



VALEO PHARMA®

August 31, 2021

Via Email PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

To whom it may concern:

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)

This submission is made on behalf of Valeo Pharma in response to the Notice and Comment on the change to the definition of Gap medicines, the references to the comparators countries and the international price tests for existing medicines and their line extensions (July 15, 2021).

Valeo Pharma is a Canadian specialty pharmaceutical company committed to creating partnerships with both international partners and with members of the Canadian Healthcare Industry in order to quickly and efficiently bring innovative products of the highest quality to the market. Valeo Pharma is a member of Innovative Medicines Canada and supports its submission to this consultation. Valeo notes that the proposed changes are not in line with the federal government's recently announced Biomanufacturing and Life Sciences strategy. In particular, we would emphasize the following points:

- 1. PMPRB should discontinue the proposal to change the price tests for existing products and their line extensions as it is inconsistent with the PMPRB's role as a regulator of excessive ceiling prices.**

The July 15, 2021, proposal to change the international price tests for existing medicines and their line extensions from the highest of the international schedule to the median seems arbitrary, inconsistent with the PMPRB's role as a regulator of excessive ceiling prices and will harm both patentees and other elements of the pharmaceutical supply chain in Canada (e.g., distributors, pharmacies, and generics).

The changes proposed indicate to the international industry that Canadian pharmaceutical pricing is unstable, subject to change on short notice and lacking rationale. The changes and general uncertainty created by PMPRB reforms will impact the attractiveness of the Canadian market for investment.

- 2. PMPRB should remain consistent with previous decisions and honor the previously noted two reporting periods for compliance purposes and a 12-month transition period from the date that the regulatory changes come into force.**

Industry has relied on the previously announced price tests and transitional time frames for corporate planning purposes. Limiting the transition period to only six months (or one reporting period) is



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inconsistent with the federal governments commitment to support the ongoing collective efforts for fighting the COVID-19 pandemic.

Thank you for the opportunity to comment on these proposed changes. We hope the PMPRB will engage with the industry on alternative transition scenarios that are more consistent with the federal government's regulatory delay and objective to allow all parties to focus on the COVID-19 pandemic.

Best regards

Frederic Fasano
President and Chief Operating Officer
Valeo Pharma