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Montreal, January 15th, 2016

Mr. Guillaume Couillard
Director, Board Secretariat, Communications and Strategic Planning
Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1
BY EMAIL: Guillaume.Couillard@pmprb-cepmb.gc.ca

RE: Response to PMPRB Notice and Comment on "Incremental Reforms to Compendium of Policies, Guidelines and Procedures"

Dear Mr. Couillard,

AbbVie Corporation (AbbVie) would like to thank PMPRB for this opportunity to review and provide comments on PMPRB Notice and Comment published December 4th, 2015 on "two proposed amendments to the Compendium of Policies, Guidelines and Procedures (Guidelines): the *Reasonable Relationship Test (Schedule 4)* and the *List Price Relative to Maximum Average Potential Price (MAPP) Verification (section C.11)*. These changes would be effective for all drugs introduced in Canada after January 1, 2016."

Please note that as a member of Canada's *Innovative Medicines Canada* (IMC) – previously known as "*Research-Based Pharmaceutical Companies (Rx&D)*" – AbbVie also supports, and is in agreement with, the comments and recommendations submitted by IMC in response to this matter.

- **Retroactive application of the proposed amendments**

Contrary to all previous consultation processes impacting changes to Guidelines, AbbVie notes that PMPRB has not provided any transition period between the current and future Guidelines, making the final changes effective retroactively to January 1, 2016, nor has PMPRB provided for appropriate grandfathering. AbbVie asserts this course of action undermines the credibility of the consultation process, clearly portraying the process is a technicality to enforce pre-established Guidelines rather than promoting a meaningful exchange with stakeholders.

AbbVie notes that there is no provision for grandfathering products that have been introduced under the existing Guidelines, nor of products that are the subject of pending investigations or proceedings. Since the final language of the future Guidelines has yet to be defined and in cases where either of the proposals negatively impact on pricing, the retroactive application of the future Guidelines creates unfairness, uncertainty and unpredictability for patentees. For example, prices of new DINs launched post January 1, 2016 in accordance to the current Guidelines could be found excessive after the fact, unfairly exposing patentees to an investigation that would otherwise have not been opened.

AbbVie recommends that the revised Guidelines be implemented in 2017 to allow for adequate time for dialogue and consultation as well as for potential grandfathering provisions to be developed appropriately.

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- **Initiative #1: Reasonable Relationship Test Amendment**

The first initiative in the proposed amendments is that the application of the Reasonable Relationship Test would be altered to use the National Average Transaction Price (N-ATP) of the comparator (if owned by the same patentee) instead of the lowest of the six publicly available prices.

AbbVie is of the opinion that this amendment does not resolve the core issue in the Guidelines whereby a patentee is currently, and will continue to be, unable to launch a line extension at the same (non-excessive) price of the comparator and therefore maintain price parity in all markets. AbbVie recognizes that in cases where line extensions for products that have been sold on the Canadian market long enough to have a significant lower price in one market (e.g. Quebec), the amendment proposed by PMPRB may reduce the number of investigations or potential excess revenues versus the current Guidelines; nonetheless, the core problem in the current Guidelines is not resolved unless a concept of price parity is introduced.

Under PMPRB's proposal, for line extensions of more recent products that have the same price in all provinces, introductory prices will be forced down to the confidential average transaction price of the reference product – which usually includes discounts, free goods, etc. Forcing the introductory price (and public list price as per initiative #2 below) to the same level of an older product - including all benefits during the introductory period - is neither fair nor realistic and, furthermore, may compromise the confidentiality of such benefits.

In all cases, this amendment raises the following concerns for AbbVie:

- it does not resolve the flaw of the Reasonable Relationship test that does not allow price parity in all markets;
- it creates a situation where different rules apply for different patentees resulting in different MAPPs for the same medicine or strength simply on the grounds of who owns the comparator product;
- it acts as a disincentive to provide benefits on current products that may have future line extensions; and
- it may compromise altogether the commercial viability of any line extension and act as a disincentive for patentees to launch in Canada, therefore preventing Canadians from accessing innovations on currently marketed products.

In order to address this issue effectively, ***AbbVie recommends that the permissible MAPP be based on the higher of: (1) the highest of the 6 publicly available sources AND (2) the market-specific MAPPs that would be found according to the prices reported in the comparator's Block 5 (i.e. a "price parity" analysis). The N-ATP would therefore be presumed to be non-excessive.***

- **Initiative #2: List Price Relative to Maximum Average Potential Price (MAPP) Verification (Section C.11)**

In regards to the second amendment, whereby list prices found in AQPP, IMS Health, McKesson Canada, ODB, PPS Pharma and RAMQ will be presumed to be excessive if they exceed the Maximum Average Potential Price (MAPP), AbbVie notes the rationale for this change is that "Board Staff has identified the need to ensure that list prices are not excessive" based on the grounds that N-ATPs reported by patentees are lower than the list prices reported in Block 5.

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AbbVie would like to point out that differences between the publicly available price of each province reported in the Block 5 and the confidential national average price are to be expected since the latter encompasses all types of benefits listed in the Patented Medicines Regulations (*subsection 4(4): for the purposes of paragraph (1) (f) (i) (…) "discounts, free goods, free services, gifts, and other benefits of a like nature"*). Furthermore, the current Guidelines (Schedule 12) already manage the N-ATP and all market specific ATPs of a new product at introduction against the MAPP in all markets. Also, Board Staff's impact analysis recognizes that if such amendment would have been applied in 2014, only 9 of the 101 drugs introduced in 2014 would have list prices more than 5% greater than the MAPP. Since only one drug resulting in an investigation was already outside the Guidelines based on N-ATP, zero additional actual investigations would have been opened. Since N-ATP effectively regulates price, AbbVie fails to understand the rationale for, and additional value of, this amendment.

More importantly, AbbVie also questions whether PMPRB has jurisdiction under the Patent Act to regulate list prices. The Patent Act (subsection 85(1)), the Patented Medicines Regulations (subsection 4(4)), and the jurisprudence (e.g. *Leo Pharma Inc.* v. *Attorney General* 2007 FC 306; *Pfizer Canada Inc.* v. *Attorney General* 2009 FC 719) clearly indicate that the prices that are controlled by PMPRB are average transaction prices, *not* list prices. This is supported by the fact that there are no means under the PMPRB regime to calculate "excess revenues" based on list prices. The December Notice and Comment does not provide those means, because the regime does not contemplate them.

Based on the questionable legality of PMPRB jurisdiction over list prices, the lack of a compelling rationale for the initiative, and the absence of additional value to PMPRB's enforcement of non-excessive prices of patented medicines, ***AbbVie recommends that this amendment be disregarded by the PMPRB.***

- **<u>Conclusion</u>**

Although we are supportive of the direction taken by PMPRB to resolve inherent issues related to the Reasonable Relationship Test, AbbVie believes the proposed amendments are not acceptable at this point, nor do they achieve PMPRB's desired outcomes. We recommend that further discussions and deliberations be undertaken to address 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 our customers or to ensure Canadians have access to new, innovative therapeutic options for currently marketed products.

AbbVie is encouraging the PMPRB to establish a clear, flexible and consultative approach to resolve these issues. We look forward to new suggestions or innovative solutions that would create a true partnership between the industry and PMPRB in ensuring non-excessive pricing in Canada while also encouraging innovation and investment. As such, AbbVie will continue to be an active participant in PMPRB's consultation process and we welcome any opportunity given by PMPRB for future dialogue and feedback on changes.

Should the Board have questions or require additional information, please do not hesitate to contact me.

Sincerely,

Laurie Dotto
Director, Government & External Affairs

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