الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guidance for Medication Error Reporting

Version 1.0

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Drug Sector

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Please visit SFDA's website for the latest update

Saudi Food and Drug Authority

Vision and Mission

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

Document Control

Version	Author	Date	Comments
Draft	Pharmacovigilance Executive Directorate	17 July 2023	
Version 1	Pharmacovigilance Executive Directorate	27 December 2023	Final

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1. Introduction

Medication safety is a critical component of patient safety. Unfortunately, medication errors do occur and are frequently undetected. Some medication errors can result in serious patient morbidity and mortality. Role of SFDA in preventing Medication errors focuses mainly on product-related medication errors which may occur due to: (Look-alike or Sound-alike similarity between two products names; Look-alike products packaging; Design similarity between two or more products from the same company; Unclear labels or poorly designed packaging). Error detection through active management and an effective reporting system (Saudi Vigilance reporting system (تيقظ) exposes medication errors and promotes safe medication practices.

The primary goal of medication error reporting is to collect information and maintain a database on the occurrence of all medication errors related to medication use at different stages of medication-use process, including but not limited to: procurement, storage, prescribing, dispensing, administration, monitoring, and other processes involved in medication management systems.

All reports submitted will maintain consumers, patients, and healthcare professional's confidentiality.

2. Purpose

This guidance is applicable to SFDA-registered medicinal products intended for human use.

It serves as a reference for consumers, patients, and healthcare professionals to inform them of their rights and responsibilities when a medication error happens. This guidance will provide information on how to report medication errors to SFDA and emphasizes the significance of reporting in promoting safe medication use by ensuring the safety of registered products.

3. Definitions

3.1 Medication Error

Medication error is defined according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) as “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.”

3.1.1 Actual error

Medication error occurred and reached the patient. If the error is detected by the patient, it is considered as actual error

3.1.2 Near miss

Medication error that has the potential to cause an adverse event (patient harm) but did not reach the patient because of chance or because it is intercepted in the medication use process.

If the healthcare professionals detected and corrected the error BEFORE it reaches the patient, it is considered as near miss.

3.2 Harm

Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

3.3 Monitoring

To observe or record relevant physiological or psychological signs.

3.4 Intervention

Intervention May include change in therapy or active medical/surgical treatment.

3.5 Intervention Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

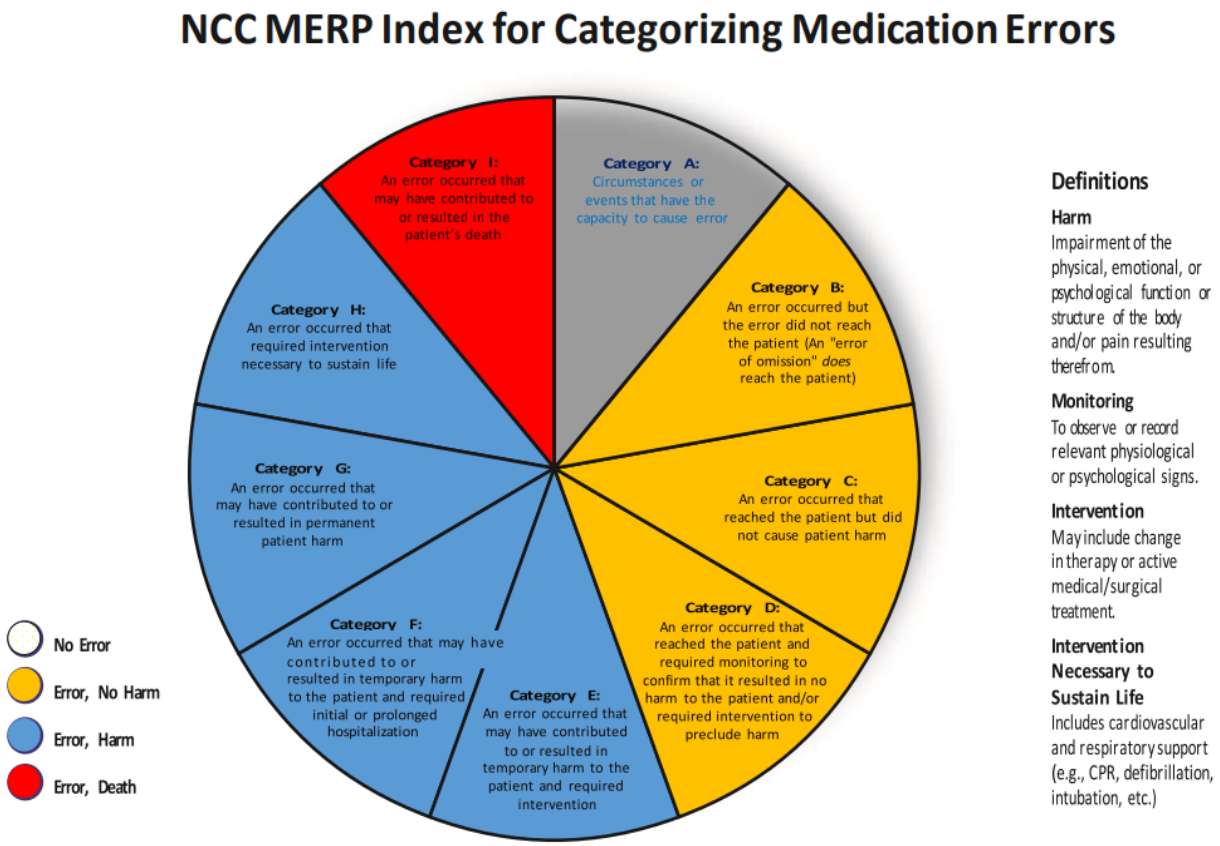
4. Saudi Vigilance reporting system (تيقظ)

