Kingdom of Saudi Arabia
Saudi Food & Drug Authority

# IMSN Annual Meeting 2023:

## Updates from Saudi Food and Drug Authority (SFDA)

**Abdulaziz S. Al Draihm, PharmD**
Director of Medication Errors Department
Medication Errors Department
Vigilance Executive Directorate, Drug Sector
Saudi Food and Drug Authority

# Introduction

- Saudi Food and Drug Authority (SFDA) is an independent regulatory body of the Kingdom of Saudi Arabia that aims to ensure food and drug safety for the nation. The Authority was founded on August 29, 2003
- The Medication Errors Department, established in 2013
- MED is responsible for all medication error reports entry and analysis. MED's goal is to increase the safe use of drug products by minimizing errors related to the naming, labeling, packaging, or design of drug products

# Introduction Cont’

- The MED is responsible for both pre-and post-registration.
- MED is responsible for reviewing the drug's name and artwork submitted by the manufacturer during the registration process.
- We worked on two guidelines for companies to help them understand the requirements for drug names and artwork in order to increase safety:
- Graphic Design Guidance for Medication Packaging.
- Guidance for Naming Medicinal Products

# Outlines

- Updates on SFDA published guidance
  - Guidance for Graphic Design of Medication Packaging
  - Guidance for Naming of Medicinal Products.
- SFDA activities to endorse IMSN's Global Targeted Medication Safety Best Practice #2 (Prepare and dispense vinca alkaloids in a minibag, never in a syringe)

# Guidance for Graphic Design of Medication Packaging

- The date of Issue was on the 8th of October 2015
- The implementation date was 28 January 2019
- This guidance is complementary to the GCC Guidance for Presenting the SPC (Summary of Product Characteristics), PIL (Patient Information leaflet), and Labeling Information with more illustrations and details to minimize medication errors. The design considerations and principles outlined can be applied to all product dosage forms. A preliminary version of this guidance was revised by Medical Error Recognition and Revision Strategies (Med-ERRS) a former for-profit subsidiary of the Institute for Safe Medication Practices (ISMP)

https://www.sfda.gov.sa/sites/default/files/2022-11/GuidanceGraphicDesignMedicationPackagingV31_0.pdf

# Guidance for Graphic Design of Medication Packaging

What is New in Version 3.1?

# Guidance for Graphic Design of Medication Packaging

| Section | Description of change |
|---|---|
| VII. Medication Errors Reports And Corrective Actions | **ADD:**<br><br>Method of reporting medication errors |
| VIII. Concentration Designation & Recommendations | **ADD:**<br><br>New section to present all recommendations for concentration designation regardless of the dosage form also the Elimination of Ratio expression. |
| IV. Design Recommendations For Secondary Packaging | **ADD:**<br><br>To differentiate between similar products names by using TALL Man Letters (bolded uppercase letters) |
| IX. A Guide To Labeling And Packaging Of Ophthalmic Preparation | **Delete:**<br><br>of the Arabic term معقم/ـة from Packaging Of Ophthalmic Preparation |
| 1.7 Warnings | **ADD:**<br><br>Warning statement<br>Warning : Paralyzing agent (Implementation Date 1-1-2023) |

# Guidance for Naming of Medicinal Products

- The date of Issue was on the 8th of October 2015
- The implementation date was 25 February 2020
- The Drug Sector in Saudi Food & Drug Authority (SFDA) has developed this document to provide guidance for companies on the factors that need to be considered when selecting an invented medicinal product name to reduce medication errors
- This document should be read in conjunction with the following drug sector documents:
  - The GCC Data Requirements for Human Drugs Submission
  - Guidelines for Variation Requirements

https://www.sfda.gov.sa/sites/default/files/2021-04/Guidance%20for%20Naming%20of%20Medicinal%20Products%20V2.1_0.pdf

# Guidance for Naming of Medicinal Products

What is New in Version 2.1?

# Guidance for Naming of Medicinal Products

| Section | Description of change |
|---|---|
| Page No. 10 | ▪ Obvious Similarities in Spelling and Pronunciation of Proprietary Names |
| Page No. 10 | ▪ Inert or Inactive Ingredients |
| Page No. 11 | ▪ United States Adopted Name (USAN) Stems |
| Page No. 16 | ▪ Incorporation of Company's Name |
| Page No. 17 | ▪ Biological Products |
| Page No. 18 | ▪ Factors to be addressed in Applications |

# Vinca Alkaloids

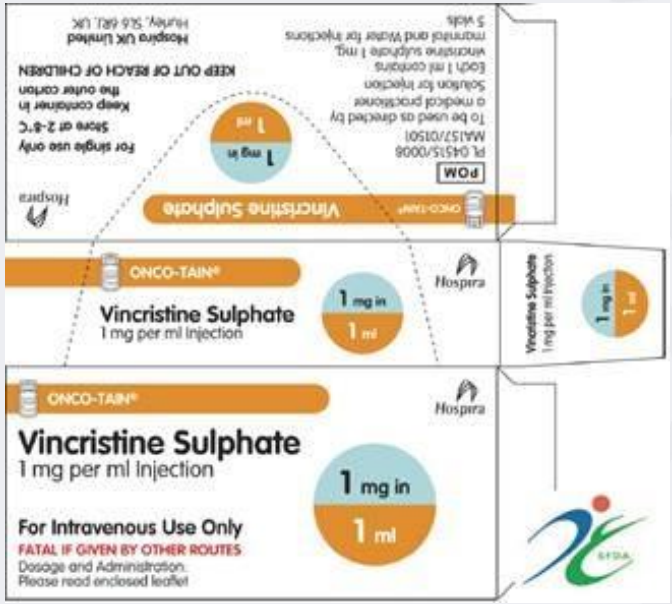
# IMSN Global Targeted Medication Safety Best Practice (GTMSBP) # 2 Prepare and dispense vinca alkaloids in a minibag, never in a syringe

