
GlaxoSmithKline company profile

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Summary

Business description

GlaxoSmithKline (GSK) is one of the world's largest research-based pharmaceutical corporations that discovers, develops, manufactures and markets branded human health products.

- Headquarters: UK, with additional operational headquarters in the USA
- Global presence: about 160 countries
- Primary markets: USA, France, Germany, UK, Italy and Japan
- Employees: approximately 103,000

GSK key figures for 2003 (in £ million)

Sales	21,441
Materials and production costs	4,188
Marketing and administration	7,563
R&D expenditures	2,770
Operating income	6,920
Net profit	4,765

GSK has two main business divisions, pharmaceuticals and consumer healthcare. This profile deals with the pharmaceuticals division, which generates 85% of GSK's sales.

The five largest selling GSK products are Seretide/Advair for asthma and Chronic Obstructive Pulmonary Disease (COPD); Paxil/Seroxat and Wellbutrin, both anti-depression drugs; Avandia/Avadamet for type 2 diabetes; and the antibiotic Augmentin. Each of these drugs generated above £800 million of sales in 2003.

GSK produces a broad range of products of special importance to developing countries, including:

- Anti-malaria drugs
- Zentel (albendazole), for de-worming and the prevention of lymphatic filariasis
- Pentosam, against leishmaniasis
- Anti-retrovirals (ARVs) for the treatment of HIV/AIDS
- Tuberculosis drugs

- Vaccines for developing countries

Corporate Social Responsibility (CSR)

CSR refers to the responsibility of a company for the social, ecological and economic impacts of its operations. GSK follows a proactive and comprehensive CSR approach. In 2003, the company formally adopted a set of Corporate Responsibility Principles. The company is highly transparent about its CSR policies and has a clear governance structure on CSR. Reporting about CSR performance is still limited on some issues, such as employment practices and internal monitoring on compliance with the company's Code of Conduct. Recent criticism concerning GSK's CSR performance includes fraudulent patent manoeuvres, irresponsible drug promotion and tax evasion.

GSK's policy for access to medicines in poor countries is outlined in its 2001 publication *Facing the Challenge*. The company identifies three key areas in which it can make a valuable contribution:

- R&D for diseases in poor countries
- Sustainable preferential pricing
- Community investment

GSK has provided voluntary licenses for the generic production of HIV/AIDS drugs in sub-Saharan Africa and offers a considerable range of medicines and vaccines at preferential prices. Furthermore, GSK has a large R&D portfolio for diseases relevant to developing countries and is also committed to undertake R&D projects on which it does not expect a commercial return. Compared to other pharmaceutical companies, GSK has a comprehensive and progressive policy for access to medicines.

Global Public-Private Initiatives (GPPIs)

GPPIs bring together different partners to address health problems in poor countries. In each of the three areas mentioned above,

GSK is actively involved in GPPIs. It participates R&D partnerships to speed the development of tuberculosis and malaria drugs and various types of vaccines, including a dengue, malaria and rotavirus vaccine. The company is also a partner in two preferential pricing frameworks:

- Accelerating Access Initiatives (AAI)
- Global Alliance for Vaccines and Immunisation (GAVI)

GPPIs for community investment include:

- Global Alliance for the Elimination of Lymphatic Filariasis (GAELF)
- GSK African Malaria Partnership (AMP)

Each company participating in the AAI individually offers preferential prices for its anti-retrovirals. For the poorest countries, GSK sets a single not-for-profit price. As of December 2003, the number of HIV patients in Africa receiving ARVs provided by all AAI companies combined was only about 150,000.

The GAVI was established in 1999 to expand the widespread use of vaccines in developing countries. The pharmaceutical industry is represented in the GAVI Board. The GAVI has identified three priority diseases: Hepatitis B, *Haemophilus influenza* type b and yellow fever. This focus has been criticized. GSK is a major supplier of Hepatitis B vaccines to GAVI, with supplies worth over \$200 million for the period 2001-2004.

The GAELF is GSK's flagship community programme. It was founded in 1998, aiming to eliminate lymphatic filariasis by 2020. GSK has committed to provide as much of its drug albendazole as required until the disease is eliminated. The drug is administered through national programmes in 34 countries. GSK also contributed cash grants and expertise. The total quantity of required albendazole for 20 years is estimated at 6 billion tablets, with a value of some \$1 billion (at wholesale prices).

The AMP was established in 2002 to reduce malaria infections and improve the

management of the illness. The partnership targets seven African countries. National ministries of health and international NGOs are directly involved. GSK provided a £1.5 million grant to fund country programmes for three years. During this period, the company seeks to demonstrate the success of the partnership and attract other donors.

In 2003 the total value of GSK's product, cash and in-kind donations was £338 million.

Analysis of GPPI involvement

Although the global community partnerships of GSK have a philanthropic nature, they also serve to build pride with employees. These GPPIs also help to build relationships with governments and other stakeholders. The Hepatitis B vaccine supplies to GAVI generate large businesses for GSK as well.

It is positive that GSK's support for GPPIs forms part of a broader policy on healthcare in developing countries. GPPIs like the AAI and R&D partnerships are directly linked to the company's core business and CSR policy. GSK dedicates considerable resources to GPPIs and is transparent about its contributions.

Lack of transparency about partnership agreements, for example for the GAELF and GPEI, prevents full external scrutiny. GSK's large donations to global community partnerships also raise a few concerns. Philanthropic contributions might be inappropriate if they would be indirectly supported by irresponsible business practices, such as tax evasion. Furthermore, the time-scale of financial commitments like the grant to the AMP is relatively short. Finally, responsibilities may be transferred from donor governments to the company, but the root of this problem lies of course with donor governments.

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List of acronyms

3TC	Epivir
AAI	Accelerating Access Initiative
ADIP	Accelerated Development and Introduction Plan
AMP	GSK African Malaria Partnership
ARV	Anti-retroviral
AZT	Retrovir
CBD	Convention on Biological Diversity
CSR	Corporate Social Responsibility
COPD	Chronic Obstructive Pulmonary Disease
DEC	Diethylcarbamazine citrate
DTC	Direct-to consumer (advertising)
DTP	Diphtheria-tetanus-pertussis (vaccine)
GAELF	Global Alliance to Eliminate Lymphatic Filariasis
GAVI	Global Alliance for Vaccines and Immunisation
GPPI	Global Public-Private Initiative
GSK	GlaxoSmithKline
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
IPPPH	Initiative on Public-Private Partnerships for Health
LF	Lymphatic filariasis
MDP	Merck Mectizan Donation Programme
MIM	Multilateral Initiative on Malaria
MMR	Measles-mumps-rubella
MMV	Medicines for Malaria Venture
MVI	Malaria Vaccine Initiative
NGO	Non-Governmental Organization
OECD	Organization for Economic Cooperation and Development
OTC	Over-the-counter (drugs)
PAHO	Pan-American Health Organisation
PATH	Program for Appropriate Technology in Health
PhRMA	Pharmaceutical Research and Manufacturers of America
RBM	Roll Back Malaria
TB	Tuberculosis
TRIPS	Trade-Related aspects of Intellectual Property rights
UNICEF	United Nations Children's Fund
USTR	United States Trade Representative
WHO	World Health Organization
WTO	World Trade Organization

Introduction

This report forms part of a broader research project on the role of companies in public-private partnerships (PPPs). Such collaborations have become an increasingly important way to stimulate sustainable development. The research project aims to contribute to a better understanding of the rationale, functioning and effectiveness of these partnerships.

This report focuses Global Public-Private Initiatives (GPPIs) for healthcare in developing countries. These GPPIs are a specific type of public-private partnerships. The report assesses company contributions and the rationale for industry involvement with GPPIs. It does not evaluate outcomes or effectiveness, nor does it deal with the governance and functioning of the partnerships in much detail. These issues are addressed in separate reports, focusing on four specific initiatives (GPEI, GAELF, RBM Partnership, Stop TB). Field studies on the implementation of these programmes in developing countries form part of the broader research project.

This company profile analyses GlaxoSmithKline (GSK), a large pharmaceutical corporation, and its involvement in GPPIs. The report consists of three parts:

1. a description of the business of the company (chapter 1);
2. an analysis of its corporate social responsibility (CSR) policies (chapters 2-3);
3. a discussion of its role in GPPIs and the contributions to these partnerships (chapters 4-6).

This integral approach allows to relate GSK's involvement with GPPIs to the core-business of the company and to broader company strategies and policies.

It should be emphasized that a company's support for PPPs (or GPPIs) is not the same as its CSR performance. PPPs and CSR should be clearly distinguished. CSR, as defined in the report, covers a broad range of issues that are all directly related to the core-business of a company (environmental issues, labour conditions, access to medicines, competition policy, etc.). CSR performance therefore primarily depends on how a corporation manages its core-business. In certain cases, PPPs may be directly related to the business operations of a company and address issues that can reasonably be considered a responsibility of the company. There will then be a link between PPPs and (a specific area of) CSR performance. However, in other cases PPPs may be completely unrelated to a company's core-business, especially when company contributions consist of cash donations only. Such initiatives are not linked with CSR at all and can be classified as corporate philanthropy or charity.

Finally, it should be noted that the report focuses on a few large GPPIs that were selected because of their relevance for the broader research project. This company profile does not provide a complete overview of the PPPs supported by GSK.

1 General characteristics

1.1 Corporate headquarters

GlaxoSmithKline plc, corporate head office
980 Great West Road
Brentford
Middlesex TW8 9GS
England
Tel. +44 20 80475000
<http://www.gsk.com>

1.2 A short history

- In 1988, SmithKline BioScience Laboratories acquires one of its largest competitors, International Clinical Laboratories Inc., increasing the company's size by half and becoming an industry leader.
- In 1989, SmithKline Beckman and The Beecham Group plc merge to form SmithKline Beecham plc.
- In 1994, SmithKline Beecham acquires Diversified Pharmaceutical Services Inc., a pharmaceutical benefits manager, and Sterling Health. This makes SmithKline Beecham the third-largest over-the-counter medicines company in the world and number one in Europe and the international markets. Focusing on human healthcare, SmithKline Beecham sells its animal health business.
- In 1995, Glaxo and Wellcome merge to form Glaxo Wellcome. Glaxo Wellcome acquires California-based Affymax, a leader in the field of combinatorial chemistry.
- In 1998, Glaxo Wellcome acquires Polfa Poznan and becomes the largest pharmaceutical company in Poland.
- In 1999, further sharpening its focus on pharmaceuticals and consumer healthcare, SmithKline Beecham divests SmithKline Beecham Clinical Laboratories and Diversified Pharmaceutical Services.
- In 2000, GlaxoSmithKline is formed through the merger of Glaxo Wellcome and SmithKline Beecham.¹

1.3 Ownership structure

GlaxoSmithKline is a public limited company. Ordinary shares are traded on the London Stock Exchange (ticker symbol GSK). American Depositary Shares (ADSs), representing two ordinary shares, are traded on the New York Stock Exchange (ticker symbol GSK).

¹ <http://www.gsk.com/about/background.htm>.

Some shareholders favour a pro-active company approach towards health problems in developing countries. The Pharmaceutical Shareholders Group, a London-based group of large institutional investors that hold shares of pharmaceutical companies, studied the business rationale for addressing the issue and assessed how well companies are managing this. In a recently published report, it recommends companies to develop a pro-active, comprehensive and consistent approach to address these problems and identifies best practices. GSK was identified as one of the leading companies, but the report also mentioned that all companies could still improve their approach.²

The California Public Employees Retirement System (Calpers) is estimated to hold over 700 million US\$ of GlaxoSmithKline stock (less than 1%). In April 2003, Calpers used this position to call upon GSK to make its HIV/AIDS available in the developing world at lower prices.

1.4 Business profile

GlaxoSmithKline (GSK) is one of the world's largest research-based pharmaceutical companies that discovers, develops, manufactures and markets human health products. It is an innovative company that produces branded products only, which it has developed itself.

The company has two main divisions, pharmaceuticals and consumer healthcare. The consumer healthcare businesses of GSK consist of over-the-counter (OTC) medicines, oral care products, such as the toothpaste brands Aquafresh, Macleans and Sensodyne, and nutritional healthcare drinks. The pharmaceuticals division is the largest part of GSK's businesses and can be divided into prescription drugs and vaccines. This report deals with the pharmaceuticals division only.

The headquarters of GSK are located in the UK, with additional operational headquarters in the USA. The company operates in some 160 national markets, the major ones being the USA, Japan, France, Germany, the UK and Italy.

GSK conducts R&D at more than 20 sites and employs 15,000 employees in R&D. The principal facilities are located in UK, USA, Japan, Italy and Belgium, and minor R&D sites are located in Canada, France and Spain. All R&D for vaccines is carried out in Belgium. GSK is involved in many different R&D partnerships with academic institutions, biotechnology companies and other pharmaceutical companies. The company has a leading position in genetics and in new drug discovery technologies.³

² Pharmaceutical Shareholders Group (September 2004). *The Public Health Crisis in Emerging Markets: An Institutional Investor Perspective on the Implications for the Pharmaceutical Industry*. London: CIS.

