March 14, 2026

Input Regarding Canada Gazette, Part I, Volume 159, Number 51: Order Providing for Reliance on Decisions of, or Documents Produced by, Foreign Regulatory Authorities in Respect of Certain Drugs

General Comments:

The Best Medicines Coalition (BMC), a national alliance of 32 patient organizations, welcomes the opportunity to provide input to the consultation outlined in the *Canada Gazette, Part I, Volume 159, Number 51: Order Providing for Reliance on Decisions of, or Documents Produced by, Foreign Regulatory Authorities in Respect of Certain Drugs.*

This submission was informed by current BMC position documents developed in consultation with BMC's member organizations. Statements and recommendations expressed here reflect areas of consensus among the member organizations listed here.

As its mission, the BMC seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and related treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. In its advocacy on related national issues, the BMC seeks policies and frameworks which recognize and embody patient-driven principles while valuing and investing in both incremental and breakthrough advancements in care. Related to this, the BMC seeks improved pathways to timely access to all medically necessary drugs and related treatments, and systems which are efficient, streamlined, transparent and accountable.

In its ongoing work, the BMC provides recommendations on selected issues within the context of policies, programs, legislation and regulations related to pharmaceutical care for patients in Canada, including regarding broad pharmaceutical care reform, pharmaceutical review, assessment and pricing, strategies to support patients with rare diseases and drug supply initiatives. ***To help us meet these ends, the Best Medicines Coalition would like to receive a briefing on Health Canada's consultations that have taken place between October 2025 to the current suite of consultations, including a high-level overview and a more strategic look at how the proposed changes impact each other, where relevant.***

The process for new drugs and related treatments to move through review, approval, assessment and decision-making processes is complex and lengthy. In many cases it takes an extended period for patients to be able to access the medications they need. This is a critical issue with implications for patient care and outcomes, sometimes with dire consequences, especially for those with unmet needs and life-threatening illnesses.

National leadership, with cooperation from all jurisdictions and at all levels, along with stakeholders, is necessary to streamline infrastructure, including review, assessment, negotiation and decision-making processes, reducing timelines at every step, including at Health Canada, the Patented Medicine Prices

Review Board (PMPRB), Canada's Drug Agency (CDA-AMC), the pan-Canadian Pharmaceutical Alliance (pCPA) and at drug programs.

All relevant departments, agencies and programs, both collaboratively and independently, must be mandated and resourced to take on and prioritize the important goal of improving timeliness. Redundancies and inefficiencies need to be addressed along with greateraccountability, transparency and parliamentary oversight.

Other than the submissions we provide to government agencies and formal meetings with Health Canada officials, which we value greatly, patients and patient groups do not have many meaningful and ongoing engagement opportunities with Health Canada. This is troubling considering that patients are the end users of the medicines, vaccines, and supplements that Health Canada approves. ***As Health Canada is considering relying on foreign regulators like the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and other agencies, it must also consider the patient engagement models that foreign regulators employ and incorporate similar engagement opportunities for patients and patient groups in Canada. To not do so not only undervalues the robust patient engagement models that our comparator countries have implemented, it undervalues patients that live in Canada. Patients and patient groups in Canada must be involved in the process of building engagement models.***

We appreciate the resource constraints of Health Canada, but respectfully note that the mandate of Health Canada is "to help Canadians maintain and improve their health." This means any changes to regulations due to resource constraints must not oppose the mandate of maintaining and improving the health of Canadians. ***Therefore, we ask for more details about how the proposed changes will bolster and improve health, not merely result in conditions that are not worse than the current state.***

Comments on executive summary:

The Best Medicines Coalition appreciates the efforts Health Canada has made in recent years to reduce gaps in market access to drugs. We agree that, while these initiatives have contributed to narrowing the access gap, there is still more to be done, some of which is outlined in this submission.

It is important to note that there is no indication of what Health Canada will do with the money saved from having fewer reviews. Health Canada should be accountable and transparent about what these savings are and how they will be spent. Patients and patient groups should have input into how these savings should be allocated.

Comments on issues section:

Health Canada notes that, despite having globally recognized alignment and competitive review times, stakeholders have recently raised concerns about the time it takes to get a product to market in Canada. This is incorrect. Patient groups, including the Best Medicines Coalition, have been raising concerns about the time it takes to get a product to market in Canada for more than a decade and, in some instances, even longer.

We agree that a regulatory approach that modifies the manner in which the Minister may examine a new drug submission by leveraging international collaboration and reliance, could allow Health Canada to refocus resources, as needed, as one way of further supporting the health and safety of Canadians, and the public interest. In addition, this approach could help narrow the gap in product availability, and

could contribute to earlier availability of products and re-aligning processes to reflect patient evidence and needs in the Canadian market. Furthermore, such an approach would provide the Minister with an additional and effective tool for the efficient review and authorization of submissions without compromising the safety, efficacy and quality of new drugs on the Canadian market.

