Patented Medicine Prices Review Board

2003-2004

Estimates
A Report on Plans and Priorities

Approved

Minister of Health Canada
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The Patented Medicine Prices Review Board (PMPRB) is an independent, quasi-judicial tribunal 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 federal government’s policy to balance consumer protection and affordable health care with the trade and industrial development objectives of pharmaceutical patent legislation.

In its quasi-judicial role, established by legislation, the Board can hold public hearings and make remedial orders when it finds a patentee has been selling a patented drug at an excessive price. It has been able to fulfill its mandate through an active policy to promote and encourage voluntary compliance with the Act.

In Canada, policy issues have continued to be dominated by discussions about health care. Among the reasons for this continued focus are the significant cost pressures 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, accounting for 16.2% of total health expenditures in 2002. Many public drug plans have reported annual increases in drug spending of 15% or more.

In 2002, two important studies on health care in Canada were released: the final report of the Standing Senate Committee on Social Affairs, Science and Technology, chaired by Senator Michael Kirby, and the Report of the Commission on the Future of Health Care headed by the Hon. Roy Romanow. Both reports highlighted the significant issues related to pharmaceuticals and made recommendations for change.

At the same time, considerable progress is being made on initiatives announced earlier. In September 2001, the federal/provincial/territorial ministers of health agreed on a multi-faceted approach to better pharmaceuticals management, including the Common Drug Review. Another 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.
As reported in our Annual Report for 2001, total sales by drug manufacturers in Canada increased 15% in 2001 to $11.5 billion, while sales of patented drugs increased by 18.9% to $7.5 billion in 2001. Patented drugs now account for 65% of total sales, up from 45% in 1996.

As in previous years, these increases are largely attributable to increased sales and utilization of existing drugs and the impact of new drugs, rather than price increases. In fact, manufacturers’ prices of patented drugs, as measured by the Patented Medicine Price Index (PMPI), rose by only 0.1% between 2000 and 2001. This result extends the period of declines and near negligible increases in the PMPI that began in 1993.

Since the establishment of the PMPRB in 1987 the ratio between Canadian prices of patented medicines and the corresponding median prices among the seven comparator countries listed in the Patented Medicines Regulations has declined and has remained relatively stable since 1994. In 2001, prices of patented drugs in Canada were about 95% of the median foreign prices, up slightly from the value of 92% recorded in 2000.

Transparency continues to be an important objective of the PMPRB. In 2002, the PMPRB implemented a recommendation of stakeholders that it publish more information on the reviews of new patented medicines for purposes of applying the Guidelines. The PMPRB believes that increased transparency and openness in the price review process can contribute to an environment that facilitates evidence-based decision-making for stakeholders, researchers and policy-makers.

2002 marked the 15th anniversary of the PMPRB. In recognition of this event, the PMPRB organized its Symposium 2002. Its purpose was to share information with stakeholders and the public and facilitate a dialogue on issues related to drug price regulation in Canada – to examine current trends and to identify the challenges and opportunities. The symposium attracted the participation of a broad range of the PMPRB’s stakeholders including representatives of consumer groups, health professionals, departments and agencies of both senior levels of government and the pharmaceutical industry.

The symposium provided a concrete example of the dual mandate of the PMPRB – to regulate prices charged by manufacturers of patented medicines to ensure they are not excessive and to report to Canadians on drug price trends and the R&D performance of the pharmaceutical industry.

Robert G. Elgie
Chairperson
MANAGEMENT REPRESENTATION STATEMENT


This document has been prepared based on the reporting principles and disclosure requirements contained in the Guide to the preparation of the 2003-2004 Report on Plans and Priorities:

- It accurately portrays the PMPRB's plans and priorities.
- The planned spending information in this document is consistent with the directions provided in the Minister of Finance's Budget and by Treasury Board of Canada Secretariat.
- It is comprehensive and accurate.
- It is based on sound underlying information and management systems.

The reporting structure, on which this document is based, has been approved by Treasury Board Ministers and is the basis for accountability for the results achieved with the resources and authorities provided.

Name: ____________________________
Wayne D. Critchley
Executive Director

Date: ____________________________

Chairperson's Message
Section II

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 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.

