Cassels

Patented Medicine Prices Review Board Adopts Amended Interim Guidance on Pricing of New Medicines

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On September 27, 2023, the Patented Medicine Prices Review Board (PMPRB) adopted its Amended Interim Guidance, which was first published on June 20, 2023. The Amended Interim Guidance will apply to the PMPRB's evaluation of the pricing of patented medicines effective immediately and until long-awaited new guidelines are developed and implemented. Under the Amended Interim Guidance, New Medicines with a list price below the Median International Price for the 11 comparator countries, referred to as the PMPRB11[1] countries, will be considered "reviewed," while New Medicines with a list price above the Median International Price will remain "under review".

In the coming weeks, the PMPRB plans "to launch a consultation on themes relevant to new guidelines." A second stage of consultation will follow in 2024 and aim to develop the new guidelines.

Background

The PMPRB's mandate is to ensure that the prices of patented medicines are not excessive and to report on pricing trends in the pharmaceutical industry. The PMPRB is an independent quasi-judicial body that operates at an arm's-length from the Minister of Health in Canada.

Following amendments to the *Patented Medicines Regulations*, the PMPRB released draft new pricing guidelines in 2022 but repeatedly delayed their implementation. Meanwhile, the PMPRB has been operating under the Interim Guidance issued on August 18, 2022 until confirming the Amended Interim Guidance on September 27, 2023.

The Amended Interim Guidance is intended to provide an expedited assessment process of the prices for New Medicines until new pricing guidelines are in place. Before adopting the Amended Interim Guidance, the PMPRB consulted with stakeholders and received 45 submissions from a broad range of respondents.

Amended Interim Guidance

The Amended Interim Guidance provides that the price of a New Medicine will be considered as "reviewed" if its list price is below the Median International Price (MIP) for the PMPRB11 countries. Otherwise, New

Medicines with a list price above the MIP for PMPRB11 countries would continue to be “under review” until the new guidelines are in place.

These measures are only intended to apply for a short-duration and do not represent a “full guideline.” Rather, they provide a temporary process to predict how international price filings will affect the level of scrutiny during internal administrative price reviews at the PMPRB.

The PMPRB has chosen to use the Amended Interim Guidance for three reasons: (1) the MIP is simple to calculate and known in advance by rights holders; (2) internal analysis indicated that the list prices of 55% of medicines introduced during 2022 were below the MIP; and (3) the Amended Interim Guidance promotes a greater degree of confidence regarding New Medicines rights holders’ status of their list prices, allowing them to negotiate discounted pricing with private and public payors.

The Amended Interim Guidance focuses on Canadian and International prices and does not look at therapeutic class comparisons or changes in the Consumer Price Index.

Next Steps: Consultation Leading to Full Guidelines

In the coming weeks, the PMPRB will be launching a “consultation on themes relevant to new guidelines” and is encouraging broad participation. The consultation will occur in two stages. First, the consultation will consider diverse themes and trends impacting healthcare and pharmaceuticals. Then, beginning in 2024, the PMPRB will focus on developing the new guidelines.

Please reach out to any member of our life sciences team if you would like to discuss the Amended Interim Guidance or the upcoming consultations to develop the new guidelines.

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[1]Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden and the United Kingdom. The United States and Switzerland are no longer included in the comparator country list.
