
Guidance on Registration and Reporting through Saudi National Vigilance System “Tayaquth” for Health Care Providers

National Pharmacovigilance Center

Data Capture Section

The main objective of National Pharmacovigilance Center is to maintain the safety and efficacy of medications and vaccines. And to achieve this objective the NPC encourages all health care providers to contribute in reporting of adverse drug events whether expected or unexpected, serious or non-serious as soon as possible.

Reporting ADE is a cornerstone in monitoring of all marketed medications and vaccines, and ensuring their safety.

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A. Registration

How to register on Saudi National Vigilance System “Tayaquth”?

Registration will save time and efforts and make it easier for data entry, since the system will retrieve the registered information and no need to re-enter them by the reporter.

Where can you find the service link?



1. Direct link: <https://ade.sfda.gov.sa/>
2. Or through Saudi FDA website : <https://www.sfda.gov.sa/en>
3. Go to “**E-services**” from the top panel
4. Click on “**Drug**” from the drop list
5. Choose “**Saudi Vigilance System**”

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Saudi Food & Drug Authority

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VISION 2030
Saudi Vision 2030
ambitious goals

All The Authority Food Drugs Medical Devices Feed Pesticides Laboratories Cosmetics Tobacco Halal Nutrition

Search

All The Authority Food **Drugs** Medical Devices Feed Tobacco Pesticides Laboratories Cosmetics Halal Nutrition

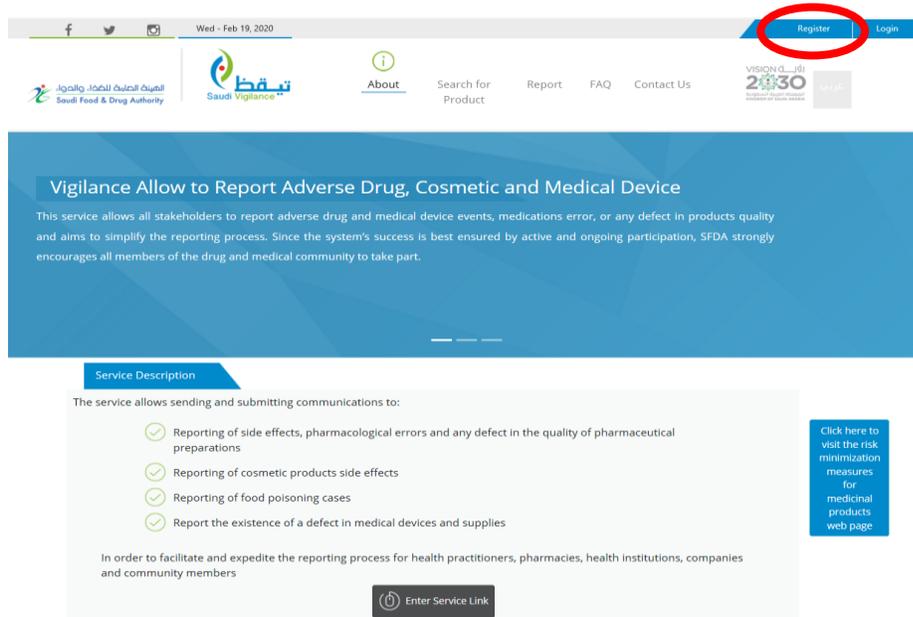
Services of the General Authority for Food and Drugs

 Saudi Drug Registration (SDR) Service page	 Saudi Drugs information system (SDI) Service page	 The National Drug & Poison Information Center (NDPIC) Service page
 Importing Batch Release and Clearance System (IBRCS) Service page	 electronic Narcotic Drugs System Service page	 Saudi Vigilance System Service page

Now, you can start registration process

Registration of Health Organization

a. Go to “**Registration**” from the top panel



Wed - Feb 19, 2020

Register Login

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Vigilance Allow to Report Adverse Drug, Cosmetic and Medical Device

This service allows all stakeholders to report adverse drug and medical device events, medications error, or any defect in products quality and aims to simplify the reporting process. Since the system's success is best ensured by active and ongoing participation, SFDA strongly encourages all members of the drug and medical community to take part.

