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CONFIDENTIAL

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Sylvie Dupont
Secretary of the Board
Patented Medicines Prices Review Board
Box L40, Standard Life Centre
333 Laurier Ave. West, Suite 1400
Ottawa, ON K1P 1C1

Dear Ms. Dupont,

Bayer Inc. is pleased to have the opportunity to provide written comments in response to the discussion paper entitled *Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Prices Guidelines.*

Bayer Inc. is a Canadian subsidiary of Bayer AG, an international research-based group with core businesses in health care, crop science and innovative materials. Our health care business in Canada includes pharmaceuticals, consumer care, diabetes care, biological products and animal health.

Bayer is a member of Canada's Research-based Pharmaceutical Companies (Rx&D) and BIOTECanada and we support the responses of both associations to the discussion paper. In our submission, Bayer would like to highlight the following areas.

GENERAL COMMENTS

Bayer strongly believes that the proposals presented outline a clear disconnect that exists between the ongoing PMPRB consultations and the pricing and reimbursement dynamics within Canada. One such example is a lack of recognition of the impact of the existing mechanisms that allow provincial bodies to control pricing via allowable price increases and market access levers.

It is our belief that PMPRB should not focus on managing individual customer's ATP, but rather focus their efforts on ensuring initial benchmark price reflects the most appropriate scientific data available, and is within global standards.

Further regulatory hurdles such as those outlined in the discussion paper have an unintentional impact: the stifling of pricing discounts and/or rebates that allow for better pricing and patient access.

As such, we question why the Board is continuing to cause concern through constant review and discussion of something that is already working. The potential gains are small, if not damaging. The potential loses for customers and patients are significant, as customers and patients will be impacted through eradication of pricing discounts and rebates, and the lack of access to needed medicines through SAP and Compassionate Use programs.

In addition, the proposals do not reflect the commitment of the federal government to reduce regulatory burden. If fact these proposals continue to create uncertainty and raise potential for price changes in Canada that are not in alignment with other countries, thus leading to further barriers that will result in addition obstacles to bringing products to Canada. Moreover, the only true impact of these proposals is an increased workload for both the PMPRB and Patentees.

As an active participant in the consultations to date, submitting two previous written responses (August 21, 2006 and November 6, 2007) and participating in a multi-stakeholder consultative meeting on September 10th, 2007, Bayer Inc. shares Rx&D and BIOTECanada's concerns that despite the active and constructive participation of patentees in this consultative process, the proposals and options identified by the Board in the Discussion Paper, with limited exceptions, do not address or take into account the submissions and recommendations by Rx&D and BIOTECanada. We therefore urge the Board to take into account and address the suggestions of Bayer, BIOTECanada and Rx&D in this and previous submissions.

Bayer Inc. also remains concerned about the Board's silo approach to policy-making. The issues under consideration by the Board are running along parallel tracks even though there are significant linkages among them. The silo approach makes it difficult to assess and comment on the proposals and options in the Discussion Paper.

Furthermore, we would like to register our concern regarding the short period of time (21 working days) allowed for comments on this most recent discussion paper, which contains a number of complex options and proposals, some of which are being presented for the first time. We sincerely hope that the Board will hold true to its commitment to Rx&D that it will allow "*opportunities for further input and comment as the overall review progresses through to the Fall*" and that in the future an appropriate amount of time for meaningful review and comment is provided.

COMMENTS ON THE BOARD'S PROPOSAL

Any Market Price Review

Bayer Inc. agrees with Rx&D and BIOTECanada's assessments that the current approach to calculating the Average Price in Canada based on a national Average Price, with the capacity to review prices in "any market in Canada", has worked and that the Board's own evidence indicates that most stakeholders are opposed to moving away from the national market approach. The efficacy of the current approach is supported by data presented in the May 2006 Discussion Guide indicating that prices for all drugs by class of customer, and by province and territory, were overwhelmingly within the range of 5% of the national Maximum Non-Excessive (MNE) price or lower.

In the discussion paper, the Board states that "in the 2006 and 2007 consultations, stakeholders expressed the view that, if price reviews are conducted at the level of any market, they should be undertaken, on a case-by-case basis, where appropriate" and indicates that "in its May 31, 2007, *Stakeholder Communiqué* the Board agreed with this approach…"

Unfortunately, the detailed proposal in the Discussion Paper is not consistent with a "case-by-case" approach. On the contrary, it would impose a *de facto* full submarket price review. The proposal would specifically apply a submarket price review for all new patented drugs and for those subject to Voluntary Compliance Undertakings and Board Orders. This change would appear to signal a new policy objective of the Board that prices in all submarkets should not exceed the national MNE price. If so, such a change would be premature. Factors touching on the appropriate definition of MNE price and the calculation of the Average Price are under study in other areas of the Board policy reviews, e.g. *LEO Pharma*.

