GSK: Profits, Patents and Patients: Access to Medicines

8

N. Craig Smith and Dawn Jarisch

Introduction

On April 22nd 2014, after a difficult year in which GlaxoSmithKline (GSK) had been accused of bribery in China and fined $3 billion by American regulators for marketing malpractice in the US, the pharmaceutical company announced a complex three-part restructuring deal with Swiss giant Novartis. The deal, one of a slew of multibillion-dollar deals in the global pharmaceutical industry, would allow GSK to focus on four key business areas – HIV, vaccines, respiratory conditions and consumer healthcare. It was seen as a win-win deal, offering both companies economies of scale that were increasingly vital for 'big pharma'. Analysts believed it would 'unlock significant shareholder value', not least because it would allow GSK to return £4 billion to investors through a B share scheme.

But would it be a win-win deal for patients? Particularly patients in developing countries where, despite a dramatic drop in the price of first-line antiretroviral (ARV) medicines following a sensational court case in South Africa from which GSK and other pharmaceuticals had withdrawn, millions of people still lacked access to essential medicines and vaccines.

"Today we live longer, healthier lives on average than at any time in history. Global life expectancy increased faster in the last 40 years than it did in the preceding 4000 – but not all groups benefited equally".

Challenging inequalities in health – from ethics to action. Rockefeller Foundation

GSK's mission: "to improve the quality of human life by enabling people to do more, feel better, live longer. We are doing this by developing innovative products and improving access to health care for patients around the world."

N. C. Smith (✉) · D. Jarisch
INSEAD, Fontainebleau, France
e-mail: Craig.SMITH@insead.edu

G. G. Lenssen, N. C. Smith (eds.), *Managing Sustainable Business*,
https://doi.org/10.1007/978-94-024-1144-7_8

While refocusing and re-energising its business portfolio, how best could GSK respond to calls that it had a social responsibility to provide affordable and appropriate medicines and vaccines? How could it reconcile the demands of patients' for treatment with its need to earn profits and protect its patents? Would it pass CEO Andrew Witty's key test of "whether you make decisions that are applauded by society or condemned by society."[1] What would be the effect on GSK's operations in other countries and its business model if it allowed the existing patent regime to be selectively ignored, or it didn't earn enough to finance further drug innovation? It seemed as if the pressure would continue no matter what the company did.

Background Events from 2000

GSK in the Early Years and the HIV/AIDS Pandemic

When GlaxoSmithKline (GSK) was formed on 27 December 2000 through the merger of Glaxo Wellcome and SmithKlineBeecham,[2] both leading pharmaceutical companies in Europe, the idea that providing access to medicine in the world's least developed countries (LDCs) was a corporate social responsibility was beginning to get media and NGO attention. A campaign for access championed by Médecins Sans Frontières was alerting society to the health needs of LDCs. For the World Health Organisation (WHO), health was a fundamental human right; three of the UN's eight Millennium Development Goals[3] were related to health, aimed at reducing child mortality (MDG 4), maternal mortality (MDG 5)and the spread of HIV/AIDS and malaria (MDG 6).

On 11 January 2001, the new CEO of GSK, Jean-Pierre Garnier, made his first in-house address, broadcast to employees around the world by satellite. Describing his aspirations for the company, he said: "The pharmaceutical industry today sells 80% of its products to 20% of the world's population. I don't want to be the CEO of a company that only caters to the rich… I want those medicines in the hands of many more people who need them." Garnier's statement struck a chord with many employees, glad to be working for a company committed to improving health and lives around the world.

At the time, GSK dominated the global market for HIV/AIDS therapies, with a 40% market share. It was the only company involved in R&D on all three top priority diseases of the WHO – malaria, tuberculosis (TB) and HIV/AIDS. Not only was resistance of TB and malaria to treatment increasing, it was estimated that more than 53 million men, women and children had HIV, 3 million had died of AIDS and

[1] Andrew Witty interview WSJ, 2011: http://live.wsj.com/video/does-a-company-have-a-soul/BF2AC683-9FC8-493C-9089-6EEB09646F97.html#!BF2AC683-9FC8-493C-9089-6EEB09646F97

[2] with Glaxo and SmithKline shareholders holding approximately 58.75% and 41.25% of the share capital of GSK respectively. The deal created the second largest research-based pharmaceutical and healthcare company in the world, with a global workforce in excess of 100,000 and a combined market capitalisation of £114 billion.

[3] The eight Millennium Development Goals (MDGs) were established following the Millennium Summit of the United Nations in 2000, with targets to be achieved by 2015.

40 million were living with AIDS.[4] Two thirds of HIV cases were in sub-Saharan Africa. Recognised as a real threat to global social and economic progress, AIDS was declared by the US government to be a threat to international security.

Although it could take several years, most people who were HIV-positive would develop full-blown AIDS as the body's immune system shut down, and there was no cure. Without access to treatment, people could die within 6 months, leaving families and the community devastated. For LDCs the effects were particularly acute, crippling their economies by depriving them of millions of productive employees and orphaning millions of children.[5]

Drug treatment could increase the quality and duration of life for HIV-positive individuals, but cost $10,000–15,000 per patient per year, and required ongoing medical supervision, particularly for the complex "triple drug cocktails". Treatment was therefore beyond the reach of LDCs, where, according to the UN, more than 1.2 billion people (including 291 million in sub-Saharan Africa) were living on less than $1 a day.[6] Less than 1% of HIV/AIDS victims in need of ARV treatment in sub-Saharan Africa were receiving it.

Drawing attention to the price of HIV/AIDS drugs in LDCs, activists argued that patent protection regimes resulted in premium prices that restricted access to essential drugs, resulting in unnecessary suffering and millions dying in the developing world. As James Sherry, then Director of Programme Development for UNAIDS, put it: "The bottom line is that people who are dying from AIDS don't matter in this world."[7]

Glaxo had worked voluntarily with government in LDCs to progressively reduce prices on HIV/AIDS drugs on a country-by-country basis. It even published its discounted price list (other companies kept their lists confidential). But such actions failed to silence the critics, who argued that these price reductions were small and did not constitute a long-term framework to ensure essential drugs reached the world's poor. Garnier was favourably disposed to addressing the HIV/AIDS crisis and the issue of access generally. He felt the industry could do more in partnership with governments and that GSK should be at the forefront, but the sheer scale of the pandemic was overwhelming.

On February 12 2001, Oxfam International, a confederation of 12 NGOs, launched a 'Cut the Cost' campaign aimed at pressuring pharmaceutical companies to make HIV/AIDS treatments available and affordable for people in LDCs. The campaigners argued that enforcement of global patent rules kept drug prices high in LDCs – which they considered morally wrong. Oxfam challenged GSK to offer comprehensive access to essential medicines and redress the balance between treatment in the developing and developed world. Joined by other prominent NGOs such as the Nobel Prize-winning Médecins Sans Frontières and Treatment Action Campaign (a champion of the access issue in South Africa) it became clear that this was a challenge to

[4] International AIDS Vaccine Initiative (IAVI), 2001.

[5] "AIDS in Africa: the Orphaned Continent," BBC News Report at http://news.bbc.co.uk

[6] United Nations Basic Facts, December 2000

[7] Barton Gellman (2000), "The Belated Global Response to AIDS in Africa," Washington Post, July 5 2000, p. A1

the industry's traditional business model. Determining how to respond would have profound strategic implications for GSK and the industry as a whole.

The South African Court Case

In South Africa, where the AIDS pandemic was the main cause of death, the Medical Research Council estimated that over 4 million (20%) adults were HIV-positive, yet only a fraction were aware they had HIV. AIDS activists under the banner of the Treatment Action Campaign, lobbied the government to disregard patent protection of specific drugs to allow generic copies to be made, in contravention of the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, due to come into effect from 2000.

Under intense public pressure, the Minister of Health authorized generic versions of patented drugs to be manufactured or imported and distributed, inciting a consortium of 39 pharmaceutical companies, including GSK, to take court action for violating the TRIPS agreement. The highly publicised case was heard in Johannesburg on 5 March 2001. Dating back to 1998, the dispute about the enforcement of drug licensing and regulatory systems in South Africa was now perceived as a conflict between 'big pharma' defending its intellectual property (patents) and President Nelson Mandela, defending poor people dying from AIDs.

The resulting anger and contempt for drug companies convinced many people that there was a case for patent infringement to give access to lifesaving HIV/AIDS drugs. But there was also another agenda, as Pien later observed, "The geographies have become intermingled and the South African court case made it so. Opinion leaders in the US, Europe and the developing countries have shifted their focus of concern. Availability of a drug was not the core of the problem, but how a company behaved as a corporate citizen. That was the real problem."