Service Description

The service allows sending and submitting communications to:

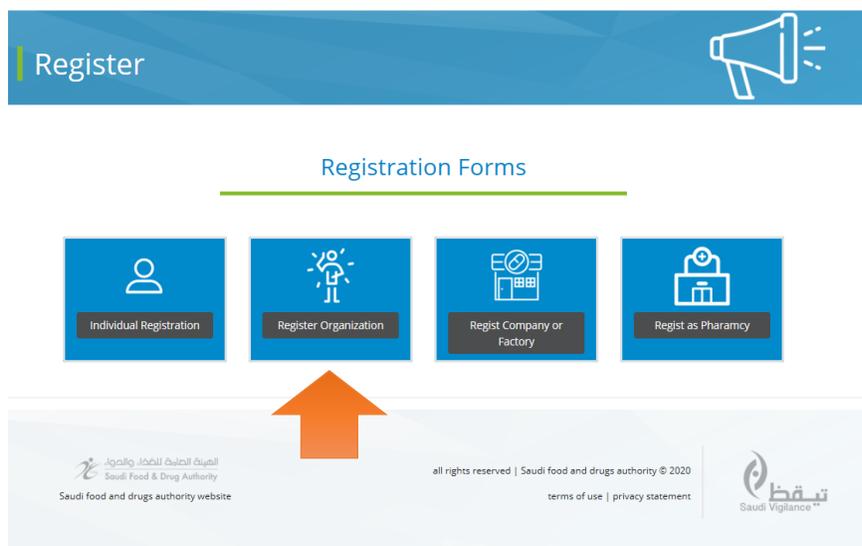
- Reporting of side effects, pharmacological errors and any defect in the quality of pharmaceutical preparations
- Reporting of cosmetic products side effects
- Reporting of food poisoning cases
- Report the existence of a defect in medical devices and supplies

In order to facilitate and expedite the reporting process for health practitioners, pharmacies, health institutions, companies and community members

Enter Service Link

Click here to visit the risk minimization measures for medicinal products web page

b. Click on “**Register Organization**”



Register

Registration Forms

- Individual Registration
- Register Organization
- Register Company or Factory
- Register as Pharmacy

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Saudi Food & Drug Authority
Saudi food and drugs authority website

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Saudi Vigilance

c. Complete registration information, then attach ***Nomination letter** and click “**Save**”

Register Organization

Register Information	
Region	--Select--
Organization Name	--Select--
Organization Fax	01xxxxxxxx
Organization Telephone	01xxxxxxxx
Name	Respoenal Person
Email	mharbi@sfd.gov.sa
Password	*****
Confirm Password	Confirm Password
Phone Number	9665xxxxxxxx
Nomination Letter <small>XML-PDF-EXCEL-IMAGE</small>	<input type="button" value="Choose File"/> No file chosen

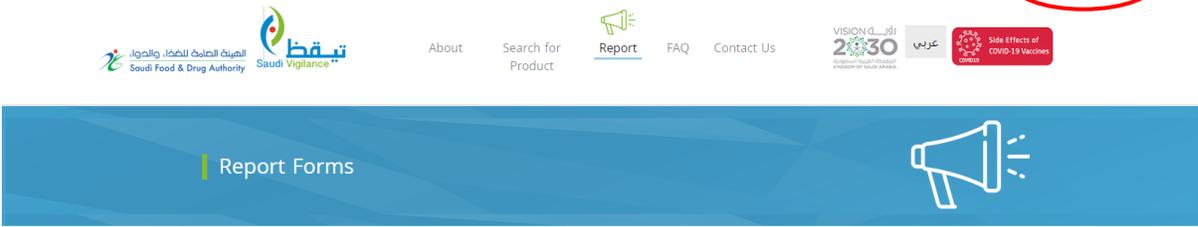
***Note:** the nomination letter will allow the person who is responsible for the organization to delegate a main user responsible for the reporting on the system. It doesn't require a specific format, only the name for the main user, signature of the delegator and stamp of the organization

