Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

PMPRB Framework Modernization

Presentation to Steering Committee
June 25, 2018

Canada

Outline

- Background on Guideline reform
- Objectives and guiding principles
- Outline of new Guidelines framework
- Technical Working Group and Next Steps

The Government of Canada is committed to making prescription drugs more affordable

"A Liberal government's... priorities for a new Health Accord will include:

We will consult with industry and review the rules used by the Patented Medicine Prices Review Board to ensure value for the money governments and individual Canadians spend on brand name drugs."

JUSTIN TRUDEAU,
PRIME MINISTER OF CANADA

Minister of Health Mandate Letter

- improve access to necessary prescription medications. This will include joining with provincial and territorial governments to negotiate common drug prices, reducing the cost Canadian governments pay for these drugs, making them more affordable for Canadians, and exploring the need for a national formulary;

Government of Canada / Gouvernement du Canada

Home → Health → Health system and services → Health-related consultations → Consulting on Proposed Amendments to the Patented Medicines Regulations

Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations

Government of Canada / Gouvernement du Canada

Home → Budget 2017 → Budget Plan

Chapter 3 – A Strong Canada at Home and in the World

Prescription Medications and Health Innovation

To promote a more innovative health care system, Budget 2017 proposes measures that include:

- Improving access to prescription medications, lowering drug prices and supporting appropriate prescribing through an investment of $140.3 million over five years, starting in 2017–18, with $18.2 million per year ongoing, for Health Canada, the Patented Medicine Prices Review Board and the Canadian Agency for Drugs and Technologies in Health.

CBC | MENU

Ontario Health Minister Eric Hoskins to chair newly created federal pharmacare committee

Hoskins resigns as provincial health minister

Vik Adhopia · CBC News · Posted: Feb 26, 2018 4:38 PM ET | Last Updated: February 26

Reform of federal drug price regime long overdue

- The PMPRB and its regulatory framework were designed at a time before the Internet or cell phones
- Built to respond to changing intellectual property standards of the mid-1980s, price protection for patentees was seen as a good trade-off for attracting R&D
- Price ceilings were based on pricing data that was public and compared against the highest R&D jurisdictions in the hopes of emulating them
- In the 30 years since, the anticipated benefits haven't materialized and the regulatory pricing model is broken

Assessing Canada's Patented Drug Pricing Regulations

Original design and intent vs. current realities

Designed to respond to realities of the mid-1980s

- Changes to IP and price regimes in exchange for increased domestic R&D investment
- Price ceilings based on public list prices that reflect market prices
- Market dominated by small molecule drugs indicated for more common ailments

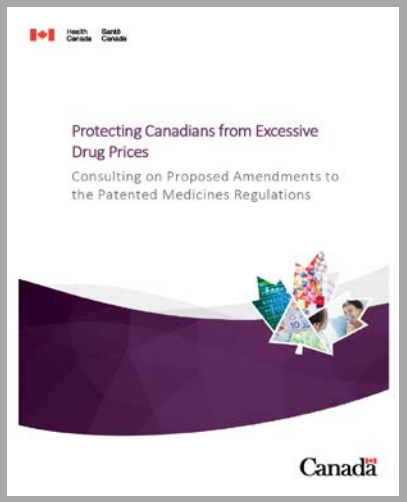
Like any technology intensive industry, pharma has evolved significantly

- Higher prices and a decline in domestic R&D investment
- Confidential rebates and inflated list prices
- Specialized biologic and genetic therapies are fastest growing drug classes

We've been consulting since June 2016

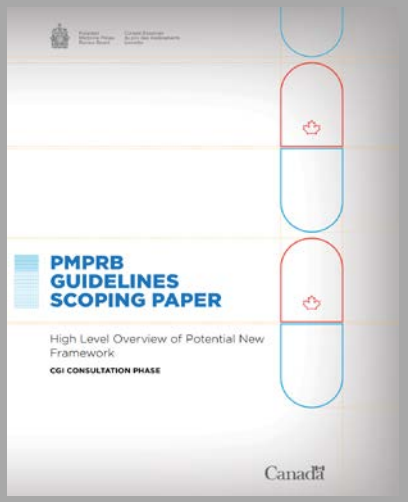
PMPRB Discussion paper on Guideline reform

