Canadian Generic Pharmaceutical Importing/Manufacturing Capacity Study

February 2022

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The following documentation and associated materials are based on EY's objective assessment of manufacturing capacity of generic pharmaceutical products in Canada. This perspective was developed through stakeholder interviews as well as document and data reviews. We relied on documentation and data provided by select CGPA member organizations as well as interviews with member organizations, CGPA leadership and other stakeholders. Data limitations exist given the availability of data and willingness to share proprietary information.

While EY undertook a review of the manufacturing capacity of the generic pharmaceutical sector in Canada, EY did not perform an audit or review (as those terms are identified by the CPA Canada Handbook - Assurance) or otherwise verify the accuracy or completeness of any information provided to us by CGPA or its member organizations. Accordingly, EY did not express any form of assurance on accuracy of data provided. The observations relating to all matters that EY provided to CGPA were designed to assist CGPA in reaching its own conclusions and do not constitute EY's concurrence with or support of Client's accounting or reporting or any other matters.

EY prepared the English language report. CGPA is responsible for any translations into French.

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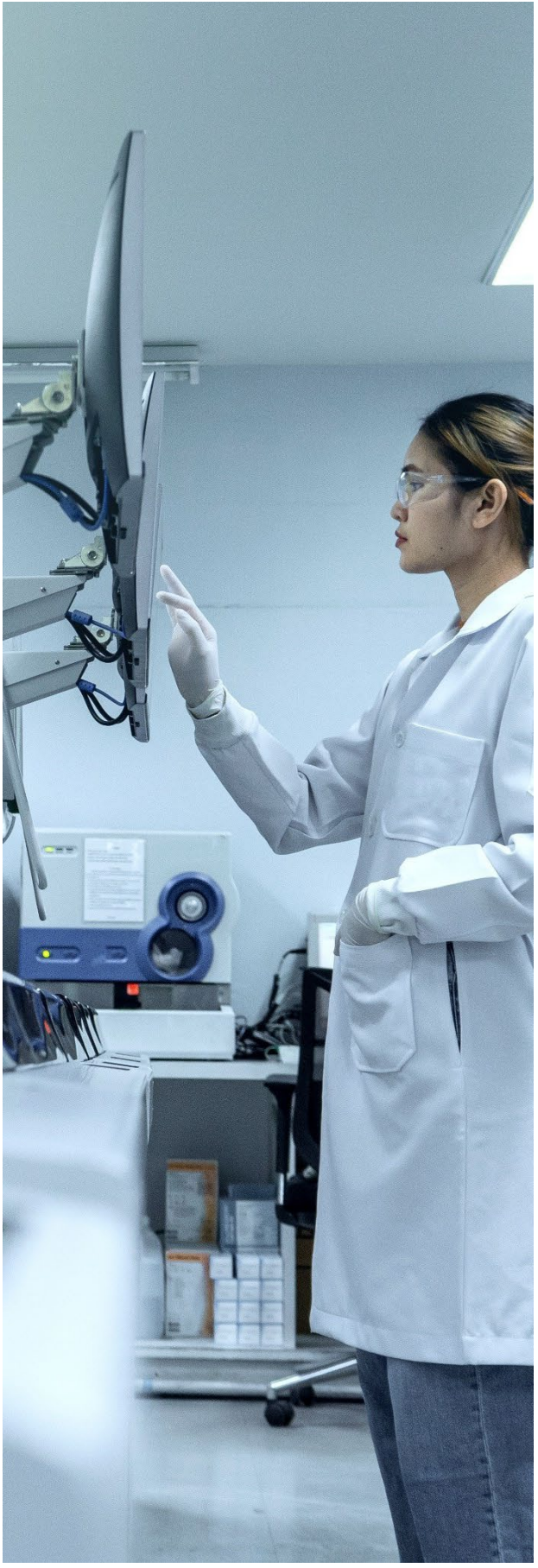
EXECUTIVE SUMMARY

Global supply chains have become increasingly complex, introducing risks, disruptions and drug shortages. These risks, such as export restrictions, interruptions to international transportation, and reliance on foreign partners, highlight the importance of secure channels of import for molecules and finished dose products into Canada. Under certain circumstances, international supply chain dependencies may pose great risks to the sustainable supply of generic medicines. Fortunately, during COVID-19 pandemic, Canadian generic pharmaceutical suppliers and manufacturers demonstrated the exceptional resilience of their supply chains and avoided drug shortages. Governments and stakeholders now have an opportunity to optimize how generic prescription medicines are supplied to Canadians and develop the industry locally.

CGPA's member companies are a cornerstone of the Canadian health system. They provide extensive therapeutics to Canada including 6,225 finished dose products over a three-year period. Approximately 44% of these finished dose products were manufactured[1] in Canada. The majority of domestically manufactured generic molecules and finished dose products align to key therapeutic categories for Canadians including medicines for the endocrine system, respiratory system, cardiovascular system, and gastrointestinal tract as well as analgesics, anesthetics and antipyretics. Sterile injectables, key for hospital-based care, are also manufactured domestically. Canada's emergency preparedness and drug planning must consider which molecules and finished dose products are manufactured domestically, and which therapeutic categories they align to, to effectively support essential drug production.

The majority of APIs (active pharmaceutical ingredients), key inputs to Canada's manufacturing capacity, are imported. There are 45 countries around the world from which member organizations import generic APIs. Based on the data provided, Canada heavily relies on trade relationships with India, the USA, and Europe to secure APIs and finished dose products. The Canadian government can further strengthen the generic supply chain reliability by securing trade agreements with the jurisdictions that domestic suppliers rely on the most as well as supporting domestic production.

[1] The definition of manufacturing includes finished dose products that arrived in Canada and were subject to repackaging.



Canada's increased reliance on imports in this sector has concerned governments, driving their interest in establishing supports that will increase domestic manufacturing capacity, for molecules, biosimilars and finished dose products, as well as reduce risks from disruption in the global supply chain. The generics market in Canada faces downward pressure on pricing with increasing costs of labour, land, transportation while navigating a complex regulatory regime. Combined, these elements are increasing the fragility of the domestic industry.

While government funding in life sciences significantly increased during the pandemic, these newly established programs will need to be evaluated to ensure that they are sufficient and drive the right outcomes in the sector. The sector also faces challenges surrounding Canada's unique regulatory and legislative requirements that must be navigated. Designed to support safety, they can also act as a barrier to market entry. Domestic generic medicine companies are urging the government to improve both regulatory processes and incentives to further advance the Canadian generics sector and access to important medicines.

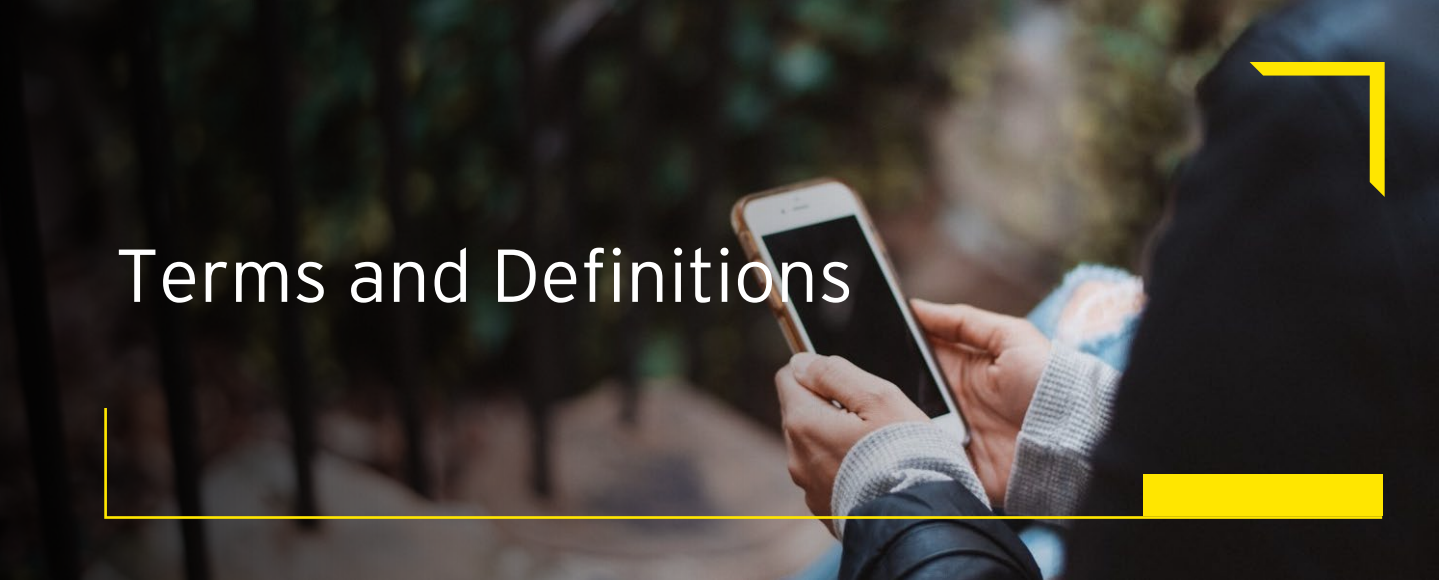
Canadian generics suppliers also face barriers in trying to remain competitive against global players. This includes difficulty in expanding their product portfolios due to the high costs of production coupled with high competition from international players that can offer molecules and finished dose products at lower costs. Local companies also find it difficult to justify the costs of investing in capabilities that would enable them to vertically integrate and expand their value chain capabilities, particularly when there are risks at multiple points along the value chain.

Recent events have also highlighted the need to develop more coordinated approaches and strategies to emergency planning. This includes the development of a more thoughtful and lasting list of essential medicines, further expanding the Critical Drug Reserve that was established by the federal government during the pandemic, as well as further investment in emergency response resources required to support local generic product manufacturing. During COVID-19, Canadian generic pharmaceutical companies maintained supply chains and avoided drug shortages under extremely challenging circumstances.

Beyond the pandemic, there is a need to address these pertinent issues to secure the supply of medicines to Canadians, offer support to domestic generic pharmaceutical companies, and prepare for future emergencies. We have outlined seven specific recommendations below that aim to address these issues while strengthening and supporting Canada's pharmaceutical supply chain.

Recommendations

1	In collaboration with domestic suppliers and negotiating bodies, existing supports and long-term strategies to promote and incentivize onshore capabilities for importing and manufacturing should be explored. Such capabilities will assure the sustainable supply of a breadth of generic medicines and the economic benefits associated with a strengthened domestic industry.
2	Opportunities to streamline approval processes for generic medicines as well as new API registration timelines should be considered. Streamlining should include an in-depth regulatory analysis that outlines opportunities to align Health Canada requirements with foreign market leaders, such as the US FDA and European Medicines Agency (EMA) as well as emergency preparedness pathways as required. Alignment opportunities with such leading regulatory authorities should not sacrifice health and safety standards but increase market entry opportunities for companies supplying generic medicines to Canadians.
3	In designing supports for the generic pharmaceutical industry, consideration should be given to providing incentives that encourage companies to bring new generic medicines to Canadians. For instance, subsidies to address high costs of domestic production and importing including workforce, operations, facilities, transportation. This would promote the expansion of product portfolios in Canada, reinforcing the breadth of supply of generic medicines.
4	Review of existing tax incentives, and additions where necessary, to support domestic manufacturing (for APIs, biosimilars and other products) should be evaluated and strengthened. This includes repealing the phasing out of the Accelerated Investment Incentive, a measure that provides tax relief on eligible newly acquired property assets and increasing the Manufacturing and Processing credit.
5	The negotiation of multi-lateral trade agreements that promote the securitization of the generic pharmaceutical supply chain should be prioritized to ensure ongoing access to APIs, finished dose products and the elements necessary to support domestic production.
6	Appropriate pricing and procurement strategies to promote and support domestic operations should be carefully explored. These strategies must balance support for domestic manufacturing with the need for a strong international supply chain. For instance, protections against the increased costs incurred during emergent times (e.g., health emergencies or international trade restrictions). To be effective, this must be assessed at the federal and provincial/territorial levels given the diverse approaches and range of incentives across Canada and different levels of government.
7	Although many generic pharmaceutical companies were able to respond quickly to the COVID-19 health crisis, there should be more collaboration to develop coordinated approaches and strategies to emergency drug planning. This includes support for a Critical Drug Reserve and to further expand it by identifying a more comprehensive list of essential medicines to prepare for the next public health emergency. Additionally, emergency response planning strategies that may expedite product development while ensuring product reliability should be explored.



Terms and Definitions

Active Pharmaceutical Ingredients (APIs) – The central ingredient of a drug that is biologically active.

Excipients – The chemically inactive substances that support in delivering the therapeutic effects of a drug.

Contract Development and Manufacturing (CDMO) – A contractor that provides comprehensive services from drug development through drug manufacturing to other pharmaceutical companies.

Drug Identification Number – The computer-generated eight digit number assigned by Health Canada to a drug product prior to being marketed in Canada.

