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Evaluation of the PMPRB regulatory performance on price review for new patented drugs in Canada, 2008-2021

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ABSTRACT

The Patented Medicine Prices Review Board (PMPRB) is the federal tribunal with a mandate to prevent "excessive" pricing of patented drugs. In 2015, the PMPRB initiated a strategic planning process, which proposed legislative changes that would strengthen its powers and broaden its mandate. In August 2019, the Government of Canada announced the implementation of the regulatory amendments. The pharmaceutical industry launched legal challenges in the Quebec and Federal Courts, which resulted in rulings that invalidated major provisions of the regulations, and the federal Health Minister withdrew the provisions in April 2022. During the 2015-2022 period, the PMPRB was engaged in public consultations, as well as media communications and policy advocacy to build support for the regulatory changes. This analysis assesses the regulatory performance of the PMPRB regarding the price review process for new patented drugs in Canada over the 14 years from 2008 to 2021 to determine whether there was any impact associated with the post-2015 period of consultation and advocacy by observing differences before (2008–2014) and after (2015-2021). We compared the number of new patented drugs and their distribution by price review status. We also examined the PMPRB budget and staffing levels over the same period. The Board does not publish the dates when new drugs were reported and assessed. Alternative data were obtained from the list of New Patented Medicines Reported to the PMPRB. We collapsed the six categories that the PMPRB publishes for the price review status of new patented drugs into three groups: compliant with the price guidelines, subject to investigation, or under review. We observed a post-2015 decline in the percentage of new patented drugs that were compliant with the price guidelines, and a corresponding increase in the percentage that were subject to investigation or under review. The number of new patented drugs reported to the PMPRB was virtually the same in the seven years before and after the release of the Board's strategic plan in 2015. We also observed a post-2015 increase in the PMPRB budget and staffing. We speculate that the PMPRB: (1) redirected its resources away from its price review responsibilities to activities that supported the consultation process and its policy advocacy goals; and (2) surreptitiously changed its interpretation and application of the threshold for triggering an investigation.

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INTRODUCTION

Policy issue

The Patented Medicine Prices Review Board (PMPRB) is a federal regulatory tribunal with a mandate to ensure that the prices of patented medicines are not "excessive" (PMPRB 2023). In 2015, the PMPRB initiated a year-long strategic planning process culminating in the December release of the Board's four-year plan (2015–2018), which proposed legislative changes that would strengthen its regulatory powers and broaden its mandate (PMPRB 2015). In August 2019, the Government of Canada announced it would implement the amendments recommended by the PMPRB, including three radical revisions to its price testing methodologies, which were: changing the reference countries used for price comparisons with Canada with a bias towards markets with lower prices; the introduction of pharmaco-economic price testing; and the power to force disclosure of commercially confidential price rebates negotiated between manufacturers and public payers. The pharmaceutical industry successfully challenged the amendments in Federal and Quebec courts, and the results of those judgments were that the latter two changes to the PMPRB's price testing guidelines were invalidated (Jospé and Gagné 2022). Subsequently, the federal Health Minister formally announced the withdrawal of these provisions in April 2022 leaving only the revisions to the reference countries intact.

From the 2015 initiation of its strategic planning process to the Minister's April 2022 announcement to withdraw part of the regulations, the PMPRB led a statutorily required public consultation process designed to obtain feedback from stakeholders about the regulatory impact. The PMPRB also engaged in policy advocacy carrying out a public relations and media campaign promoting the regulatory changes (PMPRB 2021). This analysis assesses the regulatory performance of the PMPRB regarding the price review process for new patented drugs in Canada over the 14 years from 2008 to 2021 to determine whether there was any impact associated with the post-2015 period of consultation and advocacy.

Price review process

Prior to completing the price review of a new patented drug, the PMPRB requires a scientific review by the Human Drug Advisory Panel (HDAP). The HDAP assesses the level of therapeutic improvement of the new drug and determines which existing drugs are to be used for price comparison. This information is used to determine the ceiling price at introduction. Once the scientific review is completed, the PMPRB proceeds with the price review (PMPRB 2018). The PMPRB assesses the average price (net of reported discounts and deductions) of each strength of each individual dosage form for each new patented drug reported in a year. If the price of a newly reported patented medicine is deemed to be excessive, an investigation is performed. This may result in a decision that the price is, in fact, within the PMPRB's guidelines in which case no further action is taken. If it is decided that the price is excessive, there may be a compromise between the PMPRB and the patentee, which is a voluntary compliance undertaking (VCU). A VCU is a written undertaking by the patentee to adjust its price and pay any excess benefits that may have accrued under the previous price without an admission that the price was excessive. If the issue is not resolved by a VCU, a hearing panel consisting of at least two Board members is formed to determine whether the medicine's price is excessive. Judicial review of a hearing panel can be sought in the Federal Court. The PMPRB can impose penalties and price adjustments against manufacturers of drugs deemed to be excessively priced (PMPRB 2022a).

