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النظام الإلكتروني لتسجيل الأدوية السعودي (سدر) The Saudi Drug Registration System (SDR) دليل المستخدم لنظام سدر E-SDR User Manual 12/11/2024 <u>English</u> اللغة العربية



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مقدمة

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 <u>اضغط هنا</u> 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



Public



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





Г

واجهة نظام تسجيل الأدوية السعودية

Requests							+ New F	Request
All 827 Requests	Inquiry 0 Requests	Cancellation 11 Requests	Variation 4 Requests	Objection 13 Requests	Certificate 50 Requests	Incomplete 10 Requests	Renewal 14 Requests	
Request Number		Pro	duct Number		Tra	de Name		
Request Number	r -	F	Product Number		1	rade Name		
MAH				Request Status	1			
MAH				Choose				\sim
Search	Clear							
Request	Sub-Product	Product	Trade Pr	roduct Request	Request	Latest		
# Number	Number	Number	Name Ty	уре 🕈 Туре	Date	Update Statu	is MAH	
					"Re	gistration	لنظام تيار صفحة "	جهة ا ند اخن
				ښر جديد	Re" ں مستحض My "	gistration' خدم بتسجیا Req <mark>uest</mark> s ر	لنظام تيار صفحة " تتيح للم <mark>ست</mark> يار صفحة ":	جهة ا ند اخن 0 د اخت
	J - 51 سدر.	ها في نظام و	ں تم ادخال	ضر جديد ن الطلبات التي	Re" ں مستحظ My " ض جمیع	gistration' خدم بتسجیا Req <mark>ues</mark> ts خدم باستعرا	لنظام تيار صفحة " تتيح للمست يار صفحة ": تتيح للمست	جهة ا ند اخن 0 د اخت 0
	J - 531 سدر.	ها في نظام	ی تم ادخال	ضر جديد ; الطلبات التي My M	Re" ں مستحظ My " ض جمیع	gistration' خدم بتسجیا Req <mark>uest</mark> s خدم باستعرا Requests	لنظام تيار صفحة " تتيح للمست يار صفحة ": تتيح للمست يار صفحة ":	جهة ا ند اخن 0 د اخت 0
(E-SDF	ل المدر. ظام سدر (۶	ها في نظام و SDR) الى ن	ب تم ادخالہ طام سدر (۲	ضر جديد 6 الطلبات التي My M" مكتملة من نظ	Re" ں مستحظ My ض جمیع igratior طلبات الم	gistration خدم بتسجیا Req <mark>uest</mark> s خدم باستعرا Requests خدم بنقل ال	لنظام تيار صفحة " تتيح للمست يار صفحة ": تتيح للمست يار صفحة ": تتيح للمست	جهة ا ند اخن 0 د اخت 0 د اخت
(E-SDF	الحال سدر. ظام سدر (۲	ها في نظام ر	ب تم ادخالہ طام سدر (۲	ضر جديد 6 الطلبات التي 10 My" مكتملة من نظ	Re" ب مستحظ My " ض جميع igratior طلبات الم	gistration خدم بتسجیا Requests خدم باستعرا Requests خدم بنقل ال	لنظام تيار صفحة " تتيح للمست يار صفحة " تتيح للمست يار صفحة " يار صفحة "	جهة ا ند اخن د اخت 0 د اخت 0
(E-SDF	ل سدر. ظام سدر (۶ طلبات.	ها في نظام ا SDR) الى ن	ي تم ادخال طام سدر (٢	نبر جديد ن الطلبات التي My M مكتملة من نخ ن المستحضران	Re" ی مستحظ My " فض جمیع igratior طلبات الم My	gistration خدم بتسجیا Requests خدم باستعرا Requests Requests بخدم بنقل ال Products خدم باستعرا	لنظام تيار صفحة " تتيح للمست يار صفحة " تتيح للمست يار صفحة " يار صفحة "	جهة ا ند اخن د اخت د اخت د اخت د اخت





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 <u>اضغط هنا</u>

My Products My Certificates	4 0
Ď	
Human Medicinal Product	Veterinary Product
What's Drug type ?	Select
What sort of drug is this ?	
choose 🗸	
Next >	
	Hy Froducts Hy Certificates

- 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 "
- م يتم اختيار نوع المستحضر وتصنيفه بعد ذلك يقوم المستخدم اختيار تسجيل المستحضر.





New Request Human Medicinal Product New Drog New chemical entry
Is Saudi Arabia Country of origin? Yes No
Is this product under license Yes (a) 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
Is this product registered in GCC Ves No Is this product registered in SRA
ls sis product registered in order ○ Yes ⑧ No

يقوم المستخدم تعبئة بيانات المستحضر في سبع خطوات الموضحة ادناه:

New Request						
•	o	O	o	o	o	——o
Application type						





Application type						
STEP 1						
Applicatio	n Type					
Because you ch	noose No in "Is Saudi Arabia	a Country of origin?" plea	ase complete the following:			
General Product	Information	a country of origin. prov	acconfigures and following.			
Reference Trade Na	ame					
Reference Trad	le Name					
Product strength						
Product strengt	'n					
Strength Unit						
choose			~			
Dosage Form						
choose			~			
			. L		نوع المنتج.	م یاں 0 اختیار
Application type	Product Details	Manufactures	مورة أدناه. Marketing Authorization	تج المبين في الص معامد معامد معامد	نوع المنتج. إضافة طلب من Price Centicate	ر اختیار اختیار اختیار
Application type STEP 2 Product Def	Product Details	O Manufactures	مورة أدناه. معرفي المعامين	تج المبين في الص	نوع المنتج. اضافة طلب من Pice Centicate	ر اختیار () حتیار () Surmary
Application type STEP 2 Product Def	Product Details tails	Manufactures	مورة أدناه. Marketing Authorization Add new product	تج المبين في الص	نوع المنتج. اضافة طلب من Price Centicate	ر اختیار) حتیار) Summary
Application type STEP 2 Product Def	Product Details tails t	O Manufuctures	مورة أدناه. Narkeling Authorization Add new product	لتج المبين في الص Lage status of Product	ب نوع المنتج. اضافة طلب من Price Centhcate	ريني المختيار (المختيار) المحتيار (المحتيار) کيبيسير (المحتيار)
Application type STEP 2 Product Def < Previous	Product Details tails +	Manufactures	مورة أدناه. Marketing Authorization	لتج المبين في الص Laga status of Product	نوع المنتج. اضافة طلب من Price Centicate	رین یک یک یک اختیار () () () () () () () () () () () () () (
Application type STEP 2 Product Def < Previous	Product Details	Manufactures	مورة أدناه. Marketing Authorization Add new product	لتج المبين في الص Lagai states of Product	نوع المنتج. اضافة طلب من Pree Cerificate	Next >
Application type TEP 2 Product Def Control of the second secon	Product Details tails +	Laundactures	مورة أدناه. Marketing Authorization	لتج المبين في الص Laga status of Product Save ar	نوع المنتج. اضافة طلب من Pice Centicate	یں ہوتی ہے۔ اختیار C Summary





<mark>ملاحظة</mark>: 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.
 - مكن إدخال10 مصانع API لكل مادة فعالة لطلبات التسجيل والتعديل.

		stration My Reques	sts My Migration Reque	ests My Products	My Certificates		¢ 0	
	New Request							
	Application type	Product Details	Manufactures	O Marketing Authorization	Lagal status of Product	Price Certificate	O Summary	
5	step 3 Manufacti	urers						
	Active Substar You have 1 Active subs	stance(s) you need to s	eutical Ingredi	ent (API) Ma	nufacturers			
	All Active Substances	Manufactures						
	Active Substances Select an active substance	Selection Selection	ct Manufacturer or Add new	Select Act Select an	ivity or Add new one activity	۹	+ Add	
	Active Substances		Manufactuer n	ame Activit	У		Action	
	Excipient Phar	maceutical I	ngredient (EPI)	Manufactur	ers			

بعد استكمال جميع الخطوات والانتهاء 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 أعمالى ورمز السداد هو: 144*

			Issue Date 03-09-2024 1 hours 00 minu	utes To pay	Payment Due 03-09-2024	
Cost	Vat Cost	Total				
5500	825	6325				Bill Details
volce Type) Issuing tax invoice) Issuing simplified invo	bice					





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

بیدر SOF	# 📭	Registration My Reg	wests My Mig	ration Requests My Proc	ducts My Certificate:	5		¢ 0
Му	Requests							+ New Request
	All 95 Requests	Inquiry 0 Requests	Cancellation 4 Requests	Variation 13 Requests	Objection 1 Requests	Certificate 11 Requests	Incomplete 0 Requests	Renewal 0 Requests
	Request Numbe	r		Product Number		9	Sub-Product Trade Name	
	Request Nu	mber		Product Number			Sub-Product Trade Na	me
	ман				Request Status			
	MAH				Waiting for involu-	e payment		~
	Search	Clear						
	Request # Number	Request Date	Product Number	Sub-Product Number	Product Type	Reque ¢	st Type Status	Details
	1				Herbal Product	New R	Waiting for involce payment	Details
	MAH: Comp	any Name Authorized Ha	ini 88	Last Update D	ate: 20/10/2022	S	ub Product Trade Name: Sl	DR Herbal2
	View Rev	uest Details		Request Det	ails PDF	× (Apply	
	2				Herbal Product	New R	equest Waiting for invoice payment	Details ^
	3				Human Medicinal Product	Now R	Waiting for invoice payment	Details ^
	4				Veterinary Product	Variată Reque	Waiting for invoice st payment	Details ^

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

	Invoice Number	543146112			
s	adad Biller Name	My Business Services			
	Sadad Biller Id	144			
Vat Re	gistration Number	300784838500003			
	Issue Date	03/09/2024 12:23:47			
	Payment Due	03/09/2024 13:23:47			
	Tax Invoice	View			
العميل الصحيل/صحيل	ضافة إلى ذلك، يجب على Payment method u e proceeding with j	نوع الفاكررة على أنها فاكورة حتريبية قبل عملية الدفع. با pdated. Please be aware that you can or ayment. Additionally, for tax invoice issue	طة إلى فاترزة ضريبية ما لم يتم تحديد ه Ily convert a simplified invoic ance, customers must be reg	تحطة أنه لا يمكن تحويل الفاتورة المبت توره الضبريبية. e into a tax invoice if you sp istered and logged in to the	تثيرة: ثم تحديث وسيلة الدفع. يرجى ما الدخول إلى منصبة أعمالي لإصدار القا ecify the invoice type as Aamaly platform.
Important Notice: 'tax invoice' befor					
Important Notice: 'tax invoice' befor					
important Notice: 'tax invoice' before Cost	Vat Co	ıst Tota	u		

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



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	ما فاتورة ضريبية تمريدلار من مو مخلف بابقرارك تغريبية	فضلا اختر نوع الفاتورة التي ترغب في تصدي فاتورة ضريبية مبسطة تمريدل من موغير مخلف بليفرارك الضريبية
		يرچې إضافة علف طريبي للكمال عملية الدفير + إضافة علف طريبي
		تفاصيل الفاتورة
+ 6325.0 ريال		إجمالي المبلغ المستحق
	بيانات سداد	فضلا اختر طريقة الدفع التي تناسبك
رغم المفوتر ۱44	رغم الفاتورة قالون خدمات أعمالي 543146070	سداد نظام سداد للمدفوعات

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

لي	×		أهلاً بك عميل هيئة الغ
		هان اندیك رقام طریبي؟	فضلا اختر نوع الفاتورة التي
		نعم لا البسم 🇨	فاتورة ضريبية مبسطة تصدر لكل من مو غير مكلف بالبقر
	المدينة	البسم © المنطقة	
	اکتب اسم المدینة اسم الشارع	اكتب اسم المنطقة الحي	يرجى إضافة ملف ضريبي لأكمال عما بضافة ملف ضريبي +
	اكتب اسم الشارم # الرقم النظافي	اكتب اسم الحي # رقم المبني	تفاصبل الفاتورة
i.o	1234	1234 ۳۵ الرمز البريدي	ي مالي المبلغ المستحق
		12345	فضلا اختر طريقة الدفع التي ت
	حفظ	الشاع	<u>سد/د.</u> نظام سداد للمدفوعات





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

+		البيانات الخريبية الرقم الضرببي
		تفاصيل الفاتورة
+ ئىل 6325.0		إجمالي المبلغ المستحق
	بيانات سداد	فضلا اختر طريقة الدفع التي تناسبك
	رقم الماتورة 🛛 اسم المفوتر 🛄 رقم المفوتر 144 مدمات المماتي 144 جمعاتي	سداد المتاع سداد للمتفوعات
	التجنب القلة القانورة، يحب أن يتم الدفع باستخدام خدمة سداد قبل: 03. سيتمبر 2004 م. 30 ممار 1444 م. 1247 م	
	المعناية الملية الملية	
	122.47 ف تعميل المطلبة العلية.	

						ة المالية Payme	بالمطالب ent Order Pryment M	JLo.cl
						Payment Order Di	المطالبة المائية / ate	San
						SAC	DAD Number / DAD Number	رقم ا
خدمات أعمالي - ١٨٩						Biller Name - Num	المقوتر ورقمة / ber	ושק
13:23:47 03/09/2024						Payment Order Due Date	التهاء المطالبة المالية /	540
	Bu	yer Data / g	بيانات العميز			Supp	lier Data / بورد	يانات الم
-		Name	الدسم /	فة لخدمات الأعمال	شركة ثا		Name /	الدسم
14		Address	/ Ilaigli	اذي 13321 - 3028	أنارع العليا - الصحافة الر	û 6597	Address /	العتوان
31(VAT Number	القيمة المضافة	رقم تسجيل ضوينا	30078483851000	3	VAT Number	المجموعة الضويية /	فم تسجيل
				1010332510		Commercial Registratio	n Number / الاجاري, in Number	قم السجل
						Product - Service Data	ستج - الخدمة /	انات الم
المجموع (شامل ضوية اللايمة المخافة) (Rem Subiotal (Including VAT)	طبقت الشهبة Tax Amount	تسية التنوية Tax Rate	دحومات Discount	الكمية Quantity	سعر الوحدة Unit Price	وحدق الخدمة Service Description		الدّدمة Service
6325.0 رىس	825.0 ر.س	5.15	0	•	5500.0 ر.س		اء والدواء - تجديد الاسجيل	هيئة الغذ
			55 رس	00.0	Те	iotal (Excluding VAT) / (dail	مبالغ (غير شامل القيمة المضا	اجمالي ال





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 الى صفحة خاصة لإضافة حجم العبوة لتتيح لك إضافة حجم عبوة جديد لطلبك الاساسي دون دفع رسوم إضافية.

