ANNUAL REPORT 2022

Patented Medicine Prices Review Board

Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

The Patented Medicine Prices Review Board
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STATISTICAL HIGHLIGHTS 2022

PRICE REVIEW MANDATE

- 1,138 patented medicines for human use were reported to the PMPRB, including 69 new medicines.
- 8 Voluntary Compliance Undertakings (VCUs) were accepted as of December 31, 2022.
- More than $31.2 million in excess revenues and potential excess revenues were offset by way of payments to the Government of Canada through VCUs, settlements, and Board Orders.

REPORTING MANDATE

SALES TRENDS:

- Sales of patented medicines in Canada were $18.4 billion in 2022, an increase of 5.7% from the previous year.
- Patented medicines accounted for approximately 49.0% of the sales of all medicines in Canada in 2022.

PRICE TRENDS:

- The Consumer Price Index rose by 6.8%, while the national average transaction price for patented medicines increased by 0.8%.
- Canadian list price ratios rose from third to second highest among the 31 Organisation for Economic Co-operation and Development (OECD) countries, behind only the US.

RESEARCH AND DEVELOPMENT (R&D):

R&D-TO-SALES RATIOS DECREASED IN 2022:

- 3.1% for all rights holders, a decrease from 3.4% in 2021.
- 3.2% for Innovative Medicines Canada members, a decrease from 3.5% in 2021.

R&D EXPENDITURES:

- $914.0 million in total R&D expenditures were reported by rights holders in Canada, a decrease of 1.0% over 2021.
- $748.6 million in R&D expenditures were reported by Innovative Medicines Canada members, an increase of 1.7% over 2021.

24 November 2023

The Honourable Mark Holland, 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, 2022.

Yours very truly,

Thomas J. Digby
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.

With the coming-into-force of Health Canada's amendments to the *Patented Medicines Regulations* on July 1, 2022, the PMPRB has been developing new Guidelines to implement these regulatory changes into the Board's operations. The Board acknowledges these regulatory changes reflect important court decisions, including by the Quebec Court of Appeal [*Merck Canada Inc c Procureur général du Canada*, 2022 QCA 240] and the Federal Court of Appeal [*Alexion Pharmaceuticals v Canada (Attorney General)*, 2021 FCA 157; *Innovative Medicines Canada v Canada (Attorney General)*, 2022 FCA 210].

The regular operations of the Board have continued to provide value for Canadian payers. In the fall of 2022, the Board's Hearing Panel issued a decision that found that the price of Procysbi (cysteamine bitartrate) was excessive under section 83 and 85 of the *Patent Act*, directing Horizon Therapeutics Canada to pay just over $22 million to the Receiver General of Canada. This brought the total excess revenues collected through Voluntary Compliance Undertakings (VCUs), settlements, and Board Orders in 2022 to more than $31 million.

Analytical studies conducted through the PMPRB's reporting mandate under the banner of the National Prescription Drug Utilization Information System (NPDUIS) initiative continue to show the vast pressures stemming from the increased use of higher-cost medicines in Canada. Over the last five years, sales of patented medicines have grown by an average of 1.8% per year, reaching $18.4 billion in 2022. High-cost medicines now account for 57.5% of these sales. In 2022 the 20 top-selling patented medicines in Canada, which accounted for 37.7% of total patented medicine sales, had a median treatment cost of $21,345, compared to just $803 in 2013.

Significantly, in 2022, the average list price for medicines in Canada rose from third to second highest among the 31 countries of the Organisation for Economic Co-operation and Development (OECD), behind only the US. The average list price is above all our PMPRB11 comparator countries, as may be seen in the average foreign-to-Canadian price ratios calculated using external data. It is acknowledged that the new *Patented Medicines Regulations* took effect at the mid-point of 2022, and are not expected to impact average list price ratios until later reporting cycles.

In early 2023, Douglas Clark, the PMPRB's longtime Executive Director, announced his retirement after nearly a decade with the organization. On behalf of the PMPRB, I offer our thanks for his years of dedication and commitment. As we move forward under new leadership, the PMPRB remains committed to serving Canadians through the responsible and efficient use of our regulatory powers, in collaboration with and in support of our many stakeholders and partners in the Canadian healthcare system.

Thomas J. Digby
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 price review and reporting mandate. Through its price review 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 rights holders. 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:

- Acting as an effective check on the prices of patented medicines and intervening where the Board determines a price to be excessive; and
- Providing stakeholders with price, cost, and utilization information to help them make timely and knowledgeable pricing, purchasing, and reimbursement decisions.

PROTECTING CONSUMERS IN A COMPLEX MARKETPLACE

(CADTH) Canadian Agency for Drugs and Technologies in Health; (INESSS) Institut national d'excellence en santé et en services sociaux; (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 recommend which new medicines should qualify for reimbursement by the pCPA. In Quebec, this evaluation process is conducted by INESSS.

The PMPRB is composed of up to five Board Members, Governor-in-Council appointees who are assisted in their work by public servants (Staff).

JURISDICTION

PRICE REVIEW

The PMPRB reviews the price at which rights holders (companies) sell their products to wholesalers, hospitals, pharmacies and other large distributors to ensure that this price is not excessive. This price is sometimes also known as the "factory gate" (ex-factory) price. The PMPRB does not review the prices of non-patented medicines (e.g., generics).

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 rights holder 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.

1,138 PATENTED MEDICINES

were reported to the PMPRB in 2022.

The Act requires rights holders (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, rights holders are required to file price and sales information at introduction and, thereafter, until all patents pertaining have expired. Rights holders 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 review the prices that rights holders charge for each individual strength and form of a patented medicine. If the price of a patented medicine appears to be potentially excessive, the rights holder may volunteer to lower its price and/or refund its potential excess revenues through a Voluntary Compliance Undertaking (VCU). If this fails, the Chairperson may consider whether a hearing on the matter is in the public interest. At the hearing, a panel composed of Board members acts as a neutral arbiter between Staff and the rights holder. If a Hearing Panel concludes, after hearing all of the evidence in light of the factors set out in section 85 of the Act, that the price of a patented medicine is/was excessive in any market, it can order the maximum ceiling price to be reduced to a non-excessive level. It can also order a rights holder 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 rights holders.

In addition, as a result of 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 reports, posters, presentations, briefs, and chartbooks. This program provides F/P/T governments and other interested stakeholders with a centralized, objective, and credible source of information on pharmaceutical trends.

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.

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) engagement with domestic, international, and specialized news media. The PMPRB is actively pursuing additional opportunities to leverage new and emerging media to communicate with its stakeholders and the Canadian public.

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

Thomas J. Digby

Thomas Digby was appointed Chairperson of the Board on February 1, 2023.

Thomas Digby is a lawyer with more than 25 years' experience in Canadian and US intellectual property (IP) law, in the field of pharmaceuticals. He has worked closely with diverse biotech start-ups, their venture investors, and, for 10 years, with the global pharmaceutical leader, Novartis.

Thomas attended Queen's University (BSc [Hons], 1987) and Dalhousie University (MSc [Biochem], 1990), and graduated from Dalhousie Law School (now Schulich School of Law) (JD, 1992). He is licensed to practice in both Canada and the United States (Ontario [1994], New York [1995], Massachusetts [1995], British Columbia [1998]). He was formerly registered to practice before the United States Patent and Trademark Office (2005–2012).

After articling with Blakes in Toronto, Thomas worked with a variety of biotech start-ups including Visible Genetics, Inex Pharmaceuticals, and Xenon Pharmaceuticals. At Inex, he provided IP strategy for the discovery efforts that led to the lipid-nanoparticle delivery system used in current COVID mRNA vaccines.

Thomas joined Novartis at its research headquarters in Cambridge MA (2005–2012), and later moved to the head office in Basel, Switzerland (2012–2015). At Novartis, he specialized in global transactions, led a multi-country IP enforcement program, supported the global tax team and the Novartis Venture Fund, and was regularly involved with the IP strategy of the generic (Sandoz) and innovator (Novartis) divisions.

In 2016, Thomas returned to Vancouver with his family, where he is a sole practitioner supporting the IP strategy of a small number of Canadian and US biotech clients. Among other community roles, he is a Commissioner of the Vancouver Board of Parks and Recreation.

Vice-Chairperson

Anie Perrault

Anie Perrault was appointed Vice-Chairperson of the Board on August 15, 2023.

Ms. Anie Perrault is a lawyer by training (University of Ottawa – 1992; Barreau 1993) with more than 30 years of professional experience in the public and private sectors. Her career has focused on communications and public affairs related to genomic research and biotechnology and she has held several strategic positions at a national level in this field. She was Director General of BIOQuébec from 2013 to 2022 and Vice President, Communications of Genome Canada from 2001 to 2006.

Named Sun Life Leadership – Exceptional Woman finalist in the prestigious Les Mercuriades 2021 competition, Ms. Perrault is also an accredited mediator from the Institute of Mediation and Arbitration of Quebec. Ms. Perrault was a Member (administrative judge) of the Canadian Human Rights Tribunal from 2015 to 2021, and continues to act as a mediator there today.

In 2013, Ms. Perrault received the title of Certified Corporate Administrator from the College of Corporate Administrators at Laval University. She is president of the board of directors of Génome Québec. She has also served on the board of directors of ACCESSA since 2020. She was a member of the boards of the Jeanne-Mance Foundation from 2016 to 2022, Loto-Québec from 2011 to 2021 and the University of Sherbrooke from 2016 to 2019.

Member

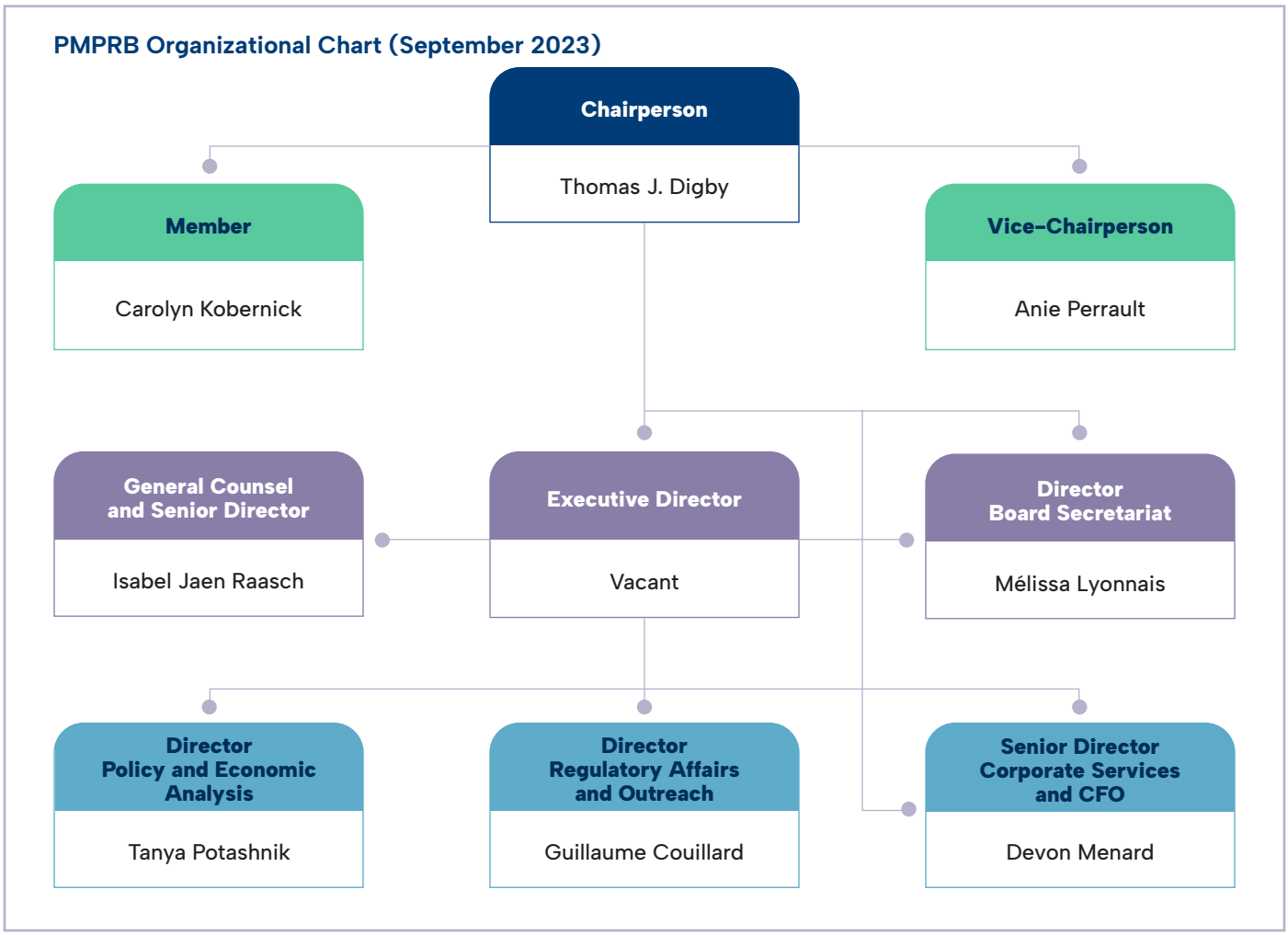
Carolyn Kobernick,
B.C.L., LL.B.

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 had been Assistant Deputy Minister of Public Law for the Department of Justice since 2006. 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 Department of Justice. 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 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.

ORGANIZATIONAL STRUCTURE AND STAFF



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; ensures that rights holders are fulfilling their filing obligations; encourages rights holders to comply voluntarily with the PMPRB's Guidelines; implements related 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 coordinates activities pursuant to the *Access to Information Act* and the *Privacy Act*, and is responsible for strategic planning and reporting. 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

The Board Secretariat manages the Board's meeting and hearing processes, including the official record of proceedings.

General Counsel

The General Counsel advises the PMPRB on legal matters, leads the legal team representing Staff in proceedings before the Board, and liaises with counsel for the Attorney General in PMPRB-related proceedings before federal and provincial courts.

BUDGET

In 2022-23, the PMPRB had a budget of $17.0 million and an approved staff level of 84 full-time equivalent employees.

TABLE 1. BUDGET AND STAFFING

	2021-22	2022-23	2023-24
Budget*	$18,892,322	$17,003,213	$17,093,674
Salaries and employee benefits	$10,175,540	$10,164,617	$10,257,961
Operating	$2,510,296	$2,375,235	$2,372,352
Special Purpose Allotment†	$6,206,486	$4,463,361	$4,463,361
Full Time Employees (FTEs)	85	84	81

* 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.

MONITORING PRICES OF PATENTED MEDICINES:

INFORMING ON PMPRB PRICE REVIEW ACTIVITIES

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 6.6%,[1] outpacing most other health care costs and growing at approximately three times the rate of inflation over the same period. At 13.6 % of total health care spending, pharmaceutical expenditure is level with spending on physicians.[2] In 2021, about 1 in 5 Canadians reported having no prescription medicine coverage while many more were under-insured or faced high deductibles or co-pays. As a result, almost 1 in 10 Canadians had to forego filling a prescription for reasons related to cost.[3]

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

REPORTING REQUIREMENTS

By law, rights holders must file information about the sale of their medicines in Canada. The Act and 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. When the review of the information filed by rights holders suggests that the price of a patented medicine may be excessive, the rights holder is given an opportunity to voluntarily lower its prices and/or refund its potential excess revenues through a Voluntary Compliance Undertaking (VCU). If the rights holder chooses not to submit a VCU, the Chairperson may consider whether a hearing on the matter is in the public interest. If such a hearing is held before a panel composed of Board members ("Hearing Panel") and that Hearing Panel concludes, after hearing all of the evidence in light of the factors set out in section 85 of the Act, that the patented medicine was priced excessively in any market, an order may be issued to the rights holder requiring that (1) the maximum ceiling price of the medicine be reduced to a non-excessive level; and/or (2) that measures be taken to offset any excess revenues that may have been earned through sales of the patented medicine at an excessive price.

Amending Regulations to the *Patent Act* were published in the **Canada Gazette, Part II**, moving forward with the implementation of a new basket of comparator countries and reduced reporting requirements for those medicines at lowest risk of excessive pricing, which came into force on July 1, 2022. The composition of reference countries moved from the previous seven (PMPRB7) to a broader group of eleven countries (PMPRB11) by removing the United States and Switzerland and adding six others (Australia, Belgium, Japan, Netherlands, Norway, and Spain).

The ***Compendium of Policies, Guidelines and Procedures*** details price tests and triage mechanisms used by Staff up to July 1, 2022, when it reviewed and investigated the prices of patented medicines. The Board is in the process of developing new Guidelines and until new Guidelines are implemented, **Interim Guidance** issued by the Board on August 18, 2022, is in operation. Guidelines are not binding and are developed in consultation with stakeholders, including the provincial and territorial Ministers of Health, consumer groups, and the pharmaceutical industry. Copies of the Act, the Regulations, and the Guidelines are available on the **PMPRB's website**.

FAILURE TO REPORT

Access to timely and accurate information regarding the sale of patented medicines is necessary for the PMPRB to fulfil its price review mandate. Therefore, rights holders and former rights holders are required to submit this information to the PMPRB within the timelines set out in the legislation. The information that must be submitted and related deadlines are set out in section 82 of the Act and in the Regulations. In 2022, two medicines were reported to the PMPRB for the first time despite being patented and sold prior to 2022 (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 rights holder 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 2022.

TABLE 2. FAILURE TO REPORT THE SALE OF PATENTED MEDICINES

Rights holder	Trade name*	Medicinal ingredient	Year medicine reported to the PMPRB as under PMPRB jurisdiction	Year medicine reported to the PMPRB with subsequent patent
Sanofi-Aventis Canada Inc.	Trurapi (2 DINs)	Insulin aspart	2021	–
Sanofi-Aventis Canada Inc.	Admelog (2 DINs)	Insulin lispro	2019	–

* Drug Identification Numbers (DINs)
Data source: PMPRB

SCIENTIFIC REVIEW

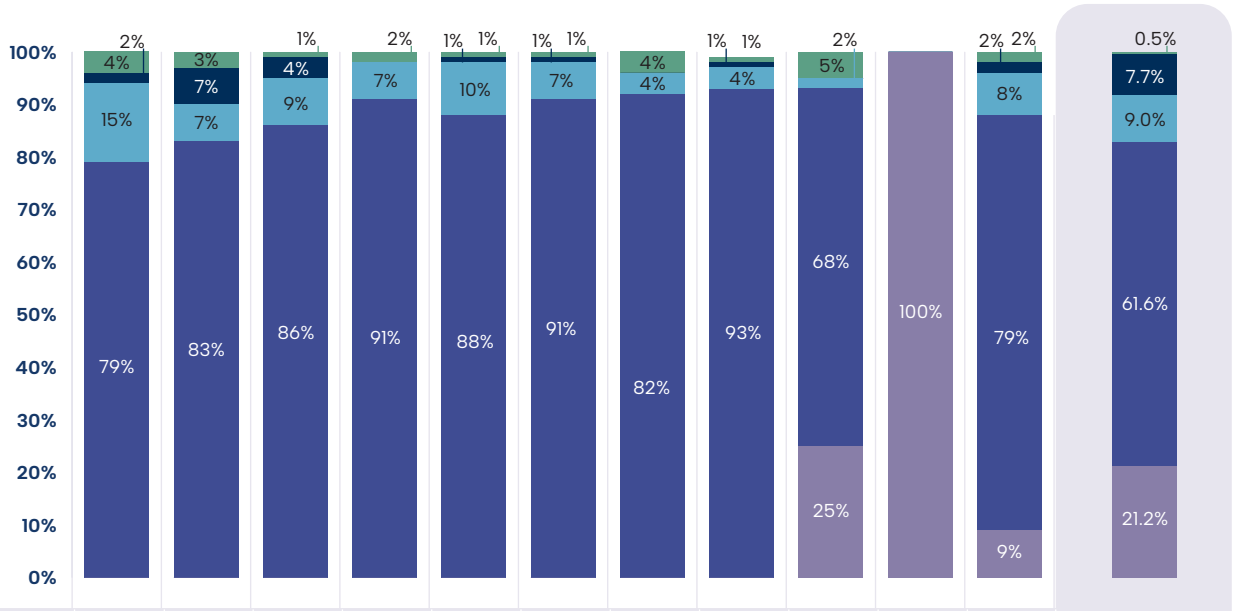
HUMAN DRUG ADVISORY PANEL

Under the Guidelines, which were operational until July 1, 2022, a scientific evaluation was done on all new patented medicines as part of the price review process. The PMPRB established the Human Drug Advisory Panel (HDAP) to provide recommendations on the categorization of patented medicines to Staff. The HDAP conducted an evaluation to provide clinical context pertaining to the scientific information that was being considered by Staff. HDAP members reviewed and evaluated the appropriate scientific information available, including any submission by a rights holder about the proposed level of therapeutic improvement, the selection of comparator medicines, and comparable dosage regimens.

The HDAP provided recommendations on 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. PERCENTAGE AND NUMBER OF NEW PATENTED MEDICINES REVIEWED, BY THERAPEUTIC BENEFIT



Number of New Patented Medicines Reviewed	2013 Intro	2014 Intro	2015 Intro	2016 Intro	2017 Intro	2018 Intro	2019 Intro	2020 Intro	2021 Intro*	2022 Intro†	Overall 2013–2022	Overall 2013–2022 Revenue Share
Under Review‡	–	–	–	–	–	–	–	–	15	69	84	21.2%
Slight/No Improvement	91	86	73	116	70	98	62	71	40	–	707	61.6%
Moderate Improvement	17	7	8	9	8	8	11	3	1	–	72	9.0%
Substantial Improvement	2	7	3	–	1	1	–	1	–	–	15	7.7%
Breakthrough	5	3	1	3	1	1	3	1	3	–	21	0.5%

* Updated to include reviews occurring after the previous Annual Report's reporting date of March 31, 2022

† Assessment as of March 31, 2023

‡ Due to the Amending Regulations and update of comparator countries, new medicine reviews were not conducted until such time as new Guidelines were finalized. As per the **Interim Guidance**, the status of a category of medicines including all new medicines is "under review".
Data source: PMPRB

Figure 1 shows the distribution of new patented medicines introduced from 2013 to 2022 by their level of therapeutic benefit. The largest percentage of patented medicines (78.6%) introduced since 2013 were categorized as "Slight or No Improvement" in therapeutic benefit over existing therapies.[4]

The "Overall 2013–2022" bar represents the therapeutic benefit breakdown for all new patented medicines introduced from 2013 to 2022. The "Overall 2013–2022 Revenue Share" bar illustrates the revenue share by therapeutic benefit for all new patented medicines introduced from 2013 to 2022.

As per the Interim Guidance issued by the Board on August 18, 2022, patented medicines without a maximum average potential price or non-excessive average price as of July 1, 2022, were not subject to price reviews by PMPRB Staff and are reported as "under review".

PRICE REVIEW

The PMPRB reviews the average price (net of reported discounts and deductions) and the list 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) (DINs) assigned by Health Canada at the time the medicine is approved for sale in Canada.

NEW PATENTED MEDICINES REPORTED TO THE PMPRB IN 2022

For the purpose of this report, a new patented medicine in 2022 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, 2021, and December 1, 2022.

There were 69 new patented medicines for human use reported as sold in 2022. Some are one or more strengths of a new active substance and others are new presentations of existing medicines. Of these 69 new patented medicines, six (8.7%) were sold in Canada prior to the issuance of the Canadian patent that brought it under the PMPRB's jurisdiction. Table 3 shows the year of first sale for these medicines.

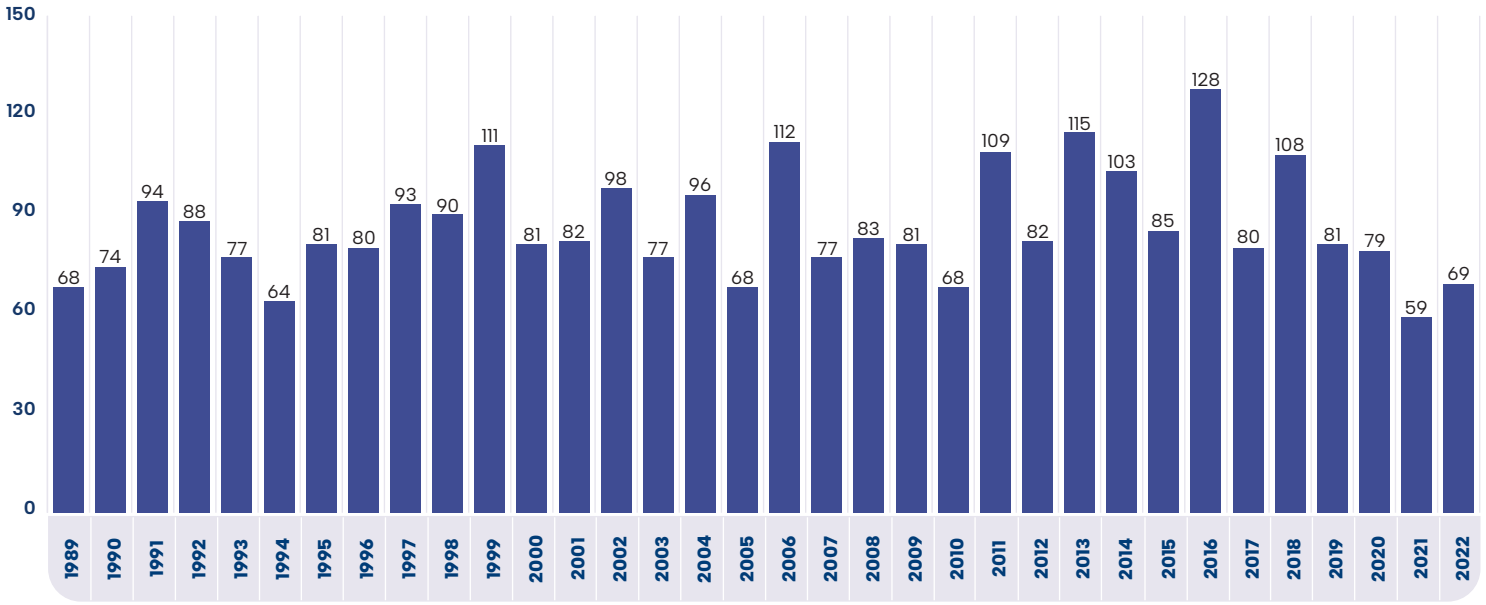
TABLE 3. NUMBER OF NEW PATENTED MEDICINES FOR HUMAN USE IN 2022 BY YEAR FIRST SOLD

Year first sold	Number of medicines
2020	1
2021	4
2022	1
Total	**6**

Data source: PMPRB

Figure 2 illustrates the number of new patented medicines for human use reported to the PMPRB from 1989 to 2022.

