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PMPRB regulations: New basket of comparator countries has arrived, absent guidance

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Amendments to the Patented Medicines Regulations (PMR) came into force on July 1 after multiple delays, creating a new basket of reference countries for the Patented Medicine Prices Review Board (PMPRB) to use when assessing whether the price of a patented medicine is "excessive" in Canada. The PMPRB has not yet published new guidelines to operationalize the amendments, and has proposed a "status quo" approach for price assessments until new guidelines are in place in this interim period.

Please see our past bulletins on PMPRB for more information on the history of the amendments to the PMR and ongoing litigation involving PMPRB[1].

What you need to know

- As of July 1, 2022, the basket of comparator countries for reference-based price tests is the PMPRB11: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden and the United Kingdom.
  - Notably, PMPRB11 does not include the United States or Switzerland, which were comparators under the former PMR.
- The PMPRB describes its regulatory framework and price tests in a set of guidelines (Guidelines). While the PMPRB issued revised Guidelines in October 2020, those Guidelines require significant revision because of the limited amendments to the PMR that came into force on July 1, 2022.
- PMPRB has indicated that it expects to consult on new Guidelines in September 2022, aiming to have final Guidelines in place by the end of 2022.
- Until the new Guidelines are in place, the PMPRB proposes the following approach for reporting and price investigations:
  - Rights holders are required to report price information based on the PMPRB11 as of July 1, 2022.
  - For patented medicines marketed in Canada prior to July 1, 2022, no price investigation will be triggered as long as the medicine's (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.
  - No price review will be conducted for new patented medicines until the new Guidelines come into effect.

- Based on past publications of and comments on Guidelines, this proposed timeline aiming to have final Guidelines in place by end of 2022 is aggressive.
- Stakeholders are invited to provide comments on the proposed interim approach before July 18, 2022. Per historical practice, it is expected that the interim approach will be adopted shortly after July 18, 2022 with minimal or no changes.

FOOTNOTES

To discuss these issues, please contact the author(s).