Patented Medicine Prices Review Board

2001 Annual Report

The **PMPRB** protects consumers and contributes to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive.

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Mission and Values of the PMPRB

The PMPRB protects consumers and contributes to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive.

The PMPRB achieves this by:

- promoting voluntary compliance with Guidelines established by the Board
- reviewing prices and taking remedial action when necessary
- analyzing and reporting to Canadians on price trends of all medicines and on research and development conducted by patentees
- consulting with interested parties on Guidelines and other matters of policy
- fostering awareness of the Board's mandate, activities and achievements through communication, dissemination of information and public education.

In fulfilling the mission we are committed to innovative leadership based on the following values:

- effectiveness and efficiency
- fairness
- integrity
- mutual respect
- transparency of process
- a supportive and challenging work environment.

All PMPRB publications are available in both official languages.
To obtain our publications, log on to our website: **www.pmprb-cepmb.gc.ca**
or call us at our toll-free number: 1 877 861-2350.

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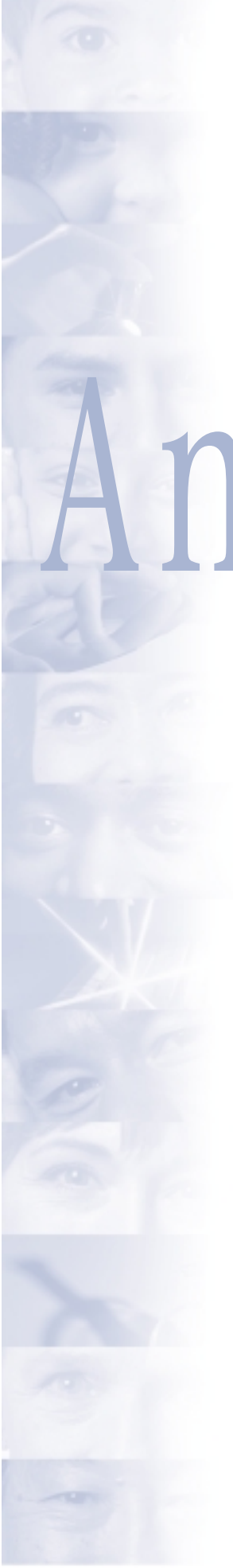

2001 Annual Report

The PMPRB protects consumers and contributes to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive.

Letter to the Minister

May 31, 2002

The Honourable Anne McLellan, P.C., Q.C., M.P.
Minister of Health
House of Commons
Ottawa, Ontario
K1A 0A6

Dear Minister:

I have the honour to present to you, in accordance with the sections 89 and 100 of the *Patent Act*, the Annual Report of the Patented Medicine Prices Review Board for the year ended December 31, 2001.

Yours very truly,

Robert G. Elgie
Chairperson

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List of Tables and Figures

Patented Drug Products for Human Use and Canadian Patentees, January 1, 2001 – December 31, 2001

This list is available on the PMPRB website: **www.pmprb-cepmb.gc.ca**, under Publications; Patented Medicines, or by calling our toll-free number: **1 877 861-2350**

Chairperson's Message

It was a tumultuous period for the world following the events of September 11. It was a time during which citizens and governments were collectively preoccupied with security issues; it was also a time when the public sector's response to the tragic events demonstrated its capacity to address new and unexpected challenges. On the domestic front, policy issues in Canada have continued to be dominated by discussions about health care.

There are many reasons for this continued focus on health issues. Cost pressures are felt in many areas. According to the Canadian Institute for Health Information (CIHI), pharmaceuticals continue to represent the fastest-growing component of health care costs and accounted for over 15% of total health expenditures in 2001. As shown in this report, total sales by drug manufacturers in Canada increased 15% in 2001 to $11.5 billion. At the provincial level, efforts are ongoing to restructure health care programs to achieve greater efficiency and cost savings. Concurrently, a number of major studies have been released and further reports and recommendations are expected in the coming months on the state of health care in Canada.

TOTAL SALES BY DRUG MANUFACTURERS IN CANADA INCREASED 15% IN 2001 TO $11.5 BILLION.

An important dimension of this public focus on health care is a growing recognition among Canadians and governments alike of the interconnectedness of health care issues in Canada. The public is looking to governments to collaborate in finding solutions that will ensure the sustainability and effectiveness of our health care system.

This emphasis on collaboration was reflected in initiatives announced by the federal/provincial/territorial ministers of health in September 2001 on a multi-faceted approach to better pharmaceuticals management. One of these initiatives is the National Prescription Drug Utilization Information System (NPDUIS), a partnership involving CIHI and the PMPRB. In establishing the first national database of publicly-funded drug plans in Canada, the NPDUIS will call on the PMPRB to continue and expand on the analyses of price and expenditure trends and cost drivers of publicly-funded drug plans previously conducted pursuant to a Memorandum of Understanding with the Minister of Health.

A significant aspect of the review of health care is the growing emphasis on consultations with Canadians. As citizens, we are being increasingly involved in the health care debate. We are becoming more aware of the underlying issues and the need to find solutions that recognize and balance the interests of all stakeholders.

In the coming year, the PMPRB's efforts will also remain focused on transparency and consultations.

In the coming year, the PMPRB's efforts will also remain focused on transparency and consultations. As reflected in our Research Agenda, a significant example of consultation is the Working Group on Price Review Issues. This Group, consisting of representatives of our main stakeholders, was established in 1999 and has advised the Board on a number of important issues. In 2001, following a period of broader public notice and comment, the PMPRB began to implement most of the Working Group's recommendations to increase the transparency of the review of the prices of new patented medicines. Beginning in 2002, we will publish summaries of the reviews by Board Staff, for purposes of applying the Price Guidelines, of new active substances. The Working Group is now continuing its review of the Guidelines.

To support our capacity to better understand the major current and emerging pharmaceutical issues, we conducted a survey of representatives of major stakeholders as part of our annual environmental scan. In carrying out this survey, we also sought to evaluate our efforts to consult and communicate with our various stakeholders. The results of this initiative were important in a number of ways, including assisting us in our annual planning process and in the development of our annual Research Agenda.

Looking ahead, we will be marking the 15th anniversary of the creation of the PMPRB in 2002. We will be using this opportunity to bring together a wide range of experts and stakeholders to discuss current issues in the area of pharmaceutical price regulation. We are planning a Symposium to be held on October 7-8, 2002. This event will provide a unique forum for promoting greater insight and understanding of the issues in this important aspect of the health care system.

We are planning a Symposium to be held on October 7-8, 2002.

I take this opportunity to thank the many people who have contributed to the PMPRB's activities over the past 12 months, and whose energies and support will be needed in the challenging year ahead.

Robert G. Elgie
Chairperson

Highlights for 2001

Sales

Total sales of all drugs for human use by manufacturers in Canada increased 15% from 2000 to $11.5 billion.

Sales of patented drugs increased by 18.9% to $7.5 billion in 2001. Patented drugs now account for 65% of total sales, up from 43.9% in 1995.

Compliance

In total, there were 82 new patented drug products introduced in 2001, including 18 new active substances. As of March 31, 2002, 63 DINs had been reviewed. Of those, 47 were considered to be within the Guidelines and 16 were priced at levels which appeared to be outside the Guidelines and investigations were commenced.

Price Trends

The prices of patented drugs, as measured by the Patented Medicine Prices Index (PMPI) rose by only about 0.1% since 2000. In most years since 1988, prices of patented drugs rose by less than the Consumer Price Index (CPI).

Since the mid-1990s Canadian prices for patented drugs have remained between 5% to 12% below the median of foreign prices. This trend continued in 2001 with Canadian prices 5% below median international prices in the seven countries used for price comparison purposes (lower than the U.S., Switzerland, the U.K. and Germany, and higher than Italy, France and Sweden).

Research and Development

Patentees reported total R&D expenditures of $1.0 billion in 2001, an increase of 12.6% over 2000. Over the same period, their sales rose by 15.3% causing the R&D-to-sales ratio to decline from 10.1% in 2000 to 9.9% for all patentees. The R&D-to-sales ratio for members of Rx&D remained at 10.6%, unchanged from 2000.

Expenditures on basic research increased by 2.5% in 2001 to reach $163.1 million, but its share of total R&D continued to decline from 17.8% in 2000 to 16.1% in 2001. This is the lowest proportion of total R&D spending on basic research ever reported by patentees since the Board began reporting such information in 1988.

About the Patented Medicine Prices Review Board

Mandate and Jurisdiction

Mandate

The PMPRB is an independent quasi-judicial body created by Parliament in 1987 under the *Patent Act*. The PMPRB protects consumer interests and contributes to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive.

The PMPRB reports to Parliament through the Minister of Health. The Annual Report, which covers each calendar year, includes a review of the PMPRB's major activities, analyses of the prices of patented medicines and of the price trends of all drugs, and reports on the R&D expenditures as reported by patent-holding drug manufacturers.

Jurisdiction

The PMPRB is responsible for regulating the prices that patentees charge for prescription and non-prescription patented drugs sold in Canada for human and veterinary use to ensure that they are not excessive. If, after a public hearing, the Board finds that a price is excessive it may order the patentee to reduce the price and take measures to offset any excess revenues it may have received. The PMPRB reviews the "factory-gate" price at which the manufacturer sells the product to wholesalers, hospitals or pharmacies. The PMPRB's jurisdiction includes patented medicines marketed or distributed under voluntary licences. The PMPRB has no authority to regulate the prices of non-patented drugs, including generic drugs sold under compulsory licences, and does not have jurisdiction over prices charged by wholesalers or retailers nor over pharmacists' professional fees.

In Canada, Health Canada assesses new medicines to ensure that they conform with the *Food and Drugs Act* and *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 a NOC, as an Investigational New Drug or under the Special Access Program.

The PMPRB regulates the price of each patented drug product, including each strength of each dosage form of a patented medicine. This is normally the level at which Health Canada assigns a Drug Identification Number (DIN).

Regulating

Prices of Patented Medicines

Sales of Drugs in Canada in 2001

Sales of Drugs in Canada

In 2001 patentees reported total factory-gate sales of patented drugs of $7.5 billion ... an increase of 18.9% over sales in 2000. Patented drugs now account for 65.0% of total sales.

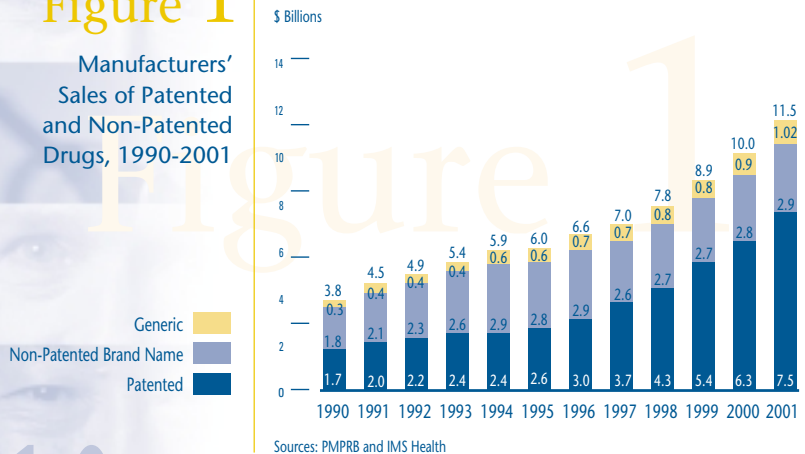
Total sales by manufacturers of pharmaceuticals for human use in 2001 in Canada are estimated at $11.5 billion, an increase of approximately 15.0% from 2000.[1] The total sales of drugs in Canada, including the sales of veterinary drugs reported by patentees for patented and non-patented drugs, were slightly higher at $11.8 billion for 2001.[2] Table 1, on page 11, shows manufacturers' sales of all drugs and of patented drugs in Canada since 1990.

In 2001 patentees reported total factory-gate sales of patented drugs of $7.5 billion. This represents an increase of 18.9% over sales in 2000. Patented drugs now account for 65.0% of total sales, up from 43.9% in 1995. The rising share of patented drugs within total drug sales may be attributed in part to the long-term effects of increased patent protection resulting from Bills C-22 and C-91 in 1987 and 1993. For further information on *Trends in Quantities of Sales of Patented Drug Products*, please refer to page 23.

Figure 1 shows the growth in annual sales of patented and non-patented drugs from 1990 to 2001. Non-patented medicines may include products that were previously subject to patent protection, those that are not yet or never will be patented, and generic copies. Information filed by patentees with the PMPRB indicates that most of the sales of non-patented drugs are not generic drugs, but rather are brand name drugs sold by companies that also sell patented drugs.

Figure 1

Manufacturers' Sales of Patented and Non-Patented Drugs, 1990-2001



Sources: PMPRB and IMS Health

1 Patentees are required, under the *Patented Medicines Regulations*, to submit to the PMPRB information showing their annual total pharmaceutical sales for both patented and non-patented drugs in Canada. They reported sales of drugs for both human and veterinary use of $9.2 billion in 2000 and $10.8 billion in 2001. Their sales of drugs for human use only represented $10.4 billion in 2001. IMS Health publishes estimated sales of pharmaceuticals by individual firms. Total sales by manufacturers can thus be estimated by adding the total sales reported by patentees and IMS Health estimated sales in Canada of generic drug companies belonging to the Canadian Drug Manufacturers' Association (CDMA).

Before 1996, total sales of drugs in Canada were estimated using information published by Statistics Canada on shipments, imports and exports of pharmaceuticals. (See Statistics Canada CANSIM No.'s D667757, D401624 and D451712.) In 1996, the PMPRB began using its current methodology for estimating total sales of drugs in Canada, because current information from Statistics Canada is not available in time for inclusion in the Annual Report.

2 Beginning with the year 1999, the calculation of manufacturers' sales of all drugs and patented drugs includes the sales of drug products for human use only. Between 1990 and 1998, sales of patented drugs for veterinary use as a percentage of total sales of patented drugs varied between 2.3% (1998) and 3.6% (1994).

Table 1 | Manufacturers' Sales of All Drugs and Patented Drugs for Human and Veterinary Use, 1990-1998; and for Human Use, 1999-2001

Year	Total		Patented		Patented Drugs as Percentage of Total
	Sales ($ billions)	Change * (%)	Sales ($ billions)	Change * (%)	
2001	11.5	15.0	7.5	18.9	65.0
2000	10.0	12.4	6.3	16.7	63.0
1999**	8.9	16.8	5.4	27.0	61.0
1998	7.8	11.4	4.3	18.9	55.1
1997	7.0	7.0	3.7	22.6	52.3
1996	6.6	10.0	3.0	12.8	45.0
1995	6.0	1.7	2.6	10.8	43.9
1994	5.9	9.3	2.4	-2.1	40.7
1993	5.4	12.5	2.4	9.4	44.4
1992	4.8	9.1	2.2	14.0	43.8
1991	4.4	18.9	2.0	13.1	43.2
1990	3.7	-	1.7	-	43.2

Sources: PMPRB and IMS Health. Prior to 1996, Statistics Canada information was used.

* Percentage changes reflect exact values of sales and not rounded values of sales.

** The percentage change from 1998 of 16.8% for total drugs and 27.0% for patented drugs represents the change in sales of drugs for human use only.

