PMPRB RESEARCH MYTH-BUSTING

Highlights:

In June and July 2020, the PMPRB presented public research webinars on topics regarding drug pricing, market size, drug launches, investment, and shortages.[1]

The PMPRB's research is framed to support its proposed Guidelines policy approach. It also aims to refute findings by other sources concluding that the PMPRB proposals have already had, or will have, a negative impact on clinical trials and access to new medicines in Canada. Specifically, the PMPRB has criticized the data and methods used by these studies.

However, there are several limitations with the PMPRB's methods which raise concerns regarding objectivity and rigor.

A comprehensive review of the existing body of research demonstrates that there is greater evidence of a decline in clinical trials and access to new medicines than there is evidence which supports the conclusion of "no impact," as advanced by the PMPRB's research. Numerous studies in the literature demonstrate the correlation between R&D/clinical trials and new drug access with drug prices/sales. Additionally, two recent analyses (IQVIA-LSO and IMC/LSO-Conference Board of Canada) suggest there are already signs of potential impacts in the time period coinciding with PMPRB regulatory amendments that were announced in August 2019 (see the Evidence Toolkit).

The following is a summary of statements made by the PMPRB, with counterpoints, supporting rationale and data sources.

[1] *"Insight into the spending on expensive drugs for rare diseases"; "Insights into the market size of patented medicines in Canada"; "Drug pricing and its impact on R&D investments, clinical trials and availability of medicines in Canada"; " Drug Shortages in Canada; An overview of the causes, reporting, and mitigation strategies in Canada and internationally; Are Canadian shortages associated with lower prices than in other countries?; A Canadian drug shortage case study with international price comparisons."*

Limitations in PMPRB Research:

PMPRB says …	In fact …	Supporting details …
Patented pharmaceutical prices in Canada are among the highest in the world and keep rising	Patented pharmaceutical prices in Canada are already below the median of our global peers and have declined to the lowest they have ever been in the history of the PMPRB's existence	The PMPRB's own data does not support its public statements: • Only 3 of the PMPRB7 countries have prices below Canada, and the price difference for those countries is minor (prices in Sweden and Italy are 3-5% below Canadian prices). (source: PMPRB Annual Reports) • Moreover, relative prices have declined over time. Prices in Canada have been around 20% below the median of the PMPRB7 for the past 3 years, which is the lowest they have ever been in the history of the PMPRB since it was first created in 1987. (source: PMPRB Annual Reports) • The PMPRB asserts that US prices are a global outlier and makes Canada's prices appear lower than they are. However, even when prices are only compared to the European countries in the PMPRB7, Canadian prices are still in line with the PMPRB7 median, according to the last five PMPRB Annual Reports. The PMPRB has acknowledged this fact in their Meds Entry Watch report series, indicating that Canadian prices for new patented drugs are consistently lower than, or in line with, the European countries. (source: PMPRB Annual Reports, Meds Entry Watch series) There are methodological issues with the price sources the PMPRB uses to claim Canada's drug prices are high relative to other nations: • The PMPRB uses "sales data" from IQVIA MIDAS, which is not an official price source to fulfill their regulatory mandate to monitor "prices", according to the Regulations. In some cases, when using this methodology, the price can be 20% lower in comparison to an official price source. (source: PMPRB Annual Report) • Comparing the price difference to the 36-country OECD median is inaccurate, since the current PMPRB basket of countries refers to prices in only 7 countries, and the new basket expands the list to 11. Moreover, many OECD countries are inappropriate comparators to Canada due to their significantly different global standing in key development measures such as quality of health care and income per capita.

