CHPI Canadian Health Policy Institute

Patented Medicines Expenditure in Canada 1990-2020

7th Edition

Patented Medicines Expenditure in Canada 1990–2020

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.

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EDITION

This is the 7TH edition of this paper to be published as a CHPI research series. 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

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EDITORIAL SUMMARY

Federal, provincial, and territorial governments claim to be committed to evidence-based policymaking. The reality is that government policies are often based on faulty evidence or unproven assumptions, which can lead to unnecessary, expensive and harmful policy choices.

Canadian pharmaceutical policy is built on the assumption that excessive prices for patented medicines are a major cause of the growth in national health expenditures (NHEX).

As a result, the country has constructed a multi-layered bureaucracy to control the cost of patented medicines. Currently several government agencies are involved in price regulation, health technology assessment, monopsony bargaining, formulary gatekeeping, and centralized procurement, plus there are proposals for a new national drug agency, a single national formulary, and national public drug insurance (pharmacare).

But the public discussion of pharmaceutical policy is afflicted by a perennial information deficit regarding the magnitude of spending on patented medicines. Policymakers, experts and media routinely misinterpret drugs expenditures reported by the Canadian Institute for Health Information (CIHI), to be mostly attributable to patented medicines. This is problematic because CIHI does not report patented medicines costs. Accurate data are available from the Patented Medicine Prices Review Board (PMPRB), and the numbers differ significantly from those reported by CIHI.

This study reconciles the data differences and explains the implications for Canada's pharmaceutical policy logic. The analysis tests the empirical validity of the assumption that the prices of patented medicines are a major driver of national health expenditure growth. It uses publicly available data from government sources including CIHI, the PMPRB, and Statistics Canada. Patented medicines expenditures are examined in comparison to the rest of NHEX, and after accounting for changes in population, inflation, and economic growth. Estimates are provided before and after accounting for public sector rebates and exclude temporary expenditures on COVID-19 emergency response.

According to PMPRB, gross national sales of patented drugs were $17.5 billion in 2020 before accounting for public sector rebates, representing only 40% of the $44.0 billion combined total reported by CIHI for spending on retail and hospital drugs, and only 6.5% of the $271 billion total national health expenditures in 2020. From 1990 to 2020 gross sales of patented medicines have never exceeded 8% of NHEX.

After accounting for public sector rebates, national expenditure on patented medicines totaled $14.9 billion in 2020, representing only 33.8% of total drugs expenditures reported by CIHI, and 5.5% of total national health expenditures.

CHPI's analysis shows that, when the correct data are examined in a proper economic context, national expenditures on patented medicines are objectively affordable and sustainable.

So then, why do policymakers myopically focus on controlling the prices of patented medicines instead of other types of healthcare expenditures? The information deficit is one explanation. Governments also probably find it technically easier to regulate pharmaceutical products than to improve efficiency in hospitals and physician care. Moreover, imposing an economic loss on

pharmaceutical companies has less political costs for governments than targeting hospitals and health professionals. The focus on the prices of patent medicines is also partly explained by industrial nationalism. The innovative pharmaceuticals industry is comprised mainly of foreign multinational companies. Canadian policymakers view public expenditure on patented medicines as a cost burden for Canadian taxpayers and an income transfer to American and European pharmaceutical companies.

The disproportionate focus on price controls raises the risk of serious unintended consequences. Evidence suggests that excessive price controls are a disincentive to launch new drugs and to invest in research and development in markets. If governments want to ensure that Canadians have early access to new medicines, and want to attract foreign direct investment to Canada, the excessive focus on price controls is counterproductive.

Price controls are not costless. Administering the price control regime consumes significant public resources that could be saved or spent to improve access to under-funded therapies. A quick review of annual financial statements for three price control agencies shows the direct cost of price regulation and HTA was over $82 million in 2020, excluding the health and economic costs of delays to launching new drugs and listing them on public formularies.

The paper concludes with a discussion of an alternative approach to price regulation of patented medicines using Germany as a model for Canada. Germany's approach to pharmaceutical pricing 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.

While it is important for governments to manage public finances responsibly, the incremental cost of providing insured access to patented drugs must be weighed against the benefits in a broader economic context. 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. The impact of excessive price regulation on the availability of patented medicines jeopardizes the potential benefits to be gained from greater utilization of new drugs. Instead of focusing on controlling the prices of patented medicines, policymakers should be trying to capture the value of therapeutic innovation.

HIGHLIGHTS

- Policymakers, experts and media routinely misinterpret drugs expenditures reported by the Canadian Institute for Health Information (CIHI), to be mostly attributable to patented medicines. This is problematic because CIHI does not report patented medicines costs. Accurate data are available from the Patented Medicine Prices Review Board (PMPRB), and the numbers differ significantly from those reported by CIHI which include non-patented drugs and ancillary costs like pharmacy dispensing fees, public drug plan administration, and even R&D spending by pharmaceutical companies.
- Importantly, both CIHI and PMPRB report drugs expenditures without accounting for rebates negotiated between manufacturers and public drug plans, which Ontario's Auditor General estimated to average 36% off manufacturers' list prices.
- According to PMPRB, gross national sales of patented drugs were $17.5 billion in 2020 before accounting for public sector rebates. Net of rebates, national expenditure on patented medicines totaled $14.9 billion in 2020.
- At $17.5 billion, gross national expenditure on patented drugs represented 40% of the $44.0 billion combined total reported by CIHI for spending on retail and hospital drugs. Net of rebates, national expenditure on patented medicines represented 33.8% of total drugs expenditures reported by CIHI.
- At $17.5 billion, gross national sales of patented drugs accounted for 6.5% of the $271 billion reported by CIHI for national health spending in Canada in 2020, excluding temporary expenditures on COVID-19 emergency response. After accounting for public sector rebates, patented medicines were only 5.5% of the $271 billion total national health expenditures in 2020.
- Excluding rebates, over the 31 years from 1990 to 2020, gross expenditure on patented medicines never exceeded 8.0% of national health expenditure. Patented drugs' percentage of national health spending in 2020 was at almost the same level as in 2000 (6.4%).
- Excluding rebates, gross national sales of patented drugs have accounted for less than 1% of GDP for the last 31 years and were approximately the same percentage of GDP in 2020 (0.8%) as in 2003 (0.8%).
- According to PMPRB there were 189 patented medicines defined as high-cost drugs in 2020 accounting for $9.1 billion in gross sales excluding rebates, which represented only 3.4% of national health expenditures and 0.4% of GDP.
- According to PMPRB there were 105 patented oncology medicines in 2020 accounting for $3.9 billion in gross sales excluding rebates, which represented only 1.5% of national health expenditures and 0.2% of GDP.
- Excluding rebates and stated in current dollars, expenditure per capita on patented oncology medicines was $104 in 2020. Stated in constant 2006 dollars, the real gross expenditure per capita on patented oncology drugs was $59 in 2020. The cost of patented oncology medicines can be compared to the total societal and health system costs associated with the disease. A recent study estimated these costs were C$26.2 billion in Canada in 2021. Stated in current dollars the economic burden of cancer in 2021 was equivalent to $682 per capita. Stated in constant 2006 dollars the societal cost per capita was $377.

