

International trade, health, and children's rights - Ecuador September 2004

Introduction

1. In Ecuador a high proportion of childhood deaths from infectious disease could be avoided if children had access to essential medicines. One of the major factors limiting access is the cost of the drugs. Ecuador has taken steps to reduce the price of essential medicines by passing a Law on Generic Medicines which requires public institutions to use generics equivalent drugs and pharmacies to promote their use.¹ However, since this law came into effect in 2000, the amount of generic drugs on the market has only increased from 8% to 12% in 2003.² Therefore, much still needs to be done to ensure that the price of quality drugs is sufficiently low in order to ensure access to essential medicines for all children.

2. Ecuador, as state party to the Convention on the Rights of the Child (CRC), must give primary consideration to the best interests of the child in all its actions according to article 3. Also, Ecuador has an obligation to promote and protect the child's right to the enjoyment of the highest attainable standard of health under article 24 CRC and the child's inherent right to life, survival and development under article 6 CRC. Inherent in the right to health and the right to life is the child's right to "sustained and equal access" to comprehensive treatment and affordable medicines without discrimination, as interpreted by CRC General Comment No.3 (2003) on HIV/AIDS and CRC General Comment No. 4 (2003) on Adolescent Health.

3. These human rights obligations, and others, are at risk of being undermined by trade-related intellectual property (IP) rules in trade agreements. Ecuador is currently negotiating the Free Trade Agreement of the Americas (FTAA) and the US-Andean Community Free Trade Agreement (FTA), both scheduled to conclude in early 2005. The proposed IP rules in these agreements could dramatically curtail Ecuador's ability to take measures that would fulfil its human rights obligations, particularly under the Convention on the Rights of the Child.

4. 3D -> Trade - Human Rights - Equitable Economy (3D) 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 the Rights of the Child can help attain this objective by reminding States that compliance with international trade rules cannot justify non-compliance with human rights obligations.

5. This submission to the Committee on the Rights of the Child pre-session Working Group outlines 3D's main concerns relating to the impact of trade rules on children's rights in Ecuador. The first part delineates our concerns relating to the impact of intellectual property (IP) rules on the child's right to health and the child's right to life, survival and development (section I). The second part outlines our concerns on the lack of transparency in the trade negotiations and how this impacts on children's rights (section II). Due to the fact that the trade negotiations are soon scheduled to end, we will submit more detailed information on these issues, in advance of the Committee's 38th Session of January 2005.

¹ Ecuador, Ley de Producción, Importación, Comercialización y Expendio de Medicamentos Genéricos de Uso Humano, *Registro Oficial*, No. 59, 2000.

² Consejo Nacional de Salud (CONASA) 2003.

I. Threats to public health and children's rights in Ecuador raised by free trade agreements:

6. As mentioned above, the two major trade agreements Ecuador is currently negotiating are the Free Trade Agreement of the Americas (FTAA) and the US-Andean Free Trade Agreement (FTA) negotiations. The FTAA is a regional trade agreement covering 34 countries across the Americas, whilst the US-Andean FTA is a bilateral trade agreement between the United States and Ecuador, Colombia and Peru (with Bolivia expected to join shortly). It is of great concern that if Ecuador negotiates these agreements without giving prime consideration to the best interests of the child, it may risk undermining its ability to fulfil its obligations under the Convention on the rights of the Child.

A. Intellectual Property and access to medicines

7. Trade-related intellectual property (IP) rights can affect access to affordable medicines which is a crucial aspect of the child's right to health and the child's right to life. Of greatest concern are patents, which grant exclusive rights over the manufacture, use or sale of an invention. Patent rights allow patent owners to keep prices of patented drugs artificially high, thereby affecting the affordability of medicines for the most vulnerable and marginalized groups.