Health Canada pre-consultation on regulatory amendments



Health Canada Gazette 1

PMPRB Guidelines scoping paper

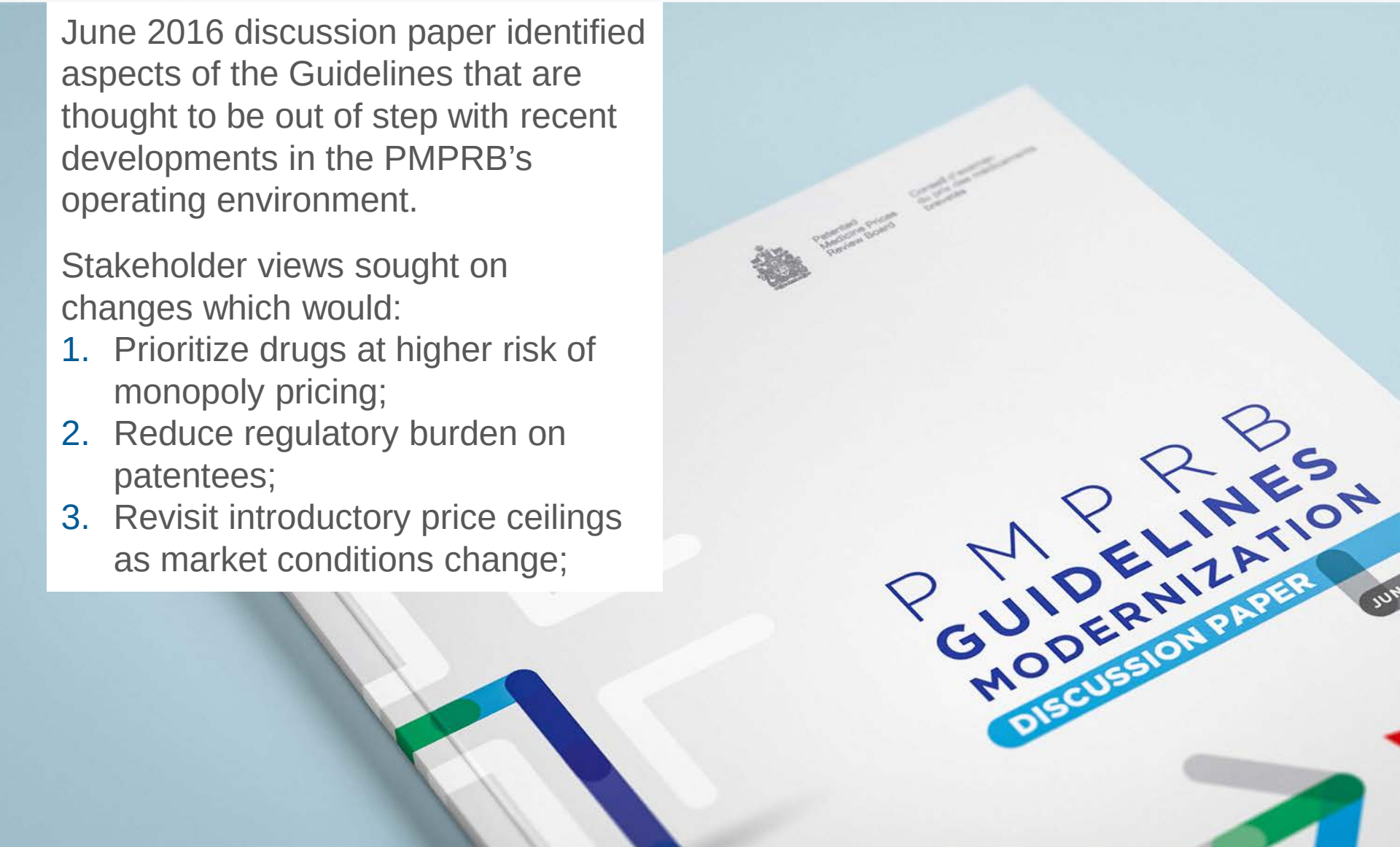


PMPRB discussion paper on Guideline reform

June 2016 discussion paper identified aspects of the Guidelines that are thought to be out of step with recent