PERFORMANCE REPORT

Patented Medicine Prices Review Board

For the
period ending
March 31, 1997

Improved Reporting to Parliament —
Pilot Document

Canada

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Foreword

On April 24, 1997, the House of Commons passed a motion dividing what was known as the *Part III of the Estimates* document for each department or agency into two documents, a *Report on Plans and Priorities* and a *Departmental Performance Report.* It also required 78 departments and agencies to table these reports on a pilot basis.

This decision grew out of work by Treasury Board Secretariat and 16 pilot departments to fulfil the government's commitments to improve the expenditure management information provided to Parliament and to modernize the preparation of this information. These undertakings, aimed at sharpening the focus on results and increasing the transparency of information provided to Parliament, are part of a broader initiative known as "Getting Government Right".

This ***Departmental Performance Report*** responds to the government's commitments and reflects the goals set by Parliament to improve accountability for results. It covers the period ending March 31, 1997 and reports performance against the plans presented in the department's *Part III of the Main Estimates* for 1996-97.

Accounting and managing for results will involve sustained work across government. Fulfilling the various requirements of results-based management – specifying expected program outcomes, developing meaningful indicators to demonstrate performance, perfecting the capacity to generate information and report on achievements – is a building block process. Government programs operate in continually changing environments. With the increase in partnering, third party delivery of services and other alliances, challenges of attribution in reporting results will have to be addressed. The performance reports and their preparation must be monitored to make sure that they remain credible and useful.

This report represents one more step in this continuing process. The government intends to refine and develop both managing for results and the reporting of the results. The refinement will come from the experience acquired over the next few years and as users make their information needs more precisely known. For example, the capacity to report results against costs is limited at this time; but doing this remains a goal.

This report is accessible electronically from the Treasury Board Secretariat Internet site: http://www.tbs-sct.gc.ca/tb/key.html

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Patented Medicine Prices Review Board

Performance Report

For the
period ending
March 31, 1997

Minister of Health Canada

Contents

Section I Chairperson's Message

I am pleased to present the Patented Medicine Prices Review Board's Performance Report and to offer a review of the PMPRB's effectiveness in fulfilling its mandate to protect consumers by limiting prices of 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 without federal price regulation and that price increases have been 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%. During that same period, total expenditures on drugs, which reflect the total consumption of both patented and non-patented drugs, continued to rise in Canada increasing to $10.8 billion in 1996, up 2.7% from 1995.

The mandate of the PMPRB 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.

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 has carried 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 *Patented Medicines 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 has experienced the largest increase in R&D expenditures since 1987, 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%.

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. 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

Section II Overview

1.0 Mandate, Role and Responsibility

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 PMPRB's Annual Report is tabled in Parliament each year and includes a review of the PMPRB's major activities, analysis 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. The Board is also responsible for inquiring into any matter which may be referred to it by the Minister of Health.

The PMPRB protects consumer interests and contributes to Canadian health care by regulating the prices charged by manufacturers of patented medicines to ensure they are not excessive.

The PMPRB's jurisdiction includes both prescription and non-prescription patented medicines sold in Canada for both human and veterinary use.

The price reviewed by the PMPRB is the price at which the manufacturer sells the product to wholesalers, hospitals or pharmacies. This manufacturer's price does not include wholesale or retail markups or dispensing fees.

The sale of patented drugs represents 45% of the sale of all drugs[1]. The Board does not regulate the prices of non-patented drugs, including generic drugs sold under compulsory licences.

2.0 Program Objective

To protect consumer interests and contribute to Canadian health care by ensuring that prices of patented medicines are not excessive.

[1] PMPRB Ninth Annual Report for the Year Ended December 31, 1996

3.0 Strategic Priorities

In addition to its ongoing statutory compliance and enforcement activities, the priorities of the PMPRB for the period of 1996-97 included the following objectives:

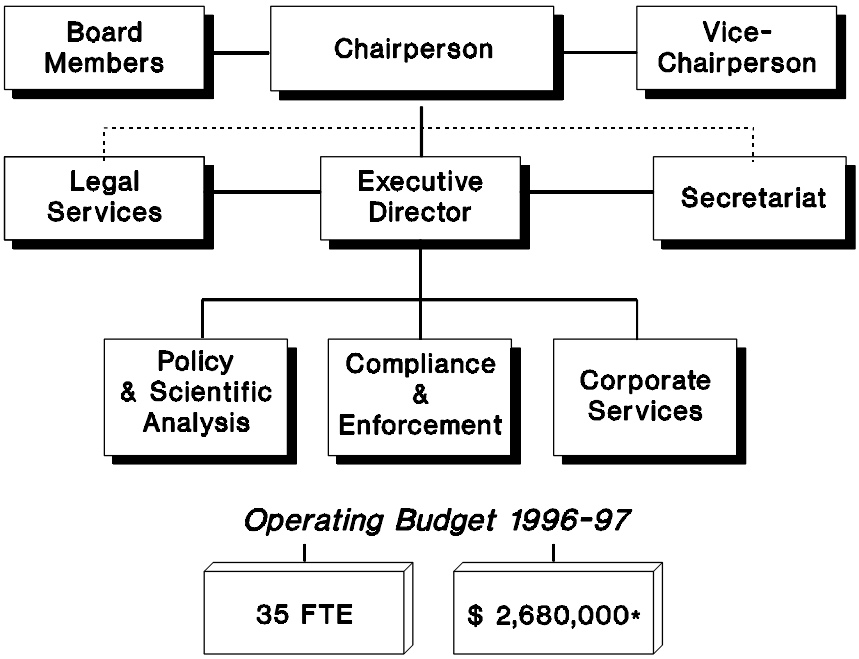
- To evaluate its price review process in order to improve its effectiveness and efficiency;
- To review its statutory requirements and its policies regarding the regulation of patented drugs for veterinary use with a view to considering the potential for deregulating veterinary drugs; and
- To provide information and analysis as may be required during the Parliamentary Review of the Patent Act in 1997.

4.0 Organization and Composition

Business Line: The PMPRB has one business line which matches the program, the Patented Medicine Prices Review Program.

Organization Structure: The PMPRB reports to Parliament through the Minister of Health. 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 Scientific Analysis, the Director of Corporate Services, the Secretary to the Board and Senior Counsel.

Figure 1: Organizational Structure of the PMPRB for 1996-97[2]



* excludes statutory benefits of $289,000

[2] Minor changes in the organizational structure took place in June 1997.

Section III PMPRB Performance

1.0 Performance Expectations

1.1 Comparison of Total Planned Spending to Actual Expenditures, 1996-97 ($ millions)

Business Line	Human Resources (Full Time Equivalent)	Operating[1]	Capital	Voted Grants and Contri-butions	Subtotal: Gross Voted Expendi-tures	Statutory Grants and Contri-butions	Total Gross Expendi-tures	Less: Revenue Credited to the Vote	Total Net Expendi-Tures
PMPRB	35	2.947	0.022	0	2.969	0	2.969	0	2.969
	33	3.066	0.035	0	3.101	0	3.101	0	3.101
Totals[2]	35	2.947	0.022	0	2.969	0	2.969	0	2.969
	33	3.066	0.035	0	3.101	0	3.101	0	3.101

Other Revenues and Expenditures	
Revenue Credited to the Consolidated Revenue Fund	0
	0
Cost of services provided by other departments	0.645
	0.645
Net Cost of the Program	3.614
	3.746

Note: Shaded Numbers denote actual expenditures in 1996-97

[1] Operating includes contributions to employee benefit plans.

[2] The difference between the Main Estimates 1996-97 and Actuals is due to:
- Supplementary Estimate 'A' - 5% carry forward of $144K from 1995-96
- Supplementary Estimate 'B' - 20% transfer factor from Salary to Non-Salary for $34K

1.2 PMPRB Planned versus Actual Spending ($ millions)

Business Lines	Actual 1993-94	Actual 1994-95	Actual 1995-96	Total Planned 1996-97	Actual 1996-97[1]
PMPRB	3.137	3.016	3.154	2.969	3.101
Total	3.137	3.016	3.154	2.969	3.101

[1] Actual funds for 1996-97 exceeded planned funds as a result of:

- Supplementary Estimate 'A' - 5% Carry Forward of $144K from 1995-96
- Supplementary Estimate 'B' - 20% transfer factor from Salary to Non-Salary for $34K