³ GSK Corporate Responsibility Report 2003.

The manufacture and supply system of GSK operates as a single global network. The company has 87 manufacturing sites and employs around 32,000 employees in production. It has two types of manufacturing sites. Primary manufacturing sites produce the active compounds used in the drugs. There are twelve of these sites, located in the UK, Ireland, the USA, Singapore and Australia. Secondary manufacturing sites convert the active compounds into finished products. There are 15 of these sites in Europe, 6 in North America, 5 in Latin America, 5 in the Middle East and Africa, 15 in the Asia/Pacific/Australia Region, 4 in China, and 1 in Japan. Vaccine manufacturing is primarily located at two sites in Belgium.

GSK employs 44,000 people in sales and has the largest sales force in the pharmaceutical industry. It has various co-marketing and co-promotion agreements with other pharmaceutical companies.⁴

For prescription drugs, the main therapeutic areas of GSK are central nervous system, respiratory, anti-infectives and gastro-intestinal/metabolic. The largest selling GSK products are Seretide/Advair for asthma and Chronic Obstructive Pulmonary Disease (COPD); Paxil/Seroxat and Wellbutrin, both anti-depression drugs; Avandia/Avadamet for type 2 diabetes; and the antibiotic Augmentin. These all generated above £ 800 million⁵ of sales in 2003.

In September 2003, GSK held the second position in pharmaceutical market, with a world market share of 6.9%. This is after Pfizer, which had a share of 10.3%. GSK is a leader in the four therapeutic areas mentioned above and in vaccines. Worldwide, it had a market share of over 20% for respiratory treatments, a share of approximately 13% for anti-infectives and close to 10% of central nervous system drugs.⁶

Generic drug manufacturers are seeking to bring generic versions of many of GSK's most important products to the market before patent expiry. Generic products competing with Paxil and Augmentin, launched in 2002 and 2003, had a considerable adverse impact on its sales and profits.⁷

1.5 Business strategy

GSK's business goal is to be a world leader in pharmaceutical industry. In order to achieve this, the company seeks to improve its R&D pipeline, using a focused drug portfolio strategy and selective in-licensing agreements for the external contracting of R&D. The company links R&D closely to commercial operations to maximise the value of its R&D

⁴ GSK Corporate Responsibility Report 2003; <http://www.gsk.com>.

⁵ This is roughly US\$ 1.3 billion and hence all of these drugs (and a few other GSK drugs too) have so-called blockbuster status.

⁶ GSK Annual Report 2003, p61; some of the market shares calculated by SOMO.

⁷ GSK Annual report 2003, p74.

portfolio. Furthermore, GSK seeks to increase brand name recognition among customers and to develop improved versions of older products, on which new patents can be obtained. It is a common strategy of branded drug producers to develop improved versions or more convenient formulations of drugs on which the patents have expired, and to persuade doctors and patients to use the enhanced version.⁸

Direct-to-consumer (DTC) advertising is an important element of GSK's marketing strategy in the US. Consumers that receive information through DTC advertising tend to request specific brand name medicines to their physicians. The company is implementing a 'sales force excellence' initiative to improve the already good reputation of GSK sales representatives among healthcare professionals. It has also started a 'marketing excellence' initiative to reduce the number of patients that do not seek the help of a doctor and remain undiagnosed, and the number of diagnosed patients that remain untreated.⁹

1.6 Key figures

Below an overview of key figures of the corporation is provided for the total businesses of GSK, that is, pharmaceuticals plus consumer healthcare. Figures for the years 1999-2000 refer to the combined businesses of Glaxo Wellcome and SmithKline Beecham and are fully comparable to figures for subsequent years.

GSK key figures of total businesses (in £ mln¹⁰, except for employees).

	2003	2002	2001	2000	1999
Sales	21,441	21,212	20,489	18,079	16,164
Materials and production costs	4,188	4,243	4,430	3,811	3,499
Marketing and administration	7,563	7,543	7,451	6,732	6,002
R&D expenditures	2,770	2,732	2,555	2,510	2,285
Operating income	6,920	6,694	6,053	5,026	4,403
Net profit	4,765	4,627	4,391	3,697	3,222
Employees	103.200	106.200	107.900	107.500	109.000

Source: GSK Annual Reports, various years.

Note that GSK's net profit margins are very high. In 2003 profits amounted to some 22% of sales, for example, which is above average for the pharmaceutical sector.¹¹ Marketing and administration costs are also very high, at almost 36% of sales in 2003. This is higher than

⁸ See SOMO (2004). *Sector profile of the pharmaceutical industry*.

⁹ GSK Annual Report 2003, p6, 10, 13.

¹⁰ GSK also states 2003 key figures in US\$ on its website, at a rate of approximately \$1.60 per £1.

¹¹ See SOMO (2004). *Sector profile of the pharmaceutical industry*.

R&D and production costs combined. This is relatively high for the pharmaceutical sector, even though it is common among large pharmaceutical companies that these expenses are much higher than R&D investment.

An overview of the sales of GSK's two main divisions is provided below. Pharmaceuticals, the division described in this report, is by far the largest and accounts for over 95% of total R&D investment.

Sales by division (in £ mln, and 2003 share of total).

Division	2003 share	2003	2002	2001	2000	1999
Pharmaceuticals	85 %	18,181	17,995	17,205	15,429	13,618
Consumer healthcare	12 %	3,260	3,217	3,284	2,650	2,546
Total	100 %	21,441	21,212	20,489	18,079	16,164

Source: GSK Annual Reports, various years.

The following table shows a break-up of pharmaceutical sales by region. The distribution of GSK's turnover over the different regions is roughly the same as the distribution of total turnover in the world pharmaceutical market. Hence, the market share of the company is more or less the same across all regional pharmaceutical markets, and the pharmaceutical sales of GSK do not show a relative focus on a specific regional market.

GSK pharmaceuticals sales by region (share of total).

Region	2003	2002	2001	2000	1999
USA	52 %	54 %	53 %	50 %	46 %
Europe	28 %	26 %	27 %	28 %	31 %
Asia Pacific excl. Japan	6 %	6 %	7 %	7 %	7 %
Japan	4 %	4 %	4 %	5 %	5 %
Middle East, Africa	4 %	4 %	3 %	3 %	3 %
Latin America	3 %	3 %	5 %	4 %	5 %
Canada	3 %	2 %	2 %	2 %	2 %

Source: GSK Annual Reports, various years.

Below a break-up of pharmaceutical sales by therapeutic category is provided. A sub-category is added for central nervous system drugs and anti-virals. The large sales for anti-depression drugs are mainly generated by Seroxat/Paxil and Wellbutrin and roughly half of the respiratory drug sales are generated by Seretide/Advair alone. GSK has a strong focus on these two areas. Note that many therapeutic categories, including anti-retrovirals (ARVs) and vaccines, show strong growth over the past five years.

Sales of pharmaceutical division by category (in £ mln, and 2003 share of total).

Therapeutic category	2003 share	2003	2002	2001	2000	1999
Central nervous system	25 %	4,455	4,511	4,007	3,279	2,720
of which depression	16 %	2,830	2,937	2,504	2,002	1,636
Respiratory	24 %	4,417	3,987	3,537	2,789	2,382
Anti-virals	13 %	2,349	2,299	2,128	1,899	1,610
of which HIV (ARVs)	8 %	1,508	1,465	1,347	1,145	982
Anti-bacterials	10 %	1,815	2,210	2,604	2,604	2,383
Vaccines	6 %	1,123	1,080	948	842	776
Metabolic ¹²	6 %	1,079	960	875	n/a	n/a
Oncology and emesis	6 %	1,001	977	838	710	613
Other	11 %	1,942	1,971	2,268	3,306	3,134
Total	100 %	18,181	17,995	17,205	15,429	13,618

Source: GSK Annual Reports, various years.

The turnover of the company's pharmaceuticals portfolio can be divided into the following three classes.

- New products, launched within the last five years. These account for 25% of sales in 2003 and turnover generated by these products is growing strongly.
- More established, franchised products. These account for 54% of sales.
- Older products, on which patents have usually expired. These account for 21% of sales and turnover is declining.

1.7 Medicines of special importance to developing countries

GSK produces a broad range of products of special importance to developing countries. These include the following products:¹³

- Anti-malarials
- Zentel, a de-worming product, generic name albendazole. Albendazole is donated by GSK as part of the lymphatic filariasis elimination campaign.
- Pentosam, a drug against visceral leishmaniasis
- Tuberculosis (TB) drugs
- Anti-retrovirals (ARVs) for the treatment of HIV/AIDS
- Vaccines

These drugs and vaccines are in general protected by patents, except for TB drugs and Zentel (albendazole), on which patents and data exclusivity periods have expired.¹⁴ Anti-malarials, ARVs and vaccines will be dealt with in some more detail.

¹² Separate metabolic drug sales data for 1999-2000 are missing in the table, because the break-up by therapeutic categories in GSK reports changed.

¹³ See GSK Corporate Sustainability Report 2003, p12.

¹⁴ See for patent information <http://www.fda.gov/cder/ob>.

Anti-malarials

GSK produces a range of anti-malarials. Older products include chloroquine, amodiaquine, and sulphadoxine/pyrimethamine. The following are GSK's newest malaria drugs:

- Halfan (halofantrine), a treatment for chloroquine resistant malaria
- Malarone (atovaquone/proguanil), a treatment and prophylaxis for malaria
- Lapdap (chlorproguanil/dapsone), a treatment for malaria where older therapies are failing due to increased resistance

GSK supplies some 30 million malaria treatments per year in Africa. The majority are supplied on the basis of tenders.¹⁵

Anti-retrovirals

Anti-retrovirals (ARVs) are HIV/AIDS drugs. The drug regime is a life-long therapy and often consists fixed-dose combinations of different ARVs. GSK is the largest provider of ARVs worldwide. For reference, a complete list of the ARVs and ARV fixed-dose combinations currently produced by GSK is provided below. The names in brackets are the generic names of the drugs.

- Epivir, also called 3TC (lamivudine)
- Retrovir, also called AZT (zidovudine)
- Ziagen (abacavir)
- Combivir (fixed-dose combination of zidovudine and lamivudine)
- Trizivir (fixed-dose combination of zidovudine, lamivudine and abacavir)
- Agenerase (amprenavir)
- Lexiva (fosamprenavir)

Agenerase and Lexiva are of the protease inhibitor type; the other ARVs are reverse transcriptase inhibitors.¹⁶ Patent protection for all of these medicine is in place.¹⁷ Combivir is an essential component of WHO-recommended HIV/AIDS treatment regimes. Sales figures of these products and a breakdown of total ARV sales to main regions are provided below. Sales of ARVs are growing across all regions.¹⁸ The share of the 'rest of the world' in supplied quantities of ARVs is larger than its share in sales revenue, because of the preferential prices for least developed countries and sub-Sahara Africa.

¹⁵ <http://www.gsk.com/about/pricing.htm>.

¹⁶ GSK Annual Report 2003, p7.

¹⁷ For more info on FDA approved drugs and patents, see the Electronic Orange Book, <http://www.fda.gov/cder/ob/default.htm>.

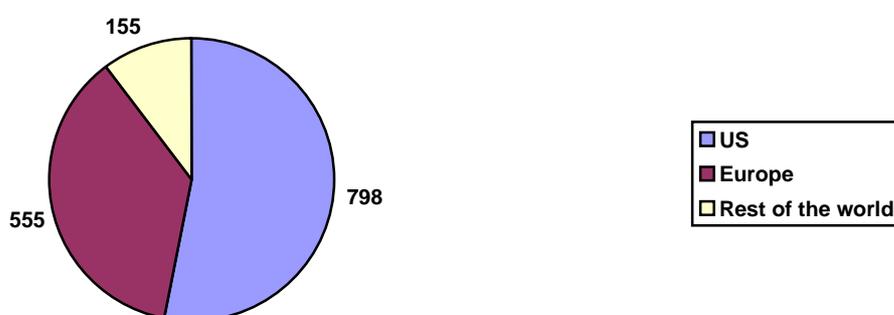
¹⁸ GSK Annual Report 2003, p62.

Sales of ARV products (million £).

Product	2003	2002	2001	2000	1999
Epivir (3TC)	293	295	302	309	325
Retrovir (AZT)	45	50	55	61	86
Ziagen	167	173	167	154	86
Combivir	589	588	606	562	454
Trizivir	376	315	167	7	-
Agenerase	31	44	50	52	31
Lexiva	7	-	-	-	-
All ARVs	1,508	1,465	1,347	1,145	982

Source: GSK Annual Reports, various years.

ARV sales by region in 2003 (£ mln).



Source: GSK Annual Report 2003.

