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Douglas Clark
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Patented Medicines Prices Review Board
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Re: PMPRB Guidelines Modernization Discussion Paper

Dear Mr. Clarke,

Consumer Health Products Canada (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.

Few OTCs and NHPs are protected by patents as they are generally not new chemical entities and are ineligible for market exclusivity. However, those that do have patents are subject to the *Patent Act* and Patented Medicines Prices Review Board (PMPRB) processes to regulate pricing even though the system intended to regulate the prescription pharmaceutical pricing market for provincial and private payers, not the consumer marketplace. CHP Canada welcomes the opportunity to participate in the public consultation to gather information on changes to the regulatory environment towards the goal of modernizing and simplifying the PMPRB guidelines and regulatory framework to ensure they are relevant and effective to protect consumers from excessive pharmaceutical prices. CHP Canada views this as an ideal opportunity to resolve a longstanding issue of consumer health products industry as a result of being captured by the *Patent Act* and PMPRB processes.

The current system of price regulation was not designed for consumer health products. A full and detailed review of the parliamentary record leading to the amendments to the *Patent Act* found no evidence at all that Parliament ever intended to regulate anything other than prescription drug prices. The discussion paper reiterates this focus by describing PMPRB's vision for a "*…pharmaceutical system where payers have the information they need to make smart reimbursement choices and Canadians can afford patented drugs they need to live healthy productive lives*." However, consumer health products are generally not reimbursed by public and private payers as they are selected and paid for by consumers themselves. Unlike prescription medicines, consumers are primarily responsible for the selection of self-care products and thus will choose products based upon a variety of attributes which are most relevant to them personally, including price. This is in stark contrast to the selection process for Rx drugs where other parties (physicians, pharmacists, payers) largely determine which product will be provided to the consumer/patient, often in isolation from the impact of price. Consumers also have the ability to choose from a range of drug substances in a given therapeutic category to treat their condition and each chemical entity within a category typically has multiple sources/suppliers to choose from. This creates a highly competitive market situation much like most consumer product markets. The highly competitive nature of

the self-care market encourages innovation and the development of new products for consumers with specific dosage forms, flavors, package sizes and configurations in order for the various brands to differentiate themselves and build market share consistent with most consumer product markets. Consumers can express their preference by the choices they make and this maximizes the incentive for manufacturers to provide optimal value for the cost of the product.

Throughout our discussions with PMPRB over the years, PMPRB has confirmed that their jurisdiction extends to all medicines captured under the definition of 'drug' the *Food and Drugs Act*, which includes prescription drugs, non-prescription drugs (OTCs), and natural health products (NHPs). However, the PMPRB has demonstrated its authority to provide administrative relief from the burden of the regulations through a compliance policy, stating "*the PMPRB does not exert jurisdiction over natural health products*," despite the fact that natural health products also fall under the *Food and Drug Act* definition of a drug and are largely indistinguishable from OTCs by consumers in the marketplace. In fact, many NHPs were regulated as OTCs prior to the advent of the NHP Regulations in 2004. We see no reason why OTCs and NHPs should not be accorded the same treatment by the PMPRB.

The OTCs that are captured by the PMPRB are subject to an administrative approach which limits intervention on these products to a complaint basis, as described in Section 4(3) of the *Patented Medicines Regulations* and in the 2010 *Compendium of Policies and Guidelines*. However, these processes continue to pose challenges for the consumer health product industry. For example, traditional marketing practices like promotional pricing and incentives (e.g. bonus packages, discount programs) in the self-care marketplace provide further benefits to consumers but are discouraged by the PMPRB guidelines since manufacturers become tied to price levels which are unsustainable over the life of the product. Retailers also have significant influence over the final cost to the consumer for self-care products and thus controlling of ex-factory prices is not an effective means of ensuring a desired consumer cost for such products.

In the future, PMPRB should be aware that the consumer health product industry is working with Health Canada to fundamentally change how products will be regulated in the future and address these regulatory disparities between OTCs and NHPs. On September 8th, Health Canada published a consultation document proposing changes to the regulation of self-care products in Canada. A paradigm shift has been proposed that would establish one consistent, risk-based set of regulations for all consumer health products, including OTCs, NHPs, and cosmetics. In order to achieve this, certain sections of the *Food and Drug Regulations*, as well as the *Natural Health Product Regulations* and the *Cosmetic Regulations* would need to be repealed in favor of establishing a new, separate set of regulations under the *Food and Drugs Act* for self-care products. This would mean that current exemptions for NHPs would no longer be relevant in this new regulatory environment. However, **the development of new regulations for self-care products creates the ideal opportunity for the PMPRB to modernize the scope and simply their regulatory framework by exempting all self-care products from the *Patented Medicines Act, Regulations* and guidelines.** By exempting all self-care products, it would enable PMPRB to have a clear, narrow focus on prescription pharmaceuticals and remain relevant and effective in achieving their vision.

We look forward to further opportunities to participate in stakeholder discussions and consultations throughout the guideline modernization process.

Sincerely,

Kristin Willemsen
Director, Scientific & Regulatory Affairs
Consumer Health Products Canada

c.c: Amanda Moir NNHPD