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Subject: **Consultations on Excessive Price Guidelines**

Dear Dr. Benoit:

Thank you for your letter of June 20, 2006, and for the opportunity to comment on the Board's Excessive Price Guidelines - particularly as they pertain to the introductory prices of patented drugs. Having worked in the Canadian Pharmaceutical Industry since 1975, I have had the opportunity to observe the development of many factors that impact the pricing and utilization of drugs in this country - including the formation and evolution of the PMPRB. The pharmaceutical environment has certainly changed substantially these past 20 years, and with respect to pricing and utilization, the PMPRB, the cost-effectiveness activities of the provincial drug benefit programs, the development of disease management/treatment guidelines and the availability of many additional therapeutic agents are among the most prominent.

I was fortunate to have been an active participant in the debate of Bill C-22 and at that time, and again at the time of the amendments brought about by Bill C-91 (February 1993), it was made clear that the mandate of the PMPRB is to ensure that neither the introductory price of new patented medicines, nor price increases for existing patented medicines, are excessive. Thus, the role of the PMPRB is to ensure that these prices do not exceed a threshold beyond which they would be considered excessive - which is distinctly different (and intentionally so) from the role of a Provincial Drug Benefit Program or Pharmacy Benefit Manager - whose objective is to provide accessibility to drug therapy at the same time as managing drug prices, utilization and overall expenditures. To fulfill its mandate appropriately, the PMPRB must appreciate the distinction between the establishment of non-excessive pricing thresholds and the assessment of cost-effectiveness of new drugs in relation to other available therapies - the latter of which can vary greatly depending on the population being covered, the perspective payer, etc.

It must also be appreciated that while the PMPRB has established guidelines limiting both introductory prices and price increases, the marketplace for pharmaceuticals is competitive - and there are factors other than the PMPRB that also significantly impact the introductory price of new drugs, their subsequent price increases (or decreases) and their overall utilization - all of which combine to determine the total amount expended on any drug product.

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

No, we believe that categorization of new patented drugs is unnecessary, unhelpful - and should be eliminated. The therapeutic value of a new medicine is not one of the factors that the Patent Act directs the Board to take into consideration, and the Board's decisions in this area (or more specifically the decisions of the Board's Human Drug Advisory Panel) have been shown to be significantly different than those of more formal drug evaluation agencies, such as the US Food and Drug Administration and the Therapeutic Products Directorate of Health Canada.

Question 1.1: Are the new patented drug categories and their definitions appropriate?

The current system employed by the PMPRB for categorization of new patented medicines is inherently subjective, and in consideration of the many ex-PMPRB factors that impact the pricing of drugs, it is neither necessary or appropriate to attempt to categorize the therapeutic value of new drugs for purposes of determining a maximum non-excessive price. The previously described revised TCC methodology is sufficient to determine whether or not the introductory price of a new medicine is excessive, and beyond that it is the cost-effectiveness analyses and expenditure impact analyses of the public and private drug benefit programs that will fundamentally address the question of therapeutic value. As such, a single approach to the test of introductory pricing can be applied to all new patented medicines.

Question 1.2: 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?

As noted above, there is no need for a system of categories. The establishment of a new "4th" category of new medicines that offer "moderate therapeutic improvement" is not necessary, since this type of therapeutic categorization has no inherent relationship to the concept of excessive pricing. The introductory price of all new patented drugs should first be examined by the revised TCC test as previously described, and subsequently by a Highest International Price Comparison (HIPC) test - but only for those drugs where the revised TCC indicates that the introductory price may be excessive.

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

The PMPRB's Guidelines need to reflect a factually consistent definition of excessive. Accordingly, the notion of "excessive pricing" cannot be tied to an average, median or other measure of central tendency - but rather can only mean a price that exceeds thresholds based on non-excessive prices in Canada and, secondarily, in international markets.

Question 2.1: 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?

