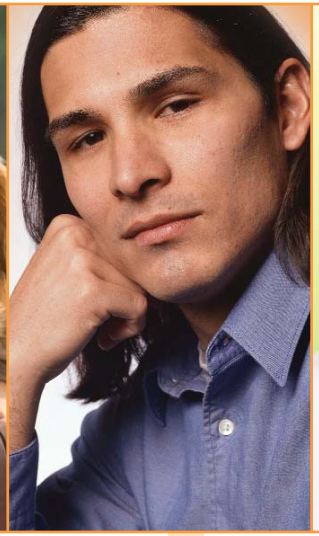
Patented
Medicine Prices
Review Board

Since 1987

ANNUAL REPORT 2008

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



Canada

www.pmprb-cepmb.gc.ca

Highlights 2008

Regulatory Mandate

Again in 2008, the PMPRB's regulatory activities increased.

Compliance

- 78 new patented drug products for human use were reported to the PMPRB. Of these, 19 are New Active Substances (marketed as 26 DINs). A total of 74 new patented drug products were reviewed of which 14 were found to be priced at levels which appeared to exceed the Guidelines and investigations were commenced.
- In total, 1,260 patented drug products for human use were under the PMPRB's jurisdiction.

Enforcement

- The Board approved 9 Voluntary Compliance Undertakings in 2008, up to and including April 2009
- The Board completed 4 hearings and issued 5 new Notices of Hearing (1 of which was in 2009). Decisions are pending in two additional matters. Currently there are 8 ongoing proceedings, including the Nicoderm matter, initiated in 1999.

Reporting Mandate

Sales Trends

- Sales of patented drug products in Canada increased by 5.0% to $13.0 billion in 2008.
- Share of total sales reported by patentees accounted for by patented drug products declined from 66% in 2007 to 64.9%, and continued the trend seen in recent years.
- The primary drivers of sales growth between 2007 and 2008 were general anti-infectives for systematic use and antiparasitic products and antineoplastics and immunomodulating agents (such as drugs used in chemotherapy).

Patented Drug Price Trends

- Prices changes in Canada – patentees' prices of patented drug products, as measured by the Patented Medicines Price Index (PMPI) rose by 0.1% from 2007 to 2008, while the Consumer Price Index (CPI) rose by 2.3%.
- Foreign-to-Canadian prices – Canadian prices were the third highest of the 7 comparator countries.
- The Median International Price (MIP)-to-Canadian price ratio stood at 0.96 from 0.98 in 2007.

Research and Development

- Patentees reported total R&D expenditures of $1.3 billion, a decline of 1.1% over 2007.
- Rx&D members accounted for 89.4% of all reported R&D expenditures in 2008, while non members of Rx&D reported R&D expenditures of $0.1 billion.
- The R&D-to-Sales ratio declined slightly for all patentees to 8.1% from 8.3% in 2007, while the R&D-to-Sales ratio for members of Rx&D remained at 8.9% as per 2007. The ratios have been below 10% for all patentees and for members of Rx&D since 2001 and 2003, respectively.

The Patented Medicine Prices Review Board

Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1
Telephone: (613) 952-7360
Facsimile: (613) 952-7626
TTY: (613) 957-4373
E-mail: pmprb@pmprb-cepmb.gc.ca
Web site: www.pmprb-cepmb.gc.ca

All PMPRB publications are available in both official languages, on line or by calling our toll-free number: 1 877 861-2350

Catalogue number: H78-2008
ISBN: 978-0-662-06859-4

PDF: Catalogue number: H78-2008E-PDF
ISBN: 978-1-100-12798-9

Patented
Medicine Prices
Review Board

Since 1987

May 29, 2009

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, 2008.

Yours very truly,

Brien G. Benoit, MD
Chairman

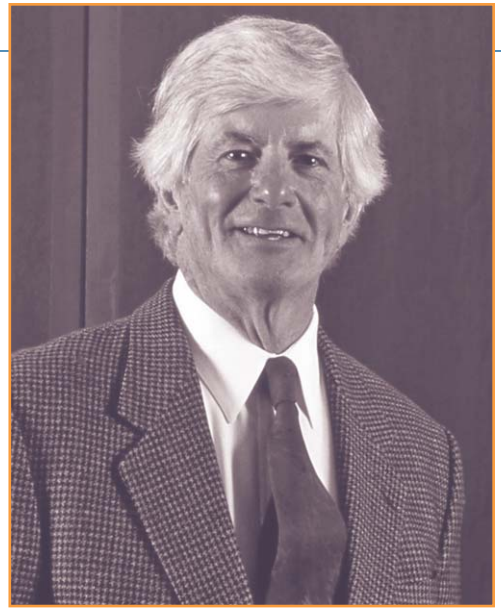
Canada

Table of Contents

List of Tables

List of Figures

Chairman's Message



The year 2008 marked the PMPRB's 20th year of operation. Throughout this period, we have witnessed important economic and social changes which have impacted Canadian health care and the pharmaceutical environment.

Also, 2008 proved to be a challenging year, with competing priorities and increasing demands on both the Board and its Staff. As part of its regulatory activities, the Board has completed four hearings and initiated four new proceedings and a fifth in early 2009. For the most part, matters before the Board focus on the scientific and pricing issues of patented brand name drug products. Some more recent cases, have also centered on the Board's jurisdiction, particularly with regard to drugs sold from outside the country through health Canada's Special Access Programme, and to patented generic drug products. While proceedings before the Board are time sensitive, resource intensive, and require dedication and thoughtful deliberation, they also provide patentees with an opportunity to be heard by the Board on issues vital to their operations. Board proceedings have, in some cases, resulted in judicial review applications before the Federal Court, which ultimately provide both the Board and patentees with clarification on the intent of the law.

The Board's consultative process relating to the review of its Excessive Price Guidelines has moved into its final stages. Initiated in 2005, this review was aimed at ensuring the fairness, transparency and predictability of the price review process. The consultations, along with the input of five working groups, were aimed at determining whether, where and how the Guidelines should be updated to be more appropriate, relevant and effective in today's modern pharmaceutical environment. Submissions on the Board's January 2008 Discussion Paper and Working Group Reports on different aspects of the Guidelines review have enabled us to craft Draft Revised Guidelines that were submitted to stakeholders for consultation in August. Having considered their comments, final Draft Revised Guidelines were issued in March 2009 for further feedback. Stakeholders have remained participative and, again, have provided useful comments and recommendations. The Board will be releasing its new Excessive Price Guidelines in June, along with an implementation date of January 1, 2010.

The Board is also pursuing its reporting activities, including through its continued collaborative work with the provinces and territories on analytical studies under the National Prescription Drug Utilization Information System.

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' participation, as needed, as their contribution to date has been invaluable.

I wish to take this opportunity to thank the Staff for its commitment, enthusiasm and continuous support. As well, I am pleased to recognize the dedication of our Board Members, and wish to thank them for their tireless efforts.

Brien G. Benoit, MD
Chairman

About The Patented Medicine Prices Review Board: Mandate and Jurisdiction

The Patented Medicine Prices Review Board 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; federal, provincial, and territorial public drug plans, which have responsibility for approving the listing of drugs on their respective formularies and determining price levels for the purpose of reimbursement; and the Common Drug Review, which provides listing recommendations based on cost-effectiveness to participating public drug plans.

Mandate

The PMPRB has a dual role:

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 pharmaceutical patentees.

Jurisdiction

Regulatory

The PMPRB is responsible for regulating the prices that patentees charge – the factory-gate price – 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 (each strength of an individual, final dosage form of a patented drug product). This is normally the level at which Health Canada assigns a Drug Identification Number (DIN).

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 is selling or because of manufacturing or processing patents, which various generic companies also hold.

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.

The PMPRB has no authority to regulate the prices of non-patented drugs, and does not have jurisdiction over prices charged by wholesalers or retailers, 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 *Patented Medicines Regulations*, 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 thereafter 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 it 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.

Health Canada assesses new medicines to ensure that they conform to the *Food and Drugs Act* and the *Food and Drug Regulations*. Formal authorization to market or distribute a medicine is granted through a Notice of Compliance (NOC). A medicine may be temporarily distributed with specified restrictions before receiving an NOC, as an Investigational New Drug or under Health Canada's Special Access Programme (SAP).

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 pharmaceutical 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. Under this provision, the Minister has directed the Board to undertake two initiatives: the National Prescription Drug Utilization Information System (NPDUIS), and monitoring and reporting on Non-Patented Prescription Drug Prices (NPPDP).

National Prescription Drug Utilization Information System

Since 2001, pursuant to an agreement by federal, provincial and territorial Ministers of Health, the PMPRB has been conducting research under the NPDUIS. The purpose of the NPDUIS is to provide critical analyses of price, utilization and cost trends so that Canada's health system has more comprehensive and accurate information on how prescription drugs are being used, and on sources of cost increases.

Non-Patented Prescription Drug Prices

In 2005, the Minister of Health, on behalf of federal, provincial and territorial Ministers of Health, directed the PMPRB to monitor and report on non-patented prescription drug prices. This function is aimed at providing a centralized credible source of information on non-patented prescription drug prices. Since April 2008, studies on non-patented prescription drug prices are conducted under the umbrella of the NPDUIS.

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 Member of the PMPRB in May of 2005, and in October of the same year he became Vice-Chairman, assuming the responsibilities of Chairman until his permanent appointment in June 2006.

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, 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.

Ms. Lindberg is currently the Executive Director of the Council of Academic Hospitals of Ontario (CAHO), an organization of 25 Academic Hospitals that are fully affiliated with a University and its Faculty of Medicine. Previously, she was with the Ontario Ministry of Health and Long Term Care, as the Assistant Deputy Minister, Health Services, with responsibilities that included the Ontario Health Insurance Plan (OHIP) and the Ontario Drug Programs.

Members

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, subsequently in private practice in Toronto with Jolliffe, Lewis & Osler and later as 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.

Left to right: Anthony Boardman, Anne Warner La Forest, Brian G. Benoit (Chairman), Mary Catherine Lindberg (Vice-Chairperson) and Tim Armstrong

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, 2002.

He is currently the Chair of the Radiation Safety Institute of Canada. His recent report to the Ontario government on trades and apprenticeship is the basis for new legislation in Ontario: *"The College of Trades and Apprenticeship Act, 2009"*.

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.

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*.

During his career, Dr. Boardman has published many articles in books and leading academic journals. Currently, he is working on the fourth edition of Cost-Benefit Analysis: Concepts and Practice.

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 panelist 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 Senior Counsel.

Executive Director

Is responsible for overall leadership of the operations of the PMPRB and managing the work of Staff.

Regulatory Affairs and Outreach

Reviews the prices of patented medicines sold in Canada to ensure that they are not excessive; encourages patentees to comply voluntarily with the Board's Excessive Price Guidelines; implements related compliance and enforcement policies; and investigates complaints into the prices of patented medicines. The Regulatory Affairs and Outreach Branch also promotes interaction with patentees.

Policy and Economic Analysis

Develops policy advice and recommendations on possible changes to the Board's Excessive Price Guidelines and on other policy issues, as needed; 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

Provides advice and services in human resources management, facilities, health, safety and security, information technology and information management; is also responsible for strategic and financial planning and reporting, audit and evaluation and liaison with federal central agencies on these topics.

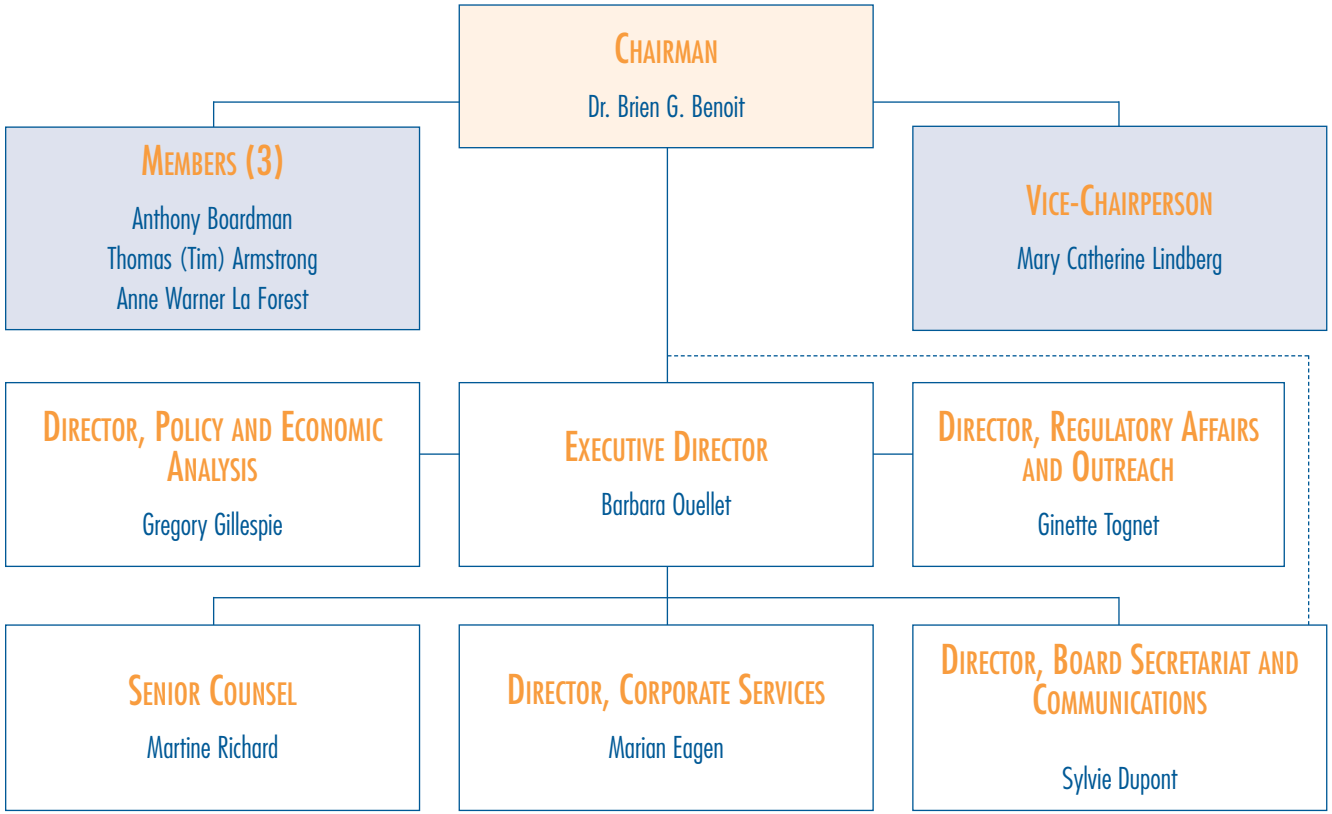
Board Secretariat and Communications

Develops and manages the PMPRB's communications, media relations and public enquiries; manages the Board's hearing process, including the official record of proceedings; and coordinates activities pursuant to the *Access to Information Act* and the *Privacy Act*.

Senior Counsel

Advises the PMPRB on legal matters and leads the prosecution team in proceedings before the Board.

Patented Medicine Prices Review Board



In 2007-2008, patentees offset excess revenues of $10.5 million by way of payments to the Government of Canada and/or to hospitals and clinics, and $27.2 million in 2008-2009. See Annex 3 for the Summary of VCUs and Board Orders.

Budget

The PMPRB operated with a budget of $11.1M in 2008-2009 and an approved staff level of 71 full-time equivalent employees. In addition to a budget for carrying out its core statutory mandate, the PMPRB budget included resources for the National Prescription Drug Utilization Information System (NPDUIS), as mandated by the Minister of Health.

Table 1 Budget

	2007 – 2008	2008 – 2009	2009 – 2010
Total PMPRB	11.925M	11.122M	11.358M
Full Time Equivalent	62	71	76

Regulating Prices of Patented Medicines

Regulatory Reporting Requirements

Under section 82 of the *Patent Act* (Act), pharmaceutical patentees are required to notify the PMPRB of their intention to offer a patented drug product for sale and the date on which they expect to begin selling it.

Under the *Patented Medicines Regulations* (Regulations), patentees are subsequently required to:

- file a Medicine Identification Sheet (Form 1) within 7 days after either the issuance of a Notice of Compliance or the date on which the patented drug product was first sold in Canada, whichever comes first. A copy of the product monograph or information similar to that contained in a product monograph when a Notice of Compliance has not been issued must also be filed at the same time as Form 1;
- report information on the introductory prices and sales covering the first day of sale in Canada of new patented drug products (Form 2), within 30 days of the date of first sale; and
- continue to file detailed information on prices and sales of each patented drug product for the first and last six-month period of each calendar year (Form 2) 30 days after the end of each period, i.e., on July 30 and January 30 respectively, for as long as the drug product remains under the Board's jurisdiction.
- Patentees selling over-the-counter drug products and drug products for veterinary use are required to file a Form 1 within 7 days after either the issuance of a Notice of Compliance or the date on which the patented drug product was first sold in Canada, whichever comes first. The prescribed Form 2 information (as above) must be reported for all periods of sale, within 30 days after the date on which the PMPRB sends a request in response to a complaint, and for the two years following the request, within 30 days after each reporting period.

The PMPRB reviews the 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 Excessive Price Guidelines (Guidelines) established by the Board. The Guidelines are published in the PMPRB's Compendium of Policies, Guidelines and Procedures.[2]

Failure to Report

In order to fulfill its regulatory mandate, as described on page 2, 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 a drug product to which a patent pertains is an important issue because it delays the price review. In 2008, four new drug products (8 DINs) were first reported to the PMPRB although they were patented and sold prior to 2008.

