March 13, 2025

Submitted via PMPRB's website for written submissions: https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines-pmprb-staff.html

Subject: Response to PMPRB Draft Guidelines for PMPRB Staff

This submission is made on behalf of Servier Canada Inc. (Servier) in response to the Patented Medicine Prices Review Board (PMPRB) Draft Guidelines for PMPRB Staff (Guidelines) published in December 2024.

As a member of Canada's Innovative Medicines Canada (IMC), Servier supports the response and position submitted by IMC to the PMPRB, as part of this consultation phase.

Servier is an international pharmaceutical company governed by a non-profit foundation. With a strong international presence in 150 countries, Servier invests over 20% of its brand-name revenue in Research and Development every year. Established in Canada for more than 45 years, Servier provides the Canadian medical community and its patients with innovative therapeutic solutions in treating cancer, diabetes, heart disease, and high blood pressure.

The mandate of the PMPRB, as established by the Patent Act (Act), is to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive. The purpose of Guidelines, which are issued pursuant to subsection 96(4) of the Act, is to provide transparency and predictability to Rights Holders regarding the process typically engaged in by the PMPRB in identifying patented medicine that may be at a greater risk for excessive pricing.

As proposed in the Guidelines, the case-by-case reviews and context-specific weighing of Patent Act factors are not only concerning, but counterintuitive and this will ultimately reduce transparency and predictability for Rights Holders. Transparent and predictable benchmarks set out in the Guidelines would help guide pricing decisions, increase voluntary compliance and reduce future potential disputes and hearings.

After careful analysis of the Guidelines, Servier would like to highlight the following points:

INTERNATIONAL REFERENCE PRICING

As confirmed by both the Federal Court of Appeal and the Quebec Court of Appeal, the PMPRB's constitutional mandate is limited to the prevention of excessive pricing as a function of patent abuse.

In keeping with the court rulings, Servier maintains that the Highest International Price (HIP) is the only price level within the PMPRB11 consistent with an excessive pricing standard. Any other

price level would not be appropriate under PMPRB's non-excessive pricing mandate as it would not reflect a focus on excessive pricing, but rather appear to be designed to regulate prices and to drive pharmaceutical prices below non-excessive thresholds.

Accordingly, it is of the utmost importance that the HIP be maintained in the Guidelines.

ANNUAL PRICE REVIEWS

As already mentioned, pricing predictability throughout a patented medicine's product life cycle is crucial for Rights Holders. Thus, re-benchmarking via annual reviews that could trigger in-depth reviews based on data that was not available and could not be predicted when the Rights Holder made its investment decision would create arbitrary price reductions. Moreover, re-benchmarking on an annual basis would clearly reflect price control over time that is inconsistent with an excessive pricing mandate.

Rights Holders need and expect a predictable maximum non excessive price over the life of a patented medicine, subject to potential Consumer Price Index (CPI) adjustments. Hence, the price of a patented medicine should be assessed against HIP at introduction and then only subsequently monitored against CPI increase. Requiring the ceiling price of patented medicine to decrease over time on an annual basis is inconsistent with preventing patent abuse.

GRANDPARENTING OF EXISTING MEDICINES & TRANSITION PERIOD

Existing medicines have entered the Canadian market in good faith and in compliance with the rules and regulations in place at the time of their market entry when the scope and impact of the new PMPRB regime could not have been reasonably foreseen. Furthermore, these medicines have already been subjected to assessment and negotiation by various Canadian agencies, and funding decisions based on value for money and affordability have already been made.

Therefore, regulating existing medicines at the same level as new medicines is unfair to Rights Holders who have already made significant investments based on business analyses done under an existing regulatory framework. Accordingly, existing medicines should be grandparented under the Guidelines.

Furthermore, existing medicines should be given a 3-year transition period to adapt to the Guidelines. This will allow Rights Holders, provincial drug plans and pharmaceutical supply chain stakeholders sufficient time to adapt to the Guidelines and to properly implement new prices.

COMPLAINTS ELIGIBILITY

Servier believes that complaints should be restricted to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts which is consistent with s. 86(2) of the Patent Act.

Complaints filed by for-profit entities would not be appropriate and will create bias in price assessments. This restriction will help ensure that the most pertinent cases of potential price excessiveness will be brought to the PMPRB's attention by key government officials with a vested interest in public health.

Also, the PMPRB must avoid automatic in-depth reviews solely on the basis of a complaint. Complaints should be validated against the HIP standard, and where pricing is at or below the HIP, complaints should be closed with no further action.

IN-DEPTH REVIEWS

It is difficult for Servier to comment on the in-depth review process as there are many unanswered questions stemming from the Guidelines. For instance, it is unclear how the PMPRB will assess therapeutic comparability based on a vast range of open-ended questions and considerations, many of which seem outside of the scope of the Act.

Servier believes that, first and foremost, the Guidelines should provide stable and predictable price thresholds. Moreover, the price of a patented medicine should be assessed at its introduction to the Canadian market and then only subsequently monitored against the allowable CPI increase. This will provide patentees with greater stability and predictability over the duration of the patent and reduce administrative burden.

Servier is committed to advancing healthcare through timely access to innovative medicines, in order to address unmet medical need for Canadian patients. Servier is hopeful that the comments provided to the PMPRB in this letter and by numerous stakeholders within this consultation process will be seriously considered in the development of the Guidelines.

As a member of the life sciences community, we appreciate the opportunity to provide feedback on this important consultation and we look forward to working collaboratively with the PMPRB and other stakeholders to address these serious concerns that ultimately affect all Canadians.

Yours sincerely,

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