According to the World Health Organization, pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug/vaccine related problems.

One of the cornerstones of developing an effective national spontaneous drug safety program is establishing an electronic system for ADE reports collection. The current system was established in 2018 as the third iteration of the system, named in Arabic as 'تيقظ'. The system aims to simplify the reporting process and maintain the data, allowing all public, HCPs, and pharmaceutical companies to report adverse drug events, medication errors, or any defect in product quality. Since the system success is best ensured by active and ongoing participation, SFDA strongly encourages all members of the medical field to take part and report via https://ade.sfda.gov.sa/ or the other different channels described in the patient information leaflet (PIL) attached with all marketed medications and the Summary of Product Characteristics (SPC), which can be accessed via Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/ .

5. NCC MERP Index for Categorizing Medication Errors

NCC MERP revised the Medication Error Index that classifies an error according to the severity of the outcome. The index considers factors such as whether the error reached the patient and, if the patient was harmed, and to what degree. It is hoped that the index will help healthcare professional and institutions to track medication errors in a consistent, systematic manner.



6. Types of Medication Errors

6.1. Prescribing Errors	Incorrect drug selection, dose, dosage form, quantity, route, concentration, rate of administration, or instruction by physician.
6.2. Omission Errors	Administration outside a predefined time interval from its scheduled administration time.
6.3. Wrong Time Errors	Administration outside a predefined time interval from its scheduled administration time.
6.4. Unauthorized Drug Errors	Administration of medication to patient without proper authorization by prescriber
6.5. Improper Dose Errors	When delivered dose grater or less than prescribed dose.
6.6. Wrong Dosage Form	Dosage form administrated different from what prescribe.
6.7. Wrong Drug Preparation.	When the drug is incorrectly formulated or manipulated before dispensing (i.e., too much or too little diluting solution added when a medication is reconstituted).
6.8. Wrong Administration Technique Errors	When the drug is administrated using different routes or at different rates.
6.9. Deteriorated Drug Errors	Despising or administration of a medication that has expired or where its physical or chemical dosage form integrity has been changed
6.10. Monitoring Errors	Inadequate drug therapy review
6.11. Compliance Errors	Failure to adhere to prescribed drug regimen.
6.12. Dispensing Errors	Dispensing in correct medication, dosage, strength, or dosage form

7. Reporting of Medication Error

7.1 Why we report medication error?

- To improve the quality and enhance the safety of patient care.
- To prevent errors that have occurred from reoccurring.
- Provides best practices for prevention of medication error in health care institutions and develop policies and procedures for medication error prevention
- Sources of information for the generation of proactive preventive strategies and best practices aimed toward medication error prevention.

