



GEP

Fundación
Grupo Efecto Positivo

Eu-Mercosur
Bi-Regional
Association Agreement:
impact of the
intellectual property
chapter on public
procurement of medicines
in Argentina

Fundación Grupo Efecto Positivo (FGEP) is a non-profit civil society organization based in Argentina, that works for the sake of improving the life conditions of people living with (PLHIV) by promoting their due exercise of rights, their empowering and their effective involvement in policy-making, and the elimination of barriers to access to essential medicines for HIV/AIDS and Hepatitis C treatment.

FGEP has a broad network of members from the civil society, from the academia and among government institutions, and has facilitated the multilateral dialogue regarding health public policies.

Through political and social incidence, the aim of FGEP is to advocate for a better access to comprehensive health services and to the treatments of HIV/AIDS, opportunistic infections and co-infections, among others. FGEP also advocates for more social inclusion for PLHIV, for public policies that improve the quality of life of PLHIV and of communities affected by HIV/AIDS epidemic, by promoting their emotional support for them and for their social environments.

In this sense, FGEP seeks to strengthen the response of civil society in Argentina to improve health public policies and to increase the access to essential medicines, mostly by overcoming intellectual property barriers. This publication is the result of FGEP's acquired experience through the development of their program on access to medicines and their involvement in international debates and in national and regional policy-making contexts.



EXECUTIVE SUMMARY

The present document has the general purpose of analyzing the impact that the Access to medicines and health would have in Argentina if a commercial agreement between Mercosur and UE is signed. The study is done in the light of the analysis of the proposal of a legal document on “Intellectual Property Rights” handed by the UE to Mercosur for its latter discussion in the event of an offer exchange that took place in May 11th, 2016.

1. EU-Mercosur Bi-Regional Association Agreement negotiations

In May 2016, after over 20 years of negotiations, many starts and stops, in a context of secrecy and lack of transparency, a third offer exchange in matters such as goods, services, investments, public procurement and intellectual property among many other subjects, happened between the EU and Mercosur, with the purpose of moving forward towards a free-trade agreement between the two blocks.

Data provided by key informants confirm that the offer provided by Mercosur in matter of goods would have coverage of 87%, whereas that of the EU would cover 89,2%. This offer exchange leaves out the meat sector and that of biofuel, apart from the inclusion- which was not contemplated in the original mandate - of chapters on intellectual property, trade and sustainable development, commodities and energy, State companies and small- and medium-sized enterprises.

2. Intellectual property protection, its impact on the access to health and the EU's proposal.

Since the 1990s, the patent legal system has been harmonized due to the WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Since then, there is little margin for its members to decide on their own intellectual property regulations. When it comes to health and medicines, the theoretical justification is based on the false idea that the protection of innovative laboratories would work as an incentive to R+D, therefore making the cost of medicines more viable and im-

proving the universal access to medicines.

In fact, the patent system causes new competitors to be excluded of the market, in most of the cases those public or private producers of generic drugs. Also due to this system, sale prices are liberalized. In the “Doha Declaration on Trips Agreement and Public Health” (2001) the effects of intellectual property protection on prices are recognized; and the countries reaffirm the WTO Members’ right to use health

safeguards in order to protect public health.

In the past decades, “new generation” free-trade agreements (FTA) have been including liberalization, deregulation and protection rules for the medicines market which are far more ambitious than the ones agreed upon within the multilateral organizations that regulate this matter (WTO and the World Intellectual Property Organization, WIPO). These new provisions on intellectual property are known as TRIPS Plus. These measures seek to reinforce the controls on intellectual property protection, reinforce biological data protection, extend patent duration as compensation for delays in medicines approval, allow the granting of patents based on the “utility” and not on the “industrial applicability” (second use patents) and guarantee “market exclusivity” by means of test data protection, to name a few.

The EU proposal on intellectual property rights has a series of TRIPS Plus provisions. There are three provisions that could imply the adoption by Argentina of more restrictive measures regarding intellectual property protection that could affect the access to medicines:

- **Exhaustion of intellectual property rights:** the principle

that once a product has been sold on a market, the intellectual property owner no longer has any rights over it. International exhaustion is an important measure, since it eases the parallel import of the same product sold at lower prices in other countries, allowing developing countries to obtain medicines at more affordable prices. There is a restriction to this solution in the EU proposal.

- **Extension patent term:** this means extending the term of a patent when it was subject to an administrative procedure for its granting. In the current negotiations between EU and Mercosur, key informants say that Mercosur’s position regarding this point is that of commitment for its State Members to make their best efforts to process patent applications efficiently and within due terms. This means that currently Mercosur does not accept the EU’s proposal.
- **Test data protection:** the members shall not allow any other producer of the same or similar drug to obtain approval to put their product in the market using as a base the marketing ap-



proval granted to the producer that submitted the results of the clinical or pre-clinical trials. This means it grants exclusivity

to the submitted test data for a term not specified in the proposal. This term should be negotiated¹.

3. Impact of the chapter on intellectual property of the EU-Mercosur agreement on public procurements of medicines in Argentina

3.1. Methodology

In order to analyse the impact of TRIPS Plus on the public procurements of anti-retroviral and hepatitis C treatments, a basket of 17 antiretroviral and antiviral drugs included in the Federal Office of AIDS and sexually transmitted diseases' vademecum was built (DNS y ETS) . This analysis was done thanks to an adaptation of the model *Intellectual Property Rights Impact Assessment* (IPRIA), developed by the *International Centre for Trade and Sustainable Development* (ICTSD)².

This is a simulation that allows the assessment of the impact on the access to medicines of intellectual property regulation-changing (IPR). This is a way of having and *ex ante* analysis of IPR as if

the chapter on “Intellectual Property Rights” currently under negotiation between EU and Mercosur came into force. This is a deterministic model (not subject to randomness or stochastic behaviour), and its main variables are:

- i. **Level of competitiveness / market exclusivity**
- ii. **Variation in average prices**
- iii. **Impact on drug expenditure**

Through the simulation, the impacts are calculated as the difference between the “status quo scenario” (for each year) and the alternative scenarios related to different kinds of alteration on

¹ In other signed FTAs, the EU agreed on a minimum 10 year period.

² Rovira, J.; Abbas, I. y Cortés, M. (2009), “Guide to the IPRIA (Intellectual Property Rights Impact Aggregate) Model”, ICTSD, Working Draft, December.

IPR (also for each year), for every variable.

The built scenarios are as follows:

- **"Status Quo Scenario" (SQS):** the *status quo* is established based on Law No. 24.481, on Patents and Utility Models and amendments, which grants 20 years of exclusivity to the patent owner, being that the same period regulated in TRIPS. Regarding test data protection, the exclusivity period is of 0 (zero) years.
- **"Patent Extension Scenario" (PES):** it considers the additional protection of a 2-year extension proposed by the EU in the chapter on intellectual property.

- **"Test Data Protection Scenario" (DPS):** Since the proposal does not specify a number of years, for the purpose of this study a 10-year exclusivity period will be considered, as that is the negotiated extension in other EU FTAs.
- **"Total Exclusivity Scenario" (TES):** it combines both PES and DPS, i.e. it considers the additional protection due to patent extension (2 years) and the exclusivity due to test data protection (10 years).

For this model and the drill to work, fixed parameters and some scenario specific parameters for the array of medicines under study must be defined. These parameters are detailed in the current study.

