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September 11, 2024

Mr. Thomas J. Digby, Chairperson
Patented Medicine Prices Review Board (PMPRB)
Box L40 | Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, K1P 1C1

Submitted By Email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: Sanofi Canada's submission to the Patented Medicine Prices Review Board Discussion Guide (Phase 2 Consultations) on New Guidelines - 2024

Dear Mr. Digby:

On behalf of Sanofi in Canada ("Sanofi"), I am pleased to provide you with our comments on the PMPRB's recently released **Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines**.

At the outset, I would emphasise that Sanofi is strongly supportive of the concurrent submissions being made by our trade associations, namely Innovative Medicines Canada, BIOTECanada and RAREi (Rare Disease Innovators) under this consultation.

Sanofi is a research-based global healthcare company. Our purpose is to pursue scientific and medical miracles to improve people's lives. We have one of the broadest and deepest product pipelines in the industry spanning medicines and vaccines across multiple indications and treatment areas. We also have an extensive specialty medicines portfolio, including for rare diseases, immunology and in oncology. Overall, we are focused on making innovation available and accessible in response to unmet patient needs.

Sanofi is proud of our history and leadership position in the Canadian life sciences sector. As a prominent manufacturer and investor, we remain on track to deliver over $2 billion in new investments by 2028. We are the largest corporate life sciences sector investor in Canadian research and development and are now among the top 25 corporate R&D contributors to Canada overall. We remain strongly committed to Canada from an investment, product, patient, employee and stakeholder perspective. Highly competitive, our global-scale Canadian investments are focused on enhancing our industrial footprint while promoting greater supply chain resilience and overall health system sustainability.

With respect to the Discussion Guide topics and the current consultation document, we wish to offer our perspective and recommendations based on our track record of pricing compliance and our intention to ensure that Canada can continue to offer globally competitive conditions for the full spectrum of biopharmaceutical research, manufacturing and supply, new product launches, and wider system partnerships with governments and stakeholders.

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At a high level, we echo the concerns raised by our trade associations that the current approach to Board Guidelines may fall short of the PMPRB's longstanding commitment to "bright-line" price tests and voluntary compliance, while retaining appropriate recourse to investigations and hearings when warranted.

We strongly encourage the PMPRB to reflect on and recommit to a stable and predictable pricing compliance regime, consistent with the Board's established statutory mandate, that promotes informed decision-making by all parties and overall pricing compliance for patented medicines. Within that approach, the Consumer Price Index (CPI) factor, as set out in the legislation, must be clearly calculated and implemented for both existing and new products.

With reference to the Discussion Document, we would like to provide comments on three aspects under consideration as the Board moves to proposed Guidelines.

1. **Price Point (Topic 1).**

It is important to highlight the recent and repeatedly reinforced mandate of the PMPRB with respect to "non-excessive" pricing. The only possible price standard consistent with this mandate is use of the Highest International Price (HIP) test. This is the only test which focuses (appropriately) on an upper pricing limit – the very definition of determining the point at which a price could be determined as excessive.

In contrast to this clear relationship to a non-excessive price standard, there have been various attempts and related discussion on alternate price points including the Median International Price (MIP) and a possible novel "midpoint" test. Sanofi recommends against both MIP and "midpoint" tests as both are inconsistent with the Board's non-excessive pricing mandate and fraught with challenges of complex and unpredictable administration. Notably, adjustments in pricing in any one comparator jurisdiction could have a dramatic impact on the calculation of a MIP or "midpoint" dependent on method and frequency of calculation. This is far less of a practical concern under a HIP focused regime, which would reflect the non-excessive reference of the overall PMPRB11.

Additionally, once the ceiling price of a medicine is established at its Canadian market introduction, and has been deemed compliant, PMPRB staff should not "re-benchmark" (i.e., reassess) the ceiling price over time for any reason other than verifying allowable inflation-based adjustments consistent with the factors specified in section 85 (1) of the *Patent Act*.

Sanofi therefore recommends that PMPRB utilize the HIP as the primary price test in the Guidelines and refrain from re-benchmarking the ceiling price over time.

2. **Treatment of Existing Products (Topic 2).**

It is important to acknowledge that existing products have achieved compliance with prior Board Guidelines. Any specific situations where this was not the case would have been addressed in past investigations and been rectified by recourse to a Voluntary Compliance Undertaking (VCU) or through the hearing process. This prior compliance was achieved based on the identical statutory basis for the PMPRB itself, which has not changed despite regulatory amendments and the current Guidelines development process.

