



Advancing Molecular Imaging and Therapy

SNM Committee on Pharmacopeia
SNM Commission on Radiopharmaceuticals

Use of Compounded¹ Radiopharmaceuticals and Adjunct Drug Preparations

Background

Some nuclear pharmacies compound certain radiopharmaceuticals and adjunct drugs, especially during times of shortages, after discontinuation by the manufacturer not related to safety issues, and for other reasons. For example, during a 13-month period (November 2001-December 2002), some nuclear pharmacies compounded sincalide for injection [Anon. Alternatives to Kinevac: shortages lead to inventive measures. *J Nucl Med.* 2002; 43(3):20N-28N). More recently, following Covidien's August 2009 notice announcing discontinuation of its Phosphocol P-32 Chromic Phosphate Suspension product, at least one nuclear pharmacy has been compounding P-32 chromic phosphate on a prescription basis for individual patients.

Discussion

Pharmacists have traditionally compounded drugs for individual patients pursuant to a prescription from the patient's care-giving physician. Such practice is specifically allowed under state laws governing the practices of pharmacy and medicine. Hence, nuclear pharmacists similarly may compound radiopharmaceuticals and adjunct drugs (hereafter referred to as compounded preparations) pursuant to a prescription from the authorized user physician responsible for performing the nuclear medicine procedure.

However, a number of issues must be considered by a nuclear medicine facility before procurement of compounded drugs from a nuclear pharmacy:

1. Is the drug available as a commercial product? [Note: a commercial drug product is defined as one that is produced, transported, and merchandised pursuant to an FDA-approved NDA or ANDA.] If so, why is the compounded preparation being considered? The compounded preparation should have justifiable patient-care advantages over the commercial product, such as dosage form, availability/delivery timeliness, or altered formulation related to patient allergy. Cost alone does not justify purchasing a compounded preparation instead of a commercial drug product.
2. Is the compounded preparation intended for routine clinical care of the patient, or is it intended for use in an investigational research study? If it is intended for research, then use of the drug may require submission of an Investigational New Drug (IND) application to the FDA.
3. Does the compounded preparation have acceptable strength, quality, and purity? If the drug is the subject of a monograph in the United States Pharmacopeia (USP), it should meet all USP specifications as demonstrated by applicable testing. If the drug is not in the USP,

appropriate specifications of strength, quality, and purity should be developed a priori and the compounded preparation should meet such specifications as demonstrated by applicable testing.

4. Is the compounded preparation to be used in a hospital or health-system facility? If so, the pharmacy department should be involved. The American Society of Health-system Pharmacists (ASHP) Guidelines on Outsourcing Pharmaceutical Services state: “The organization’s pharmacist-in-charge (e.g., a pharmacy director) must take complete responsibility for patient outcomes from all medication-related activities performed at or for the organization’s work sites, whether they are carried out by the organization’s or contractor’s on-site staff or by the contractor off-site.” Some issues that might be important in a contract between a hospital and an outside provider include compliance with applicable laws, rules, and regulations; licensure with the state Board of Pharmacy; liability insurance; and sterile preparation quality. [Ponto J. Responsibility for sincalide injection obtained from compounding pharmacies. *Am J Health-Syst Pharm.* 2002;59:1295-6.]
5. Is the compounded preparation to be used in a healthcare facility accredited by The Joint Commission (formerly JCAHO)? If so, compliance with Medication Management standards must be achieved. These standards are generally interpreted as requiring that a Pharmacy & Therapeutics Committee (or similar group) has established a formulary for medications routinely used in the hospital and that systematic policies and procedures have been established for obtaining medications not on the formulary. Accreditation by other entities may have similar requirements.
6. Will the patient’s health insurance provider be charged for the compounded preparation? If so, the facility’s compliance and billing department should be involved. Misrepresentation, either intentional or unintentional, of the compounded preparation as a commercially available (i.e., FDA-approved) product may be construed as fraud. Also, some third-party payers may not reimburse compounded preparations.
7. Are there other state regulations regarding compounded preparations? If so, these must be followed. For example, some state boards of pharmacy require the patient to be informed that he/she is receiving a compounded preparation.
8. Is there any specific radioactive materials (RAM) license condition regarding the regulatory status of radiopharmaceuticals permitted for human use? At one time many years ago, NRC regulations required that radiopharmaceuticals administered to patients must be approved by FDA for either routine use (i.e., NDA) or for investigational use (i.e., IND). This requirement may still exist as a condition in some RAM licenses.

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The terms “compound,” “compounded” and “compounding” used in this document reflect the traditional meaning of compounding, often called extemporaneous compounding, as regulated by State Boards of Pharmacy. This particular professional practice activity should not be confused with the broad range of actions addressed as compounding in USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.