Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

PATENTED
MEDICINE PRICES
REVIEW BOARD

ANNUAL REPORT 2015

Canada

STATISTICAL HIGHLIGHTS

STATISTICAL HIGHLIGHTS 2015

REGULATORY MANDATE

- 1,359 patented drug products for human use were reported to the PMPRB, including 86 new drug products.
- 5 Voluntary Compliance Undertakings were accepted as at December 31, 2015.
- $7.1 million in excess revenues were offset by way of payment to the Government of Canada, in addition to price reductions.
- 2 Notices of Hearing were issued with respect to allegations that Galderma Canada Inc. and Baxalta Canada Corporation each failed to provide required pricing and sales information.

REPORTING MANDATE

SALES TRENDS:

- There were $15.2 billion in sales of patented drug products in Canada in 2015, an increase of 9.5% from 2014.
- Patented drug products accounted for 61.8% of the total drug sales in Canada, an increase from 59.9% in 2014.

PRICE TRENDS:

- Prices of existing patented drug products were stable, while the Consumer Price Index rose by 1.1%.
- Canadian prices were third highest among the seven PMPRB comparator countries, lower only than prices in Germany and the US.

RESEARCH AND DEVELOPMENT (R&D):

- $869.1 million in total R&D expenditures were reported by patentees, an increase of 9.7% over 2014.
- $767.4 million in R&D expenditures were reported by Innovative Medicines Canada (formerly Rx&D) members, an increase of 7.8% over 2014.

R&D-TO-SALES RATIOS INCREASED IN 2015:

- 4.4% for all patentees, up from in 4.3% in 2014
- 4.9% for Innovative Medicines Canada members, up from 4.8% in 2014

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July 29, 2016

The Honourable Jane Philpott, MP
Minister of Health
House of Commons
Ottawa, Ontario
K1A 0A6

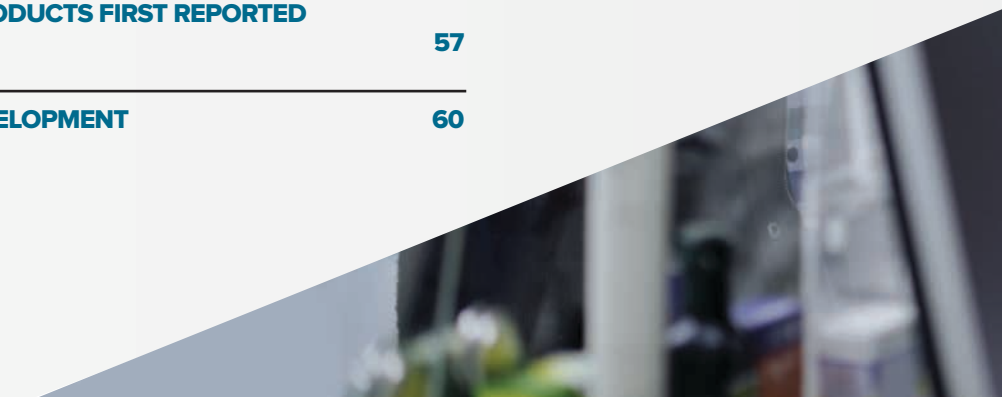
Dear Minister:

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, 2015.

Yours very truly,

Mary Catherine Lindberg
Chairperson

TABLE OF CONTENTS



LIST OF TABLES

LIST OF FIGURES

CHAIRPERSON'S MESSAGE

I am pleased to present the Patented Medicine Prices Review Board's (PMPRB) 2015 Annual Report. The PMPRB is a consumer protection agency with a dual regulatory and reporting mandate. Its regulatory mandate is to ensure that the prices of patented medicines sold in Canada are not excessive. Its reporting mandate is to provide stakeholders with information on the latest trends in pharmaceutical sales and pricing and on pharmaceutical research and development (R&D) spending in Canada.

The past year at the PMPRB has been a particularly busy one. In terms of its regulatory mandate, the PMPRB entered into Voluntary Compliance Undertakings (VCUs) following investigations into the pricing of five patented medicines, resulting in $7.1 million in excess revenues being paid to the Government of Canada by pharmaceutical patentees in 2015, increasing to $8.1 million as of May 31, 2016. The PMPRB also commenced two failure-to-file hearings against Baxalta Canada Corporation and Galderma Canada Inc. In terms of other legal developments relating to our regulatory mandate, in November 2015, the Federal Court of Appeal issued a precedent-setting decision confirming that a person need not own the patent over a particular medicine to be considered a "patentee" in respect of that medicine within the meaning of subsection 79(1) of the *Patent Act*. In upholding the finding of the original Board Panel decision, the Federal Court of Appeal found the construction of the language in the Act that relates to the PMPRB must focus on the persons in need of protection from excessive pricing (consumers) and not on those in a position to cause such pricing (patentees). The decision also reaffirmed the constitutionality of sections 79–103 of the Act. In this regard, the Federal Court of Appeal found that the Board correctly held that the control of prices charged for patented medicines comes within the jurisdiction conferred on Parliament over patents under subsection 91(22) of the *Constitution Act, 1867* when applied to patent holders, patent owners, or any other persons exercising rights under patents (such as licensees).

In terms of its reporting mandate, on March 31, 2015, the PMPRB released the first edition of its flagship annual report under the National Prescription Drug Utilization Information System (NPDUIS) initiative, *CompassRx*. This report remains the only one of its kind to identify the major drivers behind changes in prescription drug expenditures in public drug plans in Canada. In December 2015, the PMPRB released two other NPDUIS studies, *Private Drug Plans in Canada – Part 1: Generic Market 2005-2013* and the 7th edition of the *New Drug Pipeline Monitor* and in February 2016, the PMPRB released *Generics360 - Generic Drugs in Canada, 2014*. Through its unbiased reporting, the PMPRB is contributing to the broader discussion on how to reconcile finite drug budgets with optimal patient access to promising new health technologies, preparing Canadians, from drug plan managers to consumers, for important decisions that lie ahead.

Last but definitely not least, in December 2015, the PMPRB released its Strategic Plan for the years 2015–2018. The strategic objectives identified in this document are based on a thorough assessment by the PMPRB of how to respond to the current and pending threats and opportunities in its operating environment. That response is inspired by a shared vision as to how to leverage our strengths and unique legislative remit to complement the efforts of our federal, provincial and territorial partners and other stakeholders to advance our common goal of a sustainable health system.

As I will be completing my second term in June 2016, this will be my last Annual Report. It has been my great privilege to serve as Chairperson of the PMPRB for the past five years and I would like to thank my fellow Board members for their expertise, dedication and tireless work. As well, I would like to thank the Staff for its commitment, enthusiasm and continuous support. I wish you all continued success in carrying out the PMPRB's important consumer protection mandate. As my final act as Chairperson, I look forward to the June 2016 publication of the PMPRB's consultation paper on Guideline reform. Much has changed in the PMPRB's operating environment over the past decade and I am confident that input received from a wide range of stakeholders during the public consultation process which will follow the paper's release will result in a modern set of Guidelines that is responsive to those changes and advances the Government's objective of making prescription drugs more affordable and accessible for all Canadians.

Mary Catherine Lindberg

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

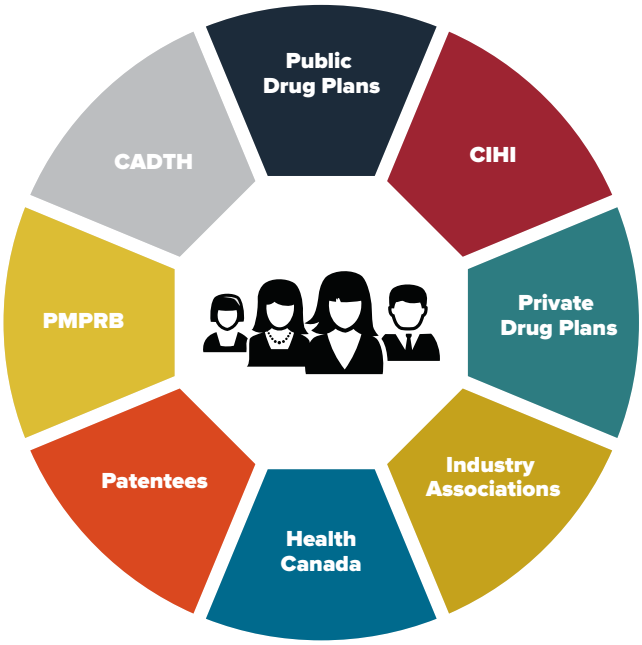
The PMPRB was created in 1987 as the consumer protection "pillar" of Bill C-22, legislation which also strengthened the patent rights of pharmaceutical manufacturers in order to spur investment in research and development (R&D) in Canada.

The PMPRB protects consumers by regulating the price of patented drugs at the factory gate level and by keeping a vigilant eye on pricing trends and industry R&D. Through our reporting function, we serve as an objective, centralized source of information on pharmaceutical trends for policy makers, drug companies, private insurers and other stakeholders.

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 research and development (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.

PROTECTING CONSUMERS IN A COMPLEX MARKETPLACE



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.

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 drugs for marketing in Canada based on their safety, efficacy and quality; federal, provincial and territorial public drug plans, which approve the listing of drugs on their respective formularies for reimbursement purposes; and the Common Drug Review, administered by the Canadian Agency for Drugs and Technologies (CADTH) in Health, which recommends drugs 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" ceiling prices for all patented drug products sold in Canadian markets; that is, the prices at which patentees (companies) sell their products to wholesalers, hospitals, pharmacies and other large distributers. The PMPRB has no jurisdiction over prices charged further along the supply chain, e.g., wholesale prices or retail prices charged by pharmacies, nor does it have the authority to regulate the prices of non-patented drugs.

The PMPRB's jurisdiction is not limited to drug products for which the patent is on the active ingredient. Rather, its jurisdiction also covers drugs for which the patents relate to, but are not limited to, the processes of manufacture, the delivery system or dosage form, the indication/use and any formulations.

Under the Act, patentees (which include any parties who benefit from patents regardless of whether they are owners or licencees 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 drug product. Upon the sale of a patented drug product, 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 before a drug is sold, they are required to comply with the Act to ensure that the prices of patented drug products sold in Canada are not excessive.

Board Staff reviews the prices that patentees charge for each individual strength and form of a patented drug product. If Staff believes that the price of a patented medicine is excessive, it will first try to reach a consensual resolution with the patentee. Failing this, the Chairperson can hold a hearing on the matter. 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

WE ARE AN INDEPENDENT AGENCY
that administers provisions of Canada's *Patent Act* related to patented medicines. As a member of the Health Portfolio, we contribute to a sustainable health care system for all Canadians.

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 drug prices, pharmaceutical trends and research and development 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 drugs, and on the R&D expenditures reported by pharmaceutical patentees, as required by the Act.

Through the National Prescription Drug Utilization Information System (NPDUIS) initiative, established by the federal, provincial and territorial (F/P/T) Ministers of Health in 2001, the PMPRB conducts critical analyses of price, utilization and cost trends for patented and non-patented prescription drugs. 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 an annual researchers' forum with academics and policy experts to discuss current research into pharmaceutical use in Canada and emerging areas for study.

COMMUNICATIONS AND OUTREACH

Over the past year, the PMPRB has continued to intensify its activities, taking a proactive approach to its traditional and social media presence. This included press release distribution, targeted social media campaigns, direct engagement with the public and interviews with domestic and international media outlets including the CBC, CPAC, *The Globe and Mail*, the *Wall Street Journal* and CBS. The PMPRB made improvements to its website and publications in terms of clarity of language and accessibility of content, and continues to respond to public enquiries and inform the public by publishing updates of Board proceedings and decisions, and research results.

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.

1,359 PATENTED DRUG PRODUCTS
were reported to the PMPRB in 2015.

1,359
PATENTED DRUG PRODUCTS

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

Mary Catherine Lindberg, BSP

Mary Catherine Lindberg was appointed Member and Vice-Chairperson of the Board in June 2006 and Chairperson of the Board in March 2011. Her second and final term as a Board Member will expire in June 2016.

From 2002 to 2009, Ms. Lindberg was Executive Director of the Ontario Council of Academic Hospitals, an organization of 25 Academic Hospitals that are fully affiliated with a university and its Faculty of Medicine. Previously, she was the Assistant Deputy Minister, Health Services, with the Ontario Ministry of Health and Long-Term Care. Her responsibilities included the Ontario Health Insurance Plan (OHIP) and the Ontario Drug Programs.

Ms. Lindberg has a degree in pharmacy from the University of Saskatchewan and holds a pharmacist license in both Saskatchewan and Ontario.

VICE-CHAIRPERSON

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

Dr. Mitchell Levine was appointed Member and Vice-Chairperson of the Board on March 3, 2011.

Dr. Levine is a professor in the departments of Medicine and Clinical Epidemiology and Biostatistics in the Faculty of Health Sciences at McMaster University in Hamilton, Ontario. He is also Director of the Centre for Evaluation of Medicines at St. Joseph's Healthcare in Hamilton.

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.

MEMBERS

Normand Tremblay, ASC, MSc, Adm.A, CMC

Normand Tremblay was appointed Member of the Board on May 31, 2012.

Mr. Tremblay is President and Chief Executive Officer of an innovative company (diaMentis inc.) which is currently developing a mental health diagnostic tool, and teaches at the Université du Québec in the area of management, project management and innovation. He brings to the Board a vast experience and expertise in strategic and operational

planning and organizational development. For over 20 years, Mr. Tremblay has been active in various areas of the business field, nationally and internationally. He has also sat on investment committees and a number of administrative boards, including the National Research Council of Canada (NRCS) from 2007 to 2010. Mr. Tremblay holds a master's degree in project management (MSc) with a specialization in best practices in product development from the Université du Québec à Trois Rivières, as well as a certificate in business governance from Laval University and is a Certified Management Consultant. He is also a member of the Order of Certified Administrators of Québec.

Richard Bogoroch, LL.B.

Richard Bogoroch was appointed Member of the Board on December 13, 2012.

Mr. Bogoroch is a personal injury and medical malpractice lawyer actively involved in the legal community. He is a past Director of the Ontario Centre for Advocacy Training and a past Director of the Advocates' Society. Mr. Bogoroch is also a member of the Toronto Lawyers Association, the Medico-Legal Society of Toronto, the Association of Trial Lawyers of America, the American Bar Association, the Advocates' Society and the Ontario Trial Lawyers Association. He has lectured and written extensively on many aspects of personal injury and medical malpractice litigation for Continuing Legal Education Programmes organized by the Law Society of Upper Canada, the Advocates Society, Osgoode Hall Law School and others.

Mr. Bogoroch graduated from McGill University with a B.C.L. in 1978 and a LL.B in 1979. He was admitted to the Alberta Bar in 1980 and called to the Ontario Bar in 1983. In 1993, he was certified by The Law Society of Upper Canada as a Specialist in Civil Litigation.

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.

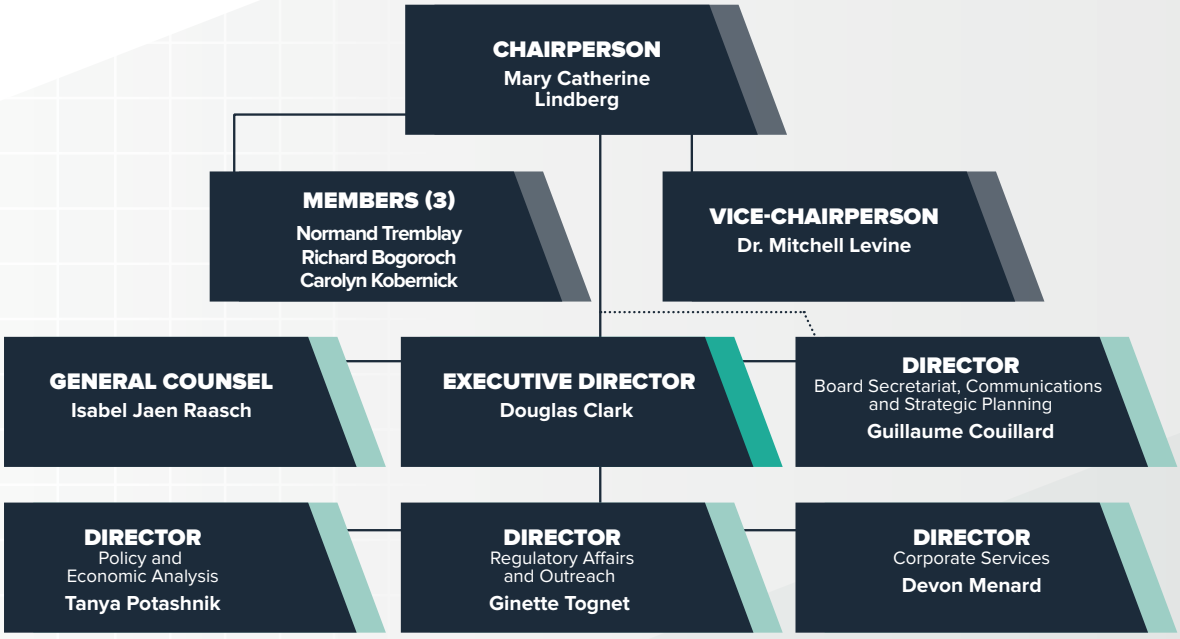
Ms. Kobernick joined the Department of Justice in 1980, where she practiced litigation and tax law at the Toronto Regional office. In 1991, she was appointed Senior General Counsel, Deputy Head, Business and Regulatory Law Portfolio, after working for over a decade in the legal services unit of the Correctional 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 L.L.B. from McGill University and is a member of the bar of Ontario. In 2012 she obtained a Certificate in Adjudication for Administrative Agencies, Boards and Tribunals from the Osgoode Hall Law School and the Society of Ontario Adjudicators and Regulators.

ORGANIZATIONAL STRUCTURE AND STAFF

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 drug products sold in Canada to ensure that they are not excessive; 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 drugs, 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; health, safety and security; information technology; and information management. It is also responsible for financial planning and reporting, 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 prosecution team in proceedings before the Board.

BUDGET

In 2015/16, the PMPRB had a budget of $10.945 million and an approved staff level of 71 full-time equivalent employees.

TABLE 1. Budget and Staffing

	2014/15	2015/16	2016/17
Budget	$10.927 M	$10.945 M	$10.965 M
Salaries	$6.903 M	$6.937 M	$6.963 M
Operating	$1.554 M	$1.538 M	$1.532 M
Special Purpose Allotment*	$2.470 M	$2.470 M	$2.470 M
Full Time Employees (FTEs)	73	71	71

* *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

With the population aging and using more prescription drugs— and sometimes more expensive types of drugs—Canada's spending on pharmaceuticals is expected to increase significantly in the years to come. Medical advancements have introduced many innovative new drugs to the Canadian marketplace to improve existing treatments and to treat conditions that previously had no pharmaceutical therapy. These include high-cost orphan drugs, biologics and cancer drugs. The PMPRB plays an important role in regulating the prices of new and existing patented drug products to ensure the sustainability of the Canadian health care system.

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 drug product 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 drug products in Canada. The *Patent Act* (Act) along with the *Patented Medicines Regulations* (Regulations) set out the filing requirements, and Board Staff reviews the pricing information on an ongoing basis to ensure that the prices are not excessive until all patents pertaining have expired.

There are several factors used for determining whether a drug product is excessively priced, 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 there is a problem with the price of a patented drug product, 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 results 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 the price is excessive, it can issue an Order to reduce the price and/or refund the excess revenues. A patentee also has the option of submitting a VCU to resolve the matter after the NOH has issued. Copies of the Act, the Regulations, the Guidelines and the *Patentee's Guide to Reporting* are posted on the PMPRB's website.

TABLE 2. Failure to Report the Sale of Patented Drugs

CURRENTLY SOLD BY	BRAND NAME	GENERIC NAME	YEAR MEDICINE CAME UNDER PMPRB'S JURISDICTION	YEAR MEDICINE CAME UNDER PMPRB'S JURISDICTION WITH SUBSEQUENT PATENT
Merck Canada Inc.	Puregon (1 DIN)	Follitropin beta	2001	
Janssen	Risperdal (6 DINs)	Risperidone	1993	2007
Janssen	Risperdal M (5 DINs)	Risperidone	2003	2007

FAILURE TO REPORT

The PMPRB relies on the patentees' full and timely disclosure of any and all patented drug products being sold in Canada to which a patent pertains. In 2015, one drug product that was patented and sold prior to 2015 was reported to the PMPRB for the first time, and 11 drug products previously reported to the PMPRB and for which the patent had expired were reported again as having another patent pertaining. Table 2 lists the drug products that were patented and sold in Canada prior to being reported to the PMPRB. In addition, following a patent audit, GlaxoSmithKline reported patents pertaining to 81 DINs (Drug Identification Numbers); 68 of the DINs had never been reported to the PMPRB and 13 DINs had previously been reported. The processing of the regulatory information for these DINs is in progress and these DINs are not included in this Annual Report.

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 2015.

IN 2015, CANADIAN PRICES WERE 28% HIGHER THAN THE MEDIAN OECD PRICE

Canada has some of the highest prices in the world. When independent data sources are used, all other countries in the PMPRB basket of comparators (with the exception of the US) have lower prices (on average) than Canada.

28%

HIGHER PRICES

SCIENTIFIC REVIEW

HUMAN DRUG ADVISORY PANEL

All new patented drug products 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 drug products to be used for comparison purposes and comparable dosage regimens.

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 drug is approved for sale in Canada.

NEW PATENTED DRUG PRODUCTS REPORTED TO THE PMPRB IN 2015

For the purpose of this report, a new patented drug product in 2015 is defined as any patented drug product first sold in Canada, or previously sold but first patented, between December 1, 2014, and November 30, 2015.