8. As member of the World Trade Organization, Ecuador is obliged to implement the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).³ The TRIPS Agreement contains a number of flexibilities which aim to reduce the adverse impacts of patent rules on prices. These flexibilities have been reaffirmed by the Doha Declaration on TRIPS and Public Health, in order to make cheaper drugs available.⁴ One of these crucial flexibilities is the ability to define and grant a compulsory license to manufacture, use or sell a generic equivalent version of a patented drug without the consent of the patent holder, as long as the patent holder is compensated.

9. Another mechanism that Ecuador could use to reduce the price of drugs is the WTO General Council Decision of 30th August 2003 (General Council Decision). This decision is a temporary waiver to the TRIPS Agreement that allows States with insufficient drug manufacturing capacity to fully benefit from compulsory licensing. Although Ecuador has some national drug manufacturing capacity, it may not always be sufficient to meet national needs. Therefore, it should be encouraged to pass implementing legislation allowing it to use this compulsory licensing mechanism as soon as possible, to ensure that it has all the tools at its disposal to fulfil its human rights obligations, of which the Convention on the Rights of the Child.

B. TRIPS-plus conditions in trade agreements: the Free Trade Agreement of the Americas (FTAA) and the US-Andean Free Trade Agreement

10. The draft IP chapters in the trade agreements under negotiations include provisions that go beyond the TRIPS Agreement (termed TRIPS-plus rules). For example, the third draft of the FTAA contains a clause that prohibits the export of drugs under compulsory license, which is contrary to the spirit of the Doha Declaration and the WTO General Council Decision. Although the draft text of the US-Andean FTA is not available to the public, the US IP proposal released before the fourth round of negotiations in September 2004 echoes other clauses found in previous FTAs negotiated by the United States.⁵ In a letter to the Andean Ministers of Trade of 10 September 2004,

³ Ecuador Ley de Propiedad Intelectual, Registro Oficial, No. 320, 1998.

⁴ 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 November 2001.

⁵ Ricardo Santamaria Daza, Serias Peticiones de Estados Unidos en Patentes, *la Republica*, Colombia, 27 August 2004.

Médecins Sans Frontières outlines how these proposals risk undermining the flexibilities permitted by TRIPS:⁶

- **Extension of the patent term for unreasonable delays:** “adjustments” of three to five years for “unreasonable delays” in granting a patent. Such provisions effectively extend the patent term beyond the TRIPS twenty year period.
- **Compulsory licensing restrictions:** limitations on the export of drugs under compulsory license. This would undermine the mechanism of the WTO General Council Decision.
- **Parallel import restrictions:** limitations on imports of patented drugs from other countries. This would be contrary to the spirit of the Doha Declaration which allows Members the freedom to decide their own regime.
- **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 for five years if the drug is new or three years if it is a known chemical entity. This protection means that patients need to wait up to five years before generic versions of the drug are available. There TRIPS Agreement does not grant these rights.
- **Marketing authorization:** drug regulatory authorities' are given the power to require generic manufacturers to get the consent of patent owners in order to use test data for marketing authorization. Since generic manufacturers cannot afford to re-do these tests, this could effectively undermine compulsory licensing.

11. Moreover, it is important to note that in July 2004 a draft presidential decree tried to include a number of these TRIPS-plus rules into national law before the end of the negotiations. In a letter to the President⁷ civil society groups criticized the decree on the grounds that it violated constitutional law and undermined Ecuador’s ability to respect, protect and fulfil the right to health, in accordance with the recommendations of the Committee on Economic, Social and Cultural Rights.⁸ Ecuador’s head trade negotiator replied to these concerns in a letter dated 23 July 2004, where he explicitly agreed that the draft decree was unconstitutional, contrary to the Doha Declaration on TRIPS and Public Health and risked impeding access to affordable medicines.⁹

II. Trade negotiation procedures: limited access to information and participation

12. Contrary to the FTAA negotiations, where civil society groups have been given access to draft texts and encouraged to submit written contributions, the US-Andean FTA negotiations have been secretive. There are only ad hoc consultations with civil society and access to information on the negotiations is limited. Although Ecuador has set up an information point on the FTA, documents cannot be consulted without knowing their title. Since there is no information on the documents available, it is not possible for civil society groups to make use of this facility. Ecuador must therefore be reminded that this is inconsistent with its obligation to respect the views of the child under article 12 CRC, to ensure access to information on the child’s physical health according to article 17 CRC and to ensure the child’s freedom to seek, receive, and impart information according to article 13(1) CRC.