developments in the PMPRB's operating environment.

Stakeholder views sought on changes which would:

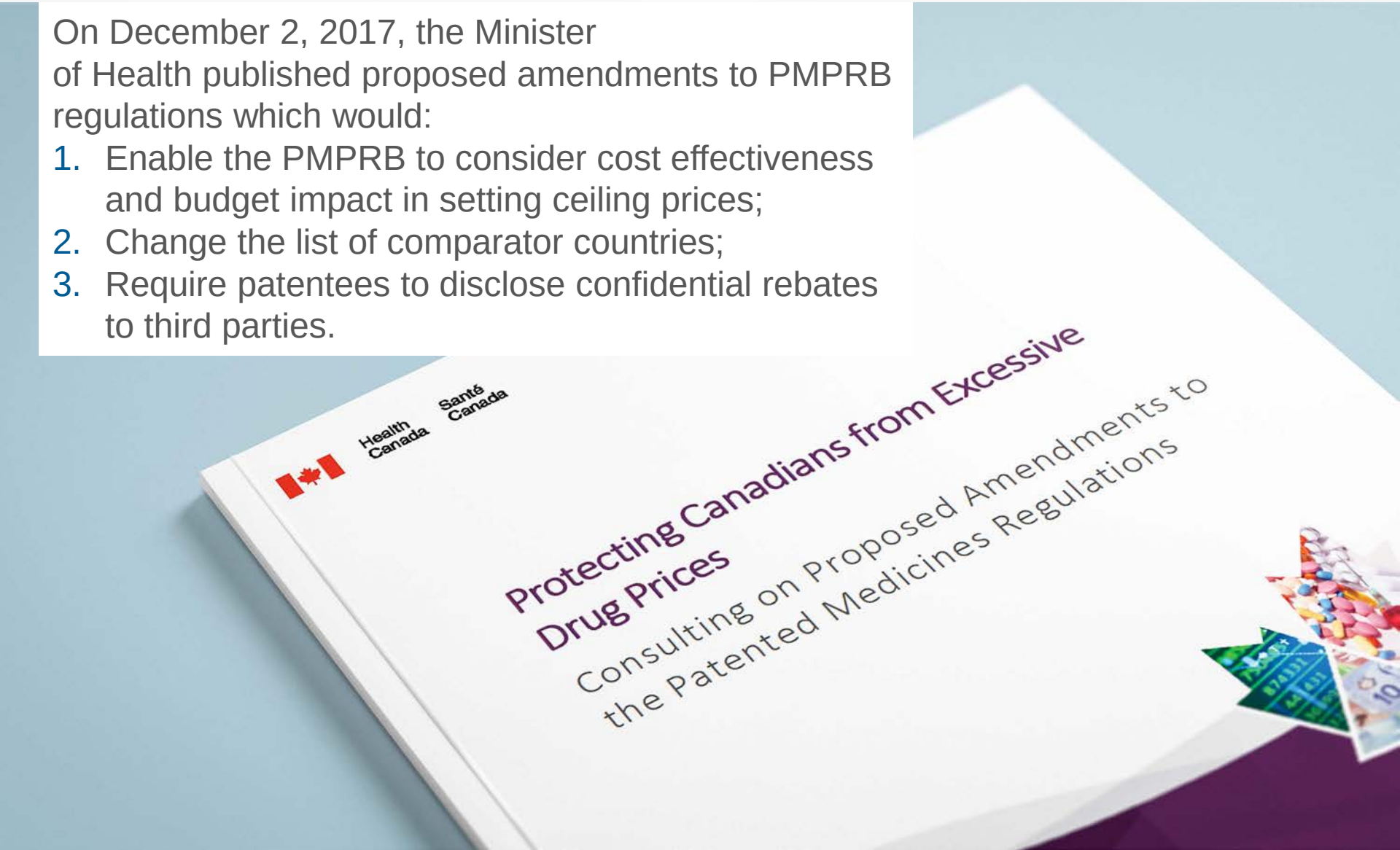
1. Prioritize drugs at higher risk of monopoly pricing;
2. Reduce regulatory burden on patentees;
3. Revisit introductory price ceilings as market conditions change;