FIGURE 2. NUMBER OF NEW PATENTED MEDICINES FOR HUMAN USE



Data source: PMPRB

PRICE REVIEW OF EXISTING PATENTED MEDICINES FOR HUMAN USE IN 2022

For the purpose of this report, existing patented medicines include all patented medicines first sold and reported to the PMPRB prior to December 1, 2021.

At the time of this report, there were 1,069 existing patented medicines:

- 819 were not the subject of investigations;
- 197 were the subject of investigations;
- 36 were under review;
- 14 were the subject of a Voluntary Compliance Undertaking;
- 2 were subject to Board Order; and
- 1 was subject to a Settlement Agreement and Order.

Table 4 provides a summary of the status of the price review of the new and existing patented medicines for human use in 2022.

TABLE 4. PATENTED MEDICINES FOR HUMAN USE SOLD IN 2022—STATUS OF PRICE REVIEW AS OF MARCH 31, 2023

	New medicines introduced in 2022	Existing medicines	Total
Total	**69**	**1,069**	**1,138**
Not Subject to Investigation	0	819	819
Under Review	69	36	105
Subject to Investigation	0	197	197
Subject to Voluntary Compliance Undertaking (VCU)	0	14	14*
Subject to Board Order	0	2	2
Subject to Settlement Agreement and Order	0	1	1

* The terms and conditions of previous years' VCUs that have carried over into 2022 are captured in this count.
Data source: PMPRB

UPDATE FROM THE 2021 ANNUAL REPORT

- 22 of the patented medicines for human use that were reported as under review in the 2021 Annual Report remain under review.
- 56 of the 169 investigations reported in the 2021 Annual Report resulted in one of the following:
  - the closure of the investigation;
  - a VCU by the rights holder to reduce the price and offset potential 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

The reduced reporting obligations for medicines with lowest risk of excessive pricing (i.e., veterinary, over-the-counter, and certain "generic" medicines) came into force on July 1, 2022, as provided for in the Amending Regulations. Staff only review 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 complaint-based investigation was undertaken in 2022.

CERTIFICATES OF SUPPLEMENTAL PROTECTION

Amendments made to the Patented Medicines section of the Act, published in the **Canada Gazette**, which came into force on June 30, 2021, extended the PMPRB's jurisdiction to medicines that are protected by a Certificate of Supplementary Protection (CSP). A CSP gives the certificate holder the same legal rights given by the patent and extends patent protection for a maximum period of two years. There were 58 CSPs reported to the PMPRB in 2022, with expiration dates ranging from 2024 to 2037. Each patent that had their duration extended through a CSP can be linked to multiple patented medicines; in total, there are 144 patented medicines linked to these 58 CSPs.

VOLUNTARY COMPLIANCE UNDERTAKINGS AND HEARINGS

VOLUNTARY COMPLIANCE UNDERTAKINGS

A VCU is a promise by a rights holder to reduce its price(s) and/or offset any potential excess revenues from the sale of a patented medicine that is subject to an investigation. The consideration of a VCU is an administrative procedure and does not constitute an admission or determination by the PMPRB that the price submitted by the rights holder, or used to calculate a revenue offset, is not excessive. However, the acceptance of a VCU by the Chairperson will result in the closure of an investigation.

In 2022, the Chairperson approved the closure of investigations based on the receipt of eight VCUs. In addition to price reductions for certain medicines, potential excess revenues totaling $921,189.80 were offset by way of a payment to the Government of Canada.

No additional VCUs met the criteria for inclusion as of May 31, 2023.

TABLE 5. VOLUNTARY COMPLIANCE UNDERTAKINGS IN 2022 UP TO MAY 31, 2023

Patented medicine (Trade name)*	Therapeutic use	Rights holder	Date of approval	Offset of potential excessive revenues	
				Price reduction	Payment to the government
VCUs in 2022					
Gilteritinib (sold under trade name Xospata) (1 DIN)	Indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation.	Astellas Pharma Canada, Inc.	February	–	$400,000.00
Fremanezumab (sold under trade name Ajovy) (2 DINs)	Indicated for the prevention of migraine in adults who have at least four migraine days per month.	Teva Canada Innovation	February	Yes	–
Burosumab (sold under trade name Crysvita) (3 DINs)	Indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older; also indicated for the treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with tumors that cannot be curatively resected or localized in adult patients.	Ultragenyx Pharmaceuticals Inc.	February	Yes	–
Dalbavancin (sold under trade name Xydalba) (1 DIN)	Indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by gram-positive microorganisms.	Paladin Labs Inc.	April	Yes	$20,181.32
Halobetasol proprionate / tazarotene (sold under trade name Duobrii) (1 DIN)	Indicated for improving the signs and symptoms of plaque psoriasis in adult patients with moderate to severe plaque psoriasis.	Bausch Health, Canada Inc.	May	–	$107,814.48
Clevidipine (sold under trade name Cleviprex) (1 DIN)	Indicated for the management of acute elevation of blood pressure in perioperative settings.	Chiesi USA, Inc.	May	Yes	–
Chlormethine hydrochloride (sold under trade name Ledaga) (1 DIN)	Indicated for the topical treatment of stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) in adult patients who have received prior skin-directed therapy.	Recordati Rare Diseases Canada Inc.	May	–	–

Continued on next page...

Patented medicine (Trade name)*	Therapeutic use	Rights holder	Date of approval	Offset of potential excessive revenues	
				Price reduction	Payment to the government
VCUs in 2022					
Olopatadine hydrochloride (sold under trade name Patanol) and olopatadine hydrochloride (sold under trade name Pataday) (2 DINs)	Indicated for the treatment of allergic conjunctivitis and the treatment of ocular itching associated with seasonal allergic conjunctivitis, respectively.	Novartis Pharmaceuticals Canada Inc.	August	–	$393,194.00
Total for VCUs approved as of December 31, 2022					**$921,189.80**
VCUs in 2023 as of May 31, 2023					
–	–	–	–	–	–
Total for VCUs approved as of May 31, 2023					**$921,189.80**

* Drug Identification Number (DIN)

HEARINGS

The PMPRB holds hearings into two types of matters:

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

EXCESSIVE PRICING

When an investigation into the price of a patented medicine is completed, and the matter is not resolved, the Executive Director may submit a report to the Chairperson. The Chairperson may decide to issue a Notice of Hearing if he or she is of the opinion that it is in the public interest. During a hearing, submissions and evidence from the parties are heard by a Hearing Panel consisting of at least two Board members. The Hearing Panel determines whether a patented medicine is being, or has been, sold at an excessive price in any market in Canada by taking into consideration the available information relating to the factors set out in section 85 of the Act. If the Hearing Panel finds the price is excessive, it can issue an order to reduce the maximum price of the patented medicine in question (or of another patented medicine of the rights holder) 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 was 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 hearing was held over several weeks in late 2020–early 2021, and in September 2022, a decision was issued by the Hearing Panel that found that the price of Procysbi was excessive under section 83 and 85 of the *Patent Act*. On October 13, 2022, the Board ordered Horizon to pay $22,028,977.26 to the Receiver General of Canada within 30 days of the order date. This was coupled with an order that the ceiling price of Procysbi be reduced to a non-excessive level.

FAILURE TO FILE–JURISDICTION

When it appears that a rights holder has failed or refused to provide the PMPRB with the pricing, sales, or revenues and like information required by law, the Executive Director may submit a report to the Chairperson. The Chairperson may decide to issue a Notice of Hearing if he or she is of the opinion that it is in the public interest to hold a hearing to determine whether the rights holder 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 rights holder has failed to report the required information, the Hearing Panel can order the rights holder to file the required pricing and sales information.

There were no new failure to file hearings as of March 31, 2023.

On May 7, 2020, the Board issued its decision on redetermination 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), which is still pending.

SUMMARY

Excess revenues and potential excess revenues totaling $31,278,774.47 were offset by payments to the Government of Canada through VCUs, settlements, and Board Orders in 2022 and up to May 31, 2023.

Since 1993, 170 VCUs have led to investigation closures. In addition, 31 notices of hearing have been issued, 14 of which were resolved through settlements prior to the hearing on the merits and 17 of which were subject to a full public hearing on the merits (10 related to allegations of excessive pricing and 7 related to allegations of failure to file). These measures resulted in price reductions and the offset of excess revenues or potential excess revenues by additional price reductions and/or payments to the Government of Canada. Over $241 million has been collected through VCUs, settlements, and Board Orders through payments to the Government of Canada.

MATTERS BEFORE THE FEDERAL COURT, FEDERAL COURT OF APPEAL, AND SUPREME COURT OF CANADA OR OTHER COURTS

A-237-19: 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. The Federal Court of Appeal heard the appeal of the Board Panel's decision in October 2020. The Federal Court of Appeal granted Alexion's appeal on July 29, 2021, and remitted the matter to the Board for redetermination. On June 21, 2022, the matter was settled through a Board order granting a discontinuation of the redetermination and related settlement agreement.

T-906-20: 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). The Board Panel's redetermination in this matter is under judicial review by the Federal Court.

T-1419-20: on November 23, 2020, Innovative Medicines Canada and 19 individual pharmaceutical companies brought an application in Federal Court for judicial review of the PMPRB's decision to issue new Guidelines on October 23, 2020 (then slated to come into effect in July 1, 2021). The application sought a declaration that the new Guidelines are *ultra vires* the *Patent Act* and an order quashing and setting aside the decision of the PMPRB to issue the new Guidelines. The matter was discontinued in August of 2022.

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

One judgment was rendered on a challenge related to PMPRB legislation that commenced in 2019:

T-1465-19: on September 6, 2019, Innovative Medicines Canada (IMC) 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* 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, IMC and the individual pharmaceutical companies filed a Notice of Appeal (A-215-20) with respect to the Federal Court decision. The Attorney General of Canada also filed a cross-appeal in respect of the invalidated amendments. Judgement on the matter was rendered on December 5, 2022, with the FCA dismissing the appellant's challenge on the change of the list of comparator countries, and not rendering a decision on additional issues which had been rendered moot.

No. 500-17-109270-192. Merck et al. v Canada (Attorney General): on August 22, 2019, 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*. In its decision issued on December 18, 2020, the Quebec Superior Court found the amendments to subsections 4(4)a) and 4(4)b) that would update the net price calculation to require patentees to include discounts and rebates provided to third parties unconstitutional and of no force or effect. The Court found the rest of the Regulations, including the other amendments, and the relevant sections of the *Patent Act* constitutionally valid. The pharmaceutical company applicants filed a Notice of Appeal with respect to the Superior Court of Quebec's decision on January 25, 2021, and the Attorney General of Canada also filed a cross-appeal in respect of the invalidated amendments. The Quebec Court of Appeal granted the appeal in part and dismissed the cross-appeal on February 18, 2022.

TABLE 6. STATUS OF BOARD PROCEEDINGS IN 2022 UP TO MAY 31, 2023

Allegations of Excessive Pricing				
Medicine	**Indication/use**	**Rights holder**	**Issuance of notice of hearing**	**Status**
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 appeal: see below. Matter (redetermination) discontinued on June 21, 2022, following a settlement agreement.
Cysteamine bitartrate (sold under trade name Procysbi)	Nephropathic cystinosis	Horizon Therapeutics Canada	January 14, 2019	Hearing held in 2020–2021. Decision issued September 1, 2022, found the price of Procysbi was excessive under Sections 83 and 85 of the Act. Board order: October 13, 2022 Payment of excess revenues: $22,028,977.26 Ceiling price of Procysbi to be reduced to a non-excessive level.

Allegation of Failure to File				
Medicine	**Indication/use**	**Rights holder**	**Issuance of notice of hearing**	**Status**
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 May 31, 2023				
Medicine	**Indication/use**	**Applicant**	**Issue**	**Date of notice of hearing/status**
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.
N/A	N/A	Innovative Medicines Canada et al	*Vires* of new Guidelines issued by the PMPRB in October 2020	Application for Judicial Review. Court File T-1419-20: discontinued in August of 2022.

ENDNOTES

[1] 4.1% 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 2022 Series C data.

[2] CIHI, National Health Expenditure Trends, 2022

[3] Statistics Canada, Insights on Canadian Society: Pharmaceutical access and use during the pandemic (November 2022)

[4] The criteria for commencing an investigation have been developed with the intention of making the most efficient use of the PMPRB's human and financial resources. The fact that the price of a patented medicine is not subject to an investigation does not necessarily mean that its price is not excessive and vice versa. It only means that the investigation criteria under the Guidelines have not been met in the particular circumstances.

KEY PHARMACEUTICAL TRENDS:

HIGHER-COST MEDICINES CONTINUE TO INFLUENCE SALES

Pharmaceutical spending is influenced by many factors, including price, utilization, the entry of newer, higher-cost medicines, and the loss of market exclusivity for older patented medicines. In 2022, there was a sizable increase in the volume of patented medicines sold, as well as a moderate rise in the sales of higher-cost medicines, resulting in an overall increase in total spending of 5.7%. Canadian list prices of patented medicines remained among the highest in the Organisation for Economic Co-operation and Development (OECD), ranking second, behind only the US.

The PMPRB is responsible for reporting on trends in pharmaceutical sales and pricing for all medicines, patented and non-patented, and for reporting research and development spending by rights holders.

Under the Regulations, rights holders are required to submit detailed information on their sales of patented medicines, including quantities sold, gross ("list") 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.

DISCLAIMERS

1. Although select statistics reported in the KEY PHARMACEUTICAL TRENDS section are based in part on data obtained under license from the MIDAS® database and the Private Pay Direct Drug Plan database proprietary to IQVIA Solutions Canada Inc. and/or its affiliates ("IQVIA"), 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 National Prescription Drug Utilization Information System (NPDUIS) analyses have been included as additional "Brief Insights" throughout this section. 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 price review activities of the PMPRB. Analysis produced under the NPDUIS initiative does not contain information that is confidential or privileged under sections 87 and 88 of the *Patent Act*.

$6.7 BILLION

of Canadian pharmaceutical sales in 2022 were for medicines that previously but no longer report to 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 have grown by an average of 1.8% per year, reaching $18.4 billion in 2022. This section looks at the most important factors driving the change in sales revenues from 2021 to 2022 and compares them to trends from previous years.

TRENDS IN SALES REVENUES

Figure 3 reports on trends in the sales of patented medicines from 1990 to 2022. Between 2021 and 2022, there was a $956 million (5.7%) increase in the sales of patented medicines. While there has been more than a ten-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), which has ranged between -1.7% and 9.4% since 2013.

Figure 3(a) gives the sales of patented medicines as a share of overall medicine sales. This share reached a peak of 72.7% in 2003 before declining to 60.7% in 2013. In 2022, patented medicines accounted for 49.0% 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) displayed in Figure 3(c) show the ongoing importance of patented medicines in the Canadian economy. Overall, per capita sales of patented medicines rose from $61.60 in 1990 to $465.12 in 2022, while sales as a percentage of GDP rose from 0.25% in 1990 to 0.67% in 2022.

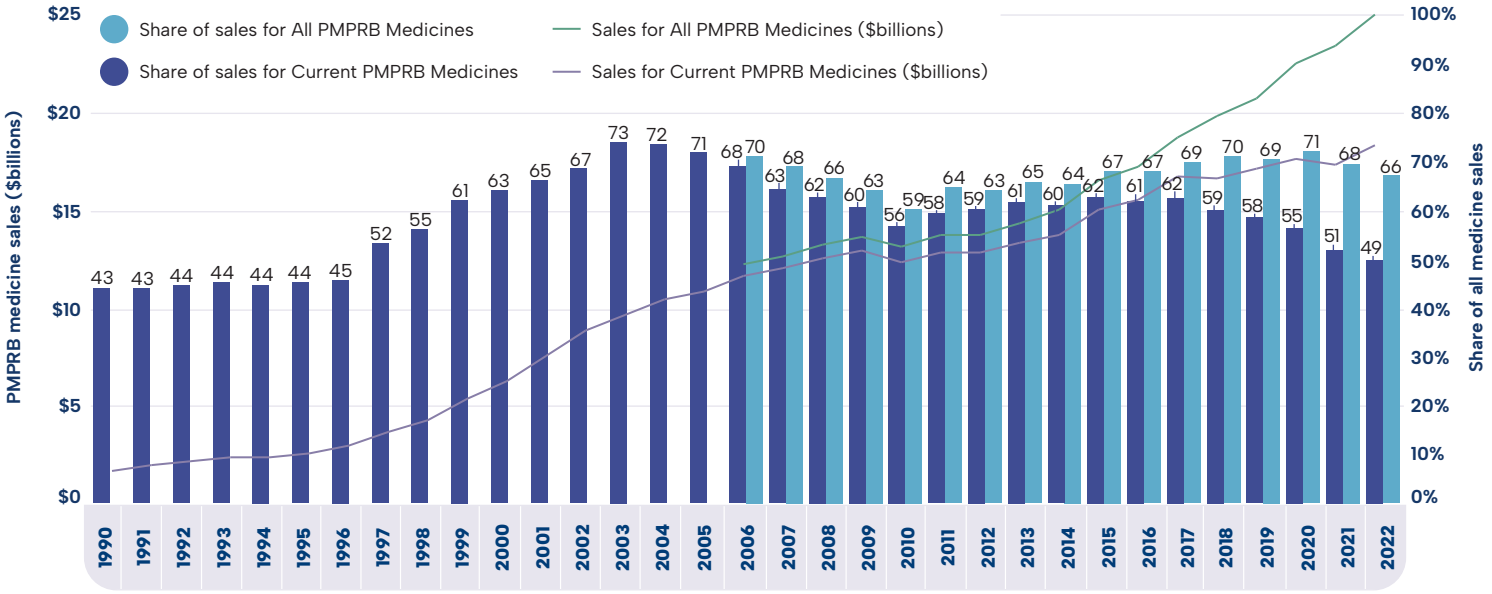
To highlight the continuing impact of patented medicines, Figures 3(a) and 3(b) also provide results for "All PMPRB Medicines". This broader category includes all medicines, current and historic, that ever reported sales to the PMPRB. Historically, medicines have experienced a substantial decrease in market share upon loss of patent protection; however, that same effect has not been observed in a number of the medicines that have stopped reporting to the PMPRB in recent years.

Sales for All PMPRB Medicines rose by 6.8% in 2022, reaching $25.1 billion or 66% of the sales of all medicines in Canada. Medicines that previously reported to the PMPRB accounted for estimated sales of $6.7 billion, or 26.6% of All PMPRB Medicine sales. This is considerably more than a decade ago when medicines that formerly reported to the PMPRB accounted for $1.0 billion, or 6.9% of All PMPRB Medicine sales.

A complete table of the data presented in Figure 3 for patented medicines currently reporting to the PMPRB is included in Appendix 2.

FIGURE 3. TRENDS IN PATENTED MEDICINE SALES, 1990 TO 2022

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

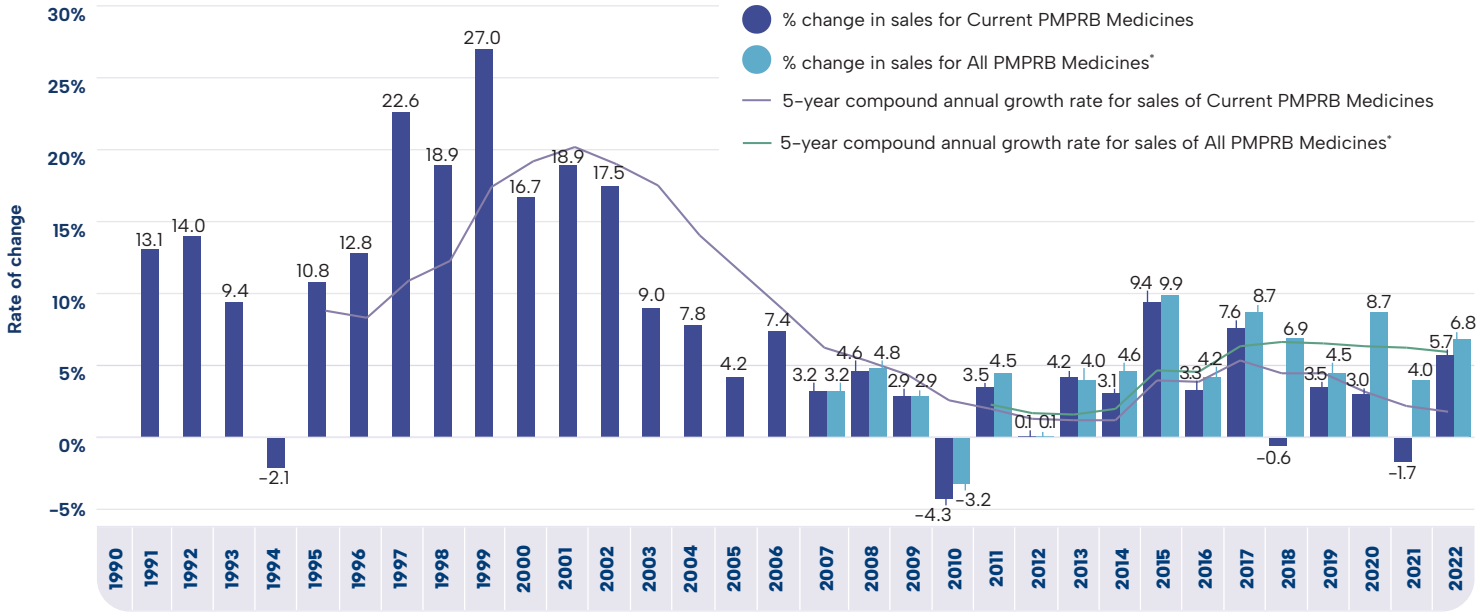


Note: To account for revised submissions from rights holders, sales are recalculated for the five years preceding the current Annual Report year. If the data has been revised, the values reported here may differ from those presented in earlier Annual Reports.

* Includes sales of currently patented medicines and medicines that once reported to the PMPRB but are no longer reporting a patent.

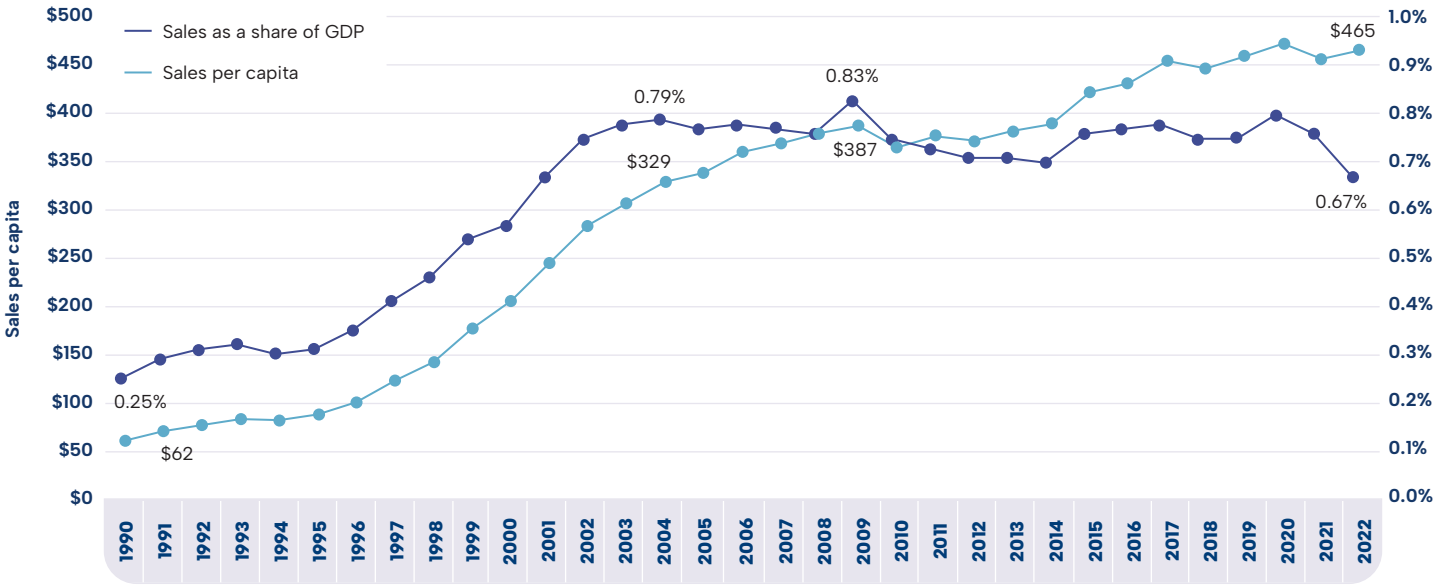
Data source: PMPRB; MIDAS® database, 1990–2022, IQVIA (all rights reserved)

(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, 1990–2022, 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:

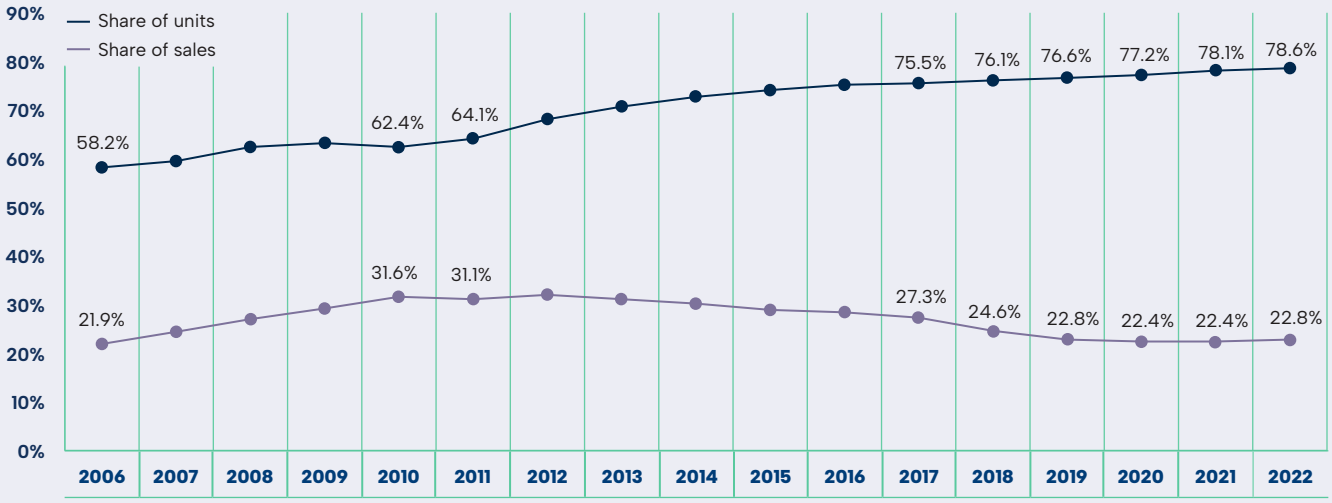
TRENDS IN THE SALES OF GENERIC MEDICINES

While sales of patented medicines increased by 5.7% in 2022, retail sales of generic medicines rose by 10.6%, from $5.88 billion in 2021 to $6.50 billion in 2022. This is a notable increase over the generally low or negative rates of change observed since 2010, which were 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 reference brand price, driving expenditures down to virtually the same level as in 2010, even as generics continued to grow as a share of units sold in the retail pharmaceutical market (Figure 4).