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;
- the ratio of research-and-development expenditures to sales revenues for individual patentees and for all pharmaceutical patentees in Canada; and
- inquiries conducted at the request of the Minister of Health.
Section III

Planning Overview

The PMPRB is funded through operating expenditures. Its jurisdiction includes both prescription and non-prescription patented medicines sold in Canada for human and veterinary use. The price reviewed by the PMPRB is the price at which the manufacturer sells a patented medicine to wholesalers, hospitals, pharmacies and other customers. The Board has no authority over the prices of non-patented drugs, including generic drugs sold under compulsory licenses, and does not have jurisdiction over prices charged by wholesalers or retailers nor pharmacists’ professional fees.

The PMPRB promotes Canadians’ access to needed medications by ensuring that prices of patented drugs are not excessive. Among other things, it has the authority to order, following a public hearing, reductions in the prices of patented medicines and measures to offset excess revenues received by patentees.

Rising health care costs
Drugs continue to account for an increasing proportion of total health spending, growing faster than any other major component of the health care system, including hospitals and physicians. Governments throughout the world have found it necessary to intervene in the pharmaceutical market because of the imperfections that exist in this market. Drugs are so important to health care that most countries seek policies to facilitate access by citizens to medically necessary medications.

All industrialized countries, with the exception of the U.S., have national systems that regulate drug prices or the profits of drug manufacturers in various ways in an attempt to contain rising drug costs. Globally, there is an interest in examining the major pharmaceutical cost drivers, such as, pricing, prescribing practices and utilization.

According to the Canadian Institute for Health Information (CIHI), pharmaceuticals continue to represent the fastest-growing component of health care costs, accounting for 16.2% of total health expenditures in 2002. Many public drug plans have reported annual increases in drug spending of 15% or more in recent years.

Federal/Provincial/Territorial (F/P/T) initiatives
In recent years, the significant growth in expenditures on pharmaceuticals has led Federal/Provincial/Territorial (F/P/T) Ministers of Health to look at the drug price trends in publicly-funded drug plans and to analyze the cost drivers in those plans. On September 26, 2001, F/P/T Health Ministers announced an agreement on a multi-faceted approach to better pharmaceuticals management.
One of these initiatives is the National Prescription Drug Utilization Information System (NPDUIS), a partnership involving CIHI and the PMPRB. In establishing the first national database of publicly-funded drug plans in Canada, the NPDUIS will call on the PMPRB to continue and expand on the analyses of price and expenditure trends and cost drivers of publicly-funded drug plans previously conducted pursuant to a Memorandum of Understanding with the Minister of Health.

The report of the Commission on the Future of Health Care
The final report of the Commission on the Future of Health Care (the Romanow Report) was released on November 28, 2002. Although the federal government has not officially responded to the recommendations in the Romanow Report, the issue of pharmaceuticals with respect to health care can be expected to receive increased attention. The PMPRB is implicated either directly or indirectly in the Report’s recommendations on pharmaceuticals.

Hoechst Marion Roussel/Nicoderm – Judicial review
In September 1999 and September 2000, Hoechst Marion Roussel Canada Inc. (HMRC, now Aventis Pharma) filed applications in the Federal Court of Canada for judicial review of decisions of the Board affirming its jurisdiction to conduct a hearing into the price of the nicotine patch, Nicoderm. This matter was initiated when the Board issued a Notice of Hearing in April 1999 to determine if the price of Nicoderm is or had been excessive under section 83 of the Patent Act.

As HMRC only named the Attorney-General of Canada as Respondent in its judicial review applications, Board Staff and the Board’s Hearing Panel applied to the Federal Court to participate in the proceedings. In a decision dated July 13, 2001, the Prothonotary of the Federal Court denied Board Staff the right to participate in the judicial review but allowed the Board Panel to intervene on a limited basis. This decision would reverse the long standing practice in the Federal Court of allowing Board Staff full participation in a judicial review of the PMPRB decisions. During 2002, the Federal Court Trial Division and subsequently the Federal Court of Appeal upheld the Prothonotary’s decision. This decision impacts the PMPRB’s capacity to ensure an adequate defence of decisions of the Board on judicial review. At this time the Board is considering its options.

