December 20th, 2023

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's Guidelines Scoping Paper Consultation

Dear Mr. Digby,

On behalf of Sanofi Canada, I am pleased to provide you with our feedback and perspective on the PMPRB's recently released "Scoping Paper" in respect of its future Guidelines. This builds upon my submission at the recent Policy Roundtable conducted on December 5th in Ottawa.

At the outset, I would emphasize that Sanofi endorses and aligns with the submissions being made by our trade associations, namely Innovative Medicines Canada, BIOTECanada and RAREi (Rare Disease Innovators) under this consultation. We have participated in all PMPRB consultations in recent years and are looking to build upon our prior representations while responding to the evolving public policy, and context for the Board's non-excessive pricing mandate.

By way of background, 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 focused on unmet patient needs. We also have an extensive history and current specialty medicines portfolio, including for rare diseases, oncology and immunology.

Sanofi is also a unique leader in the Canadian life sciences sector, and I would like to emphasize that commitment as important context for the PMPRB's considerations of the overall policy context of its activities. A prominent manufacturer for Canada's domestic biopharmaceuticals market, Sanofi remains on track to deliver over $2 billion in new investments for Canada over the period of 2018 to 2028. These global-scale investments are focused on enhancing our industrial footprint while promoting greater supply chain resilience and overall health system sustainability. Reflecting on the lessons and

experiences of recent years, pandemic preparedness is a key focus of both our ongoing planning and new investments.

Sanofi is proud to be the largest corporate life sciences sector investor in research and development, putting us among the top 25 corporate R&D contributors to Canada overall. In short, we are strongly committed to Canada and demonstrating that commitment in tangible and important ways.

With respect to the consultation on the development of the PMPRB's Guidelines and the current scoping document, we wish to offer some reflections and recommendations with an urgent desire to ensure that Canada remains a leading destination for new product launches and future investments.

Looking to the overall Guidelines development process, Sanofi would welcome the opportunity to work with the Board on providing our feedback on any specific upcoming proposals in this regard in the coming months. It is important to emphasize that the burden of PMPRB compliance falls exclusively on patentees.

Our comments are focused on three broad concepts: (1) focusing on the PMPRB's mandate; (2) promoting policy stability and predictability; and (3) the opportunity to manage patented vaccines in a differentiated manner.

1. Respecting the PMPRB's Mandate.

The PMPRB's statutory mandate is grounded in the *Patent Act* with an exclusive focus on "non-excessive" pricing. As the Board has heard from multiple stakeholders, this mandate has been unambiguously reinforced by recent court decisions.

Overall, Canada's pricing and reimbursement landscape for innovative medicines is complicated. There are multiple established agencies with separately defined mandates, affected stakeholders, with different and, at times, overlapping levels of governments involved. The PMPRB is distinct from these other agencies in both legal and practical terms. Its role as a quasi-judicial agency, focused on non-excessive public or "list" pricing, is very clearly delineated and stands apart from those other processes and bodies.

Therefore, we would recommend that the Board reiterate and give proper emphasis to its mandate in the Guidelines development process right at the outset. Doing so would have the advantage of focusing future Guidelines development efforts within the Board's purview while avoiding unwarranted or extraneous attempts to address other, out-of-scope concepts more properly managed or addressed other existing agencies and processes.

2. Promoting A Stable and Predictable Compliance Regime.

One of our key reflections on the pricing policy experience of the last number of years has been the destabilizing nature caused by a lack of clarity on future compliance requirements. This has global ramifications.

Canada benefits from innovations developed here as well as at the global level. Product launch decisions will depend on multiple factors, but compliance predictability is a key component. To be clear: under any future Guidelines, compliance requirements must be reasonably knowable (and achievable) well in advance of a patentee making a launch decision.

Predictability and operational stability will benefit all parties, including Board staff. Stability allows Board staff to apply resources to the more complex matters within its mandate. Most importantly, this stability allows all Canadians and our healthcare system to be timely beneficiaries of new medical innovations as they emerge from the global scientific research enterprise. Stability allows Canada to compete and win future R&D investments, such as those secured and underway by Sanofi. Cutting-edge medical research often depends on having reliable access to standard-of-care treatments as well as the reasonable prospect of future patient access to therapies studied in the same jurisdiction.

Reliable pharmaceutical and vaccine supply is also an important consideration for Canadians and our healthcare system. Canada's supply network for these important products is under significant pressure due to extensive cost inflation as well as many ongoing or emerging cost containment measures at the purchasing or reimbursement level.

