सत्यमेव जयते

High Commission of India
Ottawa

Canadian Pharmaceutical Market

Framework & Trends

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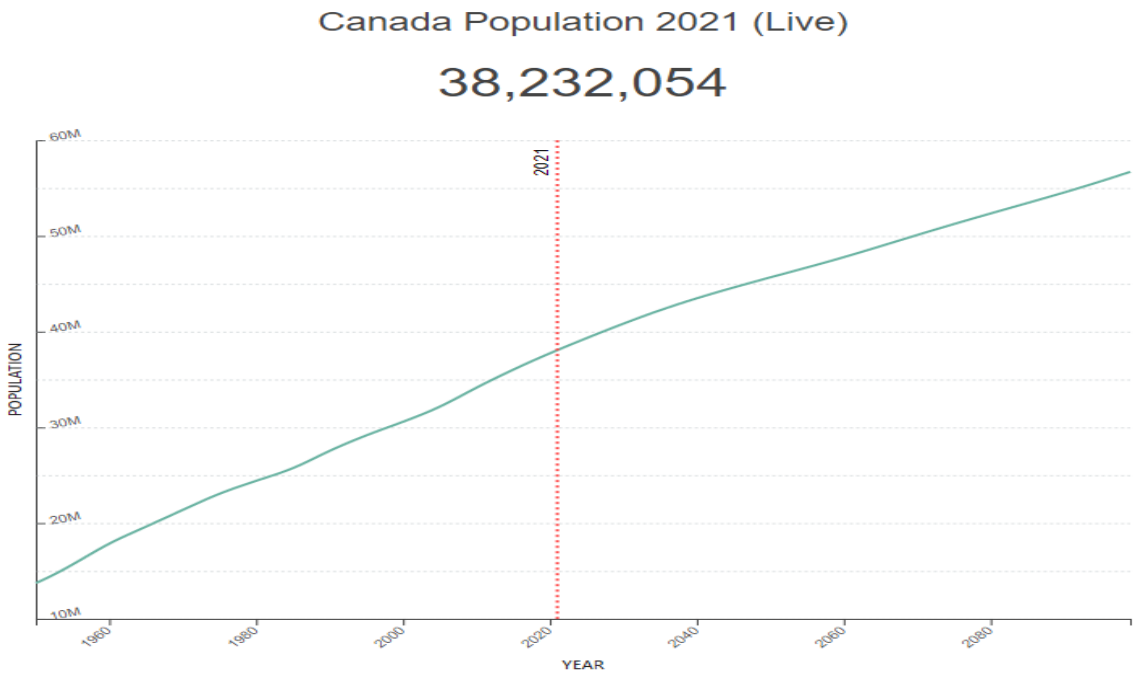
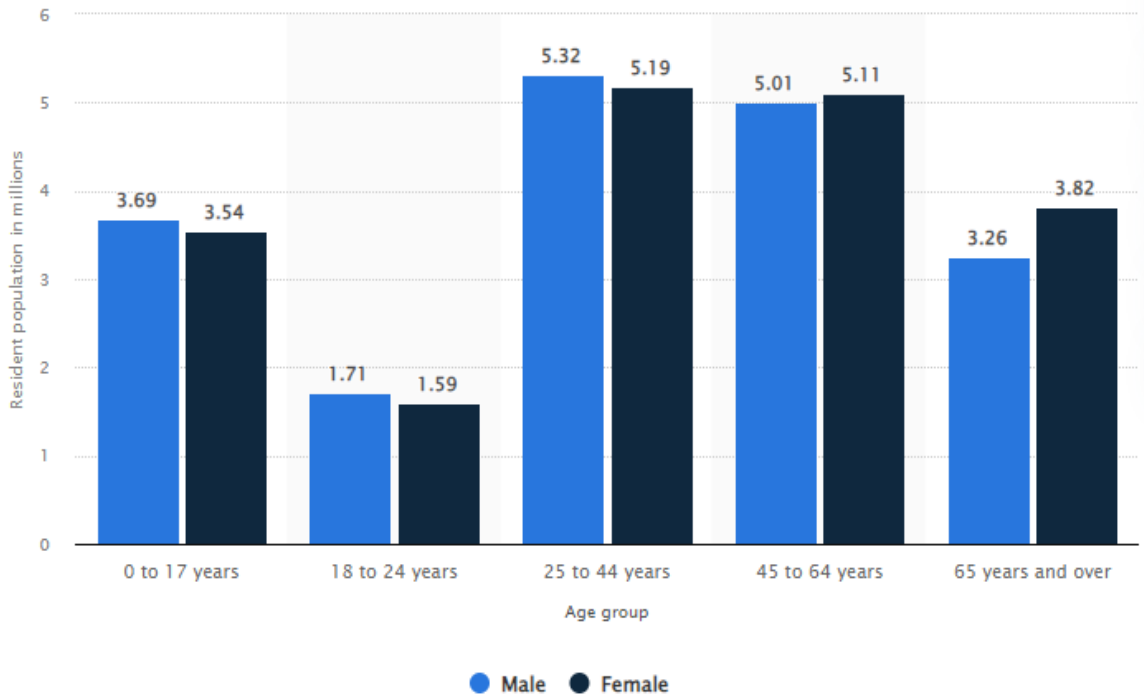
Overview

