April 14, 2005

Patented Medicine Prices
Review Board
Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

The purpose of this letter is in response to the Board's request for comments to the proposed amendments to the Patented Medicine Regulations.

1) <u>Notification of proposed price</u>

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.

Under the existing regulations, patentees file introductory price data for new products no later than 60 days after the first sale date, covering the 30 days period following the first sale. In addition, patentees file prices on or before July 30 for the January 1 to June 20 reporting period and again on or before January 30 for the July 1 to December 31 reporting period. Adding another price review to the above process will increase the regulatory burden without improving the price review process.

In addition, careful pre-launch planning demands a thorough understanding of the market (national and international) and it's competitors. As part of this planning, the price of the product is quite often established a few days prior to launch.

By requesting the price of the medicine 60 days prior to sale, the Board is in effect shortening the price planning process by 60 days and not allowing a price change if conditions demand. We feel that this amendment is not practical and will not yield the desired result. It also appears to be outside of the Board's authority.

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.

Price changes are often implemented based on competitive products and provincial formulary updates, which are quite often issued on different dates. Therefore, notification of price increases 120 days in advance is not practical.

In addition, the modification reads “for any class of customers in any market in Canada” suggests that a price increase for Contracts (Governments Hospitals), which are quite often renewed at different times or on very short notice, shall be communicated to the Board at least 120 days before the effective date of the intended price increase. Quite often the price is established at the time the contract is received. Therefore, the 120 days notification is not only impractical but impossible. It also appears to be outside of the Board’s authority.

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.

Patentees are already providing the Board with extensive pricing information, by din, by province, by customer. The proposed amendment “any amounts” is vague and will significally add to the regulatory burden resulting in more technical issues and inefficiencies in the price review process.

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:

We feel that the proposed amendment to file product monograph is unnecessary. Product monographs are publicly available on company websites.

Drafts monographs are confidential documents and are subject to change resulting in duplicate works.

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.

We support the amendment which will simplify the reporting process.

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.*

Although Merck Frosst Canada Ltd. does not sell veterinary products, we support this amendment.

We thank you for the opportunity to comment on the proposed amendment to the Patented Medicine Regulations.

V.E. Perocevic
Manager Pricing Services
(514) 428-8594 or
1-800-563-7920