Canadian Organization for Rare Disorders (CORD)

Submission to: Prioritize rare-disease therapies within the Ministerial Reliance framework

We strongly support Health Canada's move toward greater regulatory reliance and international alignment. We believe the potential public-health benefit is particularly significant for Canadians living with rare and ultra-rare diseases, where small patient populations, limited clinical evidence and the relatively small Canadian market can contribute to delayed or absent Canadian submissions. [1]

We recommend that Health Canada explicitly identify **drugs for rare and ultra-rare diseases as a priority class for expansion of the Ministerial Reliance Order and the Incorporated by Reference List**, rather than relying primarily on individual therapeutic or ATC classifications.

Specifically, we ask Health Canada to:

1. **Establish a dedicated reliance pathway for rare-disease drugs**, including orphan drugs and advanced therapies such as gene, cell and RNA-based therapies.
2. **Permit broad reliance on assessments from trusted regulators**, particularly the FDA and EMA and, where appropriate, MHRA, TGA, Swissmedic and other regulators that Health Canada determines have comparable scientific and regulatory standards.
3. **Extend the 120-day filing and general-deeming mechanisms to rare-disease therapies**, encouraging sponsors to submit to Canada at approximately the same time as they submit to major international regulators rather than waiting for a completed foreign authorization.
4. **Allow reliance on the totality of international regulatory information**, including scientific review reports, regulatory correspondence, conditional or accelerated approvals, post-market commitments and relevant real-world evidence, while retaining Health Canada's authority to address genuinely Canadian-specific considerations.
5. **Apply proportionate flexibility to differences between Canadian and foreign submissions.** Minor differences in labelling, indication wording, risk-management plans or other jurisdiction-specific requirements should not unnecessarily prevent

[1] https://www.canada.ca/en/health-canada/programs/consultation-draft-guidance-ministerial-reliance-order-certain-human-veterinary-drugs/notice.html

reliance where the underlying product, evidence and patient population are substantially the same.

6. **Align international regulatory reliance with accelerated and conditional Canadian pathways and with HTA processes**, so that efficiencies achieved at the regulatory stage translate into earlier patient access rather than simply shifting delays downstream.

7. **Measure and publicly report the impact of reliance on rare-disease access**, including time from first major international submission and authorization to Canadian filing and authorization, use of the reliance pathway, and the number of therapies that reach Canada that might otherwise not have been submitted.

For rare diseases, regulatory reliance should be regarded not simply as a mechanism for reducing administrative duplication but as an **access strategy**. Canada represents a relatively small market, and Canadians with rare diseases should not have to wait years for a therapy already rigorously assessed by a trusted regulatory partner.

We therefore encourage Health Canada to make rare and ultra-rare disease therapies an explicit priority in the next expansion of the Incorporated by Reference List and to establish a clear, predictable pathway through which international regulatory decisions and evidence can be used to support timely Canadian authorization while preserving Health Canada's responsibility for the final Canadian benefit-risk decision.

Respectfully submitted:

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