



August 5, 2014

Dear Registrants and Stakeholders:

Consultation on draft *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Products*

In accordance with the requirements of s133(1) of the *Health Professions Act* and s29.1 of the *Pharmacy and Drugs Act*, the ACP council has approved circulation of the draft *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Products* for the purpose of review and comment. Subject to reviewing comments received, it is ACP's intent to adopt new standards for compounding consistent with the national standards.

Please provide your feedback

ACP is now seeking feedback on the draft *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Products*.

We ask that you only provide comments using [this template](#), which will allow us to collate comments efficiently. Usage instructions are included on the template's first page.

As you review the draft standards, we invite you to also provide feedback on the terminology used to describe the type of personnel and on the requirement for a phased-in approach to implement the standards. Specific feedback on the competencies, knowledge, and skills listed in Appendix 3 for personnel would also be appreciated.

Concurrent with ACP's consultation, NAPRA is consulting nationally. **While ACP's consultation period extends until October 5, 2014, comments we receive before September 5 will inform ACP's submission to NAPRA's national consultation.**

Please forward your comments to the ACP office to the attention of Leslie Ainslie via email at leslie.ainslie@pharmacists.ab.ca.

Background on standard development

NAPRA established an ad hoc Pharmacy Compounding Committee in the fall of 2013 to steer the development of a suite of Model Standards for Pharmacy Compounding documents. A total of three documents will be developed, with the first two documents pertaining to non-hazardous and hazardous sterile products. The final document will address non-sterile products.

The draft *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Products* and the draft *Model Standards for Pharmacy Compounding of Hazardous Sterile Products* were developed over several months by the ad hoc committee that included input from a small group of pharmacists and pharmacy technicians involved with sterile compounding. The committee presented this draft to NAPRA's Board of Directors at its recent meeting for review and discussion. Following editorial changes, it was agreed to proceed with external consultation with stakeholders to obtain feedback on the proposed drafts.

Due to the length of these documents, NAPRA decided to proceed with the consultation in two phases. The first phase of consultation includes the *Draft Model Standards for Pharmacy Compounding of Non-hazardous Sterile Products* and the second phase will pertain to the *Draft Model Standards for Pharmacy Compounding of Hazardous Sterile Products*. We will send you another notice once the second document is ready later this summer.

The consultation on *Draft Model Standards for Pharmacy Compounding of Non-sterile Products* will occur in 2015.

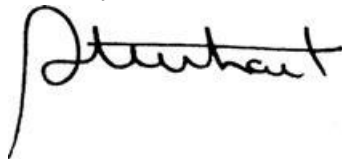
Next steps

Nationally, NAPRA's ad hoc Pharmacy Compounding Committee with support from experts in the field will review comments received. A recommendation for final review will then be made to the NAPRA Board of Directors. NAPRA is working toward having the documents finalized and approved in the fall of 2014. Implementation of the standards will be the responsibility of the individual pharmacy regulatory authority.

Provincially, ACP will contribute to the national consultation. We will collate comments we receive before October 5 and ACP's council will consider them at its October meeting. This review will inform our engagement with NAPRA about the national model standards. Once the National Model Standards are approved, ACP may adopt or adapt the standards for approval in Alberta.

We appreciate any comments you may provide. Should you have any questions, please contact Dale Cooney (dale.cooney@pharmacists.ab.ca) or Greg Eberhart (greg.eberhart@pharmacists.ab.ca). Dale and Greg can also be reached by phone at 780-990-0321.

Sincerely,

A handwritten signature in black ink, appearing to read "Eberhart", written in a cursive style.

Greg Eberhart BScPharm, CAE
Registrar