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

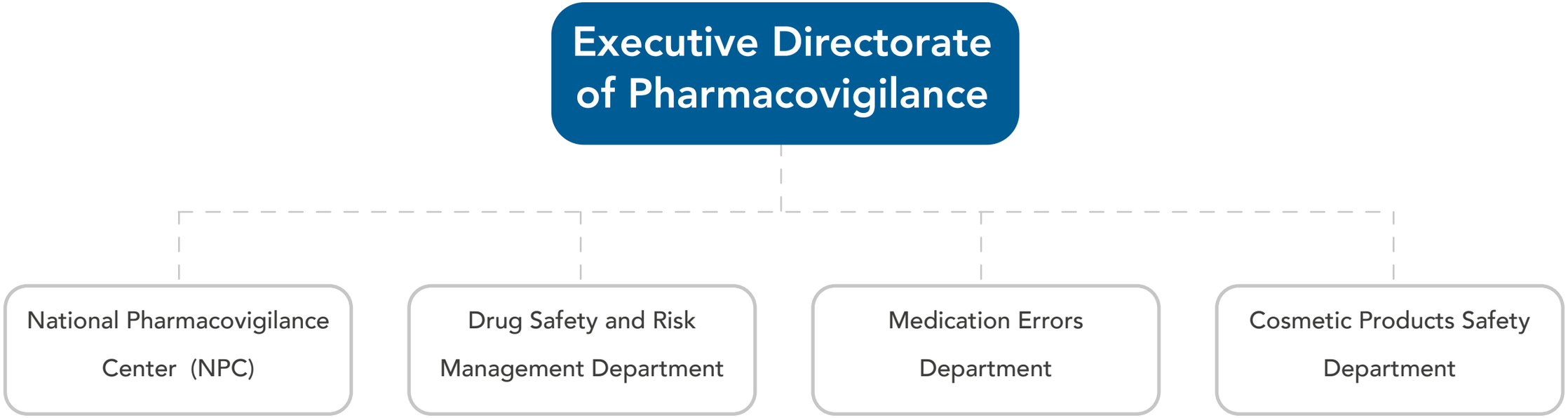
03 Veterinary Products Department

04 Pharmacovigilance Executive Directorate

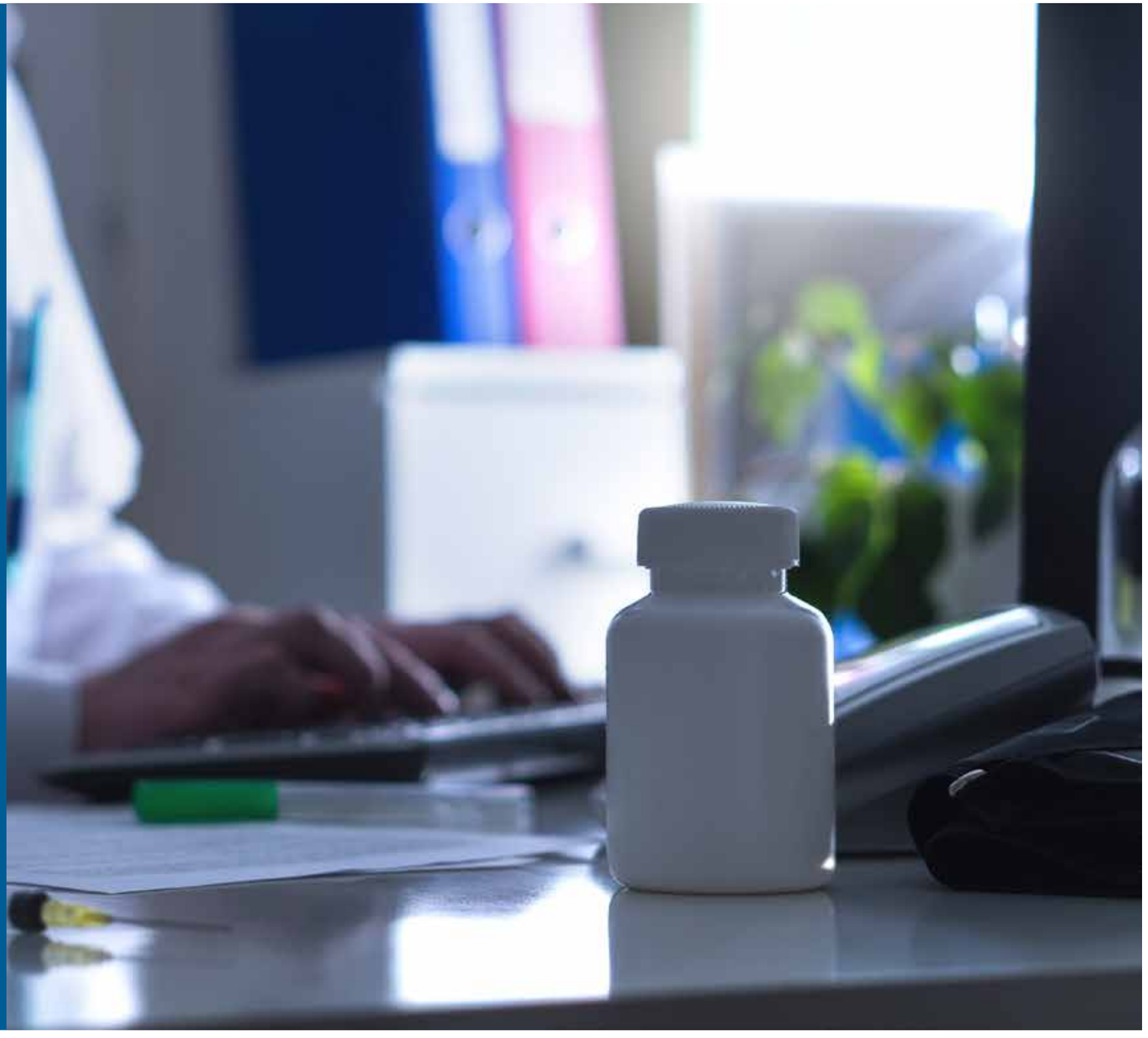
05 Benefits & Risks Evaluation Executive Directorate