7.2 When we should be report medication error?

Medication Errors that Considered Product-Relate:

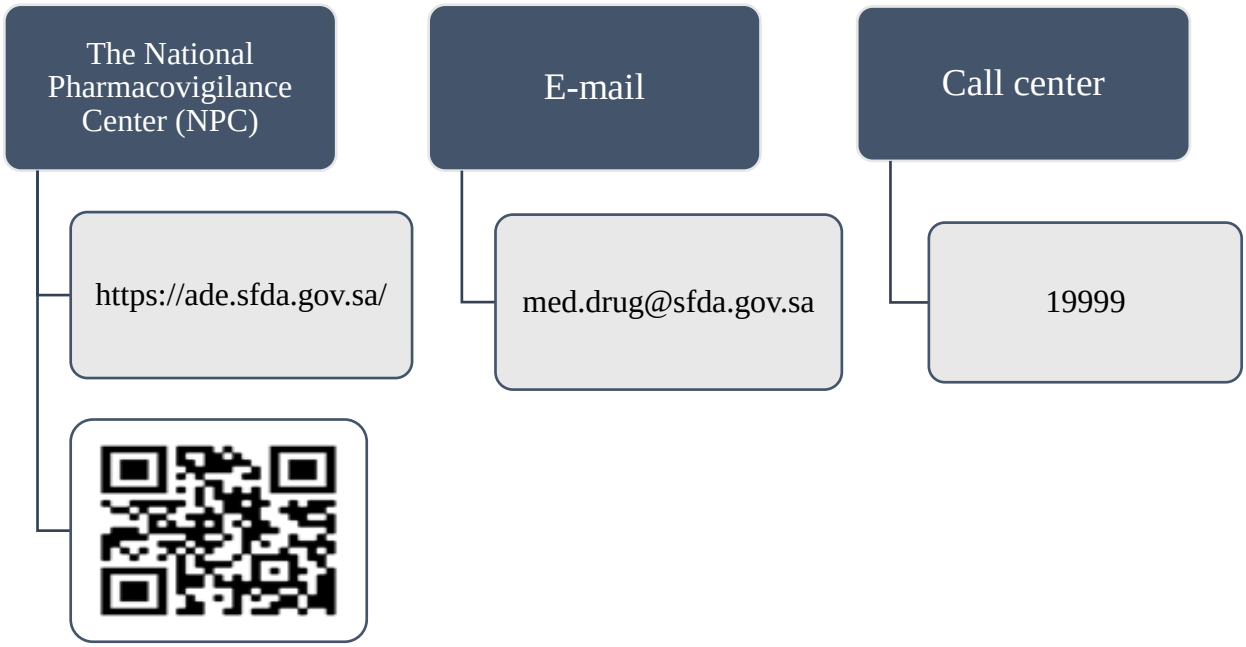
- Look-alike or Sound-alike similarity between different products names
- Look-alike products packaging
- Design similarity between two or more products from the same company
- Unclear labels or poorly designed packaging including circumstances when wrong or misleading information is presented on outer packaging or inner packaging of medicinal products.

7.3 Who can report medication error?

Consumers, patients, and healthcare professionals can utilize the different channels offered by SFDA to submit a medication error report.

7.4 How to report medication error

Participate in maintaining patient safety through reporting using the suitable reporting tools



7.5 What Happens to Submitted Medication Error Reports?

Medication error reports received via any aforementioned channels are logged into SFDA's databases then investigated to determine registration status as well as cause and contributing factors related to medicinal products. Then, assigned Qualified Person Responsible for Pharmacovigilance (QPPV) of involved product manufacturer is contacted with specific recommendations according to submitted medication error event. Other remedial actions include informing healthcare providers and patients through Risk Minimization Measures published on SFDA website; Saudi Drug Updates (SDU) publications; and use of official circulars.

Report submitter might be contacted, in some cases, if any further clarification or verification of submitted information is required.

8. How to register in “Saudi Vigilance System?

Registration in the "Saudi Vigilance System" would save the reporter time and effort while making data entry more accessible due to enrollment.