Vaccines

GSK is one of the largest vaccine producers in the world. Many of these are of special importance to developing countries. A complete list of diseases for which GSK currently produces vaccines is provided below.

Bacterial vaccines	Viral vaccines
<ul style="list-style-type: none"> • Diphtheria • Haemophilus Influenzae B • Meningococcus meningitis • Pertussis (whooping cough) • Tetanus • Typhoid fever 	<ul style="list-style-type: none"> • Hepatitis A • Hepatitis B • Influenza • Measles • Mumps • Poliomyelitis (polio) • Rubella • Varicella (chickenpox)

Source: <http://www.gsk.com/products/vaccines.jsp>.

The vaccines nowadays used in high income countries are often of a different type than those used in developing countries. For example, high income countries use diphtheria-tetanus-partussis (DTP) vaccines of the acellular pertussis type, whereas developing countries use the wholecell pertussis type. The vaccines used in high income countries are newer and have a lower risk of adverse reactions, but they are much more expensive.¹⁹ GSK produces the vaccine types for high income countries as well as those for developing countries, and operates in both types of vaccine markets.

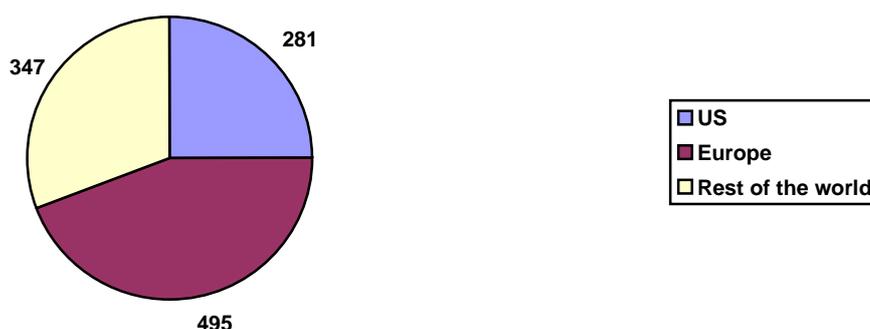
Some figures on vaccine sales by category and a breakdown of total vaccine sales to main regions are provided below. Hepatitis vaccines cover Hepatitis A and B. Infanrix is a pediatric combination vaccine used in high income countries. The basic Infanrix vaccine is for DTP, but some types also include Hepatitis B and polio, and *Haemophilus influenza* B. Note the primacy of the European market for GSK's vaccine sales and the relatively large share of the 'rest of the world' category.

Vaccine sales by main product groups (in million £).

Product group	2003	2002	2001	2000	1999
Hepatitis	417	482	445	462	480
Infanrix	336	254	238	171	210
Other	370	344	265	209	86
All vaccines	1,123	1,080	948	842	776

Source: GSK Annual Report 2003.

Vaccines sales by region in 2003 (£ mln).



Source: GSK Annual Report 2003.

UNICEF supplies

¹⁹ A. Roberfroid (November 2000). A. presentation to the GAVI Partners' Meeting, Noordwijk, the Netherlands. See <http://smain.synergynewmedia.co.uk/gavi/vaccinealliance/reference/ppt/roberfroid.ppt>; S. McKinney & S. Jarrett (14 June 2002). Update on vaccine security. See http://www.who.int/vaccines-access/supply/Vaccine_security_Jarrett_McKinney.ppt.

UNICEF procures vaccines and medicines for use in the developing world through tenders for prequalified suppliers. UNICEF also handles the procurement for the Global Alliance for Vaccines and Immunisation (GAVI) and some World Health Organization (WHO) programmes. The contracts awarded through these tenders give some information on the type and amount of vaccines and medicines a company supplies to UNICEF and to GPPIs such as GAVI. An overview of UNICEF contracts awarded to GSK is provided below. (Note that the value of the contracts is in US\$, whereas the overview of vaccine sales above is in £.) In 2002, GSK Belgium supplied US\$ 81.1 million (£ 50.7 million) worth of vaccines to UNICEF.²⁰ Total vaccine procurement by UNICEF that year amounted to approximately US\$ 220 million (£ 138 million), and GSK was by far the greatest supplier. The largest part of these supplies must have been hepatitis B vaccines. GSK is also one of the primary suppliers of vaccines to the WHO and the Pan-American Health Organisation (PAHO).²¹

UNICEF Supply Division, GSK Contract Awards 2001 - April 2004.

Awarding date	Drug	Value (US\$)	Company division
July 2003	Pharmaceuticals	363.520	GSK UK
April 2003	Pharmaceuticals	143.194	GSK UK
December 2002	ARV drugs	577.221	GSK UK
January 2002	Hepatitis B, Measles-Mumps-Rubella (MMR), Measles-Rubella (MR) vaccines	1.268.500	GSK Belgium
May 2001	Hepatitis B vaccine, funded by the Global Fund for Children's Vaccines (GFCV) for GAVI	204.150.000	GSK Belgium
May 2001	Anti-infective oral dosage forms	125.000	GSK UK

Source: http://www.unicef.org/supply/index_12/141.html.

²⁰ See http://www.unicef.org/supply/supply_division_annual_report2002.pdf. The value of actual purchases in this year does not correspond with the value of contracts awarded 2002. This is caused by contracts for long term arrangements for up to 3 years (notably the contract for GFCV Hepatitis B vaccine supplies).

²¹ <http://www.gsk.com/about/rd.htm>.

2 CSR policy: general

2.1 CSR issues in the pharmaceutical sector

The MVO-Platform, a coalition of Dutch civil society organizations and trade unions, understand by Corporate Social Responsibility (CSR) *'a process in which corporations take responsibility for the social, ecological and economic consequences of their actions - throughout their product and service delivery chain - making themselves accountable, and engaging in a dialogue with all those involved.'*²²

Some of the CSR issues that may be considered most important for the pharmaceutical sector are related to access to medicines in developing countries. These include the following:

- Industry lobbying for intellectual property protection
- Pricing policy for medicines
- R&D for developing countries' diseases
- Drugs donations policy
- Participation in Global Public-Private Initiatives (GPIs) on health

These issues will be dealt with in the next chapters.

Apart from access to medicines, other critical CSR issues in the pharmaceutical sector are the following:

- Drugs safety
- Drug promotion and advertising
- Clinical trials
- Indigenous knowledge
- Bribery, corruption and fraud
- Workplace health, safety and environment

For a discussion of these issues, see the *Sector profile of the pharmaceutical industry* by SOMO.

2.2 Positive and negative publicity

Positive and negative publicity on CSR performance is helpful to get an impression of the strong and weak aspects of a company's CSR performance. The selection below mentions some main issues only.

²² MVO Platform (2003). CSR Frame of Reference.

On the positive side, GSK was awarded for its environmental reporting in 2004. Furthermore, in 2003 it was recognized for leadership in fighting tropical infectious diseases by the American Society of Tropical Medicine and Hygiene.²³

Recent negative publicity on various CSR issues includes the following. This is a selection of major cases since 2002 on different issues.

- In June 2004, GSK was accused of hiding research data suggesting that its anti-depressant drug Paxil was ineffective and unsafe for children and adolescents, increasing the risk of suicide.²⁴ Related to this event, GSK announced that it was increasing transparency on clinical data by creating an electronic database on company-sponsored clinical trials.²⁵
- In May 2004, GSK was accused of fraudulent manoeuvres to extend patent protection over its anti-depressant Paxil and its antibiotic Augmentin, in order to prevent generic competition.²⁶
- In May 2004, GSK settled a dispute with its shareholders over perceived excessive remuneration for CEO Jean-Pierre Garnier. A previously proposed remuneration package of up to \$35 million, including bonuses, stock options and pension arrangements, at a time when shareholder return was declining.²⁷
- In 2004, GSK was charged by the US Internal Revenue Service (IRS) with underpaying US\$ 5.2 billion of taxes on profits on sales in the US between 1989 and 1996.²⁸
- In 2003, GSK was accused of changing drug names to overcharge the US healthcare provider Medicaid by US\$ 89 million.²⁹
- In 2002, GSK was accused of bribing doctors in Italy and Germany to prescribe more of its products. Bribes would have consisted of gifts such as free holidays, stereo systems, wine and cash and in Italy, doctors would have prescribed 7-8% more products of GSK per year.³⁰

In 2002, GSK was one of the top donors to political parties and candidates in the US election cycle, donating US\$ 1.3 million.³¹ Most of the support went to the Republican Party, which is most likely to defend the interests of the branded drug industry. The main domestic policy goals of the industry lobbying efforts are the following:³²

²³ GSK Corporate Sustainability Report 2003.

²⁴ Financial Times (June 3, 2004). GSK faces Spitzer suit over Paxil data.

²⁵ GSK press release (June 18, 2004). Glaxosmithkline announces major advance in on-line access to clinical trial information. See <http://www.gsk.com/media/pressreleases.htm>.

²⁶ Financial Times (May 5, 2004). NY sues GSK over patent manoeuvres.

²⁷ Financial Times (May 18, 2004). GSK pay reforms appease investors.

²⁸ <http://www.transnationale.org>.

²⁹ L'Expansion (April 17, 2003). Bayer et Glaxo condamnés pour surfacturation.

³⁰ The Guardian (February 13, 2003). GSK british drugs giant in italian bribery investigation; Financial Times (March 15, 2002). German doctors accused of taking bribes.

³¹ The Center for Responsive Politics. <http://www.opensecrets.org>.

³² Washington Post (November 21, 2002). Election Gives Drug Industry New Influence in Congress.

- to pass legislation that provides prescription benefits to the 40 million elderly and disabled people in the Medicare program;
- to prevent price controls or a list of preferred drugs that leaves out other medications;
- to fight legislation that would speed the approval and marketing of generic drugs;
- to oppose legislation that makes it easier for to import cheaper drugs from Canada;
- to oppose any limitations to public drug advertising;
- to limit damages in lawsuits on product liability.

2.3 Policies

GSK's mission is *'to improve the quality of human life by enabling people to do more, feel better and live longer'*. Its key values are performance with integrity, entrepreneurial spirit, focus on innovation, a sense of urgency, and passion for achievement. In 2003 the company formally adopted a set of 10 Corporate Responsibility Principles, identifying its key CSR issues. These can be summarized as follows.³³

1. Employee practices. GSK will treat employees fairly, encourage workforce diversity, and offer safe and healthy working conditions.
2. Human rights. GSK commits itself to upholding the Universal Declaration of Human Rights of the UN, the guidelines for Multinational Enterprises of the Organization for Economic Cooperation and Development (OECD), and the core labour standards of the International Labour organization (ILO).
3. Access to medicines. GSK will continue R&D on medicines for developing countries, find sustainable ways to provide acces to medicines, and seek partnerships to support this.
4. Leadership and advocacy. GSK will establish its own standards in CSR and seek to influence others.
5. Community Investment. GSK will invest in health and education programmes and in partnerships for health in developed and developing countries.
6. Engagement with stakeholders. GSK will engage a range of stakeholders and communicate openly about its CSR approach.
7. Standards of ethical conduct. GSK expects employees to meet high ethical standards and to adhere to the Corporate Responsibility Principles.
8. Research and innovation. GSK will ensure that its products are well evaluated and tested on safety, effectiveness and quality.
9. Products and customers. GSK will promote its products in line with high ethical, medical and scientific standards.
10. Caring for the environment. GSK will minimize waste generation and material and energy use.

³³ GSK Corporate Responsibility Report 2003, p3.

Various of these principles include an explicit commitment to comply with all applicable laws and regulations. A short elaboration of policies on various CSR issues is provided below.

With regard to **employment practices**, GSK's seeks to increase (US) workforce diversity and the number of women in management positions. There is a system of individual Performance and Development Planning to further personal development of employees.³⁴

GSK has a Code of Conduct that deals with **business integrity** in general. It specifies that employees must comply with the law and company policies, avoid conflicts of interest, and report any violations of the code.³⁵

For **drug testing**, GSK adheres to industry standards for the Conduct of Clinical Trials & Communication of Clinical Trial Results.³⁶ This code was developed in 2002 by the Pharmaceutical Research and Manufacturers of America (PhRMA), with the participation of GSK.³⁷ It contains standards and guidelines for the protection of research participants, good clinical practices, research objectivity, and the disclosure of meaningful clinical trial results regardless of the outcome.

GSK has a policy on the **animal research** that is required for R&D and the regular testing of some vaccine products. The company is committed to reduce the number of animals per study, to refine the research methods and to replace them with alternative methods whenever possible.³⁸

GSK recognizes that all nations have sovereignty over their **biological resources and indigenous** knowledge and supports the UN Convention on Biodiversity (CBD), which asks for the protection of these resources.³⁹

GSK has a corporate policy on **Pharmaceutical Marketing and Promotion Activity**, which prohibits bribery and other inappropriate ways of persuading doctors to prescribe GSK medicines. It adheres to the marketing code of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).⁴⁰ In addition, GSK introduced new regional marketing codes in 2003.⁴¹

³⁴ GSK Corporate Responsibility Report 2003, p23.