3.2 Primary results

The model results with the information projected to the year 2050 show growing impacts for each of the proposed scenarios as time goes by:

- ✓ The implementation of TRIPS Plus provisions proposed by EU to Mercosur in the chapter on intellectual property shall have a deep impact on the cost of anti-retroviral and antiviral drugs of

direct action for hepatitis C procured by the Ministry of Health and thus the impact will be deep on the health of the population of Argentina.

- ✓ In the PES -related to the patent extension due to administrative delay for approval - the effects in terms of over expenditure will be evident not before 2041. The



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- over expenditure for the DNS y ETS would be of an additional 4% for 2050.
- ✓ In the DPS the additional cost would be afforded from the first year of the coming into force of the agreement, and would rise gradually both for the Active Pharmaceutical Ingredient (API) ratio under exclusivity and for the price increase in comparison with the SQS, i.e. under status quo. Through the final year of the series, the over expenditure for the DNS y ETS would be of 26,5% over the expected situation in which no test data protection provisions were included.
 - ✓ The TES shows for the last year of the simulation (2050), an increase of over 30% on the cost expected for the status quo scenario. This is due to an increase both in the API under exclusivity and the increase in prices in a monopoly scenario.

Impacts on public procurement of drugs performed by the Ministry of Health through DNS y ETS.

Scenario	Year	% API with exclusivity	Price index	Current value of drug expenditure	Expenditure variation (mill. AR\$)	Expenditure variation / current value
Status Quo Scenario (SQS)	2020	38.9%	1.00	1,292.31.-	-	0.0%
	2025	26.1%	1.00	1,775.02.-	-	0.0%
	2030	17.9%	1.00	2,438.04.-	-	0.0%
	2035	27.3%	1.00	3,348.72.-	-	0.0%
	2040	36.8%	1.00	4,599.56.-	-	0.0%
	2045	32.6%	1.00	6,317.62.-	-	0.0%



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	2050	29.2%	1.00	8,677.42.-	-	0.0%
Patent Extension Scenario (PES)	2020	38.9%	1.00	1,292.31.-	-	0.0%
	2025	26.1%	1.00	1,775.02.-	-	0.0%
	2030	17.9%	1.00	2,438.04.-	-	0.0%
	2035	27.3%	1.00	3,348.72.-	-	0.0%
	2040	36.8%	1.00	4,599.56.-	-	0.0%
	2045	37.2%	1.04	6,596.01.-	278.39.-	4.4%
	2050	33.3%	1.04	9,031.34.-	353.92.-	4.1%
Test Data Protection Scenario (DPS)	2020	44.4%	1.05	1,356.48.-	64.17.-	5.0%
	2025	52.2%	1.26	2,242.37.-	467.35.-	26.3%
	2030	42.9%	1.28	3,108.94.-	670.90.-	27.5%
	2035	48.5%	1.21	4,057.17.-	708.45.-	21.2%
	2040	55.3%	1.17	5,370.98.-	771.42.-	16.8%
	2045	60.5%	1.26	7,987.95.-	1,670.34 .-	26.4%
	2050	56.3%	1.27	10,977.88. -	2,300.46 .-	26.5%
Total Exclusivity Scenario (TES)	2020	44.4%	1.05	1,356.48.-	64.17.-	5.0%
	2025	52.2%	1.26	2,242.37.-	467.35.-	26.3%
	2030	42.9%	1.28	3,108.94.-	670.90.-	27.5%
	2035	48.5%	1.21	4,057.17.-	708.45.-	21.2%
	2040	55.3%	1.17	5,370.98.-	771.42.-	16.8%
	2045	60.5%	1.26	7,987.95.-	1,670.34 .-	26.4%
	2050	60.4%	1.31	11,331.80. -	2,654.38 .-	30.6%



3.3. Estimation of present impacts

The following table shows the estimation of over expenditure for the Ministry of Health in the event of the EU's proposal coming into force in Argentina in 2016³:

Table. Estimation of additional expenditure afforded by DNS y ETS in 2016, Ministry of Health.

Drug	Price paid by the Ministry of Health (price/unit in US\$*)	Price of generic version in international market (price/unit in US\$*)	Amount procured by the Ministry of Health in 2016 (units)	Difference / actual expenditure and generic version expenditure (US\$*)	Years of patent extension	Estimation of additional expenditure due to patent extension (in US\$*)
Abacavir 300 mg	0.84	0.17	162,360	108,781.-	2	217,562.-
Atazanavir 300mg	4.14	0.58	5,356,020	19,067,431.-	2	38,134,862.-
Lopinavir + Ritonavir 25 mg / 100 mg	1.08	0.13	118,800	112,744.-	2	225,489.-
Tenofovir 300 mg	2.10	0.11	1,790,130	3,562,359.-	2	7,124,717.-
Total antiretrovirals for HIV						45,702,631.-
Daclatasvir 60 mg	40.67	2.18	249,480	9,602,485.-	2	19,204,970.-
Sofosbuvir 400 mg	65.98	8.93	70,784	4,038,227.-	2	8,076,454.-
Total direct acting antivirals for Hepatitis C						27,281,425.-
Total over expenditure of DNS y ETS in the Ministry of Health						72,984,056.-

* The exchange rate is the average for 2016: US\$ 1= AR\$ 14.74

Source: document elaborated on the base of information provided by the Ministry of Health, Doctors without Borders (MSF) and other key informants.

✓ The total over expenditure for the Ministry of Health is of approximately 1,075.00 million AR\$ (US\$ 73 million). Considering

³ This was done for some of the medicines within the array, since in some cases the international prices for the generic version were not found, and in some others the patent had already expired.



that in 2016 the DNS y ETS budget was of 1,775.26 million AR\$, the additional amount paid by the Ministry in the procurement of 4 antiretrovirals to

treat HIV and 2 antivirals to treat Hepatitis C -patent-protected and not the more affordable generic version available - would suffer more than a 50% increase.

4. Final conclusions

- ✓ Even when the above presented are hypothetical and long-term scenarios, the results show very clear trends regarding possible results. While it is true that medicines procurement is not the only decisive factor to assess the access to medicines, the prices paid by the State make it a crucial variable in the access to treatment.
- ✓ Both in the estimation of the future impact of the 17 current API and in the ones that may enter the market through 2050, and in the current additional cost for those 6 API, there is evidence of the exponential increase in the cost of medicines procured by the Ministry of Health. This may jeopardize the future sustainability of the access to medicines.

Final Report

Introduction

The present document has the general purpose of analysing the impact that the access to medicines and health would have in Argentina if a FTA between Mercosur and EU was to be signed. This discussion is done in the light of the analysis of the proposal of a legal document on “Intellectual Property Rights” handed by the EU to Mercosur for its latter dis-

cussion in the event of an offer exchange that took place in May 11th, 2016.

The specific purposes of the document are the following:

- To assess the TRIPS Plus protection provisions in the chapter on intellectual property proposed by the EU to Mercosur. Such provi-



sions have an impact on the Argentinean policies on access to medicines.

- To estimate the monetary impact on the public procurement of antiretrovirals and Hepatitis C

treatments in Argentina in the event of the coming into force of the WTO *plus* provisions established in the chapter on intellectual property of the EU-Mercosur agreement.

