



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 January 2024
EMA/525101/2014 1, Rev. 1
Information Management

eXtended EudraVigilance Medicinal Product Report Message (XEVPRM) Step-by-Step Guide

Insert of a Development Medicinal Product (DMP) in the XEVMPD

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union



Table of contents

DMP example specification	3
DMP submission process overview	4
1. Access EVWEB	5
2. Create your XEVPRM.....	7
Development product entity data elements	10
Pharmaceutical product elements.....	15
Drug ATC	39
Drug indications.....	43
Product attachments	50
3. Validate the XEVPRM	56
4. Send the XEVPRM	58
5. Retrieve the XEVPRM Acknowledgement.....	61
Annex	66
Insert of a sponsor organisation in the same XEVPRM.....	66
Insert of a development pharmaceutical form in the same XEVPRM.....	73
Insert of a development route of administration in the same XEVPRM.....	75
Inset of a development ATC Code in the same XEVPRM	77
Insert of an attachment in the same XEVPRM	79

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

The XCOMP (test) environment was used to create screenshots for this document.

DMP example specification

For this step-by-step exercise, the DMP will be inserted in the XEVMPD via the XEVMPD user interface (EVWEB) as per the below specifications:

SPONSOR

Sponsor X
Blue street
Dublin
DU12 5NN
Ireland

PHARMACEUTICAL FORM AND METHOD OF ADMINISTRATION

Soft capsule for oral use

QUALITATIVE AND QUANTITATIVE COMPOSITION

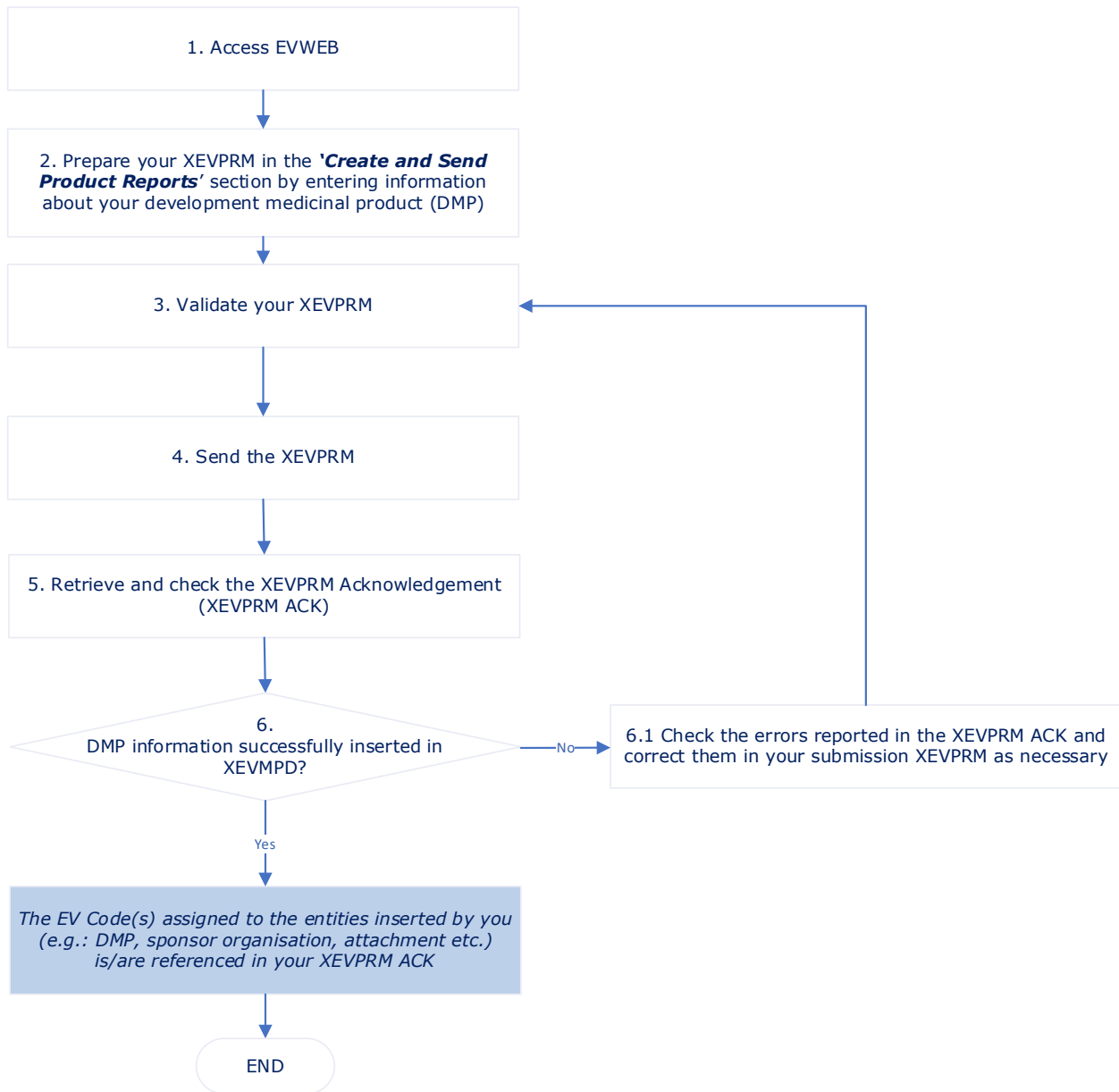
The drug, to which the sponsor refers to as "ABC001", which is the assigned product code, is studied as a capsule for the treatment of low back pain, and contains the following ingredients:

- 100 mg of Paracetamol (active ingredient)
- 100 mg of "SubstanceXYZ" (active ingredient)
- IB dated 19 January 2024 (as DOCX file type)

Additional information

Whilst it is not mandatory to reference an ATC code, indications, and an Investigator's Brochure attachment in a development medicinal product entity in the XEVMPD, this step-by-step document provides information on how these can also be referenced.

DMP submission process overview



1. Access EVWEB

Please note that you must have **ActiveX** downloaded on your computer and access EVWEB via the **IE Tab extension** as per instructions in section 'xEVMPD support' in the [EV restricted area](#).

You will also be requested to provide details for a [multi-factor authentication](#).

1) Log on to the requested EVWEB environment:

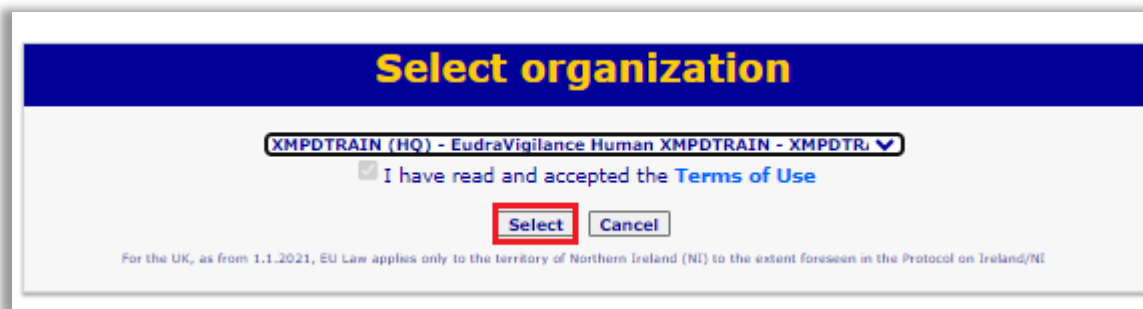
EVWEB production: <https://eudravigilance.ema.europa.eu/x>

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

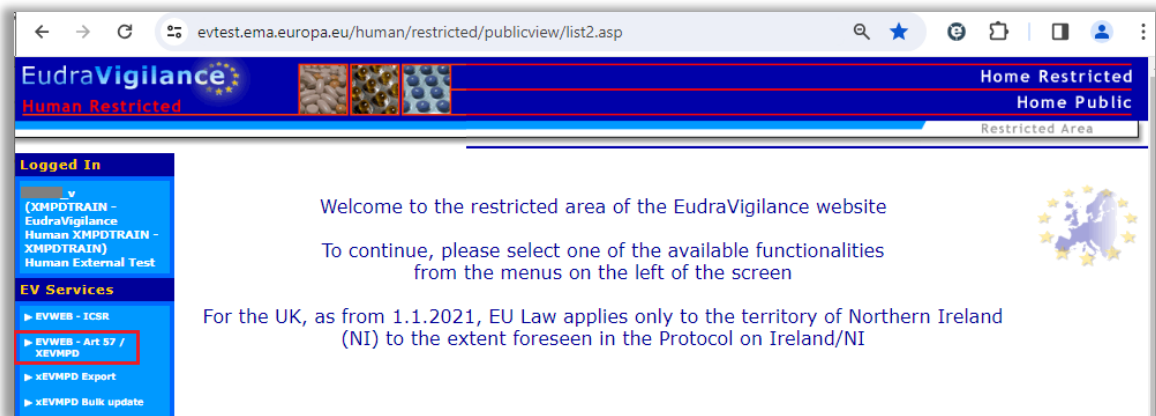
The list of organisations **for which you are registered as a user in the EMA Account Management portal** will be displayed; you can expand the list by clicking on the button shown below:



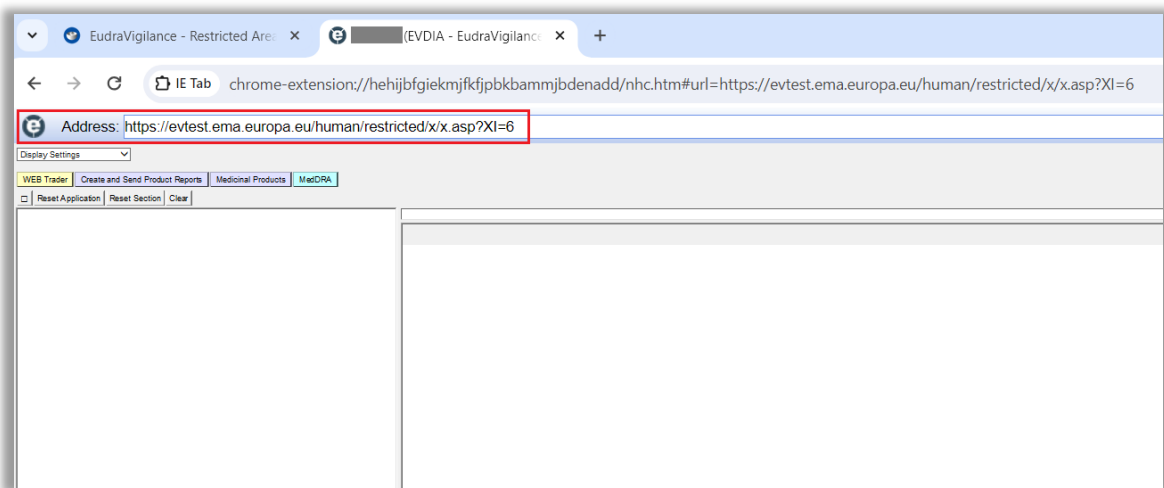
2) Select the correct organisation under which you wish to log on to the selected environment:



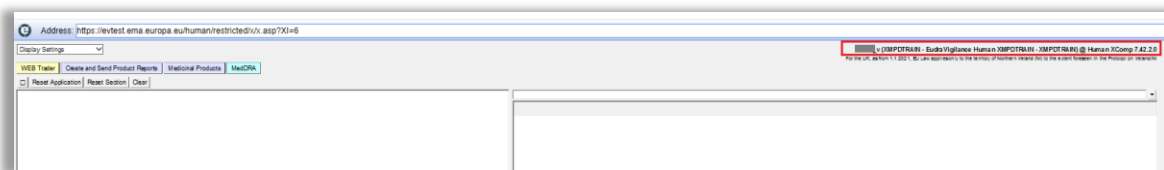
3) Once you accessed the EV restricted area, select "EVWEB – Art 57 / XEVMPD":



You are now logged in EVWEB for the **XCOMP (test) environment**:



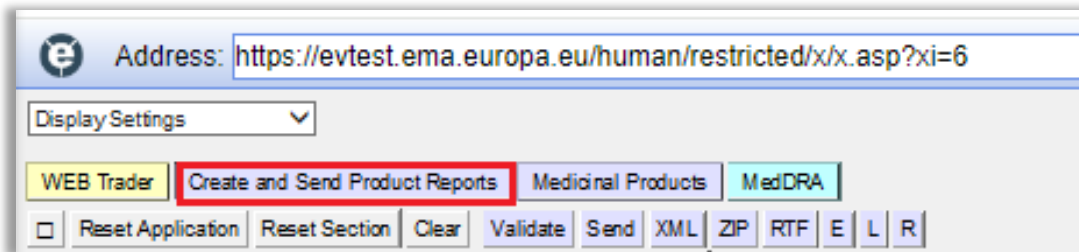
Your username, the organisation's EudraVigilance ID under which you are logged on, and the XEVMPD environment to which you are logged on, is shown in the top right corner of the screen:



2. Create your XEVPRM

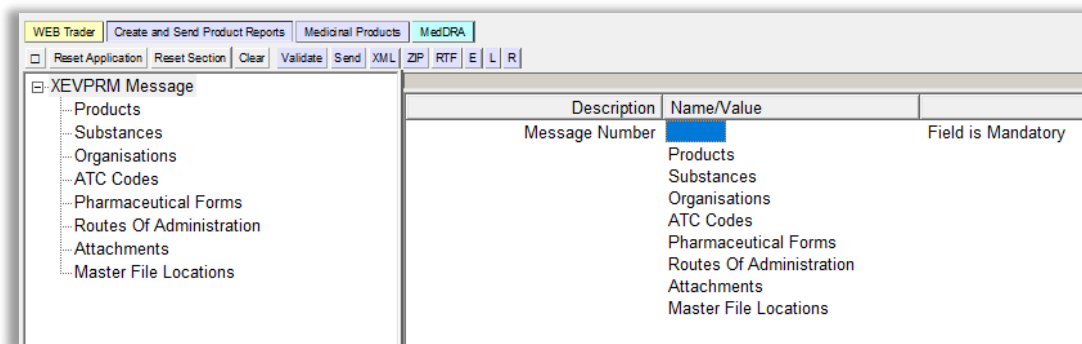
To create your eXtended EudraVigilance Medicinal Product Report (XEVPRM):

- 1) Go to the 'Create and Send Product Reports' section of EVWEB to start creating your submission XEVPRM:

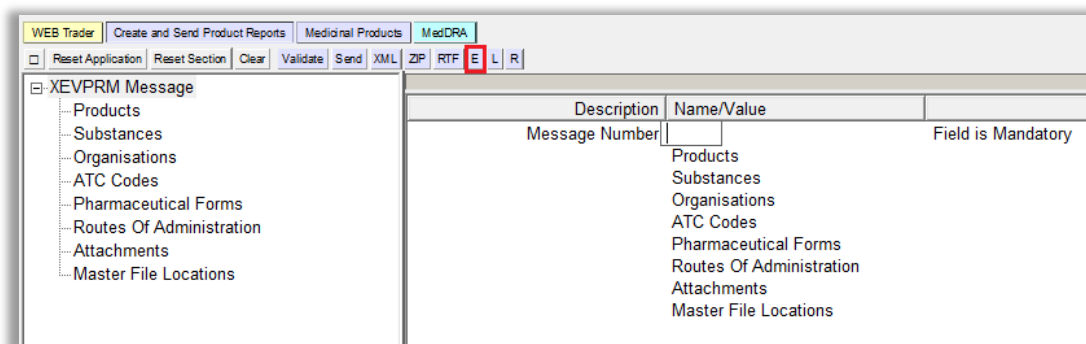


- 2) Assign a 'Message number' to your XEVPRM:

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:

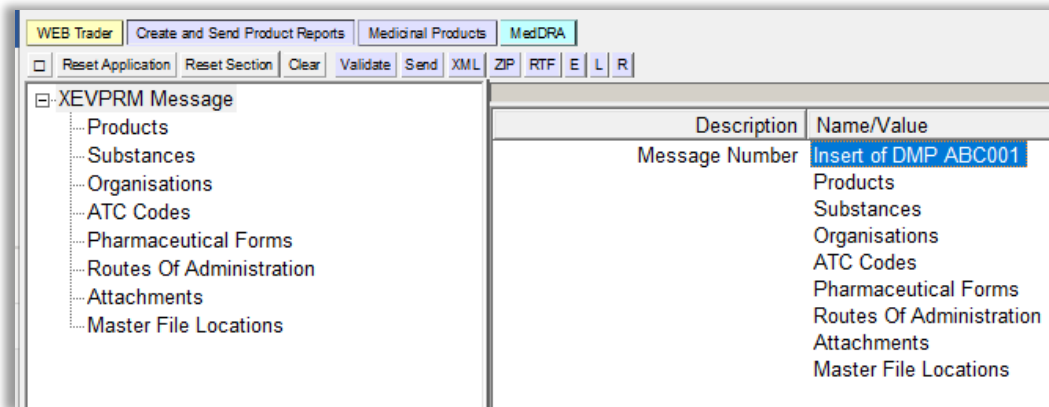


Press "Enter" on your keyboard or click on the "E" ("Text Edit") button. Both actions will activate the field and allow you to write the name you wish to assign to your XEVPRM:



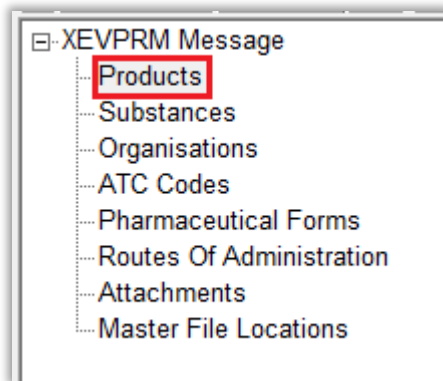
Type in the message number or name that you wish to assign to your XEVPRM.

When you finish typing, press "Enter" on your keyboard and your name/number assigned to the XEVPRM will be displayed in the 'Message Number' field:

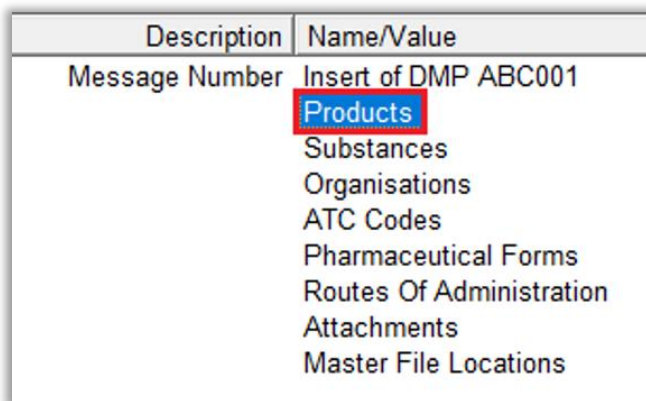


3) Create a development medicinal product entity in your XEVPRM:

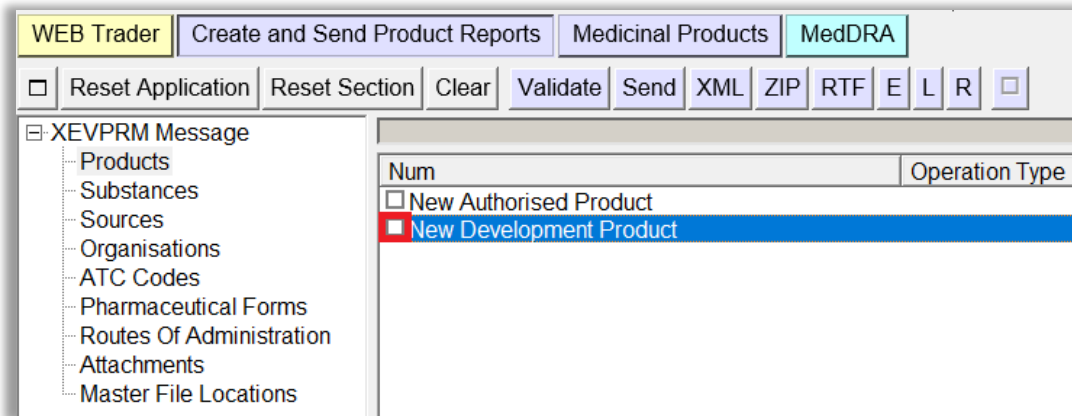
In the tree-view area click on 'Products':



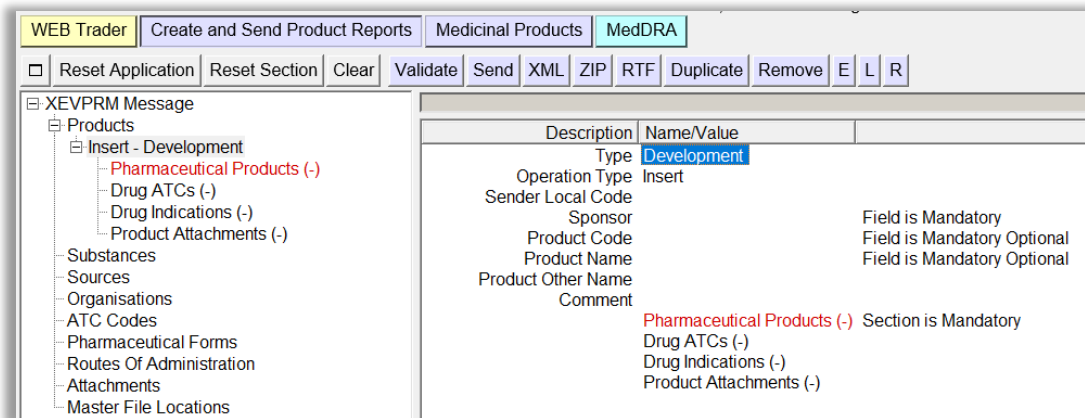
You can also or double click on "Products" section in the active area:



Select "New Development Product" by ticking the relevant box in the active area:



The active area will display the fields relevant for a DMP 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" or "Field is Mandatory Optional".
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 3. [Validate the XEVPRM](#)).
- When information is entered in the individual mandatory fields, the text "Field is Mandatory"/"Field is Mandatory Optional" disappears.

4) Enter the development product information in the individual fields as per guidance provided for each field in the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#), section 1. *Initial submission of a development medicinal product.*

Development product entity data elements

Type

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

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.

Sender Local Code

This is a non-mandatory field. It is a free text field. Should you wish to assign your own local code for your internal reference, use the same process as described in *steps 3 – 5*.

Sponsor

The "Sponsor" field is a field that will allow you to search available values.

You can select the sponsor by searching the remote (R) or local (L) look-up tables, depending on whether the sponsor organisation already exists in the XEVMPD with an assigned EV Code or not:

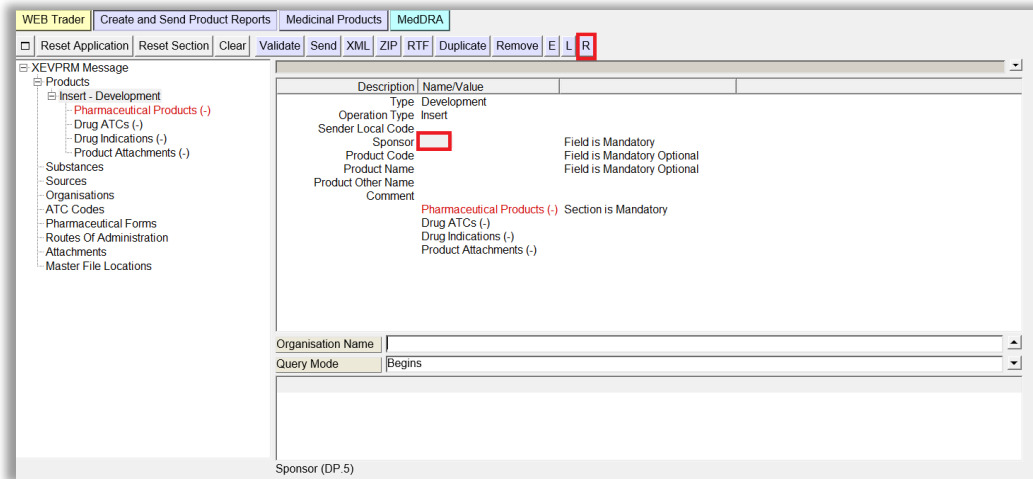
- ✚ If the **organisation name already exists in the XEVMPD** and an EV Code is therefore already assigned, or to check if the organisation already exists in the XEVMPD, search the **remote look-up table**:

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

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

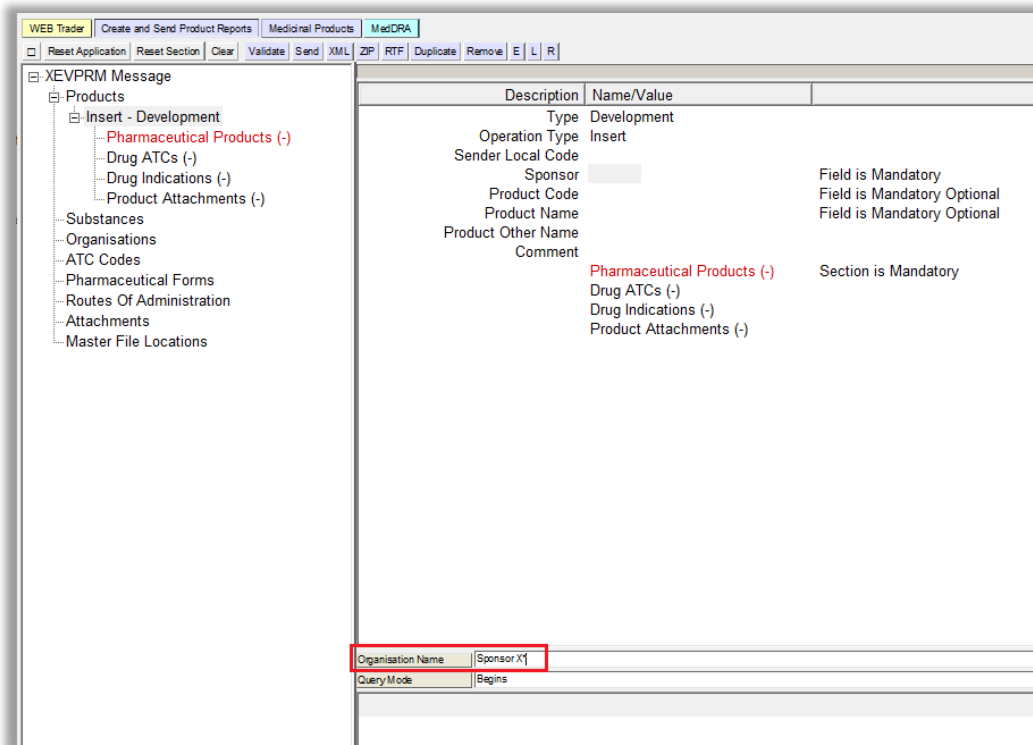
Description	Name/Value	
Type	Development	
Operation Type	Insert	
Sender Local Code		
Sponsor		Field is Mandatory
Product Code		Field is Mandatory Optional
Product Name		Field is Mandatory Optional
Product Other Name		
Comment	Pharmaceutical Products (-)	Section is Mandatory
	Drug ATCs (-)	
	Drug Indications (-)	
	Product Attachments (-)	

- Press "Enter" on your keyboard, double-click on the field, or click on the "R" (Remote look-up) button and the remote look-up search area becomes available:



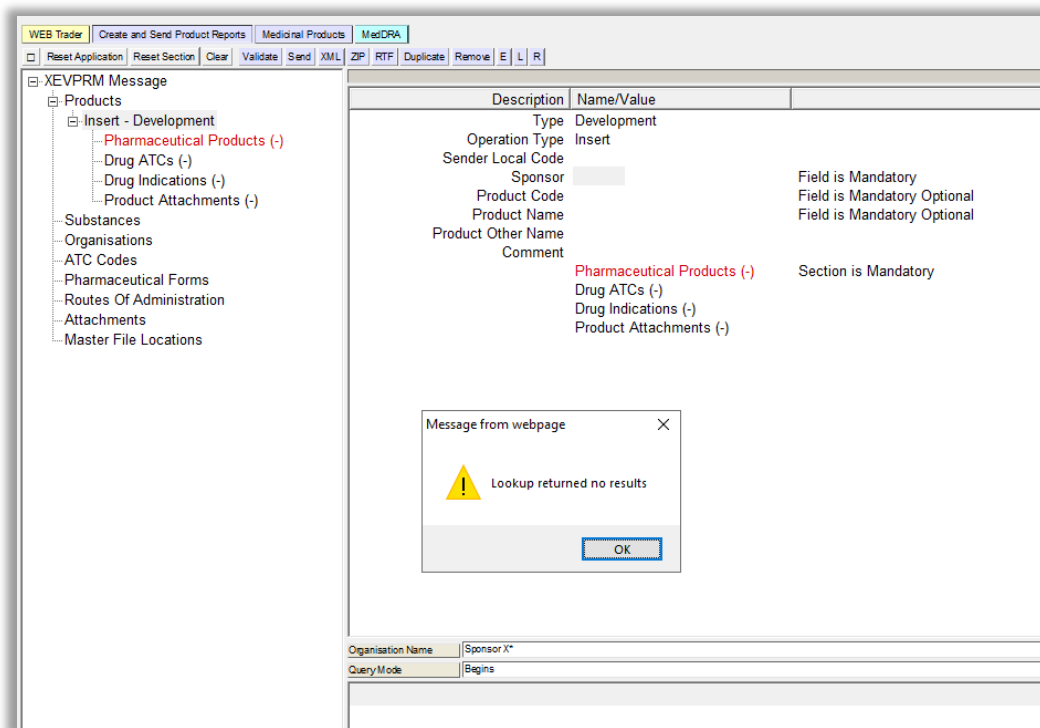
As per this example specifications, the sponsor of the DMP is "Sponsor X". You should therefore query the remote organisation look-up table for "Sponsor X" to check if this sponsor organisation is already available in the XEVMPD. It is recommended to also use one of the wild cards (*) to widen the search.

