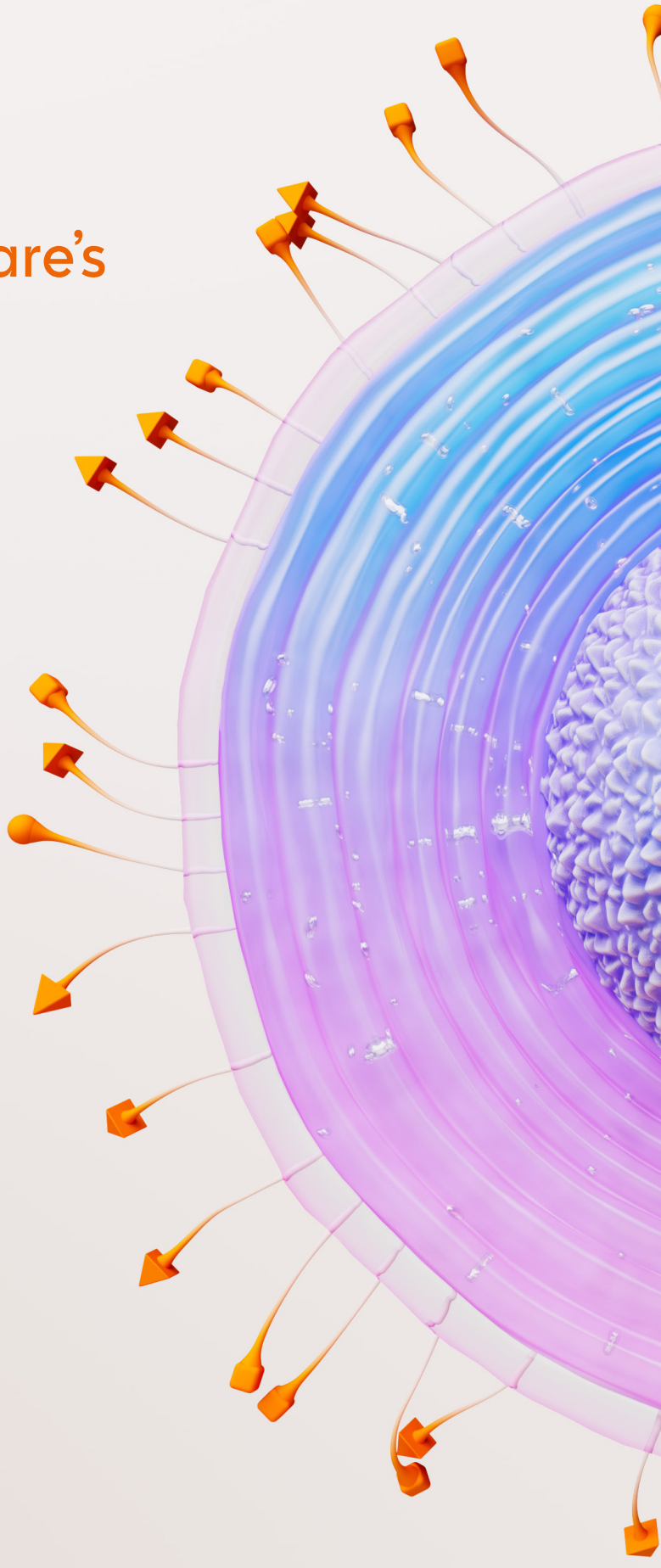
GSK

GSK and ViiV Healthcare's Submission Regarding the June 2024 PMPRB Discussion Guide

September 2024



Ahead Together

Dear Thomas Digby, Chair of the PMPRB and Members of the Board:

On behalf of GSK and ViiV Healthcare, we welcome the opportunity to provide comments regarding the PMPRB's June 2024 Discussion Guide, as part of the consultations on new pricing 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. Established in 2009, ViiV Healthcare is dedicated to delivering advances in treatment and care for people living with HIV and for people who can benefit from HIV prevention options. ViiV Healthcare aims are to take a deeper and broader interest in HIV and AIDS than any company has done before, while taking a new approach to deliver effective and innovative medicines for HIV treatment and prevention, as well as supporting communities affected by HIV.

In Canada, GSK has a long-standing presence dating back to 1902. Over time, we have grown to have one of the largest economic footprints of any multi-national pharmaceutical company in Canada, 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.

