CANADIAN HEALTH POLICY INSTITUTE

Patented Medicines Expenditure in Canada 1990-2022

8th Edition

Patented Medicines Expenditure in Canada 1990–2022

8TH Edition

ATTRIBUTION

This legacy paper is corporately authored and edited based on proprietary template models and methods that are intended to facilitate regular updates. The design and content are a cumulative reflection of the diverse contributions collectively attributable to the CHPI affiliated researchers who may have variously participated in updating each edition. Data sources, methods and editorial presentation may evolve from previous editions.

CURRENT CONTRIBUTORS

Brett Skinner, PhD, Canadian Health Policy Institute (CHPI)

ACKNOWLEDGMENTS

CHPI is grateful for past contributions by Mark Rovere.

EDITION

This is the 8TH edition of this paper. It builds on the concepts and methods from the original paper: Skinner BJ (2012). Drugs and the public cost of healthcare in Canada, 1974-1975 to 2011-2012. *Canadian Health Policy*, November 27, 2012. Toronto: Canadian Health Policy Institute.

VERSION

This is the CHPI authorized version. Previous versions circulated in peer review or posted to CHPI's Members preview section are working drafts only.

CITATION

Canadian Health Policy Institute (CHPI) (2024). Patented Medicines Expenditure in Canada 1990–2022. 8th Edition. *Canadian Health Policy*, MAR 2024. ISSN 2562-9492, https://doi.org/10.54194/RYJN9568, www.canadianhealthpolicy.com.

COPYRIGHT ©

GLOSSARY

Canadian Agency for Drugs and Technology in Health (CADTH)
Canadian Institute for Health Information (CIHI)
Consumer Price Index (CPI)
Gross Domestic Product (GDP)
Health technology assessment (HTA)
Institut national d'excellence en santé et en services sociaux (INESSS)
National health expenditure (NHEX)
Pan-Canadian Pharmaceutical Alliance (PCPA)
Patented Medicine Prices Review Board (PMPRB)
Patented medicines expenditure (PMEX)
Prescribed drugs expenditure (RXEX)
Private patented medicines expenditure (PRIVPMEX)
Public health expenditure (PUBHEX)
Public patented medicines expenditure (PUBPMEX)

HIGHLIGHTS

- The annual figures on national drugs expenditure reported by CIHI are commonly believed to be due to the cost of patented medicines. However, the actual gross direct cost of patented medicines is only 37% of the numbers published by CIHI:
    - For 2022, CIHI reported national spending on drugs (prescribed and non-prescribed) to be $49.4 billion including retail and hospital expenditure. CIHI numbers include ancillary costs and exclude rebates.
    - According to the PMPRB, gross national sales of patented drugs were $18.4 billion in 2022, when measured at manufacturer list prices. Net of rebates negotiated between manufacturers and publicly funded drug plans, national expenditure on patented medicines totaled $15.6 billion.
- Gross patented medicines expenditure represented only 5.5% of $334.4 billion in total national health expenditure reported by CIHI in 2022. After accounting for public sector rebates, net patented medicines expenditure was only 4.7% of total NHEX.
- Over the 33 years from 1990 to 2022, gross expenditure on patented medicines never exceeded 8.0% of national health expenditure.
- In 2022, net public expenditure on patented medicines totaled $5 billion accounting for only 2.1% of $239.9 billion in total public health expenditure.
- According to the PMPRB 2022 Annual Report, bilateral foreign-to-Canadian comparisons of patented medicines using matched products at purchasing power parity, showed average prices were higher in seven of the 11 other reference countries. We expect prices for patented drugs were also higher in the United States and Switzerland which the PMPRB no longer uses as reference countries.

 | ISSN 2562-9492

EDITORIAL SUMMARY

Is Canada's Patented Medicines Cost Control Bureaucracy Obsolete?

Following reforms to the Patent Act in 1987, which strengthened intellectual property protections for new pharmaceuticals in Canada, opponents of the changes argued that drug manufacturers would abuse their patent rights. Consequently, over the last three decades, successive provincial, and federal governments erected a multi-layered bureaucracy specifically to control the cost of **patented** medicines.

Currently several quasi-governmental corporate agencies are involved in price regulation (Patented Medicine Prices Review Board, PMPRB), health technology assessment (Canadian Agency for Drugs and Technology in Health, CADTH; and Quebec's Institut national d'excellence en santé et en services sociaux, INESSS), monopsony bargaining (Pan-Canadian Pharmaceutical Alliance, PCPA), formulary gatekeeping (Ministries of Health), and centralized procurement (vaccines procured by Public Health Agency of Canada, PHAC), plus there are active policy initiatives underway for a federal super bureaucracy (Canada Drug Agency), a single national formulary, and national universal single-payer publicly funded drug insurance (pharmacare).

The Canadian Institute for Health Information (CIHI) reported national spending on drugs totaled $49.4 billion in 2022, including retail and hospital expenditure. The numbers are an aggregate of several direct and indirect costs including public and private spending on patented and non-patented drugs, prescribed and non-prescribed drugs, and ancillary costs like pharmacist fees, public drug plan administration, and even R&D spending by pharmaceutical companies. CIHI drugs spending numbers also exclude rebates negotiated between manufacturers and public drug plans.

Only patented medicines are subject to the cost control bureaucracy. How much of the "drugs" expenditure reported by CIHI is attributable to patented drugs? Precise data from the Patented Medicine Prices Review Board (PMPRB) indicate gross national sales of all patented drugs at manufacturers list prices were $18.4 billion in 2022, or 37% of the total drugs and related expenditures reported by CIHI.

What is the burden on healthcare budgets from direct expenditure on patented drugs? After accounting for rebates, net national direct expenditure on patented medicines totaled $15.6 billion which represented only 4.7% of $334.4 billion in overall national health expenditure in 2022. In the same year, net public expenditure (provincial/territorial/federal drug plans, workers compensation boards, and mandatory social insurance and health premiums) on patented medicines was estimated to total $5 billion, or only 2.1% of $239.9 billion in total public health expenditure. These numbers refute alarmist claims about the cost of patented medicines.

Governments spend significant public resources on regulating the prices of patented medicines, and on determining eligibility for public drug insurance coverage for these drug products. A quick review of the 2022 financial statements shows that the annual budget for the PMPRB was $17 million, $57.1 million for CADTH, and $35.1 million for INESSS. Expenditures attributable to cost control activities in the remaining agencies were not calculable from available data. Nevertheless, the total cost of price regulation and HTA alone was over $109 million in 2022. These scarce resources could instead be used to pay for underfunded therapies for patients.

