Patented Medicine Prices Review Board

NINTH ANNUAL REPORT

For the Year Ended December 31, 1996

Mission and Values of the PMPRB

The mission of the Patented Medicine Prices Review Board (PMPRB) is to contribute to Canadian health care by ensuring that prices of 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
- analysing 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 its mission the PMPRB is 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.

Patented Medicine
Prices Review Board

CANADA

Conseil d'examen
du prix des médicaments brevetés

August 29, 1997

The Honourable Allan Rock, P.C., M.P.
Minister of Health
House of Commons
Ottawa, Ontario
KlA 0A6

Dear Minister:

I have the honour to present to you, in accordance with the provisions of sections 89 and 100 of the *Patent Act*, the Annual Report of the Patented Medicine Prices Review Board for the year ended December 31, 1996.

Yours very truly,

Robert G. Elgie
Chairperson

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Chairperson's Message

On December 7, 1996, the Patented Medicine Prices Review Board (PMPRB) passed a major milestone as it entered its 10th year of operations in its endeavour to fulfil the mandate given it by Parliament to regulate manufacturers' prices of patented medicines in Canada. As Chairperson of the PMPRB, I am pleased to take this opportunity, in the context of the 1996 Annual Report, to offer a review of the PMPRB's effectiveness in fulfilling its mandate to protect consumers through the limiting of prices for patented drugs. As the PMPRB moves into its second decade, this review of the Board's role and performance is especially timely, given the events of the past year as well as the recent parliamentary review of the drug patent legislation conducted by the Standing Committee on Industry of the House of Commons.

In looking at the performance of the PMPRB, it is important to note that the introductory prices of new patented medicines have been kept lower than they would have been and price increases kept below the rate of inflation. For the third consecutive year, manufacturers' prices of patented drug products declined in 1996. As measured by the Patented Medicine Price Index (PMPI), prices of patented drugs declined 2.1% from their level in 1995, while the Consumer Price Index (CPI) increased by 1.6% over the same period. During that same period, however, total expenditures on drugs, which reflect the total consumption of both patented and non-patented drugs, continued to rise in Canada. Based on estimates by Health Canada, total expenditures on drugs increased to $10.8 billion in 1996, a 2.7% increase from 1995.

The mandate of the PMPRB does not cover all prescription drugs. It is limited to the prices charged by manufacturers for patented drugs (prescription and non-prescription), which account for 45% of manufacturers' sales of all drugs. Nonetheless, the issue of rising drug costs in Canada remains a focus of legitimate concern and debate, as reflected by the deliberations and resulting recommendations of the Standing Committee reviewing Bill C-91. On behalf of the PMPRB, I welcomed the opportunity to make a detailed submission to the Standing Committee regarding its performance; to offer a comparison of Canadian price levels for patented medicines to those of seven OECD comparator countries listed in the *Patented Medicines Regulations*; and to provide information on related major issues such as the trend in research and development expenditures by pharmaceutical patentees in Canada.

The report of the Standing Committee on Industry, issued on April 24, 1997, underscored the concerns of Canadians about the cost of drugs and their impact on the health care system while also touching on a number of key areas directly affecting the role and mandate of the PMPRB. These areas included possible changes granting the PMPRB authority to administer provincial controls on prices of non-patented medicines, a call for review of mechanisms for regulating the prices of patented drugs, and opportunities for improving the overall transparency of the price review process. Subsequent to the release of the Standing Committee's report, the PMPRB has taken a number of actions, affirming the PMPRB's commitment to work with the government in responding to the Committee's recommendations. The Board is carrying out a review which will result in the publication of a Discussion Paper in the fall of

1997. This discussion document will be published and shared with our stakeholders to encourage comments and advice on various issues and recommendations contained in the Standing Committee's report.

While the outcome of this review and consultative process has yet to be determined, what remains clear and unchanging is the fundamental purpose of the PMPRB, which is to protect the interests of Canadian consumers. A very significant event of the past year, which served to reinforce and strengthen the PMPRB's consumer role, was the decision of the Federal Court of Appeal in 1996 in a case involving ICN and its pricing of the drug Virazole. This decision, relating to the first-ever contested case involving excessive pricing heard by the Board, has established jurisprudence which is significant for our price regulatory system. In this case, the Board applied all regulatory remedies available under the *Patent Act*, which included lowering the price of Virazole from $1,500 per vial to $200. In its decision upholding the PMPRB's jurisdiction in this matter, the Court emphasized the PMPRB's significant consumer protection role in the field of patented drug prices, as well as the responsibility of patentees to report fully to the Board and to comply with the regulatory regime.

Another major PMPRB initiative in the past year, linked directly to its consumer protection role, was the release of the "*Impact of Federal Regulation of Patented Drug Prices*", a comprehensive study of the PMPRB's impact in terms of lower prices and lower introductory prices for patented drugs. Since 1987, annual price changes for patented drugs have been kept in line with, and even below, the CPI; and Canadian prices have not only declined relative to prices in other countries, but are now less, on average, than the median of the seven foreign countries listed in the *Regulations*.

In terms of savings to the health care system in Canada, the Impact Study estimated that Canadians would have paid between $2.8 billion and $4.2 billion more over the period 1988 to 1995 in the absence of federal price regulation for patented drugs. And, as is borne out by figures for 1996 herein, this trend in savings as a result of the PMPRB's regulatory activities is continuing.

The effect of federal regulation in controlling prices and costs are complemented by provincial cost containment measures.

In carrying out its information-gathering and analysis role, the PMPRB has also released a draft report for discussion purposes, "*A Comparison of Pharmaceutical R&D Spending in Canada and Selected Countries*". Using information filed with the PMPRB by reporting patentees for Canada and the most comparable information for other countries from the Centre for Medicines Research in the United Kingdom, the report compares trends in R&D spending in Canada and the seven OECD countries used for price comparison purposes. Although Canada experienced the largest increase in R&D expenditures, it continues to lag behind the other countries in terms of total R&D spending and the average R&D-to-sales ratio. In 1996, R&D spending by patentees in Canada increased by 6.4% to $665.3 million; but the ratio of R&D spending to sales declined from 11.7% to 11.4%.

As this Annual Report demonstrates, the past year has been characterized by progress, major challenges and emerging opportunities to seek new solutions in promoting the interests of consumers and all those with a stake in the important issue of drug

prices in Canada. Through the continued dedication of the Board members and staff, we are moving forward with our current review process. In so doing, the PMPRB will be involved in discussions with stakeholders and will work in collaboration with federal, provincial and territorial governments. At the same time, in endeavouring to keep our stakeholders better informed and to facilitate public debate on the pricing, usage and cost of drugs, the PMPRB has introduced the NEWSletter which will be published twice a year, offering current information on drug prices, PMPRB activities and other news from the PMPRB. As well, the PMPRB can now be accessed through our new website: http://www.pmprb-cepmb.gc.ca.

For 10 years, the PMPRB has been instrumental in helping to protect the interests of consumers and to promote greater understanding of the complex issues involved in this major component of our health care system. I take this opportunity to acknowledge the commitment and dedication of Board members and the PMPRB staff in meeting the increasing challenges that this organization faces in fulfilling its mission.

I would be remiss if I did not acknowledge the continuing contribution of Professor Harry C. Eastman who has served as a Board member from 1987 to 1997 and as Chairperson and Chief Executive Officer from 1987 to 1995.

In preparing to meet the challenges of a new decade, the PMPRB is committed to building on its accomplishments, continuing to play a positive and effective role in serving the interests of Canadians.

Robert G. Elgie
Chairperson

The Patented Medicine Prices Review Board

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 regulating the prices charged by manufacturers of patented medicines to ensure that they 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 by patent-holding drug manufacturers.

Jurisdiction

The PMPRB is responsible for regulating the maximum prices that patentees may charge for prescription and non-prescription patented drugs sold in Canada for human and veterinary use. In most cases that price is 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 Board does not regulate the prices of non-patented drugs, including generic drugs sold under compulsory licences, and has no jurisdiction over prices charged by wholesalers or retailers and pharmacists' 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 Emergency Drug Release (EDR) 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) or General Public (GP) number.

Membership

The Board consists of no more than five part-time members appointed by the Governor in Council for a term of five years.

Chairperson: Robert G. Elgie, LL.B., M.D., F.R.C.S. (C)
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. Dr. Elgie was appointed Member and Chairperson of the PMPRB in March 1995.

Vice-Chairperson: Réal Sureau, FCA
Mr. Sureau, a chartered accountant, is President of Sureau Management Limited and Director, Business Development, Montreal Baseball Club Inc.

From June 1995 to June 1996, he was President of the Order of Chartered Accountants of Québec. Through the years, he 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. Currently, Mr. Sureau sits on the board of directors of many organizations, including Gaz Métropolitain, Groupe SOPRIN-ADS, Génécan Financial Corporation, the *Institut de réadaptation de Montréal* and *la Fondation des paraplégiques du Québec*. Mr. Sureau was appointed Member and Vice-Chairperson of the PMPRB in October 1995.

Members:
Harry C. Eastman, B.A., Ph.D., F.R.S.C.
An economist and Professor Emeritus at the University of Toronto, Professor Eastman chaired the Federal Commission of Inquiry on the Pharmaceutical Industry from 1984 to 1985. He was a member of the Ontario Council on University Affairs from 1983 to 1989 and of the Ontario Council of Health Task Force on Medical Manpower from 1982 to 1983. First appointed to the PMPRB in 1987, Professor Eastman served as its first chairperson until March 1995.

Judith L. Glennie, Pharm., D., FCSHP
Dr. Glennie is a clinical pharmacist specializing in pharmacoeconomics and outcomes evaluation. She is currently President of J. L. Glennie Consulting Inc., an affiliate researcher with the Loeb Research Institute and an assistant clinical professor with the Department of Medicine, University of Ottawa. Dr. Glennie was appointed Member of the PMPRB in March 1995.

Ysolde Gendreau, B.C.L., LL.B., LL.M., Ph.D.
Dr. Gendreau is a professor in the Faculty of Law of the Université de Montréal, where she teaches intellectual property law and competition law. She is also sessional lecturer at McGill University, where she teaches intellectual property law. Dr. Gendreau was appointed Member of the PMPRB in October 1995.

Sales of Drugs in Canada in 1996

The Pharmaceutical Industry in Canada

The global pharmaceutical industry is dominated by a number of large multinational enterprises based in several countries. Most of these companies have Canadian subsidiaries which, along with a few domestic pharmaceutical firms, account for the manufacture, sale and distribution of drugs in Canada. In 1996 it has been reported that the top ten pharmaceutical companies accounted for approximately 45% of total sales.[1] Of the top ten firms, two were Canadian companies supplying generic products.

In 1996 worldwide sales of drugs were $363 billion, an increase of 6.7% from 1995[2]. The Canadian market for drugs comprised less than 2% of the world market in 1996 having sales of $6.6 billion. This represents an increase of 10% from 1995.

In Canada, the PMPRB protects consumer interests by regulating the prices charged by pharmaceutical patentees during the time they benefit from patent protection. Ordinarily, a patentee is the exclusive supplier of a patented product, but there may also be alternative medicines available. Similarly, although a drug that is no longer protected by a patent may become the subject of competition, there are also instances where the manufacturer of a non-patented drug may remain the sole supplier.

In 1996, 72 companies reported sales of patented medicines in Canada to the PMPRB, an increase from 69 in 1995.[3]

The pharmaceutical industry continued to account for less than 2% of all sales and employment in the manufacturing sector of the Canadian economy in 1996. Because of its R&D activities, however, the industry accounted for approximately 10% of total R&D in that sector.[4] This is consistent with this industry's relative performance since 1987. (For a report on patentees' R&D expenditures in 1996, please refer to page 39).

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1 See IMS, Year in Review 1996 The Canadian Pharmaceutical Industry, Table 1.

2 SCRIP 1997 Yearbook Vol. 1, page 124.

3 A list of all reporting patentees and patented drug products appears in Table 13.

4 Statistics Canada Catalogues, 31-2003 and 88-202.

Sales of Pharmaceutical Drugs in Canada

In 1996, patentees reported total factory-gate sales of patented drugs of $3.0 billion, an increase of 12.7% from 1995. This increase is consistent with rates of increase in previous years with the exception of 1994 when there was a slight decline. Table 1 shows manufacturers' sales of all drugs and of patented drugs since 1990.

TABLE 1

Manufacturers' Sales of All Drugs and Patented Drugs,
1990 - 1996

Year	Total		Patented		Patented as Percentage of Total
	Sales ($billions)	Change* (%)	Sales ($billions)	Change* (%)	
1996	6.6	10.0	3.0	12.7	45.0
1995	6.0	1.7	2.6	8.3	43.3
1994	5.9	9.3	2.4	-0.4	40.7
1993	5.4	12.5	2.4	14.3	44.4
1992	4.8	9.1	2.1	10.5	43.8
1991	4.4	18.9	1.9	18.7	43.2
1990	3.7	-	1.6	-	43.2

Source: PMPRB, Statistics Canada and IMS Canada.
*Percentage changes reflect exact values and not rounded values.

Statistics Canada reports total sales by pharmaceutical manufacturers in Canada on an annual basis and on a monthly basis.[5] The annual reports are not usually available for one or two years.

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[5] See Statistics Canada Cansim #'s D667757, D315488, D401624 and D451712.

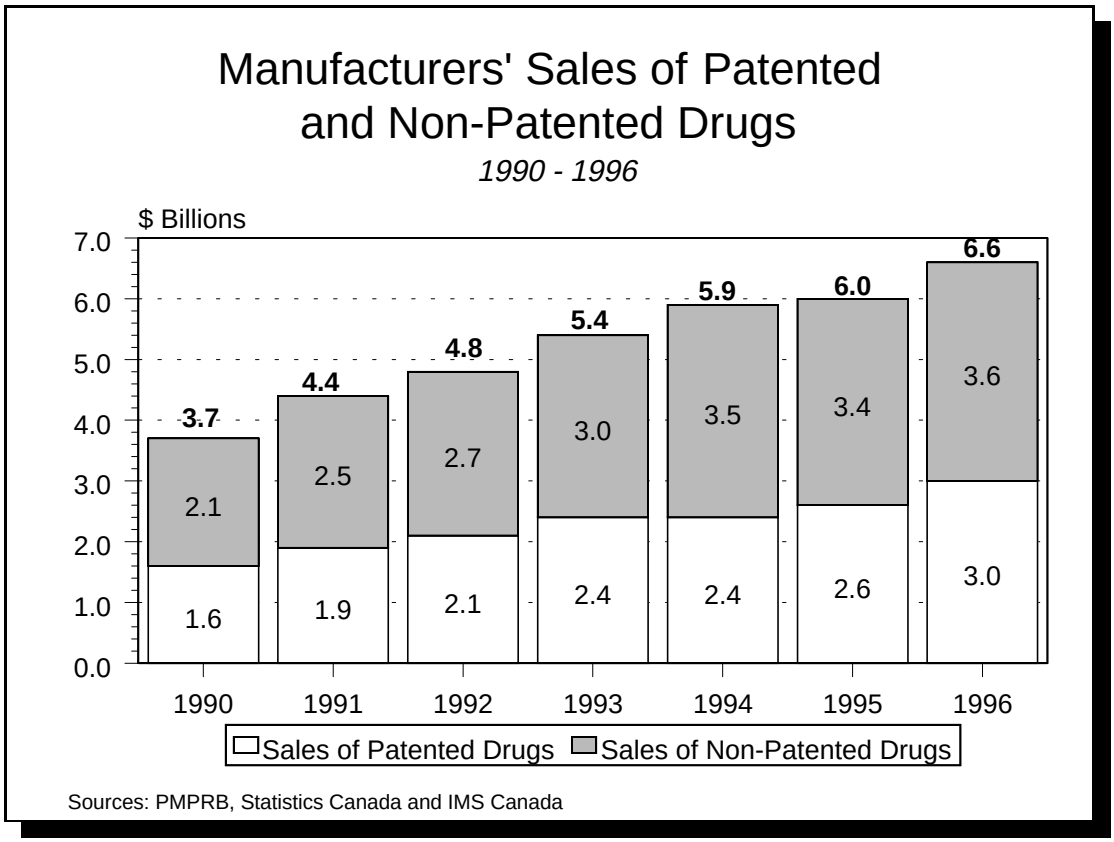
The most recent figures on annual total sales by Statistics Canada are for 1996. In the past, the PMPRB has relied on the most current monthly reports of sales by Statistics Canada as an approximation until the annual report became available, but these estimates have proved to be less than reliable. With this Annual Report the PMPRB has adopted a new method of estimating total sales for the years Statistics Canada's data are not available.

Patentees are required, under the *Patented Medicines Regulations,* to submit to the PMPRB annual total pharmaceutical sales information for both patented and non-patented drug products sold in Canada. IMS Canada Ltd. publishes reports of sales by individual firms. Total sales by all manufacturers can be estimated by adding the total sales of patentees and the estimated IMS sales for non-patentees. These estimates will be revised when the annual sales estimates published by Statistics Canada become available.

As shown in Table 1, total sales by manufacturers of pharmaceuticals in 1996 in Canada are estimated at $6.6 billion, an increase of 10% from 1995. Patented drugs represented 45% of total sales by manufacturers in 1996, slightly higher than their relative share in previous years.

Figure 1 shows the growth in annual sales of patented and non-patented drugs from 1990 to 1996. Sales of non-patented drugs can be estimated as the difference between the total sales of pharmaceuticals described above and the sales of patented drugs as reported to the PMPRB.

FIGURE 1



Non-patented medicines include products that were previously subject to patent protection, those that are not yet or never have been protected by a patent, and generic copies of patented drugs. Information filed by patentees with the PMPRB indicates that most non-patented drugs are sold by companies that also sell patented drugs. Sales of patented drugs represent about 50% of the total drug sales of patentees. IMS Canada estimates sales by non-patentees to be $723 million or 11% of the total pharmaceutical market in 1996, an increase of 18% from 1995.[6]

The PMPRB regulates the maximum prices of individual drug products, including each strength and dosage form of patented medicines. A total of 917 patented drug products were sold in Canada during all or part of 1996. This number represents a slight increase from the 900 products sold in 1995. The number of patented drugs reported to the PMPRB is smaller than

[6] Non-patentees include generic companies, many of which belong to the Canadian Drug Manufacturers Association (CDMA), and brand name companies that do not hold current patents.

the 1,332 patented drugs with a Notice of Compliance (NOC) because not all products with an NOC were actually sold in Canada during the year. In addition, drugs that do not have an NOC but are sold as Investigational New Drugs or under the Emergency Drug Release (EDR) program administered by Health Canada are subject to review by the PMPRB. In 1996 there were 21,155 drug products sold in Canada. Of these drug products approximately 6,000 were prescription drugs. Although the number of patented drug products with an NOC in 1996 represented only 6% of the total number of drug products approved for sale, sales of patented drugs accounted for 45% of total sales as shown in Table 1.

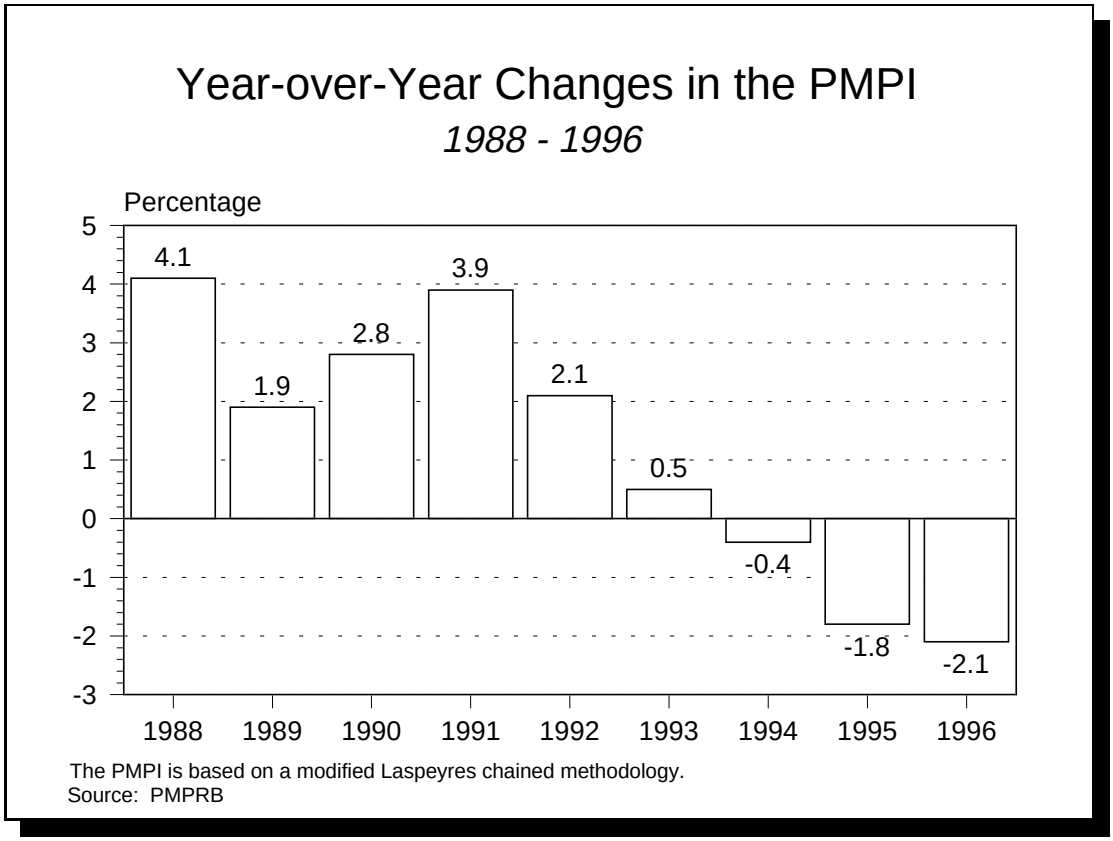
Trends in Drug Prices and Expenditures

Prices of Patented Drugs in 1996

The PMPRB maintains the Patented Medicine Price Index (PMPI), an index of manufacturers' prices for patented drugs as reported annually by the PMPRB. The PMPI measures the average change from the previous year in the actual prices of all patented drugs sold in Canada using the previous year's sales as weights to reflect each drug's importance. Because the PMPI is derived from the actual prices charged by manufacturers for all patented medicines, it provides a precise measure of price changes for drugs reported to the PMPRB.[7]

In 1996, the prices of patented medicines, as measured by the PMPI, declined by 2.1% from their level in 1995. As shown in Figure 2, this was the third consecutive year of decline; the PMPI went down 1.8% in 1995 and 0.4% in 1994.

FIGURE 2



The PMPI is based on a modified Laspeyres chained methodology.
Source: PMPRB

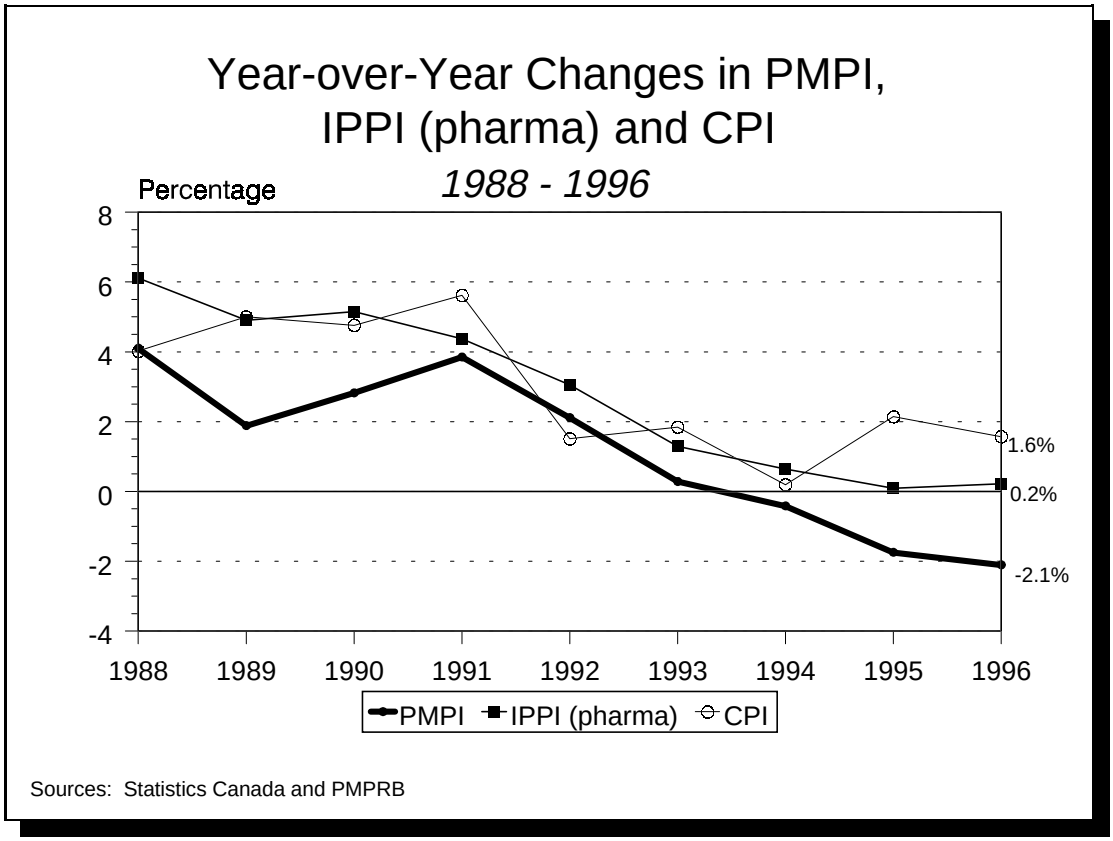
[7] See the PMPRB's *A description of the Laspeyres methodology used to construct the Patented Medicine Price Index (PMPI)*, April, 1997, for an explanation of the PMPI.