In April 2001, the drug companies dropped the case. The *Boston Globe* commented, "With their boardrooms raided and their executives being hounded in the streets, 39 of the world's largest drug makers caved in to public pressure… It was hailed as a stunning triumph for the developing world: A $360 billion industry was brought down by a country that represents just half of one percent of the pharmaceutical market."[8]

Post-merger: Facing the Challenge

But criticism of the industry continued despite its withdrawal. At GSK's AGM on May 21, 2001, campaigners from Oxfam wearing lab coats called for GSK to do more for LDCs by donating a percentage of drug revenues to a "global health fund" of the UN Secretary General. CEO Garnier's unprecedented response took some

[8] Kurt Shillinger, "AIDS Drug Victory Sours in South Africa: Government Still Refusing to Supply AZT," The Boston Globe, 23 April, 2001, p. A8

analysts by surprise. Defending GSK's actions on the access issue, he asserted that the company's priority was public health, not simply shareholder value: "We have to make a profit for our shareholders, but the primary objective of any policy put forward in the industry is public health."

On June 11 2001, in a policy document entitled 'Facing the Challenge: Our contribution to improving healthcare in the developing world', GSK made commitments in three areas:

1. Continuing investment in R&D on diseases that affect the developing world.
2. Offering sustainable preferential (not-for-profit) pricing arrangements in LDCs and sub-Saharan Africa for 'available medicines that are needed most'.
3. Taking a leading role in community activities to promote effective healthcare.

The main emphasis was on developing and providing HIV/AIDS and antimalarial medicines at preferential prices. Sustainability – the ability to deliver over the long term – would be the key criterion for any action. Pien explained the approach:

> *In the establishment of the preferential price, we don't intend to make any profit from it. What we want to do is make it sustainable. So, our internal decision algorithm in determining the preferential price involves fully charging the components of manufacturing, including overhead—so variable costs plus overhead. But we don't try to recover R&D expenditures, we don't try to recover commercial expenses—sales and marketing expenses. But then we get into this problem that is at the crux of health care delivery for HIV/AIDS. How do we get the products into the hands of the people who say that they are going to be in a position to take this drug and do something good with it? In certain ravaged parts of the world, it is impossible to get the products in the hands of the clinics.*

Several NGOs welcomed the GSK policy document. Sophia Tickell, Senior Policy Advisor to Oxfam, commented: "This is really positive. It is better than all the other initiatives the industry suggested." Others remained sceptical.

Access to Medicines and Implementation of the Access Policy

Implementing access proved to be a tough challenge. On 3 October 2002, the Dutch authorities were forced to recall GSK's Combivir and Epivir AIDS drugs after discovering that, "AIDS drugs supplied to Africa at cut rates have been illegally resold in Europe, threatening to undermine a system of preferential medicine pricing for poor countries."[9] More than 35,000 drug packets intended for Africa (with a market value of approximately €15 million) had been resold in the Netherlands and Germany. A GSK spokesman said, "We are appalled and saddened to see this. The victims of this illegal trade are the HIV/AIDS patients of Africa." Because the

[9] AIDS in Africa: the Orphaned Continent, BBC News Report at http://news.bbc.co.uk

packaging intended for Africa was identical to that used in the Netherlands and Germany, all packets had to be recalled from the market for safety reasons.

A 2002 Oxfam[10] report entitled 'Beyond philanthropy' challenged the pharmaceutical industry to adopt policies in five areas: R&D, patents, pricing, joint public/private initiatives and the appropriate use of medicines. Treatment Action Campaign (TAC) and MSF campaigned to 'Fix the Patent Laws'. Protesters said that patents on drugs and prohibitive prices prevented access to affordable medicines for people in developing countries. They argued that big pharma charged the highest price the market would bear, even if that made the product unaffordable for government health programmes and the poor.[11] With its slogan 'Life is priceless: medicine is not', Christian Aid captured the indignation felt when activists asked 'Are profits more important than people's lives?' Big pharma, they insisted, had both the means and a moral obligation to do something, citing article 25 of the Universal Declaration of Human Rights: "everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including… Medical care… Motherhood and childhood are entitled to special care and assistance."

Big pharma countered that patents only represented a small portion of total healthcare costs and that poverty was the real problem, not patents,[12] pointing out that over 95% of the 325 drugs on the WHO's Essential Drugs List were not patent-protected. GSK faced a number of complex dilemmas. If they offered differential prices for people within poor countries, governments elsewhere would ask for the same prices. Not all people within developing countries were poor – why should a millionaire pay less because he lived in a poor country? Countries like India had huge disparities in terms of wealth: how could they assist people living below the poverty line in these countries? What about poor people in rich countries? If they offered lower prices in LDCs, what would stop someone re-exporting and selling at a higher price and pocketing the difference?[13] And which medicines should be selected for lower prices?

Activists advocated the development of generic medicines (infringing patents by copying medicines) as a solution, but pharmaceutical companies argued that if their monopolies/profits were eroded in this way, it would restrict their R&D in the future, and ultimately lead to fewer new drugs and more lives being lost as a result.

GSK felt that an alternative approach was more sustainable, as explained in its second Social and Environmental Report (2003):

> We set our preferential prices for ARVs and anti-malarials at levels that cover direct costs but on which we do not make a profit. In this way we can offer these prices for as long as patients need treatment." By 2004, GSK had supplied 120 million preferentially-priced

[10] In collaboration with Save the Children and Voluntary service Overseas

[11] http://www.globalhealthcheck.org/?p=591

[12] Attaran 2004, how do patents and economic policies affect access to essential medicines in developing countries?

[13] This had happened to GSK when they offered 50% lower prices in Kenya than in UK. As 80% of pharmacy shops in Kenya are run Indians. These Indians resold to cousins with pharmacy shops in UK—Source: Klaus Leisinger 10/4/2011: http://www.youtube.com/watch?v=9drMaDVg2eY

ARV medicines to the developing world. While some welcomed GSKs approach of "opening up developing-world markets to expensive drugs", others charged that "the reality is that preferential pricing is simply a market penetration and patent protection strategy,"[14] or felt that the figures were not set in context, asking "Is the provision of anti-retrovirals… a large percentage of those needed in the developing world or not?[15]

Once the TRIPS agreement[16] came into force in 2005, copying patented medicines became illegal and companies could no longer produce new medicines generically. Some industry observers suggested that hostility between pharmaceutical companies and activists could be avoided if "restricted voluntary licenses were offered for essential medicines in developed countries. This would allow competition to lower prices for branded medicines in developing countries, while preserving profitability in the core pharmaceutical markets in rich countries."[17]

Nevertheless, Oxfam claimed that pharmaceutical companies prevented poor people from accessing inexpensive generic versions of essential medicines through "persistent inflexibility on intellectual property protection, and in some cases active lobbying for stricter patent rules and legal challenges to governments' use of TRIPS public-health safeguards".[18] It argued that: "Society expects pharmaceutical companies – with their privileged access to a global market – to develop necessary products at prices that are affordable, in presentations that are usable, and to market them ethically. The pharmaceutical industry is expected to fulfil these requirements reliably and sustainably, and by so doing, play its part in the wider responsibilities to improve the health of all."

As of 2007, Oxfam applied stringent assessment criteria for access to medicines on which it measured each company's performance on three key dimensions: R&D, pricing strategy and intellectual property (see Exhibit 8.1). GSK was assessed to have achieved "management buy-in" within R&D, to be seeking to "manage reputational risks" in its pricing strategy, and to be "adopting a defensive attitude" towards intellectual property. Helena Vines Fiestas, policy adviser for Oxfam,[19] commented that "GSK is probably the leading company within the sector. But it still falls far short of a desirable position."[20]

---

[14] http://www.ethicalcorp.com/content/pharmaceutical-industry-cross-section-cr-practice, Nov 17, 2003

[15] GlaxoSmithKline's CR Report 2005 – Ignoring the big issues, Jan 15, 2007: www.ethicalcorp.com/content/glaxosmithkline%E2%80%99s-cr-report-2005-%E2%80%93-ignoring-big-issues

[16] The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), an international agreement administered by the World Trade Organization, set minimum standards for many forms of IP, including patents

[17] Attaran 2004, how do patents and economic policies affect access to essential medicines in developing countries?

