US-ANDEAN FREE TRADE AGREEMENT

IMPACT ON ACCESS TO MEDICINES AND HEALTH IN COLOMBIA

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ACCESS TO THE MEDICINES: THE PROBLEM

In Colombia there are about 20 million inhabitants who lack adequate access to medicines, either because they do not belong to any health insurance system or because if they do, they cannot afford to pay out of their own pocket for the medicines the system does not supply to them, which represent about half of the prescriptions[1].

For example, of 200,000 AIDS patients in the country, it is estimated that 21,000 need anti-retrovirals (ARVs) but only 12,000 are taking them. The remaining 8,000 will die in the next 5 years[2]. Regarding cancer, only 30% of treatment regimes available are part of the health insurance system.[3] Two thirds of people older than 60 do not have any kind of coverage. [4]

GENERIC COMPETITION: THE SOLUTION

Studies by Oxfam, Doctors Without Borders (MSF) and Health Action International (HAI) show that the most efficient way to lower prices and improve access to medicines in low income countries is by promoting competition of generic medicines.[5]

When the patent for a medicine expires, the medicine price falls between 30% and 70%, depending on the number of generics which enter the market.[6] In Colombia, where there is an important generic industry, on average generic medicines cost 25% of the cost of their brand-name equivalent.

This price difference, along with the high quality of generics products, is the result of the application of international manufacturing standards and explains the rise in use of generics in the country. In Colombia, generic medicines today supply 67% of the national market, in units.

To maintain the ability of generic medicines to compete in the market in Colombia, it is essential to stop the FTA from establishing standards of intellectual property protection that go beyond those established in the WTO. These "TRIPS plus" measures have been conceived by the international pharmaceutical industry to extend its monopoly on the drugs market and maintain

[1] Research Network on Health Systems and Services in the Southern Cone and the International Center of Research for Development, "Evaluation of medicines policies in Colombia", 2001.
[2] Extra-official information from PAHO.
[3] National Cancer Institute, El Tiempo Newspaper, July 15, 2004, pp. 1 and 2.
[4] United Nations Population Fund, "Colombia is getting old", El Tiempo, July 18, 2004, pp. 1 and 2.
[5] OXFAM, HAI, VSO and Save The Children, "Assuring access to essential medicines", May, 2002.
[6] Frank and Salkever, 1995.

or further increase already high prices for medicines, without taking into account the social cost of these measures in developing countries.

The point is not to restrict intellectual property rights, which Colombia fully protects according to WTO rules. However, imposing more extensive protections for intellectual property with regard to medicines would cause serious damage to public health in Colombia and other developing countries.

THE US PROPOSAL FOR THE FTA: ESTABLISH "TRIPS PLUS" STANDARDS

Ignoring this reality in our country, the USTR proposal tabled in the FTA negotiations includes 19 "TRIPS plus" measures. These are listed below.

Expansion of the patentable spectrum:

- Second use patents.
- Patents for diagnostic, therapeutic and surgical methods.
- Patents of plants and animals.

Patent extension:

- To compensate for delays in granting the patent.
- To compensate for delays granting marketing approval in Colombia.
- To compensate for delays in the marketing approval in the United States.

Protection of test data as an exclusive right

Restrictions on public health safeguards

- Limits on the use of compulsory licenses.
- Elimination of parallel imports.
- Elimination of the "Bolar Exception".

Other sensitive measures:

- Flexibility in the patentability requirements to make possible the patenting of minor changes in known substances. .
- Linking the Patents Office to the FDA-type authority, by making the latter responsible for verifying the patent status ("Linkage").
- Elimination of the right to challenge patent requests.
- Reduction of the nullifcation causes on patents
- Restriction to the use of the common international denomination.

Procedural issues:

- Opportunity to modify the patent requests.
- Early distribution.
- Adequate distribution.

Nullification and Impairment Clause

ECONOMIC AND SOCIAL EFFECTS OF THESE "TRIPS PLUS" PROVISIONS

If these "TRIPS plus" standards are established in Colombia, the following economic and social effects would result.

1. **More delay in the entry of generics competition onto the market**

   In contrast, the US government is interested in strengthening competition of generic medicines domestically in order to reduce health care costs, as can be deduced by these words of President Bush: "Today, I'm taking action to close the loopholes, to promote fair competition and to reduce the cost of prescription drugs in America… Our message to brand name manufacturers is clear: you deserve the fair rewards of your research and development; you do not have the right to keep generic drugs off the market for frivolous reasons..."[7]

   There is no reason that brand-name companies that do not have the right to limit generic competition in a market with a high level of purchasing power, such as in the United States, should have that right in low income countries, where generic medicines are the only alternative for a large majority of the population, should be unacceptable.

2. **Significant increase in the price of medicines.**

   Serious studies show that just the measures providing test data protection or market exclusivity without exceptions and with retroactivity, would produce a dramatic increase of 61% in the price of medicines.[8]

   This situation would be made worse if, as a result of globalization, prices would tend to converge, since the average price of the medicines in the Andean countries would be equal to that in Mexico, which is 2.5 times higher than in Colombia.

   Looking at the problem from another angle, since in Colombia generic medicines cost on average only 25% of the price of brand-name medicines, it is logical that delaying the entry of generic medicines on the market would have a significant impact on health care expenses.