The bureaucratic machinery of cost control is time consuming and creates long waits for access to new medicines in publicly funded drug plans. Patients lose the opportunity to treat their health conditions earlier. The delay impacts not only their prognosis for survival and recovery, but also affects their quality of life.

 | ISSN 2562-9492

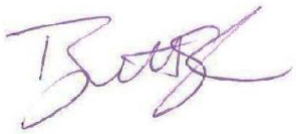
In theory, Canada's cost control agencies operate outside of the regular public service to depoliticize decision-making and are centralized at the national level equalize access to new drugs across the country's public drug plans. In practice, the agencies shield governments from democratic accountability for decisions affecting public expenditure for vital medicines and they undermine interjurisdictional policy competition that would otherwise create political pressure to cover new drugs under public formularies. Canada's patented medicines cost control bureaucracy does not work to the benefit of patients, it instead offers cover and relief to governments for rationing access to new medicines.

The system is redundant. The PMPRB and the HTA agencies CADTH and INESSS, each replicate essentially the same process used by Health Canada to evaluate the clinical evidence on the effectiveness of new drugs for marketing authorization; the price paid by public drug plans is always below the price ceiling allowed by regulation; and the ultimate decision about price and listing conditions for public insurance coverage effectively rests with each ministry of health which usually aligns with HTA and PCPA recommendations, but sometimes diverges.

The fundamental rationale for controlling the cost of patented drugs is contradicted by the facts: patents have not been abused, mainly because they do not prevent competition. Patents do not confer monopoly; they prevent competitors from profiting off someone else's innovation, but do not prohibit competition from other patented products, or from non-patented therapeutic substitutes. In fact, between-patent competition costs (i.e. lost sales revenue) the innovator at least as much as generic competition, which occurs when a drug patent term expires.[1]

Innovative pharmaceuticals improve patient health outcomes, reducing potential health system costs and indirect societal costs like economic productivity losses from untreated or under-treated illness. Excessive focus on controlling the cost of patented medicines is counterproductive. It discourages pharmaceutical manufacturers from launching new drugs in Canada, and risks limiting the availability of the most advanced therapies and reducing access to the most efficient technologies for treating diseases.

Policymakers should be trying to facilitate early adoption and broad utilization of therapeutic innovation. Healthcare resources should be allowed to flow to the most efficient uses. Germany's "managed access" approach to pharmaceutical pricing and Insurance coverage is a viable alternative to Canada's policy regime. It is based on structured negotiation instead of regulation and is designed to allow immediate interim public insurance coverage of new medicines following marketing authorization, with permanent insurance coverage pending the outcome of negotiations and adjusted for post-market health outcomes.



Brett Skinner, PhD
CEO, Canadian Health Policy Institute
Editor, Canadian Health Policy Journal

 | ISSN 2562-9492

INTRODUCTION

The purpose of this study is to: Identify net national expenditure on patented medicines in Canada; assess the affordability and sustainability of spending on patented medicines relative to changes in population, general price inflation, economic growth, and other healthcare costs; and discuss national expenditure on patented medicines in the context of the benefits of pharmaceutical innovation. The analysis uses the most recently published data from the Patented Medicine Prices Review Board (PMPRB), the Canadian Institute for Health Information (CIHI), and Statistics Canada. PMPRB data availability determined the time frame of the analysis. National sales data for patented medicines were available from 1990 to 2022. PMPRB also reported sales of "high-cost" patented medicines and oncology drugs from 2006 to 2022. Prices for patented medicines in Canada and 11 reference countries were available from the PMPRB. CIHI data on national health expenditure (NHEX) and supplemental data for gross domestic product (GDP) and population were available from 1975-2022, and for hospital expenditures from fiscal years 2005–2006 to 2021–2022. Statistics Canada data were obtained from the Consumer Price Index (CPI) which covered the years 1990-2022.

CIHI "Drugs" versus PMPRB "Patented Drugs" expenditure

In its annual NHEX trends report, CIHI publishes national publicly funded and privately funded health expenditures separately by component type or "use of funds". [**CHART 1]** The agency reports each component's associated total and per capita expenditures in current and constant dollars, and as a percentage share of national health expenditures. CIHI communications and summary publications emphasize each category's percentage share of national health expenditures, ranking them from highest to lowest. The categorization of expenditures is subjective and affects the relative weight of each category and rank relative to other components. Some component categories are narrowly defined, while others are grouped with ancillary or indirectly associated expenditures. Examples include:

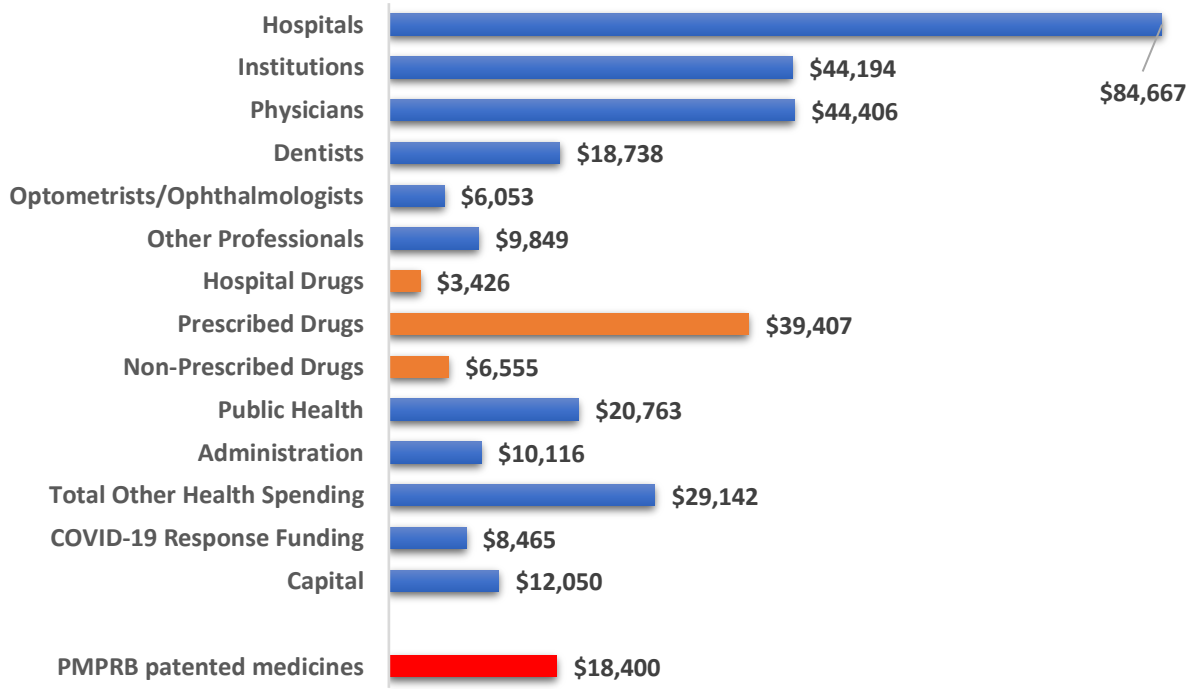
- Capital expenditures are reported separately from expenditures on hospitals and other institutions. Yet CIHI defines capital spending as consisting exclusively of "expenditures on construction, machinery and equipment of hospitals, clinics, first-aid stations and residential care facilities."[2]
- Expenditures on health professionals are reported separately for physicians, dental, vision care, and other professionals. While expenditures on nurses and other hospital-based professionals are not reported separately but are instead included under hospital expenditures. Expenditures on pharmacists are also not reported separately but are instead included under drugs expenditure.
- The administration cost of public drug insurance programs is not included under administration expenditures. Instead, it is allocated to hospitals and drugs expenditures respectively. By contrast, the administrative expenditures of public medical insurance programs are not allocated to the expenditure categories for hospitals or physicians.
- Industry expenditures on pharmaceutical research and development (R&D) are included with the drugs expenditure category instead of to the "Other: Health Research" category, misclassifying capital investment as consumption spending.[3]

