CANADIAN GENERIC
PHARMACEUTICAL ASSOCIATION

Submission to the Advisory Council on the Implementation of National Pharmacare

September 28th, 2018

PREFERRED PARTNERS IN SUSTAINABLE HEALTHCARE

CONTENTS

Canadian Generic Pharmaceutical Association

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01 EXECUTIVE SUMMARY

CGPA and its member companies are supportive of efforts to improve prescription drug coverage for Canadians. Making prescription drugs more affordable and accessible is the key value proposition of the generic pharmaceutical industry.

- CGPA and its member companies are supportive of efforts to improve prescription drug coverage for Canadians. Making prescription drugs more affordable and accessible is the key value proposition of the generic pharmaceutical industry.
- Generic prescription medicines are dispensed to fill nearly 71 percent of all prescriptions in Canada but account for less than 22 percent of the $28-billion Canadians spend annually on prescription medicines. As this data clearly illustrates, the use of generic prescription medicines is key to the affordability of a National Pharmacare program for Canadians, no matter what model is implemented.
- All Canadian governments (with the exception of the Government of Quebec) have combined their purchasing power to negotiate massive cuts to generic drug prices through the pan-Canadian Pharmaceutical Alliance (pCPA). These prices are transparent and available to all patients and payers in Canada, whether they are covered by a public or private drug plan or pay for their prescriptions out-of-pocket.
- Previous joint efforts between pCPA and CGPA have resulted in savings of over $1 billion to participating drug plans over the past five years and will continue to save $250-million per year. The new pCPA initiative announced on January 29, 2018 is estimated to save an additional $385-million in the first year, and up to $3-billion over the next five years through a combination of price reductions and the launch of new cost-saving generic prescription medicines. Savings to patients and employers are expected to match or exceed those achieved by Canadian governments.
- In July 2017, CGPA and the Government of Quebec agreed to a separate initiative that includes similar savings over the term of the five-year agreement.
- CGPA and its member companies negotiated the five-year agreements with pCPA and Quebec in good faith, are convinced that they are good deals for all parties and expect that the terms will be respected by all parties.
- Data from 2016, published by the Patented Medicine Prices Review Board (PMPRB), show that average generic drug prices in Canada declined by nearly 50-percent from 2007, more than in any other comparator country. With the additional massive price cuts that came into force in Canada in April 2018, the top-selling generic drug prices in Canada are now below the average of comparator countries.
- CGPA cautions against the pursuit of risky tendering schemes with unknown savings results that could threaten the current and future supply of cost-saving generic pharmaceutical products in Canada. By limiting the number of suppliers for a given medicine, tendering increases the risk of drug shortages and could lead to higher prices in the long-term as manufacturers are forced out of the market. If the chosen supplier or suppliers have production or other issues, there could be few, if any, alternatives to meet patient needs. Tendering is also incompatible with Canada's current intellectual property regime for pharmaceuticals because

it removes the incentive for generic manufacturers to challenge invalid and/or non-infringed patents to bring new cost-saving generic prescription medicines to market.

- In order for the generic pharmaceutical industry to succeed in Canada and benefit Canadians, it needs a stable, predictable pricing environment and it needs cooperation from provincial, territorial and federal governments to reduce the high costs and barriers to market entry. This includes the federal regulatory system in relation to international standards, it includes the varied, duplicative and redundant individual provincial / territorial formulary listing and interchangeability rules, and it includes Canada's current pharmaceutical patent regime.
- The North American Free Trade Agreement (NAFTA) is a free trade agreement between the Canada, the United States and Mexico that is currently being renegotiated. As part of the current negotiations, the United States has tabled proposals that would lengthen periods of market exclusivity for certain brand-name drugs in Canada. If Canada were to adopt these proposals, it would add to the costs of a National Pharmacare plan by delaying access to cost-savings generic and biosimilar medicines.
- There is little doubt that a National Pharmacare program in Canada could reduce costs. The duplication caused by the varied formulary listing processes employed by each province and territory increases administrative costs for both public drug plans and pharmaceutical manufacturers and leads to uneven patient access and care across Canada. A national program could also lead to better and more efficient decision-making regarding which drugs should be covered, and how and when they should be prescribed.
- The ongoing sustainability of our health-care system and drug benefit plans is highly dependent on the increased use of generic prescription medicines. Now that Canadian prices have been dramatically cut, more must be done to increase generic utilization and the resulting savings to Canada's health-care system.

CGPA MEMBER COMPANIES

Finished Dosage Manufacturers				Industry Suppliers/ Active Ingredient Manufacturers
Mylan	ODAN	omega	pharma science	acic
SANDOZ	STERIMAX INC.	TARO	teva	CapsCanada

02 CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION (CGPA)

The Canadian Generic Pharmaceutical Association (CGPA) is the national association representing Canada's generic pharmaceutical industry. CGPA's member companies specialize in the production of high quality, affordable generic prescription medicines and active pharmaceutical ingredients. CGPA members and the 11,000 Canadians who work in the industry play a vital role in the economy and support a sustainable health-care system by providing Canadians with safe, effective, affordable prescription medicines.

