NO HIGHER INTELLECTUAL PROPERTY PROTECTION STANDARDS THAT RESTRICT ACCESS TO MEDICINES: L.D. No. 1072

The standards Peru committed itself to in the FTA with the United States limit access to medicines[1]

- L.D. Nº 1072 puts into effect new conditions accepted by Peru in the FTA to protect test data, affecting the population's access to medicines.
- There is pressure from the brand-name pharmaceutical industry to obtain greater levels of protection under the process to regulate L.D. Nº 1072.

US-Peru FTA: Protection of test data affects access to medicines

Legislative Decree Nº 1072 develops the commitments regarding intellectual property and medicines that Peru agreed to in the FTA with the United States. One of the most sensitive commitments involves the protection and exclusive use of test data that delays the entry of generic medicines onto the market, affecting access to medicines.

Test data are studies on the safety and efficacy of medicines, and their protection and exclusive use bars individuals or companies other than those who carried out the studies to rely on the data to obtain the registration and marketing approval of a product, thereby granting the originator company exclusive rights to its marketing for a period of time. In practice, this system operates like a patent that does not protect the invention but rather the investment carried out in the elaboration of the studies. The exclusivity period is shorter; while patents are protected for 20 years the test data protection in the FTA is "normally five years".

The criteria "normally five years," constitutes a variable period, which could be less than five, five, 10 or 20 years. L.D. Nº 1072 indicates that it will be up to the national health authority to evaluate the "reasonable effort" carried out for the elaboration of the test data (considering the efforts and expenses that have been incurred) in order to define the period of protection and exclusivity that will be granted. The definition of the criteria to establish the periods should be included in the regulation of L.D. Nº 1072.

In the process of renegotiating the US-Peru FTA that was promoted by the Democrats, the addendum on the Intellectual Property Chapter made it possible to lower some of the protection levels for intellectual property rights. This change was not well received by the brand-name pharmaceutical industry, which warned it will seek to recover levels of protection through the process of implementing the FTA in Peru[2]. There is a need to pay close attention to this process in order to avoid pressures, which would further affect access to medicines.

The regulation of L.D. Nº. 1072 must limit the abusive use of test data protection

The limitations in access to medicines that are produced by the exclusive use of test data in the FTA with the United States demand that in the process of implementing this commitment the Peruvian government guarantees all mechanisms and exceptions that make it possible to limit this negative impact. Some of the main criteria to be included in this regulation are:

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[1] Elaborated by Roberto López, Latin America Director of Acción Internacional para la Salud - AIS.
[2] Source: Inside US Trade: "Perú Faces Complaints Over FTA Implementation on Drugs". August, 15 2008. Available in: www.aislac.org/pdf/noticias/2008/Articulo_Inside_US_Trade.pdf

To specify the period for the application and procedures for the protection and exclusive use of test data establishing the following criteria:

- To define a maximum period of protection and exclusive use of test data, allowing that the period could even be less than five years.
- To restrict the application of a lengthy period to protect the test data, requiring certain evidence that obtaining the data has involved "considerable effort" in order to avoid granting an exclusivity benefit to those products that do not merit it.
- To establish a period of exclusivity from its first registration in any of the countries that form part of the trade agreement, in order to accelerate the entrance of generic medicine.

It is urgent to monitor the process to regulate L.D. Nº 1072 and impede a situation where greater benefits are granted to the brand-name industry at the cost of the Peruvian peoples right to health and medicines.

Guarantee the use of bio-equivalency testing as an exception to the protection and exclusive use of test data. L.D. Nº 1072 recognizes the application of abbreviated procedures to obtain marketing approval, presenting bioequivalence tests[3]. This is an exception to the protection and exclusive use of test data, so that during the protection period a third party can carry out their own bioequivalence studies to request marketing approval and market a medicine, encouraging competition and greater access to medicines.

This right recognized in the FTA and in L.D. Nº1072 must be developed in the national regulation, as it constitutes an opportunity to cushion the negative impact regarding access to medicines. However, the opposition pressures were not long in coming. This issue is extremely uncomfortable for the brand-name pharmaceutical industry, which seeks to limit its application and has gotten the USTR to publicly state its concern regarding the development of this regulation in the national legislation[4].

To include TRIPS[5] flexibilities as exceptions to the protection and exclusive use of test data[6]. In the regulation of L.D. Nº1072, there is a need to explicitly incorporate the flexibilities and exceptions to the protection of intellectual property rights recognized in international treaties that our country has signed such as TRIPS and the Doha Declaration. Two of the principal mechanisms that must be guaranteed to limit the negative impact of the exclusivity granted by the patents and the protection and exclusive use of test data are: a) inclusion of the use of compulsory licenses in the case of national emergency, public interest or urgency: b) mechanisms that apply the principle of the exhaustion of intellectual property rights to permit parallel imports , that allow competing medicines to enter the market.

The significant pressure to promote higher levels of protection for intellectual property rights in the implementation and regulation of the FTA must be avoided. There is a need for the Executive to encourage an open and participatory dialogue that places the right to health and the population's access to medicines first, in the face of which Congress must exercise its watchdog role.

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[3] "(...) nada limitará la aplicación de procedimientos abreviados para el registro sanitario de productos farmacéuticos basándose en estudios de bioequivalencia y biodisponibilidad." (Art. Nº5 DL1072).

[4] Source: Inside US Trade: "Peru FTA Implementation Plagued By Wide-Ranging IPR Problems". September 19 2008. Available in: http://www.redge.org.pe/node/97

[5] Trade Related Aspects of Intellectual Property Rights - TRIPS.

[6] Declaration on TRIPS and Public Health, Ministerial Meeting Doha, Nov. 2001.

[7] "Each Member has the right to grant compulsory licenses and the freedom to determine said the grounds upon which such licenses are granted (...) to determine what constitutes a national emergency or other circumstances of extreme urgency." Declaration on The TRIPS Agreement and Public Health, Ministerial Meeting Doha, Nov. 2001.

[8] The right to property runs out when a product is placed on the market. Which is to say, it can be the object of any transaction. For example, it can be purchased and exported. A parallel import is based on this principle and is applied even for patented property. For example, if there is medicine in Ecuador under the same label with a patent, from the same producer that is cheaper than in Peru, the Peruvian government has the right to purchase it there and bring it into the country if it considers this to be convenient.

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