Submission to the PMPRB in Response to the Scoping Paper for the Consultations on the Board's Guidelines, November 2023

General

These comments are respectfully submitted in response to the call for submissions in the Scoping Paper; they should be read as a supplement to my remarks at the Policy Roundtable December 5-6, 2023 (Appendix). They represent personal observations and are not intended to reflect the views or submissions of any other person or organization.

The purpose of these consultations is to inform changes to the PMPRB's Guidelines to implement the regulatory amendments in 2022, and to assist the Board in modernizing and simplifying its administrative framework.

The Policy Roundtable illustrated the complex nature of these objectives. As a consequence, the Board may wish to consider a staged approach:

- There is some urgency to address implementation of the regulatory changes. These changes have impacted the information patentees are now filing but have left uncertainty as to how that information will be used.
- Questions related to the broader administrative framework of the Guidelines are varied and complex - and possibly less urgent. They may warrant separate consideration on a longer timeframe.

It is difficult to address all of the questions fully as the answer to one will depend on the Board's conclusions on other questions. Also, this submission does not have the benefit of considerations raised by stakeholders.

The Guidelines

As the Board has emphasized, the Guidelines are not binding on the Board or on rightsholders. But they are intended to provide certainty to rightsholders – certainty to allow them to comply with the *Patent Act* and set prices that will not be likely to trigger a hearing by the Board.

Importantly, they also provide guidance to Board Staff as to the circumstances that should require further investigation, a Voluntary Compliance Undertaking (VCU) or a recommendation to the Chair to commence a hearing. They are not binding but are consequential as they help to govern important decisions about the commercialization of drugs in Canada and thereby their potential availability to patients.

The Board is not a price regulator. The Act presumes that rightsholders are free to set prices based on:

- market conditions;
- the regulatory requirements in different jurisdictions; and
- other relevant considerations.

The PMPRB is an important factor, but only one factor, influencing price levels for patented drugs.

The work of the PMPRB has illustrated that introductory prices and prevailing prices are typically lower than what are considered non-excessive limits under the Guidelines. They also vary considerably; there is no consistent or predictable pattern to prices in Canada relative to the Guidelines or relative to other countries.

The fact that many prices are lower than the triggers provided by the Guidelines is not a sign that the Guidelines are too "generous" or that the PMPRB program is not effective. It is a sign of a dynamic market. Even with the benefits granted under the Act, patented medicines are subject to market and other forces as noted above. If there is a misapprehension that the Board sets or should set prices for patented drugs, it should strive to correct that through its communications activities.

In establishing Guidelines there is a natural tension between the avoidance of specific price regulation and the goal of providing certainty. The more the Guidelines include detailed and complex calculations (such as the GAP and DIP methodologies and market-specific price tests) the more they risk appearing to regulate prices. Ideally, the Guidelines should provide clarity without setting prices.

The Guidelines cannot restrain the Board in a hearing from considering and weighing all the relevant evidence with reference to all of the factors specified in the Act.

Current State of Play in Canada's Pharmaceutical Market

The PMPRB's Annual Reports have shown the trends in sales of patented medicines since 1987. Sales growth fluctuates from year to year. The sales and growth trends are not indicative of whether prices might be excessive.

Although it is popular to refer to the increasing cost of drugs, the data do not suggest there is a problem in the case of patented drug prices. In fact, the PMPRB's most recent Annual Report for 2021 suggests the opposite. It shows, among other things:

- "… sales … have grown by an average of 2.2% per year" over the previous five years. (p. 24)

- Increases in patented medicine prices continue to be well below increases in the CPI. (p. 48)
- "… the sales of patented medicines as a share of overall medicine sales … reached a peak of 72.7% in 2003 (but by 2021 declined to) 51.0% of the sales of all medicines in Canada." (fig. 3 (a))
- Patented drugs have accounted for a roughly consistent share of GDP per capita for the past 20 years, ranging between a high of 0.83% in 2009 to a low of 0.70% in 2014. (0.76% in 2021, fig. 3 (c))
- Since the early 1990's Canadian prices have fallen well within the range of the listed countries (PMPRB7). No drug can exceed the highest international price and remain within Guidelines, but levels, on average, have usually been lower, well below the median of the basket.
    - The PMPRB does not report on the numbers of drugs at different places within that range although it is known that some have been at the higher end and some at the lower end.

