



Patented Medicine Prices Review Board (PMPRB)  
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Subject: **Patented Medicine Prices Review Board Draft Guidelines Consultation**

On behalf of the Public Health Agency of Canada's Centre for Immunization and Respiratory Infectious Diseases (CIRID) we appreciate the opportunity to provide input into the ongoing public consultation on revisions to the PMPRB Guidelines.

In CIRID our focus is on vaccines and vaccination, and there are key differences between vaccines and other medicines that are regulated by the PMPRB that we feel are important to highlight and to take into consideration as you move forward with the proposed revisions to the Guidelines.

In Canada, vaccination is a shared responsibility among the federal, provincial and territorial (F/P/T) governments. Provincial and territorial (P/T) governments are responsible for funding, program planning, and the delivery of vaccination programs, including vaccine procurement, in their jurisdictions. The federal government - in addition to its responsibility for the regulation of vaccines and for vaccine safety monitoring - makes recommendations for the use of vaccines currently or newly approved for use in humans, and maintains a bulk procurement program (BPP) for vaccines for use by interested P/T governments.

The majority of vaccines used in Canada are provided free of charge through publicly funded vaccination programs administered by P/T governments. These public programs provide vaccines to those most at risk of vaccine preventable diseases through routine vaccination programs for infants, children and adolescents, or through programs targeted to specific high-risk populations including older adults. A private market also exists in Canada for vaccines, primarily for: travel vaccines (e.g. yellow fever vaccine); vaccines for populations not covered by publicly funded programs (e.g. influenza vaccines for healthy adults in PTs that do not have universal influenza vaccination programs); and vaccines not yet introduced as public programs (e.g. varicella zoster vaccines).

In making their decisions on vaccination programs, P/Ts rely on advice from the National Advisory Committee on Immunization (NACI). NACI is an advisory committee of experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine, public health and pharmacoeconomics. The Committee reports to PHAC and provides ongoing and timely medical, scientific and public health advice. NACI makes recommendations for the use of vaccines currently or newly approved for use in humans in Canada, including the identification of groups at risk for vaccine-preventable diseases for whom vaccination should be targeted.



In addition to advice on safety, efficacy, and the optimum use of vaccines, NACI's mandate is being expanded to include advice on the cost-effectiveness of specific vaccines as well as on acceptability, feasibility, ethical and equity considerations, as appropriate. P/Ts will also continue to assess their own specific considerations for vaccine use, based on local epidemiology, capacity, other locally relevant issues, and what they are able to purchase for their populations.

While P/Ts have responsibility for vaccine procurement for their own programs, approximately 85% of the vaccines used in publicly funded programs are now purchased through the Bulk Procurement Program (BPP) operated by Public Services and Procurement Canada (PSPC). PSPC contracts directly with vaccine manufacturers who deliver the vaccine to P/T depots for further dissemination within jurisdictions. While PSPC applies a competitive process where competition exists, contracts are usually awarded to two or more suppliers of each vaccine in order to enhance the security of vaccine supply. As such, vaccine manufacturers are reasonably assured a share of the public market in Canada.

In general, we are supportive of the amendments made to the Patented Medicines Regulations and to the proposed revisions to the Guidelines needed to implement these amended Regulations. As noted above, however, there are important differences between vaccines and other medicines, and we would like to ensure that the PMPRB takes into consideration the unique characteristics of the vaccine market in Canada as you finalize the Guidelines renewal. In particular, we would like to note the following:

- With respect to the addition of pharmacoeconomic evaluation, PHAC is developing guidelines for the economic evaluation of vaccines for NACI, as the guidelines and methods used by the Canadian Agency for Drugs and Technologies in Health (CADTH) are not entirely relevant to vaccines. Additional elements that may need to be considered for vaccines include a societal perspective that captures costs and effects outside the health care system, population level benefits, herd effects, coverage levels, waning immunity and need for booster doses and disease carriage. When cost-utility (CU) analyses are undertaken by NACI they will be published as part of the relevant NACI statement. As such, the updated PMPRB Guidelines should ensure that there is sufficient flexibility for NACI's guidelines to be part of the price assessment process including, if necessary, making specific reference to NACI or to PHAC as an acceptable organization for producing CU analyses.
- Consideration should be given to ensuring that the Guidelines allow for some flexibility with respect to the acceptable cost per quality adjusted life year (QALY) rather than adhering strictly to a fixed threshold approach. Vaccines (and potentially other medicines as well) may have different profiles requiring different considerations – e.g. some high-priced vaccines with a low disease incidence should be considered in a different context than lower priced vaccines with a high disease incidence.



- P/T public programs are likely the primary beneficiaries of price discounting in the Canadian market for vaccines that are currently, or that become, part of routine vaccination programs. As such, it would be helpful to better understand the objective of collecting prices and revenues net of all rebates, discounts, free goods or services, etc. If the intent is to remove or reduce price discrepancies between markets in Canada, this may have the unintended impact of increasing prices to public programs whose users represent those at the highest risk for vaccine preventable diseases.
- Market share for vaccines used in publicly funded vaccination programs could fluctuate significantly from year to year with changes in program scope (e.g. introduction or conclusion of catch-up campaigns); approval of new indications that significantly increase the number of recipients; and, for competitive vaccines, the share of the public market awarded to the vaccine under the PSPC BPP. While a change in the approved indication could trigger a reassessment in the categorization of a medicine and in subsequent price calculations, it would be helpful to understand how, and if, the Guidelines could also capture other potential events that may result in a significant change to a medicine's annual sales.

Once again, we would like to thank you for the opportunity to provide comments through this consultation process.

Regards,

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