3. **Losing access to medicines**

   A recent study by the Pan-American Health Organization[9] concludes that an FTA with Colombia like the one the United States signed with Central American countries (CAFTA), which contains 12 of the 19 "TRIPS plus" provisions proposed by the USTR for Colombia and the Andean region, would mean that by 2020, the health care system would have to pay an additional $940 million annually, and over 6 million Colombians who have health care coverage would be unable to access medicines. For those with AIDS, some 4,400 patients would not be able to pay for medicines, meaning they would likely die within 5 years.

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[7] George W. Bush, speech given at the White House on October 21, 2002.

[8] Fedesarrollo, "Impact of the patents regime of the pharmaceutical industry on the Colombian economy", July, 1999. "Economic and social effects of the regulations on the Colombian pharmaceutical industry", April, 2001.

[9] Pan-American Health Organization, "Determination of the Impact of strengthening Intellectual Property measures as a result of the US Free Trade Agreement: application of the model to Colombia, Bogotá, October 20, 2005.

Studies by the National University of Colombia in Bogotá[10] and the Health Ministry of Peru[11] reach similar conclusions to this study by the Pan-American Health Organization.

CONCLUSION

The debate on the "TRIPS plus" provisions in the US-Andean FTA cannot be seen only as a struggle for market share between the multinational brand-name pharmaceutical companies and the national generics industry. Above all, this is a humanitarian problem with huge social and political consequences.

The social consequences are evident because, as has been stated by Doctors Wiithout Borders to the US government, "If the US-Andean FTA creates a system blocking the use of equivalent but cheaper medicines, it will be a catastrophe for all the people in the region, since the difference in prices can mean the difference between life and death."[12]

This warning was repeated last year by a group of US legislators who, in a letter addressed to President Bush on September 30, 2004, expressed the following concerning the attempt to impose on the Andean countries a system of data protection for 5 years: "For any patient, five years without access to affordable drugs can be the difference between life and death."[13]

There will also be political consequences bad trade agreement could neutralize the benefits of the programs carried out in Colombia with US help to combat terrorism and drug trafficking.

In this context, US legislators, headed by Henry Hyde, Chair of the Committee on International Relations of the House of Representatives shared the following expectation with the Colombian government late last year. "We hope our counterparts see these discussions on trade from the perspective of the fight against narco-terrorism..... These negotiations should be used to maintain the progress we have reached together and help our neighbors to achieve peace and security."[14]

Furthermore, USTR aspirations contradict the commitments assumed by the United States in the Doha Declaration, which reaffirms the right WTO members "to protect public health and, in particular, to promote access to medicines for all."[15] Therefore, the "TRIPS plus" provisions in the US-Andean FTA violate US Trade Promotion Authority (TPA),[16] because this law mandates that the Administration respect the Doha Declaration on TRIPS and Public Health in all trade agreements it negotiates.[17]

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[10] National University of Colombia, Center for Research on Development, "Impacts of the US-Colombia Free Trade Agreement on the Health Sector of the Capital District", Bogotá, May, 2005.

[11] Health Ministry of Peru, "Evaluation of the Potential Effects on Access to Medicines of the Free Trade Agreement negotiated with the United States of America", Lima, Peru, April, 2005.

[12] MSF, setter to the USTR, March 24, 2004.

[13] Letter of 12 US Congresspeople to the President of the United States on September 30, 2004. Signed by Hilda Solís, Henry A. Waxman, Charles B. Rangel, Ciro D. Rodriguez, Sherrod Brown, Sander M. Levin, Linda T. Sánchez, Thomas H. Allen, Jim McDermott, Raúl Grijalva, Xavier Becerra and Pete Stark.

[14] Letter sent on October 1, 2004 to USTR Robert Zoellick and the Director of USDAID, Andrew Natsios, by US Congressional Representatives Henry Hyde, Chair of the Committee on International Relations, Tom Davis, Chair of the Government Reform Committee and the Chairs of the sub-committees for the Western Hemisphere, Cass Ballenger, Anti-Drug Policy, Mark Souder, and Human Rights, Dan Burton, among others.

[15] Doha Declaration on TRIPS and Public Health, WTO Ministerial Meeting, November, 2001.

[16] TPA = Trade Promotion Authority.

[17] TPA, Section 2101b.4c, 2002.

In particular, Senator Edward Kennedy, co-author this TPA amendment, recently made the following statement on the Senate floor. “The administration … should immediately stop seeking intellectual property protections that prevent access to medicines for all and should start to seek those that promote greater access to medicines for all.... And here in Congress, we have to do a better job of insisting that our trade agreements comply with the letter and the spirit of the Doha Declaration. It’s the law of the land, and it’s a matter of life and death for hundreds of millions of people in other lands. The tactics we are so shamefully using against them can only breed greater resentment and greater hatred of the United States. And we can’t afford to let that happen at this critical time in our role in the world.”[18]

The way in which the issue of access to medicines is handled in the US-Andean FTA will in large part determine the future of public health and general welfare in the Andean region. Because access to medicines is a life and death issue involving the right to health, it is not exchangeable for commercial interests. Health is not negotiable!

[18] Senator Kennedy, statement read in the United States Senate on February 16, 2005.