Innomar Strategies Submission to the Patented Medicine Prices Review Board (PMPRB)

***Draft Guidelines* Consultation**

August 4, 2020

RE: PMPRB Draft Guidelines

Thank you for the opportunity to submit written comments in response to the proposed PMPRB Draft Guidelines (June 2020 version) operationalizing the amended Patented Medicine Regulations under the Patent Act.

ABOUT INNOMAR STRATEGIES

Innomar Strategies Inc. (Innomar), a part of AmerisourceBergen, is Canada's leading specialty medications service provider. Headquartered in Oakville, Ontario, Innomar employs over 2,580 associates across Canada. Innomar owns over 150 infusion clinics employing over 600 nurses, as well as pharmacies across Canada.

We are shaped by the belief that every Canadian deserves access to the specialty medication they need, when they need it. In 2001 we began our journey to provide a new model for pharmaceutical support services tailored to meet the needs of the Canadian market. Our name, Innomar, reflects our roots in INNOvative MARket access solutions and reimbursement consulting. For the last 19 years, we have grown and expanded our portfolio of commercialization services. Still, we have kept the patient at the heart of everything we do.

Through our integrated Patient Support Programs (PSPs), we support patients in many disease areas such as oncology, rare diseases, respirology, immunology and others. Innomar's infusion clinics and specialty pharmacies closely integrate into over 120 Innomar operated PSPs to fill an important unmet need within the Canadian public health care system.

Canadian PSP services are solely funded by the manufacturer, not the public or private health care system. In some countries, the public health care systems fund specialty drug infusions, therefore making the comparison of the drug prices between Canada and these countries unreasonable. In Canada, in some cases, the manufacturers annual cost to infuse one patient with a typical specialty biologic can be as high as a low double digit percentage of the current drug price.[1] The cost to infuse one patient may include all or some of the following patient support services:

- Patient enrolment, reimbursement navigation
- Education and adherence support
- Specialty nursing and clinic services
- Pharmacovigilance

PSPs FILL A GAP IN THE CANADIAN PUBLIC HEALTH CARE SYSTEM

PSPs were created to work in tandem with the public health care system and to fill the gaps in patients' disease management needs (see Appendix A). Patients are not usually aware of how to

[1] **Note**: Nursing cost is based on an infusion 3 hours in length administered every 8 weeks. These costs increase with infusions that are longer and/or more frequent. Furthermore, generally speaking, costs to support a patient in their access to a specialty biologic will vary depending on the type of biologic, i.e. infusible, injectable, and additional patient support services offered by the manufacturer for the specialty medicine.

gain access to their medications, and often find it difficult to navigate the health care system once diagnosed. In addition, physicians also find it difficult to keep up with the administration requirements for specialty therapies and coordinate with various stakeholders including pharmacy, hospital, nurses, and payers. PSPs, therefore, enable manufacturers to execute patient support services that benefit patients and physicians.

For further information on PSPs, including their value-add, please refer to Innomar's submission to the PMPRB in response to the first draft Guidelines (November 2019 version) consultation.

OVERVIEW STATEMENT: UNINTENDED CONSEQUENCES OF PROPOSED PMPRB GUIDELINES (JUNE 2020 VERSION)

PSP services: The types of services that are currently being funded for patients and expected by physicians and the public health care system will not be sustainable, if the ceiling prices for those drugs are dramatically reduced. Canadian patients with complex chronic, rare and ultra-rare diseases will be denied assistance that allows them access to treatment.[2] A reduction or elimination of PSP services will lead to deterioration in the quality of care, non-adherence, wastage and decline in patient outcomes, ultimately resulting in increased public health care resource use and increased cost to Canadian taxpayers.

Innovative medicines: Patentees will delay or stop the launch of innovative drugs to Canada to safeguard drug prices in other markets. The growth of the Canadian life sciences sector in Ontario and across Canada will be significantly impacted, and this lack of access may lead to patients not having the chance to access important disease therapies.

ISSUE #1: REDUCE UNCERTAINTY CREATED BY THE PROPOSED APPROACH TO PRICE REGULATION

Consequences

- Unnecessary risk and uncertainty for patentees looking to launch new medicines in Canada – resulting from PMPRB's plan to monitor and measure the impact of regulatory amendments, and adjust the approach at a later date.
- Unpredictable revenues in Canada for patentees ahead of a launch decision as a result of the proposed MRP formulas and reliance on CADTH base-case re-analyses.
- Due to lack of certainty in revenues and cost analysis, patentees may choose not to launch given the risk and uncertainty.
- Unreliability in predicting allowable price ceilings throughout the product lifecycle – a result of:
    - Annual adjustment of MRP/MRP[A]
    - Re-assessment of Relevant Indication
    - Re-classification of Categories
    - Adjustment of MLP based on fluctuations in MIP

