



**Consultation on (Revised) PMPRB Guidelines:**

**Takeda Canada Submission December 5, 2022**

Takeda Canada Inc. (Takeda) is pleased to provide the comments and recommendations in response to the Government of Canada’s request for submissions regarding the Patented Medicine Prices Review Board’s (“PMPRB”) proposed Guidelines to accompany the recently amended *Patented Medicines Regulations*. The proposed Guidelines were published on October 6, 2022. The Government set the deadline for written submissions as December 5, 2022, with a stated intent of issuing new Guidelines by the end of the year.<sup>1</sup>

Takeda is a patient-focused, values-based, global pharmaceutical company committed to creating innovative therapies through research and development. Established in 1781, Takeda aims to make an impact on patients’ lives by translating science into life-changing medicines, focusing on our core therapeutic areas of neuroscience, gastroenterology, oncology, vaccines, and plasma-derived therapies. As a leader in rare diseases, Takeda brings a unique perspective to this consultation process of the 2022 proposed changes to the PMPRB Guidelines.

Takeda supports the submissions provided by both Innovative Medicines Canada (IMC) and BIOTECanada as part of this consultation process.

Furthermore, Takeda’s submission outlines the following requests:

- 1) The issuance of new Guidelines be suspended to permit meaningful consultation. There is no urgency in adopting new guidelines without sufficient consultation. The PMPRB issued interim guidelines to allow for this transition.
- 2) PMPRB to align the new pricing Guidelines with the federal government and the provinces’ life science and rare disease strategy for Canada and consider their impact on Drugs for Rare Diseases,

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<sup>1</sup> See “[Backgrounder 2022](#)” of the 2022 Proposed updates to the PMPRB Guidelines, under “Background”.

in order to minimize unintended consequences and support the coordination of effort that is needed to improve access to these medicines.

3) Amend Clause 36 of the proposed Guidelines to include blood products: “For Biosimilars, medicines for veterinary use, over-the-counter (OTC) medicines, blood products and vaccines, an investigation may be opened only when a complaint is received.”

4) Establishment of working groups and a meeting with the PMPRB. Takeda formally requests a meeting with PMPRB to discuss our concerns and suggestions.

## CONCERNS & REQUESTS

### **(a) Lack of Meaningful Consultation and Request to Suspend Issuance to Enable Same**

Takeda is responding to the latest proposed PMPRB Guidelines to express its disappointment in the short timeline for response and consideration of submissions, especially considering that they are completely different from the past guidelines, the current interim guidelines, and past draft guidelines. Takeda respectfully submits that the current timelines set by the PMPRB do not meet the duty for consultation with stakeholders as set out in Section 96(5) of the *Patent Act*.<sup>2</sup>

The PMPRB may issue guidelines relating to matters within its jurisdiction;<sup>3</sup> however, the PMPRB is specifically required under the *Patent Act* to consult with stakeholders and the public before any guidelines are issued.<sup>4</sup>

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<sup>2</sup> *Patent Act*, RSC, 1985, c P-4, s 96(5). [*Patent Act*]

<sup>3</sup> *Patent Act*, s 96(4).

<sup>4</sup> *Patent Act*, s 96(5).

When a government body is required to consult, courts have determined that it must be a “meaningful” consultation, i.e., more than paying lip service<sup>5</sup> and done in good faith,<sup>6</sup> not simply receiving and cursorily reviewing submissions, and making minor editorial changes to the Guidelines before their issuance.

As a Federal regulatory body, the PMPRB is subject to the Treasury Board of Canada Secretariat’s “Policy on Regulatory Development” (2018) (the “2018 Treasury Board Policy”<sup>7</sup>), which encompasses the principles and procedures from, among other things, the “Guidelines for Effective Regulatory Consultations” (2007) (the “2007 Treasury Board Guidelines”).<sup>8</sup> The 2007 Treasury Board Guidelines echo what is found in case law regarding duties to consult. It notes at page 1 that; “[A]lthough this guide focusses on regulatory consultation, consultation with interested and affected parties should begin long before the decision to proceed with a regulatory approach is taken. Consultations should be woven into all aspects of policy development, including the discussions as to which instrument (i.e. legislation, regulations, voluntary mechanisms, **guidelines**, or policy) would best meet the public policy objectives”. While the 2007 Treasury Board Guidelines has been replaced with the recent 2018 Treasury Board Policy, the following basic principles that were previously highlighted as being components of a consultation cannot be overlooked or ignored, namely, meaningfulness, openness and balance, transparency, and accountability.<sup>9</sup>

Most notably with regard to “meaningfulness”, the 2007 Treasury Board Guidelines state that “[o]fficials conducting the consultations.... should be impartial with respect to the views expressed and willing to

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<sup>5</sup> *Gardner v Williams Lake (City)*, 2006 BCCA 307 at para.30; *Democracy Watch v. Canada (Attorney General)*, 2018 FC 1290 at paras 82, 101, 102.

