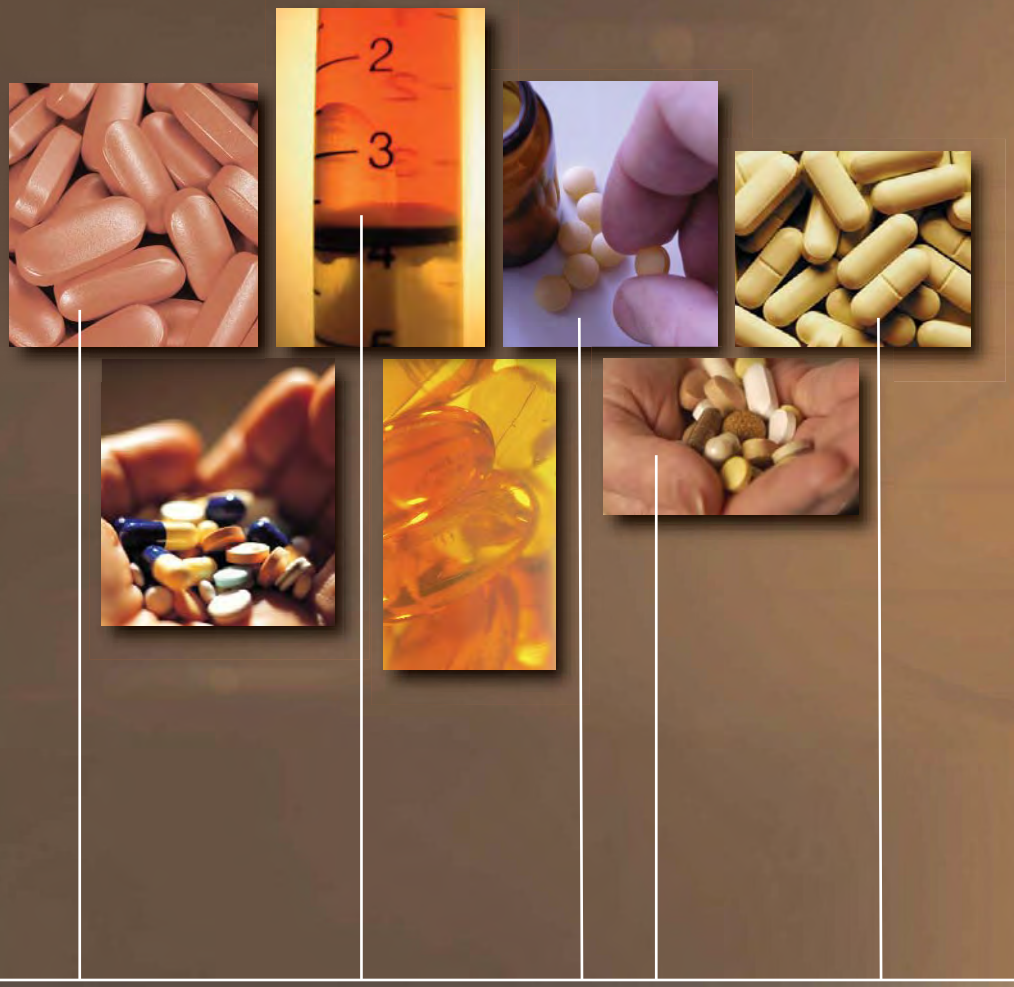
Patented
Medicine Prices
Review Board

Since 1987

Annual Report 2009



The mandate of the Patented Medicine Prices Review Board is to ensure that prices at which patentees sell their patented medicines in Canada are not excessive; and to report on pharmaceutical trends of all medicines and on R&D spending by patentees.

Canada

www.pmprb-cepmb.gc.ca

Highlights 2009

Regulatory Mandate

Compliance

- 81 new patented drug products for human use were reported to the PMPRB.
- 50 new patented drug products were within Guidelines.
- In total, 1177 patented drug products for human use were under the PMPRB's jurisdiction.

Enforcement

In 2009, and up to May 31, 2010:

- The Board approved 17 Voluntary Compliance Undertakings (VCUs), three following the issuance of Notices of Hearing.
- The Board completed five price hearings (Concerta, Neulasta, Nicoderm, Quadracel and Pentacel, and Strattera) and issued two Notices of Hearing (Neulasta, on price, and Sandoz Canada Inc., on failure to file).
- Decisions are pending in three matters (ratiopharm Inc., on failure to file, and Penlac and ratio-Salbutamol HFA, on prices). As well, the Board issued a Supplementary Order in the matter of Adderall XR. Four proceedings are ongoing (Apotex Inc. and Sandoz Canada Inc., on failure to file, and Apo-Salvent CFC Free and Copaxone (redetermination), on price).

Reporting Mandate

Sales Trends

- Sales of patented drug products in Canada increased by 2.8% to $13.3 billion in 2009.
- The share of patented drug products as a percentage of total sales continued to decline, from 64.7% in 2008 to 62.4% in 2009.
- The primary drivers of sales growth between 2008 and 2009 were antineoplastics and immunomodulating agents (such as drugs used in chemotherapy).

Patented Drug Price Trends

- The prices of patented drug products sold by patentees, as measured by the Patented Medicines Price Index, rose by 0.3% from 2008 to 2009, while the Consumer Price Index also rose by 0.3%.
- Canadian prices were the third highest of the 7 comparator countries.

Research and Development

- Patentees reported total R&D expenditures of $1.2 billion, a decline of 2.9% over 2008.
- Rx&D members accounted for 89.1% of all reported R&D expenditures in 2009.
- The R&D-to-sales ratio declined slightly for all patentees from 8.1% in 2008 to 7.5% in 2009, while the R&D-to-sales ratio for members of Rx&D declined from 8.9% in 2008 to 8.2% in 2009. The ratios have been less than 10% for all patentees since 2001 and for members of Rx&D since 2003.

The Patented Medicine Prices Review Board

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Patented
Medicine Prices
Review Board

Since 1987

May 31, 2010

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

Dear Minister:

I have the pleasure to present to you, in accordance with sections 89 and 100 of the *Patent Act*, the Annual Report of the Patented Medicine Prices Review Board for the year ended December 31, 2009.

Yours very truly,

Mary Catherine Lindberg
Vice-Chairperson

Canada

The mandate of the Patented Medicine Prices Review Board is to ensure that prices at which patentees sell their patented medicines in Canada are not excessive; and to report on pharmaceutical trends of all medicines and on R&D spending by patentees.

Executive Summary

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

About the PMPRB

The Patented Medicine Prices Review Board has a dual role:

- to ensure that prices at which patentees sell their patented medicines in Canada are not excessive
- to report on pharmaceutical trends of all medicines and on R&D spending by patentees.

The PMPRB has no authority to regulate the prices of non-patented drugs and does not have jurisdiction over prices charged by wholesalers or pharmacies, or over pharmacists' professional fees.

Governance

The Board consists of five members who serve on a part-time basis. Members, including a Chairperson and a Vice-Chairperson, are appointed by the Governor-in-Council. The Chairperson is designated under the *Patent Act* (Act) as the Chief Executive Officer of the PMPRB with the authority and responsibility to supervise and direct its work. In the event that the office of Chairperson is vacant, the Act provides that the Vice-Chairperson have all the powers and functions of Chairperson during the vacancy.

Budget

The PMPRB operated with a budget of $11.9 million in 2009–2010 and an approved staff level of 76 full-time equivalent employees.

Regulating the Prices of Patented Medicines

The PMPRB is responsible for regulating the prices that patentees charge for prescription and non-prescription patented drug products sold in Canada to wholesalers, hospitals, pharmacies or others, for human and veterinary use, to ensure that they are not excessive.

Although patentees are not required to obtain approval of the price beforehand, they are required under the Act to ensure that prices of patented drug products sold in Canada are not excessive. The Board's Guidelines detail how to determine whether a price is excessive.

Table 6 Patented Drug Products (DINs) for Human Use Sold in 2009 – Status of Price Review as of March 31, 2010

	New Drugs Introduced in 2009	Existing Drugs	Total
Total	81	1,096	1,177
Within Guidelines	50	1,003	1,053
Under Review	27	1	28
Under Investigation	4	86	90
Price Hearings		3	3
Completed Price Hearings		3	3

New patented drug products

In 2009, 81 new patented drug products for human use were introduced. Some are one or more strengths of a new active substance and others are new presentations of existing medicines. Of the 81 new patented DINs, the prices of 54 had been reviewed as of March 31, 2010.

- 50 were found to be within the Guidelines
- 4 were priced at levels that appeared to exceed the Guidelines and investigations were commenced
- the prices of 27 DINs are still under review

Price review of existing patented drugs for human use

Existing patented drug products include all patented drug products that were first sold and reported to the PMPRB prior to December 1, 2008. At the time of this report, there were 1,096 existing DINs, of which the prices of 1,003 (91.5%) were within the Guidelines and 86 were the subject of investigations.

Voluntary Compliance Undertakings

In 2009, the Board approved 10 VCUs, 3 of which followed the issuance of Notices of Hearing:

- Andriol, Schering-Plough Canada Inc.
- Brevibloc, Baxter Corporation
- Claritin Allergy & Sinus Extra Strength, Schering-Plough Canada Inc.
- Concerta, Janssen-Ortho Inc.
- Eligard, sanofi-aventis Canada Inc.
- Neulasta, Amgen Canada Inc.
- Strattera, Eli Lilly Inc.
- Suprax, sanofi-aventis Canada Inc.
- Trinipatch, Novartis Pharmaceuticals Canada Inc.
- Vepesid, Bristol-Myers Squibb Canada Inc.

In 2010, up to May 31, the Board approved 7 VCUs:

- Adenoscan, Astellas Pharma Canada Inc.
- Dicetel, Solvay Pharma Inc.
- FSME-IMMUN, Baxter Corporation
- Levemir Penfill, Novo Nordisk Canada Inc.
- Paxil CR, GlaxoSmithKline Inc.
- Voluven, Fresenius Kabi Canada
- Xarelto, Bayer Inc.

Hearings

In 2009, the Board

- issued one Notice of Hearing: Neulasta (on price)
- completed five hearings (Nicoderm, Quandracel and Pentacel); three through VCUs (Concerta, Neulasta, Strattera)

In 2010, up to May 31, the Board

- issued one Notice of Hearing: Sandoz Canada Inc. (failure to file)
- issued a Supplementary Order in the matter of Adderall XR

Decisions are pending in three matters: two on price (Penlac and ratio-Salbutamol HFA) and one on failure to file (ratio-pharm Inc.).

Four proceedings are ongoing: two on price (Apo-Salvent CFC Free and Copaxone for redetermination as ordered by the Federal Court) and two on failure to file (Apotex Inc. and Sandoz Canada Inc.).

In addition to price reductions, approximately $100 million has been reimbursed through VCUs and Board Orders by way of payments to the Government of Canada and/or to customers such as hospitals and clinics since 1993.

Review of the Guidelines on Excessive Prices

Following an extensive consultation process with stakeholders, which began in 2005, new excessive price guidelines came into effect on January 1, 2010. This thorough review was undertaken to ensure that the new guidelines remain relevant and appropriate in an evolving pharmaceutical environment.

Over the past five years, more than 100 submissions were made in response to Board discussion papers, joint working groups were formed with industry and others, and dozens of meetings were held across the country. In March 2009, stakeholders were invited to comment on the Board's second draft revised Guidelines, and the final document, the *Compendium of Policies, Guidelines and Procedures*, was published on June 9, 2009.

Board Staff held outreach sessions throughout the summer and fall of 2009 to assist patentees in better understanding the changes.

Reporting on Key Pharmaceutical Trends

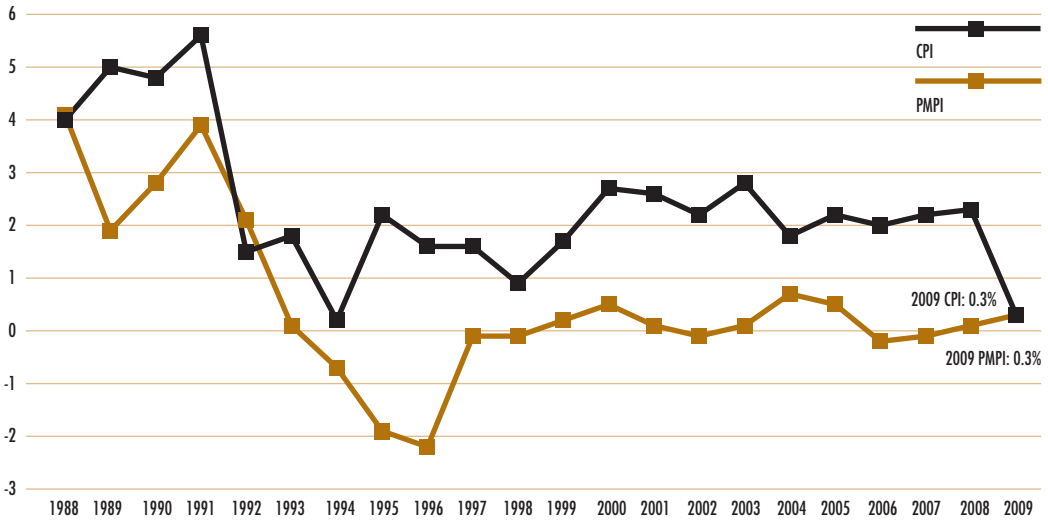
Trends in Sales of Patented Drug Products

Sales of patented drug products rose to $13.3 billion in 2009, an increase of 2.8% from $13.0 billion in 2008.

The growth in sales, however, has undergone a pronounced decline in recent years. Throughout the latter part of the 1990s, sales growth was largely driven by a succession of new "blockbuster" products that achieved very high sales volumes – in 1999, annual sales growth was 27.0%. However, since that time the pharmaceutical industry has not introduced new high-volume products in sufficient numbers to sustain double-digit sales growth. Older drug products, introduced between 1995 and 1999, still accounted for nearly 35.9% of 2009 sales.

The share of patented drug products in overall drug sales has also declined since 2003, implying that sales of generic and non-patented branded drug products have grown faster than sales of patented drug products.

Figure 6 Annual Rate of Change of Patented Medicines Price Index and Consumer Price Index, 1988–2009



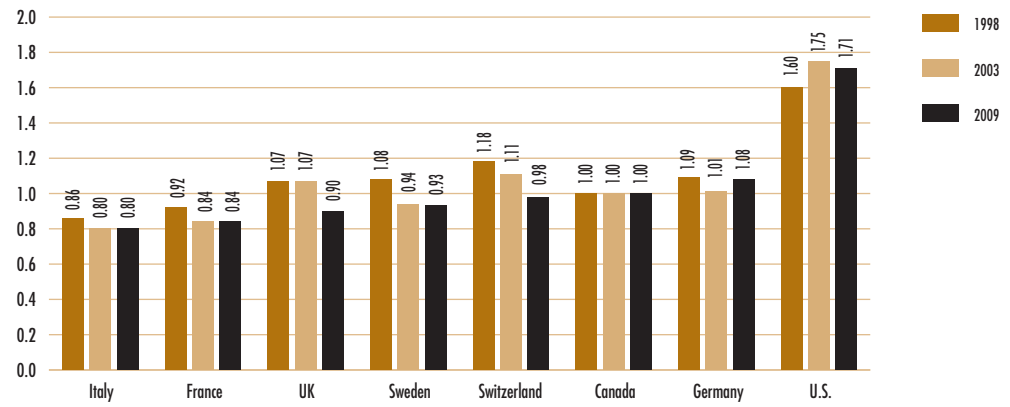
Sources: PMPRB and Statistics Canada

Price Trends

The PMPRB uses the Patented Medicines Price Index (PMPI) to monitor trends in prices of patented drug products sold in Canada. The PMPI measures the average year-over-year change in the ex-factory prices using a formula that takes a sales-weighted average of price changes observed at the level of individual products, similar to the approach used to calculate the Consumer Price Index (CPI). The PMPI is updated every six months using price and sales information submitted by patentees.

As measured by the PMPI, prices of patented drug products rose, on average, by 0.3% between 2008 and 2009.

Figure 11 Average Foreign-to-Canadian Bilateral Price Ratios at Market Exchange Rates, 1998, 2003, 2009



Source: PMPRB

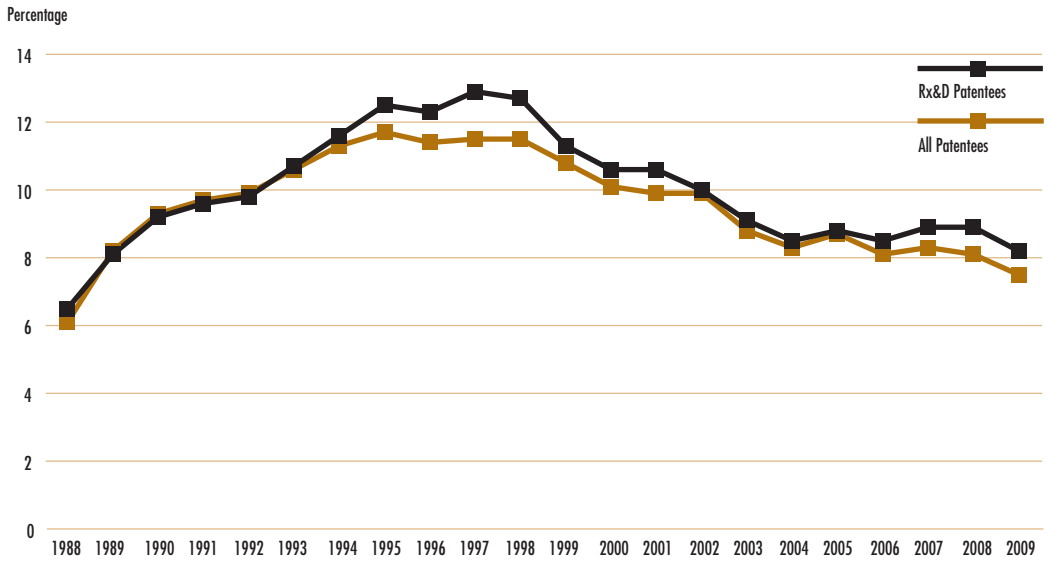
Price Change by Country

The Act and *Patented Medicines Regulations* require patentees to report publicly available ex-factory prices of their patented drug products for seven foreign comparator countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States. The PMPRB uses this information to conduct its international price comparison tests.

In general, prices of individual patented drugs in Canada are lower than the median of international prices. In 2009, average prices were higher in Germany, much higher in the U.S., and lower in the other five countries.

In 2009, prices in the United States rose by an average of 8 to 9%. Italy, Germany, Sweden, and the UK recorded much more modest average increases, while prices in France and Switzerland declined slightly.

Figure 20 Ratio of R&D-to-Sales of Pharmaceutical Patentees, 1988–2009



Sources: PMPRB

R&D Expenditures

Spending on pharmaceutical R&D was $1.2 billion in 2009, a decline of 2.9% over 2008. Members of Canada's Research-Based Pharmaceutical Companies (Rx&D) reported R&D expenditures of $1.1 billion in 2009, a decrease of 3.3% over last year.

When the Act was amended in 1987, Rx&D members made a public commitment to increase their annual research and development expenditures to 10% of sales revenues by 1996. However in recent years, R&D-to-sales ratios for all patentees and for Rx&D members have been declining. In 2009, the ratio for members of Rx&D was 8.2%, down from 8.9% in 2008, marking the seventh consecutive year it has been less than 10%.

Patentees reported spending $237.1 million on basic research in 2009 (an increase of 18.4% over the previous year) and $685.3 million on applied research. Clinical trials accounted for 76.8% of applied research expenditures.

Compared to the PMPRB's seven comparator countries, in 2007 Canada's R&D-to-sales ratio was second lowest at 8.3%, just ahead of Italy. Ratios in all other comparator countries were well above Canada's.

National Prescription Drug Utilization Information System

Through the National Prescription Drug Utilization Information System (NPDUIS), the PMPRB works with its federal, provincial, and territorial government partners to provide critical analyses of price, utilization and cost trends. In 2009, NPDUIS worked closely with its partners to support drug plan policy decision-making.

Communications

The PMPRB is committed to transparency, accessibility and stakeholder engagement. The PMPRB regularly informs its stakeholders on its activities through its publications, such as the Annual Report and its quarterly NEWSletter. All PMPRB publications, including Board decisions in hearings and VCUs, are available on its Web site.

Table of Contents

List of Tables

List of Figures

Vice-Chairperson's Message

The PMPRB marked an important chapter in its existence in 2009, and the beginning of a new one.

I would like first to acknowledge the invaluable contribution of Dr. Brien Benoit, whose term as Member, Chair and CEO of the Board ended on May 18, 2010. Dr. Benoit joined the Board in 2005, at a time when several new issues and challenges were emerging. The Board had just issued a discussion paper on price increases for patented medicines and launched an in-depth review of its Guidelines.

The main objective was to ensure that the Guidelines remained relevant and appropriate to the ever-evolving pharmaceutical environment. To ensure the broadest possible input, the Board embarked on an unprecedented level of consultation with all interested stakeholders, including the pharmaceutical industry, federal, provincial and territorial governments, consumer and patient advocacy groups, third party payers and others. Face-to-face consultations were held with stakeholders across the country, bilateral meetings were organized with all stakeholder groups, and multilateral working groups were established to examine specific issues. This consultation culminated with the release of new Guidelines in June 2009, which came into effect on January 1, 2010.

We remain committed to ensuring that our mandate is carried out in an open, effective and efficient manner and in the context of good government and accountability. To that end, we will continue to engage stakeholders, which is critically important to reach decisions that are balanced and fair and that serve all Canadians effectively.

Amid this in-depth review exercise, we pursued our regulatory and reporting activities, and responded to new compliance challenges. For the most part, matters before the Board focus on the scientific and pricing issues of patented brand name drug products. While these proceedings can be time sensitive, resource intensive, and require dedication and thoughtful deliberation, they also provide patentees with an opportunity to be heard on issues vital to their operations. In some cases, Board proceedings result in judicial reviews by the Federal Court, which provide both the Board and patentees with clarification on the intent of the law.

In 2009, we pursued our partnership with the Canadian Institute on Health Information, Health Canada and the provinces through our collaboration on the National Prescription Drug Utilization Information System, refining our goals and providing in-depth analysis and advice. Through this work, the Board helps fill information gaps and assists policy makers to better understand trends in drug prices and the factors influencing drug costs in Canada.

I would like to thank the Staff for its commitment, enthusiasm and continuous support. In particular, I want to thank the retiring Executive Director, Barbara Ouellet, for her important contribution to this organization over the last five years. As well, I would like to thank my fellow Board members, and in particular Anthony Boardman who completed his second term in March, for their dedication and tireless work.

The PMPRB is increasingly being challenged to respond to new demands, through the monitoring and evaluation of the Guidelines, acting in the public interest by holding public hearings into specific matters of potential excessive pricing, and a host of other activities. However, the commitment, dedication and expertise of Board members and staff help ensure our ability to effectively meet these challenges, to serve Canadians, and to contribute to the health care system.

Mary Catherine Lindberg
Vice-Chairperson

We remain committed to ensuring that our mandate is carried out in an open, effective and efficient manner and in the context of good government and accountability.