CGPA'S MEMBER COMPANIES ARE GUIDED BY THE FOLLOWING PRINCIPLES:

Quality and Safety

- Steadfast commitment to meeting all Canadian and global regulatory, quality and safety requirements.
- Dedication to on-going support of health-care professionals and the patients they serve through the development and supply of safe, effective medicines.

Sustainability, Reliability and Innovation

- Providing leadership for ensuring sustainable drug benefit plans and the overall Canadian health-care system.
- Developing and manufacturing a wide range of cost-effective pharmaceutical products in current and new formats for Canadian patients.
- Ongoing support for addressing drug shortages and their root causes.
- Where viable, pro-actively challenging invalid or non-infringed pharmaceutical patents, resulting in significant cost savings to Canadians and the health-care system.

Engagement

- Pro-actively engaging with stakeholders to provide ongoing support for better patient care and build a more sustainable and cost-effective health-care system.
- Providing critical industry knowledge and support for plan sponsors and health-care professionals through on-going educational activities.

Accountability, Integrity and Social Responsibility

- Long-term, time-honoured commitment to Canada, our employees and the communities in which we live and work.
- Canadian head offices with health-care professionals to assist all stakeholders in a timely manner.
- Supporting the safe and efficient disposal of unused or expired medications.
- Donating life-saving medicines to the developing world and communities in crisis.

CGPA SUPPORTS IMPROVED PRESCRIPTION DRUG ACCESS AND COVERAGE

Increasing patient access and helping to ensure sustainability of drug benefit plans and the broader health-care system is a core value of Canada's generic pharmaceutical industry. CGPA and its member companies are fully supportive of efforts to improve prescription drug coverage for Canadians.

Engagement

Integrity

Social Responsibility

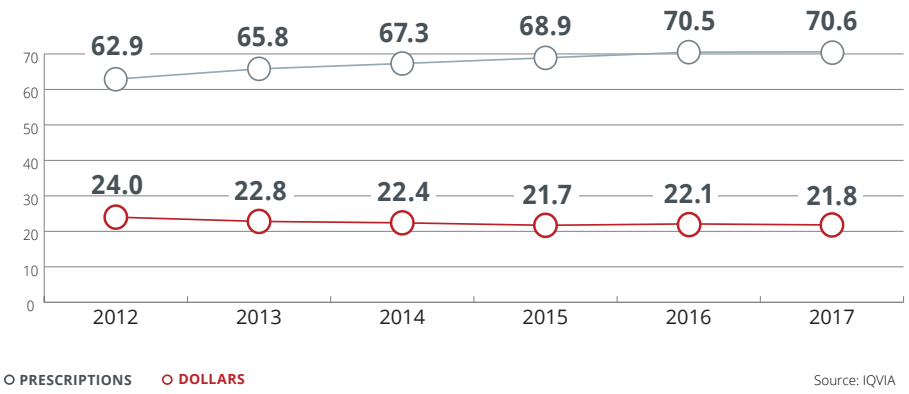
Accountability

03 CANADIAN GENERICS KEY TO AFFORDABLE AND ACCESSIBLE DRUG COVERAGE

Generic prescription medicines are key to affordable and accessible drug coverage. According to data from IQVIA, the leading source for prescription drug sales information, in 2017 generic prescription medicines were dispensed to fill nearly 71-percent of all prescriptions in Canada but accounted for less than 22-percent of the $28-billion Canadians spent on prescription medicines.

Fills **71%** of R_x for **22%** of the cost

GENERIC PERCENTAGE SHARE OF CANADIAN MARKET



Source: IQVIA

To put the cost of generics in context: In Canada, more is spent annually on health administration than on generic prescription medicines.[1]

Total Cost: **$242 Billion**
Generic Cost: **$6.4 Billion**

CANADA'S TOTAL HEALTH-CARE SPENDING – IN CONTEXT[1]

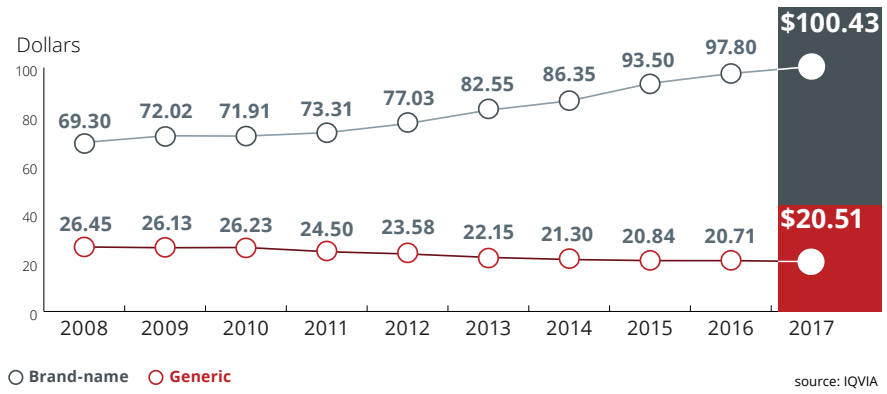
HOSPITALS	28.3%
PHYSICIANS	15.4%
DRUGS	14.0%
PUBLIC HEALTH	5.5%
ADMINISTRATION	2.9%
GENERICS	2.4%

Canada's 2017 Total spend was forecast to be 242 Billion Dollars

Data for IQVIA also shows that in 2017, the average price of a brand-name prescription was $100.43 while the average price of a generic prescription was only $20.51. The same data shows that the average price of a generic prescription in Canada has declined from $26.45 in 2008.

