Introduction

The Canadian Breast Cancer Network (CBCN) would like to thank the PMPRB for conducting consultations on the forthcoming Guidelines, and for considering our feedback on the scoping paper.

The Canadian Breast Cancer Network (CBCN) is a leading, patient-directed, national health charity committed to ensuring the best quality of care for all Canadians affected by breast cancer through the promotion of information, education, and advocacy activities. People in Canada living with breast cancer have an expectation that life saving cancer treatments should not be excessively priced when compared to international markets within the PMPRB11 because high costs creates uncertainty about whether drugs will be publicly reimbursed, and how long the reimbursement process will take.

The CBCN welcomes the opportunity to provide feedback for the PMPRB's scoping paper consultation, where we will discuss general comments on the forthcoming guidelines and general comments on theme 5, followed by specific recommendations on theme 6.

General comments

CBCN is encouraged by this consultation and would like to offer the following comments concerning the possible form and function of the guidelines, considerations for improved transparency, and the need for conflicts of interests policies.

As discussed in feedback for the Interim Guidance consultation[1], the disproportionate impact of excessively priced medicines on breast cancer patients creates significant uncertainty for patients so long as the interim guidance remains in effect. Therefore, it is imperative that guidelines which ensure adequate price reviews are developed as soon as possible, and do not compromise patient and stakeholder engagement. To achieve this balance, CBCN asks the PMPRB to consider a phased approach to implementing guidelines so that the price review uncertainties can end without further delay, stakeholder engagement can continue, and responsive guidelines can be implemented.

The roundtable on December 5th and 6th, 2023 demonstrated that many stakeholders are calling on the PMPRB for improved transparency, but how transparency was defined varied greatly. CBCN would like to echo this call for transparency which means making public both the information and rationale used to reach a decision so that those affected by policies can better engage with the decision-making process.

Part of this transparency includes improved conflicts of interest policies. CBCN invites the implementation of policies that mitigate real or perceived conflicts of interest both with the PMPRB and during stakeholder engagements as part of the PMPRB's work generally, and stakeholder engagement specifically. At a minimum, stakeholders must publicly disclose their financial conflicts, but this will need to be done in accordance with policies created by the PMPRB. An example of CADTH's conflict of interest policies can be found here as a reference.

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[1] https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/notice-comment-new-medicines/submissions/NC_Amend%20Interim%20guidelines%202023_%20submission_CBCN_EN.pdf

Theme 5

The relationship between the PMPRB and broader drug reimbursement processes are not well understood. As a result, CBCN asks for the following actions on the part of the PMPRB so patients, the public, and patient groups can better respond to question 5.1 and 5.2.

- Develop public resources that, at a minimum, meet the government of Canada's Plain language, accessibility, and inclusive communications which explain to the public how the PMPRB fits into broader government initiatives concerning drug pricing and make these resources available a minimum of 6 weeks prior to consultations on this theme.
- Conduct a consultation on this theme in 2024 that includes all stakeholders (rights holders, non-rights holders, CADTH, pCPA, and the public) to identify what efficiencies can be achieved through PMPRB collaboration with other federal departments, CADTH, pCPA, and private insurers.
- Host a minimum of 2 focus groups with stakeholders who are not rights holders in the year 2024 that generate publicly available "what we heard reports" concerning research or reports the PMPRB can generate that address knowledge gaps in the current pharmaceutical review landscape.

CBCN is confident that the PMPRB can use their position within a limited mandate to greatly impact the public's understanding of the drug pricing review systems both within Canada, and in the international context. This can be done by leveraging the PMPRB's resources to be an education partner with stakeholders and the public. To achieve this end state, the PMPRB can (1) develop resources about how the PMPRB interacts with other drug review bodies, (2) conduct further consultations on the topic of broader government alignment, and (3) host focus groups to identify themes for meaningful research and reports.

Theme 6

6.1: *What is your experience with innovative medicines and their list prices in Canada?*

CBCN routinely interacts with innovative medicines during reimbursement reviews, patient navigation, and advocating for equitable treatment access, all of which are immensely impacted by a drug's list price.

- CBCN contributes to CADTH patient submissions, funding algorithm reviews, and non-sponsored reviews. CADTH routinely cites significant reductions in price as a condition for reimbursement in oncology medicines under patent[2].
- CBCN provides individual patient navigation and advocacy, such as systems navigation or connecting patients with manufactures patient support programs while drugs undergo either the Health Canada or drug reimbursement process.
- CBCN advocates for equitable inclusion of breast cancer drugs on all provincial and territorial formularies. We engage government stakeholders through letter writing campaigns when a medicine is approved for public reimbursement in some provinces or territories but not others.

