



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Information Management

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

### Insert of an Organisation

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

## **1.1. Organisation Example specification**

For the purpose of this step-by-step exercise, you will be inserting:

A **marketing authorisation holder organisation** with the details:

PharmeX

43 Winston Road

London

E14 5EU

UK

[PharmeX@pharmex.co.uk](mailto:PharmeX@pharmex.co.uk)

A **sponsor organisation** with the details:

EraLab

Lockington Close

Margate

MA12 4JJ

UK

[EraLab@eralab.com](mailto:EraLab@eralab.com)

Additional information

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- The MAH is a medium size organisation with SME number EMA/SME/000/00/02.

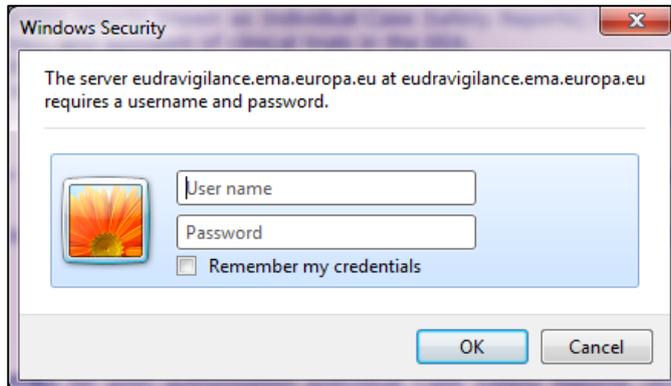
## 1.2. Create an XEVPRM

1) Log in to the requested EVWEB environment:

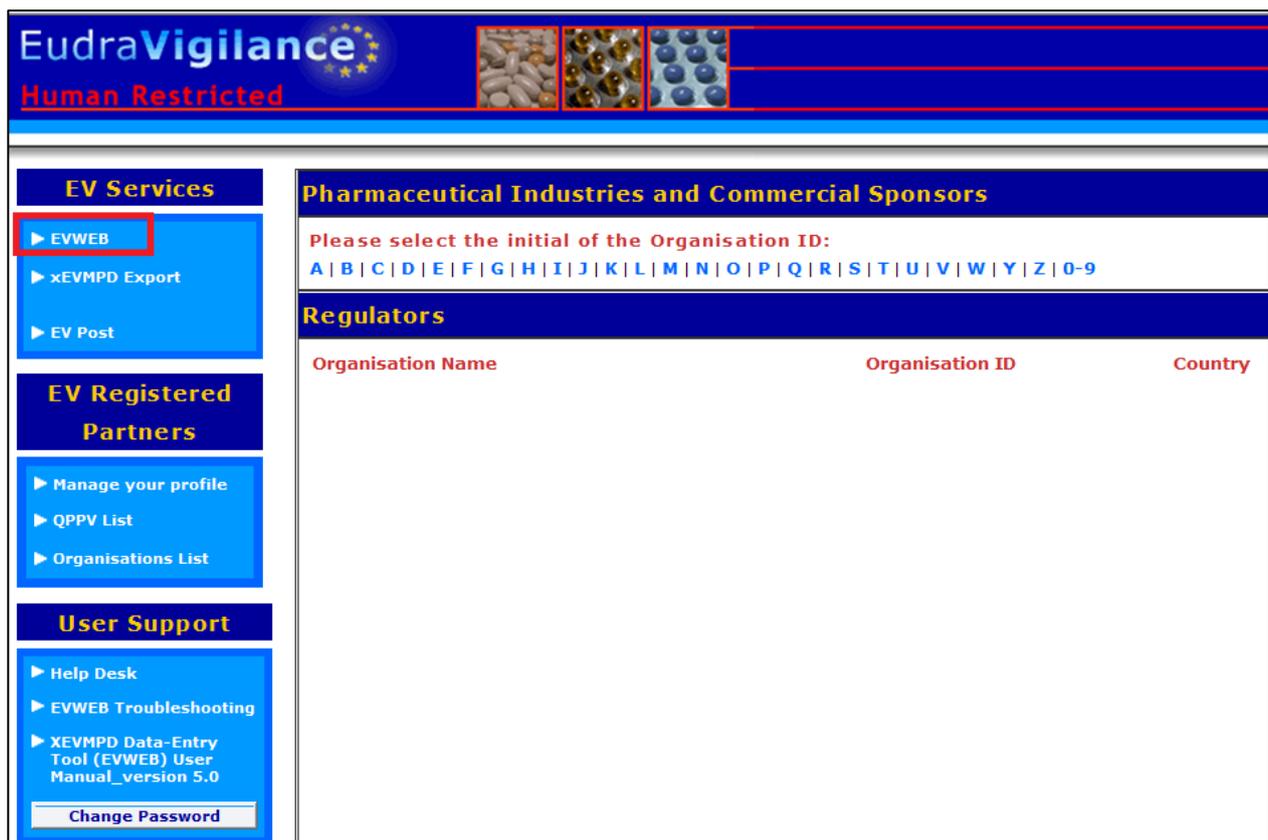
EVWEB production: <https://eudravigilance.ema.europa.eu/x>

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":

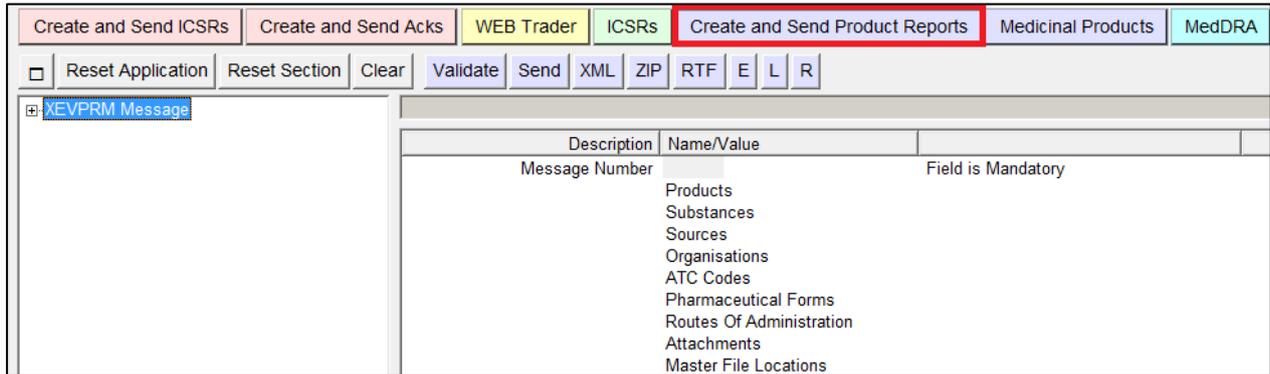
A screenshot of the EudraVigilance Human Restricted website. The header features the EudraVigilance logo and the text "Human Restricted" in red. Below the header is a navigation menu with three main sections: "EV Services", "EV Registered Partners", and "User Support". The "EV Services" section is highlighted with a red box and contains the following links: "EVWEB", "xEVMPD Export", and "EV Post". The "EV Registered Partners" section contains "Manage your profile", "QPPV List", and "Organisations List". The "User Support" section contains "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
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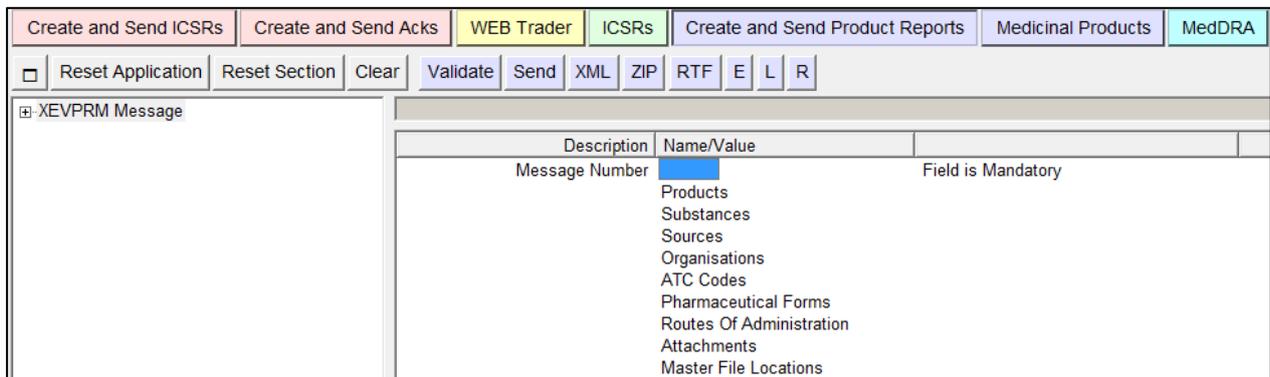
You are now logged in EVWEB – the organisation ID under which you are logged in is shown in the top right corner:



