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Commentary

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The Patented Medicine Prices Review Board has lost its way (again)

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The Patented Medicine Prices Review Board (PMPRB) is once again attracting the ire of the life sciences industry and patient groups that depend on timely access to innovative new health technologies. The source of the wrath is the PMPRB's latest iteration of "modernized" excessive price Guidelines that ignore innovation, eschew legal precedent and sow uncertainty for biopharmaceutical manufacturers considering the launch of new health technologies in Canada.

Background

Created in 1987, the PMPRB has two mandates: to ensure prices of patented medicines are not excessive and to report to Parliament on trends in the pharmaceutical industry. The latter it accomplishes reasonably well, albeit not in a timely way. It is the former price review mandate that is at issue.

Empowered by the excessive price provisions of the *Patent Act*, the PMPRB is a quasi-judicial tribunal that reviews the price of a patented medicine by considering prices of similar medicines in the same therapeutic class and prices of the patented medicine in 11 other countries (the "PMPRB-11"). It also limits price increases to changes in the consumer price index (CPI).

PMPRB in the Canadian constitutional context

Ordinarily, only provinces can regulate pricing of products and services. Pricing falls under the property and civil rights provisions of the constitution, an exclusive power of provincial legislatures. And as such, regulating prices of prescription drugs is an exclusive provincial responsibility. And provinces and territories actively regulate prescription drug prices through drug benefit formularies and pricing agreements negotiated with manufacturers. The combined buying power of the provinces is leveraged through the pan Canadian Pharmaceutical Alliance (pCPA), which negotiates prices and rebates on behalf of all government-funded drug plans.

Patents, on the other hand, are an exclusive federal power. And it is through the *Patent Act* that the federal government can issue legislation and regulations directed at drug prices. But only in the context of abuse of patent monopoly and not more generally at achieving "low" or "reasonable" drug prices. Justice David Stratas of the Federal Court of Appeal is unequivocal on this point, writing the unanimous decision in the *Alexion* case: "Were the excessive pricing provisions of the federal *Patent Act* aimed at reasonable pricing, price-regulation or consumer protection at large, they would be constitutionally suspect" (2021 FCA 157).

Patent monopolies and premium pricing

The purpose of patents is to reward the patent holder with a monopoly, and allow it to charge a premium price that would not be possible if there were competition in the absence of the patent monopoly. In exchange for time limited market exclusivity, the patent holder publicly discloses the details of its patented invention, which is then available to all upon patent expiry.

Despite a 20-year patent term, the effective period of market exclusivity for pharmaceuticals is typically eight to 10 years, as the first 10 to 12 years are taken up with clinical trials and regulatory approvals. This is the time-period during which the patent holding company has to recoup its investment and hopefully turn a profit. Once patents expire, generics enter and with mandatory substitution, the market quickly becomes almost completely generic with little or no share for the original brand medicine. The pCPA pricing framework for generics ensures prices of generics quickly fall to 25 percent of the original brand product and even lower for top selling products (as low as 15 percent of the original brand price).

Of course, there can be exceptions to the averages outlined above; periods of exclusivity can be longer (or shorter), and some recognizable brands are more successful at retaining some market share and maintaining nominal brand pricing at patent expiry (think Viagra). But many of these are not covered by government or even private drug plans, even when generic versions become available.

So what is "excessive" pricing?

The courts have confirmed that "reasonableness" is not the threshold for determining *excessive*, nor are lower prices, consumer protection at large or affordability. To be considered patent abuse, the PMPRB excessive price threshold must therefore reflect some upper limit within the context of excessive price factors listed in the *Patent Act*.

When PMPRB Guidelines propose thresholds characterized as lowest, lower of, or even median, midpoint or average, they are not consistent with the courts' determinations of what constitutes excessive pricing within the paradigm of patent abuse. Indeed, for the price of a patented medicine to be considered excessive it must exceed thresholds defined with terms like highest or higher of. For example, patented drug prices that exceed both the highest international price and the highest priced therapeutic alternative might be considered excessive in the context of abuse of patent monopoly.

Lower of the lowest: PMPRB's proposed 2022 Guidelines for New Medicines

The draft Guidelines separate patented medicines into two groups: new and existing. Existing products are those approved by Health Canada prior to July 2022 and new medicines are those approved thereafter.

For existing medicines, the proposed excessive price threshold is the highest international price. So far, so good. Nevertheless, many existing patented medicines will face price reductions because of the updated basket of reference countries used for international price comparisons. But that is an issue with the composition of the new PMPRB-11 reference countries and not the proposed Guidelines, per se.

The proposed thresholds for new patented medicines are another matter. Medicines that patentees are considering introducing in Canada from July 2022 onward face not only uncertainty but price thresholds that are repeatedly framed in terms of lower of, and lowest.