Working Group on Price Review Issues
In 2002, the Working Group submitted its two final reports, both dealing with the Guidelines for category 3 new drugs. At its December 2002 meeting, the Board reviewed the Working Group’s reports, which largely validated current practices, and accepted the recommendations for minor changes to its current practices regarding the Guidelines for category 3 new drugs. In addition, the Working Group recommended that the Guidelines should take the “value” of new drugs into account to a greater extent than is currently the case. On this recommendation, the Board agreed that there was insufficient information to
propose amendments to the Guidelines at this time and that more work is required.

Along with earlier recommendations of the Working Group on Price Review Issues that have already been implemented, the Board has undertaken to consider the establishment of milestones and time frames for the price reviews of new patented drugs under the Guidelines.
## Section IV

### Plans and Priorities by Strategic Outcomes

<table>
<thead>
<tr>
<th>Strategic Outcomes</th>
<th>Priorities</th>
</tr>
</thead>
<tbody>
<tr>
<td>To provide assurance that manufacturers’ prices for patented medicines are not</td>
<td>- review 100% of the manufacturers’ prices of patented medicines sold in Canada</td>
</tr>
<tr>
<td>excessive</td>
<td>- report on enforcement measures (VCUs &amp; Hearings) taken by the PMPRB</td>
</tr>
<tr>
<td></td>
<td>- compare the annual percentage change in the Patented Medicine Price Index (PMPI) to the annual percentage change in the CPI</td>
</tr>
<tr>
<td></td>
<td>- compare the manufacturers’ prices for new and existing patented medicines sold in Canada to manufacturers’ prices in other countries</td>
</tr>
<tr>
<td>To report on trends in manufacturers’ prices of all medicines in Canada</td>
<td>- analysis of trends in manufacturers’ prices and volume of patented products sold</td>
</tr>
<tr>
<td></td>
<td>- analysis of trends in manufacturers’ prices of all drug products (patented &amp; non-patented)</td>
</tr>
<tr>
<td></td>
<td>- a comparison of Canadian patented drug prices to prices in other countries</td>
</tr>
<tr>
<td></td>
<td>- analysis of expenditure trends, price levels and cost drivers facing public drug benefit plans (NPDUIS)</td>
</tr>
<tr>
<td>To report on the pharmaceutical research and development expenditures of patentees in Canada</td>
<td>- analysis of R&amp;D expenditures to sales revenues for each patentee and the industry as a whole based on information supplied by patentees</td>
</tr>
<tr>
<td></td>
<td>- analysis of R&amp;D expenditures by location and type of research</td>
</tr>
<tr>
<td>To continue to be a transparent, dynamic and accountable public agency recognized</td>
<td>- implementation of the Board’s decisions on the recommendations of the Working Group on Price Review Issues</td>
</tr>
<tr>
<td>as adding value to pharmaceutical policy development in Canada</td>
<td>- modern comptrollership initiative</td>
</tr>
</tbody>
</table>
Strategic Outcome #1- To provide assurance that manufacturers’ prices for patented medicines are not excessive

Under the *Patented Medicines Regulations* (Regulations), patentees are required to report on the introductory prices and sales of new patented medicines for the first 30 days of sale and to continue to file detailed information on prices and sales of each patented drug for the first and last six-month period of each year for as long as the drug remains patented. Board Staff reviews the manufacturers’ prices of all patented medicines sold in Canada to ensure compliance with the PMPRB’s Guidelines. The PMPRB receives information on 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 the Board finds prices 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.

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 when assessing whether or not the price of a patented 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 powers to the PMPRB.

Strategic Outcome #2- To report on trends in manufacturers’ prices of all medicines in Canada

Patentees are also required, under the Regulations, to submit to the PMPRB information on their annual total sales of both patented and non-patented drugs in Canada. On an annual basis, Board staff conducts analyses of this information and reports the trends in manufacturers’ prices and the volume of patented drug products sold in Canada; trends in manufacturers’ prices of all drug products – patented and non-patented; as well as a comparison of

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Canadian patented drug prices to international patented drug prices. The results of these analyses are published in the Board’s Annual Report which is available on the website: www.pmprb-cepmb.gc.ca under Publications.

On September 26, 2001, F/P/T Health Ministers announced an agreement on a multi-faceted approach to better pharmaceuticals management. One of these initiatives is the National Prescription Drug Utilization Information System (NPDUIS), a partnership involving CIHI and the PMPRB. The drug information system will bring together data from major public drug plans in Canada and permit more in-depth analyses that can be used to facilitate continuous improvement in pharmaceuticals management.

