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Documents prepared by:

Edson Meza, AIS

Red Peruana por una Globalización con Equidad (RedGE):

Acción Internacional para la Salud (AIS), Asociación Pro Derechos Humanos (APRODEH), Centro de Derechos y Desarrollo (CEDAL), Centro de Estudios y Promoción del Desarrollo (DESCO), Centro Peruano de Estudios Sociales (CEPES), Convención Nacional del Agro Peruano (CONVEAGRO), Derecho, Ambiente y Recursos Naturales (DAR), CooperAcción, Grupo Propuesta Ciudadana (GPC).

Centro Peruano de Estudios Sociales – CEPES

Av. Salaverry # 818, Jesús María
Telephone: 433 6610 / Fax: 445 0908
www.redge.org.pe/redge@cepes.org.pe

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Neva Studio S.A.C.
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Telephone: 447 6651

Medicines: One Year After the FTA between Peru and the United States

Tariff elimination has not lowered the price of medicines and new monopolies have been formed

During negotiations for the FTA, the Ministry of Foreign Commerce and Tourism promised Peruvians that the price of drugs from the United States would go down: “the reduction of trade tariffs on drugs imported from the United States will benefit consumers since they will have access to these drugs at lower prices.”¹

The FTA with the United States called for the elimination of import tariffs on medicines produced in the United States. Thus as soon as the FTA went into effect in February 2009, import tariffs were eliminated for a significant number of drugs.² This meant exemption from paying the 9% ad valorem duty,³ which if translated to the final price paid by the consumer, implied a price reduction of about 8.26%. However, monitoring conducted from April 2009 to April 2010 reveals that the prices of medicines exempt from import tariffs have not gone down, as seen in certain products sold to government entities. The reduction expected has also failed to register in the products sold in the private sector.

Impact of reducing taxes on imported goods with tariff exemptions

Item	Charge	Without FTA (1)	With FTA (2)
a.	CIF Value (US\$)	100	100
b.	+ Ad Valorem Duty (9%) US\$	9	0
c.	+ VAT 19% (CIF+AVD) US\$	20.71	19
d.	Total import duties (US\$)	129.71	119
e.	% import duties / CIF (d/a)	29.71%	19%
	REDUCTION EFFECT (2)-(1)		-10.71%

Source: ADUANET and SUNAT

Prepared by: AIS

The public sector and consumers continue to pay high prices

For the public sector, for instance, pegaptanib (Macugen®, Pfizer), a drug used for retina degeneration, should have seen a price reduction from 2,746 Peruvian nuevos soles to 2,519 soles. The same goes for kogenate FS® 1000 IU (Factor VIII, Bayer), a biological product used in cases of leukemia, that has remained at its former price of 2,725 soles despite an expected drop to 2,500 soles.

¹ <http://www.tlcperu-eeuu.gob.pe/downloads/documento/PREGUNTAS%20Y%20RESPUESTAS%20SOBRE%20EL%20TLC.pdf>

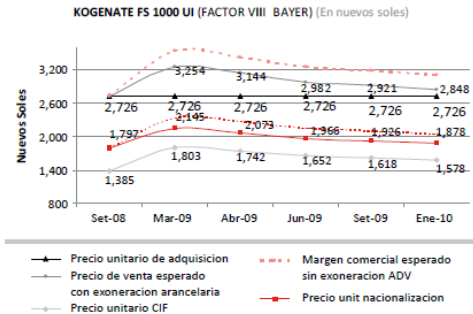
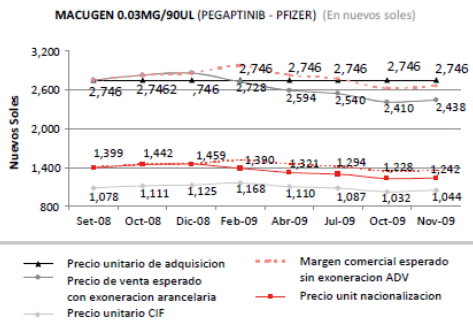
² Medicines in category A were immediately exempted, while those in categories B and C are progressively reduced until eliminated.

³ Up until 2007, pharmaceutical products were subject to a 12% ad valorem duty on the CIF price. Beginning in 2007, a new 9% ad valorem duty was assigned to pharmaceutical products, which is still in effect to date.

State Purchase of Pegaptanib (ESSALUD) October 2008 – January 2010 (in Peruvian new soles)	Government Purchase of Factor VIII (ESSALUD) October 2008 – January 2010 (in soles)
MACUGEN 0.03MG/90UL (PEGAPTANIB – PFIZER) (in soles)	KOGENATE FS 1000IU (FACTOR VIII BAYER) (in soles)

Compra estatal de pegatinib (ESSALUD)
Octubre 2008 - Enero 2010
(En nuevos soles)

Compra estatal de factor VIII (ESSALUD)
Octubre 2008 – Enero 2010
(En nuevos soles)



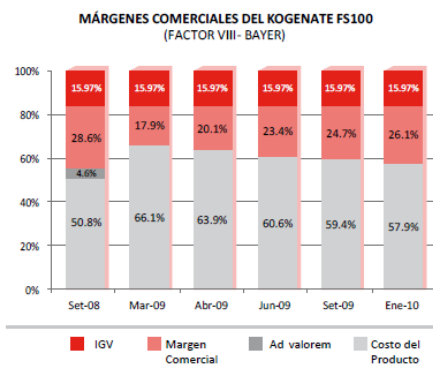
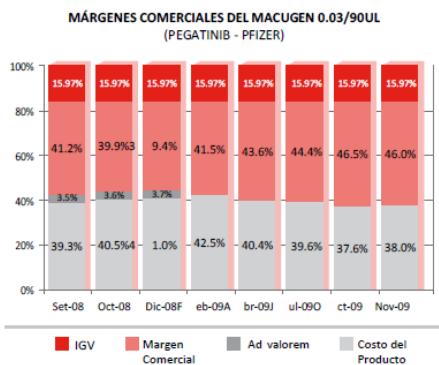
- Unit acquisition price	- Expected trade margin without ad-valorem exemption	- Unit acquisition price	- Expected trade margin without ad-valorem exemption
- Expected sale price with tariff elimination	- Import duty price per unit	- Expected sale price with tariff elimination	- Import duty price per unit
- Unit CIF price		- Unit CIF price	

In the private sector, there have even been cases of prices rising rather than lowering. For instance, methylphenidate hydrochloride 20 mg x 30 (Ritalin®, Novartis), which was expected to go down to 95.41 soles has actually risen from 99.14 to 104.00 soles. Even for the drugs who have experienced a price drop, the reduction expected from tariff elimination has not been as significant as was anticipated. ICY Hot® (3.5 oz jar, 100 mg) should have gone down to 18.94 soles, but has only registered a reduction from 21.24 to 20.64 soles. This also occurred with carboxymethylcellulose sodium (Refresh Liquegel® Eye Drops, 15 ml) which should have dropped from 64.99 to 55.39 soles but has instead been registered at 60.40 soles.

Profit Margin of Macugen 0.03 mg/90 ul September 2008 – November 2009	Profit Margin of Factor VIII October 2008 – December 2009
PROFIT MARGIN OF MACUGEN 0.03/90UL (PEGAPTANIB – PFIZER)	PROFIT MARGIN OF KOGENATE FS (FACTOR VIII – BAYER)

Margen comercial Macugen 0.03 mg/90 ul
Septiembre 2008 – Noviembre 2009

Margen comercial. Factor VIII
Octubre 2008 – Diciembre 2009



VAT	Profit Margin	Ad Valorem	Product Cost	VAT	Profit Margin	Ad Valorem	Product Cost
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The elimination of import tariffs – which in some cases also includes a reduction of CIF price – increases the profit margin of the medicines included in this analysis. In the case of pegaptanib, this meant an increase from 41.2% to 46.0%, while for Factor VIII the profit margin reduced from 28% to 26%. This is a result of the increase in the drug's CIF price (31%) when imported shortly after the tariff elimination entered into effect.

Companies that imported drugs from the United States increased their profit margin without factoring in the reduction of import costs to the product's final price, thus upping their profits. In some cases, the reduction of drugs' CIF prices contributed to this profit, in addition to the exchange rate, calculated at 7.15% for the period studied.

Who ends up with the money from exemptions?

During the period studied, the Peruvian government no longer receives US \$308,092 as a result of the exemptions stipulated in the FTA.⁴ In April 2010, there was still \$203,823 within the reimbursement term⁵ for companies that imported exempted products. If reimbursements were made, the Peruvian government's lost earnings would amount to a total of \$511,915.

Drugs Benefitting from Preferential Tariffs through the Peru-US FTA (February 2009 – April 2010)

Importer	Product	Brand	FOB Value (US\$)	CIF Value (US\$)	Amount saved through preferential tariffs (US\$)
Abbott Laboratorios S.A.	Pulmonary surfactant	Survanta	325 312.00	330 248.51	35 369.62
Bayer S.A.	Factor VIII	Kogenate	833 974.90	846 694.11	90 680.94
Distribuidora Dany S. R. Ltda.	Sodium Phosphate	Fleet	100 842.94	107 769.78	11542.14
Dubonp S.A.	Glucosamine Sulphate	Arthramine	209 889.76	227 291.03	24 342.87
Lukoll S.A.C.	Methylsalicylate +Menthol	Icy Hot	250 245.84	253 864.98	27188.94
Marketing y Ventas Vital S.A	Vasopressin	Vasopressin	4 060.00	4 282.61	458.67
Medifarma S.A.	Sevoflurane	Sojourn	145 796.70	14 242.19	15 983.84
Novartis Biosciences Perú S.A.	Metilfenidato	Ritalin	21 635.75	24 257.10	2 597.94
Pfizer S.A.	Atorvastatin Gabapentin Pegaptanib	Lipitor	8 218.14	8 337.48	892.94
		Macugen	248 500.00	252 079.66	26 997.73
		Neurontin	28 910.64	29 536.43	3 163.35
Productos Roche Q .F. S. A.	Tacrolimus	Protopic	262 925.14	305 820.59	29 417.46
Química Suiza S.A.	Paracetamol + Phenylephrine + Dextrometorphan Carboxymethyl Cellulose Sodium	Comtres	289 925.14	305 820.59	32 753.39
		Refresh	59 002.53	60 292.95	6 457.37
T & G Perú Importaciones S.A.C.	Benzocaine	Gelato Topical	2 145.00	2 352.30	251.93
TOTAL GENERAL			2 791 327.52	2 876 742.50	308 099.12

New drug monopolies

As a member of the World Trade Organization, beginning in 2000 Peru has been obligated to grant patents for a period of 20 years to products and processes, in accordance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS, 1994). This agreement confers a market monopoly to patent holders and – as experience has shown – translates into high prices for patented products. Globalization has compelled the great pharmaceutical industry to protect its investments through the patents established in the TRIPS agreement. Now the industry seeks new methods of protection through bilateral trade agreements in order to create exclusive positions in the market for protected products.

In the first case study for the period between January 1995 and February 2010, Peru granted 1,106 patents for pharmaceutical products. A total of 49 drug patents have been examined, of which only one belongs to a Peruvian company. The rest belong to foreign pharmaceuticals, three of which hold 48.9% of all patents granted. Furthermore, some medicines have been granted more than one patent, such as olanzapine, which holds eight patents⁶ and ziprasidone which has five (both drugs are used to treat schizophrenia). It is very likely that the National Institute for the Defense of Competition and the Protection of Intellectual Property (INDECOPI) is granting undue patents to

Holders of Patents Granted in Peru (sample of 49 drug patents)

Titulares de patentes otorgadas en el Perú (muestra de 49 patentes de medicamentos)

Titular	Total patentes
Pfizer Inc.	11
Novartis Ag	8
Boehringer Ingelheim	5
Grünenthal	3
Smithkline Beecham	3
Bayer	2
Eli Lilly and Company	2
Ferrer Internacional S.A.	2
Les Laboratoires Servier	2
Merck & Co. Inc.	2
Wyeth Holdings Co.	2
Otros	7
Total	49

⁴ Importers fill out a form/affidavit issued by the importer in accordance with the instructions stipulated in Supreme Decree No. 003-2009 MINCETUR.

⁵ Importers that do not request and obtain tax exemption at the time the product enters the country have a period of 12 months after the product's entry to request a reimbursement for the taxes paid. Rules of Origin, in the US-Peru Trade Agreement (18. C). <http://www.tlcperu-eeuu.gov.pe/downloads/documento/Regimen%20Origen%20APC%20Peru-EEUU.pdf> (Revisado 12/058/2010)

⁶ When there was greater competition, olanzapine was sold to the public for as low as 0.78 soles versus 15.00 soles for the brand name. After instituting a monopoly, olanzapine was sold to the public sector for 7.96 to 16.95 soles. In 2008, ESSALUD bought one million tablets of olanzapine, amounting to a total of 7,221,184.48 soles due to the prices caused by the monopoly.

inventions that do not demonstrate “novelty” and/or “inventiveness.”⁷

The FTA signed between Peru and the United States required the Peruvian government to grant protection and exclusive use of data on drug safety and effectiveness. This protection and exclusivity is “usually” granted for five years. No other company apart from the holder can use this test data to request health registration for competing products (generics). Though the protection and exclusive use of test data is not a patent, it acts like one, creating new monopolies even for drugs that are already internationally known but have never had health registration in the country. The FTA entered into effect in February 2009 and as of July 2010, six drugs have already been granted such exclusivity. To give an idea of the effects of such protection, ECALTA® – the brand-name anidulafungin drug used to fight fungal infections – currently costs 1,560 soles per injection in Spain while the complete treatment costs 23,400 soles (equivalent to 40 monthly minimum-wage salaries in Peru).

There is a list of products whose owners are requesting test data protection, which will thwart access to these medicines since such protection delays the entry of generic drugs in the market.

Drugs with Test Data Protection		
NAME	OWNER	EXPIRATION OF PROTECTION
Xarelto® 10 Mg(Rivaroxaban)	Bayer	Sept. 15, 2013
Multaq® 400 Mg(Dronedaron)	Sanofi Aventis Del Perú S.A	Jul. 2014
Ecalta® 100 Mg (Anidulafungin)	Pfizer S.A	Feb. 17, 2011
Effient® 10 Mg(Prasugrel)	Eli Lilly Interamérica Inc. S. P.	Feb. 25, 2014
Yondelis® 1 Mg(Trabectedin)	Johnson & Johnson Del Perú S.A.	Sept. 17, 2012
Onglyza 2.5 Mg(Saxagliptin)	Bristol Myers Squibb Company	Jul. 31, 2014

What can be done?

It is clear that once the FTA with the United States entered into effect, the Peruvian government has not monitored the effects of immediate tariff elimination for many of the drugs imported from the United States. Essentially, this means that eliminating the tariff did not translate into a reduction in the price of medicines – the very thing promised to Peruvians by the Ministry of Foreign Commerce and Tourism. On the other hand, INDECOPI continues to give out patents to pharmaceutical products without managing to clarify the “novelty” and “inventiveness” of the product. This can potentially lead to the accumulation of undue patents, creating unnecessary monopolies in the drug market that would prevent the entry of generics and result in high prices. Furthermore, the “protection and exclusive use” of test data granted by the General Directorate of Medicines, Supplies and Drugs (DIGEMID) is done without the public’s knowledge of what criteria is being used to determine that the data seeking such protection is the result of “considerable effort” or what criteria is used to determine the period of protection.

For these reasons, there are important tasks that must be assumed by the executive and legislative powers, as well as civil society:

The government must:

- Ensure sufficient funding for the medicines that the population needs, especially those that are most expensive or needed for catastrophic diseases. To date, numerous important medicines are not yet covered by the Essential Health Insurance Plan (PEAS) precisely due to their high costs and the costs of treatment.

⁷ Three criteria are used when granting a patent: “inventiveness” (a significant intellectual effort and contribution), “novelty” (the product must demonstrate innovation) and “industrial applicability” (it must be able to be produced).

- Constantly monitor the prices of drugs, especially those that have benefited from the elimination of tariffs in the Peru-US FTA.
- Include the “tariff elimination” factor when setting reference prices for public purchase.
- Closely monitor the behavior of medicines that enjoy patents or protection and exclusive use of test data in order to avoid monopolistic abuse. Also, the government should issue obligatory licenses or allow parallel imports when prices are based on positions of control and are essential to the population’s health care.
- Improve technical administration and make the processes of patent and test data protection more transparent. The DIGEMID should be the entity to grant patents for medicines and other pharmaceutical products.

Congress must:

- Monitor the outcome of laws and other norms that were put in effect for the Peru-US FTA.
- Draft and pass laws or modifications to existing laws in order to minimize the negative effects of multi- and bilateral trade agreements.
- Insist that public bodies ensure transparency during the processes of granting patents and test data protection.

Red Peruana por una Globalización con Equidad – RedGE
Av. Salaverry N° 818 – Jesús María. Teléfono: 433 6610. Fax: 433 1744. E-mail: redge@cepes.org.pe
www.redge.org.pe