March 17, 2025

Ms. Anie Perrault, Acting 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 Response to the Patented Medicine Prices Review Board Draft Guidelines

Dear Ms. Perrault:

On behalf of Sanofi in Canada ("Sanofi"), I am pleased to provide you with our comments on the PMPRB's recently released **Draft Guidelines (version December 2024)**. This submission builds on our record of feedback to date on the PMPRB's evolving set of policy reforms and administrative procedures.

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 in Canada and around the world.

Sanofi is particularly proud of our 110+ year heritage and leadership position in the Canadian life sciences sector. As a prominent Canadian employer, manufacturer and investor, we remain on track to deliver over $2 billion in new biomanufacturing investments by 2028. We are the largest corporate life sciences sector investor in Canadian research and development and biomanufacturing and are now among the top 25 corporate R&D contributors to Canada in any industry overall. We remain strongly committed to Canada from an investment, product, patient, employee and stakeholder perspective.

With respect to the Draft Guidelines and the current consultation document, we wish to offer our input and recommendations based on two major perspectives: our accumulated experience with and track record of non-excessive pricing compliance, and our intention to ensure that Canada continues 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.

Overall, while we are supportive of certain proposals and approaches in the Draft Guidelines, we reiterate our concern that the proposed approach appears to fall well short of the PMPRB's longstanding commitment to a more predictable, stable and workable enforcement approach through the use of "bright-line" price tests and voluntary compliance. A discretionary, open-ended approach will only foster market uncertainty and unnecessary complications for both patentees and the PMPRB.

As we have recommended in prior submissions, the PMPRB should strive for and recommit to a stable and predictable pricing regime, consistent with the Board's established statutory mandate, that enables patentees and the Board to make informed compliance decisions based on a shared understanding of operational feasibility, appropriate and accessible data sources, and procedural timelines.

With reference to the Draft Guidelines, we would like to provide specific comments on key aspects as the PMPRB works to finalize and implement its revised approach.

Price Tests

Consistent with our previous submissions to PMPRB, Sanofi is supportive of the Boards's proposed use of both the Highest International Price (HIP) Comparison test and the Consumer Price Index (CPI). This is the only appropriate approach consistent with the PMPRB's statutory mandate and recent jurisprudence with reference to non-excessive price considerations. Both also provide much needed clarity on the overall approach to compliance for patentees.

More specifically, we are supportive of the use of the HIP test for new medicines at introduction (Initial Review) to ensure their non-excessiveness. Following introduction, the preferred approach for Annual Reviews would then concentrate on the verification of allowable increases under the CPI factor. We do not support a full "rebenchmarking" approach on an annual basis against both the HIP and CPI after a given medicine is deemed compliant at introduction.

The Draft Guidelines should be amended to clarify a threshold of international comparator prices in the PMPRB11 basket to initiate an In-Depth Review in the period following a new medicine's introduction to the Canadian market. Patentees should not be discouraged – and in fact should be incentivized – to launch new products in Canada as early as possible. This benefits Canada's health system, individual patients and their families, and Canada's overall life sciences ecosystem. At the same time, international pricing can evolve quickly in the immediate post-introduction period as various markets see approvals and launches. The PMPRB should consider specifying a minimum number of international comparator prices in the PMPRB11 as a precondition for any potential In-Depth Review to be initiated. In addition to not hindering early Canadian launches, this also has the co-benefit of allowing for a more accurate picture of international prices to be available to both patentees and the PMPRB itself while avoiding premature action based on a temporary or overly narrow HIP test.

Minimize market disruptions for new and existing medicines

Consistent with the Board's proposed approach to price tests noted above, the Draft Guidelines should take a proportional and risk-based approach to the treatment of existing medicines (products with a first sale prior to 2022), including products deemed compliant up to and including the 2022 period when regulatory amendments came into force.

A critical operating principle for existing products should be to minimize market disruptions while acknowledging the good faith and achievement of prior compliance against all previous Guideline mechanisms available at any given point in time to patentees.

As noted, we support an exemption for existing products as a matter of ongoing activity. Any retrospective adjustments to previously compliant products, beyond the reasonable verification of CPI adjustments over time, would represent a substantial administrative burden on both patentees and Board staff while destabilizing prior investment decisions across the entire supply chain taken based on the only known compliance requirements

Over time on the market, we would further recommend that the PMPRB set out clear and workable allowances for patentees to manage factors beyond their direct control, most notably minor price variations linked to foreign currency exchange rates. These are subject to a high degree of variability over time. We recommend that the PMPRB set out a reasonable administrative tolerance boundary of a minimum of +/- 10% to avoid a large number of In-Depth Reviews being triggered by minor fluctuations in foreign currency exchange rates in a given reporting period.

