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Patented Medicine Prices Review Board
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Thank you for the opportunity to provide input into the Patented Medicines Prices Review Board's ("PMPRB") *Scoping Paper for the consultations on the Guidelines* published on November 10, 2023. Below, please find Hoffmann-La Roche Limited's ("Roche") response to the questions posed by the PMPRB Scoping Paper to aid in its consultation on the Board's Guidelines.

At Roche Canada, patients and science are at the heart of everything we do - and our commitment is as strong today as it was on the first day of our Canadian journey in 1931. We strive to make quality healthcare accessible to everyone while delivering meaningful benefits for patients and a sustainable healthcare system. With our combined strength in pharmaceuticals and in-vitro diagnostics, we're driving personalized healthcare forward.

Our focus is on innovative medicines and our commitment to science and patients is long-term. In order to deliver true innovation, we must explore new research avenues and take significant risks. Our success not only allows us to sustain our investments in research and development (R&D), but it also empowers us to drive forward with the development of groundbreaking medical innovations for the future. Roche is a leading R&D investor and the leading pharmaceutical company in R&D spend. In 2022, globally we invested CHF 14.1 billion in research and development.

Roche Canada is hopeful that the final guidelines will not impede our ability to bring the latest innovations to Canadians. We remain committed to working with all relevant stakeholders to build a system that is not only fair, but effective and efficient.

Theme 1: Efficient Monitoring of Prices without Price Setting.

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

- The 2010 Guidelines were anchored in principles of fairness, transparency, openness and predictability. To move forward, we need to refocus our discussions on these core principles. Guidelines that prioritize predictability, transparency, and efficiency are crucial for patentees.

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

- Roche believes that innovation should be recognized and rewarded; therefore, if the dTCC were to be utilized, it should be considered in the context of the additional value that the new medicine brings to patients, caregivers, and the broader healthcare system.

- However, it is challenging to offer our feedback on this one element in isolation; the manner and context in which it is applied is critical to its proper implementation. This issue

should be the subject of a technical working group.

1.3. Should the Board accord more weight to one or more of the factors set out in s. 85 of the Act in designing the Guidelines?

- The Canadian system of international price referencing (IRP) has been in effect for more than three decades. With an updated international reference basket (i.e. PMPRB11), IRP should be the primary measure of price excessiveness for new medicines. The balance of section 85 factors should be used as secondary considerations where the highest international price (HIP) is exceeded.

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?)

- PMPRB's Guidelines must be supported by a clear rationale grounded in its excessive price mandate. For this reason, Roche supports a review of list prices at introduction, whereby a list price of a medicine in Canada will not be considered *excessive* as long as it is lower than the HIP of the same medicine in PMPRB11 reference countries. Furthermore, rather than an initial triage, we suggest that the HIP of the PMPRB11 be the primary threshold in order to simplify the process and provide predictability.

- MIP is no longer appropriate given the modified basket of comparator countries, which now includes only countries that control drug prices. As the Federal Court of Appeal held in 2021, "[o]ver and over again, authorities have stressed that the excessive pricing provisions in the *Patent Act* are directed at controlling patent abuse, not reasonable pricing, price-regulation, or consumer protection at large", absent which, "they would be constitutionally suspect".[1]

1.5. How should the PMPRB conduct an initial review and monitor the prices of patented medicines that have few or no international prices?

- As noted above, IRP should be the primary measure of price excessiveness for new medicines at launch (i.e. HIP of the PMPRB11). The IRP test should be conclusive at the earlier of:
    - 3 years after First Sale of the new medicine in Canada, or
    - IRP search yields a price in at least 5/11 PMPRB11 countries
- If, at the end of 3 years, there are no internationally visible prices in PMPRB11 countries, Roche supports assessment based on other Section 85 factors where PMPRB's methodology is consistent with the principles that guide the analysis. The manner in which the other section 85 factors should be implemented should be the subject of a technical working group.

[1] *Alexion Pharmaceuticals Inc. v Canada (Attorney General)*, 2021 FCA 157 at ¶49

1.6. Would an expedited price review (e.g., within 90 days after initial Form 2 submission) of a new medicine based solely on international prices being below the MIP accelerate introduction of innovative medicines? How soon after an expedited review should a full price review take place?

- We support a simple and predictable price review that takes place at launch using a threshold that is based on PMPRB's excessive pricing mandate. A two-stage process that delays a conclusive assessment will introduce uncertainty that deters rapid Canadian access.

<u>Theme 2: Transition to PMPRB11 - New versus Existing Medicines.</u>

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

AND

2.2. What approach should the Board take with respect to existing medicines with prices above the HIP of the PMPRB11? Should the Board review these prices, and if so, how soon?

- Medicines that were first sold before the final implementation date of the new guidelines should be considered 'legacy' medicines and subject to the guidelines and regulations that applied at the time they were introduced. The investment, commercial, and funding decisions for these medicines were made with the rules in place at the time of launch. Preserving these medicines as 'legacy' ensures that patient access can continue without any disruptions and minimize any potential risks. Furthermore, many of these products have commercial agreements in place with public and private payers, as well as downstream market participants, and a change in pricing may affect these agreements.
- Therefore:
    - For medicines introduced prior to July 2022 (existing medicines): if existing medicines were sold at or below the non-excessive average pricing as projected in the most recent compliance letter prior to the implementation of new Guidelines, and if their price increases do not exceed the Consumer Price Index (CPI), they should be considered non-excessive.
    - For medicines introduced between July 2022 and the finalization of the new Guidelines: if those medicines were sold at or below the HIP of PMPRB 11, and if their price increase does not exceed the Consumer Price Index, they should be considered non-excessive.
    - For medicines introduced after the finalization of the new Guidelines: the new Guidelines should apply.