There were 86 new patented drug products for human use reported as sold in 2015. Some are one or more strengths of a new active substance and others are new presentations of existing medicines. Of the 86 new patented drug products, one was being sold in Canada prior to the issuance of the Canadian patent that brought it under the PMPRB's jurisdiction. The table below shows the year of first sale for these drug products.

TABLE 3. Number of New Patented Drug Products for Human Use in 2015 by Year First Sold

YEAR FIRST SOLD	NO. OF DRUG PRODUCTS
2015	85
2013	1
Total	86

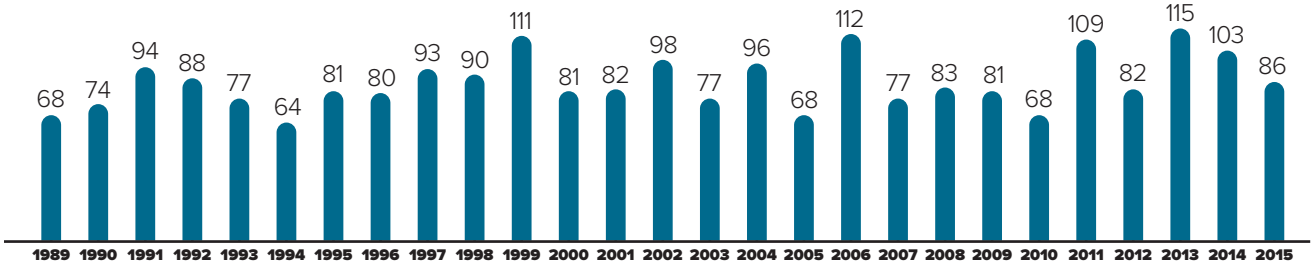
The list of *New Patented Medicines Reported to the PMPRB* is available on the website. This list includes information on the status of the review (e.g., whether the medicine is under review, within the Guidelines, under investigation, or subject to a VCU or Notice of Hearing).

Figure 1 illustrates the number of new patented drug products for human use reported to the PMPRB from 1989 to 2015.

Of the 86 new patented drug products:

- the prices of 57 had been reviewed as of March 31, 2016:
  - 38 were found to be within the Guidelines
  - 11 were at a level that appeared to exceed the Guidelines by an amount that did not trigger the investigation criteria
  - 7 were priced at levels that appeared to exceed the Guidelines and investigations were commenced
  - 1 was the subject of a VCU

FIGURE 1. New Patented Drug Products for Human Use



Source: PMPRB

For a complete list of the 86 new patented drug products and their price review status, see *Appendix 2*.

PRICE REVIEW OF EXISTING PATENTED DRUG PRODUCTS FOR HUMAN USE IN 2015

For the purpose of this report, existing patented drug products include all patented drug products that were first sold and reported to the PMPRB prior to December 1, 2014.

At the time of this report, there were 1,273 existing patented drug products:

- 922 were priced within the Guidelines
- 254 exceeded the Guidelines by an amount that did not trigger the investigation criteria
- 86 were the subject of investigations:
  - 2 were opened as the result of introductory pricing in 2012
  - 4 were opened as the result of introductory pricing in 2013
  - 4 were opened as the result of introductory pricing in 2014
  - 76 were opened on the basis of year-over-year prices
- 1 was under review
- 9 drug products were the subject of Voluntary Compliance Undertakings
- 1 drug product is the subject of a hearing
- 1 additional drug product remains the subject of a hearing although no longer patented in 2015

A summary of the status of the price review of the new and existing patented drug products for human use in 2015 is provided in Table 4.

UPDATE FROM THE 2014 ANNUAL REPORT

- Reviews of all drug products for human use reported as Under Review in the *2014 Annual Report* have been completed.
- 34 of the 61 investigations reported in the *2014 Annual Report* resulted in one of the following:
  - the closure of the investigation where it was concluded that the price was within 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 drug product (see *Voluntary Compliance Undertakings*)
  - a public hearing to determine whether the price was excessive, including any remedial Order determined by the Board (see *Hearings*)

PATENTED OVER-THE-COUNTER DRUG PRODUCTS AND PATENTED DRUG PRODUCTS FOR VETERINARY USE

Board Staff reviews the price of a patented over-the-counter drug product or a patented veterinary drug product when a complaint has been received. No complaints were received in 2015.

TABLE 4. Patented Drug Products for Human Use Sold in 2015 — Status of Price Review as of March 31, 2016

	NEW DRUG PRODUCTS INTRODUCED IN 2015	EXISTING DRUG PRODUCTS	TOTAL
Total	86	1,273	1,359
Within Guidelines	38	922	960
Under Review	29	1	30
Does Not Trigger Investigation	11	254	265
Under Investigation	7	86	93
Voluntary Compliance Undertakings	1	9	10
Price Hearings		1	1

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 drug product sold in Canada appears to have exceeded the Guidelines. A VCU represents a compromise between the PMPRB and the patentee as a result of negotiations between the parties in the view of specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value. A VCU can also be submitted by a patentee following the issuance of a Notice of Hearing.

In 2015, five VCUs were accepted. In addition to price reductions for certain drug products, excess revenues totaling $7,087,235.86 were offset by way of payments to the Government of Canada.

In 2016, as at May 31, 2016, six VCUs have been approved by the Chairperson, in the matters of Mitosol, Neoral, Apprilon, Angiomax, Samsca and Actimmune, totaling $975,589.26 in excess revenues which were offset by way of payments to the Government of Canada.

Patentees are to ensure that the prices of their patented drug products are within the Board's Guidelines during all periods in which the drug products are under the PMPRB's jurisdiction.

$157 MILLION IN EXCESS REVENUES HAVE BEEN RECOVERED

by the PMPRB through Voluntary Compliance Undertakings and Board Orders since 1993. In 2015, as a result of PMPRB investigations, 5 Voluntary Compliance Undertakings were accepted with $7.1 million in excess revenues offset by way of payment to the Government of Canada.

$157

MILLION IN EXCESS REVENUES HAVE BEEN RECOVERED

TABLE 5. Voluntary Compliance Undertakings in 2015 and up to May 31, 2016

PATENTED DRUG PRODUCT	THERAPEUTIC USE	PATENTEE	DATE OF APPROVAL	OFFSET OF EXCESSIVE REVENUES	
				PRICE REDUCTION	PAYMENT TO THE GOVERNMENT
VCUs in 2015					
Crixivan (1 drug product)*	Treatment of HIV infection	Merck Canada Inc.	April		$58,917.68
Carnitor IV (1 drug product)	Prevention and treatment of carnitine deficiency in patients with end stage renal disease	Sigma-Tau Pharmaceuticals Inc.	August		$5,688,632.64
Loprox (1 drug product)	Topical treatment of dermal infections	Valeant Canada LP	October	✓	$23,947.35
Dificid (1 drug product)	Treatment of Clostridium difficile infection (CDI)	Merck Canada Inc.	November	✓	$400,000.00
Zaxine (1 drug product)	Reduce risk of overt hepatic encephalopathy (HE) recurrence	Salix Pharmaceuticals Inc.	December	✓	$915,738.19
Total					**$7,087,235.86**
VCUs in 2016, up to May 31					
Mitosol (1 drug product)	Adjunct to ab externo glaucoma surgery	Labtician Ophthalmics Inc.	January	✓	$190.58
Neoral (1 drug product)*	Prevention of graft rejection following solid organ transplantation and treatment of transplant rejection	Novartis Pharmaceuticals Canada Inc.	February	✓	$96,466.51
Apprilon (1 drug product)	Treatment of only inflammatory lesions (papules and pustules) or rosacea in adult patients	Galderma Canada Inc.	March	✓	
Angiomax (1 drug product)	An anticoagulant in patients undergoing percutaneous coronary intervention and in the treatments of patients with moderate to high risk acute coronary syndromes due to unstable angina or non-ST-segment elevation in whom early percutaneous coronary intervention is planned	Sunovion Pharmaceuticals Canada Inc.	March	✓	$88,412.60
Samsca (2 drug products)	Treatment of clinically important, non-hypovolemic - hyponatremia	Otsuka Canada Pharmaceutical Inc.	May	✓	$200,000.00
Actimmune (1 drug product)	Chronic Granulomatous Disease and severe, malignant osteopetrosist	Horizon Pharma Ireland Limited	May	✓	$590,519.57
Overall Total					**$8,062,825.12**

* *These drug products were no longer patented in 2015 therefore, they are not included in the number of VCUs reported in Table 4* - Patented Drug Products for Human Use Sold in 2015.

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 and 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., the pharmaceutical company that holds the patent for Soliris and sells the medicine in Canada. Soliris is the first and only treatment for patients with Paroxysmal Nocturnal Hemoglobinuria—a rare and life-threatening blood disorder. The purpose of this hearing will be 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 is currently scheduled to be held in January and February 2017.

Failure to File – Jurisdiction

When Board Staff finds 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 is, in fact, bound by the reporting requirements of the Act and Regulations (i.e., under the PMPRB's jurisdiction). If the Board Panel finds, as the result of a public hearing, that the patentee is in breach of its reporting requirements, the Board Panel may order the patentee to provide the PMPRB with the required pricing and sales information.

As a result of public complaints addressed to Board Staff concerning the price of two drug products, the PMPRB announced in February and March 2016 that it will hold separate public hearings with respect to whether Galderma Canada Inc. (Galderma) and Baxalta Canada Corporation (Baxalta) are required to provide the PMPRB with the pricing and sales information stipulated in the *Patent Act* and the *Patented Medicines Regulations*. The hearing for Galderma will held September 26–29, 2016; and the hearing for Baxalta will be held November 15–17 and 21, 2016.

The Galderma proceeding relates to the medicines branded as Differin, Differin XP, TactuPump, and TactuPump Forte, for which Galderma holds the patent. These medicines are generally indicated for the treatment of acne.

NOTICES OF HEARING

Three hearings are currently before the Board.

In addition to the Soliris (Alexion) matter, Notices of Hearing were issued in February and March 2016 to determine whether Galderma Canada Inc. and Baxalta Canada Corporation each failed to provide the PMPRB with the pricing and sales information required under the *Patent Act* and the *Patented Medicines Regulations*. Hearings are scheduled in Fall 2016.

The Baxalta proceeding relates to the medicine Oncaspar, for which Baxalta holds the patent. Oncaspar is sold in Canada under Health Canada's Special Access Programme and is used in the treatment of patients with Acute Lymphoblastic Leukemia.

Two other matters remain before the Board: Apotex Inc. and Apo-Salvent CFC Free. The outcome of these matters will be examined in light of the Federal Court of Appeal's decisions in the Ratiopharm and Sandoz cases. In January 2016, Sandoz Canada Inc. and Ratiopharm Inc. (now Teva Canada Limited), applied to the Supreme Court of Canada for an Order granting leave to appeal from the Judgments of the Federal Court of Appeal.

SUMMARY

Excess revenues totaling $8,062,825.12 were offset by way of payments to the Government of Canada through VCUs and Board Orders in 2015 and up to May 31, 2016.

Since 1993, a total of 113 VCUs have been approved and 29 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 $157 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 November 6, 2015, the Federal Court of Appeal issued its decision on appeals regarding the PMPRB's jurisdiction related to salbutamol HFA and other products of ratiopharm Inc. (now Teva Canada Limited) and to a number of products sold in Canada by Sandoz Canada Inc.

The Court of Appeal upheld the finding of the original Board Panel decision that held that Sandoz and ratiopharm were patentees under section 79 of the Act because they were exercising a right to sell their products under license from the owners of a number of patents. In broadly interpreting section 79 of the Act, the Federal Court of Appeal found the construction of the language in the Act that relates to the PMPRB must focus on the persons in need of protection from excessive pricing (consumers) and not on those in a position to cause such pricing (patentees).

The decision also reaffirmed the constitutionality of sections 79–103 of the Act. In this regard, the Federal Court of Appeal found that the Board correctly held that the control of prices charged for patented medicines comes within the jurisdiction conferred on Parliament over patents under subsection 91(22) of the *Constitution Act, 1867* when applied to patent holders, patent owners, or any other persons exercising rights under patents (such as licensees).

The full text of the Federal Court of Appeal decision can be found on the Federal Court of Appeal website: http://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/126361/index.do

TABLE 6. Status of Board Proceedings in 2015 and up to May 31, 2016

ALLEGATIONS OF EXCESSIVE PRICING				
Patented Drug Product	**Indication / Use**	**Patentee**	**Issuance of Notice of Hearing**	**Status**
Apo-Salvent CFC-Free	Asthma	Apotex Inc.	July 8, 2008	Ongoing
Soliris	Paroxysmal nocturnal Hemoglobinuria Atypical hemolytic uremic syndrome	Alexion Pharmaceuticals Inc.	January 20, 2015	Pre-hearing conference: June 1, 2016 Hearing: June 27–30, 2016 and July 4–8, 2016

continued

ALLEGATIONS OF FAILURE TO FILE

Patented Drug Product	Indication / Use	Patentee	Issuance of Notice of Hearing	Status
All medicines for which Apotex is a "patentee"		Apotex Inc.	March 3, 2008	Ongoing
Differin **Differin XP** **TactuPump** **TactuPump Forte**	Acne	Galderma Canada Inc.	February 23, 2016	Hearing: September 26–29, 2016
Oncaspar	Acute Lymphoblastic Leukemia	Baxalta Canada Corporation	March 22, 2016	Hearing: November 15–17 and 21, 2016

JUDICIAL REVIEW OF BOARD DECISIONS AND APPEALS

Patented Drug Product	Indication / Use	Patentee	Issue	Date of Notice of Hearing / Status
ratio-Salbutamol HFA	Asthma	ratiopharm Inc. (now Teva Canada Limited)	Allegations of excessive pricing	July 18, 2008 • Application for leave to appeal filed at the Supreme Court of Canada: January 5, 2016
		ratiopharm Inc. (now Teva Canada Limited)	Failure to file (jurisdiction)	August 28, 2008 • Application for leave to appeal filed at the Supreme Court of Canada: January 5, 2016
		Sandoz Canada Inc.	Failure to file (jurisdiction)	March 8, 2010 • Application for leave to appeal filed at the Supreme Court of Canada: January 5, 2016
Soliris	Paroxysmal nocturnal Hemoglobinuria Atypical hemolytic uremic syndrome	Alexion Pharmaceuticals Inc.	Constitutionality of the PMPRB	January 20, 2015 • Motion to strike granted June 2016

Sandoz Canada Inc. and Ratiopharm Inc. (now Teva Canada Limited) applied to the Supreme Court for an Order granting leave to appeal from the Judgments of the Federal Court of Appeal.

In June 2015, Alexion filed an application before the Federal Court, seeking a declaration that the provisions of the *Patent Act* allowing the PMPRB to regulate excessive pricing are unconstitutional as an improper encroachment on provincial jurisdiction over property and civil rights. The Attorney General of Canada filed a motion to dismiss Alexion's judicial review regarding constitutionality which was heard in January 2016 and was granted in June 2016. Alexion is also seeking judicial review of a decision of the Board which found that Board Staff and the Chairperson were not in a conflict of interest with respect to this file. This matter has been stayed.

KEY PHARMACEUTICAL TRENDS: DRUG SALES ARE ON THE RISE

Overall spending on pharmaceuticals is influenced by many factors, including price, utilization, the market entry of newer, more expensive drugs, and older drugs "going generic". In 2015, sales of patented drugs increased by 9.5% and Canadian prices remained third highest among 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 analyses on a variety of topics related to pharmaceutical pricing and costs.

TRENDS IN SALES OF PATENTED DRUG PRODUCTS

Patentees are required under the *Patented Medicines Regulations* to submit detailed information on their sales of patented drug products, 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 drug products.[1] This section provides key statistical results from this analysis.

SALES AND PRICES

Canadians spend much more today on patented drug products than they did a decade ago, but it is important to understand that an increase in drug spending does not in itself imply rising drug prices. For example, the PMPRB's Annual Reports from 1995 through 2003 noted that sales of patented drug products 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 drug utilization.

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 drug therapy
- changes in the prescribing practices of physicians (for example, a shift away from older, less expensive drug products to newer, more expensive medications, or a shift toward higher, more frequent dosages)
- increases in the use of drug therapy instead of other forms of treatment

- the use of new drug products to treat conditions for which no effective treatment existed previously
- the use of new drug products that enter the market at a higher price than previous treatments for a given condition

SALES TRENDS

Table 7 reports patentees' total sales of patented drug products in Canada for 1990 through 2015. In 2015, sales of patented drug products increased to $15.2 billion from $13.8 billion in 2014, an increase of 9.5%. This is the highest growth rate since 2003. Indeed, it is more than two times the magnitude of any annual growth rate since 2003, and the $1.4 billion year-over-year increase ties the record for the single largest increase in sales in patented medicines in Canadian history.

The last column of Table 7 gives sales of patented drug products as a share of overall drug sales. This share rose from 43.2% in 1990 to a peak of 72.7% in 2003. It declined over the 2003 to 2009 period, but has been quite stable since. That is, sales of non-patented brand and generic drug products have generally grown at similar rates as the sales of patented drug products in recent years.

DRIVERS OF SALES GROWTH

Table 8 decomposes the sales growth that occurred between 2014 and 2015 into distinct elements reflecting the impacts of:

- previously patented drug products that have gone off-patent or left the Canadian market ("exiting drug effect")
- patented drug products introduced to the Canadian market in 2015 ("new drug effect")
- changes in prices among patented drug products with sales in Canada in both 2014 and 2015 ("price effect")
- differences in the quantities of such drug products sold in the two years ("volume effect")
- interactions of price and quantity changes ("cross effect")

The first row of Table 8 gives these impacts as dollar amounts. The second row expresses the impacts as proportions of the overall change in sales between 2014 and 2015. For the sake of comparison, the third row provides average year-over-year proportionate impacts for 2011 through 2014.[2]

The results in this table show that the increase in total sales that occurred between 2014 and 2015 was the result of two factors: increases in the quantity of existing drug products sold, and strong sales for new drugs, which offset a relatively large exiting drug effect. Proportionally, the 2015/2014 decomposition values are nearly identical to those in 2014/2013.

IN 2015, SALES OF PATENTED DRUG PRODUCTS INCREASED TO $15.2 BILLION FROM $13.8 BILLION IN 2014.

This is the highest growth rate since 2003. Indeed, it is more than two times the magnitude of any annual growth rate since 2006, and the $1.4 billion year-over-year increase ties the record for the single largest increase in sales in patented medicines in Canadian history.

$15.2

BILLION SALES IN PATENTED DRUG PRODUCTS

TABLE 7. Sales of Patented Drug Products, 1990–2015

YEAR	PATENTED DRUG PRODUCTS		SALES OF PATENTED DRUG PRODUCTS AS A SHARE OF ALL DRUG SALES (%)*
	SALES ($BILLIONS)	CHANGE (%)	
2015	15.2	9.5	61.8
2014	13.8	3.1	59.9
2013	13.4	4.2	60.7
2012	12.9	0.1	59.2
2011	12.9	3.5	58.3
2010	12.4	-4.3	55.8
2009	13.0	2.9	59.6
2008	12.6	4.6	61.7
2007	12.1	3.2	63.2
2006	11.7	7.4	67.8
2005	10.9	4.2	70.6
2004	10.5	7.8	72.2
2003	9.7	9.0	72.7
2002	8.9	17.5	67.4
2001	7.6	18.9	65.0
2000	6.3	16.7	63.0
1999	5.4	27.0	61.0
1998	4.3	18.9	55.1
1997	3.7	22.6	52.3
1996	3.0	12.8	45.0
1995	2.6	10.8	43.9
1994	2.4	-2.1	40.7
1993	2.4	9.4	44.4
1992	2.2	14.0	43.8
1991	2.0	13.1	43.2
1990	1.7	—	43.2

* *The denominator in this ratio comprises sales of patented, non-patented brand and generic drug products. Starting with the estimate for 2005, this value is derived from data contained in IMS Health's MIDAS™ database. In previous years, IMS data were used to calculate sales of generic drug products 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 IMS Health - none of these adjustments resulted in a change greater than 0.4%.*

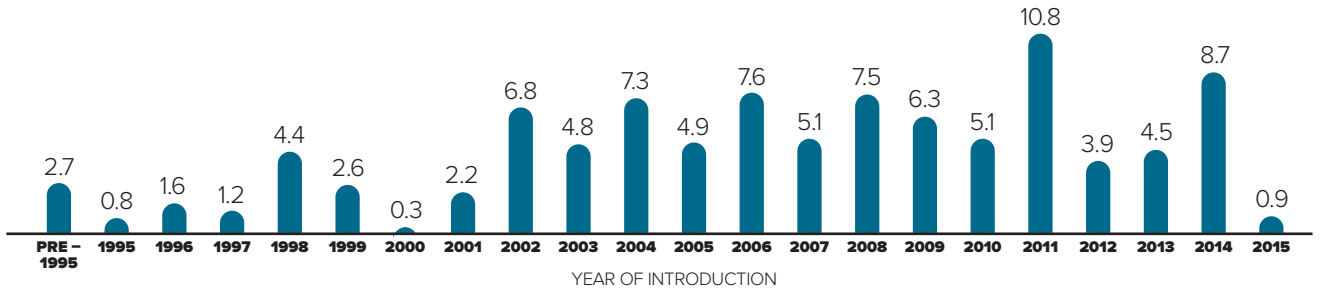
Sources: PMPRB; MIDAS™ database, 2005–2015, IMS AG. All rights reserved.[3]

TABLE 8. Decomposition of Changes in Sales of Patented Drug Products

	TOTAL CHANGE	EXITING DRUG EFFECT	NEW DRUG EFFECT	PRICE EFFECT	VOLUME EFFECT	CROSS EFFECT
Sales impact, 2015/2014 ($millions)	384.09	-344.48	354.39	1.93	386.53	-14.29
Proportion of total change, 2015/2014 (%)	100.00	-89.69	92.27	0.50	100.64	-3.72
Average proportion of total change, 2011–2014 (%)	100.00	-146.55	189.74	31.38	39.60	-14.16

Source: PMPRB

FIGURE 2. Share of 2015 Sales (%) of Patented Drug Products by Year of Introduction



Source: PMPRB

Figure 2 breaks down 2015 sales of patented drug products according to the year in which the product 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" products that ultimately achieved very high sales volumes. Despite the recent patent expiries ("patent cliff"), these products still accounted for a considerable share of patented drug sales in 2015. Most significant, however, was the introduction of several highly effective treatments for Hepatitis C in 2014, which has significantly increased the share of sales attributable to drugs released in that year.

