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Response to: *Notice and Comment – On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions* (July 15, 2021)

The July 15, 2021 proposal by the PMPRB to change the international price test for existing ("Grandfathered") medicines and their line extensions from the highest to the median of the so called PMPRB7 and to require that these price decreases be in effect by July 1 2022 are inconsistent with the PMPRB's legislative mandate to ensure that the prices charged for patented drug products are not excessive. PMPRB's own analysis indicates that these changes will introduce significant new negative impacts for patentees' existing products and will result in further uncertainty and an unreasonable burden for patentees to bear.

While these changes are being positioned as a "Notice and Comment" with an invitation for stakeholders to provide input, it is our understanding that the PMPRB intends to implement these substantial changes to the Guidelines, regardless of whether the revised/amended Regulations come into force. It is important to note that the PMPRB has previously arrived at a completely different excessive price test for existing products and time to implementation following other consultation.

While the PMPRB routinely makes subjective commentary about prices in Canada relative to other markets, and has used this as justification for significant changes to the Regulations and Guidelines, the Board has consistently failed to take the following into consideration:

- Businesses need a degree of predictability to function and plan for the near- and long-term, and naturally prioritize markets for investments and to launch innovative products and solutions on this basis. The latest proposed changes appear to be arbitrary and further exacerbate the lack of predictability in Canada.

- In context of a global pharmaceutical environment, the effective patent life of drugs in Canada is a major issue as, in our experience, it is significantly shorter (by 3-5 years) than in other developed countries. While all developed countries (including Canada) allow 20 years of patent life, the effective patent life of drugs differs due to differences in scope of patent restoration and other patent incentives:

    - Patent restoration compensates a patentee for the patent life "used up" due to regulatory approval process which erodes the time during which a patentee can recover its research and development (R&D) expenses. All countries within the "baskets" (i.e., PMPRB7 and PMPRB11), allow for up to a 5-year patent restoration period – simply put, an additional 5 years of exclusivity is generally allowed/added.

    - This is where Canada differs; patented Pharmaceuticals in Canada are routinely subject to generic competition up to 5 years earlier than "basket" countries. Up until the September 2017 implementation of the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union, Canada had ***no provisions*** for granting any patent restoration. Under the CETA agreement, Canada allows for up to 2 years (versus up to 5 years in all of the PMPRB-7 and PMPRB-11 countries) patent term restoration for drugs that meet very strict criteria (i.e., not all new drugs qualify). In addition, only drugs that receive(d) Health Canada approval after September 2017 are potentially eligible for such patent restoration.

    - Referring to the concept that country affiliates of a multinational are expected to pay their fair share to the parent company to fund future R&D, some countries can have lower prices than Canada because they have a longer period of exclusivity (i.e., without generic competition) over which they can contribute.

We trust this helps illustrate the implications in being part of a global pharmaceutical ecosystem.

Furthermore, we have relied upon the previously announced price tests and transitional timeframe for planning purposes. These latest proposed substantial changes not only significantly impact our plans, they reinforce the current international belief that the Canadian pharmaceutical pricing environment is unstable and potentially unreliable. This in in turn puts at significant risk our investment opportunities and launch plans for new medicines for Canadians.

In summary, Boehringer Ingelheim (Canada) Ltd requests that the PMPRB discontinue the arbitrary and harmful proposal to change price tests for existing products and their line extensions.

Sincerely,

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