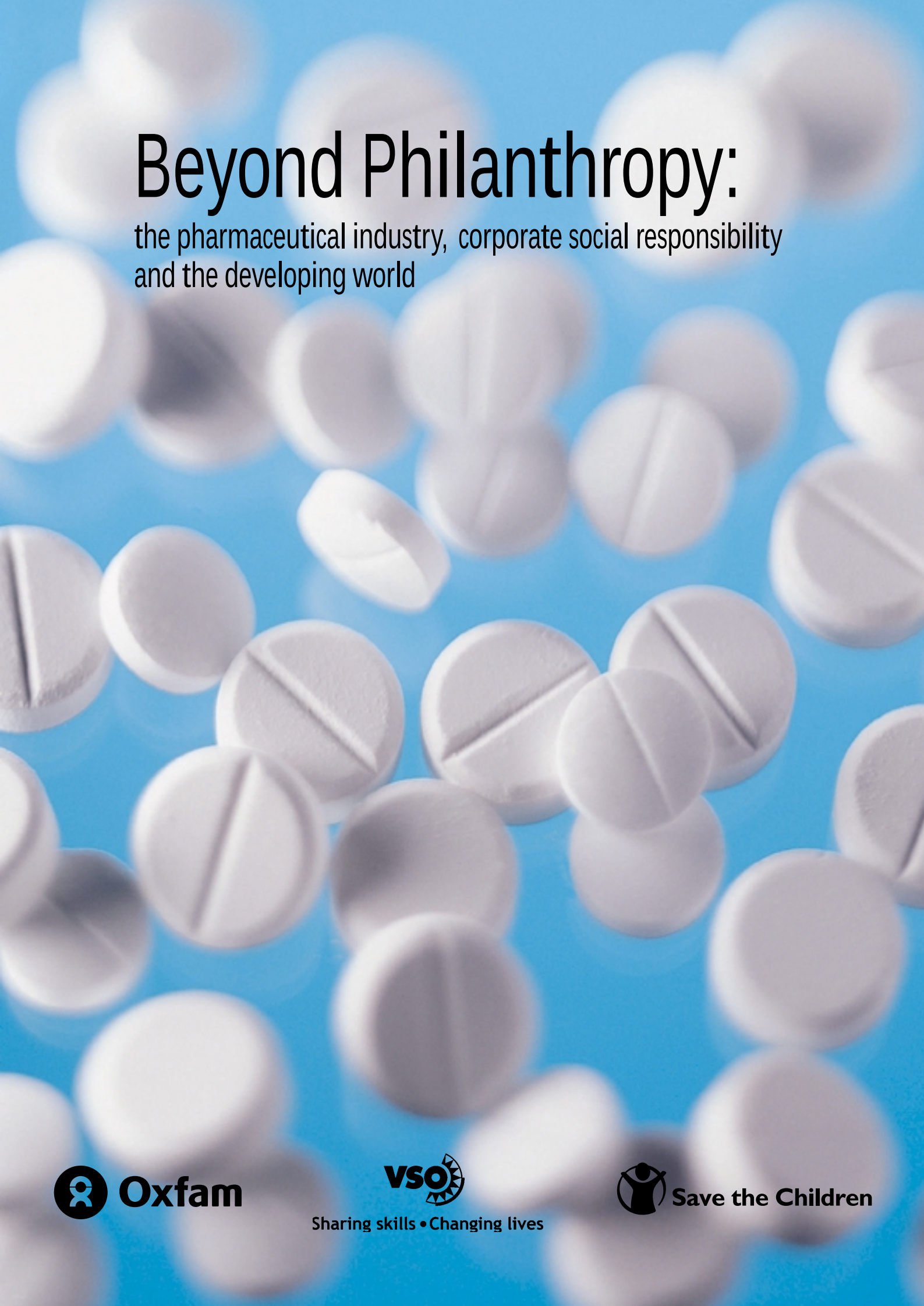

Beyond Philanthropy:

the pharmaceutical industry, corporate social responsibility and the developing world

Oxfam

VSO
Sharing skills • Changing lives

Save the Children

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An Oxfam/Save the Children/VSO joint report

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Sharing skills • Changing lives

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Acknowledgments

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Edited by Bonita Glanville Morris, Oxfam GB Creative Services Unit
Designed by white space.

Oxfam, 274 Banbury Road, Oxford OX2 7DZ
The Save the Children Fund,17 Grove Lane, London SE5 8RD
VSO, 317 Putney Bridge Road, London SW15 2PN

Contents

Executive summary

In this report, development agencies Oxfam, Save the Children, and VSO challenge the pharmaceutical industry to improve its efforts to tackle the health crisis affecting children and adults in developing countries. The HIV/AIDS pandemic has shown that the industry is not above criticism. Corporate social responsibility (CSR) policies should govern companies' core business activities in the five key areas benchmarked in this report.

Oxfam, Save the Children, and VSO believe that a responsible company should have policies on access to treatment for developing countries which include the five priorities of: pricing; patents; joint public private initiatives (JPPIs); research and development (R&D); and the appropriate use of drugs. The industry, however, currently defines its policy on access largely in terms of philanthropic ventures.

In each of the five areas addressed by the report, companies have demonstrated varying degrees of performance. The report welcomes signs of increased flexibility in the industry's approach to access to treatment in developing countries by some companies in some areas. However, the key finding is that critical challenges remain, particularly on the issue of pricing.

The report points out that companies are unwilling to address the health crisis through a systematic approach to tiered pricing of medicines for developing countries. As a result, companies appear reluctant to engage in an area where they have greatest competence. A systematic approach to drugs pricing could lower prices sustainably if delivered through an efficient system; it would also strengthen the industry's potential to improve global health with little effect on profits. Recent price reduction offers represent a welcome step forward, but as ad-hoc commitments, they cannot achieve the predictability, sustainability and efficiency necessary to meet the needs of developing countries.

In the area of patents, the report concludes that pharmaceutical companies remain unwilling to adopt a flexible interpretation of intellectual property rights to enable better access to medicines. This lack of flexibility will contribute to higher prices in developing countries.

The report also notes a considerable increase in the number of JPPIs which include donations, R&D, and price reductions. Companies clearly consider them to be a sufficient response both to the health needs of developing countries and to stakeholder expectations. For infectious diseases which exist only in developing countries, properly managed JPPIs can be of critical value. Longer-term donations are to be welcomed, but concerns about the governance of JPPIs and their wider impact on health systems also need to be addressed. Oxfam, Save the Children, and VSO believe, however, that for diseases affecting both rich and poor countries, a more flexible approach to patents and pricing would be a more effective means of ensuring that developing countries have access to medicines.

Companies have particular expertise in R&D, which is also addressed in the report. Despite examples of increased commitment to R&D into tropical diseases, only a few companies report that they have dedicated tropical disease research units. Companies are also reluctant to publish the value or proportion of R&D expenditure on such diseases, regardless of whether or not they have a dedicated research function.

The report demonstrates that once drugs are developed, most companies are unwilling to endorse World Health Organisation (WHO) standards of conduct. Companies are not prepared to make greater efforts at self-regulation in areas of marketing and drug-safety monitoring in countries with weak regulatory systems, despite the potentially negative health impacts of failing to do so. Disclosure to stakeholders on the appropriate use of medicines is particularly weak.

Oxfam, Save the Children, and VSO believe that increased accountability requires hard facts to be put into the public domain so that people can judge how and whether the industry is meeting credible CSR targets. Response to the questionnaire on which the report is based was mixed, with only three out of eleven companies (Bristol-Myers Squibb, GlaxoSmithKline, and Novartis) providing detailed, considered responses.

The report provides benchmarks against the five critical policy areas. These are intended to help investors, companies, governments, NGOs, and the public in general to judge whether a company is taking into account its impact on developing countries. The benchmarks will enable critics and investors to assess the performance of individual companies, and to make comparisons across the industry. They will help to demonstrate the effectiveness of management to deliver policies that have the most positive impact on the lives of poor people in developing countries. They will highlight how open and receptive companies are to calls for change. By adhering to the benchmarks, companies will also strengthen their risk management strategies and reduce the threat of increased regulation.

Oxfam, Save the Children, and VSO hope that the report and the benchmarks will provide an impetus to individual companies, and the pharmaceutical industry as a whole, to actively consider the needs of poor people in developing countries as a core part of their CSR.

Benchmarks

Assessment of CSR in developing countries should include demonstrable commitments against the following benchmarks:

Pricing

- The company supports calls for a systematic, global approach to pricing, overseen by an international public health body, to address the needs of developing countries.
- The company's policies support substantially lower prices of medicines in developing countries.
- The company publishes a list of pricing offers made to developing countries. Any conditions on the offers are also published.
- Price reductions are not limited to one or two "flagship" drugs but cover a range of products that are relevant to health priorities in developing countries.

Patents

- The company refrains from enforcing patents in developing countries where this will exacerbate health problems.
- The company supports lifting TRIPS restrictions on the export of generic versions of patented medicines to developing countries where a patent is not in force, in line with the Doha Declaration.
- The company does not lobby governments for stronger patent protection than that mandated by TRIPS, or for weaker public health safeguards.
- The company discloses to shareholders its lobbying position on patents and expenditure on such lobbying.

