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GSK & ViiV Healthcare's Submission Regarding the November 2023 Scoping Paper for Consultations on the Board's Guidelines

On behalf of GlaxoSmithKline Inc. ("GSK") and ViiV Healthcare ULC ("ViiV"), we welcome the opportunity to provide comments regarding the PMPRB's November 2023 Scoping Paper for consultations on the future PMPRB guidelines ("the Scoping Paper").

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 in infectious diseases, HIV, 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 many therapeutic areas.

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 over 1,700 employees across the country, and we are also consistently among the top investors in R&D in Canada. GSK has invested more than $2 billion since 2001 in Canadian pharmaceutical and vaccines R&D, with over $109 million invested in 2022 alone.

This submission has been prepared in conjunction with our partner ViiV Healthcare. ViiV is a global specialist HIV company established in November 2009 by GSK (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV and for people who can benefit from HIV prevention options. Shionogi became a ViiV shareholder in October 2012. The company's aims are to take a deeper and broader interest in HIV and AIDS than any company has done before and take a new approach to deliver effective and innovative medicines for HIV treatment and prevention, as well as support communities affected by HIV.

Together GSK and ViiV appreciate the opportunity to contribute to a meaningful dialogue and would like to recognize the positive approach that the Board has taken for stakeholder engagement. This openness is reflected in the questions asked in the Scoping Paper and by the Board during recent Policy Roundtables with stakeholders.

Because this phase of consultation is meant to set principles for forthcoming guidelines to operationalize future proposed guidelines, GSK and ViiV believe that it would be premature to comment on many of the Board's questions regarding specific price tests. These important questions would be more effectively addressed during the development of the new Guidelines.

It is from this perspective which we offer a response which focuses on the principles which must guide the direction of future Guidelines. The tried-and-true principles that were outlined by the Board in its first published bulletin in 1988: predictability, fairness, transparency, and openness.

1. PREDICTABILITY

One of the main purposes of Guidelines is to provide patentees with a set of clear and predictable rules needed to voluntarily comply with the regulatory framework. Manufacturers and others interpreting the Guidelines must be able to reasonably predict whether the price of their medicine will be considered non-excessive at launch and throughout the patent life. This means that "bright-line" tests for compliance must be a principal component of the Guidelines.

Life-Cycle Review

Past attempts at reforming the Guidelines undermined predictability when factors such as cost-effectiveness and affordability were included. While these factors appear to have been discarded by the PMPRB at this point, the Scoping Paper raises a new issue affecting predictability: subsequent price reviews. Specifically, proposals to conduct expedited reviews at introduction and subsequent reviews upon either new or more mature data, new indications, or even a change to the market comparators. The goal of this a proposal could only be to determine a 'fair' or 'reasonable' price, which in the estimation of GSK and ViiV would lie outside of the Board's mandate to protect against excessive pricing. Indeed, this type of analysis is rightly the responsibility of health technology assessment (HTA) bodies and actioned by payers in their negotiations with rights holders. HTAs have the resources and mandate to analyse the value of a new medicine, and payers can compare the true net prices of therapeutic comparators for the purpose of assessing value and negotiating agreements.

PMPRB does have jurisdiction over medicines throughout patent protection and does have an ongoing role to regulate these prices. The 'triage'-based approach discussed in the Scoping Paper, with bright-line tests, should be the basis of a reasonable approach to review over a product's lifecycle to ensure that products are not being sold excessively.

Legacy medicines (Grandfathering)

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.

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. These 'existing medicines' should not be subject to further price reviews. If the price of an existing medicine was considered compliant under the old framework, or if the price can be justified by Section 85 excessive price factors, that price should be assumed to be non-excessive. Legacy status was available to older medicines when the Guidelines were last updated in 2010 – the PMPRB should continue this precedent, owing to predictability.

2. FAIRNESS

The Scoping Paper proposes that international price comparisons could be used as a 'triage' measure to prioritize investigations. While GSK and ViiV are broadly aligned to this approach, it is important that product triggering investigations should be able to rely upon each of the Section 85 excessive price factors to demonstrate non-excessiveness.

Vaccines - Low Risk Medicines

The Board should likewise distinguish vaccine products from other patented medicines. Vaccine products, for the most part, are purchased by a central government body and their prices 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 should be reintroduced. 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 to protect patients and increase access of vaccines.

Consistency with an Excessive Price Standard

In August 2018, the Government of Canada amended regulations under the Patent Act to establish what has come to be known as the "PMPRB 11" basket of reference countries. On its face, the PMPRB 11 removes two higher price jurisdictions while adding several lower cost jurisdictions, which has the effect of constraining the ceiling price of New Medicines.

In making the decision to amend the regulations, the federal Cabinet and Treasury Board relied on a cost benefit assessment prepared by Health Canada officials that illustrated the impact of the change by anchoring to a highest international pricing test in conjunction with the new PMPRB11. Given its mandate to implement government

policy in an appropriate and predictable way, the PMPRB should not further constrain prices by selecting the Median as the reference point in future Guidelines. As previously discussed, particularly for medicines launched in Canada prior to August 2019, the highest international price (HIP) is most consistent with an excessive pricing standard.

3. Openness and Transparency

To successfully fulfil its mandate, the PMPRB must recognize its place in the broader pharmaceutical landscape and develop guidelines accordingly. GSK and ViiV are aligned with the whole-of-government approach proposed in the Scoping Paper. New Guidelines should complement, and not interfere with, federal, provincial, and territorial initiatives, such as the Government of Canada's 2021 Life Sciences and Biomanufacturing Strategy, aimed at cultivating a vibrant life science sector.

Openness and transparency can best be achieved if stakeholders are able to meaningfully participate in the development of the new Guidelines. GSK and ViiV request that the Board convene working groups of experienced stakeholders to collaborate on Guideline development. The 2011 Technical Working Group, which developed DIP methodology under the old framework, is a useful template to follow. Stakeholders worked collaboratively with the PMPRB to develop a clear and robust solution to a problem with the 2010 guidelines. If the Board establishes similar working groups for current process, elements of the new Guidelines can be evaluated and edited for clarity before publication. Unintended problems, such as those that required the development of DIP back in 2011, could be identified and solved by the very stakeholders that will apply the Guidelines to their own product portfolio.

GSK and ViiV remain available to the PMPRB board and staff for further discussion. We look forward to the forthcoming opportunities to contribute to consultations on more specific, substantive, and technical aspects of draft guidelines which should be based on these principles articulated during this preliminary scoping paper consultation.