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GlaxoSmithKline and Access to Essential Medicines (B)

Anne Duncan, NatWest Ph.D. Fellow prepared this case study under the supervision of Professor N. Craig Smith, as a basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation. Financial assistance provided by Accenture for the development of this case study is gratefully acknowledged.

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Public criticism of the pharmaceutical industry continued, despite its withdrawal from the controversial court case against the South African government. At its annual meeting, May 21, 2001 campaigners from Oxfam, dressed in lab coats, called for GSK to do more for LDCs by donating a percentage of drug revenues to the UN Secretary General's "global health fund". Some analysts were surprised by CEO J P Garnier's unprecedented response. He defended GSK's actions on the access issue, but then suggested that the company's priority was public health, not simply shareholder value: "Some months ago, when the newly merged GlaxoSmithKline was formed, I said that I did not want to be head of a company that caters only to the rich. I made access to medicines in poorer countries a priority and I take this opportunity to renew that pledge. We have 110,000 people who go to work every morning because they are pro-public health. We have to make a profit for our shareholders but the primary objective of any policy put forward in the industry is public health." (A chronology of GSK's subsequent initiatives is given in Exhibit 1.)

A basic framework for GSK's access policy had been identified in February 2001. But GSK was then only a few weeks old and specific details of policy development, coordination and implementation had to be worked out by cross-functional teams operating across the newly merged company. On June 11, 2001 a detailed three-pronged access strategy was rolled out with the publication of a document entitled, *Facing the Challenge: Our contribution to improving healthcare in the developing world*. GSK made commitments in three areas:

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

The main emphasis was on developing and providing essential medicines at preferential prices. "Sustainability", the company's ability to deliver over the long term, would be the key criterion for any action. Sixty-two (62) countries were to be offered substantially discounted prices on HIV/AIDS and malarial drugs in the GSK portfolio. In addition to offering the preferential prices to governments, GSK offered them to not-for-profit NGOs and international agencies, aid groups, churches & charities that had the facilities to appropriately monitor and treat patients in LDC's and Sub-Saharan Africa. The company also offered preferential prices on anti-retroviral therapies to African employers who provided HIV/AIDS care directly to their staff through workplace clinics.

Howard Pien (President of International Pharmaceuticals) explained GSK's 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

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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 with Oxfam commented: "This is really positive. It is better than all the other initiatives the industry suggested." But others remained concerned for several reasons. First, the timing of the document, within weeks of the collapse of the South African court case and Oxfam's protests, was seen as having been prompted only by significant, recent public criticism of the company. Perhaps the GSK document was designed merely to quiet the company's critics rather than signal a shift in its intentions. Some critics questioned the degree of internal commitment to the "new" strategy, noting that the glossy policy document was long on words and short on specific commitments against which progress could be measured.

Pien, Chrissie Kimmons (Senior Vice President, Global Public Affairs & Public Policy) and their colleagues knew that producing the policy was just a first step. Operationalising the policy and measuring progress were critical. Another cross-functional team was established with this task, led by Gunther Faber (former head of SmithKline in South Africa and now Vice President of GSK in Sub-Saharan Africa). He had helped the South African government on health care issues and participated in the development of GSK's access policy. Pien asked Chris Strutt (Vice President and Access Alignment Master) to report the number of agreements signed and other indications of progress, one year later, including input from Faber on Sub-Saharan Africa. Pien also made other managers within the international division personally responsible for progress in implementing the access policy within their areas. Managers were required to report regularly on the number of supply arrangements made under the access policy and Pien called for time to be set aside for managers to discuss their progress on access and exchange information on implementation difficulties during their regular meetings and conference calls.

Garnier, too, remained determined that GSK would play a leading role in efforts to improve the health of people in LDCs. The preferential pricing offers were just the start of a more wide-reaching role envisaged for GSK. The company sought to engage other like-minded pharmaceutical companies and governments to continue to advance the international response to the crisis. With GSK the only company involved in R&D on all three top priority diseases of the WHO—malaria, TB and HIV/AIDS—the decision was made to dedicate GSK's research facility at Tres Cantos in Spain to research new and improved treatments to fight diseases of the developing world.

