December 1, 2022

Ms. Mélanie Bourassa Forcier
Acting Chairperson
Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Subject: 2022 Proposed Updates to the Patented Medicine Prices Review Board (PMPRB) Guidelines

Dear Ms. Bourassa Forcier,

On behalf of EMD Serono, a division of EMD Inc., Canada ("EMD Serono"), I write to provide input to the Consultation on the Proposed PMPRB Guidelines (the "Proposed Guidelines").

EMD Serono, the Canadian biopharmaceutical business of Merck KGaA, Darmstadt, Germany, is committed to ensuring patients in Canada will benefit from innovative products in oncology, neurology, fertility, and endocrinology. Our pipeline includes investigational innovative therapies in neurology, oncology, and immuno-oncology. In Canada, we support research through clinical trials in multiple sclerosis (MS) and oncology. EMD Serono has its headquarters located in Mississauga, Ontario and employs more than 100 people across Canada. At present, Canada is considered a strategic country for clinical trials and among the first wave of launch countries for Merck KGaA, Darmstadt, Germany.

EMD Serono is a member of Innovative Medicines Canada (IMC) and fully supports the submission from its industry association. In this letter, I will articulate our concerns about the newly proposed approaches to regulate the prices of patented medicines specified in the Proposed Guidelines.

Following the federal Health Minister's announcement this past spring to abandon key elements of the amended *Patented Medicines Regulations*, we remained hopeful that the next iteration of the Proposed Guidelines would finally effectively balance its role to ensure non-excessive prices with the broader Government's strategic objective to foster a regulatory environment that facilitates a best-in-class life sciences sector for Canadians. Regrettably the Proposed Guidelines subject to this consultation are worst in class and are completely misaligned to the Government's commitment to build a robust life sciences sector in this country.

With respect to the proposed definition of "existing medicines", the revised Proposed Guidelines may represent an improvement over previous draft versions, and we appreciate the consideration and effort by the PMPRB to update the Guidelines based on stakeholder feedback. However, we continue to note that in their current state, aspects of the revised Proposed Guidelines continue to be a major concern. As written, the Proposed Guidelines would put patient access to medical innovations gravely at risk.

Our key concerns are outlined as follows:

1. EMD Serono expects the number of new medicines it can launch in Canada will be seriously reduced or delayed, specifically due to the removal of Therapeutic Improvement considerations and using anything but the Highest International Prices (HIPs) to define investigation criteria for new medicines.
2. Transitioning the responsibility of scientific review from the Human Drug Advisory Panel (HDAP) with their requisite expertise, to PMPRB staff, represents a major departure from previous

procedures, one which we believe will compromise the quality, transparency, consistency, and independence of the review.
3. Transition from a voluntary compliance to investigation regime creates uncertainty for rights holders.
4. The PMPRB continues to step beyond its mandate of preventing excessive prices and has instead adopted a role as a consumer protection body which courts have ruled would be "constitutionally suspect".
5. This new approach does not properly and fairly consider complex therapeutic indications, such as within oncology.

We submit that there is an opportunity to further improve the Proposed Guidelines by correcting aspects that devalue medical innovation and create significant uncertainty for manufacturers.

1. **EMD Serono expects the number of new medicines it can launch in Canada will be seriously reduced or delayed, specifically due to the removal of Therapeutic Improvement considerations and using anything but the Highest International Prices (HIPs) to define investigation criteria for new medicines.**

The new Proposed Guidelines will reduce and/or delay the number of new products launched in Canada. Removing consideration for therapeutic improvement, alongside removing the metric for new medicines to be held to a higher international price (particularly amid a revised basket of lower-priced reference countries) will do far worse than dissuade rights holders from seeing Canada as an attractive, prioritized launch market – it will make investment in Canada legitimately unviable.

The use of a "lower of" domestic comparators and median international prices approach represents a major departure from the previous guidelines. Such an approach is particularly egregious for innovation when it relies on generic prices and prices for mature products as part of the domestic Therapeutic Class Comparison (dTCC). This incorporation of generic prices as part of the dTCC calculation inherently devalues innovation as forcing to the lower of the median international price and domestic comparators removes any consideration for therapeutic improvement. PMPRB reinstated a therapeutic benefit consideration in its 2020 Draft Guidelines. To our dismay, this consideration of therapeutic benefit has now been removed in the Proposed Guidelines. As written, this "lower of" approach applies even if there is direct evidence of better efficacy and safety versus the existing products/standard of care. Even the most innovative products won't be able to achieve a price in line the with rest of the world leaving Canada utterly out of step with other comparable markets and threatening the viability of launching better and more innovative products in Canada. The net result is that Canadian patients will be unable to access new products available elsewhere.

2. **Transitioning the responsibility of scientific review from the Human Drug Advisory Panel (HDAP) to PMPRB staff represents a major departure from previous procedures, one which we believe will compromise the quality, transparency, consistency, and independence of the review.**

The prior Guidelines included a review of medicines by clinical experts on the Human Drug Advisory Panel (HDAP). In contrast, the newest Proposed Guidelines delegate this responsibility to PMPRB staff, who will only consult HDAP on an as-needed basis determined by Board staff themselves.