In sum, it appears the primary purpose of the amended regulations is to invite the Board to give less or no weight to prices in the US and Switzerland and to consider prices in the added countries; in other words, historically high prices in the US should not set a price limit for Canada.

Theme 1: Efficient Monitoring of Prices Without Price Setting

Question 1.1: What elements of the 2010 Guidelines should be retained? Which ones and why?

The 2020 Guidelines include a general statement that the Board seeks to "uphold the principles of fairness, transparency, openness and predictability." (Preamble) The Board should consider reinforcing and emphasizing these principles going forward.

In the Policy Roundtable, some stakeholders encouraged the Board to take into account the broader impact of its Guidelines in the market – for example, their potential impact on distributors and pharmacies throughout the distribution chain and their potential impact on the availability of new medicines in Canada.

Those submissions might be summarized as: "Do no harm." The Board should consider addressing that "principle" in its Guidelines going forward to confirm its recognition that its actions have direct and indirect impacts throughout the supply chain and on health care in general.

Some comments on other elements of the 2010 Guidelines appear below.

Question 1.2: Should new Guidelines continue to categorize medicines by therapeutic class comparator characteristics such as the Level of Therapeutic Improvement?

The PMPRB's Therapeutic Cass Comparison (TCC) was a relevant factor when the PMPRB was created. At that time there were few examples of other bodies that conducted and published such comparisons although they were used in less formal ways by hospital committees and other bodies.

Regulatory bodies such as Health Canada rely heavily on comparisons with existing products; today, HTA bodies conduct sophisticated reviews and comparisons taking into account not only therapeutic value but also cost-effectiveness. In the event of a hearing, the Board will likely be invited to take into account evidence of the publicly-available reviews (in Canada and elsewhere) and to weigh them appropriately in assessing excessive price.

No other program in Canada systematically conducted TCCs when first adopted by the PMPRB. Today, major drug plans rely on TCCs (or equivalents) conducted by respected agencies such as CADTH and INESSS. Many purchasers of drugs such as hospitals may conduct their own TCC for their specialized purposes.

The PMPRB has encountered many challenges with its unique TCCs:

- They are conducted by a separate expert body; while the PMPRB attempts to ensure common and consistent standards when it appoints the HDAP, there is always the room for inconsistencies in the HDAP's approach over time.
- Although scientific in nature, TCCs inherently include the unique perspective of the persons conducting them. Not all experts will reach the same conclusion.
- The Board is not bound by the TCC recommendation of the HDAP and may reach a different assessment in light of all the evidence adduced in a hearing; the only opportunity for a rightsholder to appeal an HDAP recommendation is to sell the drug at a price that will cause the Board to conduct a hearing.
- TCCs conducted by the HDAP may not align with reviews by HTA bodies, or even Health Canada's regulatory review. They may consider different evidence or give the same evidence different weights.
- The evidence is not static. The HDAP's review is ordinarily conducted at an early stage when evidence is still being collected. Concepts such as "rolling reviews" and "coverage with evidence development" did not exist when the PMPRB started using TCCs.
- For all of these reasons, disagreements often arise between the rightsholder and the HDAP. It is a challenge for Staff to resolve these disagreements readily and fairly and as a result their review often lingers for some time. The primary reason for delays in Staff reviews of new patented medicines is the challenge of resolving these disagreements.
- Even if the HDAP review is consistent with other reviews, it represents an obvious overlap and duplication in the system since HC and HTA reviews are public.

The Board's use of TCCs for purposes of the Guidelines has been fraught with many challenges over the years. It is not evident that the TCC continues to be relevant for Guidelines purposes in view of the current market environment and the changes to the list of comparator countries.

