COMMITTEE BRIEF

HOUSE OF COMMONS STANDING COMMITTEE ON HEALTH (HESA)

STUDY ON THE IMPACTS OF THE PATENTED MEDICINE PRICES REVIEW BOARD (PMPRB) AND ITS GUIDELINES ISSUED OCTOBER 23, 2020

November 6, 2020

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ABOUT INNOVATIVE MEDICINES CANADA

Innovative Medicines Canada (IMC) is an association of 43 biopharmaceutical and vaccine companies that represents the majority of patentees subject to the authority of the Patented Medicine Prices Review Board (PMPRB). IMC members re-invest around 9.97% patented medicines revenues into developing new medicines in Canada and provide some $900 million annually through patients support programs that benefit 673,000 Canadians and help provinces address health system needs.

IMC and its members have participated in every stage of a multi-year process regarding policies that would significantly change the role of the PMPRB. Throughout this process, the input of our industry and other stakeholders has been consistently dismissed or disregarded. Therefore, we are encouraged to see this critical health policy issue subject to parliamentary review and scrutiny.

Recommendation

With PMPRB changes scheduled to come into effect in a matter of weeks, our industry encourages HESA to call on the Government to remove the experimental "new economic factors" from the regulations which are the source of the majority of stakeholder concerns. At a minimum, the government should delay the implementation of PMPRB regulatory changes until the COVID-19 pandemic has abated.

Rationale: A suspension of the January 1st , 2021 scheduled implementation is needed to allow all parties to address the COVID-19 pandemic and to provide more time for the Federal Standing Committee on Health to study the issue, and to recommend alternative PMPRB changes that will not impact the timely launch of new medicines in Canada. The imposition of flawed and controversial policy changes during a national health crisis inappropriate and unreasonable given the need for governments, industry, and other stakeholders to prioritize resources to address COVID-19.

Key Considerations

- Throughout the PMPRB reform process, and in addressing the COVID-19 pandemic, the innovative pharmaceutical and vaccine industry's primary goal is to support the health and well-being of Canadians.
- Unfortunately, the PMPRB changes scheduled to come into effect on January 1, 2021 will do nothing to help achieve this objective and, unless fundamentally altered, will limit access to new medicines and vaccines in Canada.
- The proposed changes to the PMPRB reflect a multi-year policy failure, given that no savings have been realized since 2016. Additionally, a critical component of the new regime has been invalidated by the Federal Court of Canada, yet the PMPRB continues to push forward with Guidelines changes that are not ready to be implemented in less than two months.

- Innovative medicines manufacturers have put multiple alternative solutions on the table to address affordability objectives in a manner that would preserve timely patient access in the future. To date, repeated attempts by the industry to work collaboratively on a more pragmatic path forward have not been meaningfully considered by Health Canada.
- Third party analysis indicates that Canadians will realize $19.8 billion in savings over ten years on international basket changes alone (i.e. through price comparisons with other countries). This significantly exceeds Health Canada's outdated estimate of $13.2 billion in savings.
- The industry has also offered an additional $1 billion to help address rare diseases and a made-in-Canada manufacturing and commercialization accelerator.
- However, Health Canada has not engaged in meaningful dialogue on these alternatives and has consistently ignored concerns of many stakeholders, including patients, the rare disease community, life sciences groups, provinces including Quebec and Ontario, and producers of innovative medicines and vaccines.
- The PMPRB has essentially acknowledged that the proposed regime will have negative access consequences by creating exemptions from the Guidelines for COVID-19 medicines and vaccines.
    - Why is this special treatment needed for some products, but no similar measures provided for other Canadian patients who will be negatively impacted, such as those suffering from cancer, cystic fibrosis, and a range of other severe illnesses?
    - Regardless of PMPRB policy declarations, the industry and patients do not have ultimate assurances that the changes will not impact COVID-19 medicines and vaccines, because these exemptions are non-binding and subject to change by the PMPRB at any time.

ATTACHMENT - *PMPRB: Background, Key Concerns, and Impacts*

PMPRB: Background, Key Concerns, and Impacts

INNOVATIVE MEDICINES CANADA

MÉDICAMENTS NOVATEURS CANADA

Background: Health Canada and PMPRB have disregarded or dismissed fundamental stakeholder concerns at every stage

