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3225-3-15

July 5, 2006

Dr. Brien Benoit
Vice-Chairperson
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, ON K1P 1C1

Dear Dr. Benoit:

Thank you for the invitation to review the *Discussion Guide for the Consultations on the Board's Excessive Price Guidelines*. My comments are enclosed and I look forward to participating in the consultation meeting on November 16, 2006.

Sincerely,

John M. Maxted, MD MBA CCFP FCFP
Associate Executive Director, Health & Public Policy

Encl.

JMM/tl

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Comments of Dr. John M. Maxted
Submitted to the Patented Medicine Prices Review Board re: *Discussion Guide for the Consultations on the Board's Excessive Price Guidelines*

Issue 1: Is the current approach to the categorization of new patented medicines appropriate?

Question 1: Are the new patented drug categories and their definitions appropriate?

Response:

- Seem appropriate although the order may not be logical, e.g. consider breakthrough category (new drug) to only moderate or no therapeutic advantage over current products category to change in strength / dosage category

Question 2: Is it important to distinguish a medicine that offers "moderate therapeutic improvement" from a medicine that provides "little or no therapeutic improvement?" If yes, why is it important? If not, why not?

Response:

- Yes. If no therapeutic advantage over existing products, why change unless there is a suspicion the patient is reacting to a drug ingredient? On the other hand, if there is a potential for moderate improvement and the current drug is not providing full relief from the medical problem, then trying another drug may be a good idea.
- What about category 2a, 2b and 2c?

Question 3: If the answer to question 2 above is yes, on what basis would a new medicine that offers "moderate therapeutic improvement" be distinguished from a new medicine that provides "little or not therapeutic improvement"?

Response:

- Not sure of question
- Distinguish by proper categorization. Otherwise, distinguishing characteristics obviously relate to therapeutic response and potential for side effects / adverse reactions between two drugs.

Issue 2: Is the current approach used to review the introductory prices of new patented medicines appropriate?

Question 1: Are the price tests currently used to review the prices of new medicines in the various categories appropriate for that category? Why? Why

not? If not, how could these tests be amended to improve their appropriateness?

Response:

- This is a complex subject and having been only recently exposed to "price testing," I hesitate to respond. However, the categories being used make sense. Not sure if other categories should also be used. I assume not all criteria must be met at the same time for drug pricing approval. Otherwise, I'm concerned that new drugs will become unavailable to Canadians because the price is considered too high due to real economies of scale that we face in Canada compared to other world countries.

Question 2: If you think that medicines that offer "moderate therapeutic improvement" should be distinguished from medicines that provide "little or no therapeutic improvement" what would the appropriate new price test be?

Response:

- To avoid creating new "tests," could the RR test be re-configured to address this need?

Question 3: For price review purposed, "comparable medicines" are medicines that are clinically equivalent. Do you have any suggestion as to principles or criteria that should be used in determining how to identify "comparable medicines" for the purpose of inclusion in the above price tests?

Response:

- Apply the RR and/or TCC tests
- Part of the problem is that clinical equivalency needs to be defined. Are we talking about lab evaluation or human evaluation of clinically equivalent drugs? There needs to be a way to allow that the same drug may have different reactions in different people and that newer drugs with an estimated clinical equivalency may still have potential for improvement in a patient's condition or more potential market longevity because of leading edge characteristics inherent in the drug.

Question 4: Under the current Guidelines, Board Staff compares the Canadian average transaction price of the new medicine to the prices of the same medicine sold in he seven countries listed in the Regulations. However, Section 85(1) of the *Patent Act* states that the Board should take into consideration "the prices of other comparable medicines in other countries". Should the Guidelines address this factor? If so, how could this factor be incorporated into the price tests for new medicines?

Response:

- It seems that this would be an additional factor taken into consideration when/if appropriate.

Issue 3: Should the Board's Guidelines address the direction in the Patent Act to consider "any market"?

Question 1: Given the price variations by provinces/territories and classes of customer illustrated in the previous figures, it is appropriate for the Board to only consider an ATP calculated based on the total revenues from the sales for all provinces/territories and all classes of customer? Why? Why not?

Response:

- Regional variation must be taken into account because access to health care, where at all possible, should not be comprised based on geographic location. The availability of public funds for drugs is not a reasonable barrier to health care access for those who are geographically disadvantaged.

Question 2: If the current ATP calculation is not appropriate, should the Board review the prices to the different classes of customers and/or the different provinces and territories for all DINs? Or should this level of review be done on a case-by-case basis, where there is a significant variation in the prices charged?

Response:

- Given Canada's infrastructure for responsibilities in health care delivery, I would probably prefer a review only where significant price variation occurs. However, this should be tracked centrally (nationally) to prevent such risks as price creep.