Trileptal, Physioneal (3 DINs), ratio-paroxetine (3 DINs) and ratio-fluticasone were patented and sold in Canada prior to being reported as being under the PMPRB's jurisdiction. They are currently being sold by Novartis Pharma Canada Inc., Baxter Corporation and ratiopharm respectively.

Table 2 **Failure to Report**

Currently being sold by	Brand Name	Generic Name	Year Medicine came under PMPRB's jurisdiction
Novartis Pharma Canada Inc.	Trileptal 60 mg/mL	oxcarbazepine	2006
Baxter Corporation	Physioneal 13.6 mg/mL, 22.7 mg/mL, 38.6 mg/mL	glucose	2007
ratiopharm	ratio-paroxetine 10 mg, 20 mg, 30 mg tablet	paroxetine hydrochloride	2003
	ratio-fluticasone 50 mcg/dose	fluticasone propinate	2007

2 The Compendium of Policies, Guidelines and Procedures (Compendium) is available on the PMPRB's Web site under Legislation, Regulations and Guidelines, or by calling the toll-free number: 1 877 861-2350.

Failure to File (FTF) Form 2

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.

The Board is pleased to report that there were no Board Orders issued to patentees for failure to file regulatory information for the January to June and July to December 2008 filing periods.

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 under Legislation, Regulations and Guidelines.

Excessive Price Guidelines

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. In summary, the Guidelines provide that:

- prices for most new patented drug products are limited such that the cost of therapy for the new drug product does not exceed the highest cost of therapy for existing drug products used to treat the same disease in Canada;
- prices of new breakthrough patented drug products and those that bring a substantial improvement are generally limited to the median of the prices charged for the same patented drug product in other industrialized countries listed in the Regulations (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States);
- price increases for existing patented drug products are limited to changes determined by the Board's Consumer Price Index (CPI) methodology; and
- prices of patented drug products in Canada may at no time exceed the highest price for the same patented drug product in the foreign countries listed in the Regulations.

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 50. 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.

As part of the PMPRB's transparency initiative, the list of *New Patented Medicines Reported to the PMPRB* is posted on its Web site every month. This list includes information on the status of the review (i.e., under review, within Guidelines, Under Investigation, VCU, Notice of Hearing).

Human Drug Advisory Panel (HDAP)

The Board established the 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 related 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 is comprised of 3 members:

- Dr. Jean Gray MD, FRCPC, Professor Emeritus of medical education, medicine and pharmacology at Dalhousie University;
- Dr. Mitchell Levine MD, MSc, FRCPC, FISPE, Professor, Department of Clinical Epidemiology and Biostatistics, at McMaster University and Director, Centre for Evaluation of Medicines, St. Joseph's Healthcare Hamilton; and
- Dr. Adil Virani BSc (Pharm), Pharm D, FCSHP, Director of Pharmacy Services at the Fraser Health Authority and Associate Professor at the Faculty of Pharmaceutical Sciences at the University of British Columbia.

New Patented Drug Products in 2008

There were 78 new patented drug products, or DINs, for human use introduced in 2008. Some are one or more strengths of a new active substance (NAS) and others are new presentations of existing medicines.

For purposes of the PMPRB's price review, a new patented drug product in 2008 is defined as any patented drug product first sold in Canada, or previously sold but first patented between December 1, 2007 and November 30, 2008.[3]

Figure 1 below provides information on new patented drug products for human use from 1989 to 2008.

Twenty two (28%) of the 78 new patented DINs were being sold in Canada prior to the issuance of a Canadian patent which brought them under the PMPRB's jurisdiction. These DINs are denoted by a "FPG" (first patent granted) in Annex 2 on page 51. Table 3 identifies the number of patented drug products by the year in which they were first sold. The time delay between date of first sale and date of patent grant for these products ranged from several months to five years, and one which was first sold prior to the creation of the PMPRB in 1987 (Fucidin, an antibiotic sold by LEO Pharma Inc.).

FIGURE 1 New Patented Drug Products for Human Use

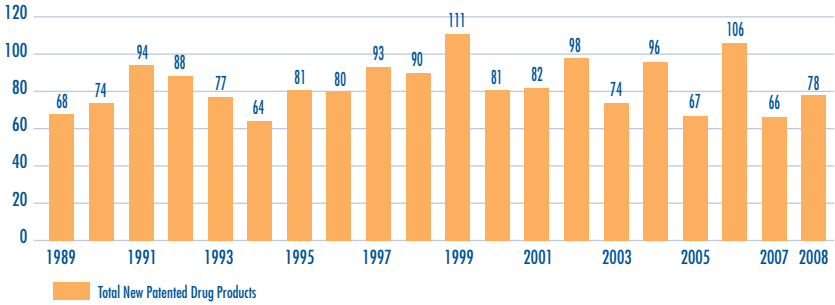


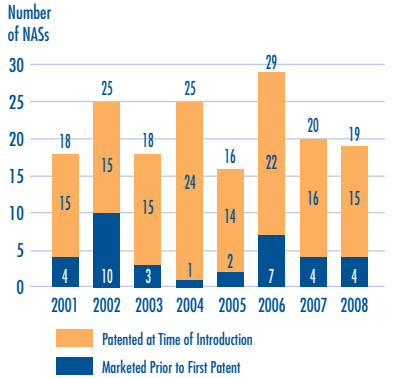
TABLE 3 New Patented Drug Products for Human Use in 2008 by Year First Sold

Year First Sold Total	# DINs
2008	58
2007	8
2006	8
2005	
2004	1
2003	2
1980	1
Total	78

New Active Substances in 2008

A new active substance (NAS) may involve more than one DIN if it is sold in more than one strength or dosage form. In 2008, there were 19 NASs marketed as 26 DINs. As shown in Figure 2, and Table 4, on page 11, four of the 19 patented NASs that came under the PMPRB's jurisdiction were sold prior to 2008.

FIGURE 2 New Active Substances, 2001 – 2008



3 Because of timing of the filing requirements under the *Patented Medicines Regulations*, and the manner of calculating benchmark prices, drug products introduced or patented in December are considered to be new patented products in the following year.

TABLE 4 New Actives Substances in 2008 (Human)

New Patented Medicines in 2008 (Human) – New Active Substances

Brand Name	Chemical Name	Company	# DINs	Therapeutic Use
Catena	idebenone	Santhera Pharmaceuticals (Canada) Inc.	1	Symptomatic management of Friedreich's ataxia
Cymbalta	duloxetine hydrochloride	Eli Lilly Canada Inc.	2	Antidepressant/analgesic
Eraxis	anidulafungin	Pfizer Canada Inc.	1	Antifungal
Frova	frovatriptan succinate	Teva Neuroscience	1	Migraine
Januvia	sitagliptin phosphate monohydrate	Merck Frosst Canada Ltd.	1	Diabetes
Natrecor	nesiritide	Janssen-Ortho Inc.	1	Acute decompensated congestive heart failure
Nevanac	nepafenac	Alcon Canada Inc.	1	Pain and inflammation following cataract eye surgery
Nimotuzumab	nimotuzumab	YM Biosciences Inc.	1	Cancer
Pradax	dabigatran etexilate	Boehringer Ingelheim (Canada) Ltd.	2	Venous throembolic events (VTE)
Relistor	methylnaltrexone bromide	Wyeth Pharmaceuticals	1	Constipation due to opioid therapy
Revlimid	lenalidomide	Celgene	2	Anemia
Torisel	temsirolimus	Wyeth Pharmaceuticals	1	Renal cell cancer
Volibris	ambrisentan	GlaxoSmithKline Inc.	2	Pulmonary arterial hypertension
Xarelto	rivaroxaban	Bayer Inc.	1	Venous thromboembolism
Zeldox	ziprasidone hydrochloride	Pfizer Canada Inc.	4	Antipsychotic

New Active Substances First Sold Prior to 2008

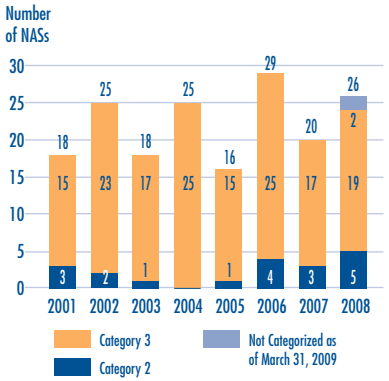
Brand Name	Chemical Name	Company	# DINs	Therapeutic Use
Intelence	etravirine	Janssen-Ortho Inc.	1	HIV
Lucentis	ranibizumab	Novartis Pharma Canada Inc.	1	Treatment of neovascular (wet) age-related macular degeneration (AMD)
Myozyme	alglucosidase alfa	Genzyme Canada Inc.	1	Treatment of Pompe's disease
Zevalin	ibritumomab tiuxetan	Bayer Inc.	1	Treatment of non-Hodkin's lymphoma

Figure 3, on page 12, provides a breakdown of the patented NASs for human use, by category assigned for price review purposes, over the eight-year period 2001 through 2008 inclusive.[4]

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.

4 For more information on categorization, please refer to the Compendium of Policies, Guidelines and Procedures.

FIGURE 3 New Active Substances by Category, 2001 – 2008



Price Review of New Patented Drug Products for Human Use in 2008

A list of the 78 new patented drug products and their price review status appears in Annex 2 on page 51. Of the 78 new patented DINs:

- the prices of 74 had been reviewed as of March 31, 2009
  - 60 were found to be within the Guidelines;
  - 14 were priced at levels which 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 50; and
- the prices of 4 DINs are still under review.

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.

TABLE 5 Summary of Review Status of New Patented Drug Products Reported to the PMPRB in 2002, 2003, 2004, 2005, 2006 and 2007

	2002	2003	2004	2005	2006	2007
New Medicines (DINs) reported in annual report	94	70	94	66	99	64
Failure to file reported after publication of annual report	4	4	2	1	7	2
Total DINs for year	98	74	96	67	106	66
Under Review	0	3	0	0	1	1
Within Guidelines	91	66	78	59	90	56
Investigation	0	0	0	0	12	7
Voluntary Compliance Undertaking (VCU)	3 (Starlix) 1 (Busulfex) 1 (Tamiflu)	1 (Dukoral)	2 (Paxil CR) 1 (Hextend) 2 (Eloxatin) 1 (Forteo)	1 (Nuvaring) 1 (Vaniqa)	1 (Denavir) 1 (Lantus)	2 (AndroGel)
Notice of Hearing (NOH)	–	–	1 (Penlac) 1 (Neulasta)	–	–	–
NOH/VCU	1 (Fasturec)	1 (Evra) 3 (Concerta)	3 (Risperdal Consta)	5 (Strattera) 1 (Concerta)	–	–
NOH Complete	1 (Dovobet)	–	1 (Copaxone) 6 (Adderall XR)	–	–	–
Federal Court	–	–	–	–	1 (Thalomid)	–

Price Review of Existing Patented Drug Products for Human Use in 2008

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, 2007. At the time of this report, there were 1,182 existing DINs:

- the prices of 1,032 existing DINs (87.3%) were within the Guidelines;
- 111 existing DINs were the subject of investigations
  - Of these, 19 were opened as result of introductory pricing

    12 in 2006

    7 in 2007
  - 92 were opened on the basis of year-over-year prices

    36 in 2008

    26 in 2007

    19 in 2006

    10 in 2005

    1 in 2003
- 9 existing DINs: Nicoderm (3 DINs), Penlac, Quadracel, Pentacel, Apo-Salvent CFC Free, ratio-salbutamol HFA and Neulasta, were the subject of hearings under section 83 of the Act. (see Hearings, on page 17);
- 16 DINs: Copaxone, Straterra (5 DINs), Adderall XR (6 DINs) and Concerta (4 DINs) were the subject of hearings that were completed by way of a VCU or Board Order; and
- 14 existing DINs were still under review.

A summary of the status of the price review of the new and existing patented drug products for human use in 2008 is provided in Table 6.

Table 6 Patented Drug Products (DINs) for Human Use Sold in 2008 – Status of Price Review as of March 31, 2008

	New Drugs Introduced in 2008	Existing Drugs	Total
Total	78	1,182	1,260
Within Guidelines	60	1,032	1,092
Under Review	4	14	18
Under Investigation	14	111	125
Notice of Hearing	0	9	9
Completed Hearings		16	16

Update of Existing Patented Drug Products from the 2007 Annual Report

In last year's Annual Report, it was reported that, of the 1,114 existing patented drug products for human use sold in 2007, the prices of 20 were still under review. The results of those reviews concluded that: 7 DINs were within the Guidelines; 4 DINs were priced at levels that appeared to exceed the Guidelines and therefore investigations were initiated; 8 DINs are still under review; and one DIN was determined not to be under the PMPRB's jurisdiction as a result of a Federal Court decision.

In its 2007 Report, the PMPRB had also reported that 97 DINs were under investigation. Of those, 33 investigations have been concluded: in 26 cases the prices were ultimately found to be within the Guidelines; in 4 cases VCUs were approved: Denavir, Vepesid, Suprax and Eligard (See Voluntary Compliance Undertakings on page 15); and, in 3 cases, Notices of Hearing were issued: Apo-Salvent CFC Free, ratio-salbutamol HFA and Neulasta (See Notices of Hearing on page 17). Sixty four DINs are still under investigation. It was also reported that 22 DINs were the subject of a Notice of Hearing (NOH) and, at the time of this report, four hearings (16 DINs) have been concluded: Copaxone, Concerta (4 DINs), Adderall XR (6 DINs), and Strattera (5 DINs). The hearings into the remaining 6 DINs (4 hearings) are ongoing.

CDR / PMPRB

The Common Drug Review (CDR) is a single process for reviewing new drugs and providing formulary listing recommendations to participating publicly-funded federal, provincial and territorial drug benefit plans in Canada. All jurisdictions are participating in the CDR except Quebec. The CDR reviews new drugs and provides an evidence-based formulary listing recommendation, based on cost-effectiveness, made by the Canadian Expert Drug Advisory Committee (CEDAC). The drug plans consider the CEDAC recommendation and also their individual plan mandates, priorities and resources when making formulary 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 (http://www.cadth.ca).

Table 7 provides information on drugs reviewed by CDR in 2008 and their status relative to the PMPRB. The CDR reviews drug products following the issuance of an NOC. The PMPRB reviews all patented drug products sold in Canada. A drug product may be sold prior to the issuance of a patent or be sold without being patented. As such, it would not be under the PMPRB's jurisdiction.

Table 7 Review Status

CEDAC Recommendation in 2008			PMPRB Status	Therapeutic Use
acamprosate calcium	Campral	To List*	Not Under PMPRB Jurisdiction	Alcohol abstinence
adalimumab	Humira	To List*	Within Guidelines	Rheumatoid arthritis
aliskiren	Rasilez	Do Not List	Within Guidelines	Hypertension
ambrisentan	Volibris	To List*	Within Guidelines	Pulmonary arterial hypertension
aprepitant	Emend	To List*	Within Guidelines	Prevention of nausea and vomiting due to chemotherapy
buprenorphine/naloxene	Suboxone	To List*	Not Under PMPRB Jurisdiction	Opioid drug dependence
carbidopa/levodopa/entacapone	Stalevo	To List**	Within Guidelines	Parkinson's disease
ciclesonide	Omnaris	Do Not List	Within Guidelines	Allergies
daptomycin	Cubicin	Do Not List	Within Guidelines	Antibiotic
duloxetine hydrochloride	Cymbalta	To List*	Within Guidelines	Antidepressant/analgesic
efavirenz/emtricitabine/tenofovir disoproxil fumarate	Atripla	To List*	Within Guidelines	HIV
etravirine	Intelence	To List*	Within Guidelines	HIV
lanthanum carbonate hydrate	Fosrenol	Do Not List	Within Guidelines	Hyperphosphatemia
paliperidone	Invega	Do Not List	Within Guidelines	Schizophrenia
posaconazole	Spriafil***	Do Not List	Within Guidelines	Antifungal
raltegravir	Isentress	To List*	Within Guidelines	HIV
ranibizumab	Lucentis	To List*	Within Guidelines	Treatment of neovascular (wet) age-related macular degeneration (AMD)
rivaroxaban	Xarelto	To List*	Subject to an Investigation	Venous thromboembolism
rivastigmine	Exelon	Do Not List	Within Guidelines	Alzheimer's disease
sitagliptin phosphate	Januvia	Do Not List	Within Guidelines	Diabetes
sitaxsentan sodium	Thelin	Do Not List	Within Guidelines	Pulmonary hypertension
tramadol hydrochloride	Tridural	Do Not List	Subject to an Investigation	Analgesic
tramadol hydrochloride	Raliva	Do Not List	Not Under PMPRB Jurisdiction	Analgesic
ziprasidone hydrochloride	Zeldox	To List*	Within Guidelines	Antipsychotic
zoledronic acid	Aclasta	Do Not List	Within Guidelines	Paget's Disease

* List with criteria/condition
** List in a manner similar to other drugs in class
*** Now known as Posanol
Sources: PMPRB and CADTH

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

Amendments to the Regulations were registered on March 6, 2008, and published in the *Canada Gazette*, Part II, on March 19, 2008. Board Staff will only review the price of a patented over-the-counter drug product and of a patented veterinary drug product when a complaint has been received. Please refer to the PMPRB Web site for further information. No complaints were received in 2008.

Update of Patented Drug Products for Veterinary Use from 2007 Annual Report

In last year's Annual Report it was reported that eight patented veterinary drug products were under review and they remain under review at the time of this report. Summary reports of the price reviews of patented drug products for veterinary use are posted on the PMPRB's Web site when the price review is completed and the price is within the Guidelines.

