
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**”



الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

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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



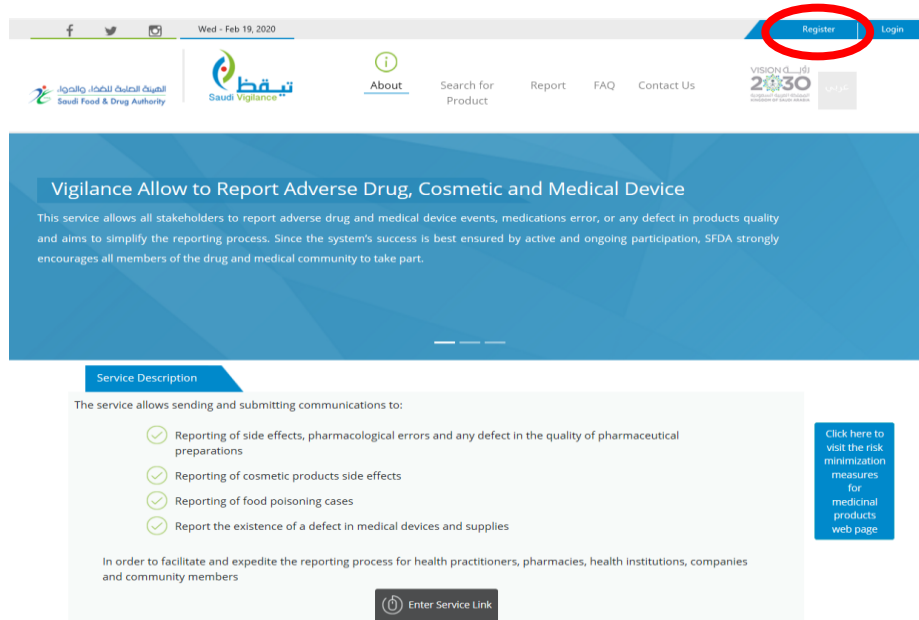
Saudi Vigilance System

Service page

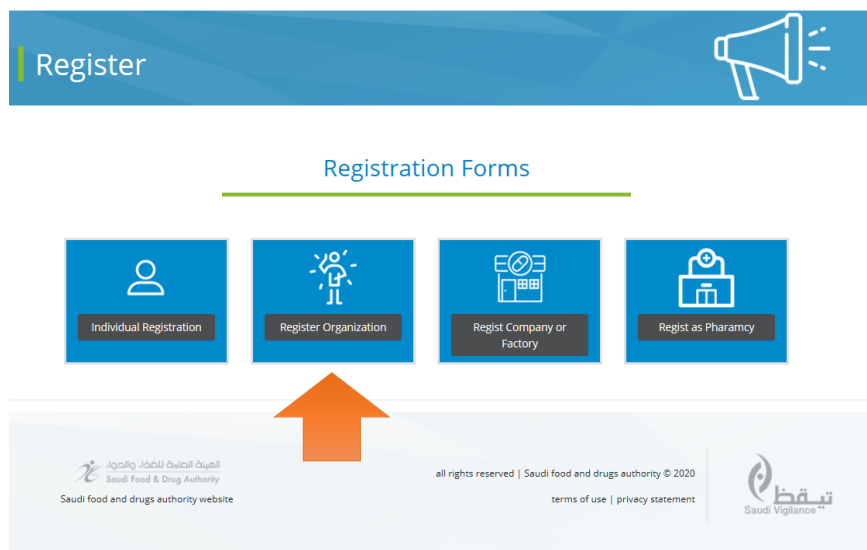
Now, you can start registration process

Registration of Health Organization

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



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



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	mhharbi@sfd.gov.sa
Password	*****
Confirm Password	Confirm Password
Phone Number	9665xxxxxxxx
Nomination Letter XML-PDF-EXCEL-IMAGE	<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




Thu - Aug 25, 2022

[Register](#)
[Login](#)