B. Reporting

1. Log in to your registered account

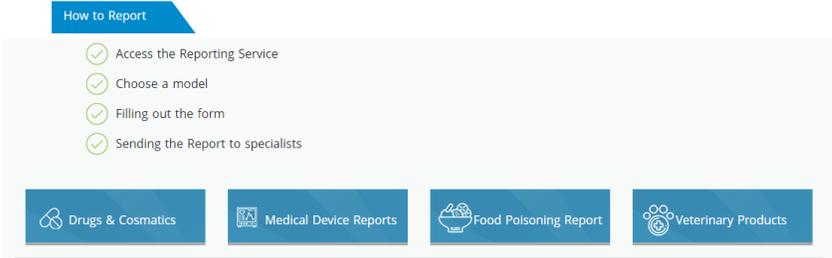


Navigation bar containing social media icons, date (Thu - Aug 25, 2022), and user options (Register, Login). The 'Login' button is circled in red.



Main navigation menu with 'Report Forms' highlighted and a megaphone icon.

Report Forms

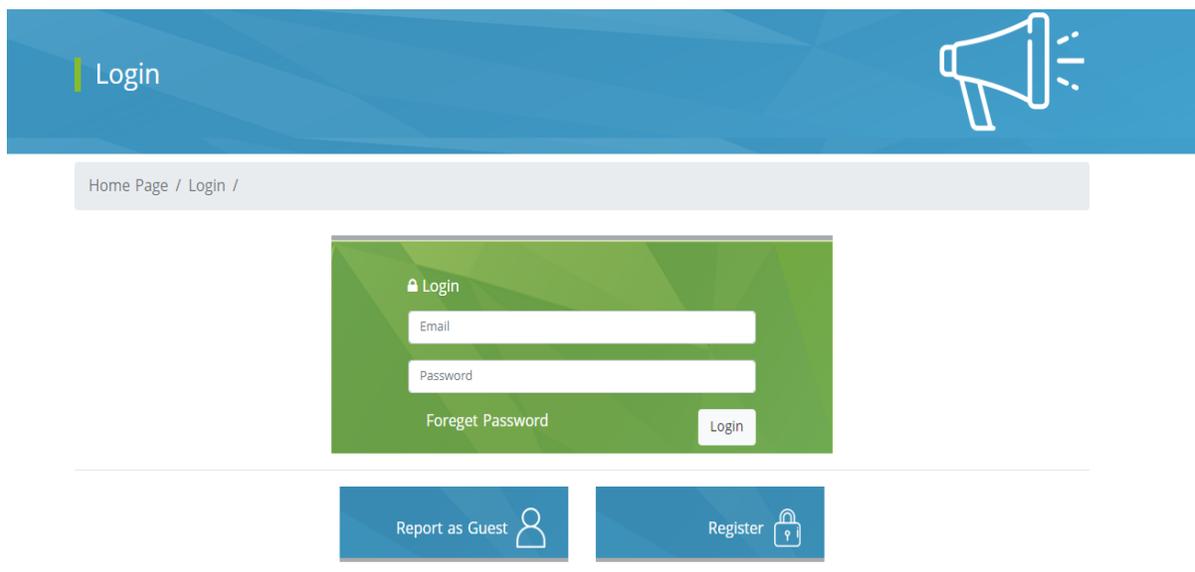


How to Report

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

Category buttons: [Drugs & Cosmetics](#), [Medical Device Reports](#), [Food Poisoning Report](#), [Veterinary Products](#)