Voluntary Compliance Undertakings

A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to adjust the price of a patented drug product to conform to the Excessive Price Guidelines (Guidelines).

Patentees are given an opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price at which a patentee is selling or has sold a patented drug product in Canada appears to have exceeded the Guidelines.

Publication of VCU

VCUs are published upon their approval by the Chairperson. Once a patentee has been informed that the terms of a VCU have been approved, the document becomes public. VCUs are posted on the PMPRB's Web site, reported in the NEWSletter, and included in the Annual Report.

Approval of a VCU by the Chairperson is an alternative compliance mechanism to the commencement of formal proceedings through the issuance of a Notice of Hearing.

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.

Since January 2008, and up to the publication of this report, a total of nine VCUs were approved, two following the issuance of a Notice of Hearing.

AndroGel, Solvay Pharma Inc.
– June 2008

Concerta[5], Janssen-Ortho Inc.
– April 2009

Denavir, Barrier Therapeutics, Canada Inc.
– May 2008

Eligard, sanofi-aventis Canada Inc.
– April 2009

Lantus, sanofi-aventis Canada Inc.
– March 2008

Strattera[5], Eli Lilly Canada Inc.
– February 2009

Suprax, sanofi-aventis Canada Inc.
– March 2009

Vaniqa, Barrier Therapeutics Canada Inc.
– February 2008

Vepesid, Bristol-Myers Squibb Canada Co.
– February 2009

5 Subject to a Notice of Hearing

AndroGel 1% topical gel is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone.

On June 24, 2008, the Chairman of the Board accepted a VCU from Solvay Pharma Inc. for AndroGel. The terms of the VCU required that Solvay Pharma reduce the price of AndroGel 2.5g/pouch to the 2008 maximum non-excessive (MNE) price of $2.1263 and offset cumulative excess revenues received from May 2002 to December 31, 2007 by making a payment of $3,327,180.61 to the Government of Canada. Solvay Pharma also reimbursed excess revenues obtained in 2008.

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

The Board issued a Notice of Hearing into the price of Concerta on July 24, 2006. On April 24, 2009, the Hearing Panel approved a VCU submitted by the parties, thus concluding the Board's proceedings. The terms of the VCU require, among other things, that Janssen-Ortho Inc. offset excess revenues in the amount of $1,464,441.58 by making a payment to the Government of Canada.

Denavir is indicated for the treatment of recurrent herpes labialis (cold sores) in adults.

On May 20, 2008, the Chairman of the Board approved a VCU submitted by Barrier Therapeutics Canada Inc. for the medicine Denavir.

Barrier undertook to reimburse the excess revenues accrued over the period of August 2006 to December 2007 in the amount of $61,021.80 by making a payment to the Government of Canada.

Denavir is no longer sold in Canada.

Eligard is indicated for the palliative treatment of advanced prostate cancer.

On April 20, 2009, the Chairman approved a VCU submitted by sanofi-aventis Canada Inc. for the medicine Eligard. In addition to ensuring that the price of Eligard in each province is not excessive based on 2009 MNE prices to be 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 will be made directly to entities that purchased Eligard in each province.

Lantus is indicated for once-daily subcutaneous administration in the treatment of adult patients with Type 1 or Type 2 diabetes mellitus and pediatric patients (age 6-17 years) with Type 1 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

On March 14, 2008, the Chairman of the Board approved a VCU submitted by sanofi-aventis Canada Inc. for Lantus. In addition to reducing the price of Lantus to a non-excessive level, sanofi-aventis offset the cumulative excess revenues it received from sales of Lantus as of September 18, 2006 by making a payment to the Government of Canada in the amount of $694,239.50 and reducing the price of another patented drug product, Altace HCT.

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

The Board approved a VCU for Strattera on February 19, 2009, thereby concluding the proceedings commenced in this matter with the issuance of a Notice of Hearing on December 15, 2006. The terms of the VCU require that the prices of Strattera not exceed the 2009 MNE prices and that Eli Lilly Canada Inc. offset excess revenues in the amount of $15,326,066.49 by making a payment to the Government of Canada. In the event that any excess revenues remain as at June 30, 2009, Eli Lilly will make a payment to the Government of Canada.

Suprax is an antibiotic used in the treatment of infections caused by susceptible strains of designated micro-organisms.

The Chairman approved a VCU from sanofi-aventis Canada Inc. for the medicine Suprax 400 mg/tablet. Among other things, sanofi-aventis was to reduce the price of Suprax so that it does not exceed the 2009 MNE price. It also offset excess revenues received by making a first payment to the Government of Canada in the amount of $97,900.30 for the period of July 1, 2007 to June 30, 2008. Payments for the July-December 2008 period was also required.

Vaniqa is indicated for slowing of the growth of unwanted facial hair in women. It is recommended as an adjunct to any hair removal technique.

On February 28, 2008, the Chairman of the Board approved a VCU submitted by Barrier Therapeutics Canada Inc., for the medicine Vaniqa.

Barrier reimbursed the excess revenues accrued over the period of November 2005 to December 2007, by making a payment to the Government of Canada, in the amount of $70,860.59.

Vaniqa is no longer sold in Canada.

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

On February 23, 2009, the Chairman approved a VCU submitted by Bristol-Myers Squibb for the medicine Vepesid. Bristol-Myers Squibb Canada Co. offset excess revenues of $53,161.48 by making payments to customers that previously purchased Vepesid at excessive prices from 2005 to 2007.

Vepesid is no longer sold in Canada.

Hearings

The PMPRB's regulatory mandate is to ensure that patentees' prices of patented medicines are not excessive.

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 excessive prices. Board decisions are subject to judicial review in the Federal Court of Canada (FC).

On January 1, 2008, there were eight ongoing hearings into the matters of Adderall XR, Concerta, Copaxone, Nicoderm, Penlac, Pentacel and Quadracel, Strattera and Thalomid. Of these hearings, five were completed. Two hearings were concluded by way of VCUs: Concerta and Strattera. More details on the VCUs are available in the VCU section of this report.

Board Orders were issued in two matters: Adderall XR and Copaxone, thus concluding these proceedings. Also, the Hearing Panel issued its decision in the matter of the medicine Thalomid. This matter is currently before the Federal Court of Appeal. More details are available under Matters before the Federal Court, on page 19.

The Board issued four Notices of Hearing in 2008, into the matters of Apotex and ratiopharm Inc., for failure to file, and into the prices of the medicines Apo-Salvent CFC Free and ratio-Salbutamol HFA. On March 16, 2009, the Board issued a Notice of Hearing into the matter of Amgen Canada Inc. and the price of the medicine Neulasta.

At the time of publication of this report, eight matters remain before the Board: Apotex (failure to file), Apo-Salvent CFC Free, Neulasta, Nicoderm, Penlac, Pentacel and Quadracel, ratiopharm (failure to file) and ratio-Salbutamol HFA.

Table 8, on page 18, provides a summary of all matters before the Board in 2008 up to the publication of this report.

TABLE 8 Status of Board Proceedings

Patented Product Drug	Indication / Use	Patentee	Issuance of Notice of Hearing – Date	Status
Adderall XR	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	Shire Canada Inc. (Shire BioChem Inc. at issuance)	January 18, 2006	Decision: April 10, 2008 Order: August 27, 2008 i) Price reduction ii) Offset of excess revenues: $5,622,863.63 iii) Remaining offset: January '08 – Sept 15 '08
Apotex Inc.			March 3, 2008	Ongoing
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 16)
Copaxone	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	Decision: February 25, 2008 Order: May 12, 2008 i) Offset of excess revenues: $2,417,223.29
Neulasta	Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with cancer receiving myelosuppressive chemotherapy	Amgen Canada Inc.	March 16, 2009	Pre-Hearing Conference: June 3, 2009
Nicoderm	Smoking cessation	sanofi-aventis Canada Inc. (Hoechst Marion Roussel Canada at issuance)	April 20, 1999	Hearing: October 5, 2009
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	Decision pending
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			
ratiopharm Inc.			August 28, 2008	Ongoing
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	Hearing: July 6, 2009
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 (Details on page 16)

Matters before the Federal Court

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

Adderall XR, Shire Canada Inc.; Concerta, Janssen-Ortho Inc.

In January 2006, the Board issued a Notice of Hearing in this matter. On December 15, 2006, the Board issued a decision dismissing a motion by Shire Canada Inc., wanting to limit the Board's jurisdiction to the period following the date of issuance of Shire's patent for Adderall XR. Shire filed an application for Judicial Review with the Federal Court (FC). The FC issued its decision on December 19, 2007, dismissing the matter. Shire appealed the decision to the Federal Court of Appeal. However, the appeal was discontinued on November 5, 2008.

In this matter, Janssen-Ortho Inc., patentee of the drug product Concerta, was a named intervener before the FC and had commenced its own judicial review with respect to the Board's jurisdiction. Janssen-Ortho also discontinued its appeal of the FC decision on November 27, 2008.

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 FC. A hearing date has not been scheduled by the FC.

Nicoderm, sanofi-aventis Canada Inc.

sanofi-aventis has filed an Application for Judicial Review of the Board's decision to have this matter proceed on the merits of the case. The FC has not yet set a hearing date for this matter.

Pentacel and Quadracel, sanofi pasteur Limited

The Board issued a Notice of Hearing in this matter on March 27, 2007.

Following the Hearing Panel's decision of November 26, 2007 denying sanofi pasteur's Motion that the Panel replace its counsel in this proceeding, sanofi pasteur filed a Judicial Review Application with the FC. The Application was dismissed.

The Panel completed the hearing on January 6, 2009 and the decision is pending.

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 ruled that it had jurisdiction over the price of Thalomid. Celgene Corporation filed an application for Judicial Review which was heard by the FC on March 3, 2009. The FC issued its decision on March 17, 2009, dismissing the Board's decision. The Attorney General of Canada has filed a Notice of Appeal with the Federal Court of Appeal. The matter has not yet been scheduled for hearing.

Since the inception of the PMPRB in 1987, the Board has approved a total of 54 VCUs and initiated 23 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. In 2008-2009, excess revenues offset by way of payments to the Government were in excess of $27 million. More details on VCUs and Board Orders are available in Annex 3 on page 54.

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 is scheduled to hear these applications on June 16 and 17, 2009.

Amendments to the *Patented Medicines Regulations*

The regulatory amendments to the *Patented Medicines Regulations, 1994* (Regulations) were registered on March 6, 2008 and received final publication in the *Canada Gazette*, Part II, on March 19, 2008. These amendments modernize the Regulations by increasing the efficiency and timeliness in the price review process for patented drug products.

This regulatory initiative began in January 2005 with the publication of a Notice and Comment proposal to amend the Regulations. Following extensive stakeholder consultations and in response to stakeholder concerns, the final amendments put into place changes regarding reporting information to the PMPRB via: Form 1, information identifying the medicine; Form 2, information on the prices of the medicine; and Form 3, information on R&D. These amendments also allowed a complaint-driven process for all over-the-counter patented drug products as well as for patented drug products for veterinary use.

Also, as of July 1, 2008, patentees are required to file electronically including providing information for all three Forms to the Board using a specified electronic document in its original format and file type, bearing the electronic signature of an authorized individual certifying that the information set out in the document is true and complete.

As part of its Outreach Program, Board Staff provided information sessions to patentees in May and June 2008 to explain how to fully comply with the regulatory amendments.

Review of the Board's Excessive Price Guidelines

The Board is in the final stages of concluding the review of its Excessive Price Guidelines, initiated in 2005. The review was undertaken to ensure that the policies, guidelines, and procedures the PMPRB employs to fulfill its mandate are relevant and appropriate, and are consistent with the principles of fairness, transparency, openness and predictability.

Throughout the Guidelines review process, the Board engaged in an unprecedented level of consultations with all interested stakeholders, including industry (i.e., brand, biotech, generic), federal, provincial and territorial governments, consumer and patient advocacy groups, third party payers, and others.

In January 2008, the Board consulted with stakeholders through its Discussion Paper: Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines. In the spring, the five multi-stakeholder working groups established by the Board submitted their respective reports on: levels of therapeutic improvement; international therapeutic class comparison; price tests; costs of making and marketing, and, price regulation of patented generic drug products.

Taking into consideration all of the input provided by stakeholders, the Board released the first version of its Draft Revised Excessive Price Guidelines for Notice and Comment in August 2008. The Board received forty-two written submissions, and subsequently held numerous teleconferences and bilateral meetings with stakeholders to better understand their concerns.

In March 2009, stakeholders were invited to provide feedback on the Board's second and final version of the Draft Revised Excessive Price Guidelines for Notice and Comment. A total of thirty-one written submissions were received from stakeholders.

The Board is completing the revisions to the Guidelines and will be releasing the new Compendium of Policies, Guidelines, and Procedures on June 9, 2009, with implementation to take place on January 1, 2010. To assist patentees in understanding and getting ready to use the new Guidelines, various educational outreach sessions will be held in the spring and fall.

Major Events and Publications in 2008-2010

Date	Event
January 2008	Release of the Discussion Paper: Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines
April 2008	Final reports from the Working Groups on therapeutic improvement and international therapeutic class comparison
May 2008	Final reports from the Canadian Generic Pharmaceutical Association (CGPA)/PMPRB Working Group and on the use of making and marketing costs for the purpose of subsection 85(2) of the *Patent Act*
June 2008	Board meetings with representatives of the brand and biotech sectors of the pharmaceutical industry
July 2008	Final report from the Working Group on price tests
August 2008	Release of the Draft Revised Excessive Price Guidelines for Notice and Comment
October 2008	Board meeting with Rx&D Board of Directors
December 2008	A series of bilateral meetings with stakeholder groups
December 2008 – May 2009	Meetings of an *ad hoc* CEO/Board level Rx&D/PMPRB group
March 2009	Release of the Draft Revised Excessive Price Guidelines for Notice and Comment
May 2009	Board approval of the new Compendium of Policies, Guidelines and Procedures
June 2009	Publication of the new Compendium of Policies, Guidelines and Procedures
June 2009	Educational outreach events for patentees
Fall 2009	Further educational sessions
January 2010	Implementation of the new Excessive Price Guidelines

Reporting Information on Key Pharmaceutical Trends

Trends in Sales of Patented Drug Products[6]

Patentees are required, under the *Patented Medicines Regulations* (Regulations), to submit detailed information on their sales of patented drug products, including information on quantities sold and net revenues received for each product by class of customer in each province/territory. This information allows the PMPRB to analyze trends in sales, prices and utilization of patented drug products. Results of this analysis are presented in this section.[7]

Sales and Prices

Canadians spend much more today on drugs 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. Previous Annual Reports have found little change on average in the prices of patented drug products along with annual sales growth exceeding 10%. In these instances, sales growth was driven by changes in the volume and composition of drug utilization.[8] 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 habits of physicians (for example, shifts away from older, less expensive drugs to newer, more expensive medications);
- greater use of drug therapy instead of other forms of treatment; and,
- use of new drug products to treat conditions for which no effective treatment existed previously.

Sales Trends

Table 9, on page 23, reports patentees' total sales of patented drug products in Canada for the years 1990 through 2008. Sales of patented drug products rose to $13.0 billion from $12.4 billion in 2007, an increase of 5.0%. 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 approximately 43% in 1990 to 72.7% in 2003. The share of patented drug products in overall drug sales has declined since 2003, implying sales of generic and non-patented branded drug products have grown faster than sales of patented drug products.[9]

6 Throughout this chapter the term "patented drug product" denotes a product currently subject to PMPRB price review.

7 All statistical results reported in this chapter are based on data submitted by patentees as of April 2009. 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 22, Trends in Sales of Patented Drug Products), price and quantity indices (page 26, Price Trends; and page 35, Utilization of Patented Drug Products) and foreign-to-Canadian price ratios (page 31, Comparison of Canadian Prices to Foreign Prices) for the five years preceding the current Annual Report year. All such recalculated values reflect currently available data. Consequently, where data revisions have occurred, values reported here may differ from those presented in earlier Annual Reports.

8 Studies conducted by the PMPRB of public pharmaceutical 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.

9 The denominator in this ratio comprises sales of patented drug products, generic drug products and non-patented branded drug products. Starting with the estimate for 2006, this value is derived from data provided in IMS Health's *Canadian Pharmaceutical Market: Drug Store and Hospital Purchases*. In previous years IMS data were used to calculate generic sales only, while sales of non-patented branded 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 patentees reporting. It should be noted that the decline in the ratio between 2005 and 2006 is partly a result of this change in methodology.

TABLE 9 Sales of Patented Drug Products, 1990 – 2008

Year	Patented Drug Products Ex-Factory Sales ($Billions)	Patented Drug Products Change (%)	Patented Drug Products as Share of All Ex-Factory Drug Sales (%)
2008	13.0	5.0	64.9
2007	12.4	3.3	66.0
2006	12.0	3.7	67.9
2005	11.5	4.7	70.8
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, IMS Health

DRIVERS OF EXPENDITURE GROWTH

Table 10, on page 24, decomposes the sales growth that occurred between 2007 and 2008 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 2008 ("New Drug Effect");
- changes in prices among patented drug products that had Canadian sales in both 2007 and 2008 ("Price Effect");
- differences in the quantities of such drug products sold in the two years ("Volume Effect"); and,
- 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 change in sales between 2007 and 2008. For the sake of comparison, the third row provides average year-over-year proportionate impacts for the period 2003 through 2007.[10]

The results in this table show that the increase in sales that occurred between 2007 and 2008 was principally the result of underlying increases in the quantities of existing patented drug products and the introduction of new patent drug products. The volume effect alone was large enough to more than compensate for a large (negative) exiting drug and cross effects and the small negative price effect. Unlike 2007, there was a large new drug effect in 2008.[11]

10 Under the scheme applied here, the "exiting drug effect" is the amount of 2007 sales generated by drug products that were under the PMPRB's jurisdiction in 2007 but not in 2008. The "new drug effect" is the amount of 2008 sales generated by drug products that were under the PMPRB's jurisdiction in 2008 but not in 2007. Other effects are derived by means of the relationship:

$$\sum p^{2008}(i)\, q^{2008}(i) - \sum p^{2007}(i)\, q^{2007}(i) = \sum [p^{2008}(i) - p^{2007}(i)]\, q^{2007}(i) + \sum p^{2007}(i)\, [q^{2008}(i) - q^{2007}(i)] + \sum [p^{2008}(i) - p^{2007}(i)]\, [q^{2008}(i) - q^{2007}(i)]$$

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 2007 and 2008. The left-hand-side in this equation represents the change in total sales of such drug products between 2007 and 2008. The three terms of the right-hand-side respectively define the volume, price and cross effects reported in Table 10, on page 24.

