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Via Online Portal Submission

August 21, 2023

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

Dear PMPRB Staff,

This submission is made on behalf of Incyte Biosciences Canada Corporation ("Incyte Canada") in response to the 2023 proposed Amendment to the Interim Guidance re: New Medicines (the "2023 proposed Amendment to the Interim Guidance").

For the reasons set out below, Incyte Canada requests that:

- The 2023 proposed Amendment to the Interim Guidance be modified to read (changes in italic and underlined):,

  "Medicines without a MAPP (Maximum Average Potential Price) or NEAP (Non-Excessive Average Price) as of July 1, 2022, are considered reviewed if their list price is *within, or below the range of* international price*s* for the PMPRB11 countries."
- PMPRB engage in a meaningful consultation with industry to create new Guidelines that provide a high degree of certainty in the pricing guidance for the assessment of list prices in Canada, and that recognize innovation.

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 2,000 employees, with 7 approved products, 25 clinical candidates and 20 molecular targets.

Incyte began its operations in Canada in the spring of 2020 with one employee, and now proudly employs 43 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 56 clinical trials,[2] of which 38 are ongoing.

The Interim Guidance

Incyte Canada, as a member of Innovative Medicines Canada ("IMC") has reviewed the submission of IMC and fully supports the comments presented therein. However, as a small biopharmaceutical company with a product portfolio that includes treatments for rare diseases, we have very specific concerns regarding the 2023 proposed Amendment to the Interim Guidance especially as it relates to New Medicines without a Maximum Average Potential Price (MAPP) or projected NEAP as of July 1, 2022 ("New Medicines").

Lack of Certainty

The Fall 2022 Proposed Guidelines, continue to provide uncertainty for New Medicines as to: (i) when the price reviews will be conducted by PMPRB staff; and (ii) the threshold for what list price may be considered excessive.

Under the 2023 proposed Amendment to the Interim Guidance , New Medicines with list prices above the PMPRB median, are considered "under review" until new guidelines are in place. In this interim period, as long as the rationale supporting a New Medicine's price is within the PMPRB11 basket, the price should be deemed non-excessive and they should be considered as reviewed. This is essential to ensure patentees can continue to launch products in absence of any pricing guidance.

The uncertainty in the 2023 proposed Amendment to the Interim Guidance is particularly onerous for a company such as Incyte. Incyte Canada was operating in Canada for a period of almost 18 months before Health Canada approved a product for market. Typically, a company starting operations in Canada will spend 2 years or more working toward a product approval, during which time no revenue is generated. It is therefore critical to have certainty regarding pricing at launch so that new drugs can be made available in Canada without the risk of a lengthy PMPRB investigation.

Rights holders should be able to predict with a high degree of certainty whether a list price will be found non-excessive so that they can properly budget and plan for the launch of a new and innovative treatment. Clear and objective interim guidance is needed to allow companies confidence in setting a non-excessive list price at the outset, while working within a clear framework of price regulation until the new guidelines are in place.

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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

Concluding Remarks

Incyte Canada aims to comply with the excessive pricing provisions of the *Patented Medicines Regulations Act*. However, the 2023 proposed Amendment to the Interim Guidance removes our ability to predict when or if a list price will be considered non-excessive by Staff.

For all of the above reasons, Incyte Canada requests that the 2023 proposed Amendment to the Interim Guidance provide some certainty for New Medicines by modifying the wording, as proposed above, to provide certainty in pricing compliance, and so as to continue to focus effort on developing new Guidelines that are clear, predictable and consistent with the objectives of the *Patent Act.*

Yours Sincerely,

Sam Stankovic, Head of Market Access
Incyte Biosciences Canada Corporation

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