<sup>6</sup> *Gardner v Williams Lake (City)*, 2006 BCCA 307 at para.30; *Democracy Watch v. Canada (Attorney General)*, 2018 FC 1290 at paras 82, 101, 102.

<sup>7</sup> Treasury Board of Canada Secretariat’s , “Guidelines for Effective Regulatory Consultations” (2007), at p. 4 : <https://www.tbs-sct.canada.ca/rtrap-parfa/erc-cer/erc-cer-eng.pdf> and also refer to Treasury Board of Canada Secretariat’s, “Policy on Regulatory Development (2018)”: 7.1.2 ([Policy on Regulatory Development - Canada.ca](https://www.tbs-sct.canada.ca/rtrap-parfa/erc-cer/erc-cer-eng.pdf)) and their “Cabinet Directive on Regulation”, 4.1.1 and 5.2.

<sup>8</sup> <https://www.tbs-sct.canada.ca/rtrap-parfa/erc-cer/erc-cer-eng.pdf>

<sup>9</sup> Treasury Board of Canada Secretariat’s, “Guidelines for Effective Regulatory Consultations” (2007), at p. 4 : <https://www.tbs-sct.canada.ca/rtrap-parfa/erc-cer/erc-cer-eng.pdf>

*allow them to influence the final version of the proposed regulations, if appropriate” (emphasis added). Here, the PMPRB has allotted themselves only a handful of weeks to review and consider stakeholders’ submissions, which is not reflective of the PMPRB’s willingness, if any, to allow the submissions to influence the final version of the Guidelines. Further, with respect to “accountability”, the 2007 Treasury Board Guidelines point out that “[a]ccountability also involves ensuring that the consultations take place **over a reasonable period of time, so that participants have sufficient time to submit their views**” (emphasis added). This is yet another principle that is not adequately reflected in this current consultation process. In addition, the 2007 Treasury Board Guidelines note that, “Departments should demonstrate accountability by documenting how the views of stakeholders were considered during the development of the regulations and informing stakeholders of how those views were used. Where stakeholder input could not be reflected in the proposed regulations, officials should be able to outline the reason(s) why”.*

Unfortunately, by the PMPRB’s design, the current timeline runs afoul of the PMPRB’s statutory duty to consult stakeholders and has not allowed itself sufficient time (nor set realistic timelines) to meet these accountability requirements. Given the short timeframe for consultation, the PMPRB has merely *presented* the new draft Guidelines to stakeholders with insufficient time for the PMPRB to carefully review and consider every submission,<sup>10</sup> and allow stakeholders to materially contribute to the new draft Guidelines before their intended issuance on January 1, 2023. Not only is this approach a marked departure from the PMPRB’s own practices, but it does not constitute meaningful consultation or satisfy the PMPRB’s statutory duty to consult.<sup>11</sup>

Notably, the PMPRB’s current approach also contradicts the PMPRB’s own recent and historic comments about the importance of consultation. In the past, the PMPRB sought to ensure that the Guidelines “remained relevant and appropriate to the ever evolving pharmaceutical environment” and went through great lengths to ensure it obtained the “broadest input into the process” of reviewing its

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<sup>10</sup> See “Feedback” tab of the “PMPRB Draft Guidelines Consultation” < <https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html>>.

<sup>11</sup> *Patent Act*, s 96(5).

Guidelines.<sup>12</sup> Given the PMPRB 's commitment to consultation and engagement with all stakeholders, the PMPRB has fallen short of its own goals.

The timeline on its face: 60 days to provide submissions and only 25 days over a holiday season (18 business days, not including any personal PMPRB staff holidays) does not enable a meaningful consultation with stakeholders which the government had noted in guidelines "*should be impartial with respect to the views expressed and willing to allow them to influence the final version of the proposed regulations*".<sup>13</sup> Nor, would this timeline enable the PMPRB to meet their duty of accountability, which has been noted by the government to be part of a meaningful consultation and includes setting realistic timelines to enable stakeholders to provide feedback, and for the PMPRB to consider them and provide reasons as to how they considered them.<sup>14</sup>

The following further supports Takeda's submission that the timelines set by the PMPRB are not adequate:

(i) **It is expected that the PMPRB will receive diverse submissions.** The diversity of the stakeholders listed under Section 96(5) of the *Patent Act* encompass consumer groups, innovative companies and non-innovative (generic/biosimilar) companies. In past consultations, submissions received were roughly a third pharma, a third consumer and advocacy groups and a third from individuals or patients.<sup>15</sup> These groups have historically taken divergent positions on substantive pricing reform issues and adequate time is required for them to be fully considered.

