



CANADIAN FEDERATION
OF NURSES UNIONS
LA FÉDÉRATION CANADIENNE
DES SYNDICATS D'INFIRMIÈRES
ET INFIRMIERS

Submission to PMPRB Draft Guidelines Consultation

January 17, 2020

The Canadian Federation of Nurses Unions (CFNU) is the voice of nearly 200,000 unionized nurses and nursing students across the country. We are proud to advocate for our members and promote the nursing profession on the national level, and we work tirelessly to protect the quality of health care for our patients and our universal public health care system. We strongly believe that this system must include universal access to prescription drugs.

We would like to express our support for the *Patented Medicines Regulations*. The regulatory changes that will come into force on July 1, 2020, will result in significant savings for Canadians. It is anticipated that the regulations will save \$13.2 billion over 10 years (\$1.32 billion per year). Considering that Canada pays the third-highest list prices on patented medicines in the OECD, this ought to be viewed as a welcome development.

The CFNU embraces these regulatory changes as well within the broader context of the changing regulatory environment for pharmaceuticals in Canada. With the federal government's commitment to implement a national universal pharmacare program, as recommended by the Advisory Council on the Implementation of National Pharmacare, the *Patented Medicines Regulations* sets the stage for further regulatory changes that will lead us to a public, single-payer pharmacare program. The savings that will result from the PMPRB's efforts will be incomplete without ensuring that all those living in Canada have equal universal access to the medicines they need.

Regarding the Guidelines for the *Patented Medicines Regulations*, the following questions and observations are intended to assist the PMPRB in further clarifying the Guidelines. These considerations were shared with us by Dr. Joel Lexchin, professor emeritus from the School of Health Policy and Management at York University. Dr. Lexchin has authored or co-authored a plethora of peer-reviewed articles about pharmaceutical policy in Canada and internationally over the course of a lengthy career.

Regarding Point 7 in the Guidelines, which states: "Every reasonable effort will be made by the PMPRB to assist patentees in understanding the Guidelines and their application": will the PMPRB make similar or comparable efforts to assist other parties – such as consumer groups – in understanding the impact of the Guidelines?

Regarding Point 27, which states: "Ad hoc audits of patentee filings, including pricing, revenue and patent information, may be conducted by Staff": will the PMPRB rely on specific criteria to determine when an ad hoc audit should be conducted?

Regarding Point 49, which lists the criteria for a drug to be classified as Category 1, there is no consideration of the therapeutic value of a medicine, except indirectly through the Incremental Cost-Effectiveness Ratio (ICER). It is unclear what effect this will have.

Regarding Point 63, which lists the situations that may trigger a reassessment for non-grandfathered patented medicines, and states: “A Category 1 patented medicine’s cost-utility analysis is updated” – is either CADTH or INESSS responsible for producing an updated cost-utility study, or could the PMPRB rely on another body for such a study?

The detractors of a public universal pharmacare program are vocal in their opposition to the *Patented Medicines Regulations* and the accompanying Guidelines. We commend the PMPRB for moving ahead with these regulatory changes in the face of a well-resourced effort to discredit the PMPRB’s work on this front.

We have concluded that the detractors of the *Patented Medicines Regulations* and Guidelines have failed to provide evidence to substantiate their claims that lowering prices for Canadian patented medicine will result in fewer clinical trials being undertaken in Canada, fewer orphan drugs being introduced into Canada, and delayed entry of orphan drugs into Canada.

We look forward to seeing the *Patented Medicines Regulations* and Guidelines come into effect.

Thank you for the opportunity to provide feedback on the Draft Guidelines, both through having us participate in the in-person consultation in Ottawa on December 10, 2019, and accepting this written submission as part of the consultations.