On July 22, 2001 at the state summit in Genoa, intergovernmental meetings were again interrupted by protests and the access issue remained prominent on the activist's agenda. The heads of state formally announced the creation of the Global Fund for AIDS, Tuberculosis and Malaria (GFATM) and the intention of their governments to support a degree of flexibility in WTO rules to help address the AIDS

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crisis. Tony Blair, the United Kingdom Prime Minister, asked his international development minister, Clare Short, to chair a working group of representatives from the UN, European Community, charitable foundations and UK pharmaceutical companies to recommend an approach to increase LDC access to essential medicines. GSK soon joined the working group.

In October 2001, GSK announced that it had granted a voluntary licence to Aspen Pharmacare, South Africa's largest producer of generic medicines, to allow it to manufacture GSK's antiretrovirals, Retrovir, Epivir and Combivir in South Africa and to sell them to the South African government and others in the not-for-profit sector. GSK waived its royalty fee and instead required a 30% fee on net sales to be paid as a donation to NGOs managing HIV/AIDS programmes in South Africa. Aspen promised to sell Combivir below the price of $2/patient/day that GSK was offering and just above the $1/patient/day quoted by Cipla, a generic producer of the drugs in India (where they were not patent protected). "We believe that we can come in, after the royalty payment, at between $1 and $1.50 per day," stated Aspen Pharmacare CEO, Stephen Saad.

In July 2002, GSK reported results on the access policy one year after it was adopted. Among the achievements was a ten-fold increase in shipments of preferentially priced Combivir to LDCs; an increase from under half a million tablets in 2001 to five million tablets in the first half of 2002 (a May 2002 study had found a fourfold increase since 2000 in the number HIV/AIDS patients in Africa receiving treatment to a total of around 35,500). GSK also reported that it had secured 95 agreements to supply preferentially priced HIV/AIDS medicines to 31 countries, including some of the world's poorest. GSK had also set up pilot projects in five African countries to assess the impact of preferential pricing of a wider range of its products.[1] GSK's philanthropic and partnership programmes had also continued. In the preceding year, GSK had donated the 100 millionth preventative treatment to support the Global Alliance effort to eliminate Lymphatic Filariasis and its Positive Action programme was supporting 21 HIV education, care and community support initiatives in 27 countries. GSK's R&D efforts were progressing as well. At the 14th International Conference on AIDS, in Barcelona, July 2002 the company announced promising results in the development of a potential vaccine that could reach the market within four years. The "integrase inhibitor" (developed with Shionogi, a Japanese firm), worked by blocking HIV's capacity to insert its genes into a cell's normal DNA. Unlike alternatives being developed by other companies, GSK's product seemed effective and showed few side effects.

The announcements on GSK's progress were juxtaposed by the actions of AIDS activists at the Barcelona conference. The access issue and drug patents and prices dominated the conference, with some activists leading violent protests. The European Commission and GSK's exhibit stands were vandalised by protesters demanding that the EU contribute more to the GFATM and that governments and the pharmaceutical industry do more.

[1] Reported in *Facing the Challenge—One Year On*, published by GSK in July 2002.

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Inside the conference, Oxfam reported that drug prices in Uganda fell by 97% when generic drugs manufactured by Cipla were introduced. Too ill to appear in person, Zackie Achmat, a leader of the South African NGO, Treatment Action Campaign, made a compelling video address to the conference. Achmat argued that despite price reductions, people in LDCs could still not afford the drugs that had radically reduced deaths from AIDS in wealthy countries. Beyond prevention efforts, he called for generic competition and for drug companies to issue non-restrictive voluntary licenses allowing generic manufacturing so that sick people could live longer. "What we are speaking of are not cold statistics but our lives," stated Achmat.[2]

