The FTA and Access to Medicines in Peru: the Economic Impact of Intellectual Property

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Introduction

The market for medicines in Peru is approximately 650 million dollars comprising nearly 14,000 products and over 1,700 active ingredients. Of these, 17% are original medicines and less than 3% of the active ingredients were patent-protected in 2004. However, original medicines account for approximately 60% of the value of retail sales. Generic copies sold under a laboratory brand (branded generics), represent 30% of market value and generic copies sold under the name of International Nonproprietary Names (INN generics), represent the remaining 10%. 70% of sales of medicines are financed by household out-of-pocket expenses, chiefly through drugstores and pharmacies (chains).

This study seeks to answer the question: what would happen to prices of and access to medicines as a result of inclusion of data protection. In this sense, this is a very timely study. However, it does not explore the effect of the FTA on other variables which have an impact on the market for medicines, as is the case of household income (by means of greater expected economic growth), or the effect of exchange rate appreciation (due to greater exports and capital inflow).

According to DIGEMID¹, over the course of the last five years, along with 56 innovative medicines introduced for the first time, there were also generic copies of these medicines, that is, approximately 12 molecules were copied every year. If the FTA had been signed five years ago, these medicines could not have entered the market. It is estimated that the FTA could affect approximately 1% of the market value per year².

The central hypothesis of this study is that data protection may be incorporated as a “shock” which would adversely impact the potential supply of generic copies, particularly branded generics, whose availability would be delayed. This would cause an additional increase in the prices of new and existing products in the market. Assuming constant inflow, with higher prices the quantity consumed would decrease in the short term, but, in the medium and long term, the change in relative prices would lead to a readjustment in the market and in the consumption of medicines.

As the increase in prices of medicines is the result of multiple “effects”, such as relative scarcity (the entry of new original products and generic copies) and the level of market monopoly (due to patents and marketing strategies, etc.), among others, it is assumed that in the future this will

¹ The General Department of Drugs and Medicinal Products of the Ministry of Health (Dirección General de Medicamentos Insumos y Drogas – DIGEMID del Ministerio de Salud).
² According to Vera (2003) “Analysis of the market for medicines which should benefit from data protection”. In 2002 there were 17 molecules which could request data protection and their copies representing approximately 3% of market value. In this study, on the basis of information from the health authorities only 56 molecules were identified until 2004, whose copies represent 5% of the market.
continue, in as much as data protection is only responsible for the differential in the increase in
prices above current trend levels.

1. Methodology
The counterfactual simulation employed consists of quantifying the results in the market for
medicines under two conditions: with and without data protection. In the absence of data
protection, the dynamics of prices would follow the current trend, but, with data protection, we
would need to simulate the effect of withdrawing the potential supply of branded generic
medicines, equivalent to 1% of market value in the first year, 2% in the second, 5% in the fifth
and so on.

a) Transmission Mechanism of the “FTA Effect”
Withdrawing the entry of generic copies, due to test data protection, is the equivalent of a “shock”
which limits the potential supply of copies and produces a new equilibrium in the market. By this
logic, the impact of the FTA is dependent on:

- The scale of the “shock”, which is the result of the market share of medicines whose active
  ingredients are likely to benefit from data protection; and
- The scale of the direct and cross price elasticities among the different types of medicines, for
  a same therapeutic group.

Diagram 1: Transmission of the FTA in the Pharmaceutical Market

The study assumes that the market for medicines is a monopoly, which can be represented by an
Almost Ideal Demand System (AIDS)\(^1\) with three types of medicines\(^4\).

The AIDS model takes the following form:

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\(^4\) Original medicines, branded generics and INN generics.
Where \( i \) is the type of medicine: 1-original, 2-branded generic and 3-INN generic.

\[
w_i = \alpha_i + \sum_j \gamma_{ij} \ln p_i + \beta_i \ln(x/p) + u_i
\]  

\( w_i \) is the market share of type I medicines, defined as:

\[
w_i = \frac{p_i q_i}{\sum_i p_i q_i} \frac{x_i}{X_M}
\]

\( x_i \) is spending on type \( i \) medicines.

\( X_M \) is spending on medicines.

\( p_i \) is the market price of type \( i \) medicine.

\( q_i \) is the quantity of type \( i \) medicine market sales.

\( p \) is the index of prices of medicines.

\( \alpha, \beta \) and \( \gamma \) are the model’s parameters.

\( u_i \) is the disturbance term under the assumption of zero mean and constant variation.

