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Sent: Wednesday, December 20, 2023 2:33 PM
To: Elena Lungu <elena.lungu@pmprb-cepmb.gc.ca>
Cc: Kilpatrick, Natasha (PHAC/ASPC) <Natasha.Kilpatrick@phac-aspc.gc.ca>; Isenor, Alexander (PHAC/ASPC) <alexander.isenor@phac-aspc.gc.ca>
Subject: PMPRB Guidelines Consultation process - informal feedback

Thank you for providing an opportunity to partake in the consultation exercise. As the Antimicrobial Resistance (AMR) Access and Innovation team in the Centre for Vaccine and Therapeutic Readiness at the Public Health Agency of Canada, we are tasked with trying to improve access to new antimicrobials for Canadians. As a result, we have heard about the challenges faced by many important stakeholders in the AMR field, in particular relating to the way that antimicrobials are valued both globally and in Canada. We appreciate PMPRB's mandate and understand that some of the feedback below may fall outside of this.

Theme 1 - Efficient Monitoring of Prices without Price Setting
Question 1.2: Should new Guidelines continue to categorize medicines by therapeutic class comparator characteristics such as the Level of Therapeutic Improvement?
Comment: 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, e.g. efficacy is eroded by generation of resistance over time and drug use is often severely restricted during the patent period. The UK has pioneered a new valuation paradigm that may more appropriately value antimicrobials by recognising the unique market pressures they face and also the socio-economic value that they bring. It may be important to consider a wider variety of categories when assigning value to this therapeutic class. This may help to avoid a scenario where current routine procedures are no longer viable because resistance has developed to currently available antimicrobials and new drugs have not been developed.

Theme 2 – Transition to PMPRB11 – New versus existing medicines
Question 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?
Comment: Although it is not necessarily the PMPRB's mandate to ensure access to drugs, retrospectively reviewing prices using the new basket of countries may increase the risk of products being withdrawn from the Canadian market – any decision made as to how the board reviews existing medicines could be conducted alongside a risk analysis that assess the likelihood of a drug leaving the market because of downward pricing pressures. Excessive profitability may be a more appropriate measure to use than just pricing information especially for therapeutics that Canada has difficulty in securing access to.

Theme 3 – Price reviews during product life cycle
Question 3.2: What criteria besides time should be used to trigger a price review?
Comment: Although it may be difficult to determine, excessive profit margins in Canada compared to comparator nations may be a useful metric to determine if a price review is necessary.

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

Question 5.1: What efficiencies could be gained by co-ordinating 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)?
Comment: Understanding more about what is being proposed with respect to this would be beneficial for commenting on this.

Theme 6 - Engaging with Patients, Health Practitioners, Pharmacy, and other Stakeholders
Question 6.1: What is your experience with innovative medicines and their list prices in Canada?
Comment: Pricing of innovative AMR related medicines in Canada appears to be a barrier to market entry according to research undertaken by our team, despite Canada having some of the highest drug prices in the world. The prices of drugs such as antibiotics does not appear to reflect their socio-economic value, this in turn correlates with a lack of investment by private companies in R&D. If this continues then it is likely that the availability of effective antimicrobials will continue to decrease. This would have wide reaching consequences.

Question 6.3: Canada and the world are facing a generation of new high-priced drugs for the treatment of rare diseases. i. Should the PMPRB view the question of whether the prices of these medicines are "excessive" through a different lens than other types of medicines? ii. What quality of evidence should the Board consider when conducting its scientific review of these medicines?
Comment: There are parallels between high priced rare disease drugs and antimicrobials, for example, new antibiotics are subject to strict stewardship criteria that restrict their use. This means that, much like rare diseases, antibiotics have a very small patient population size, especially during the patent period. However, new antibiotics are not priced to encourage R&D in the same way as rare disease treatments have been and so there is a lack of new antimicrobials making it to market. If PMPRB is considering assessing the "excessive" nature prices of rare disease drugs using a different lens, then including antimicrobials in the scope of this lens may be beneficial and could possibly be considered. We are not experts in what quality of evidence should be considered when ascribing value but organisations like CADTH/INESS and the UK's NICE are well placed to speak about models to more appropriately value antimicrobials.

Let us know if you have any questions.

Cheers,

Andrew