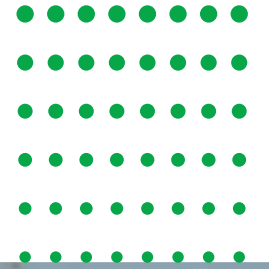




Kingdom of Saudi Arabia
Saudi Food & Drug Authority



Saudi Food and Drug Authority (SFDA): An Overview



Outline

- Saudi Food and Drug Authority (SFDA) Vision and Mission
- Organizational Chart
- SFDA Role in Preventing Medication Errors
- Medication Errors Department Activities
- Pre-Registration
- Post-Registration
- Medication Errors Reporting



Vision

To be a leading international science-based regulator to protect and promote public health



Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed



Drug Sector

The sector is responsible for safety, efficacy, and quality of human, veterinary, herbal, and cosmetic products. Depending through a series of procedure's and controls in accordance with approved international standerds.



Drug Sector

01 | Regulatory Affairs
Executive Directorate

02 | Pharmaceutical Products
Evaluation Executive Directorate

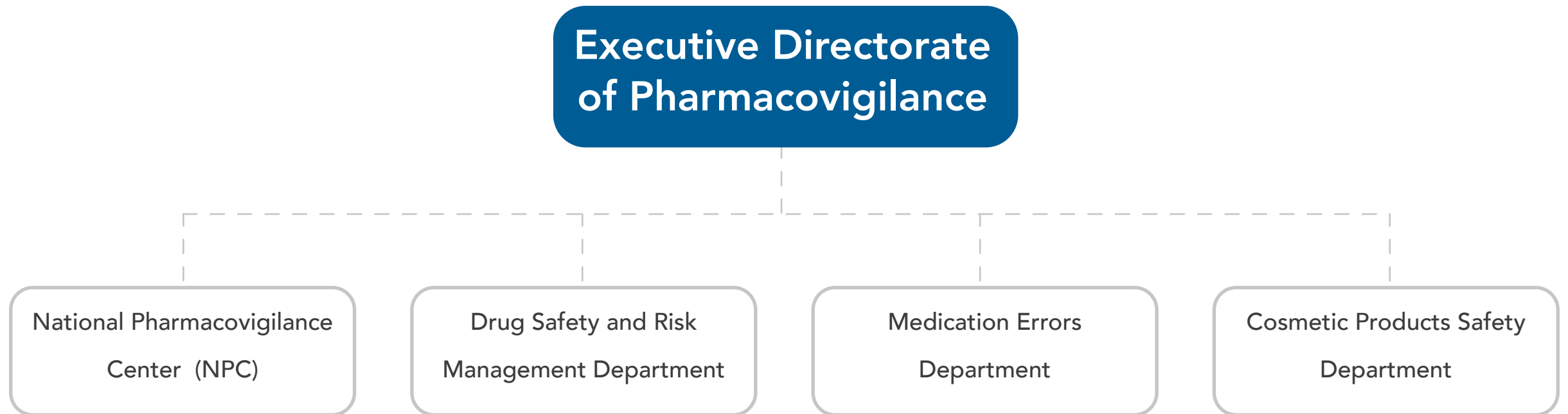
03 | Veterinary Products
Department

04 | Pharmacovigilance
Executive Directorate

05 | Benefits & Risks Evaluation
Executive Directorate

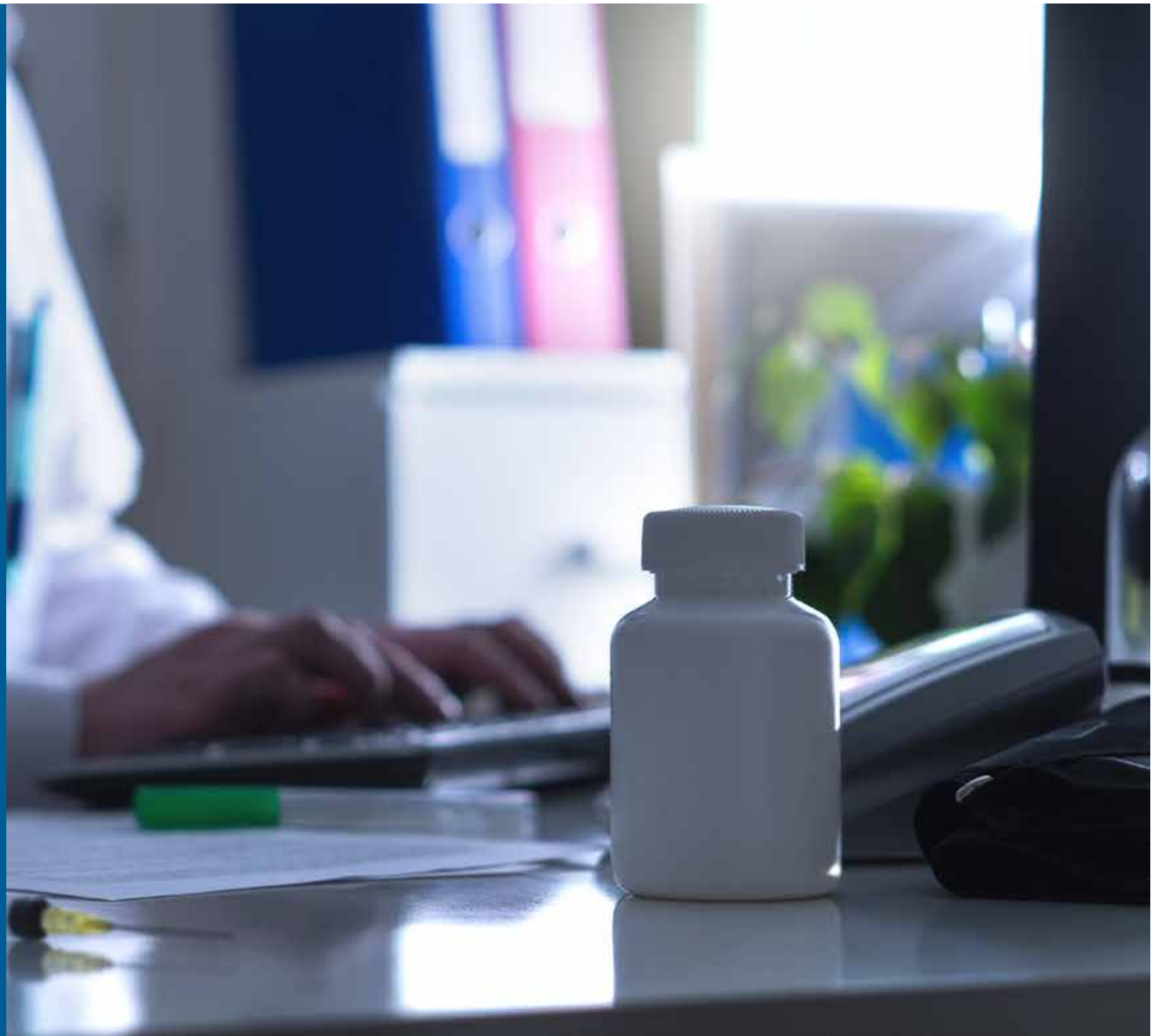
06 | Drug Availability and
Tracking Center