SALES BY THERAPEUTIC CLASS

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

Table 9 breaks out sales of patented drug products in Canada in 2015 by ATC Level 1. The table gives the 2015 sales for each class, the share of the total sales this represents and the rate at which sales grew relative to 2014. Values in the last column represent the component of overall sales growth attributable to drug products in the corresponding therapeutic class.[4] By this measure, general antiinfectives for systemic use and antineoplastics and immunomodulating agents made the largest contribution to sales growth. Lower sales of both cardiovascular system and nervous system drugs also had a significant impact on overall expenditure.

TABLE 9. Sales of Patented Drug Products by Major Therapeutic Class, 2015

THERAPEUTIC CLASS	2015 SALES ($MILLIONS)	SHARE: 2015 SALES (%)	GROWTH: 2015/2014 ($MILLIONS)	GROWTH: 2015/2014(%)	IMPACT ON CHANGE IN EXPENDITURE (%)
A: Alimentary tract and metabolism	1,599.8	10.6	94.1	6.2	7.1
B: Blood and blood forming organs	770.3	5.1	-17.8	-2.3	-1.4
C: Cardiovascular system	809.5	5.3	-104.2	-11.4	-7.9
D: Dermatologicals	100.4	0.7	-9.3	-8.5	-0.7
G: Genito-urinary system and sex hormones	536.2	3.5	23.0	4.5	1.7
H: Systemic hormonal preparations	63.0	0.4	0.7	1.1	0.1
J: General antiinfectives for systemic use	2,396.1	15.8	797.2	49.9	60.4
L: Antineoplastics and immunomodulating agents	4,723.3	31.2	489.0	11.5	37.0
M: Musculo-skeletal system	361.7	2.4	-90.4	-20.0	-6.8
N: Nervous system	1,621.0	10.7	-75.9	-4.5	-5.8
R: Respiratory system	1,237.5	8.2	73.0	6.3	5.5
S: Sensory organs	791.6	5.2	69.7	9.6	5.3
V: Various	151.8	1.0	71.3	88.5	5.4
All therapeutic classes[†]	**15,162.2**	**100.0**	**1,320.3**	**9.5**	**100.0**

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

Source: PMPRB

End Notes

1 All statistical results for patented drug products reported in this chapter are based on data submitted by patentees as of March 2016. 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 Drug Products*), price and quantity indices (see *Price Trends* and *Utilization of Patented Drug Products*) 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.

2 Under the scheme applied here, the "exiting drug effect" is the amount of 2015 sales generated by drug products that were under the PMPRB's jurisdiction in 2014 but not in 2015. The "new drug effect" is the amount of 2015 sales generated by drug products that were under the PMPRB's jurisdiction in 2015 but not in 2014. Other effects are derived by means of the relationship:

$$\Sigma\, p^{2015}(i)\, q^{2015}(i) - \Sigma\, p^{2014}(i)\, q^{2014}(i) = \Sigma\, [p^{2015}(i) - p^{2014}(i)]q^{2014}(i) + \Sigma\, p^{2014}(i)\, [q^{2015}(i) - q^{2014}(i)] + \Sigma\, [p^{2015}(i) - p^{2014}(i)]\, [q^{2015}(i) - q^{2014}(i)]$$

$p^y(i)$ is the price of drug i in year y, $q^y(i)$ is the physical volume of drug i sold in year y and Σ signifies summation over the set of drug products that were under the PMPRB's jurisdiction in both 2014 and 2015. The left-hand side of this equation represents the change in total sales of such products between 2014 and 2015. The three terms of the right-hand side define the volume, price and cross effects, respectively, reported in Table 8.

3 Although based in part on data obtained under license from the IMS AG MIDAS™ database, the statements, findings, conclusions, views and opinions expressed in this Annual Report are exclusively those of the PMPRB and are not attributable to IMS AG.

4 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 drug products.

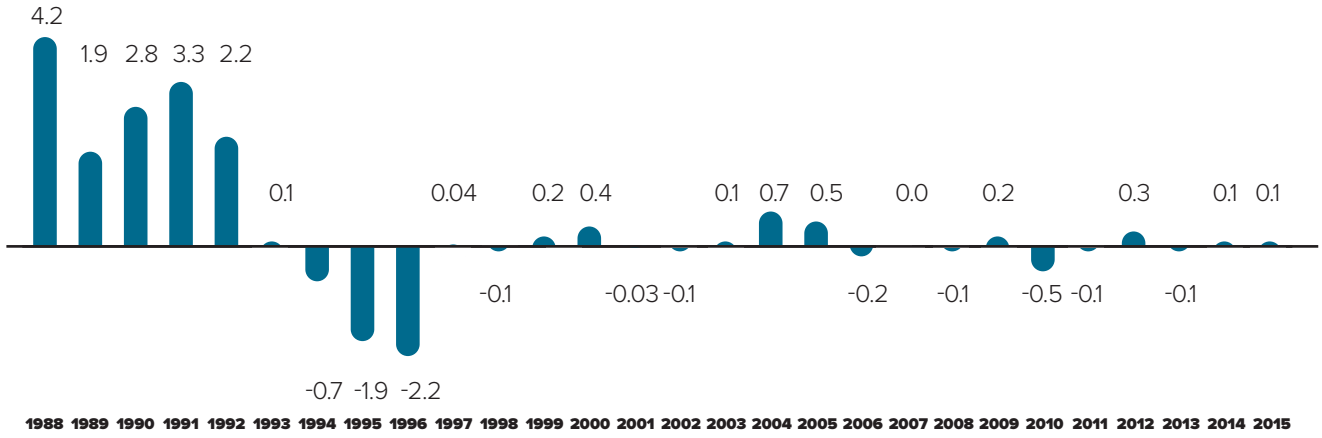
PRICE TRENDS

The PMPRB uses the Patented Medicines Price Index (PMPI) to monitor trends in prices of patented drug products. The PMPI measures the average year-over-year change in the ex-factory prices of patented drug products 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 drug products.[5] 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 drug costs. The PMPI does not measure changes in the utilization of patented drug products; a quantity index, the PMQI, is calculated for this purpose (see *Utilization of Patented Drug Products*). 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.

Figure 3 provides year-over-year changes in the PMPI for the years 1988 through 2015. As measured by the PMPI, prices of patented drug products were virtually unchanged from 2014 to 2015.

FIGURE 3. Annual Rates of Change (%), Patented Medicines Price Index (PMPI), 1988–2015

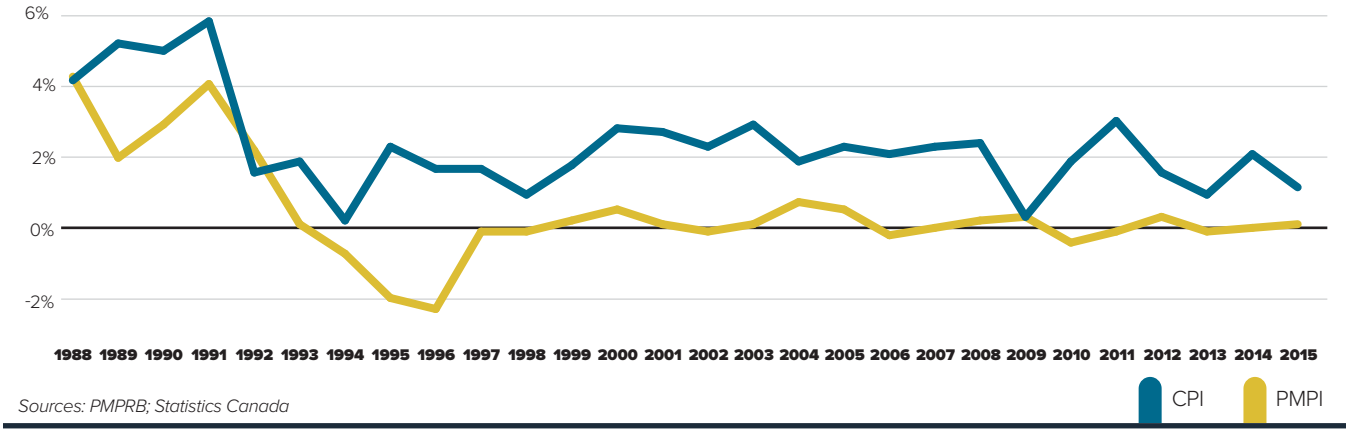


Source: PMPRB

IN 2015, THE INCREASE IN PATENTED DRUG 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.

PATENTED DRUG PRICES INCREASED LESS THAN THE CPI

FIGURE 4. Annual Rate of Change, Patented Medicines Price Index (PMPI) and Consumer Price Index (CPI), 1988–2015



Sources: PMPRB; Statistics Canada

The *Patent Act* requires the PMPRB to consider changes in the CPI, among other factors, in determining whether the price of a patented drug product is excessive. Figure 4 plots year-over-year rates of change in the PMPI against corresponding changes in the CPI. General price inflation, as measured by the CPI, has exceeded the average increase in patented drug prices almost every year since 1988. In 2015, the CPI rose by 1.1%, while the PMPI rose by 0.1% between 2014 and 2015.

It is not surprising that the PMPI has seldom kept pace with the CPI. The PMPRB's Guidelines allow the price of a patented drug product to rise by no more than the CPI over any three-year period. (The Guidelines also impose 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.[6] Increases in the PMPI normally do not reach this upper bound because many patentees do not raise their prices by the full amount permitted under the Guidelines.

GENERAL ANTIINFECTIVES FOR SYSTEMIC USE HAD THE GREATEST IMPACT ON SALES GROWTH IN 2015

This class of drugs, which includes breakthrough new treatments for Hepatitis C, accounted for 15.8% of sales in 2015, an increase of 49.9% from the previous year.

ANTIINFECTIVES SALES GREW BY

49.9%

PRICE CHANGE BY THERAPEUTIC CLASS

Table 10 provides average rates of price change among patented drug products at the level of major therapeutic classes. Results in this table were obtained by applying the PMPI methodology to data segregated by their ATC Level 1 class. The last column provides a decomposition of overall PMPI change, with each entry representing the component of the overall change attributable to drug products in the corresponding therapeutic class. By this measure, the PMPI (0.7%) reflects a general state of price stability across therapeutic classes. Note that all of the therapeutic classes saw an average rate of price change below the rate of CPI inflation.[7]

PRICE CHANGE BY CLASS OF CUSTOMER

Figure 5 presents average rates of price change by class of customer.[8] These results were obtained by applying the PMPI methodology separately to sales data for hospital, pharmacy and wholesale customers.[9] The 2015 rates of price change for these classes were, respectively, 0.0%, 1.1% and -0.2%.

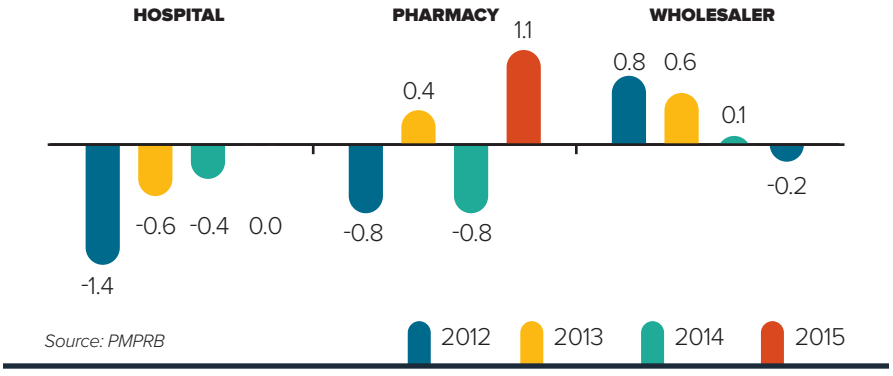
TABLE 10. Change in the Patented Medicines Price Index (PMPI), by Major Therapeutic Class, 2015

THERAPEUTIC CLASS	SHARE: 2015 SALES (%)	PRICE CHANGE: 2014 TO 2015 (%)	CONTRIBUTION: CHANGE IN PMPI (%)
A: Alimentary tract and metabolism	10.6	0.00	0.00
B: Blood and blood forming organs	5.1	0.72	0.04
C: Cardiovascular system	5.3	0.16	0.01
D: Dermatologicals	0.7	0.27	0.00
G: Genito-urinary system and sex hormones	3.5	-0.20	-0.01
H: Systemic hormonal preparations	0.4	0.22	0.00
J: General Antiinfectives for systemic use	15.8	0.70	0.11
L: Antineoplastics and immunomodulating agents	31.2	-0.35	-0.11
M: Musculo-skeletal system	2.4	-0.43	-0.01
N: Nervous system	10.7	0.34	0.04
R: Respiratory system	8.2	0.12	0.01
S: Sensory organs	5.2	0.23	0.01
V: Various	1.0	-1.59	-0.02
All therapeutic classes	100.0†	0.07	0.07

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

Source: PMPRB

FIGURE 5. Annual Rate of Change (%), Patented Medicine Price Index (PMPI), by Class of Customer, 2012–2015



Source: PMPRB

PRICE CHANGE BY PROVINCE/TERRITORY

Figure 6 presents average annual rates of price change by province/territory, obtained by applying the PMPI methodology to sales data segregated by the province/territory in which the sale occurred. These results indicate that, between 2014 and 2015, the average transaction prices of patented drug products in Quebec fell in all customer classes.

PRICE BEHAVIOUR AFTER INTRODUCTION

Does the price of a typical patented drug product change much in the years after it enters the Canadian market? To answer this question, Figure 7 provides the average ratio of the 2015 price to introductory price (the price at which the drug product was sold in its first year on the Canadian market).

The results in Figure 7 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.[10] For example, the prices of products introduced a decade ago are only 3% higher in 2015.

PRICE CHANGE BY COUNTRY

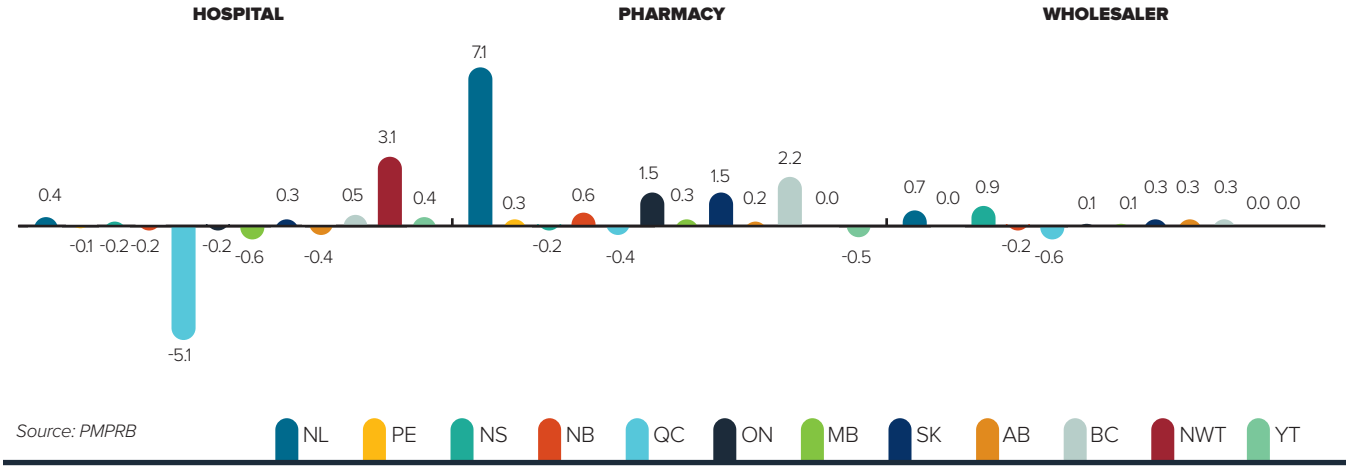
In accordance with the Act and the Regulations, patentees must report publicly available prices of patented drug products for seven foreign comparator countries ("PMPRB7"): France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.

The PMPRB uses this information to

- conduct international price comparison tests (as specified in its Guidelines)
- compare the Canadian prices of patented drug products to those prevailing in other countries

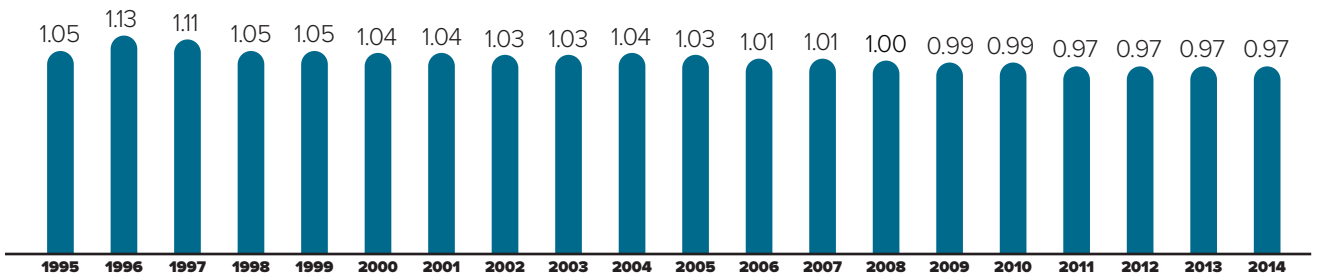
Figure 8 gives the average annual rates of price change for Canada and each of the seven comparator countries. These results were obtained by applying the PMPI methodology (with weights based on Canadian sales patterns) to the international price data that patentees

FIGURE 6. Annual Rate of Price Change, by Province/Territory* and Class of Customer, 2015



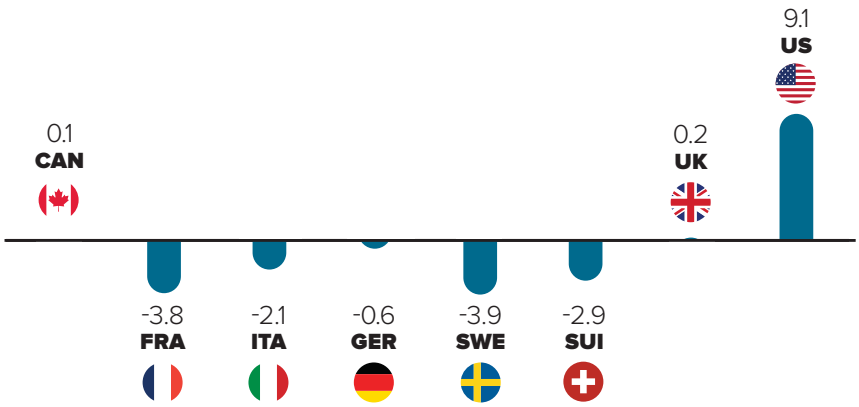
*Values for Nunavut are included in the Northwest Territories (NWT).

FIGURE 7. Average Ratio of 2015 Price to Introductory Price, by Year of Introduction



Source: PMPRB

FIGURE 8. Annual Average Rates of Price Change, Canada and Comparator Countries, 2015



Source: PMPRB

have submitted to the PMPRB. Note that results for the United States are based on prices that incorporate prices from the US Federal Supply Schedule (FSS).[11]

The results in Figure 8 indicate that in 2015, the United States saw prices rise at an average rate of 9.1%. Prices in the United Kingdom were essentially flat, while prices in France, Italy, Switzerland, Sweden and Germany declined. 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 United States) while slowly rising in Canada.

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 the actual average transaction prices and is net of rebates and discounts provided by manufacturers to their direct customers.

End Notes

5 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.

6 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.

7 Suppose R represents the overall rate of change in the PMPI and there are N therapeutic classes, indexed by 1, 2 ... N. Let $R(i)$ represent the average rate of price change in major therapeutic class i obtained by means of the PMPI methodology. Using the fact that R is a sales-weighted average of price changes taken over all patented drug products, it is easy to derive the following relationship:

$$R = w(1) \times R(1) + w(2) \times R(2) + \ldots + w(N) \times R(N)$$

where $w(i)$ represents the share of therapeutic class i in the sales of patented drug products. This relationship provides the basis for the decomposition in the last column of Table 10. Each term on its right-hand-side multiplies the average rate of price change for a given therapeutic class by its share of overall sales. The resulting value is readily interpreted as the contribution of the corresponding class to the change in the overall PMPI. Note that the size of this contribution depends on both the rate of price change specific to the class and its relative importance, as measured by its share of sales.

The decomposition in Table 10 is approximate. This is because the weights used to calculate the contribution of each therapeutic class are based on annual sales data, whereas rates of price change (whether overall or by therapeutic class) are calculated from data covering six-month reporting periods. The resulting discrepancy is normally small.

8 Sales of patented drug products are dominated by sales to wholesalers, which accounted for 79.3% of all sales in 2015. Sales to hospitals accounted for another 7.3%, while direct sales to pharmacies accounted for 5.9%. The pharmacy share has fallen precipitously since 2001, when it stood at 20.1%.

9 Results for a fourth class of customer, "Others", are not provided. This class accounted for about 7.5% of patented drug sales in 2015. Buyers in this class are principally health care institutions other than hospitals, such as clinics and nursing homes. It also includes direct sales to governments. The composition of this class is thought to vary substantially from one year to the next, rendering any analysis of price change in this class of limited value.

10 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.

