CGPA
Making Patient Care Affordable

Submission of the Canadian Generic Pharmaceutical Association to the Senate Committee on Social Affairs, Science and Technology Consideration of Bill C-64, *An Act respecting Pharmacare*

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Introduction

The Canadian Generic Pharmaceutical Association and its Biosimilars Canada division thank Members of the Committee for the opportunity to contribute to its study of Bill C-64, *An Act respecting pharmacare*.

The generic and biosimilar medicines industries are important pharmacare stakeholders and supply more than three-quarters of all prescription medicines used by Canadian patients.

We continue to seek greater clarity with respect to the proposed pharmacare regime. Many aspects will not be determined until after Bill C-64 receives Royal Assent and will remain the purview of the Minister of Health.

This submission will outline the value of generic and biosimilar medicines for Canadians, and provide our perspectives on two aspects of Bill C-64 and the February 29, 2024 pharmacare announcement – "Bulk Purchasing" and the Lists of Drugs / Formulary of Essential Medicines. In addition, this submission provides recommendations for guiding principles that should be included in the bilateral agreements to be negotiated for the implementation of pharmacare.

The Value of Generic and Biosimilar Medicines

Making prescription medicines more affordable and accessible is the key value proposition of Canada's generic pharmaceutical and biosimilar medicines industries.

That is why the Advisory Council on the Implementation of National Pharmacare's Final Report recommended policies that encourage patients and prescribers to choose cost-effective generic and biosimilar therapies to help keep national pharmacare affordable.[1]

[1] A Prescription for Canada: Achieving Pharmacare for All, June 2019. Recommendations 31-33.

Generic prescription medicines are dispensed to fill 76.9% of all prescriptions in Canada, yet account for only 22.3% of the $43.8-billion Canadians spend annually on prescription medicines according to IQVIA data.[2] A December 2023 international pricing analysis using the NAVLIN Global Database by EVERSANA found that public prices for generic prescription medicines that are benefits on provincial drug plans in Canada are 45% lower than in PMPRB11 comparator countries.[3][4]

While biologic drugs represent only 3.0% of all prescriptions filled in Canada, the high cost of these medicines is putting major pressure on drug plans.[5] Cost-saving biosimilar biologic drugs are now used to fill 11.3% of biologic drug prescriptions as public and private payers continue to implement policies to expand the use of these safe and efficacious biologic treatments.[6]

Importantly, the savings created through the use of generic and biosimilar medicines help to improve the sustainability of drug benefit plans and provide the financial headroom to fund innovative new treatments for patients.

In addition, generic and biosimilar medicines companies are important employers in the life science sector. The generic pharmaceutical industry directly employs approximately 11,000 Canadians in highly skilled positions.[7] Canada is home to an internationally significant cluster of generic pharmaceutical manufacturing facilities, and made-in-Canada generic medicines are sold in Canada and exported to more than 100 countries.

"Lists of Drugs" & Formulary of Essential Medicines

Expanding access to ensure all Canadians can benefit from the life-saving and life-altering medicines they need is an important objective. However, the list of diabetes and contraceptive medications in the pharmacare announcement of February 29, 2024 is not comprehensive, and excludes several important medications.

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[2] IQVIA data as analyzed by CGPA, 12 months ending March 2024.
[3] International Pricing and Generic Medicines, November 2023.
[4] The PMPRB 11 countries are Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden and the United Kingdom.
[5] IQVIA data as analyzed by CGPA, 12 months ending March 2024.
[6] *Ibid.*
[7] EY Study: Canadian Generic Pharmaceutical Importing / Manufacturing Capacity Study, February 2022.

There are specific and important gaps on the list of diabetes medications by sub-category that need to be addressed. For example:

DDP-4 Inhibitors
This is a class of oral diabetic medications used to treat type 2 diabetes mellitus in adults.

While there are originator medicines on the list there are currently no generic medicines included, which is inconsistent with the principle of encouraging the use of cost-effective generic and biosimilar therapies to help keep national pharmacare affordable.

In addition, DPP-4 Inhibitor monotherapy products (non-metformin containing) were excluded from the list altogether, even though there is a clinical need for these products.

SGLT2 Inhibitors
This is a class of prescription medicines that lower blood sugar in adults with type 2 diabetes.

The current list of medications includes only originator combination medicines (metformin containing). Generic combination products containing metformin are currently included on provincial drug formularies, but are not included on the list of diabetes medications.

CGPA and its Biosimilars Canada division are concerned that the limited list of drugs covered under the pharmacare plan will lead to sub-optimal prescribing to the medicines made available to the public for free, leading to sub-optimal health outcomes for patients. We are also concerned that the lack of a comprehensive approach to universal coverage may provide a disincentive for public drug plan formularies to continue their coverage of a broad range of prescription medicines, and provide a disincentive to expand coverage to include new drugs in the future. These same concerns also apply to employer-sponsored drug plans.

It is not yet clear whether future pharmacare drug lists will be comprehensive. In the current challenging fiscal environment, it is unlikely that there would be sufficient funding made available for a universal pharmacare program to provide free coverage for a comprehensive list of medications.

Recommendation:
All diabetes drugs and contraceptives that are currently reimbursed by public drug programs in Canada should be included in the list. This principle should also apply to medicines added to the list in the future.

Guiding Principles for Bilateral Pharmacare Agreements

Under Bill C-64, the federal government must negotiate and enter into bilateral agreements with individual provinces and territories. An important guiding principle for drug formulary management that is already employed by public drug programs in Canada is to reimburse for only the lowest cost alternative product of a pharmaceutical active substance.

It is also not clear what the mechanism will be for additional products to be added to the bilateral pharmacare agreements. The important drug plan formulary management appropriate use principle of maximizing the use of cost-efficient generic and biosimilar medicines when they enter the market is also not currently included in Bill C-64 or the February 29, 2024 announcement on pharmacare, which is an oversight that must be addressed.

Recommendation:
To help ensure the sustainability of the plan, Bill C-64 should be amended to clarify that only generic and biosimilar medicines be reimbursed once they are authorized for sale by Health Canada and enter the Canadian market. This principle should be included in all bilateral pharmacare agreements.

"Bulk Purchasing"

The term "bulk purchasing" is used in Bill C-64 and in the February 29, 2024 pharmacare announcement, but has not been clearly defined.

It is critical that the pharmacare regime respect the existing pharmaceutical pricing infrastructure to ensure stability of the Canadian drug supply, and to ensure Canadians continue to benefit from access to both cost-saving generic and biosimilar medicines, and the innovative new medicines Canadians need.

In Canada, prices of pharmaceutical products are controlled through the pan-Canadian Pharmaceutical Alliance (pCPA), which negotiates drug prices on behalf of federal, provincial and territorial drug plans. Through the pCPA, Canadian governments already combine their purchasing power to ensure internationally competitive drug prices for Canadians.

Prices for generic medicines are controlled through the pCPA Tiered Pricing Framework[8] and provincial / territorial legislation, regulation, and policy. According to the pCPA, previous joint efforts between pCPA and CGPA have resulted in savings of more than $4 billion to participating drug plans over the past 10 years, which will only continue to grow over the course of the new three-year agreement, which came into force on October 1, 2023.[9]

This new agreement provides a stable and predictable environment for generic manufacturers to continue to provide existing medicines for Canadians, and invest in launching new cost-saving drugs. Continued access to new generics will help public drug plans maintain their costs and provide savings for Canadians who use prescription drugs in participating public drug plans and private drug plans.

As noted above, a December 2023 international pricing analysis using the NAVLIN Global Database by EVERSANA found that public prices for generic prescription medicines that are benefits on provincial drug plans in Canada are 45 percent lower than in comparator countries.[10]

The pCPA also negotiates prices for biosimilar medicines that are set to be significantly lower than the list price for the original biologic drugs. Most public drug plans in Canada and some private plans have adopted biosimilar switching policies, which require patients to transition from an original biologic drug to a corresponding biosimilar biologic drug under the supervision of their treating physician. Such policies have saved public drug plans hundreds of millions of dollars that have been reinvested into coverage for innovative new therapies and healthcare systems.

There are increasing concerns worldwide, including in Canada, about the state of the prescription medication supply. Further price cuts would threaten Canada's ability to manufacture prescription medicines on domestic soil and result in more drug shortages for Canadians, at a time when several other countries are looking to find ways to onshore production of essential medicines.

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[8] See: pCPA Tiered Pricing Framework

[9] pCPA News Release: The pan-Canadian Pharmaceutical Alliance and the Canadian Generic Pharmaceutical Association have successfully negotiated a Renewed Three-Year Generics Initiative, August 22, 2023.

[10] International Pricing and Generic Medicines, November 2023.

Recommendation:
Federal, provincial and territorial governments should continue to exercise their power to collectively negotiate drug prices in Canada through the pan-Canadian Pharmaceutical Alliance (pCPA). This includes respecting the current pCPA Tiered Pricing Framework for generic medicines, and the future negotiation of tiered pricing framework agreements for generic medicines.

Conclusion

There remains a great deal of uncertainty and a lack of clarity with respect to many aspects of pharmacare as they are not articulated in Bill C-64. The Canadian Generic Pharmaceutical Association and its Biosimilars Canada division remain available to work with the Standing Committee on Health and the federal government to ensure pharmacare objectives are better defined and can be met.

About the Canadian Generic Pharmaceutical Association
The Canadian Generic Pharmaceutical Association (CGPA) represents Canada's generic pharmaceutical industry. The industry plays an important role in controlling health-care costs in Canada. Generic drugs are dispensed to fill 76.9 percent of all prescriptions but account for account for only 22.3 percent of the $43.8-billion Canadians spend annually on prescription medicines. Visit us at www.canadiangenerics.ca.

About Biosimilars Canada
Biosimilars Canada is a national association representing the biosimilar medicines industry in Canada. Our member companies are at the forefront of the global development and marketing of biosimilar medicines. Biosimilars Canada provides leadership in educating Canadian stakeholders about the safety and efficacy of biosimilar medicines, and advocates for policies that support their timely approval, reimbursement, market acceptance and expanded use. Biosimilars Canada is a division of the Canadian Generic Pharmaceutical Association. Visit us at www.biosimilarscanada.ca