



الدليل الإرشادي لتحديث بيانات المستحضرات في سدر

Guidance to update the database of products in SDR

#### Update Goals

- 1- Set up a database of all registered pharmaceutical products.
- 2- Ease to renew the registration certificate through SDR system.

#### أهداف التحديث

- ١ - إنشاء قاعدة بيانات بجميع المستحضرات المسجلة سابقا
- ٢ - سهولة تجديد الشهادة عن طريق النظام

## Guidance to update the database of products in SDR

الدليل الإرشادي لتحديث بيانات المستحضرات في سدر

Log in to the web site system:  
<http://sdr.sfda.gov.sa>

Then Login with your username and password

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Saudi Drug Registration

Kingdom of Saudi Arabia  
Saudi Food & Drug Authority

The Saudi Drug Registration (SDR) System is an electronic system which aims to facilitate the registration of medicinal, herbal and health products for both Human & Veterinary use.

The SDR will allow the registered establishments in Drug Establishment National Registry (DENR) to use the system in new application, renewal and variation of their products.

**Security and Confidentiality of Data**  
All data submitted online will be protected and encrypted via the SDR security infrastructure.

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قم بالدخول على موقع النظام:

<http://sdr.sfda.gov.sa>

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ثم الدخول باسم المستخدم  
وكلمة المرور

اضغط على أيقونة تحديث المستحضرات 2

Products Update

Go to "Products Update". 2

Products Update

Saudi Drug Registration

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Create New Applications

Submitted Applications

Products Update

Registered Products

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Contact Us

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الإصدار رقم ١٠٠ تاريخ ٢٠/٥/٢٠١٤ هـ

## Guidance to update the database of products in SDR

الدليل الإرشادي لتحديث بيانات المستحضرات في سدر

Choose one of your products to start updating the data, by clicking on the button "Update" 3

[Update](#)

Registration No.	Type of Application	Trade Name	Strength	Strength Unit	Volume	Unit of Volume	Dosage Form	Update Application	Status
23-###-09	Human	Trade A	1.36	%	250	ml	Concentrate for peritoneal dialysis solution	<a href="#">View</a>	Pending
37-###-10	Human	Trade B	2.27	%	500	ml	Concentrate for peritoneal dialysis solution	<a href="#">View</a>	Pending
44-###-05	Human	Trade C	500	mg			Tablet	<a href="#">View</a>	Pending
22-###-03	Human	Trade D	500, 2, 30	mg			Tablet	<a href="#">View</a>	Pending
78-###-04	Human	Trade E			0.5	ml	solution for injection	<a href="#">View</a>	Pending
41-###-07	Human	Trade F			5	ml	Ear drops*	<a href="#">Update</a>	New
48-###-08	Human	Trade G	15	mg			Tablet	<a href="#">View</a>	Pending
64-###-01	Human	Trade H	7.5	mg			Tablet	<a href="#">View</a>	Pending
88-###-08	Human	Trade I	24	mg/ml	100	ml	Oral suspension	<a href="#">Update</a>	New
97-###-09	Human	Trade J	0.4	mg/ml	120	ml	Syrup	<a href="#">View</a>	Pending

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The above table is only an example

الجدول أعلاه مثال فقط

قم باختيار أحد المستحضرات  
للبدء بإكمال المعلومات  
الخاصة به عن طريق الضغط  
على أيقونة تحديث 3

[Update](#)

## Guidance to update the database of products in SDR

In the application form ,  
Start filling out data in  
each section.

4

Note:

This application is  
identical to the new  
application form

**Type of Application**

This application concerns :

- New Drug
- Generic (Multisource)
- Biological including Biosimilars, blood products and vaccines
- Radio pharmaceutical

Please provide the following information for the product :

New Drug Application :

- Known active substance
- New Chemical Entity (NCE)

Product Information in COO:

Trade name :

Product strength :

Product Strength in Units :

Dosage form :

Marketing Authorization holder :

Name :

Address Line1 :

Address Line2 :

Address Line3 :

Postal Zip Code :

City :

Country :

Date of authorization :

Certifying Authority :

Certifying Country :

**Save** **Next**

**Contact Information**

Please fill all contact sessions below before proceeding to save.

