GSK's submission regarding the 2025 Draft Guidelines
March 2025

Dear Anie Perreault, acting Chairperson of the PMPRB and Members of the Board:

On behalf of GSK, we welcome the opportunity to provide comments regarding the PMPRB's 2025 Draft Guidelines.

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. We have leading positions in respiratory disease and specialty medicines, particularly in the areas of infectious diseases, oncology and immunology. With a robust pipeline of innovations including novel antibiotics and the broadest vaccine portfolio in the industry, GSK is committed to bringing life changing therapies to patients across a wide range of therapeutic areas.

In Canada, GSK has a long-standing presence dating back to 1902. Over time, we have grown to providing a salary injection of $94 million into the Canadian economy, with offices in Mississauga and Montreal, and a vaccine manufacturing plant in Quebec City. GSK employs approximately 1,628 full time employees across the country, and we are also consistently ranked among Canada's top research and development (R&D) spenders demonstrating our commitment to advancing healthcare innovation. Since 2001, GSK has invested more than $2 billion in Canadian pharmaceutical and vaccines R&D, with over $121 million invested in 2023 alone, including over $18.4 million into 53 active clinical trials across Canada involving 3,334 active subjects.

From this vantage point, we offer a number of recommendations and comments in response to the Draft Guidelines for consideration by the Board in the development of Final Guidelines:

Initial Review

Firstly, GSK would like to acknowledge the PMPRB's proposed use of the Highest International Price (HIP) test in the initial review process. In addition to supporting the Board's stated intention to provide predictability to Rights Holders, if the ultimate objective of the PMPRB Guidelines and hearing process is to determine if a medicine's price is excessive, HIP is the only appropriate test to trigger an in-depth review.

That said, navigating a basket of reference countries this size can be complex as it relates to launch sequence and published pricing of new products. Additionally, the expanded basket of reference countries requires calculations across several currencies and ever-changing foreign exchange rates. To accommodate the challenges associated with the shift to 11 reference countries, we request that the PMPRB consider allowing up to two reporting periods to assess the HIP of the basket and/or trigger an in-depth review, as well as the implementation of a threshold around HIP wherein an in-depth review would not be triggered unless this upper threshold is exceeded, similar to previous proposals.

New vs. existing medicines

While the PMPRB made the defensible choice with the proposed initial review process in the Draft Guidelines, we remain concerned with the Board's decision to abandon the distinction between new and existing medicines, with no concrete rationale provided despite GSK and others having raising the question across multiple forums.

As stated in previous submissions to the PMPRB, the notion of applying new regulations on a go-forward basis is not a new concept in regulatory law and public administration. For countless other panels, tribunals, and regulatory bodies, a legacy-status process is a well-established. Its fundamental purpose is grounded in the fact that difficult and controversial policy changes are, at times, necessary or unavoidable. However, where possible, a company's existing footprint should not be reprehended to deliver future-oriented changes.

The list prices of patented medicines already in the Canadian market are based upon, among other factors, the PMPRB Guidelines in force at the time. When Rights Holders initially set these prices, they evaluate and assess the Guidelines and, following scientific and price review by the PMPRB, anticipate maintaining these prices going forward. It is also worth mentioning that these prices have thus far remained compliant with the Guidelines throughout the life cycle of the medicines.

Additionally, when the Regulatory Impact Analysis Statement for the Regulations Amending the Patented Medicines Regulations (Additional Factors and Reporting Requirements) was published in the Canada Gazette II in 2019, the calculations were made based on the use of an HIP test for existing medicines.[1] Since Cabinet approval was sought and provided based on the information provided in this RIAS, and an updated comprehensive RIAS was not performed with the regulatory amendments in 2022,[2] the Board should not deviate from the assumptions in the 2019 assessment.

The PMRPB must distinguish between new medicines which are launched with new Guidelines in place (i.e., those that can predict the outcome of a Guidelines-based price review) and those medicines which existed before. If the Board remains set on abandoning this element that would support the PMPRB's stated beliefs that "transparent, predictable, and procedurally fair Guidelines provide an efficient way for rights-holders to manage risk," one year to enable existing medicines to come into compliance is not sufficient. For several years over the course of this pricing reform process, Rights Holders have operated under a cloud of uncertainty. Without the inclusion of "legacy" status for existing medicines, it is only reasonable that the Board allow for three years to become compliant with the new Guidelines, as proposed by the Discussion Guide.

