exposure to pesticides are some of the causes of rising rates of NCDs among poor people in developing countries. Yet little funding goes towards prevention and treatment.

Affordability and availability of essential medicines

According to the UN Special Rapporteur on the Right to Health, 'Almost 2 billion people lack access to essential medicines. Improving access to existing medicines could save 10 million lives each year, 4 million of them in Africa and South-East Asia. Access to medicines is characterised by profound global inequity. 15% of the world's population consumes over 90% of the world's pharmaceuticals.'[22] Though public spending in poor countries has increased, it is still not enough.[23] Budgets are under enormous strain and medicine purchases can make up a significant proportion of total public spending.

Figure 1: Out-of-pocket payments as a percentage of total national health expenditures, 2002



Source: WHO 2002b (Statistical Annex).

The cost of financing health care is still largely out-of-pocket (see Figure 1). For most individuals in developing countries, health-insurance coverage is non-existent, and spending on food and other basic needs is reduced in order to pay for essential medicines. The poorer people are, the greater the percentage of income absorbed by payments for medicines. In Brazil, the cost of medicines absorbs up to 82.5 per cent of out-of-pocket expenses for the poorest people.[24] The life-long financial commitment towards treatment of chronic diseases can drive families into a downward spiral of debt and poverty. Estimates for full income losses due to heart disease, stroke, and diabetes in Brazil, India, China, and the Russian Federation were more than $750bn in 2005, rising up to over a trillion for 2015.[25]

Additionally, poor people often choose not to get treatment or do not complete the necessary treatment when they cannot afford the cost of the medicines, and this leads to problems such as drug resistance.

For the vast majority of people in the developing world, the high prices of medicines contribute to their vulnerability. They depend in large part upon generic competition to bring prices down. A generic

medicine is typically between 20 per cent to 90 per cent cheaper than originator drugs.[26] The availability of lower-priced generics also reduces the price of originator versions through market competition.[27] Aid agencies are heavily dependent on access to inexpensive generics to meet the needs of those living below the poverty line. For example, 40 per cent of Médecins Sans Frontières' (MSF) budget for oral medicines is for generics, and up to 70 per cent of the anti-retrovirals used by PEPFAR (The United States President's Emergency Plan for AIDS Relief) are generics from India.[28] Hence the WHO affirmation that 'generic competition is the key, and governments should do all they can to increase the use of quality assured, low priced generics'.[29]

The global intellectual property regime, as established by the TRIPS Agreement, presents major obstacles to access to affordable new drugs. Twenty-year patent protection granted to 'new and inventive' products of R&D-based pharmaceutical companies results in monopolies which keep prices high. For example:

- The price of a course of pegylated-interferon, manufactured by Roche, and used to treat hepatitis C in Egypt is $6,800, or one and a half times the salary of the Minister of Health in 2004.[30]
- In Kenya, frusemide, a medication for congestive heart failure, costs 40 times the generic equivalent.[31]
- Novarsc, a drug that treats cardiovascular diseases, was seven to eight times more costly in the Philippines than in other parts of Asia, until patent expiration in 2007 brought prices down.[32]

MSF predicts another price crisis for anti-retrovirals, particularly as WHO revises its treatment guidelines to replace older first-line medicines with patented counterparts that are less toxic.[33] Although some companies dropped prices and showed some flexibility on patents for anti-retrovirals in the wake of the HIV and AIDS pandemic, they are less amenable in the case of improved first-line and second-line anti-retrovirals where generics have yet to enter the market.[34] Second-line anti-retrovirals can be up to ten times more expensive than first-line treatments.[35]

The Doha Declaration and the Paragraph 6 solution[36] reaffirmed the right of developing countries to apply the safeguards to protect public health which are built into the TRIPS Agreement. In a few cases, developing-country governments have had the tenacity to use them to reduce the prices of medicines but this has been at the expense of attracting massive pressure from the USA, the EU, and the drug companies.[37] To date, examples of successful use of compulsory licensing[38] and parallel importing[39] are few and far between.

Although least-developed countries (LDCs) have an exemption on introducing TRIPs requirements into national legislation until 2016, their high dependency on the availability of cheaper generic medicines, most of which originate from India, whose laws are already TRIPS-compliant, could significantly increase their vulnerability.

There are other reasons why medicines are unaffordable to poor people in developing countries. A recent survey found that medicines – both branded versions as well as generics – can be prohibitively expensive due to taxes, add-on costs in the supply chain, and mark-up by pharmacists and dispensing doctors. Furthermore, some public-health authorities buy expensive originator brands (even though inexpensive generics are available) and charge far above the international reference price for these medicines.[40]

High prices are not the only constraint on access to medicines. The lack of medicines relevant to diseases of the developing world also continues to hamper advances in improving poor people's health. There is a pressing need to produce new drugs that treat diseases that affect predominantly developing countries[41] like dengue and sleeping sickness; that are specially designed for use in resource-poor settings; that are adapted for use in adverse environmental conditions; and that address the specific needs of particular groups, for example pregnant or breast-feeding women. There is also a need for medicines for NCDs that are formulated so as to be effective in poor countries.

However, these are the needs of people who lack purchasing power. This, coupled with severely constrained public-health systems, means the return on investment is not sufficient to incentivise pharmaceutical companies to conduct R&D in these therapeutic areas (see Box 1). Between 1975 and 1999 only one per cent of a total 1,393 new chemical entities (NCEs) marketed were for neglected diseases. Between 1999 and 2004, there were only three new drugs for neglected diseases out of 163 NCEs.[42]

Box 1: Research and development into neglected diseases

Examples of the lack of safe, appropriate, and affordable diagnostics, drugs, and vaccines for neglected diseases include:

- 60 million people are at risk of contracting sleeping sickness. Treatment is based on a highly toxic arsenic derivative in use since 1940s and a former cancer drug from the 1980s.
- TB is responsible for nearly two million deaths each year but treatment takes six months and is difficult to implement. The most recent medicine is 30 years old.
- 340 million sexually transmitted infections occur every year. Simple, effective treatment exists but many are not getting it because of lack of simple, reliable tests.

Source: MSF Addressing the Crisis in R&D into neglected diseases, 26 January 2006

The R&D-based pharmaceutical industry has argued that without the current intellectual property regime there would be no innovation, and thus no medical advances. This argument is being heavily challenged (see Section 5). For example, in the context of developing countries, the findings of the independent Commission for Intellectual Property Rights, Innovation and Health (CIPIH) established by the World Health Assembly, show that higher levels of intellectual property protection have not resulted in increased R&D for the health needs of poor people.[43]

Oxfam believes that governments are primarily responsible for sustaining effective public-health systems that are both accessible and affordable.[44] A fundamental aspect of fulfilling these obligations is ensuring universal access to medicines. Governments should develop effective distribution channels which ensure that the appropriate medicines reach the right locations at the right time. Further key responsibilities include adopting national medicines policies, R&D portfolios, anti-counterfeiting measures, and regulatory standards that are consistent with promoting and respecting the human right to health.

However, as pointed out by the UN Special Rapporteur on the Right to Health, many states emphasise the profound impact – positive and negative – of pharmaceutical companies on the ability of governments to realise the right to the highest attainable standard of health for individuals within their jurisdictions.[45]

Oxfam acknowledges that there is a fundamental difficulty stemming from the fact that a product – medicines – upon which all of us depend for our welfare, and often our lives, is left to the vagaries of the market to distribute equitably. It is only through the collective

action of all the stakeholders that we will overcome the challenges that this poses.

In the next section, we evaluate how far one of these stakeholders – the R&D-based pharmaceutical industry – has moved in the last five years, to overcome these problems.

3 Has the pharmaceutical industry moved beyond philanthropy ?

The 2002 report 'Beyond Philanthropy'[46] analysed how far the top 12 research-based pharmaceutical companies were prepared to embed concerns about access to medicines in their policies and practices. The aim of the report was to reflect the shift in the terms of debate on the responsibilities of the pharmaceutical companies driven by the growing global health crisis and immense public pressure on the industry. The report stated that although companies had responded to the challenges of access to medicines, the tendency was for companies to implement mainly philanthropic programmes. It argued that a *responsible* company's policies would include the five priorities of pricing, patents, joint public–private initiatives (JPPIs), R&D, and the appropriate or rational use of drugs, all of which relate to the core business operations of an R&D-based pharmaceutical company. The report broadly concluded that while positive movement from the industry especially in the area of infectious diseases was welcome, there was still a long way to go in terms of affordability and availability of essential medicines.

This section reviews progress since 'Beyond Philanthropy' (i.e. between 2002 and 2007) in three of the five areas: pricing, R&D, and patents, in order to identify where there have been sufficient advancements and where gaps remain. Our review against only three areas reflects the focus of this paper. It does not discount the relevance of JPPIs or appropriate use of medicines.

The findings of the review are captured in Appendix 1. Three tables summarise the initiatives companies have taken with respect to pricing, R&D, and intellectual property. These are accompanied by three charts that give Oxfam's perspective on how companies' actions reflect their level of strategic commitment towards meeting access to medicines challenges.

Benchmark on pricing

'Beyond Philanthropy' called for companies to adopt policies that would substantially lower the prices of medicines in developing countries, and for price reductions to apply to a range of products that are relevant to health in developing countries, rather than coverage being limited to one or two 'flagship' drugs. Transparency in pricing offers was deemed necessary to enable low-capacity health authorities to make appropriate purchasing decisions. The report identified the need for a systematic global approach to pricing, overseen by an international public-health body.

The report concluded that although pricing was the one area where companies could do most to address the health crisis, it was the area in which they were doing least. Although a number of companies were offering selected drugs at lower prices or were dropping the prices of medicines for specific high-profile diseases, not one was prepared to support a global tiered-pricing system nor systematically offer lower prices in developing countries. A few companies were prepared to be transparent about their pricing as a means of providing the public with a rationale as to value.

Developments since 2002

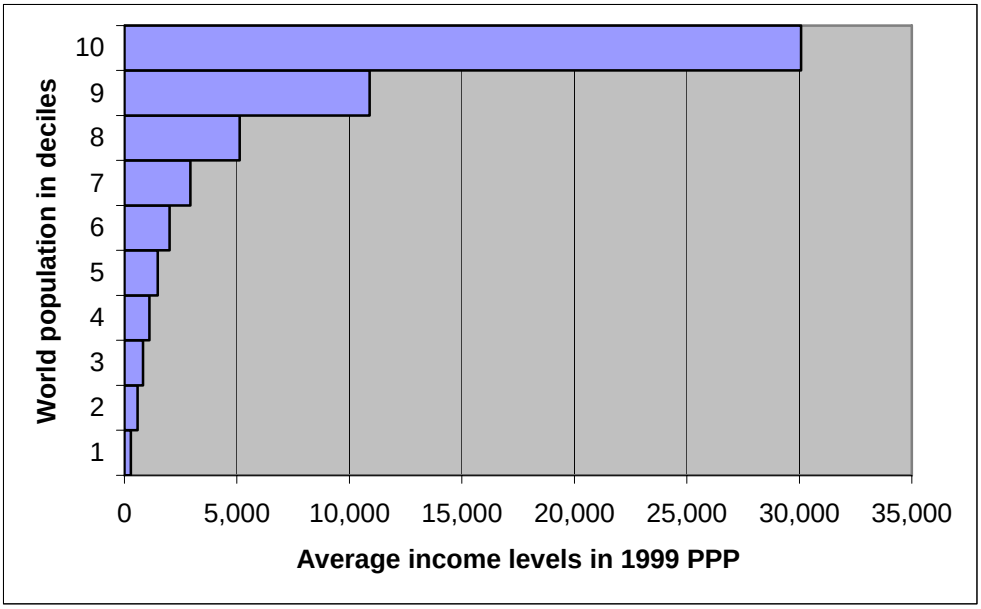
A number of companies now offer differentiated prices, but primarily for high-profile diseases like HIV and AIDS and malaria. Oxfam's interviews for this paper revealed that some companies have reduced prices in LDCs for certain diseases. Some companies are introducing tiered pricing for other treatments (e.g. GlaxoSmithKline for some antibiotics and diabetes treatments and Sanofi-Aventis for epilepsy).[47] Merck has expressed a willingness to adopt similar policies for its cervical cancer vaccine.[48]

A few companies have included middle-income countries in their differential pricing policies, again primarily for HIV and AIDS, malaria, and TB drugs. Even so, the discounted prices are often well above people's means. About 60 per cent of the world's population live on less than $2000 a year, and many discounted prices still fall out of this range (see Figure 2). For instance, Abbott's anti-retroviral Kaletra was sold at $2,200 in Guatemala, where the gross national income per capita is $2,400.[49] In 2007, Thailand issued a compulsory licence for Kaletra. Subsequently, in April of that year, the company brought prices down to $1000 per patient per annum in all middle-income countries.

