Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

ANNUAL REPORT 2019

PROTECT
EMPOWER
ADAPT

Patented Medicine Prices Review Board

STATISTICAL HIGHLIGHTS 2019

Regulatory Mandate

- 1,364 patented medicines for human use were reported to the PMPRB, including 81 new medicines.
- 12 Voluntary Compliance Undertakings were accepted as of December 31, 2019.
- $3.5 million in excess revenues were offset by way of payments to the Government of Canada, in addition to price reductions.

Reporting Mandate

SALES TRENDS:

- Sales of patented medicines in Canada reached $17.2 billion in 2019, a moderate increase of 3.5% from the previous year.
- Patented medicines accounted for approximately 60% of the sales of all medicines in Canada.

PRICE TRENDS:

- Prices of existing patented medicines were stable, while the Consumer Price Index rose by 1.9%.
- Canadian prices were fourth highest among the seven PMPRB comparator countries, lower than prices in Switzerland, Germany, and the US.
- Canadian list prices were fourth highest among 31 Organisation for Economic Co-operation and Development (OECD) countries, lower only than prices in Switzerland, Germany, and the US.

RESEARCH AND DEVELOPMENT

R&D-TO-SALES RATIOS DECREASED IN 2019:

- 3.9% for all patentees, a slight decrease from 4.0% in 2018.
- 3.9% for Innovative Medicines Canada members, a decrease from 4.3% in 2018.

R&D EXPENDITURES:

- $893.2 million in total R&D expenditures reported by patentees, an increase of 0.1% over 2018.
- $652.6 million in R&D expenditures reported by Innovative Medicines Canada members, a decrease of 9.7% over 2018.

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January 15, 2021

The Honourable Patty Hajdu, P.C., M.P.
Minister of Health
House of Commons
Ottawa, Ontario
K1A 0A6

Dear Minister:

I have the pleasure to present to you, in accordance with sections 89 and 100 of the *Patent Act*, the Annual Report of the Patented Medicine Prices Review Board for the year ended December 31, 2019.

Yours very truly,

Dr. Mitchell Levine
Chairperson

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CHAIRPERSON'S MESSAGE

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body established by Parliament in 1987 under the *Patent Act* (the Act). The PMPRB's mandate is to protect and inform Canadians by ensuring that the prices of patented medicines sold in Canada are not excessive and by reporting on pharmaceutical trends.

This past year was a busy and important one for the PMPRB. The organization focused on completing the final steps in a multiyear effort to strengthen and modernize our regulatory framework. To that end, in November 2019, we published a draft set of new pricing Guidelines, followed by the most intensive and far reaching public consultation in our more than three decades long history. In June 2020, following the Government's announcement of its decision to postpone the coming into force of the amended *Patented Medicines Regulations* (Regulations) by six months, to January 1, 2021, due to the COVID-19 pandemic, the PMPRB published a second draft set of new Guidelines that reflected our understanding of the feedback we received on the first draft. This was followed by another round of consultations which ended on August 4, 2020.

I would like to acknowledge and thank the thousands of Canadians who shared their thoughts and perspectives on the modernization of our regulatory framework particularly those who took the time to submit their views in writing. The PMPRB looks forward to issuing the final version of its new Guidelines in the fall of 2020, in anticipation of the coming into force of the amended Regulations in January 2021.

Our efforts to complete the regulatory modernization process took place in parallel to our usual and customary work under our reporting mandate of identifying and analyzing key pharmaceutical trends in Canada. In 2019-20, the PMPRB published seven analytical reports, three chartbooks and eight presentation posters under its National Prescription Drug Utilization Information System (NPDUIS) banner. The

chief takeaway from all that work is the notable rise in the sales of higher-cost medicines Canada has experienced in recent years. Over the last five years, sales of patented medicines grew by an average of 4.5% per year, reaching $17.2 billion in 2019. The increasing use of higher-cost medicines remains the primary cost driver for Canadian public and private drug plans. Indeed, high-cost, biologic, oncology and targeted treatments now account for approximately half of all sales in patented medicines in Canada. This is a dramatic increase from the 10% of less than a decade ago. To put this trend in context, in 2009, only one of the top ten selling patented medicines in Canada had a treatment cost over $1000/year. In 2019, seven of the top ten selling patented medicines had annual treatment costs that exceeded $10,000/year.

Canadian list prices of patented medicines are the fourth highest in the Organisation for Economic Co-operation and Development (OECD), still well behind the US but just marginally lower than Germany and Switzerland. Conversely, the R&D to sales ratio of pharmaceutical patentees in Canada continues its decades-long decline and now stands at 3.9%, its lowest level since the PMPRB first began reporting on pharmaceutical trends in the 1980s.

Once the PMPRB's new Guidelines are finalized and the amended regulations come into force in January 2021, we look forward to working with all of our stakeholders on a comprehensive Guidelines Monitoring and Evaluation Plan (GMEP) that will enable us to assess the impact of the new regime and fine tune it in real time so that the PMPRB can continue to protect Canadians from excessive prices while avoiding any unintended consequences to other aspects of our health care system.

The PMPRB has been in reform mode for the better part of five years. Once the final Guidelines are published and the amended Regulations come into force, we look forward to a new and exciting chapter of applying our consumer protection powers responsibly and with the best interests of all Canadians at heart.

Dr. Mitchell Levine
Chairperson

ABOUT THE PATENTED MEDICINE PRICES REVIEW BOARD: ACTING IN THE INTEREST OF CANADIANS

The Patented Medicine Prices Review Board (PMPRB) is an independent, quasi-judicial body established by Parliament in 1987 under the *Patent Act* (Act).

The PMPRB is a quasi-judicial administrative agency with a dual regulatory and reporting mandate. Through its regulatory mandate, it ensures that the prices of patented medicines sold in Canada are not excessive. The PMPRB also reports on trends in pharmaceutical sales and pricing for all medicines and on research and development (R&D) spending by patentees. In addition, at the request of the Minister of Health pursuant to Section 90 of the Act, the PMPRB conducts critical analyses of price, utilization, and cost trends for patented and non-patented prescription medicines under the National Drug Utilization Information System (NPDUIS) initiative. Its reporting mandate provides pharmaceutical payers and policy makers with information to make rational, evidence-based reimbursement and pricing decisions.

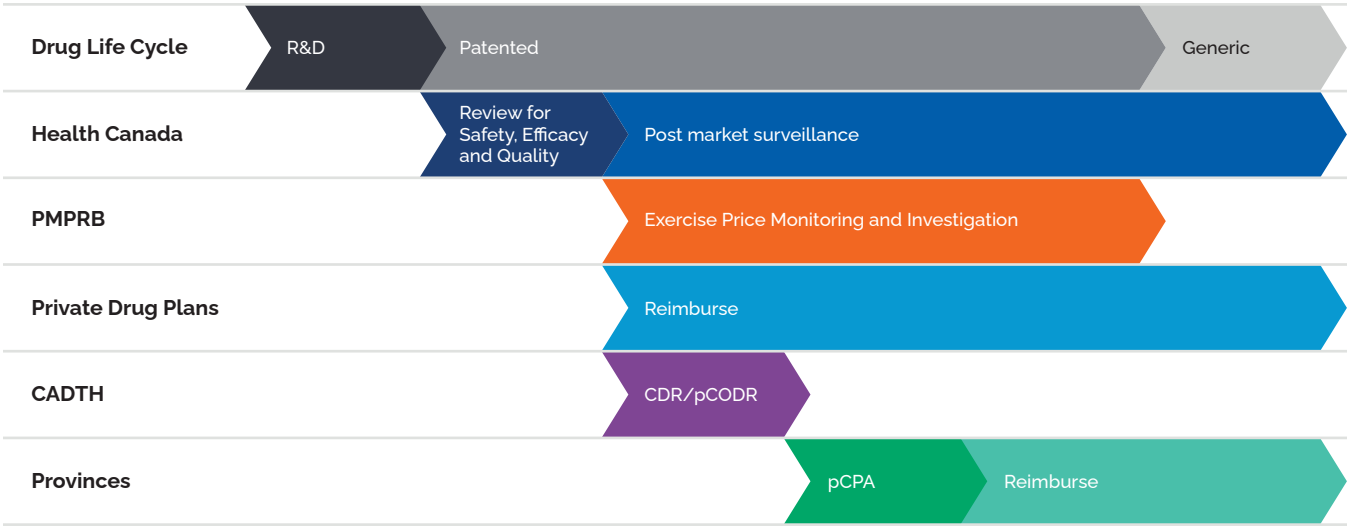
The PMPRB is part of the Health Portfolio, which includes Health Canada, the Public Health Agency of Canada, the Canadian Institutes of Health Research and the Canadian Food Inspection Agency. The Health Portfolio supports the Minister of Health in maintaining and improving the health of Canadians.

OUR MISSION

The PMPRB is a respected public agency that makes a unique and valued contribution to sustainable spending on pharmaceuticals in Canada by:

- Providing stakeholders with price, cost, and utilization information to help them make timely and knowledgeable pricing, purchasing, and reimbursement decisions; and
- Acting as an effective check on the prices of patented medicines through the responsible and efficient use of its consumer protection powers.

Protecting Consumers in a Complex Marketplace



(CADTH) Canadian Agency for Drugs and Technologies in Health; (CDR) Common Drug Review; (pCODR) pan-Canadian Oncology Drug Review; and (pCPA) pan-Canadian Pharmaceutical Alliance
Data Source: PMPRB

Although part of the Health Portfolio, because of its quasi-judicial responsibilities, the PMPRB carries out its mandate at arm's length from the Minister of Health, who is responsible for the sections of the Act pertaining to the PMPRB. The PMPRB also operates independently of other healthcare related bodies such as:

- Health Canada, which approves medicines for marketing in Canada based on their safety, efficacy and quality;
- federal, provincial and territorial (F/P/T) public drug plans, working collectively as the pCPA, which approve the listing of medicines on their respective formularies for reimbursement purposes; and
- the Common Drug Review and pan-Canadian Oncology Drug Review, administered by the CADTH, which recommends which new medicines should qualify for reimbursement by the pCPA.

The PMPRB is composed of public servants (Staff) who are responsible for carrying out the organization's day-to-day work, and Board Members, Governor-in-Council appointees who serve as hearing panel members in the event of a dispute between Staff and a patentee over the price of a patented medicine.

Jurisdiction

Regulatory

The PMPRB regulates the maximum ceiling price at which patentees (companies) may sell their products to wholesalers, hospitals, pharmacies and other large distributors. This price is sometimes also known as the "factory gate" (ex-factory) price. The PMPRB does not regulate the prices of non-patented medicines.

The PMPRB's jurisdiction is not limited to medicines for which the patent is for the active ingredient or for the specific formulation(s) or uses the patentee sells the medicine for in Canada. Rather, its jurisdiction also covers medicines for which a patent "pertains" including patents for manufacturing processes, delivery systems or dosage forms, indications/use and any formulations.

The Act requires patentees (which include any parties who benefit from patents regardless of whether they are owners or licensees under those patents and regardless of whether they operate in the "brand" or "generic" sector of the market) to inform the PMPRB of their intention to sell a new patented medicine. Upon the sale of a new patented medicine, patentees are required to file price and sales information at

OUR VISION

A sustainable pharmaceutical system where payers have the information they need to make smart reimbursement choices and Canadians can afford the patented medicines they need to live healthy and productive lives.

introduction and, thereafter, until all patents pertaining have expired. Patentees are not required to obtain approval of the price to be able to market their medicines. However, the Act requires the PMPRB to ensure that the prices of patented medicines sold in Canada are not excessive.

Staff reviews the prices that patentees charge for each individual strength and form of a patented medicine. If the price of a patented medicine appears to be potentially excessive, Staff will first try to reach a voluntary resolution by the patentee. If this fails, the Chairperson can decide that the matter should go to a hearing. At the hearing, a panel composed of Board members acts as a neutral arbiter between Staff and the patentee. If a panel finds that the price of a patented medicine is excessive, it can order the price be reduced to a non-excessive level. It can also order a patentee to make a monetary payment to the Government of Canada to offset the excess revenues earned and, in cases where the panel determines there has been a policy of excessive pricing, it can double the amount of the monetary payment.

Reporting

As required by the Act, the PMPRB reports annually to Parliament through the Minister of Health on its price review activities, the prices of patented medicines and price trends of all prescription medicines, and on the R&D expenditures reported by pharmaceutical patentees.

In addition, pursuant to an agreement by the F/P/T Ministers of Health in 2001, and at the request of the Minister of Health pursuant to section 90 of the Act, the PMPRB conducts critical analyses of price, utilization and cost trends for patented and non-patented prescription medicines under the National Prescription Drug Utilization Information System (NPDUIS). The PMPRB publishes the results of NPDUIS analyses in the form of research papers, posters, presentations and briefs. This program provides F/P/T governments and other interested stakeholders with a centralized, objective and credible source of information on pharmaceutical trends.

Among other initiatives under its reporting mandate, the PMPRB also hosts various forums, such as webinars, research forums and information sessions, with academics and policy experts to discuss and disseminate research on emerging areas for study on pharmaceutical trends in Canada and internationally.

1,364

PATENTED MEDICINES

were reported to the PMPRB in 2019.

Communications and Outreach

The PMPRB takes a proactive and plain-language approach to its external communication activities. This includes targeted social media campaigns and more conventional (e.g., email and telephone) engagement with domestic, international and specialized news media. The PMPRB is actively pursuing additional opportunities to leverage new and emerging media to communicate with Canadians and its stakeholders.

The PMPRB recognizes the importance of openness and transparency as we continue to work on modernizing the way we carry out our mandate. We communicate regularly, through various channels, about our progress, including projected timelines, and key milestones.

Engagement with stakeholders will remain a central part of our multi-faceted communications approach. Reporting on our progress helps ensure we remain focused on delivering results.

Governance

The Board consists of not more than five members who serve on a part-time basis. Board members, including a Chairperson and a Vice-Chairperson, are appointed by the Governor-in-Council. The Chairperson, designated under the Act as the Chief Executive Officer of the PMPRB, has the authority and responsibility to supervise and direct its work. By law, the Vice-Chairperson exercises all the powers and functions of the Chairperson when the Chairperson is absent or incapacitated, or when the office of the Chairperson is vacant.

The members of the Board, including the Chairperson, are collectively responsible for implementing the applicable provisions of the Act. Together, they establish the guidelines, rules, by-laws and other policies of the PMPRB provided for by the Act (section 96) and consult, as necessary, with stakeholders including provincial and territorial Ministers of Health, representatives of consumer groups, the pharmaceutical industry and others.

MEMBERS OF THE BOARD

Chairperson
Mitchell Levine,
BSc, MSc, MD, FRCPC, FISPE, FACP

Dr. Mitchell Levine was appointed Chairperson of the Board on February 13, 2018.

Dr. Levine is a professor in both the Department of Health Research Methods, Evidence and Impact and in the Department of Medicine, Division of Clinical Pharmacology & Toxicology at McMaster University in Hamilton, Ontario. He is also an Assistant Dean in the Faculty of Health Sciences and a faculty member of the Centre for Health Economics and Policy Analysis at McMaster.

Dr. Levine received his medical degree from the University of Calgary in 1979, followed by postgraduate medical training in Internal Medicine (FRCPC) and in Clinical Pharmacology at the University of Toronto (1981–1987). He received an MSc degree in Clinical Epidemiology from McMaster University in 1988.

Prior to his appointment to the Board, Dr. Levine was a member of the PMPRB's Human Drug Advisory Panel. He currently acts on an ad hoc basis as a clinical pharmacology consultant to the Ontario Ministry of Health and Ministry of Long-Term Care. In addition, he is a Deputy Editor of the ACP Journal Club: Evidence-Based Medicine.

This is Dr. Levine's second term as a Board member. He was initially appointed as its Vice-Chairperson in 2011.

Vice-Chairperson
Mélanie Bourassa Forcier
LLB., LL.L, MSc,
LL.M., DCL

Mélanie Bourassa Forcier was appointed Vice-Chairperson of the Board on June 19, 2019.

Ms. Bourassa Forcier is an Associate Professor in the Faculty of Law at the Université de Sherbrooke. She directs the Law and Health Policy, and Law and Life Sciences programs. She has expertise in the regulation, marketing and reimbursement of new medical technologies.

Professor Bourassa Forcier has published numerous books and articles on the subject of pharmaceutical regulation and health law. She holds a Ph.D. in Pharmaceutical Patent Law from McGill University, an MSc in International Health Policy from the London School of Economics and Political Science, and an LL.L. from the University of Ottawa.

MEMBERS

Carolyn Kobernick,
B.C.L., LL.B.

Carolyn Kobernick was appointed Member of the Board on June 13, 2014.

Ms. Kobernick is a lawyer and former public servant. Prior to her retirement in 2013, Ms. Kobernick was Assistant Deputy Minister of Public Law for the Department of Justice. As principal counsel to the Minister of Justice and Attorney General of Canada, Ms. Kobernick was instrumental in the development and delivery of policy for the Public Law sector. In addition to identifying key strategic, legal and operational matters, she tackled cross-cutting national issues as the liaison between the Department of Justice and other government organizations.

Ms. Kobernick joined the Department of Justice in 1980, where she practiced litigation and tax law at the Toronto Regional office. In 1991, she was appointed Senior General Counsel, Deputy Head, Business and Regulatory Law Portfolio, after working for over a decade in the legal services unit of the Correctional Service of Canada. In her role as Senior General Counsel, Ms. Kobernick was involved in complex federal policy and operational issues, including the Alaska Pipeline and Mackenzie Valley Pipeline files and the Sponsorship file.

During her career with the public service, Ms. Kobernick actively participated in many high-profile initiatives. She was Chair of the National Legal Advisory Committee and Departmental Champion for Aboriginal People and Gender Equity. She also served as the Senior Department of Justice official at the Domestic Affairs Cabinet Committee, and was appointed Senior Legal Advisor to the Government of Canada for the 2004 Gomery Inquiry.

Ms. Kobernick holds a B.C.L. and LL.B. from McGill University and is a member of the bar of Ontario. In 2012 she obtained a Certificate in Adjudication for Administrative Agencies, Boards and Tribunals from the Osgoode Hall Law School and the Society of Ontario Adjudicators and Regulators.

Dr. Ingrid Sketris
BSc (Pharm), PharmD, MPA(HSA), Clinical Toxicology Residency

Dr. Ingrid Sketris was appointed Member of the Board on June 29, 2018.

Dr. Sketris is a licensed pharmacist and a professor at the College of Pharmacy, Dalhousie University, with cross appointments to Medicine and Health Administration.

Dr. Sketris received her Doctor of Pharmacy in 1979 from the University of Minnesota, followed by her residency in Clinical Toxicology at the University of Tennessee Centre for the Health Sciences. She also received a Master of Public Administration/Health Services Administration from Dalhousie University.

She is a leader in pharmacy, and has served as President of the Association of Faculties of Pharmacy of Canada and as a board member of the Canadian Council for Accreditation of Pharmacy Programs.

Dr. Sketris is a Fellow of the Canadian Society of Hospital Pharmacists, the American College of Clinical Pharmacy and the Canadian Academy of Health Sciences. She was previously elected to the US National Academies of Practice.

Matthew Herder
B.Sc. (hons), LL.B., LL.M., J.S.M.

Matthew Herder was appointed Member of the Board on June 29, 2018.

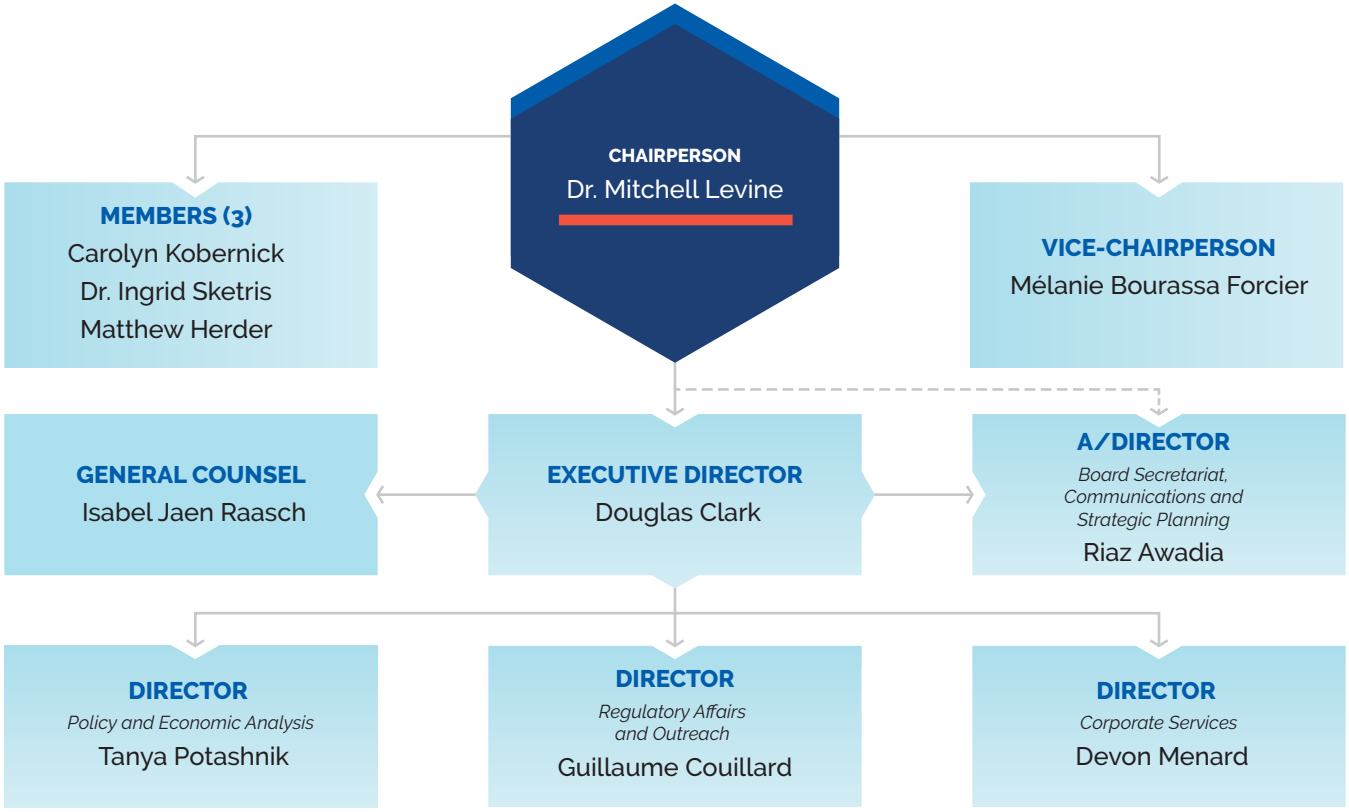
Mr. Herder is the Director of the Health Law Institute at Dalhousie University as well as an Associate Professor in the Department of Pharmacology in the Faculty of Medicine, with a cross-appointment to the Schulich School of Law.

Mr. Herder's research focuses on biomedical innovation policy, with a particular emphasis on intellectual property rights and the regulation of biopharmaceutical interventions. His work is often interdisciplinary and policy-oriented, and he has received grants from the Canadian Institutes of Health Research and the Royal Society of Canada, in addition to appearing as an expert witness before several Parliamentary committees on pharmaceutical regulation and policy.

Prior to arriving at Dalhousie, Mr. Herder was the Ewing Marion Kauffman Foundation Legal Research Fellow at New York University's School of Law. He was a Law Clerk at the Federal Court of Canada and was admitted to the Law Society of Upper Canada. Mr. Herder holds a Master of the Science of Law degree from Stanford Law School as well as two law degrees from Dalhousie University.

Organizational Structure and Staff

PMPRB Organizational Chart



Executive Director

The Executive Director is responsible for advising the Board and for the leadership and management of Staff.

Regulatory Affairs and Outreach

The Regulatory Affairs and Outreach Branch reviews the prices of patented medicines sold in Canada to ensure they are not excessive; ensures that patentees are fulfilling their filing obligations; encourages patentees to comply voluntarily with the PMPRB's Guidelines; implements related compliance policies; and investigates complaints into the prices of patented medicines.

Policy and Economic Analysis

The Policy and Economic Analysis Branch develops policy and strategic advice; leads stakeholder consultations, and makes recommendations on possible amendments to the PMPRB's Guidelines; conducts research and analysis on the prices of medicines, pharmaceutical market developments and R&D trends; and publishes studies aimed at providing F/P/T governments and other interested stakeholders with centralized, objective, and credible information in support of evidence based policy.

Corporate Services

The Corporate Services Branch provides advice and services in relation to human resources management; facilities; procurement; health, safety and security; information technology; and information management. It is also responsible for financial planning and reporting, accounting operations, audit and evaluation, and liaising with federal central agencies on these topics.

Board Secretariat, Communications and Strategic Planning

The Board Secretariat, Communications and Strategic Planning Branch develops and manages the PMPRB's communications, media relations, and public enquiries; manages the Board's meeting and hearing processes, including the official record of proceedings; and coordinates activities pursuant to the *Access to Information Act* and the *Privacy Act*. It is also responsible for strategic planning and reporting.

General Counsel

The General Counsel advises the PMPRB on legal matters and leads the legal team representing Staff in proceedings before the Board.

Budget

In 2019–20, the PMPRB had a budget of $16.6 million and an approved staff level of 82 full-time equivalent employees.

TABLE 1 Budget and Staffing

	2018–19	2019–20	2020–21
Budget*	$14,871,872	$16,612,511	$17,804,400
Salaries and employee benefits	$8,373,171	$9,636,550	$10,054,721
Operating	$3,079,220	$2,699,395	$2,491,893
Special Purpose Allotment**	$3,419,481	$4,276,566	$5,257,786
Full Time Employees (FTEs)	72	82	87

* Budget amounts are based on the Main Estimates
** The Special Purpose Allotment is reserved strictly for external costs of public hearings (legal counsel, expert witnesses, etc.). Unspent funds are returned to the Consolidated Revenue Fund.

REGULATING PRICES OF PATENTED MEDICINES: CONTINUED VIGILANCE NECESSARY

Medical advancements have introduced many innovative new medicines to the Canadian marketplace to improve existing treatments and to treat conditions that previously had no pharmaceutical therapy. However, many of these new medicines come at a very high cost. Since 1987, pharmaceutical costs in Canada have grown at an average annual rate of 7.2%[1], outpacing all other health care costs and growing at well over 3 times the pace of inflation. At 15.7% of total health care spending, pharmaceuticals now rank ahead of spending on physicians.[2] About 1 in 5 Canadians reports having no prescription medicine coverage and many more are under-insured or face high deductibles or co-pays. Almost 1 in 10 Canadians have had to forego filling a prescription medicine in the past year for reasons related to cost.[3]

The PMPRB protects the interests of Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive. It does this by reviewing the prices that patentees charge for each individual patented medicine and by ensuring that patentees reduce their prices and pay back excess revenues where appropriate.

Reporting Requirements

By law, patentees must file information about the sale of their medicines in Canada. The Act, along with the *Patented Medicines Regulations* (Regulations) set out the information required and Staff reviews pricing information on an ongoing basis until all relevant patents have expired.

There are several factors used for determining whether the price of a medicine is excessive, as outlined in section 85 of the Act.

The *Compendium of Policies, Guidelines and Procedures* (Guidelines) details price tests and triage mechanisms used by Staff when it reviews and investigates the prices of patented medicines. The Guidelines are not binding and were developed in consultation with stakeholders, including the provincial and territorial Ministers of Health, consumer groups, and the pharmaceutical industry. When an investigation suggests that the price of a patented medicine is excessive, the patentee may agree to voluntarily lower its price and/or refund its excess revenues through a Voluntary Compliance Undertaking (VCU). If the patentee

chooses not to submit a VCU, the Chairperson may hold a hearing on the matter if he feels it is in the public interest. After hearing all the evidence, if the Board finds that a price is in fact excessive, it can issue an order requiring a patentee to reduce that price and/or refund excess revenues. Copies of the Act, the Regulations and the Guidelines are available on the PMPRB's website.

Failure to Report

The PMPRB relies on patentees' full and timely disclosure of any and all patented medicines being sold in Canada to which a patent pertains. In 2019, 10 medicines were reported to the PMPRB for the first time despite being patented and sold prior to 2019. (See Table 2, Failure to Report the Sale of Patented Medicines).

Failure to File Price and Sales Data (Form 2)

Failure to file refers to the complete or partial failure of a patentee to file the information required by the Act and the Regulations to the PMPRB. There were no Board Orders issued for failure to file in 2019.

TABLE 2 Failure to Report the Sale of Patented Medicines

Patentee	Brand name	Medicinal ingredient	Year medicine reported to the PMPRB as under PMPRB's jurisdiction	Year medicine reported to the PMPRB with subsequent patent
Knight Therapeutics Inc.	Nerlynx	neratinib	2017	
Mitsubishi Tanabe Pharma Corporation	Radicut	edaravone	2018	
Bausch Health, Canada Inc	Prolensa	bromfenac	2015	
Chiesi USA Inc.	Cardene IV (4 DINs)	nicardipine hydrocholride	2012	
Sun Pharmaceutical Industries, Inc	Ilmya	tildrakizumab	2018	
Ipsen Biopharmaceuticals Canada Inc.	Increlex	mecasermin	2016	
Novo Nordisk Canada Inc.	Xultophy	insulin degludec/ liraglutide	2018	
Shire Pharma Canada Inc.	Obizur	antihemophilic factor (recombinant), porcine sequence	2017	
Sun Pharmaceutical Industries, Inc.	Odomzo	sonidegib	2012	
Indivior Canada Ltd	Suboxone (3 DINs)	buprenorphine/ naloxone	2019	

Data source: PMPRB

Scientific Review

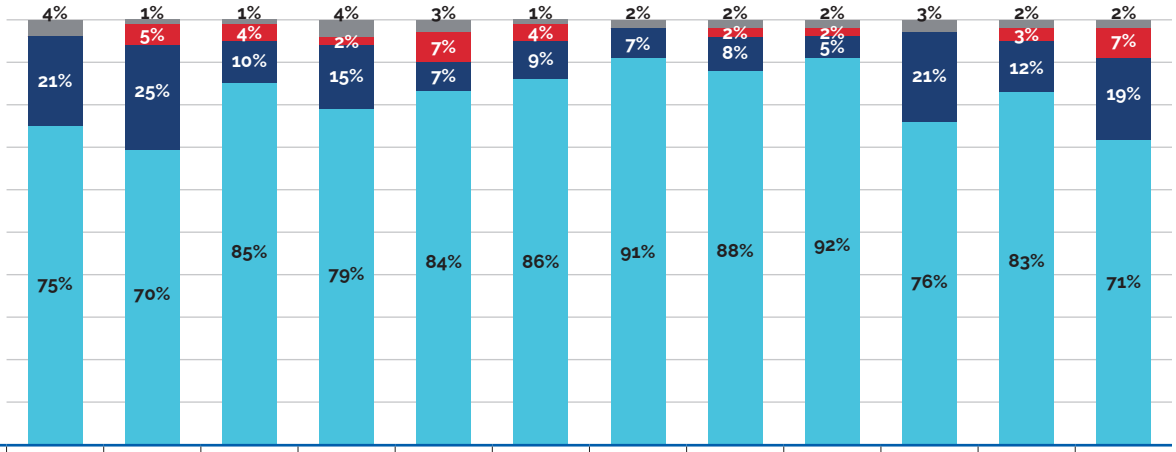
Human Drug Advisory Panel

A scientific evaluation is done on all new patented medicines as part of the price review process. The PMPRB established the Human Drug Advisory Panel (HDAP) to provide advice to Staff. The HDAP conducts an evaluation when a patentee claims the new medicine provides a therapeutic improvement. The HDAP members review and evaluate the appropriate scientific information available, including any submission by a patentee about the proposed level of therapeutic improvement, the selection of comparator medicines, and comparable dosage regimens.

The HDAP evaluates the therapeutic benefit of new patented medicines according to the following definitions:

- **Breakthrough:** A medicine that is the first one sold in Canada to effectively treat a particular illness or effectively address a particular indication.
- **Substantial Improvement:** A medicine that, relative to other medicines sold in Canada provides substantial improvement in therapeutic effects.
- **Moderate Improvement:** A medicine that, relative to other medicines sold in Canada provides moderate improvement in therapeutic effects.
- **Slight or No Improvement:** A medicine that, relative to other medicines sold in Canada, provides slight or no improvement in therapeutic effects.