- Pharmaceutical sales in Canada have a 2.1% share of the global market
- 9th largest world market
- Compound annual growth positive at 5.1% since 2015
- Market is supported by a growing elderly population and high per capita pharmaceutical spending
- Advanced and well developed regulatory system
- Focus on research and development (R&D). Emerging fields of biopharmaceuticals include gene and cell therapies, and nanomedicines
- Brand-name products account for 81.3% of Canadian sales by value and 27.1% of prescriptions by quantity. Generics account for the rest
- Well established domestic production capacity with industry clustered around Toronto, Montreal and Vancouver
- Indian Pharma exports to Canada in reached $ 406 million in 2020, growing at CAGR of ~16%

Demographics and public spending drive healthcare demand

- Current population of 38.23 million growing and will surpass 50 million by 2070.
- Fastest growth rates of any G7 nation. Canada's growth rate has been anywhere between 0.8% and 1.2% for the past ten years.
- Fertility rate is 1.53 births per woman, below the population replacement rate but population continues to grow due to migration rate of 6.375 per 1,000 people, the eighth-highest in the world.
- Median age in Canada (2011 census) was 40.6 years (male: 39.6 years; female: 41.5 years)
- Proportion of people aged 65 years and is currently estimated at 18.5%
- Medical and Health system receives directed public support
- Despite its universal healthcare system, Canada does not offer universal, public outpatient prescription drug coverage.
- Employers often provide private drug plans, and federal/provincial/territorial drug plans are available to certain elderly and low-income populations.
- Per capita medical expenditure in 2019 @ $7063, one of the highest in the world, accounting for 10.8% of the country's GDP.
- Canada is second among OECD countries, behind the United States, in the participation of private insurers in drug spending.
- Health care spending in Canada to surge beyond $300-billion due to COVID-19
  (Health Reporter)





Expenditures on drugs

- In 2019, 56% of total health expenditures were directed to hospitals, physicians and drugs
- Pharmaceuticals are the second largest component of health care expenditures, representing 15% of total health expenditure.
- Spending on pharmaceutical continued to grow, the pace has slowed in recent years across provinces and territories.
- From 2011 to 2019, the value of total pharmaceutical sales (including non-patented over the counter medicines) in Canada have increased by $ 40.3 billion, with 86.7% sold to retail drug stores and 13.3% sold to hospitals
- Governments account for 37.2% of drug expenditures and private payers account for the remaining 62.8%

Expenditure ($ billions)			
Year	Total Health Expenditure	On Drugs	Share of Total (%)
2011	199.3	33.0	16.5%
2012	207.4	33.4	16.1%
2013	212.2	33.6	15.8%
2014	218.4	33.9	15.5%
2015	227.9	35.6	15.6%
2016	237.2	37.0	15.6%
2017	245.6	38.2	15.5%
2018	254.6	38.9	15.3%
2019	265.5	40.3	15.2%

Reference- Canadian Institute for Health Information's National Health Expenditure Report

Canadian Pharmaceutical International Trade

- Between 2011 to 2020, pharmaceutical imports into Canada increased by 58%
- In the same period, Canadian pharmaceutical exports increased by 143%
- United States accounted for 64% of exports and 29% of imports in 2020

Year	Imports (in $ billions)
2011	13.6
2012	13.5
2013	13.7
2014	15.4
2015	16.9
2016	17.2
2017	17.6
2018	19.5
2019	21.5
2020	22.6

Top 5 Exporters of Pharmaceutical Products to Canada (Thousand US$)	2020 (Jan – Nov)	2021 (Jan – Nov)	% Change 2021/2020 (Jan – Nov)	Overall Position
United States	3,834,240	6,658,571	73.7%	1
Germany	1,919,446	2,167,849	12.9%	2
Switzerland	1,923,012	1,686,236	-12.3%	3
Ireland	753,835	925,213	22.7%	4
Belgium	466,404	745,972	59.9%	5
India	368,597	402,7623	9.3%	10

Domestic Sector

- Significant manufacturing base for pharmaceutical companies
- The domestic industry is made up of about abut 140 companies, of which over 50 are research-based
- Most multi-nationals have Canadian subsidiaries
- Top 10 companies accounted for 60% of the Canadian pharmaceutical sales in 2020
- In 2020, total domestic exports of the industry reached a value of $12.7 billion
- Over half of the country's production is exported and mostly to the United States.

