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Patented Medicine Prices Review Board
(Rethinking the Guidelines)
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RE: Response to PMPRB's Guidelines Modernization Discussion Paper

AbbVie Corporation (AbbVie) would like to thank PMPRB for this opportunity to provide comments on PMPRB's Guidelines Modernization Discussion Paper released on June 24th, 2016.

As a member of *Innovative Medicines Canada* (IMC) and of BIOTECanada (BTC), AbbVie supports and agrees with the comments and recommendations submitted by both organizations in response to the Discussion Paper. AbbVie's submissions offer additional perspectives on how the areas addressed in the Discussion Paper would impact our operating environment in Canada, as well as patient access to innovative medicines – medicines that have changed lives here and around the world, including those we are very proud to have developed and brought to the Canadian market.

Preparing this submission, we have found it not only difficult, but also counter-productive, to respond directly to the 12 questions posed at the end of the Discussion Paper. In our view, these questions are siloed, and, as happens all too often in our discussions about health care, conflates price regulation instruments with larger issues of affordability and health care sustainability. At AbbVie, we recognize we have a role to play in affordability, both in terms of working with payers to ensure innovations will be available and accessible to patients within the confines of the existing reimbursement environment, as well as working in concert with policymaker, physician and patient stakeholders to transform the health care system. We will share some of our successes in this below.

The issues we discuss in this submission draw a more nuanced representation of the broad ecosystem that influences the pricing and value of innovative medicines here in Canada and around the World. To draw your attention to the broader context necessary to understand the PMPRB's 12 questions, we have provided a reference table at the end of our submission that identifies how a number of the issues we raise below can be put together to answer the questions, at least in part.

SUBMISSION

AFFORDABILITY VS. NON-EXCESSIVENESS

1. It has been almost 30 years since the PMPRB came into existence. AbbVie agrees it is important for PMPRB to make sure its Guidelines are still relevant to the Canadian pricing and reimbursement environment.

2. The Canadian health care system is unlike any other country in the world, due to its limited federal involvement, with most health care expenditures (including hospitals, physicians, publicly-covered medicines etc.), with some exceptions[1], incurred and managed at the provincial and territorial levels. The private healthcare sector also plays a significant role, covering many Canadians through workplace or individually-purchased coverage.

3. The PMPRB was established to protect Canadians from potential abuse of statutory monopoly occasioned by protections granted in the Patent Act in 1987 after Canada repealed the then compulsory licensing regime, as was required in order to accord with Canada's international trade obligations. AbbVie supports the PMPRB's mandate, namely: *"(1) on the regulatory side, to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive; and (2) on the reporting side, to report on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patentees*[2]." As it stands, this mandate strikes an important balance in protecting intellectual property rights while simultaneously ensuring consumer protection by putting an upper limit on drug prices.

4. PMPRB is the first, but certainly not the only, downward pressure manufacturers face on pricing. Following PMPRB's initial review, manufacturers face a succession of assessments and negotiations, including health technology assessments conducted CADTH and INESSS, provincial drug plan committee reviews, as well as numerous private payer committee reviews. More often than not, significant risk sharing agreements are negotiated between manufacturers and public and private payers alike; these agreements remain confidential, as these risk sharing agreements are designed to respond to unique budgetary circumstances facing each individual payer. These agreements ought not bear on the real or perceived value of a medicine (which is priced by a manufacturer and, rightly, deemed excessive or non-excessive by PMPRB), as any rebates contained within the agreements are entered into by manufacturers at will, following negotiations identifying a common interest, resulting in a specific, unique and legitimate partnership with a given payer.

5. In other words, there are already multiple mechanisms to address affordability of medicines in Canada. We have many concerns about *how* organizations like CADTH and pCPA operate (which were unfortunately not addressed in the PMPRB Discussion Paper), but AbbVie's concerns will not be abated by the PMPRB *also* addressing questions of affordability. Affordability is a subjective concept that can only be determined by the particular payor who is responsible for health care spend in the larger context of its operating budget. As such, AbbVie rejects the PMPRB's suggestion that it address "affordability," instead of "non-excessiveness," as its mandate.

