PMPRB Guideline Modernization: Discussion Question Responses

- 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?
 - a. Yes
 - **b.** Should a drug that costs exponentially more than other drugs that treat the same disease be considered potentially excessive?
 - a. Yes
 - **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?
 - a. No
 - **d.** 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?
 - a. Yes, depending on whether it has any unique contribution to therapeutics of that group.
 - **e.** What economic considerations should inform a determination of whether a drug is potentially excessively priced?
 - a. Measures of charges vs cost
 - b. Comparison of charges for the drug in Canada vs other countries such as New Zealand
 - c. What value does this particular drug add to the therapeutic armamentarium?
- 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?
 - a. No, this is too confusing and further reinforces the industry advantage, and further reduces the incentives to come with lower prices!
- 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?
 - a. Don't know what s85 is.
- 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)?
 - a. Low end and get rid of the US in the mix, and add more reasonably priced 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?
 - a. Yes, only to further declare that industry promises of research are completely unreliable and almost never come to fruition. Pharma industry is not a major source of jobs (see Roger Martin on Ontario Competitiveness).
- 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?
 - a. Institute clinical value-for-money approach on a more critical basis, and re-visit regularly to see if the value has ensued.

- 7. Should the PMPRB consider different levels of regulatory oversight for patented drugs based on indicators of risk of potential for excessive pricing?
 - a. probably
- 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?
 - a. Yes, seems like good practice. It must be very common that drugs are allowed a premium price, only to be usurped in value a year later.
- 9. Should price discrimination between provinces/territories and payer types be considered a form of excessive pricing and, if so, in what circumstances?
 - a. Interesting question. I would think so. It is particularly unethical that our most vulnerable citizens (those without any drug coverage) pay the highest drug prices!
- 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?
 - a. unsure
- 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. Would apply to all
- 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?
 - a. Unsure.

From

Dr Anne M Holbrook,MD,PharmD,MSc,FRCPC
Director, Clinical Pharmacology & Toxicology
Professor, Department of Medicine, McMaster University
Medical Staff, St Joseph's Healthcare Hamilton & Hamilton Health Sciences
G624, SJHH, 50 Charlton Ave E, Hamilton, ON L8N 4A6
905 522 1155 X35269; FAX 905 540 6520
http://www.fhs.mcmaster.ca/medicine/pharmacology/