About The Patented Medicine Prices Review Board

Mandate

Regulatory: To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive.

Reporting: To report on pharmaceutical trends of all medicines and on R&D spending by patentees.

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body established by Parliament in 1987 under the *Patent Act* (Act). The Minister of Health is responsible for the pharmaceutical provisions of the Act as set out in sections 79 to 103.

Although part of the Health Portfolio, the PMPRB carries out its mandate at arm's length from the Minister of Health.[1] It also operates independently of other bodies such as Health Canada, which approves drugs for safety and efficacy and quality; federal, provincial and territorial public drug plans, which have responsibility for listing reimbursement decisions for their respective plans; and the Common Drug Review, which provides listing recommendations based on cost-effectiveness to participating public drug plans.

Jurisdiction

Regulatory

The PMPRB is responsible for regulating the prices that patentees charge for prescription and non-prescription patented drugs sold in Canada to wholesalers, hospitals, pharmacies or others, for human and veterinary use, to ensure that they are not excessive. The PMPRB regulates the price of each patented drug product. This includes each strength of an individual, final dosage form of a medicine.[2]

The Federal Court of Appeal articulated the legal requirement as to when a patent will "pertain" to the medicine. In this regard, the Court established the "merest slender thread" requirement, which is wide in scope. The Board's jurisdiction is not limited to drug products for which the patent is on the active ingredient. Rather, the Board's jurisdiction 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. Patented drugs are not limited to brand name products. A number of generic companies fall under the Board's jurisdiction by virtue of being licensees selling the same drug product as the brand company or because of manufacturing or processing patents, which various generic companies also hold.

The PMPRB has no authority to regulate the prices of non-patented drugs and does not have jurisdiction over prices charged by wholesalers or pharmacies, or over pharmacists' professional fees. Also, matters such as whether medicines are reimbursed by public drug plans, their distribution and prescribing are outside the purview of the PMPRB.

Under the Act, patentees are required to inform the PMPRB of their intention to sell a new patented drug product. Upon the sale of such a patented drug product, patentees are required to file price and sales information at introduction and, thereafter, twice a year for each strength of each dosage form of each patented drug product sold in Canada for price regulation purposes.

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 prices of patented drug products sold in Canada are not excessive. In the event that the Board finds, after a public hearing, that a price is or was excessive in any market, it may order the patentee to reduce the price and take measures to offset any excess revenues it may have received.

1 The Health Portfolio contributes to specific dimensions of improving the health of Canadians. It comprises Health Canada, the Public Health Agency of Canada, the Canadian Institutes of Health Research, the Hazardous Materials Information Review Commission, the Assisted Human Reproduction Agency of Canada and the Patented Medicine Prices Review Board.

2 Throughout this report the term "patented drug product" means each strength of an individual, final dosage form of a medicine and denotes a product under the PMPRB's jurisdiction.

Reporting

The PMPRB reports annually to Parliament, through the Minister of Health, on its activities, on pharmaceutical trends relating to all medicines, and on the R&D spending by patentees. In addition to these reporting responsibilities, under section 90 of the Act, the Minister of Health has the authority to direct the PMPRB to inquire into any other matter.

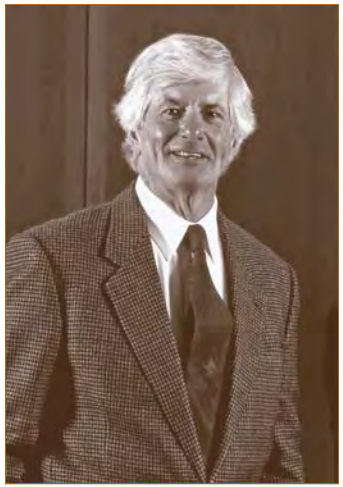
In 2001, federal/provincial/territorial Ministers of Health announced the establishment of the National Prescription Drug Utilization Information System (NPDUIS), and the Minister of Health subsequently requested that the PMPRB conduct research and analysis in support of this initiative.

In 2005, the Minister of Health, on behalf of federal/provincial/territorial Ministers of Health, directed the PMPRB to monitor and report on non-patented prescription drug prices. Since 2008, this work has been conducted under the umbrella of the NPDUIS initiative.

Governance

The Board consists of not more than five members who serve on a part-time basis. Board Members, including a Chairperson and a Vice-Chairperson, are appointed by the Governor-in-Council. The Chairperson is designated under the *Patent Act* as the Chief Executive Officer of the PMPRB with the authority and responsibility to supervise and direct its work.

Members of the Board



Chairman
Brien G. Benoit, BA, MD, MSc, FRCSC, FACS

Brien G. Benoit was first appointed as a Board Member of the PMPRB in May 2005, and in October of the same year he became Vice-Chairman, assuming the responsibilities of Chairman until his permanent appointment in June 2006. Dr. Benoit's term ended on May 18, 2010.

A neurosurgeon, Dr. Benoit is on the Active Attending Staff of The Ottawa Hospital, and is a Professor of Neurosurgery at the University of Ottawa, where he is regularly involved in the training of neurosurgical residents. Throughout his career, he has held several administrative positions including Chief of Neurosurgery of the Ottawa Civic/The Ottawa Hospital (1980–2003), Chief of Surgery of the Ottawa Civic Hospital (2002–2003), Program Director for Neurosurgery at the University of Ottawa (1995–2003), Chair of Neurosurgery at the University of Ottawa (1997–2003) and Deputy Surgeon-in-Chief of The Ottawa Hospital – Civic Campus (2002–2004).

Dr. Benoit has published extensively in leading academic journals and has participated in several multi-centre clinical trials. He was awarded Best Surgical Teacher from the Department of Surgery at the University of Ottawa in 1991 and 2000.

In addition to being a Fellow of the Royal College of Physicians and Surgeons of Canada, Dr. Benoit is a member of several professional associations including the Canadian Medical Association, the Ontario Medical Association, the American College of Surgeons, the Canadian Neurosurgical Society and the Congress of Neurological Surgeons.

Vice-Chairperson
Mary Catherine Lindberg, BSP

Mary Catherine Lindberg was appointed Member and Vice-Chair of the Board in June 2006. On May 19, 2010, Ms. Lindberg assumed the powers and functions of the Chairperson while the office is vacant.

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.

Thomas (Tim) Armstrong, BA, LLB, QC, O. Ont.

Tim Armstrong was first appointed Member of the Board in October 2002. He was re-appointed for a second term in 2007.

Mr. Armstrong practiced law from 1958 to 1974, first in the Civil Litigation Division of the federal Department of Justice, and subsequently in private practice in Toronto with Jolliffe, Lewis & Osler. He later became the senior partner of Armstrong & MacLean, specializing in administrative law litigation, presenting cases to administrative tribunals, the Ontario Courts, the Federal Court, and the Supreme Court of Canada.

In 1974, he began his career as a senior Ontario public servant as Chair of the Ontario Labour Relations Board (1974–1976), Deputy Minister of Labour (1976–1986), Agent General for Ontario in Tokyo (1986–1990), and Deputy Minister of Industry, Trade and Technology (1991–1992). He was advisor to the Premier of Ontario on Economic Development from 1992 to 1995.

Mr. Armstrong was counsel to the law firm McCarthy Tétrault from 1995 to 2002. In the 1990s he served as a member on the boards of directors of Algoma Steel, deHavilland Aircraft and Interlink Freight.

He has been Chief Representative for Canada for the Japan Bank for International Cooperation since 1996 and also serves as arbitrator and mediator by consensual, provincial and federal government appointment in the field of labour relations. In his dispute resolution work, he was appointed facilitator/mediator by the Ontario Health Services Restructuring Commission from 1998–1999. Subsequently, in 2002–2003, he was designated by the Ontario government as mediator/arbitrator under the *City of Toronto Labour Disputes Resolution Act*.

He is currently the Chair of the Radiation Safety Institute of Canada. His report to the Ontario government on trades and apprenticeship was the basis for new legislation in Ontario: *The College of Trades and Apprenticeship Act*.

Mr. Armstrong was awarded the Order of Ontario in 1995 in recognition of his contribution to public service in Ontario.

Anthony Boardman, BA, PhD

Anthony Boardman was appointed Member of the Board in January 1999 and was re-appointed in March 2005. His term ended March 10, 2010.

Dr. Boardman is the Van Dusen Professor of Business Administration in the Strategy and Business Economics Division of the Sauder School of Business at the University of British Columbia (UBC). He graduated from the University of Kent at Canterbury (BA, 1970) and Carnegie-Mellon University (PhD, 1975). Prior to taking up his position at UBC, he was a professor at the Wharton School, University of Pennsylvania.

His current research interests include public-private partnerships, cost-benefit analysis and strategic management. He has taught executive programs in Finland, China, Australia and elsewhere, and has won a number of teaching awards, including the Alan Blizzard award.

Dr. Boardman has been a consultant to many private and public organizations including Vodafone, Stora Enzo, PricewaterhouseCoopers, the Treasury of New Zealand and all levels of government in Canada. Between 1995 and 2001, he was a member of the Pharmacoeconomic Initiative Scientific Committee in BC. He served two terms as Chair of the Strategy and Business Economics Division at UBC and is currently on the editorial boards of the *Journal of Comparative Policy Analysis* and *Strategic Outsourcing: An International Journal*.

He has published many articles in leading academic journals and recently received the J.E. Hodgetts Award for the best paper published in *Canadian Public Administration* in 2008 (with A.R. Vining). He also recently completed the fourth edition of *Cost–Benefit Analysis: Concepts and Practice*, and co-edited the *International Handbook on Public–Private Partnerships*, to be published later this year.

Anne Warner La Forest, LLB (UNB), LLM (Cantab)

Anne Warner La Forest was appointed Member of the Board in March 2007.

Ms. La Forest is currently a law professor at the University of New Brunswick. Member of the New Brunswick Securities Commission since 2004, she was also the Chair of the Commission's Human Resources Committee until June 2008 and was appointed Lead Member of the Commission in July of 2008.

After working in private practice with the firm of Fraser & Beatty in Toronto for several years, Ms. La Forest joined the Faculty of Law at Dalhousie University in 1991. In 1996, she was appointed Dean of the Faculty of Law of the University of New Brunswick, a position she held until 2004. A member of the bars of New Brunswick, Nova Scotia and Ontario, Ms. La Forest has extensive experience as an arbitrator and has acted as a consultant on matters relating to human rights, employment, property and extradition law. She has been a member of the Nova Scotia Human Rights Tribunal, a member of the Social Sciences and Humanities Research Council and Chair of the Fellowships Committee. She has also served as Arbitrator in the province of Nova Scotia as well as Commissioner of the province's Human Rights Commission. She is a Fellow of the Cambridge Commonwealth Society and is currently a member of the Board of Governors of the National Judicial Institute.

She holds an LL.M. degree in International Law from Cambridge University in the United Kingdom.

Ms. La Forest has published many articles, books and case comments during her career and has been the chair or has served as a panellist at many national and international law conferences.

PMPRB Senior Staff

Senior Staff consists of the Executive Director, the Director of Regulatory Affairs and Outreach, the Director of Policy and Economic Analysis, the Director of Corporate Services, the Director of Board Secretariat and Communications, and the General Counsel.

Executive Director

The Executive Director is responsible for overall advice to the Board and for the leadership and management of the Staff.

Regulatory Affairs and Outreach

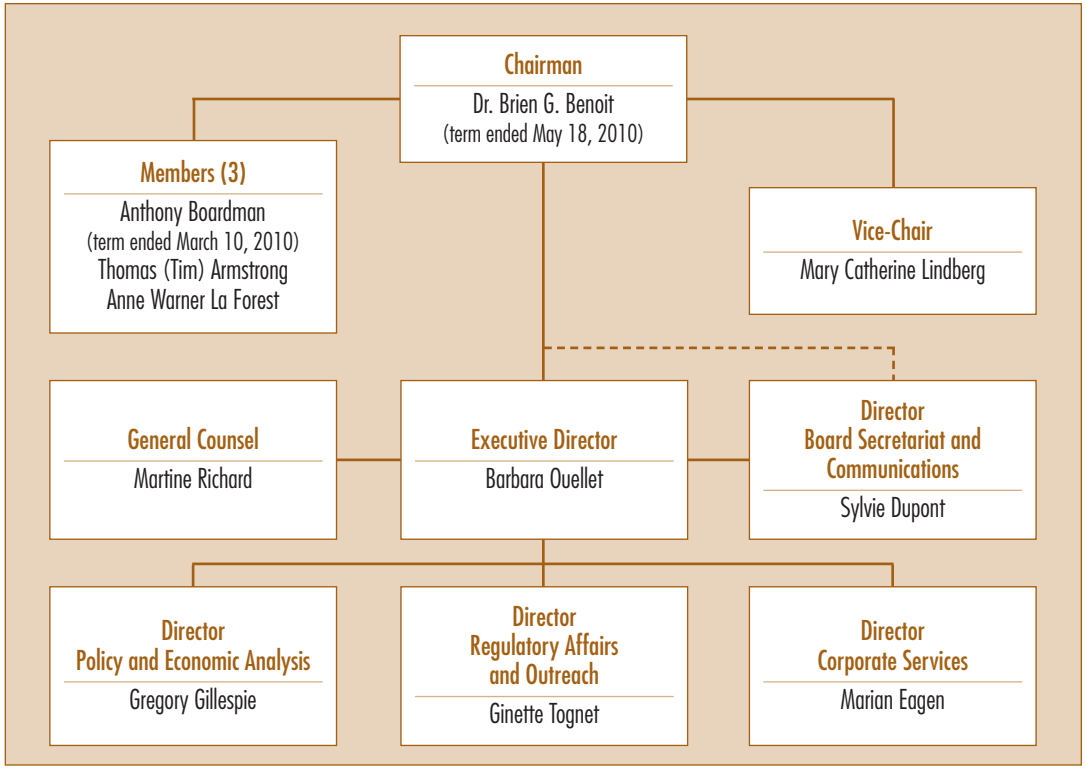
The Regulatory Affairs and Outreach Branch reviews the prices of patented drug products sold in Canada to ensure that they are not excessive; encourages patentees to comply voluntarily with the Board's Guidelines; implements related compliance policies; and investigates complaints into the prices of 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 advice and recommendations on possible changes to the Board's Guidelines and on other policy issues, as required; conducts research and economic analysis on pharmaceutical trends and prepares reports; and conducts studies both in support of compliance and enforcement and as directed by the Minister of Health.

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 strategic and financial planning and reporting, audit and evaluation, and liaison with federal central agencies on these topics.



Board Secretariat and Communications

The Board Secretariat and Communications 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*.

General Counsel

The General Council advises the PMPRB on legal matters and leads the prosecution team in proceedings before the Board.

Budget

The PMPRB operated with a budget of $11.9 million in 2009–2010 and an approved staff level of 76 full-time equivalent employees.

Table 1 Budget and Staffing

	2008–2009	2009–2010	2010–2011
Total PMPRB	$11,122 M	$11,971 M	$12,181 M
FTEs	71	76	76

Regulating Prices of Patented Medicines

Board Staff reviews pricing information for all patented drug products sold in Canada on an ongoing basis to ensure that the prices charged by patentees comply with the Guidelines established by the Board. The Guidelines are based on the price determination factors in Section 85 of the Act and have been developed by the Board in consultation with stakeholders including the provincial and territorial Ministers of Health, consumer groups, and the pharmaceutical industry. For the purposes of this section, the references to the Guidelines are to the pre-2010 Guidelines.

Regulatory Reporting Requirements

The *Patent Act* (Act) and the *Patented Medicines Regulations* (Regulations) set out the filing requirements pertaining to price regulation for a patentee or former patentee of an invention pertaining to a patented medicine that falls under the jurisdiction of the PMPRB.

Information on the reporting requirements is available in the Act, the Regulations, the Guidelines, and the Patentees' Guide to Reporting, all of which can be found on the PMPRB's Web site.

In order to fulfill its regulatory mandate, the PMPRB relies upon the patentees' full and timely disclosure of any and all drug products being sold in Canada to which a patent pertains.

Failure to Report

Failure to report a drug product to which a patent pertains is an important issue because it delays the price review. In 2009, 23 new drug products were first reported to the PMPRB, although they were patented and sold prior to 2009.

Table 2 lists the drug products that were patented and sold in Canada prior to being reported as being under the PMPRB's jurisdiction.

Failure to File Price and Sales Data (Form 2)

The Board is pleased to report that there were no Board Orders issued for the 2009 reporting period.

Table 2 Failure to Report

Currently being sold by	Brand Name	Generic Name	Year Medicine Came Under PMPRB's Jurisdiction
Biovail Pharmaceuticals Canada	Raliva 100 mg/tablet, 200 mg/tablet, 300 mg/tablet	tramadol hydrochloride	2007
Boehringer Ingelheim (Canada) Ltd.	Mirapex 0.125 mg/tablet	pramipexole dihydrochloride	2008
Hospira Healthcare Corporation (Canada)	Paclitaxel 6 mg/mL	paclitaxel	2008
	Pamidronate Disodium 30 mg/vial, 60 mg/vial, 90 mg/vial	pamidronate disodium	2003
	Precedex 100 mcg/mL	dexmedetomidine hydrochloride	2008
Genzyme Canada Inc.	Clolar 20 mg/vial	clofarabine	2005
Paladin Labs Inc.	Tridural 100 mg/tablet, 200 mg/tablet, 300 mg/tablet	tramadol hydrochloride	2007
Ranbaxy Pharmaceuticals Canada Inc.	Ran-Pantoprozole 20 mg/tablet, 40 mg/tablet	pantoprozole sodium	2008
	Ran-Rabeprazole 10 mg/tablet, 20 mg/tablet	rabeprazole sodium	2007
	Ran-Risperidone 0.25 mg/tablet, 0.5 mg/tablet, 1 mg/tablet, 2 mg/tablet, 3 mg/tablet, 4 mg/tablet	risperidone	2006

The PMPRB is responsible for regulating the prices that patentees charge for prescription and non-prescription patented drugs sold in Canada to wholesalers, hospitals, pharmacies or others, for human and veterinary use, to ensure that they are not excessive.

Human Drug Advisory Panel

The Board established the Human Drug Advisory Panel (HDAP) to provide recommendations for the categorization of new drug products and the selection of comparable drug products.

The mandate of the HDAP is to provide credible, independent, and expert scientific advice to the PMPRB respecting the development and application of the Guidelines as they relate to the scientific evaluation of patented drug products. The approach is evidence-based and the recommendations reflect medical and scientific knowledge and current clinical practice.

The HDAP was initially composed of three members:

- Dr. Jean Gray, Professor Emeritus of Medical Education, Medicine and Pharmacology at Dalhousie University
- Dr. Mitchell A.H. Levine, Professor in the Department of Clinical Epidemiology and Biostatics at McMaster University and Director of the Centre for Evaluation of Medicines, St. Joseph's Healthcare in Hamilton
- Dr. Adil Virani, Director of Pharmacy Services at the Fraser Health Authority and Associate Professor in the Faculty of Pharmaceutical Sciences at the University of British Columbia

In January 2010, as part of the implementation of the new Guidelines, membership of the HDAP was increased to six members. New members are listed below:

- Dr. Fred Y. Aoki, Professor of Medicine, Medical Microbiology and Pharmacology and Therapeutics at the University of Manitoba
- Dr. Jacques LeLorier, Professor in the Departments of Medicine and Pharmacology at the University of Montreal and Adjunct Professor in the Department of Epidemiology and Biostatistics at McGill University
- Dr. Muhammad Mamdani, Director of the Applied Health Research Centre, Li Ka Shing Knowledge Institute at St. Michael's Hospital, Toronto and Associate Professor in the Department of Health Policy, Management and Evaluation at the University of Toronto

New Patented Drug Products in 2009

There were 81 new patented drug products, or DINs, for human use reported as sold in 2009. Some are one or more strengths of a new active substance and others are new presentations of existing medicines.

For purposes of the PMPRB's price review, a new patented drug product in 2009 is defined as any patented drug product first sold in Canada, or previously sold but first patented, between December 1, 2008, and November 30, 2009.

Figure 1 provides information on new patented drug products for human use from 1989 to 2009.

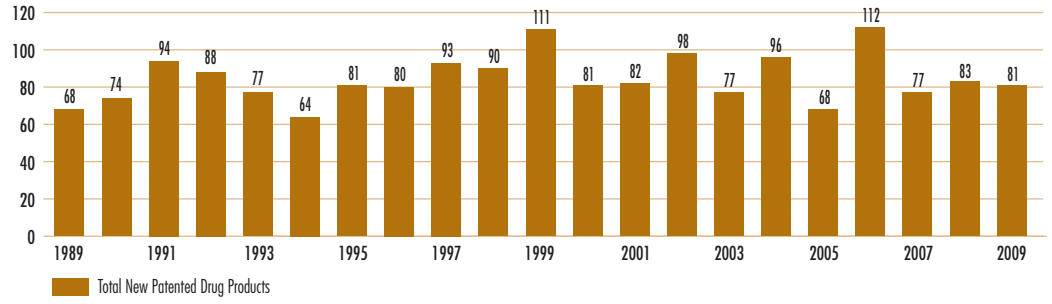
Of the 81 new patented DINs, 16 (20%) were being sold in Canada prior to the issuance of a Canadian patent that brought them under the PMPRB's jurisdiction. These DINs are denoted by "FPG" (first patent granted) in Annex 2 on page 46. Table 3 identifies the number of patented drug products by the year in which they were first sold. The delay between date of first sale and date of patent grant for these products ranged from several months to several years; one was first sold prior to the creation of the PMPRB in 1987 (Miochol-E sold by Novartis Pharma Canada Inc. for cataract surgery).

The list of New Patented Medicines Reported to the PMPRB is posted on the Web site every quarter. This list includes information on the status of the review (i.e., under review, within Guidelines, under investigation, VCU, Notice of Hearing).

TABLE 3
New Patented Drug Products for Human Use Reported to PMPRB in 2009 by Year First Sold

Year First Sold	No. of DINs
2009	68
2008	3
2007	7
2006	0
2005	0
2004	1
2003	1
1960	1
Total	**81**

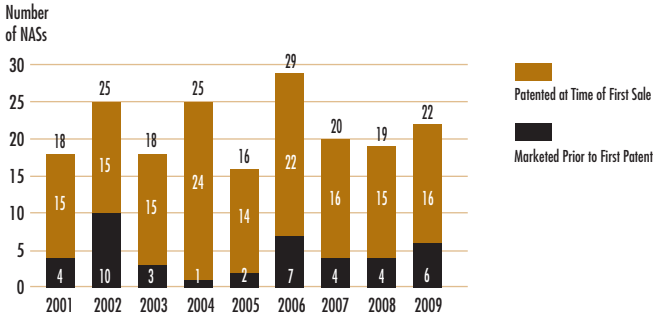
FIGURE 1 New Patented Drug Products for Human Use



New Active Substances in 2009

A new active substance (NAS) may involve more than one DIN if it is sold in more than one strength or dosage form. In 2009, there were 22 NASs marketed as 30 DINs. As shown in Figure 2 and Table 4, six of the 22 patented NASs that came under the PMPRB's jurisdiction were sold prior to 2009.

