

Medicines pricing and reimbursement in Canada

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Abstract

Objective: overview of Canadian practices for regulating, financing, and funding prescription drugs. Canada provides universal health coverage for hospital and physician services but excludes universal insurance of prescription medicines. Public plans provide 42% of financing, while private drug insurance covers 35% of expenditures and over 60% of Canadians – mainly through their employer. Canada has relatively high out-of-pocket expenditure (19% of spending) and is currently the tenth largest pharmaceutical market, following Brazil. It is wrestling with inequitable coverage, low use of biosimilars, and affordability and sustainability issues driven by rare disease drugs. Both federal and provincial/territorial governments and their agencies have roles in setting policy and regulating drug prices and costs. These include the federal Patented Medicine Prices Review Board (PMPRB) which ensures prices of new patented drugs are not excessive; the pan-Canadian Pharmaceutical Alliance (pCPA) which negotiates lower patented, generic and biosimilar drug prices on behalf of member jurisdictions; and the Canadian Agency for Drugs and Technologies in Health (CADTH) which provides most public drug plans with robust health technology assessment (HTA), including clinical, economic and budget impact analyses of new drugs. Private drug insurers tend to follow government initiatives, including the use of HTA and confidential Product Listing Agreements. Conclusions: Pharmaceutical coverage in Canada is a “patchwork” of more than 100 public drug plans and 100,000 private insurance plans. As such, it creates gaps in coverage which result in inequitable access and high out-of-pocket drug expenses for some Canadians. Canada’s decentralized health system and the absence of universal drug insurance, among other factors, likely contribute to higher per capita drug expenditure relative to comparable nations that have broader, publicly-funded universal health insurance and more rigorous policy and program strategies.

Keywords: pharmaceutical services; prescription drugs; drug costs; insurance, health, reimbursement; delivery of health care; Canada.

Precificação e reembolso de medicamentos no Canadá

Resumo

Objetivo: fornecer uma visão geral das práticas canadenses para regular, precificar e financiar medicamentos sob prescrição. O Canadá propicia cobertura universal principalmente para serviços hospitalares e médicos, porém, não inclui cobertura universal para medicamentos sob prescrição. Seguros públicos cobrem 42% do financiamento, enquanto os seguros privados cobrem 35% dos medicamentos sob prescrição, para acima de 60% dos cidadãos canadenses, sobretudo financiados por empregadores. O Canadá tem um gasto privado (*out-of-pocket*) relativamente alto (19%), e atualmente é o décimo mercado mundial, depois do Brasil. O país se digladia com cobertura desigual, baixo uso de biossimilares, além de problemas com capacidade de pagamento e sustentabilidade, principalmente em relação aos medicamentos para doenças raras. Tanto o governo federal como de territórios/províncias e suas agências desempenham papéis no estabelecimento de políticas e na regulação de preços e custos de medicamentos. Esses incluem o Painel de Revisão de Preços de Medicamento sob Patente (*PMPRB*), que garante que preços de novos medicamentos patenteados não sejam excessivos, a Aliança Farmacêutica Pan Canadense (*pCPA*), que negocia preços mais baixos para medicamentos patenteados, genéricos e biossimilares, para membros de suas jurisdições, e a Agência Canadense para Medicamentos e Tecnologias em Saúde (*CADTH*), que atua no desenvolvimento de avaliação de tecnologias em saúde (*ATS*) para a maior parte dos planos de cobertura de medicamentos, incluindo análises clínicas, econômicas e de impacto orçamentário de novos medicamentos. Seguros privados tendem a seguir as iniciativas governamentais, incluindo o uso de *ATS* e Acordos Confidenciais sobre Produtos. Conclusões: A cobertura em medicamentos no Canadá é bastante fragmentada, com mais de 100 planos de cobertura de medicamentos, e 100.000 seguros privados. Como tal, criam-se lacunas na cobertura, que resultam em acesso desigual e alto gasto privado (*out-of-pocket*) para alguns canadenses. O sistema de saúde descentralizado do país e a ausência de seguro universal para medicamentos, dentre outros fatores, provavelmente contribuem para altos custos *per capita* de medicamentos, em relação a outras nações com as quais é possível haver comparação, e que possuem cobertura pública e universal mais abrangente, além de políticas e estratégias programáticas mais rigorosas.

