October 24, 2016

Doug Clark
Executive Director
Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Re: Biogen Canada Inc. (Biogen) stakeholder feedback to the Patented Medicine Prices Review Board (PMPRB) Guidelines Modernization – Discussion Paper – June 2016

Dear Mr. Clark,

Biogen appreciates the opportunity to provide feedback to the PMPRB Guidelines Modernization Discussion paper, released June 2016. As a member of BIOTECanada, Biogen strongly supports the input provided by our industry organization. As the Guidelines become modernized, Biogen kindly requests that PMPRB work closely with our industry organizations and patentees to ensure that our feedback is incorporated, as ultimately patentees are directly impacted by any change to the Guidelines.

Biogen would like to provide the following overall stakeholder feedback to the questions posed by the PMPRB for discussion:

- First and foremost, Biogen emphasizes that any change to the PMPRB Guidelines must lead to a predictable price oversight system that does not dissuade patentees from launching a patented drug in Canada.
    - Currently, patentees "launch at risk" when commercializing a patented drug in Canada, and based on the administrative law process that the PMPRB follows, it can potentially take years for a conclusion to be reached on the determination of an excessive price.
    - The current Guidelines for determining excessive pricing, as well as the past precedence of the Human Drug Advisory Panel (HDAP), generally provide a relatively-predictable price oversight system and the means for a patentee to figure out what a non-excessive price will be. This has resulted in a high degree of price compliance over the years by patentees, as evidenced by PMPRB's own reporting data.
    - Further, if changes to the Guidelines result in unpredictable pricing outcomes, leading to significant commercial detriment or uncertainty for a patentee, then the value that a patent provides in the first place, to protect the commercial value of an innovation, would be negated.
    - When the PMPRB purports that changes are needed where patentees have "high market power", this leads to strong concerns that PMPRB will become a barrier to the Canadian commercialization of innovative patented medicines due

to unpredictable pricing outcomes across a range of therapeutic areas. PMPRB's definition of high market power—few or no therapeutic alternatives; high patient need, etc. — could apply to a broad array of therapeutic areas where the unmet patient need is highest and where innovation is needed the most. Therapeutic areas could include products for rare diseases, as well as relatively common ones, such as Alzheimer's, that currently lack any effective treatment. High market power should not automatically presume the *abuse* of monopoly patent rights as it relates to excessive pricing. Furthermore, as discussed below, there are other agencies in the market place beyond the PMPRB's purview that have the mandate to evaluate the *value* of such high market power products for appropriate pricing in the context of reimbursement. Finally, any "high market power" of a patentee is balanced by the monopsony purchasing power of relatively few payers in our market place, and within the public payers, now through a single "purchasing" collective, the Pan-Canadian Pharmaceutical Alliance (pCPA).

    - As a patentee investing significant funds into global research, including in Canada, to ultimately bring innovation to therapeutic areas of high unmet need where there are few or no therapeutic alternatives, there needs to be a predictable method to determine the upper boundary (i.e. excessive) of a pricing proposition. This is crucial to facilitate timely commercialization, proper fiscal planning, and most importantly, ensuring timely product availability for Canadians.

- Biogen emphasizes that the terms "excessive" and "affordable" are not the same, and should not be used interchangeably in the execution of PMPRB's mandate. There are multiple dimensions to a drug's price, and many of these dimensions are not within PMPRB's purview.
    - Biogen agrees with and supports that the PMPRB's mandate and jurisdiction should be on a patented drug's *excessive price*.
    - Excessiveness reflects an upper boundary, beyond which a price would be judged to be exorbitant. Affordability would reflect one's financial means, and thus for pharmaceuticals, ought to be placed in the context of the drug and overall Canadian healthcare budgets, as well as societal values. Given that PMPRB is not a payer, it cannot adequately reflect these values to determine affordability.
    - The CIHI data referenced in the BIOTECanada submission clearly show that based on several key metrics (including: prescription drug year-over-year growth, growth relative to CPI, and public spend relative to overall healthcare spend), patented drugs remain affordable.
    - Furthermore, Biogen's position is that affordability needs to be considered within the broader contexts of the drug's ***value*** in treating a disease for which the drug is intended, as well as the associated cost consequences, including medical, productivity-related, and societal costs. These evaluations are

conducted through the health technology assessment process, external to the PMPRB. Finally, if a drug does deliver compelling ***value***, then affordability ought to be placed within the context of *adequate* budgetary funding, and societal priorities as deemed by the ultimate payer, and the constituents it represents. Budgetary funding and societal priority determinations do not appear to be within the mandate of PMPRB.