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 if the price of a patented medicine is excessive. As shown in Figure 3, consumer prices, as measured by the CPI, increased in every year since 1988 by an amount greater than the PMPI with the exception of 1992.[8] In 1996, consumer prices increased by 1.6% in contrast to the continued decline in the PMPI.

It is not unexpected that the overall increases in patented drug prices have been less than the increases in the CPI. The PMPRB limits apply on a product-by-product basis; in other words, the price of no patented drug product can increase by more than the CPI and some will increase by less.

FIGURE 3



Sources: Statistics Canada and PMPRB

[8] 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 methodology is self-correcting over time. 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*.

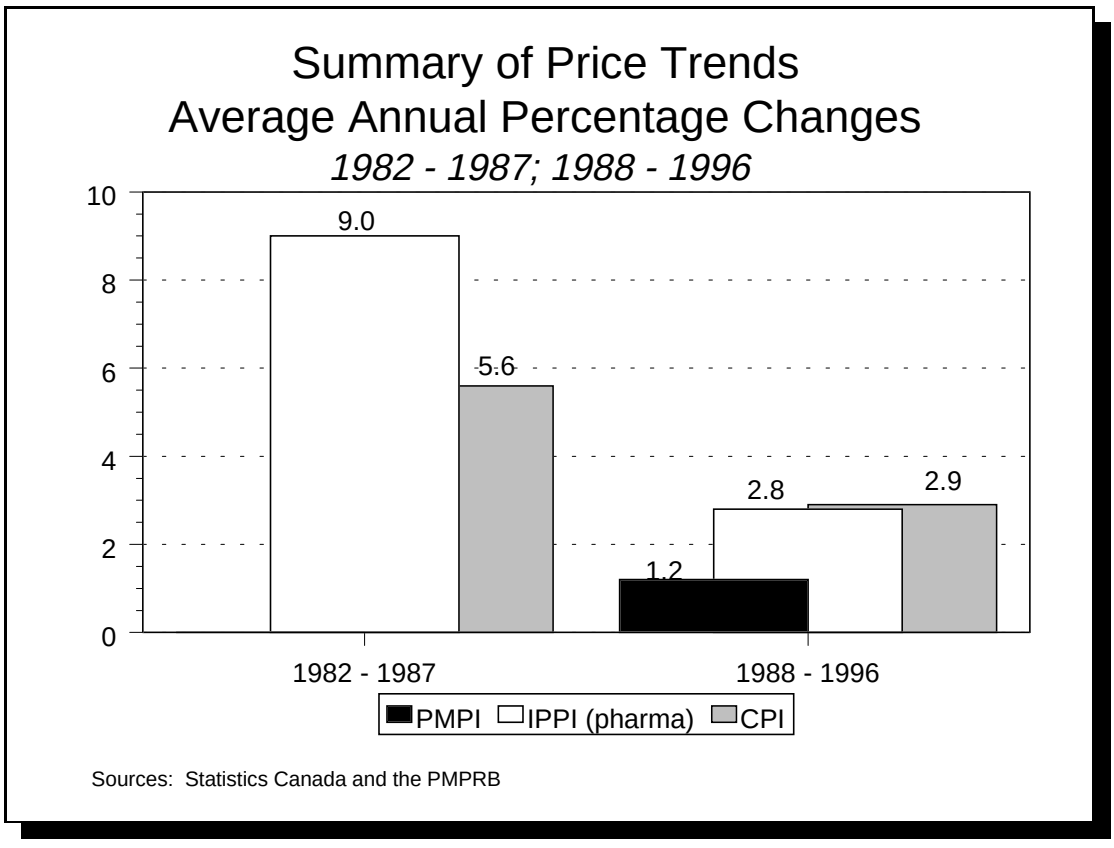
Industrial Product Price Index

The pharmaceutical component of the Industrial Product Price Index [IPPI (pharma)], published by Statistics Canada, provides an index of manufacturers' prices for all pharmaceuticals, including both patented and non-patented drugs. In 1996, the IPPI (pharma) increased by 0.2%. This represents the third consecutive year when price increases for all drugs, as measured by Statistics Canada, have been below one percent as shown in Figure 3. Figure 3 also shows that the IPPI (pharma) has increased every year since the creation of the PMPRB by an amount greater than the PMPI, and closer to changes in the CPI.

As summarized in, from 1988 to 1996, the IPPI (pharma) and the CPI have increased on average by almost the same amount at just under 3% per annum. In contrast, prices for patented drugs have increased at a significantly lower rate over that period, by 1.2% per annum, on average.

Figure 4 also shows information on pharmaceutical price trends prior to the creation of the PMPRB in 1987. From 1982 to 1987, when there was no direct regulation of drug prices, price increases of all drugs, as measured by the IPPI (pharma), averaged 9.0% per year as compared

FIGURE 4



with increases in the CPI of 5.6% per year. The decline in the rate of increase in the prices of all drugs relative to the CPI coincided with the introduction of federal price regulation of patented drugs, which represent 45% of the sales of all drugs.

These trends indicate that limiting price increases for all patented drugs has served to keep the rate of increase in prices for all drugs lower than would otherwise have been the case.

Non-Patented Medicine Price Index (NPMPI)

The PMPRB has traditionally not reported separately on price trends for non-patented drug products. For purposes of conducting a recent study, *The Impact of Federal Regulation of Patented Drug Prices*, a non-patented medicine price index was derived from the IPPI (pharma) and the PMPI. The IPPI (pharma) and the PMPI track the factory-gate prices of drug products; the IPPI (pharma) includes all drugs regardless of patent status, while the PMPI captures only patented drug products. Given these two indices it is reasonable to derive the non-patented medicine price index (NPMPI).[9]

Figure 5 shows how the non-patented medicine price index (NPMPI) increased at a higher annual rate since 1987 relative to the IPPI (pharma) and the PMPI. In 1996, the difference in the change in non-patented drug prices and patented drug prices was 4.6 percentage points; non-patented drug prices increased by 2.5%, while patented drug prices decreased by 2.1%. Figure 6 shows that over the period 1988 to 1996, the average annual increase in prices of non-patented drug products was 4.5%. This compares to 2.8% for all drugs, as measured by the IPPI (pharma), and 1.2% for patented drug products, as measured by the PMPI. As shown earlier in Figure 4, the CPI increased by 2.9%, on average, over the same time period.

FIGURE 5

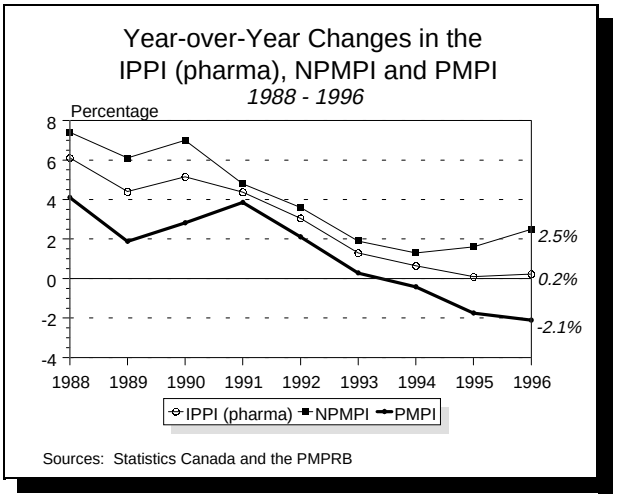
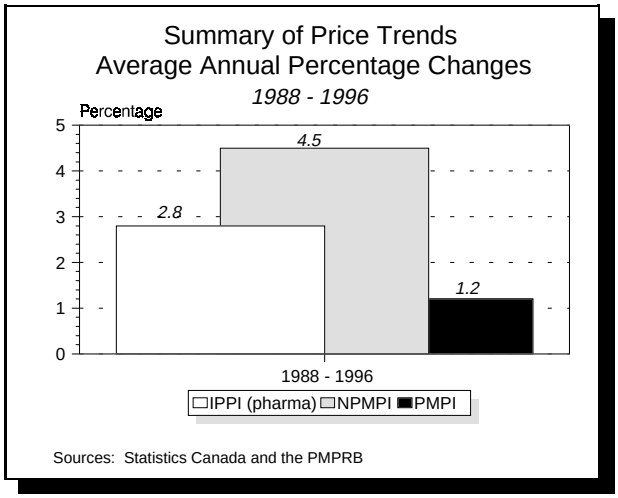


FIGURE 6



Price Trends in Canada and the United States

The trends in drug prices in Canada can be compared with those in the United States. Figures 7 and 8 compare the annual changes in the pharmaceutical component of the U.S. Product Price Index [PPI (pharma)] to the annual changes in the IPPI (pharma) both before and after the introduction of federal price regulation in Canada. The U.S. PPI (pharma) measures price

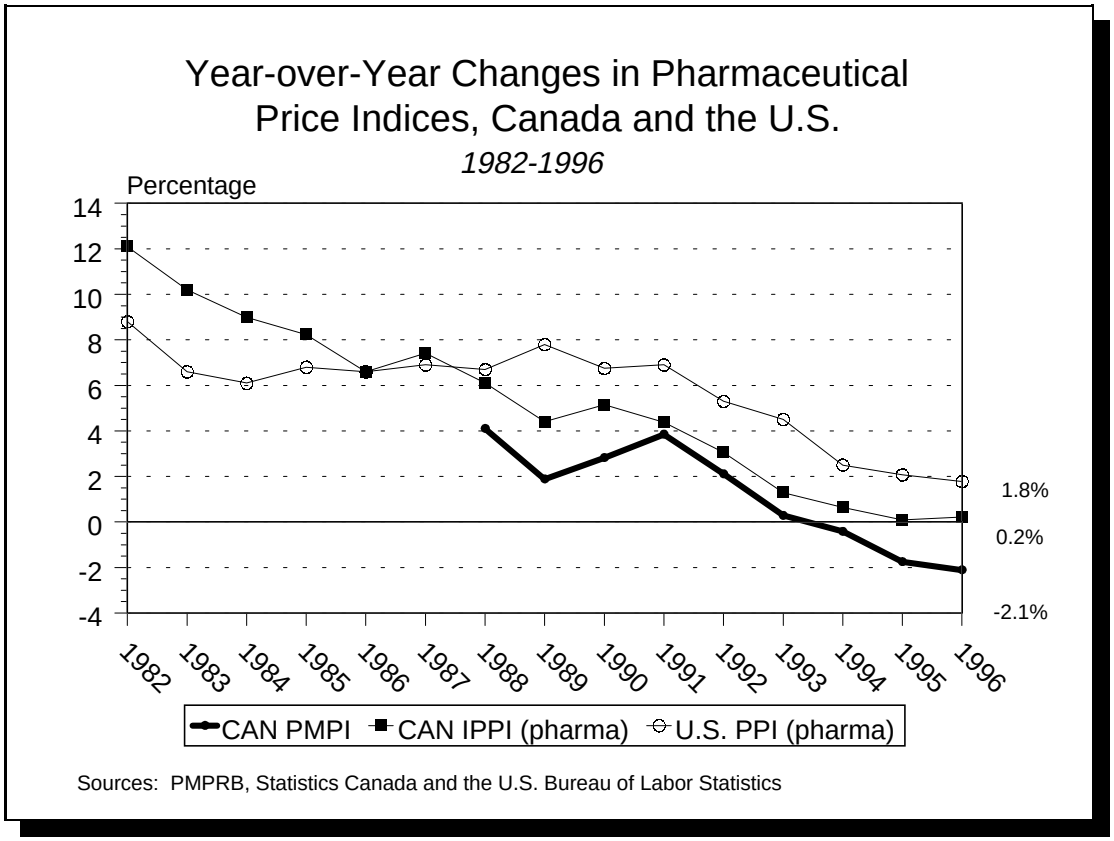
[9] See the PMPRB's *The Impact of Federal Regulation of Patented Drug Prices*, February, 1997.

increases of all pharmaceuticals at the factory-gate. It is similar in construction to the Canadian IPPI.

