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Trade Agreements and Public Health: The Possible Implications of the USMCA for Mexico

Alexandre Portes

On October 1st, 2018, US American president Donald Trump proudly announced the successful conclusion of one of his most significant projects for US trade policy: The United States-Mexico-Canada Agreement (USMCA). In his words, this "incredible new" agreement aims to "terminate and replace NAFTA and the NAFTA trade agreements".[1] Trump, who is very active on social media, added via Twitter that the USMCA "is a great deal for all three countries".[2]

Despite these words, the USMCA is not a complete rupture to the former North American Free Trade Agreement (NAFTA) nor is it necessarily good for all parties to the agreement. First, the USMCA has just a few alterations in comparison to NAFTA. It is thus more of a renegotiated NAFTA than an entirely new agreement. Nonetheless, these few alterations indeed represent a substantive change in specific fields and might impact some countries negatively. In this sense, the agreement might not be a great deal for everyone. This is particularly the case of the USMCA's new regulation on intellectual property rights (IPR). The inclusion of IPR in trade agreements is a common phenomenon in the global trade governance and was already a characteristic of NAFTA. Despite all the attention the USMCA gained during the past months, little has been discussed about the possible impacts of the new provisions on IPR for public policy in Mexico. Among the three countries of North America, this least economically developed member seems to be the one most concerned by the new regulation.

An especially relevant IPR provision from the agreement for public policy is the one on data protection. This regulation is particularly important for the pharmaceutical industry since it is common for governments to require sensitive information before they grant market approval to new pharmaceutical products. This information can be used by other companies to produce ge-

[1] Wolf, ZB (2018): Donald Trump's obsession with renaming things. In *CNN*, 10/1/2018. Available online at https://edition.cnn.com/2018/10/01/politics/trump-nafta-usmca-name/index.html, checked on 11/10/2018.

[2] Trump, DJ (2018): Twitter post on 01.10.2018. Available online at https://twitter.com/realDonaldTrump/status/1046708836407685122, checked on 11/10/2018.

neric products and to obtain market approval. NAFTA, which was concluded in 1993, already protected this type of information. Article 1711.5 stated that the parties to the agreement shall provide data protection for "not less than five years from the date of approval from the date on which the Party granted approval to the person that produced the data". This provision is repeated in the USMCA, but there is extra protection for biologics – pharmaceutical products that use biological material and often represent the cutting-edge of biomedical research.[3] In the USMCA, all pharmaceutical products receive the minimum of five years data protection, but biologics receive a minimum of ten years. In fact, this regulation entails that, after a new pharmaceutical product receives marketing approval in any of the North American countries, the information used to approve this commercialization has to be kept in secret for at least five years, or ten years in the case of biologics. The restriction in data access hinders the process of producing new generics or biosimilar products – generic versions of biologic pharmaceutical products.

This protection is welcomed by pharmaceutical companies, since they usually invest substantial financial resources in the research of new biologics. Nonetheless, the stronger regulation of USMCA points to possible negative implications for Mexican public health, for two main reasons: (i) the structure of the Mexican pharmaceutical industry and (ii) the distribution of wealth in the society. International multinational companies are a substantial part of the Mexican pharmaceutical industry. In 2012, there were only two Mexican companies in the top ten producers of pharmaceutical products in Mexico. The other eight companies on this list were foreign multinationals and represented more than 40% of the Mexican market share.[4] Apart from the relevance of international companies in the Mexican pharmaceutical market, they mostly produce medicaments with higher value. In 2017, 85 percent of the production of multinationals was patented medicaments, while 95 percent of the domestic production was generic.[5] In consequence, the Mexican pharmaceutical industry does not only play a minor role in this economic sector but is also concentrated in a field which can be negatively affected by stricter IPR provisions.

The second negative implication is related to the societal access to medicaments. Although Mexico is a relevant regional economy, its social indicators are still far behind from its OECD fellows. For 2016, Mexico was ranked worst in income inequality among the group, and, for 2017, listed

[3] US Food and Drug Adminsitration (2018): What Are "Biologics" Questions and Answers. Available online at https://www.fda.gov/aboutfda/centersoffices/ officeofmedicalproductsandtobacco/cber/ucm133077.htm, checked on 11/10/2018.

[4] Secretaría de Economía (2013): Industria Farmacéutica. Unidad de Inteligencia de Negocios. Available online at https://www.gob.mx/cms/uploads/attachment/file/62881/130820_DS_Farmaceutica_ESP.pdf, checked on 11/10/2018.

[5] Castañares, G. (2018): 9 de cada 10 medicinas que se venden en México son genéricas, 4/24/2018. Available online at http://www.elfinanciero.com.mx/empresas/9-de-cada-10-medicinas-que-se-venden-en-mexico-son-genericas, checked on 11/10/2018.

among the five countries with highest poverty rate.[6] Hence, there are still challenges for Mexican authorities to reduce the wealth gap, which affects greatly how people can access medicaments. A 2012 study by the Mexican government shows that the access to medicaments is characterized by high prices in the private sector and that expenditures in medicaments represent one third of the total spent by an average household for health care.[7] Taking this situation into account, the introduction of new biosimilars could improve the access of the Mexican population to new medicament – in particular of lower income groups. The Mexican legislation already allows such products to be registered. Even though it is an expensive process to obtain a marketing license, the possibilities to produce biosimilars give local companies the opportunity to contribute with medicaments at a lower cost. In fact, the competent Mexican authority for sanitary issues has been authorizing the commercialization of biosimilars since 2017.[8] Adding to that, 35 percent of the innovative substances in Mexico are related to biologics; biosimilars would hence represent significant savings for families and the public sector.[9]

In sum, the new provision of USMCA providing higher protection for biologics might in fact implicate an adverse effect for Mexican development. The provision hampers the production of new biosimilars which could be introduced into the market and reduce costs, both for the Mexican state and people. Finally, the Mexican industry already lacks investment in biosimilars (investment in research and development ranks lowest among the USMCA members[10]), and more protection for patented drugs might even reduce its participation in the total production. Concerning public health in Mexico, the USMCA is thus probably not such a "great deal".

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[6] OECD (2018): Database. Available online at https://data.oecd.org/, checked on 11/10/2018.

[7] Wirtz, V.; Mori, E.; Dreser, A.; Pi, Ileana; Burgos, L. (2012): Evidencia para la política pública en salud. Available online at https://ensanut.insp.mx/doctos/analiticos/SurtimientoMedicamentos.pdf, checked on 11/10/2018.

[8] Coronel, M. (2017): Ya vienen los primeros biocomparables en México. In *El Economista*, 2/14/2017. Available online at https://www.eleconomista.com.mx/opinion/Ya-vienen-los-primeros-biocomparables-en-Mexico-20170215-0004.html, checked on 11/10/2018.

[9] COFEPRIS (2017): Biocomparables, opción para reducir costos en el Sistema Nacional de Salud. Available online at https://www.gob.mx/cofepris/articulos/biocomparables-opcion-para-reducir-costos-en-el-sistema-nacional-de-salud-136953?idiom=es, checked on 11/10/2018.