abbvie

February 15, 2021

SUBMISSION FILED VIA EMAIL TO THE PMPRB CONSULTATIONS INBOX: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca
Attention: Patented Medicines Price Review Board Consultations
Dr Mitchell Levine, PMPRB Chair

RE: Notice and Comment – On the change to the definition of Gap medicines and the timeline for compliance (January 15, 2021)

Dear Dr Levine:

AbbVie welcomes the opportunity to provide comments on the change to the definition of Gap medicines and the timeline for compliance to address the delayed implementation of the Guidelines now scheduled to be enforced on July 1st, 2021. In conjunction with this submission, AbbVie is supportive of the positions expressed by Innovative Medicine Canada (IMC) and BIOTECanada (BTC), two industry associations of which AbbVie is a member.

AbbVie is an innovation-driven, patient-focused specialty biopharmaceutical company. Our mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health, and gastroenterology. AbbVie is presently the 2nd largest pharmaceutical company operating in Canada, and with the recent acquisition of Allergan, we are proud to employ nearly 1,000 Canadians. AbbVie has Canadian headquarters in Markham, Ontario, and Montreal, Québec.

Before commenting further, AbbVie would like to acknowledge that despite our engagement on this consultation, we remain opposed to multiple aspects of the October 2020 Guidelines, with many concerns outlined in our August 4th, 2020 submission[1] remaining outstanding. First, the application of the economic factors (a combination of economic thresholds and market size assessment) remained the same as in the draft version. Under these Guidelines, the price of a new, more effective and less costly medicine replacing an existing therapy would be penalized despite not creating any additional expenditure by the payer – i.e. the more effective medicine must be priced lower than the medicine that it replaces, effectively penalizing true innovation. Second, there will remain a high level of unpredictability in the long-term compliance status of launched medicines. This is because the net price ceilings calculated ("maximum rebated price" or MRP) are relying on third-party HTA assessment that will not be known until many months after a first sale occurs. Additionally, should an investigation be triggered, PMPRB Staff would no longer be bound by Guidelines and may therefore use any and all price tests deemed relevant; reducing certainty, allowing for inconsistencies, and reducing accountability and transparency in decision-making.

AbbVie maintains that the above issues will pose serious challenges to our ability to introduce new innovative medicines to Canadians and will compromise our current investments in the Canadian life sciences sector. Emerging research indicates similar concerns have already translated into tangible impact on our life science sector.[2,3] To that end, AbbVie remains committed to working with government, industry and all concerned stakeholders on a solution that meets your important public policy objectives, without undermining Canadians' access to new medicines, or driving away investment.

Regarding item "Compliance Timelines for Grandfathered and Gap Medicines":

[1] https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/submission-received/june2020/June%202020%20submission_Abbvie_EN.pdf
[2] https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada--worrying-signs-that-pmprb-changes-will-impact-research-investment.html
[3] https://lifesciencesontario.ca/new-survey-data-federal-drug-pricing-regulations-are-already-stopping-what-canadians-wantaccess-to-new-medicines-as-soon-as-possible/

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AbbVie has significant concerns with the proposal to halve the timeline for Compliance with the Maximum List Price (MLP) for Grandfathered and Gap medicines, from one year to six months. With a previously anticipated date of January 1st, 2021 for coming into force of the Regulations, it was indicated that patentees would have until January 1st, 2022, (one year or two reporting periods) to bring the pricing of Grandfathered and Gap Medicines into compliance with the new regime. In delaying the coming into force of the Regulations by six months to July 1st, 2021, it would then be reasonable to assume that patentees would have until July 1st, 2022, (one year or two reporting periods) to bring the pricing of Grandfathered and Gap Medicines into compliance with the new regime. Health Canada stated that the primary reason for the delay are the challenges posed by COVID-19 for all stakeholders, and that the delay would provide industry with additional time to prepare for the new reporting obligations. While PMPRB has stated its intent to send in new Maximum List Prices (MLPs) within 45 days of the first filing under the new Regulations and Guidelines, sufficient time also needs to be provided for patentees to have the opportunity to review and ask for clarification from PMPRB Staff should there be data discrepancies to address. The delay in the implementation of the new regime does not provide patentees with additional time to prepare as the new MLP cannot be established until the Regulations actually come into force. In reducing the compliance timeframe to effectively less than four months after receiving the new price ceilings, this newly proposed PMPRB implementation schedule is in contrast to Health Canada's supposed intent of allowing a reasonable transition. From an operational standpoint, this creates unnecessary administrative strain and burden on both patentees and PMPRB Staff by increasing the probability of investigations being triggered simply because not enough time was provided to patentees to prepare for the new obligations.

Regarding item "Definition of Gap Medicines":

With an extension of the coming into force of the Regulations from January 1st, 2021 to July 1st, 2021, AbbVie does not have a concern with the Guidelines definition of "Gap medicines" being updated to apply to medicines for which a DIN was assigned on or after August 21st, 2019, and that were first sold in Canada prior to July 1st, 2021 (extended from January 1st, 2021). This appears to be the only available option given the change to the implementation date.

AbbVie would like to note that the time period associated with the definition of "Gap medicines" has increased significantly with the multiple delays in the coming into force of the Regulations, and as such, we would invite PMPRB to simplify their transition under the new Regulations and Guidelines. Indeed, medicines for which a DIN was assigned on or after August 21st, 2019 have now been marketed in Canada for nearly 18 months, and will have been marketed for nearly two years by July 2021. By then, most Gap medicines launched in 2019 and 2020 will have received their introductory price period assessment and the Maximum Average Potential Price (MAPP) would likely already be considered "Within Guidelines" and would have served as a price reference for other Gap medicines under the current Guidelines. AbbVie would therefore propose that Gap medicines instead be subject to the Highest International Price (HIP) rule upon the July 1st, 2021 transition – similar to Grandfathered medicines. Given the significant number of products that have come to market, and extended time horizon over which the proposed new measures have not applied, AbbVie would consider this approach as more reasonable and operationally feasible than the current proposal.

In summary:

AbbVie sees the additional six-month delay as an opportunity to continue to exchange with PMRPB and government on finding a solution that meets Health Canada's important public policy objectives, without undermining Canadians' access to new medicines, or driving away much-needed investment in our health and life sciences sector. We are opposed to the proposed change to the "Compliance Timelines for Grandfathered and Gap Medicines" to limit the transition period to less than six months and are significantly concerned regarding the rationale for this change. While we take no issue with the definition of Gap medicines being refined to include the January 1st to June 30th, 2021 period, PMPRB should consider aligning the initial price tests applicable to Gap medicines with Grandfathered medicines, given the increased applicable time horizon.

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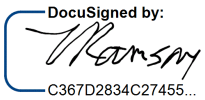
We look forward to future opportunities to provide feedback to the PMPRB and will continue to engage in future consultation processes.

Sincerely,



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