³⁵ <http://www.gsk.com/ser/2001/ser01/ser3.html>.

³⁶ <http://www.phrma.org/publications/policy/2002-06-24.430.pdf>.

³⁷ GSK Corporate Responsibility Report 2003, p32.

³⁸ GSK Corporate Responsibility Report 2003, p28.

³⁹ CoreRatings (2003). *Philanthropy or Good Business? Emerging market issues for the global pharmaceutical industry*. See <http://www.coreratings.com>. For a general information on the protection of indigenous knowledge, see SOMO (2004). *Sector profile of the pharmaceutical industry*.

⁴⁰ For a short discussion of marketing codes, see SOMO (2004). *Sector profile of the pharmaceutical industry*.

⁴¹ GSK Corporate Responsibility Report 2003, p1, 19.

For Environment, Health and Safety (EHS), GSK has a Plan for Excellence. The company has set improvement targets for EHS parameters with reference to 2001 baseline data and normalized by sales. Targets for 2005 include a 15% reduction in illness rate and lost time by injuries, a 10% reduction in water use, a 15% reduction in hazardous waste disposal and the elimination of CFC emissions.⁴²

2.4 Implementation and governance

CSR is managed by a corporate, cross-functional management team. This team coordinates the development and implementation of GSK's CSR policy and is responsible for the monitoring and reporting of CSR performance. GSK has a Corporate Responsibility Committee, consisting of three non-executive directors, that meets several times a year to review company performance and provide high level guidance on all CSR issues. Furthermore, GSK has a Risk Oversight and Compliance Council that coordinates internal control and manages major business risks, including CSR issues.⁴³

In 2002 GSK started a certification process to ensure understanding of the responsibilities related to the company's the code of conduct. 9,000 high and mid-level managers had completed certification by 2003. Concerns about compliance with applicable laws and company policies can be raised with a Corporate Compliance Officer. There also exist confidential GSK Integrity Helplines to clarify questions of employees about CSR issues. Compliance is monitored internally by the Finance, Human Resources, Legal, Compliance and Internal Audit Departments together.⁴⁴

GSK's marketing codes are available in local languages and provided to all sales and marketing employees. The company has developed a manual on sales and marketing practices and all new and existing employees receive compliance training. In 2003, the training was completed by over 10,000 employees, about a quarter of the total sales force.⁴⁵

GSK conducts annual management surveys to measure employee satisfaction.⁴⁶ It is estimated that the majority of manufacturing staff, which is about a third of the total workforce, is represented by trade unions.⁴⁷

2.5 Supply chain responsibilities

⁴² GSK Corporate Responsibility Report 2003, p22.

⁴³ <http://www.gsk.com/about/responsibility/management/index.htm>; GSK Corporate Responsibility Report 2003, p4.

⁴⁴ GSK Corporate Responsibility Report 2003, p18, 29.

⁴⁵ GSK Corporate Responsibility Report 2003, p19.

⁴⁶ <http://www.gsk.com/about/responsibility/management/index.htm>; GSK Corporate Responsibility Report 2003, p4, 29.

⁴⁷ <http://www.gsk.com/about/responsibility/people/freedom.htm>.

In 2003, 28 suppliers were audited for EHS standards.⁴⁸ Under its second Corporate Responsibility Principle, GSK has committed itself to international human rights and core labour standards. It expects suppliers, contractors and business partners to observe these standards too and in 2003 the company started introducing binding clauses on human rights standards into contracts with suppliers. Over 400 key suppliers have been requested to confirm compliance with these standards. Human rights issues have been included in EHS audits of suppliers. If contracting companies violate these standards, GSK will first try to work towards compliance and regularly perform audits. Contracts will be terminated if improvements are insufficient.⁴⁹

2.6 Stakeholder involvement

In its annual Corporate Responsibility report, GSK provides a short description of the communication and interaction with various types of stakeholders. Regular communication takes place with the following groups:

- Employees
- Healthcare professionals
- Governments and other authorities
- Investors
- Non-Governmental Organizations (NGOs) and communities
- Scientists
- UN agencies

For EHS policies, there exist consultations with community neighbours that may be affected by the company's activities and with external experts.⁵⁰ However, the outcomes of GSK's interaction with stakeholders are not always clear.

2.7 Transparency and reporting

In 2003 GSK published a Corporate Responsibility Report that address the whole range CSR issues identified by GSK's new Corporate Responsibility Principles. This report combines the contents of the separate EHS Report and Corporate & Social Responsibility Report for 2002. It deals with CSR governance and implementation structures and contains comprehensive and detailed information on company policies. Reporting on actual performance varies among CSR issues. For example, detailed information is given on EHS performance, women in management positions, and R&D diseases relevant for developing countries. On the other hand, the report does not mention the findings of internal monitoring on compliance with the company's Code of Conduct for business ethics and marketing codes. Implementation results on human rights and core labour issues are not given. Employment practices other than US workforce diversity, gender equality, personal development and workplace safety are not described.

⁴⁸ GSK Corporate Responsibility Report 2003, p5.

⁴⁹ GSK Corporate Responsibility Report 2003, p24.

⁵⁰ GSK Corporate Responsibility Report 2003, p20.

Most CSR issues and operational aspects are also addressed in the company's elaborate annual reports. The GSK website contains well-structured sections on CSR, with even more detailed descriptions of company policies, and it contains some specific information that is not included in reports. Furthermore, from 2001 on, GSK publishes a separate annual 'Facing the Challenge' booklet that describes progress made in its contribution to improving healthcare in developing countries.

2.8 Independent verification

In the CSR Frame of Reference, a document created by the coalition of Dutch civil society organizations and trade unions for CSR, 'independent verification' is described as verification carried out by organizations not linked to the company in question, and with the full trust of the stakeholders involved.⁵¹ Such organizations could be independent analysts, NGOs or trade unions, for example. Independent or other external verification of CSR performance is not mentioned in GSK's Corporate Responsibility Report and does not seem to form part of the company's CSR approach. Animal research is an exception in this respect: all practices of GSK in this area are evaluated and accredited by the independent Association for Assessment & Accreditation of Laboratory Animal Care (AAALAC).⁵² The EHS report is also externally verified.

2.9 Conclusion

Comparing GSK's Corporate Responsibility policy with the CSR Frame of Reference of Dutch civil society organizations and trade unions,⁵³ the policy covers a broad range of CSR issues. The recent formulation of Corporate Responsibility Principles and the integration of different reports support a comprehensive CSR strategy. A few issues such as taxation and competition are not explicitly addressed, though. Possible forms of irresponsible behaviour in the area of competition includes participation in cartels and price-fixing. Such practices occur in the pharmaceutical industry and cause excessive drug prices. Taxation refers to the tax payments in different countries, which depend on the distribution of company profits between local subsidiaries in different countries and the corporation. This distribution is affected, among other things, by the prices a subsidiary charges for internal transactions.

It is positive that GSK is paying increasing attention to CSR standards in its relations with suppliers. The company is assuming responsibility for CSR standards in its supply chain, and because of its strong market position, it is likely to have a significant influence on the CSR standards of contractors. The recognition of wider company responsibilities is a sign of strong commitments to CSR.

⁵¹ MVO Platform (2003). CSR Frame of Reference.

⁵² GSK Corporate Responsibility Report 2003, p28.

⁵³ MVO Platform (2003). CSR Frame of Reference.

The company is highly transparent about its CSR policies and has a clear governance structure on CSR. The amount of CSR information provided in various reports and on the company website demonstrates a strong commitment to transparency. Yet with regard to CSR performance, transparency is high on some issues but low on others. It seems that external verification (beyond animal testing and EHS) is not an integral part of GSK's approach and the results of internal monitoring are not communicated. As a consequence, it is not clear how some of the company's policies operate in practice. On some areas like environment, health and safety, GSK shows clear progress in CSR performance. On the other hand, recent negative publicity suggests that the company does not always live up to its standards and indicates serious violations of laws, the Code of Conduct, marketing codes and the industry code on the conduct of clinical trials.

It is positive that GSK explicitly refers to Human Rights, ILO core labour standards and the OECD guidelines for multinational enterprises in its Corporate Responsibility Principles. The endorsement of generally accepted international standards helps to establish a bottom line for CSR performance. Especially GSK's commitment to the OECD guidelines is a welcome initiative. These guidelines are both detailed and comprehensive, but not frequently endorsed by individual companies. However, negative publicity again suggests that GSK does not always conduct its business in line with the OECD guidelines.

3 CSR policy: medicines for developing countries

3.1 Patents

GSK stresses the need for strong patents protection for its drugs to incentivise research and development. It believes strong intellectual property rights around the world are vital to the success, innovation and sustainability of the pharmaceutical industry. Its policy is to obtain patent protection on all products of importance discovered or developed through its R&D activities.⁵⁴ The company indicates that any decisions to lift patent protection will be made on a case-by-case basis.⁵⁵ GSK believes that TRIPS⁵⁶ is *'flexible enough to allow public health interests to be addressed within a strong Intellectual Property Rights (IPR) framework'*.⁵⁷ The company therefore considers that *'neither patents nor TRIPS are a key barrier to access to medicines in the developing world and focus on them takes attention away from the real barriers'*.⁵⁸

Usually GSK is not considered a hard-liner among pharmaceutical companies with regard to lobbying for enhanced patent protection.⁵⁹ The company has stated that it is not lobbying developed country governments to press for 'TRIPS-plus' legislation (intellectual property protection beyond TRIPS requirements) in their bilateral dealings with developing countries.⁶⁰ GSK spent US\$ 6.0 million on lobbying in 2000.⁶¹

The company provided the following statement to clarify its position on IPR protection:

'GSK does not seek any strengthening of the TRIPS agreement through the WTO. However, TRIPS allows for considerable flexibility in implementation by WTO member countries, so they can address their own particular social and economic welfare concerns. As a result, some laws are implemented in ways which are more supportive of innovation by the pharmaceutical industry than others. GSK reserves the right to persuade countries to introduce innovation-friendly implementation of TRIPS. By the same token, the company accepts the rights of others to argue for different interpretations which may work to the detriment of innovation. GSK may not agree with or support these interpretations;

⁵⁴ GSK Annual Report 2003, p24.

⁵⁵ CoreRatings (2003). *Philanthropy or Good Business? Emerging market issues for the global pharmaceutical industry*. See <http://www.coreratings.com>.

⁵⁶ TRIPS: the World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights. For an overview of recent developments on TRIPS related to access to medicines, see SOMO (2004). *Sector profile of the pharmaceutical industry*.

⁵⁷ Statement of GSK in reaction to the draft report, 14 September 2004.

⁵⁸ <http://www.gsk.com/about/responsibility/intellectual/index.htm>.

⁵⁹ Communication with J. Brant, Oxfam International, 5 May 2003.

⁶⁰ Oxfam, VSO & Save the Children (2002). *Beyond philanthropy: the pharmaceutical industry, corporate social responsibility and the developing world*, p16.

⁶¹ The Center for Responsive Politics.

*however, they recognise national governments' freedom to implement as they choose within the flexibilities in TRIPS.'*⁶²

In 2000, Glaxo Wellcome (one of the two companies that merged to form GSK) sought to halt the import of Duovir, a generic version of Combivir, into Ghana. Duovir was manufactured by the Indian generics company Cipla at a cost of about US\$ 1.74 for a daily treatment.⁶³ At that time, Glaxo Wellcome offered Combivir in Ghana at a reduced price of \$2 a day. It is alleged that Glaxo Wellcome threatened to take Cipla to court.⁶⁴ Also in 2000, Glaxo Wellcome was accused of preventing Cipla from exporting Duovir into Uganda in a similar dispute.⁶⁵

The company denies that it threatened with court action, though. GSK provided the following account of what happened in the case of Ghana:

*'In August 2000, Glaxo Wellcome wrote to Cipla, who were marketing Duovir in Ghana, advising them that the company held patents in Ghana covering the constituent active ingredients in Duovir, and that importation of Duovir into Ghana represented an infringement. Based on the limited scope of the imports the company stated that it did not intend to seek immediate redress, and court action was not threatened. Since the creation of GSK [in December 2000] similar letters have not been issued.'*⁶⁶

Cipla stopped exports to the country and the distributor of the drug in Ghana stopped distributing Duovir supplies that had already arrived as well.⁶⁷ However, Glaxo Wellcome's claims of exclusive marketing rights, backed by four patents, were invalid. Three of these were issued before Ghana allowed patent protection for pharmaceuticals and the fourth was on a type of Efavir that was not used in Duovir. Glaxo Wellcome was therefore accused of deliberately lying to scare off generic competitors.

