1. What does the word “excessive” mean to you when you think about drug pricing in Canada today? For example:
    a. Should a drug that costs more annually than a certain agreed upon economic metric be considered potentially excessively priced?

        I would consider it potentially excessively priced if a drug costs more annually than a certain agreed upon economic metric. This is already implicitly accepted by the society at large. For example, few people would consider a treatment a realistic option if it costs $ 1 billion year per patient.

    b. Should a drug that costs exponentially more than other drugs that treat the same disease be considered potentially excessive?

        A drug may be considered potentially excessively priced if it offers similar overall clinical benefits but costs exponentially more than other drugs that treat the same disease. However, its pricing may be acceptable if it offers significantly more benefits than the existing drugs.

    c. 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?

        Assuming fairness means treating similar things similarly and different things differently, I would consider it acceptable if a very costly drug only treats a small group of patients because it accounts for a very small proportion of overall spending on drugs in Canada. Society needs to be able to care for its minority with a different process from its majority.

    a. 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?

        If the new drug’s price is in line with other drugs that treat the same disease, it can be assumed that the cost of the existing drugs already account for a disproportionate amount of overall spending on drugs in Canada. Therefore, the new drug’s price may be considered potentially excessive if it offers similar benefits than the existing drugs because it

offers no clinical or pricing advantages but would incur non-pricing costs of introducing the new drug into practice. In contrast, the new drug's price may be considered acceptable if it offers significantly more benefits than the existing drugs.

b. What economic considerations should inform a determination of whether a drug is potentially excessively priced?

New drug's cost relative to existing drug's cost, absolute cost of new drug, therapeutic gap (e.g., no existing treatments), absolute average cost-effectiveness, incremental cost-effectiveness, budget impact on overall drug spendings.

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?

The international public list prices are the only benchmarks available so PMPRB should continue to reference them. The discounts and rebates occur for different reasons in different jurisdictions, so it would be difficult to account for them within the Canadian context.

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?

Given that new drugs are often approved for use in the US and the EU before Canada, the Guidelines should prioritize the prices at which the same medicine has been sold in the relevant market in reference countries.

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)?

The PMPRB should set its excessive price ceilings based on the similarity of public payer and health-technology review process between Canada and the reference countries. As mentioned in the consultation discussion paper, drug pricing is not an effective policy lever to attract pharmaceutical research and

development. Therefore, it would be more relevant to reference public list prices from countries with similar healthcare coverage systems, GDP (PPP) per capita and populations, possibly drawn from the OECD countries.

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?

   The relative amount of pharmaceutical research and development conducted in Canada has no impact on which countries that I suggested for PMPRB referencing. In these days of globalizations and international companies, there are many factors other than pricing to lever investments into pharmaceutical research and development. In any case, the Canadian population is relatively small compared to other competing countries in attracting pharmaceutical research and development. Therefore, pharmaceutical industry would not consider Canadian sales market as an important factor in their decisions in research and development investments.

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?

   It is not clear of what factors are taken into account when PMPRB reviews the degree of therapeutic benefit. The pan-Canadian Oncology Drug Review (pCODR) expert review panel uses a deliberative framework that assesses overall clinical benefits based on clinical effectiveness, safety, burden of illness, and patient needs.

7. Should the PMPRB consider different levels of regulatory oversight for patented drugs based on indicators of risk of potential for excessive pricing?

   The PMPRB should consider initial screening to identify potential for excessive pricing.

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?

The price ceiling should be revised with the passage of time, perhaps within the first 5-10 years when new indications for the drug most likely emerge. The new price ceiling would be based on revision following the same deliberative framework as the initial review.

9. Should price discrimination between provinces/territories and payer types be considered a form of excessive pricing and, if so, in what circumstances?

   Price discrimination between provinces/territories and payer types can be considered a form of excessive pricing IF there is a pan-Canadian or national drug coverage process. This may be true for any drugs negotiated under the pan-Canadian Pharmaceutical Alliance.

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?

    More collaboration with CADTH/pCODR may help streamline review of therapeutic benefit and price ceiling.

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?

    A process can be established to review the potential excessive price ceiling of selective patented drugs introduced prior the proposed changes. This would help introduce more relevant pricing to the current market.

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?

    No comments.