 | ISSN 2562-9492

CIHI defines drugs expenditures much differently than PMPRB. **APPENDIX - EXHIBIT 1** shows the nuanced definitions quoted directly from CIHI's NHEX methodology notes. The data for "drugs" spending reported by CIHI encompass drug acquisition, plus total supply-chain, and other costs, ***including*** patented and non-patented (i.e., off-patent brands and generics) drugs, prescribed and non-prescribed drugs (except when reported separately), and non-drugs "personal health supplies" (included with non-prescribed drugs). The data are counted at final retail prices which include manufacturer prices, plus wholesale and retail price markups, pharmacy dispensing fees and taxes.[4] The data also ***include*** the administrative costs of public drug plans, and R&D spending by pharmaceutical companies.[5,6] The CIHI drugs expenditure data from the NHEX trends report ***exclude*** hospital spending on drugs, which is included in "hospital" expenditure. Data for hospital spending on drugs is reported separately by CIHI in its hospital spending trends report.[7]

By contrast, the data for "patented drugs" sales reported by PMPRB ***include*** total national sales of prescribed patented drugs at manufacturer (*ex-factory*) gross 'list' prices and includes hospital and non-hospital expenditures. The data for "patented drugs" spending reported by PMPRB ***exclude*** confidential price rebates (discounts) negotiated between manufacturers and public-sector drug plans, private-sector health insurers, wholesalers, retailers, and hospitals.[8] Both CIHI and PMPRB report drugs expenditure data without accounting for rebates negotiated between manufacturers and public drug plans. Data on the magnitude of rebates are not publicly available, but Ontario's Auditor General reported that the province's public drug plan received rebates averaging 36% on brand name drugs in the fiscal year 2016/17.[9] Ontario's rebate can be extrapolated across the country because all federal, provincial and territorial public drug plans participate in the Pan-Canadian Pharmaceutical Alliance, a national agency that negotiates with manufacturers on their behalf.

CHART 1. CIHI NHEX vs PMPRB PMEX 2022 ($ millions)



ESTIMATES

The data and calculations supporting the estimates are shown separately at the national level and by public and private sector in **TABLE 1** with references to sources and formulas.

Aggregate prescribed drugs expenditure (RXEX)

According to CIHI, in 2022 gross national drugs expenditure totaled $49.4 billion and was comprised of $39.4 billion for publicly funded ($17 billion) and privately funded ($22.4 billion) prescribed drugs (RX), plus $6.6 billion for non-prescribed drugs, and $3.4 billion for drugs dispensed in hospitals. Hospital drugs expenditures were allocated to the public prescribed drugs expenditures category because nearly all hospital costs are funded by the public sector. These numbers include ancillary costs and exclude rebates.

Net public patented medicines expenditure (PUBPMEX)

The PMPRB does not publish its national data for sales of patented medicines with a breakdown by public sector versus private sector payer. Using the data from CIHI, the first step was to isolate prescribed drugs spending because all patented medicines regulated by PMPRB are prescribed drugs; and public drug plans only pay for prescribed drugs. PMPRB publishes estimates of the percentage of public drugs expenditures accounted for by patented medicines, the percentage of public drug plan claims expenditures paid publicly (after patient deductibles and co-pays), and the percentage of public drugs expenditures accounted for by pharmacy dispensing charges. Following a stepwise calculation, we isolated the share of public spending on prescribed drugs accounted for by patented medicines (52.3%), then applied the plan paid percentage remainder after deductibles and co-pays (88%), pharmacist fees (83%), and manufacturer rebates (64%). The results represent the direct amount paid by publicly funded drug plans and hospitals, and the data breakdown as follows: public sector gross expenditures on patented medicines including ancillary costs were estimated to be almost $10.7 billion in 2022. Net of deductibles and co-pays this figure is reduced to $9.4 billion, and again to $7.8 billion net of pharmacist fees, and finally to approximately $5 billion net of rebates.

Net private patented medicines expenditure (PRIVPMEX)

Using the data from CIHI, we calculated the private sector share of national prescribed drugs expenditure (56.9%), with further breakdowns for privately insured spending (37%), and out-of-pocket spending (19.9%). The percentages were applied to the PMPRB total for all sales of patented medicines at list prices ($18.4 billion). The corresponding dollar figures estimated for net patented medicines expenditure were $10.5 billion in total for the private sector, $6.8 billion for privately insured expenditures, and $3.7 billion for out-of-pocket expenditure.

Net national patented medicines expenditure (PMEX)

To estimate national expenditures on patented medicines net of public sector rebates requires calculation of the monetary value of public sector rebates, which can be obtained by multiplying the discount percentage by public sector expenditures on patented medicines. However, because CIHI does not report patented medicines expenditures, and because PMPRB does not report expenditures separately by sector, the data must be calculated. To calculate net national patented medicines expenditure, we simply subtracted the value of the public sector rebate ($2.8 billion) from the PMPRB total sales for all patented medicines at list prices ($18.4 billion). The estimated net national expenditure on patented medicines totaled only $15.6 billion.

 | ISSN 2562-9492

TABLE 1. Calculation of net expenditure on patented medicines 2022.

NATIONAL DRUGS EXPENDITURES AS REPORTED BY CIHI 2022.