[2] Reference: Life Sciences Ontario. *New federal drug pricing rules are already delaying medicine launches and costing jobs in Canada, survey reveals*. February 3, 2020

Impact on the patient

- Negative impact on Canadian product launch timelines, which will delay and/or deny Canadians' access to necessary specialty medicines.
- Reduced investments to improve quality of care and health outcomes for Canadian patients due to lack of certainty in long-term drug prices.
- Patients may experience fluctuating patient support services, resulting in inconsistent health care delivery for the patient in the long-term and making complex diseases less manageable.
- Non-adherence and decline in patient outcomes – a result of inconsistent support provided to patients, will lead to more costs to the health care system.

Recommendations

- Introduce a stepwise approach to implementing the PMPRB Framework by enacting the changes to the comparator countries first. Monitor and evaluate the impact of the amended comparator countries on drug prices, access, PSP services, and the economy. If PMPRB's stated policy objective to bring Canadian prices closer to MIP of PMPRB11 is still not met, proceed with the implementation of the new economic factors.
- Keep the current approach with multi-indication pricing as it is well managed in Canada through Product Listing Agreements (PLAs) in both the public and private sectors. Changing ceiling prices for all indications may cause unnecessary risk for patentees regarding their current products. In addition, PMPRB's approach may cause patentees to abort the development of new indications in Canada.
- Reduce, at the very least, instability in long-term drug pricing by reducing the frequency of adjustments – achieve this by completing re-assessments every 3-5 years as opposed to annually. Adjustments above 10% should be enforced with a step-wise approach to reduce drastic price changes and provide a measure of certainty for industry investments.

ISSUE #2: PRICING OF DRUGS FOR RARE DISORDERS

Consequences

- Large mandatory rebates on prices of rare disease drugs, despite the proposed price floors – a result of the proposed therapeutic level criteria requirements, e.g. high quality evidence, and MRP formulas.
- Potential significant revenue reductions for patentees of rare disease drugs – a result of relying on an ICUR threshold of $150,000-$200,000 to establish whether the price of a rare disease drug is excessive. This approach is inappropriate due to the inherent ambiguity of pharmacoeconomic analyses in such patient populations. In addition, beneficial outcomes resulting from drug use may be clinically significant, however the QALYs may appear over a long time period, thereby lowering the equation's denominator leading to a high ICUR.

Impact on the patient

- Delays in Canadian launch timelines, which will deny Canadian patients' access to life-saving treatments.
- Canadian patients will no longer have access to manufacturer-sponsored financial assistance or compassionate drug access, especially at a time when unemployment rates are high due to the COVID-19 pandemic.
- Non-adherence and decline in patient outcomes – a result of reduced support provided to patients.

Recommendations

- Give special consideration for rare disease drugs with respect to evidence requirements for therapeutic level determination.
- Do not subject rare disease drugs to arbitrary "value for money" considerations.
- Retain HDAP for rare disease drugs to maintain a level of impartiality and oversight over PMPRB.

PROPOSED OFFER: TRACKING THE IMPACT OF PMPRB CHANGES

To accurately measure the impact of the new Guidelines on patients' access to medicines, PMPRB should monitor and assess the impact on patient support services that 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

Recommendation

- PMPRB to consider working with Innomar to track the impact of the PMPRB Guidelines on PSPs. For example, track some of the following: how many PSPs 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 recommends that:

- PMPRB implement a stepwise approach by first monitoring the changes to prices in Canada based on the new comparator countries and determining the impact before introducing other changes.
- PMPRB abandon the concept of re-evaluating prices when new indications are granted. Otherwise, this will lead to pharmaceutical companies focusing on one indication only.
- PMPRB limit the frequency of reassessments and adjustments to 3-5 year periods to maintain a better climate of certainty for patentees.
- Special consideration be granted for rare disease drugs.
- HDAP should be retained for rare disease drugs in order to maintain a level of impartiality and oversight over PMPRB.
- PMPRB to work with Innomar to monitor the impact of the Guidelines on patient support services that facilitate access to specialty medicines.

In conclusion, Innomar strongly believes that the proposed draft Guidelines (June 2020 version) will cause significant hardship to Canadian patients with complex chronic, rare and ultra-rare diseases. Innomar has provided key recommendations, as well as a proposed approach to monitor the impact of the proposed draft Guidelines (June 2020 version), to ensure that Canadian patients continue to gain access to treatment.

We trust that our feedback will help stress the high importance of PSPs, for both patients and the long-term sustainability of Canada's publically funded health care system. We need to ensure that cost-containment efforts are balanced with the needs and interests of Canadian patients.