- It is Biogen's position that the factors outlined in **Section 85** of the Patent Act should be the sole factors that the PMPRB takes into consideration for determining whether a price is excessive.

- Similar to pricing dynamics in other market-based industries, there does not need to be, nor is there economic justification for a *single* price across excessive, value, and acquisition prices. Nor should there be a *single* price across the different types of payers who represent widely-differing profit motives, economic and budgetary situations, constituents, priorities, acquisition volumes, etc.
    - Just like other market-based industries, prices vary across customers due to various purchasing factors and considerations—this is part of normal economic behavior between suppliers and purchasers.
    - Attempting to control this variance by determining that any price above the lower boundary of this variance as "excessive" would be interfering with and distorting the normal market dynamics. It would also run counter to the PMPRB policy of not penalizing patentees from offering benefits to a purchaser in recognition of its unique purchasing dynamic (e.g. a drug plan that represents a vulnerable population).
    - Since other public agencies exist in Canada to manage the additional elements associated with price setting that operate below the excessive threshold, Biogen asserts that the PMPRB's mandate should *continue* to be focused on setting the upper boundary or excessive price to send an appropriate, predictable, and valuable threshold to both manufacturers (patentees) and the market (payers) to operate within. Price variation under the excessive threshold is an acceptable market-based dynamic, and may often reflect the patentee offering a benefit to that individual or class of purchaser.

- Public list prices are an appropriate benchmark in determining price excessiveness regardless of what (confidential) discounts or rebates are offered to reach a mutually acceptable *acquisition* price, which accounts for value and affordability to the end payer.
    - Public list prices, like manufacturer list prices in any other market-based industry for higher cost items (e.g. military goods, transportation goods, capital equipment, etc.) provide the basis for comparisons, regardless of ultimate acquisition price. Notably, the end acquisition price can vary by purchaser type, volume purchased, contractual considerations, etc. and the discounts and rebates are often confidential.

- Thus, for purposes of setting an excessive threshold, list prices do act as a broad baseline for comparison, particularly if yearly CPI-allowable increases are reflected to account for inflation.

- The HDAP classification of a patented drug's therapeutic benefit already guides the weighting of Section 85 factors used in assessing a new product's introductory price.
  - As well, the HDAP already tends to classify most new drugs as having "little or no therapeutic benefit"—thus setting a clear and restrictive upper boundary price to be no higher than the local therapeutic comparator class (TCC). Only those few products that are classified in higher categories, affirming innovation that provides incremental benefit and value, can the price be higher than the local TCC, but these prices are still constrained through international referencing (to the median).
  - CPI is a fair method of assessing whether a product's ongoing price is excessive, as it is a widely-used economic benchmark to index the real value of a price change. Notably when many public jurisdictions do not allow patentees to recognize CPI increases, the real-dollar price of patented products is actually *decreasing* over time when adjusted for inflation.

- Using the median international price of the currently-referenced international jurisdictions is a fair and balanced method of setting the excessive price ceiling for an introductory product when it is the pivotal test. The median price accounts for the country-specific distorting factors behind a very high or very low price by selecting the middle country price as the reference.
  - The median balances the differences in the geo-political, economic, social, exchange rate, burden of disease, drug policy situations, etc., amongst the reference countries that may be reflected in a given price.
  - As discussed in the BIOTECanada submission, the United States is a relevant comparator country due to geographic, economic, trade, and standard of life reasons and similarities.

- Prices during the patent period are evaluated over time by other agencies and various payers through therapeutic reviews, and contract renewals and renegotiations.

- The patent period has also been significantly reduced through the initial evaluation process to gain reimbursement, which does not take into account any foregone revenues and more importantly, the delayed patient access during this initial period as a consideration for determining any excessive revenues. Notably, the "social contract" of a patent for pharmaceuticals already has an inherent price revision schedule whereby following the expiry of the relevant patent, the *acquisition cost* for payers is substantially "revised" downwards through the entry of generics, and subsequent entry biologics.

- Finally, it is Biogen's position that any changes to the Guidelines should:
    - Provide sufficient time for patentees to understand, plan for and adapt to the new changes;
    - Apply to those products introduced subsequent to the changes to ensure fairness in the application, and not cause unforeseen commercial uncertainty for existing marketed products.
    - Should result in improved predictability and address gaps in the current Guidelines affecting its validation and applicability.

Biogen would be happy to discuss our feedback with the PMPRB, and we look forward to a continued partnership with the PMPRB as it modernizes its Guidelines.

Sincerely,

Jason Lee
Associate Director, Market Access