ESTIMATES

# Patented Medicine Prices Review Board Canada

## Performance Report

For the period ending
March 31, 2002

Canada

## The Estimates Documents

Each year, the government prepares Estimates in support of its request to Parliament for authority to spend public monies. This request is formalized through the tabling of appropriation bills in Parliament.

The Estimates of the Government of Canada are structured in several parts. Beginning with an overview of total government spending in Part I, the documents become increasingly more specific. Part II outlines spending according to departments, agencies and programs and contains the proposed wording of the conditions governing spending which Parliament will be asked to approve.

The *Report on Plans and Priorities* provides additional detail on each department and its programs primarily in terms of more strategically oriented planning and results information with a focus on outcomes.

The *Departmental Performance Report* provides a focus on results-based accountability by reporting on accomplishments achieved against the performance expectations and results commitments as set out in the spring *Report on Plans and Priorities*.

The Estimates, along with the Minister of Finance's Budget, reflect the government's annual budget planning and resource allocation priorities. In combination with the subsequent reporting of financial results in the Public Accounts and of accomplishments achieved in Departmental Performance Reports, this material helps Parliament hold the government to account for the allocation and management of funds.



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Canadian Government Publishing — PWGSC

Ottawa, Canada K1A 0S9

Catalogue No. BT31-4/64-2002
ISBN 0-660-62143-6

## Foreword

In the spring of 2000, the President of the Treasury Board tabled in Parliament the document "Results for Canadians: A Management Framework for the Government of Canada". This document sets a clear agenda for improving and modernising management practices in federal departments and agencies.

Four key management commitments form the basis for this vision of how the Government will deliver their services and benefits to Canadians in the new millennium. In this vision, departments and agencies recognise that they exist to serve Canadians and that a "citizen focus" shapes all activities, programs and services. This vision commits the Government of Canada to manage its business by the highest public service values. Responsible spending means spending wisely on the things that matter to Canadians. And finally, this vision sets a clear focus on results – the impact and effects of programs.

Departmental performance reports play a key role in the cycle of planning, monitoring, evaluating, and reporting of results through ministers to Parliament and citizens. Departments and agencies are encouraged to prepare their reports following certain principles. Based on these principles, an effective report provides a coherent and balanced picture of performance that is brief and to the point. It focuses on outcomes - benefits to Canadians and Canadian society - and describes the contribution the organisation has made toward those outcomes. It sets the department's performance in context and discusses risks and challenges faced by the organisation in delivering its commitments. The report also associates performance with earlier commitments as well as achievements realised in partnership with other governmental and non-governmental organisations. Supporting the need for responsible spending, it links resources to results. Finally, the report is credible because it substantiates the performance information with appropriate methodologies and relevant data.

In performance reports, departments and agencies strive to respond to the ongoing and evolving information needs of parliamentarians and Canadians. The input of parliamentarians and other readers can do much to improve these reports over time. The reader is encouraged to assess the performance of the organisation according to the principles outlined above, and provide comments to the department or agency that will help it in the next cycle of planning and reporting.

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This report is accessible electronically from the Treasury Board of Canada Secretariat Internet site:
http://www.tbs-sct.gc.ca/rma/dpr/dpre.asp

Comments or questions can be directed to:

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# Patented Medicine Prices Review Board

## Performance Report

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period ending
March 31, 2002

Approved

Minister of Health

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# Section I

# Chairperson's Message

I am pleased to present the 2001 - 2002 Performance Report for the Patented Medicine Prices Review Board (PMPRB). In Canada, policy issues have continued to be dominated by discussions about health care and cost pressures are felt in many areas. According to the Canadian Institute for Health Information (CIHI), pharmaceuticals continue to represent the fastest-growing component of health care costs and accounted for over 15% of total health expenditures in 2001.

In 2001, total sales by drug manufacturers in Canada increased by 15% to $11.5 billion. Patentees reported total factory-gate sales of patented drugs for human use of $7.5 billion. This represents an increase of 18.9% over sales in 2000. Patented drugs now account for 65% of total sales, up from 43.9% in 1995. Increases in sales of drugs have translated to increases in expenditures by public and private drug plans and consumers.

On September 26, 2001, federal, provincial and territorial Health Ministers announced agreement on a multi-faceted approach to better pharmaceutical management. One of these initiatives is the National Prescription Drug Utilization Information System (NPDUIS), a partnership involving CIHI and the PMPRB. In establishing the first national database of publicly-funded drug plans in Canada, the NPDUIS will call on the PMPRB to continue and expand on the analyses of price and expenditure trends and cost drivers of publicly-funded drug plans previously conducted pursuant to a Memorandum of Understanding with the Minister of Health.

In the coming year, the PMPRB's efforts will also remain focused on transparency and consultations on policy and research questions. As reflected in our 2002 - 2005 Research Agenda, a significant example of consultation is the Working Group on Price Review Issues. This Group, consisting of representatives of our main stakeholders, was established in 1999 and has advised the Board on a number of important issues. In 2001, following a period of broader public notice and comment, the PMPRB began to implement most of the Working Group's recommendations to increase the transparency of the review of the prices of new patented medicines. Beginning in 2002, we will publish summaries of the reviews by Board Staff of new active substances, for purposes of applying the Price Guidelines. The Working Group is now continuing its review of the Guidelines.

To support our capacity to better understand the major current and emerging pharmaceutical issues, we conducted a survey of representatives of major stakeholders as part of our annual environmental scan in 2001. In carrying out this survey, we also sought to evaluate our efforts to consult and communicate with our various stakeholders. The results of this initiative were important in a number of ways, including assisting us in our annual planning process and in the development of our annual Research Agenda.