Proposed marketing authorization holder person legally responsible for placing the product on the market in KSA:

Company Name :

First Name :

Middle Name :

Last Name :

Address Line1 :

Address Line2 :

Address Line3 :

Postal Zip Code :

City :

Country :

Phone :

Fax :

E-mail :

Person/Company authorized for communication in KSA on behalf of the applicant:

Person/Company authorized for communication between the marketing authorization holder and the SFDA after authorization:

Person qualified for Pharmacovigilance in KSA:

**Previous** **Save** **Next**

**Type of Application**

**Name(s) and ATC code**

Proposed trade name :

List the active substance(s) :

Type of the active substance(s) :  Single active substance  Multiple active substances

Name of active substance(s) :

Quantity :

Unit :

Reference/Monograph standard :

**Add Active Substance**

Substance Name	Quantity	Unit	Reference

List the excipient(s) :

Name of excipient(s) :

Quantity :

Unit :

Reference/Monograph standard :

**Add Excipient**

Excipient Name	Quantity	Unit	Reference

Pharmacotherapeutic group: (Please use current ATC code) :

No ATC code has been assigned :  **ATC Lookup**

ATC Code	ATC Group

**Previous** **Save** **Next**

**Type of Application**

**Product Information**

Manufacturer name :

Manufacturing site :

City :

Country :

Dosage form :

Strength :

Package size :

Volume(if liquid) :

Route of administration :

Auricular (otic)  Buccal  Cutaneous  Inhalation  Endocervical  Endovenous  Enteric

Administration device (if applicable) :

Primary packaging :

Secondary packaging :

Proposed shelf life :

Proposed shelf life after first opening container (if applicable) :

Proposed shelf life after reconstitution or dilution (if applicable) :

Proposed storage conditions :

Proposed storage conditions after first opening (if applicable) :

Reference Pharmacopoeia :

**Previous** **Save** **Next**

## الدليل الإرشادي لتحديث بيانات المستحضرات في سدر

قم بتحديث معلومات المستحضر  
في جميع أقسام نموذج التسجيل

4

ملاحظة:  
النموذج مماثل تماماً للنموذج  
الجديد

Type of Application

Application Details

- Names and ATC Code
- Product Information
- Contact Information
- Manufacturers
- CPP
- Animal Source Material

Certificate of a Pharmaceutical Product (CPP)

Do you have a CPP? :  Yes  No

Previous Save Next

## Guidance to update the database of products in SDR

الدليل الإرشادي لتحديث بيانات المستحضرات في سدر

After finishing, click "Submit" button.

5

Submit

Also you can print the application form by clicking on "Print Application" Button

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Print Application

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Type of Application

Application Details

- ❖ Names and ATC Code
- ❖ Product Information
- ❖ Contact Information
- ❖ Manufacturers
- ❖ CPP
- ❖ Animal Source Material

Scientific Advice

PDP

Application Status

Application Status

□ Authorized

□ Pending

□ Refused

□ Withdrawn (by applicant after authorization)

□ Suspended/revoked (by competent authority)

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Print Application

بعد الانتهاء من تحديث البيانات، اضغط على أيقونة إرسال.

5

Submit

6

Print Application

## Guidance to update the database of products in SDR

## الدليل الإرشادي لتحديث بيانات المستحضرات في سدر

The status of the product will change from "New" to "Pending", meaning that the product is under study by SFDA staff.

Pending

7

Registration No.	Type of Application	Trade Name	Strength	Strength Unit	Volume	Unit of Volume	Dosage Form	Update Application	Status
23-###-09	Human	Trade A	1.36	%	250	ml	Concentrate for peritoneal dialysis solution	<a href="#">View</a>	Pending
37-###-10	Human	Trade B	2.27	%	500	ml	Concentrate for peritoneal dialysis solution	<a href="#">View</a>	Pending
44-###-05	Human	Trade C	500	mg			Tablet	<a href="#">View</a>	Pending
22-###-03	Human	Trade D	500, 2, 30	mg			Tablet	<a href="#">View</a>	Pending
78-###-04	Human	Trade E			0.5	ml	solution for injection	<a href="#">View</a>	Pending
41-###-07	Human	Trade F			5	ml	Ear drops*	<a href="#">Update</a>	New
48-###-08	Human	Trade G	15	mg			Tablet	<a href="#">View</a>	Pending
64-###-01	Human	Trade H	7.5	mg			Tablet	<a href="#">View</a>	Pending
88-###-08	Human	Trade I	24	mg/ml	100	ml	Oral suspension	<a href="#">View</a>	Pending
97-###-09	Human	Trade J	0.4	mg/ml	120	ml	Syrup	<a href="#">View</a>	Pending

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1 of 2 Page(s)

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ستغير حالة المستحضر من "جديد" إلى "معلق". هذا يدل أن المستحضر تحت الدراسة

7

Pending

## Guidance to update the database of products in SDR

## الدليل الإرشادي لتحديث بيانات المستحضرات في سدر

In case if there is any comment from SFDA staff the comments will send to your email and the status will change to "Incomplete".

