August 31, 2021

Patented Medicine Prices Review Board
Box L40
Standard Life Centre
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PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: 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

To Whom It May Concern:

I am writing to provide the Canadian Generic Pharmaceutical Association's (CGPA's) response to the PMPRB's invitation for stakeholders to comment on proposed amendments to the PMPRB Guidelines published on July 15, 2021. The CGPA is opposed to the July 15, 2021 proposals for the reasons outlined below.

The CGPA is the national association representing Canada's generic pharmaceutical industry, a group of companies which specialize in the production and marketing of high quality, affordable generic drugs. For more than 50 years, Canada's generic pharmaceutical industry has played a vital role in the country's health-care system and its economy by providing safe, effective, proven alternatives to more expensive brand-name medications. Making prescription drugs more affordable and accessible is the key value proposition of Canada's generic pharmaceutical industry.

The CGPA has been concerned about the changes to the *Patented Medicines Regulations* and PMPRB framework for several years because of the reference-based pricing system for generic medicines in Canada. Generic pricing levels in Canada are internationally competitive, and any reduction in originator prices must not have a corresponding impact on generic drug prices. Generic medicines are used to fill 73 per cent of all prescriptions in

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Canada. Generic medicines are providing tremendous value and savings for Canadians, largely due to the work the CGPA has done with the pan-Canadian Pharmaceutical Alliance (pCPA). The pCPA and CGPA have had a 5-year generic drug pricing agreement ("5-Year Agreement") in place since April 1, 2018. This follows an earlier agreement, which resulted in substantial savings for Canadians.

As such, the CGPA was both surprised and disappointed that the Regulatory Impact Assessment Statement published with the *regulations amending the regulations Amending the Patented medicines regulations (Additional Factors and information reporting requirements), no. 3* in Canada Gazette Part II on July 7, 2021 included the following false statement: *"Most provincial health ministries, public and private health insurance providers, health professional associations, academics*, *and the generic pharmaceutical industry have been supportive of the Amending Regulations, encouraging the full implementation of the regulatory changes without further delay."*

At no point has the generic pharmaceutical industry "expressed support for the amending regulations" or "encouraged the full implementation of the regulatory changes without further delay". At the very least, this demonstrates that the concerns of the generic pharmaceutical industry have not been fully taken into account in the various consultations with respect to a revised PMPRB framework.

The CGPA and its Biosimilars Canada division are opposed to the July 15, 2021 PMPRB proposals for the following reasons:

1. The proposals are inconsistent with the government's publicly stated intent to delay the implementation date to January 1, 2022 in recognition of the ongoing impacts of the COVID-19 pandemic.[1]

2. Discussions regarding the *Regulations* and the Guidelines have been ongoing for several years, with various iterative changes proposed during this time. The PMPRB is now proposing a major change to how an excessive price for existing products and line extensions is defined at a very late stage in the process, without a clear rationale for doing so.

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[1] *"The main anticipated benefit of the Regulations is to allow drug manufacturers and health system partners to remain focused on responding to the COVID-19 pandemic and provide additional time to prepare for and comply with the changes introduced in the Amending Regulations."* Canada Gazette, Part II, Volume 155, Number 14 (July 7, 2021). https://gazette.gc.ca/rp-pr/p2/2021/2021-07-07/html/sor-dors162-eng.html

3. Limited information about the anticipated impact of these latest changes is available, creating a great deal of uncertainty for all pharmaceutical stakeholders.

4. The proposed changes would be highly disruptive. Stakeholders have relied upon the previously announced price tests and transitional timeframe for planning purposes. From an international perspective, they suggest that the Canadian pharmaceutical pricing environment is unstable and subject to change on short notice and without rationale.

Thank you for reviewing the concerns of Canada's generic pharmaceutical and biosimilar medicines industries. I remain available to discuss these concerns in greater detail and answer any questions you may have.

Sincerely,

Jim Keon
President

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