

## **Possible Impact of U.S. – Peru FTA on Access to Medicines Due to Data Exclusivity Protection for Drugs**

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### **1. Introduction**

Peru has 27 million inhabitants, 50% live below the poverty line and 25% has no access to formal health care. The market of medicines reaches about 650 millions dollars that is composed for almost 14,000 products and involving to more than 1,700 of active principles. In products, 17% are original drugs but patents protect less than 3% of active principles at 2004. However, the share of the market value for original drugs is around 60%; the generic copies that are sold under a laboratory mark (branded generic) are 30% and the generic copies sold under their international generic name (generic ICD) are remaining 10%. Finally, 70% of the retail sales are paying with out of pocket.

The research looks for to respond to the specific question: what it could pass with prices and access to medicines, because of data exclusivity protection for drugs. We do not measure the effect of the FTA on other important variables to medicines market such us household income (for the expectation in economic growth), or the effect of an appreciation of exchange rate (as result of increasing in exportations and capital inflow).

According to DIGEMID<sup>2</sup>, between middle to 1999 to 2004, 56 innovative medicines were first time registered, but also were registered generic copies of this drugs, so around 12 molecules copied each year. If FTA had been signed five years ago, around 1% of the actual market value will be affected, so that means, these medicines could not have introducing in the market.

The central hypothesis of research is that data exclusivity protection can incorporate as a contracting “shock” of the potential supply of generic copies, specifically on copies for branded generics, whose introduction would be delayed five years. This shock will produce an additional prices increasing in both new and old products (original and branded). Under the assumption of constant household income, in the short term, prices increasing will diminish the consumption of medicines, but in the middle and long changes in the relative prices will take new shares in the market of medicines.

However, since drugs prices increasing is result of multiple factors, such as the relative shortage (the introduction of new original products or generic copies) and the monopoly power (for patents or marketing strategies, etc.), among other factors. If we assume that these factors will be present in the future, data exclusivity protection will be responsible for the gap of the prices increasing above the current trend.

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## 2. Methodology

We use counterfactual simulation of drugs market below two conditions: with and without data exclusivity protection. Without data exclusivity, prices would follow the current trend. However, with data exclusivity, we simulate the effect of 1% contracting in the potential generic of mark drugs supply, in the first year, 2% in the second year, 5% in the fifth year and so on.

### a) Transmission Mechanisms of “FTA Effect”

The delaying of generic copies introduction, due to data protection, is equivalent to a contracting “shock” in the potential branded generic drugs supply that induce a new market equilibrium. Therefore, the impact of the FTA will depend of:

- Magnitude of the “shock”, that depend of the market share of drugs whose active principles are susceptible to data protection; and
- Direct and cross of demand elasticities for drugs inside each therapeutic group.

### b) The Econometric Model

We suppose that drugs market structure look like a monopolist competition market and that can be represented by an Almost Ideal Demand System – AIDS with three types of medicines: 1- original drugs, 2-branded generic and 3- ICD generic. The AIDS model is:

$$w_i = \alpha_i + \sum_j \gamma_{ij} \ln p_j + \beta_i \ln(x/p) + u_i \quad (1)$$

Where  $i: 1, 2, 3$ ; and  $w_i$  it is the share market of each type of medicines, defined as:

$$w_i = \frac{p_i q_i}{\sum_i p_i q_i} = \frac{x_i}{X_Q} \quad (2)$$

Where  $x_i$  it is the expenses in  $i$ -medicines,  $X_M$  it is the total expenses in medicines,  $p_i$  it is the price of  $i$ -medicine,  $q_i$  it is the quantity  $i$ -medicine,  $p$  it is the medicines price index,  $\alpha, \beta, \gamma$  are the parameters of the model and  $u_i$  is the stochastic perturbation in  $i$ -equation.

In purpose to reflecting the consumer utility maximization, we imposed homogeneity, aggregation and symmetry constrained.

