BIOVAIL

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060698

Ms. Sylvie Dupont
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Standard Life Centre
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Dear Ms. Dupont:

Re: Biovail Pharmaceuticals' Canada response to "the Board's Excessive Price Guidelines" Discussion Guide

Thank you for the opportunity to comment on questions raised in the Discussion Guide for the Consultation on the Board's Excessive Price Guidelines released May 2006.

As the PMPRB is beginning a major review of the Guidelines including a multi-stage consultation process, it is relevant to recognize how the Guidelines work in concert with other federal and provincial bodies in controlling prices. In addition to PMPRB price reviews, market forces led by provincial and private insurance formularies are also extensively scrutinizing new product clinical and pharmacoeconomic data to determine the cost effectiveness of new product entrants. At times, the PMPRB, as the Canadian pricing gatekeeper, inadvertently restricts new patented product entrants from ever being launched in Canada by not recognizing incremental innovative investments and price corrections driven by competitive market forces. The factors that the PMPRB takes into consideration in the determination of price excessiveness may deleteriously affect Canadian patient treatment choices.

Consequently, the spirit of patent protection, and support of investment in research and development is not fully being recognized by the PMPRB. Biovail invests heavily in Canadian R&D to innovate and apply advanced proprietary drug-delivery technologies that provide significant therapeutic advantages over existing formulations. Biovail has a number of proprietary drug-delivery platforms and continues to research others that can be applied to existing in-market drugs to develop enhanced formulations that offer more consistent drug release, greater patient compliance and potentially, superior efficacy and lower incidence of side effects. This form of innovation is not particularly acknowledged by PMPRB

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thereby resulting in restricted product development, and fewer product launches which ultimately serve to restrict Canadian patient options. Since introductory prices are evaluated both at a federal level by PMPRB and at the provincial level through individual provincial formulary assessments, the PMPRB should at the very least allow these competitive market forces the opportunity to determine the cost-effectiveness of new product entrants. That is, PMPRB should be cognizant of the importance of product availability as well as affordability and let the universal accessibility reside with the provincial and private insurance formularies.

The Patent Act amendments of 1987 were based on the need to ensure stronger intellectual property protection. The Minister of Consumer and Corporate Affairs stated that the Patent Act was changed in order to stimulate investment including research and development spending in Canada. Parliament's intent was not to legislate a prices control mechanism that would discourage industrial growth. For instance, the application of new delivery technologies to existing medicines, offering incremental value to Canadian patients, is often penalized by PMPRB as its categorization and price tests don't recognize the added investments, and innovation used to create improved formulations of older and inferior formulations. New technology has allowed for the discovery of better ways to deliver existing medicines that are oftentimes in need of delivery enhancements.
The PMPRB guidelines as they exist are not conducive to the introduction of innovative medicines and delivery technology.

With regards to the specific questions raised in the discussion guide, Biovail submits the following answers:

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?

No, the drug categories are not appropriate, as their respective definitions are outdated and don't encompass all modern products such as biologics, and improved delivery technology of existing medicines. For instance, despite investments made to provide superior delivery of existing medicines potentially improving efficacy and side effect profiles, the new product, based on the current category definitions, can arguably be either categorized as either a Category 1 "line extension" or a Category 3 "me-too" drug. Consequently the application of either the "reasonable relationship test" or "therapeutic class comparison' price tests may or may not reflect increased investments made to advance formulations

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to the benefit of Canadian patients. Therefore the definitions need to be revised to reflect advances in drug technology.

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?

