Draft Guidelines for PMPRB Staff
Takeda Canada Inc. Submission
March 19, 2025

Takeda Canada Inc. (Takeda) is pleased to provide comments on the Draft Guidelines for PMPRB Staff. Takeda is a patient-focused, values-based, global pharmaceutical company committed to creating innovative therapies through research and development. Established in 1781, Takeda positively affects patients' lives by translating science into life-changing medicines, focusing on our core therapeutic areas of neuroscience, gastroenterology, oncology, vaccines, and plasma-derived therapies. As a leader in rare diseases and plasma-derived therapies, Takeda brings a unique perspective to this renewed consultation on the PMPRB Guidelines.

Takeda has actively participated in the development of the submissions of both Innovative Medicines Canada (IMC) and BIOTECanada, and we support the detailed positions put forward by both industry associations. As in our previous submissions, our detailed comments are focused primarily on areas of particular importance to Takeda: Drugs for Rare Diseases (DRDs) and Plasma-Derived Therapies (PDTs).

Drugs for Rare Diseases

Takeda is disappointed that our input, and that of others in the DRD community provided in previous consultations, has not been recognized in the Draft Guidelines. As a result, the Guidelines do not recognize the unique challenges faced by Rights Holders in developing and commercializing, DRDs.

As DRDs become more common and continue to provide innovative approaches to treatment, often for diseases without current treatment options, it is crucial that the new PMPRB Guidelines do not become an impediment to timely access to these new medicines for Canadians. To avoid such delays, Takeda recommends the final PMPRB Guidelines provide some guidance regarding how Board Staff will conduct in-depth reviews for DRDs. Specifically, we request guidance on how Therapeutic Class Comparisons (TCCs) would be developed for DRDs given their novelty.

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Publicly Funded Plasma-Derived Therapies (PDTs)

In earlier consultations, the Board acknowledged the unique nature of vaccine procurement and reimbursement in Canada and considered reserving in-depth reviews of these products to instances where there is a price complaint. Takeda provides PDTs to Canadian Blood Services and Héma Québec, through robust tendering, negotiating, and contracting processes. This procurement system achieves cost savings by consolidating volumes and soliciting competitive bids from suppliers, with the contract awarded to the bidder or bidders who best meet those criteria. As such, PDTs have low risk of excessive pricing similar to vaccines, and it would be appropriate to provide differential treatment for both vaccines sold to public payers and PDTs. In addition, it is noteworthy that publicly funded PDTs do not have a Canadian list price because of this unique procurement arrangement.

Factor	Publicly Funded Plasma-Derived Therapies	Publicly Funded Vaccines
Contracts	Almost all PDTs are sold under negotiated multi-year contracts with confidential prices. Most PDTs are not sold in the private market. Public sales of PDTs are limited to the two National blood products procurement agencies, Canadian Blood Services and Héma Québec.	Most vaccines are sold under negotiated multi-year contracts.
Federal/National Oversight	All aspects of blood product procurement are administered by Canadian Blood Services (CBS) and Héma Québec (HQ)	Vaccine contracts are administered by Public Services and Procurement Canada (PSPC).
High Degree of Purchaser Power	Both CBS and HQ are sophisticated, knowledgeable, and have the purchasing power to negotiate competitive, non-excessive prices	PSPC is sophisticated, knowledgeable, and has the purchasing power to negotiate competitive, non-excessive prices
Tender Process	PDTs often funded based on competitive tendering, ensuring consistent, fair prices and broad patient access	Vaccines are often funded based on competitive tendering, ensuring consistent, fair prices and broad patient access

Factor	Publicly Funded Plasma-Derived Therapies	Publicly Funded Vaccines
Complex Commercialization Pathway	PDTs undergo multiple reviews and assessments by: Health Canada, CADTH, Canadian Plasma-Related Product Expert Committee (CPEC), National Advisory Committee on Blood and PDTs (NAC), Provincial and Territorial Blood Liaison Committee (PTBLC)	Vaccine market access requires multiple reviews and assessment by: Health Canada, the National Advisory Committee on Immunization (NACI), Canadian Immunization Committee (CIC)
Availability of a Canadian List Price	No Canadian List Price is available.[1]	Vaccines sold exclusively to PSPC do not have a Canadian List Price.[2]
Low Risk of Excessive Pricing	All the above processes and procedures make the risk of excessive pricing very low	All the above processes and procedures make the risk of excessive pricing very low

The table above is a side-by-side comparison of factors that are similar between publicly funded vaccines and PDTs which distinguishes them from drug products procured and reimbursed through more typical processes. For the same reasons PMPRB has considered reviewing vaccines on a complaints-only basis, PDTs should also only be subject to price review in the event of a complaint. Under such a system, CBS and HQ could submit complaints to the PMPRB through the existing designated parties, particularly provincial Ministers of Health.

