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

Insert of a Pharmacovigilance System Master File Location (MFL) entity

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

1.1. MFL Example specification

For the purpose of this step-by-step exercise, the Pharmacovigilance System Master File is located at the following address:

SonoPharm GmbH
30 Goethestrasse
10623 Berlin
Germany

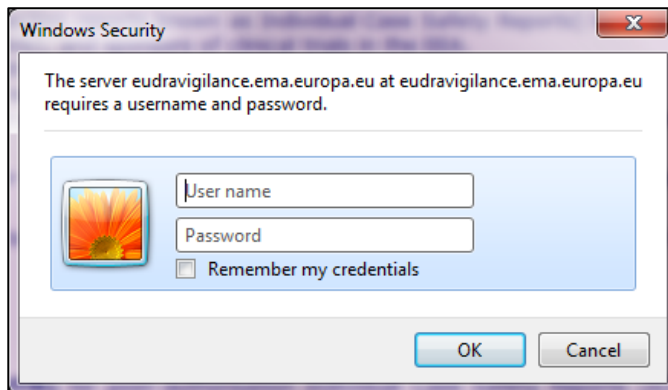
1.2. Create an XEVPRM

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>

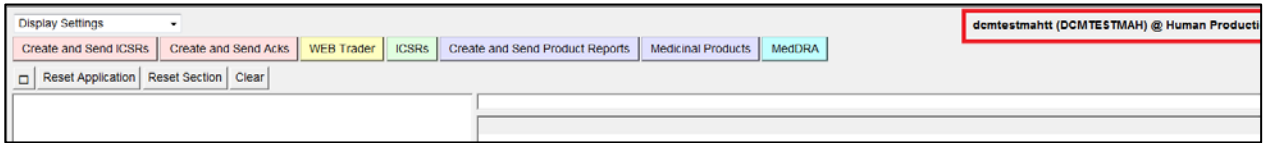
EVWEB training environment: <https://eudravigilance-training.ema.europa.eu/x/>



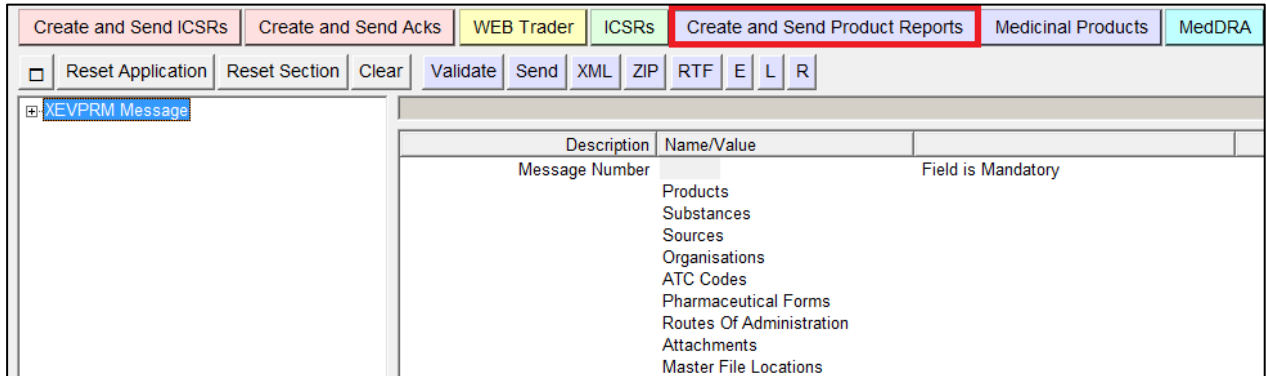
In the restricted area, click on "EVWEB":

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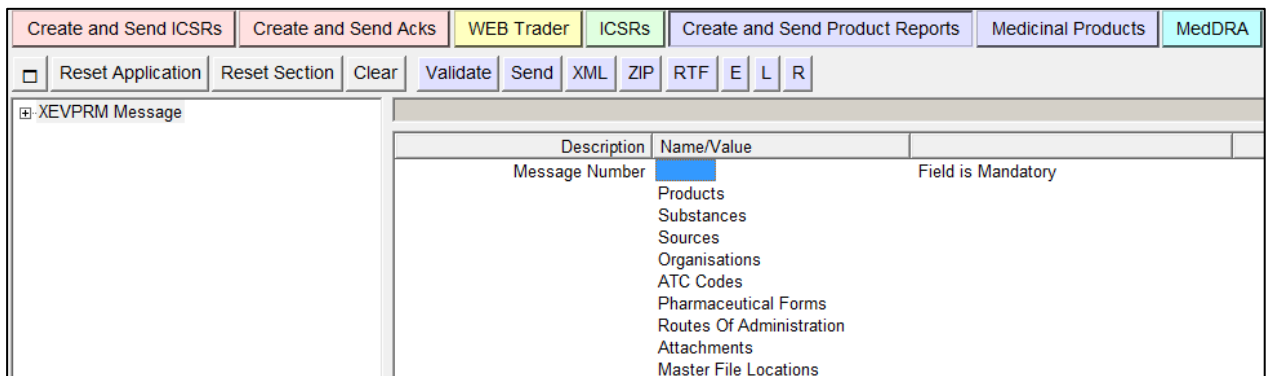
You are now logged in EVWEB – the organisation ID under which you are logged in is shown in the top right corner:



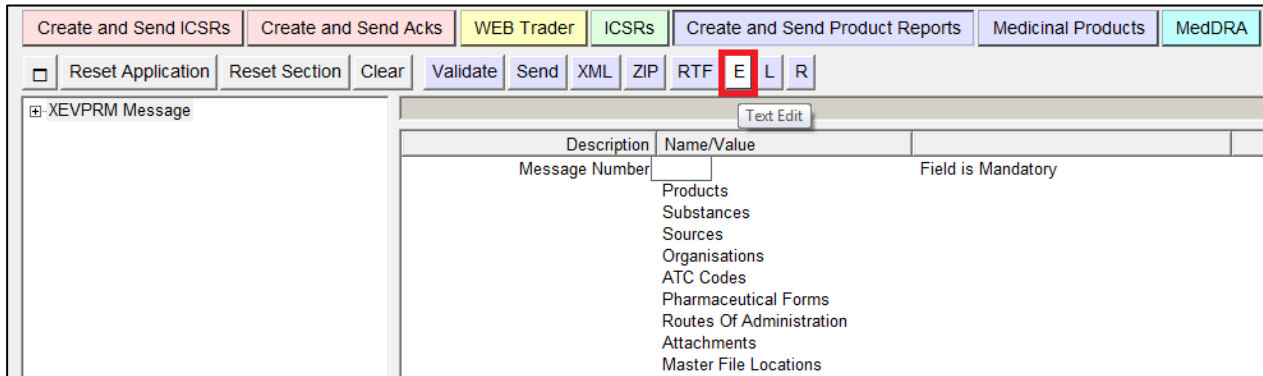
2) Go to "Create and Send Product Reports" section:



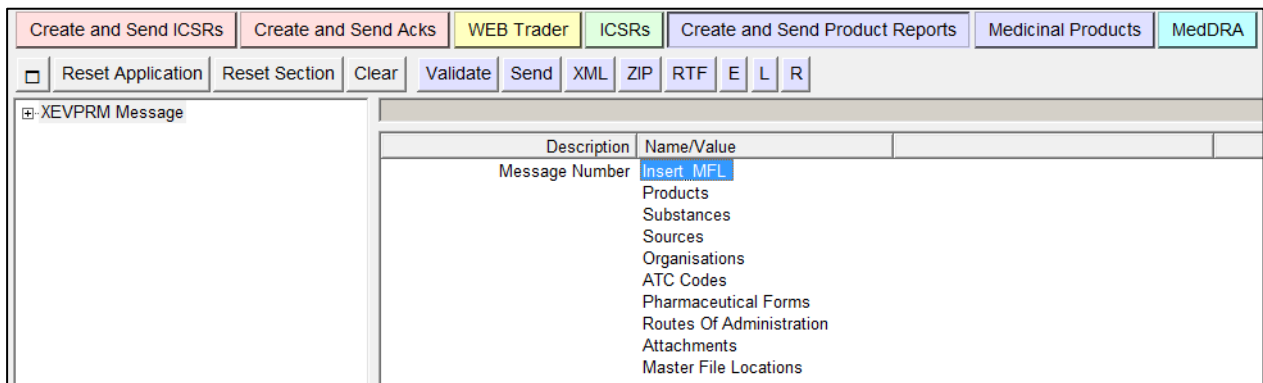
3) With your mouse, click on the area next to the "Message Number". It is a free-text field. The area will become highlighted in blue:



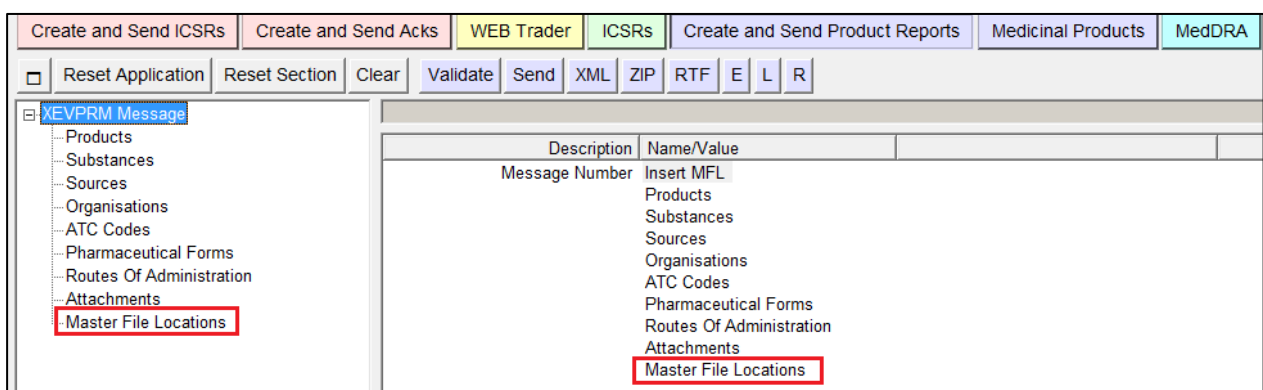
- 4) Press "Enter" on your keyboard or click on the "E" ("Text Edit") button. Both actions will activate the field and allow you to write the name you wish to assign to you XEVPRM:



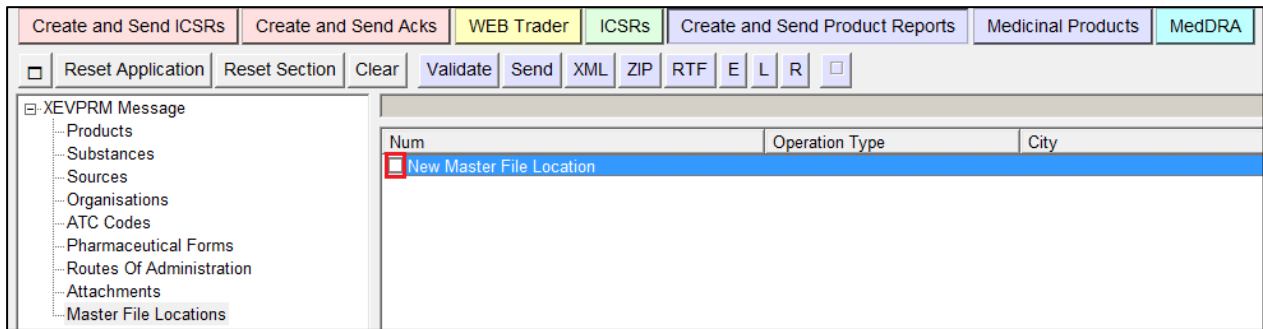
- 5) Type in the message number you wish to assign to your XEVPRM, then press "Enter" on your keyboard:



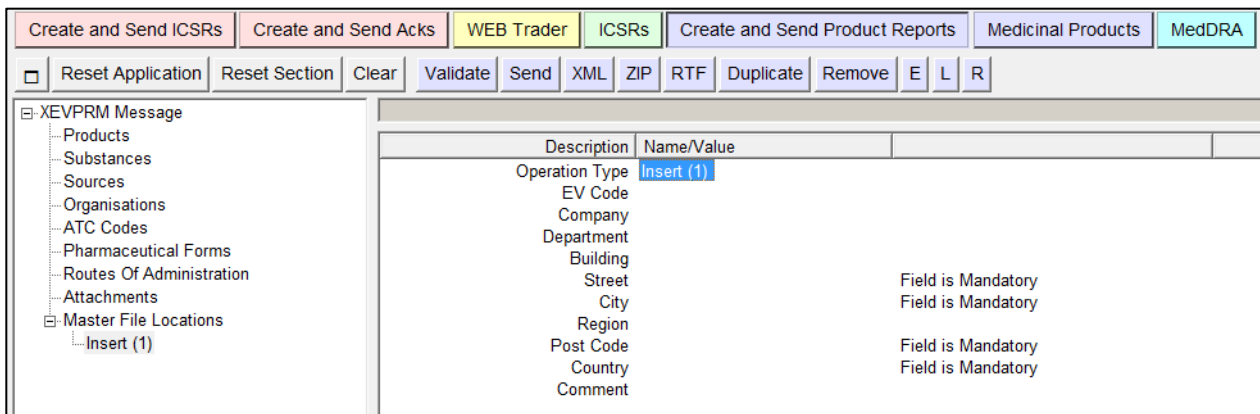
- 6) Expand the tree-view area by clicking on the "+" sign (see screenshot above) and click on the "Master File Locations" section, or double click on "Master File Locations" in the active area:



7) Select "New Master File Location " by ticking the relevant box in the active area:



The active area will display the fields relevant for a MFL entity:



- The "Operation type" field displays "Insert (1)" as a default. It is not possible to assign a different operation type.
- Mandatory fields that must be populated are highlighted with the text "Field is Mandatory".
 - Please note that not all mandatory fields are highlighted this way (some fields are business rules dependent). Additional mandatory fields/fields that must contain specific value may be highlighted during the validation process (see section 1.3. *Validate an XEVPRM*).
 - When information is entered in the individual mandatory fields, the text "Field is Mandatory" disappears.
 - Some of the fields contain look-up tables with pre-defined values. These values will be displayed if you press "Enter" on your keyboard.

Enter the relevant information in the individual fields **as per guidance provided for each field in [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance; section 1.11. Initial submission of a Pharmacovigilance System Master File Location \(PSMFL\)](#)**.

1.2.1. EV Code

The EV Code field is a field which will automatically display the assigned EV Code if maintenance related operation (i.e. NOT an insert) is performed. In you example, this field is blank because you are performing an insert of an entity.

1.2.2. Company

This is a free-text field.

Using your mouse, click on the area next to "Company". The area will become highlighted in blue:

The screenshot shows the XEVPRM Message form interface. The 'Company' field is highlighted in blue. The form includes a navigation menu on the left and a main data entry area with a table structure.

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Company		
Department		
Building		
Street		Field is Mandatory
City		Field is Mandatory
Region		
Post Code		Field is Mandatory
Country		Field is Mandatory
Comment		

Press "Enter" on your keyboard or use the "E" ("Text Edit") button. Both actions will activate the field and allow you to write your text:

The screenshot shows the XEVPRM Message form interface. The 'Company' field is now active, indicated by a text cursor. The form includes a navigation menu on the left and a main data entry area with a table structure.

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Company		
Department		
Building		
Street		Field is Mandatory
City		Field is Mandatory
Region		
Post Code		Field is Mandatory
Country		Field is Mandatory
Comment		

Type in the requested text and press "Enter" on your keyboard. The company name will be displayed in the "Company" field:

The screenshot shows the XEVPRM Message form with the following data:

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Company	SonoPharm GmbH	
Department		
Building		
Street		Field is Mandatory
City		Field is Mandatory
Region		
Post Code		Field is Mandatory
Country		Field is Mandatory
Comment		

1.2.3. Department and Building

These are free-text fields.

