Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

PATENTED MEDICINE PRICES REVIEW BOARD

ANNUAL REPORT 2017

Canada

STATISTICAL HIGHLIGHTS 2017

REGULATORY MANDATE

1,391 patented medicines for human use were reported to the PMPRB, including 80 new medicines.

- 14 Voluntary Compliance Undertakings were accepted as at December 31, 2017.
- $35 million in excess revenues were offset by way of payment to the Government of Canada, in addition to price reductions.

REPORTING MANDATE

SALES TRENDS:

- There was $16.8 billion in sales of patented medicines in Canada in 2017, an increase of 7.6% from 2016.
- Patented medicines accounted for 61.5% of the total medicine sales in Canada, an increase from 60.8% in 2016.

PRICE TRENDS:

- Prices of existing patented medicines were stable, while the Consumer Price Index rose by 1.6%.
- Canadian prices were fourth highest among the seven PMPRB comparator countries, lower than prices in Switzerland, Germany and the US.

RESEARCH AND DEVELOPMENT:

R&D-TO-SALES RATIOS DECREASED IN 2017:

- 4.1% for all patentees, a decrease from 4.4% in 2016.
- 4.6% for Innovative Medicines Canada members, a decrease from 4.9% in 2016.

R&D EXPENDITURES:

- $871.4 million in total R&D expenditures were reported by patentees, a decrease of 5.1% over 2016.
- $755.8 million in R&D expenditures were reported by Innovative Medicines Canada members, a decrease of 1.8% over 2016.

The Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Tel.: 1-877-861-2350
Fax: 613-288-9643
TTY: 613-288-9654

Email: PMPRB.Information-Renseignements.CEPMB@pmprb-cepmb.gc.ca
Web: www.pmprb-cepmb.gc.ca
Twitter: @PMPRB_CEPMB

ISSN: 1495-0561
Catalogue number: H78E-PDF

July 24 2018

The Honourable Ginette Petitpas Taylor, 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, 2017.

Yours very truly,

Dr. Mitchell Levine
Chairperson

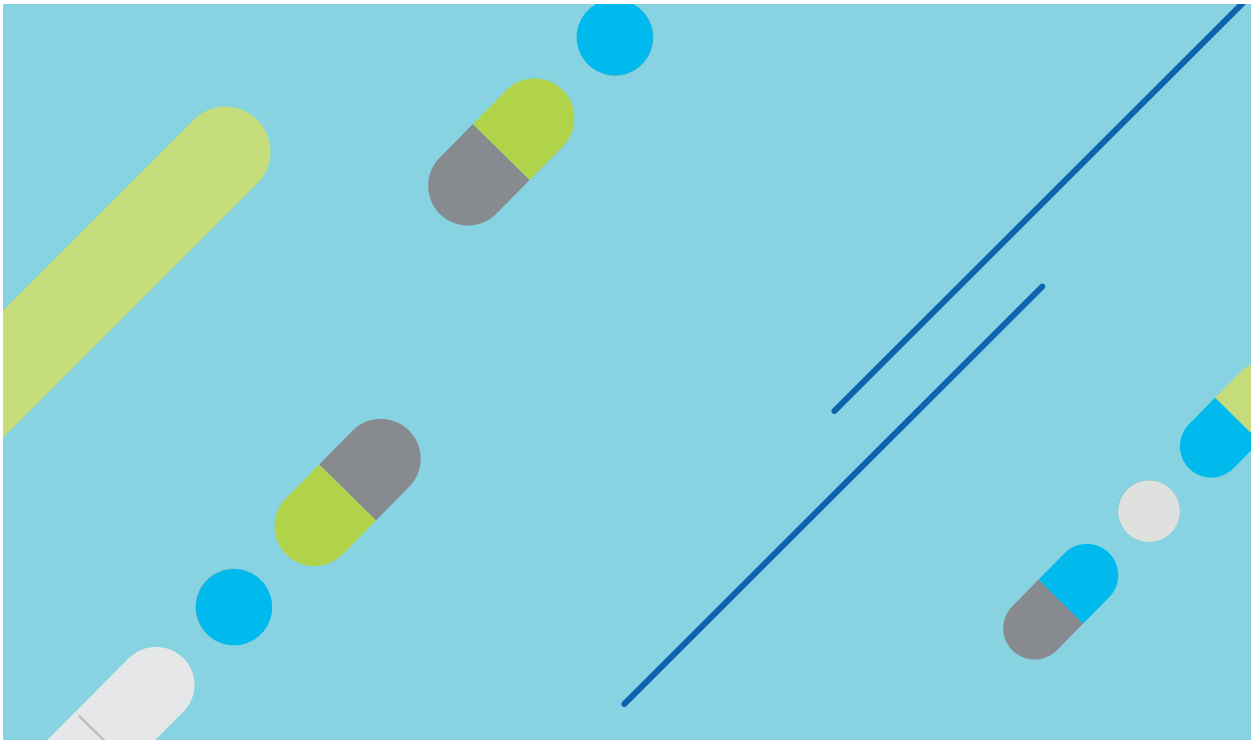


TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAIRPERSON'S MESSAGE

Thirty years ago, the Patented Medicine Prices Review Board (PMPRB) was founded with a mandate to protect consumers by ensuring that the prices of patented medicines are not excessive. Although the PMPRB's mandate has not changed in the intervening years, many aspects of its operating environment have changed significantly. To continue to carry out its mandate effectively, the PMPRB must adapt its regulatory and reporting functions in response to those changes.

To that end, in December 2017, Health Canada's proposed amendments to the Patented Medicines Regulations (Regulations) were published in Part 1 of the Canada Gazette. The Regulations are a key deliverable for the Minister of Health in her continuing efforts to improve patient access to necessary prescription medications, including by making them more affordable. If passed, they would require the PMPRB to consider factors beyond simply domestic and international list prices in carrying out its regulatory obligations. Later that same month, the PMPRB published a scoping paper, which provided an outline of potential changes to its Guidelines that would operationalize the Regulations and support our objective of moving to a risk-based approach to regulating patented medicine prices.

In addition to these regulatory reform initiatives, a number of other significant developments took place in 2017. In March, the Government announced a substantial increase in funding for the PMPRB in Budget 2017. In October, the Alexion matter resulted in the first decision on the merits from a Board panel in an excessive price hearing since 2012.

As is the case every year, 2017 also saw its share of staff and Board members come and go. However, two people who left the organization last year deserve special acknowledgement. First, Elaine McGillivray retired after 30 years with the PMPRB's Board Secretariat. Elaine was the organization's very first hire and the heart and soul of its charitable activities for as long as we can remember. Her absence is keenly felt by all of us. Second, Normand Tremblay's term as a Board member came to a close after five years of very capable and committed service. Although his personal and business commitments did not afford him the time to serve a second term on the Board, Normand's enthusiasm and vision for the PMPRB will have a lasting impact on the organization's ongoing efforts to reform and modernize how it carries out its mandate.

As for 2018, the PMPRB's focus will be on bringing the final chapter in its Guidelines modernization initiative to a close. To that end, the PMPRB will be holding targeted consultations with stakeholders on key technical and operational modalities of the new regime over the summer and early fall, and publishing a draft of the new Guidelines for broader consultation shortly thereafter. While we recognize that many of our stakeholders have divergent and even diametrically opposed points of view on the policy rationale for these changes, we hope that all of our stakeholders will work constructively with us as this process unfolds. Given the divisive nature of the subject matter, we cannot expect to achieve consensus at the end of the day, but we hope that everyone involved will come away from the process feeling properly informed, heard and understood.

Dr. Mitchell Levine
Chairperson

As for 2018, the PMPRB's focus will be on bringing the final chapter in its Guidelines modernization initiative to a close.

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 consumer protection agency with a dual regulatory and reporting mandate. Through its regulatory mandate, it ensures that the prices of patented medicines sold in Canada are not excessive. The PMPRB also reports on trends in pharmaceutical sales and pricing for all medicines and on R&D spending by patentees. Its reporting mandate provides pharmaceutical payers and policy makers with information to make rational, evidence-based reimbursement and pricing decisions.

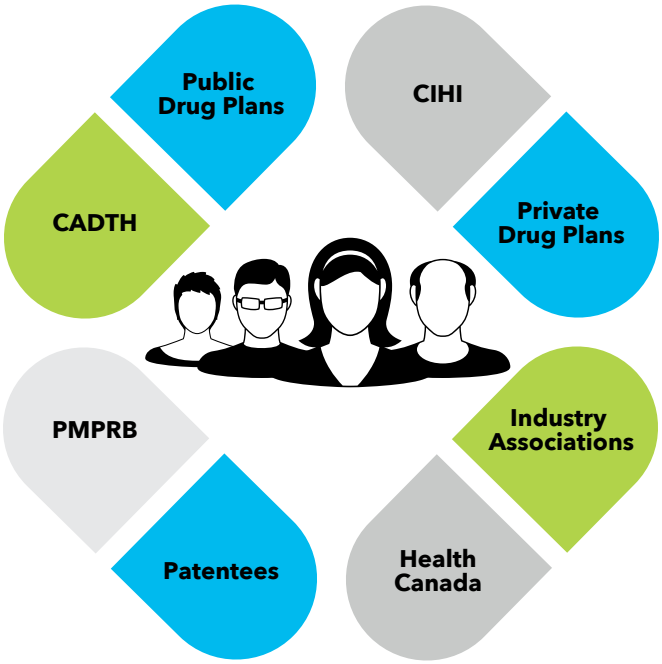
The PMPRB is part of the Health Portfolio, which includes Health Canada, the Public Health Agency of Canada, the Canadian Institutes of Health Research and the Canadian Food Inspection Agency. The Health Portfolio supports the Minister of Health in maintaining and improving the health of Canadians.

OUR MISSION

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

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

PROTECTING CONSUMERS IN A COMPLEX MARKETPLACE



OUR VISION

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

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. It also operates independently of other 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, 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 Canadian Agency for Drugs and Technologies in Health (CADTH), which recommends medicines that should qualify for reimbursement by participating public drug plans.

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

JURISDICTION

REGULATORY

The PMPRB regulates the "factory gate" (ex-factory) ceiling prices for all patented medicines sold in Canadian markets; that is, the prices at which patentees (companies) sell their products to wholesalers, hospitals, pharmacies and other large distributors. The PMPRB does not regulate the prices of non-patented medicines.

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

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

of a patented medicine, patentees are required to file price and sales information at introduction and, thereafter, until all patents pertaining have expired. Although patentees are not required to obtain approval of the price to be able to market their products, they are required to comply with the Act to ensure that the prices of patented medicines sold in Canada are not excessive.

Board Staff reviews the prices that patentees charge for each individual strength and form of a patented medicine. If the price of a patented medicine appears to be potentially excessive, Board Staff will first try to reach a consensual resolution with the patentee. Failing this, the Chairperson can decide that the matter should proceed to a hearing. At the hearing, a panel composed of Board members acts as a neutral arbiter between Board Staff and the patentee. If a panel finds that the price of a patented medicine is excessive, it can order a reduction of the price to a non-excessive level. It can also order a patentee to make a monetary payment to the Government of Canada in the amount of 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

The PMPRB is a reliable, objective source of information on medicine prices, pharmaceutical trends and R&D investment. The PMPRB reports annually to Parliament through the Minister of Health on its price review activities, the prices of patented medicines and price trends of all prescription medicines, and on the R&D expenditures reported by pharmaceutical patentees, as required by the Act.

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

Among other initiatives, the PMPRB also hosts various forums, such as webinars, research forums and information sessions, with academics and policy experts to discuss current research into pharmaceutical use in Canada and emerging areas for study.

COMMUNICATIONS AND OUTREACH

The PMPRB is committed to ensuring that stakeholders are consulted and informed of changes in the operating environment and are promptly advised of any updates to the regulatory process. Over the past year, the Regulatory Affairs and Outreach Branch continued to provide regular outreach sessions for patentees.

The PMPRB continues to take a proactive and plain-language approach to its communication activities. This includes targeted social media campaigns and more conventional (e.g., email and telephone) engagement with domestic, international and specialized media including the CBC, CTV, Radio-Canada, La Presse, The Globe and Mail, Toronto Star, the Canadian Medical Association Journal, Benefits Canada, CBS, Bloomberg News, and Boston Globe among others.

1,391

PATENTED MEDICINES

were reported to the PMPRB in 2017.

GOVERNANCE

The Board consists of up to 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 is designated under the Act as the Chief Executive Officer of the PMPRB, with the authority and responsibility to supervise and direct its work.

The Members of the Board are collectively responsible for the implementation of the applicable provisions of the Act. Together, they approve the issuance of the guidelines, rules and other policies of the Board as provided by the Act and consult, as necessary, with stakeholders including the provincial and territorial Ministers of Health and representatives of consumer groups and the pharmaceutical industry.

MEMBERS OF THE BOARD

CHAIRPERSON

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

Dr. Mitchell Levine was appointed Member and Vice-Chairperson of the Board on March 3, 2011. He was reappointed as Vice-Chairperson for a second, five year term on November 10, 2016. He was appointed Chairperson of the Board on February 13, 2018.

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

Dr. Levine received his medical degree from the University of Calgary and did postgraduate medical training in Internal Medicine (FRCPC) and in Clinical Pharmacology at the University of Toronto. He received an MSc degree in Clinical Epidemiology from McMaster University.

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

VICE-CHAIRPERSON

Position vacant

MEMBERS

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

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

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

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

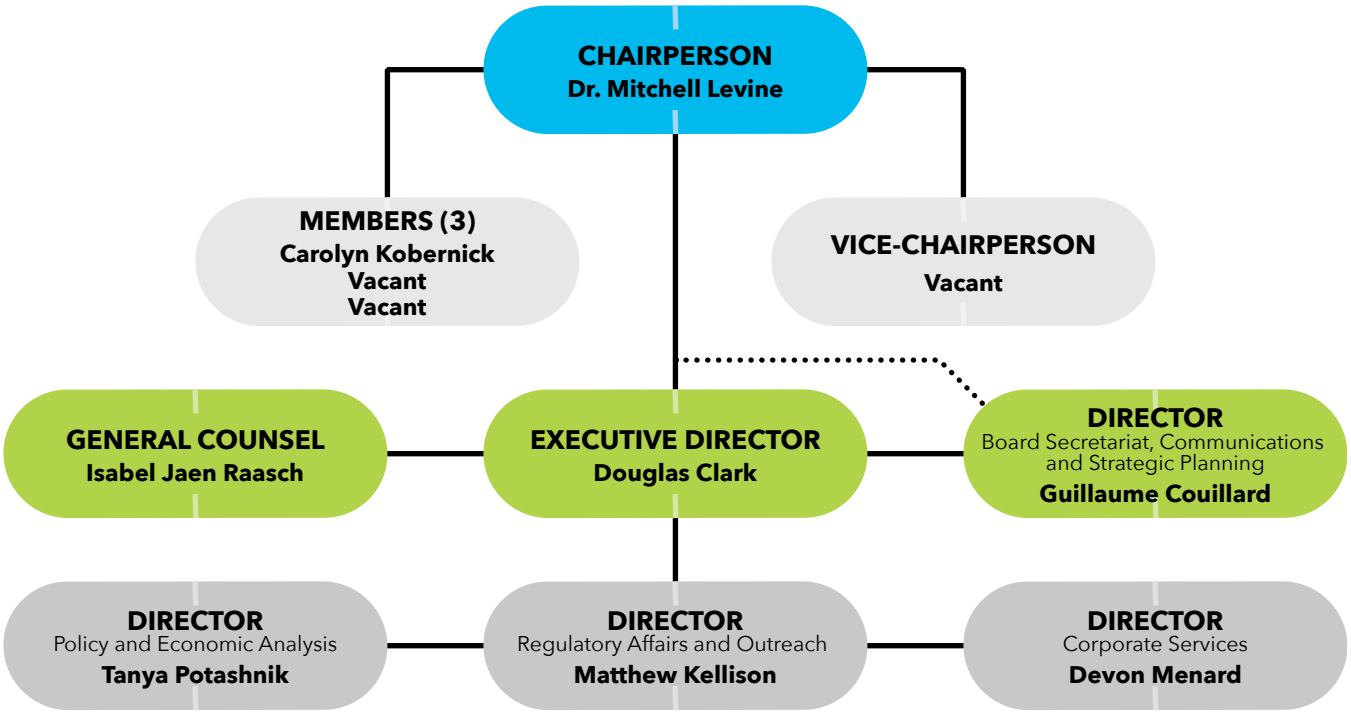
During her career with the public service, Ms. Kobernick actively participated in many high-profile initiatives. She was Chair of the National Legal Advisory Committee and Departmental Champion for Aboriginal People and Gender Equity. She also served as the Senior Department of Justice official at the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

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

As at May 31, 2018 two Member positions are vacant.

ORGANIZATIONAL STRUCTURE AND STAFF

PMPRB ORGANIZATIONAL CHART



EXECUTIVE DIRECTOR

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

REGULATORY AFFAIRS AND OUTREACH

The Regulatory Affairs and Outreach Branch reviews the prices of patented medicines sold in Canada; ensures that patentees are fulfilling their filing obligations; encourages patentees to comply voluntarily with the Board's Guidelines; implements related compliance policies; and investigates complaints into the prices of patented medicines. This branch also informs and educates patentees on the Board's Guidelines and filing requirements.

POLICY AND ECONOMIC ANALYSIS

The Policy and Economic Analysis Branch develops policy and strategic advice; makes recommendations on possible amendments to the Board'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, credible information in support of evidence based policy.

CORPORATE SERVICES

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

BOARD SECRETARIAT, COMMUNICATIONS AND STRATEGIC PLANNING

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

GENERAL COUNSEL

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

BUDGET

In 2017–18, the PMPRB had a budget of $10.866 million and an approved staff level of 66 full-time equivalent employees.

TABLE 1 Budget and Staffing

	2016–17	2017–18	2018–19
Budget*	$10.965M	$10.866M	$14.872M
Salaries	$6.963M	$6.896M	$8.373M
Operating	$1.532M	$1.532M	$3.079M
Special Purpose Allotment**	$2.470M	$2.438M	$3.420M
Full Time Employees (FTEs)	71	66	76.5

* The 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.). Any unspent funds are returned to the Consolidated Revenue Fund.

REGULATING PRICES OF PATENTED MEDICINES: CONTINUED VIGILANCE NECESSARY

Medical advancements have introduced many innovative new medicines to the Canadian marketplace to improve existing treatments and to treat conditions that previously had no pharmaceutical therapy. However, many of these new medicines come at a very high cost. Since 1987, pharmaceutical costs in Canada have grown at an average annual rate of 7.3%, outpacing all other health care costs and growing at well over 3 times the pace of inflation. At 16.4% of total health care spending, pharmaceuticals now rank ahead of spending on physicians. About 1 in 5 Canadians reports having no prescription medicine coverage and many more are under-insured or face high deductibles or co-pays. Almost 1 in 10 Canadians have had to forego filling a prescription medicine in the past year for reasons related to cost.

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

REPORTING REQUIREMENTS

Patentees are required by law to file information pertaining to the sale of their medicines in Canada. The Act along with the Patented Medicines Regulations (Regulations) set out the filing requirements and Board Staff reviews pricing information on an ongoing basis to ensure that prices are not excessive until all patents pertaining have expired.

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

The Compendium of Policies, Guidelines and Procedures (Guidelines) details the price tests used by Board Staff to determine whether the price charged by a patentee falls within the maximum allowable price. The Guidelines were developed in consultation with stakeholders, including the provincial and territorial Ministers of Health, consumer groups, and the pharmaceutical industry. When an investigation determines that the price of a patented medicine may be excessive,

the patentee is offered the opportunity to voluntarily lower its price and/or refund its excess revenues through a Voluntary Compliance Undertaking (VCU). If the patentee disagrees with the findings of the investigation and chooses not to submit a VCU, the Chairperson of the Board may issue a Notice of Hearing (NOH). After hearing the evidence, if the Board finds that a price is excessive, it can issue an order requiring a patentee to reduce that price and/or refund excess revenues. Copies of the Act, the Regulations, the Guidelines, and the Patentee's Guide to Reporting are posted on the PMPRB's website.

FAILURE TO REPORT

The PMPRB relies on patentees' full and timely disclosure of any and all patented medicines being sold in Canada to which a patent pertains. In 2017, 6 medicines were reported to the PMPRB for the first time despite being patented and sold prior to 2017. In addition, 4 medicines previously reported to the PMPRB, and for which the patents had expired, were reported again as having another patent pertaining.

FAILURE TO FILE PRICE AND SALES DATA (FORM 2)

Failure to file refers to the complete or partial failure of a patentee to comply with the regulatory filing requirements outlined in the Act and the Regulations. There were no Board Orders issued for failure to file in 2017.

TABLE 2 Failure to Report the Sale of Patented Medicines

Patentee	Brand name	Medicinal ingredient	Year medicine reported to the PMPRB as under PMPRB's jurisdiction	Year medicine reported to the PMPRB with subsequent patent
Alexion Pharmaceuticals Inc.	Strensiq	asfotase alfa	2016	
Glaxosmithkline Inc.	Menjugate Powder	Meningococcal Group C Conjugate Vaccine	2001	
Glaxosmithkline Inc.	RabAvert	Rabies Vaccine Inactivated	2005	
Leadiant Biosciences, Inc	Adagen	pegademase bovine	2010	
Leadiant Biosciences, Inc	Depocyt	cytarabine, liposomal	2001	2011
Amgen Canada Inc.	Nplate (2 DINs)	romiplostim	2009	
Allergan Inc.	Trelstar	triptorelin pamoate	2013	
Novartis Pharmaceuticals Canada Inc.	Sandostatin (3 DINs) / (1 DIN)	ocreotide	1989/1996	2011
Novartis Pharmaceuticals Canada Inc.	Sandostatin LAR (3 DINs)	octreotide	1999	2011
Paladin Labs Inc.	Frova	frovatriptan succinate	2008	2010

SCIENTIFIC REVIEW

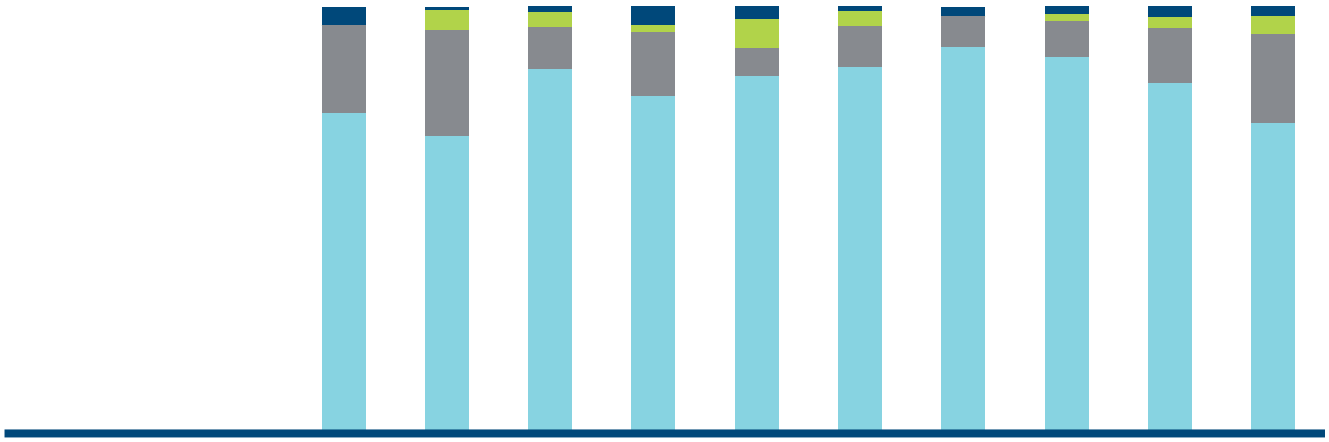
HUMAN DRUG ADVISORY PANEL

All new patented medicines reported to the PMPRB are subject to a scientific evaluation as part of the price review process. The Human Drug Advisory Panel (HDAP) was established by the Board to provide independent expertise and advice to Board Staff. HDAP conducts a review when a patentee makes a claim regarding therapeutic improvement. Panel members review and evaluate the appropriate scientific information available, including any submission by a patentee with respect to the proposed level of therapeutic improvement, the selection of medicines to be used for comparison purposes, and comparable dosage regimens.

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

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

FIGURE 1 Breakdown of New Patented Medicines by Therapeutic Benefit



	2010 Intro	2011 Intro	2012 Intro	2013 Intro	2014 Intro	2015 Intro	2016 Intro	2017 Intro	Overall 2010-2017	Overall 2010-2017 Revenue Share
Breakthrough	3	1	1	5	3	1	3	1	18	2.2
Substantial Improvement	0	5	3	2	7	3	0	1	21	4.3
Moderate Improvement	14	27	8	17	7	8	9	5	95	20.7
Slight/No Improvement	51	76	70	91	87	73	116	52	616	72.5

Source: PMPRB

OUR MOTTO

Protect, Empower, Adapt.