Engel aggregation:	$\sum_i \alpha_i = 1; \sum_i \beta_i = 0; \sum_i \gamma_{ij} = 0 \quad \forall j$	
Homogeneity condition:	$\sum_j \gamma_{ij} = 0$	(3)
Symmetry condition.	$\gamma_{ij} = \gamma_{ji}$	

These restrictions reduce the number of parameters to estimate in the pattern. In addition, by the market aggregation the model must be satisfies  $\sum_i w_i = 1$ . Therefore, we need to estimate only 2 of 3 model equations. The elasticities of the ordinary demand have been obtained as following:

$$\begin{aligned}
 \text{Elasticities price:} \quad e_{ii} &= \frac{\gamma_{ii}}{w_i} - \beta_i - 1 \\
 \text{Cross elasticities:} \quad e_{ij} &= \frac{\gamma_{ij}}{w_i} - \beta_i \left( \frac{w_j}{w_i} \right) \\
 \text{Elasticities expense:} \quad \eta_i &= 1 + \frac{\beta_i}{w_i}
 \end{aligned} \tag{4}$$

**c) Measurement of changes in drugs markets.**

Virtual price of generic of mark,  $p_2^v$ , is obtained for a reduction in market share of generic of mark, as follow:

$$p_2^v = \exp\left(\frac{[w_2 - \delta - \alpha_2 - \gamma_{21} \ln p_1 - \gamma_{i23} \ln p_3 - \beta_2 \ln(x/p)]}{-\gamma_{22}}\right) \tag{5}$$

Where  $w_2 - = w_2'$  will be the new market share for branded generic. The market share for the original medicines will be:

$$w_1 = \alpha_1 + \gamma_{11} \ln p_1 + \gamma_{12} \ln p_2^v + \gamma_{13} \ln p_3 + \beta_1 \ln(x^0 / p^0) \tag{6}$$

The share of ICD generic is obtained by remaining:

$$w_3 = 1 - w_1 - w_2' \tag{7}$$

Under profit maximization in monopolist competition market, in the short term the prices of the generic medications are found as:

$$p_3 = CMg \left( 1 + \frac{1}{e_{33}} \right)^{-1} \tag{8}$$

From market shares and generic drugs prices (branded and ICD), and solving the next three equations, the prices of the original drugs are found as:

$$gasto_1 = w_1 * gasto_M \tag{9}$$

$$\Delta\% Q_1 = e_{11} * \Delta\% p_1 + e_{12} * \Delta\% p_2 + e_{13} * \Delta\% p_3 \tag{10}$$

$$\Delta\% p_1 = \Delta\% gasto_1 - \Delta\% Q_1 \tag{11}$$

Where  $gasto_1$  it is the expense in original drugs,  $w_1$ : it is the share market of original drugs (equation 6),  $gasto_M$  it is the spend in medicines, and  $e_{ij}$  they are the ordinary demand price and cross elasticities.

The quantity consumed of generic drugs ( $Q_2$  and  $Q_3$ ) are also deduced from their market shares and generic drug prices.

**d) Impact on access to medicines**

Under the assumption that changes in volume of medicines are associates to similar changes in the access of medicines, we need to find the total quantity consumed in the country, that is:

$$Q = Q_1 + Q_2 + Q_3 \quad (12)$$

**e) Impact on medicines expenses**

The additional cost assumed by households can express as follow:

$$\Delta\% G_j = \sum_i w_{ij} (\Delta\% p_{ij} + \Delta\% q_{ij}) \quad (13)$$

The additional budget required by institutional sectors (Ministry of Health and Social Security, MINSA and Essalud) to remain constant the actual coverage, will be:

$$\Delta\% G_j = \sum_i w_{ij} \cdot \Delta\% p_{ij} \quad (14)$$

**f) Attributable effect of data exclusivity protection**

Since the assumption that patent effect it is already reflected in the medicines price inflation, the FTA effect will be de gap of expected medicines inflation with FTA and medicines inflation trend.

$$\% \text{ pij TLC} = \% \text{ pij} - \% \text{ IPCmed} \quad (15)$$

**3. Results on the Impact of the TLC**

**a) Coefficients and Elasticities**

From AIDS model and IMS-Peru data for 1999-2003, it has been estimating the parameters for the original and generic of mark medicines equations, so the parameters of the Generic ICD equation were obtained.

