Patented Medicines Expenditure in Canada 1990-2018

Are government price controls justified by the cost of innovative pharmaceuticals?

CHPI Canadian Health Policy Institute

Patented Medicines Expenditure in Canada

1990-2018

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ACCESS TO INNOVATIVE MEDICINES RESEARCH PROGRAM

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Contents

Editorial Comment

Since 1987, the prices of patented medicines in Canada have been regulated by the federal government agency known as the Patented Medicine Prices Review Board (PMPRB). On January 1, 2021, new guidelines will go into effect, that will dramatically cut the maximum prices allowed for patented medicines by the regulations. The PMPRB estimated that the changes would reduce prices by 52% from the current maximum.[1] While, an independent study demonstrated that the new regulated price ceilings could be up to 84% lower.[2]

The regulations wrongly assume that innovative drug companies will continue to supply our market at any price decreed by PMPRB. But the new price limits are hostile to innovation and will discourage pharmaceutical firms from making new medicines available to Canadians. A 2020 systematic review found 44 studies showing a significant negative relationship between drug price controls and the availability of innovative drugs.[3]

The official justification for expanding PMPRB regulatory power, is that "excessive" prices for patented drugs are creating a health care sustainability crisis. In several government documents and discussion papers, issued since 2015, the PMPRB has repeated misleading statements including, "Canada is paying higher prices for prescription drugs than most other developed countries…"[4], and "Canadian patented drug prices have been steadily rising relative to prices in the seven countries to which Canada compares itself under its regulations…"[5], and "Drugs are now the second-largest category of spending in health care…"[6], and "Since 2000, Canada's growth in patented drug expenditures as a share of GDP has increased by 184%."[7]

In the Regulatory Impact Analysis Statement presented to parliament, PMPRB blamed "innovative medicines, including those that are subject to patent protection" for Canadians "not getting the value for money they deserve."[8] "High-cost" patented drugs were specifically cited as an affordability challenge for public and private payers."[9]

None of the PMPRB claims stand up to objective scrutiny. The Board has not provided any credible evidence that the prices of patented medicines are a major driver of national health expenditure.

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[1] Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements): SOR/2019-298. Canada Gazette, Part II, Volume 153, Number 17. Registration: SOR/2019-298, August 8, 2019. PATENT ACT: P.C. 2019-1197 August 7, 2019.

[2] Rawson, Nigel SB; Lawrence, Donna (2020). New Patented Medicine Regulations in Canada: Updated Case Study of a Manufacturer's Decision-Making about a Regulatory Submission for a Rare Disorder Treatment. *Canadian Health Policy*, January 2020.

[3] Labrie, Yanick (2020). Evidence that regulating pharmaceutical prices negatively affects R&D and access to new medicines. Canadian Health Policy, June 2020.

[4] Health Canada (2017). Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations. Page 3.

[5] PMPRB (2016). PMPRB Guidelines Modernization: Discussion Paper. Page 6.

[6] Health Canada (2017). Page 3.

[7] PMPRB (2016). PMPRB Guidelines Modernization: Discussion Paper. Page 6.

[8] Regulations Amending the Patented Medicines Regulations… Page 5948.

[9] Regulations Amending the Patented Medicines Regulations… Page 5952-5954.

Patented medicines are a small fraction (6.6% in 2018) of national health expenditure, even at manufacturer 'list' prices. Net of rebates negotiated between manufacturers and public, and private payers, expenditure on patented medicines would be even smaller. Ontario's Auditor General reported that the province's public drug plan received rebates of close to 30% off list prices.

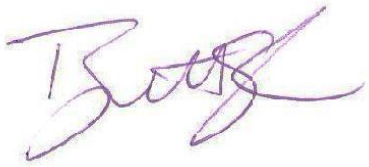
CHPI's analysis shows that, when examined in a proper economic context, national expenditures on patented medicines are objectively affordable and sustainable. Adjusting for factors like population, CPI and GDP, expenditure on patented medicines has been stable or declining for more than a decade. Canadian prices for patented medicines have remained consistently below CPI and comparable countries. In fact, Canadian prices have declined relative to foreign prices over time.

The findings suggest that the PMPRB has presented a false narrative about the impact of patented medicine prices on national health expenditures, while advocating for the expansion of its regulatory powers.

The government should instead curtail the PMPRB. Prices should be determined by voluntary negotiation between sellers and buyers. The Pan-Canadian Pharmaceutical Alliance (PCPA) already conducts price negotiations with pharmaceutical manufacturers as a monopsony, on behalf of all Federal, Provincial and Territorial public drug plans and cancer care agencies. And government has no business regulating prices on behalf of private sector retailers, drug plan sponsors, or insurers.

The cost of patented drugs must be weighed against the benefits. Pharmaceutical innovation improves patient health outcomes, reduces potential health system costs, and reduces economic productivity losses from untreated or under-treated illness.

