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RE: Notice of Intent to Seek Feedback on a Proposed Pilot Program to Prioritize Generic Drug Submissions involving Domestic Manufacturing

On July 15, Health Canada published a Notice of Intent to seek feedback on a proposed pilot program to prioritize generic drug submissions involving domestic manufacturing within the regulatory review queue.

CPMEA represents the largest producers of pharmaceutical products in Canada, manufacturing medicines for Canadians here at home, including innovative, generic and biosimilar medicines. Collectively, CPMEA members provide more than 30% of prescriptions dispensed in Canada.

The members of CPMEA are very encouraged by this development as we have advocated for a priority review process for submissions from Canadian producers. Following our constructive discussions with the Minister, we are pleased to see Health Canada moving forward with a pilot program that aligns with many of the objectives we proposed. We appreciate the openness and collaboration demonstrated by both the Minister's office and Health Canada officials throughout this process.

The members of CPMEA have given considerable thought to how a Priority Program can work and what would be most beneficial to domestic producers. We agree that a Pilot Program is a good way to develop a successful program.

As this is a new undertaking, it will be important to assess its performance and make adjustments as evidence and experience are gained. We look forward to working with Health Canada to help ensure the program evolves in a way that delivers meaningful benefits to Canadian producers while achieving its intended objectives.

We understand that the Priority Program is intended to be implemented quickly. We clearly support a fast implementation so that Canadian producers can benefit immediately.

Recognition of Canadian Pharmaceutical Producers

Domestic manufacturers make substantial investments in Canadian production and R&D facilities, skilled employment, and export capacity, and contribute to Canada's security of supply and public health objectives. The Priority Pilot Program recognizes these contributions - we welcome a 'made-in-Canada' approach to drug approvals with support for Canada's own industry. This initiative will

also support broader government objectives related to economic growth, investment attraction, pharmaceutical security, and domestic manufacturing competitiveness.

The Priority Review program could not have come at a better time and must be implemented quickly. Canadian producers are facing a very uncertain future due to the trade war with the U.S. Canada's exporters face greater tariff exposure than those from other jurisdictions. Canada is the only major pharmaceutical exporter, other than India, without a separate bilateral agreement on pharmaceuticals with the U.S. The UK, Japan, EU, South Korea and Switzerland have negotiated pharmaceutical tariffs rates of 0-15% through bilateral agreements.

When the 232 tariffs on patented medicines go into effect on September 29, 2026, and possibly on generics in August 2028, Canada will face the full impact of the 232 tariffs. Supply chains will no doubt be impacted and Canadians will rely even more on our domestic producers for continuity of supply, access to essential medicines, and reliable sources.

Objective of the Program

Health Canada has described the program as a “workload management” tool. **We recommend that Health Canada use this program to accelerate the approval of submissions from Canadian producers.**

Without faster approvals, the program will have limited value for Canadian manufacturers. The intention must be to reduce the backlog of generic submissions by prioritizing those from Canadian producers to get to the market faster. This will also ensure that cost savings accrue to Canadian payers sooner, and drug shortages are alleviated or prevented as quickly as possible.

Creating a second pathway that simply develops another backlog would not achieve these objectives. The program should instead provide a meaningful reduction in review and approval times for Canadian manufacturers.

The objective must be to improve access for patients to generics made here and to strengthen Canada's domestic pharmaceutical manufacturing ecosystem. The Priority program will provide Canadian producers with a more predictable and timely regulatory pathway.

In a global environment where many jurisdictions actively support domestic production, such an approach would help create a more level competitive landscape for Canadian manufacturers. Given the higher costs associated with manufacturing in Canada and the economic realities of a relatively small domestic market, Canadian producers are less likely to pursue products in highly saturated categories where additional entrants offer limited incremental benefit to patients or the healthcare system. As a result, the products brought forward by Canadian manufacturers often have the potential to enhance competition, improve supply security, and deliver meaningful value to Canadian patients and payers.

By enabling Canadian manufacturers to bring these products to market sooner, the program has the potential to accelerate access to affordable generic medicines while strengthening domestic supply capacity and improving Canada's ability to prevent and respond to drug shortages.

In many cases, Canadian manufacturers also invest in products that address unmet needs by introducing a first generic alternative or increase competition in therapeutic areas with only a limited number of generic suppliers.

For the Pilot to have a meaningful impact on meeting the goals of improving supply and access, the program should include improved regulatory timelines for the submissions from Canadian manufacturers and expedite communication. CPMEA recommends:

Service standards

- Screening time for submission from Canadian generic producers reduced to 25 days
- Following screening process, the file be 'picked up' within 30 days
- An overall target of 120 days from screening acceptance to completion of the review

Early identification of deficiencies

- Health Canada should provide early notice of potential deficiencies, so producers learn of significant issues quickly, and provide responses to questions submitted through pre-ANDS or pre-NDS communications for Canadian companies
- An early assessment checkpoint should be established no later than 60 days after submission
- Proactive communication of potential deficiencies before issuance of a Notice of Non-Compliance (NON); and
- Automatic resumption of review activities within 10 business days following the submission of a satisfactory response to a clarifax or NON/NOD.

Existing Priority Process

Although this is a new process for generic submissions, Priority Review has been used by HC to speed up the approval of other drug products which address an unmet medical need. **Health Canada's existing Priority Review framework demonstrates that accelerated review pathways can be implemented when policy objectives justify expedited access.**

CPMEA recommends extending priority review eligibility to qualifying Canadian producers, including Abbreviated New Drug Submissions (ANDS), and Supplemental Abbreviated New Drug Submissions (SANDS). This approach could be implemented immediately through amendments to guidance documents and would not require regulatory amendments.

