Appendix I Historical Context

Background on Federal Regulation of Patented Medicine Prices and the PMPRB's Guidelines for Price Increases

Evolution of Federal Regulation of Patent Medicine Prices in Canada

For much of its history, Canada had used a system of granting compulsory licenses to drug manufacturers as a means to promote competition in the drug industry and to facilitate access by Canadians to affordable medicines. A direct result of this policy is the development of a generic pharmaceutical industry in Canada. The 1984 *Commission of Inquiry on the Pharmaceutical Industry* (the Eastman Commission) concluded that the use of compulsory licensing over the preceding decade had saved the Canadian health care system hundreds of millions of dollars per year through the early entry of lower cost generic versions of much needed medicines. At the same time that the Eastman Commission was established, the Government of Canada was responding to concerns that this policy of compulsory licensing discouraged pharmaceutical research and development in Canada and was inconsistent with its obligations under international trade agreements.

After much debate among the public and in Parliament, amendments to the *Patent Act* (the *Act*) were passed in 1987. Drafters of the legislation established a series of pillars upon which the new *Patent Act* would be founded. The five essential pillars, as described by the government of the day, are:

- intellectual property;
- industrial benefits;
- Canada's multilateral relations;
- consumer protection; and
- health care.

Around these principles, legislators were able to develop an effective piece of legislation that responded to the concerns of the pharmaceutical industry and consumers alike. Manufacturers received greatly improved patent protection for their products and a period of exclusivity that would guarantee an equitable return on their investments. At the same time, the Patented Medicine Prices Review Board (PMPRB) was created to protect consumers by ensuring that manufacturers do not abuse their increased patent protection by charging excessive prices to Canadians.

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The industry agreed to the introduction of price controls. Further, the Pharmaceutical Manufacturers Association of Canada (PMAC)[1] member companies also committed to double their R&D spending to 10% of sales by 1996.[2] They achieved this target in 1993, maintaining it until 2003, when the ratio declined to 9.1% for members of Rx&D and 8.9% for all patentees. Thus the amendments were able to strike a balance between offering the pharmaceutical industry important incentives towards investment in R&D and protecting consumer interests.

Federal Regulation of Patented Medicine Prices

Established as an integral part of the 1987 amendments to the *Patent Act*, the PMPRB was given the mandate of regulating the prices of patented medicines sold in Canada and ensuring that prices were not excessive. The Board was given powers designed to influence the prices of patented medicines "to much the same extent that the competition fostered by compulsory licensing used to influence it."[3] The *Act* also ensures patentees of a right to a fair hearing and gives provincial ministers of health the right to intervene.

The *Patent Act* identifies factors for the Board to consider in determining whether the price of a patented medicine is excessive. While designating the factors to be considered, the *Act* gives the Board significant latitude to determine how these factors will be applied. These factors include:

- the prices at which the medicine has been sold in the relevant market;
- the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
- the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
- changes in the Consumer Price Index; and,
- such other factors as may be specified in any regulations made for the purposes of subsection 85(1) of the *Act*.

The factors in the *Act* have been operationalized in the PMPRB's *Excessive Price Guidelines* (the Guidelines) to provide clear and simple criteria for pricing, on the part of manufacturers, and for assessing prices, on the part of the PMPRB. The Guidelines were developed in consultation with stakeholders including consumer groups, provincial ministries of health and the pharmaceutical industry.

Use of CPI in the PMPRB's Excessive Price Guidelines

The establishment of CPI as one of the measures in determining if a price is excessive must be considered in light of the period during which the legislative amendments were drafted. The 1970s was characterized by high inflation throughout the world. In the ten years between 1971 and 1981, the CPI in Canada increased 137%, while manufacturer prices for patented medicines increased 109%.[4] By the 1980s, the high inflation rates observed in the previous decade began to abate, but pharmaceutical prices continued to climb. Research done by the Eastman Commission indicated that between 1980 and September 1984 patented medicine prices had increased some 57.7%, compared to an increase of 26.2% for all manufactures generally and a 38% change in CPI.[5]

1 Currently known as Canada's Research-Based Pharmaceutical Companies (Rx&D).

2 As published in the Regulatory Impact Assessment Statement (RIAS) of the *Patented Medicines Regulations*, 1988, published in the Canada Gazette Part II, Vol.22, No.20 – SOR/DORS/88-474.

3 Federal Court of Appeal, *ICN Pharmaceuticals*, 1996.

4 Government of Canada, *The Report of the Commission of Inquiry on the Pharmaceutical Industry*, 1985, p.303.

5 Ibid.

What is CPI?

The Consumer Price Index is typically used as a measure of consumer inflation which is one of the indicators of the performance of the economy. To do so, Statistics Canada applies a methodology which tracks changes in consumer prices that are experienced by a target population, measuring price changes by comparing, through time, the cost of a *fixed basket* of commodities. Because the index does not allow for substitution, a regular part of daily purchasing habits, the CPI as a measure is considered to be upward biased. Statistics Canada attempts to compensate for this by changing the components of the basket and their weight in the index every four years.

