JANSSEN-ORTHO

JANSSEN-ORTHO INC.
19 GREEN BELT DRIVE
TORONTO, ONTARIO
CANADA M3C 1L9
www.janssen-ortho.com
416.449-9444
416.449-2658

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

March 3, 2008

Dear Ms. Dupont:

Janssen-Ortho appreciates the opportunity to provide additional input into the Board's proposed changes to the Patented Medicines Regulations and the Excessive Price Guidelines. We also would like to acknowledge Barbara Ouellet and other PMPRB staff for efforts taken in the past few months to more meaningfully dialogue with the pharmaceutical industry through various discussion tables. We do however, have some concerns with many of the proposals in the Discussion Paper, particularly those related to re-benching and "any market" price monitoring, and with the options to address the Dovobet issue.

This most recent discussion document contains numerous individually complex proposals for change. Taken together, the complexity of the proposed changes is very high, and some of the proposals might interact to produce unintended consequences. It is clear that many of the proposed changes will have serious consequences for the innovative industry, and potentially for patients, particularly if the Board moves towards more active price regulation both at introduction and throughout the life cycle of patented medicines.

We are very concerned that the Board continues to insist that the FCC decision in Dovobet has broad application beyond the Board's ruling in the Dovobet hearing. We, and Rx&D, have received legal advice contrary to the Board's position on this issue, and we are very concerned that there is no discussion of maintaining the status quo, as outlined in the April 2000 Newsletter, regarding reporting requirements.

We also fundamentally disagree with any changes to the principles section of the Guidelines. Any change to these principles must consider the broad context of the Patent Act reforms that led to the creation of the PMPRB. PMPRB was not established as an independent entity with a consumer protection mandate, but rather as part of a larger initiative, based on five principles, aimed at ensuring innovative

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medicines would continue to be introduced to the benefit of Canadian patients and to encourage pharmaceutical research and development in this country.

Should you have any questions pertaining to this response, please contact Kimberly Robinson at 416-382-4823 or Lesia Babiak at 416-382-4871.

Sincerely,

Chris Halyk
President

cc: Dr Brien Benoit, Chair, Patented Medicine Prices Review Board
Mary Catherine Lindberg, Vice-Chair, Patented Medicine Prices Review Board
Thomas Armstrong, Member, Patented Medicine Prices Review Board
Anthony Boardman, Member, Patented Medicine Prices Review Board
Anne Warner La Forest, Member, Patented Medicine Prices Review Board

Janssen-Ortho Response to the Discussion Paper "Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines"

We appreciate the opportunity to provide input into the proposed changes outlined in the Discussion Paper. There is value in a collaborative process between the PMPRB and industry and we would encourage its continuation.

There are a number of complex issues presented in this Discussion Paper and very little time provided for us to review, consult with stakeholders and prepare our response. Even though we have been actively engaged in this consultation process for almost two years, new issues have emerged and we are only beginning to grasp the intricacies of the issues raised and how they could impact the industry, stakeholders and patients. We are concerned that the short timeframe for response as well as the complexity of the proposals will make it impossible for important stakeholders, many of whom are not immersed in this consultation process, to adequately respond to these proposals.

We are also concerned that the proposals will have unintended negative consequences. For example, some options presented in this paper could result in the elimination of contract or discount pricing, ultimately leading to higher prices for some stakeholders. As well, proposals related to rebenching could delay or compromise Canadian approvals for beneficial medications.

We have provided comments on each of the issues raised in the Discussion Paper, along with rationale for our position and alternative recommendations where appropriate. We ask the Board to consider our comments and alternative proposals since the proposed options in the Discussion Paper would result in an unnecessary and inappropriate expansion of the Board's mandate, increased complexity, greater administrative burden, considerable commercial uncertainty, and ultimately, unintended negative consequences for Canadian patients and their health care system.

(1) Reviewing Prices in "any market"

The Board proposes to review prices in each market, by province and class of customer, under the following circumstances

- ***When the drug is first sold in Canada***
- ***Whenever the ATP appears to exceed the MNE***
- ***When a VCU is signed or a Board order is issued following a hearing***
- ***When a substantiated complaint is received***

The Board's mandate is to ensure Canadian pharmaceutical prices are not excessive, not to micro-manage prices by province and class of customer. This mandate has historically been executed at the level of the national average transaction price, and PMPRB's own data indicate this approach has been and is effective in executing its mandate.

This proposed approach could have the unintended consequence of creating a disincentive for manufacturers to provide discounts to customers, thus disadvantaging customers who are currently benefiting from discount pricing (i.e., hospitals, institutions, etc). It would certainly lead to unnecessary administrative burden for PMPRB and patentees.