1.3 Summary of Performance Expectations

Patented Medicine Prices Review Board	
to provide Canadians with:	to be demonstrated by:
assurance that manufacturers' prices for patented medicines sold in Canada are not excessive	review of the manufacturer's prices of 100% of the patented medicines sold in Canada each year.
	favourable comparison of the annual percentage change in the Patented Medicine Price Index (PMPI) to the annual percentage change in the Consumer Price Index (CPI).
	manufacturers' prices for new and existing patented medicines no greater than manufacturers' prices charged in other countries.
	percentage of patented medicines priced within the guidelines.
information on trends in manufacturers' prices of all medicines in Canada.	complete and accurate reports on: ▸ trends in manufacturers' prices and volume of patented drug products sold; and ▸ trends in manufacturers' prices of all drug products -- patented and non-patented.
information on the pharmaceutical research-and-development expenditures of patentees in Canada.	complete and accurate publication in the Annual Report of: ▸ the ratio of R&D expenditures to sales revenues for each patentee and the industry as a whole; and ▸ R&D expenditure by location and by type of research.

2.0 Summary of Performance for 1996[3]

The following table summarizes the PMPRB's performance as of December 31, 1996 for each of the Key Results.

[3] Under the *Patented Medicines 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. Therefore, the Performance Report provides the results of its review of prices on a calendar year basis.

Patented Medicine Prices Review Board Performance Summary	
Key Results	**Performance Measures**
Non-excessive prices for patented medicines sold in Canada	New drug products: price review completed on 81 of the 84 products introduced in 1996 - 96% Existing drug products: price review completed on the 849 of the 853 drug products sold during 1996 - 99%
	Patented Medicine Price Index (PMPI) declined by 2.1% from its level in 1995 while the Consumer Price Index (CPI) increased by 1.6%
	In 1996, prices in Canada were, on average, below the median international prices of the same drug products for the second straight year
	New drug products: prices of 100% of all drugs reviewed were found to comply with the Guidelines Existing drug products: prices of 100% of all drugs reviewed during 1996 were found to comply with the Guidelines
Report on the price trends of all medicines in Canada	• the prices of patented medicines as measured by the PMPI, declined by 2.1% from their levels in 1995
	• the pharmaceutical component of the IPPI increased by 0.2% in 1996
Report on the pharmaceutical research-and-development expenditures of patentees in Canada	• 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 • patentees' R&D expenditures increased from $623.9 million in 1995 to $665.3 million in 1996

The pages following provide further details on the PMPRB's performance.

3.0 PMPRB Performance

In 1996-97, the PMPRB was responsible for regulating the $3 billion patented pharmaceutical industry in Canada with a budget of approximately $3 million. As demonstrated by the performance reported in the following section, the PMPRB continues to fulfill its mandate of ensuring the prices of patented medicines are not excessive in Canada.

3.1 Progress on Strategic Priorities

3.1.1 Evaluation of the PMPRB Price Review Process

A number of initiatives to simplify the PMPRB price review process were effected in 1996 in order to provide greater transparency and efficiency of processes. The PMPRB has streamlined its process in relation to pricing cycles, base-CPI figures, the criteria for commencing an investigation and changes to the CPI forecast methodology. Details of these initiatives are available in the Bulletin, Issue No. 19, July 1996.

The PMPRB consulted on a proposal to publish information on the PMPRB's therapeutic class comparison (TCC) for new drug products. The majority of responses suggested that the potential benefits in publishing the TCC did not appear to justify pursuit of this initiative. As such, the PMPRB decided to postpone further consideration of this proposal.

3.1.2 Regulation of Veterinary Drugs

In 1995-96, the PMPRB decided to commence a review of the statutory requirements and its policies regarding the regulation of patented drugs for veterinary use with a view to deregulating veterinary drug prices. No complaints with respect to the prices of veterinary drugs had ever been raised nor were the prices of any veterinary drugs the subject of an investigation resulting in a requirement for a Voluntary Compliance Undertaking (VCU) or a hearing. With budget cuts being effected that year and in following years, it was seen as a potential area of savings. Preliminary evaluation showed, however, that the savings that would accrue from limiting the regulation of veterinary drugs were not significant. Subsequently, work on this initiative was deferred in light of higher priorities.

3.1.3 Parliamentary Review of the Patent Act in 1997

The PMPRB conducted several studies to provide information and analysis in anticipation of the Parliamentary Review by the Standing Committee on Industry in 1997. These studies included the *Impact of Federal Regulation of Patented Drug Prices* and *A Comparison of Pharmaceutical R&D Spending in Canada and Selected Countries*. The PMPRB's studies and evidence before the

Committee did not touch on issues related to compulsory licensing, the Notice of Compliance (NOC) Regulations or other provisions of the Patent Act not related to its mandate.

