FEEDBACK FORM
Patented Medicine Prices Review Board (PMPRB)
Draft Guidelines

Document(s):

- Patented Medicine Prices Review Board PMPRB Draft Guidelines

Section in Document	Feedback
Overall	The updated PMPRB guidelines will add value to medications in Canada by ensuring: - A better collection of comparator countries - The use of QALYs (generated by a publicly funded Canadian health technology assessment (HTA) agency) at a maximum of $60,000 for most drugs as an appropriate ceiling - Provisions for a slightly higher QALY for rare disease drug that have a small market (<$12.5M) in Canada to permit better access at a reasonable price - A clearer process for calculating cost thresholds - Comparing pricing against other available therapeutic alternatives already available in Canada Overall, AHS is supportive of the draft guidelines, as a means to ensure value to Canadians for new drug entries. The one area of concern is while pricing can be reevaluated, once a price is set and usage is established, it will be difficult to significantly reduce pricing of a drug without likely causing market disruptions. Therefore ensuring a proper population and market assessment at the initial review is critical to ensure that the initial pricing is set to the correct level.
IV. Filing Requirements Pertaining to Price Reviews	#25 - Supportive of the patentee being required to provide to PMPRB the price the drug is sold at in Canada or the eleven countries set out in the Regulations - Supportive that the QALY used is prepared by the publicly funded Canadian health technology assessment (HTA) agencies

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V. Price Review Process	#33 under All other patented medicines - the additional information required will help improve transparency of pricing against similar countries with like health delivery models
A. Price Review Process for Non-Grandfathered Patented Medicines – Step #1	#37 - an interim maximum List Price ceiling being set (the "iMLP") is of benefit to ensure drugs introduced to Canada are priced appropriately upon initial entry into Canada and also does not permit market access to unaffordable medications
A. Price Review Process for Non-Grandfathered Patented Medicines – Step #2	#39 - comparing to other therapeutic options in the drug class is an appropriate way to ensure value in a new drug entry to the Canadian market #45 - agree with using the highest Canadian list price for the iMLP and MLP comparison
A. Price Review Process for Non-Grandfathered Patented Medicines – Step #3	#49 - The 50% of GDP per capita threshold may be too high. This currently translates into ~$30,000 per patient, which may allow some higher cost rarer therapies to move through to Category II too easily. An annual cost per patient closer to $10,000 would ensure better scrutiny for new drugs

A. Price Review Process for Non-Grandfathered Patented Medicines – Step #3	#51 ICER - Clearer wording on how the ICER will be calculated should occur here. The wording suggests the patentee-provided ICER would be used, but elsewhere it states the ICER would be taken from a publicly funded Canadian health technology assessment (HTA) agencies. Recommend updating the wording to clarify while the patentee should submit an ICER, in order to establish the PVT, the ICER use for calculations will be from a publicly funded Canadian health technology assessment (HTA) agency - For patented medicines with an estimated prevalence <1 in 2000 people and a market size in excess of $12.5M - The concept of paying a price premium for market sizes <$12.5M while being consistent with other drugs when the market size is small is a reasonable approach to managing rare disease - However, the challenge that needs to be recognized is once a price is set, it will be difficult to significantly reduce that cost without upsetting the market access. Therefore ensuring this market size calculation is properly captured upon initial review is critical when using this pricing option -
VII Investigations	#71 - Consider a trigger whereby if a patented medicine exceeds the price ceiling, by <5% for a period of time (e.g. three consecutive years), that an investigation will be launched by PMPRB