TREATMENT ACTION CAMPAIGN

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The Competition Commission Complaint: Questions and Answers (Last updated 30 October 2002)

1. What is the Competition Commission complaint?

COSATU, the TAC, CEPPWAWU, Hazel Tau, Nontsikelelo Zwedala, Sindiswa Godwana, Sue Roberts, Isaac Skosana, William Mmbara, Steve Andrews and Francois Venter have lodged a complaint with the Competition Commission regarding the excessive pricing of antiretroviral medicines by GlaxoSmithKline and Boehringer Ingelheim.

2. What is the Competition Commission?

The Competition Commission is an independent body. Its job is to ensure that companies compete fairly in the market and that where companies dominate a particular market, they do not abuse their powerful position.

3. Is the Competition Commission a Court?

No. However, when a complaint is lodged with the Commission, it investigates whether the complaint makes a strong case. If the Commission finds that a strong case has been made, then the commissioner (the head of the Competition Commission) refers the complaint to the **Competition Tribunal** which adjudicates the matter. Decisions taken by the Competition Tribunal can be appealed to the **Competition Appeal Court**. The law pertaining to the **Competition Commission**, the **Competition Tribunal** and the **Competition Appeal Court** is the **Competition Act 89 of 1998**.

4. What is the complaint about?

The complaint charges that GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) charge excessive prices on the following life−saving antiretroviral medicines:

- AZT (manufactured by GSK under the brand−name Retrovir)
- Lamivudine (manufactured by GSK under the brand−name 3TC)
- AZT and Lamivudine in combination (manufactured by GSK under the brand−name Combivir)
- Nevirapine (manufactured by BI under the brand−name Viramune)

The Competition Commission considers a price to be excessive if it is higher than one that is reasonably related to the economic value of the product.

5. What evidence does the complaint present that shows that excessive prices are being charged for these medicines?

The complaint compares the prices of these four patented medicines with generic prices available from elsewhere in the world. The prices of these patented medicines are far in excess of the generic prices, even with an allowance for research and development, higher profits, licensing fees and the incentive to develop new drugs .

Detailed Explanation of Evidence of Excessive Pricing

The complaint calculates an **economic value** for the four medicines. For each product the lowest priced generic version approved by the World Health Organisation is assumed to be the cost of manufacturing the drug. Since generic companies also make a profit, this is obviously an overestimate of the *cost* of manufacturing. Then the cost of research and development (and where applicable, licensing fees) are added on to the price. Finally the average profit of the pharmaceutical industry, which is higher than any industry in the world, is added on to the price. This is then considered an estimated **economic value** of the medicine, though it is far in excess of a fair price. This calculation can be summarised as follows:

ECONOMIC VALUE = LOWEST PRICED GENERIC + COST OF R&D + PROFIT

The economic value is then compared to the price at which the drug is sold by the pharmaceutical company in the South African private sector. Doing this yields the following results:

- A 300mg pill of AZT is 2.58 times the economic value.
- A 150mg pill of Lamivudine is 4.01 times the economic value.
- A combined pill with 300mg AZT and 150mg Lamivudine is 2.24 times the economic value.
- A 200mg Nevirapine pill is 1.7 times the economic value.
- The syrup form of AZT (used for treating children) is 2.27 times the economic value.
- The syrup form of Lamivudine is 1.97 times the economic value.

The following table compares the yearly prices of the medicines that are the subject of the complaint.

Product	***Price sold to SA private Sector***	***WHO approved generic***
AZT (300mg)	R 7 082.46 (US$ 674.52)	R 1 890.00 (US$ 180.00)
Lamivudine (150mg)	R 7 786.67 (US$ 741.59)	R 1 050.00 (US$ 100.00)
AZT/lamivudine (300mg/150mg)	R 9 733.33 (US$ 926.98)	R 2 782.50 (US$ 265.00)
Nevirapine (200mg)	R 4 380.00 (US$ 417.14)	R 1 743.00 (US$ 166.00)
AZT (solution)	R 5 545.52 (US$ 528.14)	(R 1 686.30 US$ 160.60
Lamivudine (solution)	R 4 288.90 (US$ 408.47)	R 1 195.74 (US$ 113.88)

6. Why does the complaint calculate such a generous economic value?

The pharmaceutical companies do not disclose their manufacturing costs. It was felt that if a very generous economic value was calculated and the brand−name prices substantially exceeded it, then it would demonstrate to the Competition Commission the level of profiteering of the pharmaceutical industry.