Question 1.3: Should the Board accord more weight to one or more of the factors set out in s. 85 of the Act in designing the Guidelines?

The 2022 amendments provide an indication of the government's intention the Board give new weight to the international price factor. There are several reasons to support this view:

- The PMPRB program was one of the first internationally to use international price comparisons (IPCs); they are now widespread.
- There is no evidence that the other actors in the Canadian pharmaceuticals environment put weight on IPCs. In contrast, IPCs are a common feature in European public reimbursement systems.
- In sum, the IPC represents an added value of the PMPRB program in the Canadian market.
- International comparisons provide an immediate and useful measure of potential excessiveness: for Guidelines purposes, they give the Board confidence that Canadian prices are not excessive as they are not out of line with other developed countries.
- IPCs are clear and straightforward in comparison to TCCs. They provide greater certainty.

That does not mean they are without challenges. Under the regulations, patentees are to file the "publicly-available" prices in other countries, but for several years the PMPRB has reported international comparisons with the new PMPRB11 and the OECD countries based on privately-held commercial information collected by a third party; presumably, the PMPRB will now begin to rely on the regulatory filings instead. After one year's experience, has the PMPRB identified any challenges obtaining and relying on the regulatory filings of patentees?

See below for comments on the CPI factor in the Act.

Question 1.4: If international prices are used as the initial triage measure for commencing investigations, what price levels within the PMPRB11 should be used as the triage measure? (e.g. HIP or MIP?)

Removing the two highest-priced countries in the basket suggests an intention that prices in the US and Switzerland not be used to establish an upper limit for "excessive" in future. Box 1 shows that 28% of existing medicines have prices higher than the HIP of the PMPRB11; therefore, the change to the PMPRB11 will be expected to have significant impact.

When the Guidelines were amended 30 years ago to provide that no drug should be priced higher than the HIP, the PMPRB reported a significant change in the relationship of Canadian and foreign prices. Within a few years, prices, on average, declined from well above the median

of foreign prices; since then, the PMPRB has reported that Canadian prices have, on average, been below median foreign prices of the PMPRB7.

The Guidelines have used the MIP in very limited circumstances – the introductory prices of breakthrough drugs and drugs with no comparators. It is likely that the inclusion of the US impacted the initial decision to rely on the MIP for breakthrough drugs; it was recognized that using the HIP would mean the US price would often set an upper limit much higher than the comparable European countries. That is not the case today.

Question 1.5: How should the PMPRB conduct an initial review and monitor the prices of patented medicines that have few or no international prices?

There are precedents for reviewing a price in the event of no international prices. In the matter of Photofrin, the Chair approved an Advanced Ruling Certificate in light of the rightsholder's undertaking to adjust its price in future if necessary to conform to the Guidelines when it was introduced in additional countries. (This approach could as easily be applied today through a VCU.) See: https://www.canada.ca/en/patented-medicine-prices-review/services/regulatory-process/advance-ruling-certificates/advanced-ruling-certificate-photofrin.html

That precedent is a reasonable approach. It gives assurance that the spirit and intent of the Guidelines is upheld and opportunity for prompt remedy by the PMPRB if it is not.

In such circumstances, the Staff should be expected to act reasonably in determining the frequency of reviewing prices in other countries and monitoring necessary adjustments.

Question 1.6: Would an expedited price review (e.g., within 90 days after initial Form 2 submission) of a new medicine based solely on international prices being below the MIP accelerate introduction of innovative medicines?

It is difficult to see how an expedited review in these circumstances would be beneficial. Drug plans do not appear to take the PMPRB review into account in their coverage decisions.

Use of the MIP as a standard in these circumstances could be counter-productive as it could create an additional barrier, whether perceived or actual, to bring a new drug to Canada. The HIP would be more appropriate.

Theme 2: Transition to PMPRB11

Question 2.1: Should the Guidelines distinguish between medicines that existed as of July 2022 (existing medicines) and medicines introduced afterwards (new medicines)?