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Report Forms


Report Forms


How to Report

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

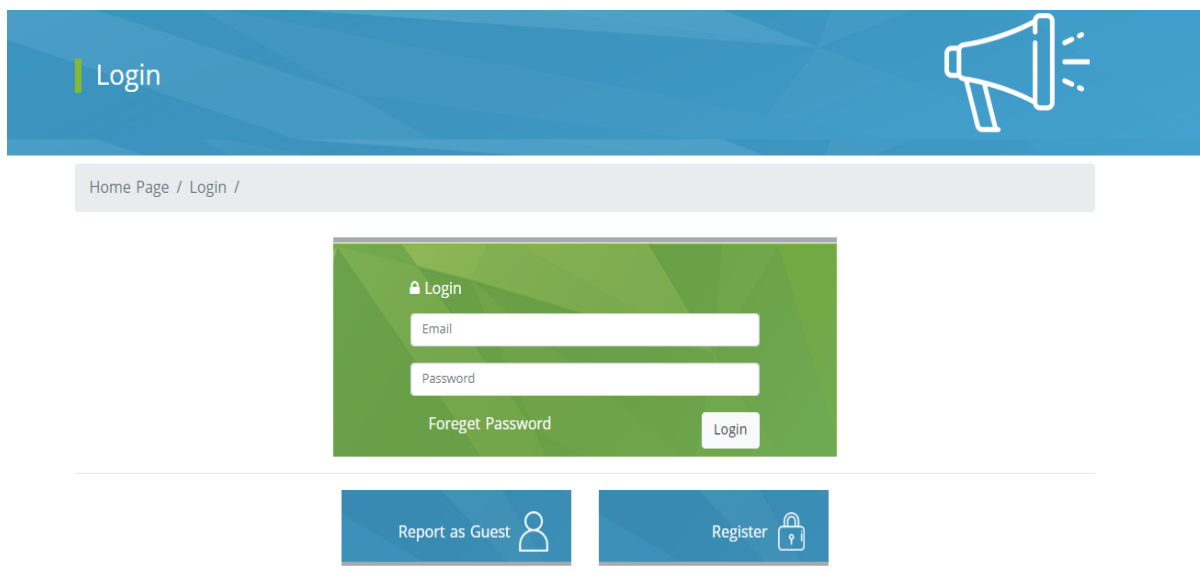

Drugs & Cosmetics


Medical Device Reports


Food Poisoning Report


Veterinary Products

2. Enter your Email and password




The screenshot shows the SFDA Login page. At the top, there is a blue header with the word "Login" and a megaphone icon. Below the header is a breadcrumb trail: "Home Page / Login /". The main content area features a green login box with the following elements:

- A lock icon and the text "Login".
- An "Email" input field.
- A "Password" input field.
- A "Foreget Password" link.
- A "Login" button.


Below the login box, there are two 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




Pharmaceutical
Products Quality




Shortage Report



Adverse Event
Following
Immunization



Adverse Drug
Reaction



Lack of Efficacy


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




Pharmaceutical
Products Quality




Shortage Report



Adverse Event
Following
Immunization



Adverse Drug
Reaction






Lack of Efficacy

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							

2. Fill out the **Patient Information**


Patient Information	
Patients Name 	<input type="text" value="Patient Name"/> Required *
Identity Number 	<input type="text" value="Identity Number"/> Required *
Age	<input type="text" value="Age"/> <input type="button" value="--Select--"/>
Gender 	<input type="radio"/> Male <input type="radio"/> Female Required *
Phone Number	<input type="text" value="Phone Number"/>
Nationality	<input type="button" value="--Select--"/>
Previous Vaccinations	<input type="text" value="Previous Vaccinations"/>
Do You have Allergy	<input type="radio"/> Yes <input type="radio"/> No

3. Enter the Vaccine Information

Vaccine Information	
Vaccine Name 	<input type="text" value="Vaccine Name"/>
Vaccination Date 	<input type="text" value="Vaccination Date"/>
Lot Number	<input type="text" value="LotNumber"/>

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 <input type="radio"/> Within 1 Day <input type="radio"/> After 6 Hours <input type="radio"/> Immediately after vaccination <input type="radio"/>	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"/>	
<input type="text"/>		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
--	----------------------

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

- 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 Please Specify	
تاريخ/وقت التطعيم	تاريخ/وقت التطعيم	
أسماء اللقاحات والأمصال وكمية الجرعة التي أعطيت للمريض في هذا اليوم		
اسم اللقاح		
الجرعة		--Select--
طريقة الإعطاء		
الشركة المصنعة		
Batch Number		
Expiry Date		
	+	
تاريخ انتهاء صلاحية اللقاح	1/1/0001 12:00:00 AM	
مصدر المعلومات لما ورد في البندين	مصدر المعلومات لما ورد في البندين	
من أين ومتى أرسل اللقاح لوحدة التحصين	من أين ومتى أرسل اللقاح لوحدة التحصين	
نتائج الفحص المخبري للقاح (في حالة الاشتباه في تغير اللقاح)	نتائج الفحص المخبري للقاح (في حالة الاشتباه في تغير اللقاح)	
اسم من قام بإعطاء اللقاح	اسم من قام بإعطاء اللقاح	
اسم من قام بإجراء الكشف قبل التطعيم	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	1/1/0001 12:00:00 AM	
ملاحظات عن أسلوب حفظ وتداول اللقاحات الأخرى الموجودة بالموقع		
درجة حرارة حفظ اللقاح	درجة حرارة حفظ اللقاح	
المذيبات	المذيبات	
الحقن	الحقن	
نوع صندوق حمل اللقاحات و طريقة حفظ اللقاح	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 للقاح

- ☐ خراج بكتيري
- ☐ خراج عقم
- ☐ التهاب موضعي شديد
- ☐ تفاعل موضعي
- ☐ آثار على الجهاز العصبي
- ☐ شلل فجائي
- ☐ شلل أطفال له علاقة باللقاح
- ☐ 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

USSU

