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ISMP Institute for Safe Medication Practices
An ECRI Company

Community/Ambulatory Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Have a Game Plan—Setting a Goal for Medication Safety During the World Cup

Problem: With the United States, Canada, and Mexico hosting the FIFA (Fédération Internationale de Football Association [French] or International Federation of Association Football [English]) World Cup in multiple cities starting this June, and in planning for other upcoming large international events such as the 2028 Summer Olympics in Los Angeles, hospitals (including EDs), urgent care centers, pharmacies, and other healthcare organizations may see an influx of patients who need medications to treat chronic conditions or who require urgent treatment while traveling. International travelers seeking medical care during these large events face increased medication safety risks, which also pose challenges for healthcare organizations within those host cities. Additionally, several states with tourist attractions might experience international travelers regularly visiting the area, so there needs to be consistent processes in place for these potential patients.

Patients may present with both prescription and over-the-counter medications labeled in a different language or with different brand names or generic names, and with drugs and treatment regimens that do not align with hospital or pharmacy formularies and practices within the United States. Vulnerabilities may include the need for translating prescriptions, labels, and medication lists; unfamiliar brand or generic drug names and strengths; look-alike or sound-alike medication names compared to US products; and unfamiliar doses, dosing units, instructions, or formulations. These factors heighten the risk of selection errors, under- or overdosing, and unintentional duplication or omission of therapy. These situations may be particularly challenging when practitioners must make decisions with incomplete or unclear medication information. Community pharmacies must also ensure that patients receive prescription directions, warnings, and counseling in their preferred language.

We have written about similar problems in the past. For example, in our December 3, 2015 article, Same Name, Different Drug Outside US, we shared that a hospital pharmacist received an order for "Cartia 100 mg" along with instructions stating that the patient would bring in their own medication. The pharmacist assumed that the patient would be taking **CARTIA XT** (dil**TIAZ**em), which did not come in a 100 mg strength. The prescriber insisted that the 100 mg was correct, so the pharmacist followed up when the patient brought the medication into the hospital. It turned out that the medication was actually aspirin, or acetylsalicylic acid, which is available under the brand name Cartia in Israel, the patient's home country (**Figure 1**).

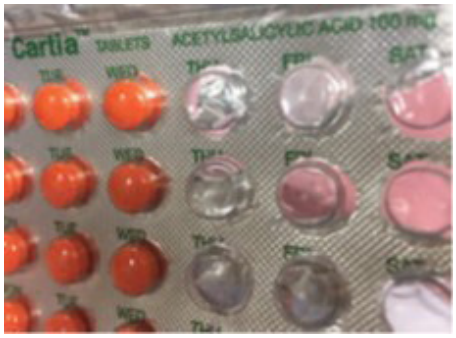

Figure 1. In multiple international markets, Cartia is aspirin.

Similar to situations that require emergency preparedness (e.g., unanticipated electronic health record [EHR] downtime), preparing for surges of international travelers requires proactive medication safety planning, clearly defined roles, readily available reference tools, and practice drills so staff can safely function when usual safeguards are limited.

Safe Practice Recommendations: Organizations need to establish a consistent process to safeguard medication use for international travelers and should consider the following:

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SAFETY briefs

Warning! Vancomycin Labeled "DYE FREE" Contains Red Dye. A pharmacist reported concerns about how vancomycin 250 mg/5 mL oral solution (NDC 69238-2261-03) by Amneal states "DYE FREE" on the bottle label (**Figure 1**); however, the prescribing information lists FD&C Red No. 40 ("red dye No. 40") as an inactive ingredient. The pharmacist had special ordered this formulation for a patient with a documented red dye allergy (anaphylaxis) due to the packaging stating "DYE FREE." Fortunately, the pharmacist double-checked the prescribing information prior to dispensing, so the patient was not harmed.

Figure 1. The label on Amneal's 250 mg/5 mL vancomycin oral solution states "DYE FREE," but FD&C Red No. 40 is listed as an inactive ingredient in the prescribing information.

The pharmacist notified the manufacturer, who confirmed that this product contains red dye. According to DailyMed, there was a label update in April 2026, which no longer includes "DYE FREE." We reached out to the US Food and Drug Administration (FDA) and Amneal to report this concern. This is a potentially life-threatening situation for patients with an anaphylactic reaction to certain dyes. We have not heard back from Amneal whether organizations who have purchased this product have been or will be notified of this mislabeling, or if they plan to recall this product.

