

Trade-related intellectual property rights, access to medicines and the right to health - Ecuador April 2004

Submitted by 3D → Trade - Human Rights - Equitable Economy¹

Introduction

1. In Ecuador, treatable diseases are often fatal, particularly in rural areas and amongst minorities and indigenous peoples. This alarming situation is compounded by the fact that only 21.5% of the population has access to medicines.² One of the major factors limiting access and timely treatment is the high cost of medicines. Reducing the price of medicines is therefore vital for the health of vulnerable groups in Ecuador.

2. Ecuador, as a State party to the International Covenant on Economic, Social and Cultural Rights has an obligation to respect, protect and fulfil the right to the highest attainable standard of health under article 12, as interpreted by General Comment No. 14(2000). Inherent in the right to health is the obligation to ensure everyone's access to affordable medicines without discrimination, in order to notably prevent, treat and control diseases.

3. Ecuador is obliged under article 2(1) ICESCR to take steps in order to progressively realize the rights in the Covenant.³ The second periodic report of Ecuador to the Committee on Economic, Social and Cultural Rights points to policy measures taken by the Ministry of Public Health to progressively remedy inequalities in access and regulate the price of medicines.⁴

4. However, these measures are being threatened by the prospect of restrictive trade-related intellectual property (IP) laws in free trade agreements: the US-Andean Free Trade Agreement on which negotiations are scheduled to begin in May 2004, and the Free Trade Agreement of the Americas (FTAA), the negotiations for which are currently underway. These agreements risk imposing an IP system on Ecuador that would raise the price of medicines for everyone and prevent the use of policy flexibilities necessary to protect the right of everyone to the highest attainable standard of health.⁵

5. 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 Committee on Economic, Social and Cultural Rights can help attain this objective by reminding States that compliance with international trade rules cannot justify non-compliance with human rights obligations.

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² See PAHO, Ecuador Basic Country Health Profile, 2001.

³ See Committee on Economic, Social and Cultural Rights (CESCR), General Comment No.3 (1990).

⁴ See CESCR, Second Periodic Report of Ecuador, E/1990/6/Add.36, paragraph 466.

⁵ See the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS Agreement) and the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 14 Nov. 2001.

6. This submission to members of the Committee on Economic, Social and Cultural Rights delineates our human rights-based concerns and recommends that Ecuador seek all available technical assistance from the Office of the High Commissioner for Human Rights (OHCHR) to ensure that its IP laws governing the manufacture, import and distribution of pharmaceuticals are negotiated and implemented in a way that enables Ecuador to fulfil its obligations under the ICESCR.

I. Access to medicines and the right to health in Ecuador

7. Access to medicines remains a luxury in Ecuador, as the vast majority of the population cannot meet the expense. Nevertheless, Ecuador, in conformity with its obligation to protect the right to health under article 12, as interpreted by General Comment No. 14(2000), has taken legislative measures to address the problem. In 2000 Ecuador passed a Law on Generic Medicines which obliges public institutions to use cheaper generic drugs that are interchangeable and equivalent to patented ones.⁶ The law also reduces the profits of pharmacies on patented medicines and encourages them to dispense generic versions.

8. Ecuador has also taken measures to fulfil the right to health by participating in regional price negotiations for antiretroviral (ARV) drugs used to treat HIV/AIDS.⁷ These negotiations with pharmaceutical companies concluded in June 2003 and achieved price cuts from 30-92% for first-line triple therapy drugs and 9-72% for second-line drugs.⁸ Of the eight companies that participated, all but one are generic drug manufacturers.⁹ The prices obtained are for the supply of public institutions for a period of one year as of June 2003. These price cuts are an important step towards providing affordable ARV drugs, since currently only 324 of the estimated 40,000 people living with HIV/AIDS in Ecuador are receiving treatment.¹⁰

9. However, these price reductions, although commendable, are limited in time and scope. Indeed, in order for Ecuador to ensure access to affordable medicines for all vulnerable groups and fulfil its obligations under article 12 ICESCR, prices for essential medicines need to be cut. In order for the price of medicines to fall across the board, competition from local and imported generic drugs is crucial.