Palavras-chave: assistência farmacêutica; medicamentos sob prescrição; custos de medicamentos; seguro de saúde; reembolso de seguro de saúde; atenção à saúde; Canadá.



Country characterisation

Canada is the second largest country in the world geographically (9,984,670 km²), but it ranks only 38th in population (38,246,108 million in 2021).^{1,2} Most Canadians live in urban areas, but there are many rural and remote communities and Canada's overall population density is sparse (four people per square km of land area).^{3,4} The country has ten provinces and three territories with ethnically and culturally diverse populations — including First Nations, *Inuit*, and *Métis* peoples, and with two official languages reflecting its history of colonization by the French and English.⁵ More recently, immigration, particularly from Asian countries, has increased Canada's multicultural diversity.⁵

The Human Development Index for Canada was 0.929 and it ranked number 16 worldwide, in 2019.⁶ Canada's gross domestic product (GDP) in 2020 was estimated at \$2.12 trillion (USD PPP 1.644 trillion⁷) and the per capita GDP was \$55,673 (USD PPP 43,258⁸). (All costs are expressed in Canadian dollars and converted to USD PPP, Purchase Power Parity).

As of 2019, Canadian life expectancy at birth was estimated as 82 years.⁹ Infant mortality rate was 4.2 and the maternal mortality rate was 7.53 (deaths per 1,000 live births, in 2019).^{10,11}

Health system characterization

In 2018, the Organisation for Economic Co-operation and Development (OECD) ranked Canada as 11th in health expenditures (USD PPP) per capita.³ However, in terms of public expenditure on health as a percentage of total health expenditures, for the same period, Canada ranked much lower (26th).³

Approximately 70% of health care expenditures in Canada are publicly financed through general taxation by the federal, provincial and territorial governments.³ The federal government oversees the Canada Health Act which ensures all Canadians have access to medically necessary health care (i.e., "insured health care services") provided in a hospital or by a physician, regardless of their ability to pay.¹² Canada's universal health care system, often referred to as Medicare, provides public coverage mainly for hospital (91%) and physician (99%) services.¹³ Public coverage is limited for health care services provided outside of a hospital—including prescription drugs.³ Unlike most high income countries with universal public health care, Canada does not include universal access to prescription drug insurance.¹⁴

The federal government is also responsible for regulatory approval of pharmaceuticals and medical devices, and for health care for certain populations (e.g., some indigenous peoples, military personnel, and prison inmates).³ However, the delivery of most health services is decentralized — the provinces and territories are responsible for financing, regulating, and providing essential health care services to their residents.^{3,12} The provinces and territories are also responsible for non-Medicare health services, including subsidizing prescription drug costs for certain groups, such as seniors and those on social assistance.^{3,15}

Provinces and territories must comply with the principles of the Canada Health Act to receive federal funding through the Canada Health Transfer.³ Most Canadians regard universal healthcare as one of Canada's defining qualities and 'access to health care based on need, not ability to pay' is a core value.¹⁶

In Canada, the federal-provincial-territorial dynamic is a crucial consideration for change and priority setting in health care. Tension between these levels of government is frequently over federal transfer payments which have been reduced over several decades from the original level of 50% of health program expenses, to about 23.5% (in 2019; now based on per capita).^{3,17} In fiscal year 2021-22, the Canada Health Transfer to the provinces and territories was just over \$43 billion (USD PPP 33.4 billion).¹⁸

Health care is the largest single program in provincial and territorial budgets, and now accounts for about 40% of total program spending.¹³ Total health care expenditure is expected to be 12.7% of Canada's GDP in 2021.¹³ Total health expenditures for 2021 are estimated to be \$308 billion (USD PPP 239.3 billion), or \$8,019 (USD PPP 6,231) per person.¹³ The pharmaceutical share of total health expenditures for this period was 13.9%.¹³ Total pharmaceutical spending for 2021 (prescription and non-prescription) is estimated to be \$1,114 (USD PPP 866) per person.¹³

