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eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Step-by-Step Guide

Maintenance operations: Update of a marketing authorisation holder (MAH) organisation entity in the XEVMPD



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All examples used in this step-by-step guide are fictitious and intended for demonstration purposes only.

1.1. Update MAH information Example specification

In this step by step guide, we are going to update the telephone number of an existing MAH organisation (i.e. an EV Code has been assigned in the XEVMPD) called 'Nobel Company'.

The new telephone number is "+44 1234 1234".

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1.2. Create an XEVPRM

1) Log in to the requested EVWEB environment:

EVWEB production: <u>https://eudravigilance.ema.europa.eu/x</u>

XCOMP (test) environment: <u>https://evtest.ema.europa.eu/x</u>

EVWEB training environment: <u>https://eudravigilance-training.ema.europa.eu/x/</u>

Windows Security	
The server eud requires a user	ravigilance.ema.europa.eu at eudravigilance.ema.europa.eu name and password.
	User name Password Remember my credentials
	OK Cancel

In the restricted area, click on "EVWEB":

Eudra Vigila Human Restricted	nce 💦 😽		
EV Services EVWEB xEVMPD Export	Pharmaceutical Industries Please select the initial of the A B C D E F G H I J K L	and Commercial Sponsors Organisation ID: M N O P Q R S T U V W Y Z 0-9	
 EV Post EV Registered Partners Manage your profile QPPV List Organisations List 	Regulators Organisation Name	Organisation ID	Country
User Support Help Desk EVWEB Troubleshooting XEVMPD Data-Entry Tool (EVWEB) User Manual_version 5.0 Change Password			

You are now logged in EVWEB – the organisation ID under which you are logged in is shown in the top right corner:

Display Settings	dcmtestmahtt (DCMTESTMAH) @ Human Producti
Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA	-
Reset Application Reset Section Clear	

2) Go to "Medicinal Products" section, select MAH in the tree view, place you mouse in the search field:

Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Crea	te and Send Product Reports	Medicinal Products	MedDRA
Reset Application R	eset Section Clear 0				1	L	1
Authorised Medicinal Pr	roducts	ļ.					
-Development Medicinal	Products	Empt	v				
Approved Substances							
Development Substance	es						
Sources							
MAHs							
Sponsors							
ATC Codes							
-Routes of Administratio	n						
Pharmaceutical Forms							
Master File Locations							
Attachments							
Abstract Compositions							
🕀 Queries							

3) Type "Nobel" and press enter, the results of your search will be displayed in the active area:

Create and Send ICSRs Create and Send Acks WEB	Trader ICSRs	Create and Send Product Reports Medicinal Products	MedDRA								
Reset Application Reset Section Clear RTF 0											
Authorised Medicinal Products	nobel	lobel									
Development Medicinal Products	Num	Name	EV Code	Count MAH Sen							
Approved Substances	0001	NOBEL LTD	ORG2772	Unite							
Seurces	0002	NOBEL TFOUR COMPANY	ORG2738	Unite							
MAHs	0003	NOBEL COMPANY	ORG2734	Unite							
Sponsors	0004	NOBEL BI PHARMA 12345 COMPANY	ORG2/30	Unite							
ATC Codes		NOBEL COMPANY	UKG2400	italy (IT)							
Routes of Administration											
Pharmaceutical Forms											
Master File Locations											
Attachments											
Abstract Compositions											
. • Queries											

4) Select the organisation which you wish to update by clicking inside the relevant box; the information for the MAH will be loaded in the tree view.

Create and Send ICSRs Create and Send Acks WEB T	Frader ICSRs	Create and Send Product Reports Medicinal Products Med	DRA		
Reset Application Reset Section Clear RTF 0					
Authorised Medicinal Products	nobel				
- Development Medicinal Products	Num	Name	EV Code	Count	MAH Ser
Approved Substances	0001	NOBEL LTD	ORG2772	Unite	
Development Substances	0002	NOBEL TFOUR COMPANY	ORG2738	Unite	
Sources	✓ 0003	NOBEL COMPANY	ORG2734	Unite	
E-MAHs	0004	NOBEL BI PHARMA 12345 COMPANY	ORG2730	Unite	
ORG2734 - NOBEL COMPANY	0005	NOBEL COMPANY	ORG2466	Italy (IT)	
Sponsors					
ATC Codes					
-Routes of Administration					
Pharmaceutical Forms					
Master File Locations					
Attachments					
Abstract Compositions					
P-Queries					

5) Click on the Organisation information corresponding to "Nobel Company" already loaded in the tree view, the dynamic buttons with different operation types will appear:

Create and Send ICSRs Create and Send Acks WEB	Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA
Reset Application Reset Section Clear XML RTF	Update Nullify Reinsert Load
-Authorised Medicinal Products	nobel
-Development Medicinal Products	Description Name/Value
-Approved Substances	Checked No
-Development Substances	Nullified No
-Sources	EV Code ORG2734
B-MAHs	MAH Name NOBEL COMPANY
ORG2734 - NOBEL COMPANY	SME Status
-Sponsors	SME Number
-ATC Codes	MAH Sender ID
 Routes of Administration 	MAH Sender Name
-Pharmaceutical Forms	Address 20 CHERRY STREET
-Master File Locations	City LONDON
-Attachments	Region
-Abstract Compositions	Postcode 4HB E16
Queries	Country Code United Kingdom (GB)
	Tel Number
	Tel Cauta Cada
	Fei Country Code
	Fax Number
	Pax Extension

6) Click on "Update"; you will be prompted to the "Create and Send Product Reports" Section with operation type "Update":

Create and Send ICSRs C	Create and Send ICSRs Create and Send Acks V		NEB Trader ICSRs			Create and Send Product Reports			Medic	inal Products	MedDRA
Reset Application Rese	t Section Clear V	alidate S	Send XIV		RTF	Remo	ove E	LR	1		
		nobel									
- Products				r	Descript	ion N	Jame/V:	alue			
Substances				One	ation Tv	ne III	Indate (2)			
Sources				oper	EV Co	nde O	BG273	<u>4</u>			
Organisations		_			T\	vne M	AH (1)	-			
Update (2) - MAH (1)	- ORG2734 - NOBEL	C		Ν	/AH Na	me N	IOBEL (COMPANY IBSA	TEST		
ATC Codes			SME Status								
Pharmaceutical Forms			SME Number								
- Routes Of Administration	n			MAH	Sender	D					
Attachments			Address					RRY STREET			
Master File Locations			City					1			
					Reg	ion					
		Pos				le 4HB E16					
			Co	untry Co	ode U	Inited Ki	ingdom (GB)				
				1	el Num	ber					
				Tel	Extens	ion					
				Tel Co	untry Co	ode					
				F	ax Numi	per					

7) Enter the new information regarding the telephone number:



8) Finally, populate the Message number field:



1.3. Validate and send an XEVPRM

1) Validate your XEVPRM by clicking on the "Validate" button.

Create and Send ICSRs	Create and Se	nd Acks	WEB Trader	ICSRs	Cre	ate an	d Sen	d Product Reports	Medicinal Products	MedDRA
Reset Application R	eset Section Cle	ear Re	plicate Valida	te Send	XML	ZIP	RTF	Duplicate Rem	ove E L R	

New window will be displayed on your screen, showing the result of your validation.

Create and Send ICSRs Create and Send Acks	WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA							
Reset Application Reset Section Clear Val	date Send XML ZIP RTF E L R							
	nobel							
Products	Description Name/Value							
Substances	Message Number Update MAH							
Sources	Products							
Organisations	Substances							
Update (2) - MAH (1) - ORG2734 - NOBEL C	Sources							
AIC Codes	Organisations							
Pharmaceutical Forms	Mensaie de página web							
Attachmente	ical Forms							
Master File Locations	Validate OK							
	Aceptar							

You can dismiss the message by clicking on "OK".

2) Save the XEVPRM for your reference by clicking on the relevant button:

Create and Send ICSRs		s Create and	Send A	ks WE	B Trader	IC	SRs	Crea	te and	Send	Product Reports	Medicinal Products	MedDRA
	Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	EL	R			

3) Send the XEVPRM by clicking on the "Send" button:

Create and Send ICSRs		s Create and	Create and Send Acks		WEB Trader		SRs	Crea	te and Sen	Product Reports				Medicinal Products	MedDRA
	Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	Remove	Е	L	R		

The below message will confirm that your XEVPRM has been sent:

Send Operation Completed If You want to View the File(s) Sent Click	
If You want to View the File(s) Sent Click	City LOK
	ence foul

If you want to view/save your file, click on "OK".

The below message will be displayed, enabling you to save your XEVPRM file on your computer:

//evtest.ema.europa.eu/X/?XI=6 - Windows Internet Explorer							
Summary			1	~			
Tamporary (for	Click here for the file						
Export)	Chek <u>nere</u> for the me						
1	Name: dcmtestmahtt-Send-DCMTESTMAH-XEVPRM						
	EVPRM Zipped Message						
	Message Number:						
To the Outbox	Name:						
1	EVERM Zipped Message						
	Message Number:						