



النظام الإلكتروني لتسجيل الأدوية السعودي (سدر)
The Saudi Drug Registration System (SDR)

دليل المستخدم لنظام سدر

E-SDR User Manual

12/11/2024

English اللغة العربية

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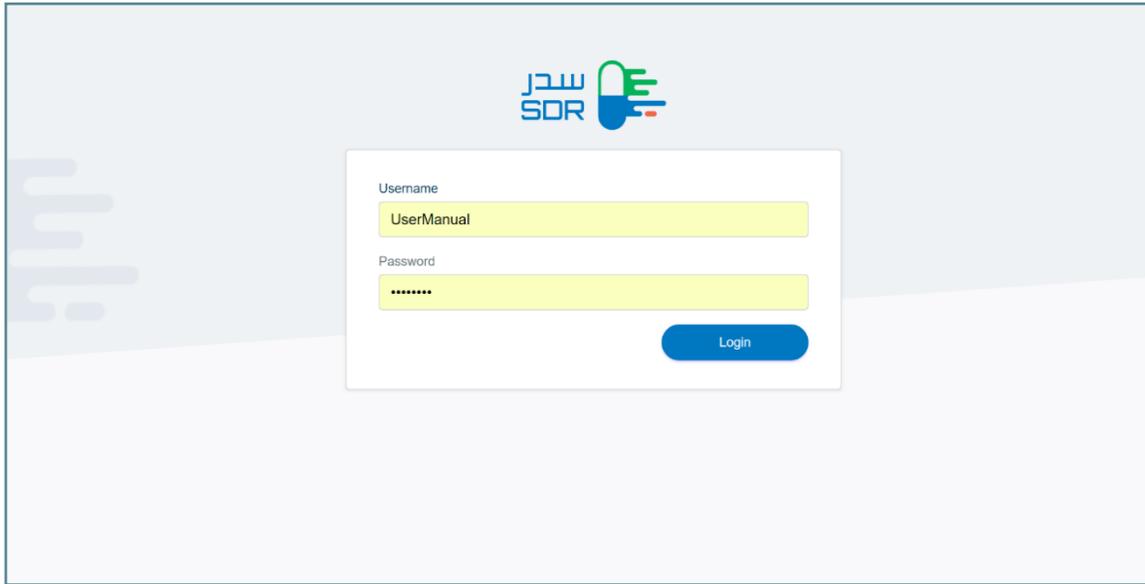
يهدف هذا الدليل لتوضيح خطوات تسجيل الادوية والمستحضرات الصيدلانية في المملكة العربية السعودية بكافة أنواعها لممثلي شركات الأدوية ووكلائها.

الخطوة الأولى: الدخول لنظام تسجيل الأدوية

الدخول على الموقع الإلكتروني لتسجيل الأدوية السعودي (سدر) عبر الرابط التالي [اضغط هنا](#) النقر على أيقونة تسجيل الدخول في أعلى يسار الصفحة



ملاحظة: على الشركة التحقق من وجود حساب لها في نظام (DENR) قبل الدخول على نظام سدر

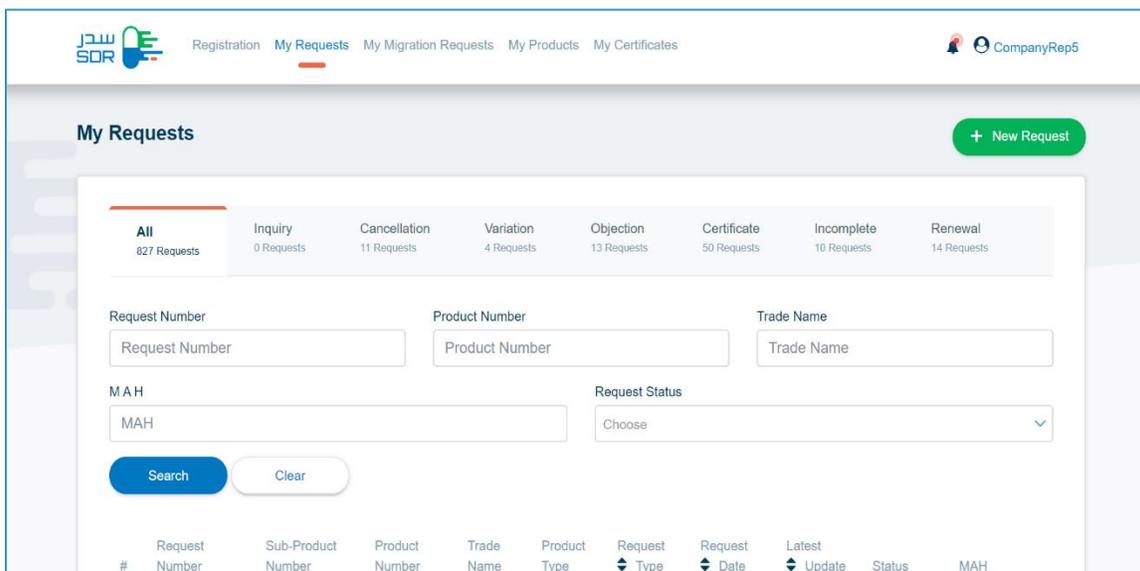


The screenshot shows the SDR login interface. At the top center is the SDR logo. Below it is a white login form with two input fields: 'Username' containing 'UserManual' and 'Password' containing seven asterisks. A blue 'Login' button is positioned at the bottom right of the form.

قبل البدء في استخدام النظام، يجب على المستخدم بتسجيل الدخول باسم المستخدم وكلمة المرور من نظام السجل الوطني للمنشآت الصيدلانية (سجل)، كما هو موضح في الشكل أدناه:



واجهة نظام تسجيل الأدوية السعودية



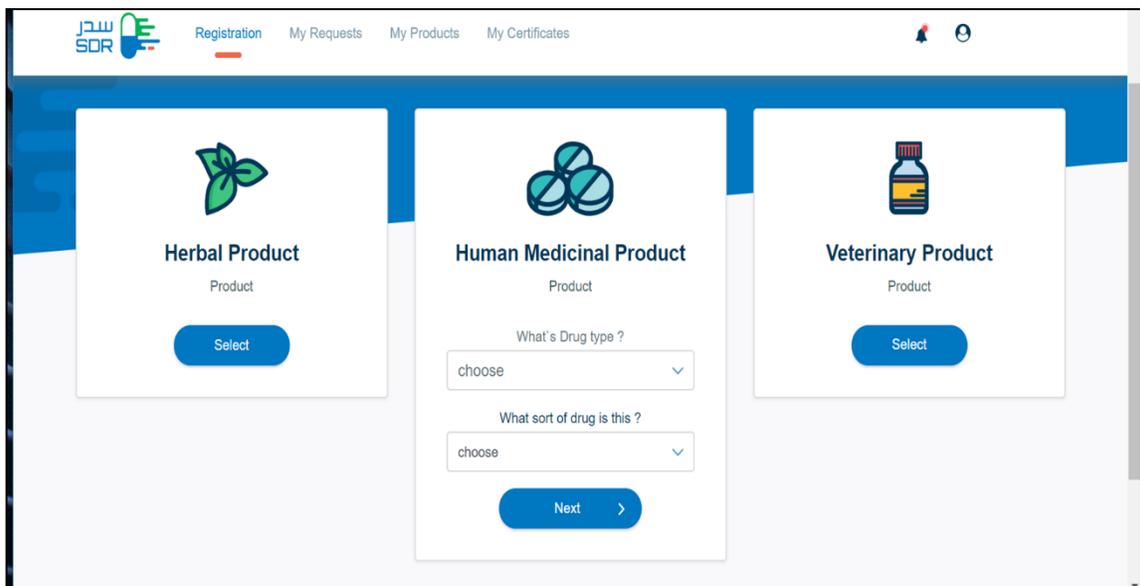
صفحات واجهة النظام



- عند اختيار صفحة "Registration"
 - تتيح للمستخدم بتسجيل مستحضر جديد
- عند اختيار صفحة " My Requests"
 - تتيح للمستخدم باستعراض جميع الطلبات التي تم ادخالها في نظام سدر.
- عند اختيار صفحة "My Migration Requests"
 - تتيح للمستخدم بنقل الطلبات المكتملة من نظام سدر (SDR) الى نظام سدر (E-SDR)
- عند اختيار صفحة " My Products "
 - تتيح للمستخدم باستعراض جميع المستحضرات الموجودة داخل الطلبات.
- عند اختيار صفحة "My Certificates"
 - تتيح للمستخدم باستعراض الشهادات

الخطوة الثانية: تسجيل الأدوية

لتسجيل مستحضر جديد يتم الضغط على ايقونة "New Request" في اعلى يمين الصفحة وسوف يتم عرض الصفحة الموضحة أدناه ليتم تحديد نوع النموذج، فيديو توضيحي [اضغط هنا](#)



○ يقوم المستخدم بتحديد نوع النموذج

1. تسجيل مستحضر صيدلاني دوائي "Human Medicinal Product"

2. تسجيل مستحضر بيطري "Veterinary Product"

3. تسجيل مستحضر عشبي "Herbal Product"

○ ثم يتم اختيار نوع المستحضر وتصنيفه بعد ذلك يقوم المستخدم اختيار تسجيل المستحضر.

New Request

Human Medicinal Product New Drug New chemical entity

Is Saudi Arabia Country of origin?

Yes

No

Is this product under license

Yes

No

Was there any scientific advice given by the SFDA for this medicinal product?

Yes

No

Is there a pediatric development program for this medicinal product?

Yes

No

Is this product registered in GCC

Yes

No

Is this product registered in SRA

Yes

No

يقوم المستخدم تعبئة بيانات المستحضر في سبع خطوات الموضحة ادناه:



• نوع النموذج

New Request

Application type Product Details Manufactures Marketing Authorization Legal status of Product Price Certificate Summary

STEP 1
Application Type

Because you choose No in "Is Saudi Arabia Country of origin?" please complete the following:

General Product Information

Reference Trade Name

Product strength

Strength Unit

Dosage Form

Authority
 Certifying Authority

• تفاصيل المنتج

- اختيار نوع المنتج.
- اختيار اضافة طلب منتج المبين في الصورة أدناه.

Application type Product Details Manufactures Marketing Authorization Legal status of Product Price Certificate Summary

STEP 2
Product Details

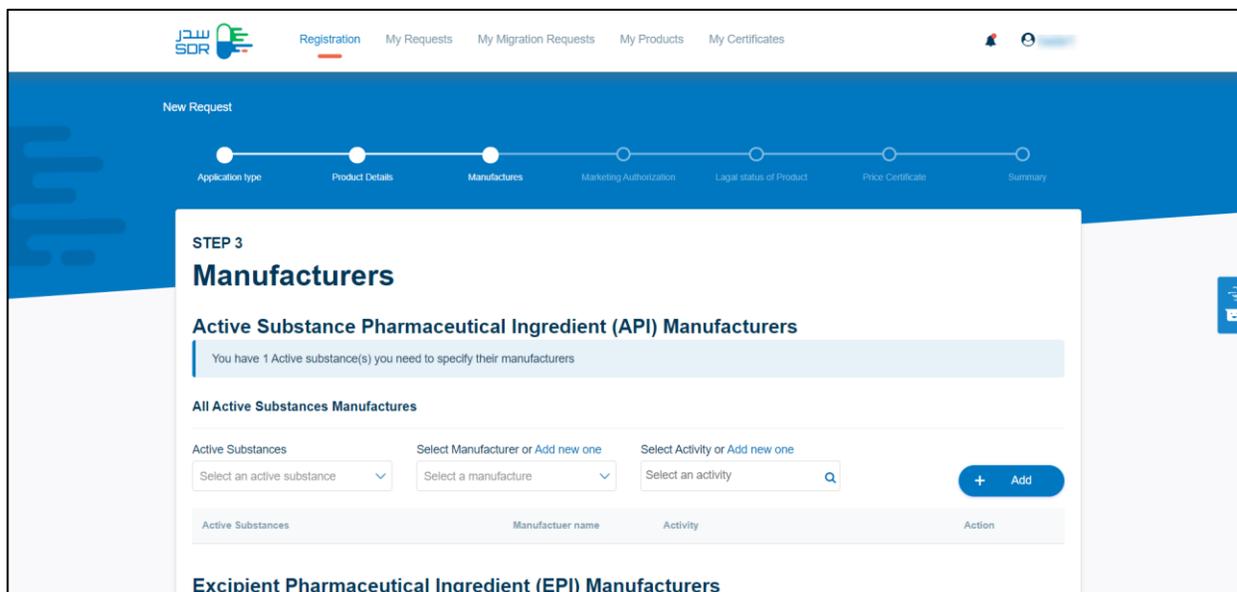
digital seal  الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Terms And Conditions User Manual FAQs 19999

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julphar | sdr-web-ib74564d7-p5vm9

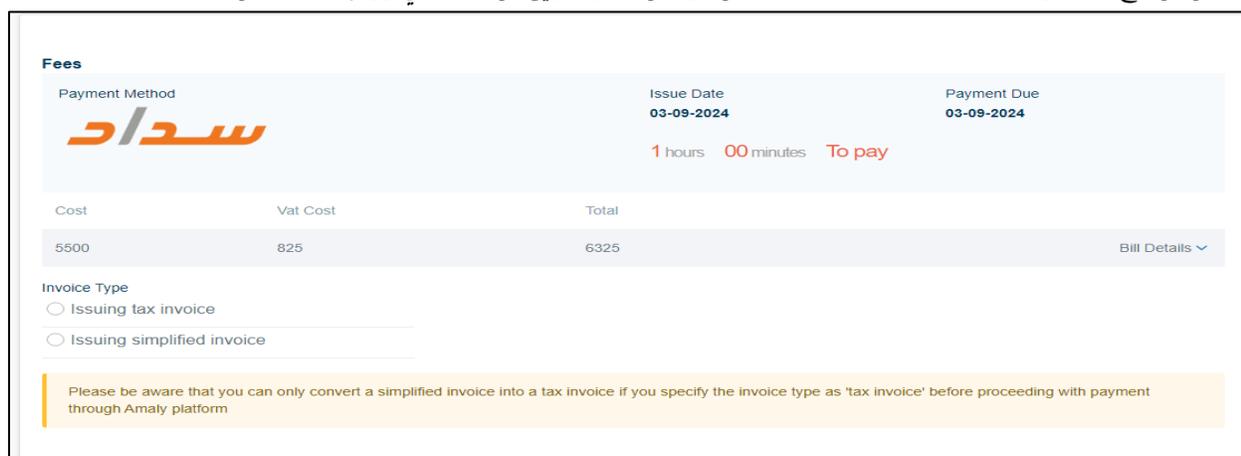
ملاحظة: يمكن للمستخدم تسجيل مستحضر يحتوي على أكثر من نوع عبوة / شكل صيدلاني / تركيز تحت رقم مستحضر واحد بأرقام طلبات مختلفة.

- إضافة المصانع
 - يمكن للمصنع إضافة مصنع مع إمكانية التعديل والحذف على بيانات المصانع بعد إضافتها وقبل إرسال النموذج.
 - يمكن إدخال 10 مصانع API لكل مادة فعالة لطلبات التسجيل والتعديل.



The screenshot shows the 'Manufacturers' step (STEP 3) of a 'New Request' process. The process flow includes: Application type, Product Details, Manufacturers, Marketing Authorization, Legal status of Product, Price Certificate, and Summary. The current step is 'Manufacturers', which is divided into 'Active Substance Pharmaceutical Ingredient (API) Manufacturers' and 'Excipient Pharmaceutical Ingredient (EPI) Manufacturers'. The API section shows a message: 'You have 1 Active substance(s) you need to specify their manufacturers'. Below this, there are three dropdown menus: 'Active Substances' (with a search icon), 'Select Manufacturer or Add new one' (with a search icon), and 'Select Activity or Add new one' (with a search icon). An 'Add' button is visible. A table below the dropdowns has columns for 'Active Substances', 'Manufacturer name', 'Activity', and 'Action'.

بعد استكمال جميع الخطوات والانتها من تعبئة جميع الخانات المطلوبة، يتم اصدار فاتورة سداد مع ظهور صلاحيات الفاتورة كما هو موضح بالشكل ادناه ملاحظة: آلية السداد للفواتير تكون عن طريق بوابة أعمال رموز السداد هو: 144



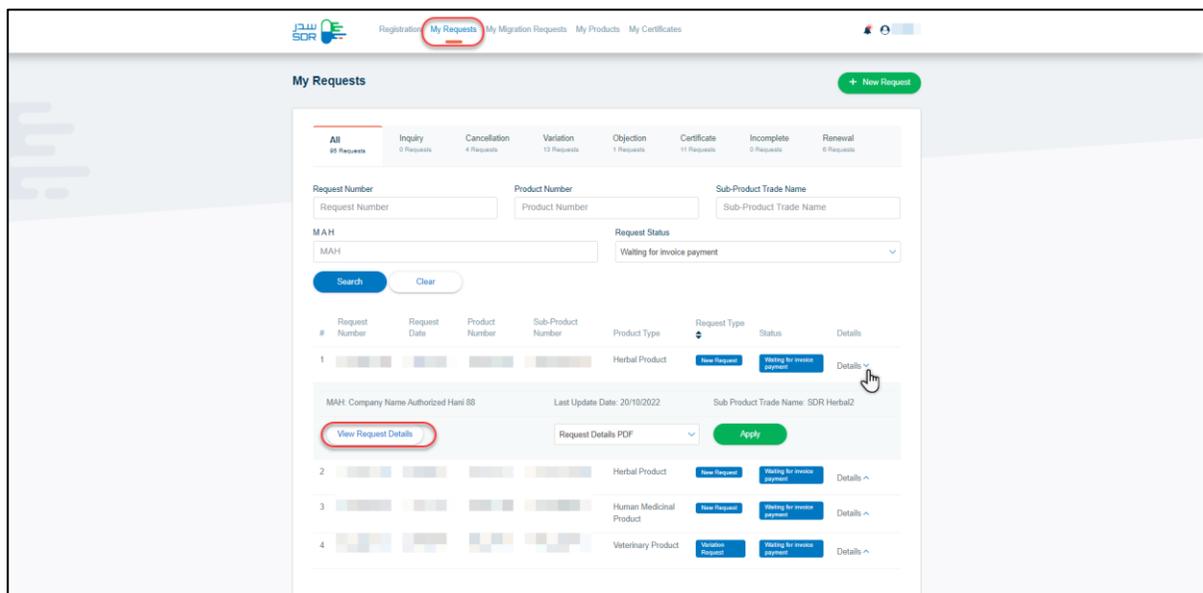
The screenshot shows the 'Fees' section of the SDR system. It displays the following information:

- Payment Method:** SDR (سدر)
- Issue Date:** 03-09-2024
- Payment Due:** 03-09-2024
- Time to pay:** 1 hours 00 minutes To pay

Cost	Vat Cost	Total
5500	825	6325

Below the table, there is a section for 'Invoice Type' with two radio buttons: 'Issuing tax invoice' and 'Issuing simplified invoice'. A note at the bottom states: 'Please be aware that you can only convert a simplified invoice into a tax invoice if you specify the invoice type as 'tax invoice' before proceeding with payment through Amaly platform'.

لاستعراض الفاتورة الضريبية مفصلة بعد دفع المقابل المالي يتم الدخول على صفحة " My Request " يتم تحديد طلب معين والضغط على الأيقونة بجانب الطلب ثم اختيار "Request Details"



يتم اختيار " Payment Summary " ثم اختيار "View" كما هو موضح ادناه



سيقوم النظام بتحويل المستخدم إلى بوابة أعمال يقوم المستخدم بالضغط على أيقونة "فاتورة ضريبية" ومن ثم " اضافة ملف ضريبي "

فضلا اختر نوع الفاتورة التي ترغب في تصديرها

فاتورة ضريبية

تصدر لكل من هو مكلف بالقرارات الضريبية

فاتورة ضريبية مبسطة
تصدر لكل من هو غير مكلف بالقرارات الضريبية

يرجى إضافة ملف ضريبي لتكامل عملية الدفع

+ إضافة ملف ضريبي

تفاصيل الفاتورة

إجمالي المبلغ المستحق

+ 6325.0 ريال

بيانات سداد

رقم الفاتورة	513146070
اسم العميل	شركات المصافي
رقم العميل	144

فضلا اختر طريقة الدفع التي تناسبك

سداد نظام سداد للمدفوعات

يتم تعبئة جميع الحقول المطلوبة الموضحة ادناه بعد استكمال جميع الحقول يتم الضغط على خيار "حفظ"

أهلاً بك عميل هيئة الف

فضلا اختر نوع الفاتورة التي

فاتورة ضريبية مبسطة
تصدر لكل من هو غير مكلف بالقر

يرجى إضافة ملف ضريبي لتكامل عما

+ إضافة ملف ضريبي

تفاصيل الفاتورة

إجمالي المبلغ المستحق

فضلا اختر طريقة الدفع التي ت

سداد نظام سداد للمدفوعات

هل لديك رقم ضريبي؟
 نعم
 لا

الاسم

المنطقة

المدنية

الحي

الرقم المينى

الرقم البريدي

الاسم المدينة

الاسم الحي

الرقم الضاهي

الرقم المينى

الرقم البريدي

1234

1234

12345

12345

حفظ

إلغاء

يمكن للمثل الشركة استعراض تفاصيل الفاتورة الضريبية بعد إنشائها من خلال اختيار "تحميل الفاتورة"

البيانات الضريبية

الرقم الضريبي: 31

تفاصيل الفاتورة

إجمالي المبلغ المستحق: 6325.0 ريال

بيانات سداد

رقم الفاتورة	اسم العميل	رقم العميل
543146112	شركة أماني	144

للحصول على الفاتورة يرجى أن يتم الدفع باستخدام خدمة سداد قبل:
03 سبتمبر 2024 م - 30 صفر 1446 هـ
1:23:47 م

فضلا اختر طريقة الدفع التي تناسبك

سداد نظام سداد للمدفوعات

تحميل الفاتورة الضريبية

البيانات المالية

Payment Order

رقم السداد / SADA Number: 144

اسم العميل / Biller Name - Number: 144

التاريخ / Payment Order Date: 13/23/47 09/09/2024

رقم العميل / Client ID: 144

AMALY

رقم العميل / Supplier ID: 144

اسم العميل / Supplier Name: 144

التاريخ / Supplier Date: 13/23/47 09/09/2024

رقم العميل / Supplier ID: 144

بيانات العميل

الاسم / Name: شركة أماني

العنوان / Address: 3028 - 13321 - المنطقة الصناعية

رقم العميل / VAT Number: 300796239510003

رقم العميل / Commercial Registration Number: 1010332910

بيانات المورد

الاسم / Name: شركة أماني

العنوان / Address: 3028 - 13321 - المنطقة الصناعية

رقم العميل / VAT Number: 300796239510003

رقم العميل / Commercial Registration Number: 1010332910

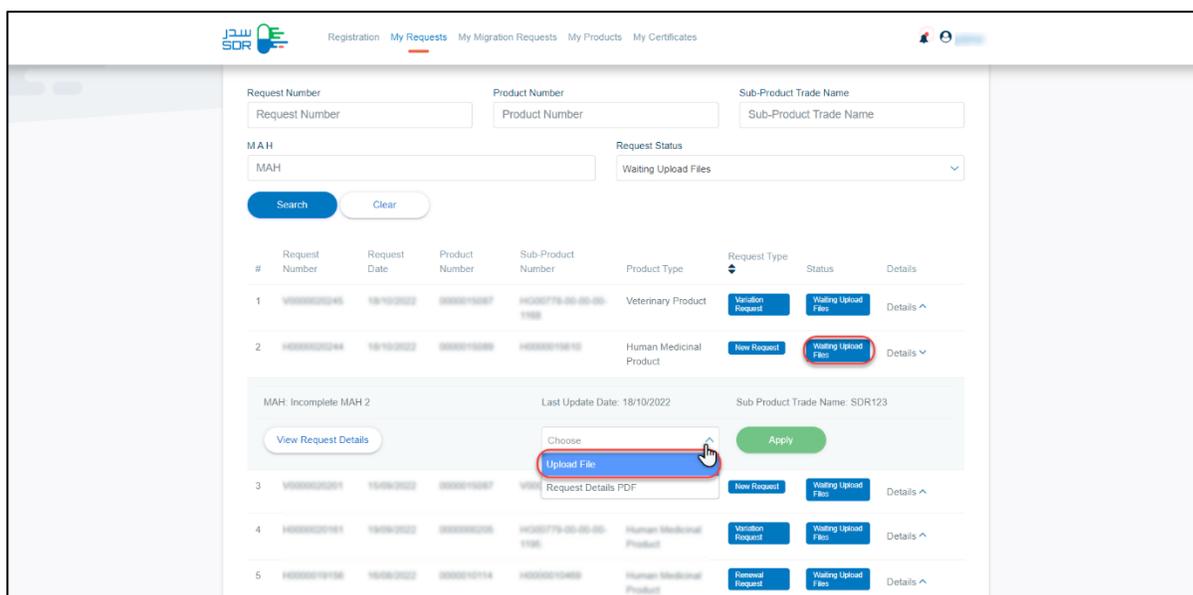
بيانات المنتج - الخدمة

الخدمة / Service	وصف الخدمة / Service Description	سعر الوحدة / Unit Price	الكمية / Quantity	الخصم / Discount	مبلغ الخدمة / Tax Amount	مبلغ subtotal (بما في ذلك ضريبة القيمة المضافة) / Main Subtotal (Including VAT)
خدمة الفاتورة والضريبة	خدمة الفاتورة والضريبة	5500.0	1	0	825.0	6325.0
Total (Excluding VAT)						5500.0

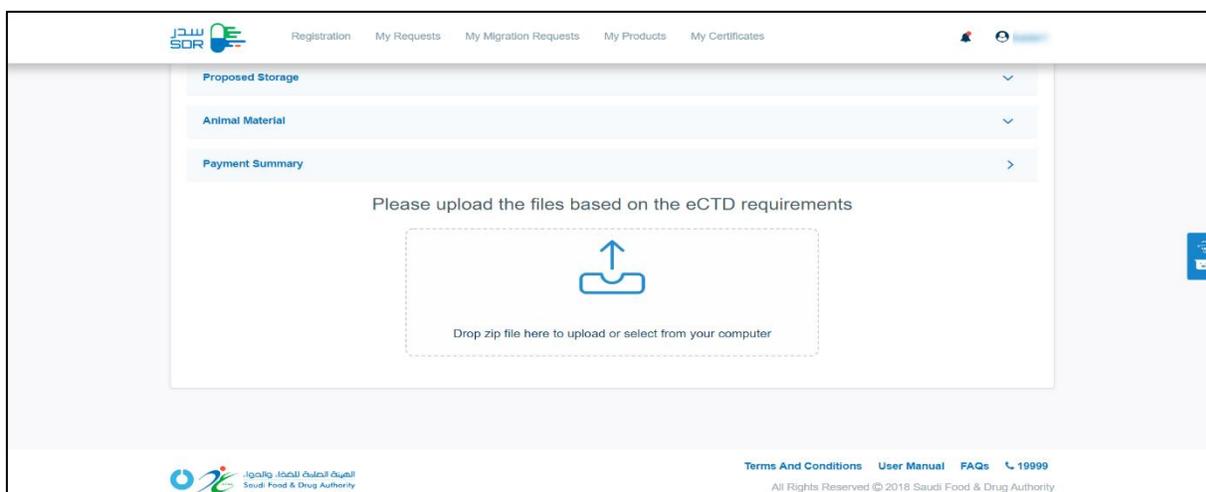
الخطوة الثالثة: قيام المستخدم برفع الملفات

- بعد السداد تكون حالة الطلب (بانتظار رفع الملفات) يتم الضغط على الأيقونة بجانب الطلب ثم اختيار "Upload File"

ملاحظة: في حال الرغبة لإضافة حجم عبوة جديد إلى طلبك الحالي، سيتم الانتقال إلى صفحة خاصة لإضافة حجم العبوة لتتيح لك إضافة حجم عبوة جديد لطلبك الأساسي دون دفع رسوم إضافية.



The screenshot shows the SDR system interface with a navigation menu at the top: Registration, My Requests, My Migration Requests, My Products, My Certificates. Below the menu, there are search filters for Request Number, Product Number, Sub-Product Trade Name, MAH, and Request Status. A table lists several requests with columns for Request #, Request Number, Request Date, Product Number, Sub-Product Number, Product Type, Request Type, Status, and Details. Request 2 is highlighted with a red box around the 'Waiting Upload Files' status. Below the table, there is a section for 'MAH: Incomplete MAH 2' with a 'View Request Details' button and a 'Choose' dropdown menu. The 'Upload File' option is highlighted with a red box and a mouse cursor. Other options include 'Request Details PDF', 'New Request', and 'Waiting Upload Files'. An 'Apply' button is also visible.



The screenshot shows the SDR system interface with a navigation menu at the top: Registration, My Requests, My Migration Requests, My Products, My Certificates. Below the menu, there are sections for 'Proposed Storage', 'Animal Material', and 'Payment Summary'. A central message reads: 'Please upload the files based on the eCTD requirements'. Below the message is a dashed box with an upload icon and the text: 'Drop zip file here to upload or select from your computer'. At the bottom, there is a footer with the SDR logo and the text: 'الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority'. The footer also includes links for 'Terms And Conditions', 'User Manual', 'FAQs', and a phone number '19999'. Copyright information: 'All Rights Reserved © 2018 Saudi Food & Drug Authority'.

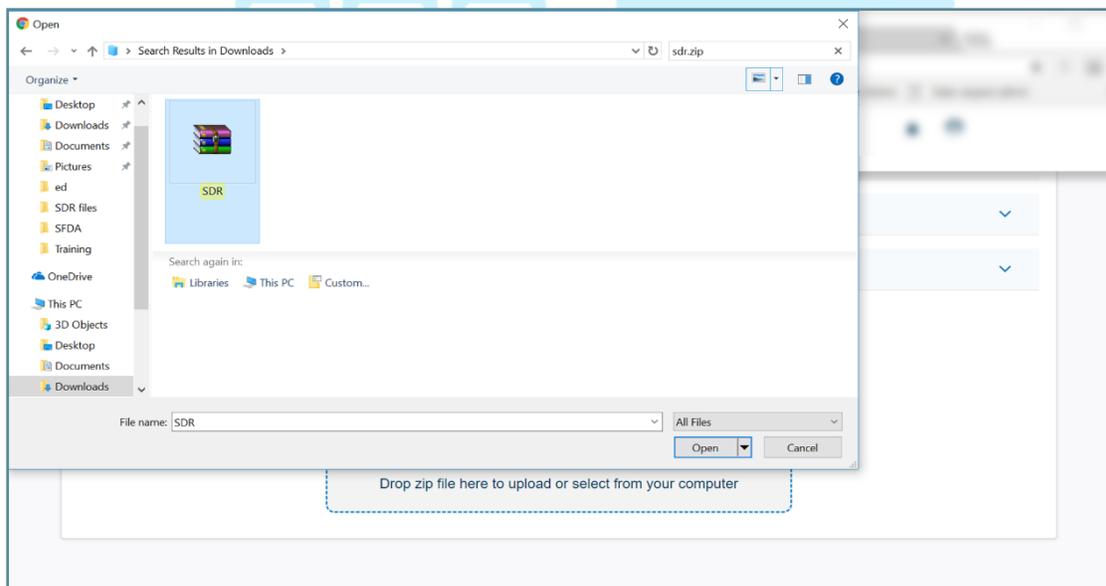
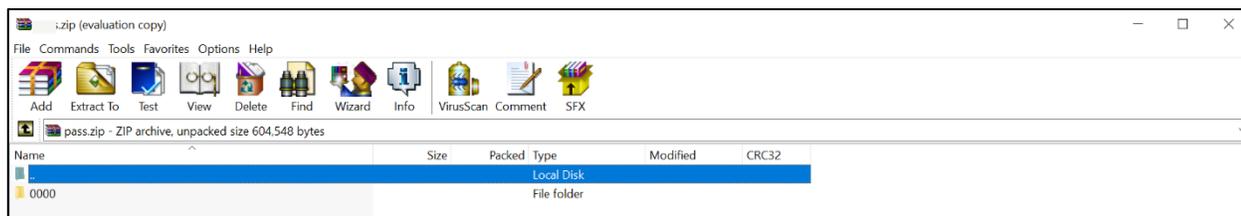
○ بعد رفع الملفات بشكل صحيح تكون حالة الطلب " Under Technical Validation " او " Need Manual Technical Validation "

- بعد اجتياز عملية التحقق بنجاح يتم ارسال الطلب لموظف الهيئة بحالة "New Request".
- في حال عدم اجتياز التحقق من الملفات يظهر النظام تقرير بالأخطاء والنواقص في الملفات ويتيح للمستخدم رفع الملفات مرة اخرى.

○ ملاحظات في عملية رفع الملفات:

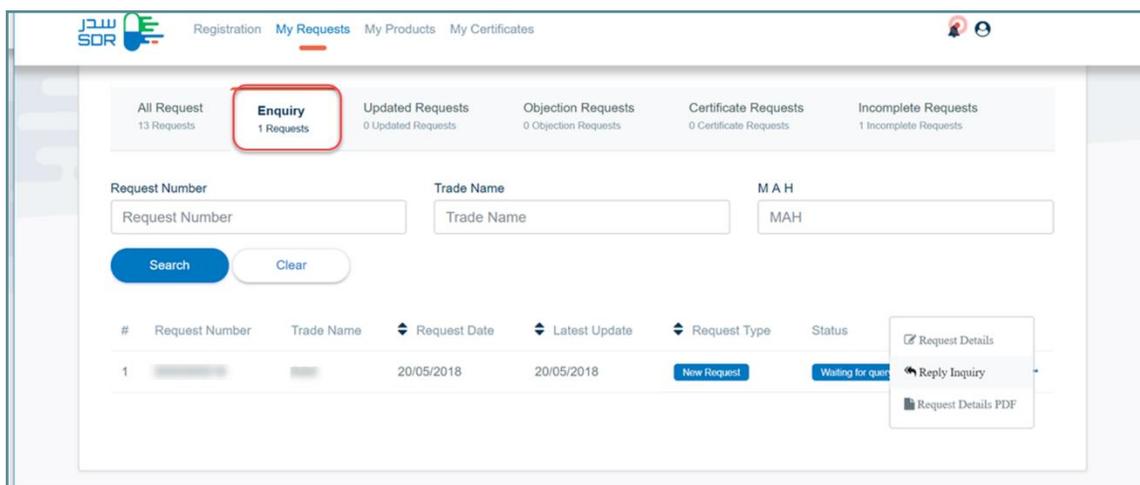
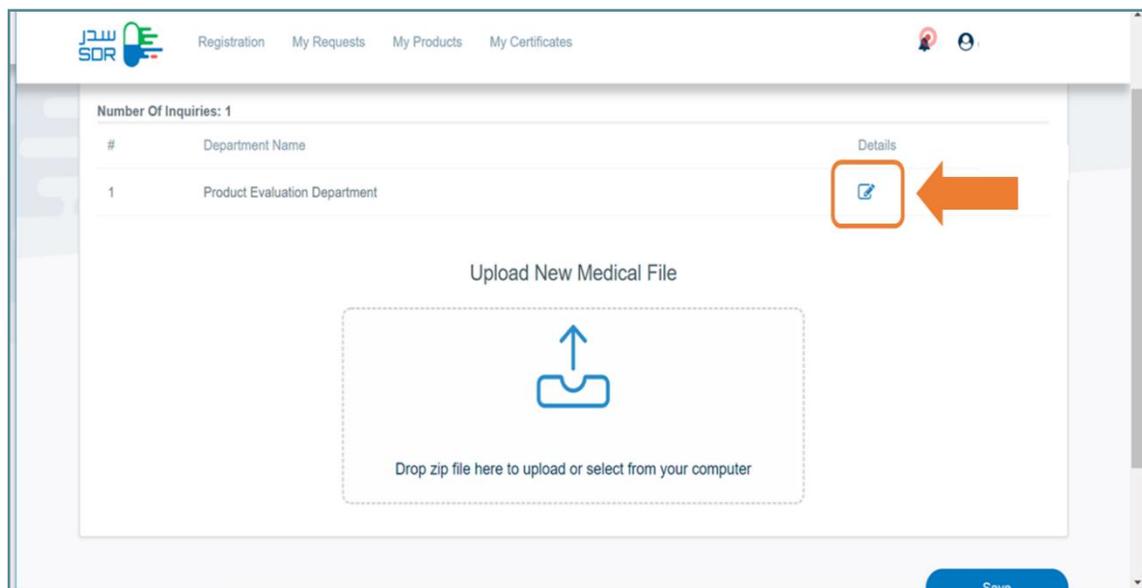
- قبل رفع الملفات للمنتجات يجب استخدام (Sub-product number) في رقم الطلب المرجعي عند تعبئة بيانات المنتج في المظروف المقدم بصيغة eCTD.
- عند رفع ملف الطلب يجب ان يكون الملف بصيغة ZIP، وداخل الملف المضغوط مجلد باسم (000X) فقط كما هو موضح بالصورة ادناه.
- يجب الاخذ بعين الاعتبار ان كل الملفات يجب ان تكون مطابقة لمتطلبات الهيئة الموجودة في الموقع

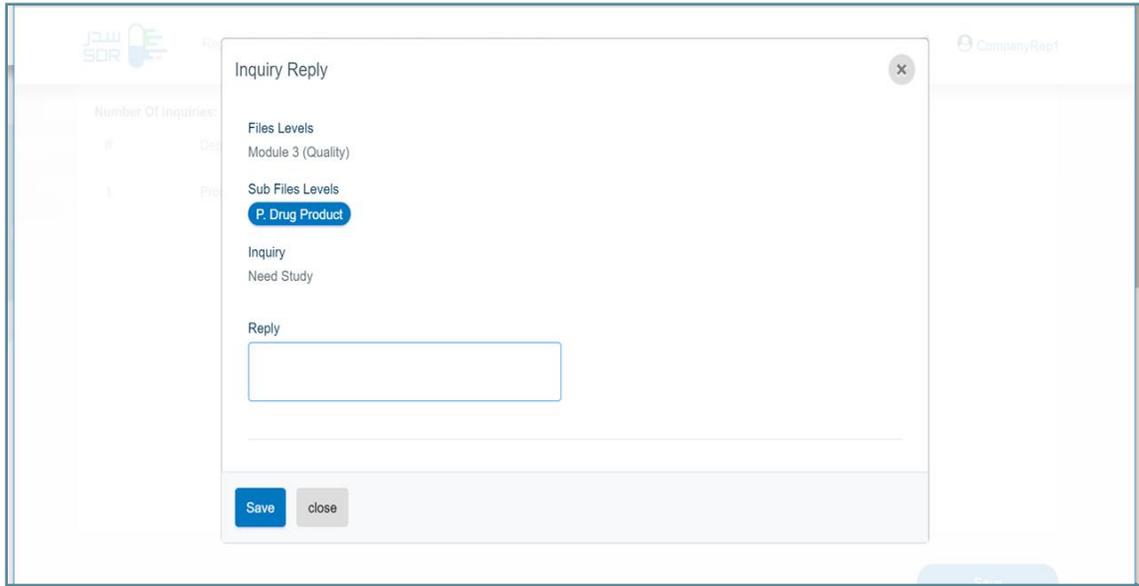
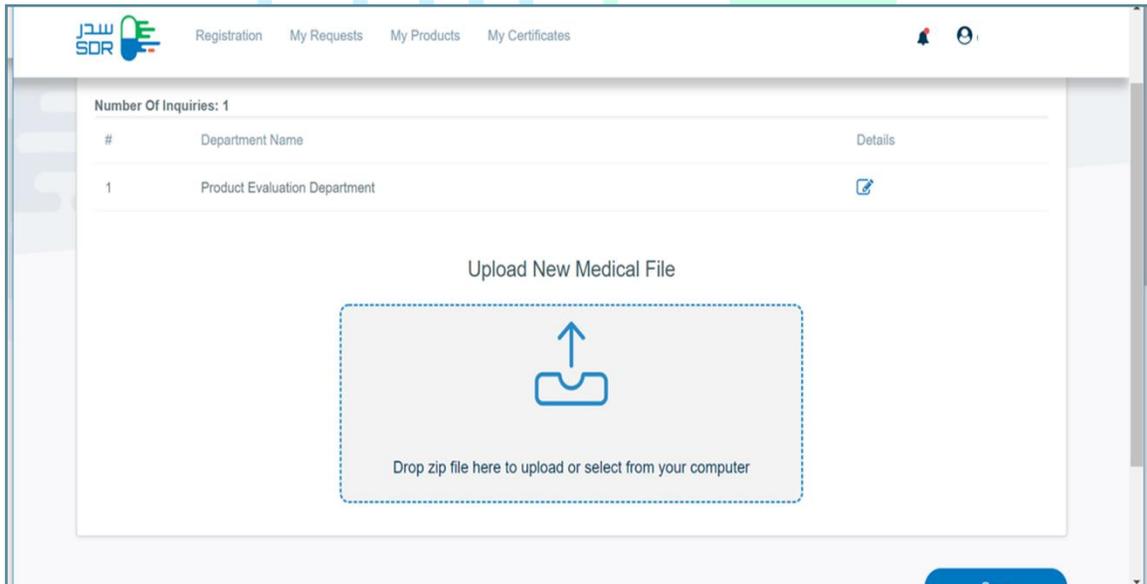
[\(اضغط هنا\)](#)



الخطوة الرابعة: إضافة الرد على الاستعلامات

- يقوم المستخدم بالنقر على (Inquiry)
- يقوم المستخدم بالنقر على ايقونة (Reply Inquiry) لاتخاذ الإجراء اللازم
- يقوم المستخدم بالنقر على 
- يقوم المستخدم بإدخال الرد على الاستفسار
- يستطيع المستخدم رفع الملفات ان وجدت.

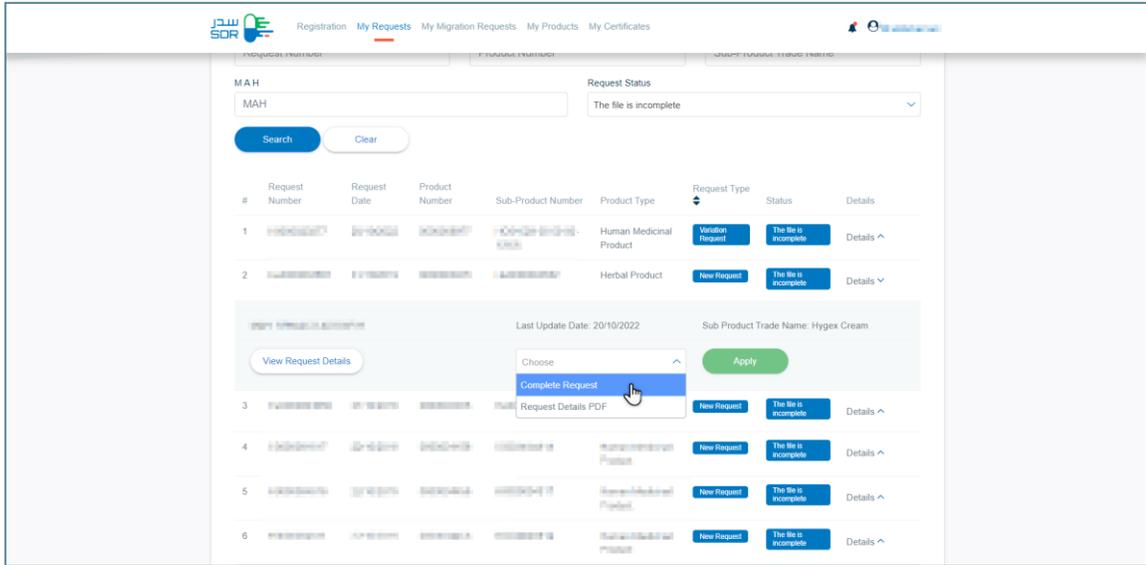



#	Department Name	Details
1	Product Evaluation Department	

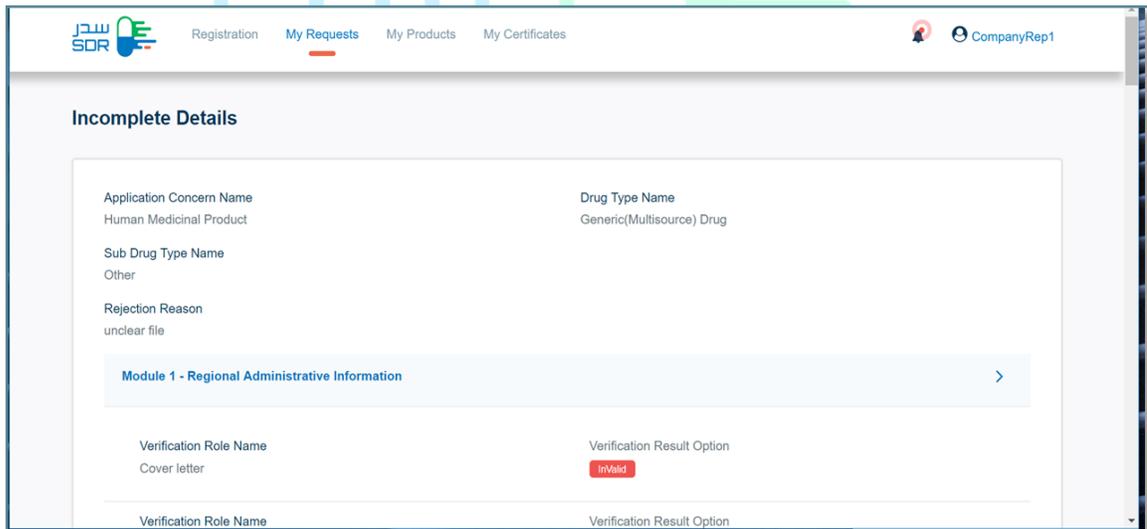
الخطوة الخامسة: استكمال الملفات

- انقر على أيقونة "Complete Request" لاتخاذ الإجراء اللازم
- يقوم المستخدم باستعراض الملاحظات
- يقوم المستخدم باختيار "Proceed"

- يقوم المستخدم بتعديل بيانات الطلب
- يقوم المستخدم برفع الملفات

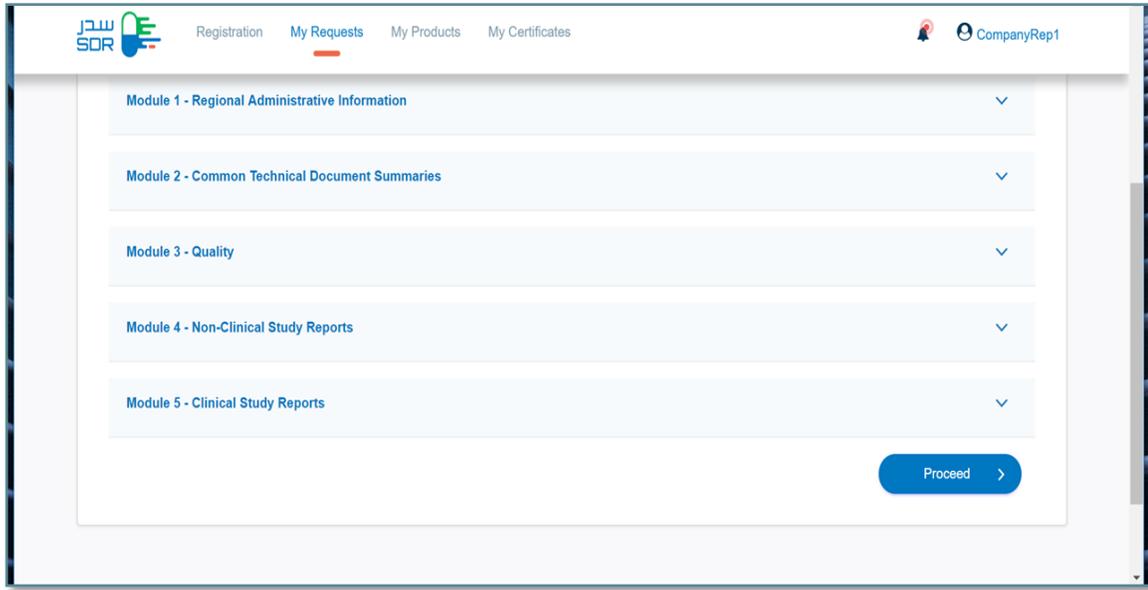


The screenshot displays the 'My Requests' interface. At the top, there are navigation tabs: Registration, My Requests (active), My Migration Requests, My Products, and My Certificates. A search bar contains 'MAH' and a 'Request Status' dropdown is set to 'The file is incomplete'. Below this is a table with columns: #, Request Number, Request Date, Product Number, Sub-Product Number, Product Type, Request Type, Status, and Details. The table lists several requests, including 'Human Medicinal Product' and 'Herbal Product'. A 'View Request Details' button is visible, and a dropdown menu is open over the table, showing 'Complete Request' as the selected option.



The screenshot shows the 'Incomplete Details' page. It features a form with the following fields and values:

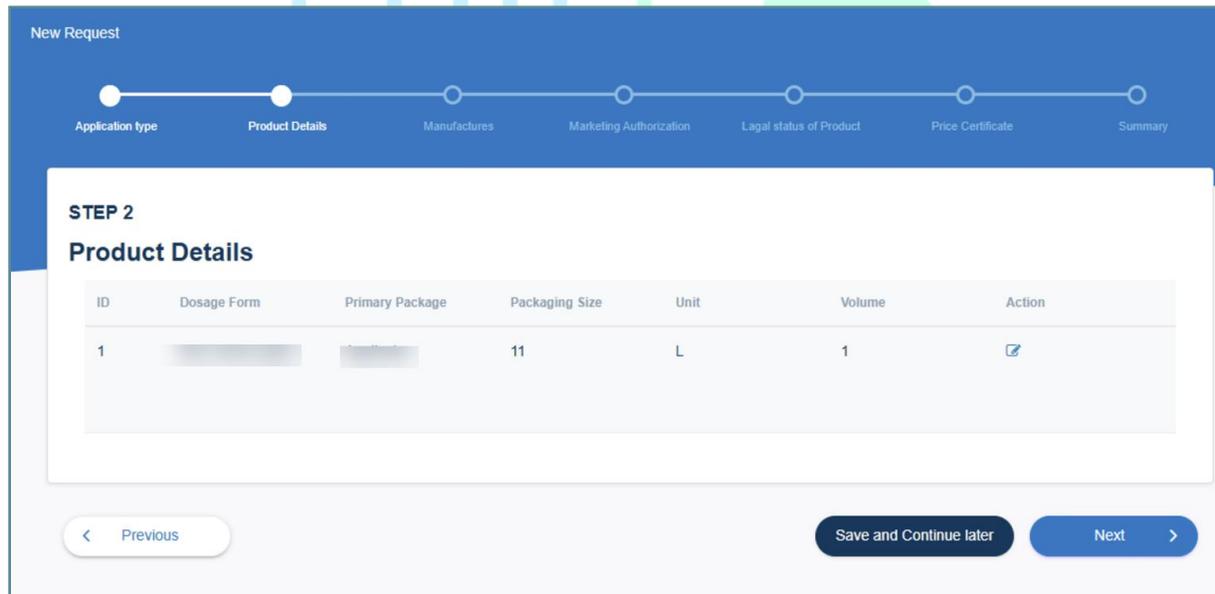
- Application Concern Name:** Human Medicinal Product
- Drug Type Name:** Generic(Multisource) Drug
- Sub Drug Type Name:** Other
- Rejection Reason:** unclear file
- Module 1 - Regional Administrative Information:** (with a right arrow icon)
- Verification Role Name:** Cover letter
- Verification Result Option:** Invalid (in a red box)



SDR SDR Registration My Requests My Products My Certificates CompanyRep1

- Module 1 - Regional Administrative Information
- Module 2 - Common Technical Document Summaries
- Module 3 - Quality
- Module 4 - Non-Clinical Study Reports
- Module 5 - Clinical Study Reports

Proceed >



New Request

Application type Product Details Manufactures Marketing Authorization Legal status of Product Price Certificate Summary

STEP 2
Product Details

ID	Dosage Form	Primary Package	Packaging Size	Unit	Volume	Action
1			11	L	1	

Previous Save and Continue later Next

Add/Update Sub-product

Sub-Product trade name in Saudi Arabia
Sub-Product trade name in English (in Saudi Arabia)

Sub-Product trade name in Arabic (in Saudi Arabia)

Ingredients
Active Substance
Type of active substance
 Single
 Multiple

Active Substance name: operator: Quantity: Unit: Reference:

Active Substance name	operator	Quantity	unit	Reference	Action
test	Less than	1	L		<input type="button" value="edit"/> <input type="button" value="delete"/>

Excipient
Excipient name: Operator: Unit:

Reference: Quantity is QS ?
 No Yes

Excipient name	operator	Quantity	unit	Reference	Action
test	Equal to	QS	L	test	<input type="button" value="edit"/> <input type="button" value="delete"/>

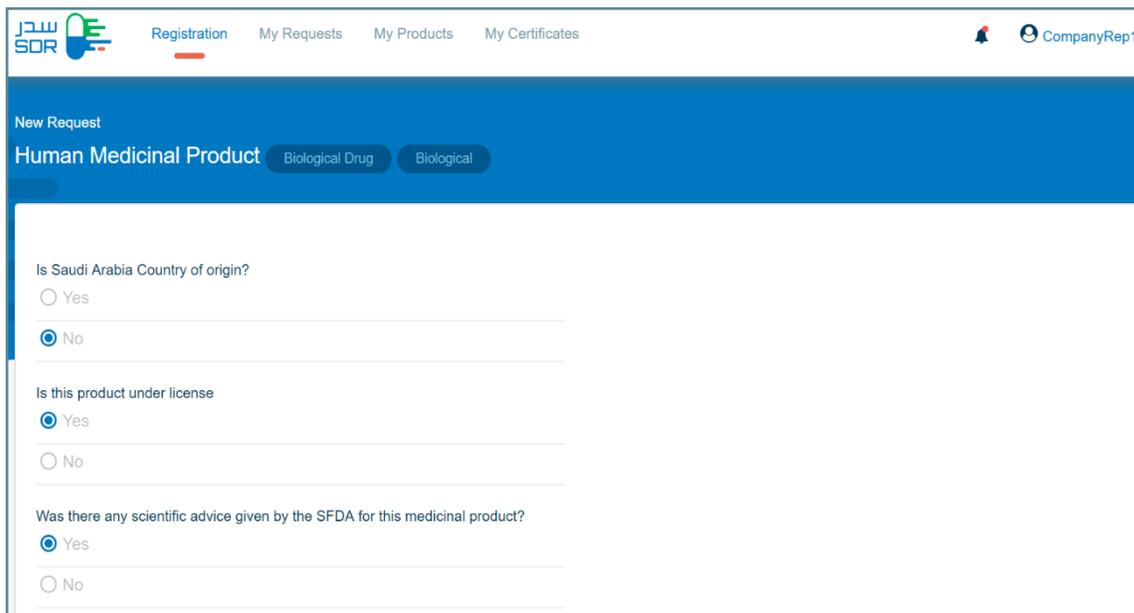
- الخطوة السادسة: إضافة "Sub-Product"
- بعد استكمال رفع الملفات يمكن لشركة المستحضرات إضافة "Sub- Product" من خلال الذهاب لصفحة My Products واختيار المستحضر المراد إضافة "Sub-Product" له كما هو موضح في الشكل أدناه:

Registration My Requests **My Products** My Certificates

ID	Barcode	Registration No.	Status	Count	Sub-Products	Actions
3		0000000389	Submitted	2	sub-Products	...
4		0000000388	Submitted	1	sub-Products	...
5		0000000387	Draft	1	sub-Products	...
6		0000000386	Submitted	5	sub-Products	...
7		0000000382	Draft	1	sub-Products	Product Details + Add Sub-Product
8		0000000370	Draft	2	sub-Products	...
9		0000000375	Draft	1	sub-Products	...

- بعد اختيار " Add Sub Product " سوف تظهر لممثل الشركة الصفحة الخاصة بالتسجيل التي تم تعبئتها سابقا في مرحلة تسجيل المستحضر.

ملاحظة: لا يمكن لممثل الشركة التعديل على البيانات المدخلة سابقا لنفس المستحضر باستثناء صفحة ال Product Details بالإضافة إلى صفحة ال Marketing Authorization Holder كما هو موضح في الشكل أدناه.



SDR

Registration My Requests My Products My Certificates

CompanyRep1

New Request

Human Medicinal Product Biological Drug Biological

Is Saudi Arabia Country of origin?

Yes

No

Is this product under license

Yes

No

Was there any scientific advice given by the SFDA for this medicinal product?

Yes

No

بعد استكمال الصفحات الخاصة بتسجيل المستحضر سوف تظهر صفحة "Product Details" حتى يتمكن ممثل الشركة من إضافة "Sub Product":

شاشة ال Legal status of product ستكون غير قابلة للتغيير بناءً على البيانات المسجلة سابقاً.

New Request

Application type Product Details Manufactures Marketing Authorization Legal status of Product Price Certificate Summary

STEP 2
Product Details

ID	Dosage Form	Primary Package	Packaging Size	Unit	Volume	Action
1			11	L	1	

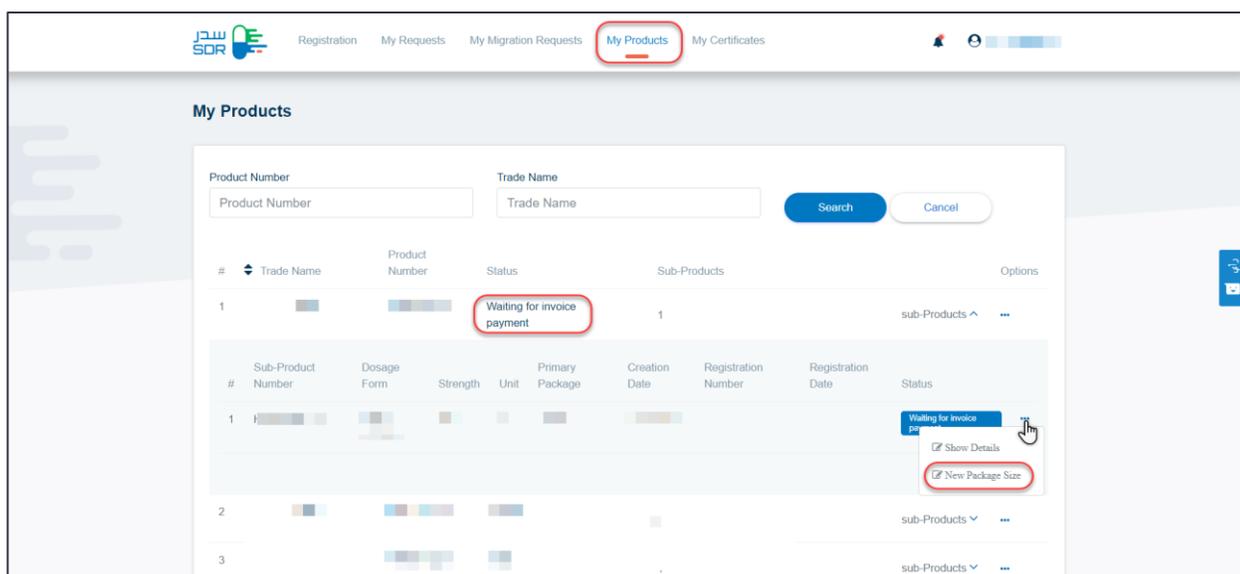
Previous Save and Continue later Next

- بعد الانتهاء من تعبئة جميع الخانات المطلوبة، يتم اصدار فاتورة سداد.
- تكون حالة الطلب "بانتظار سداد الفاتورة" "Waiting For Invoice Payment"



إضافة حجم عبوه لمنتج فرعي

يمكن لممثل الشركة إضافة حجم عبوه لمنتج فرعي بعد الانتهاء من تعبئة نموذج التسجيل وإصدار فاتورة سداد. وتكون حاله الطلب "بانتظار دفع الفاتورة" وحالة المنتج الفرعي "بانتظار دفع الفاتورة". حيث يجب على الشركة إضافة حجم العبوة الجديد قبل دفع الفاتورة حتى لا يتم احتساب أي رسوم إضافية عليها في التسجيل الجديد. لإضافة حجم عبوه جديدة بعد الانتهاء من تعبئة النموذج يقوم ممثل الشركة باختيار صفحة "My Products" يتم الضغط على الايقونة ثم اختيار "New Package Size" كما هو موضح بالشكل ادناه:

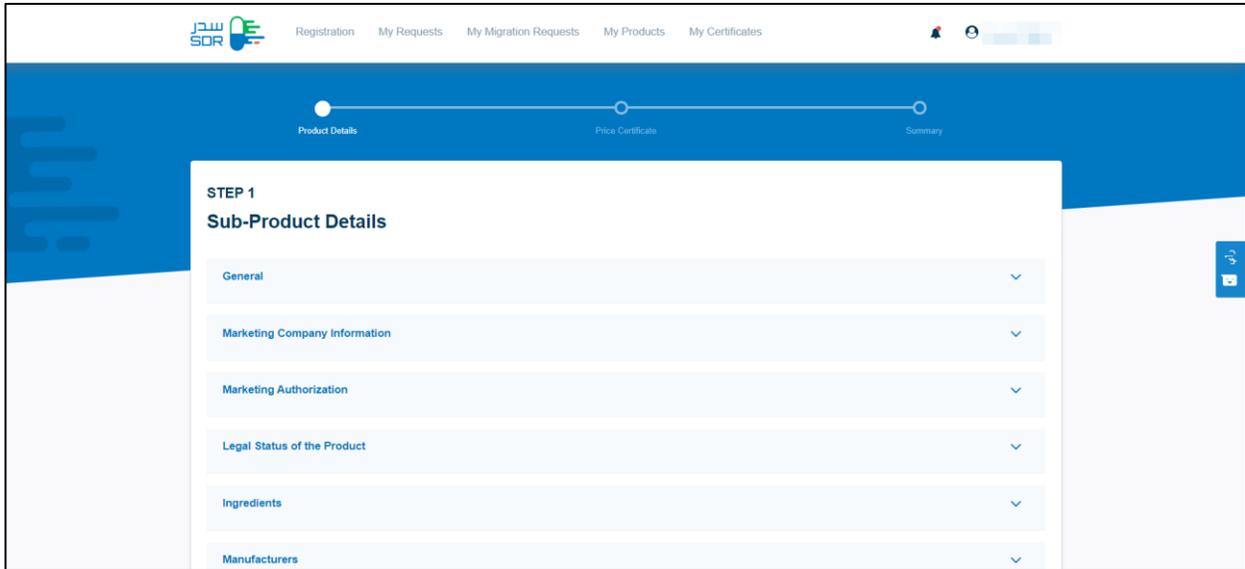


ملاحظة: لا يمكن اضافته حجم عبوه للمنتج الفرعي بعد سداد الفاتورة حتى يتم الانتهاء من دراسته وتكون حالته: "The request was accepted by the committee" ويتم احتساب رسوم على الطلب بعد ذلك.

الحالات التي تكون اضافته حجم عبوه للمنتج الفرعي برسوم هي:

- تم تسجيل المستحضر
- تم إلغاء تسجيل المستحضر
- تم انتهاء فترة تسجيل المستحضر
- شارفت شهادة التسجيل على الانتهاء

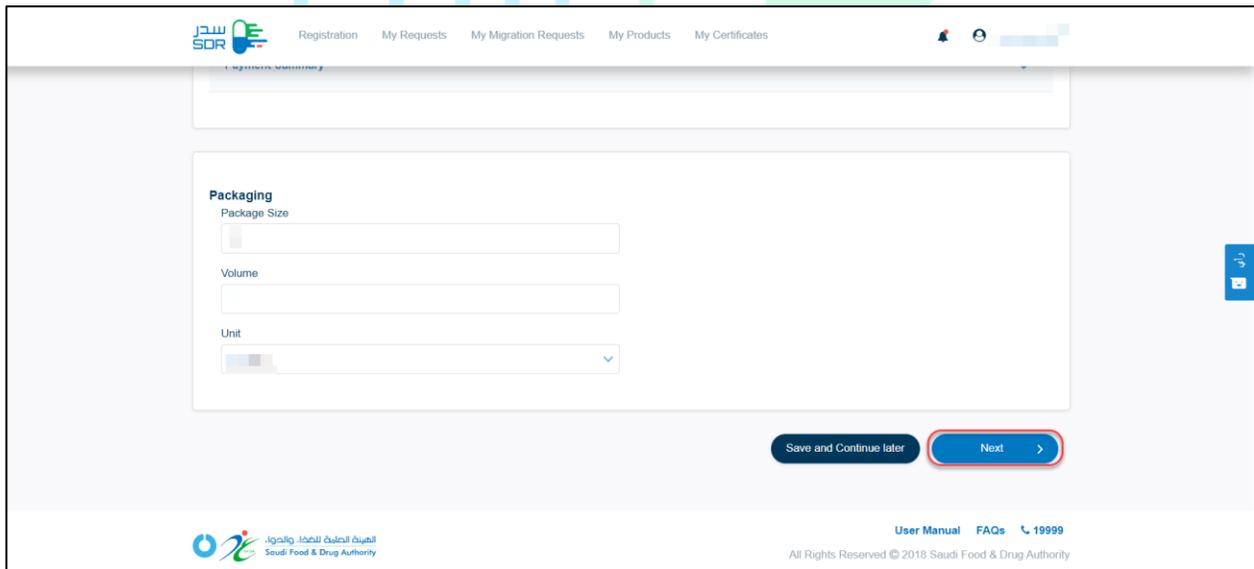
- يقوم النظام بعرض بيانات نموذج طلب التسجيل وفي نهاية الصفحة يتم تعبئة بيانات حجم العبوة، ثم الضغط على التالي.



The screenshot shows the 'STEP 1 Sub-Product Details' form. The form is divided into several sections, each with a dropdown arrow on the right:

- General
- Marketing Company Information
- Marketing Authorization
- Legal Status of the Product
- Ingredients
- Manufacturers

At the top of the page, there is a navigation menu with 'Registration', 'My Requests', 'My Migration Requests', 'My Products', and 'My Certificates'. A progress bar indicates the current step is 'Product Details', with 'Price Certificate' and 'Summary' as subsequent steps.



The screenshot shows the 'Packaging' section of the form. It includes the following fields:

- Package Size:
- Volume:
- Unit:

At the bottom of the form, there are two buttons: 'Save and Continue later' and 'Next >'. The 'Next >' button is highlighted with a red border.

The footer of the page contains the SDR logo, the text 'الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority', and the copyright notice 'All Rights Reserved © 2018 Saudi Food & Drug Authority'. There are also links for 'User Manual', 'FAQs', and a phone number '19999'.

- يتم الانتقال الى صفحة بيانات شهادة السعر وتعبأتها، بعد الانتهاء من تعبئة البيانات يتم الانتقال الى صفحة عرض ملخص الطلب، لرفع الطلب يتم تعبئة الخانات المطلوبة ثم اختيار "Submit"

ملاحظة:

في حال كان الطلب الأساسي معفي من الرسوم لا يعني ان المنتجات الفرعية معفية من الرسوم ايضا.

Price Certificate x

Pricing
Please enter the CIF and Currency, pricing department will study the request, if the product is not subject to pricing, CIF will not be included in the certificate

CIF Price Currency

Pricing in Origin Country

Ex-Factory Price ExFactory Price Currency Wholesale Price Wholesale Price Currency

Public Price Public Price Currency

Marketing Pricing
Please enter the price in countries where the product is marketed


Registration
My Requests
My Migration Requests
My Products
My Certificates

Product Details
Price Certificate
Summary

Summary

Cost	Vat Cost	Total
0	0	0

[Bill Details](#)

Declaration

By sending this request I hereby certify that the submitted are true and accurate and changes will not be made until they are approved by SFDA

Title Name

File Signature [Select file](#)

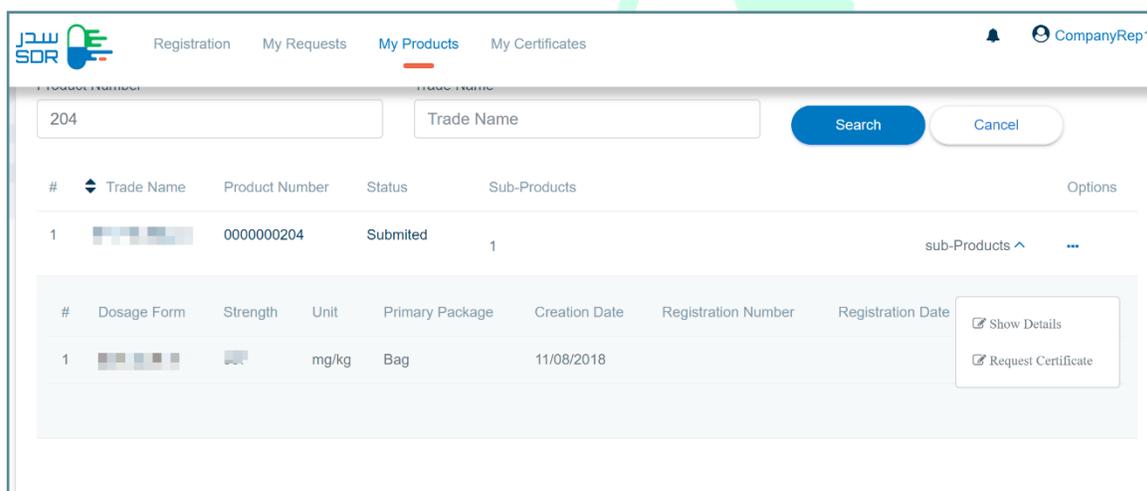
Company Stamp [Select file](#)

ملاحظات:

- في حال تم تقديم طلب حالته " The request was accepted by the committee " سوف يتم احتساب رسوم إضافية ويتم إنشاء فاتورة جديدة.
- لإضافة حجم عبوه لمستحضر معفي وجود طلب مستحضر معفي حالته " submit " وحاله المستحضر الفرعي "Waiting for upload file" يقوم النظام بعرض قائمة ال products. يقوم ممثل الشركة باختيار أحد sub product. يقوم النظام بعرض نموذج طلب تسجيل مستحضر من نوع "new Package Size" يقوم ممثل الشركة بتعبئة الطلب يقوم النظام بتحويل حالة الطلب "waiting for upload file"

الخطوة السابعة: طباعة الشهادات

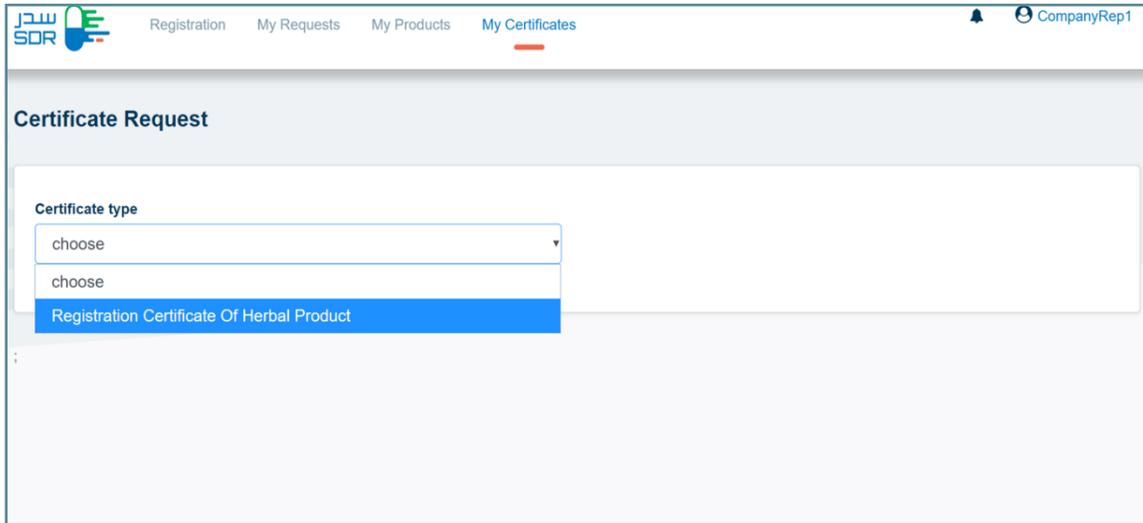
- بعد موافقة الهيئة على طلب تسجيل المستحضر يقوم ممثل الشركة بطلب طباعة الشهادة عن طريق التوجه لشاشة النظام واختيار "My Products" في الأعلى.
- اختيار اتخاذ اللازم والنقر على "Request Certificate" كما هو موضح أدناه:



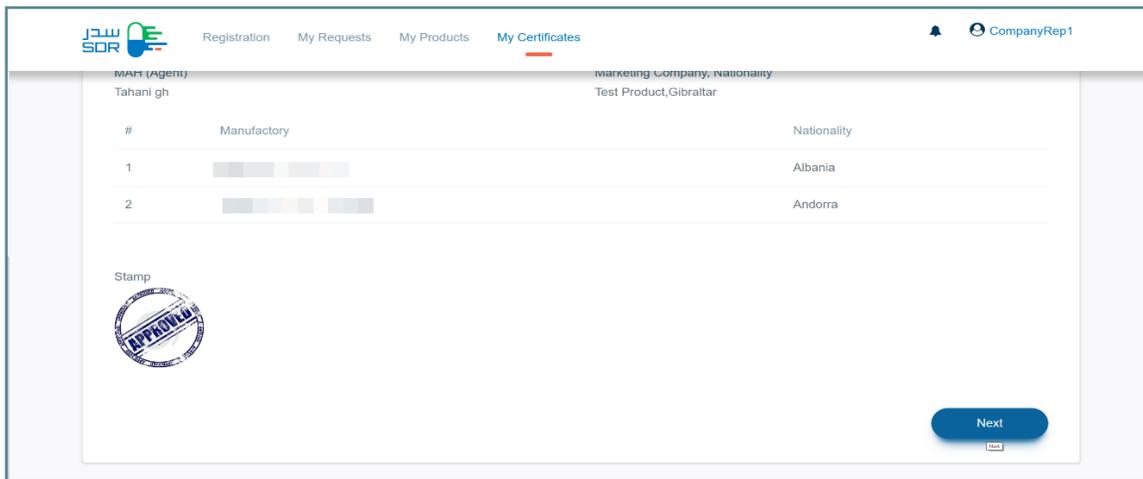
#	Trade Name	Product Number	Status	Sub-Products	Options
1		000000204	Submitted	1	sub-Products ^ ...

#	Dosage Form	Strength	Unit	Primary Package	Creation Date	Registration Number	Registration Date	Options
1			mg/kg	Bag	11/08/2018			Show Details Request Certificate

- اختيار نوع الشهادة التي يرغب ممثل الشركة بإصدارها وذلك بالانتقال من صفحة المنتجات الى صفحة الشهادات:



○ التأكد من معلومات المنتج ليتم اصدار الشهادة واختيار أيقونة “Next”



#	Manufactory	Nationality
1		Albania
2		Andorra

الضغط على طلب الفاتورة من القائمة اتخاذ اجراء لطلب الشهادة:

Fees

Payment Method	Issue Date	Payment Due
	03-12-2024	03-12-2024
1 hours 00 minutes To pay		

Cost	Vat Cost	Total	
			Bill Details ^

#	Dosage Form	Primary Package	Package Unit	Volume	Cost
1					

○ بعد السداد يمكن للممثل الشركة اصدار الشهادة عن طريق شاشة الشهادات.



[Registration](#)
[My Requests](#)
[My Products](#)
[My Certificates](#)



Certificate Request

Certificate type

choose

choose

Registration Certificate Of Herbal Product

Free Sales Certificate Of a Herbal Product

Certificate Of Pharmaceutical Product CPP

○ سوف تظهر الشهادة التي تم دفع المقابل المالي لإصدارها من خلال شاشة الشهادات الموضحة في اعلى الصفحة، ومن ثم اتخاذ الاجراء من خلال طباعة الشهادة.


Registration My Requests My Products **My Certificates**
🔔 🌐

Certificate Number

Trade Name

Certificate Type

Number of Certificate Requests : 1

#	Certificate number	Trade name	Certificate Type	Request date	
1			Registration Certificate Of Herbal Product	30/10/2018	<div style="border: 1px solid #ccc; padding: 2px; display: inline-block;"> <input type="button" value="Certificate details"/> </div> <div style="border: 1px solid #ccc; padding: 2px; display: inline-block; margin-top: 2px;"> <input type="button" value="Print certificate"/> </div>



○ شكل شهادة تسجيل مستحضر

Certificate No.: Issue Date: Expiry Date:	رقم الشهادة: تاريخ الاصدار: تاريخ الانتهاء:	شهادة تسجيل مستحضر عشبي Registration Certificate of a Herbal Product	الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority
		طريقة الوصف Legal Status	الاسم التجاري Trade Name
		الوكيل Marketing Authorization Holder (Agent)	الاسم الطبي Generic Name
		الشركة الصوقة و جنسيتها Marketing Company, Nationality	رقم التسجيل Registration Number
		الشركة الصانعة و جنسيتها Manufacturers, Nationality	الشكل الصيدلاني Dosage Form
			التركيز/الوحدة Product Strength
			مدة الصلاحية Shelf Life
			نوع العبوة Packaging Type
			حجم العبوة Packaging Size/Volume
			ظروف التخزين Storage Conditions

Stamp



ملاحظة: يمكن للعميل طلب شهادة من الأنواع التالية بنفس اجراءات العمل السابقة والتي تتكون من الشهادات التالية:

سدر
SDR

- شهادة تسجيل مستحضر صيدلاني
- شهادة تسجيل مستحضر بيطري
- شهادة تسجيل مستحضر عشبي
- شهادة حرية البيع
- شهادة مستحضر صيدلاني CPP

○ شهادة حرية البيع وشهادة مستحضر صيدلاني CPP: الشهادة الصادرة من السلطة الرقابية في الدولة التي يتم فيها التصنيع كاملا أو الخطوات النهائية لتصنيع المستحضر الصيدلاني أو من بلد الشركة الدوائية المسوقة.

ملاحظة: شهادة حرية البيع وشهادة مستحضر صيدلاني CPP يمكن الحصول عليها بعد التسجيل.

الخطوة الثامنة: طلب تعديل " Variation Request "

- عندما تكون حالة المنتج مسجل، يمكن للمستخدم طلب تعديل على بيانات المستحضر المسجل، أنواع التعديلات التي يمكن تقديمها هي:
1. تعديل يتعلق بالجودة
 2. تعديل للأمنية والفعالية
 3. التعديلات الإدارية

#	Trade Name	Product Number	Status	Sub-Products	Options
1		0000002422	Draft	4	sub-Products v ...
2		000000424	Submitted	5	sub-Products ^ ...

#	Sub-Product Number	Dosage Form	Strength	Unit	Primary Package	Creation Date	Registration Number	Registration Date	Status
1	H000000989			µg/m3	Screw cap	22/12/2018		25/12/2018	The product
2	H000000990			µg	Jar	22/12/2018		25/12/2018	Submitted
3	H000000992			kg	Ampoule	22/12/2018		04/02/2019	Submitted
4	H0000001002			billion organisms/ml	Stopper	22/12/2018			Submitted
5	H0000001013			µg	Dredging container	23/12/2018			Submitted

43 صفحة طلب تعديل

- بعد اختيار طلب تعديل يقوم النظام بتحويل الشركة الى الشاشة أدناه لاستكمال البيانات المطلوبة:

Variation Request Detail

Request type
Application Concern

Choose

Proposed Changes

Current	Proposed			
<input type="text" value="Current"/>	<input type="text" value="Proposed"/>	<input type="button" value="+ Add"/>	<input type="button" value="Cancel"/>	

Number And Title Of Variations

Choose +

Change affect
Does this change affect the last updated drug application form?