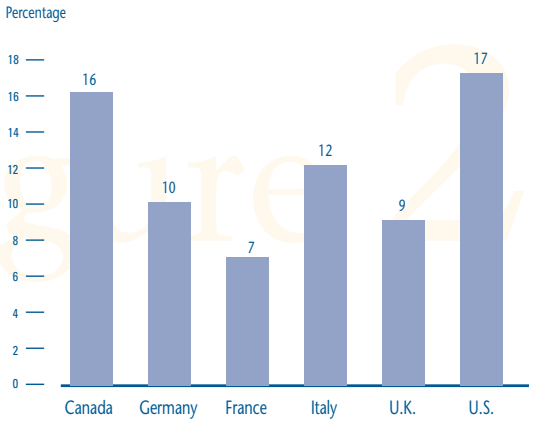
From 1990 to 1995, sales of non-patented brand name drugs accounted for more than half the total drug sales of patentees. That proportion has since declined steadily, reaching 27.3% in 2001. The sales of generic drugs are estimated at approximately $1 billion in 2001, an increase of 10% over 2000.[3]

The Global Context

Measured in terms of total sales, Canada accounted for about 2% of the world pharmaceutical market in 2001. It has been estimated that manufacturers' sales of drugs worldwide for human use increased by 8.3% to approximately $607.0 billion in 2001.[4]

Figure 2

Growth in Retail Pharmacy Sales of Drugs, 2001



Source: Scrip Magazine, February 2002

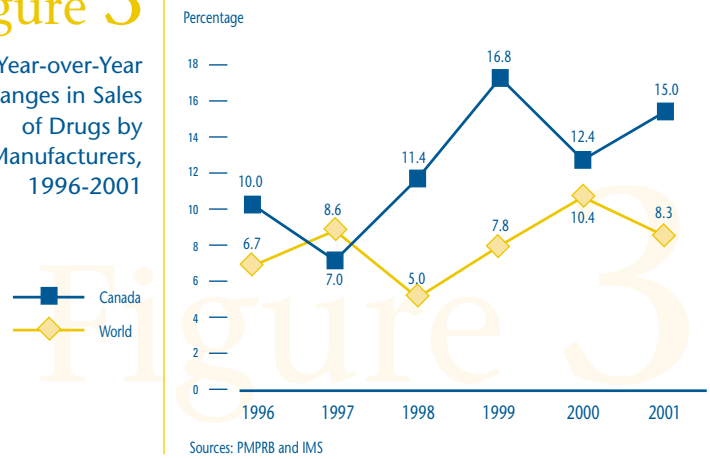
Figure 2 provides additional detail on increases in sales of drugs abroad. It has been estimated that the growth in retail pharmacy sales of drugs in each of France, Germany, Italy and the U.K. in 2001 was lower than in Canada, while retail sales growth in the U.S., by far the largest national market in the world, was slightly higher.

3 *Canadian Pharmaceutical Market: Drug Store and Hospital Purchases*, December 2001, IMS Health. Sales of generic manufacturers are estimated by adding the total sales as reported by IMS Health for those manufacturers that belong to the Canadian Drug Manufacturers Association (CDMA).

4 IMS World Review, 2001. This estimate of global sales was originally stated in U.S. dollars. The growth rate of 8.3% is based on this U.S. dollar estimate.

Figure 3

Year-over-Year Changes in Sales of Drugs by Manufacturers, 1996-2001



Sources: PMPRB and IMS

Figure 3 provides a time-series comparison of the annual changes in sales of drugs by manufacturers in Canada and the world for the period 1996 to 2001. Taking this period as a whole, manufacturers' sales grew at an average annual rate of 12.1% in Canada, compared with a global growth rate of 7.8%.

Compliance and Excessive Price Guidelines

The PMPRB protects consumer interests in Canada by ensuring that pharmaceutical patentees do not charge excessive prices during the time they enjoy patent protection. The patentee is ordinarily the exclusive supplier of a patented product, but there may also be other suppliers of the same medicine. Although a drug no longer protected by a patent may become subject to competition, there are also instances where the manufacturer of a non-patented drug may nevertheless remain the sole supplier after patent expiry.

Under the *Patented Medicines Regulations* (Regulations), patentees are required to report information on the introductory prices and sales of new patented medicines within 60 days of the date of first sale and to continue to file detailed information on prices and sales of each patented drug for the first and last six-month period of each year for as long as the drug remains patented. The PMPRB reviews the pricing information for all patented medicines sold in Canada on an ongoing basis to ensure that the prices charged by patentees comply with the Guidelines established by the Board. They are published in the PMPRB's *Compendium of Guidelines, Policies and Procedures* (Compendium) and are available on the PMPRB website at **www.pmprb-cepmb.gc.ca** under Legislation, Regulations, Guidelines or by calling our toll-free number: 1 877 861-2350.

The Guidelines are based on the price determination factors in section 85 of the *Patent Act* (Act) and have been developed 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 drugs are limited such that the cost of therapy for the new drug does not exceed the highest cost of therapy for existing drugs used to treat the same disease in Canada;
- prices of breakthrough patented drugs and those which bring a substantial improvement are limited to the median of the prices charged for the same drug in other industrialized countries listed in the Regulations (France, Germany, Italy, Sweden, Switzerland, U.K. and U.S.);
- price increases for existing patented medicines are limited to changes in the Consumer Price Index (CPI); and
- the price of a patented drug in Canada may, at no time, exceed the highest price for the same drug in the foreign countries listed in the Regulations.

Board Staff reviews the prices of all patented medicines 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 the facts. Additional information on the criteria for commencing an investigation is available in Annex 1 on page 43. An investigation could result in:

- its closure where it is concluded that the price was not outside the Guidelines;
- a Voluntary Compliance Undertaking (VCU); or
- a public hearing.

As part of the transparency initiative, beginning in 2001, the list of New Patented Medicines Reported to the PMPRB is posted on the PMPRB website every month. This list includes information on the status of the review (i.e., under review, within Guidelines, VCU, notice of hearing). Drug products "under review" also include drugs which are subject to an investigation.

New Active Substances in 2001

Health Canada reported 27 NASs in 2001 but not all were introduced to the market in that year.[5] The PMPRB's list of patented NASs in any year may differ from the list of NASs approved by Health Canada's Therapeutic Products Directorate (TPD) for the following reasons:

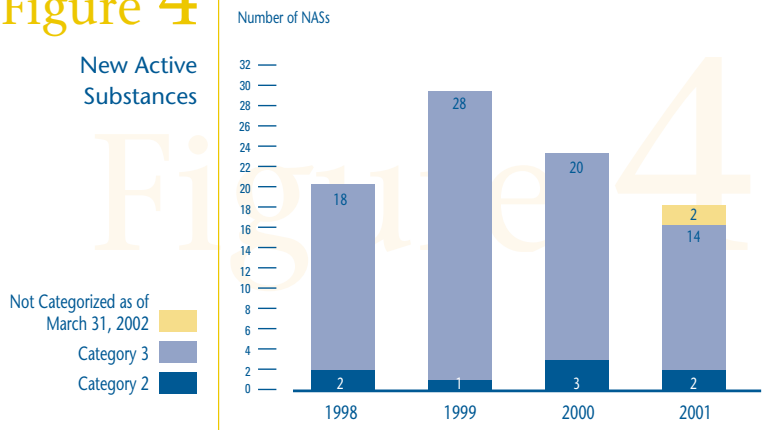
- the NAS is not subject to the PMPRB's jurisdiction;
- the NAS may not be on the TPD list because it is being sold under the Special Access Program (SAP) before it receives a Notice of Compliance (NOC); or
- the NAS may be approved but has not been sold.

As shown in Table 2, four of the 18 patented NASs that come under the PMPRB's jurisdiction were sold prior to 2001.

A new active substance may represent more than one DIN if it is sold in more than one strength or dosage form. The 18 NASs listed for 2001 were marketed as 34 presentations (DINs). Figure 4 provides a breakdown of the patented new active substances for human use,

Figure 4

New Active Substances



Source: PMPRB

In 1999, there were two medicines classified as category 2. One was the medicine Rebetron, which was not a new active substance as it is a combination of two existing medicines (interferon + ribavirin). The second category 2 medicine was Herceptin, a NAS, as reported in our 2000 Annual Report.

Table 2 | New Patented Medicines in 2001 (Human) — New Active Substances

Brand Name	Chemical Name	Company	# DINs	ATC Class
Comtan	entacapone	Novartis Pharma Canada	1	N04BX
Definity	perflutren	Bristol-Myers Squibb	1	V08DA
Kaletra	lopinavir/ritonavir	Abbott Laboratories	2	J05AE
Melacine	melanoma theraccine	Schering Canada Inc.	1	L03AX
Meridia	sibutramine hydrochloride	Knoll Pharma Inc.	2	A08AA
Nexium	esomeprazole magnesium	AstraZeneca Canada Inc.	2	A02BC
Peg-Intron	peginterferon alfa-2b	Schering Canada Inc.	4	L03AB
Prevnar	pneumococcal 7-valent conjugate vaccine	Wyeth-Ayerst Canada Inc.	1	J07AL
Rapamune	sirolimus	Wyeth-Ayerst Canada Inc.	1	L04AA
Remicade	infliximab	Schering Canada Inc.	1	L04AA
Reminyl	galantamine hydrobromide	Janssen-Ortho Inc.	3	N06DA
Tequin	gatifloxacin	Bristol-Myers Squibb	2	J01MA
Teveten	eprosartan	Solvay Pharma Inc.	3	C09CA
Zyvoxam	linezolid	Pharmacia Canada Inc.	2	J01XX
New Active Substances Introduced prior to 2001[6]				
Cerezyme	imiglucerase	Genzyme Canada Inc.	2	A16AB
Coversyl	perindopril erbumine	Servier Canada Inc.	2	C09AA
Rescriptor	delavirdine mesylate	Agouron Pharmaceuticals	1	J05AG
Sustiva	efavirenz	Bristol-Myers Squibb	3	J05AG

5 Annual Drug Submission Performance Report, January-December 2001, Therapeutic Products Directorate, Health Canada.

6 These drugs, which were on the market before 2001, came under the PMPRB's jurisdiction in 2001 with the issuance of a patent.

by category assigned for price review purposes, over the four-year period 1998 through 2001 inclusive.

New Patented Drug Products in 2001

There were 82 new patented drug products (DINs) for human use, representing 53 medicines, in 2001. For purposes of our price review, any patented drug product introduced on the market in Canada, or previously marketed but first patented between December 1, 2000 and November 30, 2001, is considered a new patented drug product in 2001.[7] There were no new patented drug products for veterinary use reported to the PMPRB in 2001.

Eleven (13.4%) of the 82 new patented DINs were being sold in Canada prior to the issuance of the 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 44. 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 seven years.

Table 3 | New Patented Drug Products in 2001 by Year First Sold

	Human
Year First Sold	**# DINs**
Total	82
2001	73
2000	1
1999	3
1998	2
1997	1
1996	–
1995	–
1994	2

Price Review of New Patented Drugs for Human Use

A list of the 82 new patented drug products and their price review status as of March 31, 2002 appears in Annex 2 on page 44. Of the 82 new patented DINs, the prices of 63 had been reviewed. Of those, 47 were considered to be within the Guidelines and 16 were priced at levels which appeared to be outside 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 43.

The Human Drug Advisory Panel[8] recommended that two new patented medicines (three DINs) should be classified as category 2 new medicines in 2001: Cerezyme (imiglucerase, Genzyme Canada Inc.), an enzyme replacement therapy for the treatment of Type I Gaucher disease; and Prevnar (pneumococcal 7-valent conjugate vaccine, Wyeth-Ayerst Canada Inc.), an active immunizing agent for the treatment of invasive pneumococcal diseases. Summary reports on Board Staff's reviews of these two medicines were published in the January and April 2002 editions of the NEWSletter and are available on the PMPRB's website under Publications; Patented Medicines.

Price Review of Existing Patented Drug Products for Human Use

For the purpose of this report, existing medicines include all patented drug products that were introduced prior to December 1, 2000. The PMPRB's Guidelines limit the price changes for existing patented drugs to changes in the Consumer Price Index (CPI). In addition, the price of a patented drug cannot exceed the highest price of the same drug product in the countries listed in the Regulations (France, Germany, Italy, Sweden, Switzerland, U.K. and U.S.)

7 Because of the timing of the filing requirements under the 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.

8 The Human Drug Advisory Panel is comprised of three outside scientific experts and provides recommendations for the categorization of new drug products and the selection of comparable drug products.

A total of 903 existing patented drug products (DINs) for human use were sold during 2001. At the time of this report:

- the prices of 826 DINs (91.5%) were reviewed and found to be within the Guidelines;
- 41 DINs were the subject of investigations commenced as a result of pricing in earlier periods;
- 3 DINs, all pertaining to Nicoderm, were the subject of a hearing under section 83 (see *Quasi-Judicial Activities* on page 18); and
- 33 DINs were still under review.

A summary of the review, compliance and investigation status, as of March 31, 2002, of the new and existing patented drug products for human use in 2001 is provided in Table 4.

Table 4 | Patented Drug Products for Human Use Sold in 2001 Status as of March 31, 2002

	New Drugs Introduced in 2001	Existing Drugs	Total
Total	82	903	985
Within Guidelines	47	826	873
Under Review	19	33	52
Subject of Investigation	16	41	57
Notice of Hearing		3	3

Update of the 2000 Annual Report

In last year's Annual Report, it was reported that of the 940 patented drug products for human use sold in 2000, the prices of 32 were still under review. The results of those reviews concluded that 13 had been within the Guidelines, but four DINs were priced at levels that appeared to exceed the Guidelines and therefore investigations were opened. At the time of this report, 15 are still under review and are included in Table 4.

The Board had also reported that 51 DINs (including three DINs of Nicoderm, which are still the subject of a hearing) were under investigation. Of the 51 investigations ongoing at the time of last year's report, Board Staff have concluded 12 of those investigations; in 11 cases, the prices were ultimately found to be within the Guidelines. One case, Zanaflex, was concluded as a result of a Voluntary Compliance Undertaking (see *Voluntary Compliance Undertaking* on page 17).

Patented Drugs for Veterinary Use

In March 1999, the PMPRB implemented, on a three-year trial basis, a complaints-driven process as an alternative means of reviewing the prices of patented veterinary medicines.[9]

There were a total of 107 existing patented drug products for veterinary use in 2001. Of the 18 reported as under review in 2000, five have been found to be within the Guidelines and 13 are still under review.

The Board did not receive any complaints with respect to the prices of any patented veterinary drug products in 2001.

The PMPRB's Research Agenda projects an evaluation of the complaints-driven process for patented veterinary medicines in 2002-2003.

9 Refer to *Excessive Price Guidelines Special Provisions for Veterinary Patentees* in the *Compendium of Guidelines, Policies and Procedures*.

Voluntary Compliance Undertaking

Under the Compliance and Enforcement Policy, patentees are given an opportunity to make a Voluntary Compliance Undertaking (VCU) when Board Staff conclude, following an investigation, that a price appears to have exceeded the Board's Excessive Price Guidelines. Approval of a VCU by the Chairperson or the Board is an alternative to the commencement of formal proceedings through the issuance of a Notice of Hearing.

In 2001, the Chairperson approved one VCU from Draxis Health Inc. for the patented medicine ***Zanaflex*** (tizanadine).

Draxis Health Inc. — *Zanaflex*

Zanaflex 4 mg/tablet is a patented medicine sold in Canada by Draxis Health and is approved for the management of spasticity. Health Canada issued a Notice of Compliance for Zanaflex on June 29, 1999. Draxis Health began selling Zanaflex on October 28, 1999 at approximately $0.6808 per tablet.