Joint Public Private Initiatives (JPPIs)

- The company's approach to JPPIs is clearly stated as part of an overarching CSR policy that addresses all issues surrounding access to medicines, including patent protection, pricing, and R&D.
- JPPIs involve ongoing commitments to resolving targeted health problems as part of a company's long-term business plan.
- The company ensures that its JPPIs do not exclude vulnerable sectors of society.
- The company ensures that its JPPIs state objectives to integrate with and strengthen national health systems, and report on their impact.
- The company provides transparent information on its involvement in the governance of JPPIs, including details of any conditions.

Research and Development (R&D)

- The company publishes target expenditure for its R&D on infectious diseases.
- The company supports and participates in JPPIs that address R&D for infectious diseases.
- The company foregoes patent rights in developing countries of drugs developed under JPPIs for infectious diseases.
- The company's pricing policy ensures that products developed as part of a JPPI are affordable to developing countries.

Appropriate Use Of Medicines

- The company has a policy that supports and complies with WHO Guidelines for Good Clinical Practice for trials on pharmaceutical products.
- The company publishes the full results of all clinical trials in a registry accessible to third parties.
- The company has a policy that supports and complies with WHO Ethical Criteria for Medicinal Drug Promotion and reports to shareholders on complaints upheld.
- The company undertakes active drug safety monitoring for any product it introduces to a country where local monitoring systems are weak and market-specific risks are high.
- The company discloses reports of any adverse drug reactions to regulatory authorities and the WHO in all relevant countries.

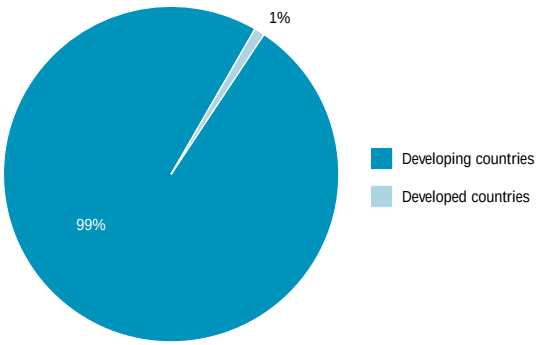
The health crisis in the developing world

Every year, infectious diseases kill 14 million people.[1] Most of these deaths are of poor people living in developing countries, particularly children under the age of five. The majority of these diseases are preventable or easily treatable.

Treatments are available for many of the biggest killer diseases. Yet many medicines that could prevent people dying and suffering ill-health are too expensive for developing countries to afford.

Just twelve infectious diseases[2] account for 20 per cent of the entire global disease and disability burden. Infectious diseases overall are responsible for 63 per cent of deaths of children aged under five years. Although some infectious diseases, such as HIV/AIDS, are a growing threat worldwide, the effects are felt disproportionately in developing countries. Poor countries carry 99 per cent of the global burden of these twelve diseases (see Figure 1).

Fig 1: Global Burden (in disability-adjusted life years) of Twelve Infectious Diseases.[3]
Source: WHO World Health Report 2001



The health crisis has many complex causes, including poverty, poor nutrition, persistent under-investment in health systems, and war. High prices of medicines are another cause.

The solutions are equally complex. Tackling disease and ill health depends critically on appropriate social and economic policies. By their very nature, they require long-term strategies and solutions. Governments of developing countries need to develop and expand their health systems, and to ensure that services are accessible to those children and adults who most need them. Donors must acknowledge the extent of the health crisis and make increased long-term commitments to strengthen health care systems. This means helping countries to develop safe and effective systems of drug procurement and distribution, as well as providing logistical and technical support to health planning, training, and delivery mechanisms. Contributions to the Global Fund to fight AIDS, TB, and Malaria (GFATM), which provides one-off grants to fight specific diseases can be only additional to such long-term support.

The private sector, and pharmaceutical companies in particular, needs to respond too. Pharmaceutical companies produce vital medicines. But medicines alone are not enough if those who need them cannot afford or access them.

The pharmaceutical industry has a role to play in ensuring that its policies and practices support the fight for health in the developing world, particularly in those countries with acute shortages of resources and poor infrastructure. Oxfam, Save the Children, and VSO acknowledge, however, that the pharmaceutical industry is not responsible for building developing countries' health systems.

The pharmaceutical industry has grown in value by 700 per cent since 1980.[4] Significant scientific advances have

been made, but developing countries are not reaping the benefits. Less than 10 per cent of world pharmaceutical sales are to developing countries (see Figure 2) and only one per cent of anticipated 2002 sales are to Africa. Spending on R&D is also skewed away from the developing world with only 10 per cent of the global pharmaceutical research and development expenditure going towards diseases that account for 90 per cent of the world's disease burden. There has never been a stronger need for the industry to make its contribution and fulfil its social responsibility.

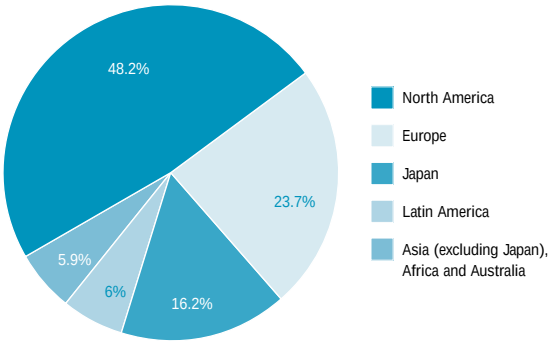


Fig 2: % of Pharmaceutical Sales (2000)
Source: IMS Health World Review 2001

1. Introduction

Oxfam, Save the Children, and VSO[5] have joined forces to produce this report due to a shared concern about the scale of the health crisis in developing countries, and a consensus that the pharmaceutical industry can play a key role in improving the health of millions of people in poor countries.

In this report we challenge pharmaceutical companies to define more clearly their commitment to corporate social responsibility (CSR) in policies which are central to their business and go beyond the industry's current philanthropic initiatives. We reflect on the industry's current performance on the basis of responses received to a questionnaire (see Appendix 1: Methodology).

We have provided benchmarks against which good CSR policy and practice in the pharmaceutical industry can be assessed. This gives companies, investors, governments, and non-government organisations (NGOs) a tool with which to assess the contribution of companies to tackling the health crisis in the developing world.

The report focuses on five key areas where the pharmaceutical industry can have a major impact on health care in developing countries.

The five areas are:
Pricing
Patents
Joint public private initiatives (JPPI)
Research and development (R&D)
Appropriate use of medicines

For each of the five key areas, we give:

- a brief outline of the current debate and why Oxfam, Save the Children, and VSO consider it a crucial area, in light of its bearing on health in poor countries.
- an explanation of how Oxfam, Save the Children, and VSO believe companies should be responding.
- a set of benchmarks which investors, companies, and governments, can use to judge a company's performance in each policy area.
- an overview of responses from eleven pharmaceutical companies surveyed against each of these benchmarks.

Oxfam, Save the Children, and VSO hope the report will encourage all pharmaceutical companies to establish and report on a CSR policy as it relates to their impact in developing countries. Such an approach would enhance transparency and accountability, particularly among those companies that have yet to address the impact of their business in developing countries.

2. The pharmaceutical industry and corporate social responsibility

Corporate social responsibility (CSR) is industry's response to growing public concern about the accountability and the social, economic, and environmental impact of global corporations.

To date, CSR has been closely linked to public relations and reputation risk management. CSR is used to reassure an increasingly anxious audience of investors, governments, consumers, and citizens that companies are trustworthy, sensitive to public pressure, able to manage their power in the public interest, and overwhelmingly, do not need further regulation.

The key challenge facing companies which are embracing the new discipline of CSR is in its content. For Oxfam, Save the Children, and VSO, CSR is about more than philanthropy. It is about the role that global companies can and should play in addressing some of the deep inequalities between rich and poor countries – inequalities which create and perpetuate poverty. It is about challenging companies to rethink their attitudes towards markets in developing countries in order to evaluate and improve the impact their business has on human development. It requires companies to review seriously how they can undertake their core business in a way that ensures the benefits are shared more evenly between rich and poor countries.

In the wake of public pressure, the pharmaceutical industry has now acknowledged that it has a more important role to play in the complex process of increasing the availability of medicines in poor countries. Since 1999, there has been a considerable increase in philanthropic programmes, with some significant sums being spent by companies in joint public private initiatives (JPPIs). There have also been interesting developments in research-based public private initiatives to tackle key infectious diseases, such as HIV/AIDS, malaria, and tuberculosis (TB).

However, the industry has not yet made a collective and systematic move to address the crucial issue of pricing - the area in which it could have the single most significant impact.

Growing attention to the pharmaceutical industry's alleged complacency in the face of the human suffering wrought by the AIDS pandemic has shown that the industry is not above criticism. The issue of access to medicines in poor countries has proved a real reputation risk, threatening investor confidence and employee morale. For example, the decision by the pharmaceutical industry to challenge the government of South Africa for not protecting its intellectual property proved to be unwise. Instead of strengthening legal safeguards, it resulted in increased public awareness of the issues surrounding prices and patents, and encouraged developing countries to stand together to demand that public health be given priority over patent protection. The industry is now faced with the possibility of more stringent regulations, which could alter market dynamics and reduce profitability.

