abbvie

August 4, 2020

SUBMISSION FILED ONLINE VIA PMPRB PUBLIC CONSULTATION "SUBMIT FEEDBACK" PLATFORM
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 revised set of proposed draft Guidelines. 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 a global research-based biopharmaceutical company with over 47,000 employees worldwide. We have close to 1,000 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.

Before commenting further, AbbVie would like to first acknowledge the August 26, 2020 decision by the Federal Court which ruled that sections of the August 21, 2019 amendments to the Patented Medicines Regulations which required the reporting of confidential third-party rebates and benefits were *ultra vires* the Patent Act. A critical component of price regulation under the Draft Guidelines is tied to assessment of a maximum rebated price (MRP) ceiling. The Draft Guidelines were developed on the premise that PMPRB staff would have access to third party rebate information, and achieving compliance to an MRP ceiling using the thresholds in the Draft Guidelines would require reporting of these third party rebates for the majority of medicines. As access to third-party rebates is fundamental to the MRP ceiling methodology (especially the floors) proposed in the Draft Guidelines, AbbVie shares IMC and BTC positions that PMPRB must either pause the current consultation to re-think the proposed Guidelines accordingly or implement significant changes to the approach in the Final version. Guidelines cannot be inconsistent with the regulations under which they are made and cannot be used to indirectly achieve what is directly prohibited under legislation.

While the revised set of Draft Guidelines include significant changes to the price tests of Grandfathered and Gap products and increased thresholds of Category 1 criteria as compared to the previously published version, we are very concerned that little of our feedback has been considered in the approach the new framework will take to review future innovations. As such, the proposed price assessments for new innovative medicines launched after Jan 1, 2021 pose serious challenges to AbbVie's ability to provide new medicines to Canadians and will compromise our current investments in the Canadian life sciences sector.

Impact on our ability to launch innovative medicines:

As per our previous submission, the Patented Medicines Regulations 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.

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. The proposed PMPRB approach completely disregards any other ability to manage cost-effectiveness and utilization risks with payers outside of unit price discounting. As price ceilings would heavily (and mostly exclusively) rely on CADTH/INESSS HTA assessment, it also implies that CADTH/INESSS staff may need to be brought in during investigations or dispute resolutions on PMRPB pharmacoeconomic price evaluations.

Furthermore, by systematically referring to CADTH/INESSS assessments in addition to imposing a -50% discount on any product without a formal HTA assessment, the proposed Guidelines force patentees to accept and CADTH/INESSS staff to perform unnecessary HTA assessments for drugs meant to be reimbursed by private payers/employers (incorrect payer perspective), not ready to be filed (sometimes NOC may be granted before enough evidence is gathered to support a full HTA dossier) or not suited for a HTA (small patient population, ethically unfeasible to have randomized controlled trials, etc.). In other words, this approach

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ultimately creates a disincentive to file for regulatory approval for any products not meant or not ready for public reimbursement. Canada has been placed on the "Watch List" published by the Office of the United States Trade Representatives in its 2020 Special 301 Report[1] as a country that may not offer adequate and effective intellectual property protections, and in citing PMPRB reform, this report cautions that "changes may significantly undermine the marketplace for innovative pharmaceutical products, delay or prevent the introduction of new medicines in Canada, and reduce investments in Canada's life sciences sector". The result will be further delays for Canadian patients to eventually access innovative medicines, risking Canada status as a tier 1 country.

While the addition of Therapeutic Class Levels (TCL) assessments may respond to feedback requesting acknowledgement of the therapeutic improvement brought by innovative medicines, the proposal under the Draft Guidelines but transforms improvement into a punitive exercise which will discourage competition and new therapeutic alternatives. As an example, a new molecule treating the same condition than another will be required to provide significant and additional discounting (up to -40%) than the first entrant despite launching with either a better safety profile for certain patient sub-groups, improved convenience, etc.

The proposed confidential price ceilings, based on a combination of economic thresholds and market size assessments, will penalize true innovation, as we expect it to apply to all breakthrough innovations. Under the Draft 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 shared during the June 29, 2020 Webinar demonstrate this point, highlighting that regulation of price ceilings is expected to drive down prices up to potentially -67.5% (-50% x -35%) per unit, without any considerations for the cost savings it brings to the healthcare system or the therapies it replaces. Another example is that if a patentee choses to submit a cost-minimization model for a new innovation, which essentially demonstrates an absence of incremental costs (or cost-savings) to payers after reimbursement, PMPRB Draft Guidelines will still impose additional average discounts of -40% to -50%. Patentees will be forced to further lower transparent ex-factory gate prices to meet those floor thresholds.

By imposing these severe price restrictions, the PMPRB is creating an environment where manufacturers will cease from offering any additional programs or investments in Canadian health care in favor of cost control. Since new product list prices must be set at the median of PMPRB11 basket of countries, AbbVie anticipates these additional mandatory discounts, even if kept "somewhat" confidential, will lead to Canada becoming an outlier amongst the international markets and in turn, to having to make difficult decisions to delay or forego launches in Canada.

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.

Predictability, fairness, and compliance:

AbbVie is concerned that the Draft Guidelines do not provide sufficient clarity and predictability to patentees regarding how compliance will be assessed and therefore do not respect procedural fairness principles.

