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Montreal, April 27th, 2009

Ms. Sylvie Dupont
Secretary of the Board
Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
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RE: Comments on "PMPRB Notice and Comment: Draft Revised Excessive Price Guidelines" (Published March 26, 2009)

Dear Ms. Dupont,

We are writing to provide comments on the above-noted Draft Revised Excessive Price Guidelines (the "Draft Guidelines"), which are due on or before April 27th, 2009. Please note that as a member of Canada's Research-Based Pharmaceutical Companies (Rx&D), Abbott also supports, and is in agreement with, the comments and recommendations submitted by Rx&D in response to this matter.

Abbott appreciates the efforts made by PMPRB in this second version of the Draft Guidelines to provide more clarity in explaining its position and various methodologies. We are pleased that PMPRB has decided to remove the exemption for Patented Generic Drug Products from the Highest International Price Comparison (HIPC) rule, has reverted the Reasonable Relationship (RR) test #3 to its original format, and has found a better methodology for RR test #2. We are also pleased to see that the Board is continuing to consider methods to allow ATP variations caused by benefits in an attempt to encourage industry to continue providing them.

However, there are a number of issues that were of great concern to Abbott raised in our last submission that PMPRB has either failed to address and/or acknowledge in its proposed methodology (e.g. De-linking methodology, multiple NEAPs, Any Market reviews, and TCC test). These will not only potentially force a price freeze over all patented medications but will seriously compromise the offering of benefits that are ultimately to the advantage of the Canadian patient. We note that these consequences would be contrary to PMPRB's proposed revised mandate statement. Abbott would encourage the Board to consider the impact this may have on Canadian patient/stakeholders before implementing any new Guidelines.

Furthermore, Abbott believes other aspects of the proposed Draft Guidelines (e.g. Any Market review, absence of meaningful de-linking, offsetting excess revenues methodology, inclusion of generics in the ITCC), will translate into an unnecessary increase in investigations and a significant increase in administrative burden on patentees. These investigations will come at a higher cost to both the industry and the Canadian patient.

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Abbott also worries about the general resolution approach taken by PMPRB in relying increasingly on investigations and ad-hoc data analysis. In its April 12th teleconference on the proposed Draft Guidelines, PMPRB's Director of Staff indicated on several occasions that many of the methodology issues raised by patentees would or could be solved systematically, depending whether the patentee can demonstrate data relevance or bring in these issues beforehand. If the Director of Staff recognizes these methodology flaws, PMPRB should be anxious to adapt the Guidelines' language to avoid uncertainty and decrease the expenditure of resources that will otherwise be necessary to routinely solve these issues. Please find enclosed in our detailed response Abbott's recommendations in that respect.

Abbott has an overarching concern at both an express and implied erosion of confidentiality embodied in the Draft Guidelines. This is more particularly dealt with in the attached detai ed submission, Section 3(a); however, it should be pointed out here that, at least in one respect, the Draft Guidelines contravene the section 87 privilege contained in the *Patent Act*. The Guidelines cannot lawfully contradict the provisions of the *Patent Act*.

Finally, PMPRB has not provided for any transition between the old and the new Guidelines. There are two concerns here. First, we do not believe that a 30 day period between the publication of the Final Guidelines (scheduled for May/June) and their implementation (July 1, 2009), as proposed by PMPRB's agenda in its January 2009 Newsletter, is reasonable. Second, there is no provision for grandfathered treatment of existing products that have been priced under the existing Guidelines, nor of products that are the subject of pending investigations or proceedings. We would also like to remind PMPRB that any mid year transition is very likely to create additional confusion on the ATP/MNE calculation. We are therefore requesting that a proper transition period (at least one reporting period ending in a calendar year end) be provided to ensure appropriate transition of existing products and to avoid mid year transitions, and that appropriate grandfathering provisions be provided.

Abbott believes that stability and predictability within the regulatory system is key to the health and prosperity of the pharmaceutical industry and thus the health and welfare of Canadian patients. Although we are supportive of some of the direction taken by PMPRB, Abbott believes the proposed Draft Guidelines are not acceptable at this point and recommends that further discussions and deliberations be undertaken on the issues highlighted in this letter. We also urge PMPRB to refrain from implementing Guidelines that could compromise the industry's ability to provide benefits to its customers.