Expensive drugs are becoming unsustainable in Canada and their prices need to be lowered.	Expensive drugs treat unmet needs, generally for small patient populations, and have demonstrated their ability to reduce health care costs, improve quality of life, and increase productivity. Drugs that treat unmet needs, such as drugs for rare diseases (DRDs), should be prioritized in Canada, not discouraged from launching in Canada. The PMPRB Guidelines will have disproportionate impacts for many rare disease medicines and, as a result, fewer will be launched in Canada. The solution to making DRDs sustainable and accessible to Canadian patients requires Canada to adopt innovative agreements that recognize the delayed nature of clinical evidence for these drugs, not to dramatically cut prices.	There are methodological issues with PMPRB data that suggests Canada spends more on drugs for rare diseases (DRDs) than other countries: • The PMPRB uses different data sets amongst jurisdictions that do not adequately capture spending in other countries in comparison to Canada. (source: PMPRB) • Fewer DRDs come to Canada, and those that do take longer to be filed, approved, and reimbursed, compared to other countries that have rare disease drug frameworks. Without a rare disease drug framework, Canada is an outlier amongst developed nations. As a result, Canadian patients do not have the access they should to these innovative medicines. (source: IMC CADTH Symposium Poster on Reimbursement timelines, *IMC Factors Associated with Regulatory Filing and Approval Timelines, presented at DIA Annual Canadian Summit, October 2018*). The PMPRB's research implies that drugs for rare diseases are expensive and of limited value, ignoring the savings they offer the health care system, productivity improvements to Canadians and, most important, the quality of life improvements for patients. PMPRB's response to a more holistic view of DRD benefits versus costs is that the consideration of such reasonable factors is outside of their mandate. • PMPRB's own data demonstrates that prices for DRDs are aligned across countries globally and therefore they are not higher in Canada than in other countries. (source: PMPRB Webinar) • The savings that "expensive" medicines bring to the health care system and to employers, and the value they bring to patients are significant but are not considered in valuations by drug budgets or the PMPRB (source: Health Affairs; the Conference Board). Other jurisdictions (e.g. Scotland), incorporate these types of indirect costs and benefits in their reimbursement value assessments as part of their orphan drug framework (source: Scottish Medicines Consortium) • The value of DRDs is demonstrated by the regulatory frameworks implemented in other countries with high unmet needs, who incentivize companies to research and develop treatments for rare diseases (e.g. FDA, EMA, and Japan). Many of these countries have streamlined patient access pathways enabling innovative value-based agreements between regulator, payer and manufacturer. These agreements utilize real world evidence and performance or outcomes-based measures. Dramatically cutting prices for DRDs and denying patients' access to these drugs is not the solution. Rather, allowing Canadian systems to adopt innovative agreements that recognize the delayed nature of clinical evidence, enable patient access, and ensure payers pay for rare disease drugs. (source: IMC CADTH Symposium Poster on Reimbursement timelines)

R&D investment is not linked to pricing, and thus, lowering prices will not reduce R&D investments in Canada. Clinical Trials in Canada have been declining over time, and the decline is unrelated to the PMPRB's new regime.	R&D investment is correlated to price because lower prices reduces sales, and therefore impacts a company's ability to prioritize Canada for its R&D investments. Particularly, the number of clinical trials is impacted. Clinical trials declined in Canada in the period after the amended Regulations were published. This decline exists despite recent efforts by Canadian governments to increase industry-funded investments. The PMPRB changes are, at a minimum, counteractive to provincial initiatives to increase clinical trial activity in Canada and may undermine this policy objective	The PMPRB continues to use an outdated SR&ED definition that was first established in 1987 during a very different business and policy environment. Using this definition provides an incomplete accounting of R&D spending in Canada. Other countries use a broader and more inclusive definition that better captures all R&D activity. As a result, R&D activity or investment in Canada is not being properly accounted for by the PMPRB. While the PMPRB has acknowledged this gap, the recent regulatory amendments intended to "modernize" the PMPRB regime did not change the R&D definition. Additionally, the PMPRB continues to assert that Canadian R&D falls short of other countries and of industry's commitment. (source: KPMG Reports 2010-2014, Summary of Pharmaceutical Survey Findings on R&D Spending and Investments by Rx&D Members; PMPRB Annual Reports) • Studies conducted by EY that include non-SR&ED categories demonstrated much higher R&D spending, totaling 9.97% of patented product revenues in 2016. (source: EY study) A recent literature review, which considers all of the available empirical evidence found a large body of evidence showing a correlation between drug prices, or price controls, with drug access and R&D investments. (source: Yanick Labrie, Canadian Health Policy Institute) • The PMPRB has not provided a literature review themselves and therefore its research on this issue and conclusion of "no evidence" was limited to an incomplete set of metrics. A recent study found that new industry-funded clinical trials in Canada have declined as a share of global industry-funded trials in the three quarters following the publication of the PMPRB regulatory changes in August 2019 (source: IMC & LSO CADTH Symposium poster on Early signs of Negative Impact) • The PMPRB finding did not employ the most relevant measure of clinical trials before concluding that there is "no impact". The PMPRB included either all sponsors, or limited to only Canadian-patentee sponsors, in its recent clinical trial measurements. Industry-sponsors, including those who do not currently have sales but who plan to enter the Canadian market, will be impacted by the PMPRB reforms. Indeed, industry sponsors are responsible for approximately 80% of Canadian clinical trials, and therefore the adverse impact of the changes to industry may also have a significant and negative impact on Canada's clinical trial ecosystem. (source: Informa Citeline, PMPRB webinar)
Canada is an attractive launch country, and new drugs will continue to be introduced even after prices are reduced. New drug access is not related to prices.	Canada is an attractive place to launch products in part due to the attractiveness of its private market, however its present status is at risk given the anticipated magnitude of the decline in sales due to the new PMPRB regime.	