Brand-Name $100.43
Generic Medicine $20.51

10-YEAR AVERAGE PRICE PER PRESCRIPTION: GENERIC vs BRAND-NAME[2]

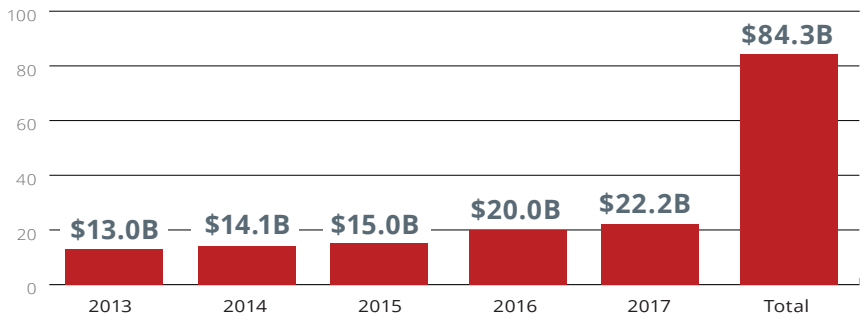


source: IQVIA

Over the past five years, the use of generic prescription medicines has saved Canada's health-care system more than $84-billion.

$84.3 Billion in Savings Over Five Years

SAVINGS OVER 5 YEARS AS A RESULT OF THE USE OF GENERIC MEDICINES*



*Methodology:

CGPA purchased IQVIA Canadian sales data used to review brand-name and generic pharmaceutical product sales from 2013 through 2017;

For each year, CGPA calculated the average annual price difference (discount) between generic prescription medicines and the brand-name versions;

CGPA used the average price differential for each year and the annual sales of generic medicines to calculate annual savings from 2013 to 2017.

04 pCPA GENERICS INITIATIVE: PAVING THE WAY FOR IMPROVED DRUG COVERAGE FOR CANADIANS

On January 29, 2018 the pan-Canadian Pharmaceutical Alliance (pCPA) and CGPA announced a new five-year initiative that will provide significant savings for all Canadians who use prescription generic drugs, participating public drug plans, and employee drug plans.

As of April 1, 2018, the prices of 67 of the most commonly prescribed generic drugs in Canada were reduced by 25 percent to 40 percent, resulting in overall discounts of up to 90 percent off the price of their brand-name equivalents. The 67 pan-Canadian Select Molecules priced at a 90 percent or 82 percent discount off the price of the brand-name versions represent more than half of all generic prescriptions dispensed in Canada in 2017.

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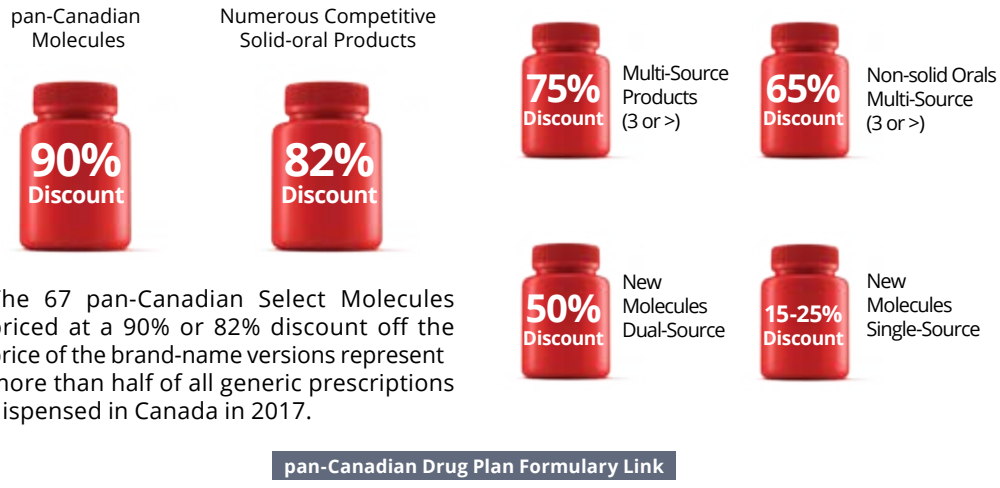
pCPA / CGPA GENERIC 2.0 PRICING FRAMEWORK

pCPA/CGPA Tiered Pricing Framework



Previous joint efforts between pCPA and CGPA have resulted in savings of more than $1-billion to participating drug plans over the past five years and will continue to save $250-million per year. The initiative that came into force on April 1, 2018 is estimated to save an additional $385-million in the first year, and up to $3-billion over the next five years through a combination of price reductions and the launch of new cost-saving generic prescription medicines. Savings to patients and employers are expected to match or exceed those achieved by Canadian governments.

