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April 27, 2009

Dr. Brien Benoit
Chairperson, Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
K1P 1C1

Dear Dr. Benoit:

The enclosed is our submission to the Patented Medicine Prices Review Board in response to the draft revised Excessive Price Guidelines issued in March 2009. We appreciate the opportunity to participate in this ongoing consultation process. Attached to this letter is a more detailed appendix which sets out specific comments on a number of the elements in the consultation package.

The proposed Guidelines include some positive changes, such as recognition of the incremental value of medicines offering moderate improvement over comparators, and improvements to the Reasonable Relationship Test. However, we are very concerned about the package as a whole. We see the proposal as a dramatic shift away from the Board's mandate of maintaining an appropriate balance between incentives for pharmaceutical research and development and protection against excessive prices, towards a system of unprecedented price regulation aimed at reducing prices over time. The level of price regulation the Board is now proposing goes well beyond the price *monitoring* originally intended by Parliament. We believe implementation of these changes would be a disincentive for pharmaceutical industry research and development investment in Canada and ultimately would reduce the availability of innovative medicines in Canada.

As we have consistently suggested throughout this process, we maintain our recommendation that the Board implement a system of true de-linking of the Maximum Non-Excessive Price (MNE) and the Average Transaction Price (ATP). Under such a system, the MNE would be established in the introductory period, with CPI applied over time. Provided no customer paid a price above this CPI-inflated introductory MNE, the price of the medicine would be considered to be non-excessive and within PMPRB Guidelines.

The attached technical appendix includes detailed comments on most aspects of the proposed changes. The detail provided below relates to the specific areas of the proposed Guidelines that we find most concerning. In our view, these particular proposals will serve to inappropriately reduce the prices of patented medicines over time and provide disincentives for manufacturers to provide benefits contrary to the PMPRB's mandate.

Legal Framework

The proposed change to the statement of the Board's mandate to include "in the best interest of Canadian consumers" is concerning and potentially misleading for some stakeholders. The Board was established as part of a broader framework designed to maintain an appropriate balance between incentives for pharmaceutical research and development and protection against excessive prices. The restatement of the Board's mandate in terms of consumer protection alone, empowers the Board to implement policies designed only to reduce prices of patented medicines, with no consideration of the negative impact on the pharmaceutical industry. Over time, this narrow approach will have unintended negative consequences for the pillars of the broader context in which PMPRB was created, namely the pharmaceutical industry's ability to invest in Canadian R&D and, ultimately, its ability to make innovative new products available to Canadian patients. As well, many of the proposed Guidelines create disincentives for industry to provide benefits to hospitals, governments and patients who participate in special access programs. An excerpt from the transcripts from the parliamentary debates on Bill C-91 highlights the inconsistency between this proposed departure from mandate and parliament's communicated intentions for the PMPRB:

> "The proposed amendments have five principal objectives: to transform Canada's pharmaceutical sector into a world-class industry led by an unprecedented increase in investment and jobs in pharmaceutical research and development; to ensure drug prices remain reasonable through the creation of an independent price review board; to guarantee that the pharmaceutical industry's commitments for research and development are met; to maintain opportunities for growth in the Canadian generic industry; and finally to harmonize Canada's intellectual property laws with those of other western industrialized nations.[1]

Source for comparator prices for Therapeutic Class Comparison tests

The draft Guidelines propose Board staff reference the publicly available price closest to the comparators' average selling price when conducting Therapeutic Class Comparison tests. Referencing any price other than the highest publicly available non-excessive price will act to reduce the prices of new medicines relative to comparators. This arises because the new medicine will be limited to a price that is below higher non-excessive prices charged by the comparator. This reduction in prices of new medicines is not consistent with the Board's mandate of ensuring prices are non-excessive. As well, by giving no concrete guidance as to the source for comparator prices, the PMPRB is creating an environment that is non-transparent and unpredictable for manufacturers. This proposed policy is also inconsistent with the Board panel's ruling in the Adderall XR hearing. In Adderall XR, the Board panel ruled that the highest publicly available price of the comparator medicine should be used to determine the Adderall XR maximum non-excessive price.