As the prices of generic medicines begin to stabilize, the return to higher rates of sales growth in 2022 reflects a sustained increase in the use of generics over the previous year.

FIGURE 4. GENERIC SHARE OF THE CANADIAN PHARMACEUTICAL RETAIL MARKET, 2006 TO 2022



Note: The results reflect prescription sales in the national retail market based on manufacturer ex-factory list prices.
Data source: MIDAS® database, 2006–2022, IQVIA (all rights reserved)
[NPDUIS Report: *Generics360, 2018* – graph updated to include data up to 2022]

DRIVERS OF THE GROWTH IN SALES REVENUES

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

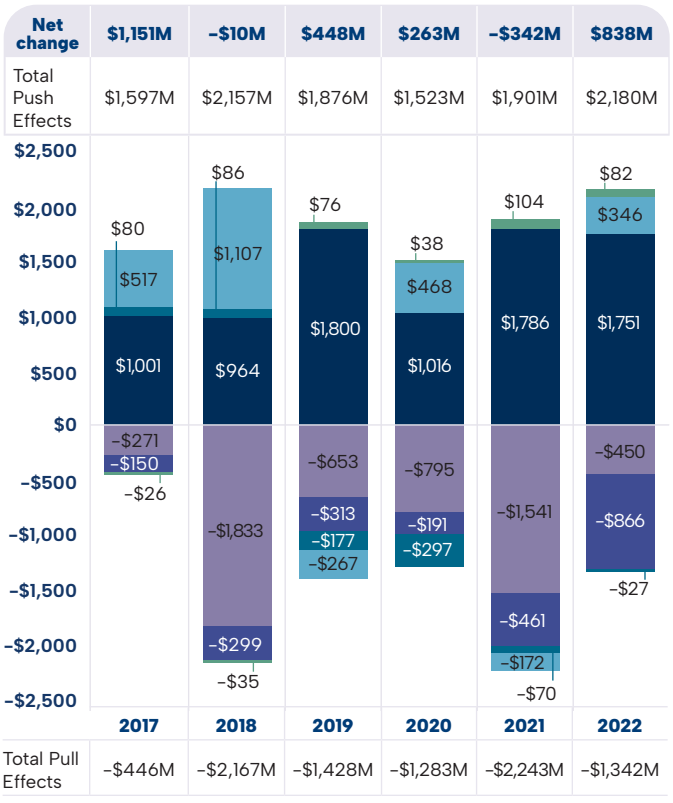
- **Volume effect:** changes in the quantity or amount of patented medicines sold.
  - This effect focuses on established medicines that were on the market for the period analyzed. Increases in the population, changes in demographic composition (e.g., shifts in the age distribution), increases in the 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 prescribing practices are among the factors that may contribute to this change.
- **Exiting effect:** previously patented medicines that have stopped reporting sales revenues 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.

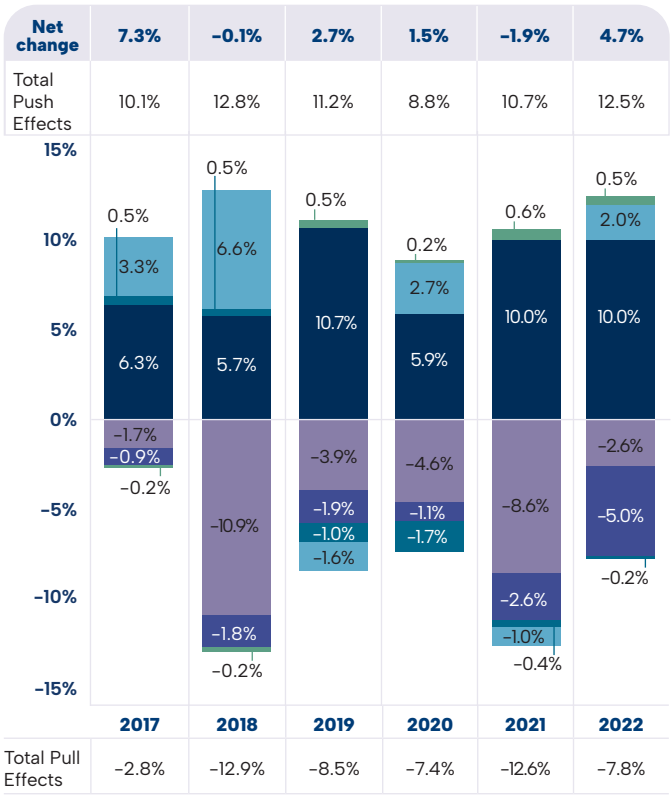
Figure 5 summarizes the major factors that drove the year-by-year change in patented medicine sales[7] between 2017 and 2022 (a) in absolute dollar amounts, and (b) as proportions of the overall annual change in sales.

FIGURE 5. KEY DRIVERS OF CHANGE IN THE SALES OF PATENTED MEDICINES, 2017 TO 2022

(a) Absolute change ($millions)



(b) Relative change (%)



Price · Volume · Mix, DAAs for Hepatitis C · Mix, Other Drugs · Loss-of-Exclusivity · Exiting

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 reported overall change in the patented medicines market reported in Figure 3(b).

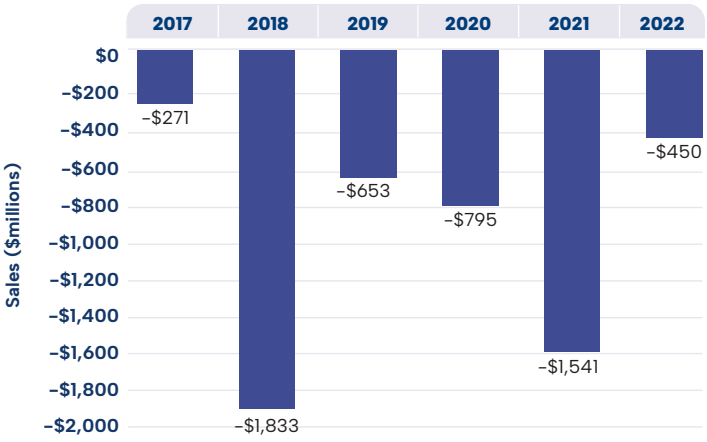
Data source: PMPRB

Changes in the prices of patented medicines have played a 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 2022, the use of higher-cost patented medicines other than DAAs put an upward pressure on expenditures of $1.8 billion (push effect of 10.0%). While growth was observed in many therapeutic areas, the increase in sales of "antineoplastic and immunomodulating agents" exceeded that of any other class. These medicines, which include oncology treatments, accounted for more than 44% of all patented medicine sales in 2022. Results by therapeutic class are discussed in further detail in the upcoming sections.

Counterbalancing the upward sales pressure from the mix effect, there was a moderate market segment shift as some high-selling medicines stopped reporting their sales to the PMPRB. The loss-of-exclusivity effect accounted for a pull effect of $0.87 billion (-5.0%) on sales in 2022. Figure 6 illustrates the change in the impact of the exiting effect since 2017 and identifies the 10 top-selling medicines that stopped reporting to the PMPRB in 2022.

FIGURE 6. PULL EFFECT ON PATENTED MEDICINE SALES FROM THE EXITING EFFECT, 2017 TO 2022



Note: If a medicine stops reporting a patent mid-way through the year, its impact may be reflected in the exiting effect in more than one reporting year. The amounts reported in any given year may not reflect an entire year's worth of sales for these medicines.
Data source: PMPRB

Top-selling medicines that stopped reporting to the PMPRB in 2022	
Breo Ellipta	-$69M
Brilinta	-$47M
Myozyme	-$41M
Somatuline Autogel	-$36M
Prolia	-$23M
Vaxzevria	-$19M
Avamys	-$16M
Pentasa	-$15M
Pristiq	-$15M
Onglyza	-$15M

BRIEF INSIGHTS:

COST DRIVERS OF PUBLIC AND PRIVATE DRUG PLANS

Canadian public drug plans and private insurers together account for over three quarters of all prescribed drug spending in Canada.[i] This includes sales for all products reimbursed by the plan, including but not limited to patented and non-patented brand medicines, patented and non-patented generic medicines, and non-patented single-source medicines.

Drug costs, including markups, represent the largest component of prescription drug expenditures and have the greatest influence on overall trends. Drug costs rose by 8.4% in public plans in 2021/22 and 4.5% in private plans in 2022.

The increasing use of higher-cost medicines, or the drug-mix effect, 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 and significant upward pressure on expenditures, accounting for an 8.1% contribution toward drug costs in public plans in 2021-22 and 5.0% toward private plan costs in 2022. Given that the impact of DAA drugs on spending growth is dwindling, having had less than 0.1% pull effects in both public and private drug plans in the past year, the DAA effect is no longer separated out from the drug-mix effect.

The significant downward force exerted by generic pricing policies implemented in 2018, captured under the price change effect, has stabilized and is no longer offsetting the increasing cost pressures from the drug-mix effect. The pull-down effect from substitution became stronger than price effect, lowering drug costs by 1.7% in public plans in 2021-22 and 2.0% of private plans in 2022. Additional savings are expected to be realized from the substitution effect in the coming years as a result of recent biosimilar policy changes in most public drug plans, as well as initiatives introduced by some private payers aimed at promoting switching from biologic originators to available biosimilars. As of March 2023, biosimilar substitution policies have been adopted by public plans in British Columbia, Alberta, Saskatchewan, Ontario, Quebec, New Brunswick, Nova Scotia, Newfoundland and Labrador, the Northwest Territories, and Yukon, and policies are under development for the remaining jurisdictions. With a strong market for biologics in Canada, these efforts may act as a means of offsetting the mounting pressure from higher-cost medicines.

For public plans, a 2.5% demographic push effect from the increased number of active beneficiaries in 2021-22 indicates the gradual returning of these drivers to pre-pandemic levels.

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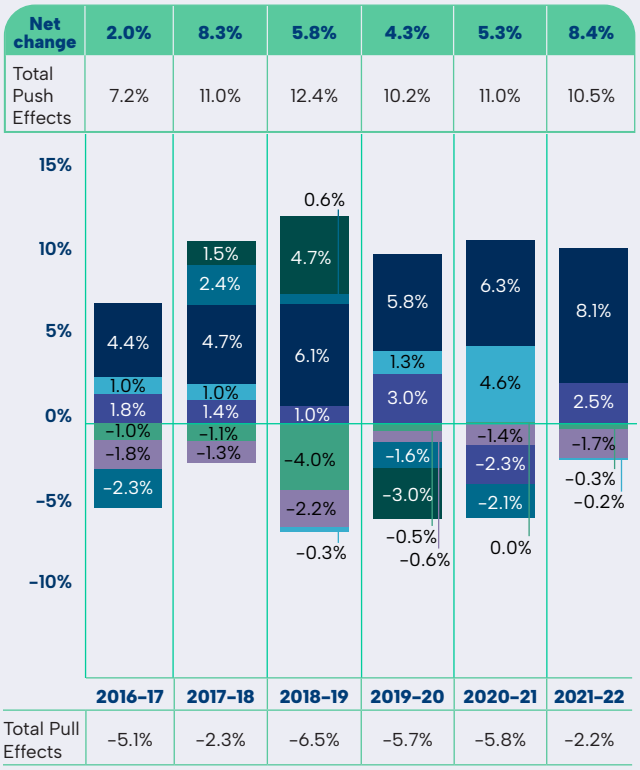
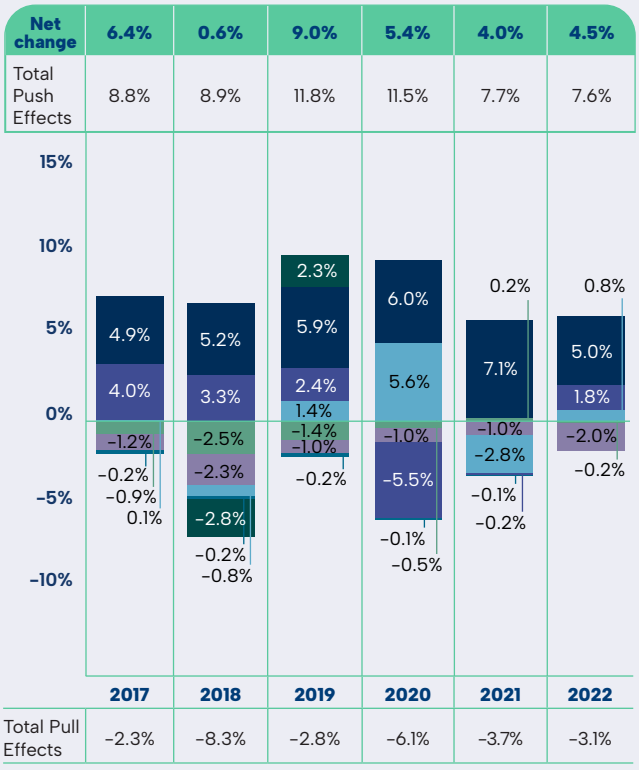
FIGURE 7. MEDICINE COST DRIVERS

(a) NPDUIS public drug plans*, 2016–17 to 2021–22



(b) Private drug plans, 2017 to 2022



OHIP+ | Drug-Mix, DAAs for Hepatitis C | Drug-Mix, Other Drugs | Volume† | Substitution | Price Change | Demographic†

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 the 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 (NIHB) Program. Results for 2020–21 onward do not include the NIHB program.

† A temporary partial data discontinuity from the private drug plans data supplier in 2021 and 2022 influenced the results for the demographic and volume effects. As such, the next Annual Report may include a revised estimate of these effects for those two years.

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

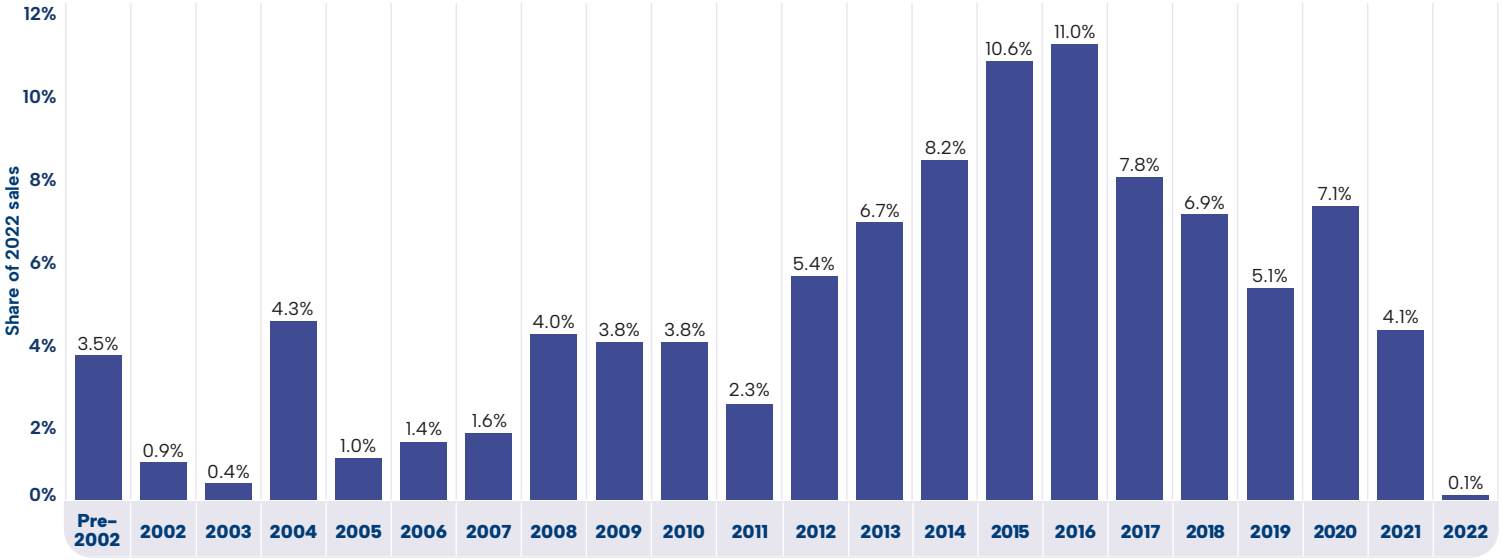
[i] Canadian Institute for Health Information. 2020. *Prescribed Drug Spending in Canada, 2020: A Focus on Public Drug Programs.* Ottawa, ON: CIHI. Available: **https://www.cihi.ca/sites/default/files/document/prescribed-drug-spending-in-canada-2020-report-en.pdf**

[NPDUIS Report: *CompassRx 2021/22*; NPDUIS Poster: Pressures behind the Rising Costs in Canadian Private Drug Plans, 2018 – graph updated to 2022]

NEWER MEDICINES DRIVING SALES REVENUES

Figure 8 breaks down the 2022 sales of patented medicines according to the year in which the medicine was first issued a Notice of Compliance (NOC) by Health 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. In recent years, 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.

FIGURE 8. SHARE OF 2022 SALES OF PATENTED MEDICINES BY DATE OF FIRST NOTICE OF COMPLIANCE (NOC)



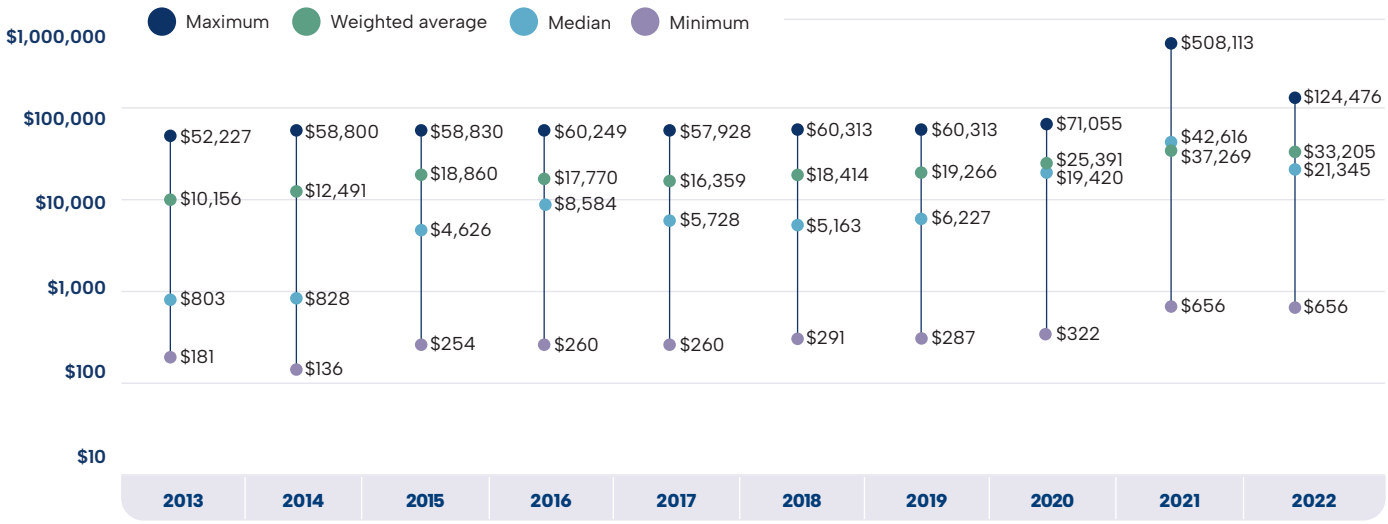
Data source: PMPRB

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 accounting for a substantial share of sales.

Figure 9 details the trend in the treatment costs of patented medicines since 2013. For many years, the majority of the 20 top-selling patented medicines had annual treatment costs under $1,000, but in recent years, costs for the top-sellers have soared into the thousands or tens of thousands of dollars. In 2022, the top 20 medicines, which accounted for 37.7% of patented medicine sales, had a median annual treatment cost of $21,345, more than 25 times the median in 2013.

FIGURE 9. ANNUAL TREATMENT COSTS FOR THE 20 TOP-SELLING PATENTED MEDICINES, 2013 TO 2022



Data source: PMPRB; IQVIA Private Pay Direct Drug Plan database, 2013–2022

High-cost medicines continue to dominate the pharmaceutical landscape

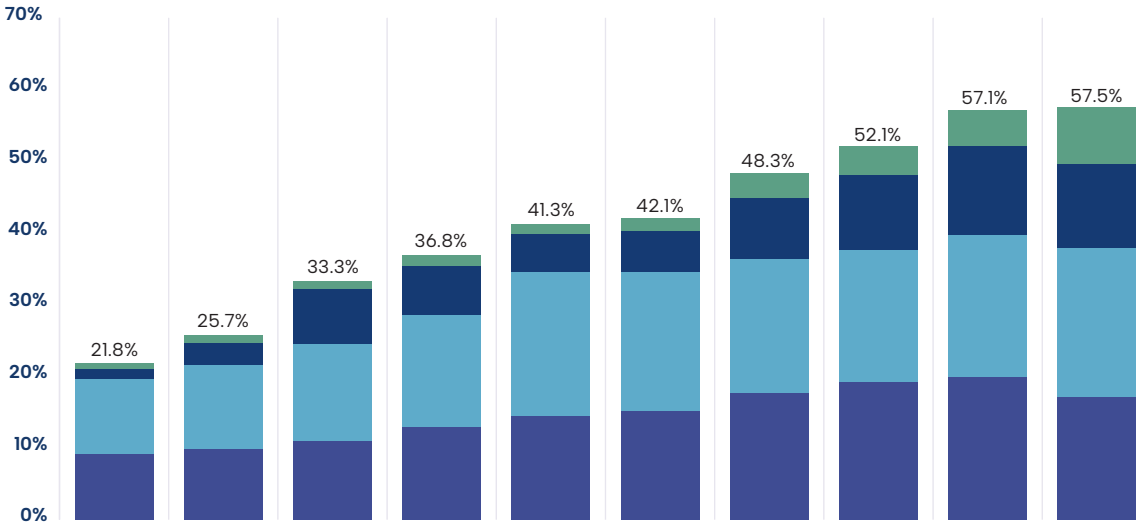
The 20 top-selling medicines in 2022 had a

MEDIAN ANNUAL TREATMENT COST OF $21,345,

compared to just $803 in 2013.

Figure 10 shows that high-cost medicines represent a growing share of the total sales of patented medicines, rising steeply from 21.8% in 2013 to 57.5% in 2022. This growth was evident in all ranges of annual treatment costs ($10,000 to $20,000; $20,000 to $50,000; $50,000 to $100,000; and $100,000 and over), with medicines in the highest cost band climbing from 0.8% to 7.9% of sales over the same period. Despite the sharp increase in their 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, 2013 TO 2022



Share of sales (%)	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
$10K to $20K	9.1	9.8	11.0	12.9	14.4	15.1	17.6	19.2	19.9	17.1
$20K to $50K	10.5	11.7	13.4	15.6	20.2	19.4	18.7	18.4	19.8	20.7
$50K to $100K	1.4	3.2	7.7	6.9	5.2	5.8	8.6	10.4	12.4	11.8
$100K+	0.8	1.0	1.2	1.4	1.5	1.8	3.4	4.1	5.0	7.9
Total*	21.8	25.7	33.3	36.8	41.3	42.1	48.3	52.1	57.1	57.5
High-cost medicines	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
Cost ($millions)	$3,624	$4,284	$5,549	$6,141	$6,864	$6,996	$8,330	$9,124	$9,956	$10,587
Total no. of medicines	105	116	129	143	150	162	172	189	201	204
$10K to $20K	39	40	42	44	47	49	52	57	60	51
$20K to $50K	45	50	58	68	69	73	71	74	74	76
$50K to $100K	11	15	17	18	20	24	29	35	38	44
$100K+	10	11	12	13	14	16	20	23	29	33
Avg. treatment cost ($thousands)	$37.8	$41.4	$44.8	$43.5	$42.7	$45.8	$51.8	$53.9	$59.0	$63.3
Estimated treatment population (thousands)	167.2	186.9	222.4	254.1	284.8	285.8	331.3	349.8	370.3	366.7
Share of total Cdn population	0.48%	0.53%	0.62%	0.70%	0.77%	0.78%	0.88%	0.92%	0.97%	0.94%

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

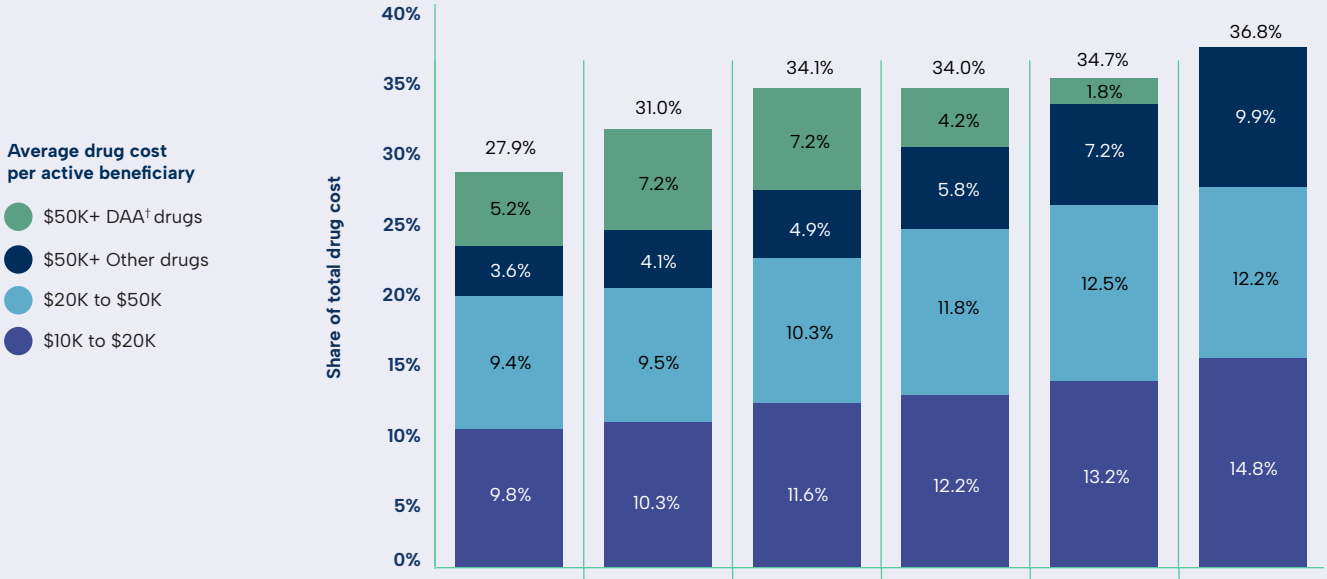
* Values may not add to totals due to rounding.

