

Local Purchasing to Improve Canada's Pharmaceutical Supply

A Canadian Manufacturer's Perspective

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Executive Summary

The COVID-19 pandemic has reminded us of Canada's dependency on the international supply of raw pharmaceutical materials and finished drug products to meet the demands of our healthcare system. The vulnerability of Canada's pharmaceutical supply was particularly evident in April 2020, when Canadian jurisdictions had to dramatically increase their demand for critical hospital products used in Intensive Care Units (ICUs) to treat COVID-19 patients.

The COVID-19 experience shows that pharmaceutical supply is a national security issue. To address this critical matter, the Canadian Generic Pharmaceutical Association (CGPA) released a [Blueprint for a Sustainable Supply of Prescription Medicines for Canadians](#) on June 17, 2020.

As a leading Canadian generic manufacturer, Pharmascience Inc. fully supports the CGPA position paper. This policy paper highlights recommendations that, in our opinion, are the likeliest to result in rapid and lasting improvements to Canada's pharmaceutical supply reliability.

1. Create **specific business subsidies** to support the expansion of production facilities operated in Canada by Canadian or international generic manufacturers and subsidize wages or training of key workers in the pharmaceutical production sector. Tie these subsidies to Key Performance Indicators (KPIs).
2. **Implement minimal Canadian manufactured contents requirements in public procurement** of medicines.
3. Create **an incentive system rewarding local Canadian manufacturing** for pharmaceuticals, based on extent of manufacturing activities and volume of local sales of Canadian manufactured products, to reverse offshoring.
4. **Create safety stockpiles of API and/or finished products for essential medicines**, to be bought in quantities exceeding normal demand by manufacturers, with risk sharing agreements with governments to cover destruction costs of the overstocked materials.

Introduction and Background

COVID-19 and Pharmaceutical Supply Sustainability

The COVID-19 pandemic has highlighted multiple and unprecedented challenges for the Canadian healthcare system, including serious potential gaps in pharmaceutical supply. Issues with the pharmaceutical supply chain that existed before the pandemic, were exacerbated to a point where there was potential for a supply breakdown for essential medicines. Thankfully, this was avoided. But there still is a clear and present threat for the Canadian supply chain of generic pharmaceuticals, which account for about 75% of prescriptions filled in Canada (2020). Pharma supply is therefore a major national security issue that needs to be dealt with to prevent any other similar public health emergencies. Health Canada has recognized that addressing drug shortages in Canada must now be a government priority (RIAS, *Canada Gazette, Part II*, Volume 155, Number 18, 11 August 2021).

Pharmascience Inc. is a major player in the search for solutions to this critical problem. As the second largest Canadian-owned pharmaceutical manufacturer; the largest pharmaceutical employer in Quebec; and a major R&D investor, Pharmascience has the scope, size, capacity, and human resources to offer a concrete contribution to enhance Canada's pharmaceutical supply. The purpose of this brief is to offer specific recommendations to federal, provincial, and territorial authorities based on our experience in this field.

The Canadian Generic Pharmaceutical Association (CGPA) published in 2020 a [Blueprint for the Sustainable Supply of Prescription Medicines for Canadians](#). In this document, the Association offers a broad set of recommendations to strengthen Canada's pharmaceutical production capability, secure and enhance the reliability of international supply of active ingredients and finished products and identify essential medicines to be produced and stockpiled domestically. As an executive member of the CGPA, Pharmascience supports the Blueprint recommendations.

Our purpose in this separate brief is to illustrate from the perspective of a Canadian company with extensive local R&D and production capacity, a subset of actions that could concretely and rapidly enhance pharma supply reliability. These measures would translate into a powerful economic stimulus for Canada. The following recommendations are therefore a fertile ground for public policy improvement.

About Pharmascience

Since its founding in 1983, Pharmascience has experienced rapid growth and has gained a leadership position in the Canadian and international generic drug industry. This flagship Canadian pharmaceutical company has remained a family-owned business with its head office in Montreal, Quebec.

Today, Pharmascience markets over 1400 products from nearly 300 product families in a broad variety of dosage forms. Pharmascience is the largest manufacturer of generic drugs in Quebec and one of the largest in Canada. It is also an important manufacturer of single source prescription drugs through its Pendopharm division, and of consumer products.

Eighty-five percent (85%) of Pharmascience's business is in Canada. But the company also distributes its products in more than 50 countries.

The company creates more than 2,550 jobs in Canada, directly, indirectly and through its induced contribution to the Canadian economy. As of November 2021, this includes approximately 1,500 workers at the Montréal and Candiac manufacturing and R&D sites, and at the Dorval distribution centre. In 2019, Pharmascience ranked as the largest pharmaceutical employer, and the 118th largest, overall, in Québec. Pharmascience also creates quality employment: the average salary of Pharmascience's employees is twice the Quebec average. Moreover, these jobs are particularly productive, with a GDP per job 1.7 times higher than the provincial average.