OBJECTIVES

The purpose of this study is to test the validity of the assumption that the prices of patented medicines are a major driver of national health expenditure growth. It has 3 research objectives:

- ✓ Identify national expenditure attributable to the prices of 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.
- ✓ Discuss national expenditure on patented medicines in the context of the benefits of pharmaceutical innovation.

DATA SOURCES

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 2020, which allowed for separate analysis of "high-cost" patented medicines and oncology drugs from 2006 to 2020. Public sector expenditures on patented medicines were estimated using data from PMPRB that were current to the fiscal year 2019-2020. CIHI data on national health expenditure (NHEX) and supplemental data for gross domestic product (GDP) and population were available from 1975-2021, and for hospital expenditures from fiscal years 2005–2006 to 2019–2020. CIHI separately reported government health expenditures related to the COVID-19 response. CIHI defines COVID-19 expenditures as: "COVID-19 Response Funding includes several broad areas such as treatment costs (30%), testing and contact tracing (10%), vaccination (27%), medical goods (31%) and other related expenses (1%)."[1] COVID-19 expenditures data were excluded from the analysis because they were a temporary occurrence. Statistics Canada data were obtained from the Consumer Price Index (CPI) which covered the years 1990-2021.

DATA DEFINITIONS

CIHI National Health Expenditure Categories

CIHI publishes national health expenditures separately by component type or "use of funds". The data are shown in **EXHIBIT 1** as reported by CIHI**.** 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. Some component categories are narrowly defined, while others are grouped with ancillary or indirectly associated expenditures. Examples include:

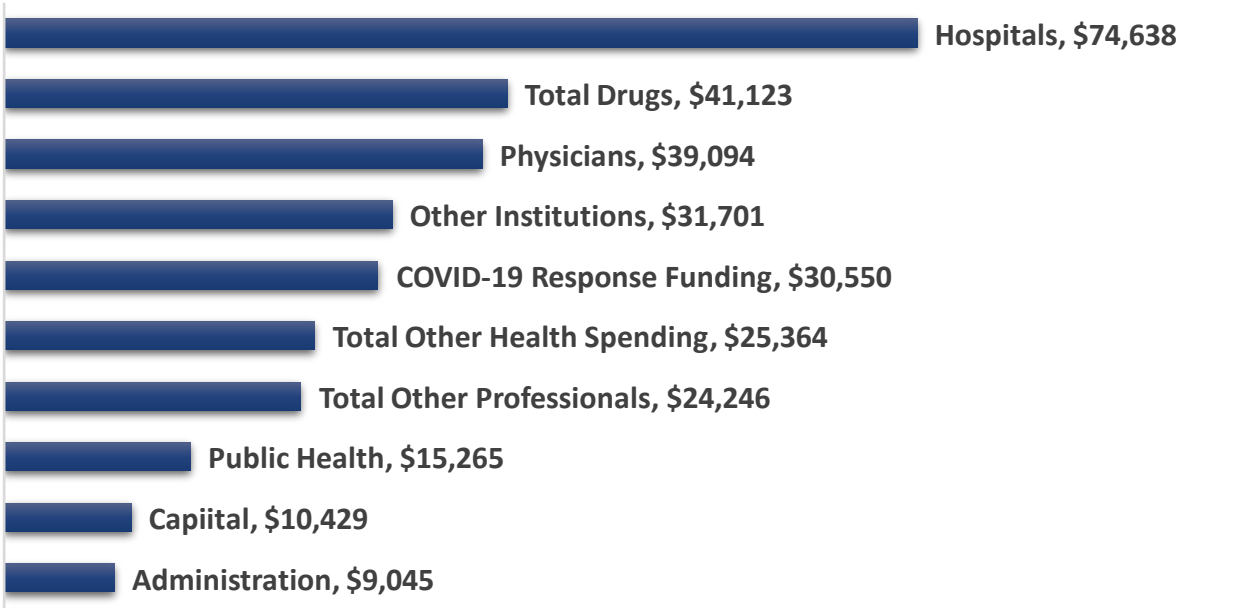
- Capital expenditures are reported separately from expenditures on hospitals and other institutions. Yet CIHI defines capital spending as consisting exclusively of "expenditures on

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]

The subjective definitional variation affects the relative weight of each category and rank relative to other components. Legitimate alternative definitions are conceivable that could change the relative ranks. Consequently, the ranks of national health expenditure categories are not very meaningful from an evidence-based policy perspective. Importantly, it is highly misleading for policymakers to reference CIHI drugs expenditure data to argue that the prices of patented medicines are a major driver of healthcare costs, because CIHI does not publish data on patented drugs. PMPRB is the only public source of national data for direct spending on patented medicines in Canada.

EXHIBIT 1. CIHI Distribution of National Health Expenditures 2020, C$ millions.