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Assess risk before the surge. Engage emergency preparedness teams and conduct a proactive risk assessment (e.g., failure mode and effects analysis) focused on medication history intake, prescribing, verification, dispensing, administration, and discharge counseling for patients with limited English proficiency (LEP) or whose medication lists may include non-US brand and generic drugs. Focus on high-alert medication scenarios where an error (e.g., name or strength mix-up) may have a higher chance of causing serious harm. Consider vulnerable steps in the medication-use process where interpreter services and additional international drug information resources may be required.

Establish clear roles and escalation pathways. Designate an interdisciplinary response team to develop interim processes when risk is elevated. Define an escalation trigger for pharmacy consultation (e.g., unclear product name or strength, non-English label with no translation services available, suspected therapeutic duplication, high-alert medications). Ensure there is an escalation pathway (e.g., on-call leadership coverage after hours) so frontline staff know who can quickly triage safety issues and mobilize additional resources if needed.

Offer language services. Make formal interpreter services available, including in-person, video call, or via telephone. Avoid using interpretation services from multilingual teammates or family members, who are not professionally trained in healthcare translation.

Document in the EHR and pharmacy dispensing systems. Build required fields to document preferred patient language and interpreter service needs in the EHR. Ensure this information is easily accessible to staff. Hospital and ambulatory care settings should automatically schedule interpreters at clinical points of service for patients who are identified with LEP.

Create a communication "triage" process. Create a policy and procedure for "unknown medication" situations: gather information, engage interpreter services, contact the pharmacy, and document what was verified and how it was verified. Standardize how unclear medication information is communicated and documented in the EHR, including when a practitioner will need further clarification.

Develop an easily accessible medication verification resource. Create a curated packet (electronic and hard copy) that is easy to find, prominently version-dated, and reviewed at least annually. Include a step-by-step guidance for: available resources that can be used for identifying international brand- and generic-named single ingredient and combination products; converting strengths/concentrations; and documenting equivalencies (what was verified, by whom, and which source was used). Focus on any important clinical dosing/monitoring/goal differences for high-alert medication classes (e.g., insulin, antithrombotics) as well as a "crosswalk" for common generic/brand names. List internal and external resources with phone numbers/workflows. This may include interpreter services, toxicology/poison centers, and medication databases (e.g., Lexidrug, Micromedex) that provide international drug information.

Strengthen medication reconciliation for international travelers. Request original medication containers, photos of labels, and a written medication list when available. Use qualified medical interpreters to obtain a medication history. Build in a "two-source verification" expectation for high-alert medications (e.g., label/photo plus a trusted drug information source; or patient's container plus pharmacist verification). When substitution to a US drug is needed, include the indication in the order and provide education before starting the medication and prior to discharge to ensure patient understanding, and to prevent duplication when the patient resumes their usual home medications.

Collaborate with community pharmacies. When proactively planning for an international travel surge, hospitals and clinics should reach out to local community pharmacies to collaborate. Notify them of the steps your organization has taken and communicate identified risks and mitigation strategies. Community pharmacies should complete similar risk assessments to ensure there

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Medications are formulated with inactive ingredients for a variety of reasons such as enhancing stability, absorption, appearance (e.g., dyes), or taste, but certain ingredients can be a hidden source for allergen exposure. Manufacturers should explicitly identify a product's inactive ingredient content on the package and label, and in the prescribing information to help ensure this information is readily available. This is especially important for medications with an inactive ingredient known to be an allergen. Drug information, electronic health record (EHR), and pharmacy software vendors will then be able to take advantage of this information to provide enhanced clinical decision support.

Hospitals and pharmacies who purchase vancomycin 250 mg/5 mL oral solution (NDC 69238-2261-03) by Amneal must be aware that it contains red dye No. 40. If you purchased this as a "dye free" option, sequester it and consider alternative products. This good catch speaks to the importance of completing a comprehensive review of packaging and labeling when new drug products are purchased. To identify inactive ingredients in medications, review the package/label and prescribing information, and/or contact the manufacturer. Evaluate your EHR and pharmacy dispensing software to determine if an alert would be triggered if the patient had a documented allergy to an inactive ingredient. Incorporate inactive ingredients as part of the review process when evaluating new drugs or formulations and prior to purchasing. For additional information

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IMPORTANT! Read and utilize the Community/Ambulatory Care Action Agenda

Items from the **January – April 2026** issues of the ***ISMP Medication Safety Alert! Community/Ambulatory Care*** newsletters have been selected and prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors. The **Action Agenda** is available as an Excel file here.

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is a standard process for medication labeling, translation, and interpreter services. In addition, community pharmacies should consider flagging these prescriptions in their system to ensure patient counseling is done and in the patient's preferred language.

