Draft Terms of Reference for Working Group to Inform the Patented Medicine Prices Review Board (PMPRB) Steering Committee on Modernization of Price Review Process Guidelines

Background

The Patented Medicine Prices Review Board (PMPRB) recently established a 'Steering Committee on Modernization of Price Review Process Guidelines'. The mandate of this **Steering Committee** is to assist the PMPRB in synthesizing stakeholder views on key technical and operational modalities of the PMPRB's new draft Guidelines.

The Steering Committee's work will be based in part on the analysis and recommendations of a technical **Working Group**, which will examine certain issues that the Steering Committee believes would benefit from the review of experts in health technology assessment and other economic and scientific matters.

The Working Group will comprise leading experts in pharmacoeconomics and the clinical evaluation of pharmaceuticals. The Working Group will meet four times between July and October 2018: twice in-person in Ottawa, and twice via video-conference. A report of the Working Group's deliberations and recommendations will be produced by the chair and submitted to the Steering Committee for consideration in October 2018.

Membership

The chair of the Working Group will be Dr Mike Paulden (University of Alberta).

Fourteen individuals will be invited to sit as members of the Working Group: the twelve individuals identified below, and two additional individuals nominated by Steering Committee members representing Innovative Medicines Canada (IMC) and BioteCanada.

The twelve identified individuals who will be invited to sit as members are (alphabetically):

1. Sylvie Bouchard (INESSS);
2. Dr Chris Cameron (Dalhousie University and Cornerstone Research Group);
3. Dr Tammy Clifford (University of Ottawa and CADTH);
4. Dr Doug Coyle (University of Ottawa);
5. Dr Irfan Dhalla (Health Quality Ontario and St Michael's Hospital);
6. Dr Peter Jamieson (University of Calgary);
7. Dr Karen Lee (University of Ottawa and CADTH);
8. Dr Christopher McCabe (University of Alberta and Institute of Health Economics);
9. Dr Stuart Peacock (Simon Fraser University and BC Cancer Agency);
10. Dr Mark Sculpher (University of York);
11. Dr Tania Stafinski (University of Alberta);
12. TBD

To contribute meaningfully to Working Group deliberations, IMC and BioteCanada's nominee should have the following background:

- A PhD in health economics, epidemiology, or a closely-related field;
- At least 5 years of experience of pharmacoeconomics and/or or the clinical evaluation of pharmaceuticals, within either academia or industry;
- Knowledge of each of the areas of focus (described below) of the Working Group.

Recommendations of the Working Group will be determined by a simple majority vote of the members. In the event of a tie, the chair will have the casting vote.

Areas of focus

The Working Group will examine and make recommendations with respect to the following considerations and questions:

1. Options for determining what drugs fall into 'Category 1'

- A Category 1 drug is one for which a preliminary review of the available clinical, pharmacoeconomic, market impact, treatment cost and other relevant data would suggest is at elevated risk of excessive pricing.

- The following criteria have been identified as supporting a Category 1 classification:

    a) The drug is 'first in class' or a 'substantial' improvement over existing options
    b) The drug's opportunity cost exceeds its expected health gain
    c) The drug is expected to have a high market impact
    d) The drug has a high average annual treatment cost

- Should other criteria be considered? What are the relevant metrics for selecting drugs that meet the identified criteria and what options exist for using these metrics?

2. Application of supply-side cost effectiveness thresholds in setting ceiling prices for Category 1 drugs

- Potential approaches for implementing a price ceiling based on a drug's opportunity cost.

- Potential approaches for allowing price ceilings above opportunity cost based on a higher willingness to pay for certain types of drugs (e.g. pediatric, rare, oncology, etc)

3. Drugs with multiple indications

- Options for addressing drugs with multiple indications (e.g. multiple price ceilings or a single ceiling reflecting one particular indication).

4. Accounting for uncertainty

- Options for using the CADTH and/or INESS reference case analyses to set a ceiling price.

- Options for accounting for and/or addressing uncertainty in the point estimate for each value-based price ceiling.

5. Perspectives

- Options to account for the consideration of a public health care system vs societal perspective, including the option of applying a higher value-based price ceiling in cases where there is a 'significant' difference between price ceilings under each perspective.

- How to define a 'significant' difference in price ceilings between each perspective.

6. Application of the market size factor in setting ceiling prices

- Approaches to derive an appropriate affordability adjustment to a drug's ceiling price based on an application of the market size and GDP factors (e.g. based on the US 'ICER' approach).

Additional areas of focus may be identified by the Steering Committee prior to the first meeting of the Working Group in July 2018.

It is anticipated that the approaches or methods recommended by the Working Group may not be identical to approaches or methods currently employed by CADTH or INESSS. Where such departures present potential hurdles for operationalization of its recommendations, the Working Group will identify potential technical or other solutions to these hurdles.

Confidentiality

Working Group members may consult with non-members on an ongoing basis but are expected to maintain the confidentiality of any materials provided to them during the course of their work.

The names of the members of the Working Group will be published on the PMPRB's website, along with a report of its deliberations, analysis and recommendations.

Governance and procedure

It is recognized that members of the Working Group may hold opposing points of view on the above issues and/or disagree with the policy rationale underlying the changes to the PMPRB's Guidelines. Members are nonetheless encouraged to work together constructively to assist the Working Group in carrying out its function.

The chair is expected to foster consensus among members, but in order to ensure that Working Group deliberations are as focused and productive as possible, the chair shall have final say on all matters of governance and procedure. Members who disagree with a decision of the chair in this regard can request that their objection be noted on the record. The chair shall make every

effort to ensure that the Working Group's final report accurately reflects any important points of convergence or contention between members.

Schedule

The Working Group will meet for the first time in-person in Ottawa in July, followed by two video-conferences in August and September. Following submission of a draft report, a second in-person meeting will be held in October.

All dates are subject to the availability of the chair and members of the Working Group.

Date	**Event**	**Purpose**
Week of 16 or 23 July 2018 (TBD)	Two day in-person meeting at the Alt Hotel in Ottawa	Overview of Working Group objectives. Summary of specific areas of focus under consideration. Allocation of tasks among Working Group members.
Week of 20 August 2018	Two hour video-conference	Update on Working Group status. Opportunity for input from Working Group members.
Week of 10 September 2018	Two hour video-conference	Update on Working Group status. Opportunity for input from Working Group members.
5 October 2018	Draft report submitted to PMPRB	Opportunity for input from PMPRB and Working Group members.
12 October 2018	Full day in-person meeting at PMPRB offices in Ottawa	Present draft report. Report draft recommendations. Final opportunity for input from PMPRB and Working Group members.
26 October 2018	Final report delivered to PMPRB	Final deliverable to PMPRB.
November 2018	Final report to be submitted for publication in a leading pharmacoeconomics journal (open access publication)	Provides additional scientific credibility to the final report and recommendations of the Working Group.

Deliverables

A draft report will be circulated to the Steering Committee and Working Group members on 5 October 2018, prior to the final in-person meeting in Ottawa. Following feedback, a final report will be delivered on 26 October 2018 and submitted for journal publication in November 2018.

Following delivery of the final report, the chair will be willing to present the recommendations of the Working Group to stakeholders and other interested parties, subject to availability.

Budget

The PMPRB may cover reasonable travel and accommodation costs of members where such funding is requested and approved in advance. Where possible, the chair of the Working Group will arrange meetings to attempt to minimize expenditures for participants.