



August 4, 2020

Douglas Clark, Executive Director  
Patented Medicines Prices Review Board  
Attention: PMPRB Guideline Consultations  
Box L40 Standard Life Centre  
333 Laurier Avenue West, Suite 1400  
Ottawa, Ontario K1P 1C1

\* Submitted via PMPRB Draft Guidelines Consultation Website

## **Re: Revised Proposed PMPRB Guidelines Published June 19, 2020**

Dear Mr. Clark,

I am writing to provide the Canadian Generic Pharmaceutical Association's (CGPA's) feedback on the revised proposed PMPRB Guidelines published June 19, 2020.

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 vast majority of generic medicines do not have patents. Some generic medicines may be patented generic drugs due to the patenting of a process or other innovation, or through a license or other arrangement with a company that has patents covering the product. Regardless of whether a generic medicine is covered by a patent or not, it must compete with other generic drugs within the market frameworks established by the provinces.

### **Potential Impact of PMPRB Changes on Prices of Generic Medicines**

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 as explained below. Generic pricing levels in Canada are internationally competitive, and any reduction in originator prices must not have a corresponding impact on generic drug prices.

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### **Canadian Generic Pharmaceutical Association**

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Generic medicines are used to fill 73 per cent of all prescriptions in 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.

The 5-Year Agreement includes a tiered pricing model which has different pricing levels depending on the number of competitors in the market. These prices are fully transparent and apply to payers in both public and private markets. Prices of generic drugs are calculated and set by the pCPA as a percentage of the price of the reference originator product at the time the first version of that generic medicine seeks to be listed on provincial formularies. Any subsequent change in the price of the originator product does not affect the price of a generic medicine already listed on provincial formularies under the Agreement. However, generic drug manufacturers begin development of new medicines several years prior to their launch on the market. Changes in the pricing of reference brand products currently on the market (for example as a result of the new international country price comparison tests) could negatively impact the pricing and market potential of the generic products under development, resulting in an increased risk of new generic medicines not launching in Canada.

The 5-Year Agreement includes a clause that requires the pCPA and CGPA to review the changes to the PMPRB framework and address potential impacts on generic drug prices. This clause was included to maintain the integrity of the agreement, ensure generic drug prices remain at sustainable levels, lower the potential risk of drug shortages for Canadians and maintain a viable generic medicines market in Canada.

However, the full impact of the changes on originator prices remains unclear and the topic of much debate, creating uncertainty about the impact of the changes on the 5-Year Agreement. The estimates of the impact of the *Patented Medicines Regulations* and PMPRB framework changes vary greatly.

The importance of the 5-Year Agreement and the internationally competitive prices of generic medicines in Canada are recognized by the PMPRB in various reports. This includes the PMPRB’s [Generics 360, 2018](#) report, which notes:

*Over the past decade, generic price-setting policies initiated by individual provincial governments and through the pan-Canadian Pharmaceutical Alliance (pCPA) have resulted in a notable decline in generic prices. The latest initiative, a five-year joint agreement between the pCPA and the Canadian Generic Pharmaceutical Association (CGPA), has gained the greatest ground, bringing Canadian prices closely in line with international norms.*

PMPRB data shows that Canadian prices for generic prescription medicines dropped to five percent below average or mean prices in comparator countries in 2018. The PMPRB’s data also shows that, since 2007, the average price of generic prescription medicines in Canada has fallen by nearly 60 per cent, with prices of some of the top-selling generics dropping by an average of 80 per cent. While prices of generic medicines have fallen in markets around the world, Canada has experienced the steepest decline of all OECD countries.

In announcing the pCPA-CGPA 5-Year Agreement, the parties issued a [joint statement](#) which noted the following<sup>1</sup>:

- As of April 1, 2018, the prices of nearly 70 of the most commonly prescribed drugs in Canada will be reduced by 25%-40%, resulting in overall discounts of up to 90% off the price of their brand-name equivalents. These drugs include those used to treat high blood pressure, high cholesterol, and depression, and are collectively used by millions of Canadians.
- More than 70% of all prescriptions reimbursed under Canada's public drug plans are generic drugs. This new initiative will not only provide savings to patients and increase the sustainability of drug plans, but will also improve pricing consistency across the country, and help drug plans increase access to new drugs in Canada.
- Previous joint efforts between pCPA and CGPA have resulted in savings of over \$1 billion to participating drug plans over the past five years, and will continue to save \$250 million per year. This initiative builds upon that foundation, and is estimated to save an additional \$385 million in the first year, and up to \$3 billion over the next five years through a combination of price reductions and the launch of new generic drugs. Savings to patients and employers are expected to match or exceed those achieved by Canadian governments.
- A key component of this initiative is that tendering will not be pursued by the participating drug plans over the five-year term. The generic drugs covered in this initiative are manufactured by multiple generic companies, helping to ensure a stable supply for Canadian patients. Pricing stability and predictability will also help to ensure that generic pharmaceutical manufacturers can continue to invest in bringing new cost-saving generic drugs to the Canadian market in the coming years.

**Recommendation:**

In light of the uncertainty with respect to originator prices, the CGPA urges the PMPRB to consult closely with both the pCPA and the CGPA as it finalizes its Guidelines and to continue that close consultation in the future to prevent serious negative impacts on the integrity of the 5-Year Agreement as well as on the introduction and sustainability of generic medicines in Canada.

