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Re: Notice and Comment – On the change to the definition of Gap medicines and the timeline for compliance

Submitted via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Dear recipients:

Boehringer Ingelheim (Canada) Ltd/ltée (BICL) would like to thank the PMPRB for the opportunity to comment on the proposed changes to the October 2020 guidelines with respect to new timeline for regulatory compliance of the maximum list price (MLP) for the so-called grandfathered products. While it is encouraging that the PMPRB continues to seek input from stakeholders, the shortened timeline for regulatory compliance poses considerable challenges.

The October 2020 guidelines allow patentees two filing periods (12 months) to ensure that their grandfathered medicines come into MLP compliance with the guidelines. On January 15, 2021 the PMPRB issued a notice that they are proposing that the compliance timeline for grandfathered drugs be reduced to one filing period, or 6 months.

The halving of the amount of time available for patentees to come into compliance imposes a significant regulatory burden not just on patentees, but on other stakeholders within the larger health care system.

This proposed change to the October 2020 guidelines will potentially affect the prices of some 1,400 medicines (and multiple thousands of DINs) that fall under the jurisdiction of the PMPRB. For each of these DINs, manufacturers will need to await notification from the PMPRB staff about the new MLP. In some

instances, these price points will involve the resetting of the so called non excessive average price (NEAP) to consider manufacturer provided benefits (such as free medicines provided to patients). As it is expected that this process may take months to complete, in reality, patentees will have far less than six months for some medicines to come into compliance.

Once the new compliant price points are confirmed, patentees will need to secure internal approval for the new prices, update internal systems, notify drug plan formularies (both private and governmental), wholesalers and buying groups. Existing agreements/contracts may need to be rewritten or renegotiated.

There is also the added administrative and financial burden placed on manufacturers at the wholesaler level. Wholesalers will request price adjustment credits for all inventory on hand, as they can no longer sell medicines to pharmacies for the same price that they paid manufacturers prior to the new Regulations and Guidelines coming into effect. It is simply not reasonable to expect patentees to be able to implement all the above in a six-month timeframe.

Recommendation:
The compliance timelines for the MLP of grandfathered drugs should remain as written in the October 2020 guidelines; that is two filing periods. No excess fees should be assessed or payable for sales until July 1, 2022. Thereafter a staggered transition period of no less than five years to achieve the new basket pricing should be in effect. Furthermore, 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.

Canadians are counting on all stakeholders in the health care system working together to get us through this pandemic. We implore the PMPRB to reconsider the proposed new timelines. At this critical point in time, manufacturers need to focus our efforts on COVID-19. We should not be expending the considerable effort and resources that will be required on compliance with the new Regulations. Returning to, at a minimum, a 12-month (2 filing) period to come into compliance would allow manufacturers to focus on COVID-19.

We thank you for the opportunity to provide commentary on this notice and look forward to continued dialogue.

Sincerely,

Carole Bradley-Kennedy
Director, Health Economics, Pricing and Outcomes Research