The potential unintended consequences from the new pricing rules are significant. Parliament is obligated to reconcile the cost-based rationale offered by the PMPRB with the evidence presented in this paper.



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

Highlights

- According to PMPRB, gross national sales of patented drugs were $16.7 billion in 2018, which accounts for 40% of the "drugs" total reported by CIHI for the same year.
- At $16.7 billion, gross national sales of patented drugs accounted for 6.6% of the $254.5 billion reported by CIHI for national health spending in Canada in 2018. Over the 29 years from 1990 to 2018, spending on patented medicines never exceeded 8.0% of national health expenditure. Patented drugs accounted for a smaller percentage of national health spending in 2018 than in 2001 (7.1%), an 18-year period of near zero average annual relative cost growth.
- Gross national sales of patented drugs have accounted for less than 1% of GDP for the last 29 years. Patented medicines expenditure was the same percentage of GDP in 2018 (0.8%) as in 2003 (0.8%), a 16-year period of zero average annual growth relative to GDP.
- 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 decade. Stated in constant 1990 dollars, the real gross expenditure per capita on patented drugs was $265 in 2018, the same as 2009.
- According to PMPRB there were 162 patented medicines defined as high-cost drugs in 2018 accounting for $7.0 billion in gross sales. Gross sales of all high-cost patented drugs represented only 0.3% of GDP and 2.7% of national health expenditures in the same year.

Objective

The purpose of this annual study is to correct common misconceptions about the cost of patented medicines in Canada. The analysis uses publicly available data to:

- ✓ Identify national expenditure attributable to the prices of patented medicines in Canada.
- ✓ Assess the affordability and sustainability of these expenditures relative to population, general price inflation, GDP and other healthcare costs.
- ✓ Discuss national expenditure on patented medicine in the context of the health-economic benefits of pharmaceutical innovation.

Data

The analysis uses the most recently published historical and comparable 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. Annual national sales data for patented medicines were available from 1990 to 2018. Annual national sales data for patented medicines defined by PMPRB as "high-cost" drugs were available from 2006 to 2018. Patented medicines price indices data were available from 1988 to 2018. Foreign-to-Canadian price ratios for patented medicines were available from 2007 to 2018. The following section explains important definitional differences between the PMPRB and CIHI numbers.

Patented Medicines Share of National "Drugs" Expenditure

CIHI defines "drugs" cost much differently than PMPRB.[10,11] CIHI does not publish data that are specific to spending on patented drugs. 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 where reported separately).
- non-drugs "personal health supplies" (included with non-prescribed drugs).
- manufacturer prices, plus wholesale and retail price markups, pharmacy dispensing fees and taxes.
- administrative costs of public drug plans.[12]
- spending by pharmaceutical companies on drug research.[13]
- ***excludes*** hospital spending on drugs, which is included in "hospital" expenditure.

PMPRB is the only public source of national data for direct spending on patented medicines in Canada. The data for "patented drugs" sales reported by PMPRB ***includes*** total national sales of prescribed and non-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 ***excludes*** confidential price rebates (discounts) negotiated between manufacturers and public-sector drug plans, private-sector health insurers, wholesalers, retailers, and hospitals.

The actual costs attributable directly to patented drugs are only a fraction of the "drugs" costs published by CIHI [TABLE 1]. In 2018, CIHI reported $33.5 billion was spent on "prescribed drugs", plus $5.8 billion on "non-prescribed drugs", for a sum of $39.3 billion on non-hospital "total drugs" expenditure. CIHI separately reported an additional $2.5 billion was spent by hospitals on drugs. The grand total of hospital and non-hospital "drugs" expenditure reported by CIHI amounts to $41.8 billion in 2018.

According to PMPRB, *gross* national sales of patented drugs were $16.7 billion in 2018, which accounts for 40% of the "drugs" total reported by CIHI for the same year. [CHART 1] Again, this is at manufacturer 'list' prices. Final prices actually paid, are net of rebates negotiated between manufacturers and public and private payers. After accounting for these rebates, the share of "drugs" expenditure going to patented medicines would be even smaller. There is no published source of national historical data on the size of these rebates, but Ontario's Auditor General reported that the province's public drug plan received rebates of close to 30% on brand name drugs in the fiscal year 2016/17.[14]

[10] CIHI National Health Expenditure Trends, 1975 to 2019 — Methodology Notes. Page 9, "Drugs".

[11] Patented Medicine Prices Review Board. Annual Report 2018.

[12] CIHI National Health Expenditure Trends, 1975 to 2019 — Methodology Notes. Page 10, "Administration" expenditure: "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."