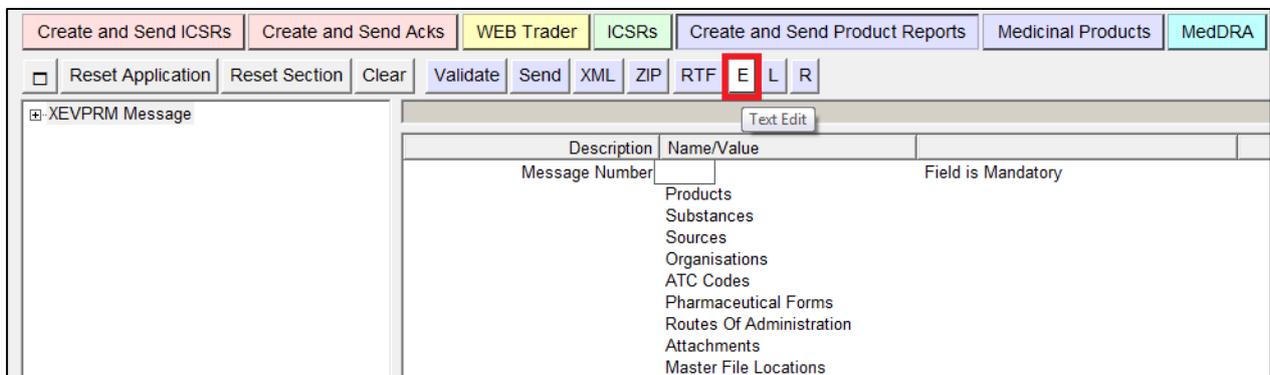
2) Go to "Create and Send Product Reports" section:



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:

The screenshot shows the 'XEVPRM Message' form. At the top, there are several tabs: 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below these are buttons for 'Reset Application', 'Reset Section', 'Clear', 'Validate', 'Send', 'XML', 'ZIP', 'RTF', 'E', 'L', and 'R'. The main area is divided into two panes. The left pane is titled 'XEVPRM Message' and is currently empty. The right pane contains a table with the following structure:

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

6) Expand the tree-view area by clicking on the "+" sign and select "Organisations" or double click on "Organisations" in the active area:

This screenshot is similar to the previous one, but the 'Organisations' item in the tree view on the right is now highlighted with a red box, indicating it has been selected.

### 1.2.1. Marketing authorisation holder (MAH) organisation

7) Select "New MAH " by ticking the relevant box:

The screenshot shows the 'XEVPRM Message' form with the tree view expanded. The left pane shows a tree structure with 'Organisations' selected. The right pane contains a table with the following structure:

Num	Operation Type	Type	Organisation Name
<input checked="" type="checkbox"/>	New MAH		
<input type="checkbox"/>	New Sponsor		

The active area will display the fields relevant for an MAH organisation entity:

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Type	MAH (1)	
MAH Name		Field is Mandatory
SME Status		
SME Number		
MAH Sender ID		
Address		Field is Mandatory
City		Field is Mandatory
Region		
Postcode		Field is Mandatory
Country Code		Field is Mandatory
Tel Number		
Tel Extension		
Tel Country Code		
Fax Number		
Fax Extension		
Fax Country Code		
E-mail Address		
Comment		

- 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.)
  - 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 1.6. Initial Submission of a Marketing Authorisation Holder \(MAH\) Organisation.](#)**

#### 1.2.1.1. 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 your example, this field is blank because you are performing an insert of an entity.

#### 1.2.1.2. Type

The value in the "Type" field is automatically set to "MAH" as per your selection.

#### 1.2.1.3. MAH Name

This is a free-text field.

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

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

- Navigation tabs: Create and Send ICSRs, Create and Send Acks, WEB Trader, ICSRs, Create and Send Product Reports, Medicinal Products, MedDRA
- Buttons: Reset Application, Reset Section, Clear, Validate, Send, XML, ZIP, RTF, Duplicate, Remove, E, L, R
- Tree view: XEVPRM Message
  - Products
  - Substances
  - Sources
  - Organisations
    - Insert (1) - MAH (1)
  - ATC Codes
  - Pharmaceutical Forms
  - Routes Of Administration
  - Attachments
  - Master File Locations
- Table:
 

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Type	MAH (1)	
MAH Name		Field is Mandatory
SME Status		
SME Number		
MAH Sender ID		
Address		Field is Mandatory
City		Field is Mandatory
Region		
Postcode		Field is Mandatory
Country Code		Field is Mandatory
Tel Number		
Tel Extension		
Tel Country Code		
Fax Number		
Fax Extension		
Fax Country Code		
E-mail Address		
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 with the MAH Name field now containing a text cursor, indicating it is active for editing.

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

Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Create and Send Product Reports	Medicinal Products	MedDRA						
<input type="checkbox"/> Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	Remove	E	L	R

<ul style="list-style-type: none"> <li>[-] XEVPRM Message           <ul style="list-style-type: none"> <li>Products</li> <li>Substances</li> <li>Sources</li> <li>Organisations               <ul style="list-style-type: none"> <li>[-] Insert (1) - MAH (1) - PharmeX</li> </ul> </li> <li>ATC Codes</li> <li>Pharmaceutical Forms</li> <li>Routes Of Administration</li> <li>Attachments</li> <li>Master File Locations</li> </ul> </li> </ul>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">Description</th> <th style="width: 40%;">Name/Value</th> </tr> </thead> <tbody> <tr><td>Operation Type</td><td>Insert (1)</td></tr> <tr><td>EV Code</td><td></td></tr> <tr><td>Type</td><td>MAH (1)</td></tr> <tr><td>MAH Name</td><td>PharmeX</td></tr> <tr><td>SME Status</td><td></td></tr> <tr><td>SME Number</td><td></td></tr> <tr><td>MAH Sender ID</td><td></td></tr> <tr><td>Address</td><td>Field is Mandatory</td></tr> <tr><td>City</td><td>Field is Mandatory</td></tr> <tr><td>Region</td><td></td></tr> <tr><td>Postcode</td><td>Field is Mandatory</td></tr> <tr><td>Country Code</td><td>Field is Mandatory</td></tr> <tr><td>Tel Number</td><td></td></tr> <tr><td>Tel Extension</td><td></td></tr> <tr><td>Tel Country Code</td><td></td></tr> <tr><td>Fax Number</td><td></td></tr> <tr><td>Fax Extension</td><td></td></tr> <tr><td>Fax Country Code</td><td></td></tr> <tr><td>E-mail Address</td><td></td></tr> <tr><td>Comment</td><td></td></tr> </tbody> </table>	Description	Name/Value	Operation Type	Insert (1)	EV Code		Type	MAH (1)	MAH Name	PharmeX	SME Status		SME Number		MAH Sender ID		Address	Field is Mandatory	City	Field is Mandatory	Region		Postcode	Field is Mandatory	Country Code	Field is Mandatory	Tel Number		Tel Extension		Tel Country Code		Fax Number		Fax Extension		Fax Country Code		E-mail Address		Comment	
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Fax Extension																																											
Fax Country Code																																											
E-mail Address																																											
Comment																																											