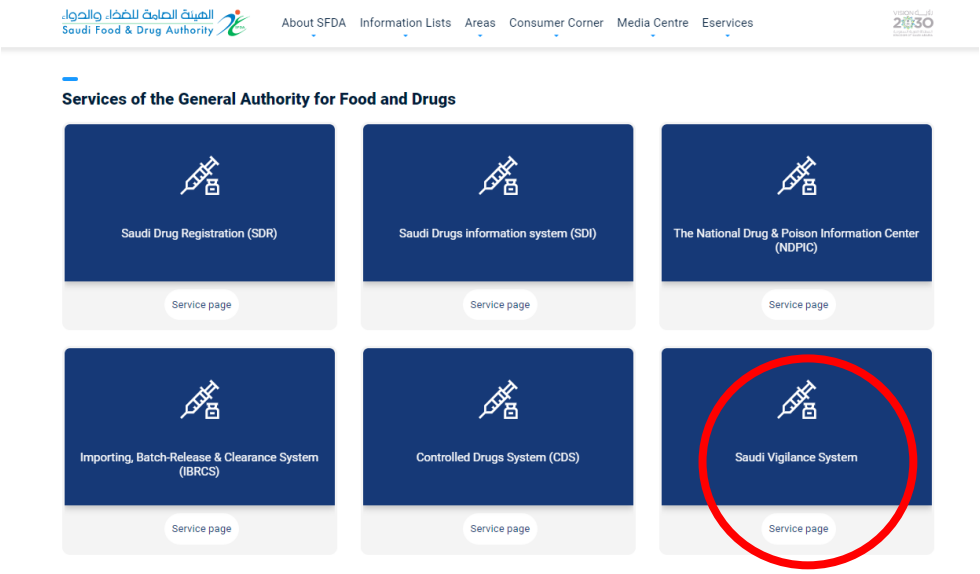
As a result, the system would retrieve the registered information, and the reporter will not have to input it again.

8.1 Where to find the link for the service?

8.1.1. Direct link (https://ade.sfda.gov.sa/)

8.1.2. OR go to |Saudi Food and Drug Authority (sfda.gov.sa) (SFDA’s website)

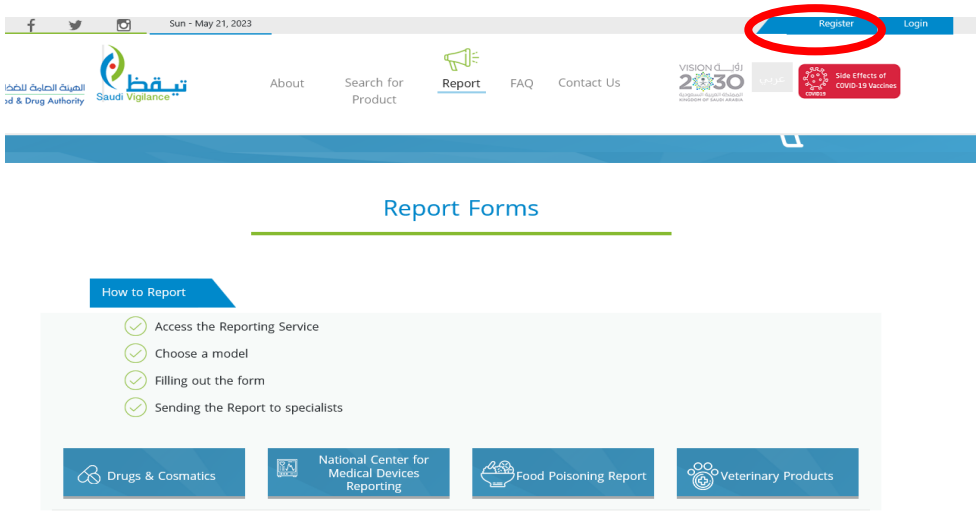
- Click on E-services top menu.
- Click on the drug option.
- Choose the “Saudi Vigilance System”.



