Who is the PMPRB?

The Patented Medicine Prices Review Board (PMPRB) is a federal independent quasi-judicial body established in 1987 under the *Patent Act* (Act). In its establishment, the government sought to create a counter balance to changes to other sections of the Act that strengthened intellectual property rights of pharmaceutical manufacturers.

Although the PMPRB is part of the Health Portfolio, it carries out its mandate at arm's-length from the Minister of Health. It also operates independently of other bodies such as Health Canada, which approves drugs for safety, quality and efficacy, and the public drug plans, which approve the listing of drugs on their respective formularies and reimbursement for eligible beneficiaries.

The PMPRB's Role

- Regulatory – To protect consumers and contribute to Canadian health care by ensuring that prices charged in Canada by manufacturers for patented medicines are not excessive; and,

- Reporting – To contribute to informed decisions and policy making, by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees.

The PMPRB's Mandate

The PMPRB's mandate under the Act is two fold: to regulate the prices that patentees charge for prescription and nonprescription patented drugs sold in Canada to wholesalers, hospitals, pharmacies or others, for human and veterinary use, to ensure that they are not excessive; and to report annually to Parliament through the Minister of Health on the PMPRB's major activities, analyses of the prices of patented medicines and of the price trends of all drugs, and reports on the R&D expenditures as reported by patent-holding drug manufacturers.

The Guidelines

The Act does not define what constitutes excessive; however, it does list the factors that the Board shall take into consideration in determining whether a price is excessive. The Board developed the Excessive Price Guidelines (Guidelines) in consultation with its stakeholders, including provincial and territorial Ministers of Health, consumer groups, the pharmaceutical industry and others. The Guidelines are designed to provide transparent predictable guidance to patentees on the approach Board Staff uses when reviewing prices of patented medicines to ensure they are not excessive.

Enforcement Procedures

From the outset, the Board has adopted a policy of voluntary compliance under which it expects patentees to set prices that conform with the Guidelines and hence are presumed not to be excessive. If a price appears to be outside the Guidelines, Board Staff will initiate an investigation.

An investigation could result in:

- a finding that the price is not excessive;
- a Voluntary Compliance Undertaking (VCU) by the patentee to reduce the price to a non-excessive price and to offset any excess revenues accrued; or,
- a public hearing.

Following a public hearing, the Board may issue an order requiring a patentee to offset the amount of the excess revenues by:

- a reduction of the price at which the patentee sells the medicine;
- a reduction of the price at which the patentee sells another medicine; or,
- a payment to Her Majesty in Right of Canada an amount specified in the order.

Since 1993, the Board has accepted 38 VCU's and issued 13 Notices of Hearing. As of October 16, 2006, there are seven on-going hearings.