Leading Pharmaceutical Companies in Canada in 2020			
Rank	Companies	Total Sales ($ billions)	Market Share (%)
1	Johnson & Johnson/Actelion	4.19	13.3
2	AbbVie	1.62	5.10
3	Novartis	1.60	5.10
4	Merck/Cubist	1.59	5.00
5	Pfizer/Hospira	1.35	4.30
6	Apotex	1.22	3.90
7	Bayer	1.20	3.80
8	Roche	1.17	3.70
8	AstraZeneca	1.13	3.60
10	GlaxoSmithKline	1.07	3.40

Pharmaceutical exports from India to Canada

- Canadian Imports from India of Pharmaceutical products was ~ US$407 Million during 2020
- Growth of almost 16%
- In 2021, growth was slightly less than expected -
  - Reduction in Canadian exports to the United States
  - Reduced off take of non-COVID related medicines in Canada
  - COVID-19 related logistical and travel restrictions
- 18-20% growth expected in 2022-23

Anita Anand, Canada's then Minister of Public Services and Procurement and the High Commissioner of India to Canada, Ajay Bisaria receive 500,000 AstraZeneca Covid-19 vaccine doses in Toronto on March 3rd, 2021

Pharmaceutical Products	2018	2019	2020	CAGR	2021 (Jan – Nov)
Imports from India	261,273	309,327	406,933	15.92%	402,763
Imports from the World				4.36%	17,015,223

In US $ Thousand

Advantage India

High Growth- Pharmaceutical industry growth rate 10-12% Expected to reach $65 bn by 2024, and ~$120-130 bn by 2030. 18.7% YoY export growth

Scale- 3000 pharma companies; over 10,500 manufacturing facilities; 60,000 generic brands across 60 therapeutic categories.

Competitive- Low cost of production and R&D leading to competitive export. Cost of manufacturing ~ 33% lower than western markets. Highest quality and testing standards.

Domestic Driven- High economic growth along with increasing penetration of health insurance in India

Policy support- Additional outlay of US $26,578.3 million that will be utilised over five years for the pharmaceutical PLI scheme in 13 key sectors such as active pharmaceutical ingredients, drug intermediaries and key starting materials.

Increasing Investments- FDI in the Indian drugs and pharmaceuticals sector reached US$130 million between April 2021 and June 2021.

Largest vaccine producer in the world

Largest manufacturers and exporters of generic medicines

Indian Pharma Industry generates over $11 bn of trade surplus every year

Barriers to entry

- Provinces/territories run separate public outpatient drug plans, coverage and eligibility vary tremendously by region.
- Navigating through the different pricing regimes and administrative complexity can present challenges for companies.
- Approval process for new drugs remains difficult, and both the number of approvals and access to new drugs are below the OECD average.
- Stringent regulatory and approval systems- time and resource demanding
- Intellectual property obstacles
- Companies need a physical presence in the marketplace and the ability to drive uptake at remunerative and sustainable cost.
- COVID-19 has magnified cost pressures and brought large-scale disruption to healthcare systems and the pharmaceutical industry.

Price control of drugs in Canada

- Canada has some the highest prices for generics in the world, in part because generics are not subject to the same pricing regulations as their patented counterparts.
- Patented drug sale account for 60 percent of the total market
- The main reason that patented medication prices are lower in Canada is because of government price controls.
- The pricing and reimbursement process for innovative pharmaceuticals is controlled at three levels:
  - -Patented Medicine Prices Review Board (PMPRB)
  - -Common Drug Review (CDR)
  - -Federal and provincial/territorial bodies operating separate reimbursement regimes
- Canadian Patented Medicine Prices Review Board (PMPRB), a federal body, set-up in 1987 to regulate medication prices and limits the maximum price that can be charged for medications.
- The PMPRB prevents excessive pricing by regulating the ex-factory price of patented medicines.
- Innovative pharmaceutical companies are required to submit pricing information to the PMPRB before introducing a new product and on a semi-annual basis
- The PMPRB reviews products based on its level of therapeutic improvement
- Then applies a price by comparing it to other medicines in the same therapeutic category; reference prices from France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States; and rates of inflation
- The approval process for new drugs remains difficult, and both the number of approvals and access to new drugs are below the OECD average

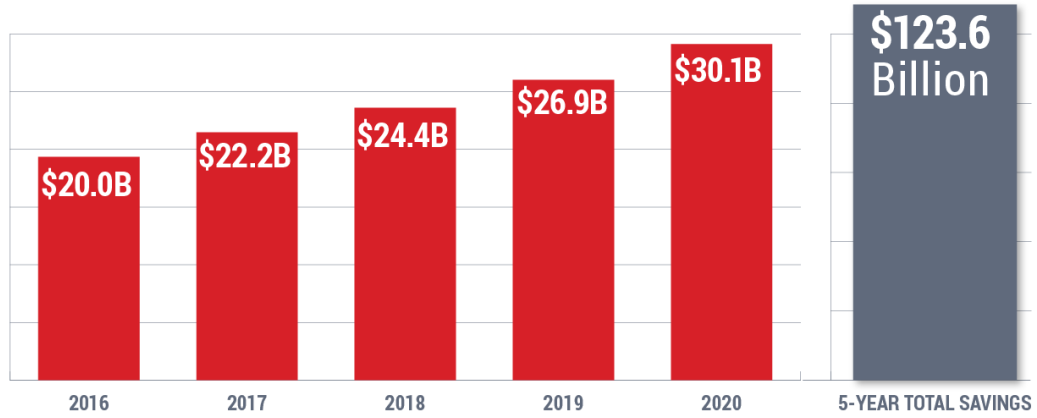
Canadian Manufacturer's Sales of Patented and Non-Patented Drugs from 2011-2019
(In $ billions)