FIGURE 1 Breakdown of New Patented Medicines by Therapeutic Benefit



Number of new patented medicines by therapeutic benefit	2010 Intro	2011 Intro	2012 Intro	2013 Intro	2014 Intro	2015 Intro	2016 Intro	2017 Intro	2018 Intro	2019 Intro*	Overall 2010–2019	Overall 2010–2019 Revenue Share
Slight/No Improvement	51	76	70	91	87	73	116	52	56	29	701	71.4%
Moderate improvement	14	27	8	17	7	8	9	5	3	8	106	19.3%
Substantial Improvement	0	5	3	2	7	3	0	1	1	0	22	7.2%
Breakthrough	3	1	1	5	3	1	3	1	1	1	20	2.1%

* Assessment as of March 31, 2020

Data source: PMPRB

Protect, Empower, Adapt.

Figure 1 illustrates the breakdown of new patented medicines in the year of introduction by therapeutic benefit for 2010 to 2019. The largest percentage of patented medicines (83.0%) introduced since 2010 were categorized as "Slight or No Improvement" in therapeutic benefit over existing therapies.[4]

The "Overall 2010–2019" bar represents the therapeutic benefit breakdown for all new patented medicines introduced from 2010 to 2019. The "Overall 2010–2019 Revenue Share" bar illustrates the revenue share by therapeutic benefit for all new patented medicines introduced from 2010 to 2019.

Price Review

The PMPRB reviews the average price of each strength of each individual dosage form of each patented medicine. In most cases, this unit is consistent with the Drug Identification Number(s) (DIN), (DINs) assigned by Health Canada at the time the medicine is approved for sale in Canada.

New Patented Medicines Reported to the PMPRB in 2019

For the purpose of this report, a new patented medicine in 2019 is defined as any patented medicine or new dosage form or strength of a patented medicine first sold in Canada, or previously sold but first patented, between December 1, 2018, and November 30, 2019.

There were 81 new patented medicines for human use reported as sold in 2019. Some are one or more strengths of a new active substance and others are new presentations of existing medicines. Of these 81 new patented medicines, 2 (2.5%) were being sold in Canada prior to the issuance of the Canadian patent that brought them under the PMPRB's jurisdiction. Table 3 shows the year of first sale for these medicines.

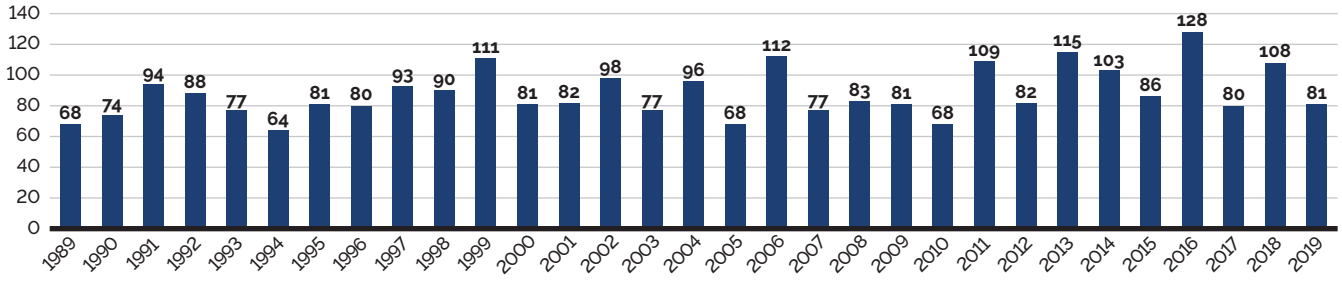
TABLE 3 Number of New Patented Medicines for Human Use in 2019 by Year First Sold

Year first sold	Number of medicines
2017	1
2018	1
2019	79
Total	**81**

Data source: PMPRB

The list of New Patented Medicines Reported to PMPRB is available on the PMPRB's website under "Regulating Prices". This list includes information on the status of the review (i.e., whether the medicine is under review, within the Guidelines, under investigation, or subject to a VCU or Notice of Hearing). Figure 2 illustrates the number of new patented medicines for human use reported to the PMPRB from 1989 to 2019.

FIGURE 2 New Patented Medicines for Human Use



Data Source: PMPRB

Of the 81 new patented medicines, the prices of 38 had been reviewed as of March 31, 2020:

- 29 were found to be within the thresholds set out in the Guidelines;
- 3 were at a level that appeared to exceed the thresholds set out in the Guidelines by an amount that did not trigger the investigation criteria; and
- 6 were at levels that appeared to exceed the thresholds set out in the Guidelines and resulted in investigations being commenced.

For a complete list of the 81 new patented medicines and their price review status, see Appendix 2.

Price Review of Existing Patented Medicines for Human Use in 2019

For the purpose of this report, existing patented medicines include all patented medicines first sold and reported to the PMPRB prior to December 1, 2018.

At the time of this report, there were 1,283 existing patented medicines:

- 919 were priced within the thresholds set out in the Guidelines;
- 202 had prices that appeared to exceed the thresholds set out in the Guidelines by an amount that did not trigger the investigation criteria;
- 122 were the subject of investigations;
- 17 were under review;
- 20 were the subject of a Voluntary Compliance Undertaking;
- 2 are the subject of a hearing; and
- 1 is subject to a price reduction and excess revenue payment order (currently partially stayed).

Table 4 provides a summary of the status of the price review of the new and existing patented medicines for human use in 2019.

TABLE 4 Patented Medicines for Human Use Sold in 2019—Status of Price Review as of March 31, 2020

	New medicines introduced in 2019	Existing medicines	Total
Total	**81**	**1,283**	**1,364**
Within Guidelines Thresholds	29	919	948
Under Review	43	17	60
Does Not Trigger Investigation	3	202	205
Under Investigation	6	122	128
Subject to Voluntary Compliance Undertaking	0	20	20[1]
Price Hearing	0	2	2
Subject to Price Reduction Order (Stayed)	0	1	1

[1]The terms and conditions of previous years VCUs that have carried over into 2019 are not captured in this count.

Data source: PMPRB

Update from the 2018 Annual Report

- Reviews of all the medicines for human use that were reported as Under Review in the 2018 Annual Report have been completed.
- 105 of the 128 investigations reported in the 2018 Annual Report resulted in one of the following:
  - the closure of the investigation where it was concluded the price was within the thresholds set out in the Guidelines;
  - a VCU by the patentee to reduce the price and offset excess revenues through a payment and/or a reduction in the price of another patented medicine (see Voluntary Compliance Undertakings); or
  - a public hearing to determine whether the price was excessive, including any remedial Order determined by the Board (see Hearings).

Patented Over-the-Counter Medicines, Patented Generic Medicines and Patented Medicines for Veterinary Use

Staff only reviews the prices of patented over-the-counter medicines, patented generic medicines and patented veterinary medicines when a complaint of excessive pricing has been received. No such complaints were received in 2019.

Voluntary Compliance Undertakings and Hearings

Voluntary Compliance Undertakings

A VCU is a written undertaking by a patentee to adjust its price to conform to the Board's Guidelines. The Guidelines set out procedures for patentees to submit a VCU when, following an investigation by Staff, the price of a patented medicine sold in Canada appears to have exceeded the thresholds set out in the Guidelines. A VCU represents a promise by a patentee geared towards a satisfactory resolution of an investigation initiated by Staff under the Guidelines. A VCU takes into account the specific facts and underlying context of a particular case. VCUs are not intended to have precedential value.

In 2019, twelve VCUs were approved by the Chairperson. In addition to price reductions for certain medicines, excess revenues totaling $3,492,454.93 were offset by way of payments to the Government of Canada.

As of May 31, 2020, the Chairperson approved the closure of an investigation after the receipt of an additional VCU totalling $75.8 thousand bringing the total payments to the Government of Canada for 2019 up to May 31, 2020 to $3.6 million.

TABLE 5 Voluntary Compliance Undertakings in 2019 up to May 31, 2020

Patented medicine brand name	Therapeutic use	Patentee	Date of approval	Offset of excessive revenues	
				Price reduction	Payment to the government
VCUs in 2019					
Triptorelin (sold under trade name Trelstar) **(1 DIN)**	Palliative treatment of hormone dependent advanced carcinoma of the prostate gland (stage D2)	Paladin Labs Inc.	January	✓	$157,159.70
Belimumab (sold under trade name Benlysta) **(2 DINs)**	An adjunct to standard therapy for reducing disease activity in adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE)	GlaxoSmithKline Inc.	March	✓	
Dupilumab (sold under trade name Dupixent) **(1 DIN)**	Treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.	Sanofi-aventis Canada Inc.	April	✓	$1,654,520.73
Alirocumab (sold under trade name Praluent) **(4 DINs)** ***Two DINs are not reporting sales since 2017.**	An adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).	Sanofi-aventis Canada Inc.	April		$426,955.62
Darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide (sold under trade name Symtuza **(1 DIN)**	An antiretroviral agent indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 infection in adults and adolescents (aged 12 years and older with a body weight at least 40 kilograms) and with no known mutations associated with resistance to the individual components of Symtuza.	Janssen Inc.	April	✓	$4,590.73
Ciproflaxacin/ dexamethasone (sold under trade name Ciprodex) **(1 DIN)**	For the treatment of infections caused by most strains of gram-positive and gram-negative microorganisms in the specific conditions including in part acute otitis media with otorrhea and acute otitis externa.	Novartis Pharmaceuticals Canada Inc.	June	✓	$141,159.41
Moxifloxacin hydrochloride (sold under trade name Vigamox) **(1 DIN)**	For the treatment of patients one year of age and older with bacterial conjunctivitis caused by susceptible aerobic gram-positive and gram-negative bacterial strains.	Novartis Pharmaceuticals Canada Inc.	June	✓	
Olopatadine hydrochloride (sold under trade name Pataday) **(1 DIN)**	For the treatment of ocular itching associated with seasonal allergic conjunctivitis.	Novartis Pharmaceuticals Canada Inc.	June	✓	$72,691.53

continued

Patented medicine brand name	Therapeutic use	Patentee	Date of approval	Offset of excessive revenues	
				Price reduction	Payment to the government
Crizotinib (sold under trade name Xalkori) **(2 DINs)**	A monotherapy for use in patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastic non-small cell lung cancer (NSCLC)	Pfizer Canada ULC	June	✓	$54,955.56
Sertraline hydrochloride (sold under trade name Zoloft) **(2 DINs)**	For the symptomatic relief of depressive illness, for symptomatic relief of panic disorder with or without agoraphobia, and for the symptomatic relief of obsessive-complusive disorder (OCD)	Upjohn Canada ULC	June	✓	$754,647.71
Desmopressin acetate (sold under trade name Nocdurna) **(2 DINs)**	An antidiuretic for the treatment of nocturia in adults with four or less nocturnal voids	Ferring Inc.	July	✓	$94,977.75
Trifluridine/ tipiracil (sold under trade name Lonsurf) **(2 DINs)**	An antineoplastic agent indicated for the treatment of adult patients with metastic colorectal cancer who have been previously treated with, or are not candidates for, available therapies including flurorpyrimidine-, oxaliplatin- and irnotecan-based chemotherapies, anti-VEGF biological agents, and if RAS wild-type, anti-EGFR agents	Taiho Pharma Canada Inc.	October	✓	
Pegademase bovine (sold under trade name Adagen) **(1 DIN)** ***Patent Lapsed in 2018. No longer under PMPRB jurisdiction**	Enzyme replacement therapy for adenosine deaminase (ADA) deficiency in patients with sever combined immunodeficiency disease (SCID) who are not suitable candidates for or who have failed bone marrow transplanation	Leadiant Biosciences, Inc.	October		$130,796.19
Total as of December 31, 2019					**$3,492,454.93**
VCUs in 2020 as of May 31, 2020					
Ixekizumab (sold under trade name Taltz) **(1 DIN)**	For the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy, and for the treatment of adult patients with active psoriasis who have responded inadequately to, or are intolerant to one or more disease-modifying antirheumatic drugs.	Eli Lilly Canada Inc.	January		$75,844.49
Total as of May 31, 2020					**3,568,299.42**

Hearings

The PMPRB holds hearings into two types of matters:

- excessive pricing; and
- failure to file–jurisdiction.

EXCESSIVE PRICING

In the event that the price of a patented medicine appears to be excessive, the Chairperson can commence a public hearing. If the Hearing Panel finds the price is excessive, it can issue an order to reduce the price of the

patented medicine in question (or of another patented medicine of the patentee) and/or to offset revenues received as a result of the excessive price. Judicial review of Board decisions can be sought in the Federal Court of Canada.

In January 2019, the PMPRB announced it would hold a public hearing in the matter of the price of the patented medicine cysteamine bitartrate sold under the trade name Procysbi by Horizon Therapeutics Canada. The purpose of this hearing is to determine whether the medicine has been or is being sold in any market in Canada at a price that, in the Board's opinion, is or was excessive: and, if so, what order, if any, should be made to remedy the excessive pricing. The matter is ongoing.

FAILURE TO FILE–JURISDICTION

When Staff believes a patentee has failed or refused to provide the PMPRB the pricing and sales information required by law, Staff will recommend that the Chairperson call a public hearing to determine whether the patentee has, in fact, breached the reporting requirements of the Act and Regulations. If the Hearing Panel finds, as the result of a public hearing, that the patentee has failed to report the required information, the Hearing Panel can order the patentee to file the required pricing and sales information.

There were no failure to file hearings as of March 31, 2020.

On May 7, 2020, the Board issued its decision on re-determination on its decision dated December 19, 2016 whereby the Board originally found that Canadian Patent No. 2,478,237 pertains to the patented medicine adapalene sold under the trade name Differin and ordered Galderma to file the required information for the period between January 1, 2010 and March 14, 2016. The Board's decision on redetermination again ordered Galderma to file the required information for the period between January 1, 2010 and March 14, 2016. On August 11, 2020, Galderma Canada Inc. filed an application for judicial review of the Board's May 7, 2020 decision on redetermination (T-906-20).

Summary

Excess revenues totaling $3,568,299.42 were offset by payments to the Government of Canada through VCUs and Board Orders in 2019 and up to May 31, 2020.

Since 1993, 154 VCUs have been approved and 30 public hearings related to allegations of failure to file and/or excessive pricing have been initiated. These measures resulted in price reductions and the offset of excess revenues by additional price reductions and/or payments to the Government of Canada. Over $210 million has been collected through VCUs, settlements and Board Orders through payments to the Government of Canada and/or to customers such as hospitals and clinics.

Matters Before the Federal Court, Federal Court of Appeal and Supreme Court of Canada or Other Courts

On October 20, 2017, Alexion Pharmaceuticals Inc. filed an application for judicial review of the Board's decision dated September 20, 2017 in respect of its finding that the patented medicine eculizumab sold under the trade name Soliris was being sold at an excessive price in Canada and ordering Alexion to lower its price (currently stayed) and make an excess revenue payment of $4,245,329.60. The Board's decision was found to be reasonable by the Federal Court via a decision dated May 23, 2019. Alexion has appealed the Federal Court's decision in the Federal Court of Appeal. This matter is currently pending.

On January 18, 2017, Galderma Canada Inc. filed an application for judicial review of the Board's decision dated December 19, 2016. In that decision the Board found that Canadian Patent No. 2,478,237 pertains to the patented medicine adapalene sold under the trade name Differin and ordered Galderma to file the required information for the period between January 1, 2010 and March 14, 2016. The Federal Court granted Galderma's judicial review application on November 9, 2017 and quashed the Board's decision. On November 21, 2017, the Attorney General appealed the Federal Court's grant of the judicial review application.

On June 28, 2019, the Federal Court of Appeal granted the appeal and issued its decision sending the matter back to the Board for redetermination. The Board's decision on redetermination issued on May 7, 2020, again ordered Galderma to file the required information for the period between January 1, 2010 and March 14, 2016. On August 11, 2020, Galderma Canada Inc. filed an application for judicial review of the Board's May 7, 2020 decision on redetermination (T-906-20). This matter is currently pending.

There are no PMPRB related matters before the Supreme Court of Canada.

Two challenges related to PMPRB legislation were commenced in 2019:

I.M.C. et al. v. Canada (Attorney General), T-1465-19: Innovative Medicines Canada and sixteen individual pharmaceutical companies brought an application in Federal Court to judicially review s. 4 (new factors), s. 6 and Schedule (new basket of countries) and ss. 3(4) (new net price calculation) of the 2019 *Amendments to the Patented Medicines Regulations* (coming into force in January, 2020) on the basis that they were *ultra vires* the regulation-making power contained in the *Patent Act*. The Federal Court issued its decision on June 29, 2020 and held that the amendments in s 4, s. 6 and the Schedule are *intra vires* the *Patent Act*, but that the amendment in ss. 3(4) is not. On September 10, 2020, I.M.C. and the individual pharmaceutical companies filed a Notice of Appeal with respect to the Federal Court decision. This matter is currently pending before the Federal Court of Appeal (A-215-20).

Merck et al. v Canada (Attorney General), No. 500-17-109270-192: six individual pharmaceutical companies brought an application for judicial review in Quebec Superior Court challenging the constitutionality of ss. 79-103 of the *Patent Act*. The Quebec Superior Court began hearings on this matter in October, 2020 and proceedings will continue in November.

TABLE 6 Status of Board Proceedings in 2019 up to May 31, 2020

Medicine	Indication/use	Patentee	Issuance of notice of hearing	Status
Allegations of Excessive Pricing				
Eculizumab (sold under trade name Soliris)	Paroxysmal nocturnal hemoglobinuria Atypical hemolytic uremic syndrome	Alexion Pharmaceuticals Inc.	January 20, 2015	Board Order: September 27, 2017 Found the price of Soliris was and is excessive under Sections 83 & 85 of the Act Payment of excess revenues: $4,245,329.60 * Application for Judicial Review and subsequent litigation: see below.
Cysteamine bitartrate (sold under trade name Procysbi)	Nephropathic cystinosis	Horizon Thearpeutics Canada	January 14, 2019	Ongoing
Allegations of Failure to File				
Adapalene (sold under trade names Differin and Differin XP)	Acne	Galderma Canada Inc.	(redetermination)	Board Order: May 7, 2020. Galderma to file the required information for the requested period. * Application for Judicial Review and prior litigation: see below.

Judicial Review of Board Decisions and Appeals pending as of March 31, 2020

Medicine	Indication/use	Patentee	Issue	Date of notice of hearing/status
Eculizumab (sold under trade name Soliris)	Paroxysmal nocturnal hemoglobinuria Atypical hemolytic uremic syndrome	Alexion Pharmaceuticals Inc.	Allegations of excessive pricing	Application for Judicial Review. Court File T-1596-17 (Re. Board Panel's decision of September 20, 2017): Decision issued May 23, 2019. Notice of Appeal (Federal Court of Appeal) filed on June 21, 2019. Court File A-237-19, Matter pending.
Adapalene (sold under trade names Differin and Differin XP)	Acne	Galderma Canada Inc.	Failure to file (jurisdiction)	Application for Judicial Review. Court File T-83-17 (Re. Board Panel's decision of December 19, 2016): Decision issued November 9, 2017 quashing in part Board Panel's decision. Notice of Appeal (Federal Court of Appeal) filed on November 21, 2017. Court File A-385-17. Decision issued on June 28, 2019. Matter sent for redetermination by the Board. Redetermination decision issued on May 7, 2020. Application for Judicial Review. Court File T-906-20 (Re. Board Panel's Decision of May 7, 2020) filed on August 11, 2020. Matter pending.

ENDNOTES

1 7.2% growth in drug spending is the average growth rate in drug spending as calculated from the Canadian Institute for Health Information (CIHI), *National Health Expenditure Trends, 1975 to 2018* Series C data.

2 CIHI, *National Health Expenditure Trends, 1975 to 2018* report

3 *A Prescription for Canada: Achieving Pharmacare for All*, Final Report of the Advisory Council on the Implementation of National Pharmacare, June 2019

4 Prior to 2010 the PMPRB categorized new medicines as follows:

- Category 1 – is a new DIN of an existing dosage form of an existing medicine, or a new DIN of another dosage form of the medicine that is comparable to the existing dosage form.
- Category 2 – is one that provides a breakthrough or substantial improvement. It is a new DIN of a non-comparable dosage form of an existing medicine or the first DIN of a new chemical entity.
- Category 3 – is a new DIN of a non-comparable dosage form of an existing dosage form of an existing medicine, or the first DIN of a new chemical entity. These DINs provide moderate, little or no therapeutic advantage over comparable medicine. This group includes those new medicines that are not included in Category 2.

For purposes of this analysis, all medicines in Category 2 were included in the Breakthrough category and all Category 1 and 3 medicines were included in the Slight or No Improvement category.

KEY PHARMACEUTICAL TRENDS: MORE EXPENSIVE MEDICINES CONTINUE TO INFLUENCE SALES

Overall spending on pharmaceuticals is influenced by many factors, including price, utilization, the entry of newer, more expensive medicines, and the loss of market exclusivity of older patented medicines. In 2019, there was a notable rise in the sales of higher-cost medicines, resulting in an overall increase in total spending of 3.5%. Canadian list prices of patented medicines remained among the highest in the Organisation for Economic Co-operation and Development (OECD), ranking fourth, well behind the US and just marginally lower than Germany and Switzerland.

The PMPRB is responsible for reporting on trends in pharmaceutical sales and pricing for all medicines and for reporting research and development spending by patentees.

Under the Regulations, patentees are required to submit detailed information on their sales of patented medicines, including quantities sold, gross and net prices, and net revenues. The PMPRB uses this information to analyze trends in the sales, prices,[5] and use of patented medicines.[6] This section provides key trends, including analyses of Canadian national, public, and private payer markets for all medicines. Note that any reference to sales in this section should be interpreted as sales revenues unless otherwise noted.

$17.2 billion sales in patented medicines in 2019

Sales of patented medicines have grown by an average of 4.5% per year over the last five years.

DISCLAIMERS

1. Although select statistics reported in the KEY PHARMACEUTICAL TRENDS section are based in part on data obtained under license from the IQVIA MIDAS® database and the IQVIA Private Pay Direct Drug Plan database, the statements, findings, conclusions, views, and opinions expressed in this Annual Report are exclusively those of the PMPRB and are not attributable to IQVIA.
2. To provide a broader perspective on pharmaceutical trends in Canada, summaries of the results of NPDUIS analyses have been included as additional "Brief Insights" throughout the Pharmaceutical Trends section of the Annual Report. A variety of public and licensed data sources are used for NPDUIS analytical studies. Many of these sources do not differentiate between patented and non-patented generic medicines; in these instances, the general term "generic" is used to include both. NPDUIS is a research initiative that operates independently of the regulatory activities of the PMPRB.

Trends in Sales of Patented Medicines

Canadians spend much more on patented medicines today than they did a decade ago. Over the last five years, sales of these medicines grew by an average of 4.5% per year, reaching $17.2 billion in 2019. This section looks at the most important factors driving the change in sales revenues from 2018 to 2019 and compares them to trends from previous years.

Trends in Sales Revenues

Between 2018 and 2019, there was a moderate 3.5% increase in the sales of patented medicines. Figure 3 reports on trends in the sales of patented medicines from 1990 to 2019. While there has been a 10-fold increase in annual sales since 1990, the year-over-year rate of change within that period has varied. This trend is highlighted by the five-year compound annual growth rate given in Figure 3(b).

Figure 3(a) gives the sales of patented medicines as a share of overall medicine sales. This share, which reached a peak of 72.7% in 2003, declined from 2004 to 2010. Since then, patented medicines have accounted for approximately 60% of the sales of all medicines in Canada.

The trends in sales per capita and sales as a percentage of the gross domestic product (GDP) show the increasing importance of patented medicines in the Canadian economy. Overall, per capita sales of patented medicines rose from $61.60 in 1990 to $458.60 in 2019, while sales as a percentage of GDP rose from 0.25% in 1990 to 0.75% in 2019 [Figure 3(c)].

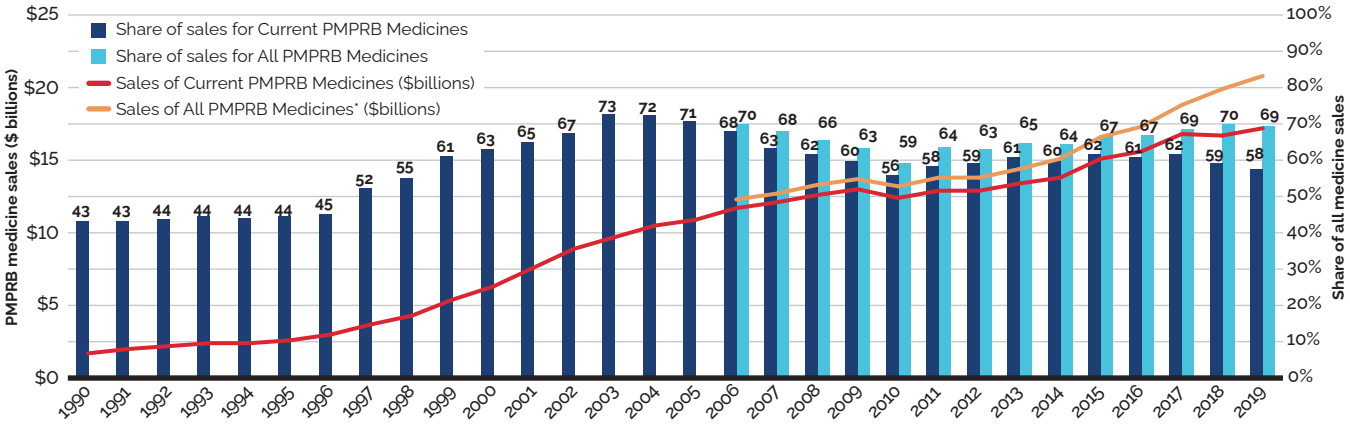
To highlight the continuing impact of patented medicines, Figures 3(a) and 3(b) also provide results for "All PMPRB Medicines". This broader category includes all medicines, current and historic, that ever reported sales to the PMPRB (since its creation).

Sales for All PMPRB Medicines rose by 4.5% in 2019. Medicines that previously reported to the PMPRB accounted for estimated sales of $3.6 billion, or 12.1% of all sales. This is considerably more than a decade ago when medicines that formerly reported to the PMPRB accounted for $0.7 billion in sales, or 3.2% of all sales.

A complete table of the data presented in Figure 3 for patented medicines currently reporting to the PMPRB is included in Appendix 3.

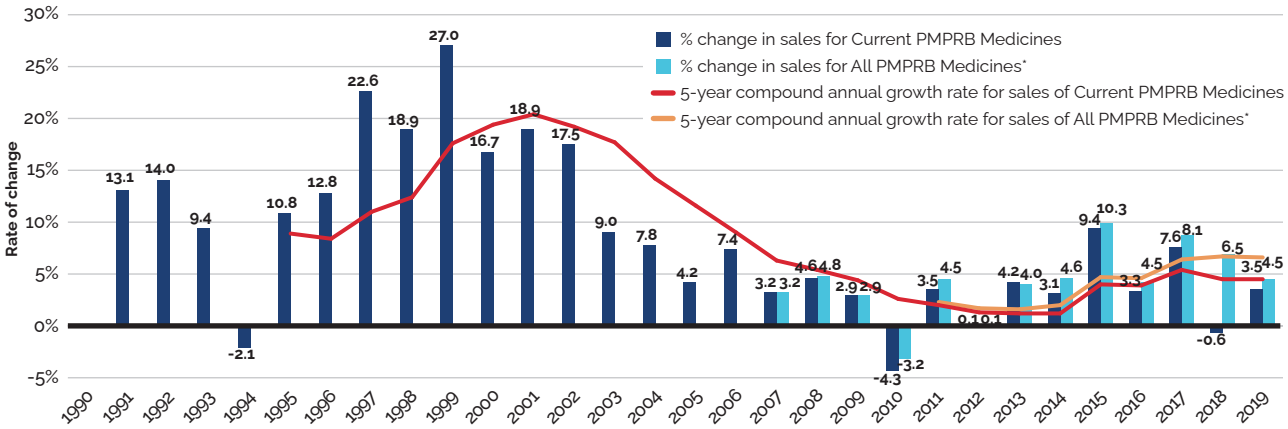
FIGURE 3 Trends in Patented Medicine Sales, 1990 to 2019

*(a) Patented medicine share of all medicine sales: Current PMPRB Medicines and All PMPRB Medicines**



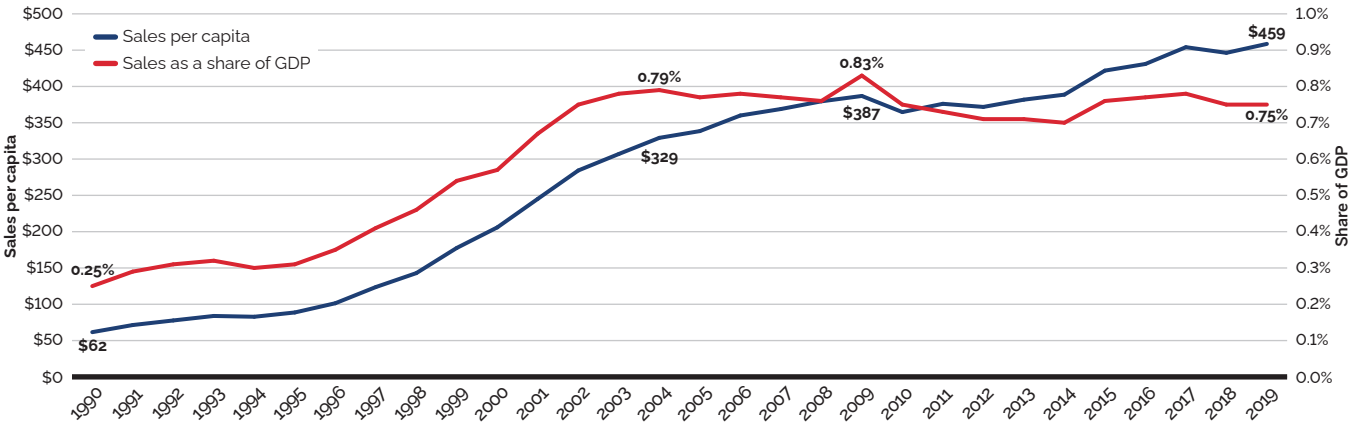
* Includes sales of currently patented medicines and medicines that once reported to the PMPRB but are no longer reporting a patent.
Data source: PMPRB; MIDAS® database, 1990–2019, IQVIA (all rights reserved)

*(b) Rate of change in patented medicine sales: Current PMPRB Medicines and All PMPRB Medicines**



Note: As data is updated each year, historical results may not exactly match those reported in previous editions.
* Includes sales of currently patented medicines and medicines that once reported to the PMPRB but are no longer reporting a patent.
Data source: PMPRB; MIDAS® database, 1990–2019, IQVIA (all rights reserved)

(c) Patented medicine sales per capita and as a share of GDP: Current PMPRB Medicines



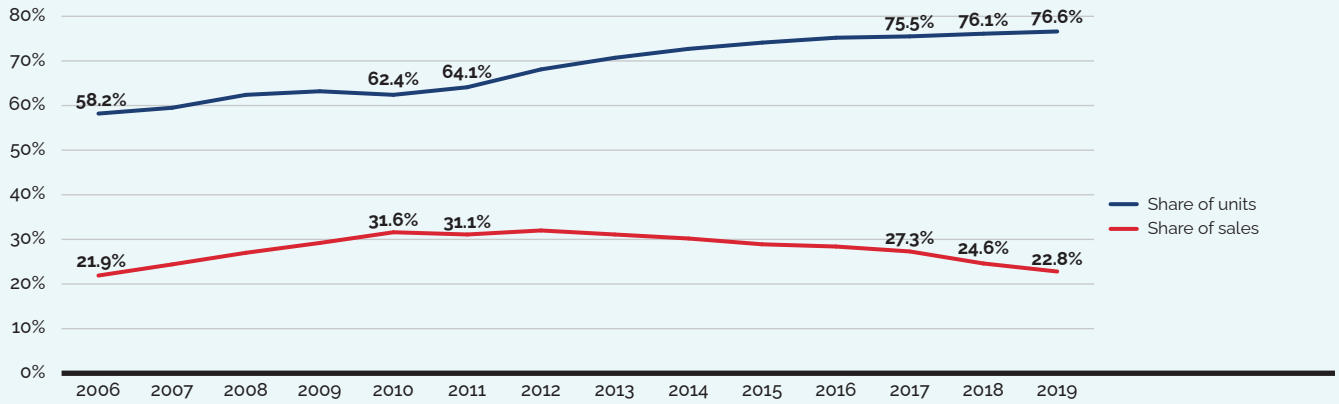
Data source: PMPRB; Statistics Canada; OECD

BRIEF INSIGHTS: TRENDS IN THE SALES OF GENERIC MEDICINES

While the sales of patented medicines increased by 3.5% in 2019, retail sales of generic medicines dropped by almost 4%. Generic sales have had low or negative rates of change since 2010, due in large part to the introduction of price-setting policies initiated by individual provincial governments and through the pan-Canadian Pharmaceutical Alliance (pCPA).