1. EU-Mercosur Bi-Regional Association Agreement negotiations

After over 20 years of negotiations, many starts and stops, in a context of secrecy and lack of transparency, a third offer exchange in matters such as goods, services, investments, government procurement and intellectual property among many other subjects, happened between the EU and Mercosur, with the purpose of moving forward towards a free-trade agreement between the two blocs. Although officials from both regions have stated that the offers are clearly insufficient to reach a mutually beneficial agreement, it was a political event where the willingness of both blocs to continue with the negotiations was positively stated.

The launching of a project to establish a free-trade area between EU and Mercosur goes back to 1995, with the signing of an inter-regional Framework Cooperation Agreement EU-Mercosur, meant to

establish a political and economic association structured around 3 pillars: political dialogue, cooperation and trade. Negotiations around the agreement faced difficulties from the beginning. Both blocs have differences in their relative development and their production structures which make purposes and results diverge substantially. Whereas the EU's main interest revolve around expanding preferences like "TRIPS Plus" in different areas (government procurement, intellectual property, services, investment, technical barriers to trade, commercial defense, trade facilitation, sustainable trade and development, electronic commerce, raw materials and energy, small- and medium-sized enterprises, State enterprises regulations) and opening the market for industrial goods, Mercosur's main interest is on gaining more access to the European



market for the trade of agricultural products.

Since the launching of the dialogue in the VI European Union - Latin America and Caribbean Summit which took place in May 2010 in Madrid -after the process had been paused in September 2004 as a result of two offer exchanges that were insufficient for both parties - negotiations were again marked by the difficulties to get to an offer exchange. On one hand, Mercosur started to pressure for the EU to acknowledge the existing asymmetries between the two blocs, and for the inclusion of Special and differential treatment (SDT) provisions that would benefit the Latin American bloc with a lower level of coverage, a slower schedule for tariff reduction and grace periods.

On the other hand, the EU argued that in the past years Mercosur countries may have undergone a rapid growing process and generalized improvement of their population's life conditions which made SDT no longer enforceable. So the EU representatives concluded that the rhythm and tariff reduction schedules should be symmetrical and reciprocal for both blocs, and they also claimed greater access to services and public procurement markets and better conditions for establishing European enterprises in Mercosur.

Finally, and after 6 years of the restarting of negotiations, in May 11th, 2016, the third offer exchange took place in Brussels. Due to secrecy, opacity and lack of transparency in the negotiations, the true content of the exchanged offers in matters of goods, services, investment, public procurement, intellectual property and other issues remains unknown.

Data from key informants show that the goods-related offer made by Mercosur would cover 87%, whereas the offer made by the EU would cover 89.2%. Furthermore, in November 2016, requests for improvements may have been done by both blocs, and the preliminary acceptance would have taken the goods-related coverage to 87.2% in the case of Mercosur and to 92% in the case of EU. Moreover, in that occasion the EU defined a list of products which explain approximately 6% of the bilateral trade as "ultrasensitive" products, for which the possible improvements claimed by Mercosur were known by the end of October, after the elections in France and Germany, due to political sensitivity.

It is worth noting that in the same offer exchange the EU had two determining victories in the framework of an effective negotiation process which was the initial spark. In the first place, the EU defensive interests were made evident



once more as they wholly excluded the meat sector and the biofuels (ethanol and biodiesel) from the offer, such products being highly competitive within the Mercosur countries and a fundamental portion of the bloc's export basket. In the second place, through the negotiation the EU gradually proposed the inclusion of new chapters which were not part of the original mandate, such as intellectual property, sustainable trade and development, electronic commerce, raw materials and energy, State enterprises and small- and medium-sized enterprises.

Regarding intellectual property rights, Mercosur has kept a non-negotiating position since the relaunching of negotiations with the EU. Indeed, from the first Negotiating Committee in the new negotiation round that took place in July 2010, Mercosur expressed to the EU their total rejection to any possibility of

adopting an expanded intellectual property rights protection that would go beyond the "Trade-Related Aspects of Intellectual Property Rights" (TRIPS) from the World Trade Organization (WTO). Upon this refusal, the EU has been firmly insisting on including an intellectual property chapter to the agreement that would cover aspects beyond TRIPS. The EU's position resulted in the submission of a chapter's text which includes all intellectual property-related issues, such as copyright, trademarks, industrial design, geographical indications, patents and varieties of plants.

Specifically, in many of the issues related to the intellectual property chapter the EU requests to Mercosur to sign international agreements that, in most cases, none of the Mercosur countries is part of, as observed in Table 1 below.

Table 1: Multilateral treaties for which EU requests Mercosur's signature

International treaties on intellectual property rights	Contracting party			
	Ar	Br	Py	Uy
Patent Cooperation Treaty (PCT)	No*	Yes	No	No
Patent Law Treaty (PLT)	No	No*	No	No
Beijing Treaty on Audiovisual Performances	No	No	No	No
WIPO Copyright Treaty (WCT)	Yes	No	Yes	Yes
Hague Agreement Concerning the International Registration of Industrial Designs	No	No	No	No



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Madrid Agreement Concerning the International Registration of Marks	No	No	No	No
International Convention for the Protection of New Varieties of Plants - Act of 1991 (UPOV 91)	No	No	No	No

* Signed but not ratified. Source: original text based on WIPO data.

With regard to the current negotiations, the general criteria for the Mercosur countries is not to sign the treaties requested by the EU, with the exception of the Patent Cooperation Treaty. For this treaty, Mercosur has made a compromise to make their “best efforts” to include the provisions contained within.

A higher protection of intellectual property rights would reduce development possibilities within Mercosur countries, since they do not create but import te-

chnology. Any restriction to the power of Mercosur enterprises of imitating technologies developed in the central countries would mean a barrier to access to the production of goods and services which generate most of the income. Furthermore, regarding the adoption of a more restrictive legislation in patent matters, this is one of the main issues related to the access to health of the population in the countries involved in the agreement, due to its impact on the medicines market.

2. Intellectual property protection and its relation to the access to health

Patent law was harmonized in the early 1990s, not before, through the referred WTO’s TRIPS Agreement. Since then, there is little or no room for manoeuvre for countries to decide on their own intellectual property regulations. All WTO countries have similar patent laws and any violation is subject to commercial

penalties (e.g. when a country where the violation was produced is forbidden to export to a given market)⁴. This harmonization also meant the adoption of regulations more favourable to intellectual property in developing countries.

As far as access to health is concerned, in theory the justification for these re-

⁴ Arza, Valeria (2016), “Patentes e innovación: de la virtud a la tragedia”, Alquimias Económicas, November 15, 2016. Available at <https://alquimiaseconomicas.com/2016/11/15/patentes-e-innovacion-de-la-virtud-a-la-tragedia/>



gulations relies on a naive and untrue concept of how the market works. From this point of view, protecting innovative laboratories which find a new drug or medicine boosts research and development (R+D), reduces medicine costs and improves universal access to medicines. In reality, far from this naive view, patent laws cause the exclusion of new competitors, specifically public and private producers of generic medicines, and lead to a free setting of selling prices which guarantees better profits within a global system segmented for each national market.

The “Doha Declaration on the TRIPS agreement and public health” (2001) acknowledges the need for the TRIPS to be part of a broader national and international action designed to cope with public health issues faced by developing and less technology-advanced countries. It also recognized that whereas intellectual property protection is important for the development of new medicines, this protection also has effects on prices. This is the reason why the countries reaffirm the right of WTO members to use some safeguards or flexibilities to the protection measures so public health needs are taken into consideration. In this sense, the agreement allows countries, for example, to make parallel

imports and issue compulsory licenses for health protection. This means that even if patent holders did not accept the license conditions offered in certain situations provided for by law, such as public interest or national emergency, the government can apply flexibilities to the granted rights and issue a compulsory license for local companies to produce and commercialize, while acknowledging the patent holder’s right by paying royalties.