- o Enter the sponsor's name in the search field and press "Enter" on your keyboard.



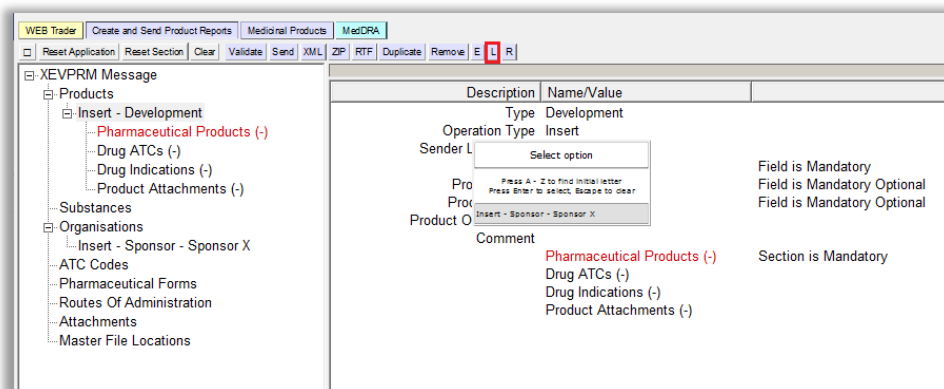
If the organisation was entered in the XEVMPD, the name of the organisation would be displayed under the search panel. You could select the organisation by clicking on its name with your mouse and, by using ENTER on your keyboard, you would reference the sponsor's name in the 'Sponsor' field.

- ✚ If the **organisation name does not exist in the XEVMPD**, the following message will be displayed:

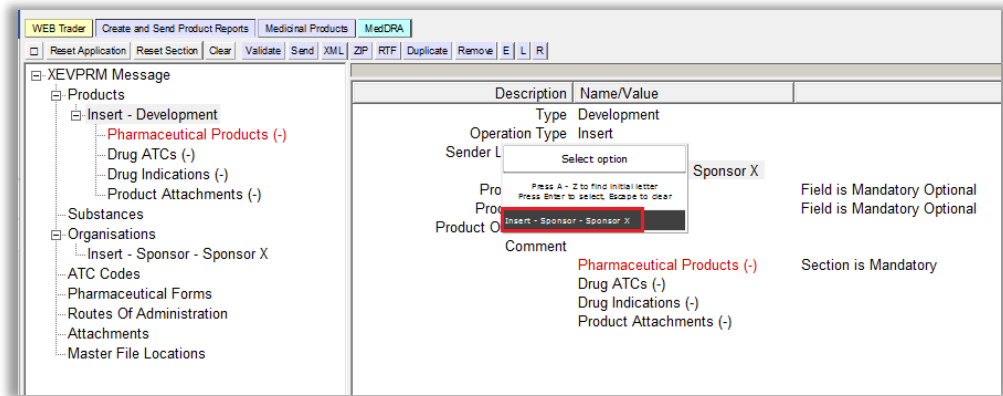


You can therefore presume that this sponsor organisation is not yet available in the XEVMPD.

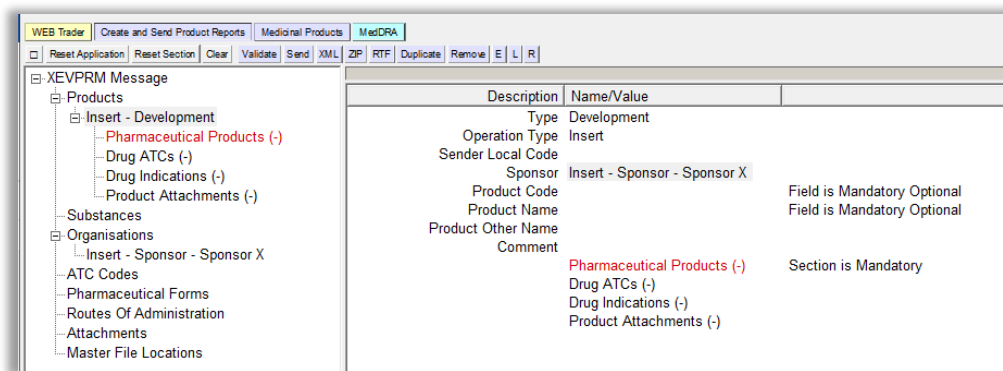
- Insert the sponsor organisation in the XEVMPD as new via the same XEVPRM using the process described in section *Insert of a sponsor organisation in the same XEVPRM* of this document.
- Then reference the sponsor organisation in the 'Sponsor' field from the **local look-up table**:
 - Click on the "L" (Local look-up) button, the field will become highlighted in grey, and the available local look-up table becomes available, displaying the organisation name, which you inserted in the "Organisations" section of your XEVPRM:



- Using your mouse, select the sponsor's name that you wish to reference in the "Sponsor" field. The name will become highlighted in black:



- Press "Enter" on your keyboard or click on the selected value with our mouse and the sponsor's name will be displayed in the "Sponsor" field:



Product Code

This is a free-text field.

Since "ABC001" is the assigned product code, this code should be inserted in this field.

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

Description	Name/Value	
Type	Development	
Operation Type	Insert	
Sender Local Code		
Sponsor	Insert - Sponsor - Sponsor X	
Product Code	 	Field is Mandatory Optional
Product Name		Field is Mandatory Optional
Product Other Name		
Comment	Pharmaceutical Products (-)	Section is Mandatory
	Drug ATCs (-)	
	Drug Indications (-)	
	Product Attachments (-)	

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:

Description	Name/Value	
Type	Development	
Operation Type	Insert	
Sender Local Code		
Sponsor	Insert - Sponsor - Sponsor X	
Product Code	<input type="text"/>	Field is Mandatory Optional
Product Name		Field is Mandatory Optional
Product Other Name		
Comment		
	Pharmaceutical Products (-)	Section is Mandatory
	Drug ATCs (-)	
	Drug Indications (-)	
	Product Attachments (-)	

Type in the required text and press "Enter" on your keyboard. The text will be displayed in the "Product Code" field:

Description	Name/Value	
Type	Development	
Operation Type	Insert	
Sender Local Code		
Sponsor	Insert - Sponsor - Sponsor X	
Product Code	ABC001	
Product Name		
Product Other Name		
Comment		
	Pharmaceutical Products (-)	Section is Mandatory
	Drug ATCs (-)	
	Drug Indications (-)	
	Product Attachments (-)	

Product Name

This is a free-text field.

In accordance with the guidance provided in section 1.6. *Product name, product code, product other name (DP.6)* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#), for our example, the "Product Name" field can be left blank as the 'Product Code' is already provided.

Should you wish to assign a product name to your DMP, use the same process as described in section [Product Code](#) of this document.

Product Other Name

This is a free-text field.

Should you wish to assign product other name to your DMP, as per guidance in section 1.6.3. *Product Other Name (DP.6.3)* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary](#)

[\(XEVMPPD\)](#) , use the same process as described in section *Product Code* of this document. For our example, you will leave this field blank.

Comment

This is a free- text field.

As per the applicable business rules referenced in section 1.7. *Comment (DP.7)* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPPD\)](#), the “Comment” field must contain the reason for nullification if operation type 'Nullification (4)' is used on the sponsor entity.

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

You have now provided information to identify the development product entity in the XEVMPPD.

You now need to provide information about the pharmaceutical product of your DMP entity.

Pharmaceutical product elements

Each medicinal product entry in the XEVMPPD must contain at least one pharmaceutical product. The technical concept of a “pharmaceutical product” refers to the qualitative and quantitative composition of a medicinal product in the pharmaceutical form approved for administration.

The “Administrable pharmaceutical form” refers to the pharmaceutical form for administration to the patient, after any necessary transformation of the authorised pharmaceutical form has been carried out.

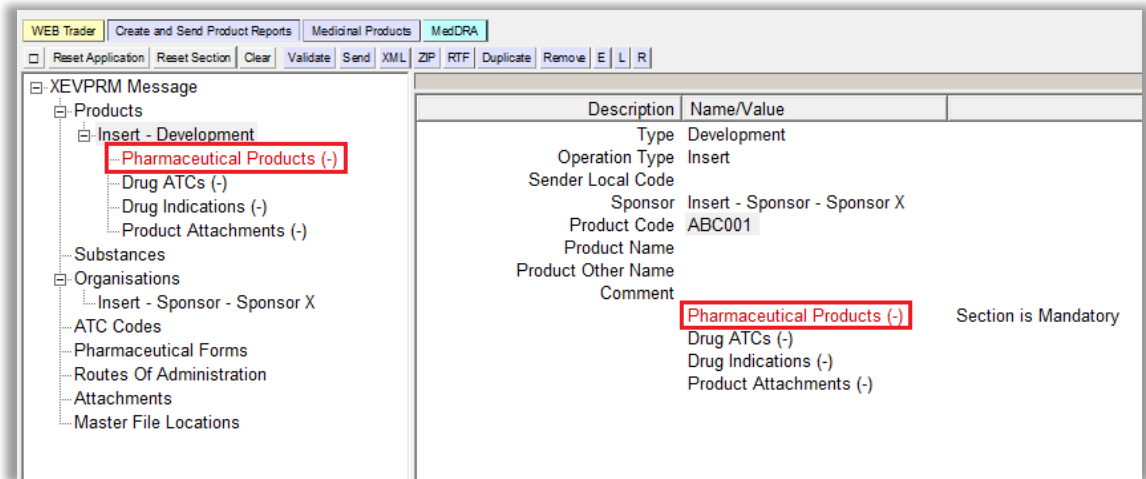
In our case, the IB makes a reference to “Soft capsule for oral use”. The correct **standard term** corresponding to “soft capsule” is “capsule, soft”. This standard term should therefore be referenced in the DMP as the administrable pharmaceutical form.

- An overview on how/when to select standard, proposed or development term of the required pharmaceutical form, or when/how to request the insert of a new pharmaceutical form, is described in *Process map 4: How to reference a pharmaceutical form term in a DMP* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPPD\)](#).

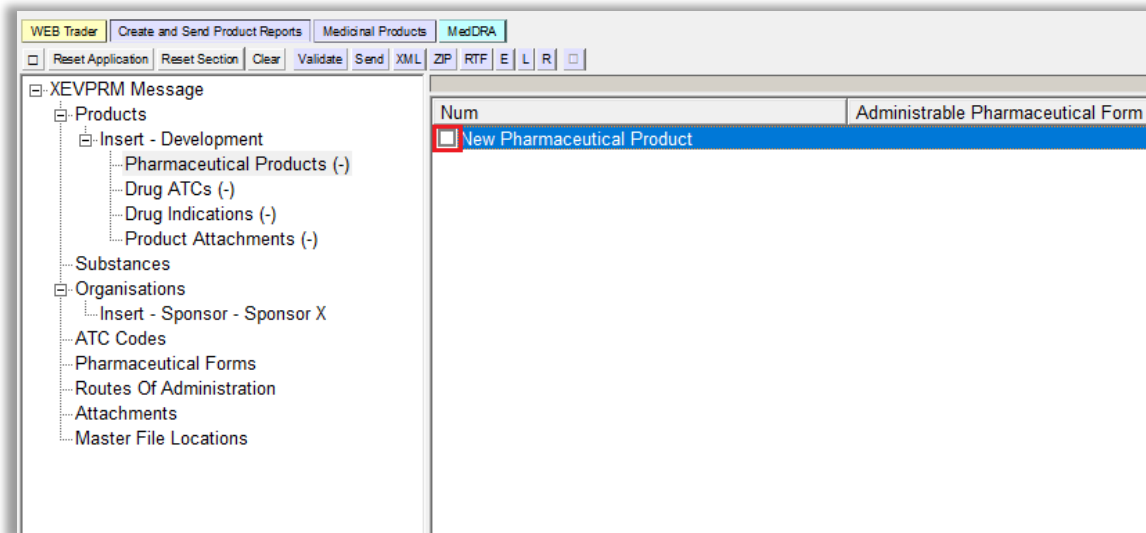
Pharmaceutical Products

This is a repeatable section; a DMP may contain more than one “pharmaceutical product”.

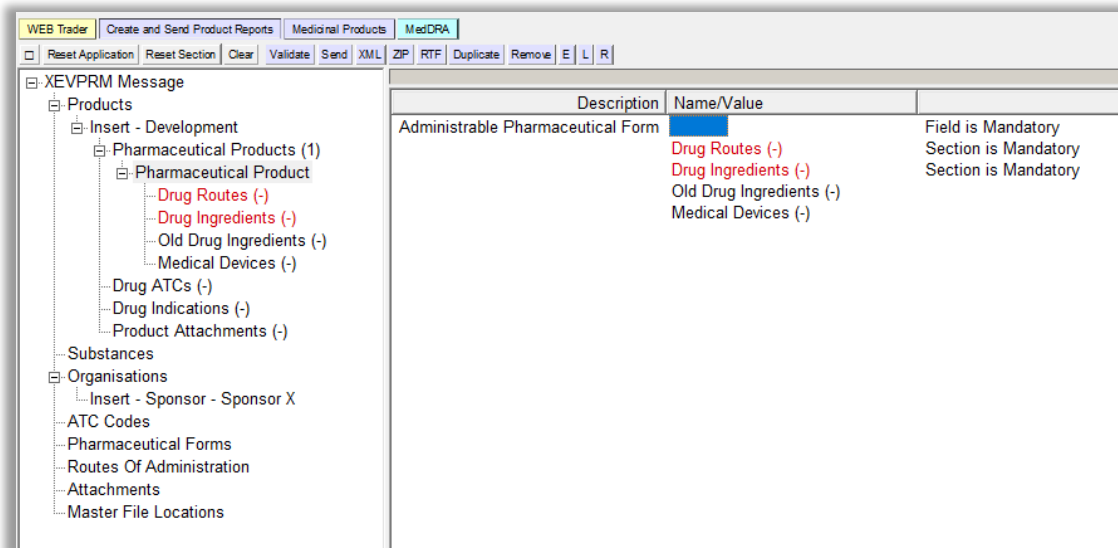
1) Click on the “Pharmaceutical Products” section in the tree-view area, or on “Pharmaceutical Products” in the active area:



2) Select "New Pharmaceutical Product" by ticking the box in the active area:



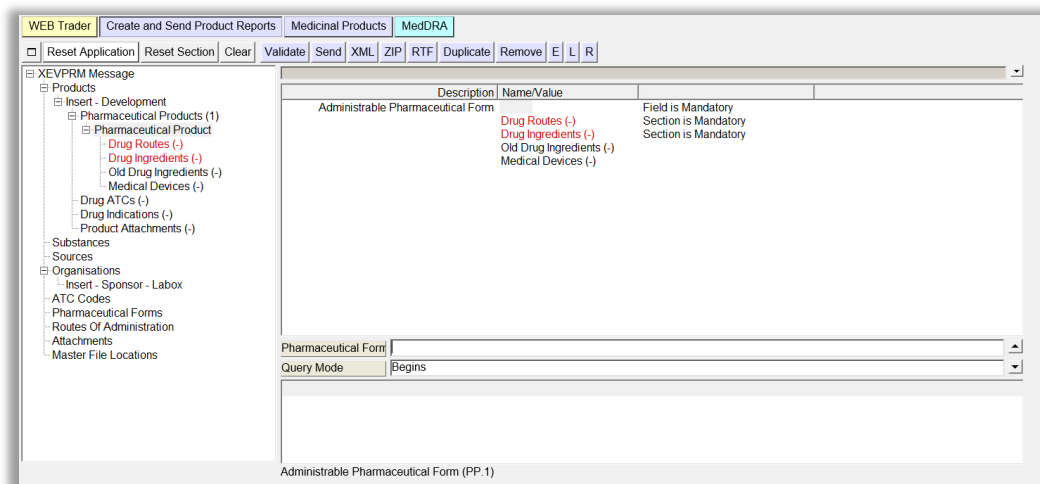
The active area will display the fields applicable for the (administrable) pharmaceutical product. The text next to "Administrable Pharmaceutical Form" is highlighted in blue:



3) Search for the required pharmaceutical form using the remote or local look-up table:

✚ If the required **pharmaceutical form name exists in the XEVMPD** and an EV Code is already assigned, or to check if the pharmaceutical form name already exists in the XEVMPD, search the **remote look-up table**:

- Press "Enter" on your keyboard, double-click on the field, or click on the "R" (Remote look-up) button and the remote look-up search area becomes available:

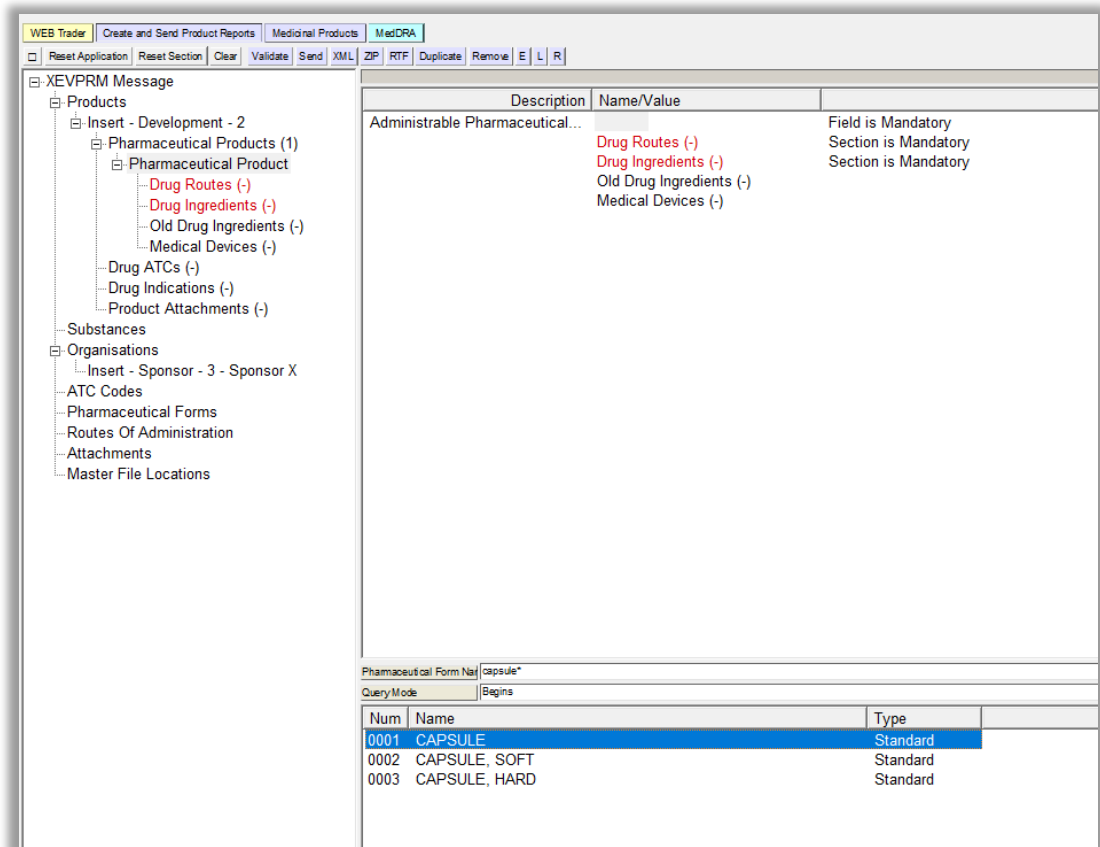


- Type in the required value; it is recommended to also use one of the wild cards (*) to widen the search:

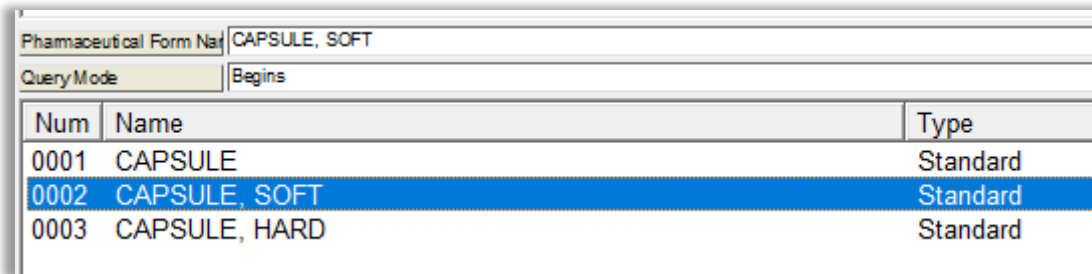


- Press "Enter".

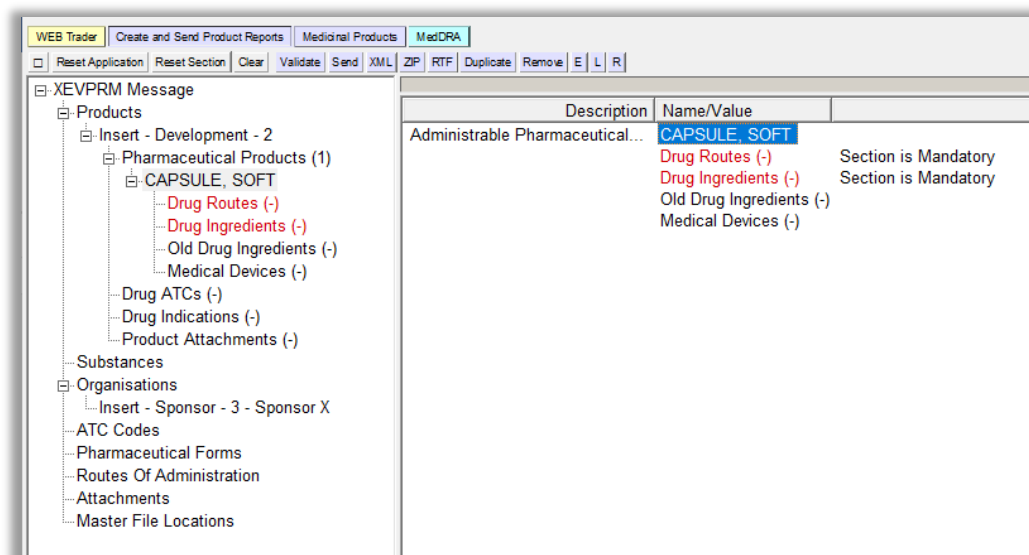
The list of available values will be displayed; the first row of the results is highlighted in blue:



- Select the required pharmaceutical form, so it is highlighted in blue:



- Double-click or press "Enter" on your keyboard and the selected value will be displayed in the "Administrable Pharmaceutical Form" field:



- ✚ If the required **pharmaceutical form name does not exist in the XEVMPD**, you should check if the pharmaceutical form name is re-mapped to another pharmaceutical form [see the tab '**Re-mapped_PDFs**' of the '[Extended EudraVigilance product report message \(XEVMPD\) pharmaceutical dose forms](#)' list].

If yes, reference the name of the pharmaceutical form to which the term was re-mapped in your DMP instead.

If not:

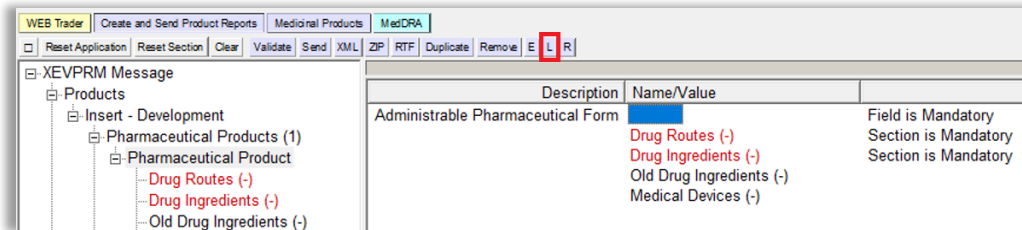
- Request the addition of a standard or proposed pharmaceutical form name in the XEVMPD via an **a change request submitted via the Referentials Management System (RMS) portal** as per information in section 5.1. *Request for an insert of a standard or proposed pharmaceutical form* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).

Once your request is processed by the RMS data stewards and an EV Code is assigned, you can retrieve the standard/proposed pharmaceutical form name from the **remote look-up table**.

- Submit a new development pharmaceutical form name in the XEVMPD via the same XEVPRM, if the pharmaceutical form is still under development in a clinical trial and therefore considered confidential, and then reference the pharmaceutical form name using the **local look-up table**.

See section *Insert of a development pharmaceutical form in the same XEVPRM* of this document for further information.

To reference a pharmaceutical form name from the local look-up table, click on the area next to "Administrable pharmaceutical form"; the area will become highlighted in blue. Then click on 'L':



The local look-up list will be displayed, and you will be able to select the pharmaceutical form that you inserted via the same XEVPRM.

Drug Routes

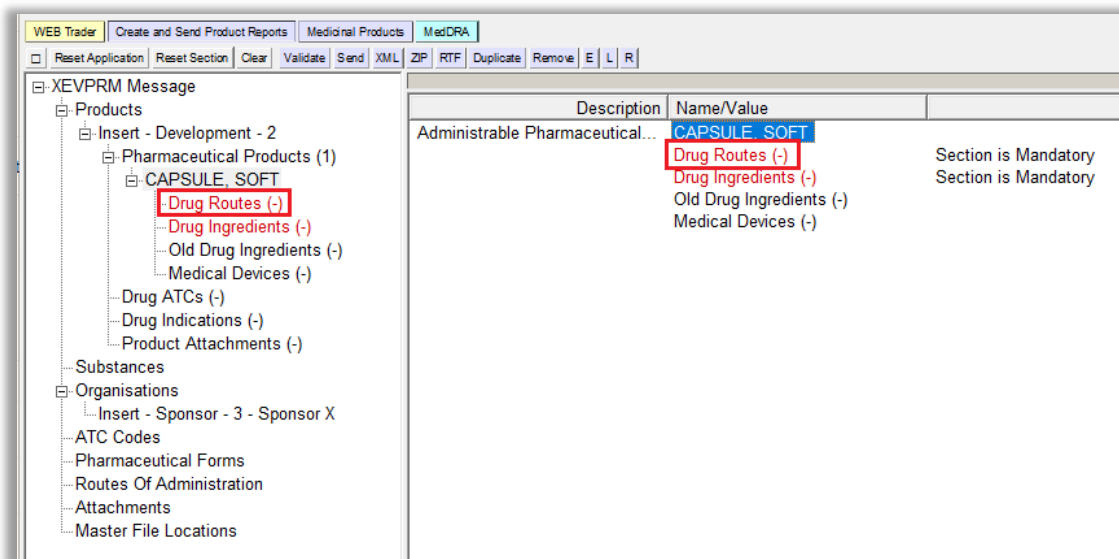
The administration route section describes the route(s) of administration i.e., the path by which the medicinal product (described as technical concept of a “pharmaceutical product”) is taken into or makes contact with the body.

This is a repeatable section.