#### 1.2.1.4. SME status

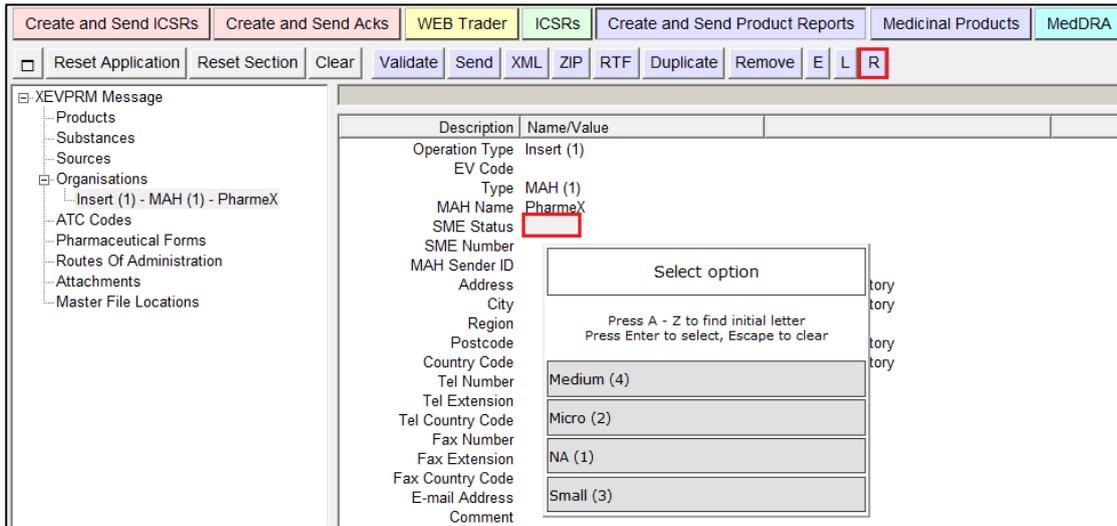
The "SME Status" field is a field that will allow you to select one of the available pre-defined values.

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

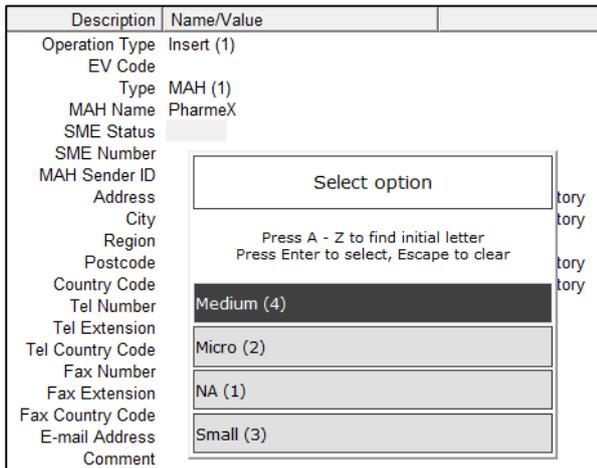
Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Create and Send Product Reports	Medicinal Products	MedDRA						
<input type="checkbox"/> Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	Remove	E	L	R

<ul style="list-style-type: none"> <li>[-] XEVPRM Message           <ul style="list-style-type: none"> <li>Products</li> <li>Substances</li> <li>Sources</li> <li>Organisations               <ul style="list-style-type: none"> <li>[-] Insert (1) - MAH (1) - PharmeX</li> </ul> </li> <li>ATC Codes</li> <li>Pharmaceutical Forms</li> <li>Routes Of Administration</li> <li>Attachments</li> <li>Master File Locations</li> </ul> </li> </ul>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">Description</th> <th style="width: 40%;">Name/Value</th> </tr> </thead> <tbody> <tr><td>Operation Type</td><td>Insert (1)</td></tr> <tr><td>EV Code</td><td></td></tr> <tr><td>Type</td><td>MAH (1)</td></tr> <tr><td>MAH Name</td><td>PharmeX</td></tr> <tr><td>SME Status</td><td></td></tr> <tr><td>SME Number</td><td></td></tr> <tr><td>MAH Sender ID</td><td></td></tr> <tr><td>Address</td><td>Field is Mandatory</td></tr> <tr><td>City</td><td>Field is Mandatory</td></tr> <tr><td>Region</td><td></td></tr> <tr><td>Postcode</td><td>Field is Mandatory</td></tr> <tr><td>Country Code</td><td>Field is Mandatory</td></tr> <tr><td>Tel Number</td><td></td></tr> <tr><td>Tel Extension</td><td></td></tr> <tr><td>Tel Country Code</td><td></td></tr> <tr><td>Fax Number</td><td></td></tr> <tr><td>Fax Extension</td><td></td></tr> <tr><td>Fax Country Code</td><td></td></tr> <tr><td>E-mail Address</td><td></td></tr> <tr><td>Comment</td><td></td></tr> </tbody> </table>	Description	Name/Value	Operation Type	Insert (1)	EV Code		Type	MAH (1)	MAH Name	PharmeX	SME Status		SME Number		MAH Sender ID		Address	Field is Mandatory	City	Field is Mandatory	Region		Postcode	Field is Mandatory	Country Code	Field is Mandatory	Tel Number		Tel Extension		Tel Country Code		Fax Number		Fax Extension		Fax Country Code		E-mail Address		Comment	
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Operation Type	Insert (1)																																										
EV Code																																											
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MAH Name	PharmeX																																										
SME Status																																											
SME Number																																											
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Comment																																											

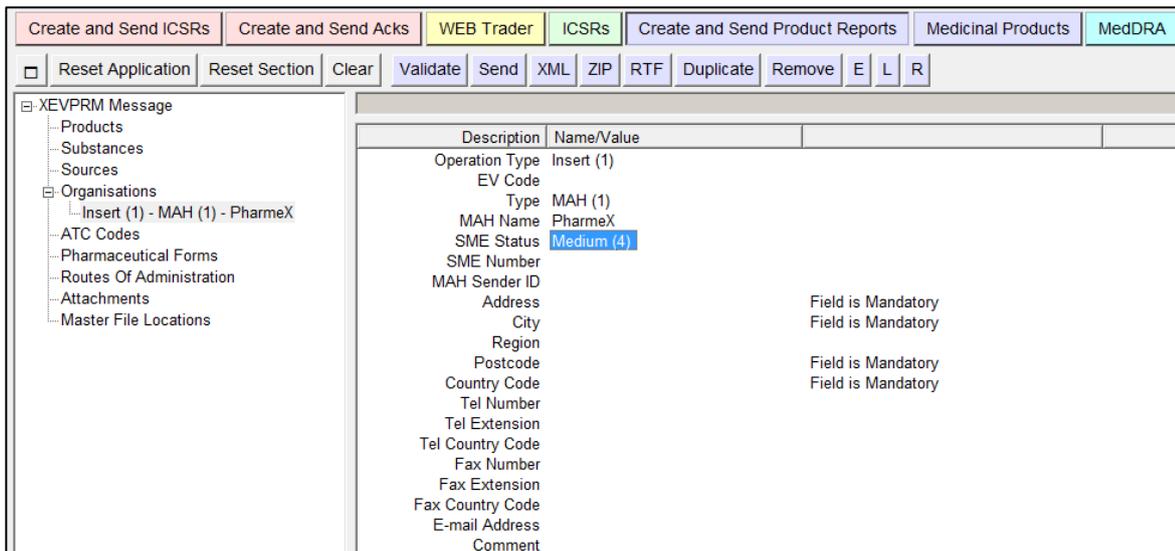
Press "Enter" on your keyboard, double-click on the field, or click on the "R" (Remote look-up) button. The values available for this field will be displayed:



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



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



### 1.2.1.5. SME Number

This is a free text field.

Should you wish to enter an SME number, you can do so by clicking on the area next to the "SME Number". The area will become highlighted in blue:

The screenshot shows the XEVPRM Message form with the following fields and values:

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Type	MAH (1)	
MAH Name	PharmeX	
SME Status	Medium (4)	
SME Number		
MAH Sender ID		
Address		Field is Mandatory
City		Field is Mandatory
Region		
Postcode		Field is Mandatory
Country Code		Field is Mandatory
Tel Number		
Tel Extension		
Tel Country Code		
Fax Number		
Fax Extension		
Fax Country Code		
E-mail Address		
Comment		

Press "Enter" on your keyboard or click on the 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 with the following fields and values:

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Type	MAH (1)	
MAH Name	PharmeX	
SME Status	Medium (4)	
SME Number		
MAH Sender ID		
Address		Field is Mandatory
City		Field is Mandatory
Region		
Postcode		Field is Mandatory
Country Code		Field is Mandatory
Tel Number		
Tel Extension		
Tel Country Code		
Fax Number		
Fax Extension		
Fax Country Code		
E-mail Address		
Comment		

Once you type in the required text, press "Enter" on your keyboard. The text will be displayed in the "SME Number" field:

Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Create and Send Product Reports	Medicinal Products	MedDRA						
<input type="checkbox"/> Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	Remove	E	L	R

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Type	MAH (1)	
MAH Name	PharmeX	
SME Status	Medium (4)	
SME Number	EMA/SME/000/00/02	
MAH Sender ID		
Address		Field is Mandatory
City		Field is Mandatory
Region		
Postcode		Field is Mandatory
Country Code		Field is Mandatory
Tel Number		
Tel Extension		
Tel Country Code		
Fax Number		
Fax Extension		
Fax Country Code		
E-mail Address		
Comment		

### 1.2.1.6. MAH Sender ID

This is a free text field.