ערכן SDR		Registr	ation My Requ	ests My Migrati	ion Requests My Product	s My Certificates				£	0
Re	ques	st Number		Pr	oduct Number		5	Sub-Product 1	Frade Name		
F	Requ	uest Number			Product Number			Sub-Produ	uct Trade Name		
МА	АН					Request Status					
Ν	MAH	4				Waiting Upload Files					~
		Search	Clear								
#	ŧ	Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Rei	quest Type	Status	Details	
1		V000020245	18/10/2022	0000015087	HG00775-00-00-00- 1108	Veterinary Product	Va Re	ariation equest	Waiting Upload Files	Details ^	
2	2	10000020244	18/10/2022	0000015088	H0000015810	Human Medicinal Product	Ne	ew Request	Waiting Upload Files	Details 🗸	
	ма	H: Incomplete MAH	12		Last Update Date	18/10/2022	s	ub Product Tr	rade Name: SDR1	23	
	C	View Request Deta	ils		Choose Upload File	÷		Apply			
3	3	V0000020201	15/06/2022	0000015087	Request Details	PDF	N	w Request	Waiting Upload Filos	Details ^	
4	1	10000020101	19/09/2022	000000205	HG000779-00-00-00- 1196	Haman Medicinal Product	MI Ri	ariation equest	Waiting Upload Files	Details ^	
5	5	H0000019156	16/08/2022	0000010114	100(0010408	Human Medicinal Product	Re	enewal equest	Waiting Upload Files	Details ^	

Animal Material Payment Summary	al Material ent Summary Please upload the files based on the eCTD requirements
Payment Summary >	ent Summary Please upload the files based on the eCTD requirements
Please upload the files based on the eCTD requirements	Please upload the files based on the eCTD requirements
Drop zip nie nere to upload or select from your computer	Drop zip file here to upload or select from your computer





- 0 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 بينات 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)

	🔊 🖬 📖	🕤 🙆. 💷 🐠			
Extract To Test View	Delete Find Wizard	Info VirusScan Comment SEX			
pass.zip - ZIP archive, unpacked s	ize 604,548 bytes				
~		Size Packed Type	Modified CRC32		
		Local Disk			
0		File folder			
Open				×	
← → × ↑ 🛢 > Sear	rch Results in Downloads >		✓ ঊ sdr.zip	×	
Organize 👻			3	- 0	
🖿 Desktop 🛛 🖈 🔨					
📜 Downloads 🖈 🚽					
🔁 Documents 🖈	3 			_	
ed	COD			_	
SDR files	SDR				~
SFDA					•
📜 Training	Search again in:				
a OneDrive	Libraries	Custom			~
.S This PC					
👆 3D Objects					
esktop					
Documents					
No Downloads				_	
File nam	ne: SDR		✓ All Files	~	
			Open 🔻	Cancel	
		Drop zip file here to uplo	ad or select from your computer		





الخطوة الرابعة: إضافة الرد على الاستعلامات

- یقوم المستخدم بالنقر على (Inquiry)
- يقوم المستخدم بالنقر على ايقونة (Reply Inquiry) لاتخاذ الإجراء اللازم

 - یقوم المستخدم بالنقر على
 یقوم المستخدم بإدخال الرد على الاستفسار
 - يستطيع المستخدم رفع الملفات ان وجدت.

Request Number	Trade Name	МАН
Request Number	Trade Name	МАН
# Request Number Trade Name	Request Date Catest Update	Request Type Status
1	20/05/2018 20/05/2018	Now Request Waiting for quer
		Paquest Datails PDF

		Registration My Req	uests My Products	My Certificates		ø	0
	Number Of Inqu	iries: 1					
	#	Department Name				Details	
5	1	Product Evaluation Dep	artment				
				Upload New Medical	File		
			Drop zip file	e here to upload or select from	n your computer		
							Saue



Public



	nquiry Reply	×	O CompanyRep1
Number Of Inquiries:	Files Levels Module 3 (Quality)		
A Pro	Sub Files Levels P. Drug Product Inquiry Need Study Reply Coose Co		
		_	
	ion My Requests My Products My Certificates	4	9 ¹
Number Of Inquiries: 1			
# Departme	nent Name	Details	
1 Product B	Evaluation Department	C	
	Upload New Medical File		

الخطوة الخامسة: استكمال الملفات

- النقر على أيقونة "Complete Request" لاتخاذ الإجراء اللازم
 - يقوم المستخدم باستعراض الملاحظات
 - یقوم المستخدم باختیار "Proceed "





- يقوم المستخدم بتعديل بيانات الطلب
 - يقوم المستخدم برفع الملفات

	MAH	ł				Request Status				
	MA	λH				The file is incomplete			~	·
		Search	Clear							
		Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Type	Status	Details	
	1	HERE	21100123	XXXXXX	HORQUERG-BE	Human Medicinal Product	Variation Request	The file is incomplete	Details ^	
	2	-	111000		14/01/01/01/01	Herbal Product	New Request	The file is incomplete	Details 🗸	
		er vessionen	-		Last Update Date	e: 20/10/2022	Sub Product	Trade Name: Hyge	ex Cream	
		View Request Deta	its		Choose Complete Requi	est n	Apply			
	3	1.000			Request Details	PDF	New Request	The life is incomplete	Details ^	
	4	100000-07	0.000	00000	10000000	Karantérékéset Postat	New Request	The file is incomplete	Details ^	
	5	1000000	214030	0000404	100000-010	Recentional and Product.	New Request	The file is incomplete	Details ^	
	6	***	10-10-00	-	10000	Not an Address of the	New Request	The file is incomplete	Details ^	
	istration	My Request	s My Pro	oducts My	y Certificates				£	O CompanyRep1
Application Concern	istration ils Name	My Request	s My Pro	oducts My	y Certificates	g Type Name			£	O CompanyRep1
Application Concern Human Medicinal Pro Sub Drug Type Name Other	istration ils Name oduct re	My Request	s My Pro	oducts My	y Certificates Drug Ger	g Type Name neric(Multisource)	Drug		£	CompanyRep1
Regit Application Concern Human Medicinal Pro Sub Drug Type Name Other Rejection Reason unclear file	istration iIS Name oduct re	My Request	s My Pro	oducts My	y Certificates Dru Ger	g Type Name neric(Multisource)	Drug		£	CompanyRep1
Application Concern Human Medicinal Pro Sub Drug Type Name Other Rejection Reason unclear file Module 1 - Regio	istration iIS Name oduct re	My Request	s My Pro	oducts My	y Certificates Drug Ger	g Type Name neric(Multisource)	Drug		£	CompanyRep1





~
~
~
~
~
Proceed >







Add/Update Sub-pr	oduct						×
Sub-Product trade name in Sau Sub-Product trade name in English	udi Arabia (In Saudi Arabia)						
Test Exemption							
Sub-Product trade name in Arabic (i	in Saudi Arabia)						
منتج معفى من الرسوم							
Ingredients Active Substance Type of active substance Single Multiple							
Active Substance name	operator	Quantity		Lipit	Reference		
Name	Choose V	0		Choose V	optional	+ Add	Cancel
Active Substance name	operator		Quantity	unit		Reference	Action
test	Less than		1	L			C 🛍
Excipient Excipient name	Operator		Unit				
Name	Choose	~	Choose		~		
Reference	Quantity is QS ?						
optional	○ No ○ Yes		+ Add	Cancel			
Excipient name	operator		Quantity	unit		Reference	Action
test	Equal to		QS	L		test	☞

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

ш SDR	Registration	My Requests	My Products	My Certificates		4 0
3		000000389	Submited	2	sub-F	Products 💙 🚥
4		000000388	Submited	1	sub-F	Products 🖌 🚥
5		000000387	Draft	1	sub-F	Products 🗠 🚥
6		000000386	Submited	5	sub-F	Products 🗠 🚥
7	-	000000382	Draft	1	sub-	Product Details Add Sub-Product
8		000000370	Draft	2	sub-F	Products ∨ …
9		000000375	Draft	1	sub-F	Products 🗠 🚥

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



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

-	My Requests My F	Products My Certificates	 	CompanyRe
w Request				
uman Medicinal Proc	Biological Drug	Biological		
Is Saudi Arabia Country of ori	gin?			
⊖ Yes				
No				
Is this product under license				
• Yes				
O No				
Mas there any scientific advis	e given by the SFDA for this	medicinal product?		
was there any scientific advic				
 Yes 				

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





شاشة الـ Legal status of product ستكون غير قابلة للتغيير بناءً على البيانات المسجلة سابقًا.

Request							
Application type	Product Details	O	O Marketing Authorizat	on Lagal status of F	Product Price	Certificate	O Summary
Product E	Details						
ID	Dosage Form	Primary Package P	Packaging Size	Unit	Volume	Action	
1		1	1	L.	1	Ø	
< Previous					Save and Continue	later	Next

- بعد الانتهاء من تعبئة جميع الخانات المطلوبة، يتم اصدار فاتورة سداد.
- o 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 واصدار 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

ļ		My Requests My Migration Requ	My Products My Certificates	4 0
'	My Products			
	Product Number Product Number	Trade Name Trade Na	me	Search Cancel
	# 🗢 Trade Name	Product Number Status	Sub-Products	Options
	1	Waiting for invo payment	Dice 1	sub-Products ^
	Sub-Product # Number	Dosage Prim Form Strength Unit Paci	nary Creation Registration kage Date Number	Registration Date Status
	1 H			Walting for invoice
	2			Rew Package Size
	3			sub-Products V

ملاحظة: لا يمكن اضافه 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 اضافه 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 العبوه، ثم الضغط على التالي.

	Registration My Requests My Migration Requests My Products My Certificate	s 4 0
_	Product Details Price Certificate	O Summary
	STEP 1 Sub-Product Details	
	General	× 🔤
	Marketing Company Information	~
	Marketing Authorization	~
	Legal Status of the Product	~
	Ingredients	~
L 2	Registration My Requests My Migration Requests My Products My Certificate	▲ ⊖
	Packaging Package Size	
	Volume	19 10
	Unit	
		Save and Continue later Next >
	المعالي المطال فيلما فيلما Saudi Food & Drug Authority	User Manual FAQs C 19999 All Rights Reserved © 2018 Seudi Food & Drug Authority





- يتم الانتقال الى صفحة بيانات شهادة السعر وتعبأتها، بعد الانتهاء من تعبئه 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.

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 00.000 Choose Pricing in Origin Country Ex-Factory Price Ex-Factory Price ExFactory Price Currency 00.000 Choose 00.000 Choose 00.000 Choose Pricing in Origin Country ExFactory Price Currency Wholesale Price Wholesale Price Currency 00.000 Choose Public Price Public Price Currency	
00.000 Choose Pricing in Origin Country ExFactory Price Currency Wholesale Price Wholesale Price Currency 00.000 Choose 00.000 Choose	
Pricing in Origin Country ExFactory Price Wholesale Price Wholesale Price 00.000 Choose 00.000 Choose	
00.000 Choose 00.000 Choose Public Price Public Price Currency	
Public Price Public Price Currency	~
abilet nee earliery	
00.000 Choose ~	
Marketing Pricing	
Registration My Requests My Migration Requests My Products My Certificates	
Registration My Requests My Migration Requests My Products My Certificates	
Registration My Requests My Migration Requests My Products My Certificates	
Registration My Requests My Migration Requests My Products My Certificates	
Registration My Requests My Migration Requests My Products My Certificates Produc Detais Produc Detais Cost Vel Cost Total	
Registration My Requests My Products My Certificates Product Details Product Details Product Details Product Details Product Details Product Details	
Registration My Requests My Migration Requests My Products My Certificaties Poduct Details Poduct Details Cost Vat Cost Total 0 0 Declaration	
Registration W Requests M V Requests M V Products M V Certificates	
Registration W proquest W products W products W products W products Image: Constraint of the constraint of th	





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 الـ products يقوم ممثل الشركة باختيار أحد الهرعي "sub product . يقوم النظام بعرض نموذج طلب تسجيل مستحضر من نوع ."new Package Size" يقوم ممثل الشركة بتعبأة 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.

204				Trade Name	9		Search	Cancel
¥ :	Trade Name	Product Nu	Imber	Status Sub	-Products			Option
1		000000020)4	Submited 1			sub-P	roducts ^
#	Dosage Form	Strength	Unit	Primary Package	Creation Date	Registration Number	Registration Date	C Show Details
1			mg/kg	Bag	11/08/2018			Request Certificate

o اختيار اتخاذ اللازم والنقر على "Request Certificate "كما هو موضح أدناه:

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





JL SD		Registration	My Requests	My Products	My Certificates	3	4	O CompanyRep1
Ce	rtificate R	equest						
	Certificate type							
	choose				•			
	choose							
Ч	Registration	Certificate Of	Herbal Product					
;								

٥ التأكد من معلومات المنتج ليتم اصدار الشهادة واختيار أيقونة "Next"

Registration	My Requests	My Products	My Certificates		1	CompanyRep1
				Marketing Company, Nationality Test Product, Gibraltar		
Manufactory					Nationality	
					Albania	
					Andorra	
						Next
	Manufactory	Registration My Requests	Registration My Requests My Products	Registration My Requests My Products My Certificates	Registration My Requests My Products My Certificates Manufactory Test Product, Gibraltar Test Product, Gibraltar	Registration My Requests My Products My Certificates Manufactory Nationality Manufactory Albania Andorra





الضغط على طلب الفاتورة من القائمة اتخاذ اجراء لطلب الشهادة:

Fees Payment	Method			Issue Date 03-12-2024 1 hours 00 minutes	То рау	Payment Due 03-12-2024	
Cost		Vat Cost	Total				
							Bill Details 🔨
#	Dosage Form	Primary Package		Package Unit		Volume	Cost
1							

بعد السداد يمكن للمثل الشركة اصدار الشهادة عن طريق شاشة الشهادات.

Certificate type			
choose			
Registration Certification	e Of Herbal Product		
Free Sales Certificate	Of a Herbal Product		
Certificate Of Pharma	ceutical 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.







