NORTON ROSE FULBRIGHT

Pharma in brief - Canada

PMPRB announces incremental reform to the *Compendium of Policies, Guidelines and Procedures*

Summary

The Patented Medicine Prices Review Board (**PMPRB**) has announced the results of the notice and comment period on incremental reforms to its Compendium of Policies, Guidelines and Procedures (**Guidelines**). As part of its ongoing commitment to consumer protection and ensuring that its regulatory framework is appropriate and responsive to relevant developments, the PMPRB sought stakeholder feedback on two proposed amendments to the Guidelines in December 2015: (i) the "Reasonable Relationship Test" (**RR Test**); and (ii) the requirement for "List Price Relative to Maximum Average Potential Price (**MAPP**) Verification" (section C.11 of the Guidelines).

After reviewing stakeholder comments, the PMPRB will amend section C.11 of the Guidelines to add the "List Price Relative to MAPP Verification" provision and will not amend the RR Test.

Requirement for "List Price Relative to MAPP Verification"

Historically, there has been little discrepancy between the National Average Transaction Price (**N-ATP**) and the public list price of drug products, and the PMPRB has not systemically evaluated whether the Canadian public list price (i.e. the publicly available prices of drug products) of a new drug exceeded the MAPP. However, due to the proliferation of non-transparent pricing and market segmentation strategies in both domestic and international markets, the PMPRB has identified the need to ensure that domestic public list prices are not excessive.

The proposed amendment to section C.11 of the Guidelines "Review of Prices of New Patented Drug Products at Introduction" reads as follows:

> C.11.14 Notwithstanding other elements of section C.11, the prices from sources identified in subsection C.11.13 [the domestic public list prices] for a new patented drug product shall not exceed the Maximum Average Potential Price (MAPP) established by appropriate introductory price test(s). If a price from these sources is found to exceed the MAPP, it would trigger an investigation by Board Staff. The first step of this investigation would be to confirm with patentees whether any sales have taken place at this price. If it can be positively ascertained by Board Staff that such sales have taken place, an investigation will proceed as described elsewhere in the Guidelines.

This requires patentees to ensure that the domestic public list prices for new drugs are below the MAPP. In addition, investigations by the PMPRB could ensue where the public list prices exceed the MAPP and sales at this price have taken place.

The amendment will be implemented on **September 1, 2016**, and the final text will be made available on the PMPRB website in September.

No change to the application of the "Reasonable Relationship Test"

The PMPRB uses the RR Test to establish a MAPP for the new strength of a patented medicine. The "reasonable relationship" refers to the association between the strength per unit and price. Currently, under Schedule 4 of the Guidelines, the PMPRB uses the lowest of six public list prices for comparison purposes.

The PMPRB recognizes that the lowest public list price may not be reflective of the average price paid by Canadians, and that there are rare situations where a non-excessive comparable drug product may have an N-ATP greater than the lowest of the six publicly available list prices. Therefore, the PMPRB proposed that where a new drug and comparable drug product are owned by the same patentee, the RR Test would use the non-excessive N-ATP of the comparable drug product to establish the MAPP instead of using the lowest of the six public list prices. In situations where the new drug and the comparable drug product are owned by different patentees, the use of the comparator's N-ATP would breach data confidentiality, and thus the PMPRB would use the lowest of the six publicly available list prices.

The PMPRB decided against implementing the amendment to the RR Test as it raised issues beyond the scope that the proposed change was meant to address, and are more appropriately addressed in the context of the PMPRB's broader framework modernization. The current practice of using the lowest of the six publicly available price sources for the RR Test, as set out in Schedule 4 of the Guidelines, remains in effect.

Links:

- PMPRB July 2016 Quarterly Newsletter announcing the incremental reforms to the *Compendium of Policies, Guidelines and Procedures*
- PMPRB Notice and Comment (December 2015) for proposed amendments to the *Compendium of Policies, Guidelines and Procedures*
- Side-by-Side Comparison of Current and Proposed Text in the *Compendium of Policies, Guidelines and Procedures*

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