As per the guidance provided in [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section 1.6. *Initial Submission of a Marketing Authorisation Holder (MAH) Organisation*, the organisation ID that corresponds to the same organisation as assigned in the EudraVigilance registration system may be provided.

Should you wish to enter the organisation ID in this field, use the same process as described in section 1.2.1.3. *MAH Name*.

### 1.2.1.7. Address, City, Region and Postcode

These are free-text fields.

To enter the requested information in these fields, use the same process as described in section 1.2.1.3. *MAH Name*.

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Type	MAH (1)	
MAH Name	PharmeX	
SME Status	Medium (4)	
SME Number	EMA/SME/000/00/02	
MAH Sender ID		
Address	43 Winston Road	
City	London	
Region		
Postcode	E14 5EU	
Country Code		Field is Mandatory
Tel Number		
Tel Extension		
Tel Country Code		
Fax Number		
Fax Extension		
Fax Country Code		
E-mail Address		
Comment		

### 1.2.1.8. Country Code

The "Country Code" 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 to "Country Code". The area will become highlighted in blue:

The screenshot shows the XEVPRM Message form with the following fields and values:

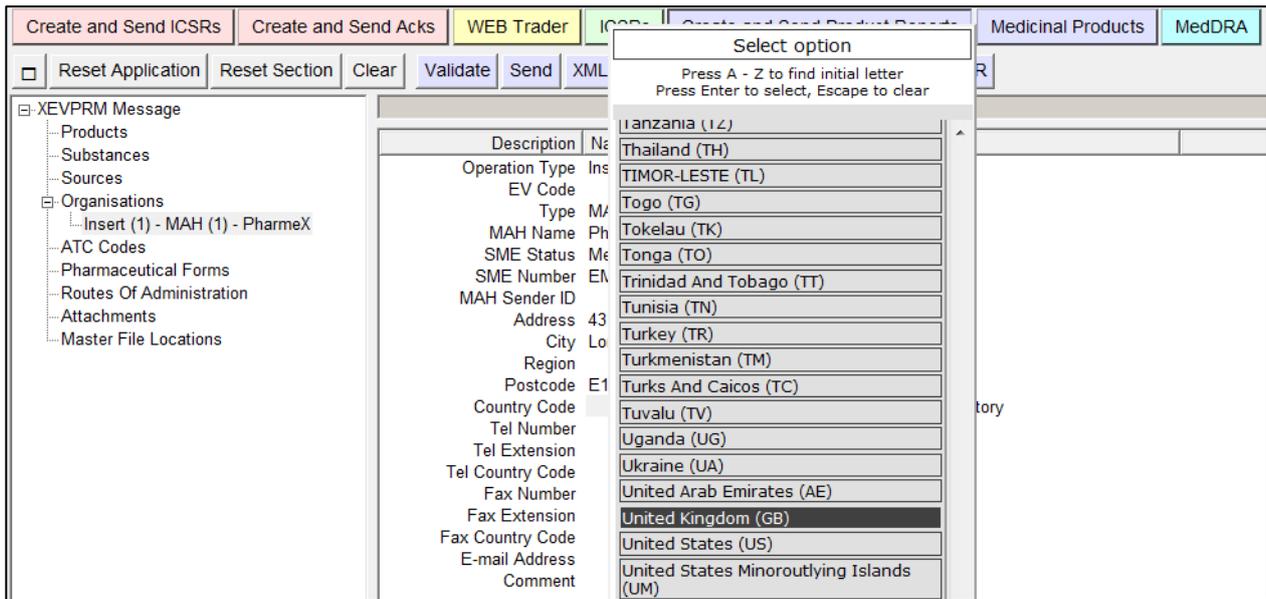
Description	Name/Value
Operation Type	Insert (1)
EV Code	
Type	MAH (1)
MAH Name	PharmeX
SME Status	Medium (4)
SME Number	EMA/SME/000/00/02
MAH Sender ID	
Address	43 Winston Road
City	London
Region	
Postcode	E14 5EU
Country Code	<span style="background-color: blue; color: white;"> </span> Field is Mandatory
Tel Number	
Tel Extension	
Tel Country Code	
Fax Number	
Fax Extension	
Fax Country Code	
E-mail Address	
Comment	

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:

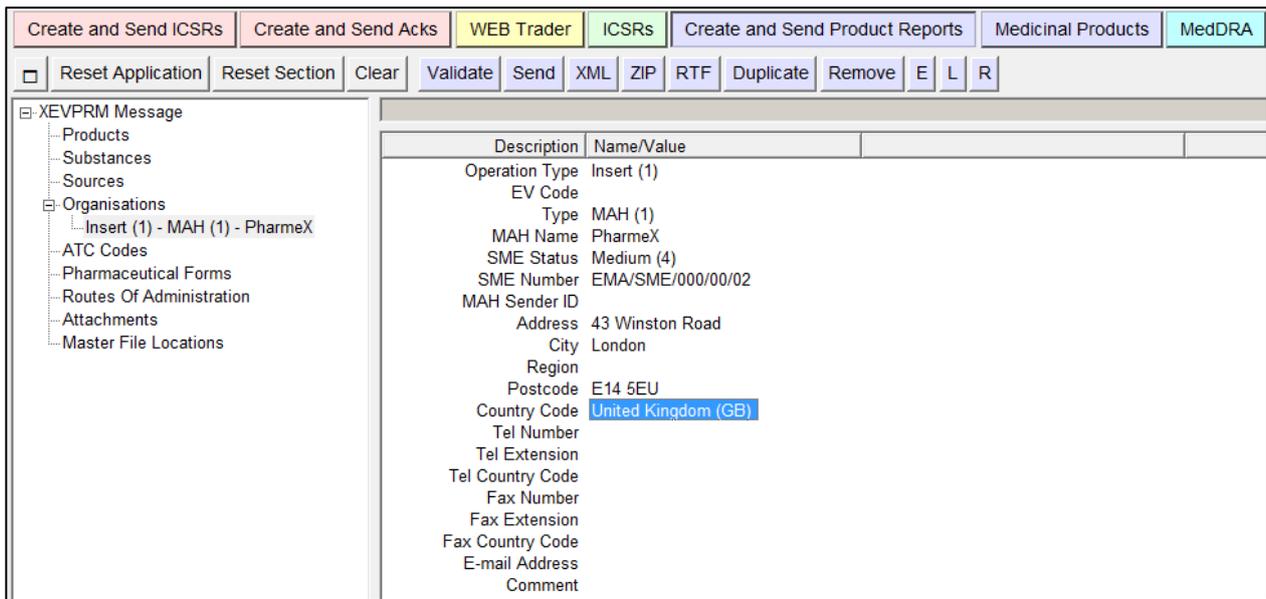
The screenshot shows the XEVPRM Message form with the Country Code dropdown menu open. The dropdown menu is titled "Select option" and contains the following list of country codes:

- 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)
- Austria (AT)
- Azerbaijan (AZ)
- Bahamas (BS)
- Bahrain (BH)

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



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



**1.2.1.9. Tel Number, Extension, Country Code, Fax Number, Fax Extension, Fax Country Code and E-mail address**

These are free-text fields.

Should you wish to enter the requested information in these fields, use the same process as described in section 1.2.1.3. MAH Name.

### 1.2.1.10. Comment

This is a free- text field, in which information can be entered using the same process as described in section 1.2.1.3. *MAH Name*.

As per business rules and guidance provided in [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section 1.6. *Initial Submission of a Marketing Authorisation Holder (MAH) Organisation*, no information should be entered in this field in this particular case.