Year	Patented	Non-Patented	Total
2011	12.9	9.2	22.1
2012	12.9	8.9	21.8
2013	13.4	8.7	22.1
2014	13.8	9.2	23.0
2015	15.1	9.4	24.5
2016	15.5	10.0	25.5
2017	16.8	10.2	27.0
2018	16.7	11.6	28.3
2019	17.2	12.7	29.9

Generic Drugs in Canada

- Generic drugs are an important area of interest under the National Pharmaceutical Strategy (NPS)
- Although Canadian patients have traditionally exhibited a strong preference for patented drugs, government cost containment measures and heavy price regulation has slowed the rate of market growth.
- The generics market is expected to grow as the government promotes generics usage and as quality perceptions improve among patients.
- Patent expirations and improved regulatory pathways for biosimilars will also bolster growth in this segment.
- Canada has some the highest prices for generics in the world

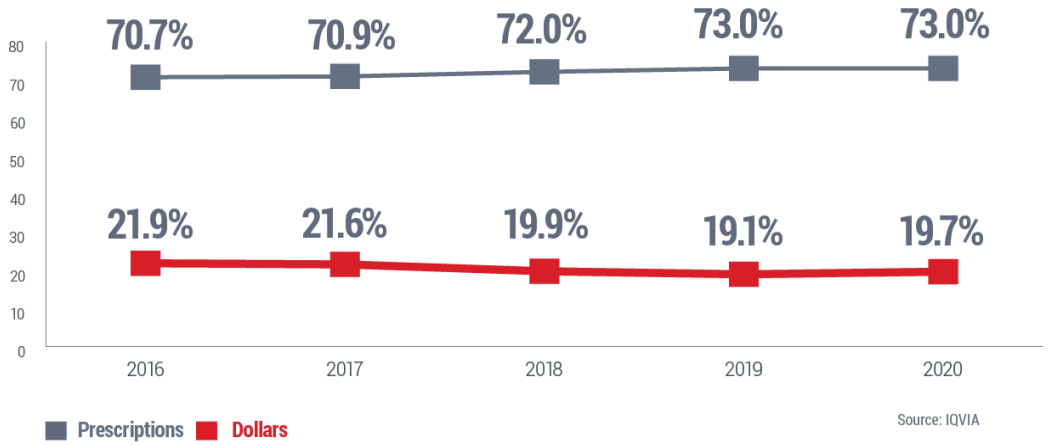
The Use of Generic Medicine Saves More Than $123-billion Over 5 Years



Source/methodology: IQVIA sales data 2016 through 20209; the annual average price difference between generic and the brand-name prescription; and annual sales of generic medicines to calculate annual savings from 2016 to 2020.

