



IMPACT ON MEDICINES' PRICES AND CONSUMPTION FROM THE TRADE AGREEMENT BETWEEN THE EUROPEAN UNION AND TWO COUNTRIES OF THE ANDEAN COMMUNITY

INTERIM REPORT SUMMARY - COLOMBIA AND PERU IMPACT STUDIES

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Date: 1 May 2009

INTRODUCTION

In September 2007, the Andean Community (CAN) and the European Union (EU) began negotiations towards an "Association Agreement", grouped around three main pillars: trade, political and cooperation. To date, five rounds of negotiations have been completed, during which the diverse positions between the CAN countries have been revealed and the EU's proposals on intellectual property rights have become ever more refined.

The European proposals on intellectual property rights (IPR) extend the benefits of rights holders beyond what is expressly contained in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); by means of supplementary patent protection and the introduction of exclusivity protection for trial data. However, these are not the only provisions sought by the EU. The enforcement of intellectual property rights occupies a pivotal place in the proposals and its negative consequences for the countries of the CAN may be of equal or greater magnitude than the other proposals on IP mentioned before.

The objective of this study is to estimate the impact of a trade agreement with the European Union on the price and access to medicines in Colombia and Peru.

METHODOLOGY

The impacts presented in this study are calculated based on the "Guide for estimating the impact of changes in intellectual property rights (IPR) on access to drugs"⁴ prepared by the World Health Organisation and the Pan American Health Organisation – WHO/PAHO. This guide describes the IPRIA (Intellectual property rights impact assessment) model.

The IPRIA has been applied in different contexts to various countries, and the most recent applications have been carried out within the framework of a consortium of organisations including the WHO, the PAHO, the World Bank Institute and the International Centre for Trade and Sustainable Development (ICTSD), who have refined the methodology. Some of the applications carried out are: Colombia (2005, 2006, 2007), Guatemala (2005), Costa Rica (2005), Bolivia (2006), Costa Rica (2008), Dominican Republic (2008), Uruguay and

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⁴ ROVIRA, Joan, et al. *Guía para estimar el impacto sobre el acceso a los medicamentos de cambios en los derechos de propiedad intelectual DPI*. PAHO/WHO. 2005



Argentina. In addition, various meetings and workshops have been organised to facilitate its dissemination and application in different countries (London, October 2005; Malaysia, June 2006; Thailand, November 2006).

The IPRIA determines the impact by means of the “scenario method”. The impact is derived from the difference between a basic scenario, which describes the current situation, and its possible evolution should changes not occur in intellectual property rights (IPRs), and alternative scenarios that describe possible evolutions with different changes in IPR.

The impacts that are assessed by the model for different time frames are:

- Level of exclusivity of the medicines on the market
- Impact on average market prices
- Impact on pharmaceutical expenditure
- Impact on the consumption of medicines

This report presents the results of the application of the IPRIA model for the articles regarding patents, (specifically the existence of a supplementary protection certificate that would extend the validity of the patent by another five years) and protection of trial data (protection with exclusivity for a period of ten years).

SCENARIOS CONSTRUCTED

Basic scenario:

Colombia: TRIPS + Decree 2085 of 2002 (which contemplates provisions regarding trial data).

Peru: Free Trade Agreement signed and in the process of being implemented with the United States.

Alternative scenario 1: Supplementary protection certificate (SPC)

The EU has proposed the following to Colombia and Peru:

Article 9.3: Supplementary protection certificate

1. “The parties recognise that medicinal and plant protection products protected by a patent on their respective territory may be subject to an administrative authorisation procedure before being put on their market. They recognise that the period that elapses between the filing of the application for a patent and the first authorisation to place the product on their respective markets, as defined for that purposes by the relevant legislation, may shorten the period of effective protection under the patent.
2. The parties shall provide for a further period of protection for a medicinal or plant protection product that is protected by a patent and which has been subject to an administrative authorisation procedure, that period being equal to the period referred to in paragraph 1, second sentence above, reduced by a period of five years.
3. Notwithstanding paragraph 2 and the possible extension for paediatric use for pharmaceutical products, the duration of the further period of protection may not exceed five years.”

This type of provision does not currently exist in TRIPS or in the national legislations of Colombia or Peru.