There is no analysis of the impact of this change on incentives to offer discounts or rebates, given the current CPI-Adjusted Methodology. For example, many "price increases" as that term is used by the Board are not increases in the price at all, but rather changes in the calculated net price due to changes in the value of discounts offered or shifts in the mix of sales. Will the change to a submarket price review change the incentives for patentees to offer discounts and rebates? How will specific markets, such as hospitals, be affected?

There is no analysis of the implications of this proposal on the workload of the Board and of manufacturers. Reviewing prices in 56 markets rather than one will clearly increase the Board's workload and add to the regulatory burden for patentees. More specifically, it will increase the burden on patentees by requiring them to ensure that prices remain within the calculated guideline maximums in 56 markets rather than one market. For Bayer, with 30 active DINs in Canada, this would necessitate 1680 reviews. Such a change is clearly inconsistent with federal policy objectives to reduce the regulatory burden by 20%.

Specifically, the proposed approach will add further complexity to the introductory pricing submission to the Board and the setting of the launch price. In the event that one class of customer is found to be above the benchmark MNE, while the others are lower, will the Board allow the other classes of customers to go up in price and one to come down? Will the

patentee be penalized with a Voluntary Compliance Undertaking (VCU)? Looking at the individual class of customer is meaningless and will bring more complexity and uncertainty to an already complex situation. This will not accomplish anything unless the Board is going to seek the VCU to be based on the excess of one class of customer. If this is the case, the VCU could be substantially higher since there is a possibility that the ATP of some classes of customers could be lower than the MNE. One also needs to ask the question, why would it be considered wrong to have different customer classes at different ATPs? Are we not trying to ensure we get the best price for the Canadian market, versus one price for all?

In general, introducing the "Any Market" investigation is meaningless since any VCU is based on overall market calculation. Furthermore, if this proposal is implemented, it will create more resistance to offer discounts to other markets in the first place since if in the future one market is found to be in excess while others are not, the patentee may not be able to increase the price for other markets after the VCU (due to market factors such as provincial formularies).

The Board has not provided the analysis and evidence to support the need for this proposal. It has not shared its analysis of the few cases where prices in submarkets exceeded the MNE prices by a significant amount nor has it explained if and why it considers its current methodologies and practices to be inadequate.

Re-setting the MNE Price

Bayer Inc. agrees with Rx&D and BIOTECanada's analyses that the current criteria for re-setting the MNE price and the practice of re-setting the price when warranted on a case-by-case basis continue to be appropriate. We are concerned that the new specific criteria proposed by the Board may limit the circumstances under which it may be prepared to re-set the price in some cases but expand them in other cases in an unpredictable way.

We are concerned about the implications for the Special Access Program (SAP). The current guidelines, at least in theory, provide that a price may be re-set when the drug receives its Notice of Compliance but the proposed criteria to re-set the MNE price in these circumstances will create an extremely high threshold. The effect of this proposal then would be to discourage manufacturers from supplying drugs under SAP at prices lower than the price that they would intend to sell at when the drug receives its Notice of Compliance. Uncertainty about the PMPRB's pricing policies may discourage manufacturers from supplying drugs to Canadians under SAP at all.

We are also concerned about the proposal to re-set the MNE price based on new "scientific information/evidence." The proposed circumstances are vague and could open the door to frequent debates whenever new scientific studies are published. This will create a great deal of additional work for the patentee and for the Board since most products, if not all, will have new data/ indications coming out after the launch. Will the Board require patentees to submit new clinical and market data when a new indication occurs? If so, this will create enormous workload for patentees and the Board, and once again increase regulatory burden, not reduce regulatory burden.

One significant question is: who will initiate the process of re-setting the MNE Price? If the Board proceeds with this proposal, it would be most sensible for the patentee to make the request – otherwise, there will be a great deal of added work for PMPRB when there is new data or indications associated with a product post-launch.

This proposal would create uncertainty and raise the potential for price changes in Canada that are not in line with pricing in other countries. We are concerned by any proposal that will create a process or a result that will put the Canadian market out of step with other major countries and add to the barriers to bringing products to market in Canada.