Finished Dose Products – The pharmaceutical products that have undergone all stages of production and testing, including packaging in its final container.

Generic Pharmaceuticals – Pharmaceutical products are of the same quality, safety, efficacy, are comprised of the same active ingredients, and are produced with the same manufacturing standards as brand name drugs.

Intermediates – The chemical compounds used in the process of generating an API.

Domestic manufacturers – For the purposes of this report, these are companies that procure inputs, such as raw materials including active pharmaceutical ingredients and intermediates, to manufacture and package finished products in domestic manufacturing facilities.

Product – For the purposes of this report, a product is defined as a molecule or finished dose product. Within this report, products may differ with respect to dosage form, strength, package size and/or country of origin[2].

Production – The manufacturing activities required to produce a finished dose product including assembly, blending, granulation, formulation and testing, as well as other general manufacturing processes and equipment management activities.

Manufacturing – The process of industrial-scale synthesis of pharmaceutical drugs including procurement, production and packaging. For the purposes of this report, this includes finished dose products that arrived in Canada and were subject to repackaging.

Therapeutic Category – The categories by which drugs are identified and grouped by the main conditions or pathology they are used to treat.

Volume – The weight, in kilograms, of pharmaceutical products.

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[2] Country of origin is based on last port of entry.

1. Study overview

In February 2021, the Canadian Generic Pharmaceutical Association (CGPA) engaged EY to help deepen the understanding of the sustainability of the Canadian pharmaceutical sector and Canada's supply of prescription medicines. In Canada and many other countries, the onset of the COVID-19 pandemic has highlighted the opportunity for increased investment in domestic infrastructure, pharmaceutical manufacturing and strengthening the global supply chain for prescription medicines. There is a global focus on building more capacity through manufacturing and secured supply chains, which should be further developed in Canada. COVID-19 recovery initiatives, including addressing surgical backlogs and care for long-haul COVID patients, will be reliant on the generic pharmaceutical industry.

CGPA's June 2020 *Blueprint for a Sustainable Supply of Prescription Medicines for Canada* identified opportunities to increase domestic capacity to import and manufacture drugs for Canada (Canadian Generic Pharmaceutical Association, 2020). To explore how to best enhance these capabilities, EY was asked to study current capacity among the CGPA membership and evaluate opportunities for optimization. This project has been designed to collect the data and report on the requirements necessary to build a coordinated and secure supply chain for generic medicines including domestic manufacturing in Canada. The following report will summarize current capacity as well as opportunities to optimize for the future and plan for when Canada's health system faces unexpected pressures.

Impact of downward pressure on pricing

Globally, as generic drug prices have decreased, there has been an increase in the penetration of generic pharmaceuticals indicating an increased prescriber and patient acceptance of generic medicines. Today in Canada, more than 73% of all retail prescriptions in Canada are filled with generics (Canadian Generic Pharmaceutical Association, 2020). In addition to supplying Canadian hospitals and pharmacies, Canada's generic pharmaceutical sector exports to more than 100 countries. Given the prevalent role of generic medicines, governments have focused on optimizing pricing to achieve savings for the healthcare system.

In response to downward pricing pressure, Canada's domestic pharmaceutical companies have increasingly relied on offshore supply and manufacturing. As a result, onshore manufacturing and support services have been weakened. Increased reliance on imports have contributed to sector job losses and made the supply chain more vulnerable. With risks recently highlighted during COVID-19, governments and stakeholders have a renewed interest in how generic prescription medicines are supplied to Canadians.

Establishing a baseline

Understanding Canada's existing importing and manufacturing infrastructure will allow CGPA to better advocate for the generic pharmaceutical sector and its members to ensure a sustainable supply of medicines for Canadians. There are reports that Health Canada has engaged pharmaceutical manufacturers in reporting exercises to gain a better understanding of the onshore supply chain, however there are no published reports of this data or publicly available information about the allocation and risks. There is still a need for an analysis of risks to the value chain and where they occur and how they contribute to drug shortages in order to develop recommendations. Considering that, this project has highlighted the opportunity to potentially develop an ongoing manufacturing capacity reporting strategy, align data collection to the strategic variables and, potentially, automate reporting systems.

Our approach

Within this context, EY executed a project to evaluate current value chains that provide generic medicines to Canada to measure current capacity in providing generics, and opportunities to optimize capacity. The report is informed by interviews with 12 CGPA member companies and importing and manufacturing data from 10 of these companies. Unless otherwise indicated, all of the data and proportions in this report are derived from the data provided by these 10 member companies.

It is important to note that, despite alliance with CGPA, these member companies are market competitors and are diverse with respect to scale, operating models, products, etc. To protect competitive advantage and organizational privacy, data have been anonymized and aggregated. This report does not represent an exhaustive summary of Canada's current or maximum importing and manufacturing capacity. Results should be interpreted with this understanding.

2. Current Canadian generic pharmaceutical sector

2.1 Section summary

This section summary outlines the pertinent points explored in Section 2 of the report.

Health Canada plays a critical role in regulating and granting market authorizations for pharmaceutical molecules and finished dose products in Canada, both brand-name and generic (Government of Canada, 2012). Generic pharmaceutical products must demonstrate that they meet the same quality, safety and efficacy as their brand name equivalents (Government of Canada, 2018). With these high standards and downward pressure on pricing, it is increasingly challenging for generic pharmaceutical companies to manufacture molecules and finished dose products in Canada and provide value to Canadians. A more robust domestic generic sector would yield several economic and health benefits for Canadians, including increases in jobs, tax revenue, infrastructure, and accessibility while maintaining the highest standards of quality.

Within the generic pharmaceuticals value chain, manufacturing can be defined across three pillars: Procurement, Production and Packaging. The capabilities of these pillars apply to companies that procure products for manufacturing and/or distribution in Canada. This report has defined these operating models as those who import (Importers) and those who manufacture (Manufacturers) while acknowledging that there is some overlap between the two groups.

- **Manufacturers** procure inputs, such as raw materials including active pharmaceutical ingredients and intermediates, to manufacture and package finished products in domestic manufacturing facilities for a wide range of products.
- **Importers** import finished generic pharmaceutical products. Some may also repackage those generic medicines to meet domestic regulations and standards.

In Section 3, we will go into greater detail to explain these operating models as well as estimates of their capacity based on our evaluation.

2.2 Sector overview

To understand the capacity to import and manufacture generic pharmaceuticals for Canadian patients as well as for export, it is important to understand broader drivers across the sector. The following section summarizes the sector at a high level, including the definition of generic pharmaceuticals, how molecules and finished dose products are regulated within the sector, the sector value chain as well as select operating models in place in Canada.

Defining generic pharmaceuticals

Generic pharmaceutical molecules and finished dose products are of the same quality, safety, efficacy, are comprised of the same active ingredients, and are produced with the same manufacturing standards as brand name drugs. Generic medicines have the same amounts and types of active ingredients as their brand-name counterparts. Non-medicinal ingredients (e.g., fillers and preservatives), referred to as excipients, may differ, but are also regulated by Health Canada (Government of Canada, 2018).

Active Pharmaceutical Ingredients (APIs) are the central ingredient of a drug that is biologically active.

Excipients are chemically inactive substances that support in delivering the drug.

Intermediates are chemical compounds that are used in the process of generating an API.

Finished products are pharmaceutical products that have undergone all stages of production and testing, including packaging in its final container.

Regulatory requirements

The federal and provincial/territorial governments play key roles in the Canadian generic pharmaceutical sector. To receive a license to manufacture and sell drugs in Canada, brand-name companies and generic drug companies must follow the same Good Manufacturing Practices (GMP) guidelines, which ensure consistent production and quality standards.

Approval for a drug is overseen by Health Canada prior to sale. The Regulator evaluates generic drugs for their safety, effectiveness, and quality. Before approval, Health Canada requires manufacturers to submit data that shows the generic drug is safe, effective and of high quality. Safety is also upheld through other laws and regulations. Following approval, providers of generic drugs to Canada must continue to adhere to and demonstrate their compliance to strict quality control procedures and standards and submit to rigorous inspections by Health Canada.

To bring a generic drug to market in Canada, manufacturers must wait until a patent expires or challenge a patent in court. Health Canada requires that patent and data protection requirements have been met before they issue a Notice of Compliance (NOC) as well as Drug Identification Number (DIN). The NOC and DIN permit the sponsor to market the drug in Canada and indicate the drug's official approval in Canada. (Government of Canada, 2019). As recently as 2016-17 the approval timeline was approximately 15 months (Government of Canada, 2018), although during COVID-19 regulators were able to significantly shortened timelines for new and/or critical drugs.

Regardless of whether a generic molecule or finished dose product is imported or manufactured in Canada, it must meet strict safety monitoring requirements of Health Canada including submissions of risk management plans for certain drugs. Quality control labs and safety reporting in Canada can be a resource intensive process. Quality control is not confined to lab operations. It must be incorporated into all activities and decisions related to quality.

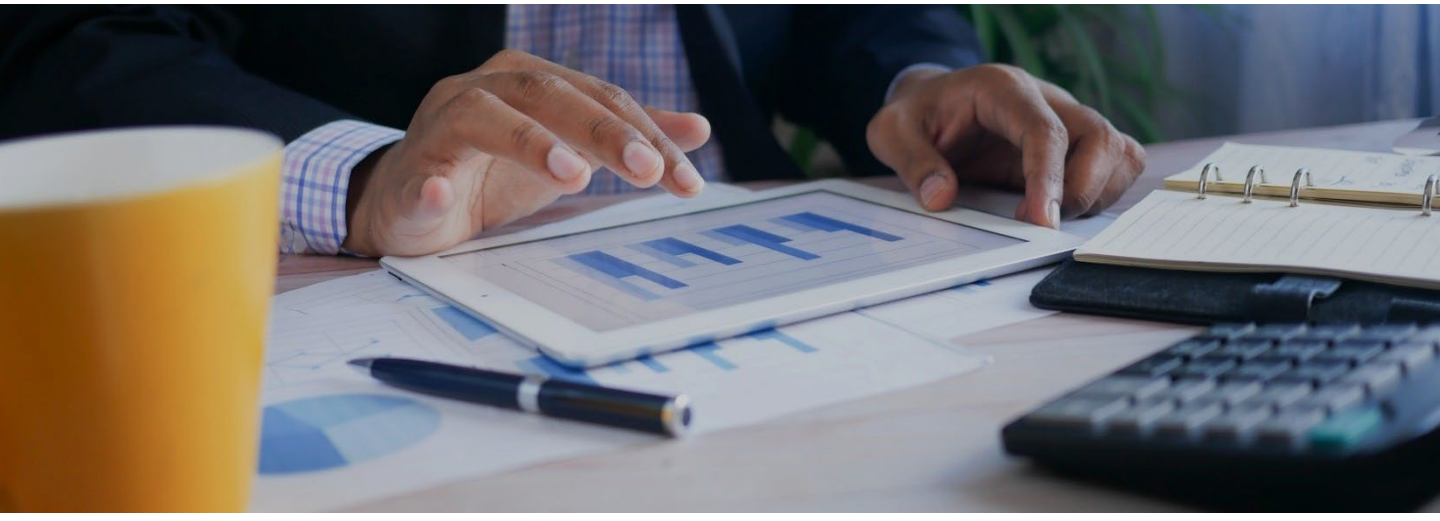
The complex approach to pricing

The Canadian government is responsible for ensuring overall market competitiveness, a key priority for Canada's Competition Bureau as they make up for approximately 10% of GDP (Government of Canada, 2007). Generic pharmaceuticals receive particular attention because of their role in keeping health-care costs low for Canadians. With different levels of coverage and pricing processes for hospital drugs and outpatient drugs, the process for pricing drugs in Canada can be complex so we have attempted to provide a simplified explanation below.

At a federal level, the Patented Medicine Prices Review Board (PMPRB) sets the maximum price of patented medicines based on international price comparisons. The PMPRB regulates the price of patented medicines in Canada and conducts studies on international prices, including multi-source / generic medicines. Provincial and territorial governments set the prices of generic medicines.

Since 2014, the pan-Canadian Pharmaceutical Alliance (pCPA), an alliance of provincial, territorial and federal governments, has collectively negotiated prices of generic pharmaceutical finished dose products with CGPA. These pricing negotiations have significantly reduced prices of generics for Canadians (Patented Medicine Prices Review Board, 2018). Since 2007, the average price of generic prescription medicines in Canada has fallen by nearly 60%, with prices of some of the top-selling generics dropping by an average of 80 % (Generics360: Generic Drugs in Canada, 2018). CGPA estimates that Canadians have saved close to $2 billion in prescription drug costs during the first half of the five-year agreement between pCPA and CGPA that came into force on April 1, 2018. Link: [Mid-Point Report Card: pan-Canadian Generics Initiative Has Delivered Close to $2-Billion in Savings – CGPA]

Drug pricing can be driven down even further through other processes. For instance, hospitals may use supply chain and group purchasing organizations to procure drugs through Request for Proposals (RFPs) which drive generic companies to compete on pricing. Fierce market competition can encourage competition for shelf space in community pharmacies. This can place pressure on companies' already tight profit margins. This report outlines some of the ways that the downward pressure on pricing has affected the security of our supply chain. There must be a balance between enhancing bargaining power to ensure appropriate supply of drugs, incentivizing drug production and ensuring the best pricing for the Canadian market.