11 As indicated above, the "new drug effect" is limited to the year in which a new patented drug is introduced to Canada. At least part of the "volume effect" will occur because of (what may be) the rapid therapeutic uptake of new drug products in the years immediately following their introduction.

In certain respects, the 2008 decomposition of sales results are typical in that the exiting drug and volume effects are consistent with the historical averages in Table 10. In other respects, the 2008 results are atypical in that both the new drug effect and the price effect are nearly three-fold their respective historical averages. The implication is that in 2008 new drug products coming onto the market in Canada explained more of the expenditure growth than has recently been experienced; while the dampening effect of declining prices on overall expenditures was also a bigger factor in 2008 than had recently been the case.

The pronounced decline in sales growth of the last few years is a striking development. The 2006 Annual Report observed that throughout the 1990s sales growth was largely driven by a succession of new "blockbuster" products that ultimately achieved very high sales volumes, and that since the beginning of the current decade, the pharmaceutical industry had not introduced new high-volume products in sufficient numbers to sustain the double-digit sales growth seen in the 1990s. As a result, 2006 sales of patented drug products were still dominated by products introduced between 1995 and 1999.

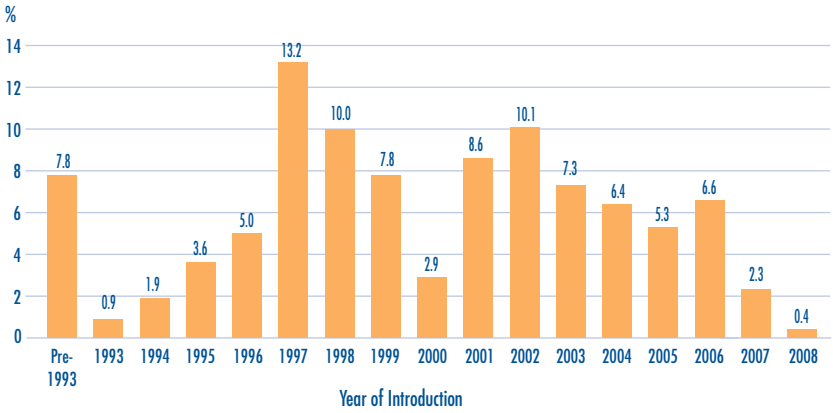
This pattern appears to be giving way somewhat in 2008. Figure 4 breaks down the share of patentees' 2008 sales by the year in which products were first sold in Canada. Sales are split almost evenly between patented drug products introduced before 2000 and those introduced in 2000 and afterwards. Nonetheless, drug products introduced between 1995 and 1999 still accounted for nearly 40% of 2008 sales.

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, 2008/2007 ($ Millions)	615.0	-287.7	545.2	-39.5	796.2	-399.1
Proportion of Total Change, 2008/2007 (%)	100.0	-46.8	88.7	-6.4	129.5	-64.9
Average Proportion of Total Change, 2003 – 2007 (%)	100.0	-48.5	33.7	2.3	112.2	0.3

Source: PMPRB

FIGURE 4 Share of 2008 Sales of Patented Drug Products by Year of Introduction



Source: PMPRB

Sales by Therapeutic Class

The PMPRB normally 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 aspect of human anatomy with which they are primarily associated.

Table 11 breaks out sales of patented drug products in Canada in 2008 by major therapeutic class, defined by ATC Level 1. The Table gives the 2008 sales for each class, the share of the total sales this represents, and the rate at which sales grew relative to 2007. Values in the last column represent the component of overall sales growth attributable to drug products in the corresponding therapeutic class.[12] By this measure, the primary drivers of sales growth between 2007 and 2008 were:

- general anti-infectives for systematic use and antiparasitic products; and,
- antineoplastics and immunomodulating agents.

These two classes jointly accounted for nearly 89% of sales growth. This is the fourth consecutive year antineoplastics and immunomodulating agents have emerged as a leading contributor to sales growth.

Table 11 Patentees' Sales of Patented Drug Products by Therapeutic Class, 2008

Therapeutic Class	Sales 2008 ($M)	Share of Total 2008 Sales (%)	Growth: 2008/2007 ($M)	Growth: 2008/2007 (%)	Share of Sales Growth (%)
A: Alimentary Tract and Metabolism	1,274.6	9.8	-327.8	-20.5	-53.3
B: Blood and Blood Forming Organs	882.3	6.8	-2.4	-0.3	-0.4
C: Cardiovascular System	3,174.7	24.5	64.4	2.1	10.5
D: Dermatologicals	128.6	1.0	1.8	1.4	0.3
G: Genito-urinary System and Sex Hormones	500.9	3.9	83.0	19.9	13.5
H: Systemic Hormonal Preparations	96.2	0.7	0.7	0.8	0.1
J: General Antiinfectives for Systemic Use; and P: Antiparasitic Products[13]	1,375.3	10.6	198.0	16.8	32.2
L: Antineoplastics and Immunomodulating Agents	2,030.5	15.6	348.8	20.7	56.7
M: Musculo-skeletal System	521.4	4.0	20.6	4.1	3.4
N: Nervous System	1,637.4	12.6	40.0	2.5	6.5
R: Respiratory System	1,023.8	7.9	76.2	8.0	12.4
S: Sensory Organs	268.7	2.1	106.9	66.1	17.4
V: Various	64.1	0.5	4.8	8.1	0.8
All Therapeutic Classes	12,978.4	100.0*	615.0	5.0	100.0*

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

Sources: PMPRB, IMS Health

12 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 for all patented drug products.

13 These groups have been combined for reasons of confidentiality.

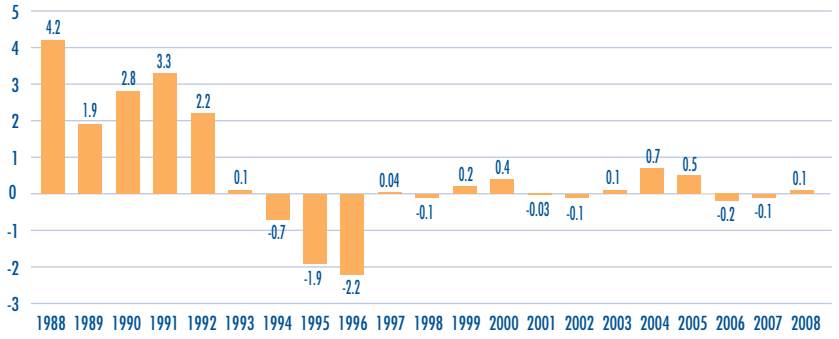
Price Trends

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 products.[14] 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.[15]

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 Patented Medicines Quantity Index (PMQI), is calculated for this purpose (see page 35, Utilization of Patented Drug Products). The PMPI does not measure the cost-impact of changes in prescribing patterns or the introduction of new drug products. 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 2008. As measured by the PMPI, prices of patented drug products rose, on average, by 0.1% between 2007 and 2008.

Figure 5 Annual Rates of Change, Patented Medicines Price Index (PMPI), 1988 – 2008



Source: PMPRB

14 More exactly, at the level defined by Health Canada's Drug Identification Number (DIN). Each DIN represents a unique combination of active ingredient(s), dosage form, and strength(s).

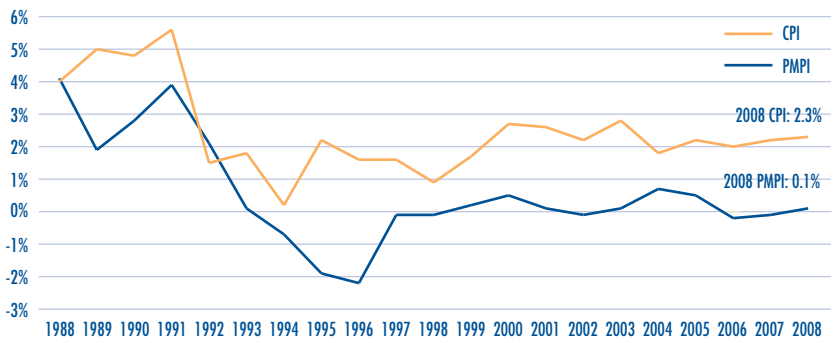
15 See the PMPRB's *A description of the Laspeyres methodology used to construct the Patented Medicines Price Index (PMPI)*, June 2000, for a detailed explanation of the PMPI. Beginning in 1999, the PMPI is restricted to products intended for human use.

Comparison of PMPI and CPI

The *Patent Act* provides that, among other factors, the PMPRB shall 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.[16] This pattern continued in 2008, with the CPI rising by 2.3%[17] and the PMPI by 0.1%.

That the PMPI has not 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 rate at which individual prices may rise over any period of three years or more.[18] Increases in the PMPI normally do not reach this upper bound because many patentees do not raise their prices by the full amount permitted under the Guidelines, or reduce their prices.

Figure 6 Annual Rate of Change, Patented Medicines Price Index (PMPI) and Consumer Price Index (CPI), 1988 – 2008



Source: PMPRB and Statistics Canada

Price Change by Therapeutic Class

Table 12, on page 28, 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 0.1% reflects stable prices across most therapeutic classes. Note that no therapeutic class saw an average price increase greater than CPI-inflation.[19]

16 The one-year increase cap allows the PMPI to rise at a faster rate than CPI in any given year. 1992 is the only year in which the PMPI rose at a faster rate than the CPI. 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. The forecast CPI inflation rate for 1992 was 3.2%, whereas the actual rate was 1.5%. For a full explanation of the CPI-adjustment methodology, please refer to the PMPRB's *Compendium of Policies, Guidelines and Procedures*.

17 Statistics Canada, CANSIM, Series V735319.

18 The one-year increase cap allows the PMPI to rise at a faster rate than CPI in any given year.

19 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:

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

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, on page 28. 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, on page 28, 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 PMPI by Major Therapeutic Class, 2008

Therapeutic Class	Share of Total 2008 Sales (%)	Price Change: 2007 to 2008 (%)	Contribution to Overall Change
A: Alimentary tract and Metabolism	12.0	-1.9	-0.2
B: Blood and Blood Forming Organs	6.9	-0.5	0.0
C: Cardiovascular System	25.1	0.4	0.1
D: Dermatologicals	0.9	0.0	0.0
G: Genito-urinary System and Sex Hormones	3.7	0.8	0.0
H: Systemic Hormonal Preparations	0.8	1.4	0.0
J: General Antiinfectives for SystemicUse; and P: Antiparasitic Products[20]	9.3	-1.0	-0.1
L: Antineoplastics and Immunomodulating Agents	14.5	-0.3	0.0
M: Musculo-skeletal System	4.2	0.9	0.0
N: Nervous System	12.6	0.2	0.0
R: Respiratory System	8.0	1.4	0.1
S: Sensory Organs	1.5	0.9	0.0
V: Various	0.5	-3.2	0.0
All Therapeutic Classes	100.0	0.1	0.1*

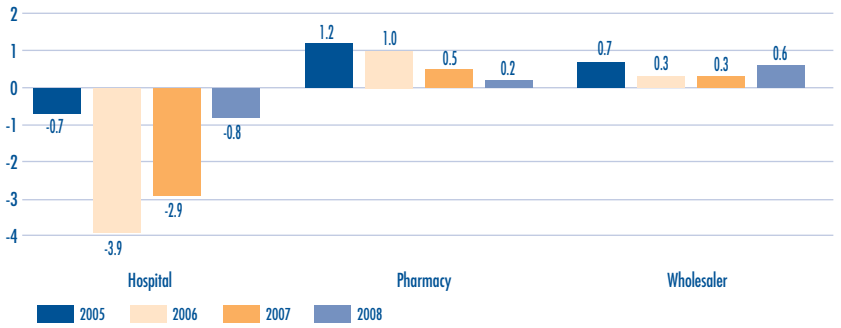
* See Footnote 19, on page 27

Source: PMPRB

PRICE CHANGE BY CLASS OF CUSTOMER

Figure 7 presents average rates of price change by class of customer. These results were obtained by applying the PMPI methodology to data on sales of patented drug products to hospitals, to pharmacies and to wholesalers.[21] Rates of price change for these classes were, respectively -0.8%, 0.2% and 0.6%. Pharmacies and wholesalers, taken together, saw an increase of 0.5%. Note that the average rate of price change in each customer class was substantially less than CPI-inflation.

FIGURE 7 Annual Rate of Change, Patented Medicines Price Index (PMPI), by Class of Customer, 2005 – 2008



Source: PMPRB

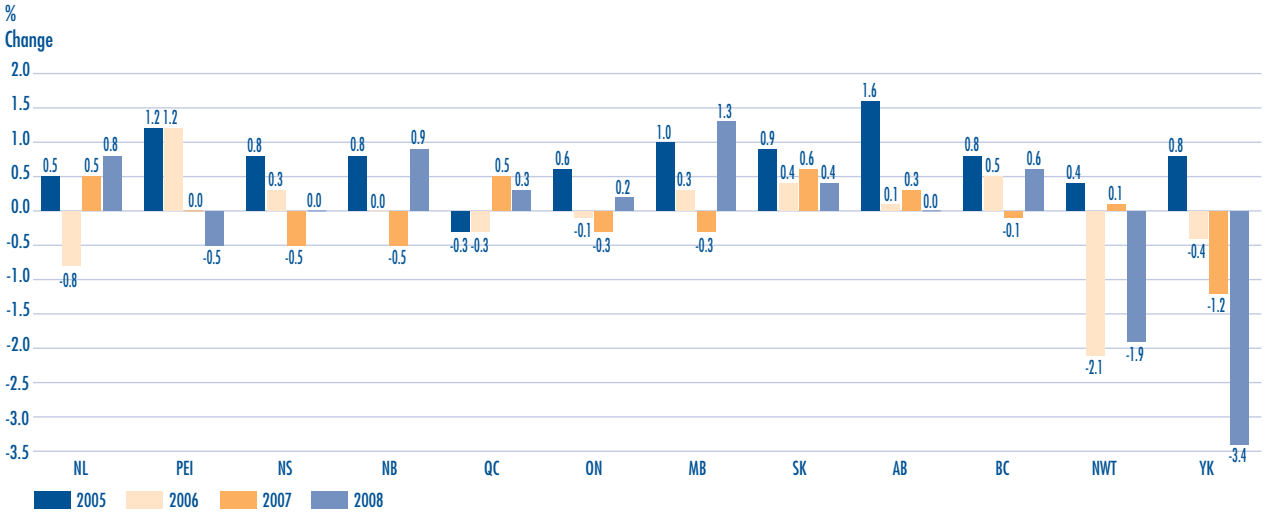
20 ATC classes J and P have been combined here for reasons of confidentiality.

21 Results for a fourth customer class, "Others", are not provided. Buyers in this class are principally healthcare institutions other than hospitals, such as clinics and nursing homes. This class accounted for about 5.5% of patented drug sales in 2008.

Price Change by Province/Territory

Figure 8 presents average annual rates of price change by province/territory, obtained by applying the PMPI methodology to data segregated by the province/territory in which the sale took place. These results indicate that between 2007 and 2008, prices of patented drug products fell on average in Prince Edward Island, the Northwest Territories and the Yukon, while prices in Nova Scotia and Alberta saw no appreciable change. The largest average price increases occurred in Manitoba (1.3%) and in Newfoundland and Labrador (0.8%). Ontario and Quebec saw average price increases of 0.2% and 0.3%, respectively. Note that the rate of price change in each province/territory was well below CPI-inflation.

Figure 8 Annual Rate of Price Change, by Province/Territory: 2005, 2006, 2007 and 2008



Source: PMPRB

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 2008 price to introductory price; that is, 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.