The initiative that came into force on April 1, 2018 is estimated to save an additional $385-million in the first year, and up to $3-billion over the next five years ...

A key component of this initiative is that tendering will not be pursued by the participating jurisdictions over the five-year term. The generic medicines covered in this initiative are manufactured by multiple generic companies, helping to stabilize supply for Canadian patients. Pricing stability and predict-ability will also help to ensure that generic pharmaceutical manufacturers can continue to invest in bringing new cost-saving generic drugs to the Canadian market in the coming years.

In July 2017, CGPA and the Government of Quebec agreed to a separate initiative that includes similar savings and no tendering over the term of the five-year agreement.

QUEBEC 5-YEAR PRICING AGREEMENT - JULY 2017

- Savings of $1.5 billion over 5-year agreement.
- Stabilizing the supply of cost-saving generic drugs.

pan-Canadian Molecules

Numerous Competitive Solid-oral Products

- Inclusion of savings from new generic launches.
- No tendering for duration of agreement.

Government recognizes the value of the generic pharmaceutical industry to Quebec's health-care system and economy.

Savings of 1.5 Billion Dollars Over 5-Year Agreement

TIERED PRICING MODEL AND THE pCPA GENERICS INITIATIVE

The pCPA Generics Initiative employs a National Tiered Pricing Framework with different pricing levels for products depending on the number of competitors in the market. The tiered framework better reflects the market factors and realities in the pricing of generic pharmaceutical products:

- 90–82% discounts for pan-Canadian molecules;
- 75% discount for multi-source products with 3 > competitors;
- 65% discount for non-solid oral products with 3 > competitors;
- 50% discount for dual-source products;
- 25%–15% discount for single-source products.

... Reduces the Risk of Drug Shortages ...

The value of the pCPA Generics Initiative to Canada's generic pharmaceutical industry is a more stable, predictable and sustainable Canadian market. This is essential for manufacturers to make decisions regarding their investments in new product development, current product viability as well as jobs, R&D and infrastructure in Canada.

The tiered pricing model is certainly preferable to tendering or sole-source contracting schemes for pharmaceutical products, which eliminate competitors and have contributed to drug shortages when employed in the hospital sector in Canada and in other jurisdictions around the world.

It should also be noted that current retail or reimbursed prices for generic prescription medicines in Canada include the cost of distributing these products across Canada, and support for the patient services provided in community pharmacies, from coast to coast to coast.

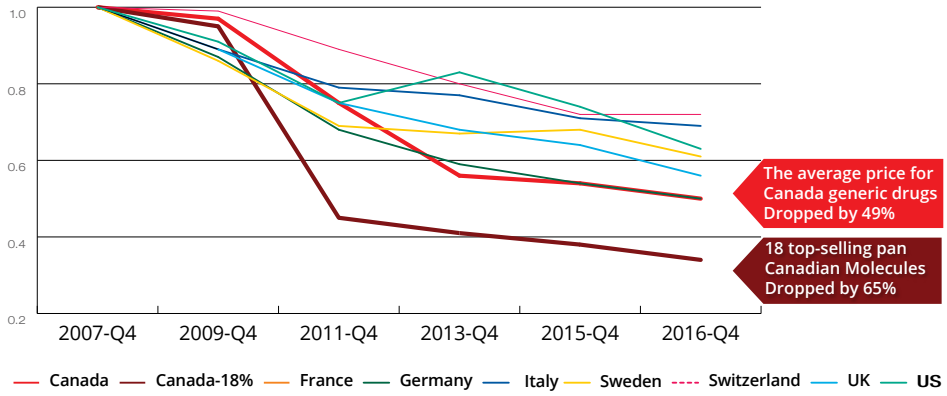
05 CANADIAN PRICES VERSUS INTERNATIONAL PRICES

The 2016 Generics360 report issued earlier this year by the Patented Medicine Prices Review Board (PMPRB) shows that average generic drug prices in Canada declined by nearly 50-percent from 2007, more than in any other comparator country.

Canadian Generics Dropped by 49%

19 Top-Selling Generics Dropped by 65%

10 YEAR CANADIAN PRICE INDEX TO SEVEN COMPARATOR COUNTRIES



01 PMPRB 2018

2015/16 DATA

Public drug plans would have paid $481M less in 2015/16 if Canada were at international median. Same report says that public drug plans would have paid $88.6M MORE if prices lower in Canada were at international median. **Not being at International median: In 2016 Canadian net increase = $392.4M**

The report stated that in 2016, the difference between median foreign and Canadian price levels for top-selling generic drugs translated into $392-million in public drug plan costs for 2015/16. Because of the age of the data the PMRPB's findings did not reflect the price cuts that took place in April 2017 and April 2018 through the pCPA Generics Initiative.