Competition in the generics sector

Competition in the generic pharmaceutical market can take place across several dimensions, including costs, market timing, patent challenges, breadth of offerings, support for pharmaceutical contract development and manufacturing (CDMO), vertical integration as well as quality and reliability:

Costs: competitive pricing is a significant market strategy for generic pharmaceuticals. With intense competition across the sector and a heavy emphasis on pricing in procurements, local pharmaceutical companies must drive down costs to secure a margin that makes sales in the small Canadian market worthwhile.

Market timing and patent challenging: companies plan product development, market authorization and launches years prior to the end of expiry of periods of market exclusivity for their brand-name counterparts. Early development and approval are key competitive advantages in the generic sector as companies that are first-to-market can obtain hospital and pharmacy customers prior to their competitors.

Breadth of product offerings: companies that hold diversified product lines can bundle offerings to customers; although customers mitigate supply risk by importing generic molecules and finished dose products from multiple providers, they are motivated to limit vendor counts to reduce administrative burdens and operating costs.

Contract development and manufacturing (CDMO): contract partners can enhance organizational capacity by contracting pharmaceutical companies to manufacture medicines and drug substances. This can range from research and development through to the final stages of manufacturing.

Vertical integration: companies can optimize operations by controlling multiple capabilities across the value chain. For example, companies that supply and manufacture their own inputs and finished goods are less reliant on external partners and can streamline their supply chain processes.

Quality and reliability: like every pharmaceutical company, providers of generics must uphold high service and quality standards, or risk removal from the market and/or reputational damage. Service quality includes distribution and inventory management, while quality – which is particularly crucial – assumes that regulatory safety standards are met.

These themes are further explored in Section 4: Canadian generic pharmaceutical sector trends.

The supply of generic pharmaceuticals

The process of bringing a generic prescription medicine to Canadians is complex and requires sophisticated scientific and advanced manufacturing technologies. This process can take several years and millions of dollars to complete (Bringing High-Quality Cost-Saving Generic Medicines to Canadians, 2020).

To supply Canadians with high-quality, cost-saving generic medicines, several complex steps are required to bring finished dose products to market. These steps, which are detailed below, include actions related to research and development as well as quality assurance and effectiveness.

Research and Development	A. Securing active pharmaceutical ingredients (API's)	• API are produced internally, or sourced from international suppliers. • Assess legal issues effecting availability and use of API in Canada. • API tested for quality and consistency prior to formulation. • Assess quality control and manufacturing practices of supplier. • Assess supplier ability to guarantee stable supply of API.
	B. Developing Formulas	• Originator product reverse engineered for composition of active and non-active ingredients. • Data collected, analysis of originator product monograph. • Various formulations of active and non-active ingredients. • Formulations are tested against brand-name product. • Develop quality control matrix for formulation integrated into manufacturing.
	C. Manufacturing and Production Testing	• Formulations tested in manufacturing setting. • Analysis of manufacturing complexity and requirements. • Equipment designed and/or purchased for dedicated production line. • Quality control matrix developed, tested for full manufacturing. • Packaging designed, produced with dedicated quality control matrix for output.
Quality Assurance and Effectiveness	D. Bioequivalence Studies and Clinical Trials	• Bioequivalency studies undertaken to measure the rate and the extent of absorption of generic drug. Results compared to originator drug. • Comparative study submitted to Health Canada. • Submissions include evidence of tests and clinical trials to measure potency, purity and stability of new drug. • Health Canada cannot approve a generic drug until all relevant intellectual property issues are addressed.
	E. Regulatory and Legal Challenges	• Under Patented Medicines (Notice of Compliance) Regulations a generic manufacturer is required to serve Notice of Allegation on the brandname manufacturer, claiming generic drug will not infringe any relevant patents. • Brand-name manufacturer can apply for an order prohibiting Health Canada from approving generic drug. Using "automatic stay" brand-name manufacturer can prevent generic product from entering market for up to 24-months simply by alleging patent infringement.
	F. Provincial / Territorial drug plan listings	• Once Health Canada has issued a Notice of Compliance (NOC) and approved the drug for sale, it can be sold anywhere in Canada. • To be reimbursed under provincial drug programs and obtain significant sales volumes, the generic drug must be listed on provincial drug benefit plans and be "interchangeable" with originator. • Manufacturer must submit an application to pan-Canadian Pharmaceutical Alliance (pCPA) and each province/ territory. It can take up to a year to have the new generic drug listed in all provinces..
	G. Patient Journey	• Patient Support Programs • Access • Education

Regulatory hurdles, reporting requirements, as well as pricing, can be some of the key drivers in helping generic pharmaceutical companies determine which molecules and/or finished dose products they will manufacture and/or import for Canada. There are multiple dimensions to the value chain which is depicted at a high level in Figure 1 (below). For the purposes of this report, the scope of the study was focused to explore importing/manufacturing and three pillars of the value chain have been defined for further examination: Procurement, Production and Packaging.

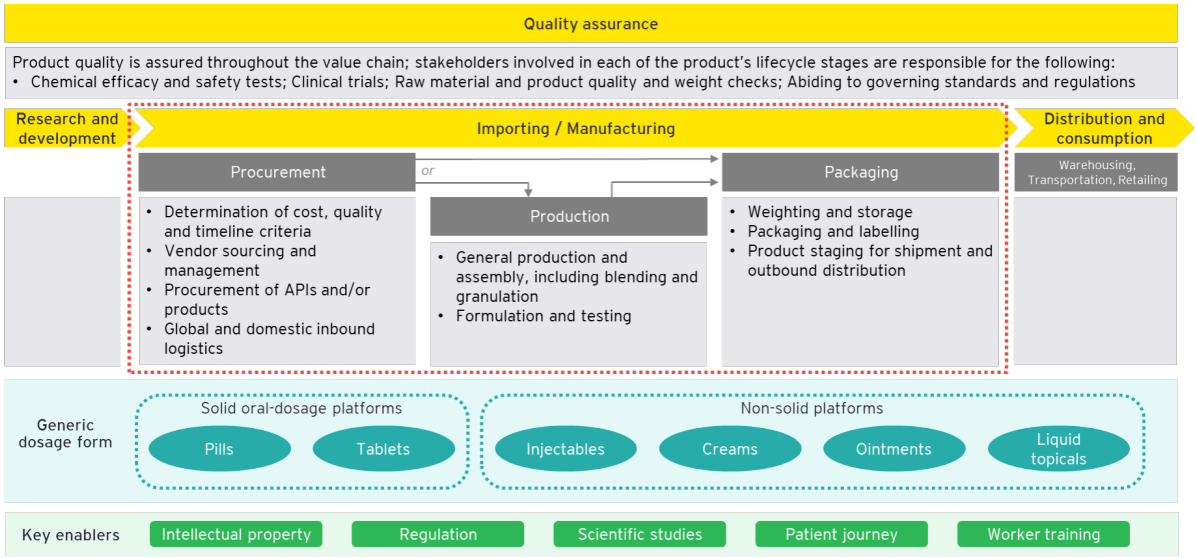


Figure 1. Generic pharmaceutical value chain

Procurement

Every pharmaceutical company, regardless of their operating model, must import some materials into Canada from raw materials to already packaged finished dose products. Constantly evaluating quality and cost of required goods, importing and managing vendors, complying with regulatory requirements and determining global and domestic inbound logistics requires significant time and resources.

Production

Pharmaceutical production refers to manufacturing activities required to produce a finished generic product. This includes product assembly, blending, granulation, formulation and testing, as well as other general manufacturing processes and equipment management activities.

Packaging

Manufacturers, and some select importers, carry out packaging activities. This includes packaging or repacking activities of finished dose products. Such activities extend to weighing, packaging, staging and, in certain circumstances, storing molecules or finished dose products for outbound distribution.

Regardless of their operating models, all generic manufacturers must adhere to rigorous quality assurance processes and the logistics of warehousing and distribution. While these are outside the scope of this report, they are intrinsically linked to importing and manufacturing capacity. This was particularly highlighted during the COVID-19 pandemic, so will be addressed in various points of this report.

International value chain dependencies

With the rise of the global market, every pharmaceutical company (generic and name-brand) in Canada relies on importing whether it is finished dose products or molecules, equipment, or parts. Some APIs are manufactured in Canada, while the majority are imported from Asia. China is known as a dominant supplier of intermediates for APIs, regardless of where the molecules are produced. Many in the sector, including CGPA, have long highlighted the risks of Canada's dependence on global suppliers. This was highlighted most recently in CGPA's *Blueprint for a Sustainable Supply of Prescription Medicines for Canadians* (Canadian Generic Pharmaceutical Association, 2020) and has drawn world-wide attention during the COVID-19 pandemic. The graphic below highlights US dependencies for APIs by country (Mullin, 2020).

Some domestic companies have international corporate relationships and close ties to international corporate parents. Some companies are vertically integrated on an international scale to varying degrees (e.g., parent companies in India may supply Canadian subsidiaries with key inputs for production). Such international corporate relationships can better secure the value chain for Canadian companies.

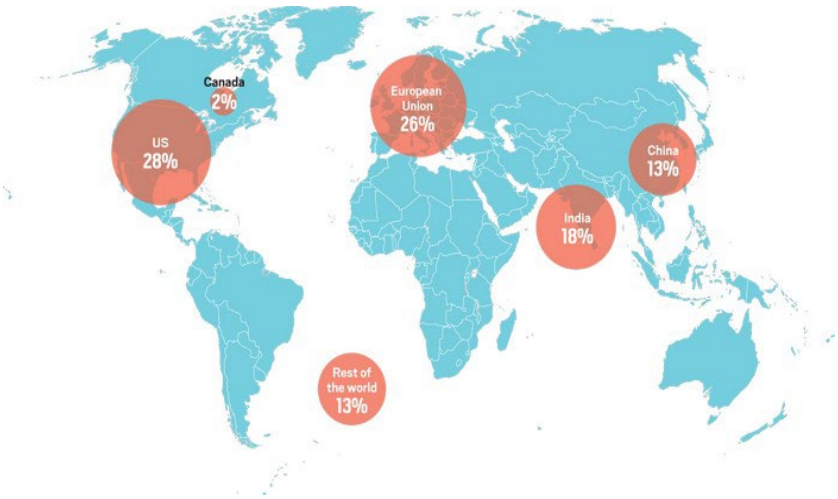


Figure 2. Plants supplying APIs to the US market (Mullin, 2020)

2.3 Value to Canadians

In 2020, generic drugs were dispensed to fill 555 million prescriptions and made up 73.2% of retail prescriptions in Canada (Canadian Generic Pharmaceutical Association, 2020). Generic pharmaceutical suppliers play an integral role in sustainably supporting the overall health and well-being of Canadians. The following sub-sections detail the value that generic prescription medicines and companies provide to Canadians. Economic benefits result from increased sector investment and sustainability. Ensured product quality standards lead to safe and effective health practices. Ease of access to generic drugs is key to ensure sustainability and protect against emergency scenarios.

2.3.1 Economic benefits

The Canadian generic pharmaceutical sector has a significant impact on the Canadian economy. Importing, manufacturing and distribution capabilities within the generic pharmaceuticals sector support Canadian job creation. Sales of generic drugs, both domestically and internationally, contribute to increasing Canada's GDP. Investing in the sector can allow companies to increase the volume and breadth of products that are manufactured and increase the degree of vertical integration of manufactures. These activities can allow for continued sector growth and development.

Research and development fuel product advancement

In addition to the research and development (R&D) investments made by name-brand pharmaceuticals, the generics sector also drives crucial growth in this area. Typically, R&D activities are targeted towards optimizing manufacturing practices, demonstrating to regulators that the generic version is substitutable with a brand-name drug that has been shown to be safe and effective, and challenging patents (Koronios, 2020). To encourage partnerships in R&D, the Canadian government has introduced Business-led Networks of Centers of Excellence (MarketLine, 2020).

Unfortunately, with reduced margins on generic pharmaceuticals, investments in R&D among generic producers is extremely low in Canada in comparison to other market leaders; Canada holds an R&D-to-domestic-sales ratio of 3.9% (PMPRB, 2019). (NOTE: The R&D-to-sales ratio numbers are for pharmaceutical patentees in Canada, which would be almost entirely brand-name drug companies. The 3.9% figure is from PMPRB's annual report and, again, would be almost all brand companies with patented products). Canada does provide tax incentives for R&D activities however reports indicate that there is little uptake among generic manufacturers or producers, despite being eligible due through manufacturing optimization. It is critical for companies to make use of the incentives available to enhance their capacity.