Regulatory performance evaluation

The HDAP service standard for completing the scientific review of new patented drugs is that patentees will receive a copy of the HDAP report within three weeks of the date of the HDAP meeting and the HDAP performance target is 100%. Annual performance data could not be found, but according to HDAP's published performance standard statement, "In 2014, 100% of the HDAP reports were sent to patentees within three weeks of the date of the HDAP meeting" (PMPRB 2018). For the price review process, the PMPRB publishes a performance target that aims to complete the price review in the 6-months following the 6-month period in which the new drug was reported meaning the effective range is therefore from 26 to 52 weeks. The PMPRB strives to achieve this standard for 80% of new drugs provided the HDAP review is complete. Using 86 new drugs reported in 2015, the PMPRB claims that, for those first sold between January and June 2015, 91.3% of patentees were advised between July and December 2015, while for those first sold between July and December 2015, 87.0% of patentees were advised between January and June 2016 (PMPRB 2016). The PMPRB does not publish similar data for each year.

METHOD

The period of the study covered 14 years from 2008 to 2021. The analysis was structured to observe differences between the time periods before (2008–2014) and after (2015-2021) the PMPRB initiated its strategic planning process. For each of the seven-year time periods, we compared the number of new patented drugs, and the distribution of these drugs by price review status. We also

examined the PMPRB budget and staffing levels over the same period. The analysis was based on simple observation of trends in descriptive statistics using counts, averages, and percentages.

The Board does not publish the dates when new drugs were first reported and the assessments were completed. Therefore, it was not possible to independently evaluate whether prices were assessed within the performance standard. Using proxy data was the only available means of evaluating the PMPRB's performance. Data were obtained from the list of New Patented Medicines Reported to the PMPRB, which is updated annually and includes information on the status of the review (PMPRB 2022b). The PMPRB's budget and staff numbers, including projections to 2022, were extracted from annual reports for 2008 to 2021 (PMPRB 2022c).

To simplify the presentation of the analysis in several charts, we collapsed the six categories that the PMPRB publishes for the price review status of new patented drugs into three categories by grouping drugs with conceptually similar status as follows: we combined "does not trigger investigation", "VCU", and "within guidelines" into one category which we labeled "compliant" with the guidelines; we also combined "notice of hearing", and "subject to investigation" into a single category labeled "investigation"; and drugs categorized as "under review" were relabeled "review". The PMPRB annual reports record counts of VCUs relating to new drugs first reported during the year and information on VCUs in place from other years (PMPRB 2022c). This study included only VCUs relating to drugs newly reported during the relevant year. For the periods before and after the PMPRB initiated reforms, we compared the count of new patented drugs reported annually to the PMPRB and the percentage share of these drugs that were: compliant with the price guidelines, subject to investigation, or under review. The PMPRB defines a drug to be under review if a decision was pending on March 31 of the year following the year that the drug was first reported. These metrics were deemed to be indicators of the regulatory performance on price review.

RESULTS

New patented drugs by PMPRB price review status

TABLE 1 displays the count of new patented drugs by PMPRB price review status from 2008 to 2021. The data are shown in bold font to signify subtotals for each of our category groupings. The table is divided into the two time periods under analysis. The percentage share of the total count of new patented drugs attributable to each of the price review status categories is shown at the bottom of the table. Over the entire period from 2008 to 2021, 1,261 new patented drugs were reported to the PMPRB. Of these, 1,136 were compliant with the guidelines; 53 were subject to investigation; and 72 were under review.

TABLE 1. New patented drugs by PMPRB price review status 2008 – 2021.

