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Montreal, February 29th, 2008

Ms. Sylvie Dupont
Secretary of the Board
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Standard Life Centre
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Ottawa, Ontario
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Subject: Written feedback to the Discussion Paper on "Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines"

Dear Ms. Dupont,

Since the beginning of the Excessive Price Guidelines Consultation process in May 2006, Abbott Laboratories Limited (Abbott) has been an active participant at each step to identify key issues and suggest constructive solutions. Abbott is pleased to provide once more our written comments on the Discussion Paper on "Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines". Please note that as a member of Canada's Research-Based Pharmaceutical Companies (Rx & D), we also support their response in this matter.

1. General Comments

- While Abbott appreciates the opportunity to provide feedback, **we would have appreciated additional time for responding to quite a lengthy Discussion Paper (25 pages)**. To provide a turn-around time of only 30 days is unreasonable. Indeed, its proposals and options contained several complex, inter-linked and critical issues that will have a major impact on patentees. As a result, please note that we were unable at times to form any recommendations, and that our position may also change in the future in light of any new parameters proposed.

- We also want to bring to your attention that **we disagree with Paragraph 4 of page 3** in the section "The Federal Court Decision in the Matter of LEO Pharma Inc." indicating that: "Representatives of the innovative pharmaceutical and biotechnology industries were given the opportunity to comment on the implications of the FCC decision during specific bilateral meetings with the Board during the summer of 2007". These bilateral meetings were <u>never</u> intended to address the FCC issue but were meant to address 8 specific issues identified in the May 31, 2007 Stakeholder Communiqué that was also referenced in the Board's Bilateral Meeting invitation letter. None of them included nor alluded to the FCC decision. Given the informality of the bilateral meetings (no formal agenda nor minutes), the Board cannot consider any discussions that may have been raised during those meetings as a formal opportunity by the industry to address the FCC issue.

- This only strengthens **Abbott's concern about the increasing complexity of the issues presented and the silo approach taken by the Board in addressing each issue individually without taking into account the potential impact of other initiatives such as the ongoing working groups and the upcoming Canada Gazette Part II. It also reinforces the lack of time allotted for a reasoned consideration of the implications of the proposed solutions.**

2. Any Market – page 4

- Although the Board response clearly states it agrees that an "Any Market" review should be done on a "case-by-case" basis, the current proposal attempts to establish grounds for a review to be done on a systematic basis. As a justification for the current proposal, the Board cites the Discussion Guide of 2006 which alleged that "…while the Average Price for some drugs in Canada are considered to be within Guidelines, the Average Price within some markets…did vary over 25% above the MNE price". We note that the 2006 Discussion Guide omitted to add that such variations occurred only in less than 5% of all DINs. Given the fact that the Board always has the capacity to review prices "in any market in Canada" as provided by section 83 of the Act, **Abbott believes there is very little justification to change the current approach of a national "Average Price" review to a systematic "Any Market" approach.**

- If, notwithstanding the foregoing submission, the proposed approach were to be implemented, **Abbott has significant concerns with the approach** and requests that the impact of the "Any Market" analysis on the enforcement process, if any, be submitted for industry consultation. It is our recommendation that this analysis be used solely to identify markets where a selling price may be above MNE and serve as a basis for investigation purposes with no impact whatsoever to the current excess revenues calculation methodology which should continue to be carried out on a national basis.

- **Abbott also believes that the introduction of a sub-market based price review will significantly expand the regulatory burden to the patentee and to PMPRB** who, from now on, will have to manage every DIN's ATP in a total of 52 markets (13 provinces and territories times 4 trade class customers).

3. Re-setting the MNE price – page 5

- In reference to "Re-setting the MNE price" issue as a whole, **Abbott does not believe that the Board has produced any evidence to support the need for the proposed changes.**

- Abbott strongly advocates that it should be made very clear that **re-setting can be done only on a patentee's initiative, not upon the Board's initiative or upon receipt of a request from anyone other than the patentee.** The Board already has many processes in place to ensure non-excessive benchmark prices (e.g. input from the Human Drug Advisory Committee, drug categorization, price tests) and is currently trying to define clear and exceptional circumstances that could justify the re-evaluation of this benchmark price. To

permit stakeholders other than the patentee to challenge a benchmark price will set a difficult and unacceptable precedent for pricing certainty in Canada.

- In reference to page 5 Proposal #1, **Abbott could be willing to support a proposal based on increased costs of making and marketing a drug, but only after proper consultations with industry and patentees on the analysis brought forward by the report to be issued by the Board's consultant in April 2008.** The Board cannot expect patentees to provide a considered opinion on this matter without having the necessary information beforehand. Additionally, Abbott disagrees with the resetting methodology proposed by the Board, which would involve either re-performing the original price test or accepting the current ATP as the MNE. The better approach would be to adjust the original MNE upward by the increase in the costs of making and marketing the drug. We also recommend that since these exceptional situations require clear guidance, elements to be considered should therefore be measurable and realistic (e.g., capital investments, transportation/distribution, and packaging.) as opposed to demonstrating financial loss.