No

Yes

44 استكمال بيانات -صفحة طلب التعديل

Variation Request Detail

Application Concern Types

- IV.PMF/VAMF

Number And Title Of Variations

Choose +

72.Change in the name and/or address of a blood establishment including blood/plasma collection centers

Procedure Type	Implementation Date
<input type="text" value="IA"/>	<input type="text"/>

Changes approval

Note that the variation request may affect information in certificates related to the sub product, please request a new certificate once variation is approved to reflect those updates

45 استكمال بيانات -صفحة طلب التعديل

- بعد استكمال البيانات المطلوبة من قبل النظام والنقر على NEXT سيقوم النظام بتحويل الشركة الى صفحة تفاصيل المنتج كما هو موضح أدناه:

Fees

Payment Method 	Issue Date 03-09-2024	Payment Due 03-09-2024
1 hours 00 minutes To pay		
Cost	Vat Cost	Total
5500	825	6325
Bill Details ▾		

Invoice Type

Issuing tax invoice

Issuing simplified invoice

Please be aware that you can only convert a simplified invoice into a tax invoice if you specify the invoice type as 'tax invoice' before proceeding with payment through Amaly platform

- في حال إعادة الطلب للشركة لأحد الأسباب التالية، بإمكان الشركة استكمال الطلب من خلال شاشة النظام My requests كما هو موضح في الصورة ادناه:

- The request is rejected because of incomplete request
- The request is rejected to exceed the time limit for answering the query
- The request is rejected because lack of requirement


Registration
My Requests
My Migration Requests
My Products
My Certificates

MAH
MAH

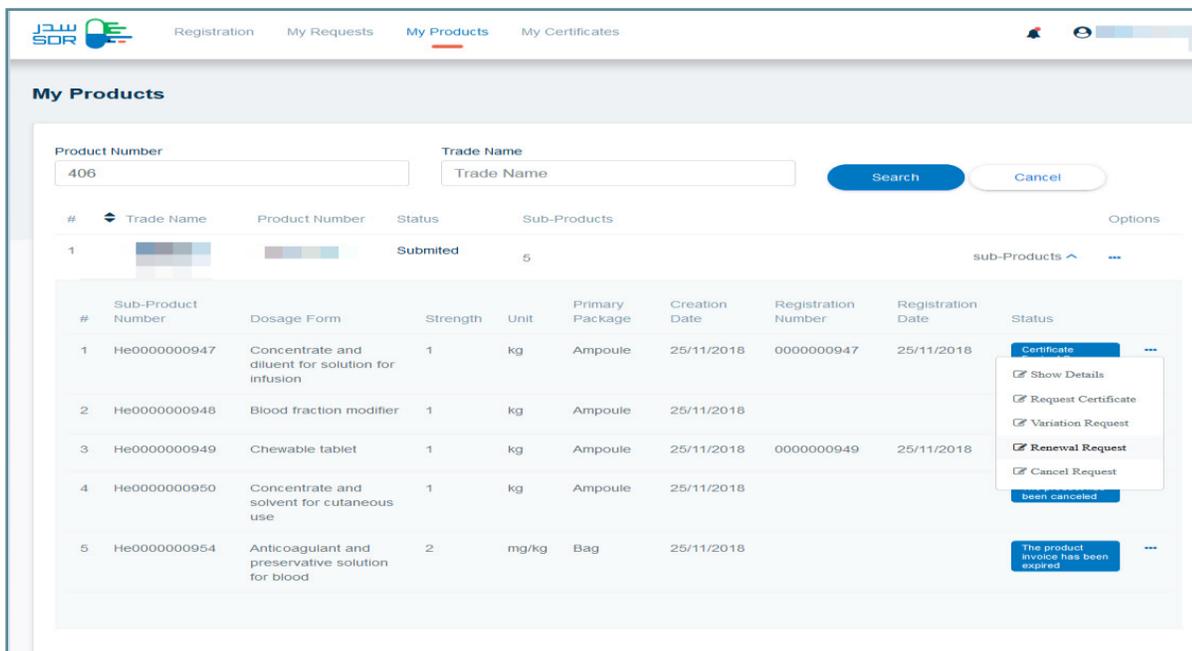
Request Status
The request is rejected to exceed the time limit for answering the query ▾

#	Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Type	Status	Details
1	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	Human Medicinal Product	Version Request	The request is rejected to exceed the time limit for answering the query	Details ^
2	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	Human Medicinal Product	New Request	The request is rejected to exceed the time limit for answering the query	Details ▾
Last Update Date: 23/10/2022 Sub Product Trade Name: Zia Pena						<input type="button" value="Apply"/>		
3	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	Human Medicinal Product	New Request	The request is rejected to exceed the time limit for answering the query	Details ^
4	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	Human Medicinal Product	New Request	The request is rejected to exceed the time limit for answering the query	Details ^
5	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	Herbal Product	New Request	The request is rejected to exceed the time limit for answering the query	Details ^

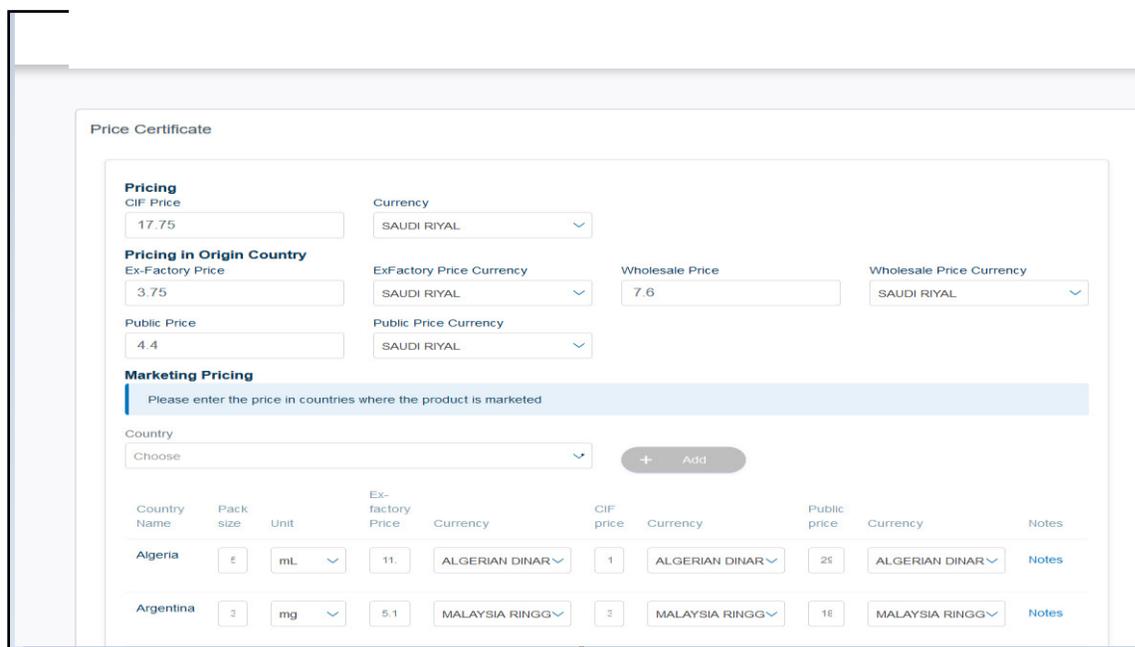
ملاحظة: في حال عدم رغبة الشركة بتغيير بيانات المستحضر المسجل سيقوم النظام بتحويل الشركة لصفحة الفاتورة

الخطوة التاسعة: تجديد المنتج

يمكن للشركة طلب تجديد المستحضر المسجل عند انتهاء فترة تسجيله أو قبل 6 أشهر من انتهاء الشهادة كما هو موضح في الشكل ادناه:



#	Trade Name	Product Number	Status	Sub-Products	Options				
1			Submitted	5	sub-Products ^ ...				
#	Sub-Product Number	Dosage Form	Strength	Unit	Primary Package	Creation Date	Registration Number	Registration Date	Status
	1	Concentrate and diluent for solution for infusion	1	kg	Ampoule	25/11/2018	0000000947	25/11/2018	Certificate
	2	Blood fraction modifier	1	kg	Ampoule	25/11/2018			Show Details
	3	Chewable tablet	1	kg	Ampoule	25/11/2018	0000000949	25/11/2018	Request Certificate
	4	Concentrate and solvent for cutaneous use	1	kg	Ampoule	25/11/2018			Variation Request
	5	Anticoagulant and preservative solution for blood	2	mg/kg	Bag	25/11/2018			Renewal Request



Country	Pack size	Unit	Ex-factory Price	Currency	CIF price	Currency	Public price	Currency	Notes
Algeria	5	mL	11	ALGERIAN DINAR	1	ALGERIAN DINAR	2%	ALGERIAN DINAR	Notes
Argentina	3	mg	5.1	MALAYSIA RINGG	3	MALAYSIA RINGG	1%	MALAYSIA RINGG	Notes

بعد ذلك تقوم الشركة بالنقر على ايقونة Submit وذلك لاستعراض الاسعار ورسوم التجديد كما هو موضح في الصورة أعلاه

Fees

Payment Method	Issue Date	Payment Due
	04-02-2019	04-02-2019
2 hours 00 minutes To pay		

Cost	Vat Cost	Total
8800	440	9240

#	Dosage Form	Strength	Strength Unit	Primary Package	Package Unit	Volume	Cost
1	Concentrate and diluent for solution for infusion	1	kg	Ampoule	g	1	8800

[Submit](#)

ملاحظات:

- صفحة التسعير وصفحة الفاتورة جميعهم في صفحة واحدة تعرض للشركة بعد النقر على Submit من خلال الصفحة الخاصة بتجديد المنتج.
- لإصدار شهادة جديده بتاريخ جديد يجب ان تكون حالة شهادة الطلب "Expired", "Expired Soon".
- وفي حال كانت حالة المستحضر "expired soon" سوف تظهر الرسالة التالية: " بعد قبول طلب التجديد, لا يمكن طلب شهادة جديدة للمستحضر الا في حال كانت حالة الشهادة الحالية منتهية
- *after receiving the renewal approval, you cannot request a new certificate until the "current certificate becomes expired*
- بعد قبول طلب التجديد, لا يمكن طلب شهادة جديدة للمستحضر الا في حال كانت حالة الشهادة الحالية " منتهية "

الخطوة العاشرة: الاعتراض

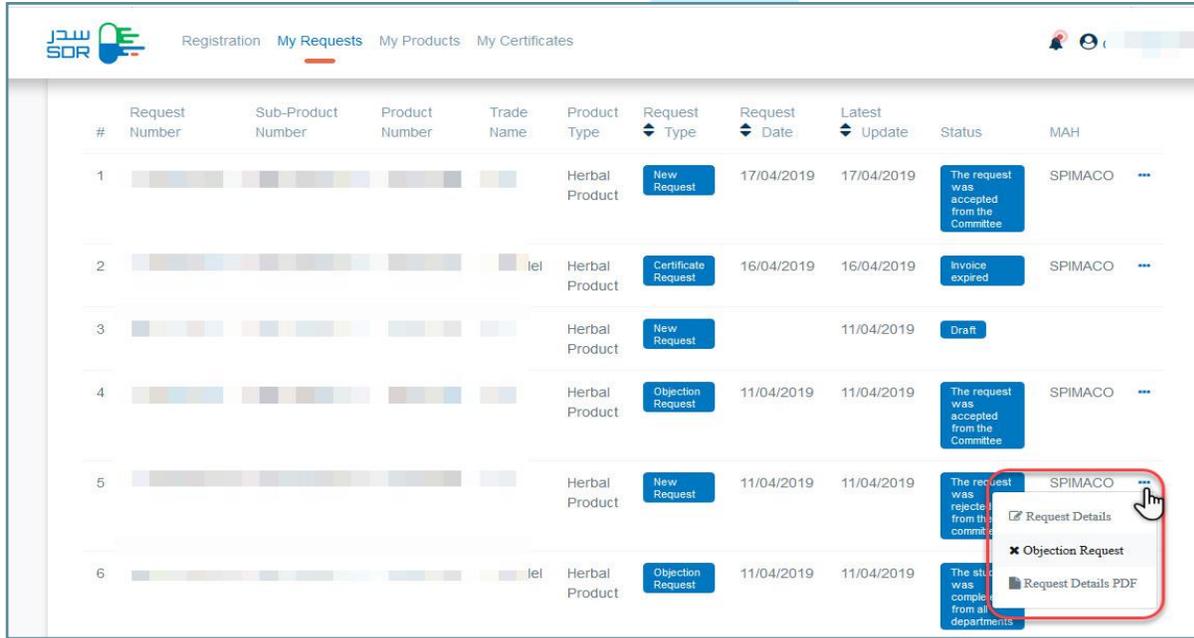
يسمح النظام لشركات الأدوية بتقديم الاعتراض على الطلبات التي تكون حالتها كالتالي:

- تم رفض الطلب من اللجنة.
- تم تسجيل المستحضر.
- تم قبول الطلب من اللجنة.

أنواع الاعتراضات التي يمكن عملها من خلال نظام سدر حسب حالة الطلب:

- في حال تم قبول طلب تسجيل المستحضر: يسمح النظام لممثل الشركة الاعتراض على السعر والاعتراض على الصلاحية.
- في حال تم قبول الطلب الخاص بالتعديل "Variation": يسمح النظام لممثل الشركة الاعتراض على السعر فقط.
- في حال تم رفض طلب تسجيل المستحضر يسمح النظام لممثل الشركة الاعتراض على قرارات الرفض.
- في حال تم رفض طلب تعديل سعر يسمح النظام لممثل الشركة الاعتراض على قرارات الرفض.
- في حال رفض طلب تعديل لبيانات غير السعر، لا يسمح لممثل الشركة بطلب اعتراض ويقوم بطلب تعديل مرة أخرى.
- في حال رفض طلب تعديل للسعر وبيانات أخرى في نفس الطلب، يسمح لممثل الشركة الاعتراض على قرار رفض السعر فقط ويقوم بتقديم طلب تعديل مرة أخرى لبقية البيانات.
- في حال رفض طلب الغاء، يسمح لممثل الشركة الاعتراض على قرار الرفض.
- في حال رفض طلب تجديد، يسمح لممثل الشركة الاعتراض على قرار الرفض.
- في حال قبول طلب التجديد، لا يسمح لممثل الشركة الاعتراض على أي طلب تم رفضه قبل تاريخ التجديد.

يتاح لشركة المستحضر بعد النقر على طلب اعتراض من خلال الشاشة التالية تعبئة النموذج وهو سبب الاعتراض وأيضا تفاصيل الاعتراض.



#	Request Number	Sub-Product Number	Product Number	Trade Name	Product Type	Request Type	Request Date	Latest Update	Status	MAH
1					Herbal Product	New Request	17/04/2019	17/04/2019	The request was accepted from the Committee	SPIMACO
2				lel	Herbal Product	Certificate Request	16/04/2019	16/04/2019	Invoice expired	SPIMACO
3					Herbal Product	New Request		11/04/2019	Draft	
4					Herbal Product	Objection Request	11/04/2019	11/04/2019	The request was accepted from the Committee	SPIMACO
5					Herbal Product	New Request	11/04/2019	11/04/2019	The request was rejected from the committee	SPIMACO
6				lel	Herbal Product	Objection Request	11/04/2019	11/04/2019	The status was completed from all departments	

The dropdown menu for request 5 shows the following options:

- Request Details
- Objection Request
- Request Details PDF


 Registration My Requests **My Products** My Certificates companyrep4

Objection Request

Objection Request Details

Fees

Payment Method: 
 Issue Date: 17-04-2019
 Payment Due: 17-04-2019

4 hours 00 minutes To pay

Cost	Vat Cost	Total	
1000	50	1050	Bill Details ^

#	Dosage Form	Strength	Strength Unit	Primary Package	Package Unit	Volume	Cost
1	Concentrate and diluent for solution for infusion	1	mg	Ampoule	g	1	1000

[Submit](#)


 Registration My Requests **My Products** My Certificates companyrep4

Price Certificate

Last Approved Pricing

Certificate

Anatomical Therapeutic Chemical (ATC)

Packaging

Shelf Life

Proposed Storage

Animal Material

Reason of objection: Choose

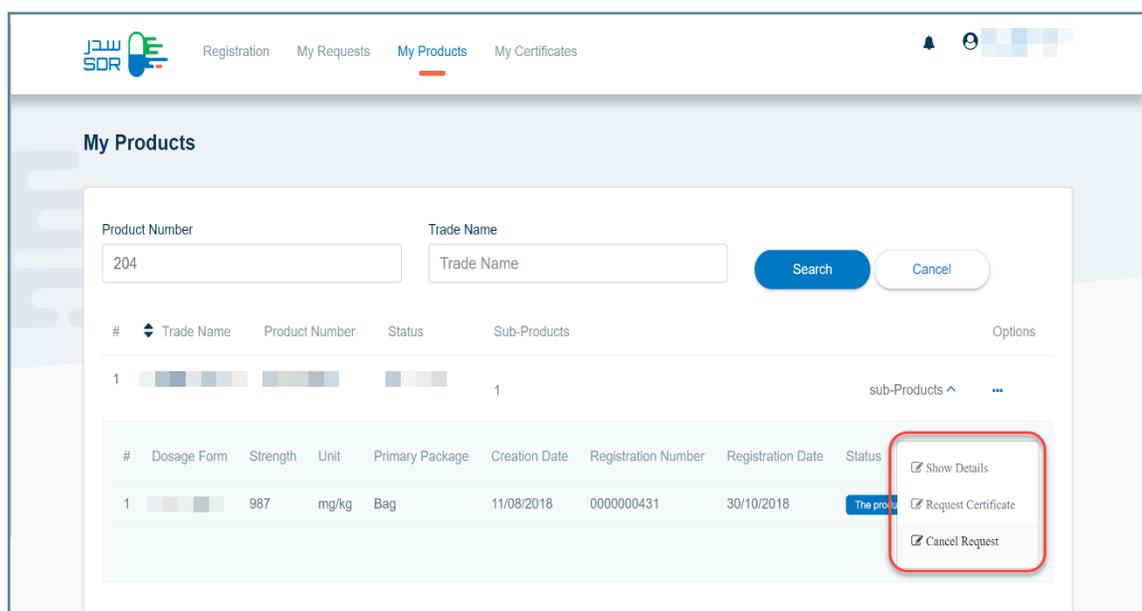
Objection Details:

[Next](#)

- بعد تعبئة البيانات الخاصة بطلب الاعتراض سواءً اعتراض على القبول أو الرفض يظهر النظام شاشة السداد والضغط على "Submit" وبعدها تتحول حالة الطلب كالتالي:
- تكون حالة الطلب " Waiting For Invoice Payment " بانتظار دفع الفاتورة.
 - بعد الدفع تتحول حالة الطلب " Waiting Upload Files " بانتظار رفع ملفات الطلب.
 - وبعد الرفع بنجاح تكون حالة الطلب " Under Technical Validation " او " Need Manuel Technical Validation " حتى يقوم النظام بالتحقق الآلي من الملفات حسب المتطلبات وحسب نوع الطلب.

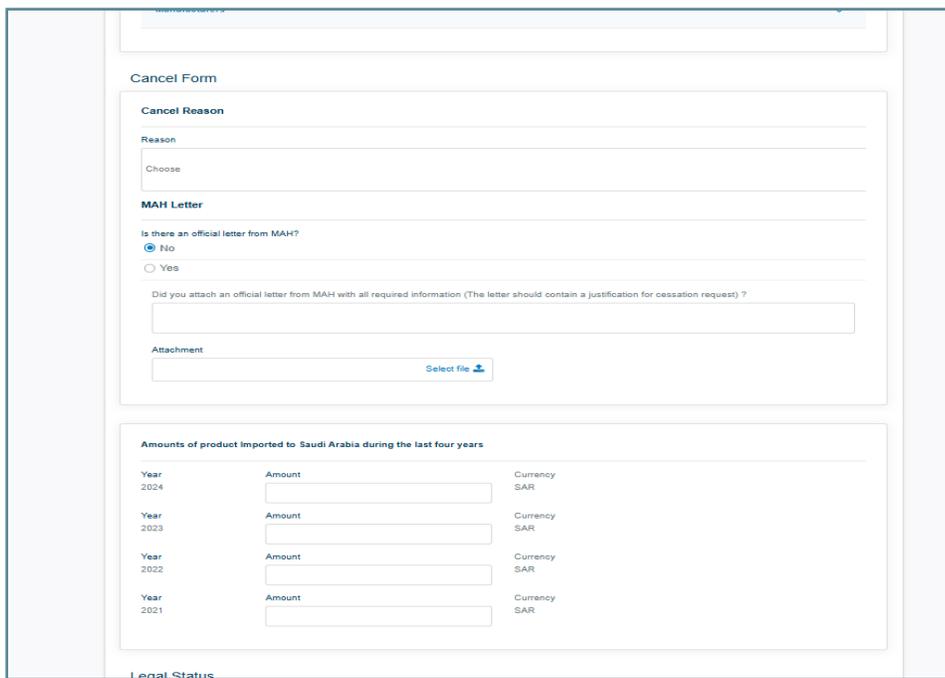
الخطوة الحادي عشر: إلغاء المستحضر.

عند الإلغاء يجب ان تكون حالة المنتج " تم تسجيل المستحضر " في صفحة التسجيل.
طريقة الإلغاء هي بالتوجه للمنتجات المسجلة واختيار خانة اتخاذ الإجراء واختيار "Cancel Request"



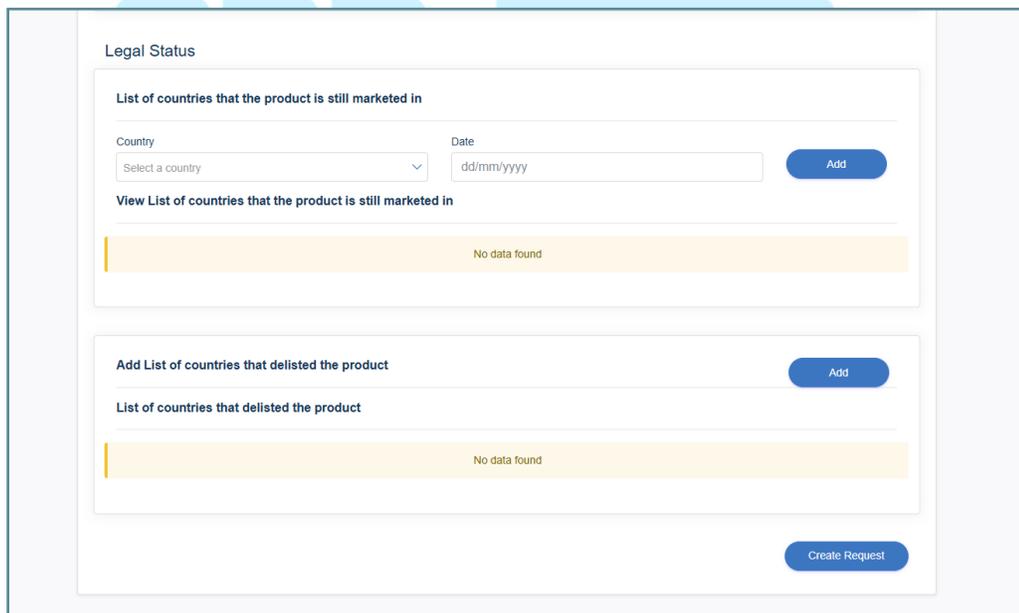
The screenshot displays the 'My Products' interface. At the top, there are navigation tabs: 'Registration', 'My Requests', 'My Products' (selected), and 'My Certificates'. The main content area has a search section with 'Product Number' (204) and 'Trade Name' fields, and 'Search' and 'Cancel' buttons. Below this is a table with the following columns: '#', 'Trade Name', 'Product Number', 'Status', 'Sub-Products', and 'Options'. The table contains one row with a product ID of 1. The 'Options' column for this product is highlighted with a red box, showing three actions: 'Show Details', 'Request Certificate', and 'Cancel Request'.

سيتم استعراض صفحة النظام الخاصة بنموذج طلب الإلغاء يتم الحقول المطلوبة الموضحة في الصورة



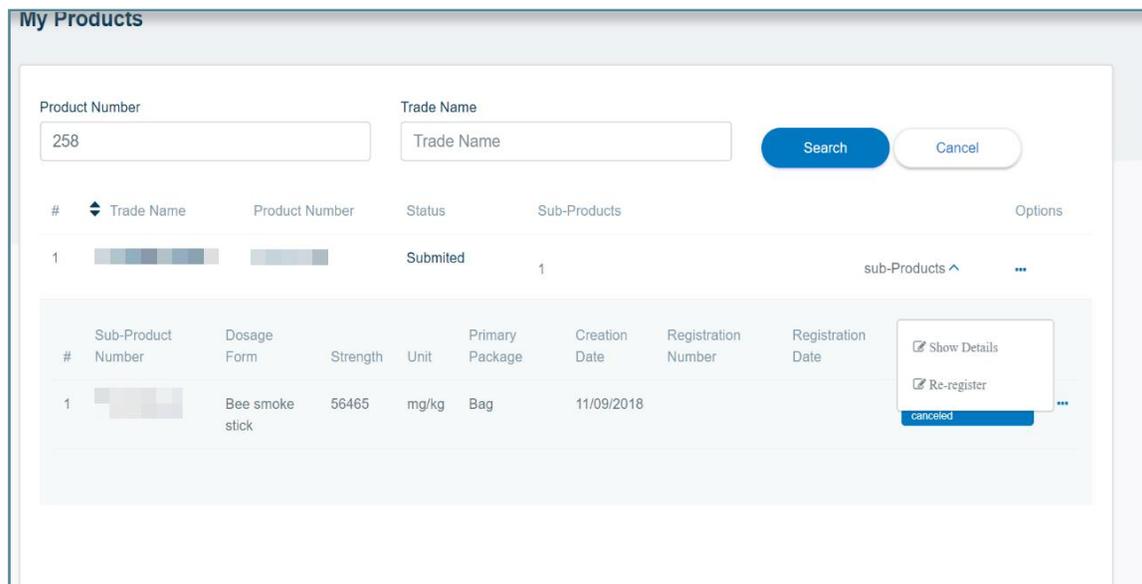
Year	Amount	Currency
2024	<input type="text"/>	SAR
2023	<input type="text"/>	SAR
2022	<input type="text"/>	SAR
2021	<input type="text"/>	SAR

والضغط على خيار "Cancel Request" في أسفل الصفحة



الخطوة الثاني عشر: إعادة تسجيل الطلب الملغي

في حال رغبة شركة المستحضرات بإعادة تسجيل الطلب الملغي، تقوم شركة المستحضرات التوجه لصفحة المنتجات ومن ثم اختيار المنتج الملغي المراد إعادة تسجيله كما هو موضح في الصورة أدناه:



My Products

Product Number: 258
Trade Name: Trade Name
Search Cancel

#	Trade Name	Product Number	Status	Sub-Products	Options
1			Submitted	1	sub-Products ^ ...

#	Sub-Product Number	Dosage Form	Strength	Unit	Primary Package	Creation Date	Registration Number	Registration Date	Options
1		Bee smoke stick	56465	mg/kg	Bag	11/09/2018			<input checked="" type="checkbox"/> Show Details <input checked="" type="checkbox"/> Re-register canceled

بعد الضغط على خانة الـ Re-register يقوم النظام بتوجيه المستخدم بتحويله الى صفحة الـ Summary مع عرض البيانات التي تسجيلها سابقا وبعد النقر على Submit يقوم النظام بتحويل الشركة لصفحة الفاتورة كما هو موضح بالصورة أدناه حتى يتمكن ممثل شركة من دفع الرسوم واستكمال الخطوات:

Summary

Fees

Cost	Vat Cost	Total
0	0	0

[Bill Details](#) ▾

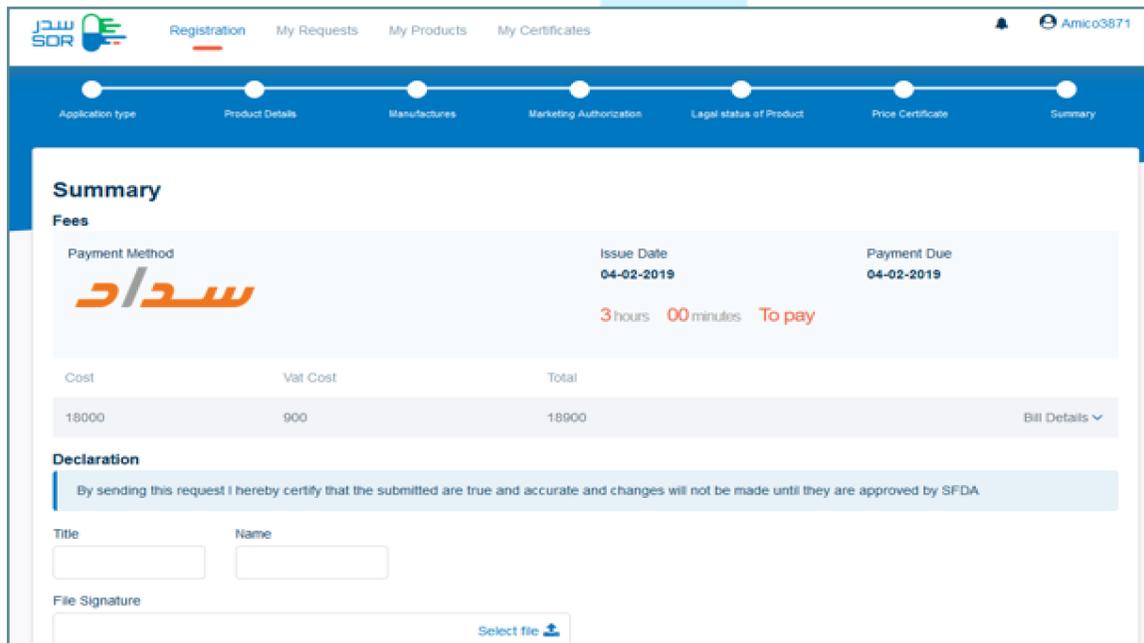
Declaration

By sending this request I hereby certify that the submitted are true and accurate and changes will not be made until they are approved by SFDA

Title Name

File Signature [Select file](#) 

Company Stamp [Select file](#) 



SDR SDR Registration My Requests My Products My Certificates Amico3871

Application type Product Details Manufactures Marketing Authorization Legal status of Product Price Certificate Summary

Summary

Fees

Payment Method	Issue Date	Payment Due
	04-02-2019	04-02-2019
3 hours 00 minutes To pay		

Cost	Vat Cost	Total
18000	900	18900

[Bill Details](#) ▾

Declaration

By sending this request I hereby certify that the submitted are true and accurate and changes will not be made until they are approved by SFDA

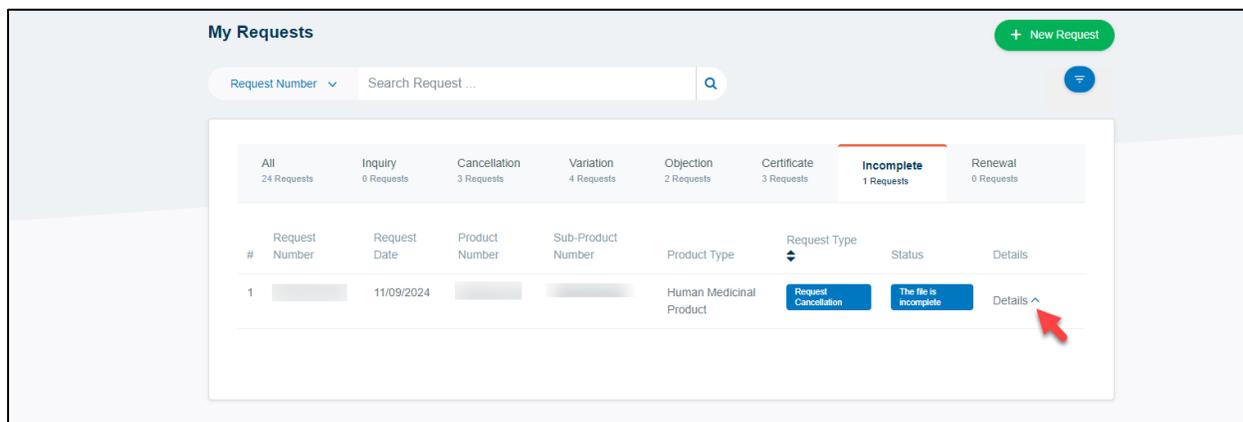
Title Name

File Signature [Select file](#) 

حالات النظام

Request status	Description
Waiting for Invoice Payment	After completing the application When issuing a query invoice Issuing an invoice to complete the file es
Waiting Upload Files	- Upon payment of the application for registration, objection or adjustment. - After reviewing the reason for technical verification failed. -When file upload fails
Under Technical Validation	- When files are uploaded successfully
Failed Technical Validation	- When file doesn't pass the technical verification
Invoice Expired	- When the invoice period expired
Under Studying	-When the file is accepted by the SFDA team in the verification step
The Product has Been Cancelled	-When the cancellation request is accepted by the Committee's officer
At the Relevant Department	-When referred to the concerned department -When the query is accepted by the concerned department
The Query Has Been Completed At "Department Name"	-After the management reviewing the query and approving
Waiting for Query Reply	- If a review is completed from all of the departments -If the review of the query is completed from one or more departments and there is no query from the rest of the departments and the final report was created so that the status of the application was "completed By the concerned department. -if the answer of the query is rejected through the product manager.
The Query was Answered	-When the company representative replies
Inquiry Incoming	-Only a company representative is allowed to read the inquiry and cannot reply to it. -The company representative can view inquiries through the "view request details" page, where a card containing the inquiry information will be added. -The company representative is allowed to reply to the inquiry by going to the "inquiries" page if the Wave has been sent, as is the current situation.

الخطوة الثالثة عشر: استعراض أسباب رفض الطلب الملغى:
عندما ينوي ممثل الشركة مراجعة سبب رفض الهيئة لطلب إلغاء المنتج، يجب أن تكون حالة المنتج "الملف غير مكتمل".
ومن ثم الانتقال إلى "التفاصيل" كما هو موضح أدناه واختيار "الطلب مكتمل".

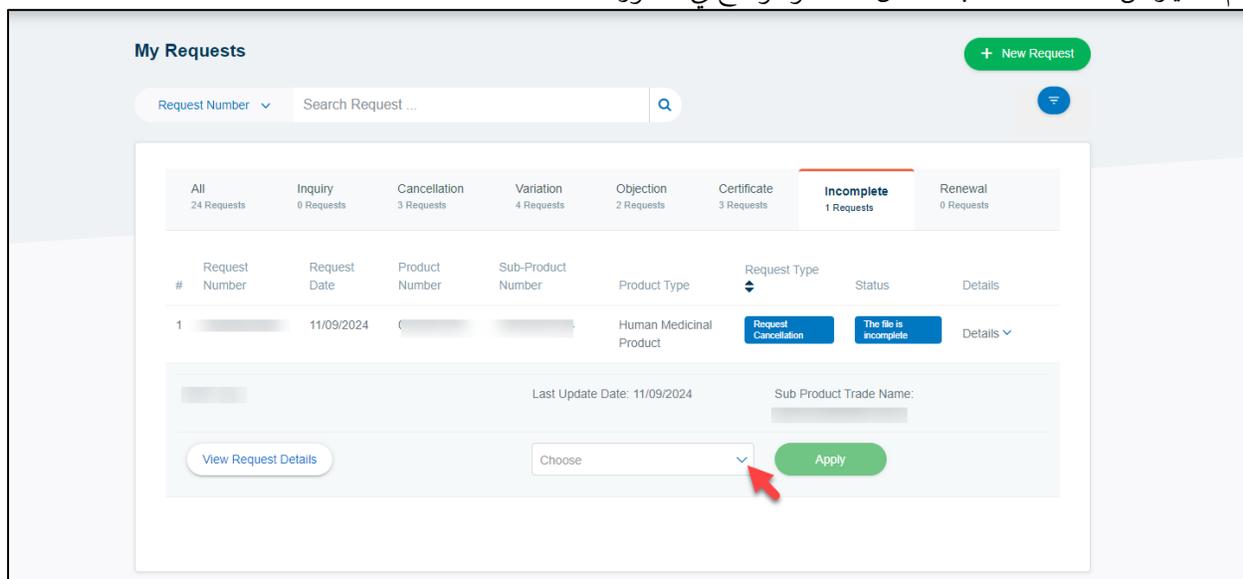


My Requests + New Request

Request Number Search Request ...

All	Inquiry	Cancellation	Variation	Objection	Certificate	Incomplete	Renewal	
24 Requests	0 Requests	3 Requests	4 Requests	2 Requests	3 Requests	1 Requests	0 Requests	
#	Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Type	Status	Details
1		11/09/2024			Human Medicinal Product	Request Cancellation	The file is incomplete	Details ^

ثم اختيار من القائمة "الطلب مكتمل" كما هو موضح في الصورة أدناه:



My Requests + New Request

Request Number Search Request ...

All	Inquiry	Cancellation	Variation	Objection	Certificate	Incomplete	Renewal	
24 Requests	0 Requests	3 Requests	4 Requests	2 Requests	3 Requests	1 Requests	0 Requests	
#	Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Type	Status	Details
1		11/09/2024			Human Medicinal Product	Request Cancellation	The file is incomplete	Details v

Last Update Date: 11/09/2024 Sub Product Trade Name:

My Requests + New Request

Request Number Q

All	Inquiry	Cancellation	Variation	Objection	Certificate	Incomplete	Renewal
24 Requests	0 Requests	3 Requests	4 Requests	2 Requests	3 Requests	1 Requests	0 Requests

Request #	Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Type	Status	Details
1	3	11/09/2024			Human Medicinal Product	Request Cancellation	The file is incomplete	Details

Last Update Date: 11/09/2024 Sub Product Trade Name:

[View Request Details](#) Apply

Complete Request

My Requests + New Request

Request Number Q

All	Inquiry	Cancellation	Variation	Objection	Certificate	Incomplete	Renewal
24 Requests	0 Requests	3 Requests	4 Requests	2 Requests	3 Requests	1 Requests	0 Requests

Request #	Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Type	Status	Details
1	3	11/09/2024			Human Medicinal Product	Request Cancellation	The file is incomplete	Details

Last Update Date: 11/09/2024 Sub Product Trade Name:

[View Request Details](#) Apply

Complete Request

الضغط على " تفاصيل " للذهاب لصفحة استعراض تفاصيل الطلب

Advanced Filters Search Clear all

Total Records: 1

Request Number	Product Number	Sub-Product Number	Sub-Product Trade Name	Drug Type	Creation/Resubmission Date	Request Type	Latest Update	MAH	Status	Details
				Generic(Multisource) Drug		Request Cancellation	21/08/2024	Cigalah	The file is incomplete	

ثم اختيار "تفاصيل طلب الإلغاء" وقم باستعراض سبب الرفض

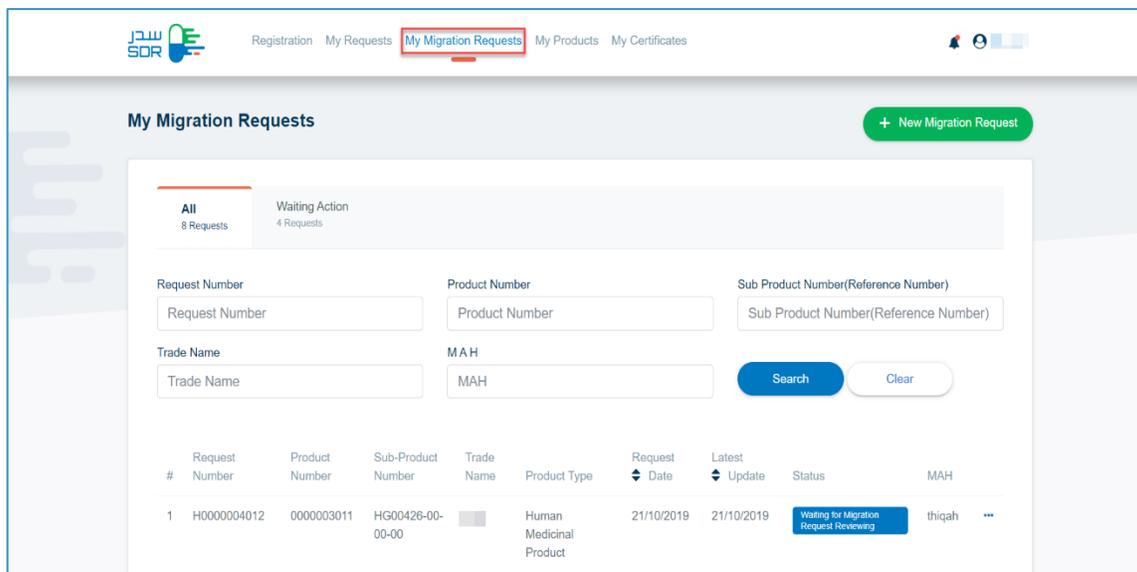
Request Details

History

Cancellation Request Details	>
General	>
Marketing Company Information	>
Reference Generic Drug General Information	>
Marketing Authorization	>
Legal Status of the Product	>
Ingredients	>
Proposed Indications	>
Strength of composition	>

عملية ترحيل البيانات

ترحيل البيانات هي عملية نقل بيانات المستحضر من نظام SDR إلى نظام E-SDR مع ملاحظة أن ترحيل بيانات المستحضرات سيكون للمستحضرات التي انتهت جميع الاجراءات التنظيمية في النظام السابق. بعد تسجيل الدخول على النظام يقوم المستخدم بالضغط على أيقونة طلبات الترحيل “My migration Request” في الشريط أعلى الصفحة.



Request #	Request Number	Product Number	Sub-Product Number	Trade Name	Product Type	Request Date	Latest Update	Status	MAH
1	H0000004012	0000003011	HG00426-00-00-00		Human Medicinal Product	21/10/2019	21/10/2019	Waiting for Migration Request Reviewing	thiqah

من صفحة طلبات الترحيل يتيح النظام خاصية تسمح للمستخدم بطلب ترحيل بيانات جديد، استعراض طلبات الترحيل وحالتها، واستعراض طلبات الترحيل بانتظار اتخاذ إجراء.

طلب ترحيل بيانات جديد

لطلب ترحيل جديد يقوم المستخدم بالضغط على أيقونة "New migration Request" في أعلى يمين الصفحة.

بعدها سوف يعرض النظام المنتجات المسجلة في نظام SDR المرتبط بنفس الحساب الرئيسي الخاص بممثل الشركة كما هو موضح أدناه:

عند الضغط على الأيقونة بجانب الطلبات، سيتيح للمستخدم ثلاث خيارات:

Product PDF Details

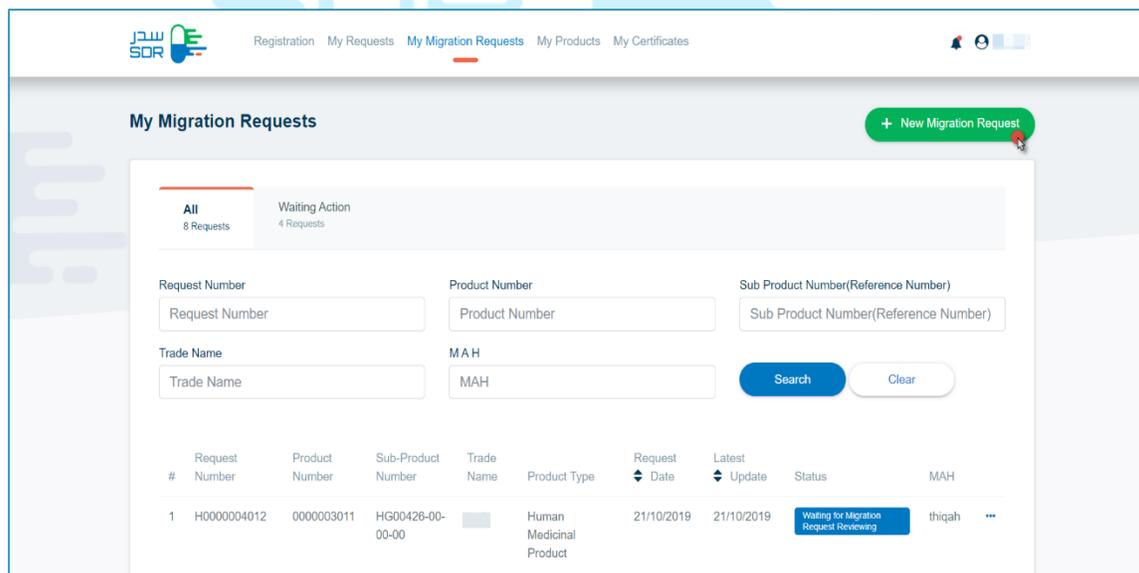
○ يتيح هذا الخيار استعراض تفاصيل المنتج

Migration as a product

○ يتيح هذا الخيار بترحيل المنتج من سدر (SDR).

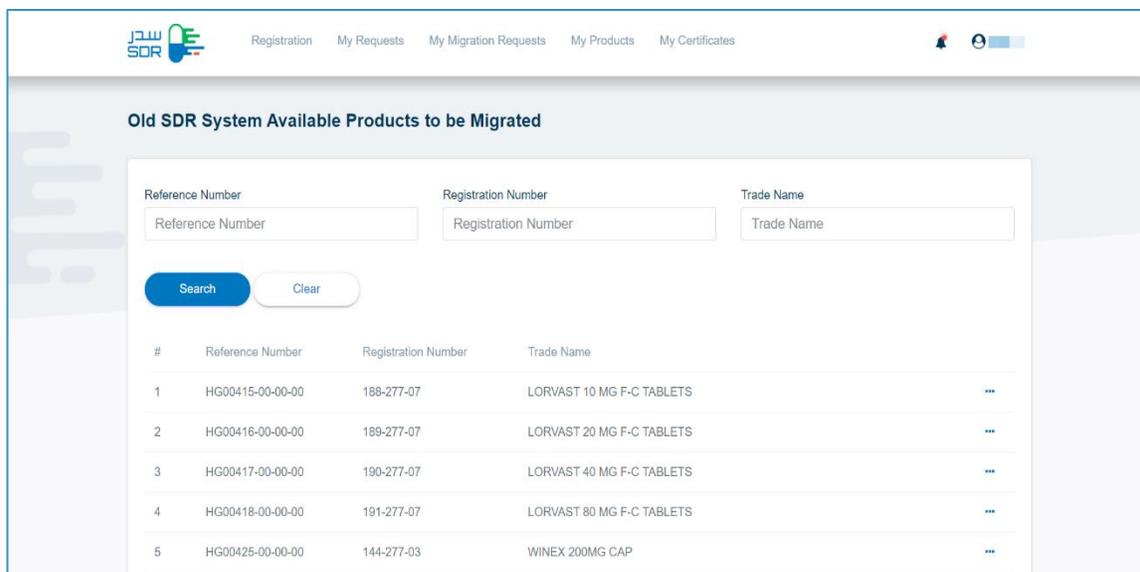
Migration as a sub product

○



The screenshot displays the 'My Migration Requests' page in the SDR system. The page includes a navigation menu at the top with options: Registration, My Requests, My Migration Requests (selected), My Products, and My Certificates. A '+ New Migration Request' button is visible in the top right corner. Below the navigation, there are two tabs: 'All' (8 Requests) and 'Waiting Action' (4 Requests). The main content area features search filters for Request Number, Product Number, Sub Product Number (Reference Number), Trade Name, and MAH. A 'Search' button and a 'Clear' button are provided. Below the filters is a table with the following columns: #, Request Number, Product Number, Sub-Product Number, Trade Name, Product Type, Request Date, Latest Update, Status, and MAH. The table contains one row of data:

#	Request Number	Product Number	Sub-Product Number	Trade Name	Product Type	Request Date	Latest Update	Status	MAH
1	H000004012	0000003011	HG00426-00-00-00		Human Medicinal Product	21/10/2019	21/10/2019	Waiting for Migration Request Reviewing	thiqah



#	Reference Number	Registration Number	Trade Name
1	HG00415-00-00-00	188-277-07	LORVAST 10 MG F-C TABLETS
2	HG00416-00-00-00	189-277-07	LORVAST 20 MG F-C TABLETS
3	HG00417-00-00-00	190-277-07	LORVAST 40 MG F-C TABLETS
4	HG00418-00-00-00	191-277-07	LORVAST 80 MG F-C TABLETS
5	HG00425-00-00-00	144-277-03	WINEX 200MG CAP

○ يتيح هذا الخيار بترحيل بيانات مستحضر فرعي من سدر (SDR) في حال المستحضر الأساسي Product موجود في E-SDR

طلب ترحيل بيانات كمستحضر " Migration as a product "

عند الضغط على أيقونة " Migration as a product " سوف يقوم المستخدم بإدخال بيانات للمنتج كاملة حسب آخر ما تمت الموافقة عليه من قبل الهيئة العامة للغذاء والدواء.

