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Alexion Ordered to Significantly Reduce Cost of Soliris

PMPRB also tells Alexion to make excess revenue payment for over-priced drug

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On September 27, a two-member panel hearing of the Patented Medicine Prices Review Board (PMPRB) issued a rare excessive-pricing decision relating to the drug Soliris (eculizumab), manufactured by Alexion Pharmaceuticals Inc. (Alexion).

What You Need To Know

- The panel found Soliris had been priced excessively on the basis of the Lowest International Price Comparison test—a methodology not described in the board's guidelines.
- As a result, Alexion is required to reduce the price of Soliris and to make a payment to offset excess revenues.
- This decision affirms that, in the context of a hearing, both the board staff and the PMPRB may depart from its published guidelines when considering the appropriate pricing thresholds for patented medicines sold in Canada.
- The adoption of a Lowest International Price Comparison test is significant as the board considers a reformulation of the basket of comparator countries.
- The decision is in line with statements made by PMPRB in the context of re-formulating the guidelines. It's also in line with communications from the Federal Minister of Health who emphasized the need to control drug costs in Canada, in particular for expensive drugs that treat rare diseases.
- Amended regulations are expected to be published soon, and will likely reflect the novel tests and considerations of this decision.

Background

Under the *Patent Act* and Patented Medicine Regulations, the PMPRB can order manufacturers of patented drugs to reduce the average price at which a drug is sold in Canada to a price not considered "excessive", and to pay the government back any excess revenue generated. The factors to consider when determining if a price is excessive are set out in the *Act*; a pricing assessment is performed by the board staff using published guidelines (the guidelines).[1]

Soliris is considered to be a 'breakthrough' drug which treats a rare and life-threatening blood disorder. It's also within a category of costly drug products that have been increasingly scrutinized by the PMPRB. In reaching its conclusion, the PMPRB indicated it's not confined to the tests set out in the guidelines and "has no choice but to deviate from the

guidelines" if the application would be unreasonable.

The PMPRB created a new test for Soliris, indicating its price must be reduced to the lowest of seven comparator country prices; the guidelines only indicate that the Canadian drug price cannot be the highest of these seven countries.

Alexion maintained throughout the hearing the actual price of Soliris had not changed and the perceived pricing changes resulted from fluxes in currency exchange beyond its control. While the PMPRB indicated currency exchange is beyond the control of a patentee, its view was that Alexion was well aware of the exchange issues—noting the guidelines provide currency exchange fluctuations are the responsibility of the patentee—and could have amended its Canadian pricing accordingly. Alexion's argument that it had "done nothing wrong" was ruled irrelevant.

Analysis

The decision demonstrates why patentees will typically attempt to avoid a PMPRB panel hearing and instead negotiate directly with board staff, which can only apply the tests as set forth in the guidelines. In a hearing, neither the board staff nor the PMPRB is confined to the guidelines; thus subject to the (apparently loose) constraints of administrative law, it may consider various factors and apply novel tests in order to assess whether a price is "excessive".

Alexion's launch price in 2009 was initially investigated by board staff and adjusted to meet the tests set out in the guidelines. A low Canadian dollar and fluctuation in currency rates in 2012 resulted in the price of Soliris being deemed excessive under the guidelines as the Canadian price appeared to be higher than corresponding international prices, even though Alexion did not raise the Canadian list price during this time. After failed negotiations with board staff, a hearing was called in 2015. Before the hearing panel, the pricing of Soliris from its launch was re-examined by PMPRB where it determined that in order to fulfil its 'consumer protection' mandate, the price paid by Canadians for Soliris should be the lowest of the seven international jurisdictions used for comparison under the regulations. Even though the historical price of Soliris was deemed excessive, the order of the PMPRB with respect to repayment of excess revenue would be calculated on the basis of the Highest International Price Comparison test (which is set out in the guidelines) so the remedy would not be overly punitive to Alexion.

This adoption of a Lowest International Price Comparison test is significant as the board considers a reformulation of the basket of comparator countries. Currently, the basket includes seven members (in order of pricing from highest to lowest): United States, Germany, Switzerland, Sweden, U.K., Italy and France. The board has recommended the adoption of a new basket of comparators. The new basket recommends excluding high priced countries such as the U.S. and Switzerland, and including Australia, Japan and countries which have lower prices than France, including Belgium, Netherlands, Norway, South Korea and Spain. Whether a highest, median or lowest comparative test is applied, it is readily apparent the new mix of countries will have a drastic effect on pricing—particularly on the floor set by the lowest price in the group.

One interesting issue that arose during the hearing was in relation to Alexion’s attempted reliance on rebates given to provincial health insurance plans in order to reduce the effective average price of Soliris. Alexion’s confidential product listing agreements (PLAs) with these provincial bodies were provided to PMPRB in the course of the hearing. A previous board decision held that provincial insurers were not customers of a patentee under the *Act.* Affirming this position, the PMPRB held these rebates would not be taken into account for the purpose of considering excess revenues.

Alexion has indicated it intends to seek judicial review of this decision.[2]

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[1] See: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492

[2] See: https://beta.theglobeandmail.com/news/national/canadian-regulator-orders-price-cut-of-expensive-us-drug-soliris/article36418703/?ref=http://www.theglobeandmail.com&

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