[1] Mr. Bill Kempling - Government member at p. 1414 Transcripts of Parliamentary Debate on Bill C -91, November 21, 1986

Introductory period "Any Market" price reviews

Taken together with requirements for full reporting of benefits, and the above noted issue of price sources, the proposed "any market" price review by province and class of customer in the introductory period will also serve to reduce prices of new medicines relative to comparators. This arises because most benefits that serve to reduce the ATP of mature medicines are linked to provincial and hospital reimbursement. Under the proposed draft Guidelines, prices for new, largely non-reimbursed and thus undiscounted medicines would be limited to the more fully-discounted prices of their comparator medicines. Then, when provincial and hospital reimbursement come into effect, the prices of the new medicines will be reduced even further, as benefit programs that serve to reduce ATP come into place.

The proposed methodology of evaluating medicines in "any market" is extremely complex, which will result in undue administrative burden for both the industry and PMPRB. The proposed methodology will make it very difficult to isolate the source of the price changes by market, and would very likely result in increased investigations and hearings to resolve what should otherwise be simple issues. This is very costly in time and resource for both the PMPRB and the industry.

In the current, less complex environment, the PMPRB is already challenged to resolve issues regarding price changes due to mix shift; the complexity of the changes proposed in the draft Guidelines will only serve to exacerbate this situation.

Generics as therapeutic class comparators

Generic manufacturers and branded manufacturers face very different cost structures and pricing restrictions. The inclusion of generic therapeutic class comparators in the Canadian market or in the international market completely ignores these industry realities and will inappropriately and grossly reduce the prices of patented medicines, contrary to the Board's mandate of ensuring that the prices of patented medicines are non-excessive. Generic products should be excluded from all PMPRB price tests for patented medicines.

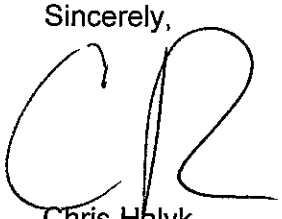
Conclusion

These and other proposed policies in the draft Guidelines would provide disincentives for branded pharmaceutical companies to offer benefits to patients participating in special access programs and to hospitals and governments, and would eventually be a barrier for branded pharmaceutical manufacturers to introduce many new medicines into the Canadian market.

The draft Guidelines are currently scheduled to come into effect on July 1, 2009, which does not provide adequate time to assess stakeholder feedback, or to allow manufacturers to respond to changes. As well, the judicial review regarding mandatory reporting of benefits is scheduled to be heard in June 2009. Implementation of any changes to the Guidelines should be put on hold until the outcome of the judicial review is known, and can be considered in the context of other proposed changes.

We urge the Board to consider the full impact of these draft Guidelines before finalizing them and encourage the Board to continue to work with industry to discuss alternative solutions that respect the PMPRB's original mandate. In previous rounds of consultation, industry has provided suggestions, such as de-linking the MNE and ATP, which the PMPRB has to date been unwilling to entertain. However, given the potentially serious repercussions of these Guidelines, we strongly urge the Board to reconsider these and other alternatives that would strike a more appropriate balance between innovation and consumer protection, as originally envisioned by parliament in establishing the Patented Medicine Prices Review Board.

Sincerely,



Chris Halyk

Cc: Health Canada:
The Honourable Leona Aglukkaq, Minister of Health
Morris Rosenberg, Deputy Minister
Michael Vandergrift, Director General, Policy, Planning and International Affairs Directorate, Health Products and Food Branch

Industry Canada:
The Honourable Tony Clement, Minister of Industry
Richard Dicerni, Deputy Minister, Industry Canada
Leah Clark, Director General, Life Science Industries Branch, Industry Canada
Ron Parker, Senior Associate Deputy Minister, Strategic Policy Sector, Industry Canada

The following is a summary of Janssen-Ortho's detailed feedback on many aspects of the proposed changes in the March 2009 Notice and Comment.

Legal Framework - Mandate:

The Board proposes revising the statement of its regulatory mandate as follows: "To ensure that the prices charged by patentees for patented drug products sold in Canada are not excessive, consistent with the interests of consumers and the Canadian health care system". The Board was established by parliament to maintain an appropriate balance between incentives for pharmaceutical research and development and protection against excessive prices. A focus on only consumer protection is in appropriate and potentially misleading to stakeholders. If the Board wishes to express its mandate in terms of one of the "pillars" of the changes to the Patent Act that created the Board, then it should provide the full context of those changes.

