

IMPLEMENTATION OF THE COVENANT ON CIVIL AND POLITICAL RIGHTS

UGANDA

Trade-related intellectual property rights, access to HIV/AIDS medicines and the fulfilment of civil and political rights March 2004

Introduction

1. The HIV/AIDS epidemic in Uganda has claimed over 800,000 lives in two decades and continues to be the country's main cause of death amongst adults.¹ In 2001, approximately 510,000 adults and 110,000 children were living with HIV/AIDS.² Access to affordable antiretroviral (ARV) medicines is vital for these people to survive and enjoy their civil and political rights.

2. State parties to the International Covenant on Civil and Political Rights (ICCPR) are obliged to protect the right to life under article 6, as interpreted by HRC General Comment No. 6 (1982) and the rights of the child under article 24, as interpreted by HRC General Comment No 17 (1989). These obligations include the need to adopt positive measures to reduce infant mortality and increase life expectancy, especially in the context of epidemics like HIV/AIDS.

3. Uganda, as State party to the ICCPR is obliged to take the necessary steps for the implementation of the rights recognized by the Covenant and has undertaken exemplary measures to fight HIV/AIDS.³ The initial report of Uganda to the Human Rights Committee underlines the fact that the government of Uganda has taken measures to limit the spread of HIV/AIDS and increase access to ARV treatment.⁴ However, these measures are being threatened by the introduction of trade-related intellectual property (IP) laws that risk raising the price of drugs in advance of the 2016 deadline specially granted to least developed countries (LDCs) by the WTO Doha Declaration on TRIPS and Public Health 2001.⁵

4. 3D ->Trade-Human Rights-Equitable Economy is a not-for-profit organization based in Geneva, Switzerland, working to ensure that trade rules are developed and applied in ways that promote an equitable economy. We believe that human rights mechanisms such as the Human Rights Committee can help attain this objective by reminding States that trade rules cannot justify non-compliance with human rights obligations.

5. This submission to members of the Human Rights Committee delineates our human rights-based concerns and recommends that Uganda seek all available technical assistance, particularly from the Office of the High Commissioner for Human Rights (OHCHR) to ensure that its IP laws

¹ See Uganda AIDS Commission Secretariat, HIV/AIDS in Uganda: The epidemic and the response, 2002.

² See UNAIDS/WHO Epidemiological Fact Sheet, Uganda, 2002 Update.

³ See Ugandan Ministry of Health, Antiretroviral Treatment Policy for Uganda, April 2003

⁴ See United Nations Human Rights Committee, Initial Report of Uganda, CCPR/C/UGA/2003/1 at paragraph 135.

⁵ See WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 14 Nov. 2001.

governing the manufacture, import and distribution of pharmaceuticals are drafted and implemented in a way that enables Uganda to fulfil its obligations under the ICCPR.

I. Access to HIV/AIDS medicines and the right to life in Uganda

6. The cost of antiretroviral (ARV) treatment has dramatically decreased since the UNAIDS Drug Access Initiative of 1997-2000. The most radical drop in prices came as a result of the import of generic ARV drugs from India in 2000.⁶ The competition created by the import of generic drugs has led to further price reductions on patented medicines under the UN Accelerated Access Initiative.⁷

7. According to research conducted by Oxfam in 2001, about 95% of the medicines used in Uganda are imported and 80% of these are generic drugs.⁸ However, despite the drop in cost due to the import of generic ARV drugs, the price of treatment remains unaffordable for most Ugandans and in 2002 only 10,000 of the 600,000 people living with HIV/AIDS had access to life-saving drugs.⁹ This situation is explicitly recognized by the government of Uganda in paragraph 135 of its initial report to the Human Rights Committee.¹⁰

8. The Ugandan pharmaceutical industry has tried to obtain a license to produce even cheaper local ARV drugs. However, their application was rejected by the Health Ministry and National Drug Authority due to the risk that the drugs would be of insufficient quality.¹¹

9. Therefore, in order to make ARV treatment affordable for the most vulnerable groups in Uganda and comply with the right to life under article 6 ICCPR and the rights of the child under article 24 ICCPR, competition from imports of cheap generic drugs must continue and the capacity of Uganda's national pharmaceutical industry must be reinforced.