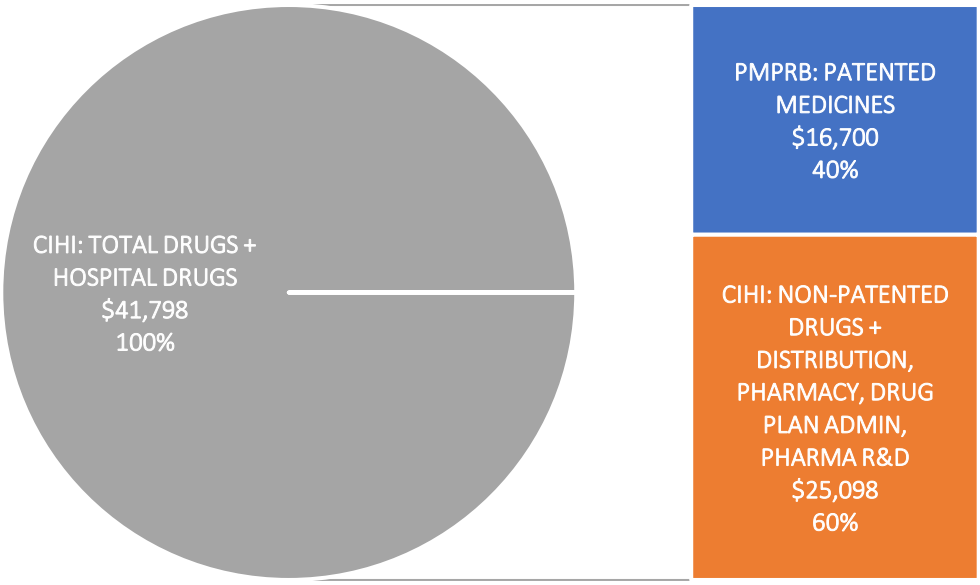
[13] Canadian Institute for Health Information. National Health Expenditure Trends, 1975 to 2018 — Methodology Notes. Page 9, "Other Health Spending" - "Health Research" expenditure: "The category does not include research carried out by hospitals or drug companies in the course of product development. These amounts would be included with either the Hospitals or Drugs category."

[14] Office of the Auditor General of Ontario. Annual Report 2017. Section 3.09 Ontario Public Drug Programs. Page 491.

TABLE 1: CIHI "Drugs" versus PMPRB "Patented Drugs" Expenditure 2018, C$ millions.

CIHI: "PRESCRIBED DRUGS"	$33,445
CIHI: "NON-PRESCRIBED DRUGS"	$5,821
CIHI: "TOTAL DRUGS"	$39,266
CIHI: "HOSPITAL DRUGS"	$2,532
GRAND TOTAL	$41,798
PMPRB: "ALL PATENTED MEDICINES"	$16,700

CHART 1: Patented Medicines Share of "Drugs Expenditures" Reported by CIHI for 2018, C$ millions.



Patented Medicines Share of National Health Expenditure

CIHI publishes national health expenditures data separately by type or "use of funds". The data for hospitals are reported separately from other institutions and capital expenditure. However, CIHI defines capital to Include "expenditures on construction, machinery and equipment of hospitals, clinics, first-aid stations and residential care facilities." For this reason, hospitals, institutions, and capital expenditures are grouped together in CHART 2 and CHART 3. Expenditures on dental care, vision care, and other health professionals were also grouped.

At $16.7 billion, gross national sales of patented drugs accounted for only 6.6% of the $254.5 billion reported by CIHI for national health spending in Canada in 2018. [CHART 2] Over the 29 years from 1990 to 2018, spending on patented medicines never exceeded 8.0% of national health expenditure. [CHART 3] Patented drugs accounted for a smaller percentage of national health spending in 2018 than in 2001 (7.1%), an 18-year period of near zero average annual relative cost growth. [CHART 4]

CHART 2: Patented Medicines Share of National Health Expenditure, 2018 C$ millions.