Since then, GSK granted a voluntary license in October 2001 to Aspen Pharmacare, the largest generics producer in sub-Saharan Africa, for the production of Retrovir, Efavir and Combivir. The license was valid for to supplies to the public health sector in South Africa and Zimbabwe. GSK forewent any royalties on the drugs, and Aspen has agreed to contribute 30% of net sales to an NGO providing support for AIDS education and services.⁶⁸ At that time GSK did not grant a license for the private health sector in these countries,

⁶² Statement of GSK in reaction to the draft report, 14 September 2004.

⁶³ Wall Street Journal (December 1, 2000). Glaxo attempts to block access to generic AIDS drugs in Ghana.

⁶⁴ Health Gap (December 23, 2000). GlaxoSmithKline snatches drugs from poor Ghanians with AIDS.

⁶⁵ <http://www.cptech.org/ip/health/firm/glaxo.html>.

⁶⁶ Statement of GSK in reaction to the draft report, 14 September 2004.

⁶⁷ Health Gap (December 23, 2000). GlaxoSmithKline snatches drugs from poor Ghanians with AIDS.

⁶⁸ Wall Street Journal (October 8, 2001). Glaxo licenses AIDS drugs to generics firm.

which remained the exclusive domain of GSK. The corporation used to charge ARV prices in the private health sector about four times as high as generic prices.⁶⁹

In October 2003, the South African Competition Commission ruled that GSK and Boehringer Ingelheim had contravened the country's Competition Act of 1998. The Competition Commission found that companies had charged excessive prices for their ARVs and that they had refused to issue licenses to generic manufacturers in return for a reasonable royalty.⁷⁰ This was widely regarded as a victory for access to medicines for poor populations, limiting the power of pharmaceutical companies. It is perceived that this outcome would permit the granting of compulsory licenses for the production of ARVs.⁷¹

GSK responded by extending the license to Aspen Pharmacare to cover the public and private sectors in all countries in sub-Saharan Africa. In December 2003, GSK reached a settlement with the Competition Commission which prevented the case being passed on to the Competition Tribunal. Under the terms of the settlement, GSK agreed to grant up to a further three licences to other drug manufacturers on similar terms to the license for Aspen Pharmacare.⁷² Since then, the company has announced the granting of licences to Thembalami Pharmaceuticals (June 2004) and Feza Pharmaceuticals (August 2004). As of September 2004, the company reports it is also making progress towards reaching agreement in relation to another voluntary licence.

GSK regards the license to Aspen Pharmacare as an experiment, because it has no experiences with such arrangements. It is expected that the licences will be able to sell the licensed ARVs at prices below GSK prices. The impact on GSK's business and ability to continue to support the marketing of ARVs in Africa remains to be seen. By granting licenses for ARVs, GSK also wants to demonstrate that there are many other, more fundamental obstacles to access to medicines than patents, such as limited healthcare infrastructure. Although the license had been granted in October 2001, by June 2004 the generic medicines had not entered the market yet, because Aspen did not receive approval from the South African government until July 2004.⁷³ Hence, GSK was right in the sense that selectively lifting patent protection has not led to a swift improvement in access to ARVs.

⁶⁹ Health Gap (17 October 2003). *South African Competition Commission announces stunning victory for access to cheaper drugs, holds GlaxoSmithKline and Boehringer Ingelheim responsible for excessive pricing and other anti-competitive practices*; GSK (2004). *Facing the Challenge: Two years on*.

⁷⁰ *South African Competition Commission finds GSK and BI responsible for 'excessive pricing' and 'abuse of market position'*. HIV Treatment Bulletin Vol. 4 No. 10, December 2003/January 2004. See <http://www.i-base.org.uk/pub/htb/v4/htb4-10/South.html>.

⁷¹ MSF Press release (16 October 2003). *MSF Welcomes Decision of South African Competition Commission to Promote Access to Medicines*. See

<http://www.accessmed-msf.org/prod/publications.asp?scntid=17102003935123&contenttype=PARA&>;

Health Gap (17 October 2003), see note 69.

⁷² Health Gap (17 October 2003), see note 69.

⁷³ Interview with J. Frain, Vice President of GSK Global Community Partnerships department, Vice President of GSK Global Community Partnerships department, 1 June 2004.

Patent flexibility has not been limited to ARVs. In 2003 GSK granted a license to the Brazilian government for the production of measles-mumps-rubella (MMR) vaccines for its own population. The deal included a technology transfer and supply component as well.⁷⁴

3.2 Preferential pricing

GSK has since long been supplying vaccines at preferential prices to UNICEF and other organizations for use in developing countries. These vaccines are procured through tenders. Preferential pricing agreements have been extended beyond vaccines recommended in the WHO's Expanded Programme for Immunisation to include combination vaccines for public immunization programmes. GSK's older malaria drugs have also been supplied at preferential prices through tenders for some time.⁷⁵

Preferential pricing for ARVs and newer anti-malarials started more recently. In 1997 GSK pioneered preferential pricing for ARVs, cutting the prices of Retrovir and Eпивir by 75%. Such price cuts have a positive effect on access to medicines. In 2000 GSK became a founding member of the Accelerating Access Initiatives (AAI), a partnership that seeks to increase access to ARVs in developing countries. Negotiations for ARV prices under the AAI have been heavily criticized, because in the past most pharmaceutical companies used to negotiate preferential prices on a case-by-case basis with individual countries. Governments were required to offer advantages to the company in exchange, such as refraining from resorting to generic drugs, or to keep medicine prices secret. Such negotiations therefore limit the transparency and reliability of preferential prices, and yield sub-optimal outcomes for developing countries.⁷⁶ At present GSK negotiates individual pricing arrangements with middle-income countries only.

In April 2001, GSK came under fire for the pricing of Ziagen, of which it is the patent holder. Ziagen is an ARV drug. It is not a first line HIV/AIDS therapy in developing countries. Ziagen was developed by the University of Minnesota using primarily public funds. Nonetheless, GSK priced the drug out of reach for developing countries. This situation was heavily criticised by the Health GAP coalition.⁷⁷

In 2001 GSK published its strategy paper *Facing the Challenge*, which articulated its policies and approach to improving healthcare in the developing world. This paper formalised the company's preferential pricing policy and also extended eligibility to more customers, countries and medicines.⁷⁸ In September 2002 and April and October 2003, the not-for-profit prices of ARVs were yet further reduced. GSK emphasizes that these prices

⁷⁴ GSK Corporate Sustainability Report 2003.

⁷⁵ <http://www.gsk.com/about/pricing.htm>.

⁷⁶ Act Up Paris (15 May 2002). "Accelerating Access" serves pharmaceutical companies while corrupting health organizations. Press release.

⁷⁷ Health Gap (April 21, 2001). *Open letter to Mr. Yudof, president of the University of Minnesota*.

⁷⁸ GSK (2001). *Facing the Challenge: Our contribution to improving healthcare in developing countries*.

are sustainable: the company does not make a profit, but the prices do cover the costs. This means that GSK can sustain the supply of these products for as long as they are needed.⁷⁹

The latest reduction of preferential prices for ARVs, in October 2003, coincided with the ruling of the South African Competition Commission that the prices charged by GSK were excessive. However, GSK claimed that price cuts in 2003 resulted from improvements to GSK's HIV/AIDS drugs manufacturing process, and economies of scale achieved. The company recently reaffirmed its committed to lower preferential prices whenever possible.⁸⁰ Current preferential prices of the GSK's ARV drugs and newer anti-malarials are shown below.

GSK's not-for-profit prices for ARVs and fixed-dose combinations.

Drug	Formulation	Price end 2003 (US\$/year)	Price end 2002 (US\$/year)
Epivir (3TC)	150 mg tablets	69	234
Retrovir (AZT)	300 mg tablets	212	438
Ziagen	300 mg tablets	887	986
Combivir	300/150 mg tablets	237	621
Trizivir	750 mg tablets	1241	1642
Agenerase	150 mg capsules	3103	n/a

Source: <http://www.gsk.com/about/pricing.htm>; MSF (1 December 2002). *Untangling the of price reductions: a pricing guide for the purchase of ARVs for developing countries.*⁸¹

GSK's not-for-profit prices for newer anti-malarials, at end 2003.

Drug	Price per max. adult treatment course (US\$)	Price per tablet (US\$)
Lapdap 80 (High strength)	0.29	0.05
Lapdap 15 (Low strength)	0.15	0.02
Malarone	12.00	1.00
Halfan	1.40	0.23

Source: <http://www.gsk.com/about/pricing.htm>.

GSK now offers its full range of ARVs and anti-malarial medicines at preferential prices. It sets a single not-for-profit price for public sector customers, aid organizations (including NGOs) and UN agencies in all least developed countries and other countries in sub-Saharan Africa, plus all projects fully-funded by the Global Fund to fight AIDS, TB and Malaria (GFATM). This means that its not-for-profit prices are now available in over 100 countries. The offer does not cover the private health sector in these countries, where GSK charges

⁷⁹ Communication with J. Frain, 21 September 2004.

⁸⁰ GSK Annual Report 2003, p28-29.

⁸¹ See <http://www.accessmed-msf.org/upload/ReportsandPublications/91220021653552/Final.pdf>.

prices for its branded medicines that are sometimes several times higher.⁸² In sub-Saharan Africa, employers who offer HIV/AIDS care and treatment directly to their staff through workplace clinics or similar arrangements are also eligible.⁸³

The single not-for-profit prices are listed in the tables above. GSK points out that its not-for-profit prices are comparable with generics. The latest version of MSF's pricing report⁸⁴ shows that Combivir, at the delivered price of 65 cents a day, is available at US\$ 237 per patient per year. This compares with the lowest generic price of 54 cents (\$197 per patient per year) and an average generic price of 70 cents (\$258 per patient per year). The generic prices do not include any freight or delivery charges, and onerous conditions may apply.

For middle income developing countries, public sector prices are negotiated on a case-by-case basis bilaterally or through the AAI. GSK recently reached an agreement with China for the supply of six ARV drugs, including Eпивir and Retrovir, at a reduced price up to 2006.⁸⁵ In exchange, the Chinese government will lift all import duties for the medicine.⁸⁶ It could not be found whether export duties are also lifted other drugs. The Chinese government will distribute the ARVs for free.

Before this agreement GSK did not market Eпивir in China, even though the drug was patented and registered. GSK does sell Combivir in China, a combination therapy of Eпивir and Retrovir, at a price of almost US\$ 3000 per year. This is more than ten times the company's preferential price for least developed countries. GSK also sells a related medicine in China called Heptodin, containing the same active ingredient as Eпивir in a different dosage, for the treatment of hepatitis B. Hepatitis B currently affects far more people in China than HIV/AIDS. Heptodin is GSK's best-selling drug in China, generating annual sales of US\$ 60-80 million, and might explain why GSK has been reluctant to sell Eпивir in China.⁸⁷ Under the new agreement, China will purchase Eпивir at a reduced price only for use against HIV/AIDS. The drug against hepatitis B will still be sold at market prices.⁸⁸

⁸² Health Gap (October 17, 2003). South African Competition Commission announces stunning victory for access to cheaper drugs, holds GlaxoSmithKline and Boehringer Ingelheim responsible for excessive pricing and other anti-competitive practices.

⁸³ GSK (2004). Facing the Challenge: Two years on; GSK Annual Report 2003, p28-29.

⁸⁴ Based on the 6th Edition of the MSF price guide dated 19 April 2004

⁸⁵ Xinhuanet (15 July 2004). *AIDS patients expect cheaper drugs*. See http://en.ce.cn/National/Government/200407/15/t20040715_1237123.shtml.

⁸⁶ De Volkskrant (13 July 2004). China koopt goedkope aidsremmer 3TC.

⁸⁷ China Daily (18 May 2004). *China can lead new fight in war on AIDS*. See http://en-1.ce.cn/Life/health/t20040518_871019.shtml.

⁸⁸ *Affordable AIDS Drug to be Available*. Xinhua News Agency (5 July 2004). See <http://www.casy.org/chron/medicine.htm>.

Supply agreements are required for the delivery of preferentially-priced ARVs.⁸⁹ As of December 2003, GSK had 175 arrangements, covering 56 least developing countries. These included 50 agreements with developing country governments signed under the AAI and 17 agreements with employers. During 2003, over 11 million Combivir tablets were supplied at preferential prices.

