

HEALTH MINISTRY OF PERU

**EVALUATION OF POTENTIAL EFFECTS OF THE FREE TRADE AGREEMENT
BEING NEGOTIATED WITH THE UNITED STATES ON
ACCESS TO MEDICINES**

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*[This document is an unofficial translation of the study's conclusions,
as taken from the Executive Summary]*

**Lima - Peru
APRIL 2005**

CONCLUSIONS

The analysis of the possible consequences of the FTA regarding access to medicine refers to the behavior of the Peruvian pharmaceuticals market as a whole. As a result, the conclusions that are outlined below must be understood in that context.

Changes expected in the pharmaceuticals market

1. As a consequence of a series of measures that deregulated the pharmaceutical market at the beginning of the 1990s, by 2004 a structure was in place in which 50% of the products corresponded to "branded generic" drugs, 33% which correspond to "INN generic" drugs sold under their scientific international nonproprietary name, and 17% to "original" brand-name drugs. In terms of sales, above all in volume, in general there has been a sustained growth in generic medicines.
2. The changes in intellectual property rules that are being negotiated in the FTA will have a direct impact on the pharmaceuticals market, principally affecting the generic brands because by increasing the number of originals that cannot be copied (and their protection period), it will swiftly decrease the relative importance of generic brands in the market.
3. Through important changes in prices, there will be significant changes in the structure of the current pharmaceuticals market. It is expected that by the end of the thirteenth year, 69% of the market will correspond to "original" brand-name drugs, 20% to "branded generic" drugs and 11% to "INN generic" drugs.
4. The "original" brand-name medicines are targeted for consumption by those with mid- or high-level purchasing power and eventually for ESSALUD [Peruvian public health insurance system]. They have all the formal distribution channels and obtain a high degree of brand fidelity, using different marketing and promotion strategies to increase demand. Generic medicines sold under their scientific name only gain access to this circuit with a great deal of difficulty and concentrate their sales in the public sector.
5. In recent years an average of 30 previously unregistered active principles are registered annually. This represents approximately a third of the new active principles that appear in the world. Although a large number of these active principles are no longer patentable, they would be able to obtain test data protection.

Changes expected in the price of medicines

6. The characteristics of the pharmaceuticals market has meant that prices in the country are higher than those in other countries in the region and even in Europe. In some cases the price differential surpasses 800%.
7. As a result of the FTA, in the first year the price of the "original medicines" could increase by 12.5%, the "branded generics" could increase by 4.3%, and the "INN generics" by 0.7%. By years 7 and 13, the former would increase by 72% and 132%, respectively, the second by 22% and 37% and the latter 4.4% and 7.7%.

Expected changes in access to medicines

8. Approximately a third of the population in the country does not have access to essential medicines. Coverage overall is very low for some diseases where lack of access has serious repercussions for life expectancy and quality of living, such as diabetes, hypertension, schizophrenia, AIDS and cancer.

9. As a result of the FTA, it is estimated that in the first five years after implementation, between 700,000 and 900,000 people will be excluded each year from receiving medicines if the Health Ministry and ESSALUD budgets or the income of the poorest households do not improve. By the sixth year, coverage is expected to improve due to the more intensive use of "INN generics." However, this does not take into account therapeutic innovations.

Impact on household spending and the budget for medicines

10. Household spending makes up 70% of purchases in the pharmaceuticals market (1.6 billion soles a year) and the Health Ministry and ESSALUD make up the remaining 30%. The impact of the FTA on expenditures for health coverage is expected to principally affect household budgets.

11. As a result of the inclusion of test data protection in the FTA, an impact is expected in the first year equivalent to US\$34.4 million of additional spending. Of that total, US\$29 million will be assumed by families (increased out-of-pocket spending) while the difference will be assumed by the Health Ministry and ESSALUD. Between years 7 and 13, additional spending will be in the range of US\$130 million to \$170 million.

Effectiveness of the exoneration of tariffs and sales tax on medicine

12. In a sample of 200 medicines to treat cancer that are sold in Peru it was observed that the exoneration of the payment of tariffs and sales tax not only failed to reduce the price of oncology medicines, but allowed companies to obtain extraordinary earnings of US\$1 million a year as of 2002.