II. Access to medicines in Ecuador and the WTO TRIPS Agreement

A. TRIPS and health

10. The price of medicines is affected by intellectual property (IP) regulations that give exclusive rights to the owners of a patented invention. Ecuador, as a member of the World Trade Organization (WTO), was obliged to amend its IP laws by January 2000 to comply with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).¹¹

11. The TRIPS Agreement is a framework agreement which provides a minimum standard of IP protection in all WTO member states. In order to reduce the adverse effects of IP rights on the cost of healthcare, the TRIPS Agreement tries to balance public and private interests. Most importantly, however, the WTO Doha Declaration on TRIPS and Public Health (Doha Declaration) expressly recognizes the need to ensure policy flexibility to States in applying IP

⁶ See Ecuador, Ley de Producción, Importación, Comercialización y Expendio de Medicamentos Genéricos de Uso Humano, Registro Oficial, No. 59, 2000.

⁷ See Process of Joint Negotiations for the Access to Antiretroviral and Reactive Drugs in the Andean Subregion, Argentina, Mexico and Paraguay, Framework Document, May 2003.

⁸ See PAHO, Fact Sheet, Antiretroviral price negotiations in 10 Latin American Countries, 2003.

⁹ See above.

¹⁰ See PAHO, Patients under antiretroviral treatment in Latin America and the Caribbean, 2003.

¹¹ See Ecuador Ley de Propiedad Intelectual, Registro Oficial, No. 320, 1998.

rights and stresses that the TRIPS 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. TRIPS flexibilities and mechanisms allowing access to medicines

12. The TRIPS Agreement and Doha Declaration give States various tools to fulfil their public health obligations and ensure access to cheaper drugs. These crucial flexibilities include, among others:

- **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.
- **Exhaustion of patent rights:** the ability to decide when patent holders lose their exclusive right over the sale of drugs. This 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”).
- **Prohibition of anti-competitive practices:** This provision gives states the ability to penalize pharmaceutical patent owners that abuse their dominant position in contractual relationships and engage in prohibitive pricing.

Ecuador should be encouraged to use these policy flexibilities, especially compulsory licensing, to supply itself with cheaper generic drugs under its essential medicines policy.

13. Another mechanism which could potentially reduce the price of medicines in Ecuador is the solution provided by the WTO General Council Decision of 30th August 2003 (General Council Decision). This waiver to the TRIPS Agreement is aimed at States’ unable to use compulsory licensing due to insufficient drug manufacturing capacity. Although Ecuador has some national drug manufacturing capacity, it may be insufficient faced with a health crisis. Thus, Ecuador should be encouraged to support a practical application of the solution in the current WTO negotiations on a permanent amendment to TRIPS. It should also be encouraged to pass legislation allowing for use of the mechanism.

III. Threats to access to medicines in Ecuador raised by free trade agreements

A. TRIPS-plus conditions in the Free Trade Agreement of the Americas (FTAA)

14. Ecuador is participating in the negotiations for a regional Free Trade Agreement of the Americas (FTAA) aiming to conclude by 2005 and covering 34 countries from across the Americas. The FTAA includes a chapter on IP rights that will apply to all signatories of the agreement. The third draft IP chapter, made public on 21st November 2003, includes various proposals that go beyond the TRIPS Agreement (termed TRIPS-plus) and that risk undermining the policy flexibilities obtained in the Doha Declaration. The most alarming are:

- **Compulsory licensing restrictions:** the draft FTAA aims to limit the scope of compulsory licensing even if the Doha Declaration gives States the right to define their own policies. Moreover, the proposals include a prohibition on the export of drugs under compulsory license, which would undermine the mechanism of the WTO General Council Decision of 30th August 2003.

- **Exhaustion of patent rights:** the draft FTAA aims to provide a minimum principle of “regional exhaustion” that would curtail imports of patented medicines sold cheaper in other countries, as the exclusive right of patent holders over marketing would not end until after the drug has been marketed in the whole region of the Americas.

B. TRIPS-plus conditions in the US- Andean Free Trade Agreement

15. Of even greater concern, however, are the free trade agreements being negotiated in parallel to the FTAA. The US-Chile Free Trade Agreement 2003 and the even stricter Central American Free Trade Agreement (CAFTA) 2003 are being used by the United States as benchmarks for other negotiations, pushing IP protection to critically high levels, and posing real difficulties for access to affordable medicines.