Should you wish to enter the name of the department/building, follow the same process as described in section 1.2.2. *Company*.

As per your specific example, these fields should remain blank.

1.2.4. Street and City

These are free-text fields.

The same process as described in section 1.2.2. *Company* should be followed to enter the relevant information:

The screenshot shows the XEVPRM Message form with the following data:

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Company	SonoPharm GmbH	
Department		
Building		
Street	30 Goethestrasse	
City	Berlin	
Region		
Post Code		Field is Mandatory
Country		Field is Mandatory
Comment		

1.2.5. Region

This is a free-text field.

Should you wish to enter the relevant information, follow the same process as described in section 1.2.2. *Company*.

As per your specific example, these fields should remain blank.

1.2.6. Post Code

This is a free-text field.

The same process as described in section 1.2.2. *Company* should be followed to enter the relevant information:

The screenshot shows a software interface with a top navigation bar containing buttons: 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below this is a secondary bar with buttons: 'Reset Application', 'Reset Section', 'Clear', 'Validate', 'Send', 'XML', 'ZIP', 'RTF', 'Duplicate', 'Remove', 'E', 'L', and 'R'. On the left is a tree view under 'XEVPRM Message' with sub-items: 'Products', 'Substances', 'Sources', 'Organisations', 'ATC Codes', 'Pharmaceutical Forms', 'Routes Of Administration', 'Attachments', 'Master File Locations', and 'Insert (1) - Berlin'. The main area is a table with columns 'Description' and 'Name/Value'. The table contains the following data:

Description	Name/Value
Operation Type	Insert (1)
EV Code	
Company	SonoPharm GmbH
Department	
Building	
Street	30 Goethestrasse
City	Berlin
Region	
Post Code	10623
Country	
Comment	

The 'Post Code' field is highlighted in blue. A note 'Field is Mandatory' is visible at the bottom right of the table area.

1.2.7. Country

The "Country" field is a field that will allow you to select one of the available pre-defined values.

Using your mouse, click on the area next "Country". The area will become highlighted in blue:

This screenshot is identical to the previous one, but the 'Country' field in the table is highlighted in blue. The 'Post Code' field now contains the value '10623'.

Description	Name/Value
Operation Type	Insert (1)
EV Code	
Company	SonoPharm GmbH
Department	
Building	
Street	30 Goethestrasse
City	Berlin
Region	
Post Code	10623
Country	
Comment	

The 'Country' field is highlighted in blue. A note 'Field is Mandatory' is visible at the bottom right of the table area.

Press "Enter" on your keyboard, double-click on the field, or click on the "R" (Remote look-up) button. The values available for this field will be displayed:

The screenshot shows the XEVPRM Message form with a dropdown menu open for the Country field. The dropdown lists the following countries: Afghanistan (AF), ÅLAND ISLANDS (AX), Albania (AL), Algeria (DZ), American Samoa (AS), Andorra (AD), Angola (AO), Anguilla (AI), Antarctica (AQ), Antigua And Barbuda (AG), Argentina (AR), Armenia (AM), Aruba (AW), Australia (AU), and Austria (AT). The 'Angola (AO)' option is highlighted with a red border.

Using your mouse, select the requested value. It will become highlighted in black:

The screenshot shows the XEVPRM Message form with the dropdown menu for the Country field. The 'Germany (DE)' option is now highlighted in black, indicating it has been selected.

Once you click on the selected value, it will be displayed in the "Country" field:

The screenshot shows the XEVPRM Message form with the Country field populated with 'Germany (DE)'. The dropdown menu is closed, and the selected value is displayed in the field.

1.2.8. Comment

This is a free- text field, in which information can be entered using the same process as described in section 1.2.2. *Company*.

As per business rules and guidance provided in [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section 1.11. *Initial submission of a Pharmacovigilance System Master File Location (PSMFL)*, no information should be entered in this field in this particular case.

You have now populated fields for a MFL entity:

The screenshot shows the XEVPRM Message interface. On the left is a tree view with 'Master File Locations' expanded to 'Insert (1) - Germany (DE) - Berlin'. The main area displays a table with the following data:

Description	Name/Value
Operation Type	Insert (1)
EV Code	
Company	SonoPharm GmbH
Department	
Building	
Street	30 Goethestrasse
City	Berlin
Region	
Post Code	10623
Country	Germany (DE)
Comment	