Figure 1 illustrates the breakdown of new patented medicines in the year of introduction by therapeutic benefit for 2010 to 2017. The largest percentage of patented medicines (82.1%) introduced since 2010 offer Slight or No Improvement in therapeutic benefit over existing therapies.[1]

The bar "Overall 2017" represents the therapeutic benefit breakdown for all new patented medicines introduced from 2010 to 2017. The bar "Overall 2017 Revenue Share" illustrates the revenue share by therapeutic benefit for all new patented medicines introduced from 2010 to 2017.

PRICE REVIEW

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

NEW PATENTED MEDICINES REPORTED TO THE PMPRB IN 2017

For the purpose of this report, a new patented medicine in 2017 is defined as any patented medicine first sold in Canada, or previously sold but first patented, between December 1, 2016, and November 30, 2017.

There were 80 new patented medicines for human use reported as sold in 2017. Some are one or more strengths of a new active substance and others are new presentations of existing medicines. Of these 80 new patented medicines, 2 (2.5%) were being sold in Canada prior to the issuance of the Canadian patent that brought them under the PMPRB's jurisdiction. Table 3 shows the year of first sale for these medicines.

TABLE 3 Number of New Patented Medicines for Human Use in 2017 by Year First Sold

Year first sold	No. of medicines
2017	78
2013	2
Total	**80**

The list of New Patented Medicines Reported to PMPRB is available on the PMPRB's website under "Regulating Prices". This list includes information on the status of the review (i.e., whether the medicine is under review, within the Guidelines, under investigation, or subject to a VCU or Notice of Hearing).

Figure 2 illustrates the number of new patented medicines for human use reported to the PMPRB from 1989 to 2017.

Of the 80 new patented medicines, the prices of 59 had been reviewed as of March 31, 2018:

- 42 were found to be within the thresholds set out in the Guidelines;
- 6 were at a level that appeared to exceed the thresholds set out in the Guidelines by an amount that did not trigger the investigation criteria; and
- 11 were at levels that appeared to exceed the thresholds set out in the Guidelines and resulted in investigations being commenced.
    - 5 of the 11 investigations were resolved by VCUs.

For a complete list of the 80 new patented medicines and their price review status, see Appendix 2.

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

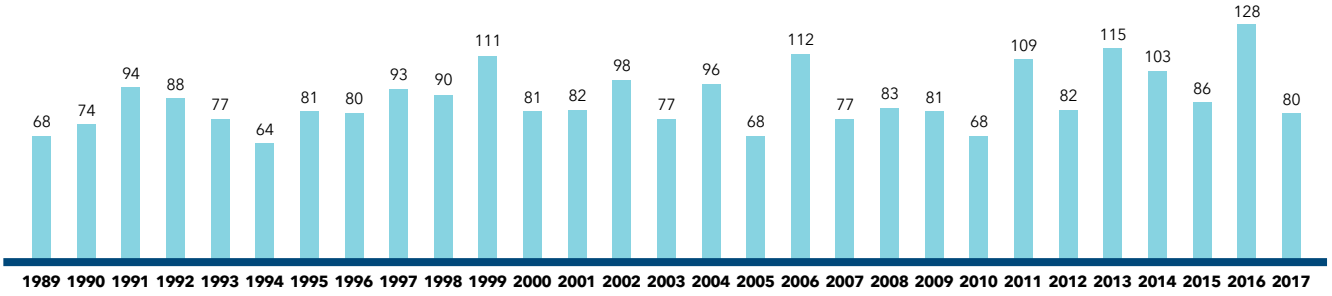
Category 1 – a new DIN of an existing dosage form of an existing medicine, or a new DIN of another dosage form of the medicine that is comparable to the existing dosage form.

Category 2 – is one that provides a breakthrough or substantial improvement. It is a new DIN of a non-comparable dosage form of an existing medicine or the first DIN of a new chemical entity.

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

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

FIGURE 2 New Patented Medicines for Human Use



Source: PMPRB

PRICE REVIEW OF EXISTING PATENTED MEDICINES FOR HUMAN USE IN 2017

For the purpose of this report, existing patented medicines include all patented medicines that were first sold and reported to the PMPRB prior to December 1, 2016.

At the time of this report, there were 1,311 existing patented medicines:

- 908 were priced within the thresholds set out in the Guidelines;
- 233 had prices that appeared to exceed the thresholds set out in the Guidelines by an amount that did not trigger the investigation criteria;
- 116 were the subject of investigations:
- 4 were under review;
- 49 were the subject of a Voluntary Compliance Undertaking; and
- 1 is the subject of a hearing.

A summary of the status of the price review of the new and existing patented medicines for human use in 2017 is provided in Table 4.

TABLE 4 Patented Medicines for Human Use Sold in 2017 – Status of Price Review as of March 31, 2018

	New medicines introduced in 2017	Existing medicines	Total
Total	**80**	**1,311**	**1,391**
Within Guidelines Thresholds	42	908	950
Under Review	21	4	25
Does Not Trigger Investigation	6	233	239
Under Investigation	6	116	122
Subject to Voluntary Compliance Undertaking	5	49*	54
Price Hearing	0	1	1

* The Voluntary Compliance Undertaking for Zerbaxa is not included in the count since the last to expire reported patent expired in October 2016.

$198

MILLION IN EXCESS REVENUES

HAVE BEEN RECOVERED

by the PMPRB through Voluntary Compliance Undertakings and Board Orders since 1993. As at May 31, 2018, as a result of PMPRB investigations, 18 Voluntary Compliance Undertakings were accepted with $35.2 million in excess revenues offset by way of payment to the Government of Canada.

UPDATE FROM THE 2016 ANNUAL REPORT

- Reviews of all medicines for human use that were reported as Under Review in the 2016 Annual Report have been completed.
- 84 of the 101 investigations reported in the 2016 Annual Report resulted in one of the following:
  - the closure of the investigation where it was concluded that the price was within the thresholds set out in the Guidelines;
  - a VCU by the patentee to reduce the price and offset excess revenues through a payment and/or a reduction in the price of another patented medicine (see Voluntary Compliance Undertakings); or
  - a public hearing to determine whether the price was excessive, including any remedial Order determined by the Board (see Hearings).

PATENTED OVER-THE-COUNTER MEDICINES AND PATENTED MEDICINES FOR VETERINARY USE

Board Staff reviews the prices of patented over-the-counter medicines or patented veterinary medicines only when a complaint has been received. No such complaints were received in 2017.

VOLUNTARY COMPLIANCE UNDERTAKINGS AND HEARINGS

VOLUNTARY COMPLIANCE UNDERTAKINGS

A VCU is a written undertaking by a patentee to adjust its price to conform to the Board's Guidelines. Under the Guidelines, patentees are given an opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price of a patented medicine sold in Canada appears to have exceeded the thresholds set out in the Guidelines. A VCU represents a compromise between the PMPRB and the patentee as a result of negotiations between the parties geared towards a satisfactory resolution of an investigation initiated by Board 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.

In 2017, fourteen VCUs were accepted. In addition to price reductions for certain medicines, excess revenues totaling $34,954,878.65 were offset by way of payments to the Government of Canada.

In 2018, as at May 31, 2018, four more VCUs have been approved by the Chairperson.

TABLE 5 Voluntary Compliance Undertakings in 2017 up to May 31, 2018

Patented medicine brand name	Therapeutic use	Patentee	Date of approval	Offset of excessive revenues	
				Price reduction	Payment to the government
VCUs in 2017					
ADCIRCA (1 DIN)	Treatment of idiopathic ("primary") pulmonary arterial hypertension (PAH) or PAH associated with connective tissue disease, congenital heart disease or anorexigen use in patients with WHO functional class II or III who have not responded to conventional therapy.	Eli Lilly Canada Inc.	August	✓	
BRIDION (1 DIN)	Reversal of moderate or deep neuromuscular blockade (NMB) induced by rocuronium or vecuronuim in adults undergoing surgery.	Merck Canada Inc.	October	✓	
CYRAMZA (1 DIN)	Single agent, or in combination with paclitaxel, for the treatment of patients with advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma, with disease progression on or after prior platinum and fluoropyrmidine chemotherapy.	Eli Lilly Canada Inc.	August	✓	
CYSVIEW (1 DIN)	Optical imaging agent indicated for use in the cyptoscopic detection of non-muscle invasive papillary cancer of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy.	BioSyent Pharma Inc.	August	✓	$4,433.13
EFFIENT (1 DIN)	Co-administered with acetylsalicylic acid (ASA), indicated for the early and long-term secondary prevention of atherothrombotic events in patients with acute coronary syndrome (ACS). as follows: a) unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) managed with percutaneous coronary intervention (PCI); b) ST-segment elevation myocardial infarction (STEMI) managed with primary or delayed PCI.	Eli Lilly Canada Inc.	August	✓	
GENVOYA (1 DIN)	A complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients 12 years of age and older (and weighing at least ≥35 kg) and with no known mutations associated with resistance to the individual components of Genvoya.	Gilead Sciences Canada Inc.	October	✓	$479,733.49 (includes excess revenues for Truvada)

TABLE 5 Voluntary Compliance Undertakings in 2017 up to May 31, 2018 *(continued)*

Patented medicine brand name	Therapeutic use	Patentee	Date of approval	Offset of excessive revenues	
				Price reduction	Payment to the government
HUMIRA (1 DIN)	Reduces the signs and symptoms of moderately to severely active rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, and a chronic skin condition called hidradenitis suppurativa. Also used to reduce the signs and symptoms of moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis, after other drugs have been tried without successful treatment of symptoms. Also used to treat non-infectious uveitis (intermediate, posterior and panuveitis) in adult patients.	AbbVie Corporation	November	✓ (AbbVie agreed not to increase the price in any market through 2019)	
PUREGON (3 DINs)	Treatment for infertility in both women and men.	Merck Canada Inc.	June	✓	$750,000.00 (includes excess revenues for Zerbaxa)
REPATHA (1 DIN)	An adjunct to diet and maximally tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD) who require additional lowering of low density lipoprotein cholesterol (LDL-C).	Amgen Canada Inc.	December	✓	$2,293,155.03
TRIDURAL (3 DINs)	Management of moderate to moderately severe pain in adults who require treatment for several days or more.	Paladin Labs Inc.	July	✓	
TRUVADA (1 DIN)	In combination with other antiretroviral agents (such as non-nucleoside reverse transcriptase inhibitors or protease inhibits) for the treatment of HIV-1 infection in adults; or In combination with safer sex practices for Pre-Exposure Prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1infection in adults at high risk.	Gilead Sciences Canada Inc.	October	✓	(combined with excess revenue for Genvoya)
Various brand names and DINs*	Various medicines for various indications.	GlaxoSmithKline Inc.	March	✓	$31,000,000.00
ZEPATIER (1 DIN)	Treatment of chronic hepatitis C (CHC) genotypes 1, 3, or 4 infection in adults with or without ribavirin, or with sofosbuvir.	Merck Canada Inc.	October	✓	$427,557.00
ZERBAXA (1 DIN)**	Treatment for susceptible complicated intra-abdominal infections in combination with metronidazole and complicated urinary tract infections, including pyelonephritis.	Merck Canada Inc.	June		(combined with excess revenue for Puregon)
Total					**$34,954,878.65**

TABLE 5 Voluntary Compliance Undertakings in 2017 up to May 31, 2018 *(continued)*

Patented medicine brand name	Therapeutic use	Patentee	Date of approval	Offset of excessive revenues	
				Price reduction	Payment to the government
VCUs in 2018, up to May 31					
DuoTrav® PQ (1 DIN)	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers, prostaglandins, or other IOP lowering agents and when the use of DuoTrav® PQ (the fixed combination drug) is considered appropriate.	Novartis Pharmaceuticals Canada Inc.	January	✓	$275,000.00
Metoject Subcutaneous (4 DINs)	A Disease Modifying Antirheumatic Drug ("DMARD") in the following diseases where standard therapeutic interventions fail: • Severe disabling psoriasis/psoriatic arthritis • Severe disabling rheumatoid arthritis ("RA")	Medexus Inc.	January	✓	
Onreltea (1 DIN)	Topical treatment of facial erythema of rosacea in adults 18 years of age or older.	Galderma Canada Inc.	February	✓	
Vectibix (1 DIN)	Treatment of previously untreated patients with non-mutated (wild-type) RAS metastatic colorectal carcinoma in combination with FOLFOX (infusional 5-fluorouracil, leucovorin, and oxaliplatin). Also, as monotherapy for the treatment of patients with non-mutated (wild-type) TAS mCRC after failure of fluoropy-rimidine-, oxaliplatim-, and irinotecan-containing chemotherapy regimens.	Amgen Canada Inc.	February	✓	
Total					**$35,229,878.65**

* The GlaxoSmithKline patent audit, which was described in the 2016 Annual Report, resulted in a Voluntary Compliance Undertaking that included 45 medicines. A number of those medicines were not sold in 2017 and therefore are not reflected in the document, List of Patented Medicines.

** The last to expire reported patent for Zerbaxa expired in October 2016.

Now more than ever, the PMPRB's role in regulating the prices of new and existing patented medicines is integral to the sustainability of Canadian health care systems.

HEARINGS

The PMPRB holds hearings into two types of matters:

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

EXCESSIVE PRICING

In the event that the price of a patented medicine appears to be excessive, the Board can hold a public hearing. If it finds that the price is excessive, it may issue an order to reduce the price of the patented medicine in question (or of another patented medicine of the patentee) and/or to offset revenues received as a result of the excessive price. Judicial review of Board decisions can be sought in the Federal Court of Canada.

In January 2015, the PMPRB announced it would hold a public hearing in the matter of the price of the patented medicine Soliris, and Alexion Pharmaceuticals Inc. (Alexion), the pharmaceutical company that holds the patent for Soliris and sells the medicine in 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 in January, February and April 2017. The decision was issued on September 27, 2017. The Hearing Panel found that the price of Soliris (eculizumab) 10 mg/mL was and is excessive under sections 83 and 85 of the Patent Act. The Panel ordered Alexion to pay to Her Majesty in right of Canada an amount of excess revenue calculated in accordance with Schedule A to the decision. The Hearing Panel also ordered Alexion to lower the list price of Soliris in Canada to no higher than the lowest price in the comparator countries set out in the Patented Medicines Regulations.

On October 20, 2017, Alexion Pharmaceuticals Inc. sought judicial review of the decision before the Federal Court.

On November 8, 2017, the Panel ordered Alexion to pay excess revenue to Her Majesty in right of Canada the amount of $4,245,329.60 on or before December 8, 2017.

The matter of whether Apo-Salvent CFC Free was excessively priced commenced in 2008 was discontinued in September 2017.

FAILURE TO FILE – JURISDICTION

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

There were no failure to file hearings in 2017. The failure to file matter involving Apotex Inc. commenced in 2008 was discontinued in September 2017.

SUMMARY

Excess revenues totaling $35,229,878.65 were offset by way of payments to the Government of Canada through VCUs and Board Orders in 2017 and up to May 31, 2018.

Since 1993, a total of 138 VCUs have been approved and 30 public hearings initiated. These measures resulted in price reductions and the offset of excess revenues by way of additional price reductions and/or payments to the Government of Canada. Over $198 million has been collected through VCUs and Board Orders by way of payments to the Government of Canada and/or to customers such as hospitals and clinics.

MATTERS BEFORE THE FEDERAL COURT OF APPEAL AND SUPREME COURT OF CANADA

On January 18, 2017, Galderma Canada Inc. filed an application for judicial review of the Board's decision dated December 19, 2016 in respect of its finding that Canadian Patent No. 2,478,237 pertains to Differin and ordering 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, and the matter is currently pending before the Federal Court of Appeal.

There are also two pending applications for judicial review before the Federal Court in respect of Board decisions made in the context of the Soliris hearing as detailed in Table 6 below.

Finally, on September 11, 2015, Alexion filed an application for judicial review regarding the constitutionality of the Board. The Federal Court granted the Attorney General's motion to strike this application on June 23, 2016. This was further upheld by a Federal Court Order dated December 28, 2016. On February 15, 2017, Alexion appealed this decision to the Federal Court of Appeal. The Federal Court of Appeal upheld the Federal Court's decision on December 7, 2017 and on June 28, 2018, the Supreme Court of Canada dismissed Alexion's subsequent request for leave to appeal the Federal Court of Appeal's decision.

TABLE 6 Status of Board Proceedings in 2017 up to May 31, 2018

ALLEGATIONS OF EXCESSIVE PRICING

Medicine	Indication/Use	Patentee	Issuance of notice of hearing	Status
Apo-Salvent CFC-Free	Asthma	Apotex Inc.	July 8, 2008	Discontinued: September 2017
Soliris	Paroxysmal nocturnal hemoglobinuria Atypical hemolytic uremic syndrome	Alexion Pharmaceuticals Inc.	January 20, 2015	Board decision: September 27 and October 20, 2017

ALLEGATIONS OF FAILURE TO FILE

Medicine	Indication/Use	Patentee	Issuance of notice of hearing	Status
All medicines for which Apotex is a "patentee"		Apotex Inc.	March 3, 2008	Discontinued: September 2017

JUDICIAL REVIEW OF BOARD DECISIONS AND APPEALS

Medicine	Indication/Use	Patentee	Issue	Date of Notice of Hearing/Status
Soliris	Paroxysmal nocturnal hemoglobinuria Atypical hemolytic uremic syndrome	Alexion Pharmaceuticals Inc.	Allegations of excessive pricing	Notice of Hearing – January 20, 2015 Board Decision on merits: September 27, 2017 Court File T-1596-17 Application for Judicial Review (re. merits): October 20, 2017 (pending) Court File T-1855-15 Application for Judicial Review (re. interlocutory motion on conflicts of interest): October 5, 2015 (pending)
			Constitutionality Challenge	Court File T-1160-16 Application for Judicial Review (re. interlocutory motion on pleading amendments): dismissed on September 2, 2016; dismissal upheld on December 28, 2016. Court File T-110-17 Application for Judicial Review (re. interlocutory motion on stay): abandoned on January 31, 2017 and discontinued on November 1, 2017. Court File T-1537-15 Application for Judicial Review: dismissed (on motion to strike) on June 23, 2016. Dismissal upheld on December 28, 2016. Court File A-51-17 Appeal: dismissed on December 7, 2017. Court File SCC 37949 Application for Leave to Appeal to the Supreme Court: dismissed on June 28, 2018.
Differin **Differin XP**	Acne	Galderma Canada Inc.	Failure to file (jurisdiction)	Notice of Hearing: February 23, 2016 Board Decision: December 19, 2016. Court File T-83-17 – Application for judicial review granted by the Federal Court: November 9, 2017. Court File A-385-17 – Notice of Appeal (pending): November 21, 2017.

KEY PHARMACEUTICAL TRENDS: MEDICINE SALES ARE ON THE RISE

Overall spending on pharmaceuticals is influenced by many factors, including price, utilization, the market entry of newer, more expensive medicines, and older patented medicines "going generic". In 2017, sales of patented medicines increased by 7.6%, and Canadian prices were in the middle of the range of the PMPRB's comparator countries (PMPRB7).

The PMPRB is responsible for reporting on trends in pharmaceutical sales and pricing for all medicines and for reporting research and development spending by patentees. In addition, the PMPRB undertakes studies and conducts analysis on a variety of topics related to pharmaceutical pricing and costs.

$16.8

BILLION SALES IN PATENTED MEDICINES

In 2017, sales of patented medicines increased to $16.8 billion from $15.6 billion in 2016.

DISCLAIMERS

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

TRENDS IN SALES OF PATENTED MEDICINES

Patentees are required under the Regulations to submit detailed information on their sales of patented medicines, including quantities sold and net revenues received for each product by class of customer in each province/territory. The PMPRB uses this information to analyze trends in sales, prices and utilization of patented medicines.[2] This section provides key statistical results from this analysis.

SALES AND PRICES[3]

Canadians spend much more today on patented medicines than they did a decade ago, but it is important to understand that an increase in spending does not in itself imply rising medicine prices. For example, the PMPRB's Annual Reports from 1995 through 2003 noted that sales of patented medicines grew at annual rates consistently exceeding 10%, while average annual rates of change for prices were less than 1%. In these instances, sales growth was driven by changes in the volume and composition of the medicines utilized.

A variety of factors can produce such changes. These include:

- increases in total population
- changes in the demographic composition of the population (for example, shifts in the age distribution toward older persons with more health problems)
- increases in the incidence of health problems requiring medicinal treatments
- changes in the prescribing practices of physicians (for example, a shift away from older, less expensive medicines to newer, more expensive medications, or a shift toward higher, more frequent dosages)
- increases in the use of medicinal treatments instead of other forms of therapy
- the use of new medicines to treat conditions for which no effective treatment existed previously
- the use of new medicines that enter the market at a higher price than previous treatments for a given condition

SALES TRENDS

Figure 3(a) reports on trends in patentees' total sales of patented medicines in Canada for 1990 through 2017. In 2017, sales of patented medicines increased to $16.8 billion from $15.6 billion in 2016, an increase of 7.6%. As shown in Figure 3(b), this is the second highest growth rate since 2004 and more than double that of 2016.

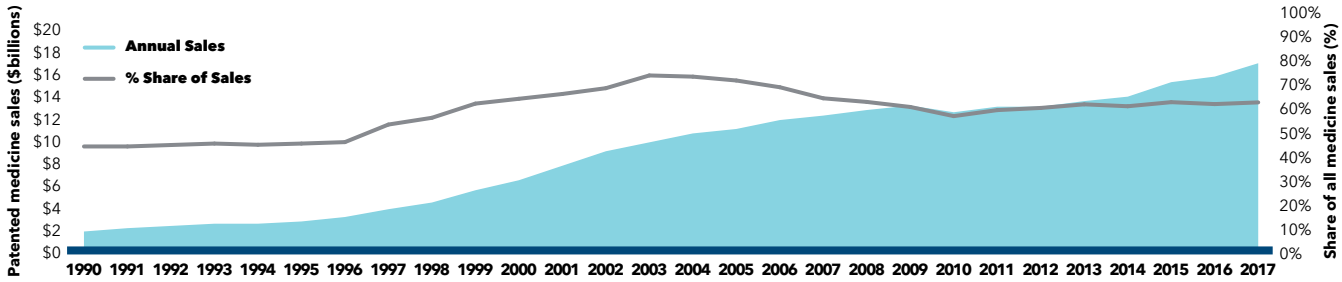
Figure 3(a) also gives sales of patented medicines as a share of overall medicine sales. This share rose from 43.2% in 1990 to a peak of 72.7% in 2003. It declined over the 2004 to 2010 period, but has been trending upward since, from 55.8% in 2010 to 61.5% in 2017. That is, sales of non-patented brand and generic[4] medicines (patented and non-patented) have generally grown at lower rates than the sales of patented medicines in recent years.

Figure 3(c) gives sales of patented medicines per capita and as a share of Gross Domestic Product (GDP). Patented medicine sales per capita rose from $61.6 in 1990 to $454.1 in 2017. Patented medicine sales as a portion of Canada's GDP tripled from 0.25 in 1990 to 0.78 in 2017.

A complete table of the data presented in Figure 3 is given in Appendix 3.