06 Drug Availability and Tracking Center

Executive Directorate of Pharmacovigilance



Role of SFDA in Preventin Medication Errors

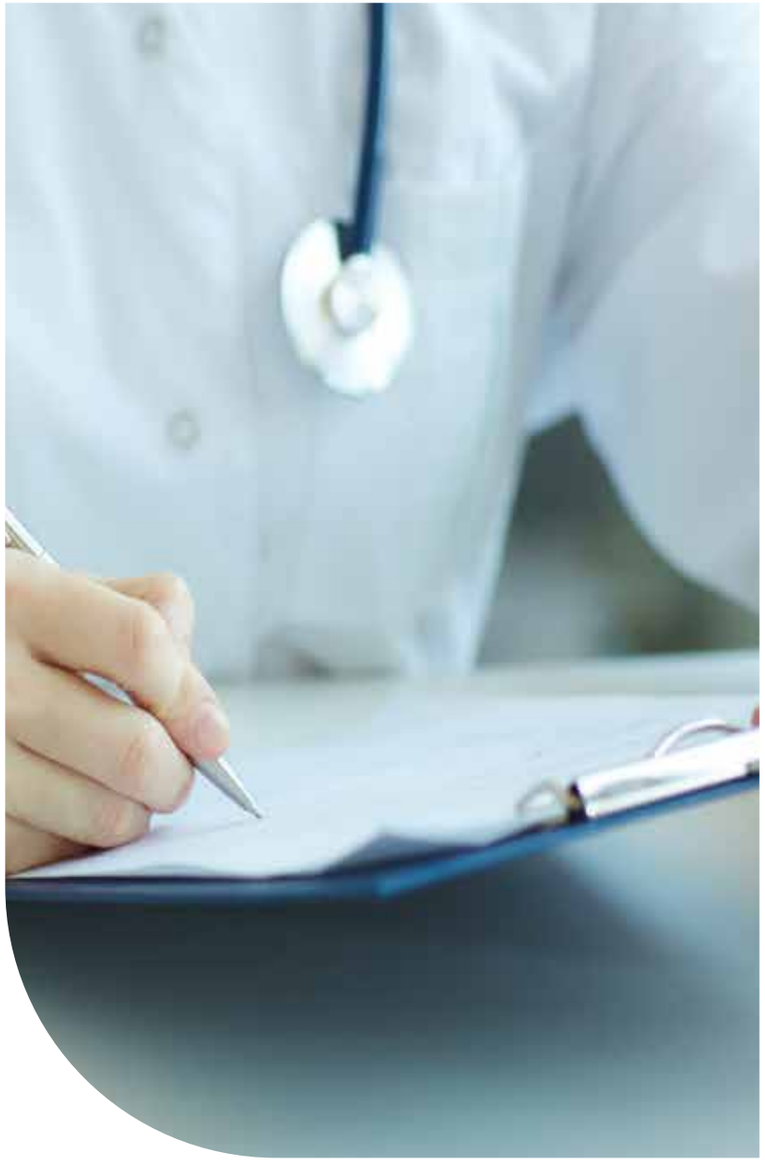


Medication Error Definition

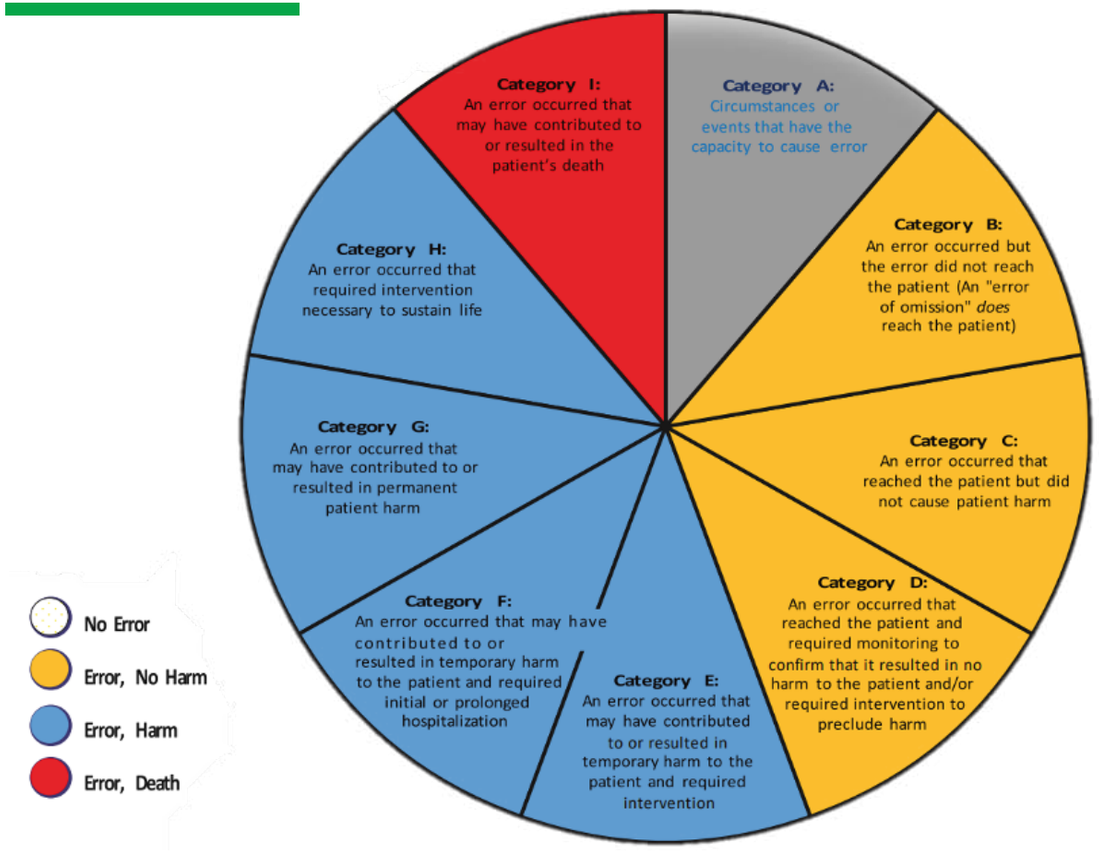