Therefore, the prices of existing medicines must not be subject to additional price reviews under the new Guidelines. The approach for existing products (previously referred to as "grandfathering") should be that those medicines and their line extensions sold at non-excessive prices prior to implementation of the new Guidelines, and with the addition of allowable CPI, are deemed to be non-excessive. This approach would be consistent with PMPRB precedent treatment for existing products including when the Guidelines were last revised in 2010.

Recent PMPRB "transition" measures explicitly relied upon the appropriate price standard of the HIP of the updated PMPRB11 basket of comparators. Looking to the future, and properly grounded in both the statute and procedural consistency with the Board's own policies, this approach should be carried forward for existing compliant products under the new Guidelines.

Sanofi therefore recommends a full exemption for existing compliant products with reference to the use of the recent Board-sanctioned HIP price test.

3. **Differential Treatment of Low-Risk Products, Including Vaccines (Topic 5).**

Consistent with our prior representations to the PMPRB as part of this larger series of consultations, Sanofi strongly supports a differential treatment for demonstrably low-risk products including vaccines and biosimilars. In addition, all medicines procured exclusively through government contracts and tenders (e.g., by Canadian Blood Services/Héma-Québec/Public Services and Procurement Canada) should also be considered as low-risk products.

These categories of products are typically subject to extensive and robust monopsonistic public procurement mechanisms, including negotiation and sophisticated tendering or contracting arrangements. In the case of vaccines, those products which fall outside of the centrally procured and administered public immunization programs are typically elective travel vaccines and of less public policy significance for the domestic Canadian marketplace. These vaccines are subject to open market competitive factors and negotiated private insurance coverage, both of which serve to ensure non-excessive and market-based competitive pricing for Canada.

There are sound economic, policy and administrative reasons for taking a differential approach to these low-risk products. From an economic perspective, the structural forces inherent in unified and exclusive central public purchasing eliminate price variations for customers while promoting intense (downward) price competition among manufacturers to secure business. The risk of excessive pricing for these products is accordingly exceptionally low and remote in this structure, if not entirely non-existent.

From a policy and administration standpoint, it is important for the Board to have clarity on its mandate and role to oversee non-excessive pricing for patented medicines. Staff resources are not infinite and should be directed to those product situations and scenarios where the risk or challenge of arriving at a non-excessive price is the greatest.

A differential approach for these products would not necessitate the outright removal of Board oversight. Consistent with "Option 2" as proposed in the Discussion Guide, moving to a more streamlined, complaints-based system would allow the Board to remain fully present and available to investigate in the rare cases where a legitimate complaint from a recognized party would be registered.

Sanofi therefore recommends that the PMPRB adopt Option 2 (complaint basis) with respect to vaccines, biosimilars and blood products.

Next Steps

There remains a larger set of technical and administrative questions regarding the Board's intended approach and enforcement in Topic 4 (Complaints), Topic 6 (Similarity of Comparators) and Topic 7 (Role of HDAP). Sanofi supports and echoes the requests from our trade associations for greater clarification to support operational predictability given the implications for the overall medicines market in Canada. Where appropriate, we would be supportive of the creation of technical working groups, consistent with Board practice in the past, to assess and recommend workable solutions to these issues.

Overall, Sanofi remains concerned about the extent of context-dependent administrative discretion for Board staff contemplated under the Discussion Guide and potential future Guidelines. From a rights-holder perspective, product decisions for Canada are competitive and long-term in nature and depend upon stable and predictable compliance policies.

As the Canadian affiliate, our ongoing role is to advocate for and ensure that Canada remains a launch destination of choice for our global organization. This critical work depends on and is greatly supported by the ability to understand and assess our compliance obligations over the long-term within a larger business plan. We also note the wider supply-chain implications of the PMPRB's regime, and the corresponding importance of sensitivity to timelines for feasible and minimally disruptive changes of any kind to the compliance regime and overall market.

Should any Board members or staff have any questions regarding the content of this submission, please do not hesitate to contact me directly. Canadians want and deserve to benefit from sustainable and timely access to new treatments available today and the innovations of tomorrow. We appreciate the opportunity to share our perspective and, as in the past, welcome continued dialogue on the most efficient and effective price compliance regime for the PMPRB, grounded in and fully consistent with its mandate and role in the larger Canadian medicines ecosystem.

Yours Sincerely,

C. McElroy

Carrie McElroy (Sep 11, 2024 06:06 PDT)

Carrie McElroy
Head, Market Access and Public Affairs