

Business & Economic Development

Pharmaceutical Sector Report

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Business for Social Responsibility





Address Unit A, 137 Shepherdess Walk
London N1 7RQ
United Kingdom

Telephone +44.(0)20.7549.0400

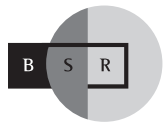
Fax +44.(0)20.7253.7440

E-mail secretariat@accountability.org.uk

Web site www.accountability.org.uk

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Business for Social Responsibility

Address 111 Sutter Street, 12th Floor
San Francisco, CA 94104-4541
U.S.A.

Telephone +1.415.984.3200

Fax +1.415.984.3201

E-mail development@bsr.org

Web site www.bsr.org

Since 1992, Business for Social Responsibility (BSR) has helped companies of all sizes and sectors achieve business objectives and efficiencies in ways that respect ethical values, people, communities, and the environment. A leading global business partner, BSR provides tools, training, advisory services and collaborative opportunities in person, in print and online that equip companies to make socially responsible business practices an integral part of business operations and strategies. Today, BSR member companies have nearly \$2 trillion in combined annual revenues and employ more than six million workers around the world.



BRODY • WEISER • BURNS

Address 250 West Main Street
Branford, CT 06405

Telephone +1.203.481.4199

Fax +1.203.481.9536

E-mail Johnw@brodyweiser.com

Web site www.brodyweiser.com

Brody Weiser Burns specializes in developing corporate community partnerships that create business value and improve the lives of low-income individuals. It provides strategic planning, stakeholder engagement, and program design for corporations, foundations, and leading nonprofit organizations.

Main Contributors

Helen Campbell is a Senior Researcher at AccountAbility. An economist, she has worked extensively on the role of the private sector in promoting economic development at AccountAbility and in the public sector. Current projects include work on Responsible Competitiveness, understanding how responsible business practice can drive economic competitiveness.

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Research Partners

We worked with a range of research partners internationally to generate a shared learning process through this research. Details of research partners are provided in Appendix D.



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Introduction to the Business and Economic Development Project

Cross-Sector Learnings

This overview is one of the products of a research program conducted by AccountAbility and BSR, assisted by Brody Wisner Burns. The core aim of the study is to normalize the management of economic impact as a regular aspect of business performance and outcomes. To this end, the project seeks to:

- Deepen the understanding of how companies are responding, and can further respond, to the growing challenge for them to improve their economic impacts.
- Identify and develop business strategies and public policies within specific industries that are likely to enhance the effective role of business in improving their economic impact.

What is Economic Impact?

‘Economics’ refers to the production, distribution and consumption of wealth in society.

‘Economic impact’ is defined as any increase or decrease in the productive potential of the economy. Economic impact extends beyond the boundaries of any single organization and is linked to both the environmental and social elements of sustainable development.

By understanding economic impact, we seek to understand how a company adds value to society.

In this report, we distinguish between “direct” and “indirect” impacts. Direct impacts are the immediate economic effects of a company’s financial transactions. Examples include the economic benefits that are created through the payment of wages and taxes. Indirect impacts are the economic effects that are created through a company’s operations or through provision of goods and services. So, for example, while having a direct impact as they create jobs, pharmaceutical companies have an indirect economic impact through the provision of drugs, which help improve the health status of the residents of a country. This improvement in health status is both an end in itself, and also has a significant and positive impact on the economy of the country.

Why is economic impact important for business to understand and deliver?

Business needs to understand and deliver on its economic impact because this is a crucial pathway through which business can create benefits (or harm) for its communities.

Understanding and improving economic impact also can help business address key issues:

- Acquiring a license to operate
- Mitigating reputational and operational risk
- Developing new products and improving sales revenue

If companies understand and account for their economic impact, this can provide a new platform from which to inform and engage stakeholders on the broader debate on the role of the sector in society. It can help articulate what companies can and can't do, and where the will and resources of other players, such as governments or NGOs is needed for constructive steps to be taken to address macro-socioeconomic issues.

Lessons Learned Across Sectors

This project looked in depth at four industry sectors: financial services, pharmaceuticals, agriculture, and extractives. This overview of the report provides the lessons learned across the four sectors. The remainder of this particular report looks in depth at the lessons learned in one sector — **pharmaceutical industry**.

The key lessons about the economic impact of companies across the sectors explored in this project include:

1. The Type of Engagement with Communities Matters. A company's indirect economic impacts on disadvantaged communities can be as great, or greater, than its direct economic impacts. For both the financial services and pharmaceutical sector, our research found that the indirect economic effects, particularly the effects that arise from access to the products and services of the sector, tended to generate the most significant economic impacts. These impacts tended to far outweigh the impacts created by the sector's employment, its plant and office locations, and its purchasing. The reverse was true for the agricultural sector. For agriculture, employment and purchasing by corporations tended to generate more significant economic impacts on low-income communities than the provision of products.

Our research has led us to develop the following thesis: The nature of engagement with low-income communities shapes whether a corporation's direct or indirect economic impacts will be more important. If a company engages with a low-income community primarily because of its labor (as in agriculture or manufacturing), direct economic impacts will be more important. If a company engages with a low-income community primarily as a market for its goods and services, indirect economic impacts will be more important. Finally, if a company engages with a low-income community primarily for its natural resources, direct impacts (such as the payment of wages) will predominate initially. In these cases, over time, indirect impacts, especially those relating to environmental effects, will become more important.

2. Infrastructure Greatly Impacts Company Contributions to Development. The scale of a company's indirect economic impacts is frequently driven by the actions of organizations outside the company's control. A company has significant control over much of its direct economic impact. It has control over which it hires, where it locates its plants, and from whom it purchases. This is much less true with regard to its indirect impacts. This can be

seen most easily in the pharmaceutical sector, where whether or not drugs are available at affordable prices is just one piece in a large puzzle. If drugs are available, but there are no doctors or clinics, and the public is largely uneducated or ill informed, there will be relatively little impact to providing affordable drugs. Conversely, if all these elements are in place, there will be a significant and positive impact from providing affordable drugs. Similarly, in the financial sector, simply providing credit to individuals who do not have access to markets, management talent, sound regulation and a viable court system, usually does not enable them to build viable businesses. These elements have to be in place before lending typically has a significant positive indirect economic impact.

This creates particularly difficult challenges for companies that are working in countries which are doing a poor job of creating the enabling infrastructure that will allow a company's products and services to create significant positive economic impact. This may be due to corruption, or a lack of ability, or simply to alternative priorities. In these cases, our research shows that there are a number of viable strategies open to companies. These include joining an industry coalition (such as Fair Trade), working with UN or multilateral organizations (such as Extractive Industries Transparency Initiative), or working with government agencies (such as Merck's Botswana Initiative). Companies also need codes of conduct clarifying how they will engage with governments, and under what terms.

3. Partnerships with Others Greatly Amplify Company Contributions to Economic Development. Partnerships and coalitions are often elements of strategies that create significant indirect economic impact on disadvantaged communities. The most successful examples in our case studies—the examples where companies were creating positive indirect economic impacts that were affecting thousands of people and creating millions of dollars of value—were primarily done with partners or in coalitions. Having a significant economic impact almost always involved creating changes in the enabling environment, which had to be done in partnership or in coalition.

While partnerships are valuable and important, it also was clear in many cases that most of the thought and energy was going into making the partnership effective rather than making it accountable. Why is accountability particularly important in the creation of indirect economic impact? Because this type of impact is often a “public good” or a “merit good.” The benefits are often spread out among community members whether or not they have a relationship with the company, and whether or not they have paid for the benefit. Public and merit goods have particular sensitivities that require greater consideration than is often given with an eye towards:

- 1) Equity – who gets the goods, and (more importantly) who doesn't?
- 2) Fairness – who pays how much and when?
- 3) Quality – who decides what the right level of quality is?

To ensure that they are addressing these sensitive issues well, our research suggests that companies need to build in accountability processes that engage the legitimate representatives of the community.

4. Engaging Governments is Often the Critical Missing Link for Successful Impact. Corporate engagement with governments and public policy can be an important way in which companies create indirect economic impacts, both positive and negative, for low-income communities. In each of the sectors studied, we found that the ways in which companies engaged with governments—as regulators, funders, and lawmakers—often had profound effects on low-income communities. In addition, companies often appeared to shape their strategies for engaging with governments in ways that often did not take into account these impacts.

A first step in addressing this issue would be the development of greater transparency about corporate engagement with governments and a company's influence over public policy. What is the sum of a company's dealings with government? What are the company's public policy objectives? And, most importantly here, what are the likely impacts on low-income communities?

Our research suggests that there can be sharp differences between the interests of national governments, local governments, and low-income communities. Simply engaging with national governments in a way that creates economic benefit for the country, as a whole does not imply that those benefits will trickle down to the poor.

5. There is No Silver Bullet: Creating Value for Communities is Driven by Context.

A consensus has not yet emerged over how to understand and implement strategies that create significant improvements in indirect economic impact on disadvantaged communities. There were considerable differences from case study to case study about what the businesses counted as economic impact, what they saw as their role, the strategy that they were pursuing, and what relationship these activities had to their core business operations. For some (like the case studies of companies located in Palestine), the key way to create economic impact was simply by being in business in their communities. For others, like some of the pharmaceutical companies, creating economic impact on disadvantaged communities was a by-product of trying to meet societal expectations. For yet others, like some of the companies in the agricultural sector, creating economic impact was part of creating a new market and trying to reach new customers. These are dramatically different but context-driven views on the realities and rationales that drive strategy for creating economic impact.

6. Businesses Fail to Account for Their Complete Economic Impacts. Very few companies are tracking or reporting either quantitative or qualitative measures of their indirect economic impacts on disadvantaged communities. Some companies report on quantitative measures of their direct impact, such as jobs created, salaries paid, and taxes paid. Some report qualitative measures of their indirect impact—programs they have created, opportunities

that they helped support, etc. For many, it's because it is too complex to determine or staff resources and expertise. For others, it's because they don't see it as their responsibility. And in some cases, it may be counterproductive, as the agriculture report suggests. Without a consensus view on what business responsibilities are for creating economic impact, it is difficult for businesses to see a clear and consistent rationale for spending time and energy collecting, analyzing, and reporting data on economic impact.

7. Models and Guidance Are Needed to Equip Business to Better Identify and Account for the Type of Impacts It Can Have. The most relevant next step is to develop industry consensus on models and frameworks for understanding, building, and accounting for indirect economic impact. Given the lack of consensus over what counts as impact, how to create that impact, and what the business role is in creating that impact, it is not appropriate to work on the development of metrics. It is an especially important first step to develop models and frameworks for understanding indirect economic impact. Once this has been attained, it will then be possible to start work on developing disclosure practices that fit the models and help us understand progress.

Our research suggests that the development of consensus can best occur industry by industry. What counts as impact, how to create it, and what the business role in creating it is, varies so significantly by industry sector that it will not be possible to develop a "one size fits all" framework.

In each industry sector, a range of stakeholders, including large companies, small companies, civil society organizations, government agencies, and community representatives, will need to develop a consensus on what the key areas are for social, environmental and economic impact. Once this is done, they can then work to develop analysis and insight on the strategies for addressing economic impact in these areas. What are the key risks and opportunities of improving (or not improving) economic performance in these areas? What are appropriate and achievable goals? Once this work is completed, it will be possible to develop methods for corporate accountability for economic impact.

Summary

In summary, our research shows that improving economic impact is a critically important way for businesses to create benefits for the communities with which they interact. And yet, the process of managing and accounting for economic impact is still in a formative stage. Businesses, civil society organizations and governments need to come together to develop a better understanding of the key pathways through which specific industries can create positive economic impact. This will enable the development of robust framework for economic impact. Business will be better able to identify and manage their economic impact, improving their reputations, license to operate, and revenues, while at the same time creating positive benefits for communities.

Executive Summary: Pharmaceutical Sector

Pharmaceutical companies provide significant socio-economic benefits to society through the impact of products on the health of individuals, through job creation, returns to investors, through supply chains in various communities and nations, and through community development and investment projects. Pharmaceutical companies also play an important role in technological innovation, which can reduce costs of economic activity elsewhere in the economy. There are expectations, however, by some stakeholders that pharmaceutical companies should contribute more to economic development, through their own activities and indirectly, through improvements in health care infrastructure and capacity. This reflects the complex role of companies in healthcare, as well as the special obligation inherent in a sector whose products and services are needed by people when they are most vulnerable.

At the macroeconomic level, there is a well-established body of health economics research that explores the relationship between health and economic development. Health can be both a cause and result of economic development. The pharmaceutical sector is specifically recognized in the UN Millennium Development Goals as an actor that can contribute to their realization.

AccountAbility and BSR have developed a methodology through which companies can begin to articulate and account for the economic impacts of their business activities—siting, employment, procurement, product and service development and delivery, contribution to taxes, investment and philanthropy (See Appendix A). In this report, we test one aspect of this methodology, product development and delivery business function on the pharmaceutical sector. Through this explores corporate understanding and accountability on the access to medicines question. As for all sectors, there is less data on product-related impacts than for other aspects of business activity. Appendix B provides a map of the pharmaceutical product cycle and where it intersects with standards and regulations.

The economic impacts of pharmaceutical products—through product development, use and delivery of medicines—on the communities that are affected by them, are diverse. They include both production-side economic impacts and consumption side product-related economic impacts. Production-side impacts might include research and development (R&D), employment in facilities, and sourcing from local suppliers. While the impact of these activities is important, the most significant economic impacts are likely to accrue to patients. Consumption-side economic impacts relate directly to the access to medicines debate. Access to medicines refers to the lack of pharmaceutical product impact, or the lack of availability of medicines for specific communities. This report focuses on, but is not restricted to, exploring corporate practice in the context of access to medicines in the developing world, this being

the key issue that defines corporate responsibility of pharmaceutical firms in the eyes of stakeholders. A number of case studies focus on the HIV/AIDS pandemic in the developing world, but we recognize that there are many other pressing access to health issues in both the developing and developed worlds.

This report explores how some pharmaceutical companies understand and account for their economic contribution to society. For some, economic impact management is already an important internal management tool and stakeholder engagement platform. For others, the value of managing economic impact is clear, but the challenge is finding ways to do it. Ideally, corporate management of economic impact allows a company to better inform and engage stakeholders on the broader debate on the role of the sector in today's society. They can better articulate what they can and cannot do, and where the will and resources of other players', such as governments or NGOs, are needed for constructive steps to be taken to address health and macro socio-economic issues.

What is an Economic Impact?

Economics refers to the production, distribution and consumption of wealth in society. Economic impact has been broadly used to define any increase or decrease in the productive potential of the economy. Economics extends beyond the boundaries of a single organization and is linked to both the environmental and social elements of sustainable development. By understanding economic impact, we seek to understand how a company adds value to society, of which its internal stakeholders are a subset.

A company's economic impact may be seen as a cost or a benefit to society, but this is not always reflected in corporate accounts. The most commonly used standard to report on economic impact is the GRI. The GRI has divided economic impacts into direct impacts and indirect impacts.

Direct economic impacts are those created by a company's financial and other relationships it has with its stakeholders—to employees, to suppliers, to shareholders, to/from government, to investors, to its key communities and being reinvested in future productive capacity, as well as with competitors. A company's investment in a community can serve as an engine of growth in the economy, through employment, boosting local supply chains and developing a new skills base.

Indirect Economic Impacts are often referred to as (supply) multiplier impacts—they may or may not be significant depending on the business model in question. Indirect impacts are the second round employment impacts of a business activity—the jobs generated along the companies supply chain or at a particular location, but not directly by the company. Third and subsequent rounds of impact are induced, or income multiplier impacts. This refers to those impacts generated by increases in wealth generated by the company's activity. Improved health can have significant multiplier effects through the economy.

Public policy settings affecting pharmaceutical product delivery are critical in the success or otherwise of medicine contribution to socio-economic development. Pharmaceutical products will have most beneficial and sustainable economic impacts where the programmes under which they are delivered engender improved infrastructure, education and governance in healthcare in the target community or country. Importantly, a better understanding of their economic contribution can provide a platform for companies to negotiate and articulate their responsibilities and manage risks and opportunities around these issues. Risks and opportunities for each company will differ and depend on the company's key stakeholders and business models, but in all cases, a better understanding of economic impact provides a useful mechanism to manage tradeoffs between the different types of costs and benefits to society that a company creates by doing business.

The intention of this report is to increase understanding of:

- How pharmaceutical companies understand and address their economic impact.
- Whether an understanding of economic impact contributes to access to medicines debates.
- How management frameworks might be developed to support economic impact management and enhanced corporate accountability in the sector.
- To test the overall framework of economic impacts aligned with business functions by exploring product related impacts of the sector on poor and disadvantaged communities.

The research methodology:

- 1) Assess sustainability reports of leading pharmaceutical companies on their coverage of economic impact (Appendix E).
- 2) We held two workshops with company representatives to share learning and develop case studies
- 3) We held a cross sectoral workshop in the US to explore commonalities and differences in managing economic impact across four selected sectors
- 4) Research partners in India, Occupied Palestinian Territories and South Africa held multi-stakeholder workshops to inform and communicate their research findings, including provision of case studies.
- 5) Developed six case studies based on in-depth interviews with companies.

In the first Section of the report, we seek to locate corporate accountability for economic impact in the broader macro economic development context. Health is a recognised driver and result of economic development, but what is less clear is the role of companies in driving these macro processes. In Section 2, we summarise the sector's key stakeholders and examine the impact they have on companies. In Section 3, we explore standards adopted by large pharmaceutical companies, and some of the key regulatory issues affecting them and their profitability. In Section 4, we explore the key issues and risks for the sector. In Section 5, we turn to the place?? of economic impact management of some of the largest pharmaceutical companies, before drawing our conclusions in Section 6.

1. Overview: Pharmaceutical Companies and Economic Development

The pharmaceutical industry is characterized by large, branded multinational enterprises (MNEs) engaging in research and development (R&D), production and marketing, as well as smaller companies that produce and market generic medicines. Featuring economies of scale in developing knowledge-intensive products and a high level of risk in R&D, the international industry is highly competitive, which has led to increasing concentration within the sector. The sector is made more complex by a web of alliances to rationalize business functions. One important manifestation of this has been the emerging role of biotechnology companies, and their relationships with each other and brand name pharmaceutical companies in the R&D processes, providing new forms of R&D competition. Generic producers present a new, more politicized form of competition to brand name leaders, particularly in the context of access to medicines debate.

Traditionally, industry risks and drivers have included R&D pipeline issues, patent protection, changing regulatory environments and product quality and liability. Producing products that save lives and improve quality of life of consumers, pharmaceutical companies were traditionally regarded as inherently responsible. But with increased societal expectations on companies to address their broader socio-economic and environmental impacts, perceptions about the sector have changed significantly. Concerns around access to medicines, animal welfare, executive pay, gene technology, and differences in public health needs and pharmaceutical business strategies have all attracted criticism.

Companies have taken different steps to address these issues. More prominent companies have responded to pressure with a range of strategies. Smaller companies, including many based in the developing world, remain under scrutiny. Most have not disclosed company policies on access issues, and thus it is difficult to assess the non-financial aspects of their corporate policies and performance.

Stakeholders have encouraged companies to improve access to cheap medicines in poor communities through donations, pricing and licensing arrangements and patent waivers. There are concerns, however, that activities such as donations are ultimately unsustainable. A key question in the debate is whether the current pharmaceutical sector business model, and requirements for continued health care innovation and broader public health governance practices, will deliver the necessary outcomes for sustainable improvements in public health to foster economic development. Some believe that the current business model is not sustainable and that this poses longer-term risks for the sector's profitability. Health care innovation requires complex management at a political, government, business and civil society level if a sustainable health care at the international level is to be created. On the other hand, many

believe that the current business model is sustainable and that global health issues need addressing via changes in other parts of the healthcare and economic systems globally. The argument being that if all pharmaceutical companies did what was asked of them, these actions alone would not ensure access to health care.

Appropriate public policy settings are crucial—to provide the right incentives for companies to research medicines that are less profitable, as well as to provide the necessary infrastructure to ensure that patients can receive available medicines. In many developing countries, clean water would be the easiest way to improve public health. Chlorine tablets can help achieve this in the short term. Although they are not under patent and very cheap, the governments of some of the poorest nations cannot afford to buy and distribute them.

Medicines work in the context of national healthcare infrastructure—expertise and number of personnel; the level of patient education; and a given culture of governance. There are long-standing debates around the priority and weighting that should be attached to these issues to achieve sustainable public health improvements, as well as who should bear responsibility for their achievement, however these specific issues fall outside the scope of this report.

Leading companies have articulated positions in driving this agenda forward, both through public policy advocacy, through the products they develop, and how they deliver them, as well as through the design of their access to medicines programmes. As well as a range of stakeholder expectations, it is for these policies and practices that companies are held accountable for. But *how* they should account for them remains debatable.

Bridging the gap between macro-economic development targets and micro-economic business level activity is largely uncharted territory. Corporate responsibility standards have only started to tackle these questions. A key to understanding *how* business contributes to broader socio-economic goals is to understand the shape and extent of its economic footprint on specific communities and markets.

The AccountAbility/BSR methodology through which companies can identify and begin to articulate significant economic impacts, is designed to align with business decision-making processes or ‘domains’ of business activity. (See Appendix A). On the basis of the initial phase of work on business and economic impact, it appeared that the most critical impacts of pharmaceutical companies could be linked to the corporate product development and delivery function. Initially, we assumed that these corporate functions would lead to more significant, and be of greater materiality, than pharmaceutical company impact through other functions, such as employment or siting choices.

The impact of decisions associated with these business functions is likely to vary from sector to sector. Across sectors, product-related impacts are least understood. Decisions on what

products to develop and how to develop them drive the branded, research based pharmaceutical companies' business model. Product related impacts are potentially the most significant pharmaceutical companies will generate. This is implicitly understood by the sector's key critics from civil society whose main concerns relate to access to medicines issues.

In the context of the access to medicines debate, the corporate responsibility question for pharmaceutical companies is understood in terms of how to get broader and more sustainable product impact of medicines in poor communities. There is a rich body of health economics research with respect to treatment models for different diseases at national and international levels, as well as research on the structure and reform of health systems at national levels for a range of developing countries, But at the business level, few pharmaceutical companies communicate what the economic impacts of their own products are on lower socio-economic groups within both developed and developing country markets.

Case History

Novo Nordisk Health Economics Studies: Denmark and Bangladesh'

Novo Nordisk estimates that if more than 50% of the 136,047 Danes that now are diagnosed with type 2 diabetes were offered insulin treatment, and 90% of the patients in need were on tablet treatment, significant gains in longevity and quality of life could be achieved. Total health care cost would remain the same but expenditure on hospitalization caused by complications (amputations, blindness and kidney failure) would be replaced by medical treatment primarily focusing on removal of the barriers to effective therapy in combination with earlier diagnose, medication and monitoring. The total costs of diabetes could be reduced by almost a half, largely due to reduced costs of non-mecical costs such as nursing because the general health and condition of people with diabetes would be better. Potentially, this would allow a gain of over 40% in production value.

