Scoping paper for the consultations on the Board's Guidelines

Patient Group Submission

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This submission is provided on behalf of Save Your Skin Foundation, CONECTed, Myeloma Canada and All.Can Canada.

Signatories to this submission include:

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About Save Your Skin Foundation

Save Your Skin Foundation (SYSF) is a national patient-led not-for-profit group dedicated to the fight against non-melanoma skin cancers, melanoma and ocular melanoma through nationwide education, advocacy, and awareness initiatives. Save Your Skin Foundation is committed to playing an active role in reducing the incidence of skin cancer in Canada, and to providing compassionate support for all Canadians living with skin cancers.

About CONECTed

The Collective Oncology Network for Exchange, Cancer Care Innovation, Treatment Access and Education (CONECTed) is network that was formed by national patient oncology organization with objectives to:

- Raise **awareness** of cancer therapies, and **educate** on value to patients, HCPs and the health care system.
- Foster **collaboration** between patient groups and medical community to meet the changing needs of clinicians and patients in this rapidly evolving environment.
- **Inform and consult with government**, bureaucrats and decision- makers on the value of cancer therapies.
- Support patient **access** to appropriate cancer therapies.

About Myeloma Canada

Myeloma Canada is a registered non-profit organization created by, and for, people impacted by multiple myeloma. As the only national organization exclusively devoted to the Canadian myeloma community, Myeloma Canada has been making myeloma matter since its founding in 2005.

Working with leading myeloma researchers and clinicians as well as other cancer organizations and local support groups across Canada and internationally, Myeloma Canada seeks to strengthen the voice of the Canadian myeloma community and improve quality of life for those impacted by myeloma through awareness, education, advocacy, fostering an empowered community and supporting clinical research to find a cure.

About All.Can Canada

All.Can Canada was established under the auspices of Save Your Skin Foundation (SYSF), a national, patient-led, not-for-profit group dedicated to leading the fight against non-melanoma skin cancers, melanoma and ocular melanoma. SYSF was established as All.Can Canada's Secretariat to lead the initiative in Canada, bringing the approach and lessons learned by the international group to Canada.

Response to Consultation

General Comments

Save Your Skin Foundation, CONECTed and Myeloma Canada have been actively engaged in each of the prior consultations regarding the PMPRB Guidelines. One of the guideline proposals was very complex that we had to resort to hiring an independent health economist to analyze them in the context of 6 oncology drugs that were available in Canada at the time, after having undergone review by CADTH.

The results of his analysis were that some of these medications would not have been approved for sale in Canada under the proposed guidelines. We shared our findings with PMPRB at a meeting between senior PMPRB representatives, our organizational representatives and the health economist.

PMPRB had acknowledged that it had not done such an analysis and accepted our findings. The Guidelines were subsequently changed in recognition of these findings.

During this consultation, the PMPRB is once again asking stakeholders to answer questions that requires an understanding of their impact in the real-world setting on oncology medications. To do so, we need specific expertise including that of health economists, statisticians and perhaps others to use real-world examples to determine the implications that the guidelines would have on access to oncology drugs, if implemented.

In order to responsibly answer the questions in the consultation on behalf of patients, we find ourselves needing access to such experts.

For example, in Question 3.3 of this consultation regarding s. 85 of the *Act*, the Board asks whether it should accord more weight to one or more of the factors in designing the Guidelines. It is not possible to know *a priori* which factors to accord more weight to, without conducting a comparative analysis of the implications of according more weight to various combinations of factors.

From the patient lens, the impact in the real-world on patients can be defined as timely access to needed therapies that are safe and effective. Any real-world analysis must therefore rely on this definition as a measure of success.

We do not have the knowledge, based on our own expertise, to conduct the required analysis in order to answer the questions properly. Additionally, patient groups do not have the resources required to hire such expertise in order to develop informed responses to such consultation questions.

As you well know, patients require urgent access to safe and effective cancer therapies. All stakeholders engaged in the consultation should have equal opportunity to resources required to provide well informed responses to the questions.

A number of other stakeholders have access to resources that permit them to conduct these kinds of analyses, but patient organizations do not. Once again, patient representatives are put at a disadvantage.

Patient representatives must no longer be put at a disadvantage in engaging in a public consultation of this magnitude because of limited access to resources.

Recommendation 1:
We therefore recommend that the PMPRB make those experts available to us to allow us to work through real-world analyses of the potential impact that different answers to the questions can have.