These results imply a remarkable degree of price stability, with the 2008 price of a typical patented drug product being within plus/minus four per cent of its introductory price, regardless of when it was introduced to the Canadian market. The results also show no tendency for prices to rise or fall after introduction, tracing out a seemingly random pattern around parity.[22]

Price Change by Country

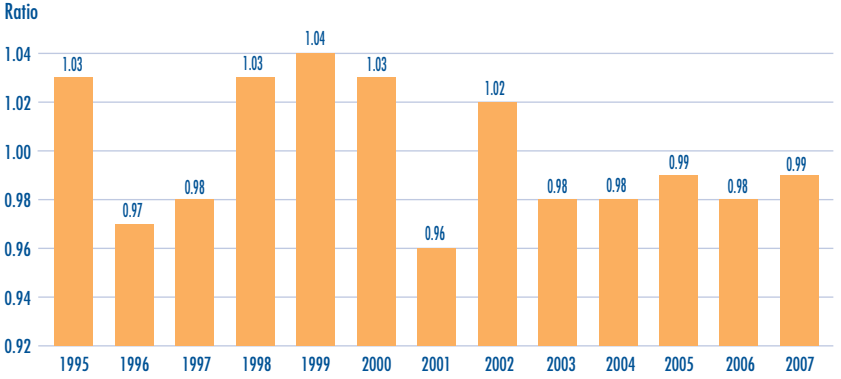
In accordance with the Act and the Regulations, patentees must report publicly available ex-factory prices of patented drug products for seven foreign comparator countries. These countries are: France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States. The PMPRB uses this 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 10 gives 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)[23] submitted by patentees; and the second incorporates prices from the U.S. Federal Supply Schedule (FSS), also submitted by patentees.[24]

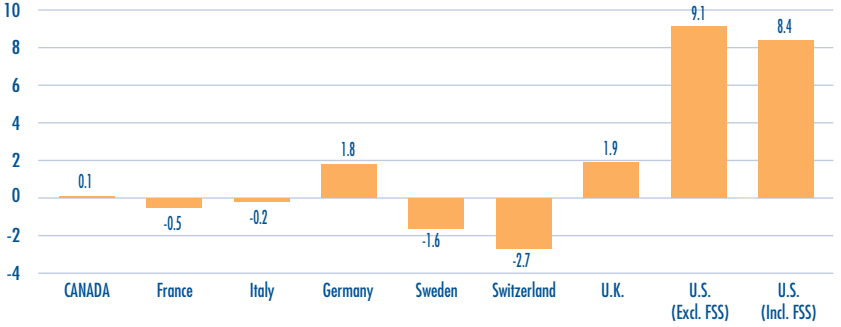
The results in Figure 10 indicate that in 2008, the United States saw prices rise on average at a rate of 8-9%. The United Kingdom and Germany saw much more modest increases of 1.9% and 1.8%, respectively. Switzerland saw the largest average decline (-2.7%).

Figure 9 Average Ratio of 2008 Price to Introductory Price, by Year of Introduction



Source: PMPRB

Figure 10 Annual Average Rates of Price Change, Canada and Comparator Countries, 2008



Source: PMPRB

22 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 their introduction.

23 The term "wholesale acquisition cost" (WAC) refers to the price paid by a wholesaler for a drug product purchased from the wholesaler's supplier, usually the drug product'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.

24 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, on pages 32 and 33, 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 reported statistic.[25]

The PMPRB has traditionally reported average foreign-to-Canadian price ratios constructed as sales-weighted geometric means of individual ratios. These results are included in Tables 13 and 14 (under the label "Geometric Mean"). The Tables also provide results obtained using a sales-weighted arithmetic average (under the label "Arithmetic Mean).[26] These latter statistics provide an exact answer to questions of the type:

"How much more / less would Canadians have paid for the patented drug products they purchased in 2008 had they paid Country X prices rather than Canadian prices for these products?"

For example, Table 13 states that the 2008 average French-to-Canadian price ratio obtained using the arithmetic mean was 0.88. This means Canadians would have paid 12% less for the patented drug products they purchased in 2008 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 that the PMPRB normally uses in applying its Price Review 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 2008 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.

25 The number of patented 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, on pages 32 and 33, cover at least 84% of 2008 Canadian sales. The reported U.S.-to-Canada price ratios cover about 95% of 2008 sales.

26 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.

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, substantially less than Canadian prices. As in previous years, 2008 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) indicate larger differences between Canada and the comparator countries. Once one accounts for international differences in cost-of-living, it appears Canadians incurred a substantially greater consumption-cost for the patented drug products they purchased in 2008 than did residents of every comparator country other than the U.S. and Germany.

Figure 11 puts these results in historical perspective. In 1987 Canadian prices were, on average, below U.S. prices but substantially above those in all other countries. By the mid-1990s the situation had changed dramatically, with Canadian prices in the mid-range of the six European countries. In 2008, 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 ten percent when compared to prices in Germany, Sweden, Switzerland and the United Kingdom.

27 This total includes seven patented drug products introduced to Canada in December 2008. These are not included among the new patented drug products discussed at page 8, in Regulating Prices of Patented Medicines.

Table 13 Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons, 2008

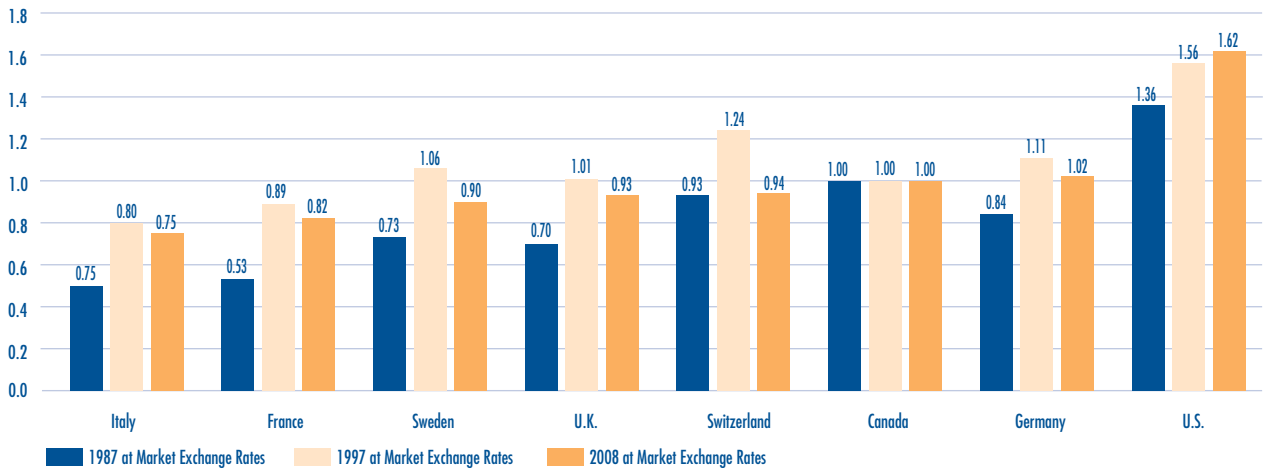
(i) At Market Exchange Rates

	Can	Fra	Ita	Ger	Swe	Swi	UK	US
Geometric Mean	1.00	0.82	0.75	1.02	0.90	0.94	0.93	1.63
Arithmetic Mean	1.00	0.88	0.83	1.10	0.96	0.99	0.98	1.76
Number of DINs	1,189[27]	753	764	873	857	807	845	1,005
Net Revenues ($ Millions)	12,978.4	10,900.1	11,029.6	11,244.5	10,976.5	11,217.3	11,042.2	12,324.8

(ii) Purchasing-Power-Parities

	Can	Fra	Ita	Ger	Swe	Swi	UK	US
Geometric Mean	1.00	0.75	0.72	1.00	0.76	0.75	0.84	1.81
Arithmetic Mean	1.00	0.80	0.79	1.07	0.80	0.79	0.89	1.96
Number of DINs	1,189[27]	753	764	873	857	807	845	1,005
Net Revenues ($ Millions)	12,978.4	10,900.1	11,029.6	11,244.5	10,976.5	11,217.3	11,042.2	12,324.8

Figure 11 Average Foreign-to-Canadian Price Ratios: 1987, 1997, 2008



Source: PMPRB

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.

Focusing again on results at market exchange rates, the average MIP-to-Canadian price ratio stood at 0.96 in 2008 applying the geometric mean, and 1.02 at the arithmetic mean. (The corresponding values for 2007 were 0.98 and 1.04.)

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 had remained above parity until 2007.

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 (meaning that U.S. prices nearly always figure importantly in the calculation of the mean foreign price but seldom serve 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 0.86 in 2008, substantially less than the value of 0.96 obtained at market exchange rates.

Table 14 Average Foreign-to-Canadian Price Ratios, Multilateral Comparisons, 2008

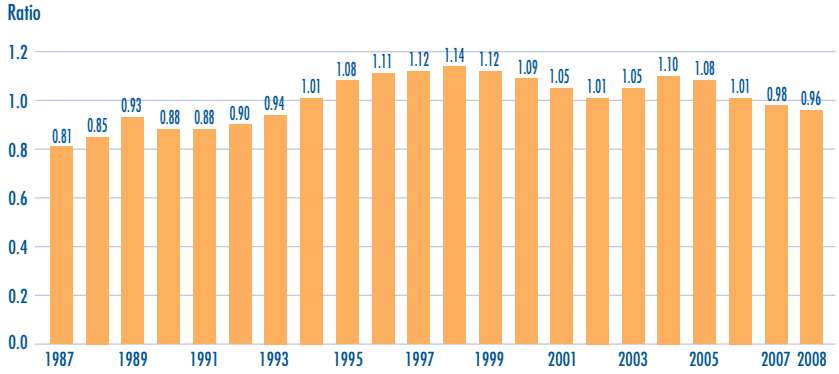
(i) At Market Exchange Rates

	Median	Minimum	Maximum	Mean
Geometric Mean	0.96	0.69	1.75	1.07
Arithmetic Mean	1.02	0.76	1.86	1.12
Number of DINs	1,125	1,125	1,125	1,125
Net Revenues ($Millions)	12,679.0	12,679.0	12,679.0	12,679.0

(ii) At Purchasing-Power-Parities

	Median	Minimum	Maximum	Mean
Geometric Mean	0.86	0.64	1.87	1.02
Arithmetic Mean	0.92	0.71	2.00	1.07
Number of DINs	1,125	1,125	1,125	1,125
Net Revenues ($Millions)	12,679.0	12,679.0	12,679.0	12,679.0

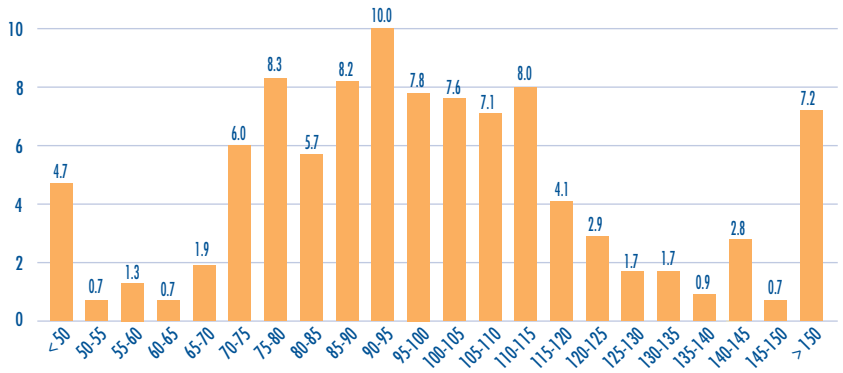
Figure 12 Average Ratio of Median International Price (MIP) to Canadian Price, Patented Drug Products, 1987 – 2008



Source: PMPRB

Figure 13 offers more detail on the product-level MIP-to-Canadian ratios underlying the averages reported in Table 13. This figure distributes 2008 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 that ratio fell).[28] These results show substantial dispersion in product-level price ratios: although patented drug products with MIP-to-Canadian price ratios between 0.90 and 1.10 accounted for 33% of sales, those with ratios less than 0.90 accounted for 37% of sales, while products with ratios exceeding 1.10 accounted for 30%. Alternatively, patented drug products with MIP-to-Canadian price ratios between 0.75 and 1.25 accounted for 69.8% of sales, those with ratios less than 0.75 accounted for 15.3% of sales, while products with ratios exceeding 1.25 accounted for 14.9%.

FIGURE 13 Range-Distribution, Sales, by MIP-to-Canadian Price Ratio, 2008



Source: PMPRB

Average 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 purchasing power parity, which have risen considerably. In light of the method used to derive these ratios, there are four factors that might account for this decline:

(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; and,

(4) a shift in sales weights favouring drug products with higher U.S.-to-Canadian price ratios.

Further data analysis reveals that the rise in average U.S.-to-Canadian price ratios at PPP is almost entirely the result of rising U.S. prices. Using 2007 U.S. prices instead of their 2008 counterparts yields U.S.-to-Canadian average price ratios very close to those presented in last year's Annual Report.[29] In contrast, replacing the 2008 values of other variables with 2007 values has little impact on these ratios.

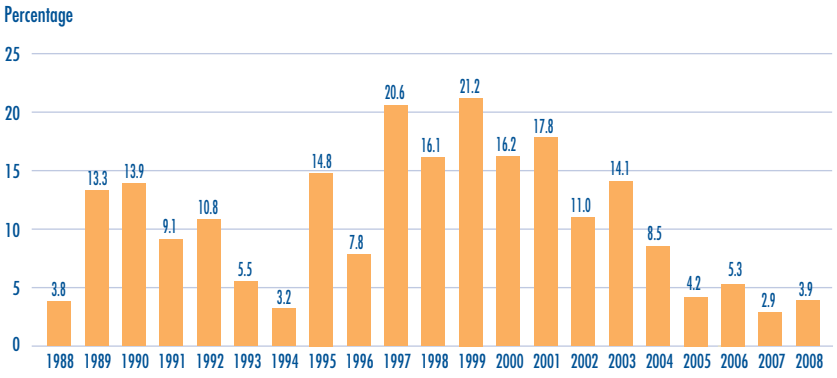
28 To produce the results in this figure, foreign prices were converted to their Canadian-dollar equivalents using market exchange rates.

29 Note that U.S.-to-Canadian ratios at market exchange rates changed only slightly between 2007 and 2008. This is because the 36-month moving average of U.S.-Canada exchange rates used in this instance show a substantial appreciation of the Canadian dollar against the U.S. dollar, reflecting exchange rate movements that occurred in 2007 and early 2008. This appreciation appears to have offset the rise in U.S. prices.

Utilization of Patented Drug Products

The price and sales data used to calculate the PMPI also allow the PMPRB to examine trends in the quantities of patented drug products sold in Canada. The PMPRB maintains the Patented Medicines Quantity Index (PMQI) for this purpose.[30] Figure 14 displays average rates of utilization growth, as measured by the PMQI, from 1988 through 2008. 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 rates of sales growth in recent years. This pattern continued in 2008, with utilization of patented drug products growing by 3.9%. Note that a rate of utilization growth somewhat less than overall sales growth is exactly what one would expect, considering the substantial "new drug effect" cited in Table 10, on page 24.

Figure 14 Annual Rate of Change, Patented Medicines Quantity Index (PMQI), 1988 – 2008



Source: PMPRB

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, on page 28, the last column provides an approximate decomposition of overall PMQI change into contributions attributable to each therapeutic class. In all but three therapeutic classes, the rate of utilization increased. Of those therapeutic classes recording higher utilization, the primary drivers of the quantity change[31] in 2008 were:

- antineoplastics and immunomodulating agents; and,
- drug products treating the cardiovascular system.

Table 15 Change in PMQI by Major Therapeutic Class, 2008

Therapeutic Class	Share of Total 2008 Sales (%)	PMQI Change: 2007 to 2008 (%)	Contribution to Overall Change (%)
A: Alimentary Tract and Metabolism	12.0	-19.4	-2.3
B: Blood and Blood Forming Organs	6.9	-2.8	-0.2
C: Cardiovascular System	25.1	7.0	1.7
D: Dermatologicals	0.9	9.1	0.1
G: Genito-urinary System and Sex Hormones	3.7	14.8	0.5
H: Systemic Hormonal Preparations	0.8	-1.2	0.0
J: General Antiinfectives for Systemic Use and P: Antiparasitic Products[32]	9.3	2.4	0.2
L: Antineoplastics and Immunomodulating Agents	14.5	17.9	2.6
M: Musculo-skeletal System	4.2	3.9	0.2
N: Nervous System	12.6	2.6	0.3
R: Respiratory System	8.0	6.1	0.5
S: Sensory Organs	1.5	35.8	0.6
V: Various	0.5	11.4	0.1
All Therapeutic Classes	100.0	3.9	3.9*

* See Footnote 31.

Source: PMPRB

30 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.

31 As in the case of Table 12, on page 28, this decomposition is only approximate. See Footnote 19, on page 27.

32 ATC classes J and P have been combined here for reasons of confidentiality.

These two classes jointly accounted for more than the entire overall increase in utilization indicated by the PMQI. Moreover, the overall increase in utilization would have been much higher, if not for the significant reduction in utilization by the alimentary tract and metabolism therapeutic class, where utilization declined by 19.4%.

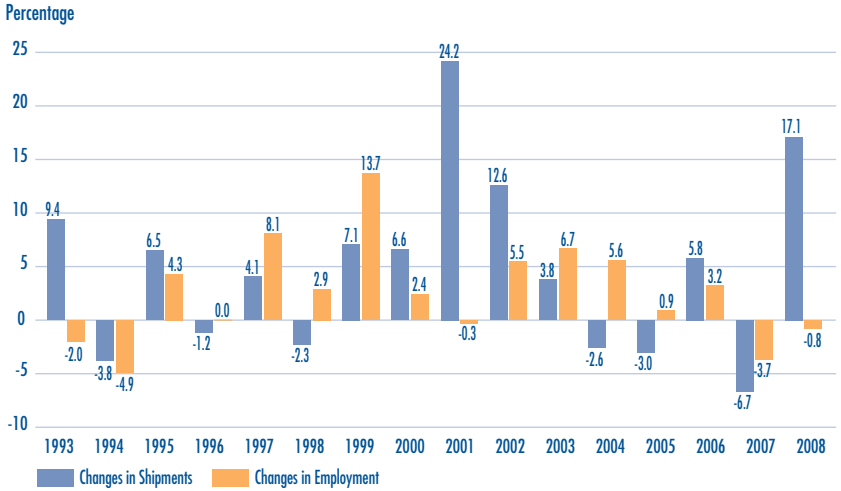
Manufacturing Trends in Canada

The global pharmaceutical industry is dominated by a number of large multinational enterprises based in countries other than Canada. Most of these companies have Canadian subsidiaries which, along with a few Canadian-based manufacturers, account for the manufacture, sale, and distribution of drug products in Canada.

