BLUEPRINT

FOR A SUSTAINABLE SUPPLY OF PRESCRIPTION MEDICINES FOR CANADIANS

CGPA

Making Patient Care Affordable

June 2020

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EXECUTIVE SUMMARY

The COVID-19 pandemic has created unprecedented challenges for supply chains for many products, including prescription medicines. Canadians have continued to have access to both their regular day-to-day medicines and the additional products needed to treat patients with COVID-19 during the pandemic period as a result of the tireless efforts of generic pharmaceutical companies. The pandemic has exposed several areas where improvements can be made to help secure a sustainable supply of prescription medicines for Canadians.

The Canadian Generic Pharmaceutical Association (CGPA) is encouraged by the renewed focus of governments on enhancing the capacity of the Canadian prescription drug industry and increasing its domestic capabilities. It is possible to strengthen Canada's existing pharmaceutical manufacturing capacity, promote a well-functioning global supply chain, and adopt a coordinated approach to better equip Canada for future health emergencies, such as the ongoing global COVID-19 pandemic, by focusing on the following three key areas:

1. Strengthening Canada's Domestic Pharmaceutical Industry

a) Investing in Canada's Pharmaceutical Infrastructure

- Help secure the viability and sustainability of Canada's pharmaceutical infrastructure with incentives, grants, guaranteed price and volume agreements, and other supports for:
    - **Production, research and development, testing and distribution facilities**
    - **Warehouse and vault capacity**
    - **Sufficient domestic reserves of active pharmaceutical ingredients**
    - **Increased safety stock of essential medicines**
    - **Increased Canadian production for hospital medicines**

EXECUTIVE SUMMARY (CONT'D)

b) Increasing International and National Regulatory Convergence and Alignment for Generic Medicines

- Broaden the scope and accelerate international regulatory alignment with trusted peer regulators such as the European Medicines Agency (EMA) and the U.S Food and Drug Administration (FDA) and remove unnecessary domestic regulatory hurdles to increase Canadians' access to safe, effective generic prescription medicines.

c) Ensuring Sustainable Pricing Levels for Non-Hospital Generic Medicines

- Review Canada's current pricing regime to ensure that it is economically feasible to manufacture medicines in Canada, and to be sufficiently competitive to acquire finished products and other inputs on the international market.

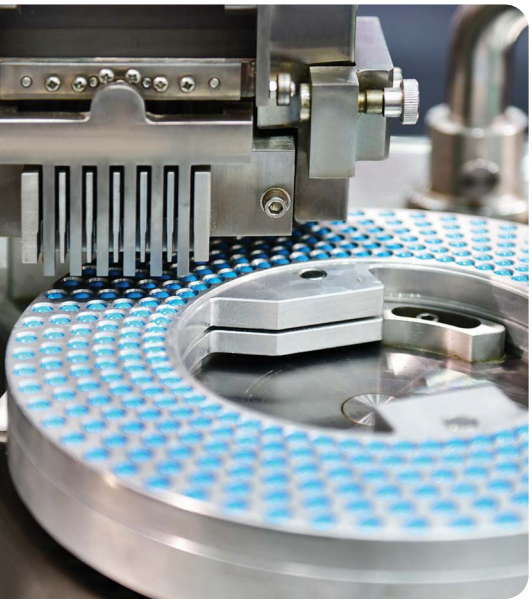
d) Increasing Generic Drug Utilization

- Increase generic medicines utilization to ensure health-care resources are being used as efficiently as possible. Canada's target should be to increase generic utilization rates from the current 73 percent of all prescriptions to 90 percent as in the United States. Based on IQVIA sales data, CGPA estimates that if the use of generic medicine in Canada were equal to the U.S. levels, Canadians would save more than $11-billion annually.

e) Building a Sustainable Domestic Market for Biosimilars

- Maximize the use of biosimilar medicines through broad implementation of well-controlled biosimilar switching initiatives for chronic therapies by public and private drug plans, including all federally-funded drug benefit programs and employee benefit programs.

- Expedite listings on provincial drug formularies without reviews that duplicate those conducted by Health Canada.



EXECUTIVE SUMMARY (CONT'D)

- Ensure sustainable pricing levels for biosimilars that reflect the high cost of doing business in Canada compared to other jurisdictions, such as the requirement to fund patient support programs, and the need to support a robust supply of biosimilar medicines for Canadians.

2. Securing and Enhancing Canada's Role in the International Pharmaceutical Supply Chain

- Prioritize the trade in high-quality generic and biosimilar medicines in all future trade negotiations and relevant international discussions, and seek greater alignment between Canada's industrial, trade and foreign policies.

3. Identifying Essential Generic Medicines to Domestically Produce and Stockpile for Canadian Needs

- Ensure a coordinated approach between federal, provincial and territorial governments to establish a list of high priority / essential medicines and then work with the generic pharmaceutical industry to put in place a plan to ensure their domestic production and / or importation.
- Build a domestic stockpile through guaranteed volume and price agreements with companies. Increasing domestic production will necessitate price and reimbursement premiums because of higher costs in the Canadian market.