11 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 drug products. The FSS prices are negotiated between manufacturers and the US Department of Veterans' Affairs. They are typically less than other publicly available US prices reported to the PMPRB by patentees.

COMPARISON OF CANADIAN PRICES TO FOREIGN PRICES

Tables 11 and 12 provide detailed statistics comparing the foreign prices of patented drug products 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 drug products (DINs) and the volume of sales encompassed by each reported price ratio.[12]

The average price ratios given in Tables 11 and 12 are sales-weighted arithmetic means of price ratios obtained for individual drug products, 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 drug products they purchased in 2015 had they paid Country X prices rather than Canadian prices?

For example, Table 11 states that the 2015 average France-to-Canada price ratio was 0.75. This means Canadians would have paid 25% less for the patented drug products they purchased in 2015 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 11 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 drug products they purchased in 2015 had they lived in Country X?

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

TABLE 11. Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons, 2015

	CANADA	FRANCE	ITALY	GERMANY	SWEDEN	SWITZERLAND	UNITED KINGDOM	UNITED STATES
At Market Exchange Rates								
Average price ratio 2015	1.00	0.75	0.87	1.16	0.94	1.00	0.92	2.70
Average price ratio 2014	1.00	0.75	0.87	1.14	0.96	0.97	0.86	2.47
At Purchasing Power Parities								
Average price ratio 2015	1.00	0.80	0.97	1.27	0.81	0.79	0.92	2.95
Average price ratio 2014	1.00	0.82	1.05	1.32	0.88	0.80	0.93	2.97
Number of patented drug products 2015	1,358	768	859	987	913	893	957	1,118
Sales ($millions)[13]	15,038.63	9,868.98	11,424.13	13,090.13	12,558.45	12,594.87	12,752.60	13,945.83

Source: PMPRB

BILATERAL COMPARISONS

Table 11 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, Italy, the United Kingdom and Sweden were appreciably lower than Canadian prices, while those in Germany were higher. As in previous years, prices reported for the United States were much higher than prices in Canada or any other comparator country. Switzerland prices were on par with Canadian prices in 2015.

It is important to note that it is not always possible to find a matching foreign price for each and every patented drug product sold in Canada. Table 11 displays how often an international price comparison was available for each of the comparator countries. For example, out of 1,359 patented drug products under the PMPRB's jurisdiction in 2015, a publicly available ex-factory price for France was available 57% of the time, whereas for the US the number was 82%. 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 product sold in Canada is available, in which case it is deemed to constitute the international median price as per the PMPRB's methodology.

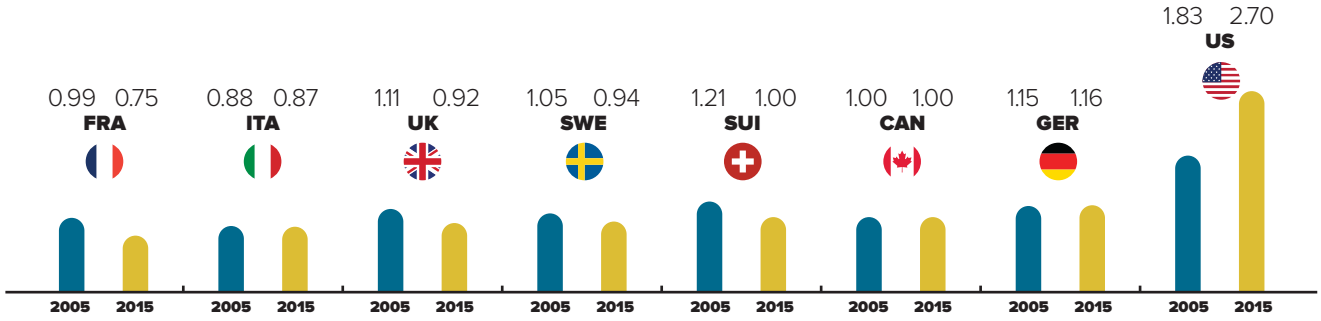
Average price ratios obtained with currency conversion at PPPs tell the same story. When international differences in cost of living are accounted for, it appears Canadians incurred a larger consumption cost for the patented drug products they purchased in 2015 than did residents of every other comparator country except Germany and the United States.

Figure 9 puts these results in historical perspective. In 2005, Canadian prices were, on average, approximately equal to or below corresponding prices in all comparators other than Italy. By 2015, Canadian prices were decidedly above prices in the United Kingdom, France Italy and Sweden, and on par with Switzerland.

If the patented medicine is being sold in one or more of the comparator countries (PMPRB7), the patentee must report the publicly available ex-factory prices to the PMPRB for each class of customer.[14] In order to assess how Canada compares to a basket of countries beyond the PMPRB7, Figure 10 uses Canadian and international prices reported in the IMS AG MIDAS™ database at the ex-factory manufacturer level, reflecting all sales to the pharmacy and hospital sectors.

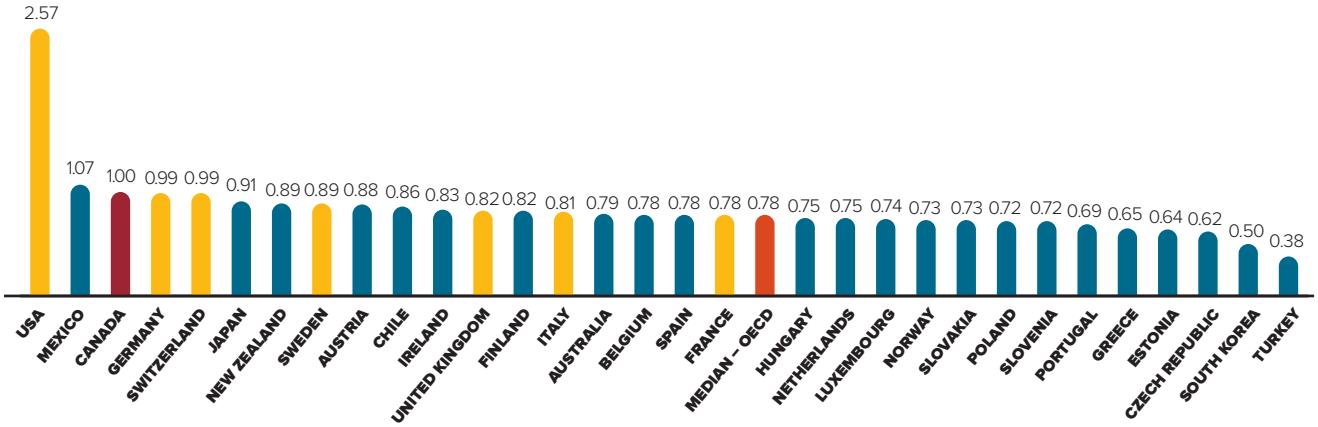
The international price comparisons reported in Figure 10 provide a bilateral price comparison using all countries in the Organisation for Economic Co-operation and Development (OECD) available in IMS AG's MIDAS™. The average foreign-to-Canadian price ratios are constructed using exactly the same approach employed to produce the ratios presented in Figure 9. These are Canadian sales-weighted arithmetic averages of the corresponding foreign-to-Canadian price ratios for individual drugs.[15] As shown below, median OECD prices are on average approximately 22% below prices in Canada, which are third highest among the 31 countries. Notably, the top three priced countries are now the US and the two countries with which it is most economically integrated (Mexico and Canada).

FIGURE 9. Average Foreign-to-Canadian Price Ratios: 2005, 2015



Source: PMPRB

FIGURE 10. Average Foreign-to-Canadian Price Ratios, Patented Drugs, OECD, 2015



Source: MIDAS™ database, 2005-2015, IMS AG. All rights reserved.

MULTILATERAL PRICE COMPARISONS

Table 12 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 seven comparator countries. 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 1.18 in 2015. (The corresponding value for 2014 was 1.13.) 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 drug product sold in Canada is available.

Figure 11 puts these results in historical perspective, giving a history of the average MIP-to-Canadian price ratios from 2001 to 2015. Although there has been considerable movement in the ratio over this period, it has remained above parity.

Figure 12 provides alternate results for the average MIP-to-Canadian price ratio at market exchange rates in 2015. To address the previously-raised point that Canadian prices are national average transaction prices whereas foreign prices are list prices, a list price to list price ratio is calculated. Using this method, the average ratio decreases from 1.18 to 1.08. It is important to keep in mind that non-transparent rebates provided to payers are currently not captured in these data.

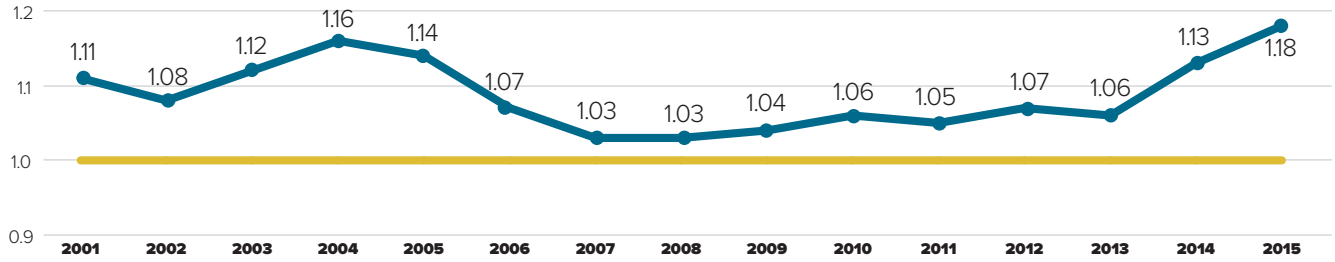
To account for the large impact of US prices in determining the median foreign price, a ratio excluding the US and a ratio including at least five countries in the calculation of the median are also provided in Figure 12. With these restrictions, the average MIP-to-Canadian price ratio drops to 0.88 and 0.90, respectively, suggesting that Canadian

TABLE 12. Average Foreign-to-Canadian Price Ratios, Multilateral Comparisons, 2015

	MEDIAN	MINIMUM	MAXIMUM	MEAN
Average price ratio at market exchange rates	1.18	0.92	2.68	1.38
Average price ratio at purchasing power parities	1.17	0.91	2.92	1.43
Number of patented drug products	1,274	1,274	1,274	1,274
Sales ($millions)	14,658.19	14,658.19	14,658.19	14,658.19

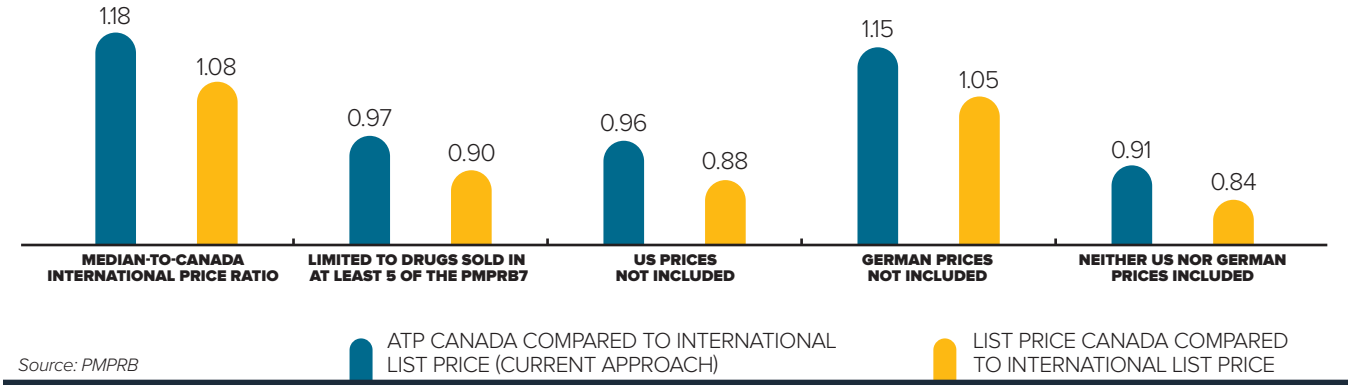
Source: PMPRB

FIGURE 11. Average Ratio of Median International Price (MIP) to Canadian Price, at Market Exchange Rates, 2001–2015



Source: PMPRB

FIGURE 12. Average Ratio of Median International Price (MIP) to Canadian Price, at Market Exchange Rates, 2015



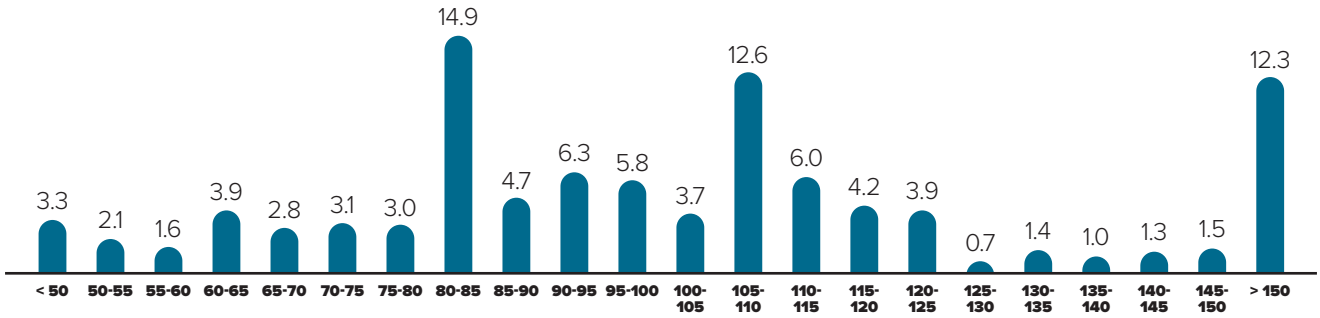
Source: PMPRB

list prices are on average 11%-13% higher than median foreign 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 (up to 60%) pay 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 23 in Appendix 3 of this report.

Figure 13 offers more detail on the product-level MIP-to-Canadian ratios underlying the averages reported in Table 12. This figure distributes the 2015 sales of each patented drug product according to the value of its MIP-to-Canadian price ratio (more exactly, according to the range into which the ratio fell).[16] These results show substantial dispersion in product-level price ratios: while patented drug products with MIP-to-Canadian price ratios between 0.90 and 1.10 accounted for 28.4% of sales, those with ratios less than 0.90 accounted for 39.4% of sales, and products with ratios exceeding 1.10 accounted for 32.2%.

In 2015, over 50% of Canadian patented drug products were priced above the median international level.[17] Table 13 shows which therapeutic categories in particular are priced above the median international levels in Canada. Drugs that share the fourth level ATC ("ATC4")[18] are grouped to identify distinct chemical/pharmacological/therapeutic subgroups, allowing for a calculation of the average MIP-to-Canadian price ratios among drugs that may be used to treat the same conditions. Table 13 identifies the top 10 ATC4s in 2015 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 drugs in 2015, sales in Canada would have been reduced by $850 million (an average reduction of 20% for these ATC4s). Of the 95 DINs classified into these 10 ATC4s, over 60% were priced above the median international price.

FIGURE 13. Range Distribution, Sales, by MIP-to-Canadian Price Ratio, 2015



Source: PMPRB

TABLE 13. Top-10 ATC4s by Total Revenues Greater than Median International Prices, 2015

DESCRIPTION	ATC4	TOTAL # OF CHEMICALS IN ATC4 (# CURRENTLY UNDER PATENT)[19]	# OF COMPANIES	TOTAL PATENTED DINS	PATENTED DINS GREATER THAN MEDIAN PRICE	2015 NET REVENUE FOR PATENTED DINS	PATENTED DINS ATC4 SHARE OF 2015 REVENUES	MIP-TO-CANADA RATIO (MIN 5) OF PATENTED DINS	$ IMPACT OF DIFFERENCE ON PATENTED DRUGS IN 2015
Adrenergics in combination with corti-costeroids or other drugs excluding anticholinergics	R03AK	5 (4)	3	11	7	$548,358,624	3.9%	65%	$173,674,570
Other antidepressants	N06AX	6 (3)	6	5	3	$314,255,201	2.2%	50%	$125,359,850
Tumor necrosis factor alpha inhibitors	L04AB	4 (3)	3	7	1	$957,621,400	6.8%	88%	$119,364,435
Antineovascularisation agents	S01LA	2 (2)	2	3	3	$590,343,927	4.2%	84%	$84,011,452
DPP-4 inhibitors	A10BH	4 (4)	4	9	9	$253,164,481	1.8%	73%	$66,625,261
Colony stimulating factors	L03AA	4 (2)	2	2	2	$190,125,072	1.4%	64%	$66,564,684
Monoclonal antibodies	L01XC	16 (11)	10	11	3	$693,886,828	4.9%	93%	$59,115,151
Glucocorticoids	R03BA	10 (5)	9	15	10	$186,643,090	1.3%	82%	$57,781,683
Proton pump inhibitors	A02BC	15 (6)	8	14	11	$310,660,124	2.2%	61%	$51,551,686
Combinations of oral blood glucose lowering drugs	A10BD	10 (5)	5	18	10	$191,094,966	1.4%	68%	$46,742,800

Source: PMPRB

End Notes

12 The number of drug products and sales these ratios encompass vary because it is not always possible to find a matching foreign price for each patented drug product sold in Canada. Note that all of the bilateral average price ratios reported in Table 11 combined represent at least 65% of 2015 Canadian sales, while the multilateral ratios in Table 12 cover over 97%.

13 There is a small discrepancy between the Canadian revenues reported in Table 11 and that reported in Table 7 ($15.04 billion vs $15.2 billion in Canadian patented medicine revenues). This is due to misfiled pricing data for a single drug, for which the revenues have been reported correctly, but the price incorrectly. As a result, this drug has been included in calculations in this document pertaining to revenues (such as Table 7), but excluded from those (such as Table 11) that involve prices.

14 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.

15 MS AG's MIDAS™ database is the source of sales data used in this analysis. MIDAS™ summarizes data obtained from IMS AG's detailed audits of pharmaceutical purchases. MIDAS™ contains information on sales of individual products, measured in both currency and physical units. It also includes information on product 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 product, IMS AG removes an estimate of wholesalers' mark-ups from the acquisition costs reported. It should be noted that the acquisition costs used by IMS AG 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.

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

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

18 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 13), "R" indicates that the drugs 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 adrengenics in combination with corticosteroids or other drugs 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/

19 For further detail, the chemicals included in Table 13 under PMPRB jurisdiction are: R03AK (budesonide/formoterol fumarate, fluticasone furoate/vilanterol, mometasone furoate/formoterol fumarate, salmeterol xinafoate/fluticasone propionate), N06AX (desvenlafaxine succinate, duloxetine hydrochloride, vortioxetine hydrobromide), L04AB (certolizumab pegol, golimumab, infliximab), S01LA (aflibercept, ranibizumab), A10BH (alogliptin benzoate, linagliptin, saxagliptin, sitagliptin phosphate), L03AA (filgrastim, pegfilgrastim), L01XC (bevacizumab, brentuximab vedotin, cetuximab, ipilimumab, obinutuzumab, panitumumab, pembrolizumab, pertuzumab, pertuzumab/trastuzumab, rituximab, trastuzumab). R03BA (budesonide, ciclesonide, fluticasone propionate aerosol, fluticasone propionate powder, mometasone furoate), A02BC (dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole magnesium, pantoprazole sodium) and A10BD (alogliptin benzoate/metformin, linagliptin/metformin, rosiglitazone maleate/metformin, saxagliptin/metformin, sitagliptin phosphate/metformin).

CANADA IS A TOP 10 GLOBAL MARKET

Canada is an important market for pharmaceuticals representing 2% of worldwide sales. Canada is consistently in the top 10 global markets for pharmaceuticals. Despite this, R&D-to-sales ratios are on average 5 times higher in PMPRB comparator countries than Canada, whereas prices are lower in the majority of these countries.

UTILIZATION OF PATENTED DRUG PRODUCTS

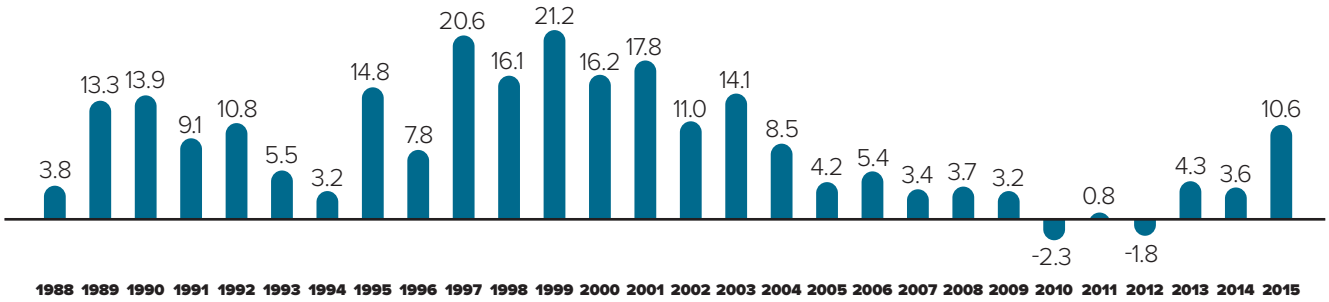
The price and sales data used to calculate the PMPI also allow the PMPRB to examine trends in the quantities of patented drug products sold in Canada. The PMPRB maintains the Patented Medicines Quantity Index (PMQI) for this purpose. Figure 14 provides average rates of utilization growth, as measured by the PMQI, from 1988 through 2015. These results confirm that in recent years, growth in the utilization of patented drug products has been the primary source of rising sales, with rates of utilization growth roughly tracking sales growth. This tracking pattern continued in 2015, with the utilization of patented drug products, on average, increasing by 10.6% between 2014 and 2015 and sales increasing by 9.5%.