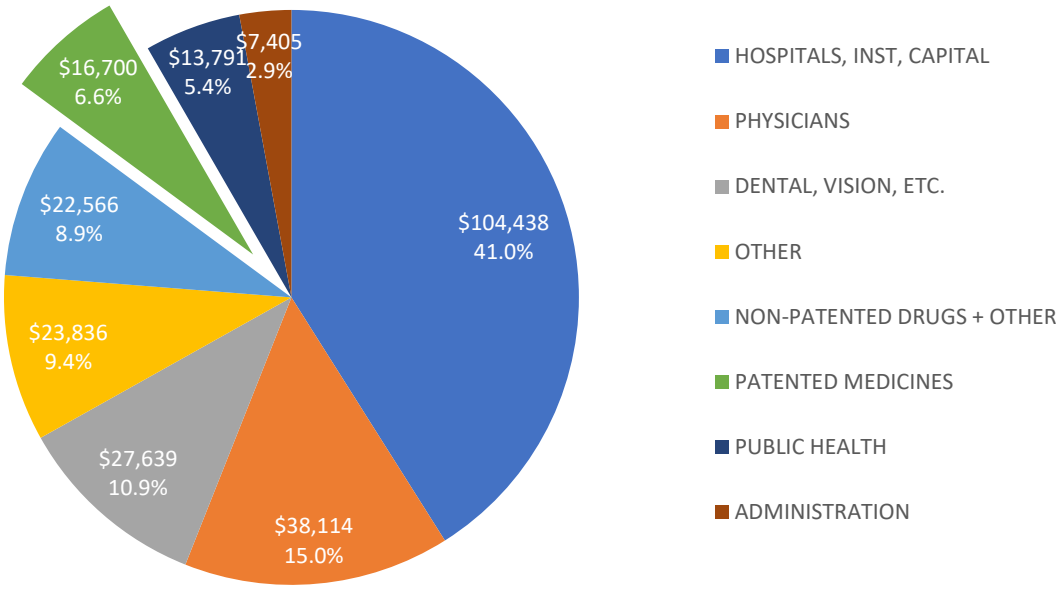


CHART 3: Patented Medicines Share of National Health Expenditure, 1990-2018 C$ millions.

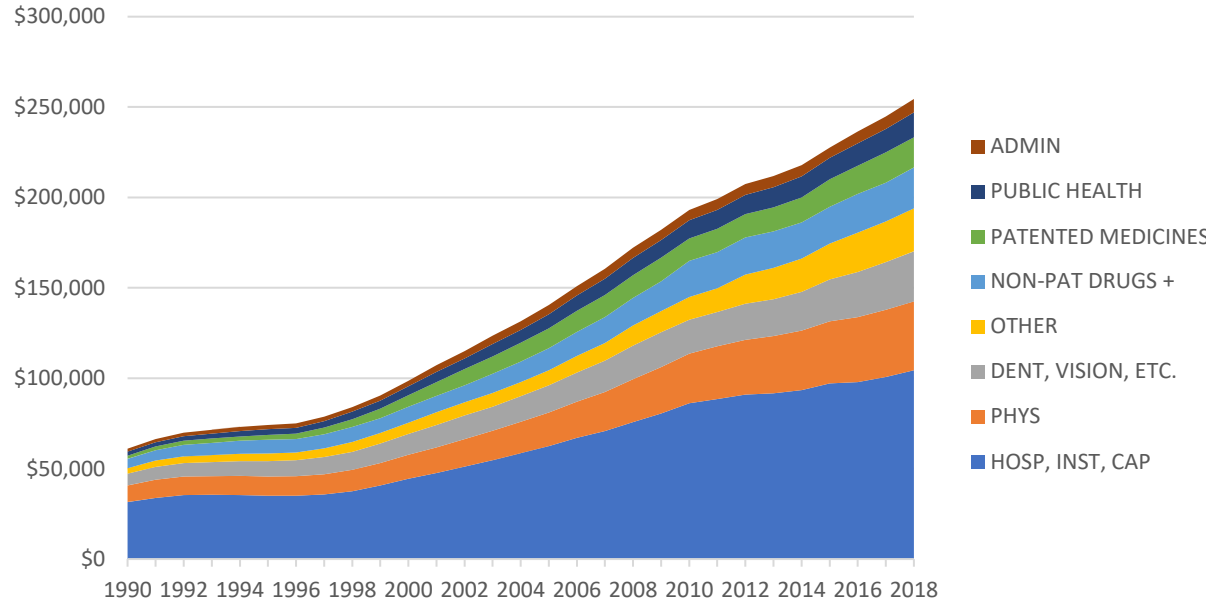
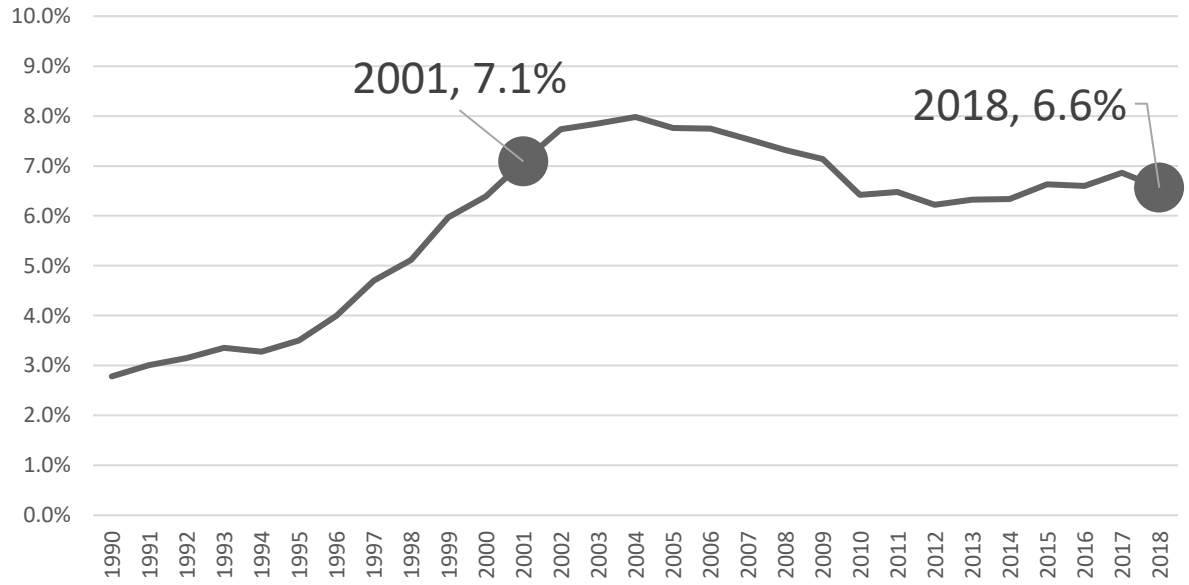