In 2018, the introduction of a five-year joint agreement between the pCPA and the Canadian Generic Pharmaceutical Association (CGPA) reduced the prices of 67 generic medicines to 10% or 18% of their brand reference price, driving expenditures down to virtually the same level as in 2010, even while retail generic use continued to increase.

FIGURE 4 Generic Share of the Canadian Pharmaceutical Retail Market, 2006 to 2019



Note: The results reflect prescription sales in the national retail market based on manufacturer ex-factory list prices.
Data source: MIDAS® database, 2006–2019, IQVIA (all rights reserved)
[NPDUIS Report: *Generics360, 2018* – graph updated for 2019]

Drivers of the Growth in Sales Revenues

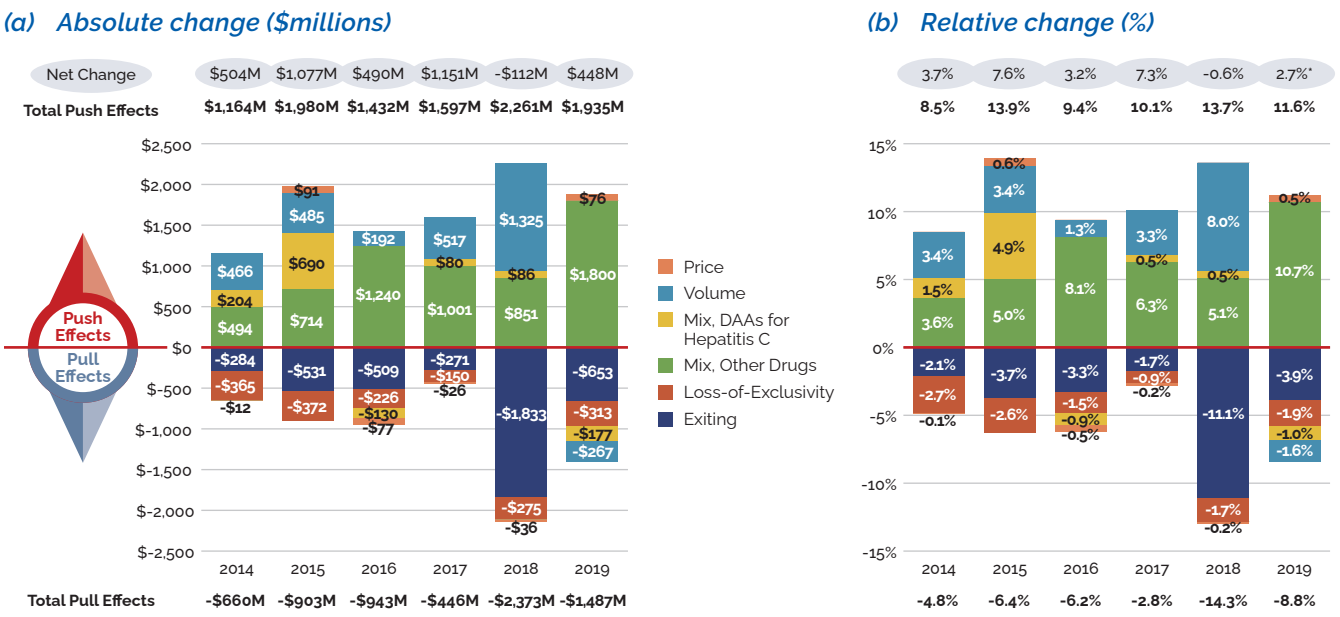
The growth in the sales revenue of patented medicines is influenced by changes in several key factors:

- **Volume effect:** changes in the quantity or amount of patented medicines sold. This effect focuses on established medicines that were on the market for the entire period analyzed. Increases in the population, changes in demographic composition (e.g., shifts in the age distribution), increases in the incidence of disease, and changes in prescribing practices are among the factors that may contribute to this effect.
- **Mix effect:** shifts in use between lower- and higher-cost patented medicines. This effect applies to both new medicines and those that were already on the market. The switch to new higher-priced medicines, the use of new medicines that treat conditions for which no effective treatment previously existed, and changes in physician prescribing practices are among the factors that may contribute to this change.
- **Exiting effect:** previously patented medicines that have stopped reporting sales revenue to the PMPRB or are no longer sold in Canada.
- **Loss-of-exclusivity effect:** medicines that have lost market exclusivity and are open to some level of generic competition but are still patented.
- **Price effect:** changes in the prices of existing patented medicines. This effect applies to both increases and decreases in the prices of patented medicines over the time period analyzed.

Some factors, such as the mix effect, will generally put an upward pressure on sales, while others, such as the loss-of-exclusivity effect, have the opposite effect.

Figure 5 focuses on the major factors that drove the year-by-year growth in patented medicine sales[7] between 2014 and 2019 (a) in absolute dollar amounts, and (b) as proportions of the overall annual change in sales. In addition to the standard sales drivers, the emergence of a new "blockbuster" medicine may have a significant influence on sales and will be monitored as a separate effect. For example, direct-acting antiviral (DAA) treatments for hepatitis C are presented separately to show their continuing impact on expenditures.

FIGURE 5 Key Drivers of Change in the Sales of Patented Medicines, 2014 to 2019



Note: When multiple factors change simultaneously, they create a residual or cross effect, which is not reported separately in this analysis, but is accounted for in the total cost change.
Values may not add to the net change due to rounding and the cross effect.

* As this model uses various measures to isolate the factors contributing to growth, the net change reported here may differ slightly from the change in sales for the patented medicines market reported in Figure 3(b).

Data source: PMPRB

Changes in the prices of patented medicines have played a very minor role in the growth in patented medicine sales over the last several years, suggesting that, on average, the prices of existing patented medicines are fairly stable. However, this does not reflect the overall increases in treatment costs due to the entry of newer, higher-priced patented medicines, the impact of which is captured by the mix effect.

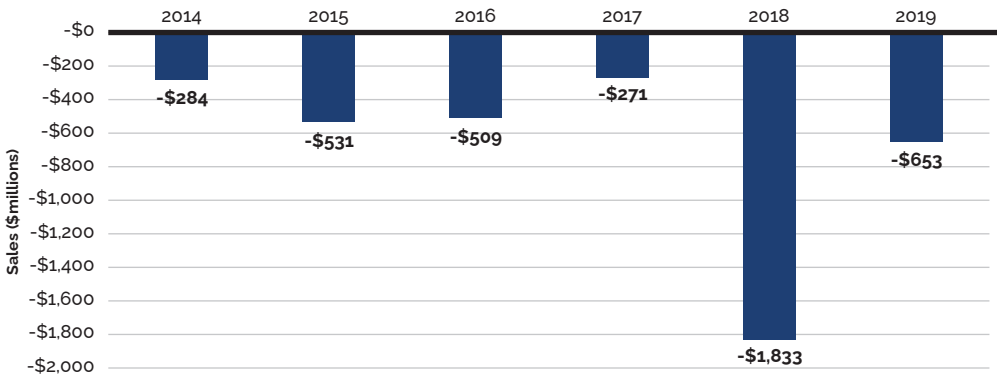
The shift to new higher-cost patented medicines has been a major driver of sales growth in recent years. In 2019, the use of higher-cost patented medicines put an upward pressure on expenditures of $1.8 billion (10.7%). While growth was observed in many therapeutic areas, the increase in sales of antineoplastic and immunomodulating agents far surpassed that of any other class, and oncology medicines accounted

for one fifth of the patented medicine sales in 2019. These results are discussed in further detail in the upcoming sections.

Counterbalancing this upward sales pressure, there was a moderate market segment shift as some high-selling medicines no longer reported their sales to the PMPRB. The exiting effect accounted for a moderate loss of over $650 million (-3.9%) in sales in 2019, returning to a level more in line with historic trends. Figure 6 illustrates the change in the impact of the exiting effect since 2014 and identifies the 10 top-selling medicines that stopped reporting to the PMPRB in 2019.

The volume effect also had a slight pull down effect on sales in 2019, reflecting a very small decrease in the total market quantity after a year of significant expansion.

FIGURE 6 Loss in Patented Medicine Sales from the Exiting Effect, 2014 to 2019



Top-selling medicines that stopped reporting to the PMPRB in 2019	
Advair	- $131M
Gamunex	- $94M
Flovent	- $67M
Advagraf	- $34M
Eligard	- $31M
Cymbalta	- $29M
Mavik	- $25M
Pulmicort	- $23M
Sevorane	- $12M
Jevtana	- $10M

Data source: PMPRB

BRIEF INSIGHTS: COST DRIVERS OF PUBLIC AND PRIVATE DRUG PLANS

The increasing use of higher-cost medicines is the primary cost driver for Canadian public and private drug plans. Over the past several years, higher-cost medicines (other than DAAs for hepatitis C) have exerted a consistent upward pressure on expenditures, accounting for a significant 6.1% contribution toward drug costs in public plans in 2018–19 and 5.9% towards private plan costs in 2019.

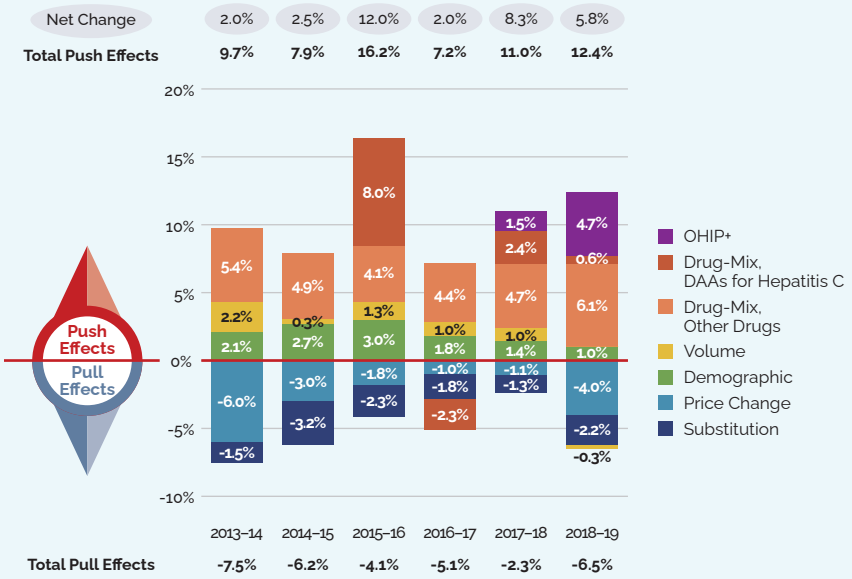
The savings from a new generic pricing policy introduced in 2018 had a significant impact on both public (fiscal year 2018–19) and private (2018) drug plan costs, reversing recent trends and offsetting the upward push from the use of higher-cost medicines in each of the respective years. However, policies such as this are not expected to have a sustained impact on cost growth over multiple years, and 2019 results for private plans indicate a return to historic levels.

Although the potential for additional generic savings is limited, given the strong market for biologics in Canada, biosimilars offer an opportunity for future cost savings. Recent policy changes announced by several public drug plans aimed at promoting switching to available biosimilars, as well as initiatives introduced by some private payers, are expected to result in significant cost reductions, helping to offset the pressure from higher-cost medicines in the upcoming years.

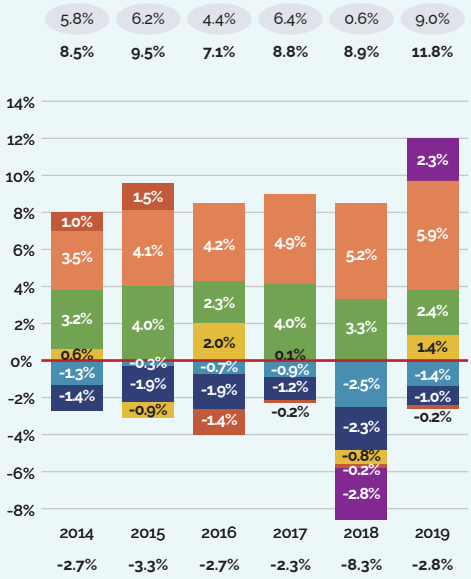
Plan design changes can also contribute significantly to growth, as was the case with the introduction of OHIP+ in Ontario in January 2018, which initially provided pharmaceutical benefits for all Ontario residents 24 and under. Since then, additional eligibility criteria have been placed on the program, the effects of which are shown in the private plan results in 2019.

FIGURE 7 Medicine Cost Drivers

(a) NPDUIS public drug plans, 2013–14 to 2018–19*



(b) Private drug plans, 2014 to 2019



Note: Public plans report on a fiscal year basis and private plans report on the calendar year. This has an impact on the magnitude of the effect of policies such as the OHIP+ program or generic pricing initiative introduced in 2018, for which most of the impact on public plans was felt in the 2018–19 fiscal year.

When multiple factors change simultaneously, they create a residual or cross effect, which is not reported separately in this analysis, but is accounted for in the total cost change.

Values may not add to the net change due to rounding and the cross effect.

* British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, and the Non-Insured Health Benefits Program

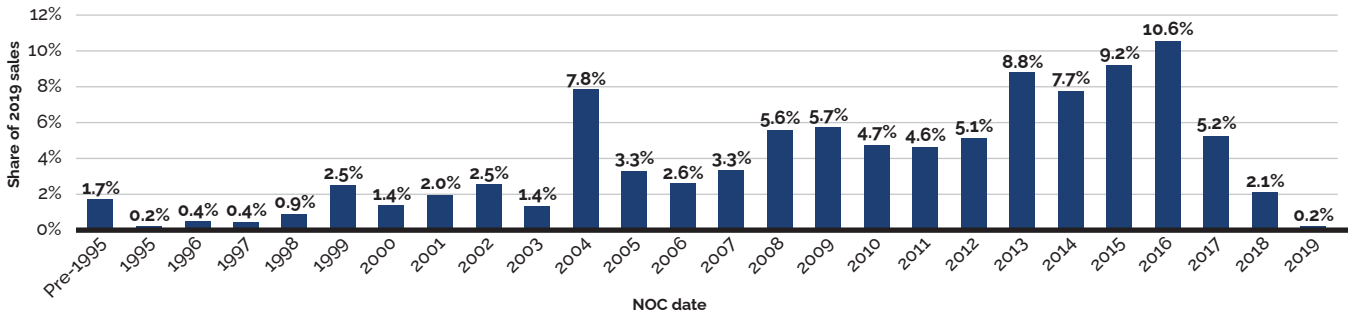
Data source: NPDUIS database, Canadian Institute for Health Information; IQVIA Private Pay Direct Drug Plan database

[NPDUIS Report: *CompassRx* 2018/19 (pre-publication results); NPDUIS Poster: *Pressures behind the Rising Costs in Canadian Private Drug Plans*, 2018 – graph updated for 2019]

New Medicines Driving Sales Revenues

Figure 8 breaks down the 2019 sales of patented medicines according to the year in which the medicine was first issued a Notice of Compliance (NOC) by Health Canada and approved for market in Canada. Throughout the latter part of the 1990s and early 2000s, sales growth was largely driven by a succession of new "blockbuster" medicines that ultimately achieved very high sales volumes. As the patents for these medicines expired, their share of sales gradually decreased. The introduction of new higher-cost medicines such as biologics, oncology medicines, and treatments for hepatitis C has accounted for a growing share of sales in recent years.

FIGURE 8 Share of 2019 Sales of Patented Medicines by Date of First Notice of Compliance (NOC)



Data source: PMPRB

Higher-Cost Medicines Driving Sales Revenues

Over the last decade, there has been a notable shift in pharmaceutical development toward more specialized medicines, with an increasing number of higher-cost medicines entering the market and realizing a significant market share.

In 2019, the trend in the shift to new or higher-cost medicines continued to put an upward pressure on overall patented medicine sales. The top 10 medicines contributed over $800 million to the increase in sales (Table 7). Most of these medicines had an average annual treatment cost greater than $10,000.[8]

TABLE 7 Top 10 Medicines Contributing to the Increase in Patented Medicine Sales, 2018 to 2019

Medicinal ingredient (Trade name)	ATC*	Date of first NOC†	Sales ($millions) 2018	Sales ($millions) 2019	Absolute change in sales ($millions) 2018–2019	Avg. annual treatment cost‡ 2019
Daratumumab (Darzalex)	L01	June-16	$10.2	$173.8	$163.7	$60,895
Glecaprevir/pibrentasvir (Maviret)	J05	Aug-17	$24.7	$131.6	$106.9	$29,551
Semaglutide (Ozempic)	A10	Jan-18	$25.2	$109.7	$84.5	$1,379
Pembrolizumab (Keytruda)	L01	May-15	$206.3	$280.4	$74.1	$40,987
Adalimumab (Humira)	L04	Sept-04	$791.0	$862.2	$71.2	$17,429
Herpes zoster vaccine (Shingrix)	J07	Oct-17	$85.2	$149.8	$64.6	$201
Palbociclib (Ibrance)	L01	Mar-16	$118.4	$180.4	$62.0	$37,698
Ibrutinib (Imbruvica)	L01	Nov-14	$205.7	$266.1	$60.4	$56,024
Lenalidomide (Revlimid)	L04	Jan-08	$408.4	$465.9	$57.5	$60,313
Apixaban (Eliquis)	B01	Dec-11	$256.6	$313.2	$56.6	$740
Total top 10 medicines§			**$2,131.7**	**$2,933.1**	**$801.4**	

Note: Highlighted medicines were also identified as top contributors in 2018.

* Level 2 of the Anatomic Therapeutic Chemical (ATC) classification system maintained by the World Health Organization.

† Date of first Notice of Compliance or Notice of Compliance with Conditions issued by Health Canada.

‡ The annual treatment cost was calculated based on the average annual cost per active beneficiary in selected private drug plans. This amount may be underestimated.

§ Values may not add to totals due to rounding.

Data source: PMPRB, IQVIA Private Pay Direct Drug Plan database, 2019

While Table 7 reports the top 10 medicines contributing to the increase in the sales of patented medicines, Table 8 compares the 10 top-selling patented medicines in 2006 and 2019, along with their treatment costs. In 2006, Remicade was the only biologic medicine to make the top 10 list, with an average annual treatment cost of $17,759. This was much higher than the rest of the medicines on the list, none of which exceeded $1,000 annually. By 2019, however, half of the top 10 medicines were biologics, with annual treatment costs ranging from $9,142 to $40,987. Only two of the top-selling non-biologic medicines in 2019 had annual treatment costs of less than $10,000, and the highest treatment cost exceeded $60,000. With collective annual sales of approximately $4.1 billion, these 10 medicines accounted for close to one quarter of the total sales for all patented medicines in 2019.

TABLE 8 Treatment Costs for the 10 Top-Selling Patented Medicines, 2006 and 2019

2006				2019					
Medicinal ingredient (Trade name)	**ATC***	**Date‡ of first NOC‡**	**Avg. annual treat-ment cost**	**Medicinal ingredient (Trade name)**	**ATC***	**Date of first NOC‡**	**Avg. annual treat-ment cost**	**Sales ($millions)**	**Share of patented sales**
1. Atorvastatin calcium (Lipitor)	C10A	Feb-97	$511	**1. Adalimumab (Humira)**	L04A	Sept-04	$17,429	$862.2	5.0%
2. Amlodipine besylate (Norvasc)	C08C	Aug-97	$417	**2. Aflibercept (Eylea)**	S01L	Nov-13	$9,142	$553.6	3.2%
3. Ramipril (Altace)	C09A	Sept-94	$271	**3. Sofosbuvir/ velpatasvir (Epclusa)**	J05A	July-16	$43,563	$475.9	2.8%
4. Venlafaxine hydrochloride (Effexor)	N06A	July-94	$446	**4. Lenalidomide (Revlimid)**	L04A	Jan-08	$60,313	$465.9	2.7%
5. Pantoprazole sodium (Pantoloc)	A02B	Sept-96	$330	**5. Sitagliptin phosphate monohydrate/ metformin hydro-chloride (Janumet)**	A10B	Sept-09	$852	$334.1	1.9%
6. Clopidogrel bisulfate (Plavix)	B01A	Oct-98	$607	**6. Apixaban (Eliquis)**	B01A	Dec-11	$740	$313.2	1.8%
7. Rosuvastatin calcium (Crestor)	C10A	Feb-03	$341	**7. Ustekinumab (Stelara)**	L04A	Dec-08	$22,618	$295.4	1.7%
8. Olanzapine (Zyprexa)	N05A	Oct-96	$977	**8. Pembrolizumab (Keytruda)**	L01X	May-15	$40,987	$280.4	1.6%
9. Salmeterol xinafoate / fluticasone propi-onate (Advair)	R03A	Sept-99	$343	**9. Ibrutinib (Imbruvica)**	L01X	Nov-14	$56,024	$266.1	1.5%
10. Infliximab (Remicade)	L04A	June-01	$17,759	**10. Rituximab (Rituxan)**	L01X	Mar-00	$11,960	$261.2	1.5%
				Total top 10 medicines‡				**$4,108.2**	**24.0%**
				Total patented medicines				**$17,238.7**	

Note: Biologic medicines are highlighted.

* Level 3 of the Anatomic Therapeutic Chemical (ATC) classification system maintained by the World Health Organization.

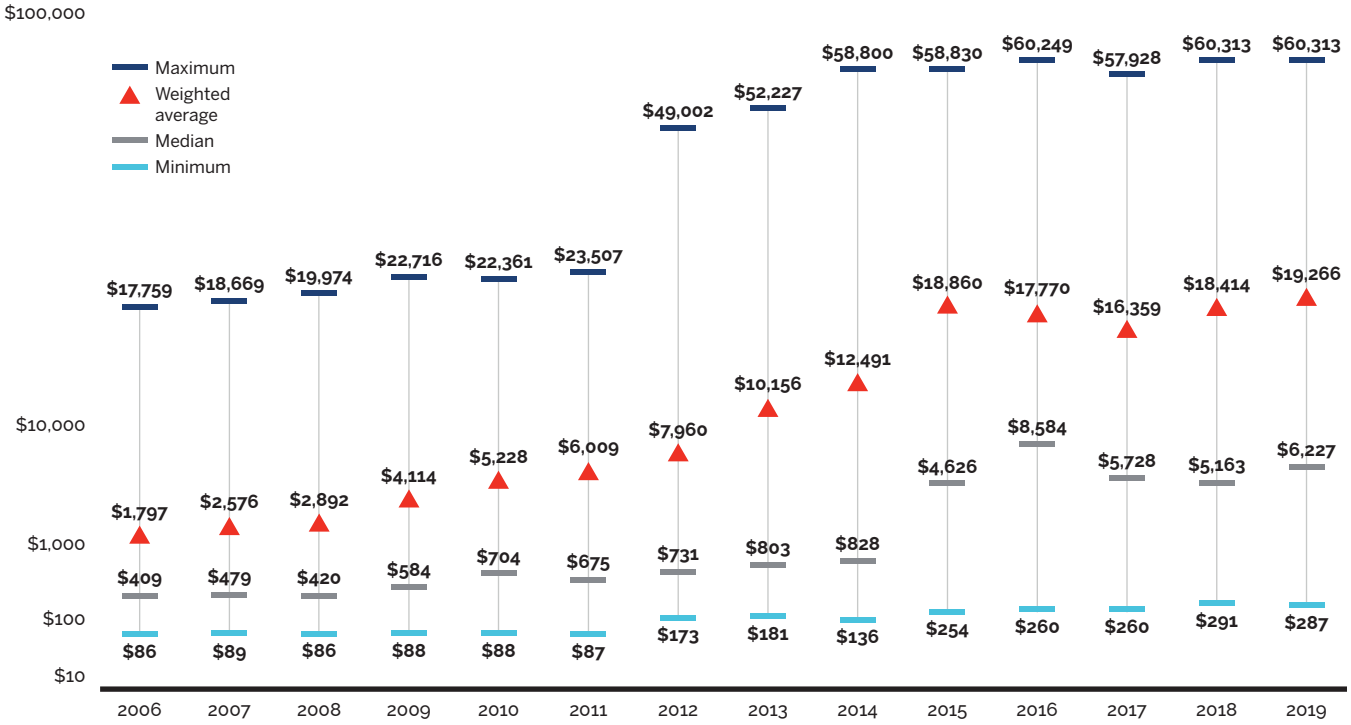
‡ Date of first Notice of Compliance or Notice of Compliance with Conditions issued by Health Canada.

‡ Values may not add to totals due to rounding.

Data source: PMPRB, IQVIA Private Pay Direct Drug Plan Database, 2019

Figure 9 details the trend in the treatment costs of patented medicines since 2006. For many years, the majority of the 20 top-selling patented medicines had annual treatment costs under $1,000; however, 2015 marked a turning point, and now most of the top sellers cost in the thousands or tens of thousands of dollars per year. This shift is reflected in the exceptional 10-fold growth in the median annual treatment cost between 2006 and 2015. In 2019, the median annual treatment cost was $6,227. In addition to their higher cost, these medicines have had a strong uptake in use, resulting in a weighted average annual treatment cost of $19,266 for the 20 top-selling patented medicines in 2019.

FIGURE 9 Annual Treatment Costs for the 20 Top-Selling Patented Medicines, 2006 to 2019



Data source: PMPRB; IQVIA Private Pay Direct Drug Plan database, 2006–2019

In 2019, high-cost medicines accounted for almost

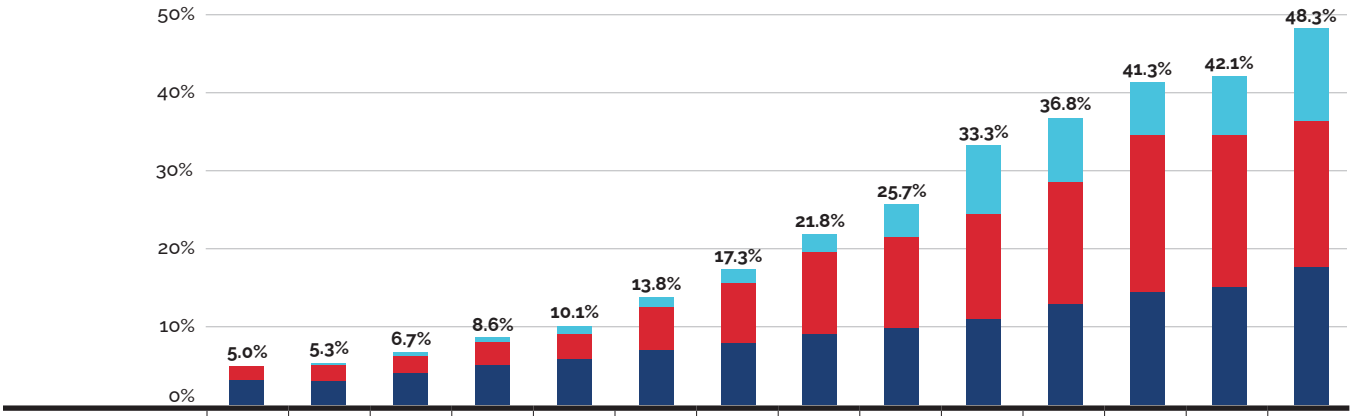
50% **of all patented medicine sales,**

as compared to 5% in 2006.

Between 2006 and 2019 the number of patented medicines in Canada with an annual average treatment cost of at least $10,000 more than quadrupled.

Figure 10 shows that high-cost medicines represent an increasingly significant share of the total sales of patented medicines, rising steeply from 5.0% in 2006 to 48.3% in 2019. This growth was evident in all ranges of annual treatment costs ($10 to $20 thousand; $20 to $50 thousand; and $50+ thousand), with medicines in the highest cost band climbing from 0.1% to 12.0% of sales over the same period. Despite the sharp increase in the share of costs, less than 1% of the population use these medicines.

FIGURE 10 Share of Sales for High-Cost Patented Medicines by Annual Treatment Cost, 2006 to 2019



Share of sales (%)	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
$10K to $20K	3.2	3.0	4.0	5.1	5.8	7.0	7.9	9.1	9.8	11.0	12.9	14.4	15.1	17.6
$20K to $50K	1.7	2.0	2.3	2.9	3.3	5.5	7.7	10.5	11.7	13.4	15.6	20.2	19.4	18.7
$50K+	0.1	0.3	0.4	0.6	1.0	1.3	1.7	2.2	4.2	8.9	8.3	6.7	7.6	12.0
Total*	5.0	5.3	6.7	8.6	10.1	13.8	17.3	21.8	25.7	33.3	36.8	41.3	42.1	48.3

High-cost medicines	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Cost ($millions)	$849	$884	$1,119	$1,413	$1,681	$2,303	$2,882	$3,624	$4,284	$5,549	$6,141	$6,864	$6,996	$8,330
Total no. of medicines	40	48	56	62	68	85	92	105	116	129	143	150	162	172
$10K to $20K	20	24	26	28	30	37	37	39	40	42	44	47	49	52
$20K to $50K	16	17	21	25	27	35	40	45	50	58	68	69	73	71
$50K+	4	7	9	9	11	13	15	21	26	29	31	34	40	49
Avg. treatment cost ($thousands)	$34.6	$42.0	$37.6	$32.2	$38.6	$37.9	$38.1	$37.8	$41.4	$44.8	$43.5	$42.7	$45.8	$51.8
Estimated treatment population (thousands)	48.1	46.5	60.3	75.1	86.2	112.8	136.9	167.2	186.9	222.4	254.1	284.8	285.8	331.3
Share of total Cdn population	0.15%	0.14%	0.18%	0.22%	0.25%	0.33%	0.39%	0.48%	0.53%	0.62%	0.70%	0.77%	0.78%	0.88%

Note: The methodology for this analysis was revised in 2018, and as such, historical results may not match those reported in earlier editions.

* Values may not add to totals due to rounding.

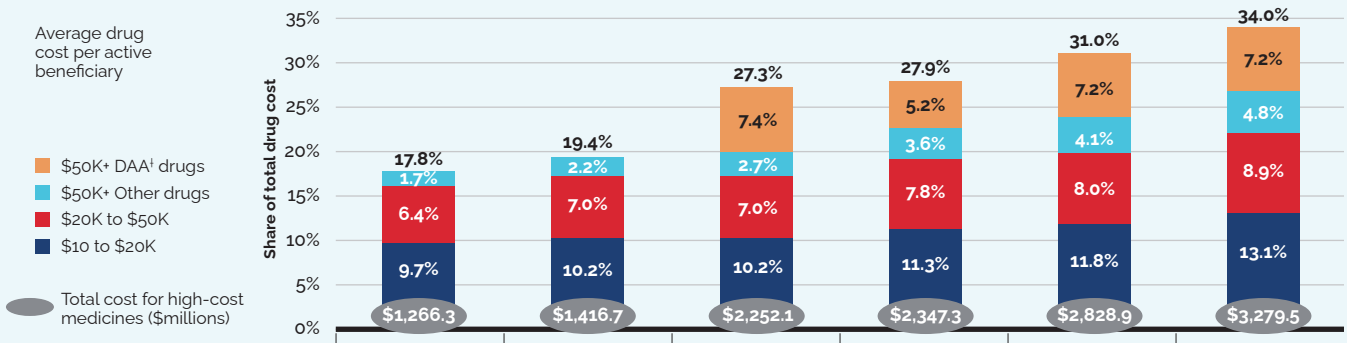
Data source: PMPRB; IQVIA Private Pay Direct Drug Plan database, 2006–2019

BRIEF INSIGHTS: HIGH-COST MEDICINES IN PUBLIC DRUG PLANS

High-cost medicines now account for 34% of all public drug plan expenditures. This is lower than the share for patented medicines reported in Figure 10 because public plan costs also include non-patented generic and non-patented single-source medicines.

In 2019, private drug plans reimbursed 205 high-cost medicines, while public plans reimbursed 115 in fiscal year 2018–19. Note that the number of oncology medicines and other high-cost medicines covered by public plans may be underestimated, as some are reimbursed through specialized programs, such as cancer care, that are not captured in the data.

