



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 April 2018
EMA/177298/2018
Information Management

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

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



Table of contents

1.1. Update MAH information Example specification	3
1.2. Create an XEVPRM.....	4
1.3. Validate and send an XEVPRM.....	8

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".

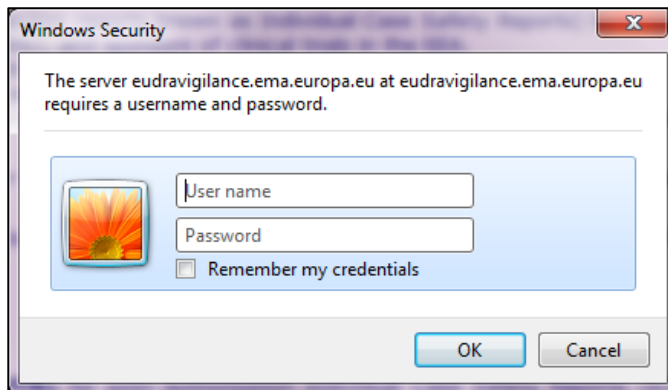
1.2. Create an XEVPRM

1) Log in to the requested EVWEB environment:

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

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

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

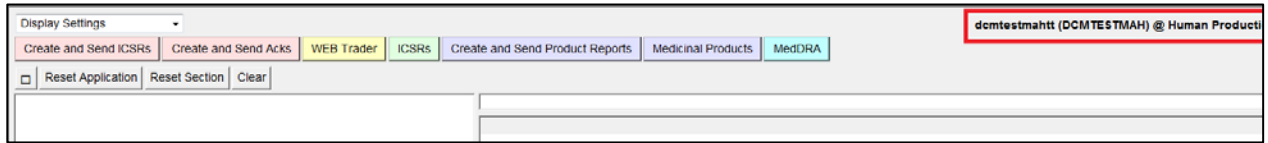


In the restricted area, click on "EVWEB":

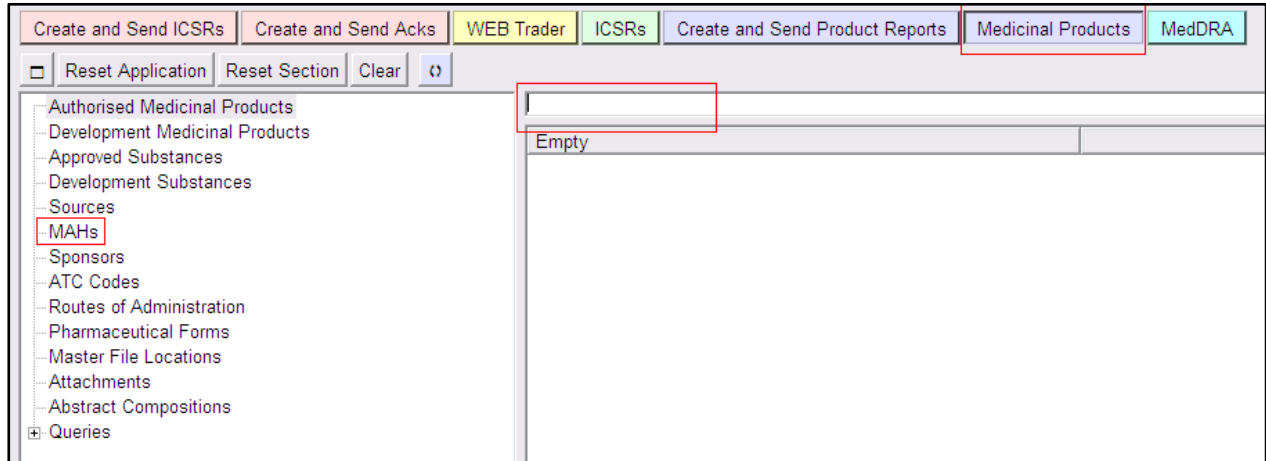
A screenshot of the EudraVigilance Human Restricted portal. The header features the EudraVigilance logo and the text "Human Restricted" in red. Below the header is a navigation menu with three main sections: "EV Services", "EV Registered Partners", and "User Support". The "EV Services" section is expanded, showing "EVWEB" (highlighted with a red box), "xEVMPD Export", and "EV Post". The "EV Registered Partners" section includes "Manage your profile", "QPPV List", and "Organisations List". The "User Support" section includes "Help Desk", "EVWEB Troubleshooting", "XEVMPD Data-Entry Tool (EVWEB) User Manual_version 5.0", and a "Change Password" button. The main content area is titled "Pharmaceutical Industries and Commercial Sponsors" and contains a prompt: "Please select the initial of the Organisation ID:" followed by a list of letters: "A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | Y | Z | 0-9". Below this is a section titled "Regulators" with a table header: "Organisation Name", "Organisation ID", and "Country".

