Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

PMPRB GUIDELINES SCOPING PAPER

High Level Overview of Potential New Framework

CGI CONSULTATION PHASE

Canada

Outline

- Introduction
- Issues with Current Approach
- Feedback on PMPRB Consultation
- New Framework
  - International Price Reference
  - Screening
  - High Priority
  - Medium and Low Priority
  - Re-benching
- Next Steps

Introduction

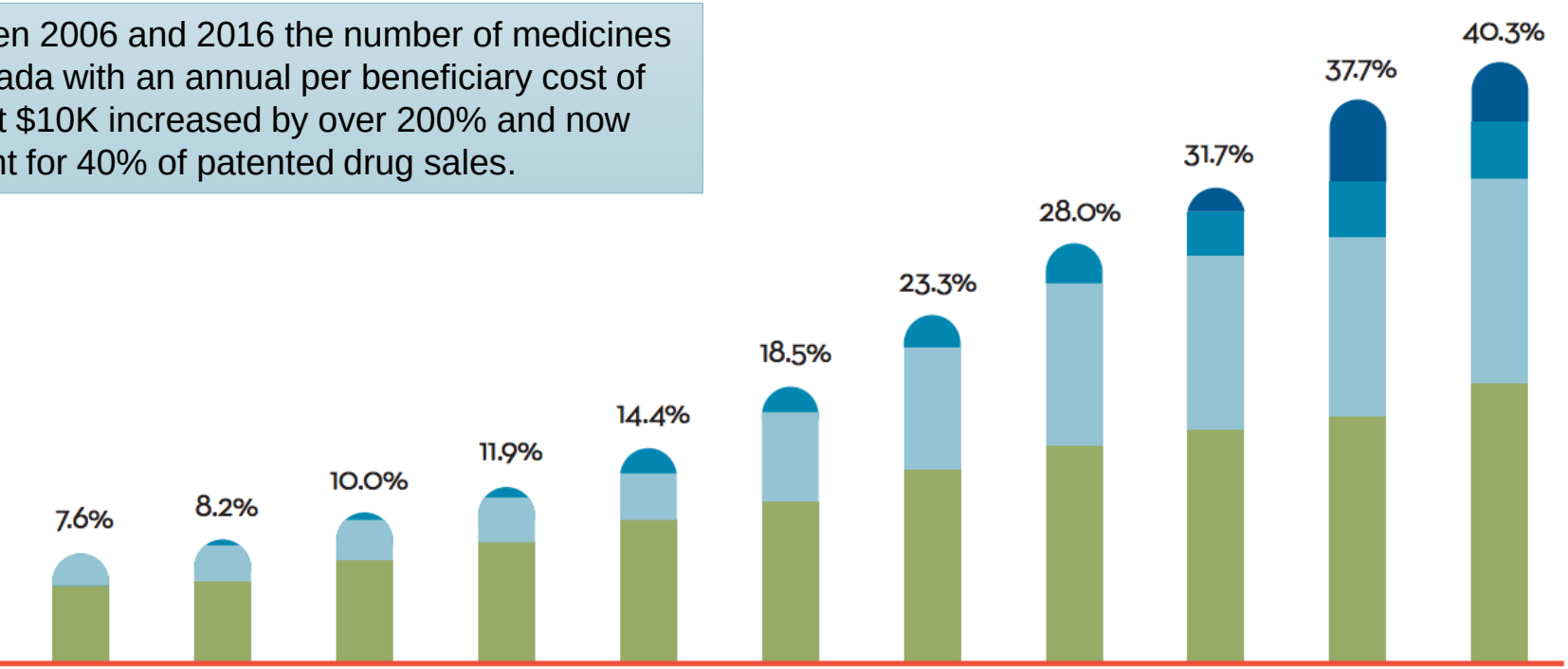
- Scoping paper is intended to be read in conjunction with proposed Patented Medicines Regulations (Regulations) amendments
- Aims to provide stakeholders with a high level outline of PMPRB's preliminary thoughts on how best to operationalize the proposed amendments
- Building on the feedback received to the 2016 PMPRB Guidelines Modernization Discussion Paper
- Intended to support a more informed, focused and productive consultation

Problems with current PMPRB approach

- Our basket of comparators is made up of premium priced countries and includes the US, an international outlier.
- Our system focuses on rewarding therapeutic benefit (not the job of a price regulator) instead of policing the risk of excessive pricing.
- All drugs are subject to the same level of regulatory scrutiny, regardless of price/cost and market dynamics.
- Our only absolute ceiling for existing drugs is highest international price.
- Me-too drugs can be priced at the top of the domestic therapeutic class.
- It is based on publicly available list prices, which are increasingly divorced from the true price net of confidential rebates/discounts.