For Bangladesh on the other hand, it has been more difficult to assess the potential impact of diabetes on the national economy, due to lack of data, which reflects a lack of resources and a lack of awareness about the disease. The Novo Nordisk study estimates that the current situation for people with diabetes in Bangladesh is closer to a worst scenario of absolutely zero access to health care or medication than to a situation of modern health care like in Denmark. Some 83% of the population in Bangladesh live on less than US\$2 a day according to UNDP. Novo Nordisk estimates that only 10% of the population has an income enabling them to afford basic health care costs. Another 13% have more or less frequent access to free clinics, while the rest (77%) are left without any form of access to health care. The study estimated that 40% of the people suffering from diabetes in Bangladesh are not able to support themselves due to disease complications, which has implications for how the formal and informal economy (45% of economic activity) functions. The lack of health care has a huge impact on the poorest and informal part of the economy where every hand is necessary to ensure the livelihood of the families. The dilemma is twofold because poor people are hit harder by complications due to insufficient diabetes treatment and the poor family units have to take care of disabled people, thus diverting efforts away from producing a daily living. At the same time, the estimated benefits of improved care in terms of longevity, quality of life and economic values were significant. Novo Nordisk's study estimates

that patient life years would increase from 3 million to 5.8 million if the current level of (insufficient) health care was offered to all people with diabetes in Bangladesh. It is worth noting that this increase means more people surviving in a better health state than currently, and they could produce 2.5 times more than currently. Further, this production value could be at least 6-10% higher if the impact of improvements in life expectancy as a result of improved diabetes care over 20 years were included, according to the WHO.

This is in part, due to the complexity of the process of getting medicines to people, and the number of actors involved in product development and distribution. Getting pharmaceutical products to the poor in developing countries relies heavily on a range of factors including political will, the geographic spread and quality of local health infrastructure, resources and expertise, and the presence and capacity of appropriate non-governmental partners. The case study below shows how a company in the Occupied Palestinian Territories perceives its impact in a conflict situation. Often, these factors are beyond the direct control of pharmaceutical companies, but may be influenced by them. For example, Novo Nordisk has built its strategy for improved access to diabetes care on WHO's four priorities for access to health.

Understanding the product-related economic impacts of medicines on poor and disadvantaged markets can help companies define how they can best address and engage in the broader access to medicines debate, manage and optimize the impact of their business activities and accountabilities, and ensure that business decisions around this issue are an effective and sustainable investment, both with respect to a company's internal and external stakeholder interests. It can also highlight shared responsibilities, and show where systemic weaknesses, such as lack of political will, trained medical professionals, or proper governance can cause potential benefits of medicines to 'leak' and even become counterproductive in certain situations (such as when medicines are traded for arms)

Pharmacare Company Background – Occupied Palestinian Territories

Pharmacare was one of a second wave of pharmaceutical companies to set up operations in the Palestinian Occupied Territories (OPT). The company's commitment to improving the economic situation for Palestinians in the face of an unstable political state has placed it in a position of leadership both within and outside the pharmaceutical sector. Pharmacare was established in 1985 in Beitunia, and created a manufacturing facility that made it good manufacturing practice (GMP) compliant in 2000. It has two distribution centers in Beitunia and Gaza city, a drugstore based in Jerusalem, and representative offices in Russia, Belarus and Azerbaijan. Pharmacare provides products to approximately 1,200 clients in the Gaza Strip and the West Bank. With 144 employees, Pharmacare has turnover of US\$4.8 million and spends approximately US\$1.4 million in salaries per year. 30% of products produced in OPT are exported to East Europe while 70% are consumed locally. Pharmacare currently holds 8% market share of local private sector market

Case History

consumption. Its products are sold mainly to intermediaries like pharmacies, doctors, medical institutions and the Ministry of Health.

A partnership agreement with Grunenthal GmbH, a German company, was signed in 2000. Currently, Grunenthal owns 27% of Pharmacare and is actively involved in management through membership in Pharmacare's board of directors. This alliance is not limited to a joint venture, but includes licensing, knowledge transfer, as well as German cooperation in market finance, technical assistance and other fields. The arrangement allows Pharmacare to produce many of Grunenthal's products and to market them in regional countries to which Pharmacare had limited access prior to the agreement.

Business drivers for consideration of economic impacts of products and services

Pharmacare measures its performance in a range of areas as a means to engage stakeholders, including business partners who seek evidence of performance and commitment. For this reason, the company tracks its performance and financial impact in a number of ways. Pharmacare produces annual financial reports, which are externally audited by Deloitte and Touche. They maintain ISO certificates by reporting to their auditors, Lloyds, on the status of ISO 9001 and ISO 14000 implementation. Presently, they are working on the final stages of implementing the internationally recognized standard, c-GMP (Current Good Manufacturing Practices).

Economic Impacts of Pharmacare's Corporate Practices

Pharmacare measures and monitors economic impact to the best of its ability and see the benefit to Palestinian society of doing so. Financially, the company has tracked pricing and learned that products are sold in the private market at prices 46% higher than Pharmacare's selling price. The public price includes 25% pharmacy profit and 1.17% value added tax (VAT). Without local pharmaceutical companies, Pharmacare estimates that customers would pay 100% more than they currently pay for drugs, although this is not substantiated. Pharmacare has also evaluated other economic impacts.

Product and Service Development, Use and Delivery

Pharmacare recognizes the international trend in trying to measure economic impacts, and is taking steps to tracking their performance. The social costs of providing product are difficult to determine locally, Pharmacare is using international information and feels that local studies would be beneficial. It is felt that international models can be used to develop local measurement systems. Local studies will require added resources and technical support, but will also increase opportunity for employment and access to medication.

Cost Reduction to Distributors

To make drugs more affordable to consumers, Pharmacare has also eased the burden of inventory costs for pharmacies. Pharmacare's liberal return policy allows pharmacies to return expired or unsold products from their shelves for full value. In this way, the vendor does not have to bear additional cost for storage and there is reduced risk of close-to-expiry products being sold for cost-related reasons.

Partnerships

Another method of delivering product to people in need is through partnerships with NGOs.

Donations are made to NGOs so that residents can take advantage of “free doctor days” once to twice per month to obtain free medication and advice. (It is not clear for which drugs or whether this may be treatment distorting).

Consumer Education

Pharmacare is also aware of the end user of their product. Because their product is produced and packaged locally, local language is used in labeling and instructions dispensed with products. This step provides a safeguard against misuse of product by those who are unable to seek proper medical advice to accompany their medication, and for those who may have obtained their medication from a friend or family member.

Economic Impact on the Poor

Through their focus on new product development and competitive pricing, Pharmacare is addressing the issue of access to medicines by the lower income segment of the population. By providing less expensive drugs to combat illness and chronic conditions, Pharmacare believes it can move closer to increasing the health of the Palestinian people, thereby rejuvenating the workforce. A healthier workforce will boost individual economic position and create increased value for local business through a stronger economy.

Opportunities to partner politically or corporately with Israel are limited as OPT is not recognized as a potential partner. Political and economic instability, combined with high unemployment, and emigration of skilled employees combine to reduce the buying power of residents.

The Health Insurance System offered by Ministry of Health is weak and poorly resourced. Advanced pharmaceuticals for chronic problems are not available because the WHO essential drug list is not updated regularly with recent products by local authorities. Customers cannot afford to purchase products on the private market. For example, the pharmaceutical sector has documented known effects of high cholesterol levels on heart disease, but the required drugs are not available in the Palestinian Health Insurance System and are not affordable in the private market. This creates a public policy gap where the sector has to do its best to ensure that patients are taking proper dosages of medication despite their financial limitations. Pharmacare specifically caters to the low income sector by using lower pricing and subsidization to make medicines more accessible. Pharmacare’s partnerships seek to provide assistance to the working poor. For the unemployed, Pharmacare has developed partnerships to make medicines available at no cost. Partnerships generally focus on product delivery.

Strategic Solutions for Accessibility: How Pharmacare Makes a Difference

One example of Pharmacare’s commitment to improving the socio-economic condition of Palestinians is their management of a medical fund. This medical fund targets those with no refuge or access to a drug provider through insurance, NGOs or similar organizations. Having ascertained that a person is in need, a prescription is provided that can be filled at a pharmacy, which bills Pharmacare directly.

The fund is resourced by Pharmacare, friends of Pharmacare and international organizations. Thus, a surplus fund is created within Pharmacare that allows for this process, which provides a

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profit to the pharmacist of 7% versus the traditional 25%. Pharmacare employs a manager to oversee this fund and it operates at no charge to customers in need. This fund was started as a temporary solution to combat negative effects of intifada, but became a long-term initiative based on need. Now that it is institutionalized, funds are available for 2004 and most of 2005.

Fund levels have risen from US\$39,000 in 2001 to US\$103,500 in 2003 and US\$125,200 in 2004. By institutionalizing the fund, there is a process in place to counter any abuse and address questions of eligibility. Annually over 4,000 people are receiving assistance from this fund and it is felt that this is only the 'tip of iceberg'. This is an indication that while the fund is making an impact in the local community, it is simply not enough to care for all the residents who are in need of such assistance. For this reason, Pharmacare relies on contributions from donors to assist in paying for the drugs.

Donors also benefit because it fills a gap in their operation. Future focus of this project is to try to encourage participation from other companies and increase support from donors so that more people can be served. To achieve the goal of creating a structured national approach to health care, the pharmaceutical sector can play a large role in bringing donors and manufacturers together to develop processes that address economic impacts of health care delivery. This type of long-term strategy is critical in creating a sustainable system that benefits the Palestinian people.

Lessons Learned, Opportunities, and Next Steps

The following are the main areas that Pharmacare judged important in moving forward in developing its approach to economic impact.

Translating international studies on product-related economic impacts for local benefit

Pharmacare has demonstrated how it has managed international information regarding medical conditions and incorporated it into its marketing and education processes. There is further opportunity to look towards international examples and apply them locally. By increasing distribution channels of research findings by larger companies and health organizations, smaller pharmaceutical companies can benefit from established learning. Although a certain amount of research and development will always be part of the drug manufacturing process for any pharmaceutical company, proving the longer-term benefits of treatments can be facilitated through the use of available international data. Pharmacare looks to the experience of larger pharmaceutical companies to manage and measure their economic impacts.

Supporting a structured approach to national health care system

When faced with the overwhelming task of influencing the economic condition of a host country, there is a tendency for companies to choose philanthropic means of influence. Philanthropy is more commonly reported and publicized because it is easier to implement, measure and promote than other means. Pharmacare has sought to focus its efforts on creating sustainable solutions.

The disadvantage for Pharmacare is the political situation in OPT and its relative corporate size. By partnering with NGOs and other governments who by working together can generate greater influence with the political decision-makers in the occupied areas, Pharmacare will be in a better position to bring about lasting economic change. Also, by working with larger international sector leaders, Pharmacare can identify the development and delivery solutions that can best support a national health care structure.

Summary

The findings and future focus that emerged from this case study indicate that there is an opportunity for Pharmacare to document its innovative practices through sustainability reporting, and continue to invest in an enhanced understanding of the economic impacts of its products and services in order to inform its business decisions and maximize benefits to the company and society. By sharing its best practices with peers, there is an opportunity for the pharmaceutical sector in OPT to create a significant economic impact in the market and achieve three goals: 1) increase accessibility to medicines, 2) move toward a structured health care system, and 3) increase innovative partnerships between international and local pharmaceutical companies.

Key questions to understanding and enhancing corporate accountability for economic impacts include:

- Which economic impacts are significant? Is it the impact of their core activities and products? Or is it more important to focus on impacts on disadvantaged communities?
- Upon whom is the desired impact? Some pharmaceutical companies, such as Merck, have used the UNDP Human Development Index to define communities for which different pricing and distribution conditions will be applied. Others have developed other mechanisms for specific products, such as the way Novartis created patient assistance programmes for Glivac as set out in the Pricing Section of the report.
- Which economic impacts are companies responsible or accountable for, whether alone or with other players? To what extent can corporate decisions in isolation—such as pricing decisions and licensing arrangements—ensure that enhanced affordability of medicines translates into enhanced accessibility? What are the best vehicles for delivering enhanced accessibility and how do companies ascertain what their responsibilities are to develop them?
- What are the regulatory and policy enablers and disablers in different markets? How do they impact on company product development and delivery options and who pays?

Asking these questions will help companies determine the point at which their economic impacts, responsibility and accountabilities intersect. They can provide a new approach for engaging with stakeholders on the issue of access to medicines, managing risk and opportunities, and enabling companies to contribute proactively to the debate on access to medicines.

They also help to highlight corporate impacts and responsibilities on the product development side, such as the question of who pays for the development of medicines:

- Within countries. For example, the US and Danish policy settings exemplify different ends of a public policy continuum in which the market plays very different roles in allocating medicines and who pays for healthcare.
- Between developed and developing countries, as has been highlighted by the access to medicines debate. Developed countries have their own health priorities while at the same time they recognize global health risks; and

- Increasingly, the debate on how the costs of innovation should be balanced between developed countries intensifies, particularly between the US and Europe.

These issues ultimately require political and societal consensus on whether and in what combination taxpayers, insurers, patients and companies pay for what type and level of healthcare. These issues are beyond the scope of this research but we recognize that they have profound implications for what companies can account for, and for how the pharmaceutical business model evolves.

2. Mapping of Players: Pharmaceutical Sector Landscape

Companies

Players in the pharmaceutical sector include: brand-name drug manufacturers, generic drug manufacturers, firms developing biopharmaceutical products, non-prescription drug manufacturers, firms undertaking research on a contract basis, universities, and hospitals and research centres also play a role in the R&D activities of this sector. A key determinant of the business model is whether, and to what extent, companies are engaged in R&D. For companies that rely on innovation as a key aspect of their business model, the regulatory and scientific framework critically affects their ability to fund ongoing investment in R&D and to protect income streams of commercialized medicines for as long as possible, through pricing policies and intellectual property rights (IPR).

The apparently opposing interests of R&D-based and generic production business models have become more politicized and compelling in recent years with the access to medicines debate. In reality, many of the larger pharmaceutical companies produce both patented and generic products as part of their business and risk management strategies. Generic companies perform a useful function in reducing costs of older medicines to make budgetary space for innovation. Generic companies have benefited from NGO pressure with some having been able to produce generics more quickly than would otherwise have been the case. The picture is, however, more complex. Generic companies do not always provide cheap medicine, as the Indian experience suggests.

The pharmaceutical industry as a whole has traditionally been very profitable compared to other sectors. It generates in excess of US\$ 400 billion in sales annually, of which around 45% is from US markets, 25% in Europe and 12% in Japan.¹ The rest of the world, especially the developing world, generates only 18% of sector sales, but makes up the vast majority of the world's population. Most drugs purchased in the developing world are generic drugs. For society, the benefits of R&D-based business activity can be characterized as enhanced

innovation, high value added jobs, taxes paid, indirect employment through sourcing and the need for continued innovation, and health outcomes. The relative importance of these varies according to stakeholder perspective. Arguably, the biggest potential economic impact is through health outcomes, such as improved quality of life and productivity, reduced hospitalization and so on.

The sector has a strong network of national and international industry associations, representing and advocating their interests at the national and international level. The IFPMA (International Federation of Pharmaceutical Manufacturer Associations) has taken a leading role on a range of international policy and political issues affecting the sector, including TRIPs (Trade Related aspects of Intellectual Property Rights), access to medicines, animal welfare and so on. EFPIA (European Federation of Pharmaceutical Industry Associations) represents European companies, mainly with the European institutions, and national industry associations are also strong advocates for industry interests. For example, PhRMA (Pharmaceutical Research and Manufacturers of America) in the US is a relatively influential institution, reflecting the sector's importance to the US (around 13% of GDP is spent on health, and a total of around 2% on medicines); the Association of the British Pharmaceutical Industry (ABPI) represents British pharmaceutical interests, including negotiating medicine prices and profit margins with the UK government. While there are industry-wide associations, the generics industry is also organized at national and international levels, in the latter case, the International Generic Pharmaceutical Alliance (IGPA) has been actively engaged in debate on access to medicines.

The pharmaceutical sector is one of the most highly regulated in the world. Typically, governments intervene throughout the product cycle, from manufacturing, product registration or approval, distribution, pricing, and to the sale to patients. (See Appendix B).

The route to market for medicines is complex and varies from country to country. Governments can play an important role in funding and discovering new medicines. In the US, publicly funded academics investigate the biology of a disease, while the industry takes the R&D process forward to develop and test new medicines. The (US-based) National Institutes of Health described this process of collaboration: “Once a potential drug is discovered, industry scientists conduct extensive...tests until they are ready to patent the invention and publish the results...further studies by the company and academic researchers on the drug's mechanism of action and its effects...fits into a framework of continuing basic and applied advances”. The NIH described the industry investment in R&D as “large and growing...By 1994, industry accounted for over half of the total national investment in medical research.”² Some governments provide different incentives for pharmaceutical companies to invest in R&D, within the context of which companies seek to develop medicines that will deliver financial returns. The role of public funding in developing medicines has become a politically contentious issue where the benefits of that investment are perceived to accrue to companies rather than the general public.³ Since 1995, R&D expenditure by pharmaceutical companies has grown at a compound rate

of 14%.⁴ The development phase is long and uncertain—about 10% of discoveries makes their way to market, and only 1 in 8 of these ever achieve commercial success. How much research is conducted depends on the cost and the expected revenue streams from the medicine. See for example, the Novartis case study, which illustrates how two drugs were developed differently for two very different markets.

Finally, there are several key factors that affect the way in which distribution chains operate, for example, whether customers are public or private sector entities, the nature and efficiency of health care infrastructure and systems, the role of internet sales, and market specific requirements or policy directions.

Case History

Citadel Aurobindo Biotech Ltd, Imunus Division

The Imunus division was originally launched as a generics specialty division of Aurobindo Pharma, the largest bulk drug manufacturer in April 2001 in India. This division, along with other specialty divisions Indus and Argus, was hived off into a joint venture called Citadel Aurobindo Biotech Ltd. (CABL) in May 2002. In May 2002, Aurobindo Pharma transferred its identified branded formulation lines to Citadel Aurobindo Biotech Limited (CABL) and formed a 50:50 marketing joint venture with Citadel Fine Pharmaceuticals Limited (CFPL). CABL markets products that are under licence from Aurobindo Pharma, US\$ 219 million player in segments such as semi-synthetic penicillins, cephalosporins, antivirals and certain lifestyle disease drugs. It ranks among the top five pharmaceutical companies in India and exports to 70 countries. In 2002-03, the company's profit after tax was US\$ 22 million. Citadel Aurobindo Biotech Ltd is a privately-owned company. Details about Citadel's ownership, internal structure and governance are not publicly available as its first annual report has not yet been published.

As is standard practice in India, the pharmaceutical industry only reports on traditional financial performance and environmental impact. Citadel's reporting details are unavailable at present.

The reported turnover of the Imunus division of Citadel is approx US\$ 876,680, or close to 4% of the total turnover. Imunus has a presence in all the four high prevalence-HIV states in South India i.e. Tamil Nadu, Andhra Pradesh, Karnataka and Maharashtra. A profile of the sales of HIV treatments of the Imunus division in three Indian states is as follows:

State	Average Monthly Sales (approximate US\$)
Andhra Pradesh ~ High prevalence	US\$ 17,533
Tamil Nadu ~ High prevalence	US\$ 17,533
West Bengal ~ Low prevalence	US\$ 4,355

Product range

Imunus was the third company to enter the market for HIV/AIDS treatment after Cipla and Genix Pharma, but is credited as the first to have introduced more treatment options at affordable prices.

Cipla entered the market with six treatment options. Within nine months of being launched, Imunus had introduced 11 treatment options. Now all the generic ARV manufacturers have all 11 treatment options available to them.

Imunus, while under Aurobindo Pharma, was the first to launch Efavirenz, the once daily NNRTI and a PI Nelfinavir in August 2001 in the domestic market offering competitive prices compared to international brands. Other domestic companies then followed suit.

In February 2002, while Imunus was still a part of Aurobindo Pharma, the Government of India reduced excise duty on all anti-HIV drugs. In an attempt to make prices even more affordable, Aurobindo Pharma successfully appealed to the concerned authorities to waive the sales tax at the central and state levels.⁵

Marketing and distribution

Citadel's strategy has been to offer discounted (not donated) prices to capture volume sales, in bulk to NGOs, and in some states through retail.

Imunus pioneered the concept of service to patient and made efforts to trim distribution channels by reaching out to NGOs and positive people's networks and self help groups (SHGs) directly. It was the first generic manufacturer in India to target the informal sector and this has helped it gain a large customer base. Imunus is the only division among the generic HIV medicine manufacturers to solely deal with HIV products. Its HIV portfolio also includes two drugs for opportunistic infections. Overall, the margins are very low compared to other divisions. While the company has not disclosed the exact financial breakup, it has indicated that some amount of subsidization from other business areas is required.

In West Bengal, where the purchasing power of patients is low compared to other states, partnerships with NGO networks has been essential to gain market share.

The TANSACS Pharmacy, attached to the Tamil Nadu State AIDS Control Society, offers company products at special discounts to patients, which are not available elsewhere in the state. Cipla has offered discounts on two of its products at the pharmacy, while both Citadel and Ranbaxy have given discounts on a range of products.

This distribution model has assured Citadel a steady monthly income and discounts at the pharmacy have been made possible by eliminating the middlemen. Citadel's monthly sales (figures unavailable) have been rising steadily in the process. TANSACS sales increased from US\$ 1,739 in December 2003 (launched on 15 December), to US\$ 7,611 in March 2004. The average sales figure per day is approx US\$ 32679. Citadel's income from TANSACS Pharmacy is around US\$ 4355 a month.

Diagnostics

Citadel has been working for a year with four doctors in two cities—Bangalore and Coimbatore—serving approximately 25 patients. Citadel reimburses the cost of the diagnostic test (twice a year) to patients if they take Citadel medicines for six months from the second diagnostic test onwards. This arrangement appears to be working well. (We have not explored potential treat-

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ment-distorting effects, nor did we assess the consistency of this against local market regulations but this is clearly an important consideration for companies.) Selection criteria for doctors are two-fold: they should have genuine concern for patient welfare and they should have a reasonably large base of poor patients.

Business Drivers

Citadel has 10% of market share. The company seeks to make up for the low margins by targeting higher volume through innovative distribution partnerships and models.