⁶Médecins Sans Frontières, *Open Letter to Ministers of Trade in Countries Negotiating the US-Andean Free Trade Agreement*, 10 September 2004.

⁷ CDES, *¿Cuanto Cuesta el Derecho a la Salud en Ecuador? Carta abierta al Presidente de la Republica*, 9 July 2004.

⁸ Committee on Economic, Social and Cultural Rights (CESCR), Thirty-second session, Concluding Observations, Ecuador E/C.12/1/Add.100, 14 May 2004.

⁹ Letter to Centro de Derechos Económicos, Sociales y Culturales (CDES) from Cristian Espinosa, Ecuadorian Head Negotiator, 23 July 2004.

Conclusion

13. Ecuador has begun taking measures to ensure access to affordable medicines, particularly through the Law on Generic Medicines of 2000. However, these measures risk being undermined by restrictive IP rules in bilateral and regional trade agreements. It is therefore imperative that Ecuador refrain from entering into agreements that would undermine its human rights obligations, particularly under the Convention on the Rights of the Child. It is also important that Ecuador undertake an impact assessment of the human rights effect of IP rules on access to affordable medicines before negotiating or implementing any new trade rules.

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Ecuador: issues of concern on trade, health and the CRC

Right to life, survival and development (article 6), right to the highest attainable standard of health (article 24 CRC) and obligation to review the treatment provided to the child (article 25 CRC)

Question: Has the government of Ecuador assessed the possible impacts on children's rights, particularly the child's right to life, survival and development and the child's right to health, of the proposed intellectual property rules in trade agreements?

Recommendation: The government of Ecuador should undertake human rights impact assessments before negotiating or implementing trade agreements, in order to ensure that they do not undermine the State's obligations under article 6 and article 24.

Best interests of the child (article 3 CRC)

Question: Has the government of Ecuador considered the best interests of the child under article 3(1) CRC when negotiating trade agreements, particularly in relation to intellectual property rules?

Recommendation: The government of Ecuador should systematically consider the best interests of the child when negotiating trade agreements and when implementing trade-related obligations into national law.

Respect for the views of the child (article 12 CRC), obligation to receive and impart information (article 13(1) CRC), and access to information on children's physical health (article 17 CRC)

Question: Has the government of Ecuador ensured the respect for the views of the child under article 12 CRC, fulfilled its obligation to receive and impart information to the child under article 13(1) and ensured access to information on the children's health under article 17 CRC, when negotiating trade agreements?

Recommendation: the government of Ecuador should make its negotiating positions public, consult widely and encourage participation of civil society groups representing children's interests whilst negotiating trade agreements or implementing trade policy.

Technical Assistance (article 4 CRC)

Question: Has the government of Ecuador requested technical assistance under article 4 CRC to ensure that its trade-related obligations are developed and implemented in ways that help it ensure the realization of the rights set out in the CRC, for instance to carry out a human rights impact assessment of new or proposed trade obligations?

Recommendation: The government of Ecuador should seek technical assistance from UNICEF and the Office of the High Commissioner for Human Rights (OHCHR), to ensure that any new or proposed trade-obligations are developed and implemented in a way that promotes the best interests of the child and is consistent with other obligations under the CRC.

Making the principles and provisions of the Convention widely known (article 42 CRC)

Question: Are Ecuador's trade officials aware of the principles and provisions of the CRC?

Recommendation: The government of Ecuador should ensure that the principles and provisions of the CRC are widely known to its trade officials, in particular those responsible for negotiating trade agreements.