Number of high-cost drugs is rising

Between 2006 and 2016 the number of medicines in Canada with an annual per beneficiary cost of at least $10K increased by over 200% and now account for 40% of patented drug sales.



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
10k-20k	5.2%	5.5%	6.9%	8.1%	9.6%	10.8%	12.9%	14.5%	15.6%	16.5%	18.7%
20k-50k	2.1%	2.4%	2.7%	3.0%	3.5%	6.0%	8.2%	10.9%	11.6%	12.0%	13.7%
50k+	0.3%	0.4%	0.5%	0.7%	1.3%	1.7%	2.2%	2.7%	3.2%	3.7%	3.8%
Total HCD	–	–	–	–	–	–	–	–	1.3%	5.5%	4.0%

Source: PMPRB Annual Report, 2016
Data Sources: PMPRB & QuintilesIMS, Private Drug Plan Direct Drug Plan Database, 2006-2016

Feedback on PMPRB Consultation

- The PMPRB has a relevant role to play in Canada's pharmaceutical ecosystem;
- There is a need for greater collaboration and coordination between and among players within that system;
- Not all patented drugs should be subject to the same level of oversight;
- Systems which recognize and reward therapeutic value send the appropriate market signal to patentees and encourage innovation;
- Drug price affordability and health system sustainability are legitimate considerations in assessing whether a price is potentially excessive and fall within the PMPRB's consumer protection mandate and regulatory purview;
- The price review process should include a life-cycle approach and be more responsive to changes in science and market conditions; and
- To the extent possible, the PMPRB should apply predictable, "bright line" tests in reviewing prices.

Summary of Proposed Amendments to the *Patented Medicines Regulations*

- New economics-based price regulatory factors
  - Pharmaco-economic value
  - Size of the market
  - GDP and GDP per capita
- Updated list of countries used for price comparison (PMPRB12)
- Complaints-based system of oversight for lowest risk patented drugs
- Require information on price adjustments (e.g., rebates, discounts) given to third parties in Canada

PMPRB Potential New 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: International Price Reference (list to list)
  - Part II: Screening
  - Part III: High risk drugs
  - Part IV: Medium and low risk drugs
  - Part V: Re-benching

Part II: Screening

- PMPRB would look primarily to the following considerations to classify new patented drugs as high priority:
  - first in class;
  - few or no therapeutic alternatives;
  - significant therapeutic improvement over existing treatment options;
  - indicated for a condition that has a high prevalence in Canada; or
  - high cost drug
  - high priority for HC or CADTH/INESSS
- Drugs that appear to meet these criteria would be considered “high risk” and would be subject to automatic investigation to determine whether their price is potentially excessive.