GSK regards preferential pricing as a new business model that is difficult to design.⁹⁰ It stresses that medicine prices should be sustainable and cover production costs, so that the supply can be sustained for as long as required. GSK states that it does not make profits on its preferentially priced ARVs and anti-malarials, but fully recovers its production costs.⁹¹ Preferential pricing is perceived as a kind of implicit contract between GSK and society, in which the developed world pays for R&D costs and compensates for the low medicine prices in developing countries.⁹² GSK states that a key consideration in its differential pricing offers is not to distort national health priorities. These offers therefore apply to a range of medicines and not to a single drug.⁹³

Five pilot projects have been set up in collaboration with NGOs to assess the impact and implications of offering a wider range of products at preferential prices in Tanzania, Uganda, Nigeria, Zambia, and Malawi. So far GSK has found that there is insufficient healthcare capacity and infrastructure in these countries to distribute medicines even at low prices.⁹⁴ Reports about these pilot projects were not yet available.⁹⁵

GSK notes that its offers of not-for-profit prices require commitments from governments to avoid price referencing and curb parallel imports.⁹⁶ Price referencing means that preferential prices may be used as a reference by healthcare providers in high income countries for negotiating lower drug prices. Parallel import is the diversion of preferentially priced medicines to high income markets, where they can be re-sold with high profits. In 2002, there was evidence of preferentially priced products destined for Africa returning to Europe. At one time GSK had to call back all its stocks of ARV drugs in the Netherlands and Belgium, because it was not sure whether they had been delivered through a secure supply chain due to parallel imports.⁹⁷ GSK now supplies preferentially

⁸⁹ MSF (December 1, 2002). *Untangling the of price reductions: a pricing guide for the purchase of ARVs for developing countries*. The MSF report is available at <http://www.accessmed-msf.org/upload/ReportsandPublications/91220021653552/Final.pdf>.

⁹⁰ M. Hunter (2003). *Report of a meeting organized by INSEAD business school and the IPPPH*. Paris, France, 30 June - 1 July 2003.

⁹¹ GSK Annual Report 2003, p28.

⁹² Interview with J. Frain, Vice President of GSK Global Community Partnerships department, 1 June 2004.

⁹³ Oxfam, VSO & Save the Children (2002). *Beyond philanthropy: the pharmaceutical industry, corporate social responsibility and the developing world*.

⁹⁴ GSK (2004). *Facing the Challenge: Two years on*; GSK Annual Report 2003, p28-29.

⁹⁵ Communication with J. Frain, 20 September 2004.

⁹⁶ GSK Annual Report 2003.

⁹⁷ Interview with J. Frain, Vice President of GSK Global Community Partnerships department, 1 June 2004.

priced ARVs in special packs and is seeking to colour differentiate the tablets themselves as well.⁹⁸

3.3 R&D

GSK claims it has the most extensive portfolio of products and R&D projects for diseases of the developing world (DDW), including the prevention and treatment of HIV/AIDS, TB and malaria. There exists a special team, based in Spain and the UK, dedicated to R&D for these diseases. Projects of this team are prioritised on their public benefits, GSK does not expect any commercial returns.⁹⁹ A similar group exists for vaccine research in Belgium. GSK does not describe any explicit targets the allocation of R&D resources to diseases of the developing world, though.¹⁰⁰

At present, GSK has some 20 programmes of particular relevance to the developing world in its R&D pipeline. These are shown in the table below.

GSK development pipeline for diseases relevant to developing countries (at end 2003).

Stage	Vaccine and drug candidates
Preclinical	Vaccines, ARVs, drugs against malaria, TB and other diseases
Phase I	HIV and dengue fever vaccines, ARVs
Phase II	Malaria and other vaccines, malaria drug
Phase III	Rotavirus and pneumococcus vaccines, ARV fixed-dose combination of Ziagen and Epivir, malaria and visceral leishmaniasis drugs

Source: GSK Corporate Responsibility Report 2003, p12.

The company reckons that there are two main possibilities to recover the R&D expenses for these medicines (assuming that this is not possible in high income markets). These two options are R&D partnerships and the procurement of a drug by a donor government or other donor organization.¹⁰¹

GSK is increasingly involved in GPPIs for the development of medicines for developing countries.¹⁰² It considers these partnerships essential to maximize the combined expertise for the development of a medicine.¹⁰³ GPPIs also offer financial support for R&D programmes. The development of the rotavirus and pneumococcus vaccines is supported by the Global Alliance for Vaccines and Immunization (GAVI), for example.¹⁰⁴ GSK carries

⁹⁸ GSK Annual Report 2003.

⁹⁹ M. Hunter (2003). *Report of a meeting organized by INSEAD business school and the IPPPH*. Paris, France, 30 June - 1 July 2003; GSK (2004). *Facing the Challenge: Two years on*.

¹⁰⁰ See also Oxfam, VSO & Save the Children (2002). *Beyond philanthropy: the pharmaceutical industry, corporate social responsibility and the developing world*, p20.

¹⁰¹ Interview with J. Frain, Vice President of GSK Global Community Partnerships department, June 1, 2004.

¹⁰² GSK Annual Report 2003, p28-29.

¹⁰³ <http://www.gsk.com/about/rd.htm>.

¹⁰⁴ <http://www.vaccinealliance.org>.

out the phase III clinical trials for the rotavirus vaccine in countries in Latin America, instead of first introducing it in high-income countries.¹⁰⁵ Latin America is hardest hit by the rotavirus, which causes diarrhoea, and GSK estimates that on this continent the disease causes the hospitalization of 10 million children per year. However, GSK explains that the trials will also be much cheaper in Latin America than in Europe or the USA, whereas reasonable infrastructure for the trials is available.¹⁰⁶

3.4 Conclusion

Since its 2001 policy paper *Facing the Challenge*, GSK has a comprehensive and progressive policy on access to medicines in developing countries. The company shows a strong commitment to improve access to medicines and is quite transparent about its policies as well as about its performance.

The license for generic production of Combivir, Eпивir and Retrovir for sub-Saharan Africa indicates that, in certain cases, GSK is prepared to lift patent protection in order to enhance access to medicines. The company offers a considerable range of medicines and vaccines at preferential prices and sets a single not-for-profit price for all customers that meet a set of objective criteria. Furthermore, GSK has a large R&D portfolio for diseases relevant to developing countries and is also committed to undertake R&D projects on which it does not expect a commercial return. Such an approach should be strongly welcomed. However, GSK's track record on access to medicines is not free from controversies, as the disputes in Ghana and Uganda and the more recent rulings of the South African Competition Commission indicate.

¹⁰⁵ GSK Corporate Responsibility Report 2003, p11.

¹⁰⁶ Interview with J. Frain, Vice President of GSK Global Community Partnerships department, June 1, 2004.

4 GPPI involvement

4.1 Overview

In its 2001 strategy paper *Facing the Challenge: Our contribution to improving healthcare in developing countries*,¹⁰⁷ GSK notes it does not have the mandate, expertise or resources to address all healthcare problems in developing countries. However, GSK identifies three key areas in which it can make a valuable contribution:

- R&D for diseases that particularly affect developing countries
- Sustainable preferential pricing for least developed countries and Sub-Saharan Africa
- Community investment

In each of these three areas, GSK is actively involved in GPPIs and other types of partnerships. An overview of the many GPPIs to improve health in developing countries in which GSK currently participates is provided below.¹⁰⁸

R&D partnerships

- Lapdap Antimalaria Product Development (LAPDAP)
- Medicines for Malaria Venture (MMV)
- Malaria Vaccine Initiative (MVI)
- Paediatric Dengue Vaccine Initiative (PDVI)
- Global Alliance for TB Drug Development (TB Alliance)

Preferential pricing framework

- Accelerating Access Initiatives (AAI)
- Global Alliance for Vaccines and Immunisation (GAVI)

Community investment partnerships, for enhancing access to medicines and strengthening local health infrastructure

- Global Alliance for the Elimination of Lymphatic Filariasis (GAELF)
- GSK African Malaria Partnership (AMP)

GSK also supports the aims of the Roll Back Malaria (RBM) Partnership, a partnership with a global coordinating function. Although the company is closely involved with the RBM Partnership, this GPPI does not have an official partners list and GSK would not describe itself as a partner.

In addition, GSK participated in three GPPIs that have come to an end:

- Action TB Programme (ATBP)
- Intercompany Collaboration for AIDS Drug Development (ICCADD)
- Malarone Donation Programme

¹⁰⁷ http://www.gsk.com/community/downloads/facing_the_challenge.pdf.

¹⁰⁸ Participation in these GPPIs was confirmed in correspondence with J. Frain, Vice President of GSK Global Community Partnerships department, 27 April 2004 (except for the RBM Partnership). See also <http://science.gsk.com/about/disease.htm>.

GSK participates in several other GPPIs too that are not specifically aimed at developing countries, including the Pharmaceutical Security Initiative (PSI) and Single Nucleotide Polymorphisms Consortium (SNP). Contrary to IPPPH information, GSK is not currently involved with the Multilateral Initiative on Malaria (MIM).¹⁰⁹

This chapter provides a description of GSK's involvement with all current GPPIs related to health in developing countries listed above. It focuses on community investment partnerships.

4.2 R&D partnerships

Lapdap Antimalaria Product Development (LAPDAP)

This R&D partnership started as an informal collaboration between SmithKline Beecham and the WHO. Discussions with the UK Department for International Development (DFID) began in 1998. In March 2001, a formal agreement was signed between GSK and the Special WHO Programme for Research and Training in Tropical Diseases (WHO/TDR). DFID, GSK and the WHO/TDR provided the main funding for LAPDAP. The University of Liverpool and the London School of Hygiene and Tropical Medicine were other major partners. The aim of the partnership was *'to develop LAPDAP as an effective oral treatment for uncomplicated malaria, primarily for use in Sub-Saharan Africa (...) at preferential prices for public health programmes.'*¹¹⁰ The drug has been approved in the UK in July 2003 and subsequently in 14 African countries. If the use of the drug is adopted by national malaria control programmes, it will be made available to them at not-for-profit prices. GSK will retain the right to market the product in the private health sector.

Medicines for Malaria Venture (MMV)

The Medicines for Malaria Venture (MMV) is a WHO-led partnership to fund the development of anti-malarial drugs and drug combinations for distribution in poor countries. The MMV supports ongoing research projects of GSK in collaboration with academic institutions. In 2003 GSK expanded its agreement with the MMV to include the development of CDA, a combination of chlorproguanil, dapson and artesunate. In April 2004 a new agreement was signed between GSK, WHO/TDR and the MMV to develop a new-fixed dose artemisinin combination therapy drug (ACT) for the treatment of malaria.¹¹¹

¹⁰⁹ Correspondence with Ms. J. Frain, 15 September 2004. The MIM receives support from the Wellcome Trust, an independent research-funding charity. The Wellcome Trust was historically linked to the Wellcome Foundation Ltd., a pharmaceutical company that later became Wellcome plc and is now part of GSK. The Wellcome Trust has a small stake in GSK. See <http://www.wellcome.ac.uk/en/1/awtvishis.html>.

¹¹⁰ <http://www.ippph.org>.

¹¹¹ Correspondence with Ms. J. Frain, Vice President of GSK Global Community Partnerships department, 27 April 2004; GSK (2004), *Facing the Challenge: Two years on*; GSK Corporate Responsibility Report 2003.

Malaria Vaccine Initiative (MVI)

The Malaria Vaccine Initiative (MVI) was established in 1999 to accelerate the development of malaria vaccines and ensure their availability in the developing world. The Gates Foundation provided initial funding of US\$ 50 million and a further 100 million in 2003. The MVI is administered by Program for Appropriate Technology in Health (PATH), a US-based not-for-profit organization. Partners include malaria experts, government agencies, public and private research institutions, and vaccine producers. In July 2003, GSK started phase II paediatric trials for its malaria vaccine candidate in Mozambique.¹¹² The MVI also supports several other vaccine candidates in phase I and II trials. The patents on the products that are being developed belong to the private companies, but if they abandon the development or subsequent marketing of the product, the MVI retains back-up development and manufacturing rights.¹¹³

Paediatric Dengue Vaccine Initiative (PDVI)

The Paediatric Dengue Vaccine Initiative (PDVI) was established in 2001 to accelerate the development and introduction of a dengue vaccine. Grants from the Rockefeller Foundation (\$1 million) and Gates Foundation (\$55 million) provide support for clinical trials in Asia and South America. GSK is one of the pharmaceutical industry partners and has a dengue vaccine candidate in phase I trials.¹¹⁴

Global Alliance for TB Drug Development (TB Alliance)

The aim of the Global Alliance for TB Drug Development is to accelerate the discovery and development of better TB drugs. It manages a portfolio of promising compounds that can be used for TB drugs, and provides funding and scientific and management guidance to support the rapid development of compounds. The TB Alliance pursues patent protection to ensure that new TB drugs are affordable for developing countries.¹¹⁵ Information on the precise nature of GSK's involvement with the TB alliance was not found. GSK does not communicate about this GPPI in its report or on its website.

4.3 Accelerating Access Initiative (AAI)

The Accelerating Access Initiative (AAI) is a cooperative endeavour of UNAIDS, the World Health Organization, UNICEF, the UN Population Fund, the World Bank, and seven research-based pharmaceutical companies. These are Merck, Abbott Laboratories, Boehringer-Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GSK and Hoffmann-La Roche.

¹¹² GSK Corporate Responsibility Report 2003, p11.

¹¹³ <http://www.ippph.org>.

¹¹⁴ <http://www.ippph.org>, <http://www.pdvi.org>.

¹¹⁵ <http://www.ippph.org>.

