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October 31, 2024

Re: Review of CUSMA

On behalf of the Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA), I am pleased to submit our comments on the **operation of the Canada-United States-Mexico Agreement (CUSMA).**

The CPMEA represents Canadian pharmaceutical manufacturers operating production facilities in Canada, making medicines for Canadian patients and for export. Our members are the largest manufacturers of medicines by volume in Canada, producing innovative, generic and biosimilar pharmaceuticals, as well as non-prescription medications. The products made by CPMEA members are used to fill over 203 million prescriptions in Canada annually, representing 26% of all prescriptions dispensed in Canada.

Canadian pharmaceutical manufacturers produce many medicines for export. They rely on access to foreign markets for their medicines and compete successfully against producers from all over the world. According to Statistics Canada, Canadian pharmaceutical exports exceeded $12 Billion in 2023, of which $9 Billion went to the U.S. and $89 Million to Mexico.[1]

> **CUSMA has a key role to play in ensuring that the Canadian pharmaceutical manufacturers continue to have unfettered access to the U.S and Mexico for our exports of medicines.**

Trade in pharmaceuticals between Mexico and Canada is limited, although Mexico is growing as an important source of Active Pharmaceutical Ingredients (API). Trade negotiators for Canada should be mindful of this as they review CUSMA and recognize the opportunity to foster the interconnectedness of the Canada-U.S.-Mexico pharmaceutical trade relationship.

Rules-based Trade in Medicines between Canada, the U.S and Mexico

Since 1995, Canada and the U.S. have been parties to the WTO Pharmaceutical Agreement, a 'zero-for-zero initiative', which eliminated tariffs on pharmaceutical products and on chemical

[1] https://www150.statcan.gc.ca/n1/pub/71-607-x/71-607-x2021004-eng.htm; Chapter 30 Pharmaceuticals

intermediates used in the production of pharmaceuticals. There are over 10,000 products on the tariff-free list. Since the 1980's, Canada and the U.S. have also been parties to the WTO Government Procurement Agreement (GPA) which sets rules to ensure open, fair and transparent competition for government procurement contracting. In 2020, the Trump Administration came very close to withdrawing from the GPA and went so far to notify its intention to remove certain medicines from the list of products covered by the GPA in order to contract with only American suppliers.

> **It should not be taken for granted, under future U.S. Administrations, that the U.S. will remain a party to the WTO agreements, or even a member of the WTO. Therefore, it is critical that CUSMA ensure continued barrier and tariff-free trade in pharmaceuticals between Canada, the U.S. and Mexico.**

National Security Measures for Pharmaceutical Products and Inputs

The U.S. Defense Production Act (DPA), a 1950's law established during the Korean War, has been invoked in recent years by both President Trump and President Biden. The DPA grants the President powers to "expand and expedite the supply of materials and services from the domestic industrial base"[2] in the interests of national security. Most recently, President Biden invoked the DPA in October 2023 to produce more essential medicines in the U.S. and reduce dependency on foreign sources.

In June 2024, the Biden Administration announced, under the auspices of the National Security Council, the establishment of the BIO5 Coalition to support secure biopharmaceutical supply chains. The members of the BIO5 are United States, the European Union, India, Japan, and the Republic of Korea. The objective of this trade alliance is to build resilient supply chains for pharmaceuticals and API and reduce dependency on certain foreign sources. The BIO5 initiative includes sourcing domestically-made medicines from trusted allies to ensure security of supply as well as support the economic benefits from reshoring. It is expected that there will be opportunities for suppliers in these countries to access contracts for critical products and inputs.

We understand that Canada is having discussions about joining the BIO5. The CPMEA strongly recommends that Canada become a partner to this trade alliance. It would be a great opportunity for Canadian medicine manufacturers to be part of this solution and could be a risk for access to medicines for Canadian patients if Canada is excluded from the trade block. This is also an important initiative to secure the medicine supply chain for Canada. As Canada prepares for the review of CUSMA, we ask negotiators to use the opportunity to advance Canada as a member of the BIO5, making it the BIO6.

> **It is important that in its trade relations with the U.S. that CUSMA negotiators ensure that medicines produced in Canada for export to the U.S. are considered as part of a broad strategy of national security for both the U.S. and Canada.**

[2] https://www.fema.gov/disaster/defense-production-act#:~:text=The%20Defense%20Production%20Act%20(DPA,from%20the%20domestic%20industrial%20base.

Government Procurement

Under the WTO GPA, as noted above, all parties must open government procurement markets to competition. There are procedures, nevertheless, to notify parties of products to be excluded from government procurement contracts in certain circumstances. Again, Canada should endeavour to ensure that Canadian-made medicines are not excluded under Buy-America provisions.