CIHI "Drugs" versus PMPRB "Patented Drugs" Expenditure

CIHI defines drugs expenditures much differently than PMPRB. 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), and 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 ***exclude*** hospital spending on drugs, which is included in "hospital" expenditure.

By contrast, the data for "patented drugs" sales reported by PMPRB ***include*** 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 ***exclude*** confidential price rebates (discounts) negotiated between manufacturers and public-sector drug plans, private-sector health insurers, wholesalers, retailers, and hospitals.[7]

EXHIBIT 2. CIHI drugs expenditure data definitions.

National Health Expenditure Trends, 2021 — Methodology Notes, Pages 9, 10, 20

"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."

"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."

"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."

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

"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."

Public Sector Rebates

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.[8] 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. 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.

ESTIMATES

Gross Public Sector Expenditures on Patented Medicines

Public sector expenditures on patented medicines were not available from the PMPRB annual report. However, CHPI was able to calculate an estimate using numbers published in the agency's "Compass Rx" and "Prescribed Drugs Spending in Canada" reports, supplemented with data from CIHI which separately reports drugs expenditures by private and public sectors.

The data from CIHI are shown by sector in **EXHIBIT 3** including drugs expenditures in hospitals. The hospital drugs expenditures reported by CIHI exclude Quebec and Nunavut. According to CIHI, national drugs expenditures in 2020 were composed of public sector spending on prescribed drugs $15.4 billion, plus private spending on prescribed drugs $19.8 billion and non-prescribed drugs $5.9 billion, plus $2.9 billion in hospital drugs expenditures were reported for a total of $44 billion.

CHPI's calculation isolating public sector expenditures on patented medicines in 2020 is shown in **EXHIBIT 4**. Hospital drugs expenditures were reallocated to the public sector prescribed drugs expenditures category because nearly all hospital costs are funded by the public sector. PMPRB publishes estimates of the percentage of public sector drugs expenditures accounted for by patented medicines, the percentage of public drug plan claims expenditures paid publicly (after patient deductibles), and the percentage of public drugs expenditures accounted for by pharmacy dispensing charges, excluding Quebec and Nunavut. The percentages were applied as a national average. Public sector gross expenditures on patented medicines were estimated to be approximately $7.4 billion in 2020.

EXHIBIT 3. CIHI distribution of national drugs expenditures 2020, C$ millions.

Provincial/territorial prescribed drugs		$12,927
Federal direct prescribed drugs	+	$1,050
Workers' compensation board prescribed drugs	+	$150
Drug insurance funds premium on prescribed drugs	+	$1,312
Sub-Total public-sector prescribed drugs		**$15,439**
Private insurers prescribed drugs		$12,769
Out-of-pocket prescribed drugs	+	$7,049
Sub-Total private-sector prescribed drugs		**$19,818**
Private over-the-counter drugs		$3,374
Private personal health supplies	+	$2,492
Sub-Total non-prescribed drugs		**$5,866**
Sub-Total non-hospital drugs		$41,123
Hospital drugs expenditure (Excl. Quebec and Nunavut)	+	$2,877
National drugs expenditures reported by CIHI		**$44,000**

EXHIBIT 4. Public sector expenditures on patented medicines 2020, net of deductibles and dispensing fees, excluding rebates, C$ millions.

Public-sector prescribed drugs (Excl. hospital drugs)		$15,439
Hospital drugs expenditure (Excl. Quebec and Nunavut)	+	$2,877
Public sector prescribed drugs expenditures (Incl. hospital drugs)		$18,316
Patented medicines % of public sector drugs expenditures	X	57.5%
Public sector expenditures on patented medicines (Incl. hospital drugs)		$10,532
Drug plan paid % of public-sector drugs expenditures	X	87.0%
Adjusted public-sector expenditures on patented medicines		$9,163
Dispensing charges % public sector drugs expenditures	-	19.7%
Public sector gross expenditures on patented medicines before rebates		**$7,358**

Net Expenditures on Patented Medicines

To get an estimate of the net expenditures on patented medicines, the value of rebates must be removed from PMPRB national expenditures and our estimate of public-sector expenditures. A calculation of the value of public sector rebates on the prices of patented medicines is shown in **EXHIBIT 5**. The 36% rebate observed by Ontario's Auditor General was applied as a national average to our estimate of public sector gross expenditures on patented medicines to produce an estimate of the value of rebates at $2.6 billion. In **EXHIBIT 6**, the value of the rebates is subtracted from our estimate of gross public sector expenditures on patented medicines ($7.4 billion), and from PMPRB data for gross national sales of patented medicines ($17.5 billion). After accounting for public sector rebates, the estimated net public sector expenditure on patented medicines totaled $4.7 billion, and net national expenditure on patented medicines totaled $14.9 billion in 2020.

EXHIBIT 5. Value of public sector rebates on the prices of patented medicines 2020, C$ millions.

Public sector gross expenditures on patented medicines before rebates		$7,358
Assumed average public sector rebate	X	36.0%
Value of public sector rebate		**$2,649**

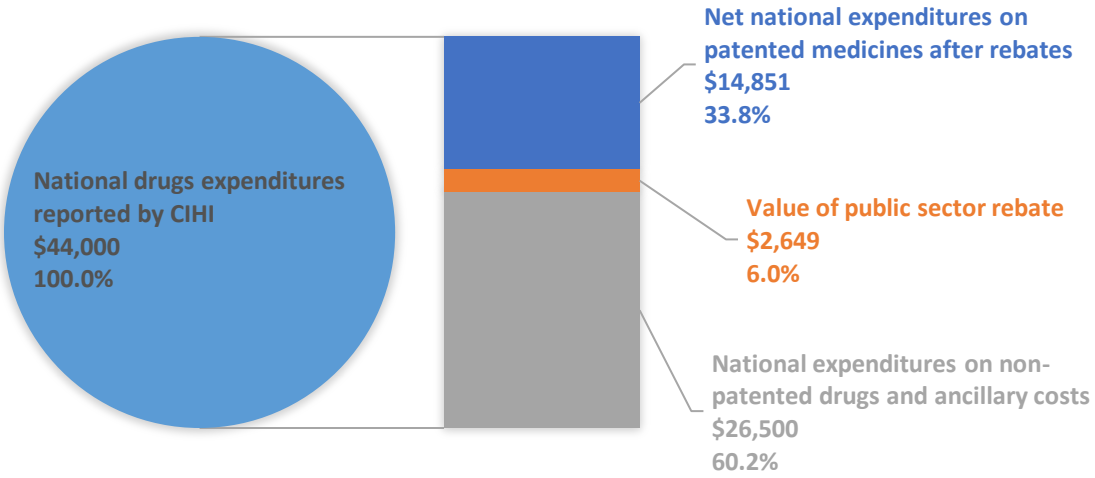
EXHIBIT 6. Net public sector and national expenditure on patented medicines 2020, C$ millions.