Executive Directorate of Pharmacovigilance





Role of SFDA in Preventin Medication Errors





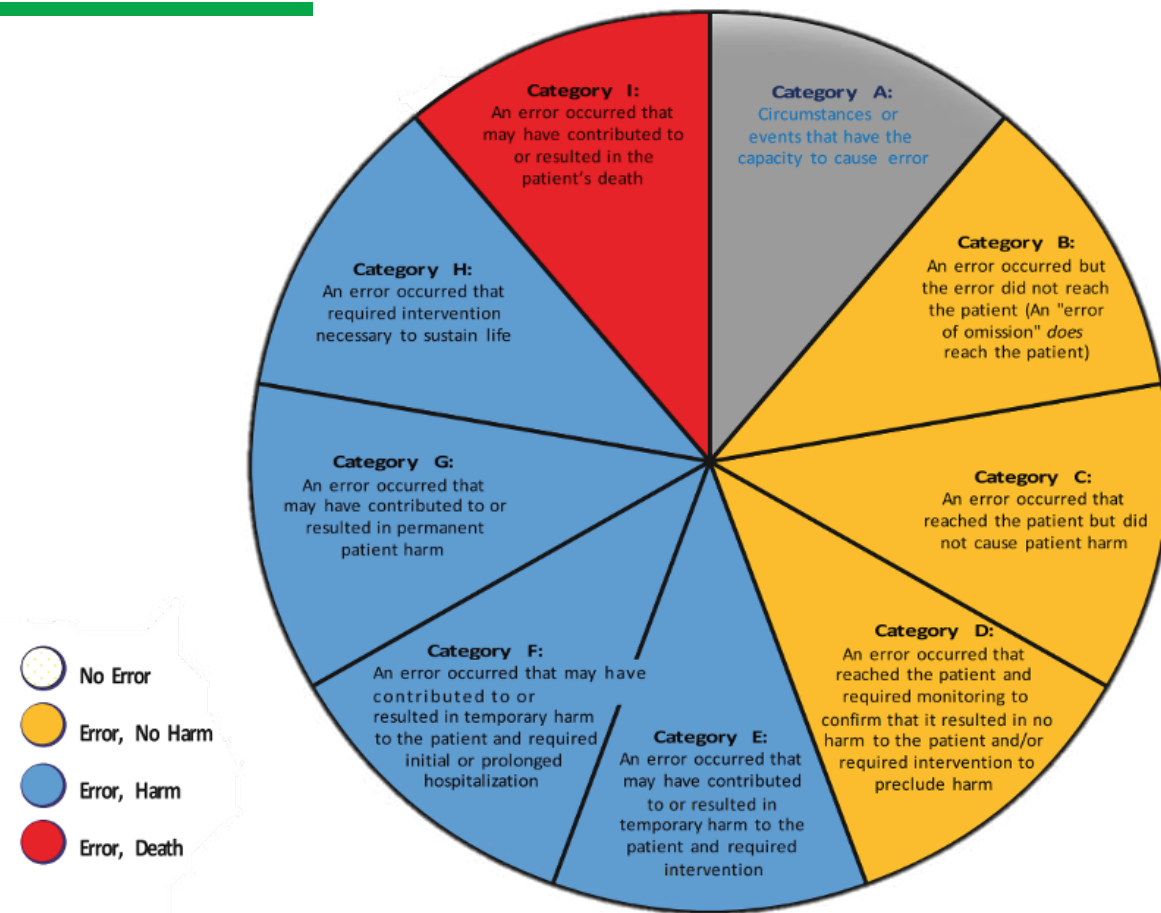
Medication Error Definition

“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 health care professional, patient, or consumer.

Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.”



NCC MERP Index for Categorizing Medication Errors



Types of Medication Error

Product-related Medication Errors

- Name Similarity
- Look-alike / Sound-alike

- Unclear labels
- Strength Expression
- Lack of Critical Information on products packaging
- Discrepancies (translation/ packaging and labeling)