"A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

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."

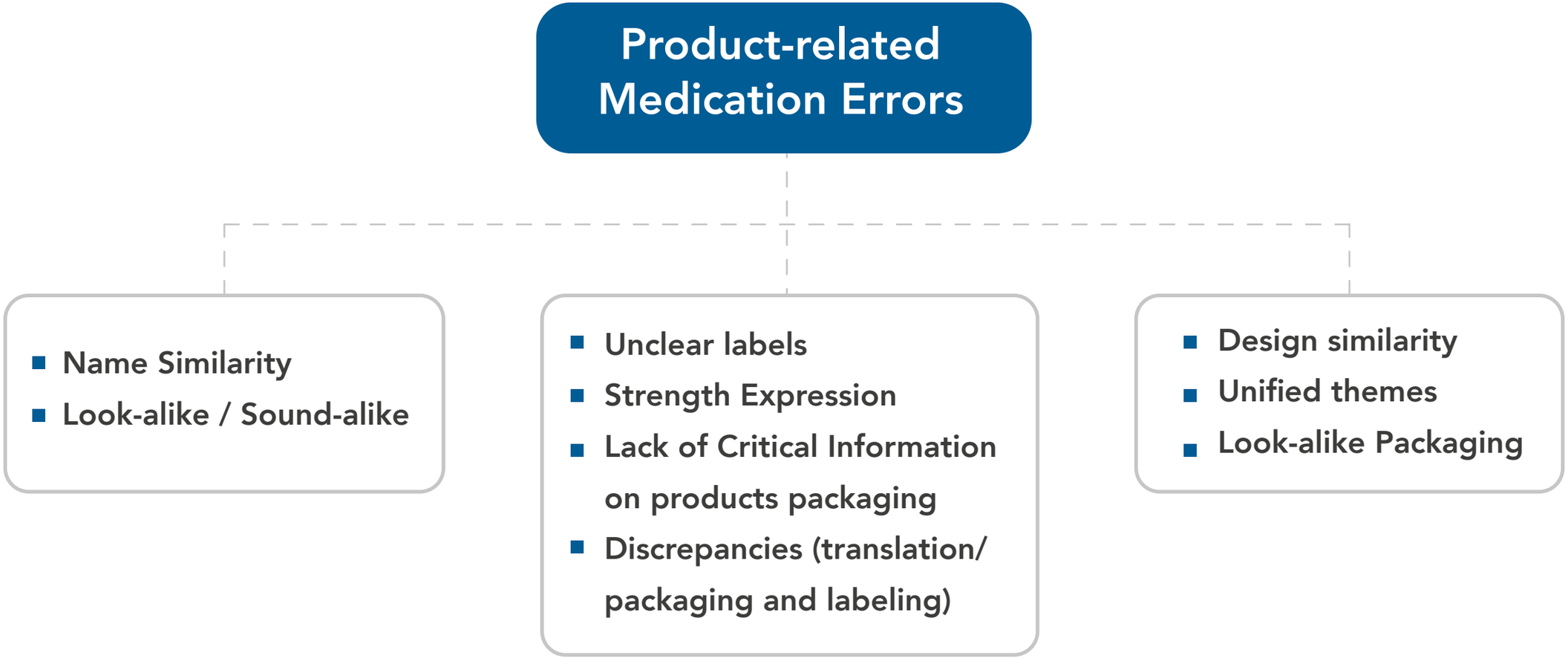
The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)