Public sector gross expenditures on patented medicines before rebates		$7,358
Value of public sector rebate	-	$2,649
Public sector net expenditures on patented medicines after rebates		**$4,709**
National gross expenditures on patented medicines before rebates		$17,500
Value of public sector rebate	-	$2,649
National net expenditures on patented medicines after rebates		**$14,851**

Patented Medicines Share of Drugs Expenditures Reported by CIHI

EXHIBIT 7 shows that the actual costs attributable directly to patented drugs are only a fraction of the "drugs" costs published by CIHI. According to PMPRB, *gross* national sales of patented drugs were $17.5 billion in 2020, which accounts for 40% of the "drugs" total reported by CIHI. After accounting for public sector rebates, net national sales of patented drugs were estimated to be only $14.9 billion in 2020, or 33.8% of the $44 billion in national drugs expenditures reported by CIHI.

EXHIBIT 7. Patented medicines net share of national drug expenditures reported by CIHI, C$ millions.



Patented Medicines Share of Health Expenditure

Excluding temporary expenditures related to COVID-19 emergency response, CIHI reported $195.7 billion for total public-sector health expenditures (PHEX) and $271.0 billion for total national health expenditures (NHEX) in Canada in 2020. Excluding public-sector rebates, at $7.4 billion public-sector spending on patented medicines accounted for only 3.8% of total public-sector health expenditures, and at $17.5 billion total national sales of patented medicines accounted for only 6.5% of total national health expenditures in 2020. **EXHIBITS 8 and 9** show simplified distributions of public sector health expenditures and national health expenditures after accounting for public sector rebates on patented medicines. In both exhibits net patented medicines expenditures are shown separately from the rebated portion. After accounting for public sector rebates, net public sector expenditures on patented medicines were only 2.4% of total public sector health expenditures, and net national expenditures on patented medicines were only 5.5% of total national health expenditures in 2020.

EXHIBIT 8. Distribution of PHEX 2020, Patented Medicines Net Expenditure After Rebates, C$ millions.

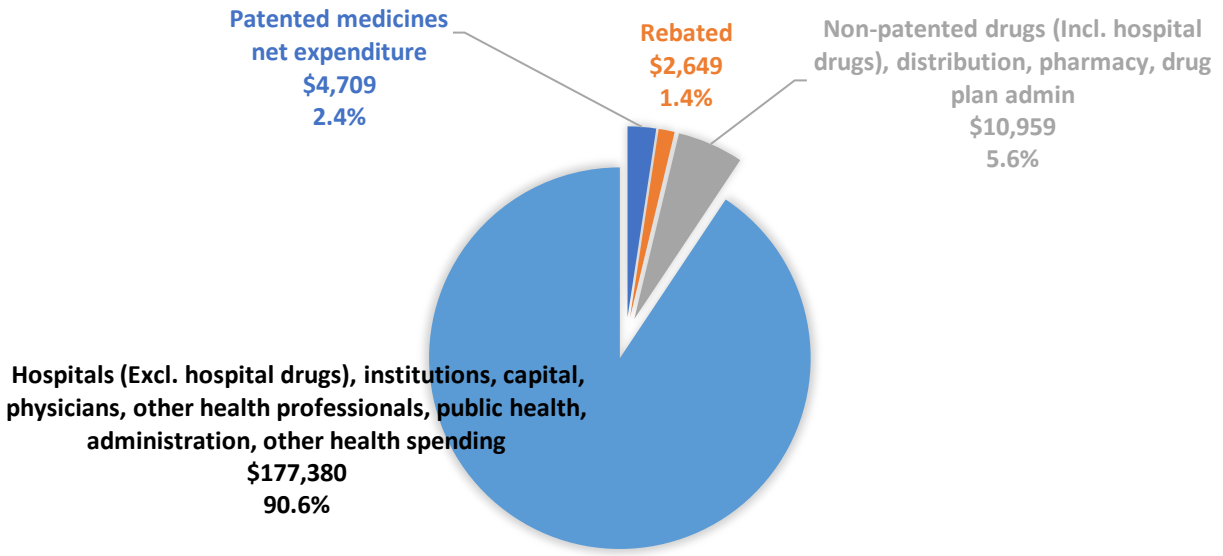
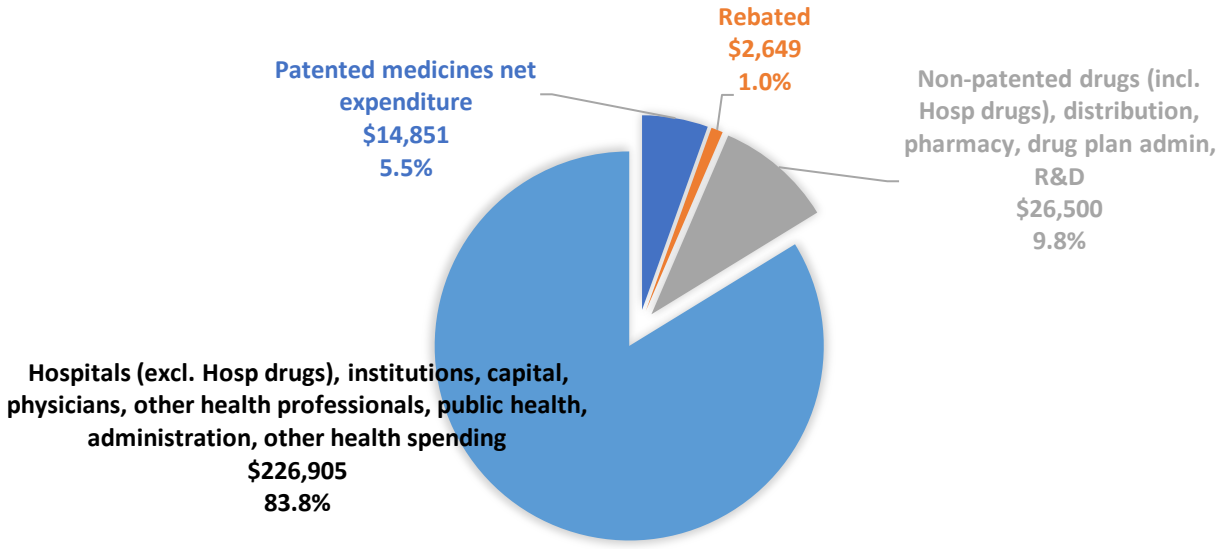