13. It was hoped that removing tariffs and sales tax would lead to a reduction of at least 20% in the final price of medicines to treat cancer. This was only observed in 8% of the products, 19% did not modify their price and 23% increased it.

Epidemiological trends in the context of the FTA

14. The projections for the next two decades show an increase in the majority of the known highly contagious diseases. Although these illnesses touch all socioeconomic groups, the poor are the most affected due to their vulnerability.

15. In the case of multi-drug resistant tuberculosis, it is estimated that the number of cases could be reduced if health programs have adequate coverage and are effective.

16. Regarding illnesses such as tuberculosis, malaria and AIDS, where traditional medications are increasingly less effective, patients must periodically change to using new pharmacological technologies. Due to the effect of the FTA on the price of medicines, this will be delayed or will not take place, with the foreseeable consequences.

RECOMMENDATIONS

1. Taking into account that the signing and implementation of the FTA will not be immediate, it is important to take advantage of this period to establish new conditions in the pharmaceuticals market that will correct the serious existing distortions in prices and ensure that these reach international levels, making it possible to mitigate the effects of the FTA. For this, we suggest the following measures:

1.1. Create a price system or "monitoring group" with the participation of civil society institutions and groups that will keep the public permanently informed as an instrument of social pressure to obligate the market to bring down prices.

1.2. Establish norms that obligate companies to disseminate their prices in a transparent manner and update this information when prices are changed.

1.3 Establish norms that obligate pharmacies in the private sector to offer a minimum list of Essential Medicines that are in high demand at the lowest prices in the market.

1.4 Ensure that the pharmacies in Health Ministry establishments can fill prescriptions that originate in other sectors, thus modifying their supply policies.

1.5 Promote and facilitate initiatives for parallel importation from countries with lower prices.

2. Strengthen initiatives in the area of public and public/private insurance in order to reduce the impact of the FTA on out-of-pocket household spending.

3. Increase the Health Ministry's budget to take into account additional expenditures for medicines and improve coverage for illnesses with a high social cost.

4. Establish efficient compensation mechanisms for ESSALD, the institution with the highest coverage for medicines in the country.

5. Given projected increase in the incidence of highly contagious diseases, the Health Ministry and ESSALUD should make a maximum effort to promote healthy behavior and life styles among the population in order to decrease the future morbidity rate from these illnesses.

6. Given that the main negative effects of the FTA on access to medicines will begin in the first years of implementation and intensify between years 7 and 10, a fund for medicines should be created with additional contributions from sectors that benefit from the FTA, for a minimum of 10 years.

7. The Ministry of Health and ESSALUD should design, implement and maintain intensive training policies in the use of medicines, generating norms and sanctions for their strict application in all establishments.

8. All practices to market and promote medicines in public health sector establishments should be minimized or prohibited, in order to limit the habitual mechanisms to induce demand.

9. INDECOPI [National Institute for the Defense of Competition and Protection of Intellectual Property] should strengthen the technical bodies responsible for granting pharmaceutical patents and inventions and should closely coordinate with the Ministry of Health.

10. There is a need to significantly increase the rate of obtaining marketing approval [from the health regulatory agency] for pharmaceuticals, as it is currently one of the lowest in the world and does not allow for post-marketing monitoring or adequate quality control over the products.

11. The obligation to market registered products within a prudent period or lose the license to market should be regulated, in order to increase competition and avoid the speculative use of the marketing approval process.

13. The rules governing the health regulatory agency should be modified, establishing:

13.1 Criteria related to efficacy, safety and need for approval of a medicine.

13.2 That all new products, based on a previously unregistered new chemical entity, be subject to a strict monitoring after being put on the market for a minimum of five years.

13.3 That the indications for this type of product must include a warning for the person prescribing it and for the consumer about the need for careful use given that its comparative safety and efficacy are yet to be established.

14. If an extension of the exoneration of tariffs and sales tax is considered as a compensation mechanism, pharmaceutical companies should provide a public and explicit commitment to ensure that this reduction benefits the population.

15. Request that pharmaceutical companies publicly compensate the population for appropriating a benefit that does not correspond to them. This compensation could be manifested as a reduction in prices or a donation of oncology medicines to ESSALUD and the Health Ministry, the two institutions that most use this type of products.