UTILIZATION GROWTH BY THERAPEUTIC CLASS

Table 14 provides average rates of utilization growth among patented drug products at the level of major therapeutic classes. The results in this table were obtained by applying the PMQI methodology to data segregated by ATC Level I class. As in Table 10, the last column provides an approximate decomposition of overall PMQI change into contributions attributable to each therapeutic class.

In 2015, levels of utilization increased in eight therapeutic classes. Increased consumption of antineoplastics and immunomodulating agents, general antiinfectives and antiparasitics, and alimentary tract and metabolism products accounted for most of the growth in overall utilization.

FIGURE 14. Annual Rate of Change (%), Patented Medicines Quantity Index (PMQI), 1988–2015



Source: PMPRB

IN 2013, CANADIANS SPENT 1.8% OF GROSS DOMESTIC PRODUCT ON DRUGS.

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

DRUG EXPENDITURES IN CANADA

1.8%

OF GDP

TABLE 14. Change in the Patented Medicines Quantity Index (PMQI), by Major Therapeutic Class, 2015

THERAPEUTIC CLASS	SHARE: 2015 SALES (%)	QUANTITY CHANGE: 2014 TO 2015 (%)	CONTRIBUTION: CHANGE IN PMQI (%)
A: Alimentary tract and metabolism	10.6	11.22	1.19
B: Blood and blood forming organs	5.1	5.13	0.26
C: Cardiovascular system	5.3	-11.99	-0.64
D: Dermatologicals	0.7	-1.17	-0.01
G: Genito-urinary system and sex hormones	3.5	0.18	0.01
H: Systemic hormonal preparations	0.4	8.12	0.03
J: General Antiinfectives for systemic use	15.8	50.57	7.99
L: Antineoplastics and immunomodulating agents	31.2	13.16	4.11
M: Musculo-skeletal system	2.4	-20.29	-0.49
N: Nervous system	10.7	-4.47	-0.48
R: Respiratory system	8.2	6.26	0.51
S: Sensory organs	5.2	10.32	0.54
V: Various	1.0	8.53	0.09
All therapeutic classes	100.0[†]	10.6	10.6

[†] *Values in this column may not add to 100.0 due to rounding.*

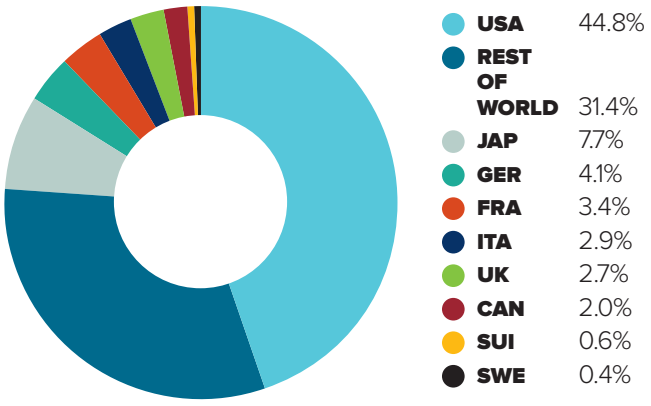
Source: PMPRB

CANADIAN DRUG EXPENDITURES IN THE GLOBAL CONTEXT

IMS Health[20] regularly reports on drug sales across a large number of countries. Based on sales data from this source, Figure 15 provides shares of global sales for Canada and each of the seven comparator countries that the PMPRB considers in conducting its price reviews (PMPRB7).[21] The Canadian market accounted for 2.0% of the global market in 2015.

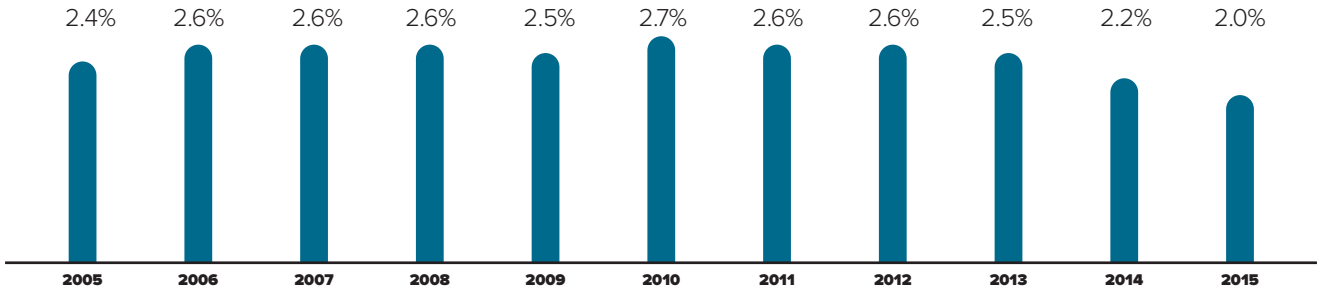
Figure 16 provides Canada's share of global sales for 2005 to 2015. The Canadian share has remained between 2.0% and 2.7% throughout this period. Though 2.0% is at the low end for Canada's average share of global sales in recent years, and marks the fifth year in a row that Canada's share has fallen, this trend is driven by rapid price increases in the United States, which grew the US share from 40.4% in 2014 to 44.8% in 2015, resulting in declining shares for all other major countries.

FIGURE 15. Distribution of Drug Sales Among Major National Markets, 2015



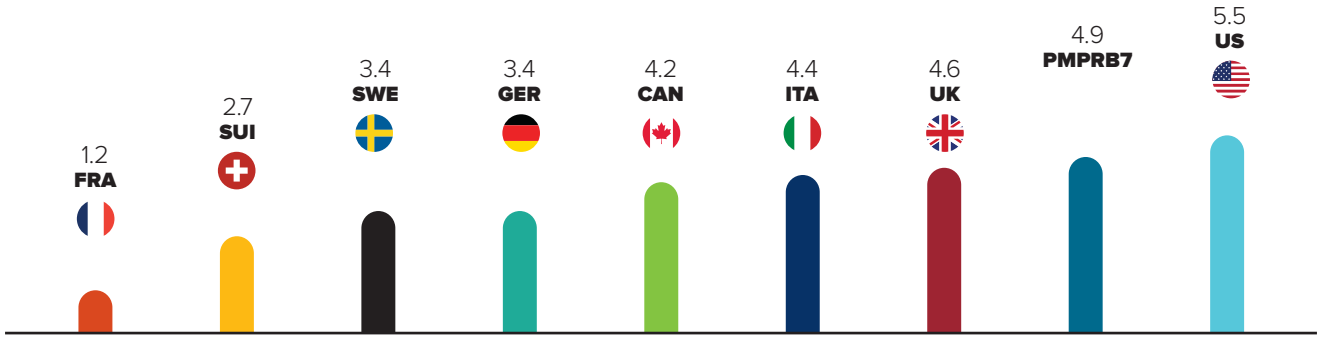
Source: MIDAS™ database, 2005–2015, IMS AG. All rights reserved.[22]

FIGURE 16. Canada's Share of Drug Sales, 2005–2015



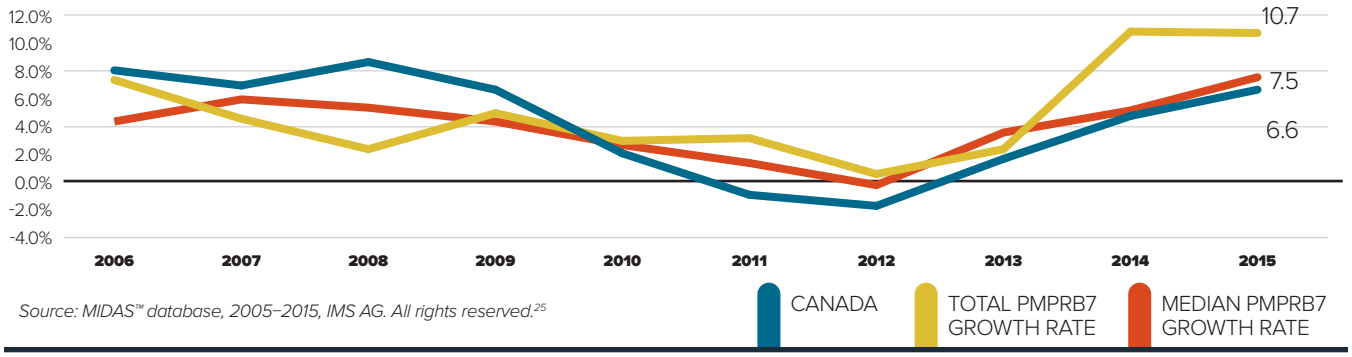
Source: MIDAS™ database, 2005–2015, IMS AG. All rights reserved.[23]

FIGURE 17. Average Rate of Growth (%), Drug Sales, at Constant 2015 Market Exchange Rates, by Country, 2005–2015



Source: MIDAS™ database, 2005–2015, IMS AG. All rights reserved.[24]

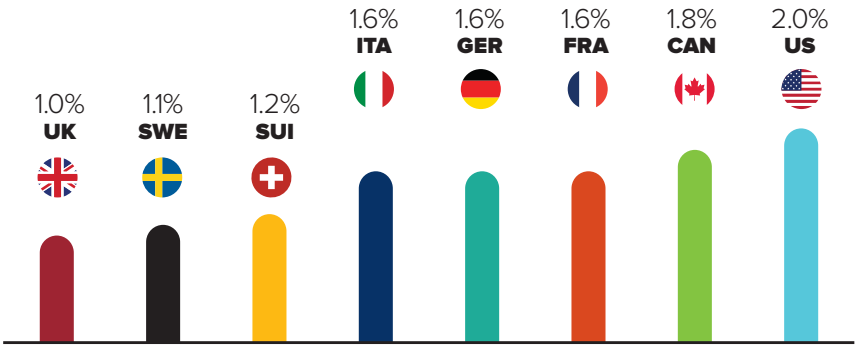
FIGURE 18. Average Annual Rate of Change in Drug Sales, at Constant 2015 Market Exchange Rates, Canada and Comparator Countries, 2006–2015



Source: MIDAS™ database, 2005–2015, IMS AG. All rights reserved.[25]

Figure 17 gives the average annual rate of growth in total drug sales for Canada and the seven comparator countries, individually and collectively (PMPRB7). From 2005 to 2015, drug sales in Canada rose at an average annual rate of approximately 4.2%. This is less than the average rate of growth in drug 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 revenues of the PMPRB7.

FIGURE 19. Drug Expenditures as a Share of GDP, 2013



Source: OECD

Figure 18 compares rates of year-over-year growth in drug sales in Canada and the comparator countries combined (PMPRB7). In 2015, for the sixth consecutive year, sales grew at a slower rate in Canada than the PMPRB7 total. As identified in the discussion of Figures 11 and 12, however, the presence of the US skews these results. Accordingly, the median of the PMPRB7 expenditure growth rate has been added to this figure, showing that Canadian expenditure growth rate has tracked the PMPRB7 expenditure growth rate quite closely since 2010.

The proportion of national income allocated to the purchase of drug products provides another way to compare drug costs across countries.[26] Figure 19 gives drug expenditures as a share of Gross Domestic Product (GDP) for Canada and the seven comparator countries based on data for 2013. Drug expenditures absorbed between 1.0% and 2.0% of the GDP in the seven comparators. The Canadian value (1.8%) lies near the upper end of this range.

Table 15 provides a historical perspective on the expenditures-to-GDP ratio. In 2005, Canada's ratio was fourth highest of the PMPRB7. Since that time, Canada's ratio has risen, while the ratios of four other countries (France, Germany, Italy and Sweden) have declined. Furthermore, Canada has the second highest drug spending per capita among the PMPRB7 (behind only the United States), 22% higher than the median of these countries.

Table 16 gives the composition of patentees' sales by therapeutic class for Canada and the seven comparator countries, individually and as an aggregate (PMPRB7).[27] The results imply a remarkable degree of similarity across countries.

TABLE 15. Drug Expenditures as a Share of GDP, 2013[28]

	SHARE: DRUG EXPENDITURES/ GDP 2013 (%)	SHARE: DRUG EXPENDITURES/ GDP 2005 (%)	GROWTH: GDP 2005–2013 (%)	DRUG SPENDING PER CAPITA ($US PPP)
Canada	1.78	1.64	33.3	761
France	1.65	1.79	34.6	622
Germany	1.55	1.58	36.7	678
Italy	1.63	1.70	25.1	572
Sweden	1.11	1.15	39.6	496
Switzerland	1.22	1.09	64.9	696
United Kingdom	1.04	1.00	19.9	367
United States	1.95	1.88	27.3	1,034

Source: OECD

TABLE 16. Distribution of Drug Sales (%) by Major Therapeutic Class for Canada and Comparator Countries, 2015

THERAPEUTIC CLASS	CANADA	PMPRB7	FRANCE	ITALY	GERMANY	SWEDEN	SWITZERLAND	UNITED KINGDOM	UNITED STATES
A: Alimentary tract and metabolism	12.6	13.6	10.0	10.4	11.1	9.4	10.8	10.8	14.6
B: Blood and blood forming organs	4.3	4.9	7.5	8.1	6.9	8.0	5.5	5.0	4.3
C: Cardiovascular system	9.8	7.5	9.4	10.6	7.2	4.7	9.7	6.8	7.2
D: Dermatologicals	3.2	3.0	2.4	2.0	2.7	2.6	3.5	3.0	3.2
G: Genito-urinary system and sex hormones	4.8	4.4	3.0	3.5	3.2	4.0	4.3	3.7	4.8
H: Systemic hormonal preparations	1.2	2.3	2.2	1.8	2.0	2.3	1.6	3.1	2.3
J: General Antiinfectives for systemic use	10.3	13.6	13.8	19.4	12.3	12.9	12.5	11.0	13.5
L: Antineoplastics and immunomodulating agents	18.7	19.2	20.3	17.3	22.7	23.1	21.2	20.1	18.8
M: Musculo-skeletal system	3.1	3.1	3.0	3.3	3.8	3.4	5.2	2.5	3.0
N: Nervous system	16.9	15.2	13.5	10.5	12.9	16.6	14.4	17.3	15.7
P: Antiparasitic products	0.2	0.2	0.2	0.0	0.1	0.2	0.1	0.2	0.3
R: Respiratory system	7.2	6.8	5.9	5.3	6.7	7.0	6.0	8.6	6.9
S: Sensory organs	4.1	2.6	3.3	2.1	2.9	3.0	4.0	4.3	2.4
V: Various	3.7	3.4	5.3	5.7	5.4	2.9	1.4	3.8	2.9
All therapeutic classes[†]	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

[†] Values in this row may not add to 100.0 due to rounding.

Source: MIDAS™ database, 2005–2015, IMS AG. All rights reserved.[29]

End Notes

20 Most of the statistical results presented in this section are based on sales data from MIDAS™ database, 2005–2015, IMS AG. All rights reserved. These data cover the pharmacy and hospital sectors.

21 The results given in Figures 15 through 19 are based on estimates of ex-factory sales revenues encompassing patented, non-patented branded and generic drug products. These estimates have been converted to Canadian dollar equivalents at annual average market exchange rates. Fluctuations in these rates can substantially influence these shares.

22 Although based in part on data obtained under license from the IMS AG MIDAS™ database, the statements, findings, conclusions, views and opinions expressed in this Annual Report are exclusively those of the PMPRB and are not attributable to IMS AG.

23 Ibid.

24 Ibid.

25 Ibid.

26 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.

27 Note that the data used to produce Table 16 encompass patented, non-patented branded and generic drug products. Hence, the results reported here for Canada are not directly comparable to those reported in Table 9, which encompass only patented drug products.

28 In order to make use of the best and most up-to-date available drug expenditure data from the OECD, the GDP in Table 15 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 15 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 11.

29 Although based in part on data obtained under license from the IMS AG MIDAS™ database, the statements, findings, conclusions, views and opinions expressed in this Annual Report are exclusively those of the PMPRB and are not attributable to IMS AG.

THE 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 drugs. The PMPRB contributes to Canada's understanding of drug 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

The National Prescription Drug Utilization Information System (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).

Its purpose is to provide policy makers and public drug plan managers with critical analyses of price, utilization and cost trends, so that Canada's health care system has more comprehensive and accurate information on how prescription drugs are being used and on sources of cost increases.

The NPDUIS Advisory Committee, composed of representatives from public drug plans in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, and Health Canada, advises the PMPRB on its research agenda and on individual studies. The Committee also includes observers from CIHI and the Canadian Agency for Drugs and Technologies in Health (CADTH).

HIGHLIGHTS

Since the last Annual Report, through the NPDUIS initiative, the PMPRB has released four analytical reports and seven posters.

- *New Drug Pipeline Monitor, 7th Edition*
- *Private Drug Plans in Canada – Part 1: Generic Market 2005–2013*
- *Generics360 – Generic Drugs in Canada, 2014*
- *CompassRx: Annual Public Drug Plan Expenditure Report, 2nd Edition*

POSTER PRESENTATIONS:

- *Cost Pressures in the Canadian Hospital Drug Market, 2006–2014*
- *The Use of Diabetes Drugs in Canadian Public Drug Plans*
- *Private Drug Plans in Canada: Cost Drivers, 2008 to 2015*
- *Private Drug Plans in Canada: High-Cost Drugs and Beneficiaries, 2005 to 2015*
- *New Drug Launch Monitor, 2009–2015*
- *Orphan Drug Launch Monitor, 2005–2014*
- *Cost Pressure of the New Hepatitis C Drugs in Canada*

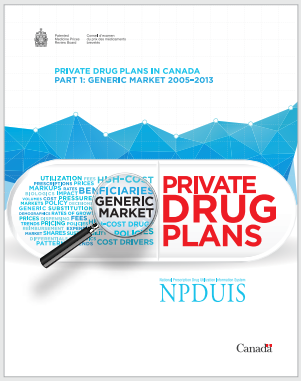
In addition, the PMPRB conducted a number of ad-hoc studies at the request of the NPDUIS participating jurisdictions in support of their policy decision making.

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, hosting information exchange sessions with researchers, and organizing information sessions with interested stakeholders to share the results of the analytical studies.

Synopses of the three most recent reports are provided in this report.

THE PMPRB WORKS COLLABORATIVELY WITH THE PROVINCES AND TERRITORIES.

PMPRB reporting has been relied upon by provinces and territories as part of the pan-Canadian Pharmaceutical Alliance's efforts to reduce brand-name and generic drug prices.

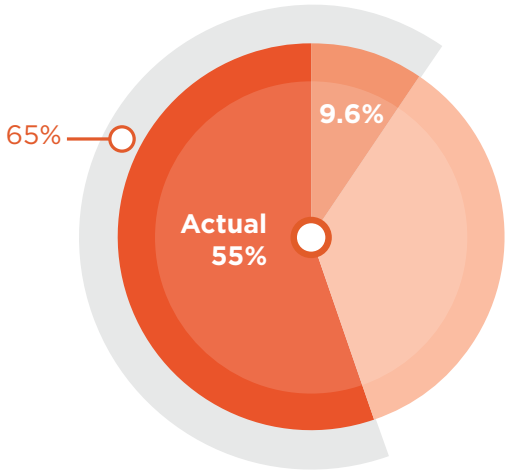


PRIVATE DRUG PLANS IN CANADA—PART 1: GENERIC MARKET 2005–2013

Private Drug Plans in Canada–Part 1: Generic Market 2005–2013 is the first of three reports in a PMPRB series that analyzes trends in Canadian private drug plans. The other two upcoming reports will focus on cost drivers and high-cost drugs. This series provides policy makers and researchers with insights into sources of cost pressures and possible areas for cost-saving opportunities.

This report analyzes the evolving generic market shares and reimbursed unit costs in private drug plans, as well as dispensing patterns and their impact on overall prescription costs. A comparative analysis with Canadian public drug plans and select international markets is also included in the study.

GENERIC SHARE OF PRESCRIPTIONS IN PRIVATE PLANS, 2013



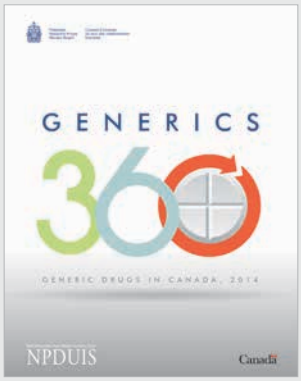
BRAND-NAME ORAL SOLID DRUGS THAT COULD HAVE BEEN REIMBURSED AT THE GENERIC PRICE LEVEL

Note: Estimated results are restricted to oral solid drugs with both brand and generic availability and with over 1,000 annual prescriptions.

Data source: IMS Brogan Private Pay Direct Drug Plan Database.

KEY FINDINGS

- Generic drugs accounted for 70% of all prescription drugs in Canada in 2013. Canada had the third-highest proportion of annual prescription generic drug use relative to the PMPRB7.
- The proportion of prescriptions for generic drugs reimbursed by Canadian private drug plans increased from 37% in 2005 to 55% in 2013, but continued to be lower than in public plans, at 71%. This was primarily due to differences in the demographic and disease profiles of the beneficiary populations.
- In 2013, if the private plans had limited the reimbursement of brand-name drugs in oral solid form to the generic price level, up to 9.6% of prescriptions would have been impacted. This would have increased the share of prescriptions reimbursed at the generic price level to 65%, resulting in an estimated reduction of up to 5.7% in retail drug costs.
- Private drug plans in Canada reimbursed a 5 to 12% lower cost per prescription for generic drugs compared to public plans in 2013 due to less frequent dispensing and a lower number of dispensing fees charged.
- Generic pricing policies introduced by most provincial governments markedly reduced the prices of generic drugs reimbursed by private plans from an average of 63% of the brand-reference price in 2010 to 42% in 2013, resulting in cost savings ranging from 8 to 13% of overall retail drug cost in 2013.
- Dispensing frequency was a key factor driving prescription costs for generic drugs in Quebec private drug plans to levels 64% higher than those in Ontario. On average, 35 units of oral solid medication were dispensed per prescription in Quebec private plans, which was much less than the Ontario average of 64 units.