Further details on these proposals are contained in the Blueprint

BLUEPRINT

FOR A SUSTAINABLE SUPPLY OF PRESCRIPTION MEDICINES FOR CANADIANS

APOTEX

Apobiologix

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Your Trusted Partner In Generics

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ABOUT

The Canadian Generic Pharmaceutical Association (CGPA) is the national association representing Canada's generic pharmaceutical industry – a dynamic group of companies who specialize in the production of high-quality, affordable generic and biosimilar prescription medicines and active pharmaceutical ingredients. Generic medicines are dispensed to fill nearly three out of every four prescriptions for Canadians.

CGPA member companies and the 11,000 Canadians that work in our industry play a vital role in Canada's economy and the sustainability of our health-care system by providing safe and effective cost-saving medicines.

THE CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION BLUEPRINT IDENTIFIES MEASURES TO:

- Enhance Canada's existing pharmaceutical manufacturing capacity and domestic capabilities
- Create a more resilient pharmaceutical supply chain with increased supply redundancy
- Ensure Canada's role within a well-functioning global supply chain
- Encourage the establishment of a more coordinated approach to equipping Canada for future health emergencies

OVERVIEW

- The COVID-19 global pandemic has increased awareness of the importance of Canada's pharmaceutical sector and the medicines companies produce, import and market for our health-care system. It has also highlighted the need for Canada to be prepared for unexpected crises.
- Unlike other industrial sectors in Canada, such as aerospace, agriculture and energy, Canada's generic pharmaceutical industry has not traditionally had access to significant government support and / or intervention to enhance its essential role in Canada's health-care system and economy.
- Government objectives and policy pursuits over the past decade, such as achieving lower prices for generic medicines, have served to weaken Canada's domestic pharmaceutical sector and resulted in job losses, increased reliance on imports, and a more vulnerable pharmaceutical supply chain for Canadians. As a result, concern is now being expressed by governments, health-care professionals and the public about increasing reliance on imports from jurisdictions that are more economically competitive for global manufacturing investment, such as China and India.
- The vulnerability of the supply chain became more evident in April 2020, when Canadian jurisdictions dramatically increased their demand of companies for critical hospital products used in Intensive Care Units (ICUs) to treat patients with COVID-19.
- Part of the problem extends beyond Canada's borders. The nature of the global pharmaceutical supply chain requires an increased focus and concerted effort by the Government of Canada to ensure Canadians are able to access the prescription medicines they need.
- Other parts of the problem require changes to Canada's regulatory and pricing regimes, which have weakened domestic capacity and the industry's position globally for more than a decade.

THREE KEY AREAS OF FOCUS

1. Strengthening Canada's Domestic Pharmaceutical Industry

2. Securing and Enhancing Canada's Role in the International Pharmaceutical Supply Chain

3. Identifying Essential Generic Medicines to Domestically Produce and Stockpile for Canadian Needs

STRENGTHENING CANADA'S DOMESTIC PHARMACEUTICAL INDUSTRY

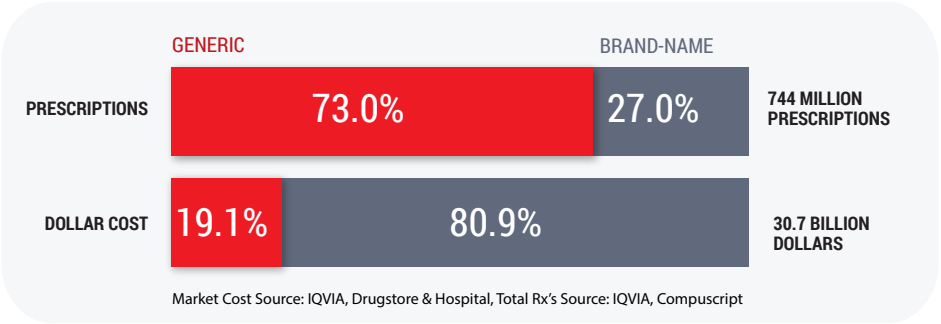
- Compared with many countries that must rely solely on importing their prescription medicines, Canada is fortunate to have extensive domestic generic pharmaceutical manufacturing capacity and capabilities. This is particularly important in times of health crises such as the current COVID-19 pandemic.
- This capacity includes manufacturing, testing, packaging, warehousing distribution and research and development facilities based primarily in Ontario and Quebec. Generic companies own and operate the largest pharmaceutical manufacturing facilities in Ontario, Quebec and Canada, and also own and operate the largest facility for the production of active pharmaceutical ingredients (APIs) in Canada.