FIGURE 2 New Active Substances, 2001–2009



Summary Reports of the price reviews of NASs are posted on the PMPRB Web site when the price review is completed and the price is within the Guidelines. Figure 3 provides a breakdown of the patented NASs for human use, by category assigned for price review purposes, over the nine-year period from 2001 through 2009 inclusive.

FIGURE 3 New Active Substances by Therapeutic Category, 2001–2009

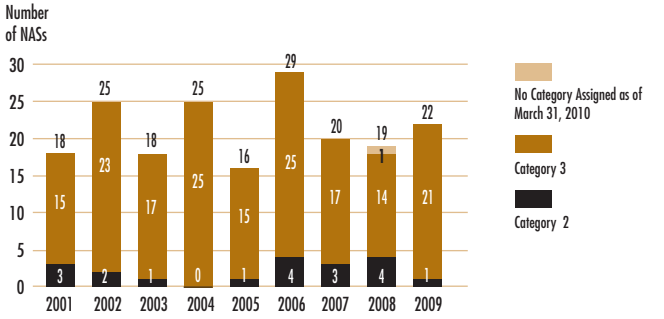


TABLE 4 New Active Substances in 2009

Brand Name	Chemical Name	Company	# DINs	Therapeutic Use
Alrex	loteprednol etabonate	Bausch & Lomb Canada Inc.	1	Allergic conjunctivitis
Cimzia	certolizumab pegol	UCB Canada Inc.	1	Rheumatoid arthritis
Doribax	doripenem	Janssen-Ortho Inc.	1	Antibiotic
Emend IV	fosaprepitant dimeglumine	Merck Frosst Canada Ltd.	1	Prevention of nausea resulting from chemotherapy
Firmagon	degarelix	Ferring Inc.	2	Prostate cancer
Lotemax	loteprednol etabonate	Bausch & Lomb Canada Inc.	1	Inflammation from cataract surgery
Metvix	methyl aminolevulinate hydrochloride	Galderma Canada Inc.	1	Antineoplastic
Multaq	dronedarone hydrochloride	sanofi-aventis Canada Inc.	1	Antiarrhythmic
Olmetec	olmesartan medoxomil	Schering-Plough Canada Inc.	2	Antihypertensive
Olmetec Plus	olmesartan medoxomil / hydrochlorothiazide	Schering-Plough Canada Inc.	3	Antihypertensive
Pristiq	desvenlafaxine succinate	Wyeth Pharmaceuticals	2	Antidepressant
Stelara	ustekinumab	Janssen-Ortho Inc.	1	Psoriasis
Synflorix	pneumococcal conjugate vaccine	GlaxoSmithKline Inc.	1	Vaccine
Tykerb	lapatinib ditosylate	GlaxoSmithKline Inc.	1	Breast cancer
Xeomin	clostridium botulinum neurotoxin type A	Merz Pharma Canada Ltd.	1	Muscle relaxant
Zolinza	varinostat	Merck Frosst Canada Ltd.	1	Antineoplastic

New Active Substances First Sold Prior to 2009

Brand Name	Chemical Name	Company	# DINs	Therapeutic Use
Abilify	aripiprazole	Bristol-Myers Squibb Canada Co.	1	Schizophrenia
Apidra Solostar	insulin glulisine	sanofi-aventis Canada Inc.	1	Diabetes
Somatuline Autogel	lanreotide acetate	Tercica Inc.	2	Antigrowth
Sprycel	dasatinib	Bristol-Myers Squibb Canada Co.	3	Leukemia
Tasigna	nilotinib	Novartis Pharma Canada Inc.	1	Leukemia
Zeftera	ceftobiprole medocaril	Janssen-Ortho Inc.	1	Antibacterial

Price Review of New Patented Drug Products for Human Use in 2009

A list of the 81 new patented drug products and their price review status appears in Annex 2 on page 46. Of the 81 new patented DINs,

- the prices of 54 had been reviewed as of March 31, 2010:
  - 50 were found to be within the Guidelines;
  - 4 were priced at levels that appeared to exceed the Guidelines and investigations were commenced (for a more detailed explanation of the criteria for commencing an investigation, please refer to Annex 1 on page 45)
- the prices of 27 DINs are still under review.

Table 5 Status of New Patented Drug Products Reported to the PMPRB, 2003–2008

	2003	2004	2005	2006	2007	2008
New Drug Products (DINs) reported in Annual Report	70	94	66	99	64	78
Failure to file reported after publication of annual report	7	2	2	13	13	5
Total DINs for year	**77**	**96**	**68**	**112**	**77**	**83**
Under Review	0	0	0	0	1*	0
Within Guidelines	72	78	60	100	71	77
Investigation	0	0	0	5	2	5
Voluntary Compliance Undertaking (VCU)	1 (Dukoral)	2 (Paxil CR) 1 (Hextend) 2 (Eloxatin) 1 (Forteo)	1 (Nuvaring) 1 (Vaniqa)	1 (Denavir) 1 (Lantus) 1 (Andriol) 3 (Trinipatch) 1 (Levemir)	2 (Androgel) 1 (Voluven)	1 (Xarelto)
Notice of Hearing (NoH)	–	1 (Penlac) 1 (Copaxone)	–	–	–	–
NoH/VCU	1 (Evra) 3 (Concerta)	3 (Risperdal Consta) 1 (Neulasta)	5 (Strattera) 1 (Concerta)	–	–	–
NoH Complete	–	6 (Adderall XR)	–	–	–	–

*as a result of a Failure to Report

Update of New Patented Drug Products reported in previous Annual Reports

Table 5 provides an update of the review status of new patented drug products, at the DIN level, reported in previous years' Annual Reports.

Price Review of Existing Patented Drug Products for Human Use in 2009

For the purpose of this report, existing patented drug products (DINs) include all patented drug products that were first sold and reported to the PMPRB prior to December 1, 2008. At the time of this report, there were 1,096 existing DINs:

- the prices of 1,003 existing DINs (91.5%) were within the Guidelines
- 86 existing DINs were the subject of investigations
  - of these, 12 were opened as result of introductory pricing
    - 5 in 2006
    - 2 in 2007
    - 5 in 2008
  - 74 were opened on the basis of year-over-year prices
- an additional 19 DINs remain under investigation, although 3 DINs were no longer sold and 16 were no longer patented in 2009
- 1 existing DIN was still under review
- 4 DINs – Apo-Salvent CFC Free, Copaxone, Penlac and ratio-salbutamol HFA – were the subject of a price hearing under section 83 of the Act (see Hearings, on page 15);
  - Penlac was not under the Board's jurisdiction in 2009 as the patent pertaining to this medicine expired in 2008
- 6 DINs – Neulasta, Nicoderm (3 DINs), Quadracel and Pentacel were the subject of price hearings that were completed by way of a VCU or a Board Order (see Hearings on page 15)
  - Nicoderm was not under the Board's jurisdiction in 2009

A summary of the status of the price review of the new and existing patented drug products for human use in 2009 is provided in Table 6.

TABLE 6 Patented Drug Products (DINs) for Human Use Sold in 2009 – Status of Price Review as of March 31, 2010

	New Drugs Introduced in 2009	Existing Drugs	Total
Total	81	1,096	1,177
Within Guidelines	50	1,003	1,053
Under Review	27	1	28
Under Investigation	4	86	90
Price Hearings		3	3
Completed Price Hearings		3	3

Update from the 2008 Annual Report

- review of 17 of the 18 drug products for human use and all of the 8 veterinary drug products reported as under review in the 2008 Annual Report have been completed
- 67 of the 125 investigations reported in the 2008 Annual Report resulted in:
  - the closure of the investigation where it was concluded that the price was within the Guidelines;
  - a Voluntary Compliance Undertaking (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, on page 12 for information on VCUs approved in 2009); and
  - a public hearing to determine whether the price was excessive, including any remedial Order determined by the Board (see page 15 for information on Hearings in 2009).

Patented Over-the-Counter Drug Products and Patented Drug Products for Veterinary Use

Board Staff will only review the price of a patented over-the-counter drug product and a patented veterinary drug product when a complaint has been received. No complaints were received in 2009.

Common Drug Review and the PMPRB

The Common Drug Review (CDR) is a single process for reviewing new drugs and providing recommendations on formulary listing to participating publicly funded federal, provincial and territorial drug benefit plans in Canada. All jurisdictions participate except Québec. The CDR reviews new drugs and provides an evidence-based recommendation by the Canadian Expert Drug Advisory Committee (CEDAC) based on cost-effectiveness. The drug plans consider the CEDAC recommendation and their individual plan mandates, priorities and resources when making listing and coverage decisions. More information on CDR and CEDAC is available from the Canadian Agency for Drugs and Technologies in Health (CADTH) Web site (www.cadth.ca).

Table 7 lists drugs reviewed by the CDR in 2009 and their status under the PMPRB Guidelines. The CDR reviews drug products once a Notice of Compliance has been issued by Health Canada. Drugs sold in Canada without a patent or before a patent has been issued do not fall under the PMPRB's jurisdiction.

TABLE 7 Common Drug Review Recommendations and PMPRB Status

CEDAC Recommendation In 2009			PMPRB Status	Therapeutic Use
alendronate sodium/cholecalciferol	Fosavance 70/5600	List**	Within Guidelines	Osteoporosis
clostridium botulinum toxin type A	Xeomin	List**	Under Review	Muscle relaxant
dabigatran extexilate	Pradax	Do Not List	Within Guidelines	Venous throembolic events
desvenlafaxine succinate	Pristiq	Do Not List	Within Guidelines	Antidepressant
eplerenone	Inspra	Do Not List	Not Under PMPRB Jurisdiction	Post myocardial infarction
insulin glulisine	Apidra	List**	Under Review	Diabetes
levodopa/carbidopa	Duodopa	Do Not List	Patented, No Sales Reported	Parkinson's Disease
lisdexamfetamine dimesylate	Vyvanse	Do Not List	Not Under PMPRB Jurisdiction	ADHD
methylnaltrexone bromide therapy	Relistor	Do Not List	Within Guidelines	Constipation due to opioid
olmesartan medoxomil	Olmetec	List**	Within Guidelines	Antihypertensive
olmesartan medoxomil/ hydrochlorothiazide	Olmetec Plus	List**	Within Guidelines	Antihypertensive
ustekinumab	Stelara	List*	Within Guidelines	Psoriasis

* List with criteria/condition
** List in a manner similar to other drugs in class

Sources: PMPRB and CADTH

Voluntary Compliance Undertakings and Hearings

Board Staff reviews the prices of all patented drug products sold in Canada. When it finds that the price of a patented drug product appears to exceed the Guidelines, and the circumstances meet the criteria for commencing an investigation, Board Staff will conduct an investigation to determine if the price of the patented drug product in fact exceeds the Guidelines. Additional information on the criteria for commencing an investigation is available in Annex 1 on page 45. An investigation could result in:

- its closure where it is concluded that the price was within the Guidelines;
- a Voluntary Compliance Undertaking (VCU) by the patentee to reduce the price and offset excess revenues obtained as a result of excessive prices through a payment and/or a price reduction of another patented drug product; or
- a public hearing to determine if the price is excessive, including any remedial order determined by the Board.

Voluntary Compliance Undertakings

A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to comply with the Board's Guidelines including adjusting its price to a non-excessive level and offsetting excess revenues. 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 can also be submitted following the issuance of a Notice of Hearing but, at this point, must be approved by the Hearing Panel.

In 2009, the Board approved 10 VCUs, three following the issuance of a Notice of Hearing (NoH):

- Andriol, Schering-Plough Canada Inc.
- Brevibloc, Baxter Corporation
- Claritin Allergy & Sinus Extra Strength, Schering-Plough Canada Inc.
- Concerta, Janssen-Ortho Inc. (NoH)
- Eligard, sanofi-aventis Canada Inc.
- Neulasta, Amgen Canada Inc. (NoH)
- Strattera, Eli Lilly Canada Inc. (NoH)
- Suprax, sanofi-aventis Canada Inc.
- Trinipatch, Novartis Pharmaceuticals Canada Inc.
- Vepesid, Bristol-Myers Squibb Canada Inc.

Andriol, Schering-Plough Canada Inc.

On October 16, 2009, the Chairman of the Board accepted a VCU submitted by Schering-Plough Canada Inc. for the patented drug product Andriol 40 mg/capsule. Under the terms of the VCU, Schering-Plough, among other things, offset excess revenues received by making a payment to the government of Canada totaling $348,605.86 and provided a discount of 21.25% against the 2009 maximum non-excessive (MNE) price to all customers.

Andriol (testosterone undecanoate) is indicated for the replacement therapy in males in conditions associated with symptoms of deficiency or absence of endogenous testosterone: for the management of congenital or acquired primary hypogonadism and hypogonadotropic hypogonadism; to develop and maintain secondary sexual characteristics in males with testosterone deficiency; to stimulate puberty in carefully selected males with clearly delayed puberty not secondary to a pathological disorder. Andriol is used as a replacement therapy in impotence or for male climacteric symptoms when the conditions are due to a measured or documented androgen deficiency.

Brevibloc, Baxter Corporation

On October 5, 2009, the Chairman of the Board accepted a VCU submitted by Baxter Corporation for the patented drug product Brevibloc. Baxter offset excess revenues received by making payments totaling $212,440.76 to customers that previously purchased Brevibloc.

Brevibloc (esmolol hydrochloride) is indicated for the perioperative management of tachycardia and hypertension in patients in whom there is a concern for compromised myocardial oxygen balance and who, in the judgment of the physician, are clearly at risk of developing hemodynamically-induced myocardial ischemia, and for the rapid control of ventricular rate in patients with atrial fibrillation or atrial flutter in acute situations when the use of a short-acting agent is desirable.

Claritin Allergy & Sinus Extra Strength, Schering-Plough Canada Inc.

On December 2, 2009, the Chairman approved a VCU submitted by Schering-Plough for the patented drug product Claritin Allergy & Sinus Extra Strength. Under the terms of the VCU, Schering-Plough offset cumulative excess revenues by making a payment to the Government of Canada in the amount of $69,950.43.

Claritin Allergy & Sinus Extra Strength (10 mg loratadine / 240 mg pseudoephedrine sulphate) is indicated for the relief of symptoms associated with allergic rhinitis, including nasal and sinus congestion, sneezing, postnasal discharge and tearing and redness of the eyes.

Concerta, Janssen-Ortho Inc.

On April 24, 2009, the Hearing Panel approved a VCU submitted jointly by the parties, thereby concluding the proceedings commenced in this matter with the issuance of a Notice of Hearing on July 24, 2006. Under the terms of the VCU, among other things, Janssen-Ortho Inc. offset excess revenues in the amount of $1,464,441.58 by making a payment to the Government of Canada.

Concerta is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Eligard, sanofi-aventis Canada Inc.

On April 20, 2009, the Chairman approved a VCU submitted by sanofi-aventis for the patented drug product Eligard. In addition to reducing the price of Eligard in the majority of provinces based on 2009 MNE prices determined as of December 31, 2009, sanofi-aventis offset the cumulative excess revenues received from January 2005 to December 2008 by making a payment to the Government of Canada in the amount of $13,127,953.14. Payments to offset excess revenues accrued during the 2009 period were made directly to hospitals, cancer clinics and cancer boards that purchased Eligard.

Eligard (leuprolide acetate) is indicated for the palliative treatment of advanced prostate cancer.

Neulasta, Amgen Canada Inc.

On October 21, 2009, The Hearing Panel approved a VCU submitted jointly by the parties, thereby concluding the proceedings initiated with the issuance of a Notice of Hearing on March 16, 2009. Under the terms of the VCU, Amgen reduced the price at which it sells Neulasta to the 2009 MNE; made a payment to the Government of Canada in the amount of $6,730,120.32 to offset any revenues above the maximum prices from the date of introduction of Neulasta to June 30, 2009; and offset revenues greater than the 2009 maximum price received by Amgen from July 1, 2009, to December 31, 2009, by making a second payment to the Government of Canada in the amount of $687,724.53.

Neulasta is a new active substance (pegfilgrastim) indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with cancer receiving myelosuppressive chemotherapy.

Strattera, Eli Lilly Canada Inc.

On February 19, 2009, the Hearing Panel approved a VCU for Strattera, thereby concluding the proceedings commenced in this matter with the issuance of a Notice of Hearing on December 15, 2006. Under the terms of the VCU, Eli Lilly offset excess revenues by making two payments to the Government of Canada in the amounts of $15,326,066.49 and $108,157.85, respectively.

Strattera is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years and over, adolescent and adults.

Suprax, sanofi-aventis Canada Inc.

On March 9, 2009, the Chairman approved a VCU from sanofi-aventis for the patented drug product Suprax 400 mg/tablet. Among other things, sanofi-aventis reduced the price of Suprax so that it did not exceed the 2009 MNE price and offset excess revenues received by making two payments to the Government of Canada in the amounts of $97,900.30 and $31,532.93, respectively.

Suprax 400 mg/tablet (cefixime) is an antibiotic used in the treatment of infections caused by susceptible strains of designated micro-organisms.

Trinipatch, Novartis Pharmaceuticals Canada Inc.

On November 18, 2009, the Chairman approved a VCU from Novartis for Trinipatch. Novartis offset excess revenues by making a payment to the Government of Canada in the amount of $47,099.61.

Trinipatch® (nitroglycerin), a patented medicine sold in Canada from March 16, 2006, to January 13, 2009, was indicated for the prevention of anginal attacks in patients with stable angina pectoris associated with coronary artery disease.

Vepesid, Bristol-Myers Squibb Canada Co.

On February 23, 2009, the Chairman approved a VCU submitted by Bristol-Myers Squibb for Vepesid. Among other things, Bristol-Myers Squibb offset excess revenues of $53,161.48 by making payments to customers who previously purchased Vepesid at excessive prices.

Vepesid (etoposide) is used in combination with other established antineoplastic agents in the treatment of neoplastic diseases.

In 2010, up to May 31, the Board approved 7 VCUs:

- Adenoscan, Astellas Pharma Canada Inc.
- Dicetel, Solvay Pharma Inc.
- FSME-IMMUN, Baxter Corporation
- Levemir Penfill, Novo Nordisk Canada Inc.
- Paxil CR, GlaxoSmithKline
- Voluven, Fresenius Kabi Canada
- Xarelto, Bayer Inc.

Adenoscan, Astellas Pharma Inc.

On May 8, 2010, the Chairman approved the VCU submitted by Astellas Pharma Inc. for the medicine Adenoscan. Under the terms of the VCU, Astellas Pharma offset cumulative excess revenues from 1996 to August 4, 2009 (patent expiry date), in the amount of $34,545.32 by making a payment to the Government of Canada.

Adenoscan (adenosine injection) is indicated as an adjunct to thallium 201 myocardial perfusion scintigraphy in patients unable to exercise adequately.

Dicetel, Solvay Pharma Inc.

On May 13, 2010, the Chairman approved the VCU submitted by Solvay Pharma Inc. for the medicine Dicetel. Under the terms of the VCU, Solvay Pharma offset cumulative excess revenues received from January 1, 2008 to December 31, 2009, by making a payment to the Government of Canada in the amount of $31,287.32. Solvay will make an additional payment to the Government of Canada for any excess revenues received from January 1, 2010 to the date of the acceptance of this VCU as calculated by Board Staff, or or before August 30, 2010.

Dicetel is indicated for the treatment and relief of symptoms associated with irritable bowel syndrome (IBS), abdominal pain, bowel disturbances and intestinal discomfort; as well as the treatment of symptoms related to functional disorders of the biliary tract.

FSME-IMMUN, Baxter Corporation

On March 31, 2010, the Chairman approved the VCU submitted by Baxter Corporation for the patented medicine FSME-IMMUN. Under the terms of the VCU, Baxter reduced the price of FSME-IMMUN and offset cumulative excess revenues received from January 1, 2002, to December 31, 2009, in the amount of $53,578.62 by making a payment to the Government of Canada.

FSME-IMMUN (tick-borne encephalitis vaccine – inactivated) is indicated for immunization against the TBE virus in individuals 16 years and older who are at risk of contact with ticks that carry TBE virus.

Levemir Penfill, Novo Nordisk Canada Inc.

On May 8, 2010, the Chairman approved the VCU submitted by Novo Nordisk Canada Inc. for the medicine Levemir. Under the terms of the VCU, Novo Nordisk Canada is to offset cumulative excess revenues received from January 3, 2006, to December 31, 2009, by making a payment to the Government of Canada in the amount of $6,035,903.54 on or before June 14, 2010. Novo Nordisk Canada also undertook to make an additional payment to the Government of Canada for excess revenues received from January 1 to March 31, 2010, based on its filing of price and sales data for the said period in the amount of the excess revenues as calculated by Board Staff.

Levemir Penfill is indicated for the treatment of adult patients with type 1 or type 2 diabetes mellitus who require a long-acting (basal) insulin for the maintenance of normal glucose homeostasis.

Paxil CR, GlaxoSmithKline Inc.

On March 31, 2010, the Chairman approved the VCU submitted by GlaxoSmithKline Inc. for the patented medicine Paxil CR. GlaxoSmithKline offset excess revenues received in the January 2004 to December 2005 reporting periods in the amount of $53,177.88 by making a payment to the Government of Canada.

Paxil CR (paroxetine hydrochloride) is indicated as a selective serotonin reuptake inhibitor in a new dosage form: controlled release tablets for the symptomatic treatment of depression and panic disorder.

Voluven, Fresenius Kabi Canada

On January 10, 2010, the Chairman approved a VCU submitted by Fresenius Kabi Canada for Voluven. Fresenius offset cumulative excess revenues in the amount of $1,448,002.25 by making a payment to the Government of Canada. Voluven is no longer under the PMPRB's jurisdiction, its patent having lapsed on August 7, 2008.

Voluven (hydroxyethyl starch) is indicated for the treatment of hypovolemia when plasma volume is required.

Xarelto, Bayer Inc.

Under the terms of a VCU approved by the Chairman on January 11, 2010, Bayer reduced the price of Xarelto and offset excess revenues received by making two payments to the Government of Canada in the amounts of $49,978.33 and $193,292.96, respectively.

Xarelto (rivaroxaban) is indicated for the prevention of venous thromboembolic events in patients who have undergone elective hip or total knee replacement surgery.

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

Hearings

In the event that the price of a patented medicine appears to be excessive, the Board can hold a public hearing, and 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. Board decisions are subject to judicial review in the Federal Court of Canada.

In 2009, the Board

- issued one Notice of Hearing – on price in the matter of Neulasta
- completed five hearings – in the matters of Concerta, Neulasta, Nicoderm, Quandracel and Pentacel, and Strattera

In 2010, up to May 31, the Board

- issued one Notice of Hearing – on failure to file in the matter of Sandoz Canada Inc.
- issued a Supplementary Order in the matter of Adderall XR

Decisions are pending in three matters: two on price – Penlac and ratio-Salbutamol HFA; and one on failure to file – ratiopharm Inc.

Four proceedings are ongoing: two on price – Apo-Salvent CFC Free and Copaxone for redetermination (as ordered by the Federal Court – see Matters before the Federal Court for more details); and two on failure to file – Apotex Inc. and Sandoz Canada Inc.

