

NEWFOUNDLAND AND LABRADOR PHARMACY BOARD

Standards of Pharmacy Practice



Pharmacy Compounding

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Guidelines to Pharmacy Compounding

October 2006



National Association
of Pharmacy
Regulatory Authorities

Association nationale
des organismes de réglementation
de la pharmacie

Introduction

In February of 2004, the Importation and Compounding of Animal Drugs Task Force met to discuss several issues related to the use of compounded products in Canada. It was decided that guidelines needed to be developed in collaboration with provincial pharmacy licensing bodies to describe when it is appropriate to compound and how to compound¹. The National Association of Pharmacy Regulatory Authorities (NAPRA) made a commitment to develop such guidelines and the Compounding Guidelines Task Force (CGTF) was formed in January 2005 to complete this initiative. The CGTF, which developed these guidelines, is made up of pharmacists from across Canada (see Appendix A) experienced in the area of compounding preparations and nominated by their provincial Pharmacy Regulatory Authority. The task force recognized that compounding is an essential part of pharmacy practice and the guidelines reflect the knowledge they felt was required to prepare a safe and appropriate product.

Once the draft guidelines were completed, they were reviewed by the NAPRA's National Advisory Committee on Pharmacy Practice, the Council of Pharmacy Registrars of Canada, and NAPRA's Executive Committee. The guidelines also underwent an extensive external review.

These guidelines, referred to as the Guidelines to Pharmacy Compounding, are not meant to supersede the *Model Standards of Practice for Canadian Pharmacists* (NAPRA, April 2003) but to enhance the area addressing compounding. (Professional Competency #4: Manage Drug Distribution).

1.0 Scope

These guidelines apply to pharmacists or their delegates in the preparation of all extemporaneous products. The CGTF based these guidelines on the following performance indicators for pharmacists fulfilling this role:

1. Have accurate knowledge and expertise to compound preparations;
2. Confirm the need for a compounded product;
3. Maintain access to contemporary equipment;
4. Use of quality ingredients and procedures;
5. Appropriate labeling;
6. Suitable containers for each unique product;
7. Safe and acceptable storage; and
8. Documentation to ensure accurate checking, duplicating, and tracing.

The key elements of good compounding include qualified and trained personnel, adequate premises and space, approved compounding procedures and instructions, suitable equipment, labels and containers, and accurate documentation.

2.0 Definitions

2.1 Compounding

Pharmaceutical preparation of components into drug products that:

1. Are considered to be within the professional practice of pharmacy, regulated by provincial regulatory authorities in accordance with guidelines and standards that ensure the quality and safety of pharmaceuticals;
2. Involve a relationship that can be demonstrated to exist between a patient and/or:
 - a) a regulated health care professional

¹ Importation & Compounding of Animal Drug Task Force, 2nd meeting notes, February 5, 2004

- b) a practitioner;
- 3. Do not circumvent regulatory requirements including the Food and Drugs Act and the Food and Drug Regulations, the National Drug Schedules, or intellectual property legislation; and
- 4. Provide a customized therapeutic solution to improve patient care without duplicating a commercially available, approved product.

2.2 Manufacturing

Preparation of products:

- 1. Are subject to all the appropriate divisions and sections of the Food and Drugs Act and Regulations, including all applicable standards and guidelines.
- 2. Require a Drug Identification Number (DIN) and/or Notice of Compliance (NOC) to be sold in Canada.
- 3. Are produced independently of the demonstrated regulated health care professional-patient relationship or valid pharmacist-veterinarian-client-patient relationship.
- 4. Are required to obtain an Establishment License (EL) (Division 1A of the Food and Drugs Act and Regulations) and meet the appropriate sections of Division 2 Good Manufacturing Practices (GMP).

