Pharmaceutical Price Review in Canada

Harry C. Eastman
Patented Medicine Prices Review Board, Ottawa, Ontario, Canada

Prior to 1987, Canada sought to moderate the prices of patented medicines by means of compulsory licences to increase competition. Since 1987, Canada has strengthened patent protection of pharmaceutical products. It has also created the Patented Medicine Prices Review Board (PMPRB) to ensure that the price of patented medicines is not excessive. The regulation of drug prices is a subject of international debate, in particular in the US in the context of the reform of healthcare and in Europe with the formation of a single European market. Canadian experience is relevant to both initiatives.

Both the federal government and the governments of the Provinces affect the prices of medicines in Canada. The particular features of the intervention of these governments have varied over time, but the fundamental pattern is constant: the federal government regulates the prices of patented medicines by its use of the Patent Act for which it is responsible, while provinces affect the prices of medicines through their reimbursement programmes.

These roles are based on the powers established for the 2 levels of government by the Constitution Act of 1867. Section 91(22) gives the federal government control of patents amongst its enumerated powers. Section 92(13) gives the provinces responsibility for ‘property and civil rights’. Thus, commercial matters, including the power to control prices, are generally a provincial responsibility, but the federal government’s enumerated powers exclude provincial competence even when these powers intrude into the general fields that the Constitution gives the provinces. The Constitution also allots healthcare as a provincial responsibility.

1. History

The use of the Patent Act to affect the prices of patented medicines in Canada has its origin in 1923 when the Act was amended to permit compulsory licensing to manufacture patented medicines in Canada virtually as a matter of right. This measure followed the introduction of compulsory licensing for medicines and food in the UK in 1919, a measure widely adopted throughout the British Commonwealth. Compulsory licensing had little effect on competition in the market for medicines in Canada, because the small size of the Canadian market relative to economies of scale in the manufacture of fine chemicals to which the patents applied made manufacturing in Canada generally unprofitable.

Concern with the prices of medicines in Canada in the 1960s led to 3 inquiries, each of which concluded that prices were too high, and proposed a range of patent and tax measures to address this perceived problem (Canada Department of Justice Restrictive Trade Practices Commission 1963; Canada, House of Commons, Special Committee on Drug Costs and Prices 1966; Canada Royal Commission on Health Services 1964). The principal result was an amendment to the Patent Act in 1969 permitting compulsory licensing to import. This measure, in addition to the wording of the Act respecting royalties, led to a significant growth of companies selling generic products under compulsory licences as well as drug products without...
Amendments to the Patent Act were passed at the end of 1987 after contentious debate among the public and in Parliament. These amendments consisted chiefly of establishing periods of exclusivity of 10 years after the NOC for the first patent on an active ingredient for medicines imported under compulsory licences, and of 7 years for medicines manufactured in Canada under compulsory licences. Medicines invented and developed in Canada could not receive compulsory licences to import, but compulsory licences to manufacture in Canada could be exercised 7 years after the NOC unless the patentee made the medicine in Canada. Given the length of time it took to obtain an NOC, a 10-year period of exclusivity after the NOC on average approximated the protection from competition given by the 20-year life of the first patent.

In view of widespread concern that these amendments would cause the prices of medicines to rise unacceptably, the PMPRB was established to ensure that the price of no patented medicine was ‘excessive’.

These 1987 amendments were an attempt to balance considerations respecting the protection of intellectual property in Canada, the encouragement of research and development in Canada, international negotiating pressure and concern for the cost of the healthcare system. The Pharmaceutical Manufacturers Association of Canada, which includes most of the patent-holding companies, nearly all of which are not Canadian-owned, had undertaken to raise the research and development to sales ratio for patentees in Canada from less than 5% in 1984 to 8% in 1991 and 10% in 1996.

The regulatory scheme has been accompanied by a number of legal challenges including one to the constitutionality of compulsory licensing of medicines itself. The grounds for the latter case included the contention that the federal government was removing property rights that were within provincial jurisdiction. However, the judgment held that modifying the terms of the temporary monopoly given to medicines by patents through the use of a system of compulsory licensing was an integral