Zanaflex was classified as a category 3 new medicine for purposes of the Board's Guidelines. A Therapeutic Class Comparison test was conducted by Board Staff using Lioresal (baclofen) and Valium (diazepam) as comparators. For purposes of the Guidelines, 24 mg per day of Zanaflex was compared to 80 mg of Lioresal and 40 mg per day of Valium.

The Board's Guidelines provide that the introductory price of a category 3 new medicine is presumed to be excessive if it exceeds the prices of all comparable drug products in the same therapeutic class.

Board Staff concluded that the price of Zanaflex of $0.6808 per tablet exceeded the 1999 maximum non-excessive (MNE) price of $0.6161 per tablet. In 2000, the price of Zanaflex continued to exceed the CPI-adjusted MNE price of $0.6327 per tablet.

The terms and conditions of the VCU were agreed to between Board Staff and the patentee. Having considered the evidence before it, the Chairperson approved the VCU submitted by Draxis Health. Under the terms of the VCU, Draxis Health has undertaken to:

- Reduce the average selling price of Zanaflex on or before November 19, 2001 so that the average price for 2001 does not exceed the 2001 MNE price.
- Offset excess revenues received by Draxis Health during the period October 28, 1999 to December 31, 2000 by making a payment to the Government of Canada, on or before November 19, 2001, in the amount of $62,599.
- To ensure that the price of Zanaflex remains within the Guidelines in all future periods in which it remains under the Board's jurisdiction.

Pursuant to section 103 of the *Patent Act*, the Minister of Health may enter into agreements with any province respecting the distribution of amounts collected as a result of orders made under the Act and VCUs.

The Zanaflex VCU is available on the PMPRB website under Publications; VCUs.

Quasi-Judicial Activities

Nicoderm, Hoechst Marion Roussel Canada Inc.

On April 20, 1999, the Chairperson of the Board issued a Notice of Hearing to consider whether, under sections 83 and 85 of the *Patent Act*, the patented medicine Nicoderm is being, or has been, sold by Hoechst Marion Roussel Canada Inc. (HMRC) in Canada at a price that, in the opinion of the Board, is excessive and if so, what order, if any, should be made. This matter was reported on page 32 of last year's Annual Report.

Following the issuance of the Board's decisions, in 1999 and 2000, affirming its jurisdiction to conduct a hearing into the price of Nicoderm, HMRC commenced two judicial review applications in the Federal Court of Canada seeking to set aside the Board's decisions. As HMRC only named the Attorney-General of Canada as Respondent in its judicial review applications, Board Staff and the Board Hearing Panel applied to the Federal Court to participate in the proceedings. Submissions were made by the parties before a Prothonotary of the Federal Court on March 13, 2001.

On July 13, the Prothonotary issued a decision denying Board Staff the right to participate as either a respondent or intervener while allowing the Board Hearing Panel to intervene on a limited basis. Both the Board Hearing Panel and Board Staff appealed the said decision. In a decision dated February 11, 2002, the Federal Court dismissed both appeals. The decision is presently being appealed before the Federal Court of Appeal.

Nicoderm is a transdermal nicotine patch. It is indicated as an aid for smoking cessation for the partial relief of nicotine withdrawal symptoms.

The Hearing Panel's decisions in this case are available on the PMPRB website: **www.pmprb-cepmb.gc.ca**, under Publications; Hearings & Decisions of the Board.

Reporting

Information on Key Pharmaceutical Trends

Trends in Drug Prices and Expenditures

Prices of Patented Drugs in 2001

The PMPRB maintains the Patented Medicine Price Index (PMPI), an index of manufacturers' prices for patented drugs reported annually to the PMPRB. The PMPI measures the average year-over-year change in the ex-factory prices of patented drug products sold in Canada. It is calculated from the net prices reported by patentees, and thus encompasses all patented drugs reported to the PMPRB.[10]

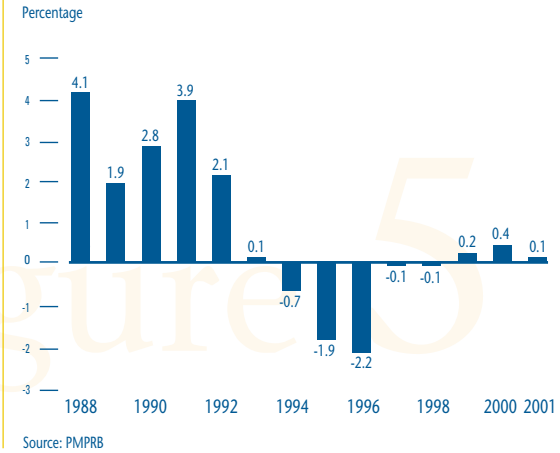
As measured by the PMPI (Figure 5), manufacturers' prices of patented drugs rose by only 0.1% between 2000 and 2001. This result extends the pattern of declines and near-negligible increases in the PMPI that began in 1993. The price stability implied by recent PMPI values is broadly based: price increases of less than 1% were recorded for the majority of drugs in 2001.

Price Trends of All Drugs — Patented and Non-Patented

The *Patent Act* provides that the PMPRB shall consider changes in the Consumer Price Index (CPI) in determining whether the price of a patented medicine is excessive. Figure 6 shows

Figure 5

Year-over-Year Changes in the PMPI, 1988-2001

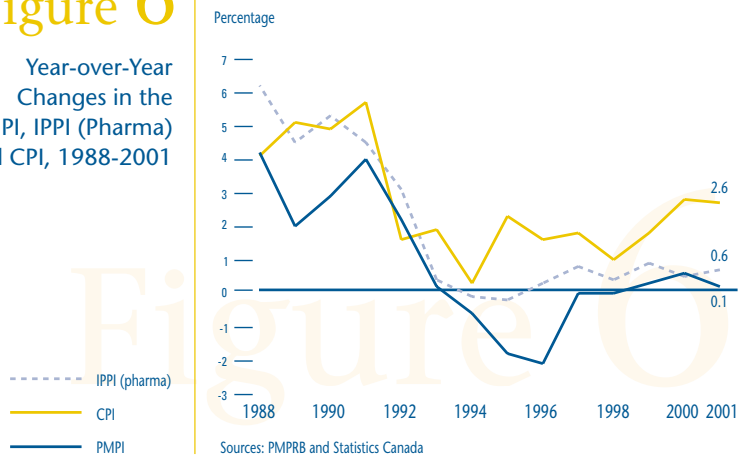


Source: PMPRB

MANUFACTURERS' PRICES OF PATENTED DRUGS ROSE BY 0.1% BETWEEN 2000 AND 2001.

Figure 6

Year-over-Year Changes in the PMPI, IPPI (Pharma) and CPI, 1988-2001



Sources: PMPRB and Statistics Canada

10 See the PMPRB's *A description of the Laspeyres methodology used to construct the Patented Medicine Price Index (PMPI)*, March 1997, revised June 2000 (S-9710). Also see *A Description of the Major Price Indexes for Pharmaceuticals*, produced by Statistics Canada and the PMPRB, January 2001, for an explanation of the PMPI. As of the 1999 Annual Report, the PMPI includes only the changes in the prices of patented drug products for human use.

that prices of patented drugs, as measured by the PMPI, have risen by less than the CPI in almost every year since 1988, the sole exception being 1992.[11] This pattern continued in 2001, with consumer prices increasing by 2.6% (compared with the 0.1% increase in the PMPI).[12]

That increases in the PMPI have been less than CPI inflation comes as no surprise. This in fact reflects a structural feature of the PMPRB's Guidelines, which are applied to patented drugs on a product-by-product basis. Among other things, the Guidelines limit price increases to the expected increase in the CPI over a three-year period. Naturally, in any such period, prices of some drug products will increase by less than the CPI or even decrease. To the extent this occurs, growth in the PMPI will tend to be less than CPI inflation.

Industrial Product Price Index (IPPI)

The pharmaceutical component of Statistics Canada's Industrial Product Price Index [IPPI (pharma)] provides an index of manufacturers' prices for all pharmaceuticals produced in Canada for domestic consumption and export. This includes both patented and non-patented drugs. In 2001, the IPPI (pharma) rose by 0.6%.[13] Figure 6 shows the IPPI (pharma) has remained virtually unchanged since 1993.

As illustrated by Figure 7, a distinct break in pharmaceutical price trends seems to have occurred in 1987. From 1988 to 2001, the IPPI (pharma) increased at an annual average rate of 2.0%, exceeding the corresponding average PMPI increase of 0.8% but falling below the average CPI inflation rate of 2.6%. A much different situation prevailed between 1982 and 1987: during this period, prices of all drugs, as measured by the IPPI (pharma), rose at an annual average rate of 9.0%, exceeding the CPI inflation rate of 5.6%.

Price Trends in Canada and the United States

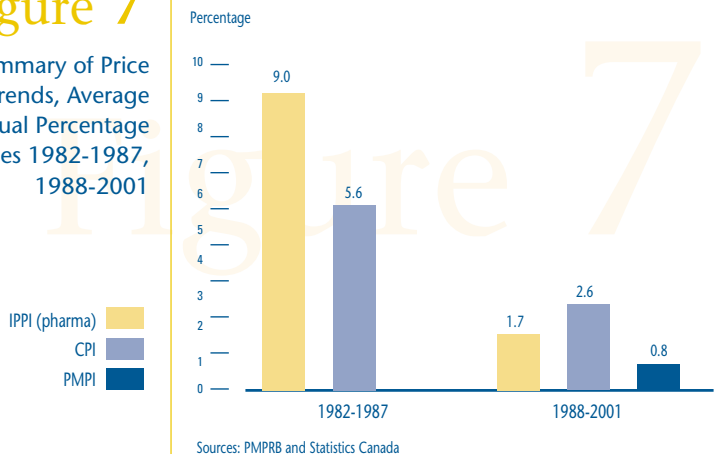
Figure 8 compares annual changes in the pharmaceutical component of the U.S. Product Price Index [PPI (pharma)] to annual changes in the IPPI (pharma) before and after 1987. The U.S. PPI (pharma) measures price increases of all pharmaceuticals at the factory gate. It is similar in construction to the Statistics Canada IPPI (pharma). Here again, a marked change in growth patterns occured at 1987. Increases observed in the Canadian IPPI (pharma) outpaced the U.S. PPI (pharma) in all years up to 1987. The opposite has occurred in all subsequent years: the average annual increase in the IPPI (pharma) declined to 1.7% between 1988 and 2001, a value well below the U.S. PPI (pharma) growth rate of 4.7%.[14]

Relationship of Canadian Prices to Foreign Prices: Past and Present

The above results demonstrate how prices of drugs in Canada have changed over time. Another way of examining drug price trends is to examine trends in Canadian prices relative to those in other countries.

Figure 7

Summary of Price Trends, Average Annual Percentage Changes 1982-1987, 1988-2001



Sources: PMPRB and Statistics Canada

11 To facilitate and encourage compliance by patentees, the PMPRB's CPI-adjusted methodology uses the forecast rate of CPI inflation published by the Department of Finance. The forecast CPI inflation rate for 1992 had been 3.2%, but the actual rate was 1.5%. For a full explanation of the CPI-adjusted methodology please refer to Schedule 4 of the PMPRB's *Compendium of Guidelines, Policies and Procedures*.

12 Statistics Canada, CANSIM, Series P100000.

13 Statistics Canada, CANSIM, Series P3515. The last six months of data are subject to revision by Statistics Canada.

14 U.S. Bureau of Labor Statistics, Producer Price Index-Commodities, Series ID: wpu063.

In accordance with the *Patent Act* and the *Patented Medicines Regulations* (Regulations), patentees are required to report all publicly available ex-factory prices for patented drugs in seven foreign countries listed in the Regulations.[15] This foreign price information is used for two purposes: (1) to conduct the International Price Comparison (IPC) tests specified in the Guidelines, and (2) to compare price levels in Canada with prices elsewhere.

Figure 9 shows the relationship between Canadian prices and the corresponding median price among the seven comparator countries over the period 1987 to 2001.[16] Canadian prices were on average 23% higher than the median international price in 1987. Since then, this ratio declined and has remained relatively stable at levels 5% to 12% below the median price since 1994. In 2001, prices in the Canadian market were about 95% of median foreign prices, up slightly from the value of 92% recorded in 2000.

15 France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S. The PMPRB seeks to verify the foreign price information reported by patentees in several ways. For example, it is possible to derive a manufacturer's ex-factory price from the prices listed in foreign formularies in six of the seven countries used for price comparisons. This method is described further in the PMPRB's study, *Verification of Foreign Patented Drug Prices*, January 2002, (S-0215).

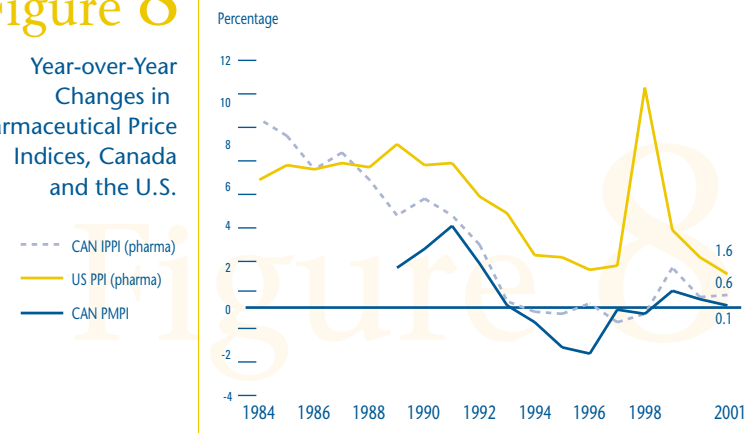
Ex-factory prices in the U.S. cannot be derived using the same methodology, as there are no regulated mark-ups in the U.S. and many customers are able to negotiate confidential discounts from published prices. As of 2000, the PMPRB includes prices available to U.S. federal departments and agencies on the Federal Supply Schedule (FSS) in calculating U.S. prices.

The FSS for pharmaceuticals is a price catalogue containing almost 23,000 pharmaceutical products. The prices the Department of Veteran Affairs (DVA) negotiates for drug products with manufacturers must represent the same, or a greater, discount off a drug's list price that the manufacturer offers its most-favoured non-federal customer under comparable terms and conditions. The FSS is available publicly on the internet.

16 This calculation is based on a revenue-weighted average of the ratio of the Canadian price to the median international price for each patented drug product sold in that year. The methodology used by the PMPRB in conducting foreign price comparisons can be found in the *Compendium of Guidelines, Policies and Procedures* and in two papers published with the PMPRB's *Road Map for the Next Decade* in 1998 entitled *Trends in Patented Drug Prices* and *Verification of Foreign Patented Drug Prices*.

Figure 8

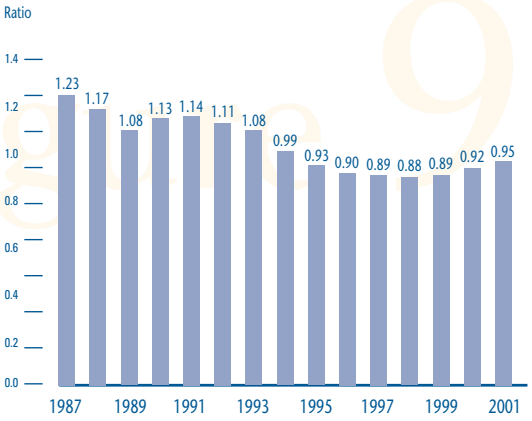
Year-over-Year Changes in Pharmaceutical Price Indices, Canada and the U.S.