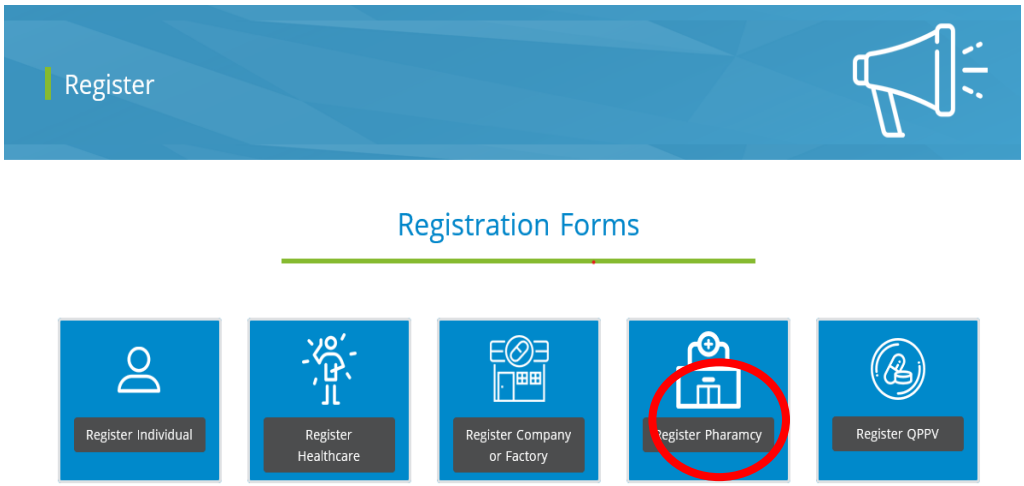
8.1.3. OR google ADE SFDA

8.2 For organization user registration

8.2.1. Click the “Register” button on the top of the home page



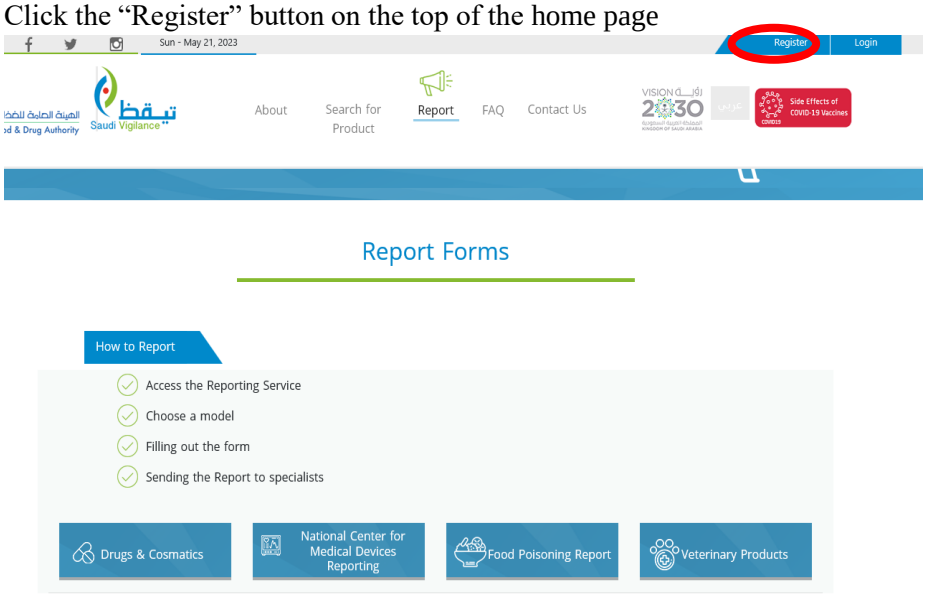
8.2.2. Select “Register Organization”