VALUE OF INNOVATIVE MEDICINES:

6. AbbVie is concerned that PMPRB, in its Discussion Paper, is considering measures that, in effect, restrict allowable prices to current size of budget lines. This inadequately values medicines, which are developed through years of investment, inquiry, and many failures before our best scientific minds deliver an innovation with the capability of profoundly impacting patients' lives. It's both unfortunate and counter-intuitive to encourage the innovative activity of scientists, while, simultaneously, prematurely limiting the maximum value of a potential innovation. As a result, we are profoundly concerned that the PMPRB Discussion Paper considers implementing measures regarding:

[1] Federal plans exist to address the healthcare needs of very specific population profile such as NIHB, Veterans, National Defense, etc.

[2] http://www.pmprb-cepmb.gc.ca/about-us/mandate-and-jurisdiction

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- the theoretical level of utilization that a drug may or may not have (and by extension its potential budgetary impact) – utilization that cannot be reasonably anticipated or measured by neither PMPRB nor a manufacturer in advance; or

- other factors that have no link to the actual clinical value and incremental benefit an innovative drug will bring to the treatment options patients will have within a specific therapeutic area; or

- international reference pricing formulas or cost containment measures that come from countries with incomparable reimbursement environments (e.g. the countries cited in the Discussion Paper that either have one main national payer, or very limited private sector involvement that is typically not bound to the same pricing rules).

7. If Canada wants to continue to benefit from cutting edge technologies and quick access to new innovative medicines, we must reward – rather than punish – that innovation, allowing a premium price proportional to the clinical value of the incremental benefits a new drug has over the existing standard of care, as we do today.

8. While we are concerned the measures considered in the Discussion Paper will discourage innovation and negatively impact our ability to successfully launch new products in the Canadian market, AbbVie most fears the combination of these measures with the ongoing reality that the collateral impact an innovative drug can have outside of the drug budget is rarely measured or accounted for within health systems. For PMPRB to move away from, rather than incorporate, the assessment of how our therapies improve overall health outcomes, introduce system efficiencies, or benefit work productivity – factors that cannot be assessed upon introduction of a new medication – compounds a perennial challenge in the Canadian health system: the true value of drugs is too often left unrealized because the system does not evolve along with new, innovative medicines.

9. It is critical that the Guidelines be consistent with and reasonable in view of the purpose of the Patent Act and the legislative intent behind the regime. The patent regime is the broader context for the PMPRB regime – just as there must be some rational relationship between a patent and a medicine, the application of the PMPRB regime to the pricing of the medicine must maintain a rational relationship to the patent right and the objects of the patent system. The underpinning of the rules of the current Guidelines is therapeutic contribution, which is consistent with the overall purpose of the Patent Act to encourage innovation. While the mandate of the PMPRB is price control, it cannot exercise its function in a manner that is contradictory to the purpose of its enabling legislation.

PMPRB'S LIMITS TO ASSESSING AFFORDABILITY

10. A distinction between price and affordability needs to be made. Even if PMPRB wanted to, AbbVie questions whether PMPRB is capable of determining price ceilings based on the capacity to pay of a specific jurisdiction or market. How, for example, does the PMPRB propose to measure what can and cannot be afforded by the Province of Ontario? What if what Ontario can afford is different than Prince Edward Island, or a private insurer? How would that information be made visible, and what data points does the PMPRB propose to use to assess affordability? Would industry have a say in these assessments to safeguard against them being arbitrary? In short, "affordability" is subjective and likely indeterminable, and cannot be what Parliament intended in drafting the legislation. The Patent Act does not support an assessment that is based upon ability of a customer to pay, and, as noted above, removing therapeutic value from the assessment would be inconsistent with the statutory scheme.

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11. Health care sustainability is a worldwide challenge, and every country is working to find solutions to affordability based on their own needs and priorities. International reference pricing is one tool being used in many countries, all with varying formulae and acting in concert with other cost containment measures to manage level of access for a given population. The current system used by PMPRB in ensuring Canadian prices are – at introduction – no higher than the international median price of seven reference countries for products with no domestic comparators and, simultaneously, cannot become the highest of these seven countries throughout the life of the product, has proven to be a simple, predictable and efficient way to ensure prices are not excessive.

