MEDISON

December 5, 2022

Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Submitted via the PMPRB Website Consultation Submission Portal

RE: Medison Pharma Canada Response to the 2022 Proposed Updates to the PMPRB Guidelines

This submission is made by Medison Pharma Canada Inc., in response to PMPRB's Draft Guidelines published on October 6, 2022. We are proud to make this submission, offering feedback that we believe will contribute to a thriving and sustainable healthcare system in Canada and is in the best interest of the patients we serve, along with our current and future business partners.

Medison is a global pharmaceutical company providing access to highly innovative therapies (HITs) to patients in international markets. **At Medison, we believe that every patient, everywhere, has the right to access breakthrough treatments.**

This is the reason why, after reviewing the PMPRB's proposed updates, we are deeply concerned that the guidelines as drafted will only make it more challenging for Canadian patients to access novel, potentially life-altering therapies. Specifically, as is detailed below, we are concerned about:

1. **The uncertainty created by no posted rules.** We believe a sustainable landscape of innovation requires transparency and predictability.
2. **The lack of regard for clinical benefit.** We believe in the importance of new therapies and that pricing should reflect the value of these new therapies to Canadians.
3. **The composition of the basket of countries.** We believe in a fair assessment of prices that supports Canada as a thriving international market for pharmaceutical and biotech innovation.

These issues actively discourage biotech innovators from launching their products in Canada. In turn, Canadian patients suffer from being unable to access the novel medicines available in other parts of the world. While we respect that it is not PMPRB's job to foster innovation, their policies should not stand in its way.

Medison Canada – Always Ahead

Medison launched in Canada in 2019 with the vision that every patient in need will have fast access to highly innovative therapies (HITs).

At Medison, we do this by working to accelerate access to HITs in jurisdictions that often get "left behind" when product launch strategies are developed. Canada is an example of one of these jurisdictions. Growing concerns about Canada's innovation climate mean, at best, it is a tertiary market for many biotech and pharmaceutical companies as they strategically consider the sequence of their launches. Sometimes, HITs never launch in Canada at all. Medison has created the first commercialization platform to accelerate multi-regional access to HITs in Canada through our partnerships with emerging biotech companies (EBCs).

Medison Canada
One Dundas St. West, Suite 2500, Toronto, ON M5G 1Z3
Tel. 1.800.696.1341
medisonpharma.com

At Medison, we work with EBCs, in an affiliate-like partnership, to help expand their reach into these international markets. To underscore the importance of this work, according to researchers, small biotech firms account for more than 60 per cent of new drug approvals in the U.S., making them an important source of product innovation.[i] We can fairly extrapolate a similar scenario here at home.

From our experience, however, many of these small-to-mid-sized companies are not scaled to consider Canada in their current business model, so these partnerships become the only viable method to bring their medicines to Canada. In this way, Medison helps create and accelerate opportunities for patients suffering from the most challenging diseases to access the treatments they need.

In only three years since inception, we were able to bring four new molecules to market in Canada.

In many cases, there has been no indicated effective therapy available for these patient populations. They and their physicians have often had no other choice than to make do with best supportive care. These are real people and families grappling with often devastating diagnoses and no obvious therapeutic option. They deserve better.

Medison offers this submission for consideration because we believe that, working together, we can do better for Canadian patients.

What is particularly befuddling is the apparent contradiction between national initiatives and programs designed to foster innovation in the life sciences and PMPRB's proposed policies that raise uncertainty and unpredictability for innovative medicines coming to Canada. For example, while Health Canada and the Access Consortium are focused on providing "faster access to safe, effective and high-quality medicines for all our populations"[ii] PMPRB policies are encouraging companies to bypass Canada – and Canadian patients – altogether.

A synopsis of our feedback is included below.

Issue #1: The uncertainty created by no posted rules.

We believe a sustainable landscape of innovation requires transparency and predictability.

As with any engagement, there needs to be a clear set of rules. In this case, pharmaceutical manufacturers need a clearly delineated set of guidelines related to the review of drug pricing in Canada. Despite their limitations, prior iterations of the PMPRB's Guidelines featured clear price tests that offered predictability and transparency. In turn, manufacturers were able to make decisions and plan the strategic, largely foreseeable, path of their products.

The current recommendations are vague and create often debilitating uncertainty for anyone trying to navigate Canada's pricing environment. As a company committed to working with small and emerging biotech companies, the lack of specificity in these guidelines can be the difference between life-changing innovations arriving on our shores or losing the opportunity to introduce new, innovative therapies for Canadians altogether.

From our own dealings with prospective partners considering entry in the Canadian market, we have noted that these companies are both confused and concerned. Without a clear path forward, including a complete understanding of the challenges ahead of them, many are deciding to delay or forgo the Canadian market entirely.

The proposed guidelines only exacerbate an already dire situation. For instance, presently, there is on average a two-year delay, which seems to be growing, between when drugs are available in the United States and Europe and when or even if they are available in Canada.[iii] Likewise, only 60% of treatments for rare disorders make it to Canada and most get approved up to six years later than in the USA.[iv]

In addition, under the updated guidelines, there is no clear set of rules to guide a company should one of their products fall under investigation. Objective, fair, and consistent application of these rules

necessitates a well-articulated process that allows companies to not only plan for the launch of products but also to defend their approach and decisions should an investigation be triggered.