The main challenge facing the company is its financial performance: i.e. net sales, costs of production, debt, tax payments, dividend distribution, shareholder value, financial reporting, and types of advertising and marketing regulation breaches. In addition, the control of greenhouse gas emissions remains a challenge as do product safety and health and safety of employees.

Aurobindo Pharma, the manufacturer of Imunus' product portfolio, has regulatory approval for manufacturing from US, UK, South Africa and Brazil. During 2000-02, Aurobindo Pharma undertook a major modernization of its production facilities to comply with US and European regulations, and in anticipation for intensified competition in global markets. Responsible manufacturing practices were seen as a critical element for global market access.

Impact of programme

A majority of the Imunus division's patients are middle-income earners, with a monthly average income of around US\$ 130. In West Bengal, the average monthly income is US\$ 43. In West Bengal, Imunus offers the most competitive prices after discounts, compared to all other generic manufacturers. This is inclusive of sales tax, which raises the cost of medicine by 10% and has not been waived in that state. The price of the products varies according to the drugs and combinations prescribed. Treatment costs range from Rs 1200 (US\$ 26) per month to Rs 8000 (US\$ 174) per month depending upon the regimen. In Imunus' experience, overall monthly sales depend on affordability, standard of living, health awareness level of the general public and the willingness of the doctors to take up the medical management of the HIV afflicted and the support extended by the family and the corporate sector.

Lessons learnt

Imunus, originally a part of Aurobindo Pharma, was hived off along with two other divisions because Aurobindo Pharma found that niche marketing presented a challenge as integrating manufacturing and marketing did not make good business sense for the company as a whole. Once Imunus was given the independence to raise its own profits, it has shaped its business model on revising pricing and distribution models as the best way to improve market access.

Imunus' strategy has been based on its core advantages of **price** and **innovative distribution partnerships** as well as a **well-motivated workforce**. Since its inception, it has used the slogan "Care for HIV Cause of Imunus". This has proved an important aspect of employee motivation and helped the division achieve its sales targets.

Imunus' **distribution models** have been continually evolving as the price of HIV medicines continues to be high. The division has also learnt important lessons from its partnerships and distribution models. For example, the division now acknowledges that **partnerships** with NGOs have not always been effective, especially when NGOs default on payments. This has often been the case in the state of West Bengal and presented a concern as the state capital, Kolkata, happens to be Citadel's largest market. Imunus has therefore resorted to dispensing its products from a retail shop in Kolkata. The shop charges a service charge of 5% on sales, but provides assured payment to the company.

Imunus' **pricing policy** has not dramatically improved its market share. It recognizes that since anti-retrovirals will always be prescription products, any company's sales will depend on its ability to liaise with and develop a relationship with doctors.

So far, the company's **modest profit margins** have been sufficient for salaries and overhead costs, but they have hindered better drug promotion efforts and limited the company's ability to deliver more quality education to doctors and patients on drug administration issues. Looking forward, it will be interesting to monitor for or how long the company is able to sustain the lower prices.

Nonetheless, there is a general absence of effective multi-sector partnerships between pharmaceutical companies, doctors, NGOs and People Living with HIV/AIDS (PLHAs). As one consequence of this, the cost of medicines has not been driven down sufficiently to truly serve the vast population of afflicted patients.

Sources: Company responses to CSM questionnaire; www.aurobindo.com for annual reports; Report on CSM Consultation on Corporate Responsibility and Economic Development in India —Pharmaceutical Sector: Focus on HIV medication, New Delhi, April 6, 2004.

Partnerships

Pharmaceutical companies have become increasingly engaged in partnership initiatives, whether with other companies, or with public agencies and NGOs, and these are well documented.⁶ Typically, the partnerships have tended to focus on challenges associated with a particular disease, whether through R&D activities or through access programmes focused on prevention or treatment, donations of drugs and other resources, or education and training programmes to enhance product delivery. R&D-based partnerships enable companies to collaborate and share costs of R&D with research partners, governments and NGOs, while access partnerships enable companies to ensure products are delivered to targeted communities who would not otherwise have access to medicines due to problems of affordability, lack of awareness and health infrastructure.

The challenge for companies is to develop mechanisms to evaluate the performance of partnerships, and to ensure that their participation provides a good return on corporate investment—both with respect to shareholder and other stakeholder interests. Key questions for partnerships include how they account to their constituent members as well as to external stakeholders. Partnerships are not, of themselves, an inherent 'good'. Their value to members

and society depends on their capacity to achieve specified and agreed outcomes, in an accountable and transparent manner.

Impacts of health partnerships take time to ascertain. Companies, governments and NGOs have focused on understanding what the health impacts are—and these can only be measured over time. Moreover, the most significant health impacts are on individuals with whom the companies have little, if any contact. Pharmaceutical companies' impacts are mediated through partners—governments, NGOs and health institutions—which have assumed responsibility for delivering improved health outcomes in their country context. The effectiveness of partnerships depends in great measure on the quality of the relationships between in-country partners and related distribution chains. Some research has been done to understand how in-country partners perceive partnerships with a range of companies or initiatives, but this field remains largely untested.⁷ The case study below reflects Merck's experience in developing effective partnerships.

Case History

Merck: African Comprehensive HIV/AIDS Partnerships (ACHAP) in Botswana

Merck & Co., Inc. is a research-based pharmaceutical products company. Merck discovers, develops, manufactures and markets innovative products to improve human and animal health, directly and through its joint ventures. In 2003, Merck achieved sales of US\$ 22 billion, employed 63,200 people worldwide, and spent over US\$ 3 billion on R&D. Merck's charitable contributions (cash and product) in 2003 were US\$843 million

Merck manages its corporate responsibility agenda through its Board and a Board Committee on Public Policy and Social Responsibility, which advises the Board on the obligations of Merck as a company whose products affect health and quality of life for people around the world, and on matters relating to ethics and integrity. In addition, the Committee reviews Merck policies and practices and their implications for the company's corporate citizenship. For example, relating to the access to medicines issue, Merck has adopted differential pricing for HIV/AIDS medicines and has engaged in a range of partnership initiatives to improve access to medicines in least developed countries.⁸

Background

Merck's HIV/AIDS research programme has spanned more than 18 years, yielding two anti-retroviral (ARV) drugs and a promising HIV/AIDS experimental vaccine. Recognizing the challenges in access to HIV/AIDS medicines in the developing world, Merck has entered into numerous partnerships with governments, international organizations, foundations, other corporations and NGOs as it attempts to deal effectively with the global HIV/AIDS pandemic. It was in this context that Merck decided to launch a comprehensive programme of HIV/AIDS prevention, care, treatment and support in one country. Merck set out to create a programme, which, if successful, could provide information useful to other developing nations, international organizations, foundations and governments of developed countries that, ultimately, would have to bear the

tremendous cost of any comprehensive plan. To be successful, this programme had to be implemented with the cooperation of the country's government that had the political will to mount an integrated fight against HIV/AIDS. The President of Botswana, Festus Mogae, expressed such a will and, given that his country was also one of the hardest hit by the HIV/AIDS epidemic (37.5% of the adult population is HIV positive), Botswana was a logical choice for the programme.

Merck sought partners from business, public sector and foundations. The Bill & Melinda Gates Foundation, already heavily involved in initiatives to improve public health, agreed to consider the yet undefined programme. In 2000, the two partners set out to work with the Government of Botswana (GOB), and established the African Comprehensive HIV/AIDS Partnerships (ACHAP) in Botswana.

The objectives of this public-private partnership are to build institutional capacity to address the HIV/AIDS epidemic in-country, strengthen the health care system in the long-term, and create and expand sustainable community initiatives relating to HIV/AIDS prevention, treatment, care and support. The Merck Company Foundation and the Gates Foundation are each contributing US\$ 50 million over five years (2000-05) to the project. Merck is also donating its ARV medicine (CRIXIVAN and STOCRIN) to the GOB's national treatment programme (named Masa). Masa provides free ARV therapy to all Botswana who need it. Of approximately 260,000 HIV-positive adults in Botswana, 110,000 are estimated to require ARV therapy and are the intended beneficiaries of Masa.

The partnership project is overseen by a Board of Directors. The Board is responsible for transparency and accountability of programme budgets and strategic direction. Since November 2003, ACHAP has been managed by Mrs Tsetsele Fantan, long-time executive and HIV/AIDS workplace programme director for Debswana, Botswana's diamond mining company. Mrs Fantan works with a team of 20 people. In addition, a number of ACHAP employees have been seconded to GOB ministries and sectors.^{9, 10}

As far as we are aware, ACHAP is the only public-private programme of its type focused on a single country. Such an approach would be difficult for national or international donors/organizations to pursue given their broader mandates.

Business drivers

Merck states that pharmaceutical companies should play a role in removing the barriers between patients and the therapies that they need, alongside governments, multilateral institutions, and NGOs. Merck believes that public health improvements play a critical role in economic development. At the same time, economic development, including long-term improvements in the pharmaceutical sector business environment, can improve public health. In this respect, Merck perceives the long-term interests of shareholders and society as consistent. Many investors recognize Merck's efforts to respond responsibly to the challenges of the HIV/AIDS epidemic and to promote access to medicines in general, given that many perceive related issues to be long-term risks to the sector.

Merck has a long-standing practice of building public health infrastructure. As a matter of course, the company consults relevant stakeholders. In shaping ACHAP, Merck drew from its

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experience with the Merck Mectizan[®] Donation Program (MDP) that has been in operation for almost 20 years to eliminate river blindness as a public health problem. In developing and participating in the MDP, Merck observed several key drivers for the partnership's success. It needed to:

- Be informed by the needs of those affected by the disease;
- Focus research resources on feasible targets related to health priorities;
- Ensure that donated medicines reached those affected through properly functioning delivery mechanisms and healthcare infrastructure.¹¹

In part, the success of Merck's partnerships to improve public health is due to the inherent long-term focus of the pharmaceutical industry. If there have been any short-term business benefits, they have been the lessons learned that could be applied to other, similar scenarios.

Impacts

The ACHAP partners perceive the success of the project as the extent to which the Government of Botswana's main objective is achieved: to reduce the incidence of HIV/AIDS and its burden on its population. The project has required a significant up-front investment in infrastructure and capacity building, and the full health and economic impacts will emerge over time. At this stage, however, the partners are encouraged by the interim ACHAP results:

- 32 treatment centres in hospitals and satellite clinics are being built nationwide—as of April 2004, 12 were operational;
- HIV prevention programmes are in place including disease awareness and destigmatization training for teachers in over 500 schools (65% of all schools in Botswana);
- 25 community-based centres are offering services such as confidential pre- and post- HIV test counseling, information and support for AIDS orphans;
- More than 1,100 healthcare professionals have had HIV/AIDS clinical care training, and more than 1,000 healthcare workers have received clinic-based HIV/AIDS training through a preceptorship programme with international experts;
- More than 500 government, NGO and other key players have been trained on project development, monitoring and evaluation, leadership skills and proposal development, media training and computer skills. Many of these areas of capacity building are not HIV/AIDS specific but do provide a fundamental basis to support Botswana's national strategic framework for HIV/AIDS.

In addition, as of June 2004, more than 27,000 patients have enrolled in the GOB's Masa programme, with more than 17,000 on therapy. After a relatively slow start, more than 1,000 new patients are being enrolled in Masa per month. Masa is currently the largest national ARV treatment programme in Africa.

A range of statistics is being collected to monitor health impacts, including the viral load of patients in which HIV/AIDS is completely suppressed after six months of treatment (85% as of June 2004), the percentage of patients who have died after initiating treatment (9%), and the percentage of patients who maintain follow-up with the programme (90%). The economic implications of these results are that most patients can return to or continue to engage in productive economic activity, there is a reduced economic burden on families, and children can continue to

go to school. In fact, rather than focusing on the performance of the individual partners, ACHAP's performance is measured by the impact on these types of parameters. Merck's medicines are essential contributors to this impact, but their effectiveness relies on the success of appropriate and sustained health care infrastructure development.

Lessons learned

Supporting the development of a national HIV/AIDS strategy is a complex political, economic and social balancing act that has required ongoing stakeholder engagement in a resource-constrained environment. In developing the partnership and project, with different political and cultural perspectives on concepts of efficiency, desired social and administrative changes and operational requirements to deliver outcomes, Merck and the other partners have found that a tightly focused and shared understanding of project objectives has been critical in keeping everyone focused on the project. In addition, results-driven performance has been critical in generating impact.

The primary role of the GOB in ACHAP is proving key to its success. In addition, ACHAP has benefited from the central role of the National AIDS Coordinating Agency in Botswana in organising multi-sector initiatives relating to HIV prevention, care and treatment.

ACHAP was designed as an independent ?? mechanism to support and enhance the GOB response to HIV/AIDS rather than as a new initiative, separate from government policy direction and implementation. To ensure integration with government processes, establishing transparency and accountability of the partnership among the partners has been fundamental, especially in terms of monitoring and evaluating health impacts. The partnership has enabled private sector management and foundation resources to support government-led planning and implementation, with each partner bringing different and complementary strengths to the partnership. This includes assisting the GOB to develop expertise in building training programmes and capacity within the government and within the health care system. Building capacity amongst policy makers has been key to promoting political and bureaucratic support in a resource-constrained environment.

The project began in a difficult environment: only a minority of Botswana were aware of their HIV status or about HIV/AIDS in general, there was widespread denial and stigma attached to the disease, and cultural issues surrounding sex and sexuality, alcohol and gender affected the risk environment for contracting the disease. Public health education programmes are beginning to improve awareness of the disease and are addressing the cultural and stigma issues.

Although the partnership was established for five years, one of the aims of ACHAP is to ensure that efforts to combat HIV/AIDS are sustainable. After 2005, Merck will continue to be associated with ACHAP and to work as a partner with the government. At the same time, the partnership is looking at other potential sources of funding, such as the Global Fund.

In the future, Merck, the Gates Foundation and the GOB hope that lessons learned from ACHAP will provide useful information to other developing nations, international organizations and NGOs, foundations and governments of developed countries interested in implementing a comprehensive plan elsewhere. For example, after observing the success to date in Botswana, the Governments of China and South Africa have expressed interest in learning more about ACHAP to help address the HIV/AIDS epidemic in their countries. In addition, the partners have learned

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important lessons about the length of time it takes to build ARV treatment capacity, and about ways to sustain compliance to HIV/AIDS treatment. Work with the University of Botswana has highlighted valuable lessons about the need to target health education programmes to different subsets of the population based on their unique set of behaviours. Furthermore, ACHAP is demonstrating that safe and secure distribution of ARVs in Africa is possible. More information about ACHAP and its activities is available at www.achap.org.

The ultimate measure of success of ACHAP will be the extent to which HIV incidence and its burden on Botswana can be reduced. Although it will be several years before this effort can be fully evaluated, success to date suggests that there truly is hope for those in developing countries affected by HIV.

Non-Government Organizations (NGOs)

There is a wide range of non-governmental interest groups representing pharmaceutical sector stakeholders, including:

Healthcare Professionals

Health care professionals are organized nationally and internationally through bodies such as the World Medical Association (WMA). The WMA was created to ensure the independence of physicians, and to work for the highest possible standards of ethical behaviour and care by physicians, at all times. WMA is an independent confederation of around 80 free professional associations.¹² Health care providers such as hospitals have a variety of objectives they want health care systems to address, and these are not always prioritized in the same way by health care funders (government or insurers) or patients. There are also questions on how the pharmaceutical sector interacts with health care professionals, and what constitutes ethical marketing and education.

Patient Groups

These vary widely between countries and according to disease and level of awareness. The International Association of Patient Organizations (IAPO) represents many patient groups internationally. Patients' organizations work at local, national, regional and international levels to represent and support patients, their families and carers and lobby companies, governments and others who affect their interests. Patient groups often have strong networks with research communities. Patient groups have established good networks for orphan diseases to share best practice internationally.

Researchers and Academics

There is a significant level of 'cross over' of scientists between R&D functions in companies and academia. Medical research institutes have played a significant role in informing companies how to address different disease issues and often play critical roles in multi-sector partnerships focused at both R&D and access issues. Academics are well placed to understand and monitor

the health impacts of partnerships, and play a critical role in helping companies understand the broader socio-economic impacts of partnerships.

Abbott Laboratories: Improving Public Health Care Systems to Deal with HIV/AIDS: Tanzania

Abbott Laboratories is a global, broad-based health care company devoted to the discovery, development, manufacture, and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 55,000 people and markets its products in more than 130 countries. In 2003, total sales were US\$ 19.7 billion, and total R&D expenditures were over US\$ 1.7 billion. Community investment and philanthropy totaled US\$ 225 million. In 2003, Abbott also recorded its 320th consecutive quarterly dividend to be paid to shareholders since 1924. In addition, 2003 marked the 31st straight year Abbott's dividends have increased.

Internal structure of the company/association:

As a global corporation, Abbott has the opportunity and responsibility to extend its core expertise, products and people for the most positive impact on the world. To ensure that citizenship is an ongoing process that is integrated into the business, Abbott established a Global Citizenship and Policy function that resides within the Investor Relations and Public Affairs organization and is led by a divisional vice president who reports to a corporate officer. The mission of the Global Citizenship and Policy function is to position Abbott as a thought leader in the field of citizenship among the world's FORTUNE 500 companies. The function is responsible for developing and driving the company's citizenship strategy, working with others to develop policies on key issues, implementing programmes, and promoting dialogue with stakeholders.

In 2003, Abbott established the Global Citizenship Working Group (GCWG), which consists of a cross-functional team from across the organization. Chaired by the Global Citizenship and Policy group, the GCWG's mandate is to drive Abbott's global citizenship agenda. It is also active in a number of policy forums and initiatives focused on the evolving roles of government, business and NGOs in a global society.

Description of programmes

A leader in HIV/AIDS research since the 1980s, Abbott is investing US\$ 100 million over five years in AIDS-related humanitarian programmes that address critical areas of need in the developing world. This commitment was announced in 2002. Abbott works with local communities, businesses, NGOs, faith-based groups and governments to help people in the world's poorest countries, including all of the countries in Africa, where the disease is most prevalent and the call for assistance is greatest.

Abbott's commitment to fight the pandemic has increased significantly in recent years, manifested in the establishment of its Global Care Initiatives. These include four interrelated programmes that provide testing, treatment, and services for those affected by HIV/AIDS in the developing world. One such programme is Tanzania Care, a partnership among Abbott, the Abbott Laboratories Fund and the government of Tanzania to modernize the country's public health

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care systems, and improve services and access to care for people living with HIV/AIDS and other serious illness, an issue that is a challenge for nearly all countries in Africa.

Created in 2002, Tanzania Care contains two key elements: restoring the country's health care facilities and systems, focusing on Muhimbili National Hospital (MNH), Tanzania's largest public hospital; and expanding access to HIV voluntary counseling and testing (VCT) to 16 of the country's 21 regional hospitals. The overarching goal of the programme is to create a public-private model that can be adapted by other governments, companies and organizations working to fight AIDS in the developing world.

The multiyear, multimillion dollar initiative specifically includes:

- Building a new 3,700 square meter outpatient department at MNH, scheduled to open in early 2005;
- Renovating and completely upgrading Muhimbili's clinical laboratories as well as other laboratories throughout Tanzania;
- Increasing the capacity of Tanzania's regional hospitals to provide VCT services as well as prophylaxis and treatment of opportunistic infections;
- Strengthening the management structure and systems, including department organization, budget process, planning cycle and financial controls within the national hospital;
- Training health care staff in HIV care and treatment, including reviewing and updating the curriculum for physician, nursing and paramedical staff at the Muhimbili Medical College; and
- Upgrading information technology, security, waste management and health information systems at MNH.

As part of the programme, Abbott provides the time and talent of employee volunteers. These specialized volunteers include senior-level executives from various functions of the company who lend their technical support in the areas of engineering and waste management, among others.

Axios, an organization dedicated to improving health care in developing countries, is serving as the implementing partner for Tanzania Care by providing strategic counsel and working with the Tanzanian government, local contractors and organizations to oversee the programme on a day-to-day basis.

Business Drivers

Abbott recognizes that access to medicines is one of the great public policy debates of our time and is likely to remain so. Facilitating quality and affordable access takes on many forms and depends on the economic, social and political environment in each country. Solutions require the leadership, expertise and resources of diverse stakeholders, including patients, health professionals, governments, health care companies and NGOs.

Addressing HIV/AIDS in the developing world is aligned with Abbott's mission as a leader in HIV/AIDS treatment and diagnostics. The company's commitment is defined by three components: a successful HIV/AIDS medicines and diagnostics business, a commitment to ongoing research and development, and innovative global citizenship initiatives that help HIV/AIDS patients. The three components are interconnected, and part of a holistic approach to improving patients' lives.

Abbott's Global Care Initiatives strengthen the company's commitment as an active and engaged partner on the global HIV/AIDS crisis, facilitating dialogue with key stakeholders, including NGOs, governments and others who share the company's concern about the pandemic. Additionally, the stakeholder engagement these programmes entail also helps drive change within the company by ensuring that the business listens to, understands and acts upon societal expectations.

While Abbott has no commercial presence in Tanzania, the company is committed to demonstrate its mission through actions—this is important to key stakeholders. The commitment is also highly motivational to employees, especially for those who serve as volunteers for the programme. In support of innovation in health care for HIV, Abbott documents learning from this programme to share with others at major conferences to help find sustainable solutions to fighting HIV/AIDS.

Impact of Programme

Abbott's efforts in Tanzania have shown significant progress toward meeting the goal of improving the country's health care system. Tanzania was chosen as Abbott intended to develop programmes in countries where it felt it could make tangible contributions to healthcare of a country that ranks 160th in UNDP's Human Development Index.

While statistics from the programme are not yet available, Abbott expects that it will enhance treatment of the disease, and also enhance counselling and testing. Moreover, improved capacity and expertise of facilities and staff will also help treat other diseases.

Specific highlights of the programme include:

MNH key achievements:

- New management structure was created and approved by MNH's board of trustees, and a new chief executive officer was appointed in November 2003. The hospital will include five new operating divisions (medical services, clinical support services, technical services, surgical services and nursing services). At the strategic level, eight management units will be created, including finance and planning; human resources and administration; research and development; information and communication technology; quality control; legal counsel; internal audit; and public relations. The new structure gives increased scope and authority to the hospital board and management. Additionally, the specialized divisions and business units create decentralized operations that mandate these groups to plan, implement and budget for annual programmes.
- The construction of the new 3,700 square meter outpatient department of MNH began in the middle of 2003 and will be completed by the end of 2004. Construction of a boundary wall to improve security at the hospital began and will be completed in July 2004.
- Renovation and complete upgrade of MNH's clinical laboratories began and will be completed by the end of 2004. This work includes rehabilitating the physical structure, as well as supplying an inventory of donated laboratory equipment and the reagents necessary for opening the bacteriology, histopathology, biochemistry, parasitology, hematology, serology and tuberculosis departments.
- Abbott volunteers assessed and selected a new information technology system for MNH; conducted a financial audit and recommended new financial procedures; and evaluated the laundry, catering, security and waste management processes and provided recommendations for new hospital systems.