FIGURE 11 Trends in the Number and Share of High-Cost Medicines, NPDUIS Public Drug Plans*, 2013–14 to 2018–19



	2013–14	2014–15	2015–16	2016–17	2017–18	2018–19
Total no. of medicines	71	84	94	102	106	115
Share of active beneficiaries	1.20%	1.30%	1.58%	1.73%	1.75%	1.71%
Share of prescriptions	0.21%	0.22%	0.28%	0.30%	0.34%	0.38%

Note: High-cost medicines are defined as having an annual treatment cost greater than $10,000. If medicines reach this threshold in any given year, they are included in the count for all other years. Thus, the number and composition of high-cost medicines in any given year may vary depending on the time of analysis.

Values may not add to totals due to rounding.

* British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, and the Non-Insured Health Benefits Program

‡ DAA: Direct-acting antivirals for the treatment for hepatitis C, which were launched in 2014 and 2015

Data source: NPDUIS database, Canadian Institute for Health Information (fiscal year data)

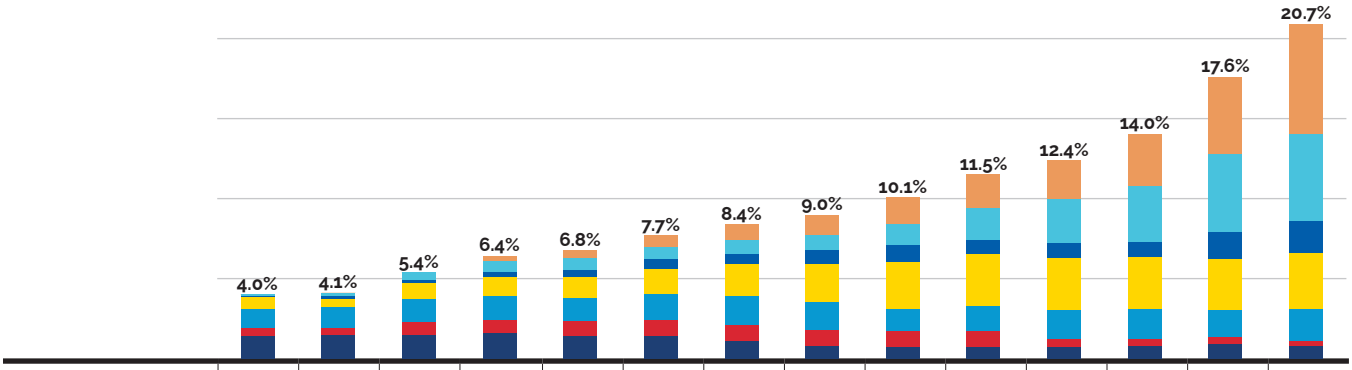
[NPDUIS Report: *CompassRx2018/19* (pre-publication results)]

The shift toward higher-cost treatments is especially evident in oncology medicines. Figure 12 shows the share of total sales for patented oncology medicines by treatment cost based on a standard 28-day treatment regimen.[9]

From 2006 to 2019, the average treatment cost for oncology medicines more than doubled, from $3,555 to $9,320. Many treatment regimens use multiple medicines resulting in even higher treatment costs per beneficiary.

The dual pressures of increasing average treatment costs and growing utilization mean that this therapeutic area is likely to continue to grow as a proportion of patented medicine sales.

FIGURE 12 Share of Sales for Patented Oncology Medicines by 28-day Treatment Cost, 2006 to 2019



Share of sales (%)	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Other*	1.4	1.5	1.5	1.6	1.4	1.4	1.1	0.8	0.7	0.7	0.7	0.8	0.9	0.8
<$2.5K	0.5	0.4	0.8	0.8	0.9	1.0	1.0	1.0	1.0	1.0	0.5	0.4	0.4	0.3
$2.5K to $3.5K	1.2	1.3	1.4	1.5	1.5	1.6	1.8	1.7	1.4	1.6	1.8	1.9	1.7	2.0
$3.5K to $5.0K	0.7	0.5	1.0	1.2	1.3	1.6	2.0	2.4	2.9	3.2	3.3	3.2	3.2	3.5
$5.0K to $7.5K	0.1	0.2	0.2	0.3	0.4	0.6	0.6	0.9	1.1	0.9	0.9	1.0	1.7	2.0
$7.5K to $10.0K	0.1	0.2	0.5	0.7	0.8	0.8	0.9	0.9	1.3	2.0	2.8	3.5	4.9	5.4
$10.0K+	0.0	0.0	0.0	0.3	0.5	0.7	1.0	1.3	1.7	2.1	2.4	3.2	4.8	6.9
Total[‡]	4.0	4.1	5.4	6.4	6.8	7.7	8.4	9.0	10.1	11.5	12.4	14.0	17.6	20.9

Oncology medicines	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Cost ($millions)	$670	$698	$895	$1,045	$1,150	$1,262	$1,379	$1,520	$1,678	$1,898	$2,050	$2,324	$2,939	$3,584
Total no. of medicines	35	35	40	43	46	53	56	60	69	72	77	80	91	94
Other*	13	12	13	10	11	10	9	9	11	10	10	10	10	9
<$2.5K	11	11	13	14	14	16	16	13	12	12	10	10	8	7
$2.5K to $3.5K	2	2	2	3	3	4	4	4	5	5	5	5	6	7
$3.5K to $5.0K	3	3	4	6	6	10	10	11	11	12	12	12	12	11
$5.0K to $7.5K	3	4	4	4	5	5	7	8	12	12	14	13	15	16
$7.5K to $10.0K	3	3	3	4	4	4	5	7	9	10	13	15	19	21
$10.0K+	0	0	1	2	3	4	5	8	9	11	13	15	21	23
Avg. 28-day treatment cost	$3,555	$3,785	$3,867	$4,492	$4,803	$4,888	$5,090	$5,564	$6,210	$6,656	$6,699	$7,039	$7,680	$9,320
Estimated treatment population (thousands)	167.1	169.7	371.1	393.2	466.7	538.6	578.7	589.0	607.6	600.1	464.9	468.6	512.5	567.1
Share of total Cdn population	0.51%	0.52%	1.12%	1.17%	1.37%	1.57%	1.67%	1.68%	1.71%	1.68%	1.28%	1.27%	1.37%	1.51%

Note: The methodology used for this analysis has been refined over the past two editions to better represent the market for oncology medicines. This includes a revised set of selection criteria, established following a thorough review and expert recommendation, as well as an updated method for determining the annual count of medicines. Thus, there may be some variation between these results and those previously reported.

These results reflect the total sales for patented medicines used in the treatment of cancer. While some of these medicines may also be used to treat other conditions, the data used for this analysis does not distinguish between indications, and thus, the reported sales may reflect some non-cancer use.

* Treatment costs for these medicines are not available.

‡ Values may not add to totals due to rounding.

Data source: PMPRB; CADTH pCODR

BRIEF INSIGHTS: ONCOLOGY MARKET IN CANADA

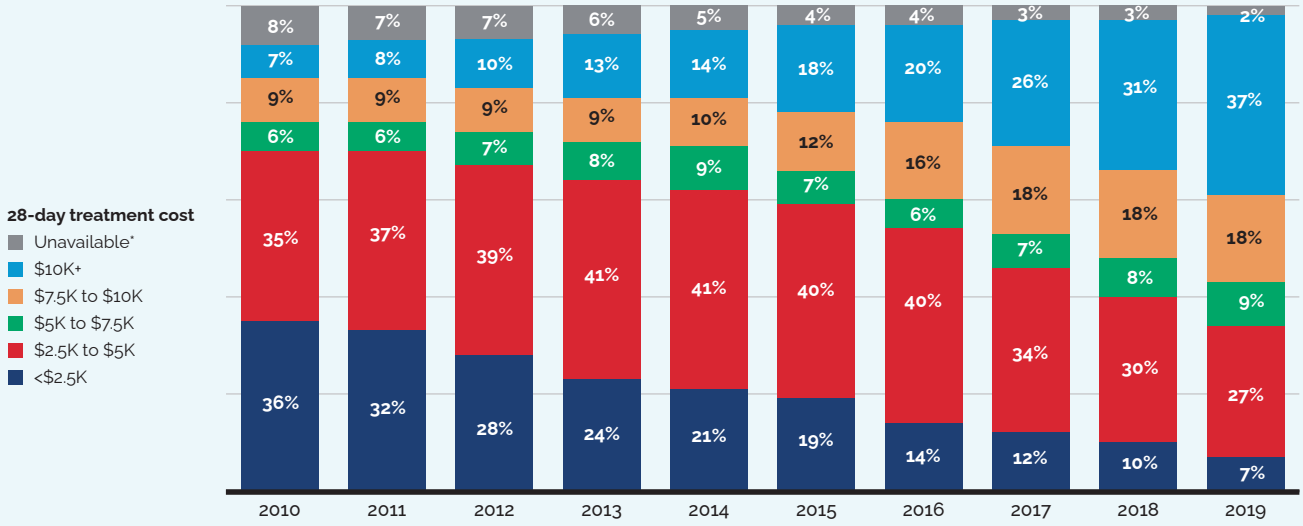
Results for the overall Canadian oncology market reflect the same trend of more expensive medicines accounting for a growing proportion of sales revenue. Figure 13 shows the share of total oncology sales by treatment cost based on a standard 28-day treatment regimen for both patented and non-patented medicines.

From 2010 to 2019, the share of revenue captured by medicines with a 28-day treatment cost greater than $10,000 grew from 7% to 37%. The oncology market as a whole shifted toward more expensive medicines, with the sales-weighted average treatment cost for the 10 highest-selling medicines more than doubling from $3,715 in 2010 to $8,365 in 2019.

As the oncology market shifted toward high-cost treatments, the overall pace of growth increased as well. The compound annual growth rate (CAGR) for 2010–2019 was 12.4%, with the highest annual growth rates occurring in 2017 (17.1%), 2018 (23.3%), and 2019 (20.2%).

The accelerating growth of this therapeutic area, from rising average treatment costs and utilization, is likely to increase cost pressures on Canadian payers.

FIGURE 13 Distribution of Sales for Oncology Medicines by 28-day Treatment Cost, 2010 to 2019



Note: While some of these medicines may also be used to treat other conditions, the data used for this analysis does not distinguish between indications, and thus, the reported sales may reflect some non-cancer use.

Values may not add to totals due to rounding.

* 28-day treatment costs are not available for these medicines.

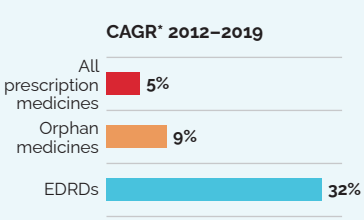
Data source: PMPRB; MIDAS® database, 2010–2019, IQVIA (all rights reserved)

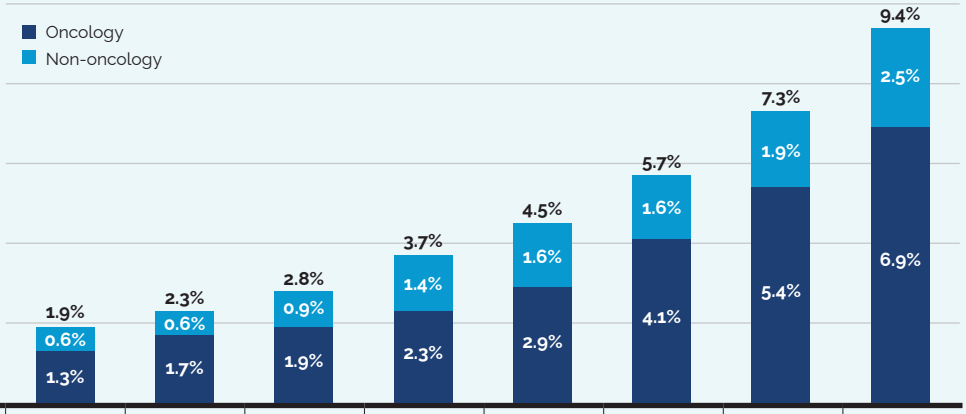
[NPDUIS Chartbook: *Oncology Medicines in Canada: Trends and International Comparisons, 2010–2019* (pre-publication results)]

BRIEF INSIGHTS: SPENDING ON EXPENSIVE DRUGS FOR RARE DISEASES

Expensive drugs for rare diseases (EDRDs) are the fastest growing market segment in Canada. From 2012 to 2019, EDRD expenditures grew by 32%, more than six times the growth rate observed for all prescription medicines. Despite the small patient population, EDRDs accounted for nearly one tenth of the entire Canadian pharmaceutical market in 2019.

FIGURE 14 EDRD Share of the Pharmaceutical Market in Canada, Oncology and Non-Oncology, 2012 to 2019





	2012	2013	2014	2015	2016	2017	2018	2019
Cumulative no. of EDRDs approved	26	31	37	48	62	71	82	93
Sales per capita	$11	$13	$16	$23	$29	$38	$50	$68

* Compound annual growth rate (CAGR) of expenditures over the study period

Data source: PMPRB; MIDAS® database, 2012–2019, IQVIA (all rights reserved); IQVIA Private Pay Direct Drug Plan database

For this analysis, EDRDs are defined as medicines with at least one orphan designation (by the US Food and Drug Administration or the European Medicines Agency) and estimated treatment costs exceeding $100,000 per year for non-oncology drugs and $7,500 per 28 days for oncology drugs.

[NPDUIS Chartbook: *Expensive Drugs for Rare Diseases: Canadian and International Markets* (pre-publication results)]

Top Therapeutic Classes Driving Sales Revenues

"Antineoplastics and immunomodulating agents", "alimentary tract and metabolism", and "general anti-infectives for systemic use and antiparasitic products" were the three top-selling therapeutic classes in 2019, accounting for close to two thirds of all patented medicine sales. The top-selling "antineoplastics and immunomodulating agents" class experienced a significant increase in sales of 17% in 2019. Conversely, sales of "respiratory system" medicines, which grew by 8.4% in 2018, experienced a significant decrease of -15.5% in 2019, as three top-selling medicines in this therapeutic class—Advair, Flovent, and Pulmicort—stopped reporting sales to the PMPRB.

Figure 15 breaks out the sales of patented medicines in Canada by therapeutic class using level 1 of the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) system.[10] Two donut graphs compare the share of total sales for each therapeutic class in 2019 to the share in 2008. The associated table gives the 2019 sales for each class and the sales growth from 2018 to 2019.

The "antineoplastics and immunomodulating agents" class accounted for a much larger share of sales in 2019 (38.8%) than in 2008 (15.6%), as more high-cost medicines entered the market over the past decade. By contrast, the share of sales of cardiovascular system medicines decreased dramatically from 24.5% to 3.3%.

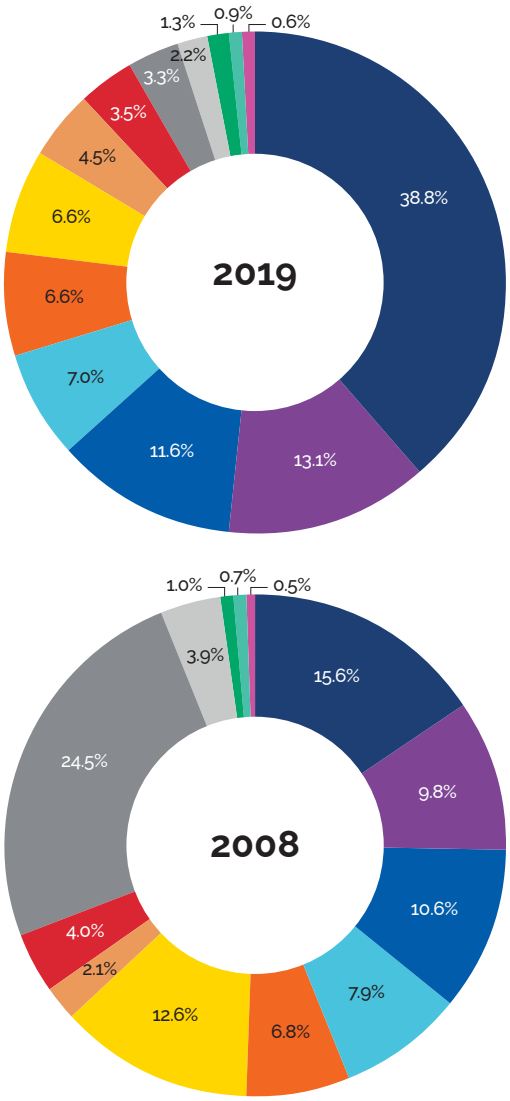
7 of the 10

TOP-SELLING MEDICINES IN 2019

had annual treatment costs exceeding $10,000.

FIGURE 15 Sales of Patented Medicines by Major Therapeutic Class, 2019

Share of sales, 2019 versus 2008



Sales of patented medicines by therapeutic class, 2019

Therapeutic class	2019 sales ($millions)	Growth: 2019/2018, $millions (rate in %)	2019 share of sales (%)
L: Antineoplastics and immunomodulating agents	$6,693.6	$970.2 (17.0%)	38.8%
A: Alimentary tract and metabolism	$2,262.2	$103.7 (4.8%)	13.1%
J: General antiinfectives for systemic use and P: Antiparasitic products*	$2,005.6	-$188.8 (-8.6%)	11.6%
R: Respiratory system	$1,199.1	-$220.8 (-15.5%)	7.0%
B: Blood and blood forming organs	$1,137.8	$39.1 (3.6%)	6.6%
N: Nervous system	$1,133.6	-$71.8 (-6.0%)	6.6%
S: Sensory organs	$778.5	-$116.9 (-13.1%)	4.5%
M: Musculo-skeletal system	$606.3	$136.9 (29.2%)	3.5%
C: Cardiovascular system	$560.5	-$76.9 (-12.1%)	3.3%
G: Genito-urinary system and sex hormones	$383.7	-$23.5 (-5.8%)	2.2%
D: Dermatologicals	$222.3	$35.9 (19.3%)	1.3%
H: Systemic hormonal preparations	$157.7	-$3.7 (-2.3%)	0.9%
V: Various	$97.7	-$6.9 (-6.6%)	0.6%
All therapeutic classes‡	**$17,239**	**$576.5**	**100%**

* These groups have been combined for reasons of confidentiality.

‡ Values may not add to totals due to rounding.

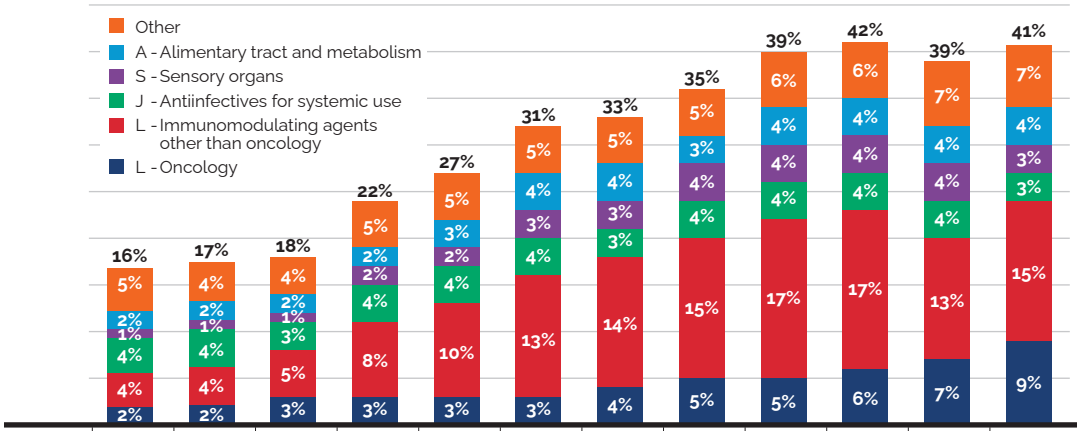
Data source: PMPRB

BIOLOGIC MEDICINES

Biologic medicines, many of which are in the high-cost category, have been capturing an increasing share of the Canadian market, from 16% of patented medicine sales in 2008 to 41% in 2019. In 2019, Humira, Eylea, and Stelara were the top-selling biologics, collectively accounting for 10% of all patented medicine sales. Figure 16 breaks down the annual growth in biologic patented medicine sales by major therapeutic class.

Although the share of biologic medicine sales has increased in many therapeutic classes, immunomodulating agents other than those for oncology had the highest uptake over the last decade, growing from 4% of total patented medicine sales in 2008 to 17% in 2017. In 2018, the share of sales for this therapeutic class dipped from 17% to 13%, as top-selling Remicade stopped reporting to the PMPRB, but the sales share increased once again in 2019, reaching 15%. Oncology medicines also represent a steadily growing share of the biologic market, increasing from 2% of patented medicine sales in 2008 to 9% in 2019.

FIGURE 16 Biologic Medicine Share of Patented Medicine Sales by Therapeutic Class*, 2008 to 2019



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Sales ($billions)	$2.6	$2.8	$2.9	$3.7	$4.4	$5.1	$5.5	$5.9	$6.5	$7.0	$6.5	$7.1

Top-selling biologic medicines	Share of 2019 sales
Humira	5.0%
Eylea	3.2%
Stelara	1.7%
Keytruda	1.6%
Enbrel	1.5%
Opdivo	1.1%
Herceptin	1.1%
Rituxan	1.1%
Darzalex	1.0%
Entyvio	1.0%
Total top 10	18.4%

Note: Values may not add to totals due to rounding.

* Level 1 of Anatomical Therapeutic Chemical (ATC) classification system maintained by the World Health Organization.

Data source: PMBRB

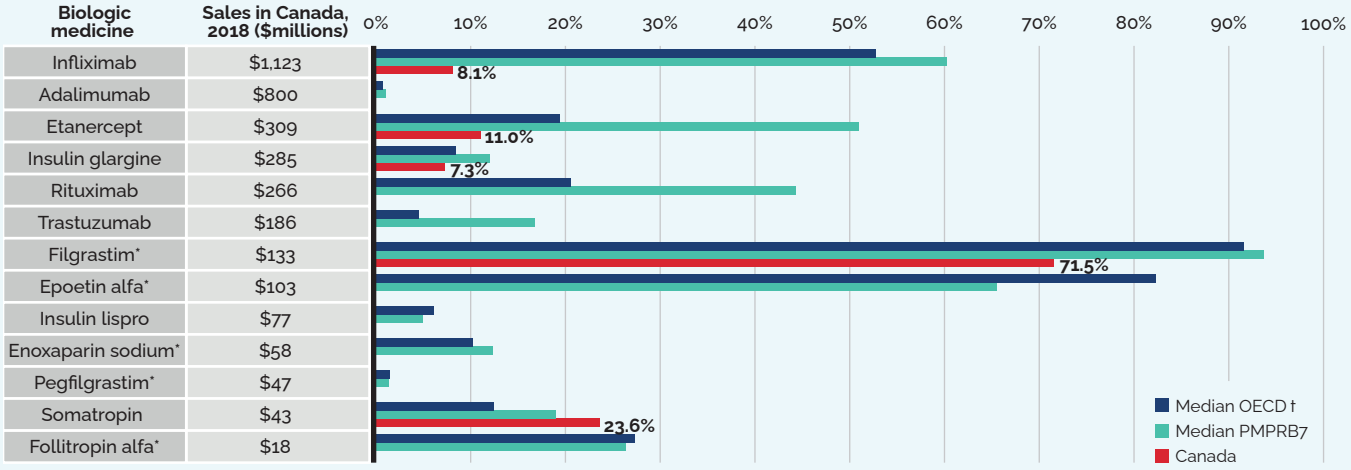
BRIEF INSIGHTS: BIOSIMILAR UPTAKE

Given the high use and cost of biologics in Canada, biosimilars offer an opportunity for significant cost savings. However, unlike generics, biosimilars are not identical to their originator medicines, but are rather highly similar versions, and Health Canada's authorization of a biosimilar is not a declaration of equivalence to the originator biologic.

While European countries have experienced some success in terms of early market entry, price discounts, and the uptake of biosimilars, Canada has lagged behind. For example, although the biosimilar Inflectra was first sold in Canada in 2015, it only represented 8% of the infliximab units sold at the end of 2018, with the originator biologic Remicade still maintaining a significant market share. This placed Canada well below the OECD median of 46% for sales shares of infliximab biosimilars.

Recently, some Canadian payers have undertaken initiatives to increase biosimilar uptake.

FIGURE 17 Biosimilar Share of Units by Medicine, Canada, the OECD, and the PMPRB7, Q4-2018



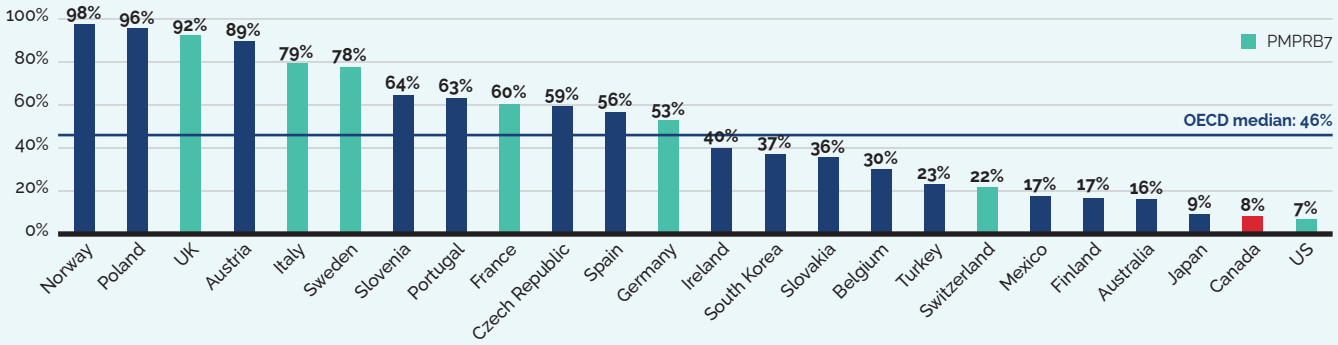
* Generally used to treat acute conditions.

† Canada is excluded from the median OECD value.

Data source: MIDAS® database, prescription retail and hospital markets, 2018, IQVIA (all rights reserved)

[NPDUIS Chartbook: *Biologics in Canada. Part 1: Market Trends, 2018*]

FIGURE 18 Uptake of Infliximab Biosimilars by Share of Units, OECD, Q4-2018



Note: Countries with limited data were excluded from the analysis.

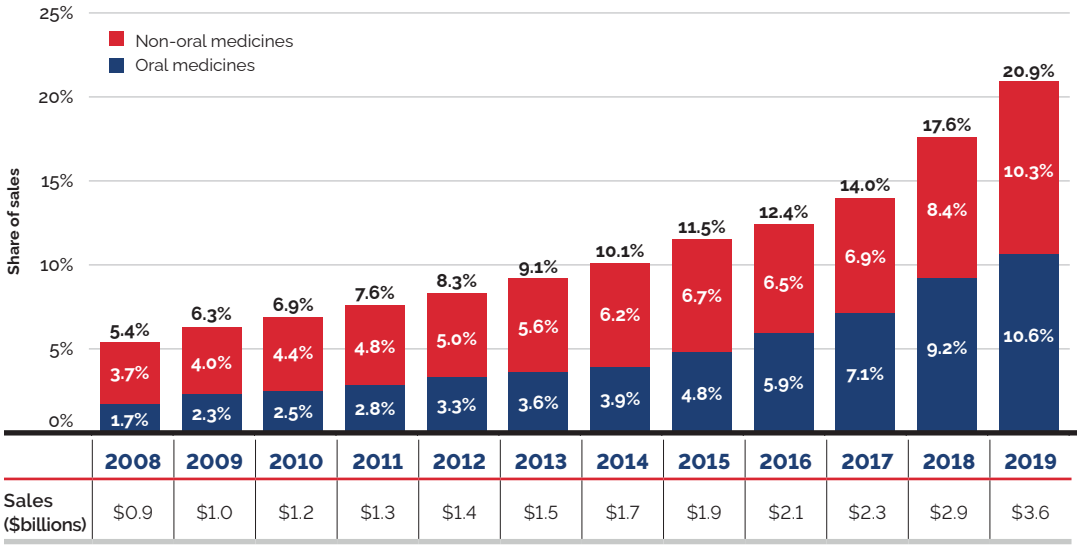
Data source: MIDAS® database, prescription retail and hospital markets, Q4-2018, IQVIA (all rights reserved)

[NPDUIS Chartbook: *Biologics in Canada. Part 1: Market Trends, 2018*]

ONCOLOGY MEDICINES

Figure 19 illustrates the growth in the sales of all oncology medicines (biologic and non-biologic) over the last decade. In 2019, oncology medicines accounted for 20.9% of total patented medicine sales, a substantial increase from 5.4% in 2008. Oral forms of cancer treatment are a noteworthy emerging segment, increasing their share of the patented medicine market from 1.7% to 10.6%, or half of all oncology medicine sales, over the same period. The oral therapy Revlimid was the top-selling oncology medicine in 2019, accounting for 2.7% of all patented medicine sales.[11]

FIGURE 19 Oncology Medicine Share of Patented Medicine Sales by Formulation, 2008 to 2019



Top-selling oncology medicines	Share of 2019 sales
Revlimid	2.7%
Keytruda	1.6%
Imbruvica	1.5%
Opdivo	1.1%
Herceptin	1.1%
Rituxan	1.1%
Ibrance	1.0%
Darzalex	1.0%
Perjeta-Herceptin	0.7%
Avastin	0.6%
Total top 10	12.6%

Note: The methodology used for this analysis has been refined over the past two editions to better represent the market for oncology medicines. This includes a revised set of selection criteria, established following a thorough review and expert recommendation, as well as an updated method for determining the annual count of medicines. Thus, there may be some variation between these results and those previously reported.

These results reflect the total sales for patented medicines used in the treatment of cancer. While some of these medicines may also be used to treat other conditions, the data used for this analysis does not distinguish between indications, and thus, the reported sales may reflect some non-cancer use.

Values may not add to totals due to rounding.

Data source: PMPRB

ENDNOTES

5 Sales and price information do not take into account indirect discounts provided to third party payers, such as product listing agreements.

6 All statistical results for patented medicines reported in this section are based on data submitted by patentees as of March 2020. On occasion, patentees may revise previously submitted data or provide data not previously submitted. This can appreciably affect the statistics in this section. To account for this possibility, the PMPRB reports recalculated sales figures (see *Trends in the Sales of Patented Medicines*), price and quantity indices (see *Price Trends* and *Utilization of Patented Medicines*), and foreign-to-Canadian price ratios (see *Comparison of Canadian Prices to Foreign Prices*) for the five years preceding the current Annual Report year. All recalculated values reflect currently available data. If the data has been revised, the values reported here may differ from those presented in earlier Annual Reports.

7 The cost driver analysis used here follows the approach detailed in the PMPRB report *The Drivers of Prescription Drug Expenditures: A Methodological Report, 2013*. As this model uses various measures to isolate the factors contributing to growth, the net change reported here may differ slightly from the reported overall growth in the patented medicines market.

8 The annual treatment cost was calculated based on the average annual cost per active beneficiary in selected private drug plans. Given the limitations of administrative data, this approximated treatment cost may be underestimated.

9 There is some overlap in the medicines reported in Figures 10 and 12, as the oncology medicines that exceeded $10,000 in annual treatment costs are reported in both graphs.

10 In this report, medicines are classified according to the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification system. This is a scientific, hierarchical system based on the principal therapeutic use and chemical composition of a medicine. The first level classifies medicines according to the element of human anatomy with which they are primarily associated.

11 The results reported for the high-cost, biologic, and oncology market segments are not mutually exclusive, as many oncology medicines are biologics and many biologics are high-cost medicines.

Price Trends

The PMPRB uses the Patented Medicines Price Index (PMPI) to monitor trends in the prices of patented medicines. The PMPI measures the average year-over-year change in the ex-factory prices of patented medicines sold in Canada using a sales-weighted average of price changes at the level of individual medicines.[12] This is similar to the approach Statistics Canada uses to construct the Consumer Price Index (CPI). The PMPI is based on an average transaction price and sales information submitted by patentees for a six-month period.

