

**PATENTED MEDICINE PRICES REVIEW
BOARD – 1995 ANNUAL REPORT**

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INTRODUCTION

The Patented Medicine Prices Review Board (the “Board” or the “PMPRB”) was established pursuant to amendments to the *Patent Act*, which came into force in December 1987. In June 1996, the *Eighth Annual Report* of the Board for the year ended 31 December 1995 was tabled in the House of Commons. These notes will summarize the main findings of the Report. Page numbers cited in the text are those found in the Report.

MANDATE OF THE PMPRB

The PMPRB is an independent quasi-judicial body whose mandate is to: (1) ensure that the prices charged by patentees for patented drug products are not excessive; (2) report annually on pricing trends in the pharmaceutical industry; and (3) report annually on the ratios of research and development (R&D) expenditures to sales for individual patentees and for the entire patented pharmaceutical sector.

The Board’s mandate is to review the prices of patented medicines sold for human or veterinary use. It does not include drugs for which there are no Canadian patents or generic drugs sold under compulsory licence. The Board reviews the price at which a patentee sells the patented medicine. This is usually the “factory-gate” price to the wholesaler or to a hospital or pharmacy. Retail and wholesale prices and pharmacists’ fees are not subject to the Board’s jurisdiction (p. 7).

A. Drug Prices

When determining whether the price of a patented medicine is excessive, the Board is required to consider the factors set out in the *Patent Act*. These include:

- the prices at which the medicine in question and medicines in the same therapeutic class are sold in Canada and in other countries named in regulations made pursuant to the *Patent Act* (Germany, France, Italy, Switzerland, Sweden, the United Kingdom and the United States);
- changes in the Consumer Price Index (CPI); and
- other factors that may be specified by regulation.

If it finds that a medicine has been sold at an excessive price, the Board can order a price reduction. It can also order a further reduction so as to recapture any excess revenue that a patentee may have earned as a result of charging excessive prices. Excess revenues can also be recouped through payments to the Crown.

The PMPRB publishes Excessive Price Guidelines for “existing” and “new” drugs. “Existing” drugs are those that were on the market before 1995 and for which a benchmark price has been established. Since pharmaceutical companies tend to change prices at six- or twelve-month intervals, on 1 January and 1 July, the PMPRB reviews prices based on six- or twelve-month pricing periods. Basically, the Guidelines provide that price increases for existing medicines must be limited to changes in the CPI for the relevant period.

“New” patented medicines are those for which the introductory price is under review and include drug products introduced between 1 December 1994 and 30 November 1995. The Board classifies these drugs into three categories. The first (Category 1) largely comprises new strengths of an existing drug. The second (Category 2) consists of drugs that are “breakthrough” products or that are substantial therapeutic improvements. The third (Category 3) comprises new drugs or new dosage forms of existing medicines that provide moderate or no therapeutic improvement over existing medicines (p. 17).

The Board reviews the introductory prices of new drug products according to their category. Generally, the prices of new drugs may not exceed the maximum price of other drugs used to treat the same disease. The introductory prices of Category 2 drugs may not exceed the median foreign prices of the drugs in the countries referred to above (p. 18).

In its *Eighth Annual Report*, the Board reported that the vast majority of existing drug products sold during 1995 were priced within its Guidelines; that is, increases in prices did not exceed increases in the CPI for the relevant period. Of the 823 existing drug products with pricing periods ending 31 December 1995, six appeared to have exceeded the Guidelines. Investigations into five products were ongoing at the time of publication of the Report (p. 19).

The prices of most new products were within the Guidelines. Over 80% of the 89 new drug products introduced in 1995 were found to have complied with the Guidelines. Investigations were commenced in relation to the products believed to be in non-compliance (p. 18).