Question 2.2: What approach should the Board take with respect to existing medicines with prices above the HIP of the PMPRB11? Should the Board review these prices, and if so, how soon?

The Board should take notice of the market uncertainty that has prevailed over the past six years. Even with the certainty of the final regulatory amendments as of July 2022, their effect on the Guidelines was unknown. It would be most appropriate to apply new Guidelines in future and not retroactively.

In the event the Board decides to use the Highest International Price of the PMPRB11 as a limit under the Guidelines for existing drugs, it should apply a reasonable transition period.

Theme 3: Price Reviews During Product Life Cycle

The questions in Theme 3 derive from the Board's jurisdiction over patented medicine prices for the duration of the patent and supplementary protection certificate.

Current practice: The Board establishes a "benchmark price" based on a review in the initial period of sales; the benchmark price is the initial price if within Guidelines or the maximum non-excessive price if not. The prices of all drugs are then reviewed on an annual basis to ensure compliance with the Guidelines for price changes (CPI) and international prices (HIP.)

The Guidelines are self-adjusting over time. If a price exceeds the CPI-adjusted limit or the HIP, the Staff will conduct an investigation. The track record suggests that rightsholders direct considerable effort to ensure that their prices remain within Guidelines.

Question 3.1: How often should price reviews be conducted?

If the Board retains guidelines reflecting the statutory CPI and/or international prices factors, Staff should continue to review prices annually based on those factors.

Question 3.2: What criteria besides time should be used to trigger a price review?

The Board has consulted from time to time on "re-benchmarking," i.e. adjusting the benchmark price based on other factors. Those consultations have not led the Board to change its approach in the past.

The Scoping Paper has not provided any information to suggest that "re-benchmarking" should be assessed again, in particular in light of today's market and reimbursement environment. If the Board considers that changes may now be appropriate as a result of these consultations, it should take into account the disruptive effect "re-benchmarking" might have throughout the distribution chain and ensure full analysis and consultation.

Question 3.3: Should the relative weighting given to different section 85 (Patent Act) factors change over the lifecycle of a medicine?

The relative weighting of the statutory pricing factors is a matter for consideration by the Board in a hearing context. No information has been presented to support any changes to the Guidelines in this regard.

Question 3.4: How should the PMPRB treat the allowable Consumer Price Index increase in the context where international list prices are decreasing?

As noted above, the Guidelines currently provide that the maximum price under the Guidelines is automatically reduced it exceeds the HIP. In other words, the international price comparison supersedes the CPI factor in this case.

In recent years, on an interim basis, the Board has not allowed CPI changes in the Guidelines. It will be difficult for the Board to continue this approach: The *Patent Act* requires it to take the CPI into account in determining if a price is excessive. It is reasonable to argue that only Parliament has the ability to limit or remove this factor.

In any event, the PMPRB's Annual Reports indicate the rate of price increases for patented drugs is not a concern:

> "General price inflation, as measured by the CPI, has exceeded the average increase in the prices of patented medicines almost every year since 2003. In 2021, the CPI rose by 3.4%, while the national average transaction price and the national list price PMPIs increased by 0.4% and 0.5%, respectively." (2021 Annual Report, p. 48)

Question 3.5: What is the ideal timing for scientific review and therapeutic comparator identification? At what price review stage(s) should scientific review be applied?

The ideal timing for scientific review and therapeutic comparator identification is in the context of a hearing in front of the Board. Otherwise they should only be necessary, if essential to the efficient functioning of the Guidelines, at the time the medicine is first sold in Canada.

Some Comments on Box 3:

Box 3 is included in the Scoping Paper to illustrate that prices in other countries may decline over time relative to prices in Canada. It is submitted that if this information is intended to inform these consultations and ultimately the Guidelines, more robust data analysis is required.

- Box 3 relies on third party data and not the publicly-available prices filed with the PMPRB. Does it represent an apples-to-apples comparison?
- If the PMPRB has established that the IQVIA data represent publicly-available ex-factory prices for patented medicines, has it published its supporting analysis?
- Is there any information to suggest that differing price movements from country to country are reflective of the impact of patents? On the contrary, they are likely to reflect differences in market conditions including actions and decisions by downstream players.