Consumer Price Index (CPI) methodology

The Board's proposed methodology currently does not align with timelines to submit price increases to provincial drug plans. In the Draft Guidelines, the proposed CPI rate will not be published when Rights Holders are required to submit increases to the provinces. For example, the annual average CPI for 2024 was published on January 21, 2025, well after the provinces required price increase submissions, starting as early as December 1, 2024. The majority of provincial deadlines to submit fall before CPI is published. The Board should consider a revised methodology such that Rights Holders could accurately determine acceptable price increases aligned to provincial submission deadlines.

Considerations for in-depth reviews

The Draft Guidelines, as written, allow for the trigger of in-depth reviews throughout the lifecycle of a product. PMPRB should consider a statute of limitations to establish the earliest date for which excess revenues can be calculated, or determine indications/comparators would be relevant for the in-depth review.

Our final recommendation related to CPI is for the deferral system. The way it is currently described in the Draft Guidelines creates uncertainty and unpredictability of the impact of such in-depth reviews for an undetermined period of time. We request that the Board consider clear boundaries around how deferrals will be determined and addressed.

[1] Canada Gazette, Part II
[2] Canada Gazette, Part 2, Volume 156, Number 14: Regulations Amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), No. 5

Vaccines

The Phase 2 Discussion Guide contemplated expanding the complaints-based process to vaccines, which was excluded from the Draft Guidelines. GSK maintains that vaccines should be added to the Draft Guidelines proposed list including patented generic medicines, over the counter medicines and veterinary medicines.

As we've stated in previous submission, the existing Canadian public tender process effectively prevents excessive pricing by design, with most tenders requiring Rights Holders to offer competitive bids discounted from the public list price. In limited instances where sole source contracts are signed, Rights Holders must certify prices are "not in excess of lowest price for similar quality & quantity" charged to any other customers.

Given this reduced risk of excessive pricing, we request that the Board reconsider the inclusion of vaccines in the proposed complaints-based process to trigger an in-depth review.

Access to antimicrobial innovation

Also absent from the proposed Guidelines was any consideration for the unique challenges associated with the development and launch of novel antimicrobials. Currently, Canadians only have access to three of the 18 antimicrobials that have come to market since 2010, and Canada lacks access to a number of the antibiotics considered essential by the World Health Organization. This challenge isn't unique to our country, however others including the United Kingdom, Sweden, France, Japan, and Germany have implemented policies aimed at overcoming the market barriers for new antimicrobials.

The Government of Canada has acknowledged that antimicrobials are exceptional, with a commitment to a pull incentive program to incentivize the launch of new drugs in Canada. The Council of Canadian Academies report, Overcoming Resistance, found that the pricing of innovative AMR-related medications in Canada appears to be a barrier to market entry. While not explicitly included in the government's pan-Canadian Antimicrobial Resistance (AMR) Action Plan, the PMPRB Guidelines can significantly impact access to these drugs. Therefore, it is crucial that the Guidelines provide special consideration for antimicrobials to ensure the Board does not inadvertently hinder Canada's progress in the fight against AMR.

To that end, we recommend that new antimicrobials are waived from the proposed Guidelines, and that the Board work with the Public Health Agency of Canada to determine an appropriate process that considers socioeconomic value, and the impact to pipeline products and future R&D in this space.

Conclusion

Once again, GSK is grateful for the opportunity to provide input into the PMPRB Guidelines development process. We are optimistic that the Board will provide thoughtful consideration to the feedback provided, and that the Final Guidelines will reflect an important balance that fulfils the PMPRB's mandate in a way that is transparent, predictable, and fair, so as not to negatively impact access to innovative medicines for Canadians and hinder the pan-Canadian, multi-sectoral efforts towards building the life sciences ecosystem in this country.

Kind regards,

Sridhar Venkatesh
President & General Manager
GSK Canada