Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Third Meeting Steering Committee

September 12, 2018

Canada

Agenda

- Approval of agenda
- Approval of minutes from August 15th meeting
- Update on roadmap and discussion of PMPRB analysis
- Status of Technical Working Group deliberations
- Topics for discussion
  - Tests for Category 1 medicines
  - Tests for Category 2 medicines
  - Use of confidential pricing information
  - Application of new regime to existing medicines
- Next Meeting

Update on Roadmap

- Written and oral feedback on all topics will be compiled in a final report.
- Draft report will be prepared for SC review after case study meeting.
- Feedback outside the scope of the proposed framework will be included in an annex as part of the public record.
- SC members will have an opportunity to provide feedback on all the topics until the report is finalized.
- Next meeting on case studies will be held in person in Ottawa.

Discussion of PMPRB Analysis

- PMPRB provided additional data to SC members on August 27
- Analysis focused on:
  - Distribution of medicines with more or less than 7 PMPRB12 countries to set the MLP
  - Impact of potential market size, clinical, and cost screens to classify Category 1 medicines
  - Analysis of Canadian ICER values
- Do SC members have additional comments or questions on this data?

Status of Technical Working Group (TWG)

- August 22-24th 7 teleconference calls, 6 topic-specific breakout sessions and one meeting of entire TWG.
  - Topic 1: Options for determining which medicines fall into Category 1
  - Topic 2: Application of supply-side cost effectiveness thresholds in setting ceiling prices for Cat 1 medicines
  - Topic 3: Establishing price ceiling for medicines with multiple indications
  - Topic 4: Accounting for uncertainty
  - Topic 5: Perspective
  - Topic 6: Options for price ceiling adjustment based on market size factor
- Further feedback has been/will be received in writing
- SC will see final TWG report in October; option for chair to present and Q&A

Approach for Today's Meeting

- Refresher on the proposed framework
- Second set of discussion topics will be presented
- SC members can seek clarification of any points in advance of providing feedback
- Written feedback will be solicited on all topics

Overview of new Guidelines framework

- A risk-based approach to price regulation that considers value and affordability, in addition to list prices in other like-minded countries.
- Basic structure can be broken down into 5 parts:
  - Part I: 'Maximum List Price' (MLP*) for all new medicines at introduction based on median of PMPRB12 (MIPC)
  - Part II: Screening of medicines into high priority (Category 1) or low priority (Category 2)
  - Part III: 'Maximum Rebated Price' (MRP**) for Category 1 medicines based on new pharmacoeconomic, market size and GDP factors
  - Part IV: Lower of MIPC and average of Therapeutic Class (ATCC) for Category 2 medicines
  - Part V: Re-benching

* *The MLP will be a ceiling based on public list prices.*

** *The MRP, which applies to Category 1 medicines only, would be applied to a medicine's average transaction price (ATP) net of all direct and indirect discounts and benefits.*

Tests for Category 1 Medicines

- Category 1 medicines would be assigned a Maximum List Price (MLP) based on the median of the PMPRB12 basket (MIPC).
- Category 1 medicines would subsequently be given a Maximum Rebated Price (MRP).
- The MRP would be based on application of the pharmacoeconomic, market size, and GDP factors.

Step 1: Pharmacoeconomic Factor

- Empirical work undertaken by Karl Claxton at the University of York suggests a $30K/QALY opportunity cost threshold for Canada.

- Category 1 medicines would be assessed against a baseline threshold of $60K/QALY*.

- Medicines that meet certain clinical characteristics (e.g., high burden of disease or significant absolute gain in QALY) may warrant a higher threshold.

**To account for the variation in QALY values across the Provinces and Territories identified in the Claxton report and in keeping with the PMPRB's mandate as a ceiling price regulator.*

Step 2: Market Size and GDP

- A Category 1 medicine may require a price adjustment beyond the $/QALY threshold if there are short term affordability concerns based on the medicine's expected use.
- Using the contribution of new medicines to GDP and GDP growth over the last five years, the PMPRB has estimated an initial market size threshold of $20M per new medicine.
- New Category 1 medicines with an estimated market size that is expected to exceed this threshold within any of their first five years of sale would have their MRP reduced by an additional percentage.
- The $20M threshold would increase based on GDP growth and/or CPI.

Application of new factors to Category 1 Medicines

Type of review	$/QALY target to set MRP	Market impact adjustment
Baseline (market size up to $20M)	$60K	N/A
"Premium" (e.g. high burden, EDRD, significant absolute QALY gain)	$90K to $150K	N/A
High Impact (market size over $20M)	$60K	10% reduction on MRP for each additional $10M market size (to 50% maximum)

Questions: Tests for Category 1 Medicines

- Is an MLP based on the median of the PMPRB12 (MIPC) for all medicines reasonable?
- Should exceptions be made to the MIPC test and, if so, when and why?
- Should the cost effectiveness threshold for Category 1 drugs vary?
- 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?

Tests for Category 2 Medicines

- Category 2 medicines have an MLP based on the lower of the MIPC and the average of the domestic therapeutic class (ATCC).
- However, no Category 2 medicines would be given an MLP that is lower than the lowest price country in the PMPRB12 (LIPC floor).
- An MRP would not be established for Category 2 medicines.
- The MLP would be established based on publicly available list (ex-factory) prices, domestically and internationally.

Questions: Tests for Category 2 Medicines

- Is an MLP based on the median of the PMPRB12 (MIPC) for all drugs reasonable?
- Should exceptions be made to the MIPC test and, if so, when and why?
- Should there be a price floor for Category 2 drugs and, if so, should it be based on LIPC?
- Should Category 2 drugs be scrutinized more or less than proposed?

Use of Confidential Pricing Information

- Price reviews would be conducted for the following customer classes:
  - National/Provincial Retail – list price assessed against MLP
  - National Private Payer – ATP assessed against MRP
  - Provincial Public Payer – ATP assessed against MRP in each market
- ATPs are calculated net of all direct and indirect discounts and benefits.
- Category 2 medicines would be assessed against MLP only.

Questions: Use of Confidential Pricing Information

- Are the proposed definitions of markets and customer classes reasonable?
- Is the proposal to use third-party pricing information for compliance with the MRP reasonable?
- Other questions proposed by SC members?

Application of New Regime to Existing Medicines

- Existing medicines would be given an interim price ceiling based on the lower of their current ceiling and the MIPC of the PMPRB12.
- Existing medicines would only be classified as Category 1 if they do not meet a $100K/QALY screen for any indication. These would be prioritized for re-benching and subject to the same methodology proposed for new Category 1 medicines.
- Category 2 drugs would be re-benched later unless a complaint is received.
- All drugs within a therapeutic class would be assessed at the same time for the purposes of the ATCC test.
- Patentees would be advised in advance of re-benching and given two reporting periods to come into compliance.

Questions: Application of New Regime to Existing Medicines

- Is the use of MIPC as an interim ceiling reasonable?
- Should existing medicines be subject to a Category 1 or 2 classification and re-benched on this basis?
- Are there reasonable alternative approaches to bringing existing medicines under the new framework?
- Other questions proposed by SC members?

Additional Questions for Consideration

- Are there opportunities to further reduce regulatory burden while still operationalizing the new factors?
- Other questions proposed by SC members?

Next SC Meeting

- The next meeting will take place in October.
- PMPRB staff will respond to feedback received from members in the interim.
- Members will review case studies presented by PMPRB staff and discuss the sequencing of the new regime relative to CADTH and pCPA processes.
- SC members are invited to provide feedback (by September 21) to identify specific issues within the context of the proposed framework that should be explored in case studies.