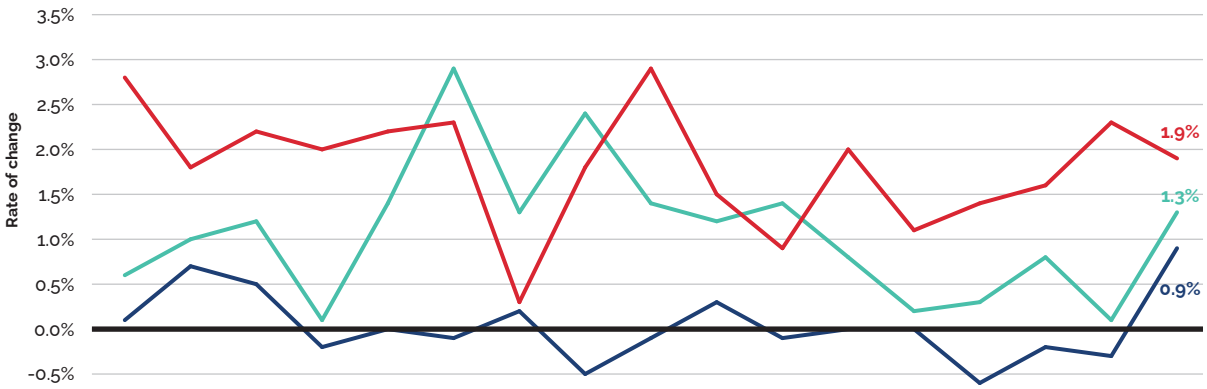
The PMPI only measures the sales growth attributable to changes in the prices of patented medicines. It does not measure changes in the use of patented medicines; this is measured by the quantity index or PMQI (see the *Utilization of Patented Medicines* section). Nor does it measure the cost impact of changes in prescribing patterns or the introduction of new medicines.

The *Patent Act* requires the PMPRB to consider changes in the CPI, among other factors, in determining whether the price of a patented medicine is excessive. Figure 20 compares year-over-year changes in the PMPI to corresponding changes in the CPI from 2003 to 2019. The PMPI is reported based on two measures: the national average transaction price, a "net" price which includes rebates and discounts; and the national list price, a "gross" price. Both measures are reported to the PMPRB by patentees. General price inflation, as measured by the CPI, has exceeded the average increase in the prices of patented medicines almost every year since 2003. In 2019, the CPI rose by 1.9%, while the PMPI increased by 1.3%.

Patented medicine prices increased by less than CPI

In 2019, the increase in patented medicine prices was, on average, less than the rate of inflation, as measured by the Consumer Price Index (CPI).

FIGURE 20 Annual Rate of Change, Patented Medicines Price Index (PMPI) and Consumer Price Index (CPI), 2003 to 2019



Rate of change (%)	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
CPI	2.8	1.8	2.2	2.0	2.2	2.3	0.3	1.8	2.9	1.5	0.9	2.0	1.1	1.4	1.6	2.3	1.9
PMPI change – National Average Transaction Price	0.1	0.7	0.5	-0.2	0.0	-0.1	0.2	-0.5	-0.1	0.3	-0.1	0.0	0.0	-0.6	-0.2	-0.3	0.9
PMPI change – National List Price	0.6	1.0	1.2	0.1	1.4	2.9	1.3	2.4	1.4	1.2	1.4	0.8	0.2	0.3	0.8	0.1	1.3

Data source: PMPRB; Statistics Canada

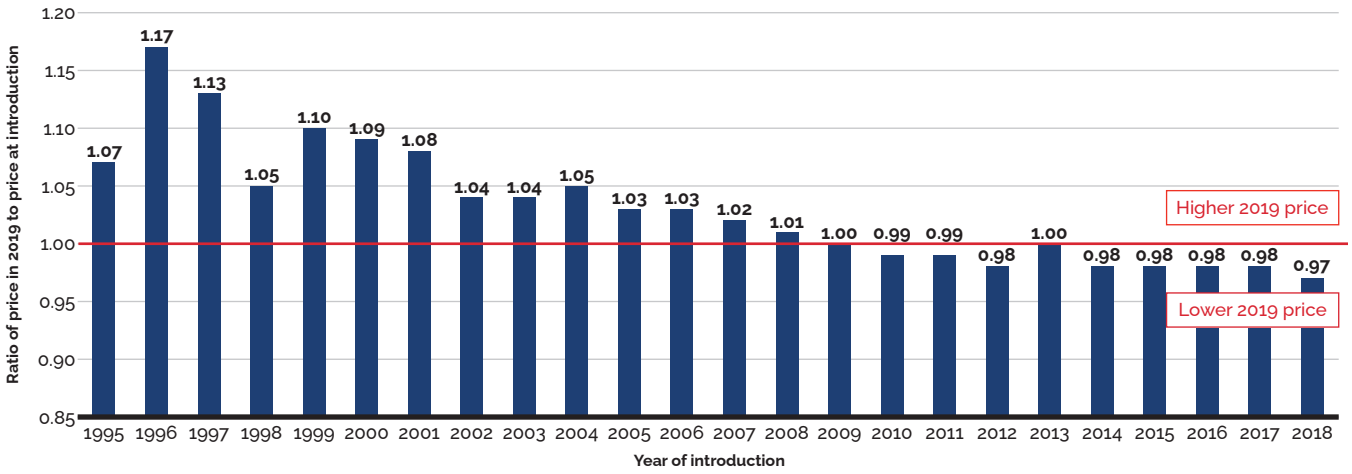
It is not surprising that the PMPI has seldom kept pace with the CPI. The PMPRB's Guidelines envisage that the price of a patented medicine should not rise by more than the CPI over any three-year period.[13] The Guidelines also contemplate a cap on year-over-year price increases equal to one and one-half times the current year rate of CPI inflation. This effectively establishes CPI inflation as an upper bound on the amount by which individual prices could rise over any three-year period. Increases in the PMPI normally do not reach this upper bound because many patentees do not raise their prices by the full amount envisaged under the Guidelines.

Price Behaviour after Introduction

Does the price of a typical patented medicine change much in the years after it enters the Canadian market? To answer this question, Figure 21 provides the average ratio of the 2019 price to introductory price (the price at which the medicine was sold in its first year on the Canadian market).

The results in Figure 21 suggest a consistent trend: prices remain stable early in their life cycle, and then gradually rise by a small amount, year-over-year, afterwards. This is consistent with the effect of the PMPRB's CPI methodology.[14] For example, the average prices of medicines introduced a decade ago are still at the same level in 2019.

FIGURE 21 Average Ratio of 2019 Price to Introductory Price, by Year of Introduction



Data source: PMPRB

Price Change by Country

In 2019, in accordance with the Act and the Regulations, patentees reported publicly available prices of patented medicines for seven comparator countries (PMPRB7): France, Germany, Italy, Sweden, Switzerland, the United Kingdom (UK), and the United States (US).

The PMPRB uses this information to

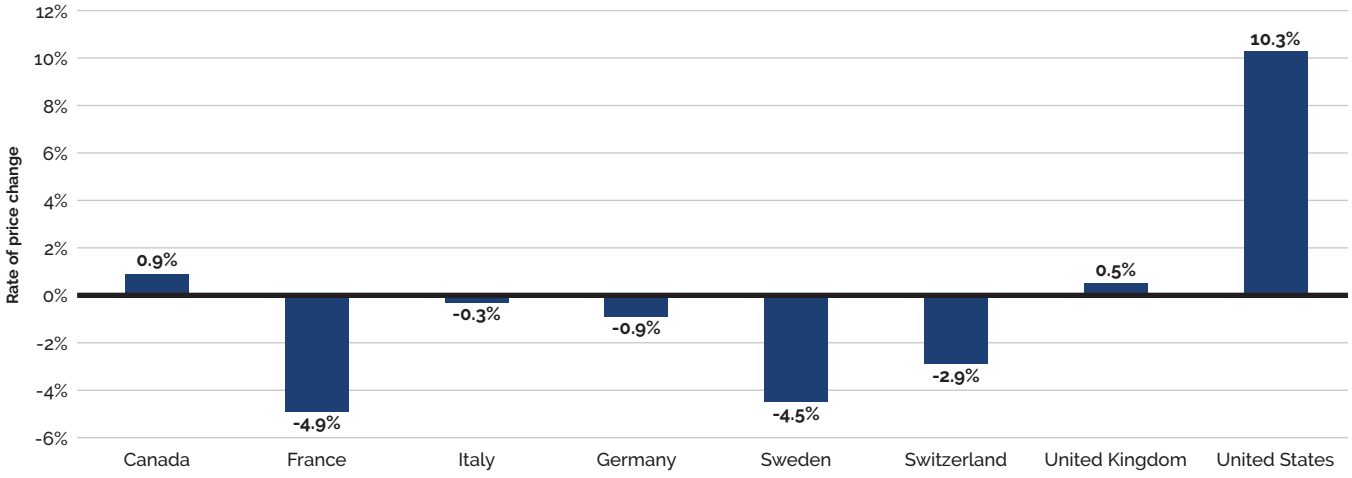
- conduct international price comparison tests; and
- compare the Canadian prices of patented medicines to those prevailing in other countries.

Figure 22 gives the average annual rates of price change for Canada and each of the PMPRB7 countries. These results were obtained by applying the PMPI methodology (with weights based on Canadian sales patterns) to the international price data that patentees submitted to the PMPRB. Note that prices from the US Federal Supply Schedule (FSS)[15] are incorporated into the US results.

In 2019, Canadian prices saw a slight increase of 0.9%, while prices in the US rose by an average of 10.3% and those in the UK increased by 0.5%. Prices in all other countries declined. These results are consistent with a long-term tendency for patented medicine prices to slowly fall over time in most comparable countries (with the exception of the US).

The foreign market results are based on publicly available gross prices, namely ex-factory price information (generally for the retail customer class) submitted by patentees to the PMPRB. The Canadian rate of change, however, is based on net prices, namely actual average transaction prices net of rebates and discounts provided by manufacturers to their direct customers.

FIGURE 22 Annual Average Rates of Price Change, Canada and the PMPRB7, 2019



Data source: PMPRB

ENDNOTES

12 These calculations are performed at the level defined by Health Canada's Drug Identification Number (DIN). Each DIN represents a unique combination of active ingredient(s), dosage form, strength(s), brand, and manufacturer.

13 Individual prices (or, for that matter, the PMPI) may rise by more than the CPI in a given year if patentees have banked price adjustments in the preceding years. This can also occur when the forecast rate of CPI inflation exceeds the actual rate.

14 This refers to the behaviour of prices on average. There may be instances where individual prices have risen or fallen substantially since introduction.

15 The pharmaceutical industry in the US has argued that the publicly available prices in that country do not reflect actual prices because of confidential discounts and rebates. Effective January 2000, and following public consultation, the PMPRB began including prices listed in the US Federal Supply Schedule (FSS) in calculating the average US price of patented medicines. The FSS prices are negotiated between manufacturers and the US Department of Veterans' Affairs. They are typically lower than other publicly available US prices reported to the PMPRB by patentees.

Comparison of Canadian Prices to Foreign Prices

Tables 9 and 10 provide detailed statistics comparing the foreign prices of patented medicines to their Canadian prices. Each table provides two sets of average price ratios. These are differentiated according to the method by which foreign prices were converted to their Canadian dollar equivalents. The tables also give the numbers of strengths and dosage forms of medicines (DINs) and the volume of sales encompassed by each reported price ratio.[16]

The average price ratios given in Tables 9 and 10 are sales-weighted arithmetic means of price ratios obtained for individual DINs, with weights based on Canadian sales patterns. Average price ratios constructed in this way provide answers to questions such as:

How much more/less would Canadians have paid for the patented medicines they purchased in 2019 had they paid Country X prices rather than Canadian prices?

For example, Table 9 states that the 2019 average France-to-Canada price ratio was 0.73. This means Canadians would have paid 27% less for the patented medicines they purchased in 2019 if they had paid French prices.

For many years, the PMPRB has reported average foreign-to-Canadian price ratios with foreign prices converted to their Canadian dollar equivalents by means of market exchange rates (more exactly, the 36-month moving averages of market rates the PMPRB normally uses in applying its Guidelines). Tables 9 and 10 also report foreign-to-Canadian price ratios with currency conversion at purchasing power parity (PPP). The PPP between any two countries measures their relative costs of living expressed in units of their own currencies. In practice, cost of living is determined by pricing out a standard "basket" of goods and services at the prices prevailing in each country.

Because PPPs are designed to represent relative costs of living, they offer a simple way to account for differences in overall national price levels when comparing individual prices, incomes, and other monetary values across countries. When applied to the calculation of average foreign-to-Canadian price ratios they produce statistics answering questions such as:

How much more/less consumption of other goods and services would Canadians have sacrificed for the patented medicines they purchased in 2019 had they lived in Country X?

Questions such as this cannot be answered by simply comparing the prices of medicines. Rather, one must first calculate what each price represents in terms of goods and services foregone. PPPs are designed for such purposes.

Bilateral Price Comparisons

Table 9 provides bilateral comparisons of prices in each of the PMPRB7 countries to corresponding Canadian prices. Focusing on the results with currency conversion at market exchange rates, it appears that, as in previous years, Canadian prices were typically within the range of prices observed among the comparator countries. Prices in France were appreciably lower than Canadian prices followed by Sweden, Italy, and the UK, while prices in Switzerland and Germany were higher. As in previous years, prices reported for the United States were much higher than prices in Canada or any other comparator country.

TABLE 9 Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons, Canada and the PMPRB7, 2019

	Canada	France	Germany	Italy	Sweden	Switzerland	United Kingdom	United States
At market exchange rates								
Average price ratio 2019	1.00	0.73	1.07	0.96	0.81	1.04	0.97	3.77
Average price ratio 2018	1.00	0.74	1.09	0.97	0.94	1.08	1.00	3.59
At purchasing power parities								
Average price ratio 2019	1.00	0.79	1.16	1.15	0.78	0.81	0.99	3.50
Average price ratio 2018	1.00	0.76	1.13	1.09	0.82	0.82	0.99	3.07
Number of patented medicines compared 2019 (DINs)	1,331	637	980	778	801	858	958	1,035
Sales ($millions)	$17,235.6	$11,317.8	$15,200.5	$13,880.7	$12,444.7	$14,872.2	$14,928.4	$15,808.5

Data source: PMPRB

It is important to note that it is not always possible to find a matching foreign price for every strength and dosage form of a patented medicine sold in Canada. Table 9 displays how often an international price comparison was available for each of the comparator countries. For example, out of 1,331 DINs for patented medicines reported as under the PMPRB's jurisdiction in 2019, a publicly available ex-factory price for France was available 48% of the time, whereas US prices were available for 78% of medicines. Given the integrated nature of the Canadian and US supply chain, it is not uncommon for the US to be the only comparator country with an available price for a strength and dosage form of a medicine sold in Canada. In this case, it is considered to constitute the international median price, as per the PMPRB's methodology.

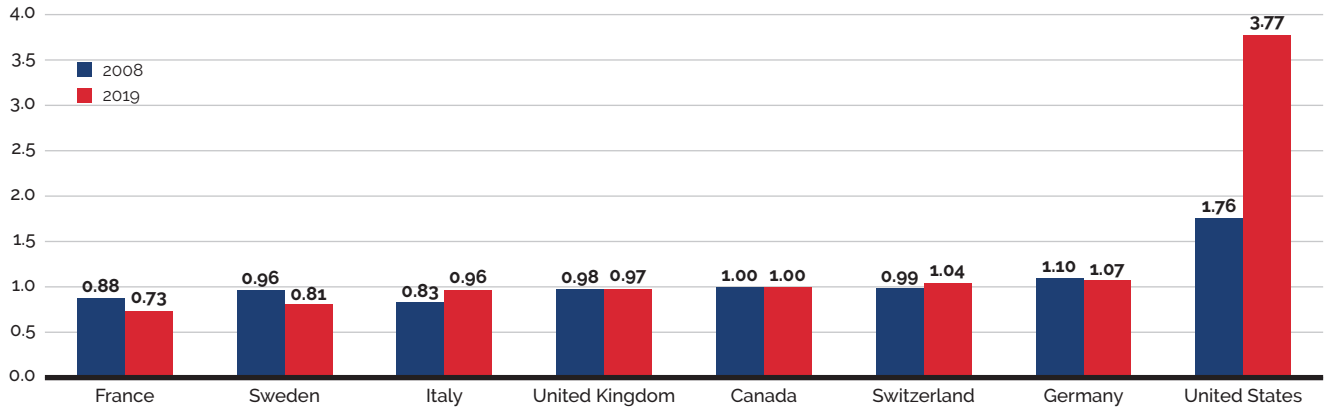
Average price ratios obtained with currency conversion at PPPs tell the same story. When international differences in the cost of living are considered, it appears that Canadians incurred a larger consumption cost for the patented medicines they purchased in 2019 than did residents of France, Sweden, Switzerland, and the UK.

Figure 23 puts these results in historical perspective. In 2008, Canadian prices were, on average, slightly higher than prices in Italy, France, and Sweden, and approximately the same as prices in the UK and Switzerland. By 2019, the gap between Canadian prices and prices in France and Sweden had grown significantly greater as the relative prices in these countries dropped, while the prices in Italy and the UK in 2019 were in line with Canadian levels. Price levels in Switzerland, Germany, and the US all exceeded those in Canada in 2019, although the gap between Canadian and German prices narrowed.

If the patented medicine is being sold in one or more of the PMPRB7 countries, the patentee must report the publicly available ex-factory prices to the PMPRB for each class of customer.[17] Using this data, Figure 23 provides sales weighted bilateral ratios comparing Canadian average transactional prices against foreign list prices. In order to assess how Canada compares to a basket of countries beyond the PMPRB7, Figure 24 uses Canadian and international prices reported in the IQVIA MIDAS® database at the ex-factory manufacturer level, reflecting all sales to the pharmacy and hospital sectors.[18] Note that the results presented in Figures 23 and 24 will differ somewhat due to the use of different data sources.

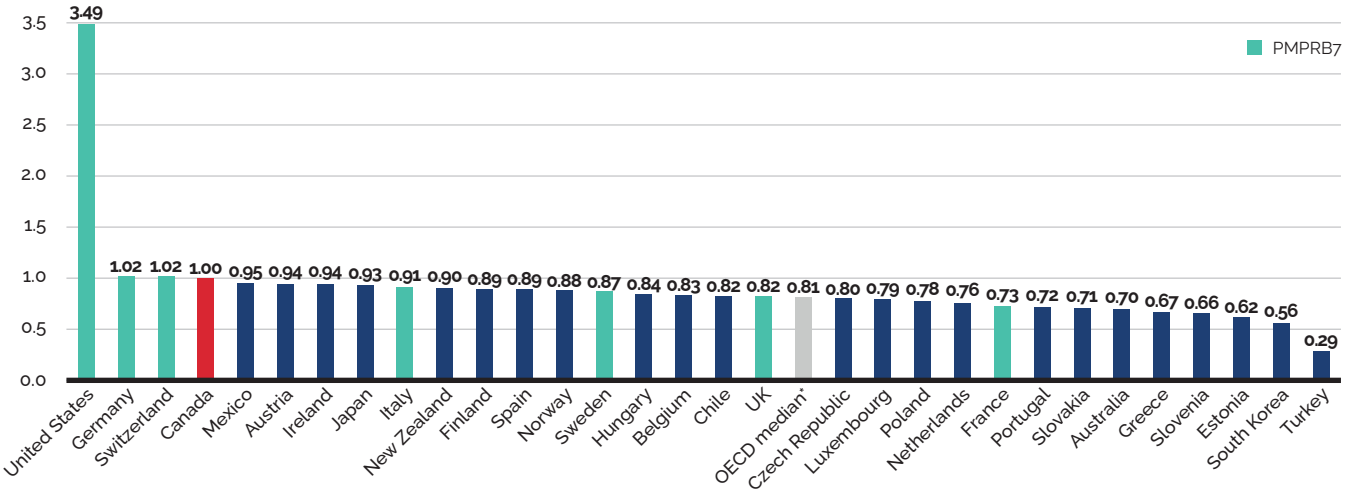
The international price comparisons reported in Figure 24 provide a bilateral price comparison for all countries in the Organisation for Economic Co-operation and Development (OECD) with available MIDAS® data. The average foreign-to-Canadian price ratios are calculated using the same approach employed to produce the ratios presented in Figure 23. These are Canadian sales-weighted arithmetic averages of the corresponding foreign-to-Canadian price ratios for individual medicines. As shown in Figure 24, median OECD prices are, on average, approximately 19% lower than price levels in Canada, which are the fourth highest among the 31 countries. Notably, the top three highest-priced countries are the US, Germany, and Switzerland.

FIGURE 23 Average Foreign-to-Canadian Price Ratios, Canada and the PMPRB7, 2008 and 2019



Data source: PMPRB

FIGURE 24 Average Foreign-to-Canadian Price Ratios, Patented Medicines, OECD, 2019



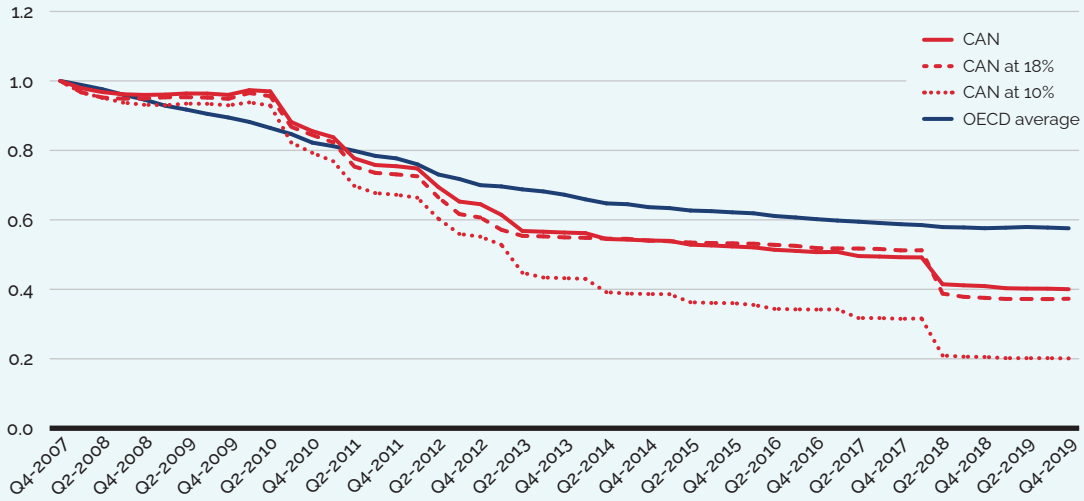
* Calculated at the medicine level for medicines with prices available in at least three foreign markets.

Data source: MIDAS® database, 2019, IQVIA (all rights reserved)

BRIEF INSIGHTS: TRENDS IN THE PRICE OF GENERIC MEDICINES

The average price of generic medicines in Canada has dropped substantially, by 60% relative to price levels in 2007 (Figure 25). This was the greatest rate of price reduction compared to all PMPRB7 markets, as generic price decreases continued to reduce the historic gap between Canadian and foreign generic price levels. The recent Canadian generic pricing policy, implemented in 2018, brought Canadian generic prices in line with average prices in Italy, although price levels are still lower in the US, Germany, and France, and significantly lower in the UK and Sweden. The average prices for all OECD countries were just 8% lower than prices in Canada in the last quarter of 2019, an improvement from the gap of 15% at the end of the previous year (Figure 26).

FIGURE 25 Price Indices and Generic Price Reductions, Canada and the PMPRB7, Q4-2007 to Q4-2019



Generic price reduction Q4-2007 to Q4-2019	
Sweden	-24%
Italy	-29%
Switzerland	-31%
France	-42%
UK	-46%
Germany	-54%
US	-59%
OECD average	-42%
CAN	-60%
CAN at 18%	-63%
CAN at 10%	-80%

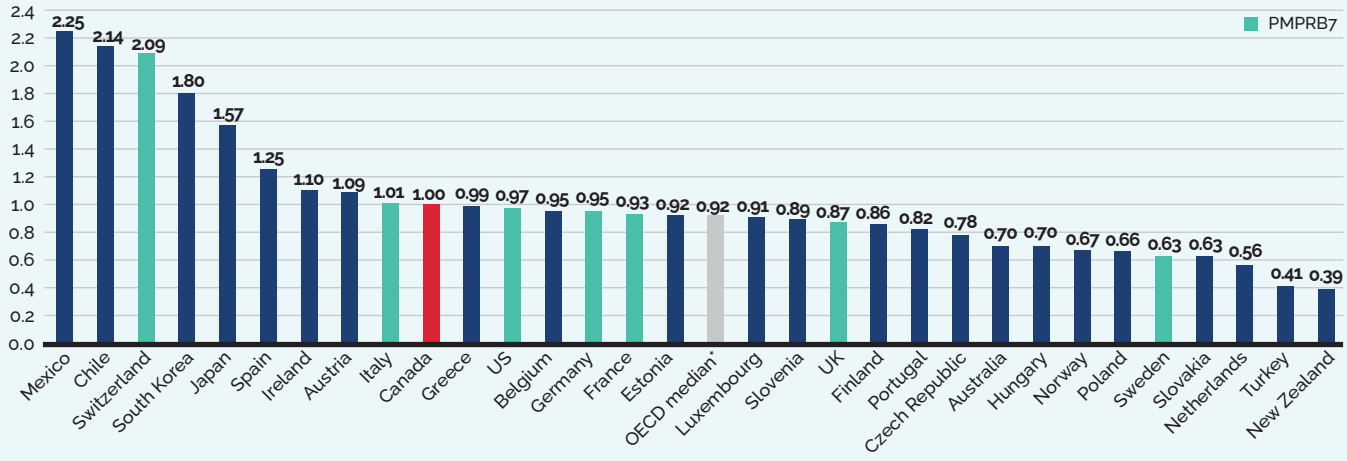
Note: The term "generic" used in this analysis includes both patented and non-patented generic medicines. Results are based on manufacturer ex-factory list prices in the national retail markets. The analysis was restricted to oral solid generic medicines that had been on the market for at least one year.

CAN at 18% and 10% refer to the 67 generic medicines reduced to 18% and 10% of their brand reference prices through the generic pricing policy introduced in April 2018.

Data source: MIDAS® database, October–December 2007 to October–December 2019, IQVIA (all rights reserved)

[NPDUIS Report: *Generics360, 2018* – graph updated for 2019]

FIGURE 26 Foreign-to-Canadian Price Ratios for Generic Medicines, OECD, Q4-2019



Note: The term "generic" used in this analysis includes both patented and non-patented generic medicines. Results are based on manufacturer ex-factory list prices in the national retail markets. The analysis was restricted to oral solid generic medicines that had been on the market for at least one year.

* The OECD median does not necessarily represent the median result for the individual countries reported in this graph, as it is calculated at the medicine level for generics with prices available in at least three foreign markets.

Data source: MIDAS® database, October–December 2019, IQVIA (all rights reserved)

[NPDUIS Report: *Generics360, 2018* – graph updated for 2019]

Multilateral Price Comparisons

Table 10 provides average foreign-to-Canadian price ratios using several multilateral measures of foreign prices. The median international price (MIP) is the median of prices observed among the PMPRB7. Other multilateral price ratios compare the minimum, maximum, and simple mean of foreign prices to their Canadian counterparts.

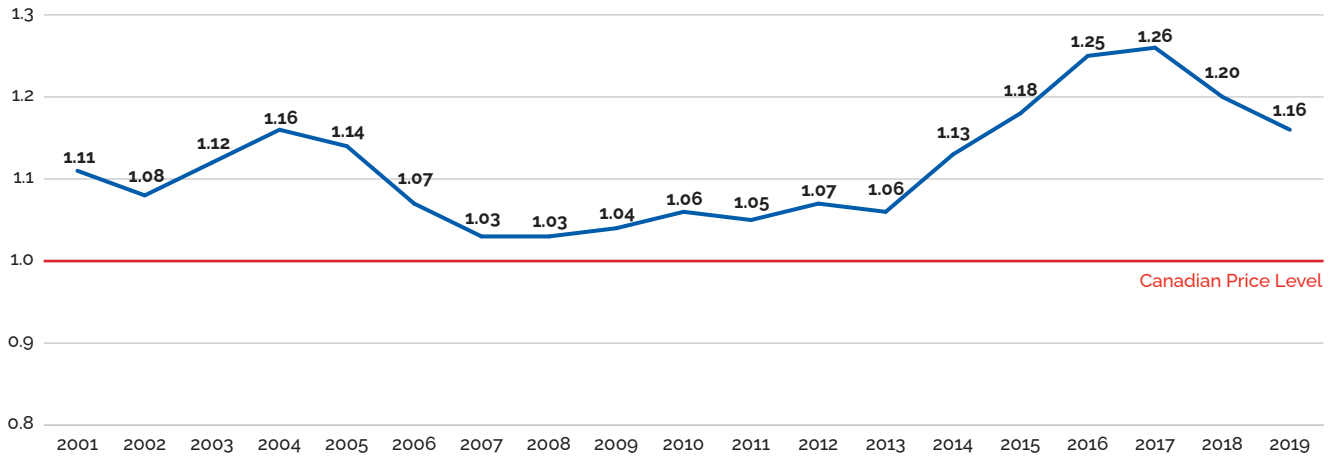
Focusing again on the results based on market exchange rates, the average MIP-to-Canadian price ratio was 1.16 in 2019, lower than the 1.20 ratio in 2018 (Figure 27). Note that mean foreign prices produce higher foreign-to-Canadian price ratios than MIPs do. This is due to the influence of US prices, which are typically much higher than prices elsewhere. Although US prices nearly always figure importantly in determining the mean foreign price, they have less impact on median international prices. Nevertheless, the US does exercise a significant influence over the average ratio of median international prices relative to Canadian prices, as the US is sometimes the only country with an available ex-factory price for a patented medicine sold in Canada.

TABLE 10 Average Foreign-to-Canadian Price Ratios, Multilateral Comparisons, 2019

	Median	Minimum	Maximum	Mean
Average price ratio at market exchange rates	1.16	0.88	3.65	1.52
Average price ratio at purchasing power parities	1.14	0.87	3.47	1.50
Number of patented medicines	1,247	1,247	1,247	1,247
Sales ($millions)	$16,841.12	$16,841.12	$16,841.12	$16,841.12

Data source: PMPRB

FIGURE 27 Average Ratio of Median International Price (MIP) to Canadian Price, at Market Exchange Rates, 2001 to 2019

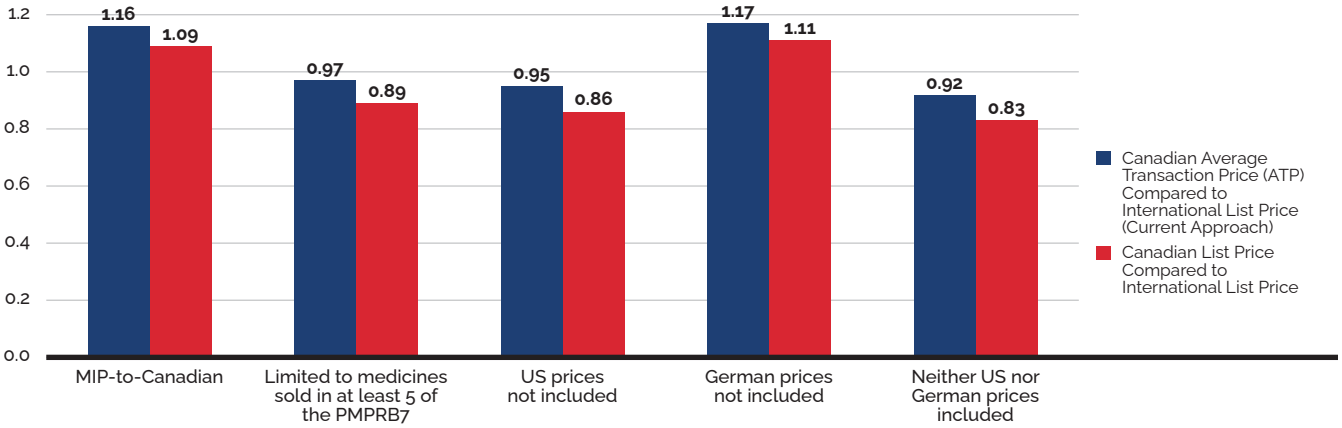


Data source: PMPRB

Figure 28 provides alternate results for the average MIP-to-Canadian price ratio at market exchange rates in 2019. To address the point that Canadian prices are national average transaction prices whereas foreign prices are list prices, a list price to list price ratio is also calculated. Using this method, the average ratio decreases from 1.16 to 1.09. It is important to keep in mind that confidential rebates provided to payers are currently not captured in this data.

To account for the large impact of US prices in determining the median foreign price, a ratio excluding the US and a ratio including at least five countries in the calculation of the median are also provided in Figure 28. With these restrictions, the average MIP-to-Canadian price ratios drop to 0.86 and 0.89, respectively, suggesting that median foreign list prices are, on average, 14% to 11% lower than Canadian list prices. In many of the comparator countries, discounts off list prices are available to all payers, both public and private. By contrast, a large portion of the Canadian market pays list prices, or close to list prices. Furthermore, it should be noted that these are average ratios—some patentees charge Canadian consumers less than median international prices, while others charge more. For MIP-to-Canadian price ratios at the patentee level, please refer to Table 22 in Appendix 4 of this report.