Overall, the usual approach for pharmaceutical companies is still to adopt specific policies on a case-by-case basis, largely reflecting the degree of publicity surrounding the disease or the country. A global

systematic approach towards tiered pricing still appears to be far off, and those companies that have introduced forms of tiered pricing still lack a clear policy of price-setting and implementation.

Figure 2: World population deciles and income levels in 1999 purchasing power parity (PPP) dollars



Source: Y. Dikhanov (2005) 'Trends in Global Income Distribution 1970–2015', from UNDP Human Development Report

'Beyond Philanthropy' considered market segmentation as a means of addressing vast disparities in wealth in developing countries. Currently, a number of companies – somewhat simplistically – segment the market into two in some developing countries: rich and middle-income people for whom medicines are priced at a level similar to those in the developed world, and poor people, who are provided with drugs at allegedly non-profit prices through philanthropic programmes and partnerships or via patient-access programmes. Novartis, Eli Lilly, and Johnson & Johnson have taken this route. GlaxoSmithKline is working on a more nuanced approach, which it calls the 'Tearing Down the Barriers' strategy. It comprises various pilot projects, including tiered-pricing models within as well as between countries; gauging the relationship between price and volume for selected products in targeted middle-income countries; and differential branding strategies in targeted middle-income countries.

Finally, with regards to transparency, most companies now publicise the prices for anti-retroviral medicines and malaria medicines, but price offers or tenders to various sectors (e.g. private, dispensing doctors) are still not transparent, making it difficult to verify 'not-for-profit' or 'at-cost' prices. If tiered pricing is to deliver sustainable low prices, it needs to be applied in a consistent and transparent manner[50] with prices set according to a standard formula with the price rationale reflecting the purchasing power and health needs of the population.

Some companies expressed an opinion that there are other factors that are as much to blame for unaffordable medicines such as abusive mark-ups and taxes, as well as inefficiencies in the procurement system and distribution chain. WHO recommends that 'Governments should remove any tariffs and taxes on health care products, where appropriate, in the context of policies to enhance access to medicines.'[51] However, factors other than tariffs – such as manufacturers' prices and mark-ups – can and do form a significant percentage of the final price,[52] and greater transparency on the part of manufacturers would allow civil society and governments to improve monitoring of price components which could result in reducing the end-price paid by patients.

Benchmark on research and development

Between 1975 and 1999 only one per cent of a total 1,393 new chemical entities (NCEs) marketed were for neglected diseases. Between 1999 and 2004, out of 163 NCEs, there were only three new drugs for neglected diseases.[53] 'Beyond Philanthropy' called for companies to support initiatives that address this gap, to forgo patent rights for drugs developed within JPPIs, and for these drugs to be made affordable to developing countries. It also asked that companies publish target expenditure for their R&D on infectious diseases.

At the time of the 2002 review, no company was prepared to disclose the value or proportion of their R&D expenditure on infectious diseases, either on an individual or aggregate disease basis, thus giving no indication as to how much companies prioritised this health need. The report welcomed the fact that several companies had announced programmes for research facilities for R&D into infectious diseases, and welcomed their participation in JPPIs, but found that no companies were able to quantify the impacts of the former nor the contributions to the latter.

Developments since 2002

In the intervening years, many companies have increased their involvement in R&D for infectious diseases prevalent in developing countries (mostly HIV and AIDS, TB, and malaria), especially through global public–private initiatives (GPPIs).[54] Companies interviewed in 2007 believe that the lack of commercial incentives to act unilaterally mean that GPPIs are the way forward to conduct R&D into diseases that predominantly affect developing countries and to bring medicines developed 'in-house' to the market. Yet to Oxfam's knowledge only one product – a non-patented once-a-day fixed-dose combination for malaria – has made it to the market as a result of a GPPI.[55] Another key issue is whether patents should be sought for medicines developed within GPPIs. In the case of the Sanofi-Aventis-DNDI anti-malarial medicine, the group decided 'not to file a patent for the formulation so that it would be more rapidly accessible to the affected populations'.[56] However, Novartis takes a different view and has stated that the company should secure patents for any products it develops through these partnerships.[57]

All the companies interviewed now publish their total R&D expenditure as a percentage of sales in their annual reports. However, companies' reported expenditure is still veiled in secrecy. Breakdowns of costs and which inputs are factored into calculations are unknown.[58] Companies still do not publish the target expenditure for R&D into diseases prevalent in developing countries.

In reporting on their participation in GPPIs, most companies do not disclose their targets in terms of the product timelines or financial and technical contributions, thus making it difficult to monitor companies' achievements against specific set targets. This lack of indicators renders it difficult to assess companies' commitment to GPPIs. Finally, the companies do not appear to address separate pricing policies for those products developed via GPPIs. They are addressed together with their pricing policies for specific products for developing countries.

From the interviews, Oxfam gathered that some companies have enhanced their portfolio of in-house R&D into infectious diseases prevalent in developing countries. The primary focus however remains on a few infectious diseases, especially HIV and AIDS, TB, and malaria. This is not misplaced, since these diseases are still important causes of death and morbidity in developing countries, especially in Africa. Demand for new medicines to combat these diseases remains high, in part due to drug resistance.

Yet, as shown in Section 2, there is a critical need for companies to have a more diverse and strengthened R&D portfolio that better

reflects the chronic lack of innovation for diseases predominantly affecting poor people in the developing world. Formulations that are suitable for use in developing-country climates, as well as, for example, particular groups like children or pregnant or breast-feeding women are still not developed to the extent needed, even though the capabilities exist. Furthermore, R&D could go into formulations that can ensure treatment is affordable, particularly for chronic diseases – for example, expensive delivery systems should be simplified when feasible.

Benchmark on intellectual property

In 'Beyond Philanthropy', the approach of drug companies to intellectual property rights in developing countries was a key indicator of a commitment to access to medicines. The report called for companies to refrain from enforcing patents where it would exacerbate health problems. It called on companies to support the safeguard mechanisms in TRIPS and to refrain from lobbying for more stringent applications of TRIPS (i.e.TRIPS-plus rules).

Little evidence was found of an increased commitment to a flexible approach to patent protection by the companies. None of the companies had a corporate policy that reflected this. Some companies indicated that they were involved in legal challenges on the right of developing countries to use existing flexibilities under the TRIPS Agreement, with cases having serious public-health implications for poor people in developing countries. None of the companies appeared to support waiving patents in generics-producing countries. Only three of the companies stated that they were not lobbying government to press for 'TRIPS-plus' commitments from developing-country governments. Others remained silent on the issue.

Developments since 2002

Despite demands from public authorities, inter-governmental organisations, civil society and patient groups, the pharmaceutical industry remains unyielding in its view that the current intellectual property regime does not constitute a serious barrier to ensuring access to medicines for poor people. The International Federation of Pharmaceutical Manufacturers Association (IFPMA) says 'Claims that patents are a barrier to access to medicines are unfounded and inaccurate'.[59] Many companies within the industry still believe that stricter levels of intellectual property protection are necessary to stimulate R&D, even in developing countries. The opposite has been confirmed by WHO which states: 'Where the market has very limited purchasing power, as is the case for diseases affecting millions of

poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market'.[60] The industry has also appeared to be narrow-minded on the needs of developing countries to have differing levels of intellectual property protection to compensate for their different levels of economic development and public-health needs.[61]

Box 2: Protecting patents: Novartis in India

In 2007, Novartis challenged – and lost – a decision by the Indian Patent Office to reject its application for a patent on its drug, Glivec (used to treat chronic myeloid leukaemia and gastrointestinal stromal tumours). Novartis' application was rejected on the grounds that Glivec did not meet the 'enhanced efficacy' requirements in the Indian Patent Law. The Patent Office based its decision on a provision – section 3(d) – of the Indian Patent Law that prohibits the patenting of new forms of known substances unless they are significantly more effective than the known substance. Section 3(d) has the effect of preventing pharmaceutical companies from taking out a patent on a product unless it contains a 'novel and inventive step'. This ensures that the entry of generic competition is not unnecessarily prevented.

Novartis also issued a writ petition on the constitutionality of section3(d) and challenged its compliance with the TRIPS Agreement. The Chennai High Court dismissed the constitutional challenge but ruled that the TRIPS compliance challenge needed to be considered by the WTO. Novartis did not appeal against this. In subsequent press coverage, Novartis CEO Dr. Daniel Vasella was quoted as saying: 'This ruling is not an invitation to investing in Indian R&D, which we would have done. We will invest more in countries where we have protection…Do you buy a house if you know people will break in and sleep in your bedroom?'(*Financial Times, 22 August 2007, 'Novartis set to switch India R&D plans after court ruling'.)*

Novartis has told Oxfam 'there is virtually no commercial market for Glivec in India'. Through its Glivec International Patient Assistance Program (GIPAP), Novartis donates the medicine to over 8000 patients in India for free. It does however sell Glivec at $24,000 per patient per year. Indian generic manufacturers provide the medicine at one-tenth of that price.

Considering the absence of a market for Glivec in India and more importantly, the fact that poor people in India are dependent upon generic competition for affordable medicines, Novartis' decision to institute the legal challenges was a wrong one. The public outrage that it attracted – more than 200,000 people expressed their discontent with the company –cost the company its reputation dearly.

Some within the industry have gone further to argue the need for even stricter intellectual property protection. Merck, Johnson & Johnson, and Pfizer, for example, support the need for explicit provisions on data exclusivity and linkage[62] to be included in national intellectual property regimes. In Oxfam's view these amount to TRIPS-plus rules.[63] These two rules have the effect of preventing

developing countries from applying public-health safeguards to introduce generic versions of medicine during the patent term and delaying the introduction of generic medicines when the patent expires. Oxfam's research shows that the imposition of TRIPS-plus rules in Jordan through the US–Jordan Free Trade Agreement has contributed to higher medicine prices (20 per cent higher than in 2001), consequently threatening the sustainability of government public-health programmes, and delaying generic competition. In Jordan, medicines needed to treat many serious diseases, including cardiovascular diseases and diabetes, are two to six times more expensive due to these rules.[64]

The industry also applies its lobbying clout to push the USA and EU to introduce TRIPS-plus rules into developing-country national laws through free-trade agreements, bilateral and multilateral negotiations, and trade sanctions, and to severely circumscribe the use of TRIPS safeguards and flexibilities to promote access to medicines.

WHO states that governments should try to procure the lowest price, quality generic available, and that to do so, they should employ all the policy tools available including the safeguards and flexibilities provided in the TRIPS Agreement.[65]

Increasingly, developing-country governments are turning to these safeguards – compulsory licensing to reduce the prices of medicines during the patent term, and the Bolar provision to register and market a medicine immediately upon patent expiration. Other countries are narrowing the scope of patent protection to curb industry abuse of the patent system, whereby numerous frivolous patents are introduced by companies to extend the patent term of a medicine far beyond 20 years. Companies have viewed the use of these provisions as inimical to the industry's interests and have pressured governments not to use them (see Box 3). A recent example is playing out in the Philippines.[66] The Philippines has the second highest medicine prices in Asia. It is estimated that half its population of 85 million lack access to affordable medicines. In February 2007, as a means to manage this situation, the Philippines House of Representatives passed the Medicines Bill in order to incorporate TRIPS public-health safeguards into its Intellectual Property Code. As the bill was being considered, evidence that the pharmaceutical industry was lobbying heavily against its passing came to light. In a press release, the Department of Health stated that it 'lauded the efforts of several lawmakers for slamming shameless lobbying of major international drug firms during the second reading'. This bill is currently being considered by Congress and similar allegations of lobbying are being made by the media.[67]

Box 3: Obstructing the use of TRIPS safeguards: Thailand case study

Thailand has made serious efforts to ensure universal access to medicines through a robust public-health system, which charges at most 30 baht (94 cents) for a visit to a clinic or hospital. This includes free provision of medicines, insofar as medicines are available at an affordable price within the public-health system. In recent years, the high price of new, patented medicines has limited the free provision of medicines through the public-health system. For example, the prices of two key anti-retroviral medicines, efavirenz, manufactured by Merck, and Kaletra, by Abbott, threatened Thailand's ability to ensure care of the existing 80,000 patients on HIV treatment, and to expand treatment to an additional 20,000 patients needing care.

Price negotiations between the Thai government and Abbott to either issue voluntary licences to generic manufacturers or reduce the price of its medicines ensued. Over a two-year period, negotiations failed to result in the company meeting Thailand's request, despite the fact that its anti-retroviral medicines were ten times more expensive than first-line treatments, and in spite of warnings from institutions, including the World Bank, that high prices for these medicines would jeopardise Thailand's much-lauded HIV treatment programme. Negotiations also ensued between the Thai government and Merck for its anti-retroviral, efavirenz. Thailand eventually issued two compulsory licences on both medicines. In response, Merck reached an agreement with the Thai government to reduce the price of efavirenz to prices comparable to generic versions. Abbott however, responded by withdrawing the registration of seven new medicines in Thailand, including a heat-stable version of Kaletra (used where there is insufficient access to electricity). The US government also placed pressure on Thailand to rescind the compulsory licences, and to discourage Thailand and other developing countries from issuing additional compulsory licences.

Other pharmaceutical companies have also refused to reduce the price of their medicines or issue voluntary licences to ensure affordability. Sanofi-Aventis for example offered its medicine clopidogrel at a price that is 60 times more expensive than the generic equivalent and 250 times more expensive than the first-line counterpart, aspirin. Clopidogrel is an antiplatelet agent used in the treatment of cardiovascular disease. The price of the medicine meant that most patients requiring it could not get treatment through the public sector. Thailand announced its intention to issue a government-use licence to produce a generic version. Sanofi-Aventis responded to Thailand's announcement by offering a special access programme that would provide up to 3.4 million tablets of the medicine at no additional cost. Simultaneously however, the company apparently exerted pressure on Thailand through two mechanisms: first, it appears to have lobbied the European Commission to urge the Thai government and the Thai Ministry of Health to withdraw the compulsory licences, and second, the company sent a warning letter to the Indian generic manufacturer, Emcure, which offered to fulfil the Thai government's tender request.

Recently, the Thai government announced that it is in a position to seek compulsory licences for another 20 medicines on its national essential

medicines list, including drugs to treat diabetes, hypertension, and various cancers.

Sources: Intellectual Property Watch, 'Twenty more drugs in pipeline for possible compulsory licenses', 2 November 2007; Ministry of Public Health and National Health Security Office Thailand, 'Facts and evicences on the 10 Burning Issues related to the Government use of patents on three patented essential drugs in Thailand', February 2007.

When interviewed by Oxfam, most companies stated their support for TRIPS safeguards and flexibilities as reaffirmed by the Doha Declaration (insisting that they should only be used in the case of emergencies or urgent situations, and only in LDCs, or for treating HIV and AIDS). Only a few of the companies interviewed have acted on this belief (see Appendix 1). Flexibility in LDCs is less impressive than it sounds. First, the TRIPS Agreement exempts LDCs from applying TRIPS rules until 2016. Second, LDCs have little generic manufacturing capacity, so companies are unlikely to see their patents being challenged in these countries anyway. Further, adhering to WTO rules in LDCs by not patenting medicines means little when pharmaceutical companies seek stricter levels of intellectual property protection in developing countries with robust generics industries, thus hampering the import of generic medicines from countries that *do* have manufacturing capability, like India or Brazil.

In African countries with commercially attractive markets, companies have shown less flexibility on intellectual property rules. In Kenya and South Africa, pharmaceutical companies are enforcing some patents on anti-retroviral medicines. Abbott, for example, has obtained and enforced patents for their new anti-retroviral medicine in South Africa, despite a massive population of people living with HIV who will soon need access to affordable versions of these new medicines.

Where voluntary licences have been issued, they have mainly been for first-line anti-retrovirals where prices are no longer a serious problem. To Oxfam's knowledge, only one voluntary licence has been issued for a second-line anti-retroviral:[68] Bristol-Myers Squibb issued one to Emcure, an Indian generics firm, for Atazanavir.[69] The only other exception is Roche's voluntary licence for oseltamivir (Tamiflu) to Hetero in India. It is worth noting that huge public pressure came to bear once a number of Indian generic companies announced their ability to produce and to sell oseltamivir (Tamiflu) at a fraction of the price.

Oxfam believes that although voluntary licences can contribute to price reductions, they are not the preferred method of ensuring lower prices. Over the last decade, evidence has repeatedly demonstrated

that generic competition is the most effective and proven method to reduce medicine prices. However, if voluntary licences are rigorously regulated to promote competition, they can play some part in ensuring access to affordable medicines in developing countries. To be useful, voluntary licences must be transparent and non-exclusive, and also include unconditional royalty-free technology transfer. Geographical restrictions should exclude only developed countries; distribution should be permitted for both the public and private sectors, and should not include any price controls or limitations on product output. Further, the licence should allow the licensee to rely on proprietary data for registration and market approval so as to avoid delay and further cost of clinical trials.

One step forward, two steps back

Has the pharmaceutical industry moved beyond philanthropy? A little, but not enough to significantly tackle the problem. 'Beyond Philanthropy' identified actions that would achieve this end. While there has been an increase in pharmaceutical company initiatives with respect to R&D into diseases that predominantly affect developing countries (and to a lesser extent, pricing policies), many of the benchmarks that it set in 2002 have not been met.

In the intervening years, the challenges to global public health have intensified, making an adequate response by the industry even more critical. Major shortcomings of current approaches include:

- a failure to implement systematic and transparent tiered-pricing mechanisms for all essential medicines of therapeutic value to poor people in developing countries, where prices are set according to a standard formula which reflect ability to pay and the price of generic versions where they exist;
- the lack of R&D to address the dearth of dedicated products for diseases that predominantly affect poor people in developing countries. This includes drug formulations that are applicable and usable in the developing world;
- persistent inflexibility on intellectual property protection, and in some cases, active lobbying for stricter patent rules and legal challenges to governments' use of TRIPS public-health safeguards, thereby preventing poor people from accessing cheaper generic versions of essential medicines.

Finally, as was the case in 2002, there is still much too heavy an emphasis on donations at the expense of exploring other ways to meet the access challenge. Often called Access Programmes and targeted only at a relatively small group of people, donated

pharmaceutical products make a limited contribution towards sustainable national health services. There have been some successes in the context of specific disease-eradication programmes: Merck's ivermectin programme (Mectizan Donation Programme) for the elimination of river blindness as a public-health problem in Africa and Latin America is an example.

Most of the evidence stacks up against their use. For example, in September 2007, Merck announced its plans to donate three million doses (one million courses) of its cervical cancer vaccine, Gardasil, to poor countries over the next five years.[70] Nearly half a million girls and women are diagnosed with cervical cancer every year, 80 per cent of whom live in poor countries. The vaccine is intended at least for all 11- and 12-year-old females, but is appropriate for all females from the ages of nine to 26, creating a market far exceeding the donation,[71] raising questions about how sustainable this donation is. The company has, however, recently indicated its intention to implement tiered pricing for the vaccine.[72]

Furthermore, donated products have been found to be unsuitable, near expiry, and unfamiliar to local prescribers. Supplies are unpredictable in terms of timing and volume. Sometimes, they do not match national clinical guidelines and can undermine clinical standards.

Critically, donations create chaos in the market for low-cost medicines, as they prevent accurate quantification of needs, and affect forward planning throughout the chain of supply from producer to patient. Undermining market competition is particularly serious, as generic companies cannot compete with free drugs: the ability to predict demand is necessary if they are to use their innate efficiencies to achieve low prices.

4 Obstacles to progress

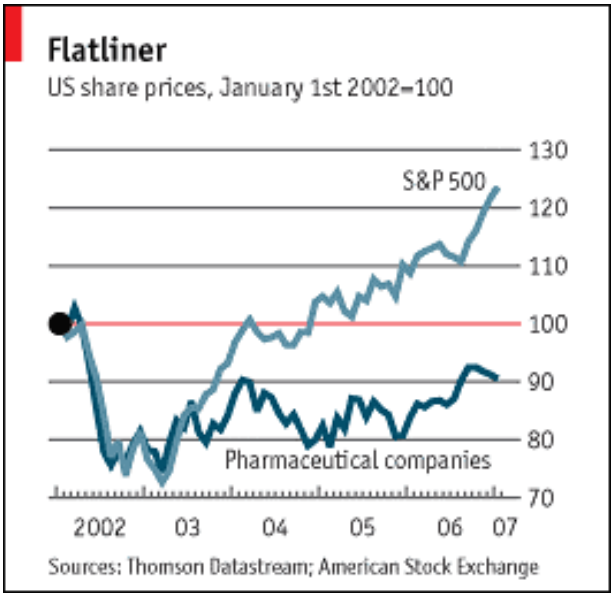
In the face of today's global health challenges, the pharmaceutical industry's contributions to meeting global health needs have been regrettably limited. Oxfam believes that there are two factors that have prevented companies from moving forward.

First, companies' pursuit of strategies that address access to medicines as an issue chiefly relevant to their own reputation, rather than a core component of their business models, has led to patchy, ad-hoc approaches which have failed to deliver sustainable solutions. The preoccupation with donations and community programmes demonstrates this clearly.

Second, as will be explained, the industry's responses to flagging financial performance – including hiking up prices and aggressive defence of patents – and increasing competition have undermined needs for lower prices, flexible approaches to patenting, and R&D investment into diseases relevant to the developing world.

Though the pharmaceutical industry remains one of the most profitable industries within the Fortune 500, it has in recent years experienced below-average performance due to deteriorating R&D productivity, unprecedented patent expirations, increased competition from generics and biotechnology companies, and an eroding reputation (see Figure 3). One analyst recently calculated that the pharmaceutical industry has lost one trillion dollars of enterprise value (this is a measure of future profitability) because of loss of faith by investors in this industry's ability to grow.[73]

Figure 3: Flatliner – US share prices



Source: Economist, 2007[74]

Propping up this failing business model has led some companies to aggressively protect two central pillars of their business models: intellectual property and prices. A large part of the problem stems from a dependency on the 'blockbuster' model. In the 1980s and 1990s most of the R&D-based pharmaceutical companies derived their huge profits from blockbuster drugs (those that generate $1bn per annum). Maximum profit margins were ensured by charging what the market could bear, defending patents unreservedly, and investing in prolonging the lifetime of a blockbuster through formulation changes. This approach has stuck, and despite the fact

that the blockbuster model is now failing to deliver, many companies are finding it difficult to break old habits. Hence we have witnessed some companies defending their patents with uncompromising vigour, hiking up prices for the remaining period of the monopoly, employing inappropriate advertising, 'ever-greening',[75] and implementing other schemes designed to maintain profitability, as the pipeline dwindles and key patents expire.

