



June 28, 2017

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Attention: Patented Medicines Regulations Consultations

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Canada

RE: Health Canada's Proposed Amendments to the Patented Medicines Regulations

AbbVie Corporation (AbbVie) is pleased to provide comments on the discussion paper *Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations*, released on May 16, 2017.

AbbVie is a global research-based biopharmaceutical company with 29,000 employees worldwide. We have more than 500 employees in Canada. Over 1 million Canadians benefit directly from our medicines. Our mission is to use our expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases.

AbbVie shares many of the goals regarding access to, affordability of, and appropriate use of patented medicines as expressed by the Minister of Health. Our vision is that all Canadians will be able to have timely and optimal access to all medicines that may improve their health. As we note below, we are unconvinced that many elements in the regulatory proposal will help all of us, as Canadians, meet this aim; and, in fact, the regulatory proposal, as it stands, may make things worse. AbbVie would like to emphasize three areas of particular concern created by the proposed regulations that we believe will heavily impact our ability to provide medicines to Canadians who could benefit from them:

Significant uncertainty and ambiguity:

Without evidence of or guidance on how these powers are expected to be used and implemented, it is impossible for AbbVie to either assess their potential impact on access to innovative medicines, on our Canadian operations or even how effective these measures may be in achieving PMPRB's objectives. Uncertainty within the industry is a disincentive for commercial investment in Canada, and thus amendments to the pricing regime must be carefully considered - unintended consequences could negatively impact patient access.

The current section 85 factors for assessing whether a price is excessive can be applied in an objective and consistent manner. The current regulatory proposal addresses the selling price of the medication based upon therapeutic comparators and international pricing, factors having a rational connection to the purpose of the Patent Act. Therapeutic value is a logical starting point for any reasoned pricing analysis, and consistent with the principles of the Patent Act. Under the current rules, innovative products, for an unmet therapeutic need or that have significant efficacy over other medicines, are afforded a higher price ceiling than a "me too" drug. This is consistent with the overall purpose of the Patent Act to encourage innovation. On the other hand, a consideration of "ability to pay" is arbitrary, subjective and likely indeterminable and therefore cannot be what Parliament intended in enacting this pricing regime. "Excessive" and "unaffordable" are not interchangeable terms - the PMPRB only has authority to determine whether the average drug price is excessive, and not to establish a price at a payer level.

Requiring provision of pharmacoeconomic analysis to PMPRB introduces unnecessary duplication of work for both PMPRB Staff and patentees and, in the view of AbbVie, hinges on a notion of affordability that is undefined in the regulatory proposal - and one that is multi-factorial and may change over time. On the other hand, if PMPRB plans to rely on analysis provided by CADTH or INESSS, this may result in access delays while waiting for HTA completion as companies would hold back actual commercial launch until price ceilings are confirmed. Furthermore, the proposal to

require patentees to provide budget impact analysis appears somewhat prejudicial in absence of real-world evidence, or create even more uncertainty for patentees if prices are constantly re-visited based on mutable thresholds.

Considering past consultations conducted and Guidelines changes implemented by PMPRB to address unintended consequences¹ from reporting rebates and other benefits, PMPRB has historically failed to explain or demonstrate why or how reporting of additional third-party rebates would allow them to discourage excessive pricing. In fact, having any policy or Guidelines that would use third party rebates or benefits to potentially lower future price ceilings will certainly put those benefits, including those to public drug plans, at risk. Although the proposal makes reference to Section 87 privilege to protect confidentiality, if PMPRB were to reset the ceiling price based on rebate information, in effect, confidential information will be made public as a result of PMPRB's actions. Without an explanation on how rebate information will be used, it is impossible to know if the information will in fact be maintained in confidence, placing manufacturers in breach of their contractual obligations if such information is supplied to PMPRB. The need for PMPRB to obtain this information is also very ambiguous. The PMPRB only has authority to request information that is necessary to determine if a patentee's average price is excessive; it is unclear how information about confidential third-party rebates would be used by PMPRB for this purpose.

AbbVie believes that as soon as an ex-factory price ceiling is set by PMPRB, any transactions occurring below that price threshold should be irrelevant to PMPRB. The regulation of pricing by the federal government must not infringe upon the division of powers in the Constitution Act. The PMPRB may regulate factory-gate pricing but its constitutional limitations do not permit interference with contractual arrangements involving patentees and entities further down the drug distribution chain or setting of a "retail" price. As noted, the PMPRB only has jurisdiction over the regulation of average pricing and it would seem that an attempt to assess an individual customer's willingness to pay goes beyond this mandate. It is the provincial payers that are responsible for health care budgets, and the proposal to assess pharmacoeconomic information that is used by the provinces is not only redundant, but suggests that PMPRB would be overstepping its constitutional limitations in setting a price ceiling based on this information. Health Canada should really seek measures that enable the PMPRB to complement efforts already implemented by the other agencies of the current healthcare framework (CADTH, INESSS, pCPA, provincial policies).

De-prioritization of innovation in a manner inconsistent with the Patent Act:

The patent regime is the broader context for the PMPRB regime and it is incorrect to interpret the scope and function of the PMPRB regime apart from the context in which it resides. Regulations that would result in hindering innovation are not consistent with the Patent Act and therefore beyond the jurisdiction afforded by the enabling legislation.