12. AbbVie believes PMPRB is not the appropriate regulator to make any decision pertaining to the affordability or sustainability of a specific drug. PMPRB does not now, nor will it have, full visibility, nor regulatory authority, over the overall budgetary impact a drug can have – particularly with respect to public and private payers with confidential listing agreements that include rebates. Further, it is unclear how PMPRB may be able to distinguish itself in this arena when, over the last 15 years, Canadian jurisdictions have individually or jointly addressed affordability by establishing a high bar for reimbursement, either via HTA (CADTH and INESSS), or via the pCPA, as discussed in (4), above.

13. Furthermore, federal price regulation must respect the division of powers of the Constitution Act. Regulation of factory-gate pricing is one matter; however there are constitutional limitations on interference with contractual arrangements involving patentees and entities further down the drug distribution chain. Introduction of an assessment of a customer's "ability to pay" could be unconstitutional on this basis.

14. AbbVie believes PMPRB does have a role to play and that PMRPB should continue to work within its current mandate, focusing on non-excessiveness. This is an assessment that PMPRB can perform in a consistent manner, while respecting the right of each province to manage its own budget.

PMPRB'S INTERPRETATION OF PRICING DATA AND TRENDS

15. AbbVie questions why PMPRB has selected the particular statistics it has featured in the Discussion Paper, when the PMPRB's own 2015 Annual Report shows Canada performing favourably in contrast to the PMPRB7. The 2015 Annual Report shows Canadian prices are actually 18% lower than the median international price, tying with Switzerland for 4th. Since 1996, Canada has oscillated between 3rd and 5th position in the PMPRB7[3]. If Canadian drug prices have ranked similarly for the past 20 years, how can PMPRB really say that Canadian prices are or are becoming too high?

16. It has been well-established, whether by CIHI or by the provinces themselves, that physician and institutional costs (hospitals, surgeries, long-term care facilities, etc.) are driving up health budgets, while budgetary expenditures for innovative medicines (6.4% of the overall health budget[4][5]) have grown at a rate less than inflation for the last 10 years. Where modest growth in drug budgets is occurring, the balance is due to high generic drug costs, wholesaler and pharmacy markups, and distribution fees. Indeed, PMPRB's NPDUIS CompassRx 2013/2014 report[6] shows that within public drug plans, where fees are usually regulated (as opposed to the private sector), at least 26% of so-called "drug

[3] In all of PMPRB's history, Canada ranked 2nd only once in 2006

[4] Skinner, B.J. Spending on patented drugs in Canada 1990 to 2014. http://www.canadianhealthpolicy.com/products/spending-on-patented-drugs-in-canada-1990-to-2014-.html

[5] LABRIE, Yanick et FRAPPIER Julie, *L'industrie de la pharmacie communautaire au Québec : un modèle à renouveler. Enjeux, constats et pistes de solutions*, Livre blanc soumis à l'Association québécoise des pharmaciens propriétaires, 7 septembre 2016

[6] PMPRB NDPUIS, CompassRx, 2nd Edition, Annual Public Drug Plan Expenditure Report, 2013/14

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expenditures" are associated with other non-medicinal fees down the distribution chain. Furthermore, while no one disputes the need to invest in hospitals and health care providers to deliver the high standard of care we enjoy in Canada, very few metrics exist to adequately account for the long-term value of those investments, or to identify how institutions and workforces may best be reallocated when breakthrough medicines completely revolutionize the standard of care. With this context in mind, we suggest the PMPRB's preoccupation with price as the driver of affordability for innovative medicines is misplaced and disagree with PMPRB's conclusion that reducing such prices would ultimately resolve any of the affordability issues raised in the Discussion Paper.