In order to determine the period of time to which the above articles would refer, our study established, from a sample of 310 products registered in the Food and Drugs Administration of the United States (FDA) in the period 2005-2008, that the average time between the request for a patent and the first marketing authorisation (period referred to by paragraph 1 of the said article) is 11 years. Therefore, in accordance with paragraph 2, the additional protection period would be 6 years (11 minus 5). However, paragraph 3 limits the additional period to 5 years and so, this is the time period assessed in this study.

Alternative scenario 2: Exclusivity of trial data

The EU has proposed the following to Colombia and Peru:

Article 10.2:

“Both Parties shall enact and implement legislation ensuring that any information submitted to obtain an authorisation to put a pharmaceutical product on the market will remain undisclosed to third parties and benefit from a period of at least ten years of protection against unfair commercial use starting from the date of grant of marketing approval in either of the Parties.

(a) During a period of at least eight years, no person or entity (public or private), other than the person or entity who submitted such undisclosed data, will without the explicit consent of the person or entity who submitted this data, rely directly or indirectly on such data in support of an application for the authorisation to put a pharmaceutical product on the market;

(b) During a ten-year period, any subsequent application for the authorisation to put a pharmaceutical product on the market would not be granted, unless the subsequent applicant submitted his/her own data (or data used with authorization of the right holder) meeting the same requirements as the first applicant. Products registered without submission of such data would be removed from the market until the requirements were met.

(c) In addition, the ten-year period referred shall be extended to a maximum of eleven years if, during the first eight years after obtaining the authorisation in either of the Parties, the holder of the basic authorisation obtains an authorisation for one or more new therapeutic indications which are considered of significant clinical benefit in comparison with existing therapies.”

The protection of trial data is a measure contemplated in TRIPS. However, this agreement does not establish any period of exclusivity for the use of this information. The right of exclusive use of the undisclosed information is an additional measure included in recent trade agreements.

In Colombia, exclusivity for five years has been granted since 2002 by decree 2085 of the Health Ministry. In Peru, the same period of five years is contemplated in the trade agreement recently signed with the United States.

The EU proposal attempts to extend this protection period for up to a maximum of eleven years. This study uses the extension up to ten years (five years more in each country) due to the lack of evidence to demonstrate the number of cases to which the additional year may be applied based on the new indications.

The discussion regarding possible impacts of the article corresponding to the enforcement of intellectual property rights will be covered in a later version of this report.



PARTIAL RESULTS

The tables presented below show the results for the total market, which is the sum of the private and public markets in Colombia and of the private and public markets in Peru. The results tables include the following columns:

% of active ingredients with protection - Shows the total percentage of the market that would be occupied by medicines protected either by the patent or protection of trial data proposals set out by the EU.

Price index - Indicates the impact that the various changes to IPR would have on the prices of medicines in the country. A value of 1 indicates no impact, higher values indicate proportional price increases. For example, a value of 1.3 indicates a price increase of 30%.

Increase in expenditure - Indicates the budgetary increases that would be necessary, based on an assessment of the entire market, in order to continue acquiring the same basket of medicines at the new prices.

Reduction in consumption if expenditure did not increase - Indicates the drop in consumption that would occur if the budget did not increase in the market assessed.

Equivalent medicines' expenditure for the poorest 20% of the population – Indicates the number of people whose medicines' costs would be covered if the budgetary increase could be spent on the poorest 20% of the population instead of the increased cost of medicines.⁵

Equivalent number of people's health expenditure is also not explained anywhere – Indicates the number of people whose health costs would be covered if the budgetary increase could be spent on health expenditure instead of the increased cost of medicines.

⁵ Ramirez M, et al. El gasto en Salud de los hogares Colombianos: un análisis descriptivo. Borradores de Investigación No 20. Universidad del Rosario. Facultad de Economía. Marzo de 2002.

COLOMBIA

Impacts on the total market (Private + Public)

