Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Introductory Remarks by

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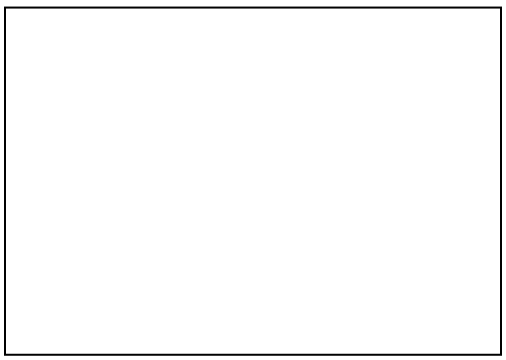
to the
Standing Committee on Health
on the
Main Estimates 2004-2005

April 18, 2005
4:30 p.m.
Room 253-D, Centre Block
Parliament Hill
Ottawa, Ontario



Good afternoon. I welcome the opportunity to appear before you as Vice-Chairperson of the Patented Medicine Prices Review Board, to address our activities and recent developments in the area of pharmaceutical pricing in Canada. As most of you know, Dr. Robert Elgie, Chair of the PMPRB from 1995 to 2005, completed his mandate in early March. Dr. Elgie was an exceptional CEO and Chairperson of the PMPRB and we wish him the best of luck in his new endeavours. The responsibilities of the Chairperson are now incumbent on the Vice-Chair until a new Chairperson is appointed.

With me today is Barbara Ouellet, recently appointed Executive Director of the PMPRB. Most of you will certainly remember Madame Ouellet, having appeared before this Committee on a number of occasions as the Director responsible for pharmaceutical policy issues at Health Canada. I take this opportunity to thank Wayne Critchley, former Executive Director of the PMPRB for 15 years, for his invaluable contribution to the organization. We wish him the best in his retirement. Following my opening remarks, I will be pleased to answer any questions you may have.

As published in the Report on Plans and Priorities, the 2005-2006 PMPRB budget is $4.373M.

Since our last appearance before this Committee in the Fall of 2003, pharmaceuticals have remained front and centre in public policy discussions. Given the importance of pricing considerations in any discussion of pharmaceuticals policy, I would like to devote a few minutes to review the responsibilities of the PMPRB in the context of Canada's public policies on pharmaceutical pricing.

Although today's consumers are taking a more active role in decisions on the use of prescription drugs, they do not make the final decision – physicians do. Physicians, in consultation with the patient, determine if drug therapy is appropriate and, if so, which medicine should be used. That is why pharmaceutical manufacturers continue to spend considerable resources marketing their products particularly to physicians. And in most cases, patients do not pay the full cost of the drugs they take. Fortunately, most Canadians have access to public or private insurance, which helps to mitigate costs. In addition, manufacturers enjoy full patent protection for their inventions. These market conditions give drug manufacturers considerable market power and, given the importance of pharmaceuticals to health care, governments have long recognized a need to intervene in this market in the public interest.

The PMPRB was created as an independent, quasi-judicial, administrative agency through amendments to the *Patent Act* in 1987. The decision by Parliament to strike a new balance of pharmaceutical patent policy and consumer protection came about following lively public debate. Among other things, the 1987 amendments increased patent protection for pharmaceuticals by restricting compulsory licensing and

established the PMPRB out of concern that patentees might abuse the increased patent protection provided by the Act. The role of the newly created PMPRB was to influence the pricing of patented medicines to much the same extent that the competition fostered by compulsory licensing used to influence it. The brand name pharmaceutical industry agreed to price controls as part of the 1987 package of expanded intellectual property rights and has since largely complied.

With the adoption of these amendments, the industry, through Rx&D, made a public commitment that the industry would increase its annual R&D expenditures as a percentage of sales to 10% by 1996, a commitment that was met in 1993. However, the R&D-to-Sales has decreased in recent years. [1]

The PMPRB was given a two-fold mandate – regulatory and reporting. Under its regulatory responsibilities, the PMPRB ensures that the manufacturers' prices, i.e. ex-factory prices, of patented medicines sold in Canada are not excessive. The PMPRB reviews the price at which a drug product is sold by the manufacturer to all purchasers, including wholesalers, pharmacies, hospitals and others.

With respect to the second portion of its mandate, the PMPRB reports annually to Parliament through the Minister of Health on: drug price trends of all medicines; analyses of cost drivers and drug utilization for public drug plans; and the R&D performance of pharmaceutical patent-holding manufacturers.