Theme 4: Investigations and Referral to Hearing

Question 4.1: Are the criteria published in the 2010 Guidelines for commencing an investigation still appropriate (assuming adjustment to PMPRB11)?

Question 4.2: How much detail should the Guidelines set out regarding what happens once an investigation is opened?

It is essential that the Board provide clear guidance and direction to Staff as to when to conduct an investigation, and what steps should be involved. In principle, an investigation by Board Staff should take into account all the statutory factors of the Act that the Board would be asked to consider in a hearing. Key considerations to keep in mind:

- Board Staff work, as an integral part of the PMPRB, under the direction of and reporting to the Chair.
- They are not an independent body like the Commissioner of Competition.
- They do not have standing in cases in the courts; the PMPRB is represented as a unitary entity.
- They do not have policy responsibility to develop pharmaceutical pricing policies in Canada nor to advocate for or pursue policy objectives – except to the extent directed by the Chair pursuant to the Act.
- It is submitted that Board Staff have the same obligations as the Board itself to behave in an impartial and objective manner in dealing with rightsholders, and other stakeholders.

The directions to Board Staff on when and how to conduct investigations should be clearly articulated and made public.

Question 4.3: Should the PMPRB continue to use Undertakings as an investigation closure mechanism?

Yes.

For reasons outlined below, the PMPRB should require more transparent undertakings in cases involving a significant remedy, including all price reductions. VCUs help to establish accountability for the rightsholder and the PMPRB and provide guidance for other rightsholders.

Minor variances from the Guidelines for technical reasons can and should be resolved administratively.

Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives

Question 5.1: What efficiencies could be gained by co-ordinating decisions and timelines of the PMPRB with those of the Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et services sociaux (INESSS) and pan-Canadian Pharmaceutical Alliance (pCPA) or insurers (public and private)?

It is not apparent that any efficiencies will be gained by coordinating decisions and timelines of the PMPRB with other agencies. Those agencies do not appear to take PMPRB status into account in their work.

The PMPRB should be aware of timelines in the drug approval and reimbursement system and seek to address any negative impacts its own actions might have. But the Board cannot coordinate the substance or outcome of its reviews with other agencies. Also, any "coordination" should be limited to sharing publicly available information and providing a "heads-up" when appropriate.

Question 5.2: How can the PMPRB optimize its presence within the Canadian bio/pharmaceutical ecosystem to support a whole of government approach to issues relating to patented medicines?

The PMPRB constitutes an important presence in the Canadian biopharmaceutical ecosystem in carrying out is mandate. It supports government policy by fulfilling its mandate. It can optimize its presence by ensuring that it provides complete, fair, objective, and transparent reports on its activities.

General Comments

As noted in my submission to the Policy Roundtable, the PMPRB should reassess its consideration of prospective parties in its quasi-judicial activities as "partners." This may not only raise legal issues in future, but may also serve to encourage inappropriate collaborations.

In this regard, it is recommended the Board assess its involvement with the NPDUIS program. The Canadian Institute of Health Information (CIHI) is the owner of the NPDUIS database. The PMPRB was asked by Health Canada to work with CIHI in the initial phase of establishing the database and to support provincial drug plan needs on analytical studies that could not be achieved by CIHI at that time.

That need no longer exists. CIHR is able to and does conduct its own analyses and publishes comprehensive reports. It collaborates with PT health ministries in this work. In many ways, the PMPRB and CIHR reports overlap and duplicate the other. PMPRB staff work closely with public drug plans to identify the types of analysis they want PMPRB staff to do, adding support to the

notion that the PMPRB and drug plans are "partners." The Board should reassess its involvement with the NPDUIS.

In the meantime, the PMPRB should assess its practice of highlighting its NPDUIS work in the Annual Report. The PMPRB maintains an active publications program for its NPDUIS reports and they are in the public domain. Including them in the Annual Report is redundant and risks confusing those activities with the Board's statutory responsibilities.