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<sup>12</sup> See page 2 of the PMPRB Newsletter, Volume 14, Issue No. 2 April 2010.

<sup>13</sup> Treasury Board of Canada Secretariat's, "Guidelines for Effective Regulatory Consultations" (2007), at p. 4 : <https://www.tbs-sct.canada.ca/rtrap-parfa/erc-cer/erc-cer-eng.pdf> and also refer to Treasury Board of Canada Secretariat's, "Policy on Regulatory Development (2018)": 7.1.2 ([Policy on Regulatory Development - Canada.ca](#)) and their "Cabinet Directive on Regulation", 4.1.1 and 5.2.

<sup>14</sup> Treasury Board of Canada Secretariat's, "Guidelines for Effective Regulatory Consultations" (2007), at p. 4 and section 4.2.3 : <https://www.tbs-sct.canada.ca/rtrap-parfa/erc-cer/erc-cer-eng.pdf>

<sup>15</sup> See [PMPRB Draft Guidelines Consultation, Backgrounder 2020](#).

(ii) **The consultation period is much shorter than prior PMPRB consultations.** The current consultation period is much shorter than other PMPRB consultations pertaining to new Guidelines (2019 and 2010), which we would submit also proposed a significant overhaul of PMPRB Guidelines. The new draft Guidelines are vastly different from both past guidelines and past draft guidelines, and should be afforded a meaningful degree of consultation.

To illustrate, the last overhaul of the PMPRB's Guidelines started with draft Guidelines first issued on November 21, 2019, with an 85-day period for submissions, ending in February 14, 2020. The PMPRB received more than 120 written submissions and originally intended to issue the Guidelines on June 1, 2020 – that is, *73 business days* after close of written submissions, as compared to the current 18 business day period for the new draft Guidelines. Importantly, during the previous consultations for the prior draft of the Guidelines, the stakeholders were invited to appear in person to make submissions to the PMPRB and working groups were struck,<sup>16</sup> which led to a number of changes in the new Guidelines. Ultimately, it was nearly one year from the initial release of the draft Guidelines in November 2019, to the scheduled issuance of the Guidelines in the Fall 2020. This timing highlights the inadequacy of the current consultation and that the PMPRB's approach is inconsistent with its own past practices.<sup>17</sup>

(iii) **The issues are new and complex and require careful and meaningful consideration by the PMPRB with reasonable and realistic timelines.** It must be acknowledged that the new draft Guidelines are a major overhaul to the current Guidelines and any previously proposed draft Guidelines. The new draft Guidelines raise a new complexity of issues which cannot be meaningfully considered in the current PMPRB consultation period. The anticipated issues include, but are not limited to, the issues

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<sup>16</sup> See: <https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines/draft-guidelines-2019.html#b5>

<sup>17</sup> Another example is the 2010 PMPRB Guidelines. The consultation period for those Guidelines spanned years, with an initial Discussion Paper in March 2005, followed by extensive consultation that culminated in the 2010 Guidelines being issued on January 1, 2010. See page 2 of the PMPRB Newsletter, Volume 14, Issue No. 2 April 2010.

as described in the IMC and BIOTECanada submissions. Of note is the lack of clarity and predictability in the new draft Guidelines departing from the previous voluntary compliance system.

The draft Guidelines is inconsistent with the PMPRB's mandate regarding excessive pricing and the detection of specific instances of patent abuse. The proposed system of investigation triggers appears to be designed to regulate pharmaceutical prices downward, which is an area of exclusive provincial jurisdiction. This runs counter to recent jurisprudence that reinforced the need for the PMPRB to respect and work within its statutory mandate. As such, adequate consultation with stakeholders on the newest draft Guidelines is necessary and mandated by the *Patent Act*.

**Request #1:** For all the foregoing reasons, Takeda herein requests that the issuance of new Guidelines be suspended to permit meaningful consultation. There is no urgency in adopting new guidelines without sufficient consultation. The PMPRB issued interim guidelines to allow for this transition.

**(b) Undue Impact on Drugs for Rare Diseases and Other Innovative Medicines**

Takeda is disappointed that the new draft Guidelines do not adequately address the concerns expressed in Takeda's prior submissions to the PMPRB in relation to past draft guidelines regarding the impact on Drugs for Rare Diseases (DRDs) and other innovative medicines.

Takeda commends the federal government for their investment of \$1 billion over two years, starting in 2022-23, with up to \$500 million per year ongoing towards the National Strategy for Drugs for Rare Disease to address the unique challenges of drugs for rare diseases. This comes as welcomed news, as Canada is one of only a few developed countries without a rare disease strategy.