The PMPRB does not set prices. Neither does it attempt to establish prices based on the costs of production nor on determining the rate of return to the manufacturer. Instead, Canada's price control system is based on protecting consumers by limiting the prices manufacturers may charge to ensure they are not excessive. The effect of this type of regime is to establish the boundaries in pricing, to define the parameters in which manufacturers may set prices.

The PMPRB operates at arm's length from government. It has the powers, following a public hearing, to order a price reduction and other remedial action if it finds that the price of a patented drug is excessive. It makes that decision based on factors set out in the Act, including the prices of drugs in the same therapeutic class in Canada and other countries, and changes in the Consumer Price Index.

The factors in the Act have guided the Board to establish the objective that prices for patented drugs in Canada, on average, should not exceed the median of prices in the other countries that we compare ourselves to -- France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S. This principle reflects the apparent objective of the Act that Canadians should not pay more than their fair share of the international costs related to the research and development of new medicines.

[1] See Table 6 on page 5, as published in the PMPRB Annual Report for 2003

When we review this evidence, the system has worked to protect consumers 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 used for comparison purposes.[2] 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 just slightly above, or 5 to 10% below, the median of foreign prices.[3]

Over the past decade, most new and existing patented drugs were priced within the Guidelines in the first instance. During this period, we approved 20 Voluntary Compliance Undertakings to lower prices and to offset excess revenues as appropriate. These undertakings provide direct evidence of the impact of the PMPRB, but represent only a small portion of the total impact. They do not measure all the occasions where a manufacturer, either on its own or following advice from Board Staff, chose to set its price within the Guidelines in the first place and not challenge the regime.

That being said, last year we began to read reports of price increases in the media and to receive questions from public drug plans about price announcements they had received. In all, we estimate that manufacturers of about 35% of patented medicines had made public announcements of price increases. While it appeared that these increases could be within our Guidelines, they will have to be reviewed after the fact – in most cases we had not been given advance notice or the opportunity to ensure they were non-excessive beforehand.

If such increases were to come about, they could represent a change in the trends in pricing in Canada over the past decade. We will need to consider if such a trend might in future set Canada apart from the European countries we use for comparison purposes.

Under the circumstances, the Board decided it was appropriate to launch a public consultation on these questions and it issued a discussion paper last month on how we should be thinking about price increases.

Of course, the Board has not reached any conclusions nor even made any proposals to change how the CPI factor is considered in price reviews. Instead, it is proceeding in a consultative way, seeking input from all stakeholders. Submissions have been requested for May 9 following which the Board will determine the next steps.

It is important to note that over the last decade, the patented drug sector has grown significantly, their share of total sales in Canada having increased from 45% to 67%.

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[2] See Figure 12 on page 6, as published in the PMPRB Annual Report for 2003
[3] See Figure 8 on page 6, as published in the PMPRB Annual Report for 2003

The growth in total sales of all drugs was also significant, reaching $15 billion in 2003. [4] These increases were reflected in expenditures by governments and by consumers through their private insurance coverage and as out-of-pocket costs. The PMPRB Annual Report for 2004 will be forwarded to the Minister of Health on May 31 and will provide the most recent information on manufacturers' sales of drugs. In its latest report, the Canadian Institute for Health Information (CIHI) estimated that total expenditures by Canadians on medicines reached $22 billion in 2004 and that drugs now represent nearly 17% of total health care spending in Canada.

As a result, public programs have sought a greater understanding of the reasons for such growth and whether it is appropriate. They have introduced new approaches to contain costs and they have sought out new approaches to collaboration.

Increasingly, the PMPRB has been asked to do more to examine the broader questions. Our studies have shown that the major factors driving up drug costs have been the impact of the introduction of new drugs and increased utilization of drugs in the health care system. Price changes for existing drugs have not been a cost driver.

The PMPRB has undertaken a number of initiatives in the context of its role in the National Prescription Drug Utilization Information System (NPDUIS). In 2001, Ministers of Health established the NPDUIS to provide critical analyses of price, utilization and cost trends so that our health system has more comprehensive, accurate information on how prescription drugs are being used and on sources of cost increases. Currently, we have a number of projects in progress that will supply the participating jurisdictions with such information.

