Better Health, Brighter Future

Takeda Canada Submission September 11, 2024:

A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines

Takeda Canada Inc. (Takeda) is pleased to provide comments on the Discussion Guide for Phase 2 of Consultations on new Guidelines.

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, Takeda's submission will focus primarily on areas of particular importance to Takeda: Drugs for Rare Diseases and Plasma-Derived Therapies, as well as important broad issues raised in both the BIOTECanada and IMC submissions.

Topic 1: International Price Comparison (IPC) Threshold

Takeda supports the Industry Associations' position that the Highest International Price (HIP)is the relevant benchmark for IPC, as it reflects the correct interpretation of the notion of "non-excessiveness". Given the change to the basket of international reference countries, specifically removal of the US and Switzerland in favour of lower-priced jurisdictions, the HIP represents a lower price threshold as compared to the previous PMPRB Guidelines. Additionally, data presented in the Discussion Guide in Figure 1 shows that 37% of new medicines currently have prices above the MIP and 21% of new medicines have prices that exceed the mid-point between the Median International Price (MIP) and the HIP. Conducting in-depth reviews of these many new medicines would consume

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enormous resources and would not constitute an efficient use of the PMPRB Staff and Board members' time.

Annual International Price Comparisons (IPC) as proposed in the Discussion Guide will lead to in-depth reviews over the lifecycle of a product based on pricing policies in the PMPRB 11 countries. This ongoing re-benching of the IPC coupled with the broad discretion the Discussion Guide, proposes to afford Board Staff in conducting in-depth reviews, and the lack of information sharing regarding the outcome of these reviews, means that patentees will have no guidance on what would constitute a non-excessive price over the life cycle of a product. There are real business consequences to this uncertainty, including lack of information on which to make appropriate financial provisions that are consistent with sound accounting practices.

This lack of predictability is not consistent with the Board's stated belief that the Guidelines should be transparent, predictable and procedurally fair.[1] It is vital that the final Guidelines provide enough detail to allow manufacturers to determine with reasonable certainty a product's long-term pricing strategy. It is clear from the long list of unanswered questions submitted to PMPRB through IMC that the Discussion Guide proposals do not accomplish this. To provide the necessary clarity, it is essential that the Board engage with working groups comprising industry technical experts to inform the details of the Guidelines and pressure test them against case studies that represent real-world complexity.

Topic 2: Existing Medicines

Takeda's position is that Existing Medicines should not be subject to additional price review if the current list price did not exceed the PMPRB compliant list price under the previous Guidelines, plus annual CPI. Even with an IPC threshold at the HIP, 32% of existing DINs could be flagged for further review. Given the large number of existing DINs, this represents a huge resource burden, and an inefficient approach to the Board's regulatory mandate. However, for any new pricing policy, we

[1] Shaping the Future – A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines. Patented Medicine Prices Review Board. p.4

support a 3-year transition period for existing medicines. Three years is a normal business planning cycle, so Rights Holders would have sufficient time to updated business plans.

Topic 7: The Role of Human Drug Advisory Panel (HDAP)

It is important for Rights Holders to have the option of making submissions to the HDAP to support its position and rationale around certain pricing matters, for example why a list price higher than the IPC or CPI is not excessive. Notwithstanding the expertise of the PMPRB Scientific Staff, there are instances where input from external experts like those that sit as HDAP members would be valuable to this review. Therefore, we propose that HDAP be consulted on an ad hoc basis when either the PMPRB Scientific Staff or the Rights Holder requests their review and recommendation.

Drugs for Rare Diseases

Even though past PMPRB Guidelines have presented obstacles to Drugs for Rare Diseases (DRDs), the Discussion Guide Proposals are silent on the unique challenges faced by Rights Holders in developing and commercializing DRDs.

A recent report published by Takeda[2] identified 200 DRDs expected to launch in Canada within the next 10 years, many of them targeting rare diseases with no currently available treatment options. Given the high unmet need for these DRDs, it is crucial that the new PMPRB Guidelines align with federal government and provincial life science and rare disease strategies to reduce barriers in accessing these important treatments when they become available.

A thoughtful approach to the unique challenges of DRD pricing is required.

[2] Enhancing Diagnosis, Access, Care and Treatment: Recommendations for Health System Readiness for Rare Disease in Canada. rare-diseases-report-2024-EN.pdf (takeda.com)

Appropriate Scrutiny on Tendered Plasma-Derived Therapies (PDTs)

Takeda provides PDTs to Canadian Blood Services and Héma Québec, through robust tendering and contracting processes. This procurement system for PDTs 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 a similar low risk of excessive pricing as vaccines, and it would be appropriate to provide differential treatment for both vaccines and PDTs.

Factor	Plasma-Derived Therapies	Tendered Vaccines
Contracts	Almost all PDTs are sold under negotiated multi-year contracts.	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
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)
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 Vaccines and PDTs which distinguishes them from drug products procured and reimbursed through more typical processes. For the same reasons PMPRB proposes to review vaccines on a complaints-only basis, PDTs should also be treated similarly

The Board has acknowledged the unique nature of vaccine procurement and reimbursement in Canada and is considering reserving in-depth reviews of these products to instances where there is a price complaint. The above comparison provides evidence to support that the risk of excessive pricing of PTDs is similarly low to that of tendered vaccines. Also, under all scenarios contemplated in the Discussion Guide, both CBS and HQ could submit complaints to the PMPRB directly or via the relevant Health Minister. Therefore, Takeda requests that all PTDs be regulated like generic and veterinary medicines, in reaction to complaints, should they arise. Specifically, we request that PTDs be exempt from annual PMPRB filing requirements, and that patentees provide data at the specific request of PMPRB, in response to a price complaint.

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, and to share examples of unnecessary PMPRB review and investigation of PDTs.