Incyte Biosciences Canada Corporation
6500 Trans Canada Hwy, Suite 400
Pointe Claire, Quebec, H9R 0A5
Canada
Email IncyteCanadaInquiry@incyte.com
Web www.incyte.com

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,

This submission is made on behalf of Incyte Biosciences Canada Corporation ("Incyte Canada") in response to the 2022 Proposed updates to the PMRPRB Guidelines ("Draft Guidelines").

For the reasons set out below, Incyte Canada requests:

- The Draft Guidelines be set aside and not implemented; and
- PMPRB engage in a robust consultation with industry to create new Guidelines that provide a high degree of certainty in the investigation process and in the assessment of whether a list price is excessive, 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 opened its first site in Canada in the spring of 2020 with one employee, and now proudly employs 25 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 41 clinical trials,[2] of which 19 are ongoing.

The Draft Guidelines

Incyte Canada has reviewed the submissions of BIOTECanada and Innovative Medicines Canada, 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 Draft Guidelines:

1. Lack of Certainty

The Draft Guidelines provide no certainty as to: (i) when an investigation will be opened; (ii) if opened, whether a list price may be considered excessive; or (iii) if closed, a medicine may still be subject to investigation.

Under the Draft Guidelines, the opening of an investigation is entirely discretionary. The Board Staff "***may***" open an investigation into the price of a patented medicine at any time (see para. 32). The Draft Guidelines always permit an investigation to be opened, creating business risk and uncertainty for companies like Incyte Canada.

The Guidelines provide no clear and objective approach for assessing whether a price is excessive and thus constituting "patent abuse".[3] The criteria for opening an investigation (see paras. 33-35) are only one factor the Staff may consider in its review (see para. 41). Rights holders should be provided with a clear framework so that they can launch their drug with a list price that is within the Guidelines.

The re-opening of a closed investigation, or a further investigation, is also subject to the same discretionary approach (see paras. 41 and 42) and thus contributes to further uncertainty.

The Draft Guidelines therefore allow a subjective case-by-case approach to assessing the list price of a patented medicine, without any clear guidance to rights holders seeking to sell their drugs in Canada at a price that is within the Guidelines.

The uncertainty in the Draft Guidelines 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

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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.

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

[3] See, for instance, *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)* 2021 FCA 157

treatment. Clear and objective guidance is needed to allow companies confidence in setting a non-excessive list price at the outset.

2. Rare Diseases

The uncertainty created by the Draft Guidelines is heightened for innovative drugs for rare diseases.

According to the Draft Guidelines:

> 41. …Medicines which are ***perceived*** by Staff as being at ***high risk of excessive pricing*** are most likely to proceed to a hearing ***or*** result in an undertaking…As always, for reasons of administrative efficiency and resource optimization, Staff will focus its efforts on achieving an outcome that ***avoids*** the need for litigation.

Drugs for rare diseases often have a high perceived cost, suggesting that these drugs—regardless of the criteria in paras. 33-35—will **always** be subject to an investigation and likely a hearing or undertaking. Further, to achieve an outcome that avoids the need for litigation, there may be a heightened pressure on Board Staff to bring the investigation to a close by way of an undertaking.

Incyte is a manufacturer of a drug for a rare disease and has a pipeline that includes further new and innovative drugs for other rare diseases. The proposed approach in the Draft Guidelines is therefore of concern to Incyte Canada. This approach will not allow rights holders to predict with any degree of certainty whether a list price will be within guidelines and will always result in a costly investigation for patented medicines for rare diseases.

The heightened pricing uncertainty for patented medicines for rare diseases may create a barrier to market access. For drugs treating rare diseases, it is all the more important to have clear and objective guidance enabling companies to set non-excessive list prices at the outset, and not risk unpredictable pricing investigations.

3. Innovation is relevant

The Draft Guidelines no longer include any pricing factors that consider innovation, unlike the approach to date where the level of therapeutic improvement was relevant.

Many drugs treating rare diseases are breakthrough scientific achievements, improvements for which there is no comparable therapy. For instance, PEMAZYRE® (pemigatinib) is the only marketed treatment for CCA target FGFR gene mutations in Canada.[4]

Any guidance that does not consider innovation is missing an important factor in assessing whether a list price is non-excessive in accordance with the pricing provisions in the *Patent Act*.

Concluding Remarks

Incyte Canada aims to comply with the pricing provisions of the *Patent Act*. However, the Draft Guidelines removes our ability to predict whether a proposed list price will be considered non-excessive by Staff. This is particularly true for innovative drugs treating rare diseases which, based on the Draft Guidelines, will necessarily be subject to an investigation and likely a hearing or undertaking. Incyte is

[4] TRUSELTIQ™ (infigratinib) has been approved but is not marketed according to Health Canada's Drug Product Database, see https://health-products.canada.ca/dpd-bdpp/dispatch-repartition.do.

proud to be recognized as an innovative biopharmaceutical company, and the Draft Guidelines lack adequate recognition of innovation.

For all of the above reasons, Incyte Canada requests that the Draft Guidelines be set aside and revised Guidelines that are clear and predictable be developed that are consistent with the objectives of the *Patent Act* after robust consultation with stakeholders.

Yours Sincerely,

Sam Stankovic, Head of Market Access
Incyte Biosciences Canada

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