Patented
Medicine Prices
Review Board

PMPRB Notice and Comment

January 2005

The Patented Medicine Prices Review Board is a quasi-judicial tribunal with the mandate to ensure that manufacturers' prices of patented medicines sold in Canada are not excessive.

Proposed Amendments to the *Patented Medicines Regulations*

1. PURPOSE

To consult with stakeholders on proposed amendments to the *Patented Medicines Regulations, 1994*.

2. BACKGROUND

Patentees' filing requirements with respect to the PMPRB are set out in the *Patented Medicines Regulations, 1994* (Regulations). The Regulations specify the information that patentees must file to the PMPRB in accordance with their obligations under the *Patent Act* (Act), and the timeframes for doing so. To guide patentees in meeting their filing requirements, the PMPRB has developed standardized reporting forms and the reference document, the *Patentees Guide to Reporting*.

Since they were initially promulgated in 1988, the most substantive amendments to the Regulations occurred in 1994. The primary reason for the 1994 amendments was to bring the Regulations up to date with the latest version of the Act.

A decade later, the Regulations need to be modernized in some areas to better reflect the information needs of the PMPRB to carry out its responsibilities under the Act.

2.1 Timelines Project

Stakeholders, including the Working Group on Price Review Issues[1], have expressed concerns in the past regarding the timeliness of the PMPRB's price reviews. In response, the PMPRB has committed publicly through its Research Agenda[2] to its Timelines Project, an initiative to study and improve the timeliness of the price review process.

Although the Timelines Project is still in progress, from the work that has been completed to date it has become apparent that the timeliness of the price review process is significantly impacted by the information that patentees file (or do not file). In studying this issue, the PMPRB has identified areas of improvement in patentees submission requirements that would support more efficient and timely price reviews in the future. These are areas where additional time, effort and coordination are often required to seek the necessary information from patentees, or to find alternative sources. Therefore, changing the Regulations to clearly indicate the information that the PMPRB requires for the timely completion of price reviews would be appropriate to propose.

1 "The Price Review Process for New Patented Medicines" – Report of the Working Group on Price Review Issues to the Patented Medicine Prices Review Board, November 2000. Available on the PMPRB website under Working Group on Price Review Issues.

2 PMPRB's Research Agenda is available on the PMPRB website under Publications.

2.2 Patented veterinary medicines

In September 2003, the PMPRB decided to implement a full complaints-driven approach for the regulation of patented veterinary drug prices. This decision was communicated to stakeholders in the PMPRB's January 2004 NEWSletter.[3]

Since the Regulations do not distinguish between the filing requirements for human drug patentees and veterinary drug patentees, they need to be amended to differentiate between the filing requirements of the two.

2.3 Editorial changes

In addition to the above, a few editorial and factual corrections should be made at the same time that the Regulations are opened up for other amendments. These changes are all very minor and do not have any impact on the policies or operations of the PMPRB.

3. PROPOSED AMENDMENTS FOR CONSULTATION

The PMPRB is seeking stakeholder input on the following proposals to amend the Regulations.

3.1 Notification of proposed price

Insert a new section 5 to the Regulations with the following text:

> *5. (1) In addition to the information referred to in paragraph 4(1) and for the purpose of section 82(1) of the Act, the patentee shall provide prior to the sixtieth day preceding the date on which the patentee first offers the medicine for sale, the price at which the medicine is intended to be sold.*

Rationale:

For new drugs, the Regulations require that patentees submit sales and price data no later than sixty days after the date of first sale. However, in cases where the patentee has formed the intent to sell, but has not yet sold, the Regulations do not require manufacturers to provide information on the proposed price.

Section 82(1) of the *Patent Act* requires a manufacturer to notify the PMPRB when it has formed the intent to sell a patented medicine in Canada. Section 82(2) further states that where the Board has reason to believe that a manufacturer intends to sell a patented medicine in Canada, it may by Board order require the patentee to provide the Board with information and documents respecting the price in which the medicine is intended to be sold. Therefore, amending the Regulations to include proposed price when the patentee has formed the intent to sell would be consistent with the Act, and would increase efficiency.