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

Robert G. Elgie

Chairperson

# Section II

# Overview

## 2.1 Mandate

The Patented Medicine Prices Review Board (PMPRB) is an independent, quasi-judicial body created by Parliament in 1987 under the *Patent Act* to protect consumer interests in light of increased patent protection for pharmaceuticals. Its mandate is three-fold:

- to ensure that the prices charged by manufacturers of patented medicines sold in Canada are not excessive;
- to report annually to Parliament on the price trends of all medicines sold in Canada; and
- to report annually to Parliament on the ratio of research and development expenditures to sales by patentees.

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 to ensure they are not excessive. 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 have jurisdiction over the prices of non-patented drugs, including generic drugs sold under compulsory licences; the prices charged by wholesalers and retailers; nor pharmacists' professional fees.

In Canada, Health Canada assesses new medicines to ensure that they conform to the *Food and Drugs Act* and *Regulations*. Formal authorization to market or distribute a medicine is granted through a Notice of Compliance (NOC). A medicine may be temporarily distributed with specified restrictions before receiving a NOC, as an Investigational New Drug or under the Special Access Program (SAP). Patented drugs sold as an Investigational New Drug or under the SAP administered by Health Canada are subject to review by the PMPRB.

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.

## 2.2 Objective

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

## 2.3 Business Line Description

***Patented Medicine Prices Review Board***
The PMPRB receives information on the prices charged by manufacturers of patented medicines in Canada, analyzes the data, and takes action, when required, to effect price reductions. Price reductions are accomplished through:

- voluntary action taken by the patentees;
- formal Voluntary Compliance Undertakings (VCUs) to lower prices and offset excess revenues; or,
- following public hearings in which prices are found to be excessive, through the issuance of remedial orders.

The PMPRB relies on voluntary compliance wherever possible since it is more effective, less time consuming and less costly to all parties. Voluntary compliance by patentees is facilitated by published Guidelines intended to assist companies in setting prices that are not excessive. These Guidelines form part of an education and communication program to inform patentees of compliance requirements and obligations.

The Guidelines are not a rigid set of decision-making rules and are not binding on the Board or on patentees. Rather, they are policies which have been approved by the Board and are used by Board Staff to review the prices being charged by patentees for their products. The Guidelines were developed in consultation with stakeholders including provincial and territorial ministers of health, consumer groups, health care associations and the pharmaceutical industry.

Under the *Patent Act*, the Board is required to consider the prices of medicines in other countries, the prices of other medicines in the same therapeutic class, changes in the Consumer Price Index (CPI), and other factors in determining whether or not the price of a medicine is excessive. The Act allows the Minister of Health, in consultation with provincial ministers of health and others, to make regulations regarding additional factors the Board shall take into consideration in determining if a price is

excessive and to assign additional duties and powers to the PMPRB. Furthermore, it authorizes the Minister of Health to require the Board to conduct inquiries into matters as determined by the Minister.

In 2001, prices of patented medicines increased by 0.1%, well below the increase of 2.6% in the Consumer Price Index (CPI). For further details see the Outcomes Achieved section on page 10.

The PMPRB also reports to Parliament on the price trends of all medicines and on the ratio of pharmaceutical research and development expenditures to sales for the patented pharmaceutical industry and individual patentees in Canada.

## 2.4 Challenges

### *2.4.1 Increase in drug expenditures*

According to its latest figures, the Canadian Institute for Health information (CIHI) has forecasted that total health care expenditures in Canada increased to $102.5 billion in 2001, up 6.9% from 2000. Spending on drugs is forecasted to have grown by 8.6% to $15.5 billion. Although public funding accounts for 72.6% of total health expenditure, it represents a smaller, but growing, share of drug expenditures. CIHI estimates that public spending on prescription drugs grew by 17.6% in 2001 and represented close to 50% of total spending on prescription drugs at the retail level.[1]

Based on filings to the PMPRB by manufacturers, their total sales of pharmaceuticals for human use, both patented and non-patented, in 2001 in Canada are estimated at $11.5 billion, an increase of approximately 15.0% from 2000.[2] In 2001 patentees reported total factory-gate sales of patented drugs of $7.5 billion. This represents an increase of 18.9% over sales in 2000. Patented drugs now account for 65.0% of total sales, up from 43.9% in 1995.

In spite of increased sales, the overall prices of existing drugs have not gone up significantly. Prices of all drugs, and of patented drugs alone, have continued to remain relatively stable throughout the last half-decade.

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1 Canadian Institute for Health Information: *National Health Expenditure Trends 1975-2001*

2 Patentees are required, under the Patented Medicines Regulations, to submit to the PMPRB information showing their annual total pharmaceutical sales for both patented and non-patented drugs in Canada. IMS Health publishes estimated sales of pharmaceuticals by individual firms. Total sales by manufacturers can thus be estimated by adding the total sales reported by patentees and IMS Health estimated sales in Canada of generic drug companies belonging to the Canadian Drug Manufacturers' Association (CDMA).

However, a recent survey conducted by the PMPRB showed that increasing prices of drugs in Canada is still a major concern for Canadians.[3]

### *2.4.2 Patent issues*

The PMPRB is essentially an economic regulatory body. It does not assign or adjudicate patent rights; with the passage of Bill C-91 in 1993, the PMPRB can no longer remove or deny any of the benefits of a patentee. The Board's focus is in protecting the public interest in the pricing of medicines, a task that involves analysis of the economic and therapeutic aspects of drugs. Nonetheless, patent issues have been front and centre in the hearings initiated by the Board. They arise because of questions regarding the extent of the PMPRB's jurisdiction and the strategic behaviour of some patentees to avoid coming under it.