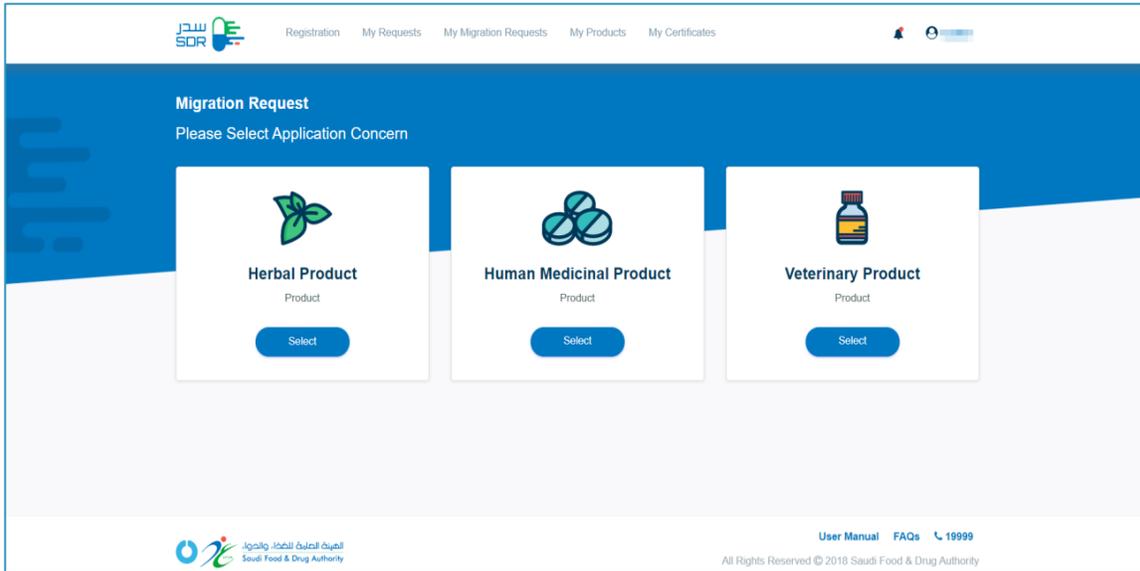
تحديد نوع النموذج:

1. مستحضر صيدلاني دوائي Human Medicinal Product
2. مستحضر بيطري Veterinary Product
3. مستحضر عشبي Herbal Product

تحديد نوع المستحضر:

- يقوم المستخدم باختيار نوع المستحضر وتصنيفه.

يقوم المستخدم باختيار تقديم طلب الترحيل.



SDR SDR Registration My Requests My Migration Requests My Products My Certificates

Migration Request

Please Select Application Concern



Herbal Product
Product

Select



Human Medicinal Product
Product

Select



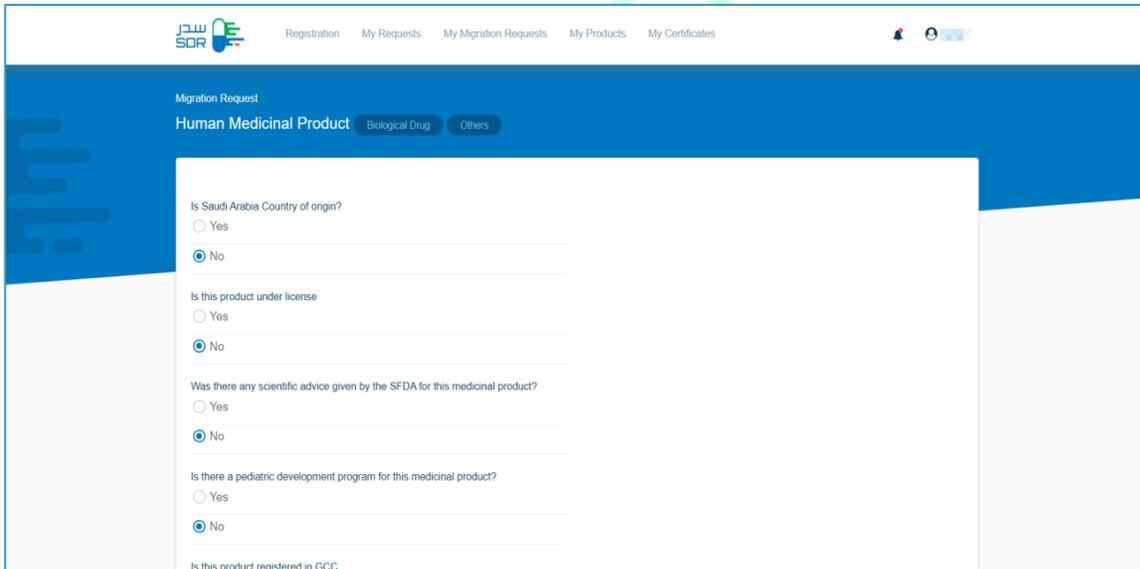
Veterinary Product
Product

Select

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يقوم المستخدم بإدخال البيانات كما في حقول الخدمة.



SDR SDR Registration My Requests My Migration Requests My Products My Certificates

Migration Request

Human Medicinal Product Biological Drug Others

Is Saudi Arabia Country of origin?

Yes

No

Is this product under license

Yes

No

Was there any scientific advice given by the SFDA for this medicinal product?

Yes

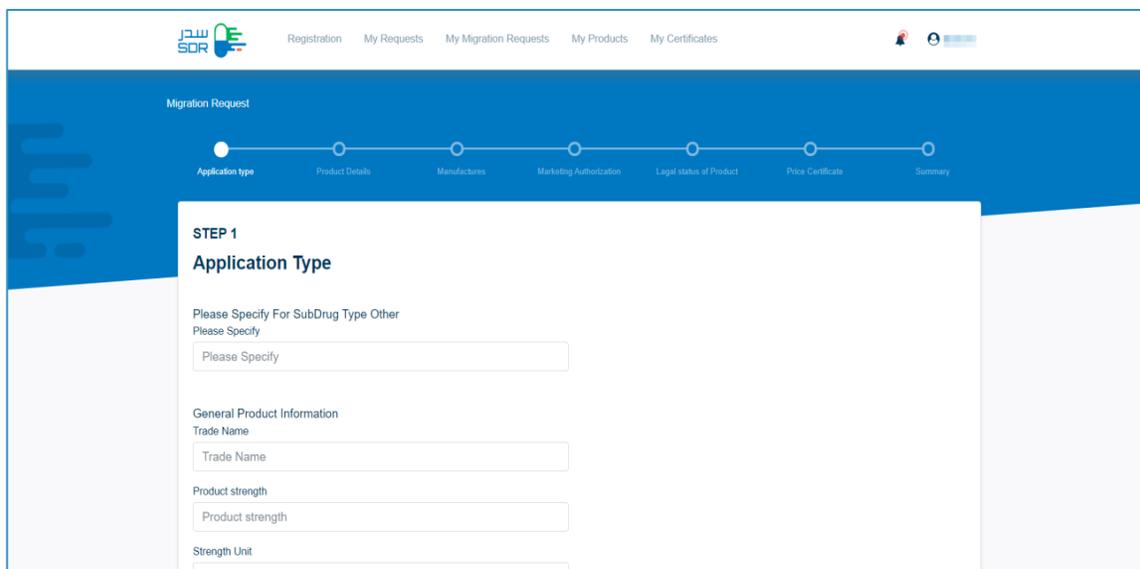
No

Is there a pediatric development program for this medicinal product?

Yes

No

Is this product registered in GCC



Migration Request

Application type Product Details Manufactures Marketing Authorization Legal status of Product Price Certificate Summary

STEP 1
Application Type

Please Specify For SubDrug Type Other
Please Specify
Please Specify

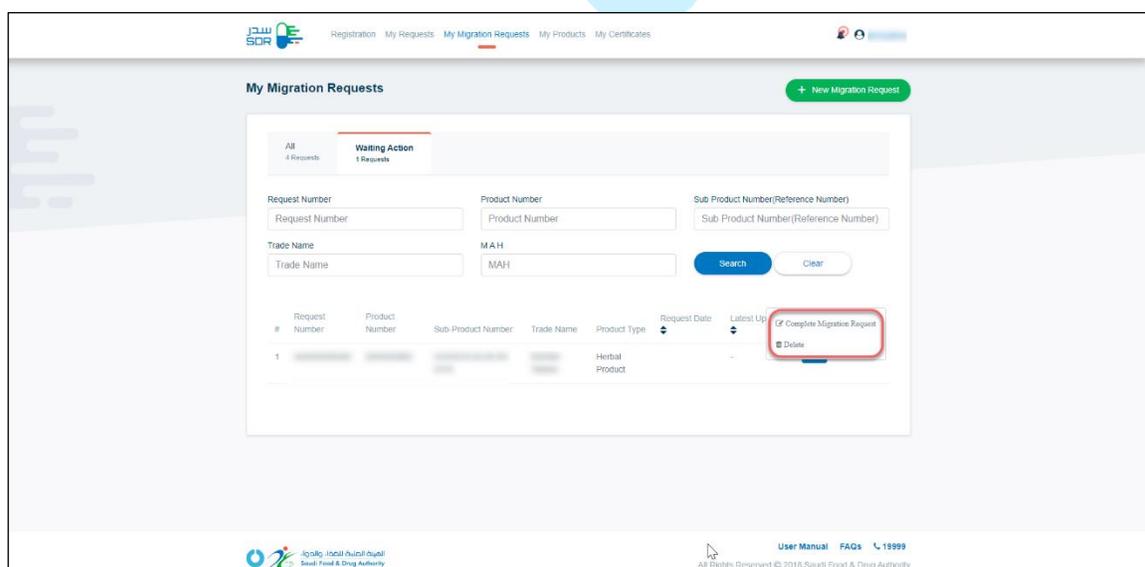
General Product Information
Trade Name
Trade Name

Product strength
Product strength

Strength Unit

بعد الانتهاء من تعبئة جميع خانا بيانات المستحضر المطلوبة وتقديمها في النظام، سوف يتم إنشاء طلب ترحيل حالته "Waiting for Migration Request Reviewing"

ملاحظة: عند عدم استكمال جميع بيانات النموذج سوف يتم حفظ الطلب كمسوده في صفحة "Waiting Action" ولاستكمال طلب مسوده يتم اختيار "Complete Migration Request". ويمكن حذف المسوده عن طريق الضغط على خيار "Delete" كما هو موضح ادناه وسوف يتم عرض رسالة تأكيديه للتأكيد على حذف الطلب.



My Migration Requests

+ New Migration Request

All 4 Requests **Waiting Action** 1 Requests

Request Number Product Number Sub Product Number(Reference Number)
Request Number Product Number Sub Product Number(Reference Number)

Trade Name MAH
Trade Name MAH Search Clear

Request #	Product Number	Sub-Product Number	Trade Name	Product Type	Request Date	Latest User	
1				Herbal Product			<input type="checkbox"/> Complete Migration Request <input type="checkbox"/> Delete

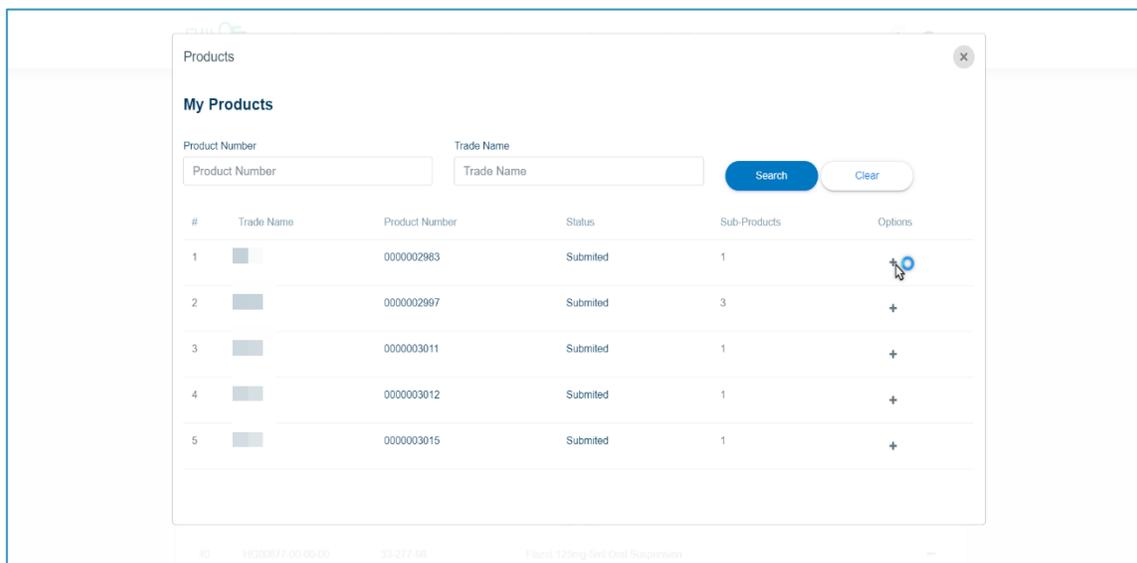
User Manual FAQs 19999

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طلب

ترحيل بيانات كمستحضر فرعي "Migration as a sub product"

عند الضغط على أيقونة "Migration as a sub product" سوف يظهر للمستخدم نافذه بالمستحضرات المتاحة في نظام سدر الجديد. يقوم المستخدم باختيار المستحضر،



ملاحظة: يجب أن تكون البيانات مكتملة، وحالة طلب الترحيل "تم ترحيل البيانات" (حتى يسمح لممثل الشركة من استعمال خدمات النظام).

ثم استكمال بيانات المستحضر الفرعي غير المشتركة التالية:

- Product information
 - باستثناء (trade name in Arabic and English)
- Manufacturer information
 - باستثناء Finished Manufacture
- Pricing information

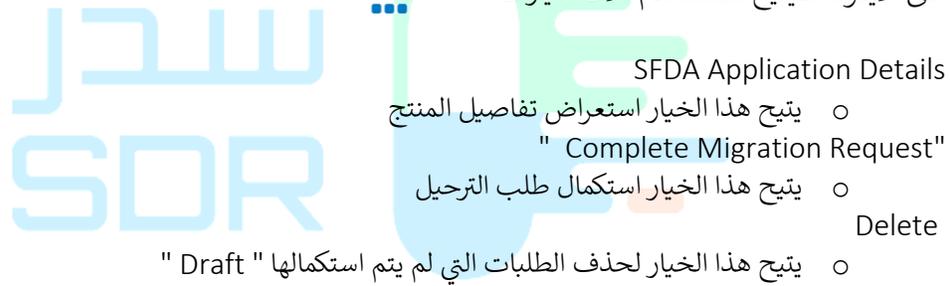
بعد الانتهاء من تعبئة جميع خانات بيانات المستحضر المطلوبة وتقديمها في النظام، سوف يتم إنشاء طلب ترحيل حالته "Waiting for Migration Request Reviewing".

بعد طلب ترحيل مستحضر

- بعد تقديم المستحضر سواء كمنتج أو منتج فرعي يتم مراجعة الطلب من قبل موظف الهيئة لقبول الطلب أو تعديله.
- في حال قبول الطلب سوف تكون حالة الطلب "Paid" في "My Requests".
- في حال تعديل الطلب من قبل موظف الهيئة سوف يظهر الطلب في صفحة "Waiting Action" وتكون حالة الطلب "Request has been updated by SFDA" وفي هذه الحالة سوف يتمكن المستخدم من اتخاذ إجراء على الطلب. في حال عدم الرد على ملاحظات موظف الهيئة خلال المدة المحددة سوف يتم قبولها تلقائياً واعتمادها بالطلب.

طلبات ترحيل بانتظار اتخاذ إجراء

يتم استعراض الطلبات المحدثة من قبل الهيئة والطلبات التي لم يتم استكمالها في صفحة "Waiting Action" لاتخاذ إجراء على الطلبات التي تم تعديلها من قبل موظف الهيئة والطلبات التي لم يتم استكمالها "Draft" يتم الضغط على الأيقونة سيتيح للمستخدم ثلاث خيارات:



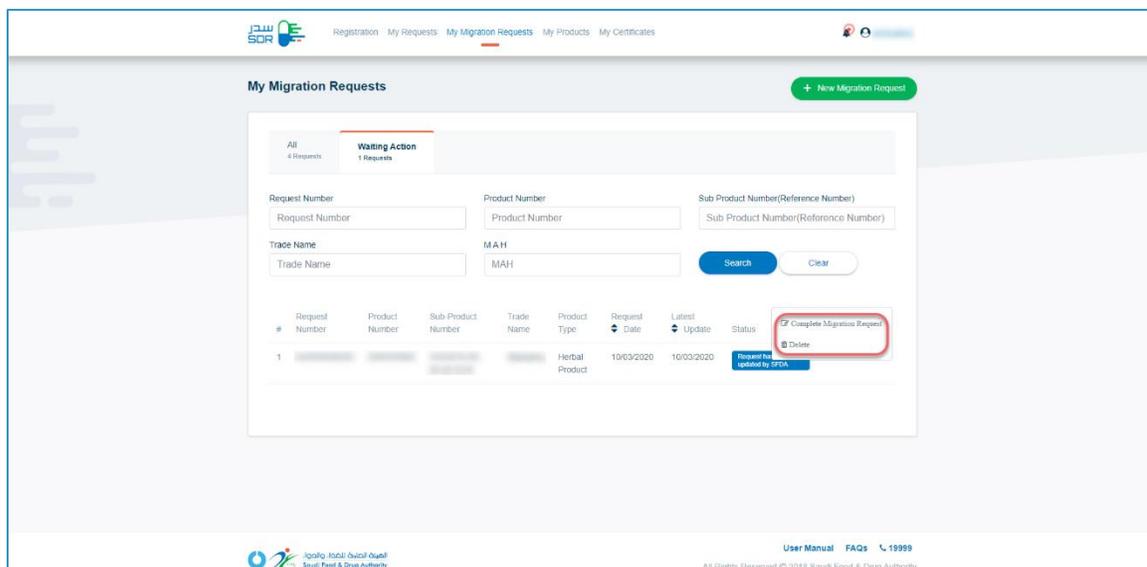
SFDA Application Details

- يتيح هذا الخيار استعراض تفاصيل المنتج
- " Complete Migration Request"
- يتيح هذا الخيار استكمال طلب الترحيل
- Delete
- يتيح هذا الخيار لحذف الطلبات التي لم يتم استكمالها " Draft "

ملاحظة: في حال تم تعديل بيانات طلب الترحيل من قبل المراجع لأول مره سوف يتم ظهور البيانات المعدلة مضلله باللون الأصفر، في حال تم تعديلها للمرة الثانية سوف يتم ظهور البيانات المعدلة مضلله باللون الأحمر. وفي حال تم الموافقة على بعض التعديلات يتم ظهور البيانات مضلله باللون الأخضر.

ليتم استكمال طلب ترحيل محدث من قبل الهيئة يتم الضغط على خيار "Complete Migration Request" لاستكمال الطلب

ويمكن حذف الطلب المحدث من قبل الهيئة عن طريق الضغط على خيار "Delete" وسوف يتم عرض رسالة تأكيدية للتأكيد على حذف الطلب.

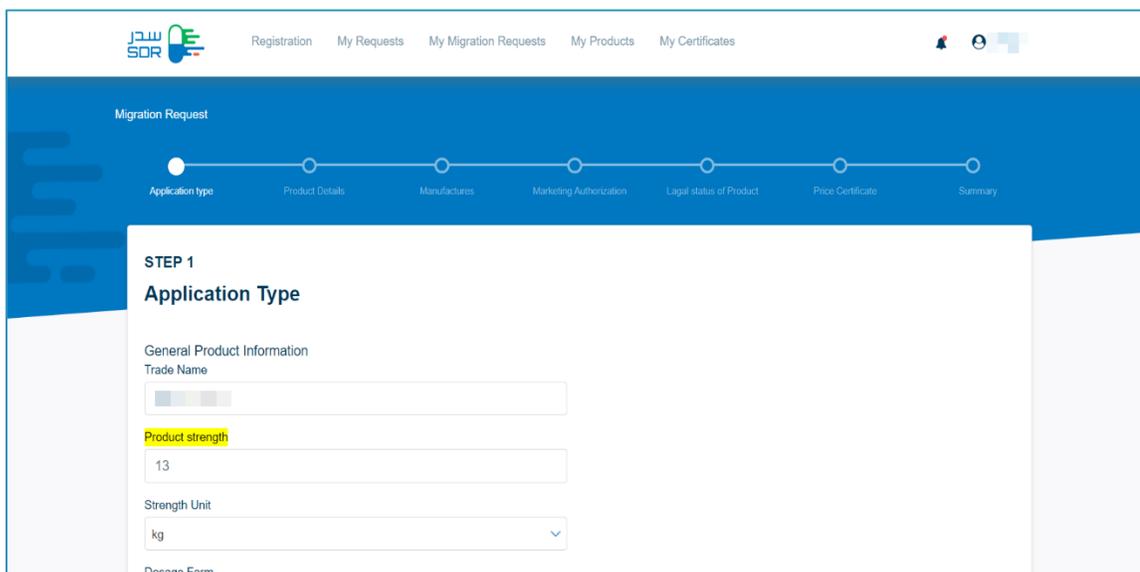


يمكن

للمستخدم الموافقة على التعديلات او التعديل على البيانات مره اخرى

- في حال الموافقة على التعديلات سيتم الموافقة على طلب الترحيل وسيتم ترحيل بيانات المستحضر تلقائياً، سيظهر المستحضر الذي تم ترحيل بياناته في صفحة الطلبات "My Requests" وتكون حالة الطلب " Paid"
- في حال التعديل على البيانات مرة أخرى، يجب على المستخدم إضافة سبب ووصف للتعديل عند اعتماد التعديل يقوم النظام بإرجاع الطلب للهيئة لمراجعة التعديلات.
- يقوم النظام بتغيير حالة الطلب من " Request has been updated by SFDA " إلى " Waiting for Migration Request Reviewing"

سوف يقوم النظام بعرض البيانات التي تم تعديلها من قبل موظف الشؤون التنظيمية محدد بلون كما هو موضح أدناه:



The screenshot shows the 'Migration Request' process in the SDR system. The current step is 'STEP 1 Application Type'. The form is titled 'General Product Information' and includes the following fields:

- Trade Name: [Text input field]
- Product strength: [Text input field with value '13']
- Strength Unit: [Dropdown menu with value 'kg']
- Dosage Form: [Text input field]

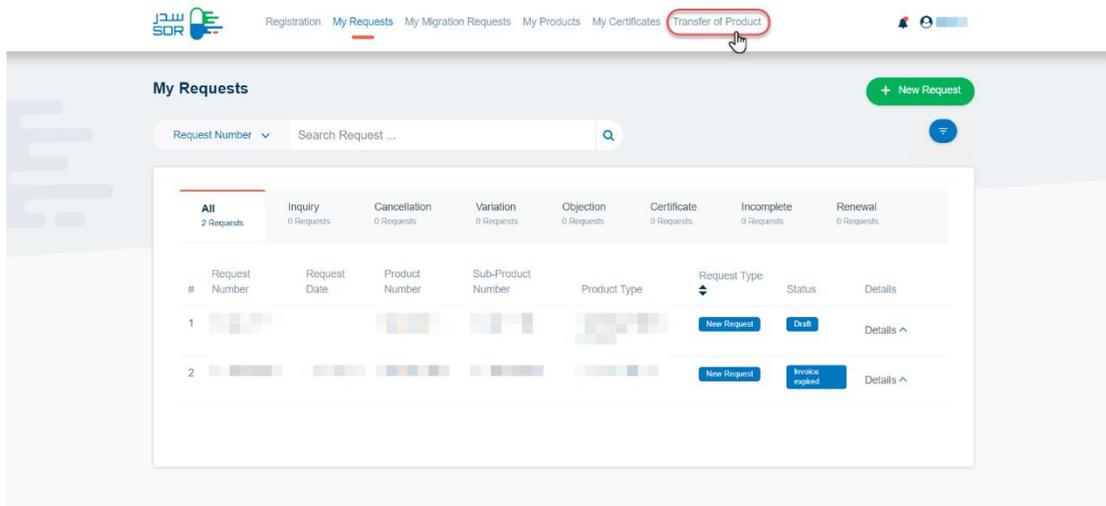
The 'Product strength' field is highlighted in yellow. The background of the form shows a progress bar with steps: Application type, Product Details, Manufactures, Marketing Authorization, Legal status of Product, Price Certificate, and Summary.

لمعرفه المزيد حول طريقه نقل البيانات من النظام القديم الى النظام الجديد الرجاء الاطلاع على دليل المستخدم المرئي

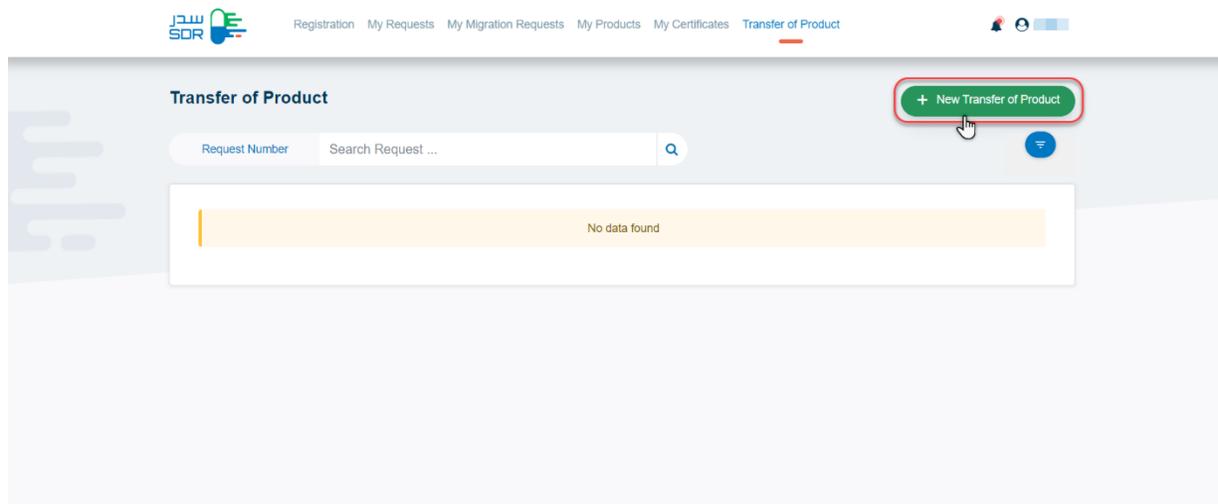
[اضغط هنا](#)

نقل نماذج مستحضر إلى حساب آخر

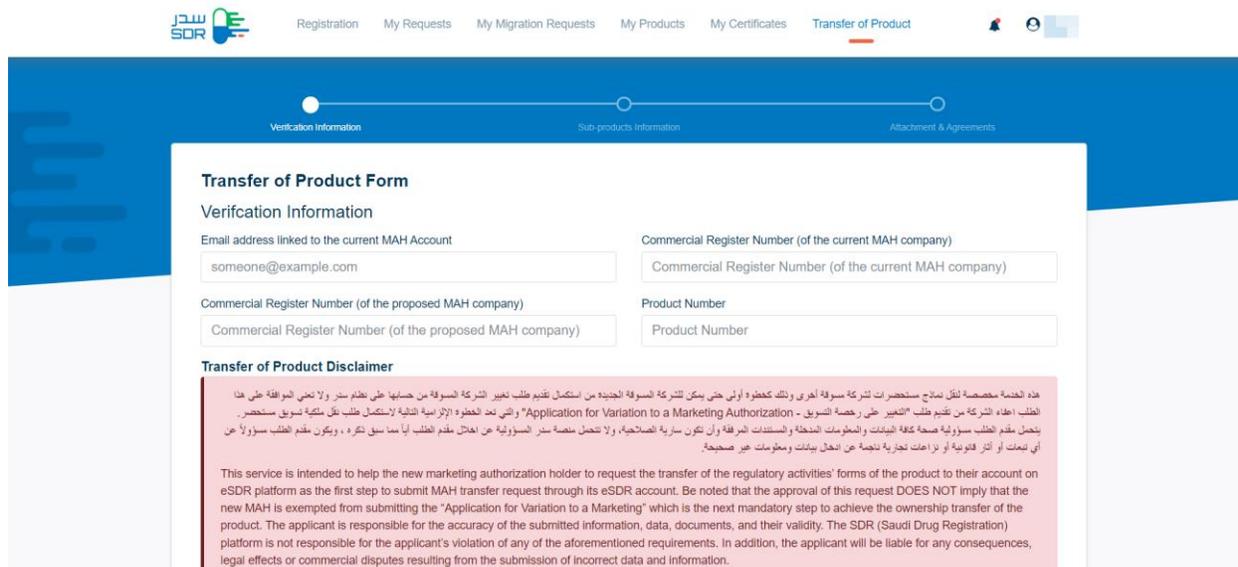
لتقديم طلب نقل نموذج مستحضر إلى حساب آخر يتم الضغط على الخيار في اعلى الصفحة Transfer of Product ليتم عرض الشاشة الخاصة بنقل المستحضرات



سيتم استعراض الشاشة الموضحة ادناه، لتقديم طلب يقوم المستخدم بالضغط على New Transfer of product



يتم تعبئة الحقول من قبل المستخدم (رقم السجل التجاري - ضافة رقم المنتج الرئيسي - والبريد الإلكتروني) للشركة المراد نقل المستحضرات منها إلى الشركة مقدمة الطلب وثم الضغط على الخيار Next



Transfer of Product Form

Verification Information

Email address linked to the current MAH Account

Commercial Register Number (of the current MAH company)

Commercial Register Number (of the proposed MAH company)

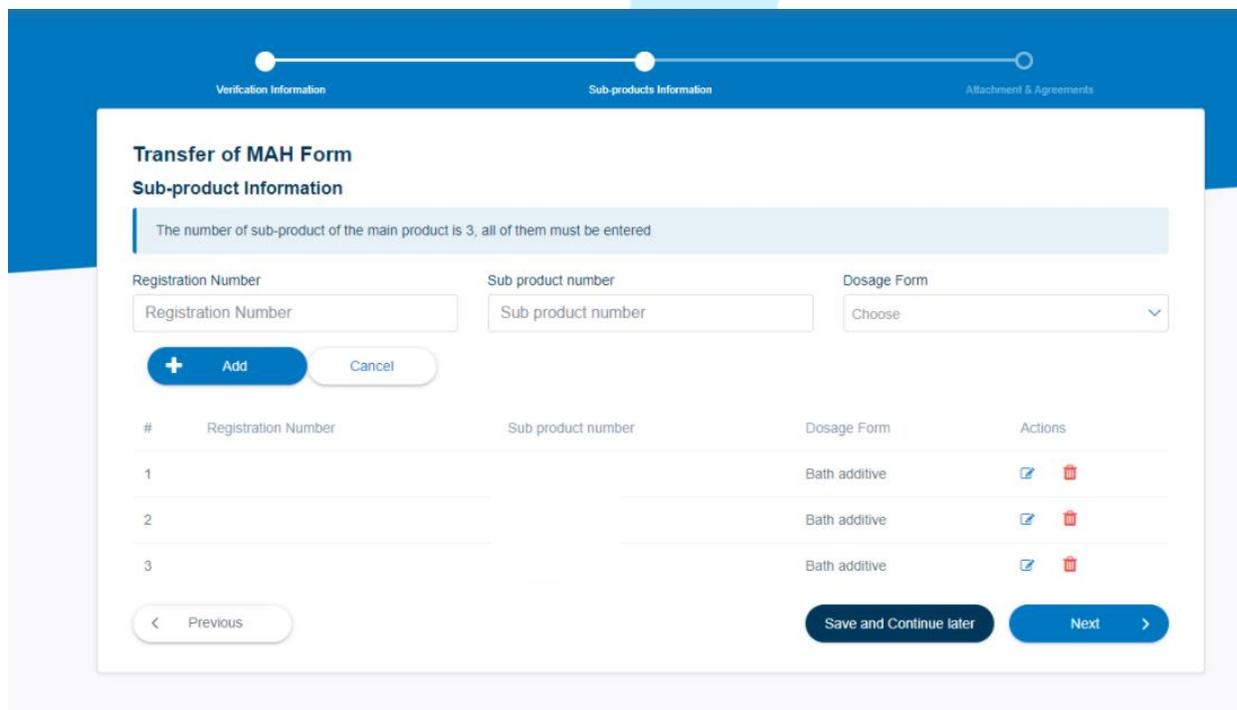
Product Number

Transfer of Product Disclaimer

هذه الخدمة مخصصة لتقليل نماذج مستحضرات لشركة مسؤولة أخرى وذلك كخطوة أولى حتى يمكن للشركة المسؤولة الجديدة من استكمال تقديم طلب تغيير الشركة المسؤولة من حسابها على نظام سدر ولا تعني الموافقة على هذا الطلب اعطاء الشركة من تقديم طلب "التغيير على رخصة التسويق - Application for Variation to a Marketing Authorization" والتي تعد الخطوة الإلزامية التالية لاستكمال طلب نقل ملكية تسويق مستحضر. يتحمل مقدم الطلب مسؤولية صحة كافة البيانات والمعلومات المنطوقة والمستندات المرفقة وأن تكون سارية الصلاحية، ولا تتحمل منصة سدر المسؤولية عن اخلال مقدم الطلب بأي ماس سبق ذكره ، ويكون مقدم الطلب مسؤولاً عن أي تبعات أو آثار قانونية أو نزاعات تجارية ناتجة عن اخلال بيانات ومعلومات غير صحيحة.

This service is intended to help the new marketing authorization holder to request the transfer of the regulatory activities' forms of the product to their account on eSDR platform as the first step to submit MAH transfer request through its eSDR account. Be noted that the approval of this request DOES NOT imply that the new MAH is exempted from submitting the "Application for Variation to a Marketing" which is the next mandatory step to achieve the ownership transfer of the product. The applicant is responsible for the accuracy of the submitted information, data, documents, and their validity. The SDR (Saudi Drug Registration) platform is not responsible for the applicant's violation of any of the aforementioned requirements. In addition, the applicant will be liable for any consequences, legal effects or commercial disputes resulting from the submission of incorrect data and information.

يتم استكمال الطلب بإضافة جميع المنتجات الفرعية المتعلقة بالمنتج الرئيسي والضغط على خيار Next



Transfer of MAH Form

Sub-product Information

The number of sub-product of the main product is 3, all of them must be entered

Registration Number

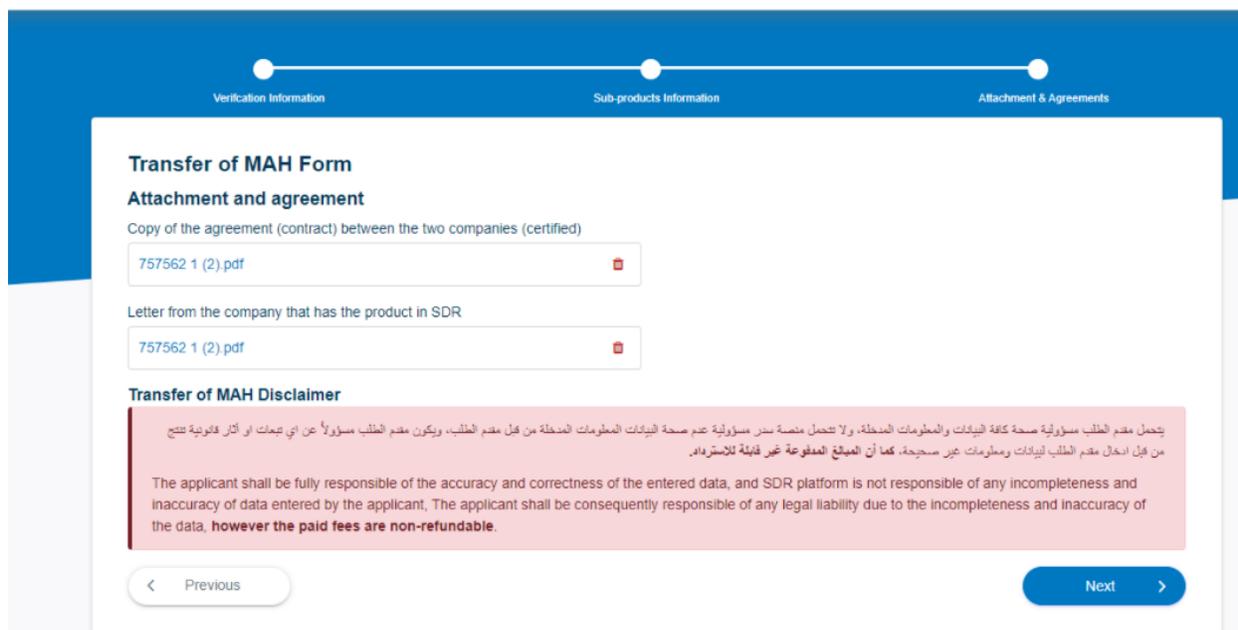
Sub product number

Dosage Form

+ Add

#	Registration Number	Sub product number	Dosage Form	Actions
1			Bath additive	<input type="button" value="edit"/> <input type="button" value="delete"/>
2			Bath additive	<input type="button" value="edit"/> <input type="button" value="delete"/>
3			Bath additive	<input type="button" value="edit"/> <input type="button" value="delete"/>

وفي نهاية تقديم الطلب يتم رفع المرفقات المتعلقة بالمنتج وتكون صيغة الملف PDF,zip,rar بعد رفع الملف بنجاح، يتم دراسة من قبل اللجنة



The screenshot shows a web interface for the 'Transfer of MAH Form' process. It includes a progress bar at the top with three steps: 'Verification Information', 'Sub-products Information', and 'Attachment & Agreements'. The current step is 'Attachment and agreement'. Below this, there are two sections for file uploads:

- Copy of the agreement (contract) between the two companies (certified):** A file named '757562 1 (2).pdf' is shown with a trash icon.
- Letter from the company that has the product in SDR:** A file named '757562 1 (2).pdf' is shown with a trash icon.

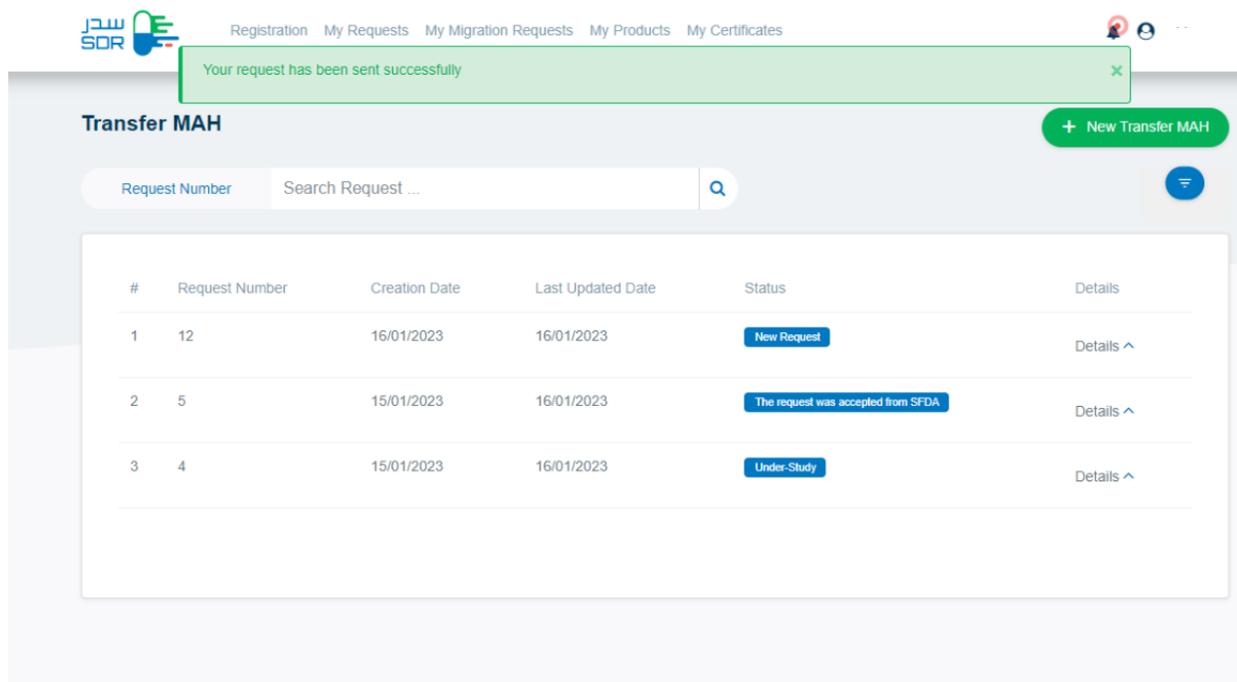
Below the uploads is a section titled 'Transfer of MAH Disclaimer' with a red background. It contains the following text:

يتحمل مقدم الطلب مسؤولية صحة كافة البيانات والمعلومات المدخلة، ولا تتحمل منصة سدر مسؤولية عدم صحة البيانات المدخلة من قبل مقدم الطلب، ويكون مقدم الطلب مسؤولاً عن أي تبعات أو آثار قانونية تنتج من قبل ادخال مقدم الطلب لبيانات ومعلومات غير صحيحة، كما أن المبالغ المدفوعة غير قابلة للاسترداد.

The applicant shall be fully responsible of the accuracy and correctness of the entered data, and SDR platform is not responsible of any incompleteness and inaccuracy of data entered by the applicant, The applicant shall be consequently responsible of any legal liability due to the incompleteness and inaccuracy of the data, **however the paid fees are non-refundable.**

At the bottom, there are 'Previous' and 'Next' navigation buttons.

بإمكان المستخدم استعراض الطلب من خلال الشاشة الخاصة بنقل المستحضرات ومعرفة حالة الطلب في حال تم القبول أو الرفض كما انه يتم ارسال بريد المرتبط بحساب الشركة المسوقة الحالية وكذلك الشركة المسوقة الجديدة يوضح حالة الطلب في حال تم قبوله او رفضه.



The screenshot shows the 'Transfer MAH' dashboard. At the top, there is a navigation bar with 'Registration', 'My Requests', 'My Migration Requests', 'My Products', and 'My Certificates'. A green notification banner at the top says 'Your request has been sent successfully'. Below this is a '+ New Transfer MAH' button. A search bar is present with 'Request Number' and 'Search Request ...'. The main content is a table with the following columns: '#', 'Request Number', 'Creation Date', 'Last Updated Date', 'Status', and 'Details'.