LINE	DESCRIPTION	$MILLIONS	DATA SOURCE
A	Prov/Terr prescribed (RX) drugs	$14,007	CIHI (2023). NHEX TRENDS
B	Federal direct RX drugs	$1,236	CIHI (2023). NHEX TRENDS
C	WCB RX drugs	$151	CIHI (2023). NHEX TRENDS
D	Drug insurance funds RX drugs	$1,589	CIHI (2023). NHEX TRENDS
E	Total public RX drugs	$16,984	CIHI (2023). NHEX TRENDS
F	Private insurers RX drugs	$14,575	CIHI (2023). NHEX TRENDS
G	Out-of-pocket RX drugs	$7,848	CIHI (2023). NHEX TRENDS
H	Total private RX drugs	$22,423	CIHI (2023). NHEX TRENDS
I	OTC drugs	$3,915	CIHI (2023). NHEX TRENDS
J	Personal health supplies	$2,640	CIHI (2023). NHEX TRENDS
K	Total non-prescribed drugs	$6,555	CIHI (2023). NHEX TRENDS
L	Total non-hospital drugs	$45,962	CIHI (2023). NHEX TRENDS
M	Hospital drugs expenditure	$3,426	CIHI (2023). Hospital Spending
N	SUM TOTAL	$49,388	L + M

ESTIMATED NET PUBLIC EXPENDITURE ON PATENTED MEDICINES 2022.

O	Public RXEX (PUBRXEX) Incl. hospitals	$20,410	E + M
P	Patented medicines % of PUBRXEX	52.30%	PMPRB (2023). CompassRx
Q	Subtotal public gross PMEX	$10,674	O * P
R	PDP paid % of PUBRXEX net deductibles and co-pays	88.00%	PMPRB (2023). CompassRx
S	Subtotal adjusted public PMEX	$9,394	Q * R
T	PDP paid % of PUBRXEX net pharmacist fees	83.00%	PMPRB (2023). CompassRx
U	Subtotal public PMEX at manufacturer list prices	$7,797	S * T
V	PDP paid % of PUBRXEX at 36% average rebate	64.00%	ON AUDITOR GENERAL
W	Public PMEX net rebates	$4,990	U * V
X	Total public health expenditures (PUBHEX)	$239,943	CIHI (2023). NHEX TRENDS
Y	Net public PMEX % PUBHEX	2.10%	W / X

ESTIMATED NET PRIVATE EXPENDITURE ON PATENTED MEDICINES 2022.

AA	Private share of national prescribed drugs expenditure (PRIVRXEX)	56.90%	H / (E + H)
AB	Insured share of PRIVRXEX (INSRXEX)	37.00%	F / (E + H)
AC	Out-of-pocket share of PRIVRXEX (OOPRXEX)	19.90%	G / (E + H)
AD	Gross national PMEX at list prices	$18,400	PMPRB (2024). Annual report
AE	Estimated private PMEX list prices	$10,470	AA * AD
AF	Estimated insured PMEX at list prices	$6,806	AB * AD
AG	Estimated out-of-pocket PMEX at list prices	$3,664	AC * AD

ESTIMATED NET NATIONAL EXPENDITURE ON PATENTED MEDICINES 2022.

AH	National expenditure on patented medicines (PMEX) at list prices	$18,400	PMPRB (2024). Annual report
AI	Estimated value of the public rebate (36% off list price)	($2,807)	W - U
AJ	National PMEX net of rebates	$15,593	AH + AI
AK	National health expenditure (NHEX)	$334,404	CIHI (2023). NHEX TRENDS
AL	Gross national PMEX % share of NHEX	5.50%	AH / AK
AM	Net national PMEX % share of NHEX	4.70%	AJ / AK

 | ISSN 2562-9492

Patented medicines share of health expenditure

Patented medicines expenditure was compared in total to both national and public sector expenditure on healthcare. **[CHART 2]** The data show that PMEX was only a small share of NHEX and PUBHEX in 2022.

CIHI reported $239.9 billion for total public health expenditures (PUBHEX) in 2022. Net direct public expenditure on patented medicines ($5 billion) was only 2.1% of total public health expenditure.

CIHI reported $334.4 billion for total national health expenditures (NHEX) in 2022. At manufacturer's list prices, gross direct national expenditure on patented medicines ($18.4 billion) represented only 5.5% of total national health expenditures in 2022. Net direct national expenditure on patented medicines ($15.6 billion) represented only 4.7% of total NHEX. CHPI examined the share of NHEX accounted for by patented medicines expenditure over the 33-year period from 1990 to 2022 **[CHART 3]**. The analysis was conducted using PMEX at list prices because of the unavailability of data about rebates over the entire timeframe. PMEX peaked at 8% of NHEX in 2004 and has since fallen steadily to 5.5% in 2022.

CHART 2. PMEX net share of NHEX and PUBHEX 2022 ($ billions).

