

March 19, 2025

**Patented Medicine Prices Review Board**

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Submitted electronically to: [PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca](mailto:PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca)Re: [Draft Guidelines for PMPRB Staff – Administrative Process for Excessive Price Hearing Recommendation](#)

Thank you for continuing to welcome input regarding PMPRB processes. The GI Society is a national charity formed in 2008 on the groundwork of its partner organization, the Canadian Society of Intestinal Research (CSIR), which was founded in Vancouver in 1976. We receive national and international attention, simply because we have earned the respect of both the gastrointestinal medical community and Canadians who battle GI and liver issues daily.

I was one of only three patient group representatives on the PMPRB steering committee back in 2018 during initial modernizing endeavors. Since the start of PMPRB's efforts to modernize the guidelines, we have always supported changing the basket of comparator countries. On March 14, I celebrated my 29<sup>th</sup> year of working for CSIR/ GI Society. Over these years, I've seen many changes in health policy and yet there is a dire need for more change.

We all know that the real public coverage price is way below the PMPRB maximum list price, and private payers also tend to pay way less than the PMPRB price. Several other players in the drug review process have come into effect since the inception of PMPRB in 1987 (e.g., the newly-renamed Canada's Drug Agency and its growing role in the health technology assessment ecosystem, pCPA, and new processes in public drug plans). These downstream processes can contribute to long delays and disparities across the country in public coverage, with patients paying the ultimate price with their health and, in some cases, their lives. Unfortunately, even in these Guidelines, deferral letters can lead to further delays in receiving necessary treatments, with medications being deferred multiple times (paragraph 74). While Health Canada's approval makes a medication technically available, public coverage remains a separate matter, and these delays create unnecessary barriers for patients seeking timely access to treatment.

However, I do acknowledge that these Draft Guidelines offer ways to increase efficiency in the review process, while considering the PMPRB's limited resources. The Guidelines also use much clearer language, especially in detailing the roles and responsibilities of Staff, Chairperson, and Board.

We also appreciate that Rights Holders have the opportunity to provide input on the Staff's Therapeutic Class Comparison (TCC) assessment. However, by including patient input, it will add significant value in this process, particularly in evaluating a medicine's comparability from a patient perspective. This includes input on the level of comparability, the selection of drug products for comparison, and dosage regimens, all of which the Guidelines state are crucial for the Staff's scientific team to consider.

Specifically, in paragraph 87, it is mentioned that "Staff may also, but is not obliged to, seek input from additional experts or specialists in exceptional cases if they feel additional input is necessary." This is a valuable opportunity for PMPRB Staff to seek feedback from patient groups. Expanding the range of sources PMPRB relies on is essential. In addition to clinical evaluations by HTAs, patient and clinician input should be included, as these perspectives offer a more complete understanding of the real-world impact of medications (paragraph 89).

**Medications are not just products.** For patients, they are the opportunity for a better quality of life, a longer life, or even a chance to save their life. I urge everyone involved in these processes to consider the real, human impact of these Guidelines. **The object of the exercise is the patient.** Let's make sure that we are putting the needs of patients first, not just in policy, but in action.

Yours sincerely,

Chief Executive Officer & Co-Founder, **Gastrointestinal Society**  
President, **Canadian Society of Intestinal Research**