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# Amgen Canada response to consultation on PMPRB draft guidelines issued on October 6, 2022

The following document constitutes the response from Amgen Canada Inc. ("Amgen" or "we") to the PMPRB's proposed draft Guidelines released for consultation in October 2022.

We support the responses to the draft Guidelines submitted by Innovative Medicines Canada and BIOTECanada. We will, however, make some supplementary comments on the current proposal.

- **Without any mechanism for recognition of innovation, the proposed Guidelines deter the launch of innovative products in Canada.**

In the proposed guidelines, new drugs in therapeutic areas with less efficacious (and sometimes much older) molecules will have their list prices tied to these molecules, unless a manufacturer is willing to face an investigation. Within an investigation Board Staff is given unlimited freedom to apply unexpected approaches to pricing. By removing assessments of therapeutic improvement, PMPRB would effectively make these most-needed innovative advancements in therapy harder to bring to market in Canada.

With potentially very low allowable prices and high uncertainty in investigations, we can expect delays or cancellations in the launch plans of innovative products in Canada. The Canadian list price is referenced by many other countries and can have a detrimental effect in large international markets, as observed by Neil Palmer in a recent article published at the MacDonald-Laurier Institute web site:

> "With lower prices (and perceived pricing thresholds), Canada will slip down the launch sequencing ladder. Global pricing teams of pharmaceutical companies establish launch sequencing plans based on the expected prices in each market and the national reference pricing systems in each country that set prices based, in large part, on prices in other countries."[1]

[1] Palmer, Neil. November 1st, 2022. "The Patented Medicine Prices Review Board has lost its way (again)". *MacDonald-Laurier Institute.* https://macdonaldlaurier.ca/the-patented-medicine-prices-review-board-has-lost-its-way-again/

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- **The proposed Guidelines do not provide guidance to manufacturers on allowable prices, or even a potential pricing range for a new launch. This vagueness is aggravated by the amount of discretion and power delegated to Board Staff.**

We appreciate the effort to create simple, bright lines rules, but the practical result of these proposed guidelines is unfortunately the opposite. Manufacturers will not be able to predict what price is allowable at the PMPRB introductory review. As a result, manufacturers will likely be unable to accurately forecast what an allowable price might be throughout the patented life of any product. The numerous triggers for re-assessment (the ever-changing domestic class comparison test, international prices, and new indications) also add to the unpredictability. These triggers will generate multiple re-assessments, some completely out of a manufacturer's control.

The difficulty is compounded by the fact that, once an investigation is triggered, there are no limitations on Board Staff's action, as also noted by Neil Palmer:

> "There is no information on how the PMPRB would conduct any investigation beyond vague references to the excessive price factors in the *Patent Act*. Patentees cannot calculate non-excessive price thresholds for their products in advance other than applying the "investigation" criteria that result in prices that are clearly contrary to every court decision that has considered the PMPRB's mandate."[2]

After the investigation, manufacturers may have to deal with allowable prices lower than the threshold that triggered an investigation in the first place (even though these proposed thresholds are already low). The only chance of reverting this would be through lengthy and resource-intensive legal disputes with PMPRB. Given this risk and the importance of Canadian list prices in the international markets, manufacturers will have to make difficult decisions on the feasibility and/or timing for a launch in Canada.

- **The investigation triggers and other proposed measures seem to be at odds with PMPRB legal mandate.**

These Guidelines will drive prices down by means of investigation triggers tied to the median international prices, lowest international prices and even price levels below these. This seems to be beyond PMPRB's mandate of monitoring for excessive pricing.

[2] Palmer, Neil. November 1st, 2022. "The Patented Medicine Prices Review Board has lost its way (again)". *MacDonald-Laurier Institute.* https://macdonaldlaurier.ca/the-patented-medicine-prices-review-board-has-lost-its-way-again/

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- **PMPRB is at odds with current federal government health initiatives.**

As mentioned before, the high level of unpredictability generated by these proposed Guidelines creates serious difficulties for pharmaceutical investment in Canada. This goes against the government's commitment to a National Strategy for Drugs for Rare Diseases and the Biomanufacturing and Life Sciences Strategies at the federal and provincial levels.

The Government of Canada has stated that "Ensuring access to critical vaccines, therapeutics and other life-saving medicines is a priority for the Government of Canada."[3] These guidelines, if implemented, would do the opposite.

**We urge PMPRB to redraft the proposed guidelines and issue clearer guidance in line with its mandate and with the government strategy to strengthen the life sciences sector, for the benefit of Canadian patients.**

Sincerely,

DocuSigned by:
John Snowden
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John Snowden
Executive Director, Value, Access & Policy
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[3] Government of Canada. "Overview of Canada's Biomanufacturing and Life Sciences Strategy". https://ised-isde.canada.ca/site/biomanufacturing/en/overview-canadas-biomanufacturing-and-life-sciences-strategy

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