Patented Medicine Prices Review Board

Since 1987

PMPRB
COMMUNIQUÉ

August 18, 2008

Stakeholder Communiqué

The Board is making all efforts to ensure transparency, accountability and good management of the price review process in its role of ensuring prices of patented medicines sold in Canada are not excessive. The Board has been consulting with all interested stakeholders on its current patented drug price regulatory regime in order to determine where and how the regime may be updated to be more appropriate, relevant and effective in today's modern pharmaceutical environment.

The Board has given careful consideration to all of the views and comments expressed throughout its consultation process. The purpose of this Communiqué is to update stakeholders on the Board's work in regard to the *Patented Medicines Regulations* (Regulations) and its Excessive Price Guidelines.

Directions on the Patented Medicines Regulations

The Regulations, enacted pursuant to the *Patent Act*, set out the information that patentees must file with the Board and the dates and form in which this information must be filed. In 2000, the Board adopted a policy that provided patentees with the discretion to include or exclude certain benefits (compassionate free goods, trial prescriptions and payments pursuant to expenditure limitation agreements) from the reporting of the average price. There were a number of developments in 2007 that caused the Board to revisit and rescind this policy. In order to enable the Board, in consultation with stakeholders, to consider options that might mitigate concerns about the impact of mandatory reporting, it decided that it would only insist upon mandatory reporting of benefits beginning with the January – June 2009 reporting period. The Board has benefited from further exchanges with the innovative brand and biotechnology industry, governments, private insurers and consumers in determining patentees' reporting obligations.

The Board's mandate is to ensure that the prices of patented medicines sold in Canada are not excessive. It views consistent and complete reporting as central to the fair, transparent and effective conduct of its regulatory mandate, and to the accuracy and relevance of its reporting of pharmaceutical price trends. The attached Backgrounder provides further information on the legal basis for mandatory reporting in accordance with the Regulations.

Given that full, mandatory reporting will be insisted upon starting with the January – June 2009 period, it is essential that patentees know what they will need to report. Taking into account the fact that the Board's mandate pertains to patented medicines that are sold in Canada, the calculation of the Average Price must include any and all benefits listed in sub-section 4(4) of the Regulations that are connected to sales transactions:

- rebates (including rebates/payments to third parties);
- discounts;
- free goods;
- free services;
- gifts; and
- other benefits of a like nature.

The mission of the Patented Medicine Prices Review Board (PMPRB) is to protect consumer interests and contribute to Canadian health care by ensuring that prices of patented medicines are not excessive and by analyzing and reporting to Canadians on price trends of all medicines and on research and development conducted by patentees.

Canada

Directions on the Excessive Price Guidelines

In its April 2008 NEWSletter, the Board summarized the responses to the different issues and options presented in its January 2008 Discussion Paper. Stakeholder feedback combined with the findings and recommendations made by the Working Groups have been instrumental in enabling the Board to crystallize its position regarding proposed changes to the Guidelines.

On August 20, 2008, the Board will be releasing a consultation package which will include the Board's directional decisions on the various matters that have arisen during the Guidelines review and the draft revised Guidelines. Stakeholders' comments will be due on October 6, 2008. The Board will finalize the new Guidelines and comment further on any transitional issues when the new Guidelines are implemented in January 2009.

Timetable

Deadlines	Products
August 20, 2008	Draft revised Guidelines posted on the PMPRB Web site for consultation
October 6	Deadline for stakeholders' submissions on the draft revised Guidelines
October 22	Board Meeting
November 17	Release of the amended Compendium of Policies, Guidelines and Procedures, and transition and implementation plans
November-December	Board Staff outreach to assist patentees in the implementation of the revised Guidelines

Once again, the Board thanks all stakeholders who have participated in this process to date and looks forward to their continued active involvement in the completion of this important exercise.

Stakeholder Communiqué

Backgrounder on Information Reporting Requirements

Patent Act

Section 83 of the *Patent Act* (Act) provides the Board with remedial powers in cases where it finds that a patentee of an invention pertaining to a medicine is selling or has sold the medicine in any market in Canada at a price that, in the Board's opinion, is excessive.

Sub-section 85(1) of the Act states the factors that the Board shall take into consideration in determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada. Sub-section 85(2) identifies other factors that the Board may consider if, after taking into consideration the factors in 85(1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price.

Sub-section 80(1) specifies the information and documents a patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide to the Board, including the price at which the medicine is being or has been sold in any market in Canada and elsewhere. Sub-section 80(2) specifies similar information that shall be provided by a former patentee.

Regulations with respect to section 80(1) or 80(2) may be enacted under section 101 of the Act specifying the information and documents that shall be provided to the Board, and the form and manner in which and times at which such information and documents shall be provided to the Board and imposing conditions respecting the provision of such information and documents.

Patented Medicines Regulations

Sub-section 4(1) of the *Patented Medicines Regulations* (Regulations) provides: *"For the purposes of paragraphs 80(1)(b) and 2(b) of the Act, information identifying the medicine and concerning the price of the medicine shall indicate*

(a) the identify of the patentee or former patentee;

(b) the generic name and brand name of the medicine;

(c) the date on which the medicine is first sold in Canada;

(d) the day or period, referred to in sub-section (2) or (3), to which the information pertains;

(e) the drug identification number assigned under the Food and Drug Regulations in respect of the medicine or, if no drug identification number has been assigned, any other identification number assigned in respect of each dosage form and strength of the medicine of the patentee or former patentee; and

(f) in respect of the day or period referred to in paragraph (d),

i) the quantity of the medicine sold in final dosage form and either the average price per package or the net revenue from sales in respect of each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory,"

Sub-section 4(4) provides: *"For the purposes of subparagraph (1)(f)(i),*

(a) in calculating the average price per package of the medicine, the actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after the deduction of the federal sales tax shall be used; and

(b) in calculating the net revenue from sales of each dosage form, strength and package size in which the medicine was sold in final dosage form, the actual revenue after any reduction in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after deduction of federal sales taxes shall be used."

Board's Mandate and Jurisdiction

The Act defines the Board's jurisdiction over a patented medicine that is being or has been sold in Canada.

Mandatory Reporting Requirement

Reporting of information to the Board is mandatory under the provisions of sub-section 80(1) of the Act, and under sub-section 4(1) of the Regulations, which specifies the information identifying the medicine and concerning the price at which the patented medicine is being or has been sold in Canada that the patentee must report. In both the Act and the Regulations the use of the word "shall" is imperative therefore the Board cannot exercise any discretion to exclude a patentee from any of the reporting requirements.

Sales

The Board's jurisdiction is limited to patented medicines that are being or have been "sold" in any market in Canada. The Regulations also refer to the "actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any benefit of a like nature". Therefore, the required information on prices, including benefits, must be in relation to sales. Conversely, any benefits not connected to sales are not to be reported for the purposes of the Board's consideration of factors in 85(1) of the Act.