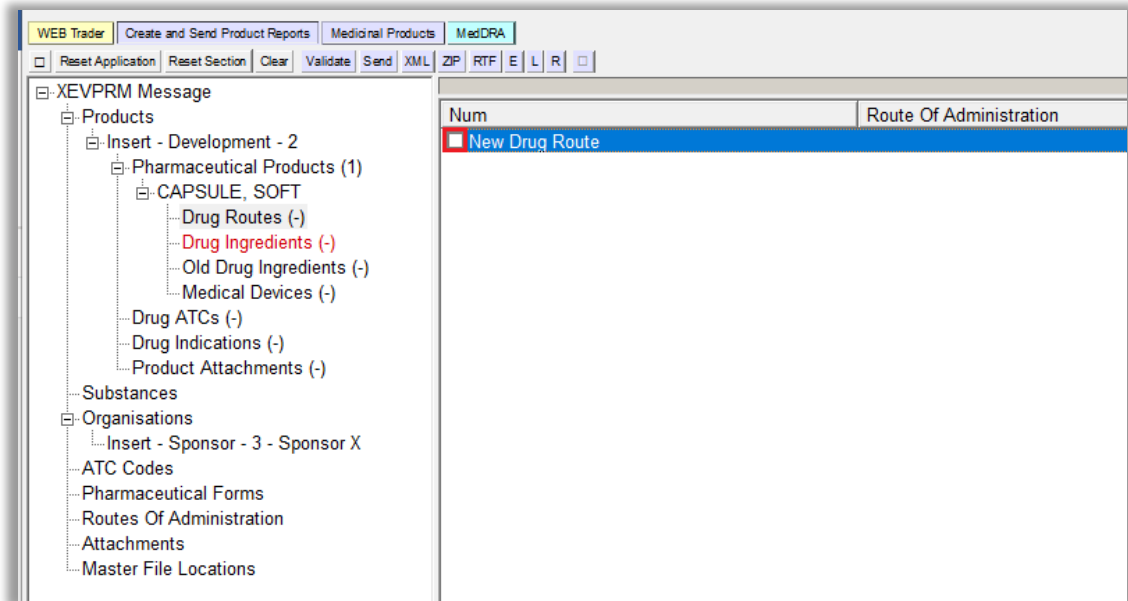
In our case, the IB makes a reference to “Soft capsule for oral use”. The correct **standard term** corresponding to “oral use” is “oral use”. This standard term should therefore be referenced in the DMP as the route of administration.

- An overview of how/when to select standard, proposed or development term of the required route of administration, or when/how to request the insert of a new route of administration in the XEVMPD, is described in *Process map 5: How to reference a route of administration term in a DMP* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).

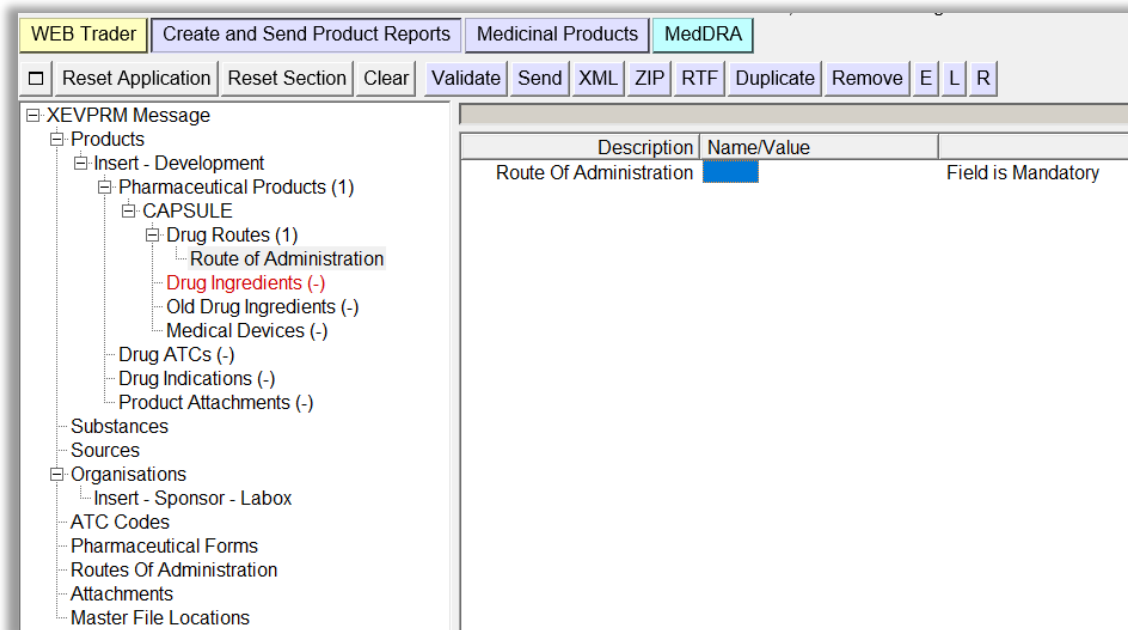
1) Click on the “Drug Routes” section within the pharmaceutical product in the tree-view area, or on “Drug Routes” in the active area:



2) Select "New Drug Route" by ticking the relevant box in the active area:



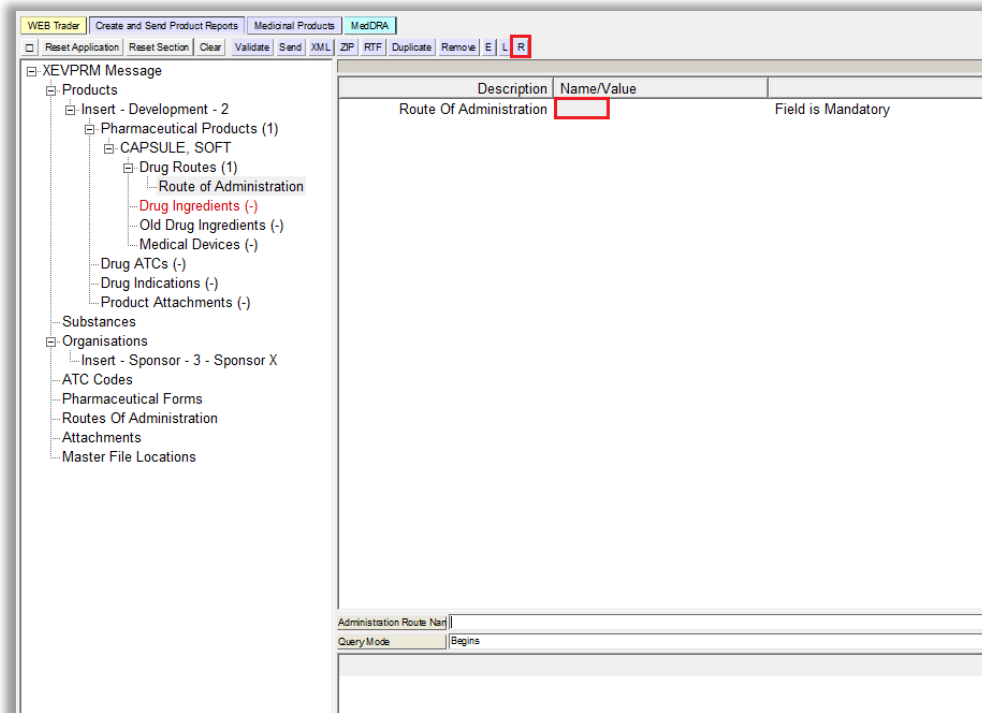
The active area will display the field (highlighted in blue) in which the route of administration of the pharmaceutical product must be specified based on the available values:



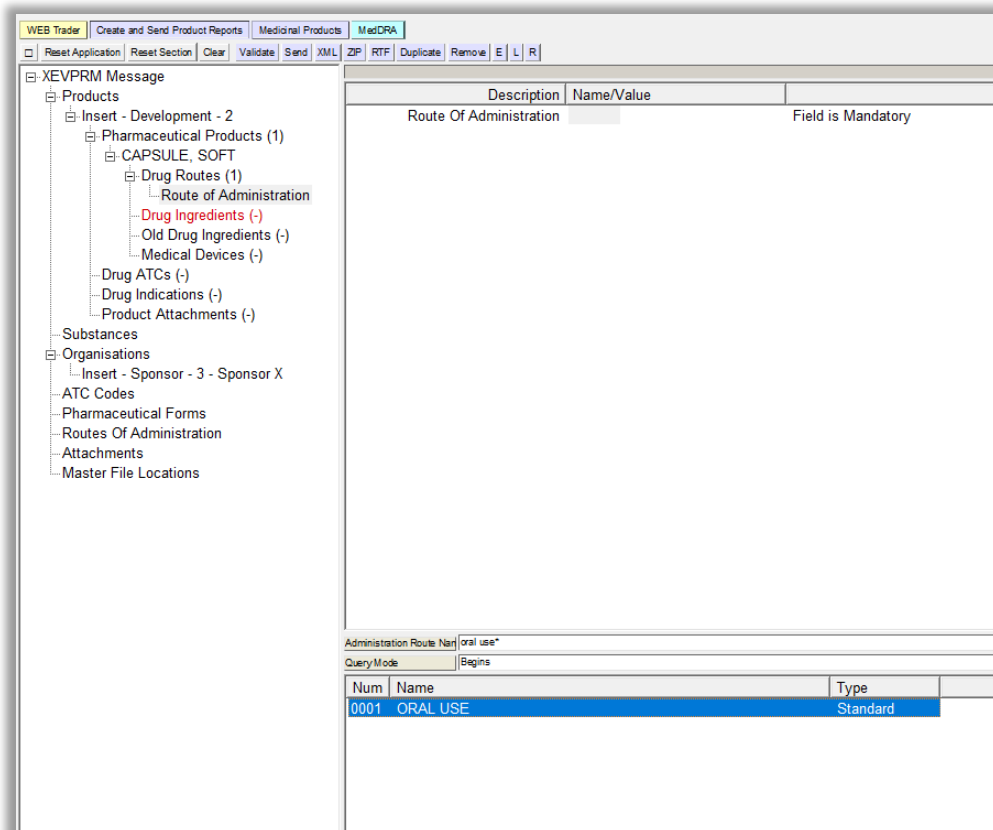
3) Search for the required route of administration using the remote or local look-up table:

- ✚ If the required **route of administration name exists in the XEVMPD** and an EV Code is already assigned, or to check if the route of administration name already exists in the XEVMPD, search the **remote look-up table**:

- Press "Enter" on your keyboard, double-click on the field, or click on the "R" (Remote look-up) button and the remote look-up search area becomes available:



- Type in the required value; it is recommended to also use one of the wild cards (*) to widen the search:



- Press "Enter".

The list of available values will be displayed; the first row of the results is highlighted in blue:

Administration Route Name		ORAL USE
Query Mode		Begins
Num	Name	Type
0001	ORAL USE	Standard

- Select the required pharmaceutical form, so it is highlighted in blue:

Administration Route Name		ORAL USE
Query Mode		Begins
Num	Name	Type
0001	ORAL USE	Standard

- Double-click or press "Enter" on your keyboard and the selected name will be displayed in the "Route of Administration" field:

The screenshot shows the MedDRA interface. On the left is a tree view with the following structure:

- [-] XEVPRM Message
 - [-] Products
 - [-] Insert - Development - 2
 - [-] Pharmaceutical Products (1)
 - [-] CAPSULE, SOFT
 - [-] Drug Routes (1)
 - ORAL USE
 - Drug Ingredients (-)
 - Old Drug Ingredients (-)
 - Medical Devices (-)
 - Drug ATCs (-)
 - Drug Indications (-)
 - Product Attachments (-)
 - Substances
 - [-] Organisations
 - [-] Insert - Sponsor - 3 - Sponsor X
 - ATC Codes
 - Pharmaceutical Forms
 - Routes Of Administration
 - Attachments
 - Master File Locations

On the right is a table with the following content:

Description	Name/Value
Route Of Administration	ORAL USE

- ✚ If the required **route of administration name does not exist in the XEVMPD**, you should check if the route of administration is re-mapped to another route of administration [see the tab '**Re-mapped_RoAs**' of the [EudraVigilance eXtended Medicinal Product Dictionary \(XEVMPD\) routes of administration list](#)].

If yes, reference the name of the route of administration to which the term was re-mapped instead.

If not:

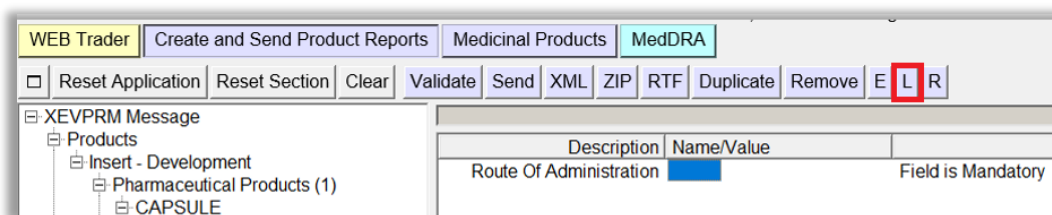
- Request the addition of a standard or proposed route of administration name in the XEVMPD via an **a change request submitted via the Referentials Management System (RMS) portal** as per information in section 6.1. *Request for an insert of a standard or proposed route of administration of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).*

Once your request is processed by the RMS data stewards and an EV Code is assigned, you can retrieve the standard/proposed pharmaceutical form name from the **remote look-up table**.

- Submit a new development route of administration name in the XEVMPD via the same XEVPRM, if the route of administration is still under development in a clinical trial and therefore considered confidential, and then reference the route of administration name using the **local look-up table**.

See section *Insert of a development route of administration in the same XEVPRM* of this document for further information.

To reference a route of administration name from the local look-up table, click on the area next to "Route of Administration"; the area will become highlighted in blue. Then click on 'L':



The local look-up list will be displayed, and you will be able to select the route of administration that you inserted via the same XEVPRM.

You now need to provide information about the active ingredients of the pharmaceutical product.

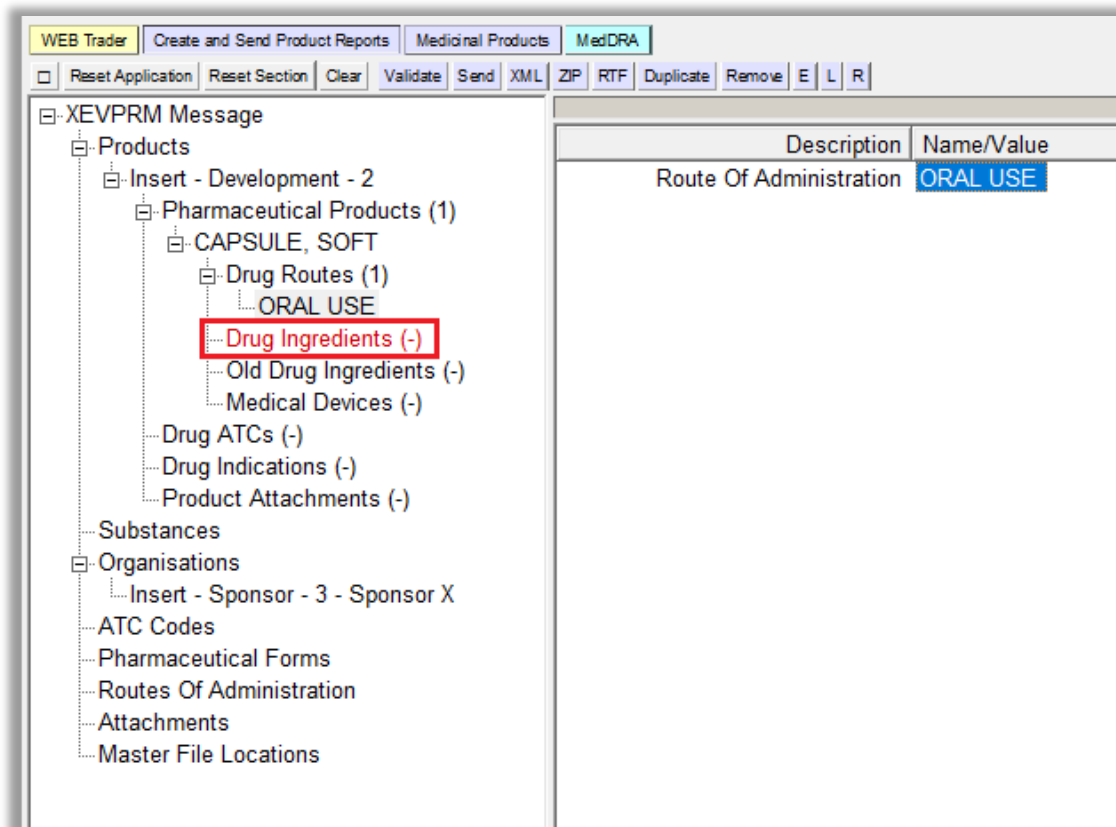
Drug Ingredients

This is a repeatable section.

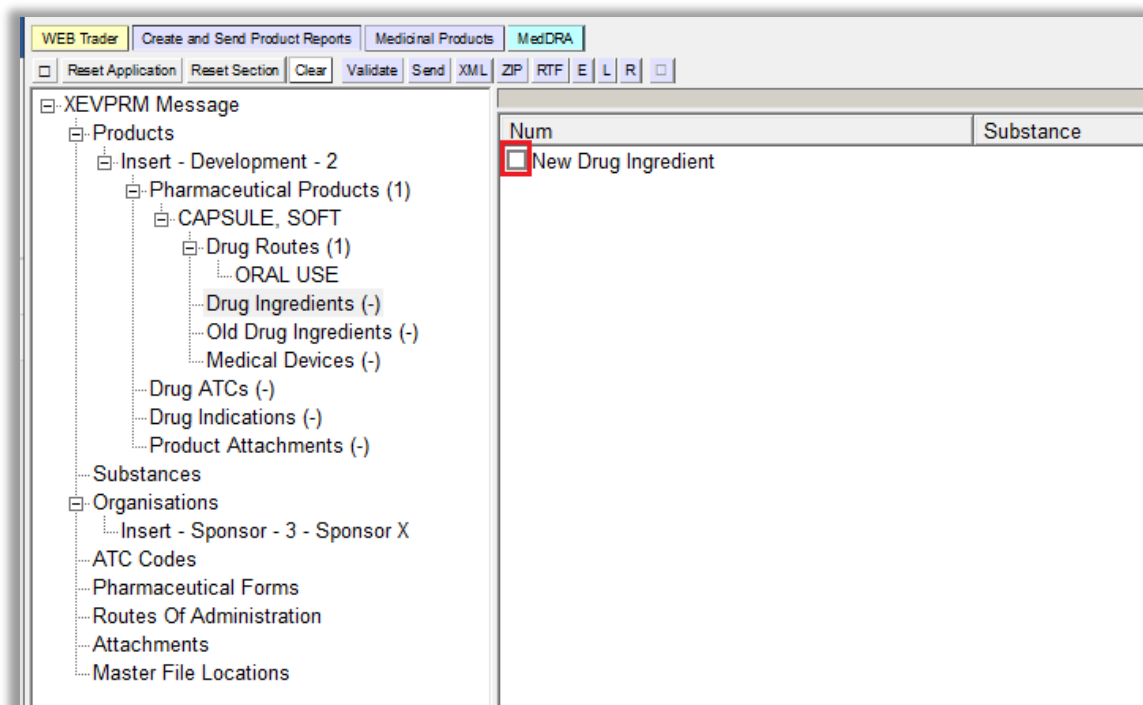
Each pharmaceutical product must contain information on the active ingredient(s), including the active ingredient substance name(s) and its/their concentration(s).

It is not mandatory to provide information on excipients for development medicinal products.

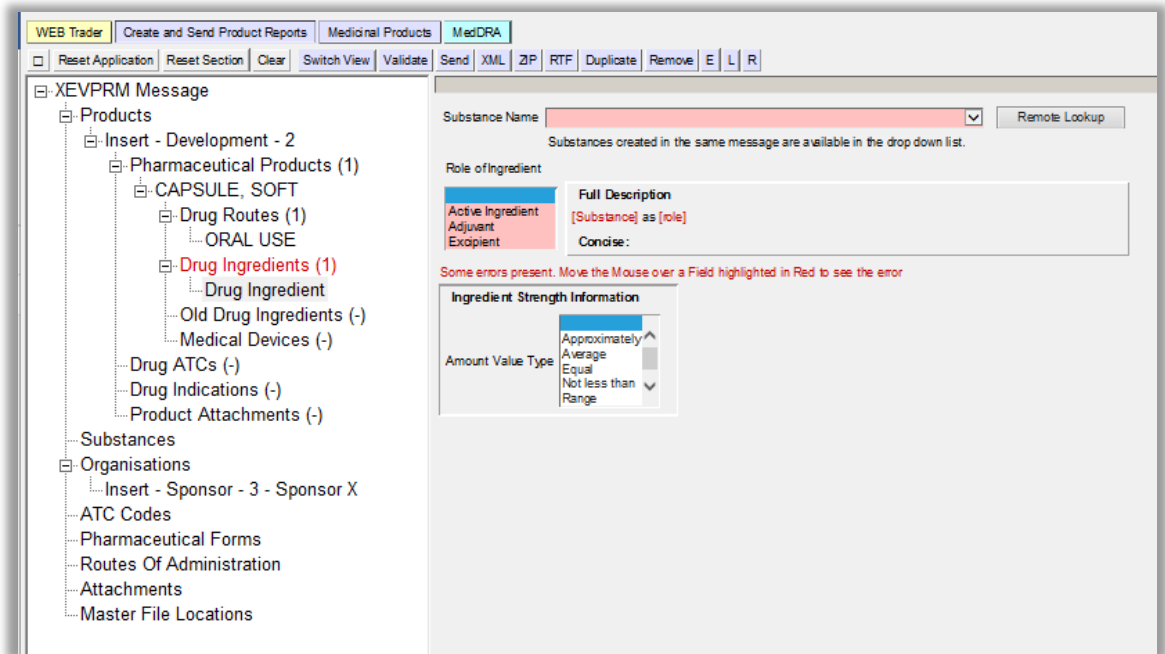
- 1)** Click on "Drug Ingredients" within the "Pharmaceutical Products" section in the tree-view area:



2) Select "New Drug Ingredient" by ticking the relevant box in the active area:

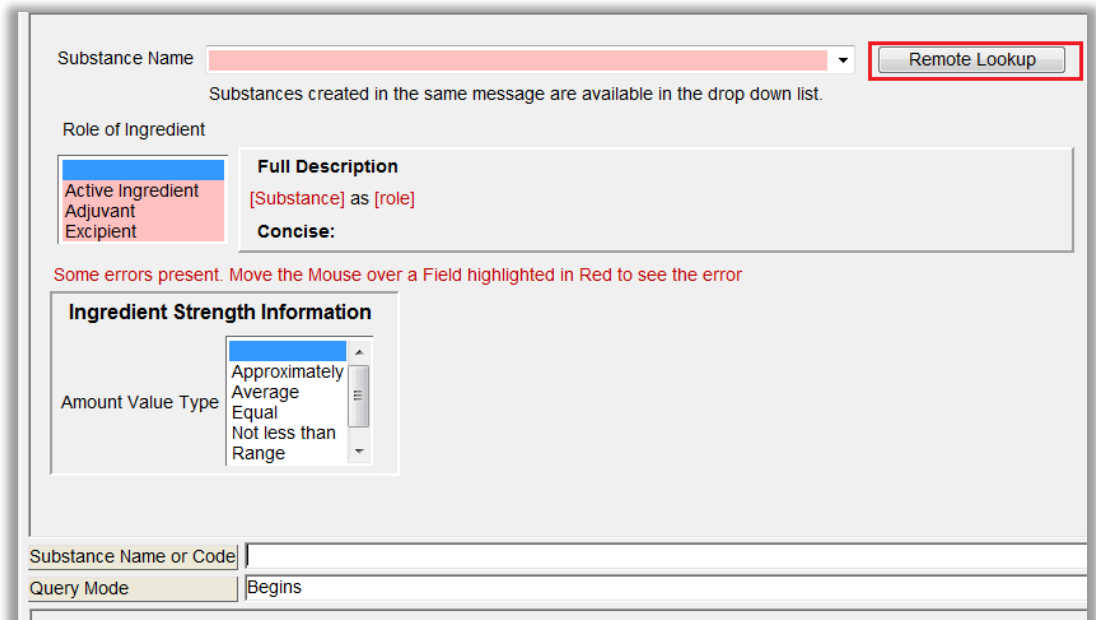


The active area will display the fields applicable for the composition of the (administrable) pharmaceutical product:



3) Search for the required substance name using the remote look-up table:

- ✚ If the required **substance name exists in the XEVMPD** and an EV Code is already assigned, or to check if the name already exists in the XEVMPD, search the **remote look-up table**:
 - Click on the **Remote look-up** button and the remote look-up search area becomes available.



- Type in the substance name (you can also use some of the wild cards, such as *) and press "Enter".

In our case, the IB states that the pharmaceutical product contains the following active ingredients: "100 mg of Paracetamol" and "100 mg of SubstanceXYZ".

The list of available values will be displayed:

Substance Name or Code: paracetamol*						
Query Mode: Begins						
Num	Name	Language	Type	Validated	EV Code	
0001	Paracetamol	Portuguese	Approved	14/10/2004 12:05:48	SUB09611MIG	
0002	Paracetamol	Spanish	Approved	14/10/2004 12:05:48	SUB09611MIG	
0003	PARACETAMOL	English	Approved	14/10/2004 12:05:48	SUB09611MIG	

- Select the required substance name so it is highlighted in blue:

Substance Name or Code: PARACETAMOL						
Query Mode: Begins						
Num	Name	Language	Type	Validated	EV Code	
0001	Paracetamol	Portuguese	Approved	14/10/2004 12:05:48	SUB09611MIG	
0002	Paracetamol	Spanish	Approved	14/10/2004 12:05:48	SUB09611MIG	
0003	PARACETAMOL	English	Approved	14/10/2004 12:05:48	SUB09611MIG	

- Double-click or press "Enter" on your keyboard and the selected substance name will be displayed in the "Substance Name" field:

Substance Name:

Substances created in the same message are available in the drop down list.

Role of Ingredient

Active Ingredient	Full Description PARACETAMOL as [role] Concise:
Adjuvant	
Excipient	

Some errors present. Move the Mouse over a Field highlighted in Red to see the error

Ingredient Strength Information

Amount Value Type	<input type="text" value=""/> <ul style="list-style-type: none"> Approximately ▲ Average Equal Not less than ▼ Range
-------------------	---

- ✚ If the required **substance** name is not available in the XEVMPD, you should request the insert of a new substance or an update of an existing substance (for example to add an alias or a translation) via the EMA Service Desk using the [Request SMS services](#) form as per the process described in section 8.1. *Request for an insert or an amendment of a substance entity of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).*

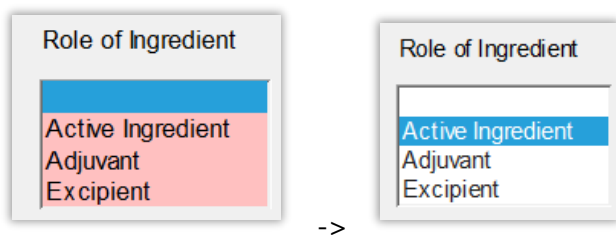
The Substance Management Service (SMS) team will assess the request and insert a new substance, or update an existing substance, as required, in the XEVMPD, and provide you with the EV Code/name of the substance to be referenced in your product entry.

You will then be able to select the required substance name from the remote look-up table.

4) Specify the role of the ingredient.

Since "paracetamol" is one of the two active substances within our pharmaceutical product, we must report this substance as an active ingredient and enter the concentration of this active ingredient.

In the "Role of Ingredient" section, click on the applicable value:



You have now specified that the substance with the name "Paracetamol" is an active ingredient in our administrable pharmaceutical product:

5) Provide the strength information for your ingredient.

The strength must be entered in the XEVMPD in accordance with the ISO IDMP standards based on a numerator and denominator. Strength can be therefore expressed in two ways:

- **As a Unit of Measure:** When the strength of a medicinal product described as a technical concept of a "Pharmaceutical Product" that has undergone a transformation (for example reconstitution) is to be specified, it is to be specified using the strength resulting from transformation undertaken exactly in accordance with the regulated product information.

EXAMPLES of units of measure: 10 milligrams per 100 millilitres, 10 milligrams per 1 single day.

- **As a unit a Presentation:** The unit of presentation is a qualitative term describing the discrete unit in which a "pharmaceutical product" is presented to describe strength or quantity in cases where a quantitative unit of measurement is not appropriate.

Whenever possible, the substance strength should be expressed as a unit of measurement.

See section 1.8.1.2.1. *Active ingredient information* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#) for further information how to correctly report a strength of the active ingredient in the pharmaceutical product.

In our case, the capsule contains 100 mg of paracetamol. Therefore, in the "Ingredient Strength Information" section, 'Equal' should be selected as the correct value:

Substance Name

Substances created in the same message are available in the drop down list.