Over the years, the Board has adopted policies concerning its jurisdiction in the case of patent dedication and pending patents. In response to comments by the Auditor General of Canada, the Board stated:

> *The Board is vigilant in watching for evidence of practices, such as patent dedication, to avoid its jurisdiction and will recommend that anti-avoidance measures be incorporated in the Act if necessary.*

### *2.4.3 Federal/Provincial/Territorial Collaboration - National Prescription Drug Utilization Information System*

As expenditures on pharmaceuticals continue to increase faster than other components of health care, federal, provincial and territorial (F/P/T) governments are seeking to address a number of pharmaceutical issues, including drug costs, utilization and efficiency of resource allocation. During the year, the PMPRB continued its longstanding participation, at the request of the Minister of Health, as an observer on the F/P/T Pharmaceutical Issues Committee (PIC).[4]

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[3] During the year, the PMPRB undertook an update of its Environmental Scan and evaluation of the effectiveness of its Consultation and Communications policies. BDO Dunwoody & Associates Ltd. (BDO) assisted in this project and conducted over 20 interviews with major stakeholders. The BDO report is available on the PMPRB website at www.pmprb-cepmb.gc.ca under Publications; Environmental Scan.

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

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

In September 2001, F/P/T ministers of health announced a multi-faceted approach to better pharmaceuticals management including, among other things, the establishment of a National Prescription Drug Utilization Information System (NPDUIS). The NPDUIS is to "provide critical analyses of price, utilization and cost trends; so that Canada's health system has more comprehensive, accurate information on how prescription drugs are being used, and sources of cost increases. In addition, doctors and pharmacists would have better information from which to provide care to patients."[5]

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

The PMPRB's expected work under the NPDUIS, including reports on trends in drug prices and utilization, is included in its Research Agenda and will be reported in the quarterly NEWSletter.

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

# Section III

# Performance of the PMPRB

## 3.1 Strategic Outcomes

| **Patented Medicine Prices Review Board** | | | |
|---|---|---|---|
| **Strategic Outcomes** | **Activities** | **Planned Results** | **Results reported in** |
| assurance that manufacturers' prices for patented medicines sold in Canada are not excessive | - review 100% of the manufacturers' prices of patented medicines sold in Canada | - manufacturers' prices for new and existing patented medicines sold in Canada are set within the limits established by the Excessive Price Guidelines (Guidelines) | 3.2.1<br>3.2.2 |
| | - report on enforcement measures (VCUs and Hearings) taken by the PMPRB | - enforcement measures taken in accordance with the *Patent Ac*t to ensure that prices are not excessive | 3.2.3<br>3.2.4 |
| | - compare the annual percentage change in the Patented Medicine Price Index (PMPI) to the annual percentage change in the Consumer Price Index (CPI) | - an annual percentage change in the PMPI that is not greater than the annual percentage change in the CPI | 3.3.1 |
| | - compare the manufacturers' prices for new and existing patented medicines sold in Canada to manufacturers' prices in other countries | - manufacturers' prices for new and existing patented medicines that are no greater than manufacturers' prices charged in other countries | 3.3.3 |
| information on trends in manufacturers' prices of all medicines in Canada | • an analysis of:<br>- trends in manufacturers' prices and volume of patented drug products sold;<br>- trends in manufacturers' prices of all drug products - patented and non-patented<br>- the comparison of Canadian patented drug prices to international prices<br>• an analysis of expenditure trends, price levels and cost drivers facing public drug benefit plans<br>• a comparison of provincial drug prices | • comprehensive reports on:<br>- trends in manufacturers' prices and volume of patented drug products sold;<br>- trends in manufacturers' prices of all drug products - patented and non-patented<br>- the comparison of Canadian patented drug prices to international prices<br>• detailed reports of expenditure trends, price levels and cost drivers facing public drug benefit plans<br>• a detailed report on interprovincial price comparison analysis | 3.3.1<br>3.3.2<br>3.3.3<br>3.3.4<br>3.3.4 |

| Patented Medicine Prices Review Board | | | |
|---|---|---|---|
| **Strategic Outcomes** | **Activities** | **Planned Results** | **Results reported in** |
| information on the pharmaceutical research-and-development expenditures of patentees in Canada | • an analysis of:<br>- R&D expenditures to sales revenues for each patentee and the industry as a whole based on information supplied by patentees;<br>- R&D expenditures by location and by type of research | • comprehensive reports of:<br>- the ratio of R&D expenditures to sales revenues for each patentee and the industry as a whole based on information supplied by patentees;<br>- R&D expenditures by location and by type of research | 3.4<br>3.4.1<br>3.4.1 |
| a more transparent and accountable public agency recognized as adding value to pharmaceutical policy in Canada | - on going consultations with a representative cross-section of stakeholders | - continue to implement the *Road Map for the Next Decade* | 3.5.1 |

## 3.2 Outcomes Achieved

### *3.2.1 Review of Patented Medicine Prices and Compliance with the Excessive Price Guidelines*

Voluntary compliance does not just happen. It requires goodwill on all sides, clear rules of the game, and confidence that effective remedies or sanctions will be applied in the event of non-compliance.

Board Staff reviews the prices of all patented drugs on an ongoing basis to determine if they comply with the Guidelines. Under the Board's policies, when a price appears to exceed the Guidelines, and the circumstances meet the criteria for commencing an investigation, Board Staff will conduct an investigation to determine the facts.[6] An investigation could result in:

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

[6] A price is considered to be within the Guidelines if it does not exceed the maximum allowed by the Guidelines and does not meet the criteria for commencing an investigation. For further information on the criteria, refer to Schedule 5, Criteria for Commencing an Investigation of the *Compendium of Guidelines, Policies & Procedures* which is available on the PMPRB website at www.pmprb-cepmb.gc.ca Legislation, Regulations, Guidelines.

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

### *New Patented Medicines*[7]

In 2001, there were 82 new patented drug products (DINs) for human use, representing 53 medicines. There were no new patented drug products for veterinary use reported to the PMPRB in 2001.

Eleven (13.4%) of the 82 new patented DINs were being sold in Canada prior to the issuance of the Canadian patent which brought them under the PMPRB's jurisdiction. The time delay between date of first sale and date of patent grant for these products ranged from several months to seven years.