Mainstream investor demands for high financial quarterly returns have perpetuated these actions to counteract poor financial performance. Under these circumstances, policies that increase access to medicines have either fallen foul of these short-term tactics or at best, fail to receive proper attention from senior management (whose own incentive packages are often tied into three- to five-year performance cycles).

Such actions have been harmful to poor people in developing countries as they have resulted not only in prohibitively high prices of branded medicines, but also have blocked inexpensive generics from entering the market. The longer-term impact of the dependency on the blockbuster model is the lack of investment in new treatments and formulations particularly for diseases prevalent in the developing world. These actions have become so embedded in corporate culture that companies pursue them even when they make neither commercial nor moral sense.

Some responsible investors have encouraged the pharmaceutical industry to take a longer-term view of its business as a means of delivering longer-lasting profits sustainably. In 2004, the UK-based Pharmaceutical Shareowners Group (a group of 14 institutional investors representing £900bn assets) released a report that outlined the risks stemming from the public-health crisis in emerging markets, and assessed how well the companies were managing the challenge. The report concluded that poor management of the issue would have significant impacts on long-term share value and that the companies needed to improve in areas including pricing, R&D, and intellectual property to mitigate the risks.

5 Addressing the challenges: reasons to change

The pharma industry has enjoyed high profit margins for many years now and the public is beginning to sit up and take notice. There is a perception that the industry has been greedy, especially with regards to patent protection and resistance to generic challenges. It is under pressure to reduce

its prices and lower its profit margins.' (Linklaters Financial Times Report)[76]

Oxfam believes that the potential for pharmaceutical companies to contribute more effectively and substantially towards increasing access to medicines for poor people in developing countries has yet to be met.

There will be some in the industry who will continue to argue against the need for companies to do more than they already do or to adopt policies that they consider to be inimical to their profitability. However, changing expectations and new realities could mean that a fundamental shift in this direction will become an inevitable requirement for long-term survival. Three of the factors that could influence this shift are outlined below.

Calls for lower prices and price transparency

With ageing populations and the ratio of non-working to working people increasing in the industrialised world, the financial demands on traditional tax-based social health-care and employer-funded models are becoming difficult to bear. As a consequence, increasingly constrained public-health systems seeking cost-efficient outcomes are demanding a price mechanism that is more economical, value-based, and transparent. Legislation aimed at controlling rising prices has been introduced.[77] Some governments are exploring payment schemes that are directly correlated to the performance of the drug, including reimbursement clauses when evidence shows under-performance, as well as limiting treatment coverage for excessively priced medicines.[78]

Persistent scrutiny from civil society and patient groups will undoubtedly result in higher levels of transparency for price-setting and other aspects of pharmaceutical companies' performance. The scientific community, regulators, and governments also want increased transparency with regards to data from all clinical studies. These pressures forecast an end to the long-lived exclusivity and secrecy around price-setting.

Current incentives for drug development are being questioned

Calls to reform the intellectual property regime so that it rewards real innovation are growing ever louder. The argument is that the current regime (which allows long patent periods which can then be further extended through 'ever-greening') means that companies have less incentive to invest in R&D into new medicines. Reformers advocate for patent incentives to be more correlated with therapeutic gains and effectiveness rather than prolonging the market exclusivity of blockbusters.

Additionally, investors, prodded by the industry's poor productivity and impending patent expirations, would like companies to widen and diversify their drug portfolio to spread risk.[79] While their interest in maintaining a strict intellectual property regime is obvious, their demands for improved innovation could contribute to the agenda for change.

WHO is also voicing serious concerns that 'the incentive effect of intellectual property rights lacks efficacy'[80] especially in developing countries. Developing-country governments and public-health advocates are unifying behind this questioning of the 'market-driven' model of drug development. Developing countries have engaged in a WHO-driven process to develop new approaches to both innovation for new medicines and access to existing medicines. In particular, developing-country governments have expressed strong support for different models of development including 'pull' mechanisms that rely[81] upon prizes in lieu of intellectual property rights.[82] The WHO process has also explored advance-purchase commitments, particularly for medicines for diseases which fail to attract sufficient investment because of low profit potential, and a medical research and development treaty, which would be additional, alternative, and complementary to the existing patent system.

New markets, new opportunities, different needs

Emerging market economies[83] are starting to prove their worth as the growth area for the pharmaceutical industry. These markets offer invaluable means of lowering the costs of R&D and manufacturing, and provide clear advantages for improving drug development. Contract research organisations based in emerging market economies are able to conduct clinical trials cheaper and faster than in developed markets. One study by DFID estimates that overall, clinical-development costs in India are 40 to 60 per cent lower than in most developed countries.[84] The large number of 'treatment-naïve' patients are particularly attractive to pharmaceutical companies for large-scale clinical trials. Furthermore, countries like China and India offer a pool of talented scientists and the relevant technology to conduct sizeable proportions of R&D.

Contract manufacturing has also emerged as an important growth area in the pharmaceuticals sector. It is estimated that the contract manufacturing market for global companies in India will hit $900m by 2010.[85] Asia hosts numerous big pharmaceutical manufacturing sites. Singapore, for instance, has increasingly positioned itself as a biomedical outsourcing destination. Global firms depend to a large extent on Indian and Chinese companies for many of their active pharmaceutical ingredients and intermediates.[86]

The market potential of developing countries is the most attractive reason for pharmaceutical companies to heavily invest in developing countries. In 2005, the emerging markets generated incremental sales almost as large as those from the US market. According to recent estimates, by 2020, Brazil, Russia, India, China, South Africa, Mexico, and Indonesia could account for up to one-fifth of global sales. China is predicted to become the seventh biggest pharmaceutical market in the world by 2010 with annual sales of $37bn.[87] If these markets continue to grow as predicted they may surpass the USA and other industrialised countries as a source of incremental sales.

The growth opportunities in emerging markets have been seized on by investors as representing the panacea to flagging performance by the pharmaceutical industry. For this potential to be realised however, investors recognise that serving these markets requires companies to adapt prices, to employ flexible distribution systems, to abandon the blockbuster model in favour of developing drugs for niche markets and if necessary, a high-volume, low profit margin model.

From Oxfam's perspective, there are two key factors that companies need to take account of when devising their strategies for entering developing-country markets.

First, while a wealthy elite exists within these countries, the vast majority of the population requires access to inexpensive medicines (see Box 4), either purchased out of their own pockets or by governments or aid agencies. Under these circumstances, a primary responsibility of the company is not to hinder access to such medicines. In order to meet this responsibility, companies should consider adopting a model which includes, as a minimum, two basic components:

1. A strategy that ensures the prices of their medicines within that market are equivalent to that which generic competition can provide. This requires either adopting a pricing scheme that allows the price to be brought down to this level; or a flexible approach towards patenting those medicines, which includes licensing to generic companies.
2. An explicit policy of supporting governments' use of the public-health safeguards and flexibilities provided under the intellectual property regime.

Second, the needs associated with access to medicines should be fully integrated into every stage of companies' operations from the R&D processes right through post-marketing. This requires companies to invest in the development of medicines that are relevant to the changing health profile of countries, that will include NCDs,

communicable diseases, and diseases that predominantly affect poor people in developing countries. It is increasingly recognised that effective medicines should be presented in formulations that are designed for poor countries. Good products are valuable only if they result in beneficial health outcomes, and therefore constraints in the delivery chain and in health facilities, usability issues for particular groups (such as children), and of labelling and packaging are important aspects of value, and need specific attention.

Box 4: Income disparities in emerging market economies and the impact on ability to pay

Fast-growing emerging markets suffer high levels of income disparity.

Share of income or consumption in five emerging market economies (%)

	GDP per capita	Richest 20%	Middle 60%	Poorest 20%
Brazil	3,284	62.1	35.3	2.6
India	640	43.3	52.2	8.9
China	1,490	50.0	45.3	4.7
South Africa	4,675	62.2	34.3	3.5

Source: Human Development Report 2006, UNDP

Arguably, the richest 20 per cent of these populations can afford to pay for pharmaceuticals. The poorest 20 per cent comprise those living on two dollars a day or less. In the E7 countries (Brazil, China, India, South Africa, Mexico, Indonesia, and Russia) 1.7bn people fall into this category. This segment of the world's population can barely afford generics. When they have to purchase medicines, it is at immense personal sacrifice unless they are provided for by governments and aid agencies. The middle 60 per cent are individuals who sit above the poverty line but are still extremely vulnerable to changes in income, economic crises, and prices of medicines. Given the limited public health care available in developing countries, they depend on inadequate private health care. They have little access to preventive health care and tend to be diagnosed late, leading to a dependency on medicines as their sole means for treatment, usually paid out-of-pocket. Any increase in prices for medicines can overwhelm their limited incomes and drive them below the poverty line.

Further factors that need to be accounted for in developing-country markets include drug promotion and clinical trials. Drug promotion has a special significance in developing countries because of the paucity of information and lack of opportunities for doctors and pharmacists to upgrade their knowledge. Studies have shown that even in developed markets, doctors are heavily influenced by drug promotion.[88] This is a serious concern given that there is evidence of a strong correlation between irrational prescribing and use of commercial sources of information.[89] Companies must be careful when conducting clinical trials in developing countries. As Pfizer acknowledges, 'because of social and cultural considerations, research undertaken in certain countries may warrant additional ethical and public health measures to ensure appropriate human subject protection in the conduct of clinical trials in these countries'.[90] It is beyond the scope of this paper to address the issues of drug promotion and marketing, drug safety, clinical trials, and drug registration. However, Oxfam believes that companies should ensure that the standards they apply in marketing and clinical trials are the same in the North and the South, and comply with WHO guidelines. They should also register their drugs as widely as possible.

In 2007, a dialogue[91] between three large pension funds (representing over $474bn of assets under management) and the pharmaceutical industry similarly found that 'these emerging markets challenge pharmaceutical companies to respond to the opportunities for commercial expansion at the same time as working in partnership with governments and others to respond appropriately to the need to increase access to medicines for people on low incomes in these markets'. It concluded that inappropriate responses would engender mistrust, the costs of which 'have been cited as inhibiting cooperation, the adoption of contractualism, the interruption of the customer relationship and regulation and restriction'.

6 Moving forward: integrating access to medicines responsibilities into core business

It is certain that pressures on the industry to meet society's expectations in terms of access to medicines will continue for a number of reasons.

First, a growing number of developing-country governments are making serious commitments towards achieving viable health services and equity of access. Without a solution to the access to

medicines problem, they cannot meet their goals and obligations to their populations. In the developing world, where the majority of people live in poverty and are highly sensitive to price rises, companies will have to respond by implementing sophisticated differential pricing policies correlated to the different income levels, or by being flexible with patent protection to ensure the desirable low price is achieved. As civil society becomes more active and effective in insisting on results, governments will have to find ways to respond. They will throw the challenge back to companies to support rather than hinder their goals.

Second, the epidemiology of public health is changing, with a more diverse range of diseases that require appropriate products. NCDs, as well as old and new infections that threaten global and local health, are now established challenges. Pressures will come from many sources including where risks cross borders and affect economic performance. For developing countries particularly, their specific contextual realities need to be taken seriously: new products are needed, formulations need to be usable, and drug information and labelling should be comprehensible. R&D will have to be tailored towards end-use realities.

Third, demands from civil society for the industry to deliver their end of the social contract are likely to grow and become more exacting. As the current models and incentives for delivering medicines that are suitable, usable, and affordable for poor people come under increasing scrutiny, so this will add to the pressure on the pharmaceutical industry to adopt different strategies that better meet global health needs.

