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Pharmaceutical Pricing and Reimbursement in Canada: An Overview for Innovative Drug Manufacturers

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The pricing and reimbursement of innovative pharmaceuticals in Canada is controlled at three levels: by the federal Patented Medicine Prices Review Board, by the 17 federal, provincial and territorial public drug plans and by the Common Drug Review. This system means that an innovative manufacturer must obtain the approval of 19 different bodies for the price of a new drug in Canada.

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Needless to say, navigating through this labyrinth of pricing regimes poses a significant challenge to drug manufacturers and impairs Canadians' access to innovative medicines. The purpose of this article is to provide international practitioners with an introduction to the various pricing and reimbursement bodies in Canada, and to highlight emerging issues and trends in the area.

Health Canada

In Canada, drugs are federally regulated under the Food and Drugs Act, and the Food and Drug Regulations administered by the health products and food branch within Health Canada, the federal health department. Health Canada reviews new drug submissions for the purposes of safety, efficacy and quality of manufacture, and issues marketing authorisations – known in Canada as notices of compliance (NOC). The regulatory review by Health Canada does not include a pharmacotherapy or pharmacoeconomic analysis relative to other marketed drug products. Following the issuance of an NOC, Health Canada's role is essentially limited to post-market surveillance, inspections, and investigations of the safety and efficacy of the drug. Contrary to popular belief, Health Canada is not involved in the regulation of drug prices in Canada.

Patented Medicine Prices Review Board

Created in 1987 under the federal Patent Act, the Patented Medicine Prices Review Board is an independent quasi-judicial body responsible for ensuring that the prices of all patented medicines sold in Canada are not excessive. The Board was created as a quid pro quo for the abolition of compulsory licensing of medicines. Patented medicines include prescription and over-the-counter drugs, vaccines, biologics and veterinary drugs.

The Federal Court has determined that the nexus between the patent and the medicine is of "broad import", and that the PMPRB needs only "slender thread of connection between a patented invention and the medicine sold in Canada" to claim jurisdiction over the price of the medicine. Patents pertaining to active ingredients, processes of manufacture, delivery systems, dosage forms, and indications for use and those capable of being used for the the medicine – whether or not they are

being worked or are feasible to use – are some of the patents that fall within the jurisdiction of the PMPRB. Consequently, the Federal Court cautions manufacturers against making a unilateral decision as to whether a patent pertains to a medicine and whether it is captured under the Board's jurisdiction.

Patentees are concerned that the PMPRB is continually expanding its jurisdiction. It had found that patent dedication ousted its jurisdiction, but the Board has now reversed this position. The Federal Court has upheld the Board's mandate creep over the price of medicines sold during the patent pending period and over medicines only made available pursuant to Health Canada's Special Access Programme. Innovative manufacturers find it troubling that case law now allows the PMPRB to exert price control in certain circumstances, such as when a manufacturer is not afforded the protection of a patent or has not received a market authorisation to sell in Canada.

The PMPRB regulates the price at which patentees or their licensees sell patented medicines to wholesalers, hospitals or pharmacies – commonly referred to as the "factory gate" or "ex-factory" price. It does not, however, have jurisdiction to regulate the prices of patented medicines throughout the distribution chain (ie, from the wholesaler to pharmacies) or to the eventual customer, the patient. Nor does it have jurisdiction to review the prices negotiated with the federal, provincial or territorial drug plans.

For the PMPRB to review the prices of patented medicines, patentees must submit specified pricing information at introduction and on a semi-annual basis. The Board then undertakes both a scientific and a review to establish whether the price of the patented medicine is an appropriate benchmark price or whether it is excessive. The scientific review is an evidence-led process that categorises medicines based on the level of therapeutic improvement: breakthrough, substantial improvement, moderate improvement, or slight or no improvement. Following the categorisation of the medicine, a corresponding price test is then applied to determine if the price may be considered excessive. The categories and price tests are set out in the Compendium of Policies, Guidelines and Procedures, which, though not binding on the Board or patentees, are rigidly adhered to by Board staff.