AbbVie does recognize the motivation for the initial 'basket' in that it aligned Canada with like countries, in part to promote biopharmaceutical innovation to take place in Canada. This was a successful policy measure throughout the 1990s despite falling off in recent years, in large part due to the evolution of research and development models that now rely on sophisticated networks of external innovation, including that taking place in Canadian universities, and the scale-up of small- and medium-sized enterprises. A great example of this evolved innovation model is AbbVie's membership in and support of the Structural Genomics Consortium (SGC) in Toronto, to which we have provided \$15.45 million, with support continuing to 2020 – investment that has not been recorded by the PMPRB in its R&D to sales ratio due to PMPRB's outmoded investment criteria – a fact PMPRB, itself, admits. As such, AbbVie believes that the current metrics used by PMPRB to measure R&D investments fail to capture adequately the true economic footprint of the pharmaceutical industry and should definitely be re-visited.

The regulatory proposal recognizes that "other factors, such as head office location, clinical trials infrastructure and scientific clusters, appear to be much more influential determinants of where pharmaceutical investment takes place." We agree, particularly with respect to the latter two points, and therefore question how the revised basket can be viewed as rationally connected to the underlying purpose of the legislative scheme. We were also troubled to see the

¹ Following LeoPharma court case in 2008, PMPRB cancelled its policy to allow patentees to include or exclude rebates from its reporting. This led to many investigations because of the changing nature of the benefits. PMPRB recognized it was not in the interest of Canadians to implement policies or Guidelines that would disincentive patentees from offering such rebates, implementing the DIP methodology and relying on publicly available prices to determine price tests.

regulatory proposal's discussion of the proposed 'basket' of countries move away from consideration of the innovation ecosystem. A confounding factor is also the lack of predictability to know how this basket will be used under PMPRB's revised Guidelines after once the Regulations are amended. Should the same conditions prevail, it is AbbVie's opinion that a more appropriate comparator basket, such as the G10 – the selection of which will permit utilization of already-existing and robust data comparing GDP, market size, investment in innovation, and, most importantly, patient health outcomes – be selected, rather than the highly tailored country list put forward in the regulatory proposal as a means to an end. On the other hand, should PMPRB set forth more restrictive Guidelines moving the international price ceiling from the highest to the median of the basket, AbbVie would agree strictly under the assurance that similar market conditions than those in the reference countries are implemented, which would mean almost instant reimbursement and access after Health Canada's regulatory approval, absence of joint negotiation process with distinct payers (i.e. elimination of pCPA), absence of co-insurance for patients, and little to no prescription criteria for physicians outside of the indication approved by Health Canada. AbbVie believes that international reference pricing policies in Canada should be coherent with the economic and innovation profile of the countries selected but should also be sensitive to the market access policies and framework in place supporting those referenced prices.

Compounding effect delaying or denying patients access to innovative medicines

While not exclusively the domain of Health Canada, AbbVie would be remiss to not express our concerns that timely access to innovative medicines in Canada is worse than it has ever been. We are very pleased at the announcement of Health Canada's pilot project review of breakthrough medicines and medicines that contribute to "health system sustainability" concurrently with HTA and we welcome scale-up of the pilot across all Health Canada submissions as soon as possible.

Instead of adding additional regulatory factors to the PMPRB – particularly ones where it is impossible to forecast what additional delays may occur and the negative impacts on the viability of biopharmaceutical operations in Canada – AbbVie is very supportive of the evidence being collected and the conversations being initiated by Innovative Medicines Canada to secure a new, pan-Canadian Framework Agreement to promote sustainable access to innovative biopharmaceutical products. We believe that PMPRB has a role to play in such a framework and that it should seek synergies as opposed to additional layers to an already complex and multi-layered system. AbbVie believes that it is premature to conclude the regulatory changes under consideration in this proposal in advance of a potential new Framework.

Conclusion

AbbVie's position on the proposed amendments to the patented medicines regulations are well represented by the submissions made by our industry associations, Innovative Medicines Canada and BIOTECanada. In summary, AbbVie is in the view that these proposals:

1. Are **inconsistent** with the government's Innovation Agenda and the Health Minister's objective to align processes to speed up access by patients to breakthrough treatments.
2. Would introduce **regulatory overlap and duplication** with existing provincial and FPT drug pricing and reimbursement systems.
3. Are **vague, ambiguous and lack clear and measurable objectives**.
4. Would create significant market uncertainty leading to **delays** in the launch of innovative therapies in Canada and **harm to investments** in clinical research.
5. Fail to be accompanied by any information on the **impact assessment** and possible unintended consequences.
6. Should only apply prospectively to new products, be accompanied with at least one year of transition period, and that companies ought not be liable to pay back revenues earned in the period between Health Canada marketing authorization and a price ceiling determination by the PMPRB.



AbbVie appreciates the opportunity to provide comment on this regulatory proposal, and is always willing to work closely with Health Canada and the PMPRB on federal regulatory and pricing policy and their implementation issues. We therefore look forward to future opportunities to provide feedback to Health Canada or PMPRB and will continue to engage in future consultation processes.

Sincerely,

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