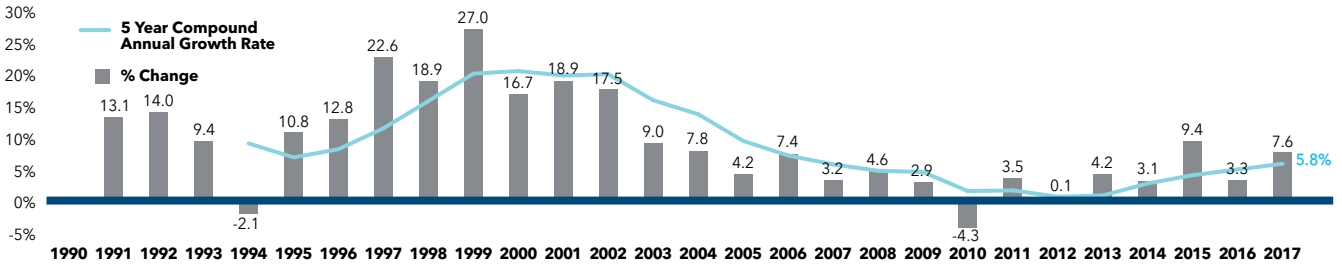
FIGURE 3 Patented Medicine Sales, 1990 to 2017

(a) Patented medicine share of all medicine sales



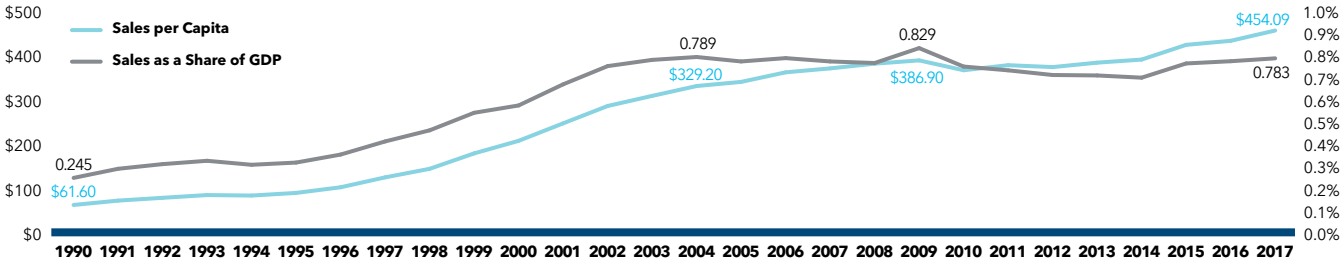
Source: PMPRB; MIDAS™ database, 1990–2017, IQVIA. All rights reserved

(b) Rate of change in patented medicine sales



Source: PMPRB

(c) Patented medicine sales per capita and as a share of GDP

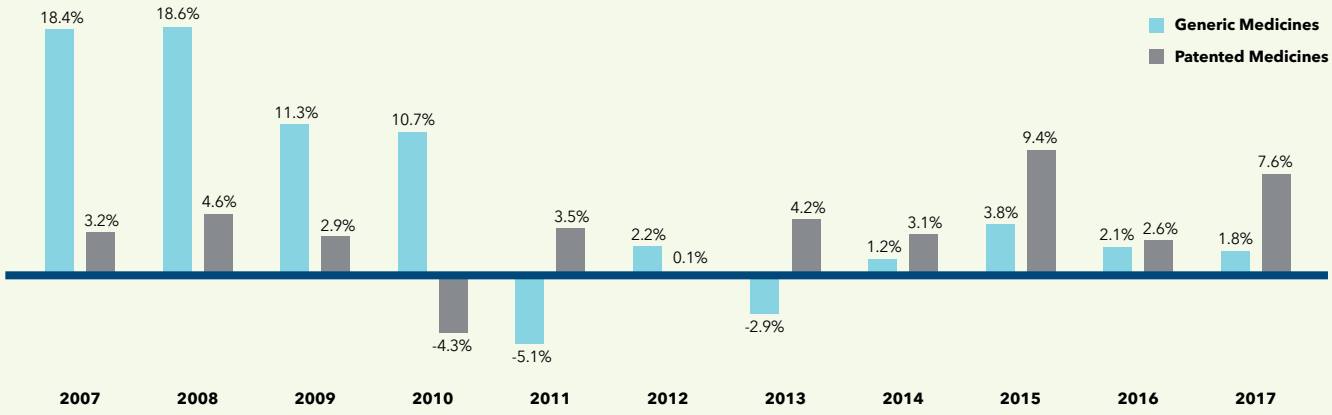


Source: PMPRB; Statistics Canada; OECD

BRIEF INSIGHTS

From 2007 to 2010, as many blockbuster medicines lost patent protection, the rates of growth in the sales of generic medicines in Canada exceeded those of patented medicines. The pattern reversed in more recent years due in part to the introduction of generic pricing policies. While the growth in the sales of generic medicine has rebounded back since, it is still lower than growth in patented medicine sales. Figure 4 compares the growth in Canadian sales for generic medicines with the growth for patented medicines over the last decade.

FIGURE 4 Rate of Change in Retail Sales, Generic vs Patented Medicines, 2007 to 2017



Source: PMPRB; MIDAS™ database, 2007–2017, IQVIA. All rights reserved

Note: The term "generic" used in this analysis includes both patented and non-patented generic medicines.

[NPDUIS Report: Generics360, 2016 (updated for 2017)] – NPDUIS is a research initiative that operates independently of the regulatory activities of the PMPRB.

DRIVERS OF SALES GROWTH

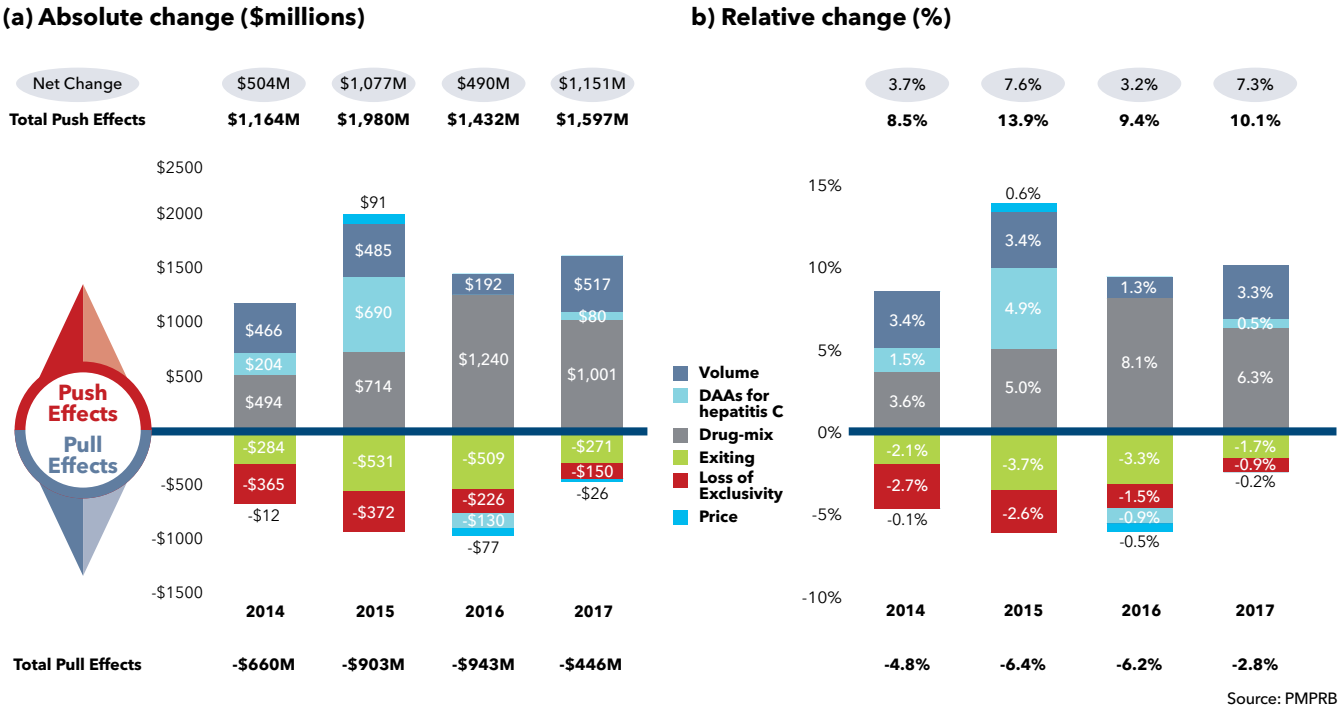
In any given year, the growth in patented medicine sales is influenced by changes in several key factors. Figure 5 breaks down[5] the year-by-year sales growth from 2014 to 2017 to show the impact of each of the following elements:

- previously patented medicines that have gone off-patent or left the Canadian market ("exiting drug effect")
- patented medicines that have lost market exclusivity, and thus are open to competition, but still hold a valid patent ("loss-of-exclusivity effect")
- use of higher-cost patented medicines, new and existing ("drug-mix effect")
- changes in prices among patented medicines ("price effect")
- differences in the quantities of such medicines sold ("volume effect")

Some factors, such as the drug-mix effect will generally put an upward pressure on sales; while others such as the loss-of-exclusivity effect may have the opposite effect. Figure 5(a) gives the yearly impact of each factor in dollar amounts, while Figure 5(b) expresses them as proportions of the overall annual change in sales.

The results in this figure show that the increase in total sales that occurred between 2016 and 2017 was the result of two key factors: increases in the quantity of existing medicines sold, and strong sales for new medicines and existing higher-cost medicines, which offset the exiting drug effect and the loss-of-exclusivity effect.

FIGURE 5 Decomposition of Changes in Sales of Patented Medicines



Source: PMPRB

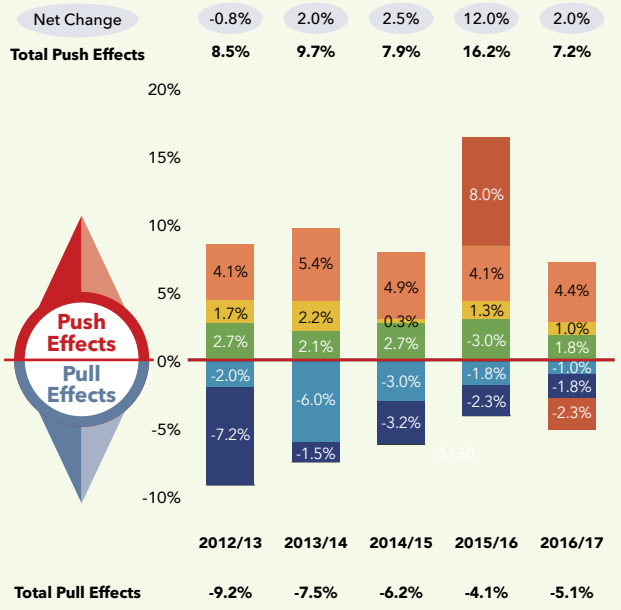
Note: When multiple factors change simultaneously they create a residual or cross effect, which is not reported separately in this analysis, but is accounted for in the total cost change. Factors may not add to net change due to rounding.

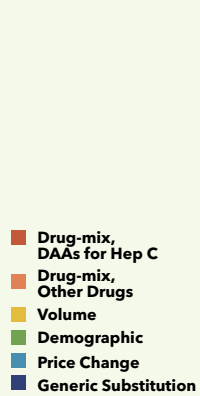
BRIEF INSIGHTS

An examination of Canadian public and private drug plan expenditures yields comparable results. Figure 6 depicts the trends in public and private drug plan cost drivers, encompassing all products reimbursed by the plans, including but not limited to patented and non-patented brand medicines, patented and non-patented generic medicines and non-patented single-source medicines. Over the past five years, higher-cost medicines (other than direct-acting antivirals (DAAs) for hepatitis C) have exerted a consistent, upward pressure of approximately 5% on the cost of medicines, while cost savings from generic and biosimilar substitution, as well as price reductions, have steadily declined.

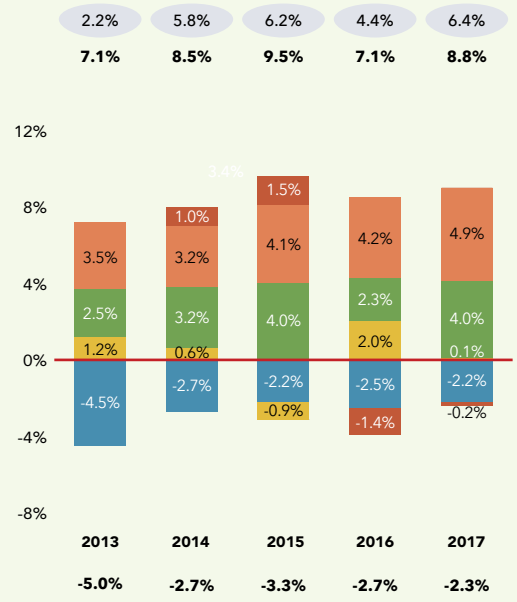
FIGURE 6 Medicine Cost Drivers

NPDUIS public drug plans*, 2012/13 to 2016/17





Private drug plans, 2013 to 2017



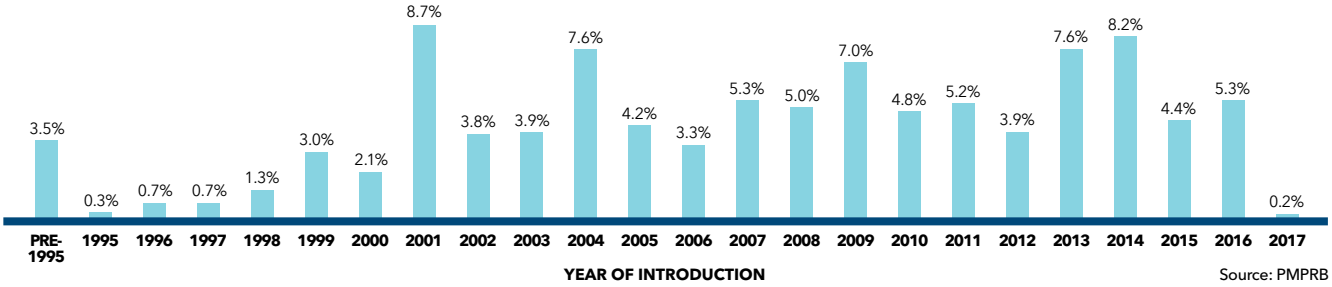
* British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon and the Non-Insured Health Benefits Program

Source: NPDUIS database, CIHI (fiscal year data); IQVIA Private Pay Direct Drug Plan Database (calendar year)
[NPDUIS Posters: Cost Drivers of Public Drug Plans in Canada, 2016/17; Cost Drivers of Private Drug Plans in Canada, 2017]

NEW MEDICINES

Figure 7 breaks down 2017 sales of patented medicines according to the year in which the medicine was first sold in Canada. Throughout the latter part of the 1990s and early 2000s, sales growth was largely driven by a succession of new "blockbuster" medicines that ultimately achieved very high sales volumes. As the patents for these medicines continue to expire, their share of sales is gradually decreasing. Recently, new higher-cost medicines such as biologics, oncology medicines and several highly effective treatments for hepatitis C launched in 2014, are influencing the share of sales in 2017.

FIGURE 7 Share of 2017 Sales of Patented Medicines by Year of Introduction

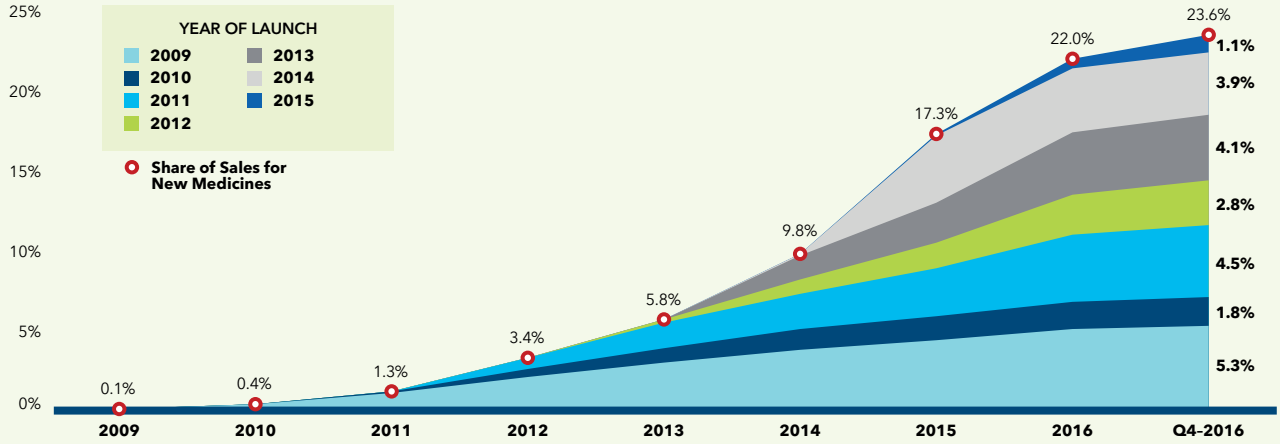


Source: PMPRB

BRIEF INSIGHTS

These findings are supported by analyses of the market entry dynamics of new medicines in Canadian and international markets. New medicines have a steep year-over-year uptake in sales. Between 2009 and 2015, an average of 37 medicines was launched annually in Canada and the PMPRB7. By the fourth quarter of 2016, they accounted for close to one quarter (23.8%) of the total brand-name pharmaceutical market in Canada.

FIGURE 8 New Medicines Cumulative Share of all Brand-Name Medicine Sales by Launch Year, 2009 to 2015



Source: MIDAS™ database, 2009–2016, IQVIA. All rights reserved
[NPDUIS Report: Meds Entry Watch, 2016]

HIGHER-COST MEDICINES

Ninety percent ($1.07 billion) of the total growth in patented medicine sales from 2016 to 2017 was driven by an increase in the sales of 10 medicines (Table 7); most of which had an average annual treatment cost greater than $10,000. The two top contributors, Epclusa and Eylea, used in the treatment of hepatitis C and retinal disorders, respectively, together accounted for slightly more than half of the sales growth. Both had substantial annual treatment costs.

TABLE 7 Top 10 Medicines Contributing to the Growth in Patented Medicine Sales from 2016 to 2017

Medicinal Ingredient (Brand Name)	ATC	Sales ($millions) 2016	Sales ($millions) 2017	Contribution to growth in patented medicine sales, 2016–2017 ($millions)	Contribution to growth in patented medicine sales, 2016–2017 (%)	Avg. annual treatment cost ($) 2017
Sofosbuvir/velpatasvir (Epclusa)	J05	26.1	518.2	492.1	41.5	42,884
Aflibercept (Eylea)	S01	250.2	397.1	146.9	12.4	8,653
Elbasvir/grazoprevir (Zepatier)	J05	9.2	80.9	71.7	6.1	42,582
Adalimumab (Humira)	L04	645.2	701.9	56.7	4.8	16,107
Apixaban (Eliquis)	B01	138.6	195.0	56.4	4.8	720
Pembrolizumab (Keytruda)	L01	19.2	74.8	55.6	4.7	31,241
Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya)	J05	18.9	69.3	50.4	4.3	10,189
Antihemophilic factor (recombinant) (Adynovate)	B02	26.4	74.4	48.0	4.0	NA
Ustekinumab (Stelara)	L04	159.9	206.0	46.1	3.9	19,071
Lenalidomide (Revlimid)	L04	293.9	338.5	44.6	3.8	57,928
Total top 10 medicines		**1,587.7**	**2,656.4**	**1,068.5**	**90.1**	
Total patented medicines		**15,599.3**	**16,784.7**	**1,185.4**		

Source: PMPRB, IQVIA Private Pay Direct Drug Plan Database, 2017.

While Table 7 reports the top 10 contributors to the growth in patented medicine sales in 2017, Table 8 lists the 10 top-selling patented medicines. The table also compares the treatment costs for the top 10 selling medicines in 2006 and 2017. In 2006, Remicade was the only biologic medicine to make the top 10 list, with an average annual treatment cost of $17,759. This cost was much higher than the rest of the top 10, none of which exceeded $1,000 annually. By 2017, however, seven of the top 10 medicines were biologics, with annual treatment costs ranging from $2,948 to $57,928. Only two of the top 10 sellers in 2017 had annual treatment cost of less than $1,000. With collective annual sales of approximately $4.4 billion, these 10 medicines accounted for over one-quarter of total sales for all patented medicines.

TABLE 8 Treatment Cost for the Top 10 Selling Patented Medicines, 2006 and 2017

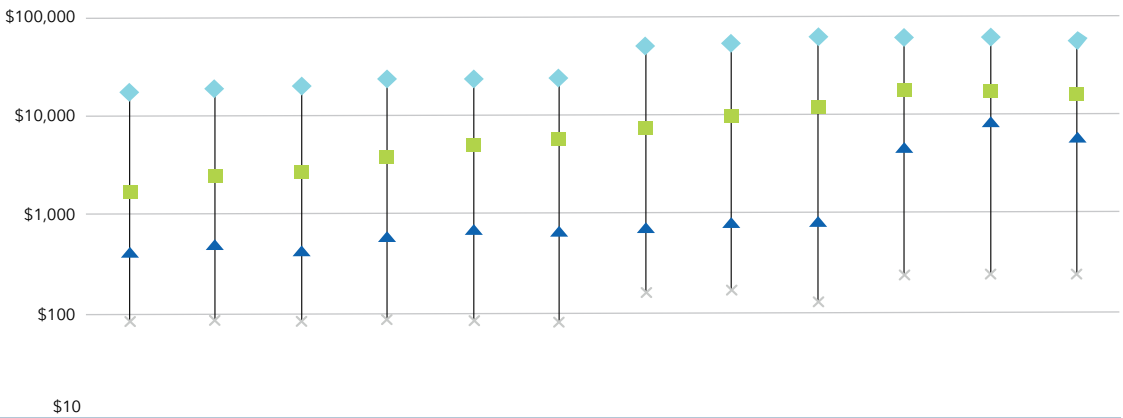
2006			2017				
Medicinal Ingredient (Brand Name)	ATC	Avg. annual treatment cost	Medicinal Ingredient (Brand Name)	ATC	Avg. annual treatment cost	Sales ($millions)	Share of patented sales (%)
1. Atorvastatin calcium (Lipitor)	C10A	$511	1. Infliximab (Remicade)	L04A	$28,804	$938.1	5.6
2. Amlodipine besylate (Norvasc)	C08C	$417	2. Adalimumab (Humira)	L04A	$16,107	$701.9	4.2
3. Ramipril (Altace)	C09A	$271	3. Sofosbuvir/velpatasvir (Epclusa)	J05A	$42,884	$518.2	3.1
4. Venlafaxine hydrochloride (Effexor)	N06A	$446	4. Aflibercept (Eylea)	S01L	$8,653	$397.1	2.4
5. Pantoprazole sodium (Pantoloc)	A02B	$330	5. Lenalidomide (Revlimid)	L04A	$57,928	$338.5	2.0
6. Clopidogrel bisulfate (Plavix)	B01A	$607	6. Etanercept (Enbrel)	L04A	$13,654	$320.4	1.9
7. Rosuvastatin calcium (Crestor)	C10A	$341	7. Ranibizumab (Lucentis)	S01L	$8,507	$312.7	1.9
8. Olanzapine (Zyprexa)	N05A	$977	8. Immune globulin intravenous (human) (Gammagard)	J06B	$2,948	$285.8	1.7
9. Salmeterol xinafoate/ fluticasone propionate (Advair)	R03A	$343	9. Insulin glargine (Lantus)	A10A	$772	$279.2	1.7
10. Infliximab (Remicade)	L04A	$17,759	10. Salmeterol xinafoate/ fluticasone propionate (Advair)	R03A	$455	$274.9	1.6
Total top 10 medicines						**$4,366.8**	**26.0**
Total patented medicines						**$16,784.7**	

Note: Biologic medicines are highlighted.

Source: PMPRB, IQVIA Private Pay Direct Drug Plan Database, 2017.

Over the last decade there has been a significant shift in pharmaceutical development toward more specialized medicines, with an increasing number of higher-cost medicines compounded by a notable uptake in their use. As illustrated in Figure 9, for many years, the majority of the top 20 selling patented medicines had annual treatment costs under $1,000; however, 2015 marked a turning point, as most of the top sellers now cost in the thousands or tens of thousands of dollars per year. This shift is reflected in the exceptional tenfold growth in the median annual treatment cost between 2006 and 2015, which was $5,728 in 2017 after reaching a high of $8,584 in 2016. In addition to their higher cost, these medicines have had a remarkable uptake in use, resulting in a weighted average annual treatment cost of $16,359 for the top 20 selling patented medicines in 2017. This is only slightly less than the maximum average annual treatment cost a decade ago.

FIGURE 9 **Treatment Cost for Top 20 Selling Patented Medicines, 2006 to 2017**



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Maximum	$17,759	$18,669	$19,974	$22,716	$22,361	$23,507	$49,002	$52,227	$58,800	$58,830	$60,249	$57,928
Weighted Average	$1,797	$2,576	$2,892	$4,114	$5,228	$6,009	$7,960	$10,156	$12,491	$18,860	$17,770	$16,359
Median	$409	$479	$420	$584	$704	$675	$731	$803	$828	$4,626	$8,584	$5,728
Minimum	$86	$89	$86	$88	$88	$87	$173	$181	$136	$254	$260	$260

Source: PMPRB; IQVIA Private Pay Direct Drug Plan Database, 2006-2017

Between 2006 and 2017 the number of patented medicines in Canada with an annual average treatment cost of at least

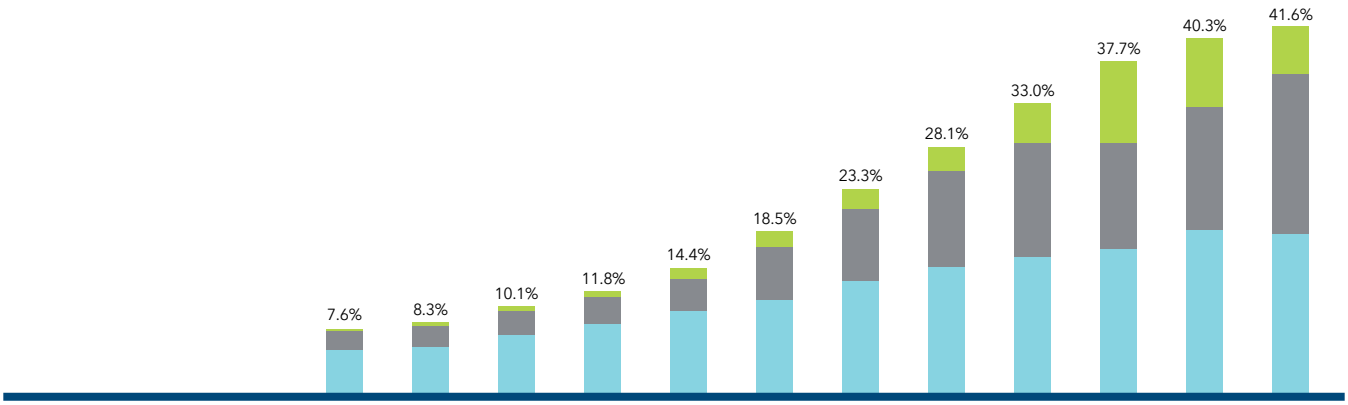
$10,000

more than tripled

and now account for over 40% of patented medicine sales as compared to 7.6% in 2006.

