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ISMP Institute for Safe Medication Practices
An ECRI Company

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Call to action: Practitioners need to warn patients about purchasing counterfeit drugs online

Problem: Practitioners should be on guard for patients who may present to different healthcare settings with adverse reactions after knowingly or unknowingly taking substandard and falsified (SF) drugs. SF drugs are counterfeit or fake drugs made to resemble genuine pharmaceutical manufacturers' medications. We warned of this growing threat to patient safety in our May 16, 2024 article, *ISMP urges increased action at the practice level to halt the growing danger of counterfeit drugs*, and our April 10, 2025 article, *Implement strategies to prevent persistent medication errors and hazards: 2025*. We are concerned that not all practitioners recognize this risk, and we urge organizations to implement measures to proactively educate patients about illegal, so-called "online pharmacies" and websites selling drugs at discounted prices. Below is a recent case reported to ISMP. While reading about this event, look for indicators that the product was not genuine and consider what changes could be implemented within your organization to protect patients from being harmed by SF drugs.

Error Reported to ISMP

A patient presented to the emergency department (ED) with uncontrolled nausea and vomiting after injecting what was presumed to be a 10 mg dose of semaglutide, rather than the intended 0.5 mg dose. The prescriber ordered intravenous (IV) 0.9% sodium chloride, metoclopramide, and ondansetron, which a nurse administered to the patient. The ED physician discharged the patient 24 hours later with prescriptions for anti-emetics to treat the persistent side effects.

Figure 1. The "sterile water" diluent came in unlabeled glass ampules, without a filter needle.

The patient told the ED staff that their provider had prescribed **WEGOVY** (semaglutide) for obesity. They could not afford the medication copay. So, the patient purchased what they thought was semaglutide for $500 through an internet website (the website was not shared with ISMP). The patient was not provided with education on how to prepare or administer the dose.

When the product arrived, the United States Postal Service (USPS) label indicated it came from a residential address. The "medication" came in a cardboard box without prescribing information or patient-specific instructions. It contained "sterile water" in unlabeled glass ampules (**Figure 1**). The patient was also only provided with 50-unit insulin syringes. The box included a carton of 10 vials with labels indicating each vial contained 10 mg semaglutide sterile lyophilized powder (**Figure 2**, page 2). The vial labels had a lot number (ZPHC768) and an expiration date (3/2027) but did not contain a national drug code (NDC) or any type of drug identification number.

The carton label stated that the product was "Produced by SecureSemaglutide Labs" and that it was "SWISS MADE" and had a "GMP" seal indicating it was manufactured in a good manufacturing

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DiazePAM 10 mg/2 mL prefilled syringe label design may result in incorrect dose. A nurse reported concerns with diaze**PAM** 10 mg/2 mL prefilled syringes by Natco (NDC 69339-0136-34, lot number A4740003). The graduated markings with the dose volume are printed on a label (i.e., sticker) that is placed onto the syringe. This sticker also acts as a tamper-evident seal that breaks when practitioners remove the syringe cap. Since the tamper-evident mechanism and the graduated markings are on the same sticker, when the nurse twisted off the syringe cap, the sticker shifted and the syringe markings moved (**Figure 1**). The nurse who submitted the report was concerned that this could result in a practitioner preparing an inaccurate dose. In this case, the nurse used an empty syringe to draw up the patient's dose from the prefilled syringe to measure it accurately using the empty syringe's scale.

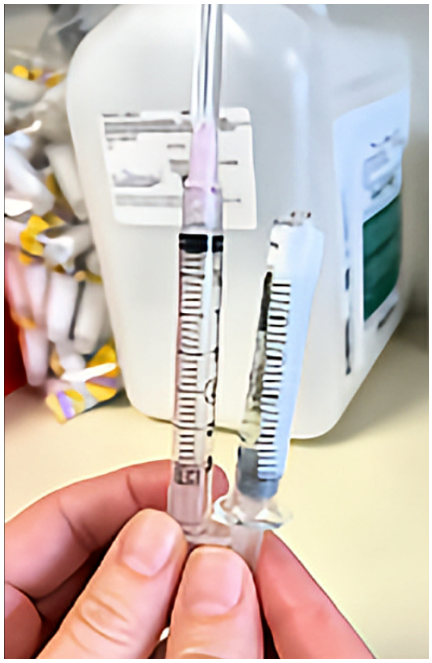

Figure 1. After a nurse removed the cap, the label with the graduated markings shifted on the diaze**PAM** 10 mg/2 mL prefilled syringe (right), so she prepared the patient's dose in another syringe. (The syringe on the left is used for comparison.)

