US-Andean FTA: Access to Medicines

I. The Problem

In Peru about 20 percent of the population has no access to health care because they cannot afford it. Only half of the population has health insurance and receives free care. People living in poverty, who make up 52 percent of the population, are for the most part not insured and either have to pay out-of-pocket or receive no care. Medicines, a basic part of the cost of health care, account for one quarter of total health spending in the country and 44 percent of household spending on health care.

In the negotiations on intellectual property in the US-Andean FTA, the US negotiating team has been pushing several provisions to increase the amount of time that invented medicines can enjoy monopoly rights in the market. Such measures would primarily apply to medicines that are newly introduced on the market and can be vital for the cure of certain diseases that have high morbidity levels.

These measures will increase the price of such medicines to levels that are much higher than what they would be without an FTA, and thus will exacerbate the problem of lack of health care endured by Peruvians, in violation of their right to health.

II. Key provisions of the intellectual property negotiations with regard to medicines

The principal measure in the FTA that will result in these effects is test data protection and exclusive use for marketing approval. This refers to the clinical studies that the producer of a medicine carries out to prove the safety and efficacy of its product in order to obtain marketing approval from the health regulatory authority.

The United States has been insisting that five years of test data protection be included in the FTA. The impact of this on prices and access to medicines is presented in part III. There are additional key issues in the negotiations on test data. First is whether safeguards or exceptions for cases of public necessity will be allowed, as may be the case with Tamiflu for the avian flu. It is important to keep in mind that WTO rules, reinforced in the Doha Declaration on TRIPS and Public Health, allow for such exceptions (compulsory licenses or parallel importation) for patents, but test data protection is a parallel mechanism to the monopoly protection for new inventions and is not covered by these rules. Second is whether the test data protection is extended only to each group of data presented or whether it also limits the possibility of

presenting new data for the same product. Both issues as negotiated in CAFTA resulted in measures that are detrimental to the Central American countries. As a result, those countries now will not be able to legally import or produce medicines that enjoy data protection in cases of public emergency, and furthermore the data protection provides protection for the product and not only for the data itself.

There are several other patent measures the US is insisting on including in the FTA. These include: 1) second-use patents, which allow patent extension when a new therapeutic use is found for an existing medicine; 2) linkage, which requires the health regulatory authority to verify the patent status before granting marketing approval; 3) patent extension beyond 20 years to compensate for unjustified delays in the granting of the patent or the granting of marketing approval; and 4) patents on surgical, diagnostic and therapeutic procedures.

III. What impact will these measures have on Peruvians? Results of the study on the impact of test data protection

1. A study by the Peruvian Ministry of Health revealed the following:

- *Increase in the price of medicines*: Accepting the FTA measures on greater test data protection and market exclusivity would limit generic competition and shift consumption toward brand-name products that enjoy market monopolies.

The study carried out by the Ministry of Health estimates that the first year the FTA is in effect, the price of medicines could increase by an average of 9.6 percent. This price increase would be progressive, leading to an increase of 55 percent by 2011, of almost 100 percent by 2017 and an increase of 162 percent by 2035 over the price of medicines today.

Implementing greater test data protection would mean, just in the first year, that Peruvians would have to spend an additional $34.4 million to maintain the same level of access to medicines and health care coverage we have today. Of these $34.4 million, $29 million would be assumed by households and the rest (5.4 million) would correspond to the additional budget that state agencies would require in order to maintain the same levels of coverage. This additional spending would increase to $199.3 million in 2017, of which almost $110 million would be assumed by Peruvian households.

- *Reduced access to medicines:* In the first five years, access to medicines would be reduced, leaving between 700,000 and 900,000 people each year unable to get health care (assuming no increase in household spending or in the budgets of the Ministry of Health or ESSALUD, the national social security and health institute).

These effects would result only from the test data protection. Other measures the US is insisting be included would only exacerbate these effects.

IV. Alternatives

Intellectual property rules should be negotiated at the multilateral, rather than bilateral, level. If the objective is to increase the monopoly protection for new inventions to ensure that investment in research is profitable and, thus, that new medicines can be discovered, the above measures in an FTA will not achieve that result.

Peru and the Andean countries represent a very small part (less than one percent) of the world market for medicines, and our markets would not increase the business profitability of the pharmaceutical industry. In fact, patents have not generated more research for essential medicines. Furthermore, if only the Andean or a few countries provide this greater protection, it would mean that the rest of the world, including some developed countries, would benefit as free riders and would not pay higher costs for new medicines although they would receive the benefits from their invention. In reality, the cost is paid by people living in poverty, who are seeing their right to health denied.

The Andean governments have already ceded in this regard and have presented an alternative proposal to US negotiators, which the latter has not even dignified by a providing a response. This proposal includes test data protection for three years, as long as the patent owner registers the product in our country within one year of having registered it in the United States. It would be important for any agreement in this regard to include safeguards for cases of public necessity and to ensure the protection be only for the data and not for the product. Furthermore, second-use patents should not be accepted, there should be no linkage between marketing approval and patent status, and patents for surgical procedures should be rejected.

November 2005

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