Patented Medicine Prices Review Board

Inside...

Canada

NEWSletter

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Since our last issue ...

Here are some of the key events which occurred since October 2000:

November 21:	Speech by Wayne D. Critchley, Executive Director, *Controlling Drug Prices in Canada: Current Issues*, to the Canadian Pharmaceutical Industry Congress [CPIC 2000], in Toronto. Highlights of the speech are available on page 7.
December 7 & 8:	The Board held its last quarterly meeting for 2000. A summary of the minutes of the meeting appears on page 3.
January 25 & 26:	Speech by Wayne D. Critchley, *Price Regulation of Patented and Non-Patented Drugs in Canada*, to the Centre for Business Intelligence Conference on Pricing, Reimbursement and Formulary Management for Canadian Pharmaceuticals, in Toronto.

If you wish to know more about the PMPRB, please contact us at our toll-free number: **1-877-861-2350** or consult our website at **www.pmprb-cepmb.gc.ca**.

Retrospective on 2000

During the past year, we have continued to see evidence of the significant increases in expenditures on pharmaceuticals in Canada. In our 1999 Annual Report, tabled in June, we reported that sales of pharmaceuticals increased 17% from the previous year while sales of patented drugs increased by 27%, the largest one-year increase ever seen in the history of the PMPRB. Provincial drug plans are reporting significant increases in their expenditures this year.

In light of these trends, our Research Agenda for 2001-2004, reported on page 6 in this issue of the NEWSletter, shows our continued focus on implementing the recommendations from our *Road Map for the Next Decade* and conducting analyses of public drug plan spending as requested by the Minister of Health.

The year 2000 also saw important precedents with the:

- Variation Order in the ICN Canada-Virazole case;
- public Notice and Comment regarding the Voluntary Compliance Undertaking submitted by Bristol-Myers-Squibb and Sanofi Synthelabo for Plavix; and,

The Patented Medicine Prices Review Board is a quasi-judicial tribunal with the mandate to ensure that manufacturers' prices of patented medicines sold in Canada are not excessive.

For more information on the Nicoderm hearing, please contact Sylvie Dupont, Secretary of the Board, at:

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All of the Board's decisions and reasons are posted on our website: **www.pmprb-cepmb.gc.ca**, under Publications, Hearings & Decisions of the Board.

- Hearing Panel's decision in August on jurisdictional issues in the hearing involving Hoechst Marion Roussel (now Aventis) and the medicine Nicoderm. Decisions of the Board on its jurisdiction in the latter matter are currently the subject of applications for judicial review in the Federal Court of Canada. ■

Your comments on our progress in fulfilling our *Road Map* initiatives and the priorities set out in our Research Agenda are always appreciated.

News from the Chair

Robert G. Elgie

On January 11 and 12, 2001, I had the pleasure of attending, along with other representatives of the PMPRB, a symposium on optimal drug therapy chaired by Dr. Stuart MacLeod and Mary Catherine Lindberg. Dr. MacLeod is the Director of the Father Sean O'Sullivan Research Centre at St.Joseph's Hospital (Hamilton) and a professor at McMaster University Faculty of Health Sciences. Mary Catherine Lindberg is Assistant Deputy Minister, Ontario Ministry of Health and Long Term Care.

The symposium provided an opportunity to share much of the work being done in this area and discuss the many challenges still ahead. We are looking forward to the report on the symposium to be published in the future.