Milestone	Lead	Industry / Patient Concerns
Canada Gazette Part I Dec 2017	Health Canada (IMC Response)	New economic factors; mandatory reporting of 3rd party payments; product launch concerns; Industry proposed alternative approaches (disregarded)
Re-assessment of CBA Impacts	3rd party (Report)	Excessive Impacts: $26 billion (vs $8.6 Health Canada estimate) NPV over 10 years
Review of Cost Benefit Analysis (CBA) Methodology	Dr. David Dodge	No industry input into review mandate, which was restricted by Health Canada to the reasonableness of the CBA without consideration of other relevant materials Report acknowledged relevant PMPRB materials were beyond analytical scope, resulting in a significant underestimation of the impact.
IMC Alternative Proposal Oct 2018	IMC	Savings comparable to government estimates to be achieved without major negative impacts through more reasonable policy tools; collaborative approach for rare diseases Rejected by Health Canada and ISED with no further discussions provided
PMPRB Steering Committee Spring 2019	PMPRB (Report)	Numerous stakeholders concerns that this was not a meaningful consultation
PMPRB Working Group Mar 2019	PMPRB (Report)	Experts called for more study in several critical areas regarding the new economic factors – concerns remain unaddressed
Canada Gazette Part II Aug 2019	Health Canada	No significant changes to the two most concerning elements (new economic factors and mandatory 3rd party payment reporting)
Guidelines 2019 (Version 1; December 2019)	PMPRB (IMC Response)	Several products already delayed launch; no solution to address DRD Serious flaws and no viable path to implement new economic factors and related maximum rebated price (MRP) concept; several new price tests in Guidelines with negative impacts **62% of stakeholder submissions either opposed the Guidelines or raised concerns**
PDCI Impact Assessment	3rd party (Report)	Guidelines worse than expected: **$41.8 Billion NPV over 10 years** (vs $8.8 in revised Health Canada estimate) - 82.8% average price reductions for rare disease medicines; 60.8% average price reductions for cancer medicines
Guidelines 2020 (Ver 2 June 2020)	PMPRB (IMC Response)	No fundamental change to the most concerning elements of the Guidelines **Over 80% of stakeholder submissions now opposed or raised concerns**
IMC 2020 Alternative Proposals (*new*)	IMC	Cost savings to assist govt affordability objectives; address rare diseases; made-in-Canada manufacturing accelerator; addressing coverage gaps through patient supports

Background: Long process, but lack of responsiveness to stakeholder concerns

2016

- PMPRB Guidelines Consultation #1
- (June – October)

2017

- Minister Philpott Speech and Launch of HC Consultation "Protecting Canadians" (May/June)
- Proposed Amendments Patented Medicines Regulations and CBA (CG1) (Dec 2 2017-Feb 14 2018)

2018

- Joint Associations letter HC & ISED
- PMPRB SC/ TWG established
- Third party review of CBA
- IMC Process concerns letter
- IMC Alternative Proposal/ DMs meeting Oct

2019

Q1/2 | Q3/4

- Letter seeking response to IMC Alternative proposals
- Regulatory changes finalized: Canada Gazette Part 2: Aug 21
- Federal Election: Oct 21
- Canada Gazette Part II
- TWG/SC Report(s) / processes Finalized
- Legal challenges launched
- Letter to new HM re suspension Dec 10
- Draft Guidelines Posted November 21
- PMPRB Meeting w Industry Dec 9