Since 1993, the Board has approved a total of 66 VCUs and initiated 24 public hearings. These measures resulted in price reductions and offset of excess revenues by way of payments to the Government of Canada and/or to customers such as hospitals and clinics.

Excess revenues offset by way of payments to the Government were in excess of $37 million in 2009 and nearly $6 million in 2010 to date.

More details on excess revenues collected under VCUs and Board Orders are available in Annex 3 on page 49.

Matters before the Federal Court

During the year, a number of Board decisions were subject to Judicial Review by the Federal Court.

Copaxone, Teva Neuroscience G.P.-S.E.N.C.

The Board issued a Notice of Hearing in the matter of Copaxone on May 8, 2006.

The Hearing Panel issued its decision and reasons on February 25, 2008, and its Order on May 12, 2008. The Respondent filed an application for Judicial Review with the Federal Court. In its decision of November 12, 2009, the Federal Court set aside the Board's decisions and returned the matter to the Board for redetermination preferably by a different panel.

Nicoderm, sanofi-aventis Canada Inc.

sanofi-aventis filed an Application for Judicial Review of the Board's decision to have this matter proceed on the merits of the case. On September 24, 2009, the Federal Court dismissed the Judicial Review.

Pentacel and Quadracel, sanofi pasteur Limited

The Board issued a Notice of Hearing in this matter on March 27, 2007. The Hearing Panel issued its decision and reasons on December 21, 2009, and an Order on March 16, 2010. sanofi pasteur filed an Application for Judicial Review of the Board's decision on January 19, 2010. At the time of publication of this report, a hearing date had not been announced.

Board August 18, 2008, Communiqué to Stakeholders

Following the Board's release of its August 18 Communiqué dealing with the issue of mandatory reporting of benefits, Rx&D et al. and Pfizer Canada Inc. commenced judicial reviews of the Board's Communiqué. The Federal Court released its decision on July 10, 2009, and concluded "that sections 4(1)(f)(i) and 4(4) of the *Patented Medicines Regulations* do not authorize the Board to require the reporting of rebates or payments made to third parties by the manufacturers of patented medicines." The decision was not appealed.

Matter before the Supreme Court of Canada

Thalomid, Celgene Corporation

A Hearing Panel of the Board heard parties on its jurisdiction in the matter of the medicine Thalomid, as provided to Canadian patients under Health Canada's Special Access Programme. In its decision of January 21, 2008, the Board asserted its jurisdiction over the price of Thalomid. Celgene Corporation filed an application for Judicial Review, which was heard by the Federal Court on March 3, 2009. The Federal Court's decision of March 17, 2009, dismissing the Board's decision, was appealed by the Attorney General of Canada. In its decision of December 21, 2009, the Federal Court of Appeal upheld the Board's decision. On April 22, 2010, Celgene Corporation was granted leave to appeal to the Supreme Court of Canada in this matter. At the time of the publication of this report, the Supreme Court of Canada had not confirmed a hearing date.

TABLE 8 Status of Board Proceedings in 2009 up to the Publication of this Report

Patented Drug Product	Indication / Use	Patentee	Issuance of Notice of Hearing – Date	Status
Adderall XR	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	Shire Canada Inc.	January 18, 2006	**Supplementary Board Order: May 5, 2010**
Apo-Salvent CFC Free	Relief of chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs	Apotex Inc.	July 8, 2008	**Ongoing**
Concerta	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	Janssen-Ortho Inc.	July 24, 2006	**VCU: April 24, 2009** *(details on page 13)*
Copaxone – *Redetermination*	Use in ambulatory patients with relapsing-remitting multitude sclerosis to reduce the frequency of relapses	Teva Neuroscience G.P.-S.E.N.C.	May 8, 2006	**Federal Court Decision: Nov. 12, 2009 ordered redetermination Hearing: Oct. 4-5, 2010**
Nicoderm	Smoking cessation	sanofi-aventis Canada Inc.	April 20, 1999	**Board Decision: April 9, 2010**
Penlac	Part of a comprehensive nail management program in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement	sanofi-aventis Canada Inc.	March 26, 2007	**Decision pending**
Pentacel	Routine immunization of all children between 2 and 59 months of age against diphtheria, tetanus, whooping cough (pertussis), poliomyelitis and haemophilus influenzae type b disease. It is sold in Canada in the form of a reconstituted product for injection combining one single dose vial of Act HIB (Lyophilized powder for injection) and one single (0.5 mL) dose ampoule of Quadracel (suspension for injection)	sanofi pasteur Limited	March 27, 2007	**Board Decision: Dec. 21, 2009 (amended March 1, 2010) Board Order: March 16, 2010 Application for Judicial Review – Jan. 19, 2010**
Quadracel	Primary immunization of infants, at or above the age of 2 months, and as a booster in children up to their 7th birthday against diphtheria, tetanus, whooping cough (pertussis) and poliomyelitis	sanofi pasteur Limited	March 27, 2007	**Board Decision: Dec. 21, 2009 (amended March 1, 2010) Board Order: March 16, 2010 Application for Judicial Review – Jan. 19, 2010**
ratio-Salbutamol HFA	Relief of chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs	ratiopharm Inc.	July 18, 2008	**Decision pending**
Strattera	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years of age and over, adolescents and adults	Eli Lilly Canada Inc.	December 15, 2006	**VCU: Feb. 19, 2009** *(details on page 13)*

Patentee	Failure to File (jurisdiction)	Date of Notice of Hearing	Status
Apotex Inc.		March 3, 2008	**Ongoing**
ratiopharm Inc.		August 28, 2008	**Decision pending**
Sandoz Canada Inc.		March 8, 2010	**Ongoing Hearing: Dec. 6-8, 2010**

Review of the Board's Guidelines

On January 1, 2010, the Board's new *Compendium of Policies, Guidelines and Procedures* (Guidelines) came into force. As per subsection 96(4) of the *Patent Act*, the Board has the authority to issue Guidelines on any matter within its jurisdiction, but they are not binding on the Board or any patentee in the context of a hearing. The Guidelines therefore provide direction to patentees and Board Staff as to how to establish and maintain non-excessive prices for patented drug products sold in Canada, as well as to outline the procedures normally undertaken when a price appears to be excessive.

The publication of the Board's new Guidelines marked the culmination of a major review process that spanned nearly five years and involved extensive consultations with all interested stakeholders, including: industry (i.e., brand-name, biotech, generic); federal, provincial and territorial (F/P/T) governments; consumer and patient advocacy groups; third party payers; and others.

Consultations with Stakeholders

In March 2005, the Board released its *Discussion Paper on Price Increases for Patented Medicines*. Feedback from stakeholders led the Board to conclude that further analysis and consultation were needed on a variety of issues, including the possible development of new categories of therapeutic improvement to acknowledge incremental innovation, the role of introductory prices as a cost driver, and price variations across markets in Canada. In addition, the constantly evolving nature of the pharmaceutical environment and the fact that the Guidelines had not been substantively reviewed since 1994 led the Board to conclude that a more comprehensive review was necessary to ensure the Guidelines remained relevant and appropriate.

In May 2006, the PMPRB released the *Discussion Paper for the Consultations on the Board's Excessive Price Guidelines*. In addition to receiving 44 written submissions, in November 2006, the Board held a series of face-to-face consultations involving 145 stakeholders in Edmonton, Montreal, Toronto, Halifax, and Ottawa.

In May 2007, the Board released a Stakeholder Communiqué outlining its preliminary decisions and directions on the issues under consultation to date. This was followed in September 2007 by a series of bilateral follow-up meetings with 73 participants drawn from industry, F/P/T governments and consumer groups. January 2008 saw the release of the *Discussion Paper on Options for Possible Changes to the Patented Medicines Regulations, 1994* and the *Excessive Price Guidelines*, which focused on ongoing Guidelines consultations and new issues raised by the Federal Court of Canada in regard to its interpretation of the *Patented Medicines Regulations*.

In early 2008, the Board also launched five multi-stakeholder working groups to address specific issues about the Guidelines, including: price regulation of patented generic drug products; levels of therapeutic improvement; the International Therapeutic Class Comparison (ITCC) test; the costs of "making" and "marketing"; and the PMPRB's price tests. Reports from each of these working groups were released throughout the spring and summer of 2008. The Board also held bilateral consultations with members of Canada's Research-Based Pharmaceutical Companies (Rx&D) and BIOTECanada.

Building on the previous consultations and many of the recommendations of the working groups, the Board released the first *Notice and Comment – Draft Revised Excessive Price Guidelines* on August 20, 2008. Board Staff arranged a total of seven information sessions for all interested stakeholders, including the pharmaceutical industry (brand-name, biotech, generic), consumers, F/P/T government representatives, and third party payers.

The PMPRB subsequently received a total of 42 written submissions and held further meetings with representatives of Rx&D, BIOTECanada, the Canadian Generic Pharmaceutical Association (CGPA) and the Ontario Public Drug Program to directly discuss their respective concerns. In the case of Rx&D, further bilateral Board-to-Board discussions were held.

> Before the Board issues any guidelines, it shall consult with the Minister, the provincial ministers of the Crown responsible for health and such representatives of the pharmaceutical industry as the Minister may designate for the purpose. *Patent Act*, subsection 96(5).

In March 2009, stakeholders were invited to provide feedback on the Board's second *Notice and Comment – Draft Revised Excessive Price Guidelines*. A total of 31 written submissions were received from stakeholders. Board Staff also arranged a total of six information sessions addressed specifically to the pharmaceutical industry (brand-name, biotech, generic), consumer groups, F/P/T governments, and third party payers to assist each sector in their understanding of revised proposals for amendments to the Guidelines.

Release of Revised Guidelines

This extensive consultation helped inform the Board's decision-making when drafting the final *Compendium of Policies, Guidelines and Procedures* published on June 9, 2009. The release of the Compendium was accompanied by the publication of a document titled *Results of the March 2009 Consultation and the Board's Revised Excessive Price Guidelines* outlining the Board's position and rationale for the final changes.

Following the publication of the new Guidelines, Board Staff held numerous outreach sessions in Toronto and Montreal to assist patentees in better understanding the changes and preparing for implementation.

Key Changes to the Board's Guidelines

The Board's revised Guidelines are written with clearer and more consistent language; use a structure that is aligned with the review and investigation processes of Board Staff; contain new sections outlining the Board's legal framework and its policies; and provide more detailed procedures for how the Guidelines will be implemented. Some of the more significant changes are as follows:

Levels of Therapeutic Improvement – The scientific review process for new patented drug products now uses four levels of therapeutic improvement (i.e., breakthrough, substantial, moderate, slight/no improvement), as opposed to the previous three categories (i.e., breakthrough/substantial, moderate/little/no, line extension). New secondary factors were also added that can be considered in the scientific review process to potentially move a product's level of therapeutic improvement from "slight/no" to "moderate." These additions were designed to recognize the increasingly incremental nature of innovation in the pharmaceutical industry.

Alignment of Price Tests – The price tests that were previously associated with the three categories used in the scientific review process were modified to align with the four new levels of therapeutic improvement. The key change is that a new patented drug product that is considered a moderate therapeutic improvement in the scientific review process is allowed additional price flexibility in the price review process, which is designed to acknowledge and reward incremental innovation important to patients.

Highest International Price Comparison (HIPC) Test – The HIPC test is now conducted on a new patented drug product at introduction at the national level, for the pharmacy and hospital customer classes (but not the wholesaler class) and for each province/territory. For an existing patented drug product, the HIPC test is only conducted at the national level if the National Average Transaction Price triggers the investigation criteria. The exception for the wholesaler class of customer was added because the HIPC test was considered unworkable for patented generic drug products (given the nature of the generic drug market approach). In wanting to ensure a consistent and fair application of the HIPC test, the Board extended the exemption to all patentees. However, since the National Average Transaction Price must not exceed the highest international price, if a patented drug product is only sold to wholesalers, the exemption does not apply.

International Therapeutic Class Comparison (ITCC) Test – The new Guidelines now include methodologies for conducting an ITCC test on which the previous Guidelines were silent. While the ITCC test is not considered pivotal, it may be used in an investigation to provide additional information. As well, in a public hearing, the Board is required to consider all the factors listed in section 85(1) of the *Patent Act*, so these methodologies provide useful direction for how the ITCC test is to be calculated. Two possible methodologies for the ITCC test are: the ratio approach and the straight class approach, both of which are undertaken using the same comparators as those used in the domestic Therapeutic Class Comparison (TCC) test. If the domestic TCC test includes generic drug products, the ITCC test will only use those generics sold by companies that also sell the same generic drug product in Canada.

Selection of Prices for Comparison Purposes – A new methodology is outlined in the Guidelines for selecting the prices of drug products used for comparison. To determine the price of a comparator drug product in the price tests, the Guidelines now list six publicly available sources of price information to be used, from which Board Staff use the lowest public price for each comparator. The highest of these prices then determines the pivotal price for the TCC test. This modification was made to enhance transparency and increase predictability of the price review process for patentees.

Any Market Price Review – Guidance was added regarding how any market price reviews are undertaken. For new patented drug products at introduction, the average price will be reviewed both nationally and for each sub-market (i.e., pharmacy, hospital, wholesaler, and each province/territory). Submarkets are reviewed for existing patented drug products only if the investigation criteria are triggered. This was added to the Guidelines because the Board's position is that some level of market-specific price review is part of its statutory mandate as set out in the *Patent Act*, and one of stakeholders' concerns during the consultation process was the possibility that some market prices may be excessive.

DIP Methodology – Guidance was included on using the DIP Methodology, which allows for potential exceptions to the Board's CPI-Adjustment Methodology when an apparent excessive price is due solely to the termination or reduction in a benefit. Subject to evidence requirements, the average price within a market employing the DIP Methodology may potentially rebound up to the highest Non-Excessive Average Price of another market. While there are criteria for the use of the DIP Methodology, the intent is to address potential disincentives stemming from the practice of patentees to offer selected benefits to their customers.

Policy on Offset of Excess Revenues – A new policy explains how excess revenues generated by patentees may be appropriately offset. This policy was put forward, among other reasons, in order to align with section 83 of the *Patent Act*, which indicates that an actual price reduction (or payment to the Crown) is necessary to offset excess revenue.

New Terminology – For new patented drug products, the term Introductory Maximum Non-Excessive (MNE) Price has been replaced by the term Maximum Average Potential Price or MAPP. For existing patented drug products, the term Maximum Non-Excessive (MNE) Price is now known as the Non-Excessive Average Price or NEAP. This change is to enhance clarity that the statute sets out that the Board's mandate relates to "average prices" in various markets.

Next Steps

The Board's new Guidelines came into effect on January 1, 2010. Moving forward, the Board remains committed to providing predictability, fairness and transparency in fulfilling its regulatory responsibilities, and will be monitoring and evaluating the application and impact of key changes to the Guidelines to ensure that they remain relevant and appropriate.

Reporting Information on Key Pharmaceutical Trends

The PMPRB reports annually to Parliament, through the Minister of Health, on its activities, on pharmaceutical trends relating to all medicines, and on the R&D spending by patentees.

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 information on quantities sold and net revenues or average prices 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.[3]

Sales and Prices

Canadians spend much more today on drug products than they did a decade ago. However, it is important to understand that an increase in drug spending does not in itself imply rising drug prices. 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.[4] 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)
- increased incidence of health problems requiring drug therapy
- changes in the prescribing practices of physicians (for example, shifts away from older, less expensive drug products to newer, more expensive medications, or a shift toward higher, more frequent dosages)
- greater use of drug therapy instead of other forms of treatment
- use of new drug products to treat conditions for which no effective treatment existed previously

Sales Trends

Table 9 on page 21 reports patentees' total sales of patented drug products in Canada for 1990 through 2009. Sales of patented drug products rose to $13.3 billion from $13.0 billion in 2009, an increase of 2.8%. By comparison, annual growth in sales of patented drug products stood at 27.0% in 1999 and remained in double-digits until 2003.

The third column of Table 9 gives sales of patented drug products as a share of overall drug sales. This share rose from 43.2% in 1990 to 72.7% in 2003. However, the share of patented drug products in overall drug sales has declined since 2003, implying that sales of non-patented brand and generic drug products have grown faster than sales of patented drug products.

3 All statistical results for patented drug products reported in this chapter are based on data submitted by patentees as of April 2010. 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 (page 20, Trends in Sales of Patented Drug Products), price and quantity indices (page 22, Price Trends; and page 31, Utilization of Patented Drug Products) and foreign-to-Canadian price ratios (page 27, Comparision 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.

4 Studies conducted by the PMPRB of public drug insurance plans indicate that increased utilization of existing and new drug products accounts for most of the recent growth in expenditures. See PMPRB, *Pharmaceutical Trends Overview Report: 1997–1998 to 2003–2004*, June 2006.

Table 9 Sales of Patented Drug Products, 1990–2009

Year	Patented Drug Products: Sales ($Billions)	Patented Drug Products: Change (%)	Sales of Patented Drug Products as Share of All Drug Sales (%)[5]
2009	13.3	2.8	62.4
2008	13.0	4.9	64.7
2007	12.4	3.3	65.4
2006	12.0	3.7	67.8
2005	11.5	4.7	70.6
2004	11.0	8.6	72.2
2003	10.2	14.3	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

Sources: PMPRB and IMS Health

5 The denominator in this ratio comprises sales of patented and 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 as patentees. Ratios reported in Table 9 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 2004.

Drivers of Sales Growth

Table 10 decomposes the sales growth that occurred between 2008 and 2009 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 2009 ("new drug effect")
- changes in prices among patented drug products with sales in Canada in both 2008 and 2009 ("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 10 gives these impacts as dollar amounts. The second row expresses the impacts as proportions of the overall change in sales between 2008 and 2009. For the sake of comparison, the third row provides average year-over-year proportionate impacts for 2004 through 2008.[6]

The results in this table show that the increase in sales that occurred between 2008 and 2009 was principally the result of underlying increases in the quantities of existing and new patented drug products sold. The volume effect alone was large enough to more than compensate for a large (negative) exiting drug effect. Note that price increases among existing patented products accounted for only 5.2% of expenditure increase.

The 2009 decomposition results are broadly consistent with the historical averages in Table 10. In particular, both the dominant volume effect and relatively small price effects observed in 2009 are typical.

Table 10 Decomposition of Changes in Sales of Patented Drug Products

	Total Change	Exiting Drug Effect	New Drug Effect	Price Effect	Volume Effect	Cross Effect
Net Revenue Impact, 2009/2008 ($ Millions)	368.8	-250.1	149.1	19.3	440.8	11.9
Proportion of Total Change, 2009/2008 (%)	100.0	-67.8	40.4	5.2	119.5	3.2
Average Proportion of Total Change, 2004–2008 (%)	100.0	-54.9	47.4	0.2	105.6	1.7

Source: PMPRB

6 Under the scheme applied here, the "exiting drug effect" is the amount of 2009 sales generated by drug products that were under the PMPRB's jurisdiction in 2008 but not in 2009. The "new drug effect" is the amount of 2009 sales generated by drug products that were under the PMPRB's jurisdiction in 2009 but not in 2008. Other effects are derived by means of the relationship:

$$\sum p^{2009}(i)\, q^{2009}(i) - \sum p^{2008}(i)\, q^{2008}(i) = \sum [p^{2009}(i) - p^{2008}(i)]\, q^{2008}(i) + \sum p^{2008}(i)\, [q^{2009}(i) - q^{2008}(i)] + \sum [p^{2009}(i) - p^{2008}(i)]\, [q^{2009}(i) - q^{2008}(i)]$$

where $p^{y}(i)$ is the price of drug "i" in year "y", $q^{y}(i)$ is the physical volume of drug "i" sold in year "y" and $\sum$ signifies summation over the set of drug products that were under the PMPRB's jurisdiction in both 2008 and 2009. The left-hand-side in this equation represents the change in total sales of such drug products between 2008 and 2009. The three terms of the right-hand-side respectively define the volume, price and cross effects reported in Table 10.

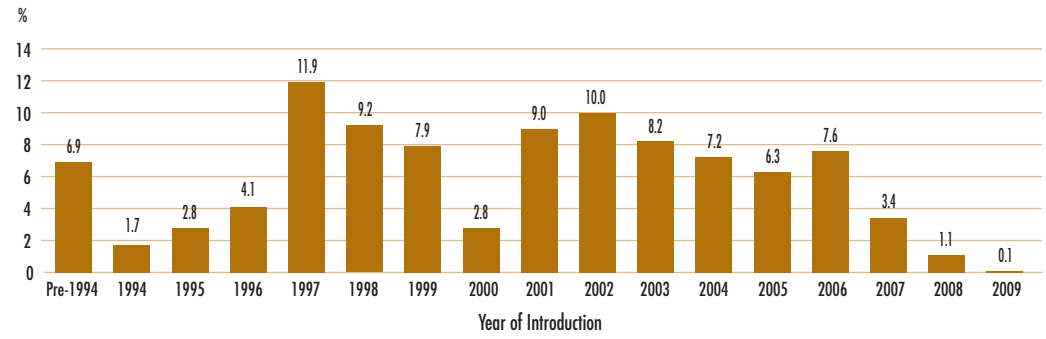
The pronounced decline in rates of sales growth over the last few years is a striking development. Throughout the latter part of the 1990s, sales growth was largely driven by a succession of new "blockbuster" products that ultimately achieved very high sales volumes. However, since the beginning of the 2000s, high-volume products have not been introduced in sufficient numbers to sustain the double-digit sales growth seen in the previous decade. Figure 4 breaks down 2009 sales of patented drug products according to the year in which the product was first sold in Canada. Sales are split almost evenly between drug products introduced up to 2000 and those introduced afterwards, with patented drug products introduced between 1995 and 1999 still accounting for 35.9% of sales in 2009.

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 at the level of therapeutic class. This is a hierarchical system that classifies drug products according to their principal therapeutic use and chemical composition. At its most aggregate level (Level 1) the ATC system classifies drug products according to the element of human anatomy with which they are primarily associated.

Table 11 breaks out sales of patented drug products in Canada in 2009 by major therapeutic class, defined by ATC Level 1. The table gives the 2009 sales for each class, the share of the total sales this represents and the rate at which sales grew relative to 2008. Values in the last column represent the component of overall sales growth attributable to drug products in the corresponding therapeutic class.[7] By this measure, antineoplastics and immunomodulating agents were the primary driver of sales growth between 2008 and 2009, with this class alone accounting for additional sales nearly equal to the overall increase.

Figure 4 Share of 2009 Sales of Patented Drug Products by Year of Introduction to Canadian Market



Source: PMPRB

Price Trends

The PMPRB uses the Patented Medicines Price Index (PMPI) to monitor trends in prices of patented drug products. The PMPI is a price index measuring 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.[8] This is similar to the approach Statistics Canada uses to construct the Consumer Price Index (CPI). The PMPI is updated every six months using price and sales information submitted by patentees.[9]

7 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.

8 For the most part, 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.

9 See the PMPRB's *A description of the Laspeyres methodology used to construct the Patented Medicine Price Index (PMPI)*, June 2000, for a detailed explanation of the PMPI. Beginning in 1999, the PMPI is restricted to products intended for human use.