If companies channel their energies into defending the status quo, they risk missing opportunities for adopting new, innovative business models that meet their needs for boosting profitability, and they will attract greater opprobrium as far as patients, civil society, and governments are concerned. If they continue a slow evolution of the existing approach without meeting society's expectations, they are likely to fall short of meeting access to medicines challenges.

Further, failure by the industry to comprehend access to medicines as a fundamental human right as enshrined in international law, and to recognise that pharmaceutical companies have responsibilities in this context, will hinder appropriate strategies from being adopted. This has prompted the UN Special Rapporteur on the Right to Health to develop a draft set of guidelines which apply provisions on the right to health to pharmaceutical companies' policies and practices. Oxfam supports this initiative and calls on the industry to do likewise.[92]

Now is the time for companies to take a bold look at new ways of doing business, incorporating a social equity bottom line into their thinking, working more flexibly, transparently, and practically with a wide range of stakeholders. The current inertia on access to medicines can be overcome by placing concerns about affordability and availability at the core of business decision-making processes and operations. To do so will require strong leadership and long-term vision.

Oxfam also believes that integrating access to medicines into the core business model will institutionalise a framework for the industry to predict, respond to, and satisfy the needs of people in developing-country markets. Investors who are encouraging pharmaceutical companies to enter emerging market economies identify the need to adapt prices, to have more flexible distribution systems, and to make products that are relevant to the markets being served, as necessary elements of a business strategy.

Oxfam recognises that the fact that a social good is being provided through the market is always going to pose challenges and is susceptible to the problems of market failure. Collective action to overcome this is an imperative.

In this context, society expects pharmaceutical companies – with their privileged access to a global market – to develop necessary products at prices that are affordable, in presentations that are usable, and to market them ethically. It is expected to fulfil these requirements reliably and sustainably, and by so doing, play its part in the wider responsibilities to improve the health of all.

Appendix 1: Oxfam's assessment of companies' performance on access to medicines

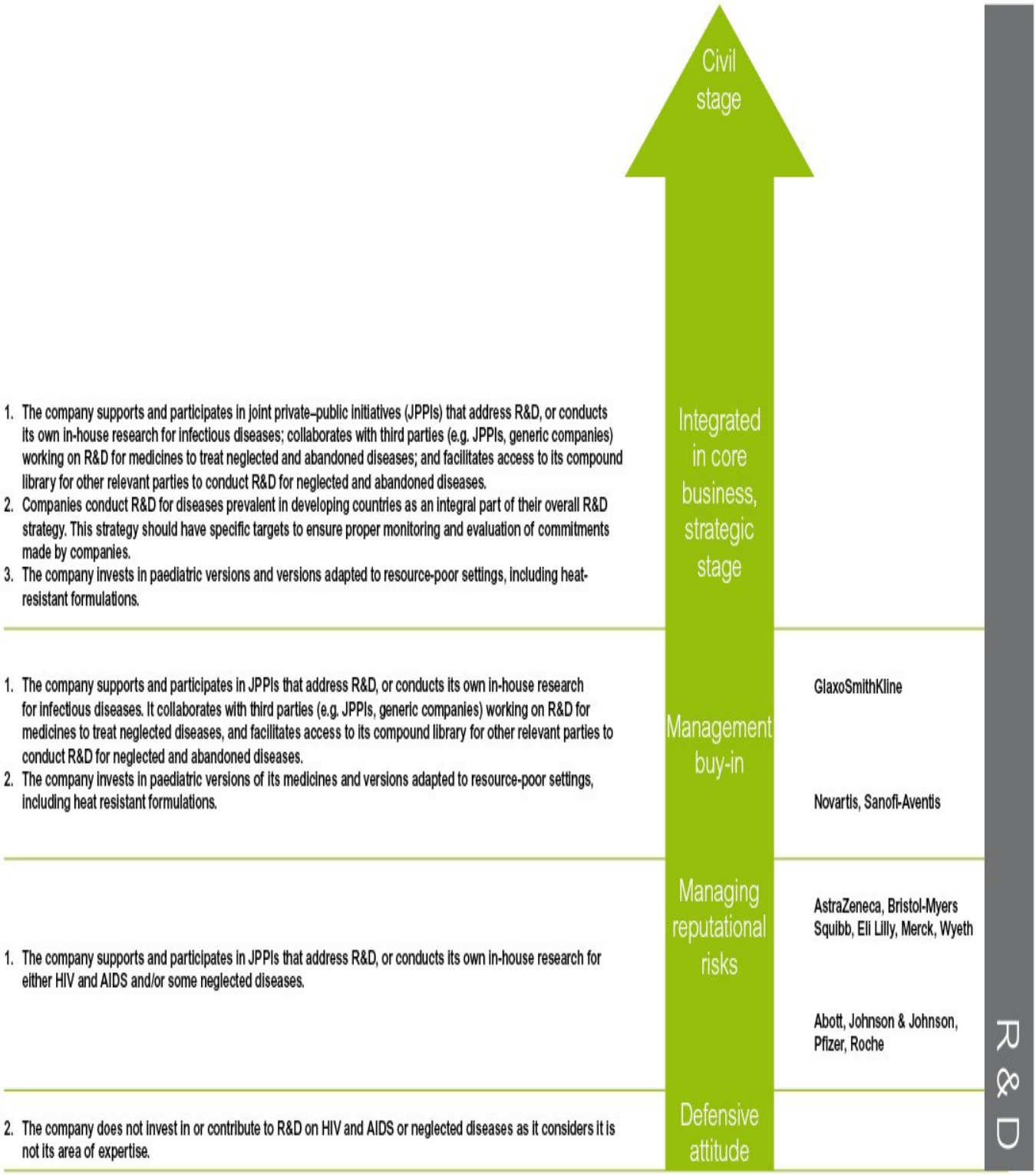
The three charts and corresponding tables describe the evolutionary progress towards corporate responsibility of each of the 12 companies interviewed about access to medicines in developing countries. The information in the tables and the charts was gathered through these interviews as well as from publicly available data.

Oxfam has compared each company's policies on pricing, intellectual property, and R&D, with our own benchmarks (updated from the original benchmarks set in the report 'Beyond Philanthropy') to reflect the current needs and environment. The five steps to corporate responsibility have been described in a Harvard Business School Review paper[93] based on the analysis of the textile sector, but they seemed wholly applicable to the pharmaceutical industry. They are:

1. *Defensive stage or attitude:* In this stage, companies deny any link between their business practices and the criticism that they face as a result of these practices.
2. *Compliance or managing reputational risks stage:* This stage could be described as corporate 'lip-service', where companies set up a series of policies and implementation systems confined to the minimum necessary to negate criticism, preserve their reputation, and reduce regulatory or legislative risks. This is often more of a public relations or marketing exercise than a re-evaluation of core business policies.
3. *Managerial stage or management buy-in:* At this stage the company starts to take responsibility for, and get involved in, managing its social and environmental impacts. This involves operational management of the company, not just public relations or marketing.
4. *Strategic stage (access to medicines integrated in core business):* This is the stage when companies learn that their business models and core businesses need to be re-aligned with societal expectations. Further, they start discovering the benefits and opportunities that integrating access to medicines challenges into core business decision-making and practices brings them. The successful first mover is likely to find many imitators.

5. *Civil stage:* This is the stage when companies actively push other companies and stakeholders within the sector to raise standards as an industry.

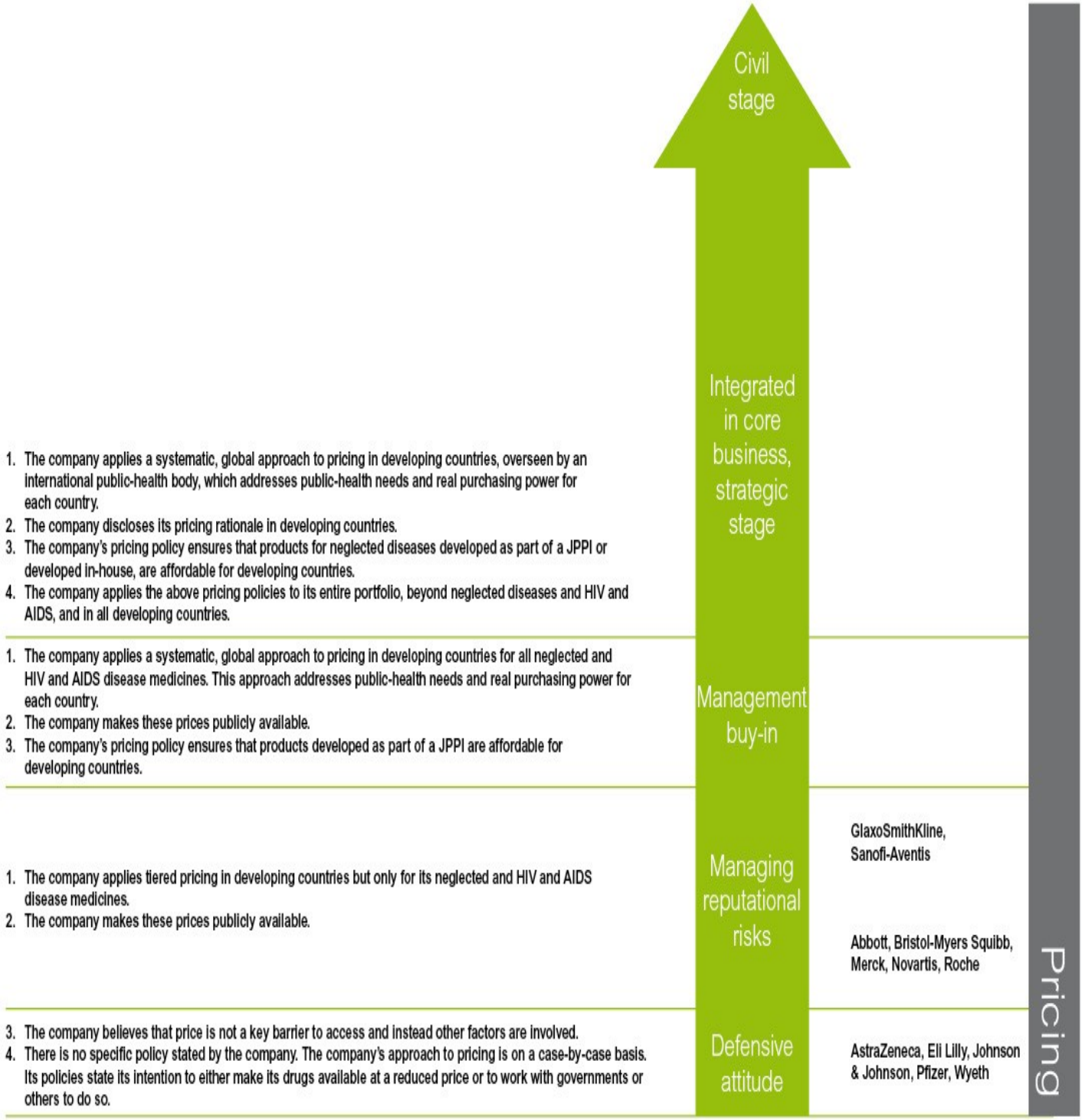
The companies interviewed and the dates on which they were interviewed are in Appendix 2.