The new medicine guidelines establish the median international price as an overall ceiling for all new patented medicines and then move stepwise lower and lower with constraints like and midpoint of median and lowest and "50% lower than the lowest international price" (PMPRB 2022).

There are occasional references to an upper end such as the "top of the therapeutic class," but that option is only in combination with other lower of, and lowest constraints. For example, the lowest cost version of each comparator (often a generic) will be used for the therapeutic class comparison. And the top of the therapeutic class is only available if it is lower than the median international price. Further, if the top of the therapeutic class is already lower than the lowest international price, the expectation is that Canadian prices should

be lower than the lowest price in the PMPRB-11 world.

Clearly the PMPRB's intent is to push Canadian prices of patented medicines to the lowest levels in its 35-year history.

Wait – haven't the Courts put an end to the PMPRB's "lower of lowest" approach to Guidelines?

Rather than respect the intent and spirit of the decision of the court decisions, the PMPRB is now attempting to avoid judicial scrutiny by characterizing the new excessive price thresholds as "investigation criteria" rather than low price thresholds that could be flagged as unconstitutional. Further, the PMPRB is suggesting enforcement is discretionary as PMPRB staff "may" commence an investigation if one or more price thresholds are breeched.

There is no information on how the PMPRB would conduct any investigation beyond vague references to the excessive price factors in the *Patent Act*. Patentees cannot calculate non-excessive price thresholds for their products in advance other than applying the "investigation" criteria that result in prices that are clearly contrary to every court decision that has considered the PMPRB's mandate.

The Guidelines suggest that the ensuing investigation by Board staff will establish a bespoke price threshold (at the Board Staff's sole discretion) and require the patentee to provide an undertaking to respect the new threshold and repay "excess revenues," or face a hearing panel. Hearings take several years and can incur significant legal costs (in the millions).

Imagine replacing 100 kilometre/hour highway speed limit signs with new signs indicating "suggested" speeds of 50 kilometre/hour. Motorists are advised that the suggested speeds are not speed limits per se, but they are warned that exceeding the suggested speeds may result in being pulled over by a traffic officer. And the officer will determine the individual speed limit and fine for each driver with no guidance other than the suggested speed criteria that resulted in the traffic stop.

Of course, drivers can always challenge the speeding ticket in court, but most will just pay the fine and move on. And many drivers will recognize that the new "suggested speeds" are really just de facto speed limits and will seek out different destinations with better highways.

The PMPRB's "investigation criteria" subterfuge may offer PMPRB some protection from judicial review, but patentees will understand the criteria to be price thresholds. They have little choice, as there is no information or guidance as to how to support or justify higher prices.

Accordingly, if investigation criteria suggest the lowest international price, or lower than the lowest price, patentees will seek other destinations for

their drugs. Large, deep pocket pharma companies might be prepared to challenge PMPRB in court, but the smaller biotech firms that bring many of the innovative rare disease drugs to market will just avoid Canada – it's just not worth the aggravation and the threat to pricing in other markets that reference Canadian prices.

Innovation doesn't matter anymore

Since the inception of the PMPRB's original Guidelines, the PMPRB had always considered the level of innovation or therapeutic improvement (breakthrough, substantial or moderate improvement) as an element of the price review process to allow for premium pricing above therapeutic comparators. This is not unique to Canada – it is a concept that is enshrined in the pricing systems of other countries (e.g., France, Germany, Italy, Switzerland, Japan).

The idea being, that if a drug can offer improvement over the current standard of care, it should de allowed a premium above other thresholds. No longer. New life extending cancer treatments are no different from reformulated pimple creams in the eyes of the PMPRB.

The former PMPRB review process included a scientific review by an independent advisory committee know as the Human Drug Advisory Panel (HDAP). The HDAP recommended a level of therapeutic improvement as well as potential comparator products for therapeutic comparisons. The HDAP has been disbanded except for *ad hoc* requests, and only for advice on comparators.

Impact of the PMPRB reforms on Canadian patients and the Canadian health care system

With lower prices (and perceived pricing thresholds), Canada will slip down the launch sequencing ladder. Global pricing teams of pharmaceutical companies establish launch sequencing plans based on the expected prices in each market and the national reference pricing systems in each country that set prices based, in large part, on prices in other countries.

Launch sequencing is not an academic theory; it is an industry best practice. Third-party vendors of international pricing data have developed sophisticated systems for establishing launch sequences for new drugs – they have become a critical tool for global pricing teams.

