

## **GlaxoSmithKline Briefing - January 2004**

Analysing GlaxoSmithKline's pharmaceutical operations and conduct in Africa and how this impacts upon the current HIV crisis sweeping the continent

### **Summary**

GlaxoSmithKline (GSK) is a global multinational company specialising in medical research, medicines and soft drinks. It supplies NUSSL with Ribena and Lucozade. The company was in the media spotlight between 2001 and 2003 because it restricted the availability of licences that allow other drug companies to manufacture cheaper versions of their patented HIV/AIDS medicines. This led to the reduced accessibility of these medicines in sub-Saharan Africa.

In December 2003, faced with a court case brought by South Africa's Competition Commission, GSK agreed to a settlement that included allowing four generic companies to produce and import their patented medicines. We believe that this settlement has resolved the issues raised at the NUSSL AGM 2003.

### **About HIV/AIDS In Africa**

Approximately 42 million people in the world have HIV/AIDS. Around 30 million of these live in sub-Saharan Africa (UNAIDS/WHO, December 2002). South Africa has the highest number of infected people; in 2002, 11 per cent of the population were infected (five million people). In addition to this appalling human cost, AIDS is damaging the economies of poor nations and is destroying societies. There are treatments, called antiretroviral medicines that increase the life expectancy of HIV positive people and to reduce the risk of mothers with HIV transferring the virus to their newborn children.

### **GSK & Medicine Prices**

GSK is to be commended for offering antiretroviral medicines on a "not-for-profit" basis to a total of sixty-three countries since the late 1990's. It has continually and drastically reduced the prices of its HIV/AIDS treatments.

Despite these welcome price reductions, the company has consistently refused to licence its patents to more than one non-generic drug company (Aspen Pharmacare). This meant that cheaper versions of the medicines were not easily accessible to people in sub-Saharan Africa, and it was this policy that led to a series of campaigns against GSK.

GSK argued that the lack of infrastructure in Africa and the refusal of the South African Government to provide HIV/AIDS drugs free of charge to its citizens were the real reason why most infected people could not get treatment.

### **GSK On The Wrong Foot - The Case Against South Africa**

In April 2001, GSK was one of 39 drug companies that brought the South African Government to court for importing cheaper versions of non-generic medicines from abroad. The drug companies argued that importing the medicines breached patent laws. The case was unsuccessful and generated international outrage against GSK. GSK later accepted that the action was a mistake.

### **The AIDS Healthcare Foundation**

In June 2002, the AIDS Healthcare Foundation (AHF), the largest non-governmental supplier of AIDS treatment to US patients, made an aggressive claim against GSK, accusing it of overcharging on AIDS medicines. The AHF claimed that GSK didn't develop AZT, and that the US Government-funded National Institute of Health did most of the research work. This case was later dropped.

The AHF lodged a second case in February 2003 against GSK's claims that it makes 'no profit' on life-saving AIDS medicines in the developing world. This led to USA's largest pension fund, the California Public Employees Retirement System, putting pressure on GSK over their policy on patents. In April 2003, GSK halved the price of the drug Combivir and the AHF withdrew its lawsuit.

### **The Treatment Action Campaign**

The Treatment Action Campaign was launched in December 1998. Its main objective was to campaign for greater access to treatment for all South Africans by raising public awareness and understanding about issues surrounding the availability, affordability and use of HIV treatments.

Its demands specific to GSK included:

GSK to grant licences to four generic companies to produce and/or import, sell and distribute the antiretroviral medicines AZT and lamivudine (historically, GSK had only granted a licence to Aspen Pharmacare).

The royalty fee on the licences to be no more than 5 per cent of net sales of the antiretroviral medicines (historically, the royalty fee that GSK requested was 30 per cent).

The licences to be for both the private and public sectors (historically, the licences granted by GSK to Aspen were limited to the public sector only).

The licensees to be able to export the AZT and lamivudine manufactured in South Africa to all 47 sub-Saharan African countries (historically, exports to sub-Saharan African countries were not permitted. They had to buy from GSK).