Sources: PMPRB and Statistics Canada

Figure 9

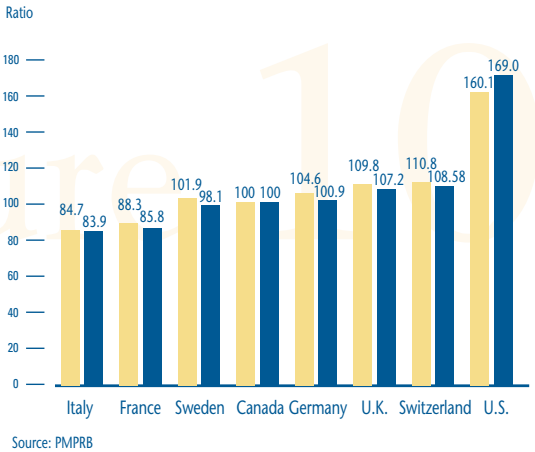
Ratio of Canadian Prices of Patented Drugs to Median International Prices, 1987-2001



Source: PMPRB

Figure 10

Average Foreign to Canadian Price Ratios, Patented Drug Products



Source: PMPRB

Figure 10 shows the relationship between Canadian prices for patented drug products and prices in each of the seven comparator countries. In 1987, Canadian prices were on average below those in the U.S., but above prices in all other countries. By the mid-1990s, the situation had changed dramatically, with Canadian prices now in the mid-range of the six European countries. This situation still existed in 2001: prices of patented drugs in Canada were slightly lower than prices in Germany, the U.K. and Switzerland, but higher than those observed in France, Sweden and Italy. As in previous years, U.S. prices appear to be substantially higher than prices in both Europe and Canada.[17]

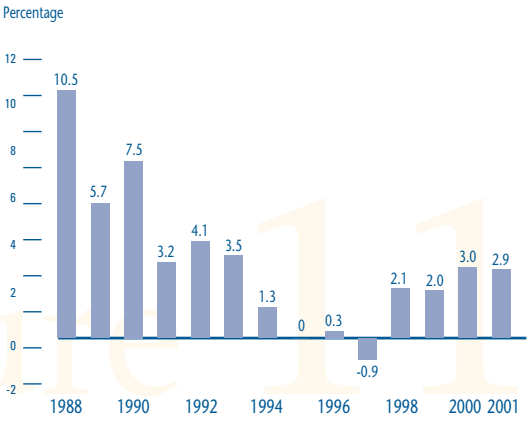
Increased Expenditures on Drugs at the Retail Level

Despite the moderating price growth described above, growth in the total drug expenditures of Canadian consumers has remained high in recent years. According to the latest figures published by the Canadian Institute for Health Information (CIHI), total spending on drugs at the retail level are the fastest growing component of health care costs, reaching 15.2% of total costs in 2001, up from 14.9% in 2000.[18] CIHI forecasts overall drug expenditure to increase by 8.6% between 2000 and 2001.[19]

Consumers often ask why changes in total drug expenditures usually exceed corresponding changes in drug prices.[20] One factor is differences in relevant price concepts. While the PMPRB reports average changes in prices at the manufacturers' level, total drug expenditures reflect changes in the quantity of drugs purchased and prices at the retail level. These prices include wholesale and retail mark-ups, as well as pharmacists' professional fees. Statistics Canada measures changes in retail prices of prescription drugs with the Consumer Price Index for prescribed medicines, CPI (Rx). Figure 11 shows prices of prescription medicines at the retail level have risen in every year since 1997, registering year-over-year growth of 2.9% in 2001.[21]

Figure 11

Year-over-Year Changes in the CPI(Rx) Index, 1988-2001



Source: Statistics Canada

17 The pharmaceutical industry in the U.S. has argued that the publicly available prices in that country do not reflect actual prices because of confidential discounts and rebates. In January 2000 the policy to include the prices listed in the U.S. Federal Supply Schedule (FSS) in calculating the average U.S. price of patented drugs came into effect. Figures 9 and 10 reflect the inclusion of the U.S. FSS prices in 2000 and 2001.

18 See the National Expenditure Trends, 1975-2001, published by the Canadian Institute for Health Information (CIHI) in 2001. Note that the figure cited for 2000 is a revision of CIHI's estimate of 15.5% published in last year's Annual Report.

19 The CIHI forecasts growth of 8.6% in total drug expenditure between 2000 and 2001. This value is based on estimates of drug expenditure at the retail level in earlier years. These estimates have been assembled from several data sources: Statistics Canada's annual Survey of Household Spending (for private out-of-pocket expenditure on prescribed drugs), provincial and federal public accounts (for public drug expenditure), data provided by the Canadian Life and Health Insurance Association (for drug benefits paid by private insurers) and information provided by the market research firm A.C.Nielson (Canada) (for expenditure on over-the-counter drugs). See *Drug Expenditure in Canada, 1985-2001*, April 2002, Canadian Institute for Health Information.

As cited in Figure 2 on page 11, Scrip Magazine has reported IMS Health's estimated 16% annual growth in retail pharmacy sales of drugs in 2001, close to the figure of 15% reported in Table 1 on page 11, for growth in total manufacturers' sales. IMS Health conducts periodic surveys of sales in a sample of pharmacies across Canada. The PMPRB is currently investigating the reasons for the discrepancy between CIHI's estimate of 2001 sales growth, on one hand, and those implied by IMS Health's pharmacy survey data and data reported by patentees to the PMPRB, on the other.

20 In its study, *Analysis of Drug Claim Costs 1997-2001*, Green Shield Canada found that while drug costs for the average claim rose at an average annual compound rate of 7.4%, drug prices decreased on average by 0.2% annually over the same period. These costs encompass patented, non-patented brand name and generic drugs included in the various private plans Green Shield administers.

21 Statistics Canada, CANSIM, Series P200202.

Even after accounting for growth in retail prices, most of the increase in spending on drugs is left to be explained. There are several other factors, mostly related to changes in the volume and composition of drug utilization that may have caused expenditure to rise beyond the moderate changes in drug prices described above. These are outlined in Figure 12.[22] The control of one factor (e.g., drug prices at the factory or retail level) does not necessarily mean control of total expenditure. Even if drug prices were constant, changes in other factors (e.g., volumes of drug products consumed) could easily produce large increases in total drug expenditure. Studies conducted by the PMPRB of provincial drug plans have suggested that increased utilization of existing and new drugs accounts for most of the recent growth in expenditures.[23] (See *Reports on Cost Drivers* on page 25.)

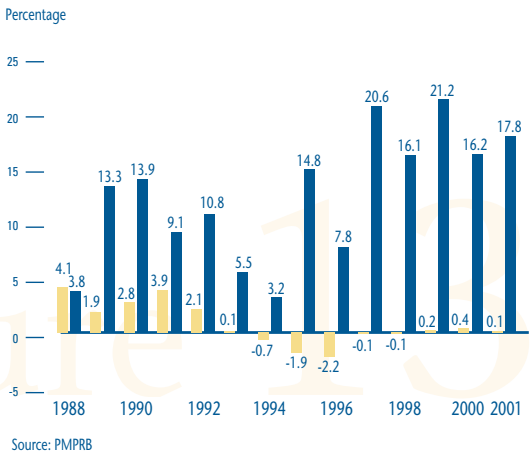
Figure 12

Factors Affecting Total Drug Expenditures

- changes in the total population
- changes in the demographics and health status of the population (i.e., towards those with increased medication needs)
- changes in the unit prices of drugs (both patented and non-patented)
- changes in retail and wholesale mark-ups and professional fees
- changes in the prescribing habits of physicians (i.e., from older, less expensive medications to newer, relatively more expensive medications [± improved therapeutic effect] to treat the same underlying diagnosis)
- changes in utilization of drugs on a per patient basis (i.e., more medications per patient per year)
- trends towards using drug therapy instead of other treatments (e.g., as alternatives to surgery in some cases)
- new diseases to be treated
- old diseases to be treated, where there existed no treatment before; old diseases better treated with new drugs

Figure 13

Year-over-Year Changes in the PMPI and the PMQI, 1988-2001



Source: PMPRB

Trends in Quantities of Sales of Patented Drug Products

Data available to the PMPRB allow it to measure changes in the quantities of patented drugs sold from year to year. To this end, the PMPRB maintains the Patented Medicine Quantity Index (PMQI), a counterpart to the PMPI designed to indicate overall trends in the utilization of patented drugs. Figure 13 displays annual average rates of utilization growth according to the PMQI. This analysis reveals that volumes of patented drugs sold have consistently risen much more quickly than prices. From 1988 to 2001, the average annual increase in quantities of patented drugs sold was approximately 12.4%, compared with an average annual increase of 0.8% in prices. This trend extends through 2001: although prices for patented medicines rose by only 0.1%, the average increase in quantities sold amounted to 17.8% of the previous year's volumes.

It should be noted that the PMQI may not be representative of tendencies in the overall pharmaceutical market, since patented drugs count for about two thirds of total drug expenditures. By construction, the PMQI treats shifts in utilization between patented drugs and non-patented drugs and changes in patent status as volume changes, whereas a broader index would treat these as changes in the composition rather than volume of utilization.

Sales by Major Therapeutic Group (ATC class)

For purposes of price review, the PMPRB classifies all drugs sold in Canada according to the current World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification system.

22 This figure is reproduced from the PMPRB's Discussion Paper, *Examining the Role, Function and Methods of the Patented Medicine Prices Review Board*, November 1997.

23 *Pharmaceutical Trends*, 1995-96 to 1999-00, September 2001.

Table 5 | Manufacturers' Sales of Patented Drugs for Human Use by Major Therapeutic Group, 2001

ATC Main Group	Manufacturers' Patented Sales in 2001	Proportion of Manufacturers' Patented Sales in 2001	Growth in Manufacturers' Patented Sales from 2000		Contribution to Total Expenditure Growth
	($ millions)	(%)	($ millions)	(%)	(%)
A: Alimentary tract and metabolism	1,010.1	13.5	233.2	30.0	19.8
B: Blood and blood forming Organs	372.2	5.0	87.5	30.8	7.4
C: Cardiovascular system	1,957.4	26.1	260.9	15.4	22.2
D: Dermatologicals	70.7	1.0	-18.9	-21.1	-1.6
G: Genito-urinary system and sex hormones	229.9	3.1	35.0	18.0	2.9
H: Systemic hormonal preparations, excluding sex hormones	58.6	0.8	10.7	22.3	0.9
J: General antiinfectives for systemic use; and P: Antiparasitic products[24]	903.9	12.1	97.8	12.1	8.3
L: Antineoplastics and immunomodulating agents	553.1	7.4	111.9	25.3	9.5
M: Musculo-skeletal system	608.6	8.1	106.2	21.1	9.0
N: Nervous system	1,100.0	14.9	143.2	15.0	12.2
R: Respiratory system	508.2	6.8	91.8	22.0	7.8
S: Sensory organs	80.1	1.1	12.1	17.7	1.0
V: Various	30.1	0.4	3.1	11.5	0.3
Totals	**7,492.8**	**100.0***	**1,174.5**	**18.7**	**100.0***

Source: PMPRB

* The percentage may not equal 100 due to rounding.

Table 5 breaks out Canadian expenditures on patented drugs in 2001 according to major therapeutic groups, showing total manufacturers' sales, proportion of total manufacturers' sales and growth in manufacturers' sales by group. (Note that proportions of sales for patented medicines may differ from proportions calculated for all drugs.)

As shown in Table 5, the highest rates of growth in manufacturers' sales of patented drugs occurred in the following three ATC System Main Groups:

- ATC Group B, drug products acting on the Blood and Blood-Forming Organs, such as anti-thrombotic agents and anti-anemic preparations;
- ATC Group A, drug products acting on the Alimentary Tract and Metabolism, such as anti-ulcerants, treatments for diabetes and anti-obesity preparations; and
- ATC Group L, drug products which are used in cancer chemotherapy, immuno-suppressive agents and immunostimulants.

The largest contributions to growth in total patented sales were made by drugs in ATC Group C (such as lipid-reducing agents and drugs treating hypertension), ATC Group A and ATC Group N (such as drugs treating depression). These three classes alone accounted for more than half the increase in manufacturers' patented sales observed between 2001 and the preceding year.

24 For 2000 and 2001, these groups have been combined for reasons of confidentiality.

Reports on Cost Drivers Facing Federal/Provincial/Territorial Drug Plans

In September 2001, the federal/provincial/territorial (F/P/T) ministers of health released a series of reports on the drug price and expenditure trends, price levels and cost drivers facing the six participating provincial drug plans. These studies were conducted by the PMPRB pursuant to a Memorandum of Understanding with the Minister of Health.

Here are the principal findings:

- Total drug expenditures grew, on average, by 11% per year over the three-year period from 1995-96 to 1998-99. The total increase in drug expenditures over the three-year period ranged from 24% in British Columbia to 41% in Alberta. Table 6 shows the changes for each of the six provinces in the study.
- These studies sought to identify the contribution of the following factors to the changes in total expenditures: price changes; changes in volume or quantity of drugs; the introduction of new drugs; the "exit," or removal of drugs from coverage; changes in the patient population covered by the drug plans; and other factors. The studies showed that increased utilization of drugs and the impact of new drugs were the major cost drivers behind total drug cost expenditures. Changes in the prices of existing drugs did not contribute to increased expenditures.
- The introduction and listing of new drugs is a significant cost driver for drug plans. Expenditures on new drugs grew quickly in most provinces with the result that newer drugs accounted for a major portion of total spending. For example, in Ontario, drugs introduced after 1992-93 represented 53% of total drug expenditures in 1998-99.
- Pharmaceutical expenditures were also broken down by the patent status of drugs. Non-patented drugs, which include generic drugs and non-patented brand name drugs, accounted for a different proportion of total expenditures in the different jurisdictions, ranging from 41% in Ontario to 50% in Nova Scotia in 1998-99. In 1998, the PMPRB estimated that non-patented drugs accounted for 45% of total drug sales in Canada.

The reports are available on the PMPRB website under Publications; Study Series; F/P/T studies.

Table 6 | Total Drug Cost Expenditures by Province, 1995-96 to 1998-99

Provinces	Drug Cost 1995-96 ($ millions)	Drug Cost 1998-99 ($ millions)	Total Percent Change	Average Annual Percent Change
British Columbia	$256.0	$318.6	24	8
Alberta	$148.0	$208.3	41	12
Saskatchewan	$104.2	$127.2	22	7
Manitoba	$122.8	$167.1	36	11
Ontario	$944.8	$1,311.3	39	12
Nova Scotia	$56.0	$71.4	28	8

Analysis of Research-and-Development Expenditures

With the adoption of the 1987 amendments to the *Patent Act* (Act), Canada's Research Based Pharmaceutical Companies (Rx&D) made a public commitment that the brand name pharmaceutical industry would increase its annual research-and-development (R&D) expenditures as a percentage of sales to 10% by 1996.

Under the Act, the PMPRB monitors and reports the R&D spending as reported to the Board by patentees, but it has no regulatory authority to influence the type of research or amount of R&D spending by patentees. The Act requires each patentee to report its revenues from the sales of drugs and the expenditures made by the patentee in Canada on R&D relating to medicine. For individual patentees, this calculation includes all revenues from Canadian sales of medicines, including revenues from licensing agreements.