As of March 31, 2002, the prices of 63 of the 82 new DINs for human use had been reviewed. Of the 63 new patented DINs reviewed, the prices of 47 (74.6%) were considered to be within the Guidelines. Sixteen new patented DINs (25.4%) were priced at levels which appeared to be outside the Guidelines and investigations were commenced.

### *Existing Patented Medicines*[8]

A total of 903 existing patented drug products (DINs) for human use were sold during 2001. As of March 31, 2002, the prices of 826 DINs (91.5%) were reviewed and found to be within the Guidelines. Forty-one existing patented DINs were the subject of investigations commenced as a result of pricing in earlier periods. Thirty-three DINs were still under review and three DINs, all pertaining to Nicoderm, were the subject of a hearing by

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[7] For purposes of the review of prices by the PMPRB, new patented medicines in 2001 include those introduced on the market in Canada or those previously marketed but first patented between December 1, 2000 and November 30, 2001. Because of the timing of the filing requirements under the Patented Medicines Regulations and the manner of calculating benchmark prices, medicines introduced or patented in December are considered to be new patented medicines in the following year.

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

the Board under s. 83 of the *Act* (refer to paragraph 3.2.4, page 14 for more information).

A summary of the review, compliance and investigation status, as at March 31, 2002, of the new and existing patented drug products for human use in 2001 is provided in Table 1.

**Table 1** Patented Drug Products for Human Use Sold in 2001 Status as of March 31, 2002

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

Source: PMPRB, Annual Report 2001

### *Patented Drugs for Veterinary Use*

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

There were a total of 107 existing patented drug products for veterinary use in 2001. Of the 18 reported as under review in 2000, five have been found to be within the Guidelines and 13 are still under review. The Board did not receive any complaints with respect to the prices of any patented veterinary drug products in 2001.

As indicated on the PMPRB's Research Agenda, an evaluation of the complaints-driven process for patented veterinary medicines will be undertaken in 2002-03.

### *3.2.2 Update of the Review of Patented Medicine Prices in 2000*

In last year's Performance Report, the Board reported that the prices of 32 new patented drug products were still under review. The results of those reviews concluded that 13 had been within the Guidelines, but four DINs were priced at levels that appeared to exceed the Guidelines and

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

investigations were opened. At the time of this report, 15 are still under review.

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

### *3.2.3 Enforcement Measures*

VCUs and Board decisions are available on the Board's website: www.pmprb-cepmb.gc.ca, under Publications; VCUs, Hearings and Decisions of the Board.

#### *Voluntary Compliance Undertakings*

Board Staff monitor and review the prices charged by patentees to ensure compliance with the Guidelines. When it appears that a price exceeds the Guidelines, Board Staff conduct an investigation to obtain the facts. If the facts lead to an allegation of excessive pricing, the patentee is given an opportunity to submit a Voluntary Compliance Undertaking to lower the price of the drug and offset excess revenues; the VCU is subject to approval by the Board's Chairperson.

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

#### Draxis Health Inc. - Zanaflex

Following an investigation, Board Staff concluded that the price of Zanaflex 4 mg/tablet of $0.6808 per tablet exceeded the 1999 maximum non-excessive (MNE) price of $0.6161 per tablet. In 2000, the price of Zanaflex continued to exceed the CPI-adjusted MNE price of $0.6327 per tablet.

The terms and conditions of the VCU were agreed to between Board Staff and the patentee. Having considered the evidence before it, the Chairperson approved the VCU submitted by Draxis Health.[10] Under the terms of the VCU, Draxis Health undertook to:

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

- Reduce the average selling price of Zanaflex on or before November 19, 2001 so that the average price for 2001 does not exceed the 2001 MNE price.

- Offset excess revenues received by Draxis Health during the period October 28, 1999 to December 31, 2000 by making a payment to the Government of Canada, on or before November 19, 2001, in the amount of $62,599.

- To ensure that the price of Zanaflex remains within the Guidelines in all future periods in which it remains under the Board's jurisdiction.

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

### *3.2.4 Public Hearings*

**Nicoderm, Hoechst Marion Roussel Canada Inc.**

As reported last year, the Chairperson of the Board issued a Notice of Hearing on April 20, 1999, in the matter of Hoechst Marion Roussel Canada Inc. (HMRC) and the price of the nicotine patch Nicoderm, to determine whether, under the *Patent Act*, Nicoderm was being sold at an excessive price.

Following the issuance of the Board's decisions, in 1999 and 2000, affirming its jurisdiction to conduct a hearing into the price of Nicoderm, HMRC commenced two judicial review applications in the Federal Court of Canada seeking to set aside the Board's decisions.[11] As HMRC only named the Attorney-General of Canada as Respondent in its judicial review applications, Board Staff and the Board Hearing Panel applied to the Federal Court to participate in the proceedings. Submissions were made by the parties before a Prothonotary of the Federal Court on March 13, 2001.

On July 13, 2001, the Prothonotary issued a decision denying Board Staff the right to participate as either a respondent or intervener while allowing the Board Hearing Panel to intervene on a limited basis. Both the Board Hearing Panel and Board Staff appealed the said decision. In a decision dated February 11, 2002, the Federal Court dismissed both appeals. The decision is presently being appealed before the Federal Court of Appeal.

[11] The Hearing Panel's decisions in this case are available on the PMPRB website: www.pmprb-cepmb.gc.ca, under Publication; Hearing and Decisions of the Board.

## 3.3 Trends in Manufacturers' Price of all Medicines Sold in Canada

### *3.3.1 Manufacturers' Prices and Volume of Patented Drugs Sold*

The PMPRB maintains the Patented Medicine Price Index (PMPI), an index of manufacturers' prices for patented drugs as reported annually to the PMPRB. The PMPI measures the average year-over-year change in the ex-factory prices of patented drug products sold in Canada. It is calculated from the net prices reported by patentees, and, thus encompasses all patented drugs reported to the PMPRB.[12]

In 2001 patentees reported total factory-gate sales of patented drugs for human use of $7.5 billion. This represents an increase of 18.9% over sales in 2000. Patented drugs now account for 65% of total sales, up from 43.9% in 1995. The rising share of patented drugs within total drug sales may be attributed in part to the long term effects of increased patent protection resulting from Bills C-22 and C-91 in 1987 and 1993.