Role of Ingredient

Active Ingredient
Adjuvant
Excipient

Full Description
 PARACETAMOL as Active Ingredient At [value] [prefix] [unit] per [value] [prefix] [unit]
Concise: PARACETAMOL [value] [prefix][unit]/[value] [prefix][unit]

Ingredient Strength Information

Amount Value Type: Expressed as:

Exact Value

	Value	Prefix	Unit
Numerator	<input type="text"/>	<input type="text"/>	<input type="text"/>
Denominator	<input type="text"/>	<input type="text"/>	<input type="text"/>

You are prompted to select whether the concentration (of the active ingredient) should be expressed as "Units of Measure" or "Units of Presentation".

As per our DMP example specification, the capsule contains 100 mg of Paracetamol (active ingredient) and you should therefore enter the concentration of the active ingredient as a unit of presentation.

Click on "Units of Presentation":

Substance Name

Substances created in the same message are available in the drop down list.

Role of Ingredient

Active Ingredient
Adjuvant
Excipient

Full Description
 PARACETAMOL as Active Ingredient At [value] [prefix] [unit] per [value] [prefix] [unit]
Concise: PARACETAMOL [value] [prefix][unit]/[value] [prefix][unit]

Ingredient Strength Information

Amount Value Type: Expressed as:

Exact Value

	Value	Prefix	Unit
Numerator	<input type="text"/>	<input type="text"/>	<input type="text"/>
Denominator	<input type="text"/>	<input type="text"/>	<input type="text"/>

The **numerator value** is a free-text field. Type in the requested value:

Substance Name: PARACETAMOL Remote Lookup

Substances created in the same message are available in the drop down list.

Role of Ingredient

Active Ingredient	Full Description
Adjuvant	PARACETAMOL as Active Ingredient At 100 [prefix] [unit] per [value] [prefix] [unit]
Excipient	Concise: PARACETAMOL 100 [prefix][unit]/[value] [prefix][unit]

Ingredient Strength Information

Amount Value Type: Approximately Average **Equal** Not less than Range Expressed as: Units of Measure **Units of Presentation**

Exact Value

	Value	Prefix	Unit
Numerator	100		
Denominator			of Presentation

The **numerator prefix** is a look-up list containing pre-defined values. Click on the arrow and select the requested value:

Substance Name: PARACETAMOL Remote Lookup

Substances created in the same message are available in the drop down list.

Role of Ingredient

Active Ingredient	Full Description
Adjuvant	PARACETAMOL as Active Ingredient At 100 milli [unit] per [value] [prefix] [unit]
Excipient	Concise: PARACETAMOL 100 m[unit]/[value] [prefix][unit]

Ingredient Strength Information

Amount Value Type: Approximately Average **Equal** Not less than Range Expressed as: Units of Measure **Units of Presentation**

Exact Value

	Value	Prefix	Unit
Numerator	100	milli (1x10 ⁻³)	
Denominator			of Presentation

The numerator prefix value is now displayed in the "Prefix" section:

Exact Value

	Value	Prefix	Unit
Numerator	100	milli (1x10 ⁻³)	
Denominator			of Presentation

The **numerator unit** is a look-up list containing pre-defined values. Click on the arrow and select the requested value:

The screenshot shows a software interface with a dropdown menu open. The dropdown list contains the following items: Gram(s), International Unit(s), Percent, Litre(s), Mole(s), 50% Embryo Infective Dose, Allergen Unit, Allergen Unit For Ambrosia Artemisiifolia, Allergy Unit Equivalent (AUeq), Allergy Unit Modified (AUM), Allergy Unit Nominal (AUN), Allergy Unit(s), Ampere, Anti-Thrombin Unit(s), Anti-Xa Activity International Unit(s), Antigen Unit(s), APL Unit(s), Arbitrary Unit(s), Becquerel(s), Bethesda Unit(s), Bioequivalent Allergy Unit(s), Biological Allergy Unit (BAU), Bodansky Unit(s), British Pharmacopoeia Unit, BU (Biological Unit), Candela, Cell Culture Infective Dose 50, Cells, and Celsius Temperature. The 'Gram(s)' option is selected and highlighted in blue. In the background, the 'Substance Name' field contains 'PARACETAMOL', and the 'Role of Ingredient' dropdown is set to 'Active Ingredient'. The 'Ingredient Strength Information' section shows 'Amount Value Type' set to 'Equal' and 'Expressed as' set to 'Range'. The 'Exact Value' section has 'Numerator' set to '100' and 'Prefix' set to 'milli (1x10⁻³)'.

The numerator unit value is now displayed in the “Unit” section:

The screenshot shows the 'Exact Value' section of the software interface. It has a table-like structure with columns for 'Value', 'Prefix', and 'Unit'. The 'Numerator' row has '100' in the 'Value' column, 'milli (1x10⁻³)' in the 'Prefix' column, and 'Gram(s)' in the 'Unit' column. The 'Denominator' row has empty fields for 'Value', 'Prefix', and 'Unit'. There is also a 'of Presentation' dropdown menu.

The **denominator value** is a free-text field. Type in the requested value:

The screenshot shows the 'Exact Value' section of the software interface. The 'Denominator' field now contains the value '1'. The 'Numerator' field still contains '100' and the 'Prefix' dropdown still contains 'milli (1x10⁻³)'. The 'Unit' dropdown still contains 'Gram(s)'. The 'of Presentation' dropdown menu is also visible.

The **denominator prefix** is a look-up list containing pre-defined values. Click on the arrow and select the requested value:

Substance Name: PARACETAMOL Remote Lookup

Substances created in the same message are available in the drop down list.

Role of Ingredient

- Active Ingredient
- Adjuvant
- Excipient

Ingredient Strength Information

Amount Value Type: Full PARA Conc

Exact Value

Numerator: 100

Denominator: 1

Unit: Gram(s)

of Presentation

Ingredient At 100 milli Gram(s) per [prefix] [unit]

ETAMOL 100 mg/[prefix][unit]

Units of Measure

Units of Presentation

The denominator prefix value is now displayed in the "Prefix" section:

Exact Value

Value	Prefix	Unit
Numerator: 100	milli (1x10 ⁻³)	Gram(s)
Denominator: 1	single	of Presentation

The **denominator unit** is a look-up list containing pre-defined values. Click on the arrow and select the requested value; in our case, this should be "capsule":

Substance Name: PARACETAMOL Remote Lookup

Substances created in the same message are available in the drop down list.

Role of Ingredient

- Active Ingredient
- Adjuvant
- Excipient

Full Description

PARACETAMOL as Active Ingredient

Concise: PARACETAMOL

Ingredient Strength Information

Amount Value Type: Approximately Average Equal Not less than Range

Expressed as

Exact Value

Value	Prefix	Unit
Numerator: 100	milli (1x10 ⁻³)	Gram(s)
Denominator: 1	single	of Presentation

Tablet

Capsule

Vial

Dose

Actuation

Ampoule

Applicator

Bag

Bar

Bead

Blister

Blister Pack

Block

Bolus

Bottle

Box

Can

Carton

Cartridge

Container

Cup

Cylinder

Disk

Drop

Film

Globule

Homeopathic Dilution

Implant

Impregnated Dressing

The denominator unit value is now displayed in the "Unit" section, and you have now recorded that one capsule contains 100 mg of the active substance paracetamol:

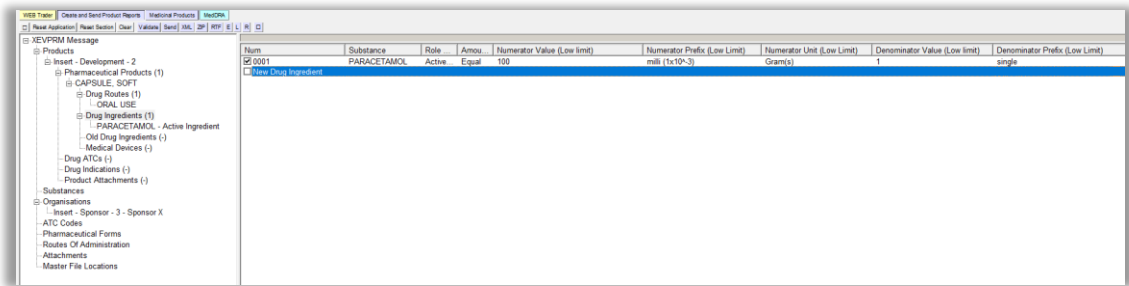
The screenshot shows a configuration form for the substance PARACETAMOL. At the top, the Substance Name is set to PARACETAMOL. Below this, the Role of Ingredient is set to Active Ingredient. The Full Description is "PARACETAMOL as Active Ingredient At 100 milli Gram(s) per Capsule (1{CAPSULE})". The Concise description is "PARACETAMOL 100 mg/Capsule". The Ingredient Strength Information section shows the Amount Value Type set to Equal, Expressed as Units of Presentation. The Exact Value section shows a Numerator of 100, a Prefix of milli (1x10^-3), and a Unit of Gram(s) of Presentation, with a Denominator of 1 and a unit of single Capsule.

Since our administrable pharmaceutical product contains not one but two active ingredients, you will also need to add information related to the second active substance, which is "100 mg of SubstanceXYZ".

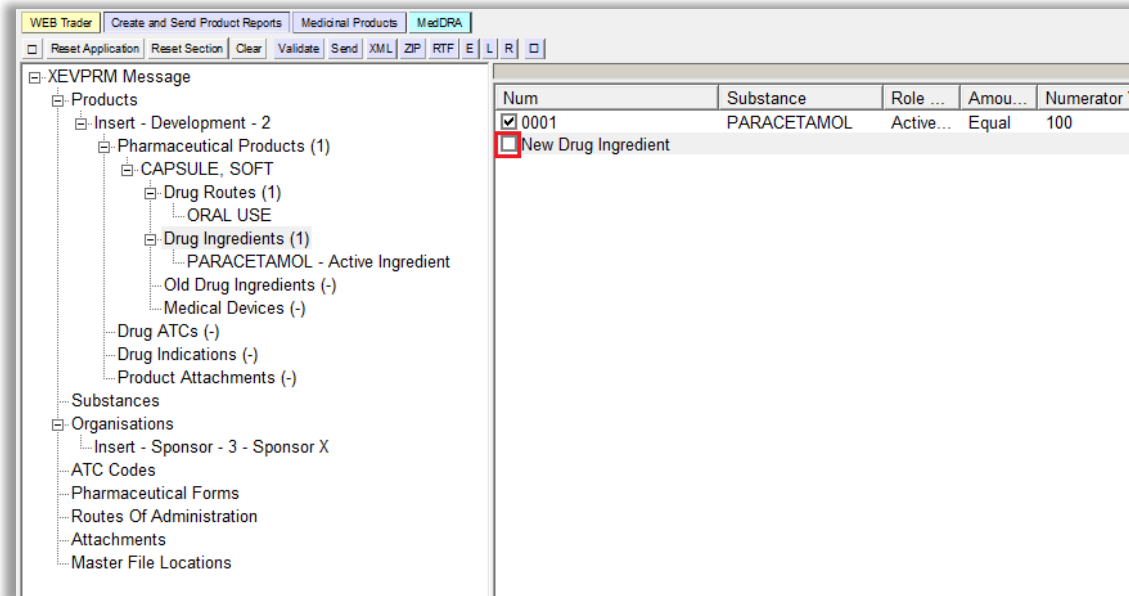
In the tree-view area, within the "Pharmaceutical Products" section, click on the text "Drug Ingredients":

The screenshot shows the XEVPRM Message tree view on the left and the configuration form on the right. The tree view shows the following structure: XEVPRM Message > Products > Insert - Development - 2 > Pharmaceutical Products (1) > CAPSULE, SOFT > Drug Routes (1) > ORAL USE > Drug Ingredients (1) > PARACETAMOL - Active Ingredient. The configuration form on the right is the same as the one in the previous screenshot, showing the details for PARACETAMOL.

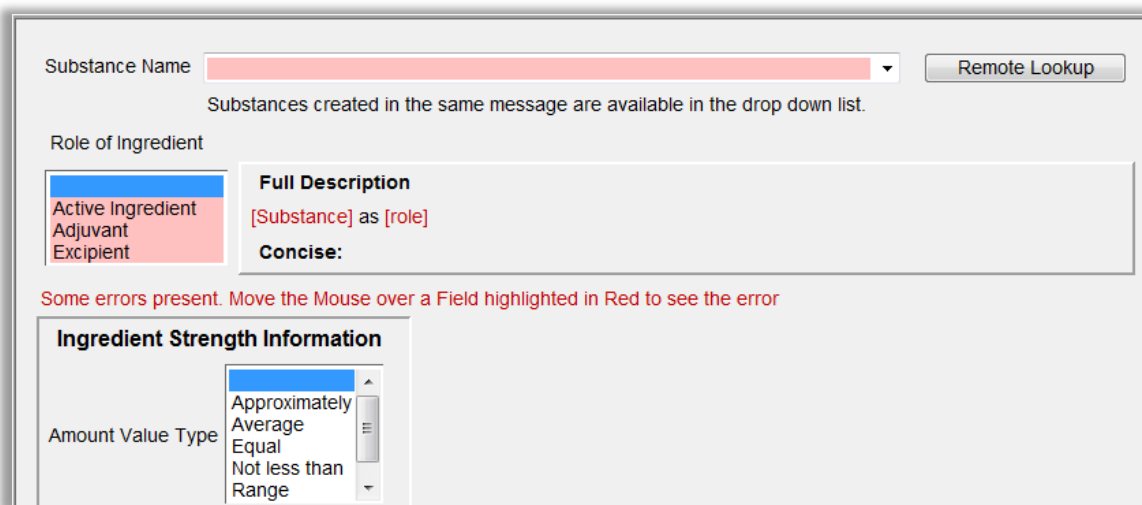
The active are displays the previously entered substance name, its role and concentration:



Select "New Drug Ingredient" by ticking the relevant box:



The active area will display the fields applicable for the composition of the (administrable) pharmaceutical product:



By clicking on the "Remote Lookup", the search area, where you can query values available for this field (i.e., substance names) will be displayed:

Substance Name

Substances created in the same message are available in the drop down list.

Role of Ingredient

Active Ingredient	Full Description [Substance] as [role] Concise:
Adjuvant	
Excipient	

Some errors present. Move the Mouse over a Field highlighted in Red to see the error

Ingredient Strength Information

Amount Value Type	<input type="text"/> Approximately Average Equal Not less than Range
-------------------	---

Substance Name or Code |

Query Mode | Begins

Type in the name of the required substance (you can also use some of the wild cards, such as *) and press "Enter":

Substance Name Remote Lookup

Substances created in the same message are available in the drop down list.

Role of Ingredient

Active Ingredient	Full Description [Substance] as [role] Concise:
Adjuvant	
Excipient	

Some errors present. Move the Mouse over a Field highlighted in Red to see the error

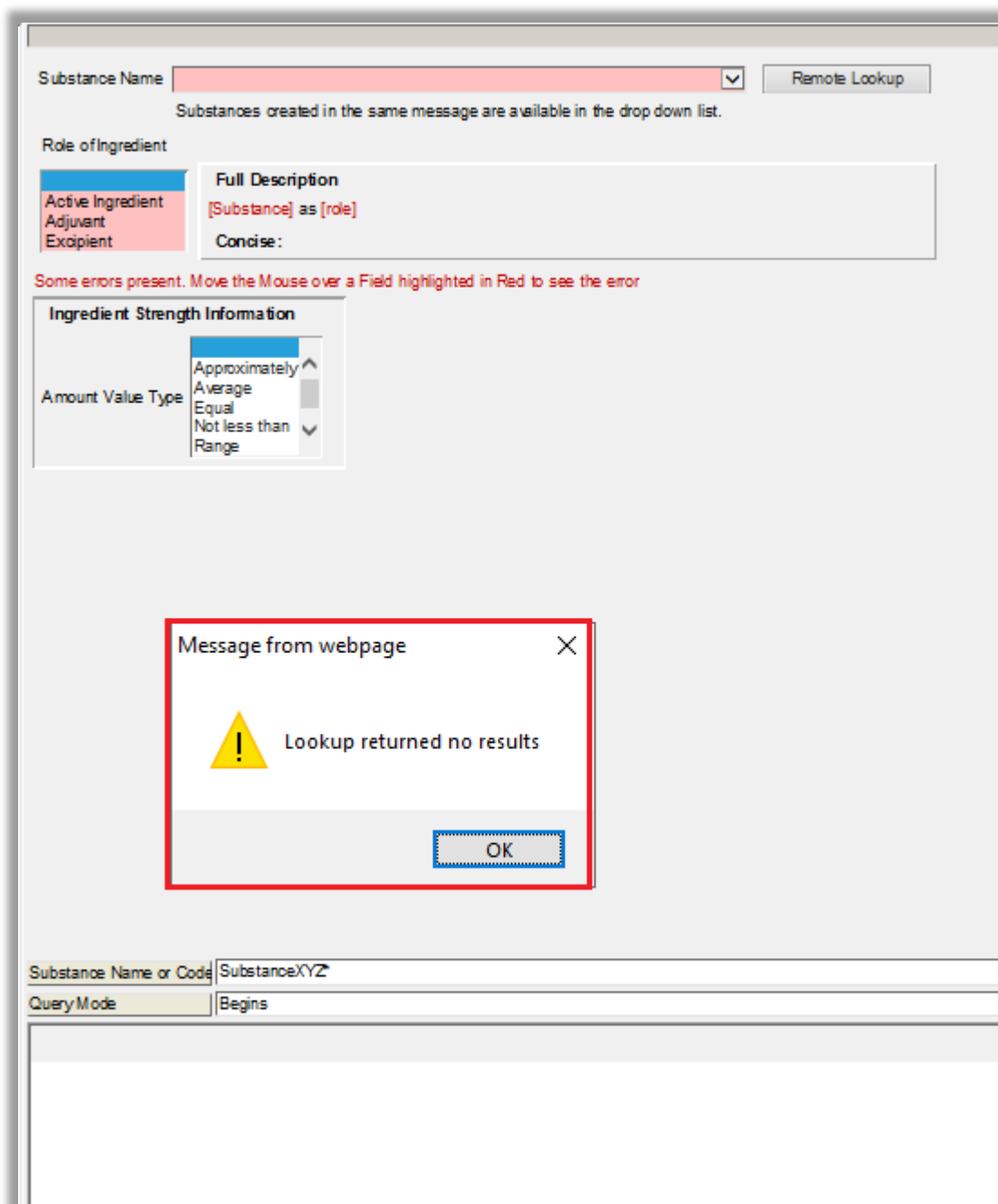
Ingredient Strength Information

Amount Value Type	Approximately ^ Average Equal Not less than v Range
-------------------	---

Substance Name or Code: SubstanceXYZ

Query Mode: Begins

In case the substance name cannot be found in the look-up list, a warning message is displayed:



This indicates that the required substance name is not available in the XEVMPD.

You should therefore request the addition of a new substance name by following the process described in section 8.1. *Request for an insert or an amendment of a substance entity* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).

When the required substance name is available in the XEVMPD, you should repeat [steps 1 – 5](#) described in this section to enter information related to the second active substance:

Substance Name

Substances created in the same message are available in the drop down list.

Role of Ingredient

Active Ingredient
 Adjuvant
 Excipient

Full Description
 SUBSTANCEXYZ as Active Ingredient At 100 milli Gram(s) per Capsule
Concise: SUBSTANCEXYZ 100 mg/Capsule

Ingredient Strength Information

Amount Value Type:

Expressed as:

Exact Value

	Value	Prefix	Unit
Numerator	<input type="text" value="100"/>	<input type="text" value="milli (1x10<sup>-3</sup>)"/>	<input type="text" value="Gram(s)"/>
Denominator	<input type="text" value="1"/>	<input type="text" value="single"/>	<input type="text" value="Capsule"/>

Our DMP now references one pharmaceutical product with two active ingredients:

WEB Tools: [Create and Send Product Name](#) | [Medicinal Products](#) | [Insights](#)

[New](#) | [Update](#) | [View Details](#) | [Close](#) | [Validate](#) | [Send](#) | [Print](#) | [Help](#) | [Close](#)

IEVPRM Message

Num	Substance	Rate	Amou	Numerator Value (Low Limit)	Numerator Prefix (Low Limit)	Numerator
<input checked="" type="checkbox"/> 0001	PARACETAMOL	Active	Equal	100	milli (1x10 ⁻³)	Gram(s)
<input checked="" type="checkbox"/> 0002	SUBSTANCEXYZ	Active	Equal	100	milli (1x10 ⁻³)	Gram(s)
<input type="checkbox"/>	New Drug Ingredient					

Products
 Insert - Development - 2
 Pharmaceutical Products (1)
 CAPSULE, SOFT
 Drug Routes (1)
 ORAL USE
 Drug Ingredients (2)
 PARACETAMOL - Active Ingredient
 SUBSTANCEXYZ - Active Ingredient
 Old Drug Ingredients (-)
 Medical Devices (-)
 Drug ATCs (-)
 Drug Indications (-)
 Product Attachments (-)
 Substances
 Organisations
 Insert - Sponsor - 3 - Sponsor X
 ATC Codes
 Pharmaceutical Forms
 Routes Of Administration
 Attachments
 Master File Locations

Drug ATC

This is a repeatable section.

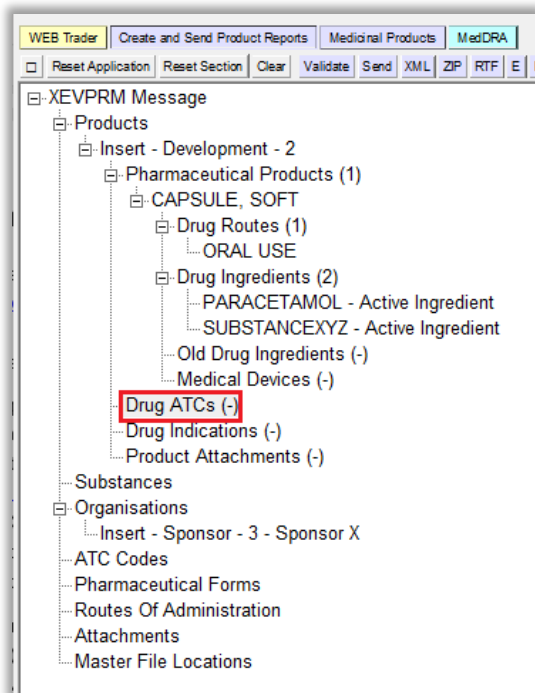
It is not mandatory to provide an ATC Code in a DMP entity. Should you wish to do so, the below described process should be followed.

In our case, we will reference the ATC Code "N02BE01" corresponding to "paracetamol", which is available in the XEVMPD as a standard ATC Code.

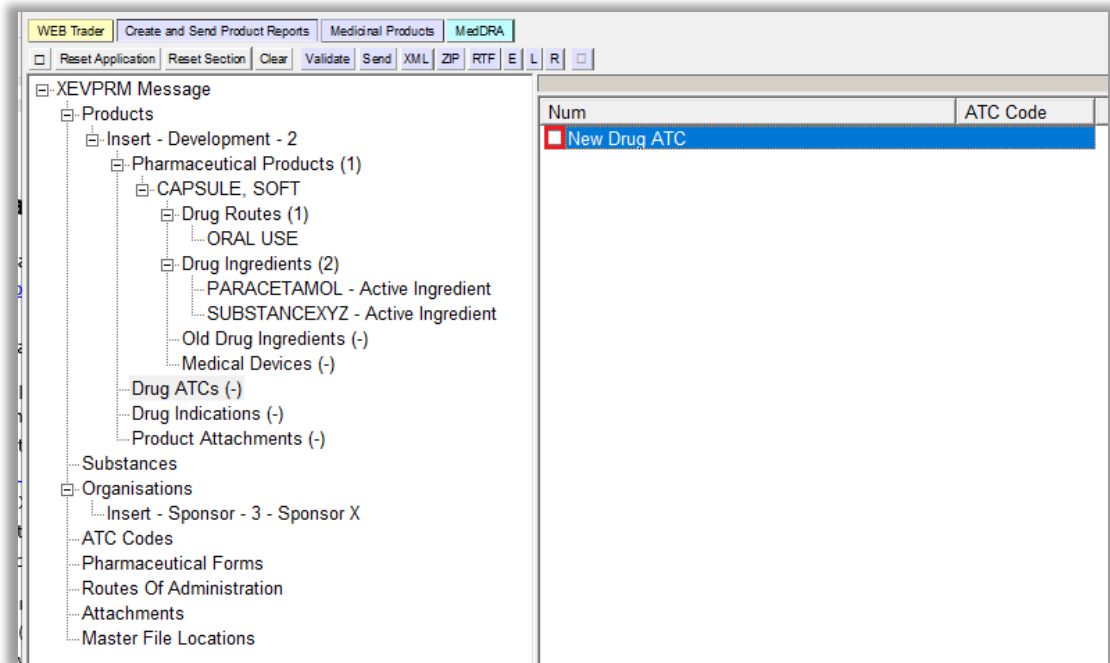
An overview of how/when to select standard, proposed or development term of the required ATC Code, or when/how to request the insert of a new ATC Code in the XEVMPD, is described in *Process map 6: How to reference an ATC Code in a DMP* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).

To reference an ATC code in the DMP

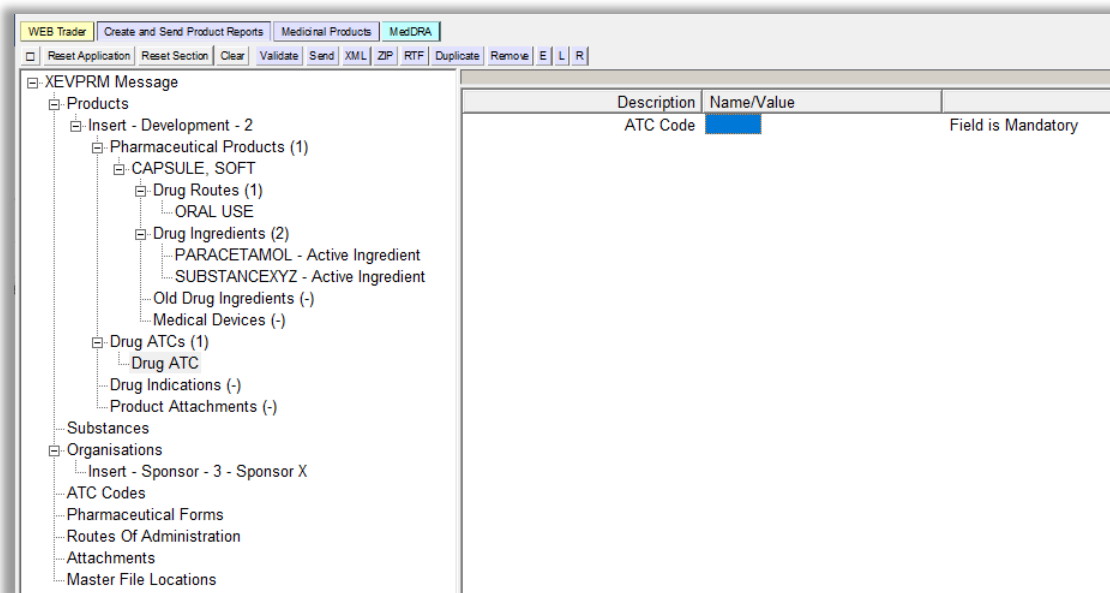
1) Click on 'Drug ATCs' section in the tree-view area:



2) Select 'New Drug ATC' in the active area:



The area next to 'ATC Code' will be highlighted in blue:



3) Search for the required ATC Code using the remote or local look-up table:

✚ If the required **ATC Code exists in the XEVMPD**, or to check if the ATC Code already exists in the XEVMPD, search the **remote look-up table**:

- Press "Enter" on your keyboard, double-click on the field, or click on the "R" (Remote look-up) button and the remote look-up search area becomes available:

Description	Name/Value
ATC Code	<input type="text"/> Field is Mandatory
ATC Code	<input type="text"/>
Query Mode	Begins

- Type in the required value; it is recommended to also use one of the wild cards (*) to widen the search. Then press 'Enter' on your keyboard.