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2008-2021
NEW PATENTED DRUGS	**79**	**81**	**69**	**110**	**82**	**115**	**103**	**86**	**128**	**80**	**108**	**82**	**78**	**60**	**1261**
COMPLIANT	**79**	**81**	**68**	**109**	**82**	**115**	**102**	**86**	**125**	**71**	**95**	**60**	**25**	**38**	**1136**
Does Not Trigger Investigation			5	11	6	7	3	12	6	3	7	4	1	2	67
VCU	2	3	2	3	6	3	2	6	5	7	8	4		2	53
Within Guidelines	77	78	61	95	70	105	97	68	114	61	80	52	24	34	1016
INVESTIGATION	**0**	**0**	**1**	**1**	**0**	**0**	**1**	**0**	**3**	**8**	**12**	**15**	**5**	**7**	**53**
Notice of Hearing				1											1
Subject to Investigation			1				1		3	8	12	15	5	7	52
REVIEW	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**7**	**48**	**15**	**72**
Under Review										1	1	7	48	15	72
COMPLIANT %	100	100	98.6	99.1	100	100	99.0	100	97.7	88.8	88.0	73.2	32.1	63.3	90.1
INVESTIGATION %	0.0	0.0	1.4	0.9	0.0	0.0	1.0	0.0	2.3	10.0	11.1	18.3	6.4	11.7	4.2
REVIEW %	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	0.9	8.5	61.5	25.0	5.7

CHART 1 shows the count of new patented drugs reported to the PMPRB from 2008 to 2021. Over the entire 14 years, the average count of new patented drugs was 90 per year. The corresponding average count for the seven years from 2008 to 2014 was 91 per year, and for the seven years from 2015 to 2021 the average count was 89 per year. A trendline is plotted on the chart showing the overall trend was virtually flat with a slight decline in the latter period.

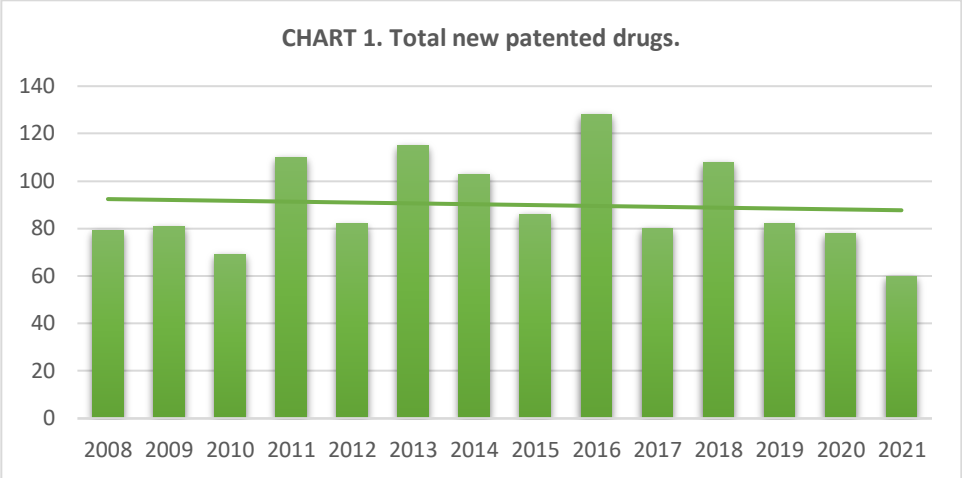


CHART 2 displays the count of new patented drugs as a total and by price review status (based on our category groupings), shown separately for comparison by the time periods under analysis. Over the seven years from 2008 to 2014, 639 new patented drugs were reported to the PMPRB; 636 of these were categorized as compliant; three as subject to investigation; and zero under review. Over the subsequent seven years from 2015 to 2021, 622 new patented drugs were reported to the PMPRB; 500 of these were categorized as compliant; 50 as subject to investigation; and 72 as under review.