According to Statistics Canada, shipments by Canadian drug manufacturers amounted to $9.8 billion in 2008, accounting for 1.6% of total shipments in the manufacturing sector.[33] The sector employed 28,697 persons, accounting for 1.5% of total employment in manufacturing.[34]

Figure 15 provides year-over-year rates of change in total shipments and employment in drug manufacturing.

Figure 15 Annual Rates of Change in Shipments and Employment in Pharmaceutical Manufacturing Sector in Canada, 1993 – 2008

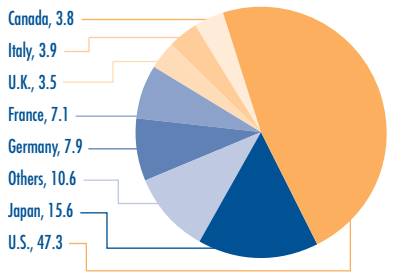


Source: Statistics Canada

Canadian Sales in the Global Context

IMS Health regularly reports on patentees' sales to the retail sector across a wide range of countries. Figure 16 shows how this amount was distributed among these markets.[35] Drug sales in Canada accounted for 3.8% of total major-market sales, a share comparable to that of Italy. The U.S. market is by far the largest, with drug sales only slightly less than the combined sales of all other markets represented in Figure 16.

Figure 16 Distribution of Drug Sales Among Major National Markets, 2008



Source: IMS Health

33 Since the *PMPRB Annual Report 2005*, Statistics Canada has rebenched the manufacturing shipments data from the 2002 Annual Survey of Manufacturing to the 2004 Annual Survey of Manufacturing. The rebenching process recast pharmaceutical and medicine manufacturing shipments significantly below previous estimates.

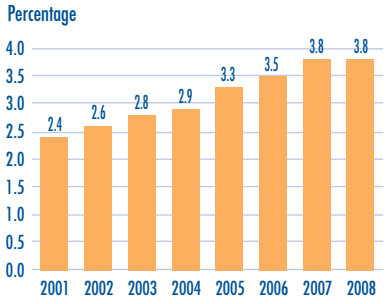
34 Statistics Canada, CANSIM, Series V800188 and V1709627

35 IMS Health's Retail Drug Monitor, 2008 (www.imshealth.com). IMS Retail Drug Monitor provides 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. These figures are at ex-manufacturer prices and include all prescription and certain over-the-counter drug products. Note that the shares given in Figure 16 are based on data for the first five months of 2008.

IMS estimates the above 13 markets account for over two-thirds of the world pharmaceutical market. This implies Canada's share of the *world* market is approximately 2.5%.

Figure 17 gives Canada's share of major-market sales for each of the years 2001 through 2008.[36] This share has risen from 2.4% in 2001 to 3.8% in 2008.

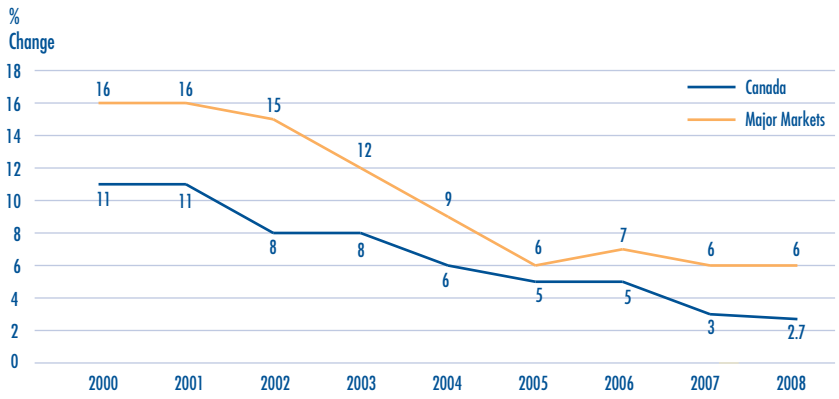
FIGURE 17 Canada's Share of Drug Sales in Major Markets, 2001– 2008



Source: IMS Health

Figure 18 compares sales growth in Canada to that in other major markets. In recent years, pharmaceutical sales have grown at a faster rate in Canada than elsewhere. This pattern continued in 2008, with year-over-year sales growth in Canada (6.0%)[37] ahead of growth in other major markets (2.7%).

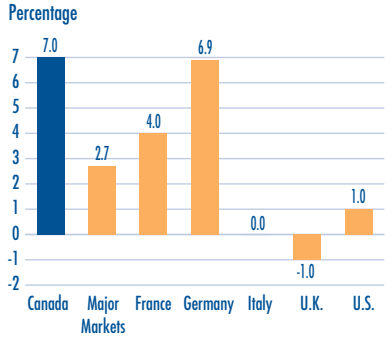
FIGURE 18 Annual Rates of Change, Drug Sales, Canada and Major Markets, 2000 – 2008



Source: IMS Health

Figure 19 gives rates of 2008-over-2007 sales growth for individual major markets. Based on IMS data, Canadian sales growth exceeded growth observed in all other comparator countries, including the U.S.

FIGURE 19 Growth in Pharmaceutical Sales, 2007 to 2008, by Major Markets



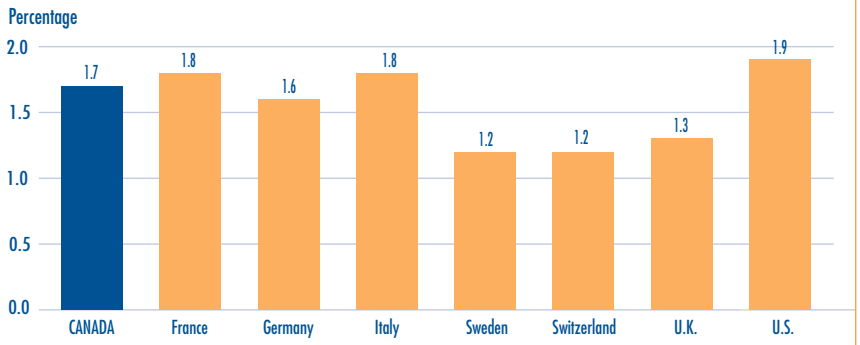
Source: IMS Health

36 To calculate the shares given in Figures 16 and 17, it is necessary to first express national sales data in a common currency. IMS Health uses market exchange rates for this purpose. This means the Canadian shares reported here will reflect changes in relative value of the Canadian dollar.

37 The Canadian growth rate reported here differs from that reported in Table 9, on page 23, for a number of reasons. Most importantly, it is derived from sales data encompassing non-patented as well as patented drug products. Note as well that these data cover only sales to the pharmacy sector.

The proportion of national income allocated to the purchase of pharmaceuticals provides another way to compare drug costs across countries.[38] Figure 20 gives drug expenditures as a share of Gross Domestic Product (GDP) for Canada and the seven comparator countries, based on data for 2006. Drug expenditures absorbed between 1.2% and 1.9% of GDP in the seven comparator countries. Canada lies near the upper end of this range.

FIGURE 20 Pharmaceutical Expenditures as a Share of GDP, 2006



Source: OECD

TABLE 16 Pharmaceutical Expenditures as a Share of GDP, 2006

	2006 Pharma Expenditure as a share of GDP (%)	2000 Pharma Expenditure as a share of GDP (%)	Pharma Expenditure Growth 2000 – 2006 (%)	GDP Growth 2000 – 2006 (%)
Canada	1.74	1.42	119.51	79.14
France	1.80	1.81	72.73	73.30
Germany	1.57	1.43	70.82	55.71
Italy	1.80	1.74	78.70	72.74
Sweden	1.22	1.18	70.03	63.97
Switzerland	1.19	1.11	72.92	61.77
U.K.	1.33	1.14	96.91	69.14
U.S.	1.93	1.46	77.41	34.36

Source: OECD

The share of national income absorbed by pharmaceutical expenditures has risen in most developed countries in recent years. Table 16 shows that, except for France, pharmaceutical expenditures grew faster than GDP between 2000 and 2006, in Canada and in all comparator countries. The results for the U.S. are especially striking: here pharmaceutical expenditures grew at more than twice as fast as national income. Pharmaceutical expenditures in Canada grew at a rate about one-and-half times that of GDP over this period.

38 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.

Table 17 gives the composition of patentees' sales by therapeutic class in Canada and in six of the comparator countries.[39] With only a few exceptions, these results imply a remarkable degree of uniformity. In almost all countries, sales are dominated by cardiovascular and central nervous system products, which account for 35% to 47% of sales. The next two leading classes - products treating the alimentary tract and products treating the respiratory system - account for a further 21% to 28% of sales.

TABLE 17 Sales By Therapeutic Class, Canada and Comparator Countries, 2007

Therapeutic Class	Canada	Foreign Average	France	Germany	Italy	Switz.	U.K.	U.S.
A: Alimentary tract and Metabolism	14.7	13.8	12.7	14.0	13.8	14.9	13.6	13.7
B: Blood and Blood Forming Organs	3.1	4.3	7.2	5.2	2.9	3.9	3.8	3.0
C: Cardiovascular System	27.2	21.2	20.9	15.8	30.9	20.0	22.3	17.1
D: Dermatologicals	2.7	2.5	1.9	2.1	2.7	3.3	2.7	2.5
G: Genito-urinary System and Sex Hormones	4.6	5.6	4.4	5.2	6.6	6.0	5.3	6.0
H: Systemic Hormonal Preparations	0.8	1.7	2.0	2.5	1.4	1.5	1.6	1.0
J: General Antiinfectives for Systemic Use; and P: Antiparasitic Products	5.2	7.2	9.4	7.7	7.6	7.6	2.8	8.0
L: Antineoplastics and Immunomodulating Agents	6.4	6.2	8.2	11.0	3.4	6.9	4.0	3.6
M: Musculo-skeletal System	6.3	5.7	6.6	6.2	5.5	6.8	4.9	4.3
N: Nervous System	19.7	19.6	15.8	19.3	13.4	18.2	23.3	27.4
R: Respiratory System	7.6	10.1	8.7	8.4	9.2	8.8	14.1	11.0
S: Sensory Organs	1.5	1.9	1.8	1.7	2.4	1.9	1.6	2.0
V: Various	0.2	0.3	0.3	0.7	0.1	0.1	0.1	0.2
Total	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: Calculated by PMPRB from sales data contained in IMS Health's MIDAS database.

39 Data used in these calculations: (1) cover only sales to pharmacies; (2) include generic and non-patented branded drug products; and, (3) are derived from surveys of drug purchasers rather than directly reported by manufacturers. Hence, the results reported for Canada in Table 17 are not directly comparable to those in Table 11, on page 25.

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 research and development (R&D) expenditure in Canada related to medicines (both patented and non-patented for human or veterinary use). The results presented below were entirely derived from data patentees have submitted to the PMPRB.

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 2008, a total of 82 companies selling human and veterinary drug products reported on their R&D expenditures. Of these, 35 were members of Canada's Research Based Pharmaceutical Companies (Rx&D).

Failure to File

Under subsection 89(3) of the Act, the PMPRB is required to report the identity of patentees that fail to file information before the due date, in accordance with Section 88 of the Act. One company, Biogen Idec Canada Inc., failed to file information on its R&D expenditure. A Board Order was issued to Biogen Idec Canada Inc. on March 27, 2009. The patentee met its filing obligations on April 9, 2009.

Sales Revenue

For reporting purposes, sales revenue is defined as total gross revenue from sales in Canada of drug products[40] and from licensing agreements (e.g., royalties and license fees from sales in Canada by licensees).

Patentees reported total 2008 sales revenue (Table 9, on page 23) of $16.3 billion, up 2.0% from 2007. Sales revenue reported by Rx&D members was $13.2 billion, accounting for 80.9% of the total. Less than 1% of reported sales revenue was generated by licensing agreements.

40 Sales data reported in this section include sales of drugs for both human and veterinary use.

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 expenditure 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 2008. R&D expenditures were $1.3 billion in 2008, a decline of 1.1 % over 2007. Rx&D members reported R&D expenditures of $1.2 billion in 2008, a decrease of 1.0% over last year. Rx&D members accounted for 89.4% of all reported R&D expenditures. Patentees that were not members of Rx&D reported R&D expenditures of $0.1 billion in 2008, a decrease of 1.8% over last year.

Table 18 Total R&D Expenditures and R&D-to-Sales Ratios of Reporting Companies, 1988 – 2008

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 (%)	R&D-to-Sales Ratio Rx&D Patentees (%)
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

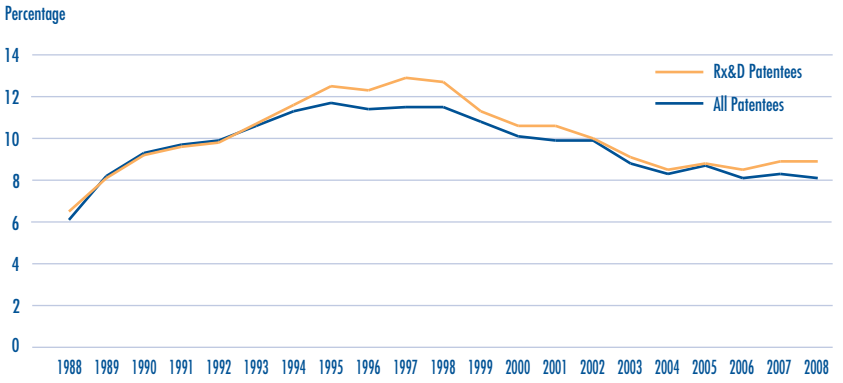
R&D-to-Sales Ratios

Table 18, on page 41, 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 expenditures to 10% of sales revenue by 1996.[41]

The ratio of R&D expenditures to sales revenue among all patentees was 8.1% in 2008, down from 8.3% in 2007. The ratio for members of Rx&D was 8.9%, the same as the previous year.[42] R&D-to-sales ratios for all patentees and for Rx&D members have been lower in recent years, after having risen from 1988 to a peak in the mid 1990s. As of 2008, the ratio for all patentees has remained below 10% for eight consecutive years, while the ratio for RX&D members has been less than 10% for the last six years.

Table 23 in Annex 4 provides details on the range of R&D-to-sales ratios. Of the 82 companies reporting in 2008, 62 had R&D-to-sales ratios below 10% in 2008. These companies accounted for 71% of total sales revenue in 2008.

FIGURE 21 **R&D-to-Sales Ratio, Pharmaceutical Patentees, 1988 – 2008**



41 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**

42 The R&D-to-sales ratios presented in Table 18, on page 41, includes 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 2008 are 7.8% and 8.7%, respectively.

Current Expenditure by Type of Research

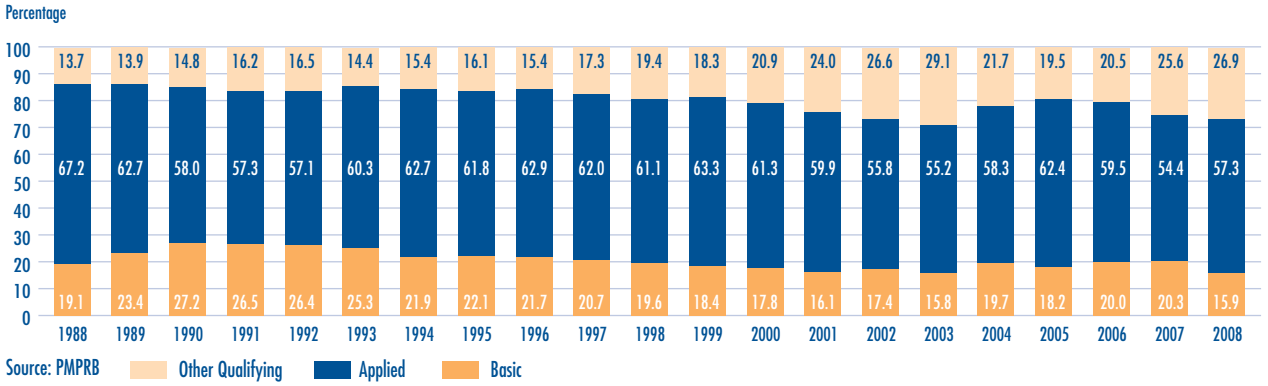
Table 19 and Figure 22 provide information on the allocation of 2008 current R&D expenditures[43] among basic research, applied and other qualifying R&D.[44] Patentees reported spending $200.2 million on basic research in 2008, representing 15.9% of current R&D expenditure and a decrease of 22.7% over the previous year. Patentees reported spending $723.2 million on applied research, representing 57.3% of current R&D expenditures. Clinical trials accounted for 74.6% of applied research expenditures.

Table 19 Current R&D Expenditures by Type of Research, 2008 and 2007

Type of Research	2008		2007		Annual Change in Expenditures (%)
	$Millions	%	$Millions	%	
Basic	200.2	15.9	259.0	20.3	-22.7
Chemical	126.4	10.0	122.6	9.6	3.1
Biological	73.8	5.9	136.4	10.7	-45.9
Applied	723.2	57.3	688.2	54.4	4.9
Manufacturing Process	90.5	7.2	92.1	7.3	-1.7
Pre Clinical Trial I	30.7	2.4	12.4	1.0	147.6
Pre Clinical Trial II	62.1	4.9	46.3	3.7	34.1
Clinical Trial Phase I	53.1	4.2	62.0	4.9	-14.3
Clinical Trial Phase II	125.0	9.9	121.6	9.6	2.7
Clinical Trial Phase III	361.8	28.7	353.8	27.9	2.3
Other Qualifying R&D	337.9	26.9	326.8	25.6	3.4
Total	1,261.3	100.0*	1,274.0	100.0*	-1.0

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

Figure 22 Current R&D Expenditures by Type of Research, 1988 – 2008



43 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.