The generic pharmaceutical sector attracts talent and creates domestic jobs

The Canadian generic pharmaceutical sector directly employs approximately 11,000 Canadians with well-paying jobs and benefits (Canadian Generic Pharmaceutical Association, 2020). Beyond direct employment, the sector has a wide footprint and supports jobs in many areas like shipping, logistics, distribution and quality assurance.

Canada is a major exporter of generic pharmaceutical products

The development of international trade in Canada is a significant economic driver. Sector experts tout the extensive benefits for exporters including economics of scale, the opportunity to learn from foreign consumers and suppliers and a competitive market that encourages continuous optimization. Increased productivity also contributes to more benefits to the broader economy. As a result, the economic benefits that Canadians realize from selling and exporting generics internationally increase with Canada's ability to sustainably supply generics domestically. Currently, Canadian generic pharmaceuticals are exported to more than 100 countries around the world and the global demand for generic pharmaceuticals is increasing at a rate of 10% each year (Canadian Generic Pharmaceutical Association, 2020). While the Canadian market itself is small, national regulatory standards mean that Canada imports and produces some of the highest quality products in the world. This reputation for high standards and reliability makes Canada a natural leader in exporting generics.

2.3.2 Reliable access and ensuring highest standards of quality

Today's complex and shifting geopolitical landscape poses increased risks to the supply of several products that are imported to Canada, especially generics. It is increasingly important for Canadians to have reliable access to generic pharmaceutical products. The COVID-19 pandemic has highlighted the precarity of Canada's prescription drug supply, but since disaster was largely averted due to creative planning within the generics sector, there is a risk that the value of reliable access may be taken for granted.

Health Canada also sets stringent health and safety regulations to ensure Canadians are receiving the highest possible quality of generic medications. Maintaining these standards also has offshore value, as products that are used or imported into Canada are recognized as having met some of the highest standards in the world.

Diverse product supply contributes to improved health outcomes

Canadians benefit greatly from having a wide selection of generic pharmaceutical products that are required to meet their health needs, especially at pharmacies. Having a diverse range of products available means that Canadians with unique needs can be assured that products are available to them. For instance, those with allergies, dietary requirements, or those who follow religious requirements may need access to drugs with different ingredients. Access to medications that meet these requirements can increase medication adherence.

Having access to a diverse supply of generic medications can also ensure there are cost-effective alternatives to brand-name drugs to meet their health needs. The more generic products are accessible, the more Canadians are able save on reliable healthcare solutions. Increased savings increases the likelihood that patients adhere to their drug regimens and can help the system avoid costly downstream treatments.

Domestic capabilities provide Canadians with more reliable generic medicine supplies

With an evolving geopolitical landscape and international supply chain disruptions, generic companies are increasingly having to think strategically about risks to their business models. The recent impacts of the COVID-19 pandemic, outlined further in section 4.3, demonstrated the importance of secure supply chains. Supply chain security does not require nationalism but does require careful and strategic planning. Strategies for supply chain security can include the use of safety stock, vertical integration with parent companies overseas, strong supplier relationships and in-depth understanding of evolving relationships across their product value chain. While all domestic generic pharmaceutical manufacturers are reliant on global suppliers, enhancing domestic capacity helps improve reliable access to product for the entire sector.

Although it is widely agreed that assured access to a sustainable supply of generic pharmaceutical products would be invaluable to Canadians, current capacity has been unknown. The purpose of this report is to assess current capacity to supply generic pharmaceuticals, whether they are imported or manufactured, as well as identify risks and challenges to capacity.

High standards of quality reduce health risks and cost burdens while supporting trust and reliability in products

Health Canada mandates that domestic generic pharmaceutical suppliers uphold and maintain extremely high product quality standards. These standards enable Canadians to receive some of the highest quality generic medicines in the world. This reduces risk of Canadians suffering health wise from potential product recalls and reduces Canada's potential cost burdens in times of emergency.

Canadian-supplied generic products commonly hold strong reputations for meeting exceptionally high quality and reliability standards. This allows Canadian consumers to consciously rely more on generic medicines, at a fraction of the cost of their brand-name equivalents, to meet their health needs. Additionally, Canadian-supplied generic products are increasingly valuable in international markets; foreign entities are increasingly attracted to high quality generic products and they are willing to pay premiums to ensure product reliability.

3. CGPA Member capacity

3.1 Section summary

This section summarizes key findings based on the data provided by 10 of CGPA's member companies.

Generic medicines are supplied through a unique and complex framework in Canada. Companies import large volumes (in kgs) of finished products, and/or active pharmaceutical ingredients (APIs) as well as manufacture many of their own products. The Canadian generic pharmaceutical sector is highly competitive, so detailed data from importing to production line and packaging could not be obtained. To compare supply chain and manufacturing capacity, the number of products managed or manufactured was used as the proxy measure for capacity.

Between 2019 and 2021, member companies produced (by manufacturing or importing) 6,225 generic pharmaceutical products for Canada, excluding APIs. Approximately 44% (n=2,743) of these products were manufactured domestically and 56% (n=3,482) were imported finished products. In addition, in the same period, approximately 4,897 (kg in thousands) of APIs were produced (through manufacturing or importing activities) for Canada[3].

The reliance on importing imported finished products can have a significant impact on the health of Canadians. Canada is heavily reliant on procuring a large volume of gastrointestinal drugs and anti-infective agents from foreign countries (measured in kgs). The majority of medicines manufactured in Canada fall into several key therapeutic categories for the endocrine system, respiratory system, cardiovascular system, and gastrointestinal tract as well as analgesics, anesthetics and antipyretics. Together, these key therapeutic categories account for 51% of domestically manufactured products (76% of the volume by weight).

Conversely, Canada has less reliance on importing through the global supply chain for a subset of generic medicines that includes respiratory tract agents and cardiovascular drugs due to having more domestic production. If Canada were to place more emphasis on its manufacturing capabilities, several key factors would need to be strengthened, including greater support through federal and provincial government incentives, understanding the risks in the economy and the labour market, the associated minimum operating costs and technology requirements for parts and equipment, and the ability to import the right raw materials and APIs in order to reliably manufacture products in Canada.

[3] To ensure anonymity, the proportions of APIs manufactured compared to imported in Canada is not provided.

A disruption to the global supply chain could also impact domestic manufacturing capabilities due to the reliance on procuring inputs, such as APIs and biosimilars, which are required in order to manufacture and package finished products. Based on the data analyzed, finished products are predominately imported from India and the majority of APIs come from India and China. There are concerns when Canada relies predominately on a handful of foreign countries to secure sufficient supply in order to manufacture medicines domestically. International government relations are increasingly important with the amplified reliance of the global supply chain and are particularly important during the pandemic.

Data from 2019-2021 suggests that companies were able to stabilize their importing activity for both finished products well as API during this volatile time in the global supply chain. Although COVID-19 put immediate pressure on companies when it came to managing supply and demand, including logistical hurdles for importing and numerous operational and workforce challenges, companies reported that they were able to work through the challenges and since then, global supply chains have re-stabilized and demand volatility settled. Many companies have reported that production has returned to steady operations.

Data Collection and Analysis Approach

As previously mentioned, data from CGPA member companies is highly confidential. To assure anonymity, data have been anonymized, grouped, aggregated and de-aggregated for various analyses.

CGPA member companies provided three distinct data sets for finished products, manufactured products and APIs. For each data request, member companies provided a list of products defined by drug molecule or therapeutic category, dosage form, strength, package size and country of origin for the last three years.

Member companies may distinguish the same drug molecule or therapeutic category[4] differently for instance to identify differences between plants, manufacturers, treatment of disease, chemical structure, or other differences. Where a drug molecule or therapeutic element is considered and treated differently by the member company, the product was treated as distinct in the analyses.

All data analyses prioritized maintaining anonymity of the data between member companies. Data were cleansed and anonymized within respective data sets before being grouped for analyses. With this data, two distinct groups were created: Products (includes finished products and manufactured products) (N=6,225); and APIs. For select analyses to smooth variation, data were grouped with respect to data reporting period (2019-2021[5]) and/or therapeutic categories. For each product and APIs, separate analysis was complete for country of origin. Where there were variations in dosage form (for instance a liquid vs a solid), analyses were done based on volume in weight. Manufactured products and finished imported products were grouped for select analysis and reviewed by therapeutic categories.

[4] Therapeutic category refers to how medicines are classified into different groups according to their chemical characteristics, structure and how they are used to treat specific disease

[5] Surveyed member companies used different fiscal years. To standardize reporting, predictive trend analyses have been used to complete data for a calendar year and support analyses.

The following 27 Therapeutic Categories (right) were identified in the data provided. For the purposes of the illustrating the aggregated data tables certain high-volume categories were highlighted in a Table format. The remaining therapeutic categories were rolled up into an "All Others" category.

Analgesics, Anesthetics & Antipyretics	Cardiovascular Drugs	Other
Baby Care Preparations	Diabetes Mellitus	Respiratory Tract Agents
Contraceptives	Nutrients & Supplements	Women's Health
Dermatology	Immunomodulator	Smoking Deterrents
Diagnostic Aids	Gastrointestinal Drugs	Dental Agents
Anti-allergic Agents	Endocrine	Nutrient Delivery System
Anti-Infective Agents	Erectile Dysfunction Medication	Detoxification Agents
Disinfectant	Musculoskeletal	
Ophthalmology	Central Nervous System Agents	
Cancer Treatment	Genito-urinary Tract Agents	

APIs and finished dose products are imported from 45 countries (right). For the purposes of illustrating aggregated data tables, several of the top countries that export to Canada are specified. The other countries are aggregated into an "All Others" category.

Austria	Czech Republic	Italy	Slovenia
Australia	Denmark	Japan	South Africa
Argentina	Finland	Luxembourg	South Korea
Bangladesh	France	Macao	Spain
Belgium	Germany	Malta	Sweden
Bulgaria	Great Britain	Mexico	Switzerland
Canada	Greece	Netherlands	Taiwan
China	Hungary	Poland	Tunisia
Columbia	India	Portugal	Turkey
Croatia	Ireland	Romania	UAE
Cyprus	Israel	Slovakia	United Kingdom
			USA

Capacity across the end-to-end value chain

Since 2019, CGPA's member companies have provided 6,225 products (finished and manufactured) and 4,897 (kg in thousands) of APIs (imported and manufactured).

For the period 2019 - 2021		Total	Manufactured	Imported Finished Dose Products
Finished Dose Products	Number of molecules[6]	6,225	2,743 (44%)	3,482 (56%)
	Weight (kgs in 000's)	53,148	6,596 (12%)	46,552 (88%)
APIs	Weight (kgs in 000's)	4,898		N/A[7]

Canada's value chain relies on manufacturing many different products in smaller volumes and importing large volumes of some products

Unsurprisingly, Canada's value chain is reliant on importing large volumes of therapeutics for Canadian use. Of the reported data, 6,596 (kg in thousands) or 88% of Canada's imported finished products are imported and only 12% manufactured domestically. Of the 6,225 products reported, 44% are manufactured in Canada and 56% are imported (Figure 1).

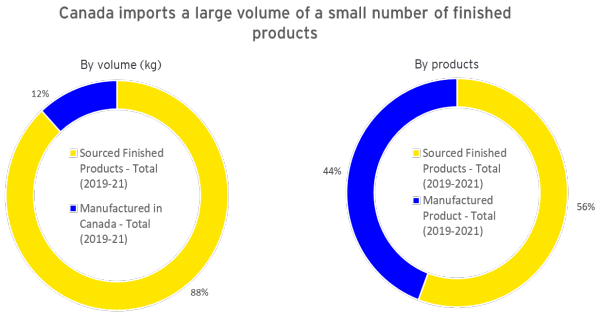


Figure 1. Finished Dose Products: Imported vs. Manufactured in Canada, by volume (kgs) (left) and number (right), aggregated from 2019 – 2021

[6] In some cases, the same molecule or finished dose product (i.e., drug molecule / therapeutic category, dosage form, strength, package size and country of origin) was reported multiple times. Member companies indicated that this can occur when a molecule or finished dose product is considered distinct internally (e.g., they may come from different plants). As a result, they have been treated as distinct in the analyses.

[7] Less than <10% of APIs are manufactured domestically. Data is not presented to maintain confidentiality of member companies.

Disruption to the global supply chain could significantly impact the health of Canadians

Gastrointestinal (GI) Drugs & Anti-infective Agents

Canada is heavily reliant on procuring a large volume of GI drugs, followed by anti-infectives[8], from foreign countries (Figure 2). Between 2019 and 2021, 24% of imported finished products were for GI drugs and anti-infectives but they made up 87% of the volume by weight. Of the finished dose products manufactured in Canada in the same period, GI drugs and anti-infectives made up 20% of the number of products (23% of the volume by weight).

