Bayer Inc.

By e-mail: sdupont@pmprb-cepmb.gc.ca

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Philip Blake
President and CEO

Sylvie Dupont
Secretary of the Board
Patented Medicines Prices Review Board
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Dear Ms. Dupont,

Re: Discussion Guide for the Consultations on the Boards' Excessive Price Guidelines

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Bayer Inc. is pleased to have an opportunity to respond to the Discussion Guide on the Board's Excessive Price Guidelines.

Bayer Inc. is a Canadian subsidiary of Bayer AG, and international research-based group with core businesses in health care, crop science and innovative materials. Our health care business in Canada include: animal health, biological products, consumer care, diabetes care and pharmaceuticals. As with all business sectors in Canada, it is apparent that price regulation sends important signals to the international markets regarding the overall jobs and investment climate in Canada. It is important that the Canadian market is viewed as an attractive market to invest, with policies and regulations that encourage more Canadian investment. This is particularly relevant to the bio-pharmaceutical sector since substantial research and development investments are made some 10-12 years before a product is approved for sale.

Bayer Inc. is a member of Canada's Research-based Pharmaceutical Companies (Rx&D), and fully supports the submission made to the Board regarding the Discussion Guide. In addition to the Rx&D submission, we would like to respond to some particular questions pertaining to the Board's Discussion Guide as noted below -

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?

As noted in the Rx&D submission, we believe that the categories employed by the Board do not adequately recognize innovation; the Board consistently reports a lower percentage of drugs as category 2 when compared to priority status reviews completed by both Health Canada and the Food and Drug Administration (refer to response by Rx&D).

Some breakthrough products receive a notice of compliance with conditions (NOC/c) in order to ensure that promising treatments reach targeted populations sooner. The Board appears to take the position that there is insufficient evidence to rate such products as breakthrough at the time of entry to the market. In such cases, the product is classed as "moderate to little improvement" for the lifecycle of the product. This is clearly not appropriate. Bayer Inc. proposes that the Board classify these breakthrough with a category 2 and then allow for follow-up review once additional data has been collected.

As it pertains to the selection of comparator drugs within the category assignment, Bayer Inc has several concerns about the methodology. Under the current system, the Board is challenged to decide on therapeutic class comparisons and refers to the WHO ATC classification to select a comparator. The World Health Organization (WHO) expressly rejects the use of the ATC classification for reimbursement/pricing decisions. According to a recent report, "basing detailed reimbursement, therapeutic group reference pricing and other specific pricing decisions on the ATC and DDD assignments is a misuse of the system. This is because the ATC and DDD assignments are designed solely to maintain a stable system of drug consumption measurement, which can be used to follow and compare trends in the utilization of drugs within and across therapeutic groups" (ref : http://www.whocc.no/atcddd/use_misuse.html)

The Board also does not consider place in therapy when determining a comparator. For example, it may not be appropriate to compare products used first-line with those used second-line and vice versa. It may not be appropriate to compare products used in different populations (i.e. stage I cancer versus metastatic cancer). It is also not appropriate to compare products with vastly different safety profiles. The difficulties in choosing a comparator are compounded by the fact that reimbursing authorities in Canada may choose different comparators. All this suggests that the Board should consider vastly simplifying its methodology; we suggest that country comparisons should be the only criteria utilized to assess the launch price of patented medicines in Canada.

We encourage the Board to develop more transparent mechanisms for the review of new products as this uncertainty makes it difficult to assess the viability of a launch into the Canadian market. For example, we have found it to be increasingly complex to identify relevant comparators (especially for Category 2 and Category 3 drugs). In our experience, international companies seeking Canadian partners to co-market/develop or out-license innovative pharmaceuticals often avoid the market due to the complexity of establishing a price and concerns that the Canadian market is too restrictive.

Bayer also has concerns with the manner in which new biological products are categorized and regulated by the Board. It is Bayer's position that the Board pricing guidelines cannot be effectively applied to blood products that are managed by the national and provincial agencies. The key rationale is:

- Blood products need to adhere to complex manufacturing and regulatory processes that do not apply to pharmaceutical or diagnostic products;
- Pricing is subject to international supply and demand for both raw materials and finished product;
- Competitive bidding and significant market power by Canadian Blood Service (CBS) and Hema-Quebec (HQ) ensures prices are not excessive;
- Other factors beyond price (security of supply, safety, quality, clinical efficacy, quality of patient life, plant capacity, whether or not Health Canada licenses the product) are inter-connected in the tendering and product selection process; these factors are clearly outside of the Board's mandate.