Source: IQVIA

Generic Share of the Market (Prescriptions/Dollars): 2016–2020

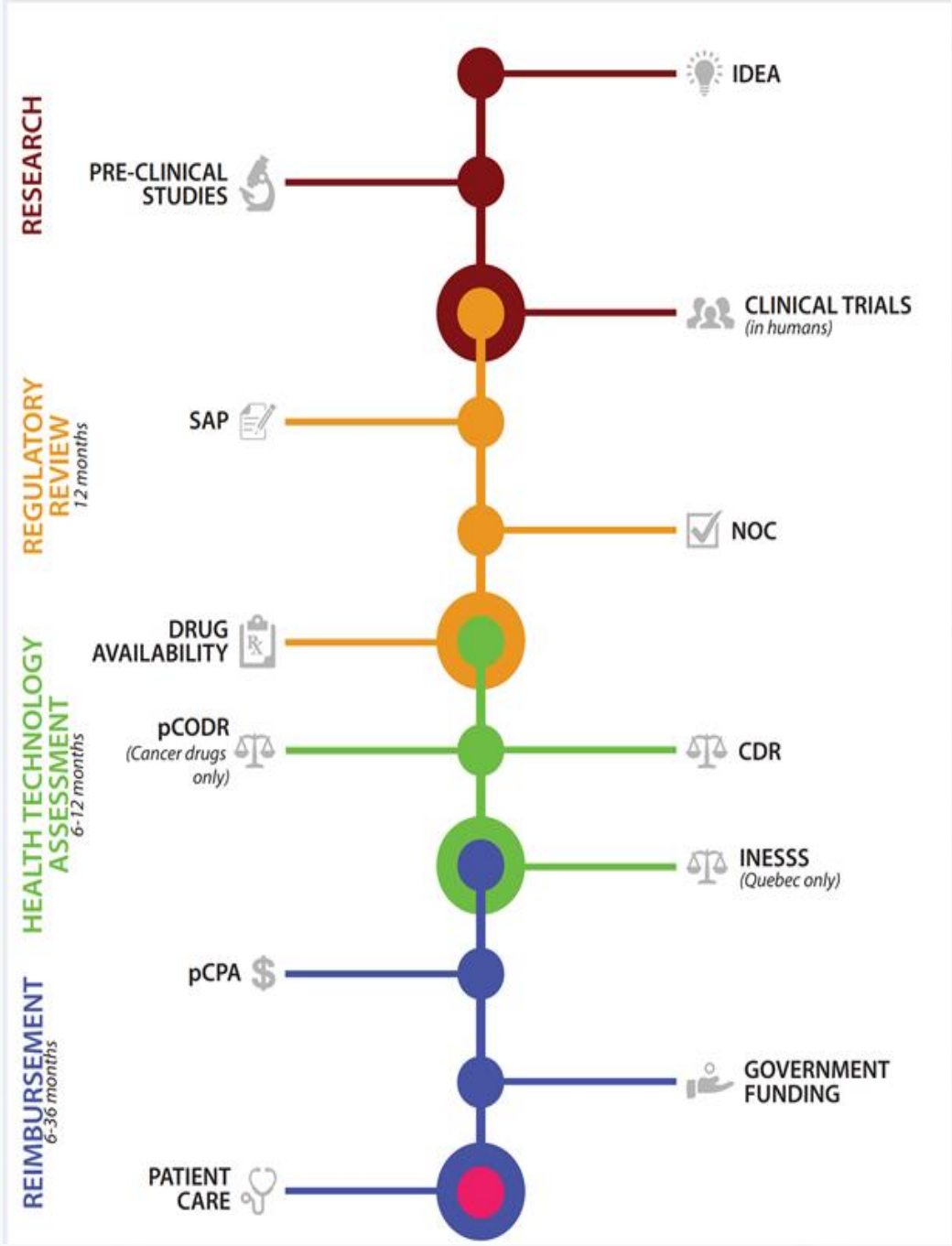


Source: IQVIA

Increased market share is a result of public and private sector drug programs relying more on cost-saving, high quality generic medicines to make patient care affordable and employee benefit plans sustainable.

Pharmaceutical importation Regulations

- Under Section C. 01.045 of the Food and Drug Regulations, the importation of Schedule F (prescription) drugs is restricted to a drug manufacturer, a registered pharmacist, a wholesale druggist, a practitioner or a resident of a foreign country while a visitor in Canada.
- Health Canada is the federal department responsible for assessing the safety of drugs
- Need to obtain a site license, which requires "the physical site in Canada where any persons (business or individual) wish to manufacture, package, label, and/or import" health products.
- Meet all of Health Canada's requirements regarding safety, sanitation, security measures and other procedures
- Important documentation for approvals and exporting to Canadian market
  - Guidance Document on the Importation Requirements for Health Products under the Food and Drugs Act and its Regulations (GUI-0084)
  - Import and Export Policy for Health products under the Food and Drugs Act and its Regulations (POL-0060)
  - Border Integrity Approach (POL-0059)
  - Policy for the Importation or Sale of Active Pharmaceutical Ingredients for Veterinary Use (POL-0018)
- More information on obtaining license may be found on Health Canada's website- Guidance Documents
- Need to obtain a Drug Identification Number (DIN) for any new pharmaceutical product, a lengthy process which requires carrying out in-depth clinical trials
- Respect all the current regulations about shipping packaging and labeling
- Natural Health Products (NHPs) (Vitamins, herbal remedies and homeopathic medicine) are not exempt– Health Canada treats them similarly to over-the-counter drugs and they require a site license and a Natural Product Number (NPN) for importation.