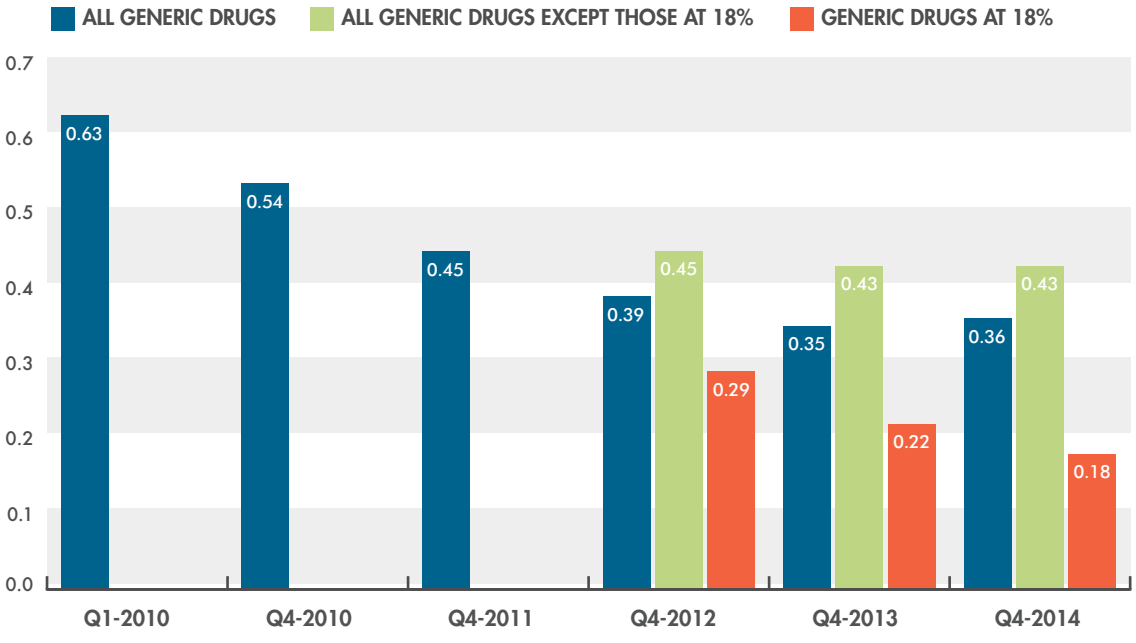


GENERICS360 – GENERIC DRUGS IN CANADA, 2014

Generics360 is an annual PMPRB report series that monitors and reports on the latest developments in generic drug pricing and markets in Canada and compares them with those of other industrialized countries. This report updates previous PMPRB research, highlighting the recent trends in Canadian generic pricing at a national level, which combines all market segments: public, private and out-of-pocket. The price of generic drugs in Canada is a critical issue for drug plan managers, policy makers and consumers.

Provincial generic pricing policies, including those initiated by the pan-Canadian Pharmaceutical Alliance, achieved significant price reductions in Canada. While theses declines exceeded the generic price reductions in foreign markets in recent years, prices of generic drugs remain appreciably higher in Canada than internationally.

AVERAGE GENERIC-TO-BRAND PRICE RATIOS, CANADA, Q1-2010 TO Q4-2014

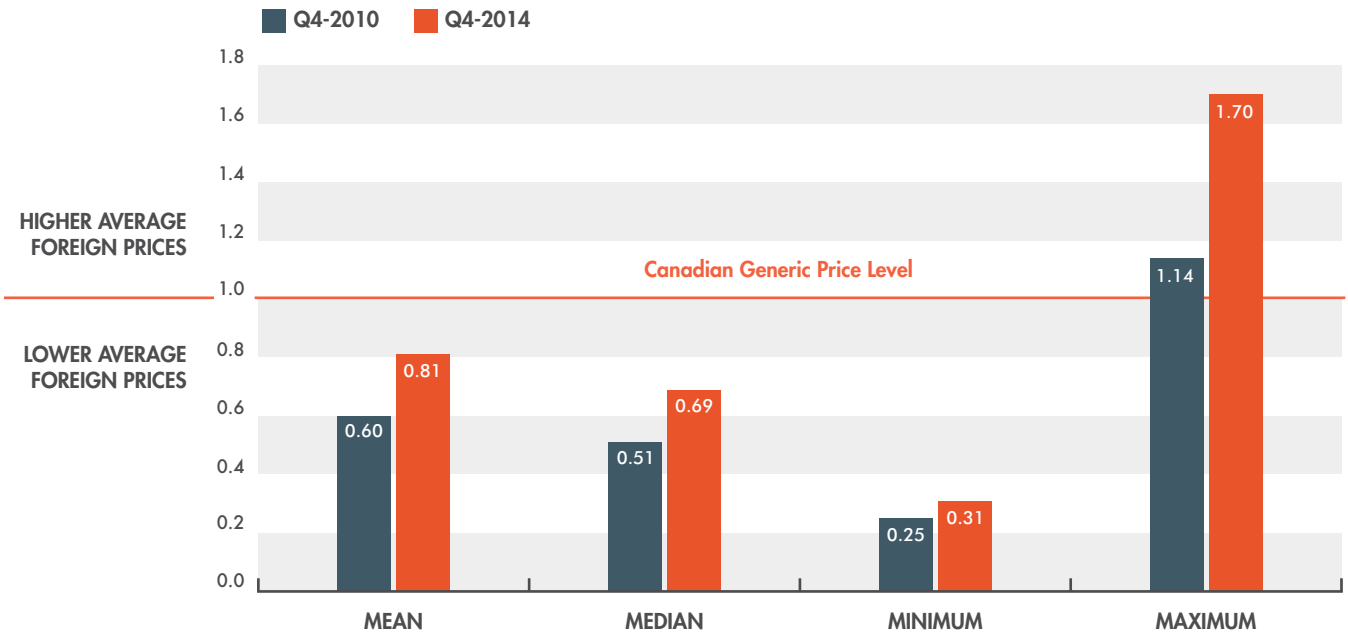


MIDAS™ database, January–March 2010 to October–December 2014, IMS AG. All rights reserved.

KEY FINDINGS

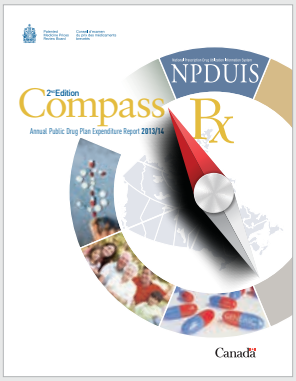
- Average generic drug prices in Canada declined from 63% to 36% of their brand-name counterparts between 2010 and 2014.
- The gap between generic drug prices in Canadian and foreign markets gradually decreased from 40% in 2010 to 19% in 2014. Most of this reduction was realized by the end of 2013.
- While the weakening Canadian dollar also contributed to reducing the gap between international generic-drug prices and those in Canada, the magnitude of this change was offset by corresponding price reductions in foreign markets.
- Generic price differences were more pronounced for drugs with estimated annual Canadian sales of more than $10 million and for drugs with six or more suppliers, with foreign mean international prices 25% and 21% lower than in Canada, respectively. These markets accounted for a large proportion of generic sales.

AVERAGE MULTILATERAL FOREIGN-TO-CANADIAN GENERIC PRICE RATIOS
GENERIC DRUGS, PMPRB7*, Q4-2010 TO Q4-2014



*France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States

Source: MIDAS™ database, October–December 2010 to October–December 2014, IMS AG. All rights reserved.

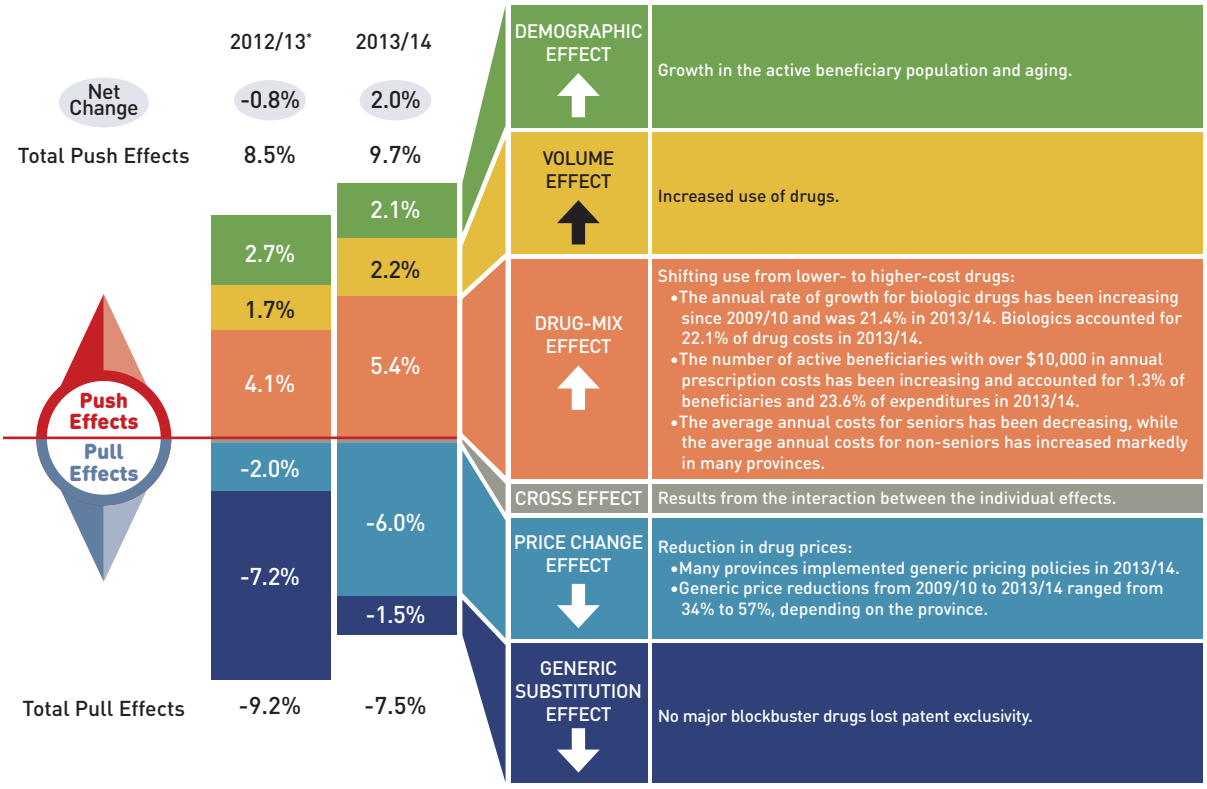


CompassRx, 2ND EDITION, ANNUAL PUBLIC DRUG PLAN EXPENDITURE REPORT, 2013/14

CompassRx is a flagship PMPRB annual report and the first of its kind to identify and unpack the major factors driving prescription drug expenditures in public drug plans in Canada. It supports policy makers and researchers in better understanding the current trends and anticipating future cost pressures and expenditure levels.

The 2013/14 *CompassRx* is the second edition of this report and identifies developing trends in demographics, pricing and the use of drugs based on the baseline established in the 2012/13 publication. It also monitors major developments in drug approval, review, pricing and reimbursement in Canada. Two new jurisdictions have been added to this edition, providing a more comprehensive view of the public plan environment.

DRUG COST DRIVERS 2012/13 VERSUS 2013/14



Note: Values may not add to totals due to rounding and the cross effect.

Data source: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information which includes the following public drug plans: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and the Non-Insured Health Benefits drug plan.

Results for 2012/13 do not capture the data for the British Columbia and Newfoundland and Labrador provincial public drug plans.

KEY FINDINGS

- In 2013/14, prescription drug expenditures in the public drug plans analyzed totaled $9.8 billion. This was composed of drug costs (74.2%), pharmacy dispensing costs (22.3%), and markups (3.5%).
- Public drug plans paid 78.7% of the overall prescription drug expenditures, with the remaining share being paid by the beneficiaries, either out-of-pocket or through a third-party private insurer.
- While the average rate of change in the cost of drugs for all NPDUIS public plans steadily declined from 2010/11 to 2012/13, reaching a low of -1.5%, this trend reversed in 2013/14, with the average drug costs increasing by 2.0%.
- The low net rate of change was driven by opposing "push" (increasing) effects and "pull" (decreasing) effects.
  - The demographic, volume and drug-mix effects had an important push effect, and in the absence of generic savings, they would have increased drug cost levels by 9.7% in 2013/14.
  - The generic price change and substitution effects had an important pull effect, and in the absence of other cost pressures, they would have decreased drug cost levels by 7.5% in 2013/14.

RESEARCH AGENDA

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

- *NPDUIS CompassRx, 3rd Edition*
- *New Drug Pipeline Monitor, 8th Edition*
- *Meds Entry Watch, 1st Edition*
- *Private Drug Plans in Canada – Part 2: Cost Driver Analysis, 2015*
- *Private Drug Plans in Canada: Part 3: High-Cost Drugs and Beneficiaries, 2015*
- *Utilization and Cost of Biologics, 2005/06 to 2012/13*
- *Potential Savings from Subsequent Entry Biologics: A Canadian Budget Impact Analysis*
- *The Canadian Drug Reimbursement Landscape: A Review of Public and Private Markets*

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

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

Innovation is vital to advancing health care. In part, the provisions of Canada's *Patent Act* are intended to foster an investment climate favorable to pharmaceutical research and development (R&D) in Canada. However, the 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 2015, it was at 4.4% for all patentees and 4.9% for members of Innovative Medicines Canada (formerly Canada's Research-Based Pharmaceutical Companies).

ANALYSIS OF RESEARCH AND DEVELOPMENT EXPENDITURES

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

DATA SOURCES

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

The Act requires each patentee to report its total gross revenues from sales of all drugs for human or veterinary use (including revenues from sales of non-patented drug products 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 R&D EXPENDITURES (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. There were no such Board Orders issued for the 2015 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 drug products but may still perform considerable research in Canada. Similarly, a company may conduct research and have no product sales at all.[30] The results presented below will not reflect the R&D expenditures of firms in either situation.

Second, as new patented drug products come onto the Canadian market and existing patents expire, the number and identity of companies required to file R&D data may change from year to year. A total of 77 companies reported on their R&D activity in 2015. Of these, 33 were members of Innovative Medicines Canada (formerly Rx&D - Canada's Research-Based Pharmaceutical Companies).

DEFINITION OF SALES REVENUES

For reporting purposes, sales revenues are defined as total gross revenues from sales in Canada of all drug products 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.[31] 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.

THE R&D-TO-SALES RATIO FOR ALL PATENTEES WAS 4.4% IN 2015

This represents a 62% decrease from a peak of 11.7% in 1995.

4.4%

R&D-TO-SALES RATIO

TOTAL SALES REVENUES AND R&D EXPENDITURES

Table 17 provides an overview of reported sales revenues and R&D expenditures over the period 1988 through 2015.

Patentees reported total 2015 sales revenues of $19.7 billion, an increase of 6.7% from 2014. Sales revenues reported by Innovative Medicines Canada members were $15.6 billion, accounting for 79.1% of the total. (Less than 1% of reported sales revenues were generated by licensing agreements.)

Patentees reported R&D expenditures of $869.1 million in 2015, an increase of 9.7% over 2014. Innovative Medicines Canada members reported R&D expenditures of $767.4 million in 2015, an increase of 7.8% over last year. Innovative Medicines Canada members accounted for 88.3% of all reported R&D expenditures in 2015.

R&D-TO-SALES RATIO

Table 17 and Figure 20 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.[32] 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 4.4% in 2015, a slight increase from 4.3% in 2014. The overall R&D-to-sales ratio has been less than 10% for the past 15 consecutive years.

The corresponding R&D-to-sales ratio for members of Innovative Medicines Canada was 4.9% in 2015, a slight increase from 4.8% in 2014.[33] The Innovative Medicines Canada ratio has been less than 10% for the past 13 consecutive years.

Table 22 in Appendix 3 provides details on the range of 2015 R&D-to-sales ratios. Of the 77 companies reporting in 2015, 90.9% had R&D-to-sales ratios below 10%.

TABLE 17. Total R&D Expenditures and R&D-to-Sales Ratios of Reporting Companies, 1988–2015

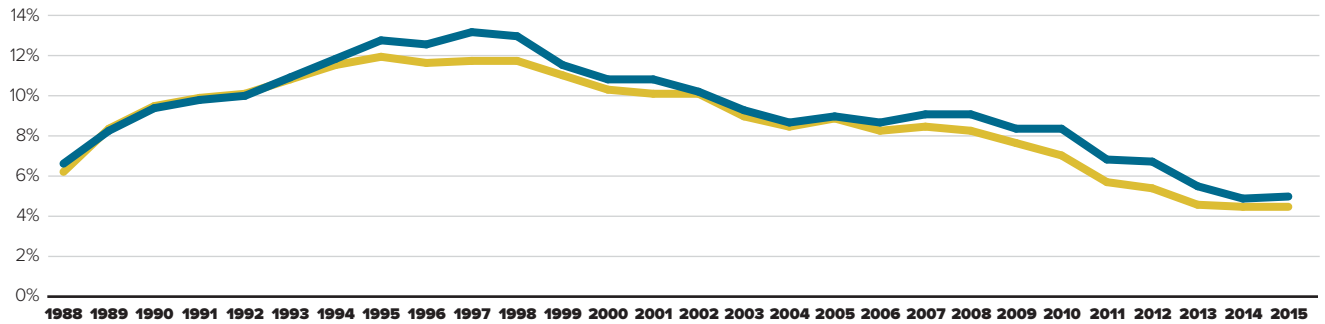
YEAR	ALL PATENTEES					INNOVATIVE MEDICINES CANADA				R&D-TO-SALES RATIO: ALL PATENTEES (%)	R&D-TO-SALES RATIO: INNOVATIVE MEDICINES CANADA PATENTEES (%)
	NUMBER OF COMPANIES REPORTING	R&D EXPENDITURES BY ALL PATENTEES ($MILLIONS)	CHANGE FROM PREVIOUS YEAR (%)	SALES REVENUES ($MILLIONS)	CHANGE FROM PREVIOUS 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 (%)		
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

continued

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 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 (%)		
2002	79	1,198.7	13.0	12,081.2	12.5	1,029.6	10.1	10,323.8	16.8	9.9	10.0
2001	74	1,060.1	12.6	10,732.1	15.3	935.2	14.7	8,835.4	14.3	9.9	10.6
2000	79	941.8	5.3	9,309.6	12.0	815.5	4.0	7,728.8	11.6	10.1	10.6
1999	78	894.6	12.0	8,315.5	19.2	784.3	9.9	6,923.4	22.8	10.8	11.3
1998	74	798.9	10.2	6,975.2	10.9	713.7	8.6	5,640.2	10.6	11.5	12.7
1997	75	725.1	9.0	6,288.4	7.4	657.4	10.3	5,098.2	4.9	11.5	12.9
1996	72	665.3	6.4	5,857.4	9.9	595.8	6.5	4,859.5	8.7	11.4	12.3
1995	71	625.5	11.5	5,330.2	7.5	559.5	9.8	4,468.8	1.4	11.7	12.5
1994	73	561.1	11.4	4,957.4	4.4	509.5	10.4	4,407.2	2.0	11.3	11.6
1993	70	503.5	22.1	4,747.6	14.0	461.4	24.0	4,321.4	14.4	10.6	10.7
1992	71	412.4	9.6	4,164.4	6.9	372.1	9.0	3,778.4	6.5	9.9	9.8
1991	65	376.4	23.2	3,894.8	18.1	341.4	24.7	3,546.9	19.5	9.7	9.6
1990	65	305.5	24.8	3,298.8	11.0	273.8	25.8	2,967.9	10.5	9.3	9.2
1989	66	244.8	47.4	2,973.0	9.4	217.6	34.7	2,685.5	7.3	8.2	8.1
1988	66	165.7	—	2,718.0	—	161.5	—	2,502.3	—	6.1	6.5

Source: PMPRB

FIGURE 20. R&D-to-Sales Ratio, Pharmaceutical Patentees, 1988–2015



Source: PMPRB

CURRENT EXPENDITURES BY TYPE OF RESEARCH

Table 18 and Figure 21 (as well as Figure 23 in Appendix 3) provide information on the allocation of 2015 current R&D expenditures[34] among basic and applied research and other qualifying R&D.[35] Patentees reported spending $102.2 million on basic research in 2015, representing 12.9% of current R&D expenditures and an increase of 24.9% over the previous year. Patentees reported spending $456.2 million on applied research, representing 57.7% of current R&D expenditures. Clinical trials accounted for 72.6% of applied research expenditures.