		• The PMPRB also did not compare Canada's clinical trials to the most appropriate global benchmark over time, and especially in the period following the publication of the PMPRB regulatory changes. Using the appropriate benchmark (i.e. Canadian trials as a share of unique global trials vs comparing to individual countries) reveals that, although Canada's share of global industry's new clinical trials had declined in recent years, it had stopped declining in the 12-month period before the PMPRB amendments were finalized but resumed the declining trend in the 9-month period following the publication of the PMPRB regulatory changes. (source: IMC & LSO CADTH Symposium poster on Early signs of Negative Impact) Recent studies have confirmed that there has been a decline in timely new drug submissions filed to Health Canada compared to global rates, a decline in the number and rate of new drug launches, and an increase in delayed or canceled drug commercializations of new drugs already approved by Health Canada: • A recent study from IQVIA-LSO found that new drug launches fell significantly in 2019 compared to global launches (source: IQVIA-LSO) • In a recent analysis, IMC and the Conference Board of Canada also found that new drug submissions have slowed down to a record low in Canada compared to global statistics in the 9 months following the announcement of the amended Regulations, and new drug commercializations have been delayed twice as often as historical trends. (source: IMC-LSO CADTH symposium poster on Early Signs of Negative Impact) • The PMPRB's research suggesting that Canada's new drug launches are not declining does not use the right metric, or measure the right time period, casting doubt on its finding that there is "no impact". (source: PMPRB webinar) • In PMPRB's previous research measuring launch rates and timelines in Canada compared to the PMPRB7 and the OECD, the PMPRB relies upon sales data by IQVIA MIDAS (e.g. Meds Entry Watch series). However, in its recent research, the PMPRB criticized using this same data source to measure new drug launches, opting for new drug approvals as a proxy for new drug launches instead. Deciding whether to file a new drug submission is a business decision made 6-12 months in advance. Therefore, new drug approvals occurring after the August 2019 PMPRB regulatory changes actually reflect business decisions made in the time period before the regulatory changes were finalized. To properly capture the impact of the PMPRB changes, it is necessary to look at the timing of business decisions made in response to the immediate environment, which

		includes submissions made to Health Canada, and launches (when the first sale was made in Canada) following August 2019. Above referenced analyses that looked at these measures have in fact found a decline (source: Meds Entry Watch series IMC-LSO CADTH symposium poster on Early Signs of Negative Impact; IQVIA-LSO) • Moreover, not all drugs that receive Health Canada approval are launched immediately, and some are never launched in Canada. Therefore, by relying on new drug approvals to measure whether new drug introductions have declined, the PMPRB does not consider business decisions to delay or not launch new drugs that are made as a result of the regulatory changes.