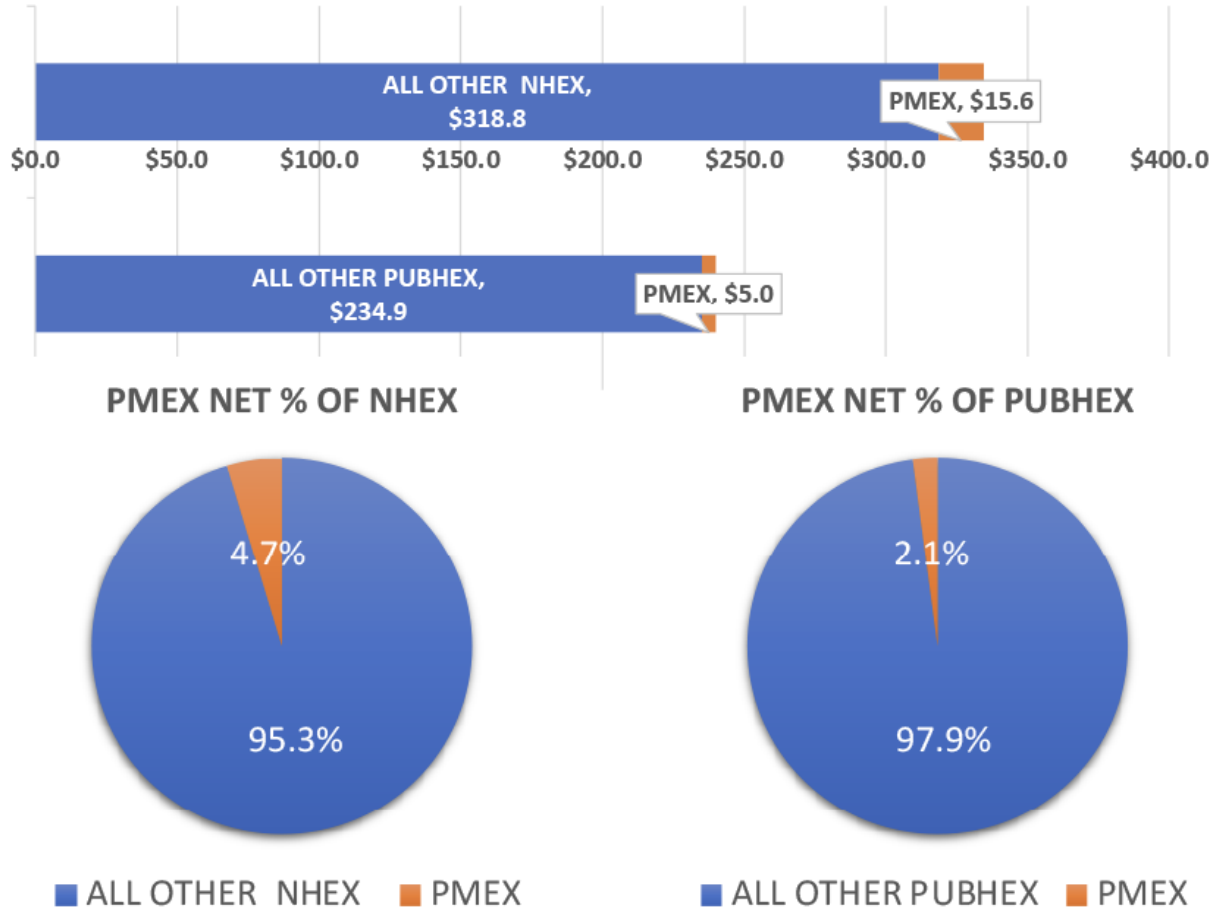
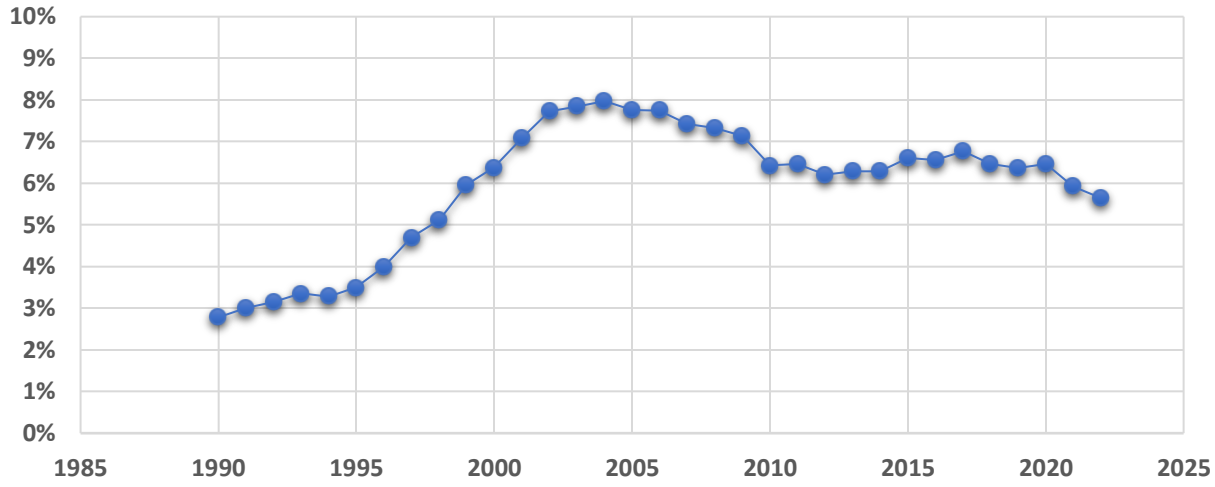


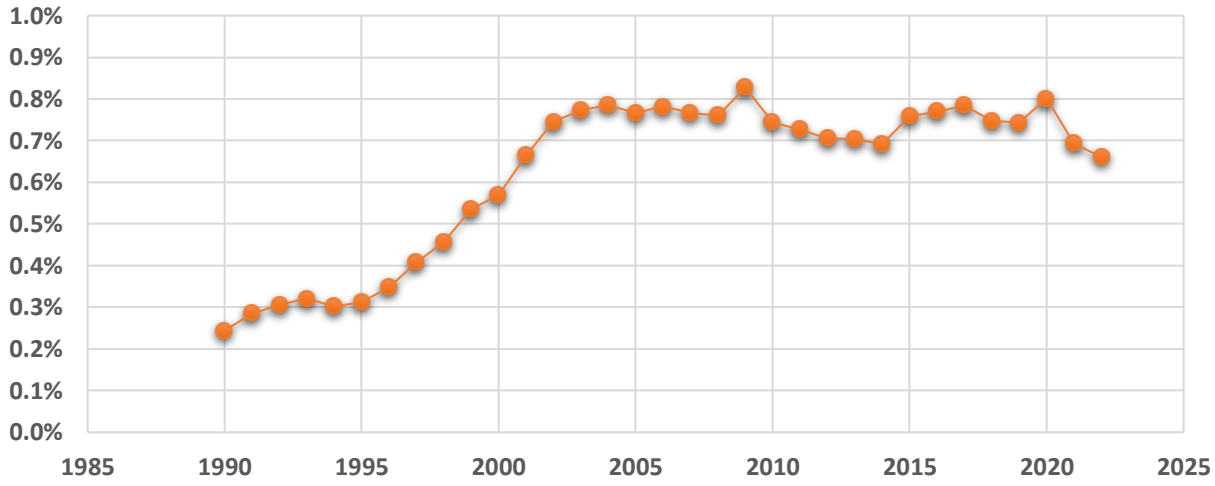
CHART 3. PMEX (at list prices) percentage of NHEX 1990-2022.



Patented medicines share of GDP 1990-2022

Policymakers tend to view spending on patented medicines as a cost instead of an investment. Short term impacts on public budgets receive more attention from government than long-term health and economic benefits. Nevertheless, even if we conceive of patented medicines expenditure only as a cost, the data show that PMEX represents a very small share of Canada's annual economic output. **CHART 4** shows PMEX at list prices from 1990 to 2022 as a percentage of the Canadian economy. Expenditure on patented medicines has been less than 1% of gross domestic product (GDP) for the past 33 years from 1990 to 2022. PMEX currently represents 0.7% of GDP, roughly the same as it has been since 2001.