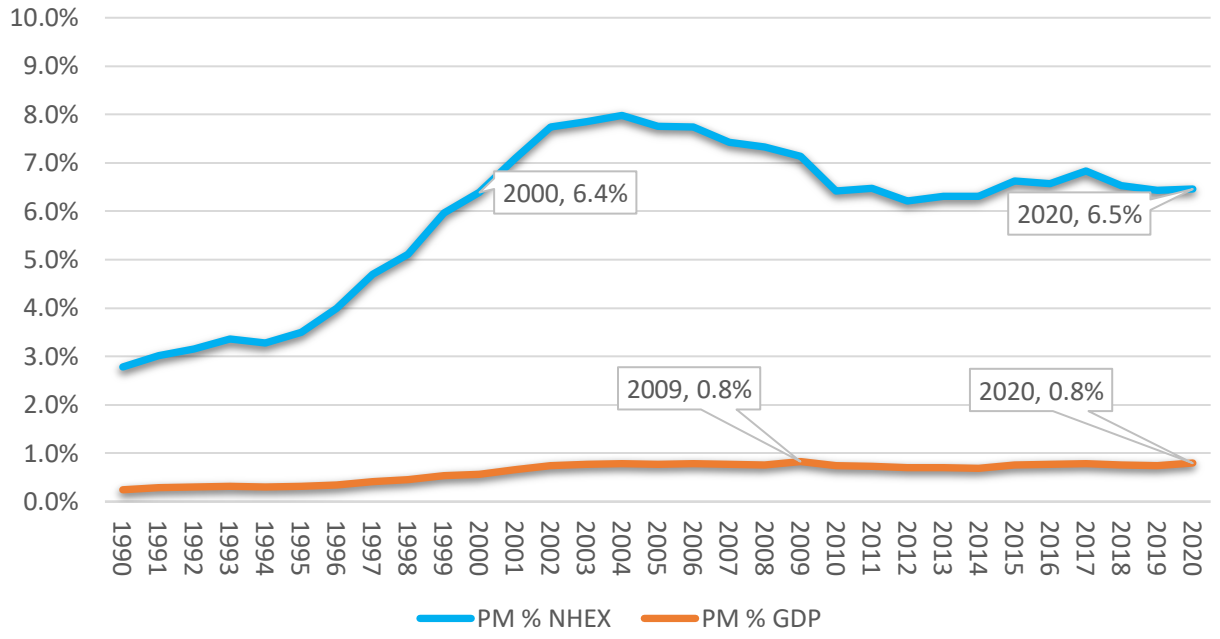
EXHIBIT 9. Distribution of NHEX 2020, Patented Medicines Net Expenditure After Rebates, C$ millions.



Patented Medicines Share of NHEX and GDP 1990-2020

EXHIBIT 10 shows historical data from 1990 to 2020 for gross sales of patented medicines excluding rebates, stated as a percentage share of national health expenditures and gross domestic product. The data indicate that over the 31 years from 1990 to 2020, spending on patented medicines never exceeded 8.0% of national health expenditure. The percentage of national health spending for patented drugs was almost the same in 2020 as in 2000 (6.4%): a remarkable 21-year period of near zero average annual relative expenditure growth. **EXHIBIT 10** also shows patent medicines as a share of GDP from 1990 to 2020. Excluding rebates, gross national sales of patented drugs have accounted for less than 1% of GDP for the last 31 years. Patented medicines expenditure was approximately the same percentage of GDP in 2020 (0.8%) as in 2003 (0.8%), an 18-year period of zero average annual growth relative to GDP.