44 Current R&D expenditures accounted for 96.5% of total R&D expenditures in 2008, while capital equipment costs and allowable depreciation expenses made up 1.7% and 1.8%, respectively.

"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.

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 2008, 49.2% of current expenditures were intramural, down from 53.3% in 2007. Research performed by other companies on behalf of patentees was 22.4% of current expenditures, while research conducted in universities and hospitals accounted for 12.9%.

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 2008, accounting for 90.2% of current R&D expenditures. Funds received from government amounted to only 2.8% of current expenditures.

Table 20 Current R&D Expenditures by R&D Performer, 2008 and 2007

R&D Performer	2008		2007		Annual Increase in Expenditures (%)
	$Millions	%	$Millions	%	
Intramural	620.5	49.2	679.5	53.3	-8.9
Patentees	620.5	49.2	679.5	53.3	-8.9
Extramural	640.8	50.8	594.5	46.6	7.7
Universities and Hospitals	162.1	12.9	177.1	14.0	-8.5
Other Companies	282.6	22.4	251.4	19.7	11.9
Others	196.1	15.5	166.0	13.1	18.1
Total	1,261.3	100.0*	1,274.0	100.0*	-1.0

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

Table 21 Total R&D Expenditures by Source of Funds, 2008 and 2007

Source of Funds	2008		2007		Annual Increase in Expenditures (%)
	$Millions	%	$Millions	%	
Company Funds	1,182.7	90.2	1,207.3	91.1	-2.1
Federal/Provincial Governments	36.3	2.8	32.8	2.5	10.7
Others	91.7	7.0	84.9	6.5	8.0
Total	1,310.7	100.0*	1,325.0	100.0*	-1.1

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

Current R&D Expenditures by Location

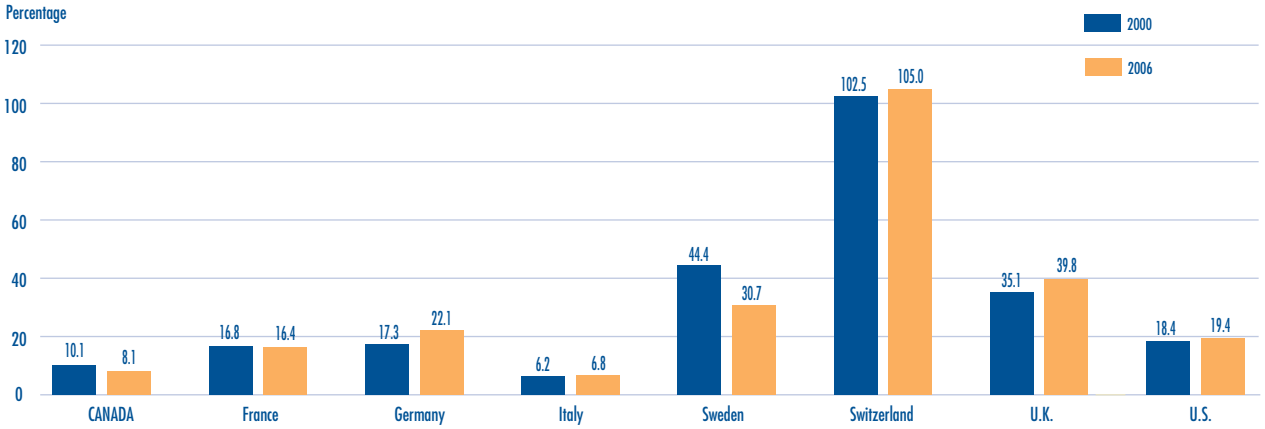
Table 22, on page 45, (as well as Table 25 in Annex 4) show current R&D expenditures by province. As in previous years, expenditures were heavily concentrated in Ontario and Quebec, with these provinces accounting for 89.5% of total expenditures. While R&D expenditures declined at a year-over-year rate of 10.2% in Western Canada, the rate of expenditure growth in Ontario (5.0%) was well above the national average (-1.0%).

TABLE 22 Current R&D Expenditures by Location, 2008 and 2007

Location of R&D	2008		2007		Annual Increase in Expenditures (%)
	$Millions	%	$Millions	%	
Atlantic Provinces	21.3	1.7	20.5	1.6	4.0
Quebec	532.5	42.2	561.7	44.1	-5.2
Ontario	596.1	47.3	567.8	44.6	5.0
Western Provinces	111.2	8.8	124.0	9.7	-10.2
Territories	0.2	0.0	0.0	0.0	–
Total	1,261.3	100.0	1,274.0	100.0	-1.0

Source: PMPRB

FIGURE 23 R&D-to-Sales Ratio, Canada and Seven PMPRB Comparator Countries, 2000 and 2006



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

THE GLOBAL CONTEXT

Figure 23 compares Canadian R&D-to-sales ratios to those in the PMPRB's seven comparator countries for the years 2000 and 2006.[45] As noted in Figure 23, Canada's ratio stood at 10.1% in 2000. Only Italy, at 6.2%, had a lower ratio in that year. Switzerland had the highest ratio at 102.5%, followed by Sweden at 44.4%. France, Germany, and U.S. were in the 16-18% range, while the U.K. was more than double (35.1%). A very similar pattern emerges in the investment-to-sales ratios for 2006. Italy (6.8%) remained at the bottom of the range, with Canada second lowest, at 8.1%. Ratios in all other comparator countries remained well above Canada's ratio.

45 Sales in Figure 23 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 drug plan policy decision-making for participating federal, provincial, and territorial governments (all expect Québec). The PMPRB and the Canadian Institute for Health Information (CIHI) are partners in this initiative.

The NPDUIS initiative involves two major elements:

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

CIHI is responsible for the first of these elements while the PMPRB (as requested by the Minister of Health under section 90 of the *Patent Act*) is principally responsible for the second. A steering committee, comprised of representatives of participating public drug plans and Health Canada, advises the PMPRB on its research agenda and individual studies.

At the time of publication of this Annual Report, several NPDUIS studies are being conducted including:

- an analysis of the use of the World Health Organization's (WHO) Defined Daily Dose in Canadian drug utilization and cost analyses;
- an analysis of the potential impact of long-term demographic change on public drug plans;
- the 2nd edition of the New Drug Pipeline Monitor; and,
- the Pharmaceutical Trends Overview Report.

Other research endeavours currently underway include:

- a comparative analysis of the recent trends in professional fee expenditures observed in Canadian public drug plans;
- the development of a methodology for decomposing program expenditure growth in the context of claims-level data; and,
- Guidelines for Forecasting Program Expenditures.

Effective April 2008, PMPRB reporting on Non-Patented Prescription Drug Prices was folded under the NPDUIS umbrella. Two trend reports pertaining to non-patented generic drugs in Canada are in progress in the summer of 2009: *Price Trends and International Price Comparisons* as well as *Market Structure - Trends and Impacts*.

Selected NPDUIS studies will highlight trends related to both patented and non-patented drug products.

Studies conducted under the NPDUIS are available on the PMPRB's Web site.

Communications

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.

The program seeks to sustain high levels of transparency, accessibility and stakeholder engagement.

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.

www.pmprb-cepmb.gc.ca

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 non-excessive price under the Board's Excessive Price 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 (FTF):
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 (FTR):
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.

Investigational New Drug (IND):
A drug that has been authorized for clinical evaluation (i.e., testing on humans) by Health Canada but that is not yet approved for sale for the indication under study.

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 has been 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 conform to the PMPRB's Excessive Price Guidelines. The Chairman may approve a VCU in lieu of issuing a Notice of Hearing if it is in the public interest. Under the Board's Compliance and Enforcement Policy, 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.

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 and 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 2008

Brand Name	Company	DIN	NAS[1]/FPG[2]	ATC[3]	Status	Category
Advagraf - 0.5 mg/capsule	Astellas Pharma Canada Inc.	02296462		L	Within Guidelines	1
Advagraf - 1 mg/capsule	Astellas Pharma Canada Inc.	02296470		L	Within Guidelines	1
Advagraf - 5 mg/capsule	Astellas Pharma Canada Inc.	02296489		L	Within Guidelines	1
Advate 2000	Baxter Corporation	02313111		B	Subject to Investigation	1
Advicor 1000/40 - 1040 mg/tablet	Sepracor Pharmaceuticals Inc.	02293501		C	Within Guidelines	1
Angeliq 1/1 - 2 mg/tablet	Bayer Inc.	02268825		G	Within Guidelines	3
Arestin - 1 mg/cartridge	Johnson & Johnson Inc.	02278219		A	Under Review	3
Atacand - 32 mg/tablet	AstraZeneca Canada Inc.	02311658		C	Within Guidelines	1
Avamys - 27.5 mcg/dose	GlaxoSmithKline Inc.	02298589	FPG	R	Within Guidelines	3
Benefix - 2000 unit/vial	Wyeth Pharmaceuticals	02293803		B	Subject to Investigation	1
Benefix - 500 unit/vial	Wyeth Pharmaceuticals	02293773		B	Subject to Investigation	1
Biphentin - 10 mg/capsule	Purdue Pharma	02277166	FPG	N	Within Guidelines	1
Biphentin - 15 mg/capsule	Purdue Pharma	02277131	FPG	N	Within Guidelines	1
Biphentin - 20 mg/capsule	Purdue Pharma	02277158	FPG	N	Within Guidelines	1
Biphentin - 30 mg/capsule	Purdue Pharma	02277174	FPG	N	Within Guidelines	1
Biphentin - 40 mg/capsule	Purdue Pharma	02277182	FPG	N	Within Guidelines	1
Biphentin - 50 mg/capsule	Purdue Pharma	02277190	FPG	N	Within Guidelines	1
Biphentin - 60 mg/capsule	Purdue Pharma	02277204	FPG	N	Within Guidelines	1
Biphentin - 80 mg/capsule	Purdue Pharma	02277212	FPG	N	Within Guidelines	1
Brevibloc Pre-Mix - 10 mg/ml	Baxter Corporation	02309238	FPG	C	Within Guidelines	1
Catena - 150 mg/tablet	Santhera Pharmaceuticals (Canada) Inc.	02314150	NAS	N	Within Guidelines	3
Cialis - 2.5 mg/tablet	Eli Lilly Canada Inc.	02296888		G	Within Guidelines	1
Cialis - 5 mg/tablet	Eli Lilly Canada Inc.	02296896		G	Within Guidelines	1
Climara Pro - 5.79 mg/patch	Bayer Inc.	02250616		G	Within Guidelines	3
Cymbalta - 30 mg/capsule	Eli Lilly Canada Inc.	02301482	NAS	N	Within Guidelines	3
Cymbalta - 60 mg/capsule	Eli Lilly Canada Inc.	02301490	NAS	N	Within Guidelines	3

Brand Name	Company	DIN	NAS[1]/FPG[2]	ATC[3]	Status	Category
Diovan-HCT 320/12.5 - 332.5 mg/tablet	Novartis Pharma Canada Inc.	02308908		C	Within Guidelines	1
Diovan-HCT 320/25 - 345 mg/tablet	Novartis Pharma Canada Inc.	02308916		C	Within Guidelines	1
Eraxis - 100 mg/vial	Pfizer Canada Inc.	02302160	NAS	J	Within Guidelines	3
Exelon 10 - 18 mg/patch	Novartis Pharma Canada Inc.	02302853		N	Within Guidelines	3
Exelon 5 - 9 mg/patch	Novartis Pharma Canada Inc.	02302845		N	Within Guidelines	3
Fosavance 70/5600 IU - 70 mg/tablet	Merck Frosst Canada Ltd.	02314940		M	Subject to Investigation	1
Frova - 2.5 mg/tablet	Teva Neuroscience	02257084	NAS	N	Within Guidelines	3
Fucidin - 250 mg/tablet	LEO Pharma Inc.	01934252	FPG	J	Within Guidelines	1
Glumetza - 1000 mg/tablet	Biovail Pharmaceuticals Canada	02300451		A	Subject to Investigation	1
Intelence - 100 mg/tablet	Janssen-Ortho Inc.	02306778	NAS/FPG	J	Within Guidelines	3
Januvia - 100 mg/tablet	Merck Frosst Canada Ltd.	02303922	NAS	A	Within Guidelines	3
Kaletra 100/25 - 125 mg/tablet	Abbott Laboratories Ltd.	02312301		J	Within Guidelines	1
Kogenate FS Bioset 2000	Bayer Inc.	02302225		B	Subject to Investigation	1
Lantus Solostar - 100 unit/ml	sanofi-aventis Canada Inc.	02294338		A	Subject to Investigation	1
Lucentis - 3 mg/vial	Novartis Pharma Canada Inc.	02296810	NAS/FPG	S	Within Guidelines	2
Myozyme - 50 mg/vial	Genzyme Canada Inc.	02284863	NAS/FPG	A	Within Guidelines	2
Natrecor - 1.5 mg/vial	Janssen-Ortho Inc.	02301393	NAS	C	Within Guidelines	3
Nevanac - 1 mg/ml	Alcon Canada Inc.	02308983	NAS	S	Under Review	
Nexium - 10 mg/pouch	AstraZeneca Canada Inc.	02300524		A	Within Guidelines	1
Nimotuzumab - 50 mg/vial	YM Biosciences Inc.		NAS		Under Review	
Omnaris - 50 mcg/dose	Nycomed Canada Inc.	02303671		R	Within Guidelines	1
Pradax - 110 mg/capsule	Boehringer Ingelheim (Canada) Ltd.	02312441	NAS	B	Within Guidelines	3
Pradax - 75 mg/capsule	Boehringer Ingelheim (Canada) Ltd.	02312433	NAS	B	Within Guidelines	3
PregVit	Duchesnay Inc.	02246067	FPG	B	Subject to Investigation	3
PregVit Folic 5	Duchesnay Inc.	02276194	FPG	B	Subject to investigation	1
Priorix Tetra	GlaxoSmithKline Inc.	02297884		J	Within Guidelines	3
Relistor - 20 mg/ml	Wyeth Pharmaceuticals	02308215	NAS	A	Within Guidelines	2
Revlimid - 10 mg/capsule	Celgene	02304902	NAS	L	Within Guidelines	2

Brand Name	Company	DIN	NAS[1]/FPG[2]	ATC[3]	Status	Category
Revlimid - 15 mg/capsule	Celgene	02317699		L	Within Guidelines	1
Revlimid - 25 mg/capsule	Celgene	02317710		L	Within Guidelines	1
Revlimid - 5 mg/capsule	Celgene	02304899	NAS	L	Within Guidelines	2
Risperdal Consta - 12.5 mg/vial	Janssen-Ortho Inc.	02298465		N	Within Guidelines	1
Seasonale .15/.03	Procter & Gamble Pharmaceuticals Canada Inc.	02296659	FPG	G	Under Review	1
Stalevo 100/25/200 - 325 mg/tablet	Novartis Pharma Canada Inc.	02305941		N	Within Guidelines	3
Stalevo 150/37.5/200 - 387.5 mg/tablet	Novartis Pharma Canada Inc.	02305968		N	Within Guidelines	3
Stalevo 50/12.5/200 - 262.5 mg/tablet	Novartis Pharma Canada Inc.	02305933		N	Within Guidelines	3
Tears Naturale Forte - 4 mg/ml	Alcon Canada Inc.	02246397	FPG	S	Within Guidelines	3
Torisel - 25 mg/vial	Wyeth Pharmaceuticals	02304104	NAS	L	Within Guidelines	3
Travatan Z - 0.04 mg/ml	Alcon Canada Inc.	02318008		S	Within Guidelines	1
Tridural - 100 mg/tablet	Paladin Labs Inc.	02296381	FPG	N	Subject to Investigation	1
Tridural - 200 mg/tablet	Paladin Labs Inc.	02296403	FPG	N	Subject to Investigation	1
Tridural - 300 mg/tablet	Paladin Labs Inc.	02296411	FPG	N	Subject to Investigation	1
Valcyte - 50 mg/ml	Hoffmann-La Roche Ltd.	02306085		J	Within Guidelines	3
Vfend - 40 mg/ml	Pfizer Canada Inc.	02279991		J	Within Guidelines	3
Volibris - 10 mg/tablet	GlaxoSmithKline Inc.	02307073	NAS	C	Within Guidelines	3
Volibris - 5 mg/tablet	GlaxoSmithKline Inc.	02307065	NAS	C	Within Guidelines	3
Xarelto - 10 mg/tablet	Bayer Inc.	02316986	NAS	B	Subject to Investigation	3
Zeldox - 20 mg/capsule	Pfizer Canada Inc.	02298597	NAS	N	Within Guidelines	3
Zeldox - 40 mg/capsule	Pfizer Canada Inc.	02298600	NAS	N	Within Guidelines	3
Zeldox - 60 mg/capsule	Pfizer Canada Inc.	02298619	NAS	N	Within Guidelines	3
Zeldox - 80 mg/capsule	Pfizer Canada Inc.	02298627	NAS	N	Within Guidelines	3
Zevalin - 1.6 mg/ml	Bayer Inc.		NAS/FPG	V	Subject to Investigation	3

Source: PMPRB

1 NAS: New Active Substance

2 FPG: First Patent Grant

3 ATC: Anotomical Therapeutic Chemical Classification System

Annex 3

Summary of Voluntary Compliance Undertakings and Board Orders – Total Excess Revenues

