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

Re: PMPRB Notice and Comment
Discussion Guide on the Board's Excessive Price Guidelines; 2006 Consultation

Dear Ms. Dupont,

The PMPRB has requested comments on its Excessive Price Guidelines as they relate to the guidelines used to determine whether the prices of patented medicines are excessive, including ideas on possible options for change. Specifically, stakeholders have been asked to respond to questions in the context of the following three specific issues:

1. the appropriateness of the current categorization of new patented medicines;
2. the appropriateness of the current approach used to review the introductory prices of new patented medicines; and
3. whether the Board's Guidelines should address the direction in the *Patent Act* to consider "any market".

Through the provision of this document, Serono Canada Inc. is pleased to offer its response to the above noted discussion paper.

It is Serono Canada's overall position that control of patented medication prices by the PMPRB imposes unfair restrictions on the manufacturers of patented pharmaceuticals or biotechnology products resulting in a loss of Canadian innovation and a reduced ability of Canadians to access important medications. Control of medication prices places patented pharmaceutical/biotech manufacturers at a disadvantage relative to manufacturers involved in other aspects of health care that are not similarly controlled (e.g., developers of medical devices or non-patented medications). This may lead manufacturers to shift development in the long-term to focus on areas that are not as restricted. In addition, restrictions on prices have been shown to result in an immediate loss of innovation in Canada, whereby manufacturers have been forced to halt the market introduction of a new medication or to stop research and development of earlier stage molecules because it would be impossible to achieve a profitable price in Canada. This prevents Canadian access to important medications available in other countries and results in job losses.

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

On the whole, we believe that the current approach to reviewing introductory prices is appropriate. We have three questions/comments related to the review of introductory prices in general.

1. It is unclear what is meant by excessive. Is an excessive price one that exceeds the calculated allowable price by an amount that is closer to 0.1%, 1%, or 10%?
2. If significant research and development has taken place in Canada, this investment should be recognized and a reasonable premium over the non-excessive price should be allowed.
3. The guidelines should recognize that newer medications have significantly higher development costs relative to "older" medications. A small premium over the non-excessive price should be allowed to compensate for the innovative effort. The cost of developing medications is significant. Often, older comparators of new medications were developed many years prior at a cost commensurate with the time in which they were developed. Although new medications are developed at a higher market cost, manufacturers are forced to price their product at "yesteryear's" price.

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?*

Yes, Serono Canada believes that the current price tests are reasonable.

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?*

N/A

Question 3: *For price review purposes, "comparable medicines" are medicines that are clinically equivalent. Do you have any suggestions 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?*

Serono Canada does not object to the current criteria for determining how to identify comparable medicines. However, the price review must consider that comparable medicines were potentially researched and developed many years earlier while the development of subsequently approved medications would have occurred at a time when the development costs were significantly higher. There should be some allowance within the Excessive Price Guidelines for manufacturers of newer products to market their products at a slightly higher price corresponding to the year in which they were introduced. Market forces will ensure that the ATP is in line with that of appropriate comparators.

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 the 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?*

Yours truly,

Deborah Brown
Regional Vice President and General Manager

Serono Canada would strongly object to the consideration of prices of comparable medicines in other countries if "other countries" refers to countries outside the seven listed in the Regulations. Other countries may have vastly different economies and/or standards of living that make a comparison with Canada difficult. The cost of a car is vastly different in many countries versus in Canada – our economy and standard of living would collapse if pricing in all sectors were held to the lowest possible comparator. Also, there could potentially be a need to constantly revise the price of a new medication in Canada to ensure that the price is not excessive compared to an ever-changing number of comparison countries as the new medication is successively launched in countries outside the "basket of seven".

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, is it 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?*

Yes, Serono Canada agrees that it is appropriate to consider an ATP calculation based on revenues generated in all jurisdictions and all classes of customer. If all jurisdictions and all classes of customer were required to have equivalent ATPs, this would create a deterrent to manufacturers providing discounts as it would be difficult to maintain uniform ATPs across markets.

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?*

Serono Canada does not object to the current ATP calculation.

Summary

In summary, we believe, above all else, that the PMPRB should not have a role in setting drug prices in a free market economy. As an innovative biotechnology company, we are looking for ways to improve the health of Canadians and we believe that Canadians value the investment in their health. Innovative healthcare should not be viewed only as an unavoidable cost today but rather as an investment in our future. As a member of BIOTECanada, we also support their view that Canadians should be at the forefront of health innovation and that this innovation should be encouraged rather than restricted.

However, we are aware that manufacturers will likely continue to be required to operate within an environment of some control and, as such, will be faced with price restrictions. Thus, the most significant portions of the Excessive Price Guidelines that should be changed relate to the categories of medications over which the PMPRB has jurisdiction and the need to recognize that, by comparing the price of new medications to those that were developed many years ago, the PMPRB is effectively forcing manufacturers to either lower the price of new products relative to their development costs or abandon their attempts to introduce these drugs.

Serono Canada believes that free market forces and Canada's reimbursement authorities would act to control prices at an appropriate level by allowing increased competition within and across drug classes. This would still allow Canadian access to important new medications that might otherwise not be marketed in Canada. Manufacturers of patented pharmaceuticals would not be at a disadvantage relative to other manufacturers of health technologies because market forces will determine the true value of their products.

However, we understand that there is concern for ever-increasing drug budgets and that, without controls, some health policy decision-makers believe that drug prices in Canada will rise to unaffordable levels. We recognize that manufacturers must operate within an environment of control and, thus, have prepared answers to the questions outlined for each issue identified in the PMPRB's discussion paper according to a more moderate view as follows.

<u>Issue 1: Is the current approach to the categorization of new patented medicines appropriate?</u>

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

- ***Category 2***
  It is Serono Canada's position that the PMPRB should only have jurisdiction in the setting of drug prices for breakthrough (Category 2) products. This is the one category where, in the absence of controls, the potential for excessive pricing exists.

  In addition, a transparent definition of breakthrough should be developed or made public. The use of the term breakthrough by the PMPRB is not the same as that employed by Health Canada's Biologics and Genetic Therapies Directorate (BGTD). This causes confusion and a lack of understanding of whether or not a product can be judged to be a breakthrough.

- ***Categories 1 and 3***
  For Categories 1 and 3, free market economics and the reimbursement system in Canada will ensure that prices are maintained within an economically viable range. In fact, Canadian prices of patented medicines have tracked 5% to 12% lower than the median of international prices (i.e., the PMPRB non-excessive price) indicating that market forces, not just PMPRB guidelines, are acting to maintain Canadian pricing. The potential for discounts relative to current Category 1 and 3 drug prices may even be encouraged through increased competition and the removal of the artificially created maximum benchmark price that all manufacturers strive to achieve.

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?*

In our opinion, there need not be a distinction between moderate and little or no improvement in therapeutic effect because the PMPRB should not govern the setting of price in this category as described above.

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 no therapeutic improvement"?*

N/A