17. In fact, PMPRB has done an excellent job fulfilling its mandate, and should be proud of its track record. Canadian prices have remained consistently at or below the median of the PMPRB7 (by more than 18% in 2015); price increases have fallen far below CPI; and manufacturers are in a very high rate of compliance, with PMPRB's enforcement process effectively addressing outliers. PMPRB is also adapting to the environment by continuously using VCUs and legal proceedings to identify which areas of the Guidelines are no longer appropriate within our evolving pharmaceutical environment, and proposing adaptations and amendments where appropriate.

POTENTIAL GUIDELINES CHANGES: MORE ANALYSIS IS NEEDED

18. When it comes to price transparency and differential pricing whereby different prices (confidential or not) will be effective with different customers, PMPRB`s Discussion Paper questions the ongoing market segmentation and seems to propose implementing a fully transparent pricing system that would require each customer to have equal access to the same price. Cases of new medicines being introduced at a different ex-factory price in different market are very uncommon. The reasons that would explain why a price would differ from one market to another after launch are typically linked to the levels of benefits being offered in such a market. AbbVie does not understand how offering benefits to different customers can be seen as a medium for promoting excessive pricing; respectfully, this falls out of PMPRB's purview. In such a system, AbbVie does not understand how a manufacturer would be able to offer any kind of benefits to its customers, and therefore such a system would be unnecessarily restrictive and likely counter-productive, particularly for public payers. Furthermore, the DIP methodology was, after a significant consultation process and via successive meetings with PMPRB, finally implemented specifically to allow manufacturers to continue to provide benefits without being penalized for the impact in their ATP. Is PMPRB now questioning the value and utility of the DIP methodology and the existence of price segmentation in that context?

19. One area that PMPRB could immediately undertake to continue its demonstrated track record while reducing unnecessary regulatory burden for manufacturers is to only apply the International Reference Pricing comparison at introduction. The current system, whereby international reference pricing is assessed throughout the patent lifespan, largely disadvantages manufacturers, who do not have control over changing conditions in the pricing ecosystem in multiple countries. Implementing new IRP ceilings on existing medicines (i.e. past the introductory period) is likely to increase the administrative burden of PMPRB Board Staff and manufacturers, leading to unnecessary investigations – largely due to annual fluctuations (e.g. exchange rates). In practice, considering Canada's high bar for HTA assessments, strenuous public negotiations and the very effective PMPRB's annual ATP monitoring, the likelihood a drug price increases significantly over time is very low. To reduce regulatory burden, AbbVie therefore suggests the current Guidelines could be improved by assessing IRP median[7] and/or HIPC[8] at

[7] IRP = international reference price median taken from PMPRB's basket of seven countries: Germany, France, Italy, Switzerland, Sweden, UK and US

introduction only and keep further international reference pricing investigations on a complaints-based approach.

20. AbbVie supports further work to improve several areas of the Guidelines that would reduce some administrative burden on manufacturers and PMPRB Board Staff, for example:

    - once a year filing;
    - moving patented medicines that have lost market exclusivity to a "complaint-based" approach that would no longer tie them to the Guidelines but only to the Patent Act & Regulations factors;
    - improve the selection of comparators and predictability of the TCC (e.g. improve HDAP review standards, etc.) and;
    - resolve other unintended consequences that creates irrelevant investigations (e.g. find a solution to allow price parity in all markets for line extensions, etc.).

21. That being said, we feel it is premature to address these proposed Guidelines amendments while the PMPRB is fixated on drifting its mandate from excessiveness to affordability.

22. Instead, AbbVie strongly recommends PMPRB perform a thorough gap analysis of current Guidelines, identify the goals PMPRB wishes to fulfill, and consult stakeholders on the changes it wishes to implement. PMPRB should also carefully review, by way of multi-stakeholder working groups with sufficient time to engage in appropriate analysis, proposed changes and draft technical language to prevent any implementation challenges due to lack of clarity on process or scope. Patentees should be allowed a reasonable period of time following Guidelines updates to adjust to the new standards of practice and internal processes.

23. AbbVie cautions PMPRB from implementing "one-size fits all" solutions to Guidelines when trying to address outlier cases, or cases that occur so infrequently they would be better addressed by VCUs or legal proceedings.