Data source: PMPRB; IQVIA Private Pay Direct Drug Plan database, 2013–2022

BRIEF INSIGHTS: HIGH-COST MEDICINES IN PUBLIC DRUG PLANS

High-cost medicines account for 36.8% 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. Public plans reimbursed 144 high-cost medicines in fiscal year 2021-22, while private drug plans reimbursed 264 high-cost medicines in calendar year 2022.

FIGURE 11. TRENDS IN THE NUMBER AND SHARE OF HIGH-COST MEDICINES, NPDUIS PUBLIC DRUG PLANS*, 2016-17 TO 2021-22



	2016–17	2017–18	2018–19	2019–20	2020–21	2021–22
Total cost for high-cost medicines ($millions)	$2,347.4	$2,829.0	$3,288.3	$3,426.0	$3,483.9	$4,009.1
Total no. of medicines§	103	107	121	130	135	144
Share of active beneficiaries	1.73%	1.75%	1.72%	2.12%	2.51%	2.98%
Share of prescriptions	0.30%	0.34%	0.38%	0.40%	0.42%	0.49%

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.

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.

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 (NIHB) Program. Results from 2020-21 do not include the NIHB program.

† DAA: Direct-acting antivirals for the treatment for hepatitis C, which were launched in 2014 and 2015. See earlier cost driver analysis (Figure 7) for more information.

‡ 2021-22 results included the cost share for >$50K DAA drugs (1.5%).

§ The total number of high-cost medicines reimbursed by the NPDUIS public drug plans is calculated using prescription drug utilization data, which includes claims for all medicines funded by public plans, and does not necessarily reflect the number of medicines listed on the formularies for these plans.

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

[NPDUIS Report: *CompassRx 2021/22* (pre-publication results)]

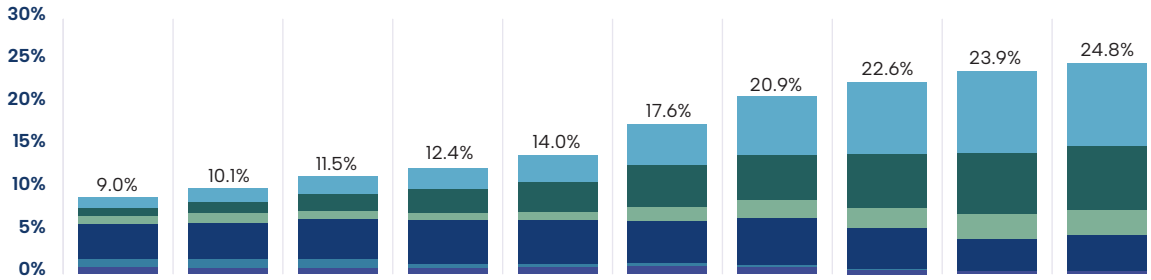
The shift toward higher-cost treatments is especially evident in oncology medicines. Figure 12 shows the share of total sales for patented oncology medicines by treatment cost based on a standard 28-day treatment regimen.[8]

The number of patented oncology medicines with 28-day treatment costs over $7,500 rose from 15 to 68 between 2013 and 2022, now accounting for 17.3% of total patented medicine sales.

As a result, the average treatment cost for oncology medicines in 2022 was $14,024, compared to $5,564 in 2013.

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, 2013 TO 2022



Share of sales (%)	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Other*	0.8	0.7	0.7	0.7	0.8	0.9	0.8	0.5	0.3	0.3
<$2.5K	1.0	1.0	1.0	0.5	0.4	0.4	0.3	0.1	0.1	0.1
$2.5K to $5.0K	4.1	4.3	4.8	5.1	5.1	4.9	5.5	4.8	3.7	4.2
$5.0K to $7.5K	0.9	1.1	0.9	0.9	1.0	1.7	2.0	2.3	3.0	2.9
$7.5K to $10.0K	0.9	1.3	2.0	2.8	3.5	4.9	5.4	6.4	7.1	7.5
$10.0K+	1.3	1.7	2.1	2.4	3.2	4.8	6.9	8.5	9.7	9.8
Total†	9.0	10.1	11.5	12.4	14.0	17.6	20.9	22.6	23.9	24.8
Oncology medicines	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
Cost ($millions)	$1,520	$1,678	$1,898	$2,050	$2,324	$2,939	$3,584	$3,947	$4,172	$4,559
Total no. of medicines	60	69	72	77	80	91	94	105	113	117
Other*	9	11	10	10	10	10	9	16	7	5
<$2.5K	13	12	12	10	10	8	7	6	7	6
$2.5K to $5.0K	15	16	17	17	17	18	18	19	21	20
$5.0K to $7.5K	8	12	12	14	13	15	16	16	20	18
$7.5K to $10.0K	7	9	10	13	15	19	21	22	25	24
$10.0K+	8	9	11	13	15	21	23	26	33	44
Avg. 28-day treatment cost	$5,564	$6,210	$6,656	$6,699	$7,039	$7,680	$9,320	$13,304	$13,478	$14,024
Estimated treatment population (thousands)	589.0	607.6	600.1	464.9	468.6	512.5	567.1	562.8	561.6	638.4
Share of total Cdn population	1.68%	1.71%	1.68%	1.28%	1.27%	1.37%	1.51%	1.48%	1.47%	1.61%

Note: The methodology for this analysis was revised in 2018 and 2019, and as such, historical results may not match those reported in earlier editions. 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

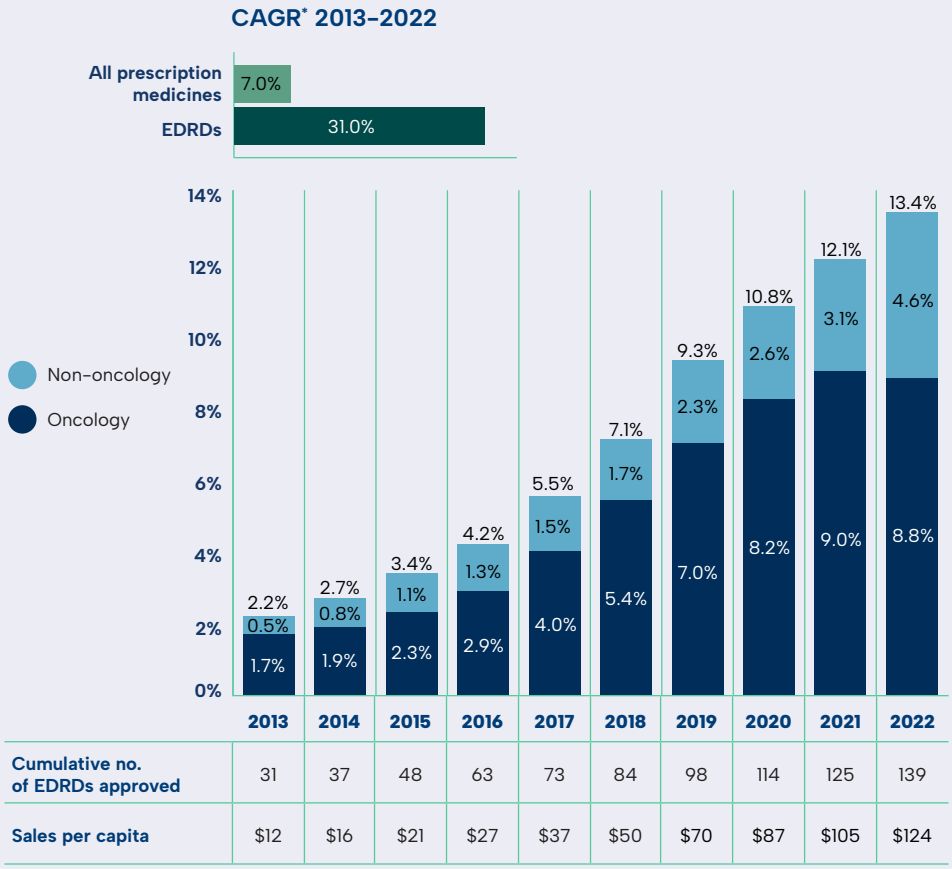
BRIEF INSIGHTS:

SPENDING ON EXPENSIVE DRUGS FOR RARE DISEASES

Expensive drugs for rare diseases (EDRDs) represent an increasing share of the Canadian pharmaceutical market, due to sales growth of existing medicines as well as the rapid pace of new launches, with at least 10 new EDRDs gaining approval in each year since 2015. Compound annual growth in EDRD sales over the past decade has been higher than the total pharmaceutical market, such that EDRDs made up 13.4% of sales in 2022. Two thirds of EDRD spending in 2022 was for oncology medicines.

Using NPDUIS drug plan data, it is estimated that 0.2% of public drug plans patients were reimbursed for an EDRD-related claim in 2022. These claims accounted for 6.8% of the total drug costs within public drug plans. This percentage does not include the use of oncology EDRDs in plans with alternative cancer coverage or EDRDs administered in hospitals, which are not recorded in the database, and may count some patients who received an orphan-designated medicine for one of its non-orphan indications.

FIGURE 13. EDRD SHARE OF THE PHARMACEUTICAL MARKET IN CANADA, ONCOLOGY AND NON-ONCOLOGY, 2013 TO 2022



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Cumulative no. of EDRDs approved	31	37	48	63	73	84	98	114	125	139
Sales per capita	$12	$16	$21	$27	$37	$50	$70	$87	$105	$124

Note: The data for this analysis was updated and, as such, historical results may not match those reported in previous editions.

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 or $7,500 per 28 days for oncology drugs.

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

Data source: PMPRB; MIDAS® database, 2013–2022, IQVIA (all rights reserved)

[NPDUIS Chartbook: *Expensive Drugs for Rare Diseases: Canadian Trends and International Comparisons, 2011–2020* – content updated for 2022]

TOP THERAPEUTIC CLASSES DRIVING SALES REVENUES

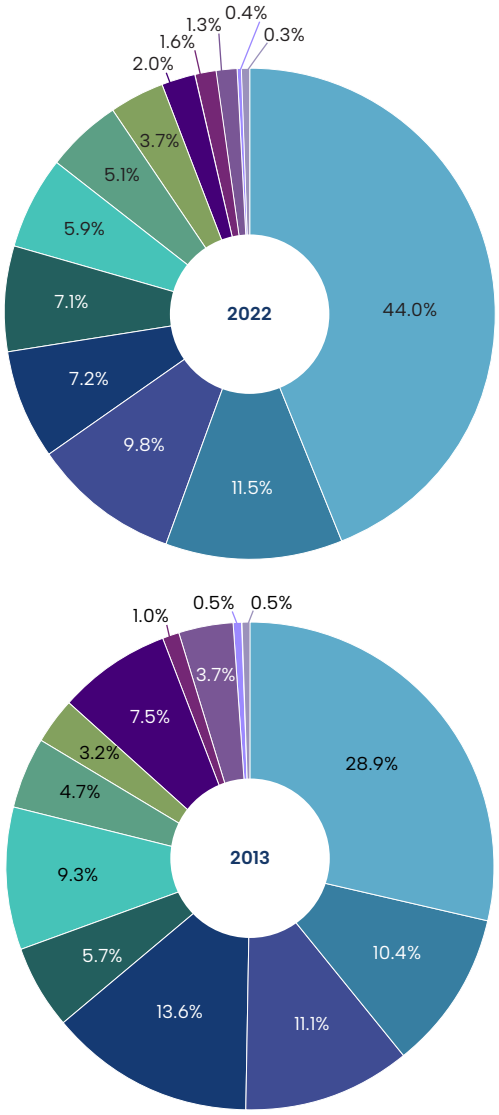
"Antineoplastics and immunomodulating agents", "alimentary tract and metabolism", and "general antiinfectives for systemic use and antiparasitic products" were the three top-selling therapeutic classes in 2022, accounting for close to two thirds of all patented medicine sales. The "antineoplastics and immunomodulating agents" class experienced a 3.3% increase in sales between 2021 and 2022 while "systemic hormonal preparations" had the greatest year-over-year decrease at -55.8%.

Figure 14 breaks down 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.[9] It compares the distribution of sales by therapeutic class in 2013 and 2022 and provides the rates of growth in sales for each class from 2021 to 2022.

The "antineoplastics and immunomodulating agents" class accounted for a much larger share of sales in 2022 (44.0%) than in 2013 (28.9%), as more oncology medicines entered the market over the past decade, many of which were high cost. By contrast, the share of sales held by "cardiovascular system" medicines decreased from 7.5% to 2.0% over the same period, continuing the trend observed in previous years.

FIGURE 14. SALES OF PATENTED MEDICINES BY MAJOR THERAPEUTIC CLASS, 2022

Share of Sales, 2022 versus 2013



Therapeutic class	2022 sales ($millions)	Growth: 2022/2021, $millions (rate in %)	2022 share of sales (%)
L: Antineoplastics and immunomodulating agents	$8,104.2	$257.2 (3.3%)	44.0%
A: Alimentary tract and metabolism	$2,112.6	$11.3 (0.5%)	11.5%
J: General antiinfectives for systemic use and P: Antiparasitic products*	$1,798.7	$197.9 (12.4%)	9.8%
N: Nervous system	$1,321.8	$164.9 (14.3%)	7.2%
B: Blood and blood forming organs	$1,298.2	-$22.8 (-1.7%)	7.1%
R: Respiratory system	$1,092.5	$380.3 (53.4%)	5.9%
S: Sensory organs	$944.2	$63.3 (7.2%)	5.1%
M: Musculo-skeletal system	$686.3	$21.8 (3.3%)	3.7%
C: Cardiovascular system	$370.2	-$4.2 (-1.1%)	2.0%
D: Dermatologicals	$294.6	-$16.7 (-5.4%)	1.6%
G: Genito-urinary system and sex hormones	$246.2	-$10.8 (-4.2%)	1.3%
V: Various	$74.2	-$9.5 (-11.3%)	0.4%
H: Systemic hormonal preparations	$59.5	-$75.0 (-55.8%)	0.3%
All therapeutic classes†	**$18,403.0**	**$957.7**	**100%**

* Medicines that stop reporting their sales to the PMPRB can factor into growth rates for the relevant therapeutic areas. Please refer to Figures 5 and 6 for a discussion on medicines that exited the patented market in 2022.

† These groups have been combined for reasons of confidentiality.

‡ Values may not add to totals due to rounding.

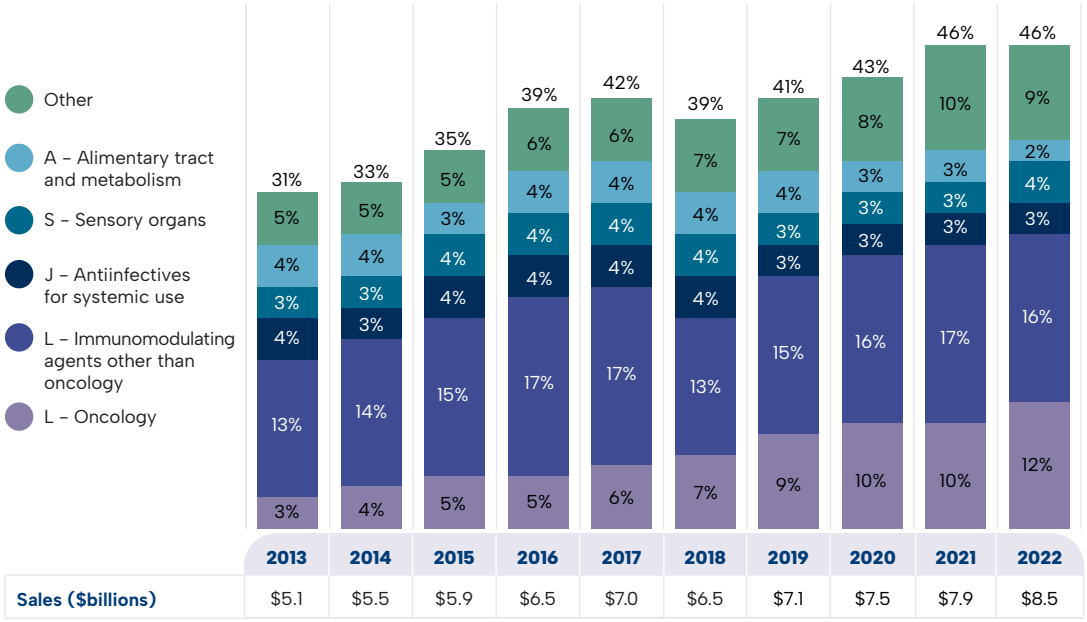
Data source: PMPRB

BIOLOGIC MEDICINES

Biologic medicines, many of which are in the high-cost category, capture a substantial share of the Canadian market. These medicines accounted for 46% of patented medicine sales in 2022, with the top three biologics alone representing more than 20% of sales. Figure 15 breaks down the annual share of sales for biologic patented medicines by major therapeutic class.

Although the share of biologic medicine sales has increased in many therapeutic classes, "immunomodulating agents other than oncology" had the highest uptake over the study period. Oncology medicines also represent a steadily growing share of the biologics market, increasing from 3% of patented medicine sales in 2013 to 12% in 2022.

FIGURE 15. BIOLOGIC MEDICINE SHARE OF PATENTED MEDICINE SALES BY THERAPEUTIC CLASS*, 2013 TO 2022



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Sales ($billions)	$5.1	$5.5	$5.9	$6.5	$7.0	$6.5	$7.1	$7.5	$7.9	$8.5

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: PMPRB

BRIEF INSIGHTS: BIOSIMILAR UPTAKE

Given the high use and cost of biologics in Canada, biosimilars offer an opportunity for significant cost savings, with list price discounts ranging from 25% to 50% off the reference biologic.[i] However, biosimilar substitution has more complexities than traditional generics as they are not considered identical to their originator medicines, but rather highly similar versions, and Health Canada's authorization of a biosimilar is not a declaration of equivalence to the originator biologic.

Recently, an increasing number of Canadian payers have undertaken initiatives to encourage switching from biologics to biosimilars with an aim of increasing biosimilar uptake. Results for the biosimilars targeted by these initiatives in 2022 show positive signs in terms of increased utilization. In British Columbia, the first Canadian province to implement a biosimilar switching initiative, biosimilars now account for 90% of the infliximab market, contributing to the increase in uptake observed nationally in recent years.

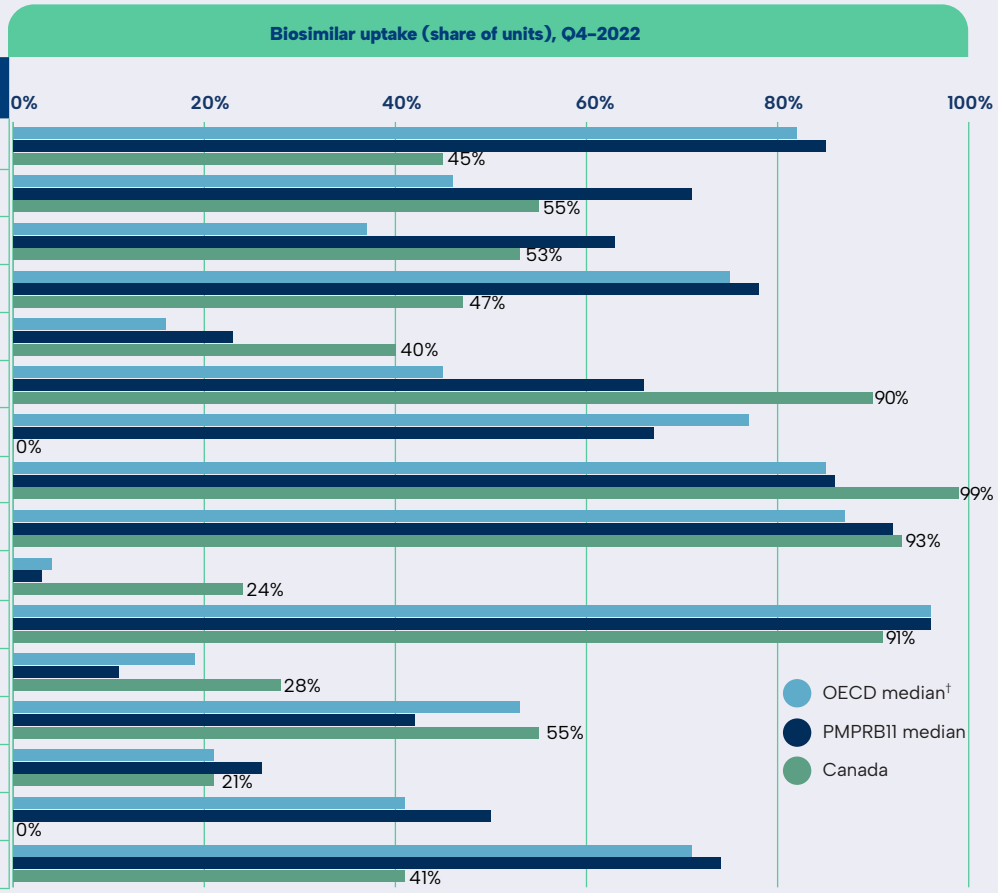
Biosimilars accounted for 45% of the total Canadian infliximab market in Q4-2022, compared to only 8% in Q4-2018, while shares in the etanercept and insulin glargine markets have increased to 53% and 40%, respectively (Figure 16). The recent market entry of biosimilars for adalimumab and rituximab have achieved sizable uptake for these two markets, reaching 55% and 47% of units sold by the last quarter of 2022, respectively.

While these results demonstrate growing use of biosimilars, biosimilar uptake in Canada is moderate compared to international markets, particularly for high-selling products. Canada's 45% biosimilar share of infliximab in 2022 was well below the OECD and PMPRB11 medians, at 82% and 85% respectively (Figure 17).

Continued on next page...

FIGURE 16. BIOSIMILAR SHARE OF UNITS BY MEDICINE, CANADA, THE OECD, AND THE PMPRB11, Q4-2022

Biologic medicine	Sales in Canada, 2022 ($millions)
Infliximab	$1,227
Adalimumab	$875
Etanercept	$240
Rituximab‡	$217
Insulin glargine	$208
Trastuzumab‡	$118
Epoetin alfa*	$116
Pegfilgrastim*	$106
Bevacizumab‡	$97
Insulin aspart	$92
Filgrastim*	$90
Insulin lispro	$80
Enoxaparin	$54
Somatropin	$45
Follitropin alfa*	$23
Teriparatide	$9



Note: The 2022 update uses PMPRB11 comparator countries in place of PMPRB7.

* Generally used to treat acute conditions.

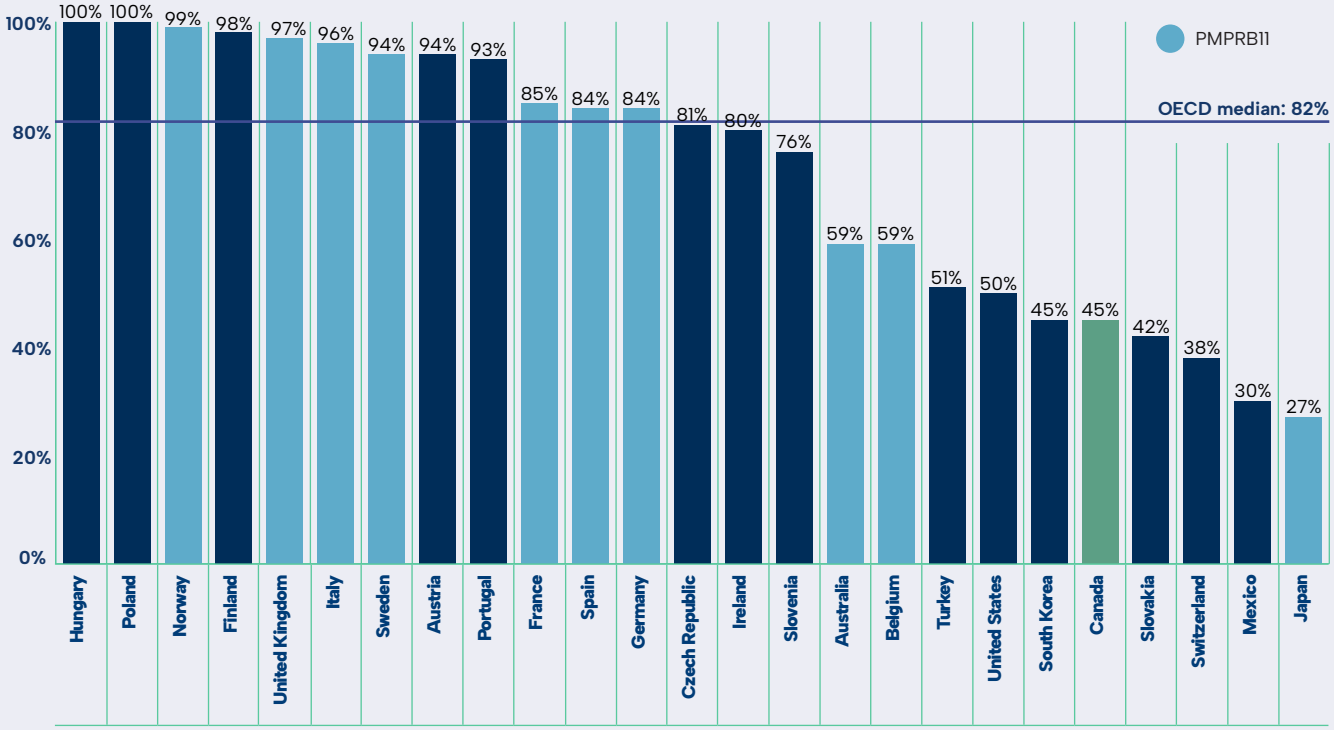
† Canada is excluded from the median OECD value.