Pharmascience's operating activities contribute \$337 million to Canada's GDP annually. They generate \$38 million in gross annual tax revenue for Quebec and \$22 million for the Government of Canada¹.

The company was also the 56th largest R&D investor overall in Canada in 2020, of all sectors combined, with between 40 and 50 million dollars invested annually², an amount larger than most subsidiaries of innovative pharmaceutical multinationals. Pharmascience's R&D activities are entirely conducted in Canada.

1- Aiseo, 2019 - Study of Pharmascience's Economic Contribution and Positioning in the Pharmaceutical Industry.

2- <https://researchinfosource.com/>

Improving Supply Chain Sustainability

- The COVID-19 pandemic has reminded us of Canada's dependency on international supply of raw pharmaceutical materials and finished drug products to meet healthcare demands. The vulnerability of Canada's pharmaceutical supply was particularly evidenced in April 2020, when Canadian jurisdictions dramatically increased their demand for critical hospital products used in Intensive Care Units (ICUs) to treat COVID-19 patients. At one point, some jurisdictions relied on a 7-days stock of some essential ICU medicines. While the worst-case scenario was avoided, these events unmistakably call for substantial improvements in supply chain sustainability.
- To address this critical health and national security issue, the Canadian Generic Pharmaceutical Association (CGPA) released on June 17, 2020, a [Blueprint for a Sustainable Supply of Prescription Medicines for Canadians](#). This document analyses the sources of the Canadian supply chain vulnerability, and identifies a series of measures to correct them by fulfilling three goals:
 1. Enhance domestic pharma manufacturing capacity.
 2. Incentivize domestic pharma production.
 3. Mitigate Canada's dependence on global supply.
- Pharmascience supports the CGPA Blueprint. Our purpose in this separate brief is to illustrate actions that could concretely and rapidly enhance pharma supply self-sufficiency, from the perspective of a Canadian company with extensive local R&D and production capacity.

1. Enhance Canada's pharma manufacturing capacity

- **Canada has long been a leader of the global generic pharmaceutical industry.** Even if this leadership position has weakened during the past two decades, our country can still count on several first-class local generic R&D, manufacturing, testing, and distribution facilities operated by both Canadian and international companies. These facilities are amongst the most technologically advanced in the world, and can produce a broad range of solid, liquid, and injectable dosage forms. They stand as a solid basis from which Canadian production capacity can be expanded if proper conditions are met.
- **Capacity enhancement is a basic component of any plan aimed at increasing Canada's pharma supply sustainability.** The fact that demand did not outpace supply during the 2020-2021 pandemic should not create a false sense of security. Increased capacity could again be required in future demand spikes caused by pandemics or other public health emergencies. Enhanced capacity would have positive impacts on the robustness and flexibility of the local ecosystem; for instance, by allowing for emergency collaboration between manufacturers with local capacity during periods of high demand. It would also positively impact Canadian manufacturers' export capacity, leading to an improved commercial balance. For these reasons, pharmaceutical capacity enhancement must be an important policy objective for Canadian authorities.
- **Pharmascience is a good example of a firm that could immediately contribute** to an increased local supply. It operates two manufacturing facilities in the greater Montreal area, as well as a warehousing and distribution facility, and has a R&D centre of excellence responsible for formulating new medicines, conducting bioavailability and other clinical tests, and for product development and manufacturing scale-up. All of Pharmascience's manufacturing and R&D activities are done in Canada. There is space and potential for capacity increases at our sites. Expansion projects are already in development.
- Unfortunately, in the current Canadian context, **there are several barriers preventing Canadian or international manufacturers to boost their local capacity.** The Canadian generic market has evolved towards lower and low growth for generic manufacturers (PMPRB 2021) with high labor costs and a complex and costly regulatory environment, by international standards. This combination of factors has led international manufacturers to favor foreign sites to expand their production and R&D activities. There have been few Canadian site expansions recently.
- As a Canadian-owned company that has made the deliberate choice to keep its global head office and all its R&D and manufacturing investments in Canada, **Pharmascience is an exception.** But as a private family company, it does not have access to the same capital sources as publicly traded multinationals and must largely fund capacity expansion projects internally. These have been impacted by the recent unfavourability of the Canadian generic market, which accounts for 85% of our business. Future capacity expansion will need help from governments, in the form of direct non-refundable subsidies or market incentives, to improve national supply chain sustainability.

- Direct financial assistance is justified by the fact that **improving the pharmaceutical supply chain sustainability is a national security matter**. It also has potential to provide an economic stimulus in a key sector. Therefore, the case for direct financing of production facilities expansion in the pharmaceutical sector is strong. Such support would be a valuable booster for Pharmascience's capacity expansion projects.
- These subsidies can be **tied to Key Performance Indicators (KPIs) measuring supply chain reliability improvement**. This is a more easily measurable objective than traditional drug discovery or clinical research tax credits, whose efficacy at fostering more R&D in Canada has often been questioned. It would allow governments to ensure that the objective has been reached and gains maintained over time.