3.2 Notification of a proposed price increase

Modify section 4 of the Regulations to add the following:

> *(4) Notwithstanding subsection (2), any proposed increase to the price of the medicine, for any class of customers in any market in Canada, shall be communicated to the Board at least 120 days before the effective date of the intended price increase.*

Rationale:

Currently, patentees are required to file their sales and price information within 30 days of the end of each six month reporting period. However, there is currently no provision in the Regulations that requires patentees to notify the PMPRB of price increases between reporting periods. In between reporting periods, the PMPRB must obtain this information from third

3 PMPRB NEWSletters are available on the PMPRB website.

party sources, such as trade notices and complaints from consumers. Making notification of a proposed price increase a mandatory reporting requirement under the Regulations would ensure that the PMPRB receives this information in a timely manner thereby allowing the prompt review of any price increase. This would also allow the PMPRB to notify patentees sooner if there appear to be pricing issues. It should be noted that this proposed amendment does not call for prior approval of a price increase, but rather seeks to ensure that the PMPRB has sufficient information between reporting periods on the state of prices.

3.3 Details on the calculation of net price and net revenues

Add the following sentence to paragraph 4(4) and (5) of the Regulations:

> *For the purpose of this paragraph, any amounts used in the calculation must be identified and reported on the appropriate form.*

Rationale:

As they are currently written, the Regulations and reporting forms require patentees to file net price or net sales, but there is no information on how patentees came to this calculation (i.e., it could be discounts, free goods, rebates, etc). To have a more complete picture of how the average price per package or the net revenue is calculated by the patentee, the Regulations should be amended to require patentees to file further particulars on the calculation of net prices and net revenues. This information is necessary for the PMPRB to have a better understanding of how the patentee arrived at its calculation of the average price per package for a particular medicine. The appropriate PMPRB reporting forms will be modified accordingly to include these details.

3.4 Product monograph / draft monograph

In section 3(1), which reads:

> *3. (1) For the purposes of paragraphs 80(1)(a) and 80(2)(a) of the Act, information identifying the medicine shall indicate*

Add:

> *i) a product monograph, or draft monograph if a notice of compliance has not yet been issued;*

Rationale:

The product monograph is a scientific document describing the drug product's properties, claims, indications and conditions for use. It is reviewed and approved by Health Canada as part of the Notice of Compliance for new drugs. The PMPRB uses the product monograph (or draft monograph in cases where the medicine has not received its Notice of Compliance) in the scientific review component of the price review process. Since it is not currently required under the Regulations, if a patentee does not submit a product monograph, the PMPRB must request it. As such, the Regulations should be modified to indicate that the product monograph/draft monograph automatically be submitted to the PMPRB for each new patented medicine.

3.5 Recognition of electronic signatures

Add the following new sections to the Regulations:

> *9. Any signature that is required by these Regulations to be shown on a record or document may be an electronic reproduction of the required signature.*
>
> *10. Any information that is required to be maintained or filed with the Board by these Regulations may be maintained or filed with the Board in any electronic format from which a printed copy of the record can be produced.*

Rationale:

In keeping with modern technology, the PMPRB strongly encourages electronic filing of information required under the Regulations. Approximately 87% of patentees are currently filing their price and sales information with the PMPRB electronically. Where the Regulations require that the information sent to the PMPRB be accompanied by a signature, patentees wishing to file electronically must also send a signed hard copy of the print out. As such, the potential for efficiency of electronic filing is not fully realized at this time. As such a change to the Regulations to formally recognize electronic filings would be appropriate.

3.6 Filing requirements for veterinary patentees

Propose adding new text to section 4(3) so that it reads as follows:

> *4. (3) The information referred to in subsection (2) shall be provided:*
>
> *(a) within 30 days after the end of each period referred to in that subsection* ***where the medicine is for human use; and***
>
> ***(b) within 30 days following receipt of a written request made by the Patented Medicine Prices Review Board where the medicine is for veterinary use.***

Rationale:

In September 2003, the PMPRB decided to implement a full complaints-driven approach for the regulation of patented veterinary drug prices. This decision was communicated to stakeholders in the January 2004 NEWSletter.[4]

Since the Regulations do not distinguish between the filing requirements for human drug patentees and veterinary drug patentees, the Regulations need to be amended. Until such time that the Regulations are amended, the current provisions for veterinary patentees remain in effect.

3.7 Editorial Corrections

In addition, the following list of amendments should be made at the same time. These amendments are considered technical in nature and reflect changes in time.

- Remove 1994 from the title of the Regulations
- Change “Minister of Health and Welfare” to “Minister of Health”
- References to “province” should read “province and territory”

4. COMMENTS

Comments on the above proposals should be forwarded to the Secretary of the Board, no later than **April 15, 2005**, at the following address:

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Standard Life Centre
333 Laurier Avenue West
14th floor
Ottawa, Ontario
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By fax (613) 952-7626; or
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4 Available on the PMPRB website.