Participants in the symposium appeared to agree that the large increases in consumption and expenditures on drugs warrant further attention and study. Expenditures for the Ontario Drug Benefit Plan are increasing at a rate above 20% in the current fiscal year, a figure similar to the 17% increase in sales in 1999 as reported by drug manufacturers to the PMPRB. During 2001, we will be continuing to monitor and report on these trends and to provide more detailed studies of drug prices for public drug plans to the Minister of Health. ■

Robert G. Elgie

The Working Group on Price Review Issues reports to the Board on the price review process for new patented medicines

At its meeting in December 2000, the Board received the Report of the Working Group on Price Review Issues on the price review process for new patented medicines. The mandate of the Working Group for this review was to make recommendations on how:

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

The Working Group made a number of recommendations, but did not achieve consensus on all aspects of how the above goals should be achieved. The Report is available on our website under Working Group on Price Review Issues, Reports. The Board will review the Working Group's Report in detail at its meeting on March 5 and 6, 2001. Information regarding its deliberations on the next steps will be communicated in the April 2001 issue of the NEWSletter.

A meeting of the Working Group had been scheduled for the end of January to continue the discussions on the issue of the guidelines for category 3 new drug products. Unfortunately due to operational workload, it has been necessary to postpone that meeting to May 2001. ■

Patented Medicine Prices Review Board - December 7 & 8, 2000 Meeting

At the December 7 & 8, 2000 meeting, the Members of the Board:

- Received the Report of the Working Group on Price Review Issues on the Price Review Process for New Patented Drugs. The Board will review the Report in detail at its next meeting scheduled for March 5 & 6, 2001.
- Heard an oral presentation by:
  - Dr. Jonathan Lomas, Executive Director of the Canadian Health Services Research Foundation, on the role and future direction of the Foundation.
- Received oral briefings on:
  - the patent application process;
  - the work by Board Staff in the context of the activities of the Federal/Provincial/ Territorial/ Task Force on Drug Prices;
  - an updated comparison of the average transaction prices for patented drugs reported to the PMPRB and prices listed in the Ontario Drug Benefit Plan formulary;
- Canada/U.S. pharmaceutical price differentials.
- Received the Compliance Report. ■

The next Board meeting is scheduled for March 5 & 6, 2001.

For any additional information, please contact the Secretary of the Board at 1-877-861-2350, or (613) 954-8299, or sdupont@pmprb-cepmb.gc.ca.

A Description of the Major Price Indexes for Pharmaceuticals - published by Statistics Canada and the Patented Medicine Prices Review Board

Both the PMPRB's Patented Medicine Prices Index (PMPI) and Statistics Canada's Industrial Product Price Index (IPPI) Pharma measure trends in the prices of pharmaceuticals. While the indexes have followed a broadly similar pattern over the last decade, they have occasionally produced different estimates of annual rates of price change. These seeming inconsistencies have lead some observers (including the Office of the Auditor General) to ask how two federal agencies could disagree in reporting changes in the prices of pharmaceuticals. In the summer of 1998 officials at Statistics Canada and the PMPRB formed a task force to foster better understanding of their indexes (and, more particularly, to address the OAG's concerns).

In a recently finalized paper, the task force concludes that differences in the behaviour of the PMPI and the IPPI Pharma are not surprising. Despite superficial similarities, the PMPI and the IPPI Pharma do not measure the same thing. The PMPI is designed to measure the overall tendency in the prices received by manufacturers for patented drugs sold in Canada. It includes the factory-gate prices of all currently patented drugs, whether imported and domestically-produced. The IPPI Pharma is designed to measure the overall tendency in the prices received by manufacturers for drugs produced in Canadian plants. It excludes import prices but includes prices for Canadian-produced drugs sold in foreign markets. Hence, only prices of those patented drug products manufactured and sold in Canada — in all likelihood, a small subset of the products covered by each index — are common to the PMPI and the IPPI Pharma.

The small range of overlap between the coverage of PMPI and the IPPI Pharma indexes goes a long way to explain observed divergences between values generated with these two approaches. Differing sampling methods are another source of divergences, as is the fact that weights used in calculating the PMPI are updated more frequently than those used to calculate the IPPI Pharma.