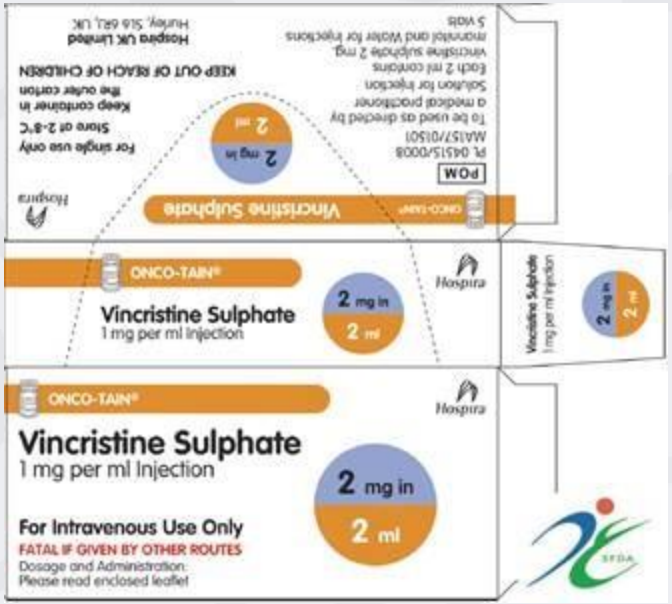
- In Dec 25 2020 IMSN Published a letter for three serious Fetal vincristine administration :
  - Morocco, April 2019 : The doctor observed that both the vinCRIStine and Methotrexate syringes were labeled "strictly intrathecal" accidentally. The error was detected through conversation between the physician and the pharmacist.
  - Guyana, January 2019 : Three children were accidentally given intravenous vinCRIStine intrathecally. Unfortunately, all three children died.
  - Norway, August 2017 : A 6-year-old boy with a brain tumor was given vinCRIStine via an Ommaya reservoir instead of methotrexate. A nurse detected the problem 20 minutes after the injection had ended. He was placed in an induced coma and died 22 days later.

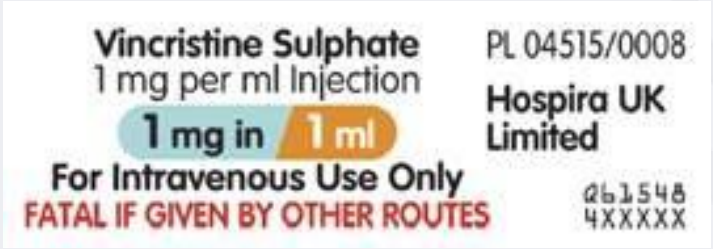
# SFDA activities to endorse GTMSBP #2

- As a precaution, we checked all of our registered Vinca products, as well as the warnings on the outside package and leaflets. After examining and comparing the data with other regulatory authorities, the outcomes and suggestions were as follow:
- Vin**BLAS**tine, Vin**CRIS**tine, and Vinorelbine are the three Vinca products that have been registered.

# VinCRIStine

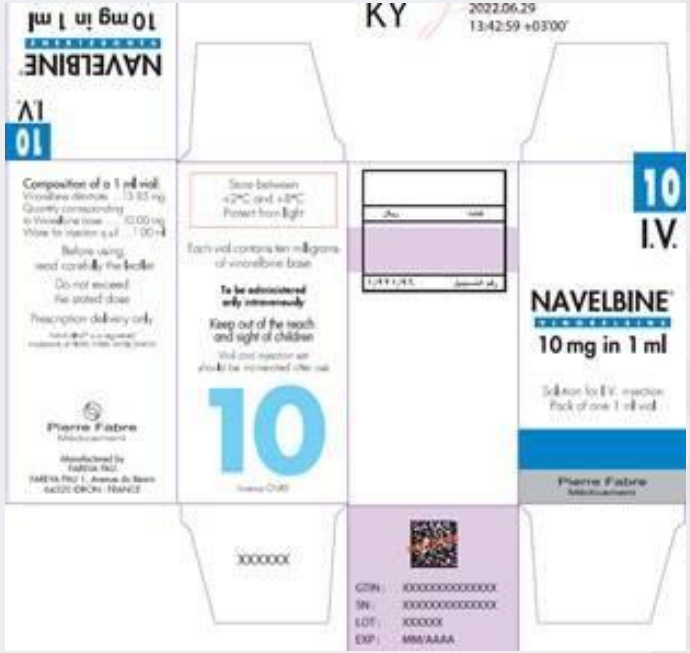



# VinBLAStine


# Vinorelbine






# SFDA Actions

- Circular was sent to All pharmaceutical companies that manufacture pharmaceutical preparations from the above-mentioned therapeutic group must commit to including a clear warning in English on the outer and inner packaging that states:

- “**FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES**”

- This technique will be implemented beginning in the second quarter of 2024

# SFDA Actions Cont’

- Labeling change to ensure dilution of vinca alkaloids, including VinBLAStine/Vinorelbine, should only be done in minibags and never in a syringe. Labeling should no longer includes instructions for preparing and administering the drug using a syringe, as this would help prevent inadvertent fatal intrathecal administration.

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# Thank You