Oxfam, Save the Children, and VSO believe that a company's CSR policy in relation to developing countries should address five specific issues: pricing; patents; JPPIs; R&D; and appropriate use of medicines. Broader aspects of CSR policies, relating to governance, are also directly relevant when assessing the quality of a company's response to the health crisis in developing countries.

If companies are to demonstrate that CSR is more than an exercise in public relations, they will need a clear, comprehensive policy on the subject. This should include measurable targets, which will be implemented and reported on by a nominated board director.
The results of implementing these policies should be reported in the company's annual report.

3. The pharmaceutical industry's response

In its response to the questionnaire sent out by Oxfam, Save the Children, and VSO, the pharmaceutical industry's overall response, with some notable exceptions, lacked transparency and provided a poor indication of stakeholder accountability – both key considerations when assessing corporate responsibility.

Only GlaxoSmithKline (GSK), Novartis, and Bristol-Myers Squibb (BMS) responded directly to the questionnaire. Abbott partially responded to the questionnaire. Merck, Bayer, AstraZeneca, Aventis, Pfizer, and Boehringer Ingelheim responded selectively with statements on their position on some of the issues in the questionnaire, but did not respond directly to the questions. Among this latter group, Bayer's response was the briefest. Only Hoffmann-La Roche did not respond at all, citing reasons of confidentiality.

The poor level of response means that we have been unable to reflect either individual company responses, or an industry norm, in a comparative and systematic way. Based only on the responses to our questionnaire, our overall transparency rating for the eleven companies approached is shown in Figure 3.

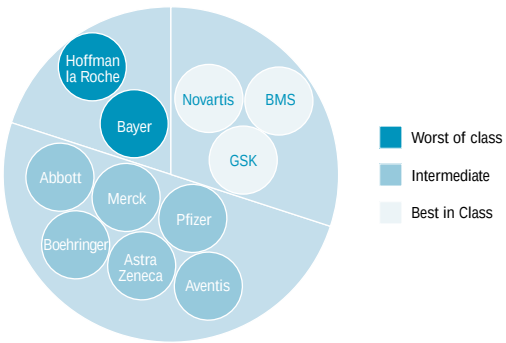


Fig 3: Overall Transparency Rating for Eleven Companies' Responses

Overall, the lack of answers or overqualified answers illustrate an industry that, despite being increasingly aware of the need to be seen to act responsibly, appears generally reluctant or unable to articulate a systematic, transparent, and accountable response to the issues raised.

Seven of the eleven companies surveyed have mission or policy statements on company values or social responsibility, but many of these do not have policies on the specific issues raised in this report. Certain aspects of access and appropriate use of medicines are raised at a general level in a number of companies' mission statements. Only two companies (Novartis and GSK) told us that they have a stated policy on access to medicines, with GSK's *Facing The Challenge* representing the industry's first attempt to address the issues of access in a comprehensive way.[6] Appropriate use of medicines formed part of four companies' stated policies (Merck, GSK, BMS and AstraZeneca).

The overall governance of CSR policies is varied, with only three companies willing to outline responsibilities for policy implementation. Merck and GSK have an explicit, additional CSR structure, with independent committees advising the board. AstraZeneca has appointed a non-executive director for CSR.

Five key issues

3.1: Pricing

Pricing is the area where companies can do most to address the health crisis. High prices of medicines hinder developing countries' efforts to provide effective health care. Lower prices could improve the long-term health of people in poor countries without significantly affecting industry profitability, providing that certain safeguards are put in place.[7] Although selective one-off price reductions can bring limited increases in access, they discourage long-term health planning in developing countries. In particular, there are no guarantees that price offers will continue and the range of products on offer is not predictable. Individually-negotiated, case-by-case price reductions are the norm, but they are not enough to meet the needs of developing countries. Companies acknowledge that the economic realities facing poor people in developing countries differ drastically from those faced by developed countries. Oxfam, Save the Children, and VSO believe that these economic differences should be formalised in a global tiered-pricing system.

A global approach to tiered pricing system would allow countries to focus their scarce resources on delivery of essential health care rather than time-consuming price negotiations. It could also increase returns to companies if done in a properly segmented market.

A global tiered pricing system would incorporate 'pro-poor' policies, segregate the world's markets, and bring long-term, sustainable, and substantially reduced prices to all developing countries. It should be managed and monitored by an international public health body such as the WHO. It should ensure access to a broad range of products and improve price information – thus increasing the buying power of developing countries; and encourage participation of pharmaceutical companies.[8]

The system should be transparent and predictable. It should encourage easy access to information to enable low-capacity health authorities to make the most appropriate purchase decisions. Transparency should be acceptable to pharmaceutical companies, some of whom already publish their reduced price offers. Transparency would also ensure that the international body can be held accountable for the management of the system.

Filling the gap between lowest price and affordability is a role the international donor community must play, both bilaterally and through initiatives such as the GFATM. By actively pursuing a policy of systematic, transparent, tiered pricing for its products, companies would enable greater cost-effectiveness of international aid, while allowing developing countries the opportunity to plan their health interventions in a more rational and sustainable manner.[9]

Pharmaceutical companies have resisted calls for tiered pricing beyond isolated concessions citing two main concerns: parallel importing and reference pricing. Oxfam, Save the Children, and VSO believe that these two real concerns can be addressed satisfactorily.

Pharmaceutical companies are concerned that the medicines they sell more cheaply in developing countries may be imported by industrialised countries (parallel importing), leading to erosion of profitability. This problem can be avoided. Most industrialised countries already prohibit the import of patented medicines from abroad without the patent-holder's consent. There is no reason why other industrialised countries should not agree to do likewise in cases where substantial price reductions are being offered to the developing world. Developing countries can also agree to prevent the export of medicines that have been offered to them at favourable prices. Clearly, the political will to do so is greater if there is a long-term commitment by the companies to maintain substantially lower prices.

Responsibility also lies with the pharmaceutical industry for strengthening market segmentation.Measures such as different labelling and packaging can be applied to specially-priced products.

Companies which remain concerned about the potential impact of parallel importing of drugs sold under a tiered-pricing system should be reassured that very few drugs sold in the developing world ever reach developed world markets. Companies should produce realistic forecasts of the possible scale and nature of the parallel-importing problem, and propose how it could be tackled constructively.

Industry is also worried that governments and health-care providers in the developed world will use lower

developing-world prices as benchmarks for negotiating their own reduced prices – known as 'reference pricing'. This concern is already being addressed by the UK Government, which has shown commitment to tiered-pricing as part of the solution to the health crisis. The Accelerated Access Initiative (AAI) also demonstrates that where political will exists, reference pricing can be eliminated.

Industry concerns about breaching WTO or anti-trust laws can also be addressed, as individual companies would continue to be responsible for setting their own prices. Additionally, the WTO itself has said that '*…differential pricing could and should play an important role in ensuring access* [to medicines]'.[10]

Oxfam, Save the Children, and VSO do not see tiered-pricing as a sufficient measure to resolve all health problems, but believe it is a necessary part of a solution. Companies have argued that tiered-pricing on its own is not the complete solution, but this adds strength to the convincing case for a global co-ordinated approach to the acute health problems facing the developing world.

Oxfam, Save the Children, and VSO propose the following benchmarks for company policy on pricing:

- The company supports calls for a systematic, global approach to pricing, overseen by an international public health body, to address the needs of developing countries.
- The company's policies support substantially lower prices of medicines in developing countries.
- The company publishes a list of pricing offers made to developing countries. Any conditions on the offers are also published.
- Price reductions are not limited to one or two "flagship" drugs but cover a range of products that are relevant to health priorities in developing countries.

Company Responses

Support for a global tiered pricing system and support for lower prices

No company is prepared publicly to support a systematic, global tiered-pricing system. The overall response of the industry to the need for lower-priced medicines is, however, varied.

> By actively pursuing a policy of systematic, transparent, tiered pricing for its products, companies would enable greater cost-effectiveness of international aid, while allowing developing countries the opportunity to plan their health interventions in a more rational and sustainable manner.

While a number of companies offer selected drugs at lower prices, there is little support for reductions on prices in all developing countries. For example, AstraZeneca states that it '*…will offer differential prices to customers as a normal part of its business on a case-by-case basis.*' Pfizer takes a different approach: '*For many patients in least-developed countries, medicines at any price are unaffordable. That is why Pfizer supports donation programs.*' While appropriate and welcome in some circumstances, donations on the scale needed to address the health crisis are not a commercially-sustainable, long-term solution.

Companies can develop pricing policies which treat developing countries as a bloc, as Boehringer Ingelheim, GSK, and Merck have all demonstrated. For example, Boehringer Ingelheim is offering nevirapine (Viramune) at reduced prices (in addition to its donation programme) '*....to a total of 77 developing countries,*' and '*…is committed to offering preferential pricing to all countries included in the lower-middle income and upper-middle income economies.*'

Transparency of pricing offers

Transparency of prices is also possible as demonstrated by the actions of Merck, Boehringer Ingelheim and GSK. Merck explains: *'Announcing these new prices publicly… simplifies the process for countries and other*

buyers… the company is also making the new prices public to increase transparency.' Merck's stance is laudable, and makes the case for transparency that has yet to be reflected by the industry's trade associations. Abbott's response to supporting a global price database is also encouraging: '*In principle, this would not pose a problem for Abbott's own drugs, the price and terms for which are already public.*'

Prices reflect public health needs

Pricing offers should not be limited to single-disease initiatives. Boehringer Ingelheim's pricing offer extends only to a single anti-retroviral, albeit with great humanitarian value. GSK recognises the need not to distort health priorities stating that '*…a key consideration in offering preferential prices for other products* [e.g. anti-diarrhoeals] *is that we do not want to distort national treatment priorities.*'[11] But this argument should not be an excuse for companies to refuse to offer cheaper prices on any medicines.