Recommendation:

The mandate should be stated simply as ""To ensure that the prices charged by patentees for patented drug products sold in Canada are not excessive." Or, if the Board feels it is important to provide a broader context to the mandate, it should include language around not only consumer protection, but also maintenance of incentives for pharmaceutical research and development.

Legal Framework – Confidential Information:

The Legal Framework has also been changed to eliminate Patent Act Section 85 protection of international price data submitted by patentees. This would mean these data would no longer be considered privileged, and the Board could publish the information without patentees' consent.

While the Form 2, Block 5 information is often publicly available, this is not always the case. The current practice of seeking patentee consent to release this information is the appropriate approach.

Recommendation:

The Board should rescind part 1, subsection 9.2.

New Terminology Introduced:

Janssen-Ortho appreciates that new terminology is being introduced as an attempt to provide additional clarity. However, we do not see how the proposed terminology acts to provide improved clarity. If the Maximum Average Potential Price (MAPP) were used as the price reference for price tests, it would certainly increase clarity. However, the proposed changes specifically state the MAPP "could not be relied upon for regulatory purposes", so we are unclear as to the value of a published MAPP and of the introduction of new terminology.

Recommendation:

The MAPP should be used as the price reference for price tests. If the Board cannot agree to this use of the MAPP, then the MAPP proposal should be abandoned.

Levels of Therapeutic Improvement - Factors

We are pleased to see an expanded list of secondary therapeutic improvement factors, as proposed in the previous Notice and Comment. "Compliance" as a secondary factor is limited to instances where "compliance improvements leading to improved therapeutic efficacy". This qualification of "compliance" essentially renders it a primary factor "improved therapeutic efficacy". and discounts the value of improved compliance, even in the absence of demonstrated therapeutic improvements. It is extremely difficult to measure the therapeutic impact of improved compliance, but it is clearly logical that patients are more likely to benefit from their medicines if they are more likely to take their medicines as prescribed.

The draft also proposed restricting the use of secondary factors to increasing level of therapeutic improvement up to moderate improvement. Janssen-Ortho concurs with the recommendation of the Working Group on Therapeutic Improvement, that secondary factors are sufficient to warrant a substantial improvement.

Recommendation:

Compliance should be listed as secondary factor, without the qualification "leading to improved therapeutic efficacy".

The wording in Part II, Chapter 1, Section 6.5 should be modified to read:

"...The secondary factors could result in the level of therapeutic improvement being assessment at up to the level of a substantial therapeutic improvement"

Introductory Price Tests

Moderate improvement

We wish to commend the Board for establishing a separate level of therapeutic improvement and price test for medicines offering moderate improvement over their comparators. This is an important acknowledgement of the value of incremental innovation, and Janssen-Ortho believes this change will reduce the need for expensive and inefficient Board enforcement activities in future.

Slight or no improvement

We are comfortable that the test for a slight or no improvement drug remains the therapeutic class comparison (TCC) test. However, the proposed Guidelines endorse the current Board Staff practice of including generic medicines in the TCC price test. We believe generics are never appropriate price comparators for branded medicines, from a cost of making and marketing perspective, because they do not face the same development costs as branded medicines.

Secondary test – Superior Comparators

The inclusion of a new secondary test for slight or no improvement medicines seems unnecessary, and the proposed test, the bottom of the TCC of superior medicines does not seem consistent with the notion of non-excessiveness. To Janssen-Ortho, the notion of "non-excessiveness", by definition means limitation to the top of any TCC constructed. Also, with the inclusion of generic medicines as valid therapeutic class comparators, this secondary test would very often result in the prices of new patented medicines be limited to those of generic medicines. Janssen-Ortho believes this is never appropriate and goes well beyond the notion of "non-excessiveness".