Please find enclosed more details on Abbott's comments and recommendations relating to:

(1) the DIP methodology and the Any Market review;
(2) the methodology for offsetting excess revenues; and
(3) unworkable, unreasonable, or unlawful aspects of the proposed Draft Guidelines.

We thank you in advance for your consideration of Abbott's comments and recommendations. Do not hesitate to contact the undersigned if you have any questions relating to this matter. We look forward to the PMPRB's response.

Sincerely,
Abbott Laboratories

Jeffrey Devlin
General Manager

Encl.

ABBOTT'S DETAILED COMMENTS AND RECOMMENDATIONS

1) DIP Methodology and Any Market Review

Since one cannot be done without the other, we are addressing here the main issues arising from the proposed DIP methodology and the Any Market review.

a) The DIP methodology proposed by the PMPRB in Schedule 10 article 1.4 states: "if the benefit(s) was offered after introduction, the Market-Specific Average Transaction Prices where benefits had been offered may increase up to the highest previous Average Transaction Price in that market without being presumed to be excessive."

This statement does not take into account that:

i) Customers within a class may not receive the same benefits;
ii) At any point and time, prices may increase by CPI whether or not a benefit is given;
iii) Prices that are lower than the NEAP may be considered excessive;
iv) Variations of benefits within one class of customers may have an impact nationally but no impact at the provincial level or vice-versa (e.g., if the main distribution center of a customer receiving a significant rebate is based in one province, other provinces that benefit from that rebate will have their ATP unchanged.)
v) Benefits may be offered during the first 6 months of a product's life (i.e. during its introduction period) in the same way and under the same conditions they are offered afterward.

Consequences of this methodology:

vi) It forces patentees to either stop/avoid providing benefits to customers and/or to implement a price freeze in respect of any trade class customers to whom they offer benefits.
vii) The absence of a "Gap" methodology and the dismissal of the Price Tests working group's recommendation (July 2008) will compromise the offering of any benefits or programs for drugs introduced in Canada. Indeed, there is little or no incentive for a patentee to offer any benefits for a drug prior to the end of the introductory period as this would reduce the ATP for the relevant determination period and may result in a reduced initial MAPP/NEAP being established for the medicine.
viii) It adds to the complexity of the model since maximum non-excessive prices are now established for each customer class/provinces and territory. This implements multiple NEAPs for a medicine, thereby increasing significantly the administrative burden of patentees. Even if PMPRB will not conduct an Any Market review systematically, patentees need to manage their data in preparation for this possibility.
ix) PMPRB has failed to provide any examples including provincial/territorial ATP variations and how they would be taken into account against their impact within an individual customer class. This brings further complexity and uncertainty for patentees on how ATPs should be managed.

x) Consequences (viii) and (ix) will trigger additional unjustified investigations and create additional administrative burden for both the patentees and PMPRB's staff.

Abbott's recommendations:

xi) To allow the Market-Specific Average Transaction Prices where benefits had been offered to increase up to the highest previous Average Transaction Price **+ CPI** in that market without being presumed to be excessive.

xii) Extend the DIP methodology to the first introductory period. If the patentee can provide the same evidence required by PMPRB under the DIP methodology, it would be unfair for PMPRB to disregard such evidence based on a matter of timing of when benefits are introduced.

xiii) Since provinces' and territories' ATP variations can only be explained at a customer class level, the Any Market Review should be limited to individual customer classes (nationally or within one province/territory) and PMPRB should avoid monitoring a province/territory ATP that includes all trade class customers.

2) Methodology for offsetting excess revenues

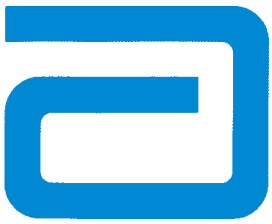
There are different statements made under Chapter 3 – Investigations, section 1.1 and in Schedule 13 that raises serious concerns on the application of this methodology. Indeed,

a) Section 1.1 of Chapter 3 – Investigations (page 22) states: "When the price of a patented drug product appears to exceed the Guidelines but not by an amount that triggers the investigation criteria (Schedule 11), the patentee will be notified and the patented drug product will be reported on PMPRB's Web site as "Appears Excessive". The patentee will be expected to reduce its NEAP and Market-Specific Average Transaction Prices and to offset any excess revenues that may have accrued, but no immediate action will be taken by Board Staff."