Figure 10 shows that high-cost medicines represent an increasingly significant share of total patented medicine sales, rising steeply from 7.6% in 2006 to a remarkable 41.6% in 2017. This sustained growth was evident in all cost bands (10K to 20K; 20K to 50K; and 50K+), with the steepest increase in the highest-cost medicines. While the new direct-acting antiviral medicines (DAAs) for hepatitis C were a major contributor to the growth in high-cost medicines, other high-cost medicines played an even more pronounced role. Despite the sharp increase in the share of costs, the number of people using these medicines remained at less than 1% of the population.

FIGURE 10 Share of Sales for High-Cost Patented Medicines, 2006 to 2017



SHARE OF SALES %	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
50K+	0.3	0.4	0.5	0.7	1.3	1.7	2.2	2.7	4.5	9.2	7.8	5.3
20K–50K	2.1	2.4	2.7	3.0	3.5	6.0	8.2	10.9	12.9	12.0	13.8	18.1
10K–20K	5.2	5.5	6.9	8.1	9.6	10.8	12.9	14.5	15.6	16.5	18.7	18.2
Total	7.6	8.3	10.1	11.8	14.4	18.5	23.3	28.1	33.0	37.7	40.3	41.6

High-cost medicines	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Medicine Cost	$967M	$1,090M	$1,372M	$1,701M	$1,982M	$2,518M	$3,105M	$3,843M	$4,503M	$5,746M	$6,985M	$6,314M
Total no. of molecules	44	53	61	67	74	93	97	108	116	126	135	144
10K–20K	27	32	33	36	38	49	48	53	53	54	55	55
20K–50K	11	12	17	19	21	27	31	37	41	46	55	67
50K+	6	9	11	12	15	17	18	18	22	26	25	22
Avg. treatment cost	$15,111	$15,631	$15,507	$15,755	$16,247	$17,071	$17,621	$18,084	$18,964	$20,660	$20,106	$20,394
Estimated treatment population	64,007	69,708	88,506	107,978	122,009	147,533	176,224	212,509	237,461	278,117	314,042	342,516
Share of total Cdn. population	0.20%	0.21%	0.27%	0.32%	0.36%	0.43%	0.51%	0.60%	0.67%	0.77%	0.86%	0.93%

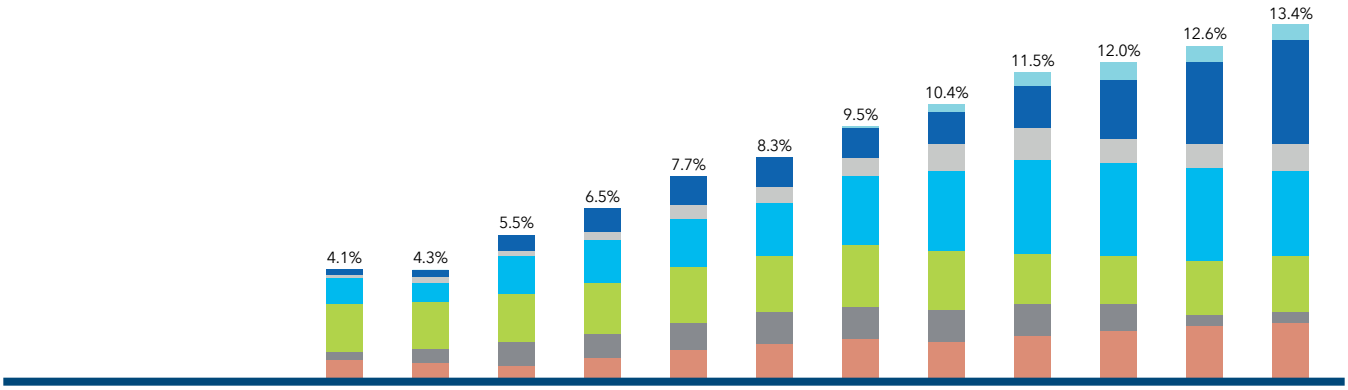
Source: PMPRB; IQVIA Private Pay Direct Drug Plan Database, 2006–2017

The shift toward higher cost treatments can also be seen when looking specifically at oncology medicines. Figure 11 shows the sales share of oncology medicines by treatment cost as a percentage of total medicine costs. These costs are based on a 28-day treatment regimen, unlike the annual treatment costs reported for high-cost medicines in Figure 10.

From 2006 to 2017, the average treatment cost for oncology medicines increased by 82%, from $3,867 to $7,057. Many of these medicines are used in multiple treatment regimens resulting in much higher treatment costs than reported. There may be some overlap in the medicines reported in Figures 10 and 11, as the oncology medicines that exceeded $10,000 in annual treatment costs are reported in both figures.

The estimated treatment population using these medicines increased over 200% from 2006 to 2017 but is still very low at 1% of the total Canadian population. The dual pressures of rising 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 11 Share of Sales for Oncology Medicines by 28-day Treatment Cost, 2006 to 2017



SHARE OF SALES %	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
10.0K+	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.3	0.5	0.7	0.6	0.6
7.5K–10.0K	0.2	0.3	0.6	0.9	1.1	1.1	1.1	1.2	1.6	2.2	3.1	3.9
5.0K–7.5K	0.1	0.2	0.2	0.3	0.5	0.6	0.7	1.0	1.2	0.9	0.9	1.0
3.5K–5.0K	1.0	0.7	1.4	1.6	1.8	2.0	2.6	3.0	3.5	3.5	3.5	3.2
2.5K–3.5K	1.8	1.8	1.8	1.9	2.1	2.1	2.3	2.2	1.9	1.8	2.0	2.1
less than 2.5K	0.3	0.5	0.9	0.9	1.0	1.2	1.2	1.2	1.2	1.0	0.4	0.4
Other*	0.8	0.7	0.6	0.9	1.2	1.4	1.6	1.5	1.7	1.9	2.1	2.2
Total†	4.1	4.3	5.5	6.5	7.7	8.3	9.5	10.4	11.5	12.0	12.6	13.4

* Treatment costs not available for these medicines

† Columns may not add due to rounding.

Oncology Medicines	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Medicine Cost	$480M	$515M	$697M	$844M	$954M	$1,076M	$1,221M	$1,388M	$1,585M	$1,812M	$1,972M	$2,256M
Total no. of molecules	20	21	25	29	33	41	46	54	62	69	79	83
Other*	5	5	6	8	8	11	11	12	13	14	14	16
less than 2.5K	6	6	6	7	7	8	8	8	10	10	11	11
2.5K-3.5K	2	2	2	3	3	4	4	5	6	6	6	6
3.5K-5.0K	3	4	7	7	9	10	11	11	11	12	12	12
5.0K-7.5K	2	2	2	2	3	3	5	7	8	9	13	13
7.5K-10.0K	2	2	2	2	2	2	3	7	8	10	13	15
10.0K+	0	0	0	0	1	3	4	4	6	8	10	10
Avg. 28-day treatment cost	$3,867	$3,879	$4,003	$3,786	$4,159	$5,490	$5,685	$5,856	$6,011	$6,242	$6,993	$7,057
Estimated treatment population	124,109	132,663	174,038	222,887	229,450	195,992	214,761	237,078	267,426	306,763	317,757	376,044
Share of total Cdn. population	0.38%	0.40%	0.52%	0.66%	0.67%	0.57%	0.62%	0.68%	0.75%	0.86%	0.88%	1.02%

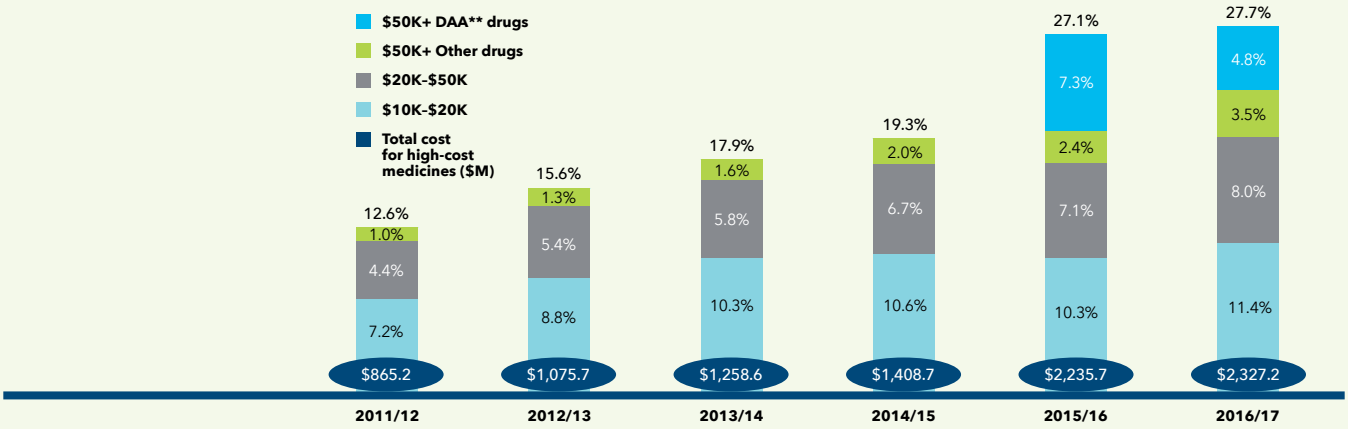
Source: PMPRB; CADTH pCODR

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 non-cancerous conditions, the data used for this analysis does not distinguish between indications, and thus, the reported sales may reflect some non-cancer use.

BRIEF INSIGHTS

High-cost medicines are also accounting for an increasing share of both public and private drug plan expenditures, as shown in Figures 12 and 13. The relative expenditures reported here are greater than for patented medicines alone, since they encompass the 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.

FIGURE 12 Trends in the Number and Share of High-Cost Medicines, NPDUIS Drug Plans*, 2011/12 to 2016/17



High-Cost Medicines	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17
Total no. of molecules	47	56	63	75	82	86
Share of active beneficiaries	0.87%	1.04%	1.18%	1.28%	1.52%	1.67%
Share of prescriptions	0.16%	0.18%	0.20%	0.22%	0.27%	0.29%

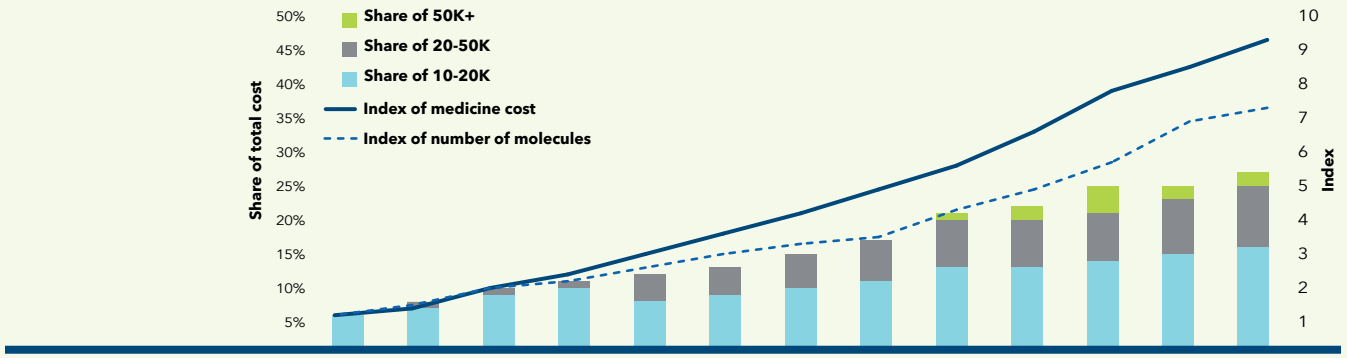
* British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Novcrd Island, Newfoundland and Labrabor, Yukon and the Non-insured Health Benefits Program

** DAA: Direct-acting antivirals, for Hepatitis C

[NPDUIS Poster: Cost Drivers of Public Drug Plans in Canada, 2016/17]

Source: NPDUIS database, CIHI (fiscal year data)

FIGURE 13 Trends in the Number and Share of High-Cost Medicines, Private Drug Plans, 2005 to 2017



	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Share of total cost	6%	7%	9%	10%	11%	13%	15%	17%	19%	22%	24%	25%	26%
Number of molecules	23	31	41	45	56	65	72	77	95	107	126	154	163

[NPDUIS Poster: Private Drug Plans in Canada: High-Cost Drugs and Beneficiaries, 2005 to 2017]

Source: IQVIA Private Pay Direct Drug Plan Database (calendar year data)

THERAPEUTIC CLASS

The PMPRB classifies medicines according to the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) system when it conducts analyses under the PMPRB Guidelines. This is a scientific, hierarchical system that classifies medicines according to their principal therapeutic use and chemical composition. At its first level of aggregation (Level 1), the ATC system classifies medicines according to the element of human anatomy with which they are primarily associated.

Figure 14 breaks out sales of patented medicines in Canada in 2017 by ATC Level 1. The two donut graphs compare the share of total sales for each therapeutic class in 2017 to the share in 2008. The associated table gives the 2017 sales for each class and the rate at which sales grew relative to 2016. Values in the second to last column of the table represent the component of overall sales growth attributable to medicines in the corresponding therapeutic class.[6] By this measure, antineoplastics and immunomodulating agents and alimentary tract and metabolism made the largest contribution to sales growth. Lower sales of nervous system medicines also had an impact on overall expenditure.

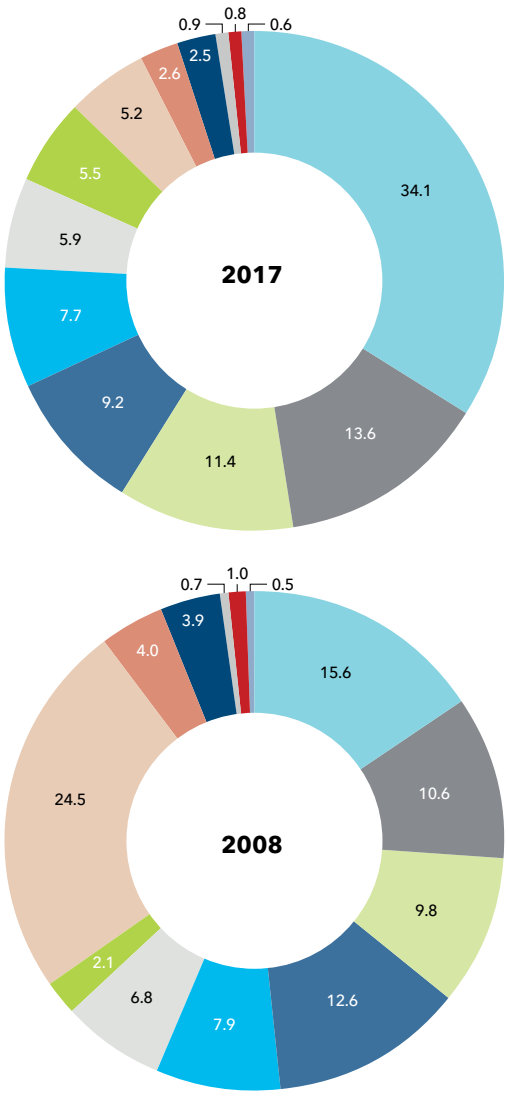
The antineoplastics and immunomodulating agents class accounted for a much larger share of sales in 2017 (34.1%) than in 2008 (15.6%), as more high-cost medicines entered the market. By contrast, the share of sales of cardiovascular system medicines decreased dramatically from 24.5% to 5.2%.

In 2017, half of the top 10 selling medicines had annual treatment costs exceeding

$10K

FIGURE 14 Sales of Patented Medicines by Major Therapeutic Class, 2017

Share of sales by therapeutic class, 2017 versus 2008



Therapeutic class	2017 sales ($millions)	Growth: 2017/2016, $millions (rate in %)	Impact on change in expenditure (%)	2017 Share of Sales (%)
L: Antineoplastics and immunomodulating agents	5,723.62	544.2 (10.5)	45.9	34.1
J: General antiinfectives for systemic use and P: Antiparasitic products*	2,279.96	62.1 (2.8)	5.2	13.6
A: Alimentary tract and metabolism	1,905.40	185.4 (10.8)	15.6	11.4
N: Nervous system	1,548.52	-53.8 (-3.4)	-4.5	9.2
R: Respiratory system	1,293.86	52.0 (4.2)	4.4	7.7
B: Blood and blood forming organs	986.89	74.6 (8.2)	6.3	5.9
S: Sensory organs	927.90	129.1 (16.2)	10.9	5.5
C: Cardiovascular system	877.44	51.4 (6.2)	4.3	5.2
M: Musculo-skeletal system	430.83	33.2 (8.3)	2.8	2.6
G: Genito-urinary system and sex hormones	412.03	1.2 (0.3)	0.1	2.5
H: Systemic hormonal preparations	153.94	83.0 (117.0)	7.0	0.9
D: Dermatologicals	138.79	13.6 (10.8)	1.1	0.8
V: Various	105.70	9.7 (10.1)	0.8	0.6
All therapeutic classes†	16,784.87	1,185.5	100.0	100.0

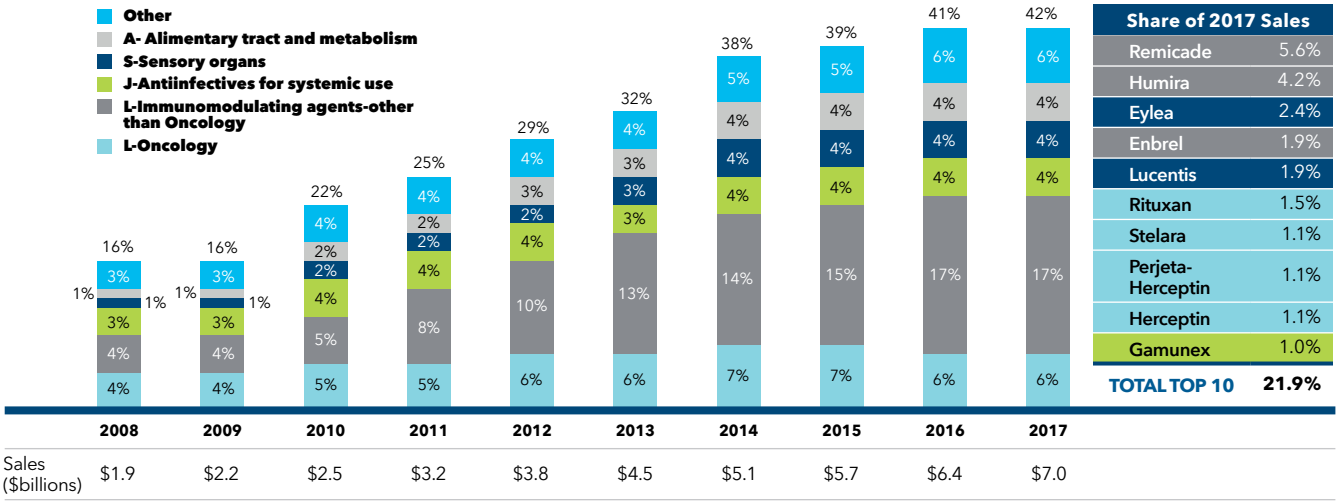
† Columns may not add due to rounding

Source: PMPRB

* These groups have been combined for reasons of confidentiality

Biologic medicines, which are well represented in the high-cost medicine category, have been capturing an increasing share of the Canadian market, from 16% of patented medicine sales in 2008 to 42% in 2017. Figure 15 breaks down the growth in biologic patented medicine sales by major therapeutic class. Although the increasing share of biologic medicine sales cuts across many therapeutic categories, immunosuppressants have had an exceptionally high uptake over the last decade, from 4% of total patented medicine sales in 2008 to 17%, less than a decade later. This increase was mainly driven by three medicines: Remicade, Humira and Enbrel.

FIGURE 15 Biologic Medicine Share of Patented Medicine Sales by Therapeutic Class, 2008 to 2017

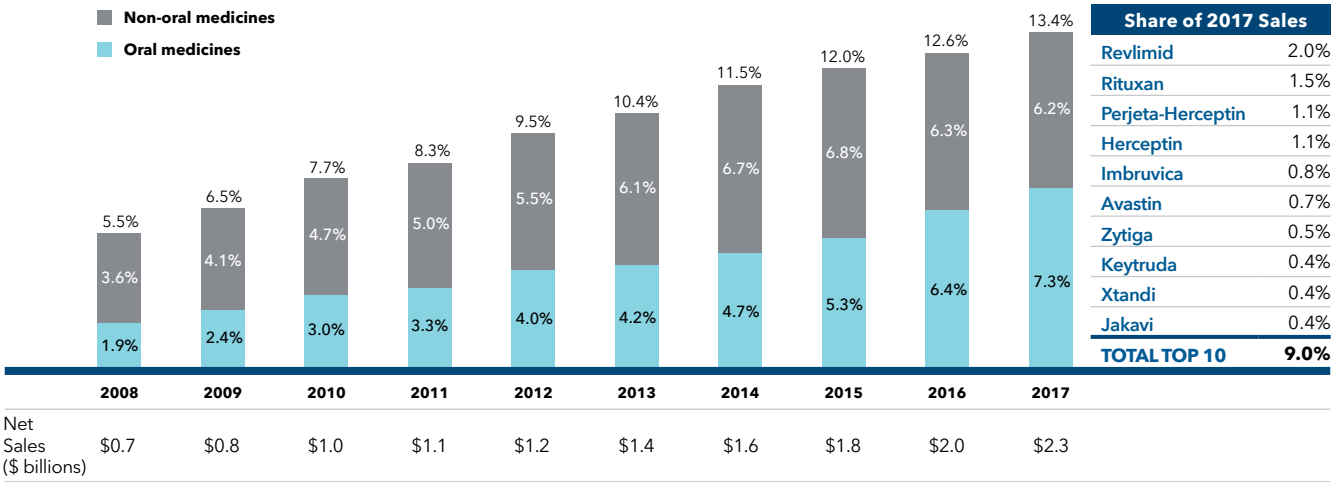


Share of 2017 Sales	
Remicade	5.6%
Humira	4.2%
Eylea	2.4%
Enbrel	1.9%
Lucentis	1.9%
Rituxan	1.5%
Stelara	1.1%
Perjeta-Herceptin	1.1%
Herceptin	1.1%
Gamunex	1.0%
TOTAL TOP 10	21.9%

Source: PMPRB

Oncology medicines are also capturing an increasing share of the patented medicine market. Figure 16 shows that cancer treatments have grown from 5.5% of total patented medicine sales in 2008 to 13.4% in 2017. Cancer treatments taken orally in particular are an emerging segment, increasing their share of the patented medicine market from 1.9% to 7.3% during the same time period. Revlimid was the top-selling oncology medicine, accounting for 2.0% of all patented medicine sales.

FIGURE 16 Oncology Medicine Share of Patented Medicine Sales, by Formulation, 2008 to 2017



Share of 2017 Sales	
Revlimid	2.0%
Rituxan	1.5%
Perjeta-Herceptin	1.1%
Herceptin	1.1%
Imbruvica	0.8%
Avastin	0.7%
Zytiga	0.5%
Keytruda	0.4%
Xtandi	0.4%
Jakavi	0.4%
TOTAL TOP 10	9.0%

Source: PMPRB

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 non-cancerous conditions, the data used for this analysis does not distinguish between indications, and thus, the reported sales may reflect some non-cancer use.

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

2 All statistical results for patented medicines reported in this chapter are based on data submitted by patentees as of March 2018. On occasion, patentees report revisions to previously submitted data or provide data not previously submitted. New data of this sort can appreciably affect the statistics in this chapter. To account for this possibility, the PMPRB has adopted the practice of reporting recalculated sales figures (see Trends in 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 such recalculated values reflect currently available data. Consequently, where data revisions have occurred, values reported here may differ from those presented in earlier Annual Reports.

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

4 Unless specified, the term "generic" in this report includes both patented and non-patented generic medicines.

5 The cost driver analysis used here follows the approach detailed in the PMPRB report titled The Drivers of Prescription Drug Expenditures: A Methodological Report, 2013.

6 This is obtained as the ratio of the year-over-year change in the dollar value of sales for the therapeutic class in question to the change in sales across all patented medicines.

PATENTED MEDICINE PRICES INCREASED LESS THAN CPI

In 2017, the increase in patented medicine prices was, on average, less than the rate of inflation, as measured by the Consumer Price Index (CPI), and therefore, did not contribute to sales growth.