Reasonable Relationship Test – Specifics

We are pleased to see the Board has reversed its position from the previous Notice and Comment regarding disadvantageous changes to the Reasonable Relationship Test. The proposed changes related to when the RR test will be used (same indication, same dosing regimen) introduces uncertainty, and could lead to irrational prices for new strengths of existing medicines, thus becoming a disincentive to manufacturers to introduce new strengths of existing medicines.

International Therapeutic Class Comparison

The draft proposed Guidelines propose the international TCC will be calculated at the median of the class or the median of the ratio of the price of the product under review to the iTCC. The proposal also confirms that the iTCC will include foreign generics if those same generics are sold in Canada. As stated above, Janssen-Ortho is of the view that any TCC test, domestic or international should be conducted at the level of the top of the TCC, consistent with the notion of non-excessiveness. We also take the view that inclusion of generics in any TCC is inappropriate.

Recommendation:

The Guidelines should be modified to specifically exclude generic medicines from all price tests, due to fundamental differences between generics and patented medicines in costs of making and marketing.

Any TCC test (domestic or international) should limit medicines to the top of the TCC, consistent with the notion of "non-excessiveness".

Language related to limitations for application of the RR test should be removed and replaced with: "The RR test will be applied to new strengths of existing chemical entities, unless the manufacturer makes a submission in support of another approach"

Comparator Pricing (Reasonable Relationship Test or Therapeutic Class Comparison :

The Board proposes that, for new medicines marketed by the same patentee as the relevant comparator medicine, the Non-Excessive Average Price (NEAP) be used as the price for price tests. When another patentee markets the comparator medicine, the Board proposes to reference the public comparator price closest to National Non-excessive Average Price for both patented and non-patented drugs. In the case of "same patentee" medicines this is the current, formal practice of the Board Staff. In the case of "another patentee" medicines, it is the informal practice of Board Staff,

counter to the statement in the current Guidelines that the Ontario Drug Benefit price will normally be the price source.

In both cases, relying on the NEAP, or the publicly available price "sufficiently close" to the NEAP, is inappropriate, as it compares new medicines offering few, or no benefits, to mature medicines that may be offering more benefits, and thus have a discounted price. This approach serves to inappropriately and excessively limit the price of new medicines relative to their comparators. This approach is also inconsistent with the Board's ruling on the price source for comparators in the Adderall XR hearing.

The proposal also reduces transparency for manufacturers. Where in the past manufacturers felt confident in choosing the ODB formulary price of expected comparators as setting their maximum price, now manufacturers have no guidance, as they are not privy to the NEAP of their comparator medicines.

In addition, this proposal represents at least partial disclosure of confidential information, as it indicates to comparators which publicly available price is closest to their NEAP. Average Transaction Price data are privileged under Section 85 of the Patent Act. Such suggestions would provide greater clarity to patentees and the Board Staff; it is consistent with the excessive price standard of the Act;

Recommendation:

Janssen-Ortho suggests PMPRB source either the highest non-excessive publicly available price or the new Maximum Average Potential Price when conducting price tests.

Any Market Review (national & market specific):

The Draft Guidelines clearly state the Board's intention to conduct routine "any market" price evaluations. At product introduction, this review will take place at the level of class of customer as well as at the level of province and territory. For existing products, "any market" price reviews will be conducted only if the National ATP appears excessive, or the Board receives a complaint.

It is also noteworthy that the Board summarized non-industry stakeholder feedback as being supportive of any market price reviews. This summary misrepresents the position of Ontario Public Drug Programs and BC Pharmaceutical Services both of whom expressed discomfort with any market price reviews.

Janssen-Ortho is very concerned about this proposal for many reasons. First and foremost, we believe that routine application of any market price reviews creates ongoing downward pressure on prices, contrary to the Board's mandate. Implementation of a system of routine any market price reviews will encourage patentees to maintain the highest prices possible for all customers, rather than offering benefits to many customers, as is the current practice.

The proposal also states Board staff will review market-specific prices in all prior periods if, for whatever reason, they conduct a market-specific price review for an existing medicine. This means that prices previously deemed by Board Staff to be within Guidelines could subsequently be deemed to be excessive. This introduces massive uncertainty. It does not seem logical that a previously non-excessiveprice could later be deemed excessive and require repayment of excess revenues.