So as to reflect the conditions to maximize the use of consumers homogeneity, aggregation and symmetry restrictions have been imposed, such as:

Engel aggregation condition:
\[
\sum_i \alpha_i = 1; \quad \sum_i \beta_i = 0; \quad \sum_i \gamma_{ij} = 0 \quad \forall j
\]

Homogeneity condition:
\[
\sum_j \gamma_{ij} = 0
\]

Symmetry condition:
\[
\gamma_{ij} = \gamma_{ji}
\]

These restrictions limit the number of parameters for making estimations on the model. Equally, market shares should meet the aggregation condition in the market, this is, \( \sum_i w_i = 1 \). With this, it is sufficient to estimate the market share of the types of medicines so that the share of third parties is obtained by the difference.

The elasticities of ordinary demand of the AIDS model (own price, \( e_{ii} \); cross price, \( e_{ij} \); and cost, \( c_i \)) are obtained in the following manner:

Own-price elasticities:
\[
e_{ii} = \frac{\gamma_{ii}}{w_i} - \beta_i - 1
\]

Cross-price elasticities:
\[
e_{ij} = \frac{\gamma_{ij}}{w_i} - \beta_i \left( \frac{w_j}{w_i} \right)
\]
Cost elasticities: \[ \eta_i = 1 + \frac{\beta_i}{w_i} \]

**c) Measuring the changes in the market for medicines**

The virtual price \( p_2^v \) compatible with the reduction in the market share of branded generics, \( w_{22} \), is obtained in the following manner:

\[
p_2^v = \exp\left(\frac{w_2 - \delta - \alpha_2 - \gamma_{21} \ln p_1 - \gamma_{23} \ln p_3 - \beta_2 \ln(x/p)}{-\gamma_{22}}\right)
\]

Where \( w_2 - w_2 = w_{22} \) will be the new market share of branded generic medicines. The market share of original medicines, will be:

\[
w_1 = a_1 + \gamma_{11} \ln p_1 + \gamma_{12} \ln p_2 + \gamma_{13} \ln p_3 + \beta_1 \ln(x/p)
\]

The share of INN generic medicines is obtained by difference:

\[
w_3 = 1 - w_1 - w_2
\]

Under equilibrium conditions in a monopoly market, prices of generic medicines in the short term are obtained in the following manner:

\[
p_3 = CMg\left(1 + \frac{1}{e_{33}}\right)^{-1}
\]

As market shares and the prices of generic medicines (branded and INN) are known, the price of original medicines needs to be consistent with expected spending on such medicines and the new prices, so as to answer:

\[
gasto_m = w_1 * gasto_m
\]

\[
\Delta\%Q_i = e_{11} * \Delta\%p_1 + e_{12} * \Delta\%p_2 + e_{13} * \Delta\%p_3
\]

\[
\Delta\%p_1 = \Delta\%gasto_1 - \Delta\%Q_1
\]

Where:

- \( gasto_m \) is spending on original medicines
- \( w_i \) is the share of original medicines (equation 6)
- \( gasto_m \) : Spending on medicines (where the original assumption remains constant).
- \( e_i \) : are the own-price and cross-price elasticities, as above.

The quantity of generic medicines (\( Q_2 \) and \( Q_3 \)) can be deduced from the fractions spent and the equilibrium prices for such products.
d) Impact on access to medicines.

Under the assumption that a percentage change in the volume of medicines goes hand in hand with a change on the same scale of those served, the impact on access to medicines can be measured through the effect on the change in the total volume of medicines taken in the country, that is:

\[ Q = Q_1 + Q_2 + Q_3 \]  \hspace{1cm} (12)

e) Impact on total cost of medicines.

The additional household cost can be expressed in the following formula:

\[ \Delta\%G_j = \sum_i w_{ij} (\Delta\%p_{ij} + \Delta\%q_{ij}) \]  \hspace{1cm} (13)

As regards the institutional sectors (MINSA and ESSALUD), under the condition of maintaining current coverage levels, the additional budget needed will amount to:

\[ \Delta\%G_j = \sum_i w_{ij} \Delta\%p_{ij} \]  \hspace{1cm} (14)

f) Net attributable effect of test data protection

As the effect of patents is already reflected in the inflation of prices for medicines, the net attributable effect of the FTA will be a rise in prices higher than the CPI for medicines, that is:

\[ \%p_{ij} \text{TLC} = \%p_{ij} - \%\text{IPC}_{\text{med}} \]  \hspace{1cm} (15)

2. Results on the Impact of the FTA

a) Estimated coefficients and elasticities

From the AIDS model and IMS-Peru data for 1999-2003, an estimation of the parameters of the equations for original and branded generic medicines was calculated. The parameters for the equation for INN generics was obtained from the restrictions on homogeneity, symmetry and aggregation included in the estimation.