PRICE TRENDS

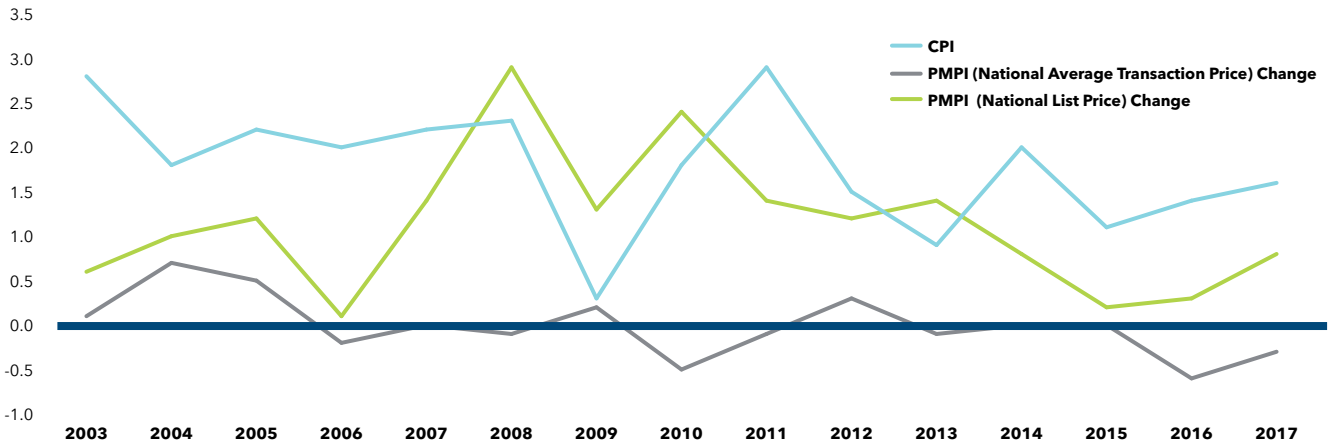
The PMPRB uses the Patented Medicines Price Index (PMPI) to monitor trends in the prices of patented medicines. The PMPI measures the average year-over-year change in the ex-factory prices of patented medicines sold in Canada. The index is constructed using a formula that takes a sales-weighted average of price changes observed at the level of individual medicines.[7] 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 for a six-month period submitted by patentees.

It is important to understand the conceptual relationship between the PMPI and medicine costs. The PMPI does not measure changes in the utilization of patented medicines; a quantity index, the PMQI, is calculated for this purpose (see the section on the Utilization of Patented Medicines). The PMPI does not measure the cost impact of changes in prescribing patterns or the introduction of new medicines. By design, the PMPI isolates the component of sales growth attributable to changes in prices.

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 17 provides year-over-year changes in the PMPI against corresponding changes in the CPI for the years 2003 through 2017. The PMPI is reported based on two measures: the national average transaction price (which includes rebates and discounts), and the national list price, both of which are reported to the PMPRB by patentees. General price inflation, as measured by the CPI, has exceeded the average increase in patented medicine prices almost every year since 2003. In 2017, the CPI rose by 1.6%, while the PMPI increased by 0.8%.

It is not surprising that the PMPI has seldom kept pace with the CPI. The PMPRB's Guidelines envisage that the price of a patented medicine should not rise by more than the CPI over any three-year period.[8] (The Guidelines also contemplate a cap on year-over-year price increases equal to one and one-half times the current year rate of CPI inflation.) This effectively establishes CPI inflation as an upper bound on the amount by which individual prices may rise over any three-year period if they are to remain within the limits set out in the Guidelines. Increases in the PMPI normally do not reach this upper bound because many patentees do not raise their prices by the full amount envisaged under the Guidelines.

FIGURE 17 Annual Rate of Change (%), Patented Medicines Price Index (PMPI) and Consumer Price Index (CPI), 2003 to 2017



Source: PMPRB; Statistics Canada

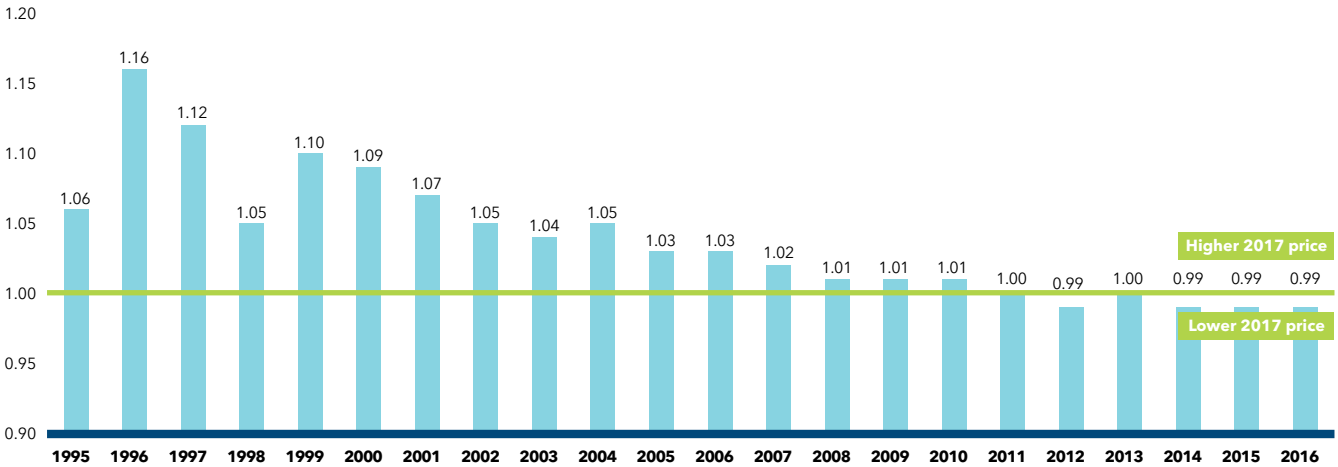
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
PMPI (National Average Transaction Price) Change	0.1	0.7	0.5	-0.2	0	-0.1	0.2	-0.5	-0.1	0.3	-0.1	0	0	-0.6	-0.3
PMPI (National List Price) Change	0.6	1	1.2	0.1	1.4	2.9	1.3	2.4	1.4	1.2	1.4	0.8	0.2	0.3	0.8
CPI Change	2.8	1.8	2.20	2.0	2.2	2.3	0.3	1.8	2.9	1.5	0.9	2.0	1.1	1.4	1.6

PRICE BEHAVIOUR AFTER INTRODUCTION

Does the price of a typical patented medicine change much in the years after it enters the Canadian market? To answer this question, Figure 18 provides the average ratio of the 2017 price to introductory price (the price at which the medicine was sold in its first year on the Canadian market).

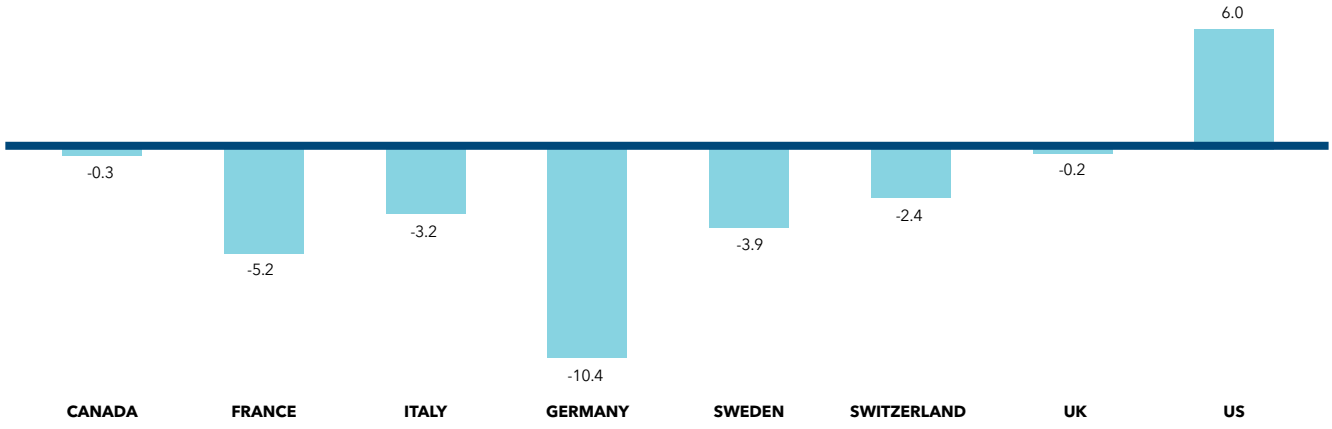
The results in Figure 18 imply a consistent trend for prices to remain stable early in the life cycle, and then to gradually rise by a small amount, year-over-year, afterwards. This is consistent with the effect of the PMPRB's CPI methodology.[9] For example; the prices of medicines introduced a decade ago are only 2% higher in 2017.

FIGURE 18 Average Ratio of 2017 Price to Introductory Price, by Year of Introduction



Source: PMPRB

FIGURE 19 Annual Average Rates of Price Change %, Canada and the PMPRB7, 2017



Source: PMPRB

PRICE CHANGE BY COUNTRY

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

The PMPRB uses this information to:

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

Figure 19 gives the average annual rates of price change for Canada and each of the seven comparator countries. These results were obtained by applying the PMPI methodology (with weights based on Canadian sales patterns) to the international price data that patentees have submitted to the PMPRB. Note that results for the US are based on prices that incorporate prices from the US Federal Supply Schedule (FSS).[10]

The results in Figure 19 indicate that in 2017, the US saw prices rise at an average rate of 6.0%, while prices in all other countries declined. Germany saw the greatest decrease, at -10.4%. These results are consistent with a long-term tendency for patented medicine prices to slowly fall over time in most comparable countries (the exception being the US).

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

7 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.

8 It is possible for individual prices (or, for that matter, the PMPI) to rise by more than the CPI in a given year. This can occur when patentees have banked price adjustments in the preceding years. It can also occur when the forecast rate of CPI inflation exceeds the actual rate.

9 It must be emphasized that this statement refers to the behaviour of prices on average. There may be instances where individual prices have risen or fallen substantially since introduction.

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

COMPARISON OF CANADIAN PRICES TO FOREIGN PRICES

Tables 9 and 10 provide detailed statistics comparing the foreign prices of patented medicines to their Canadian prices. Each table provides two sets of average price ratios. These are differentiated according to the method by which foreign prices were converted to their Canadian dollar equivalents. The tables also give the numbers of medicines (DINs) and the volume of sales encompassed by each reported price ratio.[11]

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

How much more/less would Canadians have paid for the patented medicines they purchased in 2017 had they paid Country X prices rather than Canadian prices?

For example, Table 9 states that the 2017 average France-to-Canada price ratio was 0.75. This means Canadians would have paid 25% less for the patented medicines they purchased in 2017 had they bought these products at 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.) Table 9 also reports 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 of this type:

How much more/less consumption of other goods and services would Canadians have sacrificed for the patented medicines they purchased in 2017 had they lived in Country X?

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

TABLE 9 Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons, 2017

	Canada	France	Italy	Germany	Sweden	Switzerland	United Kingdom	United States
At Market Exchange Rates								
Average price ratio 2017	1.00	0.75	0.95	1.12	0.93	1.12	0.94	3.36
Average price ratio 2016	1.00	0.77	0.92	1.09	0.95	1.09	0.99	3.08
At Purchasing Power Parities								
Average price ratio 2017	1.00	0.79	1.12	1.20	0.83	0.88	0.98	3.25
Average price ratio 2016	1.00	0.83	1.09	1.22	0.84	0.87	0.97	3.15
Number of patented medicines 2017	1,381	675	775	1,016	845	889	991	1,100
Sales ($millions)	16,784.86	9,679.62	12,611.57	14,379.87	12,960.85	14,183.17	13,567.44	15,575.41

Source: PMPRB

BILATERAL PRICE COMPARISONS

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

It is important to note that it is not always possible to find a matching foreign price for each and every patented medicine sold in Canada. Table 9 displays how often an international price comparison was available for each of the comparator countries. For example, out of 1,381 patented medicines reported as under the PMPRB's jurisdiction in 2017, a publicly available ex-factory price for France was available 49.0% of the time, whereas for the US the number was 79.6%. Given the integrated nature of the Canadian and US supply chain, it is not uncommon for the US to be the only other country for which a comparator price to a medicine sold in Canada is available, in which case it is deemed to constitute the international median price as per the PMPRB's methodology.

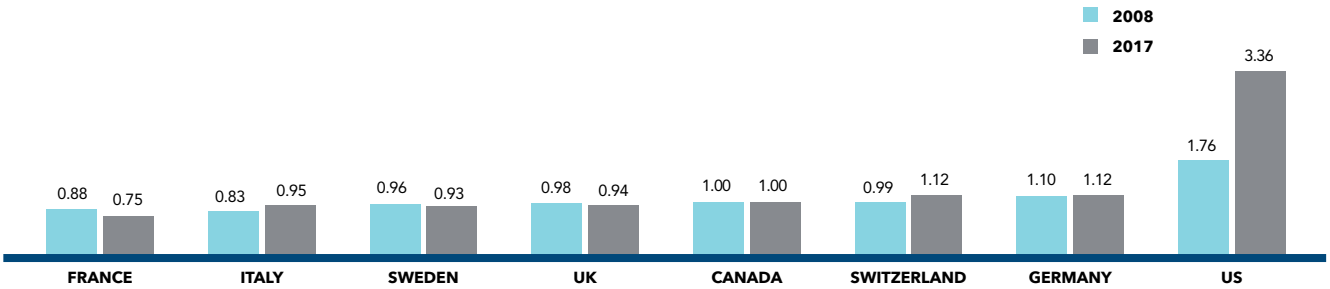
Average price ratios obtained with currency conversion at PPPs tell the same story. When international differences in cost of living are accounted for, it appears Canadians incurred a larger consumption cost for the patented medicines they purchased in 2017 than did residents of France, Sweden, Switzerland and the UK.

Figure 20 puts these results in historical perspective. In 2008, Canadian prices were, on average, slightly higher than prices in France, Italy, Sweden and the UK, and approximately the same as prices in Switzerland. By 2017, the gap between Canadian prices and prices in France, Sweden and the UK had grown slightly greater as the relative prices in these countries dropped, while the prices in Italy in 2017 were more in line with Canadian levels. Price levels in Switzerland, Germany and the US all exceeded those in Canada in 2017.

If the patented medicine is being sold in one or more of the PMPRB7 countries, the patentee must report the publicly available ex-factory prices to the PMPRB for each class of customer.[12] In order to assess how Canada compares to a basket of countries beyond the PMPRB7, Figure 21 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.

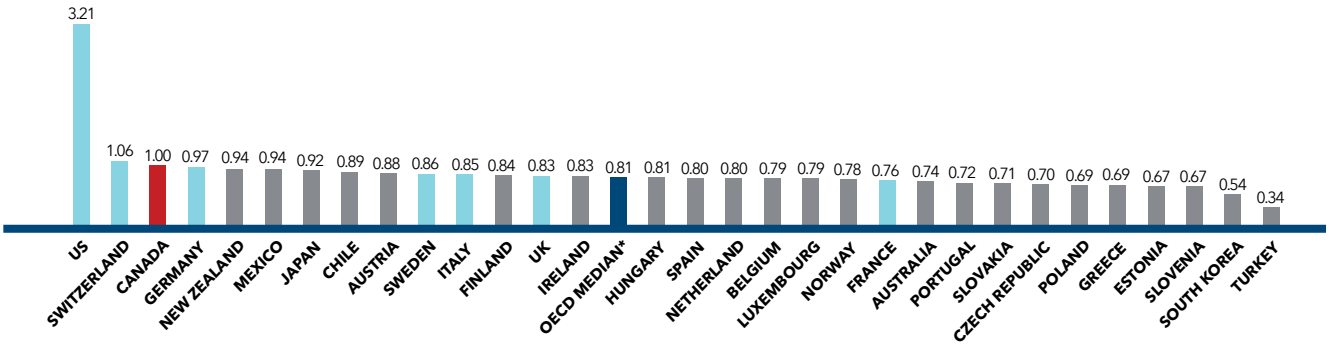
The international price comparisons reported in Figure 21 provide a bilateral price comparison using all countries in the Organisation for Economic Co-operation and Development (OECD) with available MIDAS™ data. The average foreign-to-Canadian price ratios are constructed using exactly the same approach employed to produce the ratios presented in Figure 20. These are Canadian sales-weighted arithmetic averages of the corresponding foreign-to-Canadian price ratios for individual medicines.[13] As shown in Figure 21, median OECD prices are, on average, approximately 19% below prices in Canada, which are third highest among the 31 countries. Notably, the top three highest priced countries are the US, Switzerland and Canada.

FIGURE 20 Average Foreign-to-Canadian Price Ratios, 2008 and 2017



Source: PMPRB

FIGURE 21 Average Foreign-to-Canadian Price Ratios, Patented Medicines, OECD, 2017

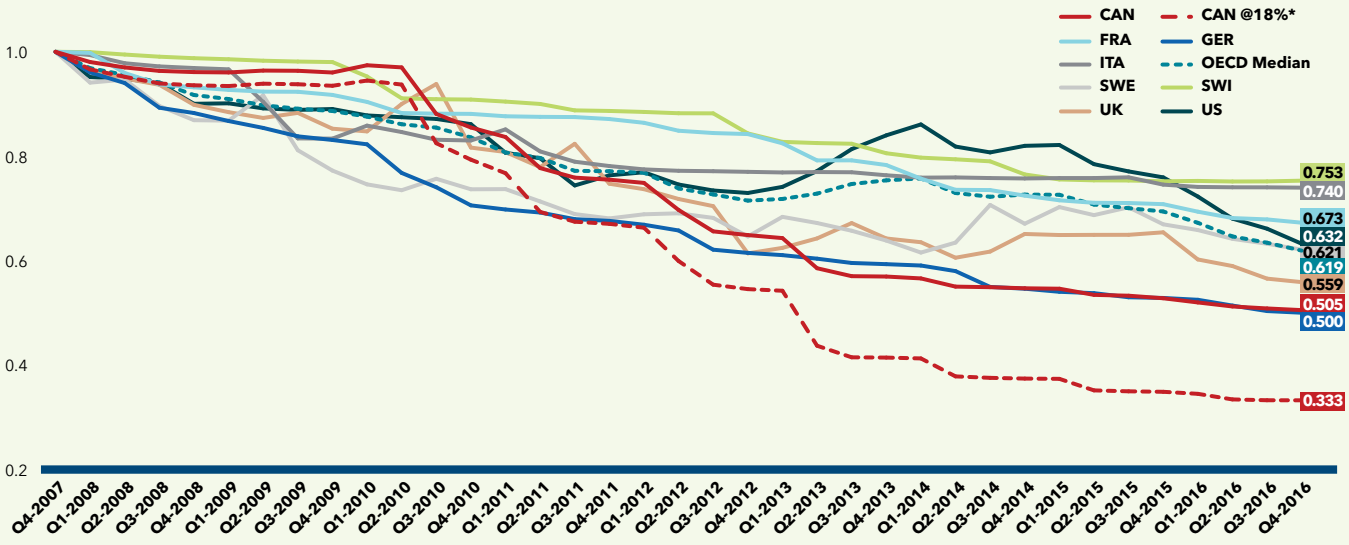


* Calculated at medicine level for medicines with prices available in at least three foreign markets

BRIEF INSIGHTS

Average generic medicine prices in Canada have been reduced to half of what they were a decade ago (Figure 22). While this decrease exceeded the overall price reductions in most PMPRB7 markets, the rate of decline has slowed in recent years. Generic price reductions coupled with a weakening Canadian dollar have gradually reduced the sizable gap between Canadian and foreign generic price levels over the past several years. Despite this, average prices in the PMPRB7 countries are still substantially less than Canadian levels, with the gap being slightly wider for the OECD countries. Canada has the seventh highest generic prices in the OECD, just below the US (Figure 23).

FIGURE 22 Price Indices for Generic Medicines, Canada and the PMPRB7, Q4-2007 to Q4-2016

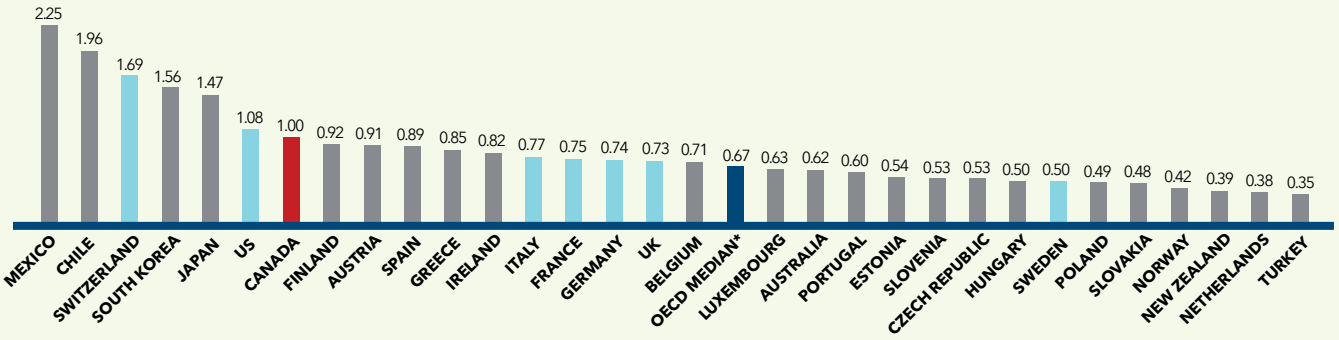


* Group of generic medicines set to 18% of the brand price through pan-Canadian Pharmaceutical Alliance negotiations.

Note: The term "generic" used in this analysis includes both patented and non-patented generic medicines.

[NPDUIS Report: Generics360, 2016]

FIGURE 23 Foreign-to-Canadian Price Ratios for Generic Medicines, OECD, Q4-2016



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

Note: The term "generic" used in this analysis includes both patented and non-patented generic medicines.

[NPDUIS Report: Generics360, 2016]

MULTILATERAL PRICE COMPARISONS

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

Focusing again on results at market exchange rates, the average MIP-to-Canadian price ratio stood at 1.26 in 2017 almost unchanged from 1.25 in 2016 (Figure 24).

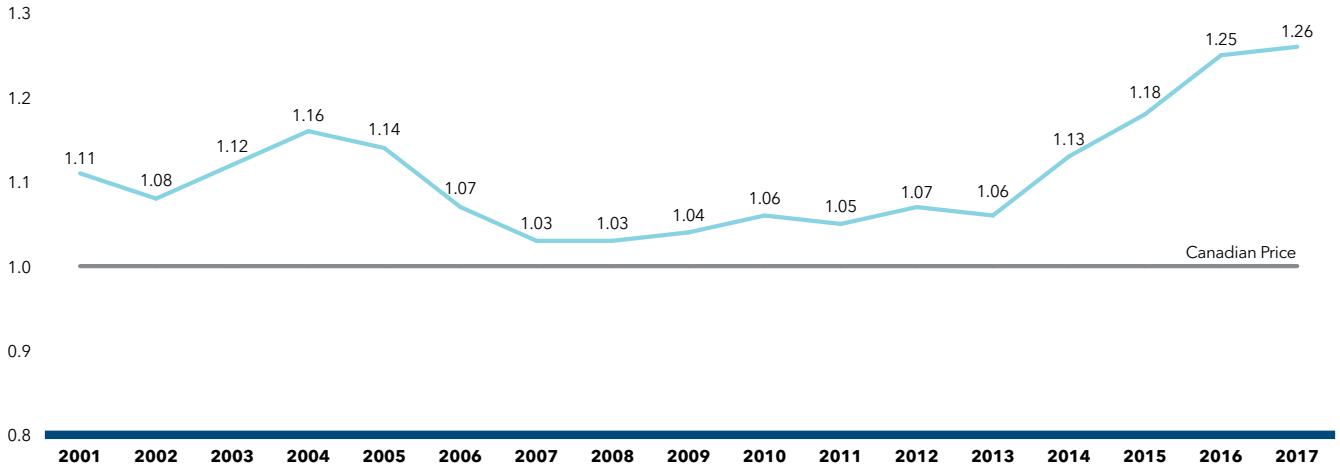
Note that mean foreign prices produce higher foreign-to-Canadian price ratios than do MIPs. This is explained by the influence of US prices, which are typically much higher than prices elsewhere. Although US prices nearly always figure importantly in determining mean foreign price, this is less so when it comes to median international prices. Nevertheless, the US does exercise a significant influence over the average ratio of median international prices relative to Canadian prices because of the not infrequent phenomenon mentioned in the previous section, whereby the US is the only country for which an ex-factory price for a patented medicine sold in Canada is available.