We thank the PMPRB for the opportunity to submit our comments in response to the proposed Guidelines and welcome further dialogue.

Sincerely,

Guy Payette
President
Innomar Strategies
3470 Superior Court, Oakville, ON L6L 0C4
gpayette@innomar-strategies.com

InSight
INDUSTRY UPDATE SERIES

MAY 2018

Value of Patient Support Programs for Specialty Medications in Canada

The use of specialty medications for the treatment of complex, chronic diseases has led to new requirements for healthcare delivery beyond the traditional dispensing activities of non-specialty products. Although there is no standard definition of a specialty medication, they are generally defined as high cost, low volume agents requiring special administration and product handling, and usually reside in the therapeutic areas of Immunology, Rare Diseases, and Oncology. Due to the complexity of specialty medications and the diseases they treat, there are needs for enhanced management, including patient education, administration, diagnostics, monitoring, and specialty logistics support services. However, the Canadian healthcare system is not equipped to provide the support that many patients need to gain access to reimbursement and drug delivery of a specialty medication, or the ongoing support and monitoring often required to improve clinical outcomes. Manufacturer-funded Patient Support Programs (PSPs) were created to work in tandem with the healthcare system to fill the gaps in these patients' disease management needs.

Gaps in Canadian Healthcare System for Specialty Medications

Many people assume that the cost of all healthcare services are covered in Canada, but this does not apply to all services for specialty medications. Clinical services are required for many specialty medications, including infusion or injections in clinics or via home care, and these services may not be covered by public or private payers. Further, specialty medications often have unique administration requirements that necessitate additional or customized training, and ongoing support of patients and their caregivers, for example: mothers who have to provide regular injections to their young children may need more frequent advice or even respite support; patients prescribed medications dosed by weight may need support for precise dosing administration; and some patients may need more contact with a healthcare professional (HCP) as their specialty medication is being titrated. Regular disease management support, including patient and caregiver education and frequent touch points, cannot always be provided readily by HCPs due to the administrative and time constraints of clinical practice, and there is often limited support available outside of physician visits, or limited knowledge of the additional public support available.

The journey to gain access to a specialty medication is daunting for patients, particularly when they are quite ill, and there is little support to navigate this difficult process. Lack of knowledge of public and private reimbursement mechanisms and criteria, and coordination of benefits; and the complexity of paperwork and testing requirements, can cause delays in treatment and much anxiety and fear amongst patients and caregivers. Additionally, Special Authorization for specialty medications is

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generally required for public and private reimbursement decision-making, and the process is complex and time-consuming for HCPs and patients alike.

Medication non-adherence leads to suboptimal health outcomes, increased healthcare resource utilization, and increased direct and total medical costs; however, the healthcare system cannot always provide the support that many patients need to stay on therapy and refill their prescriptions. The WHO reported that adherence among patients with chronic diseases averages only 50% in developed countries[1], and up to 30% of patients fail to fill a new prescription.[2,3] Interventions that can address the possible risk factors for non-adherence and sustain patient medication adherence and persistence are needed to reduce the economic and health burdens of complex chronic diseases, but services to support HCP instructions outside of clinic visits are not provided by public or private payers.

Currently, healthcare-related data necessary to determine how a patient is responding to their specialty medication is fragmented and inconsistent as it comes from many different sources. A consolidated view is not readily available to HCPs, e.g. trends in Health Assessment Questionnaire (HAQ) for rheumatoid arthritis and lab values, and there is no data available to a physician to determine whether a prescription has been filled or refilled. A more robust, formal approach to collecting data is important to help facilitate HCP access to patient data, and to enable the collection of health outcomes data that would benefit payer decision-making.

PSPs Provide Value to Help Fill the Gaps in the Healthcare System

Manufacturer-supported PSPs were created over 15 years ago to support patient access to complex medications. Now PSPs provide a more holistic approach to patient, caregiver, and HCP support when specialty medications are prescribed, including: reimbursement navigation; clinic and nursing support (infusion and injection administration/ training); patient education and counseling; risk management and adherence; specialty pharmacy and logistics services; and connection to other social support services. PSPs fill the gaps in services not readily available in the current healthcare system to help optimize health outcomes and value in patient-focused care. As a result, PSPs have demonstrated a positive impact on patient adherence, and clinical and economic outcomes.[4,5]

PSPs fill the gaps in services not readily available in the current healthcare system to help optimize health outcomes.

PSPs support patient disease management by providing rapid access to specialty drug administration and education. PSP clinic and field nurses administer injections and infusions, patient self-injection training, and rigorous safety monitoring, in the convenience of local private clinics or in patients' homes. PSP nurse case managers also provide education, and ongoing lifestyle, health and wellness support to patients via frequent touch points.