8  
In Complete

Click on update to complete the application form

9  
Update

After you complete the application form you will receive confirmation that your application is complete

Registration No.	Type of Application	Trade Name	Strength	Strength Unit	Volume	Unit of Volume	Dosage Form	1 to 15 of 19 Record(s)	Update Application	Status
23-###-09	Human	Trade A	1.36	%	250	ml	Concentrate for peritoneal dialysis solution		<a href="#">View</a>	Pending
37-###-10	Human	Trade B	2.27	%	500	ml	Concentrate for peritoneal dialysis solution		<a href="#">View</a>	Pending
44-###-05	Human	Trade C	500	mg			Tablet		<a href="#">View</a>	Pending
22-###-03	Human	Trade D	500, 2, 30	mg			Tablet		<a href="#">View</a>	Pending
78-###-04	Human	Trade E			0.5	ml	solution for injection		<a href="#">View</a>	Pending
41-###-07	Human	Trade F			5	ml	Ear drops*		<a href="#">Update</a>	New
48-###-08	Human	Trade G	15	mg			Tablet		<a href="#">View</a>	Pending
64-###-01	Human	Trade H	7.5	mg			Tablet	9	<a href="#">View</a>	Pending
88-###-08	Human	Trade I	24	mg/ml	100	ml	Oral suspension		<a href="#">Update</a>	In Complete
97-###-09	Human	Trade J	0.4	mg/ml	120	ml	Syrup		<a href="#">View</a>	Pending

1 2

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في حالة وجود تعليقات على النموذج من موظفي الهيئة ستصلك التعليقات على بريدك الإلكتروني وستتغير حالة المستحضر إلى "غير مكتمل"

8  
In Complete

لإكمال النموذج اضغط على تجديد

Update

بعد إكمال النموذج سيصل بريد تأكيد بأن النموذج كامل

## Guidance to update the database of products in SDR

الدليل الإرشادي لتحديث بيانات المستحضرات في سدر

The approved products will be in the section "Registered Products"

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Registered Products

### Saudi Drug Registration

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المستحضرات المكتملة  
ستنزل في قسم "المنتجات"  
المسجلة"

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Registered Products

## Guidance to update the database of products in SDR

## الدليل الإرشادي لتحديث بيانات المستحضرات في سدر

Now you have two new features:

1- Renew: To renew your products registration certificate

**Renew**

2- Variation Type: In case if you want to make variation 1 or 2

**Variation Type**

The screenshot shows the "Registered Products" section of the SDR system. The main table displays four rows of product information:

Registration No.	Reference Number	Type of Application	Trade Name	Product Description	Dosage Form	Renewal Date	Renew	Variation Type	Status
48###-08	HG00###-00-00-00	Human	Trade G	0.5%,50/g	Cream	31/12/1986	<b>Renew</b>	<b>Variation Type</b>	Registered
64###-01	HG00###-00-00-00	Human	Trade H	25/mg,/	Tablet	31/12/2008	<b>12</b>	<b>11</b>	Registered
88###-08	HG00###-00-00-00	Human	Trade I	10/mg,/	Tablet	31/12/2014	<b>Renew</b>	<b>Variation Type</b>	Registered
97###-09	HG00###-00-00-00	Human	Trade J	0.45%,1000/ml	Solution for injection	31/12/1994	<b>Renew</b>	<b>Variation Type</b>	Registered

Annotations with circled numbers and red boxes highlight specific features:

- 11**: Circled "Renew" button in the sidebar.
- 12**: Circled "Variation Type" button in the sidebar.
- 11**: Circled "Variation Type" button in the main table row for entry #12.
- Renew**: Red box around the "Renew" button in the sidebar.
- Variation Type**: Red box around the "Variation Type" button in the sidebar.

سيظهر عند الدخول على قسم الأدوية المسجلة خيارات:

١- تجديد: لتحديث شهادة المستحضر

**Renew**

**11**

٢- نوع التغيير: للتغيير ١ أو ٢

**Variation Type**

**12**

ما هي عناوين الاتصال التي يمكنني الاتصال بها عند الحاجة لمساعدة؟

يمكن للمتقدمين في حال احتياجهم لمساعدة:

- الإرسال على البريد الإلكتروني [SDR.DRUG@sfda.gov.sa](mailto:SDR.DRUG@sfda.gov.sa)

- أو الاتصال بالهيئة العامة للغذاء والدواء على الرقم: ٢٧٥٩٢٢٢

تحويلة: ٥٣٢٤ / ٥٧٤٠