



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

Log in to the web site system:

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

Then Login with your username and password

1

Saudi Drug Registration



- عربي
- About SDR
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- FAQs
- Contact Us

Username

1

Password

Log In

[Forgot Password?](#)

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>

ثم الدخول باسم المستخدم
وكلمة المرور

1

Go to "Products Update".

2

Products Update



اضغط على أيقونة تحديث المستحضرات

2

Products Update

Guidance to update the database of products in SDR

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

3

Update

1 to 15 of 19 Record(s)

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	View	Pending
37-###-10	Human	Trade B	2.27	%	500	ml	Concentrate for peritoneal dialysis solution	View	Pending
44-###-05	Human	Trade C	500	mg			Tablet	View	Pending
22-###-03	Human	Trade D	500, 2, 30	mg			Tablet	View	Pending
78-###-04	Human	Trade E			0.5	ml	solution for injection	View	Pending
41-###-07	Human	Trade F			5	ml	Ear drops*	Update	New
48-###-08	Human	Trade G	15	mg			Tablet	View	Pending
64-###-01	Human	Trade H	7.5	mg			Tablet	View	Pending
88-###-08	Human	Trade I	24	mg/ml	100	ml	Oral suspension	Update	New
97-###-09	Human	Trade J	0.4	mg/ml	120	ml	Syrup	View	Pending

1 2

1 of 2 Page(s)

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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

4

قم بتعبئة معلومات المستحضر
في جميع أقسام نموذج التسجيل

4

ملاحظة:

النموذج مماثل تماماً للنموذج
الجديد

Guidance to update the database of products in SDR

Type of Application

Application Details

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

Scientific Advice

PDP

Application Status

Fee Due

Scheduling

Inquiries

☑ 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

After finishing, click "Submit" button. 5

Submit

Also you can print the application form by clicking on "Print Application" Button 6

Print Application

 Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Welcome test88 Home | Logout

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

Status of the application in other regulatory agencies:
Tick the appropriate box and fill the information.

Authorized

Pending

Refused

Withdrawn (by applicant after authorization)

Suspended/revoked (by competent authority)

Previous Save Submit Print Application 6

5

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بعد الانتهاء من تحديث البيانات، اضغط على أيقونة إرسال. 5

Submit

باستطاعتك أيضا طباعة النموذج بالضغط على أيقونة "طباعة نموذج" 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

1 to 15 of 19 Record(s)

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	View	Pending
37-###-10	Human	Trade B	2.27	%	500	ml	Concentrate for peritoneal dialysis solution	View	Pending
44-###-05	Human	Trade C	500	mg			Tablet	View	Pending
22-###-03	Human	Trade D	500, 2, 30	mg			Tablet	View	Pending
78-###-04	Human	Trade E			0.5	ml	solution for injection	View	Pending
41-###-07	Human	Trade F			5	ml	Ear drops*	Update	New
48-###-08	Human	Trade G	15	mg			Tablet	View	Pending
64-###-01	Human	Trade H	7.5	mg			Tablet	View	Pending
88-###-08	Human	Trade I	24	mg/ml	100	ml	Oral suspension	View	Pending
97-###-09	Human	Trade J	0.4	mg/ml	120	ml	Syrup	View	Pending

1 2

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

7

Pending

7

Guidance to update the database of products in SDR

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 you application is complete

1 to 15 of 19 Record(s)

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	View	Pending
37-###-10	Human	Trade B	2.27	%	500	ml	Concentrate for peritoneal dialysis solution	View	Pending
44-###-05	Human	Trade C	500	mg			Tablet	View	Pending
22-###-03	Human	Trade D	500, 2, 30	mg			Tablet	View	Pending
78-###-04	Human	Trade E			0.5	ml	solution for injection	View	Pending
41-###-07	Human	Trade F			5	ml	Ear drops*	Update	New
48-###-08	Human	Trade G	15	mg			Tablet	View	Pending
64-###-01	Human	Trade H	7.5	mg			Tablet	9	8
88-###-08	Human	Trade I	24	mg/ml	100	ml	Oral suspension	Update	8
97-###-09	Human	Trade J	0.4	mg/ml	120	ml	Syrup	View	Pending

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

8

In Complete

لإكمال النموذج اضغط على تجديد

9

Update

بعد إكمال النموذج سيصل بريد تأكيد بأن النموذج كامل

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

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Registered Products

Saudi Drug Registration

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Create New Applications

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Products Update

Registered Products

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المستحضرات المكتملة
ستتقل في قسم "المنتجات
المسجلة"

10

Registered Products

Guidance to update the database of products in SDR

Now you have two new features:

1- Renew: To renew your products registration certificate

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Renew

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

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Variation Type

Saudi Drug Registration

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

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Registered Products

1 to 4 of 4 Record(s)

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	Renew	Variation Type	Registered
64-###-01	HG00###-00-00-00	Human	Trade H	25/mg,/	Tablet	31/12/2008	12	11	Registered
88-###-08	HG00###-00-00-00	Human	Trade I	10/mg,/	Tablet	31/12/2014	Renew	Variation Type	Registered
97-###-09	HG00###-00-00-00	Human	Trade J	0.45/%,1000/ml	Solution for injection	31/12/1994	Renew	Variation Type	Registered

1 of 1 Page(s)

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سيظهر عند الدخول على قسم الأدوية المسجلة خيارين:

1- تجديد: لتحديث شهادة المستحضر

Renew

11

2- نوع التغيير: للتغيير 1 أو 2

Variation Type

12

ما هي عناوين الاتصال التي يمكنني الاتصال بها عند الحاجة للمساعدة؟
يمكن للمتقدمين في حال احتياجهم للمساعدة:

- الإرسال على البريد الإلكتروني SDR.DRUG@sFDA.gov.sa

- أو الاتصال بالهيئة العامة للغذاء والدواء على الرقم: ٢٧٥٩٢٢٢

تحويلة: ٥٣٢٤ / ٥٧٤٠