We recognize these gains are valuable to patients who seek more timely access to treatments and urge Health Canada to bolster patient safety in the process. This could include clearly stating the risks Health Canada anticipates, how they plan to address these risks, and providing clear details about the reference countries Health Canada plans to use.

Comments on objectives section:

The Best Medicines Coalition supports initiatives that reduce the red tape that causes delays in drug access, including the alignment and reduction of trade barriers, such as different regulatory requirements, to achieve more timely access to drug products in Canada. At the same time, we urge Health Canada to fulfill their mandate of improving the health of Canadians as a higher priority than reducing red tape. Therefore, changes to the Order should concern unnecessary and avoidable delays rather than swiftness alone.

We share Health Canada's belief that further international collaboration is needed to determine how to best uphold the safety, efficacy, and quality of treatments. Our hope is this international collaboration will achieve these goals while also facilitating faster patient access to therapies. We support the Order's objectives to:

1. Further support the health and safety of Canadians by leveraging international partnerships to generate greater efficiencies in Health Canada reviews of submissions for drugs in Canada.
2. Reduce the delay in filing for submission for drugs in Canada.
3. Continue to strengthen and expand the use of information and decisions from foreign regulator authorities (FDR) with the longer-term goal of increased collaboration in decision-making.
4. Enable Health Canada to refocus resources as needed, as one way to support the health and safety of Canadians.

We appreciate that the Order could help encourage earlier availability of drugs to the Canadian market by facilitating more efficient reviews of drug submissions. However, Health Canada is just one body among many that influence drug availability in Canada and its efforts must be met with other efforts to reduce drug access wait times across drug access systems.

Comments on description section:

The Best Medicines Coalition appreciates the clarity provided, which notes that nothing in the Order limits the Minister's ability to consider information, documents or other material obtained from FRAs in the context of the review of drug submissions outside the deeming process. This will help to ensure that the Minister has a full picture of the information and deliberations that inform foreign regulator decisions.

Comments on scope section:

The Best Medicines Coalition does not agree with the rationale provided to not seek fuller application of the Order at this time. The Order, as proposed, will not be extended to extraordinary use to new drug submissions nor their supplements, to emergency/alternative pathways (e.g. Special Access Program or public health emergency drugs), and in other circumstances. The scope section does not include scenarios in which FRAs have approved these drugs under similar circumstances.

It is noted that the *List of Classes of Drugs and Foreign Regulatory Authorities for the Purposes of Reliance on Decisions or Documents* (IbR List) would set out the classes of drugs and FRAs that would be within the scope of the Order, which would apply for flexibility and allows updates to be made as needed, while also considering health and safety risks in managing the list. It is further noted that the decision to add an FRA to this list would take several factors into account and that the Minister would only add a drug or FRA to the IbR list under this Order where the addition is necessary for a health or safety purpose or is otherwise in the public interest and whether it is unlikely to result in unacceptable risks or uncertainties to health, safety or the environment. The Order will only apply to certain types of submissions, such as new drug submissions.

In adopting this Order, Health Canada must remember its key objectives: to maintain and improve the health of Canadians. This means Health Canada must carefully consider how they are mitigating safety risks that arise from gaps in evidence, or misaligned international reviews when this Order is implemented.

If Health Canada does move ahead with the ibR,the Best Medicines Coalition supports Health Canada's commitment to consult on any proposed changes to the IbR list and to publish updates on the Government of Canada's website. No lists should be finalized and/or published without patient and patient group engagement.

Additionally, there must be assurances that transparency and safety standards will not be compromised as measures to harmonize internationally and increase reliance on comparator countries are adopted.

Finally, international cooperation and reliance must be coupled with efforts to implement processes and systems to ensure that Canada is a preferred site for clinical trials. This could include streamlining ethics reviews and other measures to address barriers.

Comments on regulatory development section:

No comments.

Comments on regulatory analysis section:

The Best Medicines Coalition appreciates the care and attention taken to develop the proposed regulatory scenario, through which manufacturers could choose to use an approach that would allow the Minister's examination of certain components of a submission to have been deemed complete based on a decision or documents produced by a listed FRA. We agree that the use of deeming could potentially improve drug availability and allow Health Canada to refocus its resources, as needed, to further support the health and safety of Canadians.

The Best Medicines Coalition agrees that strategic use of the Order could provide timely access to drugs not currently available in Canada, once they become authorized. The Order, if used wisely, could also expedite expanded indications that include pediatric conditions of use that are not currently authorized in Canada and/or drugs where a child-friendly format is not authorized in Canada that include pediatric conditions of use. If used strategically, the Order could also expedite access for

vulnerable populations like pregnant and lactating mothers, as well as access for older adults. These measures could most certainly benefit Canadians.