Certificate Number	Trade	Name	Certificate Type	
Certificate Number	Tra	de Name	Choose	~
# Certificate number	Trade name	Certificate Type	Reques	t dat @ Certificate details
# Certificate number	 Trade name 			Q Certificate details
1		Registration Certificate Of Herbai Product	30/10/2018	Print certificate
				witt certricate







شكل شهادة تسجيل مستحضر

رقر الشهادة: :: تاريخ الإصدار: :: Issue Date: تاريخ الإصدار: :: Expiry Date:	ىر عشبي Registration Certi	شهادة تسجيل مستحض ficate of a Herbal Product	الهينة الحامة للخفار والحواء Soudi Food & Drug Authority الح
	طريقة الوصف Legal Status		الاسم التجاري Trade Name
			الاسم العلمي Generic Name
	الوكيل Marketing Authorization Holder (Agent)		رقم التسجيل Registration Number
	الشركة المسوقة و جنسيتها Marketing Company,Nationality		الشكل الصيدلاني Dosage Form
	الشركة الصانعة و جنسيتها Manufacturers Nationality		التركيز/الوحدة Product Strength
	incharacteris, readonality		مدة الصلاحية Shelf Life
		10	نوع العبوة Packaging Type
Stamo		-	حجم العبوة Packaging Size/Volume
			ظروف التخزين Storage Conditions

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

- شهادة تسجيل مستحضر صيدلاني
- شهادة تسجيل مستحضر بيطري
- شهادة تسجيل مستحضر عشبى
- شهادة حربة البيع
 شهادة مستحضر صيدلاني CPP
- مشهادة حرية البيع وشهادة مستحضر صيدلاني CPP: الشهادة الصادرة من السلطة الرقابية في الدولة التي يتم فيها التصنيع كاملا أو الخطوات النهائية لتصنيع المستحضّر الصيدلاني أو من بلد الشركة الدوائية المسوقة.

ملاحظة: شهادة حربة 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، انواع التعديلات التي يمكن تقديمها هي: 1. تعديل يتعلق بالجودة

 - 2. تعديل للمأمونية والفعالية
 - 3. التعديلات الإدارية

#	Trade Name	Product Number	Status	Sub-Prod	lucts				Option
1		0000002422	Draft	4				sub	Products V
2	- 199	0000000424	Submited	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		-	hà	Jar	22/12/2018		25/12/2018	CRequest Certificate
з	H000000992			kg	Ampoule	22/12/2018		04/02/2019	Cancel Request
4	H0000001002			billion organisms/ml	Stopper	22/12/2018			Submitted
5	H0000001013			nā	Dredging container	23/12/2018			Submitted

43 صفحة طلب تعديل





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

noose	Cancel
Proposed Changes rrent Proposed Current Proposed The And Title Of Variations Theose ange affect se this change affect the last updated drug application form? No Yes	Cancel
Current Proposed + Add	Cancel
Imber And Title Of Variations Choose Image affect Is this change affect the last updated drug application form? INO IYes INO IYes INO IYes INO IYes INO IYes IYes IYes IYes IYes IYes IYes IYes	0
Choose Iange affect Es this change affect the last updated drug application form? No Yes	0
ange affect es this change affect the last updated drug application form? No Yes	
Yes	
	Next >
ariation Request Detail	
Application Concern Types	
• IV. PMF/VAMF	
umber And Title Of Variations	
Choose	0
2.Change in the name and/or address of a blood establishment including blood/plasma collection centers	
Procedure Type Implementation Date	
IA	
nanges approval Note that the variation request may affect information in certificates related to the sub product, please request a new certificates related to the sub product, please request a new certificates approved to reflect those updates	ficate once variation

45 استكمال بيانات مصفحة طلب التعديل





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

	•		Issue Date 03-09-202 1 hours	e 24 00 minutes	То рау	Payment Due 03-09-2024	
ost	Vat Cost	Total					
500	825	6325					Bill Details
oice Type Issuing tax invoice	e						
3							

و 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 -

بیدر SDP	#	Registratio	on My Reques	My Migration	Requests My Produ	cts My Certificate	5		P 0
	ман					Request Statu	s		
	MA	н				The request	is rejected to exe	ceed the time limit for answe	ring the query \sim
		Search	Clear						
	#	Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Type	Status	Details
	1	HADRENDH	1010003	00001	ND-004 8-004	Human Medicinal Product	Variation Request	The request is rejected to exceed the time limit for answering the query	Details ^
	2	1000000	10.15210.0		10000	Human Medicinal Product	New Request	The request is rejected to exceed the time limit for answering the query	Details
	10	to para tana	10		Last Update	Date: 23/10/2022	Su	ib Product Trade Name: Zia	Pena
		View Request Deta	ails		Choose Complete R	Rejected Request	<u> </u>	Apply	
	3			10000	Request De	etails PDF quests (0)		The request is rejected to exceed the time limit for answering the query	Details ^
	4	-100000-001	*****		100000	Human Medicinal Product	New Request	The request is rejected to exceed the time limit for answering the query	Details ^
	5	NORMONIA	1000000	1000	PACKED OF	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 ٦ أشهر من انتهاء الشهادة كما هو موضح في الشكل ادناه:

Pro	oducts								
Produc	t Number		Trade N	ame					
406			Trade	e Name				Search	Cancel
#	Trade Name	Product Number St	tatus	Sub-F	Products				Option
1		S	ubmited	5				sut	-Products ^
#	Sub-Product Number	Dosage Form	Strength	Unit	Primary Package	Creation Date	Registration Number	Registration Date	Status
1	He000000947	Concentrate and diluent for solution for infusion	1	kg	Ampoule	25/11/2018	000000947	25/11/2018	Certificate
2	He0000000948	Blood fraction modifier	1	kg	Ampoule	25/11/2018			Request Certificate Variation Request
3	He0000000949	Chewable tablet	1	kg	Ampoule	25/11/2018	000000949	25/11/2018	C Ceneval Request
4	He000000950	Concentrate and solvent for cutaneous use	1	kg	Ampoule	25/11/2018			been canceled
5	He000000954	Anticoagulant and preservative solution	2	mg/kg	Bag	25/11/2018			The product invoice has been expired

Price Certifica	te					
CIF Price		Currency				
17.75		SAUDI RIYAL	~			
Pricing in	Origin Country					
Ex-Factory	Price	ExFactory Price Currency	Wholesale Price	w	holesale Price Current	су
3.75		SAUDI RIYAL	~ 7.6	\$	SAUDI RIYAL	
Public Price		Public Price Currency				
4.4		SAUDI RIYAL	\sim			
Marketing	Pricing					
Please	enter the price in countri	es where the product is marketed				
Please	enter the price in countri-	es where the product is marketed				
Please Country Choose	enter the price in countri	es where the product is marketed	- Add			
Country Choose	enter the price in countri	es where the product is marketed	+ Add			
Country Choose	enter the price in countri	Ex- factory	+ Add	Public		
Country Country Name	Pack size Unit	Ex- factory Price Currency	CIF price Currency	Public price Cu	urrency	Notes
Country Choose Country Name	Pack size Unit	Ex- factory Price Currency	CliF price Currency	Public price Cu	urrency	Notes





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

	<u> </u>		Issue Date 04-02-2019 2 hours 0	0 minutes To pay	Payment Due 04-02-2019		
Cost	Vat Cost	То	tal				
8800	440	92	240			В	ill Details 🔨
# Dosage F	orm	Strength	Strength Unit	Primary Package	Package Unit	Volume	Cost
1 Concentra	ate 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.
 - o لإصدار شهادة جديده بتاريخ جديد يجب ان تكون حالة شهادة الطلب "Expired Soon", " Expired".
- و في 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 o "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:

- ٥ 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.
 - <u>فى حال تم رفض طلب تسجيل المستحضر</u> 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 المستحضرات بعد النقر على طلب اعتراض من خلال الشاشة التالية تعبئة النموذج وهو سبب الاعتراض وأيضا تفاصيل الاعتراض.

R	Regis	tration My Requests	My Products	My Certifica	ites					R O (
#	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 recuest was rejected from the commit e	SPIMACO Request Details
6	_			lei	Herbal	Objection Request	11/04/2019	11/04/2019	The stic was	Objection Request Request Details Pl





Objection Reque	st						
Objection Request	Details						~
Payment Method			Issue Date 17-04-2019		Payment Due 17-04-2019	Э	
			4 hours	00 minutes To pay			
Cost	Vat Cost	Tot	tal				
1000	50	10	50			Bi	II Details 🖍
# Dosage Fo	rm	Strength	Strength Unit	Primary Package	Package Unit	Volume	Cost
1 Concentrat	e and diluent for solution for infusion	1	mg	Ampoule	g	1	1000
Registration	My Requests My Products	My Certificates				≰ ⊖⊙	companyrep
Registration	My Requests My Products	My Certificates				£ O	companyrep ~
Registration rice Certificate ast Approved Pricing	My Requests My Products	My Certificates				£ 0 (companyrep ~ ~
Registration rice Certificate ast Approved Pricing ertificate	My Requests My Products	My Certificates				≰ ⊖ (companyrep ~ ~
Registration rice Certificate ast Approved Pricing ertificate natomical Therapeutic	My Requests My Products	My Certificates				£ 0 (companyrep
Registration rice Certificate ast Approved Pricing ertificate natomical Therapeutic ackaging	My Requests My Products	My Certificates				£ 0 (companyrep ~ ~ ~ ~
Registration rice Certificate ast Approved Pricing ertificate natomical Therapeutic ackaging helf Life	My Requests My Products	My Certificates				£ 0 (companyrep ~ ~ ~ ~ ~
Registration rice Certificate ast Approved Pricing ertificate natomical Therapeutic ackaging heif Life roposed Storage	My Requests My Products	My Certificates				£ 90	companyrep ~ ~ ~ ~ ~ ~
Registration rice Certificate ast Approved Pricing ertificate ackaging heif Life roposed Storage nimal Material	Chemical (ATC)	My Certificates					companyrep
Registration rice Certificate ast Approved Pricing ast Approved Pricing certificate ast Approved certificate ast	Chemical (ATC)	My Certificates					companyrep ~ ~ ~ ~ ~ ~ ~ ~




- بعد تعبئة البيانات الخاصة بطلب الاعتراض سوآءا اعتراض على القبول أو الرفض يظهر النظام شاشة
 السداد والضغط على "Submit" وبعدها تتحول حالة الطلب كالتالى:
 - 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 " او " Under Technical Validation وحسب نوع "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"

SCR Registration My Requests	My Products My Certificates	▲ 0
My Products		
Product Number 204	Trade Name Trade Name	Search Cancel
# Trade Name Product Number	Status Sub-Products	Options sub-Products ^ ····
# Dosage Form Strength Unit I 1 987 mg/kg I	Primary Package Creation Date Registration Numl Bag 11/08/2018 0000000431	ber Registration Date Status & Show Details
		Cancel Request





Cancel Form	
Cancel Reason	n
Reason	
Choose	
MAH Letter	
Is there an official	letter from MAH?
O Yes	
Did you attach a	an official letter from MAH with all required information (The letter should contain a justification for cessation request) ?
Attachment	
	Select file 🔔
Amounts of prod	duct Imported to Saudi Arabia during the last four years
Year	Amount Currency
Year	Amount Currency
2023	SAR
Year 2022	Amount Currency SAR
Year 2021	Amount Currency SAR
Legal Status	
Legal Status	ار "Cancel Request " في أسفل الصفحة
Legal Status List of countries that t Country Select a country	ار "Cancel Request" في أسفل الصفحة the product is still marketed in
Legal Status List of countries that t Country Select a country View List of countries	ار "Cancel Request" في أسفل الصفحة the product is still marketed in
Legal Status List of countries that t Country Select a country View List of countries	ار "Cancel Request" في أسفل الصفحة the product is still marketed in
Legal Status List of countries that t Country Select a country View List of countries	ار "Cancel Request" في أسفل الصفحة the product is still marketed in Date dd/mm/yyyy Ad
List of countries that t Country Select a country View List of countries	ار "Cancel Request" في أسفل الصفحة the product is still marketed in
egal Status List of countries that t Country Select a country View List of countries	لر "Cancel Request" في أسفل الصفحة the product is still marketed in Date dd/mm/yyyy Ad
egal Status List of countries that t Country Select a country View List of countries t Add List of countries t	لر "Cancel Request" في أسفل الصفحة the product is still marketed in
egal Status List of countries that t country Select a country View List of countries Add List of countries t List of countries that c	لد "Cancel Request" ي أسفل الصفحة the product is still marketed in Date dd/mmyyyy Add that the product is still marketed in No data found that delisted the product Add
egal Status List of countries that t country Select a country View List of countries Add List of countries that c	لل "Cancel Request" ي أسفل الصفحة the product is still marketed in
List of countries that t Country Select a country View List of countries that of List of countries that of	لد "Cancel Request" ي أسفل الصفحة the product is still marketed in
Legal Status List of countries that to Country Select a country View List of countries Add List of countries to List of countries that countr	لله product is still marketed in
Legal Status List of countries that to Country Select a country View List of countries Add List of countries that countries th	لله product is still marketed in Date dd/mm/yyyy Ad that the product is still marketed in No data found that delisted the product delisted the product Create Request
egal Status List of countries that t country Select a country View List of countries Add List of countries that c	لر "Cancel Request" في أسفل الصفحة the product is still marketed in
Legal Status List of countries that to Country Select a country View List of countries that coun	the product is still marketed in Date dd/mm/yyyy مع that the product is still marketed in No data found that delisted the product delisted the product Create Request
List of countries that to Country Select a country View List of countries that to Add List of countries that to	لله product is still marketed in Date dd/mm/yyyy that the product is still marketed in No data found that delisted the product Aud delisted the product No data found Create Request

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





الخطوة الثاني عشر: إعادة تسجيل الطلب الملغى

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:

258	a number			Trade	Name				Search	Cancel)
ŧ	Trade Name	Product N	umber	Status		Sub	-Products				Options
				Submite	ed	1			sub	-Products ^	
#	Sub-Product Number	Dosage Form	Strength	Unit	Primary Package		Creation Date	Registration Number	Registration Date	Show Details	
1		Bee smoke stick	56465	mg/kg	Bag		11/09/2018			Canceled	