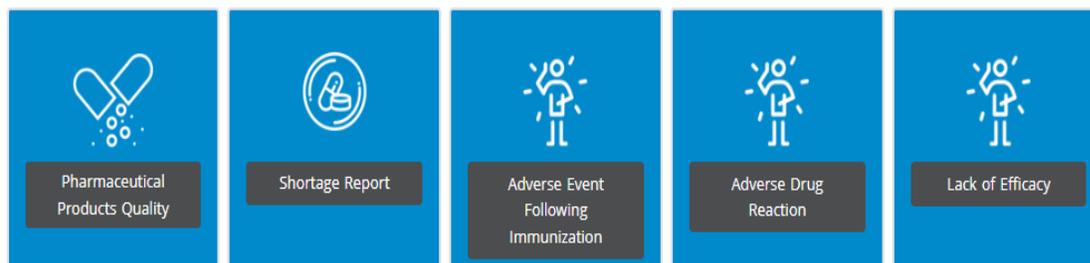
2. Enter your Email and password



The screenshot shows the SFDA website's login interface. At the top, there is a blue navigation bar with the word "Login" on the left and a megaphone icon on the right. Below this is a breadcrumb trail: "Home Page / Login /". The main content area features a green login form with the following elements: a "Login" title, an "Email" input field, a "Password" input field, a "Foreget Password" link, and a "Login" button. At the bottom of the page, there are two blue buttons: "Report as Guest" with a person icon and "Register" with a padlock icon.

3. It will shows the reporting forms according to the type of report

- I. **“Pharmaceutical product quality” form:** reporting on product quality issues
- II. **“Shortage report” form:** reporting unavailable products and their alternatives
- III. **“Adverse events following immunization” form:** reporting adverse events after receiving vaccines
- IV. **“Adverse drug reactions” form:** reporting adverse reactions after drug administration
- V. **“Lack of efficacy” form:** reporting the lack of expected response following product administration



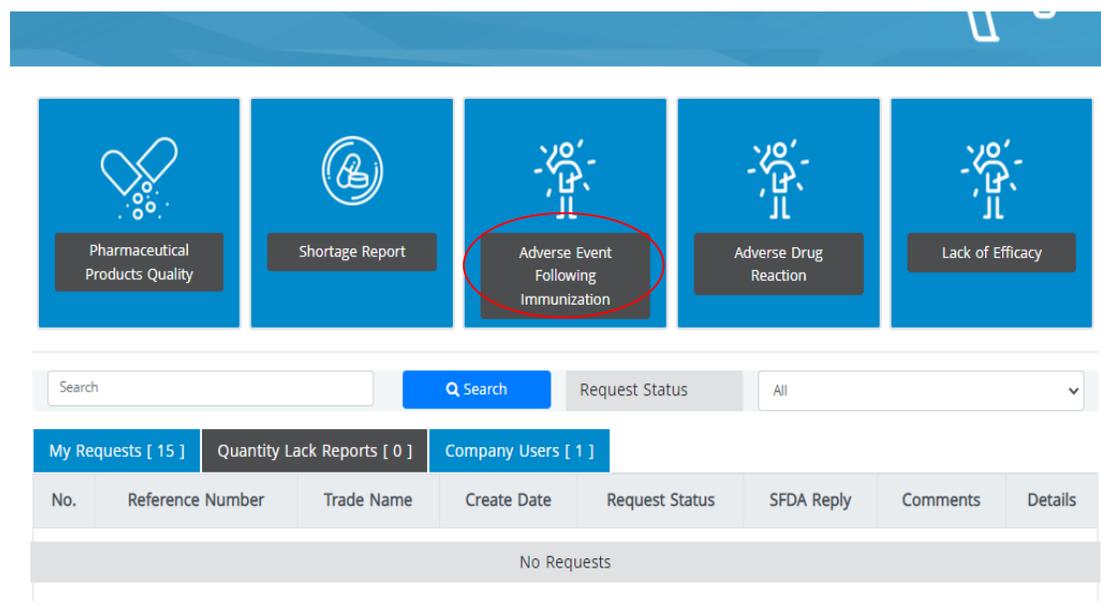
Search Q Search Request Status All

My Requests [15] Quantity Lack Reports [0] Company Users [1]

No.	Reference Number	Trade Name	Create Date	Request Status	SFDA Reply	Comments	Details
No Requests							