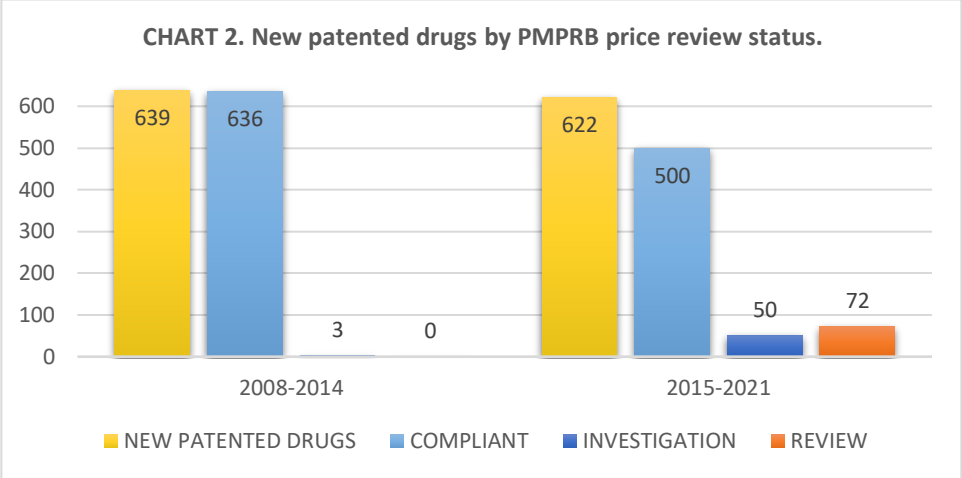
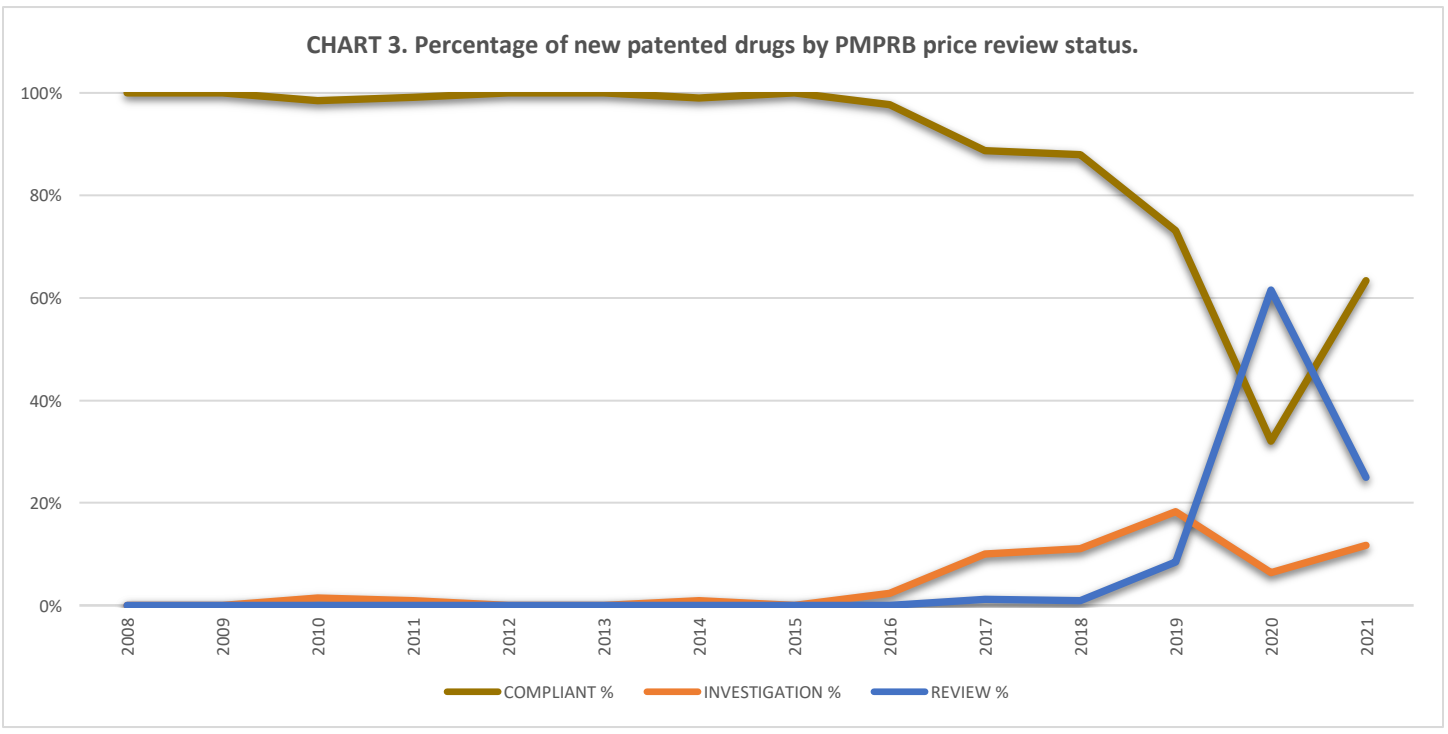