3.0 Personnel

- 3.1 Pharmacists that compound or delegate compounding activities to technical staff should have the knowledge and skills to be responsible for the preparation of the product.
- 3.2 Pharmacists should use their professional judgment when deciding whether they have the expertise to compound a specific product and should be aware of good compounding principles and practices.
- 3.3 Pharmacists unable to compound a drug product for the patient should refer the patient to a pharmacist with the ability to prepare the product.
- 3.4 The pharmacist should gather sufficient information to make knowledgeable decisions regarding the formulation and process of the compounding. Formulations should be accessed from a reputable source such as a peer-reviewed published journal. If no formulation is available, a formula should be completed using the pharmacist's knowledge in pharmacology, chemistry, and therapeutics.
- 3.5 The pharmacist should:
 - a. Assist individuals requiring a compounded item;
 - b. Counsel individuals on the appropriate use of the compounded product;
 - c. Determine whether the product should be compounded in a sterile manner;
 - d. Ensure the quality and accuracy of the ingredients;
 - e. Calculate required quantities, dilutions, percentages or other pharmaceutical calculations as required;
 - f. Be knowledgeable of the purpose of each ingredient in the compound and differentiate between active ingredients and excipients;
 - g. Recognize the potential for incompatibilities;
 - h. Determine the equipment needed to compound the product;
 - i. Prepare the product in a logical, safe, and pharmaceutically elegant manner; and
 - j. Document the required information to maintain accurate records.

4.0 Premises

- 4.1 The compounding area should be clean, sanitary, and orderly.
- 4.2 Premises should permit effective cleaning of all surfaces.
- 4.3 Premises should prevent contamination of medication and the inadvertent addition of extraneous material to the medication.

5.0 Equipment

- 5.1 Equipment used for compounding should:
 - a. Be situated in an area that permits it to function in accordance with its intended use. Equipment should be operated in a manner that prevents contamination.
 - b. Be easily and routinely cleaned to minimize the potential for contamination;
 - c. Be suitable for the preparation of the desired compound; and
 - d. Be kept clean, dry, and protected from contamination during storage to prevent the addition of extraneous materials.
- 5.2 Equipment used for measuring and weighing should be calibrated, if appropriate, on a regularly scheduled basis and documentation showing proof of calibration and servicing should be maintained in the pharmacy records.

6.0 Sanitation

- 6.1 The pharmacy should have a written sanitation program available to include cleaning requirements for the premises and equipment.
- 6.2 Written procedures detailing the minimum requirements for health and hygienic behavior of individuals performing compounding activities should be addressed in a policy manual. This should include, but not be limited to:
 - a. Suitable dress (e.g. gowns, masks, gloves, footwear);
 - b. Hand hygiene; and
 - c. Health conditions and open lesions.

7.0 Quality Control Requirements

- 7.1 Ingredients
 - 7.1.1 The pharmacist should be able to distinguish materials that require specialized handling and storage, and demonstrate safe handling techniques such as, but not limited to:
 - a. Measuring or triturating in an appropriate environment;
 - b. Donning the appropriate apparel; and
 - c. Ensuring that personnel handling the ingredients do so in a safe manner.
 - 7.1.2 The pharmacist should ensure the quality of the ingredients by using products with a standard designation such as:
 - a. BP (British Pharmacopeia), USP (United States Pharmacopeia) or NF (National Formulary) standard of quality; or
 - b. A valid lot number and beyond-use-date (if available). If expiry is not available, a date of receipt should be recorded on the raw material; or
 - c. A Certificate of Analysis (C of A) for raw materials that is maintained in the records.

- 7.1.3 Ingredients should be selected based on:
- a. Solubility;
 - b. Stability (provide an environment in which the ingredients are most likely to resist chemical change or degradation);
 - c. Compatibility;
 - d. Patient's allergies, disease state, ability to administer, and other medications;
 - e. Intended use;
 - f. Duration of treatment;
 - g. Potential drug-drug interactions;
 - h. Medication administration frequency; and
 - i. Route of Administration.

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7.2 Record Keeping

- 7.2.1 Written compounding records must be available to enable the pharmacist to check all compounded medication to ensure that all compounded products can be:
- a. Replicated in formulation and production; and
 - b. Retrieved in the event of a recall or adverse event.
- 7.2.2 Master compounding records should be written to provide an acceptable overage to compensate for ingredients lost/degraded during the process based on a recognized standard (e.g. Canadian Society of Hospital Pharmacists, United States Pharmacopeia).
- 7.2.3 Information documented on each product should include, but not be limited to:
- a. Name, lot number, and expiry of raw material;
 - b. Quantity required and quantity actually weighed;
 - c. Date of preparation and expiry;
 - d. Initials/signature of compounder and/or pharmacist responsible for the preparation and checking;
 - e. Written formula used;
 - f. Records of stepwise operating/processing instructions;
 - g. Maintenance of training records; and
 - h. Any other documentation required by the provincial regulatory authority.
- 7.2.4 Deviations from written preparation process should be avoided. If deviations occur, the pharmacist should describe the deviation and the rationale and maintain these records for a minimum of 2 years from the date originally dispensed.
- 7.2.5 A yield and reconciliation should be carried out on each compounded medication.
- 7.2.6 At all practical times during the compounding process, materials should be labeled to prevent confusion.

8.0 Labeling

- 8.1 Product labels shall follow all federal and provincial requirements.
- 8.2 Labels of compounded products should include, but not be limited to:
 - a. List of active ingredients;
 - b. Prescription or identification number of the compounded product; and
 - c. Estimated beyond-use-date printed at the end of the dosage duration.

9.0 Packaging

- 9.1 The packaging should be appropriate for the stability of the product and proper patient use.
- 9.2 A compounded product should not be made to look like an approved product.

10.0 Storage and Transportation

- 10.1 Storage and transportation instructions should be given to the patient or patient's agent verbally and in written form.
- 10.2 Raw material and the dispensed product should be stored and transported in a manner that prevents the alteration to the potency, purity, and physical characteristics of the raw material.

11.0 Documentation

- 11.1 Records of complaints from patients and adverse events regarding compounded medications should be maintained for a minimum of two years from the date the prescription was dispensed. These complaints and adverse events should be investigated to determine the cause, and appropriate measures should be taken to prevent recurrence. Results of the investigation should be included in the records.
- 11.2 Suspected adverse reactions should be reported to health authorities as appropriate.

12.0 Sterile Compounding

- 12.1 Pharmacists engaging in sterile compounding should be knowledgeable and obtain specialized technical training in this area.
- 12.2 Carefully established standards for the operation of clean rooms and the preparation of sterile products should be documented in accordance with a recognized source (e.g. Canadian Society of Hospital Pharmacists).
- 12.3 Sterility testing shall be done according to a clearly defined standard (e.g. USP) and the product assigned an estimated expiry date.

13.0 Veterinary Medicine

- 13.1 Compounding health products for use in animals requires an established pharmacist-veterinarian-client-patient relationship.
- 13.2 Compounding of medications indicated for veterinary use should follow the same guiding principles as found in this document and *Model Standards of Practice for Canadian Pharmacists* (NAPRA, April 2003).

- 13.3 Pharmacists dispensing products intended for administration to animals bred, raised, kept, or slaughtered specifically for the purpose of producing food for human consumption, and those animals, originally bred, raised, and kept for sport, leisure or other purposes, from the moment when they become destined for human consumption should be aware of relevant sections of pertinent legislation specific to that population.
- 13.4 Time required for the drug to be metabolized and excreted to ensure the animal is fit for human consumption should be added to the label for food producing animals or where necessary as assigned by the veterinarian prescribing the product.

Appendix A
NAPRA Compounding Guidelines Task Force Members

Carolyn Carruthers
Saskatchewan College of Pharmacists

Ken Dicks
Newfoundland and Labrador Pharmacy Board

Rita Ozolins
Ontario College of Pharmacists

Larry Thorne
College of Pharmacists of British Columbia

Dennis Wong
Manitoba Pharmaceutical Association

Kendra Day
Prince Edward Island Pharmacy Board

Peter Ford
New Brunswick Pharmaceutical Society

Larry Salsman
Nova Scotia College of Pharmacists

Mike Wolowyk
Alberta College of Pharmacists

NAPRA Staff Resource: Cathy Biggs (Director of Pharmacy Practice at the time of the drafting of these Guidelines)

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The National Association of Pharmacy Regulatory Authorities (NAPRA)
220 Laurier Ave. West, Suite 750
Ottawa, ON, K1P 5Z9
Tel: (613) 569-9658 Fax: (613) 569-9659 E-mail: info@napra.ca