Since the start of the pandemic, Canadian providers have been concerned about potential shortages of critical therapeutics like anti-infectives (e.g., antibiotics) that are essential for treating patients in operating rooms, intensive care units, emergency departments and palliative care. Based on the over-reliance of imports required (Health Canada, 2021) for these two therapeutic areas, as seen in the data above, they could be further investigated as a strategic area to develop manufacturing capabilities in order to mitigate future risks.

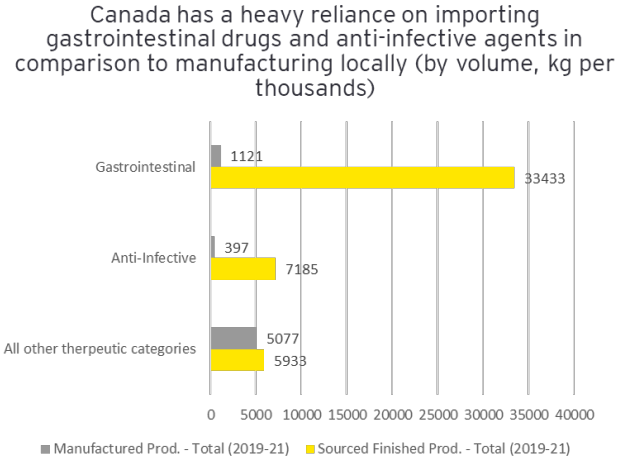


Figure 2. Imported vs. Manufactured in Canada, GI and Anti-infective medicines, by volume, aggregated from 2019 – 2021

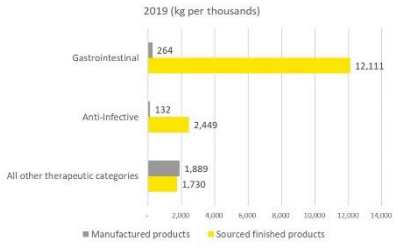


Figure 2A. 2019 Finished Dose Products: Imported vs. Manufactured in Canada, GI and Anti-infective medicines, by volume (kgs in 000's)

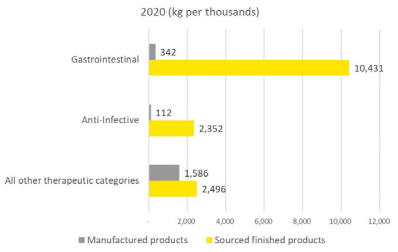


Figure 2B. 2020 Finished Dose Products: Imported vs. Manufactured in Canada, GI and Anti-infective medicines, by volume (kgs in 000's)

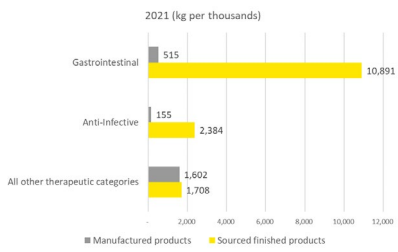


Figure 2C. 2021 Finished Dose Products: Imported vs. Manufactured in Canada, GI and Anti-infective medicines, by volume (kgs in 000

[8] The anti-infectives therapeutic category includes antibacterial, antibiotics, antifungals, antiprotozoans and antivirals.

Impact to Canadians

With low volumes of domestically manufactured therapeutics, there is a need to coordinate approaches and strategies to ensure that there is sufficient supply of essential drugs within Canada in the case of an emergency where borders are completely closed or where there is a risk of therapeutic nationalism.

Coordinated planning should include engaged consultation between Ministries of Health, pharmacy regulators, professional and pharmaceutical associations, providers and physicians to identify and regularly review high-demand medicines and to ultimately develop an essential medicines list.

During the pandemic, the Minister of Health established a Critical Drug Reserve, which provided a 3-month supply of 12 drugs that hospitals rely on for the treatment of patients with COVID-19. This provided an additional safety net by securing the supply for these key drugs to ensure Canadians had access to these treatments. Moving forward, the Critical Drug Reserve should not only be maintained, but be expanded to include a more robust list of essential medicines to ensure supply is conserved during future public health emergencies (Health Canada, 2021).

There is no distinct pattern of which therapeutic categories are predominantly imported or manufactured domestically

Although the Canadian government has been challenged with responding to a continually developing global health crisis, domestic generic pharmaceutical companies have responded quickly to the crisis. Figure 3 compares domestically manufactured therapeutic categories to how much is imported. Interestingly, Canada manufactures more cardiovascular drugs and respiratory tract agents than what is imported. Given the symptoms and treatment required to respond to the COVID-19 virus, Canada seemingly has less reliance on the global supply chain for a subset of those generic medicines and more reliance on production lines domestically. For many of the therapeutic categories across Figure 3, there is a high degree of variation between products that are manufactured in Canada compared to imported finished dose products based on volume. It should be highlighted that although Canada manufactures a large volume of product domestically, the majority of active pharmaceutical ingredients (APIs) are imported.

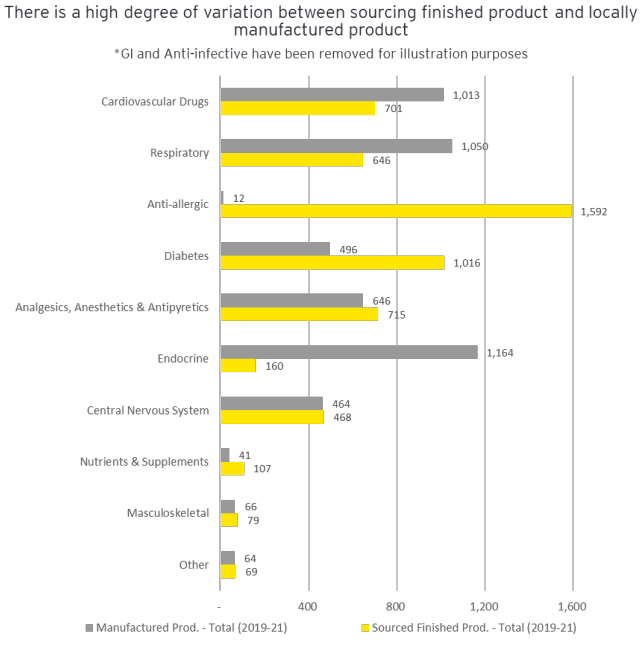


Figure 3. Sourced Finished Products vs. Products Manufactured in Canada, for all other therapeutic categories, by volume, 2019 – 2021

3.2 Importing and manufacturing capacity

There is a desire across the pharmaceutical sector to make the industry more resilient and improve incentives across Canada for both importers and manufacturers. Although the COVID-19 pandemic is thought to have exposed significant limitations and gaps in Canada's capacity to produce life-saving vaccines and therapeutic drugs at sufficient scale to meet domestic needs, CGPA members acknowledged that they were able to continue to produce their product line as needed by their customers. The pharmaceutical supply chain has been resilient, however, there is still reliance on procuring inputs, including intermediates, molecules in order to manufacture and package finished dose products in domestic facilities.

3.2.1 Importers

99% of Imported finished dose products come from South Asia, Europe and North America

The majority of Canada's generic pharmaceutical industry is focused on importing finished dose products and APIs into Canada. Canada, fortunately, continued to have relatively reliable deliveries throughout the pandemic. However, a rise in protectionism (e.g., vaccine nationalism) has revealed that strong foreign relations are essential to supporting a continuous supply.

On a global level, China is a predominant manufacturer of intermediates. These are then shipped around the world where APIs and finished dose products can be manufactured. Supply routes can be difficult to trace but Figure 4 outlines the last port before entry to Canada. From 2019-21, therapeutics were predominately imported from South Asia and Europe, making up a total of 65% of the medicines.

In the news

In March 2021, the United States announced that they were planning to share 1.5 million doses of AstraZeneca vaccine with Canada. Prior to this announcement, all of Canada's vaccines had come from either Europe of India.

When asked why Canada was one of the countries that was chosen, the administration official said: "They are our neighbors, they are our partners."

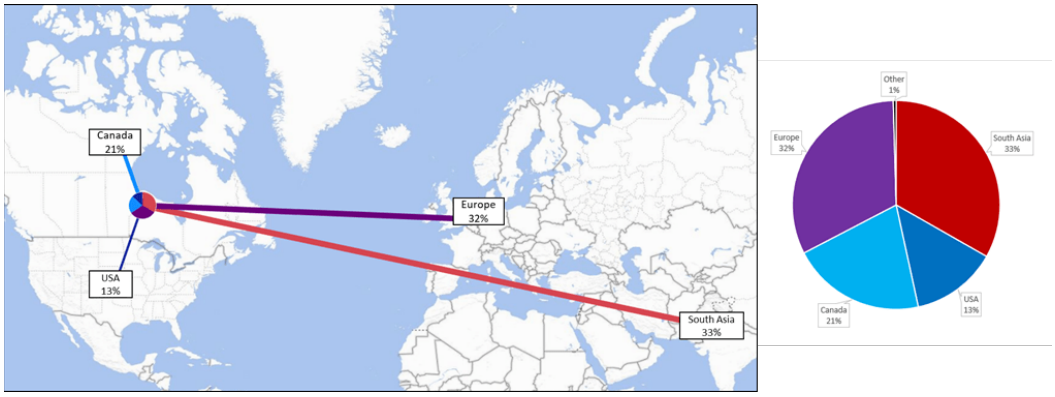


Figure 4. Global view of Sourced Finished Product by Region (Kg in 000's), 2019/2020/2021

Approximately a third of the imported products are North American made. Figure 5 reveals that there is a predominant reliance on importing finished dose products from India.

Interestingly, when looking at the total volume over time, generally there is a slight peak in 2020 for all other countries except for India. Overall, it outlines how companies were able to manage their logistics and importing mechanisms to manage changes in supply and demand due to COVID-19.

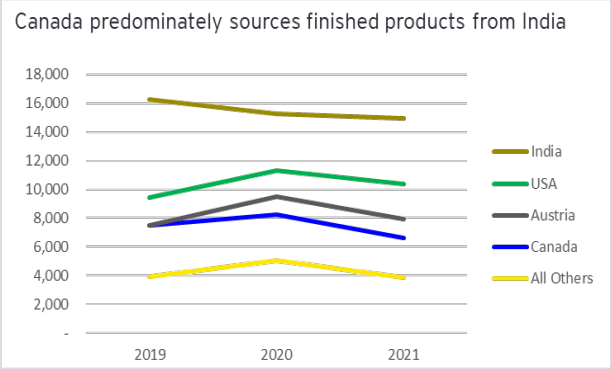


Figure 5. Sourced Finished Product by Country (kg in 000's), 2019/2020/2021

With the vast majority of APIs sourced from India and China, Canada should continue to strengthen foreign trade agreements

Almost all API's used to manufacture medicines in Canada come from abroad. The import of APIs is essential to supporting domestic manufacturing capabilities in Canada. Over the last three years, APIs were predominantly imported from India, China, Mexico, Italy and Spain (Figure 6), with the greatest reliance on India. India and China alone account for over 60% of the APIs imported for locally manufactured generic medicines.

Figure 6 also reveals that the Canadian companies were able to continue to import APIs throughout the pandemic. Based on the data provided, the total volume of API imported each year has been relatively consistent from 1,549 kgs in thousands.

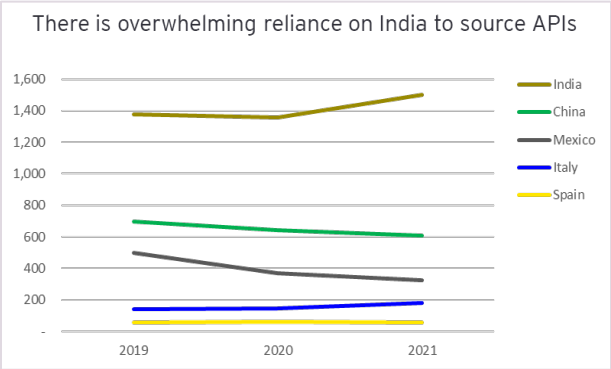


Figure 6. API Sourced by Country (kg in 000's)

There are concerns when Canada relies predominately on a handful of foreign countries to secure sufficient supply in order to manufacture medicines domestically. International government relations are increasingly important with the amplified reliance of the global supply chain, and particularly important during the pandemic. The Canadian government can further strengthen generic supply reliability by securing trade agreements with foreign jurisdictions that domestic suppliers rely on most.