For more information or a copy of the report please contact us at our toll-free number: 1-877-861-2350. ■

CIHI's National Expenditure Trends Report

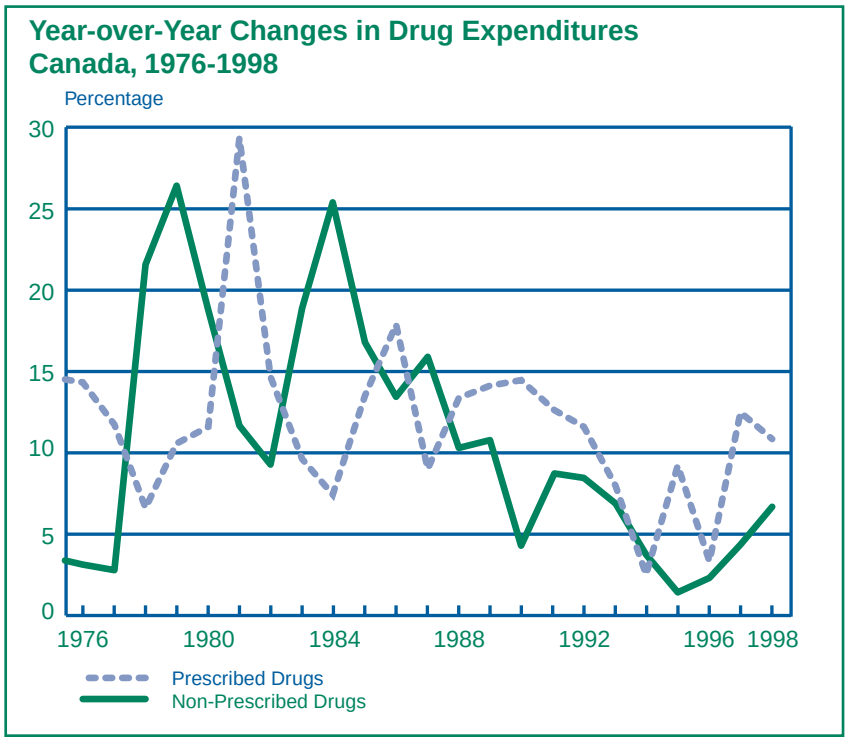
To consult the National Health Expenditure Trends Report, go to www.cihi.ca.

The Canadian Institute of Health Information (CIHI) tracks health spending by use of funds and source of finance in the National Health Expenditure Database. CIHI published its fourth annual *National Health Expenditure Trends* (1975 - 2000) report in December 2000. The Report provides detailed information on health expenditures in Canada at a national level and by province and territory. The Report contains estimates to 1998 and forecasts to 2000.

Canada's total health expenditures in current dollars was an estimated $84.0 billion in 1998. This represents an increase of $5.0 billion or 6.4% over 1997. Expenditures are forecast to have reached $89.0 billion in 1999 and $95.1 billion in 2000 (an annual increase of 6.0% and 6.9% respectively).