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

Volumes of patented drugs sold have consistently risen much more quickly than prices. From 1988 to 2001, the average annual increase in quantities of patented drugs sold was approximately 12.4%, compared with an average annual increase of 0.8% in prices. This trend extends through 2001: although prices of patented medicines rose by only 0.1% the average increase in quantities sold amounted to 17.8% of the previous year's volumes.

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

**TABLE 2** Manufacturers= Sales of All Drugs and Patented Drugs, for Human and Veterinary Use, 1990 - 1998; and for *Human Use, 1999 - 2001*

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

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

* Percentage changes reflect exact values of sales and not rounded values of sales.
** The percentage change from 1998 of 16.8% for total drugs and 27.0% for patented drugs represents the change of drugs for human use only.

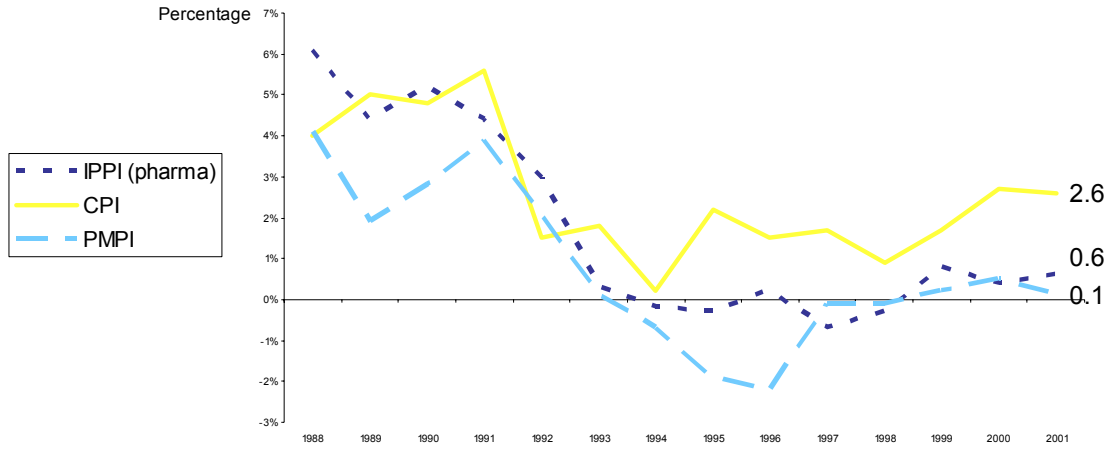
### *3.3.2 Manufacturers' Prices of All Drugs – Patented and Non-Patented*

The *Patent Act* provides that the PMPRB consider changes in the Consumer Price Index (CPI) when determining if the price of a patented medicine is excessive. Figure 1 shows that prices of patented drugs, as measured by the PMPI, have risen by less than the CPI almost every year since 1988, the sole exception being 1992.[13] This pattern continued in 2001, with consumer prices increasing by 2.6% (compared with the 0.1% increase in the PMPI).[14]

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

[14] Statistics Canada, CANSIM, Series P100000.

**FIGURE 1: Year-over-Year Changes in the PMPI, IPPI(Pharma) and CPI, 1988-2001**




Sources: PMPRB and Statistics Canada

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

The pharmaceutical component of Statistics Canada 's Industrial Product Price Index [IPPI (pharma)] provides an index of manufacturers' prices for all pharmaceuticals produced in Canada for domestic consumption and export. This includes both patented and non-patented drugs. In 2001, the IPPI (pharma) rose by 0.6%.[15] Figure 1 shows the IPPI (pharma) has remained virtually unchanged since 1993.

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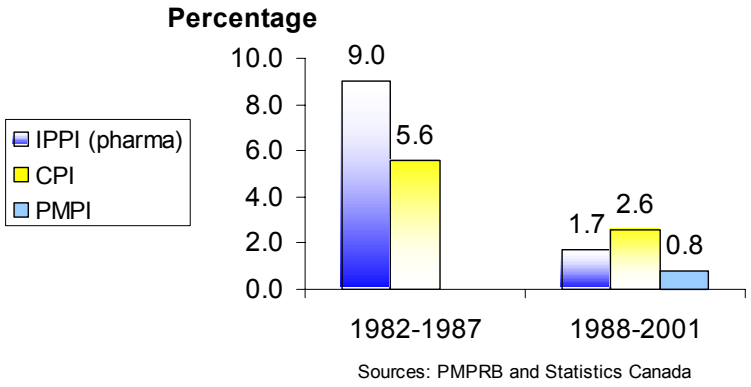
[15] Statistics Canada, CANSIM, Series P3515. The last six months of data are subject to revision by Statistics Canada.

**FIGURE 2**: **Summary of Price Trends, Average Annual Percentage Changes 1982-1987, 1988-2001**




Sources: PMPRB and Statistics Canada

As illustrated by Figure 2, a distinct break in pharmaceutical price trends seems to have occurred in 1987. From 1988 to 2001, the IPPI (pharma) increased at an annual average rate of 1.7% exceeding the corresponding average PMPI increase of 0.8% but falling below the average CPI inflation rate of 2.6%. A much different situation prevailed between 1982 and 1987: during this period, prices of all drugs, as measured by the IPPI (pharma), rose at an annual average rate of 9.0%, exceeding the CPI inflation rate of 5.6%.