You have now populated the fields for an MAH organisation entity "PharmeX":

The screenshot displays the XEVPRM Message configuration window. The top navigation bar includes buttons for '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 for 'Reset Application', 'Reset Section', 'Clear', 'Validate', 'Send', 'XML', 'ZIP', 'RTF', 'Duplicate', 'Remove', 'E', 'L', and 'R'. The main interface is split into two panes. The left pane shows a tree view under 'XEVPRM Message' with categories like Products, Substances, Sources, Organisations, ATC Codes, Pharmaceutical Forms, Routes Of Administration, Attachments, and Master File Locations. The 'Organisations' category is expanded to show 'Insert (1) - MAH (1) - PharmeX'. The right pane displays a table with two columns: 'Description' and 'Name/Value'. The table contains the following data:

Description	Name/Value
Operation Type	Insert (1)
EV Code	
Type	MAH (1)
MAH Name	PharmeX
SME Status	Medium (4)
SME Number	EMA/SME/000/00/02
MAH Sender ID	
Address	43 Winston Road
City	London
Region	
Postcode	E14 5EU
Country Code	United Kingdom (GB)
Tel Number	0207 1111
Tel Extension	222
Tel Country Code	0044
Fax Number	
Fax Extension	
Fax Country Code	
E-mail Address	<a href="mailto:PharmeX@pharmex.co.uk">PharmeX@pharmex.co.uk</a>
Comment	

## 1.2.2. Sponsor organisation

8) In the "Organisations" section of your XEVPRM , select "New Sponsor" by ticking the relevant box:

Num	Operation Type	Type	Organisation Name
<input checked="" type="checkbox"/> 0001	Insert (1)	MAH (1)	PharmeX
<input type="checkbox"/> New MAH			
<input checked="" type="checkbox"/> New Sponsor			

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

Description	Name/Value
Operation Type	Insert (1)
EV Code	
Type	Sponsor (2)
Sponsor Name	Field is Mandatory
Sponsor Sender ID	
Address	Field is Mandatory
City	Field is Mandatory
Region	
Postcode	Field is Mandatory
Country Code	Field is Mandatory
Tel Number	
Tel Extension	
Tel Country Code	
Fax Number	
Fax Extension	
Fax Country Code	
E-mail Address	
Comment	

- 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).
  - 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.

### 1.2.2.1. 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 your example, this field is blank because you are performing an insert of an entity.

### 1.2.2.2. Type

The value in the "Type" field is automatically set to "Sponsor" as per your selection.

### 1.2.2.3. Sponsor Name

It is mandatory to provide information in the Sponsor Name field.

This is a free-text field.

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

The screenshot shows the XEVPRM Message form with the 'Sponsor Name' field highlighted in blue. The form includes a navigation bar at the top with buttons for 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below the navigation bar are buttons for 'Reset Application', 'Reset Section', 'Clear', 'Validate', 'Send', 'XML', 'ZIP', 'RTF', 'Duplicate', 'Remove', 'E', 'L', and 'R'. The main form area is divided into a left sidebar with a tree view and a right main table. The tree view includes 'Products', 'Substances', 'Sources', 'Organisations', 'ATC Codes', 'Pharmaceutical Forms', 'Routes Of Administration', 'Attachments', and 'Master File Locations'. The main table has columns for 'Description' and 'Name/Value'. The 'Sponsor Name' field is highlighted in blue, and the 'Type' field is set to 'Sponsor (2)'. Other fields include 'Operation Type', 'EV Code', 'Sponsor Sender ID', 'Address', 'City', 'Region', 'Postcode', 'Country Code', 'Tel Number', 'Tel Extension', 'Tel Country Code', 'Fax Number', 'Fax Extension', 'Fax Country Code', 'E-mail Address', and 'Comment'. The 'Sponsor Name' field is marked as 'Field is Mandatory'.

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 with the 'Sponsor Name' field active and ready for text input. The form includes a navigation bar at the top with buttons for 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below the navigation bar are buttons for 'Reset Application', 'Reset Section', 'Clear', 'Validate', 'Send', 'XML', 'ZIP', 'RTF', 'Duplicate', 'Remove', 'E', 'L', and 'R'. The main form area is divided into a left sidebar with a tree view and a right main table. The tree view includes 'Products', 'Substances', 'Sources', 'Organisations', 'ATC Codes', 'Pharmaceutical Forms', 'Routes Of Administration', 'Attachments', and 'Master File Locations'. The main table has columns for 'Description' and 'Name/Value'. The 'Sponsor Name' field is active and ready for text input, and the 'Type' field is set to 'Sponsor (2)'. Other fields include 'Operation Type', 'EV Code', 'Sponsor Sender ID', 'Address', 'City', 'Region', 'Postcode', 'Country Code', 'Tel Number', 'Tel Extension', 'Tel Country Code', 'Fax Number', 'Fax Extension', 'Fax Country Code', 'E-mail Address', and 'Comment'. The 'Sponsor Name' field is marked as 'Field is Mandatory'.

Type in the requested text and press "Enter" on your keyboard. The name of your sponsor will be displayed in the "Sponsor Name" field:

Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Create and Send Product Reports	Medicinal Products	MedDRA																																													
<input type="checkbox"/>	Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	Remove	E	L	R																																						
<div style="display: flex;"> <div style="width: 30%; border-right: 1px solid black; padding-right: 5px;"> <p>[-] XEVPRM Message</p> <ul style="list-style-type: none"> <li>- Products</li> <li>- Substances</li> <li>- Sources</li> <li>- Organisations           <ul style="list-style-type: none"> <li>[-] Insert (1) - MAH (1) - PharmeX</li> <li>[-] Insert (1) - Sponsor (2) - EraLab</li> </ul> </li> <li>- ATC Codes</li> <li>- Pharmaceutical Forms</li> <li>- Routes Of Administration</li> <li>- Attachments</li> <li>- Master File Locations</li> </ul> </div> <div style="width: 70%; padding-left: 5px;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">Description</th> <th style="width: 40%;">Name/Value</th> </tr> </thead> <tbody> <tr> <td>Operation Type</td> <td>Insert (1)</td> </tr> <tr> <td>EV Code</td> <td></td> </tr> <tr> <td>Type</td> <td>Sponsor (2)</td> </tr> <tr> <td>Sponsor Name</td> <td>EraLab</td> </tr> <tr> <td>Sponsor Sender ID</td> <td></td> </tr> <tr> <td>Address</td> <td>Field is Mandatory</td> </tr> <tr> <td>City</td> <td>Field is Mandatory</td> </tr> <tr> <td>Region</td> <td></td> </tr> <tr> <td>Postcode</td> <td>Field is Mandatory</td> </tr> <tr> <td>Country Code</td> <td>Field is Mandatory</td> </tr> <tr> <td>Tel Number</td> <td></td> </tr> <tr> <td>Tel Extension</td> <td></td> </tr> <tr> <td>Tel Country Code</td> <td></td> </tr> <tr> <td>Fax Number</td> <td></td> </tr> <tr> <td>Fax Extension</td> <td></td> </tr> <tr> <td>Fax Country Code</td> <td></td> </tr> <tr> <td>E-mail Address</td> <td></td> </tr> <tr> <td>Comment</td> <td></td> </tr> </tbody> </table> </div> </div>														Description	Name/Value	Operation Type	Insert (1)	EV Code		Type	Sponsor (2)	Sponsor Name	EraLab	Sponsor Sender ID		Address	Field is Mandatory	City	Field is Mandatory	Region		Postcode	Field is Mandatory	Country Code	Field is Mandatory	Tel Number		Tel Extension		Tel Country Code		Fax Number		Fax Extension		Fax Country Code		E-mail Address		Comment	
Description	Name/Value																																																		
Operation Type	Insert (1)																																																		
EV Code																																																			
Type	Sponsor (2)																																																		
Sponsor Name	EraLab																																																		
Sponsor Sender ID																																																			
Address	Field is Mandatory																																																		
City	Field is Mandatory																																																		
Region																																																			
Postcode	Field is Mandatory																																																		
Country Code	Field is Mandatory																																																		
Tel Number																																																			
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Tel Country Code																																																			
Fax Number																																																			
Fax Extension																																																			
Fax Country Code																																																			
E-mail Address																																																			
Comment																																																			

#### 1.2.2.4. Sponsor Sender ID

It is not mandatory to provide information in this field.

This is a free text field.

The organisation ID that corresponds to the same organisation as assigned in the EudraVigilance registration system may be provided.

Should you wish to enter the organisation ID in this field, use the same process as described in section 1.2.2.3. *Sponsor Name*.