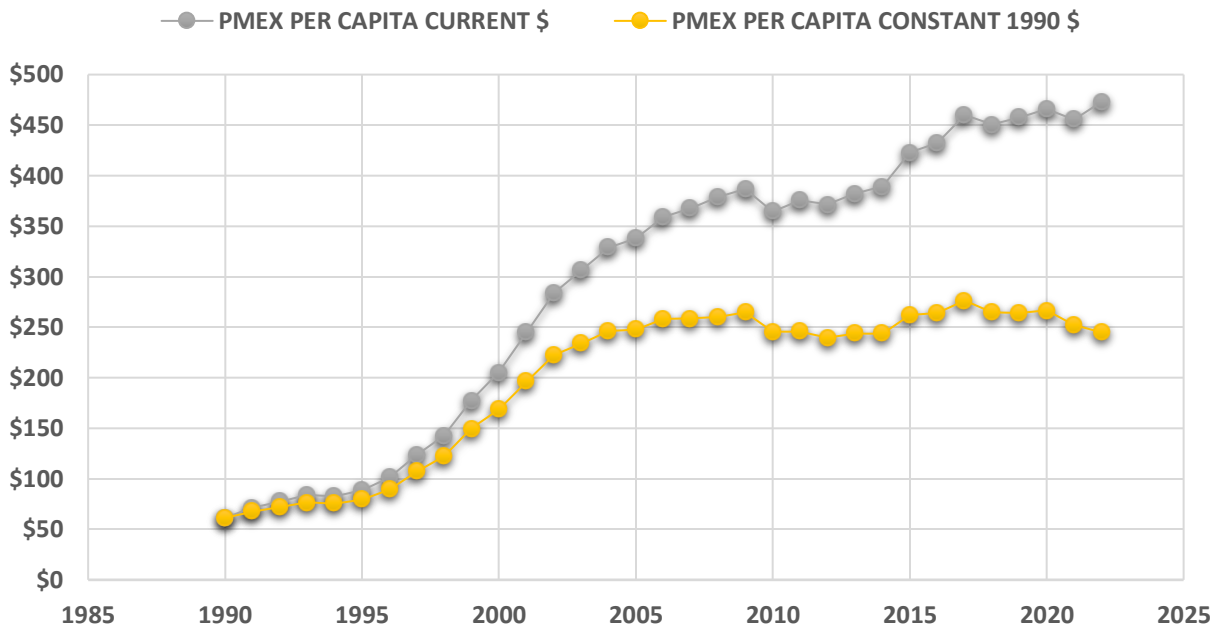
CHART 4. PMEX (at list prices) percentage of GDP 1990-2022.



Inflation and population adjusted expenditure on patented medicines

Adjusting for national population growth and inflation over time, reveals that national expenditure on patented medicines has experienced zero real average annual growth for the last 2 decades. **CHART 5** shows data from 1990 to 2022 for gross national sales per capita of patented medicines stated in constant 1990 dollars to remove the effect of population change and general price inflation. Deflating costs from the beginning of the period (constant 1990 $) shows the impact of general price inflation over the study period (1990 to 2022) starting from a common current dollar baseline. Stated in current dollars, total patented medicines expenditure per capita was $473 in 2022. Stated in constant 1990 dollars, the real gross expenditure per capita on patented drugs was $245 in 2022, which is about the same as it was in 2004 ($246).

CHART 5. Inflation and population adjusted expenditure on patented medicines 1990-2022.



Expenditure on high-cost patented medicines

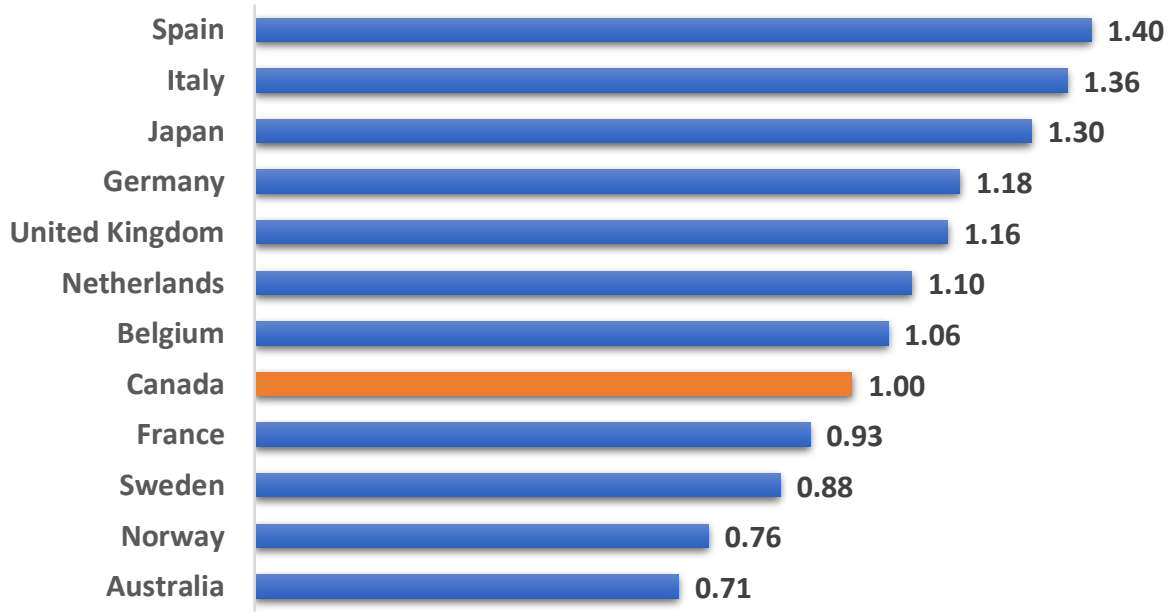
The PMPRB reports separate numbers for national expenditure on high-cost patented drugs (as a sub-category of all patented drugs) covering the period from 2006 to 2022. PMPRB defines high-cost patented drugs as medicines with annual treatment costs of more than $10,000. According to PMPRB there were 204 patented medicines defined as high-cost drugs in 2022 accounting for $10.6 billion in gross sales at list prices. Gross sales of all high-cost patented drugs represented only 3.2% of national health expenditures in 2022. Net of rebates high-cost patented medicines accounted for nearly $6.8 billion representing only 2% of NHEX.

Canadian prices for patented medicines

Canadian prices for patented drugs are moderate compared to other countries. **[CHART 6]** According to the PMPRB 2022 Annual Report, bilateral foreign-to-Canadian comparisons of patented medicines using matched products at purchasing power parity, showed average prices were higher in seven of the 11 other reference countries. The average price ratio across the seven countries was 22.3% higher than Canada.