CORONAVIRUS

COVID-19

- During the COVID-19 pandemic, Canada's generic pharmaceutical industry has been able to respond directly to current needs and proactively plan for the emerging needs of Canadians by:
    - **Redirecting domestic production to medicines that are in much higher demand in Canada and globally due to COVID-19, while also addressing potential shortages of other medications. Companies have also been able to access additional supplies of needed medicines through their global headquarters and partners.**
    - **Working with the federal / provincial / territorial governments, public health agencies, hospitals and our international partners to help develop lists of essential drugs that are needed now, and for stockpiling in the event of subsequent pandemic waves.**
    - **Ramping up / redirecting production to increase supplies of prescription medicines that might be useful treatments for COVID-19 for clinical trials.**
    - **Providing donations of products needed to protect front-line workers, including personal protective equipment (PPE) such as N95 masks, gloves, gowns and hand sanitizers.**
- The generic pharmaceutical industry in Canada directly employs some 11,000 Canadians in well-paying jobs with benefits. In addition to providing an essential service for our health-care system, these are the kinds of jobs that sustain families and communities, and will contribute to the economic stimulus Canada will need to emerge from the COVID-19-induced economic crisis. These are also the kinds of jobs that jurisdictions around the world are actively seeking to attract and retain.
- Five of CGPA's member companies have manufacturing capacity in Canada. These domestic facilities produce a wide range of generic prescription medicines including solid oral dosage form products such as pills and tablets, and non-solid products such as injectables, creams and ointments.

- In Canada, nearly 75 percent of all prescriptions are filled with generic medicines yet they account for only 19 percent of the nearly $31-billion Canadians spend annually on prescription drugs.



- These data highlight the essential role the generic pharmaceutical industry plays in making Canada's health-care system sustainable and providing the budget headroom needed for government and employee drug plans to be able to afford to provide new treatments for Canadian patients.
- Canadian patients have access to more than two thousand prescription medicines approved by Health Canada. It is unrealistic to believe that all of these products – or the ingredients required to produce them – could be manufactured or sourced in Canada in a sustainable way.
- The pharmaceutical industry and supply chain are fully globalized. Regardless of where manufacturing occurs, ingredients and inputs are sourced internationally.
- Even if domestic production was able to be increased to levels required to make all of the ingredients and finished medicines needed by Canadians, the production runs to serve the relatively small Canadian market – which represents less than two percent of the global pharmaceutical market – would not be economically viable under current market conditions. Prices would have to be significantly higher to reach break-even points for their manufacture.
- In addition, Canadian generic pharmaceutical manufacturers sustain their domestic manufacturing capacity through the export of high-quality medicines to other countries. Made-in-Canada generic medicines are exported to more than 100 countries, with the United States comprising the single largest and most important export market for our member companies.

- Increasing the resiliency and redundancy of the pharmaceutical supply chain, while supporting the continued viability and potential expansion of existing capacity to support domestic and global demand, would be a much more pragmatic and beneficial approach for Canadians than seeking to manufacture all medicines required by Canadians domestically.
- While total independence from foreign manufacturing is not possible, Canada could significantly improve its domestic sustainability with the implementation of a variety of measures discussed in detail below.
- Strengthening Canada's overall environment for generic and biosimilar medicines will make it a more attractive market to secure investments from firms' global headquarters and, as a result, ensure the introduction of new, cost-saving medicines in Canada without delay.

Investing in Canada's Pharmaceutical Infrastructure —

Given the diversity in manufacturers' domestic production capacity and supply chains, governments in Canada will need to engage with individual manufacturers on specific measures that are needed to enhance their domestic footprint and strengthen their international supply chains.

a) Investing in Canada's Pharmaceutical Infrastructure

- The CGPA is encouraged by the renewed focus of governments on enhancing the capacity of the Canadian prescription drug supply and domestic capabilities.
- Supporting the viability and sustainability of Canada's existing pharmaceutical infrastructure, which includes domestic manufacturing, testing, packaging, distribution and R&D facilities, will be important in ensuring a solid foundation from which to build and expand Canada's essential medicines capacity.
- While supporting domestic capacity is an important focus for governments, a broader and more holistic approach to supporting the generic pharmaceutical industry is needed to increase the resiliency and redundancy of the pharmaceutical supply chain for Canadians.
- Given the diversity in manufacturers' domestic production capacity and supply chains, governments in Canada will need to engage with individual manufacturers on specific measures that are needed to enhance their domestic footprint and strengthen their international supply chains.