On April 24, 1997, the Standing Committee on Industry issued its recommendations following its review of Bill C-91. Its report underscored the concerns of witnesses who appeared during its public hearings with respect to drug prices and their impact on the health care system, while touching on a number of key areas directly affecting the role and mandate of the PMPRB.

Among the recommendations directly related to the PMPRB was a recommendation that the Government review and strengthen the mandate of the PMPRB and that the PMPRB consult with consumers, health care professionals, experts and the provinces to assess its current statistical reporting and find out what other information it could provide to the public.

In its reply of April 25, 1997, the Government reaffirmed the need to protect intellectual property rights, enhance R&D activities and ensure affordable drug prices. It agreed with the Committee on the need to strengthen the PMPRB and to consider broadening its mandate to include non-patented drugs. It also agreed to work with the PMPRB to review the mechanisms for regulating the prices of patented drugs and to improve the transparency of the price review process.

Subsequent to the release of the Standing Committee's report, the Board has carried 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 consult on various issues and recommendations contained in the Standing Committee's report.

3.2 Non-Excessive Prices for Patented Medicines in 1996

3.2.1 New Drug Products[4]

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.

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

[4] 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 *Patented Medicine Regulations* and the manner of calculating benchmark prices, drug products introduced in December are considered to have been introduced in the following year.

within the Guidelines. The remaining three products (two medicines) are under review.

3.2.2 Price Review of Existing Drug Products[5]

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.

3.2.3 Voluntary Compliance Undertakings[6]

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.

3.2.4 Public Hearings

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

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 was delayed by legal challenges which were resolved in the PMPRB's favour. Following the hearing on the alleged excessive pricing issue, the Board issued its decision on July 26, 1996. The Board found that ICN had been selling Virazole at an excessive price and ordered it to lower the price of Virazole to a non-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

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5 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 *Patented Medicines Regulations*, namely France, Sweden, Switzerland, Germany, Italy, the United Kingdom and the United States.

6 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.

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.

This decision marks the Board's first findings of excessive price and a policy of excessive pricing following a hearing.

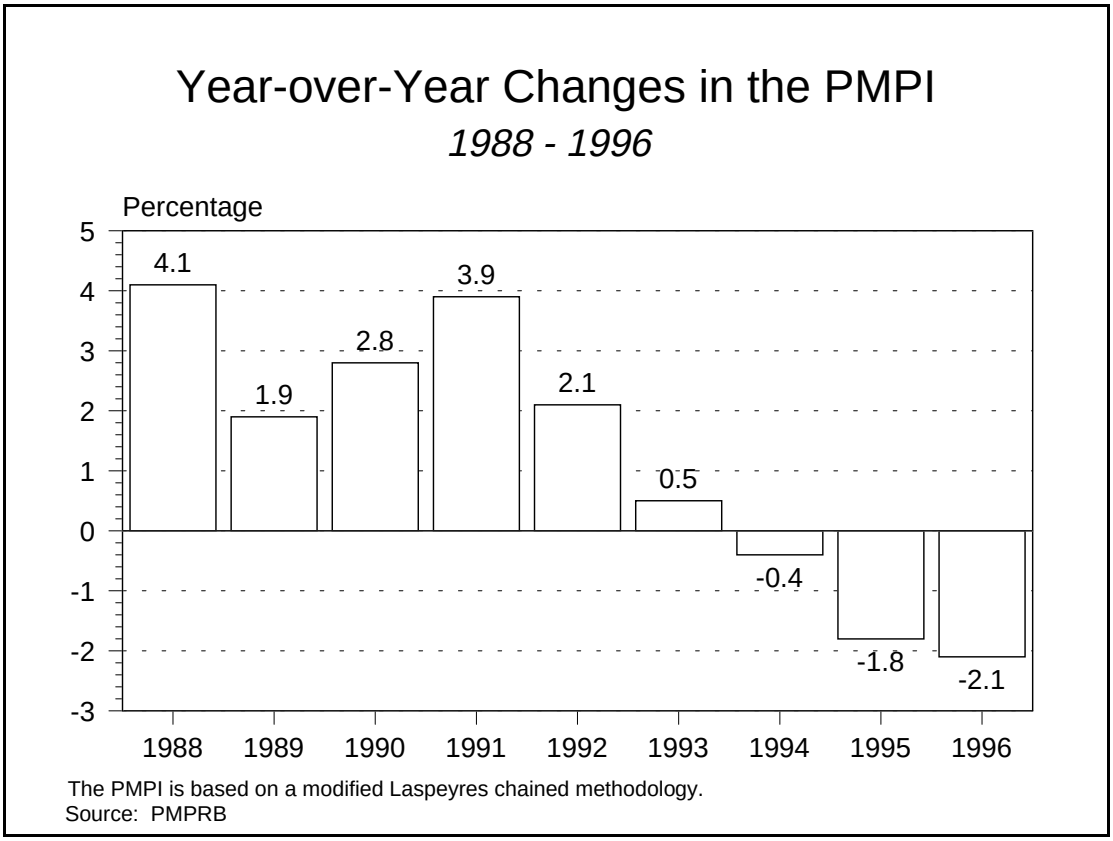
3.3 Trends in Manufacturers' Prices of Medicines in 1996