(2) Re-setting the Maximum Non-Excessive Price (MNE)

The Board proposes re-benching when:

- ***The MNE is lower than the cost of making and marketing the drug***
- ***Clinical data at launch were not sufficient to determine its category***
- ***New evidence challenges the initial categorization***

The Board proposes that re-benching follow a life-cycle approach in line with the Progressive Licensing Framework (PLF)

In theory, the proposals for re-benching could serve to raise or reduce prices for individual medicines over time. In practice, these proposals could only serve to reduce medicine prices, as payers would not accept higher re-benched prices. The notion of re-benching seems to indicate the Board believes there is a problem of excessive pricing in Canada. The PMPRB's own data belie this notion. The PMPRB's annual reports indicate that the ratio of Canadian prices to the international median for comparator countries have been consistently below parity for well over a decade, illustrating that Canadian prices are not excessive.

A patentee would unlikely ever be able to produce the necessary documentation to justify re-benching based on the criterion that the MNE price is lower than the cost of making and marketing a drug. The cost drivers for medicines include activities that take place over a number of years or decades. As well, any attempt to re-bench the price of a medicine based on the costs of making and marketing would involve divulging significant proprietary information.

Re-benching based on emerging clinical data is not consistent with the Board's mandate. The role of the PMPRB is not to assess clinical value and evidence of medicines, but rather to ensure that the prices of Canadian medicines are not excessive. There are other agencies and organizations which are focused on assessing value of medicines and making decisions on whether their value warrants reimbursement.

Allowing re-benching that follows a life-cycle approach in line with the Progressive Licensing Framework will result in an unacceptable amount of commercial uncertainty, along with added unnecessary complexity.

Finally, of great concern to us is that this proposal may undermine the Special Access Program (SAP) by discouraging manufacturers from supplying medicines at no cost or at a discounted price for these programs. These programs are in place only to benefit patients and clinicians and the price charged for these programs should not be relevant to establishing non-excessive prices.

PMPRB proposes that prices in 3 reference countries are sufficient to establish a median. PMPRB offers 3 options for the timeframe for re-benching an interim median:

- ***Status quo (at the end of 3 years),***
- ***Status quo for now, then align with the PLF, when implemented, or,***
- ***When the medicine is sold in 3 countries, regardless of how much time has elapsed since the date of first sale.***

Reducing the threshold for establishing a median international price from 5 to 3 countries makes the analysis much less robust with less accuracy. It seems illogical to change from a more robust methodology to one that would increase uncertainty and pricing variance. This approach could delay launches of beneficial medicines into Canada and result in negative implications in the treatment of Canadian patients, in situations when a medicine is first sold in three relatively low-priced markets.

An open-ended timeframe for establishing a median introduces untenable commercial uncertainty, and again, might have the unintended consequence of delaying medicine introductions in Canada.

We believe that the current system (5 countries or 3 years, whichever comes first) works well and propose that it remain unchanged.

(3) Options to Address the LEO Pharma Federal Court decision on Dovobet

The alternatives provided here are based on the notion that the FCC ruling applies to all products. We do not believe that it does. We understand that Rx&D has offered alternative legal opinions and are disappointed that they have been ignored. Janssen-Ortho has also received legal advice on this matter, which is consistent with Rx&D's position. We urge the Board to reconsider its position on the wide-ranging application of the FCC decision in Dovobet.

We support the current approach to reporting benefits as outlined in the April 2000 Newsletter. This approach allows patentees to include or exclude free goods as long as reporting is consistent from period to period. We believe that reporting compassionate and other programs should continue to be at the discretion of the manufacturer. This approach is consistent with the Board's mandate to ensure prices are not excessive, as any programs patentees choose not to report only serve to reduce ATP. If patentees remain compliant with the Guidelines while excluding some free good programs from ATP calculations, then the

prices of their medicines are in fact lower than reported, and more than compliant. We have numerous issues with the options presented. However, some of these proposals are more acceptable if the Board allows "de-linking" of the MNE and ATP and if there is no movement to reviewing prices in each submarket.

Option 1: Maintain the current Regulations and respect the outcome of the FCC decision

Please see comments in the first paragraph of Section (3). In addition, the statement provided by the FCC in the Dovobet hearing was quoted from the Patent Act. The decision in that case only addressed the Board's attempt to exclude certain free goods reported by the patentee pursuant to the Regulations; it did not require the Board to overturn its long-standing policy. It appears as if the FCC decision has been taken out of context and misinterpreted by the Board.

This proposal would provide a disincentive to provide free or reduced price compassionate use programs and as a result, we are not in agreement with this option.

Option 2: Amend the Regulations to exempt patentees from the requirement to report benefits (payments) to third party payers (F/P/T drug plans and potentially private insurers if similar payments are negotiated in the future)

This option is consistent with our view that the Regulations do not require the reporting of payments to third party payers.

Option 3: Amend the Regulations with respect to free goods to:

a) Exclude all free goods from the calculation of the Average Price;
b) Exclude free goods from the calculation of the Average Price when the free goods are only provided to a particular customer class; or
c) Exclude free goods in "non-saleable" or "sample" package sizes, that are provided to those legally able to receive such goods pursuant to the Food and Drugs Act, from the calculation of the Average Price.