Investing PMPRB Staff with the authority to conduct scientific reviews opens the door for biased or uninformed decision making. HDAP is meant to be impartial, has guaranteed scientific expertise in its membership and completes its scientific review process independent from considerations of pricing examined at the Board Staff level.

It is unclear how this assessment will be completed by Board Staff, what expertise these Staff hold to legitimize their output and what precautions will be put in place to prevent a risk of bias and abuse of power in these situations, given PMPRB staff's exposed biases against industry and patient stakeholders, and its publicly stated objectives to drive down prices of medicines. Industry will be challenged to trust Board Staff to complete scientific review ethically and responsibly, and in accordance with the Board's statutory mandate.

As such, we recommend the HDAP expert committee must continue to have a primary and regular role in the scientific review, rather than PMPRB staff.

3. **Transition from a voluntary compliance to investigation regime creates uncertainty for rights holders.**

The Proposed Guidelines with respect to what "may" trigger an investigation post-launch creates untenable uncertainty for companies trying to provide patients' access to critical and life-saving medicines. Combined with delegating this responsibility to PMPRB staff, companies may hesitate to launch products in Canada under such uncertain conditions. At a minimum, the Guidelines should establish clear principles for investigations, so that rights holders can focus on creating value for patients rather than responding to unclear requests and investigations.

4. **The PMPRB continues to step beyond its statutory mandate of preventing excessive prices and has instead adopted a role as a consumer protection body which courts have ruled would be "constitutionally suspect".**

During PMPRB's Industry webinar on November 10, 2022, Board Staff exposed its incorrect interpretation of its role and the spirit within which the Proposed Guidelines were developed. This is highly concerning given the clarity of the courts on this matter and represents a flagrant disregard for the jurisprudence.

The effect of the Proposed Guidelines will be to lower the prices of most new medicines and many existing medicines, below the 'non-excessive' threshold. Using the MIP as a high watermark for excessive prices suggests that prices in half of the markets included in the PMPRB11 are excessive, which, ipso facto, cannot be the case. The jurisprudence at both the Quebec Court of Appeal and the Federal Court makes clear that PMPRB's mandate is to ensure patented medicine prices are not 'excessive'; and not to act as a price regulator at large.

5. **This new approach does not properly and fairly consider complex therapeutic indications, such as within oncology.**

These Guidelines present significant concerns for important and life-saving oncology medicines anticipated to be commercialized around the globe in the coming years. PMPRB is remiss to not specifically consider how patient access to such medicines may be negatively affected by not making special considerations for the unique issues associated with new oncology medicines.

Firstly, we question whether PMPRB has considered how it will handle new oncology agents with multiple indications – e.g., both across many different tumour sites, and lines of therapy or treatment goals within each tumour site. The complexity of reassessments in these cases would be a real concern.

Additionally, the Proposed Guidelines provide insufficient detail as to how comparators will be determined. In many quickly evolving oncology indications, innovative products are supplanting various chemotherapy protocols as standard of care. These novel medicines often represent breakthrough improvements in efficacy, safety, and patient quality of life versus chemotherapy. Under these Proposed Guidelines, however, it will be an all-too-common scenario for the price of these new medicines to be tied to that of the chemotherapy regimen – a great many of which are falling farther down the list of preferred clinical choices, as precision oncologic treatments effectively target underlying mutations instead of only attacking the tumor. In all other facets of health technology assessment and payer value, it has been recognized that incremental improvements in oncology therapies – whether it be a few extra months to live, less toxicity and side effects or patients reporting a better quality of life – are highly valued by Canadians. PMPRB is out of step with what Canadians and all other stakeholders in the Canadian health system seem to have long understood about the uniqueness of oncology.

Furthermore, there are broader health system implications associated with PMPRB's abandonment of therapeutic improvement. For example, many new oncology medicines are being commercialized in formats which can be administered at home or in community health care settings. Decreases in health system pressures associated with reduced chair time to administer these oncology medicines represent critical wins for our overburdened health care systems. Under previously effective Guidelines, many such therapies may have been designated as moderate improvement, however no such value recognition will be considered under these Proposed Guidelines.

Conclusion

PMPRB should limit its role to investigate potentially excessive prices, i.e., those which are higher than all other markets deemed comparable. If the Proposed Guidelines are implemented in their current state, the Canadian office of EMD Serono will be severely challenged to advocate for the launch our products in Canada, let alone on a priority basis. This will negatively impact patient access to innovative medicines, including important oncology innovations in our pipeline.

Our ask is simple: Do not implement these proposed Guidelines. EMD Serono urges the federal Ministry of Health and the Ministry of Innovation, Science and Industry to delay the implementation of Proposed PMPRB Guidelines until a more equitable solution can be found. We also encourage the PMPRB to seek input through technical working groups to further revise and thoughtfully consider how these Guidelines will impact the launch of new medicines in Canada. This approach will help mitigate the issues and unintended consequences outlined above in this correspondence, by IMC, by patient groups, and by other stakeholders throughout the PMPRB consultation period.

An appropriate balance is required between improving the affordability of medicines, ensuring timely patient access to medicines, and creating a world-class innovative life sciences environment in Canada. The implementation of the PMPRB regulations and Proposed Guidelines in their current form will have the opposite effect.

Sincerely,

Russ Burrell

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CC:

The Honourable Jean-Yves Duclos
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