#	Request Number	Creation Date	Last Updated Date	Status	Details
1	12	16/01/2023	16/01/2023	New Request	Details ^
2	5	15/01/2023	16/01/2023	The request was accepted from SFDA	Details ^
3	4	15/01/2023	16/01/2023	Under-Study	Details ^

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Fifth step: complete files	73
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Add a package size of a sub-product	79
Seventh Step: Print Certifications.....	83
Eighth Step: Variation request.....	87
Ninth step: Product Renewal.....	90
Tenth Step: Objection Request.....	92
Eleventh step: Cancel the product	95
Twelfth step: Re-register the canceled product.....	97
System Status	99
Thirteenth Step: Review the reasons for rejecting the cancelled request.....	102
Migration Request.....	100
New Migration Request.....	104
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Introduction:

This user guide aims to clarifying the steps of registering and renewing drugs and products in Saudi Arabia of all kinds for representatives of pharmaceutical companies and their agents. The system can also issue certificates of medicines and products (registration, free sale) and submit requests for amendment and cancellation.

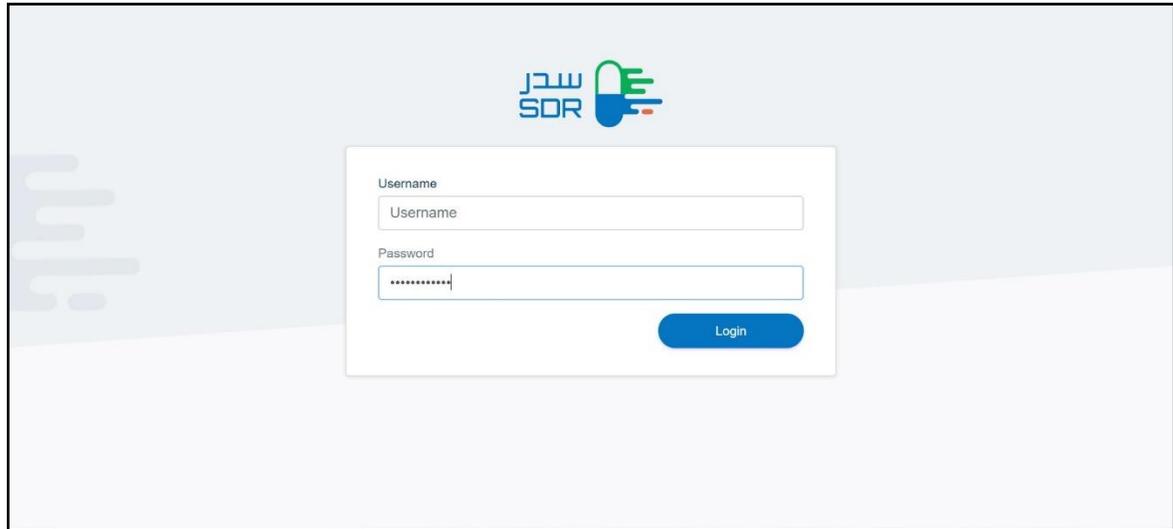
First Step: Accessing the Saudi Drug registration system as below:

- Accessing the Saudi Drug Registration Website [Click Here](#)
- Clicking LOGIN.



Note: The company representative must verify that there is an account in (DENR) system before accessing E-SDR system

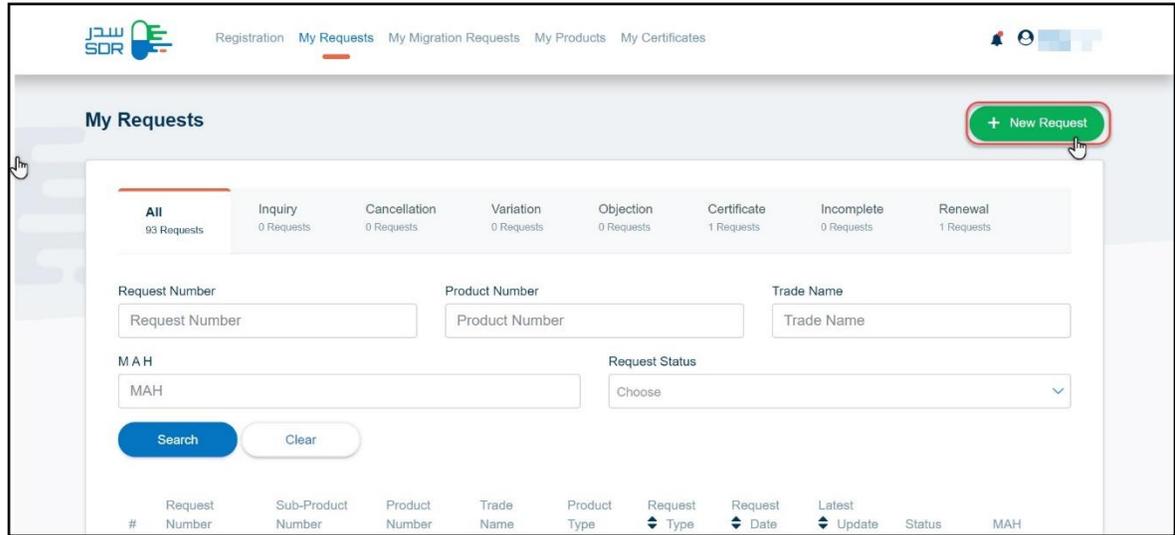
Before start using the system, the user must log in with the username and password from the National Registry of Drug Establishments (سجل), as displayed in Figure below:



The screenshot shows a login form for the SDR system. At the top center, there is the SDR logo. Below it, the form contains two input fields: 'Username' and 'Password'. The 'Username' field has the text 'Username' inside it. The 'Password' field has a series of dots for masking. To the right of the password field is a blue 'Login' button. The background of the login form is light gray with a subtle pattern of horizontal lines on the left side.



The Interface of Saudi Drug Registration System

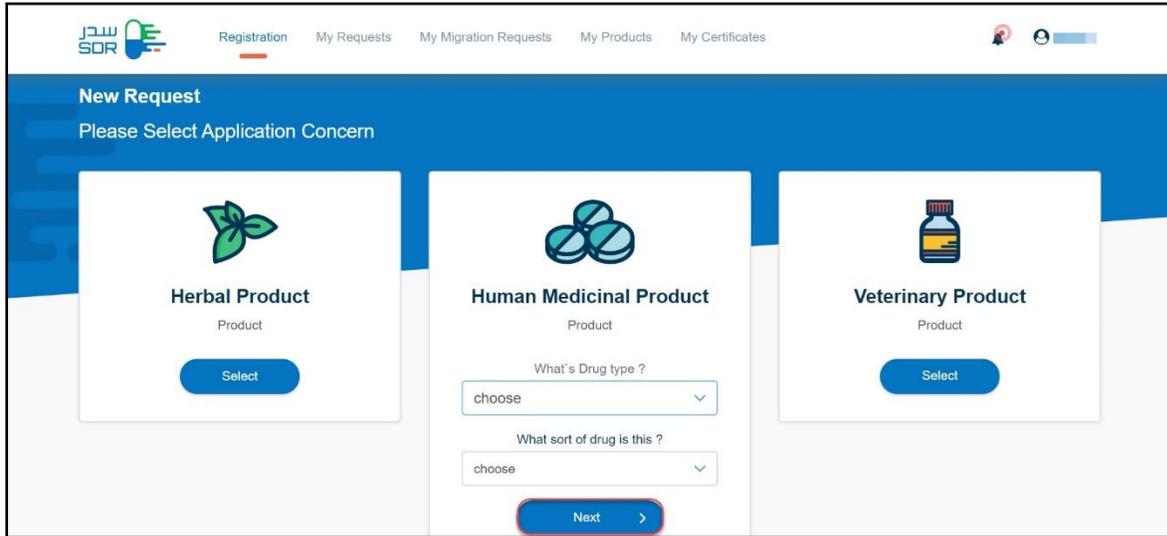


System interface tabs

- Registration tab
- My Request tab: Contains all requests that have been entered into E-SDR system.
- My Migration Request tab
- My Products tab: Contains all drugs within the Requests.
- My Certificates tab

Second Step: Registering Saudi drugs

To register a new product, click on "New Request." The page shown below will be displayed.

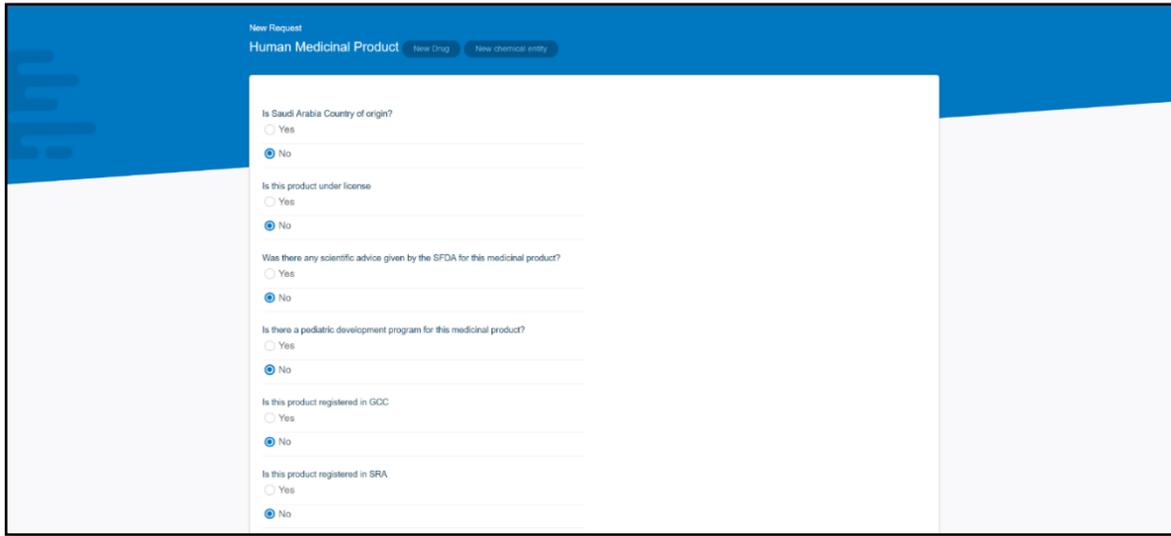


Select form Application Concern

1. Herbal Product
2. Human Medicinal Product
3. Veterinary Product

Select the product type

- The user selects the type and the sort of the product.
- The user clicks next.



New Request

Human Medicinal Product [New Drug](#) [New chemical entity](#)

Is Saudi Arabia Country of origin?

Yes

No

Is this product under license

Yes

No

Was there any scientific advice given by the SFDA for this medicinal product?

Yes

No

Is there a pediatric development program for this medicinal product?

Yes

No

Is this product registered in GCC

Yes

No

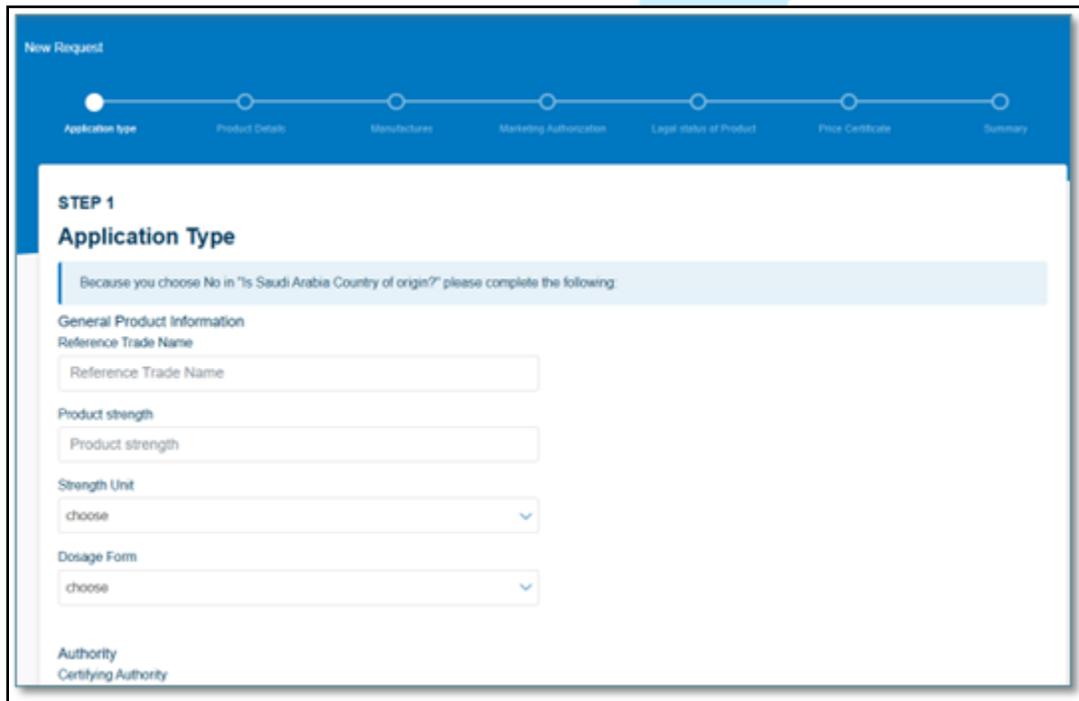
Is this product registered in SRA

Yes

No

The user fills the needed data in seven steps

- Application Type



New Request

Application type Product Details Manufactures Marketing Authorization Legal status of Product Price Certificate Summary

STEP 1

Application Type

Because you choose No in "Is Saudi Arabia Country of origin?" please complete the following

General Product Information

Reference Trade Name

Reference Trade Name

Product strength

Product strength

Strength Unit

choose

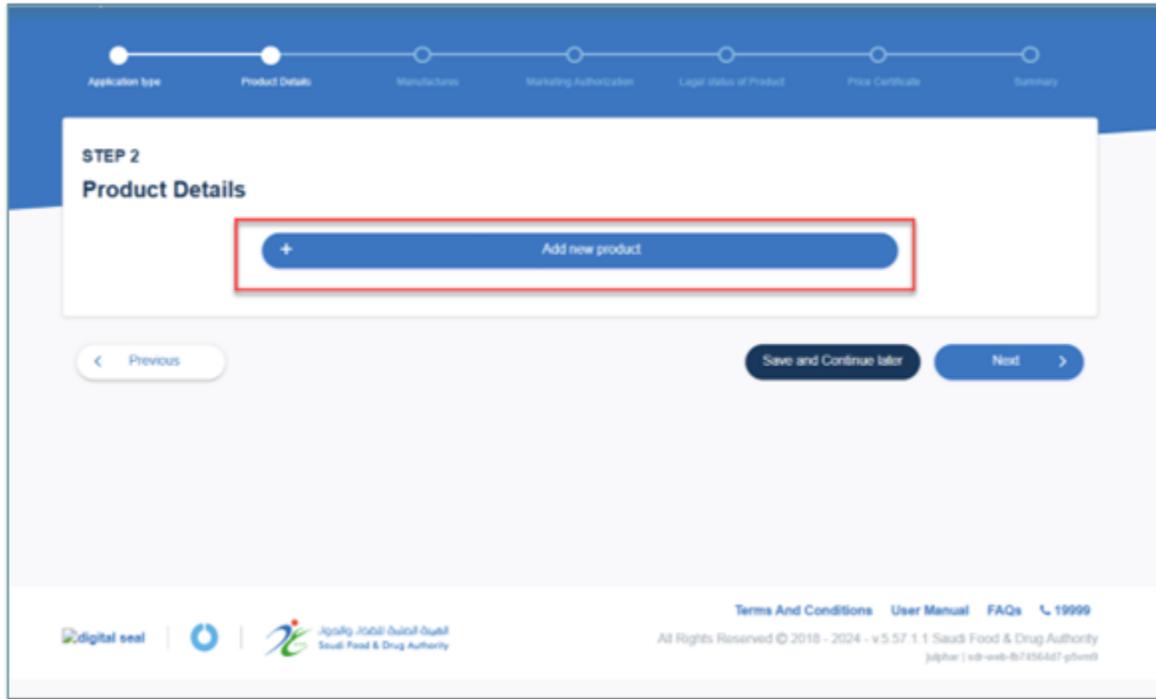
Dosage Form

choose

Authority

Certifying Authority

- Product Details
 - Chose the product type
 - Chose add product request as displayed in the figure below.

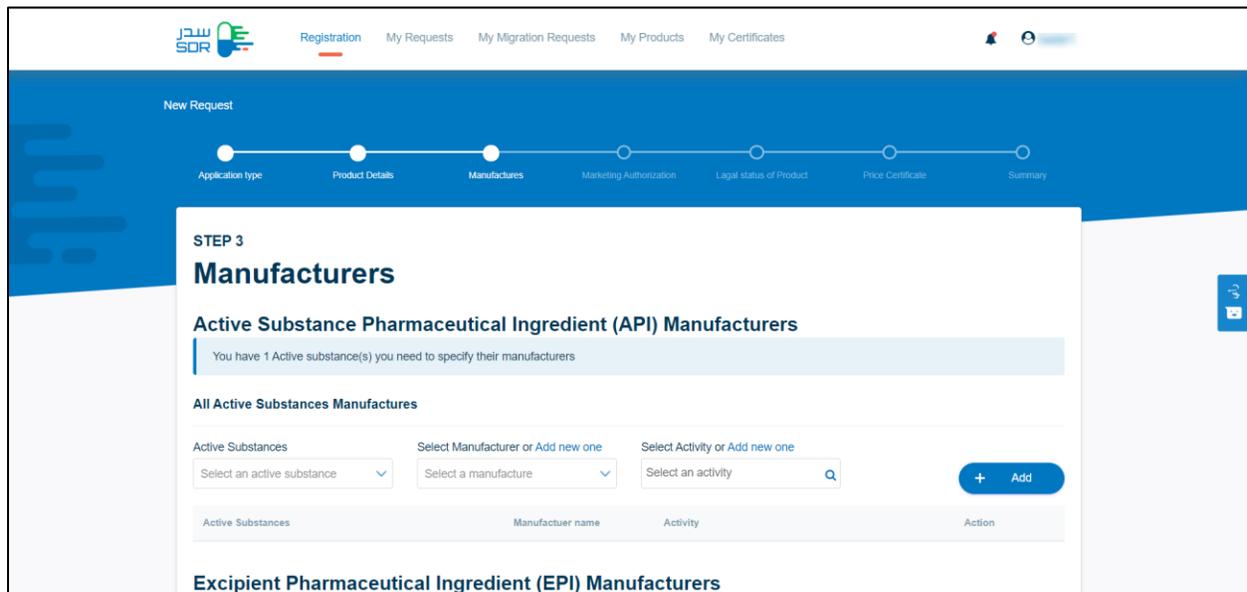


Note

- The user can register a product containing more than one type of packaging / Drug form / concentration, under one product number with different order numbers.

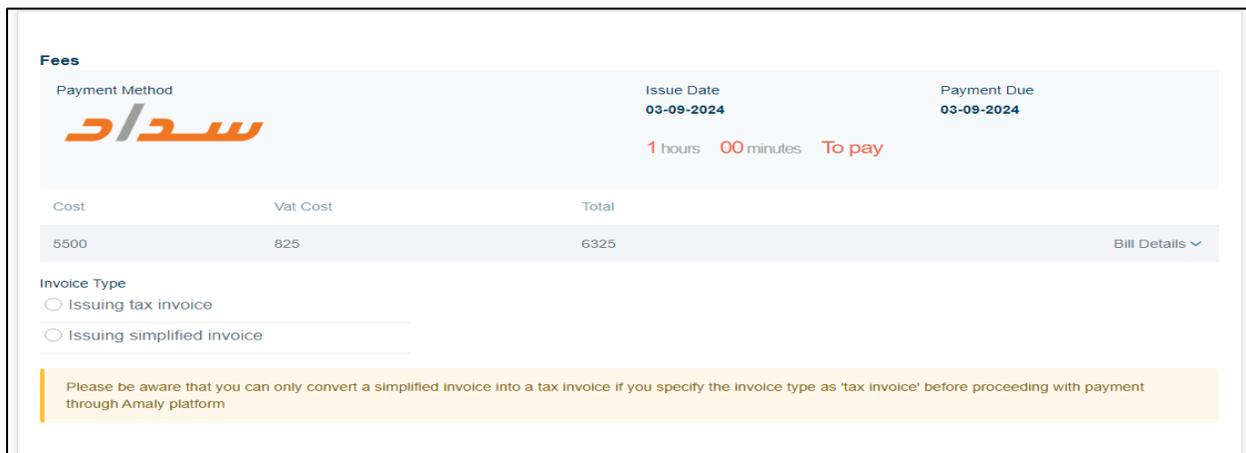
- The product must be the same type as the original request (Generic, innovative ...etc.)

- **Add Manufacturers**
 - Users can add a manufacturer. After the user adds a manufacturer, he/she can edit the data.
 - Users can add up to 10 manufacturers API for each active substance for registration and variation requests.

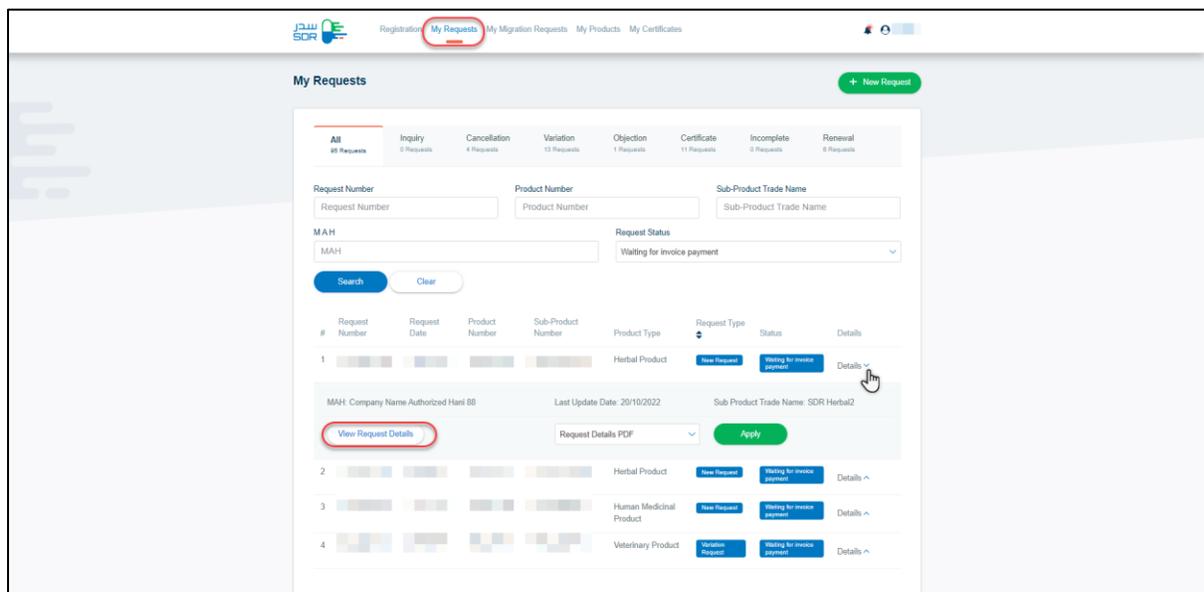


After completing all the required fields, a payment invoice will be issued.

Note: The payment mechanism for the invoices of the products companies is through my business portal and the payment code is: 144



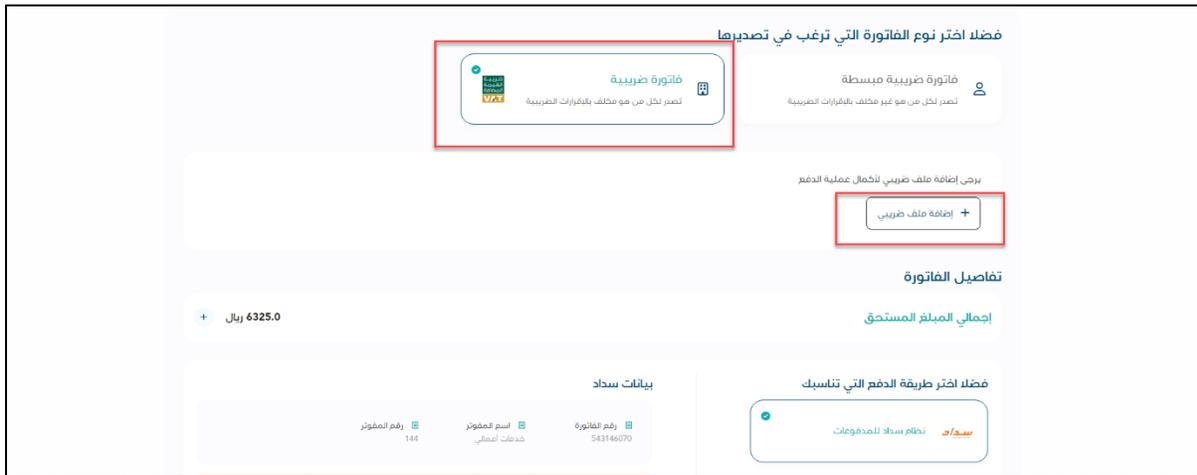
To convert an invoice into a tax invoice, enter “My Request” tab, select a request, then click on the icon next to the request, choose “Request Details.”



Choose “Payment Summary” and click on “View,” as shown below



The system will transfer the user to Amaly portal. The user clicks on the “Tax Invoice” icon and then “Add Tax File”



فضلا اختر نوع الفاتورة التي ترغب في تصديرها

فاتورة ضريبية مبسطة
تصدر لكل من مو غير مكلف بالقرارات الضريبية

فاتورة ضريبية
تصدر لكل من مو مكلف بالقرارات الضريبية

يرجى إضافة ملف ضريبي لتكامل عملية الدفع

إضافة ملف ضريبي +

تفاصيل الفاتورة

إجمالي المبلغ المستحق

6325.0 ريال

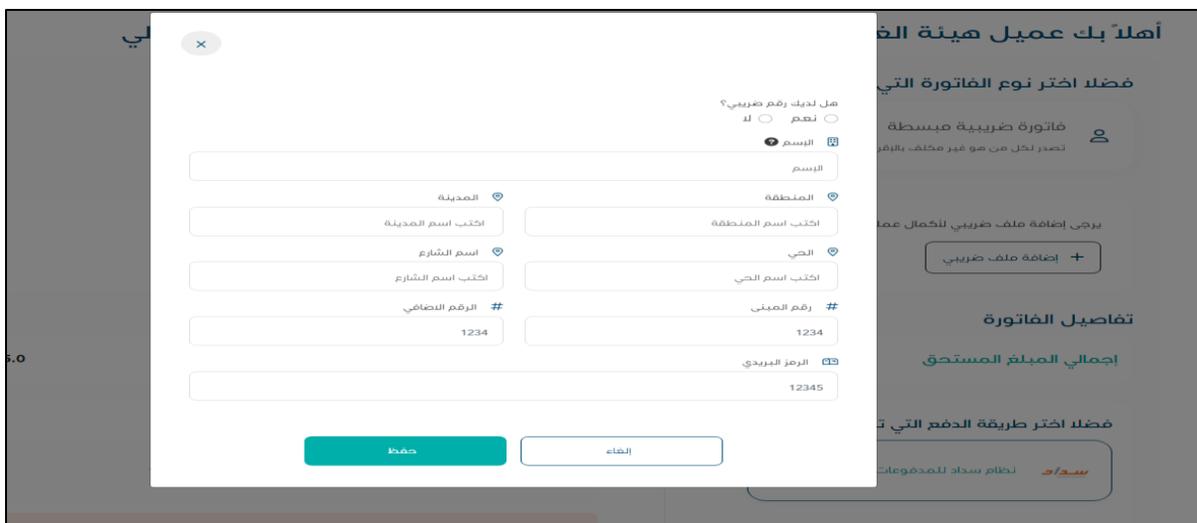
بيانات سداد

رقم الفاتورة	543146070
اسم العميل	شركات العملي
رقم العميل	144

فضلا اختر طريقة الدفع التي تناسبك

نظام سداد للمدفوعات

All required fields shown below are filled in. After completing all fields, click on the “Save”.



أهلاً بك عميل هيئة الضريبة

فضلا اختر نوع الفاتورة التي ترغب في تصديرها

فاتورة ضريبية مبسطة
تصدر لكل من مو غير مكلف بالقرارات الضريبية

فاتورة ضريبية
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يرجى إضافة ملف ضريبي لتكامل عملية الدفع

إضافة ملف ضريبي +

تفاصيل الفاتورة

إجمالي المبلغ المستحق

فضلا اختر طريقة الدفع التي تناسبك

نظام سداد للمدفوعات

هل لديك رقم ضريبي؟

لا نعم

الاسم

الاسم

المنطقة

اكتب اسم المنطقة

الحي

اكتب اسم الحي

رقم المبنى

#

1234

1234

الرمز البريدي

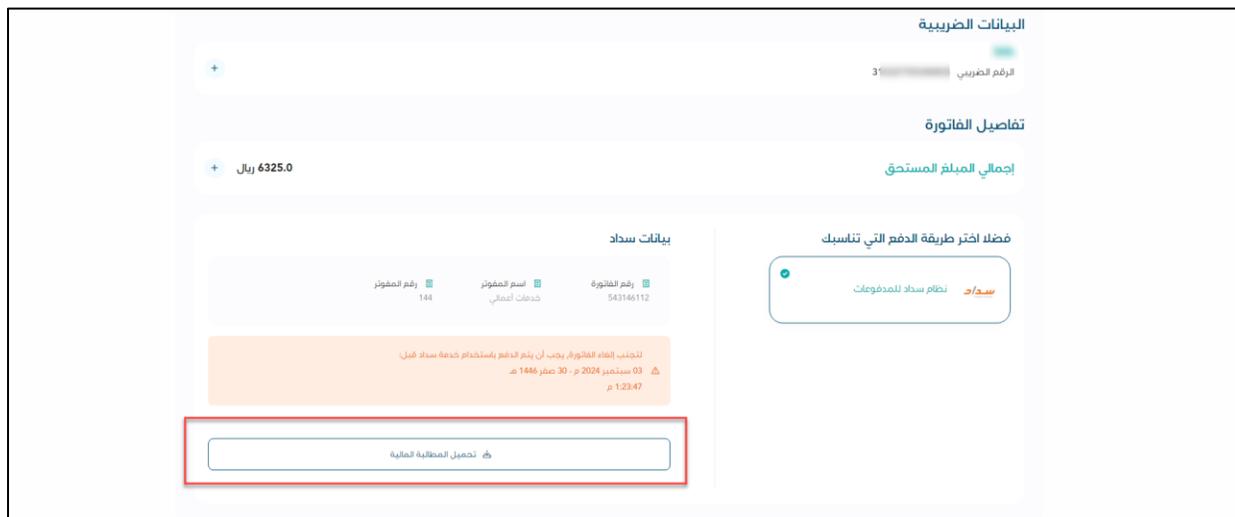
#

12345

12345

حفظ إلغاء

The user can view the invoice by clicking on "Upload Invoice."



البيانات الضريبية

الرقم الضريبي 31

تفاصيل الفاتورة

إجمالي المبلغ المستحق 6325.0 ريال

بيانات سداد

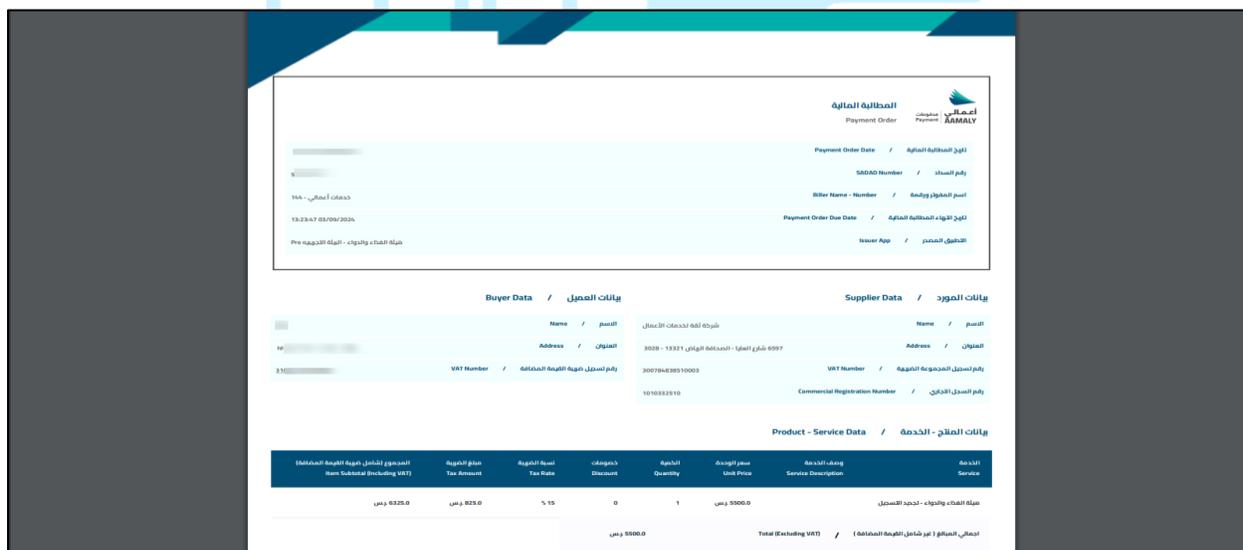
رقم الفاتورة 543146112
اسم العميل خدمات عملي
رقم العميل 144

لنجنب إلغاء الفاتورة يجب أن يتم الدفع باستخدام خدمة سداد قبل:
03 سبتمبر 2024 م - 30 صفر 1446 هـ
1:23:47 م

فضلًا اختر طريقة الدفع التي تناسبك

نظام سداد للمدفوعات

رفع تحميل الفاتورة المالية



المطالبة المالية

Payment Order

تاريخ المطالبة المالية / Payment Order Date

رقم السداد / SADA Number

اسم العميل ورقم / Biller Name - Number

تاريخ انتهاء المطالبة المالية / Payment Order Due Date

التطبيق المصدر / Issuer App

بيانات العميل / Buyer Data

الاسم / Name

العنوان / Address

رقم تسجيل الجهة الاقتصادية / VAT Number

بيانات المورد / Supplier Data

الاسم / Name

العنوان / Address

رقم تسجيل الجهة / VAT Number

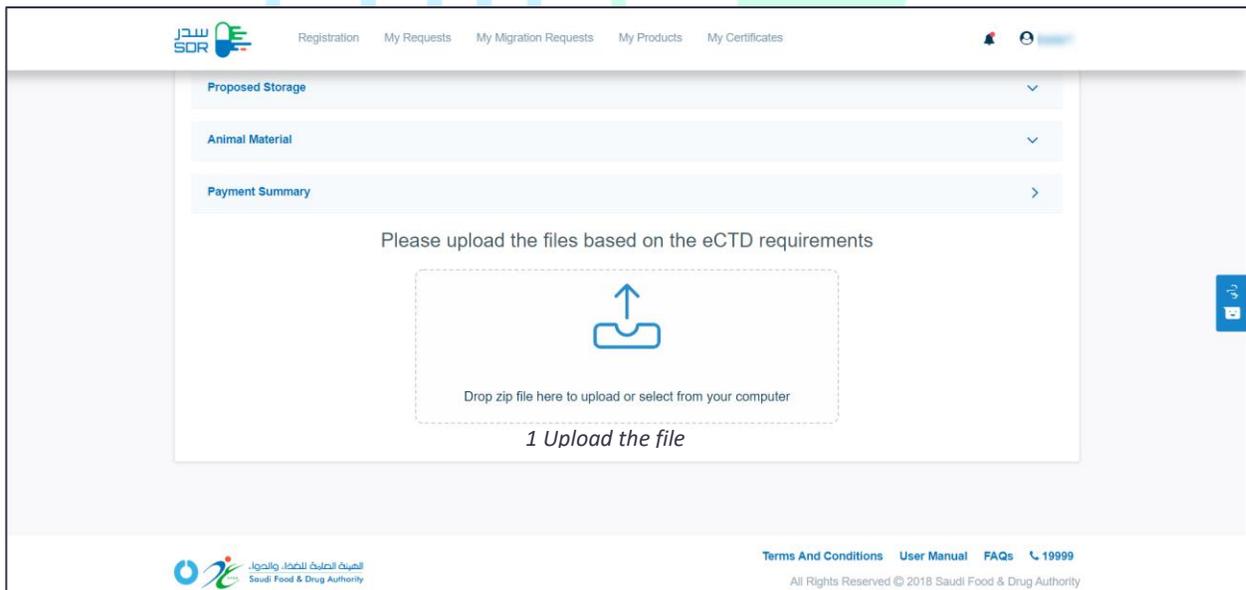
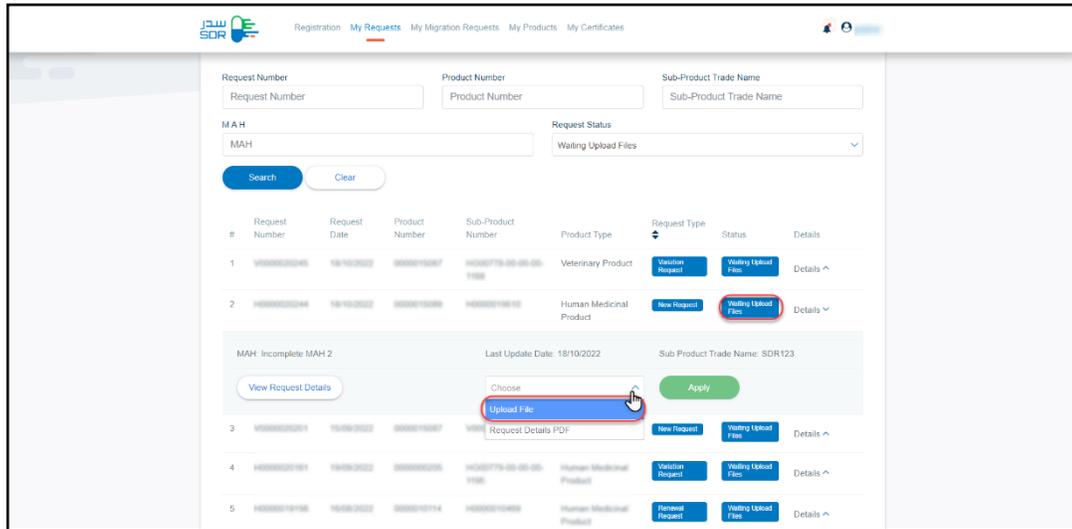
رقم التسجيل التجاري / Commercial Registration Number

بيانات المنتج - الخدمة / Product - Service Data

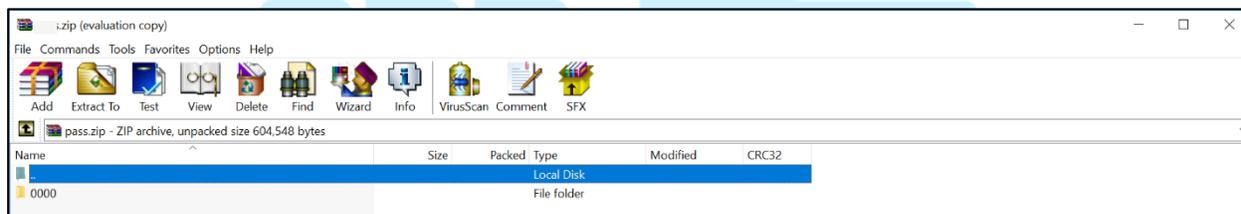
الاسم / Name	الكمية / Quantity	سعر الوحدة / Unit Price	مبلغ الفاتورة / Invoice Amount	معدل الضريبة / Tax Rate	الضريبة / Tax	الخصومات / Discounts	إجمالي / Total
خدمة الفحص والتوثيق - الخدمة المستقلة / Service Description	1	5900.0	5900.0	15	885.0	0	6785.0
إجمالي المطالبة (مع شاملة الضريبة المستضافة) / Total (Including VAT)							6325.0

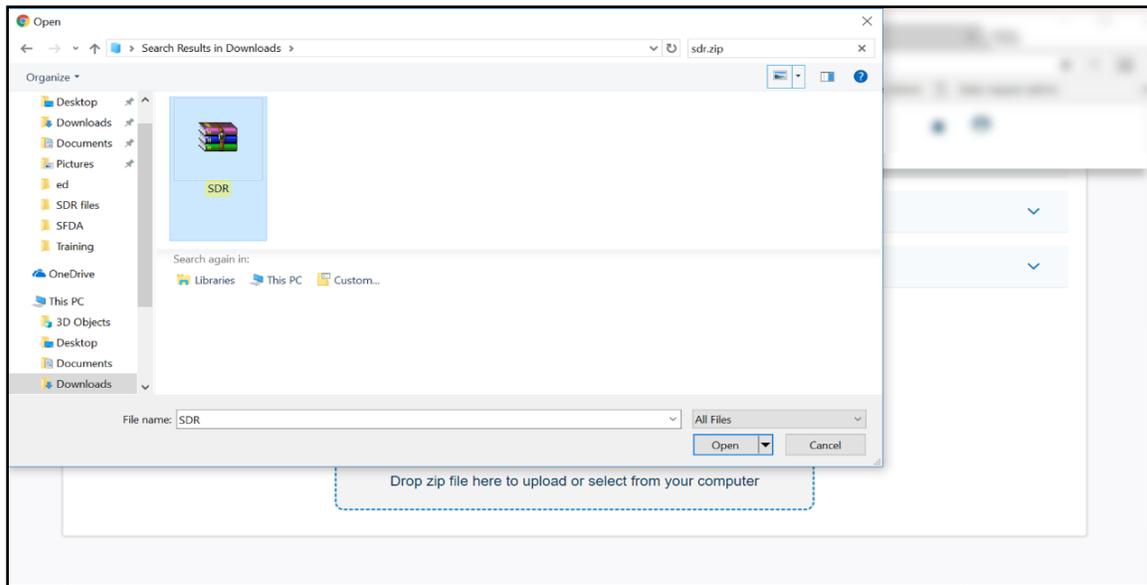
Third Step: User uploads files

- After payment, the status of the request will be “waiting upload the files”



- After correctly uploading the files, the status will be (Under Technical Validation) or (need manually validation).
 - After successfully passing the validation process, the request will be sent to SFDA with the status of "new request"
 - If the status of files validation is not passed, the system will display the errors and incomplete requested file and will allow the user to upload the files again.
- Note: File upload Processes:
 - Before uploading files, the drugs company must use the Sub (Product number) in the request Reference Number when filling the product data in the Envelop provided in eCTD format.
 - When uploading the request file, the company representative is requested to format to ZIP, so that the file to be compressed directly in ZIP format is the file with the name (000X) and not another file with a different name as displayed below and the first file in the image is the correct format to download the file.
 - Taking into consideration that all file contents must conform with SFDA regulation that listed in the Site [Click Here](#) .