1.3. Validate and send an XEVPRM

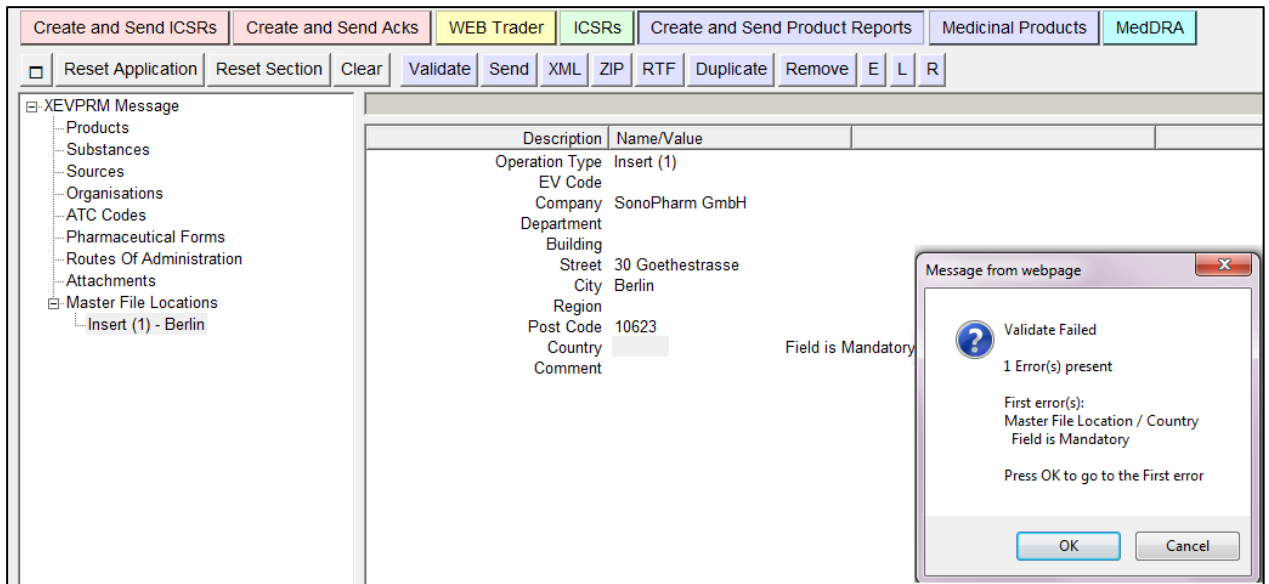
1) Validate your XEVPRM by clicking on the "Validate" button.

The screenshot shows the XEVPRM interface with the 'Validate' button highlighted in a red box. The 'Validate' button is located in the toolbar between the 'Replicate' and 'Send' buttons.

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

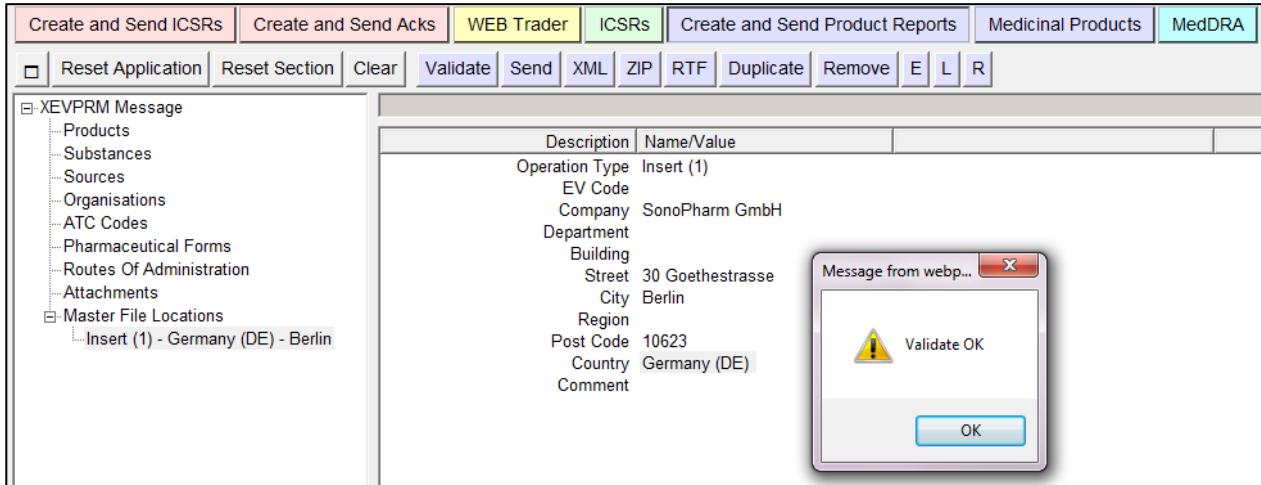
- If your XEVPRM contains any technical errors (i.e. mandatory information is missing), an error message will be displayed on your screen, describing the number of errors and specifying the location of the first error.

The field(s) where information is missing will contain the text "Field is Mandatory":



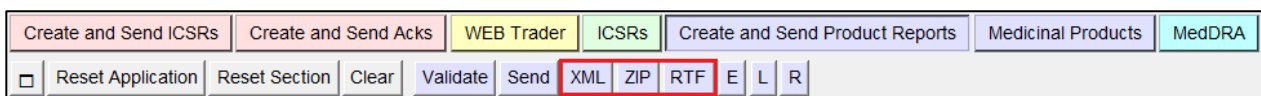
Once you click on "OK" in the error message the application will direct you to the first error. You should enter the required information /correct the submitted information and validate the XEVPRM again.