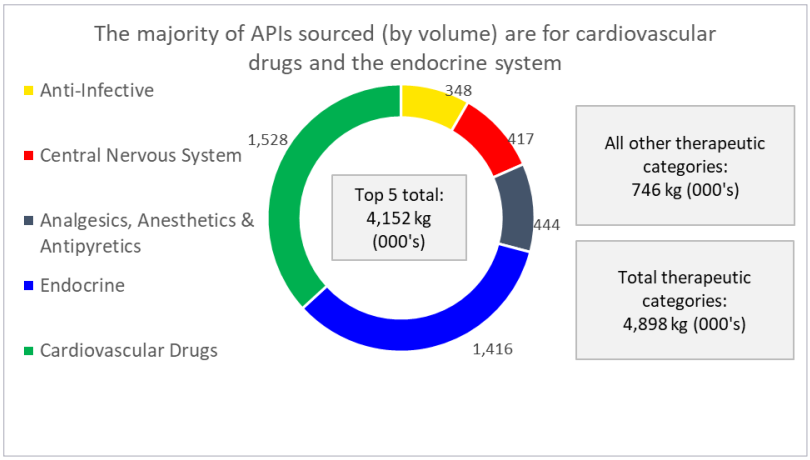


Figure 7. Total API Sourced by Therapeutic Category (kg in 000's), 2019-2021

Based on the data provided, companies are most reliant on APIs to produce cardiovascular and endocrine system medicines, which amounts to 60% of all APIs imported into Canada based on volume (Figure 7). The top 5 therapeutic categories as shown in Figure 11 account for 85% of the APIs imported over the last three years.

A disruption along the supply chain in importing APIs has the potential to impact the ability for domestic manufacturers to produce local products.

The impact of relying on a small group of international providers

There should be general awareness that when a company is reliant on a few international providers, it may be exposing itself to increased supply risks, which in turn, negatively impacts the reliable supply of generics for Canadians. An overreliance on imports leaves us vulnerable. Furthermore, the evolving geopolitical environments may pose the greatest threat to the supply of domestic generic drugs because international value chains are largely dependent on reliable trade agreements between nations. A similar sentiment should be considered with vendor management and relationships in foreign countries.

The effectiveness of logistics can also have a profound impact on disrupting supply in Canada. It can be incredibly challenging to coordinate logistic solutions to transport generic inputs and goods across the world. This further places pressures on companies from a cost, quality and timeliness of procurement perspective. As such, suppliers should diversify international transportation and logistics providers and channels to mitigate supply risks and cost disruption.

Based on the findings and the reliance generic pharmaceutical companies have on other countries and vendor supply, it is recommended that Canada establish an essential medicines list and further expand the newly established Critical Drug Reserve. The adoption of an essential medicines list into public policy could lead to lower medication costs by concentrating price competition on a smaller number of drugs and satisfy the priority healthcare needs of the population. These considerations are further detailed in Section 4.

3.2.2 Manufacturers

In the wake of responding to COVID-19, there was a spotlight on domestic pharmaceutical manufacturing capabilities. During this time, many companies responded rapidly, implementing safety protocols and solutions that enabled operators to continue an uninterrupted supply of medicines, while maintaining a high level of service to its customers. However, it has also highlighted a need for Canada to understand the importance of sustaining a resilient manufacturing economy beyond this global crisis.

Manufacturing in Canada has allowed companies to demonstrate the importance of a resilient supply chain as well as to ensure a stable supply of essential generic medicines.

Reduction in domestically manufactured unique products over time in Canada

Over the last three years, there has been a reduction in the total number of products manufactured in Canada; however, the volume of those products has remained relatively stable, with the exception of 2020 (Figure 8, Figure 9). With increasing cost pressures on generics, manufacturers are forced to optimize their margins and make strategic decisions. For instance, choosing to focus on supply chain optimization and greater local specialization on high impact, high value medicines, or greater reliance on foreign manufacturers. These factors, along with the global pandemic could have led to the decrease in the number of domestically manufactured medicines over time. Based on these factors, it is expected that the number of different products over time would decrease (i.e., due to greater specialization) and that the overall volume of those products would increase. Companies have shown that the value chain has been resilient in responding to the pandemic, however, we do see a slight dip in the volume of products produced in 2020 that could be attributed to operational challenges companies faced during the onset of COVID-19 due to supply chain issues or customer behavior. It appears that 2021 is back to 2019 levels, however additional data points would be required to establish a trend in the analysis. We should continue to look for opportunities to prevent further erosion of domestic manufacturing for all products including APIs, biosimilars and others.

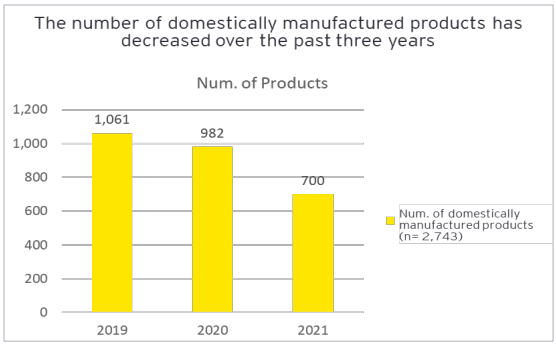


Figure 8. Total Number of Manufactured Finished Dose Products in Canada 2019 – 2021 (n=2743)

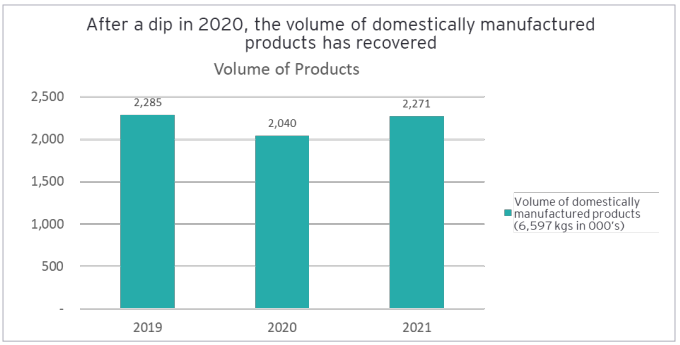


Figure 9. Total volume (kgs in 000's) of Manufactured Finished Dose Products in Canada, 2019 – 2021 (total of 6,596 thousand kg)

Canada manufactures a range of therapeutic medicines

The data shows that a diverse range of therapeutics are manufactured domestically including:

- Endocrine agents
- Respiratory tract agents
- Cardiovascular drugs
- Gastrointestinal drugs
- Analgesics, anesthetics and antipyretics.

These five therapeutic categories account for over 75% of the generic medicines manufactured in Canada (based on volume)

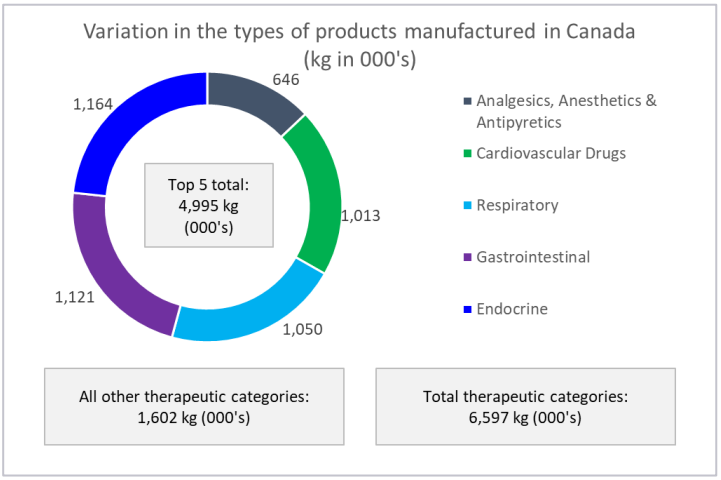
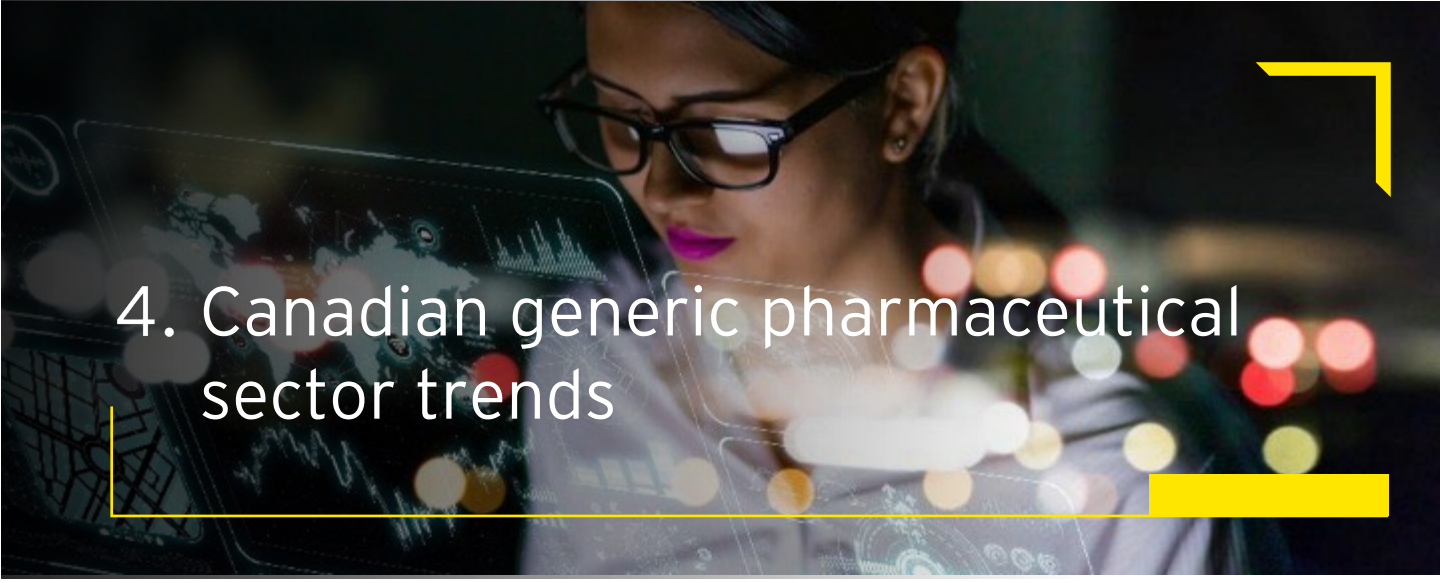


Figure 10 – Top 5 Manufactured Products in Canada by Therapeutic Category (kg in 000's), 2019-2021

In 2021, the Government of Canada released a consultation summary that considers how best to ensure that Canada is well-positioned to respond to future health emergencies and how to promote the long-term growth of the Canadian life sciences sector. As such, the government has recently announced significant investments to strengthen Canada's biomanufacturing and life sciences footprint. The generics sector should capitalize on these opportunities to strengthen and market their capabilities. With potential in the sector, Canada can look to manufacture additional necessary medicines for Canadians across a broad range of therapeutic categories (Government of Canada, 2021).

Strengthening support and incentives could fuel additional manufacturing capacity considerations

Currently, using the three years of data collects, the average number of generic product types that are manufactured in Canada is just over 900 per year. If Canada were to place more emphasis on its manufacturing capabilities, several key factors would need to be strengthened to promote and sustain manufacturing medicines in Canada. This includes, strengthening federal and provincial government incentives, understanding the risks in the economy and the labour market, the associated minimum operating costs and technology requirements for parts and equipment as well as the ability to import the right raw materials and APIs in order to reliably manufacture products in Canada. These considerations are further detailed in Section 4 of this report.



4. Canadian generic pharmaceutical sector trends

4.1 Section summary

This section of the report explores the Canadian generic pharmaceutical trends that are impacting and evolving the sector and could better support the development of our local industry. Each sub-section further studies the current market challenges that the sector faces as well as opportunities that can be optimized for the key players involved.

Government incentives and regulation

Government incentives and regulations each play a role in shaping the Canadian generics sector. Establishing the right long-term support mechanisms could help increase the domestic manufacturing capacity and create an ecosystem in which local companies can flourish. The impact of the various regulations at each level of the Canadian government has also resulted in a uniquely Canadian landscape that is sometimes difficult to rationalize when compared to foreign markets. Canadian regulatory and legislative requirements can be challenging to navigate and often act as a barrier to market entry for generic pharmaceuticals, however exploring opportunities to streamline approval processes could increase market entry opportunities for companies supplying generic medicines to Canada. An in-depth regulatory analysis, potentially in partnership with government stakeholders, could be used to leverage opportunities to optimize the process and reduce barriers to market.

Commercial development and investment

There are substantial barriers in developing new product offerings and new unique product features within the generic pharmaceutical sector in Canada including relatively small domestic market sizes, low returns on investment and high regulatory hurdles for product approvals to name just a few. However, companies can realize competitive advantages through investing in vertical integration and exploring additional value chain capabilities that produce locally transformed products in the Canadian market.

Foreign supply dependencies

There is significant supply dependence on foreign countries that implicate the domestic supply chain of generic pharmaceutical companies. There also economic risks attributed to the dependence on foreign markets include accessibility to raw materials, international supply chain logistics, as well as the ongoing shifts in geopolitical and regulatory environments. There are opportunities for the Canadian government to strengthen the generic supply reliability by securing trade agreements with foreign jurisdictions. These risks can be further mitigated if Canada held greater capacity to supply and produce generic medicines domestically.

COVID-19 impacts

Impacts of workplace safety requirements, logistical challenges and demand volatility affected costs for all CGPA member companies throughout COVID-19. Increased quality and safety standards have been upheld through investment in resources and workplace modifications. It is clear, that having a coordinated direction for member companies that reflects the products they import and manufacture as well as their role in supporting the health of Canadians is invaluable.