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practice facility (**Figure 3**). Although semaglutide approved for use in the United States is intended for subcutaneous injection only, the carton stated, "To Be Injected Subcutaneous or Intramuscular."

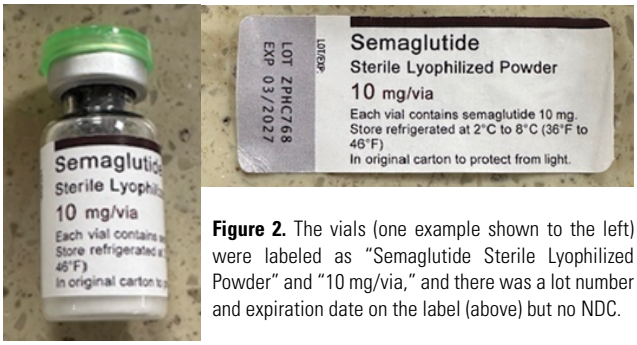

Figure 2. The vials (one example shown to the left) were labeled as "Semaglutide Sterile Lyophilized Powder" and "10 mg/via," and there was a lot number and expiration date on the label (above) but no NDC.

The carton's side panel had instructions to mix 1 mL of "sterile water" into the "vail" (i.e., vial) and that the initial dose is 0.5 mg injected subcutaneously once weekly, with titration information (**Figure 4**). The instructions did not specify the volume the patient should administer for the dose. However, if the vial contains 10 mg of drug and if the patient is to dilute it with 1 mL of sterile water (10 mg/1 mL), then the initial dose would be 0.5 mg/0.05 mL. From what the ED staff understood, the patient administered a full 10 mg vial (1 mL) using two 50-unit (0.5 mL) insulin syringes.

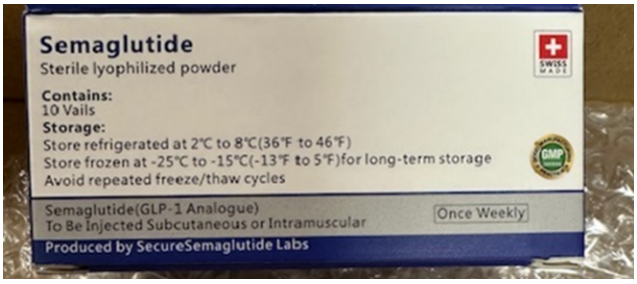

Figure 3. The carton label indicated the product is "Produced by SecureSemaglutide Labs," "SWISS MADE," with a "GMP" seal, and that it is "To Be Injected Subcutaneous or Intramuscular."

Potential Red Flags

While some issues may be more noticeable to healthcare practitioners than patients, there were several clues that something was not right:

- The drug was purchased without a prescription online "from Switzerland"
- The patient was not provided with education, and there was no pharmacist available for counseling
- The medication was shipped with a United States residential return address label
- There was no contact information (i.e., phone number) for follow-up questions
- There was no patient-specific label or instructions about what volume to administer
- The patient was sent insulin syringes without instructions on what marking on the syringe to use
- Vial was misspelled on the product labels (e.g., "via" on the vial label, "vail" on the carton label)

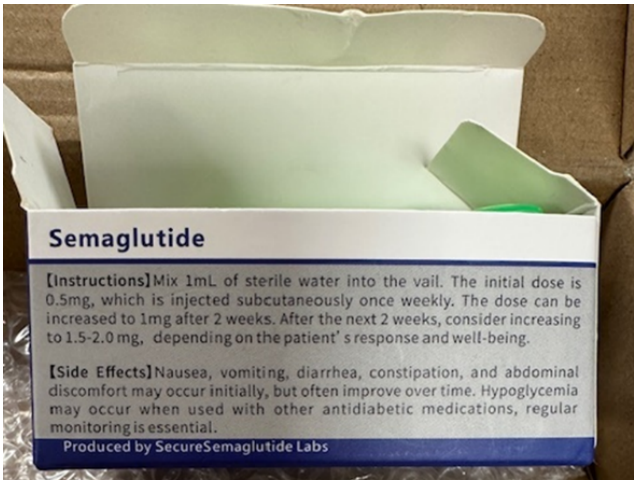

Figure 4. The instructions lack information about the volume needed to administer a dose.

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We reached out to Natco to notify them of this concern and recommend that the product design be modified so that the tamper-evident label does not include the graduated markings. Removing the cap and tamper-evident seal should not hinder the practitioner's ability to prepare and administer an accurate dose. We do not recommend transferring the syringe contents to another syringe as this defeats the safety of using a ready-to-use product. Notify staff of this risk and, for now, consider purchasing this product from an alternative manufacturer.

