

Douglas Clark, Executive Director
Patented Medicines Prices Review Board
Attention: PMPRB Guideline Consultations
Box L40 Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

***Re: Mylan Canada Submissions Regarding
PMPRB Draft Guidelines 2020 Published June 19, 2020***

Dear Mr. Clark,

Mylan welcomes the opportunity to provide comments on the revised proposed PMPRB draft Guidelines, published June 19, 2020. In conjunction with this submission, Mylan is aligned with the positions of both the Canadian Generic Pharmaceutical Association (CGPA) and Biosimilars Canada as it relates to our generic and biosimilars medicines, two industry associations of which Mylan is a member. Although Mylan is not a member of Innovative Medicines Canada (IMC), we are also supportive of their position as it relates to our currently marketed patented brand products.

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time.

Since the publication of the revised PMPRB Regulations in December 2017, Mylan has been involved at every stage of the PMPRB's consultative process through our membership with CGPA and Biosimilars Canada. Mylan is in a unique position of looking at the PMPRB's proposed changes from a generic, biosimilar and brand perspective based on our product mix. We address our concerns from each of these perspectives in the following submission.

As publication and implementation of the proposed revised draft 2020 Guidelines will have a significant and negative impact on patient access to new medicines in Canada, we believe that the PMPRB has made a number of improvements in their recently proposed draft Guidelines. However, there are a number of additional changes that need to be made prior to publication of the 2020 Guidelines.

Patented Brand Medicines

Grandfathered, Line Extension and Gap Patented Medicines

Mylan supports the PMPRB for making revisions to the most recent proposed draft Guidelines with the inclusion of sections that more appropriately address the process of excess revenues for ‘grandfathered, line extension and gap patented medicines’. These interim measures, however, are only applicable for two reporting periods with the grandfathered products being subjected to the Median International Price (MIP) within a one-year period. Mylan believes that the current proposal does not truly “grandfather” existing products. Grandfathering entails that existing rules apply to existing products and new rules apply to new products. As such, the price test of MIP should be excluded for all grandfathered and line extension medicines.

PMPRB should simply apply its international price ceiling threshold (highest for existing products) and use the current highest compliant list price rather than the current non-excessive average price (NEAP) as part of its “lower-of” tests for existing products. The NEAP is based on protected information and, asking us to systematically file a request for PMPRB staff to re-calculate a non-excessive benchmark ceiling, would be an inefficient use of ours and PMPRB staff resources. List prices are more appropriate and efficient for transitional purposes. This approach will still ensure that transition measures do not result in undue price increases during the transition period.

In addition to the above recommendations, we believe it is important that PMPRB allow for a more gradual transition of grandfathered products and that these should not be subjected to the accumulation of excessive revenues for the full 2021 calendar year. For 2022 and subsequent years, we suggest that there should be fixed maximum annual price reduction limits (e.g. no more than 5% negative list pricing impact per twelve-month period under the new regime). This should apply regardless of the policy tool or the specific price test applied in Guidelines.

Protection of Confidential Information

The latest proposed draft Guidelines, released on June 19, 2020, continue to advance the concept of a “maximum rebated price” (MRP), which reflects the inclusion of third-party payments. In light of the June 2020 Federal Court decision that, confidential third-party payments are beyond the authority of the Patent Act, calls into question the PMPRB’s fundamental regulatory approach regarding the concept of MRP. In addition to the legality related to confidentiality of the third-party payment, the new MRP calculation methodology, when combined with publicly available data, may allow third parties to reverse engineer or estimate our net prices. This is due to the introduction of a published specific pharmacoeconomic threshold equation and the availability of published public information (e.g. CADTH review reports, IQVIA data, and price lists) within a rules-based system. In other words, anyone will be able to calculate the MRP for a given product once CADTH documents are made public.

As such, any proposals that compromise confidential business information should not be considered in the 2020 Guidelines.

Patented Generic & Biosimilar Medicines

The PMPRB proposed draft Guidelines reflect a significant improvement over the previous draft with the maintenance of a complaints-based reporting requirement for patented generic medicines and the

inclusion of patented biosimilars medicines to the complaints-based reporting requirement. As the PMPRB has noted, patented generic and patented biosimilar medicines pose a low risk of excessive pricing in the domestic market.

Potential Impact of PMPRB Changes on Prices of Generic Medicines

Mylan has been concerned about the changes to the Patented Medicines Regulations and PMPRB framework for several years due to the reference-based pricing system for the generic medicines in Canada. Generic pricing levels in Canada are internationally competitive and any reduction in originator prices must not have a corresponding impact on generic prices.

The pCPA and CGPA have a 5-year generic drug pricing agreement, which has been in place since April 1, 2018. This follows an earlier agreement, which resulted in substantial savings for Canadians.