- Design similarity
- Unified themes
- Look-alike Packaging



Role of SFDA in preventing Medication Errors

■ Pre-Registration



Naming
Evaluation



Packaging
Evaluation

■ Post-Registration



Variation
Requests



Reporting

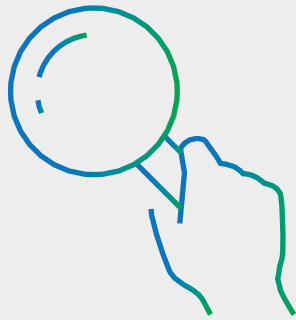


Published
Reports



Pre- Registration Activities





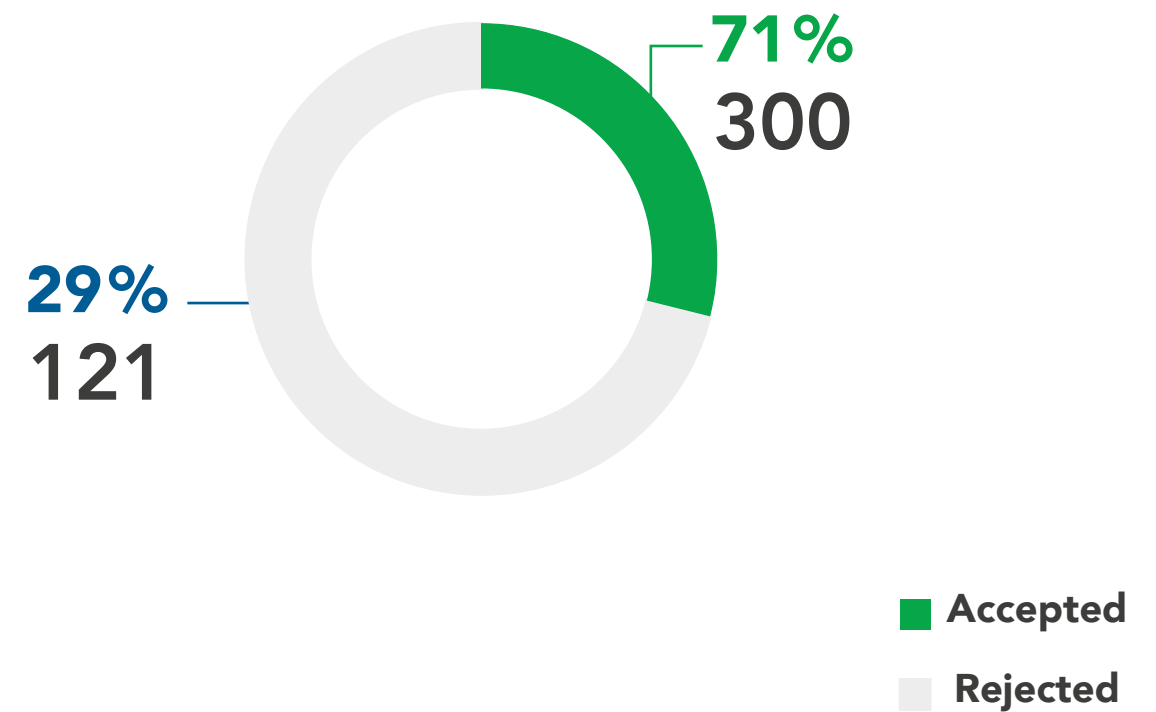
Naming Evaluation



- **SFDA Guidance for Naming of Medicinal Products**
- **Phonetic and Orthographic Computer Analysis (POCA)**
- **Saudi Name Registration (SNR)**
- **WHODrug Insight**
- **International Nonproprietary Names (INN) Stem Book 2018 (WHO)/United States Adopted Names (USAN) approved stems**
- **Martindale: The Complete Drug Reference**
- **Micromedex**
- **Lexicomp**

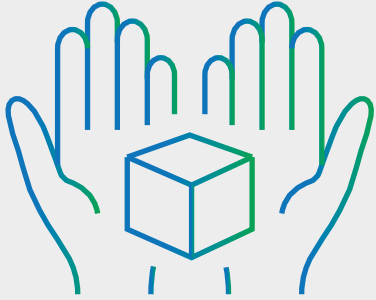


Acceptance vs. Rejection Rate of Proposed Invented Names (Calendar Year 2021)



Safety Concerns Associated with Rejected Proposed Invented Names

Name Similarity	73 (47.7%)
Incorporation of International Nonproprietary Names Stem	24 (15.7%)
Promotional/Misleading Names	15 (9.8%)
Inappropriate Use of Qualifiers	13 (8.5%)
Inappropriate Use of Company Name	8 (5.2%)
Inclusion of Dosage form/Frequency/Strength	6 (3.9%)
Use of Abbreviations	5 (3.3%)
Name Discrepancies in Submitted Files	4 (2.6%)
Indication Derived Names	3 (2.0%)
Use of Ambiguous Numbers	2 (1.3%)



Packaging Evaluation



- SFDA Guidance for Graphic Design of Medication Packaging
- Artwork Catalogue
- Country of origin packaging

Packaging Evaluation Cont.'

Color Differentiation among different strengths



Packaging Evaluation Cont'

Strength Expression/Clutter

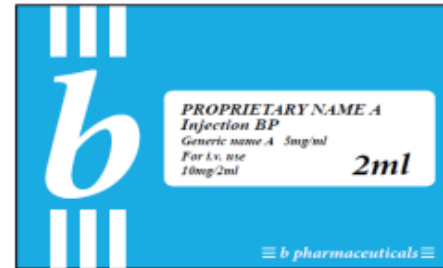
Proprietary Name

Generic Name

10 mg per 2 ml

(5 mg / ml)

For intravenous use



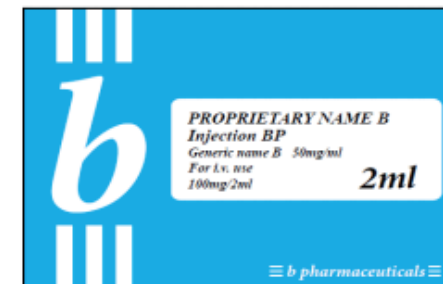
Proprietary Name

Generic Name

100 mg per 2 ml

(50 mg / ml)