Health Canada proposed regulatory amendments

On December 2, 2017, the Minister of Health published proposed amendments to PMPRB regulations which would:

1. Enable the PMPRB to consider cost effectiveness and budget impact in setting ceiling prices;
2. Change the list of comparator countries;
3. Require patentees to disclose confidential rebates to third parties.



Latest step: Steering Committee

- The Steering Committee is being asked to provide targeted stakeholder feedback on key features of a new Guidelines framework which will serve the following dual objectives:

1. Operationalize amendments to the Patented Medicines Regulations designed to lower patented drug prices; and,
2. Support a risk-based approach to regulating drug prices that simplifies and streamlines compliance for patentees.

- In deliberating on the above, the Steering Committee should seek to strike a balance between the following guiding principles:
  - Sustainability
  - Predictability
  - Consistency
  - Functionality
  - Fairness
- The Steering Committee will be assisted by a technical Working Group (the "**Working Group**") with expertise in health technology assessment and other economic and scientific matters.

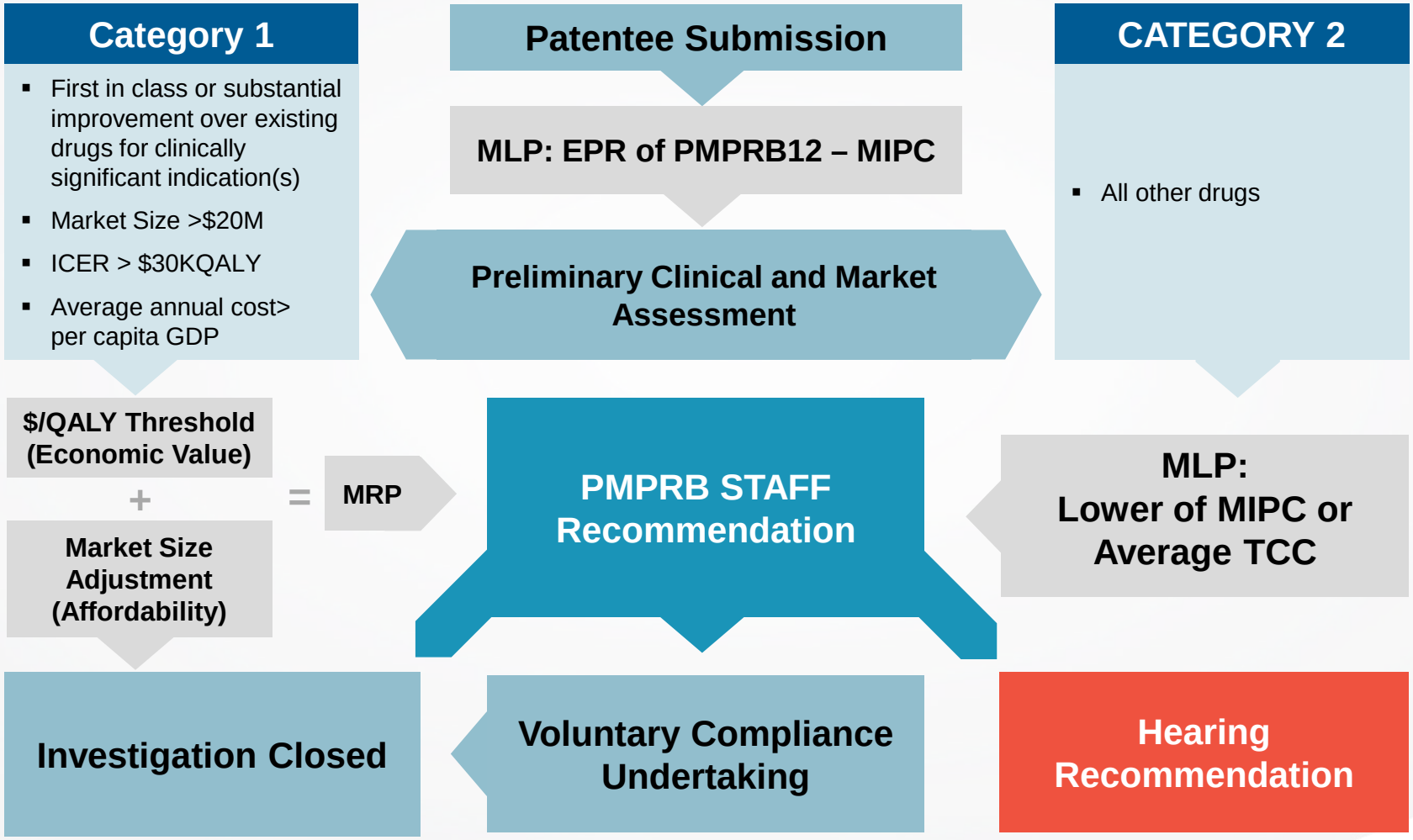
Suggested questions for Steering Committee

- Is the proposed division and treatment of Category 1 and Category 2 drugs a reasonable risk-based regulatory approach?
- Is an MLP based on the median of the PMPRB12 (MIPC) for all drugs 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 drugs based on LIPC?
