Pharmaceutical Provisions in the U.S.-Mexico-Canada Agreement (USMCA)

Myths vs. Facts

Myth: Unless Mexico and Canada increase their periods of biologic exclusivity, American pharmaceutical companies won't be able to finance the discovery of new medicines.

Fact: Fewer than 2% of the $1.2 trillion global pharmaceutical market is based in the Mexican ($10 billion) and Canadian ($21 billion) markets. When branded pharmaceutical companies make research and development investment decisions, those decisions are not based on how their products are selling in Canada and Mexico, but rather on the market potential of the United States ($450 billion), China ($80 billion), Japan ($80 billion) or Germany ($40 billion) (Source: IQVIA). Strategically, for the branded industry, including any biologic exclusivity in this trade agreement is really about establishing a precedent for future agreements and guaranteeing at least 10 years of market exclusivity in the United States.

Myth: The United States-Mexico-Canada Agreement will not affect U.S. drug prices.

Fact: Competition from generic and biosimilar medicines leads to lower drug prices for patients, with reductions, according to the FDA, of up to 80% for generic drugs alone.[1] However, the negotiated text of the USMCA would increase the period of monopoly protection from five to 12 years for chemically synthesized polypeptides, a class of drugs that are used by patients with a range of conditions including, for example, diabetes, heart failure and osteoporosis. The result would be longer periods of monopoly rights for large pharmaceutical companies and delayed access to affordable medicines for patients.

1 Generic Drugs: Questions & Answers. Food and Drug Administration. https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers.

Myth: Without additional biologic exclusivity, branded pharmaceutical companies will bypass the Mexican and Canadian markets.

Fact: Mexico's data exclusivity regime has not kept innovative pharmaceutical companies from launching biologic products in Mexico. And those products have not faced early competition from biosimilars. In fact, all the top 12 selling biologics in the United States have been registered (i.e., received marketing authorization)[2] by the Mexican regulatory authority.

- The best-selling drug in the world, Humira ($19.9 billion in global sales in 2018), was registered by the Mexican regulatory authority in 2003 and still does not face biosimilar competition in Mexico (but it does in Europe).
- Avastin ($6.85 billion in global sales in 2018) was registered in 2005 and does not face biosimilar competition in Mexico; a biosimilar was approved in Europe in 2018.
- Lucentis ($1.67 in global sales in 2018) received approval in Mexico in 2007 and does not face biosimilar competition in the market.

Myth: Nothing in USMCA will limit the ability of Congress to change U.S. law.

Fact: Any changes to domestic law related to provisions included in the USMCA are subject to dispute settlement. As currently drafted, Mexico or Canada could seek dispute settlement if Congress reduced biologic exclusivity level below 10 years in the United States. In addition, given that ensuring the 10-year biologic exclusivity provision remains is a top priority for PhRMA and its members,[3] any effort to reduce the period of biologic exclusivity in the United States will result in the branded pharmaceutical lobby aggressively advocating that U.S. law cannot be changed because of U.S. treaty obligations.

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2 Source for the Mexican data: Mexico: "Registros_Alopaticos_otorgados" page for each calendar year, 2001 – 2019 found at: https://www.gob.mx/cofepris/documentos/registros-sanitarios-medicamentos.

3 PhRMA Statement on the United States-Mexico-Canada Agreement. PhRMA. October 2018. https://www.phrma.org/press-release/phrma-statement-on-the-united-states-mexico-canada-agreement.

Myth: The biologic exclusivity period included in the original negotiated text only stops biosimilar companies from relying on the data submitted by the original biologic manufacturer but does not keep those products off the Canadian or Mexican markets.

Fact: Like U.S. law, language included in the negotiated USMCA text would preclude competition from biosimilar products until the exclusivity period expires. It would not be possible for a biosimilar company to simply rely upon the data of the original biologic product at any point, before or after the monopoly period expires. Biosimilar producers would simply not be able to launch their products in any of the three markets. A long period of biologic exclusivity would simply be another means to delay competition and keep prices high in Mexico, Canada and the United States.

Myth: Long exclusivity periods, like the 10-year period included in USMCA, should not be adjusted downward, even as the pharmaceutical research and development (R&D) process becomes more efficient.

Fact: Congress intended to create a balance between innovation and access when in 1984 it passed the Hatch-Waxman Act, which led to trillions of dollars in savings over the last 35 years. This legislation considered the financial realities of R&D but also recognized the importance of competition. However, innovations such as artificial intelligence, the growing use of biomarkers and the adoption of mobile technology in clinical trials have improved, making pharmaceutical innovation more efficient and less costly. This, in turn, reduced the need for long periods of exclusivity. For example:

- Using AI, a Boston-based company developed a new drug candidate for fibrosis in three weeks.[4]
- Greater use of mobile technology in clinical trials can save pharmaceutical companies $100-$200 million per year.[5]
- When examining eight factors increasing the efficiency of drug development, IQVIA predicts that "Biomarkers will have the greatest impact on clinical productivity yielding a 34% average increase across all phases of development."[6]

4 Hendrickson, Zachary. New research shows an AI-powered system can develop potential new drugs in just 3 weeks. Business Insider September 4, 2019.

5 Getz, Kenneth. The Adoption and Impact of Adaptive Trial Designs. Tufts Center for the Study of Drug Development. May 2013.

6 The Changing Landscape of Research and Development. IQVIA Institute for Human Data Science. April 2019.