- Some examples of the types of investments and supports that may be beneficial to generic pharmaceutical companies include (but are not limited to) the following:
    - Canada's generic pharmaceutical industry should be considered a strategic asset by governments, and be included in governments' discretionary incentive programs that offer benefits to priority industries in Canada. These benefits could include tax incentives, subsidies, grants and loans / credits. Such benefits should be available to assist companies in preserving existing domestic manufacturing infrastructure, refocusing and expanding domestic manufacturing infrastructure, and greenfield investment.
    - Supports for increased company warehouse capacity for manufacturing inputs and finished dosage forms may be required as Canada seeks to increase domestic inventories of these products. Support for the building and expansion of the vault capacity required for the storage of narcotic products as Canada seeks to build reserves for these types of medicines may also be needed.
    - As Canada seeks to increase domestic supplies of active pharmaceutical ingredients and safety stock for essential medicines, companies may require additional supports to address the significant financial burden associated with maintaining high stock levels of these key manufacturing inputs and medicines.
    - Companies can be incentivized to bring new and existing generic medicines to Canada through the reduction or elimination of Health Canada user fees for generic medicines.
    - Government support in terms of employee wages could be beneficial for companies considering refocusing or expanding their domestic manufacturing infrastructure. Such grants have been critical in the past.

- Stockpiling of essential products that are purchased by Canadian governments should incorporate a policy favouring companies located in Canada.
- Priority should be placed on companies located in Canada for public tenders, such as hospital tenders and those conducted by Public Services and Procurement Canada.

b) Increasing International and National Regulatory Convergence and Alignment for Generic Medicines

i) Health Canada Requirements

- Canada is a costly and complex jurisdiction for generic pharmaceutical manufacturers to operate in.
- During the pandemic Health Canada has been responsive in introducing regulatory flexibility measures while ensuring the quality and safety of Canada's drug supply. Measures such as flexibility in audit formats and increased timeframes for acceptability of GMP evidence have served to streamline review processes with the objective of getting and keeping products on the Canadian market and mitigating the potential for drug shortages.
- CGPA is supportive of this approach and recommends a review of these measures to determine which ones should remain in place post-pandemic. Moving forward Health Canada must take a risk-based approach to focusing its activities and resources on the areas of most benefit to ensure the safety of Canadian patients.
- Canadian-specific regulatory requirements make it difficult for companies to leverage global product development, which delays patient access to new generic medicines and increases costs for companies seeking to bring new generic medicines to the Canadian market.
- Broadening the criteria for the use of a drug marketed in a country other than Canada as the reference product for the approval of new generic medicines by Health Canada would allow companies to leverage data from other jurisdictions and better facilitate market access.

Increasing International and National Regulatory Convergence and Alignment for Generic Medicines –

During the pandemic Health Canada has been responsive in introducing regulatory flexibility measures while ensuring the quality and safety of Canada's drug supply.

CGPA is supportive of this approach and recommends a review of these measures to determine which ones should remain in place post-pandemic.

- Unclear requirements / pathways for Health Canada regulatory approval of generic medicines with high-barriers to market access, such as auto-injectors, inhalers and other drug-device combination products also delay the introduction of new and needed medicines in Canada.
- Building greater regulatory flexibility into the Health Canada Guidance Document Post-Notice of Compliance (NOC) Changes: Quality Document that will allow the industry to assess the changes from a more science and risk-based approach versus a "box ticking" exercise to avoid disruption of product supply and enable continued timely access of these medicines to Canadian patients.
- Much work remains for Canada to align with international regulatory partners such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).
- Canada currently has a Mutual Recognition Agreement (MRA) covering Good Manufacturing Practice (GMP) inspections in place with the EMA, the Therapeutic Goods Administration (TGA) of Australia and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). These MRAs are limited in scope to finished products and do not include inspections of active pharmaceutical ingredient (API) suppliers.
- Health Canada should explore the potential negotiation of MRAs for GMP inspections with Health Authorities that are members of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), with priority given to the negotiation of an MRA with the U.S. FDA. In addition, the MRAs should cover active pharmaceutical ingredients (APIs) in addition to finished products in order to further streamline GMP activities related to APIs.
- There must also be a review of Health Canada's revised cost-recovery framework for generic medicines, which came into effect April 1, 2020 and substantially increased fees for product submissions, labelling reviews and establishment licenses. Due to the broad range and number of products maintained by generic pharmaceutical manufacturers, these fees have hit the industry disproportionately hard. These fees should be substantially reduced or eliminated. Health Canada's performance timelines should also be reviewed.

Increasing International and National Regulatory Convergence and Alignment for Generic Medicines –

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ii) Additional Provincial Regulatory Requirements

- Canada's current complex approach to the delivery of prescription drug coverage also needs to change.
- Canada' provincial and territorial governments must eliminate red tape in the listing and interchangeability of generic pharmaceutical products on their drug benefit plan formularies that needlessly duplicates the work of Health Canada, increases costs for patients and payers and delays / restricts market access for generic pharmaceutical manufacturers.
- For example, while Health Canada determines "bioequivalence", it is Canada's provinces that are responsible for designating generic prescription medicines as "interchangeable" with their brand-name versions. This results in an uneven approach to the interchangeability of generic prescription medicines across Canada and can mean patients that have drug coverage through their employer, or who pay out-of-pocket, do not have access to more affordable generic drugs that are not covered by provincial drug benefit plans.