Further splitting Category 3 into two groups "moderate therapeutic improvement" and another for "little or no therapeutic improvement" will not address the aforementioned flaws with the current system. Indeed, this change will likely result in a system that poses the same inadequacy in recognizing added value associated with novel molecules and formulations inherent in a 3-category system. For instance, in the current guidelines, the PMPRB recognizes that "while the determination of breakthrough medicines should be relatively straightforward, difficulties can occur in the identification of medicines that offer substantial improvement (Category 2) rather than moderate improvement (Category 3), primarily in borderline cases." This phenomenon will undoubtedly repeat itself with borderline cases between "moderate" and "little to no improvement" categories. Therefore, the definitions must be revised to eliminate current subjectivity in distinguishing between Category 2 and 3 rather than splitting out Category 3 into products that offer "moderate improvement" and a medicine that provides "little or no therapeutic improvement."

Additionally Category 1 should be specifically reserved to include line extensions with existing dosage form of an existing medicine and not comparable dosage forms of existing medicines. This exclusion would allow for the recognition of R&D, patent protection and innovation to discovering better ways to deliver existing medicines. In the PMPRB guidelines, improved compliance and greater patient convenience are not generally taken into consideration when categorizing new products. However many patient failures to treatments are attributable to a lack of patient adherence and, typically, patient convenience plays a major role in patient adherence. Improvements in delivery technology that can provide incremental value to patients should be a factor considered by PMPRB for categorization.

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 one that provides "little or no therapeutic improvement"?

N/a

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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?

Reasonable Relationship Test

The price test for line extensions is not pertinent in all cases. For instance in the case of improved delivery technology, the reasonable relationship (RR) test does not account for investments and innovation to improve the delivery of the new formulation which may result in improved adherence, efficacy and safety. The RR test may compare introductory products to highly genericized products that have been in the market for numerous years. Yet these said products are still widely used and in need of an improved delivery technology.

International Price Comparison Test

The simple average ex-factory prices for the international price comparison (IPC) test do not account for differences in foreign and domestic policy decisions, purchasing power and inflation. The average ex-factory prices from the seven comparator countries are not inherently compatible with Canadian ex-factory prices, and therefore should not be used to establish pricing for patented medicines in Canada.

Canadian based companies, such as Biovail Pharmaceuticals, who specialize in in-licensed products, are particularly restricted by the IPC tests and this test is often recognized as a factor in not launching new products in Canada despite availability elsewhere. Unlike foreign-based companies, Canadian ones are often in-sourcing products with no control or input into domestic or foreign prices. Therefore acquisition costs should be a consideration in the determination of appropriate prices in these specific instances.

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

New formulations of existing medicines offering added benefits to patients should be compared to relevant modern comparators specifically with the products used in comparative trials rather than ever being compared to the existing dosage form alone.

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International prices should be referenced for reporting purposes as opposed to price setting due to their aforementioned shortcomings.

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 purposes on inclusion in the above price tests?

In addition to referencing ATC classifications for the identification of comparable medicines, historical price differentials between new products entering old markets could be considered as additional benchmarks to determine applicable ratios for pricing new formulations of existing medicines.

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 the 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 the new medicines?

Ratio test between the drugs in question vs. comparable drugs in other countries can be used to determine the price when appropriate comparable drugs are not available in Canada. Obtaining relevant and accurate international prices is challenging at best as mentioned in our previous response and therefore comparable international prices should be referenced in exceptional cases where comparable medicines are not available in Canada.

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Issue 3

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

Question 1

Given the price variation by provinces / territories and classes of customer illustrated by 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 appropriate for the Board to only consider an ATP calculated based on the total revenues from the sales of all provinces /territories and all classes of customers in order to adapt to various market dynamics. For instance, it should be recognized that concessions (for example, hospital tenders) are required and plausible only if they are granted to meet specific needs. The sustainability of expanding the concession is immediately eliminated if tendered pricing is expected to be transferable to all or wider classes of customers As provinces assume greater controls by negotiating pricing based on group purchasing power, the PMPRB should maintain its mandate to ensure prices are not excessive rather than universally accessible.

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?*

N/a This level of review should be done on a case-by-case basis if there is a significant variation in the prices charged. In this case, the patentee may be asked to clarify the variations.

We look forward to further discussions with you on these issues

Regards,

Douglas Herman
Vice President & General Manager

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