<table>
<thead>
<tr>
<th>Types of Medicines</th>
<th>Constant</th>
<th>Price of</th>
<th>Prices of</th>
<th>Prices of</th>
<th>Spending on</th>
</tr>
</thead>
</table>
Developing a Methodology to Assess the Impact of TRIPs-plus Provisions Affecting Drug Prices, 31st July - 1st August 2006

The results reveal a market for medicines in which INN generic medicines face stiffer competition, while originals although available in great variety (of both active ingredients and products), have managed to stand out, which make them more inelastic than substitutes. Branded generic medicines seem to imitate the commercial behaviour of originals, but are more sensitive to original substitutes or INN generics. In contrast, as INN generic medicines have limited variety in terms of active ingredients, they are very homogenous and therefore, easily replaceable. This explains why commercial margins of INN generics are minimal, whilst margins for originals and branded generics are relatively larger.

b) Impact on prices and market share

In the first year the prices of medicines is expected to increase on average by 9.6%. Original medicines would increase on average by 12.5%, branded generics by 4.3% and INN generics by 0.4%. Between years 7 and 13 prices could increase between 55% and 100%. These results are consistent with other studies carried out by the Instituto APOYO and INDECOPI.

### Table 4

<table>
<thead>
<tr>
<th>Years after</th>
<th>Prices of Medicines (Index 2005 = 100)</th>
<th>Annual Percentage Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Originals</td>
<td>5.237 (7.91)</td>
<td>-0.290 (0.51)</td>
</tr>
<tr>
<td>Branded Generics</td>
<td>45.162 (7.11)</td>
<td>-2.869 (0.45)</td>
</tr>
<tr>
<td>INN Generics</td>
<td>-50.399 (9.19)</td>
<td>4.159 (0.59)</td>
</tr>
</tbody>
</table>

1. Developed using restrictions of homogeneity, symmetry and aggregation indicated in the previous section.
   - Data was pooled from 7 therapeutic groups and 6 periods between 1999-2003 (42 observations).
   - The units of measure were daily dose and prices for daily dose.
   - The values in brackets are standard errors.

### Ordinary Cross Price Elasticities (*)

<table>
<thead>
<tr>
<th></th>
<th>Price of Originals</th>
<th>Price of Branded Generics</th>
<th>Price of INN Generics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Originals</td>
<td>-1.144</td>
<td>0.242</td>
<td>0.010</td>
</tr>
<tr>
<td>Branded Generics</td>
<td>3.078</td>
<td>-1.216</td>
<td>1.473</td>
</tr>
<tr>
<td>INN Generics</td>
<td>-126.197</td>
<td>-17.809</td>
<td>-22.743</td>
</tr>
</tbody>
</table>

(*) Elasticities for prices in 2003.
As regards market share, over the course of the next 7 years a share increase of 60% to 70% is expected, whilst generic copies would decrease by 40% to 30%.

c) Impact on access to medicines

In the first 5 years there would be a loss of access to medicines, if household income and the MINSA and ESSALUD budget for medicines remain unchanged. Between 700,000 and 900,000 Peruvians could no longer receive or be able to afford medicines.

Table 5
Impact of the FTA on Access to Medicines

<table>
<thead>
<tr>
<th>Year</th>
<th>Originals</th>
<th>Branded Generics</th>
<th>INN Generics</th>
<th>Originals</th>
<th>Branded Generics</th>
<th>INN Generics</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>39.5</td>
<td>38.9</td>
<td>21.6</td>
<td>100.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>35.4</td>
<td>36.2</td>
<td>26.1</td>
<td>97.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>32.1</td>
<td>33.7</td>
<td>31.0</td>
<td>96.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>29.3</td>
<td>31.5</td>
<td>36.3</td>
<td>97.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>27.1</td>
<td>29.4</td>
<td>42.0</td>
<td>98.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>25.2</td>
<td>27.6</td>
<td>47.9</td>
<td>100.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>23.7</td>
<td>25.9</td>
<td>54.2</td>
<td>103.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>17.9</td>
<td>17.7</td>
<td>95.1</td>
<td>130.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

d) Impact on welfare

The increase in prices due to the FTA would lead to additional spending of US$ 34.4 million, with a rise in household spending on medicines of 28.9 million. ESSALUD would require an additional budget of 3.9 million and the Ministry of Health a further 1.6 million dollars. Between year 7 and 13, supplementary spending on medicines would amount to between US$ 130 and 170 million, with households the most adversely effected.
## Impact of Data Protection on Welfare (US$ million)

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
<th>MINSA</th>
<th>ESSALUD</th>
<th>Household</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>34.4</td>
<td>1.6</td>
<td>3.9</td>
<td>28.9</td>
</tr>
<tr>
<td>6</td>
<td>62.8</td>
<td>3.3</td>
<td>8.0</td>
<td>51.5</td>
</tr>
<tr>
<td>7</td>
<td>130.7</td>
<td>9.7</td>
<td>23.2</td>
<td>97.9</td>
</tr>
<tr>
<td>13</td>
<td>169.3</td>
<td>17.6</td>
<td>41.8</td>
<td>109.9</td>
</tr>
</tbody>
</table>