Figure 7 shows the year-over-year changes in the U.S. PPI (pharma) and the Canadian IPPI (pharma) from 1982 and in the PMPI from 1988. Prior to the introduction of federal price regulation, the Canadian IPPI (pharma) increased in every year at a rate above the U.S. PPI (pharma). That trend reversed in 1987. In 1996, the U.S. PPI (pharma) increased by 1.8% from 1995 compared to only 0.2% for the Canadian IPPI (pharma).

Figure 7 also shows that, since 1987, the PMPI grew every year at a much lower rate than both the U.S. PPI (pharma) and Canadian IPPI (pharma).

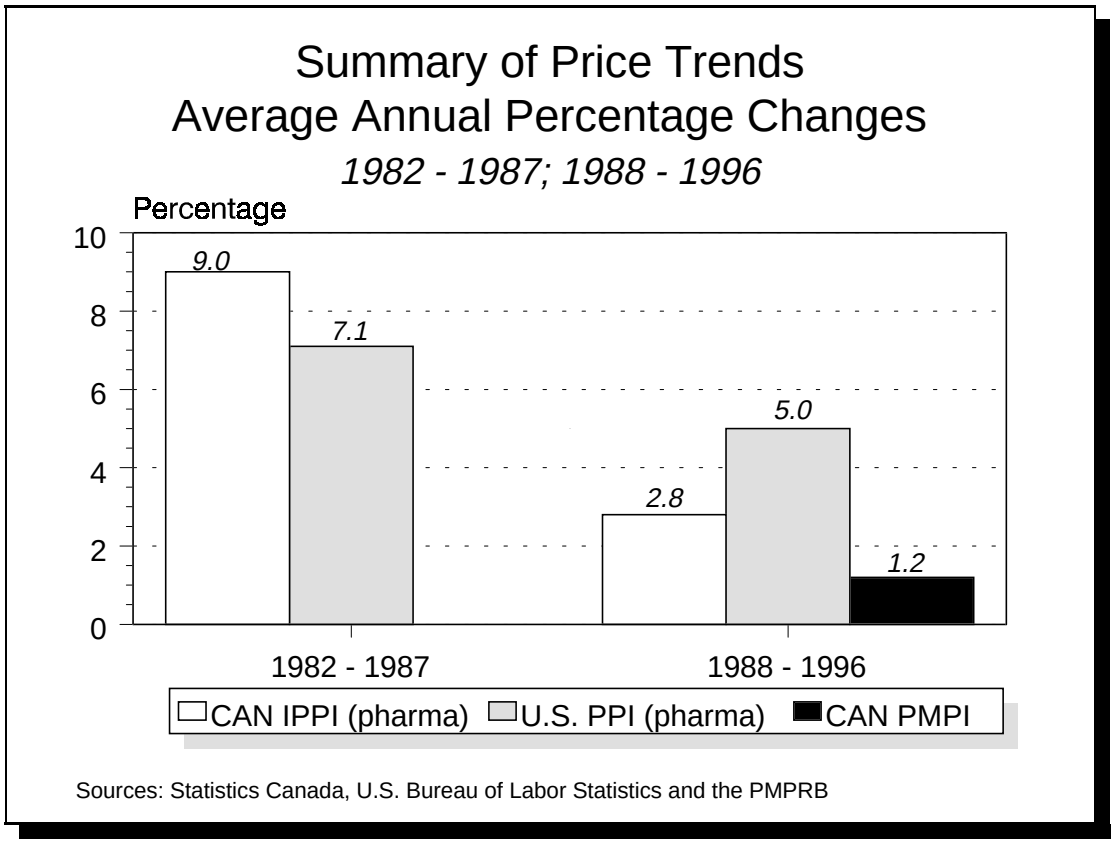
FIGURE 7



Sources: PMPRB, Statistics Canada and the U.S. Bureau of Labor Statistics

Figure 8 shows these trends in summary form during the periods prior to and after the introduction of federal price regulation. From 1982 to 1987, Canadian drug prices, as measured by the IPPI (pharma), increased by almost 9% per year, more than the average annual rate of increase of 7.1% in the U.S. By contrast, the average annual rate of increase in the IPPI (pharma) declined to 2.8% from 1988 to 1996, well below the rate of 5% for the U.S. PPI (pharma). The average annual rate of increase of patented drug prices in Canada was only 1.2% from 1988 to 1996.

FIGURE 8

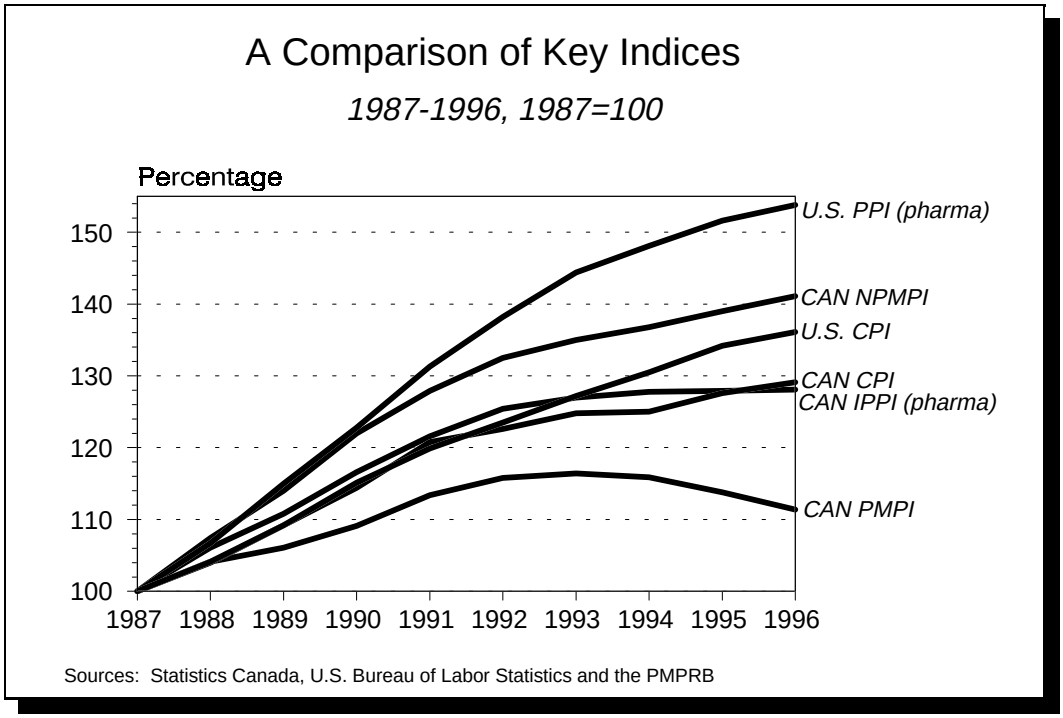


Summary of Key Price Indices

The above indices report year-over-year changes for selected pharmaceutical and related price indices. While informative, a measure of a year-over-year change does not show the cumulative effect of price changes in subsequent years. Figure 9 addresses this gap by taking all the above price indices and showing the cumulative effect of price changes from 1987 to 1996. To conduct this comparison, all indices were set at 1987 = 100.

As shown in Figure 9, the U.S. PPI (pharma) realized the largest growth of all price indices. By 1996, the U.S. PPI (pharma) had grown by 55.8% to 155.8. This compares to a 27.3% growth or 127.3 for the Canadian IPPI (pharma). Non-patented drug prices, as measured by the non-patented medicine price index (NPMPI), grew by 42.4% to 142.4 by 1996. The PMPI, measuring the prices of patented drugs, had the smallest growth at only 11.4%, reaching 111.4 by 1996.

FIGURE 9

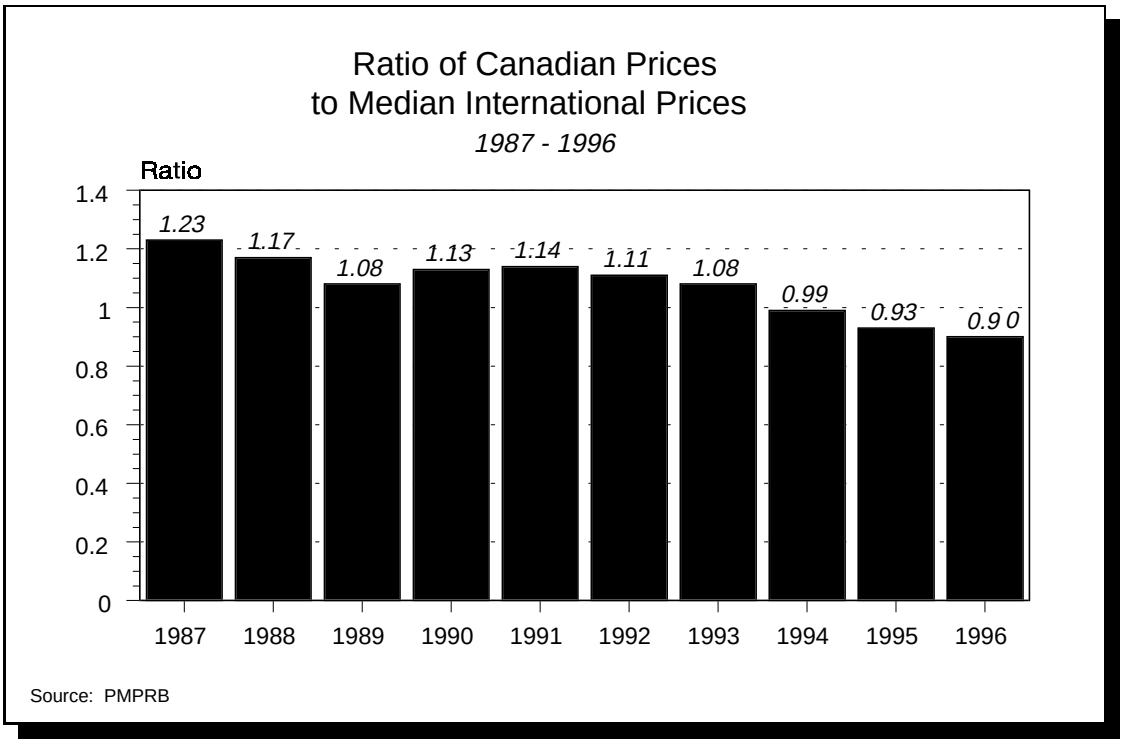


Relationship of Canadian Prices to Foreign Prices: Past and Present

The above price indices demonstrate how prices of drugs in Canada have changed over time. It was shown that in the case of patented drugs, prices have grown well under the annual rate of CPI since 1987, while prices for all drugs have grown at about the same annual rate as CPI over this time period. Another important role of price controls is to limit the level at which prices for drug products are set in the Canadian market. One way of examining the combined effect of controls on introductory prices and price increases is to examine the trend in the relationship of prices in Canada to other countries.

Figure 10 shows the relationship between Canadian prices and median international prices over the period from 1987 to 1996. It shows that the average ratio of Canadian prices to foreign prices has declined from 1.23 in 1987 to 0.90 in 1996. In other words, Canadian prices for patented drugs have declined from 23% above foreign prices to approximately 10% below. This represents about a 30 % fall in the level of Canadian prices over this time period and a 3% decline from 1995. This calculation is based on a revenue-weighted average of the ratio of the Canadian price to median international price for each patented drug product sold in that year.

FIGURE 10



Increased Expenditures on Drugs

The above price indices show that since the creation of the PMPRB in 1987, prices of all drugs, and patented drugs in particular, have increased at a more modest rate than before. Despite this moderation in price increases, total expenditures on drugs have increased more rapidly. According to Health Canada, total expenditures on drugs have increased faster than other major components of health care, and in 1996 reached 14.4% of total health expenditures (see Figure 11). Drug expenditures increased by 2.7% in 1996, 4.0% in 1995 and 3.6% in 1994 (see Figure 12). As shown in Figure 12, these increases are substantially smaller compared to growth in the early 1990's but indicate that total costs for drugs are growing faster than the CPI.