II. Access to HIV/AIDS medicines in Uganda and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

A. TRIPS, LDCs and public health

10. Uganda is a member of the World Trade Organization (WTO). It is therefore bound to implement the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which aims to provide a minimum level of IP protection in all WTO members states.

11. However, the TRIPS Agreement grants least developed countries (LDCs) the right to delay implementation into national law until 2006, and even provides for further extensions if the LDC Member makes a request for an extension to the WTO TRIPS Council. Furthermore, the Doha Declaration on TRIPS and Public Health (Doha Declaration) allows LDCs to delay enforcement of patent rights until 2016 (patents being the IP rules most affecting the cost of medicines). Uganda, as an LDC under the WTO's criteria, has the right to use these extensions.

12. The TRIPS Agreement also has provisions to ensure that countries meet their public health obligations. This is emphasized by the Doha Declaration which stresses that the TRIPS

⁶ Generic drugs are equivalent to patented drugs, and are usually made without a license from the patent holder.

⁷ See WHO, *Scaling Up Antiretroviral Therapy: Experience in Uganda: Case Study*, 2003.

⁸ See Astrid Martinez-Jones and Norbert Anyama for Oxfam GB, *Access to Antiretroviral Therapy in Uganda*, June 2002.

⁹ See WHO, 2003, note 6 supra.

¹⁰ See Human Rights Committee, 2003, note 4 supra.

¹¹ See Michael Wakabi, *Business Day*, Uganda rejects local HIV generics bid, 23 August 2001.

Agreement “can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, access to medicines for all.”

B. Access to medicines and IP reform in Uganda

13. Uganda is currently involved in a process of legislative reform which aims to implement its TRIPS obligations into national law. The Uganda Law Reform Commission has drafted an Industrial Property Bill, 2001 (IP Bill) which is being reviewed by a “TRIPS Task Force,” composed of representatives from Government ministries, the public sector and a National NGO Forum.¹² Despite participation of the NGO Forum, it is not clear whether all groups concerned have been consulted, particularly those representing women and children living with HIV/AIDS, as required by article 25 ICCPR. Moreover, the second draft of the IP Bill has not been openly made available to members of the public, contrary to the right to access information contained in article 19 ICCPR.

14. If the IP Bill is approved by Parliament this year, Uganda will have failed to make the most of the delays granted to LDCs by the TRIPS Agreement and Doha Declaration, with the risk that drugs to treat HIV/AIDS could become even more expensive. Uganda risks violating its obligation to take all measures to protect the right to life under article 6 ICCPR and every possible economic and social measure to protect children's rights under article 24 ICCPR. Uganda should therefore be encouraged to further delay implementation of the TRIPS Agreement into national law until 2006 and include a waiver in its IP rules delaying the enforcement of patent laws until 2016.

C. TRIPS flexibilities and mechanisms allowing access to HIV/AIDS medicines

15. Uganda should be encouraged to include in its IP Bill all the flexibilities and safeguards available in the TRIPS Agreement and Doha Declaration and discouraged to include provisions that go beyond the requirements of the TRIPS Agreement (termed “TRIPS-plus” provisions). The following flexibilities should be adapted to Uganda's development needs and drafted in a way that ensures access to medicines and the fulfilment of Uganda's human rights obligations under the ICCPR:

- **Compulsory licensing:** the ability of the relevant authorities to grant and define when to issue a license to manufacture or import a generic drug without the consent of the patent holder, as long as the patent holder is compensated. Prior authorization from the patent holder can be waived if there is a “national emergency or other situation of extreme urgency” such as an HIV/AIDS public health crisis. This is an important measure for Uganda to ensure continued access to cheaper generic drugs, especially once it has the capacity to produce ARV drugs.
- **Government use:** the ability of the government, or an agent, to import, manufacture, supply or use a patent without the consent of the patent holder, as long as the patent holder is informed and compensated. This measure is important to supply national ARV access programmes with cheap imported generic drugs.
- **Exhaustion of patent rights:** the ability to decide when patent holders lose their exclusive right over the sale of drugs. This freedom is a crucial policy tool for Uganda, as it enables the importation of patented drugs from countries where patent rights have already ended and are less expensive (termed “parallel importation”).
- **Exceptions to patent rights:** an example of such an exception is to allow national pharmaceutical companies to import, manufacture and test a drug prior to the expiry of the patent, in order to obtain regulatory approval, thereby ensuring that generic drugs are quickly made once the patent runs out (termed “Bolar provision”). Inclusion of a broad Bolar provision