If your XEVPRM has been created correctly, the new window will display the text "Validate OK", which means that no errors were reported:

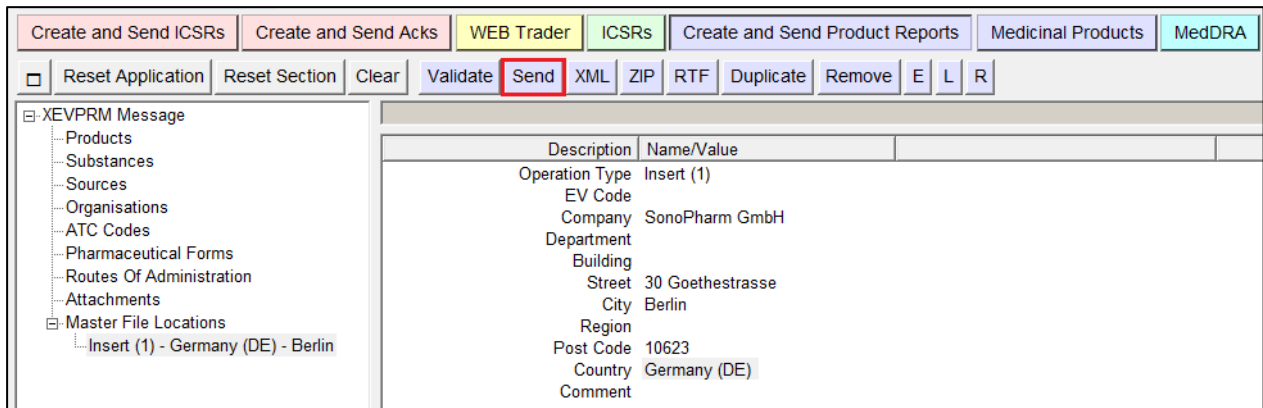


You can dismiss the message by clicking on "OK".

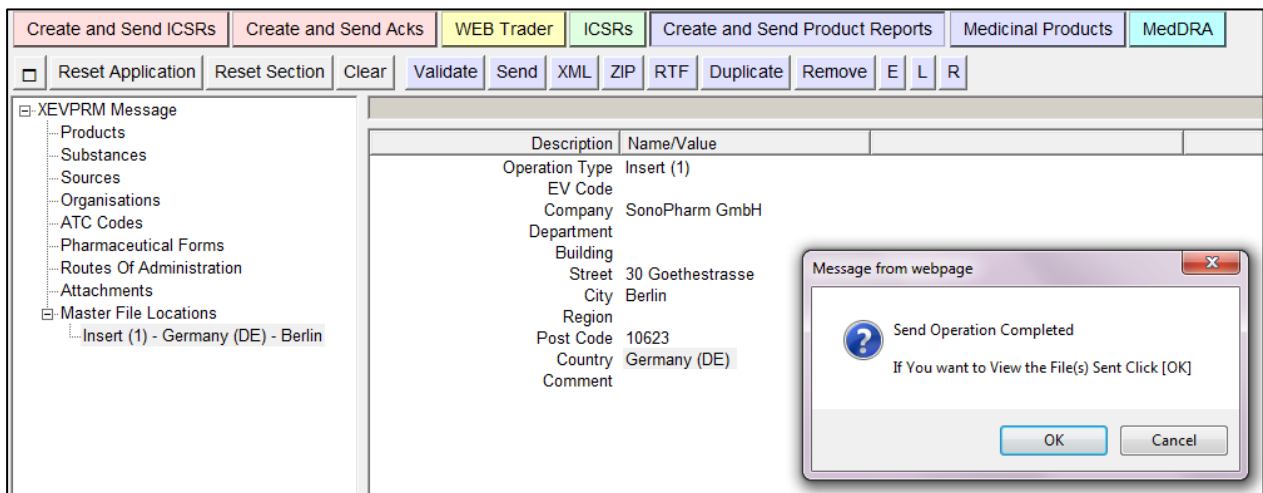
2) Save the XEVPRM for your reference by clicking on the relevant button:



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

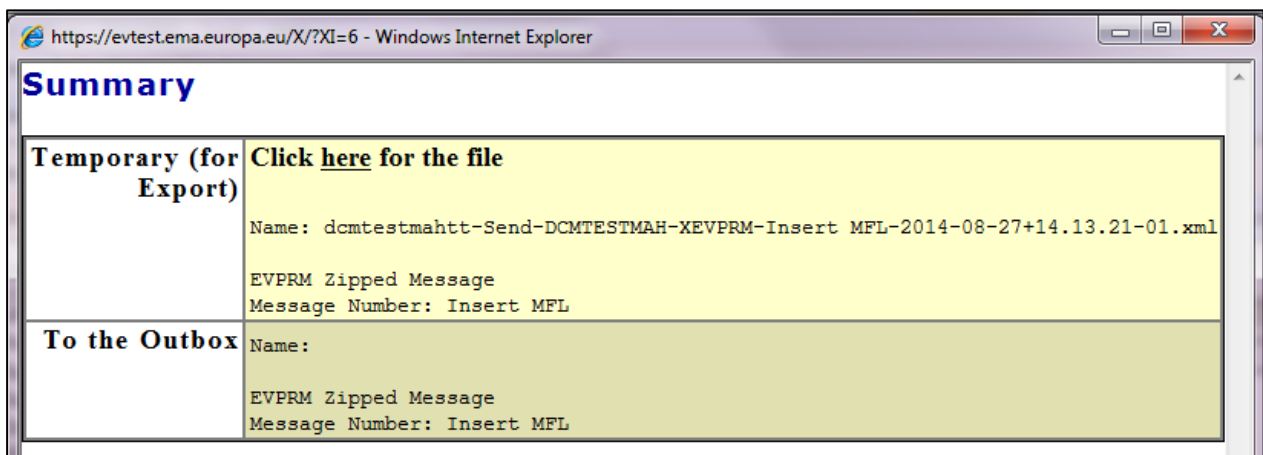


The below message will confirm that your XEVPRM has been sent:



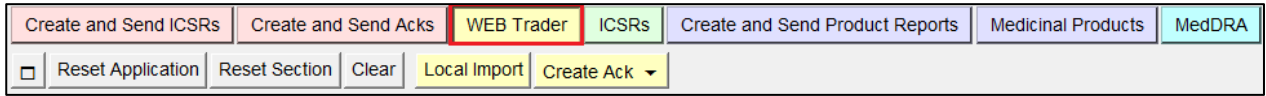
If you want to view/save your file, click on "OK".

