

Defiance Campaign - Questions and Answers about TAC and MSF Importing Generic Medicines from Brazil

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1. What medicines have been imported from Brazil?

TAC and MSF have imported generic antiretroviral medicines from Brazil. The scientific names for these medicines are Zidovudine (AZT), Lamivudine and Nevirapine. For part of the imported batch, AZT and Lamivudine are combined together into one capsule.

2. What are these medicines used for?

They stop HIV from reproducing in the human body. This allows the immune systems of people who have HIV/AIDS to get better (reconstitute). These medicines have been shown to help people with HIV/AIDS to live longer, healthier lives.

3. Have TAC and MSF broken the law?

There are patents on these medicines in South Africa. TAC and MSF have committed an act of defiance. By importing them from Brazil, TAC and MSF have infringed the patents. The constitution, which is the highest law in South Africa, protects the rights to life and dignity. By bringing in these medicines, TAC and MSF believe they are upholding these rights. Note that patent infringement is a civil matter, not a criminal one.

4. Why did TAC and MSF do this?

There are patents on these medicines in South Africa. This means that there is no competition on these drugs in South Africa. They are therefore much too expensive. By importing these drugs from Brazil in breach of the country's patent law at much lower prices, TAC and MSF are challenging both the South African government and the pharmaceutical industry. The government is being challenged to pursue voluntary and compulsory licenses (see next question) from the patent-holding pharmaceutical companies. The pharmaceutical companies are being challenged to offer non-exclusive voluntary licenses (see next question) available on their essential medicines.

5. What are compulsory licenses and voluntary licenses on medicines?

A company that holds a patent on a medicine can allow pharmaceutical manufacturers to make this medicine. If they do this, they are giving voluntary licenses to other pharmaceutical manufacturers. If a pharmaceutical company refuses to give voluntary licenses to other manufacturers, a court can order that a compulsory license be issued, giving other manufacturers the opportunity to produce the medicine. It is compulsory because the patent-holder does not have a choice. It must allow companies to manufacture the medicine in competition to it. A court will only issue a compulsory license if there is a good legal reason to do so. Furthermore, it is necessary to first ask the pharmaceutical company to issue voluntary licenses. TAC and MSF want the government to ask the pharmaceutical companies for voluntary licenses. If they refuse to adhere to the government request, the government must then pursue compulsory licenses using the courts.

6. What is meant by a non-exclusive voluntary license?

It is seldom that pharmaceutical companies issue voluntary licenses. When they occasionally do, they often limit the voluntary licenses to a few companies (usually only one) of their choice; i.e., they make the license available on an exclusive basis. A non-exclusive license, means that any company may manufacture them.

7. Why do TAC and MSF want non-exclusive compulsory and voluntary licenses on essential medicines?

This will create competition among the drug companies and ensure that their prices drop. Exclusive licenses are not good enough, because allowing more manufacturers into the market creates more competition and therefore lower prices.

8. What are the respective roles of TAC and MSF in this defiance campaign?

The organisations planned this together. MSF paid for the medicines. TAC volunteers, Zackie Achmat, Matthew Damane and Nomandla Yako, have brought the medicines into the country. Both organisations will share any legal liability that may arise from this action.

9. What role do Cosatu and Oxfam have in this campaign?

Cosatu and Oxfam support what TAC and MSF have done. Furthermore, Cosatu secretariat member, Joyce Pikane, accompanied the TAC volunteers on their mission to Brazil.

10. Which Brazilian company manufactured and sold these medicines to MSF?

Farmanguinhos, which is owned and managed by the Brazilian government, manufactured and sold these medicines to MSF Brazil. MSF Brazil has donated these drugs to the MSF antiretroviral pilot programme in Khayelitsha.

11. Are these generic medicines of the same quality as the patented versions sold in South Africa?

Tests have been conducted on them which show that from a medical point of view, they are identical in quality and effect to the patented versions sold in South Africa. Furthermore, the Medicine Control Council has granted MSF what are known as section 21 exemptions to use these medicines. The section 21 exemptions would not have been granted if the medicines were not considered to be safe and effective. No medicine can be used in South Africa (whether registered or exempted from the registration procedures) without the MCC's approval. Such approval is only granted if the MCC is satisfied that the medicines are safe and effective.

12. President Mbeki says these drugs (generic or patented) are toxic. What is TAC's response?

Nearly all medicines have side-effects, even paracetamol (which most people know by the brand-name Panado). However the benefits of antiretrovirals far outweigh the side-effects. Of course, people on antiretrovirals must be monitored regularly by their doctor or clinic. When this is done correctly, antiretrovirals are safe and effective. In Brazil, these medicines have been responsible for reducing the rate at which people with HIV die by 50%. In rich countries in Europe and North America, the rate at which people with HIV die has been reduced by over 70%. People who need antiretrovirals and do not have access to them usually die prematurely.

13. If compulsory licenses are issued on these drugs, how can South Africans be sure that generic versions will be safe to use?

No drug can be used in South Africa without the Medicine Control Council's permission. Their role is to ensure that medicines are safe and effective. Any generic medicine has to be registered with the Medicine Control Council who will check that it is safe and effective.

14. Who holds the patents on AZT, Lamivudine and Nevirapine in South Africa?

Boehringer Ingelheim holds the patent on Nevirapine. GlaxoSmithKline holds the patents on AZT and Lamivudine.