#### 1.2.2.5. Address, City, Region and Postcode

It is mandatory to provide information in the Address, City and Postcode fields.

It is not mandatory to provide information in the Region field.

These are all free-text fields.

To enter the requested information in these fields, use the same process as described in section 1.2.2.3. *Sponsor Name*.

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Type	Sponsor (2)	
Sponsor Name	EraLab	
Sponsor Sender ID		
Address	Lockington Close	
City	Margate	
Region		
Postcode	MA12 4JJ	
Country Code		Field is Mandatory
Tel Number		
Tel Extension		
Tel Country Code		
Fax Number		
Fax Extension		
Fax Country Code		
E-mail Address		
Comment		

### 1.2.2.6. Country Code

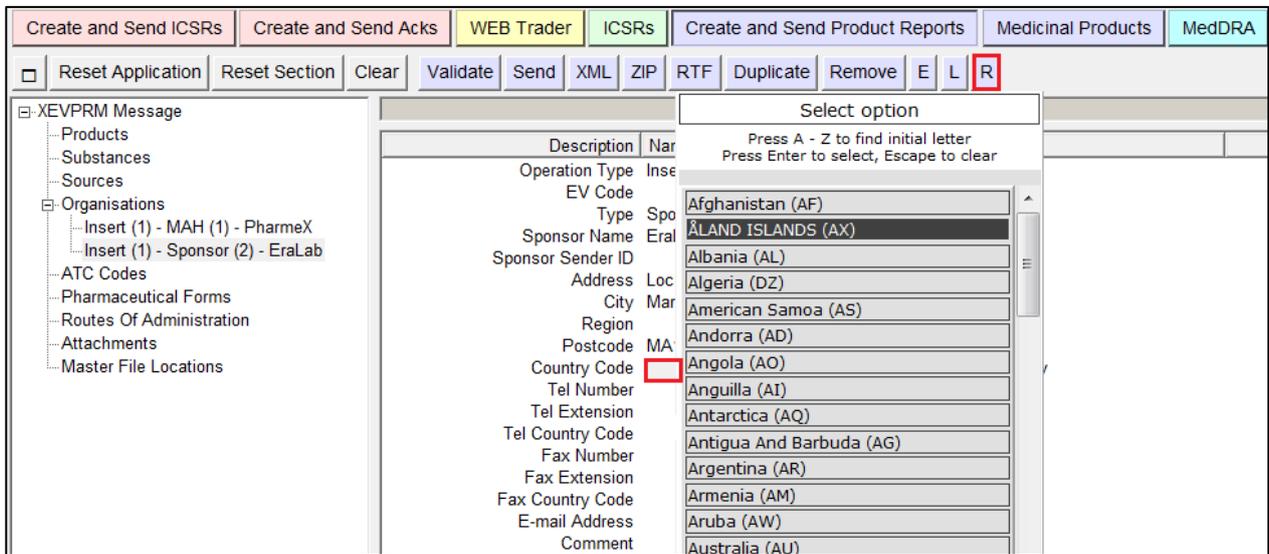
It is mandatory to provide information in this field.

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

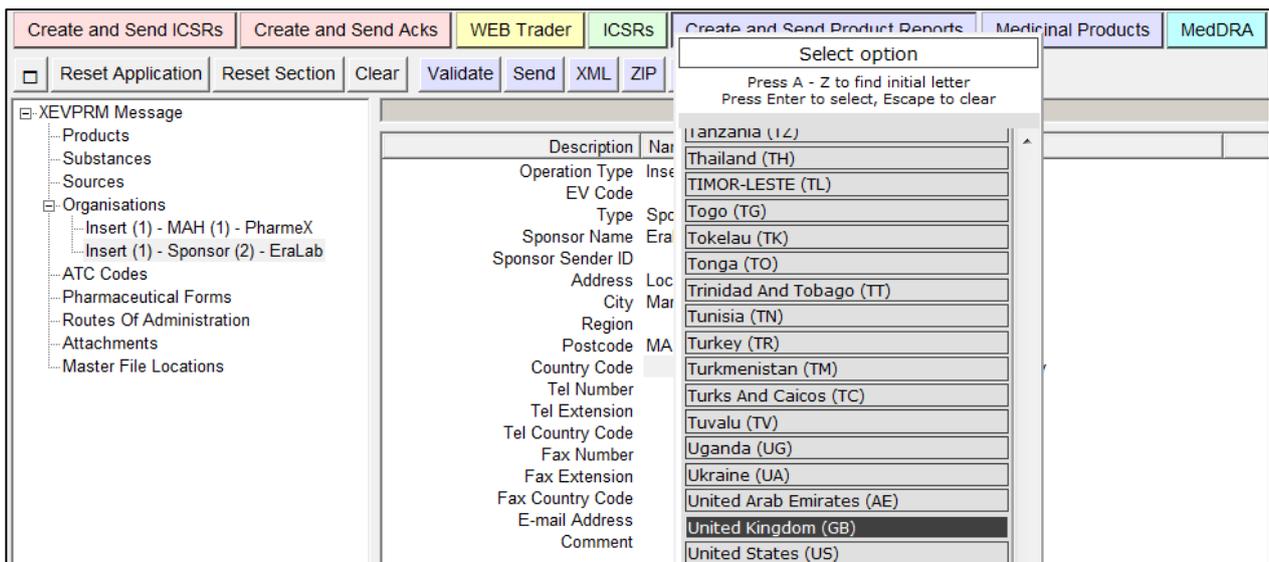
Using your mouse, click on the area next to "Country Code". The area will become highlighted in blue:

The screenshot shows the XEVPRM Message form interface. At the top, there are several tabs: "Create and Send ICSRs", "Create and Send Acks", "WEB Trader", "ICSRs", "Create and Send Product Reports", "Medicinal Products", and "MedDRA". Below the tabs is a toolbar with buttons: "Reset Application", "Reset Section", "Clear", "Validate", "Send", "XML", "ZIP", "RTF", "Duplicate", "Remove", "E", "L", and "R". On the left side, there is a tree view under "XEVPRM Message" with categories: Products, Substances, Sources, Organisations (expanded), ATC Codes, Pharmaceutical Forms, Routes Of Administration, Attachments, and Master File Locations. Under "Organisations", two items are listed: "Insert (1) - MAH (1) - PharmeX" and "Insert (1) - Sponsor (2) - EraLab". The main area of the form is a table with columns "Description" and "Name/Value". The data in the table is identical to the table in the previous image. The "Country Code" field is highlighted in blue, and the text "Field is Mandatory" is visible to its right.

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:



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



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

Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Create and Send Product Reports	Medicinal Products	MedDRA							
<input type="checkbox"/>	Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	Remove	E	L	R

<ul style="list-style-type: none"> <li>[-] XEVPRM Message           <ul style="list-style-type: none"> <li>Products</li> <li>Substances</li> <li>Sources</li> <li>Organisations               <ul style="list-style-type: none"> <li>Insert (1) - MAH (1) - PharmaX</li> <li>Insert (1) - Sponsor (2) - EraLab</li> </ul> </li> <li>ATC Codes</li> <li>Pharmaceutical Forms</li> <li>Routes Of Administration</li> <li>Attachments</li> <li>Master File Locations</li> </ul> </li> </ul>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Description</th> <th style="width: 50%;">Name/Value</th> </tr> </thead> <tbody> <tr><td>Operation Type</td><td>Insert (1)</td></tr> <tr><td>EV Code</td><td></td></tr> <tr><td>Type</td><td>Sponsor (2)</td></tr> <tr><td>Sponsor Name</td><td>EraLab</td></tr> <tr><td>Sponsor Sender ID</td><td></td></tr> <tr><td>Address</td><td>Lockington Close</td></tr> <tr><td>City</td><td>Margate</td></tr> <tr><td>Region</td><td></td></tr> <tr><td>Postcode</td><td>MA12 4JJ</td></tr> <tr><td>Country Code</td><td>United Kingdom (GB)</td></tr> <tr><td>Tel Number</td><td></td></tr> <tr><td>Tel Extension</td><td></td></tr> <tr><td>Tel Country Code</td><td></td></tr> <tr><td>Fax Number</td><td></td></tr> <tr><td>Fax Extension</td><td></td></tr> <tr><td>Fax Country Code</td><td></td></tr> <tr><td>E-mail Address</td><td></td></tr> <tr><td>Comment</td><td></td></tr> </tbody> </table>	Description	Name/Value	Operation Type	Insert (1)	EV Code		Type	Sponsor (2)	Sponsor Name	EraLab	Sponsor Sender ID		Address	Lockington Close	City	Margate	Region		Postcode	MA12 4JJ	Country Code	United Kingdom (GB)	Tel Number		Tel Extension		Tel Country Code		Fax Number		Fax Extension		Fax Country Code		E-mail Address		Comment	
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Fax Number																																							
Fax Extension																																							
Fax Country Code																																							
E-mail Address																																							
Comment																																							

**1.2.2.7. Tel Number, Extension, Country Code, Fax Number, Fax Extension, Fax Country Code and E-mail address**

It is not mandatory to provide information in these fields.

