REGULATING PRICES OF PATENTED PHARMACEUTICALS IN CANADA: THE PATENTED MEDICINE PRICES REVIEW BOARD

By Dr. Robert G. Elgie*

I. Introduction

Like most industrialized countries, Canada has experienced significant increases in expenditures on pharmaceuticals during the 1980s with the result that drugs accounted for 12.7% of total health expenditures in 1994, up from 8.8% in 1975.[1] While there are several approaches to the control of drug prices and expenditures in Canada, one of the most unique is embodied in the Patented Medicine Prices Review Board (PMPRB and Board). This federal agency, created in 1987, regulates manufacturers' prices of drugs during the time they benefit from patent protection. Rather than setting prices, it regulates maximum prices by applying an "excessive" price test.

The PMPRB is a quasi-judicial agency mandated by the Patent Act[2] to ensure that the prices of patented medicines in Canada are not excessive; it also reports annually on price trends in the pharmaceutical industry and on Canadian research and development expenditures of pharmaceutical patentees.

To place the role of the PMPRB in context, it is helpful to describe how pharmaceutical costs are regulated in Canada. Canada has a universal health care scheme, partially funded by the federal government, that is based on principles established at the federal level. However, as medicare is delivered at the provincial level, there are ten different provincial health care schemes. In contrast to most European countries, pharmaceuticals are not covered under the Canada Health Act and, therefore, the coverage of drugs at the provincial level varies. In general, provincial governments provide reimbursement pro- grams for senior citizens and those on social assistance. Provinces also provide limited assistance to persons facing catastrophic drug costs. Well over half of the market is privately insured or not insured at all, as in the United States.

The provincial drug plans account for about 32%[3] of the total market for pharmaceuticals and exert consider- able influence over the market. As provincial drug expenditures have increased dramatically in recent years, the provinces have adopted a variety of cost containment measures including generic substitution, limits on the products to be reimbursed and recently, in one province, reference-based pricing.[4] In the private market -as in the United States -third party insurers and individual employers have been forced to become more aggressive in controlling expenditures in response to demands from employers and unions.

The distinction between the federal and provincial roles in controlling the cost of drugs is based in large part on the constitutional division of powers.[5] Price regulation is ordinarily a matter of provincial responsibility but the federal Parliament has used its authority over patents to regulate drug prices directly and indirectly.

II. The Evolution of Federal Regulation of Drug Prices

During the 1960s - the decade in which Canada introduced universal health care coverage -there was considerable concern, as in the United States, about the cost of drugs. Several important studies and inquiries recommended action on the part of the federal government. The principal result was an amendment to the Patent Act in 1969[6] permitting compulsory licensing of pharmaceutical patents. This policy assisted in the development of a generic pharmaceutical industry and restrained drug expenditures by promoting price competition and providing lower cost alternatives.

By the 1980s, concerns arose that this policy discouraged pharmaceutical research and development and it became inconsistent with Canada's obligations under trade agreements. Legislation to restrict compulsory licensing in 1987 and then to eliminate it completely in 1993 attracted considerable opposition. The domestic generic industry feared limitations on its ability to grow and compete. Consumers, and in particular provincial governments, were concerned about the cost implications since they would have to wait longer for lower- priced generic copies to come to market.

The 1987 amendments to the Patent Act[7] (1987 Amendments) restricted the use of pharmaceutical patent compulsory licenses by providing minimum periods of market exclusivity. In return, the Pharmaceutical Manufacturers Association of Canada (PMAC), representing most of the multinational brand name companies, undertook to double their R&D spending to 10% of sales, an obligation they have honored.[8] The 1987 Amendments also addressed concerns about the impact on prices by creating the PMPRB. The 1993 amendments[9] completely eliminated compulsory licensing and brought pharmaceutical patent protection in Canada into line with the U.S. and other industrialized countries. These amendments also strengthened the powers of the PMPRB to control excessive prices and price increases. The Board regulates the prices charged by manufacturer's for all drugs to which a Canadian patent pertains.

Therefore, its jurisdiction applies to both prescription and non-prescription patented medicines whether for human or veterinary use. This manufacturer's price[10] does not include wholesale or retail markups or dispensing fees. Although patented drugs only represented approximately 40% of total drug sales in 1994, [11] they usually include the newer and more expensive drugs.

III. Pricing Guidelines

The PMPRB is a quasi-judicial agency consisting of five members who serve on a part-time basis. The Patent Act[12] assures patentees of a right to a fair hearing and gives provincial ministers of health the right to intervene. The Board has, however, been successful in achieving its objectives without frequent hearings.[13] It has done so through a program of voluntary compliance and clear price guidelines that are based on factors set out in the Patent Act.[14] Overall, the Board's Excessive Price Guidelines (Guidelines)[15] are based on the following principles:

a) the prices of most new drugs should not exceed the prices of drugs currently on the market that treat the same disease;
b) on average, prices in Canada should not exceed the median of prices in other industrialized countries; and
c) prices should not go up faster than the Consumer Price Index (CPI).

New drugs are separated into three categories to which different guidelines apply. The price of a line extension, which is usually a new strength of an existing drug, must bear a reasonable relationship to the prices of the existing strengths. The price of a new drug product that is the first to treat a disease effectively, or that brings a substantial improvement over existing drugs, may not exceed the higher of prices of all other drugs in the same therapeutic category in Canada, and the median price of the same drug in seven industrialized countries.[16] Other drugs which may bring only moderate or no improvement, are limited to the prices of existing drug products in the same therapeutic category.

Subsequently, the Guidelines limit price increases to changes in the CPI. In addition, the price of a patented medicine can never exceed the highest of the prices for that drug in the seven countries.

IV. Compliance with and Enforcement of the Pricing Guidelines

The Patented Medicines Regulations[17] require patentees to report to the PMPRB when a Notice of Compliance[18] has been issued by Health Canada or when a drug is first sold in any market in Canada.[19] Information about the identity, the average price, and the publicly available manufacturer's price, of each strength of an individual dosage form of a patented medicine must be provided to the Board.[20] This information must be filed within 30 days following the first sale of the drug product in Canada and for each six-month period, thereafter, so long as the drug remains subject to the patent.

In categorizing new drug products into the three groups described above, the PMPRB is assisted by an expert Drug Advisory Panel.[21] The staff help patentees determine if a proposed price would conform to the Guidelines by providing non-binding opinions. Further, at the request of a patentee, and if sufficient information is available, the Board may issue a non-binding Advanced Ruling Certificate when it is satisfied that the price at which the patentee is selling or proposes to sell a patented drug product would not be excessive.[22]
When Board staff find that the price of a patented drug product appears to exceed the Guidelines, and the circumstances are within the criteria established by the Board, an investigation is conducted to determine the facts. If the investigation confirms that the price exceeded the Guidelines, the matter is referred to the Chairperson of the Board. In these circumstances the patentee may submit a written proposal in the form of a Voluntary Compliance Undertaking (VCU) to adjust its price.[23] If no acceptable VCU is forthcoming, and the investigation has revealed that the price exceeded the Guidelines or otherwise may be or has been excessive, the Chairperson may commence a formal proceeding by issuing a Notice of Hearing and establishing a Hearing Panel.

When the Board finds, following a public hearing, that the price of a patented drug product is excessive, it may make an order[24] requiring the patentee to reduce the price of the drug product to a level the Board considers not to be excessive. In addition, the Board may order anyone or more of the following things to offset any excess revenues received by the patentee: an additional reduction in the price of the drug in question; a reduction in the price of another patented medicine sold by the patentee; and/or a payment to the government of Canada.[25] In addition, if the Board finds that there has been a policy of selling the product at an excessive price -for example if the patentee failed to comply with a previous price reduction order or VCU -the Board may order further price reductions or monetary payments to offset twice the excess revenues received by the patentee.[26]