7. Does the complaint pertain to the private and public sector?

From a legal perspective, the excessive pricing pertains to the private sector, however the TAC and its allies will be launching an associated campaign that will have repercussions for both sectors. Furthermore, many people who use the public sector buy their medicines in the private sector. Some of the supporting affidavits in the complaint are written by doctors and nurses in the public sector who want their patients to be able to access antiretroviral medicines, even if it is through the private sector. It is important to remember that antiretroviral medicines are not generally available in the public sector.

8. What relief does the complaint ask for?

The complaint requests the Competition Commission to request the following relief from the Competition Tribunal:

- Order GSK and BI to stop their excessive pricing practices.
- Declare that GSK and BI have conducted a prohibitive practice. If this is done, the companies can be sued by people who suffered loss as a result of past excessive pricing of the medicines.
- Fine GSK and BI up to 10% of their annual South African turnover.

This relief is explicitly provided for in the Competition Act.

9. What would be an adequate response from GSK and BI be to the complaint?

GSK and BI should issue non−exclusive voluntary licenses on the medicines that are the subject of the complaint on a 4 or 5% royalty fee basis. Government could also resolve this matter quickly by using its powers under the Patents Act to obtain compulsory licenses.

10.What is a non−exclusive voluntary license?

In this context, it would be where a pharmaceutical company that holds a patent on a drug allows any manufacturer who produces a safe and effective generic version to produce and sell the medicine to both the private and public sectors. This should be done on a royalty−fee basis: i.e. the patent−holder receives 4 or 5% of the sales on the generic versions.

11.What is a compulsory license?

In this context, it would be where a court orders a pharmaceutical company that holds a patent on a drug to allow other manufacturers to sell and produce safe and effective generic versions of the medicine. The patent−holder would receive some form of compensation.

12.Boehringer Ingelheim and GlaxoSmithKline have issued voluntary licenses to Aspen Pharmacare. Is this sufficient?

No. There are two serious problems with the licensing agreements that have been signed. They exclude the private sector and, even though they do not necessarily contain exclusivity clauses, they are de facto exclusive because neither company has publicly stated transparent, objective criteria that generic companies must meet in order to be able to obtain voluntary licenses. They are privately negotiated agreements and therefore simply transfers of monopoly. TAC is aware that Glaxo are charging Aspen a 30% licensing fee, far in excess of the 5% TAC has demanded.

The private sector is the only place currently where antiretroviral medicines are available on a significant scale. So offering licenses for the public sector and the small NGO sector is of very limited value at present. Furthermore, even when Government does begin to supply antiretrovirals in the public sector, it is important that the medicines are as affordable as possible in the private sector, so that more patients can afford to buy their medicines privately, thereby reducing the burden on the public sector.

It is worth noting that the Nevirapine license between Boehringer and Aspen was only signed after the Competition Commission complaint was laid, an indication the pharmaceutical companies are concerned about the publicity and legal consequences of the complaint.

13. Boehringer Ingelheim have offered to donate Nevirapine for the purposes of mother−to−child transmission prevention. How does this compare to the money they make in the South African private sector?

Boehringer's sales of Nevirapine in the South African private sector were over R8.3 million in financial year 2002. This was made from private sector sales of Nevirapine for the purposes of treatment, not mother−to−child transmission prevention. It is estimated that approximately 15,000 women would have gone through the mother−to−child transmission prevention programme in financial year 2002. Quotations for the cost of Nevirapine indicates that the price varies from R6 to R21 per mother/child pair. Assuming, very unrealistically, that all 15,000 women and children took Nevirapine and that all provinces had accepted the donation (they had not), the value of the Boehringer donation would have been at most R315,000 (assuming R21 per mother/child pair). It was probably far less. This is a small fraction of their sales of Nevirapine for treatment.

At the height of the mother−to−child transmission prevention programme in a few years time, about 200,000 women can be expected to use Nevirapine for mother−to−child transmission prevention per year. This will come to R4.2 million per year. However, the number of private sector purchasers of Nevirapine can also be expected to increase substantially, more than compensating for the donation. Also, there are probably tax deductions accruing to Boehringer due to the donation.

