The USMCA Will Keep Drug Prices Out of Reach for Patients, But Congress Can Fix It

The USMCA Creates New Barriers, Delays Patient Access to Affordable Medicines — Especially Biosimilars.

The Agreement would delay U.S. patient access to competition from low-cost, high-quality generic and biosimilar medicines, and fails to include strong incentives for their approval and uptake.

Aspects of the Proposed USMCA Conflict With U.S. Law.

Certain USMCA provisions could require either changes to U.S. law or risk immediate non-compliance with the Agreement. Because these provisions could serve as a template for future trade agreements, these inconsistencies should be addressed now to avoid possible changes to U.S. law in the future.

USMCA Lacks Incentives for Generic and Biosimilar Competition.

The USMCA lacks critical features of current U.S. law that encourage generic and biosimilar competition. By including such provisions, the USMCA can ensure that competition from more affordable generic and biosimilar medicines is available to American patients, taxpayers and payers.

Specific Concerns About USMCA Include:

The USMCA locks the U.S. into 10 years of exclusivity for expensive biologic drugs and delays patient access to biosimilars in Canada and Mexico — thus blocking U.S. exports.

- U.S.-based biosimilar manufacturers would be blocked from potential markets, hampering their ability to invest in the development of biosimilars for U.S. patients.
- As such, patients would continue to pay the high-cost of brand-name biologics, which are now the most significant driver of increased prescription drug spending.
- Moreover, this provision would limit the ability of Congress to decrease biologic exclusivity to fewer years, if it were determined that such a change would help create robust biosimilar market competition in the U.S.

The USMCA expands the definition of biologics, doubling exclusivity for certain medicines.

- The proposed USMCA would mandate that countries provide at least 10 years of biologic exclusivity for certain brand-name drugs that Congress has chosen to exclude from biologic exclusivity under U.S. law.
- Specifically, in defining a biologic subject to exclusivity, U.S. law expressly excludes proteins that are "chemically synthesized polypeptides." The USMCA contains no such exception. Accordingly, a protein that is

a chemically synthesized polypeptide would appear to be entitled to biologic exclusivity under the Agreement, even though those products are not considered biologics in the U.S.

The USMCA expands the scope of drug exclusivities beyond U.S. law.

- Under U.S. law, a generic drug may be approved when there is not a timely filed patent infringement lawsuit made in response to the notice of a Paragraph IV certification contained in an ANDA submitted beginning at year 4 of the 5-year exclusivity period. The USMCA appears to make the 5-year period applicable in all cases.

Consistency and conformance are needed.

- All of these issues should be conformed to the U.S. Hatch-Waxman Amendments and the Biosimilars Law (the BPCIA) to avoid a major disruption of the careful balance struck by Congress in enacting the approval pathways for generic and biosimilar medicines in the United States.

Congress Can Fix the USMCA:

- **Eliminate additional biologic exclusivity, which will delay patient access to biosimilars.**

- **Clarify areas of inconsistency between U.S. law and the Agreement.**

- **Rebalance the Agreement by providing an incentive for Generic Manufacturers to Challenge Brand-name Drug Patents.** A key feature of Hatch-Waxman is an incentive to challenge the validity or applicability of weak patents. This helps ensure the expedited entry of generic drugs to the market for the benefit of patients and taxpayers. USMCA should include language to promote pharmaceutical competition.

- **Ensuring a clear and robust regulatory review ("Bolar") provision.** A stronger, more robust regulatory review clause is needed in the USMCA to allow generic and biosimilar manufacturers to use a patented invention to obtain marketing approval. This provision is crucial to facilitating the production and introduction of generics and biosimilars into the market on the date of patent expiry.

- **Enhancing patent transparency by including a "best mode" requirement.** The USMCA should make disclosure of the best mode mandatory to ensure competition, particularly in the biologics market, once patents expire. Under "best mode," if there are several ways in which the invention may be put into practice, the applicant can be required to disclose the most practicable use in order to facilitate the introduction of competitive versions of the product once the patent expires.

- **Enhance transparency through a public registry for all patents and exclusivities granted to a drug.** Similar to the FDA's Orange Book, the USMCA should include a requirement to ensure the creation of a public listing of all patents and exclusivities.