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





ummary						
es						
Sect	Vet Cest	Total				
JOSI	Val Cost	IOtal				
)	0	0				Bill Details 🗸
eclaration						
By sending this request	I hereby certify that the s	ubmitted are true and accurate	and changes will not be m	nade until they are a	approved by SFDA	
e	Name					
e Signature						
		Select file 🌲				
mpany Stamp						
		Select file ᆂ				
DR 📻 Regis	tration My Requests	My Products My Certific	ates			Amico38
	tration My Requests	My Products My Certific	ates			Amico38
Application type	tration My Requests Product Details	My Products My Certific	ales og Authorization Lagel a	tabus of Product	Price Certificate	Amico38
Application type	tration My Requests Product Details	My Products My Certific	atles Pg Authorization Lagai #	tabus of Product	Price Certificate	Amico38
Application type	Aration My Requests	My Products My Certific Manufactures Market	ates	tabus of Product	Price Certificate	Amico38
Application type	Aration My Requests Product Details	My Products My Certific	attes attes assue Date 04-02-2019	talus of Product	Price Certificate Payment Due 04-02-2019	Amico38
Application type	Aration My Requests	My Products My Certific	ates rg Authorization Issue Date 04-02-2019 3 hours 00 minut	tatus of Product	Proel Certificate Payment Due 04-02-2019	Amico38
Application type	tration My Requests Product Details Val Cost	My Products My Certific	ates p Authorizatos Lagel a Issue Date 04-02-2019 3 hours 00 minut tal	tabus of Product	Price Certificate Payment Due 04-02-2019	Amico38
Application type Application type Summary Fees Payment Method Cost 18000	Aration My Requests Product Datass Val Cost 900	My Products My Certific Manufactures Market	eg Authorization Lagel e Issue Date 04-02-2019 3 hours 00 minut tal 5000	eaters of Product	Proc Certificate Payment Due 04-02-2019	Amico38
Application type	tration My Requests Product Details Valt Cost 900	My Products My Certific Marcelectures Market	ates ates ates ates ates ates ates ates	tables of Product	Price Certificate Payment Due 04-02-2019	O Amico38 Summary Bill Details ✓
Regis	Aration My Requests Product Details Valt Cost 900 est I hereby certify that to	My Products My Certific Manufactures Market To 18 he submitted are true and accura	ates ates ates ates ates ates ates ates	etables of Product	Pice Certificate Payment Due 04-02-2019	Amico38 Sommary
Acostation type Regis Acostation type Regis	Tration My Requests Product Details Valt Cost 900 est I hereby certify that th Name	My Products My Certific Manufectures Market To 18	ates ates ates ates ates ates ates base bate bate bate bate bate bate bate bat	e made until they an	Proc Certificate Payment Due 04-02-2019	Amico38
Application type	Aration My Requests Product Details Valt Cost est I hereby certify that th Name	My Products My Certific Manufactures Market To 18 the submitted are true and accura	ates ates ates ates ates ates ates ates	tabas of Product	Proc Certificate Payment Due 04-02-2019 re approved by SFDA	Amico38 Summary





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				
	-When referred to the concerned department				
At the Relevant Department	-When the query is accepted by the concerned				
	department				
The Query Has Been Completed At	-After the management reviewing the query and				
"Department Name"	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 Requ	iest		٩			
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 Ty ♦	pe Status	Details
1	11/09/2024			Human Medicina Product	Request Cancellation	The file is incomplete	Details ^

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

Request Number Search Request Q Tegenest Incomplete Renewal Renewal Renewal Requests Requests Incomplete Renewal Requests Requests Requests Requests Requests Requests Details Choose Apply	/ly Requests		+ New Request
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 Request Product Sub-Product Number Product Type Requests Details 1 11/09/2024 (Image: Sub-Product Number Product Type Requests Details 1 11/09/2024 (Image: Sub-Product Number Product Type Request Request Details 1 11/09/2024 (Image: Sub-Product Number Product Type Request Request Details 1 11/09/2024 (Image: Sub-Product Product Request Request Details 1 11/09/2024 Image: Sub-Product Product Request Sub Product Trade Name: Vew Request Details Image: Sub-Product Image: Sub-Product Image: Sub-Product Trade Name:	Request Number 👻 Search Request	٩	6
Request Wumber Request Date Product Number Sub-Product Number Product Type Request Type (Status Details 1 11/09/2024 Image: Status Image: Status Details Details Details 1 11/09/2024 Image: Status Image: Status Image: Status Details Details Image: Status Image: Status Image: Status Image: Status Details Details Image: Status Image: Status Image: Status Image: Status Details Details Image: Status Image: Status Image: Status Image: Status Image: Status Details Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status <td>All Inquiry Cancellation 24 Requests 0 Requests 3 Requests</td> <td>Variation Objection Certi 4 Requests 2 Requests 3 Req</td> <td>ficate Incomplete Renewal ucests 1 Requests 0 Requests</td>	All Inquiry Cancellation 24 Requests 0 Requests 3 Requests	Variation Objection Certi 4 Requests 2 Requests 3 Req	ficate Incomplete Renewal ucests 1 Requests 0 Requests
1 11/09/2024 Human Medicinal Product Request Cancellation The file is Request Details > Last Update Date: 11/09/2024 Sub Product Trade Name: View Request Details Choose Apply	Request Request Product # Number Date Number	Sub-Product Number Product Type	Request Type ♦ Status Details
Last Update Date: 11/09/2024 Sub Product Trade Name: View Request Details Choose	1 11/09/2024 (Human Medicinal Product	Request The file is Cancellation Details Y
View Request Details Choose Apply		Last Update Date: 11/09/2024	Sub Product Trade Name:
	View Request Details	Choose	Apply











الضغط على " تفاصيل" للذهاب لصفحة استعراض تفاصيل الطلب

Advanced Fillte	ers ^							Search		Clear all
				та	otal Records: 1					
Request Number	Product Number	Sub- Product Number	Sub- Product Trade Name	Drug Type	Creation/Resubmission	Request Type	Latest ♦ Update	МАН	Status	Details
F)	Generic(Multisource) Drug		Request Cancellation	21/08/2024	Cigalah	The file is incomplete	۲
4										Þ

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 البينات هي عملية نقل بيانات المستحضر من نظام SDR إلى نظام E-SDR مع ملاحظة أن ترحيل بيانات المستحضرات سيكون للمستحضرات التي انهت 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.

My Migr	ation Requ	uests						C C	- New Migration Request
A 81	II Requests	Waiting Action 4 Requests							
Reque	st Number			Product Nun	nber		Sub Pro	duct Number(Referen	ce Number)
Trade				MAH	vumber		Sub	Product Number(Re	ererence Number)
Trac	le Name			MAH			۶ ۲	Search	Clear
#	Request Number	Product Number	Sub-Product Number	Trade Name	Product Type	Request Date	Latest ♦ Update	Status	МАН
1	H0000004012	000003011	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 SDRالمرتبط بنفس الحساب الرئيسي الخاص بممثل الشركة كما هو موضح أدناه:

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

 يتيح هذا الخيار استعراض تفاصيل المنتج Migration as a pro يتيح هذا الخيار بترحيل المنتج من سدر (SDR).
Migration as a pro o يتيح هذا الخيار بترحيل المنتج من سدر (SDR).
 يتيح هذا الخيار بترحيل المنتج من سدر (SDR).
Migration as a sub pro
Registration My Requests My Migration Requests My Products My Certificates
All Waiting Action 8 Requests 4 Requests
All Waiting Action 8 Requests 4 Requests Request Number Product Number
All Waiting Action 8 Requests 4 Requests Request Number Product Number Request Number Product Number Sub Product Number(Reference Number) Request Number Sub Product Number(Reference Number) Sub Product Number(Reference Number)
All B Requests Waiting Action 4 Requests Request Number Product Number Request Number Product Number B Request Number Product Number Sub Product Number Sub Product Number(Reference Number) Trade Name MAH
All 8 Requests Waiting Action 4 Requests Request Number 4 Requests Request Number Product Number Breaderst Number Product Number Sub Product Number Sub Product Number(Reference Number) Trade Name MAH Trade Name MAH Request Product Sub-Product Trade Request Product State Clear
All 8 Requests Waiting Action 4 Requests Request Number Product Number Sub Product Number(Reference Number) Request Number Product Number Sub Product Number(Reference Number) Trade Name MA H Search Clear Request Product Sub-Product Trade Request Ma H Search Clear Request Product Sub-Product Trade Request Latest MAH Request Product Sub-Product Trade Request Latest MAH





שבע SDR	Registration M	ly Requests My Migration Re	equests My Products My Certific	ates	4 0
Old SD	R System Available	Products to be Migra	ated		
Referen	ce Number	Registration	Number	Trade Name	
Refe	rence Number	Registrati	on Number	Trade Name	
#	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		-

o يتيح هذا الخيار بترحيل بيانات مستحضر فرعي من سدر (SDR) في حال المستحضر الأساسي Productموجود 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.







	My Migration Requests My Products My Certificate	is 🕻 O	
Migration Request Please Select Application Concern			
Hothal Broduct	Auman Medicinal Product	Votorinary Broduct	
Product	Product Select	Product	
المیان کی الحکار والحکار الحکار والحکار والحکار والحکار والحکار الحکار والحکار والحکار والحکار والحکار والحکار و		User Manual FAQs C 19999 All Rights Reserved © 2018 Saudi Food & Drug Authority	

يقوم المستخدم بإدخال البيانات كما في حقول الخدمة.

Registration My Requests My Migration Requests	My Products My Certificates	¢ 0
Migration Request Human Medicinal Product Bological Drug Others		
Is Saudi Arabia Country of origin? Ves No		
Is this product under license Ves 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		





	Registration My Requ	ests My Migration	Requests My Products	My Certificates		R 0
Migration Request						
Application type	O Product Details	O Manufactures	O Marketing Authorization	O Lagal status of Product	O Price Certificate	O Summary
STEP 1 Applicatio	on Type					
Please Specify Please Specify	For SubDrug Type Other					
Please Speci	fy					
General Produc Trade Name	ct Information					
Trade Name						
Product strength						
Product stren	ngth					
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"

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

My Migration Requests	y Migration Requests My Products My Certificates	+ New Migration Request
All Walting Action 4 Requests 1 Reports		
Request Number	Product Number	Sub Product Number(Reference Number)
Trade Name	MAH	Sub Product Number(Reference Number)
Trade Name	MAH	Search Clear
Request Product. # Number Number Sub-	Product Number Trade Name Product Type 🖨	puest Date Latest Up CF Complete Migration Request B Delaw
	Product	
		User Manual FAQs C 19999







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،

Produc	ts						×
My Pr	oducts						
Product N	Number		Trade Name				
Produ	ct Number		Trade Name		Search	Clear	
#	Trade Name	Product Numb	ber	Status	Sub-Products	Options	
1		0000002983		Submited	1	+>0	
2		0000002997		Submited	3	+	
3		0000003011		Submited	1	+	
4		0000003012		Submited	1	+	
5		0000003015		Submited	1	+	
40	HG00677-00-00-00	33-277-98	Flazo	125mg-5mi Oral Suspensio	DIT		

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

ثم استكمال بيانات المستحضر الفرعى غير المشتركة التالية:

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

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 " .

ون عالى عبول الطلب من قبل موظف الهيئة سوف يظهر الطلب في صفحة "Waiting Action" وتكون مفحة "Waiting Action" وتكون حالة الطلب "Waiting Action" وفي هذه الحالة سوف يتمكن المستخدم من اتخاذ أجراء على الطلب. في حال عدم الرد على ملاحظات موظف الهيئة خلال المدة المحددة سوف يتم قبولها تلقائيا 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

- o يتيح هذا الخيار استعراض تفاصيل المنتج "Complete Migration Request " o يتيح هذا الخ<mark>يار اس</mark>تكمال طلب الترحيل Delete
 - م يتيح هذا الخيار لحذف الطلبات التي لم يتم استكمالها " Draft "

<mark>ملاحظه:</mark> 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 تأكيديه. للتأكيد على حذف الطلب.





All Watting Action		
Request Number	Product Number	Sub Product Number(Reference Number)
Request Number	Product Number	Sub Product Number(Reference Number)
Trade Name	ман	
Trade Name	MAH	Search Clear
Request Product Sub-Product # Number Number Number	Trade Product Request Late Name Type ♦ Date ♦ t	nsi Jpdate Slatus B Distee
· · · · · · · · · · · · · · · · · · ·	Herbal 10/03/2020 10/0 Product	33/2020 Request hat updated by SPDA
العينة المابح للغذا، والحوا		User Manual FAQs 📞 19999
	Request Number Roquest Number Trade Name Trade Name Beguest Product Sub-Product Pumber Number Number	Request Number Product Number Tade Name MAH Tade Name MAH Index Number MAH Index Number Name Number Number Number Number Number Number Image: Number Number Number Number Image: Number

للمستخدم الموافقة على التعديلات او التعديل على البيانات مره اخرى

- م 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 محدده بلون كما هو موضح أدناه:

	SOR E	Registration My Requ	ests My Migration	Requests My Products	My Certificates		4 9	
	Migration Request							
	Application type	O Product Details	Manufactures	O Marketing Authorization	Lagal status of Product	O Price Certificate	O Summary	
5	step 1 Applicatio	n Type						
	General Product Trade Name	t Information						
	Product strength 13							
	Strength Unit kg			~				
	J.							