Reporting “Adverse events following immunization” through Saudi Vigilance System

1. Click on “Adverse events following immunization” form



2. Fill out the **Patient Information**

Patient Information

Patients Name 
 Required *

Identity Number 
 Required *

Age

Gender  Male Female
 Required *

Phone Number

Nationality

Previous Vaccinations

Do You have Allergy Yes No

3. Enter the **Vaccine Information**

Vaccine Information

Vaccine Name 

Vaccination Date 

Lot Number

4. Complete the **Adverse Event Information** by choosing from the list or write it down in “Other event” field, in case it wasn’t mentioned in the list. After that, specify the seriousness of the event (serious or non-serious) according to the seriousness criteria.

Adverse Event Information

After 30 Day Within 1 Day After 6 Hours Immediately after vaccination When the reaction was occurred

Fever <input type="checkbox"/> Local Reaction <input type="checkbox"/> Dizziness <input type="checkbox"/> Fatigue and Exhaustion <input type="checkbox"/> Swollen Lips and Face <input type="checkbox"/> Sleep Disturbance <input type="checkbox"/> Itching and Sensitivity <input type="checkbox"/> Vomiting <input type="checkbox"/> Diarrhea <input type="checkbox"/> Headache <input type="checkbox"/>	Adverse Event (s)
---	-------------------

Fatigue	<input type="checkbox"/>	
Pain	<input type="checkbox"/>	
Hypersensitivity	<input type="checkbox"/>	
Erythema	<input type="checkbox"/>	
Nausea	<input type="checkbox"/>	
Lymphadenopathy	<input type="checkbox"/>	
Arthralgia	<input type="checkbox"/>	
		Other Event 
No	<input type="radio"/>	Yes <input checked="" type="radio"/>
		Seriousness
Death	<input type="checkbox"/>	Seriousness
Life threatening	<input type="checkbox"/>	
Persistent or significant disability	<input type="checkbox"/>	
Hospitalization prolongation of existing hospitalization	<input type="checkbox"/>	
Congenital anomaly	<input type="checkbox"/>	
Required intervention to prevent permanent damage	<input type="checkbox"/>	

5. Case Investigation: choose “yes” incase investigation needed in order to build investigation reports and follow-up with the case, and this depends on the seriousness of the event

No	<input type="radio"/>	Yes	<input type="radio"/>	Investigation Needed
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Note: choosing “yes” will forward the case automatically to the colleagues in the National Immunization Program

6. Make sure you have completed all the required fields, enter the code then click “send”

Required *





C. Investigation

Upon completion of Adverse events following immunization form, and choosing the option “Investigation needed”, the investigation report will appear to be filled out by the reporter

How to build an Investigational Report?

- 1) Enter patient information with full name

الاستقصاء الوبائي لحالات الآثار الجانبية الشديدة و التحسس عقب التحصين

معلومات تعريفية

Full Name 	<input type="text" value="Full Name"/>	
Age	<input type="text" value="Age"/>	<input type="text" value="---Select---"/>
Sex	<input type="radio"/> Male <input type="radio"/> Female	
Birth Day	<input type="text" value="Birth Day"/>	
Phone Number	<input type="text" value="Phone Number"/>	
Nationality	<input type="text" value="---Select---"/>	
Address	<input type="text" value=""/>	

- 2) Enter vaccine information, and patient’s current health status (don’t forget to specify the dates)