Educate staff and improve after each event. Provide just-in-time refreshers before major events, focusing on units that may be most impacted (e.g., admissions, ED, inpatient units, inpatient and outpatient pharmacy), on how to access interpreter services and the medication verification resource packet, and when to escalate to leadership. Run brief tabletop exercises or simulations using realistic "international label" and "unfamiliar brand name" scenarios to practice the workflow and identify gaps in the process. After the event surge, review safety concerns, including delays, close calls, and errors. Update tools/forms and share lessons learned with frontline teams to continuously improve the process.

Engage and educate patients. During discharge counseling and community pharmacy dispensing, ensure interpreter services are available if needed, implement the teach-back method, and have patients show and tell how they plan to take their medications. Avoid closed-ended questions and never assume patients understand how to take their medications. Emphasize if a new drug replaces a home medication, whether the home medication should be resumed or stopped after discharge or upon return to their home country, and how to avoid unintentional duplication when returning to the usual home medication. Share resources such as those found on the ISMP consumer website, Medicine Safety Tips While Traveling.

We thank Donald McKaig, RPh, from Brown University Health, for helping to write this article.

Be Prepared! New Once-Weekly 700 units/mL Awiqli Insulin Pen

In March 2026, the US Food and Drug Administration (FDA) announced approval of **AWIQLI** (insulin icodec-abae), a long-acting human insulin analog indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. According to the prescribing information, each carton of Awiqli (Novo Nordisk) will contain one 1.5 mL (1,050 units) or 3 mL (2,100 units) FlexTouch prefilled pen and 13 NovoFine needles. There will also be a 1 mL (700 unit) sample pen available.

Not only is the highly concentrated 700 units/mL formulation unique, but the once-weekly dosage and corresponding dose adjustments will be new for practitioners and patients. The recommended weekly starting dose of Awiqli in insulin-naïve patients is 70 units (0.1 mL) administered subcutaneously once weekly on the same day each week. The pen delivers doses in 10-unit increments and can deliver up to 700 units in a single injection. Practitioners may need to titrate the dose of Awiqli based on the patient's metabolic needs, blood glucose monitoring results, and glycemic control goals, with dose adjustments for renal or hepatic function and during illness. If patients need to change the day of the week to administer Awiqli, they may do so if their last dose has been at least 4 days prior. If they missed a dose, they should administer the missed dose as soon as possible if it has been 4 days or less, and then continue the once-weekly schedule 1 week from the day the missed dose was administered. If more than 4 days have passed, patients should skip the missed dose and take their next Awiqli dose on their regularly scheduled day.

A pharmacist reported concerns that the 700 units/mL concentration on the pen device is in small font, which could be overlooked by a practitioner or patient. It is also difficult to know how easy it will be for patients to differentiate between doses on the dose selector, especially since there is

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about inactive ingredients, refer to our April 24, 2025 article, Food-Drug Allergies—Inactive Ingredients Taking Active Roles.

Waste and Error Risk Tied to Inqovi Packaging. **INQOVI** (cedazuridine and decitabine) is approved for treatment of adult patients with myelodysplastic syndromes, including chronic myelomonocytic leukemia (CMML). The drug, which is available through specialty pharmacies, is formulated as tablets containing decitabine 35 mg and cedazuridine 100 mg. It is supplied in a carton containing a blister card with 5 tablets, each marked with the day of administration (**Figure 1**). The recommended dose is 1 tablet orally once daily on days 1 through 5 of each 28-day cycle. Current labeling states, "Dispense medication in the original packaging. Inqovi is a hazardous drug. Follow applicable special handling and disposal procedures."

Figure 1. Each Inqovi carton holds 5 tablets in a blister card.

Product labeling mentions drug-related hematologic adverse reactions (i.e., myelosuppression) that require reduced dosing: 1) first dose reduction: 1 tablet daily on days 1 through 4; 2) second dose reduction: 1 tablet daily on days 1 through 3; and 3) third dose reduction: 1 tablet daily on days 1, 3, and 5. According to the prescribing information, myelosuppression is the most frequent cause of dose reduction or interruption, occurring in 36% of patients. Since tablets must be dispensed in the manufacturer's original packaging, specialty pharmacies dispense full cartons containing 5 tablets, which can lead to leftover tablets, waste, and improper billing.

Medication errors are also possible when providing patients with more medication than needed. In the case of a dose reduction, patients will receive blister cards with 5 tablets with the packaging indicating to take medication on 5 consecutive days. Even if the pharmacy label directs the patient to take the reduced dose, this conflicting information may

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such a wide range of doses that can be selected from the starting dose of 70 units all the way up to 700 units! Another concern is that when switching to Awiqli from daily basal insulin therapy, there are different instructions based on the week (e.g., week 1 and week 2 have different dosing recommendations), which may also lead to prescribing or administration errors.