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- Sixty-five hospital personnel (20 doctors, 30 nurses and 15 laboratory attendants) were trained on HIV management, and the site field service engineer unit was trained on the most recent technology implemented at the site.
- A study of the medical graduates of the Muhimbili Medical College was completed, and Abbott and its partners are currently working to revise the medical curriculum at the school.

VCT key achievements

- VCT services were established at four regional hospitals (Tabora, Shinyanga, Kibaha and Morogoro).
- Forty-two staff were trained as VCT counselors, 16 laboratory staff were trained on HIV quality control testing, and 300 paramedical staff received training on basic HIV/AIDS facts, hygiene and infection control.
- Management teams were established in all four regional hospitals.
- Sensitization meetings were held with key stakeholders in the region (health management team, NGOs and faith based organizations (FBOs))
- Two NGOs were identified to serve as referral centres for patients requiring psychological support.
- National VCT guidelines were drafted.

Lessons learned

Through Abbott's humanitarian work in the developing world, the company has learned that donations alone cannot truly impact underserved communities. Governments have the primary responsibility for health care delivery in most communities, and only true collaboration between the private and public sectors to improve deteriorated health care systems, including infrastructure, training and sustainable programmes, will help turn the tide of the pandemic

Additionally, while local customs and beliefs traditionally change slowly, continuous communication—through local media, religious and local leaders and peer education—is successful in helping to remove the stigma attached to HIV/AIDS and VCT.

Companies who are active in the developing community should consider expanding their programmes to include a more holistic approach to improve health care systems. This issue is likely to gain importance as the availability of antiretroviral treatment—made possible by new international funding – increases the need to manage HIV/AIDS as a chronic disease.

The case provides an example of how pharmaceutical companies are using public private partnerships to advance access to medicines. This has been included by access to medicine advocates as one area in which companies can demonstrate enhanced responsibility on this agenda.

Access to Medicines Advocacy Groups

Oxfam, Save the Children and VSO have identified five issues to help assess corporate responsibility with respect to developing country markets. They are:

- Pricing

- Patents
- Joint Public Private Initiatives
- R&D
- Appropriate Use of Technology¹⁴

Medicines Sans Frontieres (MSF) has established advocacy positions on the access to medicines issues, including securing lower product prices through:

- “encouraging generic competition, voluntary discounts on branded drugs, global procurement, and local production...
- increased research into neglected diseases through increased funding...
- investing in R&D capability in developing countries...
- supporting alternative models for R&D...
- requesting that companies and governments find ways to bring unprofitable but medically necessary drugs back into production...
- support developing countries to implement legislation that prioritises access to medicines... and,
- lobbying for trade policies to give the highest level of protection to public health.”¹⁵

MSF acknowledges the complexity and shared responsibility of access to medicines questions, but perceptions on the breakdown of where responsibilities lie generally differs from corporate perceptions and focuses on preferred outcomes in corporate behaviour in the areas of pricing and research. MSF contends that “pharmaceutical companies should contribute to long-term solutions, such as cutting their prices for developing countries in a transparent and predictable way, and supporting increased R&D for neglected diseases.”¹⁶

In the case of the HIV/AIDS pandemic in Africa, others have expressed concerns that the focus on access to medicines and provision of cheap drugs has distracted attention from fundamental needs to develop healthcare infrastructure and distribution channels, patient education (including combating stigma), regulation and governance of national healthcare policy, and prevention.¹⁷

Governments

Pharmaceutical companies have complex relationships with governments. Governments are key customers for pharmaceutical companies and negotiate commercial contracts for the supply of medicines with companies. They may also play a role in the research process. The nature of these relationships, and the balance of commercial power between the government and pharmaceutical company, and the agreed cost, depends on a range of issues. These include whether or not the product is substitutable for other medicines or treatment regimes and relative short and long-term costs.

Governments also regulate pharmaceutical companies—on all aspects of the product development and delivery chain—and in some cases on profit. This may be perceived as creating a potential conflict of interest for government as a regulator, commercial and political player. As governments play an important role in determining the way in which the market for pharmaceutical products is structured and managed nationally and internationally, pharmaceutical companies, along with other health care actors, seek to influence government policy.

Companies have mixed performance in disclosing information on their policy positions and efforts to influence a wide range of government policies, ranging from domestic health care reform, to developing appropriate delivery mechanisms, to pricing strategies, to Trade Related Intellectual Property Rights. Enhanced transparency better informs stakeholder perceptions (including investors) on company risk, and the dilemmas companies face in balancing complex relationships with government.

Sector critics cite industry spending on political lobbying as a potential misuse of influence and a lack of transparency.

“In its budget for the fiscal year that begins on July 1, the pharmaceutical lobby earmarks \$72.7 million for advocacy at the federal level, directed mainly at Congress; \$4.9 million to lobby the Food and Drug Administration; and \$48.7 million for advocacy at the state level. In addition, the budget sets aside \$17.5 million to fight price controls and protect patent rights in foreign countries and in trade negotiations.”¹⁸

While some companies have disclosed information on political donations and policy positions on specific issues, the sector is widely criticized for the lack of transparency on its policy advocacy efforts, which potentially creates significant risks for the sector in engaging effectively with governments and other stakeholders. Companies and their stakeholders have legitimate rights to advocate their interests, and pharmaceutical companies are amongst the most knowledgeable organizations in the health field.

“Merck is committed to participating in the lobbying process by supporting non-partisan registration and political education activities, expressing our views in legislative forums, and communicating with employees, stockholders, customers, legislators, health professionals and others with common interests. Issues include controlling health care costs, and incentives for innovation, which continue to be debated world wide. It is appropriate for the company to help inform these debates. Additional information is available in Merck’s 2004 Proxy Statement.”¹⁹

The challenge for companies is to improve trust through transparency. If companies are to advance the access to medicines debate, they need to move perceptions of the industry from one in which IPR and access to medicines are mutually exclusive, to one where stakeholders have a view on the appropriate balance of incentives required to achieve sustainable innova-

tion and access to health. Like their stakeholders, individual companies have different views on what this balance should be.

International Bodies

Recognising the global nature of the access to medicine debate, and the failure of nations to address it in isolation, access to health has been a key focus for a range of inter-governmental organizations, including the WHO. The WHO's functions reflect international perspectives on:

- Articulating consistent, ethical and evidence-based policy and advocacy positions
- Managing information by assessing trends and comparing performance; setting the agenda for, and stimulating research and development
- Catalysing change through technical and policy support, in ways that stimulate cooperation and action and help to build sustainable national and inter-country capacity
- Negotiating and sustaining national and global partnerships
- Setting, validating, monitoring and pursuing the proper implementation of norms and standards²⁰

WHO programmes are implemented at the national level and are intended to support national health objectives. National health objectives and policy, may not, however, reflect best practice internationally. The WHO has not escaped the criticism leveled at many multi-lateral institutions — that policy and practice reflect the perspectives of the UN's most powerful members rather than a consensus amongst all members.²¹ Other organizations focus on specific diseases such as the Joint United Nations Programme on HIV/AIDS, UNAIDS, advocates global action on the epidemic, the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Other organizations such as the International Red Cross (IRC) as well as a range of NGOs have played a significant role in humanitarian aid distribution—including medicines. The IRC's apolitical position has enabled it to have access to countries and populations who otherwise fall outside international political architecture.

Investors

The investor community is beginning to recognize both the short- and long-term implications of the public health challenge in developing countries for the pharmaceutical sector. SRI investors hold 14% of GSK stock, the highest of any pharmaceutical company. This has been driven by the SRI community, but has yet to be adopted in the mainstream investment community. While it has been difficult to quantify the risks to corporate performance posed by access to medicines issues, there is an emerging view that companies that manage corporate responsibility risks better should outperform in the long run.²² (The March 2003 draft “Investor Statement on Pharmaceutical and the Public Health Crisis in Emerging Markets” was issued by the UK-based Pharmaceutical Shareowner Group (PSG) and followed by a

report in September 2004 (“The Public Health Crisis in Emerging Markets: An Institutional Investor Perspective on the Implications for the Pharmaceutical Industry.” The Statement established a framework of good practice for the pharmaceutical industry to increase disclosure of CR management issues, including examples in the areas of pricing and patents, public private partnerships, product diversion, R&D, product marketing (WHO Ethical Criteria for Medicinal Drug Promotion), and leadership and use of influence. In the US, there are emerging signs that institutional investors are pushing these issues. The Californian Public Employees Retirement System (CalPERS), the single largest pension fund in the US, and which holds GSK shares to the value of around US\$ 760 million, encouraged GSK to address the HIV issue not only through product pricing, but also through voluntary licensing agreements with manufacturers in developing countries. CalPERS recognized the potential risk trade-offs between voluntary licensing and the reputational risks associated with not doing so. Similarly, the Interfaith Centre on Corporate Responsibility (ICCR) HIV/AIDS Caucus representing around US\$ 33 billion announced on World AIDS Day its intention to intensify pressure on US leading pharmaceutical companies to widen access to anti-retroviral AIDS drugs in the developing world. Members of the HIV/AIDS Caucus have filed shareholder resolutions with Bristol Myers Squibb, Merck, Abbott Laboratories, Pfizer, Schering-Plough and Eli Lilly. Institutions such as Deutsche Bank, Dresdner Bank and HSBC have recognized that they will need to account for HIV impacts in financial forecasting, asset allocation, stock selection and underwriting. It is important to emphasise, however, that this level of investor interest is largely confined to the SRI community.

Following the publication of the revised King Report on Corporate Governance (King 2), the Johannesburg Stock Exchange (JSE) introduced a range of reporting requirements, including that companies disclose relevant information on their HIV policies (in the workplace). While King 2 is voluntary, some of its provisions, including triple bottom line reporting, have already been included in the JSE’s listing requirements.²³ This is likely to add significant impetus for publicly listed companies in South Africa to understand and manage the implications of its business functions for public health and socio-economic development. JSE recognition of the risks of HIV has been driven by the business and public policy. Mainstream investors in South Africa have taken these issues on board because they understand the major upheavals and ramifications of the loss of population. Cost to skills and cost of maintaining families of the AIDS sufferers are real costs for companies on the ground as well as the wider economy. This decision explicitly recognises the role of companies in managing health and the ensuing economic impacts. For other diseases, and in other countries, mainstream investors from abroad have been reticent to include social aspects of performance in their analysis of corporate risk, in part because the links between financial performance and wider economic performance are perceived to be less direct, and in part due to a lack of meaningful metrics.

3. Mapping of Standards and Regulations

Companies

Standards and regulations profoundly influence the operating environment of pharmaceutical companies across most aspects of activity. The regulatory environment varies significantly amongst countries, affecting the cost of R&D, who companies sell to, and how they produce and market their products and so on.

Reference to Product-Related Economic Impacts by Norms and Standards Used by the Pharmaceutical Sector

	ASPIRATIONAL	MANAGEMENT SYSTEMS/ CERTIFICATION/ GUIDELINES	RATING INDICES	REPORTING FRAMEWORKS
Global Reporting Initiative				■
FTSE 4GOOD			■	
Dow Jones Sustainability Index			■	
Sullivan Principles	■			
Global Environmental Management Initiative (GEMI).		■		
IFPMA Code of Pharmaceutical Marketing Practices		■		
WHO Ethical Criteria for Medicinal Drug Promotion		■		
WHO Guidelines for Drug Donations		■		
WHO Guidelines on Clinical Trials		■		
WHO Guidelines on Good Clinical Practice		■		
Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Health Care Professionals	■			
Declaration of Helsinki		■		
ICH Guideline on Good Clinical Practice		■		

Like the GRI, the AA1000 Assurance Standard is applicable across sectors. In the pharmaceutical sector, it has not been widely adopted. Companies such as Novo Nordisk, to improve their reporting and accountability processes.

Regulation of the pharmaceutical industry has traditionally focused on quality and safety issues. There are stringent requirements for companies to comply at each stage of R&D if the medicine is to be approved by the national drug approval agency. Moreover, the product approval process has become increasingly complex, costly and time consuming.²⁴ Governments have typically recognised that private market incentives are insufficient to secure a level of investment in health R&D to generate desired public health outcomes, and complemented private capacity with a range of policy interventions, including direct and indirect subsidies, intellectually property regimes, public health insurance and so on. These have been mapped against the product development and distribution process table (Appendix B) to highlight where regulations have an impact on corporate decision making, and how this in turn affects corporate economic impact.

Intellectual Property Rights (IPR)

Central to pharmaceutical companies' ability to recoup investment on R&D activities and generate income to fund current and future R&D activities is certainty that the revenues that a medicine generates in a particular market can be protected for a given time period through intellectual property rights (IPR), and that those rights will be enforced. This is achieved through patents. In effect, a patent confers a time and geographically bound monopoly status on the inventor of the patented product (a new chemical entity in this case). While a product is under patent it must compete with many other similar products often in the same therapeutic class. Generic companies tend to focus on "blockbuster" drugs when the patent expires as they are more likely to be profitable.

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CSIR, Phytopharm, Pfizer and the South African San Council: Innovation and Incentive

The Council for Scientific and Industrial Research (CSIR), a laboratory partly funded by the government of South Africa, is the largest R&D and implementation technology agency in Africa. CSIR operates as a market-oriented contract and research partner and delivers scientific and technological services to industries, parastatals or governments.

Phytopharm is a botanical pharmaceutical company listed on the London Stock Exchange. It specialises in using traditional plant remedies to develop pharmaceutical products. Phytopharm subcontracts all laboratory work to specialists while retaining full control over the direction of the research to keep overheads low and giving it access to the latest techniques. Phytopharm seeks licensing partners for development and commercialisation of its products following "proof of principle" clinical evaluation. It seeks multinational partners, with milestones paid on completion of agreed targets, submission of regulatory documents and royalties paid on sales. The company has in place a social and ethical policy, covering employee relations, respect for national laws, international policies as well as standards that it and its contractors, partners and suppliers are expected to comply with.

Background

Hoodia gordonia succulent was the subject of National Food Research Institute's (a division of CSIR) research between 1963–1971, initially as part of a project on edible, indigenous plants of South Africa. Laboratory studies at CSIR at the time provided evidence of the appetite suppressant properties contained in extracts of the *hoodia* plant. With growing concern of the impact of obesity on health in developed countries, this evidence was considered to have considerable commercial potential. CSIR patented the pharmaceutical formulations (P57)²⁶ derived from the *hoodia* without initially acknowledging the indigenous knowledge of Southern Africa's San people.²⁷ The San people had traditionally collected and used the *hoodia* plant as an appetite and thirst suppressant during food scarce times and during long hunting trips.

In 1997, CSIR agreed with Phytopharm that Phytopharm develop and conduct the initial stages of clinical trials for P57. Phytopharm (which assumed at the time that the San clan had ceased to exist²⁸) in turn sub-licensed the patent to Pfizer in 1998. Pfizer could develop and commercialise P57 globally as an oral prescription drug to treat obesity. In 2001, Survival International²⁹ informed the San people of the patenting of P57. The South African San Council³⁰ advised CSIR of its intention to initiate legal proceedings to challenge the P57 patent if the San's intellectual property rights and derivative ownership interest in P57 was not acknowledged and compensated by CSIR. Resulting negotiations between the South African San Council and CSIR, together with the Government of South Africa, lead to an agreement in 2003. CSIR and the South African San Council agreed that the San people would receive 8% of payments the CSIR secures from Phytopharm while P57 underwent trials. Once the drug is commercially available, the San people would be paid 6% of all royalties awarded to the South African patent holder, CSIR. Neither Phytopharm nor Pfizer played a direct role in the talks between the CSIR and the San people in terms of the P57 benefit sharing agreement.³¹

In highlighting the economic impact of the molecular discovery, Roger Chennells,³² a lawyer representing the San people states: “this agreement marks a turning point for indigenous people fighting to protect their role in the development of such a potentially lucrative drug.”

In December 2001, the successful completion of the proof of principle clinical study for P57 was announced. Phytopharm, which continued to invest in support of the further development of P57, completed in April 2002 the installation of a new botanical supplies unit in South Africa to substantially expand the manufacturing capacity for the product. However, in a press release (issued on 30 July 2003), Phytopharm announced its receipt of Pfizer's notice to relinquish their interest in P57, irrespective of encouraging clinical results from Pfizer's studies on the compound. As a result of this, Phytopharm is currently seeking for a new R&D partner.

Commercial interest in developing P57 has been driven by the focus of developed country governments on addressing obesity. Obesity is widely thought to contribute to heart disease and lower levels of health, and imposing growing costs on developed country health budgets. Anticipating increased demand for obesity related pharmaceutical products has impacted on corporate R&D priorities.³³

Potential Economic Impacts

P57 has been heralded by researchers as the first herbal diet compound having the potential to be a “major blockbuster.” This holds potential economic impacts for the San communities, which are

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among the poorest people in the Southern African region. It is estimated that their impoverished community has over 100,000 people living in South Africa, Botswana, Namibia and Angola.

The San Hoodia Benefit Sharing Trust (established by the South African San Council and CSIR) would manage revenues. According to Roger Chennells, the money would be divided among San people living in South Africa, Botswana, Namibia and Angola³⁴ and would be used communally, mostly for buying land and then investing in education and community social development projects.

Phytopharm's expanded manufacturing capacity is expected to attract FDI to the country and is anticipated to create more skilled employment opportunities. Export of the product is anticipated to enhance the country's balance of payments.

Lessons learned

- That indigenous knowledge systems are recognizable in court, in respect of which financial settlements can be secured;
- Molecular discoveries can have positive economic impact on indigenous people if their indigenous knowledge is recognized as a contributory factor;
- Indigenous people need legal representation and financial support to secure indigenous knowledge recognition. This is a constraint in most parts of the world;
- Stakeholder engagement in the pharmaceutical sector, particularly during the R&D process, is critical;
- Despite the legal settlement, an R&D company willing to secure venture capital for taking the drug to commercialisation is required. Without the right incentives, anticipated demand and income streams for a product, the likelihood of a drug being brought to market through the R&D and approval processes is limited.

IPR regulation is determined and enforced at the national level and varies significantly between developed and developing countries. IPR regimes in developing countries tend to be less well developed, and in many cases, are not enforced. Over 95% of patented filings globally are by nationals of the 30 OECD member countries.³⁵ Many pharmaceutical companies do not patent some of their products in developing country markets since they do not plan to market their products there. Approximately 99% of the WHO's list of 325 essential medicines are off patent, but many important new drugs are on patent, including in vital areas of non-communicable diseases. At a national level, determining what is an appropriate level of protection of IPR has long been debated in the context of balancing competition and the time-bound exclusivity conferred by the various forms of IPR. India, for example is the largest generic medicine producer in the developing world. At the same time, the total number of Indian HIV positive patients receiving ARV treatment is lower than the number of participants in the Government of Botswana's MASA programme.

Ranbaxy Super Specialties Division, Ranbaxy Laboratories

Ranbaxy Laboratories is India's largest generic pharmaceutical company with global sales of US \$1 billion. It has a presence in 106 countries and has a sizeable market share of India's export profile. The company entered the domestic ARV market after Cipla and at the same time as Aurobindo Pharma.

Ranbaxy Super Specialties is the division of Ranbaxy Laboratories Limited that sells HIV/AIDS medicine, along with oncology and nephrology medicines. The company manufactures and markets branded generic pharmaceuticals, bulk substances and intermediates. Ranbaxy also provides drugs to treat opportunistic infections and diagnostic solutions ranging from screening of HIV to tests for monitoring the infection.

Ranbaxy employs 8,000 people worldwide but has not provided a breakdown of the number of staff employed in India. The company's consolidated net profit in 2002 was Rs 6.48 billion (US\$ 141 million). Figures for 2003 were not available. Promoters hold 32.06% shares in the company.

Ranbaxy's is committed to investing approximately 6% of its global sales in R&D. Between 1996-97 and 2002, the total outlay on R&D was Rs 5.46 billion (US \$118.6 million). HIV medicines are not a part of this effort. Ranbaxy earns relatively little from its HIV medicines segment and does not appear to be focused on new product development in this area.

Ranbaxy won its first major export contract for US \$1.8 million from the Ministry of Health, Nigeria in 2001. Registrations have also been made in several countries with a high prevalence of HIV, notably, Brazil, Cambodia, Peru and Vietnam. Ranbaxy's HIV products have been approved in 30 countries.

Reporting and disclosures

Ranbaxy has one of the most detailed profiles on disclosures in the India pharmaceutical sector. Reporting is mainly confined to financial issues. In common with other companies in the sector, Ranbaxy also provides information on its products, R&D projects, environmental performance and inventory.

Description of Programmes

Agreement with Clinton Initiative

Ranbaxy was part one of a number of companies that signed an agreement with the Clinton Initiative in October 2003 to sell drugs to African and Caribbean countries. This initiative would reduce the cost of treatment from 80 cents per person/day now to 36 to 38 cents per person/day (US \$140 per person/year). According to Ranbaxy, approximately 1.5 to 2 million patients are expected to benefit from this programme by 2008. However, there are no plans to offer such highly discounted prices in India.

AIDS Awareness

Ranbaxy Community Healthcare Society is a non-profit voluntary organisation and a registered society that carries out social initiatives. It has carried out a project funded by the Madhya Pradesh State AIDS Control Society (MPSACS). The project was a targeted intervention programme for the prevention of HIV/AIDS among truckers and migrant labourers in the urban slum population of Dewas, Madhya Pradesh, where Ranbaxy has its manufacturing facility.

Business Drivers & Challenges

Ranbaxy's packaging method is its Unique Selling Proposition (USP). Medicine is packed in strip and blister packs, which impart stability to the product. The quality of products is thus ensured and the extra packaging cost absorbed.

Ranbaxy is, however, not the most competitive in terms of price. In fact, its prices are the second highest in the market after Cipla. Ranbaxy's Web site states that it is second in the domestic market in terms of market share, but gives no details. It claims to have performed better than Aurobindo Pharma and Genix Pharma in 2003.

The greatest challenge to the sale of Ranbaxy's products in both India and Africa relates to negative perceptions about the toxicity and side effects of its medications. This fear has frequently led to non-adherence to the regimen required and also boosted the market for alternative cures to HIV. Ranbaxy sees better doctor education programmes as a means of spreading greater awareness among patients on the need to adhere to drug regimens and says it continually carries out such programmes.

Effect of programmes

In terms of distribution, Ranbaxy is the only company that has retail licenses at the distribution centres from where patients collect the medicines. This results in a cost reduction of 25 to 30%. The lowest cost range is Rs 1200 (US \$26). The company provides no figures about the highest cost products.