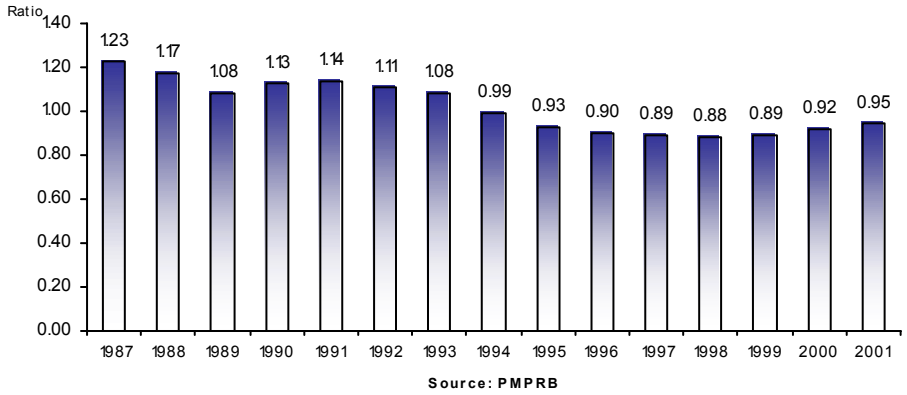
### *3.3.3 Relationship of Canadian Prices to Foreign Prices: Past and Present*

One way of examining drug price trends, taking into account introductory prices and price increases, is to examine the trend in the relationship of prices in Canada to those in other countries.

In accordance with the *Patent Act* and the *Patented Medicines Regulations* (Regulations), patentees are required to report all publicly available ex-factory prices for patented drugs in the seven foreign

countries, listed in the Regulations.[16] This foreign price information is used for two purposes: (1) to conduct the International Price Comparison (IPC) tests specified in the Guidelines, and (2) to compare price levels in Canada with prices elsewhere.

**FIGURE 3: Ratio of Canadian Prices of Patented Drugs to Median International Prices, 1987-2001**



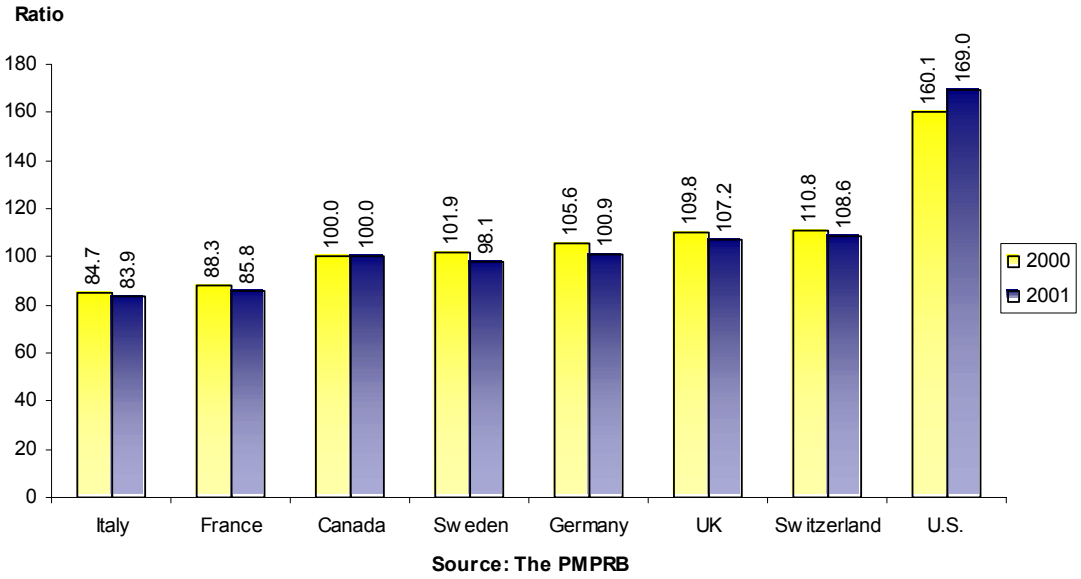

16 France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S. The PMPRB seeks to verify the foreign price information reported by patentees in several ways. For example, it is possible to derive a manufacturer's ex-factory price from the prices listed in foreign formularies in six of the seven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

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

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

Figure 3 shows the relationship between Canadian prices and the corresponding median price among the seven comparator countries over the period from 1987 to 2001.[17] Canadian prices were on average 23% higher than the median international price in 1987. Since then, this ratio declined and has remained relatively stable at levels 5% to 12% below the median price since 1994. In 2001, prices in the Canadian market were about 95% of median foreign prices, up slightly from the value of 92% recorded in 2000.

**FIGURE 4: Average Foreign to Canadian Price Ratios, Patented Drug Products**




**Source: The PMPRB**

Figure 4 shows the relationship between Canadian prices for patented drug products and prices in each of the seven comparator countries. In 1987, Canadian prices were, on average, below those in the U.S., but above prices in all other countries. By the mid-1990's, the situation had changed dramatically, with Canadian prices, now in the mid-range of the six European countries. This situation still existed in 2001: prices of patented drugs in Canada were slightly lower than prices in Germany, the U.K., and Switzerland, but higher than those observed in France, Sweden

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

and Italy. As in previous years, U.S. prices appear to be substantially higher than prices in both Europe and Canada.[18]

### *3.3.4 Reports on Cost Drivers Facing Federal/Provincial/Territorial Drug Plans*

In September 2001, the federal/provincial/territorial (F/P/T) ministers of health released a series of reports on the drug price and expenditure trends, price levels and cost drivers facing the six participating provincial drug plans.[19] These studies were conducted by the PMPRB pursuant to a Memorandum of Understanding with the Minister of Health.

Here are the principal findings:

- Total drug expenditures for grew, on average, by 11% per year over the three-year period from 1995-96 to 1998-99.

- The studies showed that increased utilization of drugs and the impact of new drugs were the major cost drivers behind total drug cost expenditures. Changes in the prices of existing drugs did not contribute to increased expenditures.

- The introduction and listing of new drugs is a significant cost driver for drug plans. Expenditures on new drugs grew quickly in most provinces with the result that newer drugs accounted for a major portion of total spending. For example, in Ontario, drugs introduced after 1992-93 represented 53% of total drug expenditures in 1998-99.