No, there is no need for new medicine categories and the same test(s) for excessive price can be applied to all new patented medicines. In an unbiased definition of excessive, the price of a patented medicine would only be considered excessive if it exceeds the CPI-adjusted Canadian prices of all other drugs in the therapeutic class and the range of prices in all comparator countries.

Question 2.2: 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?

We do not believe that such therapeutic categorization of new medicines is either necessary, consistent or critical to the mandate of the PMPRB.

Question 2.3: 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?

Comparable medicines should include all medicines that are routinely prescribed for the primary indication of the new medicine. Comparable medicines may or may not be in the same ATC class, but should be seen as therapeutic alternatives to the new medicine in clinical practice.

Question 2.4: 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?

As noted previously, a revised TCC should be the primary test for determination of the non-excessive/excessive threshold, and only new drugs whose introductory price appears to be excessive by the modified TCC would proceed to an International Price Comparison (IPC). At the IPC level, the introductory price of a new drug would be deemed excessive if its price in Canada exceeded the range of prices in the comparator countries. Experience has shown that these two tests are sufficient to resolve the vast majority of new product pricing cases, so there is no real need for the Guidelines to take into consideration the prices of comparable medicines in other countries.

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

Question 3.1: Given the price variations by provinces/territories and class 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, it is most appropriate for the Board to review prices at the Canada aggregate level. As illustrated by the data presented under Issue 3 of the Discussion Guide, the current approach is very adequate. As outlined in Figures 9 and 10, the vast majority of prices are within the range of plus or minus 5% of the Maximum Non-Excessive price (MNE), whether reviewed by province or customer classes. Clearly there is no need to review the ATP at every possible combination of province and class of customer.

Over the past several years, there has been a steady increase in the number of companies/products for which there is a single, common Canada-wide price - irrespective of province or class of customer. This is quite distinct from the volume/bulk purchase agreements and associated multiple prices that exist in other markets, and is perhaps due to Canadian values where "one low price for all" seems far more appropriate than would be, say, having patients in less populated provinces pay higher prices than those in larger provinces.

Question 3.2: 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 DIN's? Or should this level of review be done on a case-by-base basis, where there is a significant variation in the prices charged?

As noted above, the current ATP calculation is appropriate.

Conclusions

We appreciate the opportunity to provide this feedback, and thank the Board for developing the Consultation Guide and thought-provoking questions. Much has happened in the 20 years since the Board came into existence, and it is clear that pharmaceutical price increases have been far lower than the corresponding increase in the CPI. In addition, the average ratio of Canadian to Median International Prices has been below 1.0 for 11 of the past 13 years. The PMPRB Guidelines have contributed to this situation, but so too have the policies and procedures of the many sophisticated drug benefit/insurance programs - programs that will remain in place for the foreseeable future.

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Recognizing the different roles and impacts of these groups on pharmaceutical pricing, utilization and expenditures - in the future the PMPRB should focus on defining/identifying prices that appear to be excessive in the context of appropriate and up-to-date assessment of prices for other products in the same therapeutic class in Canada and, secondarily, the price of the medicine in the international comparator countries. The notion of "excessive pricing" cannot be tied to an average, median or other measure of central tendency, but rather is a price that exceeds the previously noted domestic and international thresholds. Section 85 of the Patent Act lists the factors that the PMPRB must take into account, including prices of other medicines in the same therapeutic class, international prices and changes in the Consumer Price Index. In this context, a medicine might be considered to be priced excessively if it exceeds the CPI-adjusted prices of all other drugs in the therapeutic class and the prices in all comparator countries.

The above recommended tests will be sufficient to correctly establish the maximum non-excessive price for the overwhelming majority of new drugs. Where technologically new approaches deliver dramatically different outcomes (for example, a vaccine that effectively eliminates a previously costly, long-term disease), other measures to assess non-excessive prices may be necessary - such as factoring in the overall impact of the new agent on treatment costs. However, those other measures should be set aside for a separate consultative process.

We look forward to hearing from you.

Regards,

John H. Stewart
Executive Vice President
and General Manager

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