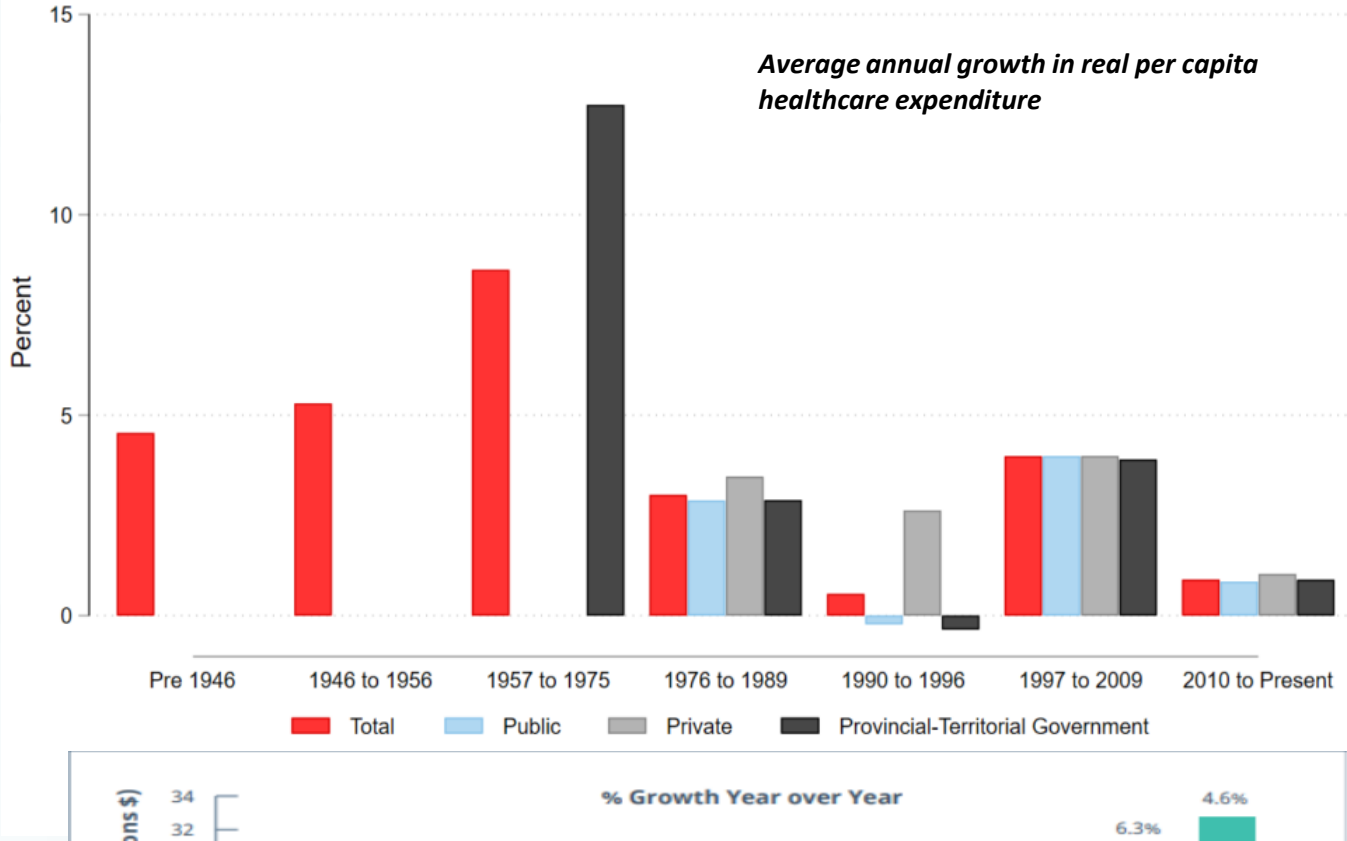
Drugs approval process in Canada

Non- MRA site inspections

- Health Canada is the federal health agency responsible for approving and regulating drugs
- It reviews new drug submissions for the purposes of safety, efficacy and manufacturing quality and issues marketing authorizations, also known as Notices of Compliance (NOC)
- Following the issuance of an NOC, it does post-market surveillance, inspections and investigations of the safety and efficacy of the drug.
- NOC reviews take on average over 13 months for chemical compounds and 21 months for biologics.
- Health Canada conducts inspections at foreign sites in what are called non-Mutual Recognition Agreement countries where Canada does not have standing agreements around drug manufacturing standards.
- Health Canada sends inspection team to the manufacturing plants, including plants in India
- Often follows lead of USFDA and can issue notices based on USFDA concerns
- Health Canada publishes information regarding emerging issues identified through the drug inspection program.
- The High Commission and our Posts liaise regularly with Health Canada for inspections in India. Visa for health inspectors is issued on priority basis to facilitate travel.