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 Productليتم عرض الشاشة الخاصة بنقل المستحضرات

			istration My Requests My Migrat	ion Requests My Pro	ducts My Certificates	ansfer of Product	4 0	
		My Requests					+ New Request	
		Request Number 🗸	Search Request		٩			
		All 2 Requests	Inquiry Cancellation 0 Requests 0 Requests	Variation 0 Requests	Objection Certifica 0 Requests 0 Reques	ate Incomplete ts 0 Requests	Renewal 0 Requests	
		Request # Number	Request Product	Sub-Product Number	Product Type	Request Type	Details	
		1		100		New Request Draft	Details ^	
		2		-		New Request Invoice expired	Details ^	
New	Fransfer o	ر f product	عدم بالضغط على	نوم المستخ	نديم طلب يق	ہحة ادناہ، لتغ	الشاشة الموض	سيتم استعراض
		Registration My R	equests My Migration Requests	My Products My	Certificates Transfer of	Product	£ 9	
	Transfer of	Dreduct)
	fransfer of	Product				C ⁺	New Transfer of Product	J
	Request N	umber Search Red	quest	C	2		•	
				No data found				
ttps://sdremp.sfda.gov.sa/1	IransferMAH/Create	الهينة الحامة للغذاء والد udi Food & Drug Authority			Terms A	And Conditions User M	lanual FAQs ∿19999 Saudi Food & Drug Authority	





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

Statistical of product Form Commercial Register Number (of the current MAH company) Someone@example.com Commercial Register Number (of the current MAH company) Commercial Register Number (of the proposed MAH company) Droduct Number Commercial Register Number (of the proposed MAH company) Product Number Commercial Register Number (of the proposed MAH company) Droduct Number Commercial Register Number (of the proposed MAH company) Droduct Number Commercial Register Number (of the proposed MAH company) Droduct Number Commercial Register Number (of the proposed MAH company) Droduct Number Droduct Disclamer Droduct Number Statistic Statisti	Verification Information	Sub-products Information	Attachment & Agreement	
Transfer of Product Form Verification Information Email address linked to the current MAH Account Commercial Register Number (of the current MAH company) Someone@example.com Commercial Register Number (of the current MAH company) Commercial Register Number (of the proposed MAH company) Product Number Commercial Register Number (of the proposed MAH company) Product Number Transfer of Product Disclaimer Product Number Ministry of the submit of the new marketing authorization to a Marketing Authorization - ago and and wice (ray to the sub- super submit of the submit MAH transfer request function to a Marketing authorization - ago and submit of the requestory of the submit the thransfer request function is the next mandatory step to achieve the ownership transfer of the regulatory activities forms of the product Number (request the submitted information, data, documents, and ther validity. The SDR (Saudi Drug Registration) Discrete 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 the applicant wild bits integet DOS NOT imply that the new MAH is exempted from submitting the 'Application to AMarketing' which is the next mandatory step to achieve the ownership transfer of the regulatory activities form submitted information, data, documents, and their validity. The SDR (Saudi Drug Registration) (gal effects or commercial disputes resulting from the submission of incorrect data and information. Next Jaga effects are commercial disputes resulting from the submission of incorrect data and informatio				
Vence Image: Sinked to the current MAH Account Someone@example.com Commercial Register Number (of the current MAH company) Commercial Register Number (of the proposed MAH company) Tensfer of Product Disclaimer Product Number Static stat	Transfer of Product Form			
Example com Commercial Register Number (of the proposed MAH company) Commercial Register Number (of the proposed MAH company) Product Number Commercial Register Number (of the proposed MAH company) Product Number Taster of Product Disclaimer Product Number Mark States in the state is an used in the state in	Verification Information	Commercial Reg	star Number (of the current MAH company)	
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Commercial Register Number (of the proposed MAH company) Product Number Commercial Register Number (of the proposed MAH company) Product Number Transfer of Product Disclaimer Product Number Mark State (b) and (Commercial Register Number (of the propos	ad MAH company) Product Number		
Transfer of Product Disclaimer A set in the set of th	Commercial Register Number (of the	proposed MAH company) Product Num	ber	
مد المنبة مسمسة لذل مندج مستعمر ث التركة سوقة لمن ورثلة كعفارة اولى غن بنكن للتركة السوقة العبود من استمل للذيم على سنوس منابع على على من ورافة على ها المن من المنع من ورافة على ها المن من منه على المن من ورافة على عن منه منه المن من منه على المنابع من منه مستعمر. والمن على على منه والمنتخب من علي المن من منه على المنابع من منه من منه من منه من منه من منه من منه منه	Transfer of Product Disclaimer			
o	ا اشتها لا تنتخب طن شبق ملیه شریع سنجمس. للله ایا سا سی کرد ، ویکن شم هلله سوز را عن This service is intended to help the new eSDR platform as the first step to submit new MAH is exempted from submitting product. The applicant is responsible for	بلون تقرير المي من Application for Variation to a Markeling و التي يحت في الارت يحيد في المراقب المحالية و لا تتمل مست من المنزية من المات مذم لا محيد في المحالية المحالية المحالية المحالية المحالية المحالية المحلمة المحلمة المحلمة المحلمة المحلمة المحلمة MAH transfer request through its eSDR account. Be noted the Application of Variation to a Markeling "which is the ne the accuracy of the submitted information, data, document in clubic distance of any of the distance that accounts in the distance of the distance of any of the distance that accounts in the distance account of the submitted information, data, documents in the distance of any of the distance that accounts in the distance that accounts in the distance that account of the distance that accounts in the distance that account is a distance that account in the distance that account is a distance that account in the distance that account is a distance that account in the distance that account is a distance that account in the distance that account is a distance that account in the distance that account is a distance that account in the distance that account is a distance that account in the distance that account is a distance that account is a distance that account in the distance that account is a distance that account in the distance that account is a distance t	لتركة من تقديم هلت الفنير على رضيت السريل - uthorization تتر للبورية لم ملحة كله البناني (المغريت المنطة او المستعدين أمر تتر الدونية أو نزاعات تجزيه نجله عن انخلل بيناني رسغرمات عر regulatory activities forms of the product to their at that the approval of this request DOES NOT imply t mandatory step to achieve the ownership transfer , and their validity. The SDR (Saudi Drug Registration addition, the achieves motion with kingh for any cooper-	الطني احلاء ال يتحاد أو أن ccount on that the of the ion)
	platorn is not responsible for the applica legal effects or commercial disputes resu Next بغط على خيار Verification Information	nia roducto o any o ne arcentencode requerients. Iting from the submission of incorrect data and information المتعلقة بالمنتج الرئيسي والظ Sub-products informatio	عميمان الفرعية المنتجات الفرعية بة جميع المنتجات الفرعية	uences, الطلب بإضاف مttachment & Agreements
Transfer of MAH Form	العلمة المالية الم	المتعلقة بالمنتج الرئيسي والظ المتعلقة بالمنتج الرئيسي والظ Sub-products Information	عميمان, المعيات الفرعية بة جميع المنتجات الفرعية	uences, الطلب بإضاف العدhment & Agreements
Transfer of MAH Form Sub-product Information	العلمة المالية المالية مالية المالية مالي مالية مالية مالي	na roducto o any o ne alveniencode requerience iting from the submission of incorrect data and information المتعلقة بالمنتج الرئيسي والظ Sub-products Informatio	عميمان الفرعية ية جميع المنتجات الفرعية	uences, غالب بإضاف بالمعالم
Transfer of MAH Form Sub-product Information The number of sub-product of the main product is 3, all of them must be entered	platform is not responsible for the applica legal effects or commercial disputes resu Next ي خيار Verification Information Transfer of MAH Form Sub-product Information The number of sub-product of the main p	na roduct is 3, all of them must be entered	عميع المنتجات الفرعية ية جميع المنتجات الفرعية	uences, فاہن باضاف سلامہ کا میں
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	العومات in and responsible for the applica legal effects or commercial disputes resu Next على خيار Verification Information Transfer of MAH Form Sub-product Information The number of sub-product of the main p Registration Number	in a roduction of any on the alternational requirements in thing from the submission of incorrect data and information المتعلقة بالمنتج الرئيسي والظ Sub-products Information roduct is 3, all of them must be entered Sub product number	عميع المنتجات الفرعية تة جميع المنتجات الفرعية Dosage Form	uences, الطلب بإضاف Wachment & Agreements
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 Registration Number Sub product number Choose	لاوزما المراجع ال مراجع المراجع الم مراجع المراجع المراحم ال مراجع ال	roduct is 3, all of them must be entered Sub product number Sub product number	عميع المنتجات الفرعية تة جميع المنتجات الفرعية Dosage Form Choose	illences, غاب بإضاف بالعدام Agreements
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 Registration Number Sub product number Image: transfer of MAH Form Sub product number Image: transfer of sub-product of the main product is 3, all of them must be entered Dosage Form Registration Number Sub product number Image: transfer of transfer of the main product is 3, all of them must be entered Choose Image: transfer of transfer	لانت is not responsible for the applical legal effects or commercial disputes resu Next على خيار Next verication Information Transfer of MAH Form Sub-product Information The number of sub-product of the main p Registration Number Registration Number the add Cancel	roduct is 3, all of them must be entered Sub product number Sub product number Sub product number	عمليع المنتجات الفرعية علي الفرعية Dosage Form Choose	ilionees, غابط بالطال بالمعادمة Actions
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 Registration Number Sub product number + Add Cancel # Registration Number # Registration Number Sub product number Dosage Form + Add Cancel # Registration Number Bath additive Image: Concel	لیوعا فالحدة مع معلی خیار Platform is not responsible for the applical legal effects or commercial disputes result Next علی خیار Verification Information Uverification Information Transfer of MAH Form Sub-product Information The number of sub-product of the main p Registration Number Registration Number + Add Cancel # Registration Number	المتعلقة بالمنتج الرئيسي والظ المتعلقة بالمنتج الرئيسي والظ Sub product is 3, all of them must be entered Sub product number	Dosage Form Dosage Form Bath arditive	il المحالية المحالية Actions
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 Registration Number Sub product number Choose	لیوعا فالحدة or commercial disputes resu Next العالى خيار Next Verification Information Transfer of MAH Form Sub-product Information The number of sub-product of the main p Registration Number Registration Number the number of sub-product of the main p	roduct is 3, all of them must be entered Sub product number Sub product number Sub product number	Dosage Form Dosage Form Bath additive	illences, غابط بیا للها ر باغدای بلاعدای مردانons کاری ش
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 Registration Number Sub product number Choose # Registration Number Sub product number Choose # Registration Number Sub product number Dosage Form Actions 1 Sub product number Bath additive C cons 2 Eath additive C cons	لانت المراجع	roduct is 3, all of them must be entered Sub product number Sub product number Sub product number	عملیمان الله فی الفر علیه علیه مربع الفرعیة الفرعیة Dosage Form Dosage Form Bath additive Bath additive	Actions کا الطلب باضاف للتعداست & Agreements





وفي نهاية تقديم الطلب يتم رفع المرفقات المتعلقة بالمنتج وتكون صيغة الملف PDF,zip,rar بعد رفع

الملف بنجاح، يتم دراسة من قبل اللجنة

Transfer of MAH Form		
Attachment and agreement		
Copy of the agreement (contract) between the	two companies (certified)	
757562 1 (2).pdf	<u> </u>	
Letter from the company that has the product in 757562 1 (2) pdf	n SDR	
Transfer of MAH Disclaimer		
ين مقدم الطلب مسؤولاً عن اي تبعات او آثار قانونية تنتج	بل منصة مدر مسؤولية عدم صحة البيانات المطومات المدخلة من قبل مقدم الطلب، ويكو مفقوعة غير قابلة للإسترداد.	عتم الطلب مسؤولية صحة كافة البيانات والمعلومات المدخلة، ولا تتحم ادخال متم الطلب لييانات ومعلومات غير صحيحة، كما أن الميالغ الم
The applicant shall be fully responsible of the inaccuracy of data entered by the applicant the data, however the paid fees are non-	he accuracy and correctness of the entered data, and SDR plat , The applicant shall be consequently responsible of any legal I refundable.	tform is not responsible of any incompleteness an liability due to the incompleteness and inaccuracy

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

				T New Hall
Request Number	Search Request		٩	
# Request Numb	Der 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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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:

- o Accessing the Saudi Drug Registration Website Click Here
- o 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:

سدر SDR		
Username		
Username		
Password		
	Login	





The Interface of Saudi Drug Registration System

All 93 Requests Inquiry 0 Requests Cancellation 0 Requests Variation 0 Requests Objection 0 Requests Certificate 1 Requests Incomplete 0 Requests Renewal 1 Requests aquest Number Product Number Trade Name Trade Name AH Request Status Request Status	Requests							+ New Requ
Product Number Trade Name Request Number Product Number AH Request Status	All 93 Requests	Inquiry 0 Requests	Cancellation 0 Requests	Variation 0 Requests	Objection 0 Requests	Certificate 1 Requests	Incomplete 0 Requests	Renewal 1 Requests
Request Number Trade Name AH Request Status	Request Number			Product Number			Trade Name	
AH Request Status	Request Numb	er		Product Number			Trade Name	
MAH	MAH				Request Sta	tus		
Gibbse	MAH				Choose			~

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.

	equests My Migration Requests My Products My Certificates	R 8
New Request Please Select Application Conc	ern	
B	B	
Herbal Product Product	Human Medicinal Product Product	Veterinary Product Product
Select	What's Drug type ?	Select
	What sort of drug is this ?	
	choose 🗸	
	Next >	
elect form Application Con	cern	
1. Herbal Pr	oduct	
2. Human M	Nedicinal Product	
3. Veterinar	v 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 Drag New chemical entry
Is Saudi Arabia Country of origin? Ves
Is this product under license Ves No
Was there any scientific advice given by the SFDA for this medicinal product? Yes
Is there a padiatric development program for this medicinal product? Yes No
Is this product registered in GCC Ves No
Is this product registered in SRA Ves No

The user fills the needed data in seven steps

Application Type

Application type	Product Details	Manufactures	O Marketing Authorization	C Lagal status of Product	O Price Certificate	O Summary
STEP 1						
Application 1	Туре					
Because you choos	e No in "Is Saudi Arabi	a Country of origin?" ple	ase complete the following	a.		
General Product Info Reference Trade Name	ormation					
Reference Trade N	lame					
Product strength						
Product strength						
Strength Unit						
choose			~			
Dosage Form						
choose			~			







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

C ~~~~~	Price Cartificade Durmary	O Lagar status of Product	O Markating Authoritation	O Manufactures	Product Details	Application type
					Details	STEP 2 Product D
			Add new product		•	
\rightarrow	Continue later Next	Save and Co				< Previous
C 19999 rug Authority 1564d7-p5em0	nditions User Manual FAQs L1 - 2024 - v 5.57.1.1 Saudi Food & Drug Au julphar sch-web-fb74564d7	Terms And Cond All Rights Reserved © 2018 - 2		ulig Jobil ðulpil ðulbil á Food & Drug Authority	0 1 76 2	Rdigital seal
	nditions User Manual FAQr - 2024 - v.5.57 1.1 Saudi Food & (julphar sch-web-fb	Terms And Cond Al Rights Reserved © 2018 - 2		ilig Jobali Quind Quadi 6 Feed & Drug Authority	0 🧷 🛎	Rdigital seal

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.