4.2 Government incentives and regulation

With increased attention on Canada's life sciences sector and the importance of securing a domestic supply of generic pharmaceuticals, the federal and provincial governments have the opportunity to provide supports and make investments that will shape the future of the sector. It will be important for governments to evaluate existing supports and identify strategic, long-term investments that will help the generics industry flourish in Canada.

The impact of the various regulations at each level of the Canadian government has also resulted in a uniquely Canadian landscape. While Health Canada has set some of the highest approval standards in the world for pharmaceuticals, the associated regulatory and legislative requirements can be challenging to navigate and act as a barrier to market entry and security of supply when they are not well aligned with those of the leading regulatory authorities in jurisdictions with large pharmaceutical markets such as the US FDA and EMA. Canadians may be missing out on access to valuable generic pharmaceuticals because it is too challenging to make them available domestically.

The importance of sustained government support

Challenge

Companies with Canadian operations have expressed that government intervention and support is required to further optimize their value chain and to invest in manufacturing capabilities and capacity.

Government support and incentives are critical in enabling the reliable supply of essential products to Canadians, especially generic medicines. This is because the sector must provide low product pricing while being faced with high operating costs. For domestic manufacturers, these costs are exacerbated by the high cost of employees that support local manufacturing activities, further reducing profit margins.

The COVID-19 pandemic increased both the government and the public's attention to Canada's pharmaceutical supply chain and highlighted need to invest in domestic infrastructure and manufacturing capabilities in the pharmaceutical sector. This need was met with investment from both the federal and provincial governments. For example, in 2021, the federal government announced a $2.2 billion-dollar biomanufacturing and life sciences strategy which included the following funding:

- $1 billion over seven years through the Strategic Innovation Fund targeting domestic life sciences and bio-manufacturing firms
- $500 million over four years for the Canada Foundation for Innovation to support the bio-science capital and infrastructure needs of post-secondary institutions and research hospitals
- $50 million over five years to create a life sciences stream in the Venture Capital Catalyst Initiative

Other funding examples include the Quebec government, which allocated $118 million in 2020 to support the life sciences industry in addition to implementing several tax measures to support the industry, and the BC government, which established the InBC Investment fund that will receive $500 million dollars over 3 years to invest in tech startups, green companies, and the life-sciences sector.

While these government programs and investments will offer significant support to the sector in the near term, continued investment will be required to ensure that it can both remain competitive globally and can attract and retain top talent. Establishing longer-term supports and incentives for the sector will help to sustain an ecosystem in which domestic suppliers and manufacturers can thrive, preventing companies from offshoring and generating a more robust domestic supply of generic medicines.

Opportunity

Recent global health events have provided the federal and provincial governments an opportunity to explore and revisit approaches to governmental support and initiatives in the domestic generic pharmaceutical sector.

Recommendation

In collaboration with domestic suppliers and negotiating bodies, existing supports and long-term strategies to promote and incentivize onshore capabilities for importing and manufacturing should be explored. Such capabilities will assure the sustainable supply of a breadth of generic medicines and the economic benefits associated with a strengthened domestic industry.

Meeting Canada's unique regulatory requirements

Challenge

Many companies are challenged with complex Health Canada product approval processes and health and safety requirements that are misaligned with the FDA, EMA and other leading regulatory authorities. The approval processes in Canada are in place to evaluate the quality, safety, and efficacy of the drug before it can be made available for use. These challenges increase barriers of entry to the Canadian market and consequently impact the reliability of the domestic supply of generic medicines for Canadians.

New drugs can be sold in Canada once they have successfully passed a review process to assess their safety, efficacy and quality. This process is typically quite lengthy for Canadian generic medicines, which can have a detrimental impact on the sector. Several domestic and foreign companies have chosen to forego the opportunity to develop certain products due to high business risks, such as delayed returns on investment, lack of regulatory pathways, and lack of predictability in product approvals. This hinders the reliable supply of generic medicines to Canadians and negatively impacts the Canadian economy. It should however be noted that drug approval processes have recently been expedited for certain critical medicines due to COVID-19.

> "The Canadian drug approval process is twice as complicated as the FDA process. We have had to abandon some products due to delays."
>
> CGPA Member Organization Stakeholder

Unique Canadian regulatory requirements pertaining to product health and safety standards also pose challenges and risks to the sustainable supply of generic medicines and locally transformed products. Members have cited the following challenges:

- Risk of unique regulatory changes as a cause of foregoing investments
- Stringent and complex regulatory requirements
- Unclear and ineffective guidance when requesting feedback to ensure compliance with standards

> "Inquiring with Health Canada and obtaining regulatory guidance is not helpful or effective."
>
> CGPA Member Organization Stakeholder

This complexity and lack of predictability can significantly impact planned business operations and result in production delays and backtracking, which in turn lead to the negative impacts mentioned above that are associated with the Canadian generics sector.

Opportunity

There is a need to strengthen inter-governmental relations to expedite and streamline processes in the generic pharmaceutical value chain. Canadian governments at both federal and provincial/territorial levels have an opportunity to consider streamlining regulatory processes and aligning currently complex and unique standards to those of larger comparable international markets, such as the United States and European Union, to lower barriers for companies to supply generics to Canadians while maintaining safety and quality standards.

Recommendation

Opportunities to streamline approval processes for generic medicines as well as new API registration timelines should be considered. Streamlining should include an in-depth regulatory analysis that outlines opportunities to align Health Canada requirements with foreign market leaders, such as the US FDA and European Medicines Agency (EMA) as well as emergency preparedness pathways as required. Alignment opportunities with such leading regulatory authorities should not sacrifice health and safety standards but increase market entry opportunities for companies supplying generic medicines to Canadians.

4.3 Commercial development and investment

There is variation among the domestic generic pharmaceutical suppliers when considering commercial development or investment opportunities to increase their Canadian importing and manufacturing capacities. Generally, many companies with presence in Canada feel that a lack of policy driven incentives and misaligned regulatory requirements drive importing and manufacturing commercial development and investment away from Canada. However, there are several factors that are discussed in this section of the report that draw companies to these decisions.

Breadth of product offerings

Challenge

Investing in research and development capabilities as well as developing new product offerings and new unique product features are commonly understood to be competitive drivers in the generic pharmaceutical sector. However, the feasibility of doing so sustainably within Canada is ambiguous and complex to a certain degree.

Many companies with generic pharmaceutical production operations in Canada have noted that it is increasingly difficult to reasonably invest in developing domestic capabilities to produce new products and product features. Anecdotal support and factors for these expectations include the following:

- High expected costs of producing generic products; including workforce, operating costs, facilities expenses, and transportation
- High levels of international competition; international players may deliver products at lower costs
- Fewer popular standard products, such as solid dose products, have patents expiring

To mitigate the risk of investing in new generic products, many companies are pursuing opportunities in increasing domestic capabilities to supply more complex generic products as well as trying to develop products where there is less competition. Furthermore, many patents for brand name complex generic products in the market are approaching expiration allowing for patent challenges. Increased generic challenges to different types of patent claims are linked to reduced market exclusivity periods for branded drugs.

Although some domestic generic players have invested in new types of products, some have had to limit new product investment and even exit certain product markets in Canada because they cannot compete on price with lower cost suppliers. This has resulted in value destruction in the sector; stimulatory solutions should be explored by sector leaders to combat the risk of this continuing in the future.

Opportunity

Canadian generic suppliers are continuously exploring investments in expanding their product portfolios. The current Canadian regulatory and governmental environments have, however, made it difficult to justify such investments.

Recommendation

In designing supports for the generic pharmaceutical industry, consideration should be given to providing incentives that encourage companies to bring new generic medicines to Canadians. For instance, subsidies to address high costs of domestic production and importing including workforce, operations, facilities, transportation. This would promote the expansion of product portfolios in Canada, reinforcing the breadth of supply of generic medicines.

Vertical integration considerations

Challenge

The trend towards vertical integration[9] in the generics sector is important to understand when informing governmental, regulatory and organizational decision-making. Many domestic pharmaceutical companies are realizing a shift in the global sector that has seen an increase in the number of vertically integrated players.

Many international and domestic companies have explored developing, importing and manufacturing capabilities within Canada as there could be great advantages to have locally transformed products in the generics market. This could theoretically expand their product offerings at reduced costs. In this scenario, the Canadian market would also be less reliant on foreign suppliers that would otherwise be responsible for the packaging and labelling of such products. Another advantage for vertical integration is a company's ability to control and manage the various parts of its value chain aligned to its strategy and potentially create a more outcome driven, patient-centric corporate culture.

Case study 1: Strengthening the generic sector

Scenario: Leslie, the CEO of an international vertically integrated generic pharmaceutical company, is evaluating whether her organization should invest in expanding its Canadian manufacturing operations. Leslie knows that her company has many more generic products that could be offered in Canada and is interested in producing products domestically. As she starts on the business case, Leslie knows that the barriers to the Canadian generics sector are high. Unique and complex regulations as well as high operating costs will be particularly challenging to justify. After incorporating the high costs and risk assumptions associated with developing manufacturing capabilities in Canada into a business case, the organization's expected return on investment is substantially lower than Leslie had hoped. Although she had hoped to expand manufacturing operations in Canada, she will need to consider expanding her organizational manufacturing capabilities in geographic regions with lower operational costs and higher production incentives and assurances. Leslie is disappointed, as this initiative could have had such tremendous impact on the health of Canadians and the local economy.

Impact: Canadians may be sacrificing access to essential generic pharmaceuticals because it is too challenging and expensive for organizations to manufacture them domestically. Sacrificing levels of access to generic products may have negative consequences for patients' health, Although some generic medicines may not be deemed essential by governments, they are often considered essential to the Canadians that need them. Additionally, Canadians may realize the economic opportunity costs associated with loss of domestic investment, such as lost manufacturing jobs, decreased levels of infrastructure and decreased tax revenues.

Leading practice: Many countries and regions incentivize generic pharmaceutical companies to invest in domestic manufacturing capabilities by providing grants, subsidies and tax-benefits. Such incentives stimulate domestic economies, help ensure a sustainable supply of generic medicines and improve the health of native populations.

In order to feasibly diversify and expand their value chain capabilities, some companies have looked to international markets due to complexities in the local environment. These foreign companies are often able to supply Canadians with lower-cost generic products that still meet Canada's safety standards.

Opportunity

Facilities and resources are currently costly to make a compelling business case for companies to develop additional Canadian importing and manufacturing capabilities; increased government incentives could be a catalyzing tool to stimulate investments supporting companies in developing locally transformed products across its value chain.

Recommendation

Review of existing tax incentives, and additions where necessary, to support domestic manufacturing (for APIs, biosimilars and other products) should be evaluated and strengthened. This includes repealing the phasing out of the Accelerated Investment Incentive, a measure that provides tax relief on eligible newly acquired property assets and increasing the Manufacturing and Processing credit.

[9] For the purpose of this study, vertically integrated companies are defined as companies that own or control multiple value chain capabilities of the their own.

4.4 Foreign supply dependencies

It is evident that pharmaceutical suppliers bear a significant reliance on organizational partners located in foreign jurisdictions to supply Canadian citizens with generic medicines. Risks tied to foreign supplier dependencies should be taken into consideration when informing domestic generic pharmaceutical decision-making, especially as internationally integrated companies are playing increasingly important roles in national supply chains around the world. Such risks can be categorized into supply risks and economic risks. Each of which impact the level of healthcare that Canadians receive.

Under certain circumstances, international supply chain dependencies may pose great risks to the sustainable domestic supply of generics. However, it should be noted that globalization has historically played an impactful role in strengthening the Canadian and global generics sector. This section of the study serves to identify the risks Canadians bear that are associated with a highly globalized supply chain. Such risks should be considered and used for organizational, regulatory, and governmental decision making.

Supply risks

Challenge

The generics value chain has many international players and is highly complex. Many companies in Canada rely on the upstream capabilities of foreign input and finished generic product providers to supply Canadians with the medicines they need. In addition to international input and finished good producers, Canadian suppliers may also rely on the services of several different transportation and logistics providers to bring generic medicines onshore.

Case study 2: Securing the supply chain

Scenario: It's May 2020 and Joe is stressed out. Passenger flights, his usual channel to import generic prescription medicines and their ingredients, are being cancelled around the world and he is forced to explore alternative forms of transportation to fulfill orders. As head of logistics for an international generic pharmaceutical provider, he and his entire team have been on the phone for days working every relationship they have to find availability on freighters or flights that can to get product onshore. Joe knows that the APIs and finished products that he brings to Canada are essential to his hospital clients and their patients. He is unsure whether his team will be able to reliable supply his clients with the products they urgently need. Even in the best-case-scenario, Joe is forecasting that his clients' orders will be delayed by at least four months.