Beyond hospital and physician services, only certain populations (low-income seniors and those on social assistance) are eligible for other publicly-funded health services, such as prescription drugs (outside of hospital), long-term care, vision and dental care.¹⁹

More than 60% of Canadians have supplemental health insurance which includes prescription drugs.^{9,20} Most (90%) of these plans are employment-based.²⁰

Challenges

One of Canada's many health care challenges is in delivering high quality health services to residents of rural and remote regions, over a large geographic area. With over 81% of its population living in urban areas, Canada is only slightly less urbanized than Brazil (87%).²¹ Canada's rural or remote residents often face health disparities. For example, Canadian indigenous peoples who live on remote reserve territories, as elsewhere in the world, have higher rates of infant, child and maternal mortality, infectious and chronic diseases, smoking, alcohol and drug abuse, and reduced life expectancy.²²

Health care cost containment is an ongoing problem and various approaches to managing this have been implemented.⁹ Drug cost containment initiatives include bulk purchasing, patient medication reviews, global budgets for hospitals and regional health authorities, and provincial drug formularies.^{9,23}

Pharmaceutical market

Canada is the 10th largest pharmaceutical market in the world (\$US), ranking just after Brazil.²⁴ In 2020, 758 million prescriptions were dispensed at Canadian community pharmacies, equivalent to roughly 20 prescriptions per person.²⁵

OECD health indicators in 2019 estimate about 39% of retail pharmaceutical sales in Canada were publicly funded, versus 34% through private insurance, and 27% paid for out-of-pocket by consumers.²⁶ (Note: this is higher than the 20% for out-of-pocket prescription drug expenditures reported by the Canadian Institute for Health Information.²⁷) In forecasts for 2021, public drug programs will account for 45% of the nearly \$37 billion (USD PPP 28.7 billion) of prescription drug spending.¹³ This does not include spending on drugs dispensed in hospitals or cancer agencies and other special programs. In addition, certain high-priced drugs,

such as drugs for rare diseases, may be funded for some patients through special programs, such as patient support programs that are partially funded by drug manufacturers.²⁸

There are more than 100 public drug plans which account for about 45% of drug spending – one of the lowest shares among OECD countries.¹⁹ Public spending on medicines is mostly (84%) provincial, with smaller contributions from Quebec's Drug Insurance Fund (3.6%), the federal government (3.0%) for specific drug programs it operates (i.e., military personnel, refugees, inmates of correctional facilities, indigenous peoples, etc.), and Workers' Compensation Boards for occupational injuries (0.4%). Annual per capita spending by public drug programs increased by 5.8% in 2021, compared to 2.2% in 2020.¹³ In 2020, 2.7% of Canadians had drug costs exceeding \$10,000 (USD PPP 7,770), and this small group accounted for 42% of all public drug program spending.²⁷

Although public coverage varies, all provinces and territories have drug programs for certain groups, such as seniors and social assistance recipients. Most provinces also provide highly variable protection from catastrophic drug expenditure, with cost-sharing scaled to income.³

Quebec, Canada's second most-populous province, is unique in providing a social insurance-based drug plan, with all residents required to obtain drug insurance coverage through this plan or through a private or employee benefit plan.²⁹ The province requires private plans to offer a formulary at least as generous as the provincial plan, and to ensure cost-sharing does not exceed the provincial standard of 35%.²⁹ Quebec currently limits out-of-pocket expenses for drugs on the provincial formulary to a maximum of \$1,161 per year (USD PPP 902).²⁹

More than 100,000 private health insurance plans provide drug coverage for more than 60% of Canadians, primarily through employment.³⁰ In 2021, spending for private drug insurance was forecast at about \$13 billion (35% of total spending, USD PPP 10.1 billion), versus about \$14 billion (38%, USD PPP 10.9 billion) in provincial spending.