NCC MERP Index for Categorizing Medication Errors



Types of Medication Error



Role of SFDA
in preventing Medication Errors

- **Pre-Registration**

Naming Evaluation

Packaging Evaluation

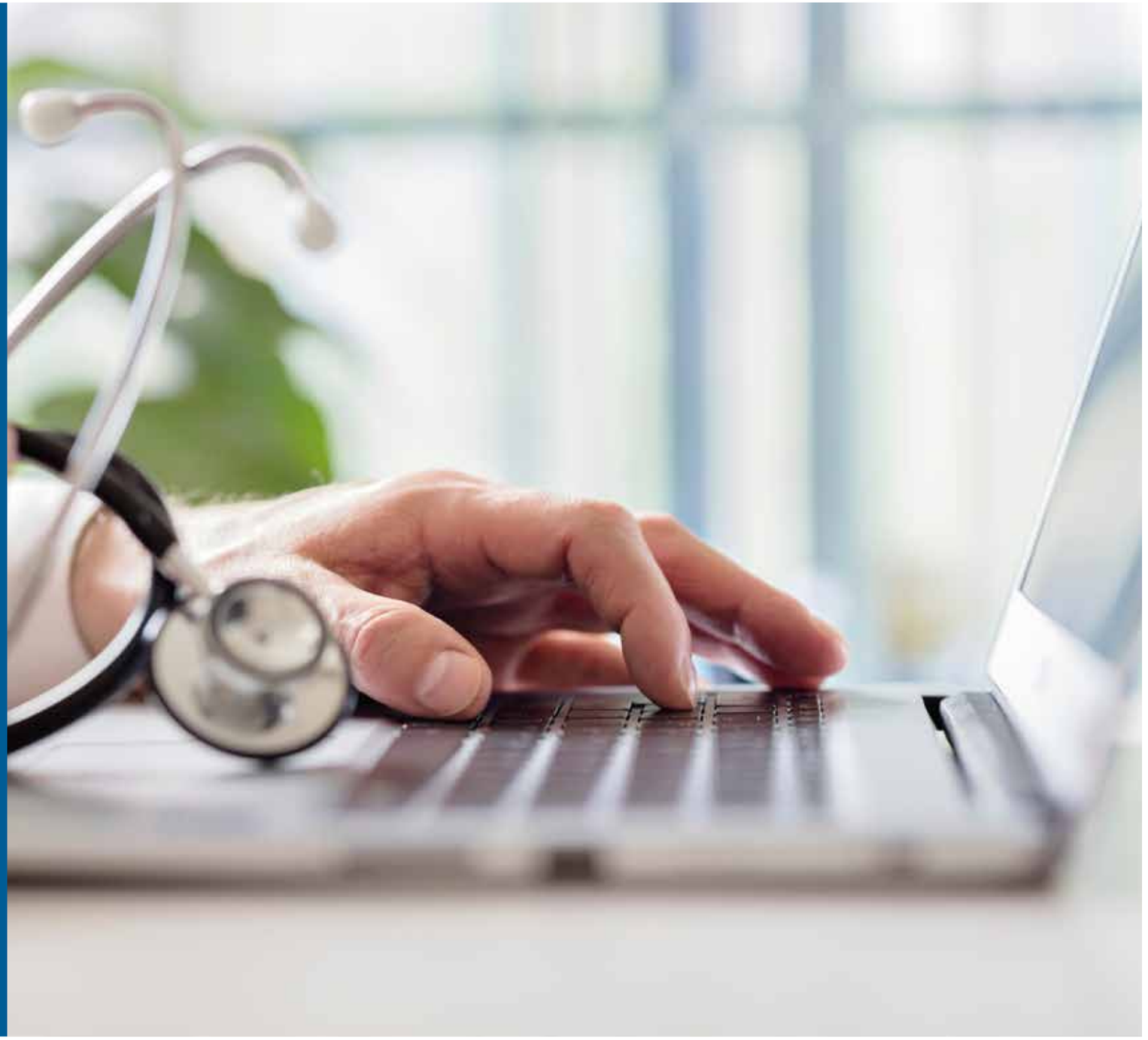
- **Post-Registration**

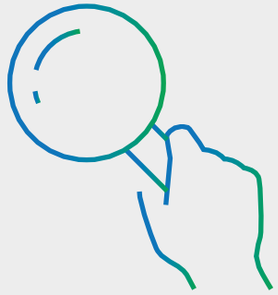
Variation Requests