Oxfam, Save the Children, and VSO acknowledge that the pricing policies adopted by Boehringer Ingelheim, GSK, and Merck were bold moves for these three companies. However, by not addressing pricing systematically across the industry, the pharmaceutical sector is failing in the one area where it has the greatest opportunity to improve public health.

3.2: Patents

Oxfam, Save the Children, and VSO recognise that patent protection creates market conditions which enable pharmaceutical companies to recoup their R&D investments and provide incentives for future research. However, the system of patent protection in industrialised countries has evolved over many years, and reflects high levels of economic and scientific development. In poor countries, where levels of development are lower, this advanced patent system is inappropriate and poses real threats to public health and industrial development.

Until now, poor countries have been able to buy cheaper copies of life-saving drugs from countries such as Brazil and India, which are able to manufacture generic drugs. When the World Trade Organisation (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is fully implemented,[12] poor countries will have to offer patent protection of at least twenty years for all pharmaceuticals. Generic production of new drugs will dry up, removing competition and leaving poor countries dependent on prices and marketing decisions made by the patent-owner. The high prices resulting from the lack of competition from cheaper generic versions will reduce access to medicines in countries where they are most needed.

TRIPS includes safeguards to allow countries to bypass patents, if necessary, by compulsory licensing. This enables them to bargain much more effectively over prices.[13] These safeguards were reconfirmed in the WTO's Doha Declaration in November 2001.

Unfortunately, in practice it is very difficult for smaller, or less developed countries, to make use of the safeguards as they lack the required manufacturing capacity and cannot afford to risk litigation or trade disputes. Poorer countries often lack the legal resources to interpret and implement the TRIPS safeguards in favour of public health and development objectives. In addition, powerful companies and rich countries have pressurised developing countries not to use the safeguards, or to implement unnecessarily restrictive legislation – dubbed 'TRIPS plus'.[14]

Another problem with TRIPS is that it does not allow countries to export affordable generic versions of patented drugs to poor countries which do not have pharmaceutical patenting, or which want to issue a compulsory licence for a medicine but do not have the capacity to produce it. In effect, TRIPS says that poor countries can keep costs down by buying generic versions of medicines patented in the rich world, but does not allow anyone to sell them. The Doha Ministerial committed the WTO to resolving this problem before the end of 2002 but some industrialised countries, notably the US and others with strong pharmaceutical sectors, are fighting a rearguard action to make solutions ineffective or unworkable.[15]

It is important to emphasise that the impact of TRIPS and patenting on the developing world will grow over time, as more countries become compliant and as new, patented drugs come on to the market. This creates the potential for more vocal criticism of the industry. Access to patented anti-retrovirals in Africa was the first major controversy, but it will not be the last.

The pharmaceutical industry has traditionally lobbied hard for high levels of intellectual property protection in developing countries. This is based partly on concerns that lower levels of protection in developing countries or frequent use of compulsory licences will lead to lower prices, which will in turn increase pressure for price reductions or even patent law reform in their industrialised-country markets. Indeed, the fact that an Indian generic anti-retroviral costs one twentieth the price of the patented version in the US has led to questioning of price policy in the US. This concern is similar to that raised by industry in relation to differential pricing (discussed in more detail in section 3.1).

Clearly, these concerns must be addressed, not through the stringent application of patents, but by building a political consensus that a segmented market between rich and poor countries is justifiable and should not lead to calls for price reductions in developed countries. Paradoxically, the pharmaceutical industry's stubborn defence of high levels of intellectual property protection in the developing world stimulates much greater questioning of the global patents system.

The industry's track record of intransigence over patent enforcement in developing countries was one of the main reasons for the public opprobrium it received during 2001. And nowhere was this more apparent than in the court case brought by the industry against the government of South Africa. A more flexible approach to patents would not only significantly increase access to medicines in poor countries, but also make negative publicity less likely. However, there is little evidence of movement in this field, despite the fierce public debate during 2001 that culminated in the Doha Declaration. This statement of WTO member states declared in November 2001 that '*TRIPS does not and should not prevent members from taking measures to protect public health*'. It attempts to establish the right of developing countries to interpret the agreement with enough flexibility to meet public health concerns. If this right is not respected, developing countries may push for amendment to the entire agreement.

Oxfam, Save the Children, and VSO propose the following benchmarks for company policy on patents:

- The company refrains from enforcing patents in developing countries where this will exacerbate health problems.
- The company supports lifting TRIPS restrictions on the export of generic versions of patented medicines to developing countries where a patent is not in force, in line with the Doha Declaration.
- The company does not lobby governments for stronger patent protection than that mandated by TRIPS, or for weaker public health safeguards.
- The company discloses to shareholders its lobbying position on patents and expenditure on such lobbying.

Company responses

Not enforcing patents in developing countries

From the responses, there is little evidence of increased commitment to a more flexible approach to patent protection by individual companies within the industry. Novartis is prepared not to apply for patents in least-developed countries (LDCs), but since LDCs do not have the capacity to manufacture generic versions of new drugs, this concession is only meaningful if they can buy them from abroad.

Pfizer denies the relevance of patents to access to medicines: '*In nearly all of the poorest countries most affected by the AIDS epidemic, patents are irrelevant to the access debate because either there is no effective patent law or patents have not been enforced*'.[16] In fact, there are 23 countries in sub-Saharan Africa which have four or more anti-retrovirals on patent, and these countries have 53 per cent of the world's HIV/AIDS patients.[17]

Voluntary licensing, whereby a company gives permission to another firm to produce a patented drug is another way for companies to adopt a more flexible approach to patents. Only GSK gives evidence that it has recently issued any voluntary licences:[18] '*We believe this will improve access to these medicines in South Africa*',

There is little evidence of increased commitment to a more flexible approach to patent protection by individual companies within the industry.

although GSK provided no evidence that they have a corporate policy on voluntary licensing. Pfizer and AstraZeneca do not believe that access is improved by issuing licenses.

Merck argues conversely that patent protection is one of the conditions that enables it to commit to philanthropic programmes: '*…doing well is a precondition to doing good: an enabling policy environment (including adequate TRIPS-compliant intellectual property standards) is a prerequisite for a company to have the wherewithal to mount a major philanthropic programme.*'[19]

Response to the question of whether a company has any patent infringement cases pending in developing countries was limited. GSK states: '*In certain cases we do take action against infringements in developing countries, and we consider the merits of doing so on a case-by-case basis*'. Novartis is currently taking action against two unspecified developing countries, and considers '*…a wide variety of countries, to a greater or lesser extent, have policies and legislation in violation of TRIPS*'. All other companies were silent on this issue.

TRIPS restrictions on exporting generics

There was no evidence that any company supports waiving patents in generics-producing countries, even if the generic equivalent is produced exclusively for export to LDCs where there is no patent, or to developing countries where a compulsory licence has been issued.

Only two companies made any response to the question of whether companies would support the right of LDCs to apply for a compulsory licence in another country. Novartis, commenting on compulsory licensing in general, argues: '*In most cases, we are not convinced that access to treatment would actually be increased by compulsory licensing*.' GSK's response is qualified : '*We are actively considering this question in the light of the mandate of the Doha Declaration. In particular, we are considering the circumstances and conditions under which such exports might be necessary or helpful. Compulsory licensing has always been a tool available where necessary in those countries which have implemented TRIPS. However, we do not consider that this issue has in any way contributed to access problems and do not believe that there should be a general right to export.*' The remaining companies were all silent on this critical issue.

Political lobbying, and lobbying position on 'TRIPS-plus'

GSK, Abbott, and Novartis all stated that they are not lobbying rich governments to press for 'TRIPS-plus' in their bilateral dealings with poor countries, which is an encouraging lead to other companies to make their position clear. Other companies chose not to respond to this question.

3.3: Joint public private initiatives (See Appendix 2)

The pharmaceutical industry has put increasing effort into joint public private initiatives (JPPIs), in which companies, public health, and finance bodies work together to target a specific disease common to many developing countries. They cover R&D, and disease prevention or treatment, and involve cash or product donations or price reductions on specific medicines and vaccines. They tend to tackle particular diseases. They may bring together a number of the following: the WHO, the World Bank, representatives of the pharmaceutical industry, NGOs, governments of developing and industrialised countries, private foundations, and research institutes. Increasingly, the pharmaceutical industry sees JPPIs as the most effective vehicle for fulfilling its responsibility for increasing access to health in developing countries. The focus of this section is on drug-based JPPIs.

Oxfam, Save the Children, and VSO acknowledge the importance of working with a wide range of institutions to tackle pressing health issues in developing countries. The distribution of medicines requires more than their availability from the manufacturer; it needs the strengthening of systems by governments and donors to deliver medicines safely and efficiently. If such interventions are to be useful to overstretched developing country governments, they must also be sustainable. We therefore believe that public and private sector players need to take a critical look at the nature of the drugs involved and the long term support needed before developing new administrative programmes.