‡ Mainly used for treatment of oncology indications and administrated in hospitals in Canada.

Data source: MIDAS® database, prescription retail and hospital markets, 2022, IQVIA (all rights reserved)

Continued on next page...

FIGURE 17. UPTAKE OF INFLIXIMAB BIOSIMILARS BY SHARE OF UNITS, OECD, Q4-2022



Note: Countries with limited data were excluded from the analysis. The 2022 update highlights PMRPB11 countries instead of PMPRB7.

Data source: MIDAS® database, prescription retail and hospital markets, Q4-2022, IQVIA (all rights reserved)

i PMPRB. 2021. Poster: Biosimilars in Canada: building momentum in the wake of recent switching policies. Presented at CADTH Symposium; November 2021. Available: **https://www.canada.ca/en/patented-medicine-prices-review/services/npduis/analytical-studies/slide-presentations/biosimilars-cadth-2021.html**

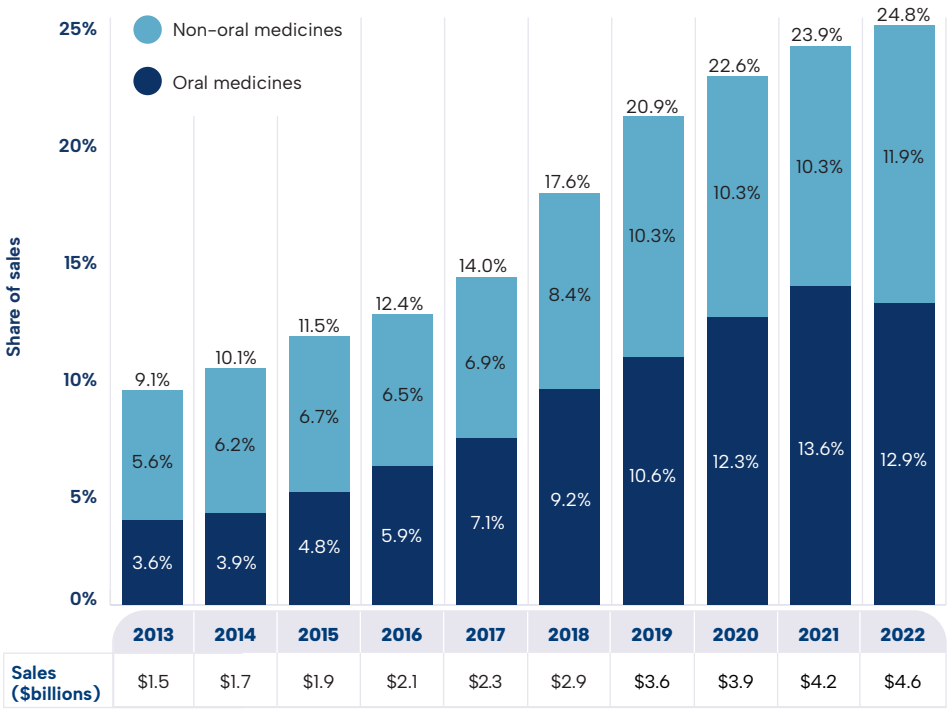
[NPDUIS Chartbook: *Biologics in Canada. Part 1: Market Trends, 2018* – graphs updated for 2022]

ONCOLOGY MEDICINES

Figure 18 illustrates the growth in the sales of patented oncology medicines since 2013. In 2022, oncology medicines accounted for 24.8% of total patented medicine sales, close to triple the 2013 share of 9.1%.

Oral forms of cancer treatment are a noteworthy emerging segment, representing more than half of all oncology medicine sales and 12.9% of the patented medicine market in 2022, compared to just 3.6% in 2013.[10]

FIGURE 18. ONCOLOGY MEDICINE SHARE OF PATENTED MEDICINE SALES BY FORMULATION, 2013 TO 2022



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Sales ($billions)	$1.5	$1.7	$1.9	$2.1	$2.3	$2.9	$3.6	$3.9	$4.2	$4.6

Note: 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-oncology 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 rights holders as of March 2023. On occasion, rights holders 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 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 considered in both graphs.

9 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.

10 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.[11] 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 rights holders 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 "Utilization of Patented Medicines"). 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 19 compares year-over-year changes in the PMPI to corresponding changes in the CPI from 2003 to 2022.

The PMPI is reported based on two measures: the national average transaction price, which is a net price; and the national list price, which is a gross price.[12] Both measures are reported to the PMPRB by rights holders. 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 2022, the CPI rose by 6.8%, while the national average transaction price and the national list price PMPIs increased by 0.8% and 0.9%, respectively.

FIGURE 19. ANNUAL RATE OF CHANGE, PATENTED MEDICINES PRICE INDEX (PMPI) AND CONSUMER PRICE INDEX (CPI), 2003 TO 2022

Rate of change (%)	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
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	0.7	3.4	6.8
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	1.0	0.6	0.4	0.8
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	1.6	0.5	0.9

Note: To account for revised submissions from rights holders, price and quantity indices are recalculated for the five years preceding the current Annual Report year. If the data has been revised, the values reported here may differ from those presented in earlier Annual Reports.

Data source: PMPRB; Statistics Canada

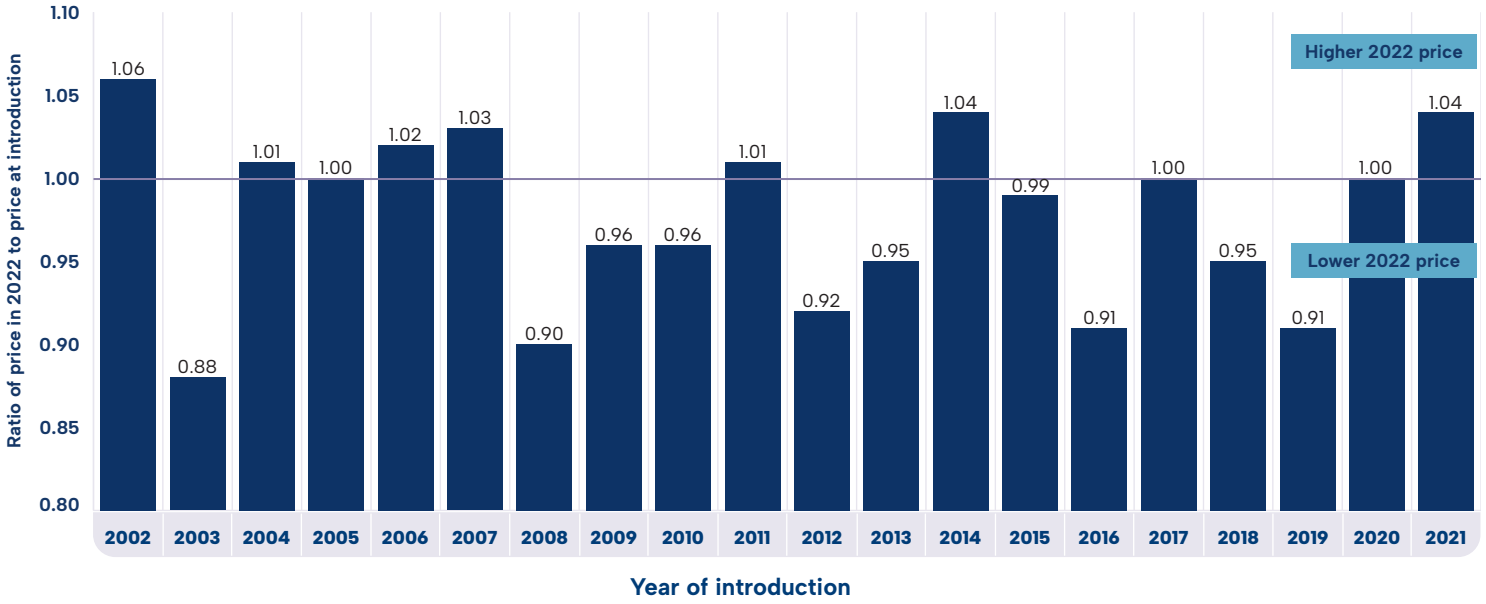
PRICE BEHAVIOUR AFTER INTRODUCTION

Do the average prices of patented medicines change much in the years after entry into the Canadian market? To answer this question, Figure 20 provides the average ratio of the 2022 average transaction price to the introductory price (the price at which the medicine was sold in its first year on the Canadian market) for medicines that entered the market each year since 2002.

The results suggest that over the last two decades, average transaction prices of patented medicines have remained relatively stable, with 2022 prices being on average 4% higher than the introductory price.[13] The average ratios for medicines introduced since 2002 ranged between 12% lower and 6% higher than their introductory prices depending on the introductory year.

A parallel analysis using list prices is available in Appendix 3.

FIGURE 20. AVERAGE RATIO OF 2022 PRICE TO INTRODUCTORY PRICE, BY YEAR OF INTRODUCTION



Note: This analysis is based on average transaction prices. For an alternative version based on list prices, see Appendix 3.
Data source: PMPRB

PRICE CHANGE BY COUNTRY

In 2022, in accordance with the Act and the Regulations, rights holders reported publicly available prices of patented medicines for 11 comparator countries (PMPRB11): Australia, Belgium, France, Germany, Italy, Japan, Spain, Sweden, Norway, the Netherlands, and the United Kingdom (UK).

The PMPRB uses this information to

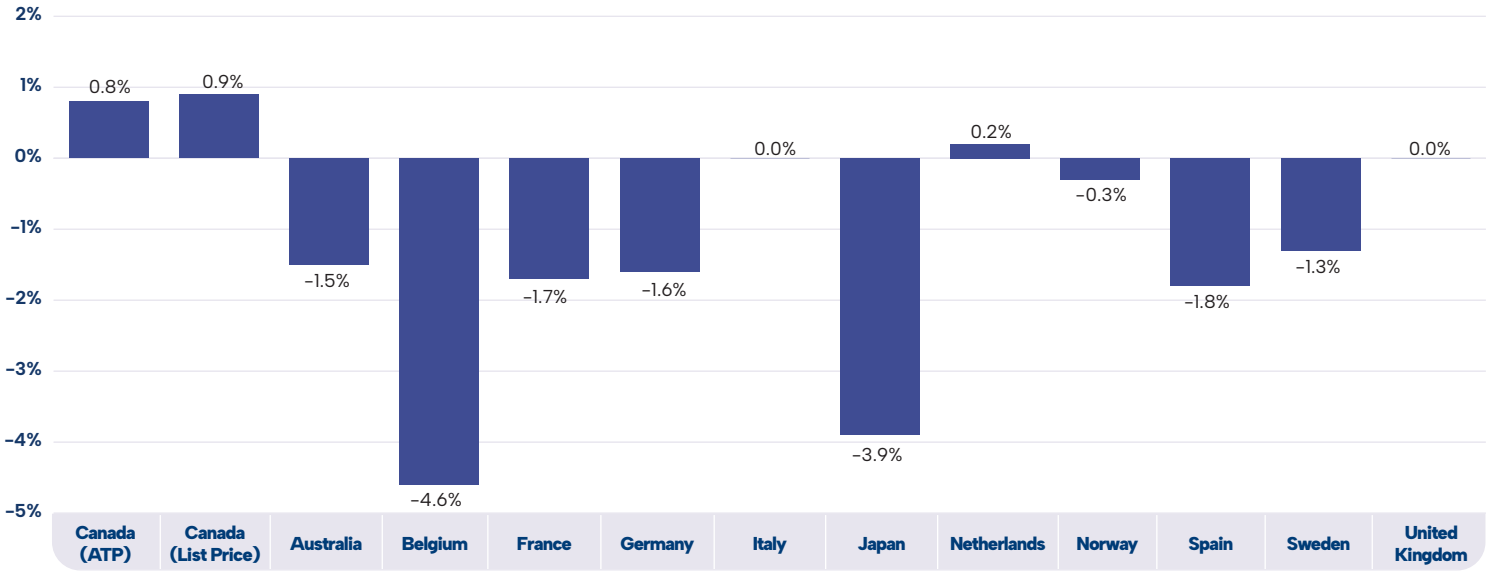
- conduct international price comparison tests; and
- compare the Canadian prices of patented medicines to those prevailing in other countries.

Figure 21 gives the average annual rates of price change for Canada and each of the PMPRB11 countries. These results were obtained by applying the PMPI methodology (with weights based on Canadian sales patterns) to the international price data that rights holders submitted to the PMPRB.

In 2022, Canadian average transaction prices saw a slight increase of 0.8%, while prices in the Netherlands, Italy, and the UK remained relatively steady. All other PMPRB11 countries saw average price decreases, most notably in Belgium (–4.6%) and Japan (–3.9%). These results are consistent with a long-term tendency for patented medicine prices to slowly fall over time in most comparator countries.

The foreign market results are based on publicly available gross prices, namely ex-factory price information (generally for the retail customer class) submitted by rights holders 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. To account for this difference, a rate of change for Canadian list prices is also provided as a point of comparison. In 2022, list prices in Canada increased by 0.9%.

FIGURE 21. ANNUAL AVERAGE RATES OF PRICE CHANGE, CANADA AND THE PMPRB11, 2022



Note: Prices for Australia, Belgium, Japan, Spain, Norway, and the Netherlands were sourced from the IQVIA MIDAS® database.

Data source: PMPRB; MIDAS® database, 2022, IQVIA (all rights reserved)

ENDNOTES

[11] 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.

[12] The national average transaction price is the Canadian "average price per package" or "net revenue from sales of each dosage form" referred to in s. 4(1)(f)(i) and 4(4) of the *Patented Medicines Regulations*; it does not include indirect rebates and discounts offered by rights holders such as certain rebates to provinces or insurers. The national list price is the gross Canadian "publicly available ex-factory price" referred to in s. 4(1)(f)(ii) of the *Patented Medicines Regulations*.

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

COMPARISON OF CANADIAN PRICES TO FOREIGN PRICES

Tables 7 and 8 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.[14]

The average price ratios given in Tables 7 and 8 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 2022 had they paid Country X prices rather than Canadian prices?

For example, Table 7 states that the 2022 average France-to-Canada price ratio for medicines available in both countries was 0.75. This means Canadians would have paid 25% less for the patented medicines they purchased in 2022 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 7 and 8 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 2022 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 8 provides bilateral comparisons of list prices in each of the PMPRB11 countries to average transaction prices in Canada. 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 in comparator countries. Prices reported for Australia, Belgium, France, Sweden, Norway, the Netherlands, and Italy were lower than Canadian prices, while prices in Germany were on par with Canada. Three countries—Japan, Spain, and the UK—continued to report prices that were higher than Canada. Year-to-year changes in these ratios may be influenced by variations in international exchange rates.

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 7 indicates how often an international price comparison was available for each of the comparator countries. For example, of the 1,112 DINs that reported a patent to the PMPRB in 2022 and had Canadian sales available at the time of analysis, 48% had a publicly available ex-factory price for France while 74% had a price for Germany. In this case, it is considered to constitute the international median price, as per the PMPRB's methodology.

When international differences in the cost of living are considered (using PPP), the average price ratios indicate that Canadians incurred a larger consumption cost for the patented medicines they purchased in 2022 than residents of Australia, France, Sweden, and Norway.

This analysis uses average transaction prices for the Canadian market. A parallel analysis using Canadian list prices is available in Appendix 3.

TABLE 7. AVERAGE FOREIGN-TO-CANADIAN PRICE RATIOS, BILATERAL COMPARISONS, CANADA AND THE PMPRB11, 2022

	Canada	Australia	Belgium	France	Germany	Italy	Japan	Netherlands	Norway	Spain	Sweden	United Kingdom
At market exchange rates												
Average price ratio 2022	1.00	0.76	0.88	0.75	1.00	0.99	1.11	0.99	0.91	1.01	0.86	1.03
Average price ratio 2021	1.00	0.71	0.88	0.74	1.00	0.98	0.90	0.77	0.88	0.96	0.88	1.00
At purchasing power parities												
Average price ratio 2022	1.00	0.71	1.06	0.93	1.18	1.36	1.30	1.10	0.76	1.40	0.88	1.16
Average price ratio 2021	1.00	0.67	1.03	0.90	1.19	1.33	0.98	0.86	0.82	1.32	0.90	1.14
Number of patented medicines compared 2022 (DINs)	1,112*	522	620	532	818	690	481	775	779	725	630	783
Sales ($millions)	$18,403.2	$14,333.6	$14,419.9	$11,827.3	$15,769.2	$14,830.9	$12,363.4	$15,672.8	$15,724.0	$14,731.0	$12,110.4	$15,587.5

Note: 2021 prices for Australia, Belgium, Japan, Spain, Norway, and the Netherlands were sourced from IQVIA'S MIDAS® database. This analysis is based on average transaction prices in Canada. For an alternative version using list prices in Canada, see Appendix 3.

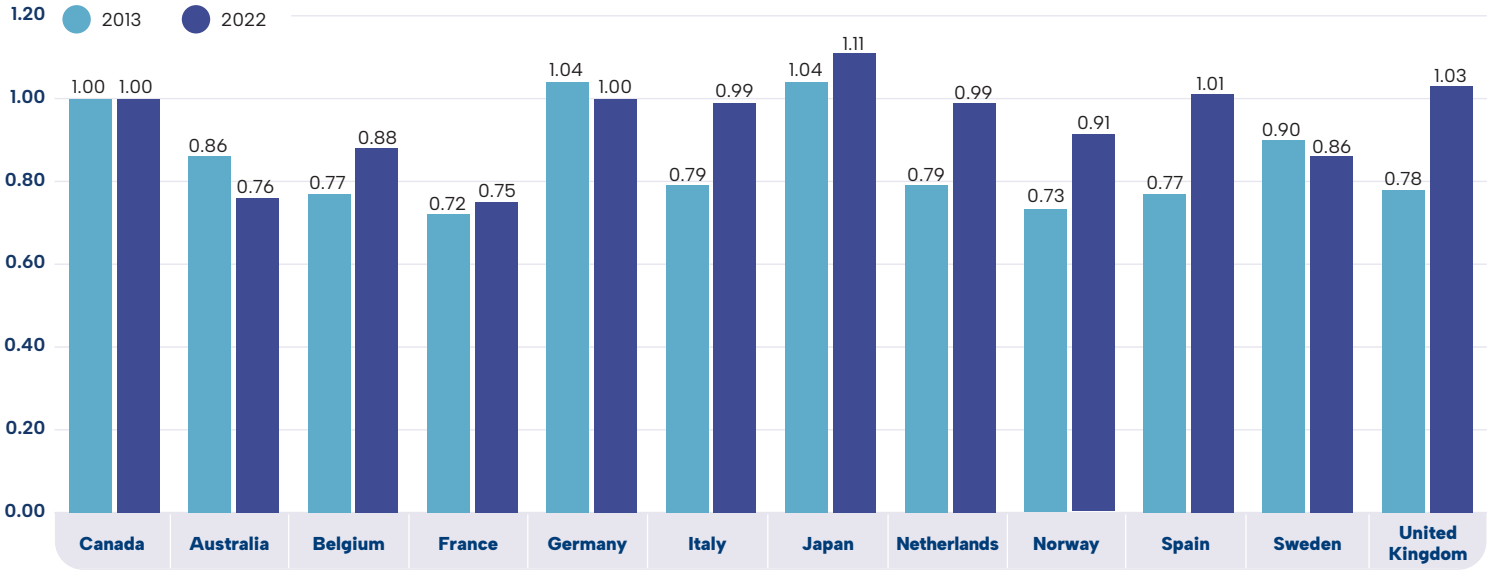
* Consistent with the methodology used throughout the Pharmaceutical Trends section, only medicines that reported to the PMPRB in 2022 and had available Canadian sales data at the time of the analysis were considered here. This is a subsection of the total number of medicines that reported to the PMPRB in 2022 and, as such, may not match the total reported in Table 4.

Data source: PMPRB; MIDAS® database, 2022, IQVIA (all rights reserved)

Figure 22 compares the 2022 foreign-to-Canadian price ratios (at market exchange rates) to those in 2013. While the ratios for Australia, Germany, and Sweden decreased over the past decade, price ratios for the eight other PMPRB11 comparators increased compared to Canada. In 2013, only three countries had a price ratio equal to or greater than 0.90, but by 2022 this number had increased to seven.

This analysis uses average transaction prices for the Canadian market. A parallel analysis using Canadian list prices is available in Appendix 3.

FIGURE 22. AVERAGE FOREIGN-TO-CANADIAN PRICE RATIOS, CANADA AND THE PMPRB11, 2013 AND 2022



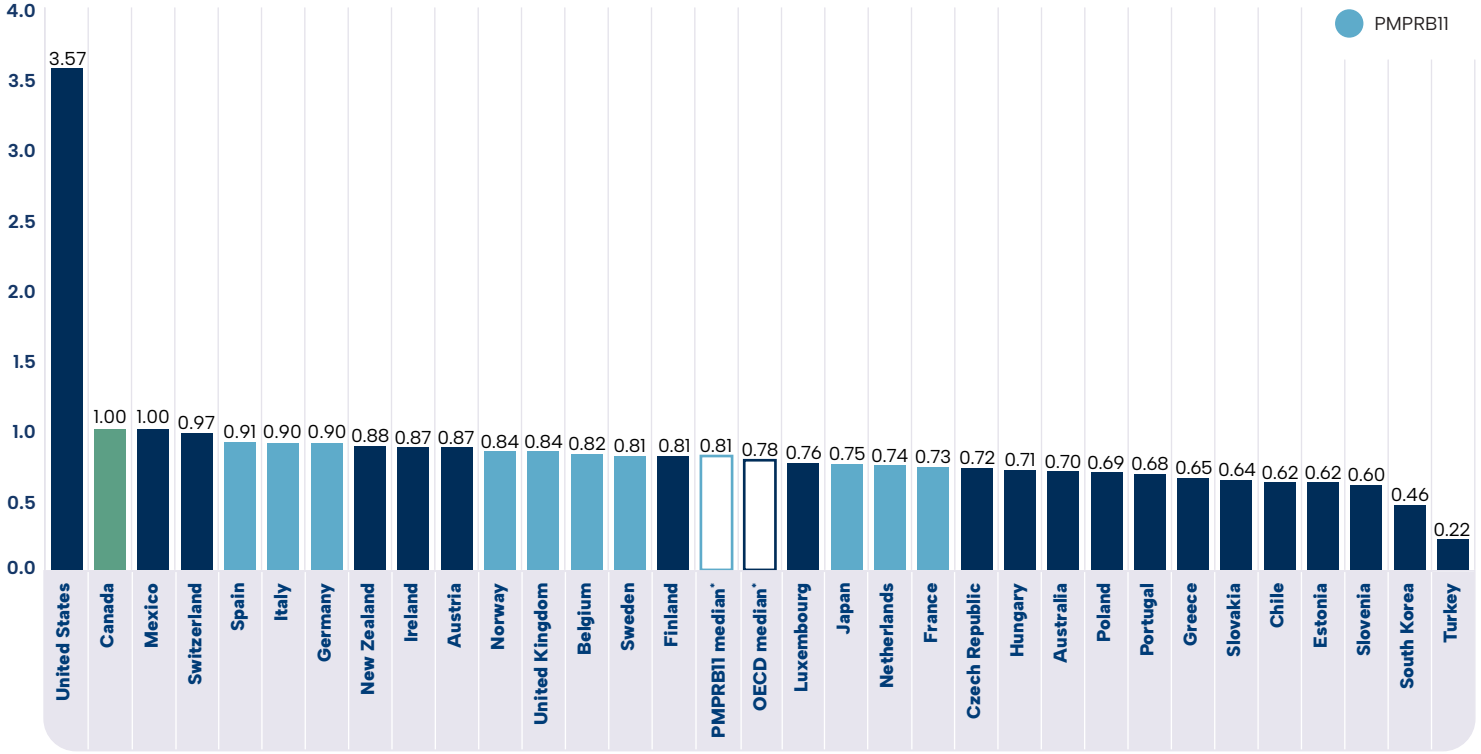
Note: 2013 prices for Australia, Belgium, Japan, Spain, Norway, and the Netherlands are sourced from the IQVIA MIDAS® database. This analysis is based on average transaction prices in Canada. For an alternative version using list prices in Canada, see Appendix 3.

Data source: PMPRB, MIDAS® database, 2013 and 2022, IQVIA (all rights reserved)

If a patented medicine is being sold in one or more of the PMPRB11 countries, the rights holder must report the publicly available ex-factory prices to the PMPRB for each class of customer.[15] Using this data, Figure 22 provides sales-weighted bilateral ratios comparing Canadian average transaction prices against foreign list prices. In order to assess how Canada compares to a basket of countries beyond the PMPRB11, Figure 23 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.[16] Note that the results presented in Figures 22 and 23 will differ somewhat due to the use of different data sources.

The international price comparisons reported in Figure 23 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 22. These are Canadian sales-weighted arithmetic averages of the corresponding foreign-to-Canadian price ratios for individual medicines. As shown in Figure 23, median OECD prices are, on average, approximately 22% lower than price levels in Canada, which are the second highest among the 31 countries.