Civil stage
1. The company supports and participates in joint private–public initiatives (JPPIs) that address R&D, or conducts its own in-house research for infectious diseases; collaborates with third parties (e.g. JPPIs, generic companies) working on R&D for medicines to treat neglected and abandoned diseases; and facilitates access to its compound library for other relevant parties to conduct R&D for neglected and abandoned diseases.
2. Companies conduct R&D for diseases prevalent in developing countries as an integral part of their overall R&D strategy. This strategy should have specific targets to ensure proper monitoring and evaluation of commitments made by companies.
3. The company invests in paediatric versions and versions adapted to resource-poor settings, including heat-resistant formulations.
Integrated in core business, strategic stage
1. The company supports and participates in JPPIs that address R&D, or conducts its own in-house research for infectious diseases. It collaborates with third parties (e.g. JPPIs, generic companies) working on R&D for medicines to treat neglected diseases, and facilitates access to its compound library for other relevant parties to conduct R&D for neglected and abandoned diseases.
2. The company invests in paediatric versions of its medicines and versions adapted to resource-poor settings, including heat resistant formulations.
Management buy-in
GlaxoSmithKline
Novartis, Sanofi-Aventis
1. The company supports and participates in JPPIs that address R&D, or conducts its own in-house research for either HIV and AIDS and/or some neglected diseases.
Managing reputational risks
AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Merck, Wyeth
Abott, Johnson & Johnson, Pfizer, Roche
2. The company does not invest in or contribute to R&D on HIV and AIDS or neglected diseases as it considers it is not its area of expertise.
Defensive attitude
R&D

Company*	R&D for diseases relevant to developing countries
Abbott	Therapeutic focus upon HIV and AIDS – they produce Aluvia, a second-line anti-retroviral heat-stable version of Kaletra and also a paediatric lower-strength version. Provide technical expertise to OneWorldHealth for the development of a low-cost Artemisin-based medicine for malaria.
AstraZeneca	R&D into treatments for TB at its own research centre in Bangalore, India.
Bristol-Myers Squibb	Claims it is the only company with once-daily oral drugs in each major treatment class for HIV. Produces key drugs for Hepatitis B.
Eli Lilly	Produces two antibiotic drugs – Capreomycin and Cycloserine – used to fight MDR-TB. Works with the Global Alliance for the development of TB drugs.
GlaxoSmithKline	R&D into 11 diseases relevant to developing countries, including HIV and AIDS, TB, and malaria, and vaccine development.
Johnson & Johnson	R&D into new medicines and diagnostics against HIV and related opportunistic infections. They currently have three HIV compounds in development.
Merck	Produces four anti-retrovirals for HIV and AIDS: Stocrin, Isentress, Atripla and Crixivan. R&D focus is on vaccines. Produces Mectizan for river blindness and lymphatic filariasis.
Novartis	The Novartis Institute for Tropical Diseases, based in Singapore, conducts research on diseases relevant to the developing world, notably TB, dengue fever, and malaria.
Pfizer	Conducts HIV and AIDS research. First in class CCR5 antagonist for HIV and AIDS. It is investigating a new malaria medicine based on a combination of azithromycin and chloroquine. It is also looking into using Zithromax against several other diseases, including, among others – shigellosis, typhoid, and cholera. Has joined the Unicef-UNDP-World Bank-WHO Special Programme for Research and Training in Tropical Diseases (TDR) programme.[94] It makes thousands of compounds in its chemical libraries available for research and testing against some of the key parasitic diseases that affect people in

	developing countries.
Roche	According to their website, Roche focuses its R&D efforts in five disease areas. Developing a formulation of our HIV treatment saquinavir for children, and new treatments for Hepatitis B and C. Has provided support and donated expertise in malaria drug development for the Medicines for Malaria Venture (MMV).
Sanofi-Aventis	Has a portfolio of five diseases – malaria, tuberculosis, epilepsy, sleeping sickness, and leishmaniasis – plus vaccines. Told Oxfam that they are considering including diabetes and mental illness. On vaccines, Sanofi Pasteur produces a monovalent poliomyelitis vaccine, and is working on a vaccine for dengue fever. It is also involved in global partnerships working on a vaccine for HIV and AIDS including the Global HIV Vaccine Enterprise. Has developed the fixed-dose combination malaria drug ASAQ in partnership with DNDi.
Wyeth	Research into bacteria such as pneumococcus, meningococcus, and group A streptococcus as well as developing vaccines for HIV and papilloma virus. Works with WHO-TDR investigating new treatments for river blindness.

* All quotes are from Oxfam's interviews with the companies – see Appendix 2.


Civil stage
Integrated in core business, strategic stage
1. The company applies a systematic, global approach to pricing in developing countries, overseen by an international public-health body, which addresses public-health needs and real purchasing power for each country.
2. The company discloses its pricing rationale in developing countries.
3. The company's pricing policy ensures that products for neglected diseases developed as part of a JPPI or developed in-house, are affordable for developing countries.
4. The company applies the above pricing policies to its entire portfolio, beyond neglected diseases and HIV and AIDS, and in all developing countries.
Management buy-in
1. The company applies a systematic, global approach to pricing in developing countries for all neglected and HIV and AIDS disease medicines. This approach addresses public-health needs and real purchasing power for each country.
2. The company makes these prices publicly available.
3. The company's pricing policy ensures that products developed as part of a JPPI are affordable for developing countries.
Managing reputational risks
1. The company applies tiered pricing in developing countries but only for its neglected and HIV and AIDS disease medicines.
2. The company makes these prices publicly available.
GlaxoSmithKline, Sanofi-Aventis
Abbott, Bristol-Myers Squibb, Merck, Novartis, Roche
Defensive attitude
3. The company believes that price is not a key barrier to access and instead other factors are involved.
4. There is no specific policy stated by the company. The company's approach to pricing is on a case-by-case basis. Its policies state its intention to either make its drugs available at a reduced price or to work with governments or others to do so.
AstraZeneca, Eli Lilly, Johnson & Johnson, Pfizer, Wyeth
Pricing

Company*	Pricing policies
Abbott	Has a transparent systematic tiered-pricing policy for HIV and AIDS medicines. Tiered-pricing for Aluvia (heat-resistant Kaletra) to 114 countries at $500 per year per patient to all African countries and LDCs and $1000 in more than 40 low-income and middle-income countries.
AstraZeneca	No mention of any systematic preferential pricing scheme. It has however made public its intention to seek partnership arrangements to make TB medicines available at affordable prices in the poorest countries. Once a candidate drug is found, they expect to develop the drug with regulatory authorities and external experts such as the Global Alliance for TB drug development. They will apply for patent protection. Addresses non-affordability through charitable donations and expanded patient access programmes. They state they 'support the concept of differential pricing in this context, provided that safeguards are in place'. AstraZeneca is looking into building partnerships, including exploring with generics, to develop the candidate drugs. The company states that it aims to donate relevant drugs.
Bristol-Myers Squibb	Has offered its HIV and AIDS medicines at a no profit price in sub-Saharan Africa since 2001 (this includes a below-cost-price for paedriatic formulations), and applies differential pricing for other markets (which were not specified).
Eli Lilly	No mention of tiered-pricing policies. Representatives of the company told Oxfam that 'we generally try to make sure that our sales into those countries are lower than our lowest price in the developed market'. Involved in donation programmes for MDR/TB medicines.
GlaxoSmithKline	Applies preferential pricing across its vaccines portfolio, and for medicines for the treatment of HIV and AIDS and malaria. This includes being the major supplier of vaccines to GAVI and providing ARVs at not-for-profit prices in sub-Saharan Africa, LDCs, and to projects fully funded by the Global Fund or PEPFAR. According to GlaxoSmithKline this adds up to around 100 countries and is comparable with generic prices when transportation costs are taken into account. Pricing of medicines for middle-income countries is set on a case-by-case basis. Preferential pricing for antibiotics and diabetes treatments is being extended to some African countries.
Johnson & Johnson	No mention of a specific pricing policy for developing countries. States that it will work with third parties to create sustainable access

	programmes.
Merck	Applies tiered-pricing to its vaccines and HIV and AIDS medicines. Sells anti-retrovirals Crixivan, Stocrin, and Atripla at no-profit prices to countries low on the Human Development Index (HDI) as well as to medium HDI countries with an adult HIV prevalence of one per cent or greater. It sells Crixivan and Stocrin at a reduced price to medium HDI countries where adult HIV prevalence is less than one per cent and at normal market prices in high HDI countries. Merck/MSD implements a differential ARV pricing policy that has provided its anti-retroviral medicines (ARVs) at prices at which the company does not profit in the poorest countries and those hardest hit by the HIV and AIDS pandemic. This policy applies to all of Merck's ARVs –Crixivan, Stocrin, Atripla, and Isentress. Has a long-term donation programme of medicines for river blindness and just made a one-off donation of GARDASIL, its cervical cancer vaccine. Has indicated its intention to implement tiered pricing for GARDASIL.
Novartis	For leprosy, malaria, and TB, medicines are provided at cost price or free. Has made a commitment to WHO to provide free treatment for all leprosy patients in the world until the disease has been eliminated from every country. Also committed to providing Coartem, its oral fixed-combination anti-malarial product, at cost. In 2006 the average treatment price of Coartem was reduced to $1 compared with $1.57 previously. Applies patient-access programmes where its medicines are donated to patients who meet set requirements.
Pfizer	No specific differential pricing policy for developing countries. However, Pfizer states that it will 'work with governments on access to Pfizer medicines needed in the fight against HIV and AIDS, malaria, and tuberculosis for those who cannot afford treatment'. Donations of Zithromax (azithromycin) for Trachoma and Diflucan (fluconazole) for certain opportunistic infections associated with HIV). The programmes are currently operating in some 75 countries.
Roche	Applies tiered-pricing to all its HIV medicines and provides them at a no-profit price to LDCs and sub-Saharan Africa, and at a reduced price to all other low-income or lower middle-income economies as defined by the World Bank.
Sanofi-Aventis	Commits to making anti-malarials available at a 'no profit no loss' price to the public sector, international, and non-government organisations. The company states that it engages in either donations or commits to providing medicines at reduced prices to certain undefined countries and organisations for its leishmainasis, sleeping sickness, TB drugs, and some vaccines.

Wyeth	No tiered-pricing policy. States that 'in addition to carefully planned programs of product donation, where appropriate, Wyeth also will consider flexible pricing terms, as they have done in the past 30 years, for example, with international donor agencies for the use of oral contraceptives in their family planning programs'.

* All quotes are from Oxfam's interviews with the companies – see Appendix 2.