B. Price Trends

The Board also reports on the price trends for all medicines. The Report reveals that from 1983 until the Board's creation in 1987, the pharmaceutical component of the Industrial Product Price Index (IPPI) – a Canada-wide index which measures price changes at the factory gate for goods sold by Canadian manufacturers – increased on average by 7.8% per annum, while the CPI increased at an annual rate of 4.2%. From 1988 to 1995, the CPI and the pharmaceutical component's annual rate of increase was slightly over 3.1% per year. Products within the jurisdiction of the PMPRB, however, had annual price increases averaging 1.6% (p. 12).

In 1995, the prices of patented medicines as measured by the Patented Medicine Price Index (PMPI) decreased by 1.75% from the 1994 level. This represents the second consecutive year of decline; the PMPI decreased by 0.42% in 1994. In contrast, the CPI increased by 2.14% in 1995 (p. 11). The Report observes that “the decline in the rate of increase in the prices of all drugs relative to the CPI coincided with the introduction of price regulation for patented medicines....” (p. 12).

Total Canadian sales of pharmaceuticals in 1995 are estimated at \$6 billion, of which patentees reported factory-gate sales of patented drugs of \$2.6 billion or 44% of the total (p. 10).

Although the PMPRB data show that patented drug prices have declined, drug expenditures in Canada increased by 3.8% in 1994. There are several reasons for this:

- the PMPRB regulates the manufacturers' prices of patented medicines, which comprise about 44% of all drug sales;
- expenditures on drugs include wholesale costs and dispensing fees, which are not part of the Board's mandate; and
- changes in total expenditures can also be attributed to changes in prescribing habits and the use of drugs (p. 14).

C. Research and Development

Prior to the 1987 amendments to the *Patent Act*, the brand-name pharmaceutical companies spent approximately 3.5% to 4.5% of sales revenue on R&D. In return for the increased patent protection afforded by the amendments, the Pharmaceutical Manufacturers Association of Canada (PMAC) committed itself to increase levels of research and development in Canada to 8% of sales by the end of 1991 and 10% of sales by the end of 1996.

The Report shows a steady increase in R&D after 1987. In 1988, the ratio of R&D expenditures to revenues from sales for the patented pharmaceutical industry as a whole was 6.1%; the ratio for the companies that were members of the PMAC was 6.5%. For 1989, these numbers were 8.2% and 8.1%, respectively. A further increase took place in 1990, with the industry as a whole reporting a ratio of 9.3% and the members of the PMAC 9.2%. The 1991 ratios were 9.7% and 9.6%, respectively, while those for 1992 were slightly higher, at 9.9% and 9.8%, respectively. Further increases were reported in 1993 and 1994; in 1993 the industry-wide ratio was 10.6% while that of the PMAC members was 10.7%. The comparative figures were 11.3% and 11.6% for 1994. In 1995, the R&D-to-sales ratio for all patentees was 11.8%; for members of the PMAC, it was 12.5% (p. 24).

For the purposes of reporting, the Board classifies research expenditures into three categories: basic, applied and other qualifying research. Basic research is scientific research with no immediate practical application. Applied research, on the other hand, is focused on a practical application. Most of the applied research taking place in the Canadian pharmaceutical industry consists of clinical and pre-clinical trials. Other qualifying research expenditures relate to drug regulation submissions, bio-availability studies and Phase IV (post-marketing) clinical trials.

In 1995, patentees reported R&D expenditures of \$623.9 million. Most of the expenditures were directed toward applied research (61.9%). Basic and other qualifying research accounted for 22.2% and 15.9%, respectively, of the expenditures (p. 24).

D. Compliance and Enforcement

The PMPRB applies a voluntary compliance policy. Published Guidelines outline the Board's views on excessive pricing and enable patentees to set prices accordingly. If the Board finds a price to be excessive, it will give a patentee an opportunity to remedy the situation voluntarily through a Voluntary Compliance Undertaking. If a voluntary resolution cannot be achieved, the Board can call a public hearing. In 1995, the Board settled three cases through Voluntary Compliance Undertakings by patentees to lower prices and initiated a hearing in one case (p. 20).

The Board estimates that its compliance and enforcement activities saved consumers \$32.7 million in 1995 and a total of \$107 million during the period 1990 to 1995 (p. 22).