Alberta College of Pharmacists

September 3, 2014

Dear Registrants and Stakeholders:

Consultation on draft *Model Standards for Pharmacy Compounding of 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 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 by November 5
ACP is now seeking feedback on the draft *Model Standards for Pharmacy Compounding of 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.

Note that these standards are quite similar in many areas to the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Product* which are also being circulated for review and comment. To facilitate easier review, standards specifically dealing with hazardous product compounding have been highlighted in yellow.

Please forward your comments to Leslie Ainslie at ACP 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 two draft Model Standards documents were adapted from the compounding standards documents recently released by one of NAPRA's members, l'Ordre des pharmaciens du Québec. Furthermore, the proposed USP <800> Chapter on Hazardous Drugs – Handling in Health Care Settings released in the spring of 2014 was also consulted during the preparation of the hazardous sterile compounding document.

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

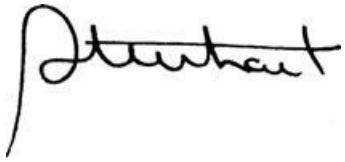
Next steps

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. 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,



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Registrar