Participants in the AAI are committed to working with governments, international organizations, and other stakeholders to find ways to broaden access while ensuring appropriate and safe drugs use for HIV/AIDS-related illnesses. The Statement of Intent, signed by the AAI partners in May 2003, is attached to this report as Appendix 1.

Each individual company is separately implementing access programmes with appropriate stakeholders. GSK's commitment under the AAI consists of the preferential pricing of its ARVs, which is described in chapter 3. As of December 2003, the number of HIV patients in Africa receiving ARV treatments provided by all AAI companies combined had risen to about 150,000.

4.4 Global Alliance for Vaccines and Immunisation (GAVI)

Short description

The Global Alliance for Vaccines and Immunization (GAVI) was established in 1999 to expand the widespread use of vaccines in developing countries. The alliance has a broad range of partners, including the WHO, UNICEF, the World Bank, developing countries, donor countries and pharmaceutical companies from both industrialized and developing countries.¹¹⁶ The Gates Foundation created the Vaccine Fund of US\$ 750 million to support it. GSK is represented to the partnership by the developed countries' industry member in the board, currently the president of Chiron. This board seat rotates among pharmaceutical industry partners, which coordinate their position among themselves and speak as a group.

The pharmaceutical industry, as a whole, has made five commitments to GAVI:

- To supply high quality vaccines
- To support training and education in developing countries
- To continue R&D on vaccines for developing countries
- To support advocacy and awareness raising
- To continue to develop technologies to facilitate administration and distribution of vaccines

Each industry partner decides on its own approach. Apart from the general industry commitments and the Guiding Principles of GAVI, commitments of partners may be recorded in Board meetings and other partners' meetings. However, there does not exist a Memorandum of Understanding or other formal agreement that specifies the commitment and responsibilities of partners to GAVI.¹¹⁷

GAVI has identified three priority diseases for expanding access to existing vaccines that are widely used in industrialized countries. These are Hepatitis B, *Haemophilus influenzae* B

¹¹⁶ <http://www.vaccinealliance.org>.

¹¹⁷ Communication with S. Gilchrist, 21 June 2004.

and yellow fever.¹¹⁸ GSK is a major supplier of Hepatitis B vaccines to GAVI, with supplies worth over US\$ 200 million for the period 2001-2004.¹¹⁹ GAVI also wants to speed the development and introduction of rotavirus and pneumococcus vaccines through Accelerated Development and Introduction Plans (ADIPs). These are detailed project plans designed to coordinate and advance the work of the public and private sectors, with the aim to shorten the lag between approval of the vaccines for use in the industrialized world and their introduction in developing countries. Each ADIP is managed by an ADIP team.¹²⁰ GSK receives support from GAVI for the current phase III clinical trials of its rotavirus and pneumococcus vaccine candidates. GAVI contributes US\$ 30 million for the development for each of these two vaccines.¹²¹ As there is a substantial market for the rotavirus vaccine in high income countries too, it is possible that the support for accelerated development yields business benefits for the company too.

Criticism on GAVI

On several occasions, the focus of GAVI on the introduction of relatively expensive vaccines has been criticized. According to some, the selected diseases would not have the highest priority from a public health point of view. It has been suggested that the burden of Hepatitis B in India has been misrepresented at 200,000 deaths per year, whereas the figure may be as low as 5,000, and that natural immunity against *Haemophilus influenzae* type b exists in India and Turkey. Hence, it is argued that the benefits of these two vaccines have been overestimated.¹²²

As of July 2004, five-year support from GAVI to 70 developing countries for new and under-used vaccines, including new combination vaccines, was estimated at US\$ 654 million. This sum does not include the support for the development of new vaccines and is additional to US\$ 337 million of five-year commitments for basic immunization services support plus US\$ 86 million over three years for injection safety.¹²³ Some have been argued that the massive resources available for the introduction of under-used vaccines would be better used in other ways and that more priority should be given to the strengthening of health infrastructure in developing countries.¹²⁴

¹¹⁸ Merck Annual Report 2000, see <http://www.anrpt2000.com/16.htm>.

¹¹⁹ See the chapter *General characteristics*, under the section on *Medicines of special importance to developing countries*, UNICEF supplies.

¹²⁰ http://www.vaccinealliance.org/home/Resources_Documents/Policy_Technical/Accelerating_RD/index.php

¹²¹ http://www.vaccinealliance.org/home/Media_Center/Press_Releases/press_110203.php.

¹²² V. Taneja (29 April 2002). *Silence of WHO is deafening*. In: BMJ, see <http://www.bmj.com>; J. M. Puliyeel (21 February 2004). *Plea to restore public funding for vaccine development*. The Lancet, vol. 363; R. K. Ohja e.a. (8 February 2002). *Vaccine promotion is circumventing market forces*. In: BMJ, see <http://www.bmj.com>.

¹²³ http://www.vaccinealliance.org/home/Support_to_Country/Country_Status/index.php.

¹²⁴ M. Starling, R. Brugha, G. Walt, A. Heaton & R. Keith (2002). *New products into old systems: The GAVI from a country perspective*. London: Save the Children; G. Yamey (23 November 2002). *WHO in 2002: Faltering steps towards partnerships*. In: BMJ, 325, 1236-1240.

Furthermore, the newly introduced vaccines are now delivered free of charge, but the current funding commitments are for a period of five years only. The governments of developing countries will not be able to support the use of the vaccines themselves. Therefore some consider the programme unsustainable.¹²⁵ GAVI has been addressing this issue of financial sustainability. A special Financing Task Force exists and GAVI requires countries receiving Vaccine Fund grants to prepare a Financial Sustainability Plan. However, a recent study shows that large funding gaps after the end of Vaccine Fund support continue to exist. The two main reasons for this problem are that the high prices of the new vaccines have not come down and that multi-year commitments from bilateral donors are still lacking. The key assumptions that GAVI would drive the prices of the vaccines down and act as a catalyst for further support by partners have not sufficiently borne out.¹²⁶

4.5 Global Alliance for the Elimination of Lymphatic Filariasis (GAELF)

Short description

The Global Alliance for the Elimination of Lymphatic Filariasis (GAELF) is GSK's flagship community programme, currently operating in 34 countries. It was founded in 1998 by GSK (then SmithKline Beecham) and the WHO with the aim to eliminate lymphatic filariasis (LF) by 2020. GSK has committed to provide as much of the drug albendazole as required until the disease is eliminated. The albendazole is donated to the WHO and at country level, the drug is administered through national programmes. Countries have to submit proposals for national programmes to the WHO.

94 million albendazole tablets were donated in 2003, valued at US\$ 18 million (£11 mln) at wholesale acquisition cost. In addition, GSK contributed grants of approximately US\$ 1.5 million (£1 mln) and staff and expertise to the partnership. Albendazole supplies since the start of GAELF amount to 240 million treatments. The total quantity of required albendazole for 20 years is estimated at 6 billion tablets, with an associated wholesale value of roughly US\$ 1 billion.¹²⁷

GAELF and the MDP

Merck, another pharmaceutical company, participates in GAELF through the Mectizan Donation Programme (MDP) and donates the drug Mectizan for treatment of LF in African countries where LF and onchocerciasis co-exist. In these countries, the WHO recommends

¹²⁵ *Expert meeting 'internationale publiek-private initiatieven in de gezondheidszorg'*. 28 November 2002, Breukelen, The Netherlands; M. Starling, R. Brugha, G. Walt, A. Heaton & R. Keith (2002). *New products into old systems: The GAVI from a country perspective*. London: Save the Children.

¹²⁶ M. Kaddar, P. Lydon & R. Levine (2 July 2004). *Financial Challenges of immunization: a look at GAVI*. Bulletin of the WHO, 82, 697-702.

¹²⁷ GSK (2004), *Facing the Challenge: Two years on*; GSK Annual Report 2003.

a combination of albendazole and Mectizan as the most effective treatment to prevent LF. In areas where onchocerciasis is not prevalent, either a combination of diethylcarbamazine citrate (DEC) and albendazole or DEC-fortified salt is used to prevent LF. In areas where onchocerciasis occurs, DEC cannot be used because it causes severe complications. GSK is not directly involved with the MDP, but co-funds activities that support the co-ordination of the GAELF and MDP where the two programmes run concurrently.

Donation policy

GSK chose to provide albendazole free of charge because donor funding to buy the medicine was not available and many of the endemic countries could not afford to buy it. This position is similar to that of Merck on the donation of Mectizan to GAELF. Most donor funds are absorbed by other health priorities, notably programmes for HIV/AIDS, malaria and TB. The funding requirements for LF elimination are small when compared to the funds required for these priority diseases.

The first major funding from non-corporate partners came in 2001, when the Gates Foundation gave \$20 million for a period of five years to accelerate the implementation of GAELF.¹²⁸ However, even with albendazole and Mectizan provided free of charge, funds are still falling short of the required amounts to expand the partnership at the intended pace. Several country proposals to join GAELF are unable to commence, pending securing the financial resources to implement the programmes. In Bangladesh, for example, the programme has not scaled up as intended due to lack of donor funds.

Governance

The GAELF is a partnership of the endemic countries, over 40 organisations including GSK, and the WHO. It has a self-governing structure that has recently been changed. The Executive Group (EG) consists of six people, which are elected, and includes one GSK representative. The EG works as a team and GSK brings in technical skills. The company has a very hands-on policy. GSK also supports fundraising for the GAELF by trying to bring in other donors. In the experience of GSK, the relationships and management of GPPIs need some time to develop.

GSK has signed a Memorandum of Understanding with the WHO that specifies its commitments to GAELF. However, this agreement is not publicly disclosed. Independent Regional Programme Review Groups (RPRGs) assess country applications to join the programme and GSK supplies the albendazole accordingly.

Integration with other GPPIs

¹²⁸ <http://www.ippph.org>.

Integration with other GPPIs is currently being considered, for example with malaria partnerships, as malaria and LF are both transmitted by mosquitos. This is being discussed, but is not yet widely practiced. Two reasons for such integration would be the possibility to access malaria funds for the elimination of LF and improved cooperation to decrease the burden on local healthcare services.¹²⁹

4.6 GSK African Malaria Partnership (AMP)

The GSK African Malaria Partnership (AMP) is a three year initiative, established in April 2002, to develop behaviour to reduce the likelihood of infections and improve the management of the illness. The target countries of the partnership are Benin, Burkina Faso, Ghana, Mali, Sudan, Togo and Uganda, seven African countries with a high disease burden. Two million people in these countries should be reached, particularly young children and pregnant women. GSK prepared a shortlist of the country programmes to be funded and provided a £1.5 million grant.

The country proposals had to be signed by the national malaria control departments, which are directly involved with the partnership. Other partners are the NGOs Freedom From Hunger, AMREF and Plan International. Freedom From Hunger runs a micro-credit scheme in West Africa and provides malaria education through its meetings. On the invitation of GSK, the Roll Back Malaria Partnership was involved with the selection of the AMP programmes. Roll Back Malaria is another GPPI that seeks to coordinate different initiatives and efforts to fight malaria.

GSK will fund the AMP for a limited period of three years, as is the case with most of its community partnerships. During this period, the corporation seeks to demonstrate the success of the partnership, which should then be able to pursue other donors to take over from GSK.¹³⁰

¹²⁹ Interview with J. Frain, 1 June 2004, and reaction to the draft report, 14 September 2004.

¹³⁰ Interview with J. Frain, Vice President of GSK Global Community Partnerships department, June 1, 2004.

5 GPPI policies¹³¹

5.1 The rationale for GPPIs

GSK is proud of its leading role in community partnerships that support healthcare. The support for such partnerships is one of the three areas where GSK considers it can make a valuable contribution to improve health in developing countries, next to R&D and preferential pricing. For the delivery of preferentially priced medicines to poor people, infrastructure is very important. GSK therefore partners with NGOs that can deliver medicines, like Médecins sans Frontières (MSF), and with employers that have private healthcare facilities, like Unilever, De Beers and Heineken.¹³² R&D partnerships for diseases of the developing world are one of the possibilities to cover the costs of drug development.

Although the global community partnerships (GCPs) of GSK have a philanthropic nature, they also serve to build pride with employees. Most employees are enthusiastic about the contributions made by GSK. The company perceives that this kind of business benefit has now become generally accepted, although in the past this used not to be the case. In addition, these partnerships help to build relationships with governments and other stakeholders.

There might be other business benefits than those mentioned above by GSK. The Hepatitis B vaccine supplies to GAVI generate large businesses for GSK. Furthermore, even if pharmaceutical companies would not have a large influence on the decisions taken by a partnership, their close involvement provides them with valuable first-hand business information. This can be useful to predict sales volumes, or to approach countries that will receive support for drug or vaccine procurement in an early stage. Public support for research and development may also yield business benefits, especially if the intellectual property rights are held by the company. In the case of the rotavirus vaccine, for example, there is a substantial market in high income countries too. The GAVI support for accelerated development may therefore generate business benefits even if supplies to developing countries would be with marginal or no profits.