For intravenous use

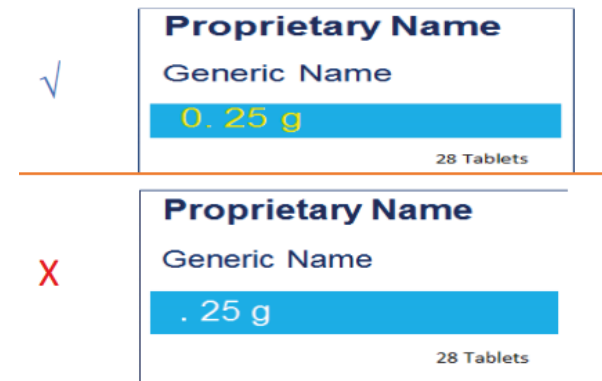
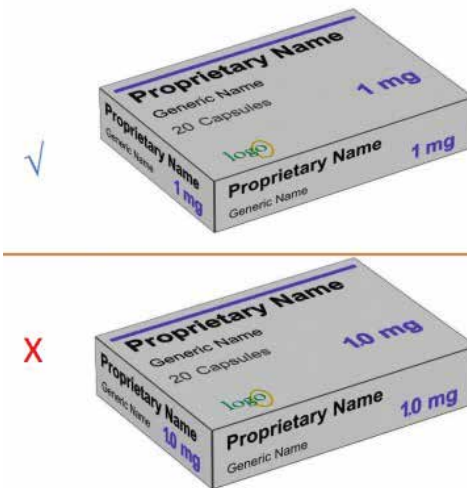
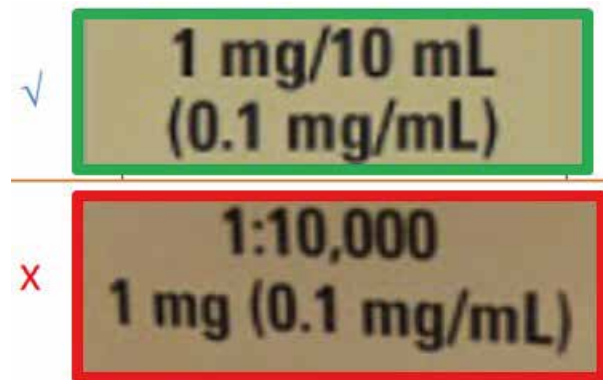


✓

✗

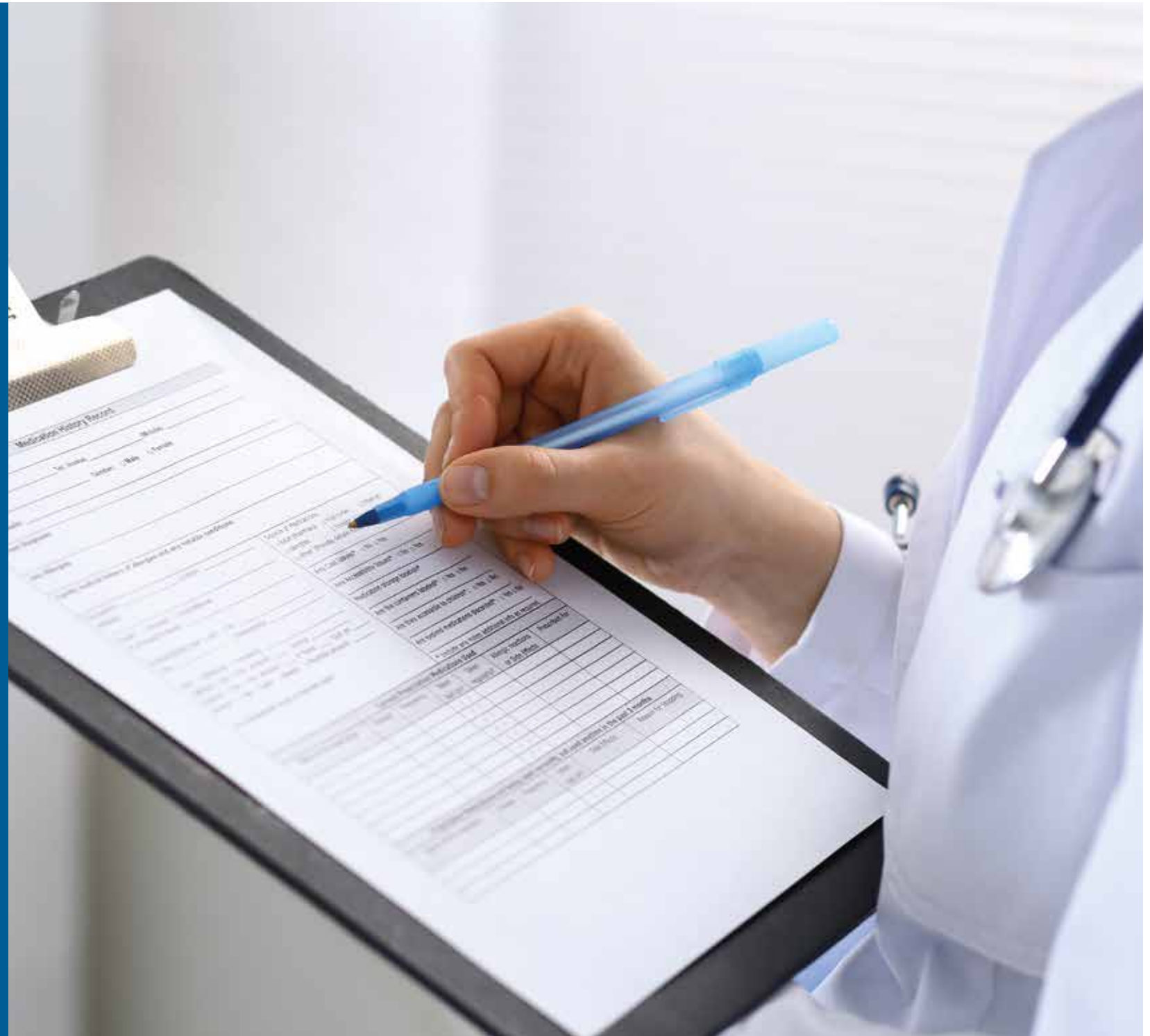
Packaging Evaluation Cont'