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[2] https://www.canada.ca/en/patented-medicine-prices-review/services/npduis/analytical-studies/posters/capt2022-alignment.html

6.2: *What role do the PMPRB Guidelines play in your decision-making process in Canada and globally (if applicable)?*

From a patient group perspective, the relationship between PMPRB guidelines and patient access to medicines is not well understood and presents a knowledge gap we hope to see addressed by the PMPRB. To address this gap, we would invite public resources, education, and training materials on how the PMPRB guidelines impact equitable access to medicines both globally (i.e. Canada vs. international comparators), and within Canada (i.e. between provinces). Please refer to our response to question 6.4 for specific recommendations.

6.3: *Canada and the world are facing a generation of new high-priced drugs for the treatment of rare diseases.*

> *i. Should the PMPRB view the question of whether the prices of these medicines are "excessive" through a different lens than other types of medicines?*
>
> *ii. What quality of evidence should the Board consider when conducting its scientific review of these medicines?*

In the face of a new generation of high-cost drugs for rare diseases, CBCN would invite guidelines that are flexible enough to not just meet the unique demands presented by reviewing these treatments, but also anticipate the review needs of future treatments. This means ensuring guidelines remain adaptable enough to mitigate the threat of path dependency, but responsive enough to ensure new high-cost drugs, whether for rare diseases or any other condition, are not excessively priced in Canada.

6.4 How can the PMPRB better engage with you?

CBCN welcomes the engagement of both rights holders and non-rights holders in the PMPRB consultation and wishes to make the following suggestions concerning how the PMPRB can better engage with the CBCN and people with breast cancer.

1. Immediately develop a publicly available patient engagement strategy that addresses how, where, and when the PMPRB intends to include both subject matter experts (such as patients, clinicians, researchers, etc.) and the wider public during the course of the current consultation (2024), and over the following 5 years that, at a minimum, reflect the government of Canada's Principals and Guidelines for public engagement.
2. Immediately address the unique logistical and accessibility needs of patients and caregivers, not for profit organizations, and stakeholders representing smaller communities or organizations by:
    a. Providing consultation materials well in advance that, at a minimum, meet the government of Canada's Plain language, accessibility, and inclusive communications standards;
    b. Asking about what accommodations are needed to remove unique barriers that may prevent or limit meaningful engagement (i.e. accessible buildings, longer meeting times, multiple media formats, etc.).

While this recommendation is intended to highlight some accessibility concerns affecting the groups mentioned, it is important that all stakeholders are engaged in a way that respects their unique accessibility needs.

3. Introduce a knowledge translation role or roles within the PMPRB by May 2024 including personnel with relevant experience either as a patient or patient advocate who can execute knowledge translation campaigns over the following 12 months and develop public resources such as:
   a. Hosting two question and answer sessions in 2024 with non-industry stakeholders where participants can learn more about how PMPRB guidelines impact them, or their organization;
   b. Create a frequently asked question's section on the PMPRB website before the end of 2024 including external links and resources for FAQ's outside of the PMPRB mandate;
   c. At a minimum, develop a 2024 – 2026 framework to ensure the federal guidelines on Canada.ca Content Style Guide and Plain language, accessibility, and inclusive communications are applied to existing and future public facing reports, guidelines, and resources starting with those materials most relevant to the current consultation.
4. Conduct further consultations on the topics of (1) user-friendly updates to the PMPRB website, (2) improving patient engagement, and (3) knowledge translation strategies within the next 10-12 months with non-industry stakeholders to ensure these historically underrepresented groups can engage meaningfully with the PMPRB.
5. Publish publicly available reports within 2 – 3 months after the conclusion of each consultation that outlines what actions will be taken over the following 3 years to address the consultation's findings. At a minimum, these reports should meet plain language and accessibility requirements outlined by the federal government in their *Plain language, accessibility, and inclusive communications* guidelines found here.

Conclusion

The CBCN would once again like to thank the PMPRB for hosting consultations with stakeholders during the roundtable earlier this month, and by receiving our written feedback above. We look forward to further consultations on the draft guidelines, and through your further actions on stakeholder engagement as discussed in the feedback provided. Please feel welcomed to contact us for participation in future consultations, focus groups, or engagement initiatives by contacting JK Harris at jkharris@cbcn.ca.