[18] November 2007, Oxfam briefing paper: 'Investing for life'

[19] In 2007

[20] http://www.ethicalcorp.com/content/glaxosmithkline-%E2%80%93-big-pharma-big-risks

In 2009, when Andrew Witty succeeded Garnier as CEO of GSK, he stated that it was "unreasonable to expect people in poorer countries to contribute to Western shareholders."[21] Witty pledged that GSK would cap prices for its drugs in the world's 50 LDCs at 25% of developed world prices, share patents for dozens of compounds, tackle neglected diseases in the developing world, and invest in health infrastructure. He explained that "Price cannot be a barrier to access. So we need to get the price right and we need to work with the international community to mobilise the resources to pay for it and the infrastructure needed to deliver, not least to remote communities."

But although GSK reduced the price of vaccines and a number of patented medicines in LDCs to no more than 25% of those charged in developed countries, providing that this covered the manufacturing costs, for millions of people its medicines were still not cheap enough. Duncan Learmouth, GSK's SVP of corporate Communications and Global Community Partnerships, admitted: "We are under no illusions that even at 25% of developed world prices, those prices are still high for the developing world."[22] To address the lack of healthcare infrastructure, GSK reinvested 20% of the profits it generated in LDCs back into the countries for strengthening healthcare infrastructure and community programmes.[23] Between 2009 and 2013, this amounted to £15 million (via partners) donations to train frontline community health workers who were the key to getting medicines and vaccines to remote rural areas.

On 30th October 2009, GSK and Pfizer launched a global specialist HIV company, ViiV Healthcare (GSK held 85%, Pfizer 15%), aiming to build on their successes to develop and provide access to HIV treatments and care for people living with HIV. Through ViiV Healthcare, GSK granted voluntary licenses to generic companies for the manufacture and supply of ARV medicines destined for sub-Saharan Africa. ViiV Healthcare made three commitments:

1. A 'not-for-profit' price commitment for its ARV portfolio to government and international procurement agencies such as the Global Fund for AIDS, Tuberculosis and Malaria
2. A £10 million seed fund to "to improve the diagnosis, treatment and care of infants and children living with HIV"
3. To give grants to the Positive Action for Children Fund (PACF) and Positive Action programmes to support a community response to the HIV epidemic

Whilst GSK recognized that "transferring the technology to produce drugs and vaccines is one of the most sustainable ways to breach the access gap between the

[21] Excerpted from Andrew Witty quote during BBC Newsnight, June 13, 2011: https://www.youtube.com/watch?v=AshbyUghJTo

[22] http://www.ethicalcorp.com/communications-reporting/how-gsks-access-medicine-plans-will-shake-big-pharma

[23] *Ibid*.

developed and developing world,"[24] it saw voluntary licenses as a "specific response to a particular set of circumstances" rather than a universal solution.

From 2010, the 'Access to medicines index' ranked big pharma's performance on sharing patents, pricing policies and developing medicine for neglected diseases that affected the poor. This served to give big pharma an incentive to improve access since it could be used as a benchmark to guide investor decisions and drew attention to the notion of social responsibility.

Founded in August 2010, the Developing Countries and Market Access (DCMA) operating unit within GSK aimed "to increase patient access to GSK medicines and vaccines for around 800 million people in least developed countries, while expanding our market presence and ensuring that our business continues to be sustainable."[25] To achieve this, GSK adopted different pricing models in different countries based on wealth[26] and ability to pay. In developing countries it adopted a lower priced/higher volume approach and rewarded salespeople based on volume of medicines delivered rather than sales targets. In middle-income countries it adopted flexible and tiered pricing. In high-income countries, GSK offered support for low-income patients, including pricing according to patient income, monthly payment plans and discount cards. For vaccines, GSK offered tiered pricing.

GSK recognised that while Africa's need for medicines was immense, it did not have the means to pay for them. As Jon Pender, Vice President of Government Affairs for GSK, explained "Africa suffers 24% of the global disease burden, it has 3% of the world health workers and it has 1% of the world's health budget."[27] In April 2011, when GSK issued a statement detailing its policy on Intellectual Property & Access to Medicines in Developing Countries, its commitments had expanded to four:

1. Preferential pricing of our medicines and vaccines
2. Investing in (R&D) that targets diseases particularly affecting the developing world, including pursuing an open innovation strategy
3. Community investment activities and partnerships that foster effective healthcare
4. Innovative partnerships and solutions, such as voluntary licensing

Nevertheless, GSK still did not accept the activists' view of patents: "It is misleading and counter-productive to focus on patents in the access debate. Patent protection stimulates and fundamentally underpins the continued research and development for new and better medicines for diseases including those which occur in the developing world. Without adequate intellectual property protection, the medicines that are needed in the developing world are far less likely to be developed."[28]

[24] GSK corporate social responsibility report 2013

[25] *Ibid.*

[26] Countries where gross per capita income was less than US$1570 would get the lowest prices

[27] Documentary patent or patients for Dutch TV, July 2011

[28] GSK Position on IP-and-access-to-medicines-in-developing-countries, April 2011

It argued that "Companies would not incur the risk and cost of innovative R&D if, shortly after launch of their products, a cheaper copy could be launched by a competitor who had the competitive advantage of not incurring developing costs and risk and who did not develop the market for the product."[29]

In 2012, the Financial Times[30] noted: "Global health programmes, in short, reflect a mixture of philanthropy and self-interest, with recognition of the potential for sales (in the developing world) and the need to maintain a good image a decade after South Africa's legal action against the drug companies over the price of HIV medicines did so much damage to the industry's reputation."

India, a major producer of generic medicines, was dubbed 'the Third World's pharmacy'. Contravening the 2005 TRIPS regulations and at odds with big pharma, India supplied generic drugs[31] to sub-Saharan Africa at prices much cheaper than branded drugs. In 2012, when a controversial EU trade agreement with India sought to stop these copycat medicines, opponents claimed the "IP rules would serve the interests of multinational pharmaceutical companies in Europe while drastically increasing medicines prices for millions of poor people in India and other developing countries."Trade treaties, they insisted, would force people in the developing world to either buy the brand-name products at high prices or die. MSF research found that companies restricted voluntary licences to LDCs and sub-Saharan Africa[32] and the Medicines Patent Pool (MPP) was "limited in its ability to convince patent-holding companies to include developing countries which are at the forefront of bearing the impact of the TRIPS agreement."[33]

In April 2013, the Indian Supreme Court ruled against Novartis's intention to overturn a law that allowed a popular patenting practice in the pharmaceutical industry known as 'evergreening,' which entailed filing and then obtaining multiple patents relating to different aspects of the same medicine. MSF welcomed the landmark ruling: "The Indian government will continue to be able to protect public health against abusive patenting practices and unwarranted monopolies and keep the door open as much as possible for access to affordable medicines for millions of people in developing countries who rely on quality generics made in India."[34]

By 2013, ViiV Healthcare had offered royalty-free voluntary licenses to 16 generic manufacturers to enable them to produce and sell low-cost versions of the full range of GSK's ARV medicines for public sector and donor programmes.[35]

---

[29] GSK policy on Intellectual Property & Access to Medicines in Developing Countries, April 2011

[30] April 23, 2012: http://www.ft.com/cms/s/0/0d2b135a-887b-11e1-a727-00144feab49a.html#ixzz35YxsjQR2

[31] Including over 80% of all medicines used to treat HIV and AIDS

[32] Untangling the Web of ARV Price Reductions, released July 2013 by the international medical humanitarian organisation Médecins Sans Frontières/Doctors Without Borders (MSF) at the International AIDS Society conference in Kuala Lumpur, http://www.msf.org.uk/article/hiv-generic-competition-pushing-down-drug-prices-patents-keep-newer-drugs-unaffordable

[33] *Ibid*.

[34] *Ibid*.

[35] In 2011, ViiV Healthcare and its licensees supplied an estimated 1.1 billion ARV tablets.

Additionally ViiV Healthcare offered not-for-profit pricing to HIV-positive patients in low-income countries and LDCs. It also supported community awareness and training campaigns, including prevention of mother-to-child transmission.

GSK used technology and innovations to improve access to its medicines for people in LDCs, as well as to prevent counterfeiting of its medicine, such as reduced pack sizes and liquid formulations of medicines for children. It partnered with Vodafone to increase vaccination rates for children in Africa by ensuring that vaccines were available when and where needed. Medicines sold in Nigeria included a scratch-off panel with a unique code on the packaging so patients could send a free SMS to check the quality and authenticity of the product.