Strength Expression/Clutter





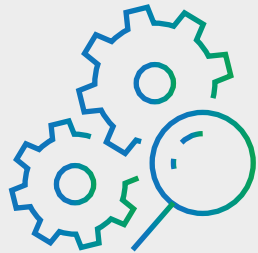
Post- Registration Activities





Post-Registration Activities

- Evaluate trade names and artwork when the company applies for a variation.
- Evaluate and analyze all reports related to medication errors, and take necessary action towards them.



Medication Errors Reporting

- Provide knowledge to boost activities in both pre- and post- marketing activities





How to Report



SFDA Call center

19999



How to Report

The screenshot displays the Saudi Vigilance website interface. At the top, there are social media icons for Facebook, Twitter, and Instagram, followed by the date 'Sun - May 29, 2022'. On the right side of the header, there are 'Register' and 'Login' buttons. The main header includes the Saudi Vigilance logo (تيقظ Saudi Vigilance) and the Saudi Food & Drug Authority logo (الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority). Navigation links for 'About', 'Search for Product', 'Report', 'FAQ', and 'Contact Us' are present. A 'VISION 2030' logo and a 'Side Effects of COVID-19 Vaccines' banner are also visible.

The main content area features a 'How to Report' section with a list of steps:

- ✓ Access the Reporting Service
- ✓ Choose a model
- ✓ Filling out the form
- ✓ Sending the Report to specialists

Below the list, there are four categories of reports:

- Drugs & Cosmetics
- Medical Device Reports
- Food Poisoning Report
- Veterinary Products

At the bottom, there are four additional categories:

- Community
- Pharmacy
- For Companies & Health Institute
Organizations & Company
- COVID19
Covid Vaccine Adverse Event

How to Report

The image shows a screenshot of the Saudi Vigilance Report Form. The form is titled "Report Form" and features a blue header with a megaphone icon. The "Contact Information" section is highlighted with a red box. Below this, the "Request Information" section is visible, with "Medication Error" selected as the "Request Type" and highlighted by a red box. Other fields highlighted with red boxes include "Trade Name", "Strength", "Dosage Form", and "Batch Number". The form also includes a section for "The incident related to product" with radio button options for "Name", "packaging /labeling", and "Both".

العبدية العامة للغذاء والدواء
Saudi Food & Drug Authority

تيقظ
Saudi Vigilance

About Search for Product Report FAQ Contact Us

2030
عربي

Report Form

Contact Information

Email Email Phone Number 966500000000

Request Information

Request Type Product Quality Adverse Drug Reactions Cosmetic Side Effect Medication Error

Trade Name English

Strength length DosageForm select—

Batch Number Batch Number

Similarity between medication names, products, inappropriate, or missing and misleading information in packaging and labeling AND did not result in a medication error.

Yes No

The incident related to product. Name packaging /labeling Both

Thank You

     Saudi_FDA | www.sfda.gov.sa