



Karen Reynolds  
Executive Director  
Office of Pharmaceuticals Management Strategies  
Strategic Policy Branch, Health Canada  
Brooke Claxton Building, 10th Floor  
70 Colombine Driveway, Tunney's Pasture  
Ottawa, Ontario K1A 0K9  
Email: [PMR-Consultations-RMB@hc-sc.gc.ca](mailto:PMR-Consultations-RMB@hc-sc.gc.ca)

**RE: Canadian Chamber of Commerce and Canadian Intellectual Property Council: Canada Gazette I  
Consultation Submission on the *Regulations Amending the Patented Medicines Regulations, Vol. 151, No. 48*  
— December 2, 2017**

### **Introduction**

The Canadian Intellectual Property Council (CIPC) is a Canadian business coalition, supported by the Canadian Chamber of Commerce, designed to provide a central voice to press for stronger intellectual property (IP) protection both in Canada and worldwide. Founded in 2008, the CIPC's primary objective is to ensure that the Canadian government provides the necessary legislative framework and sufficient resources to better protect intellectual property rights. The CIPC welcomes this opportunity to express its concerns with respect to Health Canada's proposed *Regulations Amending the Patented Medicines Regulations* (Proposed Regulations) and their potential impacts on the regulation of patented medicines prices by the Patented Medicine Prices Review Board (PMPRB)<sup>1</sup>.

In this submission, we emphasize certain aspects of the Proposed Regulations that our business community fears will negatively impact Canada's competitiveness for research-based investment. As outlined below, the CIPC is concerned that the Proposed Regulations, as currently drafted, risk devaluing innovation and IP and may disincentivize investment in research and development (R&D) in the life sciences sector.

### **The Value of Innovation and Intellectual Property for Canadian Businesses**

The PMPRB's existing regulatory framework is one that has encouraged companies to enter the Canadian marketplace, allowed companies to launch new products, and provided incentives for manufacturers to launch novel, competing products. This has benefited Canadian patients, health systems and the economy. The

---

<sup>1</sup> Canada Gazette, Part I, Regulations Amending the Patented Medicines Regulations, Vol. 151, No. 48, December 2, 2017, available at <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html>.

Proposed Regulations signal a shift in government policy-making towards lesser value being placed on IP and innovation – a significant concern for Canada’s business leaders.

The Regulatory Impact Analysis Statement (RIAS) accompanying the Proposed Regulations states that the PMPRB’s mandate is “to ensure that patentees do not abuse their patent rights by charging consumers excessive prices” during the period that they benefit from a statutory monopoly.<sup>2</sup> The Proposed Regulations, however, would seem to depart from this mandate. Rather, they reflect a growing and jurisdictionally-problematic focus on health system expenditure management and active market intervention.<sup>3</sup> While there is a legitimate federal role to play in safeguarding against excessive patented drug prices, the manner in which this is implemented must be consistent, in both spirit and letter, with the *Patent Act*.

The Proposed Regulations suggest amendments to the PMPRB’s basket of reference countries with the explicit goal of setting ceiling prices of patented medicines in Canada at the Organization for Economic Cooperation and Development (OECD) median. Specifically, the PMPRB proposes to remove the U.S. and Switzerland, with the new basket consisting of: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden and the United Kingdom. Any pricing determinations in Canada based on reference to other countries should include comparators with pro-innovation pharmaceutical policies and reflect Canada’s economic standing at the forefront of OECD economies.

We note the proposed changes would have significant financial impact for owners of intellectual property. One recent estimate puts the financial costs to the innovative pharmaceutical sector at \$26.1 billion over ten years, significantly more than the Government of Canada’s 10-year estimate of \$8.6 billion.<sup>4</sup> The government also projects that there would be no impact to the industry’s investment and employment footprint in Canada. This is a dubious assumption given the magnitude of potential financial impacts and heightened business uncertainty under the proposed regulatory approach.

### **Proposals Would Impact Canada’s Business Environment for Investment and R&D**

The CIPC is concerned that the Proposed Regulations will disincentivize investment and R&D in the biopharmaceutical sector through a significant expansion of the regulatory tools available to the PMPRB. As highlighted below, we believe that the application of the existing factors together with the new factors will increase the overall level of complexity and result in greater uncertainty for patentees – each having the potential to negatively impact investment decisions.

