

October 8, 2025

Mr. Michael Sabia
Clerk of the Privy Council and Secretary to the Cabinet
80 Wellington Street
Ottawa, Ontario
K1A 0A3
Canada

Dear Mr. Sabia,

On behalf of the Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA), we are writing to urge the government to immediately include as part of the **Buy Canadian** initiative a **‘Canada First’ prioritized regulatory path for new drug submissions submitted by Canadian drug manufacturers**.

The Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA) represents Canadian pharmaceutical manufacturers operating production facilities in Canada, making medicines for Canadian patients and export. Our members, Apotex, Pharmascience, Laboratoire Riva, Teva and Delpharm, are the largest manufacturers of medicines by volume in Canada, providing innovative, generic and biosimilar pharmaceuticals, as well as non-prescription medications.

The ‘Canada First’ regulatory priority proposal was developed by CPMEA in response to the threat posed by potential tariffs on Canadian manufacturers exporting pharmaceutical products to the United States. ‘Canada First’ would provide a prioritized regulatory review process for the new drug submissions of Canadian pharmaceutical manufacturers.

The ‘Canada First’ proposal has been presented to senior officials within the departments of Health Canada and ISED/HERC. ‘Canada First’ has also been presented to the Prime Minister’s Office, Health Minister’s Office, Industry Minister’s Office and Finance Minister’s Office. While the proposal has been positively received, the industry still awaits an indication the government plans to move forward with its development and implementation.

Recent announcements emerging from the U.S. administration increase the urgency with which Canada must respond. On September 30, in connection with Pfizer’s announcement that it will invest in augmenting its U.S. manufacturing capacity, the U.S. administration reiterated its commitment to establishing regulatory and procurement policy to give preference to American pharmaceutical manufacturers. Subsequently, the U.S. Food and Drug Administration (FDA) announced on October 3 that it will launch a pilot prioritization

program for the review of **abbreviated new drug applications (ANDAs)** (i.e., generic products). Like the ‘Canada First’ proposal, the FDA pilot program aims to use a priority regulatory path to “spur and reward investment in U.S. drug manufacturing and research and development and strengthen the domestic pharmaceutical supply chain by providing faster reviews for US generic drug manufacturers.”

Considering these developments, a corresponding Canadian response is necessary to secure Canadian pharmaceutical manufacturing and to retain production in Canada. The ‘Canada First’ policy would provide a prioritized regulatory pathway for the new drug submissions of Canadian manufacturers. Importantly, the ‘Canada First’ proposal is aligned with the Canadian government’s **Buy Canadian** policy and would help facilitate regulatory efficiency and incentivize increased investment in Canadian pharmaceutical manufacturing. It will support the retention of existing manufacturing capacity, position Canada as a strategic asset in a North American health security context, and ensure Canadian patients and payers have reliable access to affordable drugs and therapeutics.

Given these developments and policy objectives, the Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA) asks the Canadian government to immediately implement under the **Buy Canadian** initiative a ‘Canada First’ regulatory pathway for the new drug submissions of Canadian pharmaceutical manufacturers. To move the initiative forward in a timely manner, the Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA) and our member companies stand ready to work with Health Canada on the design and implementation of the Canada First regulatory pathway.

Sincerely,



Terry Creighton

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