16. The first round of negotiations for the US- Andean Free Trade Agreement is scheduled to begin on the 18th May 2004 between the United States and Colombia. Ecuador is expected to join in the negotiations shortly afterwards, followed by Peru and Bolivia.¹² It is feared that TRIPS-plus provisions from other bilateral and regional free trade agreements will be included, the most alarming being:

- **Exclusive rights over test data:** owners of patented drugs that have not yet been marketed or registered in a country are granted exclusivity over test data on safety and efficacy for a period of five years. This gives patent holders rights over data that is not confidential and has the damaging effect of delaying the manufacture of cheap generic drugs by five years.
- **Extension of the patent term for unreasonable delays:** the patent term is extended beyond the twenty years of TRIPS by allowing an “adjustment” of three to five years for “unreasonable delays” experienced during the granting of a patent. In practice, this is equivalent to extending the patent term to twenty-five years.

C. Trade negotiation procedures and access to information on health

17. Unlike the FTAA negotiations, where draft texts are made public and civil society groups are consulted throughout the process, the US-Andean Free Trade Agreement negotiations risk being as secretive and expedient as other recent negotiations have been, of which CAFTA is an example. Moreover if the CAFTA model is followed, there will be no consultation with representatives of civil society or vulnerable groups. Ecuador must be reminded that this would be a violation of the obligation to ensure freedom to seek, receive, and impart information on matters affecting health according to article 12 CRC, as interpreted by General Comment No. 14 (2000), as well as general human rights principles of accountability, access to information, and participation.

Conclusion

18. Ecuador has a duty under the ICESCR to ensure access to affordable medicines. In order to fulfil this obligation it must refrain from hastily entering into any free trade agreement that could curtail its policy flexibility to enforce IP rights in a way consistent with its human rights obligations. Moreover, it should ensure that IP rules negotiated in free trade agreements and implemented in national law are in conformity with Ecuador’s human rights obligations, including under the ICESCR.

¹² See USTR Press Release, US and Colombia to Begin FTA Negotiations on May 18: Larger US-Andean Free Trade Area Envisioned As Other Andean Countries May Participate, 23 March 2004.

Ecuador: issues of concern on access to medicines and the ICESCR

Access to affordable medicines (article 12 ICESCR, as interpreted by General Comment No. 14(2000))

Question: Has the government of Ecuador taken measures to protect policy flexibilities allowing access to medicines from being eroded by free trade agreements in order to comply with the obligation to ensure access to affordable medicines under the right to health?

Recommendation: The government of Ecuador should protect access to medicines by avoiding retrogressive measures in free trade agreements that violate the obligation to ensure access to affordable medicines enshrined in the right to health.

Access for vulnerable groups (article 12(2) ICESCR, as interpreted by General Comment No. 14(2000))

Question: Has the government of Ecuador taken steps to ensure that the implementation of trade-related intellectual property rules allows everyone access to affordable medicines, especially for vulnerable groups such as women, children, the elderly, minorities and indigenous groups?

Recommendation: The government of Ecuador should take measures to ensure that trade-related intellectual property rules are negotiated and implemented in a way that allows everyone access to medicines, especially for vulnerable groups.

Information accessibility (article 12 ICESCR, as interpreted by General Comment No. 14(2000))

Question: Has the government of Ecuador taken measures to ensure access to information on the impact of trade-related intellectual property rights on health, particularly in the context of negotiations for free trade agreements?

Recommendation: the government of Ecuador should make sure that information on trade policy positions and free trade agreements that may affect the right to health is be made accessible to the public.

Technical assistance (article 2(1) ICESCR, as interpreted by General Comment No. 3(1990) and article 23 ICESCR)

Question: Has the government of Ecuador requested human rights technical assistance in order to ensure that trade-related intellectual property rights allow access to affordable medicines enshrined in the right to health?

Recommendation: The government of Ecuador should seek human rights technical assistance from the Office of the High Commissioner for Human Rights (OHCHR), to ensure that trade-related intellectual property rights are negotiated, developed and implemented in a manner consistent with the obligations of the ICESCR.