Reporting

Published Reports

Pre-Registration Activities



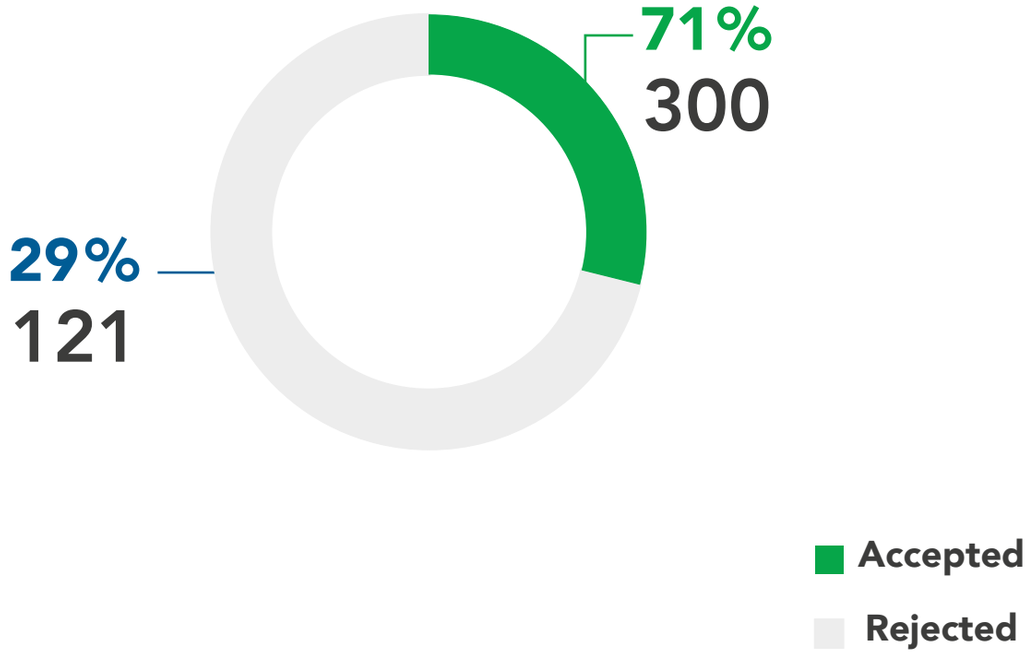


Naming Evaluation

- 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

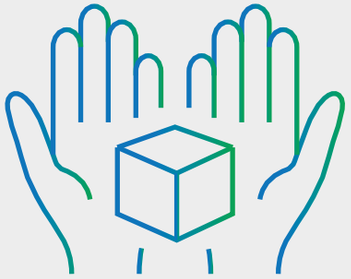
Acceptance vs. Rejection Rate

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%)