V. Impact of the PMPRB

Since the creation of the PMPRB, the annual rate of increase in patented drug prices has been consistently below the CPI and below the index for all pharmaceuticals. In fact, the Patented Medicines Price Index (PMPI) actually declined by 0.42% in 1994 for the first time.[27] Manufacturers' prices for all pharmaceuticals, as measured by Canada's Industrial Products Price Index (IPPI),

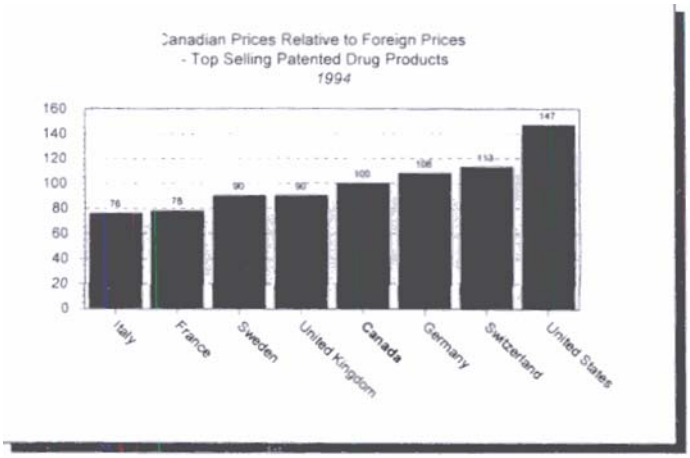
increased at a rate well above the CPI in the period from 1983 to 1987.[28] However, since the PMPRB was established, prices for patented drugs, as measured by the PMPI, increased on average only 2.1% per year or about two-thirds of the annual rate of increase in the CPI of 3.3%.[29] These modest increases in patented drug prices regulated by the PMPRB no doubt helped to slow the rate of increase of manufacturers' prices of all drugs to slightly above the CPI over the last seven years.

How do drug price trends in Canada compare with those in the United States? Canadian drug prices rose at a higher rate than those in the U.S. in the mid-1980s. However, since the creation of the PMPRB, the increases in Canadian prices have consistently been below those in the United States.[30] The prices of patented drugs in Canada have increased at an even lower rate.

While drug prices are going up no faster than consumer prices, expenditures on drugs have been increasing at a faster rate. Consistently over the years, the quantities of patented drugs sold have increased much faster than prices.[31] Clearly, increased expenditures on drugs are not simply a function of price but are also related to increases in the quantities consumed.

Another factor is the tendency of prescribers to shift to newer and more expensive drugs. The PMPRB has measured the impact of newer drugs on the total sales of patented drugs. Approximately 80 new patented drug products come on the market every year.[32] In 1994, newer drugs, on the market for five years or less, accounted for about 50% of the total market for patented drugs.[33] In these circumstances, the challenge is to ensure that prices of new drugs are reasonable, and that utilization is optimal in terms of therapeutic value and cost. This is why the PMPRB's review of the entry prices of new patented drugs is important.

Studies by the PMPRB have shown that since 1992, Canadian prices for patented drugs are coming down relative to foreign prices. As a matter of fact, in 1994, the prices of the top-selling patented drugs in Canada were actually below the median international prices for the first time.[34] This is consistent with the objective that Canadians not pay more, on average, than the median of foreign prices.[35]



While it is true that some of the major new drugs rep- resent costly additions to expenditures on health care, the prices for those drugs in Canada are well in line with those in other countries.

The effectiveness of the PMPRB translates into cost savings for the Canadian health care system. It is difficult to know how much higher the prices of patented drug products would have been in the absence of the PMPRB but it is possible to estimate the effect of its actual enforcement activities. Accumulated savings to consumers due to direct action taken by the PMPRB to remedy more than 100 apparent cases of pricing above the Guidelines between 1990 and 1994 total over $74 mil- lion. In 1994 alone, it is estimated that savings to consumers from the PMPRB's compliance and enforcement activities were almost $25 million.[36]

VI. Conclusion

In Canada, the federal government, through the Patented Medicine Prices Review Board, regulates the prices of patented drugs to ensure they are not excessive. The PMPRB's Guidelines limit the introductory price of a new drug to a non-excessive level but in some cases there may be less expensive drugs already available that are just as effective. Provincial governments, prescribers, third-party payers and employers continue to seek out ways to ensure the most optimal and cost-effective use of drugs.

