Notice of Upcoming Questionnaire

Commercial Compounding in Canada

Questionnaire: Available from April 23 to May 4, 2018

INTRODUCTION

Health Canada and the Institute for Safe Medication Practices Canada (ISMP Canada) are seeking information to better understand the current commercial compounding sector in Canada, as well as the types of commercially compounded health products purchased by practitioners and health organizations, clinics, long-term care homes, and hospitals.

A 2-week online questionnaire, prepared and conducted by ISMP Canada, will be launched on April 23, 2018. It will include 3 questions and an optional free-text comment.

BACKGROUND

Compounding[1]

Commercial compounding is a set of activities that is distinguished from (i) traditional drug compounding, performed by pharmacies, hospitals, and healthcare practitioners for individual patients or clients, and (ii) drug manufacturing.

For the purposes of the questionnaire, the following definition is being used as a *working definition* for 'commercial compounding':

> "reconstituting, diluting or otherwise preparing a drug or combining, admixing or mixing together two or more substances, at least one of which is a drug, to create a final product for the purposes of the sale or provision to another person, other than pursuant to or in anticipation of a prescription."[2,3]

Traditional compounding for specific patients by healthcare professionals is regulated by provincial or territorial regulatory authorities for the profession, e.g., pharmacy, medicine, naturopathy, nursing.

Drug Manufacturing

Drug manufacturing is regulated by Health Canada and requires compliance with the *Food and Drugs Act* and *Regulations*,[4] including compliance with Good Manufacturing Practices (GMP) and the requirement for an Establishment Licence.

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[1] Health Canada considers compounding to include:
- 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
- can involve raw materials or the alteration of the form and strength of commercially available products
- can include reformulation to allow for a novel drug delivery

(See https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/policy-manufacturing-compounding-drug-products.html)

[2] Ontario College of Pharmacists. Drug preparation premises [Internet]. Toronto (ON): The College; 2013 [cited 2018 Mar 26]. Available from: http://www.ocpinfo.com/practice-education/practice-tools/collection/dpp/

[3] New Brunswick College of Pharmacists. Regulations [Internet]. St. John (NB): The College; 2018 Feb 13 [cited 2018 Mar 28]. Available from: https://nbcp.in1touch.org/document/1733/2015%2007%2023%20REGS%20bilingual.pdf

[4] Government of Canada. Food and Drugs Act [Internet]. Ottawa (ON): Public Works and Government Services Canada; 1985 [updated 2017 Jun 2; cited 2018 Mar 28]. Available from: http://www.canadagazette.gc.ca/rp-pr/p2/2014/2014-07-02/html/sor-dors158-eng.php

QUESTIONNAIRE INFORMATION

The link to an online questionnaire be e-mailed to stakeholders on April 23, 2018. Individual responses will remain anonymous.

You will be asked if you currently purchase commercially compounded drug products, as well as to identify those products. If you do not purchase commercially compounded drug products, you are invited to provide comments.

Your help to distribute this message to your colleagues would be greatly appreciated.
If you are an association or an organization, please forward this notice to your membership.

For more information please contact ISMP Canada at info@ismp-canada.org.