FIGURE 23. AVERAGE FOREIGN-TO-CANADIAN PRICE RATIOS, PATENTED MEDICINES, OECD, 2022



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

Data source: PMPRB; MIDAS® database, 2022, IQVIA (all rights reserved)

BRIEF INSIGHTS:

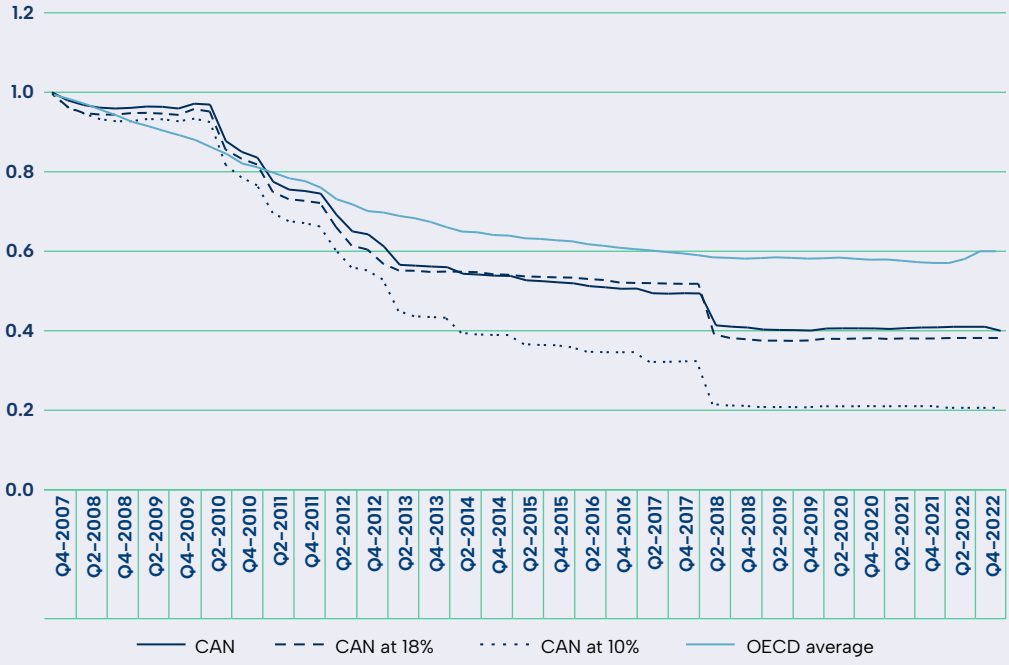
TRENDS IN THE PRICE OF GENERIC MEDICINES

The average price of generic medicines in Canada has dropped substantially, by 60% in Q4-2022 relative to price levels in 2007 (Figure 24). This was the fourth-highest rate of price reduction compared to the PMPRB11 markets, following Australia, Japan, and Germany. Since the end of 2018, Canadian average prices have had little variance.

The most recent Canadian generic pricing policy, implemented in 2018, had brought Canadian generic prices closer in line with average prices in the OECD.

Despite this shift, Canadian prices were still third highest in the PMPRB11 in the last quarter of 2022, behind only Japan and Spain (Figure 25). The median PMPRB11 country, France, had average prices 22% lower. In the broader OECD, median prices were 31% lower than in Canada, and just six other countries had higher average generic prices.

FIGURE 24. PRICE INDICES AND GENERIC PRICE REDUCTIONS, CANADA AND THE PMPRB11, Q4-2007 TO Q4-2022



Generic price reduction Q4-2007 to Q4-2022	
Australia	-86%
CAN at 10%	-80%
Japan	-64%
CAN at 18%	-62%
Germany	-60%
Canada	-60%
United Kingdom	-57%
Spain	-46%
France	-45%
OECD average	-40%
Belgium	-38%
Italy	-28%
Sweden	-26%
Norway	-11%

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. The Netherlands was excluded due to incomplete historical data.

Data source: MIDAS® database, October–December 2007 to October–December 2022, IQVIA (all rights reserved)

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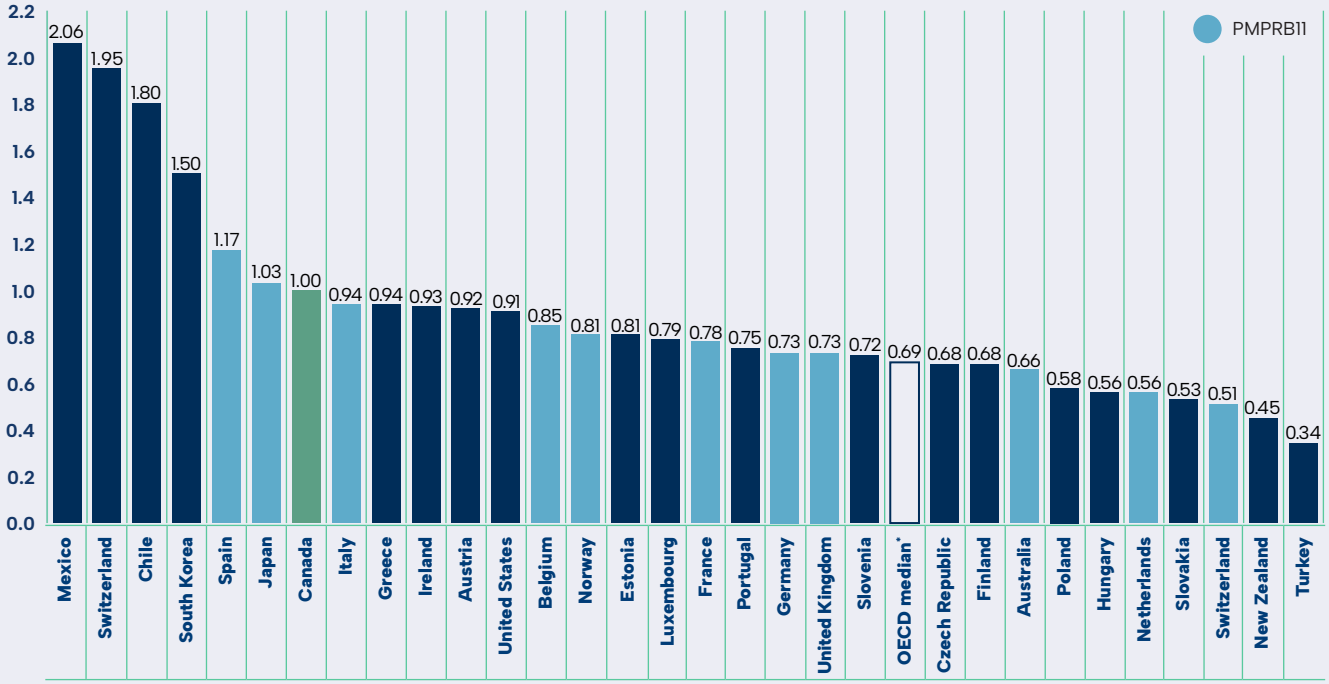
FIGURE 25. FOREIGN-TO-CANADIAN PRICE RATIOS FOR GENERIC MEDICINES, OECD, Q4-2022



* 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 2022, IQVIA (all rights reserved)

[NPDUIS Report: *Generics360, 2018* – graphs updated to 2022]

MULTILATERAL PRICE COMPARISONS

Table 8 provides average foreign-to-Canadian price ratios using several multilateral measures of foreign prices. The median international price (MIP) is the median of list prices observed among the PMPRB11. Other multilateral price ratios compare the minimum, maximum, and simple mean of PMPRB11 foreign prices to the Canadian average transaction price.

Focusing on the results based on market exchange rates, the average MIP-to-Canadian price ratio was 0.96 for the PMPRB11 in 2022, a slight increase over 2021 (Figure 26).

Both Table 8 and Figure 26 use average transaction prices for the Canadian market. Parallel analyses using Canadian list prices are available in Appendix 3.

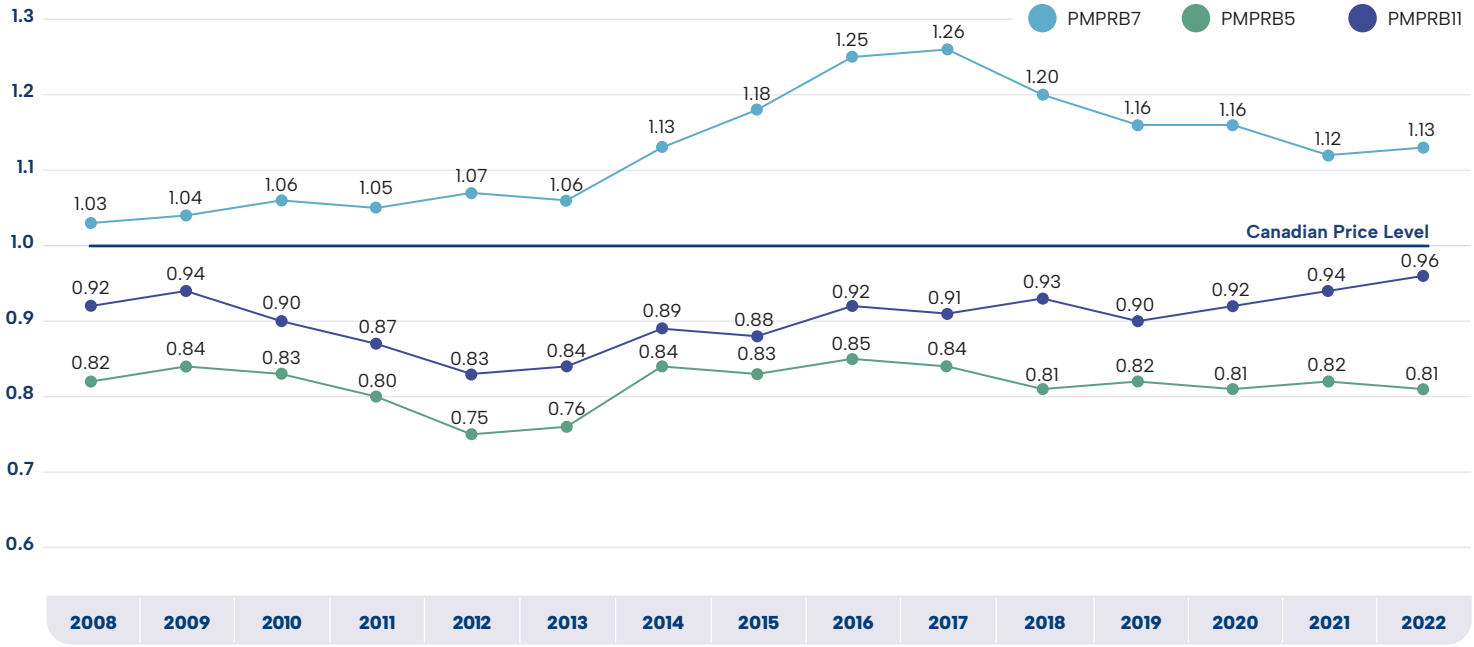
TABLE 8. AVERAGE FOREIGN-TO-CANADIAN PRICE RATIOS, MULTILATERAL COMPARISONS, 2022

	Median	Minimum	Maximum	Mean
Average price ratio at market exchange rates	0.96	0.69	1.34	0.97
Average price ratio at purchasing power parities	1.10	0.70	1.67	1.12
Number of patented medicines	955	955	955	955
Sales ($millions)	$17,713.13	$17,713.13	$17,713.13	$17,713.13

Note: This analysis is based on average transaction prices. For an alternative version based on list prices, see Appendix 3.

Data source: PMPRB

FIGURE 26. AVERAGE RATIO OF MEDIAN INTERNATIONAL PRICE (MIP) TO CANADIAN PRICE, AT MARKET EXCHANGE RATES, PMPRB7, PMPRB5, AND PMPRB11, 2008 TO 2022



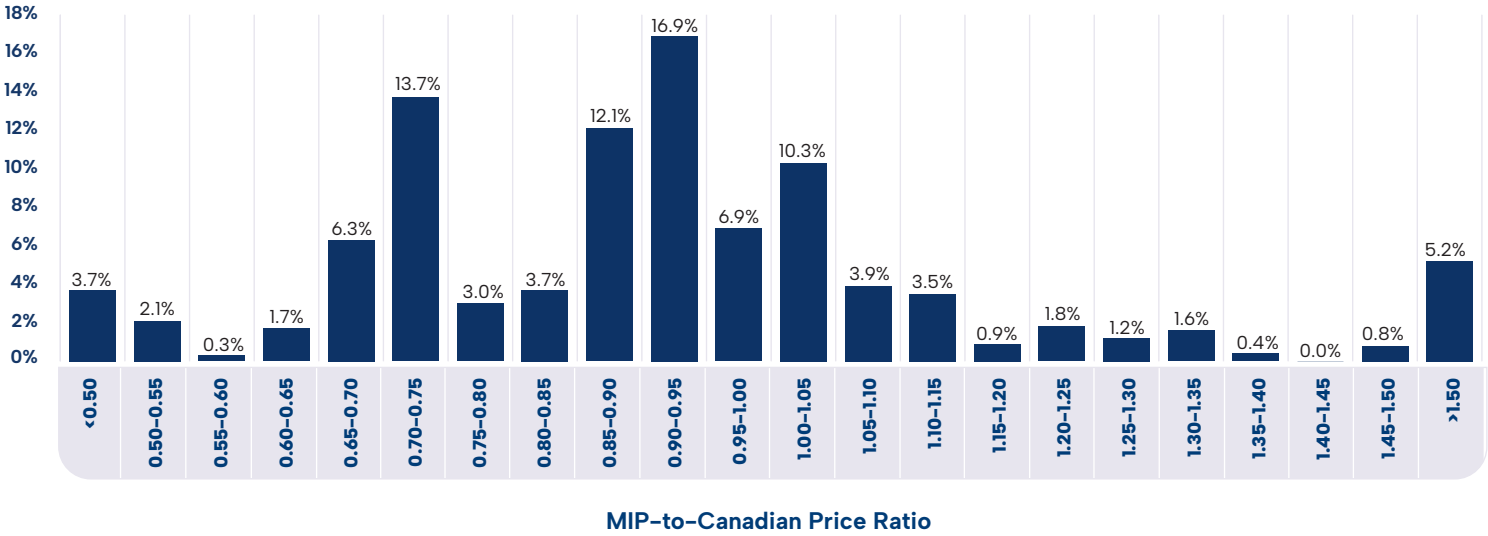
Note: PMPRB7 is France, Germany, Italy, Sweden, Switzerland, the United Kingdom (UK), and the United States (US). PMPRB5 removes Switzerland and the US. PMPRB11 is Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, and the UK. This analysis is based on average transaction prices in Canada. For an alternative version using list prices in Canada, see Appendix 3.

Data source: PMPRB; MIDAS® database, 2008–2022, IQVIA (all rights reserved)

Figure 27 offers more detail on the medicine-level MIP-to-Canadian ratios underlying the averages reported in Table 8. This figure distributes the 2022 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).[17] These results show a substantial dispersion in medicine-level price ratios: while patented medicines with MIP-to-Canadian price ratios between 0.90 and 1.10 accounted for 38.0% of sales, those with ratios less than 0.90 accounted for 46.6% of sales and medicines with ratios exceeding 1.10 accounted for the remaining 15.4%. Approximately one quarter of the medicines assessed had an MIP-to-Canadian ratio greater than 1.50.

This analysis uses average transaction prices for the Canadian market. A parallel analysis using Canadian list prices is available in Appendix 3.

FIGURE 27. RANGE DISTRIBUTION, SHARE OF SALES BY MIP-TO-CANADIAN PRICE RATIO, 2022



Note: This analysis is based on average transaction prices in Canada. For an alternative version using list prices in Canada, see Appendix 3.
Data source: PMPRB

In 2022, approximately 58% of Canadian patented medicines were priced above the median international level.[18] Table 9 examines the impact of this difference by therapeutic class. Medicines that share the fourth level ATC classification ("ATC4")[19] 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 9 identifies the top 10 ATC4s in 2022 in which the difference between Canadian and median prices had the largest effect on Canadian patented medicine spending. For example, had Canadian prices been in line with the international median for these classes of medicines in 2022, sales in Canada would have been reduced by approximately $1,559 million (an average reduction of 12% for these ATC4s). Of the 136 DINs classified into these 10 ATC4s, 53% were priced above the median international price.

TABLE 9. TOP 10 ATC4S* BY TOTAL SALES GREATER THAN MEDIAN INTERNATIONAL PRICES, 2022

Description	ATC4*	No. of companies	No. of chemicals in ATC4 (No. currently under patent)	Total patented DINs	Patented DINs greater than median price	2022 net revenues for patented DINs ($millions)	Patented DINs ATC4 share of 2022 revenues	MIP-to-Canadian ratio (min. 5) of patented DINs†	Impact of difference on patented medicines in 2022 ($millions)
Tumor necrosis factor alpha (TNF-α) inhibitors	L04AB	4	5 (3)	13	10	$861.50	4.68%	0.76	$221.87
Other muscle relaxants, peripherally acting agents	M03AX	3	3(3)	8	5	$358.80	1.95%	0.75	$211.42
Combinations of oral blood glucose lowering drugs	A10BD	5	11(6)	24	21	$400.72	2.18%	0.60	$207.08
Antineovascularisation agents	S01LA	4	5(4)	5	4	$743.37	4.04%	0.75	$190.76
Sodium-glucose co-transporter 2 (SGLT2) inhibitors	A10BK	3	4(3)	6	6	$670.00	3.64%	0.74	$178.54
Dipeptidyl peptidase 4 (DPP-4) inhibitors	A10BH	3	4(3)	7	7	$272.61	1.48%	0.52	$135.04
Selective immunosuppressants	L04AA	14	26(18)	30	4	$1,332.00	7.24%	0.94	$124.89
Centrally acting sympathomimetics	N06BA	2	5(3)	26	4	$411.17	2.23%	0.97	$105.49
Other respiratory system products	R07AX	1	5(4)	11	7	$606.14	3.29%	0.93	$93.09
Other drugs affecting bone structure and mineralization	M05BX	2	3(3)	6	4	$135.87	0.74%	0.80	$91.40

* 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 1.00.

Data source: PMPRB

ENDNOTES

[14] 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. All bilateral average price ratios reported in Table 7 combined represent at least 64% of 2022 Canadian sales, while the multilateral ratios in Table 8 cover over 96%.

[15] The publicly available ex-factory price includes any price of a patented medicine that is agreed on by the rights holder and the appropriate regulatory authority of the country.

[16] 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.

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

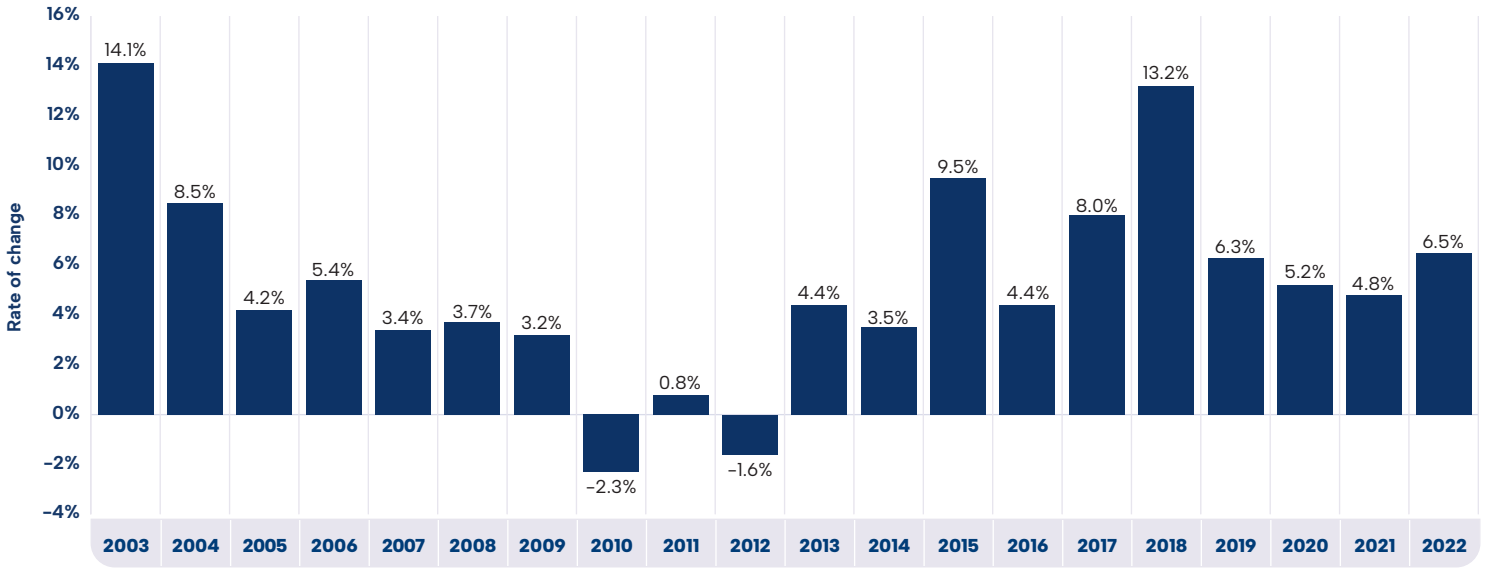
[18] This outcome is not inconsistent with the current Guidelines, which contemplate, post introduction, annual price increases in line with general inflation, as long as prices remain below the highest international price.

[19] 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 of S01LA (as found in Table 9), "S" indicates that these medicines treat the sensory organs; "01" that they specifically treat ophthalmological indications; "L" that they consist of ocular vascular disorder agents; and "A" that they are specifically antineovascularisation agents. An individual medicine belonging to this group is aflibercept (Eylea), represented by the fifth level ATC S01LA05. For further information, please refer to **http://www.whocc.no/atc_ddd_index/**

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 28 provides average rates of utilization growth, as measured by the PMQI, from 2003 through 2022.

FIGURE 28. ANNUAL RATE OF CHANGE, PATENTED MEDICINES QUANTITY INDEX (PMQI), 2003 TO 2022



Data source: PMPRB

CANADA IS A TOP 10 GLOBAL MARKET

Canada is an important market for pharmaceuticals representing 2.2% of worldwide sales in 2022.

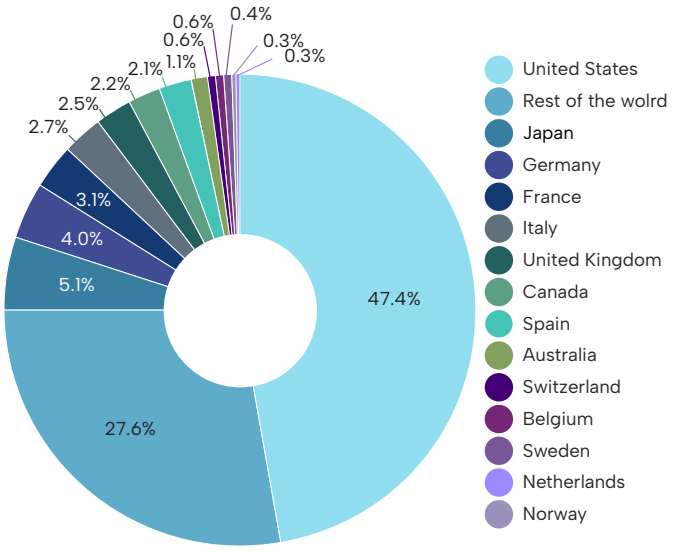
Canada spends nearly the same amount as the UK on pharmaceuticals despite having less than two thirds the population.

CANADIAN MEDICINE EXPENDITURES IN THE GLOBAL CONTEXT

IQVIA[20] regularly reports on medicine sales across a large number of countries. Based on sales data from this source, Figure 29 provides shares of global sales for Canada and other major national markets including the PMPRB11 countries.[21] The Canadian market accounted for 2.2% of the global market in 2022. Canada has been consistently at about 2.0%–2.5% over the last decade.

Figure 30 gives the average annual rate of growth in total medicine sales for Canada and the PMPRB11, individually and collectively. From 2013 to 2022, sales of medicines in Canada rose at an average annual rate of 5.5%. This is slightly above the average rate of growth in medicine sales among the PMPRB11 countries over the same period.

FIGURE 29. DISTRIBUTION OF MEDICINE SALES AMONG MAJOR NATIONAL MARKETS, 2022

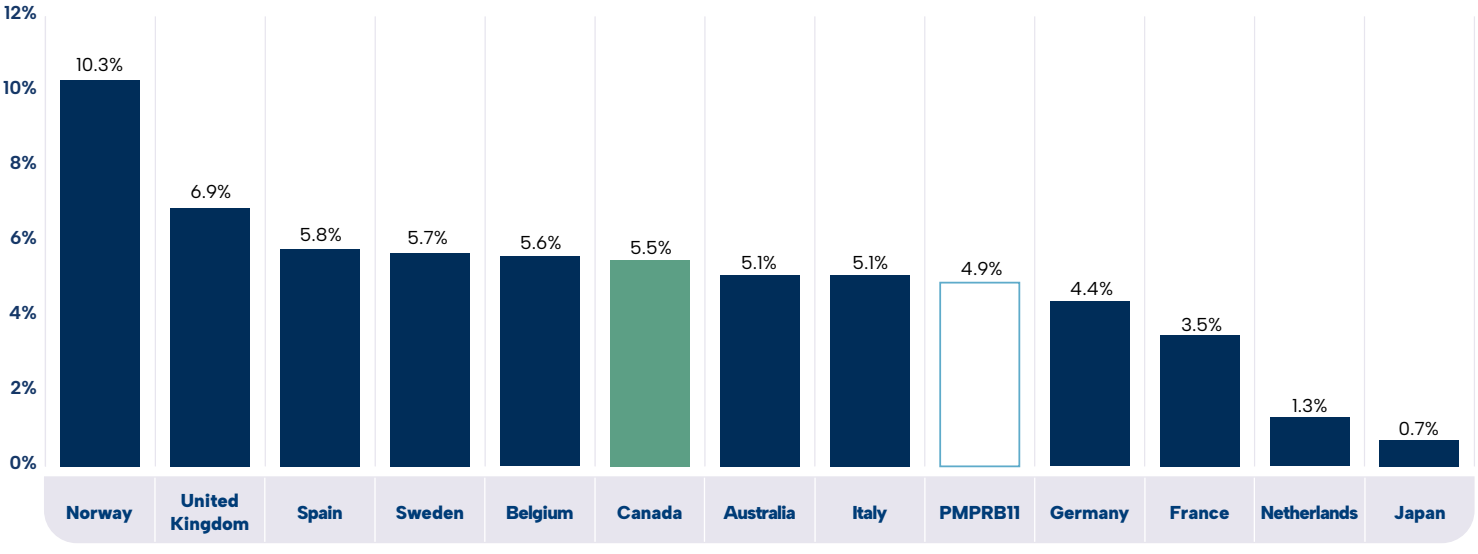


Data source: MIDAS® database, 2022, IQVIA (all rights reserved)

1.9% MEDICINE EXPENDITURES IN CANADA

In 2020, Canadians spent 1.9% of gross domestic product on medicines. This was the second highest share in the PMPRB11, behind only Japan.

