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

Alt Hotel, Ottawa, ON
26 July 2018

Chair: Dr Mike Paulden

# 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.*

# Background

*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.*

# Members

*1. Dr Chris Cameron (Dalhousie University and Cornerstone Research Group);*

*2. Dr Tammy Clifford (University of Ottawa and CADTH);*

*3. Dr Doug Coyle (University of Ottawa);*

*4. Patrick Duford (INESSS);*

*5. Don Husereau (Institute of Health Economics);*

*6. Dr Peter Jamieson (University of Calgary);*

*7. Dr Frédérick Lavoie (Pfizer Canada);*

*8. Dr Karen Lee (University of Ottawa and CADTH);*

*9. Dr Christopher McCabe (University of Alberta and Institute of Health Economics);*

*10. Dr Stuart Peacock (Simon Fraser University and BC Cancer Agency);*

*11. Maureen Smith (Patient – Health Quality Ontario);*

*12. Geoff Sprang (Agmen);*

*13. Dr Tania Stafinski (University of Alberta).*

# Observers and Reviewers

***Observers***

*1. Edward Burrows (Innovation, Science and Economic Development);*

*2. Nelson Millar (Health Canada).*

***External reviewer***

*1. Dr Mark Sculpher (University of York).*

# 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.*

# Governance and procedure

*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

| Date | Event | Purpose |
|---|---|---|
| 26 July 2018 | Full day in-person meeting 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 (TBC) | Two hour video-conference | Update on Working Group status. Opportunity for input from Working Group members. |
| Week of 10 September 2018 (TBC) | 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 in Ottawa | Present draft report. Report draft recommendations.<br>Final opportunity for input from PMPRB and Working Group members. |
| 26 October 2018 | Final report delivered to PMPRB | Final deliverable to PMPRB. |

# 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 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.*

# Background and Overview

# Group discussion

# Areas of focus

1. Options for determining what drugs fall into ‘Category 1’
2. Application of supply-side cost effectiveness thresholds in setting ceiling prices for Category 1 drugs
3. Drugs with multiple indications
4. Options for using the CADTH and/or INESS reference case analyses to set a ceiling price
5. Perspectives
6. Application of the market size factor in setting ceiling prices

# 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)*

**What are the potential approaches for considering a drug's opportunity cost and implementing a price ceiling?**

**Should higher price ceiling(s) be adopted for certain types of drugs? If so, which drugs? How should the higher price ceiling(s) be determined?**

# 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).*

**What are the available options regarding pricing for multiple indications?**

**Which option should be recommended, and why?**

# 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.*

**Do existing 'reference case' analyses provide the most appropriate estimates from which to derive a ceiling price?**

**If not, what modifications from the 'reference case' assumptions are desirable?**

**How should uncertainty be accounted for, or addressed, when setting price ceilings?**

# 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.*

**What are the key differences between a public health care system vs societal perspective?**

**What are the options to account for these differences?**

**How should a 'significant' difference be defined?**

# 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).*

**What approaches are available to consider an 'affordability adjustment' to a drug's ceiling price?**

**Should other factors be considered (in addition to market size and GDP)?**

**How should each of these factors be considered?**

# Closing