November 6, 2020

Jean-François Pagé
Clerk, Standing Committee on Health
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6

Dear Mr. Pagé:

On behalf of SANOFI Canada ("SANOFI"), we appreciate the opportunity to participate in the Standing Committee on Health ("HESA") study regarding pending changes to the Patented Medicine Prices Review Board ("PMPRB") set to be implemented as of January 1st, 2021.

SANOFI is one of the leading innovative biopharmaceutical companies in Canada and the world. With an extensive and diversified product portfolio, we have been a proud local and global health partner for Canadians for decades. Our work in Canada spans the research and development, production and distribution of vaccines (for both domestic and global markets), important advancements in cardiovascular treatments, insulin therapy for patients with diabetes, innovation to patients struggling with cancer, multiple sclerosis, immunological conditions and treatments for rare diseases and rare blood disorders.

SANOFI has worked hard to sustain the largest and most consistent investment footprint in Canada from the global life sciences sector – with R&D contributions reaching $131 million in 2019. Over and above this ongoing commitment, SANOFI was proud to secure a landmark global investment in 2017 of $570 million towards our SANOFI Pasteur Building 100 project in Ontario – the largest single investment in Canadian life sciences history. During the next 5 years, SANOFI aims to further expand its industrial and R&D footprint, bring additional therapeutic innovations to Canada, with at least 15 planned new medicine launches.

Unfortunately, the implementation of the PMPRB's new guidelines will negatively impact our organization due to the uncertainty of innovative new therapies and vaccines. Our concerns are based in not only the PMPRB's substantially expanded approach and clear intention to manage Canadian prices actively downwards, but also the significant increase in overall regulatory uncertainty given the inherent nature of the new tools the PMPRB is adopting.

Managing under a highly restrictive, complicated and burdensome pricing regime is and will be a major challenge. Many requirements remain unclear and/or subject to discretionary interpretation and enforcement by PMPRB staff. The application of pharmacoeconomic tests are inappropriate, duplicative and unprecedented. The PMPRB's attempts to intervene in the area of confidential (rebated) pricing is an intrusion into Provincial jurisdiction and has already been struck down by Canadian courts. SANOFI shares the concerns of many life sciences stakeholders at the emerging evidence of the negative impacts these changes are having even before they officially take effect in terms of both new product launches and clinical research investments.

Given the realities and continuing questions regarding the new PMPRB regime, we remain highly concerned about Canada's position as a leading launch jurisdiction within our global organization. This is especially the case given Canada's relatively small global market and the intricate nature of global product pricing policies, referencing, and other considerations. We strongly believe the current approach is counterproductive given the burden of disease facing many Canadians now and into the future.

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Our most recent submission to the PMPRB as part of its Guidelines consultation process is enclosed for your information and reference. As a general observation, our experience with participating in many of the consultations of the past number of years on this matter has been disappointing, and the final Guidelines issued do little to address our fundamental concerns. We believe this is a view you will find across many diverse stakeholders, particularly patient and non-profit organizations, who have dedicated considerable time and resources to responding to various consultations in good faith.

We are particularly concerned at the apparent implications for two areas of medicine in desperate need of innovative treatments: rare disease and oncology. The structure of the PMPRB's approach will restrict the ability of manufacturers such as SANOFI to bring forward many of these new innovative treatments. The nature of the PMPRB rules will make many new launches unviable. The clinical and evidentiary realities for many of these conditions do not support the inflexible application of price tests designed for very different purposes. The result will simply be Canada effectively closing the door to many treatments precluding any assessment of new treatments against the needs of Canadian patients. It will also prevent both public and private drug plans to structure appropriate reimbursement models to manage both risks and overall costs and benefits.

SANOFI is also disappointed that the PMPRB did not fully account for the unique aspects of vaccines and blood products, which are subject to very different review and reimbursement procedures in the Canadian system, including sole-purchase tendering. This means that these products present very different price risks for consumers given how those markets operate. The final Guidelines specify that only vaccines are to be managed on a complaints-only basis, which is an important recognition of these differences in price risk without extending a similar approach to blood products. However, vaccine manufacturers will still have to report extensive compliance information to the PMPRB irrespective of the existence of a complaint or not. This is an unfortunate burden on vaccine manufacturers, many of whom are also pursuing other important public health priorities including COVID-19 vaccines and therapeutics. In an environment where worldwide demand is higher than supply, and a time where vaccines are essential to public health. SANOFI reiterates its recommendation that the PMPRB should exclude fully vaccines and blood products from the ongoing application of the Guidelines entirely given their demonstrably lower price risks, while retaining the legislative authority to open investigations and launch hearings as necessary.

Recommendations:

Going forward, we would strongly encourage HESA to focus on a more predictable, appropriate PMPRB regime which focuses on offering clear guidelines to manage non-excessive list prices for patented medicines. Specifically, and consistent with our prior submissions on this matter, we recommend that:

- **PMPRB Guidelines should be substantially amended and clarified to focus on regulating list pricing only. This would reflect appropriately the PMPRB's mandate and role in the Canadian system while respecting Provincial jurisdiction and the determinations of Canadian courts.**

- **Canada's global position as a leading launch jurisdiction for new medicines must be a focus of any policy rationale and implementation of price regulation changes. Where warranted, the PMPRB approach must be tailored to the different realities and characteristics of the range of current and future innovative medicines and vaccines, including for rare diseases and oncology.**

- **Given the above considerations and the extent of ongoing serious stakeholder concerns, as HESA should immediately call upon the Federal Government to defer the implementation of the updated PMPRB regime until further notice, to allow for a reconsideration of the approach in terms of policy objectives, predictability, and implications for Canadian patients.**

Our industry remains very interested to explore alternative approaches with the Federal Government on price regulation. Our industry, through Innovative Medicines Canada has developed tangible proposals to reform the PMPRB, to manage higher-cost medicines, and to strengthen Canada's commercialization and manufacturing capacity.

Other models and tools have not been adequately assessed given the PMRPB's proposals have not fundamentally changed throughout the regulatory and Guidelines development process. It is not too late to contemplate a different approach. There are other ways to achieve the Government's pricing policy objectives without subjecting Canadian patients to the negative consequences of the current approach.

SANOFI would welcome the opportunity to participate in any policy dialogue to identify, evaluate and advance a different approach to PMPRB reform.

Thank you for your consideration of these comments.

Sincerely,

Marissa Poole
General Manager, Sanofi Genzyme and Country Lead, Sanofi Canada