Lessons Learnt

Ranbaxy's has sought to maintain market share rather than adopt innovative strategies to help bring down prices for needy patients in India. It has focused its efforts on higher-earning, high-value exports, as opposed to price reductions in its own Indian context. In contrast to Citadel, it has not tried to enter into any novel partnership programmes with other stakeholders, or tried to engage them to bring down the cost of medicines to patients.

Source: Responses to CSM questionnaire; Ranbaxy annual reports 2001 and 2002; and www.indiaonline.com/news/news.asp?dat=37680

The first multilateral IPR disciplines, formalized in the Trade Related Intellectual Property Agreement (TRIPs), were established following the Uruguay Round of then GATT negotiations, and address trade related aspects of IPR. In the case of medicines, these have been focused

around measures to reduce scope for parallel imports. Having signed onto TRIPs, WTO member countries are then required to amend domestic legislation and regulation so that it is consistent with TRIPs obligations over agreed timeframes. Least developed countries that are WTO members are required by TRIPs to establish minimum standards for the protection of patented products (not only medicines). This includes the ability to grant a patent for 20 years from the date of filing, and a period of exclusivity of clinical data during the medicine R&D phase.³⁶ The TRIPs agreement did not seek to define anti-competitive practices, rather, it bound the conditions under which trade in products embodying IPR can take place.

It was not until the Cancun WTO Ministerial meeting in September 2003 that agreement was reached on a mechanism to enable non-medicine producing developing countries to import medicines under compulsory licenses, if there was a national health emergency.³⁷ Previously, the agreement had required that “production under compulsory licensing must be predominantly for the domestic market,” which effectively limited the ability of countries that did not produce pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are patented.³⁸

In the context of the access to medicine debate and how this impacts on business, the recently revised TRIPs agreement provides a clearer framework and risk structure for pharmaceutical companies. Since the decision at Cancun, the EU has started currently implementing the TRIPs legislation. Canada has put forward the Access to Generics Medicine Bill that has been cautiously welcomed by the Canadian generic medicines producers. The Canadian Government introduced a bill to amend the Patents Act, with the intention that it would allow Canadian generic producers to produce drugs for export to specified developing countries under temporary licence. Under the proposed amendment, brand name manufacturers would have the “right of first refusal,” under which they could offer to match the terms of any drug sale proposed by a generic manufacturer.³⁹

NGOs have argued that patent protection can allow companies to behave less competitively in their pricing policies and charge premiums on drugs for which there is no competition. For example, MSF writes that following the decision of the Brazilian government to produce generic AIDS drugs, prices fell by 82%. The impact of patents on affordability of medicines will depend on a range of factors, including:

- Price negotiated between producer and customer
- Distributors margin
- Retailers margin
- Taxes and duties

But there are other economic tradeoffs as well. For example, where brand name companies are expected to reduce prices to match generic producer prices on an ad hoc or more sustainable basis in certain markets, this can be perceived as anti-competitive behavior. The impact on the

access to medicines issue in this case will depend on the disposition and track record of the generic company(ies) to offer sustained, discounted prices. Like brand name companies, generic drug producers are motivated by profit, and their business model has not automatically lead to business strategies to address access to medicines. It is interesting to note that despite protestations that generic companies deliver low priced medicines to improve access, the levels of public disclosure amongst generics companies in India and Africa on pricing strategies is very low.

Competition policy issues were highlighted in a recent European Court of Justice finding. The Court found that the European Commission's decision to fine Bayer for restricting trade in prescription drugs from Spain and France, which have lower prices than the UK, to the UK, was unlawful. The decision in question was a 1996 finding that Bayer had restricted parallel imports of Adalat from one member of the EU to another. While the case was eventually found in Bayer's favour, this highlights some of the legal and policy issues affecting pharmaceutical companies' adoption of differential pricing policies. At the same time, it is arguable that alternative business models based on donations are potentially more anti-competitive.

Licensing

Mozambique issued a compulsory licence for ARVs on April 5, 2004.⁴⁰ Pharmaceutical companies have sought to address concerns through voluntary means such as licensing or pricing arrangements. Voluntary licensing has typically been used by brand name companies to expand access to new markets. Like all business arrangements, these have been subject to negotiation of appropriate licensee arrangements, including strict provisions on use and control of intellectual property and distribution arrangements. Particularly in countries where available manufacturing capacity is low, it can be difficult to find manufacturers that can guarantee product quality at the same level as the original manufacturer. A number of companies have voluntarily negotiated licensing arrangements with the South African generics manufacturer Aspen Pharmacare. Boehringer Ingelheim, for example, licensed Aspen Pharmacare to produce a generic version of Viramune®, which reduces transmission of HIV from mother to child. Similarly, GSK issued a license to Aspen pharmacare to produce generic versions of three anti-retrovirals—EpiVir, Retrovir and Combivir in 2001.

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Eli Lilly and Aspen Pharmacare: Licensing Agreement

Eli Lilly and Company is a global research based pharmaceutical corporation that develops a growing portfolio of pharmaceutical products. Eli Lilly, which has a market capital of US \$85,456,875 million spends close to 19% of its budget on R&D. Eli Lilly responds to social needs through philanthropic programmes that they pursue as part of their overall approach to corporate responsibility. The total value of philanthropy for 2003 from Eli Lilly was US \$273.5 million to recipients globally. The Eli Lilly and Company Foundation⁴¹ and the Eli Lilly International Foundation⁴² carry out the company's philanthropic interests activities.

Aspen Pharmacare, which has growing subsidiaries in the UK as well as Australia, is Africa's largest generic medicines manufacturer. It is the largest listed pharmaceutical company in South Africa. Aspen has a market capital worth over R3.5 billion (about US \$500 million). It also has good black economic empowerment credentials—21% of its equity owned by black South Africans. Aspen is a major supplier of branded pharmaceutical and healthcare products, covering ethical, generic, over-the-counter, nutraceutical and personal care sub-sectors.

Aspen is a leading supplier of generic medicines to the public sector, providing comprehensive coverage of products on the Essential Drug List for some years. In 2001, Aspen was granted a voluntary licence on patents for GSK's anti retroviral drugs: AZT, 3TC and Combivir. In August 2003, Aspen launched the Aspen Stavudine, which is Africa's first generic anti-retroviral drug.

Background

Eli Lilly announced a partnership agreement with Aspen Pharmacare on 5 February 2004 to transfer technology to Aspen to manufacture and distribute essential antibiotics (Capreomycin and Cycloserine) for the treatment of multi-drug resistant tuberculosis (MDR-TB).

This partnership also involves Brigham and Women's Hospital (BWH), an affiliate of Harvard Medical school, Purdue University and the International Council of Nurses (ICN), engaged by Eli Lilly. Purdue University will be instrumental in developing Aspen's capacity through training and technical expertise. In addition, Eli Lilly will also establish a centre of excellence in South Africa through the instrumentality of the BWH/Harvard Medical School and ICN for training health care workers on the treatment regimes for MDR-TB patients. This partnership feeds into the monitoring and treatment programmes for MDR-TB by the WHO⁴³ and the Centre for Disease Control and Prevention's (CDC's), monitoring programme for MDR-TB. In addition, WHO⁴⁴ will play a critical role in the distribution of the MDR-TB drugs produced under this initiative.

Eli Lilly is assisting Aspen in the conversion of its existing facilities in Port Elizabeth (South Africa), to support the manufacture of the drugs. Eli Lilly is providing technical expertise and a training programme to complete the technology transfer and ensure the long-term success of the manufacturing partnership. Eli Lilly will introduce Aspen to their international marketing networks for distribution of the drugs as the partnership progresses.

Business Drivers

This initiative makes commercial sense for both parties due to the current high demand for MDR-TB regimes globally.

The major driver behind this agreement is the recognition of the potential health and economic costs of MDR-TB. MDR-TB represents one of the most severe threats to public health today, with both economic and social consequences. According to the Stop TB Initiative⁴⁵, MDR-TB is caused by strains of the TB bacteria that are resistant to the two most effective anti-TB drugs, Isoiazid and Rifampicin. MDR-TB often develops in patients when the wrong treatment regimens are prescribed, or as a result of non-compliance with the prescribed treatment regimen for TB. Once a strain of MDR-TB develops, it spreads to other people in the same way that "primary"

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TB is spread (through the air like common cold). Estimates from WHO indicate that an average MDR-TB patient infects up to 20 other people in their lifetime.⁴⁶

As a result of low levels of drug supplies, trained medical personnel and awareness of TB, susceptibility to MDR-TB in developing countries has increased. In addition, there is growing concern that migrants from developing countries are also spreading TB and MDR-TB in developed countries.⁴⁷

TB kills 2 million people globally each year,⁴⁸ of which 250,000 are children.⁴⁹ According to WHO, more than 8 million people worldwide become sick annually with TB, with a quarter of these cases occurring in sub-Saharan Africa.⁵⁰ About 4% of TB cases globally are resistant to at least one TB drug, and in TB hotspots,⁵¹ up to 20 % of the cases are MDR-TB.⁵² According to Aspen Pharmicare, roughly 300,000 new cases of MDR-TB occur in more than 100 countries every year.⁵³

MDR-TB threatens to return TB control to the pre-antibiotic era where no cure for TB was available.⁵⁴ According to David Heymann, M.D., Executive Director of Communicable Diseases at WHO, “without proper treatment and surveillance now, MDR-TB can easily become a global health emergency in years to come.” South Africa has an uncertain burden of TB and an erratic notification system.⁵⁵ According to the WHO’s 2003 report on the global spread of the disease, the country is ranked with the seventh-highest number of TB cases internationally, following India, China, Indonesia, Bangladesh, Nigeria and Pakistan. There is concern amongst experts that the number of TB cases is under-reported.⁵⁶

HIV/AIDS and TB form a lethal combination, each escalating the other’s progress. HIV/AIDS weakens the immune system, creating a fertile ground for TB. TB is the one of the most common HIV/AIDS-related opportunistic infections globally,⁵⁷ and is the leading cause of death among people living with HIV/AIDS in South Africa.⁵⁸ While HIV/AIDS increases the lifetime risk of a patient getting sick with TB after being infected with TB (from 10 to 50 % in South Africa), TB also accelerates HIV’s progression to full blown AIDS.⁵⁹ HIV-positive TB patients have mortality rates that are two to four times higher than HIV-negative patients do, ranging from 6 to 39% in sub-Saharan Africa.⁶⁰ South Africa is facing one of the worst dual epidemics of TB and HIV/AIDS in the world.⁶¹

The threat of TB and MDR-TB to economic development to the developing world and South Africa are of great concern. WHO and its Stop TB initiative identify the following economic impacts of TB (in general) to include:⁶²

- Loss of work time, which is 3-4 months for a primary TB patient;
- 20 to 30% decrease in TB patients’ annual household income due to lost earnings. In South Africa, lost earnings due to TB are estimated at 16 % of GDP per capita;⁶³
- About 15 years of income is lost from premature death; and
- 75% of TB infections and death occur in the 15-54 year age group, which constitutes the most economically productive age group in the population. This has obvious negative implications for a country’s work force and economic development.

The cost of TB treatment in South Africa to the government⁶⁴ is US \$2,570⁶⁵ per primary TB patient. Based on WHO’s country profile of South Africa, the total costs of TB control in the

country were estimated at around US\$ 300 million in 2003 alone.⁶⁶ Health care costs for MDR-TB patients are estimated to be a hundred times greater than that of a primary TB case.⁶⁷

Another major driver of this partnership is Eli Lilly's approach to business. Eli Lilly patented these drugs (Capreomycin and Cycloserine) in the mid-1960s. At the time their research was focused on antibiotics. By the 1980s, Eli Lilly's product portfolio had shifted. During the intervening period, the demand for MDR-TB drugs was low. However, by the mid 1980s, the demand for these drugs escalated as a result of the outbreak of HIV/AIDS. While Eli Lilly's patent for these drugs had lapsed by the early 1980s, the complex method for producing MDR-TB drugs, especially Cycloserine,⁶⁸ has precluded any generic manufacturer from doing so, as experience in India and Korea has demonstrated. This meant that Eli Lilly was the only producer of MDR-TB drugs across the globe.

With increased demands for MDR-TB drugs, Eli Lilly faced a dilemma: compromise their strategic focus on innovation and enhance their capacity to produce enough for the increasing global demand or develop the capacity of other entities towards the worldwide war against TB. Upon taking the latter position, Eli Lilly through WHO identified the four TB "hot spots" across the globe and entered into regional agreements with generic companies, of which Aspen was selected to cater for the African continent and other developing countries.

Impacts

This partnership is anticipated to deliver a range of positive economic impacts. From a health perspective, controlling TB, particularly the MDR strains, will lend weight to efforts to address HIV/AIDS. Successful TB regimens will reduce HIV positive patients' likelihood of developing full blown AIDS, thus, being able to live longer and continue to play a productive role in the economy.

From its global budget of US \$70 million,⁶⁹ Eli Lilly is contributing to foreign direct investment (FDI) into South Africa by boosting Aspen's infrastructure. In addition, Aspen's commitment will raise the profile of South Africa as a manufacturing and pharmaceutical base. The partnership is developing high-level technical skills and equipment that is the first of its kind in Africa. There is also an anticipated revenue stream from exports, which could enhance South Africa's balance of payments. Further, enhancing Aspen's manufacturing capacity also entails the creation of more jobs.

Lessons Learned

Through the partnership, Eli Lilly has demonstrated that doing good business can add value not only to the bottom line but also to the welfare of society. Eli Lilly has sustained its reputation in the market place and has more resources and capacity towards its core business strategy as an innovation-based enterprise, which includes developing new drugs and improving existing drugs within their strategic focus.

A major lesson of this initiative is that it is possible for corporations to enter into complementary agreements with other actors such as generic manufacturers in the same sector towards addressing countries' developmental priorities.

The partnership also presents a win/win situation for various parties. For Eli Lilly, the opportunity

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to concentrate on its core business strategy, which is R&D, and at the same time sustain its reputation in the market place as well as having a good corporate citizenship profile. Through this initiative, Eli Lilly demonstrates how a company's investment can be managed to realize benefits to society in a situation where the entity has other overriding interests preventing it from following through with the investment/product on its own. For Aspen, this partnership presents the opportunity to expand its market within Africa and other developing countries. For TB patients in Africa, an increased access to MDR-TB regimens at a cheaper price. For WHO, an increased access to MDR-TB medication will boost its global programmes against TB.

There is also an expectation that this initiative will create a precedent for how companies can address public health issues as well as ensure that their investments and products have outlets that can actualise the potential benefits to the society. This is important, particularly where the entity has other overriding interests preventing it from following through with the investment/product on its own.

Price Setting

Differential pricing of pharmaceutical products is not a new phenomenon. The price of pharmaceutical products is negotiated between buyers and sellers. Factors affecting the negotiated price include the relative market power of the buyer and seller, the cost structure over time of proposed and alternative treatments,⁷⁰ regulatory requirements, and so on. The price at which a company is willing to sell a drug in a particular market depends on the potential size and dynamics of the market over time, the longevity of patent protection, competition for competing products/treatment regimes, stakeholder pressure and expected returns from other markets. Indeed, differential pricing of medicines has led to concerns that US patients are bearing a disproportionately high cost of pharmaceutical innovation as governments in Europe and other countries have consistently negotiated lower prices for medicines than the US government. Europeans have typically paid drug prices 25-35% lower than in the US.⁷¹ Some stakeholders question whether preferential pricing to developing countries amounts to some parts of the world cross-subsidising health budgets of others. To be sustainable would require explicit agreement from developed country governments that they are willing to cross subsidize health in the developing world. The debate across the Atlantic over who is, and who should pay for innovation in the pharmaceutical sector, suggests that this agreement is far from being resolved. The issue of who and how health care is paid for within countries is a political balancing act between government's health budgets and priorities, patients, health professionals and institutions, and pharmaceutical companies.

In that context, pharmaceutical companies have adopted a range of approaches to address the access to medicine questions in the developing world—some have chosen to donate products

on a loss making basis; others have adopted preferential pricing schemes for specific drugs in specific countries on a loss making or break even basis, and others have adopted systematic and transparent price differentiation on a not for loss basis. In each case, companies have implicitly or explicitly decided what costs they will bear.

Novartis: Differentiated Pricing Policies: Different Markets (and Impacts)

In 2003 Novartis achieved sales of US\$ 24.9 billion and a net income of US \$5 billion. The Group invested approximately US\$ 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employs 78,500 people and operates in over 140 countries around the world.

Description of products:

Glivec® is a medication for chronic myeloid leukemia (CML) and certain stages of gastrointestinal stromal tumors (GIST). It targets a small patient population globally—1.3 per 100,000 patients are diagnosed each year. It is a unique drug used to treat a life threatening condition that cannot be substituted.⁷² Glivec is used by a few thousand new patients annually, mainly in the US and Europe.

Coartem® is an artemisinin combination therapy for malaria developed by Novartis with Chinese partners. It has proven highly effective in curing malaria, even in areas that have proven resistant to conventional anti-malarial medicines (sulfadoxine pyrimethamine and chloroquine) that had been in use in many afflicted countries. Malaria kills more than 1 million people a year, with 90% of malaria-related deaths occurring in Africa, mostly in children under 5 years of age.⁷³

The economic burden on African countries is estimated to be around US \$12 billion per year. Economists estimate that malaria is responsible for a growth burden/drain of up to 1.3% GDP per year in some African countries.⁷⁴

R&D Costs, Pricing Policies and Economic Impact of Medicines

Novartis' pricing policies for the two drugs have been designed very differently, reflecting the different situations of the products in their markets, both approaches designed to reach as many patients as possible, to achieve different impacts for two distinct markets, which cross a range of different public policy settings. In both cases, there are not perfectly substitutable products available and in that respect, their impact is unique. Neither drug promised high rates of return on Novartis' investment, but Novartis developed both drugs to meet different sets of patient needs. In 2003, Glivec had a global turnover of US \$1.1 billion, while sales of Coartem were US \$5 million (1.3 million packs to WHO at US \$1.7 million).

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Glivec**R&D Costs**

Due to unusually strong early clinical data, Novartis pushed the development of Glivec® forward, and spent a higher proportion of the development costs up front rather than spreading them over the whole development period as is the usual practice. As a result, the development time was only around 2 years.

Markets

Globally, market introduction still ongoing but US/Europe remain the largest markets for this product. It is approved in 97 countries.

Competition

Interferon is the prior standard of care for 80% of patients who are not candidates for bone marrow transfers, costing US \$1,700–3,300/month in the US, US \$1,250 in Australia and US \$4,750 in Japan. Clinical trials showed that Glivec offered patients additional benefits. Combination therapies cost around US \$28,125/year, but have much lower success rates than Glivec. The cost of Glivec ranges from US \$2,000–3,500/month depending on the phase of treatment. Novartis states the cost of Glivec is competitive, and is less expensive than standard therapies, particularly when they require hospitalization.

Pricing

For Glivec, Novartis set a universal price at US \$2,200/month. To manage the regressive impact of this pricing strategy (where the burden of cost is more significant on less wealthy patients, different health insurance schemes in the different markets), Novartis devised customized patient assistance programmes in the different countries.

The patient assistance programme is intended to ensure that those without insurance coverage or financial options can avail themselves of the medicine. Novartis recognizes its responsibility to ensure that this unique product is available at the lower ends of the market, but at the same time asserts that companies do not bear responsibility for the failure of public policy in health care. In addition to the US programme, the Glivec® Program (GIPAP) was established in 2001 to provide Glivec® to qualified patients worldwide in countries where Glivec® is approved. Glivec® must be donated in accordance with the specific approved use in a country. GIPAP is currently available in 67 countries and reaches more than 5,000 patients.

Stakeholder Consultations

Patient Groups have been consulted in developing and administering patient assistance programmes (PAP) on an ongoing basis. US based patient groups have accepted the pricing and patient assistance programmes as a sensible approach to ensuring the financial and broader socio-economic impact of Glivec®. In extending availability of Glivec® to developing country markets, consultations with government authorities have been key, as has patient group education and engagement at the appropriate time and in the appropriate situation.

Coartem

Developed in collaboration between Novartis (Ciba Geigy) and Chinese partners starting in 1994. Development took place over 5 years until product launch in 1999.

Approved in 77 countries and marketed in 28 countries. Product is dual branded as Coartem (developing countries) and Riamet® (industrialized markets) for different markets. Novartis is in partnership with WHO which manages distribution of not for profit Coartem to the public sector in developing countries.

Conventional treatments are increasingly ineffective with drug resistance 60–70% in some of the African and SE Asian countries. Coartem is effective in treating malaria where older products no longer are.

Triple pricing policy

- Coartem for WHO supplied at cost to provide affordable treatment at US \$0.90/child and 2.40/adult
- Coartem sold to the private sector at US \$4-9 in developing countries. Price differentials largely reflect in-country taxes or price mark-ups
- Riamet US \$27

Key stakeholders for Coartem include the Global Fund, WHO, UNICEF, governments, including importantly the Chinese government, NGOs such as MSF and the Mentor Initiative, and donor organizations. Novartis is not aware of patient groups for malaria in Africa.

Partnerships as Product Delivery mechanisms: The Novartis partnership with WHO for malaria (Coartem) uses the capacities of both organizations to ensure products are distributed to as many as possible in need, as determined by demand conditions. Orders are placed through local governments and purchaser must meet WHO criteria. In 2003, 3 million treatments were distributed, to the public sector and in 2004, the final figure is forecast to be 10-11 million treatments. The order is placed with WHO with requisite funds, who places the order with Novartis. The medicines are produced by Novartis in China, then dispatched to Switzerland before being forwarded to the WHO, which delivers to the local government.

Products for the WHO partnership are packaged distinctively both to maximize patient compliance and to minimize the risk of product leakage. Training materials have been developed to ensure that the product is properly administered and its effectiveness is not undermined by local conditions—such as community awareness of health and medicine, illiteracy, inadequate local health infrastructure and so forth.

In the case of Glivec,[®] the GIPAP model is designed to provide the drug to individual patients, rather than through third party distribution organizations. The Seattle-based Max Foundation administers GIPAP on behalf of Novartis and is responsible for registering qualified patients according to medical and financial requirements provided by Novartis. These are consistent with WHO Guidelines on donations. Novartis ships the drug to qualified treatment centres that service patients approved by The Max Foundation.⁷⁵ In countries where there are no Novartis representatives, Novartis may work with Axios International to administer GIPAP.⁷⁶

Novartis has strong policy positions and programmes addressing access to medicines. Novartis policy states that the primary role of the pharmaceutical sector is to “discover and market innovative products to prevent and cure diseases to improve, extend and save lives.” Within this broad remit, Novartis recognizes its role in addressing access to medicines through affordability, but also notes that the issue is more complex and requires responsibilities to be shared by governments and health systems. Novartis seeks to balance conflicting interests and incentives posed by the issues, and to reconcile profit motives with societal health needs.