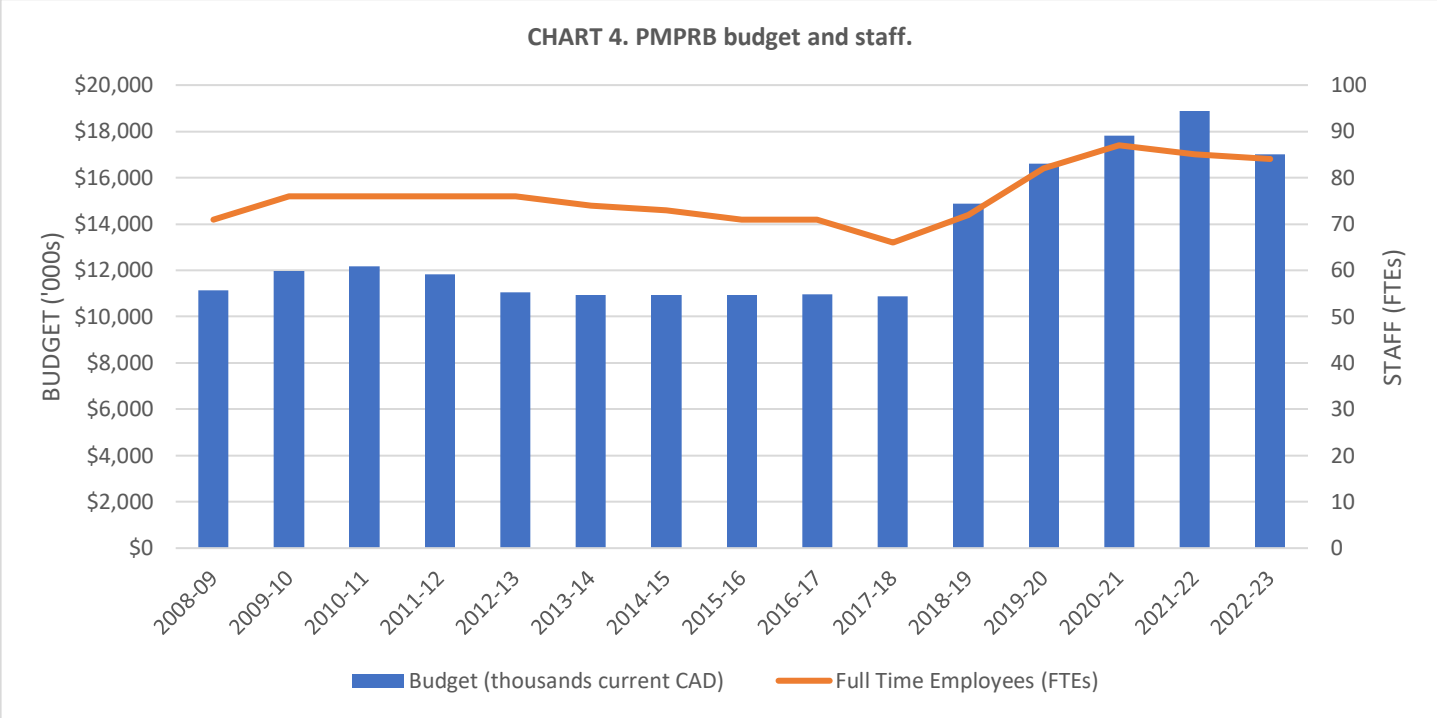
CHART 3 displays the percentage of new drugs accounted for by each price review status from 2008 to 2021. The data show that the percentage share of new patented drugs that were compliant was at or near 100% from 2008 until 2016, while the corresponding percentages under investigation and/or under review were at or near 0% over the



same time period. The percentage share of all new patented drugs that were compliant declined steadily from 97.7% in 2016 to 32.1% in 2020 before rebounding to 63.3% in 2021. The corresponding percentage under investigation climbed from 2.3% in 2016 to 18.3% in 2019 before falling again to 11.7% in 2021, while those drugs under review increased from 0% in 2016 to 61.5% in 2020 before falling to 25% in 2021.