FIGURE 30. AVERAGE RATE OF GROWTH OF MEDICINE SALES, AT CONSTANT 2022 MARKET EXCHANGE RATES, BY COUNTRY, CANADA AND THE PMPRB11, 2013 TO 2022

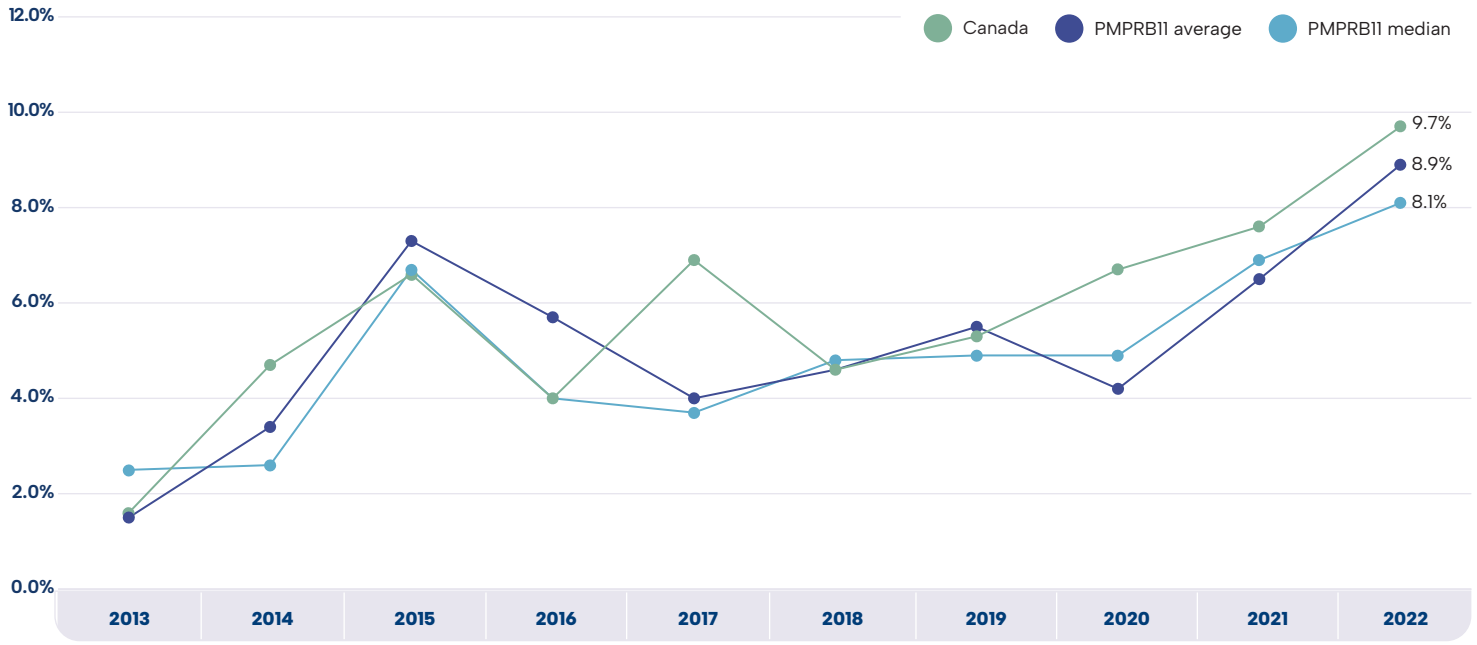


Data source: MIDAS® database, 2013–2022 IQVIA (all rights reserved)

Figure 31 compares rates of year-over-year growth in medicine sales for the entire pharmaceutical market in Canada and the PMPRB11 countries combined. In 2022, sales grew at a slightly faster rate in Canada than in the PMPRB11.

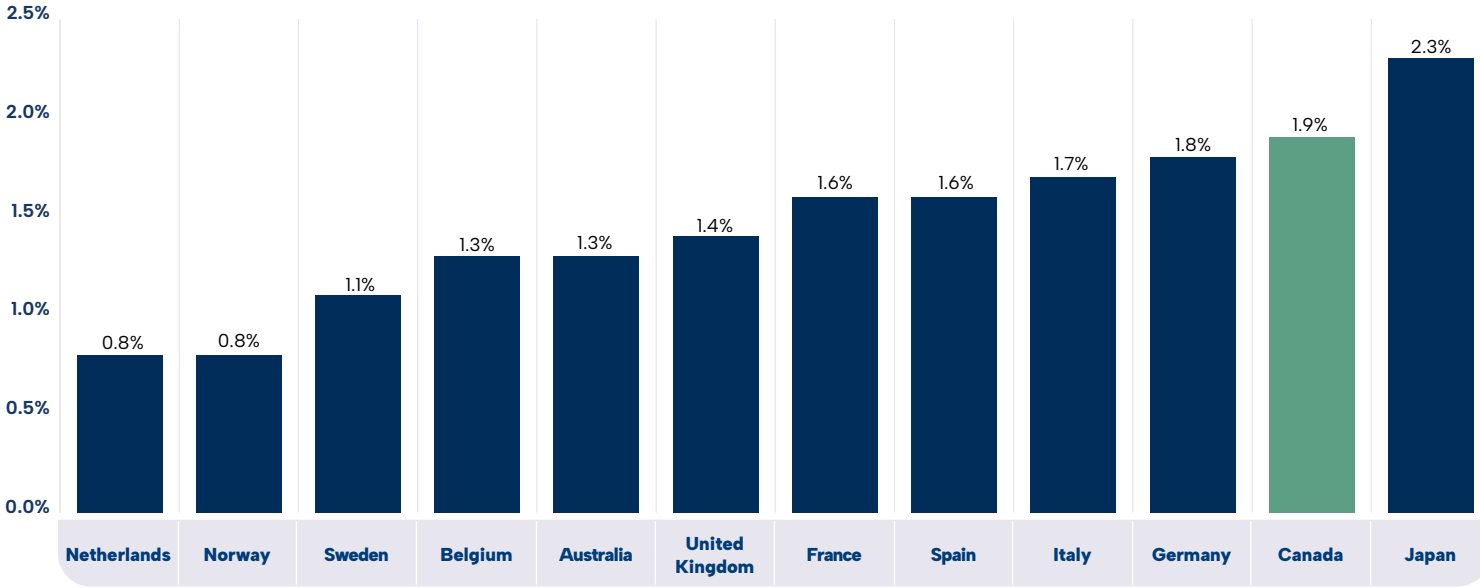
The proportion of national income allocated to the purchase of medicines provides another way to compare medicine costs across countries.[22] Figure 32 gives medicine expenditures as a share of gross domestic product (GDP) for Canada and the PMPRB11 countries based on data for 2020. Medicine expenditures absorbed between 0.8% and 2.3% of the GDP in the PMPRB11. The Canadian value of 1.9% was second only to Japan but just slightly above Germany (1.8%) and Italy (1.7%).

FIGURE 31. AVERAGE ANNUAL RATE OF CHANGE IN MEDICINE SALES, AT CONSTANT 2022 MARKET EXCHANGE RATES, CANADA AND THE PMPRB11, 2013 TO 2022



Data source: MIDAS® database, 2013–2022, IQVIA (all rights reserved)

FIGURE 32. MEDICINE EXPENDITURES AS A SHARE OF GDP, CANADA AND THE PMPRB11, 2020



Data source: OECD

Table 10 provides a historical perspective on the expenditures-to-GDP ratio and per capita spending.[23] Between 2011 and 2020, Canada's ratio was unchanged, and the ratios of three PMPR11 countries—Belgium, France, and the Netherlands—declined. In 2020, Canada had the third-highest spending per capita on medicines compared to the PMPRB11, behind the Japan and Germany.

TABLE 10. MEDICINE EXPENDITURES AS A SHARE OF GDP AND PER CAPITA, CANADA AND THE PMPRB11, 2011 AND 2020

	Share: Medicine Expenditures/GDP 2011	Share: Medicine Expenditures/GDP 2020	Growth: GDP 2011–2020	Medicine spending per capita 2011 ($US PPP)	Medicine spending per capita 2020 ($US PPP)
Canada	1.86%	1.86%	25.6%	$755	$839
Australia	1.29%	1.30%	44.1%	$583	$632
Belgium	1.41%	1.25%	39.3%	$552	$609
France	1.68%	1.62%	32.9%	$623	$726
Germany	1.54%	1.75%	37.5%	$652	$948
Italy	1.63%	1.72%	18.0%	$575	$670
Japan	1.98%	2.30%	13.4%	$707	$954
Netherlands	0.95%	0.78%	34.1%	$427	$427
Norway	1.50%	1.62%	12.2%	$397	$473
Spain	1.50%	1.62%	20.8%	$446	$560
Sweden	1.09%	1.13%	37.9%	$467	$562
United Kingdom	1.25%	1.42%	30.5%	$462	$590

Data source: OECD

Table 11 gives the composition of rights holders' sales by therapeutic class for Canada and the PMPRB11, individually by country and as an aggregate.[24] The results suggest considerable similarity across countries.

TABLE 11. DISTRIBUTION OF MEDICINE SALES BY MAJOR THERAPEUTIC CLASS, CANADA AND THE PMPRB11, 2022

Therapeutic class	Canada	PMPRB11	Australia	Belgium	France	Germany	Italy	Japan	Netherlands	Norway	Spain	Sweden	United Kingdom
A: Alimentary tract and metabolism	14.9%	11.3%	12.1%	9.7%	8.7%	10.8%	10.4%	13.5%	17.0%	12.4%	11.3%	11.2%	11.0%
B: Blood and blood-forming organs	4.4%	7.8%	5.3%	9.6%	8.6%	8.8%	9.0%	6.5%	12.3%	7.4%	6.7%	9.7%	7.8%
C: Cardiovascular system	5.8%	7.0%	4.5%	6.5%	6.4%	6.4%	7.9%	8.9%	11.8%	4.7%	7.1%	4.3%	5.0%
D: Dermatologicals	2.9%	2.3%	5.1%	1.6%	1.8%	3.2%	1.8%	2.3%	1.9%	1.7%	1.8%	2.0%	1.9%
G: Genito-urinary system and sex hormones	3.2%	2.3%	2.9%	2.2%	2.1%	2.0%	2.4%	2.4%	3.2%	3.0%	2.6%	2.7%	2.4%
H: Systemic hormonal preparations	1.1%	1.7%	1.0%	1.3%	1.7%	1.7%	1.5%	2.2%	2.1%	2.4%	1.5%	2.1%	1.4%
J: General anti-infective for systemic use	8.2%	8.9%	7.5%	7.4%	9.2%	8.9%	11.0%	7.3%	7.8%	8.9%	10.3%	10.6%	9.5%
L: Antineoplastics and immunomodulating agents	26.9%	27.4%	23.3%	35.6%	33.2%	26.5%	29.0%	23.1%	3.1%	31.1%	29.6%	27.8%	29.0%
M: Musculo-skeletal system	2.7%	3.4%	3.0%	2.5%	2.3%	3.5%	2.9%	5.4%	2.2%	3.3%	2.6%	3.4%	2.3%
N: Nervous system	15.3%	12.2%	12.9%	11.0%	11.8%	13.5%	12.0%	10.0%	17.0%	13.7%	14.6%	13.3%	12.5%
P: Antiparasitic products	0.1%	0.1%	0.2%	0.1%	0.1%	0.2%	0.0%	0.1%	0.3%	0.2%	0.1%	0.1%	0.1%
R: Respiratory system	6.5%	7.0%	9.6%	7.2%	6.3%	7.5%	6.1%	4.9%	15.2%	6.2%	7.0%	6.1%	10.1%
S: Sensory organs	4.1%	3.1%	4.5%	2.2%	3.3%	2.8%	1.8%	3.5%	4.2%	2.0%	2.7%	3.7%	4.2%
V: Various	3.8%	5.3%	8.2%	3.3%	4.5%	4.3%	4.3%	9.9%	1.9%	2.9%	2.1 %	2.9%	2.9%
All therapeutic classes*	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

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

Data source: MIDAS® database, 2022, IQVIA (all rights reserved)

ENDNOTES

20 Most of the statistical results presented in this section are based on sales data from the MIDAS® database, 2005-2022, IQVIA (all rights reserved). MIDAS® data covers the pharmacy and hospital sectors.

21 The results given in Figures 30 through 32 and Table 11 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.

22 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.

23 To make use of the best and most up-to-date data on OECD medicine expenditures, the GDP in Table 10 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 10 will be different than those generated using other methodologies. Details on purchasing power parity are provided in the text associated with Table 7.

24 Note that the data used to produce Table 11 encompasses 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 the 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 so 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 the 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 price review 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 2022, the PMPRB has published six analytical reports, one chartbook, and eight posters under the NPDUIS banner.

ANNUAL PUBLICATIONS AND REPORT SERIES

- ***Formularies in Canada – Part 3: Medicines Assessed by the Common Drug Review*** (February 2022)
- ***Meds Pipeline Monitor, 2021*** (April 2022)
- ***Meds Entry Watch, 6th Edition*** (April 2022)
- ***Drug Shortages in Canada and their Impact on Public Drug Plans, 2017/18 to 2019/20*** (September 2022)
- ***CompassRx: Annual Public Drug Plan Expenditure Report, 8th Edition, 2020/21*** (January 2023)
- ***Market Intelligence Report: Antidiabetic Drugs, 2012–2021*** (May 2023)

CHARTBOOK

- ***Expensive Drugs for Rare Diseases: Canadian Trends and International Comparisons, 2011–2020*** (January 2022)

POSTER PRESENTATIONS

- **Drug Shortages in Canada and their Impact on Public Drug Plans, 2017/18 to 2019/20**
- **The COVID-19 Pipeline: Vaccines and Treatments on the Horizon**
- **Alignment between the estimated therapeutic value of medicines and their Canadian prices**
- **The missing claimants of 2020: Who went without claims in Canada during the first year of the COVID-19 pandemic and what does it mean for public and private insurers?**
- **The COVID-19 Pipeline: Vaccines and Treatments on the Horizon**
- **Insight into approvals, marketing, and pricing of new medicines in Canadian and international markets**
- **The Cost of Drug Shortages for Canadian Insurers**
- **Canada's Evolving Market for Biosimilars and What It Means for Payers**

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

RESEARCH AGENDA

The NPDUIS research agenda for the 2023–24 fiscal year includes plans to publish the following analytical studies:

ANNUAL PUBLICATIONS AND REPORT SERIES

- *CompassRx: 9th Edition, 2021/22*
- *Meds Pipeline Monitor, 2022*
- *Meds Entry Watch, 7th Edition*
- *Meds Entry Watch, 8th Edition*
- *Market Intelligence Report: Medicines for Heart Failure*

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

ANALYSIS OF RESEARCH AND DEVELOPMENT EXPENDITURES:

TRACKING REPORTED R&D SPENDING IN CANADA

Pharmaceutical research and development (R&D) is an important piece in advancing innovation in global and national health care. In Canada, the ratio of R&D expenditures to sales revenues for pharmaceutical rights holders has been steadily decreasing since the late 1990s. In 2022, it was at 3.1% for all rights holders and 3.2% for members of Innovative Medicines Canada.

ANALYSIS OF RESEARCH AND DEVELOPMENT EXPENDITURES

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

DEFINITION OF R&D EXPENDITURES

Pursuant to section 6 of the Regulations, rights holders are required to report R&D expenditures that would have qualified for a Scientific Research and Experimental Development (SR&ED) investment tax credit under the provisions of the *Income Tax Act* that came into effect on December 1, 1987.[25] 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 rights holders.

DATA SOURCES

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

The Act requires each rights holder 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).

Rights holders submit 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 rights holders where necessary. To confirm

3.1% R&D-TO-SALES RATIO

The R&D-to-sales ratio for all rights holders was 3.1% in 2022.

This represents a 74% decrease from a peak of 11.7% in 1995.

that PMPRB staff has correctly interpreted the data submitted, each rights holder 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 rights holder's responsibility to ensure a complete and accurate Form 3 is filed within the time frame set out in the Regulations. If a rights holder fails to meet these filing requirements, the Board may issue an Order demanding compliance. No such Board Orders were issued for the 2022 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 herein should not be understood as representative of all pharmaceutical research conducted in Canada. For example, a company may sell only non-patented medicines but still perform considerable research. Similarly, a company may conduct research and have no medicine sales at all.[26] The results presented below will not reflect the R&D expenditures of firms in either scenario.

Second, as new patented medicines enter 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 2022, 100 companies reported on their R&D activity. Of these, 37 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 rights holder related to sales in Canada by licensees).

TOTAL SALES REVENUES AND R&D EXPENDITURES

Table 12 provides an overview of reported sales revenues and R&D expenditures from 1988 to 2022.

Rights holders reported total 2022 sales revenues of $29.1 billion, an increase of 6.1% from 2021. Sales revenues reported by Innovative Medicines Canada members were $23.3 billion, accounting for 80% of the total. Less than 1% of reported sales revenues were generated by licensing agreements. Rights holders reported R&D expenditures of $914.0 million in 2022, a decrease of 1.0% from 2021. Innovative Medicines Canada members reported R&D expenditures of $748.6 million in 2022, an increase of 1.7% over the previous year. Innovative Medicines Canada members accounted for 82.0% of all reported R&D expenditures in 2022.

R&D-TO-SALES RATIOS

Table 12 and Figure 33 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.[27] 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 rights holders was 3.1% in 2022, a decrease from 2021 and the lowest level yet recorded. The overall R&D-to-sales ratio has been less than 10% for the past 22 years.

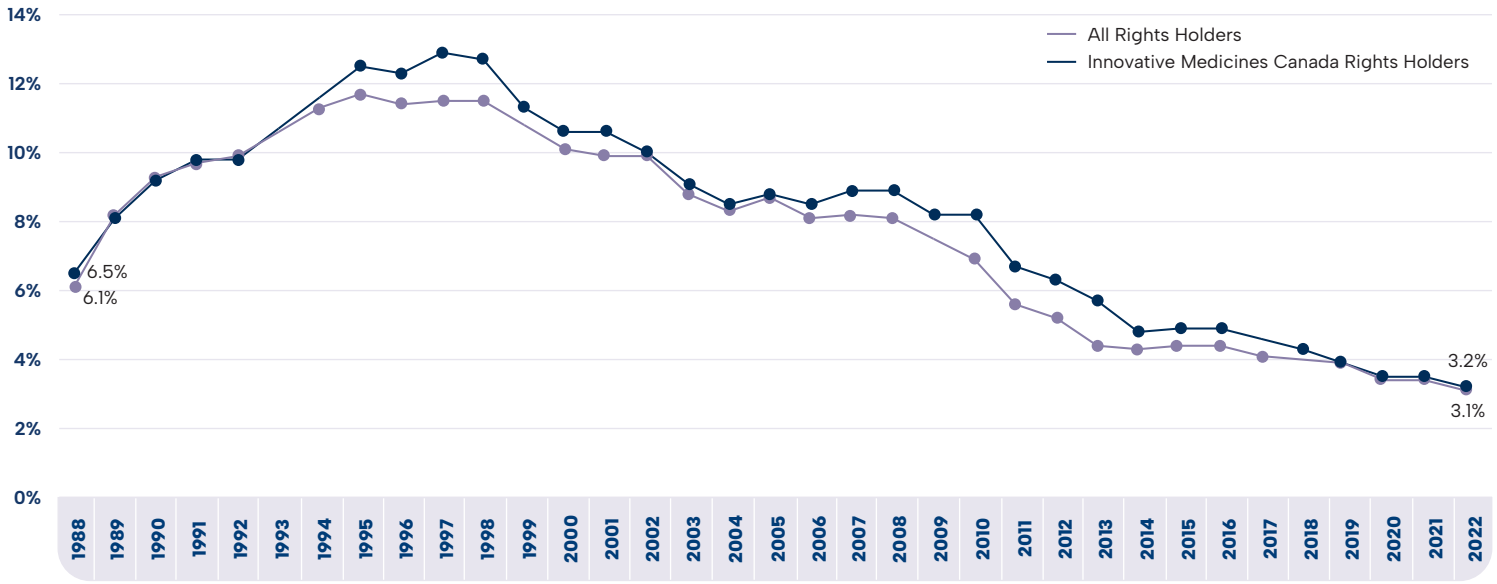
The corresponding R&D-to-sales ratio for members of Innovative Medicines Canada was 3.2%, also a decrease from 2021.[28] The Innovative Medicines Canada ratio has been less than 10% for the past 20 years. Table 20 in Appendix 4 provides details on the range of 2022 R&D-to-sales ratios. Of the 100 companies reporting in 2022, 84.0% had R&D-to-sales ratios below 10.0%.

TABLE 12. TOTAL R&D EXPENDITURES AND R&D-TO-SALES RATIOS OF REPORTING COMPANIES, 1988 TO 2022

Year	All rights holders					Innovative Medicines Canada rights holders				R&D-to-sales ratio: all rights holders	R&D-to-sales ratio: Innovative Medicines Canada rights holders
	Number of companies reporting	R&D expenditures by all rights holders ($millions)	Change from previous year	Sales revenues ($millions)	Change from previous year	R&D expenditures by Innovative Medicines Canada rights holders ($millions)	Change from previous year	Sales revenues ($millions)	Change from previous year		
2022	100	$914.0	-1.0%	$29,144.9	6.1%	$748.6	1.7%	$23,342.9	9.9%	3.1%	3.2%
2021	100	$922.9	12.2%	$27,478.5	13.2%	$735.9	11.0%	$21,243.9	12.4%	3.4%	3.5%
2020	99	$822.9	-7.9%	$24,278.2	5.1%	$662.8	1.6%	$18,902.9	12.1%	3.4%	3.5%
2019	101	$893.2	0.1%	$23,101.0	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%
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 33. R&D-TO-SALES RATIO, PHARMACEUTICAL RIGHTS HOLDERS, 1988 TO 2022



Data source: PMPRB

CURRENT R&D EXPENDITURES BY TYPE OF RESEARCH

Table 13 and Figure 34 (as well as Figure 40 in Appendix 4) provide information on the allocation of 2022 R&D expenditures[29] in basic and applied research as well as other qualifying R&D.[30] Rights holders reported spending $132.0 million on basic research in 2022, representing 14.9% of current R&D expenditures, an increase of 17.1% over the previous year. A reported $484.4 million was spent on applied research, representing 54.9% of current R&D expenditures. Clinical trials (Phase I to III) accounted for 80.0% of applied research expenditures.

TABLE 13. CURRENT R&D EXPENDITURES BY TYPE OF RESEARCH, 2022 AND 2021

Type of research	Expenditures: 2022 ($millions)	Share: 2022	Expenditures: 2021 ($millions)	Share: 2021	Annual change in expenditures
Basic	**$132.0**	**14.9%**	**$112.7**	**12.6%**	**17.1%**
Chemical	$89.1	10.0%	$70.6	7.9%	26.2%
Biological	$42.9	4.9%	$42.1	4.7%	1.9%
Applied	**$484.4**	**54.9%**	**$507.7**	**56.9%**	**-4.6%**
Manufacturing process	$38.1	4.3%	$44.3	5.0%	-14.0%
Pre-clinical trial I	$39.5	4.5%	$31.6	3.5%	25.0%
Pre-clinical trial II	$19.3	2.2%	$19.7	2.2%	-2.0%
Clinical trial Phase I	$45.2	5.1%	$53.1	5.9%	-14.9%
Clinical trial Phase II	$70.3	8.0%	$78.3	8.8%	-10.2%
Clinical trial Phase III	$272.0	30.8%	$280.7	31.5%	-3.1%
Other qualifying R&D	**$266.4**	**30.2%**	**$272.1**	**30.5%**	**-2.1%**
Total*	**$882.8**	**100%**	**$892.5**	**100%**	**-1.1%**

* Values may not add to totals due to rounding.

Data source: PMPRB

FIGURE 34. CURRENT R&D EXPENDITURES BY TYPE OF RESEARCH, 1988 TO 2022

Data source: PMPRB

CURRENT R&D EXPENDITURES BY PERFORMER

Rights holders report expenditures on research they conduct themselves (intramural) and research performed by other establishments, such as universities, hospitals, and other manufacturers (extramural).

Table 14 shows that 50.6% of 2022 current research expenditures were intramural. Research performed by other companies on behalf of rights holders made up 23.1% of current expenditures, while research conducted in universities and hospitals accounted for 14.5%.

TABLE 14. CURRENT R&D EXPENDITURES BY R&D PERFORMER, 2022 AND 2021

R&D performer	Expenditures: 2022 ($millions)	Share: 2022	Expenditures: 2021 ($millions)	Share: 2021	Annual change in expenditures
Intramural					
Rights holders	$446.6	50.6%	$417.3	46.8%	7.0%
Extramural					
Universities and hospitals	$128.4	14.5%	$147.9	16.6%	-13.2%
Other companies	$203.8	23.1%	$225.9	25.3%	-9.7%
Others	$104.0	11.8%	$101.4	11.4%	2.5%
Total*	**$882.8**	**100%**	**$892.5**	**100%**	**-1.1%**

* Values may not add to totals due to rounding.
Data source: PMPRB

CURRENT R&D EXPENDITURES BY REGION

Table 15 (as well as Tables 21 and 22 in Appendix 4) shows current R&D expenditures by region. As in previous years, current expenditures were heavily concentrated in Ontario and Quebec in 2022, with these provinces accounting for 77.4% of total expenditures.

Between 2021 and 2022, R&D expenditures increased at a year-over-year rate of 1.3% in the Atlantic provinces, 11.9% in Quebec, and 4.9% in Western Canada, and decreased at a rate of 10.0% in Ontario.

TABLE 15. CURRENT R&D EXPENDITURES BY REGION, 2022 AND 2021

Region	Expenditures: 2022 ($millions)	Share: 2022	Expenditures: 2021 ($millions)	Share: 2021	Annual change in expenditures
Atlantic provinces	$13.2	1.5%	$13.0	1.5%	1.3%
Quebec	$262.9	29.8%	$235.0	26.3%	11.9%
Ontario	$419.9	47.6%	$466.4	52.3%	-10.0%
Western provinces	$186.7	21.1%	$178.0	19.9%	4.9%
Territories	$0.1	0.0%	$0.1	0.0%	-0.3%
Total*	**$882.8**	**100%**	**$892.5**	**100%**	**-1.1%**

* Values may not add to totals due to rounding.
Data source: PMPRB

TOTAL R&D EXPENDITURES BY SOURCE OF FUNDS

Table 16 provides information on the sources of funds used by rights holders to finance their R&D activity. Internal company funds remained by far the single largest source of funding in 2022, accounting for 90.6% of total expenditures.

Funds received from government amounted to 0.6% of total expenditures.