In addition to external reporting, Novartis manages its access to medicines agenda through a range of partnerships with developing country governments as well as through international initiatives, including for diseases of the developing world such as malaria, leprosy, and tuberculosis, as well as in an R&D partnership focused on tropical diseases. Novartis engages in a range of policy dialogs and stakeholder projects around the issue, and has also engaged in work by the Pharma Shareowners Group to understand and inform the investor perspective.

Business drivers

In the case of Glivec, Novartis has sought to reconcile short term financial needs with societal needs for medicines treating life threatening conditions, through the pricing policy and patient assistance schemes. Novartis emphasizes the need to tailor different pricing schemes and other support mechanisms closely to the specific diseases, populations and medicines concerned to ensure maximum impact and a sustainable business case.

For Coartem, and the specific and complex challenges of combating malaria in developing

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countries, the WHO partnership provided a useful vehicle to address access issues and provide appropriate distribution mechanisms. The partnership has enabled Novartis to implement its policy commitments.

Effectiveness of programmes or systems.

The Glivec Patient Assistance Programmes (PAP) had a market value of US \$219 million for 2002 and 2003 world-wide and Novartis disaggregates this information into US and Global markets. Success is measured by the extent to which patients in need have access to the drug, and that it remains commercially viable.

Novartis reports that the market value of the WHO partnership in 2003 was US \$4 million, and reached 460,000 new patients bringing the total number since the programmes inception to 650,000. While it is difficult to extrapolate impacts on the ground from macro-economic health figures, the impact of Coartem in KwaZulu Natal, South Africa has been significant in health terms. With a combination of Coartem and vector control (DDT spraying), malaria cases were reduced by 78% in 2001, and again by 86% in 2002. Hospital admissions were reduced by 82% and notified malaria deaths fell by 87%. It is reasonable to expect commensurate economic benefits accruing to the individuals and families concerned (particularly given the high level of HIV/AIDS incidence in the region and impact on family income structure) through maintenance of income streams, lower medical expenses, as well as lower costs for local public health budgets. While this is difficult to quantify, it can be identified as a very important and positive economic impact of the function, development and delivery mechanisms of Coartem.

Lessons learned

For Glivec,[®] patient assistance schemes are modified on a country by country basis and it is crucial to the effectiveness of programmes that they can be adapted. For example in Argentina, they are formulated to cover patients for the time lag between when the need is identified, to when public provision of medicines becomes effective. In another example, India, where there were 580 patients under the GIPAP, the programme was modified to service only existing beneficiaries when generics were introduced to that market. Novartis assisted generic company(ies) to develop PAPs but this was not widely used. The government then gave Novartis exclusive marketing rights, at which time Novartis reopened GIPAP to Indian patients and took on another 1,400 new patients.

For companies, understanding the short and long-term costs and benefits of these programmes, and the extent to which they contribute to sustainable business and societal outcomes, are critical. This is on a loss-making basis and ultimately unsustainable for businesses and their shareholders. While this is unlikely to generate sustained improvements in health outcomes in the developing world, in specific circumstances it can work, such as through the Mectizan Donation Program.

Pfizer: International Trachoma Initiative

Pfizer is a private research-based pharmaceutical company that discovers, develops, manufactures and markets prescription medicines for humans and animals. Pfizer earned US \$45.2 billion in revenues (2003), employs around 122,000 people, will spend an estimated R&D budget of US \$7.9 billion in 2004, and sells its products in more than 150 countries.

Internal structure of the company/association The CEO leads functional and geographic divisions of Pfizer, which are split into US and global markets. Philanthropy programmes are located within the Corporate Affairs division responsible for public outreach.

Description of programmes

In 1998, Pfizer Inc and the Edna McConnell Clark Foundation contributed US \$3.2 million each to establish the International Trachoma Initiative (ITI). This followed earlier collaboration in which Pfizer's Zithromax[®] was found to be an effective single-dose option to treat children with clinically active trachoma in a pilot study in Morocco as well as controlled research trials in Egypt, The Gambia, and Tanzania. Following these developments, Pfizer considered the possibility of a large-scale donation programme of Zithromax[®], which led to the announcement in 1998 to commit to a partnership which aimed at supporting the effort to eliminate trachoma globally. Formation of the partnership took place concurrently with the founding of the WHO Global Alliance to Eliminate Trachoma by 2020 (GET 2020) in 1997. Approximately eight million treatments of Pfizer-donated Zithromax[®] were administered between 1998–2003, and Pfizer expects to donate about 135 million more treatments of Zithromax[®] over the next five years. Zithromax[®] donated through ITI for the trachoma elimination effort comprises almost 10% of product supplied to Pfizer's markets worldwide.

Given the shared objective of eliminating the disease globally, there has been close consultation with the WHO, which initially identified 16 priority countries. Within this context, ITI selection of partner countries was largely determined by disease patterns and in-country political engagement to demonstrate good results in relatively short order, which would form a basis for engaging with others. The ITI's selection was further determined by an assessment of the political will and capacity of actual and potential in-country partners to deliver programmes effectively. The ITI initially focused on five countries: Ghana, Mali, Morocco, Tanzania and Vietnam, extending to Ethiopia, Nepal, Niger, and Sudan by 2002.

The WHO's goal is to eliminate trachoma globally, which would lead to global economic benefits estimated to run almost US \$3 billion annually. There are about 6 million people largely irreversibly blinded by trachoma, and an estimated *146 million cases* of active disease in need of treatment, if blindness is to be prevented.⁷⁷ Trachoma typically causes blindness in the most productive years of working life, and has implications for the way in which families and communities earn income. This figure is based on conservative estimates that there are 3.8 million cases of blindness and 5.3 million cases of low vision in countries known or suspected to have trachoma.⁷⁸

In December 2000, the ITI announced that programmes in Morocco and Tanzania had cut prevalence of trachoma by more than 50% among 2 million people in just over one year. Since then, Morocco has achieved a reduction of active trachoma infection in children of 90% and is

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on track to eliminate it by 2005. Over 10 million people globally have been treated with Zithromax® as part of the SAFE approach.

The role of Zithromax® in the ITI is essential, but insufficient to achieve programme objectives without other interventions. ITI's approach is centered on a four component approach—SAFE:

- S**urgery to correct advanced stage trachoma
- A**ntibiotics to treat active infection—this is where Zithromax® is used
- F**ace washing to reduce risk of infection
- E**nvironmental improvement, such as access to clean water, which helps redress basic vulnerability.

So in this context, how is the economic impact of Zithromax® understood? While an internationally agreed set of performance measures for trachoma programmes has not been reached, the ITI evaluates progress of the ITI through a range of process and service statistics, which in turn are evaluated by Pfizer to understand the efficiency of the use of Zithromax® as part of the ITI programme. These include a range of financial, supply management and epidemiological measures, which are easier to track than the public policy and behavioral changes required to prevent and ultimately eliminate blinding trachoma. ITI is working towards establishing a set of performance standards on which performance in countries can be assessed.

Products are evaluated by the efficiency with which they can be accessed, their effectiveness (combination of their efficacy and ease of use), unintended consequences and adverse impacts. Against these criteria, Zithromax® has performed extremely well for the ITI. With more than 10 million people treated, there has not been a single serious adverse event reported. The ITI has recently engaged in research in partnership with academic institutions to understand how the incidence of trachoma relates to poverty, *e.g.*, levels of household wealth, to enhance understanding of the potential differential economic impact of trachoma control for societies least advantaged.

Trachoma generally afflicts people in poor and remote areas where clean water is scarce. It is difficult to isolate the economic impact of Zithromax® from the SAFE strategy, but the product does contribute to the ITI's impact. Pfizer regards that their key economic impact through the ITI is enabling people to see and be able to work, produce, earn income and keep their children in school. Given the nature of trachoma and its health impacts, Pfizer expects that the economic benefits of the ITI will emerge only after 10 years or more, when children treated begin productive work.

Pfizer is represented on the ITI Board, and representatives attend expert meetings to share learning from the field. It is through these channels that Pfizer evaluates the success of the partnership, and determines its ongoing commitment to the partnership. A key indicator for Pfizer in evaluating the programme is before and after prevalence studies, which test active infection in children under 5 years of age. In addition, although over longer time frames, behavioral studies are conducted to evaluate the extent to which the prevention and education components of the work have been imparted in target communities, such as face washing and latrine use.

Partnerships in different countries have taken different forms, and are critical to ensure product reaches the intended beneficiaries. Some are more formalized than others (such as contractual arrangements for service delivery while others are based on knowledge and in-kind resource

sharing) and have different types of accountability. Others are more opportunistic and arise when a particular capacity fills a particular programme need. For Pfizer, the attraction of the ITI model, adapted from Merck's Mectizan programme, was the creation of a separate not-for-profit entity that would determine programme priorities. Pfizer did not want to decide by itself which countries should be targeted by the programme.

While Pfizer is a core partner/donor, it has played a range of roles in the project. As Pfizer has a presence in Morocco, the quality of existing relationships with the Ministry of Health, the medical profession, UNICEF and the WHO Office has been critical in a number of ways. There was a high level of political commitment to eliminating trachoma, and the facilitative presence of Pfizer facilities for storage and distribution of Zithromax® in-country.

As part of its ongoing stakeholder engagement, often routed through MOH, the ITI has emphasized the need to raise awareness of trachoma amidst a range of competing health needs. In some cases, in-country partners have been nominated by the government, such as in the case of Vietnam, and in most cases, the ITI has liaised closely with some of the following agencies represented in country—WHO, UNICEF, and NGOs focused on blindness as well as increasing attempts to engage officials and NGOs focused on water and sanitation issues.

Business drivers

Currently, Pfizer donates through its international programmes (trachoma and HIV/AIDS) US \$200 million (wholesale value). As the programmes grow, so will the required budget to meet the need. Pfizer's shareholders have supported the company's international initiatives, despite recent declines in net profits.⁷⁹

Pfizer is conscientiously moving away from being a solely drug company to encompassing broader healthcare solutions. One of Pfizer's business imperatives is to increase access to healthcare through a number of outreach programmes. Pfizer asserts that philanthropy should not only provide resources to underserved communities but also be linked to business need. For Pfizer, this means drawing on its existing product and service capacities. Pfizer has committed to the ITI on a donation basis as it perceives an immediate need for quality medicine that the targeted communities will not be able to afford or will not elect to buy in the near future—at any price. Affordable tetracycline ointment is available but compliance with the 6-week regimen makes this option more expensive through prolonged treatment failures. Pfizer does not envisage that many of the countries targeted by ITI will become markets for Pfizer's products for the foreseeable future.

How partnerships are managed in different countries reflects different public policy and competition considerations. In the case of developing country initiatives, programmes are developed around defined health and disease objectives where Pfizer's products can play a unique role. In the context of the home US market, programmes, in partnership with other companies, have sought to address disadvantaged communities—left behind by gaps in public policy—and across a range of different diseases. With significant communities in the US dependent on patient access programmes, for instance, companies' reputations are staked on continued involvement unless public policy forces others to bridge this gap.

Lessons learned

In designing the ITI, there were a number of issues to be considered, including how to manage donations to developing countries where dissemination of medicines was fraught with resource and infrastructure constraints, the extent to which the programme reflected national health and political priorities, diversion of Zithromax® onto the black market, and finding the right in-country partners.

For Pfizer, a key risk was to ensure products were not diverted from the programme and resold on the black market. To minimize this risk, Pfizer repackages and rebrands all donated products. In the case of trachoma, products have been provided on a 'just in time' basis which minimizes scope for leakage. However, as the programme grows some in-country inventory will be necessary to avoid stock outs. So far there has been no experience of products being diverted from the programme. Products are labeled "for donation" and tablets are differentiated from commercially distributed product by being pink-coloured as opposed to a white capsule available globally. Pfizer is working to develop a label that will satisfy regulatory requirements across all countries that are beneficiaries of donations programmes, including Zithromax®. Most recently, Pfizer has completed three years of clinical trials that demonstrate that packaging Zithromax® in packages of 500 (previously 30) doesn't affect the efficacy of products. This is to facilitate distribution of the product to areas with minimal transport infrastructure.

As the size of the programme is set to expand, Pfizer worked in consultation with the ITI to develop a height-based (as opposed to weight-based) treatment to improve the ease with which medicines can be dispensed in poor and remote communities, and to reduce the cost of programmes. ITI estimates that 250–300 million doses of Zithromax® are needed to eliminate the disease. Pfizer, to start, has committed to the next 135 million treatments and will assess progress on an ongoing basis and in five years time.

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"Donation programs can make major contributions to better global public health, particularly when directed at time-limited needs such as disease eradication. At the same time, for many of the most common problems responsible for high disease burdens, donated drugs are unlikely to be a sustainable solution..." WHO Background Paper, WTO Meeting 2003"

Merck discloses details of its pricing policies for HIV/AIDS medicines required in developing countries. The pricing structure, and depth of discount made is determined by a country's position in the UNDP Human Development Index, and the prevalence of the disease in that country. GSK also discloses its pricing policy on access to medicines issues and does so on a commercially sustainable not-for-loss basis. Novartis has developed different price structures for different products to maximize their impacts, while Novo Nordisk sells its insulin to developing countries

for 20% of the average price in the US, Europe and Japan. Other companies address access through donations programmes, often combined with capacity building investments, such as shown in case studies of Merck, Abbott and Pfizer.

Some companies have expressed concerns that through systematic price differentiation, some governments may seek to negotiate lower prices and undermine the balance and overall profitability of the pricing system, and that they institutionalize an incentive structure that encourages parallel imports.

What is needed at national and international levels to provide incentive structures in which companies might be expected continuously to develop and deliver medicines required to achieve sustained improvements in developing world health outcomes are:

- Unequivocal commitments and implementation of political will from developing countries that they will commit resources to improving health care policies, capacity and infrastructure, as well generating health awareness amongst populations.
- Developed country commitment to bear some of the costs of preferential pricing by accepting high health care costs for their own citizens. This also implies sustained support for targeted R&D activities, and reaching a workable commitment with other developed countries on how this burden will be shared.
- It is important to note here that there are serious access challenges in developed countries—even in the richest countries. In the US, pharmaceutical companies have developed patient assistance schemes to partially fill the gap between US social insurance/welfare and the market. Health care reform has been hotly debated in the US for years, reflecting starkly different short and long-term interests of the various stakeholders in the system, and the difficulties of reaching a workable political consensus on health care. The extent to which pharmaceutical companies' pricing decisions have a positive impact on access to medicines will ultimately depend on how society(ies) define the social contract between companies, governments, health care professionals and institutions, research institutions, insurers and taxpayers, and then, how they fund it.

Some governments, such as the Brazilian Government, have made public statements on the willingness of companies to negotiate deeper discounts as part of their commercial negotiating tactics. Last year, Brazilian Government spokespersons revealed to the international media that it had negotiated a 25% discount on Merck's Efavirenz AIDS drug, and threatened to break patents if Abbott Laboratories and Roche Holdings did not agree to more substantial discounts. The Merck discount represented an 18% saving on the Brazilian Ministry of Health's costs in managing its universal, free HIV and AIDS drug programme. Other governments have negotiated in a more low key way, perhaps reflecting their bargaining power and health policy agendas.

4. Material Issues and Risks

The access to medicines issue leapt onto the public agenda with the 2001 South Africa Aids trial, in which a group of 39 pharmaceutical companies contested a law that would allow cheaper, generic drugs into the market. This challenge has led to fundamental questions on the longer-term viability of the business model that has traditionally focused on

- generating stable income streams through patented (time/market protected) products priced differentially; and
- funding expensive and uncertain product development processes.

Pharmaceutical companies have sought to address this issue differently, some looking to transform and redefine their business over the longer term, and others focusing on balancing their competing interests within the current business model and policy and regulatory constraints.

Risks associated with the current research-based pharmaceutical business model include:

The Cost of R&D

High risk in R&D and increasing average costs of bringing products to market, from US \$300 million in 1992 to US \$800 million in 2002,⁸⁰ has been accompanied by a rapid expansion in marketing and sales expenditure. A Hendersons report suggests that marketing and sales expenditure are more than double industry R&D expenditure and rising by 16% per year. These figures themselves, and what they represent, have been debated by the industry and its critics. Marketing and sales are a legitimate business activity, but concerns by critics highlight perceptions that the sector lacks transparency. Regulatory processes tend to reward innovative pharmaceutical products—prioritizing their consideration by regulators. Combined with changing regulatory requirements and increasing demands for value for money by health care providers, competition from generic producers, particularly those competing for developing country markets, is ever more intense.⁸¹ Increasingly informed patients also require better information on health care solutions.

While some companies have increased commitments to R&D in diseases of the developing world (DDW), the potential returns on this type of investment is low and there is significant pressure for companies to develop ‘blockbuster’ medicines that will bring in large returns. With increased competition by generics companies, there is a real question over the capacity of the pharmaceutical business model to generate solutions for national and international health care under current policy governance and commercial arrangements. GSK has a policy to continue R&D in DDW as shown in the GSK case study that follows.

GlaxoSmithKline: Vaccines Business: Model for Sustainable Business and Product Impact

GlaxoSmithKline (GSK) is a leading research-based pharmaceutical company that makes prescription medicines, vaccines, over the counter medicines, oral care and nutritional healthcare products, accounting for 7% of the world pharmaceutical business. Of £21,441 million sales, 44% are to the US market, 24% to Europe, and 17% to other markets. Its headquarters are in the UK with major operations in the US. GSK employs 101,000 people, in 117 countries. GSK's vaccine business, GSK Biologicals (Bio), has a strong focus on diseases of the developing world (DDW), and supplies around 1/3 of the world's vaccines. Of total GSK sales, 5.2% (£1,123m) came from vaccines in 2003.

The company's corporate responsibility function

GSK's Corporate Responsibility team reports to the company Board. Committee is advised by the Corporate Responsibility Strategy and Reporting team that coordinates policy across all areas of the business and addresses issues identified as aspects of the broader corporate sustainability agenda.

Description of programmes

GSK Bio's business model marks a radical shift in the sector. Traditionally, vaccines are rolled out in profitable markets, such as the US and EU first, where income streams offset past and current R&D investments, and only then might products be rolled out in less profitable, developing country markets. Rather than this regional approach, GSK Bio has adopted a global approach to vaccine development and marketing, reflecting global needs. GSK Bio is currently researching new vaccines for the three WHO priority diseases in the developing world HIV/AIDS, tuberculosis and malaria. GSK Bio has more than 16 vaccine clinical development programmes running, seven of which are for diseases that have a disproportionately high prevalence in the developing world. A research unit in Belgium conducts GSK Bio's research on these diseases. GSK also works on treatments for these diseases in the UK and Spain.

GSK's global vaccines business strategy is premised on a high volume production approach to optimise economic returns to both the business and society; and differentiated pricing strategies reflect possible volume availability and demand trend forecasts. They work with international agencies, particularly where no commercially viable market for a product exists to find sustainable financing options. For GSK Bio to continue R&D into vaccines for DDW it needs to do so in a financially sustainable manner. GSK is working towards long-term contracts at preferential prices with organizations to ensure that returns on R&D, and their ability to continue to fund R&D in these areas.

For example, GSK has developed a vaccine for meningitis (Mencevax ACW) that can be priced at symbolic €1/dose for 21 African countries if it can produce at least 6 million doses. GSK Bio's meningitis ACW135 vaccine has been specifically developed to protect against the typical meningitis strains sweeping Africa—strains A and C—plus the new strain W135 which was first occurred in 2002 in Burkina Faso, where it affected over 14,453 people and killed 1,743. Similar vaccines cost between US \$4-50/dose. MSF and other donors have purchased 6 million doses. This experience

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has emphasized the importance of getting support from international organizations early in the development phase, both to plan the introduction of new vaccines, as well as ensure appropriate infrastructure for implementation and distribution of new vaccines is in place.

Another key example of GSK being driven by medical need in developing countries is the vaccine being developed for rotavirus—a major cause of diarrhoea and vomiting, which in turn cause dehydration. The plan is to roll out the vaccine in low- and middle-income countries in Latin America and Asia before developed markets. This marks a paradigm shift in vaccine development.

Business drivers

GSK has taken a leadership position in addressing access to health issues and recognises the need for global companies to play their part in improving access to medicines in the developing world. GSK Bio targets three market types—private customers—those individuals who have the ability and desire to pay for products (reducing demands on publicly funded vaccines programmes), governments and international organizations and initiatives.

GSK has a policy commitment to contribute to governments and intergovernmental bodies in addressing global health challenges through “developing and marketing of medicines and vaccines that improve the health and quality of life of millions of people around the world. GSK maintains “We are a commercial organization that needs to make profits to fund future investment and to pay dividends to our shareholders.” It is important to note that investment refers to funding future R&D. GSK has therefore created a business model that reconciles its commitments to shareholders with long-term contributions to enhanced global health. Within this, vaccines, with their ability to control or even eradicate disease, will continue to play a critical role.

Effectiveness of programmes or systems

If developing countries are able to adopt vaccines as a means to prevent, not just treat, the major diseases affecting the developing world, the implications for national economies are significant and positive. In 2001, of the 56 million people who died from all causes, almost 11 million died from infectious diseases. The biggest causes, in descending order were, pneumonia, HIV/AIDS, diarrhoeal diseases, tuberculosis, malaria, and measles. The incidence of diseases such as measles, mumps, rubella, tetanus, polio, diphtheria, hepatitis and whooping cough have been significantly reduced in the developed world through comprehensive vaccination programmes. Vaccines are estimated to save 3 million lives annually, but 10 million children under the age of 5 years die each year. If vaccines for all causes of pneumonia and diarrhoea were available, more than 1 million child deaths could be averted.

Within this macroeconomic and health context, GSK’s product pipeline includes a malaria vaccine, and HIV vaccine, a TB vaccine and a rotavirus vaccine (against a major cause of diarrhoea). In addition to saving lives, the Global Alliance for Vaccines and Immunization (GAVI) notes the contribution of vaccines to national health systems more generally, helping to deliver results that raise awareness and political awareness of health issues, through enhanced partner coordination and funding.

Lessons learned and next steps

Key to generating sustainable business and health outcomes, GSK has learned that it is important to plan for the introduction of new vaccines and funding requirements early in the development phase, as well as the importance of a cohesive long-term business strategy to achieve sustained health impacts. Through high-volume production, economies of scale and the ensuing costs savings can be passed onto the developing world, if the political will by governments exists to purchase vaccines at low cost. GSK perceived a need to raise the profile of vaccines in the context of national health care priorities in the developing world.

As the business model is based on high-volume production, working as far in advance as possible is critical to secure markets for vaccines. In doing so, GSK Bio seeks to maintain open relationship with collaborators in research and development.