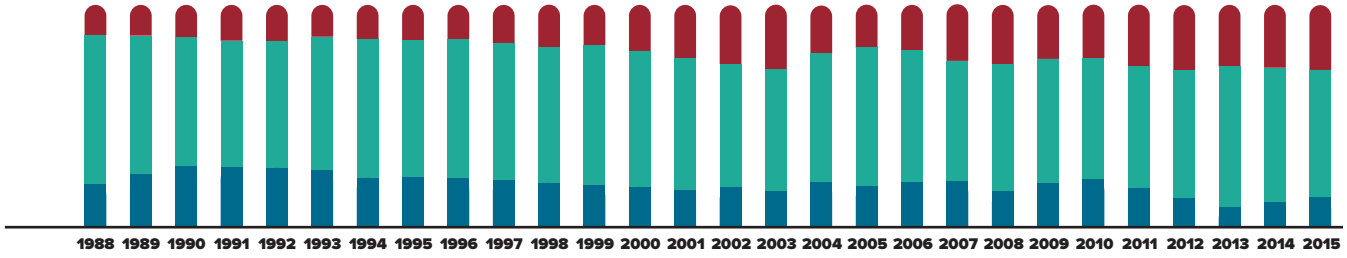
TABLE 18. Current R&D Expenditures by Type of Research, 2015 and 2014

TYPE OF RESEARCH	EXPENDITURES: 2015 ($MILLIONS)	SHARE: 2015 (%)	EXPENDITURES: 2014 ($MILLIONS)	SHARE: 2014 (%)	ANNUAL CHANGE IN EXPENDITURES (%)
Basic	**102.2**	**12.9**	**81.8**	**10.7**	**24.9**
Chemical	66.4	8.4	52.6	6.9	26.2
Biological	35.8	4.5	29.2	3.8	22.6
Applied	**456.2**	**57.7**	**467.4**	**60.9**	**-2.4**
Manufacturing process	58.0	7.3	51.4	6.7	12.8
Pre-clinical Trial I	40.4	5.1	48.9	6.4	-17.4
Pre-clinical Trial II	26.7	3.4	38.0	5.0	-29.7
Clinical Trial Phase I	25.1	3.2	25.4	3.3	-1.2
Clinical Trial Phase II	67.1	8.5	63.4	8.3	5.8
Clinical Trial Phase III	238.9	30.2	240.3	31.3	-0.6
Other qualifying R&D	**231.7**	**29.3**	**217.8**	**28.4**	**6.4**
Total†	**790.1**	**100.0**	**767.1**	**100.0**	**3.0**

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

Source: PMPRB

FIGURE 21. Current R&D Expenditures by Type of Research, 1988–2015



	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
OTHER QUALIFYING	13.7	13.9	14.8	16.2	16.5	14.4	15.4	16.1	15.4	17.3	19.4	18.3	20.9	24.0	26.6	29.1	21.7	19.5	20.5	25.6	26.8	24.3	24.2	27.8	29.4	27.8	28.4	29.3
APPLIED	67.2	62.7	58.0	57.3	57.1	60.3	62.7	61.8	62.9	62.0	61.1	63.3	61.3	59.9	55.8	55.2	58.3	62.4	59.5	54.4	57.3	56.2	54.8	55.0	57.9	63.5	60.9	57.7
BASIC	19.1	23.4	27.2	26.5	26.4	25.3	21.9	22.1	21.7	20.7	19.6	18.4	17.8	16.1	17.4	15.8	19.7	18.2	20.0	20.3	15.9	19.4	21.1	17.3	12.6	8.7	10.7	12.9

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 19 shows that 49.4% of 2015 current research expenditures were intramural. Research performed by other companies on behalf of patentees was 21.6% of current expenditures, while research conducted in universities and hospitals accounted for 17.0%.

CURRENT R&D EXPENDITURES BY SOURCE OF FUNDS

Table 20 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 2015, accounting for 91.1% of current expenditures. Funds received from government amounted to 1.0% of current expenditures.

TABLE 19. Current R&D Expenditures by R&D Performer, 2015 and 2014

R&D PERFORMER	EXPENDITURES: 2015 ($MILLIONS)	SHARE: 2015 (%)	EXPENDITURES: 2014 ($MILLIONS)	SHARE: 2014 (%)	ANNUAL CHANGE IN EXPENDITURES (%)
INTRAMURAL					
Patentees	390.0	49.4	371.8	48.5	4.9
EXTRAMURAL					
Universities and hospitals	**134.6**	**17.0**	**117.6**	**15.3**	**14.5**
Other companies	170.3	21.6	190.6	24.9	-10.7
Others	95.2	12.1	87.1	11.3	9.4
Total†	**790.1**	**100.0**	**767.1**	**100.0**	**3.0**

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

Source: PMPRB

TABLE 20. Total R&D Expenditures by Source of Funds, 2015 and 2014

SOURCE OF FUNDS	EXPENDITURES: 2015 ($MILLIONS)	SHARE: 2015 (%)	EXPENDITURES: 2014 ($MILLIONS)	SHARE: 2014 (%)	ANNUAL CHANGE IN EXPENDITURES (%)
Company funds	791.7	91.1	703.0	88.7	12.6
Federal/provincial governments	8.3	1.0	9.8	1.2	-14.6
Others	69.1	8.0	79.5	10.0	-13.1
Total†	**869.1**	**100.0**	**792.2**	**100.0**	**9.7**

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

Source: PMPRB

CURRENT R&D EXPENDITURES BY REGION

Table 21 (as well as Table 24 and Table 25 in Appendix 3) show current R&D expenditures by region. As in previous years, current expenditures were heavily concentrated in Ontario and Quebec in 2015, with these provinces accounting for 81.0% of total expenditures. While current R&D expenditures increased at a year-over-year rate of 14.6% in Western Canada, they increased by only 6.2% in Ontario and decreased in Quebec by 5.7%.

THE GLOBAL CONTEXT

Figure 22 compares Canadian pharmaceutical R&D-to-sales ratios for the years 2000 and 2013 to those in the PMPRB's seven comparator countries.[36] Canada's ratio stood at 10.1% in 2000. Only Italy, at 6.2%, had a lower ratio in that year, while Switzerland had the highest ratio at 102.5%.

In 2013, Canada stood at the bottom of the range at 4.4%, with Italy second lowest at 5.8%. Ratios in all other comparator countries remained well above Canada's. The ratio obtained by aggregating R&D spending and sales across all seven comparator countries was 22.8%, more than five times Canada's.

TABLE 21. Current R&D Expenditures by Region, 2015 and 2014

REGION	EXPENDITURES: 2015 ($MILLIONS)	SHARE: 2015 (%)	EXPENDITURES: 2014 ($MILLIONS)	SHARE: 2014 (%)	ANNUAL CHANGE IN EXPENDITURES (%)
Atlantic provinces	14.3	1.8	19.0	2.5	-24.9
Quebec	227.1	28.7	240.7	31.4	-5.7
Ontario	413.0	52.3	388.8	50.7	6.2
Western provinces	135.7	17.2	118.5	15.4	14.6
Territories	0.0	0.0	0.0	0.0	0.0
Total†	**790.1**	**100.0**	**767.1**	**100.0**	**3.0**

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

Source: PMPRB

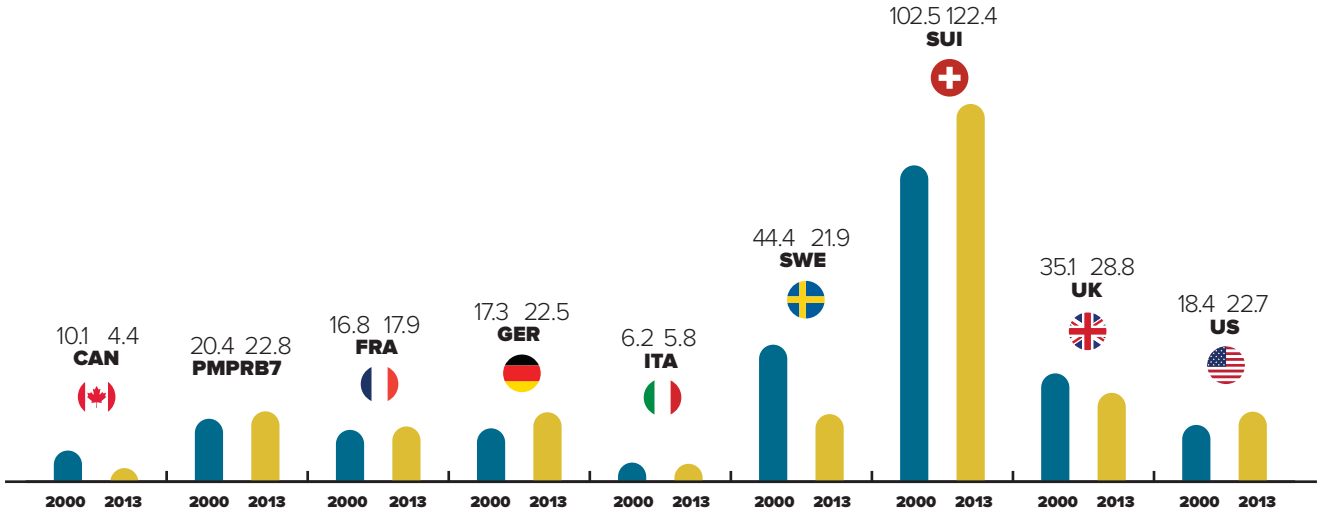
THE R&D-TO-SALES RATIO OBTAINED BY AGGREGATING R&D SPENDING AND SALES ACROSS ALL SEVEN COMPARATOR COUNTRIES WAS 22.8%, MORE THAN FIVE TIMES CANADA'S.

THE PMPRB7 AVERAGE R&D RATIO IS

5X

GREATER THAN CANADA

FIGURE 22. R&D-to-Sales Ratios, Canada and Comparator Countries



Source: PMPRB; European Federation of Pharmaceutical Industries and Associations (EFPIA): The Pharmaceutical Industry in Figures 2015, PhRMA 2015 profile

The R&D-to-sales ratios represented in Figure 22 may be compared to the average bilateral price ratios reported in Table 11 (see *Comparison of Canadian Prices to Foreign Prices* section). Several comparator countries, which have patented drug prices that are, on average, substantially less than prices in Canada, have achieved R&D-to-sales ratios well above those in Canada.

As noted in previous years' 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.

End Notes

30 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.

31 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.

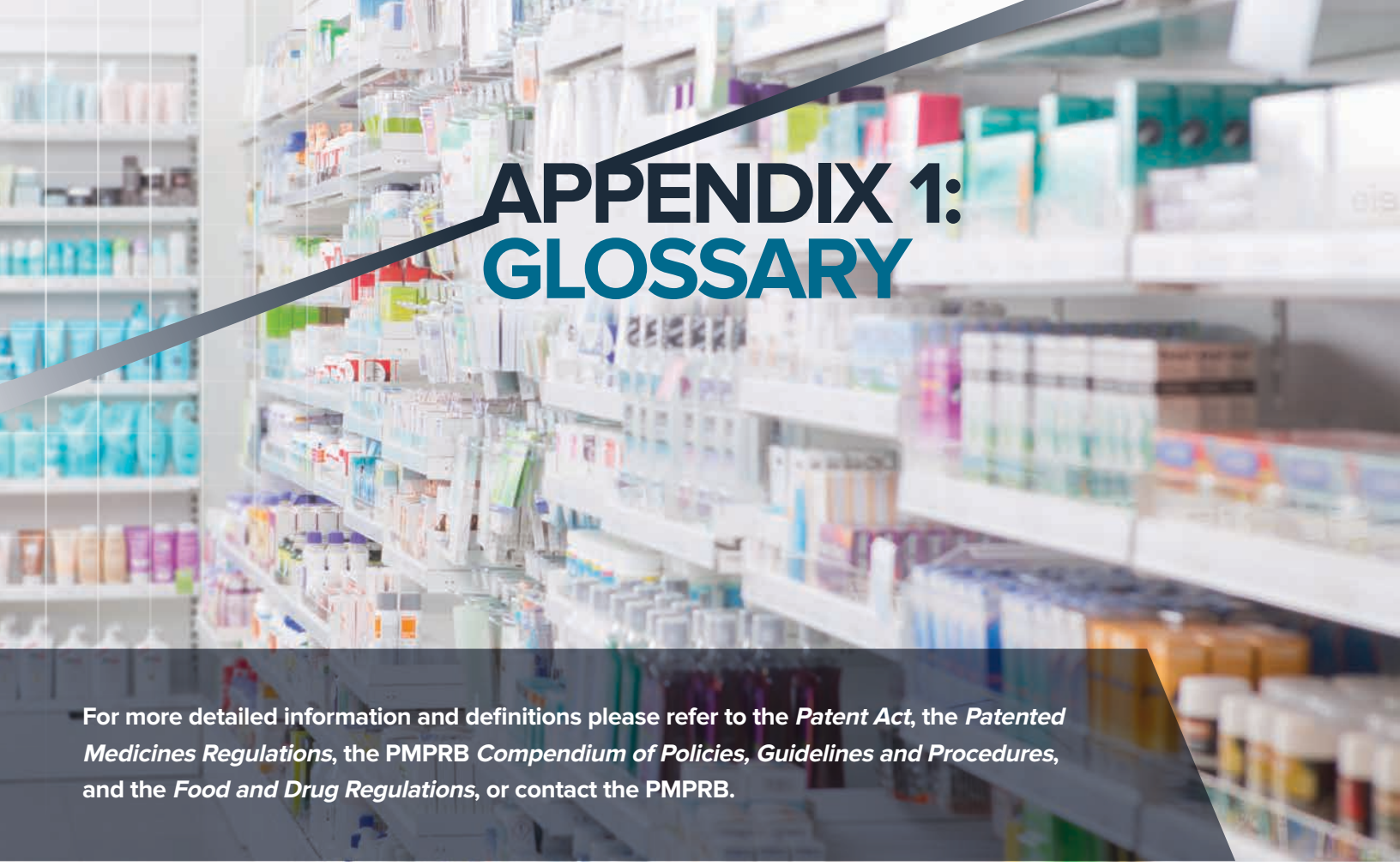
32 As published in the Regulatory Impact Assessment Statement (RIAS) of the *Patented Medicines Regulations*, 1988, published in the *Canada Gazette*, Part II, Vol. 122, No. 20 – SOR/DORS/88-474.

33 The R&D-to-sales ratios presented in Table 17 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 2015 are 4.3% and 4.8%, respectively.

34 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 90.9% of total R&D expenditure in 2015, while capital equipment costs and allowable depreciation expenses made up 7.8% and 1.3%, respectively.

35 "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 drug regulation submissions, bioavailability studies and Phase IV clinical trials.

36 Sales in Figure 22 represent domestic sales and do not include exports.



APPENDIX 1: GLOSSARY

For more detailed information and definitions please refer to the *Patent Act*, the *Patented Medicines Regulations*, the PMPRB *Compendium of Policies, Guidelines and Procedures*, and the *Food and Drug Regulations*, or contact the PMPRB.

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

ADVANCE RULING CERTIFICATE (ARC): A non-binding advance ruling certificate may be issued pursuant to subsection 98(4) of the *Patent Act* at the request of a patentee when the Board is satisfied that the price or proposed price of the medicine would not exceed the maximum non-excessive price under the Board's Guidelines.

ATC: Anatomical Therapeutic Chemical (ATC) classification system, developed and maintained by the World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology, divides drugs 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.

DEDICATION OF PATENT: A practice whereby a patentee notifies the Commissioner of Patents that it has surrendered its rights and entitlements flowing from the patent for the benefit of the public to use and enjoy. NB: As of January 30, 1995, the Board does not recognize dedication of patent as a means to remove the medicine from its jurisdiction.

DRUG IDENTIFICATION NUMBER (DIN): A registration number (drug identification number) that the Health Products and Food Branch of Health Canada assigns to each prescription and non-prescription drug product marketed under the *Food and Drug Regulations*. The DIN is assigned using information in the following areas: manufacturer of the product; active ingredient(s); strength of active ingredient(s); pharmaceutical dosage form; brand/trade name; and 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).

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 drug product being sold in accordance with regulatory filing requirements pursuant to the *Patent Act* and the *Patented Medicines Regulations*.

GENERIC PRODUCT: A drug product with the same active ingredient, strength and dosage form of a brand name drug product.

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 (i.e., royalties in the form of a share of the licensee's sales).

MEDICINE: Any substance or mixture of substances made by any means, whether produced biologically, chemically, or otherwise, that is applied or administered in vivo in humans or in animals to aid in the diagnosis, treatment, mitigation or prevention of disease, symptoms, disorders, abnormal physical states, or modifying organic functions in humans and or animals, however administered. For greater certainty, this definition includes vaccines, topical preparations, anaesthetics and diagnostic products used in vivo, regardless of delivery mechanism (e.g., transdermal, capsule form, injectable, inhaler, etc.). This definition excludes medical devices, in vitro diagnostic products and disinfectants that are not used in vivo.

NOTICE OF COMPLIANCE (NOC): A notice issued under section C.08.004 or C.08.004.01 of the *Food and Drug Regulations*. The issuance of an NOC indicates that a drug product meets the required Health Canada standards for use in humans or animals and that the 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 that provides its holder with a monopoly limited in time, for the claims made within the patent. A patent gives its holder and its legal representatives, the exclusive right of making, constructing and using the invention and selling it to others to be used.

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 drug products 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."

PENDING PATENT: An application for a patent that has not yet been issued.

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.

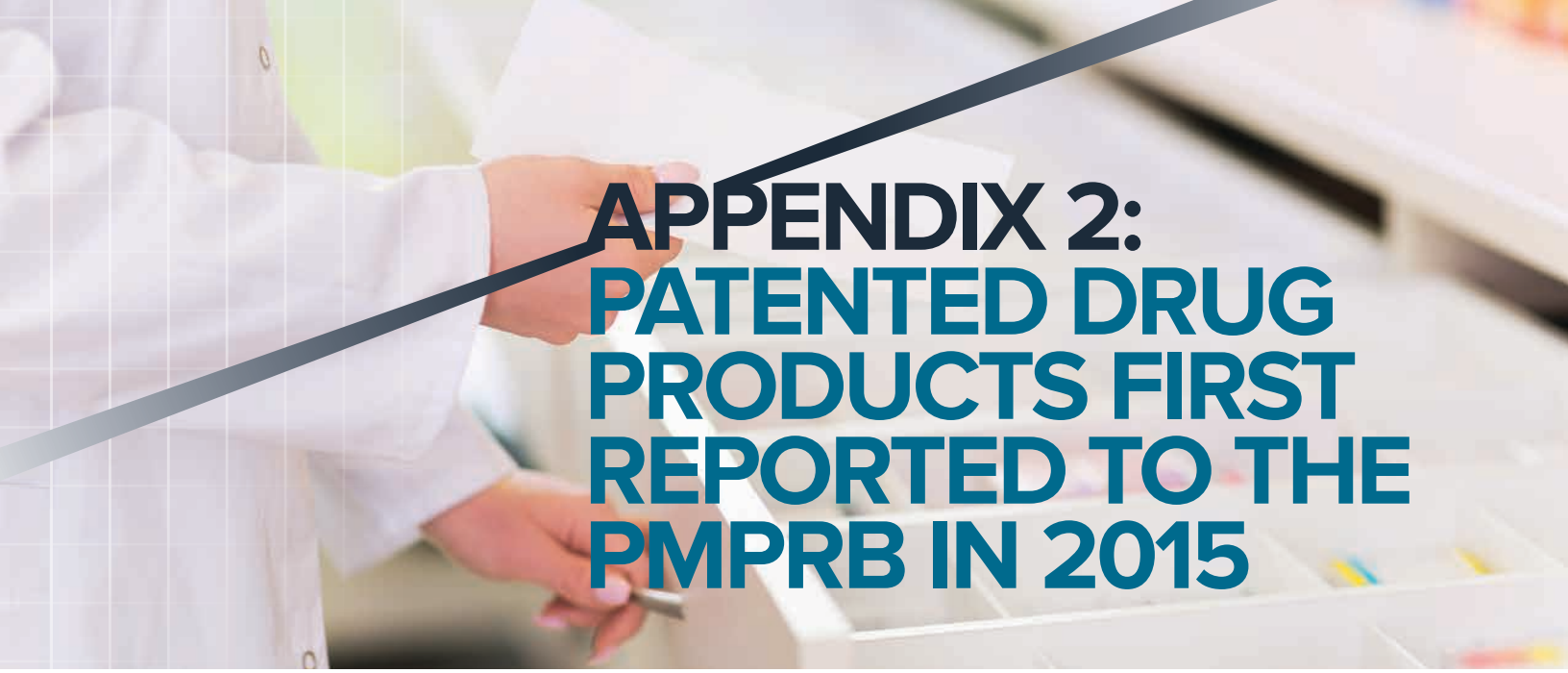
RESEARCH AND DEVELOPMENT—OTHER QUALIFYING: Includes eligible research and development expenditures that cannot be classified into any of the preceding categories of "type of research and development". It includes drug regulation submissions, bioavailability studies and Phase IV clinical trials.

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.

CURRENT RESEARCH AND DEVELOPMENT EXPENDITURES: 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 drugs that are not approved or otherwise available for sale in Canada.

VOLUNTARY COMPLIANCE UNDERTAKING (VCU): A written undertaking by a patentee to adjust its price to comply to the Board's Guidelines. The Chairperson may accept a VCU in lieu of issuing a Notice of Hearing if it is in the public interest. A VCU can also be submitted following the issuance of a Notice of Hearing. A VCU submitted at this point must be approved by the Board Hearing Panel struck to hear the matter. The Board reports publicly on all VCUs accepted by the Chairperson or the Board.