02 CNW 2017

pCPA/CGPA 2017

"Pricing Bridge Framework starting April 1, 2017 is expected to **save governments an additional $75 million next fiscal year."**

According to the news release from Canada's Health Ministers, the April 2017 pCPA generic price reductions save public drug programs an additional $75-million annually.

In the January 29, 2018 communiqué announcing the new pCPA Generics Initiative, participating jurisdictions estimated that the new initiative will save public drug plans an additional $385-million in the first year alone.

03 CNW 2018

pCPA/CGPA '17/18

"This initiative builds upon that foundation, and is estimated to **save an additional $385 million in the first year, and up to $3 billion over the next five years."**

Based on this data, participating jurisdictions are saving approximately $70-million more annually due to Canadian generic prices for these top-selling drugs being below the international median.

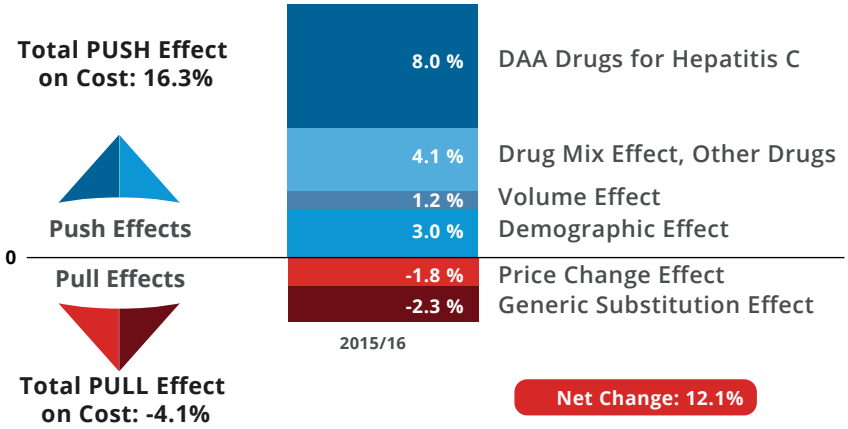
06 INCREASED GENERIC SUBSTITUTION REPRESENTS SIGNIFICANT SAVINGS OPPORTUNITY

It is important to note that the real savings to the health-care system do not come from driving down the prices of generic medicines from, for example, an 82 percent discount off the brand price to a 90 percent discount off the brand price. The real savings come from generic medicines coming to market and treatments that formerly cost, for example, one dollar per pill being available for 18 or 25 cents per pill.

In fact, the CompassRx report released by the PMPRB in May 2017 shows that the biggest "pull effect" on drug costs in Canada is shifting use from brand-name to equivalent generic products.

Highest Drug Cost Control Is Generic Substitution

PMPRB COMPASS Rx 2017 - DRUG COST DRIVERS

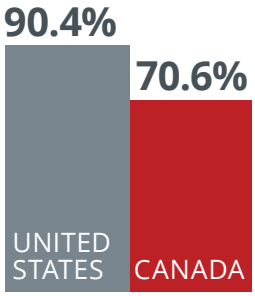


Based on data from IQVIA for the 12 months ending December 2017, CGPA estimates that for every one percent increase in the use of generic medicine Canadians would have saved an additional $527-million in 2017.

In the United States, generics were dispensed to fill 90% of all prescriptions. If the use of generic medicines in Canada were equal to U.S. levels, Canadians would have saved an additonal $10-billion in 2017.

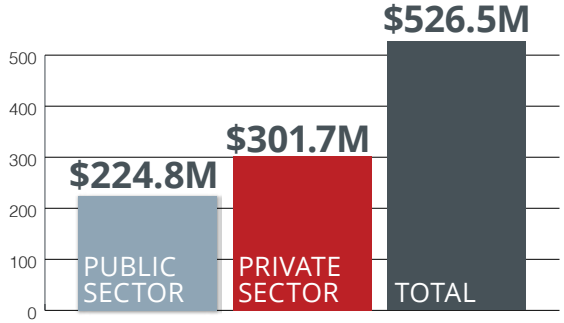
One Percent Increase in Usage = $526.5M in Savings

US vs CANADA USAGE



Source: IQVIA

SAVINGS FROM 1% INCREASE IN USE OF GENERICS[3]



07 OPPORTUNITIES FOR REGULATORY CONVERGENCE / RATIONALIZATION TO REDUCE COSTS

Canadian Context to Bring a Generic Drug to Market

There is little doubt that a National Pharmacare program in Canada could reduce costs. It should be noted that companies must look at several factors when developing a business case and deciding whether to launch a new generic in a given market. *Market size, existing competition, development and approval costs, regulatory hurdles, length of time to market and legal challenge costs must all be taken into consideration.* ***Key barriers to Canadian market entry include increasing costs of drug development, regulatory approval, patent challenges and provincial formulary listings.***[4]

Five to Seven Year Timeline for Generic Drug Development

Research & Development
Two to Three Years

01 Secure Active Pharmaceutical Ingredients (API)

- API sourced from international suppliers, or produced internally.
- 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.

02 Formulation Development

- 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 laboratory tested against originator product.
- Develop quality control matrix for formulation integrated into manufacturing.