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

With the adoption of the 1987 amendments to the *Patent Act*, Canada's Research Based Pharmaceutical Companies (Rx&D) 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 Act, the PMPRB monitors and reports the R&D spending as reported to the Board by patentees, but it has no regulatory authority to influence the type of research or amount of R&D spending by patentees. The Act requires each patentee to report its revenues from sales of drugs

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[18] The pharmaceutical industry in the U.S. has argued that the publicly available price in that country do not reflect actual prices because of confidential discounts and rebates. In January 2000 the policy to include the prices listed in the U.S. Federal Supply Schedule (FSS) in calculating the average U.S. price of patented drugs came into effect. Figure 3 and 4 reflect the inclusion of the U.S. FSS prices in 2000 and 2001.

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

and the expenditures made by the patentee in Canada on R&D relating to medicine.[20] For individual patentees, this calculation includes all revenues from Canadian sales of medicines, including revenues from licensing agreements.

Only companies with active Canadian patents pertaining to a medicine sold in Canada are required by the Act to report on R&D expenditures. As new patents are granted and others expire, the group of companies required to file R&D data may change from year to year.

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

### *3.4.1 Ratio of R&D Expenditures to Sales Revenues*

For 2001, 74 patentees reported total revenues of $10.7 billion from Canadian sales of patented and non-patented drugs, up 15.3% over 2000. Patentees are largely brand name companies that sell patented and non-patented drugs. Of total sales revenues, less than 1% was generated by licensing agreements.

As shown in Table 3, the ratio of R&D expenditures to sales revenues for the patented pharmaceutical industry was 9.9% in 2001, down from 10.1% in 2000. The ratio for the 39 companies that were members of Rx&D was 10.6% in 2001, the same as in 2000. Although the total R&D expenditures increased by 12.6%, the R&D-to-sales ratios declined because sales increased even more, by 15.3%. As a result, the R&D-to-sales ratios for

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[20] Pursuant to the Regulations, patentees report those R&D expenditures that would have been eligible for an Investment Tax Credit for scientific research and experimental development under the provision 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, should not be included in the patentees= filings. Total R&D expenditures include current expenditures, capital equipment costs and allowable depreciation expenses.

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

all patentees and Rx&D companies were lower in 2001 than in any year since 1992.

**TABLE 3** Total R&D Expenditures* and R&D-to-Sales Ratios of Reporting Companies 1988-2001

| Year | Number of 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 (%) | Rx&D Patentees*** (%) |
| 2001 | 74 | 1,060.1 | 12.6 | 10,732.1 | 15.3 | 9.9 | 10.6 |
| 2000 | 79 | 941.8[R] | 5.3 | 9,309.6 | 12.0 | 10.1 | 10.6 |
| 1999 | 78 | 894.6 | 12.0 | 8,315.5 | 19.2 | 10.8 | 11.3 |
| 1998 | 74 | 798.9 | 10.2 | 6,975.2 | 10.9 | 11.5 | 12.7 |
| 1997 | 75 | 725.1 | 9.0 | 6,288.4 | 7.4 | 11.5 | 12.9 |
| 1996 | 72 | 665.3 | 6.4 | 5,857.4 | 9.9 | 11.4 | 12.3 |
| 1995 | 71 | 625.5 | 11.5 | 5,330.2 | 7.5 | 11.7 | 12.5 |
| 1994 | 73 | 561.1 | 11.4 | 4,957.4 | 4.4 | 11.3 | 11.6 |
| 1993 | 70 | 503.5 | 22.1 | 4,747.6 | 14.0 | 10.6 | 10.7 |
| 1992 | 71 | 412.4 | 9.6 | 4,164.4 | 6.9 | 9.9 | 9.8 |
| 1991 | 65 | 376.4 | 23.2 | 3,894.8 | 18.1 | 9.7 | 9.6 |
| 1990 | 65 | 305.5 | 24.8 | 3,298.8 | 11.0 | 9.3 | 9.2 |
| 1989 | 66 | 211.8 | 47.4 | 2,973.0 | 9.4 | 8.2 | 8.1 |
| 1988 | 66 | 165.7 | - | 2,718.0 | - | 6.1 | 6.5 |

Source: PMPRB, Annual Report 2001

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

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

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

[R] Revised

As shown in Table 4, of the 74 reporting companies, 16 companies reported having performed no R&D in 2001. Sales revenues for companies with no R&D totalled $340.8 million in 2001, accounting for 3.2% of total sales revenues for the patented pharmaceutical companies. The 36 companies reporting R&D expenditures with an R&D-to-sales ratio of 10% or less in 2001 accounted for 54.0% of total sales revenues. This group included companies with total sales of $5.8 billion in 2001 compared to $4.9 billion in 2000. The 22 companies with ratios of more than 10% accounted for a smaller proportion of total sales, 42.8%, or $4.6 billion in 2001.

**TABLE 4** Range of R&D-to-Sales Ratios by Number of Reporting Companies and Total Sales Revenues

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

Source: PMPRB, Annual Report 2001

Table 5 shows how current expenditures on R&D in 2001 were allocated among basic, applied, and other qualifying R&D. Total current expenditures on R&D rose by 13.1%in 2001.

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

The lion's share of R&D spending continued to be on applied research, $604.8 million, or 59.9% of the total. Applied research is directed towards some practical application, comprising the manufacturing process, pre-clinical trials and clinical trials. Clinical trials totalled $445.8 million in 2001 and accounted for 73.7% of total applied research expenditures and

44.1% of the total current R&D expenditures. Manufacturing process accounted for $79.5 million, or 7.9% of the total current R&D expenditures, and pre-clinical trials accounted for $79.5 million or 7.9% of the total current R&D expenditures. Other qualifying research, which accounted for 24.0% of total expenditures in 2001, includes drug regulation submissions, bioavailability studies and Phase IV clinical trials.

**TABLE 5** Current R&D Expenditures* by Type of Research, 2001 and 2000

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

Source: PMPRB, Annual Report 2001

* Current expenditures exclude capital equipment and depreciation expenditures.

** Other qualifying R&D includes drug regulation submissions, bioavailability studies and Phase IV clinical trials.

*** Column may not equal totals due to rounding.

[R] Revised

In 2001, R&D spending increased in all parts of Canada. There was no significant change in the regional distribution of R&D spending in 2001. As shown in Table 6, almost 85% of total expenditures continued to be made in Ontario and Québec.

**TABLE 6** Current R&D* Expenditures by Location, 2001 and 2000

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

Source: PMPRB, Annual Report 2001

* Current expenditures exclude capital equipment and depreciation expenditures.

** Column may not equal totals due to rounding.

R Revised

## 3.5 Implementing the Road Map for the Next Decade

### *3.5.1 Transparency of the Price Review Process*

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

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

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

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

improving the transparency of the process. The Working Group's report is available on the PMPRB website.

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

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

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

### *3.5.2 Review of the Guidelines for Category 3 Drugs*

In January 2001, the Working Group turned its attention to the review of the Board's Guidelines for new drugs in category 3.[21] Thirty-eight issues were identified by the Working Group members, which they consolidated and grouped into four components:

- Therapeutic Class Comparison (TCC) validation;
- Components of a TCC;

[21] A category 3 drug product, for purposes of the Guidelines, is a new DIN of a non-comparable dosage form of an existing medicine or the first DIN of a new chemical entity. These DINs provide moderate, little or no therapeutic advantage over comparable medicines.

- Other factors (e.g. Pharmacoeconomics, Investment, Research and Development, etc); and

- Price test and value concepts.

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

### *3.5.3 Environmental Scan and Performance Evaluation*

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

#### *Environmental Scan*

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

***1. Increasing prices of drugs in Canada***

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

***2. Balancing drug prices and research and development spending***

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

***3. New technology associated with medication (genetics, biotechnology etc.)***

The emergence of new gene therapy and biotechnological drugs will have an impact on the price review process. The concern is that the new costs for the research and development of these drugs and treatments will not be adequately considered when using the current price review structure.

***4. Transparency of the PMPRB pricing review process***

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

## *Review of Consultation and Communications Policies*

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

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

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

# Section IV

# Financial Performance

## 4.1 Financial Performance Overview

The tables are presented in the following order:

1. Summary of Voted Appropriations
2. Comparison of Total Planned to Actual Spending
3. Historical Comparison of Total Planned Spending to Actual Spending
4. Revenue

The variance between total authorities and actual spending for 2001-2002 is primarily due to delays in staffing positions during the course of the year.

**Financial Table 1: Summary of Voted Appropriations**

| **Financial Requirements by Authority ($ thousands)** | | | | |
|---|---|---|---|---|
| | | | **2001-2002** | |
| **Vote** | | **Planned Spending** | **Total Authorities** | **Actual** |
| | **Patented Medicine Prices Review Board** | | | |
| 25 | Operating Expenditures | 3,617.0 | 3,820.5 | **3,534.9** |
| (S) | Contributions to employee benefit plans | 468.0 | 468.0 | **468.0** |
| | **Total Agency** | **4,085.0** | **4,288.5** | **4,002.9** |
| Total Authorities are main estimates plus supplementary estimates plus other authorities. | | | | |

## Financial Table 2: Comparison of Total Planned to Actual Spending

| Planned versus Actual Spending ($ thousands) | | | |
|---|---|---|---|
| | 2001-2002 | | |
| **Patented Medicine Prices Review Board** | **Planned Spending** | **Total Authorities** | **Actual Spending** |
| FTEs | 39.0 | 39.0 | 37.0 |
| Operating | 4,085.0 | 4,288.5 | 4,002.9 |
| **Total Gross Expenditures** | **4,085.0** | **4,288.5** | **4,002.9** |
| Less: Respendable Revenues | - | - | - |
| **Total Net Expenditures** | **4,085.0** | **4,288.5** | **4002.9** |
| **Other Revenues and Expenditures** | | | |
| Non-respendable Revenues | - | - | (62.6) |
| Cost of services provided by other departments | 690.1 | 690.1 | 647.4 |
| **Net Cost of Program** | **4,775.1** | **4,978.6** | **4,587.7** |

## Financial Table 3: Historical Comparison of Total Planned Spending to Actual Spending

| Historical Comparison of Planned versus Actual Spending ($ thousands) | | | | | |
|---|---|---|---|---|---|
| | | | 2001-2002 | | |
| **Business Line** | **Actual 1999-2000** | **Actual 2000-2001** | **Planned Spending** | **Total Authorities** | **Actual** |
| Patented Medicine Prices Review Board | 3,667.6 | 3,997.6 | 4,085.0 | 4,288.5 | **4,002.9** |
| **Total** | **3,667.6** | **3,997.6** | **4,085.0** | **4,288.5** | **4,002.9** |
| Total Authorities are main estimates plus supplementary estimates plus other authorities | | | | | |

## Financial Table 4: Revenue

| Non-Respendable Revenues ($ thousands) | | | | | |
|---|---|---|---|---|---|
| | | | 2001-2002 | | |
| | Actual 1999-2000 | Actual 2000-2001 | Planned Revenues | Total Authorities | Actual |
| Patented Medicine Prices Review Board | | | | | |
| Unplanned | 67.3 | 933.1 | - | - | **62.6** |
| **Total Non-respendable Revenues**[1] | **67.3** | **933.1** | **-** | **-** | **62.6** |
| **Total Revenues** | **67.3** | **933.1** | **-** | **-** | **62.6** |

[1] The money deposited in the NRR 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. The Minister may enter into agreements with any province respecting the distribution to that province of amounts received by the Receiver General, less any costs incurred in relation to the collection and distribution of those amounts.