The prescribing information warns that serious hypoglycemia requiring hospitalization has occurred due to accidental mix-ups between Awiqli and other insulin products or once-weekly injectable antidiabetic medicines, incorrect dose selection, and dosing frequency errors. While this long-acting insulin is not available yet in the United States, it is available in other countries. A recently published case report described a patient who unintentionally administered a 10-fold higher dose of insulin icodec as his first dose.[1] He was prescribed 70 units of insulin icodec subcutaneously once weekly and was provided with a 1 mL sample pen containing 700 units. The patient misread the concentration on the packaging and administered 700 units of icodec. Fortunately, he identified the error immediately, went to the ED, and suffered no adverse effects or hypoglycemic events, as demonstrated by continuous glucose monitoring.

According to Novo Nordisk, Awiqli is expected to be available this summer (2026). Hospitals need to educate practitioners about this new insulin product and have a plan for when patients using Awiqli are hospitalized, whether or not Awiqli is on formulary. During medication reconciliation, specifically ask the patient which day of the week they take this medication (e.g., every Monday). Evaluate your electronic health record (EHR) and pharmacy dispensing software to require a weekly dosage regimen default for Awiqli and lock this field down so that practitioners cannot change it to another frequency (e.g., daily). If patients are admitted and need to discontinue Awiqli (for whatever reason), practitioners need to account for the residual effect of Awiqli and have a plan to initiate a daily basal insulin after the 7-day duration of Awiqli.

Evaluate acute care workflows and consider if it is possible to add a patient-specific label to the insulin pen device itself (not on the removable cap), so that, before administration, the nurse can scan the patient's wristband, patient-specific barcode on the pen, and the manufacturer's barcode to ensure it is the correct product for the patient. Practitioners and patients must be educated not to use an insulin syringe to withdraw Awiqli from the pen cartridge, and to only use the NovoFine needles that come with the pen. Determine if additional strategies (e.g., store separately from other insulin products such as in the controlled substance safe, conduct an independent double check prior to dispensing and administration) are needed to safeguard the 700 units/mL pens. If it is a nonformulary product for your organization, consider whether the drug is appropriate for formulary addition, so that system safeguards can be optimized.

Organizations (e.g., hospitals, clinics, pharmacies) should provide patients with education for all Awiqli prescriptions and ensure that they understand the correct weekly frequency. When dispensing from the outpatient or community pharmacy, staff should apply a label on the pen devices, not the removable caps. When Awiqli is picked up at the pharmacy, provide mandatory counseling and require the patient to repeat back the instructions, at every encounter, to validate that the patient understands the once-weekly dosing schedule and hypoglycemic effect of the medication if taken more frequently than prescribed. Tell patients to always check the product label before each injection to confirm they are using Awiqli and not another insulin product. Instruct patients to visually verify the dialed units on the dose selector of the Awiqli pen before each injection and not to dial to the maximum single dose (700 units) of Awiqli unless this is the prescribed dose. Ensure patients understand how to recognize and manage hypoglycemia.

We encourage practitioners to maintain a heightened awareness when prescribing, dispensing, and administering this product. Report errors to ISMP, FDA, and the manufacturer.

Reference

1) Hawker K, Morein J, Gill G, Druce I. Tenfold insulin icodec overdose. *Can J Diabetes*. 2025;49(8):470-2.

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cause confusion and lead patients to take doses for five consecutive days.

ISMP has contacted the manufacturer, Taiho Pharmaceutical, about these safety concerns. Provide patients with a dosing calendar indicating which days the patient should and should not take the medication. Pharmacies may note on the blister cards which days to take or avoid taking the medication or use auxiliary labels to cover blisters that should not be opened. Pharmacists may also consider removing tablets that should not be taken prior to the patient taking the medication home. Require counseling for patients, especially those with reduced dosing, to ensure they understand their dose, days of administration, and proper storage and handling of the drug.

Special Announcement

Join MSB's Clinician Database!

Med Safety Board (MSB), an ISMP company, is actively recruiting US-based clinicians to join its MSB Clinician Database, including pharmacists, pharmacy technicians, nurses, physicians, and medication safety practitioners in outpatient pharmacies and other ambulatory settings. Those who sign up may be invited to participate in **paid** engagements, such as evaluations to assess brand names for look- and/or sound-alike concerns. Joining the database does not guarantee selection but ensures consideration for future projects aligned with your background and interests.

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