Section 85 of the Patent Act specifies that the following factors ought to be considered in determining whether a patented medicine is priced excessively: the sale price for the medicine in the relevant market; the prices of other drugs from the same therapeutic class in the relevant market; the prices of the same medicine and other medicines in the same therapeutic class in specific foreign comparator countries (namely France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States); and changes in the Consumer Price Index.

If the price of a patented medicine is found to be excessive, the PMPRB and the patentee may negotiate a voluntary compliance undertaking (VCU) that will order a price decrease in the medicine or another patented medicine sold by the patentee, order a retroactive repayment of excess revenues, or both. In the event that the PMRPB determines that the patentee has a policy of excessive pricing, it may order a retroactive payment of twice the amount of excess revenues. In the event that a VCU is not negotiated between the patentee and the PMPRB, a notice of hearing will be issued and the matter will proceed to a hearing before the Board.

Historically, very few notices of hearings were issued and even fewer proceeded to hearing. The current chairperson of the Board, however, has issued more notices since 2007 than the PMPRB had issued since its inception in 1987. Additionally, in 2009 the chairperson stated that during the first 18 years of the PMPRB, the Board recovered approximately C$25 million in excess revenues. In 2008/2009 alone, the PMPRB reported the receipt of C$27.2 million in excess revenues paid by patentees to the

government pursuant to VCUs and Board orders. The marked increase in payments reflects the Board's ever-proliferating jurisdiction and increased enforcement activities. It is also the result of a disturbing new position adopted by the Board: that a price decrease other than pursuant to a VCU or Board order cannot be used to offset excess revenues.

In addition to its regulatory mandate, the PMPRB is also responsible for reporting on pricing trends in the pharmaceutical industry, as well as the annual research and development expenditures by patentees in Canada. Typically, this is in the form of the PMPRB's annual report, which is presented to the federal parliament.

In 2004, as part of the National Pharmaceutical Strategy, the federal and provincial ministers of health directed that the PMPRB monitor and report on the prices of non-patented drugs in Canada. (One of the aims of the National Pharmaceutical Strategy is that Canada achieve international parity on the prices of non-patented medicines.) In 2006/2007, the PMPRB released four such reports. Of particular interest is that the Board reported that the prices of generic prescription drugs reviewed were lower in all international comparator countries than in Canada.

Initially, the PMPRB indicated that it would continue provide quarterly reports on non-patented drug prices but, to date, none have been issued. However, in 2007 and 2008, the Competition Bureau reported on the Canadian generic drug sector. The Bureau stated that significant reform is required in Canada to obtain generic drugs at competitive prices to help private and public drug plans to save an estimated $600 million per year and bring the prices of non-patented drugs more in line with international prices. While the establishment of the PMPRB has arguably resulted in the over-regulation of patented medicines, it appears that the prices of generic medicines have escaped any formal price regulation and are excessively priced in Canada.

Public Drug Plans

Canada's publicly funded universal medicare system is often a source of national pride. By contrast, its patchwork approach to public and private outpatient drug coverage in Canada has often been criticised for various reasons, including the high degree of administrative duplication, the disparities between the various public plans and the unequal access to marketed drug products for patients across the country.

There is no universal publicly funded prescription drug plan in Canada. Pursuant to the Canada Health Act, all drugs administered in hospitals are fully funded by the medicare system. Public outpatient drug coverage is offered at both federal and provincial or territorial levels.

At the federal level, various prescription drug plans are available to certain regulated groups. All provinces and territories, meanwhile, have implemented publicly funded drug plans for specific subpopulations. In general, the provincial and territorial governments provide drug coverage for individuals over the age of 65, individuals receiving social assistance or disability benefits and individuals with "catastrophic" drug needs (defined as "high drug cost in relation to income"). The majority of public and private plans require patients to bear some of the financial burden in the form of co-payments, deductibles and premiums.

In 2008, the Canadian Institute for Health Information reported that federal drug plans accounted for approximately 3 per cent of drug expenditure in the country while provincial drug plans amounted to approximately 40 per cent.

Given the absence of a national insurance plan for outpatient prescription drugs, many employers provide private drug insurance for employees and their dependants. A 2007 study of OECD nations, indicates that 10 per cent of the Canadian population (often referred to as the "working poor") is uninsured, without access to either public or private drug plans. The only country that fared worse than Canada in the report was the United States, where 15 per cent of the population remains uninsured.