CPMEA recommends the following amendments, as noted in italics, to the **Health Canada Priority Review Guidance**:

This policy applies to a New Drug Submission (NDS), *Abbreviated New Drug Submission (ANDS)*, Supplemental New Drug Submission (S/NDS) or *Supplemental Abbreviated New Drug Submission (SANDS)*

- I. for a serious, life-threatening or severely debilitating disease or condition for which there is substantial evidence of clinical effectiveness that the drug provides:
 - effective treatment, prevention or diagnosis of a disease or condition for which no drug is presently marketed in Canada; or
 - a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.

II. *is submitted by a “Canadian producer”*

Definition of a “Canadian Producer”

A clear and practical definition of "Canadian Producer" is essential to facilitate the implementation of the Pilot Program. The proposed Pilot Program defines “generic drug submissions involving domestic manufacturing” as the criteria for inclusion in the Pilot Program.

We recommend the qualification for the program be determined based on location of the manufacturer. This approach would:

- Reward companies that invest in manufacturing facilities, employment, capital investments, and pay taxes in Canada
- Build a sustainable regulatory environment in Canada to encourage capacity expansion by domestic producers
- Encourage the use of Canadian contract manufacturers by foreign companies to produce their generic medicines in Canada
- Allow for pre-qualification of companies to speed up access to the program.

We understand that Health Canada and ISED are investigating this issue together. We encourage a thorough examination of our proposal. One potential approach would be for ISED to determine per-qualification based on defined domestic manufacturing criteria.

Other parts of the federal government are also grappling with the definition of a ‘Canadian supplier’ for the purposes of procurement. CPMEA has recommended this definition to other departments.

CPMEA recommends a ‘Canadian Producer’ be defined as a manufacturer that:

- Generates at least 30 percent of its gross pharmaceutical revenue and/or volume in Canada from products manufactured in Canada;
- Undertakes substantial transformation of the finished pharmaceutical product in Canada; and
- Does not include products that are merely packaged or relabeled in Canada.
- Creates a clear, objective, and administratively workable threshold.
- This threshold includes all current Canadian producers and would encourage the use of Canadian Contract Manufacturers for companies that do not have facilities in Canada in order to achieve the 30% threshold.

Officials at Health Canada have suggested that drug products manufactured in Canadian facilities would be eligible for the Priority Review pathway. The members of CPMEA also support this criterion for eligibility. In other words, **products eligible for the program would be those manufactured by a “Canadian producer” and/or manufactured in Canada.**

Number of Canadian Domestic Producers

According to this definition, we estimate there are seven domestic producers of generic medicines in Canada that would be eligible for this program:

- Apotex
- Pharmascience
- Teva
- Riva
- Juno/Omega
- Taro
- Delpharm for Sandoz

In 2025, according to Health Canada data, these companies submitted approximately 50-60 ANDS which represents approximately 20% of the total received by HC. By prioritizing submissions from these producers, HC can easily manage its workflow to rapidly ‘pick up’ and process ANDS’s received from these companies.

There are also a significant number of Canadian CDMOs that sponsors could use to gain access to priority review, provided their products are manufactured domestically. This approach would ensure that the benefits of the policy are available not only to established Canadian manufacturers but also to sponsors that choose to invest in and utilize Canada's manufacturing ecosystem.

Dedicated Regulatory Project Manager for Priority Program

CPMEA recommends Health Canada establish a dedicated Regulatory Project Management function focused on Canadian producers and biomanufacturers.

A dedicated ‘Canada First’ Priority Pathway review team would enhance regulatory management and file stewardship. The team would be responsible for each submission from intake to final decision. This function would hold regular meetings with the sponsor and review team, at least monthly, to discuss progress and identify issues early.

- Improve communication throughout the review process
- Ensure submissions from Canadian generic producers are ‘picked up’ quickly
- Coordinate review activities across directorates
- Improve management of response timelines
- Enhance regulatory predictability and transparency
- Ensure the success of the program, measure performance, and provide recommendations for improvements.

What Does Success Look Like?

At CPMA, we cannot overstate how encouraged we are as the officials at Health Canada work to develop and implement the Priority Review program. We thank you for the time you have spent to understand the needs of the domestic industry and its role in *Building Canada Strong*.

This is what we think success would look like:

- A clear process to prioritize ANDS submissions from Canadian producers
- A new pathway dedicated to speeding up approvals of ANDS submissions from Canadian producers
- Approval timelines of 120 days
- Definition of a Canadian producer based on value or volume of domestic production by a company
- Prequalification of a “Canadian Producer” by ISED
- A dedicated manager/team to be a central point of contact between Health Canada and domestic producers responsible for the success of the program
- Greater alignment of the regulatory framework with the Government's economic and strategic priorities.

We are confident that a Priority Review Program for applications from Canadian producers will have positive long-term benefits for Canadian patients and Canada’s health care system. Health Canada and Canadian producers will be aligned to *Build Canada Strong* together. The volume of Canadian-made medicines will grow, and Canada will have control over our own supply chain for

essential medicines. Canadian patients will be the first to have access to new generics. Exports of medicines made by Canadian producers and approved by Health Canada - known worldwide for its quality assurance - would increase around the world.

Thank you so much for opportunity to contribute to the consultation. We are available at your convenience to discuss these proposals.

Sincerely,



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