SUBMITTED VIA EMAIL TO: pmprb.consultations.cepmb@pmprb-cepmb.gc.ca

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Dr. Mitchell Levine, M.D., M.Sc., FRCPC, FACP, FISPE
Chair, Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
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Response to: Notice and Comment – On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions (July 15, 2021)

Dear Dr. Levine:

On behalf of EMD Serono, a division of EMD Inc., Canada ("EMD Serono"), I write to provide input to the Consultation about the "*Notice and Comment – On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions*" dated July 15, 2021 ("Notice and Comment").

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. 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.

EMD Serono is a member of Innovative Medicines Canada (IMC) and fully supports its submission to this Consultation. In this letter, I articulate our additional concerns about the proposed amendments in the Notice and Comment.

The focus of the following response is the third proposed amendment in the Notice and Comment:

> **"International Price Tests for Grandfathered Medicines and their Line Extensions**
>
> Under the new Guidelines, the maximum list price ("MLP") for Grandfathered and Line extensions is set by the lower of (1) the MIP for the Schedule Countries for which the patentee has provided information for the reporting period ending June 30, 2021 under the Regulations that are currently in effect (SOR/2008-70, s.6); or (2) the medicine's ceiling (e.g. the "NEAP") under the Guidelines as they were prior to the issuance of these guidelines."

Our objection to the proposed amendment is as follows:

1. The proposed approach is arbitrary, lacks an assessment of anticipated impact and appears to be a mechanism for price control; and
2. There is insufficient notice and planning for transition, which will unduly harm patentees.

1. **The proposed approach is arbitrary, lacks an assessment of impact and appears to be a mechanism for price control**

The PMPRB has proposed a major change to how the prices of existing patented medicines and line extensions will be assessed. The PMPRB has not provided a clear rationale to support this substantial change. The proposed amendment means that all existing and Line Extension patented medicines will be re-benched at the lower of the medicine's ceiling (e.g., the Non-Excessive Average Price) and the median of the current schedule of countries starting on January 1, 2022.

If implemented, this change will reflect an arbitrary and substantial change to PMPRB policy regarding how the prices of existing products and Line Extensions are assessed. Furthermore, the PMPRB's assessment of impact of the proposed amendment is not provided and thus cannot be evaluated by concerned stakeholders or affected parties. In the absence of a clear rationale and evidence to support a change as significant as the proposed approach, this amendment is unjustifiably punitive, as its sole purpose appears to be to further lower prices of existing patented medicines. As such, this amendment is merely a mechanism for price control by the PMPRB. The recent decision of the Federal Court of Appeal in *Alexion Pharmaceuticals Inc. v Canada (Attorney General), 2021 FCA 157* clearly states at para. 50 that "[g]eneral price control is no part of the exercise" in reference to the PMPRB's mandate and jurisdiction. Further, the Court's decision states the PMPRB "went beyond its permissible statutory mandate by regulating the reasonableness of pricing, rather than preventing abusive pricing," (para. 11). We argue that the proposed amendment goes beyond the PMPRB's statutory mandate as clarified in the *Alexion* decision.

2. **There is insufficient notice and planning for transition, which will unduly harm patentees**

After a delay, the coming into force date of the Regulations is scheduled for January 1, 2022. Patentees with existing products or Line Extensions have therefore assessed impact and prepared for transition based on the existing Regulations and Guidelines.

The proposed, arbitrary amendment for existing products and Line Extensions was announced on July 15, 2021, less than six months until the new implementation date of January 1, 2022 for the Regulations and Guidelines. Furthermore, upon the close of this Notice and Comment period, there is merely three months until the coming-into-force date. The proposed amendment, coupled with a lack of time to prepare, creates significant uncertainty for patentees

The introduction of a new, arbitrary price test without sufficient time to assess, plan or transition unduly harms patentees in Canada. The harmful situation for patentees is compounded by the PMPRB announcing that compliance periods are now halved, from the original 12-month period to six months (i.e. July 1, 2022). To address these concerns, the PMPRB should reinstate the original 12-month compliance period and should not implement the proposed amendment related to existing products and Line Extensions.

The focus of the following response is to the second proposed amendment in the Notice and Comment:

"**Comparator Countries**

The comparator countries used under the new Guidelines are currently referred to as the "PMPRB11". **The PMRPB is proposing to refer to the comparator countries more by reference to the Schedule set out in the Regulations as the "Schedule Countries**".

Our objection to the proposed amendment is as follows:

1. The introduction of unfettered variability in the list of comparator countries as a result of incorporating "Schedule Countries" by reference to a Schedule that is easily amended, rather than setting out a defined list of comparator countries, creates significant uncertainty for patentees.

We interpret this amendment to mean that the "Schedule Countries" will refer to the countries defined in the Regulations at a given point in time, which is subject to change. The PMPRB has not provided any explanation or guidance as to whether it expects to revise the Schedule Countries, what criteria it will use in deciding whether to revise the Schedule Countries and in making such revisions, and how much notice it will give patentees prior to revising the list of Schedule Countries. The proposed amendment with no accompanying explanation or guidance as to how it will be utilized creates significant uncertainty for patentees and therefore unduly harms patentees in Canada.

Conclusion

The proposed amendment related to a new price test for existing products or Line Extensions is arbitrary and capricious and, if introduced, does not provide sufficient information or time for patentees to appropriately assess, plan or transition. This amendment appears to be a price control measure, which oversteps the mandate of the PMPRB, as clarified in the *Alexion* decision. Furthermore, the additional proposed amendment related to "Schedule Countries" lacks information or explanation about how it will be utilized or revised in the future. Both amendments create uncertainty and the potential for substantial harm to patentees.

Patentees and stakeholders in the pharmaceutical industry, both in Canada and at the Global level, have undertaken corporate planning by relying upon the PMPRB's previously announced price tests and timeframe to transition to the new Regulations. From an international perspective, the arbitrary amendments and insufficient notice prior to implementation indicate that the pricing environment for patented medicines in Canada is disruptive and will change with neither adequate notice nor supporting rationale. This situation creates an unfavourable environment for investment and launches of new medicines and vaccines in Canada. The PMPRB's approach creates additional uncertainty for patentees and negatively impacts patient access to innovative medicines in Canada.

We strongly urge the PMPRB to discontinue the proposed arbitrary and harmful amendments. More meaningful dialogue and consultation is necessary to mitigate 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 proposed amendments will disrupt that balance and ultimately, negatively impact patient access to innovative medicines in Canada.

Sincerely,

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