PMPRB Budget and staff

CHART 4 shows the annual budget for the PMPRB from the fiscal years 2008-09 to 2021-22, plus the additional year 2022-23 which is a projected estimate published by PMPRB. The PMPRB budget data are plotted as bars relating to the left vertical axis and its staffing data are plotted as a line relating to the right vertical axis. Between 2008-09 and 2017-18, the PMPRB's budget was reasonably stable. A significant increase in funding was awarded to the PMPRB in the 2017 federal budget "as part of the Government's commitment to making prescription drugs more accessible and affordable for Canadians" (PMPRB 2017). This resulted in a 29% increase in the PMPRB's staff (from 66 to 85) and a dramatic 74% increase in its budget (from $10.9 million to $18.9 million) between 2017-18 and 2021-22.



DISCUSSION

Comparing the data before (2008 – 2014) and after (2015 – 2021) the PMPRB initiated its reforms, we observed a decline in the post-2015 percentage of new patented drugs that were compliant with the PMPRB guidelines, and a corresponding increase in the percentage that were subject to investigation or under review. We speculate that the PMPRB: (1) redirected its human and financial resources away from price review to activities that supported the reforms, thereby creating a backlog that increased the number of drugs under review and simultaneously decreased the number of drugs that were compliant; (2) changed its interpretation of the guidelines and the standards applied to price review following the release of its strategic plan, thereby increasing the number of new drugs under investigation.

Over the same period, we observed an increase in the PMPRB budget and staffing. We also observed that the number of new patented drugs reported to the PMPRB was virtually the same in the seven years before and after the release of the Board's strategic plan in 2015. The results suggest that workload was not a factor in any differences observed before and after 2015.

This is reinforced by the low number of complaints about prices from health professionals and the public. An access to information request revealed that, between January 2009 and May 2019, the PMPRB received just 18 complaints. Fourteen complaints (77.8%) related to generic medicines, which are outside the PMPRB's jurisdiction, and one (5.5%) was about a medicine not approved for use in Canada. The remaining three medicines (16.7%) were investigated, and their prices found to be within PMPRB guidelines (PMPRB 2019).

The increase in new drugs under review occurred during the years when the PMPRB was focused on executing the required public consultations (PMPRB 2022d) and staff were possibly engaged in technical support for the introduction of the new price tests, but the purpose of the increase to its budget and staffing was to offset these demands and avoid shifting resources away from its price review responsibilities.

However, there is evidence that after its 2015 initiation of the reforms the agency was actively (and perhaps less legitimately) involved in policy advocacy by planning and carrying out at least one major public relations and media campaign designed to discredit opposition to the amendments. In a document outlining its 2021 communications plan, the PMPRB accused the biopharmaceutical industry and patient groups of "spreading disinformation" and "knowingly disseminating false information" about proposed changes to the regulations and guidelines. The document detailed plans to use traditional and social media, speaking opportunities and publications to advocate for the regulator's policy agenda and counter opposition (PMPRB 2021). Annual communications plans for previous years were not available, so it is impossible to know whether the PMPRB had engaged in such aggressive policy advocacy prior to 2021. However, the 2021 plan suggests that the agency was not culturally committed to public service neutrality. In this context, it is not unreasonable to question whether the PMPRB allowed or directed its staff to concentrate on advocacy for its proposed new role, instead of completing its regulatory responsibilities regarding price review.

Our speculation that the PMPRB acted surreptitiously to change the *de facto* interpretation and application of the guidelines is consistent with the available evidence on the agency's bureaucratic organizational behavior following the initiation of its reforms in 2015. The PMPRB has displayed a pattern of acting outside the ethical norms expected of a neutral public service agency, expressing an anti-industry bias in official communications and documents, in testimony before parliament, and in letters submitted regarding recent Board resignations (HESA 2023; Rawson 2023a; Skinner 2021; Savoie 2021; Rawson and Adams 2023; Yakabuski 2023). The agency has also openly defied court rulings, which have clarified the legal limits of the PMPRB's powers and highlighted the regulator's overreach of its mandate under the Patent Act.