Through these flexibilities, some countries like Brazil have included in their patent laws license negotiation strategies in cases of “health emergency” or “public interest”. Therefore, Brazil applied compulsory licenses in 2001 for local companies to produce antiretroviral drugs offered for free to people living with HIV as part of its government health-related policy. This generated a price plunge for these medicines both locally and globally⁵.

In the past decades, “new generation” free-trade agreements (FTA) have been including liberalization, deregulation and protection rules for the medicines market which are far more ambitious than the ones agreed upon within the multilateral organizations that regulate this matter (WTO and the World Inte-

⁵ Arza (2016), *op. cit.*

Intellectual Property Organization, WIPO). These new provisions on intellectual property are known as TRIPS Plus.

These measures seek to reinforce the controls on intellectual property protection, reinforce biological data protection within a 12-year standard, extend

patent duration as compensation for delays in the period of approval, allow the granting of patents based on the “utility” and not on the “industrial applicability” (second use patents) and guarantee “market exclusivity” by means of test data protection for 5 years, to name a few.

3. EU’s proposal regarding intellectual property

The analysis of the chapter on intellectual property proposed by the EU to Mercosur and its comparison with the related legislation in force in Argentina allows the identification of issues that go beyond the compromises made by Argentina within the WTO. Indeed, the proposal made by the EU regarding intellectual property rights has a series of WTO Plus issues. There are three provisions that could imply the adoption by Argentina of more restrictive measures

regarding intellectual property protection that could affect the access to medicines:

- Exhaustion of intellectual property rights
- Extension of patent term
- Test data protection for obtaining authorization to trade pharmaceutical products

3.1. Exhaustion of intellectual property rights

Article 3 in EU’s proposal refers to the exhaustion of intellectual property rights, principle by which once a product has been sold in a market, a rights owner has no intellectual property rights. Article 6 in TRIPS establishes that, the actions of the members of the agreement in this matter cannot be cha-

llenged by means of WTO dispute settlement, and they can choose among



national⁶, international⁷ or regional⁸ exhaustion of rights. The chapter proposed by the EU establishes that members can choose between national or regional exhaustion of intellectual property rights.

Rights exhaustion is related to parallel imports. According to a WTO definition, a parallel import happens “*when a product made legally (i.e. not pirated) abroad is imported without the permission of the intellectual property right-holder (e.g. the trademark or patent owner)*”.⁹

Within access to health government policies, international exhaustion is an im-

portant measure since it facilitates the parallel import of the same product sold at lower prices in other countries, allowing the procurement of more affordable medicines. In this sense, the EU’s proposal would put a restriction to this possibility.

The legislation in Argentina adopts the international exhaustion of rights, since it establishes that “*The right granted by the patent shall not produce any effect against any person procuring, using, importing or in any way trading the patented product or obtained through a patented process, once it is legally commercialized in any given country.*”¹⁰

3.2. Extension of patent term

Article 8.3 in the EU’s proposal establishes that the Parties may extend the period of protection under patent of a medicine when it is subject to an administrative authorisation procedure before being put on the market. The article affirms 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 market may shorten the period of effective protection under the patent, period established in 20 years by TRIPS.

⁶ The intellectual property owner can oppose the import of protected products from other countries, even if they have entered the market in those countries either by the action of the patent-holder or with their consent.

⁷ The intellectual property owner cannot oppose the import of protected products to a member Estate from another member Estate where the product is marketed with the consent of the patent holder, due to the exhaustion of intellectual property rights once the product is marketed.

⁸ This happens when the importing country is part of a free trade area.

⁹https://www.wto.org/spanish/thewto_s/glossary_s/glossary_s.htm.

¹⁰ Decree 260/96 (Section 35).



In paragraph 2 of the above mentioned article, the proposal states that the Parties shall provide for a further period of protection for a medicinal product which is protected by a patent and which has been subject to an administrative authorization procedure, that period being equal to the period referred to in the second sentence of paragraph 1, reduced by a period of 5 years. Furthermore, in paragraph 3 the proposal establishes that the duration of the further period of protection may not exceed an undetermined number of years. It is worth mentioning that TRIPS does not contemplate any sort of extension beyond the 20 years above mentioned.

In the case of medicinal products for which paediatric studies have been carried out, and the results of those studies are reflected in the product information, the Parties shall provide for a further extension of the period of protection established in paragraph 2, in a

number of months not determined in the proposal yet.

The patent extension increases the period by which the patent holder can monopolize the product. This generates the increase of the price in the national market, with negative consequences in health policies and access to medicines.

The legislation in Argentina does not contemplate the possibility of extending the period of patent protection due to delays in the marketing authorisation. In fact, it is established that *“the patent has a non-renewable twenty-year period as of the date of the filing of the application”*.¹¹

In terms of the current negotiations between EU and Mercosur, information provided by key informants shows that the position of the Mercosur Parties is to make their best efforts to process efficiently and in due time the patent applications, which implies the non-acceptance of EU's proposal in this matter.

3.3. Test data protection

Article 10.2 in the EU's proposal establishes that the Parties shall not permit any other applicant to market the same

or a similar product, on the basis of the marketing approval granted to the party which had provided the results of pre-

¹¹ Decree 260/96 (Section 35).

clinical tests or of clinical trials. This means that data exclusivity is granted for a period not determined in the proposal and subject to negotiation.¹² A period extension for data protection is also proposed in the case that 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.

According to TRIPS, Members shall protect undisclosed data against unfair commercial use (article 39.3), but there is no obligation of granting an exclusivity right on the data, which gives Members the freedom to allow the authorities in the Member countries to support the granting of marketing authorisation on the information submitted in the first sanitary registration.

Granting exclusivity rights on pre-clinical tests or clinical trials data is harmful for the government policies on access to medicines, since it delays the availability of generic medicines, puts the producers of generic medicines in the trouble of performing new clinical trials, which increases the costs of production and the prices for that matter. Also, repeating clinical trials violates the *Ethical Principles for Medical Research Involving Human Subjects* (WMA Declaration of Helsinki).

The legislation in Argentina allows the registration of pharmaceutical products based on similarities¹³, i.e., without the need for the applicant to repeat clinical trials and for that matter no data exclusivity right period is granted.

4. Impact of the chapter on intellectual property in the EU-Mercosur Agreement on government procurement of drugs in Argentina

4.1. Methodology

The analysis of the impact of WTO Plus issues on the government procurement of antiretrovirals and hepatitis C medi-

cines is performed through an adaptation of the Intellectual *Property Rights Impact Assessment* (IPRIA) model, deve-

¹² In other signed FTAs, EU agreed upon a 10-year minimum.

¹³ Law 24.766 (Article 5) “on Confidentiality of Information and Products which are legally under control of a person and are unduly disclosed in a manner contrary to fair commercial uses”.



loped by the *International Centre for Trade and Sustainable Development* (ICTSD)¹⁴.

This is a model that allows the assessment of the impact on the access to medicines of intellectual property regulation-changing (IPR). This model allows the assessment of the impact *ex ante* and *ex post*. This is a way of having and *ex ante* analysis of IPR in Argentina as if the chapter on “Intellectual Property Rights” currently under negotiation between Mercosur and EU came into force.