TABLE 16. TOTAL R&D EXPENDITURES BY SOURCE OF FUNDS, 2022 AND 2021

Source of funds	Expenditures: 2022 ($millions)	Share: 2022	Expenditures: 2021 ($millions)	Share: 2021	Annual change in expenditures
Company funds	$827.9	90.6%	$832.3	90.2%	-0.5%
Federal/provincial governments	$5.0	0.6%	$5.0	0.5%	1.1%
Others	$81.0	8.9%	$85.7	9.3%	-5.4%
Total*	**$914.0**	**100%**	**$922.9**	**100%**	**-1.0%**

* Values may not add to totals due to rounding.
Data source: PMPRB

THE GLOBAL CONTEXT

Figure 35 compares Canadian pharmaceutical R&D-to-sales ratios to those of the PMPRB11 in 2000, 2010, and 2020. These three years of data provide a snapshot of observed market trends over the past 20 years.

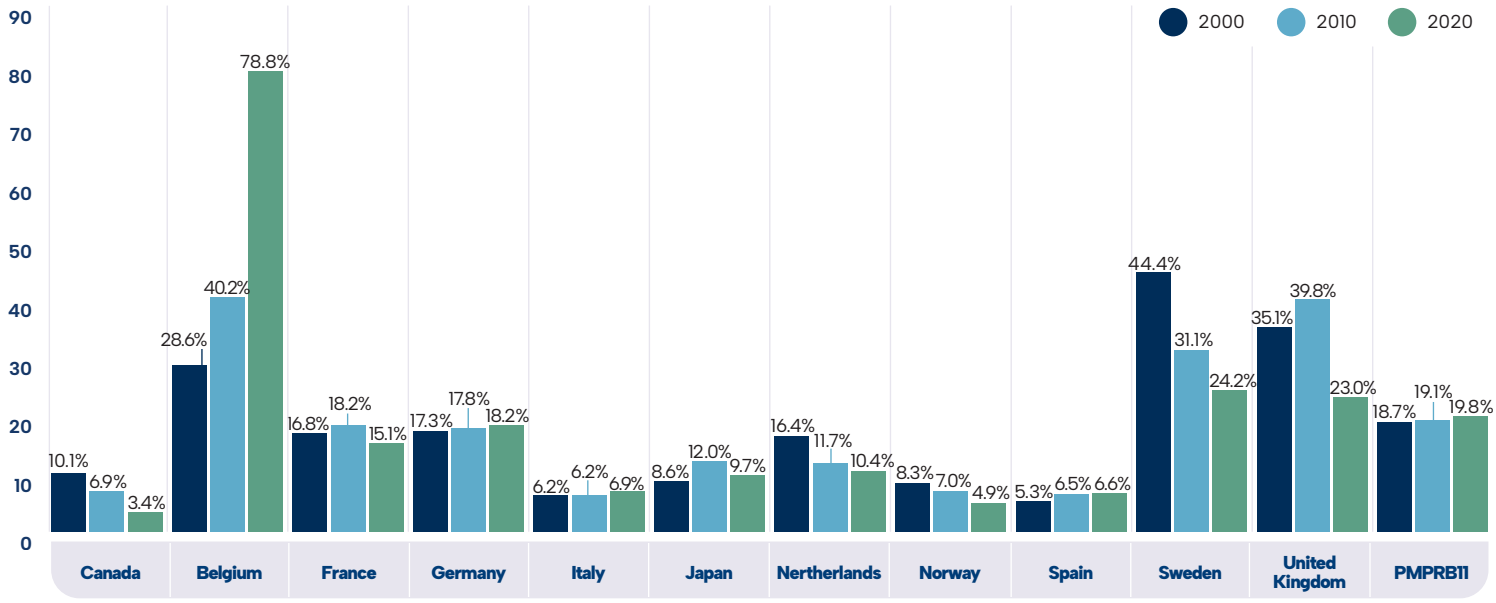
Starting in 2000, Canada had an R&D-to-sales ratio of 10.1%, lower than most PMPRB11 countries. Canada's R&D-to-sales ratio moved down to 6.9% in 2010, below all PMPRB11 countries except for Italy at 6.2% and Spain at 6.5%. In 2020, Canada's R&D-to-sales ratio dropped below that in Spain, becoming the lowest among all comparator countries at 3.4%.

The ratio obtained by aggregating R&D spending and sales across all PMPRB11 countries in 2020 was 19.8%, more than five times that in Canada. The R&D-to-sales ratios represented in Figure 35 may be compared to the average bilateral price ratios reported in Table 7 (see "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.

There are a multitude of factors that drive the location of pharmaceutical R&D, including where companies can find the best science base at a reasonable cost and have 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 35. R&D-TO-SALES RATIO, CANADA AND THE PMPRB11, 2000, 2010, AND 2020



Note: R&D data for Australia was not publicly available.
Data source: PMPRB; European Federation of Pharmaceutical Industries and Associations (EFPIA): *The Pharmaceutical Industry in Figures 2022*; JPMA

ENDNOTES

25 Changes have been made to the Scientific Research and Experimental Development (SR&ED) tax credit since its implementation, including new restrictions on deductions, while other measures have been introduced at the federal level to support innovation and R&D. As per the Regulations, the PMPRB defines R&D based on the 1987 SR&ED definition.

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

27 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.

28 The R&D-to-sales ratios presented in Table 12 include research expenditures funded by government grants. When the government-funded component is excluded, the ratios for all rights holders and for the members of Innovative Medicines Canada in 2022 remain at 3.1% and 3.2%, respectively.

29 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 on the **PMPRB website**. Current R&D expenditures accounted for 96.6% of total R&D expenditure in 2022, while capital equipment costs and allowable depreciation expenses made up 1.4% and 2.0%, respectively.

30 "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.

THE PMPRB11 AVERAGE R&D RATIO IS MORE THAN 5X GREATER THAN IN CANADA.

The R&D-to-sales ratio obtained by aggregating R&D spending and sales across all 11 comparator countries in 2020 was 19.8%, compared to just 3.4% in Canada.

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, which 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 rights holder to comply with regulatory filing requirements pursuant to the *Patent Act* and the *Patented Medicines Regulations*.

Failure to Report: The complete failure of a rights holder 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): 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 rights holders.

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.

PMPRB11: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom.

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: 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.

Rights Holder: As defined by subsection 79(1) of the *Patent Act*, "a patentee and the person for the time being entitled to the benefit of a certificate of supplementary protection for that invention, and includes, if any other person is entitled to exercise rights in relation to the certificate, that other person in respect of those rights."

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 rights holder to adjust its price to conform to the Board's Guidelines. A VCU represents a promise by a rights holder 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:
PHARMACEUTICAL TRENDS – SALES

TABLE 17. SALES OF PATENTED MEDICINES, 1990 TO 2022

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					
2022	$18.4	5.7%	1.8%	49.0%	$465.12	2.0%	0.666%
2021	$17.4	-1.7%	2.2%	51.0%	$456.14	-3.3%	0.758%
2020	$17.7	3.0%	3.2%	55.4%	$472.00	2.9%	0.801%
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%
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%

Continued on next page...

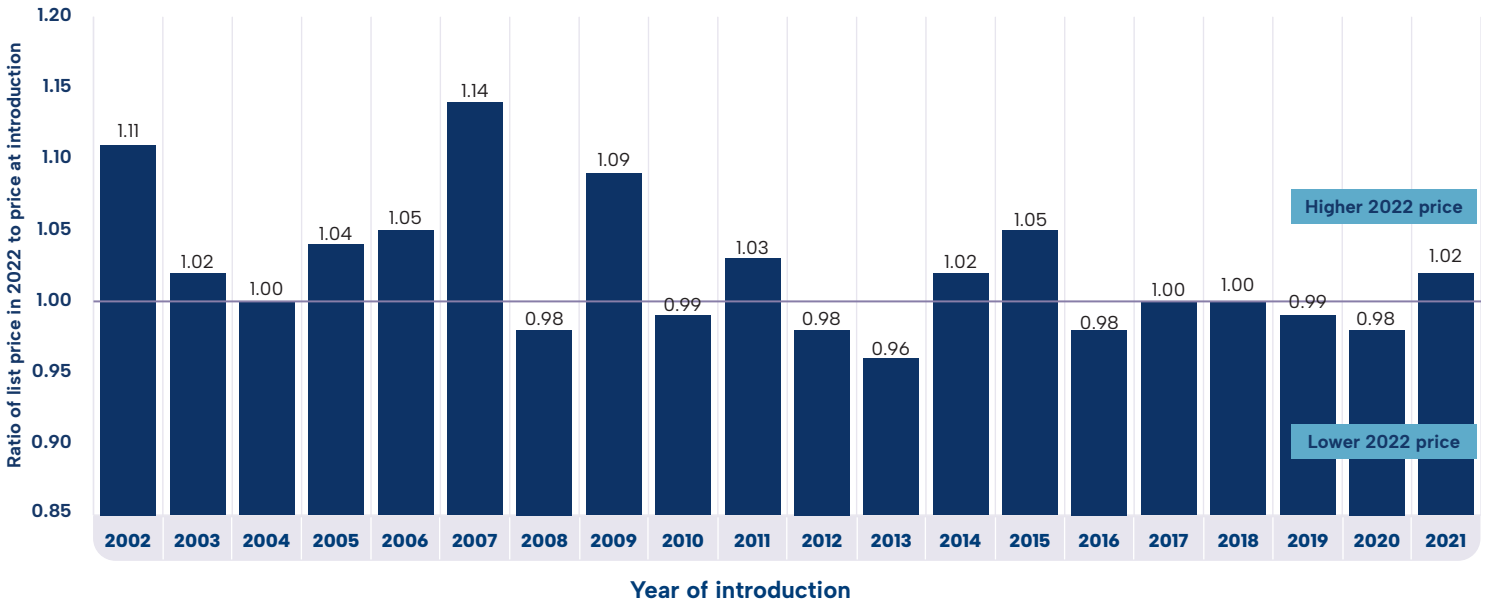
Year	Patented medicine		5-year compound annual growth rate	Sales of patented medicines as a share of all medicine sales*	Patented medicine sales per capita	Change in patented medicine sales per capita	Patented medicine sales per GDP
	Sales ($billions)	Change					
1997	$3.7	22.6%	11.0%	52.3%	$123.70	22.1%	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 rights holders. 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, 2005–2022, IQVIA (all rights reserved)

APPENDIX 3:
PHARMACEUTICAL TRENDS – CANADIAN LIST PRICE COMPARISONS

FIGURE 36. AVERAGE RATIO OF 2022 LIST PRICE TO INTRODUCTORY LIST PRICE, BY YEAR OF INTRODUCTION



Data source: PMPRB

TABLE 18. AVERAGE FOREIGN-TO-CANADIAN LIST PRICE RATIOS, BILATERAL COMPARISONS, CANADA AND THE PMPRB11, 2022

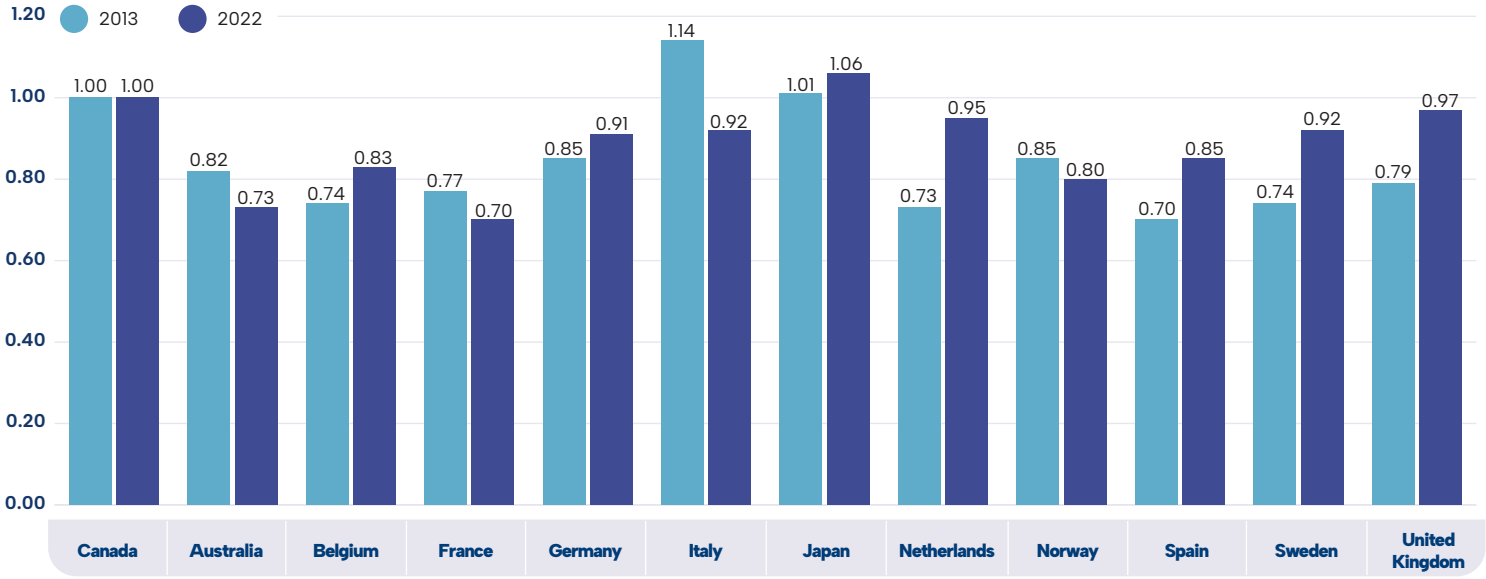
	Canada	Australia	Belgium	France	Germany	Italy	Japan	Spain	Sweden	Norway	Netherlands	United Kingdom
At market exchange rates												
Average price ratio 2022	1.00	0.73	0.83	0.70	0.91	0.92	1.06	0.95	0.80	0.85	0.92	0.97
Average price ratio 2021	1.00	0.71	0.88	0.69	0.92	0.98	0.90	0.96	0.81	0.88	0.77	0.95
At purchasing power parities												
Average price ratio 2022	1.00	0.69	0.99	0.86	1.08	1.27	1.23	1.35	0.82	0.70	1.04	1.09
Average price ratio 2021	1.00	0.67	1.03	0.85	1.11	1.25	0.98	1.32	0.86	0.82	0.86	1.08
Number of patented medicines compared 2022 (DINs)	982*	505	548	510	735	609	436	725	644	695	675	724
Sales ($millions)	$17,784.6	$14,419.6	$14,084.9	$11,574.8	$15,357.9	$14,462.5	$12,060.0	$14,305.0	$11,843.1	$15,303.0	$15,254.8	$15,216.5

Note: 2021 prices for Australia, Belgium, Japan, Spain, Norway, and the Netherlands were sourced from the IQVIA MIDAS® database.

* Consistent with the methodology used throughout the Pharmaceutical Trends section, only medicines that reported to the PMPRB in 2022 and had available Canadian sales data at the time of the analysis were considered here. For the list price analysis, only medicines from this group with a list price available in Canada were used. This is a subsection of the total number of medicines that reported to the PMPRB in 2022 and, as such, may not match the total reported in Table 4.

Data source: PMPRB; MIDAS® database, 2022, IQVIA (all rights reserved)

FIGURE 37. AVERAGE FOREIGN-TO-CANADIAN LIST PRICE RATIOS, CANADA AND THE PMPRB11, 2013 AND 2022



Note: 2013 prices for Australia, Belgium, Japan, Spain, Norway, and the Netherlands are sourced from the IQVIA MIDAS® database.

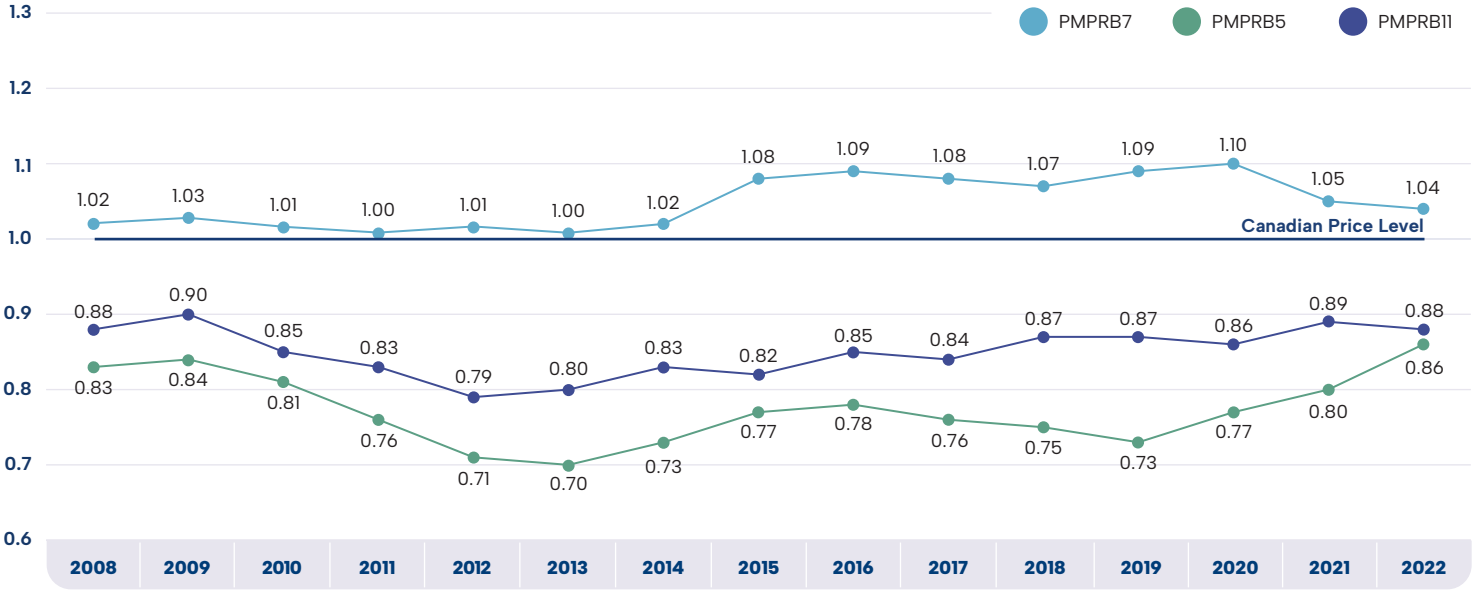
Data source: PMPRB, MIDAS® database, 2013 and 2022, IQVIA (all rights reserved)

TABLE 19. AVERAGE FOREIGN-TO-CANADIAN LIST PRICE RATIOS, MULTILATERAL COMPARISONS, 2022

	Median	Minimum	Maximum	Mean
Average price ratio at market exchange rates	0.88	0.63	1.24	0.89
Average price ratio at purchasing power parities	1.00	0.63	1.54	1.02
Number of patented medicines	860	860	860	860
Sales ($millions)	**$17,238.94**	**$17,238.94**	**$17,238.94**	**$17,238.94**

Data source: PMPRB

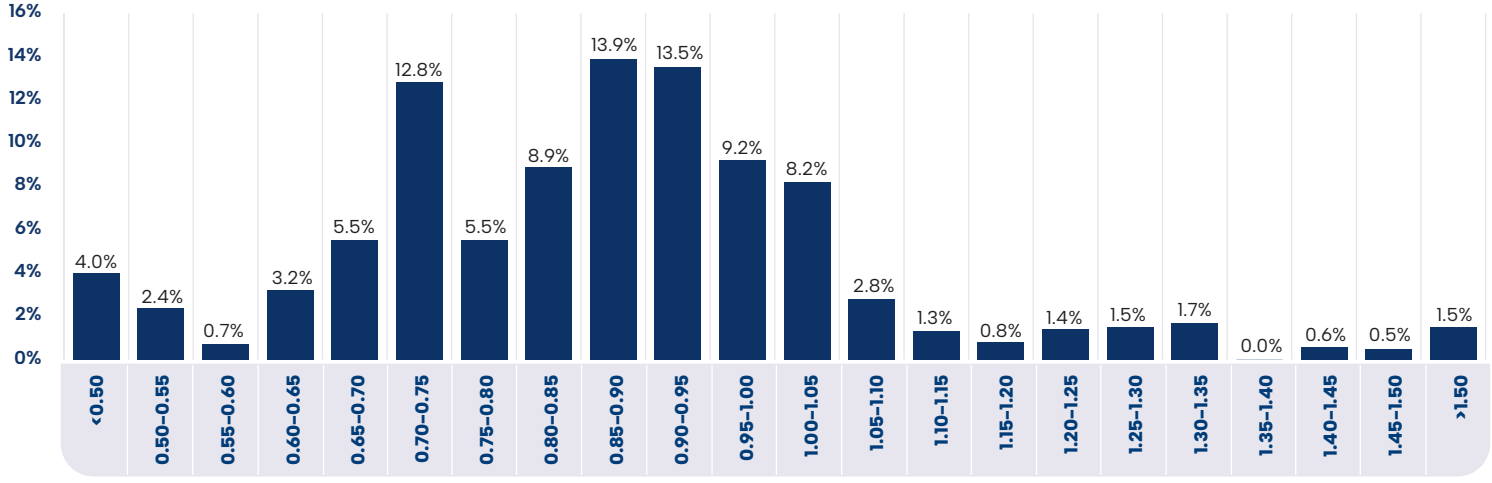
FIGURE 38. AVERAGE RATIO OF MEDIAN INTERNATIONAL PRICE (MIP) TO CANADIAN LIST PRICE, AT MARKET EXCHANGE RATES, PMPRB7, PMPRB5, AND PMPRB11, 2008 TO 2022



Note: PMPRB7 is France, Germany, Italy, Sweden, Switzerland, the United Kingdom (UK), and the United States (US). PMPRB5 removes Switzerland and the US. PMPRB11 is Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, and the UK.

Data source: PMPRB; MIDAS® database, 2008–2022, IQVIA (all rights reserved)

FIGURE 39. RANGE DISTRIBUTION, SHARE OF SALES BY MIP-TO-CANADIAN LIST PRICE RATIO, 2022



Data source: PMPRB

APPENDIX 4:
RESEARCH AND DEVELOPMENT

TABLE 20. RANGE OF R&D-TO-SALES RATIOS BY NUMBER OF REPORTING COMPANIES AND TOTAL SALES REVENUE, 2022 AND 2021

Range: R&D-to-sales ratio	Number of reporting companies: 2022	Sales revenues: 2022 ($millions)	Share: 2022 (%)	Number of reporting companies: 2021	Sales revenues: 2021 ($millions)	Share: 2021 (%)
0%	43	$3,180.7	10.9%	44	$3,017.2	11.0%
≤10%	41	$24,328.1	83.5%	43	$23,160.3	84.3%
>10%	16	$1,636.1	5.6%	13	$1,301.0	4.7%
Total*	**100**	**$29,144.9**	**100%**	**100**	**$27,478.5**	**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 2022

Data source: PMPRB

TABLE 21. CURRENT R&D EXPENDITURES BY PROVINCE/TERRITORY, 2022

Province	Expenditures: All rights holders ($thousands)	Regional share	Expenditures: Innovative Medicines Canada ($thousands)	Regional share
Newfoundland and Labrador	$1,254.08	0.142%	$729.09	0.100%
Prince Edward Island	$191.91	0.022%	$0.00	0.000%
Nova Scotia	$9,652.49	1.093%	$7,631.92	1.051%
New Brunswick	$2,077.18	0.235%	$1,540.88	0.212%
Quebec	$262,905.26	29.782%	$232,062.74	31.959%
Ontario	$419,925.56	47.570%	$321,473.70	44.272%
Manitoba	$4,632.47	0.525%	$2,679.43	0.369%
Saskatchewan	$1,740.10	0.197%	$460.96	0.063%
Alberta	$122,886.26	13.921%	$116,368.51	16.026%
British Columbia	$57,416.23	6.504%	$43,181.09	5.947%
Territories	$70.38	0.008%	$0.00	0.000%
Canada*	**$882,751.92**	**100%**	**$726,128.32**	**100%**

* Provincial/territorial values may not add to totals for Canada due to rounding.

Data source: PMPRB

TABLE 22. CURRENT R&D EXPENDITURES BY PERFORMER AND PROVINCE/TERRITORY, 2022

Province		Rights holders	Other companies	Universities	Hospitals	Others
Newfoundland and Labrador	Expenditure ($thousands)	$633.19	$426.97	$62.52	$6.45	$124.95
	Share	50.5%	34.0%	5.0%	0.5%	10.0%
Prince Edward Island	Expenditure ($thousands)	$93.39	$98.52	$0.00	$0.00	$0.00
	Share	48.7%	51.3%	0.0%	0.0%	0.0%
Nova Scotia	Expenditure ($thousands)	$1,297.74	$2,501.16	$1,234.55	$424.24	$4,194.78
	Share	13.4%	25.9%	12.8%	4.4%	43.5%
New Brunswick	Expenditure ($thousands)	$808.99	$562.35	$46.81	$168.71	$490.31
	Share	38.9%	27.1%	2.3%	8.1%	23.6%
Quebec	Expenditure ($thousands)	$74,158.76	$94,019.32	$17,970.49	$26,519.88	$50,236.80
	Share	28.2%	35.8%	6.8%	10.1%	19.1%
Ontario	Expenditure ($thousands)	$241,635.82	$76,592.97	$29,632.67	$38,395.55	$33,668.55
	Share	57.5%	18.2%	7.1%	9.1%	8.0%
Manitoba	Expenditure ($thousands)	$2,769.04	$372.18	$687.27	$609.11	$194.88
	Share	59.8%	8.0%	14.8%	13.1%	4.2%
Saskatchewan	Expenditure ($thousands)	$651.65	$ 507.02	$410.07	$0.00	$171.35
	Share	37.4%	29.1%	23.6%	0.0%	9.8%
Alberta	Expenditure ($thousands)	$94,621.40	$14,344.37	$2,631.69	$4,360.46	$6,928.34
	Share	77.0%	11.7%	2.1%	3.5%	5.6%
British Columbia	Expenditure ($thousands)	$29,869.61	$14,404.97	$2,615.83	$2,580.16	$7,945.67
	Share	52.0%	25.1%	4.6%	4.5%	13.8%
Territories	Expenditure ($thousands)	$70.38	$0.00	$0.00	$0.00	$0.00
	Share	100.0%	0.0%	0.0%	0.0%	0.0%
Canada*	**Expenditure ($thousands)**	**$446,609.97**	**$203,829.83**	**$55,291.90**	**$73,064.56**	**$103,955.62**
	Share	**50.6%**	**23.1%**	**6.3%**	**8.3%**	**11.8%**

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