

Medicines: Access, Trade and Health THE EU – ANDEAN COMMUNITY ASSOCIATION AGREEMENT

Overview

The European Union (EU) and the Andean Community (CAN) are in the process of negotiating an Association Agreement (AA). The first round of negotiations took place in September 2007 and three rounds have since been concluded. The AA will include sections on political interaction, cooperation programs and trade. The trade section of the agreement will include a chapter on Intellectual Property (IP) rights. Intellectual Property rights (IPRs) are highly controversial for public health as they can present a barrier to the access to medicines, which can be particularly detrimental in transitional and developing countries.

At present, the negotiations are on hold due to internal disagreements between the CAN countries on IP matters. It is not clear how or when the fourth round of negotiations will begin. HAI Europe is working closely with HAI Latin America to monitor the negotiations on IP regulation that potentially affect public health in the Andean region. At the European level, HAI Europe is establishing a coalition of NGOs to support this campaign.

Background

Negotiations like these rarely display equal bargaining power between the parties, and developing countries are more vulnerable to demands that could be harmful to their society. Civil society organisations in Bolivia, Colombia, Peru, and Ecuador are concerned that the EU-CAN agreement will include very rigid IP standards. Rigid IP regulations restrict and delay generic competition thereby increasing the price of medicines or keeping the prices high. In theory, provisions on Policy Coherence and Development (PCD) contained in EU treaties should compel the European Commission (EC) to recognise EU member states' commitment to support development and not to pursue stringent IP regulations that counteract that pledge. Yet, the pursuit of high IP standards remains a consistent part of EC trade policy. The EC has declared that the aim of these negotiations is to achieve "the highest existing standard of IP in the world".¹

IP Rights: TRIPS, Bilaterals and Public Health

The Trade Agreement of Intellectual Property (TRIPS) negotiated in 1994 at the World Trade Organization (WTO) contains strong IP regulation which has resulted in decreased access to medicines in many developing countries. Nevertheless, this multilateral agreement recognises the public health needs of countries and allows for flexibilities for developing countries to protect public health (TRIPS flexibilities).²

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As a principle, IP regulations in any association agreement should not go beyond those agreed in TRIPS. Yet, bilateral free trade agreements (FTAs) negotiated by the United States and the EC are often used to set higher standards of IP protection, disregarding TRIPS flexibilities. They tend to add extra provisions including, extending patents and delaying the entry of generics on the market (TRIPS-plus).

The TRIPS-plus standards, which the pharmaceutical industry has failed to obtain in multilateral platforms, secure and extend monopolies for brand name pharmaceuticals, allowing companies to charge monopoly prices and reap huge revenues. These commercial benefits are gained at the expense of the wellbeing of populations in developing countries with poor resources as they stifle competition from cheaper generic equivalents. Generics play a vital role in lowering medicine prices and raising public health standards.³

The right of developing countries to protect public health and the failure of the IP regime to cater to patients' needs in developing countries has recently been reinforced by a World Health Assembly resolution (WHA resolution 62.21) in May 2008 after fierce intergovernmental negotiations. However, bilateral trade agreements tend to ignore progress made in multilateral forums and include high IP standards.⁴

Impact Studies as an Evidence Base

Impact studies on the effect of proposed IP Rights in U.S. FTAs for access to medicines have been carried out in Colombia, Ecuador, Peru and Bolivia.^{5,6} They showed a significant increase in the cost of medicines and a substantial weakening in access.

The studies carried out in Colombia (2007) during negotiations for the FTA with the United States concluded that, if all U.S. demands had been met, there would have been:

- ◆ an increase in the price of medicines, by at least 46%;
- ◆ an increase in active substances protected by patents or data exclusivity and;
- ◆ an annual increase in public health expenditure of \$1 billion dollars by 2020.

Without enough money to cover this cost surplus, more than five million Colombians with poor resources would have lost access to essential medicines.⁷ This would have affected 12,000 HIV/AIDS patients by 2020, who would have seen their life expectancy reduced by between 5.3 and 9.9 years.⁸

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The Colombia impact studies were successfully used to lobby the U.S. congress and the Colombian government during FTA negotiations in 2007, and some harmful provisions on IP were removed from the text. HAI Europe intends to use the results of similar impact studies to provide vital feedback on the impact of the IP clauses in the EU-CAN association agreement.