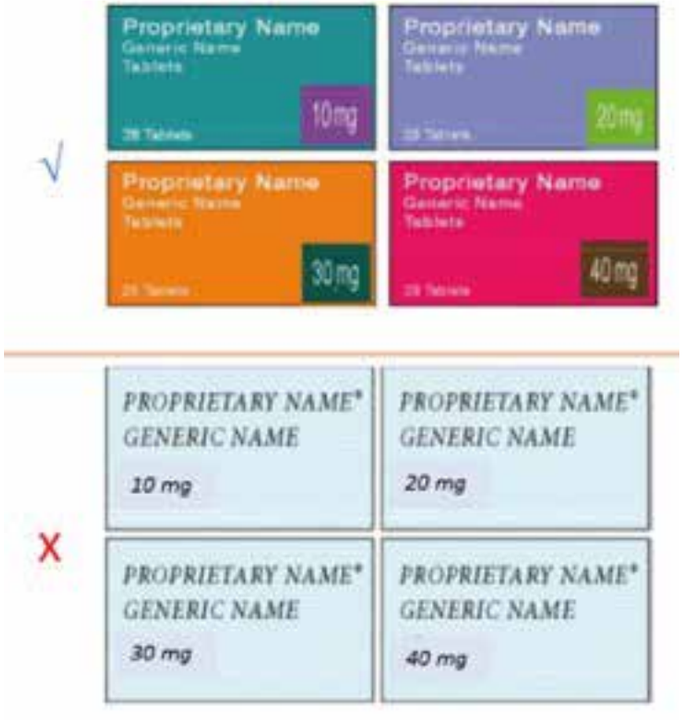


Packaging Evaluation

- 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

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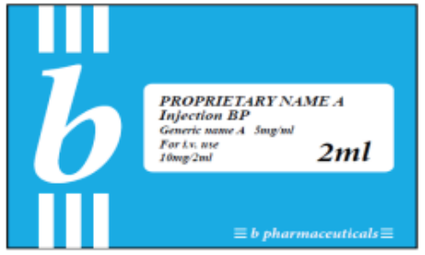
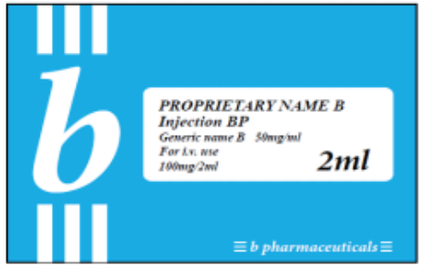




X

Packaging Evaluation Cont'

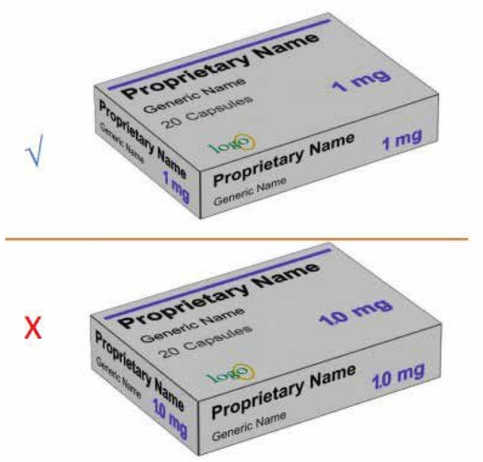
Strength Expression/Clutter

√

1 mg/10 mL
(0.1 mg/mL)

X

1:10,000
1 mg (0.1 mg/mL)



