

**Federal Health Care Partnership Comments:
PMPRB Notice and Comment;
Draft Revised Excessive Prices Guidelines
(August 2008 Version)**

Background:

The Patented Medicine Prices Review Board (PMPRB) has been undertaking consultations on possible changes to their excessive price guidelines beginning in 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 proposed changes in their *Compendium of Policies Guidelines and Procedures*, released in August 2008.

Requested Comments

**Impact of Reporting Benefits
(De-linking of the ATP from the MNE Price)**

Given that the Federal Court has offered a wide interpretation of what is constituted a "benefit," including borderline activities such as certain promotional and marketing activities, the PMPRB has offered a viable alternative to ensure that manufacturers are not penalized for offering benefits to patients and customers.

However, in soliciting comments on the recent guidance document entitled, "Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines" the PMPRB indicated that it would explore regulatory options to address the Federal Court's interpretation of benefits and the coinciding role of free goods. We encourage to PMPRB to continue to assess potential options in this area, including disaggregating the interpretation of "benefits."

Any Market Price Reviews

Evidence indicates wide variations in the price of pharmaceutical drugs across various jurisdictions and customers. In general, as the PMPRB is engaged in ensuring that prices in *any market* are not excessive, it must apply its excessive price calculations in a similar manner. Excessive revenues should be determined based on sales in specific jurisdictions and returned to those jurisdictions. This demonstrates an approach that focuses on individual customers and markets, and ensures consistency in the application of the PMPRB's mandate. Likewise, it will facilitate a more specific determination of the allocation of monies resulting from Voluntary Compliance Undertakings (VCUs) and Board Orders. Potential guideline changes that incorporate an assessment of specific price variations (in provinces and territories) will ensure equitable application of the legislation.