¹² See Samuel Wangwe for the UK Commission in Intellectual Property Rights, Country Case Study for Study 9: Institutional Issues for Developing Countries in IP Policy-Making, Administration and Enforcement: Uganda, 2002.

could help stimulate the Ugandan pharmaceutical industry in the future, and play an important role in Uganda's industrial development.

16. Since the WTO General Council Decision of 30th August 2003 (General Council Decision) Uganda has another mechanism at its disposal to facilitate access to ARV treatment. This mechanism aims to resolve the problem of States who could not use the TRIPS Agreement compulsory licensing provisions due to the limitation on imports and the fact that they lacked capacity to make their own drugs. The mechanism provided, although complex, allows the import of drugs without the importing State paying a fee to the patent holder. Uganda could qualify as an eligible importing member if it declared that it had insufficient capacity to meet its needs to respond to the HIV/AIDS public health situation. It should be encouraged to use this mechanism to guarantee continued access to cheaper generic medicines.

Conclusion

17. Uganda has a duty under the ICCPR to ensure access to affordable ARV medicines. In order to fulfil this obligation it must retain sufficient policy flexibility to enforce IP rights in a way consistent with its human rights obligations. It should therefore make use of the delays granted by the TRIPS Agreement and Doha Declaration and ensure that IP laws are drafted and implemented in conformity with its human rights obligations, including those under the ICCPR.

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For information on 3D's work in general, or on 3D's project on the impact of trade-related intellectual property rules on access to medicines and human rights, please visit www.3dthree.org or contact:

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Uganda: issues of concern on access to medicines and the ICCPR

Right to life (article 6 ICCPR)

Question: Will the government of Uganda implement the flexibilities and delays in the TRIPS Agreement and Doha Declaration in order to ensure access to HIV/AIDS medicines, thereby protecting the right to life under article 6 ICCPR?

Recommendation: The government of Uganda should ensure that its intellectual property laws ensure access to affordable HIV/AIDS medicines, in order to be consistent with its obligation not to violate the right to life under article 6 ICCPR.

Rights of the child (article 24 ICCPR)

Question: Has the government of Uganda taken special measures to ensure children's access to affordable HIV/AIDS medicines under article 24(1) ICCPR when implementing the TRIPS Agreement into national law?

Recommendation: The government of Uganda should take special measures to ensure children's access to affordable HIV/AIDS medicines under article 24(1) ICCPR when implementing trade-related intellectual property rights into national law.

Freedom to access information (article 19 ICCPR) and the right to participate in public affairs (article 25 ICCPR)

Question: Has the government of Uganda given all groups representing people living with HIV/AIDS access to information on the draft intellectual property bills under article 19 ICCPR and has it consulted with people living with HIV/AIDS in accordance with article 25 ICCPR when formulating trade policy and implementing the TRIPS Agreement into national law?

Recommendation: the government of Uganda should make sure its legislative reform proposals and trade policy positions are accessible to the public, consult widely and encourage participation of civil society groups representing the interests of all people living with HIV/AIDS when implementing trade-related intellectual property rights into national law.

Technical Assistance (article 2 ICCPR)

Question: Has Uganda requested technical assistance under article 2 ICCPR to ensure that its intellectual property rights are developed and implemented in ways that help it ensure the realization of the rights set out in the ICCPR?

Recommendation: The government of Uganda should seek technical assistance, particularly from the Office of the High Commissioner for Human Rights (OHCHR), to ensure that trade-related intellectual property rights are developed and implemented in a way that facilitates access to affordable medicines in a manner consistent with the obligations of the ICCPR.

Making the principles and provisions of the Convention widely known (article 2 ICCPR)

Question: Has Uganda taken measures under article 2 ICCPR to make its trade policy officials aware of the principles and provisions of the ICCPR?

Recommendation: The government of Uganda should ensure that the principles and provisions of the ICCPR are widely known to its trade negotiators.