The model allows the building of different simulation scenarios, so as to generate useful information for negotiation strategies and estimate the potential impacts in the event of the modification in the rules. Specifically, this is an aggregate model that enables the analysis of the impact produced by the IPR changes related to the cost of pharmaceutical products on the basis of a given period of time and a set of basic assumptions.

This is a deterministic model (not subject to randomness or stochastic behaviour), and its main variables are:

1. **Level of competitiveness / market exclusivity:** the average exclusivity in the market depends on the number of patent-protected products or products with test data protection that enter the market, and the period of duration of such market exclusivity.
2. **Variation in average prices:** it is assumed that a product under exclusivity shall have a higher price than the same product under competition conditions, which makes prices vary. The higher the portion of the market under exclusivity, the higher the market average price.
3. **Impact on the costs of medicines:** the impact of price variation depends on the shape of the demand curve, which is determined by the “price elasticity of demand” (PED): the lower the PED, the higher the impact on the cost. The model adopts a demand curve with a constant PED.

The changes are calculated on the basis of a comparison between a “status quo scenario” and the different possibilities of modifying the IPR in alternative sce-

¹⁴ Rovira, J.; Abbas, I. y Cortés, M. (2009), “Guide to the IPRIA (Intellectual Property Rights Impact Aggregate) Model”, ICTSD, Working Draft, December.

narios. Market analysis can be defined in an aggregate way or in a more specific manner, regarding a particular drug type (e.g. antiretrovirals).

Regarding the operation of the model, it contains the following definitions:

- i. **Defining the time horizon:** The initial year may be the one when IPR related changes have been introduced. The final year should be distant enough to capture the full effects of the IPR changes.
- ii. **Calculating the proportion of drugs under exclusivity:** the following variables must be taken into account: number of drugs enjoying data exclusivity in the initial year ('i'); annual flow of drugs entering the market with data exclusivity as of year 'i'; annual flow of drugs that lose data exclusivity as of year 'i'; number of drugs patented in year 'i'; annual flow of new drugs patented as of year 'i'; annual flow of drugs losing patent protection as of year 'i'. The model assumes that if product patents are introduced in year 'i', then the first drug with patent protection will enter the market in year 'i+DT', DT is the average time taken from patent filing to market registration.
- iii. **Total number of drugs in the market under exclusivity:** the total number of drugs in the market under exclusivity is the sum of the number under patent protection, the number under test data protection and the number under both types of exclusivity.
- iv. **Calculating the impact on expenditure:** the size of the pharmaceutical market in real terms and the real pharmaceutical expenditure is calculated by applying a constant rate of growth to the expenditure in the initial year in the baseline scenario or "status quo scenario". For the alternative scenarios the procedure of calculation of the impact on expenditure is the following one: the model calculates a price index of the alternative scenario for each year, based on the exclusive/competitive nature of each drug and the related price differentials.

4.2. Operation of the model

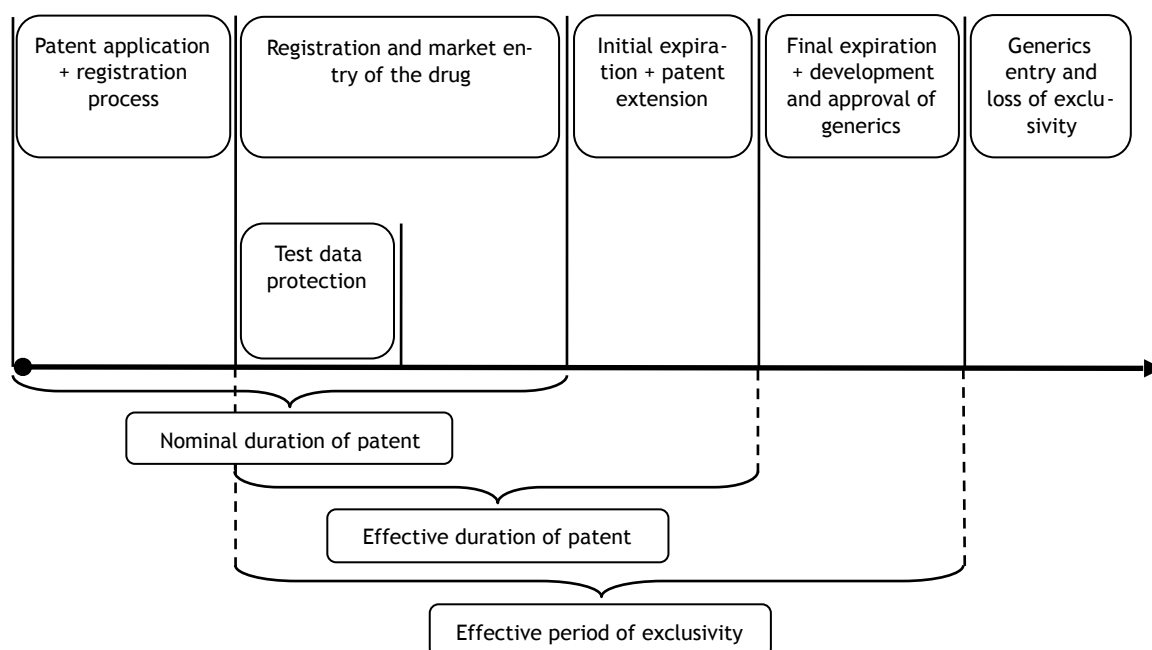
In order to apply the model, a time horizon must be defined. The initial year may be the one when IPR related changes have been introduced. The final year should be distant enough to capture the full effects of the simulated changes.

In the first place, the model calculates the total number of Active Pharmaceutical Ingredients (APIs) of every year, for which it takes the number of APIs in year 'i' and it adds and subtracts the APIs that enter and exit the market. As a next step, the model calculates the number of APIs under exclusivity as of the patent protection or test data exclusivity. For this matter, it takes the number of patent protected API with the remaining protection, and adds the new API entering year after year under protection (either with patent protection or with test data exclusivity), subtracting at the same time those API that lose exclusivity. Scheme 1 summarizes the duration of patents and of data exclusivity of APIs.

The model calculates the periods of exclusivity of the APIs that entered in a given year and estimates the number of APIs in the market under exclusivity, either through patent protection or test data protection. To that end, the year in which the exclusivity is granted is considered as year 'i', and also the number of APIs entering the market each year under this type of exclusivity and the duration of the exclusivity period for test data protection are considered.

As a result, the model obtains the total of APIs under exclusivity either by patent protection or by test data protection, at the time that estimates the proportion of API under exclusivity by dividing the result of the sum above by the total number of APIs in the market. The assumption is that the eventual simultaneous exclusivity due to both types of protection does not confer additional advantages to the API in terms of exclusivity against generic competition.

Scheme 1. Patent duration and exclusivity period



A non-linear constant price-elasticity demand function is assumed to calculate the impact of an increase in price on the quantities demanded and on expenditure. The demand curve is of the form: $q=kPe$, where $k>0$ and $e=0$ (demand is totally inelastic, which means quantity of procured drugs is constant, so the changes are made in the price and therefore, in expenditure).

During the simulation exercise, impacts are calculated as the difference between the “status quo scenario” and alternative scenarios related to different types of IPR changes (also for each year), for each variable, namely:

- i. The change in the total pharmaceutical expenditure, i.e. in the value of the pharmaceutical market (in monetary terms).
- ii. The average difference in prices of products under exclusivity and under competition.
- iii. The share of the market under exclusivity.