03 Testing Manufacturing and Production

- 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.

Federal Approvals
Two to Three Years

04 Bioequivalence Studies and Clinical Trials

- Bioequivalency studies undertaken to measure the rate, 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 generic drug until relevant legal issues addressed.

05 Regulatory Legal Challenges

- *Under Patented Medicines (Notice of Compliance) Regulations* generic manufacturer is required to serve *Notice of Allegation* on the brand-name 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.

Individual Provincial & Territorial Listings
Six Months to a Year

06 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 each province/territory. It can take up to a year to have the new generic drug listed in all provinces.

Duplication caused by the varied formulary listing processes employed by each province and territory increases administrative costs for both public drug plans and pharmaceutical manufacturers and leads to uneven patient access and care across Canada.

Bioequivalence ...

All drugs (brand-name and generic) are reviewed and authorized for sale by Health Canada before they are available for prescription. A generic drug is made to act in the same way as the brand-name drug. A company must demonstrate that its generic drug is "bioequivalent" to the brand-name drug. When two drug products are bioequivalent, it means there is no significant difference in how quickly their medicinal ingredient is absorbed and achieves a certain level in the blood (bioavailability). Since 1995, Health Canada has made a *Declaration of Equivalence* for the generic drugs it approves with the specific intention that the provinces will rely on that approval as the basis for interchangeability on their drug formularies.

In their 2016 report *Ensuring a Consistent Supply of Safe, Effective and High Quality Generic Medicines for Canada*, Delloite's authors note:

The costs for bioequivalence studies and clinical trials are significant and, given the limited market size in Canada, it may not always be the best investment for a generic manufacturer to introduce the drug into the Canadian market. Generic manufacturers in e.g. Spain (population closest to Canada), can access the entire European market with approval based on a single drug dossier making the return on investment worthwhile.

The ability for Canadian generic manufacturers to take advantage of global product development and introduce drugs from other markets, such as the U.S. or EU, can result in an increased number of generic drugs becoming available in the Canadian market. In 2015, over 700 generic approvals were issued by the United States Food and Drug Administration (U.S. Food and Drug Administration, 2015) compared to 128 generic approvals by Health Canada (Health Canada, 2015).

Non-Canadian Reference Products are allowed only in very limited circumstances thus adding costs and delaying or preventing generic drug introduction in Canada.

Currently there are very limited instances where non-Canadian Reference Products are allowed to be used as comparators in studies. Increasing the possibilities of using non-Canadian Reference Products will result in additional introduction of generic drugs as it will decrease the development costs for introducing a generic drug into the Canadian market. This will allow generic manufacturers to take advantage of global development and introduce a drug in Canada which they may have already introduced in the U.S. or EU. This helps the Canadian public as they will have more access to generic drugs as well as a reduced risk of drug shortages because of the presence of multiple suppliers.[5]

Canada is the 10th largest market for prescription drugs in the world and represents 2.3% of the market. Contrast this with the U.S., which accounts for 34.3%

Impact of Market Size

of the market and EU5 consisting of Germany, France, Italy, UK and Spain which account for 15.8% of the market (IMS Institute for Healthcare Informatics, 2014). In many cases, a generic drug manufacturer may decide not to introduce a drug into the Canadian market if it is required to perform bioequivalence studies using a Canadian Reference Product as the business case might not be favourable due to high costs and a limited Canadian market compared to the U.S. or the EU. As a result, in such instances Canadian patients may be limited to branded drug products which have higher costs compared to generic drugs.[6]

While Health Canada determines "bioequivalence", it is Canada's provinces that are responsible for designating generic drugs as "interchangeable" with their brand-name versions. This results an uneven approach to the interchangeability of generic prescription medicines across Canada and can mean that patients that have drug coverage through their employer, or who pay out-of-pocket, do not have access to more affordable generic drugs not covered by provincial drug benefit plans. Since all government employees in Canada with drug coverage are enrolled in "private" drug plans, this also increases costs for governments and taxpayers.

National Interchangeability...

A national "interchangeablity" designation for generic prescription medicines in Canada is a regulatory harmonization that would reduce the cost to bring new generic medicines to market. **Deloitte Authors:**

Once Health Canada issues a Notice of Compliance, the generic drug can be sold anywhere in Canada; however, in order to maximize sales and revenue the drug must be listed on the provincial formularies, in order for it to be eligible for reimbursement by the provincial government. The formulary specifies which drugs can be reimbursed and to what extent. For a generic drug to be added to a province's formulary, in addition to having a Notice of Compliance with a Declaration of Equivalence from Health Canada, it must meet the regulatory requirements of each individual province. Some provinces may require additional data and/or clinical trials even after the drug has been approved by Health Canada, which increases the cost of introducing a generic drug to the market, delaying patient access and savings to the province. In many cases, this can result in a generic manufacturer deciding not to introduce their generic drug in one or more provinces, or in some cases, not even filing for approval of the generic drug in Canada."[7]

Not adding a generic drug to the provincial formulary has several disadvantages. It limits the access of patients to less expensive drugs with similar effectiveness.