In establishing the first national database of publicly-funded drug plans in Canada through the NPDUIS, the PMPRB will 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. Work under the NPDUIS commenced in the 2002-2003 fiscal year and is ongoing.

**Strategic Outcome #3- To report on the pharmaceutical research-and-development expenditures of patentees in Canada**

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

The PMPRB is the only comprehensive source of information on the R&D expenditures by pharmaceutical patentees in Canada, including the R&D-to-sales ratios for individual patent holding companies. An annual report on this analysis can be found in the Board’s Annual Report which is available on the website: www.pmprb-cepmb.gc.ca under Publications.

Strategic Outcome #4- To continue to be a transparent, dynamic and accountable public agency recognized as adding value to pharmaceutical policy development in Canada

In the coming year, the PMPRB will continue to focus on transparency and consultation. Along with other recommendations of the Working Group on Price Review Issues that have already been implemented, the Board has undertaken to consider the establishment of milestones and time frames for the price reviews of new patented drugs. This project is included on the Board’s Research Agenda. Preparatory work on this project began in 2002 and it is hoped that proposals may be published for consultation in 2003-2004.

In 2002, the Working Group submitted its two final reports, both dealing with the Guidelines for category 3 new drugs. At its December 2002 meeting, the Board reviewed the Working Group’s reports, which largely validated current practices, and accepted the recommendations for minor changes to its current practices regarding the Guidelines for category 3 new drugs. In addition, the Working Group recommended that the Guidelines should take the “value” of new drugs into account to a greater extent than is currently the case. On this recommendation, the Board agreed that there was insufficient information to propose amendments to the Guidelines at this time and that more work is required.

The issue of assessing the incremental “value” of a new drug, or “value for money” is an important one. In the consultations leading to the Road Map for the Next Decade, in 1998, many stakeholders raised concerns that the Guidelines were either too flexible, or not flexible enough, in recognizing the “value” of a new drug relative to existing options. At that time, the Board committed through its Research Agenda not only to review the Guidelines for category 3 new drugs, but also those for category 2 new drugs in turn, including the use of pharmacoeconomics.

The Board has directed its Staff to develop a discussion paper on assessing the value of new drugs with the objective of developing a definition of “value” of new drugs. The discussion paper will serve to better inform the further review of the Guidelines.

The report on the review of the Guidelines for category 3 new drugs completes the Working Group’s mandate. The Board will need to assess appropriate forms for consultation on new policy issues.

As a result of the federal government’s Modern Comptrollership initiative, the PMPRB conducted a capacity assessment in 2002 to identify areas for improvement. The PMPRB is currently implementing an action plan to address the areas identified.
5.1 **Strategic Outcomes and Business line**

<table>
<thead>
<tr>
<th>Business Line</th>
<th>Strategic Outcomes</th>
<th>Total (000's)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMPRB</td>
<td>assurance that manufacturers’ prices for patented medicines are not excessive</td>
<td>$4,738.0</td>
</tr>
<tr>
<td></td>
<td>report on trends in manufacturers’ prices of all medicines in Canada</td>
<td></td>
</tr>
<tr>
<td></td>
<td>report on the pharmaceutical research and development expenditures of patentees in Canada</td>
<td></td>
</tr>
<tr>
<td></td>
<td>continue to be a transparent, dynamic and accountable public agency recognized as adding value to pharmaceutical policy development in Canada</td>
<td></td>
</tr>
</tbody>
</table>

The PMPRB has one business line which matches its program, the Patented Medicine Prices Review Board.

5.2 **Accountability**

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.
5.3 **Planned Spending**

The Planned Spending table summarizes the Main Estimates plus Supplementary Estimates, the Minister of Finance’s Budget and other associated adjustments to arrive at the total planned spending requirements for the PMPRB. It also identifies planned full time equivalents (FTE) levels over the planning period.
## Table 5.1
Patented Medicine Prices Review Board – Planned Spending