Each public drug plan provides a formulary defining which drugs are eligible and the conditions for reimbursement. Following a manufacturer's submission, a drug plan will conduct a separate pharmacotherapy and pharmacoeconomic review to determine whether a new drug will be included in its formulary.

As PMPRB jurisdiction is limited to the ex-factory price charged by a manufacturer, some provinces have enacted legislation restricting payments by manufacturers, including rebates and professional allowances, to pharmacies and wholesalers. This, to some extent, regulates the prices of patented and non-patented medicines. Furthermore, provincial legislation has been enacted requiring manufacturers to provide volume discounts or similar payments as a condition of listing on the provincial formularies. It should be noted that such payments are kept confidential.

The provincial governments' intention is to avoid artificially increased prices for the consumer, whether through a private or public drug plan or paid directly by consumers. The practical effect of the legislation, however, is for the provinces to assume price regulation at the point where the jurisdiction of the PMPRB ends, and to establish a maximum price for manufacturers to comply with to be included in the provincial drug plans.

Common Drug Review

In 2003, the Common Drug Review was implemented to centrally assess all publicly funded drug plans in Canada, with the exception of the those administered by the province of Quebec (which continues to maintain an independent review process).

The CDR has two main purposes: to streamline the review process, thereby avoiding the effort and expense historically associated with individual reviews of the public drug plans; and to provide a consistent, rigorous and evidence-based reviewing procedure which diminishes the disproportionate access to drugs among the various public plans. The CDR process requires manufacturers to submit voluminous materials regarding the clinical and economic benefits of any drug proposed for inclusion in the public drug plans. An expert panel is convened to review the materials and complete clinical and pharmacoeconomic assessments, whereupon the CDR issues a non-binding recommendation regarding inclusion on the formulary and the clinical criteria for reimbursement.

Each public drug plan then considers the CDR recommendation and arrives at its own decision about formulary listing and criteria for reimbursement. Ninety per cent of the time, however, it will follow and implement the recommendation. At the time of publication, 51 per cent of the CDR's decisions have recommended that the reviewed drug should not be listed in formularies or reimbursed by the public drug plans.

Moreover, the CDR has recommended that access to a further 32 per cent of new drugs should be limited, based on clinical criteria and conditions. To date, only 3 per cent of the CDR's recommendations support general inclusion of the new drug in a public drug plan formulary. Despite the harmonised CDR process, most public drug plans still require manufacturers to file submissions addressing issues specific to each plan, meaning the unnecessary duplication of effort and expense –

one of the very issues the CDR was intended to eliminate. The CDR was intended to streamline the drug review process and diminish the disparity in access to medicines, it has instead raised a significant barrier to drug access for patients insured by the public programmes in Canada.

The implementation of the CDR has met with great resistance from patients, health care professionals and industry members alike. One consistent criticism is that the CDR appears to be primarily focused on cost containment and not on ensuring Canadians access to innovative medicines. The 2008/2009 RX&D International Report on Access to Medicines compared the access to new small molecules and biologics in 25 OECD countries; Canada ranked an embarrassing 20th and 21st out of 25 for new small molecules and biologics.

The Future for Innovative Pharmaceuticals

The pricing and reimbursement of innovative pharmaceuticals in Canada still represents a significant challenge for manufacturers. Although the PMPRB, the CDR and the patchwork of public drug plans have become established fixtures in the regulation of drug prices in Canada, negotiating the various processes continues to be cumbersome and expensive.The extraordinary and evolving burdens imposed on manufacturers that market innovative pharmaceuticals in Canada, and the uneven access to innovative medicines from province to province and in comparison with other industrialised countries cause significant concern. Of particular concern is the expanding jurisdiction and increase in enforcement activity of the PMPRB, and the corresponding monetary payments made by patentees to the government.

Considering these problems, and in light of the more recent barriers imposed by the CDR on access to medicines pursuant to the various public drug plans, the future for and pricing of innovative medicines in Canada appears to be bleak. Historically, innovative manufacturers have chosen to market their products in Canada; given the obstacles now facing them, this may not always be guaranteed in the future.

Submitted by Ward Health