Pink vial caps lead to close call with high-alert medications. A certified registered nurse anesthetist (CRNA) found vials of phenylephrine 10 mg/mL in the pocket designated for dexmede**TOMID**ine 200 mcg/2 mL vials (**Figure 1**) in an open matrix drawer of an anesthesia tray. The dexmede**TOMID**ine vials (by Piramal Critical Care) and phenylephrine vials (by Avet) are similar in size and have similar color caps (pink) (**Figure 2**, page 3). While the color of

Figure 1. Dexmede**TOMID**ine (left) and phenylephrine (right) vials were found mixed together in the dexmede**TOMID**ine pocket in an open matrix drawer.

medication vial caps should not be relied on alone, the pharmacy had previously purchased these products from other manufacturers with different color caps. Years before, the CRNA had treated a patient who had inadvertently received 10 mg of phenylephrine intravenous (IV) push resulting in irreversible brainstem

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- The "sterile water" ampules did not contain a label
- Filter needles were not provided for use with the glass ampule
- There was no NDC or drug identification number
- The carton stated the drug should be refrigerated, but did not come packaged with cold packs; also, semaglutide should not be frozen but the carton stated, "Store frozen at -25°C to -15°C (-13°F to 5°F) for long-term storage"
- An unapproved route of administration (intramuscular) was included on the carton label
- There was no beyond-use date (BUD) provided for the reconstituted product

Safe Practice Recommendations: Healthcare organizations have a crucial role in raising awareness about the threat of SF drugs to patients. Share this case with your medication safety committee and clinical teams that care for patients in the outpatient, urgent care, and emergency settings. Provide widespread education to practitioners that about **95% of so-called online pharmacies operate illegally**.[1] Leaders must stay informed about medication-related incidents shared by safety organizations and develop mitigation strategies for known problem drugs, including glucagon-like peptide-1 (GLP-1) agonists. Monitor patients for unexpected outcomes (e.g., increased side effects) and consider if SF medications could be the culprit. When reviewing a patient's medication history, include a scripted open-ended question asking where they obtain their medications.

Share with patients the warning signs that may indicate a pharmacy could be selling SF drugs. Refer them to resources such as the US Food and Drug Administration's (FDA) BeSafeRx campaign. Educate patients about the National Association of Boards of Pharmacy's (NABP) searchable list of accredited digital pharmacies that comply with quality assurance criteria. Encourage patients to check for a licensed pharmacist's availability at any online pharmacy they are considering, which can help determine the pharmacy's legitimacy. Inform patients that when a pharmacy does not require a provider's prescription to dispense a prescription medication, the facility is likely illegal and unsafe.

Ask patients to review medication packages and labels for **spelling errors**, which is one of the **most noticeable mistakes** on SF products.[2] Ensure the drug comes with patient-specific dosing instructions and information about how to prepare and administer the dose. Patients should be suspicious if vials are not labeled, if they are not provided with an appropriate measuring device, or if the drug is not shipped according to the storage requirements on the label (e.g., states to refrigerate but does not arrive with cold packs). Stress to patients that if anything does not look right, they should check with a healthcare practitioner before taking the medication.

References

1) Brady J, Baney L. Congress holds registries and registrars accountable for rogue online pharmacies. National Association of Boards of Pharmacy (NABP). January 21, 2022. Accessed April 2, 2025.
2) How to identify fake medicines. Pfizer. Accessed April 2, 2025.

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damage, so they appreciated the severity of harm if these high-alert medications were mixed up.

Manufacturers' product labels (and vial caps) might change in color, so that should not be used to identify any medication. This speaks to the importance of reading the product label three times (when obtaining the item, just prior to use, and when discarding it or returning it to stock). To prevent misidentifying medications by viewing only the vial caps, avoid storing vials in an upright position, especially when stored in a bin or drawer below eye level. Store them in a way that always keeps their labels visible. Maximize the use of locked-lidded pockets and do not use open matrix drawers to store high-alert medications or drugs with look-alike packaging.

Figure 2. Dexmede**TOMID**ine (left) and phenylephrine (right) vial caps are the same pink color.

In addition, when the pharmacy receives a new product, conduct a proactive review of product characteristics that might cause confusion and lead to medication errors (e.g., same cap colors). When problems are recognized, consider purchasing the product from a different manufacturer. Communicate with staff when a new product is available and review the packaging, storage location (e.g., any medication trays, automated dispensing cabinets), and other pertinent information. ISMP ***Targeted Medication Safety Best Practices for Hospitals***, *Best Practice 18*, calls for maximizing the use of barcode verification prior to medication administration by expanding use, including in perioperative areas.

Reminder...
Take our survey on the current level of implementation of the ***Targeted Medication Safety Best Practices for Hospitals*** by **June 5, 2025**. Click here to start the survey.