Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Second Meeting Steering Committee

August 15, 2018

Canada

Agenda

- Summary of Working Group Meeting
- Review written feedback
- Topics for Discussion
  - Use of External Price Referencing
  - Use of List and Net Price Ceilings
  - Risk Assessment and Prioritization Criteria for Category 1 & 2 medicines
  - Re-Benching Criteria
- Review need for additional WG

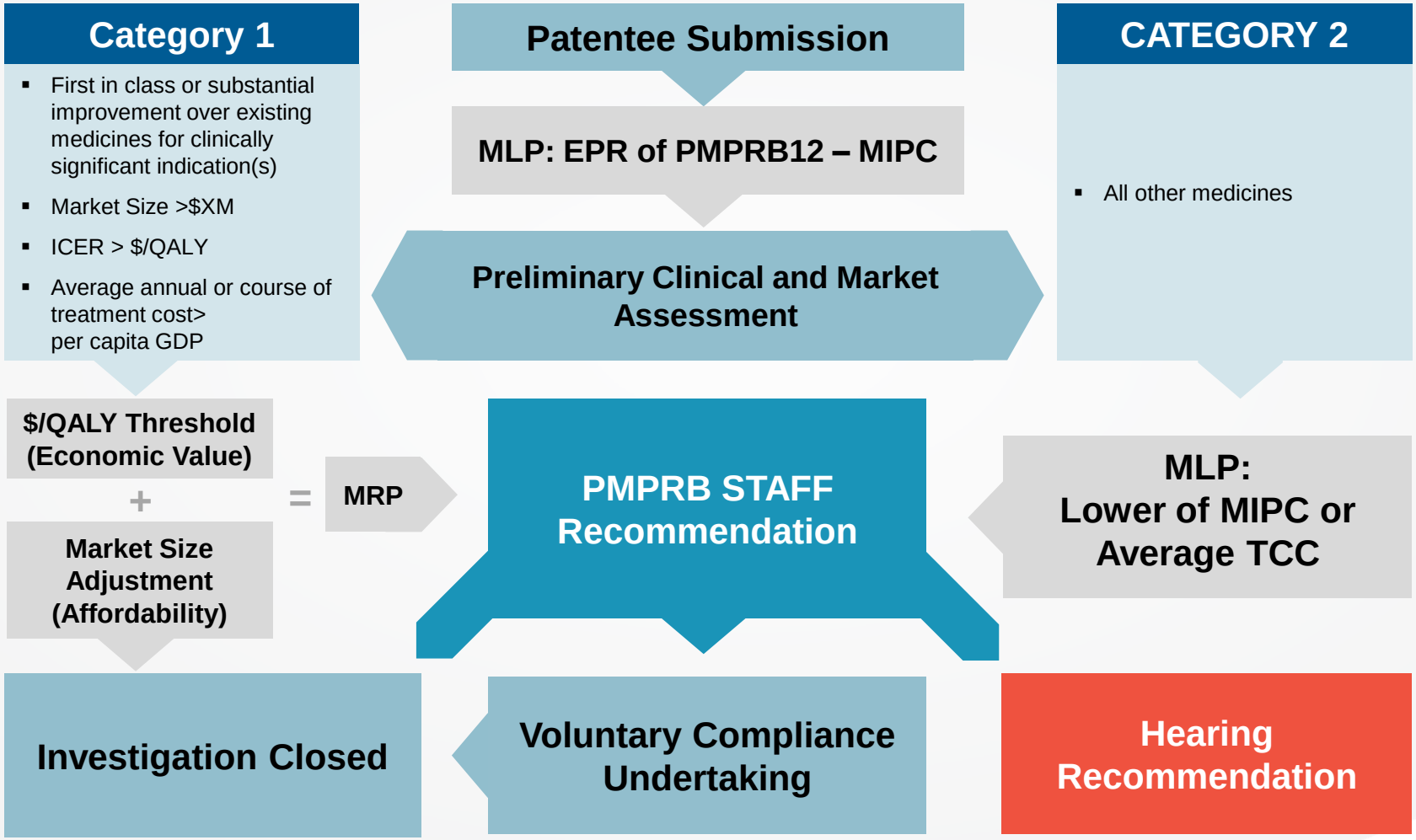
Summary of Technical Working Group (TWG) Meeting and Next Steps

- The first meeting of the TWG was held July 26, 2018 in Ottawa.
- The Terms of Reference were agreed upon by all members present.
- Board Staff presented the proposed PMPRB framework modernization structure to the members.
- Members discussed each of the topics designed to elicit specific economic feedback.
- It was agreed that subsequent meetings will be scheduled to discuss each topic in further detail. Members were surveyed for availability in advance of selecting dates for the next meeting.

Written Feedback Received to Date

- IMC, BIOTECanada, and CORD have provided written submissions on the nature and scope of the Steering Committee's work.
- At a high level, these submissions have requested a roadmap for SC meetings, a need for case study discussion, and a number of operational questions related to the proposed framework.
- Additional working groups on specific topics have also been recommended by BIOTECanada.
- The roadmap for future meetings presented to the SC on July 24 is intended to reflect this feedback. Specific operational questions will be raised and addressed in the course of topic and case study discussion.
- The need for additional working groups will also be reviewed as part of the SC's discussion of these topics.