"*Not adding a generic drug to the provincial formulary has several disadvantages. It limits the access of patients to less expensive drugs with similar effectiveness.* *Secondly, if there are no other generics in the marketplace, it limits competition for the branded drug company. Lastly, only having one supplier could increase the chance of a drug shortage if there is a disruption in supply. It is Health Canada's responsibility to determine if a generic drug is bioequivalent to a branded drug product."*[8]

As a result of Canadian specific requirements, which can prevent generic manufacturers from using global product development and/or common bulk product, the size of the Canadian market and decreasing listing prices from the provinces, making a strong business case to launch a generic in Canada is increasingly difficult.

Canada's regionally centric regulations and policies are also limiting the benefits from the globalized supply chains:

"While the regulatory framework in Canada must focus on ensuring patient safety and product quality, the existing regionally centric regulations and guidelines/policies are impeding the realization of benefits from the globalization of supply chains. Developing and/or manufacturing a product specifically for the Canadian market is an increasingly unviable option from an economic perspective. There is an increased need for harmonization of regulations as well as consolidation of best practices in the review of submissions such that Canadian companies can leverage the benefits of global supply chains. While Health Canada has been participating in the International Generic Drug Regulators Programme, the Australia-Canada-Singapore-Switzerland Consortium and the US-Canada Regulatory Cooperation Council, all of which aim to promote collaboration and convergence of generic drug regulatory programs, more needs to be done."

"Harmonizing regulations in Canada with other regulatory bodies can help generic manufacturers leverage the opportunities from globalization which ultimately benefits Canadian patients and government. The ability to leverage single product development and common bulk product will decrease costs to industry, patients and payers and decrease the time to market. It will also increase the flexibility to divert product from one market to another to minimize the potential for drug shortages. It will encourage companies to launch products in Canada by streamlining the review process, ultimately resulting in a greater variety and number of generics in Canada."[9]

Complex Molecule Pathways

Lack of generic drug pathway in Canada for certain complex molecules results in generic drugs not being introduced in the market.

There are many instances where Health Canada has not developed a generic drug pathway for complex molecules or mixtures. As a result, many of the generic drug companies are unable to introduce generic drugs into the market, even though patents have expired and generic alternatives have been introduced in other jurisdictions such as the U.S. and/or EU. In these cases, Health Canada adopts a "wait and see" approach to observe what regulatory bodies in other jurisdictions are doing. Once regulatory bodies in other jurisdictions have provided a pathway, Health Canada seems to choose the most conservative option, including requesting clinical end point studies that can be cost-prohibitive. As a result, many of the generic manufacturers decide not to introduce the drug into the Canadian market, which could have a significant cost to the Canadian public. The brand name drugs are more expensive than generics, and having only one supplier for a particular type of drug also exposes Canada to risk of drug shortages due to lack of options.[10]

Health Canada should be more proactive with establishing a generic drug pathway for complex molecules. This can be achieved by establishing a framework for introducing such generic drugs or following the lead from other regulatory bodies such as the USFDA in establishing regulatory pathways for generic drugs.[11]

... Reducing costs and barriers to market entry for cost-saving generic medicines ...

Health Canada, together with the provincial and territorial health authorities, have an opportunity and an obligation to further improve the existing regulatory framework to encourage and promote the introduction of new generic drugs into the market and to help ensure that they stay on the market based upon patient demand.[12]

In order for the generic pharmaceutical industry to succeed in Canada and benefit Canadians, it needs a stable, predictable pricing environment and it needs cooperation from provincial, territorial, and federal governments to reduce the high costs and barriers to market entry. This includes the federal regulatory system in relation to international standards, it includes the varied, duplicative and redundant individual provincial / territorial formulary listing and interchangeability rules, and it includes Canada's current pharmaceutical intellectual property regime.

DAILY COST TO PROVINCIAL FORMULARIES FROM DELAYED MARKET ENTRY*

Originator Drug* Annual Sales	Originator Drug Daily Sales	Generic Equivalent (25% of originator)	Daily Cost to Provincial Fromularies from Delayed Entry
$100,000,000	**$273,972**	**$68,493**	**$205,479**

** This example is based on using a hypothetical originator drug with annual sales of one-hundred million dollars.*

Continued price compression will also stunt the development and market introduction of new cost-saving generic and biosimilar medicines that Canadian patients and payers desperately need.

Continued price compression coupled with high costs and barriers to market entry in Canada will lead to continued decline of the generic pharmaceutical industry in Canada in terms of product development, jobs and investments.

08 TENDERING FOR GENERIC PHARMACEUTICAL PRODUCTS — A RISKY APPROACH

While CGPA and its members are supportive of efforts to improve drug coverage for Canadians, we caution against the pursuit of risky tendering schemes, such as those employed in jurisdictions such as New Zealand, with unknown savings results that could threaten the current and future supply of cost-saving generic pharmaceutical products in Canada.

... Limiting the Number of Suppliers Increases the Risk of Drug Shortages ...

