2023 PMPRB Consultation: Scoping Paper for the consultations on the Board's Guidelines
LEO Pharma Inc. Submission

Dermatology beyond the skin

LEO Pharma Inc
3389 Steeles Avenue East
Suite 110
Toronto, ON
M2H 3S8

Main +1 905 886 9822
+1 800 668 7234
(toll-free, Canada only)

www.leo-pharma.ca

December 19, 2023

Submitted via the PMPRB Website: Consultation Portal

Dear PMPRB Board Members,

Thank you for the opportunity to provide input on the Scoping Paper for the consultations on the Board's Guidelines. This submission builds on our previous submissions throughout this process and is complementary to that of Innovative Medicines Canada (IMC).

LEO Pharma A/S is a global leader in medical dermatology with a mission of helping people achieve healthy skin. The company is based in Denmark and is privately owned by the LEO Foundation, focusing on advancing science in Dermatology. LEO Pharma has a robust R&D pipeline, a wide range of therapies and a pioneering spirit. Globally, LEO Pharma invests 23% of revenue in R&D. LEO Pharma actively promotes growth in innovation and collaboration in the Canadian life science sector.

Consistent with IMC's position, LEO Pharma believes that the PMPRB's mandate must be consistent with the recent appellate court decisions which provide interpretation that the regime is to be focused on patent abuse and excessive price.[1,2] The Guidelines must be transparent and streamlined, with price tests that provides patentees predictability over the patent life of a product.

More specifically, in relation to the questions outlined in the scoping paper, LEO Pharma would like to express the following sentiments:

Question 1.1: What elements of the 2010 Guidelines should be retained? Which ones and why?

As a guiding principle, we believe that PMPRB must focus on price tests and guidance that is appropriate for the new basket of PMPRB11 countries and that is consistent with the mandate of PMPRB (re: excessive pricing).

The introduction of the PMPRB11 basket of countries resulted in the removal of two higher-priced jurisdictions and the inclusion of several lower-priced countries. This change led to a significant decrease in the ceiling price of new medicines. Considering the mandate of the PMPRB is not to engage in general price setting, but rather to regulate and ensure prices remain non-excessive, it is not appropriate to reintroduce elements from the 2010 guidelines, such as the Median International Price (MIP) as a reference point for future Guidelines as it would further constrain

prices. LEO Pharma suggests the PMPRB adopt the Highest International Price (HIP) in replacement of the MIP.

Moreover, elements from the 2010 Guidelines relating to the scientific review may not be relevant or necessary in future Guidelines given the extensive clinical evidence assessment that is conducted at various points in time in the uniquely complex Canadian drug review and approval process (e.g., Health Canada, CADTH, INESSS, some Provincial/Territorial advisory body and the newly created Canadian Drug Agency). Importantly, the *Patent Act* does not stipulate that PMPRB conducts detailed assessments of clinical evidence, nor does it stipulate that PMPRB conducts scientific review over time.

CPI adjustments should be retained in the new Guidelines as it is a factor rooted in the *Patent Act* and is a simple and pragmatic measure that PMPRB may utilize to assess compliance of old and new medicines alike (E.g., grandfathering old medicines and monitoring new medicines moving forward).

Question 1.2: Should new Guidelines continue to categorize medicines by therapeutic class comparator characteristics such as the Level of Therapeutic Improvement?

No, please see 3rd paragraph in the response above for the rationale.

Question 1.4: If international prices are used as the initial triage measure for commencing investigations, what price levels within the PMPRB11 should be used as the triage measure? (e.g., HIP or MIP?)

The Highest International Price (HIP) should be used for both introductory price setting and for triaging for investigations as the mandate of the PMPRB is to ensure prices are *non-excessive*; using the highest, rather than the median, is consistent to definition of “non-excessive”. Please see 2nd paragraph of Question 1.1 above for rationale.

With respect to the definition of “initial triage measure” mentioned above, LEO Pharma would like to seek clarity from PMPRB on this definition as it suggests further review could occur beyond initial assessment. The price ceilings should be predictable whereby no re-assessments or re-benchmarking occur over time provided the rights holder does not increase its price by more than the consumer price index. Re-benchmarking would be counterproductive to creating predictable and streamlined guidelines.

Question 2.1: Should the Guidelines distinguish between medicines that existed as of July 2022 (existing medicines) and medicines introduced afterwards (new medicines)?

Yes, in that the Guidelines should deem all existing medicines (i.e., introduced prior to the new Guidelines finalization) as “grandfathered”, including all extensions of these existing medicines, with the rationale that these medicines were compliant with the applicable regulation and Guidelines of the day. (i.e., These “grandfathered” medicines would be allowed to retain their price and would not be subject to further review.)

In closing, we look forward to engaging in next steps with PMPRB which should include formation of a technical working group to assess elements in greater granularity to develop a set of clear, streamlined, and predictable draft Guidelines. The technical working group should be composed of individuals who are well-versed in the technicalities of data filing, price tests, and pricing frameworks. As a global leader in medical dermatology, PMPRB Guidelines play a critical role in our operations as it informs pricing decisions, launch timelines, and investment decisions in Canada. We are confident that through collaboration and careful analysis, we can achieve a set

of predictable and clear Guidelines that benefit patients and ensure that Canadian patients can continue to access the medicines they need.

Thank you for considering our input on the Scoping Paper for the consultations on the Board's guidelines.

Sincerely,

Jill Archibald

Jill Archibald
President and CEO, LEO Pharma Canada

References

1. CanLII. Merck Canada inc. c. Procureur général du Canada, 2022 QCCA 240 https://www.canlii.org/en/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?autocompleteStr=merck%20canada%20qcca%20240&autocompletePos=1. Published 2022. Accessed.
2. Federal Courts Reports. Alexion Pharmaceuticals Inc. v. Canada (Attorney General). https://reports.fja-cmf.gc.ca/fja-cmf/j/en/item/521055/index.do. Published 2021. Accessed.

Dermatology beyond the skin