- Should further drug categories exist with different treatment modalities from those proposed?
- Should more or less criteria be considered in screening a drug 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 drugs be scrutinized more or less than proposed?
- Should the cost effectiveness threshold for Category 1 drugs vary?
- Should a Category 1 drug ever have more than one MRP?
- Are there economic considerations that would support a higher MRP for some Category 1 drugs than would result from the proposed application of the new factors?
- How often and in what circumstances should a drug be rebenched?
- Should confidential third party pricing information only be used for compliance purposes?
- Is there a better way to deal with existing drugs under the new framework?
- Are there opportunities to further reduce regulatory burden while respecting the dual objectives?

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 drugs at introduction based on median of PMPRB12 (MIPC)
  - Part II: Screening of drugs into high priority (Category 1) or low priority (Category 2)
  - Part III: ‘Maximum Rebated Price’ (MRP) for Category 1 drugs based on new pharmacoeconomic, market size and GDP factors
  - Part IV: Lower of MIPC and average of Therapeutic Class (ATCC) for Category 2 drugs
  - Part V: Re-benching
- The MLP will be a transparent ceiling based on public list prices but the MRP, which applies to Category 1 drugs only, will be confidential.
- To comply with the MRP, patentees of Category 1 drugs will be required to submit information on undisclosed rebates to third parties.