On September 5, 2002 Garnier announced that GSK had further reduced the not-for-profit preferential prices of its HIV/AIDS drugs by up to 33% and its anti-malarial medicines by up to 38%. These price reductions were the result of a review of manufacturing costs and increased economies of scale, something that Pien had promised would be an ongoing process. Fulfilling a commitment to better transparency, GSK published the new prices (see Exhibit 2) and announced that it had secured a total of 115 agreements to supply preferentially priced HIV/AIDS drugs in 41 countries. "We are today delivering on our commitment to review prices for these essential medicines for patients in 63 of the world's poorest countries," stated Garnier. "We are also expanding our existing initiatives in sub-Saharan Africa to find appropriate ways to offer not-for-profit prices to core public employees such as teachers, nurses, police and fire-fighters not covered by health insurance, and to private employers who do not have their own workplace clinics." Garnier also stated that GSK would supply the medicines at not-for-profit prices to all projects fully financed by the new Global Fund. In addition, GSK was seeking regulatory approval for special packaging to differentiate the preferentially-priced drugs sold under its access initiatives.

Implementation of the access policy was proving a challenge in both predictable and unpredictable ways. On October 3, 2002 Dutch authorities were forced to recall all of 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…"[3] More than 35,000 drug packets, intended for Africa (with a market value of approximately 15 million euros) had been resold in the Netherlands and Germany. GSK's 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 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.

On November 28, 2002 Prime Minister Blair hosted a meeting to launch the report of the UK government's working group on access (the group included AstraZeneca as well as GSK). The proposed framework mirrored many of the ideas that GSK had been developing. In particular, the report recommended the pricing of HIV/AIDS, TB and malaria medicines at "close to the cost of manufacture in all least developed

[2] Source: CNN, July 10, 2002
[3] Source: Reuters. Oct. 03, 2002. "AIDS Drugs for Africa Uncovered in Europe."

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countries and across Sub-Saharan Africa." It also suggested measures to prevent the re-importation of differently priced products and to benchmark LDC prices against those of the developed world.

The HIV/AIDS crisis and evolution of the access issue illustrated both the commercial as well as the wider societal context in which company executives now operated. Strutt reflected on how rapidly and radically things had changed and how they were likely to continue to do so: "We were a brand new company… I didn't realize at the time how big this was… When I came into the industry, the mentality had always been: 'we're doing everything we can, the intellectual property framework is absolutely appropriate, our opponents are not credible, there's no reason for us to give anything and governments should support us'. Seattle [the WTO meetings disrupted by protestors] was a huge signal about the way the world was changing. Now, everything is different."

GSK managers felt that the company had led the industry in responding to the HIV/AIDS crisis in a responsible and sustainable way. Within 18 months of the company's formation, the approach that Garnier had mooted in late 2000 had been developed into a detailed access policy and was being implemented with noteworthy results. But Garnier, Pien, Kimmons and other GSK officials were convinced that it was not up to GSK or the other pharmaceutical companies to carry the primary responsibility for delivering the solutions. Like others in the pharmaceutical industry and increasingly international economists and intergovernmental organizations such as the WHO, GSK officials pointed out that the access problem went far "deeper than price".

Some argued that perhaps the most viable solution would be for the wealthy countries of the world to agree to ring fence the developing world as a 'charity case'. While some pharmaceutical companies had opposed some of the recommendations of the UK government's working group on access, there was clear support for the UN Secretary General's Global Fund initiative. At the suggested level of $7-10 billion per year, such a fund would provide sufficient resources to address immediate requirements for drugs and augment the broader health care infrastructure, while also ensuring that a market-based approach to drug discovery and treatment would not be abandoned entirely. However, by December 2002 only $2.1 billion had been pledged by governments and other donors to the GFATM and it had approved only $616 million in project proposals.[4]

Thus, questions remained: just how much responsibility should GSK be prepared to shoulder, and in what areas and on what basis should it do so?

