



February 14, 2020

BY EMAIL: [PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca](mailto:PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca)

Attention: Patented Medicines Price Review Board Consultations

Dr Mitchell Levine, PMPRB Chair

**RE: Patented Medicines Price Review Board (PMPRB) proposed Guideline changes**

Dear Dr Levine,

AbbVie welcomes the opportunity to provide comments on the proposed draft Guidelines. In conjunction with this submission, AbbVie is supportive of the positions expressed by Innovative Medicine Canada (IMC) and BIOTEC Canada (BTC), two industry associations of which AbbVie is a member.

AbbVie is a global research-based biopharmaceutical company with over 30,000 employees worldwide. We have more than 500 employees in Canada. Over 1 million Canadians benefit directly from our medicines. Our mission is to use our expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases.

AbbVie shares many of the goals regarding access to, affordability of, and appropriate use of patented medicines as expressed by the Minister of Health. Our vision is that Canadians will have timely and optimal access to all medicines that improve their health. As we note below, we are very concerned by the impact that the draft Guidelines, as proposed by PMPRB, will significantly affect our ability to provide new medicines to Canadians and compromise our current investments in the Canadian life sciences sector.

**Impact on our ability to launch innovative medicines:**

While the amendments to the Patented Medicines Regulations upon coming into force will list economic factors to be considered, they do not mandate PMPRB to incorporate incremental cost-effectiveness ratios (ICERs) or market size directly into statutory price tests to conduct their appraisal of excessive pricing in the manner in which PMPRB has set out in the proposed Guidelines.

Several factors will influence the economic evaluation and actual utilization of a new patented medicine, for example: the differences in the economic assessment methodologies used by CADTH/INESSS or private payers, the comparators used in the economic analysis, the actual market size of a product being prescribed or reimbursed in a targeted patient population versus the broader disease prevalence or indication received by Health Canada, amongst others.

It is a common occurrence for patentees and for payers to disagree with an economic evaluation or reimbursement criteria, and Canadian Health Technology Agency (HTA) assessments often vary substantially from those conducted by other agencies throughout the world. To that end, different risk sharing schemes may be put in place to manage cost-effectiveness concerns (an example could be reimbursing payers for patients not responding to a medication) or budget impact risks.

AbbVie believes the PMPRB should implement processes that are complementary with the rigorous existing framework. The economic evaluation and market size assessments of a medication should only be performed by the payers who will reimburse the given medication for the specific patient population they cover. AbbVie proposes that the PMPRB use the economic factors for dispute resolution only and to exclude them from consideration directly in any price tests.

The proposed confidential price ceiling, based on a combination of economic thresholds and theoretical market size assessments<sup>1</sup>, will penalize true innovation as we expect it to apply to all breakthrough innovations. As per the proposed Guidelines, the price of a 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. PMPRB's case studies demonstrate this point, highlighting that regulation of price ceilings is expected to drive down prices by at least between 33% to 66%<sup>2</sup> without any considerations for the cost savings it brings to the healthcare system or the therapies it replaces. By

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<sup>1</sup> Draft Guidelines proposes to assess market size rebated thresholds based on units multiplied by the ceiling price as opposed to actual revenues and to impose market size oversight as long as the molecule is under PMPRB's jurisdiction. This means that the MRP ceiling could be decreased simply because a manufacturer increases the number of free goods provided.

<sup>2</sup> These case studies were shared during PMPRB Outreach sessions held in person on December 9, 10 and via Webinar on December 17. (see PMPRB website for Consultation materials)

imposing severe price restrictions, the PMPRB is creating an environment where manufacturers will cease from offering any additional programs or investments in favor of cost control.

By moving all manufacturer list price (MLP) ceiling tests to the median of the domestic Therapeutic Comparison Class (which would also include comparisons to the prices of generic or biosimilars versions of the patented medicines) the proposed Guidelines effectively remove any recognition of the therapeutic improvement of any new patented medicines introduced in an existing therapeutic class. It impedes the ability to achieve simple price parity for new formulations and dosages that could benefit more vulnerable sub-groups of patient populations such as children or older adults.

From a policy standpoint, this change alone is a clear disincentive for conducting clinical trials, introducing new therapeutic alternatives and product improvements via line extensions and, in general, to launch competitive entrants on the Canadian market.

From an excessive pricing standpoint, AbbVie believes that if a new medication is introduced at the same price of an existing domestic comparator. The proposed Guidelines should be amended to allow price parity with domestic comparators and so that a price is not deemed excessive simply because some domestic comparators might have decided to launch at a lower price point. This is especially true if those comparators are generic or biosimilar versions launched without the same research and development investments required for new, innovative patented medicines.

#### **Canada's health care standards relative to OECD countries:**

In proposing to adjust the international price ceiling test from the highest to the median of the revised basket of eleven countries (PMPRB11), PMPRB has indicated that its objective is to see and maintain Canadian drug prices to the middle of OECD countries. To that end, AbbVie would support the implementation of an absolute price ceiling at the median of the PMPRB11 basket if the ceiling was truly set at this point.

On the contrary, the additional price tests and confidential price ceilings of the proposed Guidelines are based on the mathematical combinations that, in turn, also imbed lower thresholds (the lowest between the median therapeutic class comparator (TCC) and the lowest international price (LIP) is a clear example) and so a price ceiling at the median of the PMPRB11 is not achievable. In many cases, the MLP and MRP price tests assessments of the proposed Guidelines will consider a medicine's price to be deemed excessive when in fact, the price is reduced below the lowest international price levels and domestic comparators.