Proposed PRICE Review Schematic



Old vs new regime…

Rule	How The Current Regime Works	How The Updated Regime Would Work
How international prices affect maximum prices in Canada	A new and improved drug cannot be priced higher than the median price of that same drug in the PMPRB7	All new drugs cannot be priced higher than the median price of that same drug in the PMPRB12
How domestic prices affect maximum prices in Canada	A new drug that isn't an improvement over existing drugs cannot be priced higher than the highest priced existing comparator drug in Canada	A new drug that isn't an improvement over existing drugs cannot be priced higher than the lower of the average price of existing comparator drugs in Canada and the median of the PMPRB12
How inflation affects maximum prices in Canada	The price of a drug can increase every year with inflation. However, if a drug's price decreases in one year, its ceiling price the next year will be constrained by that decrease in price.	The ceiling price of a new drug is fixed at introduction. Prices can vary freely below this level in subsequent years. .
Changes to the maximum ceiling price after a new drug enters Canada	Once a new drug is given its ceiling price, it can only change through inflation or if the drug company voluntary lowers it.	The maximum price may be rebenched after a few years based on specific changes in market conditions.

Old vs new regime (continued)

Rule	How The Current Regime Works	How The Updated Regime Would Work
Pharmacoeconomics	How much a drug costs for the amount of benefit it provides (e.g., $100 a pill for a year of healthy life) is not considered by the PMPRB in setting a maximum price	The cost-effectiveness of Category 1 drugs in terms of cost per quality-adjusted life year (QALY) is assessed against an evidence based threshold
Market size and GDP*	The total amount of money available to be spent on new drugs every year is not considered by the PMPRB in setting a maximum price	The market size of a new drug is a function of how much it costs and how many patients will need it. Drugs that are expected to have a significant market size and impact on the healthcare system will have a lower ceiling price to deter rationing.

*Each year, the amount of money available to be spent on new drugs depends on total spending on drugs the year before and how much the economy is growing. For example, if Canada spent $1000 on drugs in 2018 and its economy grew by 2%, it would have $20 more to spend on the new drugs that come to market in 2019 (for a total of $1020)

Part 1:Median international price test (MIPC)

- All new drugs are assigned a Maximum List Price (MLP) based on the median of the PMPRB 12 (MIPC).
- IMS will be used to verify international list prices.
- Category 1 drugs will be given both an MLP based on the MIPC and a Maximum Rebated Price (MRP)
- All other drugs will be deemed Category 2 and have an MLP based on the lower of the MIPC and the average of the domestic therapeutic class (ATCC).
- No Category 2 drug will be given an MLP that is lower than the lowest price country in the PMPRB12 (LIPC floor).

Part II: Screening

- Drugs will be screened into Category 1 if they are:

1. First in class or substantial improvement over existing therapy
2. Expected to have sales in excess of a $20 million/year market size threshold
3. Above a $30K/QALY threshold for clinically significant indications
4. Have an average annual treatment cost above per capita GDP.

Part III: MRP for Category 1 drugs

- Step 1: application of pharmacoeconomic factor
  - Empirical work undertaken by Karl Claxton at the University of York suggests a $30K/QALY opportunity cost threshold for Canada.
  - PMPRB will use this estimate at the screening phase to determine whether a drug should go in Category 1 or Category 2.
  - Category 1 drugs will then be subject to a baseline maximum value-based price ceiling of $60K/QALY, for reasons of practicality and efficiency.
  - Drugs that meet certain clinical characteristics (e.g., high burden of disease or significant absolute gain in QALY) may be subject to a higher $/QALY ceiling.

Part III: MRP for Category 1 drugs (continued)

- Step 2: application of market size and GDP factors
  - A Category 1 drug that meets the applicable $/QALY ceiling may still face an adjustment in price if the application of the market size and GDP factors raise affordability concerns.
  - Using new drug contribution to GDP and GDP growth over the last five years, the PMPRB is estimating a threshold of $20M per new drug.
  - New Category 1 drugs with an estimated market size that exceeds this threshold within any of its first five years of sale will require further price adjustments.
  - The adjustment would see the MRP reduced by a certain percentage discount which would increase as the expected market size increases (see next slide).
  - The $20M threshold would also increase annually based on GDP growth and/or CPI.