Theme 6: Engaging with Stakeholders

Question 6.3: Canada and the world are facing a generation of new high-priced drugs for the treatment of rare diseases.

- ***(i) Should the PMPRB view the question of whether the prices of these medicines are "excessive" through a different lens than other types of medicines?***
- ***(ii) What quality of evidence should the Board consider when conducting its scientific review of these medicines?***

Advances in health technology innovation in our time are leading in some cases to effective treatments or cures for diseases and conditions that have not been adequately treated in the past. Some innovations, such cellular and gene therapy products, do not even easily lend themselves to traditional definitions of a "patented medicine."

A high price tag does not equate to "excessive." It was arguably this misapprehension that contributed to the policies pursued in recent years that sought to expand the Board's activities in ways inconsistent with the Act and constitution.

The Board should take care that "sticker shock" over the cost of these innovative treatments does not detract from the Board's track record of ensuring their prices are not excessive under the law.

The issue of how best to ensure that these treatments become available to people who need them is indeed a challenge globally, but it is not the responsibility of the PMPRB beyond its mandate to ensure their prices are not excessive.

Transparency

Critical to the PMPRB's relationship with stakeholders and the public is communications. Regular, objective and informative communications will go a long way to address the misunderstandings about drug prices and the PMPRB's role - and will help to inform Canadian pharmaceuticals policy.

Some specific suggestions for consideration:

- A more timely Annual Report: Historically, the PMPRB made every effort to submit its Annual Report to the Minister in time to allow tabling before Parliament's summer recess. The tabling is not in the Board's hands, but in recent years it has become evident that the Minister received the report on a much-delayed schedule.
- Regular, scheduled newsletters: For many years, the NEWSLetter was published on a quarterly schedule. This helped to provide stakeholders with relevant information, including quarterly Board meetings, drug reviews, consultations, and speeches and presentations by Board members and senior staff.
- Reports on individual new drug reviews with information on how staff applied the Guidelines; such reports were published on a regular basis in the past (without compromising the statutory confidential provisions.)
- More informative VCUs, explaining why the matter prompted the review by Staff and how it was resolved.
- Speeches and articles by the Chair and Vice-Chair.

Wayne Critchley
Ottawa
December 20, 2023

APPENDIX

ORAL SUBMISSION TO PMPRB POLICY ROUNDTABLE -- DECEMBER 6, 2023

I want to thank the Board for the opportunity to appear. I also want to congratulate you on launching this public consultation – it is the most open, broadly-based consultation by the PMPRB in a generation.

I am sure you have been as impressed as I have by the quality and breadth of the submissions. Canadians believe your work is important.

Today, I will highlight the main points of my forthcoming written submission and will welcome your questions. I have provided the Board with the relevant portions of my c.v. – that experience informs my remarks.

These are personal comments, not intended to represent the views of anyone else. Perhaps you can consider my submission as an *amicus* brief.

Let me focus on three themes:

- mandate and history;
- the policy of voluntary compliance; and
- the PMPRB's relationship with its interested parties.

Mandate and History

The PMPRB program was created 36 years ago – in fact 36 years tomorrow - the midst of contentious political debate about intellectual property policy for pharmaceuticals.

The 1987 amendments enacted a wide-ranging modernization of the *Patent Act* to bring it in line with our major trading partners. That objective necessitated the ultimate elimination of compulsory licensing for medicines – a policy which had been a uniquely Canadian feature and a trade irritant.

The PMPRB was created in response to concerns that these changes would allow patentees to take advantage of their improved patent rights by raising drug prices.

As the Chair has stated, intellectual property policy is a federal responsibility, but the regulation of drug prices falls under provincial jurisdiction. The federal drafters took great care to work within their constitutional authority, resulting in the complex program that is the PMPRB.

The Board was given a specific and narrow mandate – to review prices of patented medicines and take corrective action if it finds that a price is excessive. It is a quasi-judicial tribunal, governed by the laws of natural justice and required to ensure the patentee a right to be heard in a public hearing.