FIGURE 28 Average Ratio of Median International Price (MIP) to Canadian Price, at Market Exchange Rates, 2019

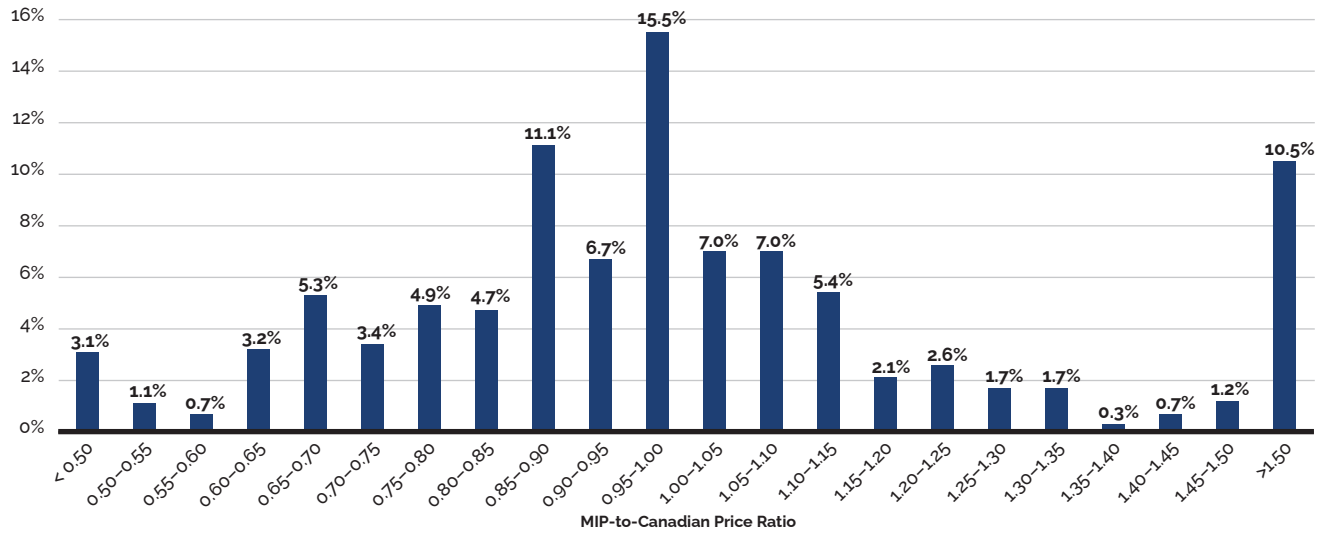


Data source: PMPRB

Figure 29 offers more detail on the medicine-level MIP-to-Canadian ratios underlying the averages reported in Table 10. This figure distributes the 2019 sales of each patented medicine according to the value of its MIP-to-Canadian price ratio (more exactly, according to the range into which the ratio fell).[19] These results show substantial dispersion in medicine-level price ratios: while patented medicines with MIP-to-Canadian price ratios between 0.90 and 1.10 accounted for 36.3% of sales, those with ratios less than 0.90 accounted for 37.4% of sales, and medicines with ratios exceeding 1.10 accounted for 26.3%.

In 2019, approximately 40% of Canadian patented medicines were priced above the median international level.[20] Table 11 shows which therapeutic categories in particular are priced above the median international levels in Canada. Medicines that share the fourth level ATC classification ("ATC4")[21] are grouped to identify distinct chemical/pharmacological/therapeutic subgroups, allowing for a calculation of the average MIP-to-Canadian price ratios among medicines that may be used to treat the same conditions. Table 11 identifies the top 10 ATC4s in 2019 in which the difference between Canadian and median prices had the largest effect on Canadian patented medicine spending.[22] For example, had Canadian prices been in line with the international median for these classes of medicines in 2019, sales in Canada would have been reduced by approximately $1 billion (an average reduction of 14% for these ATC4s). Of the 220 DINs classified into these 10 ATC4s, 54% were priced above the median international price.

FIGURE 29 Range Distribution, Share of Sales by MIP-to-Canadian Price Ratio, 2019



Data source: PMPRB

TABLE 11 Top 10 ATC4s* by Total Sales Greater than Median International Prices, 2019

Description	ATC4*	No. of companies	No. of chemicals in ATC4 (No. currently under patent)	Total patented DINs	Patented DINs greater than median price	2019 net revenue for patented DINs ($millions)	Patented DINs ATC4 share of 2019 revenues	MIP-to-Canadian ratio (min. 5) of patented DINs‡	Impact of difference on patented medicines in 2019 ($millions)
Antiinfectives for systemic use	J05AX	5	11 (10)	17	6	$699.8	4.06%	0.73	$193.3
Adrenergics in combination with corticosteroids or other medicines excluding anticholinergics	R03AK	3	4 (4)	6	4	$358.6	2.08%	0.55	$123.5
Selective immunosuppressants	L04AA	12	15 (15)	30	24	$1,883.7	10.93%	0.93	$118.6
Other antineoplastic agents	L01XC	10	20 (20)	28	9	$1,448.9	8.41%	0.94	$97.9
DPP-4 inhibitors	A10BH	4	4 (4)	9	9	$334.2	1.94%	0.72	$94.2
Combinations of oral blood glucose lowering medicines	A10BD	5	10 (10)	30	19	$400.4	2.32%	0.65	$89.9
Antineovascularisation agents	S01LA	1	1 (1)	1	1	$553.6	3.21%	0.85	$83.8
Other blood glucose lowering drugs, excl. insulins	A10BX	4	5 (5)	11	9	$431.4	2.50%	0.83	$72.4
Protein kinase inhibitors	L01XE	15	36 (36)	75	28	$957.2	5.55%	0.94	$70.7
Proton pump inhibitors	A02BC	4	6 (3)	13	10	$192.1	1.11%	0.44	$53.4

* Level 4 of the Anatomical Therapeutic Chemical (ATC) classification system maintained by the World Health Organization.

‡ For cases where the Canadian average transactional price was below the median international price, the MIP-to-Canadian ratio was set to 1.

Data source: PMPRB

Canada is a top 10 global market

Canada is an important market for pharmaceuticals representing 2% of worldwide sales. Canada spends approximately the same amount as the UK on pharmaceuticals despite having only half its population.

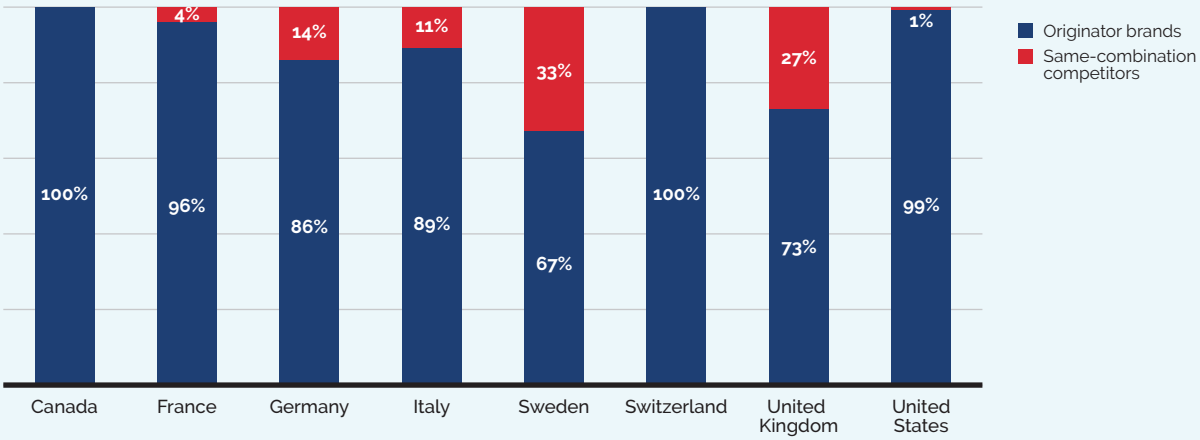
BRIEF INSIGHTS: COMBINATION INHALERS FOR ASTHMA – LIMITED GENERIC ENTRY

Inhaled corticosteroid (ICS) and long-acting beta agonist (LABA) combination inhalers used in the treatment of asthma are a $577 million market in Canada, with one of the largest price differentials between Canadian and international levels.

Combination inhalers for asthma are a complex market space, with special regulatory requirements for proving bioequivalence that may complicate generic entry. There is no international consensus with regard to regulating the design, method, and evaluation of bioequivalence studies, and in Canada, there are no current guidelines that specifically apply to this class of medicines.

Although the first combination inhaler for asthma was approved in Canada over two decades ago, the first competitor offering the same combination of medicines only gained market approval in 2018, and the first true generic didn't enter the market until 2020. Same-combination competitors were approved much earlier in all PMPRB7 countries, except Switzerland, with first recorded sales as early as 2010 in Sweden. Internationally, even where alternatives to the originator brand combination inhalers for asthma exist, the level of penetration is very different than what would be expected for an oral solid medicine, and the cost savings offered as of 2018 were often quite moderate.

FIGURE 30 Combined Revenue Share of Originator Brand Advair and Symbicort Combination Inhalers Versus Same-Combination Competitors*, Canada and the PMPRB7, 2018



* Includes both generics and subsequent brand-name competitors for the same combination of medicinal ingredients. Although one same-combination competitor was approved in Canada in 2018, there were no recorded sales in the study year.

Data source: MIDAS® database, prescription retail and hospital markets, 2018, IQVIA (all rights reserved)

[NPDUIS Report: *Market Intelligence Report: Combination Inhalers for Asthma, 2018*]

ENDNOTES

16 The number of medicines and sales these ratios encompass vary because it is not always possible to find a matching foreign price for each strength and dosage form of a patented medicine sold in Canada. Note that all the bilateral average price ratios reported in Table 9 combined represent at least 66% of 2019 Canadian sales, while the multilateral ratios in Table 10 cover over 97%.

17 The publicly available ex-factory price includes any price of a patented medicine that is agreed on by the patentee and the appropriate regulatory authority of the country.

18 IQVIA's MIDAS® database is the source of sales data used in this analysis. MIDAS® summarizes data obtained from IQVIA's detailed audits of pharmaceutical purchases. MIDAS® contains information on sales of individual medicines, measured in both currency and physical units. It also includes information on medicine manufacturer, active ingredient, brand, form, strength, pack-size, patent status, and therapeutic class. Sales estimates are based directly on the purchase information obtained in its pharmacy audits. To obtain the value of a company's ex-factory sales of a particular medicine, IQVIA removes an estimate of wholesalers' mark-ups from the acquisition costs reported. It should be noted that the acquisition costs used by IQVIA are based on invoiced prices. Off-invoice discounts, free goods, and other forms of price reduction such as rebates are therefore not represented in the MIDAS® data.

19 To produce the results represented in this figure, foreign prices were converted to their Canadian-dollar equivalents at market exchange rates.

20 This outcome is not inconsistent with the current Guidelines which contemplate, post introduction, annual price increases in line with general inflation, as long as prices remain below the highest international price.

21 ATCs used in this analysis are those maintained under the World Health Organization's Collaborating Centre for Drug Statistics Methodology. The first level of an ATC code describes the anatomical main group and has one letter. The second level divides the main groups into pharmacological/therapeutic groups and has two digits. The third and fourth levels divide these into distinct chemical/therapeutic/pharmacological subgroups and each has one letter. The fifth level defines an individual chemical substance and has two digits. For example, in the case R03AK (as found in Table 11), "R" indicates that the medicines treat the Respiratory System; "03" that they specifically treat obstructive airway diseases; "A" that they consist of adrenergics and inhalants; and "K" that they are specifically adrenergics in combination with corticosteroids or other medicines excluding anticholinergics. A specific chemical combination that is a member of this group is salmeterol xinafoate with fluticasone propionate (Advair), and is represented by the fifth level ATC R03AK06. For further information, please refer to http://www.whocc.no/atc_ddd_index/

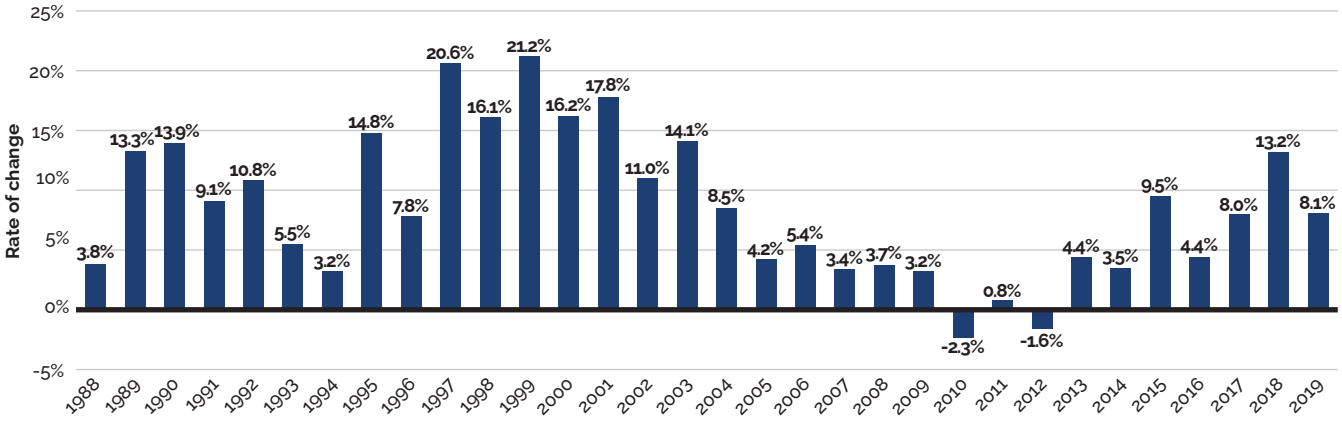
22 The medicines in Table 11 reported under the jurisdiction of the PMPRB are as follows:

- **A02BC:** dexlansoprazole, esomeprazole magnesium, lansoprazole, omeprazole magnesium, pantoprazole magnesium, pantoprazole sodium
- **A10BD:** alogliptin benzoate/metformin hydrochloride, canagliflozin/metformin hydrochloride, dapagliflozin/metformin hydrochloride, empagliflozin/linagliptin, empagliflozin/metformin hydrochloride, ertugliflozin/sitagliptin, linagliptin/metformin, saxagliptin/metformin, sitagliptin phosphate monohydrate/metformin hydrochloride
- **A10BH:** alogliptin benzoate, linagliptin, sitagliptin phosphate, saxagliptin
- **A10BX:** canagliflozin, dapagliflozin dropanediolmonohydrate, dulaglutide, empagliflozin, exenatide
- **J05AX:** daclatasvir, dolutegravir, elbasvir/grazoprevir, enfuvirtide, maraviroc, ledipasvir/sofosbuvir, letermovir, sofosbuvir, sofosbuvir/velpatasvir, sofosbuvir/velpatasvir/voxilaprevir, raltegravir potassium
- **L01XC:** atezolizumab, avelumab, bevacizumab, blinatumomab, brentuximab vedotin, daratumumab, durvalumab, inotuzumab ozogamicin, ipilimumab, nivolumab, obinutuzumab, olaratumab, panitumumab, pembrolizumab, pertuzumab, pertuzumab/trastuzumab, ramucirumab, rituximab, trastuzumab, trastuzumab emtansine
- **L01XE:** abemaciclib, acalabrutinib, afatinib, alectinib, axitinib, bosutinib, brigatinib, cabozantinib, ceritinib, cobimetinib fumarate, crizotinib, dabrafenib, dacomitinib, dasatinib, ibrutinib, lapatinib ditosylate monohydrate, larotrectinib, lenvatinib mesylate, lorlatinib, midostaurin, neratinib, nilotinib hydrochloride monohydrate, nintedanib, osimertinib, palbociclib, pazopanib hydrochloride, ponatinib hydrochloride, regorafenib, ribociclib, ruxolitinib, sofarenib tosylate, sunitinib maleate, temsirolimus, trametinib, vandetanib, vemurafenib
- **L04AA:** abatacept, adalimumab, baricitinib, belimumab, eculizumab, etanercept, everolimus, fingolimod hydrochloride, leflunomide, mycophenolate sodium, natalizumab, ocrelizumab, sirolimus, tofacitinib, vedolizumab
- **R03AK:** budesonide/formoterol fumarate dihydrate, fluticasone furoate/vilanterol, mometasone furoate/formoterol fumarate, salmeterol xinafoate/fluticasone propionate
- **S01LA:** aflibercept

Utilization of Patented Medicines

The price and sales data used to calculate the PMPI also allow the PMPRB to examine trends in the quantities of patented medicines sold in Canada. The PMPRB maintains the Patented Medicines Quantity Index (PMQI) for this purpose. Figure 31 provides average rates of utilization growth, as measured by the PMQI, from 1988 through 2019. These results confirm that in recent years, growth in the utilization of patented medicines has been a primary source of rising sales.

FIGURE 31 Annual Rate of Change, Patented Medicines Quantity Index (PMQI), 1988 to 2019

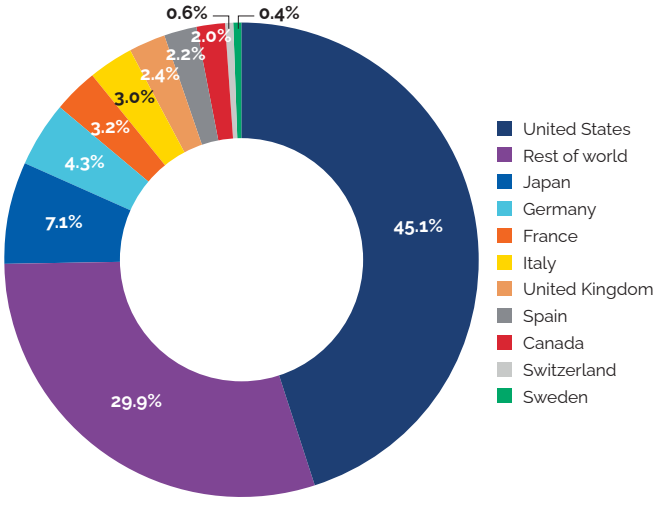


Data source: PMPRB

Canadian Medicine Expenditures in the Global Context

IQVIA[23] regularly reports on medicine sales across a large number of countries. Based on sales data from this source, Figure 32 provides shares of global sales for Canada and other major national markets including the PMPRB7 countries.[24] The Canadian market accounted for 2.0% of the global market in 2019.

FIGURE 32 Distribution of Medicine Sales Among Major National Markets, 2019



Data source: MIDAS® database, 2019, IQVIA (all rights reserved)

Figure 33 provides Canada's share of global sales for 2005 to 2019. The Canadian share has remained between 1.9% and 2.7% throughout this period. Although 2.0% is at the low end for Canada's average share of global sales in recent years, the US share grew from 40.4% in 2014 to 45.1% in 2019, resulting in declining shares for all other major countries.

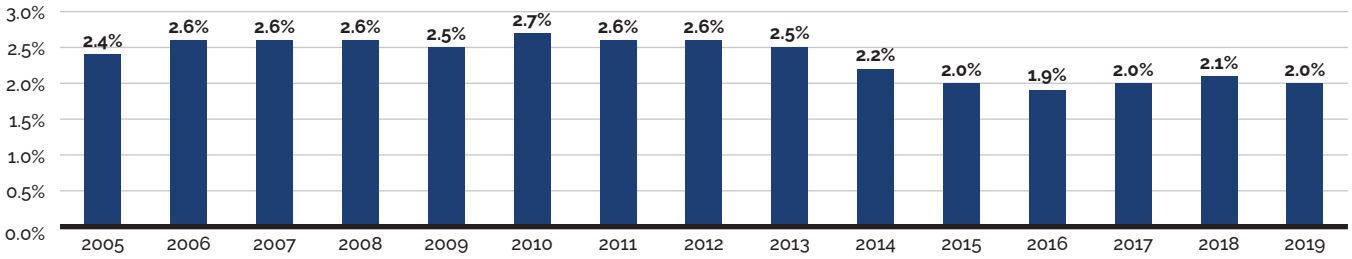
Figure 34 gives the average annual rate of growth in total medicine sales for Canada and the PMPRB7, individually and collectively. From 2005 to 2019, sales of medicines in Canada rose at an average annual rate of approximately 4.6%. This is on par with the average rate of growth in medicine sales among the PMPRB7 countries over the same period, though this average is heavily skewed by the influence of US sales.

1.8%

Medicine Expenditures in Canada

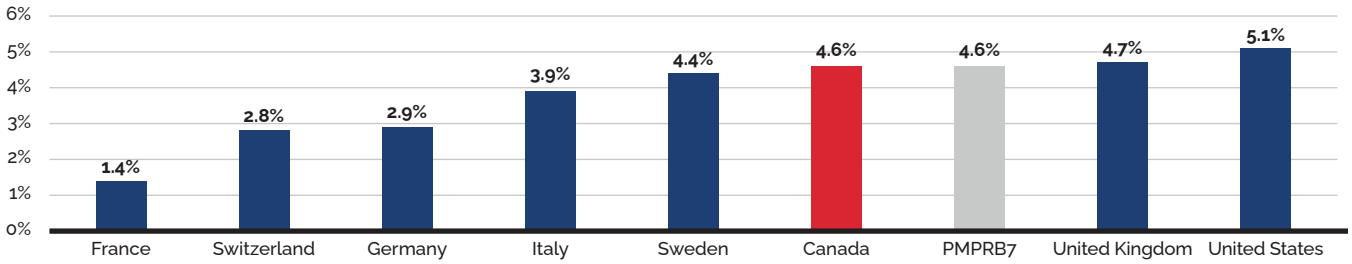
In 2017, Canadians spent 1.8% of gross domestic product on medicines. This is the 2nd highest share in the PMPRB7, behind only the United States.

FIGURE 33 Canada's Share of Medicine Sales, 2005 to 2019



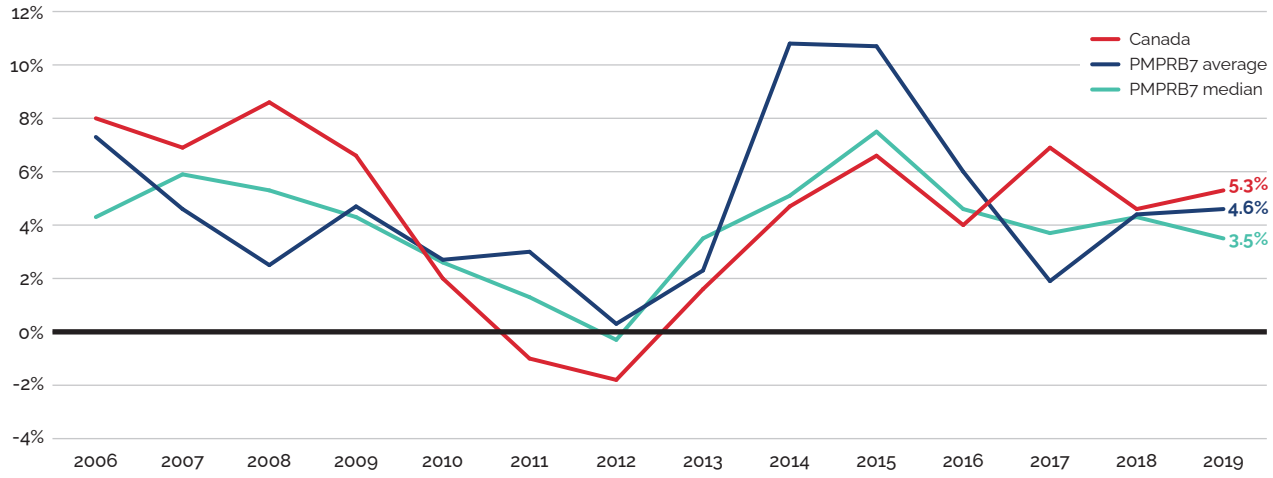
Data source: MIDAS® database, 2005–2019, IQVIA (all rights reserved)

FIGURE 34 Average Rate of Growth of Medicine Sales, at Constant 2019 Market Exchange Rates, by Country, Canada and the PMPRB7, 2005 to 2019



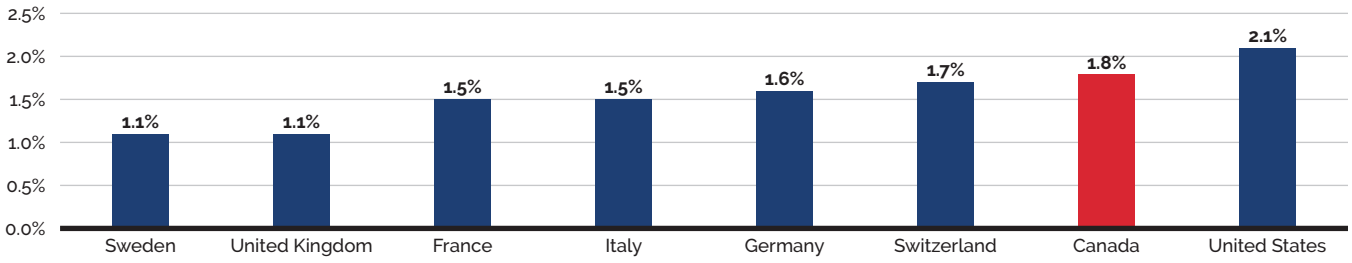
Data source: MIDAS® database, 2005–2019, IQVIA (all rights reserved)

FIGURE 35 Average Annual Rate of Change in Medicine Sales, at Constant 2019 Market Exchange Rates, Canada and the PMPRB7, 2006 to 2019



Data source: MIDAS® database, 2005–2019, IQVIA (all rights reserved)

FIGURE 36 Medicine Expenditures as a Share of GDP, Canada and the PMPRB7, 2017



Data source: OECD

Figure 35 compares rates of year-over-year growth in medicine sales for the entire pharmaceutical market in Canada and the PMPRB7 countries combined. In 2019, sales grew at a faster rate in Canada than in the other PMPRB7 countries.

The proportion of national income allocated to the purchase of medicines provides another way to compare medicine costs across countries.[25] Figure 36 gives medicine expenditures as a share of gross domestic product (GDP) for Canada and the PMPRB7 countries based on data for 2017. Medicine expenditures absorbed between 1.1% and 2.1% of the GDP in the PMPRB7. The Canadian value of 1.8% was second only to the US.

Table 12 provides a historical perspective on the expenditures-to-GDP ratio.[26] In 2005, Canada's ratio was fourth highest of the PMPRB7. Since that time, Canada's ratio has risen, while the ratios of three other countries (France, Italy, and Sweden) have declined. In 2017, Canada had the fourth highest spending per capita on medicines compared to the PMPRB7 (behind the US, Switzerland, and Germany).

Table 13 gives the composition of patentees' sales by therapeutic class for Canada and the PMPRB7, individually by country and as an aggregate.[27] The results suggest a remarkable degree of similarity across countries.

TABLE 12 Medicine Expenditures as a Share of GDP, Canada and the PMPRB7, 2017

	Share: Medicine Expenditures/GDP 2005	Share: Medicine Expenditures/GDP 2017	Growth: GDP 2005–2017	Medicine spending per capita 2005 ($US PPP)	Medicine spending per capita 2017 ($US PPP)
Canada	1.64%	1.79%	52.9%	$593	$806
France	1.79%	1.49%	56.0%	$545	$653
Germany	1.58%	1.58%	65.1%	$509	$823
Italy	1.70%	1.54%	46.6%	$505	$590
Sweden	1.15%	1.08%	71.0%	$396	$515
Switzerland	1.09%	1.66%	94.8%	$427	$963
United Kingdom	1.00%	1.14%	45.2%	NA	$469
United States	1.88%	2.05%	49.1%	$832	$1,220

Data source: OECD

TABLE 13 Distribution of Medicine Sales by Major Therapeutic Class, Canada and the PMPRB7, 2019

Therapeutic class	Canada	PMPRB7	France	Germany	Italy	Sweden	Switzerland	United Kingdom	United States
A: Alimentary tract and metabolism	13.4%	15.5%	9.6%	10.6%	10.2%	10.1%	10.4%	10.9%	17.0%
B: Blood and blood-forming organs	4.7%	6.6%	8.7%	8.3%	9.2%	9.4%	6.3%	6.7%	6.1%
C: Cardiovascular system	6.6%	4.8%	6.6%	6.6%	8.0%	4.0%	8.8%	5.9%	4.2%
D: Dermatologicals	3.2%	2.6%	2.3%	2.8%	1.9%	2.2%	3.1%	2.3%	2.7%
G Genito-urinary system and sex hormones	4.1%	3.0%	2.6%	2.5%	2.8%	3.0%	3.6%	3.1%	3.1%
H: Systemic hormonal preparations	1.3%	2.5%	2.2%	2.0%	1.8%	2.0%	1.4%	1.8%	2.7%
J: General antiinfectives for systemic use	9.2%	11.1%	11.1%	8.8%	15.8%	11.7%	10.1%	11.6%	10.9%

continued

Therapeutic class	Canada	PMPRB7	France	Germany	Italy	Sweden	Switzerland	United Kingdom	United States
L: Antineoplastics and immunomodulating agents	23.5%	24.0%	25.7%	24.9%	23.1%	25.4%	24.9%	25.3%	23.7%
M: Musculo-skeletal system	3.1%	3.3%	2.7%	4.1%	3.0%	3.9%	5.0%	3.1%	3.3%
N: Nervous system	15.6%	14.5%	13.5%	14.8%	12.3%	15.2%	15.5%	14.0%	14.7%
P: Antiparasitic products	0.1%	0.1%	0.2%	0.2%	0.0%	0.1%	0.1%	0.1%	0.1%
R: Respiratory system	7.1%	6.8%	5.9%	6.7%	5.4%	6.3%	5.8%	7.3%	6.9%
S: Sensory organs	4.7%	2.6%	3.7%	3.1%	2.1%	3.8%	4.5%	4.8%	2.4%
V: Various	3.4%	2.6%	5.2%	4.6%	4.3%	2.8%	0.5%	3.2%	2.1%
All therapeutic classes*	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

* Values may not add to 100% due to rounding.

Data source: MIDAS® database 2019, IQVIA (all rights reserved)

ENDNOTES

23 Although most of the statistical results presented in this section are based on sales data from MIDAS® database, 2005–2019, IQVIA (all rights reserved), the statements, findings, conclusions, views and opinions expressed in this Annual Report are exclusively those of the PMPRB and are not attributable to IQVIA. MIDAS® data cover the pharmacy and hospital sectors.

24 The results given in Figures 32 through 36 are based on estimates of ex-factory sales revenues encompassing all prescription medicines, including patented and non-patented branded medicines and patented and non-patented generic medicines. These estimates have been converted to Canadian dollar equivalents at annual average market exchange rates. Fluctuations in these rates can substantially influence these shares.

25 Comparisons made on this basis will reflect international differences in prices, overall utilization and patterns of therapeutic choice, as well as differences in national income.

26 To make use of the best and most up-to-date data on OECD medicine expenditures, the GDP in Table 12 was calculated using the purchasing power parity (PPP). PPPs are corrected for the relative cost of living based on a standard basket of goods, therefore, the GDP growth rates reported in Table 12 will be different than those generated using other methodologies. Details on purchasing power parity are provided in the text associated with Table 9.

27 Note that the data used to produce Table 13 encompass patented and non-patented brand-name medicines and patented and non-patented generic medicines. Hence, the results reported for Canada are not directly comparable to the results reported in Figure 15, which include only patented medicines.

NATIONAL PRESCRIPTION DRUG UTILIZATION INFORMATION SYSTEM: SUPPORTING HEALTH CARE DECISION MAKING IN CANADA

How medications are used—where, by whom, and for what—has an impact on the amount that we spend on medicines. The PMPRB contributes to Canada's understanding of medicine usage through the National Prescription Drug Utilization Information System (NPDUIS) initiative, generating comprehensive, accurate information to help guide decision making and support continued sustainability of our pharmaceutical system.

Background

NPDUIS is a research initiative established by federal, provincial, and territorial Ministers of Health in September 2001. It is a partnership between the PMPRB and the Canadian Institute for Health Information (CIHI).

At the request of the Minister of Health pursuant to section 90 of the *Patent Act*, the PMPRB has the mandate to conduct analysis that provides decision makers with critical information and intelligence on price, utilization, and cost trends of patented and non-patented prescription medicines. This ensures that Canada's healthcare system has more comprehensive and accurate information on how medicines are being used and on sources of cost pressures.