In relation to the key assumptions of the model it is worth mentioning:

- Off-patent drugs that are covered under the category of branded or unbranded generics and that the

pricing policy is uniform across all drugs.

- The difference in prices of drugs under exclusivity and under competition remains constant.
- Once the drug loses exclusivity, the price immediately falls to the

average competitive price (without regard to the time of adjustment).

- All drugs have equal market share, which remains the same along the product life cycle.

4.2. Building scenarios

This document has the purpose of estimating the impact of different TRIPS Plus measures on the price and expenditure of a set of antiretroviral medicines to treat HIV and of direct-acting antivirals to treat Hepatitis C. A description of the "status quo scenario" and of the different alternative scenarios that will be the base for the impact simulation is presented below.

- **"Status Quo Scenario" (SQS):** the *status quo* regarding intellectual property in Argentina is established based on Law No. 24.481, on Patents and Utility Models and amendments, which grants 20 years of exclusivity to the patent owner, being that the same period regulated in TRIPS. Regarding test data protection, the exclusivity period is of 0 (zero) years, pursuant to what is stated in the "Law on Confidential-

ity of Information and Products which are legally under control of a person and are unduly disclosed in a manner contrary to fair commercial uses" (Law 24.766)

- **"Patent Extension Scenario" (PES):** it considers the additional protection proposed by the EU in article 8.3 in the chapter on intellectual property. According to this, the period that elapses between the filing of the patent application for an API and the first authorisation to place the product on their respective market must be recognized, and is established in 2 years for the present study.
- **"Test Data Protection Scenario" (DPE):** It considers the data protection exclusivity period proposed by the EU. Since the proposal does not specify a number of



years, for the purpose of this study a 10-year exclusivity period will be considered, as that is the negotiated extension in other EU FTAs.

- **"Total Exclusivity Scenario" (TES):** it combines both PES and DPS, i.e. it considers the additional protection due to patent extension (2 years) and the exclusivity due to test data protection (10 years).

4.3. Imputing the data

4.3.1 Fixed parameters

First/initial year: the assumption is that the EU-Mercosur Agreement is going to come into force in 2020, with the estimation of its signature in 2018 and ratification in 2019.

Final year: the last year in the time horizon within which the impacts of the scenarios are measured. The choice of the final year should take into account the fact that the effect of a policy measure such as extension of the patent duration might take over 20 years to set in. The time horizon should elapse in at least 30 or 40 years to fully assess the effects. The current study takes 2050 as final year.

The number of drugs existing at the beginning of the initial year: the current study considers a set of API within the Vademecum of the Federal Office of AIDS and Sexually Transmitted Diseases

of the Ministry of Health (DNS y ETS). The set contains the 17 drugs in Table 2.

The value of the pharmaceutical market/ the market for the specific drug category in the initial year: this is obtained by multiplying the units of consumed medicines in the initial year by their prices and adding them all up. The expenditure of the DNS y ETS in antiretrovirals and in drugs for hepatitis C treatment in Table 2 during 2016 is of approximately 1,292.31 million AR\$.

The Annual Growth Rate of the SQE: average annual growth rate of expenditure estimated under SQE conditions. This rate for the DNS y ETS between 2012 and 2015 was calculated in 33%.

Discount rate: this study uses the 2016 average interest rate of 24.82%.for time deposits for ≥ 60 days in banking institu-



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tions (Central Bank of Argentina - BCRA).

Table 2. Total number of drugs under analysis

Drug	# patent applied	# patent granted	Year of application	Year of granting	Year of expiration
Abacavir 300 mg cap	-	017455	1999	2011	2019
	-	059120	2007	2010	2027
	-	014921	1998	2007	2018
	-	015668	1998	2009	2018
Abacavir + Lamivudina 600 mg/300 mg	-	017455	1999	2011	2019
	-	059120	2007	2010	2027
	-	014921	1998	2007	2018
	-	015668	1998	2009	2018
Atazanavir 300 mg	-	006720	2012	2017	2032
	-	014417	1999	2005	2019
Darunavir 150 mg	037797	-	2002	Withdrawn	-
Darunavir 600 mg	037797	-	2002	Withdrawn	-
Dolutegravir 50 mg	-	-	-	-	-
Efavirenz 600 mg cap	-	255251	1993	2001	2013
	077407	-	2010	Denied	-
Lopinavir + Ritonavir 25 mg/100 mg	-	005053	2005	2012	2025
	-	010634	1997	2005	2017
	077411	-	2010	Denied	-
	055734	-	2006	Denied	-
Lopinavir + Ritonavir 50 mg/200 mg	-	005053	2005	2012	2025
	-	010634	1997	2005	2017
	077411	-	2010	Denied	-
	055734	-	2006	Denied	-
Maraviroc 300 mg	-	024233	1999	2009	2019
	-	028622	2001	2007	2021
Raltegravir 400 mg	-	-	-	-	-



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Ritonavir 100 mg comp	-	019431	1999	2009	2019
Tenofovir 300 mg comp	-	-	-	-	-
Tenofovir + Emtricitabina + Efavirenz 300 mg/200 mg/600 mg	046812	-	2004	-	-
Tenofovir + Emtricitabina 300 mg/200 mg	054511	-	2006	Withdrawn	-
Daclatasvir 60 mg	-	063684	2007	2017	2027
	070016	-	2008	Denied	-
Sofosbuvir 400 mg	082064	-	2011	Withdrawn	-
	082067	-	2011	Withdrawn	-
	082066	-	2011	Withdrawn	-
	066898	-	2008	Denied	-
	044566		2004	-	-
	082068		2011	-	-
	089578		2012	-	-

4.3.2. The scenario specific parameters

The year of introduction of product patents: for the API under study, the information of patent application, granting and expiration presented in Table 2 was considered. In the case of new API entering the market as stated in 4.3.3, the year of market entry is assumed as the year of patent application.

The year of introduction of test data protection: in SQS and PES scenarios, data protection exclusivity is not contemplated. In DPS and TES scenarios, a 10-year-period of data protection exclusivity is contemplated, starting with the

introduction of new API to the market. In the case of the API in Table 2, data protection exclusivity has no retroactive effects, so those API do not enjoy that type of exclusivity.

The term of the patent: the patent law that incorporated the TRIPS to the legislation in Argentina establishes a 20-year term for every patent.

The average time taken from patent filing to market registration: in this case study such period is going to be of 7 years for every drug, according to the



information provided by experts and key informants from INPI and ANMAT regarding the average time for the granting of patents for new molecules, as is the case of antiretrovirals and hepatitis C treatments.

The extension of the patent duration as a compensation for delays in marketing approval: if Mercosur accepts the EU proposal and considering that the average time for approval is of 7 years in Argentina, the extension would be of 2 years. In SQS and DPS scenarios, which do not take into account this kind of delay, the time is 0 years.

The proportion of drugs obtaining an extension of patent duration due to as delay in marketing approval: considering that the average time for approval of the API under study is of 7 years, this proportion is of 100% in PES and TES scenarios. In SQS and DPS scenarios, which do not take into account this kind of delay, the value is 0.

Time lag between expiry of a patent of an originator product and entry of generics: it is assumed that generics enter once the patent has expired. Argentina protects data privacy through a Bolar-type provision in article 8, law 24.766, so a value of 0 is taken for every scenario.

