Patented Medicine Prices Review Board

2004-2005

Departmental Performance Report

The Honourable Ujjal Dosanjh
Minister of Health

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SECTION I – OVERVIEW

Chairperson's Message

I am pleased to present the 2004-2005 Performance Report for the Patented Medicine Prices Review Board (PMPRB). As Vice-Chairperson, I am honoured to assume the responsibilities of the Chairperson until such time as a new Chairperson is appointed.

Pharmaceuticals remain front and centre in public policy discussions. Canada's health care system, of which the PMPRB is a key part, has served to ensure that consumers are protected from excessive prices for patented medicines. In 1987, Canadian prices for patented drugs were second highest in the world, 23% above the median of foreign prices and higher than the six European countries, as set out in the *Patented Medicines Regulations, 1994* (Regulations), used for comparison purposes. After the creation of the PMPRB and the introduction of its Guidelines, that ratio declined but Canadian prices were still approximately 10% above the median in the early 1990s. Concerned that it had not achieved its objective, the Board amended its Guidelines effective in 1994. Since then, Canadian prices have consistently been in the range of 5% to 12% below the median of foreign prices.

The Regulations set out patentees' filing requirements with respect to the PMPRB. They specify the information that patentees must file to the PMPRB in accordance with their obligations under the *Patent Act*, and the timeframes for doing so.

When the PMPRB initiated its Timelines Project it became clear the Regulations need to be modernized to better reflect the information needs to conduct price reviews. In September 2004, the Board decided to consult with its stakeholders on a number of proposed amendments to the Regulations. The proposals include, among other things, that patentees be required to notify the PMPRB of the price at which a new medicine is intended to be sold, prior to the date of first sale and that patentees be required to notify the PMPRB of an intended price increase prior to its implementation. The Board is currently reviewing stakeholders' submissions following which it will determine next steps.

In addition, in 2004, the PMPRB became aware of reports in the media of price increases and began to receive questions from public drug plans about price announcements they had received. The PMPRB received information that a number of manufacturers of patented medicines had announced price increases. If such increases were to come about, they could represent a change in the trends in pricing in Canada compared to the past decade. Consequently, the Board undertook a public consultation on price increases and issued a discussion paper. The Board is also currently reviewing these submissions following which next steps will be determined.

Increasingly, the PMPRB has been asked to do more to focus on the broader questions relating to drug costs. The National Prescription Drug Utilization Information System (NPDUIS) was established by federal/provincial/territorial governments in 2002 as a partnership between the Patented Medicine Prices Review Board and the Canadian Institute for Health Information (CIHI). In the context of its role, the PMPRB has undertaken a number of initiatives. The NPDUIS provides critical analyses of price, utilization and cost trends so that our health system and policy decision-makers have more comprehensive and accurate information on

how prescription drugs are being used and on sources of cost increases. Currently, we are involved in a number of projects that will supply the participating jurisdictions with such information.

As demonstrated by the NPDUIS, collaboration among governments is an important element in addressing health care issues that affect all Canadians. In September 2004, the First Ministers agreed to build on this collaboration by developing and implementing a National Pharmaceuticals Strategy as part of their comprehensive 10-year Plan to Strengthen Health Care. They declared that: "Affordable access to drugs is fundamental to equitable health outcomes for all our citizens."

The PMPRB is proud of the contribution it has made to ensure Canadians do not pay excessive prices for patented medicines. It is dedicated to continuing to work with its partners and stakeholders in the interests of all Canadians.

Réal Sureau
Vice-Chairperson

Management Representation Statement

I submit for tabling in Parliament, the 2004-2005 Departmental Performance Report (DPR) for the Patented Medicine Prices Review Board.

This document has been prepared based on the reporting principles contained in the Treasury Board of Canada Secretariat's *Guide for the preparation of 2004-2005 Departmental Performance Reports*:

- It adheres to the specific reporting requirements;
- It uses an approved Business Lines structure;
- It presents consistent, comprehensive, balanced and accurate information;
- It provides a basis of accountability for the results pursued or achieved with the resources and authorities entrusted to it; and
- It reports finances based on approved numbers from the Estimates and the Public Accounts of Canada.

Name: Réal Sureau

Title: Vice-Chairperson

Summary Information

Department's Raison d'être

The Patented Medicine Prices Review Board (PMPRB) is an independent, quasi-judicial body created by Parliament as a result of revisions to the *Patent Act* in 1987 (Bill C-22) which increased patent protection for pharmaceuticals. The PMPRB represents a strategic component of the federal government's policy to balance consumer protection and affordable health care with the trade and industrial development objectives of pharmaceutical patent legislation. Subsequent revisions to the *Patent Act* in 1993 (Bill C-91) further increased patent protection for pharmaceutical products by eliminating compulsory licensing. The amendments also gave the PMPRB increased remedial powers and shifted ministerial responsibility for the PMPRB to the Minister of Health. Prior to that, responsibility for the PMPRB rested with the Minister of Consumer and Corporate Affairs (now the Minister of Industry), who has overall responsibility for the Act. The Minister of Health is responsible for the pharmaceutical provisions of the Act as set out in sections 79 to 103.

PMPRB's Mandate

Regulatory	To protect consumer interests and contribute to Canadian health care by regulating the maximum prices charged by manufacturers of patented medicines to ensure that they are not excessive.
Reporting	To report annually to Parliament on: • its price review activities; • the price trends of all medicines; and • the ratio of research-and-development expenditures to sales revenues for individual patentees and for all pharmaceutical patentees in Canada. To conduct inquiries at the request of the Minister of Health.

Total Financial Resources ($ thousands)

2004-2005		
Planned Spending	**Total Authorities**	**Actual Spending**
$5,301.0	$5,406.0	$4,996.7

Total Human Resources

2004-2005		
Planned	**Actual**	**Difference**
44	42	2

Summary of Performance in Relationship to Departmental Strategic Outcomes, Priorities and Commitments

Strategic Outcomes	2004–2005 Priorities/Commitments	Type	Planned Spending (000's)
To provide assurance that manufacturers' prices for patented medicines are not excessive	- review 100% of the manufacturers' prices of patented medicines sold in Canada	Ongoing	$ 5,301.0
	- take enforcement measures (VCUs & Hearings) as required	Ongoing	
	- establish timelines and milestones in the price review process for new patented medicines	New	
To report on trends in manufacturers' prices of all medicines in Canada	- conduct analysis of trends in manufacturers' prices of all medicines in Canada	Ongoing	
	- conduct analysis of expenditure trends, price levels and cost drivers facing public drug benefit plans (NPDUIS)	Ongoing	
To report on the pharmaceutical research and development expenditures of patentees in Canada	- conduct analysis of R&D expenditures to sales revenues of patentees in Canada based on data supplied by patentees	Ongoing	
To continue to be a transparent, dynamic and accountable public agency recognized as adding value to pharmaceutical policy development in Canada	- implement the Board's decisions on the recommendations of the Working Group on Price Review Issues	Ongoing	
	- conduct an evaluation of the transparency initiative	New	
	- continue implementation of the modern comptrollership initiative	Ongoing	

Actual Spending (000's)	Expected Results and Current Status
$4,996.7	• All manufacturers' prices for new and existing patented medicines sold in Canada are reviewed and in compliance with the PMPRB's Excessive Price Guidelines – Successfully met expectations For detailed information see ***Excessive Price Guidelines and Price Review Results – page 15.***
	• Timely investigation and resolution of prices that appear to exceed the Guidelines – Successfully met expectations For detailed information see ***Enforcement Measures – page 18*.**
	• An efficient and timely price review process, including target timelines for the various phases of the price review process – Expectations partially met For detailed information see ***Timelines – page 23.***
	• Canadian consumers and other stakeholders have complete and accurate information on pharmaceutical trends that contributes to informed policy development and decision-making – Successfully met expectations For detailed information see ***Price Trends – page 24***.
	• F/P/T governments and other stakeholders have credible analysis of priority pharmaceutical issues and trends – Expectations partially met For detailed information see ***NPDUIS – page 31.***
	• Federal government has accurate information on R&D expenditure trends and performance in Canada relative to historical commitments – Successfully met expectations For detailed information see ***Analysis of Research-and-Development Expenditures – page 32.***
	• Continual progress in modernizing the price review process and accounting for the achievement of the PMPRB's mandate – Expectations partially met For detailed information see ***Timelines – page 23.***
	• More transparent and relevant public communications on the full range of the PMPRB's activities – Expectations partially met For detailed information see ***Transparency – page 34.***
	• Continue implementation of the new Values and Ethics Code and a risk assessment process as part of the strategic planning process – Successfully met expectations For detailed information see ***Transparency – page 34.***

Overall Departmental Performance

Jurisdiction

Regulatory – The PMPRB reports its performance using the framework provided under the departmental strategic outcomes and Business Line. The PMPRB has one Business Line which matches its program, the Patented Medicine Prices Review Board.

The PMPRB is responsible for regulating the prices that patentees charge, the "factory-gate" price, for prescription and non-prescription patented drugs sold in Canada to wholesalers, hospitals, pharmacies or others, for human and veterinary use, to ensure that they are not excessive. The PMPRB regulates the price of each strength of each dosage form of each patented medicine sold in Canada. This is normally the level at which Health Canada assigns a Drug Identification Number (DIN).

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 an NOC, as an Investigational New Drug or under the Special Access Program.

The PMPRB has no authority to regulate the prices of non-patented drugs, including generic drugs sold under compulsory licenses, nor does it have jurisdiction over prices charged by wholesalers or retailers, or over pharmacists' professional fees. Also, matters such as distribution and prescribing are outside the purview of the PMPRB.

Patentees are required to comply with the Act to ensure that prices of patented medicines sold in Canada are not excessive. In the event that the Board finds, after a public hearing, that a price is excessive in any market it may order the patentee to reduce the price and take measures to offset any excess revenues it may have received.

Reporting – The PMPRB is required by legislation to report annually to Parliament through the Minister of Health. The Annual Report, which covers the calendar year, includes a review of the PMPRB's major activities, analyses of the prices of patented medicines and of the price trends of all drugs, and reports on the R&D expenditures as filed by patent-holding drug manufacturers. In addition, the PMPRB reports through its quarterly NEWSletter and various studies.

Pursuant to an agreement by the Federal/Provincial/Territorial Ministers of Health and at the request of the federal Minister of Health, the PMPRB conducts research under the National Prescription Drug Utilization Information System (NPDUIS). The purpose of the NPDUIS is to provide critical analyses of price, utilization and cost trends so that Canada's health system has more comprehensive and, accurate information on how prescription drugs are being used and on sources of cost increases.

Challenges

Over the past decade, there has been considerable stability in the pricing of medicines in Canada. This recent pattern had not been the historic trend. In the 1980s, prices for patented drugs in Canada were increasing at a rate more than 50% higher than increases in the rate of inflation. From 1982 to 1987 manufacturers' prices for drugs increased 9% per year on average, compared to increases in the Consumer Price Index of 5.6% per year.

Compared to countries other than the U.S., the price trends in Canada are not unique. PMPRB studies have shown that the European countries, set out in the *Patented Medicines Regulations, 1994* (Regulations), with which it compares prices have also experienced price stability over the past decade with most countries showing minimal price increases and, in some cases, price decreases. These price trends provide further evidence that Canada's drug pricing today is in line with the international community.

The price stability seen over the past decade has been the result of a combination of federal and provincial restraints on prices. However, there is now some evidence that the situation may be changing. Over the past year, a number of manufacturers have informed customers and drug plans of increases in their published prices for certain drugs. In the case of patented drugs, the PMPRB ensures that the increases are in the range of increases allowable under the PMPRB's Guidelines, but they are not always consistent with the policies of drug plans. On December 16, 2004, the Québec government released a discussion paper in which it proposed a number of changes to la Loi sur l'assurance médicaments. These changes, if implemented, would bring an end to the government's no-increase policy for the price of drugs, replacing it with a system whose cost-containment methodology is based on pharmacoeconomic principles. In Ontario, there have been no changes to the prices listed in the provincial formulary, but it has been reported that a number of manufacturers of both patented and non-patented drugs have increased prices to wholesalers and pharmacists. In the case of private plans and other provincial plans that reimburse based on pharmacists' actual acquisition cost, the impact of these price increases is being felt.

Information provided to the PMPRB, from other sources, indicated that manufacturers of approximately 35% of the patented drug products under its jurisdiction had informed the trade of price increases in 2004. In fact, the PMPRB Annual Report shows that in 2004, 52% of patented drug prices rose by between zero and the allowable maximum of 3.3%, compared to only 38% in 2001. The distribution of these price increases is as follows; 48% of patented drug prices rose by 1% or less while 52% rose between 1 and 3.3%. Restricting this analysis to the top 200 selling drugs in 2004, 42% of patented drug prices rose by 1% or less while 58% rose between 1% and 3.3%.

As a result of the price increases for drugs, and concerns about future price inflation for pharmaceuticals, the Board issued a discussion paper outlining price trends, how the Guidelines for price increases have evolved over time, and the rationale for why it may be time to review the approach used in assessing price increases. Most importantly, while the Board made no specific proposals for change, the discussion paper identified a number of questions that the Board

wanted stakeholders to consider and provide feedback on. The Board is currently reviewing the submissions it received in response to its discussion paper.

In September 2004, Canada's First Ministers agreed to develop and implement a National Pharmaceuticals Strategy as part of their comprehensive 10-year Plan to Strengthen Health Care. They declared that: "Affordable access to drugs is fundamental to equitable health outcomes for all our citizens."

The PMPRB with Health Canada and the other organizations in the health portfolio, and other departments and agencies listed in *Canada's Performance 2004*, are working to achieve a healthy population. [1] The PMPRB contributes to this outcome by ensuring that the prices charged by manufacturers for patented medicines are not excessive – affordable access to drugs is fundamental to equitable health outcomes for all Canadians.

Performance Highlights

In total, there were 94 new patented drug products introduced in 2004, including 25 new active substances. As of March 31, 2005, 90 new patented drug products had been reviewed. Of those, 68 were considered to be within the Guidelines; twenty two are subject to ongoing investigations.

The Board issued three Notices of Hearing and approved eight Voluntary Compliance Undertakings in 2004-2005.

The manufacturers' prices of patented drugs, as measured by the Patented Medicine Price Index (PMPI), fell by 0.2% in 2004. Analysis of prices by therapeutic class demonstrates considerable variability in price changes.

In 2004, the ratio of Canadian prices to the international median for comparator countries was again below parity, with Canadian patented drug prices being on average about 91% of the corresponding median international price. Prices of patented drugs in Canada were on average somewhat less than prices in Sweden, Germany, the U.K. and Switzerland, but greater than prices in France and Italy. As in previous years, U.S. prices appear to be substantially higher than prices in both Europe and Canada.

Patentees reported total R&D expenditures of $1,170.0 million in 2004, a decrease of 2% over the previous year. Rx&D members reported R&D expenditure of $1,008.3 million in 2004, accounting for 86.2% of all reported expenditures.

Patentees reported spending $221.7 million on basic research, representing 19.7% of current R&D expenditure; spending on basic research increased by 23% in 2004 relative to the previous year.

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[1] Treasury Board of Canada Secretariat, *Canada's Performance 2004;* Chapter V, The Health of Canadians. This document is available on the Treasury Board Web site: www.tbs-sct.gc.ca under Reports.

SECTION II –
ANALYSIS OF PERFORMANCE BY STRATEGIC OUTCOME

Strategic Outcome
To provide assurance that manufacturers' prices for patented medicines are not excessive.
Expected Results: • All manufacturers' prices for new and existing patented medicines sold in Canada are reviewed and in compliance with the PMPRB's Excessive Price Guidelines. • Timely investigation and resolution of prices that appear to exceed the Guidelines. • An efficient and timely price review process, including target timelines for the various phases of the price review process. **- Intermediate Outcomes** Complete work on developing, documenting, consulting on and publishing standards and/or guidelines for the price review process. Conclusion of VCUs and, where needed, Notices of Hearings. **- Immediate Outcomes** Complete work on analysis and mapping of current price review process.
Plans, priorities and commitments Conduct price reviews on 100% of the manufacturers' prices of patented medicines sold in Canada for compliance with the Excessive Price Guidelines. Take enforcement measures as required. Establish timelines and milestones in the price review process for new patented medicines.

The PMPRB reviews the pricing information for all patented medicines sold in Canada on an ongoing basis to ensure that the prices charged by patentees comply with the Excessive Price Guidelines (Guidelines) established by the Board.[2] The Guidelines are intended to provide clear criteria to permit patentees to set prices that will not be presumed to be excessive.

Excessive Price Guidelines and Price Review Results

The Guidelines are based on the price determination factors in section 85 of the Act and have been developed in consultation with stakeholders, including the provincial and territorial Ministers of Health, consumer groups and the pharmaceutical industry. In summary, the Guidelines provide that:

[2] The Guidelines are published in the PMPRB's *Compendium of Guidelines, Policies and Procedures* (Compendium) which is available on the Web site: www.pmprb-cepmb.gc.ca, under Legislation, Regulations, Guidelines.

- prices for most new patented drugs are limited such that the cost of therapy for the new drug does not exceed the highest cost of therapy for existing drugs used to treat the same disease in Canada;

- prices of breakthrough patented drugs and those which bring a substantial improvement are generally limited to the median of the prices charged for the same drug in other industrialized countries listed in the Regulations (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States);

- price increases for existing patented medicines are limited to changes in the Consumer Price Index (CPI); and

- the price of a patented drug in Canada may, at no time, exceed the highest price for the same drug in the foreign countries listed in the Regulations.

All these activities are intended to achieve compliance with the Act by ensuring that prices charged by manufactures of patented medicines are not excessive.

Price Review of New Patented Drugs for Human Use

There were 94 new patented drug products, or DINs, for human use introduced in 2004.[3] Some are one or more strengths of a New Active Substance (NAS) and others are new presentations of existing medicines.

As of March 31, 2005, the prices of 90 of the 94 new DINs for human use had been reviewed. Of the 90 new patented DINs reviewed, the prices of 68 (75.6 %) were found to be within the Guidelines. Twenty-two patented DINs were priced at levels which appeared to be outside the Guidelines and investigations were commenced.

Price Review of Existing Patented Drugs for Human Use

A total of 993 existing patented drug products (DINs) for human use were sold during 2004.[4] There were 51 investigations under way at the beginning of the year and, during 2004, investigations were opened into 11 existing patented drug products (DINs) with prices that appeared to be outside the Guidelines. Of the total 62 investigations, 41 were closed leaving 21 investigations into existing drugs ongoing at the end of the year.

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[3] For purposes of the PMPRB price review, any patented drug product introduced in Canada, or previously marketed but first patented, between December 1, 2003 and November 30, 2004, is considered a new patented drug product in 2004. Because of the timing of the filing requirements under the *Patented Medicines Regulations* and the manner of calculating benchmark prices, drug products introduced or patented in December are considered to be new patented products in the following year.

[4] For the purpose of this report, existing medicines include all patented drug products that were introduced prior to December 1, 2003. The PMPRB's Guidelines limit the price changes for existing patented drugs to changes in the Consumer Price Index (CPI). In addition, the price of a patented drug cannot exceed the highest price of the same drug product in the countries listed in the Regulations (France, Germany, Italy, Sweden, Switzerland, U.K. and U.S.).

As of March 31, 2004, the prices of 913 existing DINs (92%) were within the Guidelines. Twenty-one DINs were the subject of investigations commenced as a result of pricing in earlier periods (5 are new medicines introduced in 2002, 6 are new medicines introduced in 2003; the remaining 10 are existing medicines – five relate to price increases in 2003 and five to increases in 2004). Four DINs, 3 pertaining to Nicoderm and 1 pertaining to Dovobet, were the subject of hearings under section 83 of the Act (see Quasi-judicial Activities on page 21); and 55 DINs were still under review.

A summary of the review, compliance and investigation status, as of March 31, 2005, of the new and existing patented drug products for human use in 2004 is provided in Table 1.

In its 2003-2004 Departmental Performance Report the PMPRB reported in Section 5.4.1, Working Group on Price Review Issues, that as a result of a number of internal initiatives related to the establishment of milestones and time frames for the price review process (Timelines Review Project), there was a significant reduction in the number of ongoing investigations for new and existing patented drugs from 67 at March 31, 2003 to 51 as of March 31, 2004. In 2004, work on the Timelines Review Project continued and further initiatives were implemented which resulted in a further reduction in the number of ongoing investigations (for additional information on the Timelines Review Project see page 23). As of March 31, 2005 the PMPRB has 43 ongoing investigations.

Table 1

Patented Drug Products for Human Use Sold in 2004 - Status of Price Review as of March 31, 2005

	New Drugs Introduced in 2004	Existing Drugs	Total
Total	94	993	1087
Within Guidelines	68	913	981
Under Review	4	55	59
Under Investigation	22	21	43
Notice of Hearing	-	4	4

Update of the Review of Existing Patented Medicine Prices reported for 2003

In last year's Performance Report, it was reported that of the 974 existing patented drug products for human use sold in 2003, the prices of 41 were still under review. The results of those reviews concluded that 19 had been within the Guidelines; 4 DINs were priced at levels that appeared to exceed the Guidelines and therefore investigations were opened. Eighteen are still under review and included in the total figure of under review reported in Table 1, above.

The PMPRB also reported that 39 DINs for existing patented medicines were under investigation as at March 31, 2004. Of those, 34 investigations have been concluded: in 28 cases the prices were ultimately found to be within the Guidelines; and for 6 cases, a Voluntary Compliance Undertaking was approved – Fasturtec, One-Alpha, Tamiflu, Starnoc, Busulfex and Prolastin. (See Voluntary Compliance Undertakings, below)

Patented Drugs for Veterinary Use

In September 2003, the PMPRB decided to implement a full complaints-driven approach for the regulation of patented veterinary drug prices. This decision was communicated to stakeholders in the PMPRB's January 2004 NEWSletter. Since the Regulations do not distinguish between the filing requirements for human drug patentees and veterinary drug patentees, they need to be amended to differentiate between the filing requirements of the two. Proposed amendments to the Regulations for consultation with stakeholders were published in the January 2005 NEWSletter. The Board has published stakeholders' submissions on its Web site and is in the process of determining next steps.

In the mean time, the complaints-driven approach for regulating the prices of patented veterinary drugs remains in place. Board Staff reviews the prices of new patented veterinary medicines only. Existing veterinary medicines are subject to review only when a substantiated complaint has been received. No complaints were received in 2004.

In last year's Performance Report it was reported that seven DINs were under review. Five of those have been found to be within the Guidelines and the remaining two, plus an additional one introduced in 2003, are still under review. The summary reports of the price review of veterinary drug products are available on the Web site: www.pmprb-cepmb.gc.ca, under Other Publications; Patented Medicines; Reports on New Patented Drugs for Veterinary Use.

Enforcement Measures

Voluntary Compliance Undertakings

Under the Compliance and Enforcement Policy, patentees are given an opportunity to submit a Voluntary Compliance Undertaking (VCU) when Board Staff concludes, following an investigation, that the price set forth by the patentee appears to exceed the PMPRB's Price Guidelines.[5] Acceptance of a VCU by the Chairperson is an alternative to the commencement of formal proceedings through the issuance of a Notice of Hearing. Under the PMPRB's Compliance and Enforcement Policy, a VCU can also be submitted following the issuance of a Notice of Hearing. A VCU submitted at this point must be approved by the Board.

In 2004-2005, eight VCUs were approved for the following patented medicines:[6]

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[5] A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to adjust its price to conform to the PMPRB's Excessive Price Guidelines.

[6] The full text of the VCU is available on the Web site: www.pmprb-cepmb.gc.ca, under Publications, Voluntary Compliance Undertakings, by drug name.

- ***One-Alpha,*** [7] ***LEO Pharma Inc***.

  As reported in last year's Performance Report, on May 6, 2004, the Chairperson approved a VCU from LEO Pharma Inc. for One-Alpha (alfacalcidol). Under the terms and conditions of the VCU, LEO Pharma reduced the average selling price of One-Alpha within 30 days of acceptance of the VCU so that the average price for 2004 did not exceed the 2004 maximum non-excessive price (MNE) of $13.3750 per ml. To offset excess revenues received during the period of January 1, 2001 to December 31, 2003, LEO Pharma made a payment to the Government of Canada in the amount of $23,049.10.

- ***Fasturtec,*** [8] ***Sanofi-Synthelabo Canada Inc***.

  On May 20, 2004, the Board accepted a VCU submitted by Sanofi-Synthelabo Canada Inc. (Sanofi) with respect to the patented medicine Fasturtec. Under the terms of the VCU, Sanofi lowered the price of Fasturtec from $295.00 per vial to $124.7854 per vial, effective July 26, 2004, and agreed that the average selling price for 2004 would not exceed this price. Furthermore, Sanofi offset excess revenues of $374,373 from sales of Fasturtec for the period from May 21, 2002 to December 31, 2003. Sanofi provided rebates directly to the 28 hospitals that purchased Fasturtec over this period at the higher price.

- ***Prolastin,*** [9] ***Bayer Inc***.

  On July 9, the Chairperson accepted a VCU submitted by Bayer Inc. with respect to the price of the patented drug Prolastin. The terms of the VCU required that, for purposes of the PMPRB's Price Guidelines, the MNE price of Prolastin in 2003 be $288.00 and the average transaction price of Prolastin in 2003 not exceed this amount per vial.

  Bayer also undertook to sell Prolastin in Canada during 2004, 2005 and 2006 at a price that will not exceed the lower of (a) the $288.00 MNE price in 2003 adjusted for CPI increases in 2004, 2005 and 2006 and (b) the median international prices for the same medicine in those years. In the event that Bayer proposes to increase the price of Prolastin in any succeeding year after 2006 by more than its CPI-adjusted price as determined in accordance with the methodology established in the Guidelines, it further undertook to provide written notification to the PMPRB and satisfactory written evidence in support of the rationale for any such price increase. In light of the particular circumstances of this case, the Chairperson accepted the VCU. The PMPRB reserves its right to commence an investigation, should circumstances warrant, pursuant to its Compliance and Enforcement Policy.

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[7] One-Alpha is indicated for the management of hypocalcaemia, secondary hyperparathyroidism and osteodystrophy in patients with chronic renal failure.

[8] Fasturtec is indicated for the treatment and prevention of hyperuricemia in paediatric and adult cancer patients. It is administered intravenously in a hospital setting.

[9] Prolastin is a drug product derived from human plasma. It is indicated for a rare genetic disorder, specifically, chronic replacement therapy of individuals having congenital deficiency of alpha 1-PI (alpha 1-antitrypsin deficiency) with clinically demonstrable panacinar emphysema.

- ***Starnoc,*** [10] ***Servier Canada Inc***.

  On July 15, the Chairperson accepted a VCU submitted by Servier Canada Inc. for the drug product Starnoc. Under the terms of the VCU, for the purposes of the PMPRB's Price Guidelines, the MNE prices of Starnoc 5 mg capsule in Canada for 2000 and 2004 are $0.4526 and $0.4964, respectively while the MNE prices of Starnoc 10 mg capsule in Canada for 2000 and 2004 are $0.6816 and $0.7475, respectively.

  In addition, to ensure that the prices of Starnoc in 2004 were within the Guidelines, Servier made a payment of $739,739.99 to the Government of Canada to offset excess revenues received during the period from January 1, 2004 to June 30, 2004.

  To offset the remaining excess revenues of $3,838,801.86, Servier will maintain the prices of all of its patented medicines at levels below the CPI-adjusted prices until the end of 2005. In the event that any excess revenues have not been offset by the end of December 2005, Servier has undertaken to make a payment to the Government by January 30, 2006 for such amount.

- ***Busulfex,*** [11] ***ESP Pharma Inc***.

  On November 16, the Chairperson accepted a VCU by ESP Pharma (ESP). The terms of this VCU required that, for the purposes of complying with the PMPRB's Price Guidelines, ESP lower the average transaction price of Busulfex to the 2004 MNE price of $359.89 per ampoule. To offset excess revenues received, ESP made payments totalling $150,646.99 to the Government of Canada.

- ***Evra,*** [12] ***Janssen-Ortho Inc***.

  On February 21, 2005, the Board accepted a VCU submitted by Janssen-Ortho Inc with respect to the patented medicine Evra. Under the terms of the VCU, Janssen-Ortho lowered the price of Evra by approximately 45% to $4.47 per patch.

  To offset excess revenues from past sales of Evra accrued from the date of first sale to June 30, 2004, Janssen-Ortho made a payment to the Government of Canada in the amount of $1,359,263.67. Finally, the balance of excess revenues remaining, totalling $1,496,019.02, for the period July 1, 2004 to December 31, 2004, will be offset by reducing the price of one

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[10] Starnoc is indicated for the short-term treatment and symptomatic relief of insomnia in patients who have difficulty falling asleep.

[11] Busulfex is an antineoplastic agent indicated for use in combination with other chemotherapeutic agents and/or radiotherapy as a conditioning regimen prior to hematopoietic progenitor cell transplantation (HPCT), or bone marrow transplant.

[12] Evra is a transdermal contraceptive patch indicated for the prevention of pregnancy in women who elect to use hormonal contraceptives.

of Janssen-Ortho's patented medicines, Levaquin 5mg/mL and 25mg/mL, as of March 1, 2005.

- ***Paxil CR,*** [13] ***GlaxoSmithKline Inc***.

  In order to comply with the PMPRB's Price Guidelines, GlaxoSmithKline (GSK) undertook to reduce the average transaction price of Paxil CR by the end of the January 1 to June 30, 2005 regulatory filing period such that the average transaction price for 2005 does not exceed the 2005 MNE price of $1.5861 for Paxil CR 12.5 mg and $1.7019 for Paxil CR 25 mg.

  GSK offset excess revenues it received during the period of January 5, 2004 to December 31, 2004 by making a payment to the Government of Canada in the amount of $310,403.64.

- ***Tamiflu,*** [14] ***Hoffmann-La Roche Limited***

  In order to comply with the PMPRB's Price Guidelines, Hoffmann-La Roche Limited (Roche) agreed that the MNE price of Tamiflu 75 mg capsule was $3.7695 for the period January to December 2003; $3.8383 for the period January to December 2004; and is $3.8917 for the period January to December 2005.

  Also, Roche offset excess revenues received for the reporting periods January 1, 2003 to December 31, 2004 by making a payment to the Government of Canada in the amount of $442,973.47.

Quasi-judicial Activities

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

  On April 20, 1999, the Board issued a Notice of Hearing to consider whether, under sections 83 and 85 of the *Patent Act*, Nicoderm is being, or has been, sold by Hoechst Marion Roussel Canada Inc. (HMRC) in Canada at a price that, in the opinion of the Board, is excessive and if so, what order, if any, should be made. The matter was reported on in previous Performance Reports, Annual Reports and selected issues of the NEWSletter.

  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. The Federal Court heard the judicial review applications in this matter on May 16-17, 2005. Decisions are pending.

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[13] Paxil CR provides a controlled-release to the alternative range of presentations of Paxil, an anti-depressant. It is supplied in the form of tablets in two strengths, 12.5 mg tablet and 25 mg tablet.

[14] Tamiflu is a direct acting antiviral neuraminidase inhibitor.

- ***Fasturtec, Sanofi-Synthelabo Canada Inc.***

  As reported in last year's Departmental Performance Report, on May 20, 2004, the Board issued a Notice of Hearing in the matter of Sanofi-Synthelabo Canada Inc. (Sanofi) and the price of the patented medicine Fasturtec. On June 28, 2004, the Board concluded proceedings commenced in May in regard to the medicine Fasturtec by accepting a Voluntary Compliance Undertaking by Sanofi. Details on this matter appear in the Voluntary Compliance Undertaking section of this report on page 19.

- ***Dovobet, LEO Pharma Inc.***

  Dovobet is indicated for the topical treatment of active lesions of psoriasis vulgaris in adult patients.

  The Board issued a Notice of Hearing on November 29, 2004 in the matter of LEO Pharma Inc. and the price of the patented medicine Dovobet. The purpose of the hearing is to determine whether, under sections 83 and 85 of the *Patent Act*, LEO Pharma. is selling or has sold the medicine known as Dovobet in any market in Canada at a price that, in the Board's opinion, is or was excessive; and, if so, what order, if any, should be made.

  The Board held a pre-hearing conference on January 19, 2005 and three days of hearing in March. The Board resumes sitting on the merits of this case in September.

- ***Evra, Janssen-Ortho Inc.***

  On December 23, 2004, the Board issued a Notice of Hearing in the matter of Janssen-Ortho Inc. and the price of the patented medicine Evra. On February 21, 2005, the Board approved a VCU to reduce the price of Evra. Highlights of the VCU can be found in the Voluntary Compliance Undertaking section of this report on page 20.

Timelines

In its second report to the Board in November 2000, the former Working Group on Price Review Issues[15] recommended the establishment of milestones and time frames for the price review process. Building on this recommendation, the Health Accords of 2000 and 2003, the 2002 Federal Speech from the Throne, the 2003 Federal Budget commitments and government initiatives such as: Health Canada's Therapeutic Access Strategy (TAS);[16] and the Common Drug Review (CDR);[17] the PMPRB modified its Timelines Project to include examining ways to strengthen its price review process to keep pace with improvements in Health Canada's market approval process and to become more aligned with the CDR for F/P/T formulary listing. Over the past year the PMPRB has completed the mapping and a time analysis of the price review process, as well as identified areas for improvement.

One area that was identified as having an impact on the timeliness of the price review process is the information provided by patentees. In particular, the information required to begin the scientific review process. As part of the January 2005 NEWSletter, the PMPRB published a Notice and Comment on proposed amendments to the *Patented Medicines Regulations*. One of these amendments would require a patentee to file a product monograph. The Board is considering the submissions received, and determining next steps.

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[15] The Working Group on Price Review Issues was established in 1998 following the PMPRB's release of its *Road Map for the Next Decade*. Composed of 12 members representing the PMPRB's stakeholder groups, the Working Group's mandate was to review, analyze and report on three issues: the use of the U.S. Department of Veterans Affairs formulary prices in the international price comparison; the price review process for new patented drug products; and category 3 drug prices. The Working Group completed its work in October 2002. The Working Group's reports and other relevant materials are available on the Web site under Working Group on Price Review Issues.

[16] The TAS was initiated by Health Canada to: improve pre-market regulatory performance including timeliness of reviews; strengthen post-market safety, risk communication and understanding of therapeutic effectiveness of products in real work use; and improve access to therapies and contribute to the long-term sustainability of the health care system by performing optimal use, best practices in prescribing, and better management of affordability and products and drug plans.

[17] In 2002, Canada's Health Ministers established the Common Drug Review (CDR) to provide a single process for reviewing new drugs and providing formulary listing recommendations to participating publicly-funded federal, provincial and territorial (F/P/T) drug benefit plans in Canada

Strategic Outcome
To report on trends in manufacturers' prices of all medicines sold in Canada.
Expected Results: • Canadian consumers and other stakeholders have complete and accurate information on pharmaceutical trends that contributes to informed policy development and decision-making. **- Intermediate Outcomes** Identify and provide more informative reporting on key pharmaceutical issues of interest to Canadian consumers and other stakeholders. **- Immediate Outcomes** Assess the adequacy and utility of current price, sales and utilization indices and develop value-added new reporting tools.
Plans, priorities and commitments Analyze data and prepare and issue reports on price trends.

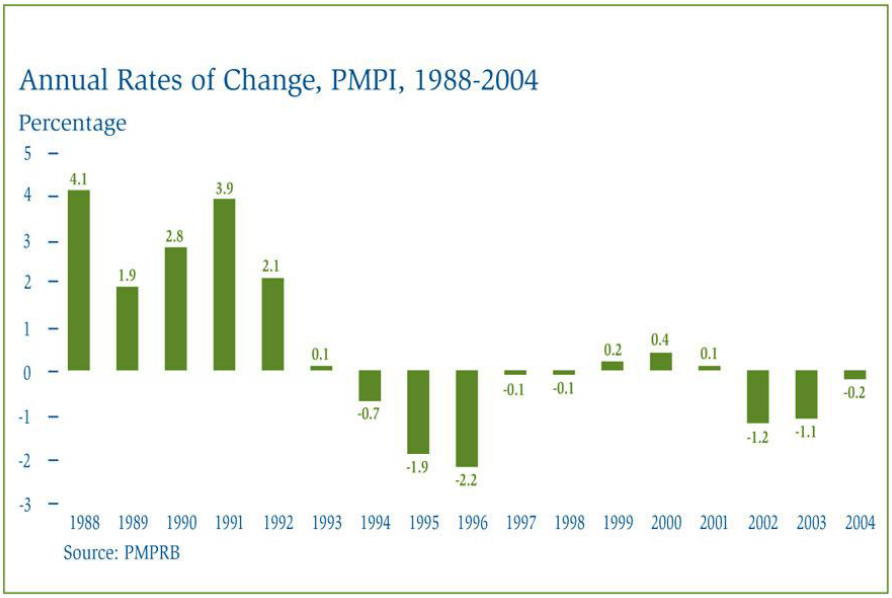
Price Trends

The PMPRB maintains the Patented Medicine Price Index (PMPI) to monitor trends in prices of patented drugs. The PMPI measures average year-over-year changes in the ex-factory prices of patented drug products sold in Canada. It is updated annually using price and sales information reported by patentees.[18]

Figure 1 provides year-over-year changes in the PMPI for the years 1988 through 2004. As measured by the PMPI, manufacturers' prices of patented drugs fell on average by 0.2% in 2004. This result continues a pattern of declines and near-negligible increases that began in 1993. As in previous years, the price stability observed in 2004 was broadly based, with a majority of patented drug prices exhibiting little or no change.

[18] See the PMPRB's *A Description of the Laspeyres Methodology used to construct the Patented Medicine Price Index (PMPI)*, March 1997, revised June 2000, for a detailed explanation of the PMPI. The PMPI measures the overall change in the prices of existing patented drug products, and is constructed by taking a sales-weighted average of rates of price change at the level of individual products. It is not designed to measure the effects of changes in the quantities of drugs consumed or substitution among drugs (for example, the use of newer drugs in place of older, and possibly less costly drugs) on sales. As of the 1999 Annual Report, the PMPI encompasses prices of patented drugs for human use only.

Figure 1



Comparison of PMPI and CPI

The *Patent Act* provides that, among other factors, the PMPRB shall consider changes in the Consumer Price Index (CPI) in determining whether the price of a patented drug is excessive. Figure 2 plots year-over-year rates of change in the PMPI against corresponding changes in the CPI. General price inflation, as measured by the CPI, has exceeded the average increase in patented drug prices almost every year since 1988.[19] This occurred again in 2004, with CPI-inflation exceeding the rate of PMPI change by approximately 2.1%, although the PMPI-CPI gap narrowed considerably between 2003 and 2004.[20]

That the PMPI has consistently risen less rapidly than the CPI is not surprising. The PMPRB's Guidelines require price increases over any three-year period to be no greater than CPI-inflation. In addition, they impose a cap on year-over-year price increases equal to one-and-one half times the rate of CPI-inflation for the year in question. These requirements, applied to patented drugs on a product-by-product basis, have the effect of establishing CPI-inflation as an upper bound on increases in the PMPI. Furthermore, movements in the PMPI have never attained this limit

[19] 1992 is the only year in which the PMPI rose at a faster rate than the CPI. To facilitate and encourage compliance by patentees, the PMPRB's CPI-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.

[20] Statistics Canada, CANSIM, Series V735319. For 2004 as a whole, consumers paid an average of 1.9% more than they did in 2003 for the goods and services included in the CPI basket. This was a smaller increase than the 2.8% annual average rise measured in 2003. According to Statistics Canada the main contributors to this slowdown were automotive vehicle insurance premiums, natural gas, cigarettes, computer equipment and supplies and purchase and leasing of automotive vehicles.

because some manufacturers either do not raise their prices by the full amount permitted under the PMPRB's Guidelines or they reduce their prices.

Figure 2

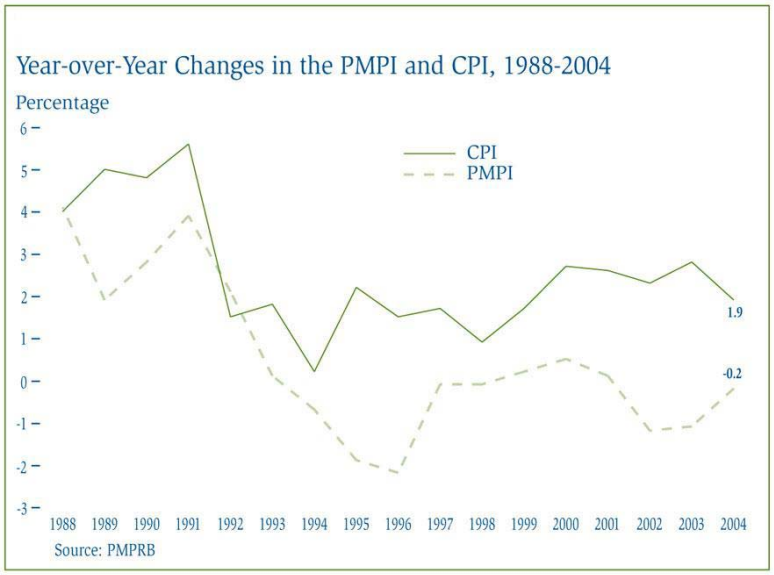


Figure 3 provides information on the extent to which manufacturers have taken the increases permitted under PMPRB Guidelines. In 2004, 52% of patented drug prices rose by between zero and the allowable maximum, compared to only 38% in 2001. Restricting the analysis to the 200 highest-selling drugs in 2004, 66% of patented drugs took price increases within the allowable maximum, compared to only 41% in 2001.

Figure 3

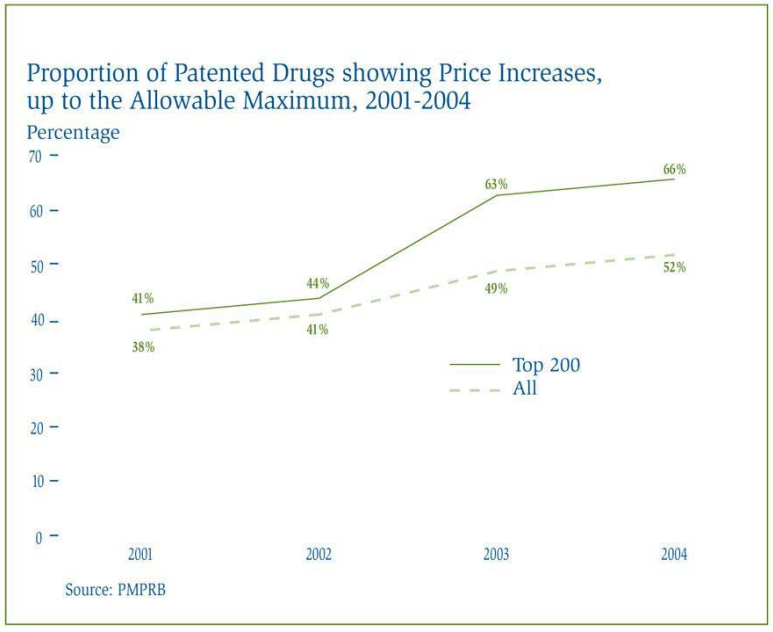
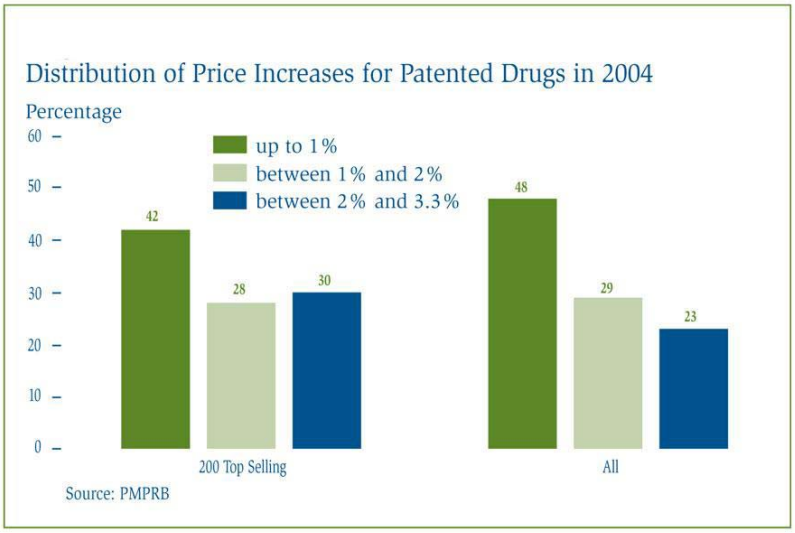


Figure 4 provides information on the distribution of price increases. In 2004, 48% of patented drug prices rose by 1% or less while 52% rose between 1% and 3.3%. Restricting the analysis to the 200 highest-selling drugs, 42% of patented drug prices rose by 1% or less while 58% rose between 1% and 3.3%. The Guidelines provide that one year price increases cannot exceed 1.5 times the forecast change in CPI. For 2004, the CPI was 2.2% and the maximum allowable price increase was 3.3%.

Figure 4



Price Change by Therapeutic Class

Table 2, provides average rates of price change among patented drugs at the level of major therapeutic classes. The results in this table were obtained by applying the PMPI methodology to data on prices of all patented drugs within a given class. The table lists each class' share of overall patented drug sales, as well as average rate of price change specific to the class. The last column multiplies each class' average rate of price change by its share of overall sales: the resulting value equals the group's "contribution" to the change in the overall PMPI (as depicted in Figure 1). The values in this column thus indicate which classes were the primary drivers of the overall price change in the entire set of patented drugs.

The results of Table 2 illustrate the inadvisability of relying too heavily on a single, comprehensive measure of price change. It is clear that several leading therapeutic classes saw price increases between 2003 and 2004, despite the drop in the PMPI. It is also clear that the single largest influence on the PMPI was the decline of prices among drugs related to the alimentary tract and metabolism (ATC Class A). The contribution of this one class more than offset the contributions of all others: without the price changes observed in Class A, the PMPI would have risen by some 0.7%.

Throughout 2004, the PMPRB was advised of a number of reported price increases for patented drugs. Due to the number of price increases reported in 2004, the PMPRB initiated a consultation with stakeholders on the issue of price increases for patented medicines. The dialogue with stakeholders on this issue began with the publication of the PMPRB discussion

paper on March 8, 2005. Further analysis on the issue of price increases for patented medicines will be conducted in 2005. The PMPRB will continue to report on this policy review through its Research Agenda. The Research Agenda is available on the Web site: www.pmprb-cepmb.gc.ca, under Publications, Research Agenda.

Table 2
Decomposition of 2004 PMPI Changes by Major Therapeutic Group

ATC Class	**Share of Total (%)**	**% Change in PMPI: 2003-2004**	**Contribution to PMPI change**
A: Alimentary tract and Metabolism	12.7	-7.3	-0.93
B: Blood and Blood Forming Organs	6.5	-0.3	-0.02
C: Cardiovascular System	25.0	0.9	0.23
D: Dermatologicals	0.83	-0.5	0.00
G: Genito-urinary System and Sex Hormones	3.2	1.6	0.05
H: Systemic Hormonal Preparations, Excluding Sex Hormones	0.78	-1.6	-0.01
J: General Antiinfectives for Systemic use; and P: Antiparasitic Products[21]	10.5	1.3	0.14
L: Antineoplastics and Immunomodulating Agents	9.6	1.1	0.11
M: Musculo-skeletal System	7.0	1.4	0.10
N: Nervous System	16.2	0.7	0.11
R: Respiratory System	6.2	0.9	0.06
S: Sensory Organs	1.14	1.2	0.01
V: Various	0.33	0.004	0.00
Sum of All Therapeutic Classes	**100.0***		**-0.2**
Source: PMPRB * The percentage may not equal 100 due to rounding.			

Comparison of Canadian Prices to Foreign Prices

In accordance with the *Patent Act* and the *Patented Medicines Regulations*, patentees must report all publicly available ex-factory prices of patented drugs in seven foreign countries: France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S. The PMPRB uses this foreign price information to:

[21] These groups have been combined for reasons of confidentiality.

– conduct the International Price Comparison (IPC) tests specified in the Guidelines; and,

– compare drug prices in Canada with other countries.

Figure 5, shows the average ratio of Canadian prices to the median of prices among the seven comparator countries (the "median international price") over the years 1987 through 2004. Canadian prices were on average 23% higher than the median international price in 1987. The average ratio declined to 0.93 in 1995, remaining at levels 5% to 12% below parity from 1995 to 2001. After rising to 1.01 in 2002, the average ratio is again well below parity: in 2004 the average ratio was 0.91.

The ratios presented in Figure 5 are sales-weighted averages of the ratio of the Canadian price to the median international price for each patented drug product for which patentees have reported one or more foreign prices. A key step in its calculation is the conversion of foreign prices in local currencies to their Canadian-dollar equivalents.[22] Year-to-year changes in the average ratio can thus reflect:

– trends in Canadian prices;

– trends in international prices;

– exchange rate movements;

– changes in the set of drug products covered (as new patented drugs are introduced to Canada and older drugs go off patent); and

– shifts in revenue shares among drug products.

Sensitivity analysis indicates that exchange rate movements – in particular, an appreciation of the Swedish kroner against the Canadian dollar – account for roughly three-quarters of the decline in the average ratio between 2003 and 2004.[23] Rising foreign prices and shifts in sales-weights account for the remainder. Movements in Canadian prices contributed almost nothing to the average ratio's decline.

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[22] The PMPRB performs all currency conversions for a given period using a simple average of spot exchange rates recorded in the preceding 36 months. This approach has a smoothing effect, limiting the influence of transitory exchange rate adjustments on Canadian-to-foreign price comparisons. It also has the property of phasing-in the effects of long-term exchange rate movements. Because of this, a long-term appreciation or depreciation of the Canadian dollar may continue to produce adjustments in Canadian-to-foreign price ratios up to three years after the exchange rate shift has taken place.

[23] The kroner have a great deal of leverage in this regard, because Swedish prices often emerge as median international prices. The same is true of the euro, being the currency in which French, Italian and German prices are reported. Movements of the U.S. dollar, in contrast, have little impact on the average ratio, since U.S. prices tend to be at the upper end of the international price distribution and hence are seldom median international prices.

Figure 5

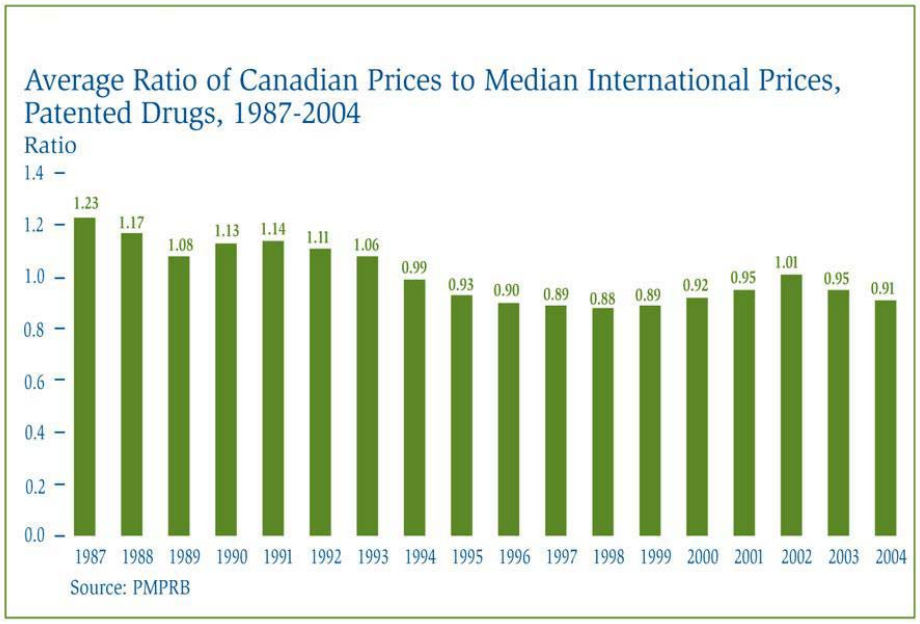
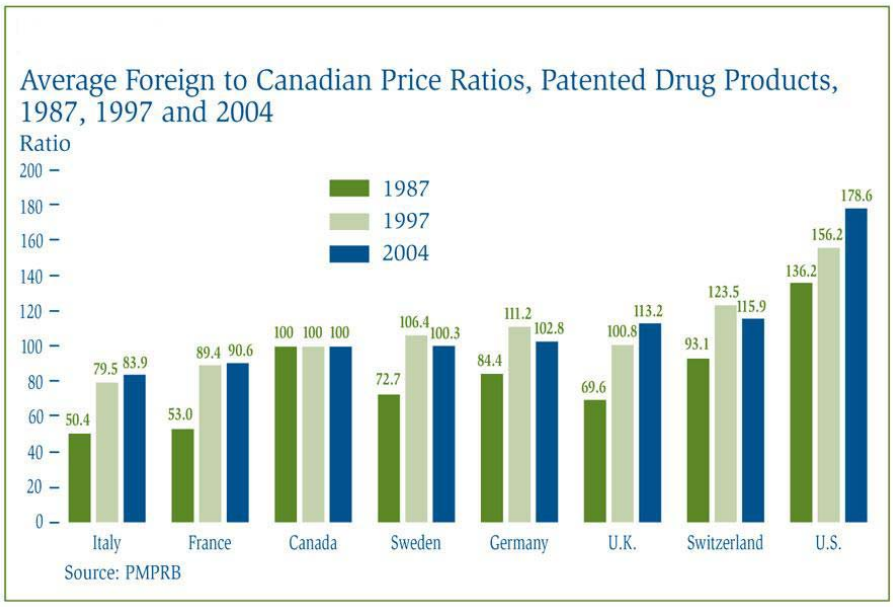


Figure 6 shows the relationship between Canadian prices for patented drug products and prices in each of the seven comparator countries. In 1987 Canadian prices were on average below U.S. prices, but above those in all other countries. By the mid-1990s the situation had changed dramatically, with Canadian prices in the mid-range of the six European countries. This situation continued in 2004, with Canadian prices of patented drugs being on average somewhat less than those in Sweden, Germany, the U.K. and Switzerland, but greater than prices in France and Italy. As in previous years, U.S. prices appear to be substantially higher than prices in both Europe and Canada.[24] The gap is widening.

[24] The pharmaceutical industry in the U.S. has argued that the publicly available prices in that country do not reflect actual prices because of confidential discounts and rebates. Effective January 2000, and following public consultation, the PMPRB began including prices listed in the U.S. Federal Supply Schedule (FSS) in calculating the average U.S. price of patented drugs. The FSS prices are negotiated between manufacturers and the U.S. Department of Veterans' Affairs. They are typically less than other publicly available U.S. prices reported to the PMPRB by manufacturers.

Figure 6



National Prescription Drug Utilization Information System (NPDUIS)

As reported in last year's Performance Report the following projects were approved for 2004-05 by the NPDUIS Steering Committee:

Non-Insured Health Benefit Pharmacy Program, 1999-2000 to 2001-2002

In September 2004, the PMPRB released its study examining spending on drugs within the Non-Insured Health Benefits (NIHB) Program of Health Canada's First Nations and Inuit Health Branch over three fiscal years. The study assessed distributional effects and the major drivers of cost and utilization change for the NIHB Pharmacy Program. Data for the study were provided by the Non-Insured Benefits Directorate of Health Canada. Highlights of the study can be found in the October 2004 issue of the NEWSletter; the full study is available on the Web site: www.pmprb-cepmb.gc.ca, under Publications, Studies and Discussion Papers.

Pharmaceutical Trends Overview Report

The Pharmaceutical Trends Overview Report will report on price and expenditure trends, price levels and cost-drivers in public reimbursement plans. Work on this project is nearing completion and release of the final report is expected in the fall/winter of 2005.

Budget Impact Analysis Guidelines (formerly Budget Impact Analysis Methodology)

This project was divided into two parts:

Phase I involved conducting a needs assessment to determine the need for budget impact analysis guidelines. The needs assessment has been completed and the PMPRB is currently reviewing the results. The results of the needs assessment should be available in the fall/winter of 2005.

Phase II is the actual development of guidelines for conducting budget impact analysis and reporting the results. Work on Phase II is dependent on the results of the needs assessment.

Program Expenditure Forecasting Methodology

The Forecast Methodology project will describe a methodology to forecast expenditures on pharmaceuticals in Canada for the total economy as well as for utilization and cost within public drug plans by major therapeutic class. Applying this methodology will produce a range of forecasts under varying assumptions related to economic activity, population aging, price inflation, and budget constraints of the various government jurisdictions. Work on this project is nearing completion. The release of the final report is expected in the summer/fall of 2005.

Strategic Outcome
To report on pharmaceutical research-and-development expenditures of patentees in Canada.
Expected Results: • Federal government has accurate information on R&D expenditure trends and performance in Canada relative to historical commitments. **- Intermediate Outcomes** Assess the relevance of overall R&D indicators and the utility of detailed breakdown of R&D information (e.g., by type of research and location). **- Immediate Outcomes** Ensure timely filing of all R&D and sales information by each patentee.
Plans, priorities and commitments Analyze data and prepare and issue reports on research-and-development trends.

Analysis of Research-and-Development Expenditures

With the adoption of the 1987 amendments to the *Patent Act* (Act), Canada's Research Based Pharmaceutical Companies (Rx&D) made a public commitment that brand name manufacturers

would increase their annual research-and-development (R&D) expenditure to 10% of sales revenue by 1996.[25]

Under the Act, the PMPRB monitors and reports on R&D spending, but has no regulatory authority over the amount or type of research spending by patentees.

The results presented here were derived from data patentees have submitted to the PMPRB. The Act requires each patentee to report its revenue from sales of drugs (including revenue from sales of non-patented drugs and from licensing agreements) and R&D expenditure in Canada related to medicines. Companies without sales of patented medicines need not report on R&D expenditure and, as new patents are granted and others expire, the set of companies required to file R&D data changes from year to year.

Total R&D expenditure reported by patentees was $1,170.0 million in 2004, 2.0% less than in 2003. Rx&D members reported R&D expenditure of $1,008.3 million in 2004, accounting for 86.2% of all reported expenditure.

The ratio of R&D expenditure to sales revenue for the patented pharmaceutical industry was 8.3% in 2004 down from 8.8% in 2003. The ratio for members of Rx&D was 8.5%, down from 9.1% in the previous year.

Patentees reported spending $221.7 million on basic research, representing 19.7% of current R&D expenditure. Spending on basic research in 2004 increased by 23% relative to the previous year.

More detailed information can be found in the PMPRB's 2004 Annual Report available on the Web site: www.pmprb-cepmb.gc.ca, under Publications, Annual Report.

[25] As published in the Regulatory Impact Assessment Statement (RIAS) of the *Patented Medicines Regulations*, 1988, published in the Canada Gazette Part II, Vol. 122, No. 20 – SOR/DORS/88-474.

Strategic Outcome
To continue to be a transparent, dynamic and accountable public agency recognized as adding value to pharmaceutical policy development in Canada.
Expected Results: • Continual progress in modernizing the price review process and accounting for the achievement of the PMPRB's mandate. • More transparent and relevant public communications on the full range of the PMPRB's activities. • Continue implementation of the new Values and Ethics Code and a risk assessment process as part of the strategic planning process. **- Intermediate Outcomes** Detailed implementation plans for new processes to enhance the ability of the PMPRB to be an efficient and accountable agency. **- Immediate Outcomes** Assess opportunities to improve the efficiency, timeliness and transparency of the drug regulatory process.
Plans, priorities and commitments Implementation of the Board's decisions on recommendations of the Working Group on Price Review Issues. Conduct an evaluation of the transparency initiative. Continue implementation of the modern comptrollership initiative.

Transparency

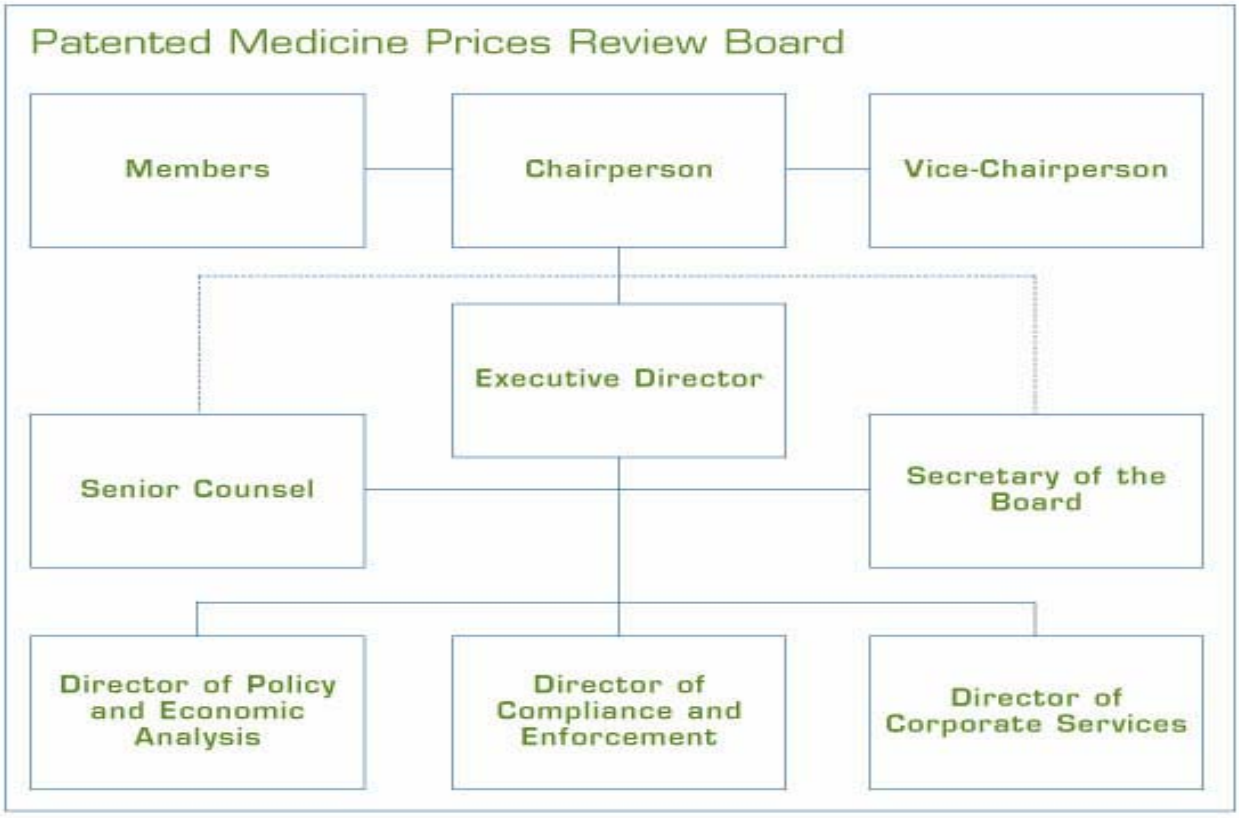
In December 2000, the Board received the second report of its Working Group on Price Review Issues, a report on the Board's price review process for new-patented medicines. Overall, the Board agreed with the Working Group's recommendations, however the Board wanted to consult more broadly on the implementation of those recommendations. In April 2001, the Board issued a Notice and Comment on transparency in the price review process.

In that Notice and Comment the Board proposed to evaluate its transparency initiatives in two years. With the acceleration of the Timelines project a number of additional transparency initiatives have been implemented such as, the publication of the schedule of meetings of the Human Drug Advisory Panel (HDAP) for 2005 and the establishment of deadlines for receipt of patentees' submissions for the HDAP's consideration. These steps were introduced to make the scientific review process more transparent and to increase its efficiency. Since work on the transparency initiatives is still ongoing, it was decided to postpone the evaluation at this time. The revised time frame for the evaluation is under consideration.

As a result of the federal government's Modern Comptrollership initiative the PMPRB has a responsibility to actively monitor the soundness of its management and control frameworks. In this regard, the PMPRB incorporated a risk assessment process into its strategic planning process. This activity is intended to ensure that management is aware of significant issues of risk or other problems in a timely manner, and that appropriate remedial action plans are developed and successfully implemented.

SECTION III – SUPPLEMENTARY INFORMATION

Organizational Information



The Board consists of not more than five members who serve on a part-time basis, appointed by the Governor-in-Council, including a Chairperson and Vice-Chairperson. The Chairperson is designated under the *Patent Act* as the Chief Executive Officer of the PMPRB with the authority and responsibility to supervise and direct its work. The Executive Director manages the work of the staff. Senior staff consists of the Executive Director, the Director of Compliance and Enforcement, the Director of Policy and Economic Analysis, the Director of Corporate Services, the Secretary of the Board and Senior Counsel.

The Compliance and Enforcement Branch is largely responsible for the review of prices for patented medicines and the Compliance and Enforcement Policy. The Policy and Economic Analysis Branch is largely responsible for conducting analyses and preparing reports on price trends and other policy and economic studies. The Secretariat, Corporate Services Branch and Senior Counsel provide regulatory, reporting and administrative support.

Financial Table 1: Comparison of Planned Spending and Full Time Equivalents

($ thousands)	2002–03 Actual	2003–04 Actual	2004–2005			
			Main Estimates	Planned Spending	Total Authorities	Actual
Patented Medicine Prices Review Board	4,231.3	4,290.3	5,301.0	5,301.0	5,406.0	4,996.7
Total	**4,231.3**	**4,290.3**	**5,301.0**	**5,301.0**	**5,406.0**	**4,996.7**
Less: Non-Respendable revenue[1]	(27.1)	(7,834.8)	-	-	-	(3,026.1)
Plus: Cost of services received without charge	666.9	768.4	825.5	825.5	825.5	825.9
Net cost of Department	**4,871.1**	**(2,776.1)**	**6,126.5**	**6,126.5**	**6,231.5**	**2,796.5**
Full Time Equivalents	**35.0**	**38.0**	**44.0**	**44.0**	**44.0**	**42.0**

(1) The money reported as non-respendable revenue does not represent revenues generated by the PMPRB. This money is a result of 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.

Financial Table 2: Use of Resources by Business Line

2004–2005						
	Budgetary				Plus: Non-Budgetary	Total
Business Line)	Operating	Total: Gross Budgetary Expenditures	Less: Respendable Revenue	Total: Net Budgetary Expenditures	Loans, Investments and Advances	
Patented Medicine Prices Review Board						
Main Estimates	5,301.0	5,301.0	-	5,301.0	-	**5,301.0**
Planned Spending	5,301.0	5,301.0	-	5,301.0	-	**5,301.0**
Total Authorities	5,406.0	5,406.0	-	5,406.0	-	**5,406.0**
Actual Spending	4,996.7	4,996.7	-	4,996.7	-	**4,996.7**

Financial Table 3: Voted and Statutory Items

Vote or Statutory Item	Truncated Vote or Statutory Wording	2004–2005			
		Main Estimates	Planned Spending	Total Authorities	Actual
25	Operating expenditures	4,636.0	4,636.0	4,741.0	4,447.8
(S)	Contributions to employee benefit plans	665.0	665.0	665.0	548.9
	Total	**5,301.0**	**5,301.0**	**5,406.0**	**4,996.7**

Financial Table 4: Net Cost of Department

($ millions)	2004–2005
Total Actual Spending	4,996.7
Plus: Services Received without Charge	
Accommodation provided by Public Works and Government Services Canada (PWGSC)	577.5
Contributions covering employers' share of employees' insurance premiums and expenditures paid by TBS (excluding revolving funds)	248.4
Less: Non-respendable Revenue[(1)]	(3,026.1)
2004–2005 Net cost of Department	**2,796.5**

(1) The money reported as non-respendable revenue does not represent revenues generated by the PMPRB. This money is a result of 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.

Financial Table 5: Sources of Non-Respendable Revenue

($ millions)	Actual 2002-03	Actual 2003-04	2004-2005			
			Main Estimates	Planned Revenue	Total Authorities	Actual
Patented Medicine Prices Review Board						
Source of non-respendable revenue[1]						
Voluntary Compliance Undertakings	27.1	7,834.8	-	-	-	3,026.1
Total Non-Respendable Revenue	**27.1**	**7,834.8**	**-**	**-**	**-**	**3,026.1**

(1) The money reported as non-respendable revenue does not represent revenues generated by the PMPRB. This money is a result of 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.