Health Technology Assessment in Canada:
Improving the System and Ensuring the Patient Voice is Heard

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General Health Technology Assessment (HTA) Issues:

- Patient organizations have expressed strong concerns and growing frustrations that challenge the efficiency and effectiveness of various Health Technology Assessment (HTA) bodies, such as the Canadian Agency for Drugs and Technologies in Health (CADTH) and provincial HTA entities. Concerns identified focus on low quality of reviews, duplication in functions, and the resources allocated to these reviews, especially since there are many layers and networks already in place and there is talk of others being under consideration.

- Patient representatives lack avenues to meaningfully consult on substantive issues such as the mandate, structure, or processes of HTA bodies, related to what they are tasked to do and how they do it. There has been a lack of engagement of patients and other stakeholders regarding broad policy direction prior to specific consultations.

- Patients and patient organizations have expressed the lack of respect and perceived worthiness of their input, which officials in lead roles within HTA have expressed. There is a seemingly diminishment of the importance of patient engagement in these areas: Drug Shortages Working Group, the Drug Safety and Effectiveness Network, the Pan-Canadian Purchasing Alliance, and Health Canada itself with the disbanding of the Office of Consumer and Patient Involvement.

Evidence and Review Methodology:

- Current HTA reviews fall short because data and analysis on patient experience and quality of life are not required as part of the clinical trial evidence submitted by manufacturers. Therefore, recommendations and decisions often do not reflect patient experiences and true patient needs.

- There is a lack of emphasis on the preventative role of health technologies and the related cost savings to health systems. Focusing on cost effectiveness as it relates only to cost containment versus cost savings has resulted in short sightedness in current HTA approaches and decisions. These decisions are unfavourable for patients.

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- The scope and mandate of public representatives on HTA bodies needs to be reviewed, clarified, and addressed to ensure that they are able to fully and meaningfully participate in deliberations. Their role must include accessing external experiences and be reflective of the evolution of patient engagement and principles of patient-centred care.

Patient Input Challenges:

Patient Experience: Although some patient groups have developed expertise, many patient group representatives express general uncertainty and lack of clarity with the submission processes, which diminishes their confidence in their own ability to prepare submissions that will meaningfully affect the HTA process and outcomes.

- While review bodies state they seek the "true" patient voice, there is limited understanding of what this actually means, what constitutes an effective articulation of the patient voice, and whether patients have had an adequate role in defining this. Related to this, restrictions on subject matter to be included in patient input submissions limit patients in their ability to address any relevant issue.

- The preparation of patient submissions is sometimes challenging in terms of collecting, assembling, and submitting patient input, straining limited staff or volunteer resources. Further, the new requirement for patient groups to review a "Patient Input Summary" within five business days puts an additional burden on resources, especially with these timelines. Given the limited length of the patient evidence submission, a review summary written by a third party is not truly necessary and it burdens the entire review process by adding an additional review layer. As well, when in summary form, the interpretations of the third party reviewer do not always reflect the patient group submitter's intention, and therefore, this process opens the door for further misrepresentation of the patient's experience and voice.

- Although difficult to quantify, there is a strong perception that input from patient organizations has significantly reduced value to these HTA bodies. Decisions made that are unfavourable for patients, with no explanation provided, despite strong patient evidence in favour, serve to reinforce these perceptions.

- Patient organizations have expressed frustrations regarding required conflict of interest declarations, including ambiguity as to how each HTA body will use this information. There are observations that HTA bodies label patient groups inappropriately as *interest groups*, a term that is derogatory and not reflective of the true patients' role within the health care system.

System Accountability: The current process is marred by uncertainty, and in some cases skepticism, regarding how HTA bodies analyze and incorporate patient input submissions into HTA reviews. The lack of formalized feedback mechanisms from HTA bodies on how they receive, consider, and use patient submissions exacerbates the situation. In addition, the HTA process in Canada lacks indicators to measure and report on its performance, and therefore, is not sufficiently transparent and accountable.

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Possible recommendations:

- ***Vision.*** Canada needs to move beyond the current system to develop a vision for the future regarding drug review and reimbursement. Together, patients and other stakeholders within and external to the health care system need to assess what patients will need ten years from now.

- ***Patient Engagement***. Incorporation of the patient perspective must be a fundamental aspect of the establishment, review, and ongoing work of HTA agencies, including involving patients in discussions about mandates, scope, policies, and processes. HTA bodies must increase efforts to engage patients.

- ***Enhanced Patient Input.*** Patients seek credibility and recognition of their technical expertise and parity with other recognized experts and other forms of evidence. HTA bodies should allow patient representatives to appear in person before review committees to provide evidence, especially where there are concerns or issues that are not included within the scope of a HTA application/submission. In cases where there is no recognized organization in a disease area, then HTA bodies should allow individual patients to provide input.

- ***Training.*** Each HTA body should develop training sessions and guidebooks for patient groups, explaining processes and proper ways for preparing effective patient submissions. Generally, there is a need to educate patients/patient groups/patient advocates about where there are opportunities to provide input regarding reviews and reimbursement decisions.

- ***Resources.*** HTA bodies should provide patient groups with a funded resource to help them prepare quality patient evidence submissions.

- ***Advisory Bodies.*** HTA agencies need to provide greater acknowledgment of the value of the patient voice, perhaps through the establishment of a “patient council” as an instituted and legitimate arm of the agency, to facilitate increased patient recognition and influence in a meaningful way.