Last September, the First Ministers agreed to build on this collaboration by developing and implementing a National Pharmaceuticals Strategy as part of their comprehensive agreement on health care. They declared that: "Affordable access to drugs is fundamental to equitable health outcomes for all our citizens." A Ministerial Task Force is focusing on a number of key areas relating to, among others, catastrophic drug coverage; introduction of a national drug formulary based on safety and cost-effectiveness; improving access to breakthrough drugs; and accelerating access to non-patented drugs and achieving international parity on prices of non-patented drugs.

We are seeing greater collaboration not only between the various levels of government in Canada but also among all participants in the health care system to improve pharmaceuticals management in the coming years.

The PMPRB is both cognizant and proud of the contribution it has made to ensuring Canadians do not pay excessive prices for patented medicines. I want to assure the Committee that the Board is committed to continuing to fully carrying out it mandate to protect Canadian consumers.

[4] See Table 4 on page 7, as published in the PMPRB Annual Report for 2003

Table 6 Total R&D Expenditures and R&D-to-Sales Ratios of Reporting Companies, 1988-2003

Year	Companies Reporting	Total R&D Expenditure[1] ($M)	Change from Previous Year (%)	Total Sales Revenue[2] ($M)	Change from Previous Year (%)	R&D-to-Sales Ratio All Patentees[3] (%)	R&D-to-Sales Ratio Rx&D Patentees[4] (%)
2003	83	1192.4	-0.5	13617.2	12.7	8.8	9.1
2002[5]	79	1198.7	13.0	12081.2	12.5	9.9	10.0
2001	74	1060.1	12.6	10732.1	15.3	9.9	10.6
2000	79	941.8	5.3	9309.6	12.0	10.1	10.6
1999	78	894.6	12.0	8315.5	19.2	10.8	11.3
1998	74	798.9	10.2	6975.2	10.9	11.5	12.7
1997	75	725.1	9.0	6288.4	7.4	11.5	12.9
1996	72	665.3	6.4	5857.4	9.9	11.4	12.3
1995	71	625.5	11.5	5330.2	7.5	11.7	12.5
1994	73	561.1	11.4	4957.4	4.4	11.3	11.6
1993	70	503.5	22.1	4747.6	14.0	10.6	10.7
1992	71	412.4	9.6	4164.4	6.9	9.9	9.8
1991	65	376.4	23.2	3894.8	18.1	9.7	9.6
1990	65	305.5	24.8	3298.8	11.0	9.3	9.2
1989	66	244.8	47.4	2973.0	9.4	8.2	8.1
1988	66	165.7	-	2718.0	-	6.1	6.5

Source: PMPRB

1 Total R&D expenditure includes Scientific Research and Development expenses – both capital and non-capital – which qualify for an investment tax credit as set out in the *Income Tax Act* and *Income Tax Regulations* as they read on December 1, 1987.

2 Total sales revenue include sales of patented and non-patented drugs for both human and veterinary use.

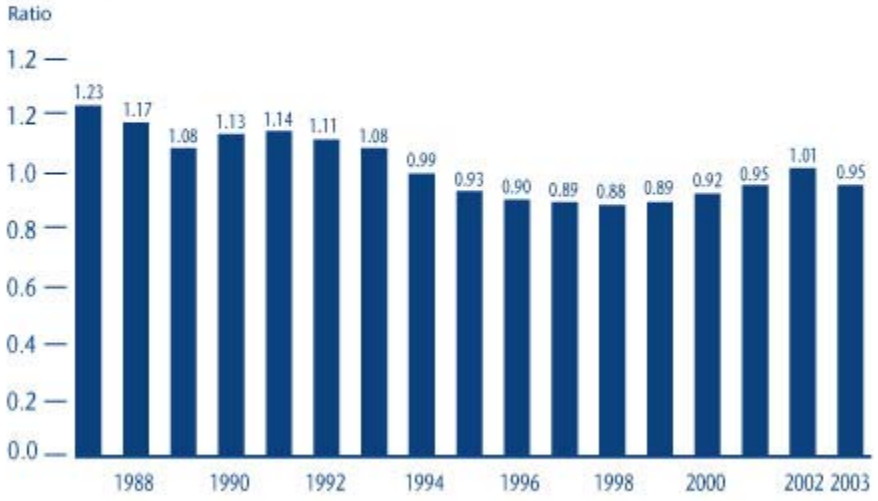
3 The R&D-to-sales ratios presented in the above table include research expenditure funded by government grants. If the government-funded component is excluded the ratios for all patentees and for the members of Rx&D in 2003 are 8.7% and 9.1%, respectively.