For these purposes, JPPIs can be divided into two

categories: those which tackle diseases affecting people from both rich and poor countries but which are relatively more burdensome to developing countries, such as HIV/AIDS and recently TB; and those which tackle neglected diseases that affect only patients in developing countries, such as river blindness and lymphatic filariasis. Drugs used in the former tend to be new products that are commercially viable in wealthier countries, but that are also desperately needed in markets where patients have no or little purchasing power. Drugs used in the latter cases are likely to have little commercial use in the developed world.

Oxfam, Save the Children, and VSO do not believe that JPPIs alone are always the most appropriate response of industry to these rich/poor diseases in developing countries.

Where a drug is expected to provide significant financial returns to its manufacturer, long-term donations are not likely to be commercially viable. Flexibility on issues such as patenting and pricing in developing countries would make a far more significant industry contribution, providing the prospect of greater, longer-term, and more sustainable access to medicines. The local, licensed production of a drug should guarantee a more sustainable supply than a limited donation of the same product. A broad, tiered pricing system should enable greater predictability and efficiency for governments than negotiations of drug donations for each and every disease.

For tackling neglected diseases affecting children and adults only in developing countries, Oxfam, Save the Children, and VSO agree that JPPIs can, with certain improvements, prove to be of critical value. Where a company has the technology for a relevant drug and can produce it without the consideration of recouping R&D costs, an indefinite donation to a public health programme should be both sustainable and highly valuable.

Yet many JPPIs to date – both for rich/poor and neglected diseases – have been limited in scope and short-term in delivery, making their benefits thinly spread and unpredictable.[20] Company commitments need to reflect a more sustainable approach.

Companies also should be able to illustrate that JPPIs benefit the most vulnerable communities, which have least opportunity of accessing medicines through other channels. This means reaching those communities with the weakest health systems on a fair basis. While all long term drug donations may be valuable, ethical questions arise if they are donated only to treat a specific disease in communities that would benefit from their broader application. Public health principles should ensure that JPPIs do not restrict treatment to a single disease if other vulnerable patients can be treated with the same drug.

Pharmaceutical companies frequently refer to the need for strong health systems in order for their drugs to be used appropriately. The temptation for JPPIs is to target countries or parts of countries where health systems are already strong and can deliver quick results. Recent research[21] has shown that the Global Alliance for Vaccines and Immunisation (GAVI) had no mechanism for avoiding this, and as a result, the most vulnerable communities can be further marginalised. JPPIs must strengthen the very systems that are required to deliver health care, at the same time as controlling diseases. Finally, JPPI strategies should be integrated into the existing health strategies of recipient countries: a new high profile donation programme can very easily distort existing priorities or absorb valuable resources from them.

If companies are to persuade investors and other stakeholders that public health needs are fully considered in their dealings with developing countries, then they must be able to provide demonstrable evidence. In this CSR policy area, transparency of objectives in JPPIs, with information on their governance, restrictions and progress, will allow external evaluation of their impact and will improve accountability. This is particularly relevant where a commercial market for the donated drug still exists, such as the drugs for the AAI.

Oxfam, Save the Children, and VSO propose the following benchmarks for company policy on JPPIs:

- The company's approach to JPPIs is clearly stated as part of an overarching CSR policy that addresses all issues surrounding access to medicines, including patent protection, pricing, and R&D.
- JPPIs involve ongoing commitments to resolving

targeted health problems as part of a company's long-term business plan.

- The company ensures that its JPPIs do not exclude vulnerable sectors of society.
- The company ensures that its JPPIs state objectives to integrate with and strengthen national health systems, and report on their impact.
- The company provides transparent information on its involvement in the governance of JPPIs, including details of any conditions.

Company responses

JPPIs should be part of company access policy

The companies' responses do not suggest any acknowledgement of a necessary connection between JPPIs and company policies on pricing and patents. Pfizer, for example, claims that '*…the watchword should be partnership*'; while at the same time, the company maintains a restrictive and inflexible approach to intellectual property protection in developing countries. Neither Merck nor Novartis responded on the value of compulsory and voluntary licensing for developing countries, yet these companies are champions of JPPIs: '*JPPIs need to become the preferred working method and not merely exceptions*.' (Novartis)

Long-term commitments

Donations to global JPPIs are now being given on a longer-term basis, which is to be welcomed. Pfizer has increased its commitment to a programme against trachoma to five years. This is also the duration of Boehringer Ingelheim's donation of nevirapine (Viramune) to help prevent mother-to-child transmission of HIV/AIDS; Merck's vaccine donation commitment made in support of GAVI; and more recently, the donations from Aventis, Bristol Myers Squibb, and Bayer, for sleeping sickness. Pfizer's initial offer of fluconazole (Diflucan) to South Africa was for two years which, after negotiation, then became an indefinite commitment. To date, there are two donations to global JPPIs that stand out for long-term commitment: Merck's drug donation for river blindness and GSK's drug donation for lymphatic filariasis. Both have been made until the disease is controlled or eliminated as a public health problem. Such indefinite commitment should be regarded as best practice. Where the drug is new and so under patent, it is encouraging that the more sustainable tiered pricing approach rather than donations is emerging as the norm. The offer from Novartis of its new artemesin-based malaria treatment (Riamet/Co-Artem) at a dual price is for an indefinite period of time. Similarly, GSK and Merck's differential pricing offers to the AAI on their patented drugs are not time-limited. But GSK's Malarone donation programme, which was stopped after the initial trial period, illustrates the problems of trying to scale-up donation programmes of a high-cost therapy.

Targeting vulnerable populations

Many JPPIs prioritise countries on the combined criteria of disease prevalence and level of development (Boehringer Ingelheim, Merck, and GSK within the AAI). Some programmes, however, favour the particular circumstances of one country, such as Merck's African Comprehensive HIV/AIDS Partnership in Botswana. Pfizer's initial fluconazole (Diflucan) donation was originally restricted to one country, South Africa, and its commitment to extend the offer to 50 developing countries was a welcome development. Pfizer's donation was originally restricted to one specific condition related to HIV/AIDS, and only after requests from activist groups and the South African government was it extended to the treatment of another, far more common, opportunistic infection.[22] The same company's azythromicin donation to developing countries remains solely for treating trachoma, despite its evident therapeutic value in treating a number of other skin, ear, and respiratory infections, including pneumonia, one of the biggest child killer diseases.[23]

Complementing national health systems

Too often, JPPIs do not take into account their impact upon countries' broader health systems and policies. For example: '*Pfizer is focusing its efforts on product donations which, in our view, provide the most direct, least costly, and fastest means to address access problems in developing countries without extensive public infrastructure.*' Cost and speed certainly need to be considered but not necessarily at the expense of other health priorities.

Companies seldom report on the impact of their JPPIs on health systems. GSK, for example '*…does not report on achievements* [of the Lymphatic Filariasis Programme] *and does not select any indicators*.' The

company has, however, acknowledged the importance of not distorting national health priorities in its pricing policy (see Pricing section). The main focus of Aventis' report on sleeping sickness, is on the value of donations. However Merck, in its ivermectin (Mectizan) donation for river blindness, reports not only on the number of treatments supplied and the number of people treated, but also attempts to reflect sustainable improvements to health care by reporting on the ability of communities to plan and deliver ivermectin themselves.

Company commitments may have more impact if they work through an existing administrative structure. For example, the Co-Artem offer from Novartis, although still in the design stage, will be implemented through the WHO's ongoing malaria work with health ministries. This does not require a costly new infrastructure and so is less likely to distort existing health care systems.

Transparent governance

Information about the internal company governance structures of JPPIs were not included in the responses. None of the companies involved in AAI chose to comment. Company statements on what conditions are attached to their involvement in JPPIs were patchy. Less than half of the companies responded to this question. GSK responded on only two of the four JPPIs we asked about.

Companies were reluctant to comment on their involvement in external governance of JPPIs. Only Novartis affirmed that a role on a JPPI board (for Co-Artem) was essential. GSK chose not to refer to its role in the governance of the Malarone programme, in which it nonetheless played a key role.[24] In recognition of the risk of donor-interests being imposed on recipient countries, Merck stated a commendable governance philosophy: '*It is critical that the public and private sectors work together in a way that lets the people who are most directly affected determine their own needs and priorities.*'

Clearly, JPPIs are not going to disappear. More accountability and transparency are needed so that their impact, both on poor people's access to medicines and on broader health systems, can be assessed.

Clearly, JPPIs are not going to disappear. More accountability and transparency are needed so that their impact, both on poor people's access to medicines and on broader health systems, can be assessed.

3.4: Research and development (R&D)

Ten per cent of the global pharmaceutical R&D expenditure goes towards diseases which account for 90 per cent of the world's disease burden. As Médecins sans Frontières has pointed out, '*With billions of dollars dedicated to health R&D, it should be possible to develop effective treatments for these diseases. However, the lack of R&D for diseases common in developing countries means that very few new drugs have been brought to market for them.*' [25]

In 2001, total global R&D expenditure is estimated at US$70 billion. Individual company spends are estimated at between US$500 million to greater than US$1 billion per year, with 25 per cent or less of these amounts spent on R&D for infectious diseases.[26] These diseases represent some of the biggest threats, especially to children's lives, yet the amount spent on research is less than the alleged cost of bringing just one new drug to market.[27]

It is not hard to understand why the research-based pharmaceutical industry does not choose to invest more in the treatment of infectious diseases. There are vast numbers of potential customers in the developing world, but poverty prevents them from entering the market. Pharmaceutical sales in the developing world are concentrated in just a handful of emerging economies, where growth prospects sound promising. But in the year 2000, even Latin America accounted for only six per cent of global pharmaceutical sales. Sub-Saharan Africa accounted for far less – only around one per cent of the total global market.