TABLE 10 Average Foreign-to-Canadian Price Ratios, Multilateral Comparisons, 2017

	Median	Minimum	Maximum	Mean
Average price ratio at market exchange rates	1.26	0.99	3.30	1.56
Average price ratio at purchasing power parities	1.23	0.96	3.22	1.53
Number of patented medicines	1,287	1,287	1,287	1,287
Sales ($millions)	16,315.90	16,315.90	16,315.90	16,315.90

Source: PMPRB

FIGURE 24 Average Ratio of Median International Price (MIP) to Canadian Price, at Market Exchange Rates, 2001 to 2017



Source: PMPRB

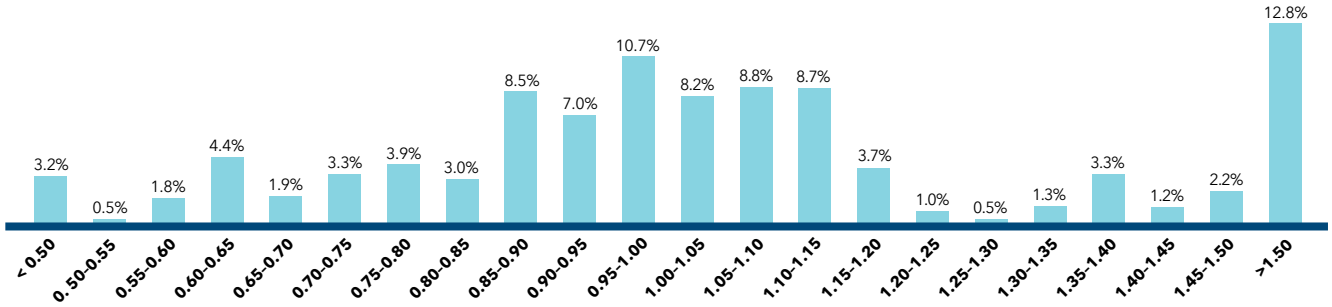
Figure 25 provides alternate results for the average MIP-to-Canadian price ratio at market exchange rates in 2017. To address the point that Canadian prices are national average transaction prices whereas foreign prices are list prices, a list price to list price ratio is also calculated. Using this method, the average ratio decreases from 1.26 to 1.08. It is important to keep in mind that confidential rebates provided to payers are currently not captured in these data.

To account for the large impact of US prices in determining the median foreign price, a ratio excluding the US and a ratio including at least five countries in the calculation of the median are also provided in Figure 25. With these restrictions, the average MIP-to-Canadian price ratios drop to 0.88 and 0.92, respectively, suggesting that median foreign list prices are, on average, 8% to 12% lower than Canadian list prices. In many of the comparator countries, discounts off list prices are available to all payers, both public and private. By contrast, a large portion of the Canadian market pays list prices, or close to list prices. Furthermore, it should be noted that these are average ratios—some patentees charge Canadian consumers less than median international prices, while others charge more. For patentee level median-to-Canadian price ratios, please refer to Table 21 in Appendix 4 of this report.

FIGURE 25 Average Ratio of Median International Price (MIP) to Canadian Price, at Market Exchange Rates, 2017

Source: PMPRB

FIGURE 26 Range Distribution, Sales, by MIP-to-Canadian Price Ratio, 2017



Source: PMPRB

TABLE 11 Top-10 ATC4s by Total Sales Greater than Median International Prices, 2017

Description	ATC4	No. of companies	No. of chemicals in ATC4 (no. currently under patent)[17]	Total patented DINs	Patented DINs greater than median price	2017 net revenue for patented DINs ($millions)	Patented DINs ATC4 share of 2017 revenues	MIP-to-Canadian ratio (min. 5) of patented DINs	Impact of difference on patented medicines in 2017
Adrenergics in combination with corti-costeroids or other medicines excluding anticholinergics	R03AK	3	4(4)	11	9	$568.2	3.39%	61%	$213.3
Antineovascularisation agents	S01LA	2	2(2)	3	3	$709.8	4.23%	78%	$161.4
Glucocorticoids	R03BA	3	10(6)	17	11	$212.8	1.27%	80%	$78.0
DPP-4 inhibitors	A10BH	4	4(4)	9	9	$290.9	1.73%	76%	$72.2
Combinations of oral blood glucose lowering medicines	A10BD	5	12(12)	29	17	$294.9	1.76%	70%	$63.9
Selective immunosuppressants	L04AA	12	23(14)	27	20	$1,552.1	9.25%	99%	$61.8
Insulins and analogues for injection, long-acting	A10AE	1	4(2)	4	4	$276.8	1.65%	79%	$53.1
Other antineoplastic agents	L01XC	6	19(17)	17	3	$735.6	4.38%	99%	$48.6
Proton pump inhibitors	A02BC	3	9(9)	13	10	$182.1	1.08%	54%	$47.9
Tumor necrosis factor alpha inhibitors	L04AB	2	4(3)	8	1	$1,109.1	6.61%	98%	$42.6

Source: PMPRB

Figure 26 offers more detail on the medicine-level MIP-to-Canadian ratios underlying the averages reported in Table 10. This figure distributes the 2017 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).[14] These results show substantial dispersion in medicine-level price ratios: while patented medicines with MIP-to-Canadian price ratios between 0.90 and 1.10 accounted for 34.8% of sales, those with ratios less than 0.90 accounted for 30.5% of sales, and medicines with ratios exceeding 1.10 accounted for 34.7%.

In 2017, approximately 50% of Canadian patented medicines were priced above the median international level.[15] Table 11 shows which therapeutic categories in particular are priced above the median international levels in Canada. Medicines that share the fourth level ATC ("ATC4")[16] are grouped to identify distinct chemical/pharmacological/therapeutic subgroups, allowing for a calculation of the average MIP-to-Canadian price ratios among medicines that may be used to treat the same conditions. Table 11 identifies the top 10 ATC4s in 2017 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 2017, sales in Canada would have been reduced by $843 million (an average reduction of 16% for these ATC4s). Of the 138 DINs classified into these 10 ATC4s, over 63% were priced above the median international price.

11 The number of medicines and sales these ratios encompass vary because it is not always possible to find a matching foreign price for each patented medicine sold in Canada. Note that all of the bilateral average price ratios reported in Table 9 combined represent at least 58% of 2017 Canadian sales, while the multilateral ratios in Table 10 cover over 97%.

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

13 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.

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

15 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.

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

17 For further detail, the medicines included in Table 11 reported as under PMPRB jurisdiction are: A10AE (insulin (ultralente) human biosynthetic, insulin detemir, insulin glargine, pork/bovine insulin/zinc), A02BC (dexlansoprazole, esomeprazole, esomeprazole magnesium, lansoprazole, omeprazole, omeprazole magnesium, pantoprazole magnesium, pantoprazole sodium, rabeprazole sodium) , A10BD (alogliptin benzoate/metformin hydrochloride, canagliflozin and metformin hydrochloride tab, dapagliflozin and metformin hydrochloride, empagliflozin/ linagliptin, empagliflozin/metformin hydrochloride, linagliptin/metformin, rosiglitazone maleate/ glimepiride, rosiglitazone maleate/metformin hydrochloride, saxagliptin/metformin, sitagliptin phosphate monohydrate and metformin, sitagliptin phosphate monohydrate/metformin h, sitagliptin phosphate/metformin hydrochloride), A10BH (alogliptin benzoate, linagliptin, saxagliptin, sitagliptin phosphate), L01XC (atezolizumab, alemtuzumab, bevacizumab, blinatumomab, brentuximab vedotin, cetuximab, durvalumab, ipilimumab, nivolumab, obinutuzumab, olaratumab, panitumumab, pembrolizumab, pertuzumab, pertuzumab/ trastuzumab, ramucirumab, rituximab, trastuzumab, trastuzumab emtansine),L04AA (abatacept, adalimumab, alefacept, anakinra, basiliximab, belimumab, cyclosporine, daclizumab, eculizumab, efalizumab, everolimus, fingolimod hydrochloride, leflunomide, muromonab-cd3, mycophenolate mofetil, mycophenolate sodium, natalizumab, sirolimus, tacrolimus, teriflunomide, tofacitinib, vedolizumab), L04AB (certolizumab pegol, etanercept, golimumab, infliximab), R03AK (budesonide/formoterol fumarate, fluticasone furoate/vilantero, mometasone furoate/ formoterol fumarate, salmeterol xinafoate/fluticasone propionate), R03BA (beclomethasone dipropionate,budesonide, ciclesonide, ciclesonide nasal aerosol, flunisolide, fluticasone propionate, fluticasone propionate inhalation aerosol, fluticasone propionate powder for inhalation, mometasone furoate, triamcinolone acetonide), S01LA (aflibercept, ranibizumab).

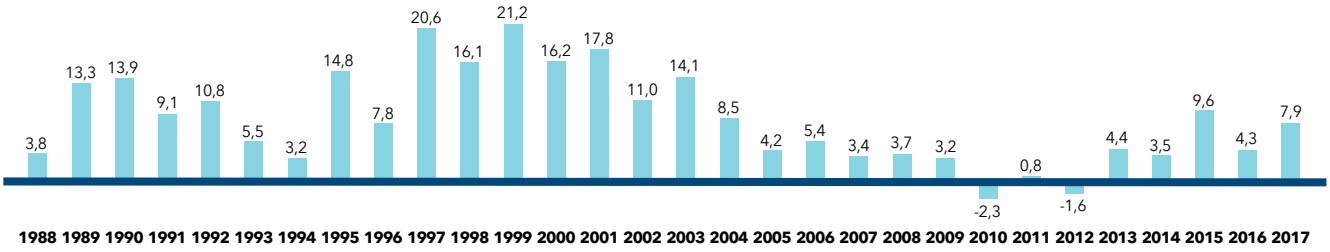
CANADA IS A TOP 10 GLOBAL MARKET

Canada is an important market for pharmaceuticals representing 2.0% of worldwide sales. Canada is consistently in the top 10 global markets for pharmaceuticals. Canada spends approximately the same amount as the UK on pharmaceuticals despite having only half its population.

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 27 provides average rates of utilization growth, as measured by the PMQI, from 1988 through 2017. These results confirm that in recent years, growth in the utilization of patented medicines has been the primary source of rising sales, with rates of utilization growth roughly tracking sales growth. This tracking pattern continued in 2017, with utilization of patented medicines, on average, increasing by 7.9% between 2016 and 2017 and sales increasing by 7.6%.

FIGURE 27 Annual Rate of Change (%), Patented Medicines Quantity Index (PMQI), 1988 to 2017

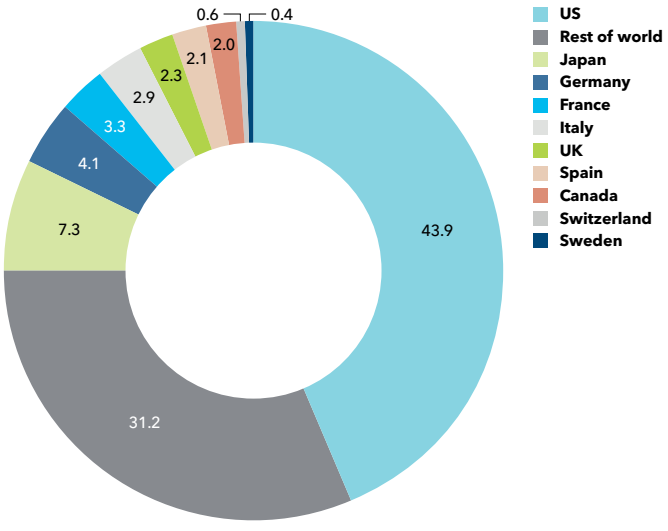


Source : PMPRB

CANADIAN MEDICINE EXPENDITURES IN THE GLOBAL CONTEXT

IQVIA[18] regularly reports on medicine sales across a large number of countries. Based on sales data from this source, Figure 28 provides shares of global sales for Canada and each of the PMPRB7 countries considered in conducting its price reviews.[19] The Canadian market accounted for 2.0% of the global market in 2017.

FIGURE 28 Distribution of Medicine Sales % Among Major National Markets, 2017



Source: MIDAS™ database, 2017, IQVIA. All rights reserved

1.8%

MEDICINE EXPENDITURES IN CANADA

IN 2015, CANADIANS SPENT 1.8% OF GROSS DOMESTIC PRODUCT ON MEDICINES.

This is the 2nd highest share in the PMPRB7, behind only the United States.

Figure 29 provides Canada's share of global sales for 2005 to 2017. The Canadian share has remained between 1.9% and 2.7% throughout this period. Although 2.0% is at the low end for Canada's average share of global sales in recent years, the US share grew from 40.4% in 2014 to 43.9% in 2017, resulting in declining shares for all other major countries.

FIGURE 29 Canada's Share of Medicine Sales %, 2005 to 2017

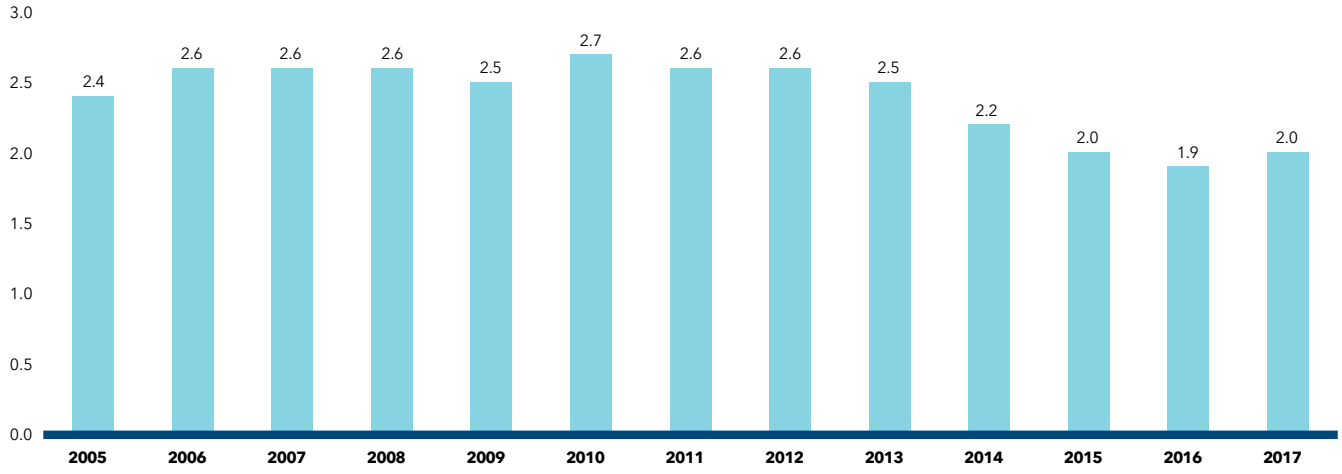


Figure 30 gives the average annual rate of growth in total medicine sales for Canada and the PMPRB7, individually and collectively. From 2005 to 2017, medicine sales in Canada rose at an average annual rate of approximately 4.2%. This is less than the average rate of growth in medicine sales among the seven comparator countries over the same period, though as is clear from the figure, this growth rate is heavily skewed by the influence of US sales on the total sales of the PMPRB7.

FIGURE 30 Average Rate of Growth (%), Medicine Sales, at Constant 2017 Market Exchange Rates, by Country, 2005 to 2017

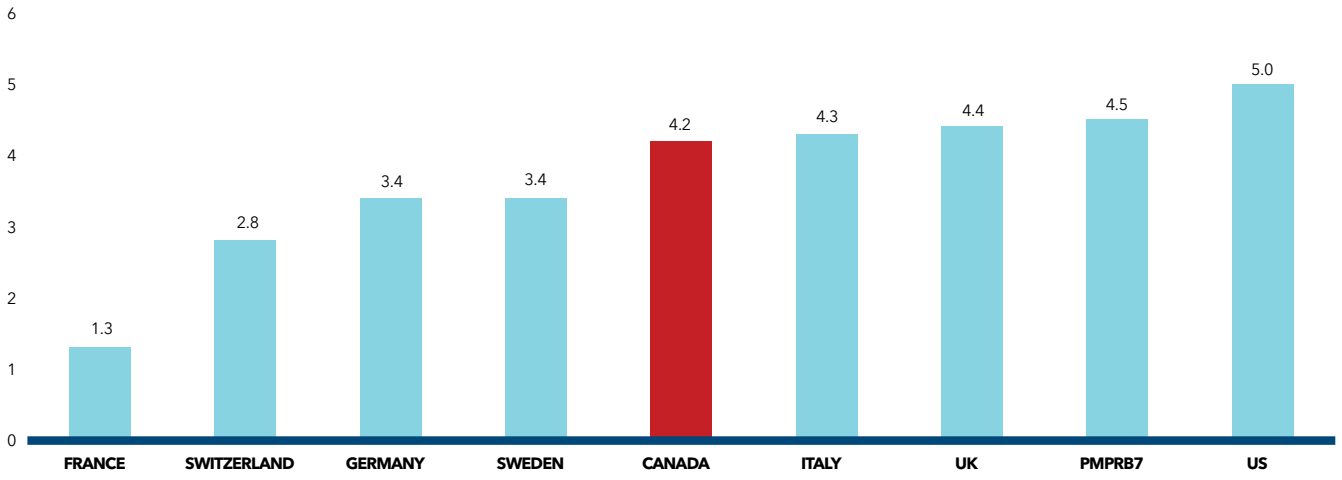
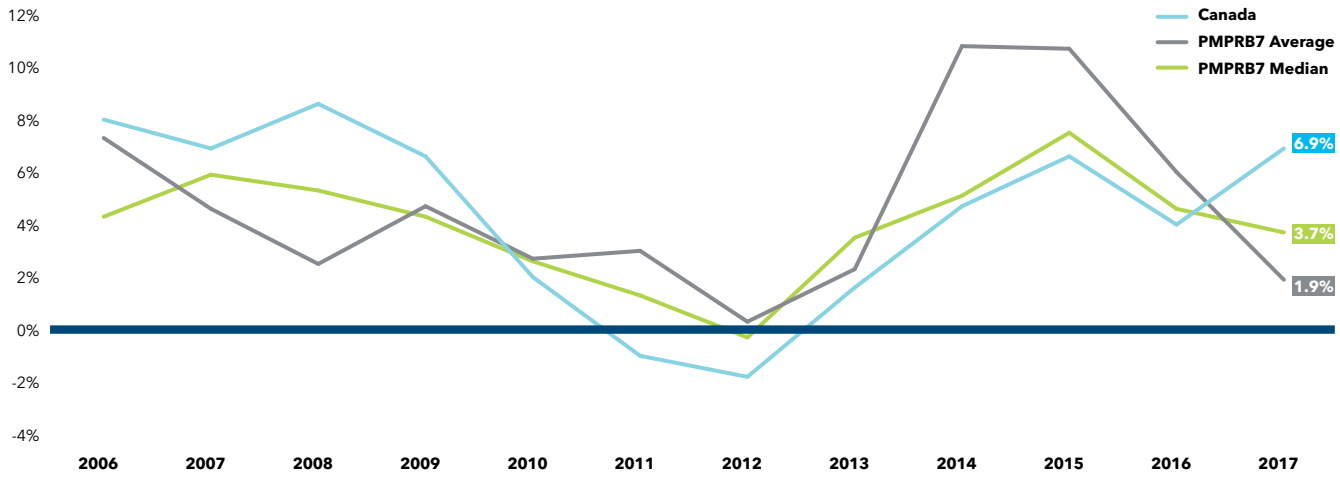


Figure 31 compares rates of year-over-year growth in medicine sales in Canada and the PMPRB7 countries combined. In 2017, sales grew at a faster rate in Canada than in any of the other PMPRB7 countries, including the US which saw a significant decrease in the rate of growth from the previous year. The Canadian expenditure growth rate in 2017 exceeded the median for the PMPRB7 for the first time since 2009.

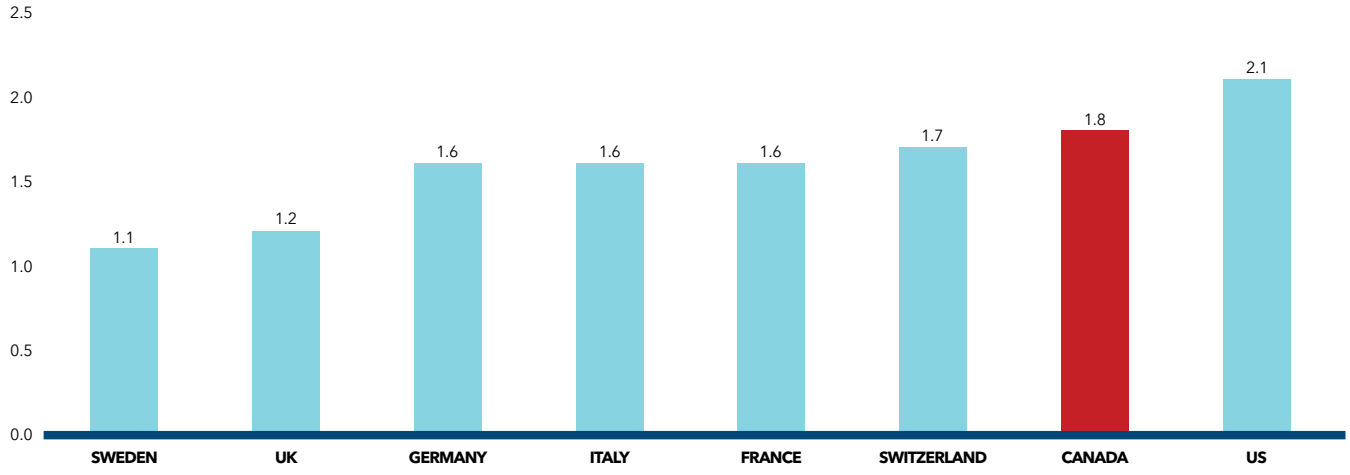
FIGURE 31 Average Annual Rate of Change in Medicine Sales, at Constant 2017 Market Exchange Rates, Canada and the PMPRB7, 2006 to 2017



Source: MIDAS™ database, 2005–2017, IQVIA. All rights reserved

The proportion of national income allocated to the purchase of medicines provides another way to compare medicine costs across countries.[20] Figure 32 gives medicine expenditures as a share of Gross Domestic Product (GDP) for Canada and the PMPRB7 countries based on data for 2015. Medicine expenditures absorbed between 1.1% and 2.1% of the GDP in the PMPRB7. The Canadian value (1.8%) was second only to the US.

FIGURE 32 Medicine Expenditures as a Share of GDP %, 2015



Source: OECD

Table 12 provides a historical perspective on the expenditures-to-GDP ratio.[21] In 2005, Canada's ratio was fourth highest of the PMPRB7. Since that time, Canada's ratio has risen, while the ratios of three other countries (France, Italy and Sweden) have declined. In 2015, Canada once again had the second highest medicine spending per capita among the PMPRB7 (again behind only the US), 18% higher than the median of these countries.

TABLE 12 Medicine Expenditures as a Share of GDP, 2015

	Share: Medicine Expenditures/GDP 2015 (%)	Share: Medicine Expenditures/GDP 2005 (%)	Growth: GDP 2005–2015 (%)	Medicine spending per capita 2005 ($US PPP)	Medicine spending per capita 2015 ($US PPP)
Canada	1.82	1.64	37.7	593	807
France	1.63	1.79	40.5	545	668
Germany	1.60	1.58	47.1	509	766
Italy	1.61	1.70	29.4	505	601
Sweden	1.09	1.15	51.3	396	519
Switzerland	1.69	1.09	81.0	427	1,056
United Kingdom	1.20	1.00	29.5	NA	497
United States	2.06	1.88	38.4	832	1,162

Source: OECD

Table 13 gives the composition of patentees' sales by therapeutic class for Canada and PMPRB7, individually by country and as an aggregate.[22] The results imply a remarkable degree of similarity across countries.

TABLE 13 Distribution of Medicine Sales (%) by Major Therapeutic Class for Canada and the PMPRB7, 2017

Therapeutic class	Canada	PMPRB7	France	Italy	Germany	Sweden	Switzerland	United Kingdom	United States
A: Alimentary tract and metabolism	13.0	14.7	10.0	10.0	10.8	10.3	10.8	10.7	16.1
B: Blood and blood-forming organs	4.6	5.7	8.1	8.7	7.8	9.3	5.9	5.9	5.1
C: Cardiovascular system	9.0	5.3	7.7	9.6	7.1	4.6	9.2	6.3	4.6
D: Dermatologicals	2.5	2.4	2.1	1.6	2.4	2.3	3.0	2.2	2.4
G: Genito-urinary system and sex hormones	4.4	4.0	2.8	3.2	2.8	3.8	4.0	3.6	4.3
H: Systemic hormonal preparations	1.2	2.6	2.2	1.8	2.0	2.2	1.5	2.6	2.7
J: General antiinfectives for systemic use	9.8	12.1	13.0	20.0	9.8	10.5	11.1	12.5	11.7
L: Antineoplastics and immunomodulating agents	19.8	21.0	22.7	18.6	23.2	24.1	22.1	21.8	20.8
M: Musculo-skeletal system	3.0	3.2	2.8	3.1	3.9	3.7	5.3	2.5	3.2
N: Nervous system	17.4	16.4	13.6	12.0	15.5	16.8	16.2	15.7	17.0
P: Antiparasitic products	0.2	0.2	0.2	0.0	0.2	0.1	0.1	0.1	0.2
R: Respiratory system	7.2	6.8	5.9	5.0	6.6	6.8	5.8	8.1	6.9
S: Sensory organs	4.4	2.5	3.5	2.0	3.0	2.9	4.4	4.5	2.3
V: Various	3.5	3.1	5.3	4.2	5.1	2.6	0.7	3.4	2.7
All therapeutic classes†	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**

† Values may not add to 100.0 due to rounding.

Source: MIDAS™, 2017, IQVIA. All rights reserved.

18 Although most of the statistical results presented in this section are based on sales data from MIDAS™ database, 2005–2017, IQVIA (all rights reserved), the statements, findings, conclusions, views and opinions expressed in this Annual Report are exclusively those of the PMPRB and are not attributable to IQVIA. MIDAS™ data cover the pharmacy and hospital sectors.