Proposed PRICE Review Schematic



Use of External Price Referencing
Part 1: Median international price test (MIPC)

- The proposed approach is that all new medicines are assigned a Maximum List Price (MLP) based on the median of the PMPRB12 (MIPC).

- The MIPC would be recalculated annually until there are at least 7 countries or 3 years post first date of sale. At that point the MLP would no longer be interim. This approach provides both predictability (e.g., exchange rate fluctuations) and reduces regulatory burden.

- Re-benching could result in the MLP being adjusted over time.

- IMS will be used to verify international list prices however filing requirements for patentees will remain unchanged for the new schedule.

Use of External Price Referencing Question for Consideration

- Is an MLP based on the median of the PMPRB12 (MIPC) for all medicines reasonable?
- Should exceptions be made to the MLP-MIPC test and, if so, when and why?
- Should there be a price floor for Category 2 medicines based on LIPC?
- Does the 7 countries or 3 years approach provide the right balance of reflecting international prices and providing stakeholders with reasonable predictability?
- Should an increasing gap between MIPC and the MLP trigger a re-bench?
- Should EPR differ depending on category or vintage of the patented medicine?
- Additional questions from SC?

Use of List and Net Price Ceilings

- The conceptual framework presented to the SC at the first meeting proposed the establishment of two ceilings for Category 1 medicines based on both list (MLP) and net (rebated) prices (MRP).

- For Category 2 medicines, the proposal is to establish one ceiling (MLP) based on list prices domestically and internationally based on the lower of the MIPC and the average of the domestic therapeutic class (ATCC). No Category 2 medicine will be given an MLP that is lower than the lowest price country in the PMPRB12 (LIPC floor).

- The approach aims to establish a net price ceiling to both protect Canada's true transaction price from being exposed and allow patentees to comply with the net price ceilings through use of all discounts/rebates direct and indirect.

Use of List and Net Price Ceilings

- Should a Category 1 medicine ever have more than one MRP?
- Are there economic considerations that would support a higher MRP for some Category 1 medicines than would result from the proposed application of the new factors?
- Should confidential third party pricing information only be used for compliance purposes?
- Additional questions from SC?

Risk Assessment and Prioritization Criteria for Category 1 & 2 Medicines

- The second part of the framework consists of a screening phase which would classify new patented medicines as either high or low priority based on their anticipated impact on Canadian consumers, including individual patients and institutional payers (e.g., public and private drug plans).
- The framework proposed high level criteria that PMPRB would use to categorize medicines as Category 1 or 2:
  - First in class or substantial improvement over existing medicines for clinically significant indication(s)
  - Market Size >Affordability Threshold
  - ICER > maximum opportunity cost threshold
  - Annual or treatment cost> per capita GDP
- medicines that appear to be high priority based on these screening factors would be subject to automatic investigation and a comprehensive review to determine whether their price is potentially excessive.

Risk Assessment and Prioritization Criteria for Category 1 & 2 Medicines

- Is the proposed division and treatment of Category 1 and Category 2 medicines a reasonable risk-based regulatory approach?
- Should further categories exist with different treatment modalities?
- Should more or less criteria be considered in screening a medicine as higher risk and where should the line be drawn with respect to the criteria?
- Should the pharmacoeconomic, market size and GDP factors apply both as screens and thresholds?
- Should Category 2 medicines be scrutinized more or less than proposed?
- Other questions proposed by SC?

Re-Benching Criteria

- All new medicines will be given an interim MLP of 3 years or until the medicine is sold in 7 countries, whichever comes first.
- MLP is then frozen, as is MRP, unless re-benching is triggered by one of the following criteria:
  - Approval of a new indication
  - Sales in excess of expected market size
  - New evidence on cost-effectiveness (e.g. CADTH therapeutic class review or lifting of HC conditions on NOC)
  - Significant changes in international prices (eg. MIPC < MIPC at intro by more than 25%)
- Patentees may apply for a re-benching with evidence of increased cost-effectiveness, smaller market, or a significant increase in CPI

Re-Benching Criteria

- Complaints received by the PMPRB will trigger an investigation, during which the PMPRB will assess whether:

  - The medicine is in compliance with the Guidelines; and
  - whether circumstances in the market have changed to warrant a rebenching/reclassification.

Re-Benching Criteria

- How often and in what circumstances should a medicine be rebenched?
- Other questions proposed by SC?

Need for Additional Working Group

- Feedback to date suggest that the PMPRB consider establishing other working groups to deal with specific issues.

- Many of the issues flagged to date are administrative in nature and would likely be better situated for a working group in a later phase of the guidelines development process (similar to DIP Working Group).

- Are there specific high-level framework topics that the SC believes are not being addressed by the SC or the existing TWG?

Next SC Meeting

- The next meeting will take place early September.

- PMPRB staff will respond to a summary of written feedback received from members following this meeting and lead a discussion on the following themes:

  - Tests for Category 1 medicines
  - Tests for Category 2 medicines
  - Use of confidential pricing information
  - Application of new regime to existing medicines