POLICY STATEMENT(S):

1. The Board of the College of Pharmacists of BC adopts the NAPRA Guidelines to Pharmacy Compounding as the Standard of Practice for registrants: *http://www.napra.org/Content_Files/Files/Guidelines_to_Pharmacy_Compounding_Oct2006.pdf*

BACKGROUND:

In 2005, the National Association of Pharmacy Regulatory Authorities (NAPRA) formed the Compounding Guidelines Task Force (CGTF). The task force was comprised of pharmacists from across Canada experienced in the area of compounding preparations. The task force members 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 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 *http://napra.ca/Content_Files/Files/Guidelines_to_Pharmacy_Compounding_Oct2006.pdf* are intended to enhance the standards of practice area addressing compounding (in BC, Role 2 of the Framework of Professional Practice).

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

- Have accurate knowledge and expertise to compound preparations
- Confirm the need for a compounded product
- Maintain access to contemporary equipment
- Use of quality ingredients and procedures
- Appropriate labeling
- Suitable containers for each unique product
- Safe and acceptable storage
- 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.

For reference, the following definitions differentiate between the activities of “compounding” and “manufacturing”:

Compounding - Pharmaceutical preparation of components into drug products that:

- 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.
- Involve a relationship that can be demonstrated to exist between a patient and / or a regulated health care professional or a practitioner.
- Do not circumvent regulatory requirements including the Food and Drugs Act and the Food and Drug Act Regulations, the National Drug Schedules, or intellectual property legislation.
- Provide a customized therapeutic solution to improve patient care without duplicating a commercially available, approved product.

Manufacturing - Preparation of products:

- Are subject to all the appropriate divisions and sections of the Food and Drugs Act and Regulations, including all applicable standards and guidelines.
- Require a Drug Identification Number (DIN) and / or Notice of Compliance (NOC) to be sold in Canada.
- Are produced independently of the demonstrated regulated health care professional-patient relationship or valid pharmacist-veterinarian-client-patient relationship.
- 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).

The NAPRA Guidelines to Pharmacy Compounding have been adopted by five other provincial pharmacy regulatory authorities (NB, NL, NS, ON and SK).