The licensees to be able to manufacture AZT, lamivudine and/or nevirapine (owned by another drug company, Boehringer Ingelheim) in combination with each other and/or any other medicines for which the licensees have licences. This is critical because it will allow triple-drug fixed dose combinations to come to the market.

The licences to apply to both adult and paediatric formulations of AZT and lamivudine.

### **South Africa's Competition Commission**

In September 2002, the AIDS Law Project lodged a complaint with the Competition Commission against GSK and Boehringer Ingelheim (BI) on behalf of four people living openly with HIV/AIDS, four health care workers, the TAC, COSATU and its affiliate CEPPWAWU. In February 2003, two further complainants joined; a police officer living openly with HIV/AIDS and the AIDS Consortium (representing more than a thousand individual and organisational members).

Alleging that the two multinational pharmaceutical groups were acting unlawfully by charging excessive prices for certain of their antiretroviral medicines to the detriment of consumers, the complaint argued that the prices charged by the groups for their essential and life saving medicines were directly responsible for the premature, predictable and avoidable deaths of women, men and children living with HIV/AIDS. The complaint showed that even when allowance is made for the costs of research and development, higher profits, licensing fees and the incentive to develop new medicines, the prices of these antiretroviral medicines were excessive.

In October 2003, the Competition Commission announced that it had decided to refer the complaint to the Competition Tribunal for adjudication. As a result of its year-long investigation, the Competition Commission found evidence to support the referral on the basis of prohibited excessive pricing as well as two additional grounds, both of which deal with the failure of GSK and BI to license generic manufacturers in certain circumstances. These additional grounds supported the argument that GSK and BI were using their patent monopolies to deny appropriate licences to other manufacturers while keeping their own prices high.

### **GSK Agrees To Grant Licences & Resolves The Issue**

On 10th December 2003, the TAC and the other complainants entered into settlement agreements with GSK and BI. The agreements met all of TAC's original demands. In signing the agreements, AIDS activists concluded their complaint against GSK and BI. TAC released a post-agreement statement stating that the terms of the agreements went well beyond what could conceivably have been won by pursuing the prosecution of the complaint under the Competition Act. More information on the agreement can be found on TAC's website. ([www.tac.org.za](http://www.tac.org.za))

### **The Committee's Constructive Engagement With GSK**

The E&E Committee had arranged a conference call with Jon Pender, GSK's Director of Governmental Affairs, on 16 December 2003 to discuss the progress on the patent issues. In the event, the issue had been resolved to the Committee's satisfaction, and the Committee wanted was able to congratulate GSK on the settlement. GSK was also pressed on whether the settlement was a landmark case that would apply to other patents in the future. The response was that it was a unique case due to the unique nature of HIV/AIDS in Africa, and that it did not set a precedent for future patent policy.

The Committee also pressed GSK on what would happen to the 5 per cent royalty from each sale. According to Oxfam (February 2001), global sales and estimated operating profit of Combivir since its launch in 1997 have comfortably exceeded £1bn and £300m respectively. If the industry claim that it costs US\$500m to bring a drug to the market is correct, then this figure has already been recouped. The Committee therefore wanted the royalty to be donated back to HIV/AIDS charities.

The GSK policy on this was not known at the time of the call, but we have since been provided with this reply: "the 5 per cent royalty from Aspen - as mentioned we have not yet received anything and have no way of knowing what we will receive as we don't know what Aspen's price or volumes will be. Extending the licence to the private sector and to all of sub-Saharan Africa, and extending the number of licences, will severely impact our HIV/AIDS business there (if we manage to retain anything at all).

So we will initially use the royalty income to cover the costs associated with maintaining our patents and product registrations, managing the Voluntary Licence

and maintaining some medical support and training in the access countries. If the royalty income became substantial we would review the situation.”

The Committee will contact GSK again in the future to determine how much revenue is brought in through the royalty, and to encourage GSK to donate this money to relevant charities.

**Useful Links**

GSK Website - [www.gsk.com](http://www.gsk.com)

Treatment Action Campaign Website - [www.tac.org.za](http://www.tac.org.za)

AIDS Law Project Website - [www.alp.org.za](http://www.alp.org.za)