The specific research priorities and methodologies for NPDUIS are established with the guidance of the NPDUIS Advisory Committee and reflect the priorities of the participating jurisdictions. The Advisory Committee is composed of representatives from public drug plans in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, the Non-Insured Health Benefits (NIHB) Program, and Health Canada. It also includes observers from CIHI, the Canadian Agency for Drugs and Technologies in Health (CADTH), the Ministère de la Santé et des Services sociaux du Québec (MSSS), and the pan-Canadian Pharmaceutical Alliance (pCPA) Office.

NPDUIS operates independently of the regulatory activities of the PMPRB. NPDUIS reports do not contain information that is confidential or privileged under sections 87 and 88 of the *Patent Act*.

Highlights

Since the start of 2019, the PMPRB has published seven analytical reports, three chartbooks, and eight posters under the NPDUIS banner.

Published Reports:

- *Meds Entry Watch, 2017* (February 2019)
- *Meds Pipeline Monitor, 2018* (May 2019)
- *Generics360: Generic Drugs in Canada, 2018* (August 2019)
- *CompassRx, 5th Edition, 2017/18* (September 2019)
- *Meds Entry Watch, 2018* (January 2020)
- *Meds Pipeline Monitor, 2019* (April 2020)
- *Market Intelligence Report: Combination Inhalers for Asthma, 2018* (April 2020)

Chartbooks:

- *The Market for Prescription Oral Solid Opioids, 2010 to 2017* (January 2019)
- *Biologics in Canada*
  - *Part 1: Market Trends, 2018* (May 2020)
  - *Part 2: Biosimilar Savings, 2018* (May 2020)

Poster Presentations:

- Biosimilars in Canada: Current Environment and Future Opportunity
- Early Insight into New Medicine Launches in Canadian and International Markets
- Generic Drug Pricing in Canada: Closing the Gap
- Uncovering the Forces Driving Costs in Canada's Public Drug Plans, 2017/18
- The Oncology Drug Market: A High-Growth, High-Price Therapeutic Area
- Combination Asthma Inhalers in Canada: Locked on High Prices
- Alignment of Oncology Drug Coverage Across Canada
- Pressures Behind the Rising Costs in Canadian Private Drug Plans, 2018

In addition, in June 2020, the PMPRB through the NPDUIS initiative released updated *Guidelines for Conducting Pharmaceutical Budget Impact Analyses for Submission to Public Drug Plans in Canada*, which were first published in 2007. These Guidelines provide a standardized approach and detailed recommendations for developing a BIA for submission to the Canadian Agency for Drugs and Technologies in Health (CADTH) or to one of the participating federal/provincial/territorial drug plans. The final recommendations are the result of a multi-year process that included extensive research and consultation with relevant stakeholders, including CADTH and participating plans.

The PMPRB continued to support and strengthen its NPDUIS engagement activities by regularly consulting with the NPDUIS Advisory Committee, participating in conferences and stakeholder committees, and organizing information sessions with interested stakeholders to share the results of the analytical studies.

Research Agenda:

The NPDUIS research agenda for the 2020–21 fiscal year includes plans to publish the following analytical studies:

Annual Publications and Report Series:

- *CompassRx, 6th Edition, 2018/19*
- *Meds Entry Watch, 2019*
- *Meds Pipeline Monitor, 2020*
- *Alignment among Public Formularies in Canada, Part 2: Oncology Drugs Assessed Through the pan-Canadian Oncology Drug Review (pCODR) Process*
- *Alignment among Public Formularies in Canada, Part 3: Oncology Drugs Assessed Through the Common Drug Review (CDR) Process*
- *Market Intelligence Report: New Oral Anti-Diabetic Drugs, 2019*

Chartbooks:

- *Oncology Medicines in Canada: Trends and International Comparisons, 2010–2019*
- *Expensive Drugs for Rare Diseases: Canadian and International Markets*

Additional research topics may be pursued based on consultation with the NPDUIS Advisory Committee.

ANALYSIS OF RESEARCH AND DEVELOPMENT EXPENDITURES: R&D INVESTMENT FALLING SHORT OF TARGET

Innovation is vital to advancing health care. In part, the provisions of Canada's *Patent Act* are intended to foster an investment climate favorable to pharmaceutical research and development (R&D) in Canada. However, the ratio of R&D expenditures to sales revenues for pharmaceutical patentees in Canada has been falling since the late 1990's and has been under the agreed-upon target of 10% since 2003. In 2019, it was at 3.9% for both all patentees and members of Innovative Medicines Canada.

3.9%

R&D-TO-SALES RATIO

The R&D-to-sales ratio for all patentees was 3.9% in 2019.

This represents a 67% decrease from a peak of 11.7% in 1995.

Analysis of Research and Development Expenditures

The Act mandates the PMPRB to monitor and report on pharmaceutical R&D spending. This chapter provides key statistics on the current state of pharmaceutical R&D investment in Canada.

Data Sources

The statistical results in this section were entirely derived from data submitted to the PMPRB by patentees.

The Act requires each patentee to report its total gross revenues from sales of all medicines for human or veterinary use (including revenues from sales of non-patented medicines and from licensing agreements) and R&D expenditures in Canada related to

medicines (both patented and non-patented for human or veterinary use). Patentees transmit this information to the PMPRB by means of its Form 3 (Revenues and Research and Development Expenditures Provided Pursuant to subsection 88(1) of the *Patent Act*).

The *Patented Medicines Regulations* (Regulations) require that each submitted Form 3 be accompanied by a certificate stating the information it contains is "true and correct". The Board does not audit Form 3 submissions, but it does review submitted data for anomalies and inconsistencies, seeking corrections or clarifications from patentees where necessary. To confirm that PMPRB staff has correctly interpreted the data submitted, each patentee is given the opportunity to review and confirm the accuracy of its own R&D-to-sales ratio before that ratio is published.

FAILURE TO FILE (FORM 3)

It is a patentee's responsibility to ensure a complete and accurate Form 3 is filed within the time frame set out in the Regulations. If a patentee fails to meet these filing requirements, the Board may issue an Order demanding compliance. No such Board Orders were issued for the 2019 reporting period.

COVERAGE

Note that companies without sales of patented medicines do not need to report their R&D expenditures to the PMPRB. This has two implications:

First, the statistical results reported here should not be taken to cover all pharmaceutical research conducted in Canada. For example, a company may sell only non-patented medicines but may still perform considerable research in Canada. Similarly, a company may conduct research and have no medicine sales at all.[28] The results presented below will not reflect the R&D expenditures of firms in either situation.

Second, as new patented medicines come onto the Canadian market and existing relevant patents expire, the number and identity of companies required to file R&D data may change from year to year. In 2019, 101 companies reported on their R&D activity. Of these, 32 were members of Innovative Medicines Canada.

DEFINITION OF SALES REVENUES

For reporting purposes, sales revenues are defined as total gross revenues from sales in Canada of all medicines and from licensing agreements (e.g., royalties and fees accruing to the patentee related to sales in Canada by licensees).

DEFINITION OF R&D EXPENDITURES

Pursuant to section 6 of the Regulations, patentees are required to report R&D expenditures that would have qualified for an investment tax credit in respect to scientific research and experimental development (SR&ED) under the provisions of the *Income Tax Act* that came into effect on December 1, 1987.[29] By this definition, R&D expenditures may include current expenditures, capital equipment costs, and allowable depreciation expenses. Market research; sales promotions; quality control or routine testing of materials, devices, or products; and routine data collection are not eligible for an investment tax credit and, therefore, are not to be included in the R&D expenditures reported by patentees.

Total Sales Revenues and R&D Expenditures

Table 14 provides an overview of reported sales revenues and R&D expenditures from 1988 to 2019.

Patentees reported total 2019 sales revenues of $23.1 billion, an increase of 1.9% from 2018. Sales revenues reported by Innovative Medicines Canada members were $16.9 billion, accounting for 73% of the total. (Less than 1% of reported sales revenues were generated by licensing agreements.)

Patentees reported R&D expenditures of $893.2 million in 2019, an increase of 0.1% over 2018. Innovative Medicines Canada members reported R&D expenditures of $652.6 million in 2019, a decrease of 9.7% over the previous year. Innovative Medicines Canada members accounted for 73% of all reported R&D expenditures in 2019.

R&D-to-Sales Ratios

Table 14 and Figure 37 also provide ratios of R&D expenditures to sales revenues. It should be noted that with the adoption of the 1987 amendments to the Act, Innovative Medicines Canada made a public commitment to increase its members' annual R&D expenditures to 10% of sales revenues by 1996.[30] This level of R&D expenditure was reached by 1993, with the ratio exceeding 10% in some years.

The ratio of R&D expenditures to sales revenues among all patentees was 3.9% in 2019, a slight decrease from 4.0% in 2018. The overall R&D-to-sales ratio has been less than 10% for the past 19 consecutive years.

The corresponding R&D-to-sales ratio for members of Innovative Medicines Canada was also 3.9% in 2019, a decrease from 4.3% in 2018.[31] The Innovative Medicines Canada ratio has been less than 10% for the past 17 consecutive years.

Table 21 in Appendix 4 provides details on the range of 2019 R&D-to-sales ratios. Of the 101 companies reporting in 2019, 80.2% had R&D-to-sales ratios below 10%.

TABLE 14 Total R&D Expenditures and R&D-to-Sales Ratios of Reporting Companies, 1988 to 2019

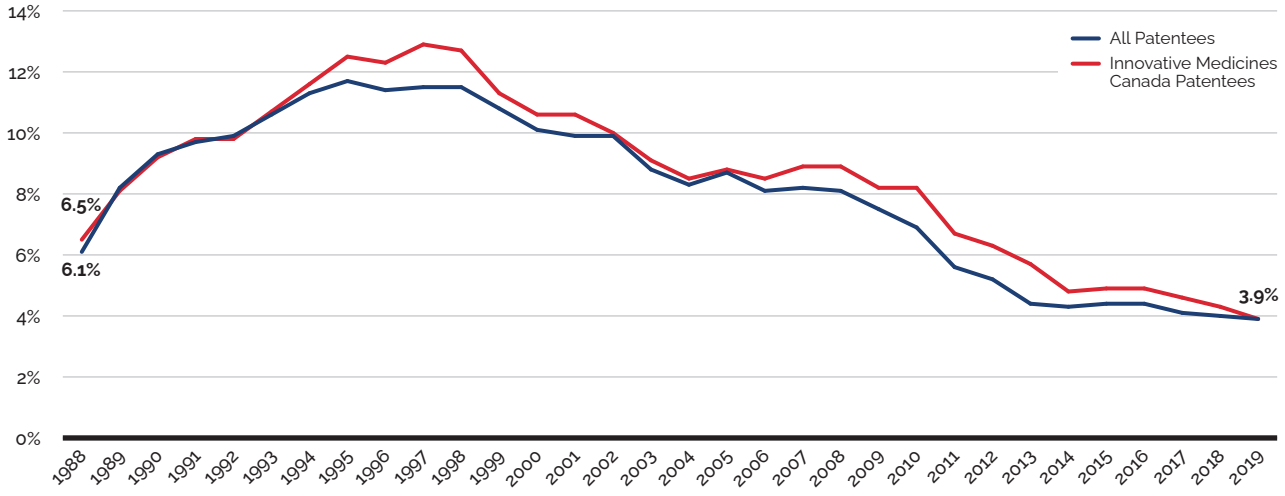
Year	All patentees					Innovative Medicines Canada patentees				R&D-to-sales ratio: all patentees	R&D-to-sales ratio: Innovative Medicines Canada patentees
	Number of companies reporting	R&D expenditures by all patentees ($millions)	Change from previous year	Sales revenues ($millions)	Change from previous year	R&D expenditures by Innovative Medicines Canada patentees ($millions)	Change from previous year	Sales revenues ($millions)	Change from previous year		
2019	101	$893.2	0.1%	$23,101.1	1.9%	$652.6	-9.7%	$16,858.8	0.4%	3.9%	3.9%
2018	93	$892.6	2.4%	$22,663.4	7.2%	$723.0	-4.3%	$16,789.7	2.7%	4.0%	4.3%
2017	85	$871.4	-5.1%	$21,147.2	1.4%	$755.8	-1.8%	$16,349.8	4.8%	4.1%	4.6%
2016	78	$918.2	5.7%	$20,855.7	5.9%	$769.9	0.3%	$15,599.9	0.2%	4.4%	4.9%
2015	77	$869.1	9.7%	$19,693.3	6.7%	$767.4	7.8%	$15,565.1	4.7%	4.4%	4.9%
2014	75	$792.2	-0.8%	$18,455.1	1.0%	$711.7	2.0%	$14,861.1	9.2%	4.3%	4.8%
2013	81	$798.3	-14.7%	$18,268.1	1.4%	$697.5	-15.4%	$13,614.8	3.4%	4.4%	5.1%
2012	85	$936.1	-5.6%	$18,021.1	1.3%	$824.1	-8.6%	$13,162.8	-2.1%	5.2%	6.3%
2011	79	$991.7	-15.8%	$17,798.8	4.7%	$901.2	-9.9%	$13,446.1	10.7%	5.6%	6.7%
2010	82	$1,178.2	-7.4%	$17,000.0	-0.3%	$1,000.2	-11.7%	$12,149.0	-11.8%	6.9%	8.2%
2009	81	$1,272.0	-2.9%	$17,051.9	4.5%	$1,132.9	-3.4%	$13,780.0	4.6%	7.5%	8.2%
2008	82	$1,310.7	-1.1%	$16,316.7	2.0%	$1,172.2	-1.0%	$13,178.2	-1.4%	8.1%	8.9%
2007	82	$1,325.0	9.5%	$15,991.0	7.3%	$1,184.4	24.8%	$13,359.8	20.0%	8.3%	8.9%

continued

Year	All patentees					Innovative Medicines Canada patentees				R&D-to-sales ratio: all patentees	R&D-to-sales ratio: Innovative Medicines Canada patentees
	Number of companies reporting	R&D expenditures by all patentees ($millions)	Change from previous year	Sales revenues ($millions)	Change from previous year	R&D expenditures by Innovative Medicines Canada patentees ($millions)	Change from previous year	Sales revenues ($millions)	Change from previous year		
2006	72	$1,210.0	-1.9%	$14,902.0	4.7%	$949.0	-8.8%	$11,131.2	-5.8%	8.1%	8.5%
2005	80	$1,234.3	5.5%	$14,231.3	0.5%	$1,040.1	3.9%	$11,821.4	0.0%	8.7%	8.8%
2004	84	$1,170.0	-2.0%	$14,168.3	4.0%	$1,000.8	0.8%	$11,819.0	8.8%	8.3%	8.5%
2003	83	$1,194.3	-0.4%	$13,631.1	12.8%	$992.9	-3.6%	$10,865.7	5.2%	8.8%	9.1%
2002	79	$1,198.7	13.0%	$12,081.2	12.5%	$1,029.6	10.1%	$10,323.8	16.8%	9.9%	10.0%
2001	74	$1,060.1	12.6%	$10,732.1	15.3%	$935.2	14.7%	$8,835.4	14.3%	9.9%	10.6%
2000	79	$941.8	5.3%	$9,309.6	12.0%	$815.5	4.0%	$7,728.8	11.6%	10.1%	10.6%
1999	78	$894.6	12.0%	$8,315.5	19.2%	$784.3	9.9%	$6,923.4	22.8%	10.8%	11.3%
1998	74	$798.9	10.2%	$6,975.2	10.9%	$713.7	8.6%	$5,640.2	10.6%	11.5%	12.7%
1997	75	$725.1	9.0%	$6,288.4	7.4%	$657.4	10.3%	$5,098.2	4.9%	11.5%	12.9%
1996	72	$665.3	6.4%	$5,857.4	9.9%	$595.8	6.5%	$4,859.5	8.7%	11.4%	12.3%
1995	71	$625.5	11.5%	$5,330.2	7.5%	$559.5	9.8%	$4,468.8	1.4%	11.7%	12.5%
1994	73	$561.1	11.4%	$4,957.4	4.4%	$509.5	10.4%	$4,407.2	2.0%	11.3%	11.6%
1993	70	$503.5	22.1%	$4,747.6	14.0%	$461.4	24.0%	$4,321.4	14.4%	10.6%	10.7%
1992	71	$412.4	9.6%	$4,164.4	6.9%	$372.1	9.0%	$3,778.4	6.5%	9.9%	9.8%
1991	65	$376.4	23.2%	$3,894.8	18.1%	$341.4	24.7%	$3,546.9	19.5%	9.7%	9.6%
1990	65	$305.5	24.8%	$3,298.8	11.0%	$273.8	25.8%	$2,967.9	10.5%	9.3%	9.2%
1989	66	$244.8	47.4%	$2,973.0	9.4%	$217.6	34.7%	$2,685.5	7.3%	8.2%	8.1%
1988	66	$165.7	—	$2,718.0	—	$161.5	—	$2,502.3	—	6.1%	6.5%

Data source: PMPRB

FIGURE 37 R&D-to-Sales Ratio, Pharmaceutical Patentees, 1988 to 2019



Data source: PMPRB

Current R&D Expenditures by Type of Research

Table 15 and Figure 38 (as well as Figure 40 in Appendix 4) provide information on the allocation of 2019 current R&D expenditures[32] among basic and applied research and other qualifying R&D.[33] Patentees reported spending $116.9 million on basic research in 2019, representing 13.5% of current R&D expenditures, an increase of 9.3% over the previous year. Patentees reported spending $520.2 million on applied research, representing 59.9% of current R&D expenditures. Clinical trials accounted for 84.6% of applied research expenditures.

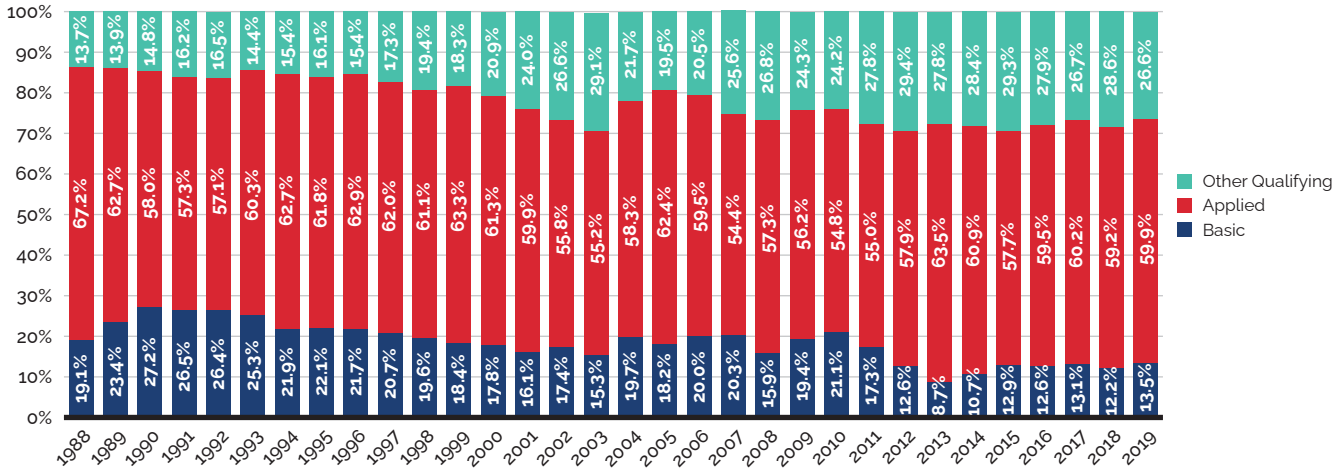
TABLE 15 Current R&D Expenditures by Type of Research, 2019 and 2018

Type of research	Expenditures: 2019 ($millions)	Share: 2019	Expenditures: 2018 ($millions)	Share: 2018	Annual change in expenditures
Basic	$116.9	13.5%	$106.9	12.3%	9.3%
Chemical	$76.2	8.8%	$69.5	8.0%	9.6%
Biological	$40.7	4.7%	$37.4	4.3%	8.8%
Applied	$520.2	59.9%	$517.1	59.2%	0.6%
Manufacturing process	$40.6	4.7%	$71.0	8.1%	-42.8%
Pre-clinical trial I	$18.6	2.1%	$19.8	2.3%	-6.1%
Pre-clinical trial II	$20.8	2.4%	$26.8	3.1%	-22.4%
Clinical trial Phase I	$40.0	4.6%	$50.5	5.8%	-20.8%
Clinical trial Phase II	$103.1	11.9%	$83.1	9.5%	24.1%
Clinical trial Phase III	$297.1	34.2%	$265.9	30.4%	11.7%
Other qualifying R&D	$231.2	26.6%	$250.2	28.6%	-7.6%
Total*	**$868.3**	**100%**	**$874.1**	**100%**	**-0.7%**

* Values may not add to totals due to rounding.

Data source: PMPRB

FIGURE 38 Current R&D Expenditures by Type of Research, 1988 to 2019



Data source: PMPRB

Current R&D Expenditures by Performer

Patentees report expenditures on research they conduct themselves (intramural) and research performed by other establishments, such as universities, hospitals, and other manufacturers (extramural). Table 16 shows that 45.3% of 2019 current research expenditures were intramural. Research performed by other companies on behalf of patentees made up 27.7% of current expenditures, while research conducted in universities and hospitals accounted for 18.3%.

TABLE 16 Current R&D Expenditures by R&D Performer, 2019 and 2018

R&D performer	Expenditures: 2019 ($millions)	Share: 2019	Expenditures: 2018 ($millions)	Share: 2018	Annual change in expenditures
Intramural					
Patentees	$394.1	45.3%	$429.7	49.2%	-8.3%
Extramural					
Universities and hospitals	$158.5	18.3%	$162.4	18.5%	-2.4%
Other companies	$240.4	27.7%	$207.0	23.7%	16.1%
Others	$75.3	8.7%	$75.1	8.6%	0.3%
Total*	**$868.3**	**100%**	**$874.1**	**100%**	**-0.7%**

* Values may not add to totals due to rounding.

Data source: PMPRB

Current R&D Expenditures By Region

Table 17 (as well as Table 23 and Table 24 in Appendix 4) show current R&D expenditures by region. As in previous years, current expenditures were heavily concentrated in Ontario and Quebec in 2019, with these provinces accounting for 79.2% of total expenditures. However, while current R&D expenditures increased at a year-over-year rate of 6.5% in Ontario, 6.7% in the Atlantic provinces, and 3.3% in Western Canada, they decreased by 13.9% in Quebec.

TABLE 17 Current R&D Expenditures by Region, 2019 and 2018

Region	Expenditures: 2019 ($millions)	Share: 2019	Expenditures: 2018 ($millions)	Share: 2018	Annual change in expenditures
Atlantic provinces	$21.1	2.4%	$19.8	2.3%	6.7%
Quebec	$246.1	28.3%	$285.8	32.7%	-13.9%
Ontario	$441.6	50.9%	$414.5	47.4%	6.5%
Western provinces	$158.8	18.3%	$153.6	17.6%	3.3%
Territories	$0.6	0.1%	$0.4	0.0%	68.4%
Total*	**$868.3**	**100%**	**$874.1**	**100%**	**-0.7%**

* Values may not add to totals due to rounding.

Data source: PMPRB

Total R&D Expenditures by Source of Funds

Table 18 provides information on the sources of funds used by patentees to finance their R&D activity. Internal company funds remained by far the single largest source of funding in 2019, accounting for 91.2% of total expenditures. Funds received from government amounted to 0.6% of total expenditures.

TABLE 18 Total R&D Expenditures by Source of Funds, 2019 and 2018

Source of funds	Expenditures: 2019 ($millions)	Share: 2019	Expenditures: 2018 ($millions)	Share: 2018	Annual change in expenditures
Company funds	$814.7	91.2%	$812.1	91.0%	0.3%
Federal/provincial governments	$5.2	0.6%	$4.5	0.5%	14.9%
Others	$73.3	8.2%	$75.9	8.5%	-3.4%
Total*	**$893.2**	**100%**	**$892.6**	**100%**	**0.1%**

* Values may not add to totals due to rounding.

Data source: PMPRB

The Global Context

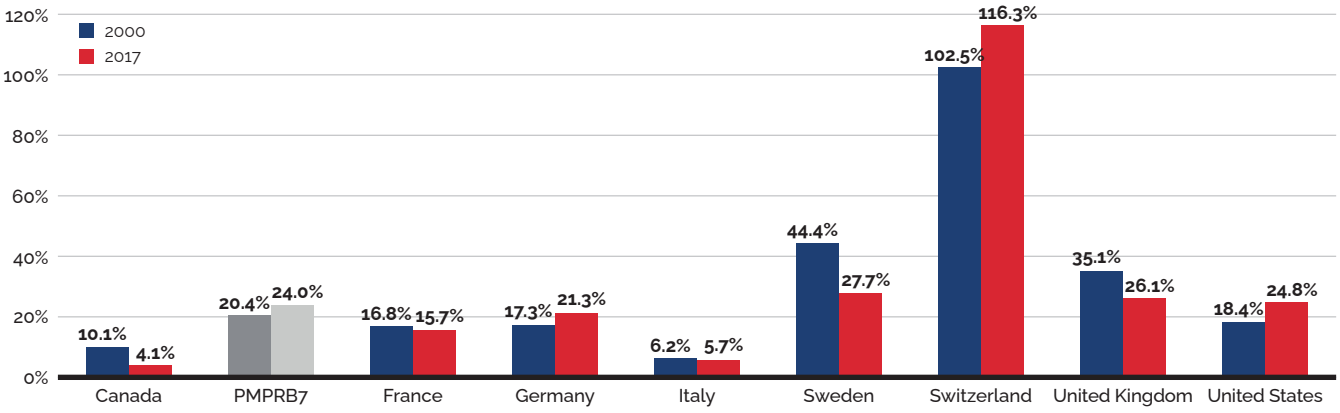
Figure 39 compares Canadian pharmaceutical R&D-to-sales ratios for 2000 and 2017 to those in the PMPRB7.[34] In 2000, Canada had an R&D-to-sales ratio of 10.1%, lower than all other PMPRB7 countries except for Italy at 6.2%. Switzerland had the highest ratio at 102.5%.

In 2017, Canada's R&D-to-sales ratio was the lowest among the comparator countries at 4.1%. Italy had a slightly higher ratio of 5.7%, while all other PMPRB7 countries remained well above Canada. The ratio obtained by aggregating R&D spending and sales across all PMPRB7 countries was 24.0%, almost six times greater than in Canada.

The R&D-to-sales ratios represented in Figure 39 may be compared to the average bilateral price ratios reported in Table 9 (see the section on *Comparison of Canadian Prices to Foreign Prices*). A number of comparator countries with patented medicine prices that are, on average, lower than prices in Canada, have achieved much higher R&D-to-sales ratios.

As noted in previous annual reports, there are a multitude of factors that drive the location of pharmaceutical R&D. These include where companies can find the best science base at reasonable cost and ready access to a quality clinical trials infrastructure. Although price levels and intellectual property protection are often cited as an important policy lever for attracting R&D, the data has not supported this link domestically or internationally.

FIGURE 39 R&D-to-Sales Ratios, Canada and the PMPRB7, 2000 and 2017



Data source: PMPRB; European Federation of Pharmaceutical Industries and Associations (EFPIA): *The Pharmaceutical Industry in Figures 2019*; PhRMA 2019 profile

6x GREATER

The PMPRB7 average R&D ratio is almost 6x greater than in Canada

The R&D-to-sales ratio obtained by aggregating R&D spending and sales across all seven comparator countries was 24.0%.

ENDNOTES

28 This is likely the situation for much of Canada's biotechnology sector. Note, however, that if a patentee commissions research from another company specializing in biotechnology research, the patentee should normally include this among the research expenditures that it reports to the PMPRB.

29 Budget 2012 proposed reductions to the Scientific Research and Experimental Development (SR&ED) tax credit and new restrictions on deductions. It also introduced new measures to support innovation and R&D. As per the Regulations, the PMPRB defines R&D based on the 1987 SR&ED definition.

30 As published in the Regulatory Impact Assessment Statement (RIAS) of the *Patented Medicines Regulations*, 1988, published in the *Canada Gazette*, Part II, Vol. 122, No. 20 – SOR/DORS/88-474.

31 The R&D-to-sales ratios presented in Table 14 include research expenditures funded by government grants. If the government-funded component is excluded, the ratios for all patentees and for the members of Innovative Medicines Canada in 2019 are 3.9% and 3.8%, respectively.

32 Current R&D expenditures consist of non-capital expenses directly related to research, including (a) wages and salaries; (b) direct material; (c) contractors and sub-contractors; (d) other direct costs such as factory overhead; (e) payments to designated institutions; (f) payments to granting councils; and (g) payments to other organizations. These elements are described in more detail in Form 3 (Revenues and Research and Development Expenditures) available from the PMPRB website. Current R&D expenditures accounted for 97.2% of total R&D expenditure in 2019, while capital equipment costs and allowable depreciation expenses made up 1.3% and 1.5%, respectively.

33 "Basic research" is defined as work that advances scientific knowledge without a specific application in mind. "Applied research" is directed toward a specific practical application, comprising research intended to improve manufacturing processes, pre-clinical trials, and clinical trials. "Other qualifying research" includes regulatory submissions, bioavailability studies, and Phase IV clinical trials.

34 Sales in Figure 39 represent domestic sales and do not include exports.

APPENDIX 1: GLOSSARY

These definitions are provided for general assistance only; they have no legal force and should be read in conjunction with the applicable legislation.

Active Ingredient or Medicinal Ingredient: Chemical or biological substance responsible for the claimed pharmacologic effect of a medicine.

ATC: Anatomical Therapeutic Chemical (ATC) classification system, developed and maintained by the World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology, divides medicines into different groups according to their site of action and therapeutic and chemical characteristics. This system is used by the PMPRB as a guide for selecting comparable medicines for purposes of price review under the Guidelines.

Drug Identification Number (DIN): A registration number (drug identification number) that the Health Products and Food Branch of Health Canada assigns to each prescription and non-prescription drug product marketed under the *Food and Drug Regulations*. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength of active ingredient(s); pharmaceutical dosage form; route of administration. Different strengths and dosage forms of a medicine may be assigned different DINs.

Drug Product: A particular presentation of a medicine characterized by its pharmaceutical dosage form and the strength of the active ingredient(s) (see "medicine" below).

Failure to File: The complete or partial failure of a patentee to comply with regulatory filing requirements pursuant to the *Patent Act* and the *Patented Medicines Regulations*.

Failure to Report: The complete failure of a patentee to have reported a patented medicine being sold in accordance with regulatory filing requirements pursuant to the *Patent Act* and the *Patented Medicines Regulations*.

License, Voluntary: A contractual agreement between a patent holder and a licensee under which the licensee is entitled to enjoy the benefit of the patent or to exercise any rights in relation to the patent for some consideration (e.g., royalties in the form of a share of the licensee's sales).

Medicine: A medicinal ingredient and/or a substance or a mixture of substances manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; or restoring, correcting or modifying organic functions in human beings or animals.

Notice of Compliance (NOC): Means a notice issued under section C.08.004 or C.08.004.01 of the *Food and Drug Regulations*. The issuance of an NOC indicates that a drug product meets the required Health Canada standards for use in humans or animals and that the manufacturer of the product is authorized to market the product in Canada.

Patent: An instrument issued by the Commissioner of Patents in the form of letters patent for an invention.

Patented Medicine Price Index (PMPI): The PMPI was developed by the PMPRB as a measure of average year-over-year change in the transaction prices of patented medicines sold in Canada, based on the price and sales information reported by patentees.

Patentee: As defined by subsection 79(1) of the *Patent Act*, "the person for the time being entitled to the benefit of the patent for that invention and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a license continued by subsection 11(1) of the *Patent Act Amendment Act*, 1992, that other person in respect of those rights;"

PMPRB7: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.

Research and Development (R&D): Basic or applied research for the purpose of creating new, or improving existing, materials, devices, products or processes (e.g., manufacturing processes).

Research and Development—Applied Research: R&D directed toward a specific practical application, comprising research intended to improve manufacturing processes, pre-clinical trials and clinical trials.

Research and Development—Basic Research: R&D defined as work that advances scientific knowledge without a specific application in mind.

Research and Development—Other Qualifying: Includes eligible research and development expenditures that cannot be classified into any of the preceding categories of "type of research and development". It includes regulatory submissions, bioavailability studies and Phase IV clinical trials.

Research and Development Expenditures: For the purposes of the *Patented Medicines Regulations*, in particular Sections 5 and 6, research and development includes activities for which expenditures would have qualified for the investment tax credit for scientific research and experimental development under the *Income Tax Act* as it read on December 1, 1987.

