PMPRB

Scoping Paper Consultation on New Guidelines

December 20, 2023

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Submission to the Patented Medicine Prices Review Board (PMPRB)
Scoping Paper 2023 Consultation

Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa ON, K1P 1C1

December 20, 2023

RE: PMPRB *Draft Guidelines*

Thank you for the opportunity to submit written comments in response to the proposed PMPRB *Scoping Paper 2023* operationalizing the amended *Patented Medicine Regulations* under the *Patent Act*.

ABOUT INNOMAR STRATEGIES

Innomar Strategies Inc. (Innomar), a part of Cencora, is Canada's leading specialty medications service provider. Headquartered in Oakville, Ontario, Innomar employs over 2,800 associates across Canada and owns over 165 infusion clinics with over 730 employed nurses, as well as owning pharmacies in every province.

Through our integrated Patient Support Programs (PSPs), Innomar is a service provider to pharmaceutical manufacturers andassists patients with gaining access to specialty medicines for chronic and complex diseases. PSPs support patients in many disease areas, including oncology, rare diseases, respirology, and immunology.

Innomar operates the most comprehensive national network of full-service specialty support and reimbursement programs, including patient enrollment, reimbursement navigation, education and adherence support, specialty nursing and clinic services, and pharmacovigilance. Innomar's infusion clinics and specialty pharmacies closely integrate into over 165 PSPs to allow patients to promptly start their drug treatment and fill an important need within the Canadian healthcare system.

Engaging with Patients, Health Practitioners, Pharmacy, and other Stakeholders

Innomar welcomes the PMPRB's solicitation of input from a range of non-industry and non-institutional stakeholders who represent diverse voices in the broader patient service community, as the PMPRB's role is part of a larger complex system that governs how medicines are approved, regulated, and distributed to Canadians across the country.

Should the PMPRB view the question of whether the prices of these medicines are "excessive" through a different lens than other types of medicines?

While Innomar remains concerned about the impact the Guidelines to be developed may have on the availability of new and innovative therapies, a principal concern also relates to the impact on specialty medication infrastructure and the effect of cost compressions on PSP operations, as Canada remains unique in that our PSP services are funded solely by the manufacturer, not the public or private healthcare system.

Many of the services that are provided to patients to support their access and adherence to therapies are built into the price of the medication. In fact, many of the therapies that will likely be impacted by the Guidelines require complex cold chain storage, handling, administration, and counseling.

Distributors and PSP providers are continuously investing in and adapting their infrastructure to ensure the safety and security of the supply chain, from manufacturers all the way to the patient. The new Guidelines to be developed should ensure clear pricing structure, as ambiguities may result in significant downstream on the ability of services to provide the level of care that Canadians have come to expect for the medications they are currently taking:

- **Innovative medicines**: If the Guidelines do not provide a clear pricing structure, this will have the potential to disincentivize manufacturers from prioritizing making medicines available in Canada now and into the future. Bringing further uncertainty to the sector within the current environment only increases the risk of compromising access to medications for Canadians. Manufacturers are evaluating their launch plans for new medicines in Canada, and in many cases will either delay or choose not to launch at all due to uncertainty associated with the new Guidelines. Canadian patients with chronic and complex diseases will not have access to life-saving new medicines as manufacturers will be unable to afford the investment to launch within Canada.[2]

- **PSP services**: Manufacturers will be unable to finance the full breadth of PSP services to support patients. Canadian patients with chronic and complex diseases will not receive services that aid with access to specialty medicines.[2] As a result, Canadian patients may suffer in their therapy as without the appropriate support mechanisms of a PSP they may drop off their medications, miss doses, and/or misuse their medications which can lead to increased burden on the public healthcare system and payers, e.g., increased medical costs, hospitalizations leads to hallway medicine, and medicine cost wastage.

Given the current environment in which specialty medicine services are operating, we continue to strongly urge that the PMPRB develop a comprehensive approach to medicine affordability and accessibility with its partners, and conduct impact assessments to inform the universality and accessibility of innovative medicines.

We believe that Canadians should have affordable access to the medications they need -- and importantly, new products need to be launched in this country to ensure that Canadian patients continue to have access to new and existing specialty, rare disease and ultra-rare drugs.

What quality of evidence should the Board consider when conducting its scientific review of these medicines?

In addition to PSPs filling a gap in the Canadian public healthcare system, importantly, PSP service offerings can provide a rich data source that in turn can inform manufacturer sponsored studies of health outcomes for patients with chronic and complex diseases. Canadian payers are increasingly looking to manufacturers to present Real-World Evidence (RWE) data to demonstrate health outcomes, including the efficacy and safety of their products; and to help support that the patient is on the appropriate drug. PSPs are a rich data source for RWE. Using PSP data, Innomar has developed numerous real-world case studies to demonstrate the value of PSPs and associated services. Examples include:

- Monitoring and management of patient treatment plans helped to achieve better and more cost-effective patient health outcomes.
- Patients who enrolled in an adherence support program benefited from enhanced medication adherence – which in turn led to better health outcomes.
- PSP data helped to identify reasons for medicine discontinuation and to develop a strategy to help patients stay on the medicine that they are responding to.
- PSP nursing support at Innomar's clinics and patients' homes generated savings to the public healthcare system through significantly reduced clinic visits. Economic benefits to patients and health system included reduced time off work to receive injections and reduced travel expenses.
- Private infusion clinics may have a shorter patient time-to-treatment initiation (TTI). This shorter TTI could ease the wait time burden for oncology infusion patients currently waiting to receive therapies in public hospitals and cancer centers in Canada.
- PSP data can help manage required negotiated product listing agreement (PLA) reporting - insurer pays only for patients that meet agreed-upon health outcomes while on a specialty medicine.

Successful high-cost specialty drugs will need to incorporate RWE across the product life cycle, and the need to link data to forecast and track outcomes over time. Particularly post-pandemic, RWE will be critical in measuring and understanding the long-term impact of the disease, which in turn will help create a

treatment roadmap and support manufacturers in expediting the launch of therapies across the world.

How can the PMPRB better engage with you?

To accurately measure the impact of the new Guidelines on patients' access to medicines, we suggest that PMPRB monitor and assess the impact on patient support services that can help to facilitate access to medicines. As a leading PSP provider and innovator in Canadian market access solutions, Innomar is well-positioned to monitor and advise the PMPRB on changes in patients' access to new and existing medicines, as well as manufacturer-sponsored:

- co-pay assistance
- compassionate drug
- infusion services and nursing support
- diagnostic services
- reimbursement navigation services
- patient care coordination
- patient education & counselling

Innomar welcomes the opportunity to work with PMPRB to track the impact of the PMPRB Guidelines on PSPs. Suggestions include tracking the number of PSPs that have been delayed or cancelled and why? How many PSPs have been created as a percentage of new Notices of Compliance compared to historical levels?

CONCLUSION

In summary, Innomar has provided key recommendations on the development of the new Guidelines in order to ensure that Canadian patients continue to have access to new and existing specialty, rare disease and ultra-rare drugs. We believe that the Guidelines will impact manufacturers' ability to launch new drugs, and subsequently fund PSP and clinic services -- services that are not currently provided by the public healthcare system, creating barriers and significant disincentives for manufacturers to bring innovative drugs to Canada.

We thank the PMPRB for the opportunity to submit our comments in response to the Scoping Paper Consultation.

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