Impact: Extraordinary international emergencies and health crises cause the security of complex international supply chains to deteriorate. This has been evident during the COVID-19 pandemic. Canadians will unfortunately bear the health burdens associated with any international supply chain constraints because the nation is largely dependent on importing generic pharmaceutical inputs and finished products from other countries. This may lead health consequences for Canadians that are reliant on generic prescription medicines.

Leading practice: To avoid international supply chain risks and assure the sustainable supply of generics, countries are examining the benefits of strong multi-lateral partnerships with foreign trading partners and have defined agreements to take planned actions in the case of international emergencies.

The domestic supply risks associated with the highly complex and globalized generics supply chain have been captured in the following three categories:

Finished product and input reliance	High-friction international logistics	Shifting geopolitical and regulatory environments
Several Canadian suppliers source finished generic products and key inputs from foreign partners and clients around the world, such as APIs. Several domestic organizations have taken steps to diversify their international material and goods providers to mitigate the risk of any supply channel disruptions. Should an organization be reliant on few international providers, it may be exposing itself to increased supply risks, which in turn, negatively impact the reliable supply of generics for Canadians.	It can be incredibly challenging to coordinate logistic solutions to transport generic inputs and goods across the world. There are several logistics providers, channels and factors that need to be coordinated to get tangible items from point-a to point-b. Similarly, suppliers should diversify international transportation and logistics providers and channels to mitigate supply risks and cost disruption.	Shifting geopolitical and regulatory environments may pose the greatest threat to the supply of domestic generic drugs because international value chains are largely dependent on reliable trade agreements between nations. Should Canada ever, for example, place any trade restrictions on countries that the country is currently heavily reliant on, such as China or India, the nation would experience significant supply chain uncertainty; domestic suppliers would need to spend a significant amount of resources identifying alternative product and service providers in various countries

Opportunity

Some generic pharmaceutical companies in Canada are highly dependent on certain goods and services providers from specific foreign jurisdictions. Domestic suppliers have an opportunity to more reliably receive goods and services by diversifying their providers. The Canadian government can further strengthen generic supply reliability by securing trade agreements with foreign jurisdictions that domestic suppliers rely on most, including India and China.

Recommendation

The negotiation of multi-lateral trade agreements that promote the securitization of the generic pharmaceutical supply chain should be prioritized to ensure ongoing access to APIs, finished dose products and the elements necessary to support domestic production.

Economic risks

Challenge

There are several economic benefits that result from a strengthened domestic generic pharmaceutical sector. The strategic actions that domestic companies take have a significant impact on local economies.

When an organization shifts any of its Canadian manufacturing capabilities to a foreign nation with lower generic supply costs, such as China or India, there may be an opportunity cost to Canada. These negative impacts may include decreases in levels of domestic employment, infrastructure, and product exportation.

Additionally, with increased reliance on foreign suppliers for generic pharmaceutical products, companies and customers alike face increased pricing risks of products in times of health emergencies and international trade restrictions. For example, if an organization is obligated to realize prolonged cost increases associated with importing and distributing a product domestically, it may need to reconsider its corporate and/or product strategy to maintain profitability.

Opportunity

Canadian governments have an opportunity to strengthen the domestic economy by incentivizing domestic suppliers to retain their Canadian operations and to promote investment opportunities that strengthen the generics sector.

Recommendation

Appropriate pricing and procurement strategies to promote and support domestic operations should be carefully explored. These strategies must balance support for domestic manufacturing with the need for a strong international supply chain. For instance, protections against the increased costs incurred during emergent times (e.g., health emergencies or international trade restrictions). To be effective, this must be assessed at the federal and provincial/territorial levels given the diverse approaches and range of incentives across Canada and different levels of government.

4.5 COVID-19 Impacts

The impact of COVID-19 on the entire global pharmaceutical sector cannot be underemphasized. Canadian governments and regulators have been challenged with responding to a continually developing global health crisis. Domestic generic pharmaceutical companies have been responsible for maintaining high quality and safety standards and managing exceptionally volatile market conditions. The COVID-19 health crisis continues to evolve but several key impacts have been identified at the time of the writing of this report.

Workplace safety requirements

Despite the challenges to workflow and the importance of maintaining capacity, all member companies have effectively followed required workplace health and safety standards. In Ontario, physical distancing, workplace sanitation, production schedule adjusting, workforce tracking and illness reporting (Government of Ontario, 2020) were put in place. These standards impacted all areas of the value chain, from the ports of entry (docks,

airports), where raw materials arrived, to the production lines. Similar workplace health and safety standards were put in place by Quebec and other provinces / territories.

In addition to meeting these standards, many companies have taken additional steps to ensure that they can safely and effectively meet product demand as customers continue to expect high-quality assurance standards and service levels. For example, some companies have invested in hiring more full-time employees over temporary staff that would meet short-term demands but increase risks of virus exposure.

Supply chain disruptions

Challenge

As international and domestic restrictions tightened in early 2020 in response to COVID-19, demand surged for many generic pharmaceutical products. However, border closures, export restrictions, and reduced transportation capacities quickly impacted the supply of many generic products. In fact, many international logistics, freight and distribution partners of domestic generic pharmaceutical companies experienced their own challenges throughout the COVID-19 pandemic.

Use of air travel was a frequent delivery method prior to COVID-19 (as air passenger flights often transport material items commercially in their cargo cabins). However, with decreased international travel, the capacity for such distribution shrunk due to a lack of passenger flight activity. Fortunately, after a few months, many airlines converted their passenger planes to support transport of supplies albeit at increased costs.

The generics supply chain was also impacted due to shipping companies cutting corners to meet their own demand and capacity pressures. For example, some freight companies would not guarantee temperature requirements for products in transit that they had previously maintained, which introduced an untenable risk of product spoilage. This shift forced many companies to focus their energy on alternative solutions, which resulted in increased transportation costs.

Case study 3: Identifying essential medicines

Scenario: Ravi, a demand planner for a Canadian generic pharmaceutical supplier, has identified an extraordinary surge in demand for a generic product that his organization has been exploring the feasibility of developing. His hospital and pharmacy clients have communicated the urgent need for this product, as it is being used to treat Canadians suffering from a new contagious virus. Ravi's organization, in turn, is doing everything it can to accelerate the required regulatory approval process for the product so that they can quickly bring the new product to market. However, Health Canada has a backlog of drug approvals and it is unclear when the organization will be able to ramp up production and supply its clients with the medicine they required. Organizational representatives have tried their best to land the required drug on Canada's Tier 3 Drug Shortage List, which has the potential to expedite required product approvals.

Impact: Timeliness is an extremely important criteria in the health sector. When it comes to medicine supply, a matter of minutes or hours can make a significant difference in patient outcomes. Unfortunately, many Canadians are at risk of suffering the consequences of delayed product approvals that are essential to their health. Domestic generic pharmaceutical suppliers are often unable to expedite their approval and production processes to meet the health demands and requirements of Canadians. Unfortunately, lives may be at risk if a generic product required to treat Canadians in a rapidly developing health crisis is not quickly included on the Tier 3 Drug Shortage List in Canada.

Leading practice: Many foreign countries actively maintain lists of essential medicines that inform defined emergency planning strategies and support the reliable and expedited supply of essential medicines to their citizens. For example, The United States' Federal Drug Association (FDA) has published a list of essential medicines, countermeasures and critical inputs that may be required during extraordinary scenarios.

These international upstream challenges initially resulted in up to six-month lag times for generic products to be supplied in Canada. Facing the threat of supply shortages, hospitals and pharmacies looked to secure their generics inventories by actively importing and, in some cases, hoarding. There are anecdotal reports of hospitals multiplying purchase requests by up to ten times. This would have been particularly true for medications that were seen as being potential treatments for COVID-19.

To ensure the security of the value chain, generic pharmaceutical companies engaged in a range of activities, including:

- Supplying at levels consistent with 2019/2020 orders
- Companies invested in maintaining health and safety standards
- Companies focused their efforts on resolving supply chain disruptions
- To meet demand, some domestic pharmaceutical suppliers relied on safety stock
- Companies made their own decisions on how to supply hospitals (within the parameters of existing contracts) and other customers
- Production lines were staffed up and down depending on demand volatility

Product demand eased in the summer of 2020 when the situation began to stabilize. Unfortunately, many companies had increased production and imports to meet demand volatility and then accumulated product and inventory surpluses. The result was disparate with some companies importing/manufacturing at maximum capacity and realizing risks of having products expire. Some larger, more vertically integrated companies experienced less supply chain friction in meeting demand and some smaller companies fared well when handling demand volatility due to their agility.

Opportunity

Logistical challenges and supply delays for generic health products proved some of the consequential impacts of an emergency health crises on the generics sector. Canadian governments, regulators and negotiating bodies should consider such risks while developing more coordinated approaches to emergency response planning as well as current policy making.

Recommendation

Although many generic pharmaceutical companies were able to respond quickly to the COVID-19 health crisis, there should be more collaboration to develop coordinated approaches and strategies to emergency drug planning. This includes support for a Critical Drug Reserve and to further expand it by identifying a more comprehensive list of essential medicines to prepare for the next public health emergency. Additionally, emergency response planning strategies that may expedite product development while ensuring product reliability should be explored.

5. Conclusions and Recommended Next Steps

The challenges that the Canadian generic pharmaceutical sector is facing did not only arise with the onset of COVID-19. CGPA's Blueprint for a Sustainable Supply of Prescription Medicines for Canadians highlights that nearly 75% of all prescriptions are filled with generic medicines. The maintenance of supply of the majority of medicines used in ICUs and hospitals across Canada during the pandemic is largely due to the generic sector managing its supply chain during this volatile time. In the past decade, governments have prioritized downward pressure on generic pricing resulting in increased reliance on offshore manufacturing. The onset of COVID-19 has highlighted the impact and need for increased investment in domestic infrastructure, including manufacturing. It is critical for Canada's generic pharmaceutical sector to be sufficiently supported to enhance systems and processes to ensure sustainability, within a globally aligned regulatory framework.

Globally, as drug prices have decreased there has been an increase in penetration of generic pharmaceuticals indicating an increased acceptance of generic medicines. For more than a decade, governments have focused on achieving lower drug prices for generics. As a result, Canada's domestic pharmaceutical manufacturing has been weakened resulting in job losses, increased reliance on imports, and exposing Canadians to a vulnerable pharmaceutical supply chain. In the face of these concerns, governments and healthcare providers are expressing apprehensions about overreliance on external jurisdictions but, until recently, have not intervened to protect an industry that is essential to Canada's health system. This is evidenced by the data analyzed. Finished products are imported predominately from India, USA, and Austria. APIs are almost exclusively imported, with 62% coming from India and China alone. The impact of various legislation, regulation, and policy at each level of Canadian governments has resulted in a complex Canadian landscape that is sometimes difficult to rationalize when compared to foreign markets.

Domestic companies have voiced concern about the fact that federal and provincial policy and regulations can either enhance or detract from the business climate for the Canadian pharmaceutical industry. **Many members have expressed that any considerations on commercial development and investment would be on hold until significant governmental incentive and regulatory process changes are made as it is currently expensive to operate as a generic pharmaceutical supplier in Canada due to the local market being small in comparison to other nations.**

Several companies have also expressed the challenge of developing additional value chain capabilities internally due to high Canadian investment barriers. Drawbacks include high expected costs of producing generic products, including workforce, operating costs, facilities expenses, and transportation, in addition to the legal, regulatory and policy barriers to generic product approvals. As a result, many companies focus their efforts on contracting vendors or developing partnerships with domestic and foreign companies to supply and/or carry out the services they require to sustainably supply Canadians with generic medicines. Strategies for supply chain security that many companies have strategically operationalized include the use of safety stock, vertical integration with parent companies overseas, strong supplier relationships and in-depth understanding of evolving relationships across their product value chain.

While the sector has demonstrated that companies are comfortable with the overall business climate, Canadian generic companies are looking to attract greater investment opportunities to further expand and grow. In order to attract more large-scale investments, Canada must improve its ability to market its advantages versus competitors. Importing, manufacturing, and distribution capabilities within the generic pharmaceuticals **sector** support Canadian job creation. Highly skilled labour pools and a stable economic climate are often highly cited as to why foreign businesses have invested in Canada. Sales of generic drugs, both domestically and internationally, also contribute to increasing Canada's GDP. Investing in the sector can allow companies to increase the volume and breadth of products that are manufactured and increase the degree of vertical integration of manufacturers. These activities can allow for continued **sector** growth and development.

As part of ensuring sustainable practices beyond the pandemic, the generics sector should also consider the clinical relevance and influence of providing a range of product offerings and services that are patient centric. Patients are becoming engaged and active consumers, forcing the health industry to transform. Generic pharmaceutical companies should recognize and ensure that they are investing in developing medicines that the market wants, differentiating their product and service offerings more effectively and preserving the value of the products they currently make. There is a profound shift in perspective around health toward well-being and wellness, greater convenience, flexibility, self-direction and personal experiences. Healthcare consumerism is on the rise, driven by individuals bringing a very different perspective to health.

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