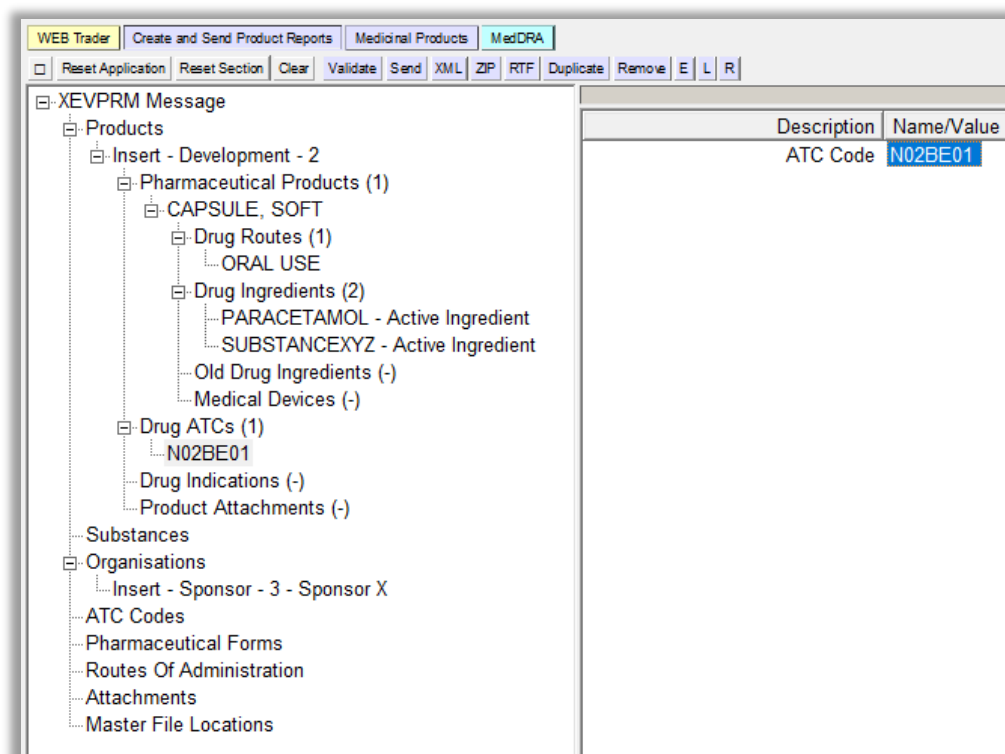
The list of available values will be displayed; the first row of the results is highlighted in blue:

ATC Code	N02BE01		
Query Mode	Begins		
Num	ATC Code	Name	Type
0001	N02BE01	PARACETAMOL	Standard
0002	N02BE99	PARACETAMOL COMBINATIONS	Proposed
0003	N02BE71	PARACETAMOL, COMBINATIONS WITH PSYCHOLEPTICS	Standard
0004	N02BE51	PARACETAMOL, COMBINATIONS EXCL. PSYCHOLEPTICS	Standard

- Select the required ATC code, so it is highlighted in blue:

ATC Code	N02BE01		
Query Mode	Begins		
Num	ATC Code	Name	Type
0001	N02BE01	PARACETAMOL	Standard
0002	N02BE99	PARACETAMOL COMBINATIONS	Proposed
0003	N02BE71	PARACETAMOL, COMBINATIONS WITH PSYCHOLEPTICS	Standard
0004	N02BE51	PARACETAMOL, COMBINATIONS EXCL. PSYCHOLEPTICS	Standard

- Double-click or press "Enter" on your keyboard and the selected value will be displayed in the "ATC Code" field:



✚ If the required **ATC Code does not exist in the XEVMPD** you can:

- Request the addition of a standard or proposed ATC Code in the XEVMPD via [a change request submitted via the Referentials Management System \(RMS\) portal](#) as per information in section 4.1. *Request for an insert of a standard or a proposed ATC Code of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).*

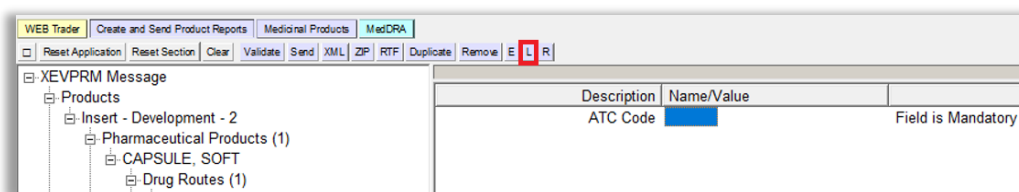
Once your request is processed by RMS data stewards and the ATC Code is available in the XEVMPD, you can retrieve the standard/proposed ATC Code from the **remote look-up table**.

- Submit a new development ATC Code in the XEVMPD via the same XEVPRM if the ATC Code is still considered confidential, and then reference the ATC Code in your DMP entity using the **local look-up table**.

See section *[Inset of a development ATC Code in the same XEVPRM](#)*

of this document for related information.

To reference a development ATC Code from the local look-up table, click on the area next to "ATC Code"; the area will become highlighted in blue. Then click on 'L':



The local look-up list will be displayed, and you will be able to select the development ATC Code that you inserted via the same XEVPRM.

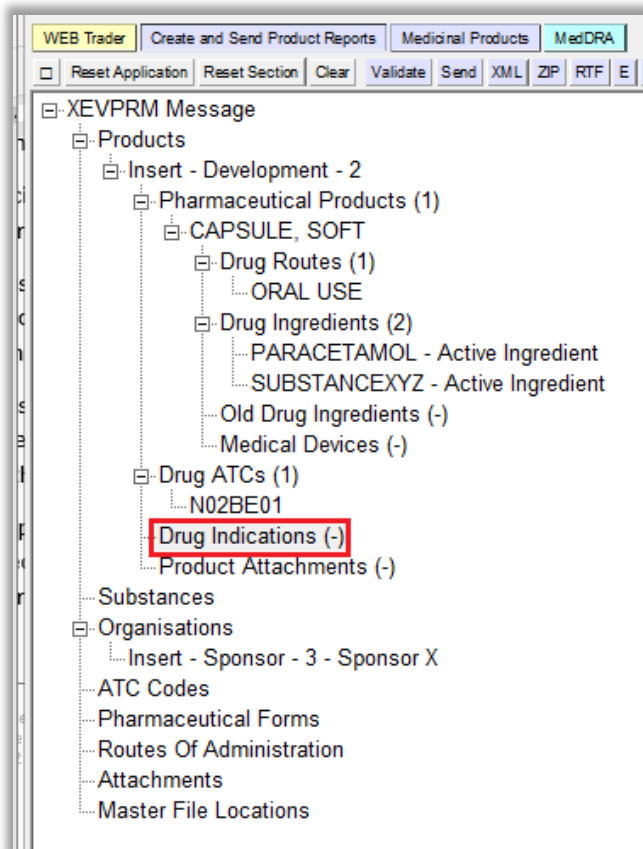
Drug indications

This is a repeatable section.

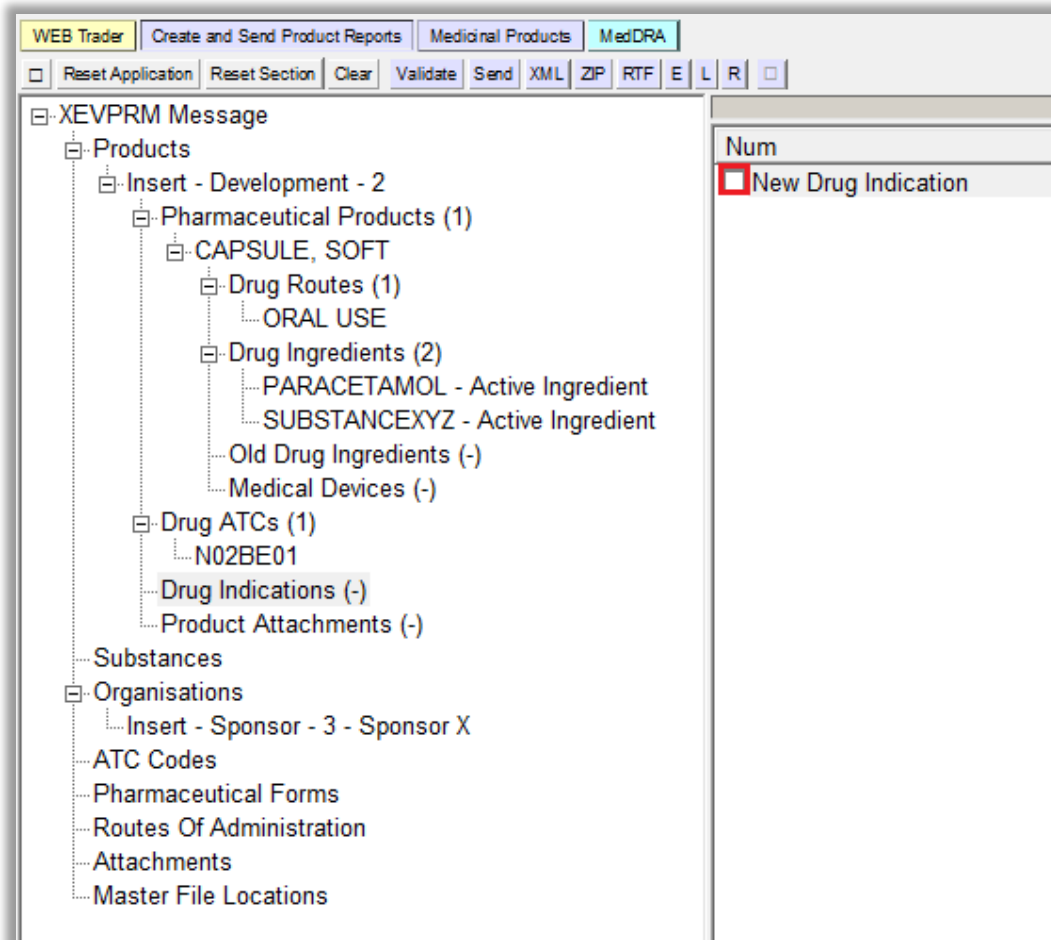
It is not mandatory to provide drug indications information in a DMP entity. Should you wish to do so, the below described process should be followed.

As per our example specifications, the pharmaceutical product is studied as a capsule for the treatment of low back pain.

1) Click on the “Drug Indications” text in the tree-view area:



2) Select “New Drug Indication” by ticking the relevant box in the active area:



The active area will display the fields applicable for MedDRA coding:

Description	Name/Value	
MedDRA Version	[REDACTED]	Field is Mandatory
MedDRA Level		Field is Mandatory
MedDRA Term		Field is Mandatory

3) Enter the information related to MedDRA coding in the individual fields as per guidance provided for each field in section 1.10. *Product indications (DP.INDs)* of the published [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).

MedDRA Version

The area next to the “MedDRA Version” is highlighted in blue:

Description	Name/Value	
MedDRA Version		Field is Mandatory
MedDRA Level		Field is Mandatory
MedDRA Term		Field is Mandatory

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:

Description	Name/Value	
MedDRA/	Select option	Field is Mandatory
MedD		Field is Mandatory
MedD	Press A- Z to find initial letter Press Enter to select, Escape to dear	Field is Mandatory
	25.0	
	25.1	
	26.0	
	26.1	

*Note: the print screens of this document are not updated whenever a new MedDRA version is available and therefore, the MedDRA versions shown in the above screenshot may be outdated. **You should always select the latest MedDRA version available in EVWEB.***

Select the most recent version in use; it will become highlighted in black:

Description	Name/Value	
MedDRA/	Select option	Field is Mandatory
MedD		Field is Mandatory
MedD	Press A- Z to find initial letter Press Enter to select, Escape to dear	
	25.0	
	25.1	
	26.0	
	26.1	

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

Description	Name/Value	
MedDRA Version	26.1	
MedDRA Level		Field is Mandatory
MedDRA Term		Field is Mandatory

MedDRA Level

Click on the area next to the "MedDRA Level". The area will become highlighted in blue:

Description	Name/Value	
MedDRA Version	26.1	
MedDRA Level		Field is Mandatory
MedDRA Term		Field is Mandatory

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:

Description	Name/Value	
MedDRA Version	26.1	
MedD	Select option	Field is Mandatory
MedD	Press A- Z to find initial letter Press Enter to select, Escape to clear Low Level Term Preferred Term High Level Term High Level Group Term System Organ Class	Field is Mandatory

Select 'Low Level Term'; it will become highlighted in black:

Description	Name/Value	
MedDRA Version	26.1	
MedD	Select option	Field is Mandatory
MedD	Press A- Z to find initial letter Press Enter to select, Escape to clear	Field is Mandatory
	Low Level Term	
	Preferred Term	
	High Level Term	
	High Level Group Term	
	System Organ Class	

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

Description	Name/Value	
MedDRA Version	26.1	
MedDRA Level	Low Level Term	
MedDRA Term		Field is Mandatory

MedDRA Term

Click on the area next to the "MedDRA Term". The area will become highlighted in blue:

Description	Name/Value	
MedDRA Version	26.1	
MedDRA Level	Low Level Term	
MedDRA Term		Field is Mandatory

Press "Enter" on your keyboard, double-click on the field, or click on the "R" (Remote look-up) button and the remote look-up search area becomes available:

Description	Name/Value	
MedDRA Version	26.1	
MedDRA Level	Low Level Term	
MedDRA Term	<input type="text"/>	Field is Mandatory

Name	<input type="text"/>
Query Mode	Begins

MedDRA Term (AP.IND.3/DP.IND.3)

Select your query mode and type in the requested value (you can also use some of the wild cards) and press "Enter". The list of available values will be displayed:

Description	Name/Value	
MedDRA Version	26.1	
MedDRA Level	Low Level Term	
MedDRA Term		Field is Mandatory

Name	low back pain*
Query Mode	Begins

Num	Name	Code
0001	Low back pain	10024891
0002	Low back pain (without radiation)	10024892

Select the requested value, double-click or press "Enter" on your keyboard. The selected value will be displayed in the "MedDRA Term" field:

Description	Name/Value
MedDRA Version	26.1
MedDRA Level	Low Level Term
MedDRA Term	Low back pain

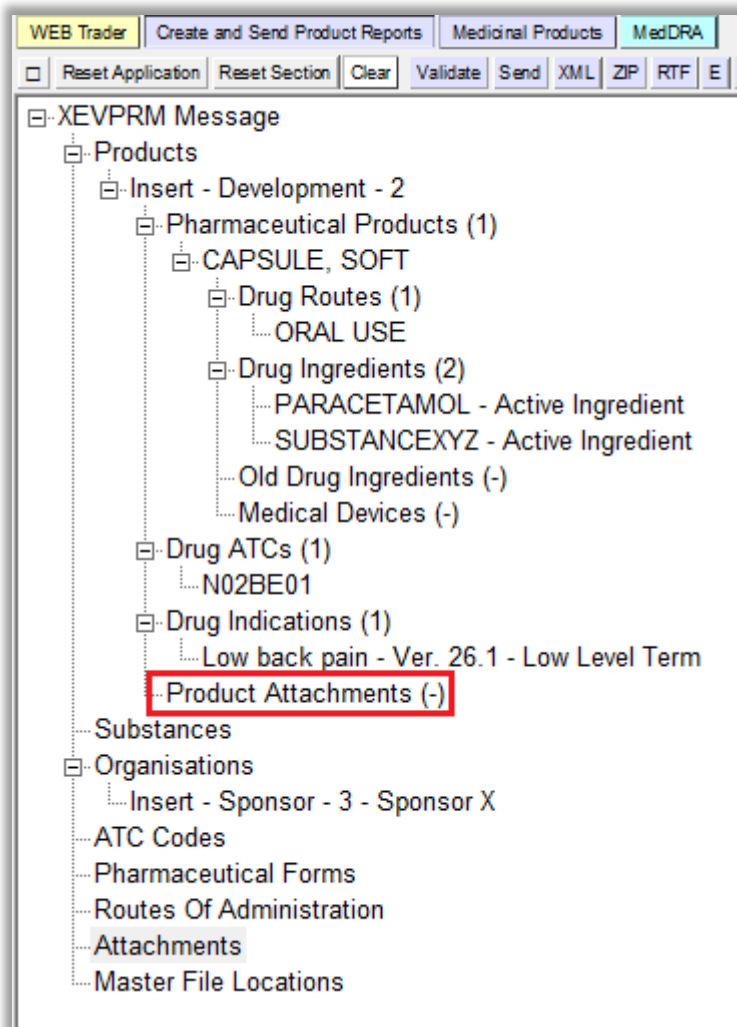
If you wish to enter additional drug indications repeat [steps 1 – 3](#) of this section.

Product attachments

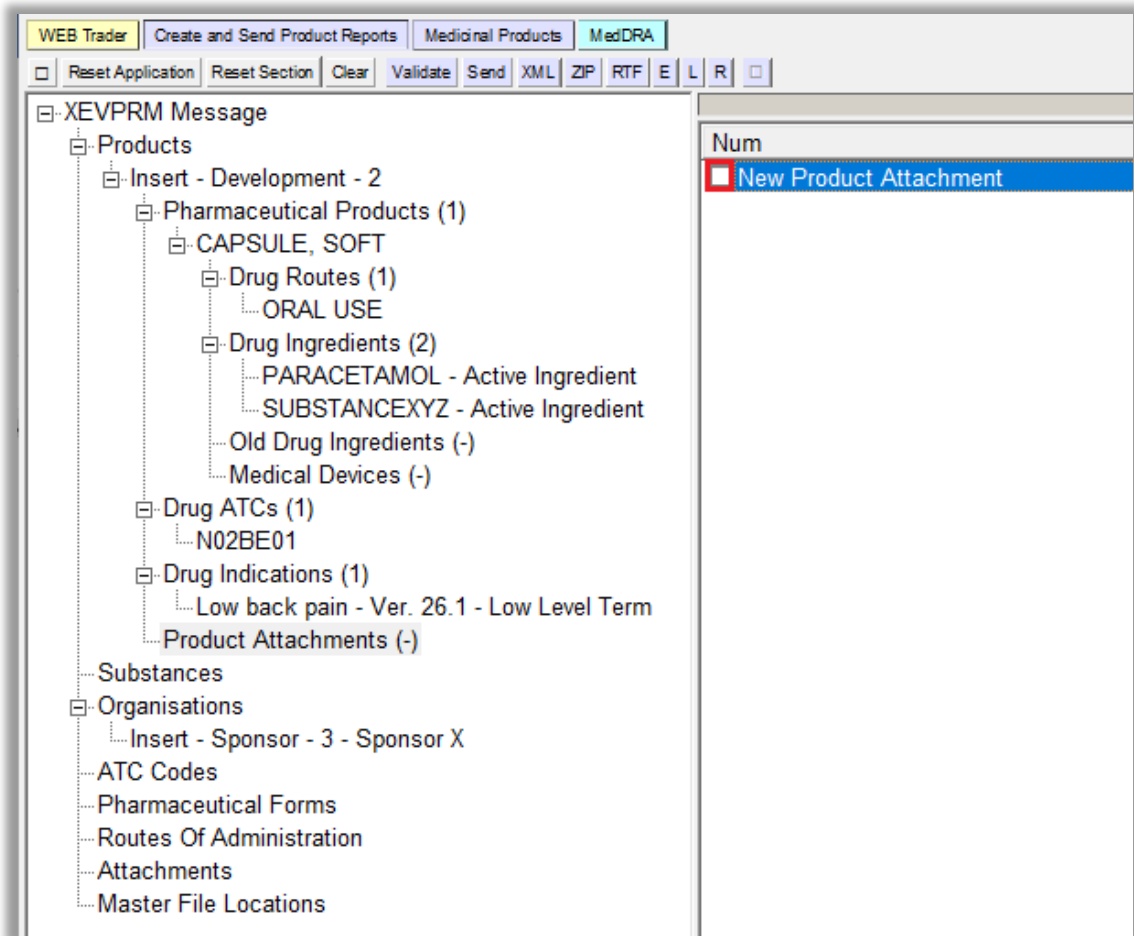
This is a repeatable section.

It is not mandatory to provide product attachments in a DMP entity. Should you wish to do so, the below described process should be followed to reference an Investigator's Brochure or other clinical trial documentation in your DMP.

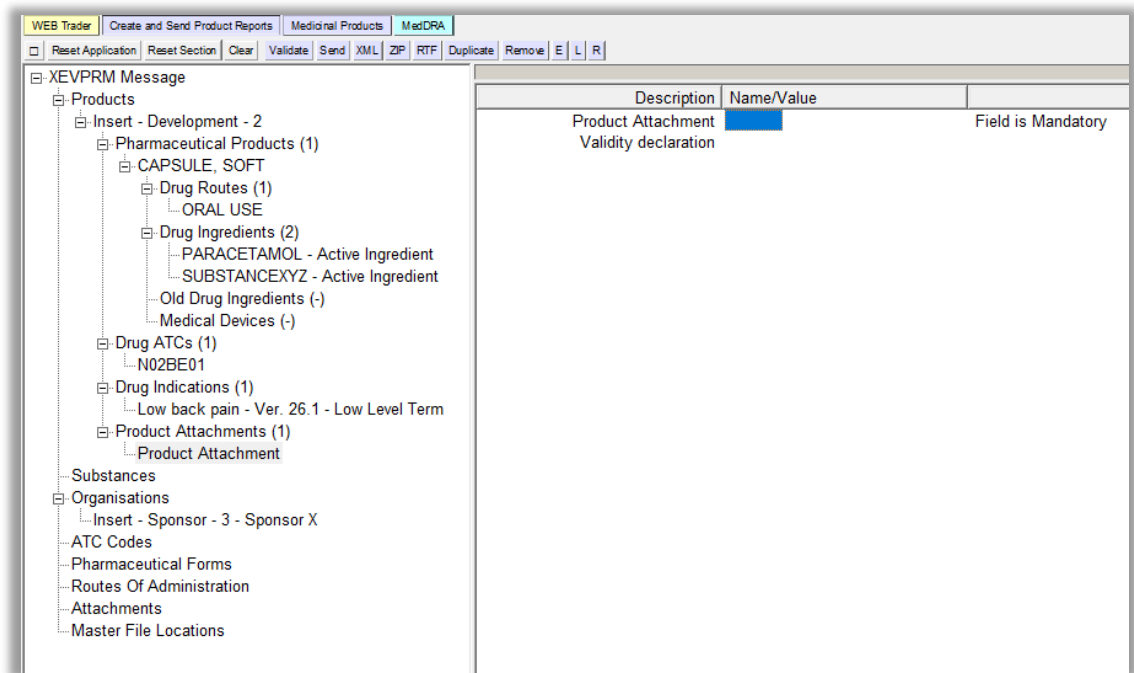
1) Click on 'Product Attachments' in the tree-view area:



2) In the active area, select "New Product Attachment":



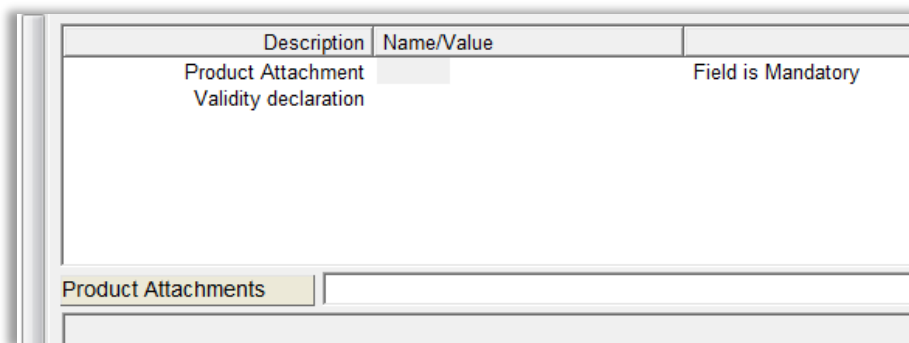
In the active area, the area next to 'Product Attachment' is highlighted in blue:



3) Search for the required attachment name using the remote or local look-up table:

✚ If the required **attachment name exists in the XEVMPD** and an EV Code is already assigned, or to check if the attachment already exists in the XEVMPD, search the **remote look-up table**:

- Press "Enter" on your keyboard, double-click on the field, or click on the "R" (Remote look-up) button and the remote look-up search area becomes available:



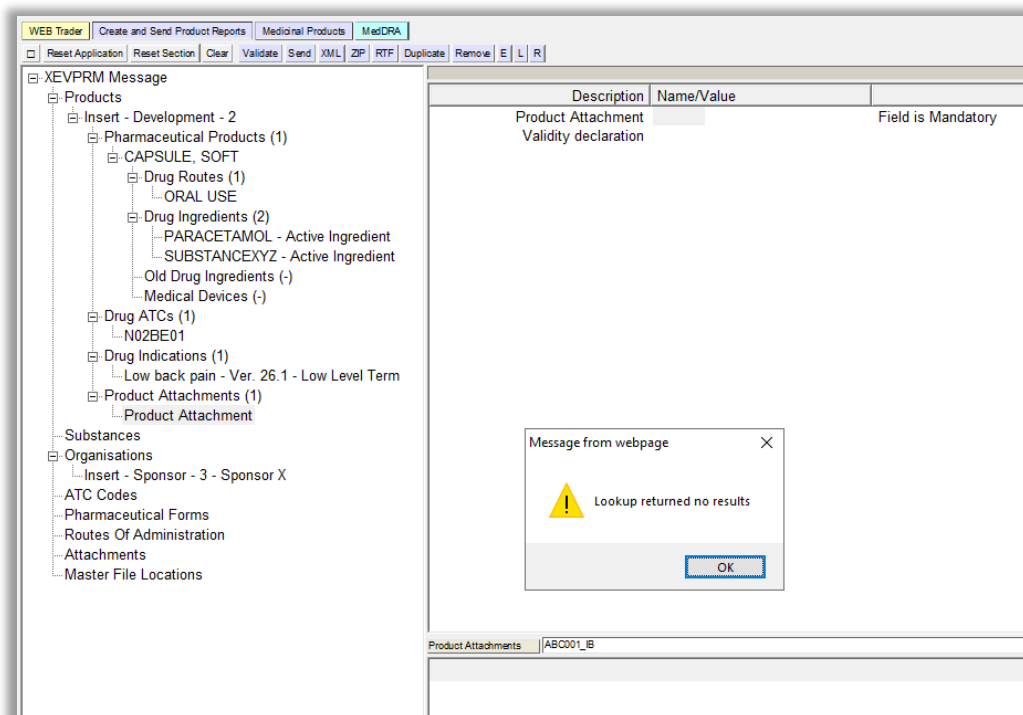
Description	Name/Value
Product Attachment Validity declaration	Field is Mandatory

Product Attachments

- Search for a document that contains information about your DMP (based on the name assigned to the document or based on the EV Code that was assigned to your attachment). You can also use one of the available wild cards. Type in the requested text/attachment EV Code and press "Enter" on your keyboard.

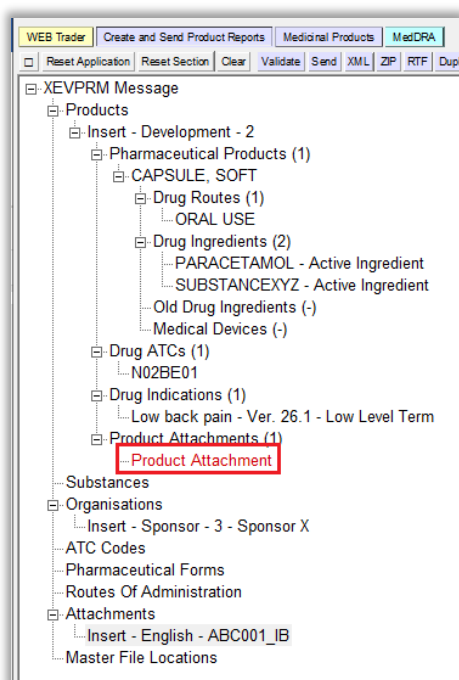
If a document is found, a result of your search will be displayed in the search area. You will be able to select it by clicking on its name with your mouse and, by using ENTER on your keyboard, you would reference the attachment in the 'Sponsor' field.

✚ If the **required attachment does not exist in the XEVMPD**, the following message will be displayed:

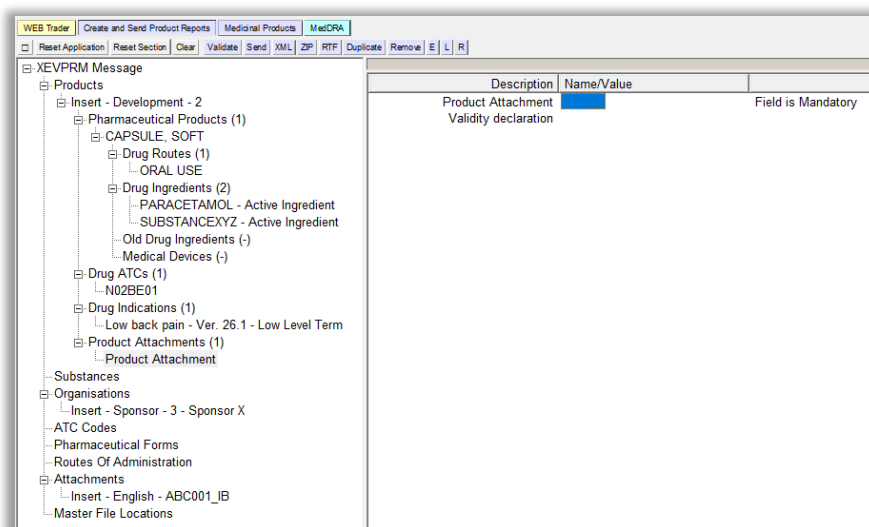


You can therefore presume that the attachment is not yet available in the XEVMPD.