> **It is critical that any definition of 'domestic production' includes Canada so that Canadian medicine manufacturers are not excluded as suppliers to U.S. entities and can participate in any procurement opportunities by government for national security and defense purposes and are not disadvantaged in competing in the overall U.S. market.**

Mutual Recognition of Inspections with FDA

CUSMA is an opportunity for Canada to advance its interest in an MRA for Inspections between Health Canada and the FDA. It is our understanding that initial discussions have been held in the context of regulatory convergence and efforts to reduce inefficiency and redundancy at the agencies. CPMEA supports Canada's efforts to conclude an agreement.

The production facilities of the members of CPMEA are regularly inspected by the FDA as well as. Health Canada, with many duplicated activities. Yet all parties are agreed that both country's regulatory agencies provide exceptional oversight and regulatory rigor. The U.S. has established Mutual Recognition Agreements (MRA) for inspections with the European Union as well as the United Kingdom. Canada also has similar MRAs with other countries.

> **A MRA between Canada and the U.S. for mutual recognition of inspections would materially reduce the costs of producing in Canada for the U.S. market, increase efficiency and facilitate trade in medicines between the two countries. It would also reduce costs at Health Canada for conducting its inspections.**

Regulatory Convergence

Under the auspices of CUSMA, there is an opportunity for Canada to encourage greater convergence between the FDA and Health Canada on regulatory requirements for submissions. The adoption of streamlined requirements would serve to avoid duplicative clinical and technical work and the generation of additional data which do not add any value.

> **For Canadian producers that develop products for the U.S., greater alignment between Canada and U.S. would be a benefit to speed up our ability to grow export sales through faster and more efficient access to the large U.S. market.**

Intellectual Property Protection for Pharmaceuticals Under CUSMA

The United States often requires measures to align IP regimes through its bilateral and multilateral agreements. CUSMA is no exception. CUSMA's pharmaceutical provisions aim to balance measures to "encourage innovation and access to medicine," and the IPR chapter reaffirms the WTO Doha Declaration on TRIPS and Public Health. Increases in IP protection under CUSMA may

serve to increase innovation, however, it is unclear which provisions in the IP chapter will improve access to medicines.

Data Exclusivity for Biologics: As Canada prepares for the review of CUSMA, we encourage our negotiators to defend the current level of data protection that Canada provides for all pharmaceutical products, including biologics.

During the negotiation of CUSMA, the US pharmaceutical industry strongly advocated for Canada and Mexico to adopt longer periods of data exclusivity for biologics, specifically to increase DP to 10 years. This was a contentious issue within the U.S. Congress and was eliminated in the final text. At the time, some Members of Congress argued that if a trade deal includes a defined term of data protection for biologics, it will restrict the ability of Congress to lower that period in the United States in the future. The same would be true for regulators in Canada.

The biosimilar market is still developing in Canada, and longer periods of protection for biologics will discourage investment in competing products. CPMEA urges Canada to reinforce its original position in CUSMA on data protection for biologics.

Patent Term Restoration: A recent revision of Canada's IP regime came as a result of CUSMA. Under the agreement, parties are required to provide a patent term adjustment (PTR) to compensate for 'unreasonable" delays in the processing of patent applications. Canada was required to implement its obligations under this provision within 4.5 years after CUSMA entered into force for patents filed on or after December 1, 2020. The provisions are expected to come info force on or before January 1, 2025.

Canada's final PTR will not include an export exemption, meaning that companies will be prevented from developing and manufacturing a product in Canada during the Patent Term Adjustment period for export to a country that does not have a PTR regime, as many do not. This will be a significant barrier for Canadian producers to compete in other markets. It is disappointing that Canada did not to provide an export exemption for its PTR period. By way of example, as part of its obligation under CETA, Canada implemented a Supplemental Protection Certificate (SPC) in 2017 to compensate for delays in marketing approval. Yet, Canada's SPC regime includes an export exemption which allows Canadian generics and biosimilars manufacturers to develop and produce a product in Canada and export to countries where there is no extended protection or where protection has expired.

Conclusion

Trade agreements like CUSMA have a critical role on reinforcing the importance of global access to medicines and health care products. The events during the early days of Covid when borders were closed to exports highlights the need for agreements between countries that specifically include medicines, especially during times of crisis.

As negotiators prepare for the review of CUSMA in 2025, we hope that the BIO5 will become the BIO6, and that CUSMA will reinforce unfettered access to the U.S. market for Canadian medicines producers, ensuring that Canadian manufacturers are not excluded from any aspect of government procurement for pharmaceuticals covered by CUSMA.

In addition, an MRA for Inspections by the FDA should be made a priority for Canada - to reduce our production costs and improve the competitiveness of Canadian pharmaceutical manufacturers for the export market.

We wish you well as you start the process leading to the official review of CUSMA with the United States and Mexico.

Sincerely,

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