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Re: Patented Medicine Prices Review Board (PMPRB) Draft Guidelines Consultation

Submitted via email

Dear recipients:

Boehringer Ingelheim (Canada) Ltd/ltée ("BICL") would like to thank the Patented Medicine Prices Review Board ("PMPRB") for its continued engagement with stakeholders on the draft guidelines. We are encouraged to see that the PMPRB is working to address the concerns articulated by stakeholder groups across Canada. The new guidelines will shape the Canadian health care landscape for decades to come and it is critical that the framework is clear, workable, and does not result in any unintended consequences.

Boehringer Ingelheim Canada continues to engage in constructive dialogue on the new guidelines and maintains that our participation in the consultation process should not be construed as acceptance of the constitutionality of Sections 79-103 of the *Patent Act* and the *Patented Medicines Regulations*, which are currently under review by the Superior Court of Québec.

ELEMENT 1. Transition time to compliance with new MLP for existing products should be gradual.

We appreciate that the PMPRB has clarified that grandfathered products have until December 1, 2021 to become compliant with the new MLP. However, this does not address the fundamental issue that the entire financial impact will need to be absorbed in one fiscal year. As a result, all manufacturers (and the life sciences ecosystem they interact with) will need to make very difficult employment and investment decisions in anticipation of that December 2021 date.

Recommendation:
Introduce a staggered transition period of no less than five years to achieve the new basket pricing should be in effect. In addition, no excess fees should be assessed or payable until a product has transitioned to the new MLP under the transition period wherein price reductions are capped to no more than 5% per 12-month period for the five-year period. The adoption of this recommendation will ensure that the significant economic impact of the proposed changes to the life sciences ecosystem will be optimally managed over time.

ELEMENT 2. Confidential Rebates: It is unclear how patentees are to comply with this framework.

Given the June 2020 Federal Court decision that confidential third-party payments are *ultra vires* the *Patent Act*, we are unable to see how it is possible to comply with the Maximum Rebated Price (MRP) as outlined in the draft guidelines. The MRP concept was drafted specifically in contemplation of and in reliance upon the now-struck subsection 4(4) of the Amended Regulations. Simply put, the PMPRB cannot calculate or apply the MRP as it was initially contemplated. Patentees may find themselves having to meet the MRP targets through modulating the flow of substantial quantities of free medicines solely for the purposes of meeting pricing calculations. The use of free goods to align with pricing regulations that are calculated on renewing periods is disruptive to the market, attracts competition concerns, and is offside the purpose of providing free medicines to address patient need on a compassionate case-by-case basis. As patentees cannot accurately report the average transaction price in a manner consistent with the aforementioned judgement nor avoid the mandated MRP with free goods, we strongly suggest that the PMPRB abandon the entire MRP concept.

Recommendation:
Due to the Federal Court decision, the Maximum Rebated Price framework is unworkable and should be abandoned.

ELEMENT 3. The revisions to the pharmacoeconomic (PE) factors do not address the underlying problems with the proposed framework.

The one consistent message that that has been communicated by the PMPRB and Federal Ministry of Health as the rationale for updating the guidelines is that public prices in Canada are too high relative to the OECD median. The 2018 PMPRB Annual Report, only recently made available (July 10, 2020) suggests otherwise. By way of example, the PMPRB itself reported that in 2018, Canadian prices were on average approximately 17% below the median international price of the current PMPRB-7 reference countries, and fell by 0.4% on average relative to prices in 2017 with a CPI increase in Canada of 2.3% in the same period. Furthermore, pharmaceutical sales declined by 0.6% in 2018 compared to 2017.

In any event, it is our belief that ensuring the price of new drugs is no higher than the median PMPRB 11 fully achieves that goal. Implementation of the PE factors for Category 1 new drugs introduces significant levels of uncertainty to patentees. Certainty and predictability are fundamental to decisions regarding launch viability and launch sequencing. Substantial unpredictability and uncertainty flowing from pharmacoeconomic analysis will necessarily impact decisions regarding the viability and timing to introduce new drugs into the country.

In our February 2020 submission, we expressed our concern that the proposed implementation of the PE factors was problematic due to the cumulative nature of the tests. Simply put, when the PE factor tests were layered upon one another at the proposed thresholds, the resulting prices were so low that patentees would have to ask the very difficult questions as to whether it was commercially viable to bring a new medicine to Canada.

The PMPRB has attempted to address this in the revised draft guidelines by implementing more reasonable cost per QALY thresholds, increasing the threshold for 12 month treatment costs, increasing the market size threshold and setting floors on price reductions. However, in practice, the implementation of the PE factors has the unintended consequence of restricting medicine availability. While the PMPRB has proposed a "floor" on how low prices can be reduced relative to the pharmacoeconomic value (cost per QALY) of a medicine, this floor can be further reduced by the absolute revenue ("market size") realized by a medicine.

Furthermore, there are no provisions in the draft guidelines to prevent prices from being driven below the lowest international price. The end result of these cumulative tests is that the PMPRB is policing the actual and marginal revenues for any given patented medicine. This framework drives patentees to mitigate the market size test by reducing or capping the availability of drugs. This approach is incongruous with the PMPRB's intent of preventing abuse of patent; instead, it effectively extends the PMPRB's role into setting the market price for medicines, which is clearly the purview of the provinces and private insurance plans.