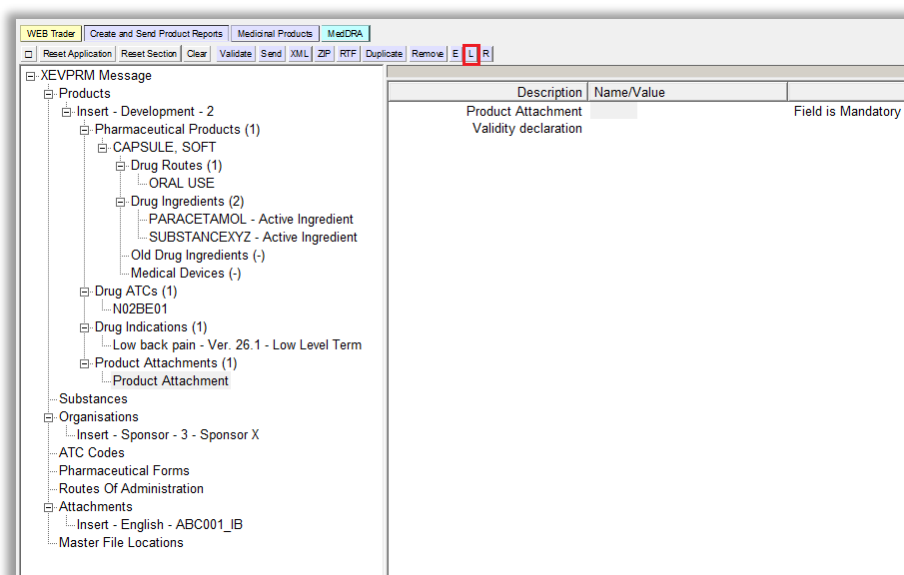
- Insert the attachment in the XEVMPD as new via the same XEVPRM using the process described in section *Insert of an attachment in the same XEVPRM* of this document.
- Reference the attachment in the 'Product Attachment' field from the **local look-up table**:
 - Go back to your development medicinal product entity by clicking on the "Product Attachment" in the "Product Attachments" section in the tree-view area:



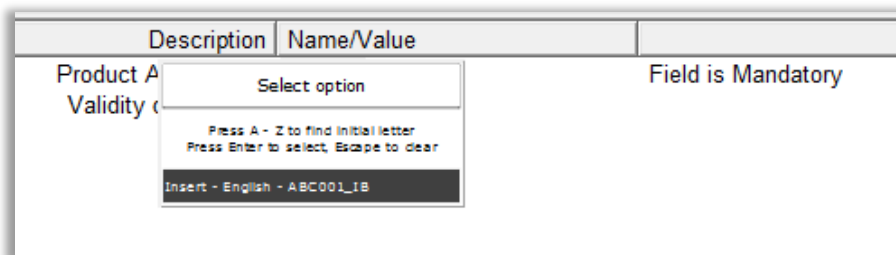
The active area will display the fields relevant for an attachment submission; the area next to "Product Attachment" is highlighted in blue:



- Click on the "L" (Local look-up) button; the area will become highlighted in grey, and the local look-up table becomes available, displaying the attachment, which you inserted in the "Attachments" section of your XEVPRM:



- Select the attachment name you wish to reference in the "Product Attachment" field. The name will become highlighted in black:



Once you press "Enter" on your keyboard or click on the selected value with your mouse, the attachment name will be displayed in the "Product Attachment" field:

Description	Name/Value
Product Attachment Validity declaration	Insert - English - ABC001_IB

Since we are performing an insert of a DMP and no previous attachment was referenced to this DMP entity, it is not necessary to enter the "Validity declaration" information in this particular case.

You have now provided all mandatory information and some optional information (ATC Code, indications, and an attachment) for an initial submission of a DMP information in the XEVMPD, as per the DMP example specification:

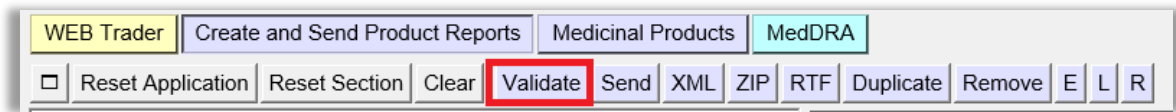
The screenshot shows the WEB Trader interface with the XEVPRM Message tree on the left and a table of product details on the right. The tree is expanded to show the following structure:

- XEVPRM Message
 - Products
 - Insert - Development - 2
 - Pharmaceutical Products (1)
 - CAPSULE, SOFT
 - Drug Routes (1)
 - ORAL USE
 - Drug Ingredients (2)
 - PARACETAMOL - Active Ingredient
 - SUBSTANCEXYZ - Active Ingredient
 - Old Drug Ingredients (-)
 - Medical Devices (-)
 - Drug ATCs (1)
 - N02BE01
 - Drug Indications (1)
 - Low back pain - Ver. 26.1 - Low Level Term
 - Product Attachments (1)
 - Insert - English - ABC001_IB
 - Substances
 - Organisations
 - Insert - Sponsor - 3 - Sponsor X
 - ATC Codes
 - Pharmaceutical Forms
 - Routes Of Administration
 - Attachments
 - Insert - English - ABC001_IB
 - Master File Locations

Description	Name/Value
Type	Development
Operation Type	Insert
Sender Local Code	
Sponsor	Insert - Sponsor - 3 - Sponsor X
Product Code	ABC001
Product Name	
Product Other Name	
Comment	Pharmaceutical Products (1) Drug ATCs (1) Drug Indications (1) Product Attachments (1)

3. Validate the XEVPRM

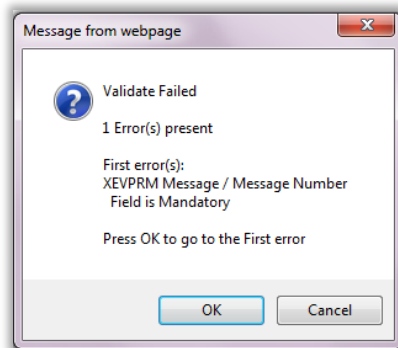
Validate your XEVPRM by clicking on the "Validate" button:



A 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.

For example, if the 'XEVPRM Message' number was not referenced in the XEVPRM, the message will be as follows:



Once you click on "OK" in the error message the application will direct you to the first error. The field(s) where information is missing will contain the text "Field is Mandatory", e.g.:

Description	Name/Value	
Message Number	[Redacted]	Field is Mandatory
	Products	
	Substances	
	Sources	
	Organisations	
	ATC Codes	
	Pharmaceutical Forms	
	Routes Of Administration	
	Attachments	
	Master File Locations	

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:

Address: <https://evtest.ema.europa.eu/human/restricted/x/x.asp?xi=6>

Display Settings

WEB Trader | Create and Send Product Reports | Medicinal Products | MedDRA


Reset Application | Reset Section | Clear | Validate | Send | XML | ZIP | RTF | E | L | R

XEVPRM Message

- [-] Products
 - [-] Insert - Development - 2
 - [-] Pharmaceutical Products (1)
 - [-] Drug ATCs (1)
 - [-] Drug Indications (1)
 - [-] Product Attachments (1)
 - [-] Insert - English - ABC001_IB
 - [-] Substances
- [-] Organisations
- [-] ATC Codes
- [-] Pharmaceutical Forms
- [-] Routes Of Administration
- [-] Attachments
 - [-] Insert - English - ABC001_IB
 - [-] Master File Locations

Description	Name/Value
Message Number	Insert of DMP ABC001
	Products
	Substances
	Organisations
	ATC Codes
	Pharmaceutical Forms
	Routes Of Administration
	Attachments
	Master File Locations

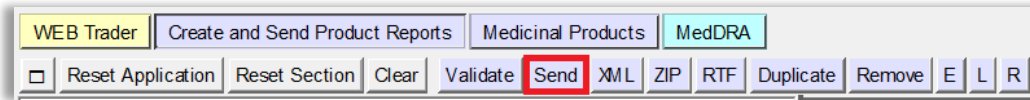
Message from webpage X

 Validate OK

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

4. Send the XEVPRM

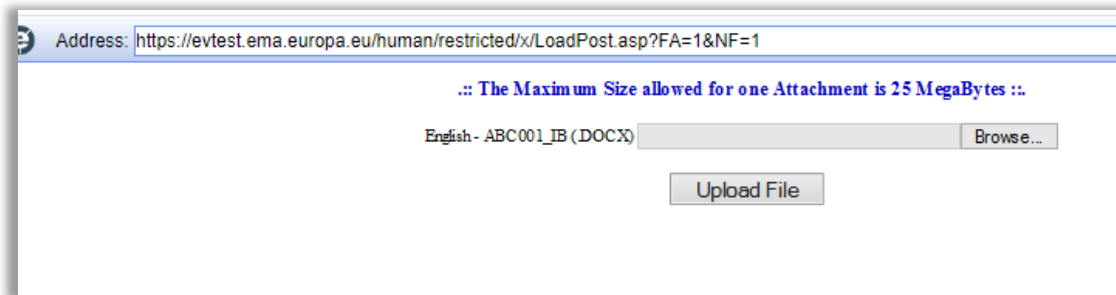
1) Send the XEVPRM by clicking on the "Send" button:



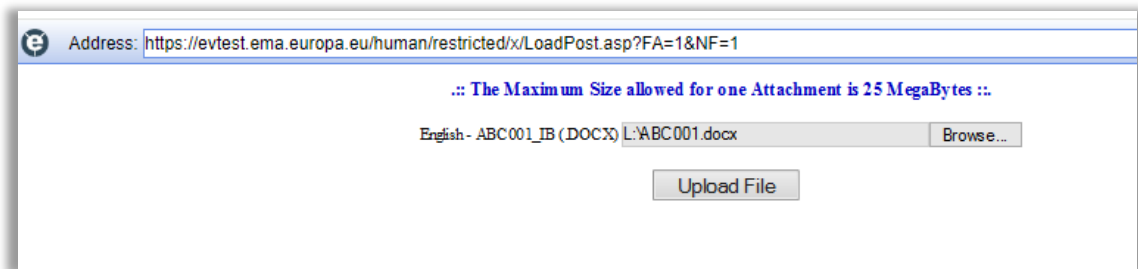
If your organisation is registered as a **Gateway user**, the 'Send' button will not be available to you in the menu. You will need to save the XEVPRM as a ZIP file and submit it via the EV Post functionality available in the EV restricted area. Refer to the [XEVMPD Data-Entry Tool \(EVWEB\) User Manual](#), section 'Use EV Post functionality'.

If your organisation is registered as a **WebTrader user** and the 'Send' button is not available to you in the menu, this might be linked to your user role or organisation set-up. Please check your user/organisation set up and contact the [EMA Service Desk](#) for assistance, if needed.

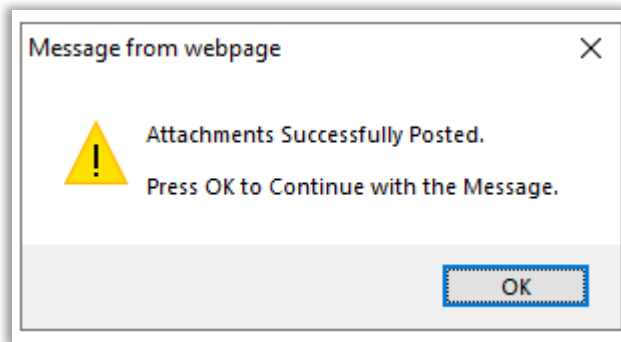
The below message will be displayed on your screen if you included a submission of a PPI attachment for your development product:



2) Retrieve your PPI attachment from the location on your computer and upload the file by clicking on 'Browse':

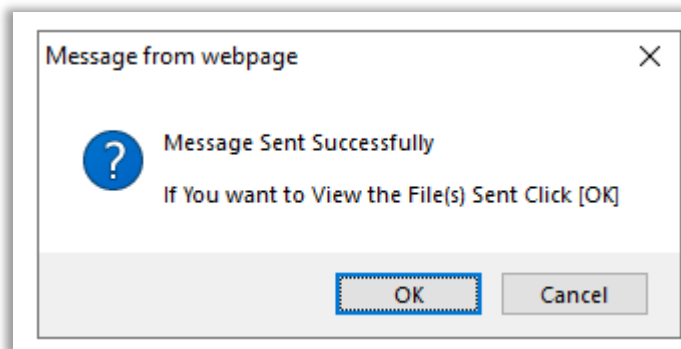


3) Click on "Upload File"; the following message will be displayed in a new window:



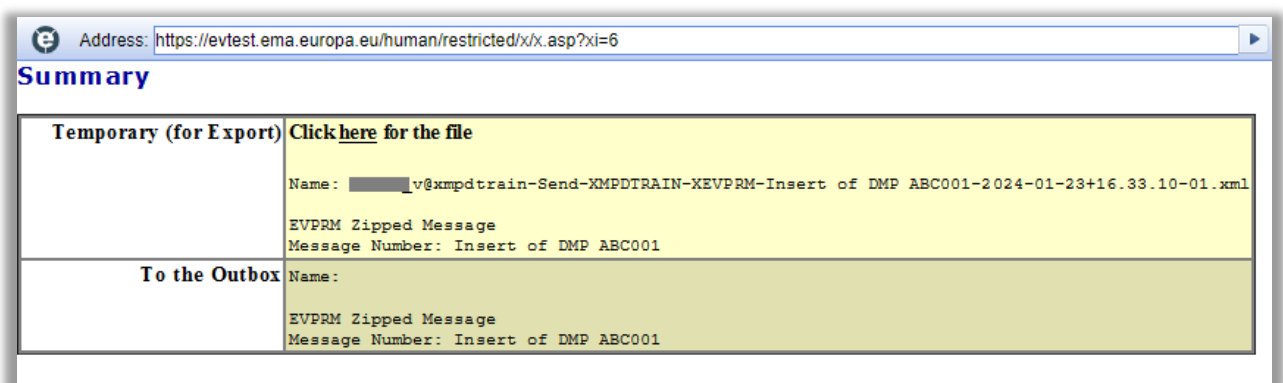
4) Dismiss the message by clicking on "OK".

A new window will pop up on your screen confirming that your XEVPRM has been sent:

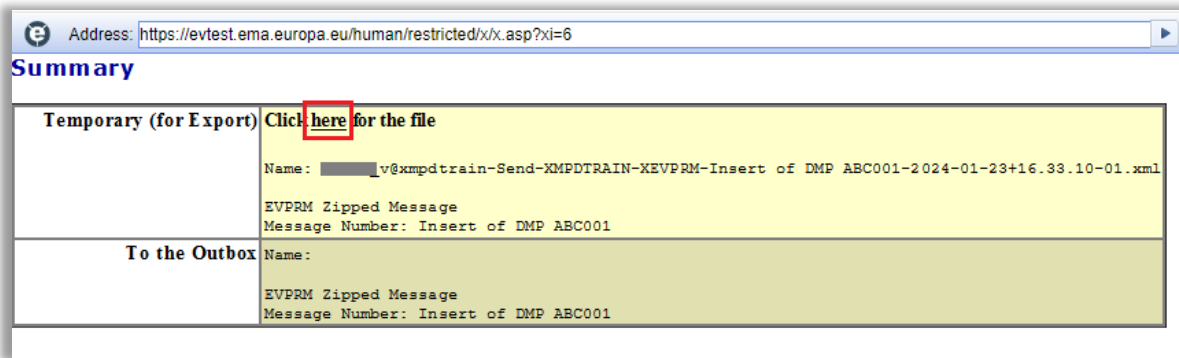


5) If you want to view/save your file, click on "OK".

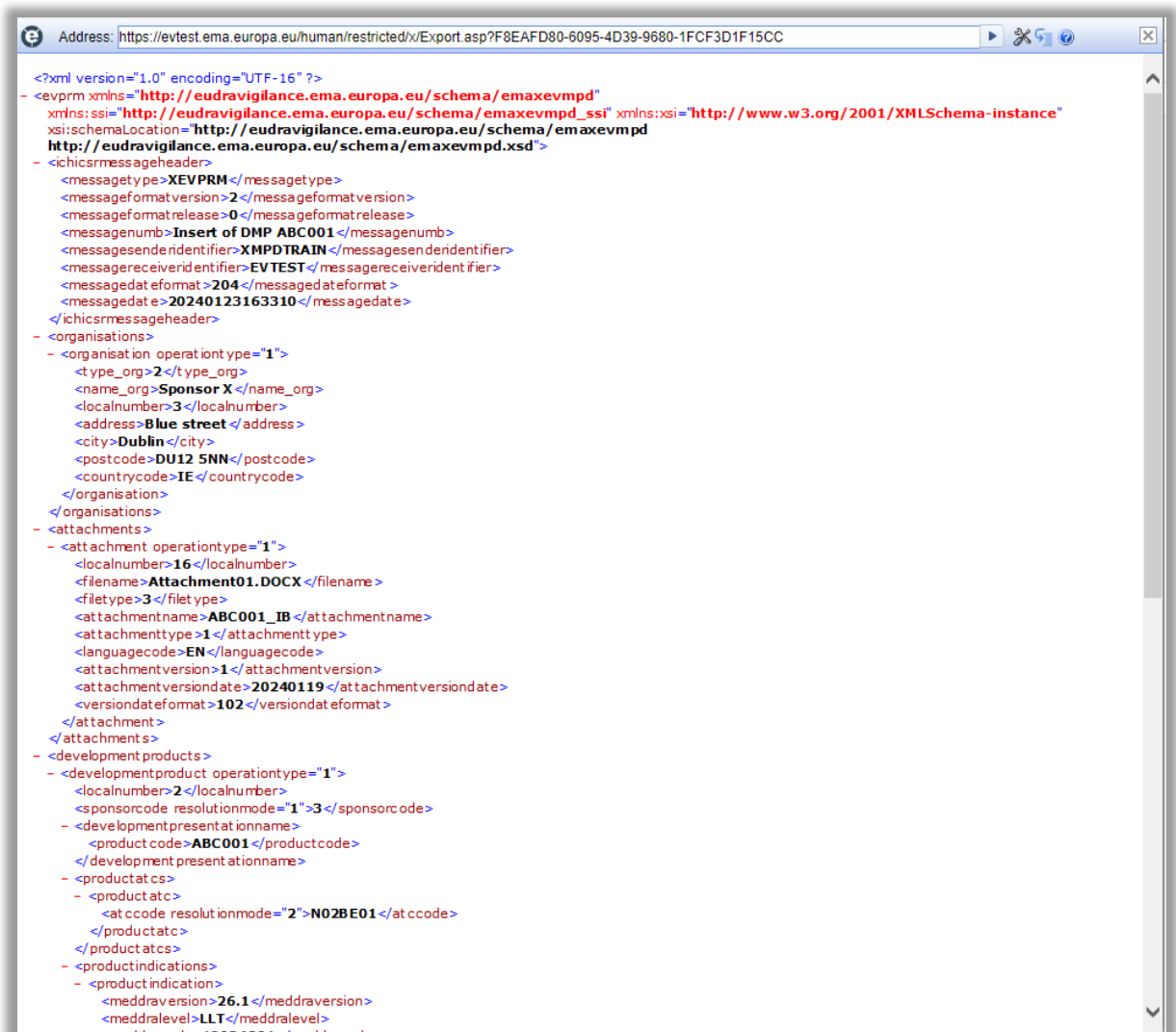
The below message will be displayed, enabling you to save your XEVPRM file in an XML format on your computer:



Click on 'here':



A new window will open containing the XML version of your XEVPRM:



6) Click on **ctrl+S** on your keyboard to save the file as an XML file type on your computer.

If you wish to save the XML/RTF/ZIP file of your file **before it is sent**, please refer to the [XEVMPD Data-Entry Tool \(EVWEB\) User Manual](#), section 'Save, Reload and Send an XEVPRM'.

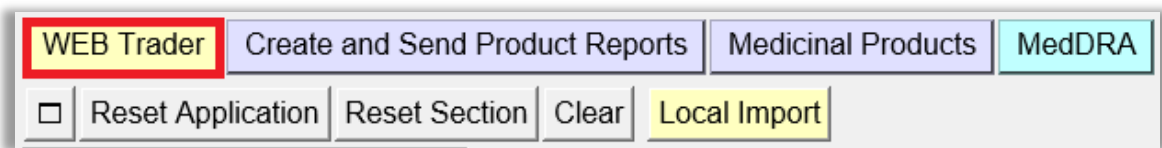
You have now successfully saved the XML file of the submitted XEVPRM.

5. Retrieve the XEVPRM Acknowledgement

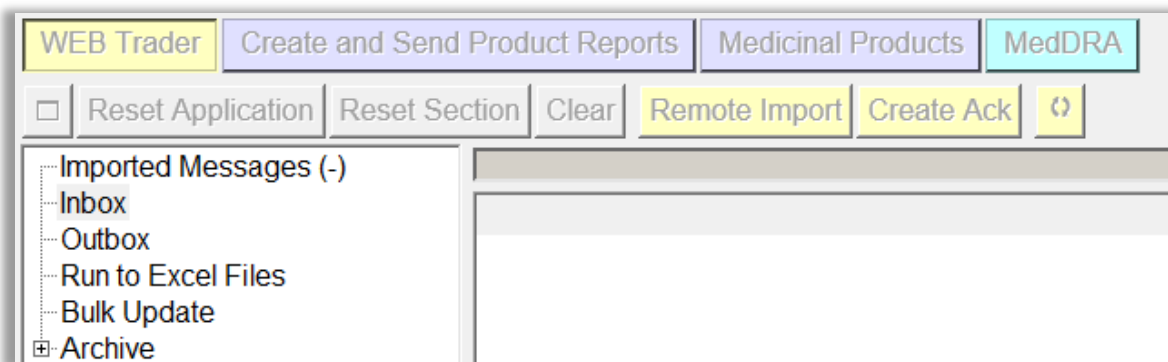
If the sender organisation ID from which the XEVPRM was sent is registered in EudraVigilance as a **WebTrader** user, then you will be able to retrieve XEVPRM Acknowledgements in the 'Web Trader' Inbox section of EVWEB.

If the sender organisation ID from which the XEVPRM was sent is registered in EudraVigilance as a **Gateway** user, then you will NOT be able to retrieve XEVPRM Acknowledgements in the 'Web Trader' Inbox section of EVWEB. Users from **Gateway** organisations should check with their gateway provider where the XEVPRM ACKs are stored.

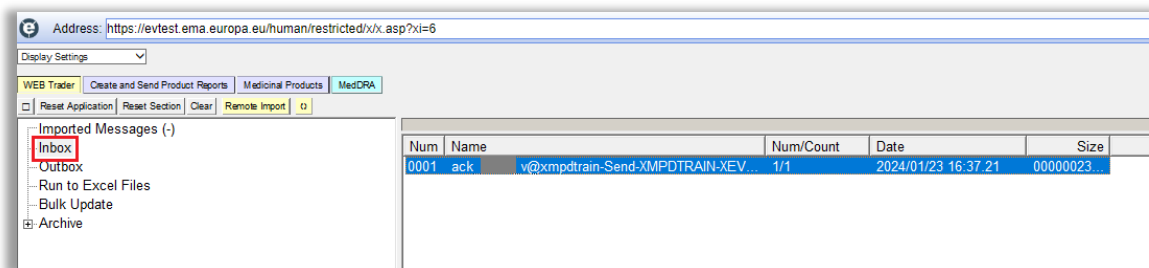
1) Go to the "Web Trader" section:



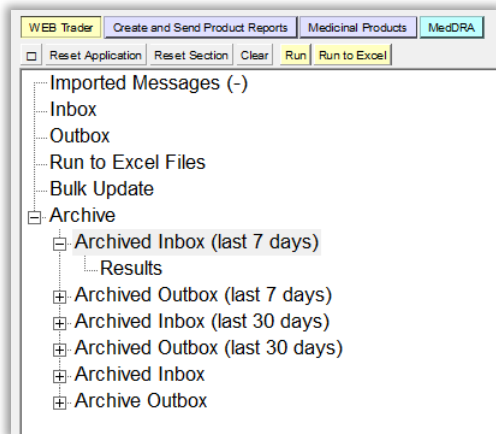
If you are looking for the XEVPRM ACK **on the same date** as the date when the XEVPRM was submitted, click on "Inbox"; the application will appear "frozen" for a second or two:



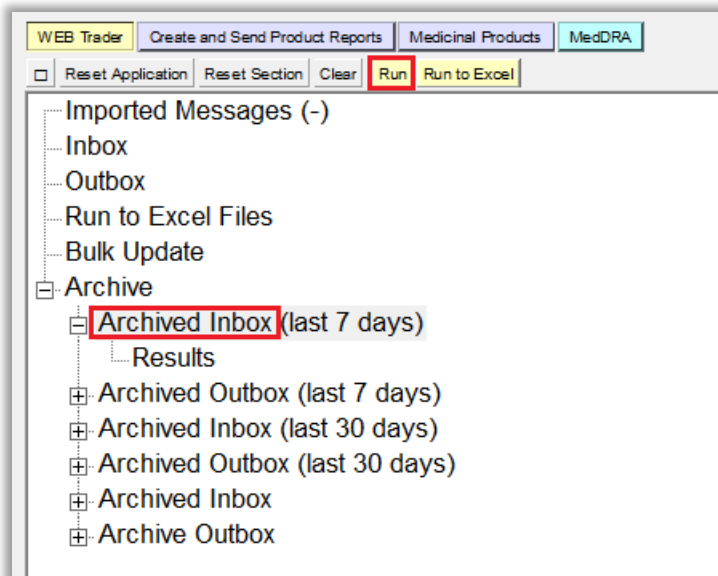
After a few seconds, the active area will display all XEVPRM ACKs sent to your organisation's ID that day (the first message will be automatically highlighted in blue):



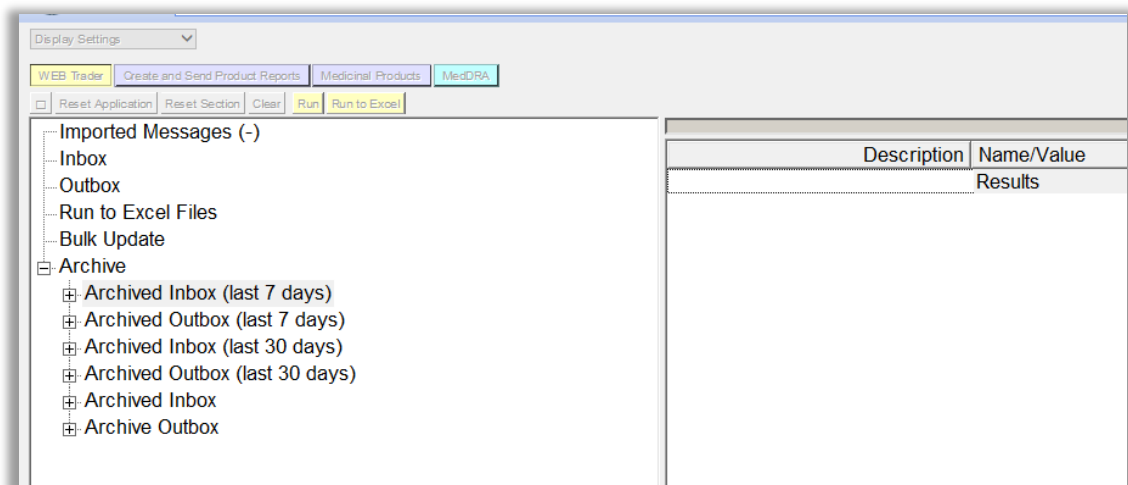
If you are looking for the XEVPRM ACK **on a different date** than the date when the XEVPRM was submitted, expand the 'Archive' section, and select the "Archived Inbox" for the relevant period:



2) Click on the 'Archived Inbox' for the required period and then "Run":

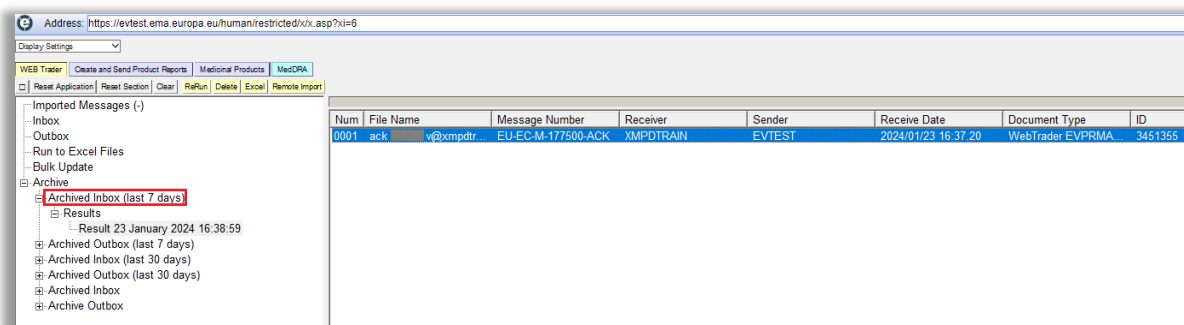


The application will appear "frozen" for a second or two:

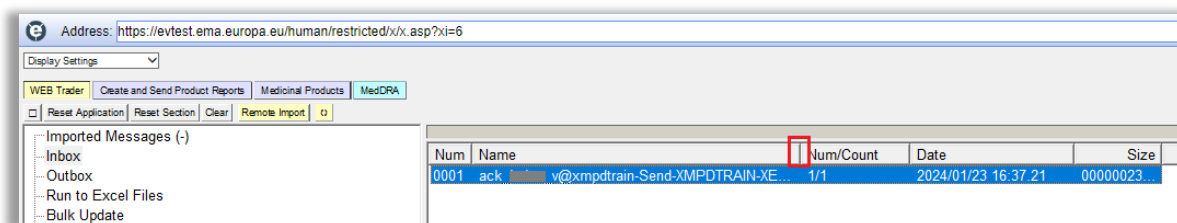


After a few seconds, the active area will display all XEVPRM ACKs sent to your organisation's ID for that period.