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



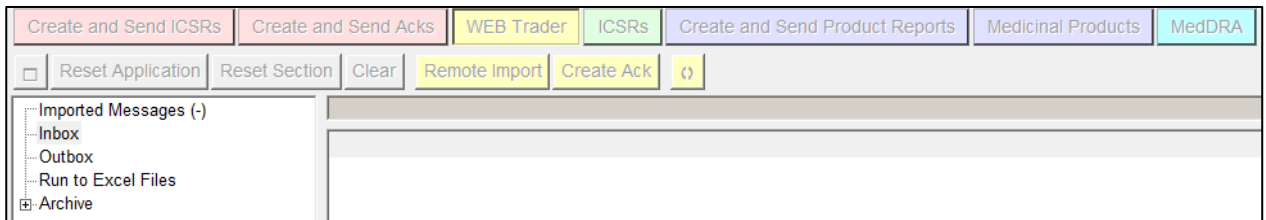
1.4. Retrieve the XEVPRM Acknowledgement (XEVPRM ACK)

1) Go to the "Web Trader" section:



2) Click on "Inbox" (or "Archived Inbox" under "Archive", depending on when you decide to retrieve your XEVPRM ACK).

The application will appear "frozen" for a second or two:



After a few seconds, the active area will display XEVPRM ACKs sent to your organisation's ID (the first message will be automatically highlighted in blue):

Num	Name	Num/Count	Date	Size
0001	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert ...	0/14	2014/08/27 14:18.43	00000030...
0002	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert ...	0/14	2014/08/27 11:02.41	00000037...
0003	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert ...	0/14	2014/08/22 12:35.56	00000050...
0004	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert ...	0/14	2014/07/30 13:43.28	00000031...
0005	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert ...	0/14	2014/07/30 11:20.27	00000031...

To view the ACK name in full, expand the section by placing your cursor on the separator line between "Name" and "Num/Count", click and drag towards the right until the full name is visible:

Num	Name	Num/Count	Date	Size
0001	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert ...	0/14	2014/08/27 14:18.43	00000030...
0002	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert ...	0/14	2014/08/27 11:02.41	00000037...
0003	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert ...	0/14	2014/08/22 12:35.56	00000050...
0004	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert ...	0/14	2014/07/30 13:43.28	00000031...
0005	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert ...	0/14	2014/07/30 11:20.27	00000031...

Num	Name	Num/Count	Date	Size
0001	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MFL-2014-08-27+14.13.21-01.xml	0/14	2014/08/27 14:18.43	00000030...
0002	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MAH and sponsor-2014-08-27+10.58.16-01.xml	0/14	2014/08/27 11:02.41	00000037...
0003	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Luna 21 PharmaL contraceptive tablets-2014-08-22+12.31.28-01.xml	0/14	2014/08/22 12:35.56	00000050...
0004	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Sponsor_AllenLab-2014-07-30+13.39.50-01.xml	0/14	2014/07/30 13:43.28	00000031...
0005	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_MAH_PharmaCompany Ltd-2014-07-30+11.16.29-01.xml	0/14	2014/07/30 11:20.27	00000031...

3) Based on the XEVPRM number, which you assigned to your message, find the XEVPRM ACK.

Click on the relevant row with your mouse (the message will be highlighted in blue):

Num	Name	Num/Count	Date	Size
0001	ack_dcmtestmahht-Send-DCMTESTMAH-XEVPRM-Insert MFL-2014-08-27+14.13.21-01.xml	0/14	2014/08/27 14:18:43	00000030...
0002	ack_dcmtestmahht-Send-DCMTESTMAH-XEVPRM-Insert MAH and sponsor-2014-08-27+10.58.16-01.xml	0/14	2014/08/27 11:02:41	00000037...
0003	ack_dcmtestmahht-Send-DCMTESTMAH-XEVPRM-Insert_Luna 21 PharmaL contraceptive tablets-2014-08-22+12.31.28-01.xml	0/14	2014/08/22 12:35:56	00000050...
0004	ack_dcmtestmahht-Send-DCMTESTMAH-XEVPRM-Insert_Sponsor_AllenLab-2014-07-30+13.39.50-01.xml	0/14	2014/07/30 13:43:28	00000031...
0005	ack_dcmtestmahht-Send-DCMTESTMAH-XEVPRM-Insert_MAH_PharmaCompany Ltd-2014-07-30+11.16.29-01.xml	0/14	2014/07/30 11:20:27	00000031...

