

September 12, 2026

Health Canada Consultation on a Proposed Pilot Approach to Prioritize Certain Generic Drug Submissions Involving Domestic Manufacturing Within the Review Queue

Introduction

Thank you for the opportunity to contribute to Health Canada's consultation on a proposed pilot approach to prioritize certain generic drug submissions involving domestic manufacturing within the review queue.

The Canadian Ophthalmological Society (COS) is the national authority on eye and vision care in Canada, representing over 1,100 ophthalmologists and residents. We advocate for vision health for all Canadians and strive to support our members in providing excellent medical and surgical eye care. Reliable and timely access to medications is essential to preserving sight and preventing avoidable visual disability.

Health Canada proposes a targeted, time-limited pilot under which domestic manufacturing would be considered as an additional factor when sequencing eligible abbreviated new drug submissions (ANDS) and supplemental abbreviated new drug submissions (SANDS) for review, without changing the scientific standards, evidentiary requirements, performance targets, or regulatory decision-making.

The COS recognizes and supports the intent of the proposal to encourage domestic manufacturing. We thereby support the pilot in principle, provided it is carefully designed and transparently evaluated as part of a broader strategy for pharmaceutical supply resilience. The proposal may improve Canada's ability to prevent and respond to drug shortages by strengthening domestic manufacturing capacity. However, domestic manufacturing is only one component of a resilient pharmaceutical supply. The following additional factors and recommendations should also be considered in the design and evaluation of the pilot.

Additional Considerations and Recommendations

1. Maintain patient need and health-system benefit as central priorities

Health Canada's core mission is to help Canadians maintain and improve their health. As this innovative approach is considered, urgent health and safety needs should remain central to decision-making.

Additional priorities should include whether a medication:

- Addresses an existing or recurrent shortage;
- Has limited or no appropriate therapeutic alternatives;
- Introduces the first generic competitor; or
- Improves affordability or patient access;

These factors are particularly important when interruptions in access could delay essential care or result in preventable morbidity, including vision loss.

2. Consider resilience across the entire supply chain

Domestic manufacturing may strengthen Canada's pharmaceutical capacity. However, modern pharmaceutical supply chains are global, and products manufactured in Canada may depend on internationally sourced active pharmaceutical ingredients, packaging materials or specialized services. Health Canada should therefore consider factors beyond the location of final manufacturing, including the availability and diversity of critical suppliers, manufacturing sites, and alternative products.

Domestic manufacturing and diversified international sourcing are complementary approaches in pharmaceutical supply resilience.

3. Monitor for unintended effects on access to other important medicines

Monitoring should assess the effect of the pilot on both qualifying and non-qualifying submissions. A successful pilot would promote domestic manufacturing without materially delaying submissions for products that could provide greater clinical value, expand access to medications, increase competition, or generate significant savings for patients and drug plans.

Health Canada should retain the flexibility to prioritize clinically important products regardless of where they are manufactured, particularly when they address an existing shortage or an unmet patient need.

4. Measure actual product availability and supply stability

The full effects of the pilot may take time to become apparent. Its success should therefore be assessed using measures that extend beyond the timing of regulatory review, including:

- Time from submission to actual product availability;
- Consistency and continuity of supply;
- The frequency and duration of shortages; and
- The effects on competition, affordability, and patient access.

The most meaningful outcome is not simply whether a submission is reviewed earlier, but whether Canadians obtain more reliable access to the medications they need.

Conclusion

The COS supports Health Canada's objective of strengthening domestic pharmaceutical capacity and improving the reliability of Canada's medicine supply. This pilot may achieve that if domestic manufacturing is considered alongside clinical need, supply-chain diversification, and actual product availability.

Ultimately, the success of the pilot should be judged by whether it improves Canadians' reliable access to safe, effective, and affordable medications. The COS would welcome continued engagement and would be pleased to provide eye health-specific expertise regarding essential medications and the consequences of supply disruptions for Canadians.