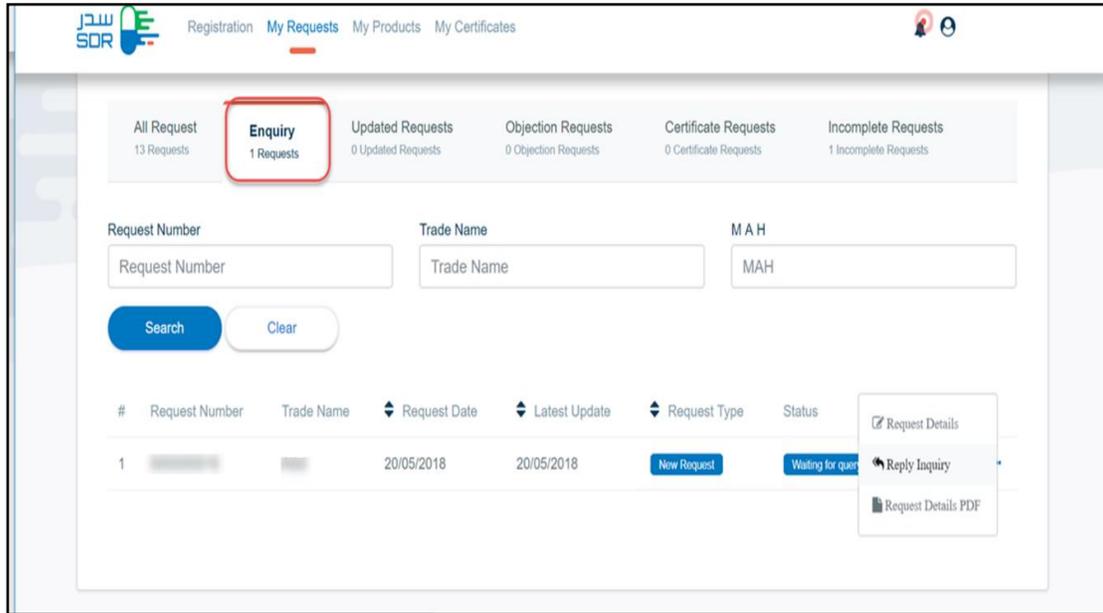


To learn more about the registration steps for all types of drugs.

Fourth Step: Add response to inquiries

The system enables the company representative to receive inquiries after being evaluated by all departments at once.

- User clicks on (Enquiry).
- User clicks on (Reply Enquiry) to take an action.
- User clicks on 
- The user fills in the response to the query.
- User can upload files if there is any.



Registration **My Requests** My Products My Certificates

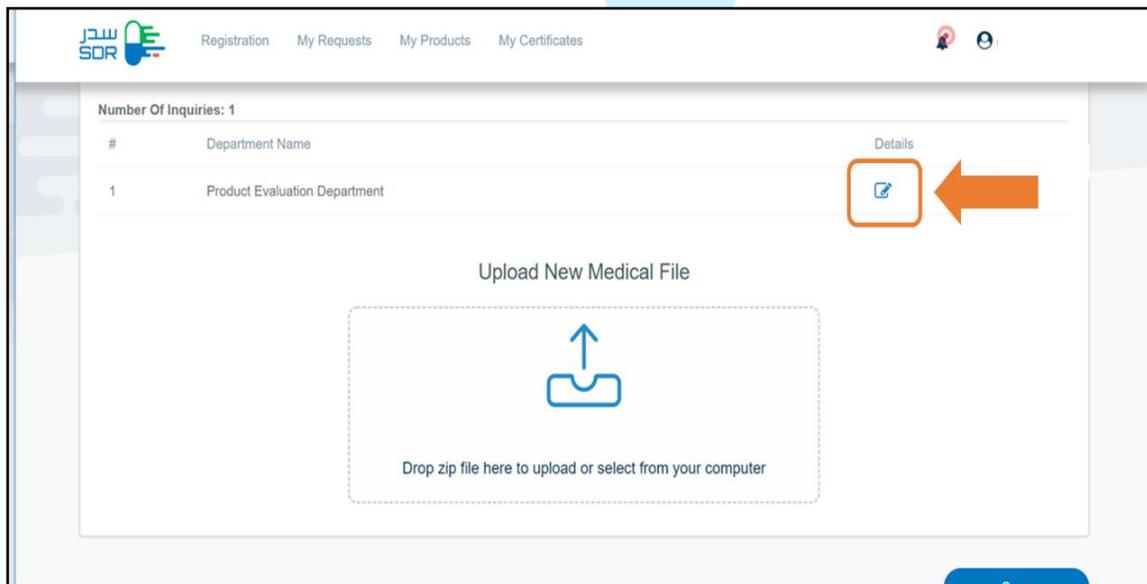
All Request 13 Requests **Enquiry 1 Requests** Updated Requests 0 Updated Requests Objection Requests 0 Objection Requests Certificate Requests 0 Certificate Requests Incomplete Requests 1 Incomplete Requests

Request Number: Request Number Trade Name: Trade Name MAH: MAH

Search Clear

#	Request Number	Trade Name	Request Date	Latest Update	Request Type	Status
1			20/05/2018	20/05/2018	New Request	Waiting for query

- Request Details
- Reply Inquiry
- Request Details PDF

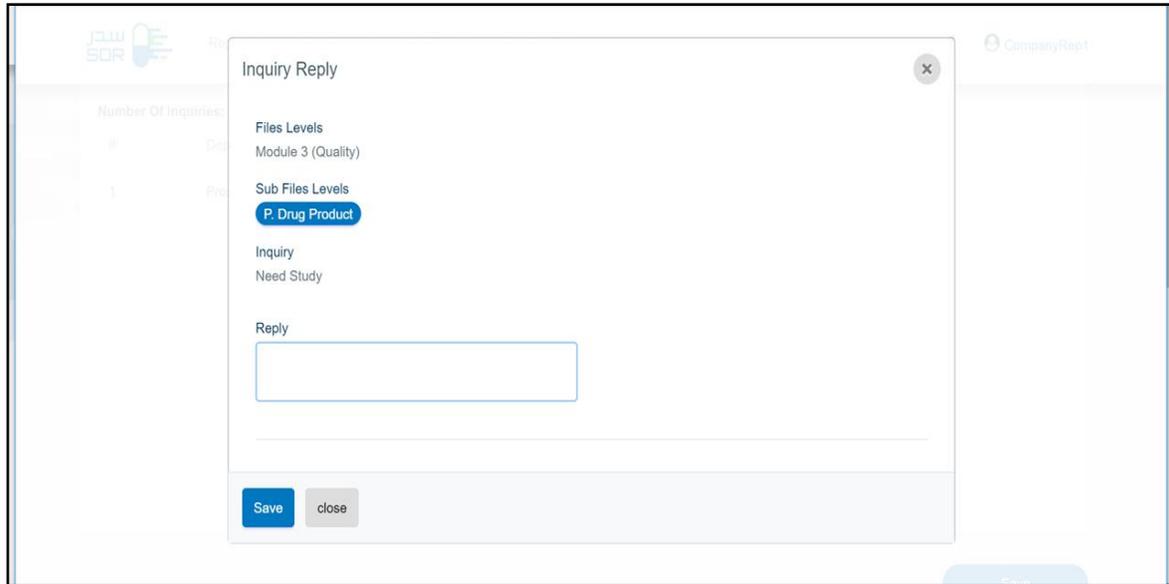
Registration **My Requests** My Products My Certificates

Number Of Inquiries: 1

#	Department Name	Details
1	Product Evaluation Department	

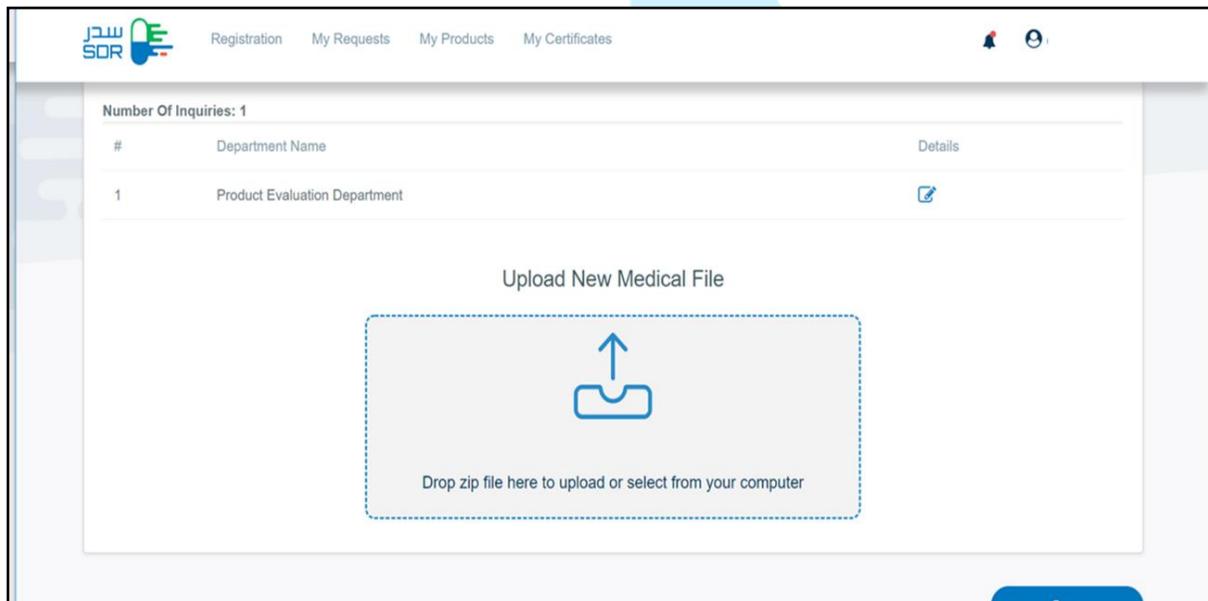
Upload New Medical File

Drop zip file here to upload or select from your computer



The screenshot shows a modal window titled "Inquiry Reply" with a close button (X) in the top right corner. The form contains the following sections:

- Files Levels:** Module 3 (Quality)
- Sub Files Levels:** P. Drug Product (highlighted in blue)
- Inquiry:** Need Study
- Reply:** A text input field with a yellow border.
- Buttons:** "Save" (blue) and "close" (grey) buttons at the bottom.

The screenshot shows the main dashboard of the SDR system. At the top, there are navigation tabs: "Registration", "My Requests", "My Products", and "My Certificates". The user's name "CompanyRep1" is visible in the top right corner.

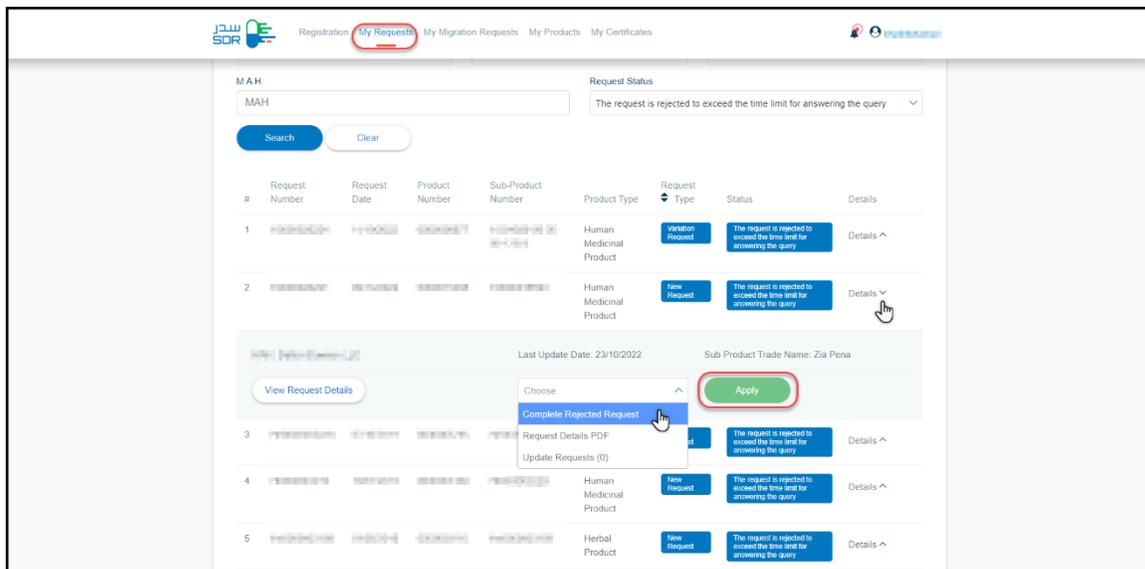
The main content area displays:

- Number Of Inquiries:** 1
- Inquiry Table:**

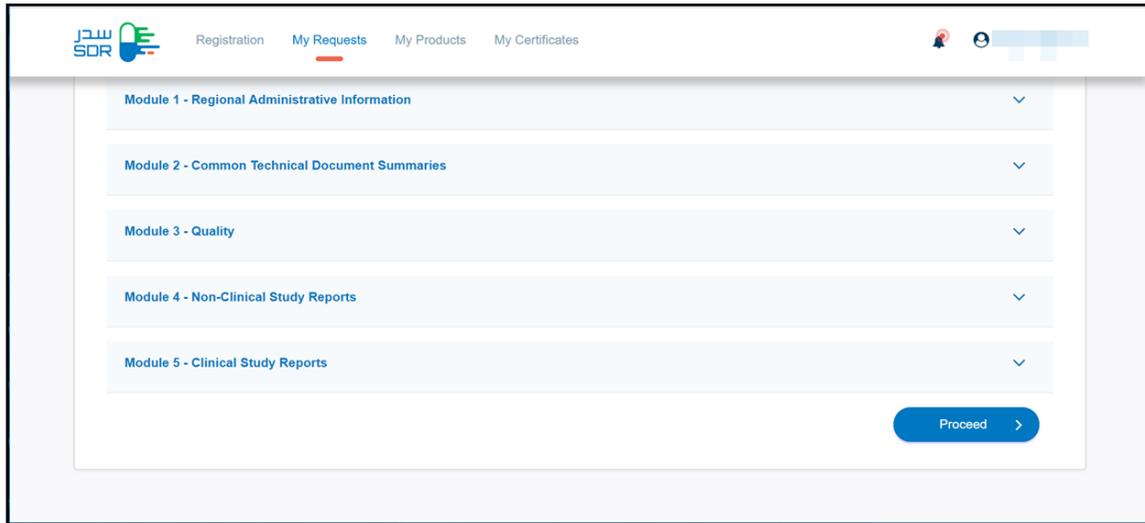
#	Department Name	Details
1	Product Evaluation Department	
- Upload New Medical File:** A section with a dashed border containing an upload icon and the text "Drop zip file here to upload or select from your computer".

Fifth step: complete files

- User selects complete request in order to take an action.
- User views the reason of rejection.
- User selects proceed.
- User selects editing the requested data.
- User can upload files if asked from SFDA.



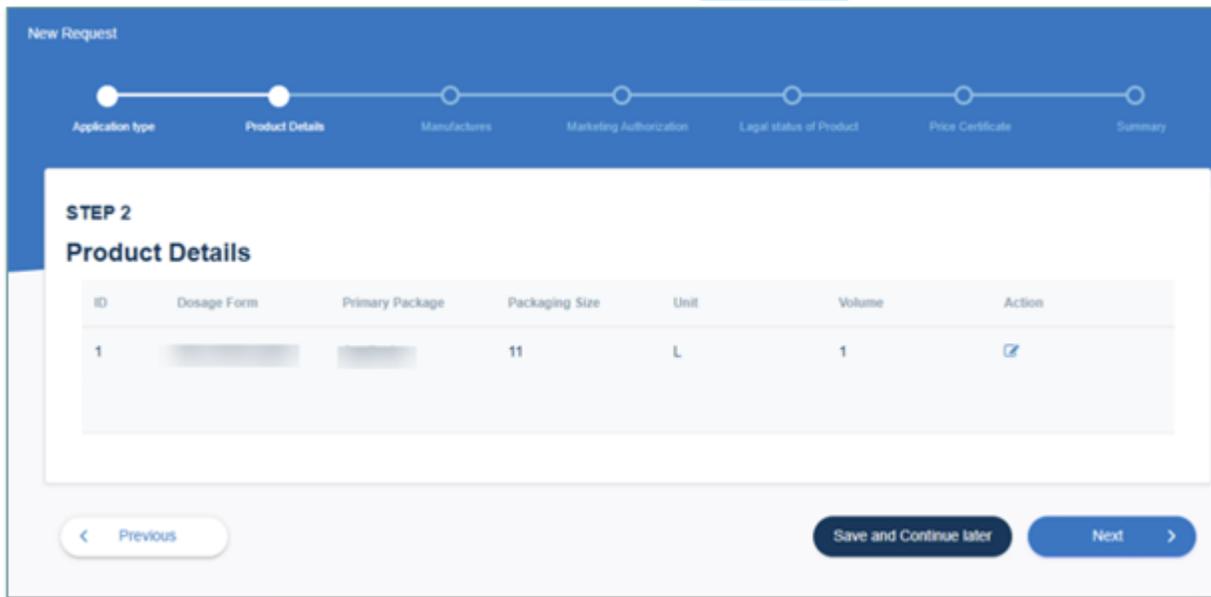
The screenshot displays the 'My Requests' section of the SDR system. At the top, there is a search bar for MAH (Marketing Authorization Holder) and a 'Request Status' dropdown menu. Below this is a table with columns for Request #, Request Number, Request Date, Product Number, Sub-Product Number, Product Type, Request Type, Status, and Details. The table contains five rows of data, all with a status of 'The request is rejected to exceed the time limit for answering the query'. A dropdown menu is open over the 'Request Type' column of the third row, showing options: 'Choose', 'Complete Rejected Request', 'Request Details PDF', and 'Update Requests (0)'. The 'Complete Rejected Request' option is highlighted. To the right of the dropdown, there is an 'Apply' button. The interface also shows navigation tabs for 'Registration', 'My Requests', 'My Migration Requests', 'My Products', and 'My Certificates'.



Registration My Requests My Products My Certificates

- Module 1 - Regional Administrative Information
- Module 2 - Common Technical Document Summaries
- Module 3 - Quality
- Module 4 - Non-Clinical Study Reports
- Module 5 - Clinical Study Reports

Proceed >

New Request

Application type Product Details Manufactures Marketing Authorization Legal status of Product Price Certificate Summary

STEP 2
Product Details

ID	Dosage Form	Primary Package	Packaging Size	Unit	Volume	Action
1			11	L	1	

Previous Save and Continue later Next >

Add/Update Sub-product

Sub-Product trade name in Saudi Arabia
 Sub-Product trade name in English (in Saudi Arabia)

Sub-Product trade name in Arabic (in Saudi Arabia)

Ingredients
 Active Substance
 Type of active substance
 Single
 Multiple

Active Substance name operator Quantity Unit Reference
 Choose... 0 Choose.. optional + Add Cancel

Active Substance name	operator	Quantity	unit	Reference	Action
test	Less than	1	L		✎ ✖

Excipient
 Excipient name Operator Unit
 Choose... Choose..

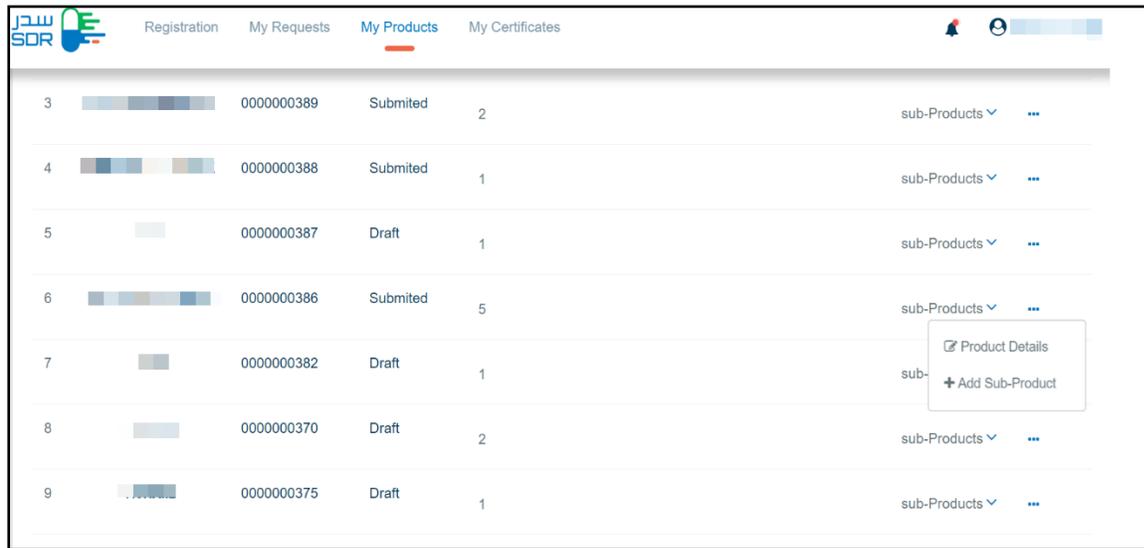
Reference Quantity is QS ?
 No Yes + Add Cancel

Excipient name	operator	Quantity	unit	Reference	Action
test	Equal to	QS	L	test	✎ ✖

Sixth step: Add sub product

The company representative can submit "sub-product" files after the initial submission on the same request, and it will be in the form of "size new package", "new dosage" and "new strength"

After completing the upload, the company representative can add "Sub Product" by going to "My Products" screen and chose the product to add SUB PRODUCT as displayed in the figure below:

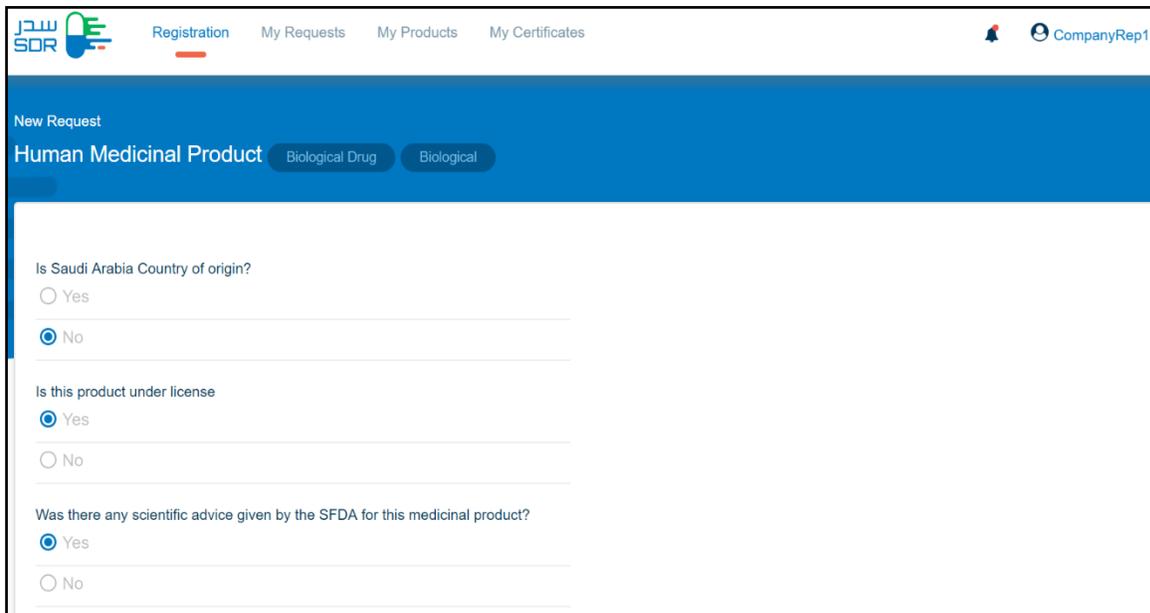


Product ID	Status	Count	Sub-Products
000000389	Submitted	2	sub-Products
000000388	Submitted	1	sub-Products
000000387	Draft	1	sub-Products
000000386	Submitted	5	sub-Products
000000382	Draft	1	sub-Products
000000370	Draft	2	sub-Products
000000375	Draft	1	sub-Products

- After selecting Add Sub Product, the company representative will see the registration page that was previously filled at the product registration phase.



Note: The company representative cannot modify the previous entered data for the same product Except for the “Product Details page” and “the Marketing Authorization Holder page,” as displayed below.



The screenshot shows the SDR web application interface. At the top, there is a navigation bar with the SDR logo, a notification bell, and the user profile 'CompanyRep1'. Below the navigation bar, the main content area is titled 'New Request' and 'Human Medicinal Product'. There are two tabs: 'Biological Drug' and 'Biological'. The form contains three questions with radio button options:

- Is Saudi Arabia Country of origin?
 - Yes
 - No
- Is this product under license
 - Yes
 - No
- Was there any scientific advice given by the SFDA for this medicinal product?
 - Yes
 - No

After skipping the product registration, the "Product Details" screen will appear so that the company representative will be able to add "Sub product":

The Legal status of product screen will be unchangeable based on previous recorded data.

New Request

Application type Product Details Manufactures Marketing Authorization Legal status of Product Price Certificate Summary

STEP 2
Product Details

ID	Dosage Form	Primary Package	Packaging Size	Unit	Volume	Action
1			11	L	1	✎

[Previous](#) [Save and Continue later](#) [Next](#)

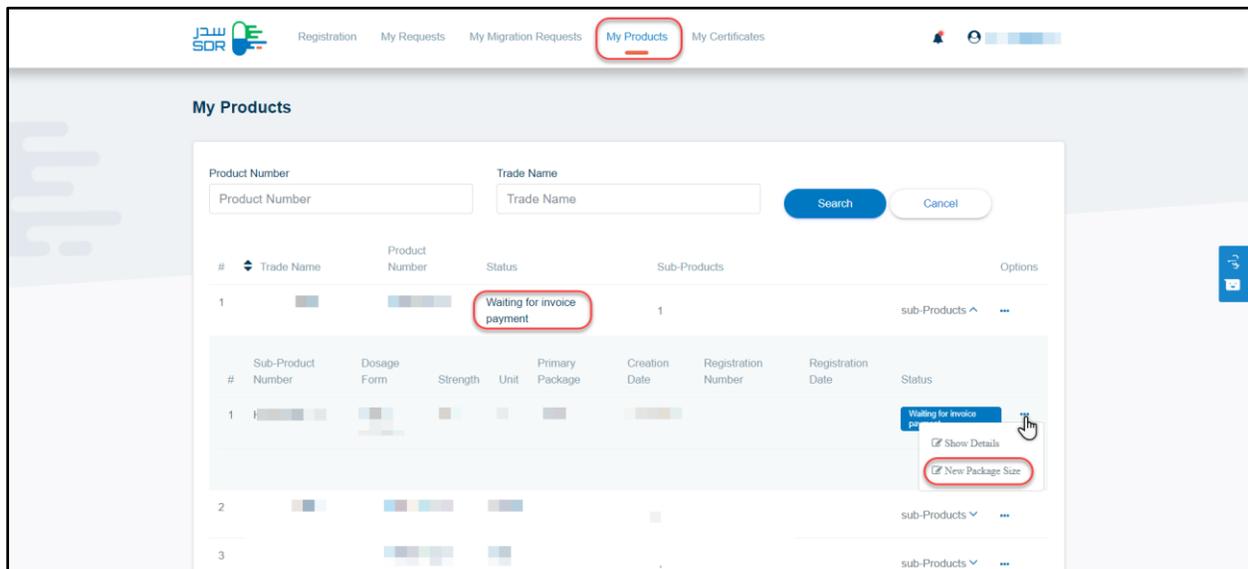


- After completing all required fields, a payment invoice will be issued.
- The status of the order is "waiting for invoice payment"

Add a package size of a sub-product

The company representative can add a package size of a sub-product after completing all the new registration steps and issuing a payment bill. The status of the request will be "Waiting for invoice payment", add the new package size in this case will be free of charge.

To add a package size after registering the product, selects "My Products" tab, then click on the icon After that, choose "New Package Size" as shown in the figure below:



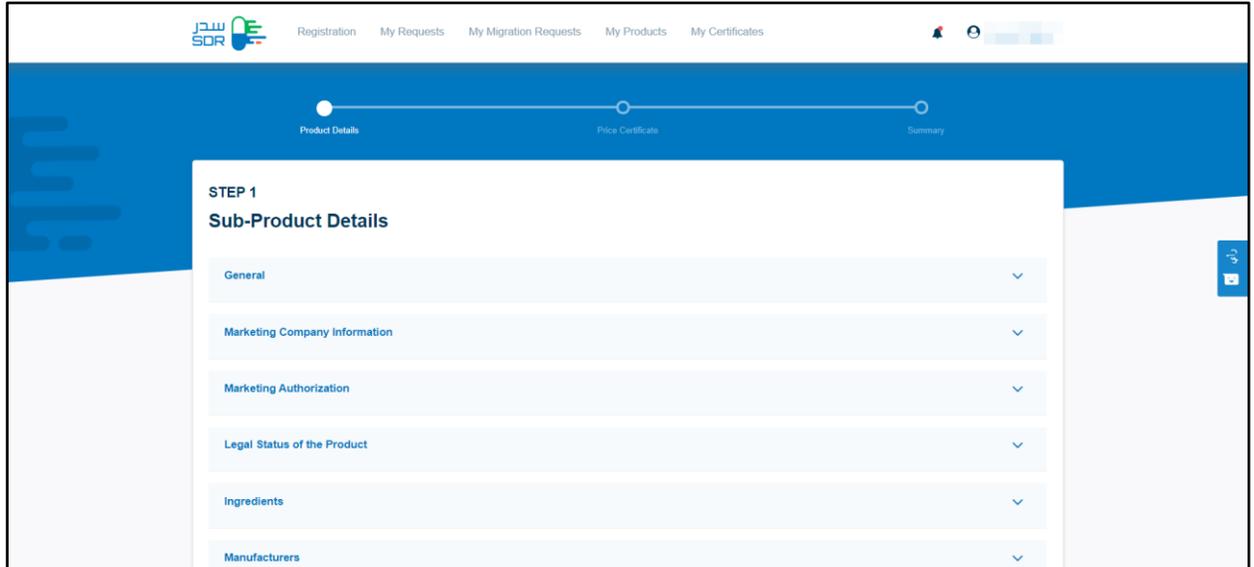
Note: After the invoice payment, it is not possible to add a new package size to the sub-product

until the study of the request is complete and its status is: "The request was accepted by the committee", and there will be fees for this request.

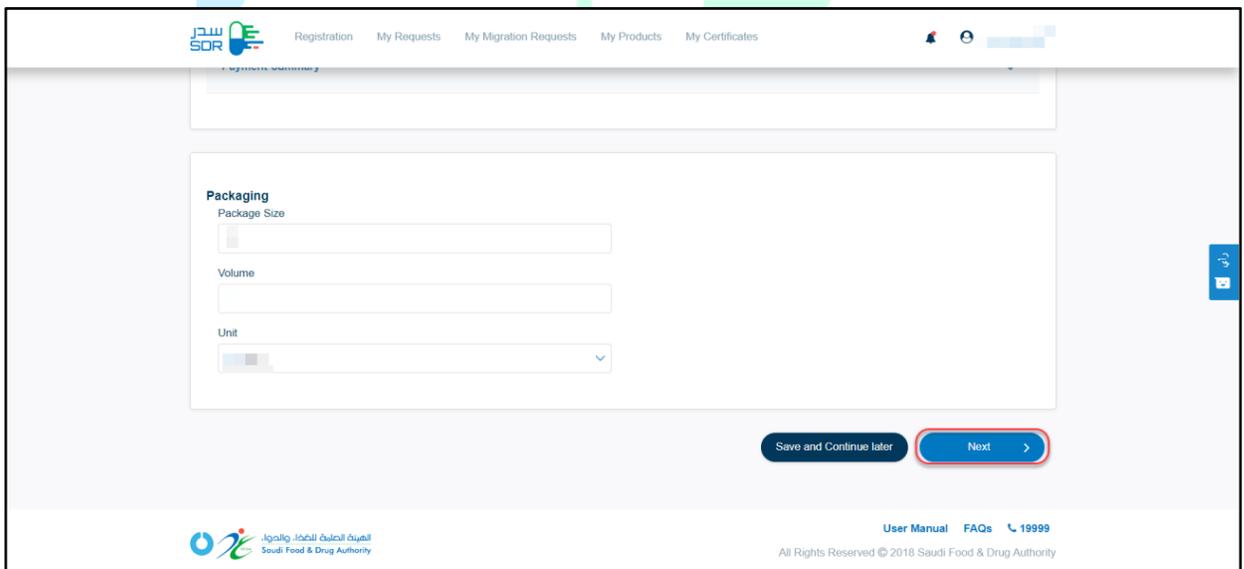
Cases of adding new package size will be chargeable are:

- The product has been registered
- The product registration has been canceled
- The product registration certificate expires soon
- Certificate expired

- The system will display all the data of the registration request form, and at the end fill out the package size data, then click Next



The screenshot shows the 'STEP 1 Sub-Product Details' form. The navigation bar includes 'Registration', 'My Requests', 'My Migration Requests', 'My Products', and 'My Certificates'. A progress indicator shows three steps: 'Product Details' (active), 'Price Certificate', and 'Summary'. The form contains several expandable sections: 'General', 'Marketing Company Information', 'Marketing Authorization', 'Legal Status of the Product', 'Ingredients', and 'Manufacturers'. A 'Save' button is visible on the right side of the form.



The screenshot shows the 'Packaging' section of the registration request form. The navigation bar and progress indicator are the same as in the previous screenshot. The 'Packaging' section includes input fields for 'Package Size', 'Volume', and 'Unit'. At the bottom of the form, there are two buttons: 'Save and Continue later' and 'Next >'. The footer contains the SDR logo, the text 'الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority', and links for 'User Manual', 'FAQs', and '19999'. Copyright information 'All Rights Reserved © 2018 Saudi Food & Drug Authority' is also present.

- The next step is the price certificate, fill out all the required fields then click “next” to move to the summary page. To submit the request, fill out all the required fields then click “Submit”

Note: If the main order is tax-exempt, this does not mean that additional items are also tax-exempt.

Price Certificate ✕

Pricing
Please enter the CIF and Currency, pricing department will study the request, if the product is not subject to pricing, CIF will not be included in the certificate

CIF Price Currency

Pricing in Origin Country

Ex-Factory Price ExFactory Price Currency Wholesale Price Wholesale Price Currency

Public Price Public Price Currency

Marketing Pricing
Please enter the price in countries where the product is marketed


Registration
My Requests
My Migration Requests
My Products
My Certificates

Product Details
Price Certificate
Summary

Summary

Cost	Vat Cost	Total
0	0	0

[Bill Details](#)

Declaration
By sending this request I hereby certify that the submitted are true and accurate and changes will not be made until they are approved by SFDA

Title Name

File Signature [Select file](#)

Company Stamp [Select file](#)

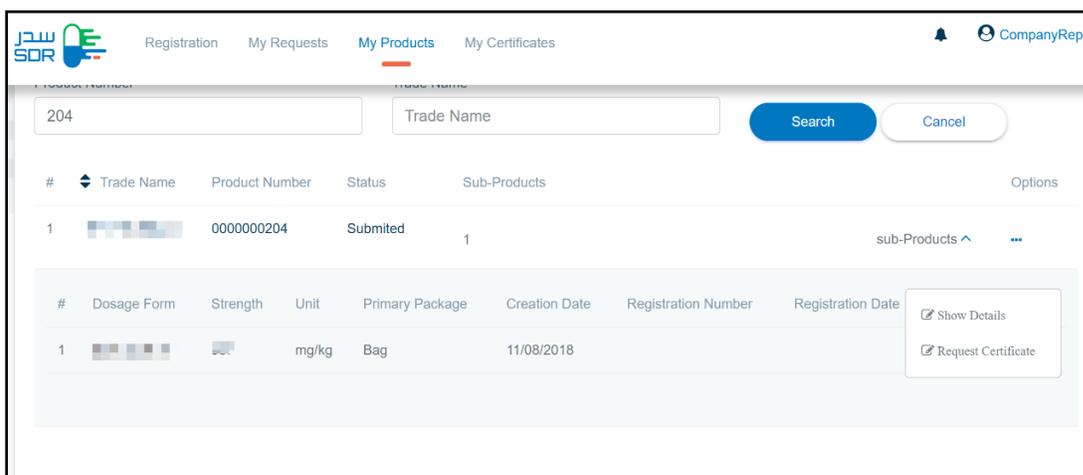
Notes:

- If the request status is "request was accepted by the committee", a SADAD payment bill will show before submitting the application.
- To add the pack size for an exempted product, the request status is "submitted", and the status of the sub-product is "Waiting for upload file". The system displays the list of products. The company representative must select one of the exempt sub-products. The system displays a product registration request form of type "new Pack Size." The company representative must fill out the request application. Then the request status will change to "waiting for upload file."

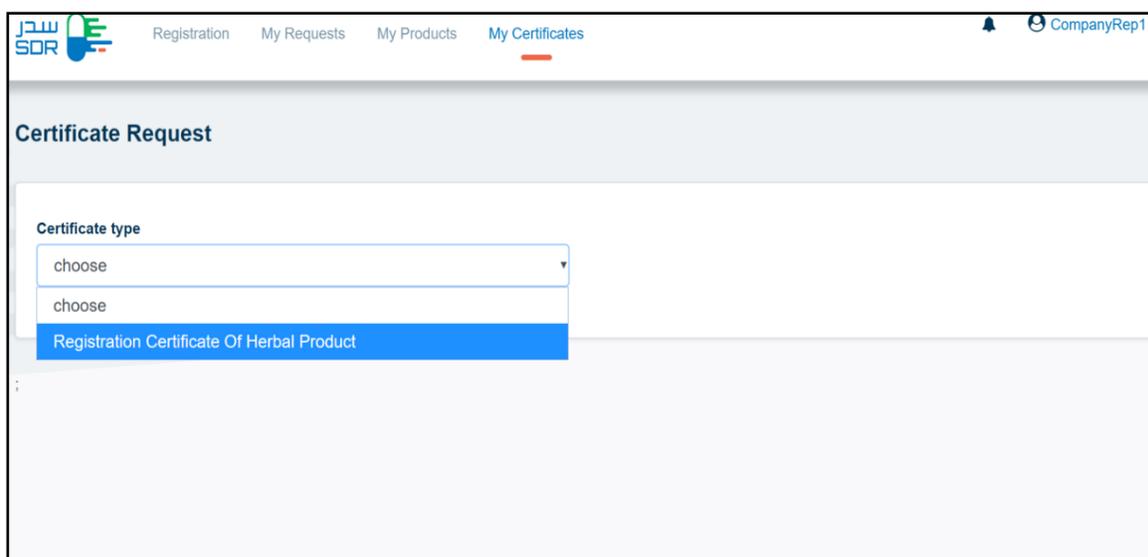


Seventh Step: Print Certifications

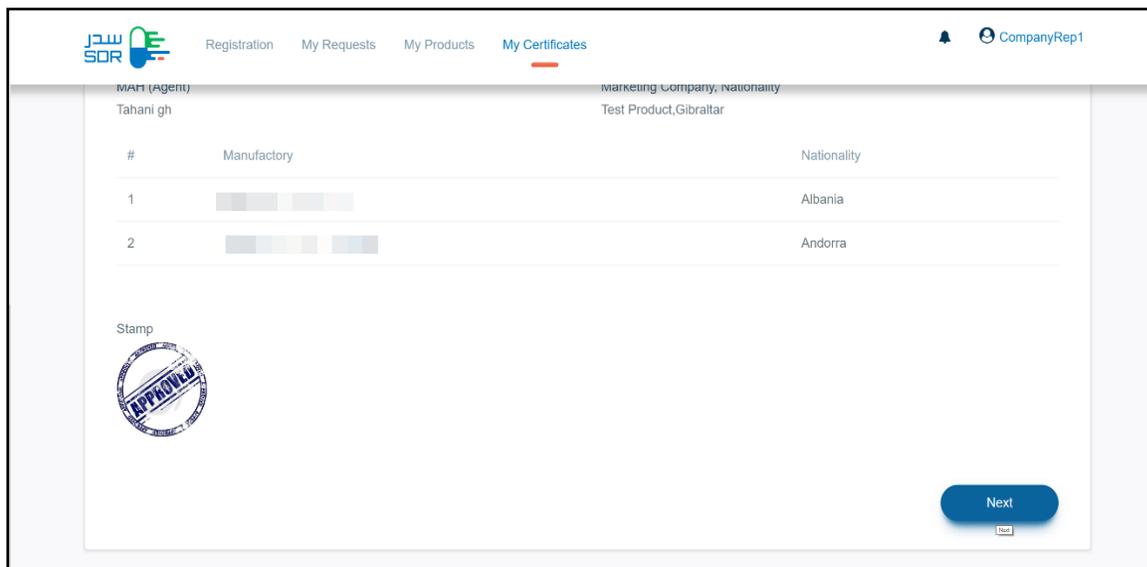
- After SFDA approves the request for registration of the product, the representative of the company should request to print the certificate by going to system screen choosing my products at the top.
- Choose “Take Action” and click on Request Certificate as displayed in Figure below.