GSK explains that the albendazole donations to the GAELF do not provide the company with a competitive advantage by lowering the marginal production costs of Zentel, a commercial drug for de-worming with the same active ingredient, because the production of albendazole and Zentel are separated. Albendazole is manufactured in France and Zentel is manufactured in other countries. The two drugs have a different colour and shape as well.¹³³

¹³¹ This chapter is largely based on an interview with J. Frain, Vice President of GSK Global Community Partnerships department, 1 June 2004.

¹³² GSK (2004), Facing the Challenge: Two years on.

¹³³ Communication with J. Frain, 21 September 2004.

As the funds that are spent on GCPs are taken from company profits, GSK elaborately reports to its shareholders how this money is spent. Shareholders have the opportunity to express their opinion about these partnerships but rarely do so. However, the corporation considers it has a sort of license, in the form of an unwritten contract with its shareholders, to allocate funds to community initiatives. GSK explains that its commercial success allows it to sustain a broad range of philanthropic partnerships. In many cases GSK's support consists of funding for healthcare programmes only and in principle these grants could be provided by other companies or other donors as well.

GSK considers that it is ultimately the responsibility of developing countries governments to provide healthcare and to allocate funds to it. The company is aware that GPPIs clearly entail a risk of draining resources away from other healthcare programmes. It therefore prefers GPPIs to be country-led. GAELF is an example of this, where countries have to submit proposals for national programmes to the partnership.¹³⁴

5.2 Management of GPPIs inside the company

The management of GPPIs inside GSK depends on the nature of the partnership.

- Global community partnerships (GCPs) are managed by a special GCP department. At the time of the merger (2000) this department was established to focus philanthropy on community-based healthcare. These partnerships are purely philanthropic and include several GPPIs, such as GAELF and the AMP, as well as other types of partnerships.
- Partnerships involving vaccines are managed by the biological department of the corporation.
- R&D partnerships are managed by the R&D department.

GSK does not have a corporate foundation for its community investment grants. However, there exist country-based foundations in France, Italy, Spain, the Czech republic, Romania, the USA and Canada.¹³⁵

In order to prevent conflicts of interests, the GCP department claims it operates independently from the rest of the corporation. Decisions about drug donations are made on the basis of need and with the endorsement of the local GSK country manager whose commercial market could be correspondingly reduced.

GSK's support for the GAELF is a long-term forward commitment. The generic drug albendazole is also sold as a de-worming agent by GSK under the brand name Zentel. The Zentel tablet looks differently to prevent diversion of the donated albendazole product.

¹³⁴ The company statements in this section come from the interview with J. Frain, 1 June 2004 (see note 131).

¹³⁵ GSK Annual Report 2003, p31.

The GAELF is working towards integrating LF elimination with de-worming programmes, but there is still some way to go.

In other GPPIs, the risk of conflicts of interests is usually limited by a formal agreement specifying the outline of the partnership. Like the partnerships themselves, these agreements and safeguards differ from case to case. For Lapdap, for instance, the agreement specifies GSK will be allowed to sell the drug in private markets, whereas the corporation committed itself to provide Lapdap at low prices for developing countries. GSK notes that it is this kind of formal commitments to public health goals that distinguishes GPPIs from commercial partnerships.

5.3 Selection of Global Community Partnerships

The GCP department prefers to identify the initiatives it supports itself, along the lines of its strategic priorities. The general focus is on health and education. Thus, the company identifies the issues it wishes to support and searches for partners working on these issues. GSK also receives requests for grants, but only responds to these if the programmes fit well with the priorities of the corporation. Partners and GCPs are selected on the basis of the ability of partners to run a programme, the infrastructure available, and the scale and type of the programme.

5.4 GPPI strategies

GSK has three ways of providing medicines at low prices or for free:

- Albendazole donations to GAELF
- Humanitarian donations (mainly antibiotics)
- Preferential pricing offers

GSK recognizes the importance of not distorting national health priorities, which is a key consideration in its differential pricing offers.¹³⁶

GSK stresses that medicine prices should cover production costs and in general considers medicine donations to be unsustainable in the long term. GSK explains that its policy on preferential prices for ARVs, anti-malarials and vaccines is based on the enormous requirements for these products and the 'open-ended' nature of their need. However, a difference is made between different kinds of treatments. The medicine donations to GAELF are considered an exception, because the objective of GAELF is finite - the elimination of the disease. Although the medicine donations to this partnership are huge, the company explains that they are not unlimited. The disease will be eliminated in an area if the population has received an annual treatment for five subsequent years, which is the lifetime of an adult worm. This contrasts with e.g. ARV treatment, a lifelong therapy. It therefore becomes feasible to sustain the albendazole donations.

¹³⁶ Oxfam, VSO & Save the Children (2002). *Beyond philanthropy: the pharmaceutical industry, corporate social responsibility and the developing world.*

Similarly, GSK donates products for humanitarian relief, for instance in the case of disasters and refugee situations. These are also contributions for limited time periods. The donations consist for 90% of antibiotics. They are made at the request of governments and NGOs and are always be approved by the recipients. NGO partners for humanitarian assistance include AmeriCares, InterChurch Medical Assistance, MAP International and Project HOPE.¹³⁷ Offers are generally from existing inventories, although they may also be specifically manufactured for donations.

5.5 Valuation of drug donations

The valuation of drug donations is important, because it has been estimated that in some cases the tax exemptions granted for drugs donations may cost the US government even more than the procurement of preferentially priced drugs or generics.¹³⁸

Some of the drug donations that are provided by manufacturing facilities in the USA qualify for tax deductions. These donations are valued at US wholesale acquisition prices, both for the calculation of tax exemptions and for public reporting purposes. GSK reports mentions that the decision what medicines (intended for donations) are produced where depends on logistics and production capacities, not on possible tax benefits. Antibiotics are mostly produced in the USA because of the infrastructure available. Albendazole is produced in France and the donations of this medicine do not yield tax benefits. The stated value of Abendazole donations is based on its lowest wholesale value, which is at approximately \$0,20 in India.

5.6 GCP budget and total support through GPPIs

At the corporate level, a separate budget for GCPs is allocated to four geographical areas: the UK, the rest of Europe, the USA, and the rest of the world. In 2003 the total value of GSK's community activities was £338 million, including product, cash and in-kind donations.

In the UK, GSK provides support to programmes in the areas of health, medical research, science education, arts and the environment. For the rest of Europe, the focus is on improving children's health only. In the USA, the focus is on improving public education and access to healthcare for children and seniors, while in the rest of the word it is healthcare education and capacity. Apart from the GAELF and AMP, GSK's other global disease programme is Positive Action, which focuses on HIV/AIDS education and care. Positive Action supports 38 local programmes in 34 countries, including several sub-Sahara Africa countries, the UK, China, and Russia.¹³⁹

¹³⁷ GSK (2004). GlaxoSmithKline's Commitment to Community Investment.

¹³⁸ A. Guilloux (October 2000). Hidden price tags: disease-specific drugs donations, costs and alternatives. MSF.

¹³⁹ Source: GSK Annual Report 2003, p29-31.

In addition to corporate funding for healthcare programmes, there are also local initiatives and other kinds of support such as medicine donations. An overview of the resources contributed to the various components of Global Community Investment is provided below.

GSK community investment (in £ million).

Programme component	Corporate	Local companies	Total support
<i>Cash contributions</i>			
UK	4	7	11
Rest of the world	n/a	n/a	68
<i>Total cash contributions</i>			79
<i>Product donations</i>			
Patients Assistance Program	125	-	125
Product donations for humanitarian assistance ¹⁴⁰	105	-	105
Albendazole donations	11	-	11
<i>Total product donations</i>			241
Total (cash + products)			320

Source: GSK Annual Report 2003, p29-31, and calculations by SOMO.

Total support includes £ 17 million of management expenses for the various programmes. 59% of total support is in the form of GSK products, 40% is in cash and 1% is in kind.¹⁴¹ The total support, valued at £338, was equivalent to 5.3% of GSK's profit before tax.¹⁴²

¹⁴⁰ These values are based on US acquisition prices. Recipient country acquisition prices might be lower.

¹⁴¹ GSK Corporate Responsibility Report 2003. p5, 15. The 59% of product donations does not match with the figures in the table; the £241 of product donations is 71% of the total support of £338. The reason for this discrepancy is not clear; perhaps humanitarian assistance or US product donations include a cash component too.

¹⁴² GSK Annual Report 2003, p29.

6 Analysis and conclusions on GPPIs

GSK is engaged in many GPPIs and other 'community partnerships'. The company has a clear public policy on healthcare in developing countries and the company's support for GPPI forms part of this larger policy. GSK dedicates considerable resources to GPPIs. The company is quite transparent on the amount of cash contributions and donations. Total contributions to developing countries are large, both in absolute terms and as a proportion of profits, and roughly equal to total support to uninsured patients in the US and other projects in the US and Europe.

Tax exemptions do not play a major role in GSK's programmes for developing countries. This conclusion is supported by the fact that the albendazole donations, which are estimated to become very large over a period of twenty years, do not generate any tax benefits. GSK is transparent about the valuation of donations and consistently indicates in its communications how the value of donations is determined.

GSK pays attention to the issue of sustainability and recognizes that donations are not a structural solution. The albendazole donations are an exception, though. The company explains that donations make sense in this case because of the predictable and finite amount of albendazole that is needed. So GSK uses preferential pricing for newer medicines like ARVs, whereas it donates albendazole, an older medicine that is not protected by patents anymore and exposed to generic competition. Although this may be coincidence, it appears that other pharmaceutical companies make similar choices.

Product donations like albendazole raise several concerns. First, to a large extent the need for donations is caused by a lack of commitment from donor governments. Funds are clearly falling short in the case of GAELF and it is positive that GSK sought to bring in other donors. However, it might also be possible that the large donation programmes of companies like GSK are indirectly enabled by excessive profits on sales in high income countries. Hypothetically, a company that supports GPPIs may at the same time show irresponsible practices in its core-business; recall that GSK recently been accused of fraudulent patent manoeuvres, irresponsible drug promotion and underpaying billions of taxes. This would lead to the paradoxical situation that pharmaceutical companies take over donor government responsibilities, using funds that might have accrued to these governments in the absence of excessive drug prices and tax evasions.

Second, there does exist a market for Zentel (albendazole) in developing countries too, as a de-worming product. The donation of albendazole could therefore have the effect - whether intended or not - of causing unfair competition for generic manufacturers of Zentel. For these reasons, one might consider donor governments funding medicine procurement at preferential prices more appropriate than a company donating medicines for free.

It is positive that global community partnerships are managed by a separate department of GSK that operates independently from commercial operations. There is little doubt about the integrity of this department. However, this does not take away the concerns mentioned above, like donations that are indirectly sustained by irresponsible business practices and unfair competition for generic drug producers. These concerns relate to the operations of the company as a whole.

GSK's involvement with the various GPPIs described in this report suggests that a clear boundary between the responsibilities of the company and the responsibilities of donor governments is lacking. The contributions to global community partnerships, including several GPPIs, consist largely of grants. GSK contributes specific management expertise, but the funds could equally be provided by non-pharmaceutical companies or other types of donors. The support to global community partnerships is therefore merely philanthropic.

Although the commitment of GSK to improve healthcare is of course positive, these grants raise a few concerns. First, philanthropic contributions might be inappropriate when supported by irresponsible business practices, as hypothesised above. Second, merely financial contributions do not support the rationale for partnerships, which generally consists of various partners combining their specific expertise.

In contrast to the vague border with donor government responsibilities, GSK does have a clear and positive approach for dealing with beneficiary countries' governments. The company pays attention to integration with the local healthcare sector and in GPPIs like GAELF the implementation of programmes is country-led.

It is positive that written agreements exist for partnerships in which GSK participates, because this clarifies commitments and interests. It is also positive that R&D agreements, such as for Lapdap, do already include commitments for supply at preferential prices once the drug is developed. However, transparency about these issues is severely lacking because the agreements between partners are not always disclosed, for example in the case of GAELF. Hence, it is not clear if GSK's conditions and different responsibilities fully operate in practice.

The three-year financial commitments to the AMP (and other community partnerships) raise a few questions. This contrasts with the support to GAELF that is not time-restricted. On the positive side, GSK has provided critical initial funding and has clearly paid attention to the issue of sustainability by determining a phase-out strategy of seeking other donors to take over from GSK. However, the three-year period of support is relatively short. Even when success can be demonstrated, it is not sure whether other donors will be available, because there is a general shortage of donor funds as was already indicated by GAELF.

The analysis of GSK's involvement with the GPPIs studied in this report provides a clear picture of the company's role and contributions. It shows that the company has been making valuable contributions and that the initiatives form part of a broader policy for

access to medicines. At the same time, the analysis put forward some concerns about the appropriateness of donations and grants that need to be addressed. There also turns out to be scope for improvements with regard to the low transparency about partnership agreements and the relatively short time-scale of financial commitments.

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