The 5-Year Agreement includes a tiered pricing model, which has different pricing levels depending on the number of competitors in the market. These prices are fully transparent and apply to payers in both public and private markets. Prices of generic drugs are calculated and set by the pCPA as a percentage of the price of the brand reference originator product at the time the first version of that generic medicine seeks to be listed on provincial formularies. Any subsequent change in the price of the brand reference originator product does not affect the price of a generic medicine already listed on provincial formularies. Generic drug manufacturers begin development of new medicines several years prior to their launch on the market. Changes in the pricing of reference brand products currently on the market (for example as a result of the new international country price comparison tests) could negatively impact affect the pricing and market potential of the generic products under development, resulting in an increased risk of generics not launching in Canada. The introduction of new generics into Canada is important moving forward as these future launches will provide savings to patients and public/private payers as well as increasing the sustainability of our drug programs and allowing expanded access for new drugs.

The 5-Year Agreement includes a clause that requires the pCPA and CGPA to review the changes to the PMPRB framework and address potential impacts on generic drug prices. This clause was included to maintain the integrity of the agreement, ensure generic drug prices remain at sustainable levels, and lower the potential risk of drug shortages for Canadians by maintaining a viable generics market in Canada.

In recognition of the current 5-Year Agreement between pCPA and CGPA, and of the agreed pricing that is in place, pricing of those molecules included in the agreement should not be impacted as a result of new PMPRB regulations, or as a result of re-setting of pricing for related brand molecules. In terms of generic products already in the pipeline, we believe that there should be benchmark setting of the brand reference price for the next 5 years, which would be based on historical brand reference pricing.

Complaints-Based Reporting for Patented Generic Medicines

The proposed revised PMPRB Guidelines confirm that patented generic medicines will be included on the list of products that will be subject to a complaints-based approach:

Notwithstanding the above, in the case of patented Biosimilars, patented Generic medicines, patented medicines for veterinary use and over the counter (OTC) patented medicines, an investigation will only be commenced by Staff if a complaint is received.¹

The approach to complaints-based reporting in the revised draft PMPRB Guidelines is consistent with the Board's existing complaints-based reporting policy for all patented generic medicines, reflects the low risk of excessive pricing for these medicines, and is supported by the Mylan.

It is Mylan's understanding that PMPRB intends on continuing to apply these conditions to patented generic drugs under the new Framework. We believe that the same conditions to trigger an investigation should apply to patented biosimilar medicines and, as such, the PMPRB should include patented biosimilar medicines under the Policy on Generic Medicines.

Categorization of Patented Generic and Patented Biosimilar Medicines

Mylan was pleased to see a more accurate and comprehensive definition of "patented generic medicines", which is included in the revised draft Guidelines:

Patented medicines that obtain market authorization in Canada with a demonstrated bioequivalence to a reference drug or by otherwise relying on the dossier of a previously approved drug with the same active ingredient (i.e. either through a New Drug Submission or an Abbreviated New Drug Submission).²

The proposed revised Guidelines also confirm that patented generic medicines and patented biosimilars will only be categorized as a Category II drugs:

In addition, even if they would otherwise meet the Category I criteria, all new patented Biosimilars and new patented Generic medicines will be classified as Category II.³

Mylan is in support of the above proposed revisions to the proposed PMPRB draft Guidelines.

Price Tests Required for Patented Biosimilar Medicines Investigations

Mylan remains concerned regarding the price tests that would be applied to patented biosimilar medicines in the event an investigation for a patented biosimilar is triggered. We are of the position that price tests used in assessing excessive revenues for patented originator medicines should not be applied to patented biosimilar medicines under the proposed draft Guidelines.

As Biosimilars Canada noted in its February 2020 submission, international price comparisons for patented biosimilars are inappropriate as marketplace policy frameworks for biosimilars around the world are evolving rapidly. Several of these frameworks are not considered by sponsors to be sustainable and there is an increasing risk of sponsors exiting these markets as a result. For example, some markets are permitting originator companies to undercut biosimilars to undermine competition. While this may lead to short term price advantages, this type of approach is not conducive to long-term sustainable competition and continuity of drug supply systems. Biosimilar prices are already regulated by provincial governments to be lower than patented reference biologic medicines, which are currently regulated in both Canada, as well as compared internationally, by the PMPRB.

In the case of an investigation, Mylan proposes that the PMPRB establish a separate test for patented biosimilars, which takes into account only the domestic price of the applicable reference biologic drug in Canada, as adjusted by CPI.

Thank you for the opportunity to provide constructive feedback on the revised proposed PMPRB draft Guidelines, published June 19, 2020. We look forward to the finalization of the PMPRB Guidelines.

References:

- ¹ PMPRB revised draft Guidelines, para. 89
- ² PMPRB revised draft Guidelines, footnote 14
- ³ PMPRB revised draft Guidelines, para. 60