Pharma

ALTANA



050409

ALTANA Pharma Inc.
435 North Service Road West
1st Floor
Oakville, Ontario
L6M 4X8
Tel. 905-469-9333
Toll Free 1-888-367-3331
Fax 905-469-4883
www.altanapharma.ca

Secretary of the Board
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West
14th Floor
Ottawa, Ontario
K1P 1C1

3225-3-13

April 14, 2005

**RE: Proposed amendments to the *Patented Medicines Regulations, 1994***

ALTANA Pharma would like to offer the following comments in response to the amendments to the *Patented Medicines Regulations, 1994* that were proposed by the Patented Medicine Prices Review Board (PMPRB) in February 2005. ALTANA Pharma also supports the comments and feedback put forward by Rx&D™ in their submission.

Reference is made below to the proposed amendments outlined in the January 2005 Newsletter.

Section 3.1 Notification of proposed price

The PMPRB proposes to add a new section to the Regulations:

> 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.

ALTANA Pharma supports the intent of the PMPRB to increase the efficiency of the price review process for new drugs. However, practically speaking, the expectations may be unrealistic. Pharmaceutical manufacturers generally launch a medicine (i.e. offer the medicine for sale) immediately after receiving approval from Health Canada in the form of a Notice of Compliance (NOC). The date for receiving approval is granted from Health Canada and cannot be accurately determined ahead of time by the patentee. A patentee may be forced to wait until receiving NOC to submit a proposed price and thereby access to a new medicine may be delayed by 60 days.
If this amendment does proceed, manufacturers also need to understand the implications of submitting a proposed price based on an incorrectly anticipated NOC date. If a NOC is significantly delayed, does the patentee have the opportunity to change the proposed price to reflect market conditions that may have changed during the delay?

Section 3.2 Notification of a proposed price increase

The PMPRB proposes to modify section 4 of the Regulations:

> (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.

Again, ALTANA Pharma supports the intent of the PMPRB to conduct a prompt review and approval of any price increase. However, requiring notification of a price increase 120 days in advance is not practical considering the competitive market that we operate in. Price increases may be implemented in response to changing market conditions such as price changes of competitive products, introduction of new products, or changes in the reimbursement of specific products through government drug programs. Such changes may require a response in the form of a price increase as quickly as possible, and a 120-day notification requirement is not practical. Additionally, it is understood that price reviews are based on an average annual selling price. Submitting a proposed price increase 120 days in advance of its implementation would not add any efficiencies to the process, since the review cannot begin until the increase takes place.
Should this amendment proceed however, it is essential that PMPRB provide assurances that price increase information provided to them remains confidential while it is under consideration during the 120-day period.

Section 3.3 Details on the calculation of net price and net revenues

The PMPRB proposes to 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.

The wording around this proposed amendment is unclear, since it refers to "appropriate forms" that are not identified. Assuming these forms are yet to be created, it would be appropriate to initiate the amendment at such time as the appropriate forms are available. Additionally we do not see the need to institute a formal change since Board staff may currently request additional information from a patentee if net revenue or net price calculations are unclear.

Section 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

The PMPRB proposes to add:

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

ALTANA Pharma understands the importance of the product monograph as a reference during the scientific review component of the price review process. However, considering the proposed amendment outlined in Section 3.1, whereby a proposed price

would be required 60 days in advance of launch, only a draft product monograph would be available for review. It is not uncommon for the wording of a product monograph to be changed within the final stages before a NOC is granted from Health Canada. A price review should only be based on a final approved product monograph and we would be happy to comply with this requirement after receiving approval in the form of a NOC. Again, assurances regarding confidentiality are critical should this amendment proceed.

Section 3.5 Recognition of electronic signatures

The PMPRB proposes to 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.

ALTANA Pharma agrees with and supports this amendment.

Section 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.

ALTANA Pharma has no comment on this proposed amendment.

ALTANA Pharma supports changes to the Regulations where necessary, with a goal of enabling efficiencies in the price review process. Thank you for providing us with the opportunity to comment on the proposed changes to the Regulations.

Kind regards,

Trish Petersen

Trish Petersen
Manager, Government and External Affairs
ALTANA Pharma

cc: Wai-Man Kwan
Vice President, Regulatory and External Affairs
ALTANA Pharma Inc.

Marc Desmarais
Vice President, Federal Government Affairs
Rx&D™