Net						
	w Request					
	Application type Product Details	Manufactures Marketing	O	f Product Price Certificate	O Summary	
	STEP 3 Manufacturers Active Substance Phar You have 1 Active substance(s) you n	maceutical Ingredient (API) Manufacture	ers		
	All Active Substances Manufactur	es				
	Active Substances Select an active substance	Select Manufacturer or Add new one Select a manufacture	Select Activity or Add new Select an activity	Q	+ Add	
	Active Substances	Manufactuer name	Activity		Action	
	Excipient Pharmaceuti	cal Ingredient (EPI) Mar	nufacturers			

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

			Issue Date 03-09-2024 1 hours 00 minutes	Payment Due 03-09-2024	2
Cost	Vat Cost	Total			
5500	825	6325			Bill Details 🗸
voice Type) Issuing tax invoice) Issuing simplified invo	ice				





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."

ji e		Registration My Requests	My Migrat	ion Requests My Prod	ucts My Certificate	5		# 0
N	ly Requests							+ New Request
	All 95 Requests	Inquiry Can 0 Requests 4 Re	cellation quests	Variation 13 Requests	Objection 1 Requests	Certificate 11 Requests	Incomplete 0 Requests	Renewal 6 Requests
	Request Number		P	roduct Number		Sub-Proc	uct Trade Name	
	Request Numb	ber		Product Number		Sub-P	roduct Trade Nar	me
	ман				Request Status			
	MAH				Waiting for invol	ce payment		~
	Search	Clear						
	Request # Number	Request Pro Date Nur	duct mber	Sub-Product Number	Product Type	Request Type	Status	Details
	1				Herbal Product	New Request	Waiting for involve payment	Details
	MAH: Compan	y Name Authorized Hani 88		Last Update D	ate: 20/10/2022	Sub Prod	ict Trade Name: SE	DR Herbal2
	View Reque	est Details		Request Deta	ils PDF	~ ~	pły	
	2				Herbal Product	New Request	Waiting for invoice payment	Details ^
	3				Human Medicinal Product	New Request	Whiting for invoice payment	Details 🔨
	4				Veterinary Product	Variation Request	Waiting for invoice payment	Details ^

Choose "Payment Summary" and click on "View," as shown below

yment summary						
	Invoice Number	543146112				
	Sadad Biller Name	My Business Services				
	Sadad Biller Id	144				
Vat R	Registration Number	300784838500003				
	Issue Date	03/09/2024 12:23:47				
	Payment Due	03/09/2024 13:23:47				
	Tax Invoice	View				
سيل الصجيل/صجيل Important Notice 'tax invoice' befo	حسافة إلى ذلك، يجب على الم e: Payment method u ore proceeding with p	يره على أنها فاترره خريبية قبل عملية الدفي با) pdated. Please be aware that you o ayment. Additionally, for tax invoice	یرہ صریبیة ما لم یم تحدید نوع الفاد an only convert a simplifie issuance, customers mus	كن تحويل الفاكورة المبسطة إلى فاك d invoice into a tax invoi t be registered and logge	وسيلة الدفع, يرجى ملاحظة أنه لا يمّ سة أعمالي لإسدار الفاتورة الضريبية. ce if you specify the invoice ed in to the Aamaly platform	تلبيه: ثم تحديث الدخرل إلى منص type as ١.
Cost	Vat Ce	ost	Total			
5500	825		6325		Bil	I Details 🗸





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

		ما فاتورة خريبية تمر نخل من مومنف بابقرارات تم	فضلا اختر نوع الفاتورة التي ترغب في تصدير فاتورة ضريبية مبسطة نصر نخل من موغير مخلف بالإبارات الطريبية	
			یرمی إضافة علف طریبی للکمال عملیة الدفع + إضافة علف طریبی تفاصیل الفاتورة	
+ لىل 6325.0	اسم تمقوتر 🗧 رقم المقوتر مدعك الملي	بیانات سداد قم ستوره 54146870	إجمالي المبلغ المستحق فضلا اغتر طريقة الدفع التي تناسبك سيراد نفام سداد للمدفوعات	
J		J (E	

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

ڀ	×		أهلاً بك عميل هيئة الغ
		مالدادية منسر ؟	فضلا اختر نوع الفاتورة التي
		سى بديد رسم طريبي٠ ○ نعم ○ لد الإسم �	فاتورة ضريبية مبسطة تصور لخل من موفير مخلف بالاف
		البسم	
	المدينة اكتب اسم المدينة	المنطقة اكتب اسم المنطقة	يرجى إضافة ملف ضريبي لأكمال عما
	اسم الشارع اختب اسم الشارع	الحي اكتب اسم الحي	+ إضافة ملف ضريبي
	# الرقم النضافي	# رقم المبنى	تفاصيا , الفاتورة
5.0	1234	1234 الرمز البريدي	بحصالي المبلغ المستحق
		12345	
	حفظ	النتاء	فضلا اختر طريقة الدفع التي ت
			<i>سداد</i> نظام سداد للمدفوعات





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







Third Step: User uploads files

- **2** 0 🚃 Registration My Requests My Migration Requests My Products My Certificates Product Number Request Number Sub-Product Trade Name Product Number Sub-Product Trade Name Request Number ман Request Status MAH Waiting Upload Files Clear Requ Date Product Typ Human Product MAH: Incomplete MAH 2 View Request Details 5 H0000019156 16/08/2022 0000010114 1400 Details ^ Registration My Requests My Migration Requests My Products My Certificates ¢ 0 Proposed Storage \sim Animal Material Payment Summary > Please upload the files based on the eCTD requirements -1× Drop zip file here to upload or select from your computer 1 Upload the file Terms And Conditions User Manual FAQs \$19999 الهيئة الصادة للضفاء والحواء Soudi Food & Drug Authority All Rights Reserved © 2018 Saudi Food & Drug Autho
- 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 <u>Click Here</u>.







© Open		×	-
← → × ↑ 🔋 > Search Results in Downloads >	✓ U sdr.zip	×	
Organize -	📼 • 🔳	0	
🖿 Desktop 🛷 🔨			
🖡 Downloads 🖈 💦 🦷			
🗈 Documents 🖈			
🔚 Pictures 🖈			
ed SDR			
SDR files			~
SFDA			
Training		_	
ConeDrive			×
Libraries This PC Custom			
S This PC			
3D Objects			
Desktop			
Documents			
Downloads			
File name: SDR	~ All Files	\sim	
	Open 🔻 Cance	1	
		.1	
Drop zip file here to upload or sele	t from your computer		
)		
		_	

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.
- o User clicks on
- The user fills in the response to the query.
- User can upload files if there is any.





All Request Enquiry 13 Requests 1 Requests	Updated Requests 0 Updated Requests	Objection Requests 0 Objection Requests	Certificate Rec 0 Certificate Requ	uests ests	Incomplete Requests 1 Incomplete Requests
Request Number	Trade Name	9	М	AH	
Request Number	Trade Na	ame		MAH	
Search Clear	\supset				
# Request Number Trade	e Name 🔶 Request Date	Latest Update	Request Type	Statu	S Ctana Davit
1	20/05/2018	20/05/2018	New Request	Waiti	ing for quor Reply Inquiry
					Request Details PDF
J- S		5 1		5	
Registration My R	PLUE	J Q Ay Certificates		5	₽ <u>0</u>
Registration My R umber Of Inquiries: 1	PLUE	J Ay Certificates		5	Patalis
Image: state of the state o	equests My Products M	J Ay Certificates			Details
umber Of Inquiries: 1 # Department Name 1 Product Evaluation Do	aquests My Products M	J Ay Certificates			Dotails
umber Of Inquiries: 1 # Department Name 1 Product Evaluation Do	aquests My Products M apartment	Ay Certificates	File		Details
umber Of Inquiries: 1 # Department Name 1 Product Evaluation Dr	equests My Products M epartment	Ay Certificates	File		Details







	Inquiry Reply	O CompanyRep1
Number Of Inquiries: P Dej 1 Pro	Files Levels Module 3 (Quality) Sub Files Levels P. Drug Product Inquiry Need Study Reply	
	Save	



	Registration My Reques	sts My Products My Certificates	\$ \Q
Number Of Inqu	uiries: 1		
#	Department Name		Details
1	Product Evaluation Depart	nent	Ø
		Upload New Medical File	




Fifth step: complete files

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

JJUU SDR	Registratio	My Reques	My Migration	Requests My Produ	cts My Certificate	5		P 0 militar
ма	н				Request Statu	s		
M	AH				The request is rejected to exceed the time limit for answering the			ering the query \sim
	Search	Clear						
#	Request Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Type	Status	Details
1	100104001	1110003	00001	10404-00 8-004	Human Medicinal Product	Variation Request	The request is rejected to exceed the time limit for answering the query	Details ^
2	10000	10.10.00.0		10000	Human Medicinal Product	New Request	The request is rejected to exceed the time limit for answering the quory	Details 🗸
	der behand ander	ar i		Last Update	Date: 23/10/2022	Su	ib Product Trade Name: Zia	Pena
	View Request Det	nis		Choose Complete R	lejected Request		Apply	
3	******	1010000	NOTION OF	Request De	tails PDF quests (0)		The request is rejected to exceed the time limit for answoring the query	Details ^
4	-			100000	Human Medicinal Product	New Request	The request is rejected to exceed the time limit for answering the query	Details ^
5	14000000	1000004	1000	***(*)*(****	Herbal Product	New Request	The request is rejected to exceed the time limit for answering the query	Details 🔨





עובן SDR	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	>



~	optication type	Product Defails	Manufactures	Marketing Author		Lagal status of Product	Price Certificate	Summary
s [.] P	TEP 2 roduct	Details						
	ID	Dosage Form	Primary Package	Packaging Size	Unit	Volume	Action	
	1			11	L	1	Ø	
0	C Previou	8				Save and Co	ntinue later	Next >









Add/Update Sub-p	roduct						×
Sub-Product trade name in Se Sub-Product trade name in Englis	audi Arabia h (in Saudi Arabia)						
Test Exemption							
Sub-Product trade name in Arabic	(In Saudi Arabia)						
مثلج معفي من الرسوم							
Ingredients Active Substance Type of active substance Single							
O Multiple							
Active Substance name	operator	Quantity	Uni		Reference		
Name	Choose 🗸	0	c	hoose 🗸	optional	+ Add	Cancel
Active Substance name	operator		Quantity	unit		Reference	Action
test	Less than		1	L			GK 😐
Excipient Excipient name	Operator		Unit				
Name	Choose	~	Choose		~		
Reference	Quantity is QS ?						
optional	○ No ○ Yes		+ Add	Cancel			
Excipient name	operator		Quantity	unit		Reference	Action
test	Equal to		05			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:





ערבן SDR	Registration	My Requests	My Products	My Certificates	¢ 9
3		000000389	Submited	2	sub-Products ∽ 🛛 🚥
4		000000388	Submited	1	sub-Products 🗸 🛛 🚥
5		000000387	Draft	1	sub-Products 🗸 🛛 🚥
6		000000386	Submited	5	sub-Products V
7		000000382	Draft	1	Sub- + Add Sub-Product
8		000000370	Draft	2	sub-Products 🗸 🚥
9		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.

ew Request Iuman Medicinal Product Biological Drug Biological	
Luman Medicinal Product Biological Drug Biological	
Is Saudi Arabia Country of origin?	
O Yes ● No	
Is this product under license	
© Yes O No	
Was there any scientific advice given by the SFDA for this medicinal product?	
O No	

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





ew Request							
Application type	Product Details	Manufacture	s Marketing Au		al status of Product Pri	ce Certificate	O Summary
STEP 2							
Product D	Details						
ID (Dosage Form	Primary Package	Packaging Size	Unit	Volume	Action	
1		10000	11	L	1	œ	
(
< Previous					Save and Contin	ue later	Next >
	_						_

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

- 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:

בر SC	#	Registrati	on My Requests	My Migratio	n Requests	My Products	My Certificates		¢ 9	
Му	y Produ	icts								
	Product Nu Product	mber Number		Trade	Name de Name			Search	Cancel)
	# 🕈 T	rade Name	Product Number	Status		Sub-Pro	oducts			Options
	1			Waiting	for invoice t) 1			sub-Products ^	
	# Nu	ib-Product imber	Dosage Form S	trength Unit	Primary Package	Creation Date	Registration Number	Registration Date	Status Weiting for invoice	
									Par C Show Do New Pac	etails kage Size
	2								sub-Products ¥	
	3								sub-Products 🗸	

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 and²its^ostatus 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

	Registration My Requests My Migration Requests M	ty Products My Certificates 🖡 O	
_	Product Details Price	o Certificate Summary	
	STEP 1 Sub-Product Details		
	General		~
	Marketing Company Information		~
	Marketing Authorization		~
	Legal Status of the Product		~
	Ingredients		~
	Manufacturers		~
	Registration My Requests My Migration Requests My	y Products My Certificates 🗳 😌	
	Packaging Package Size		
	Volume		() () ()
	Unit		
	▼		
		Save and Continue later Next	>
	د بارمان المثال مواد المبالية	User Manual FAQs All Rights Reserved © 2018 Saudi Food & D	L 19999 Drug Authority





• 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.

Pricing					
CIF Price	Currency	uest, il the produ	ICT IS NOT Subject to pricing, CIF will	not be included in the certificate	
00.000	Choose	~			
Pricing in Origin Country	, ExEactory Price Currency		Wholesale Price	Wholesale Price Current	v
00.000	Choose	~	00.000	Choose	~
Public Price	Public Price Currency				
00.000	Choose	~			
Marketing Pricing Please enter the price in co	ountries where the product is markeled				

Nexter Details Cost Vat Cost Total 0 0 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	JILU SDR	Registration My Requests My	Migration Requests My Products My Cer	tificates	0
Cost Vat Cost Total 0 0 0		Product Details	Price Certificate	Summary	
Cost Vat Cost Total 0 0 0 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 Title Image: Select file 1 Company Stamp	Summary				
0 0 0 Bill Details ~	Cost	Vat Cost	Total		
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 I Select file Select file Select file Company Stamp Select file	0	0	0		Bill Details 🗸
Title Name	Declaration By sending th	is request I hereby certify that the subn	nitted are true and accurate and changes will not b	e made until they are approved by SFDA	
File Signature Select file 1 Company Stamp	Title	Name			
Select file 🚣	File Signature				
Company Stamp			Select file 1		
	Company Stamp				





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.

204				Trade Nam	e		Search	Cancel
#	Trade Name	Product N	umber	Status Sut	o-Products			Options
1		00000020	04	Submited 1			sub-F	Products ^
#	Dosage Form	Strength	Unit	Primary Package	Creation Date	Registration Number	Registration Date	C Show Details
1			mg/kg	Bag	11/08/2018			C Request Certificate

• 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:

	Registration	My Requests	My Products	My Certificates	A	O CompanyRep1
Certificate	Request					
Certificate ty	ре					
choose				v		
choose						
Registrat	on Certificate Of	Herbal Product				
;						





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

9		Registration My	Requests	My Products	My Certificates			OcompanyRep1
	MAH (Agent) Tahani gh					Markeung 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						
Paymen	It Method			Issue Date 03-12-2024	Payment I 03-12-202	Due 24
				1 hours 00 minutes	То рау	
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 Nequest		
Certificate type		
choose	•	
choose		
Registration Certificate Of Herbal Product	t	
Free Sales Certificate Of a Herbal Produc	et	
Certificate Of Pharmaceutical Product CF	PP	

• 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.