8.2.1. Complete the register information, attach the nomination letter, then click “Save”

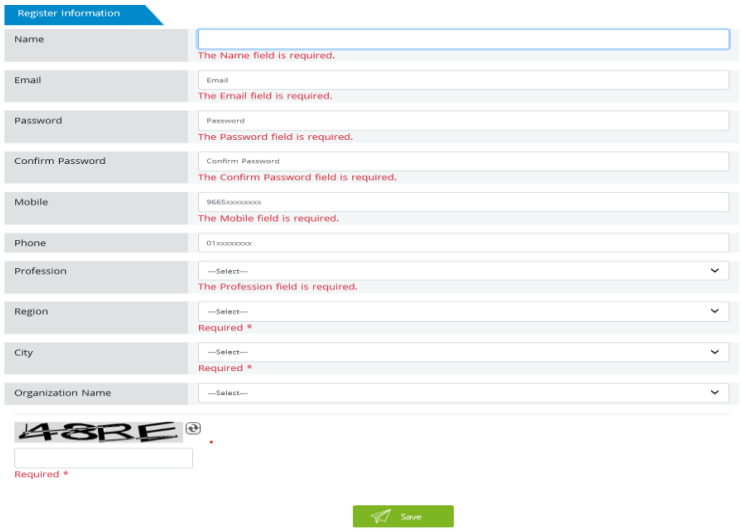
8.3 For individual user registration

8.3.1. Click the “Register” button on the top of the home page



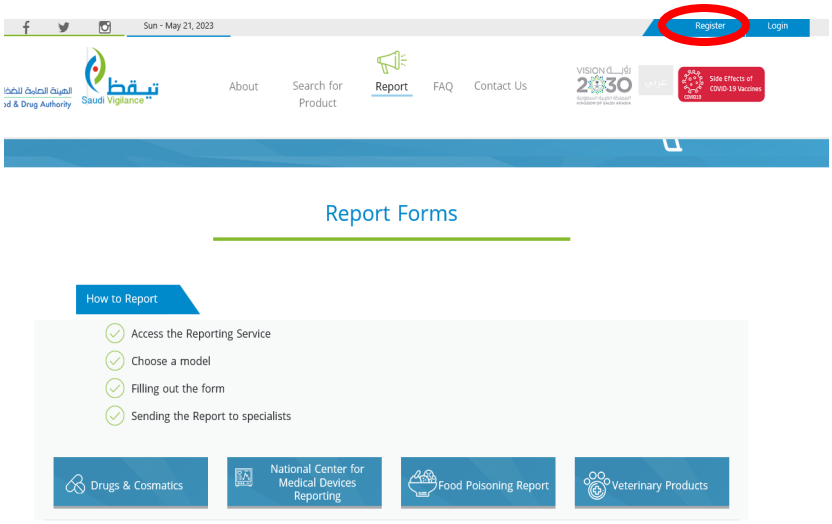
8.3.2. Select “register individual”

8.3.3. Complete the register information then click “Save”

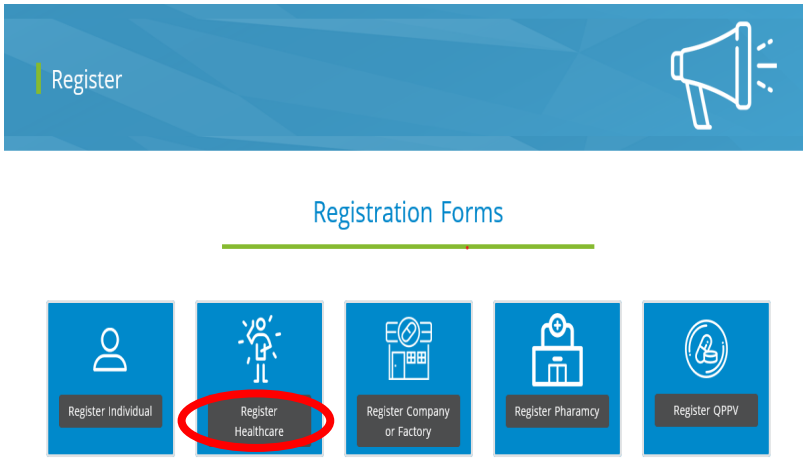


8.4 For healthcare user registration:

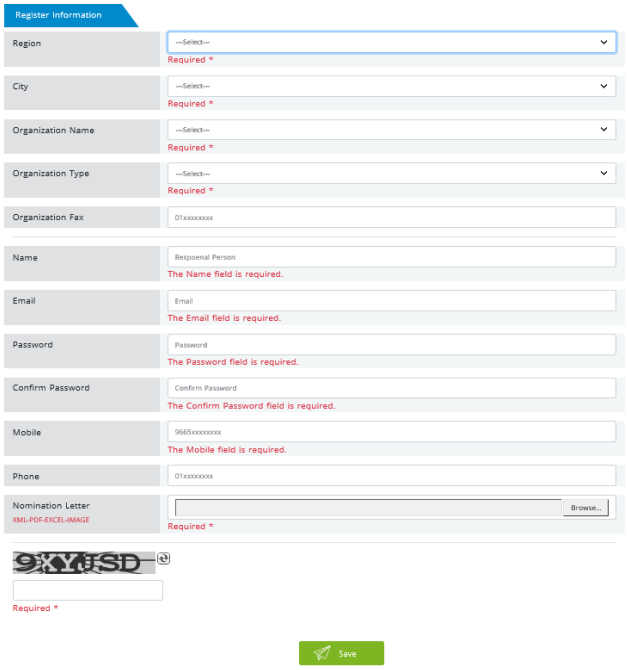
8.4.1. Click the “Register” button on the top of the home page