- Choose the type of certificate that the company representative wants to issue by moving from the Products screen to the Certificates screen as displayed below:



- Confirm the product information to issue the certificate and choose the icon "NEXT"



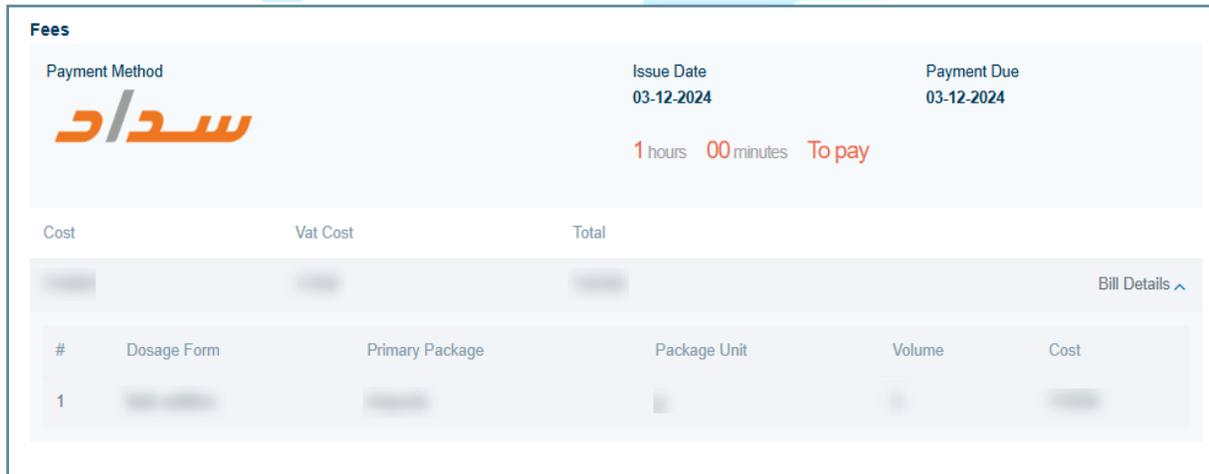
MAH (Agent) Tahani gh Marketing Company, nationality Test Product, Gibraltar

#	Manufactory	Nationality
1		Albania
2		Andorra

Stamp

Next

- Chose the invoice request from the list "Take action" in order to request the certificate:



Fees

Payment Method  Issue Date 03-12-2024 Payment Due 03-12-2024

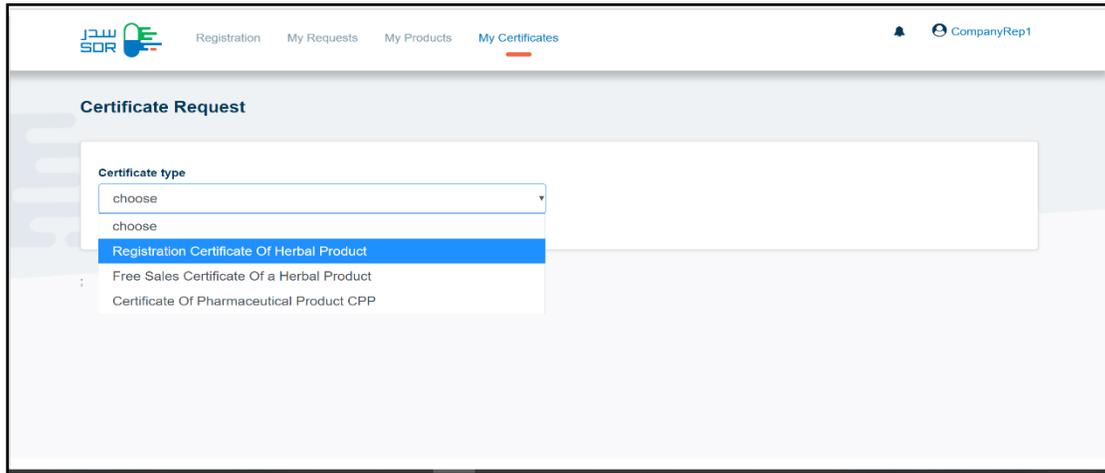
1 hours 00 minutes To pay

Cost	Vat Cost	Total

Bill Details ^

#	Dosage Form	Primary Package	Package Unit	Volume	Cost
1					

- After payment, the company representative can issue the certificate through the certificates screen.

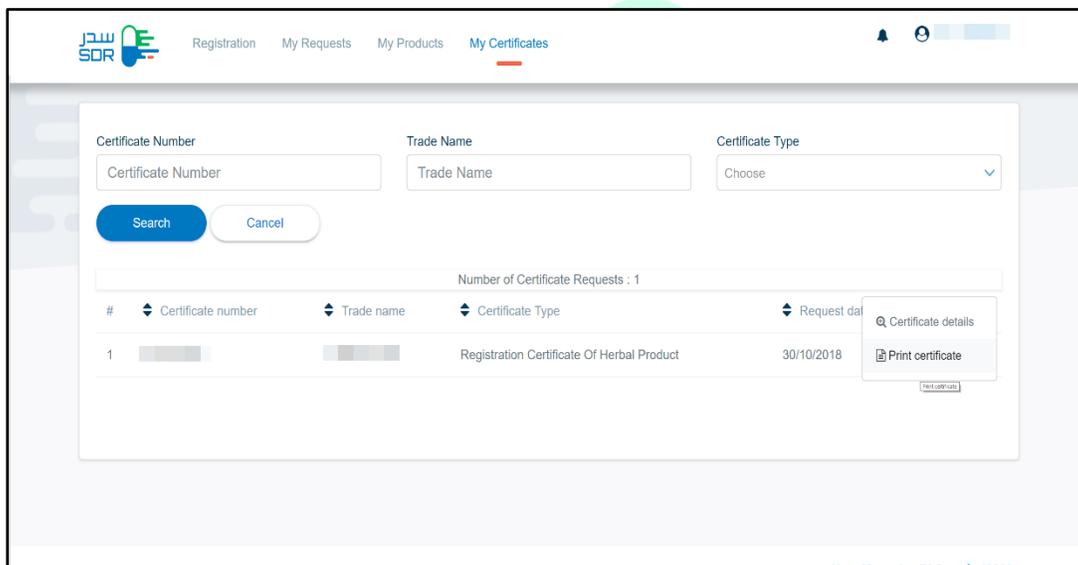


Certificate Request

Certificate type

- choose
- choose
- Registration Certificate Of Herbal Product
- Free Sales Certificate Of a Herbal Product
- Certificate Of Pharmaceutical Product CPP

- The paid certificate will be displayed through the certificate screen as displayed at the top of the screen, and company representative can print the certificate immediately.



Registration My Requests My Products My Certificates

Certificate Number Trade Name Certificate Type

Certificate Number Trade Name Choose

Search Cancel

Number of Certificate Requests : 1

#	Certificate number	Trade name	Certificate Type	Request date	
1	[redacted]	[redacted]	Registration Certificate Of Herbal Product	30/10/2018	Certificate details Print certificate

- Certificate form of drug registration

Certificate No.: Issue Date: Expiry Date:		رقم الشهادة: تاريخ الإصدار: تاريخ الانتهاء:	شهادة تسجيل مستحضر عشبي Registration Certificate of a Herbal Product	الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority
		طريقة الوصف Legal Status	الاسم التجاري Trade Name	
		الوكيل Marketing Authorization Holder (Agent)	الاسم العلمي Generic Name	
		الشركة الصوقة و جنسيتها Marketing Company, Nationality	رقم التسجيل Registration Number	
		الشركة الصانعة و جنسيتها Manufacturers, Nationality	الشكل الصيدلاني Dosage Form	
			التركيز/الوحدة Product Strength	
			مدة الصلاحية Shelf Life	
			نوع العبوة Packaging Type	
			حجم العبوة Packaging Size/Volume	
			ظروف التخزين Storage Conditions	

Stamp



Note:
The

customer can request a certificate of the following types of the same previous work procedures as the following:

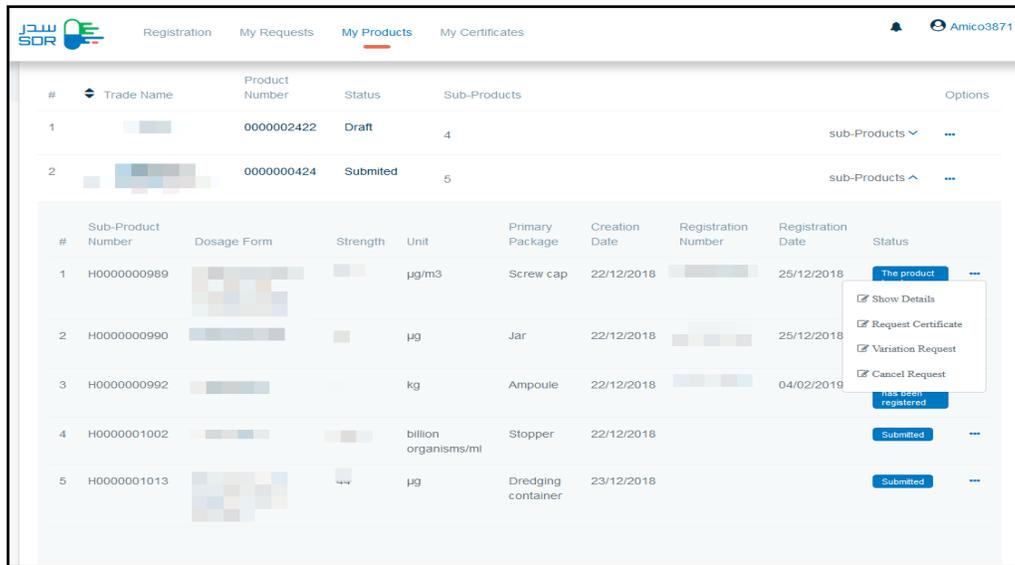
- Certificate of registration of a Drug product
- Certificate of registration of a veterinary product
- Herbal registration certificate
- Free of sale certificate
- CPP pharmaceutical product certificate

- Free Sale Certificate and CPP pharmaceutical product certificate: Certificate issued by the supervisory authority in the country in which the manufacturing is carried out.

Note: The free sale certificate and CPP certificate can be obtained after registration.

Eighth Step: Variation request

- When the product status is registered, the system will allow the user to request a variation as displayed in the picture below:



#	Trade Name	Product Number	Status	Sub-Products	Options
1	[Redacted]	0000002422	Draft	4	sub-Products v ...
2	[Redacted]	000000424	Submitted	5	sub-Products ^ ...

#	Sub-Product Number	Dosage Form	Strength	Unit	Primary Package	Creation Date	Registration Number	Registration Date	Status	Options
1	H000000989	[Redacted]	[Redacted]	µg/m3	Screw cap	22/12/2018	[Redacted]	25/12/2018	The product	...
2	H000000990	[Redacted]	[Redacted]	µg	Jar	22/12/2018	[Redacted]	25/12/2018	Registered	...
3	H000000992	[Redacted]	[Redacted]	kg	Ampoule	22/12/2018	[Redacted]	04/02/2019	Registered	...
4	H0000001002	[Redacted]	[Redacted]	billion organisms/ml	Stopper	22/12/2018	[Redacted]		Submitted	...
5	H0000001013	[Redacted]	[Redacted]	µg	Dredging container	23/12/2018	[Redacted]		Submitted	...



- After choosing a variation request, the system will direct the company representative to the screen below to complete the requested data as below:

Variation Request Detail

Request type
Application Concern

Choose

Proposed Changes
Current

Current

Proposed

Proposed

+ Add Cancel

Number And Title Of Variations

Choose +

Change affect
Does this change affect the last updated drug application form?

No

Yes

Next >



Variation Request Detail

Application Concern Types

- IV, PMF/VAMF

Number And Title Of Variations

Choose +

72.Change in the name and/or address of a blood establishment including blood/plasma collection centers

<p>Procedure Type</p> <p>IA</p>	<p>Implementation Date</p>
--	-----------------------------------

Changes approval

Note that the variation request may affect information in certificates related to the sub product, please request a new certificate once variation is approved to reflect those updates

< Previous

Next >

- After completing the data as needed by the system and press NEXT, the system will direct the user to product details screen as displayed below:

Fees

Payment Method 	Issue Date 03-09-2024	Payment Due 03-09-2024
1 hours 00 minutes To pay		

Cost	Vat Cost	Total	
5500	825	6325	Bill Details ▾

Invoice Type

Issuing tax invoice

Issuing simplified invoice

Please be aware that you can only convert a simplified invoice into a tax invoice if you specify the invoice type as 'tax invoice' before proceeding with payment through Amaly platform

If the request is rejected for one of the following reasons, the company representative can complete the order through My requests screen as displayed in the picture below:

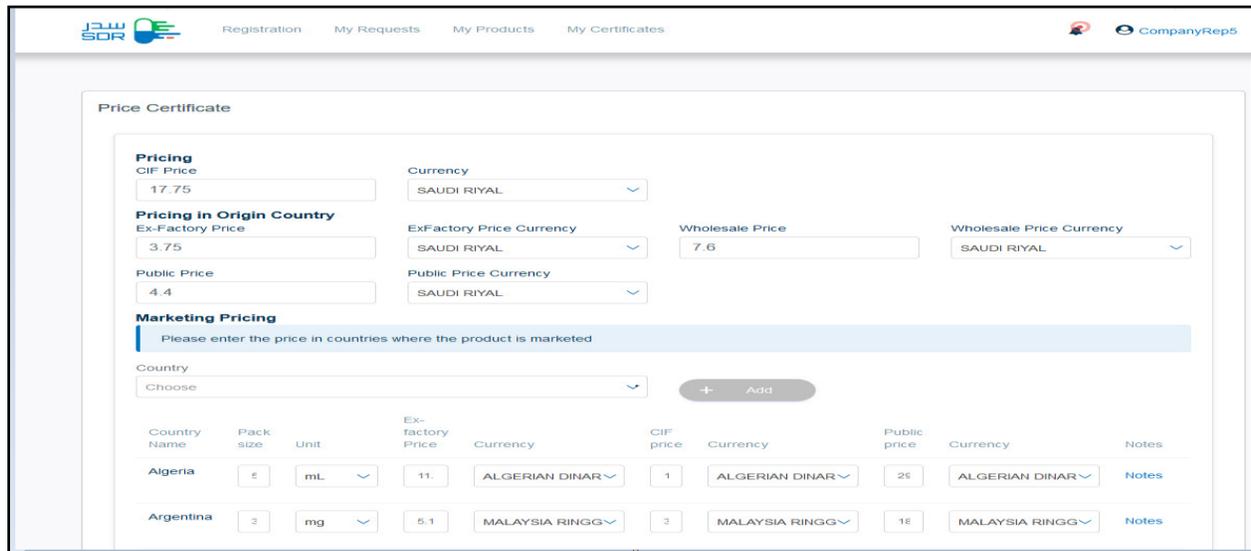
- The request is rejected because of incomplete request
- The request is rejected to exceed the time limit for answering the query
- The request is rejected because lack of requirement

Note:

- To issue a new certificate, the status of the certificate must be "expired", "expired soon".
- And if the certificate is "expired soon", the following message will appear "after receiving the renewal approval, you cannot request a new certificate until the current certificate becomes expired"

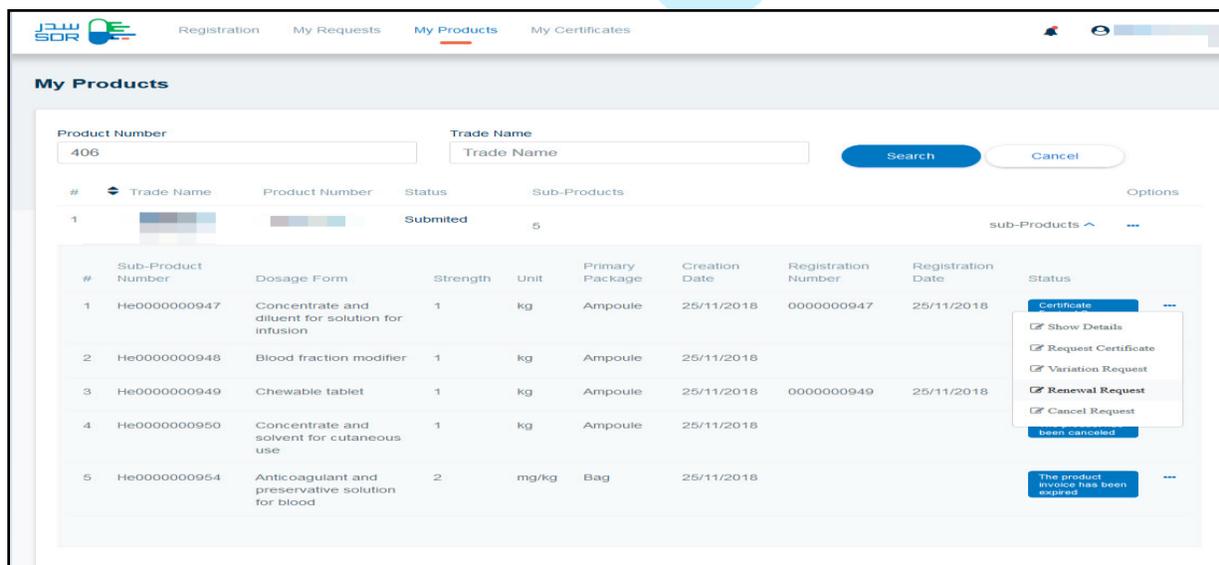
Ninth step: Product Renewal

If the company representative intends to renew the product, in case if the product is finished or about to finish, the company representative can renew the product by going to the product screen and selecting the finished product and creating a renewal request, as displayed in the figure below:



The screenshot shows the 'Price Certificate' form. It includes sections for Pricing, Pricing in Origin Country, and Marketing Pricing. The Pricing section has fields for CIF Price (17.75) and Currency (SAUDI RIYAL). The Pricing in Origin Country section has fields for Ex-Factory Price (3.75), ExFactory Price Currency (SAUDI RIYAL), Wholesale Price (7.6), and Wholesale Price Currency (SAUDI RIYAL). The Marketing Pricing section has a table for entering prices in different countries.

Country Name	Pack size	Unit	Ex-factory Price	Currency	CIF price	Currency	Public price	Currency	Notes
Algeria	5	mL	11.	ALGERIAN DINAR	1	ALGERIAN DINAR	2%	ALGERIAN DINAR	Notes
Argentina	3	mg	5.1	MALAYSIA RINGG	3	MALAYSIA RINGG	1%	MALAYSIA RINGG	Notes



The screenshot shows the 'My Products' page. It includes a search bar for Product Number (406) and Trade Name. Below the search bar is a table of products with a dropdown menu for the first product.

#	Trade Name	Product Number	Status	Sub-Products	Options
1			Submitted	5	sub-Products ^

#	Sub-Product Number	Dosage Form	Strength	Unit	Primary Package	Creation Date	Registration Number	Registration Date	Status
1	He0000000947	Concentrate and diluent for solution for infusion	1	kg	Ampoule	25/11/2018	0000000947	25/11/2018	Certificate
2	He0000000948	Blood fraction modifier	1	kg	Ampoule	25/11/2018			Show Details
3	He0000000949	Chewable tablet	1	kg	Ampoule	25/11/2018	0000000949	25/11/2018	Request Certificate
4	He0000000950	Concentrate and solvent for cutaneous use	1	kg	Ampoule	25/11/2018			Variation Request
5	He0000000954	Anticoagulant and preservative solution for blood	2	mg/kg	Bag	25/11/2018			Renewal Request

Fees

Payment Method 	Issue Date 04-02-2019	Payment Due 04-02-2019
2 hours 00 minutes To pay		

Cost	Vat Cost	Total
8800	440	9240

[Bill Details ^](#)

#	Dosage Form	Strength	Strength Unit	Primary Package	Package Unit	Volume	Cost
1	Concentrate and diluent for solution for infusion	1	kg	Ampoule	g	1	8800

[Submit](#)

- After that the user clicks the Submit icon to review the prices and renewal fees as displayed in the image above.

Note: Pricing screen as well as fees screen are all in one screen in the system will be displayed after press Submit through the screen of renewal product.

Tenth Step: Objection Request

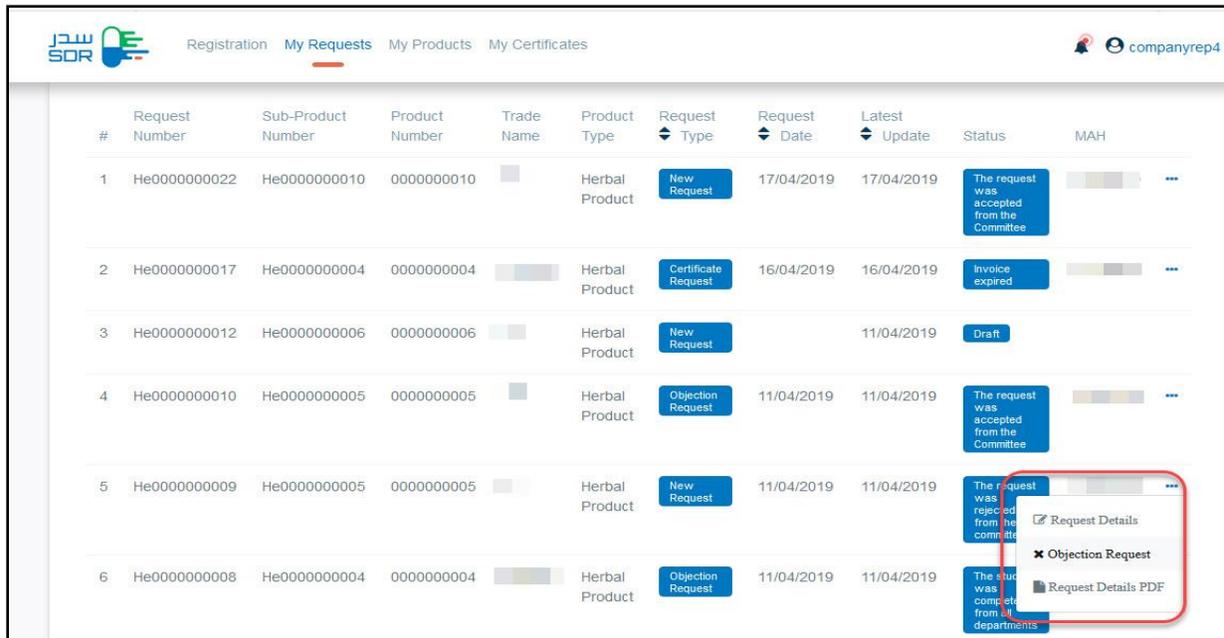
The system allows companies to make objections on requests whose status is as follows:

- The request was rejected by the committee.
- The product has been registered.
- The request was accepted by the committee.

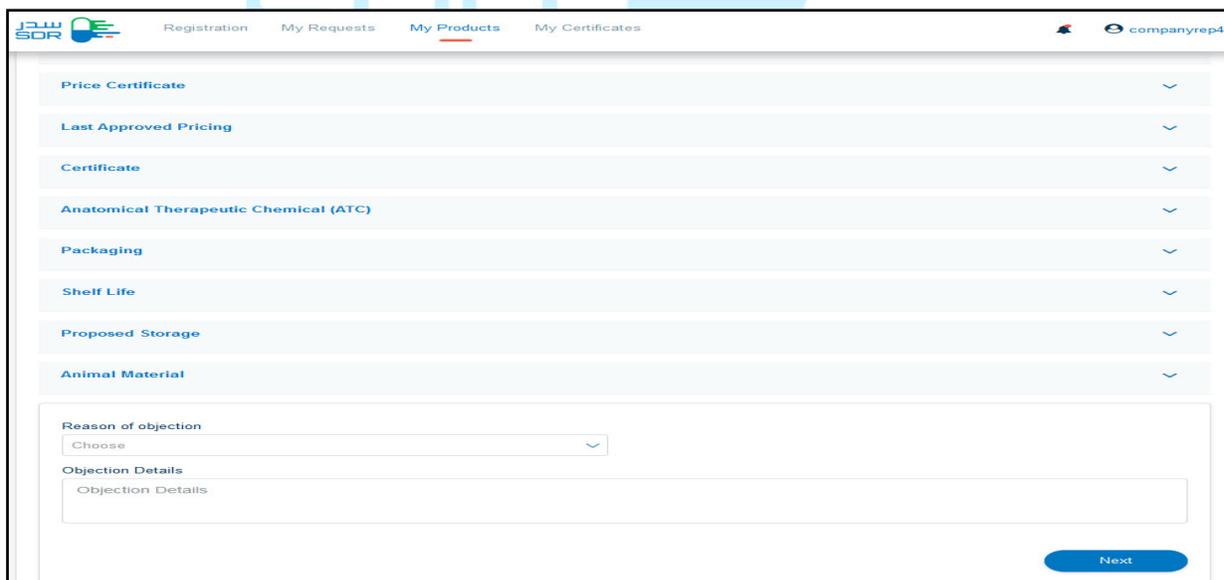
Types of objections that can be made through the E-SDR system in accordance with the status:

- If the product registration request is accepted, the system allows the company representative to raise objection to the price and the expiry duration.
- If the request for "Variation" is accepted, the system allows the representative of the company to raise an objection to the price only.
- If the product registration request is rejected, the system allows the company representative to raise objection to the rejection decisions.
- If a price adjustment request is rejected, the system allows the company representative to raise objection to the rejection decisions.
- If a request for modification of non-price data is rejected, the representative of the company is not allowed to request an objection, and requests Variation again.
- If a request for a price adjustment and other data is rejected in the same order, the representative of the company can only raise objection to the decision of rejecting the price and submit a request for an adjustment to the rest of the data.
- If a request for cancellation is rejected, the representative of the company can submit objection to the rejection decision.
- If a renewal request is rejected, the representative of the company can raise objection to the rejection decision.
- If the renewal request is accepted, the company representative is not allowed to object any rejected request prior to the renewal date.

The Company representative can fill out the form after clicking “objection request” which’s the reason and the details for the objection



#	Request Number	Sub-Product Number	Product Number	Trade Name	Product Type	Request Type	Request Date	Latest Update	Status	MAH
1	He0000000022	He0000000010	0000000010		Herbal Product	New Request	17/04/2019	17/04/2019	The request was accepted from the Committee	
2	He0000000017	He0000000004	0000000004		Herbal Product	Certificate Request	16/04/2019	16/04/2019	Invoice expired	
3	He0000000012	He0000000006	0000000006		Herbal Product	New Request		11/04/2019	Draft	
4	He0000000010	He0000000005	0000000005		Herbal Product	Objection Request	11/04/2019	11/04/2019	The request was accepted from the Committee	
5	He0000000009	He0000000005	0000000005		Herbal Product	New Request	11/04/2019	11/04/2019	The request was rejected from the committee	
6	He0000000008	He0000000004	0000000004		Herbal Product	Objection Request	11/04/2019	11/04/2019	The study was completed from all departments	



Price Certificate

Last Approved Pricing

Certificate

Anatomical Therapeutic Chemical (ATC)

Packaging

Shelf Life

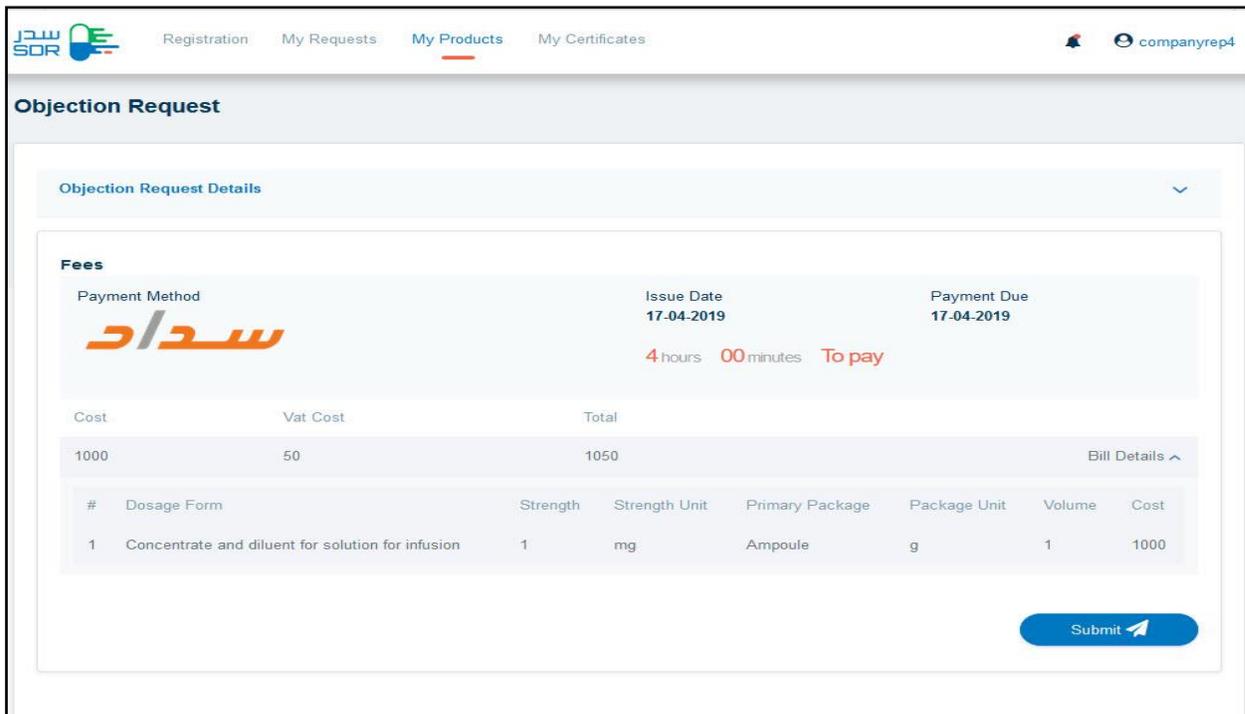
Proposed Storage

Animal Material

Reason of objection
Choose

Objection Details
Objection Details

Next



Objection Request

Objection Request Details

Fees

Payment Method:  Issue Date: 17-04-2019 Payment Due: 17-04-2019

4 hours 00 minutes To pay

Cost	Vat Cost	Total
1000	50	1050

Bill Details

#	Dosage Form	Strength	Strength Unit	Primary Package	Package Unit	Volume	Cost
1	Concentrate and diluent for solution for infusion	1	mg	Ampoule	g	1	1000

Submit

After filling in the data for the objection request, the system displays the payment screen for payment only in case of "price objection" and then the order status is changed as follows:

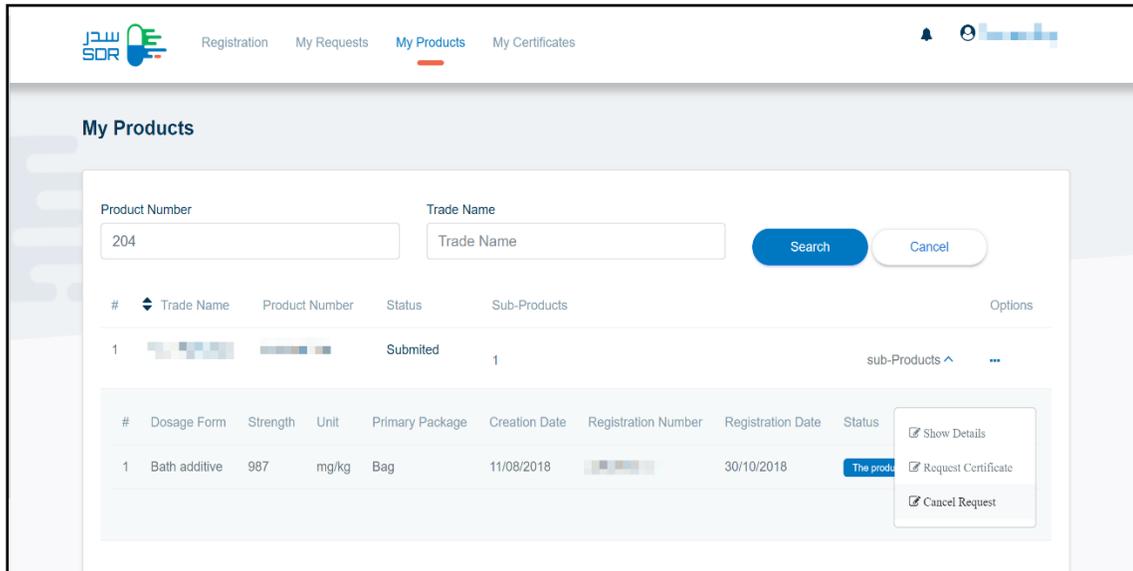
- The request status is "Waiting for invoice payment" pending the payment of the invoice.
- After payment, the status of the request "Waiting upload files" pending the upload of the request files.
- After successfully uploading, the status of the request is "Under technical validation" until the system automatically checks the files according to the requirements and according to the type of request.

Note: Payment is not required for other objection cases.

Eleventh step: Cancel the product

When the company representative intends to cancel the product, the product status must be "registered" on My product.

The process of cancelling is to go to the “take action “below and choose cancel request.



The screenshot displays the 'My Products' interface. At the top, there are navigation tabs: 'Registration', 'My Requests', 'My Products' (active), and 'My Certificates'. The main content area is titled 'My Products' and contains a search form with 'Product Number' (204) and 'Trade Name' fields, along with 'Search' and 'Cancel' buttons. Below the search form is a table with the following columns: #, Trade Name, Product Number, Status, and Sub-Products. The table contains one row with the following data: # 1, Trade Name [blurred], Product Number [blurred], Status Submitted, and Sub-Products 1. A dropdown menu is open for the first product, showing options: 'Show Details', 'Request Certificate', and 'Cancel Request'.

The system screen will display the cancel request form to fill in the required fields that's displayed in the figure and click submit under the bottom of the screen and choose Cancel Request.

Amounts of product Imported to Saudi Arabia during the last four years

Year	Amount	Currency
2018	<input type="text"/>	SAR
Year	Amount	Currency
2017	<input type="text"/>	SAR
Year	Amount	Currency
2016	<input type="text"/>	SAR
Year	Amount	Currency
2015	<input type="text"/>	SAR

Note: In the "amount product imported to Saudi Arabia during the last four years" category, if the product is registered in the past two years only, the representative of the company will only fill the box for the years 2015 and 2014 by (0).

Legal Status

List of countries that the product is still marketed in

Country	Date	
<input type="text" value="Select a country"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="button" value="Add"/>

View List of countries that the product is still marketed in

No data found

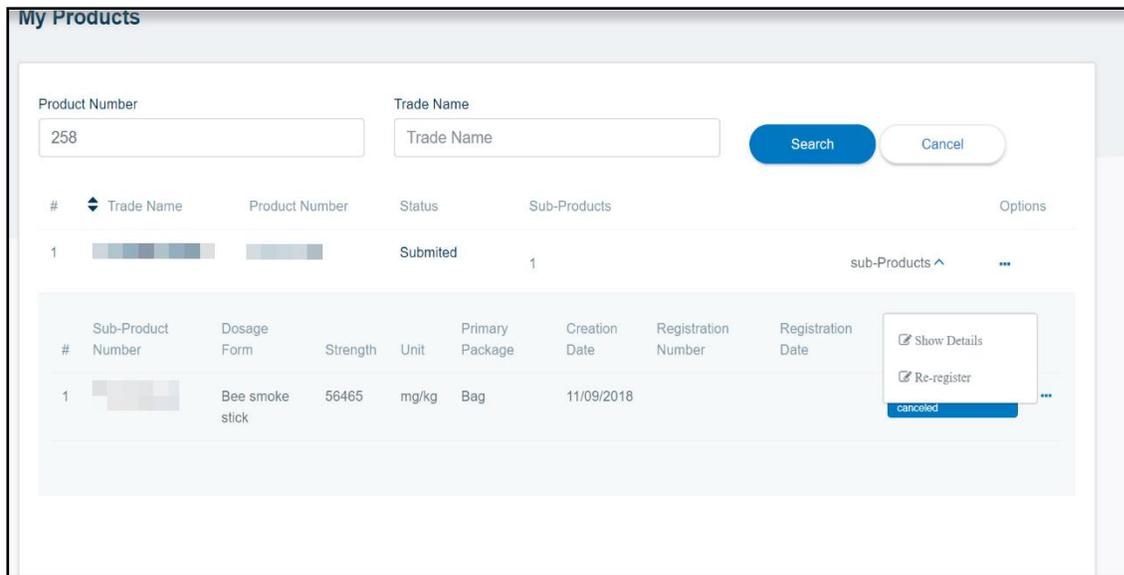
Add List of countries that delisted the product

List of countries that delisted the product

No data found

Twelfth step: Re-register the canceled product

In case if the company representative intends to re – register their canceled product, the drug company will go to the product screen and then choose the canceled product to be re-registered as displayed in the picture below:



After clicking on the Re-register icon, the system will direct the company representative to direct him to the Summary screen with the display of previously recorded data. After clicking Submit, the system will direct the company representative to the invoice screen as displayed on figure 55

Summary

Fees

Cost	Vat Cost	Total	
0	0	0	Bill Details ▾

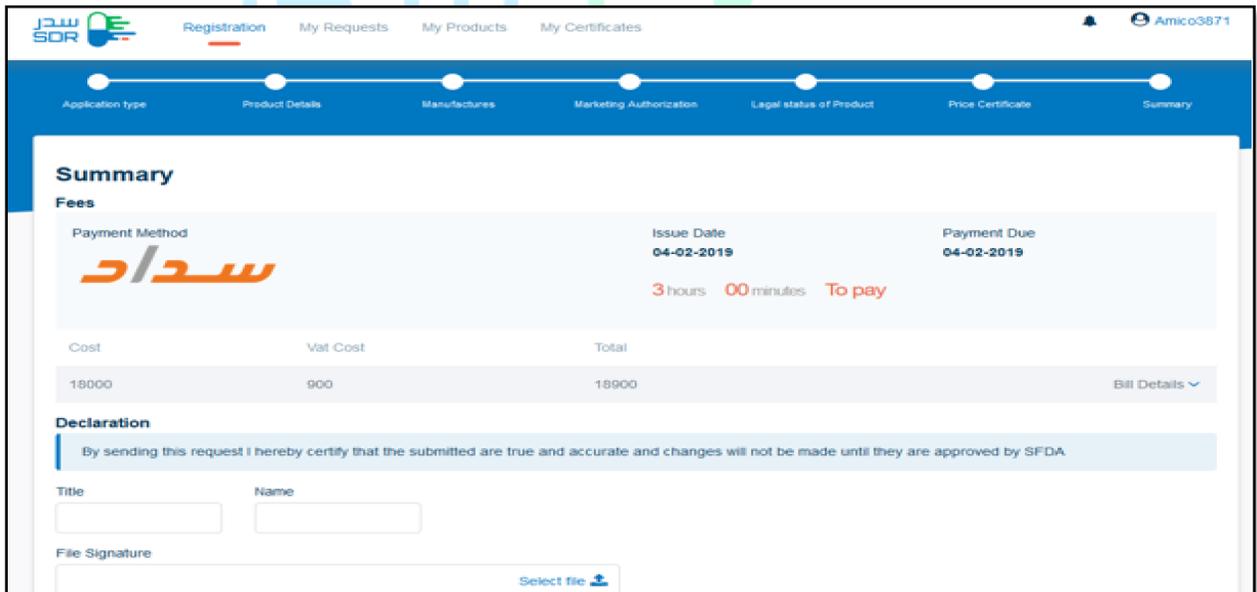
Declaration

By sending this request I hereby certify that the submitted are true and accurate and changes will not be made until they are approved by SFDA

Title Name

File Signature [Select file](#) 

Company Stamp [Select file](#) 



SDR SDR Registration My Requests My Products My Certificates Amico3871

Application type Product Details Manufactures Marketing Authorization Legal status of Product Price Certificate Summary

Summary

Fees

Payment Method	Issue Date	Payment Due
	04-02-2019	04-02-2019
3 hours 00 minutes To pay		

Cost	Vat Cost	Total	
18000	900	18900	Bill Details ▾

Declaration

By sending this request I hereby certify that the submitted are true and accurate and changes will not be made until they are approved by SFDA

Title Name

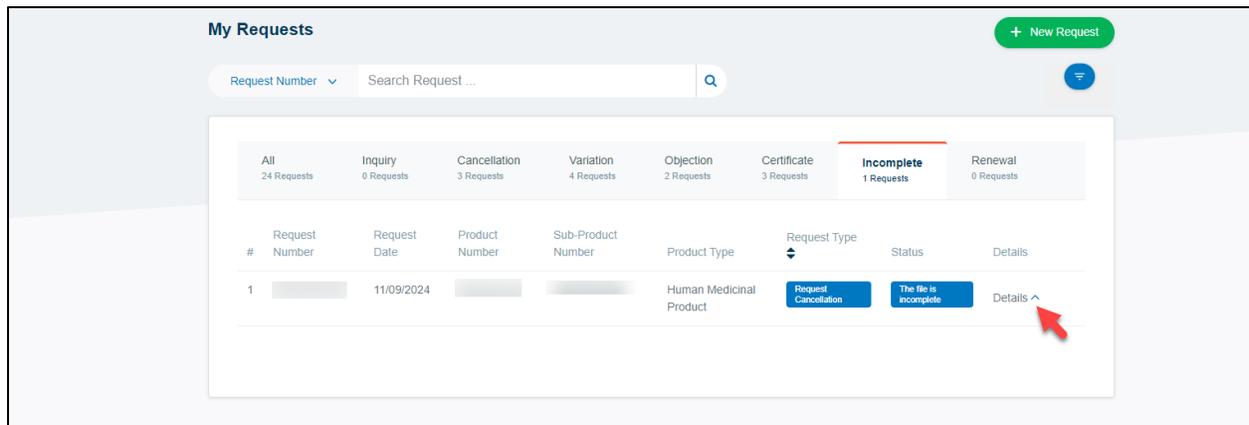
File Signature [Select file](#) 

System Status

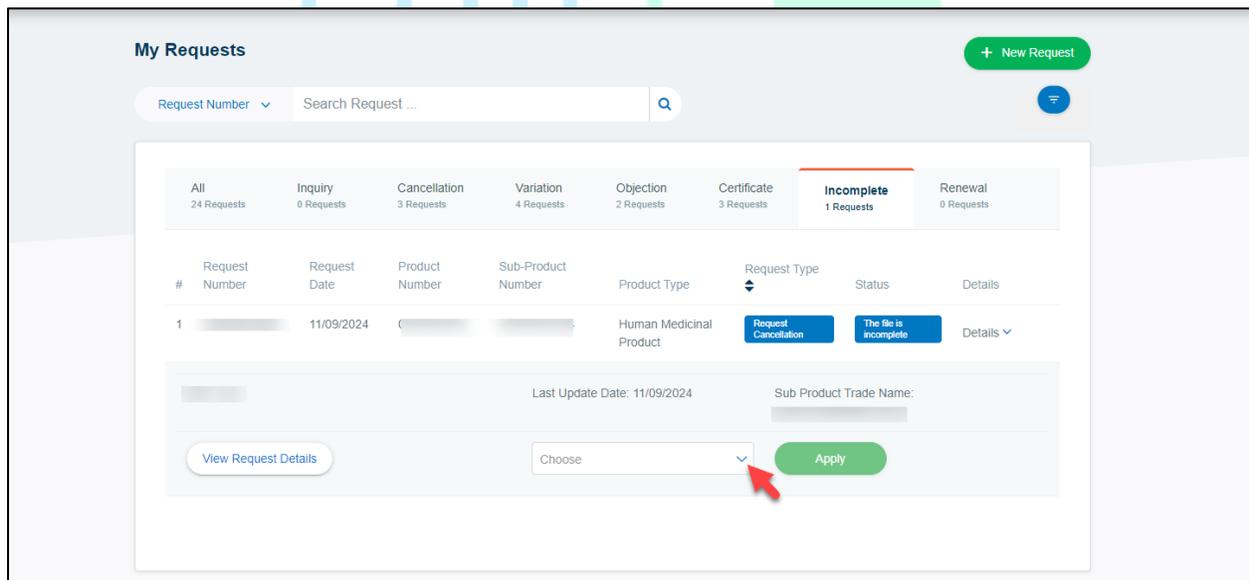
Request status	Description
Waiting for Invoice Payment	After completing the application When issuing a query invoice Issuing an invoice to complete the files
Waiting Upload Files	- Upon payment of the application for registration, objection or adjustment. - After reviewing the reason for technical verification failed. -When file upload fails
Under Technical Validation	- When files are uploaded successfully
Failed Technical Validation	- When file doesn't pass the technical verification
Invoice Expired	- When the invoice period expired
Under Studying	-When the file is accepted by the SFDA team in the verification step
The Product has Been Cancelled	-When the cancellation request is accepted by the Committee's officer
At the Relevant Department	-When referred to the concerned department -When the query is accepted by the concerned department
The Query Has Been Completed At "Department Name"	-After the management reviewing the query and approving
Waiting for Query Reply	- If a review is completed from all of the departments -If the review of the query is completed from one or more departments and there is no query from the rest of the departments and the final report was created so that the status of the application was "completed By the concerned department. -if the answer of the query is rejected through the product manager.
The Query was Answered	-When the company representative replies
Inquiry Incoming	-Only a company representative is allowed to read the inquiry and cannot reply to it. -The company representative can view inquiries through the "view request details" page, where a card containing the inquiry information will be added. -The company representative is allowed to reply to the inquiry by going to the "inquiries" page if the Wave has been sent, as is the current situation.