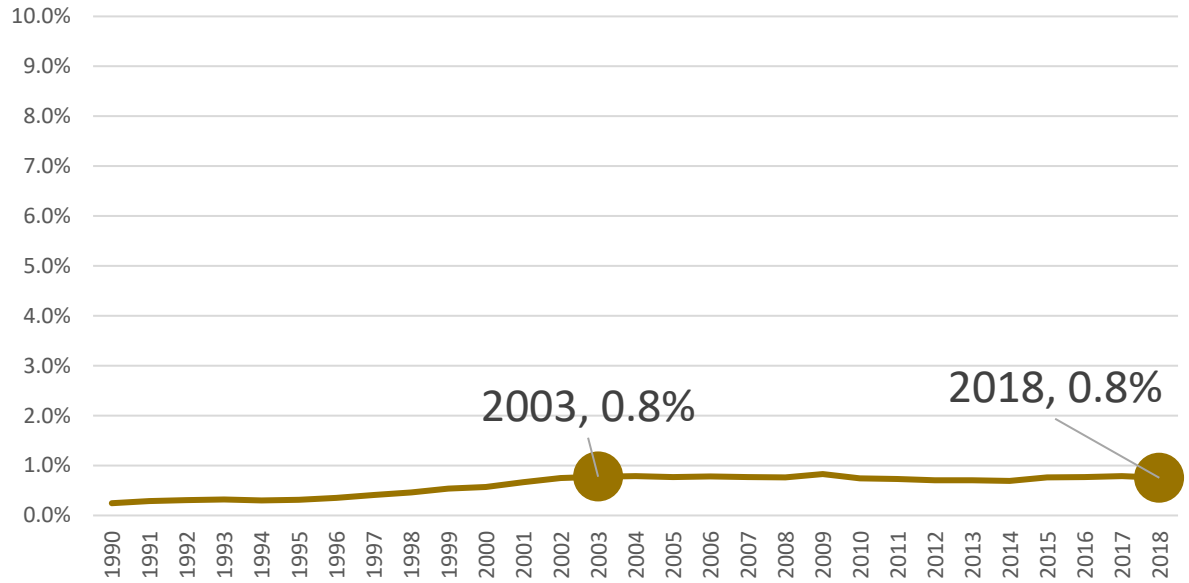
CHART 4: Patented Medicines Share of National Health Expenditure, 1990-2018.



Patented Medicines Share of GDP

Gross national sales of patented drugs have accounted for less than 1% of GDP for the last 29 years. [CHART 5] Patented medicines expenditure was the same percentage of GDP in 2018 (0.8%) as in 2003 (0.8%), a 16-year period of zero average annual growth relative to GDP.

CHART 5: Patented Medicines Share of Gross Domestic Product, 1990-2018.