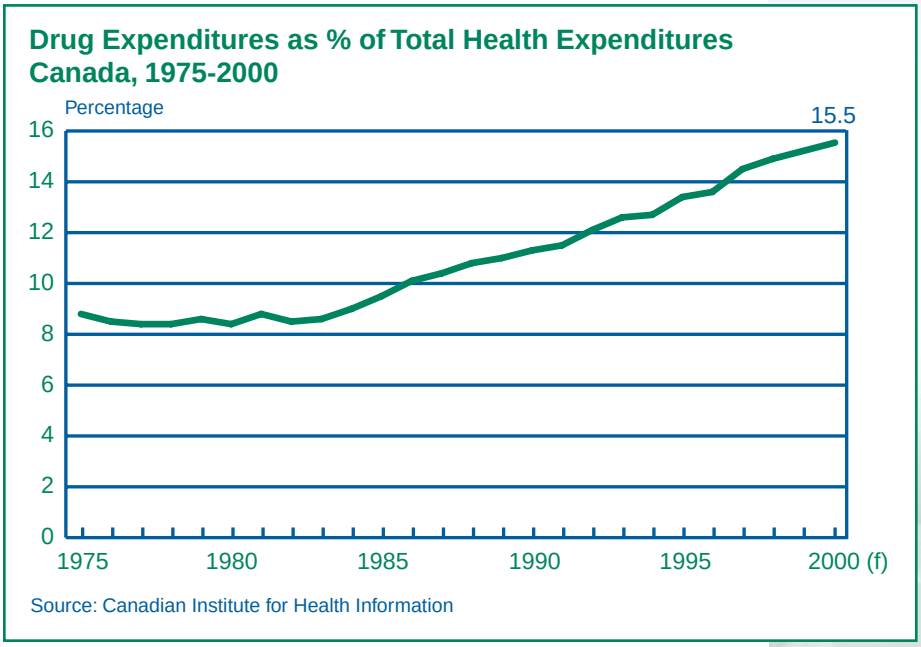
Expenditures on drugs (both prescribed and non-prescribed) have constituted the second largest category of health expenditures since 1997. Previously, spending on drugs ranked third after hospitals and physician services. Canada's total drug expenditures in current dollars was an estimated $12.4 billion in 1998 and forecast to have reached $13.5 billion in 1999 and $14.7 billion in 2000. This is an increase of 9.5% over 1997, 8.9% over 1998 and 9.0% over 1999. Expenditures on prescribed drugs were estimated to have increased by 10.6% in 1998 over 1997 as shown in Figure 1. It should be noted that for CIHI's purposes, drug expenditures exclude drugs used in hospitals.

Figure 1



CIHI estimates that expenditures on drugs accounted for 14.8% of total health expenditures in 1998. That figure is forecast to increase to 15.2% in 1999 and 15.5% in 2000 (Figure 2). According to CIHI, expenditures on prescription drugs constituted 11.1% of total health expenditures and 75.2% of total drug expenditures in 1998. ■

Figure 2



PMPRB's Research Agenda 2001-2004

Issue	Description Advisory	Committee	Key Deliverables	Date
New Medicine Price Review Process	Price review process for new patented drugs	PMPRB Working Group on Price Review Issues	Results of Board's detailed review of Working Group Report	April 2001
Category 3 Drug Prices	Review the methods to conduct therapeutic class comparisons and the guidelines for category 3 drugs, including use of pharmacoeconomics	PMPRB Working Group on Price Review Issues	1. Meeting of Working Group 2. Report	May 2001 TBA[1]
Category 2 Drug Prices	1. Review the appropriateness of the median price test for category 2 drugs 2. Review the appropriate test when fewer than 7 countries 3. Review the appropriateness of the "Highest Price Rule"[2] 4. Use of pharmacoeconomics 5. Review methodology for calculating the average price for a foreign country when conducting an International Price Comparison[2]	Advisory Committee and schedule to be determined following review of the guide-lines for category 3 drugs.		
Analysis of publicly funded drug plans	Reports on drug prices and cost drivers including: • Pharmaceutical price trends by participating provincial and territorial drug plans • Overview of pharmaceutical trends • Comparison of Canadian and foreign prices of non-patented single source drugs • Interprovincial drug comparison analysis	Federal/Provincial/ Territorial Working Group on Drug Prices	Reports to the Federal Minister of Health	2001-2002
Evaluation	1. Evaluation of the Consultation Policy published in 1998 (Road Map for the Next Decade) and of the Communications Policy 2. Evaluation of complaints-driven approach to regulating the price of veterinary drugs 3. Verification of foreign patented drug price information filed by patentees using the methods described in the Verification of Foreign Patented Drug Prices study published in 1998 (Road Map for the Next Decade)		Report Report Report	2001-2002 2002-2003 2001-2002

1. To be determined in consultation with the Working Group on Price Review Issues.
2. The review of this item is not limited to category 2 drug products.

In our *Road Map for the Next Decade*, we committed to publishing the Research Agenda as part of our annual planning process. Among other things, the Research Agenda identifies initiatives that are currently, or may become, subject to public consultations.