While patents are designed to assure companies of a return on their R&D investment, this materialises only if there is a large enough market to pay for the end product. The extreme poverty in developing countries means that the market for medicines to treat infectious diseases is limited. Pharmaceutical companies are therefore reluctant to invest in R&D for these diseases. Companies' argument that increased intellectual property protection will lead to increased R&D does not bear scrutiny. The current dearth of R&D into neglected diseases proves that poor countries are of limited attraction to commercially-based R&D companies.

The countries in which a potential market does exist are characterised by imbalances in access to medicines among rich and poor. Where increased R&D is stimulated by the market potential, it is likely to be concentrated on diseases prevalent among better-off sectors of the population who can pay. Diseases linked to poverty, such as parasitic conditions, are unlikely to be strong candidates.

Companies need to include in their access policy targets for expenditure on R&D into infectious diseases, particularly for those diseases neglected because of their prevalence in poor countries. This requires transparency in companies' R&D expenditure for such diseases, whether as part of their internal activities or as part of a JPPI. Although companies tend to view such information as commercially sensitive, disclosing expenditure against targets would provide companies with an opportunity to prove publicly their commitment to poor country diseases.

The limits to the return on investment mean that industry alone cannot be expected to finance the level of funding required to research and develop new drugs for developing-country diseases. A substantial increase in public funding is also needed for poverty-focused pharmaceutical research and to ensure that successful products can be delivered effectively.

The industry, however, can make a significant contribution with its expertise in research and its ability to bring a drug to market. As several companies are showing, private sector expertise, time, and funds can combine with public-sector resources to pursue the search for new drugs for infectious diseases. For any of these initiatives, however, it is vital that any resulting medicines can be distributed to ensure the maximum access for poor households. Companies should be prepared to forego patent rights and to sell such medicines at affordable prices in the developing world.[28] A company can also contribute to R&D by taking off patent, or donating knowledge on a product which they have no plans to develop, but which could be used by another company to develop a drug for an infectious disease.

Oxfam, Save the Children, and VSO propose the following benchmarks for company policy on research and development:

- The company publishes target expenditure for its R&D on infectious diseases.
- The company supports and participates in JPPIs that address R&D for infectious diseases.
- The company foregoes patent rights in developing countries of drugs developed under JPPIs for infectious diseases.
- The company's pricing policy ensures that products developed as part of a JPPI are affordable to developing countries.

Company responses

Publish the value of R&D spent on infectious diseases

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 over the past three years. Abbott and BMS simply said that it was not their policy to disclose such information; Novartis gave '*competitive reasons*' for not sharing the information requested; and GSK claimed that it did not analyse its expenditure in this way. GSK was, however, able to state the proportion of R&D projects allocated to eleven infectious diseases: '*In October 2001, between 15 and 20 per cent of clinical development projects was for the eleven listed diseases. This figure includes drugs and vaccines*'.

Several companies have recently announced programmes for research facilities specifically for R&D into infectious diseases, including AstraZeneca's Bangalore research centre focusing on TB and the Novartis centre for tropical diseases in Singapore. These are welcome initiatives, as is GSK's continued commitment to dedicated R&D into tropical diseases and HIV/AIDS. However, the impact of such programmes should be considered in the light of

the overall needs of developing countries, and not assessed out of context. Still more is needed.

Several companies contribute to JPPIs such as the Global Alliance for TB Drug Development (GATB), but none were able to quantify their contributions. BMS has a policy of not disclosing its company R&D figures, but was able to provide the value of contributions its Foundation has made: '*Over a ten-year period, commitments of unrestricted grants* [from the BMS Foundation] *have totalled US$12.5million in the area of infectious diseases (24 investigators in 23 institutions). US$85 million of the US$115 million (over five years) through the Secure The Future initiative is designated for medical research on HIV/AIDS*.' Aventis, Pfizer and Merck, are not at present prepared to substantiate their statements to stakeholders about infectious diseases by providing expenditure figures.

Participate in JPPIs for infectious diseases

The majority of companies surveyed are contributing to research-based public private collaborations in their therapeutic areas. This has involved funding of a new JPPI, such as the contribution by BMS to the GATB; developing a treatment as a collaborative public/private research project, such as AstraZeneca's commitment to GATB for any discoveries from its new research centre in Bangalore; or providing a public body with the results of research which the company has decided to cease, as happened in 1994 with the malaria vaccine researched by Hoechst (now Aventis).

JPPIs are seen by some companies as the way to share the risks and responsibilities. Aventis argues that: '*It is dictated by reality that private companies alone can not provide the know-how needed, and that alone they cannot take the risk of investing into fields where governments do not even succeed in getting existing cheap drugs to the patients*.'

Therefore, while AstraZeneca hopes to recoup its R&D investment in its Bangalore centre through sales of any resulting therapy in industrialised countries, it is also considering access in developing countries. The company states that it is building its '*…relationship with the GATB and will consider the most appropriate partnerships (JPPI) for any product we may discover*'.

Forego patent rights in developing countries for JPPI drugs

No company has a set policy. GSK stated that '*…ownership of rights to use IP (intellectual property) rights are negotiated on a case-by-case basis as part of the partnership arrangement. IPRs are an important incentive to encourage R&D.*'

JPPI drugs made affordable to developing countries

While companies were not asked about this specific aspect of their policy, a positive and welcome trend in the distribution plans of new therapies is emerging that aims to improve access in developing countries. For example, companies are committing to supply their new malaria therapies to the WHO at a discounted price, while maintaining commercial prices in industrialised markets. This has happened irrespective of whether the therapy was discovered or developed in collaboration with a public research body.

Abbott, for example, has committed to providing bulk artesunate for the WHO's anti-malaria programmes. This builds on the precedent of Novartis, which has developed a dual-priced, dual-marketing strategy for their new artemesin-based malaria treatment, Riamet/Co-Artem. Since responses to our questionnaire were received, Bayer has announced an initiative with the Medicines for Malaria Venture to develop a new artemisone-based malaria medicine, which will be distributed at a price '*…that would allow all segments of the population who suffer from malaria in the developing countries to receive treatment.*'[29]

3.5: Appropriate use of medicines

Appropriate (or rational) use of medicines means the approval, prescription, and safe use of pharmaceutical products to treat diseases for which they have a proven beneficial effect. Incomplete or prejudiced information leads to ill-informed decision-making, which can result in patients using drugs that have little clinical benefit, or are not proven to be safe for that patient group.

The overuse of antibiotics and anti-diarrhoeals for non-specific childhood diarrhoea, the indiscriminate use of injections, and the excessive use of antibiotics for treating minor respiratory infections are all common inappropriate uses of medicines.

Inappropriate use of medicines is a particular problem in developing countries where there are weak national laws and regulations concerning the use of drugs. The pharmaceutical industry should be able to demonstrate that it can conduct business responsibly in countries with weak domestic systems governing drug use. Failure to do so exposes vulnerable patients to potentially fatal consequences, increases drug resistance, and exposes companies to increased reputation risks.

Companies can encourage appropriate use of medicines by rigorously following internationally-accepted guidelines. The WHO is mandated to set international norms and standards in public health and a number of their guidelines and codes have been approved by the World Health Assembly, which represents 191 governments of the world. Many of these guidelines are detailed in the sections that follow.

Other bodies which have set guidelines on these issues, such as the International Conference on Harmonisation (ICH)[30] and the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), do not have the broad global public health focus or the legitimacy of the WHO.

WHO guidelines should be the 'gold standard' for industry, governments, and practitioners alike. These parties should support the WHO's process of updating its guidelines to ensure they are as user-friendly as possible to all member countries.

Oxfam, Save the Children, and VSO agree that governments should play the key role in the development and enforcement of national and international laws and guidelines. However, we also believe that pharmaceutical companies should take responsibility for their own products. They have a responsibility to prevent harmful drug use by encouraging appropriate prescription and usage patterns in compliance with WHO guidelines. Ethical drug promotion, good clinical trial practice and monitoring of adverse drug reactions are all core company responsibilities that cannot be waived by reference to weak and poorly-enforced national laws in developing countries or by the existence of industry guidelines.

Clinical trials

Companies should ensure that the management of their clinical trials follow WHO Guidelines for Good Clinical Practice.[31] These guidelines are the only broad ethical standard for clinical trials that have been developed with the involvement of governments of developing countries. They cover issues such as the role and responsibilities of an ethics committee for each trial, the balance of risks and benefits to participants and society, and the procedures for ensuring the informed consent of all participants, including children.

ICH Guidelines on Good Clinical Practice are also frequently cited, but their legitimacy outside the seventeen countries for which they were developed is questionable, since, '[although] *…many clinical trials are conducted in developing countries, there has been no consultation between ICH and key officials from these countries.*'[32] The existence of these two different standards should be rationalized through the WHO's review of its own guidelines.

Information on results of clinical trials needs to be made fully and freely available. Knowledge of drug safety and efficacy informs national decisions on which drugs to license and which to include on the national essential drugs list, as well as determining clinical guidelines for their use. Medical practitioners need independent information for treating common conditions. Yet concern has been raised, among professionals and the WHO, that trial results may be chosen selectively for publication, and unfavourable data may be omitted.[33] Only full provision of trial results, as recommended by the WHO, will ensure that the information published by companies is not a selective interpretation of the facts.

Drug promotion[34]

Pharmaceutical companies should ensure that their policies and practices support the appropriate use of medicines. Unethical promotion may encourage the use of unlicensed and unnecessarily expensive drugs, or drugs for non-approved indications. It may involve a company offering bribes to prescribers and dispensers, paying experts to write journal articles which they themselves have not researched, or provide misleading, inaccurate, or incomplete information on medicines.[35]

The WHO Ethical Criteria for Medicinal Drug Promotion were agreed in 1988 and gave the pharmaceutical industry '*…a framework to ensure that promotional practices are in keeping with acceptable ethical standards.*'[36] These comprehensive standards should guide all companies' promotional activities. The WHO is developing a strategy for monitoring the Ethical Criteria that will eventually be used to hold the pharmaceutical industry to account for unethical drug promotion.

Despite continued international recognition of the need for the WHO Criteria,[37] the pharmaceutical industry is reluctant to adhere to the WHO standard and favours instead the weaker IFPMA Code of Pharmaceutical Marketing Practices. In many developing countries where national regulations are weak, the IFPMA code is not even able to provide minimum standards for drug promotion, as it gives precedence to national decisions.[38] The tendency among companies to defer to developing countries' weak national regulations is an evasion of their own responsibility.

Despite the limitations of the IFPMA code, there is a complaints procedure. Regular disclosure by companies of the complaints upheld by the IFPMA and other bodies would help shareholders determine the extent of companies' ethical behaviour, and the increase in risk caused by non-compliance with promotional standards. Such disclosure should provide companies with the incentive to improve their compliance.[39]

Drug safety

Any adverse reactions to a drug need to be monitored and communicated in a timely and responsible manner. This is necessary both to enable users to recognise harmful reactions and stop using the drug, and to ensure the drug is used as safely as possible in the future. Since reporting systems in many developing countries are weak there may be no effective channel for patients and health practitioners to notify the relevant authority.

In the absence of strong health systems, pharmaceutical companies have a particular responsibility to ensure that adverse drug reactions (ADRs) for the drugs that they donate or sell in developing countries are actively monitored at the post-marketing stage as well as during clinical trials.

In addition, particular risk situations may exist where products are introduced into new markets, for example where patients' ethnic profile differs. Companies should account for such risks by means of specifically designed post-marketing surveillance studies. It is imperative that the results of such drug safety monitoring, both locally and internationally are made fully available. Companies should provide this information to the WHO and local regulatory authorities in all countries where their products are marketed.[40]

Oxfam, Save the Children, and VSO propose the following benchmarks for company policy on appropriate use :

- The company has a policy that supports and complies with WHO Guidelines for Good Clinical Practice for trials on pharmaceutical products.
- The company publishes the full results of all clinical trials in a registry accessible to third parties.
- The company has a policy that supports and complies with WHO Ethical Criteria for Medicinal Drug Promotion and reports to shareholders on complaints upheld.
- The company undertakes active drug safety monitoring for any product it introduces to a country where local monitoring systems are weak and market-specific risks are high.
- The company discloses reports of any adverse drug reactions to regulatory authorities and the WHO in all relevant countries.

Company responses

Trials in line with WHO guidelines

Novartis and BMS were the only companies to state explicitly that their clinical trials policies complied with WHO guidelines. GSK and AstraZeneca referred instead to the ICH Guidelines for Good Clinical Practice, which GSK called the, '*…global standard adopted by the pharmaceutical industry*.'

Publishing results of trials in registry

No company is currently prepared to support the WHO recommendation for the creation of a registry of trials accessible to third parties, including Novartis and BMS who are relatively transparent in other areas. Merck

stated: '*We do not support the inclusion of all details of trials in a registry accessible to third parties; clinical trial data are subject to privacy laws and regulations, and the information is proprietary.*' GSK is currently reviewing its policy, and has the opportunity to build on work of Glaxo Wellcome, which had taken steps towards some active disclosure in this area.

Ethical drug promotion

When asked if company policy complied with WHO Ethical Criteria, most referred instead to the IFPMA Code of Pharmaceutical Marketing Practices, with only Novartis saying it complied with the WHO standard. Encouragingly, Novartis did not believe that the IFPMA process was sufficient. '*We believe the IFPMA standards serve as a sound baseline. However, they cannot replace strong corporate standards. In some areas, our internal standards exceed IFPMA standards*.'

BMS was the only company to acknowledge the importance of corporate responsibility where regulations are weak: '*Bristol-Myers Squibb believes that the IFPMA guidelines are particularly important in countries where no government standards/policies exist on drug promotion. In countries where fully-articulated government standards exist, the IFPMA guidelines are less relevant in that promotional practices will be regulated by sovereign governments*.' However, BMS is not prepared to state full compliance with the WHO Ethical Criteria, stating their drug promotion policy, '*…is consistent with the general spirit and tenets of the WHO Ethical Criteria*.'

Only three companies responded directly to the question of whether they would consider disclosing complaints upheld by promotion-monitoring authorities to shareholders: all said that they would not consider it.

Drug safety monitoring and disclosure

Companies were asked if they undertook active ADRs monitoring in developing countries. Only Novartis specifically confirmed this, but provided no additional information to support this statement.

Most companies did not address the absence of effective regulation and monitoring procedures in most developing countries. BMS said that its "*post-marketing reporting system relies on spontaneous reporting of adverse events… which are then analysed centrally and provided to regulatory authorities.*" But this is insufficient in countries where there is no effective channel for patients and health practitioners to notify the company concerned.

A number of companies stated that they refer ADR reports to the relevant authorities, but unless these include the results of specific post-marketing studies, drug safety could be compromised.

4. Conclusion

Oxfam, Save the Children, and VSO challenge the pharmaceutical industry to adopt a new definition of CSR that addresses the health crisis of developing countries. CSR must include the adoption of policies in five areas that impact on developing countries: pricing, patents, joint public private initiatives, research and development, and the appropriate use of medicines. There is most scope to make a positive impact on public health in developing countries by adopting pro-development pricing policies.

The report acknowledges the considerable changes over the past year. The industry's interest and focus on infectious diseases in developing countries is to be welcomed. However, one of the key challenges it is facing is to recognise that increased accountability requires hard facts to be put into the public domain so that people can judge how and whether the industry is meeting the targets set. The provision of this information in the form of reporting on measurable targets that can be independently monitored and verified, will enable both critics and investors to assess the performance of individual companies, and to make comparisons across the industry. The benchmarks proposed in this report aim to facilitate that process.

Endnotes

[1] Heymann, D. Editorial, Bulletin of the World Health Organisation, vol 80(3) 2002.

[2]Hepatitis B, HIV/AIDS, malaria, measles, onchocerciasis, polio, respiratory infections, TB, trypanosomiasis, trachoma, lymphatic filariasis, leprosy.

Cardiovascular, neuropsychiatric, and dietary disorders are also a growing problem in developing countries. The questionnaire restricted itself to infectious diseases since these are still the biggest killers in developing countries, especially amongst children.

[3]Figures compiled from disability-adjusted life years (DALY) estimated for 2000. One DALY can be thought of as one lost year of 'healthy' life and the burden of disease as a measurement of the gap between current health status and an ideal situation where everyone lives into old age free of disease and disability.

[4]PhRMA – Pharmaceutical Industry Profile 2002.

[5]This report has been compiled by the UK members of Save the Children and VSO, and by Oxfam International.

[6]Merck and Boehringer Ingelheim considered that their publicly-available statements on access represented the company's position.

[7]WHO/WTO Norwegian Foreign Ministry workshop April 2001.

[8]Street Price, a VSO position paper October 2001.

[9]*Macroeconomics and Health: Investing in Health for Economic Development,* Report of the Commission on Macroeconomics and Health, December 2001.

[10]WHO/WTO Norwegian Foreign Ministry workshop April 2001.

[11]GSK, *Facing The Challenge* June 2001.

[12]If developing countries had product-patenting in the past, the deadline for compliance was 2000; if not, the deadline is 2005. All least-developed countries have until 2016 to comply, with the possibility of further extensions. It should be noted that many countries have become TRIPS-compliant before their deadline, due to pressure from industrialised countries.

[13]As Brazil demonstrated in 2001 when it succeeded in drastically reducing the price of anti-retrovirals supplied by Roche and Merck.

[14]The US is pushing Chile to agree, as part of a bilateral free-trade deal, that it will strengthen its patent regime beyond the requirements embodied in WTO intellectual property rules. *Inside US Trade*, 22 March 2002.

[15]See *TRIPS and Public Health – the next battle*, an

Oxfam Briefing Paper, March 2002.

[16]Responses to Oxfam Questions on Medicines in Developing Countries.