**Complaints-Based Reporting for Patented Generic Medicines**

The proposed revised PMPRB Guidelines confirm that patented generic medicines will be included on the list of products that will be subject to a complaints-based approach:

*Notwithstanding the above, in the case of patented Biosimilars, patented Generic medicines, patented medicines for veterinary use and over the counter (OTC) patented medicines, an investigation will only be commenced by Staff if a complaint is received.<sup>2</sup>*

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<sup>1</sup> <https://www.newswire.ca/news-releases/a-joint-statement-from-the-pan-canadian-pharmaceutical-alliance-and-the-canadian-generic-pharmaceutical-association-671651014.html>

<sup>2</sup> PMPRB revised [draft Guidelines](#), para. 89

The approach to complaints-based reporting for patented generic medicines in the revised draft PMPRB Guidelines is consistent with the Board’s existing complaints-based reporting, reflects the low risk of excessive pricing for these medicines, and is supported by the CGPA.

Under the Policy on Generic Medicines (B.8.4), which was added to the [Compendium of Policies, Guidelines and Procedures \(Compendium\)](#) in February 2017 and has applied since the July 1, 2016 reporting period, Board Staff will commence an investigation into the price of a patented generic drug if all of the following three conditions are 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 onus of proving to Board Staff that a Patented Generic Drug is subject to, and compliant with, a pricing agreement with pCPA will rest with the patentee for that Patented Generic Drug.

PMPRB Staff confirmed to CGPA Staff via email on June 29, 2020 that it is their intent to continue to apply these conditions to patented generic drugs under the new Framework. The CGPA supports this approach. The CGPA is concerned that the Board has not yet contemplated any conditions to trigger an investigation into patented biosimilar drugs. The CGPA notes that the same conditions would be appropriate for patented biosimilar medicines. As such, the PMPRB should create a new combined Policy on Generic and Biosimilar Medicines (B.8.4) which applies the existing three conditions to both patented generic drugs and patented biosimilar drugs. Alternatively, a new Policy on Biosimilar Medicines could that includes these three conditions could be created.

The CGPA had previously raised concerns about the definition of “Patented Generic Drug” included in the *Patented Medicines Regulations* published in Canada Gazette Part II on August 21, 2019. While the stated intent of the Regulatory Impact Assessment Statement was to reduce PMPRB reporting obligations for patented veterinary, over-the-counter, and generic medicines, the CGPA was disappointed that the definition of *generic medicine* in the final *Regulations* was based on Health Canada Abbreviated New Drug Submission (ANDS) approval pathway instead of something more reflective of the market-based realities for these products. Health Canada officials have acknowledged to CGPA that a generic medicine was defined in the *Regulations* as a product that is approved through the ANDS pathway because they had difficulty creating a more accurate legal definition that was inclusive of all generic medicines.

The CGPA was pleased to see a more accurate and comprehensive definition of “patented generic medicines” is included in the revised draft Guidelines:

*Patented medicines that obtain market authorization in Canada with a demonstrated bioequivalence to a reference drug or by otherwise relying on the dossier of a previously approved drug with the same active ingredient (i.e. either through a New Drug Submission or an Abbreviated New Drug Submission).<sup>3</sup>*

The CGPA notes that the submission types listed in this definition do not include all generic drug submission pathways. As such, the CGPA recommends that the following submission types be included:

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<sup>3</sup> PMPRB revised [draft Guidelines](#), footnote 14

- Supplementary Abbreviated New Drug Submissions (SANDS) and Supplementary New Drug Submissions (SNDS), which can introduce a new dosage form, strength or new presentation (injectable) that can lead to the issuance of a new Drug Identification Number (DIN).
- DIN Applications for Division 1 Drugs, which can lead to the issuance of a new DIN.

The proposed revised Guidelines also confirm that patented generic medicines and patented biosimilars will only be categorized as Category II drugs:

*In addition, even if they would otherwise meet the Category I criteria, all new patented Biosimilars and new patented Generic medicines will be classified as Category II.<sup>4</sup>*

*A Category II patented medicine that is approved for a new indication (except for Biosimilars and Generic medicines) may be reassessed as Category I if it triggers the relevant screening criteria. For example, if the patented medicine's actual revenues increase above the annual Market Size Threshold, contrary to the initial market size estimate filed by the patentee.<sup>5</sup>*

CGPA supports this approach as it reflects the fact that both patented generic medicines and patented biosimilar medicines are sold in multi-source environments and are priced based on a percentage discount off of a reference drug that already falls under the PMPRB's jurisdiction.

**Recommendations:**

The approach to complaints-based reporting as included in the revised draft PMPRB Guidelines is fully consistent with the Board's existing complaints-based reporting policy for all generic medicines and the low risk of excessive pricing for these products. As such, the CGPA supports the adoption of the complaints-based reporting framework for patented generics as outlined in this document. The CGPA also supports the categorization of patented generic medicines and patented biosimilar medicines as Category II drugs.

The definition of patented generic medicines provided in Footnote 14 should include a more comprehensive list of generic submission pathways. In addition to the ANDS and NDS pathways, the list should be expanded to include SANDS, SNDS and DIN submissions.

PMPRB Staff have confirmed to CGPA Staff by email that they intend to continue to apply the existing three conditions as outlined in the Policy of Generic Medicines of the [Compendium of Policies, Guidelines and Procedures \(Compendium\)](#) to trigger an excessive pricing investigation for a patented generic medicines. The CGPA fully supports this approach, with the same conditions also applied to trigger investigations into patented biosimilar medicines.

<sup>4</sup> PMPRB revised [draft Guidelines](#), para. 60

<sup>5</sup> PMPRB revised [draft Guidelines](#), para. 81

Thank-you for reviewing these submissions of the Canadian Generic Pharmaceutical Association. We look forward to discussing these concerns with you in greater detail, and remain available to provide any clarifications or answer any questions you may have.

Sincerely,

A handwritten signature in black ink that reads "Jim Keon". The signature is written in a cursive style with a large initial "J" and "K".

Jim Keon  
President  
Canadian Generic Pharmaceutical Association