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Proprietary Name

Generic Name

0. 25 g

28 Tablets

X

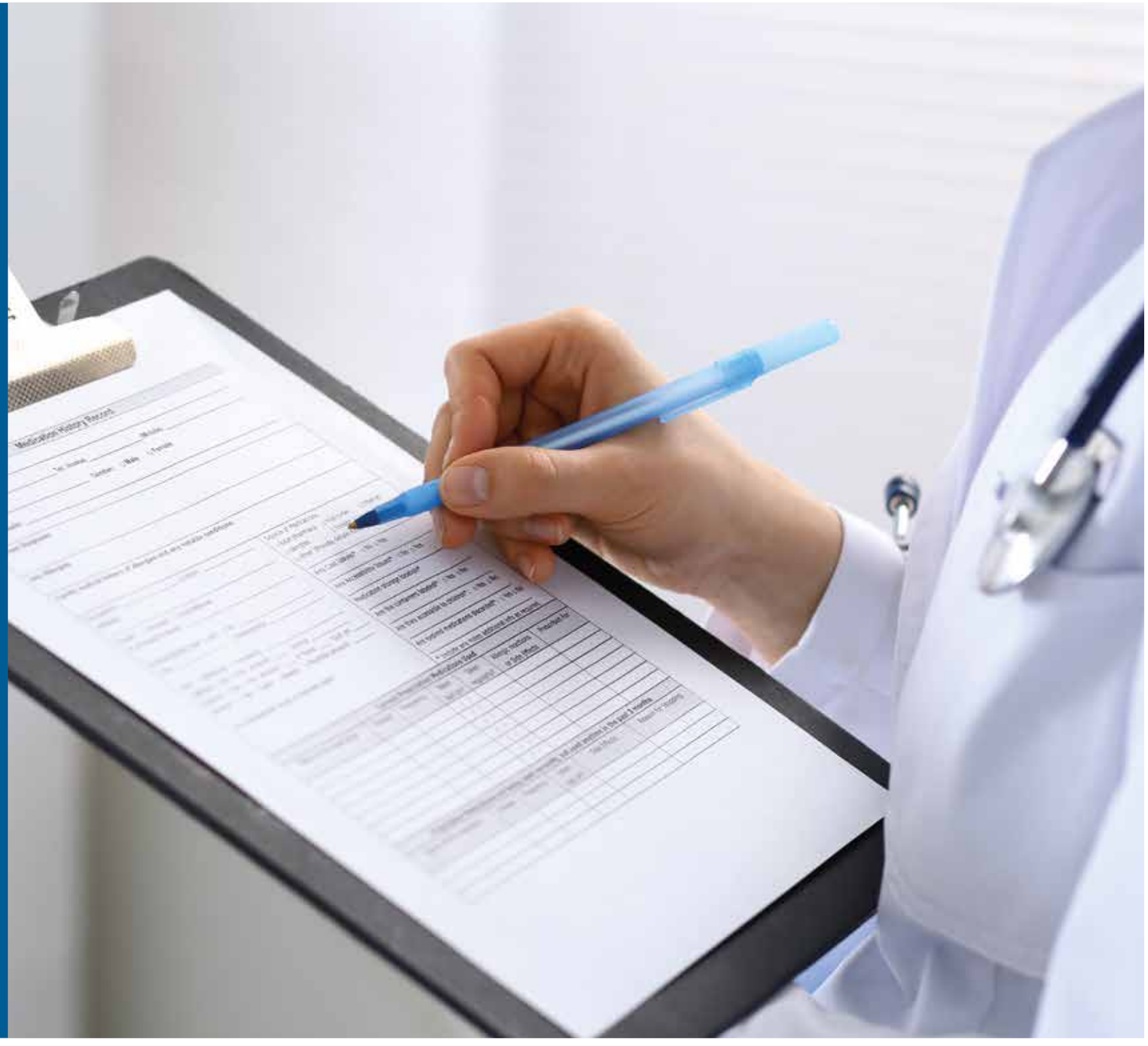
Proprietary Name

Generic Name

. 25 g

28 Tablets

