Mood Disorders Society of Canada
Société pour **les troubles de l'humeur** du Canada
www.mooddisorderscanada.ca

Submission to PMPRB March 10, 2025,

Introduction

On behalf of Mood Disorders Society of Canada (MDSC) we wish to thank the PMPRB for giving us the opportunity to present a submission regarding proposed changes to the PMPRB Guidelines. MDSC is a national, registered, not-for-profit, volunteer health charity committed to ensuring that people affected by mood disorders enjoy the fullest, most productive lives possible, within a healthy, stigma-free environment. MDSC's overall objective is to provide people with mood disorders with a strong, cohesive voice at the national level to improve access to treatment, inform research, and shape program development and government policies with the goal of improving the quality of life for people affected by mood disorders.

We appreciate the opportunity to provide input on the PMPRB's Draft Guidelines and wish to highlight key concerns from a patient-centered perspective. While we recognize the Board's mandate to ensure that the prices of patented medicines in Canada are not excessive, we believe that aspects of the Guidelines create uncertainty and lack of predictability that, ultimately, for patients can result in a delay in and/or lack of access altogether to innovative treatments, which may be discouraged to launch in Canada for mental illnesses.

Uncertainty and Lack of Predictability Impacts Investment & Patient Access to Medications

The Guidelines do not provide certainty on pricing outcomes, price ceilings, or compliance expectations. This creates uncertainty for manufacturers, which may lead to delays or decisions not to launch medications in Canada, particularly in mental illness where new drug options are needed.

Further, the multi-step review process (Initial Review, Annual Review, and In-Depth Review) means that even if a drug is initially accepted in Canada, it could later be flagged for further scrutiny, making long-term availability increasingly uncertain for patients. Additionally, some drugs will undergo a 12-28 month In-Depth Review, further delaying access.

If manufacturers anticipate difficulties in navigating PMPRB regulations, they may prioritize launches in markets with more predictable frameworks, potentially limiting access to newer treatments for mental illnesses for patients in Canada. A clearer, more predictable pricing framework would encourage manufacturers to continue bring innovative medications to Canada benefitting Canadian patients living with mental illnesses.

Guidelines Not Patient Centred

Although the PMPRB's mandate is to ensure its prices are not excessive, there is no patient-centred pricing considerations. The Guidelines should include mechanisms for incorporating patient perspectives, especially for medications addressing significant unmet needs, such as medications for mental illnesses.

Potential for Reduced Investment in Medications for Mental Illnesses

The research and development of psychiatric medications often require long-term, stable pricing to encourage innovation and availability. Again, the Guidelines' unpredictability and lack of clear thresholds could discourage investment in drug development for the Canadian market in this therapeutic

area, which will result in fewer options for Canadian patients living with mental illnesses.

Initial Review

Basket of Scheduled Countries

The basket of eleven countries that has been determined as comparators is reasonable from the patient perspective in and of itself. However, many of the 11 countries are not aligned with Canada in pricing practices.

The Guidelines emphasize price comparisons with other countries (PMPRB11), but pricing policies and mandates vary across healthcare systems. The comparator countries are countries that already “price manage” in their jurisdictions via other mechanisms. By using “price managed” countries PMPRB mandate moves away from ensuring prices are not excessive, to price management focusing on ensuring that prices are as low as possible, which in the end impacts patients’ access to medications for the aforementioned reasons.

Additionally, the focus on international pricing may not reflect Canadian population & patient needs. International pricing comparisons do not account for Canada's unique mental health challenges, including disparities in access across provinces and rural/remote areas.

List Price selection

The selection of the official formularies for the highest international price (HIP) in the basket of countries is appropriate. If comparison to HIP is satisfactory, there should be no further analysis required.

Separately, the provincial formulary price is typically reviewed for value by the Canadian Drug Agency and may be negotiated by the pan-Canadian Pharmaceutical Alliance. However, provinces that have agreed to reimburse a drug may set different prices, as they are not required to follow the alliance's

negotiated price. This raises questions about how the PMPRB will address variations in pricing across provinces.

Annual Review

Re-evaluating prices annually would, again, shift the PMPRB role closer to price management vs its mandate of ensuring prices are not excessive. Initiating an Annual Review adds to the aforementioned uncertainty and unpredictability for manufacturers trying to plan in the long term with initial and sub-indications for a medication, which again impacts patient access as drugs may be delayed in coming to Canada, or decisions may be made to not bring the medication to Canada at all.

In depth review process

Complaints process

The complaints process does pose some challenges.

By allowing complaints to be issued in such a broad and open manner, the PMPRB is creating a situation where a multitude of unnecessary complaints will be issued. There should be clear qualifiers for issuing a complaint: a price is excessive / higher than the HIP. If a medication is priced below the HIP, no further review should be required, as it already aligns with the mandate of preventing excessive pricing.

Private insurance companies should not be allowed to file complaints.

Domestic TCC

MDSC is concerned that the PMPRB has not clarified when generic products or biosimilars would be considered appropriate comparators or what evidence would be evaluated in the Scientific Review.

Role of Patient Input

Finally, patients and/or patient organizations should be able to submit pricing concerns: Patients and advocacy groups should be allowed to raise concerns about the unavailability of medications due to pricing uncertainty.

Thank you for the opportunity to provide a submission to the PMPRB Guideline changes.

Regards,

Dave Gallson

Dave Gallson
National Executive Director
Mood Disorders Society of Canada
P: 705 471 6101