Average delay in market entry of generics due to patent extension -(patent market registration linkage): there is no evidence of how long that could be in non-industrialized countries. In this case study the value is 0 for every scenario.

The period of market exclusivity due to test data protection: in SQS and PES scenarios this kind of exclusivity is not contemplated, so the value assumed is 0. In DPS and TES scenarios, 10 years are contemplated, according to the time requested in other EU negotiations.

The price differential between the average price of a drug under market exclusivity and that under competition: it was defined as a ratio of 2.37 between the average price of patent protected antiretrovirals and hepatitis C drugs procured by the Ministry of Health and the price of generics.

The price differential between the average price of a branded generic of an off patent drug and an unbranded (INN) generic version of the same drug: the effect of brands is not assessed in this study, so in order to avoid influence in the rest of the variables, a value of 1 was used.

The price-elasticity of demand for drugs: a value of 0 is used, implying a

perfectly inelastic demand, which means the quantity is not altered when

there is a change in the price, therefore increasing drug expenditure.

4.3.3. The annual input data

The number of new drugs entering the market in a particular year: according to several studies that show that approximately 2% of new API enter the market every year, a hypothetical value of 1 was assumed, in order to have an integer for the purpose of the exercise and to get a “minimum” estimation, taking into account the total number of API included in the DNS y ETS vademecum for 2016 (78 API).

The number of newly patented drugs entering the market in a given year: it is estimated that 100% of the new drugs entering the market do so with a patent application that, after the delay period above stated, is approved.

The proportion of unbranded generics: this case study does not makes a difference between branded and unbranded generics, and therefore this variable is given a value of 1 in every scenario.

The number of new drugs with market exclusivity due to test data protection: it is assumed that all the API entering the market immediately obtain exclusivity due to test data protection. In all cases it is assumed that data protection as well as patent protection (after the average 7-year delay in the approval) happen simultaneously. The degree of exclusivity does not differ for the fact that it enjoys either of the types of exclusivity foreseen in the model. In DPS and TES scenarios, a value of 100% is assumed for the newly registered API. SQS and PES scenarios do not contemplate this type of protection, and therefore the value is 0%.

In Table 3 below, a summary of the fixed parameters assumed for this exercise is presented. Furthermore, a summary of the characterisation of scenario specific parameters for each scenario is presented in Table 4.

Table 3. Fixed parameters in the impact estimation exercise



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Parameter	Value	Source
Initial year	2020	Definition specific for the study
Final year	2050	Definition specific for the study
Existing API at the beginning of the initial year	17	DNS y ETS
Value of the market (million AR\$)	1,292.31	DNS y ETS
Annual growth rate	33.00%	Average annual growth rate of expenditure for the DNS y ETS 2012-2015
Discount rate	24.82%	Time deposits for ≥ 60 days (BCRA)

Table 4. Scenario specific parameters for the impact estimation exercise

Parameter	SQS	PES	DPS	TES
Year of introduction of product patents	2003	2003	2003	2003
Year of introduction of test data protection	2050	2050	2020	2020
Term of the patent	20	20	20	20
Average time taken from patent filing to market registration	7	7	7	7
Tolerance of delay in patent approval in EU-Mercosur	-	5	-	5
Extension of the patent duration as a compensation for delays	0	2	0	2
% of API that obtain patent extension	0%	100%	0%	100%



Number of years in which generics enter the market due to patent expiration	0	0	0	0
Average delay in market entry of generics due to patent market registration linkage	0	0	0	0
Period of market exclusivity due to test data protection	0	0	10	10
Price differential between the average price of a drug under market exclusivity and that under competition	2.37	2.37	2.37	2.37
Price differential between the average price of a branded generic of an off patent drug and an unbranded (INN) generic	1	1	1	1
Price-elasticity of demand for drugs	0	0	0	0
Number of new drugs entering the market in a particular year	1	1	1	1
% of newly patented API	100%	100%	100%	100%
Number of new drugs with market exclusivity due to test data protection	0	0	100%	100%
% of unbranded generics	100%	100%	100%	100%

4.4. Primary results

The primary results of the adapted IPRIA model for the data in this study are presented in Table 5 below. Each column represents the following information for a series of selected data.

"Protected API" column: total market share corresponding to products with any kind of protection (patent or test data protection).

"Price index" column: assumed impact of the different IPR changes on the pri-



ces of medicines in Argentina. A value of 1 indicates no impact; >1 values indicate increases that are directly related (e.g. a value of 1.5 indicates 50% of price increase).

"Expenditure variation" column: budget modifications done by the Ministry of Health in order to continue to procure the same basket of medicines with new market prices, in constant million AR\$ (2016).

The results of the model with information projected through 2050 show growing impacts as time goes by for each of the proposed scenarios, according to Table 5. Were WTO Plus issues proposed by EU to Mercosur in the chapter on intellectual property to be implemented (extension of patent term and test data protection) the impact would be huge on the Ministry of Health expenditure through the DNS y ETS for the procure-

ment of antiretrovirals and direct-acting antivirals to treat hepatitis C, therefore causing great impact on the access to health for the population of Argentina.

Through the analysis of the different scenarios, it can be observed that in the PES scenario -related to patent extension due to administrative delays for approval - the effects of additional expenditure will be evident not before 2041, year in which the patents for API submitted as of 2020 will be extended as a consequence of the eventual inclusion of the provisions proposed by the EU for the FTA with Mercosur. In 2045 that additional expenditure would be of approximately 278 million AR\$ (current value), whereas for the final year of the series the expenditure would be of about 354 million AR\$. Thereby, the increase in the DNS y ETS additional expenditure would be of over 4%.

Table 5. Impacts on public procurement of medicines done by the Ministry of Health through DNS y ETS

Scenario	Year	% API with exclusivity	Price index	Current value of drug expenditure	Expenditure variation (mill. AR\$)	Expenditure variation / current value
Status Quo Scenario (2020)	2020	38.9%	1.00	1,292.31.-	-	0.0%
	2025	26.1%	1.00	1,775.02.-	-	0.0%
	2030	17.9%	1.00	2,438.04.-	-	0.0%
	2035	27.3%	1.00	3,348.72.-	-	0.0%



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(SQS)	2040	36.8%	1.00	4,599.56.-	-	0.0%
	2045	32.6%	1.00	6,317.62.-	-	0.0%
	2050	29.2%	1.00	8,677.42.-	-	0.0%
Patent Extension Scenario (PES)	2020	38.9%	1.00	1,292.31.-	-	0.0%
	2025	26.1%	1.00	1,775.02.-	-	0.0%
	2030	17.9%	1.00	2,438.04.-	-	0.0%
	2035	27.3%	1.00	3,348.72.-	-	0.0%
	2040	36.8%	1.00	4,599.56.-	-	0.0%
	2045	37.2%	1.04	6,596.01.-	278.39.-	4.4%
	2050	33.3%	1.04	9,031.34.-	353.92.-	4.1%
Test Data Protection Scenario (DPS)	2020	44.4%	1.05	1,356.48.-	64.17.-	5.0%
	2025	52.2%	1.26	2,242.37.-	467.35.-	26.3%
	2030	42.9%	1.28	3,108.94.-	670.90.-	27.5%
	2035	48.5%	1.21	4,057.17.-	708.45.-	21.2%
	2040	55.3%	1.17	5,370.98.-	771.42.-	16.8%
	2045	60.5%	1.26	7,987.95.-	1,670.34.-	26.4%
	2050	56.3%	1.27	10,977.88.-	2,300.46.-	26.5%
Total Exclusivity Scenario (TES)	2020	44.4%	1.05	1,356.48.-	64.17.-	5.0%
	2025	52.2%	1.26	2,242.37.-	467.35.-	26.3%
	2030	42.9%	1.28	3,108.94.-	670.90.-	27.5%
	2035	48.5%	1.21	4,057.17.-	708.45.-	21.2%
	2040	55.3%	1.17	5,370.98.-	771.42.-	16.8%
	2045	60.5%	1.26	7,987.95.-	1,670.34.-	26.4%
	2050	60.4%	1.31	11,331.80.-	2,654.38.-	30.6%

