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Submission to the Patented Medicine Prices Review Board (PMPRB)
Draft Guidelines 2022 Consultation

Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa ON, K1P 1C1
December 5, 2022

RE: PMPRB *Draft Guidelines*

Thank you for the opportunity to submit written comments in response to the proposed PMPRB *Draft Guidelines 2022* operationalizing the amended *Patented Medicine Regulations* under the *Patent Act*. Innomar Strategies supports the submission by the Neighbourhood Pharmacy Association of Canada and believes it is important to emphasize some specific points that we believe will have a negative impact on patients and patient care in Canada.

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 2,800 associates across Canada and owns over 160 infusion clinics, employing over 625 nurses in pharmacies in every province.

Through our integrated Patient Support Programs (PSPs), Innomar is a provider to pharmaceutical manufacturers to enable patients gain 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 enrolment, reimbursement navigation, education and adherence support, specialty nursing and clinic services, and pharmacovigilance. Innomar's infusion clinics and specialty pharmacies closely integrate into over 160 PSPs to allow patients to promptly start their drug treatment, and fill an important need within the Canadian healthcare system.

RECOMMENDATIONS:

1. **Provide clear and distinct criteria for patentees in cases where no other PMPRB11 country list price is available.**
2. **Provide greater clarity and transparency for specific cases in which drug prices will be reassessed.**
3. **Re-establish role of the Human Drug Advisory Panel (HDAP) allowing opportunity for patentees to provide scientific evidence to PMPRB to attest to therapeutic improvement and re-introduce criteria for therapeutic levels of improvement where evidence supports higher price, rewarding manufacturers with higher price where appropriate.**

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IMPACT OF PROPOSED 2022 DRAFT GUIDELINES

The currently proposed changes will produce a negative impact on patients through an arbitrary reduction in prices via:

- Innovative medicines: Manufacturers are evaluating their launch plans for new medicines in Canada, either delaying or choosing not to launch at all due to uncertainty associated with the new regulations. 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 here.[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.[1]

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.

RECOMMENDATION 1: Provide clear and distinct criteria for patentees in cases where no other PMPRB11 country list price is available. Specific criteria and increased certainty may help incentivize patentees to launch in Canada earlier, increasing access to medicines for Canadian patients.

Impact on the patient if 2022 draft guidelines are implemented	Consequences
- Lack of clarity on PMPRB investigation criteria will delay or prevent patients from receiving medicines due to uncertainty with the new regulations. - Reduction in possible treatments for many patients, particularly in disease areas with little to no treatment options in the rare disease space.	Manufacturers will have no incentive to launch in Canada first given uncertainty of investigation criteria.

RECOMMENDATION 2: Create greater clarity and transparency for specific instances in which drug prices will be reassessed. This includes providing price reassessment clarity for medicines with new indications.

Impact on the patient if 2022 draft guidelines are implemented	Consequences
- Canadian patients could experience fluctuating patient support services leading to unpredictable and inconsistent healthcare delivery for the patient in the long-term - Uncertainty associated with unstable pricing makes complex diseases less manageable - Inconsistent support provided to patients may lead to misuse of medicines, non-adherence and decline in patient outcomes resulting in more costs to the healthcare system as described above	Unstable and unpredictable drug pricing over time Lack of clarity leading to an environment of instability for all patients, with particular impact for those enrolled in PSPs

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

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RECOMMENDATION 3: Re-establish role of the Human Drug Advisory Panel allowing opportunity for patentees to provide scientific evidence to PMPRB to attest to therapeutic improvement, rewarding manufacturers with a higher price where appropriate. Re-introduce criteria for therapeutic levels of improvement where evidence supports higher price.

Impact on the patient if 2022 draft guidelines are implemented	Consequences
- A reduction in services that offer much needed support that Canadian patients are unable to access within the public system, resulting in delays and significant reduction in patient access to specialty medicines - Investigations will delay manufacturers from seeking access/ approval for novel treatments	Manufacturers have less incentive to launch in Canada if new medicine's therapeutic improvement level is not recognized relative to those treatments currently available Not considering therapeutic improvement level as an evaluation criterion does not encourage new drugs that are truly novel

CONCLUSION

In summary, Innomar has provided key recommendations on the proposed 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 proposed 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. Finally, we believe that the drastically reduced consideration period following the latest release of new guidelines does not do justice to the impact of these changes and the valuable input that multiple stakeholders are providing.

We thank the PMPRB for the opportunity to submit our comments in response to the proposed Guidelines.

Sincerely,

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