

**Canadian Pharmaceutical Manufacturers and Exporters Alliance  
Alliance des fabricants et exportateurs pharmaceutiques du Canada**

Science Strategy  
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June 10, 2024

**Re: Public Health Agency of Canada Science Strategy Consultation**

On behalf of the Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA), I am pleased to submit our comments to the Public Health Agency of Canada (PHAC) Science Strategy Consultation.

The CPMEA represents Canadian pharmaceutical and biopharmaceutical manufacturers operating production facilities in Canada, making medicines for Canadian patients and for export. Our members are Canadian corporations headquartered in Canada; the largest manufacturers of medicines by volume in Canada, producing generic and biosimilar medicines, as well as brand products and non-prescription medications.

The PHAC consultation asks stakeholders how to generate knowledge and use science to inform public policy about population health. One of the most important conditions for a resilient public health community is access to the entire spectrum of medicines used by Canadians every day. As PHAC considers its priorities for research and knowledge gathering, we recommend understanding the implications of public policy decisions on the domestic Canadian pharmaceutical manufacturing sector.

Recognition of the importance of local production of essential medicines as a requisite for public health and national security is growing around the world. The European Union, for example, through its Critical Medicines Alliance, is working with the generic and biosimilar industry towards strategies to boost national manufacturing, to build resiliency in the medicines supply chain, and ensure sovereignty of source. The U.S. Congress has held hearings on the issue of drug shortages and critical drug supplies and is considering legislative action to provide incentives to onshore and nearshore manufacturing – similar to their strategy to attract producers of semi-conductors. BARDA, an arm of the U.S. Department of Defense, is working in a consortium with industry partners to expand U.S. production capacity of medical products for national security reasons.

**Public Health Consequences of Canada’s Dependence on Imported Medicines**

In the past, Canada has had a rich history of drug manufacturing with a significant number of companies that manufactured pharmaceuticals in Canada. As a nation, we exported large volumes to the U.S.; as recently as 2016, Canada had a trade surplus with the U.S. in pharmaceutical exports.

Sadly, over the last 8 years, domestic production has declined, and pharmaceutical products manufactured in Canada now account for only 12%<sup>1</sup> of the finished products consumed by Canadian patients. Most of the production in Canada is by generic and contract manufacturers, without whom Canada's pharmaceutical supply chain would be extremely vulnerable.

The impact of this loss of local manufacturing is unfortunate especially at a time of increasing global geopolitical tension. Canada's heavy reliance on imported medicines creates a potentially catastrophic vulnerability in the supply chain. **If Canadians cannot depend on domestic production to meet their needs, we are facing a looming public health and national security crisis.**

### **Drug Shortages**

Canada has experienced a high incidence of drug shortages in the last few years and awareness of this public health concern has followed. There are many stakeholders involved in finding solutions, none more important than manufacturers within Canada's borders who make and distribute prescription medicines.

The causes of drug shortages are multi-faceted: ever-changing regulatory requirements; delays in approvals, inflexible DEL and GMP rules; lack of critical drug reserves; lower pCPA prices with no inflationary adjustments; and increases in costs for inputs and API, to name a few.

A full understanding of the root causes of shortages is an opportunity for PHAC to add evidence to the debate around solutions to alleviate Canada's drug shortage problem.

### **Health Equity**

While health equity is largely viewed as the domain of governments and providers, pharmaceutical manufacturers also play an important role in closing gaps in access and outcomes. A significant way to promote health equity is to ensure the availability of high quality, affordable medications.

Policies to support robust domestic generic and biosimilar drug development will increase access to treatment options and encourage competition leading to lower prices. Overall, this will improve health outcomes and reduce health care costs for individuals and society and help to alleviate health disparities among population groups.

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<sup>1</sup> Canadian Generic Pharmaceutical Importing/Manufacturing Capacity Study, Ernest and Youn; 2021.  
[https://canadiangenerics.ca/wp-content/uploads/2022/02/02.22-EY-CGPA-Capacity-Study\\_FINAL-1.pdf](https://canadiangenerics.ca/wp-content/uploads/2022/02/02.22-EY-CGPA-Capacity-Study_FINAL-1.pdf). pg. 21

### **Emergency Management**

Canada's pharmaceutical manufacturers are critical to ensure access to medicines during emergencies. This was never more apparent than during the Covid 19 crisis. At the beginning of the pandemic, supply chain management teams at Canada's drug producers were suddenly thrust into the spotlight as borders were closed and planes were grounded. Demand for all types of medicines spiked as consumers and health professionals ordered additional stock and/or hoarded medicines.

Across the supply chain, generic suppliers leapt into action to manage stock, allocate orders for their customers, and to engage with PHAC and Health Canada and other government officials to ensure equitable supply management. Canadian patients narrowly missed a knock-on crisis of severe shortages and lack of access, due to the extraordinary efforts of the (often) unsung heroes in supply chain management.

Many lessons were learned about how to respond in a crisis - lessons that would be valuable to share with PHAC. Canadian producers clearly demonstrated that they are integral to the public health community, making us better equipped to prevent, withstand, and recover from emergencies.

Thank you for the opportunity to be part of the conversation on PHAC's science strategy. As you develop your science strategy, we recommend that you consider the role of domestic production of medicines as an important contribution to public health system resilience and security. CPMEA and its members would be happy to meet to discuss the issues outlined in this submission.

Sincerely,

Terry Creighton

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*The Canadian Pharmaceutical Manufacturers and Exporters Alliance – Alliance fabricants et exportateurs pharmaceutiques du Canada (CPMEA) represents pharmaceutical companies that manufacture in Canada. We have come together in an Alliance to tell the story about drug production in Canada and to raise awareness of the unique issues facing our industry. The CPMEA founding members are Apotex Inc, Pharmascience and Laboratoire Riva.*