14 February 2018

Patented Medicines Consultations
Karen Reynolds
Executive Director
Office of Pharmaceuticals Management Strategies
Strategic Policy Branch
Health Canada
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Tunney's Pasture
Ottawa, Ontario K1A 0K9

VIA FIRST CLASS MAIL AND EMAIL (PMR-Consultations-RMB@hc-sc.gc.ca)

Re: Proposed Amendments to the Patented Medicines Regulations, Canada Gazette, *Part I*

Dear Ms. Reynolds:

Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to Canada's request for comments on Proposed Amendments to the Patented Medicines Regulations published on 2 December 2017 (the "*Proposed Regulations*").

IPO is an international trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. IPO's membership includes about 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members. IPO membership spans over 30 countries.

IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; and disseminating information to the public on the importance of IP rights. IPO appreciates Canada's effort to allow stakeholders the opportunity to provide comments on the *Proposed Regulations*, which demonstrates Canada's commitment to transparency and public participation in the rulemaking process.

IPO has concerns about the *Proposed Regulations.* IP rights and the value of innovation are severely undermined when the cost of developing pharmaceutical improvements is not accurately taken into account. IPO acknowledges Canada's interest in managing its health care system. In order to maintain and improve the quality of any health care

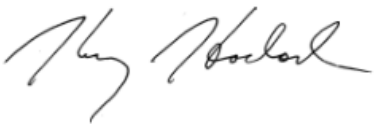
system, the price of new medicines should not be driven to a level that would discourage innovation. As the *Proposed Regulations* currently read, they would lessen the incentive for new medicines to be developed.

We are particularly concerned about the changes to the list of comparator countries under section 4(1)(f)(iii) that remove the United States and Switzerland — and add Australia, Belgium, Japan Netherlands, Norway, Republic of Korea, and Spain. The U.S. and Switzerland are home to many of the world's pharmaceutical and biotechnology research companies. Furthermore, the removal of the U.S. and the absence of other countries such as Mexico, another one of Canada's largest trading partners, is concerning. Also troubling is the selection of countries for the list that in general have lower drug prices than Canada — without considering the impact this has on accessibility to new medicines in those jurisdictions. Market-based pricing for pharmaceuticals provides the requisite incentive for innovative manufacturers to pursue the risks of drug development in order to bring new medicines into these jurisdictions more quickly. The *Proposed Regulations* are thus a disincentive for innovators to bring new medicines to market more quickly.

We are also concerned about the reduction in reporting requirements for patented generic medicines (approved by means of ANDS). Generic medicines are exempt from the continual reporting of cost-utility analysis information unless requested by the Board. At the same time, innovative manufacturers have expansive reporting requirements under the "merest slender thread"[1] basis for jurisdiction by the PMPRB. This results in a situation that disadvantages innovators who create new medicines.

We again thank Canada for permitting IPO to provide comments and would welcome any further dialogue or opportunity to provide additional information.

Sincerely,



Henry Hadad
President

[1] *ICN Pharms. Inc. v. Canada* (Staff of the Patented Medicine Prices Review Board)(C.A.)(1997) 1 F.C. 32 (ICN).