Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

# Update on the PMPRB

## Market Access Summit

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# Overview of Today's Presentation

- 1) The PMPRB – a misunderstood mandate.
- 2) Update on the Guidelines Consultations.

# PMPRB – Mandate

# PMPRB – Mandate

- **PMPRB:**
  - Established via amendments to the Patent Act in 1987.
  - Independent quasi-judicial statutory body with a mandate to monitor the prices of patented medicines sold in Canada to ensure that they are not excessive.
  - Fulfills its mandate by holding public hearings to determine whether the prices of specific patented medicines are excessive.
  - Empowered to issue non-binding Guidelines on matters within its jurisdiction.

# PMPRB – Mandate

- **The PMPRB  is NOT a general price regulator:**
  - As the Federal Court of Appeal recently stated, “pure price regulation or price fixing is not valid.”
  - We are not empowered to set a ceiling for the list prices of patented pharmaceutical products except in the rare context of a formal hearing process leading to a price ceiling reduction order.
- **The PMPRB is NOT a barrier to entry:**
  - Authorization from the PMPRB is not needed to enter or to remain in the Canadian market.

# PMPRB – Mandate

- **What is meant by “excessive price”?**
- **Parliament has not provided a definition, rather it is a contextual case-by-case determination to be made in a hearing.**
- **Subsection 85(1) of the Patent Act provides four factors for assessing whether a given price for a given medicine is excessive or not:**
  - The price of the medicine and its different sizes and dosage forms;
  - prices of other medicines in the same therapeutic class;
  - prices of the medicine abroad;
  - changes in the Consumer Price Index.

# Organizational Structure

- **New appointments since February 2023:**
  - New President and Vice-President.
  - New Board members.
  - Appointment of a new Director General.
- **A few reminders :**
  - The Chairperson is designated under the Patent Act as the chief executive officer of the PMPRB and has the authority and responsibility to supervise and direct its work.
  - The Board develops and publishes the guidelines.
  - Only the Board, siting in a hearing Panel, can decide whether a price is excessive under the Patent Act.
  - The staff, through its Director General, assists the Board in carrying out its work.
  - Discretion rests with the Chairperson and the Board.

# Development of the new Guidelines

# General Role of the Guidelines.

- PMPRB may, but is not obligated to, issue non-binding guidelines.
- The Board does not have the capacity to conduct hearings for each patented medicine under its jurisdiction.
  - Need a mechanism to narrow-down the number of cases that are advanced for recommendation for a hearing.
- Guidelines guide Staff and provide transparency to interested parties regarding the process the Staff will use to identify potential cases to recommend that the Chairperson consider for hearings.
- Breaking news: PMPRB is currently developing new guidelines.

# The PMPRB has new regulations to address

- Amendments to the Patented Medicines Regulations came into force on July 1, 2022.
- These amendments resulted in a new set of comparator countries (“PMRB11”) and reduced submission requirements for medicines deemed to have the lowest risk of excessive pricing. All rights holders are now filing PMPRB11 data.
- Changes to the PMPRB Guidelines are now required to address the regulatory amendments and recent jurisprudence, and to deliver on the PMPRB’s commitment to modernize and simplify its administrative framework.
- The PMPRB is currently in consultations to make the necessary changes to the Guidelines.

# Development of guidelines – What has been done

- **Consultation launch in October 2023.**
- **Three (3) phase consultation.**
- **Phase 1 – Completed**
  - Scoping Paper
  - Policy Roundtable
- **Board is in Phase 2 of consultations.**
  - Phase 2 forms the backbone of the development of draft technical guidelines.

# Development of guidelines – What has been done

- **The proposed framework, included in Phase 2, would include:**
  - 60-day review for all medicines below the International Price Comparison (IPC) criteria that will be chosen by the Board.
    - If drug is launched first in Canada, it will be automatically reviewed.
  - In-depth reviews only for certain patented medicines.
  - Potential complaints mechanisms.
  - Annual monitoring of the IPC.

# Development of guidelines – next steps

- The Board is in Phase 2 of consultations.
- Phase 2 forms the backbone of the development of draft technical guidelines.
- Launch of Phase 3 of the consultations i.e. issuance of draft technical Guidelines, expected in the coming months.
- More stakeholder engagement expected.
- Final Guidelines: aiming for first half of 2025 (will depend on consultations).

# Conclusion

- The PMPRB is in a transition phase.
- Ambitious program with the development of new guidelines as the main priority.
- Stakeholder engagement is key.