Press "Enter" on your keyboard or double-click with your mouse and the XML of the XEVPRM ACK will be displayed on your screen, showing the operation result and the assigned EVCode(s):

The screenshot shows a web browser window with the URL <https://evtest.ema.europa.eu/X/Export.asp?1E747AF9-E3F7-47B7-995E-6089DF5ACA85>. The browser displays the following XML content:

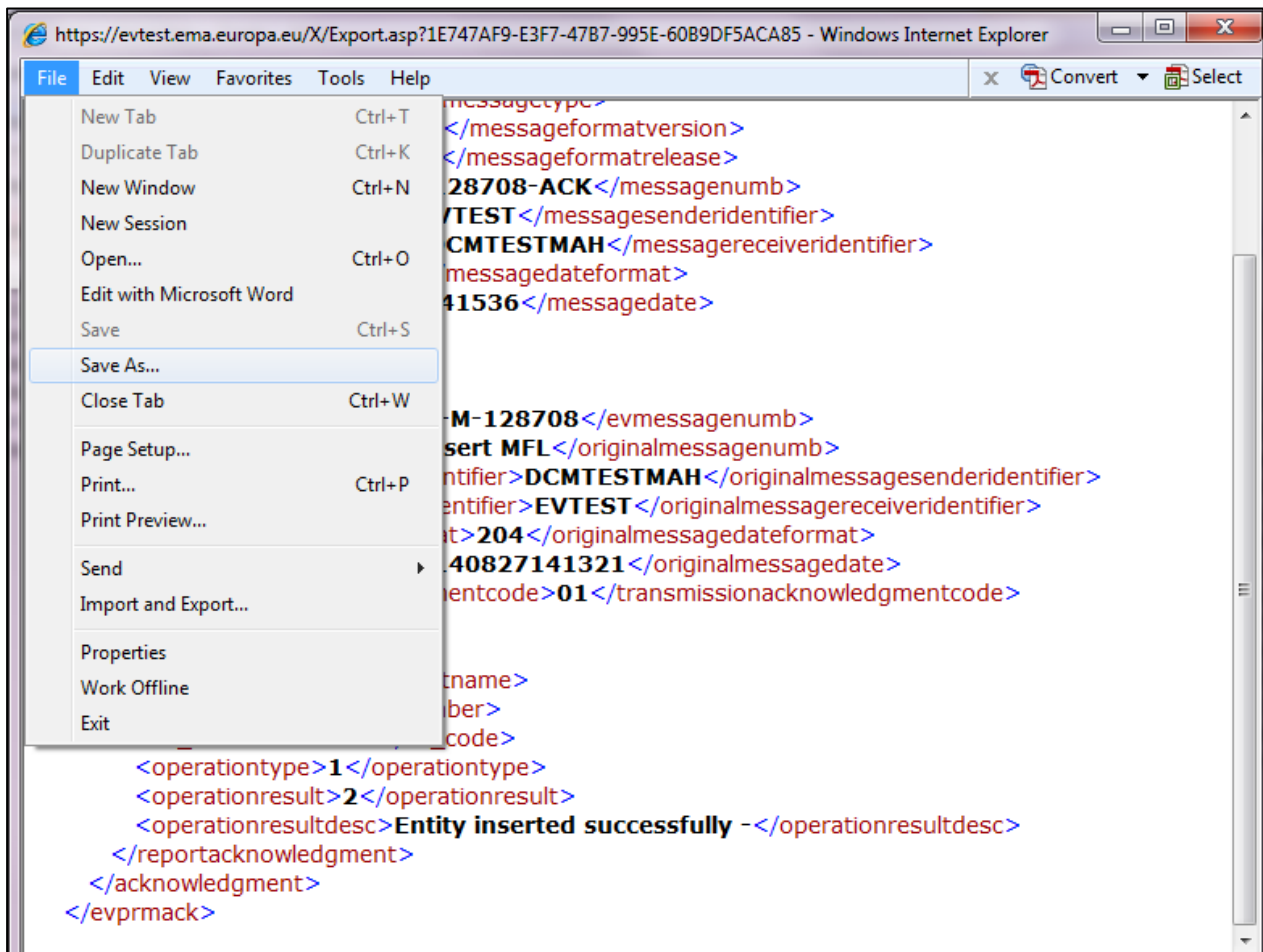
```

<messageformatversion>1.0</messageformatversion>
<messageformatrelease>1.0</messageformatrelease>
<messagenumb>EU-EC-M-128708-ACK</messagenumb>
<messagesenderidentifier>EVTEST</messagesenderidentifier>
<messagereceiveridentifier>DCMTESTMAH</messagereceiveridentifier>
<messagedateformat>204</messagedateformat>
<messagedate>20140827141536</messagedate>
</ichicsrmessageheader>
- <acknowledgment>
  - <messageacknowledgment>
    <evmessagenumb>EU-EC-M-128708</evmessagenumb>
    <originalmessagenumb>Insert MFL</originalmessagenumb>
    <originalmessagesenderidentifier>DCMTESTMAH</originalmessagesenderidentifier>
    <originalmessagereceiveridentifier>EVTEST</originalmessagereceiveridentifier>
    <originalmessagedateformat>204</originalmessagedateformat>
    <originalmessagedate>20140827141321</originalmessagedate>
    <transmissionacknowledgmentcode>01</transmissionacknowledgmentcode>
  </messageacknowledgment>
  - <reportacknowledgment>
    <reportname>MFL</reportname>
    <localnumber>3</localnumber>
    <ev_code>MFL7942</ev_code>
    <operationtype>1</operationtype>
    <operationresult>2</operationresult>
    <operationresultdesc>Entity inserted successfully -</operationresultdesc>
  </reportacknowledgment>
</acknowledgment>
</evprmack>

```

The insert of your MFL entity was successful.

- 4) You can save the XML file of the XEVPRM ACK on your computer by going to "File" and selecting "Save As":



You have now successfully retrieved the XEVPRM Acknowledgement.