Specialty drugs, almost all of which are biologics, now account for about 30% of total drug market spending but benefit less than 2% of all patients. According to Telus Health, the largest private pharmacy benefits manager in Canada, spending on specialty drugs, defined loosely as those costing \$10,000 (USD PPP 7,770) or more annually, has been increasing at much faster rates than traditional pharmaceuticals.³¹

Drugs for rare diseases may include specialty, gene and cell therapies. These drugs present significant funding challenges for public and private payers, with a floor cost of \$100,000 (USD PPP 77,700). More than half cost more than \$200,000 (USD PPP 155,400) annually and a handful now cost more than \$1 million (USD PPP 777,001).³² Drugs for rare diseases amount to 10% of all prescription drug spending in Canada and this spending increased much faster than any other drug category between 2012 and 2020.³²

All provinces and most private drug plans require generic substitution. Generic drugs accounted for 73% of all retail prescriptions in 2020, and about 20% of prescription drug spending.³³ All provincial and most private drug plans require switching to generic drugs, although private plans continue to have lower generic substitution rates than provincial plans: 65% vs. 77% in 2019.³³

Biosimilar drug spending has been relatively limited to date, but it is increasing. Following the lead of British Columbia in 2019, five provinces now mandate switching. The largest province, Ontario, announced its intention in February 2020, but has not yet implemented it. Several private insurers follow provincial switching requirements once implemented. There are 45 biosimilars marketed (36) or approved (9) for 14 originator products.³⁴

Overview of medicines regulation, costs and prices

The federal department of health (Health Canada) is the national authority that regulates, evaluates and monitors the safety, efficacy and quality of drugs, devices, and diagnostic products.³⁵ All drugs granted marketing authorization in Canada are reviewed by the Health Products and Food Branch to ensure that they meet the requirements of the *Food and Drugs Act*. Policies and guidance for drug reviews are available on Health Canada's website.³⁶ The Health Canada Drug Product Database lists drugs authorized for sale in Canada.

Health Canada's Priority Review Process allows for a faster review of drugs for life-threatening or severely debilitating conditions for which there are few effective therapies already on the market. The Special Access Programme allows physicians to gain access to drugs which are not currently available in Canada. Health Canada also conducts market surveillance, monitors adverse drug reaction reports, investigates complaints and problem reports, and manages drug recalls.³⁵

In addition to Health Canada, three other organizations play important roles in controlling drug access, prices and costs.

Patented Medicine Prices Review Board

The Patented Medicine Prices Review Board (PMPRB) was established by the Canadian Parliament in 1987 under the Patent Act. The PMPRB is an independent quasi-judicial body with two core mandates:

- (i) Regulatory: to ensure patented drug prices are "not excessive", and
- (ii) Reporting: to provide information on trends in drug prices, sales, and research and development spending.³⁷

The regulatory process comprises of a scientific review, which assesses the level of therapeutic improvement of a new patented drug and a price review, which is conducted on an ongoing basis to ensure that the prices charged by manufacturers comply with the Board's Guidelines.³⁸

Manufacturers are required by the Act to file information about the prices and sales of their patented drug products at market entry and twice annually thereafter until the patent expires.³⁹ The PMPRB compares the median prices of new patented drugs to a reference set of seven countries (PMPRB7: France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the USA), which will be replaced by a new group of 11 comparators (PMPRB11: Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, and the United Kingdom) when new Regulations are implemented. The new, larger comparator group excludes two high-price countries (USA and Switzerland) and adds six lower price countries: Australia, Belgium, Japan, Netherlands, Norway and Spain.

The Canadian price cannot exceed the median drug price in the comparator countries. Price increases cannot exceed the change in the Consumer Price Index as calculated by Statistics Canada. The Board has authority to investigate a price that appears excessive, and if it exceeds the Guidelines, the Board may order:

- (i) The manufacturer to reduce the price or take any other steps necessary for compliance through a Voluntary Compliance Undertaking (VCU); or
- (ii) A public hearing to ensure a non-excessive price through a remedial order.