The Guidelines also limit price increases for patent- ed drugs and limit prices with reference to international prices. In this way, Canadians can be confident that they are paying no more than a fair portion of the international research and development costs of a major new drug.

Endnotes

1. Total health expenditures were $72 billion in 1994 or 9.7% of GDP. In comparison, health expenditures were 14.30;0 of GDP in the U.S.
2. Patent Act, R.S.C. 1985, c. p-4, as am. R.S.C. 1985, c. 33 (3rd Supp.); S.C. 1992, c. 1; 1993, c. 2; c. 15; c. 44; 1994, c. 26; C. 47 (not yet in force); 1995, c.1.
3. *National Health Expenditures in Canada,* 1975-1994, Supply and Services Canada, 1996, *Table* 42. In 1994 total provincial public sector spending on drugs totalled $2.7309 billion, or 29.7% of $9.1794 billion total spending on drugs (public and private) in Canada.
4. A funding methodology whereby the province of British Columbia's drug plan funds those covered under it at a level based on the cost of a single reference standard drug therapy for specified conditions. This standard is defined as that thereapy which is supported by evidence based medicine to meet the needs of the majority of patients with a particular condition. For patients who are unable to tolerate, or who are unresponsive to the referenced thereapy, special authority is granted for funding of another therapy. If a patient chooses, (s)he may pay for the difference in price between the reference drug and another drug.
5. *Constitution Act,* 1867, ss. 91(22), and 92(13); In re Manitoba Soc'y of Seniors Inc. and Attorney Gen. of Canada, Manitoba t,c Court of Queen's Bench January 17, 1991, 10 Man. R. (2d) 141, .; 35 C.P.R. (3d) 66; upheld on appeal to Manitoba Court of Appeal in October, 1992.
6. Patent Act, R.S.C.1970, C. P-4, s.41.
7. An Act to amend the Patent Act and to provide for certain matters in relation thereto, S.C.1987, c.41.
8. PMPRB Seventh Annual Report for the Year Ended December 31 , 1994, pp. 18-28: Analysis of Research and Development Expenditures.
9. Patent Act Amendment Act, 1992, S.C. 1993, c.2.
10. The manufacturer's price is also referred to as the "ex-factory price."
11. PMPRB Seventh Annual Report, for the Year Ended December 31, 1994, figure 1: Patented and Non-Patented Drugs -Factory Gate Sales and Number of Products, 1994. Sales at the manufacturer's gate for all drugs in 1994 were $5.94 billion. Patented drugs represented 40.24% of the total, a decline from 44% in pre- vious years.
12. *Patent Act,* R.S.C. 1985, c. P-4, as am. R.S.C. 1985, c.33 (3rd Supp.); S.C. 1992, c.1 ; 1993, c. 2; c. 15; c. 44; 1994, c. 26; c. 47 (not yet in force); 1995, c.1
13. The PMPRB has only issued three Notices of Hearing; two cases were settled by Voluntary Compliance Undertakings and the third is ongoing. In contrast, the Board has received over 100 voluntary undertakings by patentees to adjust prices to comply with the Guidelines and, since 1993, to offset excess revenues received. *Patent Act,* ss. 85. (1) Factors to be considered. -In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:

    (a) the prices at which the medicine has been sold in the relevant market;

    (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;

