

February 20, 2026

**Re: Health Canada Consultation on the Removal of the Reconsideration Process for Priority Review and Advance Consideration for Notice of Compliance with Conditions (NOC/c)**

To whom it may concern,

Thank you for the opportunity to provide input on Health Canada's proposal to eliminate reconsideration pathways for Notices of Compliance with Conditions (NOC/c).

This consultation addresses the proposed removal of the reconsideration process for both Priority Review requests and Advance Consideration requests under the NOC/c policy. These decisions function as early gatekeeping mechanisms that shape review timelines, evidence pathways, and ultimately the timeliness of patient access. As such, changes to reconsideration processes have implications not only for sponsors, but also for patients whose conditions may be assessed early in the regulatory process as not meeting thresholds of seriousness, unmet need, or acceptability of uncertainty.

Priority Review and Advance Consideration mechanisms are critically important for people living with serious, chronic, and debilitating conditions such as arthritis. Nearly six million Canadians live with arthritis, a group of diseases that can cause persistent pain, fatigue, functional limitation, and progressive disability. The impacts of arthritis extend far beyond physical symptoms, affecting daily activities, employment, caregiving responsibilities, mental health, and the ability to participate fully in community and social life. Despite this substantial burden, arthritis is often not recognized as meeting the criteria, leaving many patients facing prolonged delays in access to therapies that could meaningfully alter disease progression and quality of life.

Decisions related to Priority Review and Advance Consideration therefore have a particularly high impact for these communities.

*The Canadian Arthritis Patient Alliance is a grassroots, patient driven, independent, national organization with members across Canada and supporters in Canada and beyond. We believe the first expert on arthritis is the individual who lives with the condition and help them to speak up for themselves. The organization is a small virtual organization and powered by volunteers who all live with various forms of arthritis.*

*Redesigning the process, not just eliminating steps*

Patient communities are often informed of Priority Review and Advance Consideration determinations only after decisions have been finalized, rather than being meaningfully engaged early in the process. This limits opportunities for patients to convey the real-world consequences of delayed access and undermines confidence that lived experience has been adequately considered.

We recognize Health Canada's rationale for proposing the removal of reconsideration processes, including the goal of improving regulatory efficiency and the observation that reconsideration requests have been infrequent or rarely resulted in changed decisions. However, limited use of reconsideration does not diminish its importance as a procedural safeguard in cases where early assessments may not fully capture disease burden, cumulative disability, or lived experience.

If Health Canada proceeds with eliminating reconsideration processes for Priority Review and Advance Consideration for NOC/c, it is essential that the work currently addressed through reconsideration be redesigned and moved earlier in the regulatory process. Early and structured engagement with interest holders — particularly patient groups — must be embedded within decision-making. People living with arthritis are uniquely positioned to articulate disease burden, cumulative disability, and the long-term consequences of delayed or inadequate treatment. Their needs are central to the intent of Priority Review, yet their perspectives are too often underrepresented or insufficiently weighted in regulatory decisions.

In the absence of reconsideration, early patient engagement becomes the primary opportunity to ensure that patient perspectives on disease severity, unmet need, and real-world impact are accurately reflected before decisions are finalized.

*Need for guidance on patient engagement*

Second, Health Canada should develop and publish clear guidance outlining how meaningful early engagement with patient communities will occur. This guidance should specify when engagement will take place, how patient input will be considered alongside clinical and regulatory evidence, and how decisions will be communicated. Clear and transparent expectations would promote more consistent, equitable, and trusted decision-making, while enabling patient organizations to participate effectively and responsibly.

In summary, removing reconsideration processes for Priority Review and Advance Consideration for NOC/c without a corresponding redesign that centres early patient engagement risks

disproportionately disadvantaging people living with serious, chronic conditions such as arthritis. We urge Health Canada to ensure that any regulatory changes reflect the scale, complexity, and lifelong impacts of arthritis, and that they strengthen — rather than weaken — pathways to timely and appropriate access.

Thank you for considering these comments. We appreciate the opportunity to contribute to this important consultation.

Sincerely,

*Virtually signed by*

Laurie Proulx  
Managing Director