In addition to a price reduction, the PMPRB may order the manufacturer to potentially offset up to twice the excess revenues to that date. The offset can be done through an additional price reduction or payment may be made to the federal government. Those funds are then distributed to provincial and territorial health ministries. Even though more than half of drug costs are paid by employers or individual patients, excess revenues flow only to governments.³⁹

The Strategic Plan 2015-2018 outlines the major environmental changes affecting the Board's mandate.⁴⁰ In 2016 and again in late 2019, public consultations were announced to review the Board's Guidelines, the operational rules for the Regulations under the Patent Act. Submissions to the PMPRB were publicly available on its website. A consultation on the Regulations occurred in 2017. The first major changes in more than 30 years to PMPRB regulations were announced in August 2019 and revised Guidelines followed in October 2020.⁴¹

In June 2021, the PMPRB closed a public consultation on a new Guidelines Monitoring and Evaluation Plan (GMEP). The GMEP will improve transparency by reporting on the proposed changes to the Guidelines and Regulations. There are four focal areas: patented drug prices, access to medicines, the pharmaceutical ecosystem, and PMPRB processes.⁴²

The federal government has allowed implementation of the Regulations to be deferred four times, citing the Covid-19 pandemic and the need for additional consultations. Court challenges have been launched in both the Federal Court and in Quebec's Superior Court by the brand drug industry association (Innovative Medicines Canada) and drug manufacturers seeking to overturn the proposed changes to those Regulations. At time of writing (May 2022), only the change to the PMPRB11 has been consistently upheld. The government also proposed other requirements to limit prices.⁴³ These included the use of pharmacoeconomic value, growth in market size, and GDP per capita. The most contentious change has been mandating information on confidential price rebates, but both courts have determined the PMPRB has no authority to implement this change.

It is uncertain whether the PMPRB intends to introduce previously announced repricing of older ("grandfathered") patented drugs, a practice already in place in France and Switzerland. After changing the unit of measurement from median to highest price among the PMPRB11, potential savings have been significantly reduced to about 5%.

Implementation of new Regulations will occur on July 1, 2022, however, only the change to the PMPRB11 will proceed.⁴¹ Overall, projected cumulative savings on patented drugs have been cut by more than half from \$13.2 billion⁴⁴ (USD PPP 10.3 billion) over 10 years to \$6.2 billion⁴⁵ (USD PPP 4.8 billion) between 2020 and 2030.

pan-Canadian Pharmaceutical Alliance

The pan-Canadian Pharmaceutical Alliance (pCPA) was established in 2010 to negotiate lower prices for most new drugs, all generic drugs, and to ensure price transparency for biosimilars.⁴⁶ The pCPA operates on behalf of all provinces and territories and some federal drug plans. The pCPA conducts individual negotiations for new brand-name drugs that apply only to public plans. In contrast, the whole market benefits from pCPA initiatives to reduce generic drug prices and mandate biosimilar price transparency. The pCPA is funded by participating jurisdictions and an administrative office is hosted by the Province of Ontario.

Since 2010, pCPA negotiations have achieved overall annual savings (as of March 2021), of \$2.16 billion (USD PPP 1.7 billion) for brand name drugs, and \$740 million (USD PPP 575 million) for generic drugs.⁴⁶ This represents about 18% of public drug plan costs,⁴⁷ and 12% of generic drug sales in 2020.⁴⁸

a) Brand Drug Prices

The pCPA begins its negotiations with drug manufacturers after receiving the outcomes of health technology assessments (HTAs) conducted by CADTH and Quebec's *Institut national d'excellence en santé et en services sociaux* (INESSS). About 80% of all new drugs are reviewed by pCPA. A guidance document (April 2019) includes a glossary, objectives, process description and timelines.⁴⁹