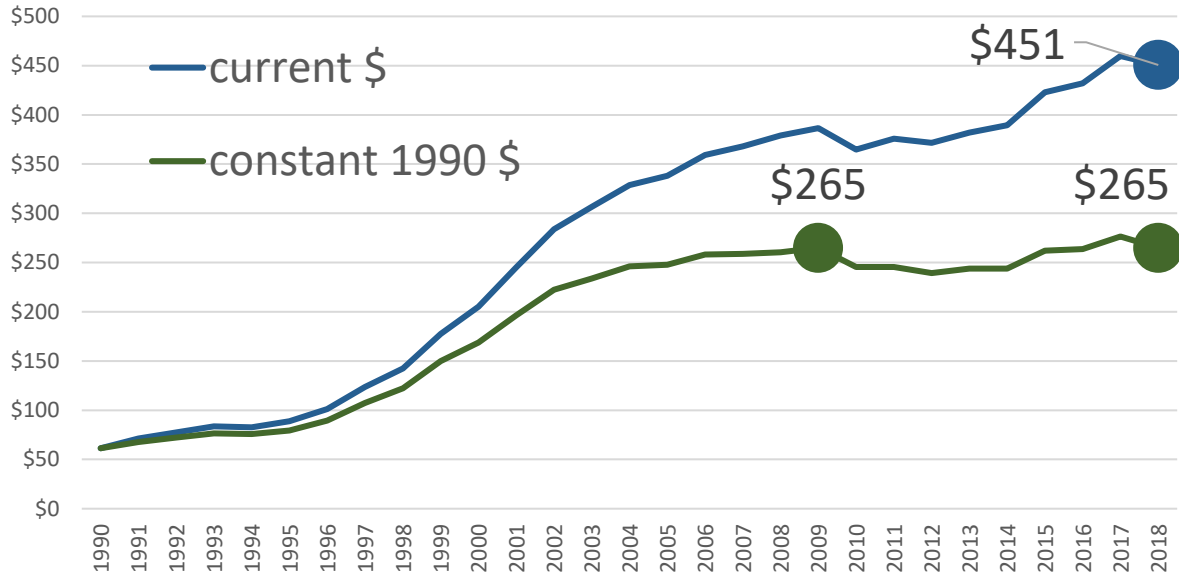


Real Expenditure on Patented Medicines

Stated in current dollars, patented medicines expenditure per capita was $451 in 2018. [CHART 6] Historical data from 1990 to 2018 were available for population and the CPI that allowed for a conversion of gross national sales of patented medicines into per capita costs stated in constant 1990 dollars to remove the effect of 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 2018) starting from a common cost point versus the current dollar baseline.

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 decade. Stated in constant 1990 dollars, the real gross expenditure per capita on patented drugs was $265 in 2018, the same as 2009.

CHART 6: Patented Medicines Expenditure Per Capita, Current $ versus Constant $, 1990-2018.



High-Cost Patented Medicines

PMPRB publishes data for national expenditure on high-cost patented drugs (as a sub-category of all patented drugs) covering the period from 2006 to 2018. PMPRB defines high-cost patented drugs as medicines with annual treatment costs of more than $10,000. According to PMPRB there were 162 patented medicines defined as high-cost drugs in 2018 accounting for $7.0 billion in gross sales. Gross sales of all high-cost patented drugs therefore represented only 0.3% of GDP [CHART 7] and 2.7% of national health expenditure [CHART 8] in the same year.

CHART 7: High-Cost Patented Medicines Share of Gross Domestic Product, 2006-2018.

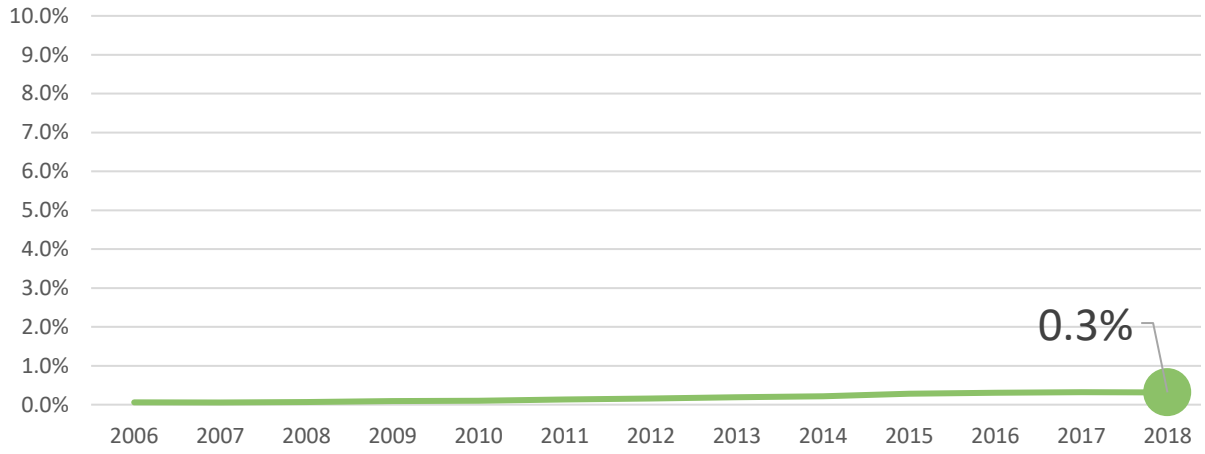
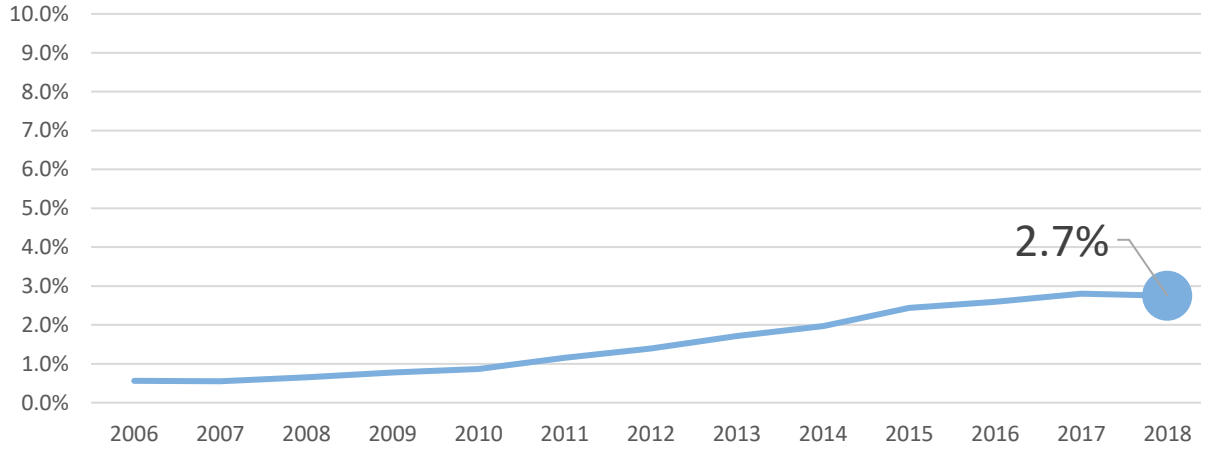