Together, GSK and ViiV Healthcare would like to acknowledge the PMPRB's stepwise and consultative approach to the development of Guidelines. We understand that final decisions on the new pricing Guidelines are still to come, and that the PMPRB remains open to feedback. That said, our companies continue to have serious concerns regarding the apparent direction of travel for this pricing reform exercise. While some minor details have emerged through the Discussion Guide, the overall thrust of the document remains largely unchanged from earlier consultation proposals put forward by the PMPRB. At their core, the pricing reform proposals put forward in the Discussion Guide would create an untenable level of uncertainty for pharmaceutical manufacturers, in part due to an excessive level of discretion for PMPRB staff. We will address this in our submission for the Board's consideration, as follows below.

Topic 01

Price level within the PMPRB11 to be used in the initial and post-initial price review

When the Discussion Guide was released in June 2024, our companies were disappointed to find that there are no longer any references whatsoever to what has previously been referred to as "grandfathering" (henceforth referred to as "legacying") in regard to medicines that were approved by Health Canada and launched in Canada prior to the commencement of the current round of pricing reforms, which track to Cabinet decisions made in 2019, and the subsequent passage of new regulations in 2019 and 2022.

Medicines approved and launched in Canada prior to the above-mentioned regulatory reforms should be provided legacy status under the longstanding pricing Guidelines that were in place at the time. The various changes and adjustments to Canada's drug pricing frameworks that are contemplated in the Discussion Guide should apply on a go-forward basis only. To retroactively apply any such changes is a severe and detrimental change in course.

The Discussion Guide states that, "the Board believes that transparent, predictable, and procedurally fair Guidelines provide an efficient way for rights-holders to manage risk." Our companies share this view. One fundamental element of previous iterations of reform proposals published by the Board[1][2] that did aim towards providing a certain level of predictability for patent holders was the notion of "legacying" – i.e. drawing a clear and meaningful distinction between new and legacy medicines for the application of the International Price Comparison (IPC) test.

Surprisingly, the June 2024 Discussion Guide abandons the concept of legacying in any meaningful sense (the Board's proposal to offer a form of temporary or transitional legacying to legacy medicines, with ranges of duration and lack of clarity around the pricing test that would apply represents a shadow of former legacying approaches proposed by the Board), with no legitimate rationale provided for withdrawing this topic from consideration. As responsible companies dedicated to researching, developing and commercializing innovative medicines to improve the lives of Canadians, we are not amused by this "disappearing legacy" trick.

The notion of legacying is not a new concept in regulatory law and public administration. For countless other panels, tribunals, and regulatory bodies, legacying is a well-established process. 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.

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.[3] 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,[4] the Board should not deviate from the assumptions in the 2019 assessment.

1 *2022 Proposed updates to the PMPRB Guidelines - Canada.ca*
2 *PMPRB Draft Guidelines Consultation - Canada.ca*
3 *Canada Gazette, Part II*
4 *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*

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.

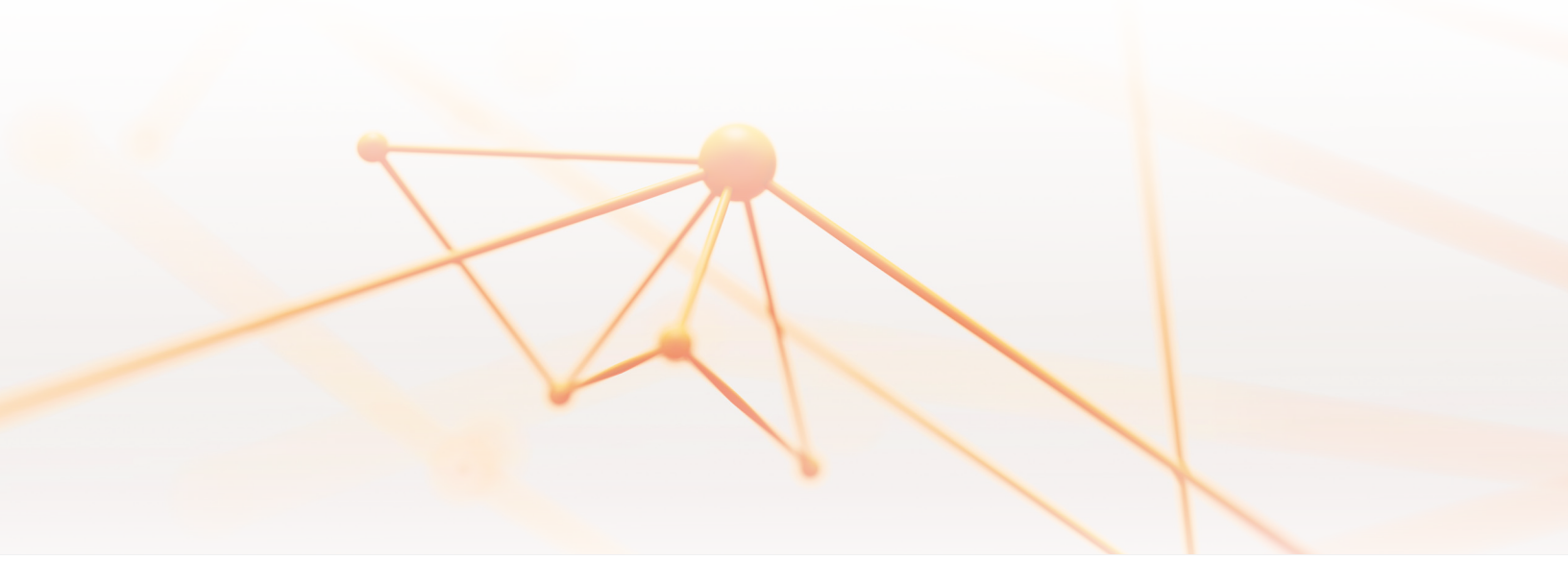
To abide by the Board's commitment to predictability, prices of existing medicines determined to be compliant under the previous Guidelines should be provided legacy status and not subject to further review under the new Guidelines.