8.4.2. Select “register healthcare”

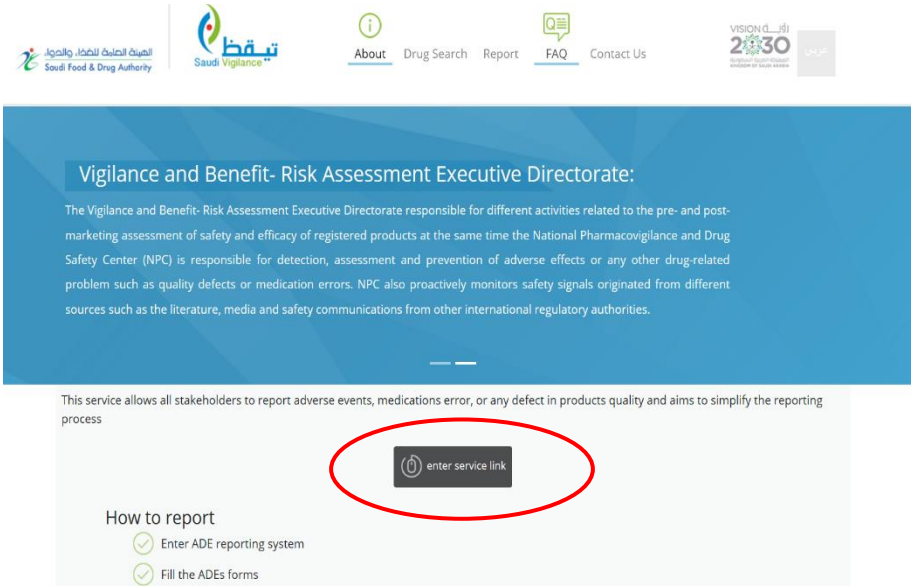


8.4.3.Complete the register information then click “Save”

