Trading Away Health in the EU-Mercosur Trade Agreement

Proposed EU provisions would undermine public health and access to medicines

The EU-Mercosur trade agreement is currently under negotiation between the European Union (EU) and Mercosur countries of Argentina, Brazil, Paraguay and Uruguay. In the course of these negotiations the EU has proposed harmful intellectual property (IP) provisions that could potentially raise treatment costs by creating new monopolies and delaying the entry of affordable generics in the market. If these IP proposals are included in the final agreement, access to essential medicines will be restricted for millions of people across Mercosur countries. Furthermore, the capacity of these countries to promote global price reductions will be seriously undermined.

The EU proposal on IP includes measures[1] that go beyond the World Trade Organization (WTO) TRIPS Agreement and that could jeopardize the access to medicines in countries that already face severe shortfalls in their public health budgets.

The following provisions tabled by the EU would have a harmful impact on access to affordable medicines:

Data exclusivity

Data exclusivity refers to a practice whereby, for a fixed period of time, drug regulatory authorities are asked to withold the registration of generic medicines, negatively impacting access to medicines.[2] In fact, the strongest impact may be felt in a country whereupon data exclusivity could block the entry of generic medicines even if there is no patent for a medicine in force. Some Latin American countries that already agreed to introduce data exclusivity provisions under other free trade agreements are now dealing with its disruptive impacts on health. For instance, the implementation of data exclusivity rules cost Colombia US $396 million in additional expenses for its public health system between 2003 and 2011.[3] In Peru the inclusion of data exclusivity measures under the EU-Andean Trade Agreement will contribute to an estimated increase of $459 million in the country's total pharmaceutical expenditure in 2025.[4] Implementing the Central-American Free Trade Agreement has resulted in price increases in Guatemala of as much as 846 percent, due to data exclusivity provisions enacted.[5] These concrete impacts reveal that data exclusivity can prolong the market exclusivity period and delay the entry of price-lowering generic competition. Therefore, any clauses for data exclusivity should be removed from the EU-Mercosur FTA.

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[1] Chapter on Intellectual Property Rights. Available at: http://trade.ec.europa.eu/doclib/docs/2016/november/tradoc_155070.pdf

[2] World Health Organization, Briefing Note: Access to Medicines, March 2006. Available at: http://www.searo.who.int/entity/intellectual_property/data-exclusively-and-others-measures-briefing-note-on-access-to-medicines-who-2006.pdf ; See also Carlos Correa, "Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement" (2002), Page 47-51, available at: http://apps.who.int/medicinedocs/pdf/h3009ae/h3009ae.pdf

[3] Cortés Gamba M, Rossi Buenaventura F, Vásquez Serrano M. Impacto de 10 Años de Proteccion de Datos en Medicamentos en Colombia. [Online] IFARMA and Fundación Misión Salud; Bogotá D.C., Colombia, 2012. Available from: http://www.mision-salud.org/wp-content/uploads/2013/02/IMPACTO-DE-10-A%C3%91OS-DE-PROTECCION-DE-DATOS-EN-COLOMBIA.pdf. [Accessed September 27, 2017]

[4] IFARMA. Impact of the EU-Andean Trade Agreement on Access to Medicines in Peru. [Online] Health Action International Europe and IFARMA Foundation 2009. Available from: http://haieurope.org/wp-content/uploads/2010/12/11-Nov-2009-Report-IFARMA-Impact-Study-on-EU-Andean-Trade-Agreement-in-Peru-EN.pdf [Accessed September 22, 2017].

[5] Shaffer E, Brenner J. A trade agreement's impact on access to generic drugs. [Online] Health Affairs 2009; 28(5):w957-w968. Available from: http://content.healthaffairs.org/content/28/5/w957.full.pdf+html

Enforcement – Border measures

Border measures on alleged patent infringement proposed by the EU go beyond the requirements of the TRIPS Agreement and might lead to seizure of legitimate generic medicines in transit. Between 2008 and 2009 at least 19 shipments of legal generic medicines were wrongfully seized while in transit in Europe.[6] The shipments were suspected of infringing patent rights (or in the case of Germany trademark rights) in Europe, even though there were no patents on the relevant products in both the sending country (particularly, India) and the receiving countries.[7] The shipments included drugs used to treat HIV/AIDS, schizophrenia, Alzheimer's, cholesterol and hypertension, and were being shipped to countries in Latin America, Africa and Oceania. Dutch customs authorities seized, for example, the HIV drug abacavir sulfate as it was shipped from India to a donor-funded treatment program in Nigeria, resulting in a disruption in the supply chain of legal generic versions of lifesaving drugs.[8] EU regulations for the seizure of goods-in-transit are an example of misusing TRIPS rules in the name of combating counterfeit medicines and create risks of impeding legitimate free movement of generic medicines and thereby undermining generic competition.[9] Those regulations have been challenged by Brazil and India as not compliant with TRIPS Agreement rules.[10] Ultimately these provisions have no legitimate legal or public health objective, and instead only disrupt access to life saving generic medicines, particularly in developing countries. Provisions for border enforcement – especially those related to seizure of goods-in-transit – should be removed the EU-Mercosur FTA.

Supplementary Protection Certificates

Supplementary protection certificates (SPCs) are an example of an additional monopoly right, intended to expand monopoly protection for medicines beyond the twenty-year patent term and avoid generic competition. By prolonging the monopolies of originator pharmaceutical companies, SPCs lead to unaffordable medicines prices for longer periods of time – threatening the sustainability of national healthcare systems and delaying patients' access to lifesaving medical innovation. For example, due to an additional monopoly granted by SPCs, there was a 10-year delay for European countries to import or produce generic versions of imatinib mesylate, a medicine used to treat leukaemia.[11] Even the lowest current generic price of imatinib mesylate across a range of EU Member States is up to three times more expensive than the equivalent generic price in India, where generic competition began much earlier. [11]

SPCs are counterproductive to stimulating innovation as they create incentives for companies to focus on prolonging monopolies through ever-greening strategies.[11]For example, in association with the expanded monopoly of multiple SPCs, the average prices of trastumazab, a medicine treating breast cancer, across 10 European Union countries range from €456.29 to €1582.25 per vial (150mg) while the biosimilar versions have been available in India much earlier and are now available for €169.28 per vial (150mg).[11] Experiences in other countries have also shown that there is no evidence of increased investment, or visible incentive to innovate for

[6] Brazil and India file complain against EU over seizure of generic medicines, *BMJ 2010;340:c2672,* Available from: http://www.bmj.com/content/340/bmj.c2672 [Accessed September 22, 2017].
[7] Europe: HAI Europe (2009a) 'Dutch seizure puts pressure on access to medicines in developing countries', press release, 6 February, http://haieurope.org/wp-content/uploads/2010/11/6-Feb-2009-Press-release-Dutch-seizure-of-generic-medicines.pdf ; MSF (2009) 'Letters to EC on Netherlands Customs Seizures', http://www.msfaccess.org/content/letters-ec-netherlands-customs-seizure; HAI Europe (2009b) 'Another seizure of generic medicines destined for a developing country, this time in Frankfurt', press release, 5 June, http://haieurope.org/wp-content/uploads/2010/11/5-Jun-2009-Press-release-Seizure-of-generic-medicines-in-Frankfurt.pdf
[8] Europe: HAI Europe (2009a) 'Dutch seizure puts pressure on access to medicines in developing countries', press release, 6 February, http://haieurope.org/wp-content/uploads/2010/11/6-Feb-2009-Press-release-Dutch-seizure-of-generic-medicines.pdf ; MSF (2009) 'Letters to EC on Netherlands Customs Seizures', http://www.msfaccess.org/content/letters-ec-netherlands-customs-seizure
[9] HAI and MSF (2015), Empty Gestures: The EU's Commitment to Safeguard Access to Medicines: Review of European Union's Trade and Development Policy 2015, Available from: http://trade.ec.europa.eu/doclib/docs/2015/october/tradoc_153865.pdf [Accessed September 22, 2017].
[10] Brazil and India file complain against EU over seizure of generic medicines, *BMJ 2010;340:c2672,* Available from: http://www.bmj.com/content/340/bmj.c2672 [Accessed September 22, 2017].
[11] MSF and more than 30 civil society organisations, Open submission on supplementary protection certificates for medicinal products in the European Union, Available from: https://www.msfaccess.org/sites/default/files/MSF_assets/IP/Docs/IP_EU_Civil%20Society%20Open%20Submission%20on%20SPCs_ENG_2017.pdf [Accessed September 22, 2017].

novel pharmaceuticals after the introduction of patent term extensions.[12] Therefore, SPCs must be excluded from the text of the FTA being negotiated.

Médecins Sans Frontières (MSF) urges EU-Mercosur negotiators to reject these proposed measures and provisions., The new strategy for trade and investment adopted by the European Parliament in 2016 (point 30), "reminds the Council, in this regard, to meet its commitments to the Doha Declaration by ensuring that the Commission explicitly guarantees access to medicine when negotiating pharmaceutical-related provisions within the framework of future bilateral and regional trade agreements with developing countries". The negotiation on IP provisions should instead incorporate directives dictated by resolution 2071 adopted in 2015 by the European Parliamentary Assembly,[13] which calls for alternatives to the current patent-based pharmaceutical innovation model.

[12] Australia Government. Pharmaceutical Patent Review Report 2013. Pages 64, 67-72. Available from: https://www.ipaustralia.gov.au/sites/g/files/net856/f/2013-05-27_ppr_final_report.pdf . [Accessed September 22, 2017]

[13] Council of Europe, Parliamentary Assembly. Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests? Available from: http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=22154&lang=en [Accessed September 27. 2017].