APPENDIX 2: PATENTED DRUG PRODUCTS FIRST REPORTED TO THE PMPRB IN 2015

	BRAND NAME	COMPANY	DIN	STATUS	LEVEL OF THERAPEUTIC IMPROVEMENT/ CATEGORY*
1	ASMANEX TWISTHALER - 100 mcg/ dose	Merck Canada Inc.	02438690	Subject to Investigation	**SN**
2	BREO ELLIPTA 200/25	GlaxoSmithKline Inc.	02444186	Under Review	
3	COMBIVENT RESPIMAT - 20/100	Boehringer Ingelheim (Canada) Ltd.	02419106	Within Guidelines	**SN**
4	COSENTYX - 150 mg/ml	Novartis Pharma Canada Inc.	02438070	Within Guidelines	**SN**
5	CYRAMZA - 10 mg/ml	Eli Lilly Canada Inc.	02443805	Under Review	
6	CYSVIEW - 100 mg/vial	BioSyent Pharma Inc.	02436639	Within Guidelines	**MI-P**
7	DAKLINZA - 30 mg/tablet	Bristol-Myers Squibb Canada Co.	02444747	Within Guidelines	**SN**
8	DAKLINZA - 60 mg/tablet	Bristol-Myers Squibb Canada Co.	02444755	Within Guidelines	**SN**
9	DUAKLIR GENUAIR - 412 mcg/dose	AstraZeneca Canada Inc.	02439530	Does Not Trigger Investigation	**SN**
10	DYMISTA 137/50	MEDA Pharmaceuticals Ltd.	02432889	Under Review	
11	EGRIFTA - 1 mg/vial	Theratechnologies Inc.	02438712	Under Review	
12	ELLA - 30 mg/tablet	Allergan Inc.	02436329	Subject to Investigation	**SN**
13	ENTRESTO 24.3/25.7	Novartis Pharma Canada Inc.	02446928	Within Guidelines	**SI**
14	ENTRESTO 48.6/51.4	Novartis Pharma Canada Inc.	02446936	Within Guidelines	**SI**
15	ENTRESTO 97.2/102.8	Novartis Pharma Canada Inc.	02446944	Within Guidelines	**SI**
16	ENTYVIO - 300 mg/vial	Takeda Canada Inc.	02436841	Within Guidelines	**SN**
17	EXELON PATCH 15 - 27 mg/patch	Novartis Pharma Canada Inc.	02432803	Within Guidelines	**SN**
18	FETZIMA - 20 mg/capsule	Actavis Speciality Pharmaceuticals Co.	02440970	Within Guidelines	**SN**
19	FETZIMA - 40 mg/capsule	Actavis Speciality Pharmaceuticals Co.	02440989	Within Guidelines	**SN**
20	FLUAD PEDIATRIC - 22.5 mcg/dose	Novartis Pharma Canada Inc.	02434881	Subject to Investigation	**SN**
21	FLULAVAL TETRA - 15 unit/dose	GlaxoSmithKline Inc.	02420783	Within Guidelines	**SN**
22	FORXIGA - 10 mg/tablet	AstraZeneca Canada Inc.	02435470	Within Guidelines	**SN**
23	FORXIGA - 5 mg/tablet	AstraZeneca Canada Inc.	02435462	Does Not Trigger Investigation	**SN**
24	FUMAGILLINE - 20 mg/capsule	sanofi-aventis Canada Inc.		Within Guidelines	**B**

	BRAND NAME	COMPANY	DIN	STATUS	LEVEL OF THERAPEUTIC IMPROVEMENT/ CATEGORY*
25	GARDASIL 9	Merck Canada Inc.	02437058	Subject to Investigation	**MI-P**
26	HOLKIRA PAK 12.5/75/50/250	Abbvie	02436027	Within Guidelines	**SN**
27	HUMALOG KWIKPEN - 200 unit/ml	Eli Lilly Canada Inc.	02439611	Within Guidelines	**SN**
28	ICLUSIG - 15 mg/tablet	Paladin Labs Inc.	02437333	Within Guidelines	**MI-P**
29	INCRUSE ELLIPTA - 62.5 mcg/dose	GlaxoSmithKline Inc.	02423596	Within Guidelines	**SN**
30	INSPIOLTO RESPIMAT 2.5/2.5	Boehringer Ingelheim (Canada) Ltd.	02441888	Within Guidelines	**SN**
31	JAKAVI - 10 mg/tablet	Novartis Pharma Canada Inc.	02434814	Within Guidelines	**SN**
32	JANUMET XR 100/1000	Merck Canada Inc.	02436808	Within Guidelines	**SN**
33	JANUMET XR 50/500	Merck Canada Inc.	02416786	Within Guidelines	**3**
34	JARDIANCE - 10 mg/tablet	Boehringer Ingelheim (Canada) Ltd.	02443937	Under Review	
35	JARDIANCE - 25 mg/tablet	Boehringer Ingelheim (Canada) Ltd.	02443945	Under Review	
36	JINARC	Otsuka Canada Pharmaceutical Inc.	02437503	Within Guidelines	**SN**
37	JINARC	Otsuka Canada Pharmaceutical Inc.	02437511	Within Guidelines	**SN**
38	JINARC	Otsuka Canada Pharmaceutical Inc.	02437538	Within Guidelines	**SN**
39	KALYDECO - 50 mg/pack	Vertex Pharmaceuticals Canada Inc.	02442612	Under Review	
40	KALYDECO - 50 mg/pack	Vertex Pharmaceuticals Canada Inc.	02442620	Under Review	
41	KEYTRUDA - 50 mg/vial	Merck Canada Inc.	02441152	Under Review	
42	KOGENATE FS - 1000 unit/vial	Bayer Inc.	02291533	Under Review	
43	KOGENATE FS - 2000 unit/vial	Bayer Inc.	02302217	Under Review	
44	KOGENATE FS - 250 unit/vial	Bayer Inc.	02291517	Under Review	
45	KOGENATE FS 3000 unit/vial	Bayer Inc.	02342731	Under Review	
46	KOGENATE FS - 500 unit/vial	Bayer Inc.	02291525	Under Review	
47	LODALIS - 3.75 g/dose	Valeant Canada LP	02432463	Does Not Trigger Investigation	**SN**
48	MITOSOL - 0.2 mg/ml	Laptician Opthalmics Inc.		VCU	**MI-S**
49	MOVANTIK - 12.5 mg/tablet	AstraZeneca Canada Inc.	02442467	Within Guidelines	**SN**
50	MOVANTIK - 25 mg/tablet	AstraZeneca Canada Inc.	02442176	Within Guidelines	**SN**
51	NIASTASE RT - 1 mg/vial	Novo Nordisk Canada Inc.	02417103	Does Not Trigger Investigation	**SN**
52	NIASTASE RT - 2 mg/vial	Novo Nordisk Canada Inc.	02417111	Does Not Trigger Investigation	**SN**
53	NIASTASE RT - 5 mg/vial	Novo Nordisk Canada Inc.	02417138	Does Not Trigger Investigation	**SN**
54	OFEV - 100 mg/capsule	Boehringer Ingelheim (Canada) Ltd.	02443066	Within Guidelines	**SN**
55	OFEV - 150 mg/capsule	Boehringer Ingelheim (Canada) Ltd.	02443074	Within Guidelines	**SN**
56	PANTOPRAZOLE MAGNESIUM - 40 mg/tablet	Aspri Pharma Canada Inc.	02441853	Under Review	
57	PERGOVERIS - 150 unit/kit	EMD Serono Canada Inc.	02445301	Subject to Investigation	**SN**
58	PLEGRIDY	Biogen Idec Canada Inc.	02444402	Under Review	
59	PLEGRIDY - 125 mcg/syringe	Biogen Idec Canada Inc.	02444399	Under Review	
60	PLIAGLIS 70/70	Galderma Canada Inc.	02398028	Subject to Investigation	**SN**
61	REPATHA - 140 mg/syringe	Amgen Canada Inc.	02446057	Under Review	

	BRAND NAME	COMPANY	DIN	STATUS	LEVEL OF THERAPEUTIC IMPROVEMENT/ CATEGORY*
62	REVESTIVE - 5 mg/vial	Shire Canada Inc.	02445727	Under Review	
63	REVLIMID - 20 mg/capsule	Celgene Inc.	02440601	Within Guidelines	**SN**
64	ROSIVER - 10 mg/g	Galderma Canada Inc.	02440342	Within Guidelines	**SN**
65	SAXENDA - 6 mg/ml	Novo Nordisk Canada Inc.	02437899	Within Guidelines	**SN**
66	SIGNIFOR LAR - 40 mg/vial	Novartis Pharma Canada Inc.	02437260	Under Review	
67	SIGNIFOR LAR - 60 mg/vial	Novartis Pharma Canada Inc.	02437279	Under Review	
68	SIMBRINZA	Alcon Canada Inc.	02435411	Within Guidelines	**SN**
69	SPIRIVA RESPIMAT - 5 mcg/dose	Boehringer Ingelheim (Canada) Ltd.	02435381	Subject to Investigation	**SN**
70	SYLVANT - 100 mg/vial	Janssen Inc.	02435128	Under Review	
71	SYLVANT - 400 mg/vial	Janssen Inc.	02435136	Under Review	
72	TACHOSIL 2/5	Takeda Canada Inc.	02439026	Within Guidelines	**SN**
73	TECHNIVIE 12.5/75/50	Abbvie	02447711	Under Review	
74	TEFLARO - 400 mg/vial	Actavis Speciality Pharmaceuticals Co.		Within Guidelines	**SN**
75	TOUJEO SOLOSTAR - 200 unit/ml	sanofi-aventis Canada Inc.	02441829	Under Review	
76	TRANSLARNA - 250 mg/pouch	PTC Therapeutics International Limited		Under Review	
77	TRULICITY - 1.5 mg/ml	Eli Lilly Canada Inc.	02448602	Under Review	
78	TYBOST - 150 mg/tablet	Gilead Sciences Inc.	02411423	Does Not Trigger Investigation	**SN**
79	VITEKTA - 150 mg/tablet	Gilead Sciences Inc.	02411180	Within Guidelines	**SN**
80	VITEKTA - 85 mg/tablet	Gilead Sciences Inc.	02411172	Within Guidelines	**SN**
81	VYVANSE - 10 mg/capsule	Shire Canada Inc.	02439603	Under Review	
82	XARELTO - 15 mg/kit	Bayer Inc.	02441535	Under Review	
83	XTANDI - 40 mg/capsule	Astellas Pharma Canada Inc.	02407329	Does Not Trigger Investigation	**SN**
84	ZYDELIG - 100 mg/tablet	Gilead Sciences Inc.	02438798	Within Guidelines	**SN**
85	ZYDELIG - 150 mg/tablet	Gilead Sciences Inc.	02438801	Within Guidelines	**SN**
86	ZYKADIA - 150 mg/capsule	Novartis Pharma Canada Inc.	02436779	Within Guidelines	**SN**

* *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*

Sold prior to implementation of new Guidelines in 2010:

Category 1 *An existing or comparable dosage form of an existing medicine*

Category 2 *A non-comparable dosage form of an existing medicine, or the first DIN of a new chemical entity that is a breakthrough or provides a substantial improvement over comparable existing DINs*

Category 3 *A non-comparable dosage form of an existing medicine, or the first DIN of a new chemical entity that provides moderate, little or no therapeutic advantage over comparable existing DINs*

APPENDIX 3: RESEARCH AND DEVELOPMENT

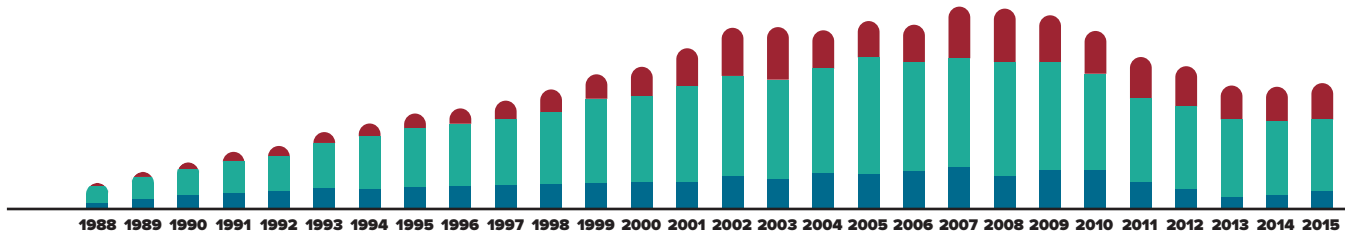
TABLE 22. Range of R&D-to-Sales Ratios by Number of Reporting Companies and Total Sales Revenue

RANGE: R&D-TO-SALES RATIO	NUMBER OF REPORTING COMPANIES: 2015	SALES REVENUES: 2015 ($MILLIONS)	SHARE: 2015(%)	NUMBER OF REPORTING COMPANIES: 2014	SALES REVENUES: 2014 ($MILLIONS)	SHARE: 2014(%)
0%	32	1,999.9	10.2	28	2,008.8	10.9
≤10%	38	15,767.8	80.1	39	15,604.9	84.8
> 10%	7	1,925.6	9.8	8	805.4	4.4
Total	**77**	**19,693.3**	**100.0†**	**75**	**18,455.1**	**100.0†**

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

Source: PMPRB

FIGURE 23. Current R&D Expenditures ($millions) by Type of Research, 1988-2015



	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
OTHER QUALIFYING	21.7	31.8	42.8	57.6	64.9	68.8	80.8	96.5	97.1	117.5	145.3	154.7	187	242.6	304.4	332.6	244.2	230.1	237.4	326.8	337.9	296.8	270.8	265.2	266.9	215	217.8	231.7
APPLIED	106.6	143.1	167.2	203.5	224.1	290.9	336.5	369.3	396.4	421.3	458	535.2	547.2	604.8	637	631.5	658.3	737.5	689.6	688.2	723.2	685.3	613.4	525.1	525.5	492.2	467.4	456.2
BASIC	30.3	53.5	78.3	94.2	103.7	120.7	117.4	132	136.6	140.4	146.8	155.9	159.1	163.1	198.6	180.3	221.7	215.1	232.4	259	200.2	237.1	235.9	164.9	114.6	67.6	81.8	102.2

Source: PMPRB

TABLE 23. Ratios of R&D Expenditures to Sales Revenue by Reporting Patentee[1], 2015 and 2014

COMPANY	R&D-TO-SALES RATIO (%) 2015	R&D-TO-SALES RATIO (%) 2014	MIP-TO-CDN PRICE RATIO (%) – 5 COUNTRY LIMIT
Abbott Laboratories, Ltd.	0.0	0.0	44
AbbVie Corporation[2,3,4]	3.0	2.2	105
Actavis Specialty Pharmaceuticals Co. (Watson Pharma Co.)	0.0	0.1	-
Actelion Pharmaceuticals Canada Inc.[2,4]	2.6	4.2	104
Aegerion Pharma Canada Ltd.[3]	0.0	1.9	-
Alcon Canada Inc.	0.6	0.1	-
Alexion Pharmaceuticals Inc.[3]	0.0	0.0	-
Allergan Inc.	2.4	5.0	69
Amgen Canada Inc.[2,3]	5.3	6.0	88
Aspri Pharma Canada Inc.	0.0	0.0	-
Astellas Pharma Canada Inc.[2,6]	3.6	2.0	130
AstraZeneca Canada Inc.[2,3]	4.9	3.0	76
Baxalta Canada Corp.[5]	0.0	-	-
Baxter Corporation	0.0	0.3	102
Bayer Inc.[2]	5.5	5.2	90
BGP Pharma ULC.[10]	0.0	-	-
Biogen Idec Canada Inc.[3]	10.8	10.2	105
BioMarin Canada Inc.[3]	47.0	42.5	-
Biovitrum AB	0.0	0.0	-
BioSyent Pharma Inc.[5]	0.0	-	-
Boehringer Ingelheim (Canada) Ltd.[2]	5.5	4.5	87
Bracco Diagnostics Canada Inc.	0.0	0.0	-
Bristol-Myers Squibb Canada[2, 3]	10.8	9.7	118
Celgene Inc.[3]	1.6	2.0	102
Correvio (UK) Ltd. (Iroko International LP)	0.0	0.0	-
CSL Behring Canada Inc.	0.2	0.5	-
Duchesnay Inc.	14.3	12.5	-
Eisai Limited[2,3]	1.2	0.9	78
Eli Lilly Canada Inc. (includes Provel Animal Health Division)[2,3]	3.3	4.3	76
EMD Serono Canada Inc.[2]	0.0	5.8	-
Ferring Pharmaceuticals Inc.[2]	0.0	0.0	94
Galderma Canada Inc.	0.0	0.0	-
Gilead Sciences Canada, Inc.[2]	16.2	22.6	106
GlaxoSmithKline Inc.[2]	5.8	8.5	68

continued

COMPANY	R&D-TO-SALES RATIO (%) 2015	R&D-TO-SALES RATIO (%) 2014	MIP-TO-CDN PRICE RATIO (%) – 5 COUNTRY LIMIT
Grifols Canada Ltd. (Talecris Biotherapeutics Ltd.)[3]	0.0	0.0	—
Hoffmann-La Roche Ltd. Canada.[2,3]	5.1	4.9	—
Horizon Pharma PLC.[5]	0.0	—	—
Hospira Healthcare Corp.	0.0	0.0	—
Ipsen Biopharmaceuticals Canada Inc.[3,5]	0.0	—	—
Janssen Inc.[2,3]	3.4	3.3	—
Johnson & Johnson Inc.	0.0	0.0	89
Johnson & Johnson Medical Products	0.0	1.7	—
Lantheus MI Canada Inc.	0.0	0.0	—
LEO Pharma Inc.[2]	1.6	1.2	50
Lundbeck Canada Inc.[2]	2.0	0.8	51
Lupin Pharma Canada Limited[5]	0.4	—	—
Mallinckrodt Canada Inc.	0.0	0.0	—
McNeil Consumer Healthcare Canada	3.8	3.8	—
Meda Pharmaceuticals Ltd.[5]	0.0	—	30
Merck Canada Inc.[2,3]	2.2	2.4	70
Merus Labs	0.0	0.0	
Merz Pharma Canada Ltd.	1.3	5.8	—
Novartis Pharmaceuticals Canada Inc.[2,3]	3.9	6.4	86
Novo Nordisk Canada Inc.[2,3]	2.0	2.9	78
Octapharma Canada Inc.[5]	0.1	—	—
Otsuka Canada Pharmaceutical Inc. (OCPI)[2]	4.5	48.0	104
Paladin Labs Inc.[2]	0.2	0.0	—
Pfizer Canada Inc.[2, 3]	0.9	1.2	83
Purdue Pharma[2]	3.9	4.6	—
PTC Therapeutics International Ltd.[5]	0.0	—	—
Ranbaxy Pharmaceuticals Canada Inc.	0.0	0.0	—
Salix Pharmaceuticals Inc.	0.0	45.9	—
Sanofi Canada Inc.[2, 8]	2.1	2.4	71
Sanofi Pasteur Ltd.[2,3,7]	80.1	67.1	—
Seattle Genetics Inc.	7.2	5.2	—
Servier Canada Inc.[2]	2.6	4.7	
Shire Canada Inc.[2,3]	0.0	0.2	93
Shire Human Genetic Therapies[2,3]	0.0	1.6	—
Sunovion Pharmaceuticals Canada Inc.[2]	0.0	0.0	—

continued

COMPANY	R&D-TO-SALES RATIO (%) 2015	R&D-TO-SALES RATIO (%) 2014	MIP-TO-CDN PRICE RATIO (%) – 5 COUNTRY LIMIT
Takeda Canada Inc.[2,3]	0.0	0.0	40
Theratechnologic Inc.[5]	0.0	—	—
Teva Canada Innovation[3]	0.1	0.7	101
Tribute Pharma Canada Inc.	0.0	0.0	25
UCB Canada Inc.[3]	1.0	1.7	88
Valeant Canada Ltd.[3,9]	5.0	0.0	143
Vertex Pharma Canada Inc.	72.5	66.5	
VIIV Healthcare ULC[2]	0.0	0.0	—

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 2013.

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 24. Current R&D Expenditures by Province/Territory, 2015

PROVINCE	EXPENDITURES: ALL PATENTEES ($THOUSANDS)	REGIONAL SHARE (%)	EXPENDITURES: INNOVATIVE MEDICINES CANADA ($THOUSANDS)	REGIONAL SHARE: (%)
Newfoundland	2,999.41	0.380	2,563.02	0.371
Prince Edward Island	5.43	0.001	0.00	0.000
Nova Scotia	8,455.91	1.070	7,729.53	1.120
New Brunswick	2,793.94	0.354	2,279.21	0.330
Quebec	227,133.63	28.747	179,680.40	26.030
Ontario	412,975.46	52.268	375,049.74	54.332
Manitoba	5,918.95	0.749	4,455.34	0.645
Saskatchewan	2,575.71	0.326	1,867.80	0.271
Alberta	89,902.36	11.379	82,351.90	11.930
British Columbia	37,344.27	4.726	34,314.02	4.971
Territories	0	0.000	0	0.000
Canada[†]	**790,105.07**	**100.0***	**690,290.97**	**100.0***

[†] Values in this column may not add due to rounding.

Source: PMPRB

TABLE 25. Current R&D Expenditures by Performer and Province/Territory, 2015

PROVINCE		PATENTEES	OTHER COMPANIES	UNIVERSITY	HOSPITALS	OTHERS
Newfoundland	$000	701.33	1,247.63	512.97	263.14	274.34
	%	23.4	41.6	17.1	8.8	9.1
Prince Edward Island	$000	0.00	0.00	5.43	0.00	0.00
	%	0.0	0.0	100.0	0.0	0.0
Nova Scotia	$000	1,190.80	3,263.46	781.80	2,096.15	1,123.69
	%	14.1	38.6	9.2	24.8	13.3
New Brunswick	$000	395.16	1,012.86	486.14	560.46	339.32
	%	14.1	36.3	17.4	20.1	12.1
Quebec	$000	86,732.19	70,362.09	12,955.95	15,892.56	41,190.84
	%	38.2	31.0	5.7	7.0	18.1
Ontario	$000	218,209.52	73,581.32	37,683.76	46,040.23	37,460.65
	%	52.8	17.8	9.1	11.1	9.1
Manitoba	$000	1,657.98	1,904.39	628.18	820.82	907.57
	%	28.0	32.2	10.6	13.9	15.3
Saskatchewan	$000	326.99	1,091.95	832.42	77.03	247.32
	%	12.7	42.4	32.3	3.0	9.6
Alberta	$000	65,191.69	7,530.44	5,578.50	3,967.28	7,634.45
	%	72.5	8.4	6.2	4.4	8.5
British Columbia	$000	15,613.81	10,253.61	2,206.64	3,248.59	6,021.63
	%	41.8	27.5	5.9	8.7	16.1
Territories	$000	0.0	0.0	0.0	0.0	0.0
	%	0.0	0.0	0.0	0.0	0.0
Canada	$000	390,019.48	170,247.75	61,671.78	72,966.25	95,199.81
	%	49.4	21.5	7.8	9.2	12.0

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