FIGURE 11

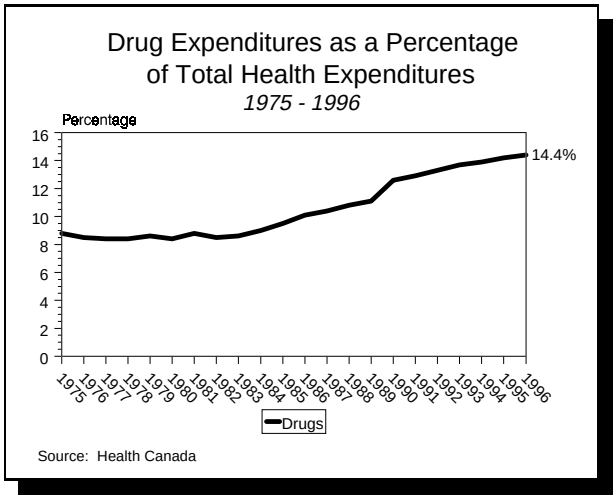
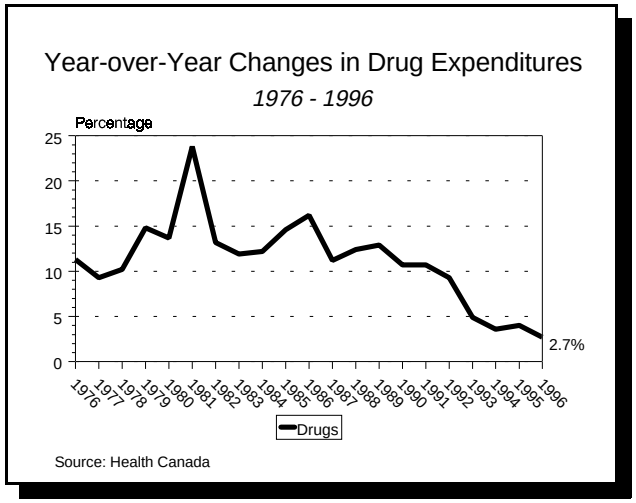


FIGURE 12



Several factors may account for this phenomenon of higher total drug costs and moderating drug prices. Firstly, expenditures on drugs include wholesale and retail mark-ups and dispensing fees which are not included in the PMPI and the IPPI (pharma). Secondly, changes in total expenditures result from increases in the population, changes in the demography of the population, and changes in prescribing habits and utilization of drugs. For example, consumption of larger quantities of drugs could result in increased expenditures even if prices go down. Similarly, shifts in prescribing from cheaper drugs to more expensive ones will result in increased costs even if the actual price levels of products involved do not change.

Trends in Quantities of Sales of Patented Drug Products

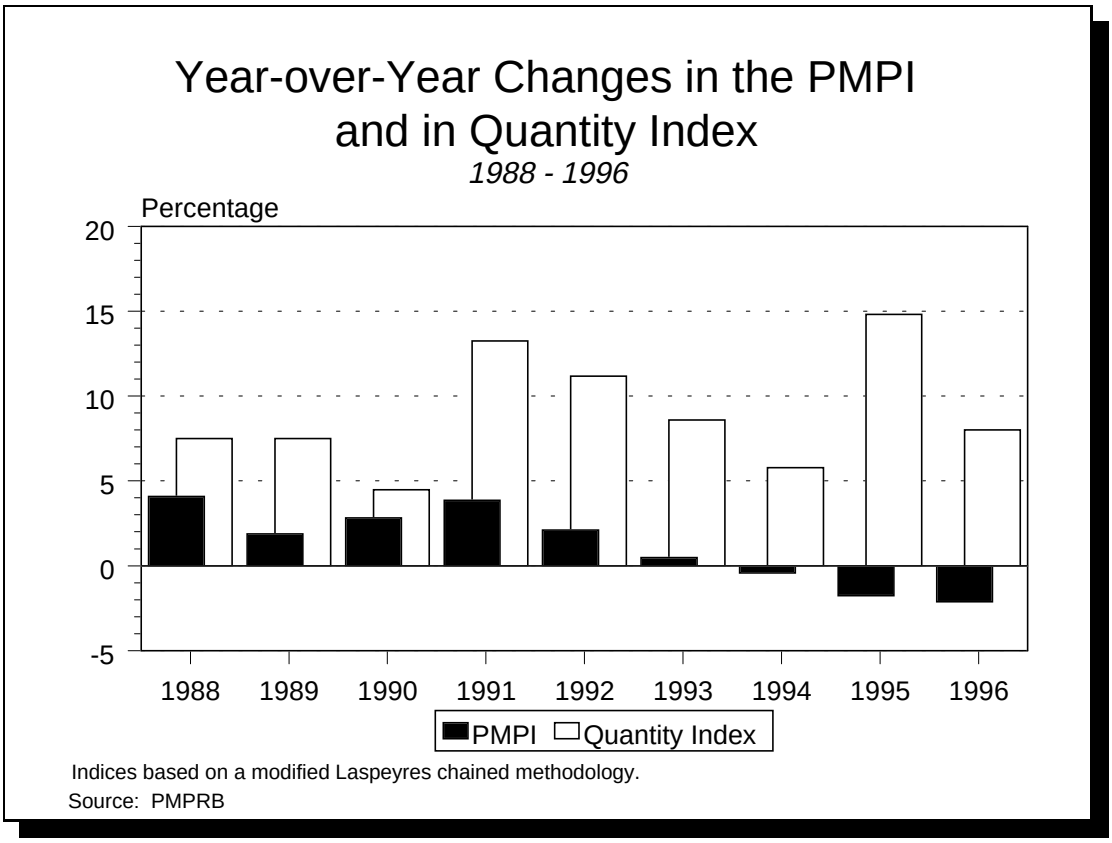
Data available to the PMPRB allow it to measure changes in the quantities as well as the prices of patented drugs sold from year to year. This analysis reveals that the quantities of patented drugs sold have consistently increased at a much faster rate than prices. As shown in Figure 13, this trend has continued in 1996. In 1996, prices for patented medicines declined 2.1%, on average, but the quantities sold increased 8.0%.

From 1988 to 1996, the average annual increase in quantities of patented drugs sold was approximately 9% as compared with an average annual increase of 1.2% in their prices.

The index for the quantities of patented drugs sold may not be representative of total sales of all pharmaceuticals. Among other things, this analysis does not take into account shifts in utilization between patented drugs and non-patented drugs; nor does it account for changes in patent status. For example, drugs continue to be consumed even though their patents expire and their prices are no longer subject to the PMPRB's jurisdiction.

The information available to the PMPRB does not permit a full explanation of the reasons for the increase in the quantities of patented drugs sold. Further study is required.

FIGURE 13



Sales by ATC Classification

The PMPRB classifies all drugs sold in Canada according to the Anatomical Therapeutic Chemical (ATC) classification system.

Table 2 breaks out the 917 patented drug products sold during 1996 according to the major ATC classifications, showing the number of drug products and total revenues from sales for each group. (The breakdown for patented medicines may differ from that for all drugs, including non-patented medicines.)

TABLE 2

Patented Drug Products by ATC Classification, 1996

Major ATC Classification		Patented Drug Products		Revenue from Sales	
		#	%	$M	%
A.	Alimentary tract and metabolism	104	11.3	448	15.1
B.	Blood and blood forming organs	22	2.4	37	1.3
C.	Cardiovascular system	118	12.9	848	28.5
D.	Dermatologicals	32	3.5	82	2.8
G.	Genito-urinary system and sex hormones	36	3.9	123	4.1
H.	Systemic hormonal preparations, excluding sex hormones	22	2.4	25	0.9
J.	General antiinfectives for systemic use	176	19.2	438	14.7
L.	Antineoplastics and immunomodulating agents	66	7.2	154	5.2
M.	Musculo-skeletal system	44	4.8	89	3.0
N.	Nervous system	78	8.5	390	13.1
P.	Antiparasitic products	3	0.3	0	0.0
R.	Respiratory system	51	5.6	195	6.6

S.	Sensory organs	22	2.4	22	0.7
V.	Various	36	3.9	29	1.0
	Veterinary products	107	11.7	91	3.1
	Totals	**917**	**100**	**2,972**	**100**

Source: PMPRB

Rows and columns may not add to totals due to rounding.

General antiinfective drugs (ATC classification J) accounted for the largest number of patented drug products, 19.2%, and 14.7% of total sales. Other groups, accounting for 15% or more of the revenues from sales, were cardiovascular drugs (ATC classification C), and alimentary tract and metabolic drugs (ATC classification A). Although drugs affecting the nervous system (ATC classification N) only accounted for 8.5% of patented drug products, they accounted for 13.0% of total sales.

The number of patented drugs for veterinary use declined from 114 to 107, or 11.7% of the total. The revenue from sales of patented veterinary drugs increased slightly from $86 million to $91 million in 1996, and continued to represent over 3.0% of the total sales of patented drugs.

Impact of Federal Regulation of Patented Drug Prices

In February 1997, the PMPRB released its study, *The Impact of Federal Regulation of Patented Drug Prices*. The purpose of the study was to evaluate the impact of price regulation by estimating what the prices of patented drug products would have been and how much more would have been spent on patented drugs in Canada had federal price regulation not been established in December 1987. The total savings to the Canadian health care system were estimated to be between $2.9 billion and $4.2 billion over the period 1988 to 1995. Total patented sales in Canada were approximately $16.3 billion over the same period. Federal regulation of prices and provincial cost-containment measures have resulted in complementary policies to control prices and costs.

The analysis assumed that legislation extending patent protection to pharmaceuticals (Bill C-22 and Bill C-91) would have been enacted without any federal price regulation. The study did not attempt to compare the impact of price regulation to that of the previous regime of compulsory licensing.

The estimated impact of federal price regulation was calculated by subtracting the value of actual sales of patented drugs from the estimated value in the absence of price regulation over the period from 1988 to 1995. There are two elements which must be identified when determining this impact - the impact of price regulation on introductory prices of new drug products and the impact on price increases of all patented drug products.

To estimate the likely growth in patented drug prices, in the absence of regulation, the study used three different price indices to simulate price growth. These were: the Consumer Price Index (CPI), the Non-Patented Medicine Price Index (NPMPI) and the pharmaceutical component of the U.S. Product Price Index (PPI). These price indices provided reasonable approximations of how patentees would have increased prices annually for existing patented drugs.

The total estimated savings from limiting price increases over the years 1988 to 1995 ranged between $873 million and $2.03 billion.

The other element of federal price regulation is the limiting of introductory prices of new patented drugs entering the Canadian market. The patented drug products included in this analysis are those that were introduced after federal price regulation was introduced in 1987. Total sales for this group of patented drug products were approximately $8.62 billion or 53% of sales in all years.

The savings derived from limiting the introductory prices of new patented drugs entering the Canadian market over the period 1988 to 1995 were estimated to be $1.89 billion.[10]

[10] Canadian prices declined about 25% compared to foreign prices during that same period. Prices dropped from 23% above the median of foreign prices in 1987 to 7% below in 1995.

These savings were combined with the savings realized from limiting price increases of patented drugs over the eight year period. In all cases, the impact increased in each year and, by 1995 was between $846 million and $1.08 billion. Expressed in another way, Canadians paid between 24% and 29% less for patented drugs in 1995 than they would have in the absence of federal price regulation.

Compliance and Excessive Price Guidelines

Under the *Patented Medicines Regulations* (*Regulations*), patentees are required to report information on the sales and prices of new patented medicines and to continue to file detailed information on sales and prices of each patented drug for the first and last six-month period of each year. The PMPRB reviews this pricing information on an ongoing basis to ensure that the prices charged by patentees comply with the Guidelines established by the Board. The Guidelines are published in the PMPRB's *Compendium of Guidelines, Policies and Procedures*.

The Guidelines are based on the price determination factors in section 85 of the *Patent Act*. In summary, the Guidelines provide that:

- prices for most new drugs are limited to the range of prices in Canada for existing drugs used to treat the same disease;
- prices of breakthrough drugs and those which bring a substantial improvement are limited to the median of the prices charged for those drugs in other industrialized countries listed in the *Regulations* (France, Germany, Italy, Sweden, Switzerland, UK, and US);
- price increases for existing medicines are limited to changes to the Consumer Price Index (CPI); and
- the price of a patented drug in Canada may, at no time, exceed the range of the prices for the same drug in foreign countries.

New Drug Products in 1996

For purposes of the review of prices charged in 1996, new drug products include those introduced between December 1, 1995 and November 30, 1996. Because of the timing of the filing requirements under the *Regulations* and the manner of calculating benchmark prices, drug products introduced in December are considered to have been introduced in the following year.

Eighty-four (84) patented drug products (DINs) were first sold in Canada in 1996. This is consistent with the average number of new patented drug products introduced annually in Canada over the last several years.

Most of the drug products are for human use. Only four new DINs for veterinary use were introduced in 1996. Except for 1994, veterinary products have generally represented well below 10% of the total number of new patented DINs each year.

More and more patentees request advisory assistance prior to the introduction of a new medicine to ensure that they are in compliance with the Board's Guidelines. In 1996, the PMPRB received requests for pre-sale advisory assistance concerning 38 DINs, representing 45.2% of total new DINs, of which 18, or 21.4% of total new DINs,

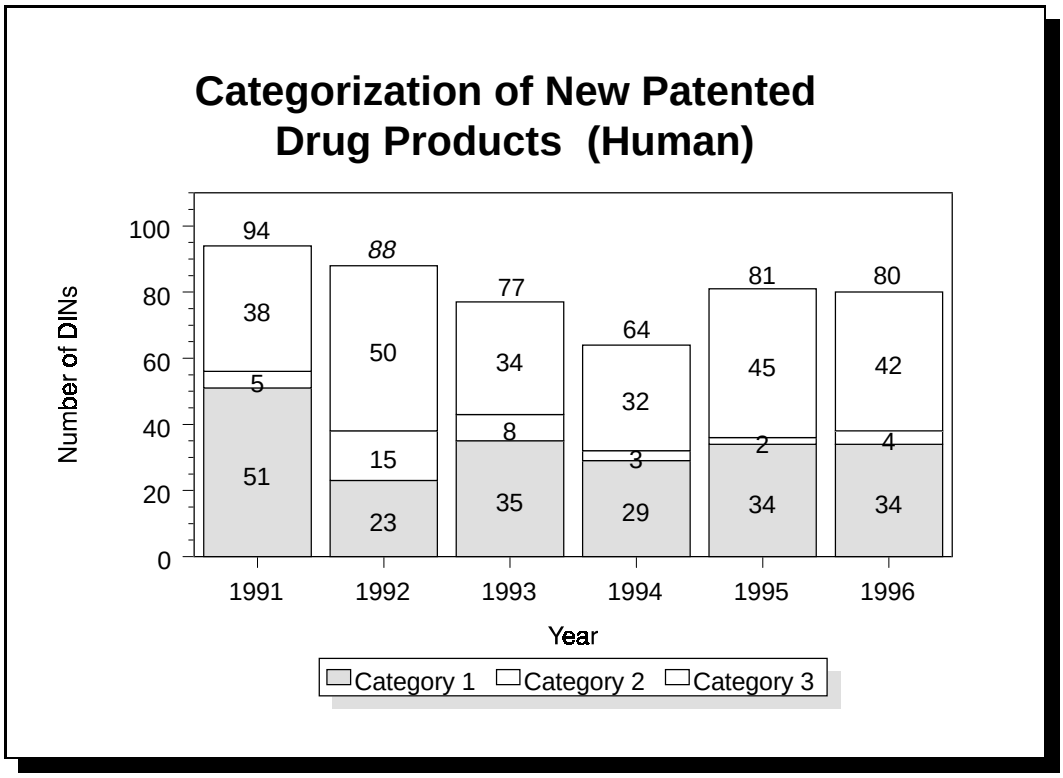
were requests for categorization of the new medicines as breakthroughs or substantial improvements.

The Board's Guidelines establish three categories of new patented drug products for purposes of conducting introductory price reviews.[11]

- 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.

Figure 14 provides a breakdown by category of the new DINs introduced in 1996 as compared to the preceding five years. The higher proportion of category 2 and 3 drug products in 1992 was due in part to a higher number of patented new active substances for human use introduced in that year. Table 12, on page 55, lists the drug products included in each category in 1996.

FIGURE 14



Source: PMPRB

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

New Active Substances in 1996

Among the new patented DINs for human use introduced in Canada in 1996, there were 21 new active substances (NASs)[12] compared to 20 NASs in 1995. A listing of the NASs and their assigned categories appears in Table 3. A NAS may represent more than one drug product if it is sold in more than one strength or dosage form. The 21 NASs listed were marketed as 37 presentations (DINs) in 1996.

The list of NASs approved by the Health Protection Branch (HPB) in any year differs from the list of NASs introduced for sale as new patented drugs. In some circumstances, a patented drug may be sold before it receives a Notice of Compliance (NOC) or it may not be introduced until later. For example, eleven of the 21 NASs were granted an NOC by HPB in 1996; eight received NOCs in 1995, one in 1994 and one in 1993. In total, HPB issued NOCs for 34 NASs in 1996 for sale in Canada, but not all were introduced to the market in that year. Not all NASs approved by HPB are subject to the PMPRB's jurisdiction. Twenty of the NASs approved by HPB in 1996 are patented medicines and five more are known to the PMPRB as having patents pending.

For 10 of the 21 patented NASs in 1996 manufacturers made submissions that they be categorized as breakthrough or substantial improvement drugs, category 2. After thorough review, the Human Drug Advisory Panel (HDAP)[13] recommended that three NASs (4 DINs) be designated category 2 (as indicated in Table 3) with the remainder of the NASs being grouped into category 3, which comprises drugs providing moderate, little or no improvement over existing drugs.

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[12] Health Canada now uses the term "New Active Substance", or NAS, in place of the term "New Chemical Entity" (NCE), to more accurately reflect both new biological and chemical substances.

[13] The Human Drug Advisory Panel (HDAP) is a panel of external clinicians established by the PMPRB to provide expert advice and recommendations with respect to the categorization of new drug products and the selection of comparable drug products.

TABLE 3 **Patented Medicines Introduced in Canada in 1996**
New Active Substances (Human)

CHEMICAL NAME	BRAND NAME	COMPANY	CATEGORY	ATC CLASS
ABCIXIMAB	**REOPRO**	ELI LILLY CANADA INC.	2	B01AC
ACARBOSE	**PRANDASE**	BAYER INC.	3	A10BF
ADAPALENE	**DIFFERIN**	GALDERMA CANADA INC.	3	D10AD
ALENDRONATE SODIUM	**FOSAMAX**	MERCK FROSST CANADA INC.	3	M05BA
AMIFOSTINE	**ETHYOL**	ELI LILLY CANADA INC.	2	V03AF
ANASTROZOLE	**ARIMIDEX**	ZENECA PHARMA INC.	3	L02BG
BICALUTAMIDE	**CASODEX**	ZENECA PHARMA INC.	3	L02BB
CARVEDILOL	**COREG**	SMITHKLINE BEECHAM PHARMA INC.	3	C07AG
CEFEPIME HYDROCHLORIDE	**MAXIPIME**	BRISTOL-MYERS SQUIBB PHARMACEUTICAL GROUP	3	J01DA
DORZOLAMIDE HYDROCHLORIDE	**TRUSOPT**	MERCK FROSST CANADA INC.	3	S01EC
GEMCITABINE HYDROCHLORIDE	**GEMZAR**	ELI LILLY CANADA INC.	3	L01BC
GRANISETRON HYDROCHLORIDE	**KYTRIL**	SMITHKLINE BEECHAM PHARMA INC.	3	A04AA
IOTROLAN	**OSMOVIST**	BERLEX CANADA INC.	3	V08AB
MEROPENEM	**MERREM**	ZENECA PHARMA INC.	3	J01DH
MYCOPHENOLATE MOFETIL	**CELLCEPT**	HOFFMAN -LAROCHE LIMITED	3	L04AA
OLANZAPINE	**ZYPREXA**	ELI LILLY CANADA INC.	3	N05AH
PIRBUTEROL ACETATE	**MAXAIR**	JOUVEINAL INC.	3	R03AC
RALTITREXED	**TOMUDEX**	ZENECA PHARMA INC.	3	L01BA
RITONAVIR	**NORVIR**	ABBOTT LABORATORIES LIMITED	2	J05AE
STAVUDINE	**ZERIT**	BRISTOL-MYERS SQUIBB PHARMACEUTICAL GROUP	3	J05AX
VALACYCLOVIR HYDROCHLORIDE	**VALTREX**	GLAXO WELLCOME INC.	3	J05AB

Price Review of New Patented Drugs in 1996

The Excessive Price Guidelines are summarized on page 30 and are published in the *Compendium of Guidelines, Policies and Procedures*[14].

At the time of this report the PMPRB had found that the introductory prices of 81 of the 84 new patented drug products (over 96%) introduced in 1996 were within the Guidelines. The remaining three products (two medicines) are under review.

Price Review of Existing Drug Products in 1996

For the purposes of this report, existing medicines include all patented drug products that were on the market before 1996. The PMPRB's Guidelines limit the price changes for existing patented drugs to changes in the Consumer Price Index (CPI). Also, prices cannot exceed the highest price of the same drug product in the countries listed in the *Regulations*.[15]

A total of 853 patented drug products were sold during 1996. The prices of 849 drug products (over 99%) were within the Guidelines. At the time of this report, the prices of four drug products (four medicines) were under review.

Update of Eighth Annual Report

In the 1995 Annual Report, the PMPRB reported that a Notice of Hearing had been issued to ICN Canada Ltd. and ICN Pharmaceuticals Inc. relating to the drug Virazole. This hearing was completed with an Order against ICN to lower the price of Virazole and to take specified measures to offset double the excess revenues received. (For more details, please see page 35.)

It was also reported that investigations into 25 new and existing drug products were being conducted. Since then, the investigations involving twenty-four drug products, have been concluded following receipt of further evidence which established that the prices were within the Guidelines. The one remaining investigation is continuing.

[14] Chapter 1, section 6.

[15] France, Germany, Italy, Switzerland, Sweden, United Kingdom and United States.

Enforcement Activities

Voluntary Compliance Undertakings

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 Guidelines. The Policy requires that a VCU ensure that a price will be adjusted to conform with the Guidelines and, where appropriate, include measures to offset excess revenues that may have been received by the patentee. Approval of a VCU by the Chairperson or Board is an alternative to the commencement of formal proceedings through the issuance of a Notice of Hearing.

In 1996, the Chairperson approved one VCU by Boehringer Ingleheim (Canada) Ltd. to reduce the price of Prostep, 30 and 15 mg nicotine patches. This VCU was reported on page 20 of the 1995 Annual Report.

Public Hearings

ICN Canada Ltd. and ICN Pharmaceuticals Inc. (ICN)

As first reported on page 21 of last year's annual report, the Chairperson issued a Notice of Hearing on August 15, 1995, regarding alleged price increases by ICN for Virazole. According to the Notice of Hearing, it was alleged that ICN had increased the price of Virazole by 277% in 1994 and 1995 contrary to the Guidelines.

Virazole (ribavirin) is indicated for lower respiratory tract infection due to respiratory syncytial virus in hospitalized infants and children.

The hearing on the alleged excessive pricing issue was conducted over eight days from April 9 to July 4, 1996 and the Board issued its decision on July 26 and ordered ICN to lower the price of Virazole to a non-excessive price. The Board found that ICN had been selling Virazole at an excessive price. The Board also found that ICN had engaged in a policy of excessive pricing since January 1994. It concluded that "the actions of ICN warrant the exercise of the Board's remedial powers to the full extent permitted by the *Patent Act*, that is an order which will recover twice the cumulative excess revenues received by ICN Canada Ltd. to date."

The Board ordered ICN to make payments to the Government of Canada in the total amount of $1.2 million and to reduce the price of Virazole from $1540 to approximately $200 per 6 gram vial, which is $200 below the maximum non-excessive price. This additional price reduction remains in effect until the earlier of December 31, 1999, or the date on which an amount equal to twice the cumulative excess revenues, for a total of $3.5 million, has been offset by the sum of the amount paid and the cumulative price reductions. In the event that the cumulative excess revenues have not been offset by December 31, 1999, ICN shall, no later than January 31, 2000, make a payment to the Government of Canada equal to the balance of excess revenues outstanding as at December 31, 1999.

ICN complied with the Board's Order and abandoned its appeals in this matter. This decision marks the Board's first findings of excessive price and a policy of excessive pricing following a hearing.

A summary of the decision of the Federal Court of Appeal on the jurisdiction of the PMPRB in this case appears on page 37.

Decision of the Federal Court of Appeal on the Jurisdiction of the PMPRB

In its decision in the case of *ICN Canada Ltd. and ICN Pharmaceuticals Inc. (ICN)*, handed down on August 7, 1996, the Federal Court of Appeal rejected ICN's application for judicial review of the Board's decision on its jurisdiction in this case, and confirmed the Board's broad interpretation of its jurisdiction over patents that pertain to medicines.

The issue considered by the Federal Court of Appeal was whether the PMPRB had jurisdiction to regulate the price of the medicine Virazole. Among other things, ICN argued that one patent did not pertain to Virazole because ICN used a different, non-patented, process to manufacture the drug. It also argued that another patent did not pertain, in part because ICN had disclaimed certain parts of it.

The PMPRB's jurisdiction over patented medicines flows from subsection 79(2) of the *Patent Act* which reads in part as follows:

> "...an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine".

In its review of the legislative history, the Court stated that the purpose of the 1993 amendments to the *Patent Act* were "to empower the PMPRB to influence the pricing of patented medicines to much the same extent that the competition fostered by compulsory licencing used to influence it".

Accordingly, the Court found that the language used in the legislation and particularly sections 83(1) and 79(2) reflect this policy objective and should be granted a broad interpretation in order to permit the attainment of this objective. The Court disagreed with ICN's position that the provisions should be narrowly interpreted.

In particular, the Court of Appeal concluded that there need only be "the merest slender thread" between the patented invention and drug in question. To require more "would provide a window of opportunity for pharmaceutical companies to avoid the jurisdiction of the Board and would limit the ability of the Board to protect Canadian consumers from excessive prices."