c) Ensuring Sustainable Pricing Levels for Non-Hospital Generic Medicines

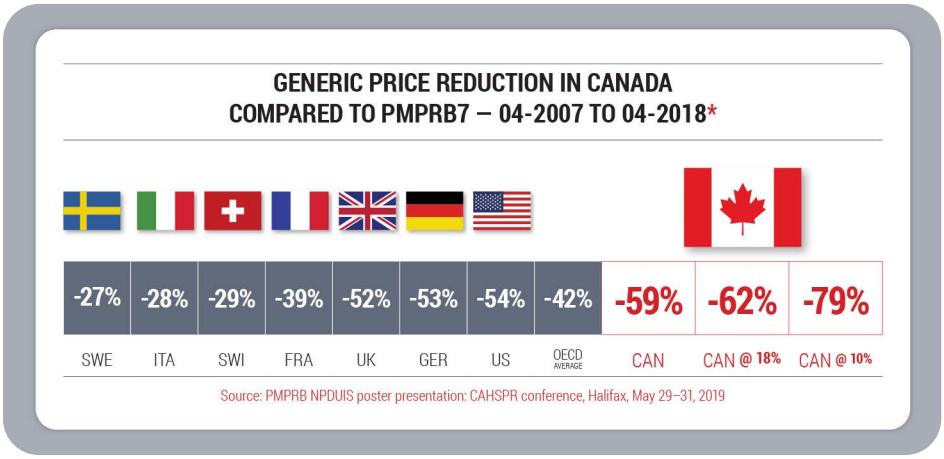
- Since the mid-2000s, there have been steep declines in the prices of generic medicines in markets around the world as governments and payers worked to better manage overall health-care costs.
- This resulted in new cost structures for companies which led to industry consolidation and an increased concentration of the production of the inputs, such as active pharmaceutical ingredients, finished medicines, in low-cost jurisdictions such as China and India.
- Data released by the federal government's Patented Medicine Prices Review Board (PMPRB) last year shows that, since 2007, the average price of generic prescription medicines in Canada has fallen by nearly 60 percent, with prices of some of the top-selling generics dropping by an average of 80 percent.[1]

Ensuring Sustainable Pricing Levels for Non-Hospital Generic Medicines –

Data released by the federal government's Patented Medicine Prices Review Board (PMPRB) last year shows that, since 2007, the average price of generic prescription medicines in Canada has fallen by nearly 60 percent, with prices of some of the top-selling generics dropping by an average of 80 percent.[1]

1. http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1468&lang=en

- While prices of generic medicines have been reduced in markets around the world, Canadian prices have experienced a steeper decline than prices in many other major pharmaceutical markets, including the PMPRB's seven comparator countries (France, Germany, Italy, Sweden, Switzerland, United Kingdom and the United States). The PMPRB's data shows that in 2018 Canadian prices for generic prescription medicines dropped to five percent below the average or mean prices of these comparator countries.[2]



Ensuring Sustainable Pricing Levels for Non-Hospital Generic Medicines –

From 2007 to 2018, Canada's average 59 percent price decline was also greater than that of the average of all Organisation for Economic Co-operation and Development (OECD) countries, which was 42 percent.[3]

- From 2007 to 2018, Canada's average 59 percent price decline was also greater than that of the average of all Organisation for Economic Co-operation and Development (OECD) countries, which was 42 percent.[3]
- While these massive price declines have saved Canadians billions of dollars, they have also required generic pharmaceutical manufacturers in Canada to carefully manage their operations in order to remain financially viable and competitive. For example, just-in-time production and limited inventories are part of the reality of cost-containment.
- In addition, it is a simple, unavoidable fact that Canada is an expensive and complex jurisdiction in which to operate compared to other countries. Some of the reasons for this include:
    - **The complex and high-cost regulatory environment generic drug makers must navigate in Canada in order to get their medicines onto pharmacy shelves and into hospitals.**

2. http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1468&lang=en
3. http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1468&lang=en

- Differences in wages and benefits paid to Canadians versus employees in low-cost jurisdictions against whom they must compete.
- Differences in taxation levels and costs of building and operating production facilities in Canada versus other lower-cost jurisdictions, such as construction, power and water.
- Canada's relatively small market size and large geographical size.

- Being a high-cost and complex jurisdiction places Canada in a challenging position in terms of enhancing the sustainability of its domestic supply.
- Further, the COVID-19 pandemic has created significant new costs for Canada's generic pharmaceutical manufacturers that they are not able to recoup given Canada's regulated, fixed-pricing regime. Some of these cost increases are due to:

  - Increased prices for finished dosage form products, Active Pharmaceutical Ingredients (APIs) and other inputs, which are sourced on the world market and where manufacturing output has been reduced in several key jurisdictions due to local lockdowns, physical distancing and other COVID-19-related restrictions.
  - Dramatic increases to transportation costs, particularly for air cargo freight, due to the suspension of most international air passenger flights that are typically used for the transportation of medicines.
  - The additional costs of ensuring facilities and employees have the proper personal protective equipment (PPE) and follow the necessary procedures to safeguard their health and that of their families, their communities and the prescription drug supply.