Moreover, the revised draft guidelines do not address the fundamental conceptual problem with the market size test. As we articulated in our February 2020 submission, the PMPRB does not contemplate the reality that new medicines are not always an additional cost to the healthcare system. Often it is the case that a new medicine displaces existing, less cost-effective medicines. However, the draft guidelines, as written, treat every medicine as an incremental cost to the system for the purposes of market size. This approach belies the intent of PE tools, such as budget impact analyses.

Lastly, on July 24, 2020, the Office of the President of the United States announced the signing of an Executive Order that would allow states, wholesalers and pharmacies to legally import medicines from Canada and other countries. To date, five states (Florida, Vermont, Colorado, Maine and New Mexico) have enacted legislation to establish programs for importing medicines from Canada. Under the proposed guidelines, patentees would be penalized for sales to wholesalers who, without the patentee's knowledge or permission, may choose to export medicines to markets outside of Canada.

We recommend that the Board limit the tests applied to new products to the median of the PMPRB 11 and allow the existing and effective market forces within Canada (e.g., the Pan-Canadian Pharmaceutical Alliance [pCPA]) to assess value for money.

Recommendation:
The PE factor thresholds should only apply to extraordinary circumstances and when the MLP significantly exceeds the basket of comparator countries. This approach would be consistent with the PMPRB's intent to police outliers and those who abuse their monopoly power granted by patents. The adoption of this approach will ensure that patients and the health system realize the benefits resulting from innovative treatments.

ELEMENT 4. The regulations severely penalize patentees for not submitting medicines to health technology assessment bodies.

Over half of Canadians receive their drug coverage through employer-sponsored or self-financed private insurance plans. Yet, the health technology assessment agencies adopt a public health care system perspective when evaluating medicines. This is highly problematic as the public health care system perspective does not take into account beneficial aspects of a medicine that may be valuable to these private insurance plan sponsors. For example, a medicine that allows an employee to miss fewer days of work or return to work faster is worth substantially more to an employer than it is to the public drug plans, which are largely responsible for senior citizens (those who are 65 years of age or more).

Under the draft guidelines, a new Category 1 medicine that does not have a health technology assessment report will be subject to an automatic 50% reduction to its MLP, irrespective as to whether the medicine primarily serves patients insured by public drug plans or private drug plans. This penalty is so severe that the PMPRB is effectively setting public health policy and forcing all patentees to undergo a lengthy health technology assessment, even in instances where it is not in patients' best interests.

Recommendation:
There should be no automatic MLP and MRP penalties if a medicine does not have a health technology assessment report. In addition, drug claims reimbursed by private insurers should not count towards the market size threshold. This will ensure that innovations that are impactful for patients and systems who rely on the private sector.

ELEMENT 5. An extraordinary expansion of PMPRB staff powers

The revised draft guidelines confer extraordinary authority to PMPRB staff members creating significant uncertainty to patentees. Throughout the draft guidelines and consultation process, the PMPRB has made it clear it can reserve the right to disregard the Guidelines in the event of an investigation. In addition, the PMPRB has made no mention of the procedures or rules that would be followed in the event of an investigation.

In addition, it appears the scientific review process, including the assignment of the Therapeutic Criteria level, will rest with PMPRB staff and that the Human Drug Advisory Panel (HDAP) will only be consulted on an ad-hoc basis at the request of PMPRB staff. Given that much of the outcomes included in the description of items considered appear to be subjective in nature ("clinically impactful improvements"; "clinically relevant increases"; "limited meaningful clinical impact"; etc.,) there is significant concern that decisions resulting in significant decreases in MRP will be made by individuals who may not be clinical experts, especially when considering rare diseases.

Recommendation:
Therapeutic criteria should be assessed by the HDAP. The HDAP should consult external clinicians in the relevant therapeutic area and patients when assessing therapeutic criteria. In addition, there should be clear policies and procedures with respect to how PMPRB staff will operationalize any/all investigations. Engagement of external clinical experts will fully bring into scope the patients' needs and a medicine's impact on clinical practice.

ELEMENT 6. Therapeutic class comparison tests include the prices of generic molecules.

The draft guidelines state that domestic therapeutic class comparisons (dTCC) and international therapeutic class comparisons (iTCC) will be carried out by identifying comparators within a molecule's anatomical therapeutic chemical (ATC) class. In doing so, the PMPRB has made no provisions to exclude generic molecules from these comparisons. This is problematic. A patent, by its very nature, serves to reward the patentee with a limited time exclusivity for their innovation. In doing so, policy makers support innovation and help prevent market failure that may occur if patents did not exist. By using generic molecules in the dTCC and iTCC tests, the PMPRB is undermining the value of a patent. This serves as a strong disincentive to bringing new medicines to Canada.

Recommendation:
Generic molecules should not be included in the dTCC and iTCC tests. Inclusion of generic molecules to determine pricing of patented products is contrary to acknowledging the impact of innovations. Innovations have demonstrated positive impact on both patient and health system outcomes.

Conclusion

While there has been some positive movement with regards to the price test for existing ("grandfathered") medicines, the current draft guidelines (as written) provide little or no predictability with respect to the prices of new patented drugs. The lack of commentary regarding a floor price is concerning and provides a further disincentive to bring innovative new drugs to Canada. Changes to the draft guideline (as recommended above) would serve to alleviate some of the concerns outlined in this document while still achieving the intent of preventing excessive pricing.

We thank the PMPRB for its ongoing efforts to engage stakeholders and we look forward to continued constructive dialogue. Such exchanges will enable the identification of progressive policy options to optimize pharmaceutical management whilst focusing on ensuring Canadian patients continue to have timely access to life-saving innovative treatments.

Sincerely,

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