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Compounding: Are You Doing It?

Pharmacy Connection | February 15, 2018

College Council adopted NAPRA's *Model Standards for Pharmacy Compounding of Non-Sterile Preparations* at their meeting in December 2017. While an implementation date has yet to be determined, these new standards (once formally published by NAPRA) will require pharmacy professionals to place a renewed focus on the preparation of non-sterile products in pharmacies.

IS YOUR PHARMACY ENGAGED IN COMPOUNDING?

Health Canada considers compounding to be the following:

> "The combining or mixing together of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing. It can involve raw materials or the alteration of the form and strength of commercially available products. It can include reformulation to allow for a novel drug delivery. Compounding does not include mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on an approved drug's labelling material. [1]

Before compounding a non-sterile preparation, the need for the compounded product should be confirmed by checking for commercially available preparations in the Health Canada's Drug Product Database and contacting manufacturers. [2] To comply with the Health Canada policy on compounding, this confirmation is required in order to validate the lack of product availability and avoid duplicating an approved drug.

Non-sterile preparations can be categorized as simple, moderate or complex [3] (as outlined in *United States Pharmacopeia (USP) Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations*). A number of factors go into determining the type of preparation and level of risk when compounding preparations. Pharmacists and pharmacy technicians who compound non-sterile preparations should evaluate their practice, develop service-related procedures and implement appropriate quality controls for both patients and compounding personnel, with a view to guaranteeing the overall quality and safety of non-sterile preparations.

HOW TO PREPARE FOR THE STANDARDS

As the College considers an appropriate implementation date, expect additional communication and education related to compliance with the standards.

The release of the standards will be accompanied by a guidance document which will provide pharmacists and technicians who compound non-sterile preparations with the details necessary to evaluate their practice, develop service-related procedures, and implement appropriate quality controls for both the protection of patients and compounding personnel.

In advance of the publication of the standards by NAPRA, pharmacy professionals are encouraged to review current policies and procedures, master formulations and Safety Data Sheets.

1. Health Canada. Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051). Retrieved at: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/policy-manufacturing-compounding-drug-products.html#a7
2. Ontario College of Pharmacists. Quality and Safety in Compounding Non-Sterile Preparations. Retrieved at: http://www.ocpinfo.com/library/practice-related/download/Quality%20and%20Safety%20in%20Compounding%20Non-Sterile%20Preparations.pdf
3. USP <795> Pharmaceutical Compounding—Nonsterile Preparations. Retrieved from: http://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc795.pdf

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