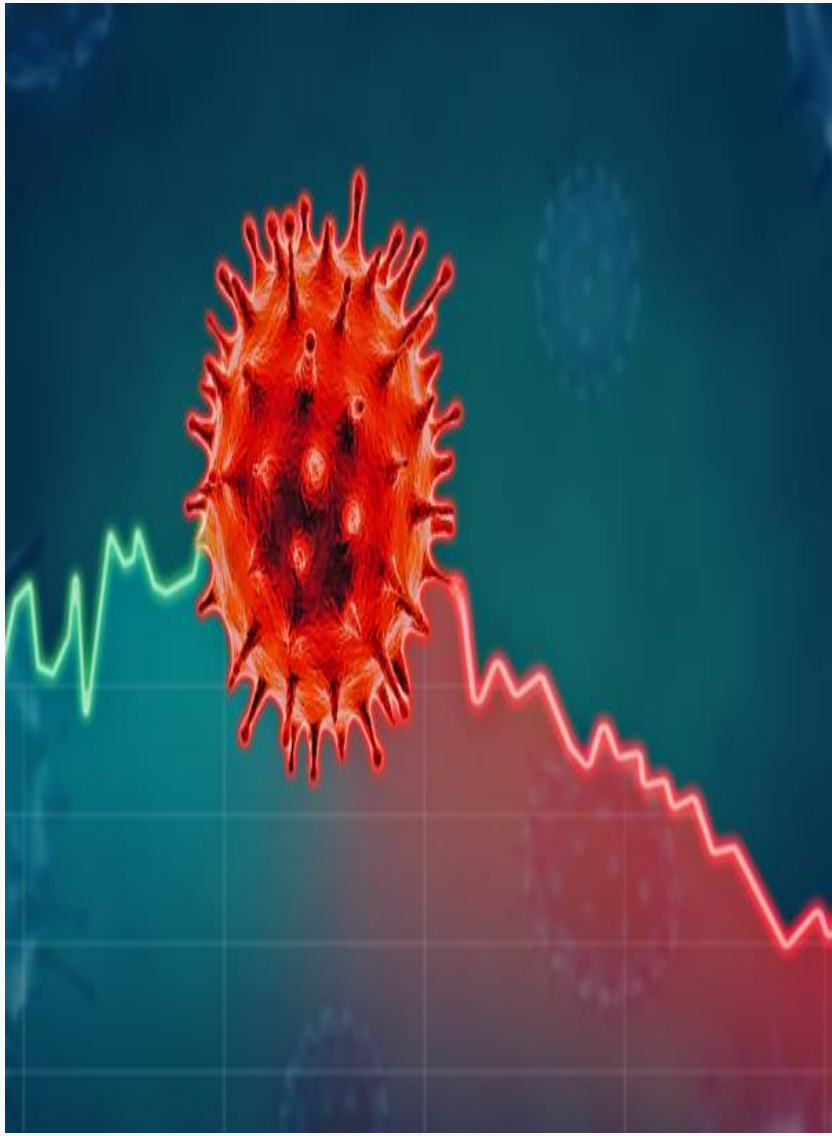
Factors affecting the market

- Rising income (with health spending being highly responsive to increases in income)
- Longer life spans, Growing and aging populations with associated demand for services
- Reduced mortality from chronic disease
- Technological change with new procedures and diagnostic techniques
- The regulatory landscape has dictated downstream demand for pharmaceuticals
- Supplier-induced demand and the rise of defensive medicine by physicians doing excessive diagnostic testing for fear of malpractice suits
- Labour productivity factors and health sector-specific price inflation
- Changes in rationing of health procedures and care quality over time by government
- Public Financial constraints- National Pharma Plan?
- Impact of COVID-19 pandemic



Trends and Growth Areas- Impact of COVID 19

- In response to the pandemic Canada has pledged $275 million to fund research
- Canada has also taken steps to allow domestic producers to obtain compulsory licensing for patented products.
- Massive procurement of COVID-19 vaccines
- Canada imposed a ban on export of prescription drugs to US
- Domestic production of PPE has increased significantly since March 2020. Many of the raw materials are locally sourced,
- The pandemic impacted use of acute medications for common infections.
  - In April 2020, average claims for acute medications, such as antibiotics for common infections, dropped by 22%.
  - Claims for acute medications did see a rise towards the latter half of 2020
- Specialty drugs continue to drive up eligible costs. They account for a third of overall costs – yet are used by just 1.3 per cent of total claimants. Most prescribed specialty drugs were for Rheumatoid arthritis, Skin disorders and Cancers
- Average eligible costs for specialty drugs increased by 8.7% for insured Canadians aged 25 to 64, compared to 1.3% for non-specialty or traditional drugs.
- Mental health claims continue to rise among insured Canadians
  - Claims for drugs used to treat depression increased by 10 per cent for adults and 22 per cent for dependents in 2020.
  - For 20–39-year-olds, the number of claimants for antidepressants climbed from the seventh most prescribed type of medicine at 5.6 per cent in 2016 to fourth spot at 7.9 per cent by the end of 2020.