Application of International Price Comparison Tests

The Discussion Guide refers to the existing position of many rights holders that the Highest International Price (HIP) is the most appropriate price level for the Guidelines to use, because it is not possible for a price below the HIP to be "excessive." The Guide then points to two previous instances (Adderall XR and Procysbi) where consideration of the therapeutic class comparators (TCC) rendered a price above the midpoint to be excessive. Given the fact that the Board has proposed TCC prices are not to be a factor in the initial price review of the new Guidelines, and the initial review does not determine whether or not a price is excessive, the previous referenced cases are not relevant to the consideration of the most appropriate level for IPC identification criteria.

Additionally, if the Board's intention is to provide predictability for Rights Holders, HIP must be the price level used in the initial review. Besides being a seemingly arbitrary saw-off between HIP and Median International Price (MIP), as compared to the HIP, a midpoint price test would more regularly fluctuate, in part due to international currency fluctuations which are out of any pharmaceutical manufacturer's control (and indeed also out of the PMPRB's control), creating a constantly moving trigger for a potential in-depth reviews by PMPRB staff, resulting in unpredictability for Rights Holders.

And finally, the Discussion Guide acknowledges the administrative burden for PMPRB staff created by IPC identification criteria set at a level below HIP. In addition to maintaining a sustainable workflow, the use of HIP in initial and post-initial reviews supports the PMPRB to remain within the scope of its mandate to ensure that the prices of patented medicines sold in Canada are not excessive, as confirmed by the Quebec Court of Appeal in 2022.



Topic 02

The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criterion for an Existing medicine is met

The Discussion Guide is clear that the PMPRB will not distinguish between "New medicines" or "Existing medicines," however 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. Rights Holders initially set these prices based upon assessment of the Guidelines and, after Scientific and Price review by the PMPRB, had a reasonable expectation that they could maintain these prices going forward.

> *It is our position that in order to provide predictability to Rights Holders, an objective of the Guidelines, as stated in the Discussion Guide, the PMPRB must distinguish between new and existing medicines, wherein existing medicines considered compliant under the previous Guidelines will not be subject to additional price reviews under the new Guidelines.*

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. Patentees initially set these prices based upon assessment of the Guidelines and, after Scientific and Price review by the PMPRB, had a reasonable expectation that they could maintain these prices going forward.

Additionally, as previously noted, when the Regulatory Impact Analysis Statement (RIAS) 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.[5] 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,[6] the Board should not deviate from the assumptions in the 2019 assessment.

[5] *Canada Gazette, Part II*

[6] *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*

Topic 03

Criteria for CPI-Related Price Increases

We are pleased to see the PMPRB continues to consider a mechanism for inflationary price increases, because like manufacturers in other sectors, Rights Holders also continue to see increasing costs across the manufacturing supply chain. That said, in the development of a CPI methodology, the Board must ensure that it is reasonable, predictable, and fair, and is reflective of the fact there may be years Rights Holders are unable to take an increase and enables them to take advantage of those increases at a later date.

Topic 04

Who may submit a complaint?