Takeda strongly urges the Board to adopt a "complaints-based price review policy" for PDTs as part of the final guidelines. Specifically, this policy would exempt PDTs from all initial, annual, and in-depth review, unless a complaint is received. As a result, Board Staff would only review reported information on the identity of PDTs and/or pricing of PDTs upon receipt of a complaint. As detailed below, there are two compelling reasons for the Board to adopt this policy. First, the Board has legal jurisdiction to adopt a complaint-based price review policy, which is grounded in its governing legislation as exemplified by past precedent. Second, this Board has previously recognized that certain classes of medicines are at

[1] CBS and HQ provide universal public access to products they reimburse. Therefore, these products are not sold in the private market and thus they do not have Canadian list prices.

[2] Some vaccines reimbursed by PSPC have a Canadian list price because they are also sold in the private market.

low risk of excessive pricing due to unique market characteristics.[3]

- **Legal jurisdiction for complaints-based price review.** There is precedent for the PMPRB adopting a complaints-based price review policy for categories of medicines that represent a low risk of excessive price. In 2017, the Board adopted a complaints-based price review policy for patented generic drugs on the basis that this class of drugs "represent a potentially lower risk category of patented medicines, and therefore a lower priority for PMPRB regulatory investigation."[4] According to its policy on generic medicines, no price review was conducted by Staff unless: (i) a complaint was received; (ii) the generic drug was the only generic on the market; and (iii) the generic drug was not subject to, or compliant with, a price agreement with the pCPA. The Board's policy on patented generic drugs remained in place until July 1, 2022, when amendments to the *Patented Medicines Regulations* further exempted patented generic drugs from all reporting requirements, unless requested by the Board.[5]

  Consistent with the Board's prior policy on patented generic drugs, the Board has jurisdiction under the *Patent Act* and *Patented Medicines Regulations* to adopt complaints-based price review policies in its guidelines for Staff. The Board's governing legislation does not require the Board to review prices or conduct investigations on all reported patented medicines. It is only once the Board decides to review a particular medicine for excessive price according to section 83 of the *Patent Act* that it "shall" consider all applicable subsection 85(1) excessive price factors.

- ***PDTs are a class of medicines at low risk of excessive price.*** As set out above, it is well-established that PDTs represent a class of medicines at low risk of excessive pricing. The sale of PDTs is subject to a robust tendering, negotiating, and contracting process administered by two sophisticated and highly experienced stakeholders: CBS and HQ. CBS and HQ have monopoly purchase power to secure cost savings in this area by consolidating volumes, soliciting competitive bids, and negotiating multi-year contracts. Overall, PDTs are subject to a particularly complex commercialization pathway that includes review by Health Canada, CADTH, Canadian Plasma-Related Expert Committee, National Advisory Committee on Blood and Blood Products, and the Provincial and Territorial Blood Liaison Committee. Takeda is justifiably concerned that if PDTs are

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[3] PMPRB, *Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines* (June 2024) at p. 27.

[4] PMPRB, Compendium of Policies, Guidelines and Procedures (February 2017) at p. 16, "B.8 Policy on Generic Medicines".

[5] *Patented Medicines Regulations*, SOR/94-688 at ss. 3(3.1) and 4(3).

not exempt from regular PMPRB price review, there will be difficult market disruptions that potentially cannot be overcome in what is already a challenging commercialization pathway for drug manufacturers like Takeda in this therapeutic area.

As tendered/contracted products, PDTs belong to a low-risk class of medicines.[6] Subjecting PDTs to a complaints-based policy would preserve valuable Board resources for high-priority excessive price matters while ensuring that PDTs negotiated agreements can be fulfilled as intended to ensure optimal access for Canadian patients.

Finally, while we understand the Guidelines are not intended to be a recipe for compliance, we are concerned that the proposed Guidelines do not provide rights holders with enough transparency or predictability. Historically, PMPRB published the results of price reviews for all new medicines. Access to this information provided valuable insight into the PMPRB process. Takeda recommends that, wherever possible, PMPRB share the results of in-depth reviews. The composition of TCCs, for example, is not proprietary and visibility to this information would help rights holders to respond appropriately to in-depth reviews and manage pricing risk.

Once again, Takeda thanks the Board for the opportunity to provide these comments, and for the renewed approach to the consultation on the Guidelines. Takeda would welcome the opportunity to engage with the PMPRB through working groups and other meetings to assist in developing an appropriate approach to pricing and access, particularly for DRDs.

[6] *See Draft Guidelines for PMPRB Staff* at Appendices, "Assessment of individual subsection 85(1) factors, separately" – "85(1)(a) – the prices at which the medicine has been sold in the relevant market" (considers if the medicine is a tendered product or if the Rights Holder reported contract sales).