It is critically important that the PMPRB's future Guidelines adequately account for changing prices in the wider economy (as measured by the Consumer Price Index, CPI). This must be a core operational and policy consideration for the PMPRB, fully consistent with its inclusion as a relevant PMPRB factor in the *Patent Act*. Any future Guidelines should also offer clear and predictable rules governing price adjustments aligned with changes in the CPI.

Finally on this set of issues, it is worth highlighting that the Government of Canada, as well as other levels of government around the country, have rightly made regulatory agility and operational efficiency as focus areas of public policy reform. Sanofi joins with many other stakeholders in strongly encouraging the PMPRB to take a similarly modernized, predictable and forward-looking approach to the Guidelines.

3. Important Considerations for Vaccines.

Vaccines are a major part of Sanofi's global and Canadian mission and mandate and are fundamental to our corporate history and major investments in Canada. These remarkable innovations are a critical health intervention to manage both known and emerging infectious diseases. Vaccines literally impact and safeguard the lives of millions of Canadians and our fellow citizens around the world. As medical interventions, they require not just the latest cutting-edge developments in therapeutic science but also

the most complex and sophisticated industrial and supply chain capacity and scale of almost any industry in the world.

Canada's system for the pricing and reimbursement of vaccines is highly sophisticated and has evolved over decades. It is characterized by various established and mandatory elements which qualitatively differentiate vaccines from other therapeutics and cost inputs into our health system.

Beyond the often separate and extensive public health administration and delivery pathways, new vaccines are subject to separate expert reviews for clinical, value and implementation considerations. This work principally occurs via the National Advisory Committee on Immunization, or NACI, and results in recommendations for coverage and adoption.

Unlike most other new medicines, vaccines are then typically procured centrally by a federal Department (Public Services and Procurement Canada) on behalf of the Provinces and Territories using a range of structured tools including formal tendering mechanisms. We have also seen the more recent use of separate Advance Purchase Agreements (APAs) in the vaccine space.

Other patented vaccines principally reimbursed through the private market, while a very small share of overall spending, are also subject to commercially competitive pricing dynamics. This category of vaccines includes optional travel vaccines, which by definition are discretionary and delivered through private clinics rather than mandated by domestic public health immunization policies. We note that the privately reimbursed vaccines market is also subject to a range of pricing factors and supply chain intermediaries well beyond the patentee's ex-factory list price, including wholesale and retail markups. The ability to shape or dictate final customer prices may be impacted by those factors.

The net result of these structures and highly differentiated review and purchasing practices is a vaccines market which is both qualitatively and structurally different than that of other medicines. For future PMPRB Guidelines purposes, these acknowledged differences translate to a uniquely managed and much lower excessive pricing risk for Canadians.

Accordingly, we would strongly recommend that the PMPRB take an appropriately nuanced and explicit up-front approach to patented vaccines reflecting these realities and attendant low-risk of non-excessive pricing. The compliance obligations and overall regulatory burden on patentees with vaccines subject to PMPRB jurisdiction should be adjusted to reflect known structures, activities and risks to non-excessive pricing.

Conclusions – Way Forward

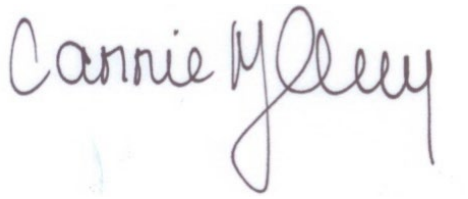
The Scoping Paper is the start of the much longer process of revising and issuing new PMPRB Guidelines. Sanofi is interested in learning much more detail about how the Board intends to implement the recently adopted regulatory changes, namely changes to the list of international comparator countries, while remaining consistent with its established mandate.

Sanofi encourages the PMPRB to strive for clarity, predictability, and operational efficiency in the new Guidelines. Patentee compliance should be both a stated and a shared goal, with investigations and hearings remaining the exception rather than the preferred approach to enforcing the Guidelines and implementing the Board's non-excessive pricing mandate.

As stated above, there is also an available and well-supported opportunity for the PMPRB to treat patented vaccines in a much more risk-adjusted manner reflecting the key features of that unique market and remaining consistent with modern regulatory practices.

Should any Board members or staff have any questions regarding the content of this submission, please do not hesitate to contact me directly. Together, Sanofi is seeking to work with PMPRB and other stakeholders to ensure that Canada remains a globally competitive market for new medicines. We should never take this for granted. Canadians want and deserve to benefit from sustainable and timely access to new treatments available today and those that scientific enterprise has yet to uncover.

Yours Sincerely,



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