Patients regularly face medicine shortages as New Zealand struggles to secure supply

BEN HEATHER
Last updated 05:00, February 6 2016

Pharmacists say drug shortages are getting worse, with shortages nearly constant.

By limiting the number of suppliers for a given medicine, tendering increases the risk of drug shortages and could lead to higher prices in the long-term as manufacturers are forced out of the market. If the chosen supplier or suppliers have production or other issues, alternatives to meet patient needs may not be available.

REUTERS World Business Markets Politics TV

HEALTH NEWS

Drug shortages prompt question: are some medicines too cheap?

Ben Hirschler

LONDON (Reuters) - Philip Aubrey buys medicines for British government-funded hospitals across London, capital of the world's fifth-largest economy, but last year he struggled to secure supplies of a basic AIDS drug.

Tendering Generic Drugs: What Are the Risks?

October, 2012

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Due to Canada's intellectual property regime for pharmaceuticals, tendering also removes the incentive for generic pharmaceutical manufacturers to challenge invalid and/or non-infringed patents and bring new cost-saving generic prescription medicines to market. Manufacturers rarely, if ever, challenge invalid or non-infringed patents in markets with tendering schemes as there is little or no reward in attempting to enter the market early if sales will be lost to a lower-priced bidder.

In *Tendering Generic Drugs: What Are the Risks*, authors Aidan Hollis and Paul Grootendorst identify the significant savings achieved for Canada's Healthcare System as a result of challenges to invalid and/or non-infringed patents.

For each of these five top-selling drugs, we estimate the savings to drug plans and consumers attributable to early generic entry in the tables below. The calculations are straightforward. Suppose that generic firms did not challenge patents, knowing that the benefits of doing so would be rapidly eroded by competitive tendering. Then generic entry would have been substantially delayed, in some cases by years.[13]

DELAYS AVOIDED BY GENERIC LITIGATION

Drug Name	Generic Entry Date	Date of Expiry of Last Patent on Patent Register	Delay in Competition if No Litigation (Days)
Ramipril	12 Dec. 2006	20 Aug. 2020	5,000
Atorvastatin	19 May, 2010	21 May 2022	4,385
Amlodipine	9 July, 2009	21 Aug. 2021	4,426
Pantoprazole	5 March 2008	8 Dec. 2018	3,930
Venlafaxine	2 Aug. 2007	12 March 2017	3,510
Average Delay			**4,250**

We estimate the savings created by generic litigation below, assuming that the average price following generic entry is 50% of the brand price. Obviously, if the generic price were lower, there would be even larger savings for payers, so these calculations are intended only to illustrate the potential magnitude of the savings.[14]

SAVINGS ACHIEVED BECAUSE OF GENERIC LITIGATION

Drug Name	Total Savings Due to Generic Litigation
Ramipril	$2.6 Billion
Atorvastatin	$7.5 Billion
Amlodipine	$2.8 Billion
Pantoprazole	$1.8 Billion
Venlafaxine	$1.6 Billion
Total Savings from Five Top-selling	**$16.3 Billion**

... pCPA / CGPA Tiered Pricing Framework maintains the incentive to bring new cost-saving generic medicines to market ...

Unlike pricing mechanisms such as tendering schemes, the Tiered Pricing Framework of the pan-Canadian Pharmaceutical Alliance (pCPA) Generics Initiative helps maintain the incentive for generic pharmaceutical manufacturers to challenge invalid and / or non-infringed patents under Canada's patent rules for pharmaceuticals.

It is in the interest of Canadian payers, including Canada's provinces and territories, to ensure that these incentives remain in place. The top-selling generic drug in Canada, Atorvastatin, was genericized only in February 2012 in New Zealand, almost two years later than in Canada. Olanzapine and Venlafaxine became generically available in New Zealand approximately four years later than in Canada.

Care must be taken to ensure that the most meaningful potential benefits of a National Pharmacare program are not overshadowed by pricing schemes that reduce the current and future availability of cost-saving generic prescription medicines.

National Pharmacare is about improving patient access, care and outcomes, as well as affordability.

Footnotes/Sources/Methodology:

1. Source: CIHI National Health Expenditure Trends, 1975 – 2017, IQVIA 2017
2. Source/Methodology: IQVIA, average price is based on total prices of prescriptions (price of drug plus any mark-ups and professional dispensing fees) divided by the estimated number of prescriptions dispensed in Canadian retail pharmacies (excludes hospitals, includes retail new and refills).
3. Source/Methodology: IQVIA data and CIHI public private market share. CGPA calculations.
4. Deloitte•, *Ensuring a Consistent Supply of Safe, Effective and High Quality Generic Medicines for Canadians,* October, 2016, 3
5. Ibid, 4
6. Ibid, 17
7. Ibid, 4
8. Ibid, 17
9. Ibid, 1
10. Ibid, 14
11. Ibid, 15
12. Ibid, 22
13. Aidan Hollis and Paul Grootendorst, *Tendering Generic Drugs: What Are the Risks,* October 2012, 9
14. Aidan Hollis and Paul Grootendorst, *Tendering Generic Drugs: What Are the Risks,* October 2012, 10