These are free-text fields.

Should you wish to enter the requested information in these fields, use the same process as described in section 1.2.2.3. *Sponsor Name*.

**1.2.2.8. Comment**

This is a free- text field, in which information can be entered using the same process as described in section 1.2.2.3. *Sponsor Name*.

As per the applicable business rules, the "Comment" field must contain the reason for nullification if operation type 'Nullification (4)' is used on the sponsor entity.

No information should be entered in this field in this particular case since you are performing an 'Insert (1)'.

You have now populated the fields for a sponsor organisation entity "EraLab":

Create and Send ICSRs		Create and Send Acks		WEB Trader		ICSRs		Create and Send Product Reports		Medicinal Products		MedDRA	
Reset Application		Reset Section		Clear		Validate		Send		XML		ZIP	
RTF		Duplicate		Remove		E		L		R			

<ul style="list-style-type: none"> <li>[-] XEVPRM Message <ul style="list-style-type: none"> <li>[-] Products</li> <li>[-] Substances</li> <li>[-] Sources</li> <li>[-] Organisations <ul style="list-style-type: none"> <li>[-] Insert (1) - MAH (1) - PharmeX</li> <li>[-] Insert (1) - Sponsor (2) - EraLab</li> </ul> </li> <li>[-] ATC Codes</li> <li>[-] Pharmaceutical Forms</li> <li>[-] Routes Of Administration</li> <li>[-] Attachments</li> <li>[-] Master File Locations</li> </ul> </li> </ul>	Description		Name/Value	
	Operation Type		Insert (1)	
	EV Code			
	Type		Sponsor (2)	
	Sponsor Name		EraLab	
	Sponsor Sender ID			
	Address		Lockington Close	
	City		Margate	
	Region			
	Postcode		MA12 4JJ	
	Country Code		United Kingdom (GB)	
	Tel Number			
	Tel Extension			
	Tel Country Code			
	Fax Number			
Fax Extension				
Fax Country Code				
E-mail Address		<a href="mailto:EraLab@eralab.com">EraLab@eralab.com</a>		
Comment				

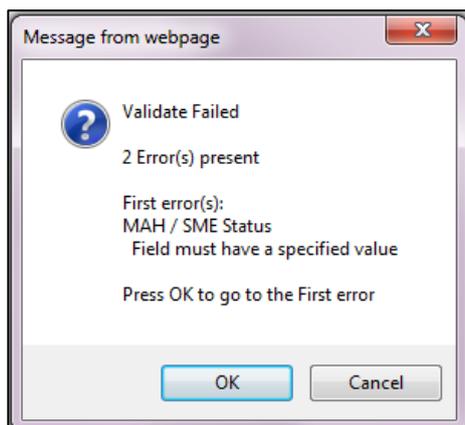
### 1.3. Validate and send an XEVPRM

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

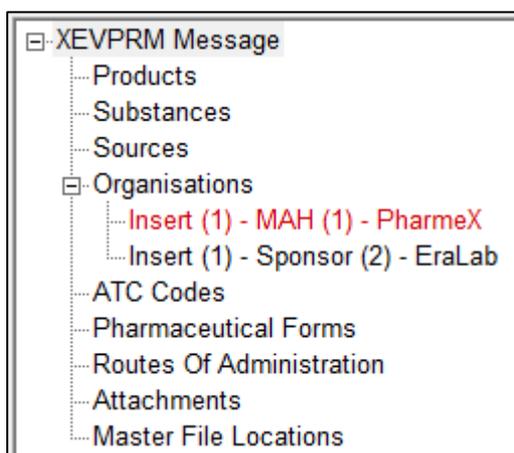


New window will be displayed on your screen, showing the result of your validation:

If your XEVPRM contains any technical errors (i.e. mandatory information is missing), an error message will be displayed on your screen:

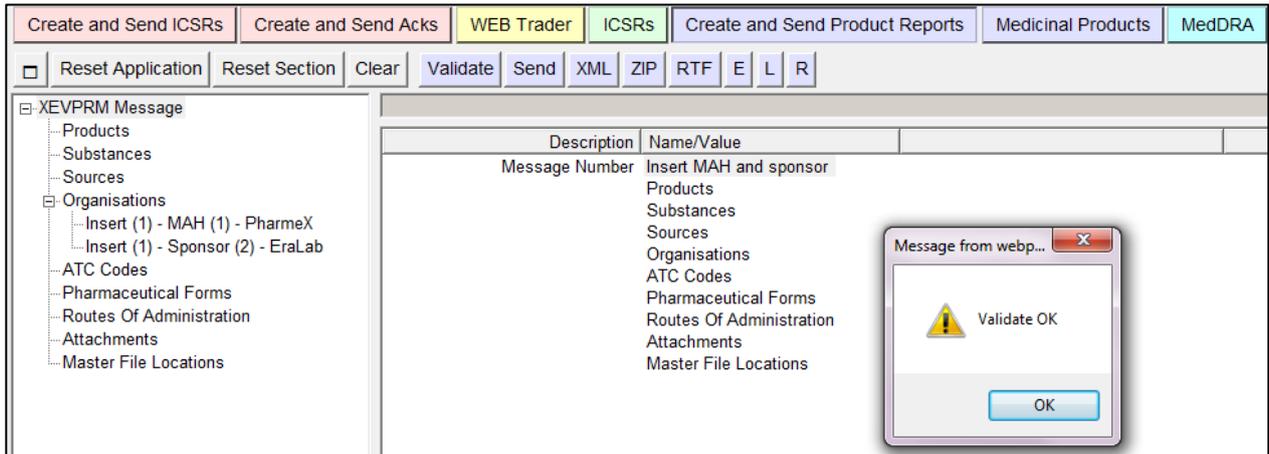


The section, where these errors occurred will be highlighted in red and/or the fields where information is missing will contain the text "Field is Mandatory":



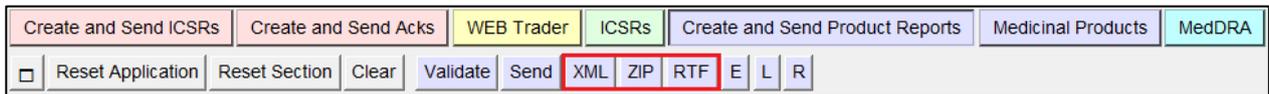
Once you click on "OK" in the error message or click on the section highlighted in red, the application will direct you to the first error. You should enter/correct the required information and validate the XEVPRM again.

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".

