CGPA
Making Patient Care Affordable

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Patented Medicine Prices Review Board
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Submitted via PMPRB Online Submission Form

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I am writing to provide comments of the Canadian Generic Pharmaceutical Association (CGPA) in response to the Discussion Guide for PMPRB Phase 2 Consultations on new Board 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 77 percent of all prescriptions but account for only 22.3 percent of the $45-billion Canadians spend annually on prescription medicines.

Background Context – Generic Medicines

In Canada, prices of generic pharmaceutical products are controlled through the pan-Canadian Pharmaceutical Alliance (pCPA) Tiered Pricing Framework and provincial / territorial legislation, regulation and policy – regardless of whether a generic medicine is associated with a patent.

Since 2014, the pCPA Generics Initiative has provided billions of dollars in savings to participating jurisdictions, employers that sponsor drug plans for their employees and Canadian patients. It has also provided much-needed market stability and predictability for generic pharmaceutical manufacturers attempting to operate in the fractured Canadian market. A renewed three-year pricing initiative for generic drugs came into effect on October 1, 2023.

According to pCPA, previous joint efforts between pCPA and CGPA have resulted in savings of more than $4-billion to participating drug plans over the past ten years, which will only continue to grow over the course of this new pan-Canadian agreement.

Because the prices negotiated by pCPA and CGPA are transparent and available to all payers in Canada, the additional savings to employer-sponsored drug plans and Canadian patients are estimated to be equal to that of Canadian governments. It is important to note

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that there is no price differentiation with respect to generic medicines associated with one or more patents, and those that have no patents. No market power or exclusivity is conferred for a generic medicine by an association with a patent.

In Canada, the use of generics translates to savings of more than $42-billion annually. Some of the most prescribed generic medicines are priced at a 90 percent discount off the price of the brand-name drug. That means up to 10 patients can be treated for the cost of treating one patient with the brand-name version.

Data from EVERSANA's NAVLIN database shows that public prices for generic medicines that are benefits on provincial drug benefit plans in Canada are 45 percent lower than in the PMPRB11 comparator countries (weighted median). These results clearly demonstrate that drug prices paid by Canada's public payers are significantly lower than public pricing in international comparator countries. Policy makers must recognize these results when making decisions related to generic pricing that may threaten Canada's access to prescription drugs.

There are increasing concerns worldwide, including in Canada, about the state of the prescription medication supply. Health Canada recently set up a directorate to specifically focus on drug shortages. Further reductions to Canadian generic drug prices would further stress the resiliency of the industry when there are already supply problems.

The CGPA and its member companies have concerns over any measures that could impact the price of pharmaceutical products in Canada and, as a result, the supply of new and existing generic pharmaceutical products in the Canadian market. Given that generic prescription medicines are dispensed to fill more than three quarters of all prescriptions in Canada, further price cuts to generic pharmaceutical products in Canada will threaten the supply of medicines upon which Canadians rely.

Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criterion for an Existing medicine is met.

It remains the position of CGPA that the new Guidelines should not be retroactively applied.

Prices of generic pharmaceutical products are regulated and set as a percentage of the equivalent brand-name product. In direct relation to CGPA's concerns with respect to the potential impact on the current and future supply and availability of cost-saving generic prescription medicines, it is CGPA's recommendation that application of the finalized Guidelines be effective on the date of their application and not retroactive. Existing products should be fully grandfathered from new Guideline requirements.

CGPA notes that the current Board position as included in the Discussion Guide is to provide a transition period for existing products, and not grandfather existing medicines from the new Guideline requirements. In advance of the August 13, 2024 webinar, the CGPA's Biosimilars Canada division submitted a question asking for additional information to be

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provided with respect to the Board's rationale for not grandfathering existing medicines. This question was not addressed during the webinar.

The Phase Two Discussion Guide seeks feedback on whether the transition period should be one, two or three years. If the Board ultimately does not agree to grandfather existing medicines despite the significant concerns raised by CGPA, its Biosimilars Canada division and other organizations, we request that the Board consider a transition period of at least five years to minimize the disruption to the pharmaceutical supply chain for generic and biosimilar manufacturers, patients, and other pharmaceutical stakeholders.

Topic 4: The individuals/groups permitted to submit a complaint

The PMPRB has implemented complaints-based reporting for pharmaceutical products with low risk of excessive pricing, including patented generic drugs, veterinary drugs, and over-the-counter drugs. This approach should be maintained in future PMPRB Guidelines, and should also be extended to include biosimilar medicines, which are also of low risk of excessive pricing.

CGPA is encouraged that the Discussion Guide recognizes the need to prevent misuse to reduce administrative burden and maintain predictability for patentees with respect to a complaints process.

Under the current Compendium of Policies, Guidelines and Procedures, which were updated in February 2017, Board Staff only review information relating to the identity and pricing of the patented generic drug if an investigation was commenced by Board Staff, and Board Staff would only commence such an investigation if three conditions were met:

- A complaint has been received in respect of the patented generic drug;
- The patentee of the patented generic drug is the only company in Canada which is selling a generic version of the drug in Canada; and
- The patented generic drug is not the subject of a pricing agreement with the pan-Canadian Pharmaceutical Alliance (pCPA) to which it is compliant.

The CGPA seeks confirmation from the Board that the three triggers required to commence an investigation will be maintained under the new Guidelines.

Avoiding the potential for frivolous complaints is important as they would have the effect of diverting limited PMPRB investigative resources from high-risk originator patented medicines, which is not in the best interests of Canadians and is inconsistent with the mandate of the PMPRB as prescribed under the *Patent Act*. It would also be a drain on resources for a company that is required to respond to the frivolous complaint.

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Narrowly restricting the scope of individuals permitted to submit a complaint is the most powerful and effective safeguard that the Board can put in place to prevent misuse of the complaints-based reporting system.

CGPA is of the view that *Option 1: limit complaints to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts* would significantly reduce the potential for misuse of the complaints-based reporting system and is consistent with s. 86(2) of the *Patent Act.* Further, CGPA does not support Option 2B, Option 3 or Option 4 as these options do not provide sufficient safeguards to prevent misuse of the complaints-based reporting system.

Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines.

The CGPA Canada supports Option 2, whereby the PMPRB will only open a review for patented biosimilars and/or vaccines when a complaint is received. As the PMPRB itself has noted, patented biosimilar biologic drugs pose a very low risk of excessive pricing in the domestic market. Previous versions of the draft guidelines included a complaints-based reporting requirement for patented biosimilars, which should be maintained under the future PMPRB Guidelines.

Such a complaints-based approach has already been implemented for other products that also have a low risk of excessive pricing, including patented generic drugs, patented veterinary drugs and patented over-the-counter drugs.

With respect to in-depth reviews resulting from a complaint, clarity is needed with respect to how these will be conducted for patented generic and patented biosimilar medicines.

In-depth reviews are considered by originator rights holders as the main Guideline policy that they must account for when making pricing and launch decisions. Price tests for originator medicines are not appropriate for medicines that are approved by Health Canada based on bioequivalence or similarity to a reference originator medicine and are direct competitors to a reference originator medicine (e.g., generic and biosimilar medicines).

Price tests designed for patented originator medicines do not consider the market realities and other important considerations for generic and biosimilar medicines. A separate test for these products that is focused on the domestic market is needed for investigations into patented biosimilar medicines.

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Thank you for reviewing this submission. The CGPA looks forward to continuing this important discussion.

Sincerely,

Jim Keon
President