CardinalHealth

Pharmacy Insights

Essential news for the pharmacy

Are non-FDA approved drugs being administered in your facility?

As with all medications used in the hospital, the management of radiopharmaceuticals falls under the purview of the Director of Pharmacy (DOP). The involvement of the DOP in nuclear medicine is gradually evolving and includes the need to demonstrate oversight of diagnostic and therapeutic radiopharmaceutical use. These medications used in nuclear medicine are prescription drugs and are subject to The Joint Commission Medication Management Standards or similar standards that are audited against by other accreditation bodies.

Drug use control for radiopharmaceuticals follows a unique model. These drugs are frequently outsourced to commercial nuclear pharmacies, which are licensed by the state boards of pharmacy.[1] Unfortunately, some licensed nuclear pharmacies may sell non-Food and Drug Administration (FDA) approved radiopharmaceuticals that are compounded from non-FDA approved source ingredients rather than using the commercially available FDA-approved radiopharmaceuticals. This is being done without meeting a significant patient need and in contravention of the FDA Compliance Policy guide (CPG) section 460.200. According to the CPG 460.200, these "copies" are considered to be unapproved new drugs and the FDA believes that they fall "outside the bounds of traditional pharmacy practice" and are in violation of the Federal Food, Drug, and Cosmetic Act.[2]

As a result, a Director of Pharmacy that is responsible for the management of medication use in the hospital should be aware that some nuclear medicine departments may unknowingly administer non-FDA approved radiopharmaceuticals. These drugs do not originate from an FDA-approved manufacturer with the NDA or aNDA for the commercially available radiopharmaceutical.

How to determine if a drug has not been approved by the FDA?

An FDA-approved commercially available radiopharmaceutical, like any approved drug, must go through the lengthy and rigorous FDA approval process to ensure that these products are safe and effective. This process includes:

- Approval by the FDA of a New Drug Application (NDA) or Abbreviated New Drug Application (aNDA).
- Approved drugs can only be manufactured in facilities registered with the FDA (per *21 U.S.C. §360*).
- Approved drugs must be listed with the FDA (per *21 U.S.C. §360(j)*).
- Approved drugs must be manufactured in conformance with FDA Current Good Manufacturing Practices (cGMP) regulations (per *21 C.F.R. Part 210 and 211*).[3]
- Failure to have approved drugs manufactured in appropriate facilities and drug listed causes them to be misbranded (per *21 U.S.C. §352(o)*).
- Failure to adhere to cGMP regulations can cause such drugs to be adulterated (per *21 U.S.C. §351(a)(2)(B)*).

These same requirements apply to all FDA-approved diagnostic and therapeutic radiopharmaceuticals that are used in nuclear medicine.

The National Association of Nuclear Pharmacies (NANP) is an industry-wide radiopharmacy trade association that works on behalf of nuclear pharmacies in the United States. The NANP supports appropriate pharmacist compounding of pharmaceutical and radiopharmaceutical preparations for use in nuclear medicine. The NANP does not support:

> "making copies of commercially available pharmaceuticals, including radiopharmaceuticals, a practice which has been deemed illegal by FDA" or "the use of non-FDA approved ingredients when FDA-approved

ingredients are available".[4]

In the past, the NANP newsletter provided commentary which cautioned radiopharmacists about the potential for professional liability in using compounded radiopharmaceuticals. Specifically, if a patient suffers harm or misdiagnosis, there may be an increased difficulty in defending against negligence or malpractice if a compounded product was used, especially if it was a copy of a commercially available product.[5]

The Society of Nuclear Medicine supports the appropriate use of radiopharmaceutical compounding as outlined in its statement on the "Use of Compounded Radiopharmaceuticals and Adjunct Drug Preparations." It outlines the issues that a nuclear medicine department should consider before purchasing compounded drugs from a nuclear pharmacy. It states that compounded products should have justifiable patient-care advantages over the commercial product and that cost alone does not justify purchasing a compounded preparation instead of a commercially available drug product. It also addresses reimbursement concerns that may be associated with the use of non-FDA approved compounded products.[6]

How to be sure that your facility only administers FDA-approved radiopharmaceuticals?

The best way to help ensure that radiopharmaceuticals, which are considered to be safe and effective, are administered in a nuclear medicine department is to use FDA-approved, commercially manufactured radiopharmaceuticals. Here is full list of radiopharmaceuticals, their approved manufacturers and trade names. Nuclear medicine practitioners who receive any of the listed radiopharmaceuticals that originate from sources other than the identified manufacturers may be using unapproved copies. The list also highlights FDA-approved radiopharmaceuticals that may potentially have unapproved copies commercially available in the marketplace.

To help ensure that the nuclear medicine department is administering only FDA-approved radiopharmaceuticals, ask your contracted nuclear pharmacy provider to verify the origin of any radiopharmaceutical by providing your facility with:

- The packing list from the originating manufacturer to verify calibration and delivery date.
- The package insert of the radiopharmaceuticals dispensed.

Is accreditation at risk if an unapproved drug is administered in my facility?

As specified by The Joint Commission (TJC) Medication Management Standard .02.01.01 (MM.02.01.01), the hospital or out-patient facility is responsible for the selection and procurement of medication(s). MM.02.01.01, Element of Performance #2, states that:

1. Members of the medical staff, licensed independent practitioners, pharmacists, and staff involved in ordering, dispensing, administering, and/or monitoring the effects of medications develop written criteria for determining which medications are available for dispensing or administering to patients.
2. The hospital develops criteria for selecting medications, which, at a minimum, include the following:
    - Indications for use (See also MM.05.01.01, EP 10)
    - Effectiveness
    - Drug interactions
    - Potential for errors and abuse
    - Adverse drug events
    - Sentinel event advisories
    - Other risks
    - Costs

All drugs used within the hospital or out-patient facility should be commercially available FDA-approved products, when available. Those individuals and facilities that elect to use non-FDA approved drugs manufactured in non-cGMP facilities may be exceeding their scope of practice, thereby possibly placing their facility's accreditation at risk as well as increasing their personal and professional liability if there is an adverse reaction to the patient caused by that product's use. For details, contact your accreditation agency.

References

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