<table>
<thead>
<tr>
<th>(thousands of dollars)</th>
<th>Forecast(^{(1)}) Spending</th>
<th>Planned(^{(3)}) Spending</th>
<th>Planned(^{(3)}) Spending</th>
<th>Planned(^{(4)}) Spending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budgetary Main Estimates (gross)</td>
<td>3,681.0</td>
<td>4,738.0</td>
<td>4,738.0</td>
<td>3,804.0</td>
</tr>
<tr>
<td>Non- budgetary Main Estimates (gross)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Less: Respendable revenue</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total Main Estimates</strong></td>
<td>3,681.0</td>
<td>4,738.0</td>
<td>4,738.0</td>
<td>3,804.0</td>
</tr>
<tr>
<td><strong>Adjustments(^{(2)})</strong></td>
<td>778.3</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Net Planned Spending</strong></td>
<td>4,459.3</td>
<td>4,738.0</td>
<td>4,738.0</td>
<td>3,804.0</td>
</tr>
<tr>
<td>Less: Non-respendable revenue</td>
<td>(17.6)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Plus: Cost of services received without charge</td>
<td>663.9</td>
<td>709.7</td>
<td>709.7</td>
<td>670.4</td>
</tr>
<tr>
<td><strong>Net Cost of Program</strong></td>
<td>5,105.6</td>
<td>5,447.7</td>
<td>5,447.7</td>
<td>4,474.4</td>
</tr>
</tbody>
</table>

| Full Time Equivalents | 36.0 | 41.0 | 41.0 | 34.0 |

\(^{(1)}\) Reflects the best forecast of total planned spending to the end of the fiscal year including funding allocated for the NPDUIS. (For more information on NPDUIS see Strategic Outcome # 2 in this document.)

\(^{(2)}\) Adjustments are to accommodate approvals obtained since the Main Estimates and include Budget initiatives, Supplementary Estimates etc.

\(^{(3)}\) The estimated total planned spending for the next two fiscal years includes funding allocated for the NPDUIS.

\(^{(4)}\) The estimated total planned spending for the 2005-2006 fiscal year does not include funding allocated for the NPDUIS as funding arrangements beyond 2004-2005 are pending.
**Table 6.1**

**Sources of Non-respendable Revenue***

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patented Medicine Prices Review Board</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Sources of non-respendable revenue</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voluntary Compliance Undertaking</td>
<td>17.6</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total Non-respendable Revenues</strong></td>
<td>17.6</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

* The money reported as non-respendable revenue (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.

**Table 6.2**

**Net Cost of Program for the Estimates Year**

<table>
<thead>
<tr>
<th>(thousands of dollars)</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Planned Spending (Gross Budgetary and Non-budgetary Main Estimates plus Adjustments)</td>
<td>4,738.0</td>
</tr>
<tr>
<td><strong>Plus: Services Received without Charge</strong></td>
<td></td>
</tr>
<tr>
<td>Accommodation provided by the Public Works and Government Services Canada (PWGSC)</td>
<td>495.0</td>
</tr>
<tr>
<td>Contributions covering employers’ share of employees’ insurance premiums and expenditures paid by the TBS</td>
<td>214.7</td>
</tr>
<tr>
<td><strong>5,447.7</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Less: Non-respendable Revenue</strong></td>
<td>-</td>
</tr>
<tr>
<td>2003-2004 Net cost of Program</td>
<td>5,447.7</td>
</tr>
</tbody>
</table>
Section VII

General Information

Listing of Board Members

The Patented Medicine Prices Review Board consists of no more than five part-time members appointed by the Governor-in-Council. As of January 31, 2003 the Board members were:

Chairperson:

Robert G. Elgie, C.M., LL.B., M.D., F.R.S.C.(C)

Vice-Chairperson:

Réal Sureau, FCA

Members:

Thomas E. (Tim) Armstrong, Q.C., O. Ont.
Anthony Boardman, B.A. (hons), Ph.D.
Ingrid S. Sketris, BSc (Phm), Pharm.D., MPA (HSA)

Statutory Annual Reports and Other PMPRB Reports {tc "Statutory Annual Reports and Other PMPRB Reports " \ 2}

Legislation Administered and Associated Regulations

  R.S. 1985, c. 33 (3rd supp.), and as further amended by
  S.C. 1993, c. 2

- *Patented Medicines Regulations*, 1994 SOR/94 - 688, as amended by
  SOR/95 - 172
Guidelines

- Compendium of Guidelines, Policies and Procedures
- (Proposed) Rules of Practice and Procedure (June 2001)

**ANNUAL REPORT Series (1989 to 2001)**

**NEWSletter Series (1997 to 2003)**