1. The company does not lobby developed-country or developing-country governments or pursue legal avenues to impose or enforce patent rules that exceed minimum obligations under the TRIPS Agreement, or that weaken the use of public-health safeguards. The company should publicly accept the use of TRIPS safeguards and flexibilities.
2. The company supports lifting TRIPS-related restrictions on the export of generic versions of patented medicines to least-developed countries and to developing countries that have insufficient or no manufacturing capacity, in line with the Doha Declaration. The company supports extending the non-implementation of patent rules for pharmaceuticals in LDCs beyond 2016.
3. The company does not apply for patents for the purpose of 'ever-greening' existing medicines, i.e. the extension of pharmaceutical monopolies beyond the initial 20-year term. Therefore, companies should not seek patents for new indications of existing medicines, new formulations, or combinations of existing medicines, nor should they seek patents for modifications of existing chemical entities or pharmaceuticals unless these changes are novel, show an innovative step, and have significant therapeutic advantages.
4. The company extends the relevant intellectual property policies to all medicines in its portfolio, and does not limit its policies only to medicines needed to treat HIV and AIDS, tuberculosis, and malaria.
5. The company renounces all patent rights on medicines developed for infectious diseases under JPPIs in developing countries.
6. The company follows Oxfam's best-practice guidelines when issuing voluntary licences (VLs).
Civil stage
Integrated in core business, strategic stage
1. The company does not lobby developed-country or developing-country governments or pursue legal avenues to impose or enforce patent rules that exceed minimum obligations under the TRIPS Agreement, or that weaken the use of public-health safeguards. The company should publicly accept the use of TRIPS safeguards and flexibilities.
2. The company supports lifting TRIPS-related restrictions on the export of generic versions of patented medicines to LDCs and to developing countries that have insufficient or no manufacturing capacity, in line with the Doha Declaration. The company supports extending the non-implementation of patent rules for pharmaceuticals in LDCs beyond 2016.
3. The company does not apply for patents for the purpose of 'ever-greening' existing medicines, i.e. the extension of pharmaceutical monopolies beyond the initial 20-year term. Therefore, companies should not seek patents for new indications of existing medicines, new formulations, or combinations of existing medicines, nor should they seek patents for modifications of existing chemical entities or pharmaceuticals unless these changes are novel, show an innovative step, and have significant therapeutic advantages.
4. The company renounces all patent rights on medicines developed for infectious diseases under JPPIs in developing countries.
5. The company considers applying non-exclusive VLs on its HIV and AIDS and neglected diseases products.
Management buy-in
1. The company does not lobby developed-country or developing-country governments or pursue legal avenues to impose or enforce patent rules that exceed minimum obligations under the TRIPS Agreement, or that weaken the use of public-health safeguards. The company should publicly accept the use of TRIPS safeguards and flexibilities.
2. The company considers applying VLs on its HIV and AIDS and neglected diseases products.
3. The company is flexible with its patent rights on medicines developed for infectious diseases under JPPIs in developing countries.
Managing reputational risks
4. The company denies that patents are a barrier to access to medicines.
5. The company lobbies for stricter intellectual property frameworks in developing countries and/or lobbies or challenges developing countries' rights to use or implement the TRIPS flexibilities and safeguards in its legislation.
Defensive attitude
GlaxoSmithKline, Bristol-Myers Squibb, Merck, Roche
Abbott, AstraZeneca, Eli Lilly, Johnson & Johnson, Novartis, Pfizer, Sanofi-Aventis, Wyeth
Intellectual Property

Company*	Intellectual property policies for developing countries
Abbott	Believes in the need for strong intellectual property rights in all countries. Does not believe in voluntary licensing. Irresponsible response to the Thai government with regards to the compulsory licence issued for Kaletra. Has provided access to a few of its patents (for a potent class of antibiotics), to the Global Alliance for TB Drug Development.
AstraZeneca	Believes in enforcing strong intellectual property rights and will apply for patent protection for all its products.
Bristol-Myers Squibb	Believes in the need for strong intellectual property rights. Has provided VLs for ARVs for sub-Saharan Africa. It has announced royalty-free VLs and a full technology transfer to two generic companies for the ARV, atazanavir. Has a policy of not enforcing patents for HIV products in sub-Saharan Africa. In keeping with this policy it has finalised immunity from suit agreements in sub-Saharan Africa for stavudine and didanosine with more than ten generic manufacturers. Agreed that the FDA can make right of reference to dossiers and product registration files for generic companies to secure approval of generic combination products under the PEPFAR programme.
Eli Lilly	Believes in the need for strong intellectual property rights and will enforce them across their portfolio. It will however 'no longer seek patent protection in most of the countries that we consider lesser developed countries, mainly sub-Saharan Africa countries'.
GlaxoSmithKline	Has stated it is prepared to discuss VLs on a case by case basis. To date, VLs granted by GSK have been for the supply of ARVs, the vast majority of which have been for sub-Saharan Africa. GSK believes that voluntary licences are 'not a universal solution to HIV and AIDS but a specific response to a particular set of circumstances'. Has granted voluntary licences to eight generic companies for the manufacture and supply of anti-retrovirals to both the public and private sectors in sub-Saharan Africa. Has also granted a VL for the manufacture of its flu antiviral, Relenza, to a Chinese generic company for supplies to select low-income countries. GSK offices in Thailand and India were subject to demonstrations against GSK's patents applications for COMBID/COMBIVIR in those countries. Prior to these demonstrations, GSK decided to abandon its patents and patent applications directed to a specific formulation of Combivir wherever they exist. This includes the patent applications which were the subject of the demonstrations in Thailand and India. GlaxoSmithKline Philippines has allegedly lobbied to prevent the House of Representatives from passing the Cheaper Medicines Bill.

Johnson & Johnson	Does not specifically address intellectual property in developing countries except for HIV and AIDS. One of their subsidiaries (Tibotec) granted a royalty-free licence to the International Partnership for Microbicides (IPM) on an anti-retroviral to be used as a microbicide.
Merck	Stated its openness to issuing voluntary licences. Has granted Aspen and Adcock Ingram in South Africa a voluntary licence on a first-line anti-retroviral (efavirenz). Has patents for two ARVs (CRIXIVAN and STOCRIN) in South Africa and one (CRIXIVAN) in Democratic Republic of Congo, but their general policy is not to file patents for their HIV and AIDS products in Africa.
Novartis	Has a policy to not file for patents in LDCs. See challenge to Indian Patent Law in Box 2.
Pfizer	Believes in strong intellectual property rights and states that it will have 'zero tolerance' when it comes to defending them. Challenged the Philippines government over their use of one of the TRIPs flexibilities in relation to Pfizer's drug Norvasc and has allegedly lobbied to prevent the House of Representatives from passing the Cheaper Medicines Bill.
Roche	Will not seek to file patents on any of its medicines in any LDC, and will not sue any generic company that serves LDC markets with any of its drugs. With regards to HIV and AIDS medicines, the same policy applies for all of sub-Saharan Africa.
Sanofi-Aventis	Has not made any public statement about intellectual property with regards to developing countries. Has not sought a patent with regards to its malaria drug (ASAQ) developed in partnership with DNDi. Allegedly exerting pressure on Thailand regarding the Thai government's decision to issue a compulsory licence for its cardiovascular drug, clopidogrel.
Wyeth	States that 'should patent exclusivity prove to be the sole barrier to access to medicines in a specific instance, Wyeth is committed to taking appropriate action – on a case-by-case basis – working with local and international partners to overcome such a barrier in the most effective and sustainable way'.

* All quotes are from Oxfam's interviews with the companies – see Appendix 2.

Appendix 2: Companies interviewed and interview dates

Abbott	29th January 2007
AstraZeneca	22nd December 2006
Bristol-Myers Squibb	13th November 2006
GlaxoSmithKline	21st November 2006 and 17th January 2007
Gilead	26th January 2007
Eli Lilly	11th January 2007
Johnson & Johnson	13th December 2006
Merck	12th December 2006
Novartis	4th December 2006
Pfizer	14th December 2006
Roche	5th December 2006
Sanofi-Aventis	3rd January 2007
Wyeth	25th January 2007

Notes

1 K. Bluestone, A. Heaton, and C. Lewis (2002) 'Beyond Philanthropy: The Pharmaceutical industry, corporate social responsibility and the developing world', Oxfam, Save the Children UK, and VSO. Available at: www.oxfam.org.uk/resources/policy/health/downloads/beyondphilanthropy.pdf (last accessed October 2007).

2 www.theglobalfund.org/en/about/malaria/ (last accessed January 2007).

3 World Health Organisation (2005) 'Preventing chronic diseases: a vital investment', Geneva: WHO. Available at: www.who.int/chp/chronic_disease_report/en/ (last accessed October 2007).

4 "15 per cent of the world's population consumes over 90 per cent of the world's pharmaceuticals" which translates to 85 per cent of the population consuming less than 10 per cent of the world's pharmaceuticals. P. Hunt (2007) 'Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines', draft for consultation prepared by the UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

5 P. Trouiller, P. Olliaro, E. Torreele, J. Orbinski, R. Laing, and N. Ford (2002) 'Drug development for neglected diseases: a deficient market and a public-health policy failure', The Lancet 359 (9324): 2188–94; for updated figures see E. Torreele and P. Chirac (2005) 'Global framework on essential health R&D', The Lancet 367 (9522): 1560–1.

6 K. Bluestone, A. Heaton, and C. Lewis (2002)op.cit.

7 The Innovest Healthcare Team (2007) 'Industry Engagement – Second Interim Report', Haarlem: Access to Medicine Index; The Innovest Healthcare Team (2007) 'Scoping Report & Stakeholder Review', Haarlem: Access to Medicine Index, all available at: www.atmindex.org (last accessed October 2007); S. Tickell (2007) 'Pharma Futures: Prescription for Long-Term Value', SustainAbility Ltd. All available at: www.sustainability.com (last accessed October 2007).; Interfaith Center on Corporate Responsibility (ICCR) (2006) 'Benchmarking AIDS, New York.

See also the World Health Organisation Intergovernmental Working Group on Public Health, Innovation and Intellectual Property which held its first session in December 2006 (www.who.int/phi/en).

9 Abbott Ltd., AstraZeneca, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Pfizer, Roche, Sanofi-Aventis, and Wyeth. We also interviewed Gilead to understand its portfolio on HIV/AIDS. We are grateful to these companies for taking part in our research. We should point out that some of the companies have contested our opinions, particularly with regard intellectual property and its impacts on access to medicines.

10 www.theglobalfund.org (last accessed October 2007).

11 www.theglobalfund.org/en/about/malaria/ (last accessed January 2007).

12 www.who.int/tb/dots/dotsplus/en/index.html (last accessed October 2007).

13 www.who.int/mediacentre/factsheets/fs104/en/ (last accessed January 2007).

14 M. A. Aziz, A. Wright, A. Laszlo, A. De Muynck, F. Portaels, A. Van Deun, C. Wells, P. Nunn, L. Blanc, and M. Raviglione, for the WHO/International Union Against Tuberculosis And Lung Disease Global Project on Anti-tuberculosis Drug Resistance Surveillance (2006) 'Epidemiology of antituberculosis drug resistance (the Global Project on Anti-tuberculosis Drug Resistance Surveillance): an updated analysis', The Lancet 368 (9553): 2142–54.

15 J. Bryce, C. Boschi-Pinto, K. Shibuya, and R. E. Black (2005) 'WHO estimates of the causes of death in children', The *Lancet* 365 (9465): 1147–52.

16 www.who.int/infectious-disease-report/2000/ch4.htm (last accessed October 2007).

17 S. Tickell (2005) 'The Antibiotic Innovation Study: Expert Voices on a Critical Need', Uppsala: ReAct, Action on Antibiotic Resistance. Available at: http://soapimg.icecube.snowfall.se/stopresistance/ATT00043%20(2).pdf (last accessed October 2007).

18 These are also known as chronic diseases.

19 www.who.int/infectious-disease-report/2000/ch4.htm (last accessed October 2007).

20 World Health Organisation (2005), op.cit.

21 World Health Organisation (2005), op.cit

22 P. Hunt (2007) 'Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines', draft for consultation prepared by the UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

23 'Recent data collected and analysed by the African Union on Government health spending among SSA countries and presented in its 'Progress Report on the Implementation of the Plans of Action of the Abuja Declarations for Malaria, HIV/AIDS and Tuberculosis' paint an interesting picture. According to this data, about a third of Sub-Saharan African countries are allocating ten per cent or more of their national budgets to the health sector, 38 per cent of countries allocate five–ten per cent while 29 per cent of them allocate below five per cent. The Report also shows that West and Central Africa contain most of the countries that allocate less than five per cent. Botswana, according to this data, is the only country that has achieved the Abuja target of 15 per cent, while countries nearing this target include The Gambia (13 per cent), Ghana (13 per cent), Namibia (12 per cent), Sao Tome and Principe (14 per cent), Tanzania (13 per cent), Uganda, and Zimbabwe (all at 14.5 per cent).' African Union (2006) 'Universal Access to HIV/AIDS,

Tuberculosis and Malaria Services by a United Africa by 2010', paper presented at the Special Summit of African Union on HIV/AIDS, Tuberculosis and Malaria (ATM), in Abuja, Nigeria, 2–4 May. Available at: www.africa-union.org/root/au/conferences/past/2006/may/summit/doc/en/

SP_PRC_ATM5_Financial_factors.pdf (last accessed October 2007).