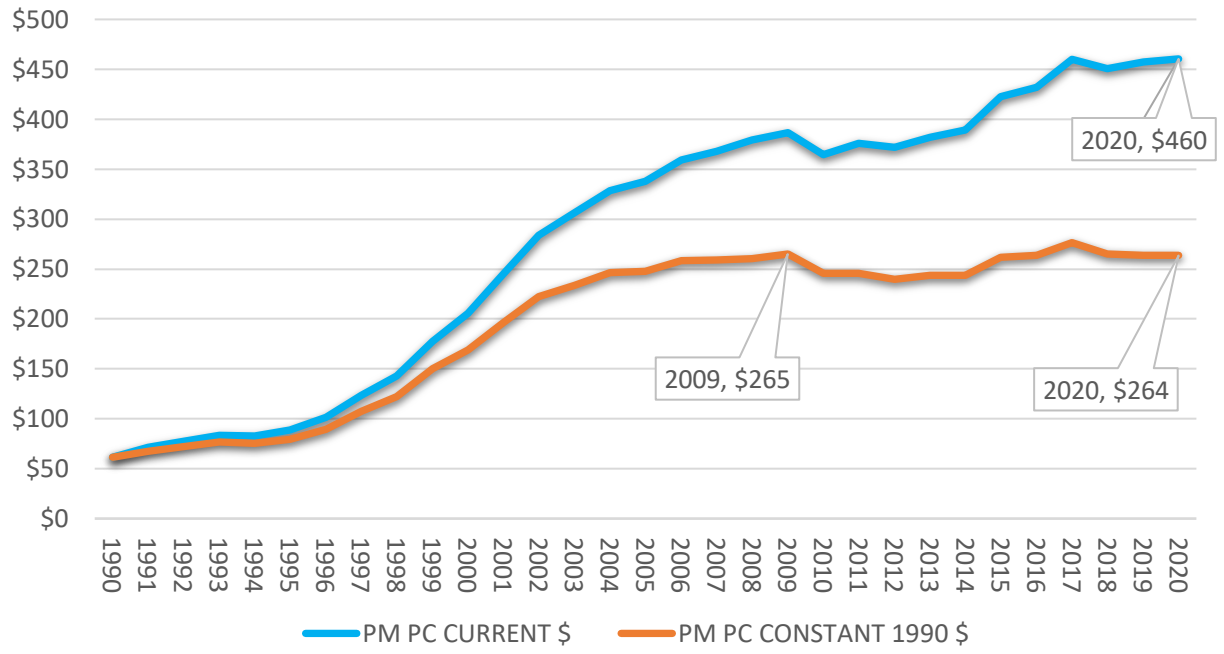
EXHIBIT 10. Patented Medicines Share of NHEX and GDP 1990-2020.



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 decade. **EXHIBIT 11** shows data from 1990 to 2020 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 2020) starting from a common point versus the current dollar baseline. Stated in current dollars, total patented medicines expenditure per capita was $460 in 2020. Stated in constant 1990 dollars, the real gross expenditure per capita on patented drugs was $264 in 2020, which is slightly below 2009 when it was $265: a 12-year period of flat average annual growth.

EXHIBIT 11. Inflation and Population Adjusted Expenditure on Patented Medicines 1990-2020.



Expenditure on High-Cost Patented Medicines

EXHIBIT 12 shows PMPRB data for national expenditure on high-cost patented drugs (as a sub-category of all patented drugs) covering the period from 2006 to 2020. PMPRB defines high-cost patented drugs as medicines with annual treatment costs of more than $10,000. According to PMPRB there were 189 patented medicines defined as high-cost drugs in 2020 accounting for $9.1 billion in gross sales. Gross sales of all high-cost patented drugs represented only 3.4% of national health expenditures and 0.4% of GDP. **EXHIBIT 13** shows data from 2006 to 2020 for gross national sales per capita of high-cost patented medicines stated in constant 2006 dollars to remove the effect of population change and general price inflation over the study period. Stated in current dollars, expenditure per capita was $240 in 2020. Stated in constant 2006 dollars, the real gross expenditure per capita on patented drugs was $137 in 2020. The data indicate that spending on high-cost patented medicines has been increasing constantly since 2006. However, high-cost drugs still compose only a small fraction of national health expenditure.

EXHIBIT 12. High-Cost Patented Medicines Share of NHEX and GDP 2006-2020.

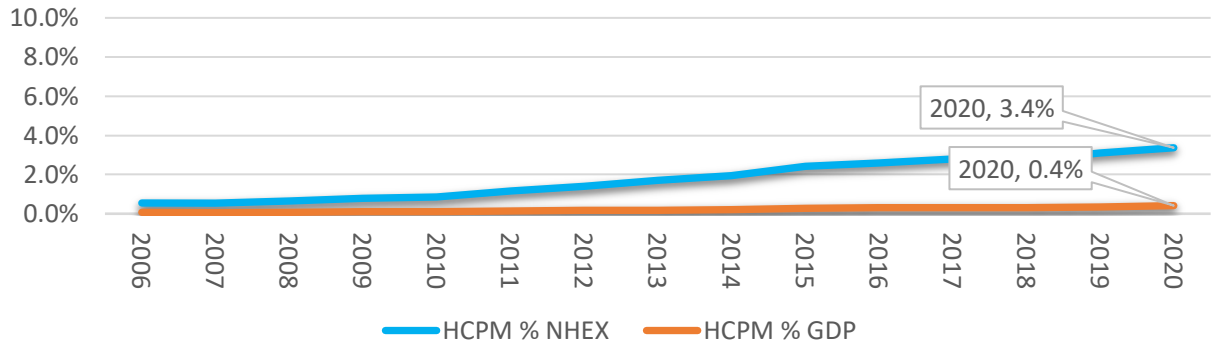
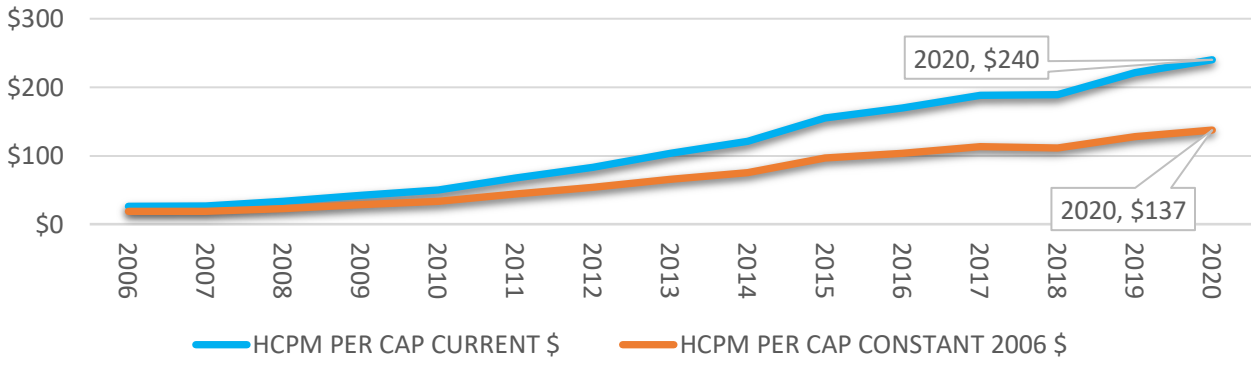


EXHIBIT 13. Inflation and Population Adjusted Expenditure on High-Cost Patented Medicines 2006-2020.



