April 8, 2026

Response to CDA-AMC's Draft Guidance for Incorporating Impacts on Informal Caregivers and Productivity Outcomes in Economic Evaluations

Innovative Medicines Canada & BIOTECanada are the primary associations representing the innovative medicines industry in Canada. We thank the CDA-AMC for the opportunity to provide feedback on the current consultation on their guidance for incorporating impacts on informal caregivers and productivity outcomes in economic evaluations.

The current set of unprecedented policy directives emerging worldwide, namely the May 2025 U.S. Executive Order on Most-Favored Nation and related policies, carry significant implications for Canada's access to new medicines. All interested parties within the life sciences ecosystem must be engaged in policy responses to mitigate risk and maintain Canada's access to innovative treatments. IMC and BIOTECanada would like to emphasize the importance of discussing system-level challenges and the ways in which the CDA-AMC can improve Canadians' access to innovative medicines in this context.

There's an opportunity for HTA in Canada to evolve its clinical and economic methodologies to better capture the full value of innovation, enabling more balanced clinical value and pricing discussions and more timely patient access. While there is a need to better incorporate quality of life and productivity measures into health technology assessment (HTA), it is unclear if the proposed changes will ultimately improve Canada's overall recognition of pharmaceutical value. As such, we recommend an overarching review of the use of HTA tools within the Canadian system.

As noted in our previous responses to CDA-AMC consultations, **we propose that the CDA-AMC establish a working group with the innovative industry** to find ways to adapt CDA's HTA processes and methods to optimize patient access and respond to broader global pharmaceutical shifts including a broadening of the measures of HTA value.

We appreciate CDA-AMC's efforts towards ongoing evolution of methods through providing guidance on frequently used elements within the societal perspective for economic evaluations. We would encourage the CDA-AMC to provide sponsors with the option to incorporate the societal perspective for all types of reviews.

The innovative medicines industry requests that CDA-AMC consider the following perspectives:

Earlier Engagement

Due to the importance of the given elements within this guidance document, the innovative industry recommends the CDA-AMC consider the additional feedback in the Appendix to ensure the guidance provided is implemented effectively. This additional input demonstrates that the

breadth of content requires careful consideration of the implications for implementation. We would welcome an opportunity to meet with the CDA-AMC in advance of final guidance development to clarify key aspects of the guidance and allow for a robust exchange of perspectives.

Flexibility needed

The innovate medicines industry welcomes the CDA-AMC's efforts to incorporate additional elements within the economic evaluations. However, flexibility is needed, for example, with respect to having to produce Canadian data. Information to populate economic evaluations can, in some instances, be Canadian but alternate generalizability sources may be appropriate and required. As disease-specific health utility values may be difficult to obtain, those for caregivers will likely be more challenging as this data has not been historically collected. The current draft sets evidentiary requirements that may be impossible to attain in many cases. We would welcome the opportunity to discuss alternative solutions with respect to model inputs and requirements where data recommended in the guidance is not available. Caregiver burden is a critical and important consideration for HTA assessments and needs to be evaluated quantitively using best available information, **as well as qualitatively** in a context that is broader than economic evaluations.

Considerations for use in Decision Making

The innovative medicines industry highlights our recent submission to the Health Economics Methods Advisory Group's Draft Report on defining appropriate benefits for economic evaluation of health care technologies. We reiterate the importance of including broader economic and societal impacts, such as productivity improvements, reduced caregiver burden and decreased reliance on, and impacts to, expensive institutional care and other publicly funded areas of the healthcare system, to enable access to innovations designed to enhance workforce participation or enable treatment in a community setting. Many new innovative therapies improve patient quality of life by reducing toxicity, travel time, and hospitalization costs, and improve ability to work and workplace productivity thereby also improving economic resilience.

The current guidance focuses on what sponsors need to produce, but it misses the equally important other side of the equation which pertains to how such evidence will be evaluated. As such, additional clarity is requested on how these factors:

- Will be used by the expert review committees for their deliberations and decision making;
- Will intersect with the patient and clinician input process at CDA-AMC;
- Specifically, will inform the pharmacoeconomic model, report reviews and subsequent recommendation

From a deliberation and decision-making transparency perspective, expert review committees should have clear and explicit guidance for how they are to consider and weigh caregiver burden data and evidence. Caregiver burden evidence should be published in product clinical evidence review, health economic and recommendation documents.

Finally, we encourage the CDA-AMC to evaluate the implementation of these methods in a pre-defined time and to publish findings accordingly. This could include a review of recommendation reports for files that considered caregiver burden data, summarizing the evidence that was submitted, and appraising how the evidence was considered by the expert review committees and informed final CDA-AMC recommendation reports. Thank you for reviewing this input. We appreciate the opportunity to comment on the Guidance and welcome further discussion on any of the points delivered in this response.

Appendix:

Comments on data availability:

- It is unclear within the draft guidance document what alternative sources of information should be used and how the CDA-AMC would proceed when disease specific health utilities are unavailable or difficult to obtain for affected patients. These will also likely be challenging to obtain for caregivers as well.
- The guidelines emphasize primary clinical trial data collection and Canada-specific data. While ideal, this is often not feasible. The guidance should provide more explicit support for the use of high-quality secondary data and literature-based estimations in cases where trial-based collection is not possible.
- Although real-world evidence (RWE) is also mentioned as a source, there are challenges with robustness of patient instruments used in clinical trials and CDA-AMC citing "uncertainty" from those results, so anticipate this would be even more challenging with caregiver information from both trials as well as RWE.