    (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

    (d) changes in the consumer price index; and

    (e) such other factors as may be specified in any regulations made for the purposes of this sub- section. [No such regulations have been made.]
15. *PMPB Compendium of Guidelines, Policies and Procedures,* Chapter 1: Excessive Price Guidelines
16. *Patented Medicines Regulations, SOR/94-688,* as am. *SOR/95.* 172. The seven countries are: Germany, France, Italy, Sweden, Switzerland, the United Kingdom and the United States.
17. Patented Medicines Regulations, 1994 *SOR/94-688.*
18. In Canada drugs must be approved by the Health Protection Branch of Health Canada (Health Canada) prior to being market- ed. Approval for marketing is called a Notice of Compliance.
19. New drugs may be sold without a Notice of Compliance in rare circumstances such as pursuant to the Emergency Drug Release program.
20. *PMPRB Compendium of Guidelines, Policies and Procedures,* Chapter 1: Excessive Price Guidelines, 2. -Unit of Price Review: the Guidelines are applied to the average price of each strength of an individual dosage form of a patented medicine. In most cases, the unit is consistent with a product's Drug Identification Number assigned by Health Canada.
21. *PMPRB Compendium of Guidelines, Policies and Procedures,* Chapter 3: Scientific Review Procedures.
22. *Patent Act,* ss. 98(4) Certificates -Where any person satisfies the Board that the Board would not have sufficient grounds to make an order under section 83 in respect of the person, the Board may, after the person pays any fees required to be paid by the regulations, issue to the person a certificate to that effect, but no certificate is binding on the Board.
23. The Board report~ publicly on all VCUs in its Annual Reports.
24. *Patent Act,* ss. 83 (1) Order re excessive prices. -Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells th~ medicine in that market to be reduced to such level as the Board considers not to be excessive as is specified in the order.
25. *Patent Act,* ss. 83 (2) Idem. Subject to subsection (4), where the Board finds that ~ patentee of an invention pertaining to a medicine has, while a' patentee, sold the medicine in any market in Canada at a price that, In the Board's opinion was excessive, the Board may, by order, direct the patentee to do anyone or more of the following things as will, in the Board's opinion, offset the excess revenues i estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price:

    (a) reduce the price at which the patentee sells the medicine in any market in Canada, to such extent and for such period as is specified by the order;

    (b) reduce the price at which the patentee sells one other medicine to which a patented invention of the patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or

    (c) pay to Her Majesty in right of Canada an amount specified in the order.

26. *Patent Act,* 55. 83i (4) Where policy to sell at excessive price. - Where the Board, having regard to the extent and duration of the sales of the medicine at an excessive price, is of the opinion that the patentee or former patentee has engaged in a policy of selling the medicine ,at an excessive price, the Board may, by order, in lieu of any order it may make under subsection (2) or (3), as the case may be, direct the patentee or former patentee to do one or more of the thing~ referred to in that sub3ection as will, in the Board's opinion, offset not more than twice the amount of the excess revenues !estimated by it to have been derived by the patentee or former patentee from the sale of the medicine at an excessive price.
27. *PMPRB Seventh f4nnual Report, for the Year Ended December* 31, 1994: Pharmaceutical Trends Analysis -Trends in Price and Volume of Patented Drug Products.
28. *PMPRB Seventh Annual Report, for the Year Ended December* 31, 1994: Pharmaceutical Trends Analysis -Price Trends of All Drug Products -Patented and Non-Patented.
29. *Id.*
30. Statistics Canada, *Industrial Products Price Index (Pharmaceuticals)*, 1984-1994; United States Bureau of Labour Statistics, *Product Price Index (PharmaceutIcals)* 1984-1994.

31. *PMPRB Seventh i4nnual Report, for the Year Ended December* 31, 1994: Figure 3- Patented Drug Products Price and Volume Index, 1988-1994.
32. *PMPRB Seventh Annual Report, for the Year Ended December* 31, 1994:Table 15i-: Patented Drug Products Introduced in 1994.
33. PMPRB Study S-'607, *The Top* 200 *Selling Patented Medicines in Canada* (1994)
34. *Id.*
35. *Id.*
36. PMPRB Study S-9506, *Estimated Savings From Compliance and Enforcement.*

---

*Robert G. Elgie, LL.B., M.D., is the Chairperson of the Patented Medicine Prices Review Board. This article was prepared specifically for the *Digest.*