The cost of Nevirapine for the mother−to−child transmission prevention programme is small (less than 1% of the cost); it is an expense that Government could easily absorb without a donation.

14. Did the TAC try to negotiate with the pharmaceutical companies before lodging the complaint?

Since its inception in 1998, the TAC has campaigned for the pharmaceutical industry to lower medicine prices and issue non−exclusive voluntary licenses. On many occasions we have negotiated with the industry or attempted to do so. We will continue negotiating and engaging with the pharmaceutical companies. It is worth noting that at the time of filing the complaint, Boehringer Ingelheim had refused to meet with the TAC. After the complaint was filed, Boehringer approached TAC requesting a meeting.

15. Who are the complainants and what are they saying?

- *Hazel Tau.* Hazel lives openly with HIV. Her affidavit explains how she has become sick and needs antiretroviral medicines. She earns a salary but cannot afford the medicines at their current prices. She could afford them if they were available for R400 to R500 per month. Hazel is the first complainant.
- *Nontsikelelo Zwedala.* Nontsikelelo lives openly with HIV. She lives in a squatter camp in Phillipi township. Her affidavit tells how she became very ill with AIDS, but was fortunate to be able to obtain antiretroviral treatment via a trial. Her health has since recovered remarkably. She will not be able to afford her medicines once her post−trial period comes to an end, but she will be able to access them through the Gugulethu antiretroviral programme.
- *Sindiswa Godwana.* Sindiswa lives openly with HIV. Like Nontisikelelo she also managed to access antiretroviral medicines through a trial. However, when her post−trial period ends she does not know how she will be able to access antiretroviral medicines.
- *Isaac Skosana.* Isaac lives openly with HIV. His affidavit describes how he is becoming very sick. He needs antiretroviral treatment but he cannot afford to pay for a regimen that would

be appropriate for him. He might be able to afford the drugs if they were between R400 to R500 per month.

- *Sister Sue Roberts.* Sue is a nurse at Helen Joseph Hospital. She sees many patients with HIV who need antiretroviral medicines. Her affidavit explains how the high prices of antiretrovirals render them inaccessible for most of her patients. Furthermore, some of her patients on medical schemes are limited from buying the regimen appropriate for them or cannot switch to a different more expensive regimen. She describes the awful situation nurses in the public sector have to face everyday because their patients cannot afford to pay for the medicines they need.
- *Dr. William Mmbara.* William is a doctor working in Hillbrow for the Rhema Christian Service Foundation, an NGO. William states that he wants to treat his patients with antiretroviral medicines. However, he explains that most of his patients cannot access them because they are too expensive. Nor does his NGO have the money to provide antiretrovirals for their patients.
- *Dr. Steve Andrews.* Steve is a doctor practising at the Brooklyn Medical Centre in Cape Town. Steve explains that many of his patients who take antiretroviral treatment have do so through clinical trials. Many on medical schemes began taking sub−optimal regimens because this is all their medical aids would cover. Currently about 35% of his patients require antiretroviral medicines but cannot afford them.
- *Dr. Francois Venter.* Francois is a doctor working at the Johannesburg General Hospital HIV clinic. He explains that most of his patients have to take a sub−optimal antiretroviral regimen with many side−effects, because it is the cheapest and they cannot afford to pay more. He explains how if the prices were not an issue he would advise many of his patients to take AZT, Lamivudine and either Efavirenz or Nevirapine. He describes the frustration of seeing patients having to stop their treatment because they cannot afford to continue paying for them.
- *Congress of South African Trade Unions (COSATU).* COSATU describe in detail, citing many facts and figures, how most South African workers cannot afford access to antiretroviral medicines at their current prices. It describes the devestating effects on them and their families.
- *Chemical, Energy, Paper, Printing, Wood and Allied Workers' Union (CEPPWAWU).* CEPPAWU's affidavit affirms the facts of the COSATU affidavit about the way in which workers are affected by lack of access to antiretroviral (ARV) treatment.
- *Treatment Action Campaign (TAC).* The TAC describes their interest in the case and their efforts to engage and negotiate with the respondents.