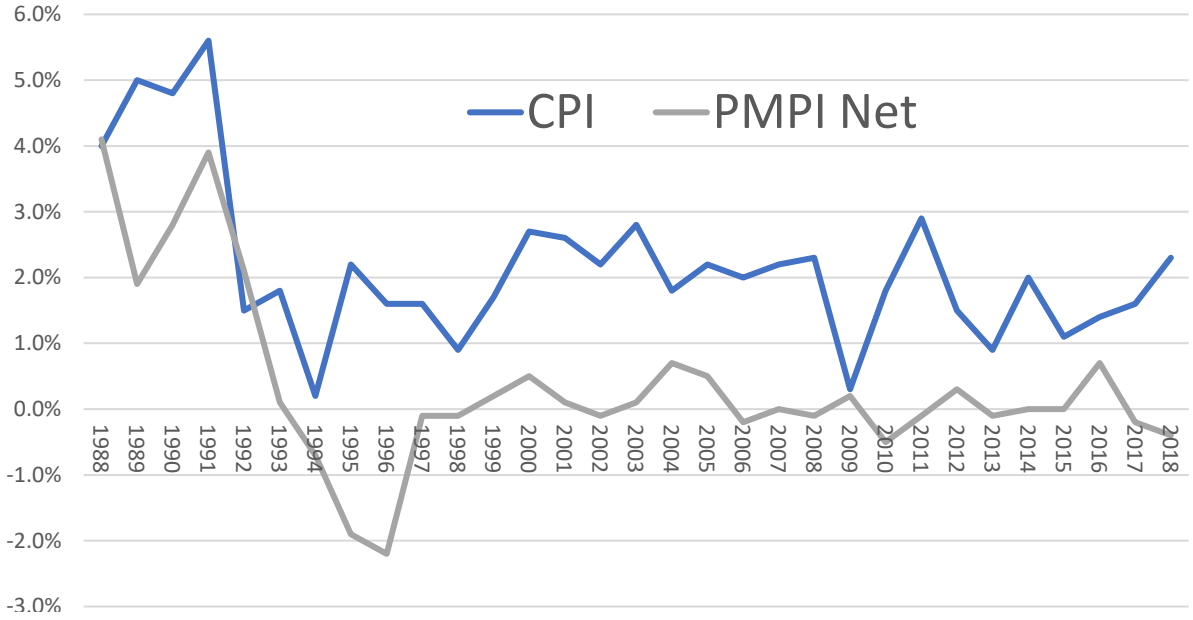
CHART 8: High-Cost Patented Medicines Share of National Health Expenditure, 2006-2018.



PMPI versus CPI

Data were available from PMPRB annual reports showing its Patented Medicines Price Index (PMPI), which measures the annual change in the prices of patented medicines sold in Canada from 1988 to 2018 against comparable data from Statistics Canada's Consumer Price Index (CPI), which measures the annual change in the prices of a basket of goods and services representative of general inflation across the total economy.[15] [CHART 9] The PMPRB data show that the net prices of patented drugs in Canada have grown slower than the rate of general inflation in 29 of the 31 years from 1988 to 2018.

CHART 9: Patented Medicines Price Index versus Consumer Price Index, 1988-2018.