Data Sources

Companies that reported sales of patented medicines in 2001 were also required to file R&D data for that calendar year as per the *Patented Medicines Regulations* (Regulations). Consequently, companies that had no sales of patented medicines in 2001 were not required by the Act to report on R&D expenditures. As new patents are granted and others expire, the group of companies required to file R&D data may change from year to year.

The information reported in this chapter is derived from reports filed with the Board by patentees. Under the Regulations, patentees are required to certify that the information reported is true and correct by an officer of the company. The PMPRB does not audit but attempts to reconcile the information and to seek corrections or clarifications from patentees if it finds any discrepancies. Each patentee is also given the opportunity to confirm the R&D-to-sales ratio calculated by the PMPRB for that company before publication of this report.

For 2001, 74 companies selling human and veterinary drug products filed reports on R&D. Sales of drugs for both human and veterinary use are included for the purpose of this section of the report. Of those 74 companies, 39 were Rx&D members. The data from the 74 reporting firms are the basis of this report.

Revenues from Sales

As shown in Table 7 on page 27, the 74 patentees reported total revenues of $10.7 billion from Canadian sales of patented and non-patented drugs in 2001, up 15.3% over 2000. Patentees are largely brand name companies that sell patented and non-patented drugs. Of total sales revenues, less than 1% was generated by licencing agreements. The total sales revenues reported by the 39 Rx&D members totalled $8.8 billion, accounting for 82.2% of the total sales revenues.

R&D Expenditures

Pursuant to the Regulations, patentees are required to report those R&D expenditures that would have been eligible 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.[25] Market research, sales promotions, quality control or routine testing of materials, devices or products and routine data collection are among the expenditures that are not eligible for an Investment Tax Credit and therefore should not be included in the patentees' filings. Total R&D expenditures include current expenditures, capital equipment costs and allowable depreciation expenses.

As shown in Table 7, the total R&D expenditures reported by all the companies was over $1.0 billion in 2001, an increase of 12.6% over 2000. The expenditures reported by the 39 Rx&D members totalled $935.2 million in 2001, which accounted for 93.5% of the total R&D expenditures for the patented pharmaceutical industry as a whole.

25 The definitions of research and development for purposes of the *Patented Medicines Regulations* are based on definitions under the *Income Tax Act* in 1987 and differ in some respects from definitions used for tax purposes today. The R&D information filed by patentees with the PMPRB is not necessarily consistent with what may ultimately be allowed by the Canada Customs and Revenue Agency for purposes of the *Income Tax Act*.

Table 7 | Total R&D Expenditures* and R&D-to-Sales Ratios of Reporting Companies, 1988-2001

Year	Companies Reporting	Total R&D Expenditures* ($ millions)	Change from Previous Year (%)	Total Sales Revenues** ($ millions)	Change from Previous Year (%)	R&D-to-Sales Ratio	
						All Patentees (%)	Rx&D Patentees*** (%)
2001	74	1,060.1	12.6	10,732.1	15.3	9.9	10.6
2000	79	941.8R	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

* Total expenditures include current expenditures, capital equipment expenditures and allowable depreciation expenses. If the expenditures funded by government are excluded, the ratios for all patentees and for the members of Rx&D decrease to 9.7% and 10.4%, respectively.

** Total sales revenues include sales of patented and non-patented drugs for both human and veterinary use.

*** In the past, Rx&D has reported that its members have achieved a higher R&D-to-sales ratio than reported by the PMPRB. Not all members of Rx&D are required to report to the PMPRB each year as, under the *Patent Act*, only companies with active Canadian patents pertaining to a medicine sold in Canada are required to report on R&D expenditures. For example, some biotechnology companies are engaged in R&D but are not required to report to the PMPRB as they have not made sales of a patented product during this reporting year.

R Revised

R&D-to-Sales Ratios

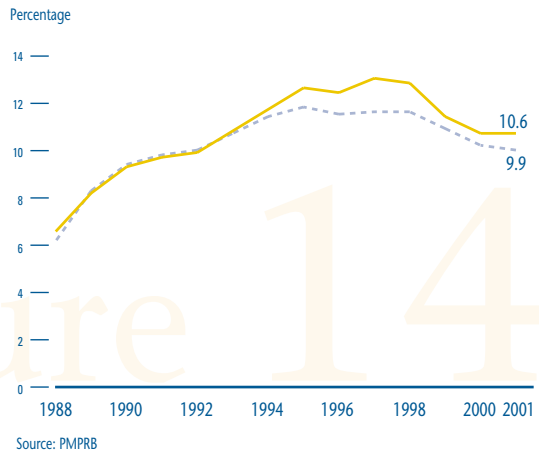
The ratio of R&D expenditures to sales revenues for the patented pharmaceutical industry was 9.9% in 2001, down from 10.1% in 2000 (Table 7). The ratio for the 39 companies that were members of Rx&D was 10.6% in 2001, the same as in 2000. Although the total R&D expenditures increased by 12.6%, the R&D-to-sales ratios declined because sales increased even more, by 15.3%. As a result, the R&D-to-sales ratios for all patentees and Rx&D companies were lower in 2001 than in any year since 1992.

As shown in Figure 14, the R&D-to-sales ratios for all patentees and Rx&D members increased from 1989 to the mid-1990s but have declined in recent years. In 2001, the R&D-to-sales ratios were 9.9% and 10.6% respectively.

THE RATIO OF R&D EXPENDITURES TO SALES REVENUES FOR THE PATENTED PHARMACEUTICAL INDUSTRY WAS 9.9% IN 2001, DOWN FROM 10.1% IN 2000

Figure 14

R&D-to-Sales Ratio, Pharmaceutical Patentees, 1988-2001



Source: PMPRB

Table 9 in Annex 3, on page 46, provides details on the range of R&D-to-sales ratios. Of the 74 reporting companies, 16 companies reported having performed no R&D in 2001. Sales revenues for companies with no R&D totalled $340.8 million in 2001, accounting for 3.2% of total sales revenues for the patented pharmaceutical companies. The 36 companies reporting R&D expenditures with an R&D-to-sales ratio of 10% or less in 2001 accounted for 54.0% of total sales revenues. This group included companies with total sales of $5.8 billion in 2001 compared with $4.9 billion in 2000. The 22 companies with ratios of more than 10% accounted for a smaller proportion of total sales, 42.8%, or $4.6 billion in 2001.

EXPENDITURES ON BASIC RESEARCH INCREASED BY 2.5% IN 2001, BUT ITS SHARE OF TOTAL R&D CONTINUED TO DECLINE FROM 17.8% IN 2000 TO 16.1% IN 2001.

Table 10 in Annex 3, on page 47, lists all reporting patentees and their R&D-to-sales ratios.

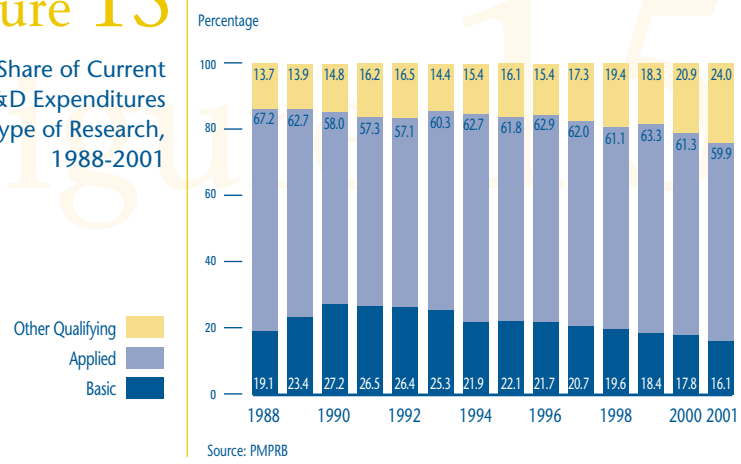
Current Expenditures by Type of Research

Current expenditures accounted for $1.0 billion, or 95.3% of total R&D expenditures. Capital equipment costs and allowable depreciation expenses amounted to 3.4% and 1.3%, respectively. Total current expenditures on R&D rose by 13.1% in 2001.

Table 11 in Annex 3, on page 49, shows how current expenditures on R&D in 2001 were allocated among basic, applied and other qualifying R&D.

Figure 15

Share of Current R&D Expenditures by Type of Research, 1988-2001



Source: PMPRB

Patentees reported spending on basic research of $163.1 million, or 16.1% of the total current R&D expenditures in 2001. Basic research is defined as work that advances scientific knowledge without a specific application in view. Expenditures on basic research increased by 2.5% in 2001, but its share of total R&D continued to decline from 17.8% in 2000 to 16.1% in 2001. As shown in Figure 15, this is the lowest proportion of total R&D spending on basic research ever reported by patentees since the Board began reporting such information in 1988.

The lion's share of R&D spending continued to be on applied research, $604.8 million, or 59.9% of the total. Applied research is directed towards some practical application, comprising the manufacturing process, pre-clinical trials and clinical trials. Clinical trials totalled $445.8 million in 2001 and accounted for 73.7% of total applied research expenditures, and 44.1% of the total current R&D expenditures. Manufacturing process accounted for $79.5 million, or 7.9% of the total current R&D expenditures, and pre-clinical trials accounted for $79.5 million, or 7.9% of the total current R&D expenditures. Other qualifying research, which accounted for 24.0% of total expenditures in 2001, includes drug regulation submissions, bioavailability studies and Phase IV clinical trials.

Figure 16 in Annex 3, on page 46, shows current expenditures on R&D by type of research from 1988 to 2001.

Current Expenditures by R&D Performer and by Source of Funds

Pharmaceutical patentees report their expenditures on research they conduct themselves (intramural) and research performed by others, including universities and hospitals and other manufacturers (extramural). Table 12 in Annex 3, on page 49, shows that most R&D was carried out by patentees. In 2001, 54.0% of R&D expenditures was directed to R&D performed by patentees, compared with 58.1% in 2000. Expenditures on R&D performed by other companies on behalf of patentees incurred the largest increase with

43.4%, from $158.6 million in 2000 to $227.5 million in 2001. Expenditures on R&D performed by universities and hospitals increased by 10.4% to $159.6 million from 2000. The category "others" includes individuals, organizations such as private clinics, and federal and provincial governments. This category increased by 10.0% in 2001.

In 2001, as in previous years, most of the R&D expenditures of pharmaceutical patentees were funded internally. In 2001, more than 96% of all patentees' R&D was funded by internal funds and funds provided by associated companies. Refer to Table 13 in Annex 3, on page 50, for more details.

Current R&D Expenditures by Location

In 2001, R&D spending increased in all parts of Canada. There was no significant change in the regional distribution of R&D spending in 2001. Almost 85% of total expenditures continued to be made in Ontario and Québec. Tables 14 and 15 in Annex 3, on pages 50 and 51, show the current R&D expenditures as reported by province and by R&D performer for 2001.

Policy and Research Initiatives

Research Agenda

In our 1998 *Road Map for the Next Decade*, we committed to publishing the Research Agenda as part of our annual planning process. Among other things, the Research Agenda identifies initiatives that are currently, or may become, subject to public consultations. It also outlines current or upcoming projects which we are working on or will be undertaking.

In 2001, the information gathered and feedback we received through the update of our Environmental Scan was influential in our annual planning process. These consultations helped us to establish key priorities for the Research Agenda 2002-2005 published in our January 2002 NEWSletter.

Our Research Agenda is available on our website at **www.pmprb-cepmb.gc.ca** under Publications.

Transparency of the Price Review Process

During the *Road Map for the Next Decade* consultations, many stakeholders suggested that the price review process (i.e., the process by which Board Staff review prices for purposes of applying the Guidelines) be more open and transparent. Some sought greater opportunities to provide input during the process; many saw a benefit to practitioners and patients providing more information on the therapeutic and cost considerations involved in the review.

In the *Road Map*, the Board noted stakeholders' concerns regarding the transparency and the timeliness of the price review of new patented medicines. The Board set out its commitment to:

- make the price review process more open and transparent to all stakeholders;
- improve the efficiency and timeliness of the process; and
- maintain a high level of quality in the assessments made by Board Staff.

This issue was referred to the Working Group on Price Review Issues (Working Group) for consideration. The Working Group was tasked with looking at the price review process for new patented drug products and considered all the relevant issues in evaluating and proposing options for improving the transparency of the process.

In December 2000, the Working Group submitted its report on the price review process for new patented medicines to the Board. At its meeting in March 2001, the Board considered the report in detail and reached a decision for further action. The Working Group's report is available from the PMPRB website.

Overall, the Board agreed with the Working Group's recommendations and following a Notice and Comment, the Board made the following decisions regarding transparency in the price review process.

- To publish summary reports on the results of the reviews by Board Staff for purposes of applying the Guidelines:
  - for all new active substances introduced after January 1, 2002; and
  - for those drug products introduced after January 1, 2001 that were categorized as "breakthroughs" or "substantial improvements".
- To incorporate the Board's commitment to the principle of transparency of the price review process, within the context appropriate for this administrative tribunal, within the *Compendium of Guidelines, Policies and Procedures*.
- To instruct Board Staff to develop options for aggregate reports on new patented medicines.

For 2001, two medicines, Prevnar and Cerezyme, were categorized as "breakthroughs" or as "substantial improvements". The summary reports for these medicines were published in the January and April 2002 editions of the NEWSletter and are available on the PMPRB website under Publications; Patented Medicines.

Working Group on Price Review Issues

The PMPRB's Working Group on Price Review Issues (Working Group) is a 12-member consultative group representing our key stakeholders, provincial and territorial ministers of health, consumer, advocacy and senior groups, health associations and the pharmaceutical industry. The Working Group was established in 1999 to review, analyze and provide reports to the Board for consideration on three matters: 1) use of U.S. Federal Supply Schedule (FSS) prices in international price comparisons; 2) transparency in the price review process; and 3) excessive Price Guidelines for drugs in category 3.

The implementation of the recommendations of the Working Group on the first issue, use of the FSS, and its report on the transparency of the price review process were reported in the PMPRB's Annual Report for 2000. More detailed information on the implementation of the transparency initiative is available on page 31 of this Report.

In January 2001, the Working Group turned its attention to the review of the Board's Guidelines for drugs in category 3. These drugs include medicines that are not breakthrough or substantial improvements over existing therapies and historically have represented the lion's share of new drugs. Thirty-eight issues were identified by the Working Group members, which they consolidated and grouped into four components:

- Therapeutic Class Comparison (TCC) validation;
- Components of a TCC;
- Other factors (e.g. Pharmacoeconomics, Investment, Research and Development, etc); and
- Price test and value concepts.

The Working Group agreed that their review of the Guidelines for drugs in category 3 would be reported on in two separate documents. The first report would address the first three components identified above and was submitted to the Board in May 2002. The second report will address the fourth issue and is expected to be submitted to the Board for consideration in the fall of 2002.

Federal/Provincial/Territorial Collaboration — National Prescription Drug Utilization Information System

The role of pharmaceuticals as a component of the health care system is expanding, and federal, provincial and territorial (F/P/T) governments are increasingly facing a number of pharmaceutical issues, including drug costs, utilization and efficiency of resource allocation. During the year, the PMPRB continued its long-standing participation, at the request of the Minister of Health, as an observer on the F/P/T Pharmaceutical Issues Committee (PIC).[26]

In 2001, the PMPRB continued to carry out analyses of price and expenditure trends and cost drivers of publicly-funded drug plans under a Memorandum of Understanding (MOU) with the Minister of Health. (See *Reports on Cost Drivers* on page 25.)