24. An example where PMPRB could have undertaken more appropriate stakeholder engagement was in the context of the recent Notice and Comment released in December 2015. This Notice and Comment indicated that PMPRB would be implementing two Guidelines changes prior to completion of a 30 day consultation period, which also ran over Christmas holidays. While PMPRB eventually extended the consultation period and removed retroactive implementation, it also eliminated the implementation of one of the two proposed changes, suggesting that PMPRB had not sufficiently thought through this proposed reform. Efforts could have been more focused and fruitful had PMPRB worked more collaboratively with industry to workshop proposed changes via working groups (see 19). As an additional point, AbbVie notes that the industry is left with many unanswered questions over the enforcement and workability of the most recent Guidelines change with respect to ensuring that list prices are below MAPP in Any Market.

25. AbbVie wishes to highlight the great work PMPRB has been doing related to their reporting mandate, especially in its partnership with CIHI to create the National Prescription Drug Utilization Information System (NPDUIS). This initiative aims *"to provide policy makers and public drug plan managers with*

[8] HIPC = highest international price comparator based on PMPRB's basket of seven countries

critical analyses of price, utilization and cost trends, so that Canada's health care system has more comprehensive and accurate information on how prescription drugs are being used and on sources of cost pressures"[9]. AbbVie believes PMPRB should expand this work to cover the private market, distribution processes, etc. in order to better inform and influence decision-makers on how to develop policies to address system's inefficiencies past the first point of sale.

➢ Conclusion

AbbVie is supportive of the PMPRB ensuring that the Guidelines remain relevant in the current pricing and reimbursement environment, and to continue its important mandate to determine that innovative medicines are not priced excessively. Affordability outcomes cannot be limited to price and need to be balanced along with the other outcomes each jurisdiction is seeking to achieve in terms of healthcare efficiencies and priorities. As such, we do not agree that PMPRB, as a federal regulator, has the mandate or capability to appropriately evaluate questions of affordability or sustainability. As previously mentioned, affordability and sustainability related to the cost of patented medicines are already assessed by multiple actors in the reimbursement ecosystem (HTAs, pCPA, private payers, etc.).

AbbVie asserts that PMPRB should continue to anchor its price evaluations according to therapeutic improvement. To do otherwise would disincentive innovation.

In that context, PMPRB could further simplify its Guidelines, removing some administrative burden, and improve on its reporting capabilities to provide governments with better information to inform health system decision-making.

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 medicines.

We thank PMPRB for the opportunity to respond to the Discussion Paper. In turn, AbbVie encourages the PMPRB to establish a clear, flexible and consultative approach and we look forward to opportunities to collaborate with PMPRB on solutions that would ensure non-excessive pricing in Canada while also driving innovation and investment, particularly in the context of the Innovation Agenda currently being prepared by the Minister of Innovation, Science and Economic Development.

AbbVie looks forward to future opportunities to provide feedback to PMPRB and will continue to engage in future consultation processes. Should the Board have questions or require additional information, please do not hesitate to contact me.

Sincerely,

Stéphane Lassignardie
General Manager
AbbVie Corporation

Encl: Reference table: PMPRB Discussion Paper questions & AbbVie answers

[9] http://www.pmprb-cepmb.gc.ca/en/npduis/about-npduis

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Reference table: PMPRB Discussion Paper questions & AbbVie answers

DP Question	Addressed in Paragraph	DP Question	Addressed in Paragraph
1 – excessiveness	3 to 14; 18-19	**7 – different levels of reg oversight**	17; 20;23
2 – Intl reference	6; 11; 19	**8 – price ceiling revised through time**	19
3 – Section 85 factors	6 to 9; 13-14; 19	**9 – price discrimination**	18
4 – IRP formula	6; 11; 18-19; 21	**10 – Other guidelines changes**	17 to 24
5 – R&D	7	**11 – application of changes**	21 to 24
6 – other factors to address affordability	2 to 14; 17; 22	**12 – legislative changes**	20-21;24-25

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