(Statistics Canada)

While legislators were interested in ensuring that patentees reaped the full reward from their research, there was certainly some concern expressed about the fact that drug prices increased at a rate higher than the growth in the CPI.[6] By tying future price increases to changes in the rate of inflation, patentees would be able to compensate for the impact of inflation on cost of their inputs, but nothing more. Therefore, at the time when patentees were increasing their prices faster than inflation, the inclusion of CPI as a factor in the PMPRB's assessment of prices allowed manufacturers some flexibility in pricing, while protecting the interests of Canadian consumers by placing limits on pharmaceutical price inflation.

The 1994 Changes to the CPI Guidelines

The original Guidelines for price increases, developed in 1988, provided that:

> *"the price of a DIN at the time of a review (the current price) will be compared with the benchmark price of the medicine adjusted for the cumulative change in the Consumer Price Index (CPI-adjusted price). Where the current price of the DIN is greater than the CPI-adjusted price, the current price will be presumed to be excessive unless there is significant evidence to the contrary".*

By the early 1990s the PMPRB identified a number of problems with the application of the Guidelines that would certainly compromise price stability in the future. In particular, because the original CPI Guideline did not include a limit on period of time over which cumulative changes could be calculated, there were concerns over the impact should a large cumulative change be applied in a single year. In 1992 the Board pointed out in Bulletin 9 that:

> *"under the present Guidelines, patentees can accumulate allowable increases starting from the benchmark period for use in subsequent periods. Accordingly, if a patentee does not increase its prices by the increase in the CPI in a given year, it may use the remainder to increase its price by more than the change in CPI in a subsequent year and still remain within Guidelines".*

The data available at that time suggested that had manufacturers decided to apply all of the allowable increases at one time, the resulting increase would have been in the order of 20%, and more as the years progressed (see Figure 1).

6 Harvie Andre, "Notes for opening remarks to Legislative Committee on Bill C-22" December 16, 1986.

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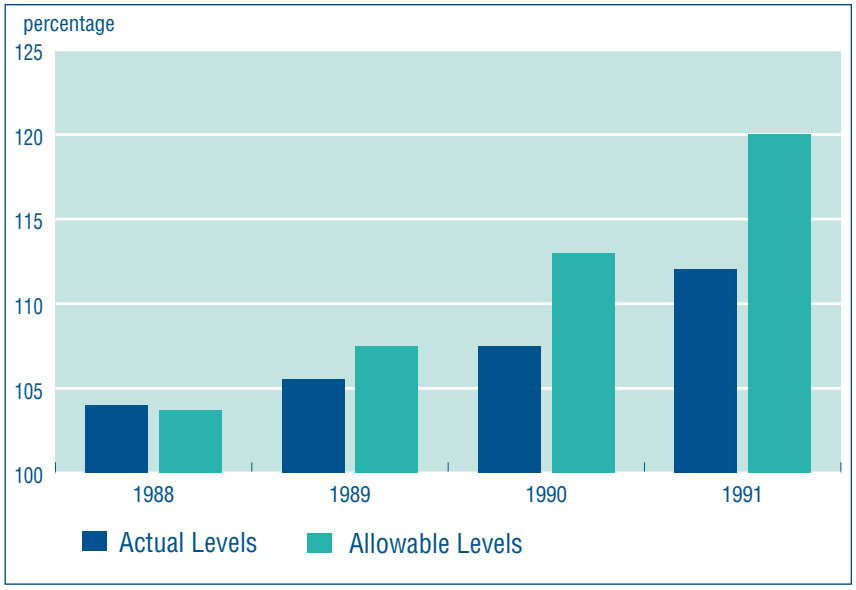
Figure 1 Price Trends of Patented Medicines 1988-1991



Laspeyres Chain Index based on a weighted average of prices.

Source: PMPRB

To protect consumers and prevent what could have been significant one time price hikes, the PMPRB proposed, as part of a larger package of Guideline amendments, that this section of the Guidelines be amended to limit price increases to a one year increase in the CPI. Published in Bulletin 9, in October 1992, the proposal became the subject of extensive consultation.

Stakeholders' views on the proposal differed. While consumer groups favoured the idea of further limiting price increases, industry representatives expressed concerns over restrictions of their pricing flexibility. As a follow-up to this and other Guideline amendment proposals, the PMPRB established an ad hoc multi-stakeholder committee, the Working Group on Technical Issues, to review the issue.

The report of the Working Group, tabled in June of 1993, was not in favour of the original proposal to restrict price increases taken in a single year to a one year change in CPI. The concern of the Working Group was that, given the loss of pricing flexibility, this method would act as an incentive for patentees to take price increases where they might not have taken one before. It was also argued that this proposal would complicate the pricing activities of the industry, requiring companies, for example, to set 1994 prices in the middle of 1993 based on projected prices for the rest of the year plus a CPI factor. This would force patentees to bear the risk of inaccurately predicting not only the price for 1994, but also price for 1993.