GSK outlined a number of responsible business commitments to address global health needs as of 2012 – "health for all, our behaviour, our people and our planet". In its 2013 Corporate Responsibility Report, it reported on each area, including six behavioural and 10 health commitments (see Exhibit 8.2). Its access policy seemed to be producing results: between 2010 and 2013 GSK reported a 60% increase in the volume of medicines supplied to least developed countries.[36] Nevertheless, a study it commissioned by the International Centre for Social Franchising in 2013 identified a key problem: "...for the most part, existing healthcare delivery models target the more affluent emerging middle class, rather than the poorest."[37]

From the beginning, donations were a key part of GSKs access strategy.[38] In 2013, it donated £221 million for global community investments and £146 million in medicines. It was particularly proud of its work in actively donating tablets to support the WHO's 2020 goals to eliminate lymphatic filariasis (LF) or 'elephantiasis', a tropical disease caused by a parasitic worm, transmitted via mosquitoes, where a person's arms, legs and genitalia swell to several times their normal size. When the WHO/SmithKline partnership started out in 1997, "more than 120 million" were said to be suffering from LF. By 2013, GSK claimed that its tablet donations had reached over 600 million people.[39] Nevertheless, after 16 years of donations, there were still over 120 million infected, and about 40 million disfigured and incapacitated by the disease.[40]

GSK stated[41] that it wanted "to adapt our business model to improve the availability and affordability of high quality products" so that they could be made "accessible to as many people who need them as possible." It increased the number of pricing tiers for vaccines to seven, based on gross national income per capita (reflecting ability to pay) an approach designed to support countries which committed to vaccination for the long term.

---

[36] GSK corporate social responsibility report 2013

[37] GSK corporate social responsibility report 2013

[38] GSK donated medicines and vaccines in response to natural disasters and planned programmes. In 2008, GSK valued its donations (calculated according to the industrialised retail price), in-cash social investments, and other charitable projects at £124 million.

[39] GSK Corporate Responsibility Report 2013

[40] http://www.who.int/mediacentre/factsheets/fs102/en/

[41] GSK corporate social responsibility report 2013

The supply of medicines was only part of the problem. GSK stated that "We are committed to improving access to our products –irrespective of where people live or their ability to pay– by focusing on the affordability and availability of our products, and investing in strengthening health systems." To ensure that people had access to medicines and services, GSK recognised that it was necessary to train community health workers and explore new healthcare delivery models to "drive out inefficiencies in the procurement, storage, prescribing and use of drugs."[42]GSK felt that this was a "shared responsibility between all sectors of national and global society, including national governments, industrialised donor countries, NGOs, industry and multilateral organisations such as the World Bank, WHO and UNAIDS."[43]

Consequently, collaborations were an increasingly important component of GSK's access strategy. GSK partnered with a number of government organisations and NGOs, including the Global Alliance to Eliminate LF,[44] the GAVI Alliance, the Global Fund to fight AIDS, TB & Malaria, Save the Children Fund, and the World Health Development Organisation. In 2013, GSK committed US $750,000 to the United Nations' 'One million community health workers' campaign[45] which aimed to put a million health workers in rural sub-Sahara Africa by 2015.

> *The reason why we are engaged in these issues is because we think it is the right thing to do for patients and because we think this is the right thing to do for business.*[46]

Research in GSK

In 2013, GSK spent £3.4 billion on R&D, of which £496 million was invested in vaccine R&D, with an estimated return of 13%. This was the most productive R&D year in GSK's history, with five new medicines approved, including a new treatment for HIV (Tivicay, launched through ViiV Healthcare).

GSK operated a large research facility in Spain dedicated to R&D for diseases of the developing world, where its drug development projects were said to be "prioritised by their socio-economic and public health benefits, rather than by their commercial returns."[47] Within the facility, GSK created an 'Open Lab' where independent researchers could access resources and expertise to advance their own research projects. It allowed external researchers to screen GSK's compound library to potentially identify treatments for neglected tropical diseases. By the end of 2013, 38 visiting scientists had used the Open Lab. GSK committed to help eliminate and control 10 neglected tropical diseases affecting 1.4 billion of the world's poorest

[42] GSK policy on Intellectual Property & Access to Medicines in Developing Countries, April 2011

[43] *Ibid.*

[44] GSK were a founding member

[45] GSK corporate social responsibility report 2013

[46] Jon Pender discusses GSK's efforts in Africa, May 22, 2012: www.youtube.com/watch?v=oHKX7gkj9M0

[47] GSK – Our commitment to fighting Malaria, Oct 2013

people by the year 2020. It committed US$10 million to the Global Health Investment Fund to finance the development of medicines, vaccines and interventions for diseases that affected LDCs.

GSK vaccine research was focused on overcoming the challenges encountered during storage and transport (maintaining vaccines at an optimal temperature in remote regions often resulted in wastage) and on developing vaccines against cancer, HIV, malaria, tuberculosis and dengue fever. In 2013, GSK partnered with the Bill and Melinda Gates foundation (BMGF) on a $1.8 million effort to develop heat-stable vaccines.

GSK was the first pharmaceutical company to share its clinical trial results,[48] and shared its findings on 13,500 compounds which had a potential to inhibit the malaria parasite and tuberculosis, including 180 that were particularly promising. The malaria compound information was shared with 160 groups around the world, the tuberculosis compounds with 10 research groups. In 2013, this access to data was expanded to share its clinical study reports and anonymised patient data.

Nevertheless, opponents accused GSK of releasing material from its trials only in response to specific requests, and of hiding behind patient confidentiality to prevent a clear view of trial data, counter to its stated concerns about transparency and advancing research. As psychiatrist Dr. David Healy blogged, "If those of us who have been participants in trials thought some remote risk of a breach of privacy was being used to prevent the disclosure of details that would save someone else's life but threaten GSK"s profits, most of us would likely be horrified."

Vaccines at GSK

Back in 2007, GSK had surprised the world by announcing that it was working on a combination vaccine called Globorix to protect children against diseases such as meningitis A and C, diphtheria, tetanus and hepatitis B. The vaccine cost GSK $400 million to develop. Designed specifically "to meet a pressing public health threat in Africa", GSK did not expect sales of Globorix to recoup the cost of R&D. Whilst Médecins sans Frontières welcomed the news, an anonymous blogger on the "Science of the invisible" blog asked whether Globorix would be "a loss leader", questioning whether GSK was responding to developing countries' healthcare challenges.

GSK was the market leader in vaccines and produced more than 30 vaccines for children and adults (see Exhibit 8.3). Vaccination prevented disease, death and disability, and was thus one of the most cost-effective preventive measures. Yet vaccines were not adequately reaching the developing world. In response, the Global Alliance for Vaccines and Immunisation (GAVI),[49] had been set up to ensure universal access to vaccines and protection against life-threatening diseases. GSK part-

[48] Through the launch of its Clinical Trial Register on the internet in 2004

[49] A public private partnership founded in 2001 between the Bill and Melinda Gates Foundation, WHO, UNICEF and the World Bank as part of the 'Decade of Vaccines Collaboration'

nered with UNICEF, who purchased vaccines on behalf of the GAVI. As vaccines were volume-dependent, this was a win-win – it increased production volumes as GSK sold to more customers, lowered manufacturing costs and improved planning; which allowed GSK to offer lower prices to GAVI.

In 2011, GSK provided the rotavirus vaccine[50] to GAVI at $2.50 per dose, and $5 to fully immunise a child – a 67% reduction on the lowest public price. When GSK sold at these lower prices, it took precautionary measures such as monitoring for unusual sales activity to ensure that low-cost vaccines were not used elsewhere. Allan Pamba, Director of Public Engagement and Access Initiatives, explained "This can, of course, only go so far, but we believe that the potential benefit of low-cost vaccines for people in developing countries outweighs the risk."

In 2013, 862 million vaccine doses were delivered to 170 countries, and over 80% of vaccines sold were used in developing countries. GSK had contributed 15.8 billion doses of the oral polio vaccine and committed to supply 500 million doses of vaccines to GAVI for use in developing countries.[51] Nevertheless, WHO estimated that 22 million children in developing countries still had no access to life-saving vaccines. GAVI estimated that only 5% of children in the world received all 11 essential vaccines. And whilst various vaccines against HIV were being developed, none had proven effective.[52]

GSK followed a three-pronged approach to malaria[53]:

1. Innovation of new malaria medicines and vaccines in partnership with the Medicines for Malaria Venture (MMV)
2. Through the Africa Malaria Partnership, GSK invested in preventative measures, such as using bed nets and indoor spraying. (£4 million between 2001 and 2013).
3. Preferential pricing for antimalarial medicines in LDCs and sub-Saharan Africa

Then in 2014, after 30 years of research, GSK announced that a vaccine against malaria –RTS,S – was ready to be launched in 2015.[54] Dr. Joe Cohen, Vice-President of R&D Emerging Diseases, told the FT[55]: "Data from a late-stage trial that is still in progress suggest the candidate vaccine can almost halve the number of malaria cases in children aged five to 17 months, on top of reductions from bed nets and other tools." In an interview with the WSJ,[56] CEO Andrew Witty said "When the

[50] A vaccine that protects children against Rotavirus

[51] (Included supplying at least 30% of the vaccines for the Global Polio Eradication Initiative (a public private partnership of national governments and the WHO) until 2017). GSK corporate social responsibility report 2013

[52] WHO website 2014.