We believe that the past practice of establishing joint technical working groups is a constructive and appropriate way to explore the necessary level of detail while avoiding any impractical or unintended consequences from the approach to In-Depth Reviews. Key process questions currently lacking sufficient details, including the expected treatment of complex and/or multi-indication medicines, the rationale for the use of certain comparators, and how and when Board staff may make recourse to the Human Drug Advisory Panel (HDAP) are key opportunities for further work.

Special Provisions on Complaints

Sanofi has identified a number of concerns with the proposed approach to complaints in the Draft Guidelines. We were particularly disappointed at the omission of patented vaccines and blood products from the list of in-scope product categories subject to In-Depth Reviews based on complaints exclusively (Sec. 65). This can and must be corrected in the final Guidelines.

As noted, and substantiated at length in prior submissions, both vaccines and blood products are recognized product categories that are already subject to extensive and highly-managed reimbursement mechanisms. These established structures, focused on negotiation and product procurements, substantially reduce the potential risk of non-excessive pricing to the point of practical non-existence. There is minimal to no consumer-facing risk for these products and subjecting them to the full range of filing requirements and extensive PMPRB reviews is poor and potentially duplicative public policy. It is excessive from a regulatory burden standpoint and a misdirected use of public resources overall.

Beyond the availability of certain optional travel vaccines, in a market already subject to open competition among manufacturers, we see no public policy basis for imposing the full extent of PMPRB compliance requirements on vaccines and blood products. These have and continue to be managed successfully by other public agencies and negotiating/purchasing mechanisms.

It is critical to reiterate that at no point would including these products lessen the PMPRB's jurisdiction or enforcement. Should a scenario emerge where a Ministry of Health believes that a proposed list price is outside the Guidelines and cannot be managed appropriately in the procurement process, they would retain full and complete recourse to the Complaints process for Board evaluation and potential further action. A complaints-only approach is the most efficient and effective manner to align the PMPRB's activities with other established health system agencies and requirements without diluting its non-excessive price mandate and overall jurisdiction.

On the matter of proposed eligible complainants (Sec. 67), we oppose the inclusion of any parties beyond Ministers of Health from a Canadian jurisdiction. This will avoid setting out a process which risks being unmanageable and/or subject to inappropriate use with the attendant drain on limited PMPRB resources.

Public-office holders play an important role in the funding and organization of our health system. They are accountable to the general public and are subject to independent scrutiny on an ongoing basis. In contrast, the private-sector, including insurance companies and their trade associations, play a very different role in our marketplace. The possibility – indeed probability – of the emergence of conflicts of interest are considerable in granting recourse to a complaints process above and beyond normal practice of business.

Outside of applicable legal and regulatory obligations and recourse to dispute resolution and the court system for all parties, one side of a free and fair commercial private sector negotiation should not have recourse to a separate public complaints process which potentially disadvantages the other party. This lacks basic procedural fairness and imposes an unnecessary public process to displace what is and should be a private business practice.

The private sector, including insurers, are already implementing and pursuing a range of commercial practices relevant to product reimbursement, including negotiated and other forms of managed agreements with manufacturers. This is customary and appropriate in a private sector context and should not be interfered with or destabilized by a public agency privileging one party over another.

Further, we do not support the Draft Guidelines proposal to allow for complaints to trigger an automatic In-Depth Review. All parties have a shared interest in a process based on the PMPRB's mandate and overall predictability and consistency. Without clear Guidelines on the standard for and handling procedures for any complaint, there is an ongoing risk of spurious or unfounded complaints being used inappropriately and consuming finite PMPRB resources. Complaints must be directly linked to the PMPRB's statutory mandate and specifically the Sec. 85 price factors set out in the *Patent Act*.

Procedural fairness would also require that the details and associated evidence for any complaint moving to an In-Depth Review is shared with the patentee in question to allow the PMPRB to receive a full accounting of the totality of relevant information for a given product review.

Finally, we recommend that any calculation of excess revenue resulting from a complaint be limited to the date at which the complaint was accepted by the PMPRB. To minimize disruption for all parties, products which had been deemed compliant in prior filing periods should not be subject to retroactive remedies.

Next Steps

We appreciate the opportunity to share our perspective on the Draft Guidelines. Overall, while the use of the HIP and CPI are important and appropriate procedural touchstones, Sanofi remains concerned about the extent of discretion and unpredictability embedded within the proposed approach. Product launch and investment decisions for Canada are both highly competitive and long-term in nature. Canada benefits from stable and predictable compliance policies, including in respect of non-excessive pricing at introduction and over the life cycle of a given product.

Should any Board members or staff have any questions regarding the content of this submission, please do not hesitate to contact me directly. We remain firmly committed to ensuring that Canadians benefit from sustainable and timely access to new medicines. 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,

Carrie McElroy (Mar 18, 2025 13:40 EDT)

Carrie McElroy
Head, Market Access and Public Affairs