In their Action Plan for Health System Renewal in September 2000, Canada's First Ministers agreed to improve cost-effectiveness, develop options for a common inter-jurisdictional drug review process, and examine best practices. In addition, the federal government committed to strengthen post-approval surveillance. To assist in these objectives, F/P/T governments require accurate and timely national information and analysis on individual prescription drug use and drug costs. While comparable national information on the use and costs of other areas of health care (e.g. hospitals and physician services) exists, there is currently no national source of standardized comparative information on prescription drug utilization.

In September 2001, F/P/T ministers of health announced a multi-faceted approach to better pharmaceuticals management including, among other things, the establishment of a National Prescription Drug Utilization Information System (NPDUIS). The NPDUIS is to "provide critical analyses of price, utilization and cost trends; so that Canada's health system has more comprehensive, accurate information on how prescription drugs are being used, and sources of cost increases. In addition, doctors and pharmacists would have better information from which to provide care to patients."[27]

The NPDUIS is being established as a partnership between the Canadian Institute for Health Information (CIHI) and the PMPRB. For the PMPRB, the NPDUIS represents a natural evolution of the work that was previously conducted under the MOU between the Minister of Health and the PMPRB.

The PMPRB's expected work under the NPDUIS, including reports on trends in drug prices and utilization, is included in our Research Agenda. More information on the NPDUIS will be reported in future issues of the NEWSletter.

26 PIC is responsible for joint F/P/T activities on pharmaceutical issues. PIC is made up of government officials from each province and territory as well as representatives from Health Canada and other federal departments and agencies. PIC reports to the Advisory Committee on Health Services, which reports to the Conference of Deputy Ministers of Health.

27 News Release, Conference of federal/provincial/territorial ministers of health, St. John's, Newfoundland, September 26, 2001.

Environmental Scan and Performance Evaluation

During the year, we undertook an update of our Environmental Scan and evaluation of the effectiveness of our Consultation and Communications policies. BDO Dunwoody & Associates Ltd. (BDO) assisted us in this project and conducted over 20 interviews with major stakeholders. The main results are summarized as follows:

Environmental Scan

The objective of the environmental scan was to identify the major issues facing the pharmaceutical sector over the next three to five years. A number of issues and concerns were identified; however, the following four were the most prevalent and are listed in the order of importance based on the frequency of responses.

1. **Increasing prices of drugs in Canada**
   The majority of stakeholders, other than the pharmaceutical industry, feel that the issue of increasing prices of drugs will be a continuous concern. They indicated that the rising price of drugs is increasing the overall cost of health care for Canadians. This increased health care cost impacts the availability of medications and treatments to those who really require it, especially with our aging population.

2. **Balancing drug prices and research and development spending**
   A major issue that the stakeholders felt existed is the need to balance price regulation of drugs and the need for research and development of new drugs and treatments in Canada.

3. **New technology associated with medication (genetics, biotechnology etc.)**
   The emergence of new gene therapy and biotechnological drugs will have an impact on the price review process. The concern is that the new costs for the research and development of these drugs and treatments will not be adequately considered when using the current price review structure.

4. **Transparency of the PMPRB pricing review process**
   Several of the stakeholder groups indicated that they felt the PMPRB needs to be more transparent during and after the price review process in order to increase consumers' confidence in the process.

Review of Consultation and Communications Policies

The second component of the questionnaire was focused on obtaining feedback and recommendations on our efforts to consult and communicate with our various stakeholders. Some common themes emerged from the interviews of stakeholders.

The brand name industry representatives felt that they have not been well consulted and are not adequately consulted or represented on the Working Group on Price Review Issues. Conversely, most of the other stakeholders felt that the consultations are appropriate and that there is a good diversity of members on the Working Group. The majority of our stakeholders interviewed suggested that we hold more public meetings and increase the number of face-to-face meetings with the various individual stakeholders. It was also suggested that we involve more, and smaller, organizations in our consultations.

In general, the interviewees considered that communications have improved over the past few years. They found our website, NEWSletter and annual reports very useful, but felt there is still room for some improvement.

We wish to thank those who have accepted our invitation to participate. Their input will help us in identifying the major trends and issues that may impact the PMPRB over the next few years. In addition, it will assist us in evaluating the effectiveness of our Consultation and Communications policies.

The BDO report is available on our website at **www.pmprb-cepmb.gc.ca** under Publications; Environmental Scan.

Communications

Our Communications Program is aimed at cultivating an understanding and awareness of our role, jurisdiction, and regulatory and reporting functions. We work to provide our stakeholders with timely, accurate and factual information through a variety of channels. More importantly, we strive to ensure open lines of communications with our stakeholders through diverse consultation and feedback mechanisms.

We adhere to guiding principles that contribute to the effectiveness and consistency of our communications activities. Some of these principles include:

- assuring timely response to stakeholder and public inquiries;
- facilitating two-way communications by providing ample opportunities for feedback and participation in all communications activities; and
- maintaining a consistent corporate approach to ensure that stakeholders and the public can easily identify our publications.

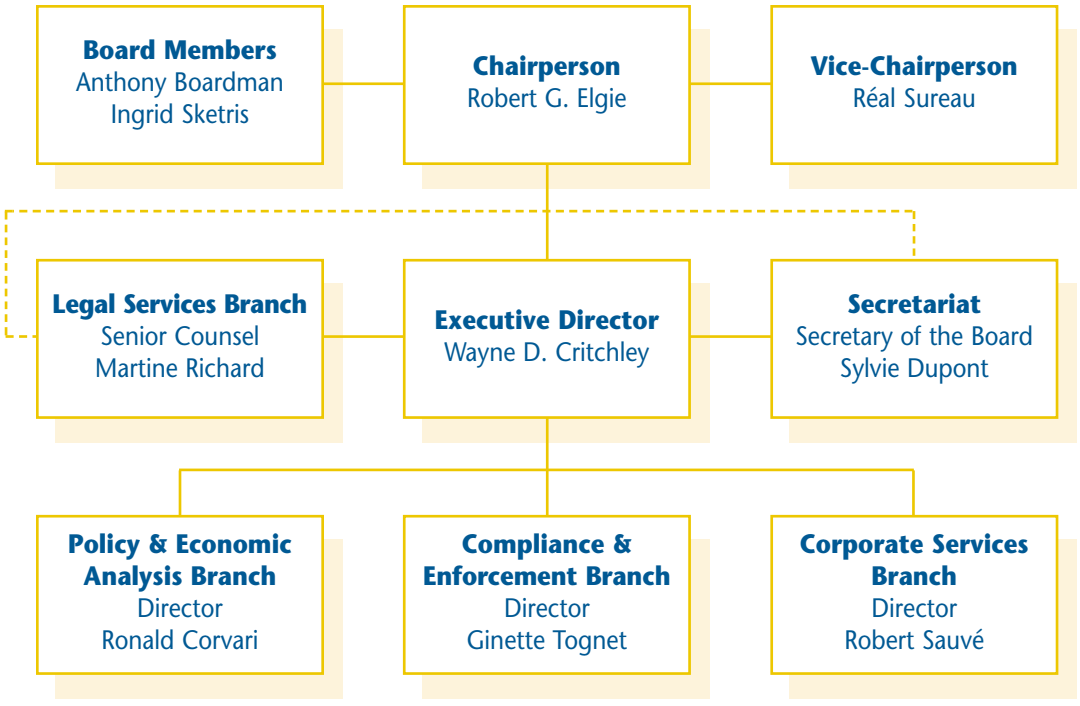
To better gauge the effectiveness of our communications program, last summer we conducted an evaluation of our consultation and communications policies through a survey of our main stakeholder groups. As a result, we have enhanced a number of our main communications activities to respond to the issues raised by stakeholders. These include widening the range of information available in print and on our website and creating an on-line feedback form to increase accessibility.

As the PMRPB enters its 15th year of operation, the main objectives will be to continue to be transparent and open in all our communications and to strive to engage stakeholders through a variety of information dissemination, feedback and participatory mechanisms.

Governance

The Board consists of not more than five members who serve on a part-time basis, appointed by the Governor-in-Council, including a Chairperson and Vice-Chairperson. 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. The Executive Director manages the work of the Staff. Senior Staff consists of the Executive Director, the Director of Compliance and Enforcement, the Director of Policy and Economic Analysis, the Director of Corporate Services, the Secretary of the Board and Senior Counsel.

Organization Structure of the PMPRB



Members' Biographies

Chairperson: Robert G. Elgie

LL.B., M.D., F.R.C.S. (C), LL.D. (hon.)

Dr. Elgie, a lawyer and neurosurgeon, Fellow of the Royal College of Surgeons (Neurosurgery), was the founder and first Director of Dalhousie University's Health Law Institute from 1991 to 1996. He was also the part-time Chair of the Workers' Compensation Board of Nova Scotia from 1992 to 1996. Dr. Elgie has taught at the Medical Schools of Queen's University and the University of Toronto, and has held several positions with the Scarborough General Hospital, including Chief of Medical Staff. In 1977, he was elected to the Ontario Legislative Assembly and subsequently served in several Cabinet positions. He resigned from the Ontario Legislature in September 1985 to become Chair of the Workers' Compensation Board of Ontario, where he served until 1991. In October 2000, Dr. Elgie was appointed to the Ontario Press Council. In May 2001, Dr. Elgie was awarded an honorary degree by Dalhousie University: Doctor of Laws, honoris causa, in recognition of his outstanding personal achievements. Dr. Elgie was appointed Member and Chairperson of the Board in March 1995 and re-appointed in March 2000.

Vice-Chairperson: Réal Sureau FCA

Mr. Sureau, a chartered accountant, is President of Sureau Management Limited. From January 1997 to February 2000, he was Director of Business Development of the Montréal Baseball Club. From June 1995 to June 1996, he was President of the Order of Chartered Accountants of Québec. Through the years, Mr. Sureau was a member of several committees of the Order, including the Disciplinary Committee, the Professional Practice Committee, the Professional Development Committee and the Committee on Government Finances. He was Vice-President, Finance, at Forex and Canam-Manac. Mr. Sureau sits on the board of directors of many organizations, including Gaz Métropolitain and the Institut de réadaptation de Montréal. Mr. Sureau was appointed Member and Vice-Chairperson of the Board in October 1995 and re-appointed in October 2000.

Left to right:
Robert Elgie, Chairperson
Ingrid Sketris
Réal Sureau, Vice-Chairperson
Anthony Boardman

Members:

Anthony Boardman B.A., Ph.D.

Dr. Boardman is the Van Dusen Professor of Business Administration in the Strategy and Business Economics Division, Faculty of Commerce and Business Administration at the University of British Columbia (UBC). He graduated from the University of Kent at Canterbury, England, (B.A., 1970) and Carnegie-Mellon University (Ph.D., 1975). Prior to taking up his position at UBC he was a professor at the Wharton School, University of Pennsylvania. Dr. Boardman's current research interests include privatization, cost-benefit analysis and strategic management. During his career, he has published many articles in leading academic journals. Recently, he completed the second edition of *Cost-Benefit Analysis: Concepts and Practice*. Dr. Boardman has been a consultant to many private and public organizations, including Vodafone, Stora Enzo, Pricewaterhouse Coopers, the Treasury of New Zealand and all levels of government in Canada. He is also an excellent teacher and has taught executive programmes in Finland, China, Australia and elsewhere. As a member of the MBA Core Team at UBC, he recently won the Alan Blizzard award. Between 1995 and 2001, Dr. Boardman was a member of the Pharmacoeconomic Initiative Scientific Committee which made recommendations to B.C. Pharmacare on the cost-effectiveness of new drugs. Dr. Boardman was appointed Member of the Board in January 1999.

Ingrid S. Sketris

BSc(Phm), Pharm.D., MPA(HSA)

Dr. Sketris is a Professor at the College of Pharmacy and School of Health Services Administration and an Associate Professor of the Department of Community Health and Epidemiology, Dalhousie University. She is a consultant to the pharmacy department of the Queen Elizabeth II Health Sciences Centre, Halifax. Since 2000, Dr. Sketris holds a Chair in health services and nursing from the Canadian Health Services Research Foundation/ Canadian Institutes of Health Research (Cosponsored by the Nova Scotia Health Research Foundation). She is a graduate of the University of Toronto (BSc(Phm), 1977), University of Minnesota (Pharm.D,1979), University of Tennessee Center for the Health Sciences (Residency in Clinical Toxicology/Pharmacy Practice, 1980) and Dalhousie University (MPA(HSA) 1989). She is a fellow of the Canadian Society of Hospital Pharmacists and the American College of Clinical Pharmacy.

Dr. Sketris is currently on the Editorial Boards of the Canadian Journal of Clinical Pharmacology, Clinical Therapeutics, and Drugs and Therapeutics for Maritime Practitioners. She was a member of the scientific advisory panel of the Canadian Coordinating Office for Health Technology Assessment from 1996-1998. Dr. Sketris' research interests include examining the impact of changes in Pharmacare policy and the use of drugs and health services particularly related to the population of Nova Scotia. She has numerous publications in the area of transplantation therapeutics and pharmacoepidemiology. Dr. Sketris was appointed Member of the Board in May 1999.

Budget

Table 8 | Financial Performance

	Actual Spending 2000-2001 ($ thousands)	Forecast Spending 2001-2002 ($ thousands)
Total PMPRB	3,997.6	4,199.0
Full Time Equivalents	38.0	38.0

The PMPRB operated with a budget of $4,199,000 in 2001-2002 and a staff of 38 employees.

It should be noted that for the last two and one-half years, the PMPRB's operating budget has included additional funding of approximately $550,000 per year for the PMPRB under a Memorandum of Understanding (MOU) with the Minister of Health to provide analyses of public drug plan spending. The MOU expired on March 31, 2002. In September 2001, federal/provincial/territorial ministers of health announced their decision to establish the National Prescription Drug Utilization Information System (NPDUIS) to continue and expand on the work done under the MOU. The NPDUIS is established through a partnership arrangement between the PMPRB and the Canadian Institute for Health Information. The Business Case approved by F/P/T Ministers provides for an annual budget of close to $1.0 million for the PMPRB's contribution to the NPDUIS. More information on the NPDUIS is available on page 33.

For additional information on the PMPRB budget, please visit our website at **www.pmprb-cepmb.gc.ca** under Publications; Reports to Parliament.

Publications

We seek to inform our stakeholders regularly through our publications. Some of these publications, such as the Annual Report and the NEWSletter, are published at regular intervals throughout the year while others are released in response to program and corporate requirements.

Publications	Release Date
Annual Report	Yearly-June
Articles	
– *Peer-Reviewed Studies in the PMPRB Price Review Process*	October
– *Patent Pertaining — What is a company to do?*	October
– *Filing Requirements — A Reminder*	April 2002
CPI-Adjustment Factors	Yearly-April
Environmental Scan and Performance Evaluation of the Consultation and Communications Policies	October
NEWSletter	Quarterly
Patented Medicines	
– Reported to the PMPRB in 2001 (including the review status for each drug)	Monthly
– Reports on New Patented Drugs:	
1. Prevnar	January 2002
2. Cerezyme	April 2002
Notice and Comment	
– *Transparency in the Price Review Process*	April
Research Agenda	Yearly-January
Speech Series	
– *Enhancing Transparency in Drug Price Regulation*	March
– *A Delicate Balance: Can Government Promote R&D and Control Drug Costs at the Same Time?*	December
– *Drug Patents and Drug Prices: The Role of the PMPRB*	March 2002
Study Series	
– S-0215 — *Verification of Foreign Patented Drug Prices*	January 2002
Summary of Board Meetings	Quarterly
Voluntary Compliance Undertaking	
– Zanaflex	October

The analyses conducted by the PMPRB under the Memorandum of Understanding with the Minister of Health on price and expenditure trends, price levels and cost drivers of publicly funded drug plans are also available.