TABLE 11 Sales of Patented Drug Products by Major Therapeutic Class, 2009

Therapeutic Class	Sales 2009 ($M)	Share of Total 2009 Sales (%)	Growth: 2009/2008 ($M)	Growth: 2009/2008 (%)	Share of Sales Growth (%)
A: Alimentary Tract and Metabolism	1,095.4	8.2	-179.2	-14.1	-48.6
B: Blood and Blood Forming Organs	872.7	6.5	-9.4	-1.1	-2.6
C: Cardiovascular System	3,267.9	24.5	93.6	2.9	25.4
D: Dermatologicals	104.0	0.8	-17.2	-14.2	-4.7
G: Genito-urinary System and Sex Hormones	546.0	4.1	44.8	8.9	12.2
H: Systemic Hormonal Preparations	94.9	0.7	3.0	3.3	0.8
J: General Antiinfectives for Systemic Use; and P: Antiparasitic Products**	1,363.7	10.2	-20.8	-1.5	-5.6
L: Antineoplastics and Immunomodulating Agents	2,387.6	17.9	357.1	17.6	96.9
M: Musculo-skeletal System	524.6	3.9	5.6	1.1	1.5
N: Nervous System	1,639.4	12.3	2.0	0.1	0.6
R: Respiratory System	1,070.1	8.0	54.4	5.4	14.7
S: Sensory Organs	303.4	2.3	34.7	12.9	9.4
V: Various	64.2	0.5	0.0	0.1	0.0
All Therapeutic Classes	13,334.0	100.0*	368.6	2.8	100.0

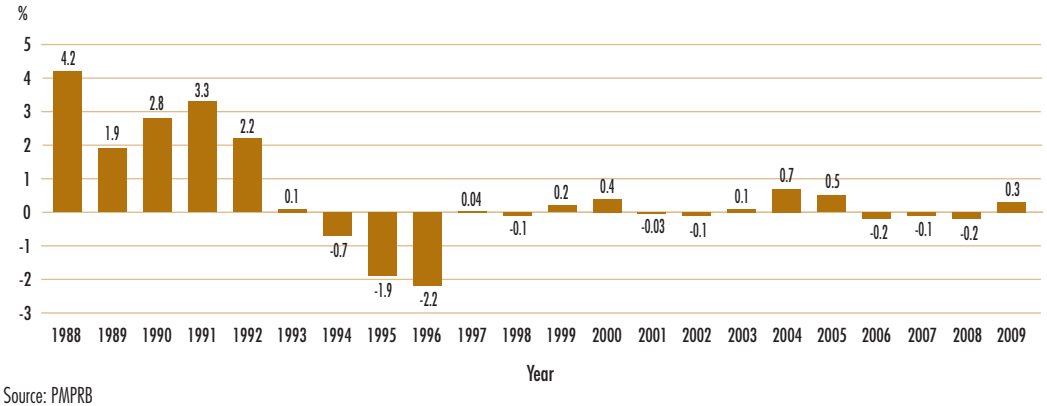
* Values in this column may not add to 100.0 due to rounding. ** These groups have been combined for reasons of confidentiality.

Source: PMPRB

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 page 31, 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 5 provides year-over-year changes in the PMPI for the years 1988 through 2009. As measured by the PMPI, prices of patented drug products rose, on average, by 0.3% between 2008 and 2009.

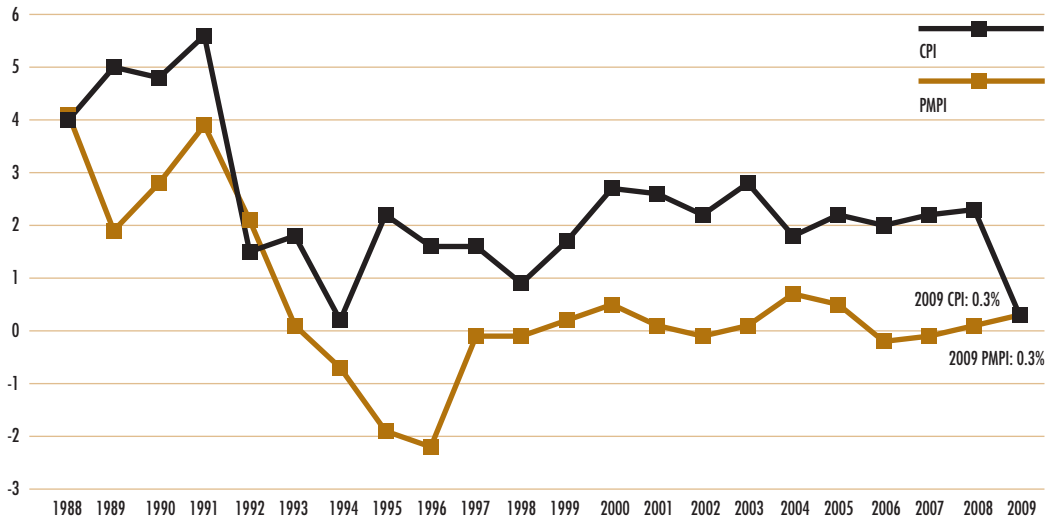
FIGURE 5 Annual Rate of Change of Patented Medicines Price Index, 1988–2009



Source: PMPRB

The Act requires that, among other factors, the PMPRB consider changes in the Consumer Price Index (CPI) in determining whether the price of a patented drug product is excessive. Figure 6 plots year-over-year rates of change in the PMPI against corresponding changes in the CPI. Inflation, as measured by the CPI, has exceeded the average increase in patented drug prices almost every year since 1988. In 2009, the rise in the PMPI equaled that year's (unusually low) rate of CPI inflation.[10]

FIGURE 6 Annual Rate of Change of Patented Medicines Price Index and Consumer Price Index, 1988–2009



Sources: PMPRB and Statistics Canada

That the PMPI has seldom kept pace with the CPI is not surprising. 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 individual prices may rise over any period of three years or more.[11] Increases in the PMPI normally do not reach this upper bound because some patentees do not raise their prices by the full amount permitted under the Guidelines, or choose to reduce their prices.

Price Change by Therapeutic Class

Table 12, on page 25, 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 I 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 slight overall increase in the PMPI of 0.3% reflects a general state of price stability across therapeutic classes. Note that no therapeutic class saw an average price increase greater than CPI inflation in 2009.[12]

10 Statistics Canada, CANSIM, Series V735319. For 2009 as a whole, consumer prices rose by 0.3%, a significantly smaller increase than the 2.3% rise posted in 2008, and significantly less than the 2009 forecast rate of 2.0%. The actual CPI increase of 0.3% in 2009 was the smallest since the annual increase of 0.1% in 1994.

11 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 two years. It can also occur when the forecast rate of CPI inflation exceeds the actual rate. To facilitate and encourage compliance by patentees, the PMPRB's CPI-Adjustment Methodology uses the forecast rate of CPI inflation published by the Department of Finance. Patentees must satisfy the PMPRB's price-adjustment rules based on calculations incorporating either the forecast or actual rate of CPI inflation for the year in question. This raises the possibility of price increases exceeding CPI inflation whenever forecast CPI inflation exceeds actual CPI inflation. Note that this will not be a permanent gain to the patentee, as the PMPRB's three-year price-adjustment rule will eventually bring cumulative price increase back into line with cumulative (actual) CPI inflation.

12 Suppose R represents the overall rate of change in the PMPI. Suppose 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 12. 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 corresponding class' contribution 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 (measured by its share of sales).

The decomposition in Table 12 is approximate. This is because the weights used to calculate the contribution of each therapeutic class are based on annual sales data, whereas rate of price change (whether overall or by therapeutic class) are calculated from data covering periods of six months. The resulting discrepancy is normally very small.

TABLE 12 Change in the Patented Medicines Price Index by Major Therapeutic Class, 2009

Therapeutic Class	Share of Total 2009 Sales (%)	Price Change: 2008 to 2009 (%)	Contribution to Overall Change
A: Alimentary Tract and Metabolism	8.2	-1.1	-0.1
B: Blood and Blood Forming Organs	6.5	0.1	0.0
C: Cardiovascular System	24.5	0.6	0.2
D: Dermatologicals	0.8	0.7	0.0
G: Genito-urinary System and Sex Hormones	4.1	0.8	0.0
H: Systemic Hormonal Preparations	0.7	0.6	0.0
J: General Antiinfectives for Systemic Use; and P: Antiparasitic Products**	10.2	1.7	0.2
L: Antineoplastics and Immunomodulating Agents	17.9	0.6	0.1
M: Musculo-skeletal System	3.9	-0.8	0.0
N: Nervous System	12.3	0.2	0.0
R: Respiratory System	8.0	1.1	0.1
S: Sensory Organs	2.3	0.3	0.0
V: Various	0.5	-9.3	0.0
All Therapeutic Classes	100.0*	0.3	0.3

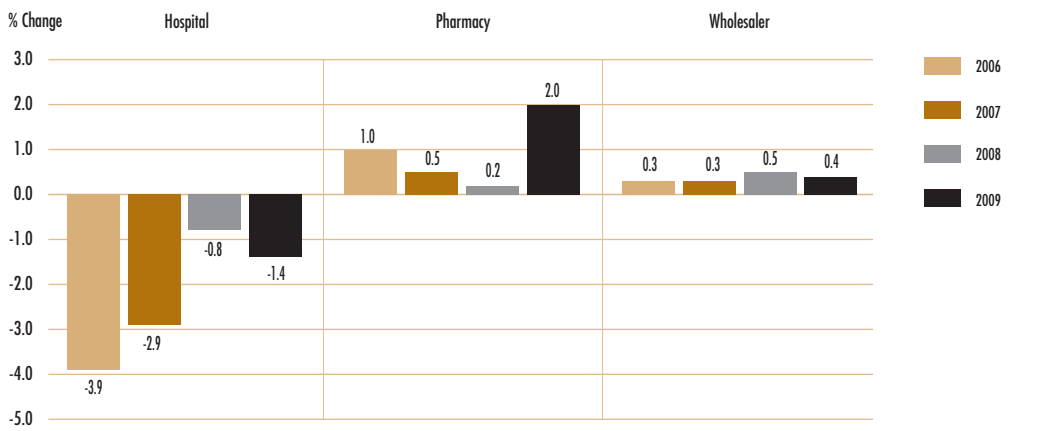
* Values in this column may not add to 100.0 due to rounding. ** These groups have been combined for reasons of confidentiality.

Source: PMPRB

Price Change by Class of Customer

Figure 7 presents average rates of price change by class of customer.[13] These results were obtained by applying the PMPI methodology separately to sales data for hospitals, pharmacies and wholesalers.[14] The 2009 rates of price change for these classes were, respectively -1.4%, 2.0% and 0.4%.

FIGURE 7 Annual Average Rate of Price Change of Patented Drug Products by Class of Customer, 2006–2009



Source: PMPRB

13 Sales of patented drug products are dominated by sales to wholesalers, which accounted for 80.4% of all sales in 2009. Sales to hospitals accounted for another 8.7%, while direct sales to pharmacies accounted for 3.7%. The pharmacy share has fallen precipitously since 2001, when it stood at 20.1%.

14 Results for a fourth class of customer, "Others", are not provided. This class accounted for about 7.2% of patented drug sales in 2009. Buyers in this class are principally healthcare 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.

Price Change by Province/Territory

Figure 8 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 2008 and 2009, prices of patented drug products in Prince Edward Island, Quebec, Manitoba, the Northwest Territories and the Yukon fell on average. The largest average price increases occurred in Newfoundland and Labrador (1.7%), Alberta (1.2%), and New Brunswick (1.0%).

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 9 provides the average ratio of 2009 price to introductory price (the price at which the drug product was sold in its first year on the Canadian market). The figure provides a separate average ratio for drug products introduced in 1995, those introduced in 1996, and so forth.

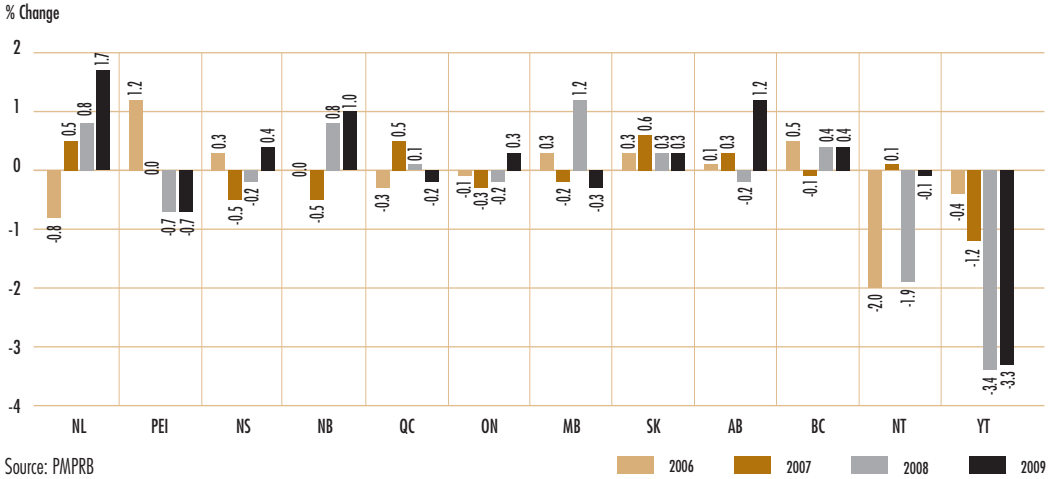
The results in Figure 9 imply no consistent tendency for prices to either rise or fall after introduction, with the 2009 price of a typical patented drug product being within a few percentage points of its introductory price, regardless of when it was introduced to the Canadian market.[15]

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: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. The PMPRB uses this information

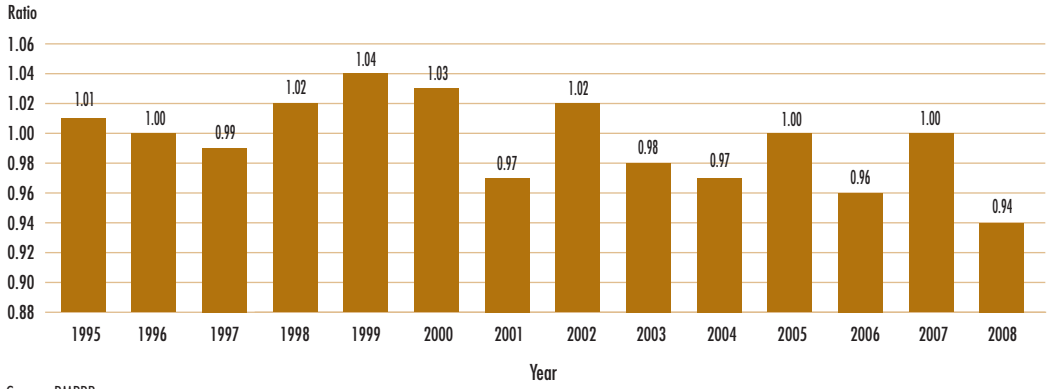
- to conduct the international price comparison tests specified in its Guidelines; and
- to compare the Canadian prices of patented drug products to those prevailing in other countries.

Figure 8 Annual Average Rate of Price Change, Patented Drug Products, by Province/Territory, 2006–2009



Source: PMPRB

Figure 9 Average Ratio of 2009 Price to Introductory Price for Patented Drug Products by Year of Introduction



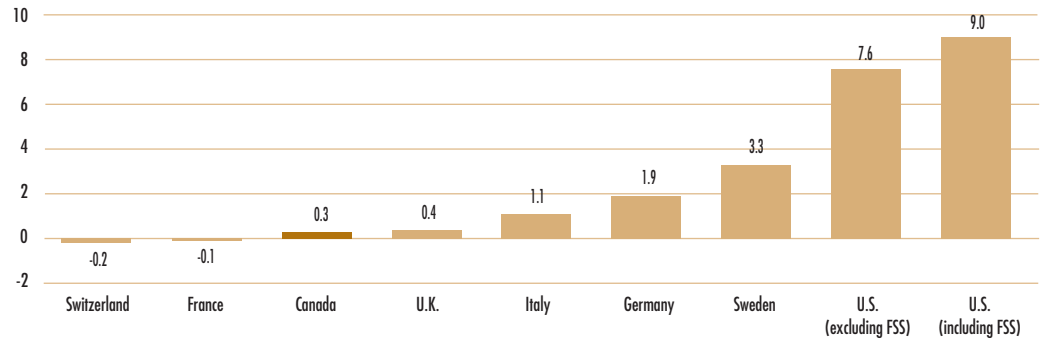
Source: PMPRB

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

Figure 10 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 international price data submitted to the PMPRB by patentees. Note that two results are presented for the United States. The first of these is restricted to published U.S. "market" prices (typically wholesale acquisition costs)[16] submitted by patentees, and the second incorporates prices from the U.S. Federal Supply Schedule (FSS), also submitted by patentees.[17]

The results in Figure 10 indicate that in 2009, the United States saw prices rise on average at a rate of 8–9%. Italy, Germany, Sweden and the UK saw much more modest average increases, while prices in France and Switzerland declined slightly.

FIGURE 10 Annual Average Rates of Price Change for Canada and Comparator Countries, 2009



Source: PMPRB

16 The term "wholesale acquisition cost" (WAC) refers to the price paid by a wholesaler for a drug purchased from the wholesaler's supplier, usually the drug's manufacturer. A publicly disclosed WAC is typically a manufacturer's list price and, as such, may not reflect all discounts provided by the manufacturer.

17 The pharmaceutical industry in the U.S. 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 U.S. Federal Supply Schedule (FSS) in calculating the average U.S. price of patented drug products. The FSS prices are negotiated between manufacturers and the U.S. Department of Veterans' Affairs. They are typically less than other publicly available U.S. prices reported to the PMPRB by patentees.

Comparison of Canadian Prices to Foreign Prices

Tables 13 and 14 provide detailed statistics comparing the foreign prices of patented drug products to their Canadian prices. Each table provides four sets of average price ratios. These are differentiated according to (1) the averaging formula applied, and (2) 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 price ratio reported.[18]

The PMPRB has traditionally reported average foreign-to-Canadian price ratios constructed as sales-weighted geometric means of individual ratios. Such results are included in Tables 13 and 14 (under Geometric Mean). The tables also provide results obtained using a sales-weighted arithmetic average (under Arithmetic Mean).[19] These statistics provide answers to questions of the type:

> *"How much more/less would Canadians have paid for the patented drug products they purchased in 2009 had they paid Country X prices rather than Canadian prices for these products?"* [20]

18 The number of drug products and sales encompassed vary among comparator countries because it is not always possible to find a matching foreign price for every patented drug product sold in Canada. It is worth noting in this regard that all of the average price ratios reported in Tables 13 and 14 cover at least 81% of 2009 Canadian sales. The reported U.S.-to-Canada price ratios cover about 95% of 2009 sales.

19 Let RG represent the average price ratio obtained using the geometric method, RA the average price ratio obtained using the arithmetic method. Let $p(i)$ represent the Canadian price of drug i, $pf(i)$ its foreign price (converted to Canadian dollars) and $w(i)$ its share of Canadian sales. Then $RG = \prod [pf(i)/p(i)]^{w(i)}$ (where $\prod$ signifies multiplication over all patented drug products), while $RA = \sum w(i)[pf(i)/p(i)]$ (where $\sum$ signifies summation over all patented drug products).

It is readily demonstrated that RG can never exceed RA. It is also possible to show that the difference between RA and RG will increase with the extent of variation among individual price ratios, and that RG will equal RA only in the special case where all product-level price ratios have the same value.

20 The difference between these two statistics, however, is that while the geometric mean provides an approximate answer, the arithmetic mean provides an exact answer. Consequently, as of 2010, the PMPRB will be using only the arithmetic mean.

For example, Table 13 states that the 2009 average French-to-Canadian price ratio obtained using the arithmetic mean was 0.90. This means Canadians would have paid 10% less for the patented drug products they purchased in 2009 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 13 also reports foreign-to-Canadian price ratios with currency conversion at purchasing power parity (PPP). The PPP between any two countries measures their relative cost-of-living expressed in their own currencies. In practice, cost-of-living is determined by pricing out a standard set or "basket" of goods and services at prices prevailing in each country. Because PPPs are designed to represent relative cost-of-living, they offer a simple way to account for differences in 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 the form:

> *"How much more/less consumption of other goods-and-services would Canadians have sacrificed for the patented drug products they purchased in 2009 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 13 Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons, 2009

At Market Exchange Rates

	Canada	*France*	*Italy*	*Germany*	*Sweden*	*Switzerland*	*United Kingdom*	*United States*
Geometric Mean	1.00	0.84	0.80	1.08	0.93	0.98	0.90	1.71
Arithmetic Mean	1.00	0.90	0.86	1.15	0.99	1.03	0.96	1.85
Number of DINs	1,180	762	765	868	851	817	855	992
Net Revenues ($Millions)	13,334.0	11,606.8	10,884.6	11,811.4	11,915.2	11,827.4	11,728.6	12,661.1

At Purchasing-Power-Parities

	Canada	*France*	*Italy*	*Germany*	*Sweden*	*Switzerland*	*United Kingdom*	*United States*
Geometric Mean	1.00	0.72	0.73	0.98	0.76	0.74	0.81	1.85
Arithmetic Mean	1.00	0.76	0.79	1.05	0.80	0.78	0.87	2.00
Number of DINs	1,180	762	765	868	851	817	855	992
Net Revenues ($Millions)	13,334.0	11,606.8	10,884.6	11,811.4	11,915.2	11,827.4	11,728.6	12,661.1

Source: PMPRB

Bilateral Comparisons

Table 13 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 roughly in the middle of the pack on average. Prices in Italy and France were, on average, appreciably lower than Canadian prices. As in previous years, U.S. prices were substantially higher than prices in Canada or any other comparator country.

Average price ratios obtained with currency conversion at PPPs, provided at the bottom of Table 13, tell a somewhat more dramatic story. Once international differences in cost-of-living are accounted for, it appears that Canadians incurred a substantially greater consumption cost for the patented drug products they purchased in 2009 than did residents of every comparator country other than Germany and the United States.

Figure 11 puts these results in historical perspective. In 1998, Canadian prices were, on average, higher than prices in France and Italy but below prices in the five other comparator countries. This pattern was largely unchanged as of 2003. In 2009, Canadian prices were, on average, decidedly above prices in Italy and France, much below prices in the United States, but within a margin of plus/minus 10% of prices in Germany, Sweden, Switzerland and the United Kingdom.

