September 11, 2024

This submission is made on behalf of Rhythm Pharmaceuticals Canada Inc. in response to the July 2024 Discussion Guide entitled Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines.

Rhythm is a new rights holder in Canada, having launched our first product and indication in July 2023. As a new rights holder in Canada, we have concerns with the PMPRB's proposed guidelines and potential implementation of these guidelines. Generally, we find the proposed guidelines to be complex, and subject to a broad range of interpretation and thus, a high level of uncertainty for new rights holders such as Rhythm. In greater specificity, our concerns are related to the following topics:

1. **Time to review a new medicine.**
2. **Application of foreign exchange rates as related to the PMPRB basket of 11 comparator countries at initial reporting and during annual reviews.**
3. **The 6.1.1 Price level within the PMPRB11 to be used in the initial and post-initial price review (section 6.1.1 of the Discussion Guide).**

We would like to outline the details regarding our concerns pertaining to the above noted three topics.

1. **Time to review a new medicine.**

In Rhythm's view, the proposed guidelines unnecessarily delay confirmation of non-excessive pricing. For example, a rights holder must submit their first sale pricing within 30 days of launch, however it is only upon the submission of the first reporting period that the medicine is reviewed. Additionally, the new rights holders must wait an additional 60 days following the first reporting period to receive confirmation from PMPRB of non-excessive pricing. This can result in upwards of 8+ months to learn of the pricing status. Potential retroactive payments for 8+ months and the significant investment in the Canadian landscape to launch products is a significant risk for new rights holders in Canada. This leaves new rights holders with a high level of risk that their anticipated price may not be accepted and could negatively impact launch viability in Canada. It is our position, that prices for new medicines should be reviewed at the submission of the first sale, vs following the first reporting period to reduce the length of time to ensure certainty in pricing.

2. **Application of foreign exchange rates as related to the PMPRB basket of 11 compactor countries at initial reporting and during annual reviews.**

There was no commentary within the Discussion Guide regarding to the application of foreign exchange rates as it pertains to the PMPRB basket of 11 comparator countries at neither the initial submission, nor during annual review periods. Given that Canadian rights holders are being compared to foreign prices, it would be beneficial to ensure that there is clarity of the application of foreign exchanges rates.

Rhythm feels that a transparent exchange rate reference that is not subject to interpretation is necessary for rights holders to appropriately calculate pricing in relation to the PMRPB basket of international country comparators. The current grid posted on the PMPRB website (https://www.canada.ca/en/patented-medicine-prices-review/services/are-you-patentee/exchange-rates/exchange-rates-2023.html) is confusing and open to different interpretations. It is our view that there is opportunity within the Discussion Guide to provide clear and transparent direction regarding the rates of exchange to be used during initial submissions and during regular reporting periods.

Additionally, it is Rhythm's position that there should not be an annual review that could result in consistent annual price reductions solely as a result in fluctuations in foreign exchange rates. For example, a new rights holder may submit and receive confirmation of a non -excessive price during its launch year. However, if fluctuations in foreign exchange rates in relation to the PMPRB basket of 11 international country comparators reduces the MIP, the original non-excessive price should not require a price reduction in relation to the initial confirmed non-excessive price (assuming no other changes in the basket of 11 country comparator prices and number of comparator countries). Foreign exchange rates are highly variable and are far outside of the influence of the industry and the country writ large. Additionally, the logistical costs and time to administer constantly changing prices solely as a result of foreign exchange rate fluctuations is unnecessary and could also be problematic for private and public payers to monitor and adjust.

With the above in mind, there is no direction contained within the Discussion Guide regarding the application of foreign exchange rates and we feel this is a significant omission and guidance is needed to ensure clear and transparent guidelines for all Canadian rights holders.

3. **The 6.1.1 Price level within the PMPRB11 to be used in the initial and post-initial price review (section 6.1.1 of the Discussion Guide**).

It is Rhythm's position that the median price point identified within proposed guidance is not aligned with PMPRB's mandate regarding excessive prices and the patent abuse. With this in mind, the HIP as it relates to the PMPRB basket of 11 international comparator countries, is the most appropriate determinant of non-excessive pricing. The MIP is a de facto price regulating mechanism and not appropriate for determining non-excessive pricing.

In closing, we note that the recent webinar conducted by PMPRB used case studies to illustrate the potential implementation of the proposed guidelines. However, these illustrations raised concerns about the likelihood of a case-by-case management approach with context-specific determinations, which would be inappropriate and difficult to ensure transparency and consistency of reviews.

Thank you for your consideration of our submission.