Is It Compounding or Manufacturing?

This resource is intended to assist pharmacy professionals in understanding the differences between compounding and manufacturing. The following diagrams are adapted from the Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051) and the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations.

Guiding Principles for Compounding

All drug compounding and manufacturing activities performed are to be regulated and fall under either the federal or the provincial/territorial jurisdiction

Distinguishing between compounding and manufacturing activities is made on a case-by-case basis

Compounding should only be done if there is a therapeutic need or lack of product availability and should not solely for economic reasons for the healthcare professional

Compounding must not be used as a means to bypass the federal drug review and approval system

Product should be produced from an authorized drug or Active Pharmaceutical Ingredient (API) used in an authorized drug for use in Canada or listed in a recognized Pharmacopoeia (USP, PhEur, PhF, PhI, BP, CF, NF, Codex - Schedule B Food and Drugs Act.)

When there is a shortage or no supply of a commercially available product and the healthcare professional has determined a medical need for this product, the product may be compounded during that period of time only

The compounded product must provide a customized therapeutic solution to improve patient care without duplicating an approved drug product

A pharmacy may prepare drugs in very limited quantities, in anticipation of a prescription by compounding or repackaging multiple units, not for immediate use, in a single process, by the same operator in accordance with a standardized batch preparation procedure

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Questions to Help Determine Whether You Are Engaged in Compounding

GUIDELINE	COMPOUNDING	MANUFACTURING
Under which level of jurisdiction does the activity fall?	Provincial	Federal
Who performs the activity?	Pharmacy professionals	Pharmaceutical manufacturers
What sets out the requirements to be met?	• *Pharmacy Act* • NAPRA Model Standards and Guidance Document for Pharmacy Compounding of Non-sterile Preparations	• *Food and Drug Act & Regulations* • GUI-0001: Good manufacturing practices [GMP] guide • GUI-0002: Guidance on Drug Establishment Licences [DEL]
Is there a demonstrated patient-healthcare professional relationship?	✓	✗
Is there third-party reselling of the product outside of the patient-healthcare professional relationship?	✗	✓
Is the activity regulated, and facility possibly inspected, by the province/territory?	✓	✗
If producing product in anticipation of a prescription, is the amount produced consistent with the history of prescriptions received?	✓	✗
Is there an inordinate amount of product produced **or** on a regular basis?	✗	✓
Is an identical product (e.g. dosage form, strength, formulation) commercially available?	✗	✓
Is the product and/or compounding service promoted or advertised to the general public rather than strictly to healthcare professionals?	✗	✓
Does the drug product require only minor modification prior to direct administration when such modification amounts to mere directions for use?	✗	✓
Is the compound a non-prescription product produced and offered for sale to the general public in the pharmacy?	✗	✓

[1]In the case of an animal this is known as the Veterinarian - Client - Patient Relationship