It is also unclear why the Board needs to expand its activities in this way given its excessive price mandate. There are existing mechanisms in other bodies to ensure that drug plans are able to adjust their coverage and reimbursement criteria based on new scientific evidence. Such a re-review by the Board would be redundant.

The Board has not provided an analysis of the extent to which it has re-set MNE prices in the past under the current criteria nor provided an analysis of what the impact of its proposals would be. Several of the proposed criteria are not fully developed, e.g., "costs of making and marketing" and the Progressive Licensing Framework. For this reason alone, it would not be appropriate to adopt the proposals on "re-setting the MNE price" at this time.

Federal Court Decision in the Matter of LEO Pharma Inc. (Dovobet)

Bayer Inc. supports Rx&D and BIOTECanada's views that the Federal Court decision in the *LEO Pharma* case does not require the Board to make the policy change announced in the April 2007 NEWSletter. We understand that Rx&D has provided the Board with a legal opinion that supports that conclusion and that while the Board has received different legal advice; it has not shared that advice with stakeholders. Bayer urges the Board to meet with Rx&D to discuss this issue further.

As Rx&D has rightly pointed out, manufacturers such as Bayer have learned to work with the current system for close to 15 years, but it is less than ideal. The lengthy discussions on the implications of the *LEO Pharma* decision illustrate that tinkering with the current system may only create additional problems and potential market distortions. In our view, it would be appropriate to revisit the CPI-Adjustment Methodology and to look seriously at the concept of de-linking the MNE price and the Average Price. Such an approach would be consistent with the *Patent Act* and could be used as a basis for establishing a model that is much simpler and less cumbersome both for the Board and for patentees.

Bayer shares Rx&D and BIOTECanada's concerns about those regulatory options that, in our view, are inconsistent with the *LEO Pharma* decision. They will have the effect of discouraging manufacturers from offering drugs under compassionate programs and in general from offering special pricing programs.

The guidelines options, especially option 2, move in a more positive direction in that they would help to mitigate the negative impact of the current CPI-Adjustment Methodology. However, they will not address the fundamental problem that basing the MNE price on a previous net Average Price creates a disincentive to offer lower prices or special rebates or incentives. That disincentive can only be addressed through a true "de-linking" of the Average Price and MNE price.

Along with Rx&D and BIOTECanada, Bayer is very supportive of the concept of "de-linking" the Average Price and maximum non-excessive (MNE) price for purposes of the guidelines as discussed in meetings with Board Staff. Unfortunately, the guideline changes proposed in the Discussion Paper do not include this option.

"De-linking" refers to establishing the MNE price at launch based on the appropriate excessive price tests and then adjusting it annually based on changes in the Consumer Price Index (CPI). It would do away with adjusting the MNE price each year based on the Average Price in an earlier year. This model is fully consistent with the Board's excessive price mandate, is much less cumbersome than the current methodology and the options presented in the paper, and would preserve incentives for compassionate programs. We urge the Board to consider this option as part of the discussion on resolving the Federal Court decision on *Leo Pharma – Dovobet*.

We also support Rx&D's view that on of the options for consideration should be the "status quo," i.e., to maintain the April 2000 policy and the flexibility to include or exclude compassionate and other special pricing programs in the Average Price. In our view, this option is available to the Board as a matter of policy, but if it considers it a regulatory matter, the Board could propose a regulatory change.

We support the option to exclude benefits to third-party payers from reporting and from calculation of the Average Price. In our view, such reporting is not required by the Regulations nor by the *LEO Pharma* decision in any event, but it will be helpful for the Board to confirm its position that such reporting is not required.

Bayer submits that the most important factors in deciding which options should be used in addressing the issues arising from the FCC decision are:

Does not impact the willingness for patentees to meet customer needs through an offer of "Free Goods", Price reductions, Compassionate and SAP programs,

- Allows the patentees if desired to maintain the MNE without penalizing the patentees by lowering MNE due to the price concession program

While Bayer appreciates the opportunities to share our views on the Discussion Paper, we are disappointed that the Board has not addressed previous submissions submitted by Bayer, Rx&D, BIOTECanada and others, in that most of the proposals and options presented in the Discussion Paper reflect an almost complete lack of acknowledge of the participation of patentees, your largest stakeholder. We sincerely hope that the Board will reconsider the direction of these proposals and provide the opportunity for further comment. Should you

require any further information or input, please do not hesitate to contact either myself or Kory McDonald, Director of Federal Government Affairs.

Yours very sincerely,
BAYER INC.

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