Successful negotiations lead to a letter of intent (LoI) and then a confidential Product Listing Agreement (PLA) between each participating jurisdiction and the drug manufacturer. The PLA includes the recommended terms and conditions to fund a drug including a budget impact analysis. Discounted prices have been the most common outcome, although other types are used and more are under consideration to reflect rare disease drugs.⁴⁷ Each jurisdiction chooses whether to list any new drug and determines its own drug formulary.⁴⁶

b) Generic Drug Pricing

Historically, generic drug prices have been set as a percentage of the brand drug price. The pCPA introduced a tiered pricing framework in April 2014 that sets a national reference price based on the number of generics in the market.⁵⁰ It later negotiated a five-year (2018-23) agreement with the generic drug industry association to lower prices for 67 commonly-used generic drugs to either 18% or 10% of the original patented drug price.⁵¹

In December 2010, median Canadian generic drug prices were about twice the median price in the PMPRB7. Since then, provincial and pCPA pricing policies have driven prices significantly lower. By Q4 2018, PMPRB7 median prices were 13% lower, and mean prices were 5% higher than Canadian prices. Average generic prices dropped 59% in Canada over the ten-year period ending December 31, 2018, relative to a 42% drop in the OECD average price (using local currencies) over that same period.⁵²

c) Biosimilars

The pCPA negotiates biosimilar prices in tandem with the HTA, although only INESSS continues to perform HTA. Savings relative to the original biologic have been between 25% and 50%. Since 2016, the pCPA has required all biosimilars (then called Subsequent Entry Biologics) to provide a "transparent price to benefit all Canadians."⁵³

In 2020, biosimilar sales were \$542 million (USD PPP 421 million), 5.4% of all biologic sales. Canada had realized just 23% (\$168 million, USD PPP 131 million) of potential savings from biosimilar switching.⁵⁴

Private Drug Plans

Private drug plans are not regulated for scope of coverage or cost-sharing except in Quebec. Health insurers are regulated either by the federal or provincial governments but mostly for financial metrics such as capital adequacy. Unlike public drug plans, each insurer and pharmacy benefit manager (collectively called carriers) independently sets a "reasonable and customary" price for each drug it reimburses.



Most carriers use similar approaches and tools as their provincial counterparts, including HTAs and negotiated Product Listing Agreements (PLAs) for new brand drugs. Prior authorization is also used to screen appropriate use of certain prescribed drugs that may be expensive, have uncertain benefit or are often prescribed outside Health Canada's approved indication. The most common targets for PLAs are high-priced specialty, cancer and rare disease drugs.⁵⁵ PLAs have been positioned by insurers as a competitive advantage to attract and retain clients.⁵⁵

The insurance industry association has recommended closer coordination between the two payer groups. They have asked for a place on the PMPRB Board and that the pCPA set a single national price for patented drugs, but neither of these have occurred.^{55,56} One concern is that negotiated discounts may be less favourable if drug manufacturers must spread available funding for discounts across both the public and private markets. There is also uncertainty that each private insurer will act in solidarity with public payers in drug price negotiations.^{55,57}

Overview of Health Technology Assessment (HTA) for pricing and reimbursement

In addition to CADTH (the Canadian Agency for Drugs and Technologies in Health), the national health technology assessment (HTA) agency, the HTA infrastructure has expanded to provincial and regional levels to facilitate greater alignment of evidence-based information to meet the needs of decision-makers.⁵⁸ This has taken various forms, including Quebec's INESSS and Health Quality Ontario (HQO) as provincial HTA agencies, as well as the Alberta provincial government's use of partner agencies to produce assessments.⁵⁹ There are also hospital, university, and institutional HTA units that complement these other approaches.⁶⁰ Increasing collaboration and coordination between all Canadian HTA producers is recognized as a priority.⁶⁰