Almost all countries (except the US, UK, and Sweden) apply some form of international price referencing, and while the methodologies and baskets of reference countries vary, the implications are clear. It is important for manufacturers to launch in high price countries first, and low-price countries last. Launch sequencing analysis begins by considering country specific price setting algorithms and the impact each price has on other countries. The final launch sequence may consider other factors like expected dates of market

authorization, location of clinical trials and clinical experts, local health care priorities, etc. But the starting point is pricing in the international context. And with relatively low Canadian prices, Canadian patients can expect to have access later than other countries, if at all.

The other barrier to launch is uncertainty. If manufacturers cannot figure out what the maximum allowable price will be in a particular market, or there is a risk of unacceptably low prices, they will not launch.

Is the PMPRB even relevant anymore?

The new PMPRB Guidelines are the PMPRB's latest attempt to re-establish relevance. When the PMPRB was created in 1987 there was no pCPA, health technology assessment was in its infancy and drug plans simply accepted the prices offered by manufacturers.

The PMPRB filled an important policy vacuum even though it limited its focus to "excessive pricing." Subsequently the provinces eventually developed polices that led to lower prices through greater reliance on health technology assessments and pCPA price negotiations that focused on value and affordability for the health care system. The PMPRB had become largely irrelevant to the provinces.

However, private drug plans (and plan sponsors, typically employers) continue to benefit from the PMPRB as private insurers often cover drugs that are not benefits on provincial drug plans nor do private insurers benefit from the negotiated rebates paid to provinces (nor should they!). In fact, according to the Canadian Institute for Health information (CIHI), the majority (55 percent) of drug expenditures in Canada are paid through private insurance plans or out of pocket by patients. The PMPRB has a role to ensure that privately insured and uninsured patients are protected from excessive prices. And private drug plans can negotiate even lower prices with manufacturers when they see fit.

Secondly the PMPRB has a reporting mandate that remains relevant. Despite the recurring tardiness of the PMPRB Annual Reports, the data contained therein are useful for policy analysis of price and expenditure trends in the pharmaceutical sector, even if the PMPRB's accompanying analysis is sometimes infused with anti-industry bias. Nevertheless, the PMPRB reported data can be very useful for policy analysis and is relied upon by academics and industry analysts.

Further, the PMPRB Annual Reports have confirmed year-after-year that the pharmaceutical industry has been largely compliant with the PMPRB Guidelines, that Canadian prices are well within the range of prices in other industrialized countries and that price increases are well below inflation. In fact, the PMPRB had become seemingly irrelevant because it was quietly successful in addressing the gaps that cannot be addressed by the pCPA and provincial governments.

So where to go from here

The PMPRB needs to get back to its statutory mandate. First, abandon the proposed 2022 Guidelines. Second, develop pricing guidelines that respect the court decisions and reflect high price thresholds consistent with abuse of a patent monopoly. Again, a patent monopoly anticipates premium pricing – that is its purpose.

Third, recognize innovation – and bring back levels of therapeutic improvement as an element in assessing excessive pricing. These are well understood by industry, notwithstanding their complaints that pricing authorities tend to understate innovation in their assessments. However, there has always been considerable correlation between the assigned levels of improvement among the countries that do so. France's ASMR system is fairly predictive of the additional benefit classification in Germany and the PMPRB level of improvement in Canada.

Fourth, put in place guidelines that offer clear bright line pricing tests that are easily applied by manufacturers so that they understand the PMPRB pricing limits. That would reduce uncertainty for manufacturers, which improves the probability of timely availability in Canada.

In addition, engage with industry – not just after the fact, but during the guidelines development process. Part of the reason that PMPRB reforms have taken more than six years is that the PMPRB staff often appear to have little understanding of the practical implications of their Guideline proposals. The result has been Guidelines that are vague, impractical and that would lead to price levels far lower than even the PMPRB's theoretical expectations.

And engage with patient groups to develop a process whereby they can contribute to the price review process. The PMPRB likes to claim a consumer protection role, something the courts have struck down with respect to pricing at large – but consumer protection is not just about prices. Consumers (patients and the health care system) are dependent on access to innovative pharmaceuticals. As it stands, the PMPRB's proposed Guidelines are a barrier to that access.

The pharmaceutical industry is not the enemy. Nor are patient advocates who are passionate about gaining timely assess to new technologies that have the potential to improve their health or even save their lives. The PMPRB has demonstrated little to no interest in patient health or health outcomes. It is time that changed.

About the author

W. Neil Palmer is a (somewhat) retired pharmaceutical policy expert who worked at the PMPRB in its formative years and contributed to the development of the initial PMPRB Guidelines. He subsequently co-founded a successful pricing and market access consultancy (PDCI Market Access) that was acquired by McKesson Canada in 2020. He has been recognized by federal and provincial courts in more than a dozen cases as an expert in pharmaceutical pricing and reimbursement.

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