Part III: High-risk drugs – two step test

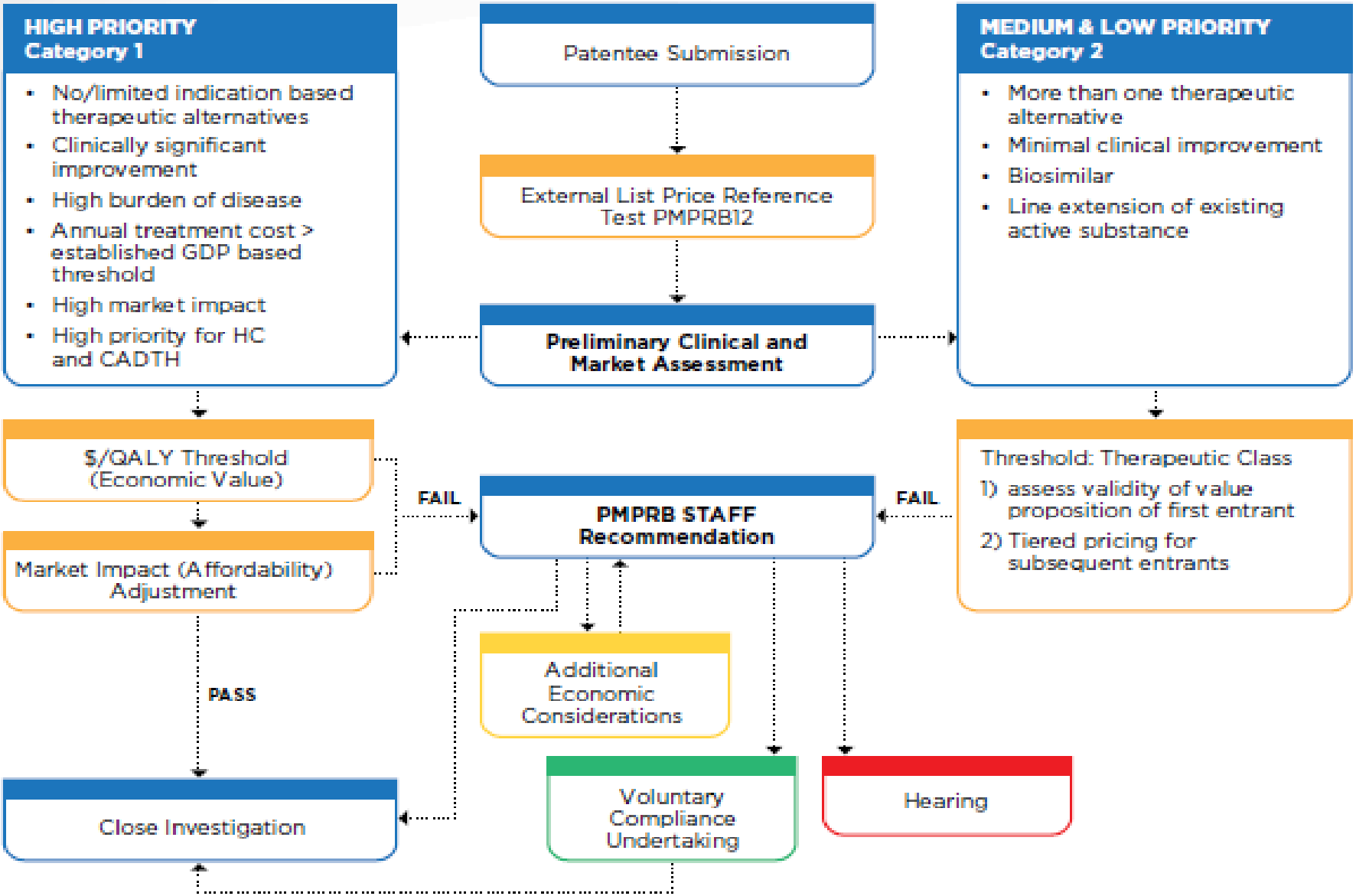
1. Assessment of the incremental cost per quality adjusted life year ($/QALY), as determined by CADTH or INESSS, against an explicit threshold
    - Drugs that prolong life or provide significant QALY gains could be subject to a higher ceiling price than would result from application of the threshold
2. Assessment of whether a drug that meets the $/QALY threshold should have its price further adjusted based on expected impact on payers
    - The test would consider the market size of the new drug against GDP growth
    - The test could also be used to allow a price adjustment upward in instances where a drug has a very high opportunity cost but very small market impact due to the extreme rarity of the condition

A patentee that failed either test would be given an opportunity to explain its price to the PMPRB based on the cost of making/marketing the drug, or other commercial considerations.

Part IV: Medium and low-risk drugs

- Drugs in this category would be expected to:
  - have a minimum number of therapeutic alternatives;
  - offer little or no therapeutic improvement over the standard of care; or
  - be subject to some degree of competitive discipline upon market entry
- Medium priority drugs would be subject to the same PMPRB12 test as high priority drugs.
  - Would also be subject to a percentage reduction from the price of the first in class drug, increasing stepwise for each successive entrant.
- Low-risk drugs, with several therapeutic alternatives or generic competition:
  - would not be subject to an introductory or ongoing s.85 analysis; and
  - would be investigated on a complaints basis only

PROPOSED PRICE REVIEW SCHEMATIC*



*For discussion purposes only, not intended to bind or limit the PMPRB or the Government in the application and interpretation of legislation

Part V: Re-benching

- Over time, the new framework would also include periodic re-benching of drugs to ensure price ceilings remain relevant in light of new indications or change in market conditions.
- Could result in an increase or decrease of the ceiling price.

Key questions for stakeholders in 2018

In seeking to operationalize the regulatory amendments…

1. What considerations should PMPRB use in screening drugs for high priority price review?
2. To what extent should low priority drugs be scrutinized?
3. How should a cost effectiveness threshold be established?
4. Should the application of a threshold be subject to further adjustment depending on market size considerations?
5. How should re-benching work and when should it occur (and to what drugs)?
6. What price tests should the PMPRB apply to the new PMPRB12?
7. How should the PMPRB make use of confidential third party pricing information?

Next Steps

- The PMPRB will officially consult on a revised set of proposed Guidelines in the spring of 2018.
- The Minister of Health has indicated that the new regulatory framework should be in place by January 2019.