Update on items which appeared on 2000-2003 Research Agenda

Issue	Description	Status	Reference
New Medicine Price Review Process	Price review process for new patented drugs	The Working Group finalized its Report to the Board at its October 2000 meeting. The Board received the Report at its December 2000 meeting. The Board will consider the specific recommendations and proposals for implementation at its March 2001 meeting.	(See 2001-2004 Research Agenda)
Category 3 Drug Prices	Review the methods to conduct therapeutic class comparisons and the guidelines for category 3 drugs, including use of pharmaco-economics	The Working Group held its first meeting on this issue in October 2000. The Working Group will hold its next meeting in May 2001.	(See 2001-2004 Research Agenda)
Pharmaceutical Price Indices	To review drug price indices reported by Statistics Canada and PMPRB	Complete	Details in January 2001 issue of NEWSletter
Regulating Non-Prescription (OTC) Patented Drug Prices	Approach to non-prescription (over the counter) patented drug prices	**See note below.	

** In the January 2000 issue of the NEWSletter it was reported that this initiative had been advocated by the non-prescription drug industry and that no other stakeholders had expressed concerns. This continues to be the case. Given this and given the number of issues that continue to be outstanding on the Research Agenda, it is not expected that any specific action will be taken in the period reported. As a result, this item has not been carried over to the 2001-2004 Research Agenda. Staff will however continue to monitor the situation to determine if further work is required.

CPIC 2000

Summary of an Address by Wayne D. Critchley at Canada's Pharmaceutical Industry Congress (CPIC) - November 21, 2000

In a recent address, Wayne D. Critchley, Executive Director of the PMPRB, reported on some of the current issues in drug price regulation in Canada.

- *The significant growth in spending on pharmaceuticals.* Overall, the prices of existing drugs have not gone up in recent years, sales of drugs, but expenditures by governments and consumers have been increasing at double digit rates.
- *The international context and comparisons with other countries.* Prices for patented drugs in Canada continue to be in the mid-range of prices in six European countries. While prices in the US are often higher, measures of drug expenditures by the OECD show that spending on drugs in Canada and the U.S. was roughly comparable, at 1.3% and 1.4% of GDP respectively, in 1997.

The [record] increase in sales of patented drugs, due no doubt in part to increases in patent protection over the last 13 years, reinforces the continuing importance of public oversight of drug prices.

The system of federal drug price controls will continue to evolve with changes in the market and the jurisprudence. These changes are occurring through the public hearing process and the courts and through policy reviews that are the subject of extensive consultation with stakeholders.

- *PMPRB policy initiatives.* The Board continues to report progress on the initiatives set out in the Road Map for the Next Decade and the Research Agenda. The second report of the Working Group on Price Review Issues, on how to make the price review process more open and transparent, is under consideration by the Board. The Working Group is now examining the guidelines for new patented drugs in category 3.
- *Recent jurisprudence.* Decisions by the Board in three cases during 2000 have established new precedents and jurisprudence under the Patent Act: the Variation Order involving ICN Pharmaceuticals and Virazole; the Voluntary Compliance Undertaking by Bristol-Myers Squibb and Sanofi-Synthelabo regarding Plavix; and decisions by the Board on its jurisdiction in the course of proceedings involving Hoechst-Marion Roussel (now Aventis) and the nicotine patch Nicoderm. The decisions in the latter case are the subject of applications for judicial review in the Federal Court of Canada.

This speech is available in its entirety on our website, under Publications, Speech Series. ■

PMPRB Upcoming Events

March 5 & 6:	Board Meeting, Ottawa
March 6 & 7:	Speech by the Executive Director, to the Maximizing Market Access Conference, Toronto
March 26 & 27:	Speech by the Chairperson, to PHARMAC 2001, Toronto

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Comments

We want to hear from you. If you have any comments, ideas or suggestions on topics you wish to see covered in the NEWSletter, please let us know.

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