[53] GSK – Our commitment to fighting Malaria, Oct 2013

[54] http://www.gsk.com

[55] FT, 25 April 2014: http://www.ft.com/cms/s/0/21788c96-be6d-11e3-a1bf-00144feabdc0.html#ixzz2ztByUsuq

[56] http://live.wsj.com/video/does-a-company-have-a-soul/BF2AC683-9FC8-493C-9089-6EEB09646F97.html#!BF2AC683-9FC8-493C-9089-6EEB09646F97

data for the malaria vaccine was first shared with the development team, the guys broke down crying. This shows the human emotion invested in this… which creates the soul of the company."[57] Having understood that children in Africa who would benefit from the vaccine could not pay for it, GSK made a conscious choice to develop[58] and finance the vaccine, and committed to make it available for cost of goods plus 5%. The 5% was destined to be reinvested in R&D for a second-generation malaria vaccine or vaccines against other tropical diseases.

Scandals at GSK

A series of scandals at GSK caused people to question its motives. Criminal investigations into allegations of bribing doctors and paying off competitors to stall competitive product releases undermined its claim that "being a responsible business is essential to our strategy, and how we deliver success is just as important as what we achieve."[59]

At the AGM in 2003, shareholders had voted against the remuneration report in what was seen as "the biggest shareholder revolt of its kind in UK corporate history". They were particularly angry about an estimated $35.7 million "golden parachute" Garnier would receive if he lost his job, which drew media accusations of corporate greed.

In 2004, GSK was accused of compromising the safety of patients with its antidepressant Paxil. It was discovered that GSK had failed to disclose the results of numerous trials indicating that the drug increased the risk of teen suicides. Paxil was subsequently banned for use by minors.[60]

In October 2010, GSK was ordered to pay $96 million to former employee Cheryl Eckard for failing to address the serious manufacturing contamination problems she reported at their Cidra plant in Puerto Rico in 2002, where breakdowns on production lines meant that products were contaminated with bacteria, or mixed up such that medicines produced were either too strong or too weak.[61]

In 2012, GSK pleaded guilty to criminal charges in the USA and paid $3 billion fines for illegally marketing drugs, offering doctors 'an endless list of potential

[57] http://live.wsj.com/video/does-a-company-have-a-soul/BF2AC683-9FC8-493C-9089-6EEB09646F97.html#!BF2AC683-9FC8-493C-9089-6EEB09646F97

[58] Partnering with the Path Malaria Vaccine Initiative, a non-profit group FT, 25 April 2014: http://www.ft.com/cms/s/0/21788c96-be6d-11e3-a1bf-00144feabdc0.html#ixzz2ztByUsuq

[59] GSK corporate social responsibility report 2013

[60] GSK responded by promising to reveal all its trials and to publish all its data, regardless of their outcome, and other large drug companies followed. FT April 16, 2014 -When use of pseudo-maths adds up to fraud

[61] Bad Medicine: The Glaxo Case: http://www.youtube.com/watch?v=NJh9o-MCPXw. When Eckard issued warnings to shut down the plant & detailed 9 high risk areas in the plant, no one listened & she was subsequently sacked

perks and bribes', such as yacht trips, massages and balloon rides, in return for prescribing drugs.

In 2013, GSK was accused of corruption, price-fixing and quality controls in China. The Chinese police said GSK had transferred 3 billion yuan ($489 million) to travel agencies and consultancies to bribe doctors to promote its products. GSK described the allegations as "shameful", agreed that some of its executives in China appeared to have broken the law and consequently dismissed "dozens of employees", made changes to its sales incentive schemes, and stopped payments to doctors for making speeches, and to healthcare professionals for attending medical conferences.[62]

Against this backdrop, even when GSK tried to do good, people questioned its intentions. For example, when GSK and Save the Children formed a global partnership to help save a million children's lives in the world's poorest regions, Rageh Omaar, reporting for ITV in Africa, commented:

> Global pharmaceutical companies have a long controversial record in developing countries, many wonder why things will be different now… Aid agencies and multinational corporations like Glaxo Smith Kline have the ability to come together to stop children dying needlessly from preventable diseases. But the question is what are the motives behind this partnership?[63]

Access to Medicines in 2014

In 2014, 2 billion people still lacked adequate access to medicines to stay healthy. And with insufficient understanding of health issues an estimated 10 million premature deaths occurred.[64] Under-five mortality was greatest in sub-Saharan Africa (followed by Southeast Asia). Activists claimed that millions of children were dying of preventable causes and that even small investments in health in the poor countries could make a dramatic difference to people's lives. NGOs continued to argue that compulsory licences should be granted to drive down drug prices. As Leena Menghaney, Manager of MSF's Access Campaign in India, explained, "Countries need to tackle the problem of high drug prices head on, by making sure unwarranted patents are not granted, and by issuing compulsory licences when drugs are priced out of reach so that more affordable generic versions can be made." Rohit Malpani,

[62] http://video.ft.com/2563890263001/Mild-pain-relief-for-GSK/Companies, Jul 24, 2013: GlaxoSmithKline has become embroiled in a corruption probe concerning some of its Chinese staff and FT April 2, 2014 Big pharma's rise in China not held back by scandals and Chinese woe for GSK, The Times, 5 April 2014

[63] ITV news at 10 pm, 10 May 2013: https://www.youtube.com/watch?v=B9kwBxXXXCs&list=PLvDyxtKlIcnhWNg8UevNidThqmxxtj9kU

[64] Novartis Foundation—Klaus Leisinger 10/4/2011: http://www.youtube.com/watch?v=9drMaDVg2eY

spokesman for Oxfam USA, argued that "ultimately, for least developed countries it's only generic competition that's going to get prices down to an affordable level."[65]

HIV had moved from being the key issue to just one of a number of health problems including vaccines, tuberculosis, malaria, neonatal, tropical diseases and pneumonia (see Exhibit 8.4). The difference in death rates from non-communicable diseases (NCDs) and other diseases between the developed and developing world was stark. While the developing world had addressed the problems of AIDS and people with HIV were living longer, the burden of chronic NCDs was heavier. Breast cancer, cardio-vascular disease and smoking-, alcohol- and obesity-related conditions were also affecting people in low-income countries. The WHO estimated that the number of deaths from chronic NCDs was more than four times those from AIDS, TB and malaria in low and middle-income countries. It claimed that with the right access to medicines, around 8 million NCD deaths could be prevented each year in the developing world.[66] NCDs now presented the same sort of major health challenges and global burden that AIDS once had. But while AIDS was now adequately financed and widely understood, awareness of chronic NCDs and the opportunities for health impact in LDCs were not.

By 2014, many developing countries were seeking to move towards universal health insurance coverage as advocated by the WHO, but only Ghana, Rwanda, Kenya, Nigeria and South Africa had any formal structure for health insurance. What worked elsewhere didn't work in much of Africa. The challenge was not just about making medicines more affordable but more available. Several interconnected factors determined whether patients received the right medicine at the right place and time, including diagnosis and care, remaining in care, lack of healthcare workers, infrastructure investment, individual lifestyles, education and environment. The cost of treatment was not just the price of the drugs but the cost of transport and of time taken off work for patients – often to walk long distances and queue for treatment.

GSK and the Novartis Deal

By 2014, GSK was the fourth largest global pharmaceutical company (see Exhibit 8.3). It had manufacturing sites in 86 countries and a commercial presence in 150 markets. Turnover was £26.5 billion, consisting of pharmaceuticals (67% of group turnover, including medicines for cancer, heart disease and viral infections such as HIV), vaccines (13% of group turnover) and consumer healthcare products.

