PMPRB releases long-awaited draft guidelines regarding excessive drug pricing under new regime

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Federal price controls for patented medicines have been part of Canadian law for approximately 35 years. The Patented Medicine Prices Review Board's (PMPRB) mandate is to prevent excessive pricing of patented medicines. Recently, as part of a modernization effort, the PMPRB has updated its approach to excessive pricing, including through amendments to the *Patented Medicines Regulations*.

After controversy that led to invalidation of some of PMPRB's proposed amendments, the PMPRB finally released much awaited Draft Guidelines [PDF] to complement the recent amendments to the *Patented Medicines Regulations* that came into force on July 1, 2022.

The Draft Guidelines provide rights holders with more prescriptive criteria for the potential triggering of an investigation for excessive pricing of patented medicines. This Update includes key proposed changes to PMPRB guidance for stakeholders' consideration while the Draft Guidelines are undergoing consultation.

Proposed changes you need to know

1. New basket of comparator countries

The Draft Guidelines reference a new basket of comparator countries (PMPRB11): Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden and the United Kingdom. The new basket excludes the United States and Switzerland (countries that allow the free market pricing of drugs) and adds six new countries with lower drug prices than Canada.

Requiring Canadian patented medicine prices to be benchmarked only against countries that set prices through national price control regimes (e.g., national pharmacare programs) should have a tendency to lower the price that the PMPRB considers to be excessive for patented medicines.

2. Distinction between 'existing' and 'new' medicines

Patented medicines will be separated between “existing” and “new” medicines, instead of based on therapeutic categories. Existing medicines are medicines for which an NOC was issued prior to July 1, 2022 and include any line extensions of these same medicines. New medicines are all other medicines. The criteria that the PMPRB will consider in opening an investigation will vary depending on whether a medicine is an “existing” or a “new” medicine.

3. Only list price used for investigation criteria

Investigation criteria will apply to list price only and will not fluctuate annually based on average transaction prices (ATP) the year before and a formula derived from CPI. The ATP was calculated based on the total net revenues across all markets divided by the total number of units across all markets. The list price is the highest price charged in the market. This approach will not impact reporting obligations for filing ATP with PMPRB.

Benchmarking the highest price charged for patented medicines in the market against the international price of the new basket of comparator countries may cause industry participants to scrutinize list prices more closely, in order to avoid triggering an investigation.

4. Excessive price test for investigation criteria

The excessive price test for investigation criteria is streamlined to international price comparison and/or domestic therapeutic class comparator (dTCC) only and no longer changes from year to year:

- For existing medicines, it is whether the list price exceeds the *highest* international price for the PMPRB11.
- For new medicines, it is whether the list price exceeds the *median* international price for the PMPRB11 (unless the list price is higher than dTCC, in which case an investigation may be triggered regardless).

The lower threshold of the excessive price test for new medicines is consistent with PMPRB’s aim to shift its focus to potential excessive pricing of new medicines.

It is unclear how the PMPRB expects the number of overall investigations to be reduced when the list price (highest price) is benchmarked against a basket of comparator countries all of which do not have a free market for pricing drugs.

5. Reduced obligations for medicines at lower risk of excessive patent-driven pricing

For over-the-counter (OTC) medicines, generic, biosimilars, vaccines, certain non-prescription controlled substances and veterinary medicines, the reporting obligations are reduced and PMPRB will open an investigation only after receiving a complaint and not of its own accord.

Next steps

Stakeholders and members of the public are invited to provide feedback on the Draft Guidelines before December 5, 2022.

The PMPRB aims to release Final Guidelines by the end of 2022, which is a notably short timeline to meaningfully incorporate any feedback received during the consultation period.

Until the Final Guidelines are released, the "status quo" approach continues to be in place for the interim period:

- For existing patented medicines (marketed in Canada prior to July 1, 2022), no investigation will be triggered if (a) national average transaction price (N-ATP) remains at or below its most recent non-excessive average price (NEAP) as established under the existing Guidelines; and (b) list price does not increase.
- For new patented medicines, no price review will be conducted.

For more information on the implementation of the PMPRB Guidelines and *Patented Medicines Regulations*, please contact a member of Osler's Intellectual Property Group.