To obtain our publications, please call us at 1 877 861-2350 or (613) 952-7360, or access them on our website at **www.pmprb-cepmb.gc.ca**.

Glossary

Note To Reader: 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 Guidelines, Policies 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. (Ingrédient actif)

Advance Ruling Certificate (ARC): A non-binding certificate may be issued pursuant to subsection 98(4) of the *Patent Act* at the request of a patentee when the Board is satisfied that the price or proposed price of the medicine would not exceed the maximum non-excessive price under the Board's Guidelines. (Certificat de décision au préalable)

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. (ATC)

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. (Cession d'un brevet)

NB: As of January 30, 1995, the Board does not recognize dedication of patent as a means to remove the medicine from its jurisdiction. (See PMPRB Bulletin 17, page 3.)

Drug Identification Number (DIN): A registration number that the Health Protection 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. (Numéro d'identification de drogue)

Drug Product: A particular presentation of a medicine characterized by its pharmaceutical dosage form and the strength of the active ingredient(s). (Produit médicamenteux)

Drug Product, Existing: An existing drug product is a DIN for which a benchmark price has been established in accordance with the Board's Guidelines. (See Chapter 1, subsection 3.3 of the *Compendium of Guidelines, Policies and Procedures*.) (Produit médicamenteux existant)

Drug Product, New: A new drug product is one for which the introductory price is under review. Patented drug products are considered new in the year during which they are first introduced on the market in Canada or the year they receive their first patent(s) if previously marketed. For price review purposes, new drug products for a given year are those introduced between December 1, of the previous year and November 30, of the reporting year. Because of the filing requirements under the *Patented Medicines Regulations* and the manner of calculating benchmark prices, drug products introduced in December are considered to have been introduced in the following year. (See Chapter 1, subsection 3.2 of the *Compendium of Guidelines, Policies and Procedures*.) (Produit médicamenteux nouveau)

Emergency Drug Release (EDR) Program: See Special Access Program.

Generic Product: A drug product with the same active ingredient, strength and dosage form of a brand name drug product. (Produit générique)

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. (Drogue de recherche)

Licence, Compulsory: A licence granted by the Commissioner of Patents in accordance with subsection 39(4) of the *Patent Act* that has been continued pursuant to subsection 11(1) of the *Patent Act Amendment Act*, 1992 which permits the licencee to import, make, use or sell a patented invention pertaining to a medicine. Royalties payable are determined by the Commissioner of Patents who sets the terms of licences pursuant to subsection 39(5) of the *Patent Act*. Except for those compulsory licences issued prior to December 20, 1991, which are continued pursuant to subsection 11(1) of the *Patent Act*, licences issued after December 20, 1991 have no effect. (Licence obligatoire)

Licence, Voluntary: A contractual agreement between a patent holder and a licencee under which the licencee 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 licencee's sales.) (Licence volontaire)

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*. (See *Compendium of Guidelines, Policies and Procedures*, Introduction, subsection 1.5.) (Médicament)

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 Drug Regulations*. The issuance of an NOC indicates that a drug product meets the required Health Canada standards for use in humans or animals and that the product is approved for sale in Canada. (Avis de conformité)

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. (Brevet)

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 (pertaining to a medicine) and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a licence continued by subsection 11(1) of the *Patent Act Amendment Act*, 1992, that other person in respect of those rights;" (Breveté)

Pending Patent: An application for a patent that has not yet been issued. (Brevet en instance)

NB: In cases where a medicine is sold before a patent is issued, it is the Board's policy once the patent is issued, to review the price of the medicine as of the date on which the patent application was laid open for public inspection. (See PMPRB Bulletin 15, page 7.)

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). (Recherche et développement)

Research and Development — Applied Research: Work that advances scientific knowledge with a specific practical application in view such as creating new or improved products or processes through manufacturing processes or through preclinical or clinical studies. (Recherche et développement — recherche appliquée)

Research and Development — Basic Research: Work that advances scientific knowledge without a specific application in view. (Recherche et développement — recherche fondamentale)

Research and Development — Clinical Research: The assessment of the effect of a new medicine on humans. It typically consists of three successive phases, beginning with limited testing for safety in healthy humans then proceeding to further safety and efficacy studies in patients suffering from the target disease. (Recherche et développement — recherche clinique)

Research and Development — Preclinical Research: Tests on animals to evaluate the pharmacological and toxicological effects of medicines. (Recherche et développement — recherche pré-clinique)

Research and Development Expenditures: For the purposes of the *Patented Medicines Regulations*, 1994, 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. (Dépenses en recherche et développement)

Special Access Program (SAP): A program operated by Health Canada to give practitioners access to drugs that are not approved or otherwise available for sale in Canada. (Formerly the EDR Program.) (Programme d'accès spécial)

Voluntary Compliance Undertaking (VCU): A written undertaking by a patentee to adjust its price to conform with the PMPRB's Excessive Price Guidelines (see Chapter 1 of the *Compendium of Guidelines, Policies and Procedures*). Pursuant to the Board's Compliance and Enforcement Policy (see Chapter 2, section 7), the Chairperson or the Board may approve a VCU in lieu of issuing a Notice of Hearing if it is consistent with the *Patent Act* and the policies of the Board and in the public interest. The Board reports publicly on all VCUs approved by the Chairperson or the Board. (Engagement de conformité volontaire)

Annexes

Annex 1
Criteria for Commencing an Investigation

A price is considered to be within the Guidelines unless it meets the criteria for commencing an investigation. The criteria represent the standards the Board applies in order to allocate its resources to investigations as efficiently as possible. Their existence should not be construed as indicating that the Board accepts any deviation from the Guidelines. The Board is satisfied that its criteria assure all significant cases of pricing outside the Guidelines will be subject to investigation. In most instances where a price exceeds the maximum allowable price by an amount too small to trigger an investigation in one year, it is offset by a price below that which is permitted by the Guidelines the following year. 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.

Criteria 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
- Complaints 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
- Complaints with significant evidence.

For more information on the Criteria for Commencing an Investigation, please consult Schedule 5 of the *Compendium of Guidelines, Policies and Procedures* available on our website at **www.pmprb-cepmb.gc.ca**, under Legislation, Regulations, Guidelines.

Annex 2
Patented Drug Products Introduced in 2001

Brand Name	Company	DIN	NAS[1]/FPG[2]	ATC[3]	Status	Category
Allegra 120 mg/tab	Aventis Pharma Inc.	02242819		R	Within Guidelines	1
Androderm 12.2 mg/patch	Paladin Labs Inc.	02239653		G	Within Guidelines	3
Atacand Plus 16/12.5	AstraZeneca Canada Inc.	02244021		C	Within Guidelines	3
Atridox 44 mg/dose	GlaxoSmithKline Consumer Healthcare	02242473			Under Review	
Baycol 0.8 mg/tab	Bayer Inc.	02243223		C	Within Guidelines	1
Cerezyme 200 units/vial	Genzyme Canada Inc.	02230694	NAS/FPG	A	Within Guidelines	2
Cerezyme 400 units/vial	Genzyme Canada Inc.	02241751	NAS/FPG	A	Within Guidelines	2
Children's Motrin 50 mg/tab	McNeil Consumer Healthcare	02243178		M	Under Review	
Children's Motrin 100 mg/tab	McNeil Consumer Healthcare	02243179		M	Under Review	
Claritin Kids 1 mg/mL	Schering Canada Inc.	02241523		R	Within Guidelines	1
Comtan 200 mg/tab	Novartis Pharma Canada Inc.	02243763	NAS	N	Within Guidelines	3
Coversyl 2 mg/tab	Servier Canada Inc.	02123274	NAS/FPG	C	Within Guidelines	3
Coversyl 4 mg/tab	Servier Canada Inc.	02123282	NAS/FPG	C	Within Guidelines	3
Definity 150 FL/mL	Bristol-Myers Squibb Pharmaceutical Group	02243173	NAS	V	Under Review	
Depocyt 10 mg/mL	Paladin Labs Inc.	02241150		L	Under Review	
Differin 1 mg/mL	Galderma Canada	02148757		D	Under Review	
Ditropan XL 5 mg/tab	Janssen-Ortho Inc.	02243960		G	Under Review	
Ditropan XL 10 mg/tab	Janssen-Ortho Inc.	02243961		G	Under Review	
Eprex 6000 units/syr	Janssen-Ortho Inc.	02243401		B	Within Guidelines	1
Eprex 8000 units/syr	Janssen-Ortho Inc.	02243403		B	Within Guidelines	1
Estalis-Sequi 140/50	Novartis Pharma Canada Inc.	02243529		G	Within Guidelines	1
Estalis-Sequi 250/50	Novartis Pharma Canada Inc.	02243530		G	Within Guidelines	1
Estradot 37.5 0.585 mg/patch	Novartis Pharma Canada Inc.	02243999		G	Within Guidelines	1
Estradot 50 0.78 mg/patch	Novartis Pharma Canada Inc.	02244000		G	Within Guidelines	1
Estradot 75 1.17 mg/patch	Novartis Pharma Canada Inc.	02244001		G	Within Guidelines	1
Estradot 100 1.56 mg/patch	Novartis Pharma Canada Inc.	02244002		G	Within Guidelines	1
Fucithalmic 10 mg/g (unit dose dropper)	Leo Pharma Inc.	02243861		S	Under Review	
Fucithalmic 10 mg/g (multi dose tube)	Leo Pharma Inc.	02243862		S	Under Review	
Hydromorph Contin 18 mg/cap	Purdue Pharma	02243562		N	Within Guidelines	1
Kaletra 133.3/33.3	Abbott Laboratories Limited	02243643	NAS	J	Under Review	
Kaletra 80/20	Abbott Laboratories Limited	02243644	NAS	J	Under Review	
Lamictal 2 mg/tab	GlaxoSmithKline Inc.	02243803		N	Under Review	
Losec Mups 10 mg/tab	AstraZeneca Canada Inc.	02242461		A	Within Guidelines	1
Losec Mups 20 mg/tab	AstraZeneca Canada Inc.	02242462		A	Within Guidelines	1
Lipitor 80 mg/tab	Pfizer Canada Inc.	02243097		C	Within Guidelines	1
Malarone 250/100	GlaxoSmithKline Inc.	02238151	FPG	P	Under Review	
Melacine 1.25 mL	Schering Canada Inc.	02241211	NAS	L	Within Guidelines	3
Meridia 10 mg/cap	Knoll Pharma Inc.	02243163	NAS	A	Under Review	
Meridia 15 mg/cap	Knoll Pharma Inc.	02243164	NAS	A	Under Review	
Micardis Plus 80/12.5	Distributed by GlaxoSmithKline Inc.	02244344		C	Under Review	
Mirena 52 mg/pouch	Berlex Canada Inc.	02243005		G	Within Guidelines	3
Nexium 20 mg/tab	AstraZeneca Canada Inc.	02244521	NAS	A	Within Guidelines	3
Nexium 40 mg/tab	AstraZeneca Canada Inc.	02244522	NAS	A	Within Guidelines	3
One Alpha 0.002 mg/mL (oral drops)	Leo Pharma Inc.	02240329		A	Within Guidelines	1

Annex 2 continued

Brand Name	Company	DIN	NAS[1]/FPG[2]	ATC[3]	Status	Category
One Alpha 0.002 mg/mL (injection)	Leo Pharma Inc.	02242502		A	Under Review	
Peg-Intron 74 Fgm/vial	Schering Canada Inc.	02242966	NAS	L	Under Review	
Peg-Intron 118.4 Fgm/vial	Schering Canada Inc.	02242967	NAS	L	Under Review	
Peg-Intron 177.6 Fgm/vial	Schering Canada Inc.	02242968	NAS	L	Under Review	
Peg-Intron 222 Fgm/vial	Schering Canada Inc.	02242969	NAS	L	Under Review	
Pepcid Complete 10/800/165	Johnson & Johnson Merck	02243053		A	Within Guidelines	3
Prevnar 0.5 mL/vial	Wyeth-Ayerst Canada Inc.	02244081	NAS	J	Within Guidelines	2
Protopic 1 mg/g	Fujisawa Canada, Inc.	02244148		L	Under Review	
Protopic 0.3 mg/g	Fujisawa Canada, Inc.	02244149		L	Under Review	
Rapamune 1 mg/mL	Wyeth-Ayerst Canada Inc.	02243237	NAS/FPG	L	Within Guidelines	3
Remicade 100 mg/vial	Schering Canada Inc.	02244016	NAS	L	Under Review	
Reminyl 4 mg/tab	Janssen-Ortho Inc.	02244298	NAS	N	Within Guidelines	3
Reminyl 8 mg/tab	Janssen-Ortho Inc.	02244299	NAS	N	Within Guidelines	3
Reminyl 12 mg/tab	Janssen-Ortho Inc.	02244300	NAS	N	Within Guidelines	3
Renagel 400 mg/tab	Genzyme Canada Inc.	02244309		V	Under Review	
Renagel 800 mg/tab	Genzyme Canada Inc.	02244310		V	Under Review	
Rescriptor 100 mg/tab	Agouron Pharmaceuticals Canada Inc.	02238348	NAS/FPG	J	Within Guidelines	3
Retin-A Micro 1 mg/g	Ortho Derm., Div. of Johnson & Johnson Inc.	02243914		D	Under Review	
Rosasol 10 mg/g	Stiefel Canada Inc.	02242919		D	Within Guidelines	1
Sensodyne-F 5%/0.24%	GlaxoSmithKline Consumer Healthcare	02243131		A	Within Guidelines	1
Seroquel 150 mg/tab	AstraZeneca Canada Inc.	02240862		N	Within Guidelines	1
Singulair 4 mg/tab	Merck Frosst Canada Inc.	02243602		R	Within Guidelines	1
Sustiva 50 mg/cap	Bristol-Myers Squibb Pharmaceutical Group	02239886	NAS/FPG	J	Under Review	
Sustiva 100 mg/cap	Bristol-Myers Squibb Pharmaceutical Group	02239887	NAS/FPG	J	Under Review	
Sustiva 200 mg/cap	Bristol-Myers Squibb Pharmaceutical Group	02239888	NAS/FPG	J	Under Review	
Tequin 400 mg/tab	Bristol-Myers Squibb Pharmaceutical Group	02243182	NAS	J	Within Guidelines	3
Tequin 10 mg/mL	Bristol-Myers Squibb Pharmaceutical Group	02243184	NAS	J	Within Guidelines	3
Teveten 300 mg/tab	Solvay Pharma Inc.	02240431	NAS	C	Under Review	
Teveten 400 mg/tab	Solvay Pharma Inc.	02240432	NAS	C	Under Review	
Teveten 600 mg/tab	Solvay Pharma Inc.	02243942	NAS	C	Under Review	
Triaminic Softchews Cough 7.5 mg/tab	Novartis Consumer Health Canada Inc.	02243032		R	Within Guidelines	3
Trizivir 150/300/300	GlaxoSmithKline Inc.	02244757		J	Within Guidelines	3
Ventolin Diskus 0.2 mg/dose	GlaxoSmithKline Inc.	02243115		R	Under Review	
Zomig Rapimelt 2.5 mg/tab	AstraZeneca Canada Inc.	02243045		N	Within Guidelines	1
Zyprexa Zydis 5 mg/tab	Eli Lilly Canada Inc.	02243086		N	Within Guidelines	1
Zyprexa Zydis 10 mg/tab	Eli Lilly Canada Inc.	02243087		N	Within Guidelines	1
Zyvoxam 600 mg/tab	Pharmacia Canada Inc.	02243684	NAS/FPG	J	Within Guidelines	3
Zyvoxam 2 mg/mL	Pharmacia Canada Inc.	02243685	NAS	J	Within Guidelines	3

The Board's Guidelines establish three categories of new patented drug products for purposes of conducting introductory price reviews.