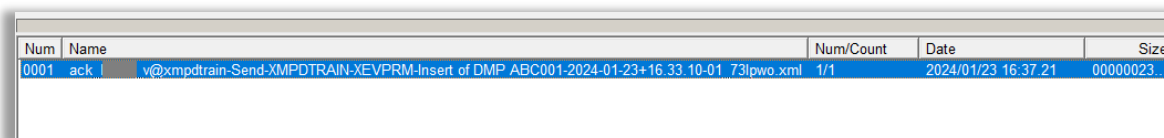
The first message will be automatically highlighted in blue:



To view the ACK name in full, expand the section by placing your cursor on the separator line, then click and drag the cursor to the right until the full name is visible:



You can also double click on the separator line:



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

In case that multiple results are displayed, select the relevant ACK by clicking on the relevant row with your mouse (the message will be highlighted in blue), then press "Enter" on your keyboard or double-click with your mouse.

The XML of the XEVPRM ACK will be displayed on your screen, showing the operation result and, if the insert was successful, the assigned EV Code(s):

```

Address: https://evtest.ema.europa.eu/human/restricted/x/Export.asp?B08213AC-3B9A-4236-9D80-8722991FBE95

<?xml version="1.0" encoding="UTF-8" ?>
- <evprmack xsi:noNamespaceSchemaLocation="http://eudravigilance.ema.europa.eu/schema/ackoevmpd.xsd"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
- <ichicsrmessageheader>
  <messagetype>EVPRACK</messagetype>
  <messageformatversion>1.0</messageformatversion>
  <messageformatrelease>1.0</messageformatrelease>
  <messagenumb>EU-EC-M-177500-ACK</messagenumb>
  <messagesenderidentifier>EVTEST</messagesenderidentifier>
  <messagereceiveridentifier>XMPDTRAIN</messagereceiveridentifier>
  <messagedatformat>204</messagedatformat>
  <messagedate>20240123163512</messagedate>
</ichicsrmessageheader>
- <acknowledgment>
- <messageacknowledgment>
  <evmessagenumb>EU-EC-M-177500</evmessagenumb>
  <originalmessagenumb>Insert of DMP ABC001</originalmessagenumb>
  <originalmessagesenderidentifier>XMPDTRAIN</originalmessagesenderidentifier>
  <originalmessagereceiveridentifier>EVTEST</originalmessagereceiveridentifier>
  <originalmessagedatformat>204</originalmessagedatformat>
  <originalmessagedate>20240123163310</originalmessagedate>
  <transmissionacknowledgmentcode>01</transmissionacknowledgmentcode>
</messageacknowledgment>
- <reportacknowledgment>
  <reportname>ATTACHMENT</reportname>
  <localnumber>16</localnumber>
  <ev_code>ATT47223</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>
  <reportname>ORGANISATION</reportname>
  <localnumber>3</localnumber>
  <ev_code>ORG10004</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>
  <reportname>DEVELOPMENTPRODUCT</reportname>
  <localnumber>2</localnumber>
  <ev_code>PRD131743</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully Version 1</operationresultdesc>
</reportacknowledgment>
</acknowledgment>
</evprmack>

```

In our case, the inserts of the DMP, attachment and sponsor entity were successful, and the EV Codes assigned to the individual entities are referenced in the XEVPRM ACK:


```

Address: https://evtest.ema.europa.eu/human/restricted/x/Export.asp?B08213AC-3B9A-4236-9D80-8722991FBE95

<?xml version="1.0" encoding="UTF-8" ?>
- <evprmack xsi:noNamespaceSchemaLocation="http://eudravigilance.ema.europa.eu/schema/ackxevm
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
- <ichicsrmessageheader>
  <messagetype>EVPRACK</messagetype>
  <messageformatversion>1.0</messageformatversion>
  <messageformatrelease>1.0</messageformatrelease>
  <messagenumb>EU-EC-M-177500-ACK</messagenumb>
  <messagesenderidentifier>EVTEST</messagesenderidentifier>
  <messagereceiveridentifier>XMPDTRAIN</messagereceiveridentifier>
  <messagedateformat>204</messagedateformat>
  <messagedate>20240123163512</messagedate>
</ichicsrmessageheader>
- <acknowledgment>
- <messageacknowledgment>
  <evmessagenumb>EU-EC-M-177500</evmessagenumb>
  <originalmessagenumb>Insert of DMP ABC001</originalmessagenumb>
  <originalmessagesenderidentifier>XMPDTRAIN</originalmessagesenderidentifier>
  <originalmessagereceiveridentifier>EVTEST</originalmessagereceiveridentifier>
  <originalmessagedateformat>204</originalmessagedateformat>
  <originalmessagedate>20240123163310</originalmessagedate>
  <transmissionacknowledgmentcode>01</transmissionacknowledgmentcode>
</messageacknowledgment>
- <reportacknowledgment>
  <reportname>ATTACHMENT</reportname>
  <localnumber>16</localnumber>
  <ev_code>ATT47223</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>
  <reportname>ORGANISATION</reportname>
  <localnumber>3</localnumber>
  <ev_code>ORG10004</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>
  <reportname>DEVELOPMENTPRODUCT</reportname>
  <localnumber>2</localnumber>
  <ev_code>PRD131743</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully Version 1</operationresultdesc>
</reportacknowledgment>
</acknowledgment>
</evprmack>

```

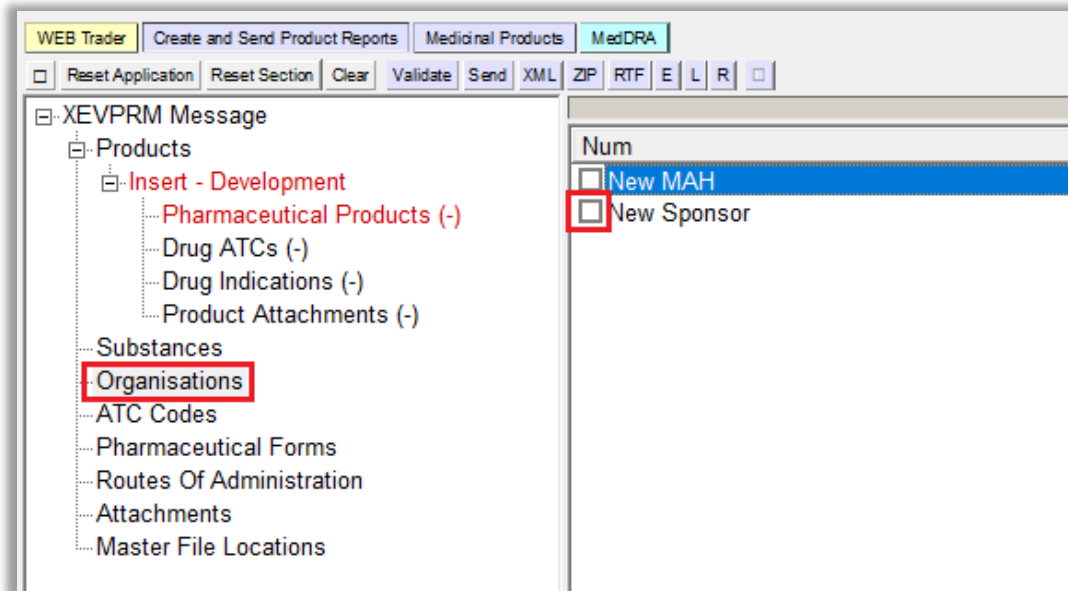
You can save the XML file of the XEVPRM ACK on your computer by clicking **ctrl+S** and saving it as an xml file type.

You have now successfully retrieved the XEVPRM Acknowledgement.

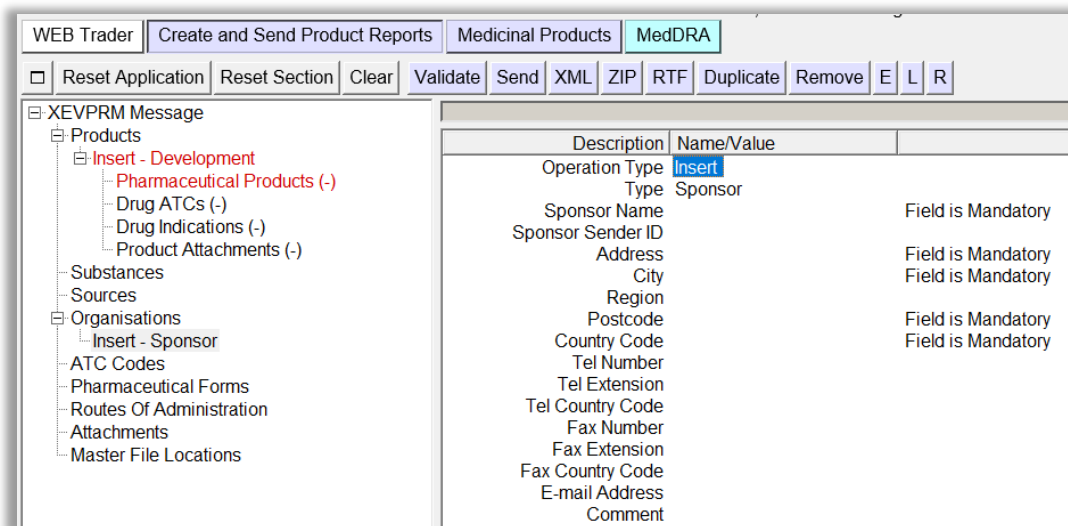
Annex

Insert of a sponsor organisation in the same XEVPRM

1) Using your mouse, click on the "Organisations" section in the tree-view area and select "New Sponsor" by ticking the relevant box in the active area:



The active area will display the fields relevant for a sponsor organisation 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 3. Validate).
- When information is entered in the individual mandatory fields, the text "Field is Mandatory" disappears.

2) Enter the sponsor organisation information in the individual fields as per guidance provided for each field in section 3. *Initial submission of a sponsor information* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).

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.

Type

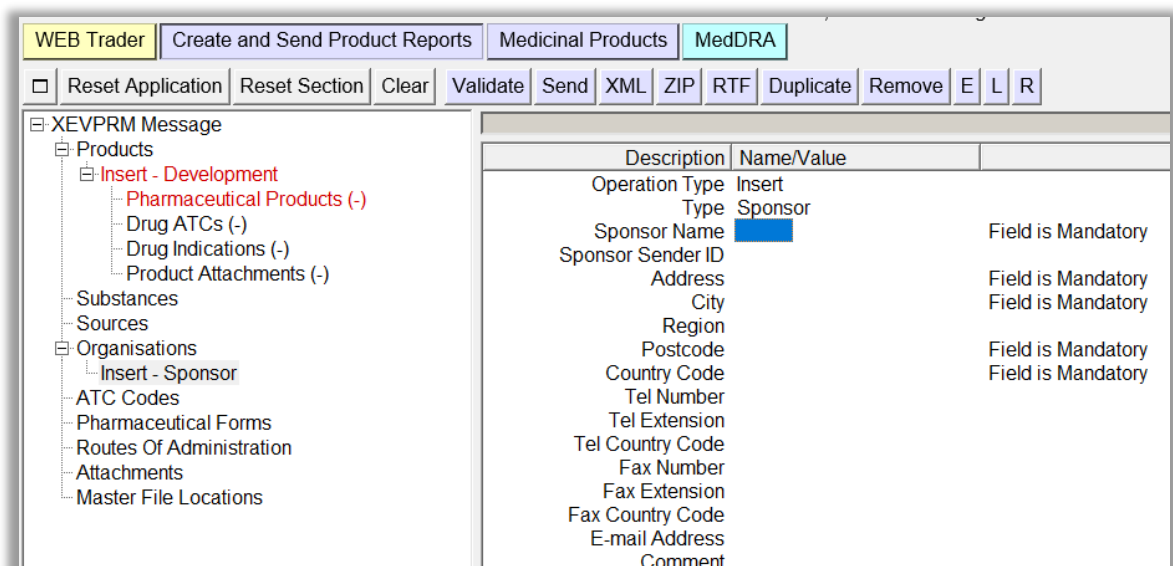
The value in the "Type" field is automatically set to "Sponsor" as per your selection.

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:



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:

WEB Trader | Create and Send Product Reports | Medicinal Products | MedDRA

Reset Application | Reset Section | Clear | Validate | Send | XML | ZIP | RTF | Duplicate | Remove | E | L | R

XEVPRM Message

- Products
 - Insert - Development
 - Pharmaceutical Products (-)
 - Drug ATCs (-)
 - Drug Indications (-)
 - Product Attachments (-)
 - Substances
 - Sources
 - Organisations
 - Insert - Sponsor
 - ATC Codes
 - Pharmaceutical Forms
 - Routes Of Administration
 - Attachments
 - Master File Locations

Description	Name/Value	
Operation Type	Insert	
Type	Sponsor	
Sponsor Name	<input type="text"/>	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		

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

WEB Trader | Create and Send Product Reports | Medicinal Products | MedDRA

Reset Application | Reset Section | Clear | Validate | Send | XML | ZIP | RTF | Duplicate | Remove | E | L | R

XEVPRM Message

- Products
 - Insert - Development
 - Pharmaceutical Products (-)
 - Drug ATCs (-)
 - Drug Indications (-)
 - Product Attachments (-)
 - Substances
 - Sources
 - Organisations
 - Insert - Sponsor - Sponsor X
 - ATC Codes
 - Pharmaceutical Forms
 - Routes Of Administration
 - Attachments
 - Master File Locations

Description	Name/Value	
Operation Type	Insert	
Type	Sponsor	
Sponsor Name	Sponsor X	
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		

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 [Sponsor Name](#).

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 [Sponsor Name](#):

Description	Name/Value	
Operation Type	Insert	
Type	Sponsor	
Sponsor Name	Sponsor X	
Sponsor Sender ID		
Address	Blue street	
City	Dublin	
Region		
Postcode	DU12 5NN	
Country Code		Field is Mandatory
Tel Number		
Tel Extension		
Tel Country Code		
Fax Number		
Fax Extension		
Fax Country Code		
E-mail Address		
Comment		

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:

WEB Trader | Create and Send Product Reports | Medicinal Products | MedDRA

Reset Application | Reset Section | Clear | Validate | Send | XML | ZIP | RTF | Duplicate | Remove | E | L | R

XEVPRM Message

- Products
 - Insert - Development
 - Pharmaceutical Products (-)
 - Drug ATCs (-)
 - Drug Indications (-)
 - Product Attachments (-)
 - Substances
- Organisations
 - Insert - Sponsor - Sponsor X
 - ATC Codes
 - Pharmaceutical Forms
 - Routes Of Administration
 - Attachments
 - Master File Locations

Description	Name/Value	
Operation Type	Insert	
Type	Sponsor	
Sponsor Name	Sponsor X	
Sponsor Sender ID		
Address	Blue street	
City	Dublin	
Region		
Postcode	DU12 5NN	
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, double-click on the field, or click on the "R" (Remote look-up) button. The values available for this field will be displayed:

WEB Trader | Create and Send Product Reports | Medicinal Products | MedDRA

Reset Application | Reset Section | Clear | Validate | Send | XML | ZIP | R

XEVPRM Message

- Products
 - Insert - Development
 - Pharmaceutical Products (-)
 - Drug ATCs (-)
 - Drug Indications (-)
 - Product Attachments (-)
 - Substances
- Sources
- Organisations
 - Insert - Sponsor - Labox
 - ATC Codes
 - Pharmaceutical Forms
 - Routes Of Administration
 - Attachments
 - Master File Locations

Description	Name/Value	
Operation Type	Insert	
Type	Sponsor	
Sponsor Name	Sponsor X	
Sponsor Sender ID		
Address	Blue street	
City	Dublin	
Region		
Postcode	DU12 5NN	
Country Code		Field is Mandatory
Tel Number		
Tel Extension		
Tel Country Code		
Fax Number		
Fax Extension		
Fax Country Code		
E-mail Address		
Comment		

Select option

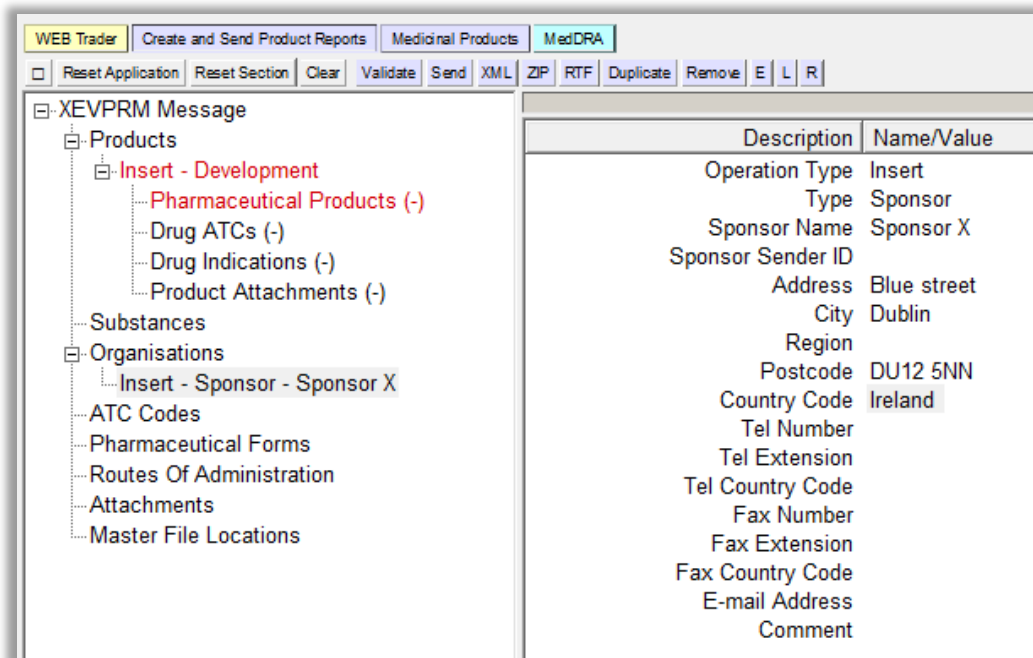
Press A - Z to find initial letter
Press Enter to select, Escape to clear

- Afghanistan
- ÅLAND ISLANDS
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua And Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas

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:



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 [Sponsor Name](#).

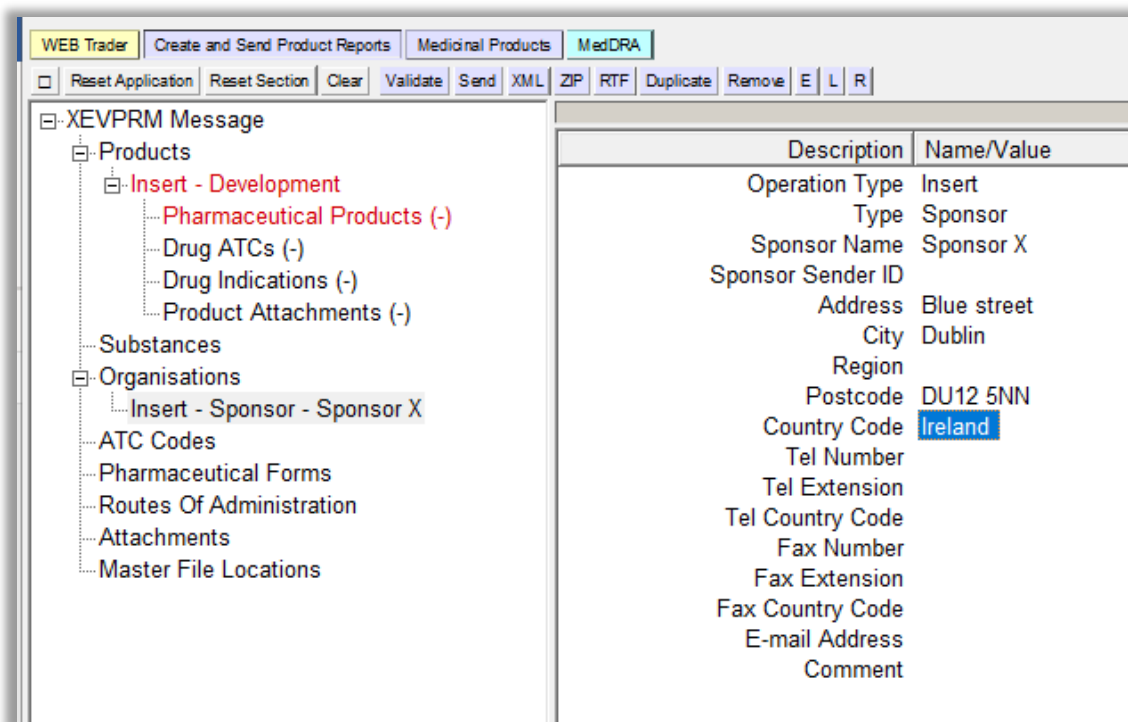
Comment

This is a free- text field, in which information can be entered using the same process as described in section [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 case since you are performing an 'Insert (1)' of an entity.

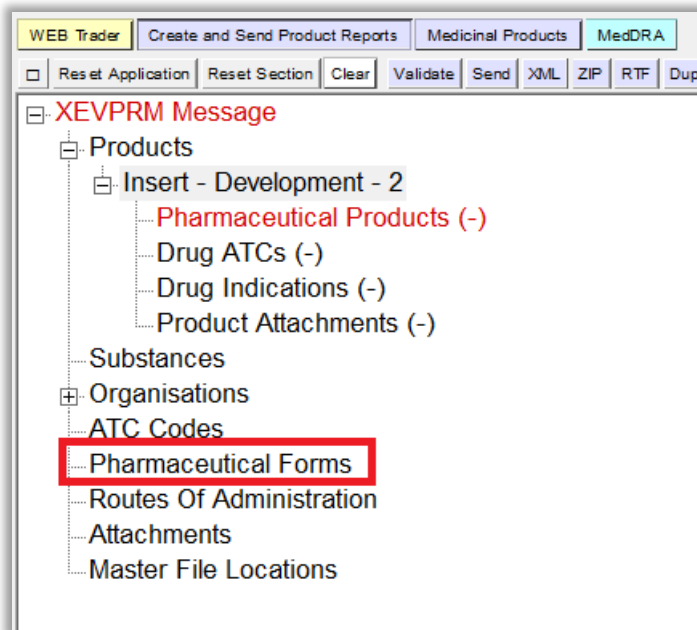
You have now populated the fields for a sponsor organisation entity "Sponsor X":



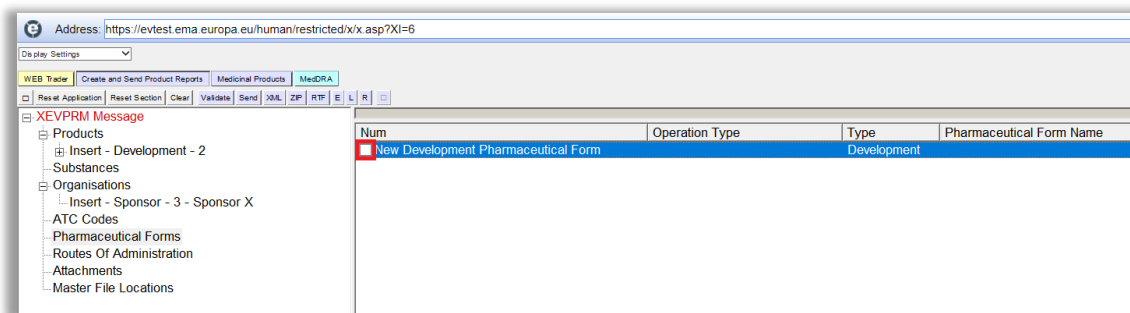
3) To reference this sponsor organisation in your DMP, you should retrieve the organisation in the 'Sponsor' field using the **local look-up table**.

Insert of a development pharmaceutical form in the same XEVPRM

1) In the tree-view area, click on the "Pharmaceutical forms" section:



2) Select "New Development Pharmaceutical Form" by ticking the relevant box in the active area:



The active area will display the fields applicable for a development pharmaceutical form:

Description	Name/Value
Operation Type	Insert
Type	Development
Pharmaceutical Form Name	Field is Mandatory
Version Date	
Previous EV Code	
Comment	

The 'Operation Type' field will display 'Insert' and the 'Type' field will have the value 'Development' assigned by default.

3) Enter the relevant information in the individual fields as per guidance for each field described in section 5.2. *Insert of a development pharmaceutical form* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).

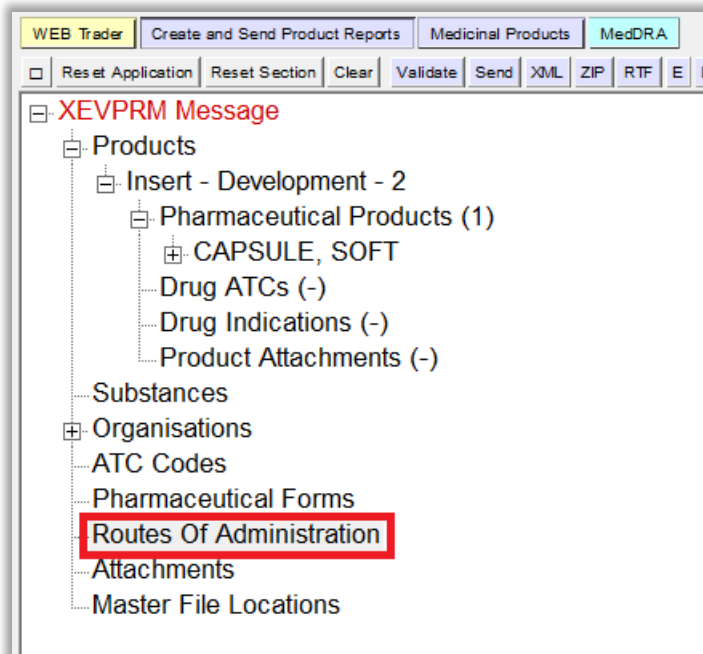
To activate the individual fields and enter the required information:

- Using your mouse, click on the area next to each field. The area will become highlighted in blue;
- Press "Enter" on your keyboard to activate the field;
- Either type in the required text (if the field is a free-text field) or select the value from a pre-defined table/calendar;
- In case of free-text field, once you type in the required information, press "Enter" on your keyboard for the information to be saved in that field.

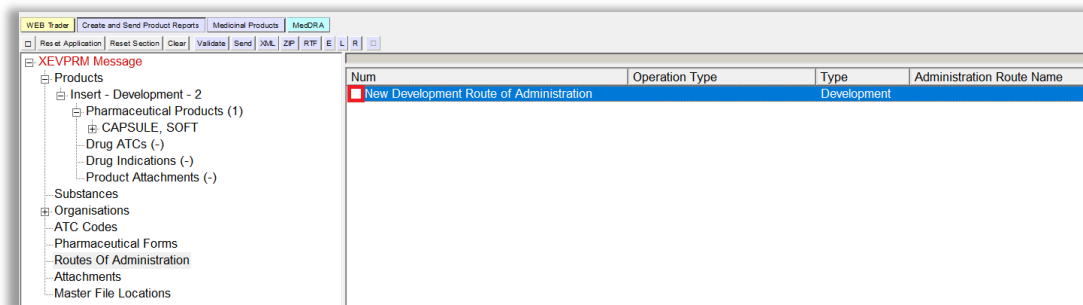
4) To reference this development pharmaceutical form in your DMP, you should retrieve the pharmaceutical form name in the 'Administrable Pharmaceutical Form' field of your DMP using the **local look-up table**.

