Medication Safety Alerts

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This column draws on US and Canadian experience and may include, with permission, material from the *ISMP Medication Safety Alert!*, a biweekly bulletin published by the Institute for Safe Medication Practices (ISMP), Huntingdon Valley, Pennsylvania.

TINZAPARIN LABEL CHANGES IN RESPONSE TO MEDICATION INCIDENT REPORTS

Two cases from the database of the Institute for Safe Medication Practices Canada (ISMP Canada) illustrate problems with labelling for tinzaparin.

Case 1

At midnight, a nurse received an order for "Tinzaparin 18,000 units SC x 1 dose now" for a patient with a diagnosis of possible pulmonary embolism. The nurse obtained the prefilled syringe from an automated medication dispensing unit but could not find the name tinzaparin printed on the label. No pharmacist was on duty overnight, so the nurse paged the on-call pharmacist, who verified that Innohep (which did appear on the product label) is the brand name for tinzaparin and stated that the manufacturer's labelling problem would be reported to the hospital's Safe Medication Practices Committee in the morning.

Omission of the generic drug name on a marketed prefilled syringe (Figure 1) creates the potential for error; in this case, the situation delayed administration of the drug to a patient with possible pulmonary embolism.

Case 2

A nurse received an electronic order for "Tinzaparin 10,000 units SC q24h" with the first dose due "stat" for a patient with acute deep vein thrombosis. The nurse obtained a multidose vial from an automated medication dispensing unit and misinterpreted the vial label as indicating that it contained 20 000 units of tinzaparin in a volume of 2 mL. She withdrew half of the 2 mL volume in the vial (1 mL) and administered it to the patient subcutaneously. She checked the package again soon after and asked the pharmacist for assistance in reading the label. The pharmacist confirmed that the vial actually contained 40 000 units tinzaparin in 2 mL or 20 000 units per millilitre.

The patient in this case received double the intended dose of tinzaparin because of misinterpretation of information about the total drug amount on the multidose vial label (Figure 2).

Medication Labelling Requirements

The Regulations of the Canadian Food and Drugs Act[1] specify that "the inner and outer labels of a drug shall show: . . .

(i) the proper name, if any, of the drug which, if there is a brand name for the drug, shall immediately precede or follow the brand name in type not less than one-half the size of that of the brand name,

(ii) if there is no proper name, the common name of the drug".

The regulations also specify that "No person shall sell a drug that is not labelled as required by these Regulations."[1]

Medication labelling standards and guidelines have been developed[2,3] to inform pharmaceutical manufacturers how to design labels with the end user in mind. The standards and guidelines indicate that liquid injectable medication labels must contain the following information:

- common (generic) name of the drug
- the total amount of drug ingredient(s) per total volume, followed by the concentration of drug ingredient(s) as amount per 1 mL.

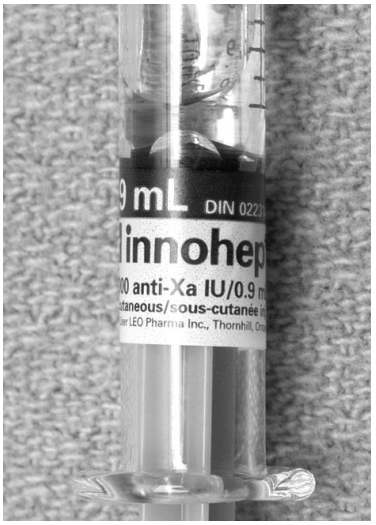

Figure 1. Manufacturer's prefilled syringe containing tinzaparin, labelled with the company's brand name, Innohep.

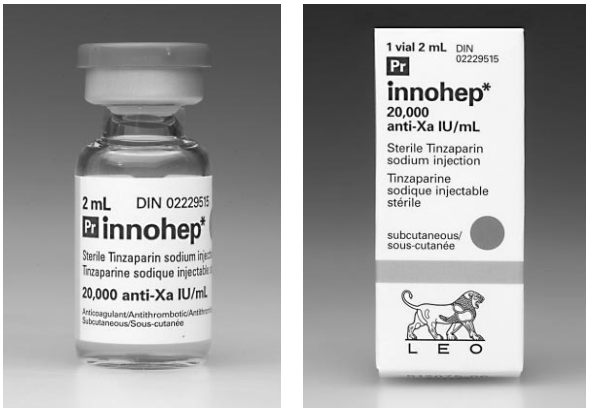

Figure 2. The vial and outer package label for product containing tinzaprin 20,000 units/mL do not indicate the total amount per total volume (i.e., 40,000 units/2 mL); the label information was misinterpreted as 20,000 units/2 mL.

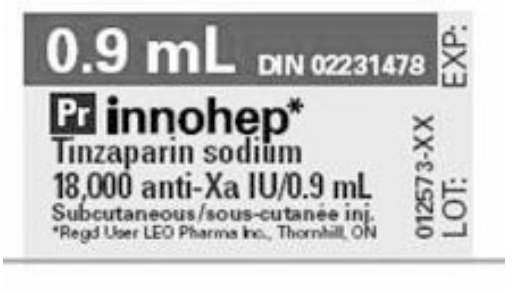

Figure 3. The manufacturer's new label for the prefilled syringe now includes the generic drug name (tinzaparin sodium).

Although manufacturers usually comply with the minimum standards and additional guidelines, there may be cases like the ones presented here when they are not followed. Pharmacists are well positioned to identify these issues. It is important to welcome reporting from others (e.g., nurses, physicians, and patients), and to take action when error-prone situations have been identified. A proactive approach also includes examination of medication packaging and labelling as part of the review process for formulary addition requests and when products are received through inventory management.

The hospital reporting the incidents shared above decided to take action. First, the issues were brought to the attention of the hospital's Safe Medication Practices Committee and ISMP Canada. The label and packaging of all tinzaparin products on the hospital formulary were scrutinized for compliance with medication labelling standards.[1-3] A list of recommendations was formulated and communicated in writing to the manufacturer (LEO Pharma Inc), and copies of the correspondence were sent to ISMP Canada.

Reommended Label Changes

Prefilled Syringes

- Print the generic name (tinzaparin) on each syringe in a font size equal to that of the brand name (Innohep).
- Increase the font size for the quantity of drug in the syringe.
- Include volume calibration scales on all prefilled syringes.

Multidose Vials

- In addition to the concentration (20 000 units/mL), indicate on the package and the vial itself the total amount of drug per total volume (i.e. 40 000 units/2 mL) in bold type.
- Increase the vial size while keeping the volume and quantity of drug the same, to increase the size and improve the legibility of the label.

Recently, the manufacturer released new prefilled syringe labels (Figure 3). In addition, the labels for the multidose vial and its package have been revised to include the term "multidose".

Conclusions

Patient safety is a shared responsibility. Pharmaceutical manufacturers are expected to follow minimum standards and to design medication labels with the end user in mind. "Branding information" or "marketing information" should not replace critical information such as the generic drug name. This article reminds pharmacists about medication labelling requirements and the value of the pharmacist's role in identifying problems with specific products. In addition, it demonstrates the influence of a single institution, which reported the medication incidents to allow shared learning and worked collaboratively to achieve changes for enhanced patient safety.

References

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