Gender-based analysis plus

Section 1: Institutional GBA Plus Capacity

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body established by Parliament in 1987 under the *Patent Act* (Act). The PMPRB has a dual mandate: in its regulatory role, it protects consumers by ensuring that the prices of patented medicines are not excessive; in it reporting role, it provides information on pricing trends in the pharmaceutical industry in Canada.

The PMPRB reviews the prices of the first sale of a patented medicine at arm's-length by the patentee, directly to a class of customer, namely a wholesaler, hospital, pharmacy or other. The PMPRB has no authority over prices charged by wholesalers or retailers or over pharmacists' professional fees.

The PMPRB does not set the prices at which patented medicines can be sold but determines the Maximum Average Potential Price and the Non-Excessive Average Prices at which these medicines can be sold in Canada. Prices do not need to be approved by the PMPRB before patented medicines are sold in Canada.

The PMPRB considers GBA Plus in its decision-making processes when needed. Since the price of a medicine does not vary by user, while the PMPRB's price review process does not take explicit account of the diversity of user groups or their economic situation, lower medicine prices, and associated savings for all payers, will benefit all populations directly through lower out of pocket costs and indirectly through health system reinvestments and improved access to better care.

The PMPRB mandate makes it unable to undertake any GBA Plus initiatives.

Section 2: Gender and Diversity Impacts, by Program

Core Responsibility: Regulate Patented Medicine Prices

Program Name: Patented Medicine Price Regulation Program

Target Population: All Canadians

Key Impacts: Not applicable

GBA Plus Data Collection Plan:

The information provided to the PMPRB by patentees as set out in the *Patent Act* (the Act) and the *Patented Medicines Regulations* (Regulations) does not take explicit account of the diversity of user groups or their economic situation, consequently the price review process cannot consider these factors. By law, patentees must file information about the sale of their patented medicines in Canada. The Act and the Regulations set out the following five factors to be used for determining whether a patented medicine is excessively priced, as outlined in section 85 of the Act:

- the prices at which the medicine has been sold in the relevant market;
- the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
- the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
- changes in the Consumer Price Index; and,
- any other factors that may be set out in regulations.

The PMPRB reviews the average price of each strength of an individual dosage form of each patented medicine. In most cases, this unit is consistent with the Drug Identification Number (DIN) assigned by Health Canada at the time the drug is approved for sale in Canada.

Program Name: Pharmaceutical Trends Program

Target Population: All Canadians and public and private drug plan administrators

Key Impacts: Not applicable

GBA Plus Data Collection Plan:

The PMPRB is responsible for reporting on trends in pharmaceutical sales and pricing for all medicines and for reporting research and development spending by patentees. Under the Regulations, patentees are required to submit detailed information on their sales of patented medicines, including quantities sold, gross and net prices, and net revenues. The PMPRB uses this information to analyze trends in the sales, prices, and use of patented medicines. The sales and price information does not take into account indirect discounts provided to third party

payers, such as product listing agreements. The PMPRB provides information on key pharmaceutical trends, including analyses of Canadian national, public, and private payer markets for all medicines. Given the information provided to the PMPRB by patentees as set out in the Act and the Regulations does not take explicit account of the diversity of user groups or their economic situation, the reporting program cannot consider these factors.