- A key part of ensuring the sustainability of Canada's supply of generic prescription medicines will be examining Canada's current pricing regime to ensure that it is economically feasible to produce medicines – in particular essential medicines – in Canada, and to be sufficiently competitive to acquire finished products and other inputs on the international market. This is particularly true during the global COVID-19 pandemic as countries compete to source and acquire the same medicines and manufacturing inputs that are needed by Canadians.
- In addition, reference-based pricing policies that lower the reimbursement price of entire therapeutic categories hurts the economic viability of drug products that are priced subject to the pan-Canadian Pharmaceutical Alliance (pCPA) assessed levels and threatens other policies that support sustainable pricing levels. It is especially important to ensure that pending changes by the PMPRB aimed at lowering the price of brand-name medicines in Canada are not leveraged to lower reimbursement for entire therapeutic classes, as this would undermine the domestic generic pharmaceutical industry's ability to develop and launch new cost-saving generic medicines in the Canadian market.

Increasing International and National Regulatory Convergence and Alignment for Generic Medicines –

Governments in Canada, most appropriately through the pCPA, must also work with manufacturers to develop pricing solutions that help ensure that generic pharmaceutical products with high barriers to market entry are introduced in Canada.

Generic Pharmaceutical Products with High Barriers to Market Entry

- Governments in Canada, most appropriately through the pCPA, must also work with manufacturers to develop pricing solutions that help ensure that generic pharmaceutical products with high barriers to market entry are introduced in Canada.
- These generic medicines have higher development, regulatory and manufacturing costs and include pre-filled syringes, and other drug-device combination products such as auto-injectors or inhalers, which add significantly to manufacturer's costs.
- The pCPA Tiered Pricing Framework (TPF)[4] is not currently structured to price these products at sustainable levels. Unless changes are made, generic pharmaceutical manufacturers may stop developing and marketing these products in the Canadian market, which will harm patients, force payers to reimburse the higher-priced brand-name versions and hurt generic pharmaceutical manufacturers.

4. https://www.pcpacanada.ca/generic-drug-framework

d) Increasing Generic Drug Utilization

- The ongoing sustainability of our health-care system and drug benefit plans are highly dependent on the increased use of generic prescription medicines. More must be done to increase market access for generic pharmaceutical manufacturers and the utilization of the medicines they produce.
- CGPA estimates that for every one percent increase in the use of generic medicines, Canadians save an additional $586-million. In the United States, for example, generic medicines are dispensed to fill 90 percent of all prescriptions. If the use of generic medicines in Canada was equal to U.S. levels, Canadians would have saved an additional $11-billion last year.
- CGPA recommends mandatory generic drug substitution policies to encourage patients and prescribers to choose the most cost-effective therapies, and increase patient and prescriber awareness about the equivalency of generic and brand-name prescription medicines. CGPA further encourages the adoption of "true" mandatory generic substitution policies that would mandate patients and prescribers to choose the most cost-effective therapies.
- Strategies such as charging lower co-payments for generic equivalents and addressing the negative impact of brand-name coupon cards on drug benefit plans are also important initiatives that CGPA recommends.
- Canada's provinces are responsible for designating generic prescription medicines as "interchangeable" with their brand-name version, and many insurance providers rely on public formulary lists for their mandatory generic substitution policies. In Saskatchewan and Manitoba, interchangeability is restricted to drugs that are publicly funded, which limits access to cost-saving generic versions of the many prescription drugs not covered by government drug plans. In British Columbia, Alberta, Quebec, New Brunswick, and Prince Edward Island interchangeability is left to pharmacy professional discretion, and only drugs listed on the benefit formularies are incorporated into generic substitution adjudication systems.

Increasing Generic Drug Utilization —

CGPA estimates that for every one percent increase in the use of generic medicines, Canadians save an additional $586-million. In the United States, for example, generic medicines are dispensed to fill 90 percent of all prescriptions. If the use of generic medicines in Canada was equal to U.S. levels, Canadians would have saved an additional $11-billion last year.

- As Canada looks to become better prepared for potential future waves of COVID-19 and other health emergencies, it is essential that limited health-care resources are being used as efficiently as possible. The money saved through the increased utilization of generic medicines can, for example, be invested in providing coverage for new treatments and vaccines, enhancing health services, and better protecting health-care workers and patients.