The recent case of the drug Soliris illustrates this latter point. In that case, the Federal Court of Appeal ruled that the PMPRB illegally expanded its mandate from preventing patent abuse as evidenced by "excessive pricing" to regulating "reasonable" prices by introducing a new price testing standard – Lowest International Price Comparison (LIPC) – that contradicted its own guidelines (Alexion Pharmaceuticals Inc. v. Canada (Attorney General) 2021). According to the Board, the price of Soliris had to be lower than that of all seven comparator countries. The issue was whether the Board went beyond the limits of its power, appropriately interpreted, to find excessive pricing under section 85 of the Patent Act. Referring to the actions of the PMPRB, the court summary reads,

> "The Board obfuscated, making it impossible for a reviewing court to know whether the Board had helped itself to a power it does not lawfully have. Of more concern was that the Board may have helped itself to powers the statute has not given it… The Board misunderstood the mandate Parliament gave it under section 85… The Act aims at a balance between incentivizing the research and development of patented medicines and their introduction into Canada through the grant of a monopoly and protecting against abuse of that monopoly. General price control is no part of the exercise. Judging by the reasons it gave, the Board disregarded most of the authorities on this matter… It could be seen from its decision that the Board was pursuing a general price regulation mandate… One of the most controversial parts of the Board's decision in this case was its departure from the guidelines it has enacted to assist itself and others in applying section 85. Those guidelines refer to the highest international price as a key comparator. Instead, the Board found that Soliris was excessive because its price was more than the lowest international price… the Board's departure from the guidelines and its imposition of a requirement that the medicine be lower than all seven comparator countries was unprecedented. It was a marked departure from its own authorities… Therefore, the Board's decision could not stand. It was quashed and remitted to the Board for re-determination."

The PMPRB had previously introduced the LIPC into VCU negotiations on drugs manufactured by other companies which had accepted the PMPRB's condition (**TABLE 2**), but it had never previously tried to *impose* the LIPC test until Soliris. Incredibly, even following the court's invalidation of the LIPC in the 2021 Soliris case, the PMPRB defiantly continued in 2022 to push for the application and use of the LIPC test in VCU negotiations (**TABLE 2**).

TABLE 2. Examples of the PMPRB attempting to introduce a new "lowest international price comparison" price test into voluntary compliance undertakings contrary to its statutory powers, its own guidelines, and in defiance of the federal court.

Repatha (December 11, 2017) http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1351&lang=en.
Tegsedi (August 27, 2020) http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1489&lang=en.
Onpattro (August 31, 2020) http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1490&lang=en.
Aimovig (October 22, 2020) http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1491&lang=en.
Crysvita (February 2, 2022): http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1494&lang=en.

Our findings are important because the sudden increase in the percentage of new drugs that were under review or subject to investigation probably introduced significant uncertainty into what was previously a stable regulatory environment, and potentially caused pharmaceutical manufacturers to delay launching new drugs in the Canadian market. The post-2015 changes in the PMPRB's price review metrics are correlated with a decline in the number of new drugs being submitted to Health Canada for review. In a previous study, Rawson (2023b) found that between 2006 and 2014, on average, 83% of drugs submitted to the U.S. Food and Drug Administration and/or the European Medicines Agency were also submitted to Health Canada. However, the number of drugs submitted to Health Canada between 2015 and 2020 decreased so that, by 2020, the percentage of new drugs submitted in the United States and/or Europe that were also submitted in Canada was only 44%.

The post-2015 increase in the number of new drugs under review also possibly exacerbated existing administrative delays caused by the price review process, which are over six months to a year when the HDAP and PMPRB service performance targets are combined. Without published data on the start and completion dates for the price reviews, it is impossible to independently determine with accuracy the extent of the delays.

These outcomes represent real costs for patients and industry. If these costs are the result of decisions made by the PMPRB to redirect public resources to activities other than its primary price review responsibility, or if the interpretation and application of the guidelines were surreptitiously changed by the PMPRB, the Board should be held accountable.

With almost all the proposed changes to the PMPRB's regulations and guidelines having been stayed, the federal government should consider revoking the PMPRB mandate, which is redundant given the existence of health technology assessment agencies like the Canadian Agency for Drugs and Technology in Health (CADTH) and purchasing organizations like the pan-Canadian Pharmaceutical Alliance (PCPA) which acts as a monopsony buyer on behalf of all public drug plans.

Parliament should at least require the PMPRB to publish data that allows for an independent evaluation of its performance, and to act within the boundaries of its court-confirmed mandate. Parliament should also consider reducing the PMPRB's budget and staff. Between 2008 and 2017, the PMPRB completed its regulatory role in a timely manner with 12% fewer staff than it had in years between 2018 and 2021 (on average 73 versus 82 FTEs), even though the average number of newly reported drugs between 2008 and 2017 (93 per year) was 14% higher than in 2018 to 2021 (82 per year). Retaining the enlarged staff would seem to be a waste of public funds.

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