GSK was proud to have held the number one position on the Access to Medicines Index from its conception. Shareholder returns also appeared to be high on management's agenda: in 2014 the dividend was increased by 6%. In a video released in

[65] http://www.ethicalcorp.com/communications-reporting/how-gsks-access-medicine-plans-will-shake-big-pharma

[66] Source: WHO 2008

April 2014,[67] Philip Thomson, SVP of Communications and Government Affairs, said healthcare was -

> *an area which fundamentally requires responsibility. It is something that the company takes very seriously. At the core of the company is innovation and access, and the two are intrinsically linked. What it should tell you is that we don't see any difference between our commercial success, our shareholder return, and our responsibility and the contribution we should make to society.*

On 22 April 2014, GSK announced the terms of a complex three-part $20 billion restructuring deal with Swiss pharmaceutical Novartis[68]:

1. GSK would sell its portfolio of cancer drugs to Novartis for up to $16 billion; ($1.5 billion in milestone payments subject to drug trial successes)
2. GSK would buy Novartis's vaccines unit for up to $7.1 billion ($5.25 bn plus a potential $1.8bn in milestone payments subject to vaccine successes.)[69] This would give GSK 29% of the global vaccine market. "GSK's late-stage development pipeline would be further strengthened with the addition of four new candidate vaccines from Novartis." The new business would have more than 20 different vaccines in development, including assets to prevent hospital and maternal infections and diseases prevalent in developing countries such as malaria and tuberculosis.
3. Novartis and GSK would combine their consumer health businesses in a joint venture, with 2013 pro forma revenues of £6.5 billion and GSK holding 63.5% of shares and 7 out of 11 seats on the board

Announcing the agreement, Andrew Witty, GSK chief executive, stated[70]:

> *Opportunities to build greater scale and combine high quality assets in vaccines and consumer healthcare are scarce. With this transaction we will substantially strengthen two of our core businesses and create significant new options to increase value for shareholders…. The acquisition of Novartis' vaccines business will significantly enhance the breadth of our vaccines portfolio and pipeline, notably in meningitis, with the addition of Bexsero, an exciting new vaccine for prevention of meningitis B. The acquisition will also strengthen our manufacturing network and reduce supply costs…*
>
> *Finally, and very importantly, this transaction strengthens GSK's offering to patients and consumers. We will expand our portfolio to both help treat illness and prevent disease, and we will broaden our scope to improve human health with the acquired R&D and innovation expertise.*

---

[67] GSK: Evolving our business model- https://www.youtube.com/watch?v=j1uWVMOlhdw

[68] Regulatory News Service, Apr-22-2014:GSK announces major transaction with Novartis. It was expected to complete during the first half of 2015

[69] The deal included Novartis's promising new Bexsero vaccine for meningitis B, but excluded flu vaccines

[70] Regulatory News Service, Apr-22-2014: GSK announces major transaction with Novartis.

The deal would increase annual turnover to £26.9 billion and allow GSK to focus on four key business areas – HIV, vaccines, respiratory conditions and consumer healthcare.[71] It was perceived as a win-win deal, driving sustainable sales growth, allowing overheads to be spread over a bigger portfolio, and the companies to become more efficient and more productive in the long term. In the financial media it was perceived to benefit everyone: the companies could improve their long-term earnings, allowing shareholders to earn increasing returns, while patients would receive new drugs quicker through a speedier R&D process. As the FT[72] explained:

> *Both companies get to specialise and focus resources on areas they are good at. To paraphrase Novartis' chief executive, Novartis can get more value out of Glaxo's cancer labs than Glaxo can, while Glaxo can make Novartis' vaccines business work harder. If it works, everyone's a winner. Consumers get more new drugs, more quickly. Shareholders and management avoid the indigestion problems that always come with any big merger. And nobody has to shell out ridiculous fees to investment banks to broker the whole thing.*

Exhibit 8.1: Oxfam's Assessment Criteria for Access to Medicines

Expected behaviour in each of Oxfam's three assessment areas of a pharmaceutical company that has reached the top '*civil stage*' – when it actively pushes other companies and stakeholders within the sector to raise standards as an industry.

Research and Development

1. The company supports and participates in joint private-public initiatives (JPPIs) that address R&D, or conducts Its own in-house research For infectious diseases: collaborates with third parties (e.g. JPPIs, generic companies) working on R&D for medicines to treat neglected and abandoned diseases; and facilitates access to Its compound library for other relevant parties to conduct R&D for neglected and abandoned diseases.
2. Companies conduct R&D for diseases prevalent in developing countries as an integral part of their overall R&D strategy. This strategy should have specific targets to ensure proper monitoring and evaluation of commitments made by companies.
3. The company invests in paediatric versions and versions adapted to resource-poor settings, including heat-resistant formulations.

Pricing Strategy

1. The company applies a systematic, global approach to pricing in developing countries, overseen by an international public-health body, which addresses public-health needs and real purchasing power for each country.

[71] These revenues would be split across Pharmaceuticals 62%, Consumer Healthcare 24%, and Vaccines 14%, (FT 22/04/2014: Novartis buys GSK business for up to $16bn http://www.ft.com/cms/s/0/2bc1c1c0-c9e6-11e3-ac05-00144feabdc0.html#ixzz2ziPC13dI)

[72] FT 26/04/2014

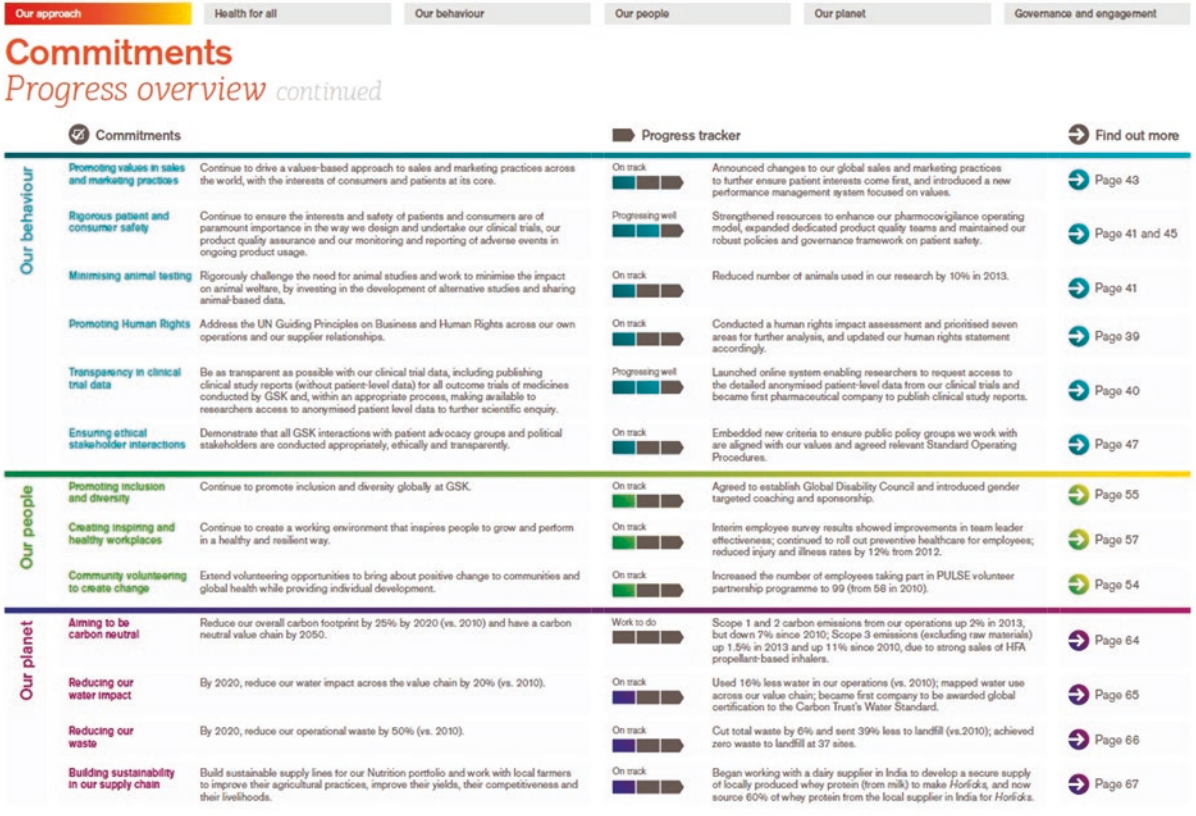
2. The company discloses its pricing rationale in developing countries.
3. The company's pricing policy ensures that products for neglected diseases developed as part of a JPPI or developed in-house, are affordable for developing countries.
4. The company applies the above pricing policies to its entire portfolio beyond neglected diseases and HIV and AIDS, and in all developing countries.