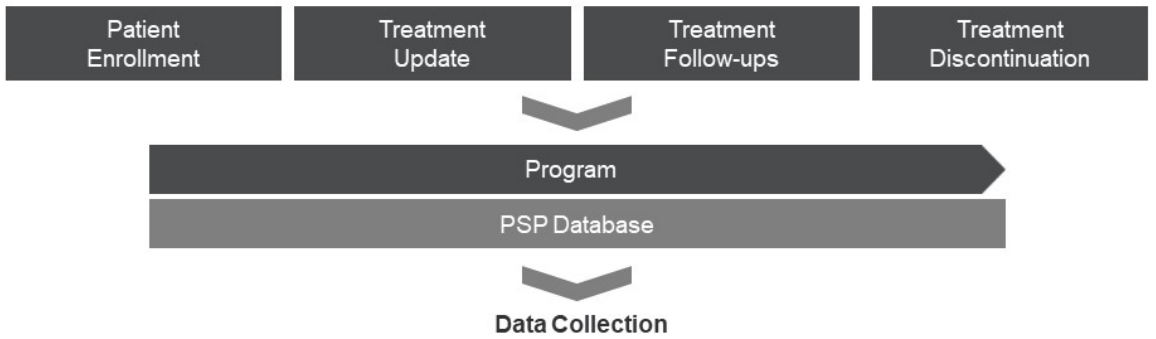
Reimbursement specialists have experience with the complexity of drug reimbursement navigation, and support patients through their entire journey to help ensure patients get on drug faster and maximize their coverage. Changes in health care policy pose challenges for reimbursement, as do

the forms, policies and requirements that can change and vary greatly by provincial and private payers; however, PSP reimbursement specialists are experts in the payer landscape and the technology required to expedite the process. They support patients and HCPs in completing all payer forms, submissions, and escalation of denials. Field case managers also support physicians and nurses in their clinic by helping to coordinate testing and appointments, and to support the administrative burden of the reimbursement process.

PSP nurse case managers are integral in supporting patient adherence to help optimize treatment outcomes. They are a single point of contact for each patient to support patient health literacy; support understanding of the patient's treatment regimen and expected results; coordinate of drug ordering and delivery so there is no gap in their treatment; and to follow up with the patient to ensure they are adhering to their treatment plans. Nurse case managers provide motivation and knowledge to empower patients, assess patients for non-adherence risk factors, and customize patient touch points based on patient need. Touch points can include a variety of mediums, including regular phone calls, and technology-based adherence interventions. Additionally, nurse case managers can connect patients and families to support services that they may not be aware of, such as, patient advocacy groups, government-funded programs, social workers, etc. If a fully integrated model is used, the access to pharmacy data can also help to quantify patient non-adherence, and nurse case managers can provide this information via a regular feedback loop to the prescribing physician.

Healthcare-generated data obtained by PSPs can provide important insights for HCPs, payers, and manufacturers. Through on-line PSP portals, HCPs can readily access consolidated patient-specific data, such as disease scores, and medication adherence and persistence. As payers look to manufacturers to present real world evidence, patient data from PSPs can be used to assess treatment patterns, and health and economic outcomes (Figure 1). A variety of patient-reported health outcome studies can be performed, including: quality of life, product effectiveness, treatment adherence, safety, health resources utilization, and indirect costs such as productivity loss, out-of-pocket costs and the cost of informal care. From a manufacturer perspective, these health outcomes studies can align to global strategy and be leveraged to support reimbursement and listing.

Figure 1: Data Generated from PSPs



Baseline information	Demography, social economic status, disease severity, quality of life, previous treatment, concomitant medications
Treatment patterns	Treatment duration, treatment dose, treatment schedule, treatment discontinuation reason
Health outcomes	Disease-specific questionnaires for disease severity and quality of life
Health & economic outcomes	Co-payment, disability, and work productivity questionnaires

PSPs provide value by helping patients to better manage chronic diseases and optimize complex treatment by filling the gaps in services that are not provided in the current healthcare system. The future focus of PSPs will be on an evolution in integrating the process and efficiencies for patients, HCPs, payers, and manufacturers that will offer increased value to all stakeholders. By offering a more seamless experience for patients and HCPs, and greater cost effectiveness through investment in digital technology, connectivity to healthcare systems, and the provision of health outcomes data, PSPs will be even more able to maximize patient health outcomes.

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This article is one in a series provided by Innomar Strategies to update manufacturers on relevant changes and new information in the specialty pharmaceutical marketplace.