We have read the *Guidelines Modernization Discussion Paper* and are providing our comments below:

Questions for Discussion

1. What does the word "excessive" mean to you when you think about drug pricing in Canada today? For example:
   - Should a drug that costs more annually than a certain agreed upon economic metric be considered potentially excessively priced?
     - Yes, although a crucial question is how the agreed upon metric is determined.
   - Should a drug that costs exponentially more than other drugs that treat the same disease be considered potentially excessive?
     - Yes, unless it has 1) demonstrated significantly improved clinical outcomes/results; 2) a significantly improved safety profile (eg. reduced side effects), or 2) provides an alternative or initial treatment for new indications that can justify the cost premium vs. other similarly available options. However, even if there is a perceived therapeutic benefit over existing therapies, there should be an initial screening for the potential for abuse of statutory monopoly before clinical evidence of therapeutic superiority is considered. Feature benefits (eg. once daily versus twice daily) should not be considered to be a product benefit.
   - In considering the above two questions, does it matter to you if a very costly drug only treats a small group of patients such that it accounts for a very small proportion of overall spending on drugs in Canada?
     - No
   - Conversely, if a drug's price is below an agreed upon metric and in line with other drugs that treat the same disease, should it be considered potentially excessive if it accounts for a disproportionate amount of overall spending on drugs in Canada?
     - No - however reassessment of an entire portfolio (similar to what Switzerland does every 3 years) could be considered to address this scenario.
   - What economic considerations should inform a determination of whether a drug is potentially excessively priced?
     - International Price Comparisons e.g. use the Organization for Economic Cooperation and Development (OECD) average followed by Domestic Price Comparisons.
     - NOTE: Another option is to compare drug costs versus the costs in the countries listed in Figure 2 on page 16 with the exception of the two outliers (i.e. USA and Turkey).

2. Given that it is standard industry practice worldwide to insist that public prices not reflect discounts and rebates, should the PMPRB generally place less weight on international public list prices when determining the non-excessive price ceiling for a drug?
   - Yes – it is likely that the Canadian experience re: discounts/rebates is similar in other countries & should be considered by PMPRB when determining the non-excessive price ceiling for a

drug. However, as another option PMPRB should expand the number of countries used to compare prices e.g. use median for OECD.

3. In your view, given today's pharmaceutical operating environment, is there a particular s. 85 factor that the Guidelines should prioritize or weigh more heavily in examining whether a drug is potentially excessively priced?
   - Yes, International Price Comparisons (OCED median) followed by Domestic Price Comparisons.

4. Should the PMPRB set its excessive price ceilings at the low, medium or high end of the PMPRB7 countries (i.e., the US, the UK, Sweden, Switzerland, Germany, France and Italy)?
   - Option #1 The excessive price ceiling should be set at OECD median
   - Another option - Excessive price ceilings should be set at the low end of the PMPRB7 countries as the USA skews the median up.

5. Does the amount of research and development that the pharmaceutical industry conducts in Canada relative to these other countries impact your answer to the above question and if so, why?
   - No, history would suggest that countries that host multinational headquarters of major pharmaceutical companies will continue to be major centres of R&D, whereas Canada will only be a secondary player.

6. What alternatives to the current approach to categorizing new patented medicines (based on degree of therapeutic benefit) could be used to apply the statutory factors from the outset and address questions of high relative prices, market dynamics and affordability?
   - We agree with the alternative proposed in the Discussion Paper i.e. "An approach toward categorizing new patented drugs ... would be to conduct an initial screening based on indicators of potential for abuse of statutory monopoly, rather than clinical evidence of therapeutic superiority. Such an approach would apply indicators that are rationally and directly connected to the statutory factors as the starting point in the analysis of whether a drug might be priced excessively..."

7. Should the PMPRB consider different levels of regulatory oversight for patented drugs based on indicators of risk of potential for excessive pricing?
   - Yes, this would allow for a more strategic and targeted use of Board's time and resources.

8. Should the price ceiling of a patented drug be revised with the passage of time and, if so, how often, in what circumstances and how much?
   - Yes, it should be reviewed every 3 -5 years (implementing model similar to Switzerland – reassessing on an ongoing basis such that the entire portfolio is reassessed every three years)

with the goal of reducing the ceiling as new drugs of the same therapeutic category are introduced. The exception would be for a drug for which new indications have been introduced.

9. Should price discrimination between provinces/territories and payer types be considered a form of excessive pricing and, if so, in what circumstances?
    - Yes, in all circumstances where the drug is prescribed for the same indication(s) and to with the consideration for consumers to pay what the lowest priced province pays.

10. Are there other aspects of the Guidelines not mentioned in this paper that warrant reform in light of changes in the PMPRB's operating environment?
    - Yes, the Reasonable Relationship Test in relation to biosimilar drugs.

11. Should the changes that are made to the Guidelines as a result of this consultation process apply to all patented drugs or just ones that are introduced subsequent to the changes?
    - To all patented drugs. This may require setting up a system like Switzerland or France where all drug prices are assessed on a scheduled basis (every 3-5 years).

12. Should one or more of the issues identified in this paper also or alternatively be addressed through change at the level of regulation or legislation?
    - This should be considered a possibility, but probably not at this time. However, dependent on current pricing regulations/ legislations/policies in jurisdictions, and if a significant number of patentees do not conform to the Board's rulings, then a change in regulation or legislation should be considered.