b) Section 5.2 of Part II – Policies (page 11) states: "If the National ATP exceeds the MAPP or national NEAP, but does not trigger the criteria for commencing an investigation (Schedule 11), the patentee will be notified and the patented drug product will be reported on the PMPRB Web site as "Appears Excessive". The patentee will be expected to decrease its price and offset any excess revenues (see PMPRB's Policy on the Offset of Excess Revenues in section 7)."

c) Section 7.2 of Part II – Policies (page 11) sates: "To offset excess revenues via a price reduction, the average price of a patented drug product will only be considered to have been reduced if it is below the previous year's Non-Excessive Average Price; not taking an allowable price increase will not be considered for purposes of offsetting excess revenues."

d) Section 1.3.1 of Schedule 13 – Offset of Excess Revenues (page 44) states: "Excess revenue balances below the amount sufficient to trigger the investigation criteria that are carried for six consecutive six month reporting periods (3 years) will be expected to be offset through a VCU."



These statements raise serious concerns given that:

i) Only the outcome of an investigation can authorize PMPRB to require a patentee to take corrective actions. Statement (d) is even more troublesome because PMPRB expects the patentee to go directly to a VCU without a proper investigation to confirm whether or not a price has been excessive or not.
ii) A number of reasons could cause a National ATP to either exceed or fall below the national NEAP (e.g., volume shifts, benefits variations, price increases occurring at different times in different provinces, etc.). The belief that a price reduction can only be implemented if the average price is below the previous year's NEAP demonstrates a lack of understanding of the market reality. There are serious concerns as to the workability of such an approach.
iii) For the same examples provided in ii), it is quite natural that a national ATP may exceed the national NEAP in one reporting period but that it may no longer exceed the national NEAP of the next reporting period because the latter was adjusted with CPI methodology. That is exactly why the investigation criteria were developed (5%, $50,000 threshold, etc.), that is, to allow a certain flexibility to both the patentee and PMPRB in order to avoid an unnecessary investigation.
iv) If a product appears to exceed the Guidelines, to refer to it as "appears excessive" automatically sends a presumption that the product is, in fact, excessive.
v) Policies and methodology (a), (c), and (d) were never raised nor discussed in the previous Draft Guidelines published last August or Working Groups reports.

Abbott's recommendations:

vi) Abbott requests PMPRB to provide more details on the rationale behind these new additions (a), (c) and (d).
vii) As long as it may take for small excess revenues to build up over the years, it may take as much time to offset these without ever exceeding the national ATP. If none of these amounts trigger the investigation criteria, patentees should not be required to implement any actions.

3) Unworkable, unreasonable or unlawful aspects of the proposed Draft Guidelines

The following lists different issues and concerns Abbott has from various sections of the proposed Draft Guidelines. Please find Abbott's comments and recommendations underneath each of them.

a) Protection of Privileged and Confidential Information (Part 1, Section 9.3, page 9) – "The privilege provided under subsection 87(1) does not extend to information and materials collected by the PMPRB, including any analysis performed by Board Staff of that information" and "Any information that a patentee or former patentee submits to the PMPRB that is in the public domain will not be considered privileged under subsection 87(1) of the Act. This information includes the publicly available ex-factory prices of a

patented medicine in Canada and other countries listed in the Regulations (Form2, Block 5)..."

i) Abbott is very concerned at the absence from the Draft Guidelines of the PMPRB's prior statement of the "governing principle", which is that of confidentiality (see Current Guidelines, Preamble, section 4.2) and the statement that the Act "aims to protect commercially-sensitive information, as well as some publicly available information i.e. ex-factory foreign prices (*idem*, section 4.3).

ii) First, other than the minor exceptions provided for in subsection 87(2) of the *Patent Act* and the exception constituted by disclosure *at* a public hearing, the statutory privilege provided for in section 87 of the *Patent Act* is absolute. Unlike the Draft Guidelines, the *Patent Act* makes no distinction between information supplied by the patentee which is not publicly available and information supplied by the patentee which is publicly available. *Any* information or document provided to the PMPRB under section 80, 81 or 82 or in any proceeding under section 83 is privileged, including but not limited to Form 2 - Block 5 information. PMPRB has admitted the plain meaning of section 87 in the current Guidelines. The proposal to publish Form 2 - Block 5 information is unlawful. Furthermore, Abbott submits that it is critical to the proper administration of the statutory scheme creating the PMPRB that PMPRB pursuant to regulatory requirements, including prices, documents and other information, are governed by the statutory privilege and are maintained in the strictest confidence by the PMPRB. Often, apart from the need to protect Abbott's confidential information, Abbott owes duties of confidentiality to third parties in respect of information provided to the PMPRB.