Issue #2: The lack of regard for clinical benefit.

We believe in the importance of new therapies and that pricing should reflect the value of these new therapies to Canadians.

As currently outlined, the Draft Guidelines will no longer consider the therapeutic value of a drug when assessing either its comparators or final price. In fact, whether a drug is a breakthrough or not is considered "extraneous content" by PMPRB.[v] As a result, the proposed PMPRB guidelines will fundamentally and negatively shift the innovative medicine environment in Canada.

At Medison, we are passionate about medical innovation. It is our raison d'être; we are deeply committed to pursuing, fostering and investing in opportunities for innovation around the globe. Rather than being extraneous content, we know that these innovations save lives.

The proposed guidelines are punitive to new entries. The lack of reasonable domestic comparators, especially in situations where off-label therapies are currently being used, means the price of innovative therapies face an artificially-low price ceiling. This not only favours companies who bring "me-too" drugs to market as well as second and subsequent market entrants, but also actively discourages new innovation.

When we are unable to incentivize innovation, at the very least supporting an environment in which companies are able to recoup their investment in product development, we risk losing access to new answers for patients.

Under these proposed guidelines, unmet need will inevitably be left unmet.

Issue #3: The composition of the basket of countries.

We believe in a fair assessment of prices that supports Canada as a thriving international market for pharmaceutical and biotech innovation.

In July 2022, PMPRB introduced PMPRB11, the updated basket of comparator countries for reference-based price tests. These include Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden and the United Kingdom. The addition of Australia, Japan, Belgium, and Norway along with the exclusion of the United States and Switzerland, comparators under the former regulations, is notable and has a significant downward impact on prices. For instance, there was a recent assessment of list prices in Canada and across the reference markets. This review relied on a sample of drugs sold in Canada in 2019 and reviewed by the PMPRB. Ultimately, it found that the median international price (MIP) test was on average 10% lower under the new PMPRB11 basket compared to the previous PMPRB7.[vi]

The new guidelines effectively introduce a "non-excessive" price ceiling of, at most, the median PMPRB11, and often lower should companies wish to avoid investigation. PMPRB suggests the domestic Therapeutic Class Comparison (dTCC) < MIP scenario will occur in approximately 7% of cases[vii]; we believe this to be a gross underestimation of the number of products impacted. PMPRB has substantial latitude in selecting the TCC and in many cases would be able to find therapies that are used but not indicated or not effective.

The partners we work with at Medison have expressed grave concern about not only the impact of the proposed guidelines on final prices for their medicines, but the significant downstream impact of these guidelines on pricing in other jurisdictions.

In particular, international partners will inevitably wait to see final pricing for a specific product or therapeutic category, so they can take that direction into account in their planning and assessment of the market potential. If future partners wait to bring therapies to Canada, this means Canadian

patients will also wait; often, patients who do not have the time to spare. To illustrate, Medison research demonstrates that of the 213 orphan drugs approved in either the United States, Europe or both, only 51% were approved over the same timeframe in Canada, and it took a mean average of 213 days longer compared to the US and 305 days longer than the European Medicines Agency (EMA).

The causes of delays in patients receiving access to highly innovative therapies vary in each of the jurisdictions Medison serves but a consistent theme is the very real impact of pricing oversight on launch sequencing. While some processes (like Project Orbis which focuses on collaboration among international regulators) have been implemented to help ensure alignment across international markets with respect to drug approvals, access to drugs in Canada is often delayed based on pricing decisions.

The unfortunate reality is that Canada is no longer a tier 1 market. The uncertainty generated by the proposed PMPRB guidelines, and the impact of the same on the planning of global launch sequencing, is making it even more challenging to convince small biotech companies to take on the risk of launching here.

At Medison, we call on PMPRB to consider and address the potential difficulties posed by the proposed guidelines. We know that we share a commitment to Canadian patients and their wellbeing and we remain hopeful that we can forge a path forward that best serves the health of patients both here at home and around the world.

Sincerely,

Maureen Hazel

Maureen Hazel

Senior Manager, Market Access

Cc: Pamela Minden, General Manager, Medison Pharma Canada

---

[i] York University. Study examines R&D project success in small biotech firms. August 7, 2022 Study examines R&D project success in small biotech firms – YFile (yorku.ca)

[ii] Government of Canada. Access Consortium Strategic Plan 2021 – 2024. Access Consortium Strategic Plan 2021-2024 - Canada.ca

[iii] Santosuosso, M., et al. "HPR56 Challenges of Funding Orphan Medicinal Products in Canada: Quantification of Approval Rate and Reimbursement." Value in Health 25.7 (2022): S476.

[iv] Canadian Organization for Rare Disorders (CORD). https://www.raredisorders.ca/our-work/

[v] PMPRB industry webinar re 2022 Proposed updates to the PMPRB Guidelines

[vi] Labban, Margaret. Pharmaceutical Technology. Canada's PMPRB reform delays add uncertainty. July 2021. https://www.pharmaceutical-technology.com/pricing-and-market-access/canadas-pmprb-reform-delays-add-uncertainty-html/

[vii] PMPRB industry webinar re 2022 Proposed updates to the PMPRB Guidelines

Medison Canada
One Dundas St. West, Suite 2500, Toronto, ON M5G 1Z3
Tel. 1.800.696.1341
medisonpharma.com