



**Your Generics &  
Biosimilars Industry**



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Dear Gentlemen:

We are writing on behalf of our respective industry associations, which combined represent the North American producers of generic and biosimilar prescription medicines. Our members in Canada, Mexico, and the United States engage in the highly skilled research, development, and manufacturing that is required to bring affordable, life-saving medicines to patients. Combined, generic medicines produced by our members saved North American patients, governments, and private insurers over \$300 billion in 2016 alone, and in Mexico MX\$24,000,000,000 in the last four years. Moreover, the promise of biosimilar medicines will allow patients, governments, and private payers of health care to save untold billions due to savings from highly expensive biotechnology drugs that currently face no meaningful market competition. The biosimilar industry is growing and fragile, and we must ensure that a renegotiated North American Free Trade Agreement (NAFTA) does not damage these companies – including by extending monopoly pricing for brand name biologic drugs.

As you continue the complex work of modernizing NAFTA, we wanted to provide background on the North American market for affordable generic and biosimilar medicines and convey our shared goals for these negotiations.

## **I. Background on the Generic Medicine and Biosimilar Market in North America**

There is active trade in pharmaceuticals among the three NAFTA partners with more than 480 million consumers in North America. Many of our member companies manufacture in, import from, and export to more than one NAFTA market. The generic and biosimilar medicine industry is also a major contributor to the North American economy. In the United States, generic and biosimilar companies manufactured over 61 billion doses of medicine domestically in 2016, employing over 36,700 skilled workers in the U.S. In Mexico between 2007 and 2016, pharmaceutical companies generated over 10,000 jobs including both generic and branded medicines, totaling over 86,700 total jobs. Generic pharmaceutical companies are Canada's primary pharmaceutical manufacturers and exporters, and are among the top R&D spenders across all industrial sectors. The industry operates the largest life sciences companies in the Canadian provinces of Ontario and Quebec, and directly employs more than 11,000 Canadians in highly skilled research, development and manufacturing positions. Made-in-Canada generic medicines are currently exported to more than 115 countries.

Canada, Mexico, and the United States also have the largest integrated economy in the world, with shared supply chains and similar consumer preferences. Due to the size and integration of the North American market and the large volume of trade within the continent and with other nations, any approaches that apply to a combined North American market are more likely to be used as a starting point for regulators, customs authorities, and policymakers in other countries. While U.S. and Canadian regulators have long influenced the global regulatory environment, Mexico has increasingly become an important reference for countries with respect to regulatory coherence (good regulatory practices), regulatory cooperation, and sector-specific regulatory alignment. Indeed, Mexico's network of twelve Free Trade Agreements have enabled it to "export" North American approaches to other trading partners.

## **II. Goals for NAFTA Renegotiation**

Since NAFTA was originally negotiated, much has been accomplished within the World Trade Organization (WTO) to ensure that Members' commitments under the Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS Agreement") do not impede Members' abilities to enact policies to promote access to affordable, life-saving generic and biologic medicines. In 2001, WTO Members adopted the Doha Declaration on TRIPS and Public Health, which articulated the need for balance between protection of intellectual property rights for innovative drugs and policies to allow greater access to affordable generic and biosimilar medicines. As you seek to update NAFTA's intellectual property rights protections, it is essential that the balance between innovation and affordability of medicines is maintained. We encourage you to ensure that NAFTA's intellectual property rights chapter explicitly affirm this balance, and avoids imposing additional onerous barriers to affordable medicines that would increase drug prices and delay access, such as measures that would expand monopolies held by brand name pharmaceutical companies through longer marketing or data exclusivity periods, or mandates to extend a patent term based on delays in granting the patent or obtaining marketing approval.

**In particular, we believe that including a new provision in NAFTA to mandate biologic drug exclusivity – above and beyond the protections already provided by voluminous patents – will harm the growing biosimilar industry which aims to provide price competition to the most expensive biological drugs and allow patients to benefit from affordable biological medicines.**

We also encourage the three governments to enhance the intellectual property provisions of NAFTA to incorporate provisions that facilitate the development of affordable generic and biologic medicines in North America, including those that would:

- **Require a research (Bolar) exception to facilitate timely access to generic and biosimilar competition once patents have expired.** NAFTA should include a research exception to patents during the patent term to ensure that generic and biosimilar development may occur during the patent or exclusivity term, so that patients may benefit from generic and biosimilar competition the first day that patents end.
- **Require patent transparency** such as disclosure of the “best mode” for carrying out an invention as part of a patent application and a public registry for all patents and exclusivities granted to a drug.
- **Enhance initial generic drug and biosimilar competition** by requiring an incentive to challenge patents and exclusivities for reference drugs and granting a reward to those that do so.

We also support measures that will promote trade in generic and biosimilar medicines among NAFTA partners and contribute to the ability to use the North American market as a platform to export to the rest of the world. In most of the NAFTA market, generic drug penetration is already high (for example, 89 percent in the United States, 86 percent in Mexico and 70 percent in Canada). Our members’ ability to develop export markets is increasingly critical to their success and their ability to deliver new generic and biosimilar products – and less expensive medicines to patients – at home.

An updated NAFTA can play an important role in increasing the efficiency of the North American pharmaceutical market by incorporating provisions that would streamline the regulatory process, including through:

- **Regulatory harmonization and recognition where appropriate.** A mutual recognition agreement on inspections between Canada and the United States– similar to the agreement reached between the United States and the European Union – is a particular priority. To better align regulation while not reducing levels of patient protection requires new levels of cooperation between regulatory agencies that encompass the entire life cycle of rulemaking: from joint information-gathering and research to joint regulatory planning; from developing joint regulatory proposals to establishing joint stakeholder advisory committees; from coordinating on regulatory roll-out so that the same rules apply throughout the North American market at the same time to better aligning implementation and enforcement so that redundant requirements are eliminated, and collaborating on retrospective review.

Crafting new sectoral disciplines in emerging technology areas and developing a North American strategy for using international standards, guidelines, and recommendations, as

well as conformity assessment or control, inspection, or approval procedures, as tools for alignment of regulatory approaches will help unleash economic growth and innovation and provide the highest levels of health, safety, and environmental protection. The high-level focus of the U.S., Mexican, and Canadian administrations on regulatory reform should help in these efforts, since regulators will be actively looking to identify potential regulatory cost savings. Regulators' use of standards and conformity assessment systems developed in the private sector, and efforts to increase regulatory alignment with major trading partners could reduce compliance costs.

- **Addressing regulatory approval backlogs for generic medicines** with special emphasis on expediting the approval of "first generics" will ensure that patients can benefit from generic and biosimilar price competition immediately upon the expiration of patents and exclusivity.

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More detail on these issues is contained in our individual submissions to our respective governments. We look forward to working closely with you to achieve a new NAFTA that promotes trade in the full range of pharmaceutical products throughout the North American market and facilitates the significant health care savings that generic and biosimilar medicines deliver to North American patients.

Sincerely,



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