BIOTECanada

Friday, August 25, 2006

Sylvie Dupont
Secretary of the Board, PMPRB
Patented Medicine Prices Review Board
Box L40, Standard Life Center
333 Laurier West, Suite 1400
Ottawa, ON, K1P 1C1

Dear Ms. Dupont

BIOTECanada is the national association representing the broad spectrum of biotech constituents including emerging and established companies in the health, agricultural, and industrial sectors, as well as academic and research institutions and other organizations dedicated to the long term and sustainable development of biotechnology, its practices and products.

It is BIOTECanada's position that the proposed PMPRB guidelines on excessive pricing cannot be effectively applied to products developed within the biotech industry. Biotech products are unique in respect to the type of products produced; the size of the market, costs associated with development and the small availability of comparable or substitute products. We would like to address two unique product subsets: biological therapeutics and vaccines.

In the case of vaccines, most are sold under contracts in place between the manufacturer and the provinces/territories and are under the administration of PWGSC. The Provinces/Territories and PWGSC are sophisticated, knowledgeable and are able to use purchasing power to negotiate contracts that provide optimal arrangements in terms of price, quality, supply, and investment. In addition vaccines procurement policy uses a competitive tendering process where the lowest bidder is granted a contract to supply the customer with the specific vaccine. This insures that patented vaccines are fairly priced within the markets.

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

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

The current consensus among industry participants is that the new patented drug categories and their definitions are not appropriate. The primary reason for this is that the categories and definitions do not recognize and value innovation. The PMPRB continues to evaluate new technologies using old standards. Because of its mandate, *the PMPRB should only be involved in assessing breakthrough drugs* (since market forces automatically take care of prices for following entrants).

Q1.2: Is it important to distinguish medicines that offer "moderate therapeutic improvement" from a medicine that provides "little or no therapeutic improvement?" If yes, why is it important? If not, why not?

The *Patent Act* (Subsection 85(1)) establishes the responsibility of PMPRB for ensuring that patented medicines are not sold at an excessive price. The Board's mission is to intervene when a patentee has used its exclusive position in the market and has a price which is deemed excessive. PMPRB should have no role vis-à-vis the clinical effectiveness of the product, and any move by the board to define "moderate therapeutic improvement" would be inappropriate.

Q 1.3: 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?"

As in the previous question the PMPRB's main objective is to determine what constitutes excessive pricing for patented medicines.

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

The current approach used to review the introductory price of new patented vaccines and biologics in Canada is not appropriate, especially for vaccines. In fact, provincial and national jurisdictions use a tender process for these products and have over the years managed to negotiate prices that are not excessive. For these products at the very least, an additional federal role is not necessary. Given the fact that the competitive bid process through Public Works and Government Services Canada (PWGSC) establishes a fair market price for vaccines in Canada further intervention by PMPRB is not necessary.

Vaccines are considered a public health necessity. However, downward pressure on pricing due mainly to the tendering process has lead to extraordinary industry consolidation to such an extent that from the 25 companies producing vaccines for routine immunization 30 years ago, only 5 remain.[1] This in turn has had a negative impact on the amount of research and development in these preventative therapies as further explained in following excerpt from THE LANCET article.

"In diagnosing the problems facing the vaccine financing system, the Institute of Medicine's Committee on the Evaluation of Vaccine Purchase Financing in the United States recognized that a strong relationship exists between the system for purchasing and administering vaccines and the stability and growth of the U.S. vaccine supply industry. Although vaccines represent important tools for disease prevention and have significant social value, they frequently generate lower revenues than drugs and other health care services, and provide a less attractive opportunity for private investment in the

[1] THE LANCET Infectious Diseases Vol 4 April 2004

pharmaceutical industry. ***To resolve these tensions, the committee recommends strategic reforms that balance public health goals with the need to provide industry a rate of return that is adequate to supply current products and also develop new vaccines."***[1]

Q 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?

The current tests used to review the prices of new medicines in the various categories are not appropriate due to the fact that the tests do not take into account both the economic costs and benefits of innovation.

The prices themselves should reflect the changing economic value of currency and should reflect changes in inflation and purchasing power. In addition to price tests, there should be a clear definition of "excessive price" and a justification for the PMPRB's position.

Q 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?

The PMPRB's mandate is to deal with excessive pricing in new patented products and not cost effectiveness associated with incremental improvement.

Q 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?

Since most innovative biotech products have no direct comparables, prices of a new product should be positioned within the same price range as the same product in the markets of comparable countries. In addition, the biotech industry is different than traditional pharmaceutical products in that the availability of products is often supply constrained. The ability to secure these scarce products is often evaluated on a global market. The inflexibility of the current guidelines does not recognize this nuance of the biotech industry and as such limits or jeopardizes the healthcare provided to Canadians.

Q 2.4: Under the current Guidelines, Board Staff compares the Canadian average transaction price of the new medicines to the prices of the same medicines sold in 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 test of the new medicines?

Though the current PMPRB guidelines allude to the possibility of this method being used, if the PMPRB wishes to pursue this approach further, it should

outline the principles, criteria and process involved in this shift. This could only be done after consultations on a fully developed explanatory document. It is of key importance that the guidelines are set in congruence with comparable products across comparable countries.

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

Q 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?

As previously mentioned due to the nature of a federal tendering system for vaccines there is currently very little price discrepancy among provinces. This is a result of provincial rules that do not allow provinces to pay a higher price than anywhere else in Canada. Therefore we believe that the board should not pursue this evaluation method.

Thank you for giving BIOTECanada the opportunity to voice its opinion regarding the PMPRB's current & proposed price guidelines. We look forward to discussing the matter in greater detail at one of the fall face-to-face meetings.

Sincerely,

Philip Schwab
Vice-President, Policy and Sector Affairs
BIOTECanada