Research and Development Expenditures–Current: Consist of the following non-capital expenses directly related to research work: (a) wages and salaries, (b) direct material, (c) contractors and subcontractors, (d) other direct costs such as factory overhead, (e) payments to designated institutions, (f) payments to granting councils, and (g) payments to other organizations. These elements are described in greater detail in the *Patentees' Guide to Reporting*—Form 3, available on the PMPRB website under Regulatory Filings.

Special Access Programme (SAP): A program operated by Health Canada to give practitioners access to medicines that are not approved or otherwise available in Canada.

Voluntary Compliance Undertaking (VCU): A written undertaking by a patentee to adjust its price to conform to the Board's Guidelines. A VCU represents a promise by a patentee geared towards a satisfactory resolution of an investigation initiated by Staff as per the Guidelines. A VCU takes into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

APPENDIX 2: PATENTED MEDICINES FIRST REPORTED TO THE PMPRB IN 2019

TABLE 19 Patented Medicines First Reported to the PMPRB in 2019

Brand Name	Company	DIN	Status (full year 2019)	Level of therapeutic improvement/ category*
Actemra – 162 mg/syringe	Hoffmann-La Roche Limited, Canada	2483327	Within Guidelines	SN
Aimovig – 140 mg/milliliter	Novartis Pharmaceuticals Canada Inc.	2487306	Subject to Investigation	SN
Aimovig – 70 mg/milliliter	Novartis Pharmaceuticals Canada Inc.	2479613	Subject to Investigation	SN
AKLIEF – 50 mcg/gram	Galderma Canada Inc.	2494175	Under review	Under review
BELSOMRA – 10 mg/tab	Merck Canada Inc.	2483513	Within Guidelines	SN
BELSOMRA – 20 mg/tab	Merck Canada Inc.	2483548	Within Guidelines	SN
BELSOMRA – 15 mg/tab	Merck Canada Inc.	2483521	Within Guidelines	SN
BRINEURA – 30 mg/milliliter	Biomarin Pharmaceuticals Canada Inc.	2484013	Within Guidelines	B
Brivlera – 10 mg/milliliter	UCB Pharma Canada Inc.	2452995	Within Guidelines	SN
Calquence – 100 mg/capsule	Astrazenea Canada Inc.	2491788	Under review	Under review
CRYSVITA – 10 mg/milliliter	Ultragenyx Pharmaceuticals Inc.	2483629	Under review	Under review
CRYSVITA – 20 mg/milliliter	Ultragenyx Pharmaceuticals Inc.	2483637	Under review	Under review
CRYSVITA – 30 mg/milliliter	Ultragenyx Pharmaceuticals Inc.	2483645	Under review	Under review
DELSTRIGO 100/300/300 – 700 mg/tab	Merck Canada Inc.	2482592	Within Guidelines	SN
DOVATO 50/300 – 350 mg/tab	ViiV HealthCare ULC	2491753	Under review	Under review
Dupixent – 200 mg/syringe	Sanofi-aventis Canada Inc.	2492504	Under review	Under review
Emgality – 120 mg/milliliter	Eli Lilly Canada Inc.	2491060	Under review	Under review
Emgality – 120 mg/milliliter	Eli Lilly Canada Inc.	2491087	Under review	Under review
ENGERIX-B – 1 Dose	Galderma Canada Inc.	2487039	Under review	Under review
ENGERIX-B PEDIATRIC – 1 Dose	Galderma Canada Inc.	2487020	Under review	Under review
Envarsus PA – 0.75 mg/tab	Paladin Laboratories Inc.	2485877	Within Guidelines	SN
Envarsus PA – 1 mg/tab	Paladin Laboratories Inc.	2485885	Within Guidelines	SN
Envarsus PA – 4 mg/tab	Paladin Laboratories Inc.	2485893	Within Guidelines	SN
EVENITY – 105 mg/syringe	Amgen Canada Inc.	2489597	Under review	Under review
Gamifant – 10 mg/vial	Swedish Orphan Biovitrum, SOBI AB		Under review	Under review

continued

Brand Name	Company	DIN	Status (full year 2019)	Level of therapeutic improvement/ category*
GILENYA – 0.25 mg/capsule	Novartis Pharmaceuticals Canada Inc.	2482533	Within Guidelines	SN
Hemlibra – 105 mg/vial	Hoffmann-La Roche Limited, Canada	2479656	Subject to Investigation	MI-P
Hemlibra – 150 mg/milliliter	Hoffmann-La Roche Limited, Canada	2479664	Subject to Investigation	MI-P
Hemlibra – 30 mg/milliliter	Hoffmann-La Roche Limited, Canada	2479621	Subject to Investigation	MI-P
Hemlibra – 60 mg/vial	Hoffmann-La Roche Limited, Canada	2479648	Subject to Investigation	MI-P
IDELVION – 1000 IU/vial	CSL Behring	2451352	Under review	Under review
JETREA 1.25 mg/milliliter	ThromboGenics N.V.	2452154	Within Guidelines	SN
KYMRIAH – 1 Dose	Novartis Pharmaceuticals Canada Inc.	2480514	Within Guidelines	MI-P
Lenvima – 12 mg/day	Eisai Limited	2484129	Under review	Under review
Lenvima – 4 mg/day	Eisai Limited	2484056	Under review	Under review
LORBRENA – 100 mg/tab	Pfizer Canada Inc.	2485974	Within Guidelines	MI-P
LORBRENA – 25 mg/tab	Pfizer Canada Inc.	2485966	Within Guidelines	MI-P
Metoject Subcutaneous – 10 mg/syringe	Medexus Inc.	2454831	Under review	Under review
Metoject Subcutaneous – 12.5 mg/syringe	Medexus Inc.	2454750	Under review	Under review
Onpattro – 2 mg/milliliter	Alnylam Pharmaceuticals Inc.	2489252	Under review	Under review
ONSTRYV – 100 mg/tab	Valeo Pharma	2484668	Under review	Under review
ONSTRYV – 50 mg/tab	Valeo Pharma	2484641	Under review	under review
ORILISSA – 200 mg/tab	Abbvie	2481340	Within Guidelines	SN
ORKAMBI 100/125 – 225 mg/granule	Vertex Pharmaceuticals Canada Inc.	2483831	Under review	Under review
ORKAMBI 150/188 – 338 mg/granule	Vertex Pharmaceuticals Canada Inc.	2483858	Under review	Under review
RADICAVA – 30 mg/dose	Mitsubishi Tanabe Pharma Corporation	2475472	Under review	Under review
SIGNIFOR LAR – 10 mg/vial	Novartis Pharmaceuticals Canada Inc.	2480425	Does Not Trigger Investigation	SN
SIGNIFOR LAR – 30 mg/vial	Novartis Pharmaceuticals Canada Inc.	2480433	Does Not Trigger Investigation	SN
SKYRIZI – 75 mg/syringe	Abbvie	2487454	Within Guidelines	SN
SPINRAZA – 2.4 mg/milliliter	Biogen Canada Inc.	2465663	Under review	Under review
TASIGNA – 50 mg/capsule	Novartis Pharmaceuticals Canada Inc.	2481715	Within Guidelines	SN
TECENTRIQ – 60 mg/milliliter	Hoffmann-La Roche Limited, Canada	2492393	Under review	Under review
TEGSEDI – 189 mg/milliliter	Akcea Therapeutics Canada	2481383	Under review	Under review
TREMFYA One-Press – 100 mg/milliliter	Janssen Inc.	2487314	Within Guidelines	SN
VASCEPA – 1 g/capsule	HLS Therapeutics Inc.	2495244	Under review	Under review
Velphoro – 500 mg/tab	Vifor International AG	2471574	Under review	Under review
Veltassa – 16.8 g/sachet	Vifor International AG	2481367	Under review	Under review
Verkazia – 1 mg/milliliter	Novartis Pharmaceuticals Canada Inc.	2484137	Does Not Trigger Investigation	MI-S
VERZENIO – 100 mg/tab	Eli Lilly Canada Inc.	2487101	Within Guidelines	SN

continued

Brand Name	Company	DIN	Status (full year 2019)	Level of therapeutic improve-ment/ category*
VERZENIO – 150 mg/tab	Eli Lilly Canada Inc.	2487128	Within Guidelines	SN
VERZENIO – 200 mg/tab	Eli Lilly Canada Inc.	2487136	Within Guidelines	SN
VERZENIO – 50 mg/tab	Eli Lilly Canada Inc.	2487098	Within Guidelines	SN
VITRAKVI – 20 mg/milliliter	Bayer Inc.	2490331	Under review	Under review
VIZIMPRO – 15 mg/tab	Pfizer Canada Inc.	2486024	Within Guidelines	SN
VIZIMPRO – 30 mg/tab	Pfizer Canada Inc.	2486032	Within Guidelines	SN
VIZIMPRO – 45 mg/tab	Pfizer Canada Inc.	2486040	Within Guidelines	SN
Vyvanse – 10 mg/tab	Takeda Canada Inc.	2490226	Under review	Under review
Vyvanse – 20 mg/tab	Takeda Canada Inc.	2490234	Under review	Under review
Vyvanse – 30 mg/tab	Takeda Canada Inc.	2490242	Under review	Under review
Vyvanse – 40 mg/tab	Takeda Canada Inc.	2490250	Under review	Under review
Vyvanse – 50 mg/tab	Takeda Canada Inc.	2490269	Under review	Under review
Vyvanse – 60 mg/tab	Takeda Canada Inc.	2490277	Under review	Under review
VYZULTA – 0.24 mg/milliliter	Bausch Health, Canada Inc.	2484218	Within Guidelines	SN
Wakix – 20 mg/tab	Paladin Laboratories Inc.		Under review	Under review
Wakix – 5 mg/tab	Paladin Laboratories Inc.		Under review	Under review
XELJANZ – 10 mg/tab	Pfizer Canada Inc.	2480786	Within Guidelines	SN
XERMELO – 250 MG/Tab	Ipsen Biopharmaceuticals Canada Inc	2481553	Within Guidelines	SN
Xultophy – 100 unit/milliliter	Novo Nordisk Canada Inc.	2474875	Under review	Under review
Xyntha Solofuse – 500 unit/syringe	Pfizer Canada Inc.	2374064	Under review	Under review
ZEULIDE DEPOT – 22.5 mg/vial	Verity Pharmaceuticals	2462699	Under review	Under review
ZEULIDE DEPOT – 3.75 mg/dose	Verity Pharmaceuticals	2429977	Under review	Under review

SN Slight or No Improvement
MI-S Moderate Improvement – Secondary
MI-P Moderate Improvement – Primary
SI Substantial Improvement
B Breakthrough
Data source: PMPRB

APPENDIX 3: PHARMACEUTICAL TRENDS – SALES

TABLE 20 Sales of Patented Medicines, 1990 to 2019

Year	Patented medicine		5-year compound annual growth rate	Sales of patented medicines as a share of all medicine sales*	Patented medicine sales per capita	Change in patented medicine sales per capita	Patented medicine sales per GDP
	Sales ($billions)	Change					
2019	$17.2	3.5%	4.5%	57.5%	$458.60	2.7%	0.748%
2018	$16.7	-0.6%	4.5%	59.0%	$446.30	-1.7%	0.751%
2017	$16.8	7.6%	5.4%	61.5%	$454.09	5.4%	0.783%
2016	$15.6	3.3%	3.9%	60.8%	$430.94	2.2%	0.770%
2015	$15.1	9.4%	4.0%	61.6%	$421.80	8.5%	0.760%
2014	$13.8	3.1%	1.2%	59.9%	$388.70	1.8%	0.696%
2013	$13.4	4.2%	1.2%	60.7%	$381.80	2.7%	0.706%
2012	$12.9	0.1%	1.3%	59.2%	$371.80	-1.2%	0.708%
2011	$12.9	3.5%	2.0%	58.3%	$376.10	3.1%	0.729%
2010	$12.4	-4.3%	2.6%	55.8%	$364.70	-5.7%	0.746%
2009	$13.0	2.9%	4.4%	59.6%	$386.90	1.9%	0.829%
2008	$12.6	4.6%	5.4%	61.7%	$379.50	2.9%	0.762%
2007	$12.1	3.2%	6.3%	63.2%	$368.90	2.5%	0.769%
2006	$11.7	7.4%	9.0%	67.8%	$360.00	6.3%	0.784%

continued

Year	Patented medicine		5-year compound annual growth rate	Sales of patented medicines as a share of all medicine sales*	Patented medicine sales per capita	Change in patented medicine sales per capita	Patented medicine sales per GDP
	Sales ($billions)	Change					
2005	$10.9	4.2%	11.6%	70.6%	$338.50	2.8%	0.769%
2004	$10.5	7.8%	14.2%	72.2%	$329.20	7.2%	0.789%
2003	$9.7	9.0%	17.7%	72.7%	$307.00	8.0%	0.776%
2002	$8.9	17.5%	19.2%	67.4%	$284.30	16.0%	0.748%
2001	$7.6	18.9%	20.4%	65.0%	$245.20	19.1%	0.666%
2000	$6.3	16.7%	19.4%	63.0%	$205.90	15.9%	0.571%
1999	$5.4	27.0%	17.6%	61.0%	$177.60	24.3%	0.538%
1998	$4.3	18.9%	12.4%	55.1%	$142.90	15.4%	0.459%
1997	$3.7	22.6%	11.0%	52.3%	$123.70	22.1%	0.409%
1996	$3.0	12.8%	8.4%	45.0%	$101.40	14.2%	0.350%
1995	$2.6	10.8%	8.9%	43.9%	$88.70	7.2%	0.314%
1994	$2.4	-2.1%	—	40.7%	$82.80	-1.4%	0.304%
1993	$2.4	9.4%	—	44.4%	$83.90	7.9%	0.322%
1992	$2.2	14.0%	—	43.8%	$77.70	8.8%	0.307%
1991	$2.0	13.1%	—	43.2%	$71.40	16.0%	0.286%
1990	$1.7	—	—	43.2%	$61.60	—	0.245%

* The denominator in this ratio comprises sales of patented and non-patented brand medicines and patented and non-patented generic medicines. Starting with the estimate for 2005, this value is derived from data contained in IQVIA's MIDAS® database. In previous years, IQVIA data was used to calculate sales of generic medicines only, while sales of non-patented brand products were estimated from data submitted by patentees. This approach was abandoned because of anomalies related to year-to-year changes in the set of companies reporting to the PMPRB. Ratios reported for years before 2005 likely overstate the patented share, but by only a small amount. This small bias in no way invalidates the strong upward trend evinced by the results for the years 1990 through 2003. Ratios since 2009 have also been revised slightly as a result of data updates from IQVIA—none of these adjustments resulted in a change greater than 0.4%.

Data source: PMPRB; MIDAS® database, 2005–2019, IQVIA (all rights reserved)

APPENDIX 4: RESEARCH AND DEVELOPMENT

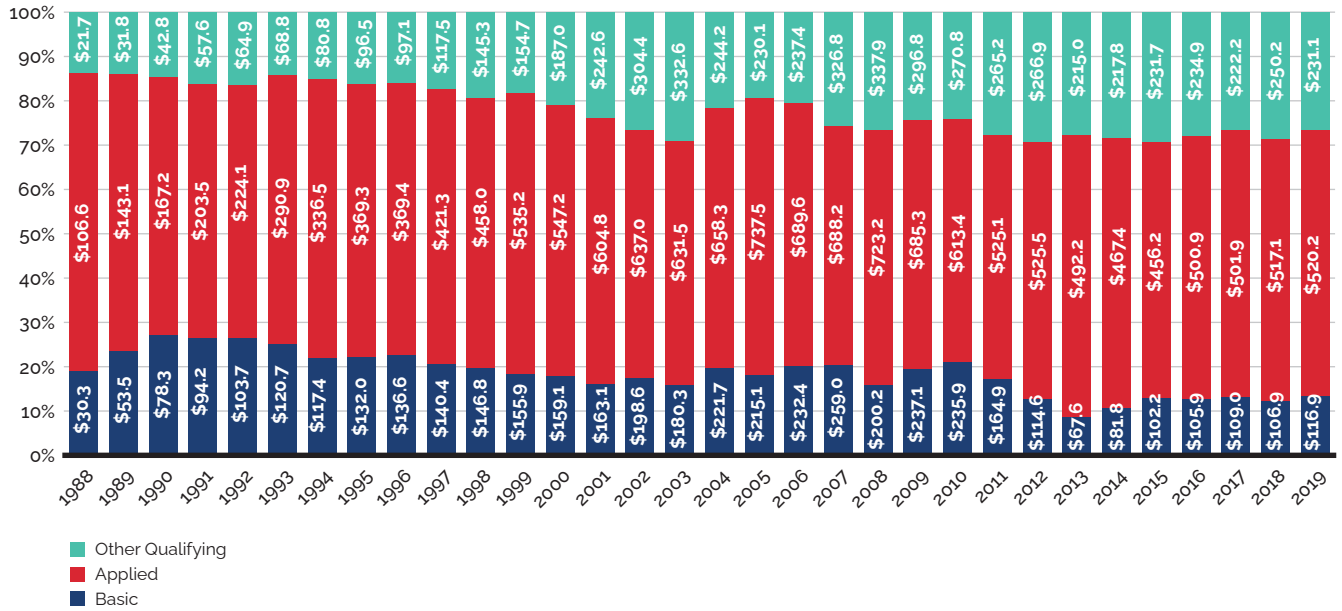
TABLE 21 Range of R&D-to-Sales Ratios by Number of Reporting Companies and Total Sales Revenue, 2019 and 2018

Range: R&D-to-sales ratio	Number of reporting companies: 2019	Sales revenues: 2019 ($millions)	Share: 2019 (%)	Number of reporting companies: 2018	Sales revenues: 2018 ($millions)	Share: 2018 (%)
0%	44	$3,119.4	13.5%	38	$2,764.4	12.2%
≤10%	37	$17,123.6	74.1%	39	$17,682.7	78.0%
>10%	20	$2,858.1	12.4%	16	$2,216.3	9.8%
Total*	**101**	**$23,101.1**	**100%**	**93**	**$22,663.4**	**100%**

* Values may not add to totals due to rounding.

Data source: PMPRB

FIGURE 40 Current R&D Expenditures ($millions) by Type of Research, 1988 to 2019



Data source: PMPRB

TABLE 22 Ratios of R&D Expenditures to Sales Revenue by Reporting Patentee[1], 2019 and 2018

Company	R&D-to-sales ratio 2019	R&D-to-sales ratio 2018	MIP-to-Cdn price ratio – 5 country limit	Canadian sales compared to PMPRB7 sales 2019	Canadian sales compared to rest of OECD sales 2019
AbbVie Corporation[2,3]	2.9%	2.7%	0.95	2.9	2.5
Acerus Pharmaceuticals	0.0%	0.0%	—	—	—
Aerie Pharmaceuticals Inc.	0.0%	0.0%	—	—	—
Alexion Pharmaceuticals Inc.[3]	0.0%	0.0%	0.93	—	—
ALK-Abelló A/S	0.0%	0.3%	1.14	3.1	2.4
Alkermes Inc.	13,400.7%	10,732.8%	—	—	—
Allergan Inc.	1.6%	1.4%	0.73	1.1	1.0
Alnylam Pharmaceuticals Inc.[3,4]	0.0%	—	—	—	—
Altius Healthcare Inc.	23.4%	17.8%	—	—	—
Amgen Canada Inc.[2,3]	3.9%	3.6%	0.89	2.3	2.1
Amicus Therapeutics UK Ltd	0.0%	0.0%	1.92	—	—
Aralez Pharmaceuticals Inc.	0.0%	0.0%	—	—	—
Aspen Pharmacare Canada Inc.	0.0%	0.0%	1.02	3.9	1.1
Astellas Pharma Canada Inc.[2]	0.3%	1.1%	1.44	3.4	2.1
AstraZeneca Canada Inc.[2,3]	10.1%	7.7%	0.78	4.8	3.9
Avir Pharma Inc.[3]	0.0%	0.0%	1.04	—	—
Bausch Health Canada Inc.[3]	0.4%	0.6%	1.08	1.1	0.9
Baxter Corporation	0.1%	0.0%	1.42	0.5	0.3
Bayer Inc.[2,3]	3.5%	5.4%	1.01	14.7	6.4
BGP Pharma ULC	0.0%	0.0%	—	83.1	57.79
Biogen Idec Canada Inc.[3]	11.4%	16.5%	1.05	2.2	1.8
BioMarin Canada Inc.[3]	2.5%	7.6%	1.00	—	—
BioSyent Pharma Inc.	0.0%	0.0%	—	—	—
Bioverativ Canada Inc.[3]	3.5%	1.7%	1.74	—	—
Boehringer Ingelheim (Canada) Ltd[2]	1.9%	2.2%	0.93	3.3	2.6
Bristol-Myers Squibb Canada[2,3]	11.7%	10.4%	1.01	63.8	38.9
BTG International Ltd	0.0%	0.0%	—	—	—
Celgene Inc.[3]	1,176.4%	1.9%	1.02	0.4	0.3
Cheplapharm Arzneimittel GmbH	0.0%	0.0%	0.73	—	—
Chiesi USA Inc.[4]	0.0%	—	—	0.03	0.01
Cipher Pharmaceuticals Inc.	0.9%	1.3%	—	—	—
Covis Pharma BV[4]	0.0%	-	0.89	—	—
CSL Behring Canada Inc.[3]	0.2%	0.2%	5.32	—	—
Duchesnay Inc.	1.3%	0.7%	—	6.9	6.5
Eisai Ltd[3]	4.2%	3.2%	0.94	1.2	0.6

continued

Company	R&D-to-sales ratio 2019	R&D-to-sales ratio 2018	MIP-to-Cdn price ratio – 5 country limit	Canadian sales compared to PMPRB7 sales 2019	Canadian sales compared to rest of OECD sales 2019
Eli Lilly Canada Inc. (incl. Provel Animal Health Division)[2,3]	10.1%	7.3%	0.98	1.3	1.2
EMD Serono Canada Inc.[2]	0.0%	0.0%	0.89	3.8	3.7
Ferring Pharmaceuticals Inc.[3]	0.0%	0.0%	0.84	3.6	2.5
Galderma Canada Inc.	0.0%	0.0%	0.45	4.9	4.1
GE Healthcare Inc.	0.0%	0.0%	—	—	—
Gilead Sciences Canada Inc.[3]	14.8%	10.3%	0.83	2.9	2.3
GlaxoSmithKline Inc.[2]	3.3%	5.4%	0.69	59.9	14.7
Grifols Canada Ltd (Talecris Biotherapeutics Ltd)[3]	0.0%	0.0%	—	—	—
HLS Therapeutics Inc.[4]	0.0%	—	—	214.8	68.2
Hoffmann-La Roche Ltd Canada[2,3]	5.2%	6.8%	1.12	16.4	7.4
Horizon Pharma PLC [2,3]	0.0%	0.0%	—	—	—
Intega Skin Sciences Inc.[4]	0.0%	—	—	—	—
Intercept Pharmaceuticals Inc.	11.4%	13.4%	—	0.2	0.1
Ipsen Biopharmaceuticals Inc.[2,3]	0.1%	0.2%	1.00	1.9	1.3
Janssen Inc.[2,3]	2.3%	2.4%	1.06	8.1	6.3
Jazz Pharmaceuticals[3]	37.9%	9.3%	—	0.1	0.1
Johnson & Johnson Medical Products	1.0%	0.9%	—	3.7	2.0
Knight Therapeutics Inc.[2]	12.4%	18.2%	0.53	—	—
Labtician Théa.	13.9%	37.1%	0.84	—	—
Lantheus MI Canada Inc.	0.0%	0.0%	—	—	—
LEO Pharma Inc.[2]	0.1%	0.1%	0.65	11.2	7.3
Lundbeck Canada Inc.[2]	0.5%	0.5%	0.67	8.2	5.5
Lupin Pharma Canada Ltd	0.0%	0.0%	0.98	0.3	0.3
Medexus Inc.	0.0%	0.0%	0.99	—	—
Merck Canada Inc.[2,3]	5.2%	4.3%	0.94	4.8	3.7
Merus Labs	0.0%	0.0%	—	—	—
Merz Pharma Canada Ltd	0.0%	0.0%	0.95	1.9	1.2
Noden Pharma DAC	0.0%	0.0%	1.14	2.3	2.1
Novartis Pharmaceuticals Canada Inc.[2,3]	3.2%	3.4%	0.92	5.1	3.4
Novo Nordisk Canada Inc.[2,3]	1.8%	1.6%	0.96	1.9	1.7
Octapharma Canada Inc.	2.0%	0.5%	—	—	—

continued

Company	R&D-to-sales ratio 2019	R&D-to-sales ratio 2018	MIP-to-Cdn price ratio – 5 country limit	Canadian sales compared to PMPRB7 sales 2019	Canadian sales compared to rest of OECD sales 2019
Otsuka Canada Pharmaceutical Inc. (OCPI)[2]	0.8%	0.2%	0.98	4.2	2.0
Paladin Labs Inc.[2]	0.2%	0.2%	0.91	—	—
Partner Therapeutics Inc.	0.0%	519.6%	—	—	—
Pediapharm Inc.	0.0%	0.0%	—	—	—
Pfizer Canada Inc.[2,3]	0.5%	0.3%	1.08	3.6	2.9
Pharmascience Inc.	0.0%	12.4%	—	—	—
Pierre Fabre Dermo-Cosmétique Canada Inc.	0.0%	0.0%	1.02	0.6	0.2
Purdue Pharma[2]	2.1%	2.1%	1.17	14.1	12.3
Sandoz Canada Inc.	0.0%	0.0%	—	11.0	7.2
Sanofi Canada Inc.[2,3]	1.7%	1.5%	0.85	27.6	11.7
Sanofi Pasteur Ltd[2,3]	44.5%	51.7%	0.88	—	—
Santen SAS[4]	0.0%	—	—	—	—
Searchlight Pharma Inc.[4]	0.0%	—	—	—	—
Seattle Genetics Inc.	12.2%	16.6%	1.10	—	—
Seqirus Canada Inc.[3]	31.9%	870.2%	1.22	0.2	0.1
Servier Canada Inc.[2,3]	7.8%	4.4%	1.09	18.6	4.7
Shire Canada Inc.[3]	0.0%	0.0%	1.25	41.0	17.9
Shire Rare Disease Business Unit[3]	0.0%	0.0%	1.08	—	—
Sprout Pharmaceuticals Inc.	0.0%	0.0%	—	—	—
Sun Pharmaceutical Industries Inc.[4]	57.0%	—	—	—	—
Sunovion Pharmaceuticals Canada Inc.[2]	0.0%	0.0%	0.89	0.9	0.9
Swedish Orphan Biovitrum AB (Sobi)[3]	0.0%	0.0%	1.07	0.05	0.01
Taiho Oncology Inc.[3]	4.6%	0.0%	1.04	3.8	0.7
Takeda Canada Inc.[2,3]	0.2%	0.2%	0.92	1.6	1.1
Theratechnologies Inc.[2]	444.5%	0.0%	—	—	—
Teva Canada Innovation[3]	0.04%	0.1%	0.91	4.9	3.9
ThromboGenics NV	814.4%	359.7%	0.98	—	—
UCB Canada Inc.[3]	35.8%	41.5%	1.01	1.3	1.0
Ultragenyx Pharmaceutical Inc.[3,4]	24.5%	—	—	—	—
Upjohn Canada ULC[2,4]	0.0%	—	0.89	—	—
Valeo Pharma[4]	0.0%	—	0.58	—	—

continued

Company	R&D-to-sales ratio 2019	R&D-to-sales ratio 2018	MIP-to-Cdn price ratio – 5 country limit	Canadian sales compared to PMPRB7 sales 2019	Canadian sales compared to rest of OECD sales 2019
Verity Pharmaceuticals Inc.[4]	0.0%	—	—	—	—
Vertex Pharma Canada Inc.[3]	0.01%	0.0%	1.12	—	—
Vifor International AG[4]	0.0%	—	0.62	—	—
ViiV Healthcare ULC[2]	0.0%	0.0%	1.08	3.1	2.5

[1] To avoid double counting sales revenues, revenues from royalties are included in calculating each company's ratio but not included in calculating industry-wide ratios. Federal and provincial government grants are subtracted from the R&D expenditure in calculating individual R&D-to-sales ratios but are included in calculating industry-wide ratios. Differences between the list of companies filing data on prices and those filing R&D data are due to differences in the reporting practices of patentees and their affiliates or licensees. Note as well that some veterinary patentees (i.e., those without revenue from sales of products for human use) are required to file information on R&D expenditures but not price and sales information.

[2] Member of Innovative Medicines Canada.

[3] Member of BIOTECanada.

[4] Not a patentee in 2018.

Data source: PMPRB

TABLE 23 Current R&D Expenditures by Province/Territory, 2019

Province	Expenditures: All patentees ($thousands)	Regional share	Expenditures: Innovative Medicines Canada ($thousands)	Regional share
Newfoundland and Labrador	$2,951.52	0.340%	$1,988.37	0.340%
Prince Edward Island	$4,139.76	0.477%	$175.03	0.027%
Nova Scotia	$10,024.97	1.155%	$8,209.17	1.283%
New Brunswick	$4,029.90	0.464%	$3,351.72	0.524%
Quebec	$246,143.58	28.348%	$198,465.26	31.009%
Ontario	$441,599.39	50.859%	$373,726.88	58.393%
Manitoba	$5,202.75	0.599%	$3,038.10	0.475%
Saskatchewan	$2,679.13	0.309%	$681.66	0.107%
Alberta	$103,834.22	11.958%	$21,801.20	3.406%
British Columbia	$47,067.34	5.421%	$28,585.42	4.466%
Territories	$615.66	0.071%	$0.00	0.000%
Canada*	**$868,288.22**	**100%**	**$640,022.82**	**100%**

* Provincial/territorial values may not add to totals for Canada due to rounding.
Data source: PMPRB

TABLE 24 Current R&D Expenditures by Performer and Province/Territory, 2019

Province		Patentees	Other companies	Universities	Hospitals	Others
Newfoundland and Labrador	Expenditure ($thousands)	$1,035.20	$988.66	$219.86	$51.92	$655.88
	Share	35.1%	33.5%	7.4%	1.8%	22.2%
Prince Edward Island	Expenditure ($thousands)	$470.03	$3,494.72	$175.00	$0.00	$0.00
	Share	11.4%	84.4%	4.2%	0.0%	0.0%
Nova Scotia	Expenditure ($thousands)	$1,580.50	$3,844.92	$1,884.84	$249.44	$2,465.27
	Share	15.8%	38.4%	18.8%	2.5%	24.6%
New Brunswick	Expenditure ($thousands)	$1,217.44	$540.10	$48.05	$234.48	$1,989.83
	Share	30.2%	13.4%	1.2%	5.8%	49.4%
Quebec	Expenditure ($thousands)	$64,753.72	$112,157.11	$16,141.31	$22,302.83	$30,788.60
	Share	26.3%	45.6%	6.6%	9.1%	12.5%
Ontario	Expenditure ($thousands)	$220,761.83	$92,140.81	$54,778.03	$44,679.30	$29,239.42
	Share	50.0%	20.9%	12.4%	10.1%	6.6%
Manitoba	Expenditure ($thousands)	$2,904.88	$831.73	$267.90	$453.12	$745.12
	Share	55.8%	16.0%	5.1%	8.7%	14.3%
Saskatchewan	Expenditure ($thousands)	$910.06	$722.00	$863.25	$38.78	$145.04
	Share	34.0%	26.9%	32.2%	1.4%	5.4%
Alberta	Expenditure ($thousands)	$79,238.41	$11,610.41	$5,673.52	$3,031.74	$4,280.14
	Share	76.3%	11.2%	5.5%	2.9%	4.1%
British Columbia	Expenditure ($thousands)	$21,172.97	$14,065.57	$5,331.51	$1,648.11	$4,849.18
	Share	45.0%	29.9%	11.3%	3.5%	10.3%
Territories	Expenditure ($thousands)	$93.76	$0.00	$130.22	$261.68	$130.00
	Share	15.2%	0.0%	21.2%	42.5%	21.1%
Canada*	**Expenditure ($thousands)**	**$394,138.80**	**$240,396.05**	**$85,513.49**	**$72,951.41**	**$75,288.47**
	Share	**45.4%**	**27.7%**	**9.8%**	**8.4%**	**8.7%**

Note: For each jurisdiction, the share for each category represents the percentage of total R&D expenditures for the given province or territory (or nationally for the total R&D in Canada).

* Provincial/territorial expenditures may not add to totals for Canada and shares across individual rows may not add to 100% due to rounding.

Total R&D expenditures are the sum of current expenditures and capital expenditures (equipment + depreciation).

Data source: PMPRB

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