Certificate Number	Trade	Name de Name	Certificate Type	\
Search Cancel				
		Number of Certificate Requests : 1		
# Certificate number	Trade name	Certificate Type	Reque	est dar Q Certificate details
1		Registration Certificate Of Herbal Product	30/10/201	8 Print certificate
				First cediticate





o Certificate form of drug registration

لقهاد: : الإحدار: Issue Date: Expiry Date: : : : : : : : : : : : : : : : : : :	ر عشبي رقم Registration Cerl تاريخ	شهادة تسجيل مستحض ificate of a Herbal Product	طوعالو الخواء الخامة الخام الحواء Saudi Food & Drug Authority	Note: The
	طريقة الوصف Legal Status		الاسم التجاري Trade Name	
			الاسم العلمي Generic Name	
	الوکیل Marketing Authorization Holder (Agent)		رقم التسجيل Registration Number	
	الشركة المسوقة و جنسيتها Marketing Company,Nationality		الشكل الصيدلاني Dosage Form	
	الشركة الصانفة و جنسيتها Manufacturars Nationality		التركيز /الوحدة Product Strength	
	manufocurroro, realizinancy		مدة الصلاحية Shelf Life	
			نوع العبوة Packaging Type	
Stamp		-	حجر العبوة Packaging Size/Volume	
			ظروف التخزين Storage Conditions	
(termin)				

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 Opponone sub-Products sub-Products sub-Products sub-Products	RU										
1 000002422 Praft 4 sub-Products	#	Trade Name	Product Number	Status	Sub-F	Products					Options
2 000000424 Submed 5 Sub-Product Sub-Product Sub-Product Registration Registration Registration Status Image:	1		0000002422	Draft	4				sub	-Products 🗸	
# Number Dosage Form Strength Unit Primary Package Creation Date Registration Number Registration Date Registration Date	2	- 19	0000000424	Submited	5				sub	-Products 🔨	
1 H000000989 L L Lg/m3 Screw cap 22/12/2018 25/12/2018 To product	#	Sub-Product Number	Dosage Form	Strength	Unit	Primary Package	Creation Date	Registration Number	Registration Date	Status	
2 H000000990 μg Jar 22/12/2018 25/12/2018 PRepared Certificate 3 H000000992 kg Ampoule 22/12/2018 04/02/2019 Cancel Request 4 H000001002 billion organisms/ml Stopper 22/12/2018 04/02/2019 Submitted 5 H000001013 Hg Pregular 23/12/2018 Submitted ••	1	H000000989			µg/m3	Screw cap	22/12/2018		25/12/2018	The prod	uct
3 H0000000992 kg Ampoule 22/12/2018 04/02/2019 4 H000001002 billion organisms/ml Stopper 22/12/2018 Submited *** 5 H000001013 ## #g Dredging container 23/12/2018 Submited ***	2	H000000990			μg	Jar	22/12/2018		25/12/2018	C Request Co	ertificate Request
4 H0000001002 billion organisms/ml Stopper 22/12/2018 Submitted ••• 5 H0000001013 H0000001013 H0000001013 H0000001013 Lange Lange Lange Container 23/12/2018 Submitted •••	3	H000000992			kg	Ampoule	22/12/2018		04/02/2019	Cancel Ree nas been registere	quest
5 H0000001013 µy µg Dredging 23/12/2018 Submited ***	4	H0000001002			billion organisms/n	Stopper	22/12/2018			Submittee	
	5	H0000001013		upup	hð	Dredging container	23/12/2018			Submittee	





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

Application Concern	
Choose	
Proposed Changes Current	Proposed
Current	Proposed + Add Cancel
Number And Title Of Variat	ions
Choose	
Change affect Does this change affect the last u	pdated drug application form?
⊖ Yes	
	Next
2	SDR 5
2	SDR 5 -
riation Request Detai	
riation Request Detai	SOR 5-
riation Request Detail	SOR 5-
riation Request Detail application Concern Types • IV. PMF/VAMF mber And Title Of Variations	SOR 55
riation Request Detail pplication Concern Types • IV. PMF/VAMF mber And Title Of Variations hoose	
riation Request Detail pplication Concern Types • IV. PMF/VAMF mber And Title Of Variations hoose	
riation Request Detail application Concern Types • IV. PMF/VAMF mber And Title Of Variations hoose	address of a blood establishment including blood/plasma collection centers
riation Request Detail application Concern Types • IV. PMF/VAMF mber And Title Of Variations hoose 2.Change in the name and/or rocedure Type	address of a blood establishment including blood/plasma collection centers
riation Request Detail pplication Concern Types • IV. PMF/VAMF mber And Title Of Variations hoose 2.Change in the name and/or rocedure Type IA	address of a blood establishment including blood/plasma collection centers
riation Request Detail application Concern Types • IV. PMF/VAMF mber And Title Of Variations hoose 2.Change in the name and/or rocedure Type IA	address of a blood establishment including blood/plasma collection centers Implementation Date
riation Request Detail application Concern Types • IV. PMF/VAMF mber And Title Of Variations hoose 2.Change in the name and/or rocedure Type IA anges approval Note that the variation request is approved to reflect those up	address of a blood establishment including blood/plasma collection centers Implementation Date t may affect information in certificates related to the sub product, please request a new certificate once variation dates
riation Request Detail pplication Concern Types • IV. PMF/VAMF mber And Title Of Variations hoose 2.Change in the name and/or rocedure Type IA anges approval Note that the variation reques is approved to reflect those up	Address of a blood establishment including blood/plasma collection centers Implementation Date t may affect information in certificates related to the sub product, please request a new certificate once variation dates
riation Request Detail pplication Concern Types • IV. PMF/VAMF mber And Title Of Variations hoose 2.Change in the name and/or rocedure Type IA snges approval Note that the variation reques is approved to reflect those up	BOR Solar



• 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:

Payment Method	U	Issue Date 03-09-202 1 hours	4 00 minutes To pay	Payment Due 03-09-2024	
Cost	Vat Cost	Total			
5500	825	6325		Bill	Details 🗸
voice Type Issuing tax invoice Issuing simplified inv	voice				
Please be aware that y	ou can only convert a simplified in	nvoice into a tax invoice if you specify th	ne invoice type as 'tax inv	pice' before proceeding with paymer	it

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:

Pr	rice Certificate										
	Pricing										
	CIF Price		Currency								
	17.75		SAUDI RIYAL		~						
	Pricing in Orig	in Country	ExEaston/ Dris	Curroney		Wholesale Briss	_		Wholesale	Drice Currer	
	3.75		SAUDI RIYAL	ecurrency	~	7.6	2		SAUDI RIY	AL	ic y
	Public Driso		Dublic Drise Ci	money							
	4.4		SALIDI RIVAL	unency	\sim						
			BABBININAL								
	Marketing Pric	ling									
	Please enter	the price in countries wh	ere the produc	ct is markete	d						
	Country										
	Choose				~	+ Add					
		F	×-								
	Country P	ack f	actory	ency	CIF	Currency		Public	Currency		Notes
				ency	price	Guirency		price	Currency		
	Algeria	e mL 🗸	11. AL	GERIAN DIN	AR~ 1	ALGERIA		29	ALGERIAN		Notes
	E Desister)		
₩ (Registra	tion My Requests	My Product	s My Ce	ertificates					*	0
Pro	Registra	tion My Requests	My Product	s My Ce	ertificates					<u> </u>	0
≓ Pro	Registra	tion My Requests	My Product	s My Ce	ertificates					× ·	0
Prc roduc	Registra	tion My Requests	My Product	s My Ce Name	ertificates					*	0
Produce 406	Registra oducts	tion My Requests	My Product Trade	s My Ce Name de Name	ertificates			Searc	n	Cancel	•
Pro Pro 406	C Registra Coducts Ct Number Trade Name	tion My Requests	My Product	s My Ce Name de Name Sub-P	ertificates			Searc	n	Cancel	e
Produce 406	C Registra	tion My Requests	My Products Trade Trade Status Submited	s My Ce Name de Name Sub-P	ertificates			Searc	n	Cancel -Products ^	optic
Produce 406 #	Carlos Registra Coducts Coducts Coduct Codu	tion My Requests	My Product Trade Trade Status Submited	s My Ce Name de Name Sub-P 5	ertificates.	Creation	Registratio	Searc	h sub	Cancel -Products ^	Optic optic
부 (Prc 406 # 1	Registra Acceleration Content Registra Content Conten	Iton My Requests	My Products Trade Status Submited Strength	s My Ce Name Ge Name Sub-P S Unit	ertificates Products Primary Package	Creation Date	Registratio	Searc D	n sub sub	Cancel -Products ~ Status	Opti-
Prc	Registra Registra Colucts Trade Name Trade Name Sub-Product Number He000000947	tion My Requests	My Product Trade Status Submited Strength r	s My Ce Name de Name Sub-P 5 5 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	ertificates Products Primary Package Ampoule	Creation Date 25/11/2018	Registratio Number 00000094	Searc n Ru Dr 17 25	h sub egistration ate	Cancel Products ~ Status Centicate Centicate	optie
Prc	CRESSING CR	tion My Requests Froduct Number Dosage Form Concentrate and diluent for solution fo infusion Blood fraction modifie	My Product Trade Trade Status Submited Strength r 1 ar 1	s My Ce Name do Name Sub-P S Unit kg	Primary Package Ampoule	Creation Date 25/11/2018 25/11/2018	Registratio Number	Searc n Re Di	n sub egistration ate	Cancel Products ~ Status Centificate C Show D C Request	etails Certificate
Prc roduc 406 # 1 1 2 3	Registration coducts ct Number Trade Name Sub-Product Number He000000947 He000000948 He00000049	tion My Requests Product Number Dosage Form Concentrate and dituent for solution fo infusion Blood fraction modifie Chewable tablet	My Product Trade Status Submited strength r 1 1	s My Ce Name Ge Name Sub-P S Unit kg	Products Products Products Ampoule Ampoule	Creation Date 25/11/2018 25/11/2018 25/11/2018	Registratio Number 000000094	Searc n Re 17 25	h sub egistration ate 5/11/2018	Cancel Cancel Status Centucida Centu	etails Certificate n Request
Prc 406 # 1 1 2 3 4	Registra Registra Cuucts Trade Name Trade Name Number He000000947 He000000949 He000000949	tion My Requests	My Product Trade Status Submited strength r 1 1 a 1	s My Ce Name Sub-P 5 0 4 8 9 4 8 9 4 8 9 4 8 9 4 9	Products Products Products Ampoule Ampoule Ampoule	Creation Date 25/11/2018 25/11/2018 25/11/2018	Registratio Number 00000009-	8earc n Re 17 25	h sub segistration ate 5/11/2018	Cancel Products ~ Status Centricele Ø Show D Ø Reseaver Ø Cancel J Denn Cancel Denn Cancel	etails Certificate a Request Request

Fees Payme			Issue Date 04-02-2019 2 hours 0	00 minutes To pay	Payment Due 04-02-2019		
Cost	Vat Cost	To	tal				
8800	440	92	40			E	3ill 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
-							
_			0				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:

- o 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

		Out-Desident	Developed	Treedo	Des des d	Deres and	Diama di	1.11.11		
#	Number	Number	Number	Name	Туре	Type	Date	 Update 	Status	MAH
1	He000000022	He0000000010	000000010		Herbal Product	New Request	17/04/2019	17/04/2019	The request was accepted from the Committee	-
2	He000000017	He000000004	000000004		Herbal Product	Certificate Request	16/04/2019	16/04/2019	Invoice expired	
3	He000000012	He0000000006	000000006		Herbal Product	New Request		11/04/2019	Draft	
4	He0000000010	He000000005	000000005		Herbal Product	Objection Request	11/04/2019	11/04/2019	The request was accepted from the Committee	-
5	He000000009	He0000000005	000000005		Herbal Product	New Request	11/04/2019	11/04/2019	The request was rejected from he comn itte	Request Details
6	He000000008	He000000004	000000004		Herbal Product	Objection Request	11/04/2019	11/04/2019	The stuc was complets from all	Objection Request Request Details PDF
									departments	
	Registration	My Requests	My Produc	ts My (Certificates				departments	🐔 \varTheta compa
Price Co	Registration	My Requests	My Produc	ts My d	Certificates				departments	Compa
Price Cr	Registration ertificate proved Pricing	My Requests	My Produc	ts My d	Certificates				departments	Compa
Price Co Last Ap Certifica	Registration entificate proved Pricing ate	My Requests	My Produc	ts My d	Certificates				departments	Compa Compa
Price Co Last Ap Certifica Anatom	Registration ertificate proved Pricing ate	My Requests	My Produc	ts My d	Certificates				departments	 O compa ~ ~<
Price Ci Last Ap Certifica Anatom Packag	Registration ertificate proved Pricing ate alcal Therapeutic ing	Chemical (ATC)	My Produc	ts My c	Certificates				departmente	 Compa <l< td=""></l<>
Price C Last Ap Certifica Anatom Packag Shelf Li	Registration ertificate proved Pricing ate aical Therapeutic ing	Chemical (ATC)	My Produc	ts My d	Certificates				departments	 € compa ~ ~
Price C Last Ap Certific Anatom Packag Shelf Li Propose	ertificate proved Pricing ate alcal Therapeutic ing ife ed Storage	My Requests	My Produc	ts My d	Certificates				departments	 G compa ~ ~<
Price C Last Ap Certifica Anatom Packag Shelf Li Propose Animal	Registration ertificate proved Pricing ate ate ing ife ed Storage Material	My Requests	My Produc	ts My d	Certificates				departments	 Compa <l< td=""></l<>
Price Co Last Ap Certifica Anatom Packag Shelf Li Propose Animal Reason Choose	Registration ertificate proved Pricing ate ate ate ate ate ate ate ate ate ate	Chemical (ATC)	My Produc	ts My d	Certificates				departments	 Compa <l< td=""></l<>

Objection R	equest Details							~
Fees								
Payment M	Nethod V			Issue Date 17-04-2019		Payment Due 17-04-2019		
2	2			4 hours (00 minutes To pay			
Cost	Vat Cost		To	tal				
1000	50		10	50			Bil	Details 🔨
# Dos	age Form	ş	Strength	Strength Unit	Primary Package	Package Unit	Volume	Cost
	contrate and diluent for colution for	infusion	1	mg	Ampoule	g	1	1000

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.

My Pro	oducts								
Product 204	t Number			Trade Na Trade	me Name		Search		Cancel
#	Trade Name	Produc	t Number	Status	Sub-Products				Options
1				Submited	1			sub-	Products ^
#	Dosage Form	Strength	Unit	Primary Package	Creation Date	Registration Number	Registration Date	Status	Show Details
1	Bath additive	987	mg/kg	Bag	11/08/2018	1000	30/10/2018	The produ	Request Certificate

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.

ear	Amount	Currency
18		SAR
ar	Amount	Currency
17		SAR
'ear	Amount	Currency
016		SAR
ar	Amount	Currency
015		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).