Dedicating the right people to the research and commercial aspects of the business was also critical to the success of the vaccines business. Crucial to business success is the commitment of both management and employees to develop global vaccines. There is a strong management commitment to ensure that learning across research teams is maximised, so that innovation across products can be maximised, and vaccines get to market, and to patients quickly.

For the uptake of new vaccines, developed to meet a global need, GSK has implemented a world wide international development and regulatory process from the product development side. This means that all clinical studies, regardless of study location, are carried out to the highest international standards in all aspects. Together with the required technical and clinical data, these studies form a core global regulatory package, which can be used to meet the regulatory requirements of any country worldwide.

In addition to the ‘cost of R&D’ pharmaceuticals are being criticized for making vast R&D investments in ‘designer’ life style drugs but not investing in DDW. While some companies are disclosing some information on their investment in DDW, greater transparency on the proportion of R&D expenditure spent on different types of medicines has been called for.

At the same time, it is important to recognize that there are a range of factors for companies to invest in DDW that required multi-stakeholder approaches. Barriers to private R&D in these areas include the state of science and complexity of the science, fears that intellectual property rights may be violated, poor expected returns. Push factors might include public funding for research, tax credits for R&D, measures to mitigate risk associated with research process, which might be improved by fast track approval processes, shared cost and risk sharing arrangements and so forth.

Ethical Issues

Another aspect of perceived, rather than scientifically derived quality, are issues related to ethics. Many pharmaceutical companies have policies on ethical issues—ranging from animal

testing, human clinical research, stem cell research, use of genetic materials—as well as creating governance structures to oversee ethical questions and dilemmas in the company. Transparency and engagement on these dilemmas can help to inform stakeholders and minimize associated reputational and business risks.

In many countries, there is discussion, and different levels of tolerance for pharmaceutical marketing methods, including through hospitality, training and sponsorship given to doctors and medical organisations, the effects of drug promotion on public procurement decisions, direct-to-consumer advertising. Clearly these are difficult issues to resolve, and societies need to balance individual rights to make own decisions against their right to appropriate treatment and company efforts to educate or persuade consumers (doctors and/or patients) to purchase their products.

Safety and product quality

Product quality issues arguably present the most significant risks to investment value of companies. The threat of litigation in pharmaceutical companies' key markets can subject companies not only to expensive litigation, but a political and consumer backlash affecting a company's license to operate.⁸³ As for many companies that engage in manufacturing, there are also production related risks around environmental performance, for which most pharmaceutical brand-name companies disclose performance information.

Ability to manage pricing strategies to access markets

This is a key risk for companies who have sought to price higher in their main, developed country markets. As well as increased pressure to sell/give more product, at lower prices, in developing country markets, pricing decisions are influenced by factors including market competition, government regulation, and currency fluctuation. As these conditions vary amongst countries, prices also vary. Medicines face competition from competing medicines and treatment options.

Some companies have developed transparent pricing policies and offer drugs to developing countries on a not-for-loss basis. Others cross-subsidize provision of drugs to developing countries with income streams from developed country markets, which can be a difficult political balancing act. But consumers in developed countries also want cheaper medicines. Developed country governments need to balance both their national and global access to medicines agenda, as well as 'negotiate' with other developed and developing countries how the international cost of addressing health care in the developing world should be covered and who should pay. There is an important free rider question that can only be addressed through concerted political will at the international level.

Investors/Access to Credit

Investors are increasingly recognizing the short- and long-term non-traditional risks facing the pharmaceutical sector. As set out earlier, there has been a range of interventions made by some in the investor community on a range of societal concerns about the role of the pharmaceutical sector in addressing a range of public health issues. These are likely to persist, and become more systemic as public debate over health issues matures. Mainstream investment analysts regard the number and duration of patents on key medicines in a company's product portfolio and view the risk of parallel imports as significant, a key driver for companies to take careful positions on issues around patents and licensing arrangements. They have yet to tackle access to medicines in a consistent way and do not require companies to manage these programmes in a rigorous or consistent manner.

Employee Health and Productivity

An increasing number of companies have anticipated the economic costs of disease for their business—productivity losses, reduced labour efficiency and morale, absenteeism, increased staff turnover and training, prevention and treatment bills, changing market demographics, diverted management time, and so on. The South African HIV/AIDS experience has highlighted these issues for companies. In the US, these considerations underline company negotiations with health insurers and pharmacy benefit management (PBMs). Internal business drivers have led to a number of companies developing and implementing strategies to manage the impact of HIV on their business. In South Africa, GSK has business partnerships with Heineken and Anglo American to provide medicines to the companies' personnel. Abbot Laboratories also provides HIV medicines to its employees in South Africa.

Assessing the costs and benefits of corporate HIV strategies is difficult. Again, they will depend to a large extent on local attitudes towards HIV, patient familiarity and understanding of use of prescribed medicines, ability to pay, presence and quality of local health infrastructure and personnel. Clearly, these issues affect when costs are incurred and when the benefits will be reaped over the longer term.

5. Place of Economic Impact Management in Pharmaceutical Company Strategy

In the first phase of this work on “Business and Economic Development,” Accountability and BSR reviewed 68 company reports and found that company reporting on economic issues and impact is limited, both in quantity and quality. In part, this was attributed to the limitations of emerging process, reporting and assurance standards, both in terms of what issues they covered; confusion of the difference between economic impacts and financial impacts; and for whom economic impacts should be measured. This is also true for the pharmaceutical sector—while some companies have adopted aspects of the GRI, most have not explicitly reported their economic impacts. This would include both costs and benefits of their business activities to society.

In the case of the pharmaceutical sector, the full economic cost of producing medicines would include financial costs, as well as any negative environmental or health impacts generated. The full economic benefits would include the value created for shareholders, for customers, employees, suppliers, government (taxation) as direct economic impacts. But it is arguable that the most significant impacts of the sector are indirect impacts.

To understand economic impacts, we can categorize them as:

- 1) Production related impacts on specific communities which would include how siting of laboratories or factories might impact on a communities economic activity, generate employment, manage waste disposal, manage concerns over clinical testing on animals and so on. This would also include how companies decide to allocate R&D spending.
- 2) Consumption related impacts might include the impact of products or services on a specific community, at a local, regional, national or international level. The access to medicine debate has implicitly assumed that the impact of consumption of certain medical products is a ‘good’ and seeks to broaden the indirect and induced economic benefits of consuming medicines.

Intuitively, the indirect and induced economic impacts of *consumption* of medicines are a significant economic impact of the pharmaceutical sector. It can have profound impacts on the capacity of individuals, communities and countries to engage in economic activity. Companies do not have full control over whether and how indirect economic benefits manifest, but do provide a vital ingredient to their realization.

What is critical in understanding economic impacts, is defining the target community. Through outreach activities on specific initiatives, partnerships and pricing arrangements, companies have implicitly identified which communities are the most significant, and on which they expect their products to have a positive impact on within the constraints on

product distribution in the market in question. Some companies have specified global criteria for communities to be eligible for discounted products, others assess programmes on a case-by-case basis.

Birzeit – Occupied Palestinian Territories: Local Economic Impact

Birzeit is the fourth largest company in OPT and the third most profitable; sales of 392 products leads to a turnover of US\$12 million annually. Birzeit employees 210 Palestinians. A total of 35% of Birzeit's sales are to government, with 25% sold to NGOs who in turn serve the poor. A portion of total sales are also to pharmacies. It also exports a small percentage of its products. Birzeit holds 23% of total market share. Average price per product is US \$4.15, but we do not have details of product profile. It is estimated that 40% of products are purchased by average income level consumers, and over 25% are used by the poor. Products sold to the poor are not purchased directly by the consumer but distributed through government health insurance channels.

Business Drivers

Birzeit appreciates the value of measurement and has been publishing financial reports since 1974. Advisory assistance and auditing services have been provided by KPMG, and Lloyds audits their compliance to ISO9001. Birzeit is working with Lloyds to become ISO14000 certified to further measure business performance standards.

Measurement of economic impact is a critical strategy for local companies operating in OPT. The economic condition can only be improved if companies are able to track what is working effectively to address the issues of the poor. However, the OPT political situation is a major factor in business operations. A recurrent issue in discussion with OPT companies was that product testing and registration could only be applied by Palestinian authorities to Palestinian companies, but not for other pharmaceutical companies selling drugs in the OPT. Birzeit maintains that 'leveling the playing field' would lead to greater profitability that would increase employment and production, as well as accessibility of medicines. With a level playing field, Birzeit feels that local companies who are currently trying to do good will be in a much better position to have greater positive economic impact.

Economic Impacts

Although programmes have been implemented to address the issue of accessibility to drugs, no measurement tools have been developed to track progress of programmes. No statistical data is available or collected specifically on economic impacts of the pharmaceutical industry on the Palestinian community. There are very limited resources available to track economic impacts because of the day-to-day focus on survival in the turbulent political environment. Economic information is viewed as useful and would be utilized for better planning, better marketing and ultimately better profitability. Companies are currently operating by instinct.

The economic impact of Birzeit's products is achieved in a range of ways: Birzeit measures cost savings to the Palestinian consumer in part based on the fact that it offers

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Palestinians generic versus brand name products. Savings to consumers from generic drugs has been significant, and access to drugs has been facilitated through the lower costs of these medicines, although not quantified. This ratio of generic to branded drugs is similar for many other drugs.

Pricing for greater accessibility

Prices of drugs produced by Birzeit are at least 40% lower than imported drugs. Birzeit sometimes donates and sometimes sells its drugs at a greater reduced price to institutions that then distribute them for free, including CARE International and Medical Aid for OPT (MAP) International. Free medicine is provided to local medical organizations.

Consumer education

Birzeit supports health programmes designed to prevent illness and increase well-being amongst Palestinians, such as programmes to screen and prevent osteoporosis and phalacemia (iron deficiency).

Lessons Learned

The current partnership structure between Palestinian pharmaceutical companies and NGOs needs to change. Palestinian pharmaceutical companies view NGOs as their clients and provide them with a discounted rate for the work they are doing with people in need. It is the NGO who ultimately determines the best course of treatment for the patient, as well as the delivery of the product. Decisions may include whether the medication will be provided at no cost or if it will be subsidized with a coupon. Although providing donations to NGOs does assist the Palestinian situation to a degree, companies like Birzeit are interested in developing a process that would allow local government and business to have greater control over the industry.

Reporting

Many pharmaceutical companies have already sought to understand their economic impact and have communicated this through a range of mechanisms, including reporting. Most commonly used across sectors are the GRI Economic Indicators. These seek to measure the direct economic impacts—the direct flows of money between an organization and key stakeholders—payments to employees, suppliers, government, investors, and from customers.

The GRI also provides for companies to identify indirect economic impacts across business models, but no specific indicators have been developed for these types of impacts. Some pharmaceutical companies, such as Novartis, Novo Nordisk and Aspen Pharmacare have published cash value added statements that reflect flows of monies to stakeholders (employees, retained earnings, shareholders, financial institutions, public authorities). These too provide a measure of direct economic impacts. Most companies have referred to or reported discounted or donated products as a global figure for their programme activities. (Appendix C shows which

pharmaceutical companies have reported against GRI indicators).

For the pharmaceutical sector, indirect impacts are critically important. Indicators for indirect economic impacts, externalities or impacts that are not reflected in the cost and price of monetary transactions, such as the cost of environmental degradation or the benefit of improved water quality, have not been developed at a generic level. Induced, or multiplier effects such as the impact a business has on creating business opportunities and prospects for economic activity in the community are difficult to measure, but there is a body of health economics literature that seeks to understand some of these questions.

Most large companies describe their experience of these initiatives in CSR Reporting on their Web site or through publication in journals. Disclosure, however, remains ad hoc and the quality of publicly disclosed information is highly variable in the sector.

Reporting direct economic impacts is relatively straightforward, and most of the companies do disclose some or all of them in their annual reports, whether or not they present the data in the GRI format. But for the significant indirect economic impacts that pharmaceutical companies have through their products, the pharmaceutical sector has been less likely to describe their indirect economic impacts using *qualitative indicators* than non-science based sectors. This is in part related to the potentially serious consequences for both patients and the company if a company's claims are misleading or misconstrued. An important driver of successful pharmaceutical companies has been an ability to provide evidence-based and verifiable scientific assessments of the health impact of medicines. Health economics do, however, influence companies' strategies towards specific markets, and can be developed to understand and manage indirect economic impacts at a corporate level beyond reporting. That being said, there is no consensus within the sector on what might be a suitable set of indicators. This, in part, reflects divergent business models on how to address access to medicines issue, and therefore, what indicators would best capture corporate contribution to the issue. As a result, corporate reporting approaches differ significantly in this sector, led by companies such as Novo Nordisk, GSK and Novartis.

Novo Nordisk: Optimizing Its Economic Footprint

Novo Nordisk is a healthcare company and world leader in diabetes care with a net turnover of DKK 27 billion (€3,6 Billion) and profits of DKK 5 billion (€0,7 Billion) in 2003. It holds 17% of the world market in diabetes care and more than 50% in insulin. Headquartered in Denmark, it employs 19,241 people in 69 countries, and markets its products in 179 countries. Most production takes place in Denmark, and the company also has plants in China, Brazil, France, Japan, and South Africa. Direct economic impacts on customers are understood as sales. In 2003 99% of sales were outside Denmark.

Since the foundation of Novo Nordisk's forbears in the 1920s and the creation of hospitals and research centres, the company's performance has reflected its commitment to the role that business

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can play in contributing to socio-economic performance, in particular through R&D and the impact of the pharmaceutical products on health. Company research conducted at the Steno Diabetes Centre and Hagedorn Research Laboratory (in 1989 transformed to independent basic research components of Novo Nordisk) was internationally recognized with a designation as WHO Collaborating Centre for Research and Training on the Pathogenesis of Diabetes Mellitus. In 2003, Novo Nordisk established a partnership with Oxford University and the UK National Health Service (NHS) in a new research and care initiative the Oxford Centre for Diabetes, Endocrinology and Metabolism (OCDEM).

Novo Nordisk's work on the economic bottom line, economic impact analysis and socio-economic studies are budgeted and managed in Corporate Diabetes Programmes, which is part of Corporate Stakeholder Relations (people, reputation, innovation) headed by an Executive Vice President.

Description of programmes

Novo Nordisk has managed sustainable environmental and social development issues since the 1970s. Addressing the challenge of achieving both business profitability and sustainable socio-economic and environmental performance has driven Novo Nordisk to innovate business tools. Novo Nordisk continuously analyses all aspects of its business performance to manage socio-economic impact, ranging from diversity projects in the workplace, supplier evaluations, environmental and CO2 strategies, to partnerships in R&D and customer related projects in both the developed and developing countries.

Novo Nordisk started measuring its economic footprint in 1999 with case studies of the domestic production sites and developed an economic stakeholder model in 2001, based on the economic indicators in the GRI to show the economic relationships between the company and society. Since then, company reporting has evolved to disclose its direct and indirect economic impacts on customers, suppliers, employees, investors and the public sector at the global level, and at selected production sites. Novo Nordisk has augmented the information on flows of monies to stakeholders by using cash added value measures. Also reported, based on direct economic impacts, is the contribution that the company makes to Danish national GDP, to national export income and employment, as well as employee contributions to the tax base. In 2002, Novo Nordisk estimated the level of indirect employment generated by the company in Denmark. Much of this quantified information refers to the impact of Novo Nordisk's business processes on key stakeholders—qualitatively, Novo Nordisk has also identified longer term impacts that it has through investment in R&D, training and production capacity.

Novo Nordisk's uses the same methodology measuring the direct and indirect economic footprint at local production sites for Danish plants. Differences in impact are attributed to the size of the plant, municipality, the type of economic activity, and whether the area is residential or industrial. For Clayton (US), adjustments were made for the local tax system. At the local level, key stakeholders are employees and local government.

Since 2002, Novo Nordisk has increasingly focused on how to understand and manage the *indirect* economic impacts of its products on the health of individuals and nations, which it regards as the most significant impacts of Novo Nordisk. The indirect economic benefits can be understood as benefits of the individual's improved health—for the lives and livelihoods of patients and their

families, as well as for national health policies and budgets. Novo Nordisk has a sophisticated stakeholder engagement process to assist efforts to maximize the impacts of its products within national healthcare systems, which can face a range of financial, political, regulatory and capacity constraints to optimal health outcomes. What is unique about Novo Nordisk's approach is its focus on barriers to optimal treatment, which it regards as partly or wholly rooted in basic economic conditions of life. Diabetes is becoming a disease of the developing world—over the next 25 years the number of people with diabetes is set to more than double to more than 300 million and 80% of those will live in developing countries. Novo Nordisk offers insulin products at 20% of the average price in OECD to the 49 least developed countries according to UN definitions. While immediate health issues such as HIV/AIDS and contagious tropical diseases have captured attention on the access to medicine agenda, diabetes is an emerging health and development pandemic for the developing world. These future perspectives for the developed and developing world lead Novo Nordisk to develop scenarios (Vision 2020) in 2002 and 2003 better to understand the future of diabetes.

For Novo Nordisk to maximize the positive impacts of medicines on patients, the company needs to understand how a given quantity, quality and priced product gets from Novo Nordisk to patients, through a healthcare system, and is delivered to and used by patients in a particular country context. The quality of the distribution chain and consequent access to medicines are affected by prices that may change due to duties/taxes and wholesale/retail mark ups; quality may be affected by storage conditions etc; stocks may leak from the system; health professionals may not fully understand/advise patients and patients may not comply with usage instructions. These factors can erode the potential health and economic benefits of the product. While these issues are beyond Novo Nordisk's direct control, the company seeks to influence them through programmes focusing on awareness raising, education, early diagnosis and assessment of treatment. By having transparent pricing and disclosing information on the economic impact of its activities, Novo Nordisk is better able to determine its broader responsibility for a sustainable economic development.

Since 1999/2000, Novo Nordisk has managed innovative programmes that attempt to remove the barriers to the optimal use of their products and solutions. These initiatives focus on solutions and improved treatment outcomes for patients and healthcare providers. Novo Nordisk has built relationships with key stakeholders through a range of partnership mechanisms—education of health care providers and patients, partnerships with health care authorities in combination with National Diabetes Programmes (NDP)—which generate opportunities for the company to distinguish itself as a sustainable business leader in this field. Novo Nordisk has engaged almost all of its 69 country affiliates in workshops on NDP, as well as developed practical tools for affiliates. 131 different activities have been implemented in 43 countries, such as awareness campaigns, prevention/early diagnosis of type 2 diabetes and developing/implementing guidelines. Research on socio-economic impact of health care and studies (Diabetes Attitudes Wishes and Needs—DAWN) that improve understanding of patients' psycho-social situation, are part of these efforts. Novo Nordisk's DAWN study examines the importance of patient-centred care strategies, awareness and communication for treatment outcomes and for success of the health care systems. Novo Nordisk has created worldwide awareness of the findings of the DAWN study for improved diabetes care with collaborations between people from more than 30 countries. The aim is to facilitate changes to the healthcare systems, policies, and clinical practices in diabetes care so that both

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healthcare professionals and patients overcome psychosocial barriers to use of the most effective therapies for preventing long-term complications. The evaluation of the socio-economic impact of the programme is an integral part. The economic dimension was further strengthened in a ground-breaking study “Socio-economic impact of Diabetes” published in the 2002 (the first part for Type 1 Diabetes in Denmark) and in 2003 followed by an analysis of the socio-economic impact of type 1 and 2 in Denmark and Bangladesh. The study shows the economic impact or burden of current versus improved health care models and identifies the human, quality of life and economic costs and benefits to society of improved treatment of diabetes.

Business drivers

Novo Nordisk seeks to balance sustainable economic, social and environmental performance and processes with profitability. Stakeholder engagement processes are a means by which it can identify opportunities and manage risks, including strategic planning to adapt to new challenges to the more traditional R&D-based pharmaceutical business model. Accounting for economic impact informs local and national government of contributions and externalities, and contributes to the corporate long-term license to operation, as well as motivating employees and communities. It also provides a platform for stakeholder engagement to discuss what impacts Novo Nordisk can and should manage.

It is generally agreed that diabetes is a growing economic burden although it does compete with many other diseases for attention. When Novo Nordisk is discussing diabetes with the Health Authorities and Key Opinion Leaders consensus focus in particular on the need for and economic benefits of better data management, better organization and cooperation between different sectors of health care and communication between patients and health care providers.

Novo Nordisk is not only concerned about its impacts, but is trying to define a unique business model based on stakeholder needs and to strategically manage dilemmas that conflicting financial and economic targets can create. The business model focuses on making it possible to be a good corporate citizen delivering health benefits to customers and society, profit for investors and income for employees. This model includes the markets of less developed countries as it assumes that partnerships can create values and development that isolated action alone cannot.

Economic impact analysis also plays a role as a risk management tool for investors by uncovering issues that are or may become socially and politically important. Recently investors have started asking for analysis to show the business case for the triple bottom line and for economic impact.

Impact of programmes

In conducting the health economics research, Novo Nordisk identified the key stakeholders as customers (patients and health care providers) and political decision makers. Novo Nordisk expects research will inform the way in which it engages with policy makers and identify appropriate roles for Novo Nordisk to begin to address the economic burden of diabetes on individuals and society. This includes development of a sustainable diabetes care model for developing countries, as well as informing the type of partnership programmes—that would be most effective and appropriate in different developing country contexts. Many of these have been reported in Novo

Nordisk's sustainability reports. Novo Nordisk expects this research to contribute to the development of global approaches to managing chronic diseases, including diabetes.

In March 2002, shareholders decided to donate €70 million over 10 years to establish an independent organisation; the World Diabetes Foundation (WDF) dedicated to improving diabetes care for the world's poorest people. The donation addresses needs for additional funding, one of WHO's four priorities for improving access to health care. WDF focuses on projects in the developing world to support sustainable health care developments in prevention and treatment of diabetes. It is seeking to attract new partners, such as those involved in foot care, eye care and other diabetes-related issues. Within 3–4 years, the WDF, started by Novo Nordisk, will directly benefit 18 million people with diabetes and indirectly over three times that number. These figures do not include impacts of global and regional projects.

Novo Nordisk's partnership model for sustainable diabetes care in the poorest developing countries is based on bringing several players (health care authorities and professionals and other stakeholders) together, and create contracts with action plans, milestones and follow up measures that can enable diabetes care in the developing countries without long-term dependence on outside resources. Novo Nordisk has implemented this model in eight developing countries (China, India, Bangladesh, Cost Rica, El Salvador, Malaysia, Tanzania, and Zambia). Novo Nordisk and WDF supports diabetes and foot clinics, for example, in Tanzania where a network of diabetes clinics nation wide is being established expected to be run by the Tanzanians themselves in 2005. The clinics are estimate to provide access to diabetes care to 100,000 out of the 350,000 people that know they have diabetes in Tanzania. In Bangladesh a foot clinic has been established at a leading hospital and physicians are trained through distance learning programmes. In China the focus is on implementing diabetes action plans and 31 centres of excellence is planned over the next 5 years covering 311 cities each with a population of half a million or more.