4 UNAIDS/World Health Organization, "AIDS Epidemic Update: December 2002."

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Exhibit 1: Chronology of GSK Initiatives on the Access Issue

December 27, 2000	Glaxo and SmithKline officially became one company, GlaxoSmithKline (GSK), J. P. Garnier is named Chief Executive Officer.
February 22, 2001	Basic framework for GSK's access policy is outlined by Garnier.
May 21, 2001	At the GSK annual shareholder's meeting on, Oxfam campaigners dressed in lab coats call on GSK to donate a percentage of all drug sales to the new "global health fund". J.P. Garnier responds with the statement that the company's top priority was in fact public health, not simply shareholder value.
June 2001	United Nations special session on HIV/AIDS establishes time-bound targets for governments and the UN to be held accountable for their progress in addressing the international AIDS crisis.
June 11, 2001	GSK publishes *"Facing the Challenge: Our contribution to improving healthcare in the developing world*", announcing the details of a three-pronged access to medicines strategy. Specific intentions on product development, product pricing and community partnerships include: • Continuing investment in the research and development of diseases that affect the developing world. • Offering sustainable preferential (not-for-profit) pricing arrangements in Least Developed Countries and sub-Saharan Africa for currently available medicines that are needed most • Taking a leading role in community activities that promote effective healthcare.
July 22, 2001	Group of 7/8 heads of state meeting, Genoa, Italy African development, and Access to Medicines issues at the top of the agenda. Protestors interrupt meetings. Formal announcement of creation of Global Fund for AIDS, Tuberculosis and Malaria (GFATM); governments indicate intention to support flexibility in WTO rules to help address the AIDS crisis. British Prime Minister Tony Blair appoints international development secretary Clare Short to chair a working group of representatives from the UN, European Community, charitable foundations and UK pharmaceutical companies to recommend an approach to increase access to essential medicines in the developing world. GSK joins the UK working group.
October 1, 2001	GSK grants voluntary licence to South Africa's largest producer of generic medicines, Aspen Pharmacare, for GSK's patents on Retrovir, Epivir and Combivir in South Africa. Aspen promises to sell Combivir below GSK's price of $2/patient per day, and just above Cipla's quote of $1/patient per day. GSK waives royalty fee and requires 30% fee on net sales to be donated to NGOs managing HIV/AIDS programmes in South Africa.
July 10, 2002	14th International AIDS Conference, Barcelona, Spain. GSK reports results on the Access policy one year after adoption. Achievements include[5]: • Ten-fold increase in shipments of preferentially priced Combivir to the developing world, • 95 arrangements to supply preferentially priced HIV/AIDS medicines to 31 countries, • Creation of pilot projects in five African countries to assess the impact of preferential pricing of a broader range of GSK products. • Continuation and expansion of philanthropic and partnership programmes: ⇒ Positive Action programme supports 21 HIV education, care and community support initiatives in 27 countries. ⇒ GSK donates 100 millionth preventative treatment as part of its unlimited commitment to the elimination of Lymphatic Filariasis. • Progress on R&D for new HIV/AIDS treatments and promising results in the development of a potential vaccine. The "integrase inhibitor" being developed with Japanese firm Shionogi, works by blocking HIV's capacity to insert its genes into a cell's normal DNA. GSK's product seems effective, shows few side effects, and could reach the market within four years.
September 5, 2002	Garnier announces further progress on implementation of GSK's Access policy: • Further reduction in GSK's not-for-profit preferential prices on HIV/AIDS medicines by up to 33% and its anti-malarial medicines by up to 38%. Fulfilling it's commitment to greater transparency, GSK publishes the new prices (see Exhibit 2) noting that the reductions result from ongoing review of manufacturing costs and of increases in economies of scale. • Total of 115 arrangements to supply preferentially priced HIV/AIDS medicines in a total of 41 countries. • Intention to supply GSK's medicines at not-for-profit prices to all projects fully financed by the new Global Fund (GFATM). • GSK seeking regulatory approval for special packaging to differentiate the preferentially-priced medicines sold under its Access initiatives.
October 3, 2002	Dutch authorities are forced to recall all of GSK's Combivir and Epivir AIDS drugs after discovering that more than 35,000 HIV/AIDS drug packets, intended for Africa (market value of close to 15 million euros) had been resold in the Netherlands and Germany.
November 28, 2002	British Prime Minister Blair hosts meeting to launch UK Access policy working group's report, including a five point framework, supported by GSK and AstraZeneca, members of the working group. Group recommends that HIV/AIDS, TB and malaria medicines be provided by pharmaceutical companies at "close to the cost of manufacture in all least developed countries and across sub-Saharan Africa". Measures also suggested to prevent re-importation of differently priced products, and to prevent benchmarking of developed world prices with developing world prices. Observers suggest that US pharmaceutical companies will lobby the US government to resist adopting and implementing the UK group's recommendations.
December 1, 2002	International AIDS Day. UNAIDS-WHO update on the AIDS epidemic reveals worsening trends with 3 million AIDS related deaths in 2002,42 million people living with AIDS, and rapid expansion of the disease in Eastern Europe and Central Asia. The report also cites continuing problems in developing and delivering effective international, national and local level responses to reverse the trends.