The PMPRB no longer compares prices from the United States and Switzerland because they are deemed to be "high cost" jurisdictions, but it is expected they would exceed Canada. Which means that Canada ranked 10th of 14 current and former high-income PMPRB reference countries.

CHART 6. Average foreign-to-canadian price ratios, bilateral comparisons, Canada and the PMPRB11, 2022 PPP.



DISCUSSION

Benefits of pharmaceutical innovation

While it is important for governments to manage public finances responsibly, the cost of providing insured access to patented drugs must be weighed against the benefits. Pharmaceutical innovation improves patient health outcomes, reduces potential health system costs, and reduces indirect societal costs like economic productivity losses from untreated or under-treated illness. There is a large body of empirical evidence confirming the beneficial health and economic impact of pharmaceutical innovation. The research literature covers large populations over long periods of time and therefore captures the introduction of both breakthrough and incremental innovative medicines. This is important because it refutes the concerns of innovation skeptics who discount the value of new medicines that are deemed to be only minor improvements over existing therapies. A small sample of the literature is summarized below:

- A systematic literature review conducted in 2019, found 68 studies published in peer-reviewed academic journals from 1990 to 2018 confirming that greater use of innovative pharmaceuticals is empirically associated with treatment efficiencies and net societal health and economic benefits.[10]
- A 2016 study investigated the impact that pharmaceutical innovation had on utilization of hospital care by cancer patients in Canada from 1995 to 2012. During this period, the number of cancer patient hospital days declined by 23%, even though the number of new cancer cases diagnosed increased by 46%. The study showed that the types of cancer (breast, prostate, lung, etc.) that experienced more innovation in pharmaceutical treatments had larger declines in utilization of hospital care. If no new drugs had been registered during the 1980-1997 period, there would have been 1.72 million additional cancer patient hospital days in 2012, at a cost of $4.7 Billion in hospital expenditure, whereas total spending on cancer drugs (old and new) in 2012 was an estimated $3.8 Billion.[11]
- A 2015 study found that in Canada the types of cancer that experienced greater innovation in pharmaceutical treatments had larger declines in the premature mortality rate, controlling for changes in the incidence rate. The study found that, in the absence of pharmaceutical innovation during the period 1985-1996, the premature cancer mortality rate would have increased about 12% during the period 2000-2011. Most of the innovative drugs were off-patent by 2011, but evidence suggests that, even if these drugs had been sold at branded rather than generic prices, the cost per life-year gained would have been below US$5,000, a figure well below even the lowest estimates of the value of a life-year gained.[12]
- A 2013 study examined the health-economic benefits associated with spending on pharmaceuticals in Ontario from 2007 to 2012. The study found that the added costs associated with the use of innovative pharmaceuticals were offset by reductions in the use of other types of health care resources and a reduction in the productivity losses associated with disease because of improved health outcomes. In particular, the $1.2 Billion spent on six classes of pharmaceutical drugs in 2012 generated offsetting health and societal benefits of nearly $2.4 Billion in the same year.[13]
- A 2012 study examined the impact of access to innovative pharmaceuticals on life expectancy using data on 30 countries during the period 2000-2009, finding that life expectancy increased faster in countries using newer drugs. In fact, pharmaceutical innovation explained 73% of the observed increase in life expectancy.[14]

 | ISSN 2562-9492

- A 2009 study evaluated the impact of access to new medicines on patient survival in a study population of 102,743 subjects using Quebec's provincial health plan data. The study found that the use of newer medications was associated with a statistically significant mortality risk reduction relative to older medications and concluded that drug innovation had a significant beneficial impact on the longevity of elderly patients.[15]
- A 2005 study found a strong statistical relationship between drug spending and health outcomes, especially for infant mortality and life expectancy at 65. The analysis showed that substantially better health outcomes are observed in provinces where higher drug spending occurs. Simulations showed that if all provinces increased per capita drug spending to the levels observed in the two provinces with the highest spending level, an average of 584 fewer infant deaths per year and over 6 months of increased life expectancy at birth would result.[16]
- A 2002 study using data on the entire U.S. population from 1996 to 1998 found that the use of newer drugs reduced non-drug spending by 7.2 times as much as drug spending.[17]

Alternative to price regulation: structured negotiation

Germany provides a real-world model for pharmaceutical pricing and reimbursement in its public drug plans, which is based on structured negotiation instead of regulation and designed to allow immediate interim insurance coverage following marketing authorization, with permanent insurance coverage pending the outcome of negotiations.[18] Under the German Medicines Market Reorganization Act (AMNOG) 2011, pharmaceutical manufacturers launching a new drug on the market, are free to set the price for a maximum of twelve months. Manufacturers must submit clinical evidence to the Federal Joint Committee (G-BA) that proves the additional benefit of the drug. If there is additional therapeutic benefit, the manufacturer negotiates the price at which the drug will be reimbursed by the statutory health insurance funds. Price negotiations must reach agreement within six months. If no agreement can be reached, an arbitration board decides on the reimbursed price using European reference prices. There is an appeal process. Drugs lacking evidence of additional therapeutic benefit are reimbursed in the reference group price system.

Applying this model to Canada, the federal price regulations would be eliminated. New active substances would be listed on drug plan formularies immediately following market authorization. The initial formulary list price would be the manufacturer's suggested price and would be used as a benchmark for rebates negotiated with the pCPA or directly with the drug plans. Negotiations would be informed, but not determined, by publicly available international reference prices and the HTA process. When negotiations were complete, the difference between the manufacturer's suggested price and the negotiated price would be retrospectively applied to sales that occurred in the interim period. Negotiations would be time limited and if agreement could not be reached, would progress to arbitration. The formulary listing would expire if either party rejected the arbiter's price and revenues earned under the interim price would be rebated according to the arbiter's price. Manufacturers would have the option to request renegotiation in the future if new clinical or cost effectiveness data emerged, or any other circumstances changed the value proposition of the drug product. The pCPA would be obliged to accommodate a second round of negotiation. The proposed changes would expedite insured access to new drugs while leaving the bargaining leverage of the payer (formulary exclusion) and the seller (withholding product) ultimately intact.

 | ISSN 2562-9492

Alternative to silo-based budgeting: dynamic funding

CIHI's emphasis on the categorical ranks of health expenditures reinforces silo-based approaches to public sector budgeting. Silo-based budgeting tends to maintain categorical spending levels in static proportions. It is problematic because it prevents funding from flowing to the most efficient uses. Policymakers should instead explore dynamic funding models with flexible allocation mechanisms and economic incentives to encourage money and resources to follow the most efficient uses for maximizing patient health outcomes.

 | ISSN 2562-9492

APPENDIX

EXHIBIT 1. CIHI drugs expenditure data definitions.