19 The results given in Figures 28 through 32 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.

20 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.

21 In order to make use of the best and most up-to-date available medicine expenditure data from the OECD, the GDP in Table 12 was calculated using the Purchasing Power Parity (PPP). Due to the fact that PPPs are corrected for relative cost of living based on a standard basket of goods, the GDP growth rates reported in Table 12 are different than those that would be generated using other methodologies. For further details on the Purchasing Power Parity, please see the explanation associated with Table 9.

22 Note that the data used to produce Table 13 encompass patented and non-patented branded medicines and patended and non-patented generic medicines. Hence, the results reported here for Canada are not directly comparable to those reported in Figure 14, which encompass only patented medicines.

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

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

BACKGROUND

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

At the request of the Minister of Health pursuant to section 90 of the Patent Act, the PMPRB provides policy makers and public drug plan managers with critical analyses of price, utilization and cost trends of patented and non-patented prescription medicines. This ensures that Canada's health care systems have more comprehensive and accurate information on how prescription medicines are being used and on sources of cost increases.

The PMPRB conducts its NPDUIS analytical reporting under the guidance of the NPDUIS Advisory Committee. The Committee advises and supports the PMPRB in establishing research priorities, in the development of research methodologies and in the interpretation of analytical results. It 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, the Yukon, and Health Canada. It also includes observers from CIHI, the Canadian Agency for Drugs and Technologies in Health, the Ministère de la Santé et des Services sociaux Québec, and the pan-Canadian Pharmaceutical Alliance Office.

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

HIGHLIGHTS

Since the release of the last Annual Report, the PMPRB has published three analytical reports and seven posters under the NPDUIS banner.

PUBLISHED REPORTS:

- Alignment Among Public Formularies in Canada – Part 1: General Overview (October 2017)
- Generics360: Generic Drugs in Canada, 2016 (February 2018)
- Meds Entry Watch, 2016 (June 2018)

POSTER PRESENTATIONS:

- Cost Drivers of Public Drug Plans in Canada, 2016/17
- The New Drug Landscape: International Availability and Pricing, 2016
- Generic Drugs in Canada, 2016
- Private Drug Plans in Canada: High-Cost Drugs and Beneficiaries, 2005 to 2017
- Cost Drivers of Private Drug Plans in Canada, 2017
- The Cost of Drugs for Age-Related Macular Degeneration in Canada and Internationally
- The Cost of New Oral Antidiabetic Drugs in Canada and Internationally

In addition, the NPDUIS conducted a number of ad hoc studies at the request of the NPDUIS participating jurisdictions.

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

In response to stakeholder requests and to inform the dialogue on national pharmacare in Canada, NPDUIS developed a three-part report series "Alignment Among Public Formularies in Canada" that explores the current gaps and overlaps in Canadian public drug plan formularies. The next two parts in the series are slated for publication in the upcoming fiscal year, as highlighted in the Research Agenda.

RESEARCH AGENDA

The NPDUIS research agenda for the two upcoming fiscal years includes the following analytical studies:

- Meds Entry Watch, 2017 Edition
- CompassRx, 4th Edition, 2016/17
- Market Intelligence Reports on (1) Age-related Macular Degeneration Drugs and (2) New Drugs for Type-2 Diabetes
- New Drug Pipeline Monitor, 8th Edition
- Alignment Among Public Formularies in Canada, Parts 2 and 3: Drugs Assessed through the Common Drug Review (CDR) Process; and, Oncology Drugs assessed through the pan-Canadian Oncology Drug Review (pCODR) Process
- Private Drug Plans in Canada Parts 2: High-Cost Drugs and Beneficiaries

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

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

Innovation is vital to advancing health care. In part, the provisions of Canada's Patent Act are intended to foster an investment climate favorable to pharmaceutical research and development (R&D) in Canada. However, the percentage of R&D-to-sales by pharmaceutical patentees in Canada has been falling since the late 1990's and has been under the agreed-upon target of 10% since 2003. In 2017, it was at 4.1% for all patentees and 4.6% for members of Innovative Medicines Canada.

4.1%

R&D-TO-SALES RATIO

THE R&D-TO-SALES RATIO FOR ALL PATENTEES WAS 4.1% IN 2017.

This represents a 65% decrease from a peak of 11.7% in 1995.

ANALYSIS OF RESEARCH AND DEVELOPMENT EXPENDITURES

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

DATA SOURCES

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

The Act requires each patentee to report its total gross revenues from sales of all medicines for human or veterinary use (including revenues from sales of non-patented medicines and from licensing agreements) and R&D expenditures in Canada related to medicines (both patented and non-patented for human or veterinary use). Patentees transmit this information to the PMPRB by means of its Form 3 (Revenues and Research and Development Expenditures Provided Pursuant to subsection 88(1) of the Patent Act).

The Patented Medicines Regulations (Regulations) require that each submitted Form 3 be accompanied by a certificate stating the information it contains is "true and correct". The Board does not audit Form 3 submissions, but it does review submitted data for anomalies and inconsistencies, seeking corrections or clarifications from patentees where necessary. To confirm that PMPRB staff has correctly interpreted the data

submitted, each patentee is given the opportunity to review and confirm the accuracy of its own R&D-to-sales ratio before that ratio is published.

FAILURE TO FILE (FORM 3)

It is a patentee's responsibility to ensure a complete and accurate Form 3 is filed within the time frame set out in the Regulations. If a patentee fails to meet these filing requirements, the Board may issue an Order demanding compliance. No such Board Orders were issued for the 2017 reporting period.

COVERAGE

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

First, the statistical results reported here should not be taken to cover all pharmaceutical research conducted in Canada. For example, a company may sell only non-patented medicines but may still perform considerable research in Canada. Similarly, a company may conduct research and have no medicine sales at all.[23] The results presented below will not reflect the R&D expenditures of firms in either situation.

Second, as new patented medicines come onto the Canadian market and existing relevant patents expire, the number and identity of companies required to file R&D data may change from year to year. A total of 85 companies reported on their R&D activity in 2017. Of these, 33 were members of Innovative Medicines Canada.

DEFINITION OF SALES REVENUES

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

DEFINITION OF R&D EXPENDITURES

Pursuant to section 6 of the Regulations, patentees are required to report R&D expenditures that would have qualified for an investment tax credit in respect to scientific research and experimental development (SR&ED) under the provisions of the Income Tax Act that came into effect on December 1, 1987.[24] By this definition, R&D expenditures may include current expenditures, capital equipment costs and allowable depreciation expenses. Market research, sales promotions, quality control or routine testing of materials, devices or products and routine data collection are not eligible for an investment tax credit and, therefore, are not to be included in the R&D expenditures reported by patentees.

TOTAL SALES REVENUES AND R&D EXPENDITURES

Table 14 provides an overview of reported sales revenues and R&D expenditures over the period 1988 through 2017.

Patentees reported total 2017 sales revenues of $ 21.1 billion, an increase of 1.4% from 2016. Sales revenues reported by Innovative Medicines Canada members were $16.3 billion, accounting for 77% of the total. (Less than 1% of reported sales revenues were generated by licensing agreements.)

Patentees reported R&D expenditures of $871.4 million in 2017, a decrease of 5.1% over 2016. Innovative Medicines Canada members reported R&D expenditures of $755.8 million in 2017, a decrease of 1.8% over last year. Innovative Medicines Canada members accounted for 86.7% of all reported R&D expenditures in 2017.

R&D-TO-SALES RATIOS

Table 14 and Figure 33 also provide ratios of R&D expenditures to sales revenues. It should be noted in this context 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.[25] This level of R&D expenditure was reached by 1993, with the ratio exceeding 10% in some years.

The ratio of R&D expenditures to sales revenues among all patentees was 4.1% in 2017, a decrease from 4.4% in 2016. The overall R&D-to-sales ratio has been less than 10% for the past 17 consecutive years.

The corresponding R&D-to-sales ratio for members of Innovative Medicines Canada was 4.6% in 2017, a decrease from 4.9% in 2016.[26] The Innovative Medicines Canada ratio has been less than 10% for the past 15 consecutive years.

Table 20 in Appendix 4 provides details on the range of 2017 R&D-to-sales ratios. Of the 85 companies reporting in 2017, 87.1% had R&D-to-sales ratios below 10%.

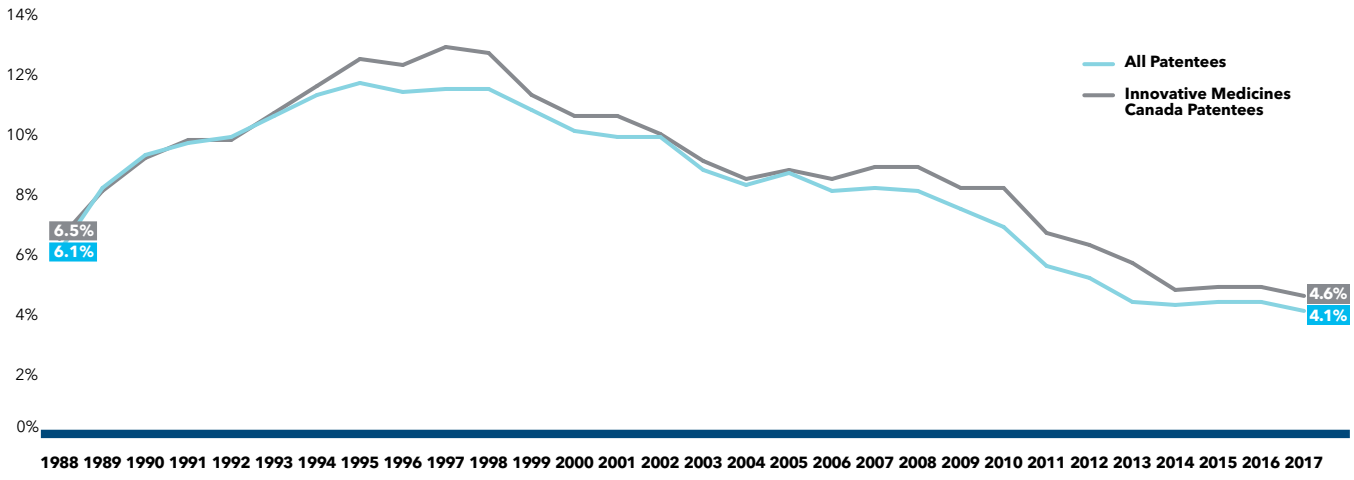
TABLE 14 Total R&D Expenditures and R&D-to-Sales Ratios of Reporting Companies, 1988 to 2017

Year	All Patentees					Innovative Medicines Canada					
	Number of companies reporting	R&D expenditures by all patentees ($millions)	Change from previous year (%)	Sales revenues ($millions)	Change from previous year (%)	R&D expenditures by Innovative Medicines Canada patentees ($millions)	Change from previous year (%)	Sales revenues by Innovative Medicines Canada Patentees ($millions)	Change from previous year (%)	R&D-to- sales ratio: all patentees (%)	R&D-to-sales ratio: Innovative Medicines Canada patentees (%)
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

Year	All Patentees					Innovative Medicines Canada				R&D-to- sales ratio: all patentees (%)	R&D-to-sales ratio: Innovative Medicines Canada patentees (%)
	Number of companies reporting	R&D expen-ditures by all patentees ($millions)	Change from previous year (%)	Sales revenues ($millions)	Change from previous year (%)	R&D expendi-tures by Innovative Medicines Canada patentees ($millions)	Change from previous year (%)	Sales revenues by Innovative Medicines Canada Patentees ($millions)	Change from previous year (%)		
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

Source: PMPRB

FIGURE 33 R&D-to-Sales Ratio, Pharmaceutical Patentees, 1988 to 2017



Source: PMPRB

CURRENT R&D EXPENDITURES BY TYPE OF RESEARCH

Table 15 and Figure 34 (as well as Figure 36 in Appendix 4) provide information on the allocation of 2017 current R&D expenditures[27] among basic and applied research and other qualifying R&D.[28] Patentees reported spending $109 million on basic research in 2017, representing 13.1% of current R&D expenditures, an increase of 2.9% over the previous year. Patentees reported spending $501.9 million on applied research, representing 60.3% of current R&D expenditures. Clinical trials accounted for 72.3% of applied research expenditures.

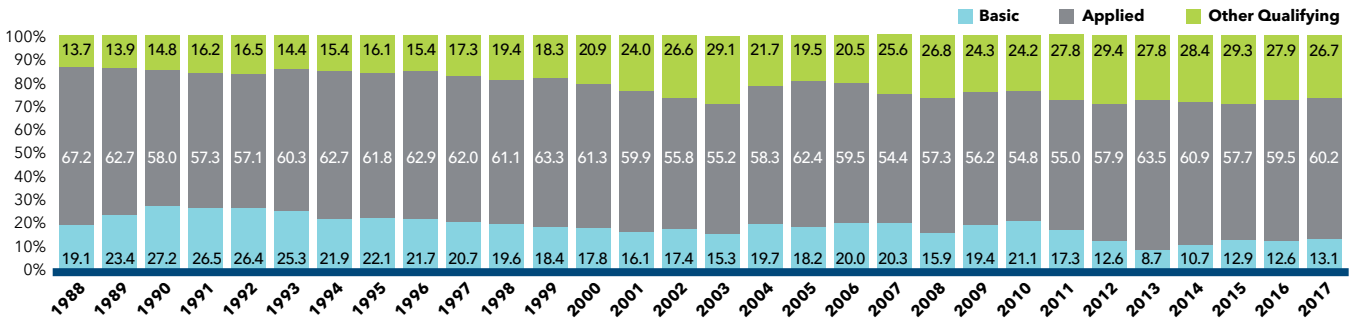
TABLE 15 Current R&D Expenditures by Type of Research, 2017 and 2016

Type of research	Expenditures: 2017 ($millions)	Share: 2017 (%)	Expenditures: 2016 ($millions)	Share: 2016 (%)	Annual change in expenditures (%)
Basic	**109.0**	**13.1**	**105.9**	**12.6**	**2.9**
Chemical	61.4	7.4	72.1	8.6	-14.8
Biological	47.6	5.7	33.8	4.0	40.8
Applied	**501.9**	**60.3**	**500.9**	**59.5**	**0.2**
Manufacturing process	72.9	8.8	79.7	9.5	-8.5
Pre-clinical Trial I	31.6	3.8	37.2	4.4	-15.1
Pre-clinical Trial II	34.6	4.2	24.6	2.9	40.7
Clinical Trial Phase I	41.2	4.9	49.4	5.9	-16.6
Clinical Trial Phase II	58.7	7.0	68.1	8.1	-13.8
Clinical Trial Phase III	262.9	31.6	241.9	28.8	8.7
Other qualifying R&D	**222.2**	**26.7**	**234.9**	**27.9**	**-5.4**
Total	**833.1**	**100.0†**	**841.7**	**100.0†**	**-1.0**

† Values in this column may not add due to rounding

Source: PMPRB

FIGURE 34 Current R&D Expenditures by Type of Research, 1988 to 2017



Source: PMPRB

CURRENT R&D EXPENDITURES BY PERFORMER

Patentees report expenditures on research they conduct themselves (intramural) and research performed by other establishments, such as universities, hospitals and other manufacturers (extramural). Table 16 shows that 45.1% of 2017 current research expenditures were intramural. Research performed by other companies on behalf of patentees was 26.7% of current expenditures, while research conducted in universities and hospitals accounted for 17.9%.

TABLE 16 Current R&D Expenditures by R&D Performer, 2017 and 2016

R&D performer	Expenditures: 2017 ($millions)	Share: 2017 (%)	Expenditures: 2016 ($millions)	Share: 2016 (%)	Annual change in expenditures (%)
Intramural					
Patentees	375.3	45.1	394.9	46.9	-4.9
Extramural					
Universities and hospitals	148.7	17.9	131.4	15.6	13.2
Other companies	222.6	26.7	213.6	25.4	4.2
Others	86.5	10.4	101.8	12.1	-15.0
Total†	**833.1**	**100.0**	**841.7**	**100.0**	**-1.0**

† Values in this row may not add due to rounding.

Source: PMPRB

5x

GREATER

THE PMPRB7 AVERAGE R&D RATIO IS 5X GREATER THAN CANADA

The R&D-to-sales ratio obtained by aggregating R&D spending and sales across all seven comparator countries was 24.2%, more than five times Canada's.

CURRENT R&D EXPENDITURES BY REGION

Table 17 (as well as Table 22 and Table 23 in Appendix 4) show current R&D expenditures by region. As in previous years, current expenditures were heavily concentrated in Ontario and Quebec in 2017, with these provinces accounting for 83.1% of total expenditures. While current R&D expenditures decreased at a year-over-year rate of 10.8% in Western Canada and 0.9% in Ontario, they increased by 3.9% in Quebec.

TABLE 17 Current R&D Expenditures by Region, 2017 and 2016

Region	Expenditures: 2017 ($millions)	Share: 2017 (%)	Expenditures: 2016 ($millions)	Share: 2016 (%)	Annual change in expenditures (%)
Atlantic provinces	15.7	1.9	16.0	1.9	-2.0
Quebec	283.1	34.0	272.6	32.4	3.9
Ontario	409.5	49.1	413.1	49.1	-0.9
Western provinces	124.9	15.0	140.0	16.6	-10.8
Territories	0.0	0.0	0.0	0.0	0.0
Total†	**833.1**	**100.0**	**841.7**	**100.0**	**-1.0**

† Values in this line may not add due to rounding

Source: PMPRB

TOTAL R&D EXPENDITURES BY SOURCE OF FUNDS

Table 18 provides information on the sources of funds used by patentees to finance their R&D activity. Internal company funds remained by far the single largest source of funding in 2017, accounting for 90.8% of total expenditures. Funds received from government amounted to 0.7% of total expenditures.

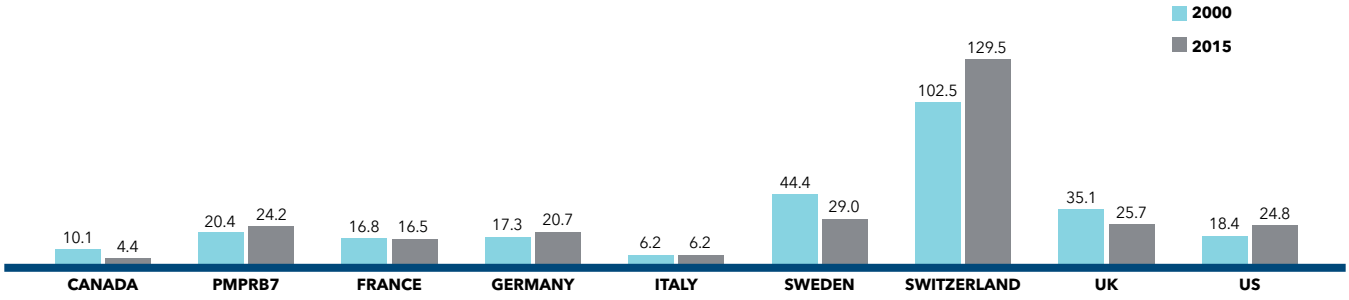
TABLE 18 Total R&D Expenditures by Source of Funds, 2017 and 2016

Source of funds	Expenditures: 2017 ($millions)	Share: 2017 (%)	Expenditures: 2016 ($millions)	Share: 2016 (%)	Annual change in expenditures (%)
Company funds	791.1	90.8	848.5	92.4	-6.8
Federal/provincial governments	6.0	0.7	5.4	0.6	10.6
Others	74.3	8.5	64.3	7.0	15.6
Total†	**871.4**	**100.0**	**918.2**	**100.0**	**-5.1**

† Values in this line may not add due to rounding

Source: PMPRB

FIGURE 35 R&D-to-Sales Ratios, Canada and the PMPRB7



Source: PMPRB; European Federation of Pharmaceutical Industries and Associations (EFPIA): The Pharmaceutical Industry in Figures 2017, PhRMA 2017 profile

THE GLOBAL CONTEXT

Figure 35 compares Canadian pharmaceutical R&D-to-sales ratios for the years 2000 and 2015 to those in the PMPRB7.[29] In 2000, Canada had an R&D-to-sales ratio of 10.1%, lower than all other PMPRB7 countries except for Italy, at 6.2%. Switzerland had the highest ratio at 102.5%.

In 2015, Canada's R&D-to-sales ratio was the lowest among the comparator countries at 4.4%. Italy had a slightly higher ratio of 6.2%, while all other PMPRB7 countries remained well above Canada. The ratio obtained by aggregating R&D spending and sales across all PMPRB7 countries was 24.2%, more than five times Canada's.

The R&D-to-sales ratios represented in Figure 35 may be compared to the average bilateral price ratios reported in Table 9 (see the Comparison of Canadian Prices to Foreign Prices section). Several comparator countries, which have patented medicine prices that are, on average, substantially less than prices in Canada, have achieved much higher R&D-to-sales ratios.

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

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

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

25 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.

26 The R&D-to-sales ratios presented in Table 14 include research expenditures funded by government grants. If the government-funded component is excluded, the ratios for all patentees and for the members of Innovative Medicines Canada in 2017 are 4.1% and 4.6%, respectively.

27 Current R&D expenditures consist of non-capital expenses directly related to research, including (a) wages and salaries; (b) direct material; (c) contractors and sub-contractors; (d) other direct costs such as factory overhead; (e) payments to designated institutions; (f) payments to granting councils; and (g) payments to other organizations. These elements are described in more detail in Form 3 (Revenues and Research and Development Expenditures) available from the PMPRB website. Current R&D expenditures accounted for 95.6% of total R&D expenditure in 2017, while capital equipment costs and allowable depreciation expenses made up 2.7% and 1.7%, respectively.

28 "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.

29 Sales in Figure 35 represent domestic sales and do not include exports.

APPENDIX 1: GLOSSARY

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

ACTIVE INGREDIENT or MEDICINAL INGREDIENT: Chemical or biological substance responsible for the claimed pharmacologic effect of a medicine.

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

DRUG IDENTIFICATION NUMBER (DIN): A registration number (drug identification number) that the Health Products and Food Branch of Health Canada assigns to each prescription and non-prescription drug product marketed under the Food and Drugs Regulations. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical dosage form; route of administration.

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

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

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

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

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

NOTICE OF COMPLIANCE (NOC): Means a notice issued under section C.08.004 or C.08.004.01 of the Food and Drug Regulations. The issuance of an NOC indicates that a drug product meets the required Health Canada standards for use in humans or animals and that the product is approved for sale in Canada.

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

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

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

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

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

RESEARCH AND DEVELOPMENT–BASIC 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 –OTHER QUALIFYING: Includes eligible research and development expenditures that cannot be classified into any of the preceding categories of "type of research and development". It includes regulatory submissions, bioavailability studies and Phase IV clinical trials.

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

RESEARCH AND DEVELOPMENT EXPENDITURES–CURRENT: Consist of the following non-capital expenses that are 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 from the PMPRB Website under Regulatory Filings.

