British Columbia Response to PMPRB Discussion Guide

Response to Issue 1 – Is the current approach to the categorization of new patented medicines appropriate?:

- The new patented drug categories are generally appropriate. If they are going to be revised, how this impacts the appropriateness of selecting comparator drugs for price tests should be focused on first, as it is the most important aspect.

- The first drug in a new class doesn't necessarily mean that it is a breakthrough (an example being angiotensin receptor antagonists); having an additional category may be helpful for these types of medications.

- It would likely be very difficult to delineate the definitions of "moderate improvement" from those with "little improvement"; again this should be considered in context of whether it would negatively affect the appropriateness of selecting comparator drugs for price testing.

Response to Issue 2 – Is the current approach used to review the introductory prices of new patented medicines appropriate?:

- What is the rational for choosing a particular ATC level when doing a therapeutic class comparison test? Are there restrictions on how broad (how low an ATC level) a class can be made? What are the implications of limiting or not limiting the class level? How consistent is the determination of class level between classes?

- Are generic drugs that meet the criteria ever included in price testing? If so, when? If not, why, and could/should these be considered?

- For the derivation of the introductory price of Category 3 drugs, what is the rational for the excessive price determination being set at the maximum of the therapeutic class, rather than the average or median?

- When determining prices for categories 2 and 3, has controlling/weighting for volume of sales or market share been considered to determine what the maximum should be?

Response to Issue 3 – Should the Board's Guidelines address the directions in the Patent Act to consider "any market"?:

- Subtracting rebates, discounts, refunds, free goods, free services, gifts and other such benefits from revenue in the calculation of the average transaction price limits what drug companies are willing to negotiate with the provincial drug

programs. Any negotiations between the provincial programs and the manufacturers have the potential to reduce a company's ATC, potentially limiting the prospect of future price increases. What would be the consequences of not including these components in the determination of price increases?