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Product-Related Issues Lead to Potential Errors with Investigational Drugs

Huntingdon Valley, Pa.—Routine practices used to name, label, package, and store investigational drugs raise serious patient safety concerns, warns the Institute for Safe Medication Practices (ISMP). In the most recent issue of the *ISMP Medication Safety Alert!* newsletter, the Institute outlines some of those concerns and provides recommendations for safe use.

Safety Concerns

- **Drug names.** Investigational drugs are often identified by a number preceded by an abbreviation of the sponsoring company's name. This may lead to mistakes, including similar names due to participation in multiple studies by same sponsor and truncation of long letter/number designations by pharmacy computer systems. Other mistakes could be due to products receiving a generic or common name during a study that remains on the product label, and changes in code names.

- **Drug labels.** Many investigational drugs are labeled using a very small font size with little use of bold type, color, tall-man letters, or other strategies to help differentiate products. This can lead to confirmation bias when products are selected from the shelf, since the packaging looks so similar.

- **Drug packaging**. Many oral investigational drugs are not supplied in unit-dose packages. Some parenteral drugs may require dozens of vials to prepare a single dose, which sensitizes practitioners to expect to use multiple vials during preparation and makes recognition of overdoses less likely.

- **Tablet markings**. Tablet strengths often look identical and have no markings to help differentiate the strengths. While this may be essential for blinded studies, the same batches of look-alike tablets may be used for open label studies where the tablet strength is known to all participants.

- **Expiration dates.** Some sponsors do not list an expiration date and one must be obtained by calling an interactive voice system. The lag time involved has resulted in expired drugs not being replaced in time, or required direct intervention with the sponsor to avoid dispensing a drug that would reach expiration during outpatient use.

- **Space limitations**. Investigational drugs are often stored on crowded shelves, in unrestricted areas, and other unsafe storage conditions, increasing the risk of choosing the wrong look-alike investigational drug.

- **Reporting errors**. System-based causes of investigational drug errors under the sponsor's direct control—naming, labeling, and/or packaging—are rarely addressed during reporting. Once an error has been reported to the drug's sponsor it is often unclear whether it must be reported to FDA.

- **Risk of errors not considered**. Error-prone conditions may be obvious to practicing healthcare providers but scientists working on new drug development, product manufacturing, and protocols for clinical trials are rarely well versed in basic medication safety principles. There appears to be little regulatory oversight governing the labeling, packaging, and nomenclature used to identify investigational drugs.

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Safe Practice Recommendations

ISMP recommends several steps that organizations can take to reduce the risk of medication errors when using investigational drugs.

- **Promote safe storage**. Provide adequate space to stock investigational drugs separate from other medications. Consider storage when reviewing new protocols submitted for IRB approval, and address concerns before participating in the study. Notify sponsors that unneeded study medications and supplies will be discarded by a specific date if not picked up before then. If possible, consider moving unneeded supplies to a secure space outside the pharmacy until retrieval.

- **Highlight information**. A pharmacy-prepared auxiliary label can be affixed to individual drugs or a bag that holds vials/containers of the same drug/strength/concentration, to supply information that is missing or poorly visible on the product label. You also can use colored highlighter or pen to bring attention to key information. Auxiliary labels and highlights should be applied before drugs are added to stock or dispensed to patient care areas.

- **Enhance prescription labeling**. Sponsors usually do not allow investigational drugs to be transferred out of the original container. When dispensing an investigational drug to a patient, the pharmacy should provide a supplemental label that meets all standards for prescription dispensing that are applicable in the state.

- **Educate sponsors**. Perform a safety risk assessment on new investigational drugs and communicate the issues related to medication errors to the sponsor during the study initiation meeting.

- **Assess error potential during investigational review board (IRB) review**. An organization's IRB should include pharmacists, and investigational drug protocols and other medication issues should be assessed for safety before approval is granted. If drug labeling and packaging information has not been provided with the protocol, request information from the sponsor to help facilitate evaluation.

- **Report errors.** Report errors to the IRB and study sponsor. ISMP also urges organizations to report errors with investigational drugs to the USP-ISMP Medication Errors Reporting Program (or write to ismpinfo@ismp.org). By learning more about errors, patient safety advocates can work with sponsors in the pharmaceutical industry to spur necessary changes. Appropriate agencies within The National Institutes of Health (NHI) also should be notified so they can monitor trials appropriately.

For a complete copy of the *ISMP Medication Safety Alert!* newsletter article on this topic, visit http://www.ismp.org/Newsletters/acutecare/articles/20071101.asp. For interviews with ISMP experts on investigational drug errors, contact Renee Brehio at 704-831-8822.

About ISMP: The Institute for Safe Medication Practices (ISMP) is a 501c(3) nonprofit organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process.

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