Average Foreign-to-Canadian Bilateral Price Ratios: Analysis of Changes

By and large, the international price comparisons reported above are very similar to those reported in last year's Annual Report. The largest change involves the average U.S.-to-Canadian price ratios obtained at market exchange rates, which have risen considerably (from 1.63 to 1.71 in the case of the geometric mean, and from 1.76 to 1.85 in the case of the arithmetic mean). In light of the method used to derive these ratios, there are five factors that might account for this change:

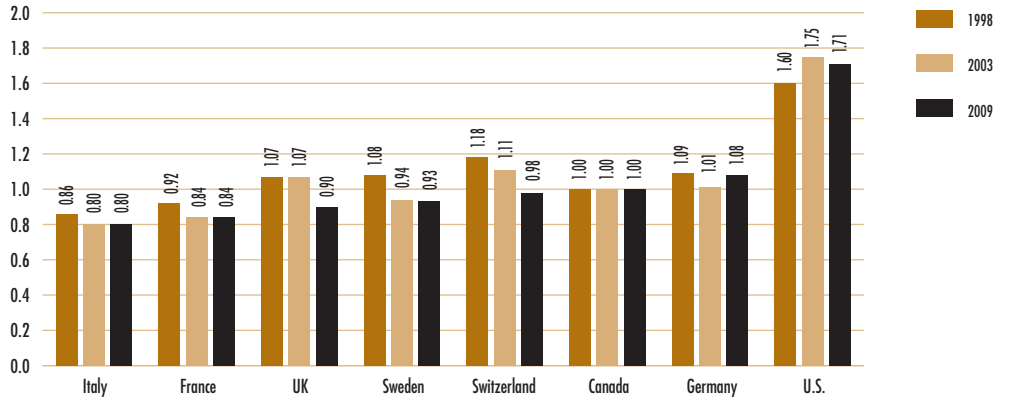
(1) a change in currency conversion factors that acts to raise the Canadian-dollar equivalents of U.S. prices
(2) rising U.S. prices
(3) declining Canadian prices
(4) a change in the set of encompassed drug products that on balance favours products with higher U.S.-to-Canadian price ratios
(5) a shift in sales-weights that on balance favours drug products with higher U.S.-to-Canadian price ratios

Further analysis reveals the rise in average U.S.-to-Canadian price ratios was entirely the result of rising U.S. prices. Changes in sales-weights acted to somewhat moderate the impact of U.S. price increases. Changes in other factors had little impact on the average price ratios.

Multilateral Price Comparisons

Table 14 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.

Figure 11 Average Foreign-to-Canadian Bilateral Price Ratios at Market Exchange Rates, 1998, 2003, 2009



Source: PMPRB

Table 14 Average Foreign-to-Canadian Price Ratios, Multilateral Comparisons, 2009

At Market Exchange Rates

	Median	*Minimum*	*Maximum*	*Mean*
Geometric Mean	0.98	0.73	1.85	1.11
Arithmetic Mean	1.04	0.79	1.98	1.16
Number of DINs	1,112	1,112	1,112	1,112
Net Revenues ($Millions)	13,044.6	13,044.6	13,044.6	13,044.6

At Purchasing-Power-Parities

	Median	*Minimum*	*Maximum*	*Mean*
Geometric Mean	0.84	0.64	1.92	1.02
Arithmetic Mean	0.90	0.71	2.06	1.07
Number of DINs	1,112	1,112	1,112	1,112
Net Revenues ($Millions)	13,044.6	13,044.6	13,044.6	13,044.6

Source: PMPRB

Focusing again on results at market exchange rates, the average MIP-to-Canadian price ratio stood at 0.98 in 2009 applying the geometric mean, and 1.04 at the arithmetic mean. (The corresponding values for 2008 were 0.97 and 1.02.)

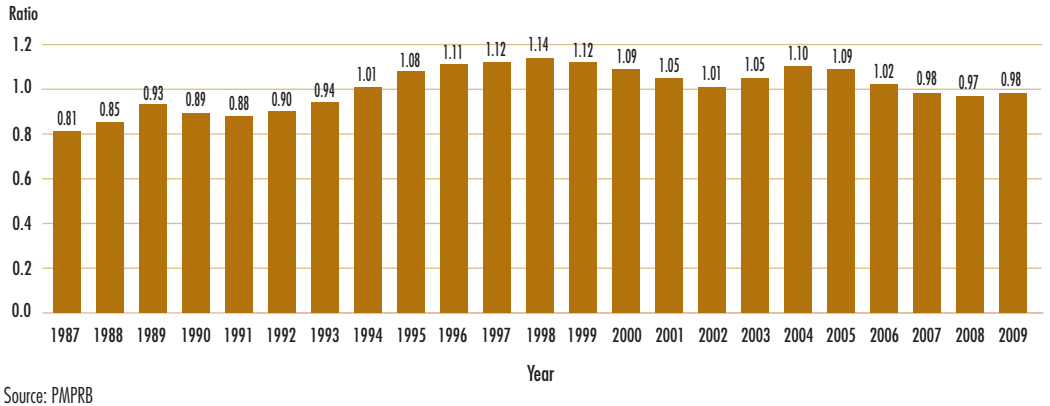
Figure 12 puts this result in historical perspective. MIPs were on average 19% less than corresponding Canadian prices in 1987. By 1998, MIPs were on average 14% higher than Canadian prices. The average MIP-to-Canadian price ratio has remained within 3% of parity since 2006.

Results obtained with other multilateral measures are much as one would expect. Interestingly, it appears that mean foreign prices typically produce higher foreign-to-Canadian price ratios than do MIPs. This is readily explained by the influence of U.S. prices, which are typically much higher than prices elsewhere. U.S. prices nearly always figure importantly in the calculation of the mean foreign price but almost never emerge as median international prices.

As with the bilateral comparisons, differences between results obtained at market exchange rates and at PPPs are striking. These affirm that while Canada may be a "medium price" country in purely monetary terms, Canadians actually sacrifice appreciably more consumption to acquire patented drug products than do residents of most comparator countries. With currency conversion at PPPs, the average MIP-to-Canadian price ratio (calculated as a geometric mean) was 0.84 in 2009, substantially less than the value of 0.98 obtained at market exchange rates.

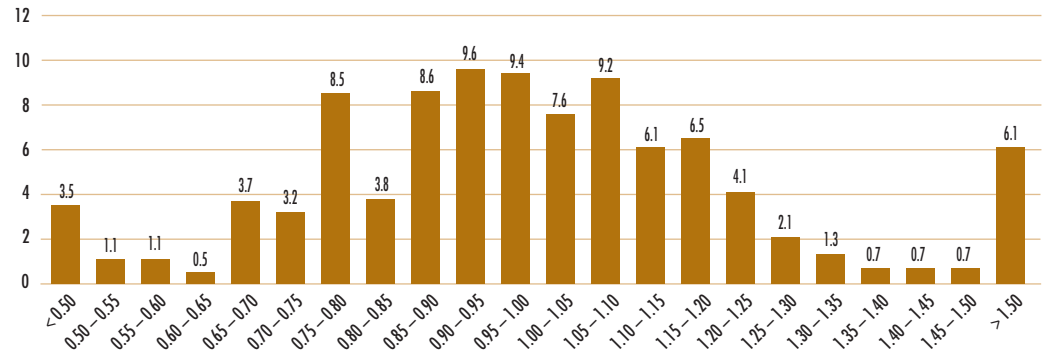
Figure 13 offers more detail on the product-level MIP-to-Canadian ratios underlying the averages reported in Table 14. This figure distributes the 2009 sales of each patented drug product according to the value of its MIP-to-Canadian price ratio (more exactly, according to the range into which the ratio fell).[21] 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 35.8% of sales, those with ratios less than 0.90 accounted for 34.1% of sales, and products with ratios exceeding 1.10 accounted for 30.1%.

FIGURE 12 Average Ratio of Median International Price to Canadian Price of Patented Drug products, 1987–2009



Source: PMPRB

FIGURE 13 Range Distribution of Sales by MIP-to-Canadian Price Ratio of Patented Drug Products, 2009



Source: PMPRB

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

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 Medicine Quantity Index (PMQI) for this purpose.[22] Figure 14 provides average rates of utilization growth, as measured by the PMQI, from 1988 through 2009. These results confirm that 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 in recent years. This pattern continued in 2009, with utilization of patented drug products growing by 3.5%. Note that a rate of utilization growth somewhat greater than overall sales growth is exactly what one would expect, considering the substantial (negative) "exiting drug" and minimal price effects reported in Table 10 on page 21.

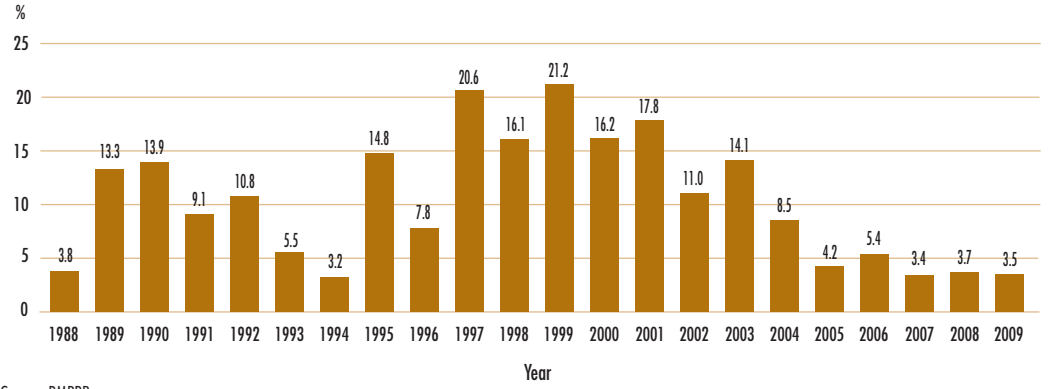
Utilization Growth by Therapeutic Class

Table 15 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 12 (see page 25), the last column provides an approximate decomposition of overall PMQI change into contributions attributable to each therapeutic class.

In 2009, levels of utilization rose in all but two therapeutic classes, with the class Alimentary Tract and Metabolism seeing a substantial decline in utilization. A single class, Antineoplastics and Immunomodulating Agents, accounted for most of the growth in overall utilization. Drug products related to the Cardiovascular System and the Respiratory System also contributed appreciably to utilization growth, but their influence was much reduced in comparison with earlier years of this decade.

22 Like the PMPI, the PMQI is calculated using a chained Laspeyres index formula, with ratios of physical quantities in successive periods replacing the price ratios of the PMPI. Here again, the index is obtained as a revenue-weighted average of ratios at the level of individual products. Since the PMQI covers only patented drug products it should not be taken to represent utilization trends in the entire pharmaceutical market.

Figure 14 Annual Average Rate of Change of the Patented Medicines Quantity Index, 1988–2009



Source: PMPRB

Table 15 Change in the Patented Medicines Quantity Index by Major Therapeutic Class, 2009

Therapeutic Class	Share of Total 2009 Sales (%)	Price Change: 2008 to 2009 (%)	Contribution to Overall Change
A: Alimentary Tract and Metabolism	8.2	-9.2	-0.8
B: Blood and Blood Forming Organs	6.5	-0.7	0.0
C: Cardiovascular System	24.5	2.4	0.6
D: Dermatologicals	0.8	-1.1	0.0
G: Genito-urinary System and Sex Hormones	4.1	7.3	0.3
H: Systemic Hormonal Preparations	0.7	6.2	0.0
J: General Antiinfectives for Systemic Use and P: Antiparasitic Products**	10.2	0.0	0.0
L: Antineoplastics and Immunomodulating Agents	17.9	15.5	2.8
M: Musculo-skeletal System	3.9	3.1	0.1
N: Nervous System	12.3	0.0	0.0
R: Respiratory System	8.0	6.4	0.5
S: Sensory Organs	2.3	14.0	0.3
V: Various	0.5	16.7	0.1
All Therapeutic Classes	100.0*	3.5	3.5

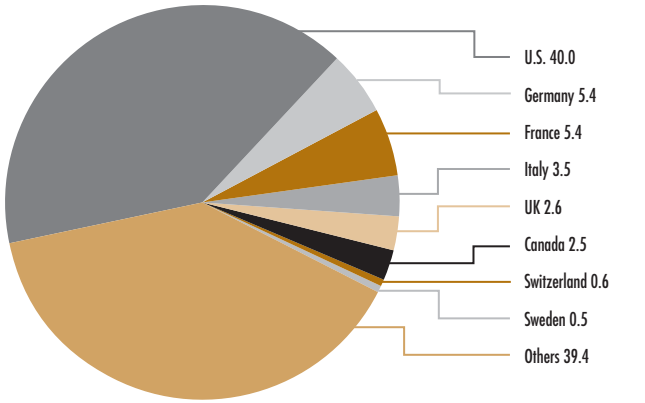
* Values in this column may not add to 100.0 due to rounding. ** These groups have been combined for reasons of confidentiality.

Source: PMPRB

Canadian Drug Expenditures in the Global Context

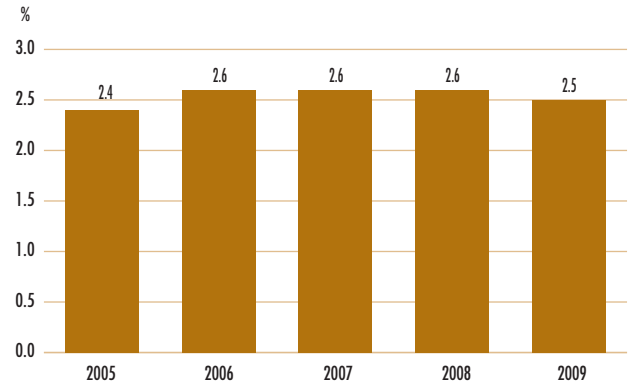
IMS Health[23] regularly reports on drug sales across a large number of countries. Based on sales data from this source, Figure 15 provides shares of global sales for Canada and each of the seven comparator countries the PMPRB considers in conducting its price reviews.[24] In 2009, the Canadian market accounted for 2.5% of the global market, a share only slightly smaller than that of the United Kingdom.

Figure 15 Distribution of Global Drug Sales Among Major National Markets, 2009



Source: IMS Health

Figure 16 Canada's Share of Global Drug Sales, 2005–2009

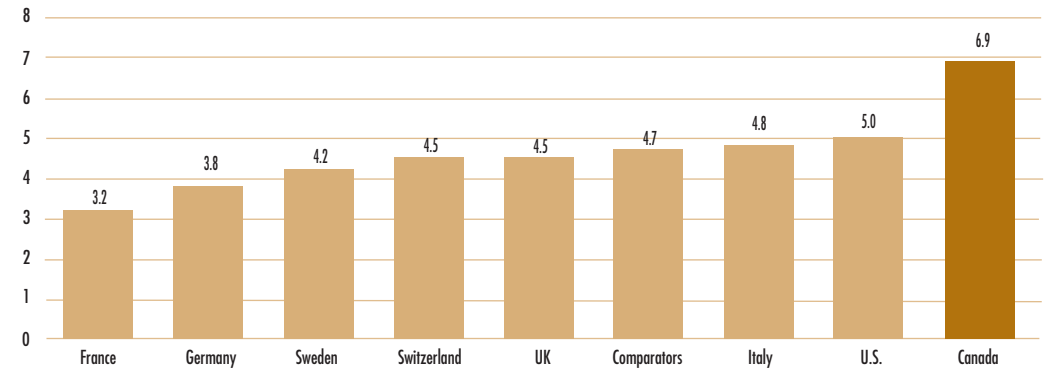


Source: IMS Health

Figure 16 provides Canada's share of global sales for each of the years 2005 through 2009. This share has remained between 2.4% and 2.6% throughout this period.

Figure 17 gives the average annual rate of growth in total drug sales for Canada and the seven comparator countries, individually and together. From 2005 to 2009 the sales growth in Canada increased at an annual average rate of approximately 6.9%. Drug sales among the seven comparator countries rose at an annual average rate of 4.7% over the same period.

Figure 17 Average Rate of Growth of Drug Sales, at 2009 Market Exchange Rates, by Country, 2005–2009



Source: IMS Health

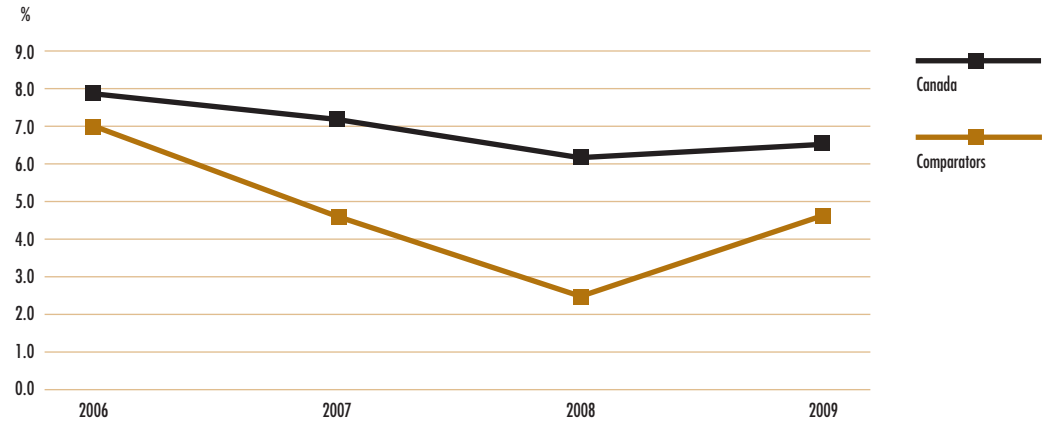
23 In previous Annual Reports, results presented in this section were largely based on data from IMS Health's Retail Drug Monitor, which provided estimates of direct (i.e., from the manufacturing company) and indirect (i.e., through a wholesaler) drug purchases by pharmacies in 13 major markets (Argentina, Australia, Brazil, Canada, France, Germany, Italy, Japan, Mexico, New Zealand, Spain, the U.K. and the U.S.). Beginning this year, results in this section are based on sales data from IMS Health's MIDAS database. These data cover both the pharmacy and hospital sectors, as well as a substantially larger set of countries than data from the Retail Drug Monitor.

24 The results given in Figures 15 through 18 are based on sales estimates encompassing patented and non-patented brand and generic drug products from IMS Health's MIDAS database. These estimates represent sales converted from own-currencies to Canadian dollar equivalents at market exchange rates. Fluctuations in these rates can substantially influence these shares, in addition to utilization and price trends.

Figure 18 compares rates of year-over-year growth in drug sales in Canada and the comparator countries taken together. Sales growth in Canada has exceeded growth in the comparators throughout this period.

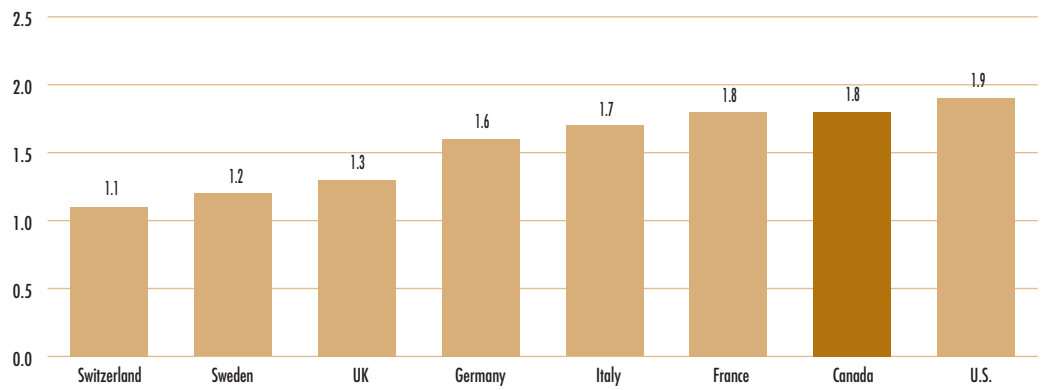
The proportion of national income allocated to the purchase of drug products provides another way to compare drug costs across countries.[25] Figure 19 gives drug expenditures as a share of Gross Domestic Product (GDP) for Canada and the seven comparator countries based on data for 2007. Drug expenditures absorbed between 1.1% and 1.9% of GDP in the seven comparators. Canada lies near the upper end of this range.

FIGURE 18 Average Annual Rate of Change in Drug Sales for Canada and Comparators, 2006–2009



Source: IMS Health

FIGURE 19 Drug Expenditures as a Share of GDP, 2007



Source: OECD

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

The share of national income absorbed by drug expenditures has risen in most developed countries in recent years. Table 16 shows that drug expenditures grew faster than GDP between 2000 and 2007 in Canada and all of the comparator countries except France and Italy. The results for the U.S. are especially striking, where drug expenditures grew at twice the rate of national income. Canadian drug expenditures grew at approximately one-and-half times the rate of GDP over this period.

Table 17 gives the composition of patentees' sales by therapeutic class for Canada and the seven comparator countries, individually and as an aggregate.[26] With the exception of cardiovascular drug products (which account for a substantially larger part of overall sales in Canada than anywhere else), these results imply a remarkable degree of similarity across countries.

TABLE 16 Drug Expenditures as a Share of GDP, 2007

	2007 Drug Expenditures as a share of GDP (%)	2000 Drug Expenditures as a share of GDP (%)	Drug Expenditures Growth 2000 – 2007 (%)	GDP Growth 2000 – 2007 (%)
Canada	1.79	1.42	140.18	90.78
France	1.79	1.81	68.46	70.06
Germany	1.57	1.43	79.92	63.83
Italy	1.68	1.74	77.43	83.87
Sweden	1.22	1.18	55.74	50.71
Switzerland	1.11	1.11	42.79	42.48
UK	1.33	1.14	85.33	59.19
U.S.	1.92	1.46	102.70	54.14

Source: OECD

TABLE 17 Drug Sales by Major Therapeutic Class for Canada and Comparator Countries, 2009

Therapeutic Class	Canada	Comparators	France	Italy	Germany	Sweden	Switzerland	United Kingdom	United States
A: Alimentary Tract and Metabolism	12.6	12.0	10.4	10.7	11.9	9.9	12.6	11.0	12.4
B: Blood and Blood-Forming Organs	4.0	6.7	8.3	7.6	5.4	7.2	5.3	5.3	6.6
C: Cardiovascular System	21.6	12.5	15.0	16.8	11.6	9.0	14.3	12.5	11.9
D: Dermatologicals	2.8	2.3	2.3	2.2	2.5	2.3	3.5	3.1	2.1
G: Genito-Urinary System and Sex Hormones	4.6	5.0	3.3	4.1	4.1	4.8	4.4	4.2	5.4
H: Systemic Hormonal Preparations	1.0	1.6	1.7	1.7	2.0	2.4	1.4	1.9	1.4
J: General Antiinfectives for Systemic Use	6.6	10.5	11.5	13.6	10.2	10.2	11.2	9.8	10.2
L: Antineoplastics and Immunomodulating Agents	10.0	12.3	14.6	13.1	14.8	14.5	12.9	10.7	11.6
M: Musculo-Skeletal System	6.0	4.9	5.3	5.7	5.9	7.1	6.8	5.3	4.5
N: Nervous System	18.1	18.7	13.9	11.6	16.2	18.6	16.1	19.1	20.3
P: Antiparasitic Products	0.2	0.1	0.2	0.0	0.1	0.1	0.1	0.3	0.1
R: Respiratory System	6.9	7.8	6.4	6.1	7.2	8.4	6.6	9.9	8.1
S: Sensory Organs	2.2	2.1	2.1	1.7	1.9	2.2	2.5	2.6	2.2
V: Various	3.6	3.7	5.0	5.1	6.2	3.3	2.2	4.2	3.1
All Therapeutic Classes	100.0*	100.0*	100.0	100.0	100.0	100.0*	100.0*	100.0*	100.0*

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

Source: IMS Health

26 Note that data used to produce Table 17 encompass patented, non-patented brand and generic drug products. Hence, the results reported here for Canada are not directly comparable to those in Table 11 (see page 23), which encompass only patented drug products.

