PMPRB Advisory Note

Hepsera – Gilead

July 2005

This Advisory Note provides information on the PMPRB price review process and the patented medicine Hepsera.

The mandate of the Patented Medicine Prices Review Board (PMPRB) is two-fold:

Regulatory – To protect consumer interests and contribute to Canadian health care by ensuring that prices charged by manufacturers for all patented medicines sold in Canada, under prescription or over the counter, are not excessive.

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 is a quasi-judicial tribunal that carries out its mandate independently of other bodies such as Health Canada, which approves drugs for safety and efficacy and public drug plans, which approve the listing of drugs on their respective formularies for reimbursement purposes.

The Board has no authority to approve drugs for sale, to authorize their use, nor to take drugs off the market. It is mandated to review the prices being charged by manufacturers of patented drugs for compliance with the *Patent Act*. If, following a public hearing, the Board finds that a price is excessive it may order a reduction in the price to a non-excessive level.

It is important to note that matters such as the decision to use and payment for any medicine, whether patented or not and whether prescribed or not, are all matters outside the purview of the PMPRB.

Price Review Process

In accordance with the *Patent Act*, the Board has established price guidelines in consultation with provincial ministers of health, consumer groups, the pharmaceutical industry and other stakeholders. The determination of whether a price is "excessive" is based on the factors listed in the *Patent Act*, which include prices of other drugs within the therapeutic class and prices at which the drug is sold in other countries.

The general effect of the Guidelines is to limit the prices of most new patented drugs to the highest price of comparable drugs on the Canadian market that treat the same

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condition or disease; in the case of a breakthrough drug, the price in Canada may not exceed the median of the prices for the same drug in seven other industrialized countries specified in the *Patented Medicines Regulations, 1994*.

The PMPRB provides pre-sale advisory assistance to all patentees that request it in order to assist them in pricing their products within the Guidelines at the outset. Patentees may also seek an Advance Ruling.

Compliance
All patentees must comply with the *Patent Act* to ensure that the prices of their patented medicines are not excessive. If the PMPRB finds, following a public hearing, that a patentee has been selling a patented drug at an excessive price, it can order, for example, a price reduction and payment of excessive revenues. In addition, should the Board find that the patentee has engaged in a policy of excessive pricing, it can order the patentee to pay double the excessive revenues.

Hepsera

- Gilead obtained market approval for Hepsera (adefovir dipivoxil) from Health Canada on August 27, 2003, and has been free to sell Hepsera in Canada at any time since then.

- The PMPRB does not have the authority to prevent the sale of a drug product based on its price nor to remove a drug product from the market.

- Although patentees are required to notify the PMPRB of their intention to sell a patented medicine, they are not required to obtain approval of its price by the PMPRB prior to it being sold in Canada.

- In the case of Hepsera, Gilead **sought and received pre-sale advisory assistance** from Board Staff with respect to its proposed price for Hepsera. In providing advisory assistance, Board Staff (i) advises the patentee as to the appropriate methodologies to be applied to review the price of the medicines; (ii) for new active substances, refers the matter to the Human Drug Advisory Panel[1] for an assessment of appropriate comparator medicines, if any; and (iii) provides

[1] The mandate of the Human Drug Advisory Panel is to provide credible, independent and expert scientific advice to the PMPRB respecting the development and application of the PMPRB Guidelines related to the scientific evaluation of patented medicines.

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a non-binding opinion as to whether the proposed price would be within the Guidelines.

- Once Gilead begins selling Hepsera in Canada, it will be subject to the PMPRB's jurisdiction at which time the PMPRB will review the actual price at which it is being sold to ensure that it complies with the Guidelines.

  In the interim, all inquiries on the availability of Hepsera in Canada should be addressed to Gilead directly. You will want to contact Edward Gudaitis, General Manager, Gilead Sciences Canada Inc., at Toll Free (800) 445-3235 ext 6245; Mobile phone: (289) 242-9105; E-Mail: Edward.Gudaitis@gilead.com.

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