اللقاح

أعطي في	<input type="radio"/> أخرى <input type="radio"/> حملة تطعيمية <input type="radio"/> التطعيم الروتيني <input type="text" value="Please Specify"/>
تاريخ/وقت التطعيم	<input type="text" value="تاريخ/وقت التطعيم"/>
أسماء اللقاحات والأمصال وكمية الجرعة التي أعطيت للمريض في هذا اليوم	
اسم اللقاح	<input type="text"/>
الجرعة	<input type="text"/> --Select--
طريقة الإعطاء	<input type="text"/>
الشركة المصنعة	<input type="text"/>
Batch Number	<input type="text"/>
Expiry Date	<input type="text"/>
	<input style="background-color: #007bff; color: white; border: none; padding: 2px 5px; font-weight: bold; font-size: 1.2em; border-radius: 3px;" type="button" value="+"/>
تاريخ انتهاء صلاحية اللقاح	<input type="text" value="1/1/0001 12:00:00 AM"/>
مصدر المعلومات لما ورد في البندين	<input type="text" value="مصدر المعلومات لما ورد في البندين"/>
من أين ومتى أرسل اللقاح لوحدة التحصين	<input type="text" value="من أين ومتى أرسل اللقاح لوحدة التحصين"/>
نتائج الفحص المخبري للقاح (في حالة الاشتباه في تغير اللقاح)	<input type="text" value="نتائج الفحص المخبري للقاح (في حالة الاشتباه في تغير اللقاح)"/>
اسم من قام بإعطاء اللقاح	<input type="text" value="اسم من قام بإعطاء اللقاح"/>
اسم من قام بإجراء الكشف قبل التطعيم	<input type="text" value="اسم من قام بإجراء الكشف قبل التطعيم"/>
الوضع الصحي الحالي للمريض	<input type="radio"/> Recovered <input type="radio"/> Recovering <input type="radio"/> No Improvement <input type="radio"/> Fatal
Death Date	<input type="text" value="1/1/0001 12:00:00 AM"/>
ملاحظات عن أسلوب حفظ وتداول اللقاحات الأخرى الموجودة بالموقع	
درجة حرارة حفظ اللقاح	<input type="text" value="درجة حرارة حفظ اللقاح"/>
المذيبات	<input type="text" value="المذيبات"/>
الحقن	<input type="text" value="الحقن"/>
نوع صندوق حمل اللقاحات و طريقة حفظ اللقاح	<input type="text" value="نوع صندوق حمل اللقاحات و طريقة حفظ اللقاح"/>

3) Specify the type of vaccine and route of administration

الحقن المستخدمة	
هل تم استخدام الحقن ذاتية التعطيل	<input type="radio"/> Yes <input checked="" type="radio"/> No
هل تم استخدام أكثر من حقنة في عملية إعداد اللقاحات التي تحتوي على مذبذبات	<input type="radio"/> Yes <input checked="" type="radio"/> No
هل يتم استخدام نفس المذبذبات الموصى بها لنفس اللقاح	<input type="radio"/> Yes <input checked="" type="radio"/> No

4) Describe the details of the event (onset dates, Laboratory results, treatment..)

Patient	
الأعراض مع توضيح تاريخ ووقت بداية كل منها	الأعراض مع توضيح تاريخ ووقت بداية كل منها
الفحوصات المخبرية (ذات العلاقة)	الفحوصات المخبرية (ذات العلاقة)
هل حدثت آثار جانبية عقب جرعات لقاحات سابقة أو آثار جانبية لأي عقار أو خلافه	هل حدثت آثار جانبية عقب جرعات لقاحات سابقة أو آثار جانبية لأي عقار أو خلافه
العلاج المعطى	العلاج المعطى

5) Choose the event's outcome and category, then enter the code and send

نتيجة الأثر الجانبي

نتيجة الأثر الجانبي

- الآثار الجانبية شكلت خطورة على حياة المريض
- استدعيت حجز المريض بالمركز الصحي
- استدعيت حجز المريض بالمستشفى
- أدت إلى إعاقة دائمة

تصنيف الأثر الجانبي للفاح

- خراج بكتيري
- خراج عقم
- التهاب موضعي شديد
- تفاعل موضعي
- آثار على الجهاز العصبي
- شلل فجائي
- شلل أطفال له علاقة بالفاح
- متلازمة جليان باري
- اعتلال الدماغ
- التهاب الدماغ
- التهاب أغشية المخ
- نوبات تشنجية مع ارتفاع درجة الحرارة
- نوبات تشنجية دون ارتفاع درجة الحرارة
- فقد السمع

اسم الطبيب

Name of Physician/Doctor Who receive the case

U.S.S.U. 