The proposed PMPRB Guidelines have the potential to weaken an already-arduous process and outweigh positive potential of a rare disease strategy as the proposed changes do not recognize and embrace innovation. Takeda believes that the only way forward requires broad co-ordination across key stakeholders such as government, industry and patient organizations. This would not only reduce current challenges but also encourage the emergence of new treatments.

Lastly, the federal government has introduced various biopharmaceutical strategies aimed at making Canada a more attractive jurisdiction for biopharmaceutical investment. It is critical that the PMPRB ensure that its reform efforts align with the broader governmental strategies and policies. The proposed

Guidelines work against the intent of the initiatives by making Canada a highly uncertain and unpredictable jurisdiction for global investment. This could have a significant impact on research and development, access to clinical trials and attracting and retaining top talent.

**Request #2:** PMPRB to align the new pricing Guidelines with the federal government and the provinces' life science and rare disease strategy for Canada and consider their impact on DRDS, in order to minimize unintended consequences and support the coordination of effort that is needed to improve access to these medicines.

### **(c) Inconsistency in Scrutiny Applied to Blood Products and Vaccines**

Blood products and vaccines share similar procurement methods and should, therefore be treated equally by the PMPRB. Within the new proposed Guidelines, an investigation on a vaccine will only be opened once a complaint is received. The reasoning behind this distinction of vaccines from other medicines is that most vaccines are subject to a public tendering process designed to award the contract to the bidder with the best value proposition. Vaccines are procured by Public Services and Procurement Canada and are therefore considered at low risk for excessive pricing by the PMPRB.

Blood products are typically subjected to a robust tendering process by the Canadian Blood Services and Héma Québec. The procurement system of vaccines and blood products achieve cost savings by consolidating volumes and soliciting competitive bids from suppliers, with the contract awarded for a set period of time to the bidder or bidders who best meet those criteria. As such, blood products typically have similarly low risk of excessive pricing as vaccines and it would be appropriate to have consistent treatment by the PMPRB.

**Request #3:** Amend Clause 36 of the proposed Guidelines to include blood products: “For Biosimilars, medicines for veterinary use, over-the-counter (OTC) medicines, blood products and vaccines, an investigation may be opened only when a complaint is received.”

### **(d) Establishment of Technical Working Groups and Request for Meeting**

From the consultations to-date, the PMPRB has not issued any study or impact analysis of the new draft Guidelines, including on the health care system and the various stakeholders, which includes individual



patients. This reinforces the importance of meaningful consultation to allow stakeholders to educate the PMPRB on stakeholder impact. It is submitted that the PMPRB would be better served by suspending the current consultation; establishing technical working groups to leverage the expertise of the various stakeholders; and re-releasing a revised Guidelines package that is consistent with its mandate.

Once the PMPRB has reviewed the submissions, Takeda would welcome the opportunity to engage with the PMPRB through working groups and other meetings to assist with developing an alternative approach to pricing and access for DRDs. To that end, we seek an opportunity to meet with the PMPRB in a virtual or in-person meeting at its earliest convenience, to discuss how the new draft Guidelines can be revised and operationalized in a way that is consistent with the PMPRB's mandate and core principles, while striking a balance with the interests of stakeholders and Canadian patients. Our knowledge of global best practices would assist the PMPRB as it works to design a set of innovative and inclusive solutions for the pharmaceutical industry and Canadians. In particular, Takeda would be able to assist the PMPRB with developing a clearer approach to pricing and access for DRDs, which represent the most fragile aspect of the Canadian pharmaceutical market.

**Request #4:** Establishment of working groups and a meeting with the PMPRB. Through this written submission, Takeda Canada formally requests a meeting with PMPRB to discuss our concerns and suggestions. Please connect with the Takeda contact on your record for further arrangements.

**Legal Disclaimer:** This submission and any other engagement in consultations with the PMPRB regarding the Patented Medicines Regulations, as amended, and related Draft Guidelines are without prejudice and are not intended and should not be interpreted as supporting the amendments to the PMPRB Regulations or Draft Guidelines. Takeda reserves its full legal rights to oppose any aspect of the *Patented Medicines Regulations* and related Guidelines.

## **Final Thoughts**

Takeda believes the PMPRB, like many other health policy stakeholders, shares our goal of providing Canadians with effective therapies in a timely and accessible manner. However, we feel some of these proposed changes are out of alignment with other pan-Canadian efforts currently underway aimed at improving patient access to DRDs. We also feel that these changes could undermine the attractiveness

of Canada as a destination for global research and product launches.

While we thank the PMPRB for the opportunity to share our concern, we encourage the PMPRB to extend the timeline of the interim Guidelines in order to provide a meaningful consultation. The proposed Guidelines have enormous consequences for Canadian patients as well as the broader life science ecosystem. We owe it to Canadians to have thorough and thoughtful engagement, to address their needs properly.