However, it remains to be seen if the Order will actually result in greater efficiency in reviewing drugs that address unmet medical needs and are not currently available in Canada. If only applied in limited circumstances, the Order will not improve drug review efficiency significantly, nor will the anticipated benefits reach most Canadians in marked and meaningful ways. According to Canada's Drug Agency, in 2024 155 drugs were submitted to Health Canada for regulatory approval, 10% more than the average of the previous four years. Given that Health Canada expects a minimum of 19 submissions annually will use the Reliance Order, the overall impact of the Order on expediting access to medicines may be negligible. Health Canada's commitment to the proposed Order starting with limited classes of drugs and FRAs on the IbR list with the intent to expand in the future will be key in ensuring the benefits of the Order reach as many patients in Canada as possible. This must be achieved as quickly as possible.

Canada's health technology assessment bodies must be ready to address any evidence gaps that relying on FRAs may result in. It is noted that these bodies may encounter difficulties conducting evaluations if information provided in Health Canada summaries of decisions, or similar documents, is not available as the result of the deeming process. Health Canada must work with CDA-AMC and INESSS to ensure that the Order does not compromise the efficiencies and effectiveness that Canada's HTA bodies have implemented in their review processes.

Health Canada must also work with CDA and INESSS to find a way to clearly (in plain language) let clinicians and patient groups know when they are responding to an open call on a reimbursement review for a drug that has been, or will be, wholly or in part, receiving it's NoC based on decisions or documents from FRAs. In addition, it should be included in the fine print of any drug approved for use by patients in Canada that foreign decisions or documents were used in the evaluation where Canadian data was insufficient.

Comments on implementation, compliance and enforcement section:

While the Best Medicines Coalition appreciates the need to start small and gain more experience with the Order before expanding its reach, Health Canada must work diligently and quickly to grow the IbR list to include new classes of drugs if it plans to really move the dial on expedited patient access to medicines. Canada is well-behind its international comparators when it comes to reliance on FRAs. As a result, too many patients in Canada have waited too long to access the treatments they need. Some have not been able to access the treatments they need at all. The Reliance Order could be the change these patients need to get medicines faster, but only if it can be used as a tool to assess the classes of drugs they need to access now and in the future.

Final thoughts:

The Best Medicines Coalition appreciates the opportunity to provide feedback into the consultation outlined in ***Canada Gazette, Part I, Volume 159, Number 51: Order Providing for Reliance on Decisions of, or Documents Produced by, Foreign Regulatory Authorities in Respect of Certain Drugs.***

In addition to the recommendations above, we call on Health Canada to provide clarity on:

- How foreign regulators will be selected and used: Will the selected foreign regulators be a standard list that is used for all drugs being considered, or will different countries be consulted

for different drug classes? For example, if there are five countries on the list, will all five be used in reviewing oncology drugs?
- Whether the same list of foreign regulators will be used for pediatric and adult populations.

Overall, the Reliance Order could benefit from providing greater clarity on what is being proposed.

The Best Medicines Coalition looks forward to working with Health Canada to ensure the benefits of this Order reaches the most patients in Canada as possible.

BEST MEDICINES COALITION
COALITION POUR DE MEILLEURS MÉDICAMENTS

About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of 32 patient organizations. The BMC seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and related treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. The BMC's areas of interest include drug approval, assessment, and reimbursement, as well as patient safety and supply issues. As an important aspect of its work, the BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care. The BMC's core activities include issue education, consensus-based position development, and advocacy, making certain that patient-driven positions are communicated to decision makers and other stakeholders. The BMC was formed in 2002 as a grassroots alliance of patient advocates. In 2012, the BMC was registered under the federal Not-for-profit Corporations Act and operates under the direction of a Board of Directors composed of representatives of member organizations and elected annually.

Asthma Canada
Brain Tumour Foundation of Canada
Canadian Arthritis Patient Alliance
Canadian Breast Cancer Network
Canadian Cancer Survivor Network
Canadian Council of the Blind
Canadian Cystic Fibrosis Treatment Society
Canadian Epilepsy Alliance
Canadian Hemophilia Society
Canadian PKU & Allied Disorders
Canadian Skin Patient Alliance
Canadian Spondyloarthritis Association
CanCertainty
Crohn's and Colitis Canada
Cystic Fibrosis Canada
Eczema Society of Canada
Family Alliance on Severe Mental Illnesses
Fighting Blindness Canada
Health Coalition of Alberta
Huntington Society of Canada
Kidney Cancer Canada
Lung Health Foundation
Lymphoma Canada
Medicines Access Coalition – BC
Migraine Canada
Millions Missing Canada
Mood Disorders Society of Canada
Ovarian Cancer Canada
Parkinson Canada
Platelet Disorder Support Association
Psoriasis Canada
the cancer collaborative