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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

Sanofi Canada's submission to the Patented Medicine Prices Review Board's consultation on amending the interim guidance regarding new medicines

Sanofi Canada (Sanofi) welcomes the opportunity from the Patented Medicine Prices Review Board (PMPRB) to comment on the proposed update to the approach for conducting interim price reviews on new medicines, pending the development of new Guidelines.

Sanofi is an innovative global healthcare company driven by one purpose: we chase the miracles of science to improve people's lives. Today, from our state-of-the-art facilities in Canada, we research, develop, manufacture, and distribute Sanofi products to people in Canada and around the world.

As Canada's largest biopharmaceutical producer, Sanofi protects over 7 million Canadians annually against infectious diseases. We operate a world-leading vaccine Research & Development (R&D) and biomanufacturing facility in Toronto and provide life changing vaccines and pharmaceuticals to Canadians. Our focus on patient needs has driven our R&D efforts, leading to the development of new and innovative medicines, vaccines and other treatments that address unmet medical needs in Canada and globally. In 2021 alone, we invested $143 million in R&D, which makes us one of Canada's top R&D investors. As a trusted Canadian healthcare industry leader, Sanofi is on track to deliver over $2 billion in new investments in Canada between 2018 and 2028, including a $925M end-to-end influenza and pandemic readiness manufacturing facility, announced in 2021. This will modernize our industrial operations, strengthen our manufacturing, and supply chain resilience, and contribute to Canadian health system sustainability.

We would like to emphasize that this submission builds on and fully endorses the submission of our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada.

Overall, the interim guidance must be in line with the Government of Canada's priorities of growing the life sciences sector for both the benefit of Canada's economy and for the benefit of

Canada's healthcare system. As detailed in Canada's Biomanufacturing and Life Sciences Strategy[1] and in Canada's National Strategy for Drugs for Rare Diseases[2], the federal government is prioritising building a strong and resilient domestic biomanufacturing and life sciences sector, which includes enabling innovation by ensuring world class regulation. Through this, the Government of Canada's aim is to make Canada a more attractive destination for leading life sciences firms to establish and grow and to make Canada a globally competitive hub of innovation. These agile and streamlined regulatory approaches will support access to products that are needed by Canadians. Sanofi intends to play our part in delivering life-saving treatments to patients in Canada and across the world.

Sanofi would encourage the PMPRB to enhance policy transparency and operational predictability for the Canadian market as it relates to future price compliance to novel medicines. While the Board is seeking to accomplish this through extending certain aspects of the Interim Guidance in the current Notice and Comment, there are several important factors to consider. To ensure lasting stability for the PMPRB's legislative and regulatory mandate over the long-term, it is essential to establish distinct, predictable, and enforceable revised Guidelines through comprehensive consultations with stakeholders.

We would strongly encourage that the Board reconsider its proposed application of international median price tests. The Interim Guidance and any future PMPRB Guidelines should reflect the PMPRB's mandate under the *Patent Act*. Consistent with these frameworks as well as the stated policy direction from the Government of Canada, Sanofi strongly supports the view that price compliance for new medicines should be assessed with reference to the **entire** basket of international comparators. Under a non-excessive pricing mandate, any price within the range of the new PMPRB11 (i.e., countries that have been selected for comparison purposes because they do not have excessive prices) should be considered compliant.

There are also challenges with respect to the proposed approach to price increases. The Interim Guidance and any future Guidelines should also offer clear and predictable rules governing price adjustments aligned with the Consumer Price Index (CPI). The importance of measuring changing prices in the wider economy (as measured by the CPI) should not be overlooked or omitted as a core operational and policy consideration. CPI is a mandatory legislated factor in the *Patent Act* for the purposes of the PMPRB's determination of non-excessive prices. The proposed approach places an unreasonable limitation on patentees inconsistent with the legislative framework and should be adjusted accordingly. Locking Interim Period price levels to a past fixed period of time fails to account for the realities of changing prices.

[1] Health Canada and ISED, Canada's Biomanufacturing and Life Sciences Strategy, July 28th 2021

[2] Health Canada, Government of Canada improves access to affordable and effective drugs for rare diseases, Government of Canada improves access to affordable and effective drugs for rare diseases - Canada.ca, March 22nd 2023

Sanofi is fully aligned with our industry associations in supporting a move away from multiple price re-assessments to support the PMPRB's objective of providing greater stability and predictability to patentees and reducing administrative burden.

Overall, the PMPRB should seek to provide stable price ceilings where possible to promote compliance**.** There remains a lack of clarity on what is meant by "considered as reviewed," and how this status brings about more predictability to patentees, how it affects how these files will be treated during the interim period, and how "reviewed" and other new medicines will be assessed once the new guidelines eventually come into force.

Clearly, much more consultation and dialogue is warranted in regard to policy intent and operational feasibility. Sanofi is interested in working constructively with the PMPRB to develop future guidelines that offer stability and predictability for all parties. We have a shared interest in clarifying policy objectives and promoting an efficient and effective use of resources by all parties. Greater compliance certainty and predictability for all sides should encourage a more efficient use of resources with the goal of improving and sustaining access to new medicines for Canadians and maintaining Canada's competitiveness as a destination for innovation.

Sincerely,

Stephanie Veyrun-Manetti
Country Lead and General Manager Specialty Care, Sanofi Canada

Sanofi Canada