[17]Consumer Project on Technology, http://www.cptech.org/ip/health/africa/dopatentsmatterinafrica.html

[18]Aspen in South Africa in 2001 for AZT, 3TC, and Combivir.

[19]Merck – *Successful public/private partnerships in global health: lessons from the MECTIZAN donation Program* – Jeffrey Sturchio and Brenda Colatrella 2002.

[20]Heaton, A. *JPPIs – meeting children's right to health?* Save the Children UK, May 2001.

[21] Starling M, Brugha R and Walt G, *New Products into Old Systems*, Save the Children UK, with London School of Hygiene and Tropical Medicine, 2002.

[22]Personal communication from Patricia Lambert, legal adviser to the Minister of Health, South Africa, March 2002.

[23]Guilloux, A. and Moon S, *Hidden price tags: disease-specific drug donations*, Medécins sans Frontières, Oct 2000.

[24]Shretta, R. et al, *A political analysis of corporate drug donations: the example of Malarone in Kenya,* Health Policy and Planning June 2002; 16:2.

[25/26]MSF: *Fatal Imbalance,* November 2001.

[27]Calculations based on information in UNDP *Human Development Report 1999*.

[28]Such conditions should apply to the tax credits for R&D in infectious diseases announced in the UK government's 2002 budget.

[29]http://www.news.bayer.com/News/News.nsf/id/2002-0154

[30]The ICH was established by the research-based pharmaceutical industry and regulatory authorities in seventeen high-income countries. There are concerns that these standards could impede the availability of essential drugs in developing countries. The WHO has pointed out that the ICH "*has no legal mandate from the international community*", and that "*the interests of approximately 85% of the world's population are not directly represented within the ICH process*." (Essential Drugs Monitor 30. WHO 2001.)

[31]These build on the 1948 Declaration of Helsinki made by the World Medical Association, an independent confederation of free professional associations from 70 countries. The WHO guidelines are currently under revision to ensure that they are more user-friendly.

[32]*Essential Drugs Monitor 30*, World Health Organisation 2001.

[33]See Quick, J, *Maintaining the integrity of the clinical evidence base*, Bulletin of the World Health Organisation, 2001, 79 (12) and Davidoff, F. et al, *Sponsorship, authorship, and accountability*, The Lancet 358: 9285, 10 September 2001.

[34]Promotion, in this context, means all informational and persuasive activities by manufacturers and distributors which aim to induce the prescription, supply, purchase, and/or use of medicinal drugs. Source: Ethical Criteria for Medicinal Drug Promotion, WHO.

[35]Recent examples of such alleged activities include – *German doctors face investigation in drugs scandal*, BMJ 23 March 2002;324:693; Davidoff, F. et al *Sponsorship, authorship, and accountability*, The Lancet 10 September 200; 358: 9285; *Pfizer gets a dressing down over promoting unlicensed drugs*, BMJ, 30 March 2002; 324:753.

[36]WHO Ethical Criteria for Medicinal Drug Promotion summary.

[37]For example, a round-table of interested parties organised by WHO in 1997 affirmed the continued existence of unethical drug promotion and noted the need to bridge the gap between policy and practice. According to country assessments carried out by SEAM (Strategies for the Enforcement of Appropriate Medicines) at Management Sciences for Health, '*…where information is available, it often comes from the pharmaceutical industry and in all likelihood does not represent national or local needs.'* (SEAM Conference 2001 Roundtable 5; http://www.msh.org./seam/ conference/roundtable5.html).

[38]Mintzes B, *Blurring the boundaries,* Health Action International Europe 1998.

[39]The UK Medicine Promotion Authority runs probably the most highly-regarded complaints procedure for breaches of promotional standards, in this case the code of practice of the Association of British Pharmaceutical Industries. Most companies covered in this report have been found to breach the code repeatedly.

[40]The WHO collects information on ADRs in collaboration with the Uppsala Monitoring Centre, Sweden.

5. Appendices

Appendix 1

Methodology

The following 11 companies were approached :

Abbott Laboratories
AstraZeneca
Aventis
Bayer
Boehringer Ingelheim
Bristol-Myers Squibb
GlaxoSmithKline
Hoffmann-La Roche
Merck & Co
Novartis
Pfizer

Companies were selected on the basis either of their drug portfolios in relation to the infectious diseases being examined; their current or historical policies and programmes for developing countries; or because of a research facility established for R&D into infectious diseases.

Companies were sent a questionnaire asking for specific policy positions on the issues covered in this report and were invited to discuss the issues with the authors before responding. Quotations from the companies in the report ('Company responses') are taken from their responses to the questionnaire, or from sources to which a company directed us, where that source was specific to the question asked. The report does not reflect all the responses but presents those which illustrate a specific company position or reflect what we believe to be an industry norm.

For the development of the questionnaire and report, support was enlisted from a group of external advisers from the WHO, the medical profession, the socially-responsible investment sector, the CSR sector, NGOs, and academia.

Appendix 2

On the basis of the twelve diseases selected, the questionnaire identified the following major programmes (including JPPIs), where the supply of medicines is a major component:

Company	Programme	Public health objective
Pfizer	Zithromax donation programme	Elimination of trachoma
Pfizer	Diflucan donation programme	Treatment of cryptococcal meningitis, oesophageal infections related to HIV/AIDS
Merck	Mectizan donation programme	Treatment and control of onchocerciasis (river blindness), prevention of lymphatic filariasis (LF) in countries where onchocerciasis and LF coexist
Merck	African Comprehensive HIV/AIDS Partnership in Botswana	Prevention, education, care, and treatment of HIV/AIDS
Merck	Donation to Global Alliance on Vaccines and Immunisation.	Expand immunisation in developing countries.
Boehringer Ingelheim	Viramune donation programme	Use of nevirapine for the prevention of mother to child transmission of HIV
Aventis	Aventis – WHO partnership on sleeping sickness (donation of pentamidine, melarsoprol, eflornithine)	Treatment of human African trypanosomiasis (sleeping sickness)
GSK	Albendazole donation	Elimination of lymphatic filariasis
GSK	Malarone donation programme (former)	Treatment of malaria
Novartis	Multi drug therapy (MDT) donation	Elimination of leprosy
Novartis	Co-Artem partnership	Reduced price malaria treatment
Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, GSK, Merck, and Roche	Accelerated Access Initiative Global partnership	Preferential pricing of antiretrovirals for prevention and treatment of HIV/AIDS in countries with adequate health systems
New Research centres AstraZeneca Novartis Pfizer	 Bangalore Singapore Uganda/Makarere University	 TB Tropical diseases HIV/AIDS
Global R&D programmes (multiple partners)	Medicines for Malaria Venture (MMV) Global Alliance for TB Drug Developement International AIDS Vaccines Initiative (IAVI) Roll back malaria (RBM) Global Alliance for Vaccines And Immunisation (GAVI)	Malaria TB HIV/AIDS Malaria Hib, Hepatitis B, yellow fever

Beyond Philanthropy Benchmarks

Assessment of Corporate Social Responsibility in developing countries should include demonstrable commitments against the following benchmarks:

Pricing

- The company supports calls for a systematic, global approach to pricing, overseen by an international public health body, to address the needs of developing countries.
- The company's policies support substantially lower prices of medicines in developing countries.
- The company publishes a list of pricing offers made to developing countries. Any conditions on the offers are also published.
- Price reductions are not limited to one or two "flagship" drugs but cover a range of products that are relevant to health priorities in developing countries.

Patents

- The company refrains from enforcing patents in developing countries where this will exacerbate health problems.
- The company supports lifting TRIPS restrictions on the export of generic versions of patented medicines to developing countries where a patent is not in force, in line with the Doha Declaration.
- The company does not lobby governments for stronger patent protection than that mandated by TRIPS, or for weaker public health safeguards.
- The company discloses to shareholders its lobbying position on patents and expenditure on such lobbying.

Joint Public Private Initiatives (JPPIs)

- The company's approach to JPPIs is clearly stated as part of an overarching CSR policy that addresses all issues surrounding access to medicines, including patent protection, pricing, and R&D.
- JPPIs involve ongoing commitments to resolving targeted health problems as part of a company's long-term business plan.
- The company ensures that its JPPIs do not exclude vulnerable sectors of society.
- The company ensures that its JPPIs state objectives to integrate with and strengthen national health systems, and report on their impact.
- The company provides transparent information on its involvement in the governance of JPPIs, including details of any conditions.

Research and Development (R&D)

- The company publishes target expenditure for its R&D on infectious diseases.
- The company supports and participates in JPPIs that address R&D for infectious diseases.
- The company foregoes patent rights in developing countries of drugs developed under JPPIs for infectious diseases.
- The company's pricing policy ensures that products developed as part of a JPPI are affordable to developing countries.

Appropriate Use Of Medicines

- The company has a policy that supports and complies with WHO Guidelines for Good Clinical Practice for trials on pharmaceutical products.
- The company publishes the full results of all clinical trials in a registry accessible to third parties.
- The company has a policy that supports and complies with WHO Ethical Criteria for Medicinal Drug Promotion and reports to shareholders on complaints upheld.
- The company undertakes active drug safety monitoring for any product it introduces to a country where local monitoring systems are weak and market specific risks are high.
- The company discloses reports of any adverse drug reactions to regulatory authorities and the WHO in all relevant countries.

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