As it stands, the proposed Guidelines will inevitably move the Canadian price of future innovative medicines to the lower end of the PMPRB11 basket, if not below. AbbVie is extremely concerned that if the PMPRB does not address this very important issue, Canada will become a country with inferior standards of care, unattractive to future clinical trial investments and be branded with a newly earned reputation for having one of the poorest access to innovative medicines amongst the OECD countries. This is not consistent with Canadian values.

#### **Grandfathering, compliance, and transition:**

The Regulations will grandfather certain medications – specifically those issued a DIN prior to the publication of the final Regulations - from the application of new economic factors and related additional reporting requirements. While the Draft Guidelines seem to propose to extend grandfathering measures to the line extensions of the molecules launched after the Regulations publication date, they also propose to apply the same economic thresholds and price reassessments criteria to line extension as are applied to non-grandfathered molecules.

This dual approach where certain DINs of a same molecule are being subject to different pricing rules does not address several key scenarios that will arise overtime<sup>3</sup> and create unnecessary and unreasonable complexity for line extensions that should simply be grandfathered. In fact, this situation poses yet another risk for potential launch cancellations for line extensions with improved characteristics and patient benefits.

AbbVie strongly recommends that the PMPRB adapt its Guidelines such that any new DIN pertaining to a grandfathered molecule be grandfathered from the economic thresholds and price tests in the Guidelines. This would simplify greatly the transition process, prevent future price disparity within the same molecule and remove a significant disincentive to continue to launch line extensions for Canadians.

<sup>3</sup> For example, under the proposed Guidelines, (1) a new DIN introduced as a line extension of a grandfathered molecule receiving a new Relevant indication would be subject to a price reassessment whereas the DINs of the grandfathered molecule would not; (2) a similar new DIN becoming a category 1 after surpassing the market size thresholds; etc.





The introduction of several reassessment criteria combined with the management of two price ceilings (MLP and MRP) across molecules with multiple DINs and multiple indications will make compliance extremely challenging. This is particularly true in the Canadian environment vs. elsewhere in the PMPRB11, where net price negotiations are managed across more than 30 public and private payers. This imposes an unnecessary burden on both patentees and PMPRB staff as patentees may likely challenge investigations year over year until weighted average sales and rebates reach an accurate net average transaction price (which AbbVie estimates could take up to three years after the first sale).

Irrespective of the MRP thresholds, the proposed methodology also carries significant concerns for AbbVie as it enables any external third-party to determine confidential net price ceilings beyond an aggregate level but rather to the fourth decimals of a specific molecule. This sensitive information may prove to be another disincentive to launch medications in Canada for obvious Global competitive reasons.

AbbVie believes that the proposed transition period of four months is unreasonable<sup>4</sup>. PMPRB is introducing the most significant changes in the last 30 years, and it is critical that patentees are given the appropriate time to assess and incorporate the final Guidelines, once published, into our planning and operational processes so that launch decisions can be made before products are first sold.

We are very concerned that working groups between PMPRB and patentees have yet to be formed, this despite PMPRB confirming in recent outreach sessions that several sections in the proposed Guidelines should continue to be worked on. A longer transition period is necessary to avoid unnecessary market disruption with launch prices constantly being revised as existing products are shifted under the new basket rules or "gap" products launched between August 21, 2019 and July 1, 2020 are subject to reassessment under the new Guidelines.

AbbVie recommends that patentees be given at least a full reporting period (six months) before implementing new introductory price review assessments under the new Guidelines (i.e. if the final Guidelines are published by July 1, 2020 then the implementation date for new price assessments would be January 1, 2021).

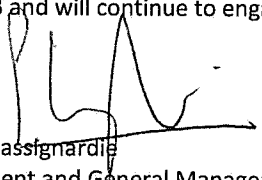
In terms of enforcement and compliance, AbbVie recommends to allow a full calendar year (12 months) after being notified of a new price ceiling, in order to become compliant (i.e. if a price ceiling is confirmed on January 1, 2021, full compliance would be expected as of Jan 1, 2022 at which enforcement via excess revenues would begin).

In summary, AbbVie is of the view that the proposed Draft Guidelines:

1. Significantly compromises our ability to launch innovative medicines leading to delays in the launch of innovative therapies in Canada and harm to investments in clinical research, putting Canada's life sciences sector at risk of falling to the lower ranks of OECD countries.
2. Adds unnecessary complexity and uncertainty to business planning, reporting and compliance by the introduction of economic factors, third-party economic assessments and net price ceilings.
3. Be accompanied with reasonable transition timelines of at least one full reporting period, and not less than a calendar year, to come into compliance. Additionally, companies should not be liable to pay back revenues earned in the period between Health Canada marketing authorization, the price ceiling determination by the PMPRB and the transition period it will take to achieve compliance with a new ceiling.

AbbVie appreciates the opportunity to participate in the draft Guidelines consultation process and wants to work closely with the PMPRB on pricing policy and associated implementation issues. We look forward to future opportunities to provide feedback to the PMPRB and will continue to engage in future consultation processes.

Sincerely,



Stéphane Lassignard  
Vice-President and General Manager  
AbbVie

<sup>4</sup> Calculated based on transition period of September 1 to December 31 2020, assuming PMPRB can notify patentees of all new ceilings in August and implementation date of Jan 1, 2021 as communicated by PMPRB.