15. What are the price differences between the medicines bought in Brazil and the ones sold here?

GlaxoSmithKline has offered AZT and Lamivudine (in combination) to the South African government at US\$2 per day (at the current exchange rate this is about R22.80 per day). Farmanguinhos sell it to MSF at US\$0.96 (about R10.94) per day. Boehringer Ingelheim sell Nevirapine for US\$1.19 (about R11.63) per day in South Africa. Farmanguinhos sell it to MSF at US\$0.59 (about R6.76) per day.

16. Why are these medicines not patented in Brazil?

Brazil's patent laws only started applying to pharmaceutical products in 1997. Therefore, all drugs developed before then are not patented in Brazil. This includes AZT, Lamivudine and Nevirapine. For more on the

situation on Brazil, see TAC's fact sheet on the Brazilian response to HIV/AIDS.

17. TAC has imported medicines as part of a defiance campaign before. What is different this time?

TAC continues to import generic fluconazole from Biolab in Thailand in defiance of Pfizer's patent. This campaign has saved and improved the lives of about a thousand people. However, fluconazole is a medicine used to treat opportunistic infections that occur in people with HIV/AIDS. The antiretrovirals imported from Brazil are used to control HIV itself so that it is less likely for infected people to get opportunistic infections. Eventually, nearly everyone with HIV needs antiretrovirals to continue living.

18. Why have these three antiretroviral medicines been chosen?

MSF is conducting a pilot treatment programme in Khayelitsha. The standard first-line regimen for their patients is AZT, Lamivudine and Nevirapine or AZT, Lamivudine and Efavirenz. By buying the generic versions from Brazil, MSF can substantially increase the number of people on this programme (currently 85 people).

19. DDI and D4T are cheaper than AZT and Lamivudine. Why does MSF not use these drugs instead?

Firstly, the AZT and Lamivudine from Brazil are cheaper than the versions of ddI and d4T available in South Africa. Furthermore, for most people, AZT and Lamivudine are a better option to begin with than ddI and d4T.

20. As with fluconazole, will these medicines be made generally available to the public through doctors?

NO! Antiretroviral medicines are expensive and require more complex logistics to administer and monitor than fluconazole. These drugs are being imported only for use in the MSF programme in Khayelitsha. Unfortunately, they cannot be offered to anyone not on the programme. Ultimately, this enormous task must fall upon the state and the private sector as a whole. It can only happen on a large scale once the government adopts a national HIV/AIDS treatment and prevention plan.

21. GlaxoSmithKline has given Aspen Phamacare a voluntary license to produce AZT and Lamivudine. Why is this not good enough? Why did MSF and TAC not get the drugs from Aspen?

The license is exclusive and it has draconian conditions attached to it. Aspen may only sell their drugs to NGOs and the public sector. TAC and MSF are demanding that non-exclusive voluntary licenses be made available for sale to both the public and private sectors. Furthermore, Aspen's drugs are not yet ready and they have indicated that their price will be higher than Farmanguinhos's price.

22. Boehringer Ingelheim have offered Nevirapine for free. How can the

price possibly get lower than that?

The company has offered Nevirapine for free only for the use of mother-to-child transmission prevention in the public sector. It is not offered for free as part of an antiretroviral treatment programme. TAC has calculated that Boehringer's donation of Nevirapine amounts to approximately R1.5 million per year (using Boehringer's price) if a country-wide mother-to-child transmission prevention programme is fully implemented. Putting just 355 people with AIDS on Nevirapine for a year exceeds the donation amount in revenue. The donation is double-edged and aimed at taking attention off the area where the real costs for South Africa lie: treating people with HIV/AIDS.

23. The pharmaceutical companies say that compulsory licenses are property theft and that if they are issued South Africa will be doing what Mugabe has done in Zimbabwe. What is TAC's response?

Firstly, a compulsory license is something allowed by South African and international law, after due process. Secondly, when a compulsory license is issued, the generic manufacturers have to compensate the patent-holder. TAC has asked that generic manufacturers pay a 5% royalty fee to the patent-holders. The analogy with Zimbabwe is ridiculous. In Zimbabwe, the law has been ignored and perverted. Even the forcibly evicted farmers in Zimbabwe do not deny that there is a need for land reform. However, what is wrong in Zimbabwe is the means that have been used to carry out Mugabe's so-called land reform programme. While compulsory licenses on medicines will save lives, Mugabe's actions are endangering lives.

24. Would issuing compulsory licenses put the South African government in breach of its international obligations?

South Africa is a signatory to the World Trade Organisation Trade Related Aspects of Intellectual Property Rights (TRIPs) agreement. This agreement sets out the minimum standards of intellectual property protection that countries must abide by. This agreement makes provision for compulsory licenses. Furthermore, in a recent meeting of the World Trade Organisation's members in Doha, Qatar, it was agreed that TRIPs should not stand in the way of a country's health concerns. The South African government can pursue compulsory licenses without breaching its international obligations and without scaring off foreign investors (if the process is managed correctly).

25. What is TAC's position on local production of generic antiretrovirals?

Local production is essential for a number of reasons. It will (a) create more competition, (b) insulate, to some extent, the prices of antiretrovirals against the depreciation of the rand and (c) create jobs. Both local production and importation of antiretrovirals will be essential to meet the country's (and the SADC region's) treatment needs. Antiretrovirals need to be taken for life. It is therefore crucial that the supply of these medicines be sustainable. The best way of guaranteeing this is via competition between producers, including local ones.

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