Analysis of Research and Development Expenditures

The Act mandates the PMPRB to monitor and report on pharmaceutical research and development (R&D) spending (while giving the PMPRB no regulatory authority to consider the amount or type of patentees' research spending in the context of its price regulation). This chapter provides key statistics on the current state of pharmaceutical research investment in Canada.

Data Sources

The Act requires each patentee to report its total gross revenue from sales of all drugs for human or veterinary use (including revenue 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). The results presented below were entirely derived from data that patentees have submitted to the PMPRB via Form 3 (Revenues and Research and Development Expenditures Provided Pursuant to subsection 88(1) of the *Patent Act*).

The Regulations require that R&D data submitted to the PMPRB be accompanied by a certificate stating that the submitted information is "true and correct". The Board does not audit 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 these data, each patentee is given the opportunity to review and confirm the accuracy of its own R&D-to-sales ratio before publication in this report.

Companies without sales of patented medicines need not report on their R&D activity. For this reason, as new patents are granted and others expire, the set of companies required to file R&D data may change from year to year. In 2009, a total of 81 companies selling human and veterinary drug products reported on their R&D expenditures. Of these, 33 were members of Canada's Research-Based Pharmaceutical Companies (Rx&D).

Failure to File (Form 3)

It is a patentee's responsibility to ensure complete information is filed within the time frame set out in the Regulations. Although, in most cases, patentees ultimately comply with the filing requirements, an issue exists if patentees fail to file complete information within the time frames specified in the Regulations.

There were no Board Orders issued for the 2009 reporting period for a failure to file Form 3 information on revenues and R&D expenditures.

Sales Revenue

For reporting purposes, sales revenue is defined as total gross revenue from sales in Canada of drug products and from licensing agreements (e.g., royalties and license fees related to sales in Canada by licensees).

Patentees reported total 2009 sales revenues (Table 18) of $17.1 billion, an increase of 4.5% from 2008. Sales revenue reported by Rx&D members was $13.8 billion, accounting for 80.7% of the total. Less than 1% of reported sales revenue was generated by licensing agreements.

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 for scientific research and experimental development under the provisions of the *Income Tax Act* in effect on December 1, 1987. 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 patentees' filings.

Table 18 provides total R&D expenditures reported by patentees over the period 1988 through 2009. R&D expenditures were $1.2 billion in 2009, a decline of 2.9% over 2008. Rx&D members reported R&D expenditures of $1.1 billion in 2009, a decrease of 3.3% over last year. Rx&D members accounted for 89.1% of all reported R&D expenditures. Patentees that were not members of Rx&D reported R&D expenditures of $138.6 million in 2009, an increase of 0.1% over last year.

Table 18 Total R&D Expenditures and R&D-to-Sales Ratios of Reporting Companies, 1988–2009

Year	Companies Reporting	Total R&D Expenditures ($M)	Change from Previous Year (%)	Total Sales Revenue ($M)	Change from Previous Year (%)	R&D-to-Sales Ratio	
						All Patentees (%)	Rx&D Patentees (%)
2009	81	1,272.0	-2.9	17,051.9	4.5	7.5	8.2
2008	82	1,310.7	-1.1	16,316.7	2.0	8.1	8.9
2007	82	1,325.0	9.5	15,991.0	7.3	8.3	8.9
2006	72	1,210.0	-1.9	14,902.0	4.7	8.1	8.5
2005	80	1,234.3	5.5	14,231.3	0.5	8.7	8.8
2004	84	1,170.0	-2.0	14,168.3	4.0	8.3	8.5
2003	83	1,194.3	-0.4	13,631.1	12.8	8.8	9.1
2002	79	1,198.7	13.0	12,081.2	12.5	9.9	10.0
2001	74	1,060.1	12.6	10,732.1	15.3	9.9	10.6
2000	79	941.8	5.3	9,309.6	12.0	10.1	10.6
1999	78	894.6	12.0	8,315.5	19.2	10.8	11.3
1998	74	798.9	10.2	6,975.2	10.9	11.5	12.7
1997	75	725.1	9.0	6,288.4	7.4	11.5	12.9
1996	72	665.3	6.4	5,857.4	9.9	11.4	12.3
1995	71	625.5	11.5	5,330.2	7.5	11.7	12.5
1994	73	561.1	11.4	4,957.4	4.4	11.3	11.6
1993	70	503.5	22.1	4,747.6	14.0	10.6	10.7
1992	71	412.4	9.6	4,164.4	6.9	9.9	9.8
1991	65	376.4	23.2	3,894.8	18.1	9.7	9.6
1990	65	305.5	24.8	3,298.8	11.0	9.3	9.2
1989	66	244.8	47.4	2,973.0	9.4	8.2	8.1
1988	66	165.7	-	2,718.0	-	6.1	6.5

Source: PMPRB

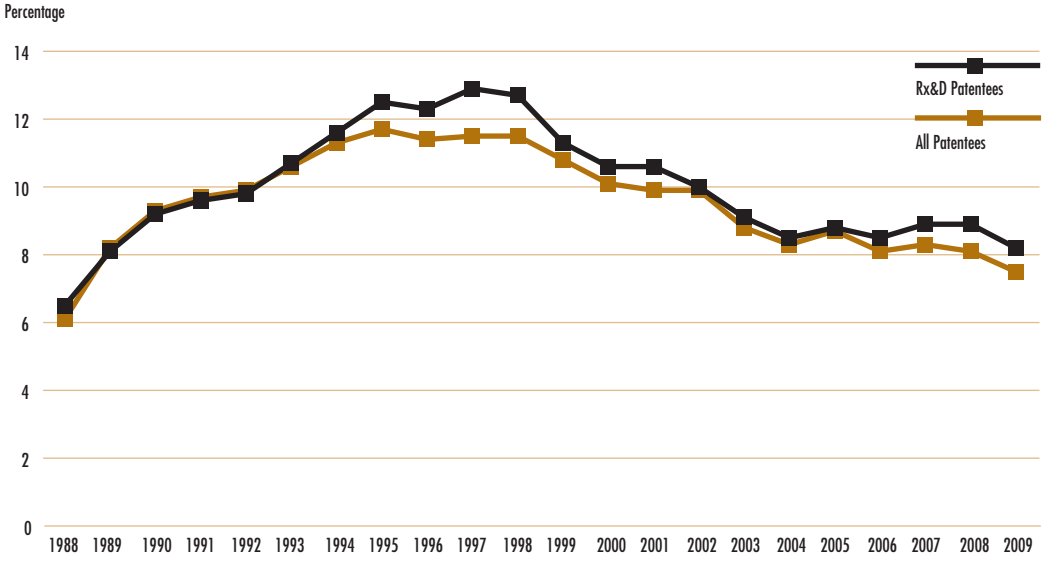
R&D-to-Sales Ratios

Table 18 also provides ratios of R&D expenditures to sales revenue. With the adoption of the 1987 amendments to the Act, Rx&D made a public commitment to increase their annual research and development (R&D) expenditures to 10% of sales revenue by 1996.[27]

The ratio of R&D expenditures to sales revenue among all patentees was 7.5% in 2009, down from 8.1% in 2008. This is the lowest ratio since 1989, and also represents the ninth consecutive year it has been below 10%. The ratio for members of Rx&D was 8.2%, down from 8.9% in 2008.[28] This is the lowest ratio since 1990, and also represents the seventh consecutive year it has been below 10%. Overall, the R&D-to-sales ratios for all patentees and for Rx&D members have been on a downward trend since the mid 1990s.

Table 24 in Annex 4 provides details on the range of R&D-to-sales ratios. Of the 81 companies reporting in 2009, 63 had R&D-to-sales ratios below 10% in 2009. These companies accounted for 71% of total sales revenue in 2009.

FIGURE 20 Ratio of R&D-to-Sales of Pharmaceutical Patentees, 1988–2009



Sources: PMPRB

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

28 The R&D-to-sales ratios presented in Table 18 include research expenditures funded by government grants. If the government-funded component is excluded, the ratios for all patentees and for the members of Rx&D in 2009 are 7.3% and 8.0%, respectively.

Current Expenditures by Type of Research

Table 19 and Figure 21 (as well as Figure 24 in Annex 4) provide information on the allocation of 2009 current R&D expenditures[29] among basic and applied research and other qualifying R&D.[30] Patentees reported spending $237.1 million on basic research in 2009, representing 19.4% of current R&D expenditures and an increase of 18.4% over the previous year. Patentees reported spending $685.3 million on applied research, representing 56.2% of current R&D expenditures. Clinical trials accounted for 76.8% of applied research expenditures.

Current Expenditures by R&D Performer and Source of Funds

Patentees reported expenditures on research they conduct themselves (intramural) and research performed by other establishments, such as universities, hospitals and other manufacturers (extramural). Table 20 shows that, in 2009, 51.6% of current expenditures were intramural, up from 49.2% in 2008. Research performed by other companies on behalf of patentees was 19.9% of current expenditures, while research conducted in universities and hospitals accounted for 15.4%.

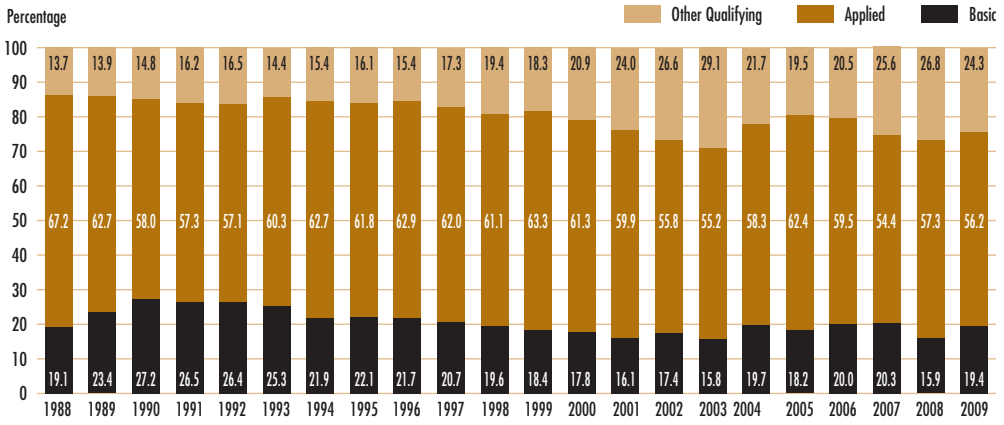
Table 19 Current R&D Expenditures by Type of Research, 2009 and 2008

Type of Research	2009 $Millions	2009 %	2008 $Millions	2008 %	Annual change in Expenditures (%)
Basic	**237.1**	**19.4**	**200.2**	**15.9**	**18.4**
Chemical	125.6	10.3	126.4	10.0	-0.6
Biological	111.5	9.1	73.8	5.9	51.1
Applied	**685.3**	**56.2**	**723.2**	**57.3**	**-5.2**
Manufacturing Process	86.9	7.1	90.5	7.2	-4.0
Pre Clinical Trial I	7.7	0.6	30.7	2.4	-74.9
Pre Clinical Trial II	64.2	5.3	62.1	4.9	3.4
Clinical Trial Phase I	45.0	3.7	53.1	4.2	-15.3
Clinical Trial Phase II	116.4	9.6	125.0	9.9	-6.9
Clinical Trial Phase III	365.1	29.9	361.8	28.7	0.9
Other Qualifying R&D	**296.8**	**24.3**	**337.9**	**26.9**	**-12.2**
Total	**1,219.2**	**100.0***	**1,261.3**	**100.0***	**-3.3**

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

Source: PMPRB

Figure 21 Current R&D Expenditures by Type of Research, 1988–2009



Source: PMPRB

29 Current R&D expenditures consist of non-capital expenses directly related to research, including (a) wages and salaries; (b) direct material; (c) contractors and sub-contractors; (d) other direct costs such as factory overhead; (e) payments to designated institutions; (f) payments to granting councils; and (g) payments to other organizations. These elements are described in more detail in *Form 3*, Revenues and Research and Development Expenditures available from the PMPRB Web site under the heading Regulatory Filings. Current R&D expenditure accounted for 96% of total R&D expenditure in 2009, while capital equipment costs and allowable depreciation expenses made up 2.2% and 1.8%, respectively.

30 "Basic research" is defined here 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.

Table 21 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 2009, accounting for 89.6% of current R&D expenditures. Funds received from government amounted to only 2.6% of current expenditures.

Current R&D Expenditures by Region

Table 22 (as well as Table 25 in Annex 4) show current R&D expenditures by region. As in previous years, expenditures were heavily concentrated in Ontario and Quebec, with these provinces accounting for 87.4% of total expenditures. While R&D expenditures increased at a year-over-year rate of 19.7% in Western Canada, they declined in Ontario by 4.6% and in Quebec by 6.5%.

Table 21 Total R&D Expenditures by Source of Funds, 2009 and 2008

Source of Funds	2009 $Millions	2009 %	2008 $Millions	2008 %	Annual Increase in Expenditures (%)
Company Funds	1,139.6	89.6	1,182.7	90.2	-3.6
Federal/Provincial Governments	33.8	2.6	36.3	2.8	-6.9
Others	98.6	7.7	91.7	7.0	7.5
Total	**1,272.0**	**100.0***	**1,310.7**	**100.0***	**-2.9**

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

Source: PMPRB

Table 20 Current R&D Expenditures by R&D Performer, 2009 and 2008

R&D Performer	2009 $Millions	2009 %	2008 $Millions	2008 %	Annual Increase in Expenditures (%)
Intramural					
Patentees	628.8	51.6	620.5	49.2	1.3
Extramural					
Universities and Hospitals	187.9	15.4	162.1	12.9	15.8
Other Companies	242.6	19.9	282.6	22.4	-14.1
Others	159.9	13.1	196.1	15.5	-18.4
Total	**1,219.2**	**100.0***	**1,261.3**	**100.0***	**-3.3**

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

Source: PMPRB

Table 22 Current R&D Expenditures by Region, 2009 and 2008

Location of R&D	2009 $Millions	2009 %	2008 $Millions	2008 %	Annual Increase in Expenditures (%)
Atlantic Provinces	19.6	1.6	21.3	1.7	-8.3
Québec	498.0	40.8	532.5	42.2	-6.5
Ontario	568.5	46.6	596.1	47.3	-4.6
Western Provinces	133.1	10.9	111.2	8.8	19.7
Territories	0.0	0.0	0.2	0.0	-84.1
Total	**1,219.2**	**100.0***	**1,261.3**	**100.0***	**-3.3**

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

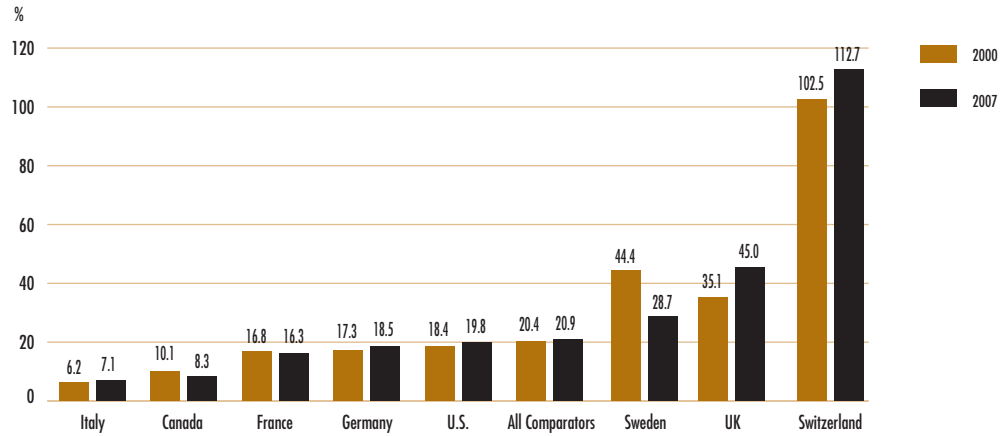
Source: PMPRB

The Global Context

Figure 22 compares Canadian R&D-to-sales ratios to those in the PMPRB's seven comparator countries for the years 2000 and 2007.[31] As noted in Figure 22, 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%. A similar pattern emerges in the investment-to-sales ratios for 2007. Italy remained at the bottom of the range at 7.1%, with Canada second lowest at 8.3%. Ratios in all other comparator countries remained well above Canada's ratio. The ratio obtained by aggregating R&D spending and sales across all comparators countries was 20.9%, two and a half times the value obtained for Canada.

It is worth comparing the R&D-to-sales ratios represented in Figure 22 to the average bilateral price ratios reported in Figure 11 on page 29. Such a comparison reveals no obvious correlation between a country's R&D-to-sales performance and its policies with regard to the pricing of patented drug products. In particular, several comparator countries have achieved R&D-to-sales ratios well above those in Canada despite patented drug prices that are, on average, not substantially higher (or even less) than prices in this country. France constitutes a particularly interesting point of comparison with an R&D-to-sales ratio twice that observed in Canada despite prices that are, on average, at least 10% less than their Canadian counterparts.

Figure 22 R&D-to-Sales Ratio for Canada and Seven PMPRB Comparator Countries, 2000 and 2007



Source: PMPRB, European Federation of Pharmaceutical Industries and Associations, PhRMA

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

National Prescription Drug Utilization Information System

The National Prescription Drug Utilization Information System (NPDUIS) provides critical analyses of price, utilization and cost trends in Canada to support decision-making by participating federal, provincial and territorial public drug plans. The NPDUIS initiative involves two major elements:

- development of a database incorporating data on individual claims reimbursed by public drug plans; and
- production of analytical reports using information in this database.

The Canadian Institute for Health Information (CIHI) is responsible for the first element, while the PMPRB (as requested by the Minister of Health under section 90 of the *Patent Act*) is principally responsible for the second element.

The NPDUIS Steering 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. In 2009, the NPDUIS Steering Committee held quarterly teleconference calls and met twice in Ottawa.

During 2009, the PMPRB advanced work underway on projects examining professional fee expenditures, the prices of generic drug products and the impact of generic entry on drug utilization. Following a priority-setting discussion at the May meeting of the NDPUIS Steering Committee, work also began to examine potential savings associated with some top-selling drugs expected to go off-patent, wholesale up-charge policies and the use of diabetes test strips.

As part of the ongoing efforts to communicate the results of NPDUIS research and engage researchers outside of government, the PMPRB also facilitated a joint meeting between the NPDUIS Steering Committee and the Pharmaceutical Policy Research Collaboration (PPRC), a network of academic researchers examining pharmaceutical issues through grants provided by the Canadian Institutes of Health Research. The meeting provided policy makers and researchers with an excellent opportunity to share perspectives, exchange information, and identify common priorities for future policy research.

In September 2001, federal/provincial/territorial Ministers of Health established the National Prescription Drug Utilization Information System to provide Canada's health system with more comprehensive, accurate information on the use of prescription drugs and their drivers.

Communications

The PMPRB Communications Program seeks to sustain high levels of transparency, accessibility and stakeholder engagement.

Communications Program

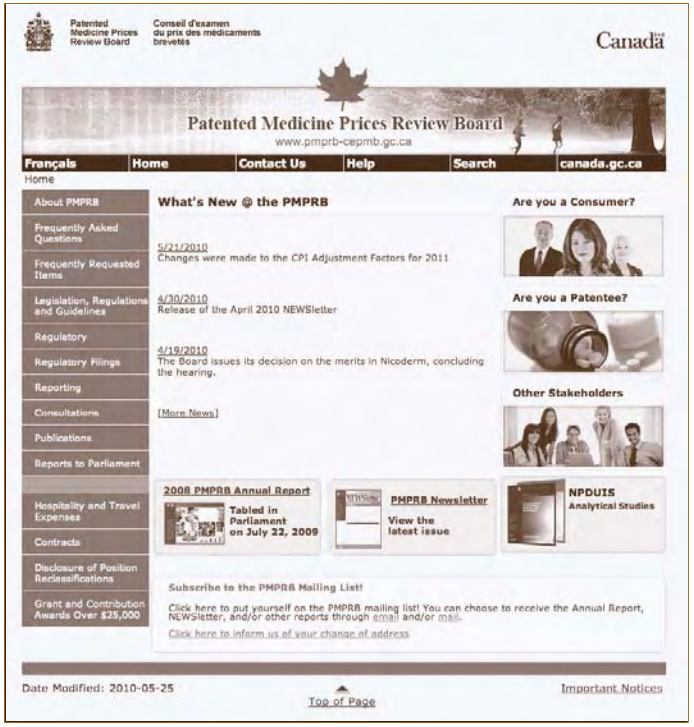
The Communications Program is primarily responsible for planning and managing the PMPRB's external communications activities, as well as raising the organization's visibility.

It focuses on adapting to the changing requirements of the PMPRB's operating environment. The main responsibilities of developing and managing the external communications activities also include relations with the media and reporting on the Board's quasi-judicial proceedings.

Publications

The PMPRB regularly informs its stakeholders on its activities through its publications. The Annual Report and the NEWSletter, published quarterly, along with other publications, are released in response to program and corporate requirements.

All PMPRB publications, including Board decisions in hearings, are available on its Web site.



Glossary

This glossary is included for the convenience of the reader. 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 Drugs 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 average potential 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 Drugs 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 in respect of a medicine issued by the Health Products and Food Branch of Health Canada under section C.08.004 of the *Food and Drugs 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.

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

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

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

Research and Development — Other Qualifying: Includes eligible research and development expenditures that cannot be classified into any of the preceding categories of "type of research and development". It includes 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 Web site 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 Chairman may approve 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 approved by the Chairman or the Board.

Annexes

Annex 1

Criteria for Commencing an Investigation

A price is considered to be within the Guidelines unless it meets the criteria for commencing an investigation. The criteria represent the standards the Board applies in order to allocate its resources to investigations as efficiently as possible. Their existence should not be construed as indicating that the Board accepts any deviation from the Guidelines. The Board is satisfied that its criteria ensure all significant cases of pricing outside the Guidelines will be subject to investigation. The Board expects the prices of all patented medicines to be within the Guidelines and evidence of persistent pricing outside the Guidelines, even by a small amount, may be used as a criterion for commencing an investigation.

Board Staff will commence an investigation into the price of a patented drug product when any of the following criteria are met:

New Drug Products

- The introductory price is 5% or more above the **maximum non-excessive price**;
- Excess revenues in the introductory period are $25,000 or more; or
- There is a complaint with significant evidence.

Existing Drug Products

- A price is 5% or more above the **maximum non-excessive price** there are cumulative excess revenues of $25,000 or more over the life of the patent after January 1, 1992;
- Cumulative excess revenues are $50,000 or more over the life of the patent after January 1, 1992; or
- There is a complaint with significant evidence.

For more information on the Criteria for Commencing an Investigation, please consult the *Compendium of Policies, Guidelines and Procedures*, available on the PMPRB's Web site under Legislation, Regulations and Guidelines.