Predictability:

- The net price ceilings calculated (MRP) are either relying on third-party HTA assessment that will not be known until many months after a first sale occurs. Confidential assessments of therapeutic class level (TCL)/domestic therapeutic class comparison (dTCC) tests are also based on very broad and undefined criteria. Patentees will therefore be unable to predict net price ceilings or how TCL/dTCC are likely to be conducted prior to launch.
- Draft Guidelines clearly indicates that PMPRB Staff will no longer be bound by Guidelines as soon as an investigation is triggered and may therefore use any and all price tests deemed relevant. AbbVie recognizes that guidelines are not legally binding and cannot be used to fetter the discretion of PMPRB Staff acting on behalf of PMPRB. However, guidelines are intended to enhance the quality of decision-making and administrative justice by increasing certainty, reducing inconsistencies, and raising accountability. Guidelines provide transparency in decision-making. Thus, in exercising its discretion, PMPRB staff must adhere to the principles of fairness and avoid arbitrary decision making. AbbVie is concerned that a complete departure from the Guidelines in the case of an investigation may lead to inconsistencies that undermine administrative justice. If PMPRB staff first assess price ceilings and then compliance based on the Guidelines, the same Guidelines principles should first prevail under investigations and only be amended for exceptional circumstances.

[1] https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf

Fairness:

- From a PEP calculation perspective, first in class products will be subject to lower MRP ceilings than subsequent entrants. The most significant innovations (i.e. breakthrough drugs) replacing older generations are bound to yield higher ICURs with higher probability for reaching maximum MRP floor whereas second entrants, that could be deemed more cost effective vs the same breakthrough drug, will be less likely to trigger MRP floor threshold.
- From a TCL perspective, competitive entrants bringing similar mode of actions will be penalized by even lower MRP ceilings floors despite bringing high or moderate therapeutic improvements over the original breakthrough drug.
- The Draft Guidelines offer no provision or relief for rare disease or highly specialized medicines not suited for HTA ICUR assessments yet responding to high unmet needs. The MLP PMRPB11 MIP rule should be sufficient to ensure pricing of these medicines is not excessive, while not discouraging the filing of regulatory approvals in Canada for these medicines.
- Patented biosimilars and generics are provided full relief from Guidelines and economic factors application (no MRP and moves to complaint-based system only). The introduction of a biosimilar or generic version of a patented medicine is typically seen as a material market event that quickly creates a natural volume erosion of the market share and sales of the patented originator. The same relief should therefore also apply to the originator (MRP ceilings should be dropped and product should move to complaint based only) as there is no reason to believe the branded version would pose any excessive pricing risk any longer once biosimilar/generic version enters the Canadian market. Continuing to strictly regulate the originator biologic while exempting biosimilars from these price tests is arbitrary and inequitable.

Compliance:

- As per the proposed transition timelines, the Guidelines will only be finalized a few months before the targeted implementation date of Jan 1, 2021 and PMPRB will only be able to confirm MLPs and MRPs following the January 30, 2021 filing. In view of this, PMPRB should provide a one-year grace period and commence compliance reviews using the Jan-June 2022 sales period - if price actions are implemented in 2021, patentees would be able to demonstrate those actions in the average transaction prices reported. Otherwise, July-December 2021 average transaction price will appear outside of Guidelines when in fact, price actions have been properly implemented prior to the December 31 deadline. This result is fundamentally unreasonable.
- Similarly, for new products introduced in 2021 and beyond, the schedule proposed by PMRPB does not allow enough time for the patentee to implement any price actions with sufficient time to demonstrate compliance via the average transaction prices. AbbVie believes grace periods to allow compliance should begin, at the very least, in the reporting period commencing AFTER a new ceiling is communicated.
- 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 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).

Summary:

PMPRB has continually stated that this current reform is the most significant undertaking since PMPRB came into existence. Given that the Draft Guidelines were developed in view of a premise (reporting of third-party rebates) that has been ruled to be judicially invalid, PMPRB must pause and must ensure that the Guidelines are consistent with legislative constraints. In summary, AbbVie is of the view that the proposed Draft Guidelines must be amended to:

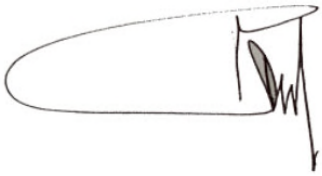
1. Not implement a punitive framework against rare disease products, highly specialized medicines, breakthrough drugs and competitive follow-on entrants. This environment will significantly compromise the ability of global pharmaceutical manufacturers to prioritize or accelerate the launch of innovative medicines in Canada. There will be delays for Canadian patients to access these 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. Remove unnecessary complexity and uncertainty to business planning, reporting and compliance created by the introduction of economic price tests, third-party economic assessments, net price ceilings across multiple DINs, extremely broad therapeutic assessments criteria and unlimited discretion for PMPRB Staff to apply any rules once a product is under an investigation.

3. Be accompanied with reasonable transition timelines to come into compliance. Additionally, companies should not be liable to financial penalties on 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.

4. Be complementary to the existing HTA and payer budget impact review processes and focus on implementing a simpler and predictable framework focussing on preventing excessive pricing rather than targeting net price control. Such a framework should be mainly based on transparent pricing using the basket of reference countries and should allow new entrants price parity amongst themselves.

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,



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