2. Incentivize domestic pharma production

- Enhancing manufacturing capacity is a logical first step to improving pharma supply but would not by itself compensate for the lost production capacity Canada has experienced over the past 10-20 years.
- Over that period, the **international generic pharmaceutical supply chain has undergone significant pressure stemming from price reduction**. This is a worldwide phenomenon. But it is particularly noticeable in Canada, where the average selling price of generic medicines has dropped over 60% since 2010. This price pressure has led to the offshoring of production to foreign suppliers in countries with lower wages and human resources costs, and weaker regulatory requirements. Clusters of API manufacturers have developed in India and China, which now account for 66% of global supply. Developed countries like Canada now largely rely on them for their manufacturing capacity.
- The cost of manufacturing pharmaceuticals in Canada is higher than in these competing hubs. The only way Canadian or international manufacturers will choose to invest more on local production is if it is rewarded in the market to partially offset production cost differences in competing countries. This will need to be mitigated by market incentives to allow expanded capacity to be rewarded by competitive profitability.
- One such incentive would be **through public procurement of medicines**. Publicly run tenders could be structured in a way that ensures, through split awards, defined minimum levels for Canadian-manufactured products. This would be applicable to Canadian or international firms with Canadian facilities. As the local awards would be for part of the tenders only, and would be justified by national security and environmental objectives, this would be consistent with international trade agreements signed by Canada

- Incentives should not be limited to tendered drugs. Most of pharma production is set to meet demand from the retail pharmacy market for medicines dispensed through public and private formularies. To favor local production governments could create **an incentive system rewarding Canadian pharmaceutical manufacturing**, based on the volume of local sales of Canadian manufactured products. For instance, an incentive based on the extent of local production activities could be designed and rebated back to the manufacturer to partially compensate for the higher cost of manufacturing in Canada.
- Through government audits, the levels of Canadian production could be determined to define rebate levels proportional to the level of domestic manufacturing activity.
- It must be remembered that increasing local production has significant **positive environmental impacts**, by reducing transportation of materials and relying more on Canadian production facilities operating under stricter environmental regulations than most of the competing countries.

3. Mitigate dependence on global API supply chain

- Even before the COVID-19 pandemic, **significant stress existed on the Canadian generic pharmaceutical supply chain**. Supply interruptions have occurred because of supplier issues, or tighter regulatory standards (eg. standards on impurities), for which international suppliers cannot adjust rapidly. This was already generating regular backorder situations before COVID.
- The sudden shock of **the pandemic exacerbated this tension between supply and demand during the Spring of 2020**. It intensified international competition between countries to secure stocks for essential medicines. Country or regional lockdowns have impacted transportation inside countries such as India. International transportation of materials has slowed down. Ports have been closed, or have experienced slowdowns because of staff or container shortages, and air transportation was dramatically reduced. Costs have skyrocketed, raising 4 to 5-fold in comparison to pre-COVID levels.
- These issues have been exacerbated by **demand spikes at the wholesale or pharmacy levels** at the beginning of confinement measures in March and April 2020. Measures had to be put in place to limit dispensed quantities of prescription drugs in pharmacies.
- The Canadian generic industry was able to absorb the pandemic shock, mainly because it kept running from pre-COVID, built-in inventories. Companies were also able to secure additional inventories of finished products from other countries when hospital demand soared. The industry was also able to consolidate its supply chains based on the first wave experience during the remainder of 2020 and 2021.

- **But international supply threats will not go away without government intervention.** The CGPA Blueprint contains multiple recommendations to strengthen the pricing system and increase utilization of generic drugs and biosimilars, that may make Canadian manufacturers less vulnerable to the ebbs and flows of API and finished products supply from international sources.
- One measure however could offer more significant relief from international supply. Manufacturers could be supported for **creating permanent safety reserves of APIs or finished products for essential medicines**, which could be stocked in quantities exceeding normal demand. Until now, safety reserves have only been created with short-term, emergency goals in mind. Permanent safety reserves for pre-identified essential medicines would be a substantial improvement.
- Manufacturers ordering larger quantities than normal demand would do so at a financial risk, if ingredients reach their expiry date unused. They would **need risk sharing agreements with governments to cover destruction costs of the overstocked materials** and avoid being penalized for acting in the public interest.
- During the pandemic, Canadian federal, provincial, and territorial jurisdictions have been working together towards a **national list of essential drugs**, that could be used by the jurisdictions as a starting point to work with generic pharmaceutical manufacturers to put in place a plan to promote essential drug stockpiling.

Summary of Pharmascience recommendations – Supply Chain Self-Sufficiency

1. Create **specific business subsidies** to support the expansion of production facilities operated in Canada by Canadian or international generic manufacturers and subsidize wages or training of key workers in the pharmaceutical production sector. Tie these subsidies to Key Performance Indicators (KPIs).
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