ICN Canada Ltd. remains under the Board's jurisdiction with respect to its sales of Virazole at least until 2006.

The reasons for decisions handed down by the Board, the Federal Court and Federal Court of Appeal in this case are available upon request by contacting the Secretary to the Board.

Analysis of Research-and-Development (R&D) Expenditures

With the adoption of the 1987 amendments to the *Patent Act*, the Pharmaceutical Manufacturers Association of Canada (PMAC) made a public commitment that the brand name pharmaceutical industry would increase its annual R&D expenditures as a percentage of sales to 10% by 1996.

Under the *Patent Act*, the PMPRB monitors and reports on R&D spending 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 the PMPRB to report on how much each patentee spends annually on pharmaceutical R&D in relation to revenues and on how much the patented industry as a whole spends on R&D. 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 1996 were also required to file R&D data for that calendar year as per the *Patented Medicines Regulations (Regulations)*. Only companies with active Canadian patents pertaining to a medicine sold in Canada are required by the *Patent 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.

For 1996, 72 companies, including 41 PMAC members, filed reports on R&D. The data from these firms are the basis of this report. Of these 72 companies, 11 reported no eligible R&D expenditures for 1996. Sales revenues for these 11 companies totalled $112.6 million in 1996, accounting for 1.9% of total sales revenues for the patented pharmaceutical industry.

TABLE 4

Total R&D Expenditures* and R&D-to-Sales Ratios, 1988 - 1996

Year	Companies Reporting	Total R&D Expenditures* ($M)	Change from Previous Year (%)	Total Sales Revenues ($M)	Change from Previous Year (%)	R&D-to-Sales Ratio	
						All Patentees (%)	PMAC Patentees (%)
1996	72	665.3	6.4	5,857.4	9.9	11.4	12.3
1995[r]	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 federal and provincial government grants, capital equipment expenditures and allowable depreciation expenses.

[r] Revised

R&D Expenditures

Pursuant to the *Regulations*, patentees must 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. 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 are ***not*** included in the patentees' filings. Total R&D expenditures include current expenditures, capital equipment costs and allowable depreciation expenses.

Revenues from Sales

The 72 patentees reported total revenues of $5.9 billion from Canadian sales of patented and non-patented drugs in 1996, up 9.9% over 1995. Of total sales revenues, less than 1% was generated by licensing agreements.

R&D-to-Sales Ratios

The ratio of R&D expenditures to sales revenues for the patented pharmaceutical industry was 11.4% in 1996, down from 11.7% in 1995. The ratio for the 41 companies that were members of the PMAC was 12.3% in 1996, down from 12.5% in 1995.

As shown in Table 5, of the 72 reporting companies, 11 companies (15.3%) reported having performed no R&D in 1996; 33 companies (45.8%) reported R&D-to-sales ratios between 0 and 10%; and 28 companies (38.9%) reported ratios of 10% or more. Table 10, on page 45, lists all reporting patentees and their R&D-to-sales ratios. It is interesting to note that 36 of the 69 companies that reported R&D in 1995 experienced a decline in their R&D-to-sales ratio in 1996. Each patentee was given the opportunity to confirm the calculated R&D-to-sales ratio before publication of this report.

TABLE 5 Range of R&D-to-Sales Ratios by Number of Reporting Companies

Range of R&D-to-Sales Ratio	Number of Reporting Companies	Distribution in %
0%	11	15.3
0% to 10%	33	45.8
>10%	28	38.9

Source: PMPRB

As shown in Table 4, patentees reported total R&D expenditures of $665.3 million in 1996, an increase of 6.4% over 1995. Current expenditures accounted for $630.1 million or 94.7% of total R&D expenditures. Capital equipment costs and allowable depreciation expenses amounted to 3.9% and 1.3% respectively.

Table 6 shows how current expenditures on R&D in 1996 were allocated among basic, applied, and other qualifying R&D. Total current expenditures on R&D rose by 5.4% in 1996.

TABLE 6

Current R&D Expenditures* by Type of Research, 1995 and 1996

Type of Research	1996		1995[r]		Change in Expenditures 1996 / 1995 %
	$M	%	$M	%	
Basic	136.6	21.7	132.0	22.1	3.5
Applied	396.4	62.9	369.3	61.8	7.3
Other Qualifying	97.1	15.4	96.5	16.1	0.6
Total	630.1	100.0	597.8	100.0	5.4

Source: PMPRB

***** Current expenditures exclude capital equipment and depreciation expenditures.

[r] Revised

Spending on basic research was $136.6 million or 21.7% of the total. Basic research is defined as work that advances scientific knowledge without a specific application in view. The lion's share of R&D spending continued to be on applied research, $396.4 million or 62.9% of the total. Applied research is directed towards some practical application, comprising the manufacturing process, pre-clinical trials and clinical trials. Clinical trials accounted for 81.5% of total applied research expenditures, $323.2 million, while manufacturing process accounted for $41.4 million, or 10.4% of the total, and pre-clinical trials accounted for $31.8 million or 8.1% of the total. Other qualifying research expenditures are for drug regulation submissions, bioavailability studies and Phase IV clinical trials.

Figure 15 shows current expenditures on R&D by type of research from 1988 to 1996 and Figure 16 shows their shares of expenditures during those years.

FIGURE 15

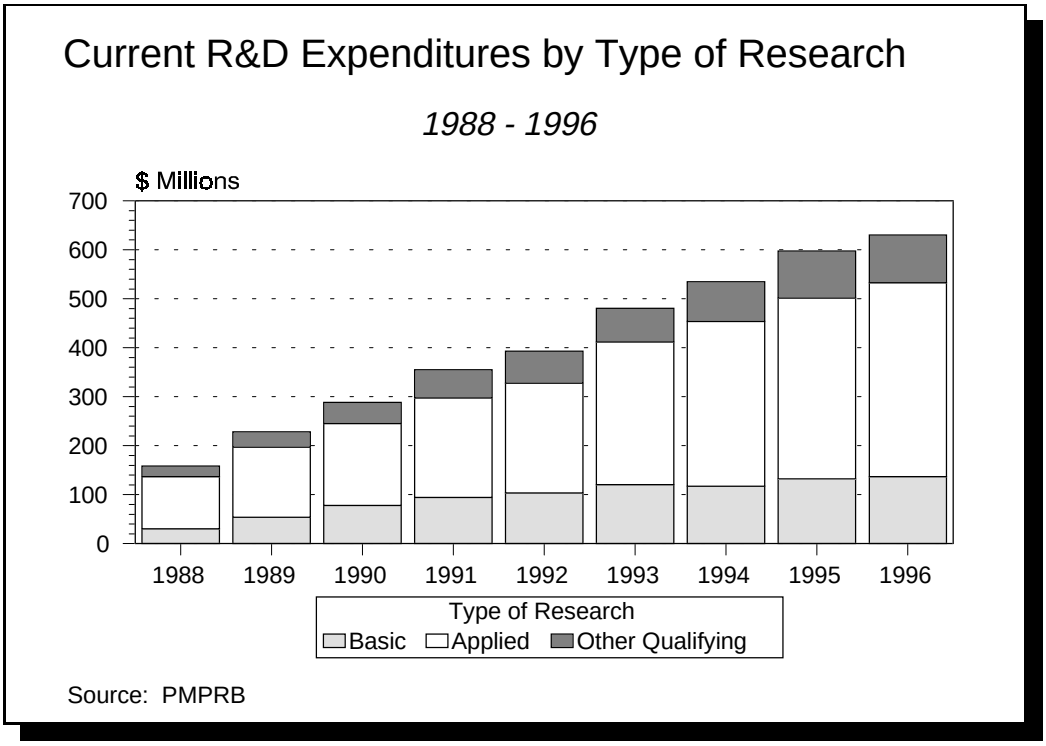
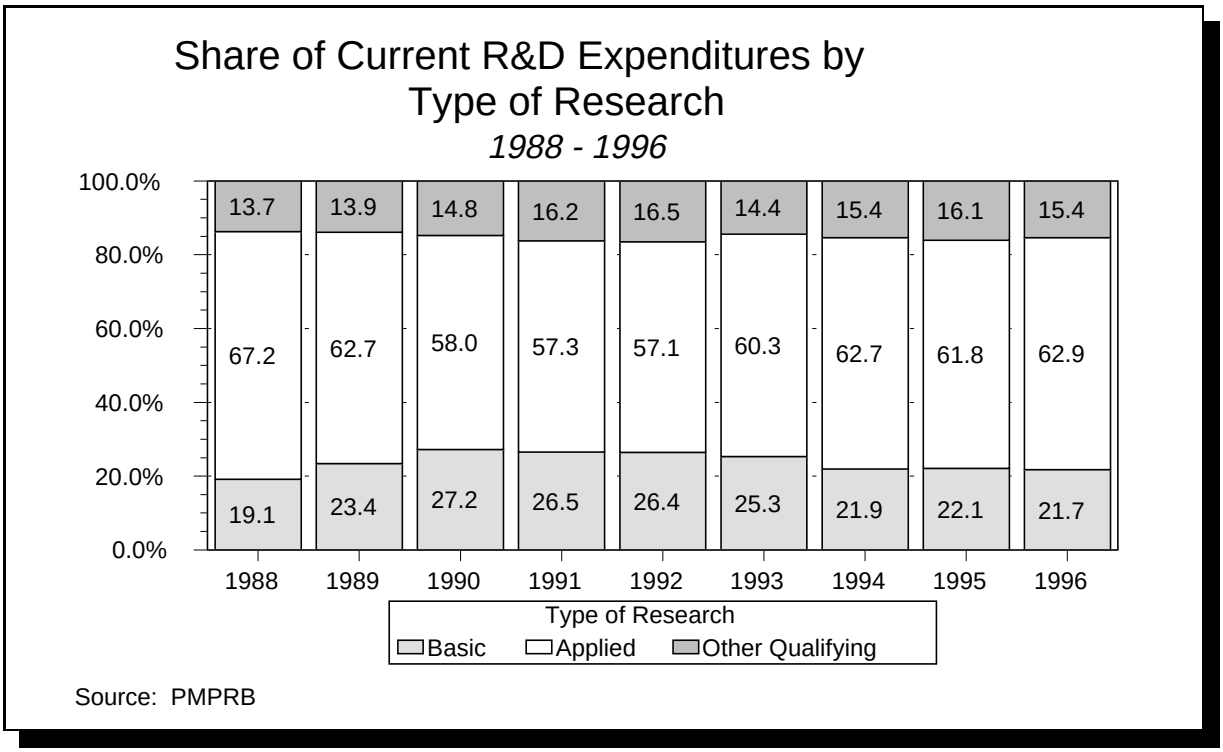


FIGURE 16



While spending on basic research went up by 3.5% in 1996, its share of total R&D declined from 22.1% in 1995 to 21.7% in 1996. Spending on basic research, as a percentage of total current R&D expenditures, declined from greater than 25% of the total from 1990 to 1993 to approximately 22% since then.

Pharmaceutical patentees may report their expenditures on research they conduct themselves (intra-mural) and research performed by others, including universities and hospitals and other manufacturers (extra-mural). Table 7 presents the current R&D expenditures by R&D performer and identifies the intra-mural and extra-mural expenditures. Most R&D was carried out by patentees. In 1996, 55.6% of R&D expenditures was directed to R&D performed by the patentee, compared with 57.0% in 1995. Expenditures on R&D performed by other companies on behalf of patentees incurred the largest increase, from $61.4 million in 1995 to $70.3 million in 1996, a 14.5% increase. Expenditures on R&D performed by universities and hospitals increased by 11.9% to $146.8 million from 1995. The category "others" includes individuals, organizations such as private clinics, and federal and provincial governments. This category incurred a decrease of 3.3%.

TABLE 7

Current R&D Expenditures* by R&D Performer, 1995 and 1996

R&D Performer	1996		1995[r]		Change 1996 / 1995 %
	$M	%	$M	%	
Intra-mural					
- Patentees	350.6	55.6	340.7	57.0	2.9
Extra-mural					
- Universities and Hospitals	146.8	23.3	131.2	21.9	11.9
- Other Companies	70.3	11.2	61.4	10.3	14.5
- Others	62.4	9.9	64.5	10.8	-3.3
Total	630.1	100.0	597.8	100.0	5.4

Source: PMPRB

***** Current expenditures exclude capital equipment and depreciation expenditures.

[r] Revised

In 1996, as in previous years, most of the R&D expenditures of pharmaceutical patentees were funded internally. Table 8 shows that in 1996, more than 98% of all patentees' R&D was funded by internal funds and funds provided by associated companies. The share of funding by governments and others declined to 0.7% and 0.9%, respectively.