For a) and b) Janssen-Ortho currently includes free goods in the ATP calculations and believe that this is necessary and appropriate in order to manage compliance with the PMPRB's guidelines as they currently operate. Under this proposal, this would no longer be possible. We are not in agreement with this option and as outlined in the first paragraph of Section (3) we urge the Board to consider alternative legal interpretations to the Dovobet FCC ruling before undertaking Regulatory changes that appear unnecessary.

For c) samples are currently not included in the ATP calculation. Although this change would update the Board's policy, it does not represent a real change.

Option 4: Amend the Regulations to change "free services" to "services (free or partially subsidized)" in the calculation of the Average Price.

This change seems reasonable.

Option 5: Amend the Regulations to exclude "gifts" from the calculation of the Average Price

Gifts to physicians are inconsistent with the Rx&D code and as a result, this proposal would have no impact.

Option 6: Amend the Regulations to permit the Board to disallow any or all benefits which it determines, pursuant to a public hearing, were implemented by a patentee for the purpose of reducing its liability in regard to excessive pricing in terms of the calculation of excess returns.

This option completely lacks transparency, creates absolute uncertainty, and would give the Board too much discretion in the management and monitoring of ATP. We vehemently disagree with this proposal.

(4) Rulings on price increases (CPI Methodology)

The Board is proposing using the highest previous non-excessive Average Price (if the price drops due to a new benefit); and/or allowing patentees to come to market with an ATP lower than MNE and then raise prices to the introductory MNE in future periods

These proposals do appear to be an improvement on the current CPI methodology, but they are unnecessarily complex.

ALTERNATIVE PARAGRAPH: We are in agreement with the approach to "de-link" the Average Price and the MNE price. Under this proposal, the introductory MNE price for the medicine would be adjusted over time based on changes in the MNE and not based on changes in the Average Price. This option would achieve the Board's objectives in a more transparent and less complex manner.

(5) Principles

The Board proposes to amend the preamble to the Guidelines to state the following principle: "the Board's mandate is to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive, thus protecting the interests of consumers."

We fundamentally disagree with this change to the Guidelines. The PMPRB was established in 1987 on the basis of 5 pillars, only one of which speaks to consumer protection. Any change of this nature would have to include the context of the reforms that led to the creation of the PMPRB and make reference to the other pillars of the reform package, namely: intellectual property protection, international trade agreements, industrial benefits and improved healthcare.

(6) Categories of medicines

The Board is studying options to create a fourth category of medicine that would recognize "incremental innovation" between the category of "breakthrough or substantial improvement" and "moderate, little or no improvement." The consultation document states that "the Board believes that some assessment of therapeutic value is needed".

In this latest consultation document, the Board has failed to acknowledge Rx&D's proposal for no categories and one simple test where prices are limited to no higher than the Canadian Therapeutic Class Competitor and the range of international prices. It is highly inappropriate to disregard the views of the industry in this matter, and suggests an inherent bias against the industry in this consultation process.

That said, while Janssen-Ortho supports the Rx&D position as the preferred option, we believe a fourth category would be an improvement over the current system of categories if it recognized the important value of medicines providing incremental innovation. This would only be true, however, if the work on price tests does not lead to lower prices for the existing 3 categories. Any discussion of changes to the current categories must be coupled with a discussion of the price tests to be applied to those categories.

(7) Costs of making and marketing

The Board has formed a Working Group to gain a better understanding of when it would be appropriate to consider these costs (which the Board has the power to consider, as a secondary factor, under s. 85(2) of the Patent Act). Consultants have been engaged to provide reports, in April 2008, on the economic and accounting issues related to evaluating these costs.

Cost of making and marketing a medicine is difficult if not impossible to isolate, as much of the work involved in making and marketing a drug in Canada is conducted globally over years and decades. Also information like cost of goods is proprietary and in many cases is not divulged to the majority of employees at innovator companies, let alone to third parties. In practice, it is difficult to see how this factor could ever be considered in establishing guidelines for non-excessive prices.

The Future

We appreciate the opportunity to comment on the proposals outlined in this Discussion Paper. We have also appreciated the willingness and openness by PMPRB Staff to meet with us in the past few months through Rx&D and BIOTECanada Working Groups to dialogue more actively on a variety of issues facing PMPRB and the industry. Many of the proposals presented in the Discussion Paper are of great concern however, as they result in increased complexity, greater administrative burden and a great deal of commercial uncertainty as well as being outside of the Board's mandate. As a result, we have provided our comments and alternative suggestions for consideration by the Board. We believe that changes should seek to increase certainty, decrease complexity and allow for MNE to be adjusted with the CPI. We appreciate the PMPRB working with industry to amend current guidelines and look forward to a favourable response from the Board.