Application of new factors to Category 1 drugs

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

Part IV: MLP for Category 2 drugs

- As mentioned, Category 2 and have an MLP based on the lower of the MIPC and the average of the domestic therapeutic class (ATCC).
- However, no Category 2 drug will be given an MLP that is lower than the lowest price country in the PMPRB12 (LIPC floor).

Part V: Re-benching

- All new drugs will be given an interim MLP of 3 years or until the drug 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

How compliance with new price ceilings will be assessed

- Price reviews will be conducted for the following customer classes:
  - National Retail – list price assessed against MLP
  - National Private Payer – average transaction price (ATP) assessed against MRP
  - Provincial Public Payer – ATP assessed against MRP in each market
- ATPs are calculated net of all discounts to determine compliance with confidential MRP.
- Category 2 drugs will be assessed against MLP.

How pricing complaints will be managed

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

1. a drug is in compliance with the Guidelines; and
2. whether circumstances in the market have changed to warrant a rebenching/reclassification.

Application of new Guidelines to existing drugs

- Existing drugs will be given an interim price ceiling based on the MIPC of the PMPRB12.
- An existing drug will only be classified as Category 1 if it fails a $100K/QALY screen for any indication.
- Existing drugs that are screened into Category 1 will be prioritized for re-benching.
- Category 2 drugs will be re-benched later unless a complaint is received.
- All drugs within a therapeutic class will be assessed at the same time for the purposes of the ATCC test.
- Patentees will be advised in advance of re-benching and given two reporting periods to come into compliance.

Reminder: suggested questions for Steering Committee

- Is the proposed division and treatment of Category 1 and Category 2 drugs a reasonable risk-based regulatory approach?
- Is an MLP based on the median of the PMPRB12 (MIPC) for all drugs reasonable?
- Should exceptions be made to the MLP-MIPC test and, if so, when and why?
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Technical questions for analysis and recommendation by the Working Group

- The draft Terms of Reference for the Working Group identify the following issues:
    - The economic and scientific rationale for selecting specific criteria for screening drugs as high priority and associated metrics
    - How opportunity cost and willingness to pay should factor into the application of cost effectiveness thresholds
    - How to address drugs with multiple indications
    - How to make optimal use of CADTH and INESSS analyses and how to account for uncertainty in doing so
    - How to assess affordability by applying market size and GDP factors
- The Steering Committee has until July 13 to identify further issues it believes would benefit from expert review and analysis.

Annex

ICER calculations for Canada based on Patented drugs sales

Item	Parameter	2012	2013	2014	2015	2016	Source
1	Growth in GDP 2014–15 (+1%)	2.75%	3.48%	3.57%	1.94%	2.43%	OECD
2	Total Healthcare spending ($B)	$205.40	$209.30	$215.80	$222.10	$228.00	CIHI
3	Contribution of patented medicines %	6.43%	6.50%	6.53%	6.80%	6.80%	Calculation (Row 4 / Row 2)
4	Contribution of patented medicines ($B)	$13.20	$13.60	$14.10	$15.10	$15.50	PMPRB
5	Annual threshold for net healthcare cost growth for all new patented medicines ($M)	$363	$473.28	$503.37	$292.94	$376.65	Calculation (Row 1 X Row4)
6	Average number of patented medicines per year	35	35	35	35	35	PMPRB
7	Annual threshold of average cost growth per new patented medicine ($M)	$10.4	$13.5	$14.4	$8.4	$10.8	Calculation (Row 5 / Row 6)
8	Annual threshold for estimated budget impact for each new patented medicine ($M) Multiplied by 2	$20.7	$27.0	$28.8	$16.7	$21.5	Calculation (Doubling of Row 7)
9	Annual threshold for estimated budget impact for each new patented medicine ($M) Multiplied by 3	$31.1	$40.6	$43.1	$25.1	$32.3	Calculation (Tripling of Row 7)