Having disclosed its own differential pricing policy, formulated to ensure access to health and continued business sustainability, Novo Nordisk hopes research will stimulate discussion around health care in the developing world, and the level of political commitment required by developed country governments to enable companies to differentiate prices on a commercially viable basis, as well as addressing questions about funding of the development of healthcare policy, capacity and infrastructure in developing countries. A challenge for Novo Nordisk has been to understand how to manage these objectives across countries that have differing political views on what should be the role of the state and business in health care, differing formal and informal economic structures, as well as political and social differences affecting perceptions on wealth and 'health distribution.'

Stakeholder feedback on Novo Nordisk's reporting of economic impact has been very positive. Feedback from internal and external stakeholders suggests that efforts to quantify impacts has made the issues more tangible for stakeholders, and helps them to understand and compare the issues highlighted in a broader context.

Lessons learned

In conducting health economic surveys, Novo Nordisk has sought to define the health and macro-economic issues that its products can play; in particular how they might ameliorate health conditions, as well as defining the key obstacles to achieving good health and economic outcomes

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at the country level. Novo Nordisk seeks to stimulate debate around the costs and benefits to developed and developing societies of health care, the importance of appropriate health care delivery systems to address diabetes, and that responsibilities must be shared. In particular Novo Nordisk work on investigating how good or bad health impacts economic opportunities both within countries and amongst countries and what could happen if health care burdens, particularly in the developing world are not addressed. Novo Nordisk believes that, by sharing responsibilities and knowledge, innovative and improved systems can be developed.

Novo Nordisk's research also emphasizes trade-offs between allocating scarce corporate and societal resources to current health issues and anticipating emerging health challenges. Understanding its economic impact helps Novo Nordisk navigate and contribute to these discussions. This is also an important part of building 'license to operate now and in the future. Novo Nordisk is committed to contribute to sustainable development and use economic impact analysis to understand what drives change and to show how the necessary changes can be brought about.

One of the biggest challenges in conducting health economics studies are the barriers to access to existing data, the lack of systematic data collection and the lack of cooperation between those that actually do collect data. Novo Nordisk works to contribute to improved collection and access of data through building data management systems for corporate as well as societal use.

Novo Nordisk educates employees in the importance of providing solutions instead of products; that customers are people with diabetes and health care providers; and that the ultimate success criteria for our product delivery and for profitability is if it contributes to improved health of people. Novo Nordisk believes that prosperous future for society at large is good for the company. The purpose of socio economic analysis on company level is to support our ability to measure how the company can contribute to societal improvements through our process, products and how these products are utilized.

Reporting is an important, but only one way in which companies seek to manage and communicate their understanding and positions on economic impact issues. Reporting is a subset of a broader range of strategies some pharmaceutical companies have developed to understand and manage their socio-economic footprints. We have seen the Novo Nordisk case study. Pfizer UK has commissioned research that estimated that for each person directly employed by Pfizer, nearly five jobs are supported by Pfizer's activities in the UK. Pfizer has published information relating to the direct economic impact of expenditures on R&D in the UK market place as well as to the UK government in taxes.⁸⁵ Describing, and in these examples estimating the size of economic impact is an important stakeholder engagement tool for both companies. The challenge for companies is to develop ways to disclose meaningful information on their most significant economic impacts—those experienced by patients and the health of communities and nations more generally.

Reporting against industry specific standards is also limited but worth exploring further. As set out in the section on regulation and standards, there are a range standards generated by international organizations such as WHO, industry bodies and multi-stakeholder initiatives that companies might consider disclosing against to improve transparency.

6. Conclusions and Next Steps

The access to medicines debate has highlighted the significance of public health to sustainable economic development at the macro economic level. While some proponents of the debate have urged companies to do more, in a quantitative sense, by increasing affordability of medicines, more needs to be done to understand *how* corporate activities, such as the provision of cheap medicines, fit into the access to medicines debate. By understanding and beginning to map how medicines have an impact in different regulatory and health care environments, we can understand how to achieve sustainable improvement in the health of poor and disadvantaged communities around the globe.

For companies to articulate and refine their contribution to societal objectives, understanding the economic impacts of its business decisions and programmes is a helpful starting point. Corporate understanding of their business' economic impact in specified poor communities helps to link micro level impacts with desired macroeconomic outcomes. We have seen through the case studies how pharmaceutical company decisions have economic impacts through many aspects of product development and delivery—how companies manage and account for these business functions is critical to their accountability. We have also seen the difficulties in ascribing economic values to health—which in itself is a cause of and result of economic development, but is also regarded by many stakeholders as a basic human right.

Some pharmaceutical companies understand the contribution their products' make on a community, the economic costs and benefits they imply, as well as the contribution their products can make to a community. By optimizing investment decisions in access to medicines programmes and partnerships, companies can best justify resource allocation decisions both to internal and external stakeholders, and make the best possible contribution to those they seek to benefit. In managing risks and opportunities, enhanced transparency and explanation of corporate relationships with governments would be a useful starting point.

If the industry is to have a significant impact in shaping the debate in this area, then understanding corporate economic impacts will provide a constructive and dynamic platform for engagement with stakeholders.

Towards Consistency?

The case studies demonstrate how some pharmaceutical companies have interpreted aspects of their economic impacts. They demonstrate the complexity of factors affecting how pharmaceutical products impact, and the player and framework conditions influencing their contribution to health and socio-economic development.

At the same time, they show that for the sector as a whole, there is a *lack of consistency* of approach to economic impact. This applies to both direct and indirect economic impacts.

As this study illustrates, measurement and reporting of direct production side impacts, where standards already exist, is still relatively underdeveloped. Most importantly, however, for the pharmaceutical sector, this also applies in the area of indirect and consumption side impacts. Some companies disclose only general descriptions of some of their programmes, others provide detailed year-on-year statistics on a range of specific indicators.⁸⁶ Reporting against established frameworks and criteria, such as those set out in the Pharmaceutical Shareholders Group and Oxfam and Save the Children⁸⁷ is variable. Few pharmaceutical companies report against all criteria to a credible degree.

The way in which information is disclosed for different medicines often varies within companies. Companies such as GSK, Novo Nordisk and Novartis have gone furthest to standardize their disclosures on access to medicine related issues, while others have lead work in other important areas. While sector leaders have found innovative ways to communicate with stakeholders in a credible way, the sector is, overall reacting to stakeholder concerns rather than setting a proactive agenda.

Accounting for Economic Impact

Greater consistency of disclosures, both across business areas within companies and across companies would go some way to address persistent mistrust of the sector. Understanding access to medicines in the context of corporate economic impact is a way forward for companies to engage stakeholders in the access to medicines debate. It provides flexibility to accommodate different corporate strategies to address access to medicines – whether they be to find new business models, or through philanthropic programmes. Overall, exploring the economic impact of pharmaceutical companies through their product development and distribution function was a useful way to surface most of the access to medicines issues that pharmaceutical companies are grappling with. Companies agreed that the single largest set of impacts they had was through their product development and distribution function.

It enables companies to conceptualize that debate, recognizing the range of players required to maximize the impact of medicines on health, and potential ‘leakages’ of product impact, and communicate some of the more complex issues within an accessible framework and language. Economic impact can inform companies in defining target communities for different projects, as well as define broader accountabilities and responsibilities on where company products are likely to have the desired impacts. Drawing on broader bodies of health economics research, the WHO and others, have informed pharmaceutical companies’ decision making on where their investment (whether through pricing strategies, R&D efforts? or philanthropy projects) would have the greatest impact.

Another key advantage of reporting and related engagement processes related to economic impact is that they can enable more informed *internal decision-making*. Whatever business model companies adopt, a richer understanding of potential product impact in specific pro-

grammes or product lines, can inform companies how to make best use of their investment in access to health issues. This is essential in persuading internal stakeholders of the rationale for choosing one project over another, one partner over another, or one country over another as the focus of corporate access to medicines efforts.

As a key and growing product delivery mechanism for medicines provided on both a commercial and philanthropic basis, there is a clear need for greater partnership accountability. Much work has been done, such as by Merck, to understand what makes health partnerships work effectively. But there is also a need to understand what is needed to make partnerships accountable, not only to members, but to their external stakeholders. If companies are to 'scale up' and manage a range of partnerships concurrently, better partnership accountability is needed. This is true for all sectors, but is of critical importance to the pharmaceutical sector where partnerships may be the only delivery option to address access to medicines questions, as well as playing an important role in innovation.

Gaps in Methodology

Having applied the methodology developed by AccountAbility and BSR to the pharmaceutical and other sectors, it has become clear that it should be expanded to include an additional business function. A recurrent issue in public debate has been the potential impact of corporate influence on government policy. Much of the perceived lack of transparency of the sector has been driven by concerns that corporate and industry lobbying will mitigate against stakeholder preferences. The loudest criticisms internationally have stemmed from concerns that private lobbying efforts by governments have led to IPR regimes that counter publicly disclosed access to medicines agendas. Clearly, whether or not this is true in individual cases, it would have economic impacts.

Similarly, how companies manage their relationships with governments and other customers in developing countries can entrench system-wide distortions. Corruption is a well recognised 'tax' on development and poses risks for pharmaceutical companies doing business in some developing countries.

We therefore propose the methodology includes an addition business function – Government Relations. This would enable companies to include in their economic impact assessment corporate policies and practices relating to lobbying, political donations, corruption and transparency and a rationale for these decisions. Corporate responses to these issues are critical across all sectors, but particularly important in the health sector where the relationships between companies and government are multi-faceted. Strategies might include more widespread adoption and implementation of internal Codes of Conduct on bribery and transparency. Similarly, wider sectoral participation in multi-stakeholder initiatives to address transparency issues that could provide valuable insight to pharmaceutical companies. While some companies disclose corporate positions on these issues, there is clearly a gap between public disclosures and perceptions that only enhanced transparency and corporate accountability can address.

Appendix A

Relationship between Business Activity & Economic Impact⁸⁸

1. Facilities and Siting Management

- Real Estate

Where it locates its facilities?

What it locates there?

How it locates its facilities

2. Employment

Who is hired?

How many?

For what kinds of jobs?

How staff are developed?

Diversity?

3. Product and Service Development, Use and Delivery

- R&D
- Business Units

Accessible to whom?

What it sells?

How it manufactures?

Where customers can access products or services?

How it delivers?

Who vendors are?

Diversity?

Where it buys from?

R&D spillovers?

4. Sourcing and Procurement

How it sources services?

Who its vendors are?

Diversity?

Where it buys from?

5. Investments and fiscal contributions

- Finance Department
- Treasury

Where it borrows money?

Where it invests?

Taxes paid

6. Philanthropy and Community Investment

Appendix B

Pharmaceutical Product: Development and Delivery

Phase	Discovery	Development	Approval	Manufacturing	Marketing/ Distribution
Company Activities	New chemical entity (NCE) discovered. Apply for patent	Pre-clinical research and clinical trials which may be undertaken privately or publicly		Safety and quality assurance processes	Post marketing surveillance–quality management Develop/implement partnerships on access to medicines Implement patient assistance schemes for lower income patients Advertising and promotion (nature of this varies from country to country)
Standards and Regulations affecting product cycle		Clinical Standards <ul style="list-style-type: none"> ■ Guidelines for Good Clinical Practice of the International Conference on Harmonization (ICH) ■ WHO Guidelines for Good Clinical Practice ■ Declaration of Helsinki 	Based on Clinical Trials, Product Safety Licenses product for sale	Good manufacturing guidelines (e.g. FDA)	Depends on who is customer–public or private organization.
Public Policy Frameworks affecting product cycle	Intellectual Property Rules–Register Patent Policies affecting Innovation				National Marketing/ Advertising Body Guidelines Regulations for public/private health insurance and health care provision Policies for public health authority to undertake commercial negotiations with companies Company reporting to drug regulators

Appendix C

Pharmaceutical Company Reporting against GRI Indicators 2003

	Abbot	AstraZeneca	Aventis	Bayer	BMS	Boehringer Ingelheim	Eli Lilly	Forest Laboratories	GSK	Merck	Novo Nordisk	Novartis	Pfizer	Roche	Shering-Plough	Wyeth
GRI EC1		■	■	■	■						■					
Net sales																
EC2			■													
Geographic breakdown of markets																
EC3	■		■													
Cost of all goods, materials and services purchased																
EC4																
Percentage of contracts that were paid in accordance with agreed terms, excluding agreed penalty arrangements																
EC5			■		■						■		■			
Total payroll and benefits broken down by country or region																
EC6			■		■						■					
Distributions to providers of capital																
EC7			■								■					
Increase/decrease in retained earnings at end of period																
EC8					■						■					
Total sum of taxes of all types paid broken down by country																
EC9																
Subsidies received broken down by country or region																
EC10		■	■						■		■					
Donations to community, civil society, and other groups broken down in terms of cash and in-kind donations per type of group																
GRI EC 11 (+)											■					
Supplier breakdown by organization and company																
EC12 (+)											■					
Total spent on non-core business infrastructure development																
EC13 (+)						■					■					
The organizations indirect economic impacts. (Identify major externalities associated with the reporting organization's products and services).																
GRI Draft HIV Indicators											■					
Indicators																

Appendix D

Research Partners

The African Institute of Corporate Citizenship (AICC)

The African Institute of Corporate Citizenship (AICC) is based in South Africa. The aim of the AICC is to advance corporate citizenship in Africa. AICC was established in 2001 as a non-profit organization committed to leading Africa's corporate citizenship practice through advocacy, research, capacity building, and leadership and network development.

Centre for Social Markets (CSM)

The Centre for Social Markets (CSM) is an independent non-profit organization dedicated to making markets work for the triple bottom line—people, planet and profit. Through our offices in India and the United Kingdom, and an international network of partners and associates, CSM promotes responsible entrepreneurship, ethics and accountability worldwide. Founded in 2000, we are a values-based organization committed to sustainable development and human rights.

Fundação Dom Cabrale (FDC)

About FDC

Fundação Dom Cabral (FDC) is an educational centre for executives and companies based in Brazil. It was created in 1976 as a branch of the Extension Center of the Catholic University. It is an autonomous, nonprofit institution, managed to produce results for the community, its allied companies and clients.

Fundación PROhumana

Fundación PROhumana is a non-profit, non-politically affiliated, independent, private organization, which carries out its work in citizen and corporate social responsibility since 1998. Its Mission is to promote a culture of citizen and corporate social responsibility in Chile through proactive citizenship, expressed in individuals, institutions and firms.

Instituto Ethos

Instituto Ethos is a pioneering organisation of the Corporate Social Responsibility movement in Brazil. São Paulo-based, Ethos acts throughout the country and maintains partnerships with key organizations involved with CSR all over the world.

OPT Trade Center–PalTrade

OPT Trade Center–PalTrade is a national, non-profit, fully private sector, membership-based organization. It operates through offices in the West Bank and Gaza Strip and has strong market networks worldwide

PalTrade, strives to develop the capabilities of the private sector by assisting Palestinian firms in all aspects of international trade.

Appendix E

Corporate Responsibility Reports Reviewed (2002-3)

Abbot Laboratories	Merck
AstraZeneca	Novartis
Aventis	Novo Nordisk
Baxter	Pfizer
Bristol-Myers Squibb: 2003 Sustainability Report	Wyeth
GlaxoSmithKline	

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- International Federation of Pharmaceutical Manufacturers Association (IFPMA) Web site
- Medicines sans Frontieres Web site www.msf.org
- PhRMA Web site
- UNAIDS Web site
- World Health Organization Web site
- World Medical Association Web site
- World Trade Organization (WTO) Web site

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79 Personal communication with Deputy director of Tamil Nadu State AIDS Control Society (TANSACS), Dr Palanachamy.
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26. P-57 (the appetite suppressant compound from the Hoodia plant), works by mimicking the effect that glucose has on nerve cells in the brain (in effect fooling the body into thinking it is full, even when it is not), thus curbing appetite. Clinical trials in the United Kingdom suggest P-57 could reduce appetite by up to 2,000 calories a day, making it a potential runaway success in the multimillion-dollar dieting industry.
27. The San people are located in the region of the Kalahari Desert of Southwest Africa and are estimated to have a population of about 100,000. Politically, socially and economically, they have been marginalised over the past century, with consequences such as land dispossession and forced relocation to 'reserves' as well as poverty.
28. According to Barnett (17 June 2001), "The CEO of Phytopharm reported that he had been led to believe that 'the bushmen had died out' and therefore, implicitly, that there was none left to assert whatever rights they might have had." See "In Africa the Hoodia cactus keeps men alive. Now its secret is 'stolen' to make us thin", *the Observer* (London). Retrieved 14 April 2001 from <http://www.observer.co.uk>. See also, Stephenson D.J., 2003: The Patenting of the P57 and the Intellectual Property Rights of the San peoples of Southern Africa, page 11.

29. A global NGO that supports tribal people towards protecting their lives, lands and human rights.
30. The South African San Council is part of a three nation San Council called WIMSA (Working Group of Indigenous Minorities in Southern Africa) based in Windhoek (Namibia), which currently represents the 100,000 San people in South Africa (8,000), Namibia (35,000) and Botswana (57,000). WIMSA is currently trying to reach out to the San people of Angola.
31. See Stephenson D.J., 2003: The Patenting of the P57 and the Intellectual Property Rights of the San peoples of Southern Africa, page 11.
32. A human rights lawyer who in 1999 helped the San win back a large portion of their ancestral homelands in South Africa.
33. It is estimated that there are over 70 million obese adults in the western world, of which 5% are estimated to be severely obese. In the USA alone, annual costs concerning obesity-related diseases exceed US\$ 70 million. Also, estimates of the potential market size vary widely from about US\$ 4 to 30 billion, including the over-the-counter market. See <http://www.phytopharm.com/press/Re164final.htm> and <http://www.phytopharm.com/press/Re110final.htm>.
34. The San people of Angola are not yet formally included as beneficiaries under this deal, pending the success of WIMSA's efforts to reach out to them.
35. "The Pharmaceutical Industry and the Patent System", Hon. Bruce A Lehman, Intellectual Property Institute, 2003
36. "Philanthropy or Good Business? Emerging market issues for the global pharmaceutical industry", Core Ratings, May 2003, p.4
37. www.wto.org/english/tratop_e/trips_e/gc_stat_30aug03_e.htm
38. WTO Website, www.wto.org
39. "Canada sets out bill on export of generic drugs", Financial Times, 6 November 2003
40. <http://www.cptech.org/ip/health/c/mozambique/moz-cl-en.pdf>
41. This foundation (which was established in 1968) is funded from the company's profits and the annual appropriation for philanthropy, designed to annually place Eli Lilly among the top 10 donor companies in the US.
42. This foundation was formed in 1992 and is based in Germany. Its purpose is similar to that of the US-based Eli Lilly and Company Foundation but has a particular focus on the support of international scientific and education work. Since its inception, the German foundation has invested more than €4 million (US\$ 4.7 million) in support of more than 80 projects worldwide. Most of the projects deal with cancer, diabetes, neuroscience, and infectious diseases, and are focused primarily on R&D efforts.
43. For more information on WHO's DOTS-Plus programme (a strategy currently under continuous development and testing for the management of MDR-TB), see www.who.int
44. Note that WHO's Global TB Drug Facility is a programme created by a collaboration of tuberculosis specialists that purchase drugs in bulk and oversee their distribution. The programme, which has reached nearly two million TB patients over the past two years, has created a larger and more competitive market for TB drugs, driving down the cost of the drugs. See <http://www.stoptb.org/GDF/default.asp>
45. An initiative hosted by the World Health Organisation (WHO). See www.who.int
46. See <http://www.aspenpharmacare.co.za/showarticle.php?id=181>
47. See Edwards, J.R., "TB and MDR-TB Coming to America - Illegal Immigrants Spreading Infection", the National Review Commentary, <http://www.rense.com/general110/infect.htm>. See also from WHO, <http://www.who.int/mediacentre/factsheets/who104/en/>
48. See <http://www.who.int/mediacentre/factsheets/who104/en/>
49. See <http://www.stoptb.org/tuberculosis/default.asp>
50. See <http://www.who.int/mediacentre/factsheets/who104/en/>
51. Latin America, Asia, Eastern Europe and sub Saharan Africa.
52. See http://www.tballiance.org/2_1_2_MDR_TB.asp and http://www.tballiance.org/2_1_C_AGlobalThreat.asp
53. See <http://www.aspenpharmacare.co.za/showarticle.php?id=181>
54. See Stop TB Initiative, www.who.int
55. See WHO's country profile of TB in South Africa, http://www.who.int/tb/publications/global_report/2004/en/SouthAfrica.pdf
56. See Morbidity/communicable diseases section on South Africa's Health and related indicators website, <http://www.hst.org.za/sahr/98/indicat.htm>
57. See University of Michigan Health Systems, <http://www.med.umich.edu/hiv aids/opinf.html>
58. Harry Hausler (PH. D), Clinical Research Unit, Department of Infectious and Tropical Diseases London School of Hygiene and Tropical Medicine. See <http://www.journ-aids.org/TB%20and%20HIV-AIDS.htm#Background>
59. Ibid

60. Ibid
61. Ibid
62. See www.stoptb.org/organisation/documents/factsheets/TBP_fact_sheet_for_WTBD_2004.doc
63. See also Floyd et al., British Medical Journal, 1997.
64. TB control is a priority for the Department of Health (DoH) in South Africa. The DoH provides most of the TB services, having determined that diagnosis and treatment for TB should be free.
See http://www.who.int/tb/publications/global_report/2004/en/SouthAfrica.pdf and www.doh.gov.za.
Also note that TB funding is part of the government's overall primary care budget.
See http://www.who.int/tb/publications/global_report/2004/en/SouthAfrica.pdf
65. According to the WHO and Stop TB Initiative. See www.stoptb.org
66. Note that while there is no dedicated national TB budget, the National Treasury provides funds for TB control along with several other health care programmes directly to Provincial Departments of Health through the Equity Share Grant for Health. See http://www.who.int/tb/publications/global_report/2004/en/SouthAfrica.pdf
67. See <http://www.stoptb.org/tuberculosis/poorly.managed.tb.prg.html>
68. This drug is produced using complex technology called "Lyophilisation", which uses a freeze dried method.
69. This amount has been budgeted for by Eli Lilly for its global MDR-TB initiative, which apart from Aspen Pharmacare, involves other regional partners in China, India and Russia.
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This study is comprised of four separate industry reports:

- Finance
- Pharmaceutical
- Agriculture
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