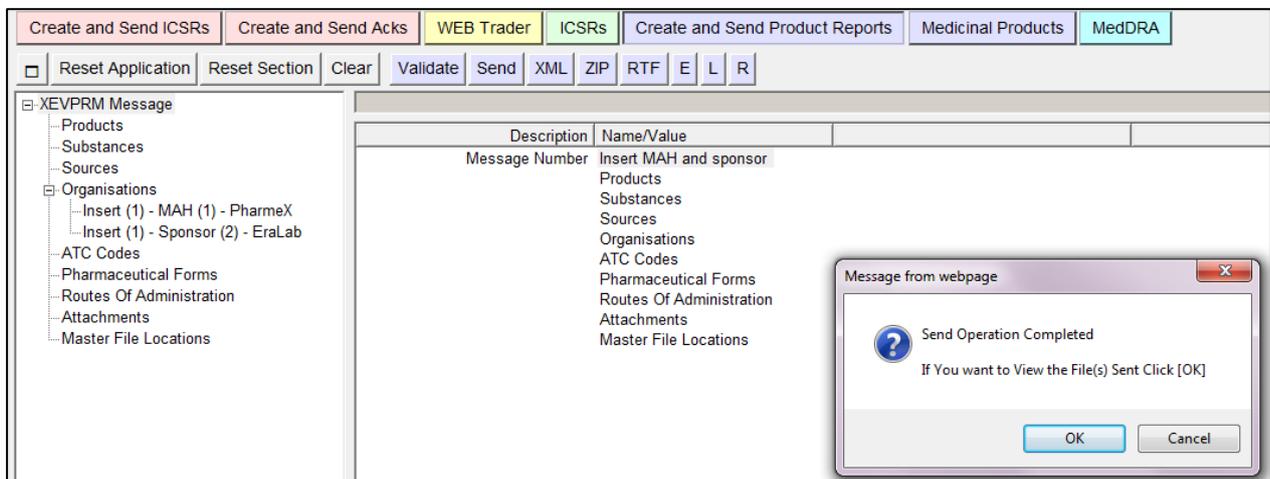
2) Save the XEVPRM for your reference by clicking on the relevant button:



3) Send the XEVPRM by clicking on the "Send" button. The below message will be displayed on your screen:

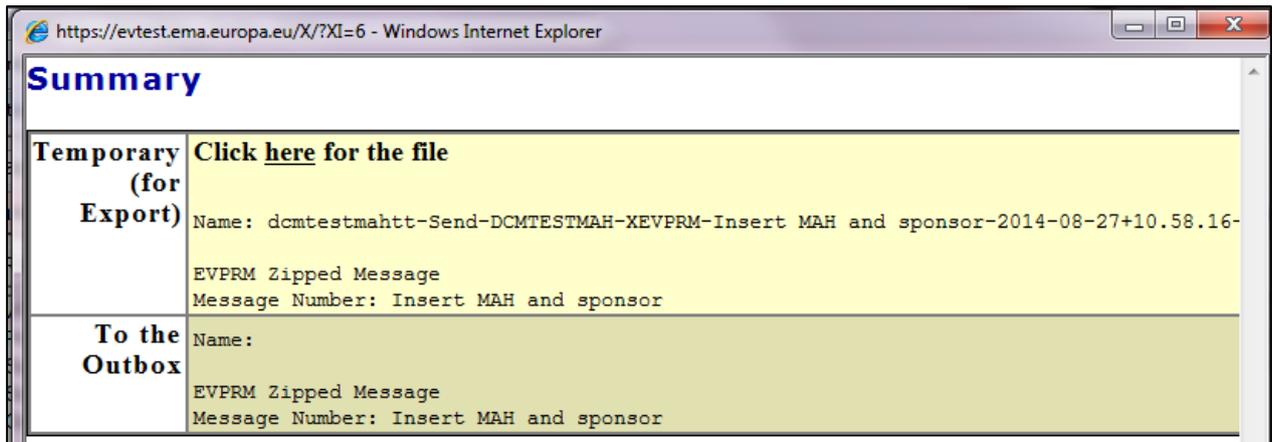


The below message will confirm that your XEVPRM has been sent:



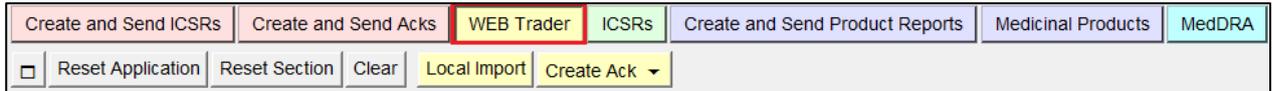
If you want to view/save your file, click on "OK".

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):

The screenshot shows a list of XEVPRM ACKs in a table format. The first row is highlighted in blue. The table has columns for 'Num', 'Name', 'Num/Count', 'Date', and 'Size'.

Num	Name	Num/Count	Date	Size
0001	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_MAH and sponsor-2014-08-27+10.58.16-01.xml	0/13	2014/08/27 11:02:41	00000037...
0002	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Luna 21 PharmaL contraceptive tablets-2014-08-22+12.31.28-01.xml	0/13	2014/08/22 12:35:56	00000050...
0003	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Sponsor_AllenLab-2014-07-30+13.39.50-01.xml	0/13	2014/07/30 13:43:28	00000031...
0004	ack_dcmttestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_MAH_PharmaCompany Ltd-2014-07-30+11.16.29-01.xml	0/13	2014/07/30 11:20:27	00000031...
0005	ack_alcintestmah-Send-DCMTESTMAH-XEVPRM-QPPV update-2014-07-14+15.01.39-01.xml	0/13	2014/07/17 14:52:39	00000030...
0006	ack_alcintestmah-Send-DCMTESTMAH-XEVPRM-Insert_ProductX_vb-2014-07-02+14.59.32-01.xml	0/13	2014/07/02 15:03:57	00000037...
0007	ack_alcintestmah-Send-DCMTESTMAH-XEVPRM-Insert_Goshi 25 Capsules_vb-2014-07-02+11.15.28-01.xml	0/13	2014/07/02 11:19:56	00000044...
0008	ack_alcintestmah-Send-DCMTESTMAH-XEVPRM-Update_ORG4187_vb-2014-07-02+11.07.11-01.xml	0/13	2014/07/02 11:11:56	00000030...
0009	ack_alcintestmah-Send-DCMTESTMAH-XEVPRM-Insert_Nikko tablets_vb-2014-07-02+10.03.28-01.xml	0/13	2014/07/02 10:07:55	00000044...
0010	ack_alcintestmah-Send-DCMTESTMAH-XEVPRM-Insert_DrugVero_vb-2014-07-02+10.01.59-01.xml	0/13	2014/07/02 10:05:55	00000043...
0011	ack_alcintestmah-Send-DCMTESTMAH-XEVPRM-DrugVero_insert_vb-2014-06-26+13.17.33-01.xml	0/13	2014/06/26 13:22:16	00000049...
0012	ack_alcintestmah-Send-DCMTESTMAH-XEVPRM-Nikko tablets_insert_vb-2014-06-26+13.01.53-01.xml	0/13	2014/06/26 13:07:15	00000049...
0013	ack_alcintestmah-Send-DCMTESTMAH-XEVPRM-Test product_insert_vb-2014-06-26+12.04.10-01.xml	0/13	2014/06/26 12:09:14	00000038...

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:

The screenshot shows a close-up of the table with the first row expanded. The 'Name' column is now wider, showing the full name of the message. A red box highlights the separator line between the 'Name' and 'Num/Count' columns.

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...

The screenshot shows another close-up of the table with the first row expanded. The 'Name' column is now wider, showing the full name of the message.

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
0001	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MFL-2014-08-27+14.13.21-01.xml
0002	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MAH and sponsor-2014-08-27+10.58.16-01.xml
0003	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Luna 21 PharmaL contraceptive tablets-2014-08-22+12.31.28-01.xml
0004	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Sponsor_AllenLab-2014-07-30+13.39.50-01.xml
0005	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_MAH_PharmaCompany Ltd-2014-07-30+11.16.29-01.xml

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 displaying XML data. The XML content is as follows:

```

<messagedate>20140827105959</messagedate>
</ichicsmessageheader>
- <acknowledgment>
- <messageacknowledgment>
  <evmessagenum>EU-EC-M-128703</evmessagenum>
  <originalmessagenum>Insert MAH and sponsor</originalmessagenum>
  <originalmessagesenderidentifier>DCMTESTMAH</originalmessagesenderidentifier>
  <originalmessagereceiveridentifier>EVTEST</originalmessagereceiveridentifier>
  <originalmessagedateformat>204</originalmessagedateformat>
  <originalmessagedate>20140827105816</originalmessagedate>
  <transmissionacknowledgmentcode>01</transmissionacknowledgmentcode>
</messageacknowledgment>
- <reportacknowledgment>
  <reportname>ORGANISATION</reportname>
  <localnumber>1</localnumber>
  <ev_code>ORG4828</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully -</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>
  <reportname>ORGANISATION</reportname>
  <localnumber>2</localnumber>
  <ev_code>ORG4829</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully -</operationresultdesc>
</reportacknowledgment>
</acknowledgment>
</evprmack>
  
```

The XML shows two successful insertions of MAH and sponsor organisations, both with an operation result of 2 and the description "Entity inserted successfully".

The insert of your MAH and sponsor organisations was successful.