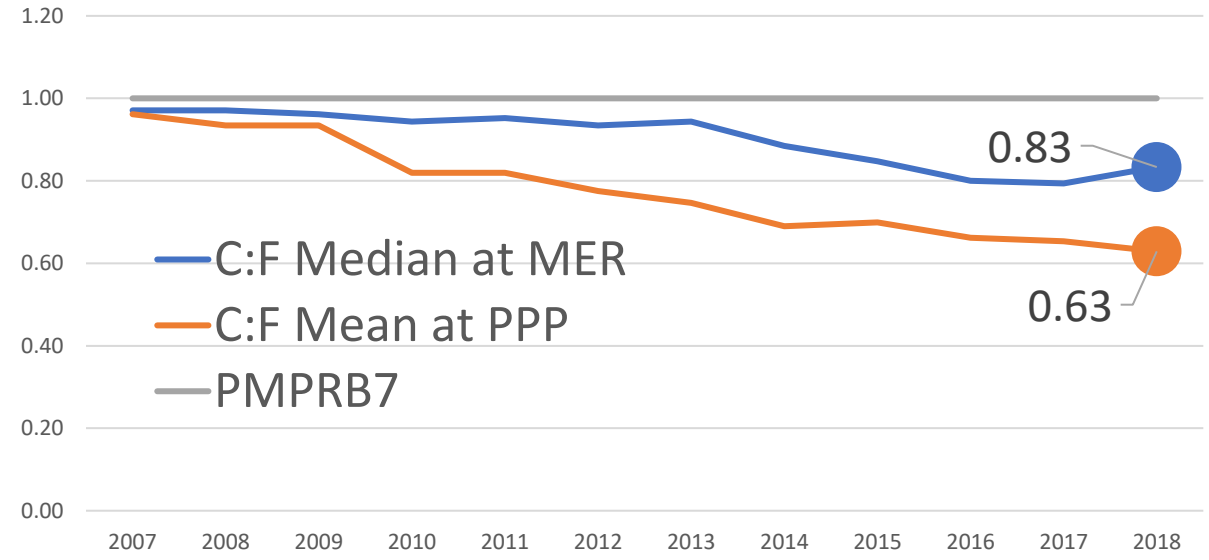
[15] PMPRB's 2017 annual report contained both gross and net prices in separate PMPI's for the first time. PMPI gross data were only available from 2003 to 2018. PMPI gross price data were excluded for consistency with earlier presentations of this data.

Canadian versus Foreign Prices for Patented Medicines

Data published in the PMPRB's annual reports from 2007 to 2018 compared foreign-to-Canadian price ratios for patented medicines across all matching products (n 1,287 in 2018). The PMPRB reports the ratios, holding Canadian prices constant (= 1), and with foreign prices averaged across seven countries including United States, United Kingdom, Germany, France, Switzerland, Italy, and Sweden (PMPRB7).

CHPI inverted these data to show Canadian-to-foreign price ratios, holding the foreign average constant. [CHART 10] Analysis of the data confirmed that, adjusted for the market exchange rates (MER) of currencies, median Canadian prices were lower than median foreign prices for the last 12 years, as much as 17% lower in 2018. When the PMPRB used mean (or average) prices, and adjusted currencies at purchasing power parities (PPP), Canadian prices also remained below foreign prices over the entire study period, declining to 37% lower by 2018.

CHART 10: Canadian-to-Foreign Patented Medicine Prices Ratios, Market Exchange Rates and Purchasing Power Parities, USA, GBR, GER, FRA, SWI, ITA, SWE, 2007-2018.



COST versus BENEFITS

The cost of patented drugs must be weighed against the health-economic 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.

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.[16]

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.[17]

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.[18]

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.[19]

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

[16] Canadian Health Policy Institute (CHPI). Evidence that innovative medicines improve health and economic outcomes: focused literature review. *Canadian Health Policy*, April 2019.

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

[18] 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.

[19] 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.

using newer drugs. In fact, pharmaceutical innovation explained 73% of the observed increase in life expectancy.[20]

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.[21]

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.[22]

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.[23]

[20] 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.

[21] 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.

[22] 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.

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

Data Sources

Canadian Institute for Health Information (CIHI 2019):

National Health Expenditure Trends, 1975 to 2019 — Methodology Notes.

National Health Expenditure Database, 1975 to 2019.

Table A.3.1.1 Total health expenditure by use of funds, in millions of current dollars, Canada, 1975 to 2019.

Table G.14.1 Expenditure on drugs by type and source of finance in millions of current dollars, Canada, 1985 to 2019.

Table A.1.1 Provincial/territorial hospital spending by type of expense in millions of current dollars, Canada (excluding Quebec and Nunavut), 2005–2006 to 2018–2019.

Appendix A.1 Gross domestic product at market prices by province/territory and Canada, in millions of current dollars, by year, 1975 to 2019.

Appendix D.1 Population by province/territory and Canada, in thousands, by year, 1975 to 2019.

Patented Medicine Prices Review Board (PMPRB). PMPRB 2018 Annual Report:

Figure 19. Annual Rate of Change, Patented Medicines Price Index (PMPI) and Consumer Price Index (CPI), 2003-2018.

Table 10. Average Foreign-to-Canadian Price Ratios, Multilateral Comparisons, 2018. (historical data from ARs 2008-2017).

Table 19. Sales of Patented Medicines, 1990 to 2018.

Figure 11. Share of Sales for High-Cost Patented Medicines by Annual Treatment Cost, 2006 to 2018.

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