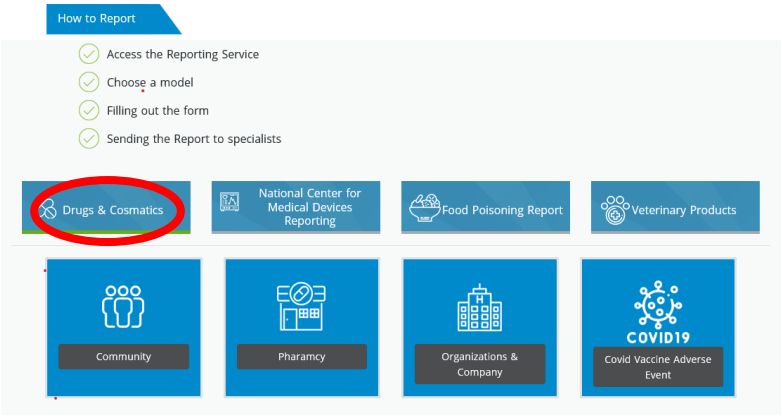


9. How to Report Medication Error on Saudi Vigilance System?

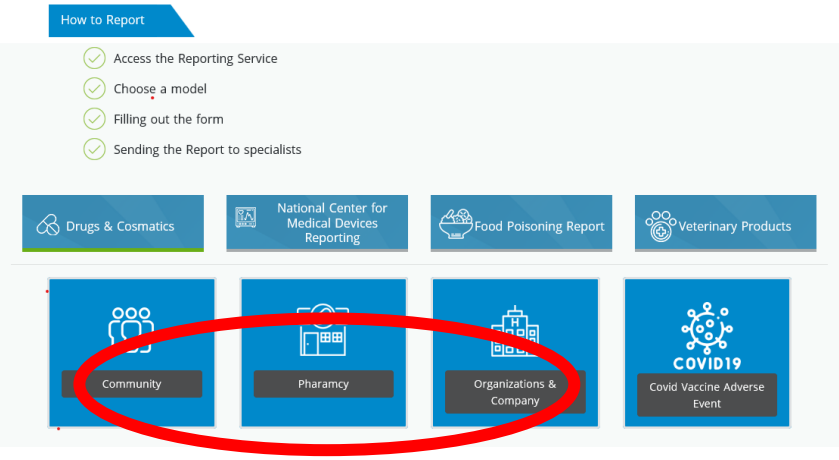
9.1. Enter the service link



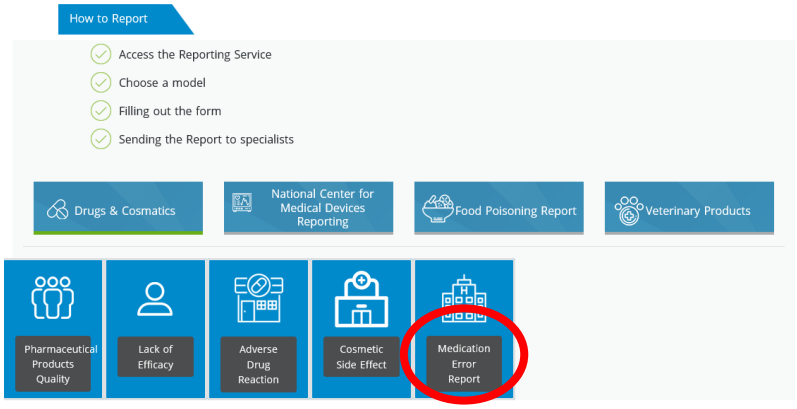
9.2. Click on “Drugs & Cosmetics Report” icon



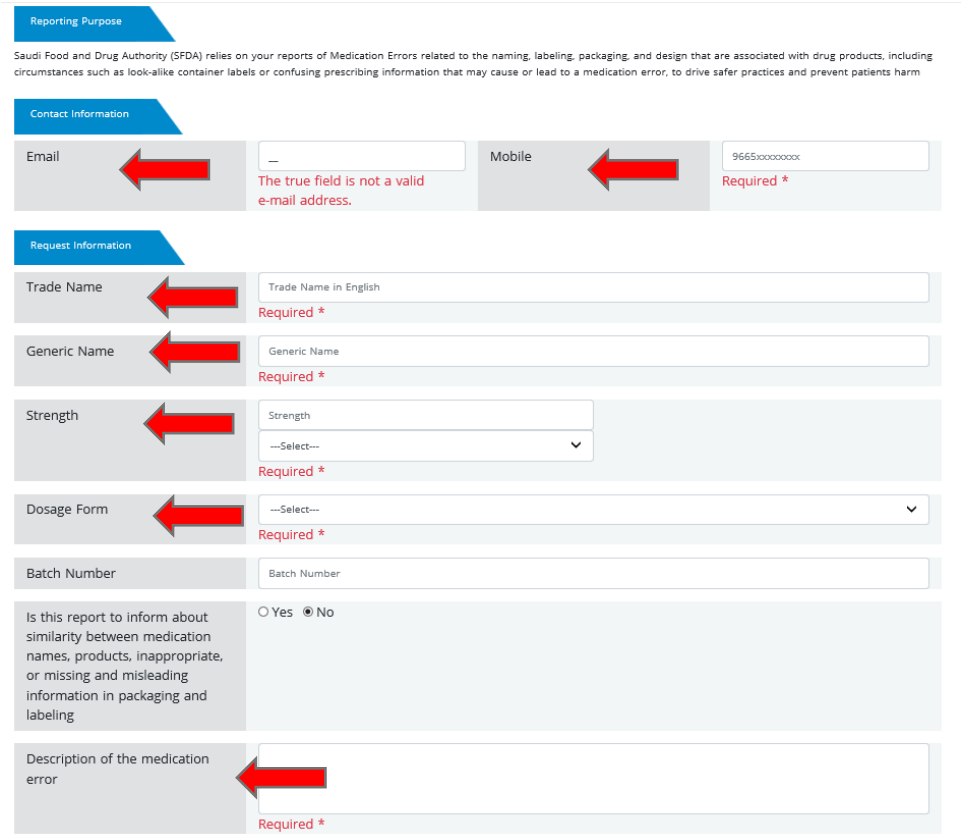
9.3. Select your specialty (community or pharmacy or organization)



9.4. Click on “medication error report”



9.5. Fill out the mandatory fields in the report form:



9.6. Fill out the mandatory fields then Select send: