



Council of Senior Citizens'
Organizations of B.C.
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Submission to the PMPRB Draft Guidelines Consultation by the Council of Senior Citizens' Organizations of British Columbia (COSCO – BC) *submitted February 14, 2020*

The Council of Senior Citizens Organization of BC welcomes this opportunity to comment on the significant changes to the regulations in the 1985 Patent Act that will come into effect on July 1, 2020 and which will be implemented by the Patented Medicine Prices Review Board (PMPRB). Our comments and recommendations are submitted on behalf of the 80,000 members of our affiliated seniors and retiree groups as well as individual members that COSCO represents across the province of British Columbia.

We understand that while these changes to the regulations will be implemented by the PMPRB, the PMPRB itself may in future become part of the proposed Canadian Drug Agency. This new Agency is envisioned to take responsibility to not only assess the effectiveness of new prescription drugs but also to negotiate drug prices on behalf of Canada's drug plans with a view to lowering the cost of drugs to Canadians by up to \$3 billion per year. By working in cooperation with provincial/territorial governments, it is anticipated that results of these analyses of effectiveness would lead into the development of a national formulary. (See News Release March 25, 2019 from Health Minister Petipas-Taylor)

COSCO-BC views the changes proposed in this PMPRB Guidelines 2019 document as a much needed first step toward the overarching goal of implementing National Pharmacare and thereby saving Canadians an estimated \$6 billion or more per year. We support the changes proposed in the Guidelines as taking considerable steps forward to ensure that pharmaceutical prices are set in a responsible manner and that drug prices will be reduced. We further appreciate that decisions will look at both the effectiveness as well as the cost of the drugs and that expected impacts of quality of life will be included in the assessment process.

COSCO values this consultation on the PMPRB Guidelines, which we see as a well-thought out approach to managing drug prices, and one which brings new elements into the decision making process. We fully support that a population health perspective is being used to assess the cost-effectiveness of new drugs. We appreciate that pharmacoeconomic assessments will be conducted by various independent agencies, particularly the pan-Canadian Oncology Drug Reviews, the Canadian Agency for Drugs and Technology Assessment, and the *Institut national d'excellence en santé et services sociaux*. We would also support the excellent work conducted by the Therapeutics Initiative of BC which conducts rigorous research and assessments on drug policy and which has undoubtedly contributed to the province of BC enjoying some of the lowest drug prices across Canada.

Impact of the Proposed Reforms.

COSCO wishes to provide a perspective from the view point of seniors in Canada.

According to CIHI, seniors aged 65 and over account for roughly 40% of all spending on prescribed drugs and 55% of public drug program spending, while accounting for just 17% of the population. Furthermore, seniors used on average more drugs than other age groups due primarily to receiving prescriptions for multiple chronic conditions.

<https://www.cihi.ca/sites/default/files/document/drug-use-among-seniors-2016-en-web.pdf>

The new regulatory approach proposed is much needed to ensure that seniors are receiving appropriate, effective and cost-effective drugs that will enhance their overall health and well-being. COSCO sees the following attributes as particularly noteworthy.

1. As these reforms are implemented together with National Pharmacare, restructuring of the drug approval process by conducting assessments will speed up drug approvals thereby ensuring that Canadians have similar levels of access to new drugs as do other countries.
2. All Canadians, including seniors, will be more secure that the drugs they are taking are safe, which is particularly important to those 65 and over who are often prescribed multiple drugs for multiple conditions.
3. Canadian seniors will feel more confident that the prices they are paying for drugs are in line with prices from other countries.
4. Canadians will be reassured that their extended drug benefits plans will remain sustainable – whether public or private. Many of the 100,000 private plans may become unsustainable if current pricing models prevail. And the ability to control prices at a reasonable level is a key component of the proposed National Pharmacare plan.
5. Canadians will appreciate that the federal government is doing its job to ensure that their hard-earned dollars are not feeding excessive profits for the pharmaceutical industry and that the dollars they do spend on patented medicines will be beneficial to their health.
6. Canadians will welcome that their government is standing up to the pharmaceutical industry and acting in the best interests to ensure the health of Canadians as they age.

Price Review Process

We support the step by step process detailed in Section V of the report and the inclusion of additional factors in the price review process identified in paragraph 33, for patented medicines after 21 August 2019, including pharmacoeconomic value, market size and gross domestic product. Applying these indicators to determine pharmaceuticals at most risk of being priced excessively (defined as Category I patented medicines), will allow the PMPRB to more effectively deploy its resources to those patented medicines most in need of further review.

COSCO also is in accord with the proposal to look at 12-month treatment costs and to estimate the market size of a drug in determining its appropriate price as outlined in Appendix D. The market size results in downward adjustments on drug prices as annual revenues increase and thus to some extent takes into account increasing market size as the number of patients taking a patented medicine increases.

Comments on Rare Diseases

Special provision is also made in the price review for drugs being used to manage rare diseases. We do have concerns about the overuse of the term 'rare diseases' which includes conditions with a prevalence of up to 1 in 2000 Canadians each year. With an estimated Canadian population of close to 38,000,000, this would give a prevalence of up to 19,000 at any given time. While this prevalence ratio is in line with those used by various other countries, use of the term 'rare disease' might imply to the population at large that there is only a very limited number of patients with the disease across the country, probably fewer than several hundred. We believe this term must be used with care to avoid misleading the general public.

We are also concerned that much of the patient input on policies for rare diseases is coming from patient advocacy groups that are well-funded by the pharmaceutical industry – for example the Canadian Organization for Rare Disorders lists more than 40 corporate leaders including major pharmaceutical companies as well as well over 100 Affiliate members who primarily represent disease groups. Patient representatives from these groups may be considered to be well-funded by the pharmaceutical companies who in turn are benefiting from the often high prices the patients (or their drug plans) are paying for the patented medicines they are using to treat their conditions. We do sympathize with patients struggling to find appropriate treatments for unusual conditions. What we call for is methods whereby patients can be supported to provide independent input into drug decisions and that the conflicts of interest as noted by the Globe and Mail on December 13, 2018 be clearly delineated when patient advocacy groups are providing input into public policy.

Summary

Overall, COSCO supports the Proposed Guidelines circulated for consultation as essential steps to realize the cost benefits that are anticipated as national pharmacare is implemented. The steps proposed are a marked improvement over current processes and over time can be expected to reduce significantly the cost of patented medicines for Canadians.

Further, COSCO recommends that as these new regulations are implemented, and as the responsibilities of the PMPRB are merged into the proposed Canadian Drug Agency, and that as a national formulary is developed and that the goal of single-payer national pharmacare is achieved - that at every step along this path, representatives from non-profit groups which are independent of funding from pharmaceutical companies be included in decision-making and appeal processes.