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

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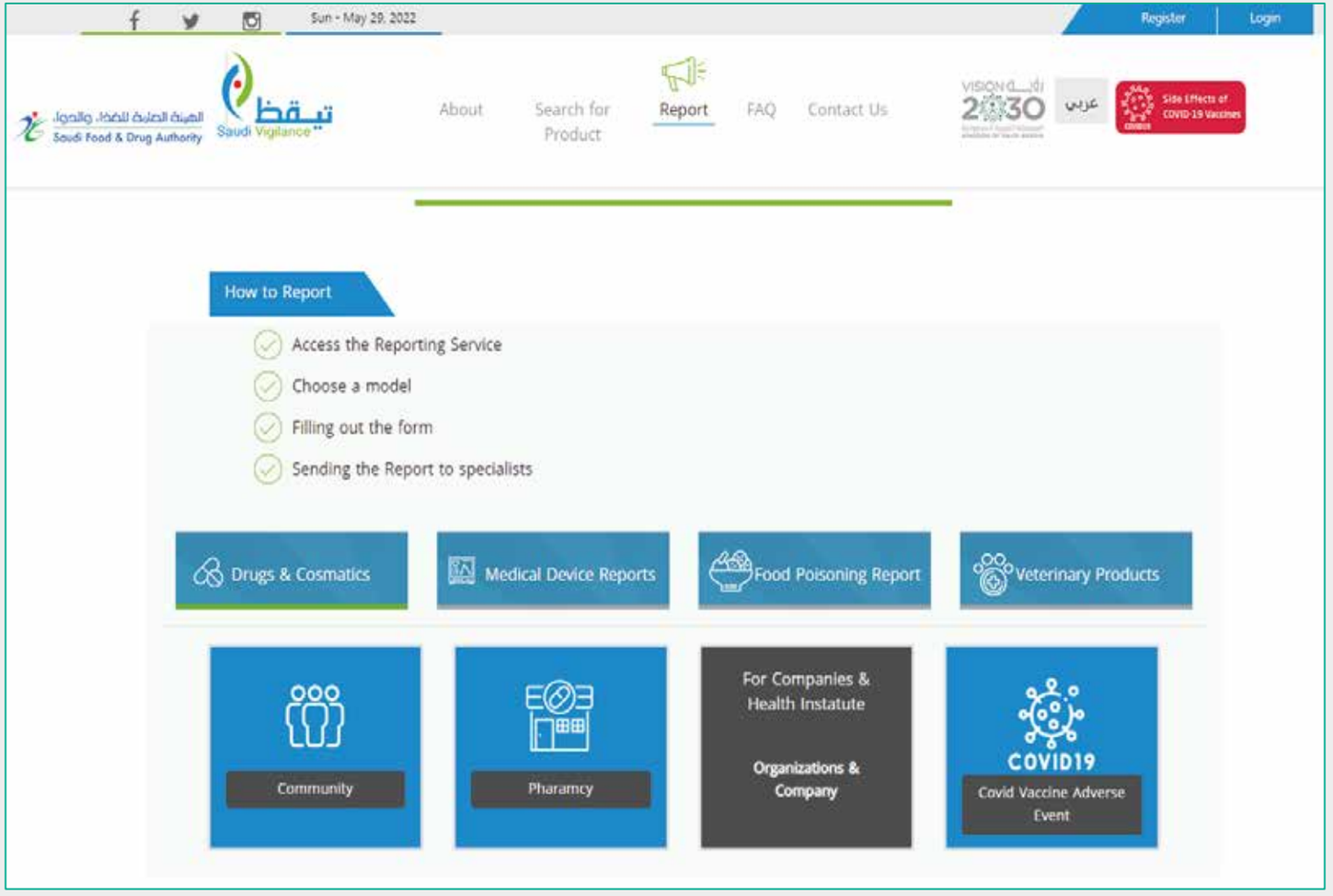
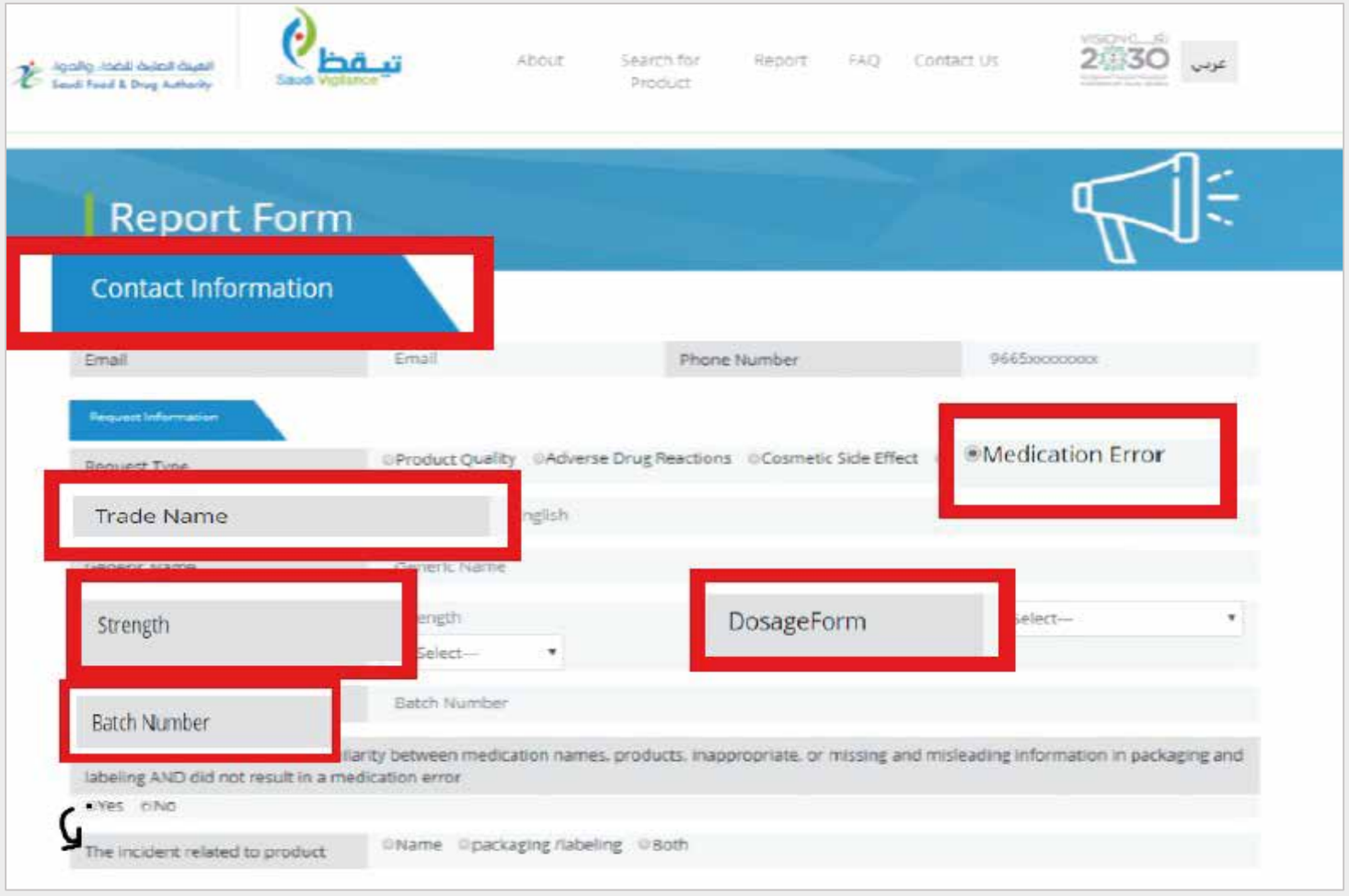
Saudi Vigilance

How to Report



How to Report



Thank You