Comments from ***Federal Health Care Partnership (FHP)***

Patented Medicine Prices Review Board (PMPRB) Discussion Paper –
Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines

Background:

The Patented Medicine Prices Review Board (PMPRB) has been undertaking consultations on possible changes to their excessive price guidelines since 2005. In addition, a federal court decision in the matter of Leo Pharma directly impacted the application of the PMPRB's price guidelines.

The PMPRB is soliciting comments from stakeholders on possible options for: 1) pricing scenarios where any market in Canada should be considered in calculations of excessive prices, 2) circumstances where the current CPI methodology may be amended, and 3) consideration of where the maximum non-excessive (MNE) price for an existing medicine may be reset.

Guidelines Changes - Any Market Price Review:

There is consideration that the calculation of an average price for Canada may not include significant price variations in certain jurisdictions (in excess of 25% in some cases). The below circumstances are being considered as viable occasions where a price review at the level of any market would be conducted.

1. At introduction (during the period of first sale of a medicine in Canada), the PMPRB will ensure that the Average Price for all markets (i.e., for each class of customer and for each province/ territory) does not exceed the MNE price.

2. In future years, if the Average Price for Canada appears to exceed the MNE price in any period, as part of the investigation Board Staff will review the price for each class of customer and each province/territory to determine in which market(s) the price appears to be excessive.

3. If a patentee enters into a Voluntary Compliance Undertaking (VCU), or is subject to a Board order following a public hearing, the PMPRB will review prices in each market (i.e., each class of customer and each province/territory) for all reporting periods covered by the VCU or order to ensure that the price in any market does not exceed the MNE price.

4. Any substantiated complaint of apparent excessive prices in any market will be investigated.

Federal Health Care Partnership (FHP) Comments:

- *There have been reports of wide variations in the price of pharmaceutical drugs across the country. Potential guideline changes that incorporate an assessment of specific price variations (in provinces and territories) will ensure equitable application of the legislation.*

Guidelines Changes - Re-Setting the MNE Price:

The Board seeks comments on the following proposed circumstances when it would be appropriate to consider re-setting the MNE price on a case-by-case basis.

1. When the MNE price can be shown to not cover the patentee's cost of making and marketing the drug.
    - Potential Cost Rationales: an Investigational New Drug (IND) or Special Access Programme (SAP) sold at an artificially low price is approved for sale; or when a new government regulation or policy imposes additional costs on the patentee and the MNE price of the drug; and when an ongoing shortage (length of shortage to be determined) of the drug ingredient increases the acquisition cost of the ingredient.

2. When the scientific information/evidence available at the time the medicine was first introduced was not sufficient to determine with confidence its category of therapeutic improvement, or when new post-market evidence suggests the initial categorization was inappropriate.
    - Potential Scenarios: when a product is sold as an IND or under the SAP and proper clinical trials have not been completed; a Notice of Compliance with Conditions (NOCC) has been granted but Health Canada has specified further research to confirm health outcome improvement; a drug is indicated for rare, life-threatening disease and the scientific evidence is very limited (due to a limited patient population).

3. When the Median of the International Price Comparison is the pivotal test and the medicine is sold in too few countries at introduction.

FHP Comments:

Option 1

- *The definitions of "making" and "marketing" will require explicit definitions that clearly identify the scope of each term as it applies to price calculations.*
- *Particularly the cost of "marketing" should be analysed to ensure that the scope of the definition is appropriate with all applicable Canadian legislation. Marketing may involve discretionary spending on the part of patentees and would*

require explicit criteria to avoid subjective determinations and calculations of costs in this area.

- *The assessment of additional costs imposed by a government action will require legitimate (and substantiated) estimates of the costs in question.*
- *It is advisable that the considerations of a shortage include an assessment of whether the shortage is a result of actions (or inaction) undertaken by the patentee.*

Option 2

- *The second option, regarding new scientific information, is worthwhile. Notably, it may raise additional questions about the applicability and role of scientific information/evidence as factors in price reviews. For example, could a recalculation of the MNE be undertaken for a drug that has been found to treat additional conditions? It is worth considering the full implications of the second proposal and its potential impact on the relationship between price calculations and evidence in general.*
- *It is advisable that the PMPRB avoid relying on industry determined product development phases (such as clinical trials) to determine when the MNE should be reset. Such measures do not provide enough of a rigorous and objective approach to reassessing the MNE.*

Option 3

- *We support this option.*

General Comments

- *The above circumstances are conditions where it is viable to consider re-setting the MNE price. However, we reiterate the preceding comments that the circumstances should be pre-determined and clearly documented to ensure consistency and accuracy in their application.*
- *In general, we encourage the PMPRB to incorporate the life-cycle approach to the regulation of drug prices, which recognizes new evidence as a result of market development. Provided it is feasible, the PMPRB may elect to align the process with Health Canada's Progressive Licensing Framework (PLF). However, it is important to recognize that the PLF does not contain international linkages, which the PMPRB relies upon to undertake price reviews.*

Options to Address Issues Arising from the Federal Court of Canada Decision

Regulatory Options

Option 1 Maintain the current Regulations and respect the outcome of the FCC decision.

Option 2 Amend the Regulations to exempt patentees from the requirement to report benefits (payments) provided to third-party payers (F/P/T drug plans and potentially private insurers if similar payments are negotiated in the future).

Option 3 Amend the Regulations with respect to free goods:

i. Amend the Regulations to exclude all free goods from the calculation of the Average Price.
ii. Amend the Regulations to exclude free goods from the calculation of the Average Price when only free goods are provided to a particular customer class.
iii. Amend the Regulations to exclude free goods in "non-saleable" or "sample" package sizes, that are provided to those legally able to receive such goods pursuant to the Food and Drugs Act, from the calculation of the Average Price.

Option 4 Amend the Regulations to change "free services" to "services (free or partially subsidized)" in the calculation of the Average Price.

Option 5 Amend the Regulations to exclude "gifts" from the calculation of the Average Price.

Option 6 Amend the Regulations to permit the Board to disallow any or all benefits which it determines, pursuant to a public hearing, were implemented by a patentee for the purpose of reducing its liability in regard to excessive pricing in terms of the calculation of excess revenues.

FHP Comments:

General Comment

- *In addressing the provision of free goods, it is advised that the PMPRB adhere to the definition of "sell" as it is outlined in the Food and Drug Act.*

Guidelines Options – Possible Changes to the CPI Adjustment Methodology for Determining the MNE Price

Option 1 Amend the methodology in the Guidelines for the establishment of the MNE price by using in the CPI-adjustment methodology the highest previous non-excessive Average Price, if the actual Average Price declines due to a new or increased benefit.

Option 2 Amend the methodology in the Guidelines for the establishment of the MNE price by using the greater of the introductory MNE price and the CPI-adjustment methodology using the highest previous non-excessive Average Price, if the actual Average Price declines due to a new or increased benefit.

FHP Comments:

- *We recommend adopting Option 2, which will allow patentees some discretion in adopting a price below the MNE, recognizing that (incremental) price increase may occur as the life-cycle of the medicine matures. However, it is important to fully address the application of the methodology in defining a (potential) maximum single year increase so that any return to the MNE would adopted through a phased-in approach.*