Annex 2

Patented Drug Products Introduced in 2009

Brand Name	Company	DIN	NAS[1]/FPG[2]	ATC[3]	Status	Category
Abilify - 2 mg/tablet	Bristol-Myers Squibb Canada Co.	02322374		N	Within Guidelines	1
Abilify - 5 mg/tablet	Bristol-Myers Squibb Canada Co.	02322382		N	Within Guidelines	1
Abilify - 10 mg/tablet	Bristol-Myers Squibb Canada Co.	02322390		N	Within Guidelines	1
Abilify - 15 mg/tablet	Bristol-Myers Squibb Canada Co.	02322404	NAS/FPG	N	Subject to Investigation	3
Abilify - 20 mg/tablet	Bristol-Myers Squibb Canada Co.	02322412		N	Within Guidelines	1
Abilify - 30 mg/tablet	Bristol-Myers Squibb Canada Co.	02322455	FPG	N	Within Guidelines	1
Actonel - 150 mg/tablet	Procter & Gamble Pharmaceuticals Canada Inc.	02316838		M	Within Guidelines	1
Alimta - 100 mg/vial	Eli Lilly Canada Inc.	02306433		L	Within Guidelines	1
Alrex - 2 mg/mL	Bausch & Lomb Canada Inc.	02320924	NAS	S	Under Review	3
Apidra - 100 unit/mL	sanofi-aventis Canada Inc.	02279460	FPG	A	Within Guidelines	1
Apidra - 100 unit/mL	sanofi-aventis Canada Inc.	02279479		A	Under Review	1
Apidra Solostar - 100 unit/mL	sanofi-aventis Canada Inc.	02294346	NAS/FPG	A	Within Guidelines	3
Atacand Plus 32/12.5 - 44.5 mg/tablet	AstraZeneca Canada Inc.	02332922		C	Under Review	1
Atacand Plus 32/25 - 57 mg/tablet	AstraZeneca Canada Inc.	02332957		C	Under Review	1
Azarga 1/0.5 - 1.5 mg/mL	Alcon Canada Inc.	02331624		S	Under Review	3
Cayston - 75 mg/vial	Gilead Sciences Inc.	02329840		J	Under Review	3
Cimzia - 200 mg/mL	UCB Canada Inc.	02331675	NAS	L	Under Review	3
Coversyl Plus HD 8/2.5 - 10.5 mg/tablet	Servier Canada Inc.	02321653		C	Within Guidelines	1
DDVAP Melt - 240 mcg/tablet	Ferring Inc.	02285010		H	Within Guidelines	1
Doribax - 500 mg/vial	Janssen-Ortho Inc.	02332906	NAS	J	Under Review	3
Emend IV - 115 mg/vial	Merck Frosst Canada Ltd.	02324679	NAS	A	Within Guidelines	3
Firmagon - 80 mg/vial	Ferring Inc.	02337029	NAS	L	Within Guidelines	3
Firmagon - 120 mg/vial	Ferring Inc.	02337037	NAS	L	Within Guidelines	3
Infanrix-Hexa	GlaxoSmithKline Inc.	02253852		J	Within Guidelines	3
Janumet 50/500 - 550 mg/tablet	Merck Frosst Canada Ltd.	02333856		A	Under Review	3
Janumet 50/850 - 900 mg/tablet	Merck Frosst Canada Ltd.	02333864		A	Under Review	3
Janumet 50/1000 - 1050 mg/tablet	Merck Frosst Canada Ltd.	02333872		A	Under Review	3
Lotemax - 5 mg/mL	Bausch & Lomb Canada Inc.	02321114	NAS	S	Under Review	3
Lumigan - 0.1 mg/mL	Allergan Inc.	02324997		S	Under Review	1

Brand Name	Company	DIN	NAS[1]/FPG[2]	ATC[3]	Status	Category
MabCampath - 30 mg/vial	Genzyme Canada Inc.	02290960		L	Under Review	1
Metvix - 168 mg/g	Galderma Canada Inc.	02323273	NAS	L	Within Guidelines	3
Mezavant - 1200 mg/tablet	Shire Canada Inc.	02297558	FPG	A	Within Guidelines	1
Micardis Plus 80/25 - 105 mg/tablet	Boehringer Ingelheim Canada Ltd.	02318709		C	Within Guidelines	1
Miochol-E - 20 mg/vial	Novartis Pharma Canada Inc.	02133326	FPG	S	Subject to Investigation	1
Multaq - 400 mg/tablet	sanofi-aventis Canada Inc.	02330989	NAS	C	Under Review	3
Niaspan FCT - 500 mg/tablet	Sepracor Pharmaceuticals Inc.	02309254		C	Under Review	1
Niaspan FCT - 750 mg/tablet	Sepracor Pharmaceuticals Inc.	02309262		C	Under Review	1
Niaspan FCT - 1000 mg/tablet	Sepracor Pharmaceuticals Inc.	02309289		C	Under Review	1
Olmetec - 20 mg/tablet	Schering-Plough Canada Inc.	02318660	NAS	C	Within Guidelines	3
Olmetec - 40 mg/tablet	Schering-Plough Canada Inc.	02318679	NAS	C	Within Guidelines	3
Olmetec Plus 20/12.5 - 32.5 mg/tablet	Schering-Plough Canada Inc.	02319616	NAS	C	Within Guidelines	3
Olmetec Plus 40/12.5 - 52.5 mg/tablet	Schering-Plough Canada Inc.	02319624	NAS	C	Within Guidelines	3
Olmetec Plus 40/25 - 65 mg/tablet	Schering-Plough Canada Inc.	02319632	NAS	C	Within Guidelines	3
Oxycontin - 15 mg/tablet	Purdue Pharma	02323192		N	Within Guidelines	1
Oxycontin - 30 mg/tablet	Purdue Pharma	02323206		N	Within Guidelines	1
Oxycontin - 60 mg/tablet	Purdue Pharma	02323214		N	Within Guidelines	1
Plavix - 300 mg/tablet	Bristol-Myers Squibb Canada Co.	02330555		B	Under Review	1
Prezista - 400 mg/tablet	Janssen-Ortho Inc.	02324016		J	Within Guidelines	1
Prezista - 600 mg/tablet	Janssen-Ortho Inc.	02324024		J	Subject to Investigation	1
Pristiq - 50 mg/tablet	Wyeth Pharmaceuticals	02321092	NAS	N	Within Guidelines	3
Pristiq - 100 mg/tablet	Wyeth Pharmaceuticals	02321106	NAS	N	Within Guidelines	3
Rasilez HCT 150/12.5 - 162.5 mg/tablet	Novartis Pharma Canada Inc.	02332728		C	Under Review	3
Rasilez HCT 150/25 - 175 mg/tablet	Novartis Pharma Canada Inc.	02332736		C	Under Review	3
Rasilez HCT 300/12.5 - 312.5 mg/tablet	Novartis Pharma Canada Inc.	02332744		C	Under Review	3
Rasilez HCT 300/25 - 325 mg/tablet	Novartis Pharma Canada Inc.	02332752		C	Under Review	3
Seroquel XR - 150 mg/tablet	AstraZeneca Canada Inc.	02321513		N	Within Guidelines	1
Somatuline Autogel - 60 mg/syringe	Tercica Inc.	02283395	NAS/FPG	H	Within Guidelines	3
Somatuline Autogel - 90 mg/syringe	Tercica Inc.	02283409	NAS/FPG	H	Within Guidelines	3

Brand Name	Company	DIN	NAS[1]/FPG[2]	ATC[3]	Status	Category
Somatuline Autogel - 120 mg/syringe	Tercica Inc.	02283417	FPG	H	Within Guidelines	3
Sprycel - 20 mg/tablet	Bristol-Myers Squibb Canada Co.	02293129	NAS/FPG	L	Within Guidelines	2
Sprycel - 50 mg/tablet	Bristol-Myers Squibb Canada Co.	02293137	NAS/FPG	L	Within Guidelines	2
Sprycel - 70 mg/tablet	Bristol-Myers Squibb Canada Co.	02293145	NAS/FPG	L	Within Guidelines	2
Sprycel - 100 mg/tablet	Bristol-Myers Squibb Canada Co.	02320193	FPG	L	Within Guidelines	1
Stelara - 45 mg/vial	Janssen-Ortho Inc.	02320673	NAS/FPG	L	Within Guidelines	3
Synflorix	GlaxoSmithKline Inc.	02320541	NAS	J	Within Guidelines	3
Tamiflu - 30 mg/capsule	Hoffmann-LaRoche Limited	02304848		J	Within Guidelines	1
Tamiflu - 45 mg/capsule	Hoffmann-LaRoche Limited	02304856		J	Within Guidelines	1
Tasigna - 200 mg/caplet	Novartis Pharma Canada Inc.	02315874	NAS/FPG	L	Subject to Investigation	3
Temodal - 140 mg/capsule	Schering-Plough Canada Inc.	02312794		L	Within Guidelines	1
Temodal - 180 mg/capsule	Schering-Plough Canada Inc.	02312816		L	Within Guidelines	1
Tykerb - 250 mg/tablet	GlaxoSmithKline Inc.	02326442	NAS	L	Under Review	3
Xamiol - 0.55 mg/g	LEO Pharma Inc.	02319012		D	Within Guidelines	1
Xeomin - 100 unit/vial	Merz Pharma Canada Ltd.	02324032	NAS	M	Under Review	3
Xyntha - 250 unit/vial	Wyeth Pharmaceuticals	02309483		B	Within Guidelines	1
Xyntha - 500 unit/vial	Wyeth Pharmaceuticals	02309491		B	Within Guidelines	1
Xyntha - 1000 unit/vial	Wyeth Pharmaceuticals	02309505		B	Within Guidelines	1
Xyntha - 2000 unit/vial	Wyeth Pharmaceuticals	02309513		B	Within Guidelines	1
Yaz 28 3/0.02	Bayer Inc.	02321157		G	Within Guidelines	1
Zeftara - 500 mg/vial	Janssen-Ortho Inc.	02313103	NAS/FPG	J	Within Guidelines	3
Zolinza - 100 mg/capsule	Merck Frosst Canada Ltd.	02327619	NAS	L	Under Review	3
Zostavax	Merck Frosst Canada Ltd.	02315939		J	Under Review	1

[1] NAS: New Active Substance
[2] FPG: First Patent Grant
[3] ATC: Anatomical Therapeutic Chemical Classification System

Source: PMPRB

Annex 3

Excess Revenues Collected Under Voluntary Compliance Undertakings and Board Orders, 2006–2010

Since 1993, the Board has approved a total of 66 VCUs and initiated 24 public hearings. These measures resulted in price reductions and offset of excess revenues by way of payments to the Government of Canada and/or to customers such as hospitals and clinics.

Excess revenues offset by way of payments to the Government were in excess of $37 million in 2009 and nearly $6 million in 2010 to date.

A total of $63.8M in excess revenues collected through VCUs and Board Orders (following Hearings) was paid to the Government of Canada in 2006 to 2010. The PMPRB was given the authority to collect excess revenue when the *Patent Act* was amended in 1993 and the power to issue Compulsory Licenses was removed.

	2006	2007	2008	2009	2010 (as of May 31)
Following an Investigation					
VCUs	4	3	4	7	6
($)	$198,482	$877,866	$4,568,083	$13,700,190	$1,863,802
Resulting From Hearings					
VCUs		3		3	
($)	$669,515[1]	$5,194,599		$23,530,627	$786,882[1]
Orders		1	1		2
($)		$3,736,398	$5,622,864		$3,057,809
Total $	**$867,997**	**$9,808,863**	**$10,190,947**	**$37,230,817**	**$5,708,493**

[1] As per VCU approved in previous year.

Annex 4

Research & Development

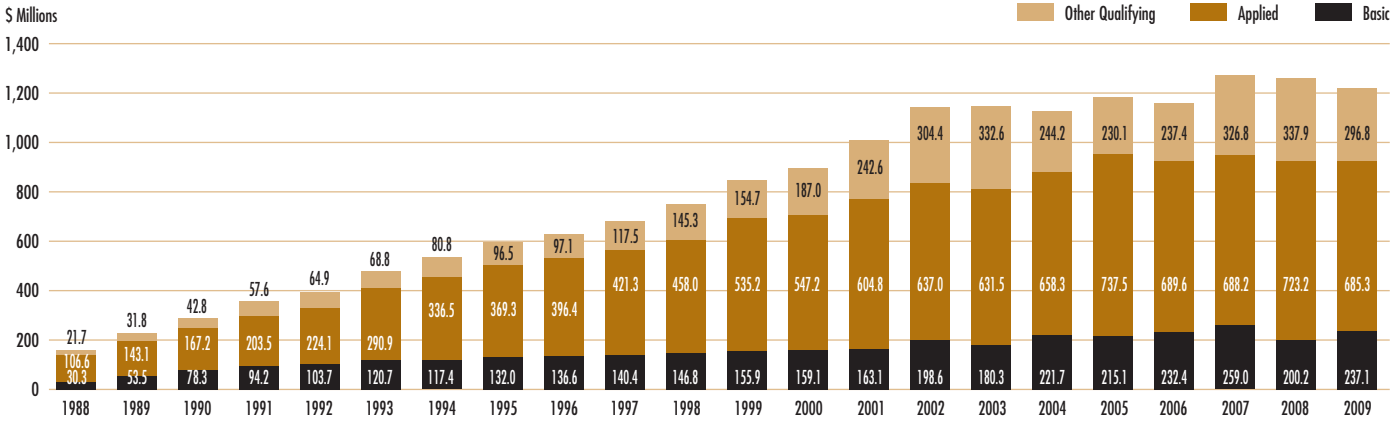
Table 23 Range of R&D-to-Sales Ratios by Number of Reporting Companies and Total Sales Revenue

Range: R&D-to-Sales Ratio	2009 Number of Reporting Companies	2009 Total Sales Revenue $Millions	2009 Total Sales Revenue % Share	2008 Number of Reporting Companies	2008 Total Sales Revenue $Millions	2008 Total Sales Revenue % Share
0%	23	561.9	3.3	25	737.7	4.5
≤ 10%	40	12,081.7	70.9	37	10,803.3	66.2
> 10%	18	4,408.3	25.9	20	4,775.7	29.3
Total	**81**	**17,051.9**	**100.0***	**82**	**16,316.7**	**100.0***

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

Source: PMPRB

Figure 23 Current R&D Expenditures by Type of Research, 1988–2009



Source: PMPRB

TABLE 24 Ratios of R&D Expenditures to Sales Revenue by Reporting Patentee[1], 2009 and 2008

Company	R&D-to-Sales Ratio (%) 2009	2008
Abbott Laboratories, Ltd.[2,5]	2.8	4.9
Abraxis BioSciences Canada Inc.[5]	24.6	17.6
Actelion Pharmaceutiques Canada Inc.[2]	9.3	7.8
Alcon Canada Inc.	0.3	0.3
Allergan Inc.	9.5	6.6
Amersham Health Inc. (GE Healthcare Inc.)	0.0	0.0
Amgen Canada Inc.[2,5]	7.1	6.1
Astellas Pharma Canada Inc.[2,9,5]	12.7	10.4
AstraZeneca Canada Inc.[2,5]	6.1	6.7
Axcan Pharma Inc.[2]	40.8	27.7
Baxter Corporation[5]	0.1	0.2
Bayer Inc., Healthcare Division[2]	3.3	3.2
Biogen Idec Canada Inc.[2,5]	6.6	1.6
Biovail Pharmaceuticals Canada, Division of Biovail Corporation[5]	4.6	23.5
Biovitrum AB[6]	0.0	–
Boehringer Ingelheim (Canada) Ltd.[2]	15.9	22.0
Bracco Diagnostics Canada Inc.	0.0	0.0
Bristol-Myers Squibb Pharmaceutical Group[2,5]	10.1	13.3
Celgene Canada[5]	2.8	–
Duchesnay Inc.	3.4	12.3
Eli Lilly Canada Inc. (includes Provel Animal Health Division)[2,5]	10.2	11.4
EMD Serono Canada Inc.[2,5]	15.7	2.9
Enzon Pharmaceuticals Inc.	0.0	0.0
Ferring Inc.	4.8	2.9
Fournier Pharma Inc.[2,4]	0.0	0.0
Fresenius Kabi Canada	0.7	0.7
Fresenius Medical Care Canada	0.0	0.0

Company	R&D-to-Sales Ratio (%) 2009	2008
Galderma Canada Inc.	0.4	1.1
Genzyme Canada Inc.[5]	0.6	1.3
Gilead Sciences Inc.[5]	32.6	45.8
GlaxoSmithKline Inc.[2,5]	13.3	11.3
Graceway Pharmaceuticals	0.0	0.0
Hoffmann-La Roche Ltd. Canada[2,5]	5.2	3.8
Hospira Healthcare Corp.	0.0	0.0
INO Therapeutics	6.9	2.1
Iroko International LP	0.0	0.0
Janssen-Ortho Inc.[2,5]	7.0	8.7
Johnson & Johnson Merck, Consumer Pharmaceuticals of Canada	0.0	0.0
Lantheus MI Canada Inc.	0.0	0.0
LEO Pharma Inc.[2]	2.5	3.7
Les Laboratories Inc.[7]	0.0	0.0
Lundbeck Canada Inc.[2]	3.2	3.9
Lundbeck Inc. (Ovation Pharmaceuticals Inc.)	0.0	0.0
McNeil Consumer Healthcare Canada	1.9	2.9
Merck Frosst Canada Ltd.[2,5]	12.1	14.8
Merck Frosst –Schering Pharma[2]	0.3	0.7
Merz Pharma Canada Ltd.[6]	109.7	–
Novartis Consumer Health Canada Inc.	0.0	0.0
Novartis Pharmaceuticals Canada Inc.[2,5]	18.1	16.7
Novo Nordisk Canada Inc.[5]	1.5	3.1
Nycomed Canada Inc.[2,3,5]	0.6	0.7
Ortho Dermatological, Division of Johnson & Johnson Inc.	0.0	0.0
Otsuka America Pharmaceuticals	0.0	0.0
Paladin Laboratories Inc.[2]	0.2	0.2

Company	R&D-to-Sales Ratio (%)	
	2009	2008
Pfizer Canada Inc.[2,5]	4.1	4.9
Pharmascience Inc.	9.9	8.5
Procter & Gamble Pharmaceuticals Canada, Inc.[2,5]	0.6	0.6
Pharmaceutical Partners of Canada Inc.	0.0	0.0
Purdue Pharma[2]	1.9	1.7
Rare Disease Therapeutics Inc.	0.0	0.0
sanofi pasteur Ltd.[2,5,10]	52.7	53.9
sanofi-aventis Pharma Inc.[2,11]	9.4	14.2
Santhera Pharmaceuticals Canada Inc.[5]	7.8	111.9
Schering-Plough Canada Inc.[2,5]	3.2	3.5
Sepracor Pharmaceuticals Canada Inc. (Oryx Pharmaceuticals Inc.)	0.0	0.0
Servier Canada Inc.[2]	8.7	10.9
Shire Canada Inc.[2,5]	0.0	0.0
Shire Human Genetic Therapies[5]	2.1	3.8
Solvay Pharma Inc.[2,5]	6.6	14.6
Sopherion Therapeutics Canada Inc.	118.1	0.0
Stiefel Canada Inc.	3.8	0.7
Takeda Canada Inc.[2,5,6]	16.2	–
Talecris Biotherapeutics Ltd.[5]	0.5	0.9
Tercica Inc.[6]	0.0	–
Teva Neuroscience Canada[5]	2.7	4.8
Tyco Healthcare Group Canada Inc.	0.0	0.0
UCB Pharma Canada Inc.[5]	44.1	55.6
Unither Biotech Inc.	0.0	0.0
Valeant Canada Ltd.[8]	2.9	1.8
Wyeth Pharmaceuticals[2,5]	23.1	24.1
YM Biosciences Inc.[5]	13611.6	12658.8

Notes:

1. Revenue from royalties is included in calculating each company's ratio, but not included in calculating industry-wide ratios (to avoid double-counting of sales revenue). 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. Also, 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 Rx&D.
3. Formerly known as Altana Pharma Inc. (prev. BYK Canada Inc.)
4. Merged with Solvay Pharma Inc.
5. Member of BIOTECanada.
6. Not a patentee in 2008.
7. Les Laboratories Inc. is the patent owner; however, BLES Biochemicals is the licensee as well as manufacturer.
8. Formerly known as ICN Canada Ltd.
9. Formerly known as Fujisawa Canada Inc.
10. Formerly known as Aventis Pasteur Ltd.
11. Formerly known as Aventis Pharma Inc.
12. Division of Paladin Labs Inc.

Source: PMPRB

TABLE 25 Current R&D Expenditures by Province/Territory and by R&D Performer, 2009

Province		R&D Performer							
		Patentees	Other Companies	University	Hospitals	Others	Total	Rx&D	Percentage of Expenditures
Newfoundland	$(000)	532.43	1,783.35	359.85	866.34	972.39	4,514.37	4,216.05	0.370
	%	11.79	39.50	7.97	19.19	21.54	100.00	0.386	
Prince Edward Island	$(000)	18.95	173.92	8.50	74.61	20.97	296.96	296.96	0.024
	%	6.38	58.56	2.86	25.12	7.06	100.00	0.027	
Nova Scotia	$(000)	1,906.06	2,905.62	2,935.84	1,543.72	2,277.57	11,568.81	10,872.11	0.949
	%	16.47	25.11	25.37	13.34	19.68	100.00	0.995	
New Brunswick	$(000)	403.00	1,378.96	58.61	913.30	417.13	3,171.00	3,151.64	0.260
	%	12.70	43.48	1.84	28.80	13.15	100.00	0.288	
Quebec	$(000)	286,568.24	111,927.18	12,387.11	27,214.27	59,898.47	497,995.27	483,908.19	40.846
	%	57.54	22.47	2.48	5.46	12.02	100.00	44.290	
Ontario	$(000)	270,062.91	100,499.60	47,288.46	67,174.87	83,489.79	568,515.63	491,738.32	46.630
	%	47.50	17.67	8.31	11.81	14.68	100.00	45.007	
Manitoba	$(000)	2,829.21	1,589.09	655.51	1,899.34	1,155.54	8,128.69	7,216.81	0.667
	%	34.80	19.54	8.06	23.36	14.21	100.00	0.661	
Saskatchewan	$(000)	1,178.23	747.33	1,122.70	426.51	713.93	4,188.71	4,136.69	0.344
	%	28.12	17.84	26.80	10.18	17.04	100.00	0.379	
Alberta	$(000)	54,137.76	8,826.83	10,846.93	2,700.31	4,955.80	81,467.63	49,420.14	6.682
	%	66.45	10.83	13.31	3.31	6.08	100.00	4.523	
British Columbia	$(000)	11,121.19	12,797.33	2,400.58	7,050.27	5,944.68	39,314.04	37,587.34	3.225
	%	28.28	32.55	6.10	17.93	15.12	100.00	3.440	
Territories	$(000)	00.00	00.00	00.00	00.00	34.00	34.00	34.000	0.003
	%	00.00	00.00	00.00	00.00	100.00	100.00	0.003	
Canada	**$(000)**	**628,757.99**	**242,629.21**	**78,064.10**	**109,863.54**	**159,880.27**	**1,219,195.11**	**1,092,578.27**	**100.00**

Notes to reader:

- 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