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

VOLUNTARY COMPLIANCE UNDERTAKING (VCU): A written undertaking by a patentee to adjust its price to conform to the Board´s Guidelines. A VCU represents a compromise between the PMPRB and the patentee as a result of negotiations between the parties geared towards a satisfactory resolution of an investigation initiated by Board Staff as per the Guidelines. A VCU takes into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

APPENDIX 2: PATENTED MEDICINES FIRST REPORTED TO THE PMPRB IN 2017

	Brand name	Company	DIN	Status*	Level of therapeutic improvement/ category**
1	Adlyxine – 0.05 mg/mL	Sanofi-Aventis Canada Inc.	02464276	Under Review	Under Review
2	Adlyxine – 0.1 mg/mL	Sanofi-Aventis Canada Inc.	02464284	Under Review	Under Review
3	Adlyxine – 1 N.A./kit	Sanofi-Aventis Canada Inc.	02464349	Under Review	Under Review
4	Akynzeo 300/0.5 – 300.5MG / capsule	Purdue Pharma	02468735	Under Review	Under Review
5	Bepreve – 15 mg/mL	Valeant Canada LP	02456532	Within Guidelines	SN
6	Blexten – 20 mg/tablet	Tribute Pharmaceuticals Canada Ltd	02454130	Does Not Trigger Investigation	SN
7	Cerdelga – 84 mg/capsule	Sanofi Genzyme, a division of Sanofi-Aventis Canada Inc.	02463261	Subject to Investigation	SN
8	Cimzia – 200 mg/mL	UCB Canada Inc.	02465574	Under Review	Under Review
9	Dysport Therapeutic – 300 unit/vial	Ipsen Biopharmaceuticals Canada Inc.	02460203	Within Guidelines	SN
10	Dysport Therapeutic – 500 unit/vial	Ipsen Biopharmaceuticals Canada Inc.	02456117	Within Guidelines	SN
11	Esbriet – 267 mg/tablet	Hoffmann-La Roche Limited	02464489	Within Guidelines	SN
12	Esbriet – 801 mg/tablet	Hoffmann-La Roche Limited	02464500	Within Guidelines	SN
13	Fiasp – 100 unit/mL	Novo Nordisk Canada Inc.	02460408	Within Guidelines	SN
14	Fiasp FlexTouch – 100 unit/mL	Novo Nordisk Canada Inc.	02460424	Within Guidelines	SN

	Brand name	Company	DIN	Status*	Level of therapeutic improvement/ category**
15	Fiasp Penfill – 100 unit/mL	Novo Nordisk Canada Inc.	02460416	Within Guidelines	SN
16	Glyxambi 10/5 – 15 mg/tablet	Boehringer Ingelheim (Canada) Ltd.	02459752	Within Guidelines	SN
17	Glyxambi 25/5 – 30 mg/tablet	Boehringer Ingelheim (Canada) Ltd.	02459760	Within Guidelines	SN
18	Hemangiol – 3.75 mg/mL	Pierre Fabre Dermo – Cosmétique Canada Inc.	02457857	Does Not Trigger Investigation	SI
19	Ilaris – 150 mg/mL	Novartis Pharmaceuticals Canada Inc.	02460351	Under Review	Under Review
20	Isentress HD – 600 mg/tablet	Merck Canada Inc.	02465337	Under Review	Under Review
21	Izba – 0.03 mg/mL	Novartis Pharmaceuticals Canada Inc.	02457997	Within Guidelines	SN
22	Kevzara – 150 mg/syringe	Sanofi-Aventis Canada Inc.	02460521	Within Guidelines	SN
23	Kevzara – 200 mg/syringe	Sanofi-Aventis Canada Inc.	02460548	Within Guidelines	SN
24	Keytruda – 25 mg/mL	Merck Canada Inc.	02456869	Under Review	Under Review
25	Kyprolis – 10 mg/vial	Amgen Canada Inc.	02459930	Does Not Trigger Investigation	SN
26	Kyprolis – 30 mg/vial	Amgen Canada Inc.	02459949	Does Not Trigger Investigation	SN
27	Leukine – 250 mcg/vial	Sanofi-Aventis Canada Inc.		Subject to Investigation	SN
28	Lixiana – 15 mg/tablet	Servier Canada Inc.	02458640	Within Guidelines	SN
29	Lixiana – 30 mg/tablet	Servier Canada Inc.	02458659	Within Guidelines	SN
30	Lixiana – 60 mg/tablet	Servier Canada Inc.	02458667	Within Guidelines	SN
31	Mavenclad – 10 MG/tablet	Emd Serono Canada Inc.	02470179	Under Review	Under Review
32	Maviret 100/40 – 140 mg/tablet	Abbvie	02467550	Under Review	Under Review
33	Metoject Subcutaneous – 17.5 mg/syringe	Medexus Inc.	02454769	VCU	SN
34	Metoject Subcutaneous – 20 mg/syringe	Medexus Inc.	02454866	VCU	SN
35	Metoject Subcutaneous – 22.5 mg/syringe	Medexus Inc.	02454777	VCU	SN
36	Metoject Subcutaneous – 25 mg/syringe	Medexus Inc.	02454874	VCU	SN
37	Mictoryl – 30 mg/capsule	Duchesnay Inc.	02460262	Within Guidelines	SN
38	Mictoryl – 45 mg/capsule	Duchesnay Inc.	02460270	Within Guidelines	SN

	Brand name	Company	DIN	Status*	Level of therapeutic improvement/ category**
39	Mictoryl Pediatric – 5 mg/ tablet	Duchesnay Inc.	02460289	Does Not Trigger Investigation	SN
40	Movapo – 10 mg/mL	Paladin Labs Inc.	02459132	Under Review	Under Review
41	Ocaliva – 10 mg/tablet	Intercept Pharmaceuticals Inc.	02463148	Within Guidelines	MI-P
42	Ocaliva – 5 mg/tablet	Intercept Pharmaceuticals Inc.	02463121	Within Guidelines	MI-P
43	Ocrevus – 30 mg/mL	Hoffmann-La Roche Limited	02467224	Under Review	Under Review
44	Odefsey 200/25/25 – 250 mg/tablet	Gilead Sciences Canada Inc.	02461463	Within Guidelines	SN
45	Onivyde - 4.3 mg/mL	Shire Canada Inc.	02467135	Under Review	Under Review
46	Orkambi 125/100 – 225 mg/tablet	Vertex Pharmaceuticals Canada Inc.	02463040	Under Review	Under Review
47	Otixal 3/0.25 – 3.25 mg/mL	Pediapharm Inc.	02459655	Under Review	Under Review
48	Procysbi – 25 mg/capsule	Horizon Pharma PLC	02464705	Subject to Investigation	MI-S
49	Procysbi – 75 mg/capsule	Horizon Pharma PLC	02464713	Subject to Investigation	MI-S
50	Quinsair – 100 mg/mL	Horizon Pharma PLC	02442302	Subject to Investigation	SN
51	Repatha – 120 mg/mL	Amgen Canada Inc.	02459779	Subject to Investigation	SN
52	Revlimid – 2.5 mg/capsule	Celgene Inc.	02459418	Within Guidelines	SN
53	Rexulti – 0.25 mg/tablet	Otsuka Canada Pharmaceutical Inc.	02461749	Within Guidelines	SN
54	Rexulti – 0.5 mg/tablet	Otsuka Canada Pharmaceutical Inc.	02461757	Within Guidelines	SN
55	Rexulti – 1 mg/tablet	Otsuka Canada Pharmaceutical Inc.	02461765	Within Guidelines	SN
56	Rexulti – 2 mg/tablet	Otsuka Canada Pharmaceutical Inc.	02461773	Within Guidelines	SN
57	Rexulti – 3 mg/tablet	Otsuka Canada Pharmaceutical Inc.	02461781	Within Guidelines	SN
58	Rexulti – 4 mg/tablet	Otsuka Canada Pharmaceutical Inc.	02461803	Within Guidelines	SN
59	Rixubis – 1000 unit/vial	Baxalta Canada Corporation	02431947	Under Review	Under Review
60	Rixubis – 2000 unit/vial	Baxalta Canada Corporation	02431955	Under Review	Under Review
61	Rixubis – 500 unit/vial	Baxalta Canada Corporation	02431939	Under Review	Under Review
62	Rydapt – 25 mg/capsule	Novartis Pharmaceuticals Canada Inc.	02466236	Within Guidelines	B

	Brand name	Company	DIN	Status*	Level of therapeutic improvement/ category**
63	Silenor – 3 mg/tablet	Paladin Labs Inc.	02398257	Within Guidelines	SN
64	Silenor – 6 mg/tablet	Paladin Labs Inc.	02398265	Within Guidelines	SN
65	Stelara – 130 mg/vial	Janssen Inc.	02459671	Within Guidelines	SN
66	Tecentriq – 60 mg/mL	Hoffmann-La Roche Limited	02462990	Within Guidelines	SN
67	Tivicay – 10 mg/tablet	ViiV Healthcare ULC	02461218	Within Guidelines	SN
68	Tivicay – 25 mg/tablet	ViiV Healthcare ULC	02461226	Within Guidelines	SN
69	Translarna – 125 mg/pouch	PTC Therapeutics International Limited		Within Guidelines	SN
70	Tremfya – 100 mg/mL	Janssen Inc.	02469758	Under Review	Under Review
71	Varithena – 1.3 mg/mL	BTG International Ltd.	02444267	Within Guidelines	MI-P
72	Vectibix – 20 mg/mL	Amgen Canada Inc.	02308509	VCU	SN
73	Vemlidy – 25 mg/tablet	Gilead Sciences Canada Inc.	02464241	Under Review	Under Review
74	Viberzi – 100 mg/tablet	Allergan Inc.	02460904	Within Guidelines	SN
75	Viberzi – 75 mg/tablet	Allergan Inc.	02460890	Within Guidelines	SN
76	Vosevi 400/100/100 – 600 mg/tablet	Gilead Sciences Canada Inc.	02467542	Under Review	Under Review
77	Vyvanse – 70 mg/capsule	Shire Canada Inc.	02458071	Does Not Trigger Investigation	SN
78	Xolair – 150 mg/syringe	Novartis Pharmaceuticals Canada Inc.	02459795	Within Guidelines	SN
79	Xolair – 75 mg/syringe	Novartis Pharmaceuticals Canada Inc.	02459787	Within Guidelines	SN
80	Zinbryta – 150 mg/mL	Biogen Canada Inc.	02459620	Within Guidelines	SN

* Compliance status as of the end of the January to December 2017 reporting period. Medicines shown as under review are as of March 31, 2018.

** Sold after implementation of new Guidelines in 2010:

SN Slight or No Improvement

MI-S Moderate Improvement – Secondary

MI-P Moderate Improvement – Primary

SI Substantial Improvement

B Breakthrough

APPENDIX 3: PHARMACEUTICAL TRENDS – SALES

TABLE 19 Sales of Patented Medicines, 1990 to 2017

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 (%)	Patented medicine sales per GDP (%)
	Sales ($billions)	Change (%)					
2017	16.8	7.6	5.8	61.5	$454.1	5.4	0.783
2016	15.6	3.3	4.9	60.8	$430.9	2.2	0.770
2015	15.1	9.4	4.0	61.6	$421.8	8.5	0.760
2014	13.8	3.1	2.7	59.9	$388.7	1.8	0.696
2013	13.4	4.2	0.8	60.7	$381.8	2.7	0.706
2012	12.9	0.1	0.6	59.2	$371.8	-1.2	0.708
2011	12.9	3.5	1.6	58.3	$376.1	3.1	0.729
2010	12.4	-4.3	1.5	55.8	$364.7	-5.7	0.746
2009	13.0	2.9	4.5	59.6	$386.9	1.9	0.829
2008	12.6	4.6	4.7	61.7	$379.5	2.9	0.762
2007	12.1	3.2	5.7	63.2	$368.9	2.5	0.769
2006	11.7	7.4	7.1	67.8	$360.0	6.3	0.784

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 (%)	Patented medicine sales per GDP (%)
	Sales ($billions)	Change (%)					
2005	10.9	4.2	9.4	70.6	$338.5	2.8	0.769
2004	10.5	7.8	13.6	72.2	$329.2	7.2	0.789
2003	9.7	9.0	15.8	72.7	$307.0	8.0	0.776
2002	8.9	17.5	19.9	67.4	$284.3	16.0	0.748
2001	7.6	18.9	19.7	65.0	$245.2	19.1	0.666
2000	6.3	16.7	20.4	63.0	$205.9	15.9	0.571
1999	5.4	27.0	20.0	61.0	$177.6	24.3	0.538
1998	4.3	18.9	15.7	55.1	$142.9	15.4	0.459
1997	3.7	22.6	11.4	52.3	$123.7	22.1	0.409
1996	3.0	12.8	8.1	45.0	$101.4	14.2	0.350
1995	2.6	10.8	6.8	43.9	$88.7	7.2	0.314
1994	2.4	-2.1	9.0	40.7	$82.8	-1.4	0.304
1993	2.4	9.4	–	44.4	$83.9	7.9	0.322
1992	2.2	14.0	–	43.8	$77.7	8.8	0.307
1991	2.0	13.1	–	43.2	$71.4	16.0	0.286
1990	1.7	–	–	43.2	$61.6	–	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 were used to calculate sales of generic medicines only, while sales of non-patented brand products were estimated from data submitted by patentees. This approach was abandoned because of anomalies related to year-to-year changes in the set of companies reporting to the PMPRB. Ratios reported for years before 2005 likely overstate the patented share, but by only a small amount. This small bias in no way invalidates the strong upward trend evinced by the results for the years 1990 through 2003. Ratios since 2009 have also been revised slightly as a result of data updates from IQVIA—none of these adjustments resulted in a change greater than 0.4%.

APPENDIX 4: RESEARCH AND DEVELOPMENT

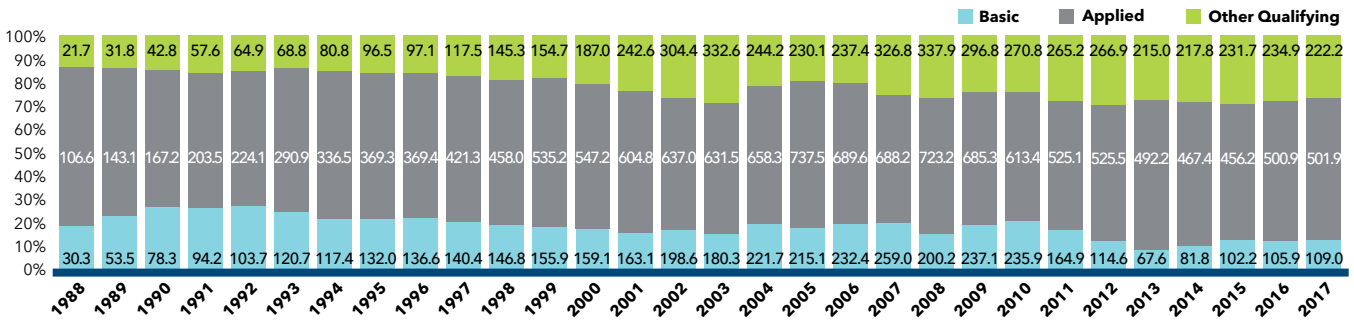
TABLE 20 Range of R&D-to-Sales Ratios by Number of Reporting Companies and Total Sales Revenue

Range: R&D-to-sales ratio	Number of reporting companies: 2017	Sales revenues: 2017 ($millions)	Share: 2017(%)	Number of reporting companies: 2016	Sales revenues: 2016 ($millions)	Share: 2016(%)
0%	33	1,662.1	7.8	30	2,204.5	10.6
≤10%	41	17,566.3	83.1	40	16,791.7	80.5
> 10%	11	1,918.8	9.1	8	1,859.5	8.9
Total	**85**	**21,147.2**	**100.0†**	**78**	**20,855.7**	**100.0†**

† Values in this column may not add to 100.0 due to rounding

Source: PMPRB

FIGURE 36 Current R&D Expenditures ($millions) by Type of Research, 1988 to 2017



Source: PMPRB

TABLE 21 Ratios of R&D Expenditures to Sales Revenue by Reporting Patentee[1], 2017 and 2016

Company	R&D-to-sales ratio (%) 2017	R&D-to-sales ratio (%) 2016	MIP-to-Cdn Price Ratio (%) – 5 country limit	Canadian share of sales to PMPRB7 (2017)	Canadian share of sales to OECD (2017)
AbbVie Corporation[2,3,4]	2.2	1.7	103	2.6	2.4
Acerus Pharmaceuticals[5]	0.0	2.2			
Actelion Pharmaceuticals Canada Inc.[2, 4]	4.2	3.6	151	3.7	2.5
Alcon Canada Inc.	0.2	0.9	101	5.5	1.7
Alexion Pharmaceuticals Inc.[3]	0.0	0.0	96		
ALK-Abello AS.[5]	0.0		185	2.0	1.7
Allergan Inc.	1.1	1.2	81	0.9	0.9
Altius Healthcare Inc.	0.0				
Amgen Canada Inc.[2,3]	3.7	4.7	88	2.5	2.3
Aspen Pharmacare Canada Inc.[5]	0.0	0.0	76	5.4	1.7
Astellas Pharma Canada Inc.[2,6]	1.8	2.0	163	2.8	1.8
AstraZeneca Canada Inc.[2,3]	7.5	6.6	88	5.0	4.0
Baxalta Canada Corp.	0.0	0.0	254		
Baxter Corporation	0.02	0.0	115	0.4	0.3
Bayer Inc.[2]	6.8	5.9	108	10.5	5.6
BGP Pharma ULC[10]	0.0	0.0	78	71.3	27.4
Biogen Idec Canada Inc.[3]	11.9	10.2	109	1.5	1.4
BioMarin Canada Inc.[3]	11.2	4.5	103		
Biovitrum AB	0.0	0.0	87	0.7	0.6
BioSyent Pharma Inc.	0.0	0.0			
Bioverativ Canada Inc.[3,5]	0.7		203		
Boehringer Ingelheim (Canada) Ltd.[2]	3.8	5.0	109	3.1	2.5
Bracco Diagnostics Canada Inc.	0.0	0.0			
Bristol-Myers Squibb Canada[2]	10.3	13.6	110	27.6	21.6

Company	R&D-to-sales ratio (%) 2017	R&D-to-sales ratio (%) 2016	MIP-to-Cdn Price Ratio (%) – 5 country limit	Canadian share of sales to PMPRB7 (2017)	Canadian share of sales to OECD (2017)
BTG International Ltd.[5]	0.0				
Celgene Inc.[3]	1.1	1.5	107	0.5	0.4
Cheplapharm Arzneimittel GmbH.[5]	0.0		69		
Cipher Pharmaceuticals Inc.[5]	2.1	0.0			
Correvio (UK) Ltd. (Iroko International LP)	0.0	0.0		1.4	1.3
CSL Behring Canada Inc.	0.5	0.2	128		
Duchesnay Inc.	0.7	2.5		15.1	13.1
Eisai Limited[3]	7.4	8.9	99	0.8	0.4
Eli Lilly Canada Inc. (includes Provel Animal Health Division)[2,3]	9.5	6.7	88	1.5	1.4
EMD Serono Canada Inc.[2]	0.0	0.0	76	3.6	3.5
Ferring Pharmaceuticals Inc.[2]	0.0	0.0	88	3.6	2.6
Galderma Canada Inc.	0.0	0.0	52	5.0	4.2
Gilead Sciences Canada, Inc.[2]	11.1	16.4	109	3.0	2.5
GlaxoSmithKline Inc.[2]	5.9	5.6	63	35.5	13.2
Grifols Canada Ltd. (Talecris Biotherapeutics Ltd.)[3]	0.0	0.0			
Hoffmann-La Roche Ltd. Canada[2,3]	5.9	5.6	101	10.8	6.5
Horizon Pharma PLC.[3,5]	0.0				
Intercept Pharmaceuticals Inc.[5]	27.4				
Ipsen Biopharmaceuticals Inc.[3,5]	0.3	0.1	106	0.3	0.2
Janssen Inc.[2,3]	2.6	3.6	104	7.8	6.3
Jazz Pharmaceuticals	11.9	16.5		0.9	0.9
Johnson & Johnson Medical Products	0.4	0.3		2.3	1.4
Knight Therapeutics Inc.[2,5]	24.8		60		
Lantheus MI Canada Inc.	0.0	0.0			

Company	R&D-to-sales ratio (%) 2017	R&D-to-sales ratio (%) 2016	MIP-to-Cdn Price Ratio (%) – 5 country limit	Canadian share of sales to PMPRB7 (2017)	Canadian share of sales to OECD (2017)
Leadiant Biosciences Inc.[5]	0.0		136		
LEO Pharma Inc.[2]	0.04	0.1	65		
Lundbeck Canada Inc.	1.1	0.0	77	6.6	5.4
Lupin Pharma Canada Limited	0.0	0.0	100	0.2	0.2
Medexus Inc.[5]	0.0	0.0	46		
Merck Canada Inc.[2,3]	3.8	2.9	91	4.3	4.6
Merus Labs	0.0	0.0	96	23.0	13.7
Merz Pharma Canada Ltd.	1.9	2.0	98	1.5	1.1
Novartis Pharmaceuticals Canada Inc.[2,3]	3.9	3.6	87	5.0	3.7
Novo Nordisk Canada Inc.[2,3]	1.6	1.1	87	1.8	1.6
Octapharma Canada Inc.	20.6	6.6			
Orion Corporation[5]	0.0				
Otsuka Canada Pharmaceutical Inc. (OCPI)[2]	1.0	1.3	131	2.1	1.0
Paladin Labs Inc.[2]	0.3	0.2	78		
Pediapharm Inc.[5]	0.0				
Pfizer Canada Inc.[2,3]	0.6	1.0	110	3.1	2.6
Pharmascience Inc.[5]	9.2	8.4			
Pierre Fabre Dermo-Cosmétique Canada Inc.[5]	0.0		114		
Purdue Pharma[2]	3.6	4.8	156		
PTC Therapeutics International Ltd.	149.6	130.5			
Sanofi Canada Inc.[2,3,8]	1.7	1.6	81	30.9	11.3
Sanofi Pasteur Ltd.[2,3,7]	72.1	68.0			
Seattle Genetics Inc.	5.7	9.8	115		
Seqirus Canada Inc.[3,5]	20.8				

Company	R&D-to-sales ratio (%) 2017	R&D-to-sales ratio (%) 2016	MIP-to-Cdn Price Ratio (%) – 5 country limit	Canadian share of sales to PMPRB7 (2017)	Canadian share of sales to OECD (2017)
Servier Canada Inc.[2]	1.8	2.1	116	80.9	20.5
Shire Canada Inc.[2,3]	0.0	0.0	108	3.1	2.8
Shire Rare Disease Business Unit[2,3]		0.0			
Sunovion Pharmaceuticals Canada Inc.[2]	0.0	0.0	121	1.2	1.2
Takeda Canada Inc.[2,3]	0.9	0.0	90	2.9	1.6
Theratechnologic Inc.[2]	0.0	0.0			
Teva Canada Innovation[3]	0.1	0.2	101		
Tribute Pharma Canada Inc.	0.0	0.0			
UCB Canada Inc.[3]	9.9	16.9	97	1.4	1.1
Valeant Canada Ltd.[3,9]	0.7	3.1	58	6.0	5.4
Valneva Austria GmbH.[3,5]	0.0	0.0			
Vertex Pharma Canada Inc.[3]	5.5	47.5	229		
VIIV Healthcare ULC[2]	0.0	0.0	116	2.8	2.4

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

2 Member of Innovative Medicines Canada.

3 Member of BIOTECanada.

4 Spin-off of Abbott's proprietary products division into a separate legal entity effective Oct. 31, 2012.

5 Not a patentee in 2016.

6 Formerly known as Fujisawa Canada Inc.

7 Formerly known as Aventis Pasteur Ltd.

8 Formerly known as Aventis Pharma Inc.

9 Formerly known as ICN Canada Ltd.

10 "BGP Pharma ULC" to house the former "Abbott" and "Fournier" pharmaceutical brands in Canada.

TABLE 22 Current R&D Expenditures by Province/Territory, 2017

Province	Expenditures: All patentees ($ thousands)	Regional share: (%)	Expenditures: Innovative Medicines Canada ($ thousands)	Regional share: (%)
Newfoundland	2,496.85	0.300	1,885.11	0.262
Prince Edward Island	1,065.69	0.128	0.00	0.000
Nova Scotia	9,084.33	1.090	7,792.99	1.082
New Brunswick	3,012.24	0.362	2,874.80	0.399
Quebec	283,127.94	33.983	216,170.24	30.024
Ontario	409,474.38	49.149	376,520.53	52.295
Manitoba	5,920.79	0.711	4,257.91	0.591
Saskatchewan	1,757.18	0.211	1,202.98	0.167
Alberta	78,709.88	9.447	76,503.32	10.626
British Columbia	38,487.04	4.620	32,781.14	4.620
Territories	0.00	0.000	0.00	0.000
CANADA*	**833,136.31**	**100.0**	**719,989.02**	**100.0**

* Values in this row may not add due to rounding.

Source: PMPRB

TABLE 23 Current R&D Expenditures by Performer and Province/Territory, 2017

Province		Patentees	Other Companies	Universities	Hospitals	Others
Newfoundland	$000	940.74	735.44	130.26	198.14	492.26
	%	37.7	29.5	5.2	7.9	19.7
Prince Edward Island	$000	0.00	1,065.69	0.00	0.00	0.00
	%	0.0	100.0	0.0	0.0	0.0
Nova Scotia	$000	977.48	3,665.26	1,113.60	1,585.08	1,739.92
	%	10.8	40.3	12.2	17.5	19.1
New Brunswick	$000	460.61	630.35	1,328.95	202.46	389.87
	%	15.3	20.9	44.1	6.7	12.9
Quebec	$000	94,564.60	112,957.13	15,979.61	18,141.40	41,485.19
	%	33.4	39.9	5.6	6.4	14.7
Ontario	$000	200,030.65	82,703.25	38,222.45	55,660.56	32,857.45
	%	48.9	20.2	9.3	13.6	8.0
Manitoba	$000	2,478.36	1,486.80	484.33	536.47	934.83
	%	41.9	25.1	8.2	9.1	15.8
Saskatchewan	$000	40.33	941.28	474.82	155.81	144.93
	%	2.3	53.6	27.0	8.9	8.2
Alberta	$000	60,267.05	7,108.35	4,916.49	2,605.89	3,812.10
	%	76.6	9.0	6.2	3.3	4.8
British Columbia	$000	15,579.38	11,308.30	4,759.31	2,208.88	4,631.18
	%	40.5	29.4	12.4	5.7	12.0
Territories	$000	0.00	0.00	0.00	0.00	0.00
	%	0.0	0.0	0.0	0.0	0.0
CANADA	**$000**	**375,339.21**	**222,601.85**	**67,409.83**	**81,297.68**	**86,487.74**
	%	**45.1**	**26.7**	**8.1**	**9.7**	**10.4**

NOTES:
- The percentage under each R&D category gives the percentage of all money spent in that category in that province.
- Expenditures as a percentage of total means percentage of R&D expenditures in that province compared to total R&D in Canada.
- Rows and columns may not equal totals due to rounding.
- Current expenditures plus capital expenditures (equipment + depreciation)=total R&D expenditures.

Source: PMPRB