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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 November 2023 Scoping paper for the consultations on the Board's 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 to a team of more than 2,400 employees, with eight approved products, 22 clinical candidates and 17 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 44 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 62 clinical trials in Canada,[2] of which 39 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 Considerations

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

Efficient Monitoring of Prices without Price Setting: Incyte Biosciences Canada Corporation recommends retaining only those elements of the 2010 Guidelines that promote fair market access and encourage innovation. Specific provisions should be included in the guidelines, supporting the efficient review of compliance within the international price reference basket (i.e., equal to or lower than the highest international price – HIP - of PMPRB11 markets) within the introductory period - within 3 years of product launch in Canada or when five PMPRB11 markets have pricing information available, whichever comes first. Annual price monitoring, allowing for CPI increases, is possible using existing mechanisms.

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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.incytebiosciences.ca/pdf/pemazyre-product-monograph-english.pdf, accessed December 18, 2023
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.incytebiosciences.ca/pdf/minjuvi-product-monograph-english.pdf, accessed December 18, 2023

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

The assessment of a novel, patented product through a therapeutic class comparison in situations where there is no international price comparisons available within the timeframe noted above (i.e. within 3 years of product launch in Canada or when five PMPRB11 markets have pricing information available, whichever comes first) should consider the unique characteristics of the disease for which the drug is being launched, and the potential impact of pricing decisions on investment in research and development in that therapeutic space.

Transition to PMPRB11 – New versus Existing Medicines: Products available in Canada prior to July 1, 2022, that were compliant with the guidelines at the time (i.e., within the range of PMPRB7 prices) should be grandfathered from new Guideline requirements and should immediately be considered "reviewed" by PMPRB, meaning that such prices will not be subject to further price review by PMPRB through any new guidelines.

Price Reviews during Product Life Cycle: Prices of patented medicines should not be 're-benched' after introduction. International reference prices become less relevant over the course of the product's life cycle in Canada, as there are significant differences in how other markets function regarding pricing and access. Furthermore, re-benching introduces significant unpredictability for patentees and complexity to the system, including existing agreements with wholesalers, retailers, and payers, and will have the impact of becoming administratively burdensome for all stakeholders.

Investigations and Referral to Hearing: Incyte Biosciences Canada Corporation supports a predictable Guideline that define price tests to be applied for medicines under PMPRB jurisdiction. If a price appears to exceed the ceiling set out by the price tests (as determined by these new guidelines), then an investigation could be undertaken if warranted, to determine if the test was being appropriately applied. Guidelines should set out sufficient details to ensure the principles of fairness, transparency, predictability, efficiency, and voluntary compliance.

Conclusion

Incyte Biosciences Canada Corporation looks forward to collaborating with the PMPRB to ensure that the recommendations herein address the scoping document appropriately to address the complexities of the patented pharmaceutical landscape. We appreciate the opportunity to contribute to the development of guidelines that prioritizes the health and well-being of Canadians while balancing the interests of all stakeholders affected by PMPRB activities.

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