HTA for medicine reimbursement

Health technology assessment expert panels, in particular, CADTH's Common Drug Review (CDR) and pan-Canadian Oncology Drug Review (pCODR), undertake comprehensive assessments to establish the clinical, cost-effectiveness and potential budget impact of new drugs.⁶¹ The CDR and pCODR reduce duplication of effort across jurisdictions by providing a single evidence assessment of new drugs or new indications for existing drugs. CADTH makes recommendations to federal, provincial and territorial governments and their cancer agencies about whether a new drug should be publicly funded.⁶¹ Recommendations are formulated by the Canadian Drug Expert Committee (CDEC) which consists of 14 members and a Chair. Two are public members, while the remaining 12 represent technical experts, such as physicians, pharmacists, economists, or other professionals with expertise in general practice, internal medicine, clinical pharmacology, clinical epidemiology, health services research, ethics, or behaviour change. Based on the recommendations each jurisdiction decides which drugs to list on its public formulary.⁶²

The following elements inform CDEC recommendations: input from patients and caregivers, clinical and economic evidence, input from clinical experts, existing treatment options, submitted price of drug under review and publicly available prices of comparators, and a

sponsor's requested reimbursement terms and evidence supporting these conditions. Broadly, criteria considered during deliberations include comparable or added clinical benefit and 'acceptable' cost/cost-effectiveness relative to one or more appropriate comparators.^{61,63-65}

Where there is significant unmet need and uncertain but promising clinical evidence (e.g., suggesting substantial reduction in morbidity and/or mortality), CDEC may recommend reimbursement with conditions. Significant unmet need includes consideration of the rarity of the condition, absence of alternatives and the ability to identify the condition with reasonable diagnostic accuracy.

The CADTH horizon scanning program identifies new and emerging health technologies, including new pharmaceuticals, that are likely to have a significant impact on health care.⁶⁶ CADTH staff monitor health information sources to identify health technologies not yet widely used in Canada. For example, a recent publication reviewed prescription drug expenditures from 2001-2023, with a horizon scan of new drugs that are expected to have significant budget impacts.⁶⁷

Private drug plans have separate HTA and drug price negotiation processes. Private insurers and pharmacy benefit managers may undertake their own HTA reviews although it is not clear if these differ substantially from those undertaken by CADTH and INESSS, since none was published. Telus Health recently described its approach to a budget impact analysis.⁶⁸

Policy and Pricing Case Summaries

Quebec

An example of significant changes in drug policy and plans that impacted drug costs and utilization occurred in the province of Quebec, Canada's second most populous province with about 8.6 million residents.² In 1997, Quebec adopted a social insurance model to achieve universal drug insurance and control costs for the provincial government.⁶⁹ Residents of Quebec are legally mandated to have drug insurance. Any employer providing a supplemental health plan to its employees must include a drug plan with a formulary and cost-sharing limits that are no less generous than the provincial drug plan. Quebec provides significant subsidies for low-income residents. A separate provincial agency, the *Régie de l'assurance maladie du Québec* (RAMQ) administers the public health and prescription drug insurance plans.⁷⁰

Quebec's Best Available Price (BAP-15) policy, in place from 1994 until it was terminated in 2013, appears to have increased Quebec's share of research and development, but may also have decreased generic substitution rates relative to the rest of Canada.⁷¹ This has since changed, and generic substitution rates in Quebec are now 76.7%, above the national average of 73.0%.⁴⁸

National Pharmacare

In 2015 the federal government announced it planned to implement a national public drug insurance plan, called national pharmacare. Proposed since the 1940s, the federal Advisory Council on the Implementation of National Pharmacare estimated that comprehensive, public, single-payer national pharmacare would reduce total annual spending by \$4.8 billion (USD PPP 3.7 billion) in 2027.⁷² However, despite public support,^{72,73} the federal government is not introducing comprehensive national drug insurance. Other tactics are underway, including a new Canadian



Drug Agency (CDA) Transition Office which is working with provinces, territories, and other partners to develop a national formulary and CDA's vision and mandate. This may include better alignment of functions now performed by the pCPA, CADTH and Health Canada. Health Canada has held public consultations⁷⁴ to develop a national strategy for drugs for rare diseases (DRDs), expected later in 2022. New federal DRD funding of about \$500 million (USD PPP 389 million) annually is to begin in April 2022.