Intellectual Property

1. The company does not lobby developed-country or developing-country governments or pursue legal avenues to impose or enforce patent rules that exceed minimum obligations under the TRIPS Agreement, or that weaken the use of public-health safeguards. The company should publicly accept the use of TRIPS safeguards and flexibilities.
2. The company supports lifting TRIPS-related restrictions on the export of generic versions of patented medicines to least-developed countries and to developing countries that have insufficient or no manufacturing capacity, in line with the Doha Declaration. The company supports extending the non-implementation of patent rules for pharmaceuticals in LDCs beyond 2016.
3. The company does not apply for patents for the purpose of 'ever-greening' existing medicines, i.e. the extension of pharmaceutical monopolies beyond the initial 20-year term. Therefore, companies should not seek patents for new indications of existing medicines, new formulations, or combinations of existing medicines, nor should they seek patents for modifications of existing chemical entities or pharmaceuticals unless these changes are novel, show an innovative step, and have significant therapeutic advantages.
4. The company extends the relevant intellectual property policies to all medicines in its portfolio, and does not limit its policies only to medicines needed to treat HIV and AIDS, tuberculosis, and malaria.
5. The company renounces all patent rights on medicines developed for infectious diseases under JPPIs in developing countries.
6. The company follows Oxfam's best-practice guidelines when issuing voluntary licences (VLs).

Source: Author compilation from extracts in November 2007, Oxfam briefing paper: 'Investing for life'

Exhibit 8.2: Commitments – Progress Overview in GSK Corporate Responsibility Report 2013



Our approach | Health for all | Our behaviour | Our people | Our planet | Governance and engagement

Commitments

Progress overview continued

	Commitments		Progress tracker		Find out more
Our behaviour	Promoting values in sales and marketing practices	Continue to drive a values-based approach to sales and marketing practices across the world, with the interests of consumers and patients at its core.	On track	Announced changes to our global sales and marketing practices to further ensure patient interests come first, and introduced a new performance management system focused on values.	Page 43
	Rigorous patient and consumer safety	Continue to ensure the interests and safety of patients and consumers are of paramount importance in the way we design and undertake our clinical trials, our product quality assurance and our monitoring and reporting of adverse events in ongoing product usage.	Progressing well	Strengthened resources to enhance our pharmacovigilance operating model, expanded dedicated product quality teams and maintained our robust policies and governance framework on patient safety.	Page 41 and 45
	Minimising animal testing	Rigorously challenge the need for animal studies and work to minimise the impact on animal welfare, by investing in the development of alternative studies and sharing animal-based data.	On track	Reduced number of animals used in our research by 10% in 2013.	Page 41
	Promoting Human Rights	Address the UN Guiding Principles on Business and Human Rights across our own operations and our supplier relationships.	On track	Conducted a human rights impact assessment and prioritised seven areas for further analysis, and updated our human rights statement accordingly.	Page 39
	Transparency in clinical trial data	Be as transparent as possible with our clinical trial data, including publishing clinical study reports (without patient-level data) for all outcome trials of medicines conducted by GSK and, within an appropriate process, making available to researchers access to anonymised patient level data to further scientific enquiry.	Progressing well	Launched online system enabling researchers to request access to the detailed anonymised patient-level data from our clinical trials and became first pharmaceutical company to publish clinical study reports.	Page 40
	Ensuring ethical stakeholder interactions	Demonstrate that all GSK interactions with patient advocacy groups and political stakeholders are conducted appropriately, ethically and transparently.	On track	Embedded new criteria to ensure public policy groups we work with are aligned with our values and agreed relevant Standard Operating Procedures.	Page 47
Our people	Promoting inclusion and diversity	Continue to promote inclusion and diversity globally at GSK.	On track	Agreed to establish Global Disability Council and introduced gender targeted coaching and sponsorship.	Page 55
	Creating inspiring and healthy workplaces	Continue to create a working environment that inspires people to grow and perform in a healthy and resilient way.	On track	Interim employee survey results showed improvements in team leader effectiveness; continued to roll out preventive healthcare for employees; reduced injury and illness rates by 12% from 2012.	Page 57
	Community volunteering to create change	Extend volunteering opportunities to bring about positive change to communities and global health while providing individual development.	On track	Increased the number of employees taking part in PULSE volunteer partnership programme to 99 (from 58 in 2010).	Page 54
Our planet	Aiming to be carbon neutral	Reduce our overall carbon footprint by 25% by 2020 (vs. 2010) and have a carbon neutral value chain by 2050.	Work to do	Scope 1 and 2 carbon emissions from our operations up 2% in 2013, but down 7% since 2010; Scope 3 emissions (excluding raw materials) up 1.5% in 2013 and up 11% since 2010, due to strong sales of HFA propellant-based inhalers.	Page 64
	Reducing our water impact	By 2020, reduce our water impact across the value chain by 20% (vs. 2010).	On track	Used 16% less water in our operations (vs. 2010); mapped water use across our value chain; became first company to be awarded global certification to the Carbon Trust's Water Standard.	Page 65
	Reducing our waste	By 2020, reduce our operational waste by 50% (vs. 2010).	On track	Cut total waste by 6% and sent 39% less to landfill (vs.2010); achieved zero waste to landfill at 37 sites.	Page 66
	Building sustainability in our supply chain	Build sustainable supply lines for our Nutrition portfolio and work with local farmers to improve their agricultural practices, improve their yields, their competitiveness and their livelihoods.	On track	Began working with a dairy supplier in India to develop a secure supply of locally produced whey protein (from milk) to make *Horlicks*, and now source 60% of whey protein from the local supplier in India for *Horlicks*.	Page 67

Exhibit 8.3: The Pharmaceutical Market and Research Process

The global pharmaceutical market grew from $220 billion in 1999 to $808 billion in 2013,[73] with the Americas accounting for 44% of sales and an estimated 60% of industry profits. Only 1.4% of sales value came from the combined Middle East and Africa.

In 2013, with 2.8% of the global market, GSK was the fourth largest pharmaceutical company after Pfizer (7.5%), Merck (5.3%) and AstraZeneca (4.4%).[74] The industry was highly competitive but one of the most profitable. GSK had a profit margin of 20.5% (Pfizer's was 42.7%, Merck's 10.0%, and AstraZeneca's 10.0%).[75]

The global vaccine market, which represented 3.4% of the total global pharmaceutical market[76], grew by approximately 10% per annum. GSK was the leading producer with 23% of the market, followed by Sanofi (20%), Merck (14%), Pfizer (13%) and Novartis (10%).[77]

The costs of research, legal and regulatory constraints (to ensure the safety and efficacy of medicines) and patents restricted new entrants. Prices came under pressure as governments sought to reduce the financial burden of health systems, prompting investor concern that the industry might not deliver the profits they were used to. Moreover, research took years, with only a small chance of a positive outcome.[78] The research process entailed laboratory research, product development, animal experiments, and clinical trials with patient volunteers to prove the efficacy of the drug prior to obtaining regulatory approval, and marketing. According to the Pharmaceutical Research and Manufacturers of America trade group (PhRMA), out of 5000–10,000 screened compounds, only 250 entered preclinical testing, of which only five entered human clinical trials and only one would be approved. By 2012, some commentators[79] estimated that the full cost of bringing a new medicine to market had reached $1.5 billion.

The industry's business model was based on finding 'blockbuster' drugs and then protecting them by the patent system. A patent gave exclusive rights to supply the product in the country where it was granted, essentially ensuring a monopoly for 20 years, during which profits would help recoup the high cost of R&D. Multiple patents were involved, including patents for the compound, process and formulation (i.e. type of dose). Patent holders could grant voluntary licenses to other manufacturers to make or sell generic versions of their medicine within the boundaries of stated countries, in return for a royalty on these sales.

---

[73] Pharmaceuticals Industry Profile: Global, April 2014, 1–33, MarketLine

[74] Pharmaceuticals Industry Profile: Global, April 2014, 1–33, MarketLine

[75] *Ibid*.