Insert of a development route of administration in the same XEVPRM

1) In the tree-view area, click on the "Routes of administration" section:



2) Select "New Development Route of Administration" by ticking the relevant box in the active area:



The active area will display the fields applicable for a development route of administration:

Description	Name/Value
Operation Type	Insert
Type	Development
Administration Route Name	Field is Mandatory
Version Date	
Previous EV Code	
Comment	

The 'Operation Type' field will display 'Insert' and the 'Type' field will have the value 'Development' assigned by default.

3) Enter the relevant information in the individual fields as per guidance for each field described in section 6.2. *Insert of a development route of administration* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).

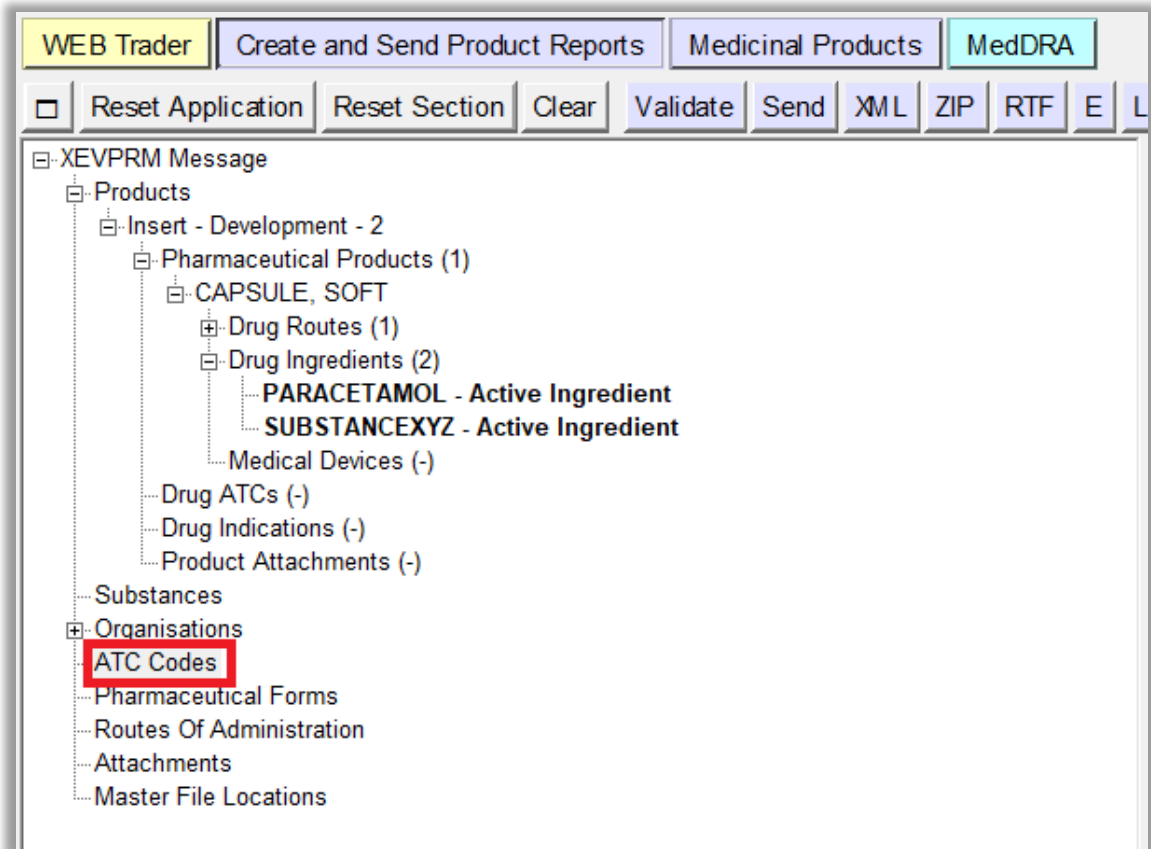
To activate the individual fields and enter the required information:

- Using your mouse, click on the area next to each field. The area will become highlighted in blue;
- Press "Enter" on your keyboard to activate the field;
- Either type in the required text (if the field is a free-text field) or select the value from a pre-defined table/calendar;
- In case of free-text field, once you type in the required information, press "Enter" on your keyboard for the information to be saved in that field.

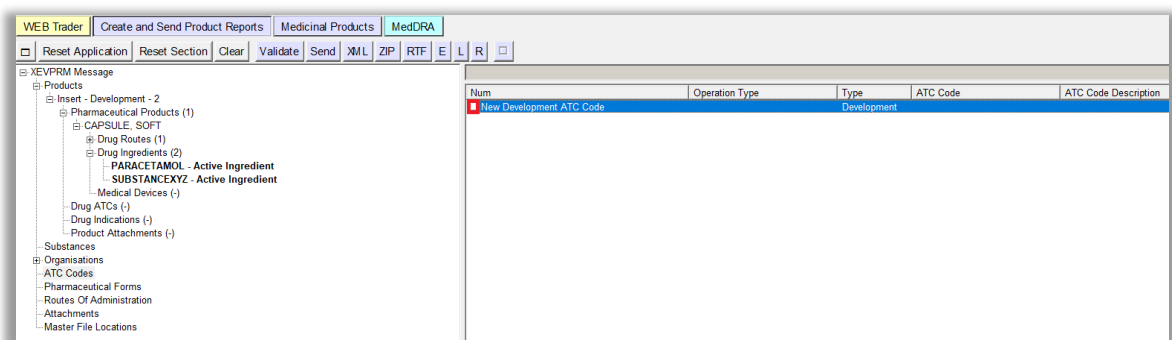
4) To reference this development route of administration in your DMP, you should retrieve the route of administration name in the 'Route of Administration' field of your DMP using the **local look-up table**.

Inset of a development ATC Code in the same XEVPRM

1) In the tree-view area, click on the "ATC Codes" section:



2) Select "New Development ATC Code" by ticking the relevant box in the active area:



The active area will display the fields applicable for a development ATC Code:

Description	Name/Value	
Operation Type	Insert	
Type	Development	
ATC Code		Field is Mandatory
ATC Code Description		Field is Mandatory
Version Date		
Comment		

The 'Operation Type' field will display 'Insert' and the 'Type' field will have the value 'Development' assigned by default.

3) Enter the relevant information in the individual fields as per guidance for each field described in section 4.2. *Insert of a development ATC Code* the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPPD\)](#).

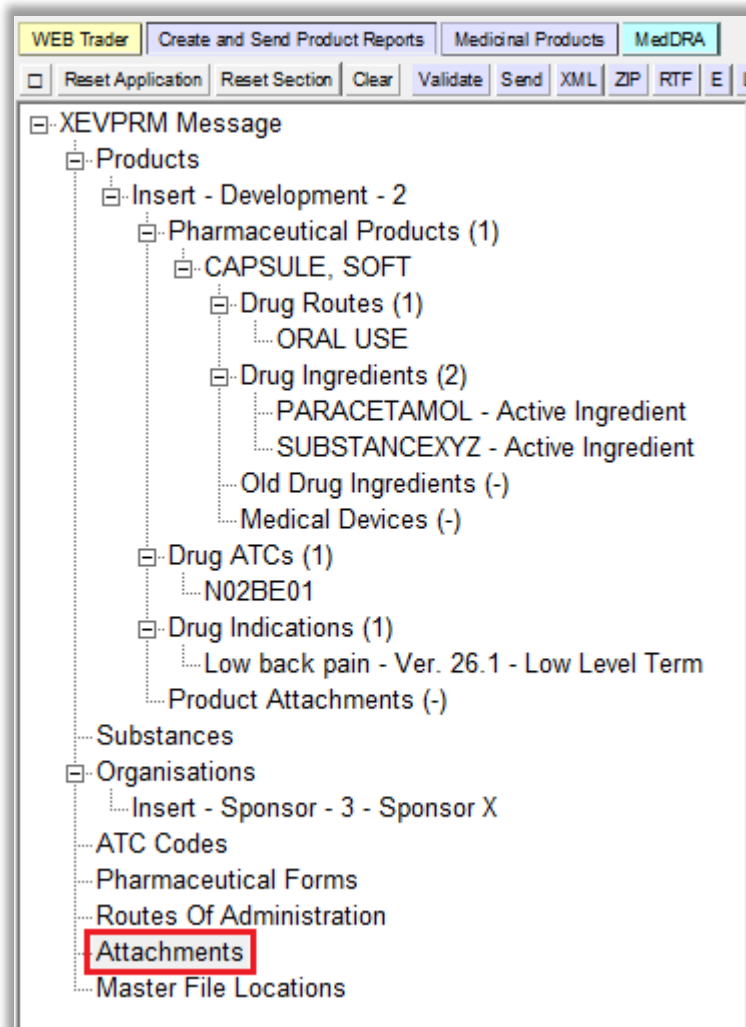
To activate the individual fields and enter the required information:

- Using your mouse, click on the area next to each field. The area will become highlighted in blue;
- Press "Enter" on your keyboard to activate the field;
- Either type in the required text (if the field is a free-text field) or select the value from a pre-defined table/calendar;
- In case of free-text field, once you type in the required information, press "Enter" on your keyboard for the information to be saved in that field.

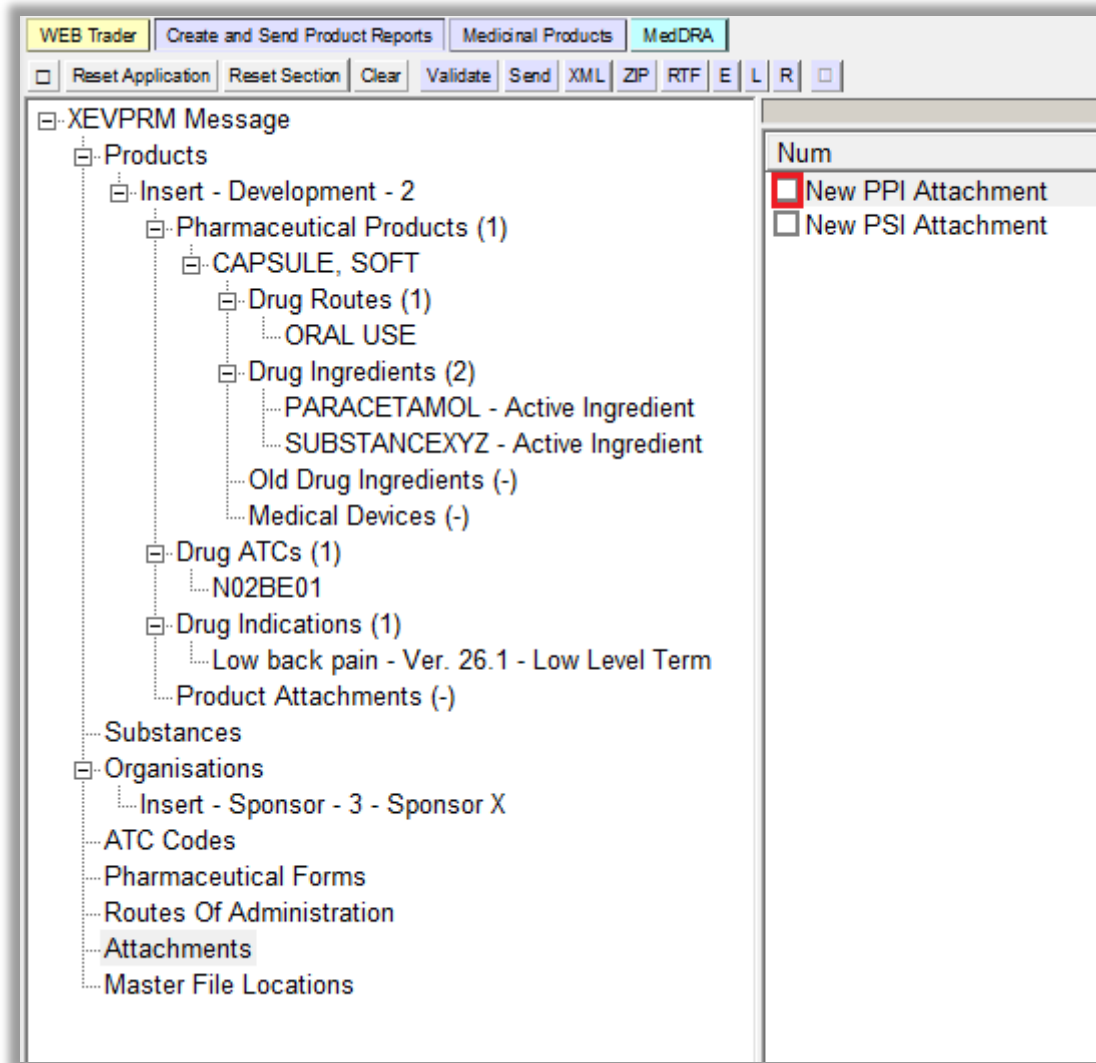
4) To reference this development ATC Code in your DMP, you should retrieve the ATC Code in the 'ATC Code' field of your DMP using the **local look-up table**.

Insert of an attachment in the same XEVPRM

1) In the tree-view area, click on the “Attachments” section:



2) Select “New PPI Attachment” by ticking the relevant box in the active area:



The active area will display the fields applicable for a PPI attachment.

3) Enter the relevant information in the individual fields as per guidance for each field described in section 7. *Initial submission of an attachment* of the [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).

File type

The "File Type" field is a field that will allow you to select one of the available pre-defined values. "PDF" will be automatically assigned and highlighted in blue:

Description	Name/Value	
File Type	PDF	
Name		Field is Mandatory
Type	PPI	
Language		Field is Mandatory
2nd Language		
Version Number		Field is Mandatory
Version Date		Field is Mandatory

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

Description	Name/Value	
	Select option	Field is Mandatory
	Press A - Z to find initial letter Press Enter to select, Escape to clear	Field is Mandatory
2nd L	DOC	Field is Mandatory
Version	DOCX	Field is Mandatory
Vers	PDF	Field is Mandatory
	XLS	
	XLSX	

Select the requested value; it will become highlighted in black:

Description	Name/Value	
	Select option	
	Press A - Z to find initial letter Press Enter to select, Escape to clear	
2nd	DOC	
Versio	DOCX	
Ve	PDF	
	XLS	
	XLSX	

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

Description	Name/Value	
File Type	DOCX	
Name		Field is Mandatory
Type	PPI	
Language		Field is Mandatory
2nd Language		
Version Number		Field is Mandatory
Version Date		Field is Mandatory

Name

This is a free-text field.

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

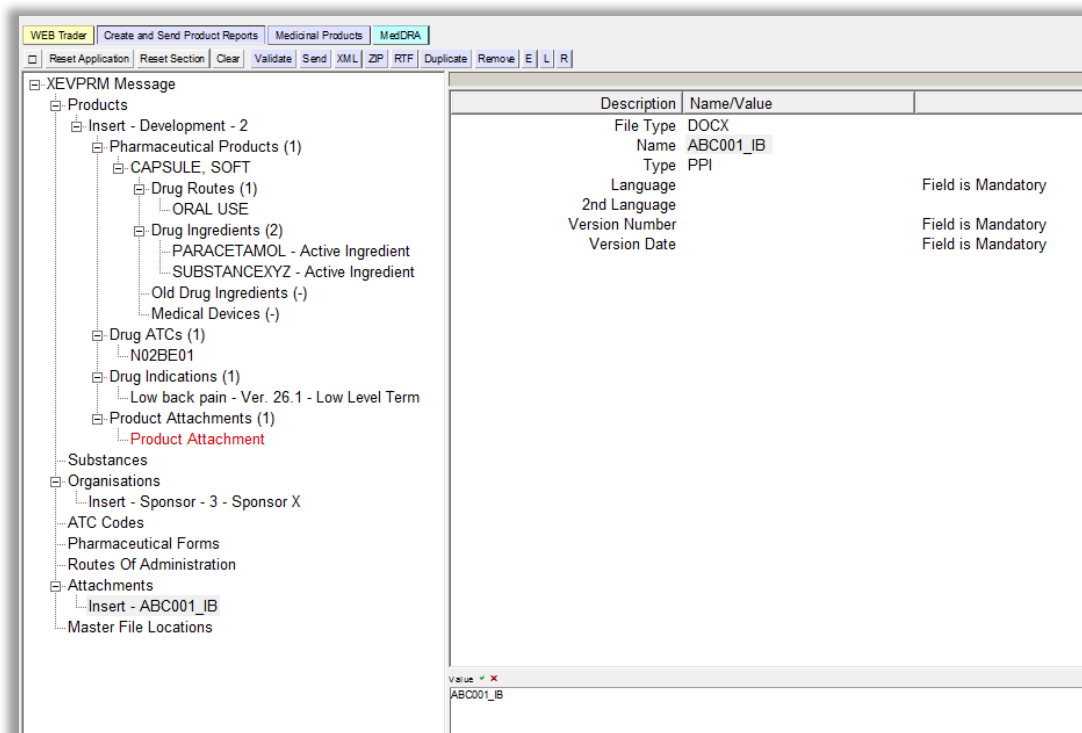
Description	Name/Value	
File Type	DOCX	
Name	<input type="text"/>	Field is Mandatory
Type	PPI	
Language		Field is Mandatory
2nd Language		
Version Number		Field is Mandatory
Version Date		Field is Mandatory

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:

Description	Name/Value	
File Type	DOCX	
Name	<input type="text"/>	Field is Mandatory
Type	PPI	
Language		Field is Mandatory
2nd Language		
Version Number		Field is Mandatory
Version Date		Field is Mandatory

Value

Type in the requested text and press "Enter" on your keyboard:



The name of your attachment will be displayed in the “Name” field:

Description	Name/Value	
File Type	DOCX	
Name	ABC001_IB	
Type	PPI	
Language		Field is Mandatory
2nd Language		
Version Number		Field is Mandatory
Version Date		Field is Mandatory

Type

The type of your attachment is automatically assigned as per your earlier indication:

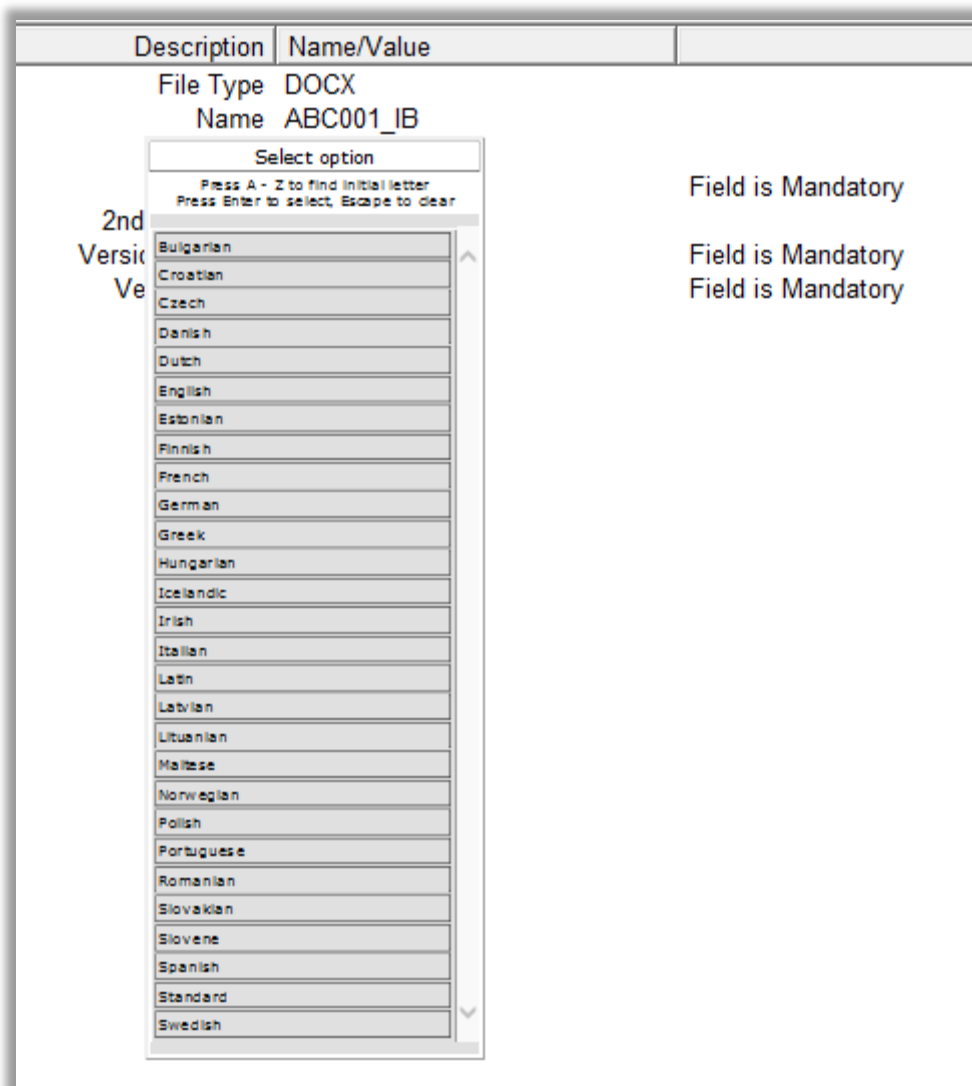
Description	Name/Value	
File Type	DOCX	
Name	ABC001_IB	
Type	PPI	
Language		Field is Mandatory
2nd Language		
Version Number		Field is Mandatory
Version Date		Field is Mandatory

Language

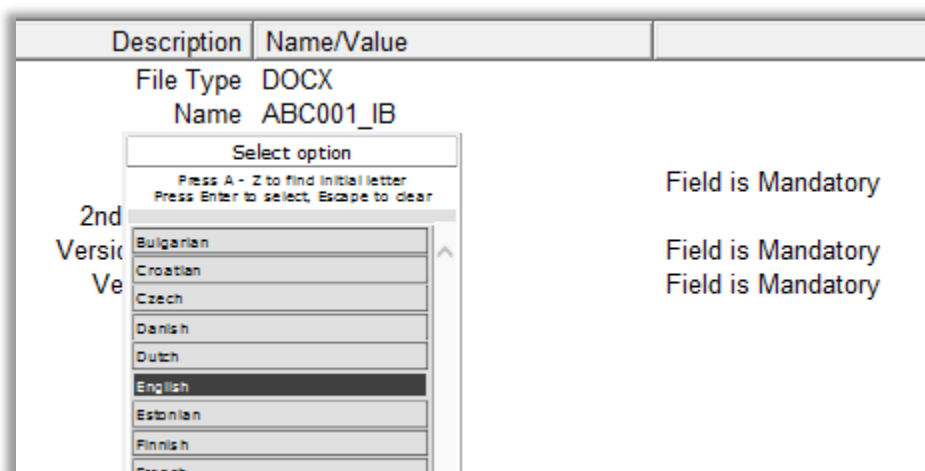
The "Language" field is a field that will allow you to select one of the available pre-defined values. Using your mouse, click on the area next to "Language". The area will become highlighted in blue:

Description	Name/Value	
File Type	DOCX	
Name	ABC001_IB	
Type	PPI	
Language		Field is Mandatory
2nd Language		
Version Number		Field is Mandatory
Version Date		Field is Mandatory

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 "Language" field:

Description	Name/Value	
File Type	DOCX	
Name	ABC001_IB	
Type	PPI	
Language	English	
2nd Language		
Version Number		Field is Mandatory
Version Date		Field is Mandatory

2nd Language

This field is not a mandatory field. It should be used only if the content of the attachment is provided in two languages. In that case, the same process described in section [Language](#) should be followed to enter the second language code.

Version number

This is a free-text field.

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

Description	Name/Value	
File Type	DOCX	
Name	ABC001_IB	
Type	PPI	
Language	English	
2nd Language		
Version Number	 	Field is Mandatory
Version Date		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:

Description	Name/Value	
File Type	DOCX	
Name	ABC001_IB	
Type	PPI	
Language	English	
2nd Language		
Version Number	<input type="text"/>	Field is Mandatory
Version Date		Field is Mandatory

Type in the requested text and press "Enter" on your keyboard. The version number will be displayed in the "Version Number" field:

Description	Name/Value	
File Type	DOCX	
Name	ABC001_IB	
Type	PPI	
Language	English	
2nd Language		
Version Number	1	
Version Date		Field is Mandatory

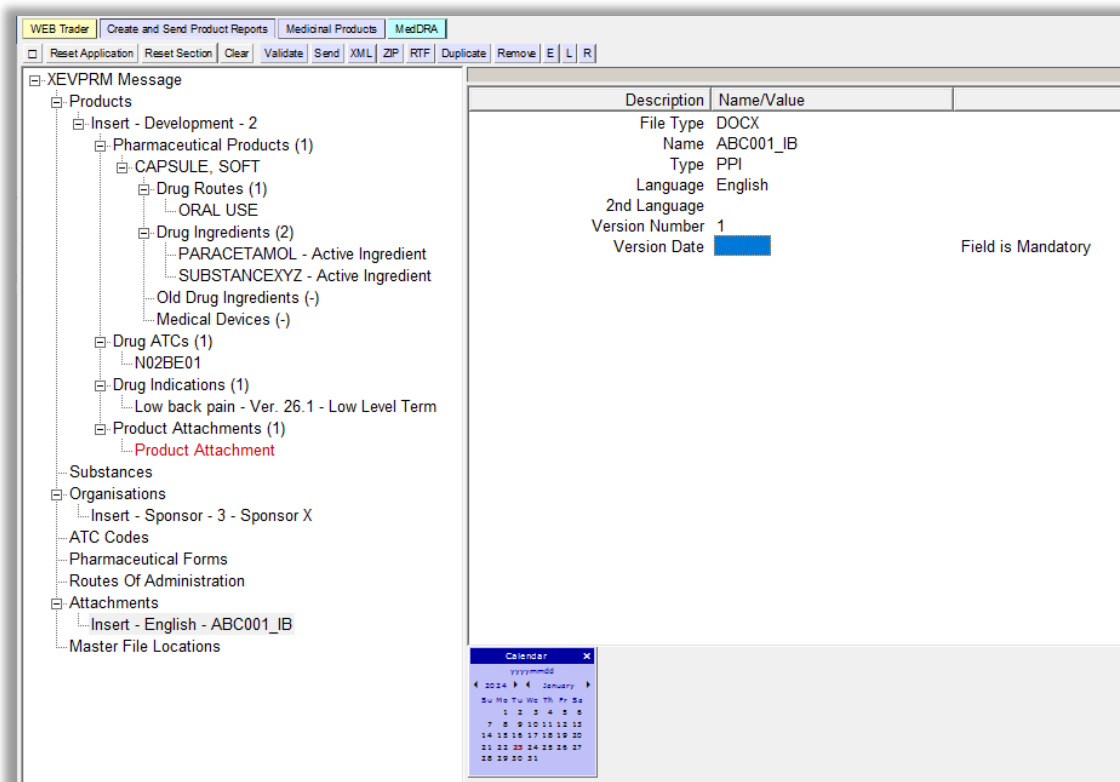
Version Date

The "Version Date" field is a graphical interface that recalls a calendar, which allows you to select the requested date.

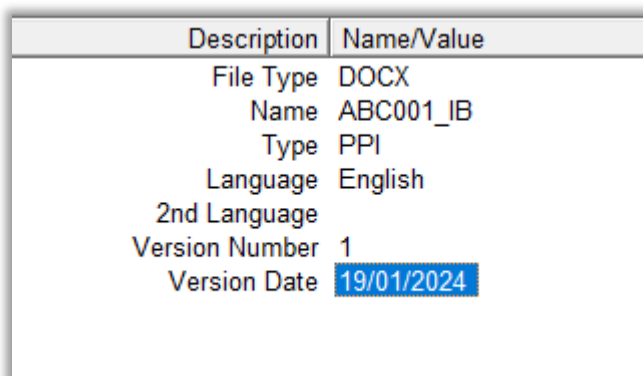
Using your mouse, click on the area next to "Version Date". The area will become highlighted in blue:

Description	Name/Value	
File Type	DOCX	
Name	ABC001_IB	
Type	PPI	
Language	English	
2nd Language		
Version Number	1	
Version Date		Field is Mandatory

Press "Enter" on your keyboard or double-click with your mouse. A calendar will be displayed:



Using your mouse, select the requested date; the date will be displayed in the field:



You have entered information for all fields required for the submission of a PPI attachment.

4) To reference this newly created PPI attachment in your DMP, you should retrieve the attachment name in the 'Product Attachment' field using the **local look-up table**.