e) Building a Sustainable Domestic Market for Biosimilars

- Biologic medicines have become important treatment options across a wide number of medical conditions including rheumatoid arthritis, cancers, diabetes, growth disorders, inflammatory digestive disorders and psoriasis, but can have a high cost because they generally require a complex manufacturing process.
- The rising cost and use of biologics are putting a major strain on Canada's public and private drug programs. In 2019 biologic drugs accounted for 31.2% of Canada's drug costs but were used to fill just 1.7% of prescriptions, according to IQVIA data.
- Competition for several of these products is available in Canada with the introduction of biosimilar biologic drugs. Biosimilars are approved by Health Canada as having demonstrated similarity to a reference biologic drug and no clinically meaningful differences in safety and efficacy. CGPA member companies are among the global leaders in the development and marketing of biosimilar medicines.
- By the end of May 2020 Health Canada had approved 24 biosimilars for sale in Canada, and was reviewing an additional 15 submissions for new biosimilars.
- Many Canadian payers require the use of biosimilars for new or "biological-naïve" patients, which supports the rapid adoption of biosimilars for acute treatments, such as in oncology. Other types of biologics are used for many years to treat chronic conditions. Canadian and international experience has shown that targeted market policies are needed to support the expanded use of biosimilars in the treatment of chronic conditions.

Building a Sustainable Domestic Market for Biosimilars –

The rising cost and use of biologics are putting a major strain on Canada's public and private drug programs. In 2019 biologic drugs accounted for 31.2% of Canada's drug costs but were used to fill just 1.7% of prescriptions, according to IQVIA data.

- As the PMPRB recently noted in its two-part chart book Biologics in Canada[5] published in May 2020, "[B]iosimilars offer an excellent opportunity for significant cost savings; but this is a complex market space, and these potential savings have yet to be fully realized." The PMPRB estimates that if the uptake of biosimilars in Canada had matched the OECD median average at current prices in 2018, Canada's savings from biosimilars would have increased from an estimated $94 million to $346 million.

- The impacts of COVID-19 on Canada's health care system and economy will put cost effectiveness and value for money even more at the forefront of drug reimbursement decision making. In this context, closing the gap in biosimilar uptake between Canada and OECD countries will become critically important.

- Maximizing the use of biosimilars through well-controlled switching initiatives would contribute to system sustainability and ensure a rationale use of limited public funds. In its Biosimilar biologic drugs in Canada: Fact Sheet[6] Health Canada confirms that, "Patients and health care providers can have confidence that biosimilars are effective and safe for each of their authorized indications. No differences are expected in efficacy and safety following a change in routine use between a biosimilar and its reference biologic drug in an authorized indication."

- Such well-controlled switching policies have already been successfully implemented by the public drug programs of British Columbia and Alberta, and by private insurers such as Green Shield Canada and Pacific Blue Cross.

- Worldwide there have been at least 178 clinical trials involving approximately 21,000 switched patients which confirm that switching from an originator biologic drug to a biosimilar biologic drug is not associated with any major efficacy, safety, or immunogenicity issues.[7]

5. https://www.canada.ca/en/patented-medicine-prices-review/services/reports-studies/biologics-in-canada.html
6. https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html
7. **The Efficacy, Safety, and Immunogenicity of Switching Between Reference Biopharmaceuticals and Biosimilars: A Systematic Review**, American Society for Clinical Pharmacology and Therapeutics, March 2020, https://ascpt.onlinelibrary.wiley.com/doi/full/10.1002/cpt.1836

- Canada has been viewed by biosimilar sponsors as a market with high barriers to entry and market adoption, and has been uncompetitive in attracting biosimilar investment. Addressing the following market barriers could make Canada a more attractive place for investment in new biosimilars:

    - **Maximize the use of biosimilar medicines through broad implementation of well-controlled biosimilar switching initiatives for chronic therapies by public and private drug plans, including all federally-funded drug benefit programs and employee benefit programs.**
    - **Expedite listings on provincial drug formularies without reviews that duplicate those conducted by Health Canada.**
    - **Ensure sustainable pricing levels for biosimilars that reflect the high cost of doing business in Canada compared to other jurisdictions, such as the requirement to fund patient support programs, and the need to support a robust supply of biosimilar medicines for Canadians.**

Building a Sustainable Domestic Market for Biosimilars —

Maximize the use of biosimilar medicines through broad implementation of well-controlled biosimilar switching initiatives for chronic therapies by public and private drug plans, including all federally-funded drug benefit programs and employee benefit programs.

SECURING AND ENHANCING CANADA'S ROLE IN THE INTERNATIONAL PHARMACEUTICAL SUPPLY CHAIN

- As noted above, the pharmaceutical industry and supply chain are globalized. No matter the country in which production takes place, the vast range of medicines currently produced requires that ingredients and inputs are sourced from other countries.
- In addition, Canada's generic pharmaceutical industry exports to more than 100 countries, with the United States comprising our most important export market. Thousands of Canadian jobs are directly linked to Canadian generic pharmaceutical manufacturers having access to foreign markets, making exports essential to the industry's domestic footprint and, therefore, the security of its prescription drug supply.

Securing and Enhancing Canada's Role in the International Pharmaceutical Supply Chain –

...Canada's generic pharmaceutical industry exports to more than 100 countries, with the United States comprising our most important export market. Thousands of Canadian jobs are directly linked to Canadian generic pharmaceutical manufacturers having access to foreign markets...