<u>Theme 3: Price Reviews during Product Life Cycle.</u>

3.1. How often should price reviews be conducted? (1-5 years). Should they be different

for small molecules (average 10-year exclusivity period) versus biologics (average 20+ year exclusivity period)? Should they be different for medicines for rare diseases?

- A framework that is predictable and efficient is critical to the health of the life sciences sector in Canada. Therefore, Roche proposes the following:
    - Conduct a price review at introduction: the list price of a new medicine in Canada will not be considered *excessive* as long as it is lower than the highest international price of the same medicine in PMPRB11 reference countries.

      AND

    - Monitor annually thereafter: the list price of a medicine in Canada will not be considered *excessive* if it increases within the range of 3-year lagged Consumer Price Index (CPI).
- We see no basis to distinguish between small and large molecules in the number of price reviews. The forms of protection for exclusivity are the same for both small molecules and biologics in Canada, i.e. data protection of 8 years (plus 6 months extension) applies to both, and a patent term of 20 years from filing applies to patents in general.

3.2. What criteria besides time should be used to trigger a price review? Approval of a significant new indication? Significant change to the therapeutic class comparators? Availability of new/stronger evidence related to benefit vis-à-vis therapeutic class comparators? Departure from identified pricing thresholds?

- A price review should be triggered at introduction where the list price exceeds HIP, or later in the life cycle where the permitted CPI adjustments are exceeded.
- Roche does not support re-benching or re-assessing the "excessiveness" of an ex-factory list price in Canada based on changes to the therapeutic class comparators, new evidence, approval of a new indication or what occurs with prices internationally.
    - Re-benching introduces significant unpredictability for patentees and complexity to the system. For Canadian patentees, having a predictable list price at launch is important for determining the commercial viability of new medicines. This predictability is also required throughout the product lifecycle. PMPRB must not introduce uncertainty in the middle of the medicine's lifecycle by triggering a re-assessment. This will negatively impact Roche's ability to provide comprehensive patient support and may interfere with Roche's ability to sustain existing listing agreements.
    - IRP of ex-factory prices become less and less relevant over the course of the product's life cycle. Canada's pricing and access environment is markedly different from other PMPRB11 markets, and international price referencing is most relevant when it is done at introduction. Re-benching using IRP can result in unreasonable conclusions due to differences in market dynamics, different access and pricing policies, foreign exchange rate fluctuations and PMPRB11 countries launching or discontinuing a medicine.

3.3. Should the relative weighting given to different section 85 (Patent Act) factors change over the lifecycle of a medicine?

- Roche supports making IRP the primary test that underpins a simple, predictable and efficient voluntary compliance regime. If a list price of a medicine is above the highest international price in PMPRB11 at introduction, assessment of the list price against other section 85 factors is appropriate. We recommend this topic be explored through a technical working group.

3.4. How should the PMPRB treat the allowable Consumer Price Index increase in the context where international list prices are decreasing?

- As mentioned in Question 3.2, IRP of ex-factory prices become less and less relevant over the course of the product's life cycle: Canada's pricing and access environment is markedly different from other PMPRB11 markets and international price referencing is most relevant when it is done at introduction.

3.5. What is the ideal timing for scientific review and therapeutic comparator identification? At what price review stage(s) should scientific review be applied?

- See our response to Question 1.2. on this issue. We believe a scientific review at the PMPRB should only occur in exceptional cases.

Theme 4: Investigations and Referral to Hearing

4.1. Are the criteria published in the 2010 Guidelines for commencing an investigation still appropriate (assuming adjustment to PMPRB11)?

AND

4.2. How much detail should the Guidelines set out regarding what happens once an investigation is opened?

AND

4.3. Should the PMPRB continue to use Undertakings as an investigation closure mechanism?

- The proper procedures and content of investigations and referrals to hearings will depend on the steps that precede them. Therefore, we cannot provide specific comments on this theme. Roche is generally in favour of retaining Voluntary Compliance Undertakings (VCU) as one available means of negotiating a mutually agreeable resolution to an investigation.

Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives.

5.1. What efficiencies could be gained by coordinating decisions and timelines of the PMPRB with those of the Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et services sociaux (INESSS) and pan-Canadian Pharmaceutical Alliance (pCPA) or insurers (public and private)?

AND

5.2. How can the PMPRB optimize its presence within the Canadian bio/pharmaceutical

ecosystem to support a whole of government approach to issues relating to patented medicines?

- Canadians wait two years, on average, for access to new medicines through public drug plans following Health Canada approval, which is nearly *double* the average time for access amongst 20 peer OECD countries. While Roche supports coordination between Health Canada, HTA agencies, pCPA and insurers to reduce the time it takes for patients to access medicines, the PMPRB works in a separate and parallel workstream; therefore an efficient and whole-of-government approach would be one where each agency optimizes their clear mandate. For the PMPRB, this mandate is one of excessive price.

Conclusion

We hope PMPRB finds our submission helpful in building the full set of new Guidelines, in a predictable, transparent and efficient framework to evaluate the price and value of medicine in Canada. We believe in working collaboratively to find solutions to achieve a future where the best healthcare innovations are embraced by and delivered within a sustainable and resilient healthcare system.

Regards,

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