- Category 1 — a new DIN of an existing or comparable dosage form of an existing medicine, usually a new strength of an existing drug (line extension).
- Category 2 — the first drug product to treat effectively a particular illness or which provides a substantial improvement over existing drug products, often referred to as "breakthrough" or "substantial improvement".
- Category 3 — a new drug or new dosage form of an existing medicine that provides moderate, little or no improvement over existing medicines.

For complete definitions of the categories, refer to the *Compendium of Guidelines, Policies and Procedures*, Chapter 3, section 3.

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

Annex 3
Research & Developement

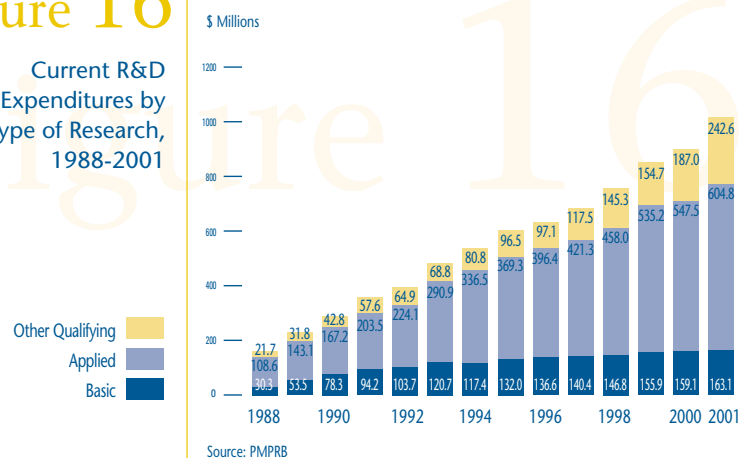
Table 9 | Range of R&D-to-Sales Ratios by Number of Reporting Companies and Total Sales Revenues

Range of R&D-to-Sales Ratio	2001			2000		
	Number of Reporting Companies	Total Sales Revenues ($ millions)	(%)	Number of Reporting Companies	Total Sales Revenues ($ millions)	(%)
0%	16	340.8	3.2	17	349.5	3.8
0%-10%	36	5,792.8	54.0	39	4,860.5	52.2
> 10%	22	4,598.5	42.8	23	4,099.6	44.0
Total	74	10,732.1	100.0	79	9,309.6	100.0

Source: PMPRB

Figure 16

Current R&D Expenditures by Type of Research, 1988-2001



Source: PMPRB

Table 10 | Ratios of R&D Expenditures to Sales Revenues by Reporting Patentee,[1] 2001 and 2000

Company	R&D-to-Sales Ratio (%)	
	2001	2000
3M Canada Inc.	0.04	0.0
Abbott Laboratories, Limited	1.9	1.9
Agouron Pharmaceuticals Canada Inc.	43.0	58.4
Alcon Canada Inc.	0.0	0.0
Allergan Inc.[2]	6.7	8.2
Alpha Therapeutic Corporation (not a patentee in 2000)	0.0	–
AltiMed Pharmaceutical Inc.	0.0	0.0
Alza Canada	0.0	0.0
Amersham Health Inc.[3]	0.0	1.1
Amgen Canada Inc.[2]	45.2[4]	65.7[4]
AstraZeneca Canada Inc.[2]	9.3	10.1
Aventis Pasteur Limited	45.8[4]	49.3[4]
Aventis Pharma Inc.[2]	14.0	13.1
Axcan Pharma Inc.[2]	24.2	22.7
Ayerst Veterinary Laboratories, Division of Wyeth-Ayerst Canada Inc.	0.0	0.0
Baxter Corporation	0.1	0.2
Bayer Inc., Healthcare Division[2]	7.1	7.0
Bayer Inc., Agriculture Division	1.9	1.6
Berlex Canada Inc.[2]	6.0	5.8
Biogen Canada Inc.	37.6	105.0
Biovail Pharmaceuticals, Division of Biovail Corporation[5]	30.7	60.8[R]
Boehringer Ingelheim (Canada) Ltd.[2]	23.2[4]	25.5[4]
Bracco Diagnostics Canada Inc.	0.0	0.0
Bristol-Myers Squibb Pharmaceutical Group[2]	13.4	8.9
BYK Canada Inc.[2]	12.8	22.1
Canderm Pharma Inc.	1.6	1.8
Cangene Corporation	299.0[4]	224.4[4]
Chiron Canada Limited[6]	7.6	0.0
Dermik Laboratories Canada Inc.	0.0	0.6
Draxis Health Inc.	12.8	16.1
Eli Lilly Canada Inc. (includes Elanco Animal Health Division)[2]	10.6	11.5
Ferring Inc.	1.7	1.3
Fournier Pharma Inc.[2]	6.1	6.6
Fujisawa Canada Inc.[2]	11.4	13.0
Galderma Canada	0.5	0.5
Genzyme Canada Inc.	0.9	0.0
GlaxoSmithKline[2]	9.1	13.4
GlaxoSmithKline Consumer Healthcare Inc.[7]	0.0	0.0
Guilford Pharmaceuticals (not a patentee in 2000)	0.0	–
Hoffmann-La Roche Canada Limited[2]	5.1	6.7
ICN Canada Ltd.	1.6	1.7
Janssen-Ortho Inc.[2]	10.1	9.0
Johnson & Johnson Merck, Consumer Pharmaceuticals of Canada	0.0	0.0

Table 10 continued

Company	R&D-to-Sales Ratio (%)	
	2001	2000
Knoll Pharma Inc.[2]	8.2	9.3
Leo Pharma Inc.[2]	7.8	7.4
Ligand Pharmaceuticals (Canada) Inc.	0.0	0.0
Lundbeck Canada Inc.[2]	3.7	8.9
McNeil Consumer Healthcare Canada	0.8	1.2[R]
Medicis Canada Ltd.	0.0	0.0
Merck Frosst Canada Ltd.[2]	13.5	14.3
Merial Canada Inc.	0.3	0.4
Novartis Animal Health Canada Inc.	0.3	0.2
Novartis Consumer Health Canada Inc.	1.3	1.2
Novartis Ophthalmics[8]	12.0	3.2
Novartis Pharmaceuticals Canada Inc.[2]	9.0	11.1
Novo Nordisk Canada Inc.	1.0	1.3
Organon Canada Ltd.[2]	3.2	2.9
Ortho Dermatological, Division of Johnson & Johnson Inc.	0.0	0.0
Paladin Laboratories Inc.[2] (not a patentee in 2000)	6.9	–
Pfizer Canada Inc., Animal Health Group	1.3	–[9]
Pfizer Canada Inc.[2]	11.4	9.2
Pfizer Canada Inc., Consumer Healthcare Division[10]	0.6	5.7
Pharmacia Canada Inc.[2]	7.3	11.2
Procter & Gamble Pharmaceuticals Canada, Inc.[2]	11.9	15.7
Purdue Pharma[2]	4.4	4.7
Sanofi-Synthélabo Canada Inc.[2]	27.7	34.9[4]
Schering Canada Inc.[2]	8.9	8.9
Servier Canada Inc.[2]	19.9	0.0
Solvay Pharma Inc.[2]	1.7	8.3
Stiefel Canada Inc.[2] (not a patentee in 2000)	2.2	–
The Liposome Company, Inc.	0.0	1.9
Tyco Healthcare Group Canada Inc.[2, 11]	0.02	0.01
Wyeth-Ayerst Canada Inc.[2]	13.7	12.0
Yamanouchi Pharmaceutical Co. Ltd.	0.0	0.0

Source: PMPRB

1 The revenues from royalties are included in calculating each company's ratio, but are deducted, when appropriate, for the industry-wide aggregation to avoid double-counting. Federal and provincial government grants have been netted from the expenditures used to calculate the individual R&D-to-sales ratios but are included in the aggregate statistics. Differences between the list of firms filing data on prices and those filing R&D data are due to differences in reporting practices between patentees and their affiliates or licencees as well as the fact that veterinary patentees are required to file information on R&D expenditures, but some are not required to report price and sales information each year.
2 Member of Rx&D. This information has been added at the request of stakeholders and is based on published sources.
3 Formerly known as Nycomed Amersham Canada Ltd.
4 These ratios have been verified with the companies. The largest part of their R&D expenditures was provided by non arms length companies.
5 Formerly known as Crystaal Corporation, Division of Biovail Corporation International
6 Formerly known as Pathogenesis Canada Ltd.
7 Formerly known as Block Drug Company (Canada) Ltd.
8 Formerly known as CIBA Vision Canada Inc.
9 In 2000, Pfizer Animal Health Group was included with Pfizer Canada Inc.
10 Formerly known as Warner-Lambert Canada Inc. (Parke-Davis)
11 Formerly known as Mallinckrodt Medical Inc.

R Revised

Table 11 | Current R&D Expenditures* by Type of Research, 2001 and 2000

Type of Research	2001		2000		% Change in Expenditures 2001-2000
	($ millions)	(%)	($ millions)	(%)	
Basic	163.1	16.1	159.1	17.8	2.5
– Chemical	84.3	8.3	69.3	7.7	21.6
– Biological	78.8	7.8	89.8	10.0	-12.2
Applied	604.8	59.9	547.5R	61.3	10.5
– Manufacturing Process	79.5	7.9	66.3R	7.4	19.9
– Pre Clinical Trial I	56.5	5.6	34.1	3.8	65.7
– Pre Clinical Trial II	23.0	2.3	21.3	2.4	8.0
– Clinical Trial Phase I	23.2	2.3	17.8	2.0	30.3
– Clinical Trial Phase II	96.2	9.5	85.8	9.6	12.1
– Clinical Trial Phase III	326.4	32.3	322.1	36.0	1.3
Other Qualifying R&D**	242.6	24.0	187.0	20.9	29.7
Total* **	**1,010.5**	**100.0**	**893.6R**	**100.0****	**13.1**

Source: PMPRB

* Current expenditures exclude capital equipment and depreciation expenditures.
** Other qualifying R&D includes drug regulation submissions, bioavailability studies and Phase IV clinical trials.
*** Columns may not equal totals due to rounding.

R Revised

Table 12 | Current R&D Expenditures* by R&D Performer, 2001 and 2000

R&D Performer	2001		2000		% Change in 2001-2000
	($ millions)	(%)	($ millions)	(%)	
Intramural					
– Patentees	545.2	54.0	519.3R	58.1	5.0
Extramural					
– Universities and Hospitals	159.6	15.8	144.6	16.2	10.4
– Other Companies	227.5	22.5	158.6	17.7	43.4
– Others	78.2	7.7	71.1	8.0	10.0
Total	1,010.5	100.0	893.6R	100.0	13.1

Source: PMPRB

* Current expenditures exclude capital equipment and depreciation expenditures.

R Revised

Table 13 | Total R&D Expenditures* by Source of Funds, 2001 and 2000

Source of Funds	2001		2000		% Change in 2001-2000
	($ millions)	(%)	($ millions)	(%)	
Company Funds	1,022.4	96.4	918.6R	97.5	11.3
Federal/Provincial Governments	22.4	2.1	5.3	0.6	322.6
Others	15.3	1.4	17.9	1.9	-14.5
Total	1,060.1	100.0**	941.8R	100.0	12.6

Source: PMPRB

* Total expenditures include capital equipment and allowable depreciation.
** Columns may not add up due to rounding.
R Revised

Table 14 | Current R&D Expenditures* by Location, 2001 and 2000

Location of R&D	2001		2000		% Change in 2001-2000
	($ millions)	(%)	($ millions)	(%)	
Atlantic Provinces	26.2	2.6	25.1	2.8	4.4
Québec	423.2	41.9	372.1	41.6	13.7
Ontario	427.2	42.3	394.4R	44.1	8.3
Western Provinces	133.5	13.2	102.0	11.4	30.9
Territories	0.4	0.0	0.012	0.0	3233.3
Total	1,010.5	100.0	893.6R	100.0**	13.1

Source: PMPRB

* Current expenditures exclude capital equipment and depreciation expenditures.
** Columns may not add up due to rounding.
R Revised

Table 15 | Current R&D Expenditures by Province and by R&D Performer, 2001

Province		R&D Performer							Percentage of Expenditures
		Patentees	Other Companies	University	Hospitals	Others	Total	Rx&D	
Newfoundland	$(000)	1,236.80	1,111.40	1,065.10	446.71	883.64	4,743.66	4,019.01	0.47
	%	26.07	23.43	22.45	9.42	18.63	100.00	0.45	
Prince Edward Island	$(000)	0.00	296.15	50.75	0.70	68.28	415.88	366.13	0.04
	%	0.00	71.21	12.20	0.17	16.42	100.00	0.04	
Nova Scotia	$(000)	3,067.29	4,183.65	1,408.80	7,067.68	1,448.11	17,175.53	16,523.26	1.70
	%	17.86	24.36	8.20	41.15	8.43	100.00	1.86	
New Brunswick	$(000)	954.57	965.30	131.00	696.15	1,176.57	3,923.59	3,095.88	0.39
	%	24.33	24.60	3.34	17.74	29.99	100.00	0.35	
Quebec	$(000)	261,369.06	99,942.98	10,002.74	29,729.14	22,181.15	423,225.07	407,556.46	41.88
	%	61.76	23.62	2.36	7.02	5.24	100.00	45.79	
Ontario	$(000)	251,604.29	69,140.66	23,987.97	47,139.04	35,339.56	427,211.54	344,413.40	42.28
	%	58.90	16.18	5.62	11.03	8.27	100.00	38.70	
Manitoba	$(000)	12,533.46	2,541.27	1,104.51	5,855.52	2,981.40	25,016.16	13,702.08	2.48
	%	50.10	10.16	4.42	23.41	11.92	100.00	1.54	
Saskatchewan	$(000)	2,394.61	2,409.83	1,827.49	1,447.50	983.66	9,063.08	8,380.52	0.90
	%	26.42	26.59	20.16	15.97	10.85	100.00	0.94	
Alberta	$(000)	7,779.62	23,151.95	8,732.30	5,996.40	9,328.40	54,988.66	51,953.04	5.44
	%	14.15	42.10	15.88	10.91	16.96	100.00	5.84	
British Columbia	$(000)	4,309.01	23,745.34	4,691.98	7,958.81	3,688.77	44,393.91	39,632.51	4.39
	%	9.71	53.49	10.57	17.93	8.31	100.00	4.45	
Yukon; N.W.T.; Nunavut	$(000)	0.00	0.00	21.00	241.02	118.00	380.02	380.02	0.04
	%	0.00	0.00	5.53	63.42	31.05	100.00	0.04	
Canada	$(000)	545,248.70	227,488.54	53,023.64	106,578.66	78,197.54	1,010,537.08	890,022.31	100.00
	%	53.96	22.51	5.25	10.55	7.74	100.00	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.