Medication Error Department Updates

What is "Medication Error?"

Saudi Food & Drug Authority (SFDA) uses the definition of a medication error as set forth by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). Specifically, a medication error is "*any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."* It is important to note that these errors might be detected in the premarket stage of product development using appropriate evaluation methods.

Medication error department (MED) goal: is to increase the safe use of drug products by minimizing errors related to the naming, labeling, packaging, or design of drug products.

The Medication error department Responsibility Include:

- MED is responsible for all medication error (ME) reports (entry & analysis).
- **Pre-marketing Activities:**

Evaluation of proposed proprietary names for registration, renewal & variation of pharmaceutical products, for their potential to cause sound-alike or look-alike medication errors. Together with reviewing proposed product designs, labeling and outer packaging for their potential to cause MEs.

- **Post-marketing Activities:**

Communication with marketing authorization holders (MAHs), healthcare institutions/ professionals and monitoring for post-marketing ME reports, including those presented in periodic safety update reports. Finally, issue medication safety alerts, circulate, and Dear Health Care Provider Letter (DHCL).

What type of medication error does the MED focus on?

Medication errors that occur due to sound-alike or look-alike similarity between two drug names (either the invented name or the non-proprietary name) unclear labels, or poorly designed packaging.

Accurate interpretation of a product's name is essential to ensure that the correct product is procured, prescribed, prepared, dispensed, and administered to the patient. Product names that look or sound alike can lead to medication errors and, potentially, result in patient harm by increasing the risk of healthcare practitioners misprescribing or misinterpreting the correct product name, dispensing the wrong product, or administering it incorrectly.

NOTE: SFDA will not share your personal information without your specific permission.

We offer different channels to report your MERs:

Mail/ Correspondents:
Vigilance Executive Directorate
Saudi Food and Drug Authority-Drug sector
4904 Northern Ring Road
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia

Phone:
+966 11 8806000/ +966 11 2038222
Unified number: 19999

E-mail:
npc.drug@sfda.gov.sa
Med.drug@sfda.gov.sa

Online (Reporting Format):
https://ade.sfda.gov.sa/Request/AddAdverseDrugReactionsPublic
Medication Errors should be reported using (Medication Error) form. Healthcare professionals "Physicians, Pharmacists, Dentists, Nurses …etc." and the public can report Medication Errors via this form.

Keep In Mind: The Medication Error department in SFDA mainly focus on naming, packaging, and labeling related reports since their main scope is regulatory issues.

Next Month's Topic:

The psychological phenomenon called "confirmation bias", whereby a person reading a medication label sees what he or she expects to see, rather than what is actually printed there.