iii) Second, any erosion of the PMPRB's confidentiality obligations is counterproductive to the stated aim of PMPRB, which is to promote open and constructive dialogue and information exchange with patentees. For example, relying on the protections afforded by section 87, patentees frequently provide PMPRB with Form 2 - Block 5 information which would not otherwise be available to PMPRB (and therefore would be outside of the regulatory requirement to supply only "publicly-available information").

iv) Third, publication of commercially sensitive information (not limited to foreign pricing) is an improper and unlawful fettering of the discretion of PMPRB under subsection 86(1) of the *Patent Act*, which provides that it is PMPRB *at a hearing following representations by the patentee* who determines whether disclosure of sensitive information or documents shall be made *at a hearing*.

v) Fourth, some information provided to PMPRB may be individually but not collectively publicly-available - the law recognizes and protects the value of collective information.

vi) Fifth, the statement in the Draft Guidelines that "the privilege does not extend to information and materials collected by the PMPRB, including any analysis performed by Board Staff of that information" needs to be clarified in three ways: 1. the "collection" of information and materials by PMPRB needs to be specified to be from third party sources not under any direct or indirect obligation of confidentiality to the patentee; 2. the "collection" of information and documents by Board Staff needs to be completely independent of the information supplied by the patentee, or else that

activity by Board Staff will contravene the springboard principle of confidentiality; 3. the analysis of the information independently collected by the Board Staff needs itself to be independent of the information supplied by the patentee; i.e., the analysis can in no way be informed by the patentee's confidential and privileged information, this again to avoid contravention of the springboard principle plus the ability to "reverse engineer" the patentee's information.

vii) Finally, it should be confirmed that any information and documents submitted by a patentee in support of a "DIP" or other price adjustment submission will be treated as absolutely privileged under section 87 of the *Patent Act*.

b) Price Review Process for products categorized as Slight or No Improvement (Chapter 2, section 2.9(a)): "...the new drug product will be presumed to be excessive if the national ATP or any Market-Specific ATP exeeds the lower of: (a) The lowest non-excessive price of the superior drug products identified based on a TCC test, and (b) the median international price determined by the MIPC test."

i) This means that any new drug that falls in that category will be limited to the generic pricing of the class of drugs identified by HDAP as being "superior". Considering that generic pricing is not under the PMPRB's jurisdiction and is subject to totally different market pricing dynamics, Abbott believes it is unfair and unreasonable to limit the price of a new patented drug to this comparator. The use of generic pricing runs directly contrary to the reason why the ITCC Working Group (albeit in the context of the ITCC) dismissed generic pricing in a domestic TCC as being a problem. The only reason that the WG-ITCC did not see a problem involving generic prices in a DTCC was on the basis that the highest price would always be used. This has been ignored in the formulation of a TCC that uses a "lowest price in class" approach.

ii) We recommend to PMPRB to completely remove section 2.9 (and the related section 2 from Schedule 8) and, should no comparator be found for that category, move directly to 2.10 (or section 8 in Schedule 8), as is the case in the current Guidelines.

c) Use of historical data during investigations (Chapter 3, section 1.3): "The examination will include an analysis of the pricing history of the patented drug product from introduction for both the national ATP and Market-Specific ATP (i.e., for each class of customer (hospital, pharmacy, wholesaler) and each province/territory)."

i) Abbott is concerned about the vagueness of this statement and would like to know how PMPRB will be using historical information in its investigation. Although we understand that historical data is helpful in understanding the variations of the ATP (national or market-specific), PMPRB should recognize that if a product is within guidelines in year X, then it cannot be deemed excessive 15 years later due to an analysis derived from an investigation. This would contradict PMPRB's approach where a market-specific analysis is only valid if the national ATP surpasses the NEAP of that year.

d) Delay for replying to investigation notifications (Chapter 3, section 1.4): "...if the patentee should have known that a price would appear excessive based on its own filings