The Board's Guidelines, with price tests designed to review pricing of traditional pharmaceuticals, are not well suited for blood products and it is Bayer's position that pricing for blood products, particularly those procured by competitive tendering processes, should not be subject to those Guidelines.

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?

Bayer Inc believes that developing additional categories for new medicines is unwarranted and will add further administrative complexity to the Board's mandate. All new patented medicines provide innovation and bring additional treatment options for health care practitioners and patients. All new products (even those defined by the Board as "providing little or no therapeutic improvement") provide important cash flows for companies to invest in other diseases that presently have no treatment options. We believe that the Board should not create additional categories for medicines

but rather adopt a broader definition of excessive pricing (as per Rx&D's submission) and allow the final purchasers of medicines (public and private drug plans) and health care professional to make decisions about the value of medicines.

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"?

Not applicable.

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

As mentioned above, there is too much uncertainty and complexity in the review process itself. There is limited dialogue that can occur between the Board and the company before a product is actually launched; this effectively causes companies to launch product with uncertainty regarding the final price. As mentioned in our introduction, the international markets do not view this uncertainty favorably.

The other concern that Bayer has is the current methodology or the classification of category 3 drugs forces a comparison to older drugs (with constrained prices) that may not be relevant in today's clinical practice which tends to put further downward pressure on the launch price of new drugs. This does not encourage companies to launch innovative products into the Canadian market and may explain why some pharmaceuticals are not made available to Canadians. Clearly this was not the intent of Parliament in the creation of the Board.

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?

The Board should act in a broad capacity to ensure prices are not excessive at a National level but then allow public and private agencies to make reimbursement decisions based on the value of the medicine from a broader health care system and societal perspective.

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?

We do not agree with the need to create additional price tests. We believe that the current price tests should be streamlined and simplified.

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? Clinically equivalent but do not offer the same value?

Addressed this earlier under issue #1, question #1.

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?

Since the price of comparator drugs in other countries is influenced by many other factors, we do not believe the guidelines should be amended to address this. For example, pricing and reimbursement authorities in many countries have negotiated industry agreements with manufacturers that consider jobs, investments, R&D commitments, price concessions, and other matters. This is clearly outside the mandate of the Board. In addition, there is the practical matter that many comparator drugs available in Canada may not be available in other markets. The review of the international prices of comparator drugs would unnecessarily complicate the mandate and focus of the Board.

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 it is appropriate to calculate an average transaction price (ATP) based on sales from all provinces/territories and classes of customers. If the Board attempts to "control" prices in these different markets, this will lead to a perverse incentive to raise the prices in all markets. We also note from the % of DINs that deviate from the maximum non–excessive price by class of customer (Figures 7, 8, and 9) is not substantial. Hospitals tend to have a

greater variation in pricing since contracting and tendering play a much more significant role in that sector.

Jurisdictionally, it also does not seem appropriate for the Board to regulate the price of patented medicines by class of customer. In the introductory comments of the discussion guide, it is clear that the board "... *operates independently of other bodies such as Health Canada, which approves drugs for safety, quality and efficacy, and the public drug plans, which approve the listing of drugs on their respective formularies and reimbursement for eligible beneficiaries*" (Discussion Guide, p. 2). If one class of customer reimburses a medicine at a price lower (or higher) than the MNE, this is reasonable and appropriate.

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?

No the Board should not be reviewing ATP based on class customers. However as noted in the Rx&D response, in exceptional cases it may be appropriate to review prices in individual regions or classes of customers. This could be handled using a complaints-driven model that the Board has adopted for other categories of medicines that fall under their jurisdiction.

In summary, the Board has, up to now, been successful in reducing Canadian prices relative to world prices. Evidence (Grootendorst, Di Matteo) has shown that the Canadian public has been a net beneficiary of extended patent protection through Bill C91 and C22. Attempts to expand the Board's mandate in order to depress prices further will inevitably upset this balance.

Thank you again for the opportunity to comment on this important issue and I look forward to discussing these matters further at the public Consultations latter this year.

Sincerely,

Philip Blake,
President and CEO
Bayer Inc.