- A challenge for increased Canadian production and export is that governments around the world are also looking to increase domestic production and self sufficiency in medicines and, specifically, essential medicines needed for COVID-19 and other potential health emergencies.
- It is critical for both patient access and the Canadian economy that international borders remain open for the timely import and export of prescription medicines and the inputs required to manufacture them.
- The Government of Canada must prioritize the trade in generic medicines in all future trade negotiations and relevant international discussions and seek greater alignment between Canada's industrial, trade and foreign policies.
- Canada has provided important international leadership in promoting global supply chain connectivity during the COVID-19 pandemic, particularly with respect to essential health products such as medicines. The CGPA appreciates the efforts of the Government of Canada to work with key trading partners to secure commitments to facilitate the cross-border movement of goods, services and people by maintaining open and connected supply chains throughout the pandemic.
- These efforts have helped to ensure that domestic generic manufacturers continue to have access to the active pharmaceutical ingredients, excipients and other inputs they need for manufacturing medicines for patients in Canada and other countries.
- The CGPA recommends that the Government of Canada continue its leadership in this area by promoting the benefits of a globally diverse and secure supply chain for medicines. Global Affairs Canada, working with Health Canada, should negotiate a plurilateral agreement to promote a cooperative approach to securing the Canadian pharmaceutical supply chain.

- This will help ensure diversity of supply when responding to global health challenges and natural disasters while also avoiding the potential for export controls or other barriers to trade in medicines when such challenges and disasters arise.
- In addition, coordinating the expansion of pharmaceutical manufacturing with Canadian allies will allow for economies of scale and a coordinated approach to global pandemics.
- Possible signatories to such an agreement could include countries with which Canada already has plurilateral trade agreements in place, such as our partners in CUSMA (United States and Mexico), CETA (27 Member States of the European Union) and CPTPP (Australia, Brunei, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam), as well as other important trading partners such as India, Israel, Jordan and the United Kingdom.

IDENTIFYING ESSENTIAL GENERIC MEDICINES TO DOMESTICALLY PRODUCE AND STOCKPILE FOR CANADIAN NEEDS

- The current COVID-19 pandemic has resulted in governments in Canada making a higher priority of coordinating the identification and stockpiling of essential medicines. This must continue.
- These efforts should include the inputs, such as Active Pharmaceutical Ingredients (APIs) as well as finished prescription medicines.
- The federal, provincial and territorial governments and Canada's hospital sector must take a coordinated approach to establishing a list of essential medicines and then work with the generic pharmaceutical industry to put in place a plan to ensure their domestic production and / or import.

Identifying Essential Generic Medicines to Domestically Produce and Stockpile for Canadian Needs —

The federal, provincial and territorial governments and Canada's hospital sector must take a coordinated approach to establishing a list of essential medicines and then work with the generic pharmaceutical industry to put in place a plan to ensure their domestic production and / or import.

- The list of medicines will include those drugs most needed to treat patients in hospitals as well as drugs upon which Canadians most rely that are dispensed at community pharmacies.
- To facilitate this, the essential products for Canada's stockpile should be purchased with guaranteed volume and price agreements. This will help ensure the predictability and viability of Canadian-based manufacturing and supply from international sources.
- The stockpiling effort could be enhanced by incentivizing manufacturers to build a reserve of both finished medicines and the Active Pharmaceutical Ingredients (APIs) required for their manufacture. Given the potential financial losses due to expiry of these products should they not be used, government risk-sharing with manufacturers must be a component of these measures.
- In addition, the federal government, which should coordinate these purchases, must encourage contracting with multiple suppliers and ensure, whenever possible, that no one company supplies the entire market in order to reduce Canadians vulnerability to supply disruptions.
- Increasing domestic production will necessitate price and reimbursement premiums.

CONCLUSION

- The Canadian Generic Pharmaceutical Association (CGPA) is encouraged by the renewed focus of governments on enhancing the capacity of the Canadian prescription drug supply and increasing domestic capabilities.
- Supporting the viability and sustainability of Canada's existing pharmaceutical infrastructure, which includes domestic manufacturing, testing, packaging, distribution and R&D facilities and enhanced importation channels, will be important in ensuring a solid foundation from which to build and expand Canada's essential medicines capacity.
- By implementing the recommendations in this report, it is possible to enhance Canada's existing pharmaceutical manufacturing capacity, promote a well-functioning global supply chain, and adopt a coordinated approach to better equip Canada for future health emergencies.
- Given the diversity in manufacturers' domestic production capacity and supply chains, governments in Canada will need to engage with individual manufacturers on specific measures that are needed to enhance their domestic footprint and strengthen their international supply chains.
- CGPA and its member companies look forward to working with Canadian governments and other stakeholders to turn the objective of a sustainable supply of prescription medicines for Canadians into a reality.

CGPA

Making Patient Care Affordable

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