(e.g., where the price increased by more than would be permitted under the CPI-Adjustment Methodology), the period of time may be as short as seven calendar days."

i) This deadline is unacceptable and unjustifiable. First, the new electronic format of PMPRB filings does not allow a patentee to see this information as it did before.

ii) Second, given that additional analysis is needed from the patentee to respond to any investigation notification and that any number of reasons can prevent patentee's staff from responding within a week's notice (business travels, vacation, etc.) Abbott strongly objects to this change and requests justification for what appears to be a punitive provision based on a presumption of misconduct.

iii) Finally, given that it often takes PMPRB up to 6 months to provide routine correspondence, it is not seen how a punitively short response time for the patentee will improve the process.

e) Use of NEAP in the Therapeutic Class Comparison (TCC) Test (Schedule 3, page 28): "Board Staff will find the public price that is sufficiently close to the National Non-Excessive Average Price of the patented drug product used for comparison purposes."

i) Given that the NEAP is derived from the ATP, which we expect to include all benefits related to a drug, Abbott believes it is unfair for PMPRB to require from patentees that the price of a new product be limited by the benefits offered under another existing drug.

ii) For the same reason i), Abbott is concerned about the confidentiality of the ATP provided to PMPRB. Indeed, even if PMPRB does not provide the actual NEAP used in a TCC, strategic and commercially sensitive information could easily be unveiled (for example, if PMPRB limits a product price to $5 for a comparator drug which has a publicly available price of $10).

iii) Abbott does not agree with Director of Board Staff's position during PMPRB's Teleconference (April 12th) in that "this methodology has always been used successfully and therefore there is not valid reason to change it". On the contrary, the implementation of PMPRB's August 18th communiqué will lead to a significant increase in ATP variations because patentees will no longer be allowed to include/exclude benefits in its calculation. As a result, the likelihood for PMPRB to find NEAPs "close enough" to the list price as before (usually 10%) will also drop accordingly. Abbott recommends that PMPRB recognize this upcoming shift and take this opportunity to correct a methodology flaw that could become a recurring problematic issue.

iv) Abbott would like to advise PMRPB that predictability is key to the introduction of new drugs on the Canadian market. Evaluations and analysis to decide whether a product will be launched are done at least 1-2 years beforehand. It should be reasonable for patentees to believe that a public Canadian price will be attainable for a new comparable drug in the same country. Otherwise, Canadians may be deprived of new medications available in other countries.

v) Abbott recognizes that PMPRB only has jurisdiction over the ex-factory price of a patented drug. We therefore recommend that for comparisons with a public price, either PMPRB uses a National or Market-Specific Non-Excessive Average Price that is free from benefits, or simply uses the MAPP inflated with CPI.

vi) Abbott also recommends that all drugs be compared according to the same standards, i.e. that the public/published price should always be used for all TCC tests, regardless of whether the drug is sold by the same patentee or not. The assessment of a drug's price should not be related to its owner but to the ongoing market price of its therapeutic comparators.

f) Use of generics in the International TCC test (Notice and Comment, Introductory Price Tests section, page (vi) & Schedule 7, page 35): "The Board does not support the complete exclusion of generic drug products from the test, but given the vast number of potential generic drug product comparators in foreign countries, it acknowledges that the inclusion of all available generic drug products could unfairly skew the results of the test."

i) This is contrary to the clear recommendations made by the ITCC Working Group in its April 2008 final report. The ITCC working group discussions and the selection of its participating stakeholders were coordinated by PMPRB to ensure proper and fair representation of the health care sector.

ii) In this report, the ITCC Working group "recognizes that generic drugs may be included in the domestic TCC, but notes that this does not ordinarily impact the MNE price, because the price test attached to the domestic TCC is the "top" of the TCC and in most cases the generic drug will not constitute the "top" of the domestic TCC. Similarly, if the price test for the ITCC were the "top" of the ITCC, the inclusion of generics would have little impact. However, the WG-ITCC does not support the inclusion of generic comparators if the price test for the ITCC will be any measure below the "top" of the ITCC. The availability and use of generic drugs varies widely in the comparator countries and there is considerable variation in their prices."

iii) The burden of price control visited upon a patented medicine should not be increased by comparison with a non-innovative product. Abbott recommends that PMPRB modifies its position and adapt the ITCC Working Group's recommendation.