As observed, the impact on expenditure will be substantially higher were test data protection provisions for a 10-year period to be included (as is customary in

other EU FTAs). In this case, drugs would enjoy protection and exclusivity for such period from the very moment they enter the market, even when they still do not



have a patent granted by competent authority. In fact, in the DPS scenario that additional expenditure would be effective since the first year of coming into force of the agreement, and would undergo progressive increases due to the share of API under exclusivity as well as due to the price increase in comparison with the SQS scenario, i.e. status quo. Towards the final year of the series, the DNS y ETS's drug expenditure would reach approximately 2,300 million AR\$ (current value), which is 26.5% more than the intended expenditure if

test data protection provisions were not to be included.

In the assumption of the approval of both kinds of provisions within the EU-Mercosur agreement -patent extension and test data protection- the TES scenario shows an additional cumulative impact for the final year (2050) of 2,650 additional million AR\$, resulting in an increase of the intended expenditure under status quo of over 30%, due to the increase of API under exclusivity as well as due to price increase under monopoly.

4.5. Estimation of present impacts

Parallel to the estimation of the model, an estimation was performed for the adoption of the proposal of extending the period of validity of drug patents in the government procurements performed by the Ministry of Health of Argentina for a portion¹⁵ of the total number of antiretrovirals and hepatitis C antivirals detailed in Table 6 below.

In order to estimate the extension of the validity period of selected drug patents, a period between patent application and granting of registration was

considered. In order to estimate the extension of the validity period for the product patent 5 years were subtracted (period proposed by the EU) to that period¹⁶. Then, unit prices and quantities of drugs under analysis procured by the Ministry of Health in 2016 were collected and the prices of the generic versions available in the international market were identified.

The Ministry of Health expenditure in analysed drugs (C) was calculated on the base of paid prices, procured

¹⁵ The estimation was done for a portion of the total number of drugs, since there was no informed international price for some generic versions, and also because for some drugs patent has already expired.

¹⁶ Given the difficulties to obtain this data for every API, the decision was to use an average period of 7 years, which is the time lag of delay for patent approval of new molecules, according to information provided by experts and key informants from INPI and ANMAT.

quantities and necessary daily intakes. The Ministry of Health expenditure in the event of the procurement of the generic versions of those same drugs (D) was also estimated. The difference between C and D is the over expenditure due to patent monopoly. The cost of patent extension was estimated by multiplying the difference between C and D by the estimated patent extension period.

Thus, if drug prices increase due to higher protection, allocated government budget should be increased. Otherwise, the number of procured drugs will be reduced and the same will happen with access to treatments. Table 6 below presents an estimation of the additional Ministry of Health expenditure in the event of the EU proposal being in force in Argentina in 2016.

Table 6. Estimation of additional expenditure afforded by DNS y ETS in 2016, Ministry of Health.

Drug	Price paid by the Ministry of Health (price/unit in US\$*)	Price of generic version in international market (price/unit in US\$*)	Amount procured by the Ministry of Health in 2016 (units)	Difference / actual expenditure and generic version expenditure (US\$*)	Years of patent extension	Estimation of additional expenditure due to patent extension (in US\$*)
Abacavir 300 mg	0.84	0.17	162,360	108,781.-	2	217,562.-
Atazanavir 300mg	4.14	0.58	5,356,020	19,067,431.-	2	38,134,862.-
Lopinavir + Ritonavir 25 mg / 100 mg	1.08	0.13	118,800	112,744.-	2	225,489.-
Tenofovir 300 mg	2.10	0.11	1,790,130	3,562,359.-	2	7,124,717.-
Total antirretrovirales for VIH						45.702.631.-
Daclatasvir 60 mg	40.67	2.18	249,480	9,602,485.-	2	19,204,970.-
Sofosbuvir 400 mg	65.98	8.93	70,784	4,038,227.-	2	8,076,454.-
Total direct action antivirals de acción for Hepatitis C						27,281,425.-
Total additional expenditure of DNS y ETS of Ministry of Health						72,984,056.-



* The exchange rate is the average for 2016: US\$ 1= AR\$ 14.74

Source: document elaborated on the base of information provided by the Ministry of Health, Doctors without Borders (MSF) and other key informants.

Were the patent extension for antiretrovirals to happen as proposed by the EU, The over expenditure for the Ministry of Health would be of approximately 675 million AR\$ (45 million US\$). For the same case in hepatitis C treatments, over expenditure would be of about 403 million AR\$ (27.3 million US\$). Thus, total over expenditure for DNS y ETS would be of about 1,075 million AR\$ (73 million US\$).

Consequently, considering that in 2016 the DNS y ETS budget was of 1,775.6 million AR\$, the over expenditure for the Ministry of Health in the procurement of 4 antiretrovirals for HIV treatment and 2 antivirals for hepatitis C treatment -all patent-protected and not the more affordable generic version available - would represent almost half of the budget.

5. Final conclusions

This study has been done through a simulation in different scenarios of the additional impacts in the expenditure of the DNS y ETS in the Ministry of Health of Argentina for the procurement of antiretrovirals for HIV treatment and antivirals for hepatitis C treatment. Such impacts would be a consequence of the acceptance of TRIPS *plus* provisions- patent term extension and test data protection - proposed by the EU within the FTA negotiations with Mercosur countries.

Even when the scenarios are long term and hypothetical, performed under the acceptance of certain simplifying considered reasonable, preliminary results enable the prediction of very clear

trends regarding the estimated results. It is worth noting that even when drug procurement is not the only parameter for access assessment, given the prices afforded by the State, drug procurement is a critical variable regarding access to treatment. In this sense, medicines should be seen as social goods that allow for medical care and the health and life protection or recovery.

Both the future estimation of the impacts in the 17 API currently in the market as well as the ones that would enter the market through 2050, and the estimation of the over expenditure for a series of 6 API in the event of patent exclusivity, show exponential over expenditure for the Ministry of Health in



the procurement of the above-mentioned treatments, all this putting future sustainability in jeopardy.

So far, according to off-the-record information regarding the negotiations, Mercosur countries are not intending to accept the EU proposal within the FTA of extending patent terms due to administrative delays in approval or implementing test data protection. Were Mercosur position to be respected, the status quo in the present legislation of Argentina

would remain unaltered. Notwithstanding, given the pressure exerted by the EU in the last round of negotiations, and given the compromises made by Mercosur in several chapters within the negotiations, the possibility of the inclusion of that kind of provisions in the final text of the agreement is totally feasible. If that was the situation, a potential for a severe blow to the State financing of treatments as well as to the access to those treatments by the population would be high.



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