**Table N° 1: Coefficients estimated by Type of Medications**

Types of Medicines	Constant	I price of Original	Prices of Generic of mark	Prices of Generic DCI	Expense in Medications
Original	5.237 (7.91)	0.096 (0.11)	0.067 (0.05)		-0.290 (0.51)
Generic of Mark	45.162	0.067	-0.985	0.404	-2.869

	(7.11)	(0.05)	(0.13)	(0.04)	(0.45)
Generic ICD <sup>1/</sup>	-50.399 (9.19)	-0.163 (0.087)	0.918 (0.094)	-0.404 (0.04)	4.159 (0.59)

1/ Built under homogeneity, symmetry and aggregation the restrictions

Notes: thought a pool of data with 7 therapeutic groups and 6 periods 1998-2003 (42 observations).

The units of measures were defined dose day and prices for dose day.

The numbers in parentheses are the standard error.

**Table N° 2: Demand Direct and Cross Elasticities (\*)**

	Price of original drugs	Prices of Generic of mark	Prices of Generic ICD
Original	-1.144	0.242	0.010
Generic of Mark	3.078	-1.216	1.473
Generic ICD	-126.197	-17.809	-22.743

(\*) elasticities presented are obtained using data for 2003.

The results show that ICD generic has a high price elasticity that reflect a high market competition, because there are very homogeneous products based on a little variety in active principles. On the other hand, original drugs have a demand with more inelastic on prices, in spite of great variety in active principles and in products. It is possible because they have could make product differentiation. The branded generic drugs spread to imitate the commercial behavior of the originals, but it is more sensitive to the original or ICD generic substitutes. Under this conditions the mark-up in DCI generic drugs are minimum, while the margins in the originals and branded generic drugs are bigger.

### c) Impact in prices and market share

In the first year of implementation of the FTA the prices of medicines would increase by an average of 9.6%. The original drugs prices would increase 12.5%, the generic of mark in 4.3% and the DCI generic in 0.4%. By the years 6 to 12, prices could increase between 55% and 100%.

**Table 3: Impact of FTA on Prices of Medicines**

Years later	Medicines Price Index (year 0 = 100)	Yearly variation in Percentage		
		Original	Generic of Mark	Generic ICD
1	<b>9.6%</b>	<b>12.5%</b>	<b>4.3%</b>	<b>0.7%</b>
2	19.1%	11.1%	3.9%	0.7%
3	28.6%	9.9%	3.5%	0.7%
4	37.8%	8.8%	3.2%	0.7%
5	46.7%	7.9%	2.9%	0.7%
6	55.4%	7.1%	2.6%	0.7%
13	99.6%	3.9%	1.6%	0.4%

Regard to the market share variation, it is expected that original drugs will increase their participation from 60% to 70%, while generic drugs will reduce from 40% to 30%.

**d) Impact in the access to medications**

In the first five years of implementation, between 700,000 and 900,000 people will be unable to get access to health care each year or they could not finance the purchase of medicines.

**Table N° 4: Impact of the TLC On the Access to the Medications**

Years after	Volume of Medicines (Year 1 = 100)			
	Original	Generic of Mark	Generic ICD	Total
0	39.5	38.9	21.6	100.0
1	35.4	36.2	26.1	<b>97.6</b>
2	32.1	33.7	31.0	<b>96.8</b>
3	29.3	31.5	36.3	<b>97.1</b>
4	27.1	29.4	42.0	<b>98.5</b>
5	25.2	27.6	47.9	100.8
6	23.7	25.9	54.2	103.7
12	17.9	17.7	95.1	130.6

**e) Impact in welfare**

- During the first year, Peruvians would have to spend an additional US\$34.4 million to maintain the same level of access to medicines.
- Households would increase their expenses in medicines for US\$ 28.9 millions.
- The Social Security in Health (Essalud) would require additional budget for US\$ 3.9 millions.
- Ministry of Health would require additional budget for of US\$ 1.6 millions. In 2003, the total expenditure of the Ministry of Health on medicines was US\$35 million.
- From year 7 to year 13, the lost in welfare for increasing in drug costs would be among US \$130 and US\$170 millions. Most of these amount would be supported by Households

**Table 5: Impact of the Protection of Data in the Well-being  
(Millonesde US \$)**

Year	Total	MINSAs	ESSALUD	Household
1	34.4	1.6	3.9	28.9
6	62.8	3.3	8.0	51.5
7	130.7	9.7	23.2	97.9
13	169.3	17.6	41.8	109.9