[5] Source: Company interviews, and published document "Facing the Challenge - One Year On" (GSK, July 2002)

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Exhibit 2: GSK's Sustainable Not-For-Profit Preferential Prices (as of September 5, 2002)

GlaxoSmithKline sets a single, sustainable preferential price for ARVs and antimalarials to a wide range of customers[1] in the Least Developed Countries[2] and sub-Saharan Africa[3] (a total of 63 countries). Sustainable preferential pricing means setting prices at levels that meet our costs, thereby ensuring we can sustain supply of these high-quality products for as long as patients need them. From 5 September 2002 these preferential prices are:

HIV/AIDS Medicines

Medicine	Treatment Regimen / Day	Approximate Cost / Day		Reduction from previous $ price
		£	$	%
Epivir	150mg x 2	0.41	0.64	0%
Retrovir	300mg x 2	0.77	1.20	-25%
Combivir	450mg x 2	1.09	1.70	-15%
Ziagen	300mg x 2	1.73	2.70	-29%
Trizivir	750mg x 2	2.85	4.45	-33%
Agenerase	150mg x 16	5.43	8.50	-2%

Anti-malarial Medicines

Medicine*	Treatment Regimen / Course	Approximate Cost / Treatment Course**		Reduction from previous $ price
		£	$	%
Malarone	4 tablets per day for 3 days #	7.67	12.00	-38%
Halfan	250mg x 6 (3 doses of 2 tablets taken at 6 hr intervals)	0.90	1.40	-7%

Prices for anti-malarial treatments for children will be lower because the dosing for children is based on body weight.
* Our other anti-malarials, including chloroquine, Amodiaquine, sulphadoxine/pyrimethamine, have been available at preferential prices, determined in competitive tender, for some time.
**The cost/day and cost/treatment course figures have been rounded to the nearest tenth of a dollar.
1 tablet contains 250mg atovaquone and 100mg proguanil.

NOTE: £ prices based on the spot exchange rate on 4 September 2002 of US$1.564 = £1.00. Customers wishing to purchase in currencies other than US dollars will be invoiced at the US$ spot rate at time of transaction.
Supply of all products requires that they are licensed for use in the country to which they are to be supplied. To address clinical concerns regarding resistance and, in some cases, hypersensitivity reactions, we will seek to ensure that our products reach the patients who need them in clinical conditions where they can be appropriately monitored.
For middle-income developing countries we will continue to negotiate public sector prices for these treatments on a case-by-case basis to improve affordability, as is our current practice. This is done both bilaterally and through the Accelerating Access Initiative.
[1] Eligible customers include the public sector, not-for-profit NGOs, aid agencies, UN agencies and international purchase funds such as the Global Fund to fight AIDS, TB and Malaria. Additionally, because of the gravity of the situation in sub-Saharan Africa, employers there who offer HIV/AIDS care and treatment directly to their staff through workplace clinics or similar arrangements are also eligible.
[2] 49 Least Developed Countries (UN definition):
Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Cape Verde, Central African Republic, Chad, Comoros, Djibouti, DR Congo (Zaire), Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea Bissau, Haiti, Kiribati, Lao People's DR, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Sudan, Tanzania, Togo, Tuvalu, Uganda, Vanuatu, Yemen, Zambia
[3] Additional sub-Saharan African countries:Botswana, Cameroon, Congo, Cote d'Ivoire, Gabon, Ghana, Kenya, Mauritius, Namibia, Nigeria, Seychelles, South Africa, Swaziland, Zimbabwe

Source: GSK 5 September 2002.

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