Organisation Name	Organisation ID	Country
-------------------	-----------------	---------

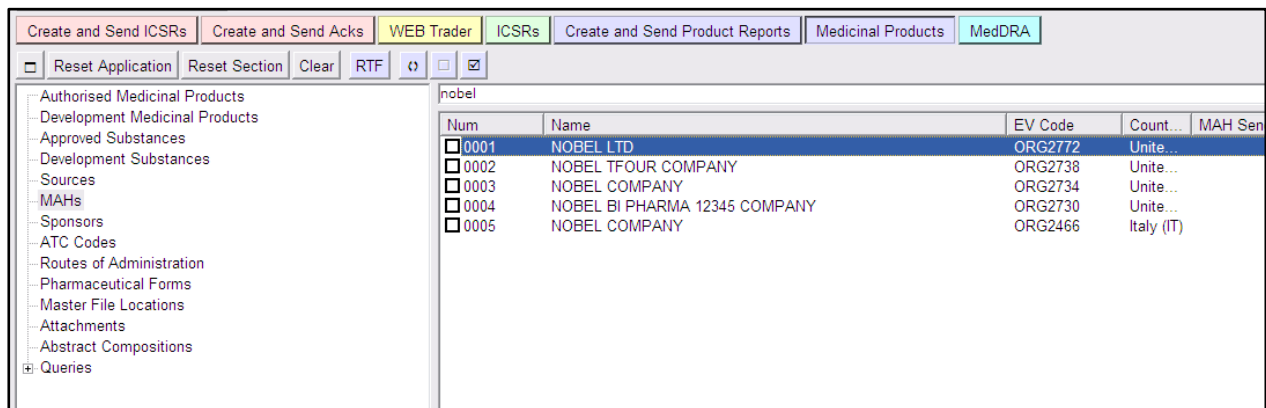
You are now logged in EVWEB – the organisation ID under which you are logged in is shown in the top right corner:



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



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



- 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.

Num	Name	EV Code	Count...	MAH Ser
<input type="checkbox"/> 0001	NOBEL LTD	ORG2772	Unite...	
<input type="checkbox"/> 0002	NOBEL TFOUR COMPANY	ORG2738	Unite...	
<input checked="" type="checkbox"/> 0003	NOBEL COMPANY	ORG2734	Unite...	
<input type="checkbox"/> 0004	NOBEL BI PHARMA 12345 COMPANY	ORG2730	Unite...	
<input type="checkbox"/> 0005	NOBEL COMPANY	ORG2466	Italy (IT)	

- 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:

Description	Name/Value
Checked	No
Nullified	No
EV Code	ORG2734
MAH Name	NOBEL COMPANY
SME Status	
SME Number	
MAH Sender ID	
MAH Sender Name	
Address	20 CHERRY STREET
City	LONDON
Region	
Postcode	4HB E16
Country Code	United Kingdom (GB)
Tel Number	
Tel Extension	
Tel Country Code	
Fax Number	
Fax Extension	

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

Description	Name/Value
Operation Type	Update (2)
EV Code	ORG2734
Type	MAH (1)
MAH Name	NOBEL COMPANY IBSATEST
SME Status	NA (1)
SME Number	
MAH Sender ID	
Address	20 CHERRY STREET
City	LONDON
Region	
Postcode	4HB E16
Country Code	United Kingdom (GB)
Tel Number	
Tel Extension	
Tel Country Code	
Fax Number	

- 7) Enter the new information regarding the telephone number:

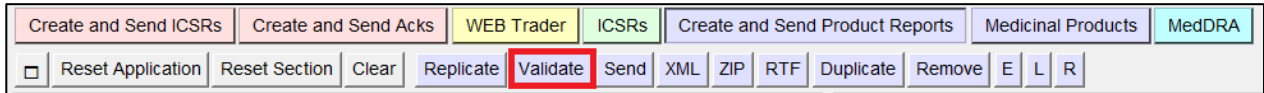
Address	20 CHERRY STREET
City	LONDON
Region	
Postcode	4HB E16
Country Code	United Kingdom (GB)
Tel Number	1234 1234
Tel Extension	
Tel Country Code	+44

- 8) Finally, populate the Message number field:

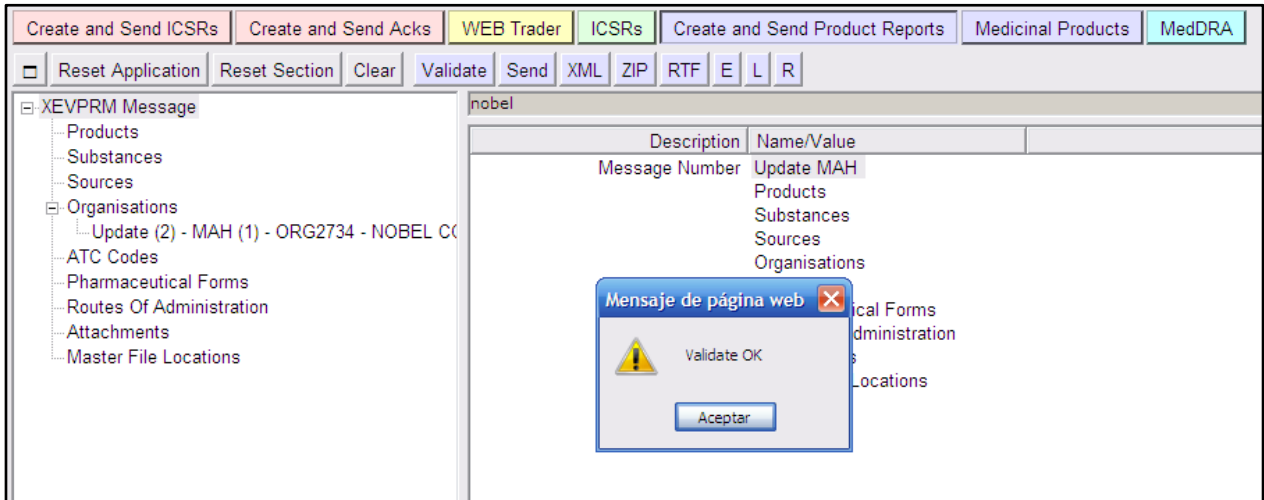
Description	Name/Value
Message Number	Update MAH
Products	
Substances	
Sources	
Organisations	
ATC Codes	
Pharmaceutical Forms	
Routes Of Administration	
Attachments	
Master File Locations	

1.3. Validate and send an XEVPRM

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

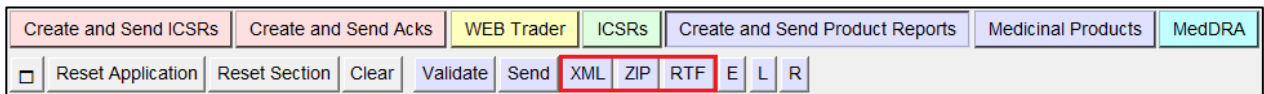


New window will be displayed on your screen, showing the result of your validation.

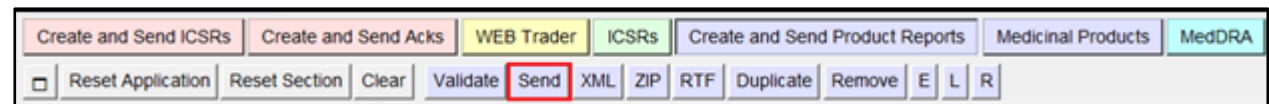


You can dismiss the message by clicking on "OK".

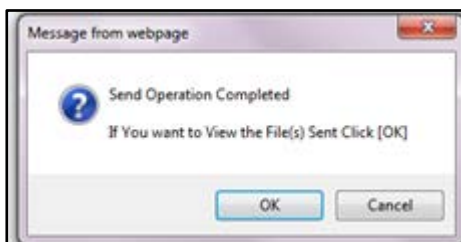
2) Save the XEVPRM for your reference by clicking on the relevant button:



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



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



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:

