



February 14 2020

Tanya Potashnik  
Director, Policy & Economic Analysis Branch  
Patented Medicines Price Review Board  
333 Laurier Avenue West, Suite 1400  
Ottawa, ON

Submitted via email: [PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca](mailto:PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca)

**Re: Draft PRMPRB Guidelines 2019**

Dear Ms. Potashnik,

CHP Canada is the industry association that represents the companies that make evidence-based over-the-counter medicines (OTCs) and natural health products (NHPs). These are the products you can find in every Canadian home. From sunscreens and vitamins, to pain relievers and allergy medications, people use consumer health products to maintain their health and manage their minor ailments. This is a fundamental part of self-care, which is vital to the health of Canadians, to the sustainability of our healthcare system and the strength of our economy.

Few NHPs and OTCs have patents, but those that do remain captured by the *Patent Act* and the *Patented Medicines Regulations* even though these provisions designed to protect Canadians from excessive prescription drug pricing are not relevant in the dynamics of the consumer health products market place. In our view, not all patented drugs should be subject to the same level of regulatory oversight and that all patented self-care products should be excluded from the scope of the Patented Medicines Act, Regulations and guidelines. As such, we recommend that patented self-care products, like over-the-counter drugs and natural health products should be excluded from the scope of the *PMPRB Guidelines, 2019*.

We appreciate with the recent amendments to the Patented Medicines Regulations [SOR/2019-298] that the reporting burden for OTC drugs was reduced so that sponsors of patented OTCs would only be required to report price and sale information upon request by the PMPRB. In such instances, reporting information in accordance with the *PMPRB Guidelines, 2019* would be overly burdensome and may not be relevant for OTC drugs. For example, a patented OTC in Canada may be a prescription drug in the other comparative countries and would not be an appropriate comparison regarding price, product information and product use relative the Canadian OTC product. If patented OTC and NHP drugs cannot be excluded from this guidance then an abbreviated process and requirements for these products should be developed.

Lastly, we share concerns raised by Innovative Medicines Canada about the operationalization and the significant and impact the *PMPRB Guidelines, 2019* would have on patient access to new medicines in Canada.

Thank you for the opportunity to input into this consultation, we trust our comments will be carefully considered.



Sincerely,

*Kristin  
Willemsen*

Kristin Willemsen  
Director, Scientific & Regulatory Affairs