3.3.1 Trends in Manufacturers' Prices of Patented Drugs[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.

[7] 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.

FIGURE 2: Year-over-Year Changes in the PMPI, 1988 - 1996



3.3.2 Trends in Volume of Patented Drugs

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. 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.

3.3.3 Trends in Manufacturers' Prices 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.

In 1996, the IPPI (pharma)[9] 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.

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.

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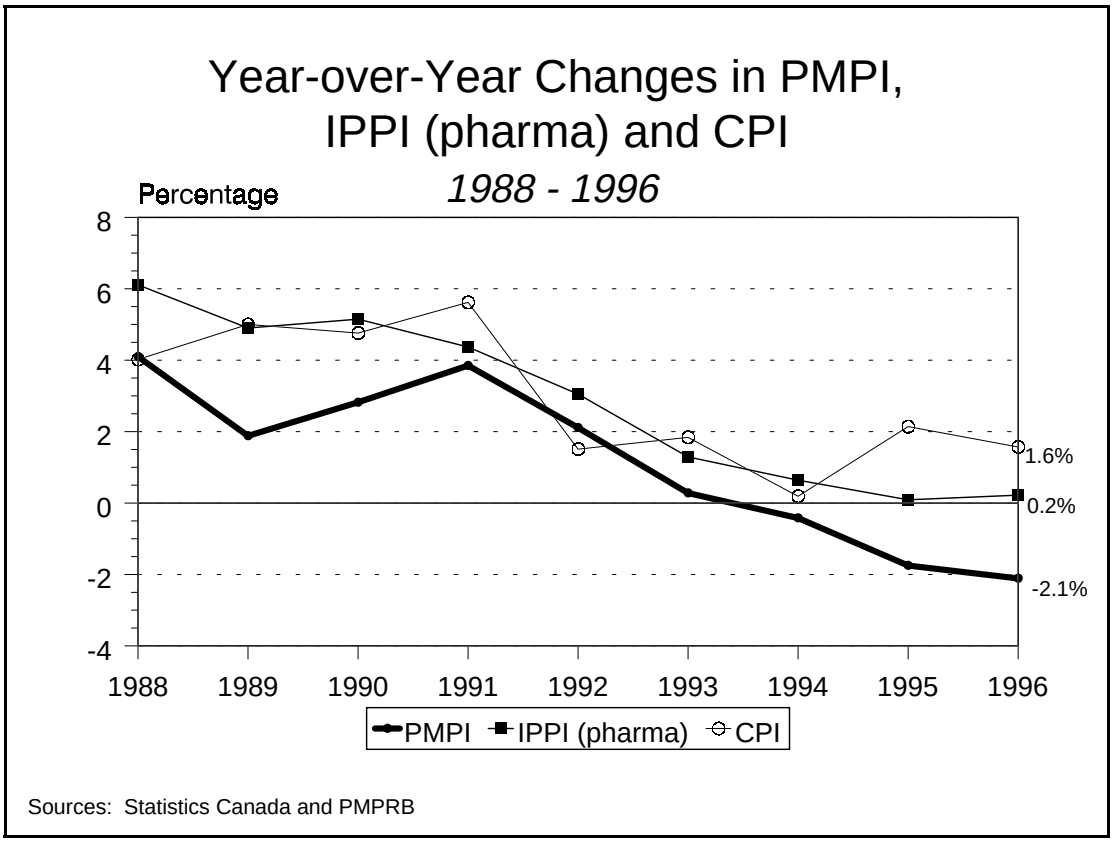
[8] To facilitate and encourage compliance by patentees, the PMPRB's CPI-adjusted methodology uses the forecast rate of CPI inflation published by the Department of Finance. The methodology is self-correcting over time. The forecast CPI inflation rate for 1992 had been 3.2%, but the actual rate was 1.5%.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

[9] 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.