24 M. A. Dominguez Uga and I. Soares Santos (2007) 'An Analysis Of Equity In Brazilian Health System Financing', Health Affairs 26 (4): 1017.

25 World Health Organisation (2005) op. cit., p. 82.

26 European Generics Medicines Association at www.egagenerics.com/gen-basics.htm. The term 'originator drug' means the first version of a medicinal product developed and patented by an originator pharmaceutical company which receives exclusive rights to marketing the product.

27 Ibid.

28 Médecins Sans Frontières (n.d.) 'Examples of the importance of India as the "Pharmacy for the Developing World"'. Available at: www.doctorswithoutborders.org/news/access/background_paper_indian_generics.pdf (last accessed October 2007).

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30 M. Kamal-Yanni, M. Hassan Khalil, A. Ahmed Hassan, M. Shedeed, A. Faisal, and A. Hassan (2006) 'Patents and access to new medicines: the case of Hepatitis C in Egypt', unpublished research.

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33 Médecins Sans Frontières (2007) 'Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries', tenth Edition. Available at: www.accessmed-msf.org/documents/Untangling10.pdf (last accessed October 2007).

34 Ibid.

35 Médecins Sans Frontières (November 2007) 'A step forward? The battle between Big Pharma and poor AIDS victims is heating up, but the outcome is far from certain'. Available at: www.msf.org/msfinternational/invoke.cfm?objectid=8A855BBF-15C5-F00A-258F8828CFF6A216&component=toolkit.article&method=full_html (last accessed November 2007).

36 The Doha Declaration through paragraph six acknowledged the need for WTO members to identify a mechanism that developing countries with insufficient or no drug manufacturing capacities could use to import generic versions of patented medicines under compulsory licenses.

37 Oxfam International (2006) 'Patents versus Patients: Five years after the Doha Declaration', Oxfam Briefing Paper No. 95, Oxford: Oxfam International.

38 Compulsory licensing by a government allows a government to temporarily override a patent and authorise production of generic equivalents of patented medicines in the public interest.

39 Parallel importation allows countries to import a patented product marketed in another country at a lower price.

40 M. Ewen and D. Dey (2005) 'Medicines: too costly and too scarce'. Available at: www.haiweb.org/medicineprices/2005/PricingbriefingpaperFINAL.doc (last accessed October 2007).

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42 P. Trouiller, P. Olliaro, E. Torreele, J. Orbinski, R. Laing, and N. Ford (2002) 'Drug development for neglected diseases: a deficient market and a public-health policy failure', The Lancet 359 (9324): 2188–94; for updated figures see E. Torreele and P. Chirac (2005) 'Global framework on essential health R&D', The Lancet 367 (9522): 1560–1.

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This finding is similar to that of the UK-sponsored Commission on Intellectual Property Rights which reported in September 2002. Available at: www.iprcommission.org/graphic/documents/final_report.htm (last accessed October 2007).

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45 UN Special Rapporteur on the Right to Health, Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, draft for consultation, 19 September 2007

40 K. Bluestone, A. Heaton, and C. Lewis (2002), op.cit.

47 Oxfam interview with GlaxoSmithKline on 21 November 2006 and 17 January 2007, and with Sanofi-Aventis, 3 January 2007.

48 Oxfam interview with Merck, 12 December 2006.

49 World Development Indicators 2006 Database, World Bank. www.worldbank.org

50 Price transparency is now recognised as a crucial factor in price reduction and WHO, some governments, and NGOs have adopted various initiatives to address it. MSF publishes an annual report with WHO and UNAIDS on prices for medicines for HIV and AIDS, TB, and malaria. The Global Fund and UNITAID have also committed to price transparency.

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52 M. Olcay and R. Laing (2005) 'Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation?', prepared for the Commission on Intellectual Property Rights, Innovation and Public Health. Available at: www.who.int/intellectualproperty/en/ (last accessed November 2007).

53 P. Trouiller, P. Olliaro, E. Torreele, J. Orbinski, R. Laing, and N. Ford (2002) 'Drug development for neglected diseases: a deficient market and a public-health policy failure', The Lancet 359 (9324): 2188–94; for updated figures see E. Torreele and P. Chirac (2005) 'Global framework on essential health R&D', The Lancet 367 (9522): 1560–1.

54 These are heavily dependent on philanthropic donations, which account for 79 per cent of all funds, with the public sector chipping in only 16 per cent. M. Moran (2005) 'The new landscape of neglected disease drug development', London School of Economics and Welcome Trust, p. 33.

55 This was developed through a partnership between Sanofi-Aventis and the Drugs for Neglected Diseases Initiative (www.dndi.org).

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57 Oxfam interview with Novartis, 4 December 2007.

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59 See www.ifpma.org/Issues/issues_intell.aspx (last accessed October 2007).

60 op.cit.

61 A. Subramaniam (2004) 'Medicines, Patents and TRIPS', Finance & Development 41 (1).

62 Data exclusivity creates a new system of monopoly power, separate from patents, by blocking the registration and marketing approval of generic medicines for five or more years, even when no patent exists. Drug

regulatory agencies are prevented from applying clinical trial data developed by the originator company to establish the safety and efficacy of a medicine in order to approve the marketing of a generic medicine already shown to be equivalent to the original medicine. This delays or prevents generic competition. The TRIPS Agreement protects only 'undisclosed data' to prevent 'unfair commercial use'; it does not confer other exclusive rights or a period of marketing monopoly. Linkage prohibits a drug regulatory authority from registering generic versions of a medicine until after the patent has expired, with no exceptions. Thus, public agencies that normally are responsible for only verifying a drug's safety and efficacy have to become a sort of patent police, with the burden of enforcing private property rights, instead of requiring the patent owner to use the judicial system to that end.

63 This view is contested by a number of pharmaceutical companies including Pfizer and Merck.

64 Oxfam International (2007) 'All costs, no benefits: how TRIPS-plus rules in the US-Jordan FTA affect access to medicines', Oxfam Briefing Paper No. 102, Oxford: Oxfam.

65 World Health Organisation and Health Action International (2006) op.cit. p. 55.

66 Another example in the Philippines pertains to Pfizer's lawsuit against the Filipino Government for its use of the Bolar provision to import a generic version of the hypertension medicine, Norvasc in anticipation of patent expiry. See Oxfam International, Patents vs. Patients, op cit. pp 21- 22.

67 Manila Standard Today, "On cheap drugs: Kill-bill lobby revived", August 2007.

68 Boerhringer Ingelheim(BI) has a voluntary licensing strategy for its first-line anti-retroviral medicine, nevirapine. In all LDCs and low-income countries, the company sells the branded product at the reported production cost of US$219 per patient per year (PPPY) and to middle-income countries at US$438 PPPY. According to the company, this is 90 per cent less than the price in developed countries. However, Indian generic manufacturers have offered a generic version at US$45 PPPY to low and middle-income countries, through the Clinton HIV/AIDS Initiative. BI has recently announced a so-called Non-assert Declaration to any WHO-prequalified generics manufacturer to produce nevirapine containing medicines for LDCs, low-income countries or any other country in Africa free of royalties. As long as the generics company does not use the brand name Viramune© or similar packaging to the original product and, specifies the geographical area that the product is to be sold in, BI will not enforce its patent on nevirapine or its paediatric formulation.

69 T. Amin and P. Radhakrishnan (2007) 'Voluntary licensing practices in the pharmaceutical sector: an acceptable solution to improving access to affordable medicines?', unpublished commissioned research for Oxfam.

70 Merck Press Release:' Merck to Donate Three Million Doses of Gardasil®, its Cervical Cancer Vaccine, to Support Vaccination Programs in

Lowest Income Nations', New York, 26 September, 2007. Available at: www.merck.com/newsroom/press_releases/product/2007_0926.html (last accessed November 2007).

71 *New York Times*, 'US approves use of cervical cancer vaccine', 9 June 2006.

72 E-mail communication with Merck, 20 November 2007.

73 *The Economist*, 'Billion dollar pills', 25 January 2007. Available at: www.economist.com/business/displaystory.cfm?story_id=8585891 (last accessed October 2007).

74 *Ibid.*

75 This is a practice of introducing minor modifications to existing medicines which are then patented so that upon expiry of the original patent, generic manufacturers are prevented from introducing generic versions.

76 Linklaters, FT Corporate Solutions, Financial Times Research Centre, 'Rebuilding the reputation of the pharmaceutical industry', November 2005, p. 29.

77 For instance, several bills aimed at reducing barriers to generic competition (generics biologics bill, parallel importation bill, Patent reform act) are in the pipeline to be introduced in the US Congress.

78 J. Whalen (2007) 'Europe's Drug Insurers Try Pay-for-Performance', *Wall Street Journal*, 12 October. Available at: http://online.wsj.com/article/SB119214458748556634.html (last accessed October 2007).

79 S. Tickell (2007) *op.cit.*

80 World Health Organisation Commission on Intellectual Property Rights, Innovation and Public Health (2006), *op.cit.*, p. 172.

81 The WHO IGWG has asked for developing countries to provide submissions on improving innovation and access to medicines. Numerous country submissions to the WHO have indicated support for new forms of innovation, including prizes, to replace patents. See country submissions at www.who.int/phi/submissions/memberstates/en/index.html.

82 See for example the InnoCentive Open Innovation Marketplace (www.innocentive.com/servlets/project/ProjectInfo.po).

83 A term coined in 1981 by Antoine W. van Agtmael of the International Finance Corporation, an emerging (or developing) market economy (EME) is defined as an economy with low-to-middle per capita income. Such countries

constitute approximately 80 per cent of the global population, representing about 20 per cent of the world's economies.

84 C. Grace (2004) 'The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines', DFID Health Systems Resource Centre.

85 Boston Consulting Group, quoted in 'Indian Pharma Industry Quest for Global Leadership', Assocham/Cygnus. Available at: www.cygnusindia.com/Articles/Indina_Pharma_Industry_Quest_for_Global_Leadership-09.11.pdf

86 Federation of Indian Chambers of Commerce and Industry (FICCI) (2005) 'Competitiveness of the Indian Pharmaceutical Industry in the New Product Patent Regime', FICCI Report for the National Manufacturing Competitiveness Council (NMCC), March. Available at: http://www.ficci.com/studies/pharma.pdf (last accessed October 2007).

87 Mentioned in S. Tickell (2007) *op.cit.*, p. 27.

88 Health Action International, HAI Drug promotion database. Available at: www.haiweb.org (last accessed 8 November 2007).

89 T. I. Bhutta (1996) 'Deception by design: pharmaceutical promotion in the third world', *British Medical Journal* 313: 60 (6 July).

90 Oxfam interview with Pfizer, 14 December 2007.

91 The three pension funds are ABB, OPERS, and USS. S. Tickell (2007) *op.cit.*

92 P. Hunt (2007) *op.cit.*

93 S. Zadek (2004) 'The Path to Corporate Responsibility', *Harvard Business School Review*.

94 Unicef-UNDP-World Bank-WHO Special Programme for Research and Training in Tropical Diseases, www.Who.int/tdr/.

This paper was written by Helena Viñes Fiestas with Sumi Dhanarajan, Rohit Malpani, Mohga Kamal-Yanni, Phillipa Saunders and Stewart Atkins. Oxfam acknowledges the assistance of Jennifer Brant, Barbara Dockalova,Marg Ewen, Penny Fowler, Duncan Guest, Nina Henderson-Andrade, Chalermsak Kittitrakul, Gopa Kumar, Jessica Lovas,Rosette Mutambi, Sophia Tickell and Shalimar Vitan. Oxfam is grateful to the companies for participating in the research for this paper. It is part of a series of papers written to inform public debate on development and humanitarian policy issues.

For further information on the issues raised in this paper please e-mail advocacy@oxfaminternational.org.

The information in this publication is correct at the time of going to press.

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