The Board's mandate has been consistently confirmed by the courts over the years – never expanded nor diluted.

The PMPRB model was novel and remains unique in the world today. No other jurisdiction attempts to restrain drug prices based on patent status and no one uses a judicial or quasi-judicial process for that purpose.

Although your mandate has not changed since 1987, the broader environment has evolved dramatically. You know about the great strides in pharmaceutical innovation. And you are well aware of the challenge of ensuring Canadians have access to the best and most appropriate treatments when needed.

That's a tough job, but it is not the job of the PMPRB.

How do other countries approach it? As payers or funders, they apply health technology assessment to evaluate the value of drugs; they limit and control coverage; and they engage in sophisticated negotiations with manufacturers to get the best price possible. Sometimes they decide not to purchase or cover a treatment at all.

In other words, they use the same approaches that Canadian payers, notably provincial drug plans, have come to use since 1987. In fact, this country has been at the vanguard of the development and use of health technology assessment internationally. The interjurisdictional cooperation in use of HTA and in joint price negotiation must be the envy of many EU countries. And could be a model for interjurisdictional cooperation in many other fields.

Voluntary Compliance Policy

Your Scoping Paper explains why voluntary compliance is critical to this program. In this regard, objective commentators must view the program as a success.

Voluntary compliance requires several elements: Clear guidelines; consistent and fair application; and follow through when necessary.

I submit it also requires transparency. A word you have heard often over the last two days.

My written submission will flesh out some specific ideas about how the Board can - and should - enhance its transparency -- primarily to support compliance -- but also to increase public confidence that the agency is doing its job.

You know that a public hearing by the PMPRB usually takes three years – followed by court appeals that are often as long. Although the Board may impose significant financial remedies, I submit that it is the risk of protracted litigation and market uncertainty that creates the strongest incentive for rightsholders to comply.

This raises an important issue for the PMPRB. Its unique legal framework as an integrated tribunal means that the Board itself does not participate in a price review prior to a hearing. The Board cannot delegate the ultimate decision on excessive price to the Board Staff --- BUT the ability of Staff to threaten a hearing gives them tremendous leverage in negotiating an undertaking. I know – I used it.

Greater transparency can go a long way to improve the accountability of the Board as an agency and in particular its staff.

One specific measure would be to re-institute and enhance the practice of publishing the reasons for a conclusion by Staff that a price is within guidelines and for the Chair's approval of a Voluntary Compliance Undertaking.

Theme 5

Finally, I want to touch on theme 5, the PMPRB's relationship with other parties in the ecosystem. This must be a highly nuanced discussion.

On one hand, the PMPRB needs to communicate with governments and other stakeholders and be aware of their priorities; but it must also be prepared to draw a line if that communication moves too close to real or potential influence or interference.

The Board should consult with patentees and other stakeholders while avoiding a bias, real or perceived, in favor of one side or another. This is why open, public consultations are best in my view.

This brings us to the PMPRB's use of the term "partner" in reference to agencies such as CADTH, INESSS and the pCPA. These organizations may be parties in a hearing – in fact the owners of pCPA have a statutory right to intervene.

I worry that treating some of the potential parties in a proceeding before you as "partners" sends the wrong message – and puts the Board's policy-making and quasi-judicial decisions at risk. In my view, if those entities have views on the matters in your Scoping Paper they should put them on the public record like everyone else and not assume you will treat them differently behind closed doors.

Follow-up consultations should provide an opportunity to assess your relationship with public and private insurers, patient advocacy groups and others and - also your role in various government programs such as the NPDUIS.

Conclusion

It is time to wrap up.

The Board has significant challenges:

- To amend its guidelines and policies to adjust to the 2022 amended regulations;
- To establish appropriate relationships with interested parties; and
- To restore public confidence in the integrity of the program.

You should not expect that everyone will agree with your actions but may you succeed in increasing their understanding of what you are doing and why it is important.

Wayne Critchley
Ottawa
December 6, 2023