Our companies request that the board extend the ability to file a complaint no further than Option 2B (Health Ministers plus public and private payors. Public payors (provincial and federal drug plans) and private payors (insurance companies) are well-resourced with access to industry knowledge enabling them to approach issues related to drug pricing in an informed way. Expanding the scope could heighten the risk of vexatious complaints, potentially placing an additional and avoidable burden on the Board, and its staff, who serve as adjudicators for these complaints, as well as Rights Holders.

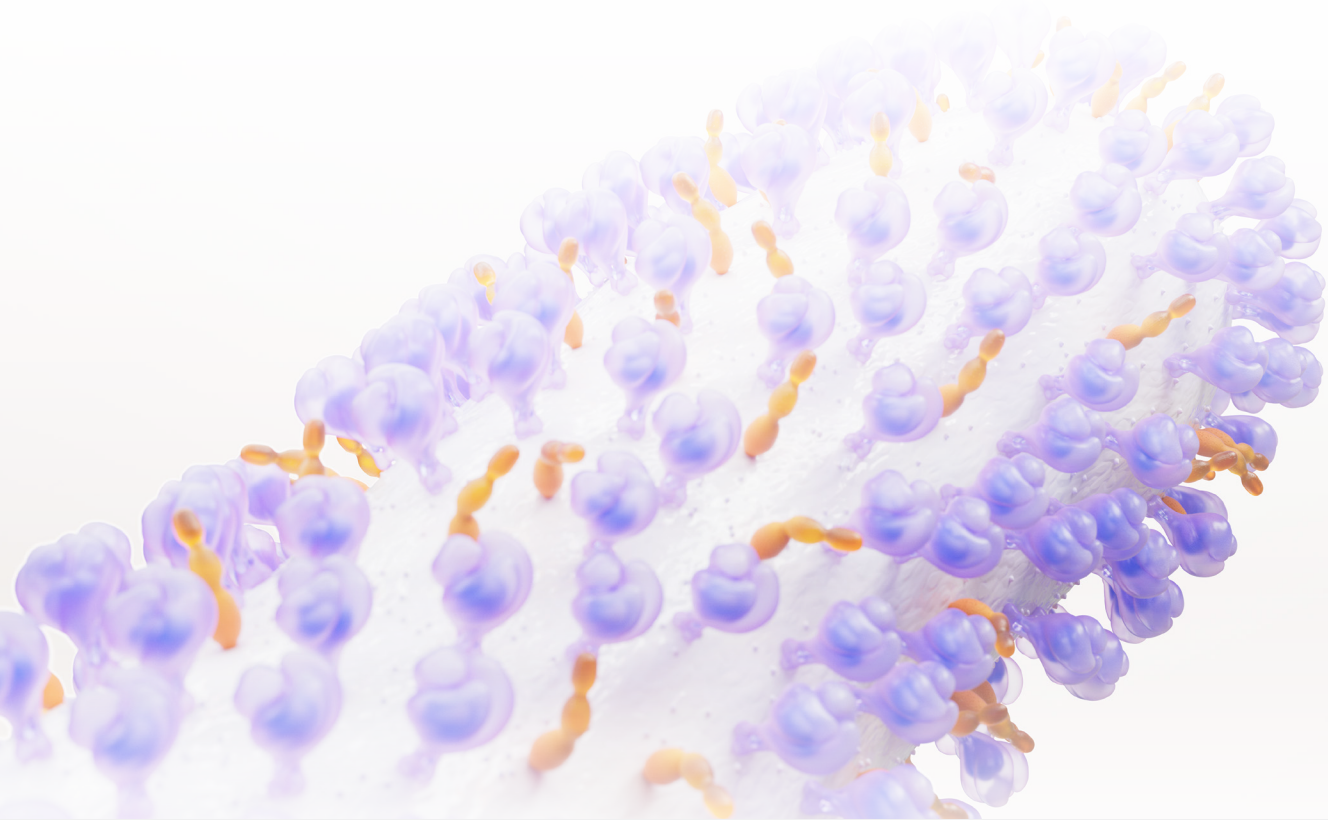
Topic 05

Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines.

Vaccine products, for the most part, are purchased by a central government body and their prices are determined either through negotiation or tendering.

The longstanding evidence shows that these products are at low risk for excessive pricing. Therefore, a complaint-based approach for vaccines and other low risk products was sensibly proposed in prior draft Guidelines and is the appropriate option.

While there are private-market vaccines commercialized in Canada, payers remain the appropriate party to negotiate reasonable pricing in these contexts. Price regulation is not an effective tool in protecting patients and enhancing vaccine accessibility.




GSK