Date of Approval	Medicine	Patentee	Excess Revenues	Excess Revenues Offset by Payments to the Government of Canada
Apr. 24, 2009	Concerta	Janssen-Ortho Inc.	$1,464,441.58	$1,464,441.58
Apr. 23, 2009	Eligard	sanofi-aventis Canada Inc.	$13,127,953.14	$13,127,953.14
			$14,592,394.72	**$14,592,394.72**
Mar. 4, 2009	Suprax	sanofi-aventis Canada Inc.	$97,900.30	$97,900.30
Feb. 23, 2009	Vepesid	Bristol-Myers Squibb Canada Co.	$53,161.48	Customers
Feb. 19, 2009	Strattera	Eli Lilly Canada Inc.	$15,326,066.49	$15,326,066.49
Sep. 29, 2008	Adderall XR - ORDER	Shire Canada Inc.	$5,622,863.63	$5,622,863.63
June 25, 2008	AndroGel	Solvay Pharma Inc.	$3,327,180.61	$3,327,180.61
			$399,206.25	$399,206.25
			$16,573.84	$16,573.84
June 11, 2008	Copaxone - ORDER	Teva Neauroscience	$2,417,223.29	$2,417,223.29
May 20, 2008	Denavir	Barrier Therapeutics Canada Inc.	$61,021.80	$61,021.80
			$27,321,197.69	**$27,268,036.21**
Mar. 4, 2008	Lantus	sanofi-aventis Canada Inc.	$694,239.50	$694,239.50
Feb. 28, 2008	Vaniqa	Barrier Therapeutics Canada Inc.	$70,860.59	$70,860.59
Dec. 20, 2007	Dovobet	LEO Pharma Inc.	$870,425.68	$870,425.68
Sep. 26, 2007	Zemplar	Abbott Laboratories Ltd.	$58,741.67	Hospitals
Sep. 18, 2007	Dovobet - ORDER	LEO Pharma Inc.	$3,736,398.71	$3,736,398.71
Sep. 13, 2007	OctreoScan	Bristol-Myers Squibb Canada Co.	$387,181.87	$7,439.82
				(and payments to customers)
June 28, 2007	Forteo	Eli Lilly Canada Inc.	$333,629.25	Prices lower than MNE
June 4, 2007	Risperdal Consta	Janssen-Ortho Inc.	$4,386,172.99	$4,386,172.99
			$322,927.12	$322,927.12
May 14, 2007	Airomir	3M Canada Company	$485,498.58	$485,498.58
			$11,346,075.96	**$10,573,962.99**

Date of Approval	Medicine	Patentee	Excess Revenues	Excess Revenues Offset by Payments to the Government of Canada
July 14, 2006	Eloxatin	sanofi-aventis Canada Inc.	$1,767,078.84	Hospitals and Cancer Clinics
July 14, 2006	Hextend	Hospira Healthcare Corporation (Canada)	$8,823.60	$8,823.60
June 20, 2006	NuvaRing	Organon Canada Ltd.	$115,584.93	$115,584.93
Apr. 8, 2006	Dukoral ™	sanofi pasteur Limited	$74,073.32	$74,073.32
			$1,965,560.69	**$198,481.85**
Dec. 15, 2005	Risperdal	Janssen-Ortho Inc.	$669,426.81	$669,426.81
Dec. 15, 2005	Dukoral ™	sanofi pasteur Limited	$481,198.49	$481,198.49
Sept. 9, 2005	Ortho 7/7/7	Janssen-Ortho Inc.	$99,892.72	$99,892.72
July 25, 2005	Starlix	Novartis Pharma	$174,306.29	$174,306.29
July 14, 2005	Ceretec	Amersham Health Inc.	$278,112.65	By price reduction
			$1,702,936.96	**$1,424,824.31**
Mar. 7, 2005	Tamiflu	Hoffmann-La Roche Limited	$442,973.47	$442,973.47
Mar. 7, 2005	Paxil CR	GlaxoSmithKline Inc.	$310,403.64	$310,403.64
Feb. 17, 2005	Evra	Janssen-Ortho Inc.	$3,000,000	$1,359,263.67
Nov. 16, 2004	Busulfex	ESP Pharma	$144,215.55	$144,215.55
July 15, 2004	Starnoc	Servier Canada Inc.	$739,739.99	$739,739.99
July 9, 2004	Prolastin	Bayer Inc.		By price reduction
June 25, 2004	Fasturtec	Sanofi-Synthelabo Canada Inc.		By price reduction
May 6, 2004	One-Alpha	LEO Pharma Inc.	$23,049.10	$23,049.10
			$4,660,381.75	**$3,019,645.42**

Date of Approval	Medicine	Patentee	Excess Revenues	Excess Revenues Offset by Payments to the Government of Canada
Oct. 21, 2003	Dostinex	Pfizer Canada Inc.	$42,116.31	$42,116.31
Apr. 26, 2003	Aromasin	Pharmacia Canada Inc.	$87,484.65	By price reduction
Mar. 31, 2003	Remicade	Schering Canada Inc.	$7,792,650.89	$7,792,650.89
Sept. 16, 2002	Differin Pledget	Galderma Canada Inc.	$17,575.12	$17,575.12
Oct. 15, 2001	Zanaflex	Draxis Health Inc.	$62,559	$62,559
June 30, 2000	Plavix	Bristol-Myers Squibb/Sanofi	$583,065	$583,065
Aug. 11, 1999	Anaprox	Hoffmann-La Roche Limited	$67,252.55	$67,252.55
Apr. 29, 1998	Humalog	Eli Lilly Canada Inc.	$666,824	$666,824
Jul. 26, 1996	Virazole - ORDER	ICN Canada Ltd.	$3,460,014	$1,200,000
Mar. 5, 1996	Prostep	Boehringer Ingelheim (Canada) Ltd.	$14,959	$14,959
Oct. 10, 1995	Betaseron	Berlex Canada Inc.	$27,415	By price reduction
May 23, 1995	Hepatate II	Amersham Canada Limited	$16,286	By price reduction
Apr. 20, 1995	Beclomethasone	Kenral Inc.	$72,054	$72,054
Nov. 28, 1994	Ortho 7/7/7 (21 & 28) pack	Ortho-McNeil Inc.	$487,091	$444,571
Nov. 14, 1994	Minocin (50 & 100) mg	Cyanamid Canada Inc. Lederle Laboratories	$84,813	$84,813
Oct. 18, 1994	Habitrol (7, 14, 21) mg	Ciba-Geigy Canada Inc.	$3,600,000	$2,950,000
Sept. 26, 1994	Ponderal (60 mg)	Servier Canada Inc.	$144,894	$144,894
Dec. 20, 1993	Lopid/Gemfibrozil (300mg & 600 mg)	Parke-Davis	$1,635,970	$1,635,970
Nov. 22, 1993	Megace (40 & 160) mg)	Bristol-Myers Squibb Pharmaceutical Group	$993,157	$993,157
Nov. 2, 1993	Hytrin (10 mg)	Abbott Laboratories Limited	$24,510	$24,510
Sept. 28, 1993	Metrogel (7.5 mg/g)	Cyanamid Canada Inc. Lederle Laboratories	$406,642	$406,642
June 10, 1993	Imovane (7.5 mg)	Rhône Poulenc Rorer Canada Inc.	$1,663,393	$1,663,393
June 2, 1993	Activase (vials)	Genentech Canada Inc.	$1,755,000	$1,755,000
			$23,705,725.52	**$20,622,005.87**
	Total for all VCUs and Board Orders Combined		**$85,294,273.29**	**$77,699,351.37**

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	2008 Number of Reporting Companies	2008 Total Sales Revenue $Millions	2008 Total Sales Revenue % Share	2007 Number of Reporting Companies	2007 Total Sales Revenue $Millions	2007 Total Sales Revenue % Share
0%	25	737.7	4.5	26	510.7	3.2
≤10%	37	10,803.3	66.2	43	11,651.2	72.8
> 10%	20	4,775.7	29.3	13	3,829.1	24.0
Total	82	16,316.7	100.0	82	15,991.0	100.0

Source: PMPRB

Figure 24 Current R&D Expenditures by Type of Research, 1988 – 2008

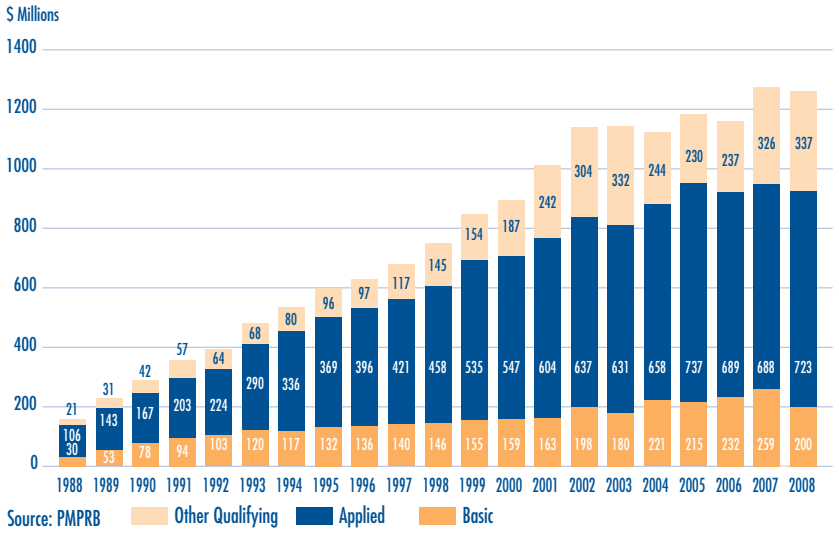


TABLE 24 Ratios of R&D Expenditures to Sales Revenue by Reporting Patentee[1] 2008 and 2007

Company	R&D-to-Sales Ratio (%) 2008	2007
Abbott Laboratories Limited [2]	4.9	3.3
Abraxis BioSciences Canada Inc. [5]	17.6	3.2
Actelion Pharmaceutiques Canada Inc. [2]	7.8	5.1
Alcon Canada Inc.	0.3	0.3
Allergan Inc.	6.6	6.8
Amersham Health Inc (GE Healthcare Inc,)	0.0	0.0
Amgen Canada Inc. [2, 5]	6.1	8.4
Astellas Pharma Canada Inc. [2, 5, 9]	10.4	7.7
AstraZeneca Canada Inc. [2,5]	6.7	7.3
Axcan Pharma Inc. [2]	27.7	24.8
Baxter Corporation [5]	0.2	0.2
Bayer Inc., Healthcare Division [2, 5]	3.2	3.7
Biogen Idec Canada Inc. [2, 5]	1.6	2.5
Biovail Pharmaceuticals Canada, Division of Biovail Corporation [5]	23.5	59.5
Boehringer Ingelheim (Canada) Ltd. [2]	22.0	24.6
Bracco Diagnostics Canada Inc.	0.0	0.0
Bristol-Myers Squibb Pharmaceutical Group [2, 5]	13.3	9.9
Duchesnay Inc.	12.3	4.6
Eli Lilly Canada Inc. (includes Provel Animal Health Division) [2, 5]	11.4	7.5
EMD Serono Canada Inc. [2, 5]	2.9	2.6
Enzon Pharmaceuticals Inc.	0.0	0.0
Ferring Inc.	2.9	1.2
Fournier Pharma Inc. [2, 4]	0.0	0.0
Fresenius Kabi Canada	0.7	0.0
Fresenius Medical Care Canada [6]	0.0	–
Galderma Canada Inc.	1.1	0.0
Genzyme Canada Inc. [5]	1.3	3.4
Gilead Sciences Inc. [5]	45.8	54.2
GlaxoSmithKline [2, 5]	11.3	13.1
GlaxoSmithKline Consumer Healthcare Inc.	0.0	0.0
Graceway Pharmaceuticals	0.0	0.0
Hoffmann-La Roche Limited [2, 5]	3.8	4.7
Hospira Healthcare Corp.	0.0	0.008
INO Therapeutics Inc.	2.1	2.4
Iroko International LP	0.0	0.0
Janssen-Ortho Inc. [2, 5]	8.7	8.4
Johnson & Johnson Merck, Consumer Pharmaceuticals of Canada	0.0	0.0
Lantheus MI Canada Inc. [6]	0.0	–
LEO Pharma Inc. [2]	3.7	1.7
Les Laboratories Inc. [7]	0.0	0.0
Lundbeck Canada Inc. [2]	3.9	3.5
McNeil Consumer Healthcare	2.9	3.1
Merck Frosst Canada Ltd. [2, 5]	14.8	17.4
Merck Frosst – Schering Pharma [2]	0.7	0.7
Novartis Consumer Health Canada Inc.	0.0	0.0
Novartis Pharma Canada Inc. [2, 5]	16.7	14.6
Novo Nordisk Canada Inc. [5]	3.1	3.9
Nycomed Canada Inc. [2, 3, 5]	0.7	2.2
Organon Canada Ltd. [2]	2.4	2.4
Ortho Dermatological, Division of Johnson & Johnson Inc.	0.0	0.0
Otsuka America Pharmaceuticals [6]	0.0	–
Ovation Pharmaceuticals Inc.	0.0	0.0
Paladin Labs Inc. [2]	0.2	0.2
Pfizer Canada Inc. Animal Health Group	0.3	0.3
Pfizer Canada Inc. [2, 5]	4.9	5.1
Pharmaceutical Partners of Canada Inc.	0.0	0.0

Pharmascience Inc.	8.5	8.3
Procter & Gamble Pharmaceuticals Canada, Inc. [2, 5]	0.6	0.7
Purdue Pharma [2]	1.7	1.8
Rare Disease Therapeutics Inc.	0.0	0.0
RGR Pharma Ltd.	0.0	0.0
Sandoz Canada Inc. [6]	0.0	–
sanofi pasteur Limited [2, 5, 10]	53.9	46.3
sanofi-aventis Pharma Inc. [2, 11]	14.2	12.7
Santhera Pharmaceuticals Canada Inc. [5, 6]	111.9	–
Schering-Plough Canada Inc. [2, 5]	3.5	3.8
Sepracor Pharmaceuticals Inc. [12]	0.0	0.0
Servier Canada Inc. [2]	10.9	14.6
Shire Canada Inc. [2, 5]	0.0	0.0
Shire Human Genetic Therapies [5]	3.8	
Solvay Pharma Inc. [2, 5]	14.6	5.5
Sopherion Therapeutics Canada Inc.	0.0	617.8
Squire Pharma [2, 13]	0.4	0.08
Stiefel Canada Inc.	0.7	0.2
Talecris Biotherapeutics Inc. [5]	0.9	2.3
Teva Neuroscience [5]	4.8	6.3
Tyco Healthcare Group Canada Inc.	0.0	0.0
UCB Pharma Canada Inc. [5, 6]	55.6	–
Unither Biotech Inc.	0.0	0.0
Valeant Canada Ltd. [8]	1.8	2.2
Wyeth Pharmaceuticals [2, 5]	24.1	18.8
YM Biosciences Inc. [5, 6]	12658.8	–

Source: PMPRB

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 licencees. 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 Limited
11. Formerly known as Aventis Pharma Inc.
12. Formerly Oryx Pharmaceuticals Inc.
13. Division of Paladin Labs Inc.

TABLE 25 Current R&D Expenditures by Province and by R&D Performer, 2008

Province		R&D Performer: Patentees	Other Companies	University	Hospitals	Others	Total	Rx&D	Percentage of Expenditures
Newfoundland	$(000)	531.35	1,660.65	514.19	538.95	1,688.88	4,934.02	4,864.81	0.391
	%	10.76	33.65	10.42	10.92	34.22	100.00	0.428	
Prince Edward Island	$(000)	1.78	293.98	11.69	68.73	108.62	484.80	484.80	0.038
	%	0.36	60.64	2.41	14.17	22.40	100.00	0.043	
Nova Scotia	$(000)	1,636.12	3,412.52	801.81	3,628.79	3,935.27	13,414.50	12,474.36	1.064
	%	12.19	25.43	5.97	27.05	29.33	100.00	1.099	
New Brunswick	$(000)	430.38	1,030.33	51.55	449.96	531.94	2,494.15	2,478.44	0.198
	%	17.25	41.31	2.06	18.04	21.32	100.00	0.218	
Quebec	$(000)	333,208.71	107,273.28	9,862.34	28,624.58	53,524.23	532,493.15	497,641.58	42.216
	%	62.57	20.14	1.85	5.37	10.05	100.00	43.31	
Ontario	$(000)	242,486.17	136,745.84	31,609.66	64,330.54	120,909.78	596,081.99	538,081.43	47.258
	%	40.68	22.94	5.30	10.79	20.28	100.00	47.393	
Manitoba	$(000)	5,578.11	4,931.91	563.10	1,894.10	1,826.51	14,793.73	11,641.41	1.173
	%	37.70	33.33	3.80	12.80	12.34	100.00	1.025	
Saskatchewan	$(000)	1,044.02	870.44	663.21	407.53	896.36	3,881.56	3,658.95	0.308
	%	26.89	22.42	17.08	10.49	23.09	100.00	0.322	
Alberta	$(000)	31,224.84	15,339.16	6,202.41	2,269.80	4,985.56	60,021.77	32,574.00	4.759
	%	52.16	25.55	10.33	3.78	8.30	100.00	2.869	
British Columbia	$(000)	4,410.04	10,819.40	4,129.91	5,546.84	7,628.43	32,534,63	31,244.65	2.579
	%	13.55	33.25	12.69	17.04	23.44	100.00	2.752	
Yukon; N.W.T.; Nunavut	$(000)	00.00	169.88	00.00	00.00	44.44	214.32	214.32	0.017
	%	00.00	79.26	00.00	00.00	20.73	100.00	0.019	
Canada	$(000)	620,551.53	282,547.39	54,409.87	107,759.83	196,080.01	1,261,348.62	1,135,358.76	100.00

Source: PMPRB

– 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.