BASIC SCENARIO: TRIPS plus 2085				
YEAR	A.I. WITH PROTECTION			
2010	9%			
2015	15%			
2020	19%			
2025	15%			
2030	14%			
EFFECTS OF SCENARIO 1: Extension of patents via SPC				
YEAR	A.I. WITH PROTECTION	PRICE INDEX	INCREASE IN EXPENDITURE (In millions USD)	Equivalent medicines' expenditure for the poorest 20% of the population
2010	9%	1.00	0.00	0
2015	15%	1.00	0.00	0
2020	20%	1.01	31.43	380,251
2025	23%	1.03	172.54	1,715,530
2030	22%	1.04	278.71	2,277,078
EFFECTS OF SCENARIO 2: Trial data				
YEAR	A.I. WITH PROTECTION	PRICE INDEX	INCREASE IN EXPENDITURE (In millions USD)	Equivalent medicines' expenditure for the poorest 20% of the population
2010	20%	1.08	203.71	3,645,887
2015	26%	1.08	234.84	3,456,123
2020	28%	1.06	235.82	2,853,275
2025	27%	1.05	275.95	2,743,698
2030	25%	1.05	342.80	2,800,656
EFFECTS OF SCENARIO 3: Patents (SPC) + data				
YEAR	A.I. WITH PROTECTION	PRICE INDEX	INCREASE IN EXPENDITURE (In millions USD)	Equivalent medicines' expenditure for the poorest 20% of the population
2010	19%	1.08	198.47	3,551,948
2015	26%	1.08	234.84	3,456,123
2020	29%	1.07	267.25	3,233,526
2025	31%	1.08	448.49	4,459,229
2030	30%	1.09	621.51	5,077,734

PERU

SCENARIO: TRIPS plus 2085	
YEAR	A.I. WITH PROTECTION
2010	20%
2015	41%
2020	58%
2025	60%
2030	56%

EFFECTS OF SCENARIO 1: Extension Patents via SPC					
YEAR	A.I. WITH PROTECTION	PRICE INDEX	INCREASE IN EXPENDITURE (In Millions US \$)	REDUCTION IN CONSUMPTION IF EXPENDITURE NOT INCREASED	Equivalent number of people's health expenditure
2010	20%	1.00	0.00	0.0	0
2015	41%	1.00	0.00	0.0	0
2020	59%	1.02	18.94	-0.02	206,264
2025	69%	1.11	134.34	-0.10	1,462,818
2030	70%	1.19	321.70	-0.16	3,502,974

EFFECTS OF SCENARIO 2: Trial data					
YEAR	A.I. WITH PROTECTION	PRICE INDEX	INCREASE IN EXPENDITURE (In millions US \$)	REDUCTION IN CONSUMPTION IF EXPENDITURE NOT INCREASED	Equivalent number of people's health expenditure
2010	21%	1.02	18.08	-0.02	196,822
2015	46%	1.07	32.17	-0.07	350,274
2020	70%	1.17	144.79	-0.14	1,576,574
2025	73%	1.16	203.20	-0.14	2,212,634
2030	67%	1.15	249.93	-0.13	2,721,434

EFFECTS OF SCENARIO 3: Patents + data					
YEAR	A.I. WITH PROTECTION	PRICE INDEX	INCREASE IN EXPENDITURE (In millions US \$)	REDUCTION IN CONSUMPTION IF EXPENDITURE NOT INCREASED	Equivalent number of people's health expenditure
2010	21%	1.02	18.08	-0.02	196,822
2015	46%	1.07	32.17	-0.07	350,274
2020	72%	1.19	163.73	-0.16	1,782,838
2025	81%	1.27	338.03	-0.21	3,680,788
2030	81%	1.34	571.63	-0.26	6,224,408



DESCRIPTION OF RESULTS

Highlights from results for the year 2030 are detailed below:

COLOMBIA

If the patent period is extended for an additional five years, there could be an increase in medicines' expenditure of approximately 280 million USD in Colombia. This sum would be enough to cover the maximum medicines' expenditure of more than 2 million Colombians in the poorest 20% of the population.⁵

The provisions on the exclusivity of trial data proposed by the European Union could increase medicines expenditure by over 340 million USD, equivalent to the medicines' expenditure of 2.8 million Colombians in the poorest 20% of the population.

Implementing supplementary protection certificates and exclusivity of trial data as proposed by the European Union would increase expenditure by over 620 million USD, equivalent to the medicines' expenditure of 5 million Colombians in the poorest 20% of the population.

PERU

The extension of the patent period by five years could increase prices by 19%, requiring an increase of 321 million USD in expenditure for Peru. This is equivalent to the health expenditure of more than 3 million Peruvians.

The provisions on the exclusivity of trial data proposed by the European Union could increase medicines' prices by 15%, requiring an increase of nearly 250 million USD on medicines, equivalent to the health expenditure of 2.7 million Peruvians.

Implementing supplementary protection certificates and exclusivity of trial data as proposed by the European Union would increase medicines' prices by 34%, which would require expenditure to increase by over 570 million USD, equivalent to the health expenditure of more than 6.2 million Peruvians.