2020

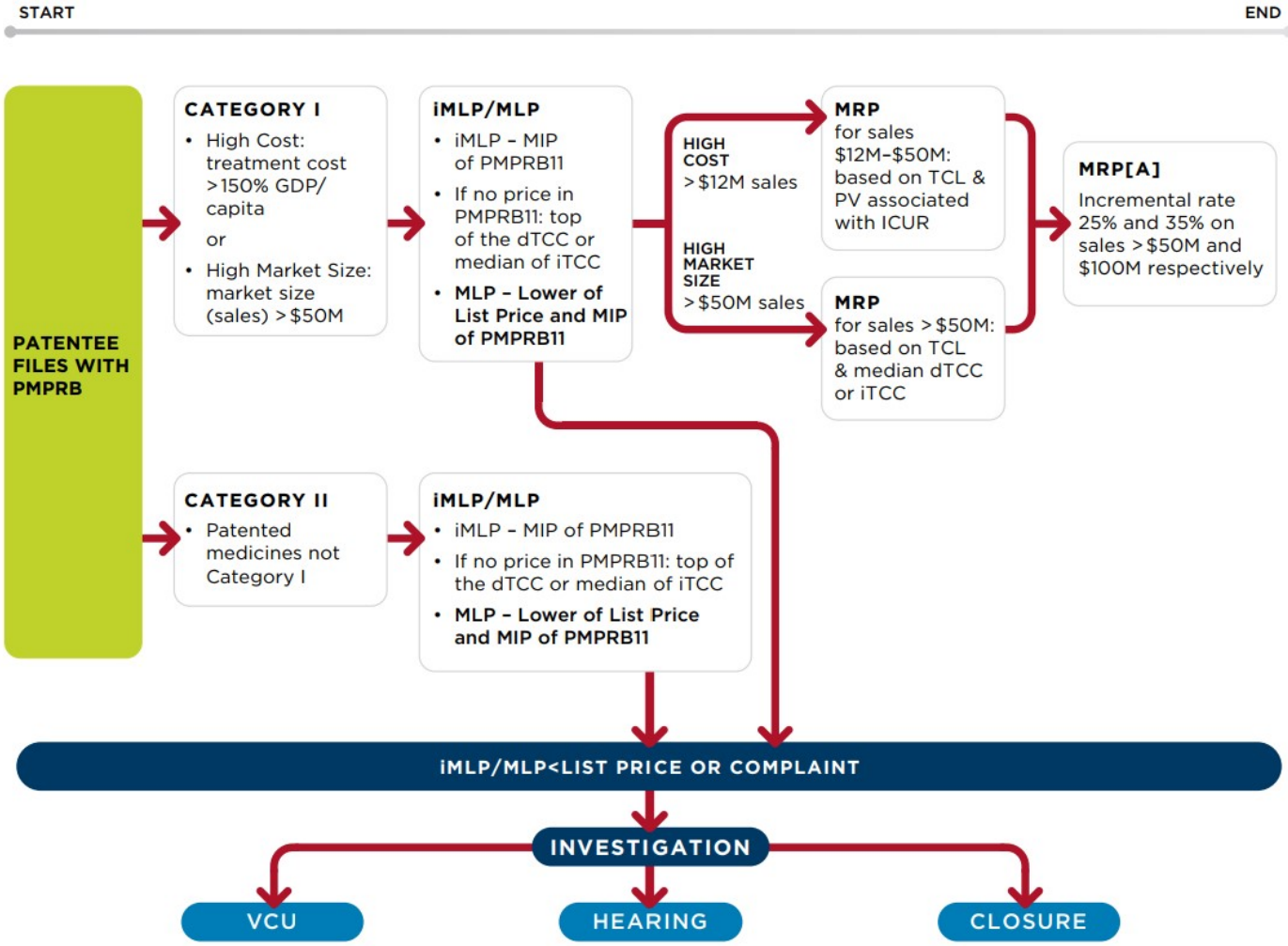
Q1 | Q2 | Q3 | Q4

- Technical working groups: None
- COVID-19
- Regs Delayed 6 months due to COVID-19
- Regs to be in effect Jan 1, 2021
- PMPRB Policy Forum: Cancelled
- PDCI Guidelines Impact Report $41.8 Billion NPV/ 10 years
- Federal Court Invalidates a Central Regulatory Change June 29
- PMPRB Meeting w Industry July 21
- Guidelines Finalized Oct 23
- PMPRB Guidelines responses submitted: Feb 14
- Draft #2 Guidelines Posted June 2020
- PMPRB Guidelines #2 responses submitted: August 4

Top concerns: Flawed policies that will impact the launch of new drugs and vaccines

- New Economic Factors
  - Pharmacoeconomics/HTA; Market size; GDP / GDP-per-Capita (these will make Canada an international outlier and discourage investment, clinical trials and new drug launches)
  - These are new/experimental and are the source of severe industry concern regarding future drug and vaccine launches in Canada
  - PMPRB regulatory changes introduce pharmacoeconomic factors not used anywhere else in the world as part of price regulation
  - Easy to remove from regulation. Their removal would enhance predictability for medicine and vaccine producers at a critical time and send the signal that government intends to balance affordability objectives with access to future innovations and vaccines in Canada.
  - The PMPRB has not factored in the effects the changes will have on the launch of new medications or on the number of clinical trials occurring in Canada
- Mandatory reporting of third-party payments
  - Provision invalidated by Federal Court of Canada on June 29, 2020, but decision is under appeal.
  - Unclear whether PMPRB will respect the letter and the spirit of the court decision.

Guidelines are convoluted: Stakeholders still do not know how rules coming into force on Jan 1, 2021 will be applied



Guidelines Consultations Demonstrate Mounting Stakeholder Opposition to PMPRB Changes

February 14, 2020 Guidelines

August 4, 2020 Guidelines

65% responses *opposed*

80%+ responses *opposed (112 submissions)*

50% access / launch concerns

65% access / launch concerns

PDCI MARKET ACCESS
Canada's Leading Pricing and Reimbursement Consultancy

Impact of International Basket Changes Alone are Significant and Exceed Previous Estimates (PMPRB11)

Government's public savings commitment

$13.2 billion
in the next decade*

Impact of PMPRB11 Basket Changes Alone

$19.8 billion
over 10 years**

*https://www.canada.ca/en/health-canada/news/2019/08/government-of-canada-announces-changes-to-lower-drug-prices-and-lay-the-foundation-for-national-pharmacare.html
**Per PMPRB Guidelines, assumes Gap products set at the median; existing products set at the top of the PMPRB11

Key Concerns by the Numbers

- **Only 15 of 54 drugs** approved by the FDA since 2019 have been submitted to Health Canada for approval.
- At least **6** planned drug launches by member companies have been delayed, including for rare diseases and the area of antimicrobial resistance (AMR)
- **30% – 40%** fewer new drug submissions made within 12 months of the drug being submitted for approval elsewhere in the globe , compared to the previous 3 years (24%).
- Asked which of their therapeutic areas in Canada will be negatively impacted by the PMPRB changes, pharma executives said: **oncology** (53%), **rare disorders** (44%), **immunology** (36%), **diabetes** (14%), and **vaccines** (11%).

Source: IMC analysis; "Early signs of negative impacts for patients of Health Canada Pharmaceutical Pricing Reforms" – IMC-Life Sciences Ontario