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Via Online Portal Submission

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Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa ON, K1P 1C1

Dear PMPRB Staff,

Introduction:
Incyte Biosciences Canada Corporation appreciates the opportunity to provide input as a stakeholder in response to the June 26, 2024, Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines.

About Incyte

Incyte is a global biopharmaceutical company focused on the discovery, development, and commercialization of proprietary therapeutics. The company had its start in 2002 and has grown globally to a team of more than 2,400 employees, with eight approved products, twenty-two clinical candidates and seventeen molecular targets. Our company is dedicated to advancing innovative therapies to address unmet medical needs, particularly in the field of oncology, hematology, inflammatory and autoimmune diseases.

Incyte began its operations in Canada in the spring of 2020 with one employee, and now proudly employs forty-four people.

Since opening its doors in Canada, Incyte has launched two new and innovative products in Canada: MINJUVI® (tafasitamab) and PEMAZYRE® (pemigatinib).[1] Incyte has also sponsored sixty-two clinical trials in Canada,[2] of which thirty-nine are ongoing.

Incyte Biosciences Canada Corporation is committed to the development and commercialization of novel medicines that have the potential to improve patient outcomes and enhance the standard of care. As a stakeholder in the Canadian healthcare ecosystem, we acknowledge the importance of balancing affordability with the need for continued investment in research and development.

Key Consideration - Patient Access to innovation:

The guidelines should prioritize patient access to innovative therapies, ensuring adoption of innovative medicines in the Canadian healthcare system as in other G7 nations and in many OECD comparator nations.

Market Dynamics and predictability: It is essential to consider the unique dynamics of the Canadian pharmaceutical market, including the impact of small patient populations and the necessity for companies to recoup investments in research and development through predictable pricing regulation.

Efficiency: with the July 1, 2022 adoption of PMPRB11 in the Guidelines, the domestic therapeutic class comparisons (dTCC) are no longer relevant as they may include inappropriate comparisons to generic medicines and unpredictable reassessments of the dTCC over time. A simple and streamlined approach to implement the PMPRB11 international schedule would be best for all stakeholders and consistent with the PMPRB's non-excessive pricing mandate.

Recommendations

We believe that the following positions will not only support our efforts but also ensure that Canadians have access to the latest and most effective treatments.

1. Price Level within PMPRB 11 (Topic 1):
We advocate for the use of the highest international price (HIP, i.e. **Option 2**) as the benchmark for price reviews. A pricing model that reflects the HIP encourages investment in pharmaceutical innovation and ensures that companies like ours can continue to fund cutting-edge research. This, in turn, leads to the development of new medicines that can address the unmet medical needs of Canadians.

2. Time Frame for International Price Comparison (IPC) Identification of Existing Medicines (Topic 2):
A three-year time frame (i.e. **Option 3**) for assessing Existing Medicines whose list prices are above the IPC identification criteria provides a balanced approach that considers the natural fluctuations in the market as well as the opportunity to manage supply-chain to allow for price changes. This period allows for a more stable and predictable environment, which is essential for long-term investment in research and development.

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[1] PEMAZYRE® (pemigatinib) is approved for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma (CCA) with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. CCA is a rare cancer: https://www.newswire.ca/news-releases/incyte-announces-health-canada-conditional-approval-of-pemazyre-r-pemigatinib-as-first-targeted-treatment-for-adults-with-previously-treated-unresectable-locally-advanced-or-metastatic-cholangiocarcinoma-836731805.html.
MINJUVI® (tafasitamab) a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody, in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, who are not eligible for autologous stem cell transplant (ASCT): https://www.newswire.ca/news-releases/incyte-announces-health-canada-approval-of-minjuvi-r-tafasitamab-in-combination-with-lenalidomide-for-the-treatment-of-adults-with-relapsed-or-refractory-diffuse-large-b-cell-lymphoma-886719371.html

[2] Health Canada, Clinical Trials Database, https://health-products.canada.ca/ctdb-bdec/search-recherche.do

3. In-Depth Review based on Consumer Price Index (CPI) Increase Criteria (Topic 3):
The option to review cumulative CPI-increases over two years (i.e. **Option 2**) in the determination of an in-depth review allows the time for any price-corrections required to ensure compliance. Additionally, we agree with BioteCanada's position that allowable CPI-based list price increases should not trigger in in-depth review, and that an annual price review with an international price comparison is no longer relevant following initial price review at product introduction.

4. The individuals/groups permitted to submit a complaint (Topic 4):
Incyte proposes that the Federal Minister of Health, **alone**, is the only relevant office-holder responsible for the PMPRB (i.e. **modified Option 1**). Currently, the Provincial Ministers of Health continue to implement healthcare including listing innovative medicines where Canadians wait an average of 25 months following a product's Health Canada approval for its inclusion on Provincial Drug Program Formularies.

7. Future Role of HDAP (Topic 7):
As the current guideline for an 'in-depth review' does not specify exactly how PMPRB staff will conduct such a review, and if required by such a new set of guidelines for technical/experiential input, then there is a role for an ad-hoc Human Drug Advisory Panel (HDAP) to convene for a clinical evaluation (i.e. **Option 1**). In such a circumstance, there must be sufficient notification and time allowed for a manufacturer to prepare and submit a dossier (as per prior PMPRB guidelines) for evaluation of the product.

Conclusion

Incyte Biosciences Canada is dedicated to advancing healthcare through groundbreaking research and development. Our positions outlined above align with our commitment to innovation and our goal of bringing new and potentially life-changing medicines to Canadian patients. We look forward to a regulatory framework that supports the introduction of new medicines to the Canadian healthcare system.

Thank you for considering our input.

Yours Sincerely,

Sam Stankovic, Head of Market Access
Incyte Biosciences Canada Corporation

cc:
Christine Lennon
Vice-President and General Manager
Incyte Biosciences Canada Corporation