Other Initiatives

Choosing Wisely Canada, a clinician-led campaign, addresses overuse of tests and treatments, including pharmaceuticals, and provides recommendations to governments, providers, and the public on reducing low-value care.⁷⁵

The Canadian Deprescribing Network is also aimed at improving patient safety by reducing inappropriate use of pharmaceuticals among seniors (i.e., over-prescribing).⁷⁶

Lessons learned and perspectives for improving existing pricing and reimbursement

Canada has high per capita drug expenditures compared to OECD countries that provide universal public drug insurance.^{77,78} This suggests efforts to reduce pharmaceutical prices and expenditure in Canada have been far less effective than elsewhere.^{77,79}

The federal government provides relatively limited direct funding for health services, however it could be a policy leader and play a larger role in public drug financing.

Ongoing discord between the federal government and provincial governments over health transfers, as well as political and economic interests (e.g., the pharmaceutical industry and private insurers) have impeded efforts to create national coverage quality standards and introduce a national pharmacare insurance plan.^{77,78,80}

The latest failure to launch a comprehensive national public drug plan ensures that private drug insurance continues to play a large role in financing prescription drugs in Canada.

Despite the lack of a national drug insurance plan, virtually all Canadians have access to good quality private or provincial drug insurance plans that cover most of their prescription drug costs. However, some Canadians may not have enough drug insurance to minimize out-of-pocket expenses.

Differences and inequalities in public and private drug coverage across the country affect those most vulnerable, such as the working poor, part-time employees or the unemployed.⁸⁰

Efforts to control drug costs have included the use of health technology assessments, such as those provided by CADTH's Common Drug Review and INESSS, price reviews of new patented drugs by the PMPRB, and collaborative, national price negotiations for public plans by pCPA.⁸⁰ The pCPA has effectively improved pricing for new and generic drugs, and ensured price transparency for biosimilars.

Across all payers, better coordinated drug utilization systems and data are needed to support more complex decisions that often need to be made more quickly.

Initiatives to reduce inappropriate use of medications, such as Choosing Wisely Canada and the Canadian Deprescribing Network, may help to both reduce drug and health care costs and to improve patient safety.^{75,76,80}

Final considerations and recommendations

In Canada's decentralized health care system, provincial and territorial governments fund prescription drugs for seniors and those on social assistance, and most provinces offer all residents variable levels of protection from catastrophic drug expenses. Quebec uniquely provides mandatory universal drug insurance. The federal government's drug programs for specific populations (e.g., military personnel, refugees, inmates of correctional facilities, aboriginals, etc.) and Workers' Compensation Boards offer drug coverage to some segments of the population.

Although facing challenges similar to those of other publicly-funded universal health care systems, Canada continues to provide hospital and medical services with virtually no cost-sharing. In these two categories, coverage is deep, but the basket of publicly-paid health services under Medicare is very narrow relative to other universal health systems.

New high-priced drugs have challenged and reinforced Canadian strategies to contain drug costs, including proactive health technology assessments, price reviews and negotiations, drug monitoring and utilization reviews, and initiatives to promote appropriate drug use. Greater coordination between public drug plans and private drug insurers will also be essential to manage high-cost drugs and overall drug expenses.

Amid those diverse strategies to contain public drug expenditure, bulk purchasing and price negotiations are key. Further strategies implemented to manage pharmaceutical expenditure include global budgets for hospitals, negotiated pharmacy fee schedules, managed drug formularies that include negotiated Product Listing Agreements, use of generic and biosimilar drugs where possible, drug utilization monitoring, and patient medication reviews by pharmacists. In addition, collaborative, centralized health technology assessment initiatives ensure high-quality clinical and economic evidence is available to inform public drug plan decision-making.

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CB- contributed sections to the first draft, reviewed first, second and third drafts of the manuscript, addressed comments of co-authors, provided comments on other authors' contributions.

TS- contributed sections to the initial draft and provided comments on first and second drafts.

ET- drafted the initial manuscript, reviewed additional sections provided by co-authors and the translation, addressed co-authors' and editors' comments.



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Conflict of interest statements

The authors declare that there are no conflicts of interest regarding this article.

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