Comments on submission requirements:

- Expectation for inclusion, scope and detail of an impact inventory is unclear; does it need to be included in all submissions that include an economic analysis from the societal perspective, regardless of whether caregiver health related quality of life (HRQoL) and/or patient/caregiver productivity impacts are integrated in this analysis? Scope of impact inventory template goes well beyond scope of this guidance; it is unclear whether all rows need to be completed, if so, we recommend that CDA-AMC accept fit-for-purpose detail in the "notes" column (e.g., "parameter not anticipated to have a meaningful impact", "robust evidence not available").
- Formal caregiving is not a focus in this document as the CDA-AMC assumes that paid caregiving costs are addressed through existing guidance. We believe that excluding it in this document could lead to an incomplete picture of the total care burden. We recommend that the CDA-AMC include a brief section on formal caregiving and the preferred approach for the Canadian HTA context, including how to address jurisdictional differences in supportive care delivery across the country.

Comments on methodology:

- The friction cost (FC) method may misrepresent or significantly undervalue the long-term gains to the patient and society. In addition, the evidence for parameterisation of the FC approach (i.e. friction period, multiplier effect) requires further research to establish empirically relevant data. The human capital (HC) approach for patient and caregiver productivity focuses on the employee's lost work capacity rather than the employer's short-term replacement costs and includes all values of potential lost production. There is no global alignment or consensus on whether the HC or FC is better. In some cases, both may be relevant, or even in combination. We recommend that sponsors have flexibility in choosing a method based on available data.

- Patient and caregiver impacts should be captured among distinct social and ethical considerations in the CDA-AMC's patient group input templates and review reports, discussed during the expert committee deliberation, and addressed in the recommendations, in line with the CDA-AMC's deliberative framework.
- Ideally, societal perspective is more broadly and permanently recognized in the reference case (with this "impacts on informal caregivers and productivity outcomes" as one part of broadening) so that it can be transparently and consistently used in decision-making.
- The guidance focuses on caregiver burden associated with new interventions; however, it is equally important to consider the counterfactual (i.e., caregiver burden without treatment). In some cases, not treating may result in greater caregiver burden, which should be explicitly considered. Additionally, the document should recognize that a societal perspective can incorporate broader societal consequences.
- The recommended use of the friction cost approach (3-month period) may underestimate productivity impacts, particularly in chronic or severe conditions where replacement is not immediate or possible. Greater flexibility in methodological approach, or clearer justification for this preference, would strengthen the guidance.
- The assumption of equal weighting between patient and caregiver QALYs may not reflect societal or decision-maker preferences and lacks a clear empirical basis. This assumption could materially impact results. Further justification or flexibility (e.g., scenario analyses with alternative weights) would be appropriate given this uncertainty.
- While the guidance acknowledges challenges related to multiple caregivers, further direction is needed. Without clear methodological guidance, there is a risk of inconsistent application or unintended bias (e.g., overestimating value in conditions with larger caregiver networks). It may not be appropriate to assign equal weight in all cases, for example, if a caregiver is a parent, or if multiple caregiving parents are affected, or if a child or other relative must receive treatment in another community and there are other children in the family. This is an example of the potential for additional societal complexity. We also recommend that CDA-AMC provide guidance on what constitutes sufficient disease specific evidence for multiple caregivers. CDA-AMC should strongly consider that patient input is acceptable evidence to inform this.
- Not all caregiving situations will be the same, so further thought may be required to consider both an average caregiving situation as well as a reasonable range, which may also depend on the severity of the patient's condition and any treatments they are receiving. Scenario analyses should be performed to allow for variation.
- While interactions (lines 423-427) between caregivers and patients HRQoL may have an impact upon each other, it should be acknowledged that these impacts from clinical trials and in the real world may differ and analyses should best account for variability within the intended population.
- Methods for valuation of productivity outcomes are discussed, as how they can be included as scenario analyses, in lines 548-615. In some circumstances and depending on the direction of

the CDA-AMC societal perspective pilot, inclusion of these outcomes may be appropriate in base case analyses.

- Beyond wage replacement other valuation of the societal value for productivity does not appear to be considered – i.e., tax implications, disability insurance, absenteeism. Although "opportunity cost to health systems" (line 571) is mentioned, no methodological guidance appears to be provided.
- Furthermore, CDA-AMC should provide guidance on what evidence for bereavement long-term effects for caregivers would be considered acceptable. While the EQ-5D is a standard for patients, its appropriateness as a sole measure for caregivers is debatable. Caregiving impacts often extend beyond "health-related" quality of life into broader well-being, which may not be captured sufficiently by the EQ-5D. We suggest the guidance allow for broader validated instruments (e.g., those capturing social care impacts) or secondary data, without labeling them as "experimental".

Comments on reporting and impact

- There is a lack of consistency regarding why caregiver HRQoL impacts can be aggregated into the ICER while productivity outcomes are reported separately (relegated to scenario analyses only and outside of the ICER value). We recommend that for transparency and consistency, both should be eligible for inclusion in the primary analysis and ICER result when supported by robust data.