Expenditure on Patented Oncology Medicines

According to PMPRB there were 105 patented oncology medicines in 2020 accounting for $3.9 billion in gross sales, which represented only 1.5% of national health expenditures and 0.2% of GDP [**EXHIBIT 14**]. **EXHIBIT 15** shows data from 2006 to 2020 for gross national sales per capita of patented oncology medicines. Stated in current dollars, expenditure per capita was $104 in 2020. Stated in constant 2006 dollars, the real gross expenditure per capita on patented oncology drugs was $59 in 2020. Similar to the experience of high-cost drugs, spending has been increasing constantly since 2006. Introductory price increases are not as significant as other explanatory factors including growing utilization and evolving treatment regimens that use multiple medicines. Yet ultimately, patented oncology medicines account for only a small fraction of national health expenditure. The cost of patented oncology medicines can also be compared to the economic burden of cancer. A recent study estimated the economic burden of cancer in Canada in 2021. From a societal perspective, cancer-related costs were estimated to be $26.2 billion in Canada in 2021.[9] Stated in current dollars the economic burden of cancer in 2021 was equivalent to $682 per capita. In constant 2006 dollars the societal cost per capita was $377.

EXHIBIT 14. Patented Oncology Medicines Share of NHEX and GDP 2006-2020.

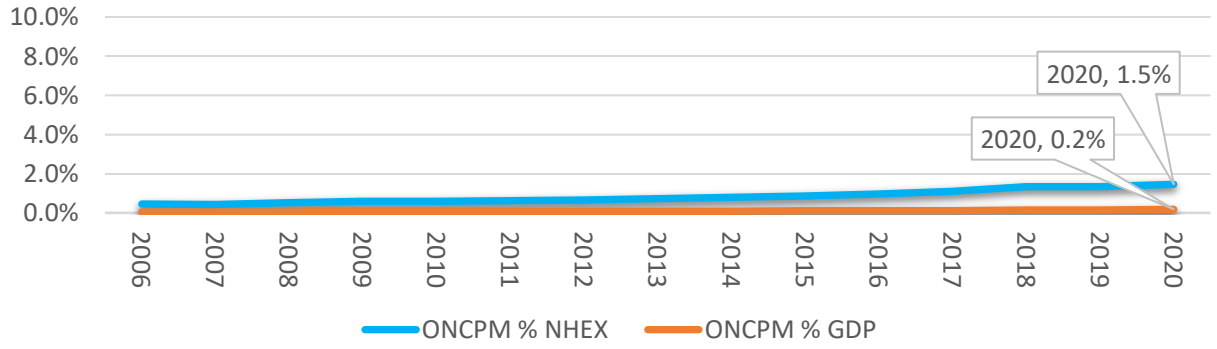
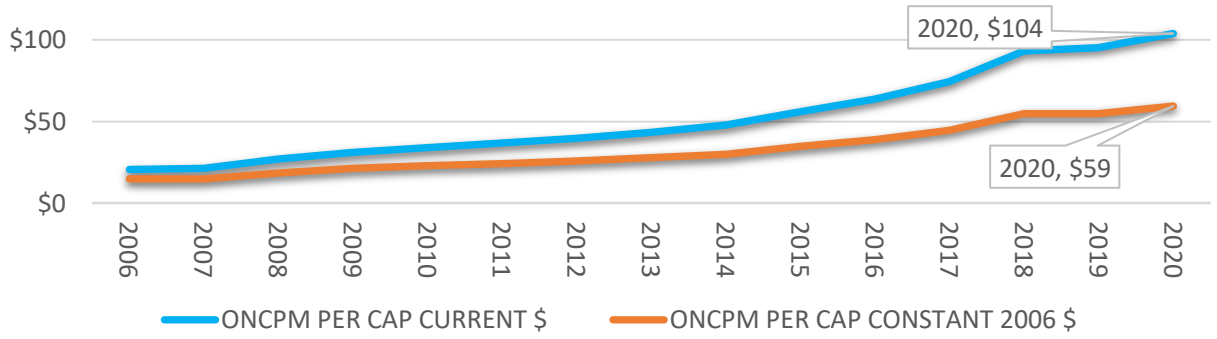


EXHIBIT 15. Inflation and Population Adjusted Expenditure on Patented Oncology Medicines 2006-2020.



DISCUSSION

Price Control Bureaucracy

A myopic focus on the cost of new drugs has driven the evolution of a complex, time-consuming and expensive, multi-layered bureaucracy to control the cost of patented medicines. Currently several government 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 (rebates negotiated with federal, provincial and territorial public drug plans under product listing agreements or PLAs), and centralized procurement (vaccines procured by Public Health Agency of Canada, PHAC), plus there are proposals for a federal super bureaucracy (Canada Drug Agency), a single national formulary, and national public drug insurance (pharmacare).

Administering the price control regime consumes significant public resources. A quick review of annual financial statements for the agencies listed above shows that $16 million was spent to sustain the PMPRB in 2020, over $36 million for CADTH, and $30 million for INESSS. Expenditures attributable to price control activities in the remaining agencies were not calculable from available data. Nevertheless, the direct cost of price regulation and HTA was over $82 million.

There are also non-monetary costs that are unaccounted for by policy makers. Evidence suggests that excessive price controls are a disincentive to launch new drugs and to invest in research and development in markets.[10, 11, 12, 13, 14, 15, 16] If governments want to ensure that Canadians have early access to new medicines, and want to attract foreign direct investment to Canada, the excessive focus on price controls is counterproductive.

