Canadian Antimicrobial Innovation Coalition Submission:
PMPRB Phase 2 Consultations on New Guidelines

September 11, 2024

Submitted via the PMPRB Website: Consultation Submission Portal

Dear PMPRB Members,

The Canadian Antimicrobial Innovation Coalition (CAIC) appreciates the opportunity to provide input on the Patented Medicines Pricing Review Board (PMPRB)'s new Guidelines, which aim to improve efficiency in achieving PMPRB's legislative mandate.

CAIC is a member-based non-profit organization helping to protect Canada's population from the rise in antimicrobial resistance. Our mandate is to protect Canadians by positioning Canada as a leader in antimicrobial resistance research and product development, economic growth, and investment. Our varied membership aligns with our commitment to this goal and with the positions and recommendations contained in CAIC's submission to the consultation on the new PMPRB Guidelines.

We would like to start by commending the PMPRB for its efforts to consult a wide variety of stakeholders. We appreciate the PMPRB's renewed commitment to transparency and engagement throughout this process and look forward to continued collaboration to achieve a sustainable pricing system.

In this context, CAIC would like to provide the following general recommendations and considerations with respect to questions posed in the scoping paper, which we hope can inform the PMPRB's approach in the pre-consultation phase and beyond.

Categorization of Antimicrobials

Using "level of therapeutic improvement" to categorize antimicrobials may not be appropriate as it does not take into consideration many of the unique pressures that this therapeutic class is under. For example, in the case of antimicrobials, efficacy is eroded by the generation of resistance over time and drug use is often severely restricted during the patent period. Many antimicrobials cease being comparators due to resistance, and as such, it is necessary to continue innovation regardless of the level of therapeutic improvement. Further, the use of non-inferiority studies means that clinical evidence demonstrating improvement over other options is often lacking. We recommend a different method of categorizing antimicrobials that accounts for these challenges.

Valuation Methods

An example that could be applied to certain cases is the valuation paradigm that has recently been introduced in the United Kingdom. This approach may more appropriately value antimicrobials by recognizing the unique market pressures they face and the socio-economic value they provide. The United Kingdom approach pays companies a fixed annual fee for antimicrobials, based primarily on a health technology assessment of their value to the National Health Service instead of by quantity. This subscription model could be applied to consider factors that specifically complicate antimicrobial pricing. However, we emphasize that this method of valuation may not be applicable or desirable for all cases.

In addition to the United Kingdom, countries such as Sweden, Japan, France, and Germany have implemented policies that aim to address the broken market for new antimicrobials by providing incentives for market entry.

The Government of Canada has endorsed pull incentive models to incentivize antimicrobials commercialization as part of the G7. For this reason, PMPRB Guidelines must consider Canada's commitments with respect to incentivizing antimicrobials R&D and market adoption.

Factoring in Socio-Economic Value

We recommend that the PMPRB consider a wider variety of categories when assigning value to this therapeutic class. A more holistic valuation, where antimicrobials are assessed for their value to society, would help to avoid a scenario where current routine procedures are no longer viable because resistance has developed to currently available microbials and new drugs have not been developed. Comparator products will likely be generics, which will have significantly lower prices than a new product; however, the new product may be able to treat infections that are resistant to those comparator products. The current system would not reflect the additional societal value the new product would add. As such, second or third-line oncology products or rare disease products may be better comparators for pricing than older antimicrobials.

Risk Analysis

Countries may increase the risk of products being withdrawn from the Canadian market, so any decision made as to how the board reviews existing medicines could be conducted alongside a risk analysis that assesses the likelihood of a drug leaving the market due to downward pricing pressures.

Barriers to Market Entry

According to the Council of Canadian Academies report, Overcoming Resistance, the pricing of innovative AMR-related medications in Canada appears to be a barrier to market entry. This was further highlighted in the Office of the Auditor General's (OAG) report on the Government of Canada's activities regarding AMR. The OAG found that although both the Public Health Agency of Canada and Health Canada know that successfully encouraging companies to bring new antimicrobials to the Canadian market would require a combination of regulatory and economic incentives, not enough has been done to improve market access to new antimicrobial drugs available in other countries.

The prices of drugs such as antibiotics do not reflect their socioeconomic value, which correlates with a lack of investment by private companies in R&D. If this continues, then the availability of effective antimicrobials will continue to decrease. Pricing is a barrier to entry, and antibiotic pricing fails to reflect their socio-economic value.

Importance of Innovation in the Antimicrobial Context

New antibiotics are not priced to encourage R&D in the same way as rare disease treatments have been, leading to a lack of new antimicrobials making it to market. As in the case for rare disease drugs, if PMPRB is examining higher prices with a different lens, then applying a different lens to antimicrobials can be beneficial to patients and the broader health system.

Reference Pricing

Other countries have proposed reference pricing programs, which can create a barrier to introducing products in Canada and be subject to reference pricing in their own countries. For this reason, it is easier to apply the United States government sales price for antimicrobials introduced in the Canadian market. However, this approach is not possible due to the exclusion of U.S. from the PMPRB pricing basket. In our view, considering an alternative pathway would be more favourable.

Additionally, six of the eleven proposed reference countries listed as Potential Sources for Foreign Prices: PMPRB11 are members of the G7. Since 2021, G7 Finance and Health Ministers have committed to taking additional steps to address antibiotic market failure, create economic conditions to preserve the effectiveness of essential existing antibiotics and ensure their access, and bring novel antibacterials to market that address public health needs. Addressing the market failure for antibiotics included supporting relevant pull incentives, implementing new pilot projects, contributing to new national governance structures to develop economic strategies to strengthen antibiotic development, and exploring legislative and regulatory measures. As countries on the PMPRB11 adopt incentive programs, the pricing of antibiotics may be skewed, impacting the pricing considerations of antibiotics by the PMPRB.

Conclusion

Creating new Guidelines for pharmaceutical pricing in Canada is a crucial and timely project. All viewpoints and variables must be considered to ensure Canadians receive the care they need. In the antimicrobial context, this means lowering barriers to entry to ensure novel products are available in the face of increasing antimicrobial resistance.

CAIC would like to thank the PMPRB for considering our recommendations and including us in the consultation process. We look forward to continued engagement with the PMPRB in the future.