Latest Developments- Decision 486

Due to a deepening split between Bolivia and Ecuador, and Peru and Colombia, the negotiations have halted. The disagreement centres on ‘Decision 486’, an article which defines IP regulations for the four members of the Andean Community. The FTAs that Peru and Colombia have recently signed with the United States include specific IP provisions that affect decision 486. The disagreement revolves around IP, traditional knowledge and biodiversity.⁹ On 13th August 2008, Ecuador joined Peru and Colombia in accepting changes to 486. Bolivia will most likely not accept any changes to the 486 decision and this impasse could very well break up the CAN.

Before Ecuador changed its position, the EC was considering two-speed negotiations with Colombia and Peru on one hand, and Ecuador and Bolivia on the other. Yet, the EC does not have the mandate to negotiate outside the CAN. Any negotiations outside the CAN would depend on authorisation from the EU Parliament.

The Campaign

HAI Europe and HAI Latin America are forming an alliance between European and Latin American civil society to monitor and lobby negotiations that affect public health issues and most notably, access to medicines.

HAI Europe will coordinate civil society efforts in Europe and raise awareness at the European Parliament and the European Council about the potentially harmful impact of the AA on public health in the Andean countries. As Policy Coherence for Development is a component of official EU policy, we will express our concerns via the broader PCD framework.

HAI Latin America will bring together civil society organisations in the region, lobby their respective national governments and provide the evidence base to support the HAI Europe advocacy campaign.

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Key messages

- ◆ Bilateral negotiations between countries with asymmetrical levels of development pose a threat to the weaker countries' public health needs.
- ◆ TRIPS-plus clauses lower access to medicines in developing countries. This is inconsistent with EU goals on development and therefore, counteracts EU provisions on policy coherence for development.
- ◆ Civil Society efforts are of vital importance to avoid these threats from becoming a reality. A civil society alliance between European and Latin American NGOs to monitor negotiations will strengthen the evidence base and legitimacy of the advocacy campaign.

On 15th-18th October 2008, a strategy meeting for CSO coalition members will be held in Bogota, Colombia. Two representatives from each Andean country will be present, as well as representatives from HAI Europe. This is a unique opportunity to exchange our ideas, information and concerns and to develop a clear strategy for our campaign.

References

- ¹ Chief of the European negotiating team mentioned at the beginning of the negotiations in 2007, the goal was the establishment of the highest existing standards of IP in the world (source: IFARMA).
- ² Doha Declaration on TRIPS, 2001, confirms the right to these flexibilities.
- ³ CIPIH report, WHO 2006.
- ⁴ Susan, Shell. The Global IP upward ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play, June 9, 2008. George Washington University.
- ⁵ The studies were developed by IFARMA/HAI and Mision Salud, Colombian NGOs in collaboration with the PAHO and WHO. (Find attached the summary of Impact Studies done in Peru (2005), Ecuador (2005) and Bolivia (2006).
- ⁶ Similar studies using a slightly different model have been carried out in Thailand where a FTA is being negotiated with the US. Chutima Akalephan et al(2005), Jiraporn Limpananont et al (2008).
- ⁷ Cortes, Miguel, La propiedad intelectual en el TLC acordado entre los gobiernos de Colombia y Estados Unidos: Análisis del texto y cálculo de los impactos sobre el gasto farmacéutico y el acceso a medicamentos en Colombia. MISIÓN SALUD, IFARMA. Translation in EN by OXFAM(2006).
- ⁸ Cortes, Miguel et al, Impacto del tratado de libre comercio firmado por los gobiernos de Colombia y Estados Unidos sobre la esperanza de vida de los pacientes viviendo con VIH-SIDA en Colombia. MISIÓN SALUD, IFARMA, 2007.
- ⁹ The main problem centres are data exclusivity provisions that in effect can extend the patent after it expires.