Theme 1: Efficient Monitoring of Prices without Price Setting

Theme 1 Questions	Reponses
Question 1.1: What elements of the 2010 Guidelines should be retained? Which ones and why?	As discussed above, to answers these questions we require an expert analysis. Please see **Recommendation 1**.
Question 1.2: Should new Guidelines continue to categorize medicines by therapeutic class comparator characteristics such as the Level of Therapeutic Improvement?	
Question 1.3: Should the Board accord more weight to one or more of the factors set out in s. 85 of the Act in designing the Guidelines?	
Question 1.4: If international prices are used as the initial triage measure for commencing investigations, what price levels within the PMPRB11 should be used as the triage measure? (e.g. HIP or MIP?)	
Question 1.5: How should the PMPRB conduct an initial review and monitor the prices of patented medicines that have few or no international prices?	
Question 1.6: Would an expedited price review (e.g., within 90 days after initial Form 2 submission) of a new medicine based solely on international prices being below the MIP accelerate introduction of innovative medicines? i. How soon after an expedited review should a full price review take place?	

Theme 2: Transition to PMPRB11 – New versus Existing Medicines

Theme 2 Questions	Reponses
Question 2.1: Should the Guidelines distinguish between medicines that existed as of July 2022 (existing medicines) and medicines introduced afterwards (new medicines)?	To answers these questions, we must first know the implications of establishing this distinction between existing medicines and new medicines. On its face, it would appear that existing medicines are already on the market and the price may well have been negotiated between the manufacturer and the pCPA. If the implication is decreased access to needed medications for patients, then this distinction should not be made. In principle, the PMPRB11 should apply prospectively and not retrospectively, and any retrospective review should be done on a case-by-case basis taking into account the type of drug, its target population and its market status in Canada, among other factors.
Question 2.2: What approach should the Board take with respect to existing medicines with prices above the HIP of the PMPRB11? Should the Board review these prices, and if so, how soon?	

Theme 3: Price Reviews during Product Life Cycle

Theme 3 Questions	Reponses
Question 3.1: How often should price reviews be conducted? (1-5 years). i. Should they be different for small molecules (average 10-year exclusivity period) versus biologics (average 20+ year exclusivity period)? Should they be different for medicines for rare diseases?	We are not in a position to respond to these two questions. From the patient perspective, the optimal choice is one that improves timely access to safe and effective treatment that are needed.
Question 3.2: What criteria besides time should be used to trigger a price review? i. Approval of a significant new indication? ii. Significant change to the therapeutic class comparators? Availability of new/stronger evidence related to benefit vis-à-vis therapeutic class comparators? iii. Departure from identified pricing thresholds?	

Question 3.3: Should the relative weighting given to different section 85 (*Patent Act*) factors change over the lifecycle of a medicine?	As discussed under **General Comments**, it is not possible to know *a priori* which factors to accord more weight to, without conducting a comparative analysis of the implications of according more weight to various combinations of factors. From the patient lens, the impact in the real-world on patients can be defined as timely access to needed therapies that are safe and effective. Any real-world analysis must therefore rely on this definition as a measure of success.
Question 3.4: How should the PMPRB treat the allowable Consumer Price Index increase in the context where international list prices are decreasing?	We are not in a position to respond to these two questions. From the patient perspective, the optimal choice is one that improves timely access to safe and effective treatment that are needed.
Question 3.5: What is the ideal timing for scientific review and therapeutic comparator identification? At what price review stage(s) should scientific review be applied?	

Theme 4: Investigations and Referral to Hearing

Theme 4 Questions	**Reponses**
Question 4.1: Are the criteria published in the 2010 Guidelines for commencing an investigation still appropriate (assuming adjustment to PMPRB11)?	If these criteria have been appropriate before the PMPRB11, we would need to know why the introduction of the PMPRB11 would change that.
Question 4.2: How much detail should the Guidelines set out regarding what happens once an investigation is opened?	Sufficient details to allow the relevant stakeholders to make their case should be set out in the Guidelines.
Question 4.3: Should the PMPRB continue to use Undertakings as an investigation closure mechanism?	If this process has served the parties well to date, there is no reason to change it.

Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives

Theme 5 Questions	Reponses
Question 5.1: What efficiencies could be gained by co-ordinating decisions and timelines of the PMPRB with those of the Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et services sociaux (INESSS) and pan-Canadian Pharmaceutical Alliance (pCPA) or insurers (public and private)?	PMPRB is a quasi-judicial body, created under the *Patent Act*, with a specific legislated mandate. It is expected to fulfill its mandate exclusively and objectively. It reports in through Health Canada for purposes of the drug pricing Regulations while other parts of the *Act* report in through the Minister of Innovation, Science and Economic Development. It is responsible to determine whether the price being proposed for the sale of a drug or other treatment in Canada is excessive. If the price is deemed to be excessive based on the criteria set out in the Regulations to the *Patent Act*, the manufacturer must lower the price to meet these criteria or will not be permitted to sell the product in Canada. Quasi-judicial bodies including Agencies, Boards, and Tribunals, make decisions on behalf of the government, when it is impractical or inappropriate for the government to do so itself. They must behave impartially in their decision-making process.[1] Quasi-judicial bodies are under a duty to act in accordance with the rules of natural justice, giving persons specially affected by the decision a reasonable opportunity of presenting their case, listening fairly to both sides and reaching a decision untainted by bias.[2] They also have the right to engage specific expertise to assist in providing needed advice and input.[1]

[1] Blake S. *Administrative Law in Canada*. 6th ed. Markham, Ont: LexisNexis Canada; 2017.
[2] Yogis JA, Cotter C, Gifis SH, Barron's Educational Series I. *Barron's Canadian Law Dictionary*. 6th ed. Hauppauge, N.Y. : Barron's Educational Series; 2009.

	The rules of natural justice apply to all decision makers and those advising them, *e.g.,* the Board of Directors, the staff of PMPRB and any advisors on whom they rely. Therefore the question regarding partnerships is irrelevant. Furthermore, the PMPRB cannot base its timelines on that of another government body. It must fulfill its role within the required timeline for it to do so effectively and efficiently, irrespective of the timelines of other bodies. **Recommendation 2:** PMPRB must adhere to the rules regarding quasi-judicial bodies in its processes.
Question 5.2: How can the PMPRB optimize its presence within the Canadian bio/pharmaceutical ecosystem to support a whole of government approach to issues relating to patented medicines?	The PMPRB does not have an obligation to optimize its presence, but to fulfill its legislated mandate.

Theme 6: Engaging with Patients, Health Practitioners, Pharmacy, and other Stakeholders

Theme 6 Questions	Reponses
Question 6.1: What is your experience with innovative medicines and their list prices in Canada?	In conducting its role as the decision maker regarding excessive drug pricing in Canada, the PMPRB reports in through Health Canada. Public engagement activities by the PMPRB should therefore align with the principles outlined in the Health Canada (HC) and the Public Health Agency of Canada (PHAC) Guidelines on Public Engagement, published November 2019.[3] These Guidelines recognize the importance of public engagement as an important part of the democratic process and allows Health Canada and the Public Health Agency of Canada to fulfill key responsibilities, including the following:
Question 6.2: What role do the PMPRB Guidelines play in your decision-making process in Canada and globally (if applicable)?	
Question 6.3: Canada and the world are facing a generation of new high-priced drugs for the treatment of rare diseases.	

[3] Health Canada, Public Health Agency of Canada. *Guidelines on Public Engagement*.; 2019. doi:H14-153/2019E-PDF. https://www.canada.ca/content/dam/hc-sc/healthy-canadians/migration/publications/health-system-systeme-sante/guidelines-public-engagement-publique-lignes-directrice/alt/HC-PHAC%20Guidelines%20on%20Public%20Engagement%202019.pdf

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?	• "Foster information exchange and knowledge sharing to improve the understanding of health issues and build relationships among interested and affected parties"[3] • "Facilitate discussions between HC and PHAC and individuals, groups and organizations, external to the Government of Canada, to provide opportunities to shape government policies, programs, services and regulatory initiatives"[3] • "Consider the feedback and perspectives of individuals and groups in the development or assessment of government policies, programs, services and regulatory initiatives in order to inform decisions"[3] • "Enable informed decision-making that ultimately fulfills the mandates of HC and PHAC and improves the health and safety of Canadians"[3]
Question 6.4: How can the PMPRB better engage with you?	**Recommendation 3:** PMPRB should be available to stakeholders who want to discuss broad subject matter including the interpretation of its policies, procedures and practices.