SASKATCHEWAN COLLEGE OF PHARMACY PROFESSIONALS

CompEX

General Guideline on Compounding and Manufacturing Activities[1]

1) Is there a demonstrated patient-health care professional relationship?
    - Compounding – Yes
    - Manufacturing – No

2) Is there third-party reselling of the product outside of the patient-health care professional relationship?
    - Compounding – No
    - Manufacturing – Yes

3) Is the activity regulated, and facility possibly inspected, by the province/territory?
    - Compounding – Yes
    - Manufacturing – No

4) If producing product in anticipation of a prescription, is the amount produced consistent with the history of prescriptions received?
    - Compounding – Yes
    - Manufacturing – No

5) Is there an inordinate amount of product produced or on a regular basis?
    - Compounding – No
    - Manufacturing – Yes

6) Is an identical product (e.g. dosage form, strength, formulation) commercially available?
    - Compounding – No
    - Manufacturing – Yes

7) Is the product and/or compounding service promoted or advertised to the general public rather than strictly to health care professionals?
    - Compounding – No
    - Manufacturing – Yes

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[1] Health Canada, Health Products and Food Branch Inspectorate. *Policy on manufacturing and compounding drug products in Canada* (POL-0051). Ottawa, ON: Health Canada; 2009. Available from*: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/pol_0051-eng.php. Modified from Appendix 1*

8) Does the drug product require only minor modification prior to direct administration when such modification amounts to mere directions for use?
    - Compounding – No
    - Manufacturing – Yes

Compounding must always be carried out within a patient–health care professional relationship or, in the case of a compounded veterinary product, within a veterinarian–client–patient relationship. In the absence of a patient-specific prescription, and with a prescriber's order for office use, compounders may prepare a compounded product at an appropriate scale, time or frequency to ensure it is being used within a patient–health care professional relationship.

Compounders may also prepare batches of compounded product in limited quantities in anticipation of future prescriptions. Requests to compound preparations in bulk quantities for distribution or sale outside a patient–health care professional relationship generally fall into the realm of manufacturing and are thus outside the jurisdiction of pharmacies[2]. The questions above provide a general guideline on differentiating between compounding and manufacturing activities.

[2] National Association of Pharmacy Regulatory Authorities (NAPRA). *Guidance Document for Pharmacy Compounding of Non-sterile Preparations.* Ottawa, ON: NAPRA; 2018. Available from: *https://napra.ca/sites/default/files/documents/Mdl_Stnds_Pharmacy_Compounding_Nonsterile_Preparations_Guidance_June2018_FINAL.pdf*