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Subject: Gilead Sciences Canada Follow-up Submission: BIOTECanada-PMPRB Bilateral Meeting

Dear Dr. Benoit,

On behalf of Gilead Sciences Canada Inc., I would like to thank you for the opportunity to participate in the recent bilateral meeting between the Board, PMPRB Staff and BIOTECanada. In response to that meeting, I would like to take this opportunity to submit written comments regarding the Board's review of the Excessive Price Guidelines. The comments that follow are the position of Gilead Sciences Canada Inc.

Gilead Sciences Canada supports the observation made by BIOTECanada that the mandate of the PMPRB should remain consistent with the mandate specified in the *1987 Patent Act Amendments* (Bill C-22) – to ensure that prices charged by patentees for patented medicines are not excessive. It is not in the interests of improving the health of Canadians or in encouraging investment in science and technology for the PMPRB to expand its mandate or to make changes to its guidelines that would discourage the introduction of new therapeutic technologies in Canada.

Categorization

In the May 31st Communiqué, the Board has noted that it is examining the possibility of establishing definitions or parameters to recognize the value of "moderate improvement." Gilead Sciences Canada is supportive of this consideration by the Board to recognize the value of "moderate improvement."

The concept of an additional category to accommodate products that generate this "moderate improvement" has been proposed. A challenge with describing and defining an additional category is that no matter where the boundaries of this category are established, there will likely be circumstances in the future that could bring up the need for *another* additional category. Most patentees are more concerned with gaining a ruling from the PMPRB that a price is acceptable, than with the final categorization of the new technology by the PMPRB. Therefore, rather than focusing on the creation of an additional category to recognize "moderate improvement," it may be more prudent to focus on a mechanism that allows for the recognition of "moderate improvement" within the existing price tests and categories used by the PMPRB.

One way to recognize this incremental improvement is to allow products that have been determined to provide "moderate improvement" the flexibility to be priced within a range bound by the highest price within the therapeutic class comparison and the international median price. This approach would respect the goal of keeping Canadian prices no higher than the international median price while at the same time allowing flexibility to price outside the bounds of the therapeutic class comparison. Whether this "moderate improvement" price is capped by a pre-specified percentage above the therapeutic class comparison ceiling or whether patentees are allowed to take market dynamics into consideration when setting prices within the range between the therapeutic class comparison and the international median is a point for further discussion.

International Therapeutic Class Comparison

To determine the excessiveness of introductory prices, the Board has indicated its interest in identifying appropriate therapeutically comparable medicines in comparator countries.

Gilead Sciences Canada believes that in order to make international comparisons valid, the PMPRB must focus its choice of comparator countries on those countries with similar intellectual property protection regimes and similar pharmaceutical purchasing and funding mechanisms as found in Canada. As with any purchased good, the pricing of pharmaceuticals is influenced by the structure of the pharmaceutical market into which a specific product is being introduced. Therefore, if the PMPRB is interested in considering comparator countries other than those currently identified in the Regulations, it should focus its consideration on countries with similar market structures as the countries within the current comparator basket.

Costs of Making and Marketing

Gilead Sciences Canada understands the concern of the Board that while, to date, the Board has not had to give consideration to subsection 85(2) to make a determination of excessive pricing, this situation could arise in the future.

To provide direction if and when these situations arise, the Board should consider the following:

- Explicitly define what costs of making and marketing would not be allowable for consideration by the Board. By its vary nature, the consideration of costs of making and marketing will be an exceptional circumstance. As a result, it will be extremely difficult to define in advance all possible scenarios for consideration. However, by ruling out in advance certain scenarios that would not be considered, this would provide a degree of clarity to manufacturers, the Staff and other stakeholders as to what circumstances would warrant further exploration.
- In cases where costs of making and marketing can be consider in the process of determining whether a price is excessive, only give consideration to changes in cost driven by changes in Canadian regulation or policy.

Gilead Sciences Canada would like to call the Board's attention to the difficulty in calculating costs of making and marketing a particular therapeutic technology, particularly in cases where the technology is the property of an international organization. It is possible that such information may not be available to the patentee or may not be within the knowledge and/or control of the patentee in Canada. However, if the patentee can demonstrate that a change in the local Canadian regulatory or policy environment has impacted the Canadian pricing of its technology, then this may be a valid circumstance to review whether a price is excessive in light of the cost of making and marketing that technology.

Re-benching

The Board has indicated its desire to keep the review process simple and easy-to-follow. To be consistent with this message, Gilead Sciences Canada believes the Board should consider price "re-benching" only on a case-by-case basis.

An example of a circumstance where price re-benching could be considered by the Board is as follows:

1. When new clinical data is generated that provides evidence of a greater clinical outcome than first reported.

   For example, a new product is introduced and on the basis of the available clinical data at the time of introduction, a therapeutic class comparison is considered to be the appropriate price test. However, over time, new clinical data is generated that demonstrates a significant impact on morbidity and/or mortality from this product. On the basis of this new outcomes data, it may be appropriate to consider whether the therapeutic class comparison is still valid and whether the price of the product can be re-benchmarked at the international median.

Any Market

It is appropriate for the Board to maintain a national perspective when examining average transaction pricing and compliance with MNE targets. Three factors support this position. First, intellectual property protection afforded by patents is national in scope. Therefore the position taken by the Board of conducting price reviews from a national perspective is appropriately aligned with the scope of patent protection. In addition, as the PMPRB is a Federal agency, a national mandate is consistent with the jurisdiction of agencies / bodies of the Federal Government.

Second, by nature of its definition, the average transaction price is a composite metric. Some prices will be below the final average price with some prices being above the final average. As per the Board's processes, as long as this average transaction price is at or below the MNE target price, there should be no issue with the compliance status of a particular product.

The third factor that supports this national perspective is that in the majority of cases, whether one looks at specific types of customers or specific geographies, the introductory price of new DINs and the MNE fall within +/- 5% of each other (data presented in Figures 8 and 9 on page 14 of the Discussion Guide released May 2006). Therefore, there appears to be a national consistency in the pricing practices of patentees around this MNE target price.

Larger variations from the MNE appear to be contained within the hospital sector (Figure 8, page 14 of the discussion guide). These variations are likely driven by the structure of the hospital purchasing process and by the presence of large hospital buying groups in Canada. As these buying groups expand their customer base nationally, these variations from the MNE are and will continue to be available to hospitals throughout Canada.

Therefore, the process utilized by the Board of looking at the national average transaction pricing is consistent with the dynamics of the Canadian market and should be maintained. If there are individual customer or geographical variations that require review by the Board, the Board should only consider reviewing these issues if the overall national ATP rises above the MNE target. If the overall ATP remains at or below the MNE target, then consistent with the national perspective

required by the Board and with the methodology used to calculate the average transaction price, there is no cause for review.

Any concerns by individual geographies or groups of customers that they will bear an undo burden from the high costs for new technologies or drugs for rare conditions can be dealt with through P/T coordination or through the development of a coordinated approach by F/P/T members towards some form of national catastrophic drug funding. The mandate of the PMPRB should remain focused on issues of appropriate price ceilings.

Gilead Sciences Canada appreciates the opportunity to clarify our position on the proposed amendments to the Excessive Price Guidelines. We look forward to working with the Board as the consultation process continues to ensure that Canada remains a preferential jurisdiction for investment, development, and introduction of the most advanced medical technologies.

Thank you for the opportunity to provide comments.

Regards,
GILEAD SCIENCES CANADA INC.

Edward Gudaitis
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