Benefits of Pharmaceutical Innovation

The impact of excessive price regulation on the availability of patented medicines jeopardizes the potential benefits to be gained from greater utilization of new drugs. 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.[17]

- 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.[18]
- 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.[19]
- 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.[20]
- 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.[21]
- 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.[22]
- 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.[23]

- 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.[24]

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.[25] 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.

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.

CONCLUSION

This paper challenges the empirical validity of the assumption that the prices of patented medicines are a major cause of the growth in national health expenditures. Accounting for changes in population, inflation and economic growth, national expenditures on patented medicines are objectively affordable and sustainable. The excessive focus on price controls is counterproductive because it jeopardizes the availability of new medicines and discourages R&D investment in Canada. The lost potential health and economic gains almost certainly outweigh the incremental cost of pharmaceutical innovation to public drug budgets. Germany's structured negotiation approach to pricing and reimbursement has advantages over Canada's multi-layered price control bureaucracy.

DATA SOURCES

i. Canadian Institute for Health Information (CIHI).
   a. Trends in Hospital Spending, 2005–2006 to 2019–2020 — Data Tables — Series A: Hospital Spending by Type of Expense. Ottawa, ON: CIHI; 2021. 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 2019–2020.
   b. National Health Expenditure Trends, 2021 — Methodology Notes.
   c. National Health Expenditure Database, 2021.
      i. Table A.3.1.1 Total health expenditure by use of funds, in millions of current dollars, Canada, 1975 to 2021.
      ii. Table B.3.1 Public-sector health expenditure by province/territory and Canada, in millions of current dollars, 1975 to 2021.
      iii. Table G.14.1 Expenditure on drugs by type and source of finance in millions of current dollars, Canada, 1985 to 2021.
      iv. Appendix A.1 Gross domestic product at market prices by province/territory and Canada, in millions of current dollars, by year, 1975 to 2021.
      v. Appendix D.1 Population by province/territory and Canada, in thousands, by year, 1975 to 2021.

ii. Patented Medicine Prices Review Board (PMPRB).
   a. PMPRB 2020 Annual Report.
      i. Figure 20. Annual Rate of Change, Patented Medicines Price Index (PMPI) and Consumer Price Index (CPI), 2003-2020.
      ii. Table 10. Average Foreign-to-Canadian Price Ratios, Multilateral Comparisons, 2020. (Historical data from ARs 2008-2017).
      iii. Table 20. Sales of Patented Medicines, 1990 to 2020.
      iv. Figure 10. Share of Sales for High-Cost Patented Medicines by Annual Treatment Cost, 2006 to 2020.
      v. FIGURE 12. Share of Sales for Patented Oncology Medicines by 28-day Treatment Cost, 2006 to 2020.
   b. CompassRx, 7th edition: Annual Public Drug Plan Expenditure Report, 2019/2020.
      i. Figure 1.2. Prescription drug expenditures in NPDUIS public drug plans, 2019/20 ($million). Plan-paid share of total prescription cost.
      ii. Figure 1.5. Annual rates of change in drug costs by market segment, NPDUIS public drug plans*, 2018/19 to 2019/20.
      iii. Figure 1.7. Annual dispensing costs as a share of total prescription drug expenditures, NPDUIS public drug plans, 2017/18 to 2019/20.

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

REFERENCES

1. CIHI National Health Expenditure Trends, 2021 — Snapshot, Hospitals, Drugs and Physicians — Still the 3 largest health spending categories. https://www.cihi.ca/en/national-health-expenditure-trends-2021-snapshot.
2. CIHI National Health Expenditure Trends, 2021 — Methodology Notes.
3. CIHI National Health Expenditure Trends, 2021 — Methodology Notes.
4. CIHI National Health Expenditure Trends, 2021 — Methodology Notes.
5. CIHI National Health Expenditure Trends, 2021 — Methodology Notes. Page 9, 20.
6. CIHI National Health Expenditure Trends, 2021 – Methodology Notes. Page 10.
7. Patented Medicine Prices Review Board. Annual Report 2020.
8. Office of the Auditor General of Ontario. Annual Report 2017. Section 3.09 Ontario Public Drug Programs. Page 491.
9. Garaszczuk R, Yong JHE, Sun Z, de Oliveira C. The Economic Burden of Cancer in Canada from a Societal Perspective. Curr Oncol. 2022 Apr 14;29(4):2735-2748. doi: 10.3390/curroncol29040223. PMID: 35448197; PMCID: PMC9025082.
10. Labrie, Yanick (2020). Evidence that regulating pharmaceutical prices negatively affects R&D and access to new medicines. Canadian Health Policy, June 2020. https://www.canadianhealthpolicy.com/
11. Patricia M. Danzon, Y. Richard Wang and Liang Wang (2005). The impact of price regulation on the launch delay of new drugs – evidence from twenty-five major markets in the 1990s. Health Economics, 14: 269–292 (2005).
12. Margaret K. Kyle (2007). Pharmaceutical Price Controls and Entry Strategies. Review of Economics and Statistics, Volume 89 | Issue 1 | February 2007 p.88-99.
13. Patricia M. Danzon and Michael F. Furukawa (2008). International Prices and Availability of Pharmaceuticals In 2005. Health Affairs 27, no. 1 (2008): 221–233; 10.1377/hlthaff.27.1.221.
14. Joan Costa-i-Font, Nebibe Varol, Alistair McGuire (2011). Does price regulation affect the adoption of new pharmaceuticals? The Centre for Economic Policy Research.
15. Nebibe Varol & Joan Costa-i-Font & Alistair McGuire (2011). Explaining Early Adoption of New Medicines: Regulation, Innovation and Scale. CESifo Working Paper Series 3459, CESifo Group Munich.
16. Panos Kanavos, Anna-Maria Fontrier, Jennifer Gill, Olina Efthymiadou (2019). Does external reference pricing deliver what it promises? Evidence on its impact at national level. The Journal of Health Economics.
17. 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/
18. Lichtenberg, Frank R (2016). The Benefits of Pharmaceutical Innovation: Health, Longevity, and Savings. Montreal Economic Institute. June 2016.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

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

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