CGPA
Making Patient Care Affordable

December 5, 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 feedback of the Canadian Generic Pharmaceutical Association (CGPA) to the consultations on the proposed changes to the PMPRB's Guidelines.

The CGPA is the national association representing Canada's generic pharmaceutical industry and, through its Biosimilars Canada division, the manufacturers of biosimilar medicines. The industry plays an important role in controlling health-care costs in Canada. Generic drugs are dispensed to fill 74 percent of all prescriptions but account for only 21 percent of the $37-billion Canadians spend annually on prescription medicines.

The CGPA and its member companies have concerns over the impact of the proposed Guidelines on the pricing and, therefore, supply of new and existing generic pharmaceutical products in the Canadian market.

1. Special Provisions and Timing

In terms of section 4 (36) and (37) of the proposed Guidelines, it is the position of CGPA that the PMPRB's role is to ensure that prices of patented medicines in Canada are not excessive. Given that generic and biosimilar medicines in Canada are priced significantly lower than the prices of their innovator reference products, prices of these medicines are, by definition, not excessive.

In addition, prices of generic and biosimilar pharmaceutical products in Canada are controlled through the pan-Canadian Pharmaceutical Alliance (pCPA) Tiered Pricing Framework and provincial / territorial legislation, regulation and policy.

Generic and biosimilar prescription medicines should, therefore, should not be subject to further controls in the Canadian market through the PMPRB.

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2. CGPA Concerns with Respect to Pricing / Supply / Future Launches

The proposed Guidelines, coupled with the 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 prices of generic prescription medicines will be directly affected by the new PMPRB Guidelines due to the reference-based pricing system that is in place for these products in Canada. Generic prices in Canada are set as a percentage of the brand reference price through the pCPA Tiered Pricing Framework and provincial / territorial drug benefit plan rules. Further price cuts to generic pharmaceutical products in Canada will threaten the supply of medicines upon which Canadians rely. Generic prescription medicines are dispensed to fill nearly three quarters of all prescription in Canada.

The proposed Guidelines will introduce greater uncertainty for generic pharmaceutical manufacturers due to fluctuations in prices of brand-name reference products. The proposed Guidelines appear to provide no bright line rules or predictability. They propose an open-ended set of powers for Board staff to trigger investigations and to create rules on a product or situation specific basis. In addition, international pricing provisions mean that brand-name drug companies may have to demonstrate compliance at any time as international prices fluctuate, which could result in price erosion over time. This will make it difficult for generic companies to adequately assess the potential economic viability of future launches of cost-saving generic and biosimilar medicines in the Canadian market.

The CGPA remains concerned about the impact of the new PMPRB 11 basket of comparator countries, which will reduce the prices of existing brand-name products that generic manufacturers are planning to launch when patents expire. The federal Parliamentary Budget Officer (PBO) estimates patented drug prices could be reduced by approximately seven percent just from moving to the new PMPRB 11 comparator countries. As a result, prices of generic medicines will be reduced by a corresponding amount.

In addition, due to inflation and the lack of a CPI price increase mechanism for generic prescription medicines in Canada, net prices for Canadian generic pharmaceutical manufacturers have been effectively cut by 13.1 percent over the past seven years.

Due to disruptions to the global supply chain and increasing costs, generic manufacturers cannot sustain further price cuts and maintain important jobs and investments in Canada's life sciences sector. Additional price cuts will threaten the viability of existing medicines and the introduction of new cost-saving generics in the Canadian market. They will threaten Canada's ability to manufacture prescription medicines on Canadian soil, which runs counter to the objectives of the Government of Canada's Life Sciences and Biomanufacturing Strategy. A February 2022 study by consulting firm EY Canada commissioned by CGPA shows that the number of generic medicines domestically produced has declined by 35 percent since 2019.

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

Sincerely,

Jim Keon
President

CC: The Honourable Jean-Yves Duclos, Minister of Health
Stephen Lucas, Deputy Minister of Health