Via email: douglas.clark@pmprb-cepmb.gc.ca

October 24, 2016

Mr. Doug Clark
Executive Director
Patented Medicine Prices Review Board
1400 - 333 Laurier Avenue West
Ottawa ON K1P 1C1

Dear Mr. Clark,

On behalf of Sanofi, I would like to thank you for the opportunity to provide comments on the "PMPRB Guidelines Modernization Discussion Paper, June 2016." We support the need for consultation with all stakeholders on potential changes to the PMPRB and we would welcome an opportunity to be part of future working groups and consultations responsible for reviewing current operating guidelines as well as any future proposed changes.

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi entities in Canada (Sanofi) include the Diabetes and Cardiovascular Diseases Business Unit, the General Medicines, Established Products and Consumer Healthcare Business Unit, Sanofi Pasteur (vaccines), Sanofi Genzyme (rare diseases, multiple sclerosis and oncology) and Merial (animal health). Together they employ close to 1,700 highly skilled and competent people across all of Canada. In 2015, Sanofi companies invested $133.3 million in R&D in Canada, creating jobs, business and opportunity throughout the country. Sanofi's total R&D investment represented more than 20% of their sales and this percentage ranked among the highest in the Canadian pharmaceutical industry.

Sanofi has a long tradition of bringing innovative medicines to Canadian patients. Complying with Canadian and provincial regulations, including PMPRB guidelines, has always been an important part of the development and introduction of our new medicines. We believe that PMPRB has been succesful in achieving its dual role: a regulatory role which consist in ensuring that prices charged by patentees for patented medicines sold in Canada are not excessive and, a reporting one which involves reporting on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patentees.

It is to be noted that the Canadian environment has evolved tremendously since the PMPRB's inception in 1987. Over the past 25 years, Canadians have witnessed the establishment of two important direct influencers on drug pricing: the pCPA and HTA (CDR/INESSS) . These two bodies play a key role in Canada as they are responsible for pricing and access to medicines in publicly funded drug programs. These regulatory and HTA agencies have had a significant and immediate effect on drug pricing and health care costs via cost effectiveness thresholds and confidential rebates. Whereas the PMPRB exerts

downward pressure via international and local comparisons, HTA and the pCPA, act in an additive and complementary manner by determining thresholds of value and affordability

Canada is the only country with two parallel processes – the PMPRB (national) and the pCPA/HTA - which protect consumers against excessive pricing of patentees. The PMPRB was never intended to interfere with the provincial role in formulary management and manufacturer-payer market dynamics. Modernization of the role of the PMPRB, in this regard, will likely result in redundancy and/or conflict with respective HTA and provincial payers in Canada. Further modernization of the PMPRB, as contemplated in the discussion paper, should avoid duplicating resources and efforts in areas (mainly affordability and access) already managed by CDR/INESSS, pCPA and even, more recently by insurance providers. Any overlap with existing Canadian agencies would discourage new innovation and investment in Canada and create unnecessary administrative burden to patentees which inevitably would translate into longer delays for Canadians to access new innovative medicines.

Based on the Modernization Discussion Paper, here are additional comments on select topics that we would like to expand upon.

<u>"Affordable" vs "Excessive"</u>

It is noted that the vision of the PMPRB now includes statements of 'affordability' in contrast to the existing mandate of managing 'excessive' pricing. The term 'excessive' connotes a comparison to a standard or reference. In the case of the PMPRB, comparisons are made to the PMPRB7 countries and also to local therapeutic class comparison where applicable. "Affordable" is a value judgment and is made in context of those purchasing, managing or allocating resources. We believe 'affordability' falls within the mandate and jurisdiction of payers in Canada and should not be within the mandate the PMPRB. As mentioned previously, affordability, as well as access are best managed by the existing key provincial payer and HTA bodies, namely HTA (CADTH, INESSS) and the pCPA. PMPRB resources and efforts would not be optimized by addressing the same issues already handled by these bodies.

<u>Recognition of Therapeutic Improvement</u>

Pharmaceutical development operates on the principle of incremental innovation. That is, some new products will bring large improvements and others will introduce rather modest improvement and benefits. While new incremental innovations are constantly being developed, the PMPRB policies continue to see these products as 'me-too' and provincial payers have demanded discounted prices. Therapeutic value and benefit to patients is the currency by which innovation is measured. It is important that we continue to recognize the medical and therapeutic value of bringing innovation to Canada.

The suggestion that the PMPRB would conduct an initial screening based on indicators of potential for abuse of statutory monopoly, rather than clinical evidence of therapeutic superiority is fraught with

challenge and is not within the mandate of the PMRB. Interpretation of what would be indicators of potential abuse, the establishment of a pre-established threshold and determination of drugs that are 'likely to cause rationing by public and private drug plans' brings additional judgment and interpretation than exists currently and should not constitute the basis for the evaluation of new medicines.

International Price Comparisons

The use of the median of international prices versus using the mean (average) of international prices ensures that US prices (or the country with the highest prices) are typically removed or have less weight within any analysis of new product pricing. The inclusion of US FSS pricing in these analyses also removes the disproportionate influence of the US in any PMPRB review of prices. Consistent with the submission from Innovative Medicines Canada, Sanofi supports the establishment of criteria *a priori* for the potential inclusion of any new country to the basket. That is, "if we are to change the list of comparator countries, we should expect to base the new basket on economic relationships, similar economies and purchasing power as well as health system standards." There is no strong evidence to support changing the comparator countries for the sole purpose of lowering Canadian patented drug prices.

While the Canadian pharmaceutical environment has evolved since the inception of the PMPRB, the role and mandate of the PMPRB continues to be relevant and impactful. Since inception of the PMPRB, provincial payers (CADTH, INESSS, pCPA) and HTA agencies have taken a larger role in the management and allocation of scarce resources and this has positively impacted healthcare costs and prices of new and existing medicines downward. The PMPRB has acted to complement these agencies to further control drug prices in Canada.

A welcoming Canadian environment for the steady launches of new innovative medicines represents the first step in bringing new drugs to Canada. We trust that the PMPRB modernization exercise will help maintain such an environment. We believe that the best solutions can only be generated when there is a true collaboration between all impacted stakeholders. We look forward to engaging with the PMPRB in order to better address ways of improving the current guidelines.

Thank you once again for the opportunity to comment on the Discussion Paper. I look forward to providing further context to our perspectives above during Phase 2 of the consultations.

Sincerely,

Robert Tam
Head, Government Affairs

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