In its deliberations to develop an alternative proposal, the Working Group identified a number of principles to guide its recommendation. These principles included:

- to prevent one-year price increases which significantly exceed current inflationary trends;
- to promote price predictability for consumers including hospitals and public drug plans;
- not to unduly disrupt existing marketing practices of industry;
- not to create incentives for patentees to increase prices by the full allowable amount each year in an attempt to avoid losing pricing flexibility in the future; and
- to be transparent.

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Eventually, the Working Group recommended a compromise that would limit the period of cumulative increases to three years, and apply a ceiling or cap on the amount of the price increase permitted in a single year. The new proposed CPI Guideline allowed patentees to retain a sufficient level of flexibility in their pricing activities, but consumers would be protected from large single year increases, especially during periods of high inflation.

Taking effect on January 1, 1994, the new CPI Guideline specified that the price of an existing medicine product during the period under review will be presumed to be excessive if the cumulative change in price over a three year period is in excess of the cumulative change in CPI during the same period. In addition, any one-year price increase in the current pricing period may not exceed 1.5 times the forecast change in the actual CPI. In other words, if a patentee did not increase its price by the full allowable amount in the first or second year, it would be allowed to take some of the unused increase in the next year provided the annual increase was no more than 1.5 times the growth in the CPI. This methodology is self adjusting over time in that annual increases on average over the years could never be more than increases in the CPI. In periods of high inflation, that is greater than 10%, the cap is limited to five percentage points more than the forecast change.

As a transitional measure, a patentee with a product whose price in 1994 and 1995 faced a reduction solely as a result of the change in the CPI-adjusted methodology was not required to lower the price from the non-excessive average price of the previous year. A price at the same level as the previous year was considered to be within the Guidelines.

This Guideline for price increases has remained unchanged since it was implemented more than a decade ago. In order to provide patentees with sufficient notice for price planning for the following year, the PMPRB publishes its CPI adjustment factors in the April NEWSletter each year. The adjustment factor is based on forecasted changes in the CPI in the next year. For the purposes of the annual review of prices, the PMPRB applies the higher of either the actual or forecasted change in CPI. Since forecasts are always based on the actual CPI, this approach is self-adjusting over time. The PMPRB has published the full methodology in Schedule 4 of the Guidelines.[7]

At around the same time that the PMPRB amended its Guidelines to further restrict price increases, some provincial governments also implemented new cost-containment policies including restrictions on price increases for patented and non-patented medicine.

The combined effects of the amendments to the Guidelines and the implementation of provincial cost containment policies were evident in the years following 1994. In 1994, for the first time, manufacturers' prices of patented medicines as measured by the PMPI declined over the previous year's prices, by 0.7% (see Figure 2). This pattern of decline or near-negligible increases has continued for the past decade.

7 For more information on the CPI adjustment factor and methodology see the PMPRB's Compendium of Guidelines, Policies and Procedures, http://www.pmprb-cepmb.gc.ca/english/View.asp?x=150&mp=135.

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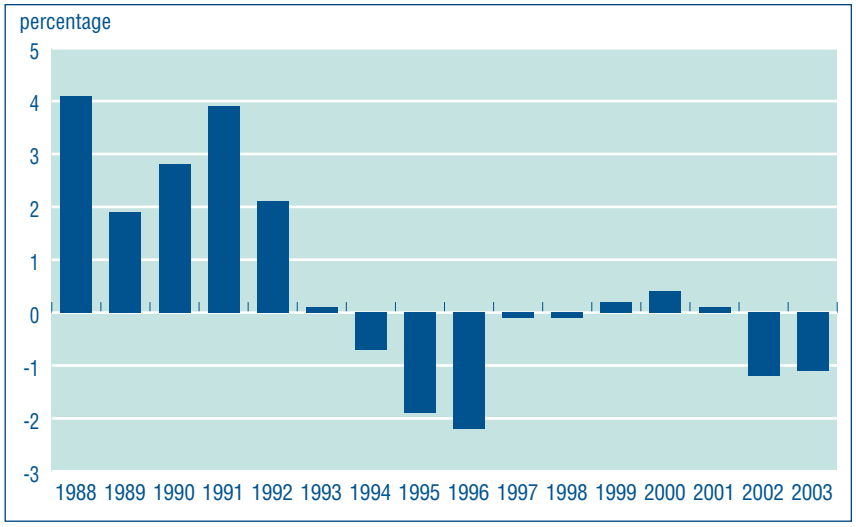
Figure 2 Year-Over-Year Changes in the PMPI, 1988-2003



Source: PMPRB

In addition to the changes to the CPI Guidelines, the PMPRB amended the Guidelines related to international price comparisons. Compared internationally, Canadian prices on average fell from being 23% above the median price of the seven comparator countries in 1987 to below the median in 1994. Amendments in 1993 ensured that the prices charged in Canada for patented medicines should not be the highest in the world. Combined with the CPI adjustment, made the same year, this amendment helped to control price inflation even further. Since 1994, with the exception of 2002, prices in Canada have remained below the international median and in line with policy objectives.