July 18, 2022

Douglas Clark
Executive Director
Patented Medicine Prices Review Board
Box L40, Standard Life Centre 333 Laurier Avenue West Suite 1400
Ottawa, Ontario K1P 1C1

Submitted via PMPRB Online Submission Form

Dear Mr. Clark,

I am writing to provide the response of the Canadian Generic Pharmaceutical Association (CGPA) to the consultations on the *PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations* published on June 30, 2022.

The CGPA represents Canada's generic pharmaceutical industry. The industry plays an important role in controlling health-care costs in Canada. Generic drugs are dispensed to fill more than 73 percent of all prescriptions but account for account for less than 20 percent of the $32-billion Canadians spend annually on prescription medicines.

As you are aware, the CGPA has been engaged in consultations with respect to proposed changes to the *Regulations* and the PMPRB Guidelines for several years. The inclusion of a revised list of international reference countries in the final *Regulations* will have significant impacts on a broad range of stakeholders beyond pharmaceutical patentees, including pharmacies, distributors and generic pharmaceutical manufacturers.

The changes to the *Regulations* and the pending development of new PMPRB Guidelines come at a time when there is significant uncertainty facing the generic pharmaceutical industry as negotiations towards a new pricing agreement for generic medicines between the pan-Canadian Pharmaceutical Alliance (pCPA) and the CGPA are underway. The current agreement expires in April 2023.

The prices of generic medicines could inadvertently be impacted by the new PMPRB Guidelines due to the reference-based pricing system that is in place for these products in Canada.

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The CGPA remains concerned about the impact of the new PMPRB 11 basket of comparator countries and the lack of clarity with respect to the treatment of grandfathered products which, if not addressed correctly, would reduce the prices of existing brand-name products that generic manufacturers are planning to launch when patents expire. This would negatively impact the feasibility of new generic products and investments by the industry, which runs counter to the objectives of the Government of Canada's Life Sciences and Biomanufacturing Strategy.

To avoid these negative consequences, the CGPA recommends that the new PMPRB Guidelines confirm that medicines currently marketed and those that are launched prior to the publication of the final new PMRPB Guidelines are exempt from reassessment against the PMPRB11.

The CGPA also supports a minimum transition period of two reporting periods (12 months) following publication of the new Guidelines. This is consistent with the PMPRB's April 2019 commitment to allow patentees and other pharmaceutical supply chain stakeholders to adapt to the new regime. A longer transition period could be considered.

With respect to the proposed Interim Approach there remains a lack of visibility in terms of how the PMPRB will review new medicines for excessive prices. This will create significant uncertainty for stakeholders, and create risks for patentees that may delay or deter them from launching new products in Canada. To reduce this uncertainty and risk, the CGPA recommends that the PMPRB include the following in a revised Interim Approach:

1. Clarify that the highest available non-excessive average price (NEAP) will set the benchmark for the interim period.

2. Confirm that patentees will not be required to pay excessive revenues for sales during the interim period.

Thank you for reviewing these concerns of the generic pharmaceutical industry. The CGPA looks forward to continuing the discussion as the PMPRB consults on its new draft Guidelines in the fall.

Sincerely,

Jim Keon
President