The proposed any market review is also extremely complex and difficult to manage for both manufacturers and Board Staff. PMPRB-defined "markets" are not homogeneous. In our experience, prices can appear to be excessive, when in fact they are not, and it can be extremely complex, challenging and time consuming for manufacturers to provide justification for the apparent excessiveness.

The circumstances under which any market reviews would be conducted based on a complaint also needs to be clarified.

Recommendation:

The Board should publish an erratum noting they misrepresented the view of BC Pharmaceutical Services and the Ontario Public Drug Programs on this issue.

Routine, any market price reviews should not be conducted, under any circumstance. Any market price reviews should be reserved for instances where the national ATP appears to exceed the MNE. Board Staff should exercise significant discretion in resolving cases of apparent excess revenues where it is clear those excesses are apparent rather than real. When an any market review is conducted, it should be limited to the time period during which the national ATP appeared to exceed the MNE.

Any market price reviews based on complaints should require clear evidence of excessiveness, and manufacturers should have access to the details of all complaints.

Re-Setting the Non-Excessive Average Price After Introduction

The Draft Guidelines propose that the MNE for a product first sold under SAP can be re-set once an NOC is received, based on cost of making and marketing arguments.

This proposal ignores the fact that there are many reasons manufacturers may want to offer products through SAP at reduced prices that would not be commercially viable in the long-term. This proposal will force manufacturers to charge the full commercial price on SAP sales, to the detriment of patients.

Recommendation:

The Guidelines should be modified to allow for full rebenching at NOC for products sold prior to Health Canada approval.

CPI Adjustment & DIP Methodology:

We see several issues with this methodology. The proposal is enormously complicated. Despite attempts by the Board and Board Staff to explain its application, each example presented to clarify the methodology only raises new questions. It is also not clear why the proposal excludes CPI increases during the period of benefits that eventually end. Finally, the information that would be required to take advantage of the DIP methodology may be confidential, and manufacturers might not be able to share the information with the PMPRB.

Recommendation:

We urge the Board to reconsider a system of true de-linking of the MNE and ATP. The proposed DIP methodology is impossibly complex.

Investigations & Excess Revenues

Offsetting Excess Revenues

The Draft Guidelines propose that foregone price increases in a subsequent period are not sufficient to offset excess revenues in a previous period, but rather a true price reduction in the subsequent period is required. This seems unnecessarily punitive, and inconsistent with the Board's current approach of allowing annual CPI increases when calculating excess revenues for VCUs and Board Orders resulting from hearings.

Recommendation:

The Guidelines should specifically allow for price increases foregone to offset excess revenues.

Repayment of Excess Revenues below the Investigation Threshold

Currently, PMPRB investigations are triggered once excess revenues exceed the MNE by 5% or excess revenues exceed $50,000, or in the case of a complaint. Under the current Guidelines, excess revenues under $ 50,000 can be carried for products indefinitely. In the new Draft Guidelines excess revenues less than $ 50,000 that persist for 3 years must be repaid, regardless of amount. It is extremely difficult to ensure all ATPs equal the MNE in an environment of different prices between markets and routine price increases, and it is unrealistic to expect manufacturers to achieve this. Until now, Janssen-Ortho has been of the view that maintaining excess revenues below the investigation threshold is an acceptable interpretation of the Guidelines. By the PMPRB's own estimation, it is not uncommon for manufacturers to maintain sub-threshold excess revenues for years. That situation argues for the fact that other manufacturers and the Board has seen this as an acceptable practice to date.

Recommendation:

Section 1.3.1 of Schedule 13 should be struck. If PMPRB insists on making a change to the practice of allowing "sub-threshold" excess revenues, there should be some cushion allowed as a margin for error. Also, any change to this policy must allow for a period of "grandfathering" for manufacturers who would trigger the new criteria.

Timing of Implementation

The Board proposes to implement changes to the Guidelines effective July 1, 2009. This timing does not allow the Board time to adequately consider comments on the new aspects of this Notice and Comment.

Recommendation:

Implementation of any changes to the Guidelines should be put on hold until the outcome of the judicial review is known, and can be considered in the context of other proposed changes.