FIGURE 3: Year-over-Year Changes in PMPI, IPPI (pharmaceutical) and CPI, 1988 - 1996



Sources: Statistics Canada and PMPRB

3.4 Research-and-Development Expenditures of Patentees in 1996

Patentees' research and development expenditures increased from $623.9 million in 1995 to $665.3 million in 1996, but the ratio of R&D expenditures to sales revenues for the pharmaceutical industry fell from 11.7% in 1995 to 11.4% in 1996. Details of the R&D expenditures, including the R&D to sales ratio for each patentee and the R&D expenditures by location and by type of research, are reported in the Ninth Annual Report, Analysis of Research-and-Development (R&D) Expenditures, page 27.

4.0 Key Reviews

Results of Program Evaluation Studies
None
Results of Internal Audits
None
Other Key Reviews
The Impact of Federal Regulation of Patented Drug Prices, PMPRB, February 1997 • From 1988 to 1995, estimated savings to Canadian health care as a result of federal regulation was 24 to 29% or $2.8 to $4.2 Billion .
Deloitte and Touche report " Review of Drug Price Information and Practices Used by the PMPRB, April 14, 1997 • The report found that the practices used in the PMPRB's review of drug information were satisfactory.
Standing Committee on Industry Report, April 24, 1997 • Several recommendations were made affecting the role and mandate of the PMPRB including to review and strengthen its mandate.
A Comparison of Pharmaceutical Research and Development Spending in Canada and Selected Countries, 1997 • The paper reported that although Canada has experienced the largest increase in R&D expenditures since 1987, it continues to lag behind the other countries in terms of total R&D spending and the average R&D-to-sales ratio.

Section IV Supplementary Information

1.0 Listing of Statutory and Agency Reports for 1996-97

Statutory

PMPRB Ninth Annual Report, For the Year Ended December 31, 1996

Other

The Impact of Federal Regulation of Patented Drug Prices, February 1997

A Comparison of Pharmaceutical Research and Development Spending in Canada and Selected Countries, 1997

2.0 Contacts for Further Information

Sylvie Dupont-Kirby, Secretary to the Board, PMPRB (613) 954-8299

Website: http://www.pmprb-cepmb.gc.ca

3.0 Financial Summary Tables

3.1 Summary of Voted Appropriations Authorities for 1996-97 - Part II of the Estimates Financial Requirements by Authority ($ millions)

Vote	(million of dollars)	1996-97 Main Estimates	1996-97 Actual[1]
	Program		
	Patented Medicine Prices Review Board		
30	Program expenditures	2.680	2.812
(S)	Contributions to employee benefit plans	0.289	0.289
	Total PMPRB	2.969	3.101

[1] Actual funds for 1996-97 exceeded planned funds as a result of:

- Supplementary Estimate 'A' - 5% Carry Forward of $144K from 1995-96
- Supplementary Estimate 'B' - 20% transfer factor from Salary to Non-Salary for $34K

3.2 Revenues to the Consolidated Revenue Fund (CRF) ($ millions)

Business Lines	Actual 1993-94	Actual 1994-95	Actual 1995-96	Total Planned 1996-97	Actual 1996-97
PMPRB	6.478	3.624	0.087	0.00	0.00
Total Revenues to the CRF	6.478[1]	3.624[1]	0.087[1]	0.00	0.00

[1] The money deposited to the CRF does not represent revenues generated by the PMPRB. This money includes payments made by patentees to the Government of Canada through Voluntary Compliance Undertakings (VCUs) or Board orders to offset excess revenues.

3.3 Legislation Administered by the PMPRB

The Minister shares responsibility to Parliament for the following Acts:

Patent Act R.S.C. 1995, p-4, as amended