

August 21, 2023

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

I am writing to provide the feedback of the Canadian Generic Pharmaceutical Association (CGPA) to the consultations on the proposed update to the approach for conducting interim price reviews on new medicines, pending the development of new 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 75 percent of all prescriptions but account for only 22 percent of the \$39-billion Canadians spend annually on 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.

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.

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.

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In addition, pCPA and CGPA are expected to announce shortly a new three-year Generics Initiative that builds upon successes achieved to date.

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, 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. Given that generic prescription medicines are dispensed to fill 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.

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.

As you may be aware, 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.

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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. In Canada, almost all active pharmaceutical ingredients are imported, with [60 percent from China and India](#).

Despite these challenges, there is also cause for optimism, if these challenges are addressed.

As noted above, the majority of Canada's prescription drug supply is through generics, which are less expensive but just as efficacious as brand-name medicines. The use of generics translates to savings of more than \$37-billion annually or over \$2,500 in savings per household, demonstrating the affordability advantage generics represent.

According to a 2022 study by [EVERSANA](#), a leading provider of global commercial services to the life sciences sector, based on its [NAVLIN Data](#), Canadian generic reimbursed prices, which are set by pCPA and provincial / territorial governments, are 45 percent lower than 11 comparator countries such as Australia, France, Germany, Italy, Spain and the United Kingdom.

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.

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 percent 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.

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Indeed, [a trio of medical doctors recently 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.

In June 2023, Federal Health Minister Jean-Yves Duclos [announced that Health Canada has launched a 60-day 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.

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. 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.

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

Sincerely,

A handwritten signature in black ink that reads "Jim Keon". The signature is written in a cursive style.

Jim Keon
President

CC: The Honourable Mark Holland, Minister of Health
Stephen Lucas, Deputy Minister of Health