Thirteenth Step: Review the reasons for rejecting the cancelled application:

When a company representative intends to review the reason for the SFDA's rejection of the product cancellation request, the product status must be "The file is Incomplete" on My Request. The review process is to go to "Details" below and choose Completed Request.



Then choose from the menu "Request Completed" as shown below:



My Requests + New Request

Request Number 🔍

All 24 Requests	Inquiry 0 Requests	Cancellation 3 Requests	Variation 4 Requests	Objection 2 Requests	Certificate 3 Requests	Incomplete 1 Requests	Renewal 0 Requests
--------------------	-----------------------	----------------------------	-------------------------	-------------------------	---------------------------	---------------------------------	-----------------------

#	Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Type	Status	Details
1	<input type="text" value=""/>	11/09/2024	<input type="text" value=""/>	<input type="text" value=""/>	Human Medicinal Product	<input type="button" value="Request Cancellation"/>	<input type="button" value="The file is incomplete"/>	Details ▾

Last Update Date: 11/09/2024 Sub Product Trade Name:

My Requests + New Request

Request Number 🔍

All 24 Requests	Inquiry 0 Requests	Cancellation 3 Requests	Variation 4 Requests	Objection 2 Requests	Certificate 3 Requests	Incomplete 1 Requests	Renewal 0 Requests
--------------------	-----------------------	----------------------------	-------------------------	-------------------------	---------------------------	---------------------------------	-----------------------

#	Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Type	Status	Details
1	<input type="text" value=""/>	11/09/2024	<input type="text" value=""/>	<input type="text" value=""/>	Human Medicinal Product	<input type="button" value="Request Cancellation"/>	<input type="button" value="The file is incomplete"/>	Details ▾

Last Update Date: 11/09/2024 Sub Product Trade Name:

 ▾

Click on 'Details' to proceed to the order details review

Advanced Filters Search Clear all

Total Records: 1

Request Number	Product Number	Sub-Product Number	Sub-Product Trade Name	Drug Type	Creation/Resubmission Date	Request Type	Latest Update	MAH	Status	Details
				Generic(Multisource) Drug		Request Cancellation	21/08/2024	Cigalah	The file is incomplete	

Then select “Cancellation Request Details” and review the reason for rejection.

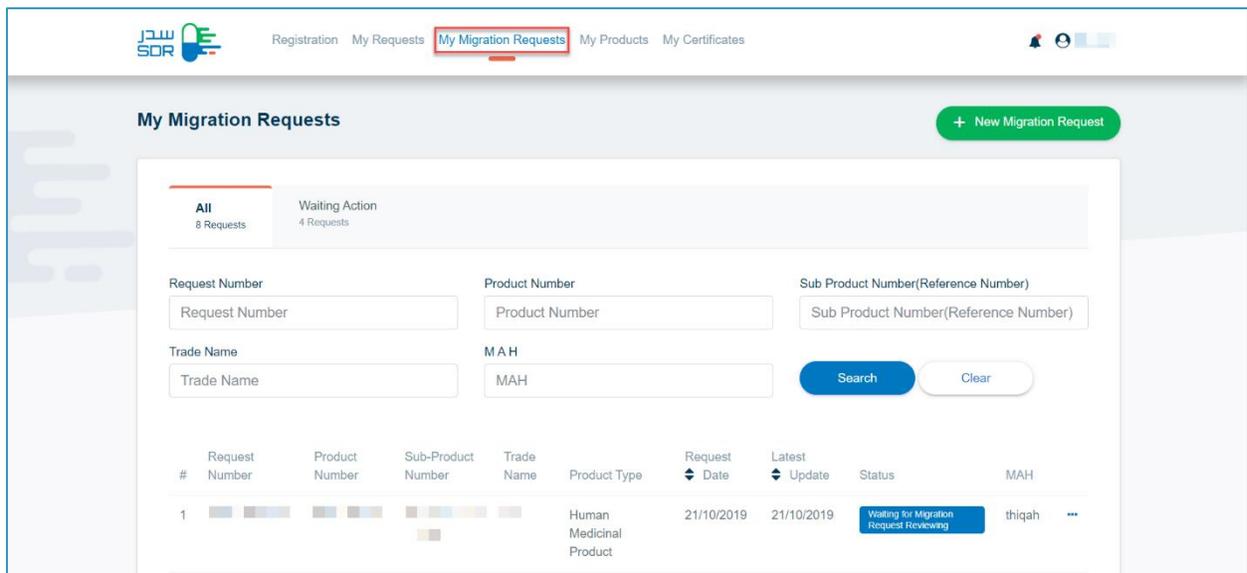
Request Details History

Cancellation Request Details	>
General	>
Marketing Company Information	>
Reference Generic Drug General Information	>
Marketing Authorization	>
Legal Status of the Product	>
Ingredients	>
Proposed Indications	>
Strength of composition	>

Migration Request

Migration is the process of transferring products from SDR system to E-SDR system. The migration will be on the completed request the old dam system.

After Sign into the system the user should click on “My Migration Request” on the bar at the top of the page.

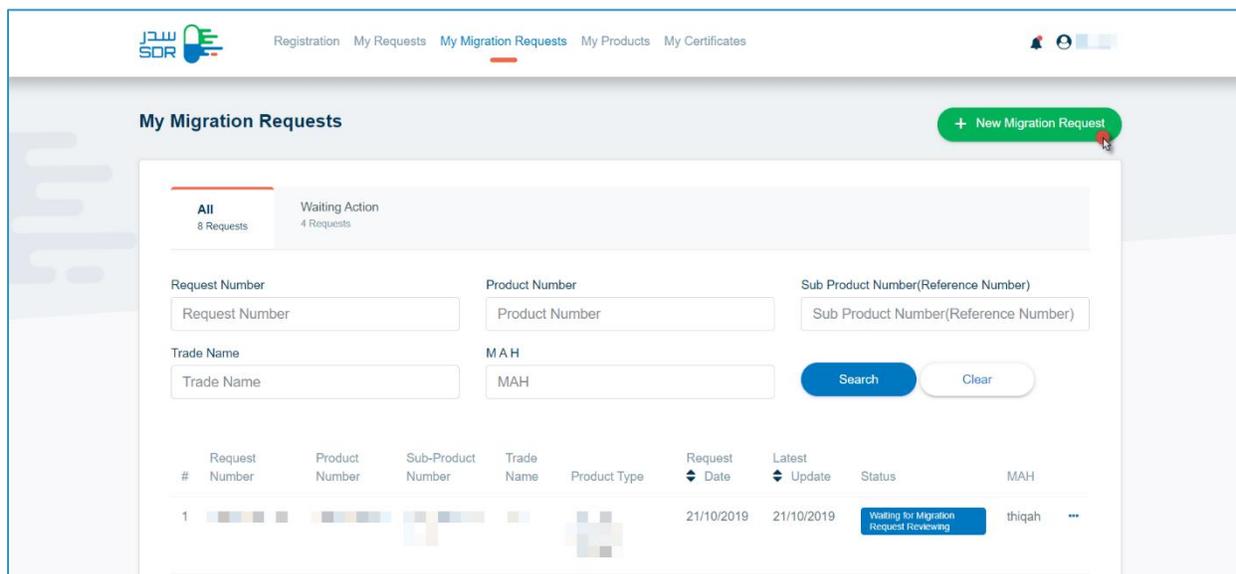


Request #	Request Number	Product Number	Sub-Product Number	Trade Name	Product Type	Request Date	Latest Update	Status	MAH
1					Human Medicinal Product	21/10/2019	21/10/2019	Waiting for Migration Request Reviewing	thiqah

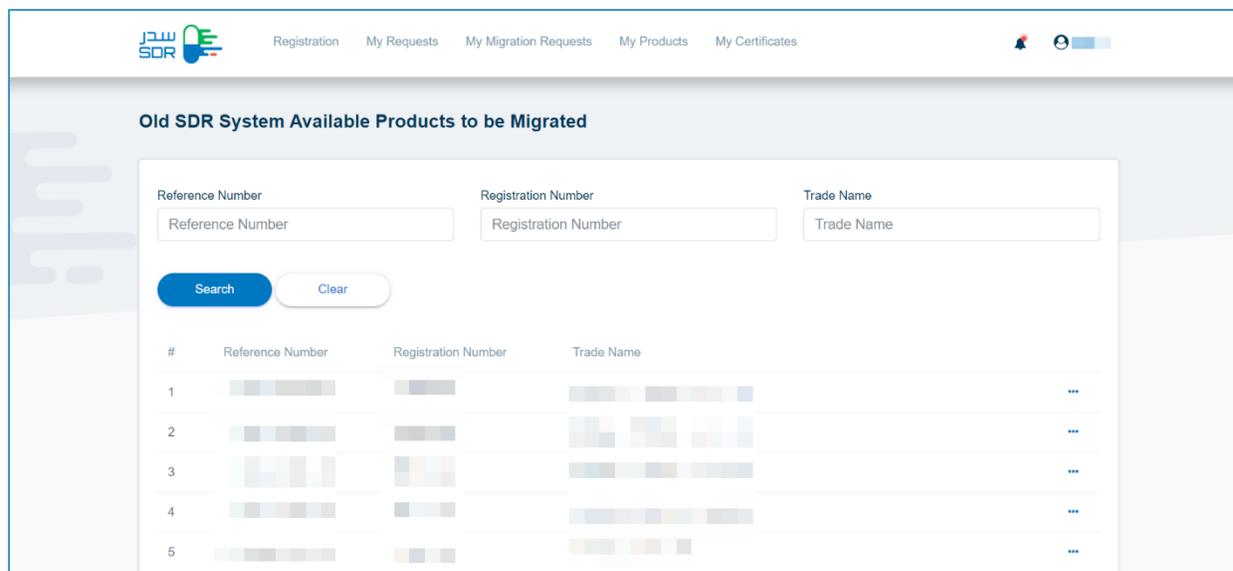
From the Migration Requests page, the system provides a feature that allows the user to request new data migration, review migration request and its status, and migration requests that's waiting action

New Migration Request

To request a new migration, the user should click on "New migration Request" icon at the top right of the page.



After that the system will show the available products from SDR to be migrated, that's associated with the same main account of the company's representative as shown below:



When  click on the icon next to the requests, the user will have three options:

Product PDF Details

- This option allows to view product details

Migration as a product

- This option allows to migrate the product from SDR.

Migration as a sub product

- This option allows to migrate a sub-product data from SDR system if the main product on E-SDR.

Migration as a product Request

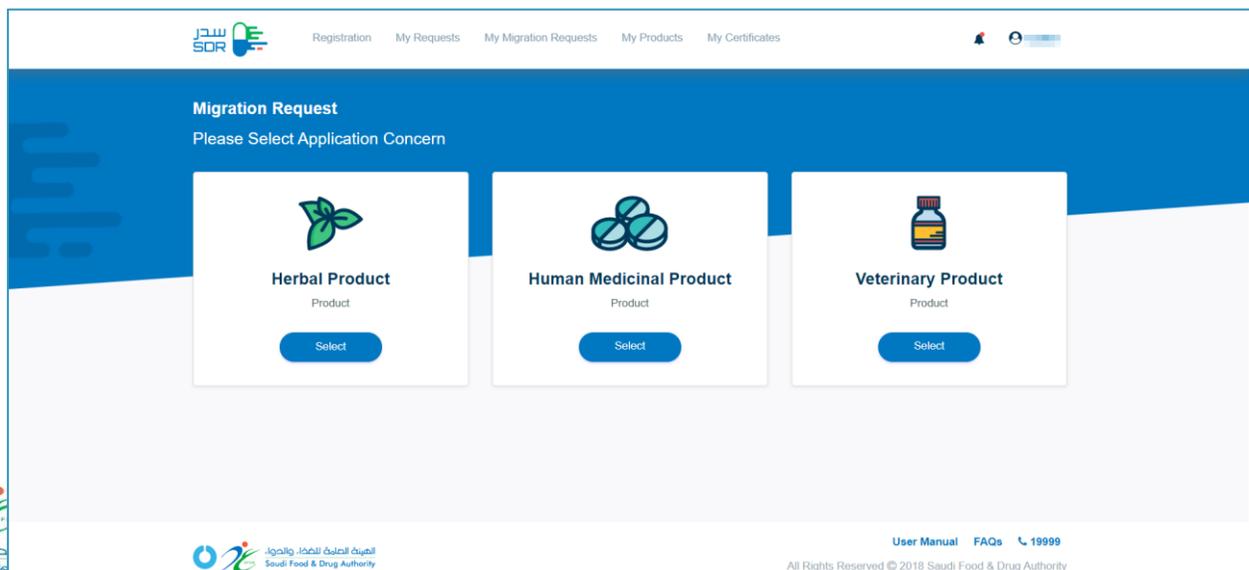
When you click on the "Migration as a product" icon, the user should fill the product data as in the registration form.

Select the form type:

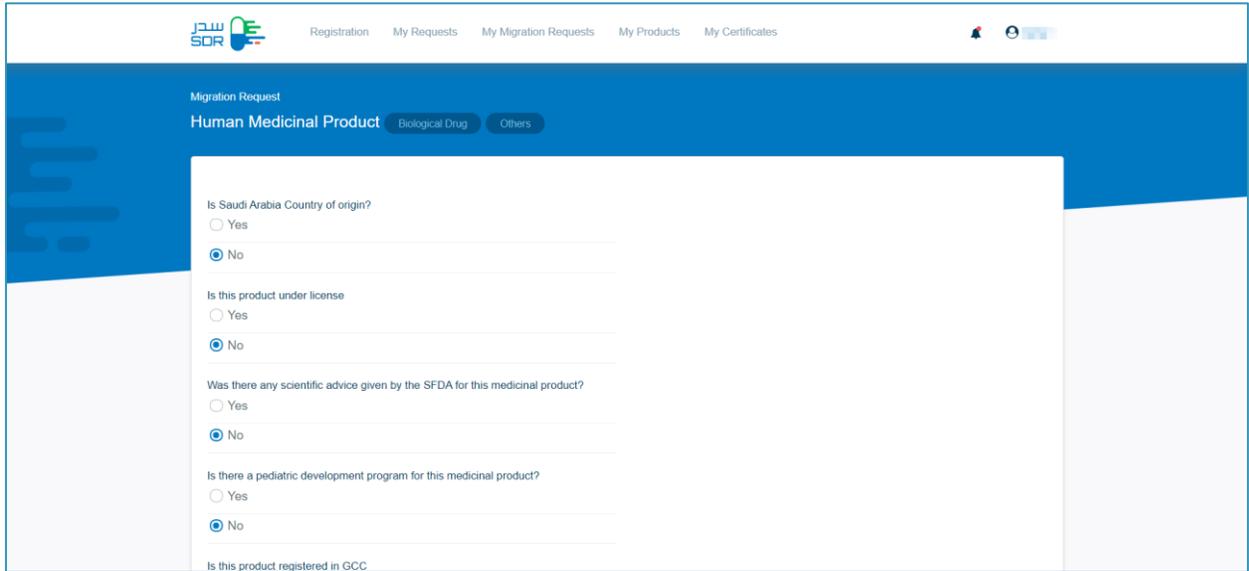
- Human Medicinal Product Restoration
- Veterinary Product
- Herbal Product

Select type of product

- Then select the classifies the product type.
- Register the product

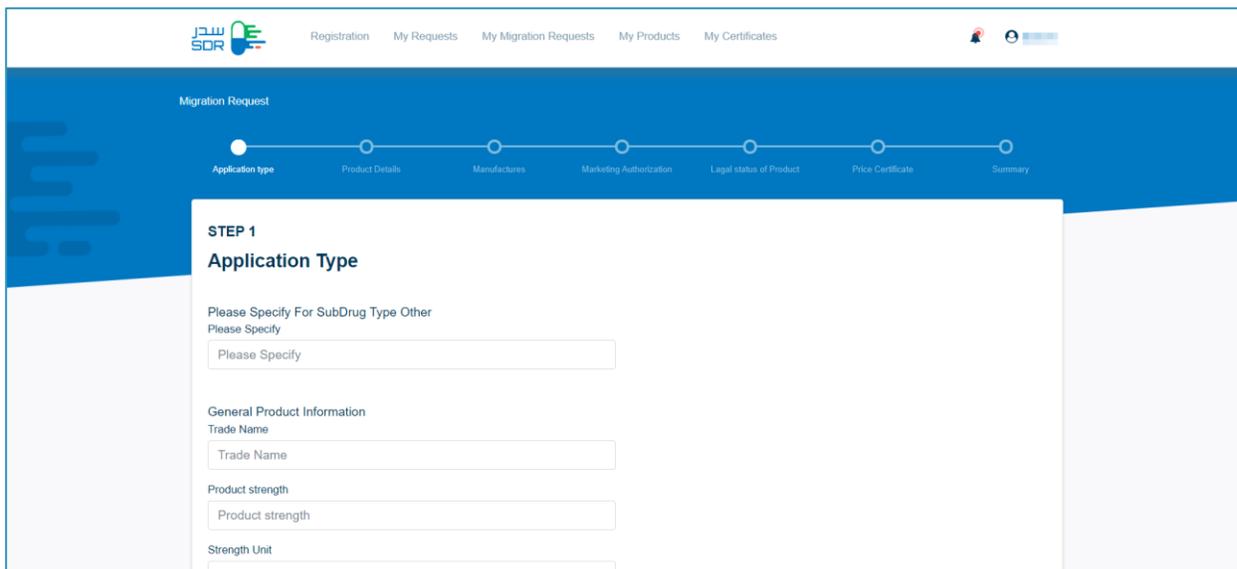


The user fills the needed data as displayed below



The screenshot shows a web application interface for a Migration Request. The page title is "Migration Request" and the main heading is "Human Medicinal Product". There are two tabs: "Biological Drug" and "Others". The form contains several questions with radio button options:

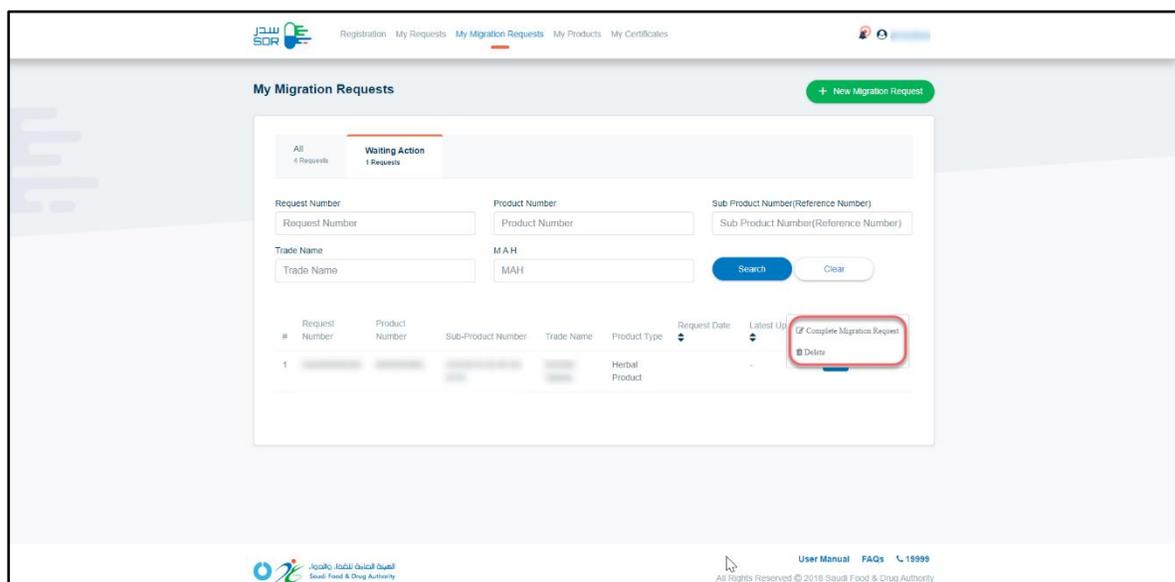
- Is Saudi Arabia Country of origin?
 Yes
 No
- Is this product under license?
 Yes
 No
- Was there any scientific advice given by the SFDA for this medicinal product?
 Yes
 No
- Is there a pediatric development program for this medicinal product?
 Yes
 No
- Is this product registered in GCC



After completing all the required fields, and submitted on the system, a request with status "Waiting for Migration Request Reviewing" will be issued. "Waiting for Migration Request Reviewing" will be issued.

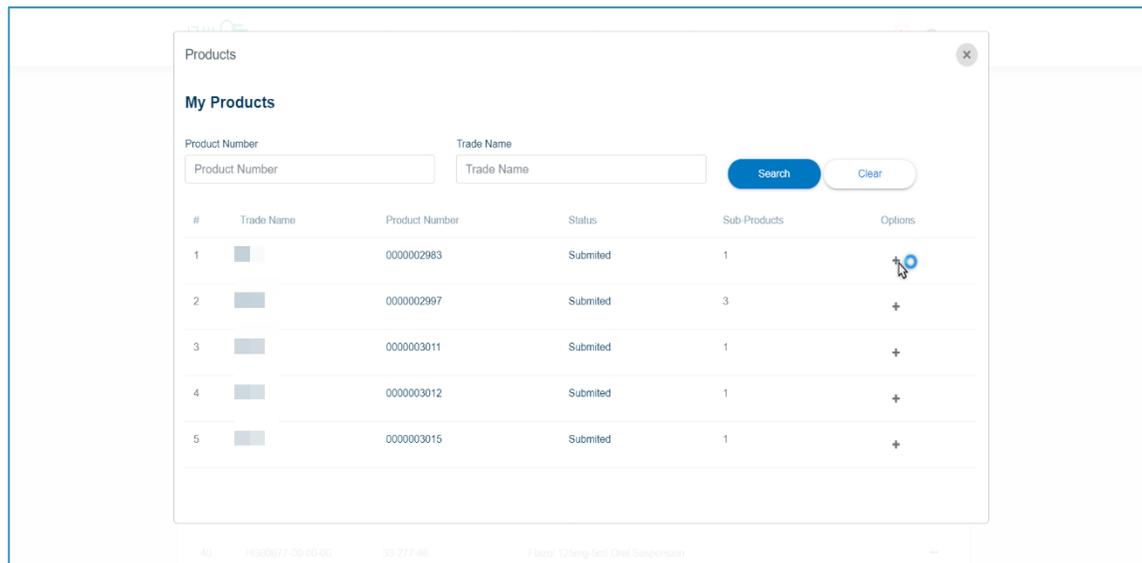
Note: in case if not completing the application, will be saved as a draft on "Waiting Action" page

- To complete the request, select "Complete Migration Request."
- The draft can be deleted by clicking on "Delete" option as shown below, then a confirmation window will be displayed to confirm



Migration as a sub product Request

When the user clicks on "Migration as a sub-product" icon, a window with the available products on the E-SDR will show.



- The user selects the product
 - Note: The data for the sub product must be complete, and the status of the migration request is "Data migrated" (in order to allow the company's representative to use the system services).
- Then complete the following non-shared sub-product data
 - Product information
 - Except (trade name in Arabic and English)
 - Manufacturer information
 - Except (Finished Manufacture)
 - Pricing information

Once all required data fields have been filled and submitted to the system, a migration request will be issued with a status "Waiting for Migration Request Reviewing"

After a Migration Requesting

After submitting a migration request whether as a product or a sub-product, the request will be reviewed by the SFDA to accept or edit it

- If the request is accepted the migrated product will appear on " My Requests " page and the status of the request will be "Paid".
- If the request edited by the SFDA, the request will appear on the "waiting Action" page, and the status will be "Request has been updated by SFDA," in which case the user will be able to take action on the request.
- In the case that the data of the migration request is updated from the reviewer for the first time, the modified data will be highlighted in yellow, and in case it is updated for the second time, the modified data will be highlighted in red. As for accepted modified data, the system will highlight the data in green.

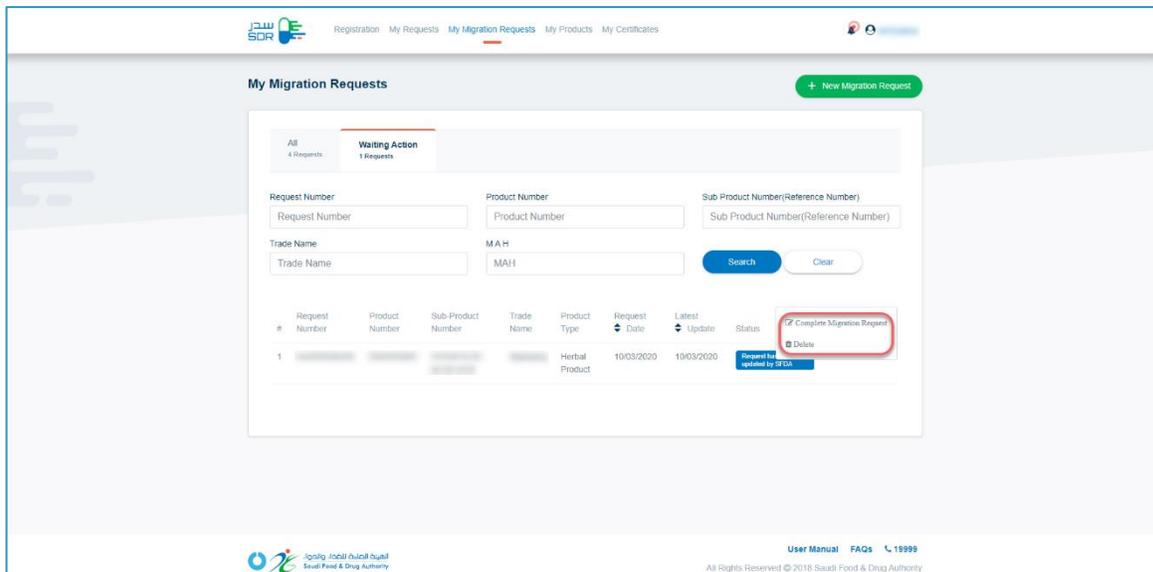
Migration Request Waiting for Action

The Edited requests by the SFDA will be appears on "Waiting Action" page

To take action on requests that have been modified by the SFDA and the requests that have not been completed "Draft" Click on the icon it will give the user three options:

- Old SFDA Application Details
 - This option allows browse product details
- Complete Migration Request"
 - This option allows to complete the migration request
- Delete
 - This option allows to delete draft request

To complete a modified migration request by the SFDA, click on the "Complete Migration Request" option to complete the request

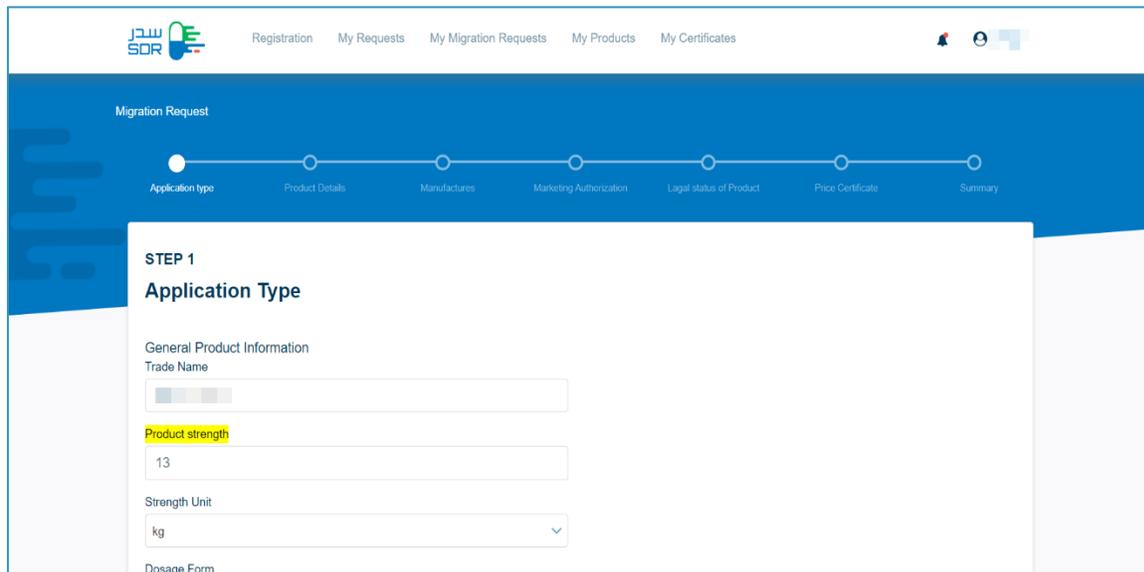


The user can delete the request that has been modified by the FDA by clicking on "Delete" option as shown below, then a confirmation window will be displayed

The user can accept the modifications by the SFDA or modify the data again

- If the modification by the SFDA was accepted by the user, the migration request will be approved and posted automatically, the migrated product will appear on "My Requests" page and the status of the request will be "Paid"
- In case of any further data modification the user must mention the reason and description of the modified data then the request will be sent to the SFDA to review it.
- And the status will be changed from "Request has been updated by SFDA" to "Waiting for Migration Request Reviewing"

The system will display the data that has been modified by the SFDA highlighted as shown below:

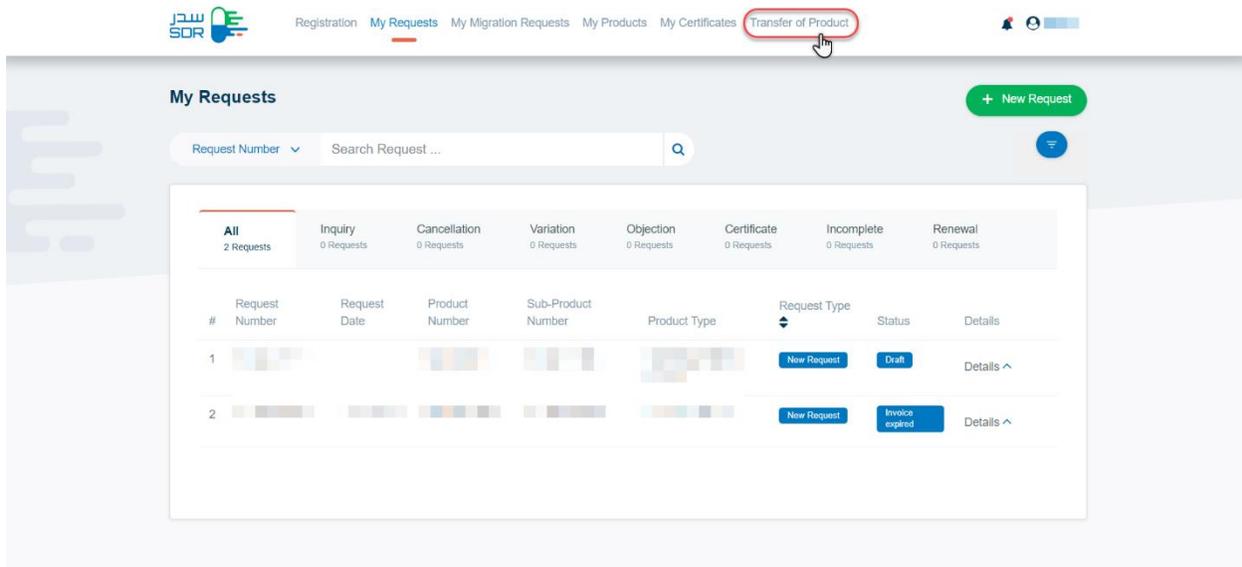


The screenshot displays the 'Migration Request' workflow in the SDR system. The navigation bar includes 'Registration', 'My Requests', 'My Migration Requests', 'My Products', and 'My Certificates'. The main content area shows a progress bar with steps: 'Application type', 'Product Details', 'Manufactures', 'Marketing Authorization', 'Legal status of Product', 'Price Certificate', and 'Summary'. The 'Application type' step is currently active. Below the progress bar, the 'STEP 1 Application Type' form is shown. Under 'General Product Information', the 'Trade Name' field is empty. The 'Product strength' field is highlighted in yellow and contains the value '13'. The 'Strength Unit' dropdown menu is set to 'kg'. The 'Dosage Form' field is also visible but empty.

To learn more about migration steps from SDR to E-SDR system, please [Click Here](#)

Relocation of the product application to other account

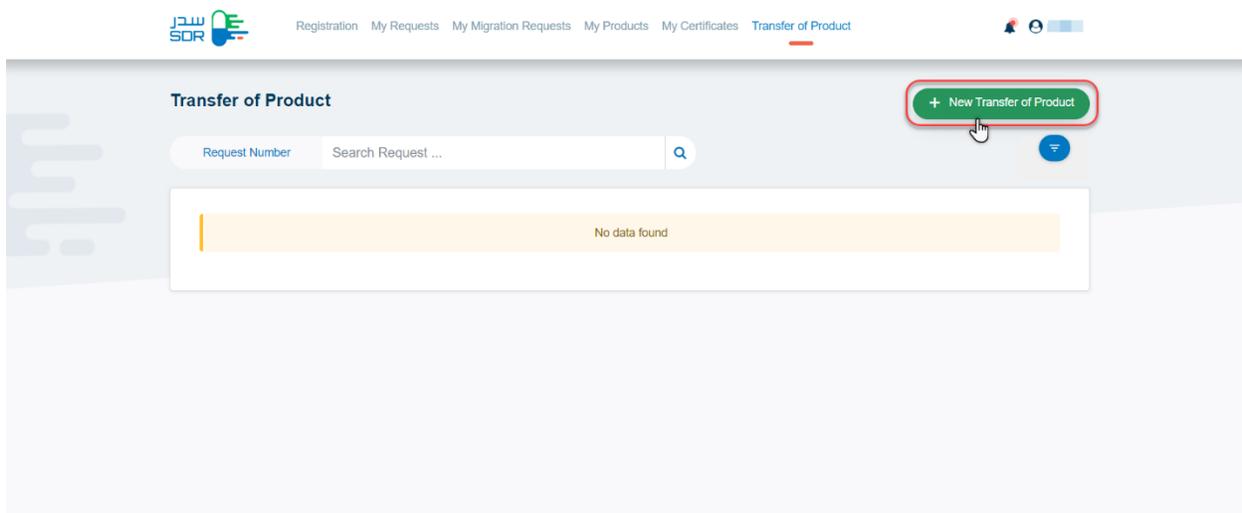
To submit relocation of the product application to another account, click on Transfer of Product



The screenshot shows the 'My Requests' page in the SDR system. The navigation menu includes 'Registration', 'My Requests', 'My Migration Requests', 'My Products', 'My Certificates', and 'Transfer of Product'. The 'Transfer of Product' menu item is highlighted with a red circle. Below the navigation, there is a search bar and a '+ New Request' button. A table displays the following data:

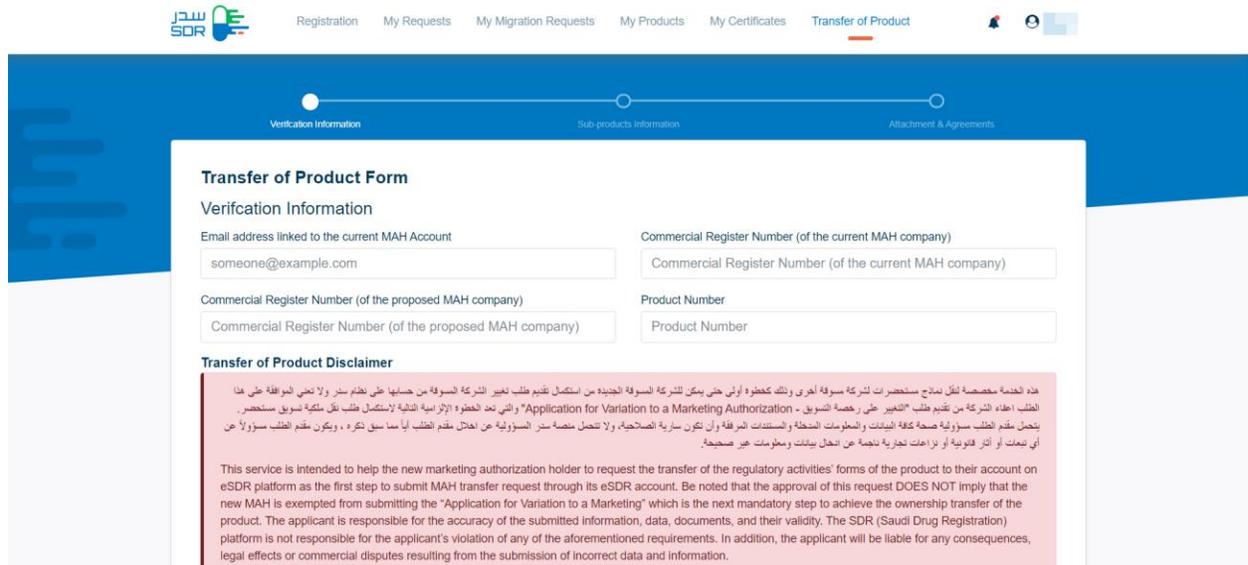
#	Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Type	Status	Details
1						New Request	Draft	Details ^
2						New Request	Invoice expired	Details ^

Click on New Transfer of product,

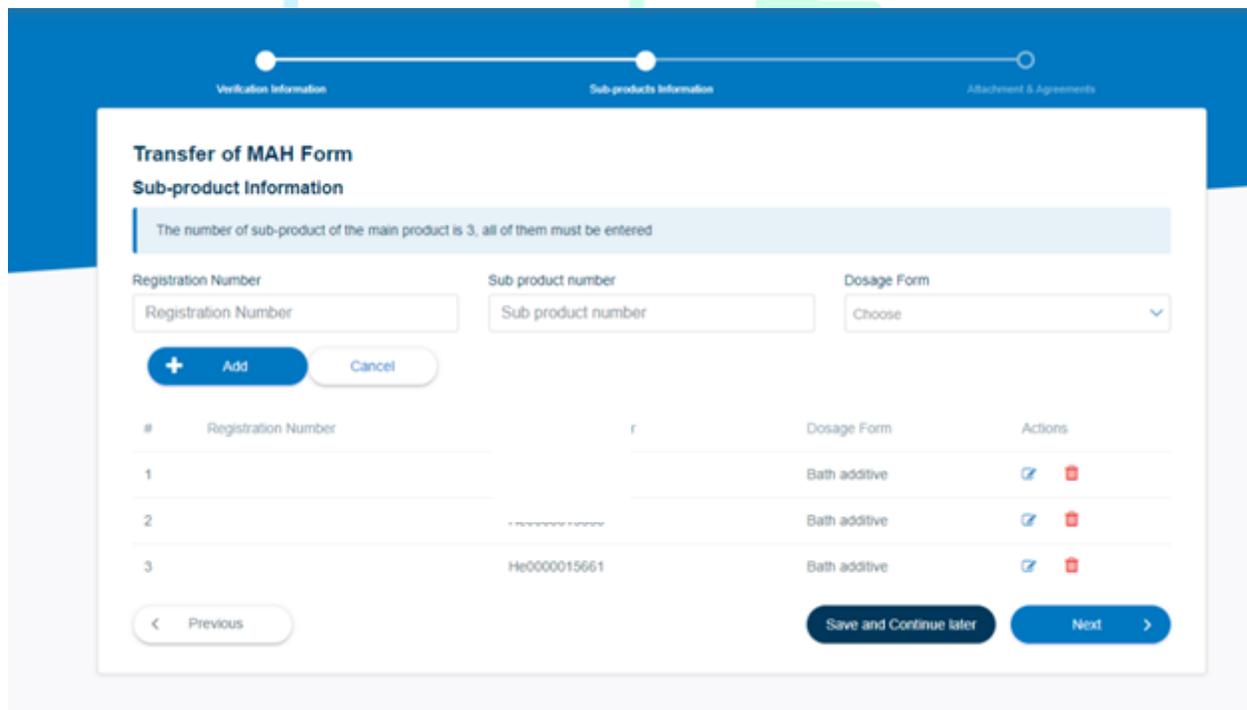


The screenshot shows the 'Transfer of Product' page in the SDR system. The navigation menu includes 'Registration', 'My Requests', 'My Migration Requests', 'My Products', 'My Certificates', and 'Transfer of Product'. The '+ New Transfer of Product' button is highlighted with a red circle. Below the navigation, there is a search bar and a 'No data found' message.

Fill out the transfer ownership application (three forms)



Add all sub-products related to the main product and click on the Next



Users must upload a file (the file format must be "Pdf - rar - zip") Then confirm the application submission.

dr/transferMAH/Complete?q=8zLUqng89VvIHtmvkiyaUUA==

SDR SDR Registration My Requests My Migration Requests My Products My Certificates **Transfer of MAH** gaiderma

Verification Information Sub-products Information Attachment & Agreements

Transfer of MAH Form

Attachment and agreement

Copy of the agreement (contract) between the two companies (certified)

757562 1 (2).pdf

Letter from the company that has the product in SDR

757562 1 (2).pdf

Transfer of MAH Disclaimer

يحمل مقدم الطلب مسؤولية صحة كافة البيانات والمعلومات المدخلة، ولا تتحمل منصة سدر مسؤولية عدم صحة البيانات المدخلة من قبل مقدم الطلب، ويكون مقدم الطلب مسؤولاً عن أي تبعات أو آثار قانونية تنتج من قبل إدخال مقدم الطلب لبيانات ومعلومات غير صحيحة، كما أن المبلغ المدفوع غير قابل للاسترداد.

The applicant shall be fully responsible of the accuracy and correctness of the entered data, and SDR platform is not responsible of any incompleteness and inaccuracy of data entered by the applicant, The applicant shall be consequently responsible of any legal liability due to the incompleteness and inaccuracy of the data, **however the paid fees are non-refundable.**

< Previous Next >

Users can view the application status through the Transfer of Product tab, choose a request, and press Details

la.gov.sa/SDR/TransferMAH

SDR SDR Registration My Requests My Migration Requests My Products My Certificates **Transfer of MAH** gaiderma

Your request has been sent successfully

Transfer MAH

+ New Transfer MAH

Request Number Search Request ...

#	Request Number	Creation Date	Last Updated Date	Status	Details
1	12	16/01/2023	16/01/2023	New Request	Details ^
2	5	15/01/2023	16/01/2023	The request was accepted from SFDA	Details ^
3	4	15/01/2023	16/01/2023	Under-Study	Details ^