4 In the past, Rx&D has reported that its members have achieved a higher R&D-to-sales ratio than reported by the PMPRB. Recall, however, that the *Patent Act* requires only companies with active Canadian patents pertaining to a medicine sold in Canada to report on R&D expenditure. This means that some Rx&D members do not report their R&D expenditure - for example, biotechnology companies engaged in research but without sales of a patented product in Canada.

5 Revised since the release of the *PMPRB 2002 Annual Report*.

FIGURE 12

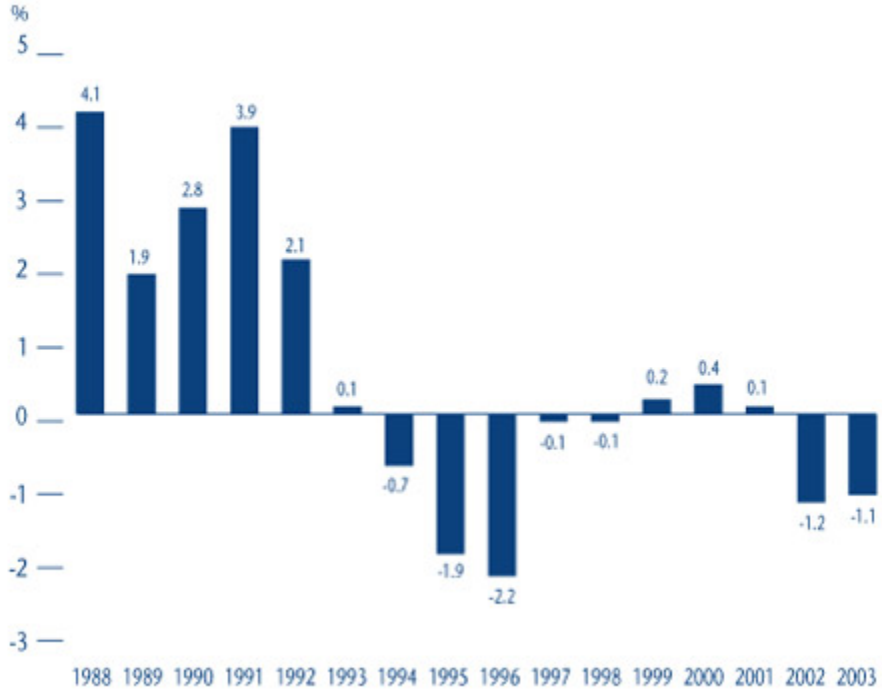
Ratio of Canadian Prices of Patented Drugs to Median International Prices, 1987-2003



Source: PMPRB

FIGURE 8

Year-Over-Year Changes in the PMPI, 1988-2003



Source: PMPRB

Table 4 Manufacturers' Sales of All Drugs and Patented Drugs for Human and Veterinary Use 1990-1998; and Human Use 1999-2003

Year	Total		Patented		Patented Drugs as Percentage of Total
	Sales ($ billions)	Change * (%)	Sales ($ billions)	Change * (%)	
2003	15.0	14.5	10.1	14.8	67.4
2002	13.1	13.9	8.8	17.3	67.4
2001	11.5	15.0	7.5	18.9	65.0
2000	10.0	12.4	6.3	16.7	63.0
1999**	8.9	16.8	5.4	27.0	61.0
1998	7.8	11.4	4.3	18.9	55.1
1997	7.0	7.0	3.7	22.6	52.3
1996	6.6	10.0	3.0	12.8	45.0
1995	6.0	1.7	2.6	10.8	43.9
1994	5.9	9.3	2.4	-2.1	40.7
1993	5.4	12.5	2.4	9.4	44.4
1992	4.8	9.1	2.2	14.0	43.8
1991	4.4	18.9	2.0	13.1	43.2
1990	3.7	-	1.7	-	43.2

* Percentage changes are based on exact (not rounded) sales figures.

** The percentage change from 1998 of 16.8% for total drugs and 27.0% for patented drugs represents the change in sales of drugs for human use only.

Sources: PMPRB and IMS Health