---

<sup>2</sup> RIAS at p 4500.

<sup>3</sup> RIAS at pp 4497, 4499–4500, 4503–4506.

<sup>4</sup> PDCI, “Proposed Amendments to the Patented Medicines Regulations: A Critical Appraisal of the Cost-Benefit Analysis” January 2018, [http://www.pdci.ca/wp-content/uploads/2018/01/20180129\\_PDCI-Critical-Assessment-PM-Regs-Amendments\\_Report-Final.pdf](http://www.pdci.ca/wp-content/uploads/2018/01/20180129_PDCI-Critical-Assessment-PM-Regs-Amendments_Report-Final.pdf)

- **Indirect Price Adjustments.** Canada proposes to require manufacturers to report all indirect price reductions given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts, or any other benefit in Canada. The RIAS provides little additional information on the purpose and use of this information, potential legal concerns and the risk of significant and negative consequences for other market participants, raising the substantial concerns about the possibility of commercially-damaging disclosure of confidential information that could impact sensitive negotiations contrary to overall patient interests. The CIPC views this as an overreach of government oversight that is troubling for businesses in the pharmaceutical sector and beyond.
- **New Price Determination Factors.** The Proposed Regulations introduce new price determination factors including “pharmacoeconomic value” based on an arbitrary monetary threshold of the value of an additional year of life; price ceilings based on projected market size; and gross domestic product (GDP) and GDP/capita. Particularly in the case of pharmacoeconomics and market size, these new factors are inconsistent with the PMPRB’s mandate to regulate patent abuse in the form of excessive prices. The changes would empower the PMPRB to consider subjective pharmacoeconomic modeling information which is a significant departure from the more fact-based price information it currently employs. CIPC recommends that Canada remove these new factors from the proposed regulation.
- **Reporting requirements.** The proposed new price regulation factors create new reporting obligations for patentees, which are broad, potentially onerous, and contain a number of significant ambiguities that create unacceptable compliance risk for patentees. We have concerns that new reporting requirements would seem to compel market forecast information as part of federal price regulation. The CIPC is unaware of other sectors that are mandated with the reporting of business forecast information of this nature. We do not believe that it is appropriate to single out IP-intensive sectors through a forecast-based regulatory approach. Any reporting obligations should be in line with precedents and best practices across other federally regulated sectors. For many years, the PMPRB has consistently and systematically underreported the R&D levels of pharmaceutical companies operating in Canada, thereby underestimating the innovative pharmaceutical industry’s contribution to private sector R&D spending and lessening the government’s ability to address investment in R&D needs. To the extent that the PMPRB should have a mandate to report on R&D spending in Canada, the CIPC encourages the Government of Canada to update the regulatory R&D definition so that the PMPRB can accurately calculate the significant R&D contributions made by pharmaceutical patentees to the Canadian knowledge-based economy.
- **Lack of transition in regulation.** The proposed regulations lack of sufficient transition measures for existing products which runs contrary to established regulatory practices in Canada. Given the substantial business impacts, compliance costs, and erosion of value to IP assets and related

investments, the CIPC strongly urges that any changes apply only to products launched after the regulations come into force. Products currently on the market should be fully exempt from any new regulatory provisions.

In conclusion, the CIPC recommends that Canada not proceed with changes to the PMPRB's mandate that would harm Canadian innovative biopharmaceutical companies and undermine the competitiveness of Canada's innovative medicines sector. Any PMPRB policy changes should be based on meaningful consultation and ensure that the PMPRB's role is placed in its proper context with the many other price regulating agencies already active in the Canadian pharmaceutical marketplace. Any changes to the PMPRB's basket of comparator countries or other pricing methods, likewise, must be based on evidence, only made after a sound consultative process, and must include reasonable transitional measures to avoid or minimize disruptions to existing business arrangements. The views of the CIPC are expressed in light of our coalition's shared value for innovation and intellectual property rights, as well as our strong desire to conduct business within a Canadian regulatory environment that incentivizes business investments and R&D amongst patentees.

Best regards,  
Scott Smith  
Director, Intellectual Property and Innovation Policy  
Canadian Chamber of Commerce