biogen idec

June 13, 2013

Sylvie Dupont
Director, Board Secretariat
Patented Medicine Prices Review Board

Re: The PMPRB has proposed changes to its CPI Adjustment Methodology and to the Patented Medicines Regulations—Notice and Comment

Dear Ms. Dupont,

Biogen Idec Canada Inc. (Biogen) is pleased to provide feedback to the PMPRB proposed changes to its CPI Adjustment Methodology and to the Patented Medicines Regulations. Biogen commends PMPRB for continuing to be open and transparent to all stakeholders, especially patentees through its engagement and solicitation of feedback prior to implementing changes.

Initiative 1:

- Given that the 2014 forecast CPI adjustment factors have already been published back in April 2013, and patentees may have already incorporated this information into their 2014 planning, Biogen recommends that no changes to the CPI methodology be implemented until the 2015 reporting year.
- PMPRB has proposed using the actual laggard CPI to replace the forecast CPI for price increase, however it has not provided details on what this laggard CPI would be, including what trailing period (e.g. 12 months?), and from what point (e.g. current forecasted CPI for the following year is communicated in April of the current year—would the laggard CPI for the following year price increase still be communicated in April of the current year and be the trailing 12 months from April of the current year or the 12 months of the previous calendar year?). Biogen recommends that PMPRB provide some clarity, and perhaps an example.
- PMPRB has also not provided details on how the 3-year CPI rule would be applied using laggard CPI. Again, providing more clarity, and an example would be useful for patentees to understand application of laggard CPI better.

Initiative 2:

- Biogen is supportive of moving to annual regulatory filing of Form 2 for existing drug products.
- With respect to new products, it appears that semi-annual filing may still be required depending on when the first sale occurs (e.g. if first sale occurs between Jan and end of May, the introductory period is still the first half), thus semi-annual filing does not appear to be entirely eliminated for patentees.

- Providing an ex-factory price as proxy for average transaction price in itself is not a concern as long as PMPRB does not make any compliance judgment based on this, and PMPRB continues to use the ATP net of benefits during the introductory benchmark period for compliance evaluation.
- Although Board Staff note that patentees usually start selling a new drug product at list price and introduce benefits subsequently, Biogen would like to ensure that the PMPRB continues to allow the DIP methodology to be applied during the introductory benchmark period, so that an IBP* (i.e. ATP without benefits) can be used if benefits in the introductory period subsequently fluctuate or discontinue.

Biogen appreciates the opportunity to provide comments. If there are any questions or concerns, please do not hesitate to contact me.

Sincerely,

Jason Lee
Senior Manager, Market Access and Government Affairs