Trends and Growth Areas- II

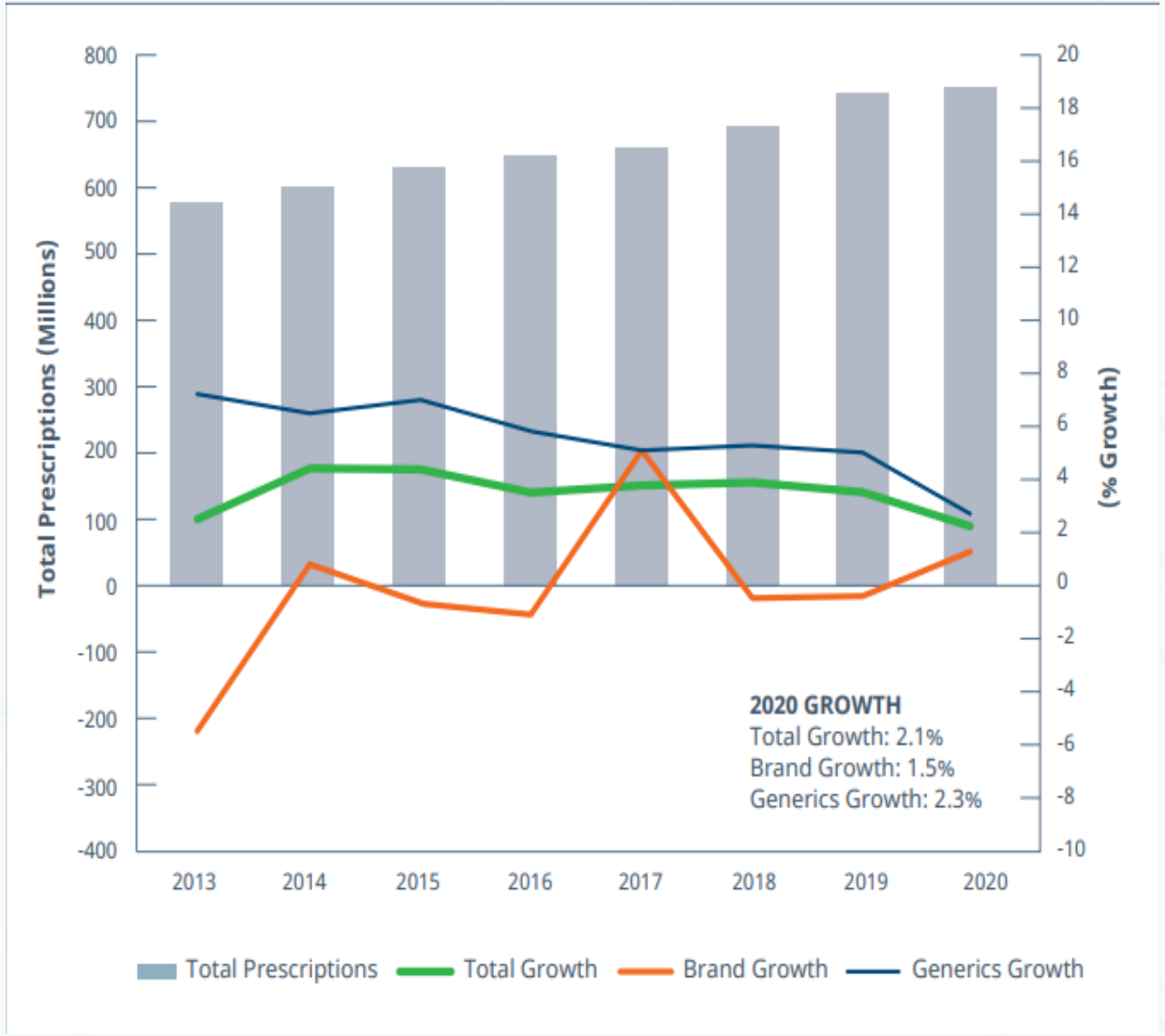
- Non-communicable diseases, such as diabetes, cancer, asthma and cardiovascular conditions, account for 97% of the total disease burden.
- Over 10 percent of the population has diabetes and 16 percent has prediabetes.
- Number of new cases of cancer is forecast to increase by 182,000 in 2012 to 246,000 in 2025
- ~8.5% of the population has asthma, which has been increasing in prevalence over the past 30 years
- 4% percent of Canadians have heart disease
- Leading therapeutic categories include medicines for arthritis, ophthalmology and autoimmune diseases
- These ten pharmaceutical products accounted for 16% of 2020 industry sales
- The generics market is expected to grow as the government promotes generics usage and as quality perceptions improve among patients.

Leading pharmaceutical products in Canada in 2020

Rank	Products	Therapeutic subclass	Total sales ($ millions)	2020 Growth (%)	Company
1	Remicade	Anti-arthritic	1,153.0	2.0	Merck
2	Humira	Anti-arthritic	931.0	8.5	AbbVie
3	Eylea	Ophtalmology	560.0	3.3	Bayer/Regeneron
4	Stelara	Autoimmune	476.0	24.0	Bayer/Regeneron
5	Epclusa	Liver health	385.0	-40.1	Gilead
6	Elquis	Blood Thinner	331.0	20.8	Pfizer/Bristol-Myers
7	Imbruvica	Autoimmune	323.0	31.8	AbbVie
8	Lucentis	Ophthalmology	318.0	-4.5	Novartis
9	Keytruda	Autoimmune	308.0	19.6	Merck
10	Xarelto	Blood Thinner	269.0	9.0	Bayer

Trends and Growth Areas- III

- Overall drug purchases in Canada are projected to continue growing.
- Over the past 20 years this spending has grown at an average annual rate of 6%, three times the average inflation rate. Annual average growth of 5.3% and 7.1% in the retail and hospital sectors, respectively.
- An analysis of prescription drug expenditures found that total prescription drug purchases in Canada in 2020 reached $32.7 billion, an increase of 4.3% from the previous year. (3.8% growth in retail, 6.9% in hospital).
- Prescription drug claims for acute care medications, such as antibiotics, saw significant declines at the onset of the COVID-19 pandemic
- Claims for specialty drugs designed to treat rarer, yet increasingly chronic diseases continue to account for a large percentage of eligible costs
- Claims for medications to treat mental health conditions also increased.
- New approvals of specialty drugs, esp. diabetes and oncology drugs and generic formulations of the top 25 drugs may influence drug purchases in 2021 to 2023.
- Bioequivalents are the next frontier.
- Emerging fields of biopharmaceuticals include gene and cell therapies, and nanomedicines



After - *Canadian Journal of Health Technologies*
Drug Data Trends & National Benchmarks ***Report***

High Commission of India
Ottawa, Canada

Commercial Wing

- Strategic advise on Canadian market
- Identification of potential business partners in Canada
- Publicity and Outreach
- Compliance Requirements
- Guide to doing business in Canada
- Sectoral Analysis
- Market Intelligence
- Technology Reporting- Tech Reporter
- Participation in Canadian Market Fairs/Exhibitions
- Visa Issues

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