National Health Expenditure Trends, 2023 — Methodology Notes, Pages 9, 16, 21.

P9: "Drugs — At the aggregate level, this category includes expenditures on prescribed drugs and non-prescribed products purchased in retail stores. Estimates represent the final costs to consumers including dispensing fees, markups and appropriate taxes. This category has been disaggregated at the Canada level in NHEX data tables to provide information on the following subcategories:

- Prescribed drugs — Substances considered to be drugs under the Food and Drugs Act and that are sold for human use as the result of a prescription from a health professional.
- Non-prescribed drugs — Include 2 subcomponents: over-the-counter drugs and personal health supplies.
    - Over-the-counter drugs — Therapeutic drug products not requiring a prescription.
    - Personal health supplies — Include items used primarily to promote or maintain health such as oral hygiene products, diagnostic items such as diabetic test strips, and medical items such as incontinence products."

P9: "The Drugs category does not include drugs dispensed in hospitals and, generally, in other institutions. These are included with the category Hospitals or Other Institutions."

P9: "The administrative costs of operating hospitals, drug programs, long-term care programs and other non-insured health services are not included under the category Administration, but rather are included under the category of service, for example, Hospitals, Other Institutions and Drugs."

P16: "Other Health Spending, Health Research" "The category does not include research carried out by hospitals or drug companies in the course of product development. These amounts would be included with either the Hospitals or Drugs category."

P21: "NHEX drug spending includes administration costs of pharmacare programs and drug spending from the ministry health and other ministries."

P21: "CIHI's National Prescription Drug Utilization Information System (NPDUIS), captures standardized, comparative information on public drug programs, including spending in Canada. The data source for drug spending in NHEX is different from that for NPDUIS. Provincial/territorial government prescribed drug expenditure in NHEX primarily includes drugs that are dispensed through provincial/territorial drug subsidy programs. Its data source is the provincial/territorial public accounts and special data requests made to ministries of health. NPDUIS includes claim-level data adjudicated by public drug programs and submitted by the ministry of health. The amount paid by the drug program toward an individual's prescription costs is reported, including the drug cost, professional fees paid to the pharmacy and the markup charged by the pharmacy. This amount may or may not reflect the impact of any rebates from drug manufacturers."

 | ISSN 2562-9492

DATA SOURCES

i. Canadian Institute for Health Information (CIHI).
   a. Trends in Hospital Spending, 2005–2006 to 2021–2022 — Data Tables — Series A: Hospital Spending by Type of Expense. Table A.1.1.
   b. National Health Expenditure Trends, 2023 — Methodology Notes.
   c. National Health Expenditure Database:
      i. Table A.3.1.1 Total health expenditure by use of funds.
      ii. Table B.3.1 Public-sector health expenditure.
      iii. Table G.14.1 Expenditure on drugs by type and source of finance.
      iv. Appendix A.1 Gross domestic product at market prices.
      v. Appendix D.1 Population.

ii. Patented Medicine Prices Review Board (PMPRB).
   a. PMPRB 2022 Annual Report.
      i. Table 17. Sales of Patented Medicines.
      ii. Figure 10. Share of Sales for High-Cost Patented Medicines by Annual Treatment Cost.
      iii. Table 7. Average foreign-to-Canadian price ratios, bilateral comparisons, Canada and the PMPRB 11, 2022.
   b. CompassRx, 7th edition: Annual Public Drug Plan Expenditure Report, 2021/2022.
      i. Figure 1.2. Prescription drug expenditures in public drug plans. Plan-paid share of total prescription cost.
      ii. Figure 1.5. Annual rates of change in drug costs by market segment.
      iii. Figure 1.7. Annual dispensing costs as a share of total prescription drug expenditures.

iii. Statistics Canada. Table 18-10-0005-01 Consumer Price Index, annual average, not seasonally adjusted.

REFERENCES

1. Frank R. Lichtenberg and Tomas J. Philipson (2002). The Dual Effects of Intellectual Property Regulations: Within- and Between-Patent Competition in the U.S. Pharmaceuticals Industry. The Journal of Law and Economics, Volume 45, Number S2, October 2002.
2. CIHI National Health Expenditure Trends, 2023 — Methodology Notes.
3. CIHI National Health Expenditure Trends, 2023 — Methodology Notes.
4. CIHI National Health Expenditure Trends, 2023 — Methodology Notes.
5. CIHI National Health Expenditure Trends, 2023 — Methodology Notes.
6. CIHI National Health Expenditure Trends, 2023 – Methodology Notes.
7. Trends in Hospital Spending, 2005–2006 to 2021–2022 — Data Tables — Series A.
8. Patented Medicine Prices Review Board. Annual Report 2022.
9. Office of the Auditor General of Ontario. Annual Report 2017. Section 3.09 Ontario Public Drug Programs. Page 491.
10. Canadian Health Policy Institute (CHPI). Evidence that innovative medicines improve health and economic outcomes: focused literature review. Canadian Health Policy, April 2019. https://www.canadianhealthpolicy.com/

11. Lichtenberg, Frank R (2016). The Benefits of Pharmaceutical Innovation: Health, Longevity, and Savings. Montreal Economic Institute. June 2016.

12. Lichtenberg FR (2015). The impact of pharmaceutical innovation on premature cancer mortality in Canada, 2000–2011. International Journal of Health Economics and Management. September 2015, Volume 15, Issue 3, pp 339-359.

13. Hermus G, Stonebridge C, Dinh T, Didic S, Theriault L (2013). Reducing the Health Care and Societal Costs of Disease: The Role of Pharmaceuticals. The Conference Board of Canada, July 2013.

14. Lichtenberg FR (2012). Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009. National Bureau of Economic Research (NBER), Working Paper No. 18235. July 2012.

15. Frank R. Lichtenberg, Paul Grootendorst, Marc Van Audenrode, Dominick Latremouille-Viau, Patrick Lefebvre (2009). The Impact of Drug Vintage on Patient Survival: A Patient-Level Analysis Using Quebec's Provincial Health Plan Data. Value in Health, Volume 12, Number 6, 2009.

16. Pierre-Yves Crémieux et al (2005). Public and Private Pharmaceutical Spending as Determinants of Health Outcomes in Canada. Health Economics, Vol. 14, No. 2, February 2005, pp. 107-116.

17. Lichtenberg FR (2002). Benefits and Costs of Newer Drugs: An Update. National Bureau of Economic Research (NBER), Working Paper No. 8996. June 2002.

18. OECD (2018). Pharmaceutical Reimbursement and Pricing in Germany. Organisation for Economic Cooperation and Development.

 | ISSN 2562-9492