Add
Add
Add

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:

258	t Number			Trade Na	Name				Search	Cancel	
#	Trade Name	Product N	umber	Status		Sub-F	Products				Options
1				Submite	d	1			sub	-Products ^	
#	Sub-Product Number	Dosage Form	Strength	Unit	Primary Package		Creation Date	Registration Number	Registration Date	C Show Details	
1		Bee smoke stick	56465	mg/kg	Bag		11/09/2018			Re-register	

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

, ,			
Fees			
Cost	Vat Cost	Total	
0	0	0	Bill Details 🗸
By sending this requ	lest I hereby certify that the subr	mitted 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 🌲	

Application type	Product Details	Manufactures Mar	keting Authorization	Lagal status of Product	Price Certificate	Summary
Summary						
Fees						
Payment Method			Issue Date		Payment Due	
	LL I		04-02-2019		04-02-2019	
			3 hours 0	Ominutes To pay		
Cost	Vat Cost		Total			
18000	900		18900			Bill Details 🛩
Declaration						
By sending this requ	est I hereby certify that the	submitted are true and acco	urate and changes w	ill not be made until th	ey are approved by SFDA	
Title	Name					
File Signature						

System Status

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	-After the management reviewing the query and					
"Department Name"	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.

Request Number Search Request Q Total All Inquiry Cancellation Variation Objection Certificate Incomplete Renewal 0 Requests 0 Reques	My Requests							+ New Reque
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 Request Product Sub-Product Product Type Request Type	Request Number 🗸	Search Requ	est		٩			Ē
Request Request Product Sub-Product Product Type Request Type Status Details 1 11/09/2024 Human Medicinal Product Human Medicinal Product Request Cancelation The file is Econoplate Details	All 24 Requests	Inquiry 0 Requests	Cancellation 3 Requests	Variation 4 Requests	Objection 2 Requests	Certificate 3 Requests	Incomplete 1 Requests	Renewal 0 Requests
1 11/09/2024 Human Medicinal Request Cancellation Details A Product Details A	Request # Number	Request Date	Product Number	Sub-Product Number	Product Type	Request	Type Status	Details
	1	11/09/2024			Human Medicina Product	Request Cancellation	The file is incomplete	Details ^

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

Request Number Search Request Q Test All 24 Requests Inquiry 0 Requests Cancellation Variation 2 Requests Objection 2 Requests Certificate Incomplete 1 Requests Renewal 0 Requests Request 0 Requests 0 Requests 2 Requests 2 Requests 1 Requests 0 Requests # Number Date Number Product Product Type Request Details 1 11/09/2024 Human Medicinal Product Request Sub Product Trade Name: Details V View Request Details Choose Apply Apply	Request Number Search Request Q All 24 Requests Inquiry 0 Requests Cancellation 3 Requests Variation 4 Requests Objection 2 Requests Certificate 1 Requests Incomplete 1 Requests Renewal 0 Requests Request Request Product Sub-Product Number Product Type Request Type Status Details 1 11/09/2024 Human Medicinal Product Request Sub Product Trade Name: Details ~ View Request Details Choose Apply	My Requests							+ New Reques
All Inquiry Cancellation Variation Objection Certificate Incomplete Renewal 24 Requests 0 Requests 3 Requests 2 Requests 2 Requests 1 Requests 0 Requests Request Request Product Sub-Product Product Type Status Details 1 11/09/2024 11/09/2024 Last Update Date: 11/09/2024 Sub Product Trade Name:	All Inquiry Cancellation Variation Objection Certificate Incomplete Renewal 0 Requests 0 Requests <t< td=""><th>Request Number 🗸</th><td>Search Requ</td><td>iest</td><td></td><td>٩</td><td></td><td></td><td></td></t<>	Request Number 🗸	Search Requ	iest		٩			
Request Request Product Sub-Product Product Type Request Type 1 11/09/2024 1 11/09/2024 Human Medicinal Product Request of the file is Details 1 11/09/2024 Last Update Date: 11/09/2024 Sub Product Trade Name: Details View Request Details Choose Apply Apply	Request # Request Date Product Number Sub-Product Number Product Type Request Type Status Details 1 11/09/2024 11/09/2024 Image: Status Image: Status Details Image: Status 11/09/2024 Image: Status Image: Status Details Image: Status 11/09/2024 Image: Status Image: Status Details Image: Status Image: Status Image: Status Image: Status Details Image: Status Image: Status Image: Status Image: Status Details Image: Status Image: Status Image: Status Image: Status Details Image: Status Image: Status Image: Status Image: Status Details Image: Status Image: Status Image: Status Image: Status Details Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Image: Status Im	All 24 Requests	Inquiry 0 Requests	Cancellation 3 Requests	Variation 4 Requests	Objection 2 Requests	Certificate 3 Requests	Incomplete 1 Requests	Renewal 0 Requests
1 11/09/2024 Human Medicinal Product Request Concentation The file is product Details ~ Last Update Date: 11/09/2024 Sub Product Trade Name: View Request Details Choose Apply	1 11/09/2024 Human Medicinal Product Request Cancellation The file is noomplete Details ~ Last Update Date: 11/09/2024 Sub Product Trade Name: View Request Details Choose Apply	Request # Number	Request Date	Product Number	Sub-Product Number	Product Type	Request Ty	/pe Status	Details
Last Update Date: 11/09/2024 Sub Product Trade Name: View Request Details Choose Apply	Last Update Date: 11/09/2024 Sub Product Trade Name: View Request Details Choose Apply	1	11/09/2024	(Human Medicinal Product	Request Cancellation	The file is incomplete	Details 🗸
View Request Details Choose Apply	View Request Details Choose Choose Apply				Last Update	e Date: 11/09/2024	Sub I	Product Trade Name:	
		View Request	Details		Choose			Apply	

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

Advanced Fillte	ers 🔨							Search		Clear all
				т	otal Records: 1					
Request Number	Product Number	Sub- Product Number	Sub- Product Trade Name	Drug Type	Creation/Resubmission	Request Type	Latest ♦ Update	MAH	Status	Details
F		Ē	1	Generic(Multisource) Drug		Request Cancellation	21/08/2024	Cigalah	The file is incomplete	۲
•										Þ

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

iest 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.

y Migration Ro	equests						•	New Migration Request
All 8 Requests	Waiting Action 4 Requests							
Request Number			Product Nur	nber		Sub Pro	oduct Number(Reference	Number)
Request Numb	er		Product I	Number		Sub	Product Number(Refe	erence Number)
Trade Name			MAH					
Trade Name			MAH				Search Clo	ear
Request	Product	Sub-Product	Trade		Request	Latest		
request	Niccoshine	Number	Nome	Draduat Tuna	≜ Data		Statue	MAH

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.

ly migration R	equests					•	 New Migration Reques
All 8 Requests	Waiting Action 4 Requests						
Request Number		Product Num	nber		Sub Pro	oduct Number(Referer	nce Number)
Request Numb	er	Product Number			Sub Product Number(Reference Number)		
Trade Name		MAH					
Trade Name		MAH				Search	Clear
Request # Number	Product Sub-Produ Number Number	ict Trade Name	Product Type	Request Date	Latest Update	Status	MAH
				21/10/2019	21/10/2019	Waiting for Migration	thigab

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:

SOR F- Registration My Red	uests My Migration Requests My Products	My Certificates	# 0
Old SDR System Available Pro	ducts to be Migrated		
Reference Number	Registration Number	Trade Name	
Search Clear	Registration Humber	Hade Name	
# Reference Number Ro	egistration Number Trade Name		
1			
2			
3			
4			
5			

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:

a. Human Medicinal Product Restoration

- b. Veterinary Product
- c. 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

Registration My Requests My Migration Requests M	y Products My Certificates ≰
Migration Request Human Medicinal Product Biological Drug Others	
Is Saudi Arabia Country of origin? Yes I 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	

	SDR 📴 Registration My Requests My Migration Requests My Products My Certificates 🖉 O
	figration Request
	Application type Product Details Manufactures Manhering Authorization Lagal status of Product Price Certificate Summary
5	STEP 1 Application Type
	Please Specify For SubDrug Type Other Please Specify Please Specify
	General Product Information Trade Name
	Trade Name Product strength Resolute strength
	Strength Unit

After completing all the required fields, and submitted on the system, a request with statues "a payment invoice 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

SDR E Registration My Requests My Migration Requests My Products My Certificates
My Migration Requests + New Migration Request
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 Number Sub-Product Number Trade Name Product Type 1 Hetal Product Type Date Latest Up (C Complete Magnetin Request b Date Date Date Date Date Date Date Date
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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 shows.

	Produc	cts						×
	My Products							
	Product Number Product Number			Trade Name				
				Trade Name		Search	Clear	
	#	Trade Name	Product Numb	er	Status	Sub-Products	Options	
	1		0000002983		Submited	1	+0	
	2		0000002997		Submited	3	+	
	3		0000003011		Submited	1	+	
	4		0000003012		Submited	1	+	
	5		0000003015		Submited	1	+	
	40	HG00677-00-00-00	33-277-98	Flazo	ol 125mg-5ml Oral Suspension			

- 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)
 - o Manufacturer information
 - Except (Finished Manufacture)
 - o 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:

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

My Migration Requests	+ New Myration Request
All Waiting Action 4 Repairs 1 Repeats	
Request Number	Product Number Sub Product Number(Reference Number)
Request Number	Product Number Sub Product Number(Reference Number)
Trade Name	ман
Trade Name	MAH Clear
Repeat Product Bub Product # Number Number Number 1	Trade Product Request Latest Name Type Complex Magnetian Request Product Output Data Output Data Output Data Output Data Output Data Output Data Output Data
Saudi Feed & Drug Authority	User Manual FAQs 1, 19999 All Rinkin Reserved (2, 2016, Sawti Fond & Drug Authority
SUF	

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 statue 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:

	Registration My Red	quests My Migration Re	equests My Products	My Certificates		4 0	
Migration Request							
Application type	O Product Details	O	O Marketing Authorization	O Lagal status of Product	O Price Certificate	O Summary	
STEP 1							
Applicatio	on Type						
General Produc Trade Name	t Information						
Product strength							
Strength Unit							
kg			\checkmark				
Desega Form							

To learn more about migration steps from SDR to E-SDR system, please Click Here



Public



Relocation of the product application to other account

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

	My Requests					-	+ New Request
	Request Number V Sea	arch Request		٩			
	All Inquin 2 Requests 0 Requ	y Cancellation ests 0 Requests	Variation 0 Requests	Objection Certifie 0 Requests 0 Reque	cate Incompl ests 0 Reques	s 0 Requests	
	Request Re # Number Da	equest Product ate Number	Sub-Product Number	Product Type	Request Type	Status De	tails
	1				New Request	Draft De	talls ^
	2		-		New Request	Invoice expired De	talls ^
NI							
on Ne	w Transfer of pr	oduct,	on Requests My Pro	oducts My Certificates 1	Transfer of Product		£ 0
on Ne	w Transfer of pr	roduct, n My Requests My Migrati	on Requests My Pro	oducts My Certificates 1	Transfer of Product		£ 0
on Ne	W Transfer of pr	oduct, n My Requests My Migrati	on Requests My Pro	iducts My Certificates 1	ransfer of Product	+ New ¹	Transfer of Product
on Ne	W Transfer of pr Constraints Transfer of Product Request Number Ser	roduct, m My Requests My Migrati	on Requests My Pro	oducts My Certificates 1	Transfer of Product	(+ New C	Fransfer of Product
on Ne	W Transfer of pr Constraints Transfer of Product Request Number Sec Sec	roduct, m My Requests My Migrati	on Requests My Pro	ducts My Certificates 1	'ransfer of Product	(+ New	Transfer of Product
on Ne	W Transfer of pr Registratio	roduct, n My Requests My Migrati	on Requests My Pro	aducts My Certificates 1	'ransfer of Product	(+ New	Fransfer of Product
on Ne	W Transfer of pr Registratio	roduct, n My Requests My Migrati	on Requests My Pro	aducts My Certificates 1	'ransfer of Product	(+ New	Fransfer of Product
on Ne	W Transfer of pr Registratio	roduct, an My Requests My Migrati	on Requests My Pro	aducts My Certificates 1	'ransfer of Product	(+ New	Transfer of Product
on Ne	W Transfer of pr Registratio	roduct, an My Requests My Migrati	on Requests My Pro	ata found	Transfer of Product	(+ New	Transfer of Product
on Ne	W Transfer of pr Registratio	roduct, n My Requests My Migrati	on Requests My Pro	ata found	'ransfer of Product	(+ New)	Transfer of Product







Fill out the transfer ownership application (three forms)

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

Verification Information	Sub-products Information	A	tachment & Agreements
Transfer of MAH Form			
Sub-product Information			
The number of sub-product of the main produ	ct is 3, all of them must be entered		
Registration Number	Sub product number	Dosage Form	
Registration Number	Sub product number	Choose	
Add Cancel Registration Number	r	Dosage Form	Actions
1		Bath additive	a
2		Bath additive	Ø 📋
3	He0000015661	Bath additive	a 📮

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





Verifcation Information	Sub-products	Information	Attachment & Agreements	
Transfer of MAH Form				
Attachment and agreement	the companies (codified)			
757562 1 (2).pdf	two companies (certified)			
Letter from the company that has the product in	n SDR			
757562 1 (2).pdf	â			
Transfer of MAH Disclaimer				
ن مقدم الطلب مسؤولاً عن اي تبعات او أثار قالونية تنتج	: البرادات المعلومات المدخلة من قبل مقدم الطلب، ويكو	مدخلة، ولا تتحمل منصبة سدر مسؤولية عدم صبحة م	يتحمل مقدم الطلب مسؤولية صنحة كافة البيانات والمعلومات ا	
The applicant shall be fully responsible of t	the accuracy and correctness of the en	لما أن المبالغ المدفوعة غير قابلة للاسترداد. tered data, and SDR platform is not	من قبل ادخال مقدم الطلب للبيانات ومعلومات غير صحيحة، ، responsible of any incompleteness and	
inaccuracy of data entered by the applicant the data. however the paid fees are non-	t, The applicant shall be consequently refundable.	responsible of any legal liability due	to the incompleteness and inaccuracy of	
< Previous			Next >	

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

Transfer MAH				+ New T
Request Number Sear	ch Request		٩	
# 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 ·