- In reference to page 6 Proposal #2, **Abbott cannot consider this proposal until there is a broader experience base with progressive licensing**. Therefore, this proposal should be considered only after Health Canada actually implements such an initiative.

- In reference to page 7 Proposal #3, **the timeframe and number of international comparators should be kept as status quo.** The number of countries should not be brought down to 3 because the median calculation methodology increases the possible variation in price (closer to the highest or closer to the lowest of the 3). **Having 5 comparators leaves 3 countries to choose a median from and therefore provides a better representation of international pricing for the Canadian market.** Furthermore, Abbott is concerned that the reduction of 5 countries to 3 countries was never previously brought up for consideration and was introduced in the Discussion Paper without any rationale. It is our opinion that changes or proposals coming from the Board should come from legitimate and documented concerns and be justified by a rationale and impact analysis.

4. SECTION IV page 11 – REGULATORY OPTIONS to address issues arising from the FCC decision

- As a preliminary comment, Abbott would like to take this opportunity to indicate that we do not agree with PMPRB's interpretation of the FCC decision in the LEO Pharma/Dovobet case. The ruling of this case did reiterate the Patent Act in enumerating the list of factors that should be included in the ATP calculation, but in no way did it challenge the current and well established April 2000 Board Policy of allowing patentees to choose to include or exclude certain benefits as long as they were being consistent. In light of this, **Abbott questions why none of the proposals presented by the Board includes maintaining the current policy (April 2000 NewsLetter)** for patentees to include/exclude benefits as long as the chosen practice is consistent throughout the life of the DIN.

- **Abbott strongly agrees with page 11 Option 2** to amend the regulations to exempt patentees from the requirement to report benefits (payments) provided to third-party payers (F/P/T drug plans and potentially private insurers if similar payments are negotiated in the future). Strictly speaking, an exemption may not be required, since third party payers are not "customers", as noted by the Board; however, such an exemption would serve a clarifying function.

- With reference to option 3, **Abbott supports page 13 Options (i), (ii) and (iii).** We might also support including the free goods in the ATP calculation (except in the cases of options 3b and 3c) only if option 2 to the CPI methodology is implemented or if a de-linking methodology between MNE and ATP is agreed upon.

- In reference to page 14 Option 4, **free services (or partially subsidized) should, in our opinion, be excluded from the ATP calculation because their costs are rarely "DIN specific" and/or may be addressed to serve different therapeutic areas.** Inclusion of such amounts will give rise to many alternative possibilities as to how costs may be linked to one specific DIN and will **carry a high risk of inconsistencies across reporting periods.** As such, it is our opinion that regulations or a policy be developed to either exempt patentees from including free services altogether or give them the choice to include or exclude free services, as long as it is consistent throughout the life of the DIN.

- **Abbott strongly disagrees with page 14 Option 6** and believes this regulation has no purpose other than to give the Board complete discretion to deem a benefit ineligible for inclusion in the calculation of ATP. If the regulations are amended to clarify ATP inclusions and/or exclusions, an additional discretionary power of the Board is not needed. Such a wide discretionary power would render it very difficult for a patentee to obtain a remedy in the Federal Court in the event of a disagreement with the Board's decision.

5. Guidelines Options page 16 – Possible changes to the CPI-Adjustment Methodology

- By definition, a price below the MNE is "non-excessive" and the patentees should be entitled to increase prices up to this threshold. If an ATP returns to an original value due to the termination of a given benefit program, but remains under the MNE, the Board will have fulfilled its mandate of ensuring that the drug is not excessively priced.

- Abbott understands that a 100% ATP rebound after a number of years may be perceived as an "excessive" price increase. However, we believe that restricting ATP rebound may prevent patentees from implementing meaningful short-term (e.g., 1-3 years) benefit programs. Also, we would like to bring to the attention of the Board that the proposed restrictions on ATP variations add yet another level of complexity to the ATP review process.

- Abbott supports the principle of page 17 option 2 but based on the foregoing, we **believe the various repercussions of the proposed option are too great to make an informed formal recommendation at this point**. Various issues need to be addressed to fully understand the impact of ATP "rebound" restrictions included in this proposal. Other avenues are also worthy

of exploring, such as a complete de-linking of the ATP from the MNE, where ATP variations, as long as remaining under the MNE, would be tolerated.

- Finally, we **strongly recommend that a formal evaluation of all options be conducted, including an option that contemplates significant ATP rebound while considering its true impact on patients' needs.** Such an evaluation may reveal that this option is viable, provided that any negative impact is dealt with on a case-by-case basis, hence saving the majority of patentees from additional onerous ATP/MNE management/reporting requirements.

In closing, while our industry appreciates the opportunity to comment on potential and proposed changes, perhaps this time would have been better served if this took place after all committees and consultant's reports (ITCC, TI and Price Tests working groups, Canada Gazette part II, Cost of Making and Marketing report, etc.) are received this April.

Sincerely,

Laurie Dotto
Director, Government & External Affairs
Abbott