[76] IMS health 2011

[77] Source –Kresse and Shah, 2010)

[78] According to the pharmaceutical industry, it cost around $1 billion to bring a new drug to market and the average time from discovery to approval of new medicine was 13 years, with a success rate of less than 5%. Source US National Institute of Health

[79] Source: J. Mestre-Ferrandiz, J. Sussex and A. Towse, The R&D cost of a new medicine, Office of Health Economics, December 2012

Once the patent had expired, other manufacturers could produce and market the same medicine under a generic name. With no R&D to cover and manufacturing costs low, they could offer generic medicines at much lower prices. For example, the arrival of generic competition to GSKs dermatology products saw its sales decline 58% to £13 million. Patent expiry was therefore a major concern. In search of a new business model, the pharmaceutical industry saw 'a splurge of multibillion-dollar deals and rumours', including 'speculation over a $100bn approach by Pfizer for AstraZeneca'..[80]

Because profitability in low and middle-income countries was small, big pharma had little incentive to develop medicines for those markets – what were significant threats to health in the developing world were of negligible market size elsewhere, such as HIV-positive mothers and children. The generic manufacturers did not have the resources to carry out clinical trials to develop these medicines. In 2012, more than 90% of people receiving ARV treatment lived in low and middle-income countries, a market estimated to be worth $1.5 billion (less than 10% of the value of the global market). The paediatric market accounted for 7% of the total ARV market and was confined to low and middle-income countries (childhood HIV having been almost eliminated elsewhere).[81] Once generic manufacturers had entered the ARV market, big pharma left them to supply this unprofitable segment. By 2012 they were supplying over 95% of first line ARV medicines in low and middle-income countries.[82]

Exhibit 8.4: Key Diseases Affecting the Developing World

At the beginning of the twentieth century, there was a 20-year life expectancy gap between the developed and developing world. A disproportionate volume of research focused on health in developed countries to the neglect of those in LDCs.[83]

Over the years, HIV/AIDS had received a lot of media attention, finance and concerted efforts from NGOs such as Christian Aid's 'Stop the AIDS' campaign and the annual 'World AID'S day'. By 2014, billions of dollars had been committed to global funds to fight AIDS, TB and malaria, and millions of people were on ARV drugs in low and middle-income countries.[84] The scale-up in ARV treatment had been impressive, from 0.8 million people in sub-Sahara Africa in 2005 to 3.9 million in 2009. The price of first and second-line ARVs to treat HIV had dropped because of increased competition among generic producers. First-line

[80] FT April 25, 2014 Drug innovation: In the recovery room

[81] HIV medicines – technology and market landscape, UNITAID, March 2014

[82] Global update on HIV treatment 2013: results, impact and opportunities published by UNAIDS, the WHO and UNICEF in June 2013

[83] *Ibid.*

[84] In 2012, an estimated US$ 18.9 (16.6–21.2) billion was available for HIV programmes in low- and middle-income countries; GLOBAL REPORT UNAIDS report on the global AIDS epidemic 2013. Care and treatment services consumed more than half (55%) of HIV expenditure in 2012, while prevention programmes represented 19% of HIV spending, 12% was spent on programme management and administration. Source: GARPR 2013

ARVs had fallen from $10,000 in the early years, to around $140[85] per person per year, and medicines used in second-line combination treatment[86] had fallen from $700 in 2008[87] to around $300 per year.[88]

The threat of AIDS drastically diminished through a combination of prevention and treatment. AIDS-related deaths peaked in 2005. Globally, new HIV infections had peaked in 1997 and continued to decline. In 2012, an estimated 9.7 million people[89]in low and middle-income countries obtained ARV therapy and the UN goal of having 15 million people in treatment worldwide by 2015 appeared reachable. Although 34 million people worldwide were living with HIV in 2014,[90] AIDS was no longer perceived as a pandemic. Drugs had transformed AIDS from a death sentence to a chronic disease: a person infected with HIV at age 25 could expect to live into their 70s.[91] Drugs were available for HIV-positive pregnant women, which eliminated the transmission of AIDS to babies and led to enormous reductions in the number of children with HIV.[92] Progress towards the goals of 'zero new infections' and an 'AIDS-free generation' prompted UNAIDS to announce "today we have the tools we need to lay the groundwork to end the AIDS epidemic."[93]

However, since AIDS still was a life-long condition, millions in the developing world would require years of sustained HIV drug treatment. Yet access to treatment varied considerably within and between countries: 3.4 million children were living with HIV and without treatment, 33% of HIV-infected infants would die before the age of one, 50% by 2 years old.[94] Only 10 of the 29 ARV medicines available in 2013 were approved for use with children. Because of difficulties supplying the liquid formulation required by infants and smaller batch sizes, they tended to be higher priced than adult formulations.[95]

[85] Price of a WHO-recommended one-pill-a-day first-line combination (tenofovir/lamivudine/efavirenz)

[86] zidovudine/lamivudine + atazanavir/ritonavir

[87] http://www.unitaid.eu/en/resources/news/198-unitaid-and-the-clinton-hivaids-initiative-announce-new-price-reductions-for-key-drugs

[88] Untangling the Web of ARV Price Reductions, released July 2013 by the international medical humanitarian organisation Médecins Sans Frontières/Doctors Without Borders (MSF) at the International AIDS Society conference in Kuala Lumpur, http://www.msf.org.uk/article/hiv-generic-competition-pushing-down-drug-prices-patents-keep-newer-drugs-unaffordable

[89] Under the 2010 WHO guidelines, 61% (57–66%) of all persons eligible

[90] www.christianaid.org.uk/Images/Advent-2013-reflections.pdf

[91] reported at the 2012 XIX International AIDS Society conference

[92] the annual number of newly infected children in 2012 was 260,000 (230000–320,000) in low- and middle-income countries, 35% lower than in 2009; GLOBAL REPORT UNAIDS report on the global AIDS epidemic 2013

[93] GLOBAL REPORT UNAIDS report on the global AIDS epidemic 2013

[94] HIV medicines – technology and market landscape, UNITAID, March 2014

[95] *Ibid*.

In sub-Saharan Africa, where 25 million lived with HIV,[96] approximately three quarters of adults had not achieved viral suppression as a result of shortfalls at each stage of the treatment cascade.[97] In 2014, 1.6 million HIV-related deaths occurred in Africa,[98] where more than 90% of mother-to-child transmission occurred, and only 65% of pregnant women with HIV received treatment.

The earlier ART treatment was initiated, the greater its benefits. But a report published by UNAIDS, the WHO and UNICEF in June 2013 noted that "structural, operational, logistical and social barriers, including stigma, discrimination, and punitive laws and policies" hindered access to HIV testing or resulted in patient 'loss' between testing and starting treatment. WHO guidelines on HIV treatment[99] in 2013 indicated that 28.6 million were eligible for ARV therapy in low- and middle-income countries and that substantially faster scale-up was needed.

Moreover, there was a problem of resistance to AIDS drugs over time. UNITAID reported increased cases of resistance from 4.8% in 2007 to 6.8% in 2010 in low and middle-income countries.[100] As patients developed resistance to second-line ARVs, they needed to switch to a new generation of HIV drugs. According to the WHO, 3.6% of adult patients were on second-line treatments in 2012; 3% of patients on first-line ARVs needed to switch to second-line regimens annually. However, the minimum cost of these medicines in the poorest countries was $2000 per year.[101] In conformity with TRIPS regulations, medicines developed after 2005 could no longer become generics. NGOs warned that if resistance to generic drugs continued, death rates would return to the levels of the 1980s. Would history repeat itself, with access to HIV treatment again subject to the ability to pay?

Tuberculosis accounted for 1.3 million deaths in 2012 and a quarter of its victims were HIV-positive. Even with medicines and the preventive use of bednets, malaria was responsible for over half a million deaths globally every year. Christian Aid noted that "Most shockingly, despite the fact that malaria is both a preventable and curable disease, most of those deaths occur among African children."[102] The economic cost of malaria was high, consuming "around 40% of all public health

[96] *Ibid*.

[97] GLOBAL REPORT UNAIDS report on the global AIDS epidemic 2013

[98] HIV medicines – technology and market landscape, UNITAID, March 2014

[99] HIV treatment guidelines provided by the WHO (WHO), issued in June 2013, recommended starting treatment when an individual's CD4 count fell below 500 cells/μL and immediately for pregnant women, HIV-positive partners in serodiscordant couples, children younger than five and people with HIV-associated tuberculosis and Hepatitis B.

[100] HIV medicines – technology and market landscape, UNITAID, March 2014

[101] Nearly 15 times the price of first-line treatment. Untangling the Web of ARV Price Reductions, released July 2013 by the international medical humanitarian organisation Médecins Sans Frontières/Doctors Without Borders (MSF) at the International AIDS Society conference in Kuala Lumpur,http://www.msf.org.uk/article/hiv-generic-competition-pushing-down-drug-prices-patents-keep-newer-drugs-unaffordable

[102] http://www.christianaid.org.uk/pressoffice/blog/world-malaria-day-2013.aspx

expenditure in endemic countries."[103] Comparing charts of disability-adjusted life years (DALYs) by disease demonstrated that whilst AIDS was still prevalent in sub-Saharan Africa, other infections and parasitic diseases accounted for more loss-of-life-years. Non-communicable diseases (NCDs) were increasingly affecting health.

More than 1 billion people, including 800 million children, were believed to succumb to tropical diseases, and pneumonia was one of the biggest killers of under-fives.

[103] http://www.gsk.com/responsibility/health-for-all/tackling-diseases-in-developing-countries.html