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) on the Scoping Paper for the consultation on the Board'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 more than 76 percent of all prescriptions but account for only 22.4 percent of the $41.5-billion Canadians spend annually on prescription medicines.

Every day in Canada, an average of 2.2 million prescriptions are dispensed using generic medicines.

In Canada, the use of generics translates to savings of more than $37-billion annually or more than $2,500 in savings per household. As of 2022 the average price of a brand-name prescription is $125.77, while the average price of a generic prescription is only $22.33. As these data clearly illustrate, the use of generic prescription medicines is key to the affordability of prescription drug coverage for Canadians.

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. CGPA also points out that the Final Report of the Advisory Council on the Implementation of National Pharmacare recommended mandatory generic substitution policies to encourage patients and prescribers to choose the most cost-effective therapies. It also recommended increasing patient and prescriber awareness about the equivalency of generic and brand-name prescription medicines

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.

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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.

Complaints-Based Reporting for Patented Generic Pharmaceutical Products

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.

Such a complaints-based reporting regime reflects the low risk of excessive pricing for patented generic medicines due to the following:

- Patents on generic medicines do not confer a market monopoly or market advantage. A patented generic medicine does not receive a higher price or special treatment over a non-patented generic medicine – it must operate within the marketplace policy frameworks established for all generic drugs.

- No market differentiation can be achieved through the existence of a patent on a generic medicine. Generic medicines in Canada are authorized for sale as bioequivalent to the brand-name reference product. The sponsor of a generic medicine cannot make claims that it is better or more effective than its reference drug or other generic medicines approved using the same reference product, regardless of whether it has a patent or not.

- While it is possible that some generic medicines could have patents, many others do not, which makes the PMPRB intervention ineffective as a price regulation tool and creates inequities amongst competitors.

- There are often multiple products of the same active substance competing in the market, including the reference drug.

- The prices for generic medicines are negotiated through the pan-Canadian Pharmaceutical Alliance (pCPA) and regulated by provincial / territorial governments to be lower than the price of the originator product, which is already regulated by PMPRB.

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New Guidelines Should Not be Applied Retroactively

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.

Existing Price Controls for Generic Pharmaceutical Products in Canada

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.

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.

Reimbursed Prices of Generic Medicines in Canada are 45% Lower than PMPRB11

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.

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The NAVLIN database is networked across more than 100 countries worldwide with more than 650 global sources which are monitored daily for prices, HTAs and policy and tendering data. The system has less than 24 hours speed for updates made from the time of publication with 5.5 million price points and 99.8 percent data accuracy.

The NAVLIN data sources contain both the ex-factory and public pricing of generic prescription medicines. The use of public pricing is the most accurate way to compare Canadian prices versus international comparator countries, because the public price is the actual and final price that is paid in these markets. The use of public pricing is therefore the most appropriate pricing source for public policy makers to use when implementing new policies and regulations that impact generic drug pricing. The use of ex-factory pricing has limitations, among them that the reported prices may not reflect the prices the consumer paid or what public and private plans reimbursed.

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

Further reductions in the price of prescription medicines in the Canadian market will have significant impacts on a broad range of stakeholders beyond pharmaceutical patentees, including patients, pharmacies, distributors and generic pharmaceutical manufacturers.

As noted above, in Canada, prices of generic prescription medicines are set as a percentage of the brand reference price through the pCPA Tiered Pricing Framework and provincial / territorial drug benefit plan rules. 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.

Impact of Inflation / Rising Costs

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.

It is CGPA's position that, given rising costs due to inflation and other factors, pharmaceutical manufacturers in Canada should be eligible for CPI increases to ensure the economic viability of the prescription medicines upon which Canadians rely.

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Stability of Canadians' Supply of Prescription Medicines Must be a Priority

There are increasing concerns worldwide, including in Canada, about the state of the prescription medication supply. It is the view of CGPA and its member companies that governments need to be more attentive to this growing issue. In Canada, there have been 2,462 discontinued products reported since 2017, an alarming figure that should serve as a wake-up call to policy makers in Canada since the discontinuations are often a direct result of the inability to economically produce prescription medications in this country.

Similarly, in the European Union, it has been reported that 26 percent of generic medicines, 33 percent of antibiotics and 40 percent of cancer medicines are no longer available in European markets.

And in the United States, the lack of supply of generic medications, including for chemotherapy, is a growing concern. In fact, the U.S. government has assembled a team to find long-term solutions for shoring up the pharmaceutical supply chain, at a time when the United States remains heavily reliant on medicines and drug ingredients from India and China. This is a clear demonstration that the U.S. government is taking the concerns so seriously that it considers the precarious supply chains that go into producing pharmaceuticals to be a national security concern.

Canada's reliance on active pharmaceutical ingredients from China and India, where production is far cheaper, is a growing concern in this time of geopolitical instability and increased diplomatic tensions. According to a February 2022 study by consulting firm EY Canada, almost all active pharmaceutical ingredients are imported into Canada, with 60 percent from China and India.

In June 2023, the federal government announced that Health Canada has launched a consultation with Canadians on how the government and its stakeholders and partners can better prevent and mitigate shortages of drugs and other health products, along with a series of stakeholder roundtables. This action is welcome, but must be coupled with real recognition of the economic factors behind these shortages.

The EY Canada study also shows that the number of generic medicines domestically produced has declined by 35 percent since 2019. Further price cuts 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.

Further reductions to Canadian generic drug prices at this time of inflationary pressures would further stress the resiliency of the industry when there are already supply problems.

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Instead, increasing the uptake of generics, whether in public drug benefit plans where generics are currently dispensed to fill 78 percent of prescriptions compared to closer to 90 percent in the U.S., or just 68 precent in private-sector coverage, would help save Canadians money as generics are significantly more affordable than their brand-name counterparts.

Helping to secure and strengthen the generic pharmaceutical sector is not only good for our supply of medicines and Canadian jobs, but also because it provides important additional savings to Canadian patients, governments and employers. It is estimated by CGPA that for every one percent increase in the use of generic medicines, Canadians save an additional $810-million.

For years, the industry, medical profession and policy experts have called on the federal, provincial and territorial governments to ensure the reliability, resiliency and stability of Canada's domestic generic-drug manufacturing. Governments must work with industry to ensure Canadians have access to a safe, sustainable supply of medications and to ensure good-paying Canadian jobs in this sector remain secure.

Indeed, a trio of medical doctors wrote in The Globe and Mail: "*Better strategies include improving our demand-and-supply forecasting capability, ensuring redundancy in the supply of essential medicines, and, chiefly, increasing our domestic production of essential medicines*." That word "redundancy" is often perceived as negative, however the global COVID-19 pandemic served to highlight that redundancy is essential for the security of supply.

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

Sincerely,

Jim Keon
President

CC: The Honourable Mark Holland, Minister of Health

Stephen Lucas, Deputy Minister of Health