TABLE 8

Total R&D Expenditures* by Source of Funds, 1995 and 1996

Source of Funds	1996		1995[r]		Change 1996 / 1995 %
	$M	%	$M	%	
Company Funds	654.4	98.4	608.7	97.3	7.5
Federal/Provincial Governments	4.7	0.7	7.6	1.2	-38.2
Others	6.2	0.9	9.2	1.5	-32.6
Total	665.3	100.0	625.5	100.0	6.4

Source: PMPRB

***** Total expenditures include capital equipment and allowable depreciation.

[r] Revised

In 1996, R&D spending increased in all regions except Québec. The largest increases occurred in the Atlantic and Western provinces, by 31.0% and 23.7%, respectively. There was no significant change in the regional distribution of R&D spending in 1996. As shown in Table 9, almost 90% of total expenditures continued to be made in Ontario and Québec. Table 11, on page 51, lists the current R&D expenditures by province and by R&D performer for 1996.

TABLE 9

Current R&D Expenditures* by Location, 1995 and 1996

Location of R&D	1996		1995[r]		Change 1996 / 1995 %
	$M	%	$M	%	
Atlantic Provinces	11.0	1.8	8.4	1.4	31.0
Québec	264.7	42.0	266.3	44.6	-0.6
Ontario	286.1	45.4	267.9	44.8	6.8
Western Provinces	68.3	10.8	55.2	9.2	23.7
Total	630.1	100.0	597.8	100.0	5.4

Source: PMPRB

***** Current expenditures exclude capital equipment and depreciation expenditures.

[r] Revised

TABLE 10

Ratios of R&D Expenditures to Sales Revenues by Reporting Patentee[1], 1995 and 1996

Company	R&D-to-Sales Ratio (%)	
	1996	1995
3M Pharmaceuticals, 3M Canada Inc.	2.0	0.9
Abbott Laboratories, Limited	1.9	1.8
Alcon Canada Inc.	0.02	0.02
Allergan Inc.	15.6	3.9
Alpha Therapeutic Corporation	0.0	0.0
Altimed Pharmaceuticals Company	0.0	[2]

Company	R&D-to-Sales Ratio (%)	
	1996	1995
Amersham Canada Limited	1.2	2.2
Amgen Canada Inc.	99.9[3]	101.0[3] (revised)
Astra Pharma Inc.	13.9	10.1
Ayerst Veterinary Laboratories	0.8	1.9
Baxter Corporation	0.2	0.2
Bayer Inc.	8.7	9.3
Bayer Inc., Agriculture Division	4.7	5.3
Berlex Canada Inc.	8.0	6.3
Block Drug Company (Canada) Ltd.	0.0	0.0
Boehringer Ingelheim (Canada) Ltd.	37.3	37.7
Boehringer Mannheim Canada Ltd.	8.0	15.2
Bracco Diagnostics Canada Inc. (not a patentee in 1995)	0.0	
Bristol-Myers Squibb Pharmaceutical Group	11.9	13.4
Canderm Pharmacal Ltd.	2.5	0.0
Cangene Corporation	271.5[3]	159.0[3]
Carter-Horner Inc. (formerly Frank W. Horner Inc.)	6.0	4.9
CIBA-Geigy Canada Ltd.	7.6	7.9
Connaught Laboratories Limited	68.8	75.1

Company	R&D-to-Sales Ratio (%)	
	1996	1995
Dahi Animal Health Inc. (not a patentee in 1995)	0.0	
Dermik Laboratories Canada Inc. (not a patentee in 1995)	0.0	
Draxis Health Inc.	10.9	15.0
Du Pont Merck Pharma Inc.	9.4	11.5
Eli Lilly Canada Inc.	12.2	11.0
Fabrigen Inc.	0.0	0.0
Ferring Inc.	2.5	5.4
Fournier Pharma Inc. (not a patentee in 1995)	11.1	
Fujisawa Canada Inc.	17.9	0.3
Galderma Canada Inc.	0.0	0.0
GenDerm Canada Inc.	0.9	1.4
Glaxo Wellcome Inc.	11.5	13.6
Hoechst Marion Roussel Canada Inc.	15.1	15.3
Hoffmann-La Roche Limited	10.2	16.3
ICN Canada Limited	7.0	8.1
Immuno (Canada) Ltd.	0.8	3.9
Janssen-Ortho Inc.	10.6	[4]
Johnson & Johnson Merck (not a patentee in 1995)	0.05	

Company	R&D-to-Sales Ratio (%)	
	1996	1995
Jouveinal Inc.	2.8	2.8
Leo Laboratories Canada Ltd.	8.7	6.0
Ligand Pharmaceuticals	98.8[3]	22.0
Liposome Company Inc.	0.0	0.0
Mallinckrodt Medical Inc.	1.3	1.7
Mallinckrodt Veterinary Inc.	1.3	3.8
McNeil Consumer Products Company	2.5	2.1
Merck Frosst Canada Inc.	14.4	15.6
Nextar Pharmaceuticals Inc. (not a patentee in 1995)	0.0	
Novo Nordisk Canada Inc.	1.4	2.3
Organon Canada Ltd.	2.2	1.4
Pfizer Canada Inc. (includes Norden Laboratories)	11.3[5]	7.7
Pharmacia Upjohn Inc.	11.6	[6]
Pharmascience Inc.	13.4	12.0
Procter & Gamble Pharmaceuticals Canada, Inc.	14.1	22.2
Purdue Frederick	7.9	5.9
Rhône-Poulenc Rorer Canada Inc.	10.1	8.7[7]
Sandoz Canada Inc.	12.0	12.1

Company	R&D-to-Sales Ratio (%)	
	1996	1995
Sanofi Winthrop	11.8	14.5
Schering Canada Inc.	7.1	9.1
Searle Canada Inc.	6.2	8.3
Servier Canada Inc.	10.0	8.5
SmithKline Beecham Pharma Inc.	9.0	9.0
Solvay Kingswood Inc.	14.2	8.5
Warner-Lambert Canada Inc. (Parke-Davis)	17.6	20.0
Warner-Wellcome Consumer Health Products	2.4	3.6
Westwood-Squibb, Division of Bristol-Myers Squibb Canada Inc.	0.5	1.6
Wyeth-Ayerst Canada Inc.	12.6	16.4
Yamanouchi Pharmaceutical Co., Ltd.	0.0	0.0
Zeneca Pharma Inc.	7.6	9.6[8]

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.

[2] Syncare Pharmaceutical Inc. and Kenral Inc. merged in 1996 to form Altimed Pharmaceuticals Company. The R&D-to-sales ratio for Kenral Inc. was 0.0% in 1995. With respect to Syncare Pharmaceutical Inc., in 1995, they were included with Hoffmann-La Roche Limited.

[3] These ratios have been verified with the firm and are due to the fact that funding for R&D expenditures was provided by associated companies.

[4] Formerly under Johnson & Johnson Pharmaceutical Companies in Canada. The R&D-to-sales ratio for Johnson & Johnson Pharmaceutical Companies was 11.0% in 1995.

[5] Pfizer Canada Inc. includes Pfizer Animal Health, formerly known as SmithKline Beecham Animal Health. The R&D-to-sales ratio for Pfizer Canada Inc. and Pfizer Animal Health are, respectively, 13.4% and 2.7%.

[6] Pharmacia Inc. and The Upjohn Company of Canada merged in 1996. The R&D-to-sales ratio for Pharmacia Inc. and The Upjohn Company of Canada were, respectively, 13.9% and 8.8% in 1995.

[7] Rhône-Poulenc Rorer Canada purchased Fisons Corporation. The R&D-to-sales ratio for Rhône-Poulenc Rorer Canada and Fisons Corporation were, respectively, 8.7% and 1.4% in 1995.

[8] Zeneca Pharma Inc. purchased Ohmeda, Division of Canadian Oxygen Limited. The R&D-to-sales ratio for Zeneca Pharma Inc. and Ohmeda, Division of Canadian Oxygen Limited were, respectively, 9.6% and 1.4% in 1995.

TABLE 11 **Current R&D Expenditures by Province and by R&D Performer, 1996**

Province		R&D Performer						Percentage of Expenditures
		Patentees	Other Companies	University	Hospitals	Others	Total	
Newfoundland	$(000)	782.50	106.18	529.70	456.92	324.39	2,199.68	0.35
	%	35.6	4.8	24.1	20.8	14.7	100	
Prince Edward Island	$(000)	0.70	50.31	93.66	8.01	110.75	263.43	0.04
	%	0.3	19.1	35.6	3.0	42.0	100	
Nova Scotia	$(000)	526.12	693.78	2,148.55	2,487.02	1,414.19	7,269.64	1.15
	%	7.2	9.5	29.6	34.2	19.5	100	
New Brunswick	$(000)	51.35	243.54	111.83	227.93	647.77	1,282.42	0.20
	%	4.0	19.0	8.7	17.8	50.5	100	
Quebec	$(000)	176,115.62	34,388.09	10,037.26	25,127.90	19,014.45	264,683.32	42.01
	%	66.5	13.0	3.8	9.5	7.2	100	
Ontario	$(000)	161,014.82	26,697.01	16,317.57	50,859.42	31,215.20	286,104.02	45.40
	%	56.3	9.3	5.7	17.8	10.9	100	
Manitoba	$(000)	5,283.23	890.31	1,107.26	2,530.09	1,527.39	11,338.28	1.80
	%	46.6	7.9	9.8	22.3	13.5	100	
Saskatchewan	$(000)	343.11	695.26	2,074.94	1,769.78	1,198.23	6,081.31	0.97
	%	5.6	11.4	34.1	29.1	19.7	100	
Alberta	$(000)	3,507.43	3,896.05	10,197.22	7,882.69	4,055.23	29,538.62	4.69
	%	11.9	13.2	34.5	26.7	13.7	100	
British Columbia	$(000)	3,022.52	2,663.30	5,498.07	7,363.52	2,817.35	21,364.77	3.39
	%	14.1	12.5	25.7	34.5	13.2	100	
Yukon & N.W.T.	$(000)	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	%	0.0	0.0	0.0	0.0	0.0	0.0	
Canada	$(000)	350,647.38	70,323.82	48,116.05	98,713.28	62,324.96	630,125.49	100.0
	%	55.6	11.2	7.6	15.7	9.9	100	

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.

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* and the Compendium of Guidelines, Policies and Procedures, or contact the PMPRB.

Active Ingredient: Chemical responsible for the claimed pharmacologic effect of a drug product.

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

ATC: Anatomical Therapeutic Chemical classification system that divides drugs into different groups according to their site of action and therapeutic and chemical characteristics. This system is used as a guide for selecting comparable medicines for purposes of price review.

Dedication of Patent: A practice whereby a patentee notifies the Commissioner of Patents that it has surrendered its rights and entitlements flowing from the patent for the benefit of the public to use and enjoy (PMPRB Bulletin 15, January 1995, p.4).

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 Drug Regulations*. The DIN is assigned using information in the following areas: manufacturer of the product; active ingredient(s); strength of active ingredient(s); pharmaceutical dosage form; brand/trade name; and route of administration.

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

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.)

Drug Product, New: A new drug product is one for which the introductory price is under review. Drug products are considered new in the year during which they are introduced in Canada. For price review purposes, new drug products for 1996 are those introduced between December 1, 1995 and November 30, 1996. 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.)

Emergency Drug Release (EDR) Program: A program operated by Health Canada to give practitioners access to drugs that are not approved or otherwise available for sale in Canada. Health Canada may authorize the sale of a quantity of drug for use in the treatment of a patient under the care of that practitioner.

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

General Public (GP) Number: A number that the Health Protection Branch of Health Canada assigns to proprietary medicines that are registered according to the requirements of Division 10 of the *Food and Drug Regulations*. These products may be sold in non-pharmacy outlets in certain provinces.

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.

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

Medicine: Any substance or mixture of substances made by any means, whether produced biologically, chemically, or otherwise, that is applied or administered *in vivo* in humans or in animals to aid in the diagnosis, treatment, mitigation or prevention of disease, symptoms, disorders, abnormal physical states, or modifying organic functions in humans and or animals, however administered.

For greater certainty, this definition includes vaccines, topical preparations, anaesthetics and diagnostic products used *in vivo*, regardless of delivery mechanism (e.g., transdermal, capsule form, injectable, inhaler, etc.). This definition excludes medical devices, *in vitro* diagnostic products and disinfectants that are not used *in vivo* (Compendium of Guidelines, Policies and Procedures, Introduction, subsection 1.5).

Notice of Compliance (NOC): A notice in respect of a medicine issued by the Health Protection 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.

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 the patentee the exclusive right to make, sell or otherwise exploit the invention for the term of the patent.

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;"

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

Research and Development — Applied Research: 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.

Research and Development — Basic Research: Work that advances scientific knowledge without a specific application in view.

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.

Research and Development — Preclinical Research: Tests on animals to evaluate the pharmacological and toxicological effects of medicines.

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.

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.