

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

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# 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 <u>EV restricted area</u>.

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:

← → C 😁 evtest.e	ma.europa.eu/human/restricted/os/organizationselection.asp	Q	☆	0	Ď			-	:
EudraVigilance					H	ome Hi	Res ome	tric Pub	ted olic
					Re	stric	ted A	rea	
	Select organization								
	EVDIA (HQ) - EudraVigilance Human EVDIA - EVDIA							Î	
	For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NII) to the extent foreseen in the Protocol on I	reland/NI							

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:

Address: https://evtest.ema.europa.eu/human/restricted/x/x.asp7XI=6	
Digity Seting V VIES Take Clean and Sent Product Report Medicine Products MedDRA	VORFORGER - Electric Vigitarie Human (Narrotex) - Salectina (Narrotex) Portex - Salectina (National) - Sa e Nationa (National) - Salectina (National) - Salec
Peset Application   Read: Section   Dear	

# 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:

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				

#### 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:

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

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

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	Description	Name/Value	1		
Substances	Message Number		Field is Mandatory		
ATC Codes		Substances			
Pharmaceutical Forms Routes Of Administration		ATC Codes			
Attachments Master File Locations		Routes Of Administration			
		Master File Locations			

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:

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

**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:

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

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

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					
<ul> <li>Products</li> <li>Substances</li> <li>Sources</li> <li>Organisations</li> <li>ATC Codes</li> <li>Pharmaceutical Forms</li> <li>Routes Of Administration</li> <li>Attachments</li> <li>Master File Locations</li> </ul>	Num     Operation Type       New Authorised Product     New Development Product				

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

WEB Trader Create and Send Product Reports Medicinal Products MedDRA					
Reset Application Reset Section Clear Va	lidate Send XML ZIP RTF Duplicate Remove E L R				
XEVPRM Message					
E Products	Description Name/Value				
<ul> <li>Insert - Development</li> <li>Pharmaceutical Products (-)</li> <li>Drug ATCs (-)</li> <li>Drug Indications (-)</li> <li>Product Attachments (-)</li> <li>Substances</li> <li>Sources</li> <li>Organisations</li> </ul>	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				
ATC Codes Pharmaceutical Forms Routes Of Administration Attachments Master File Locations	Pharmaceutical Products (-) Section is Mandatory Drug ATCs (-) Drug Indications (-) Product Attachments (-)				

- 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 <u>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.</u>

#### **Development product entity data elements**

#### Туре

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:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA					
Reset Application Reset Section Clear Va	idate Send XML ZIP RTF Duplicate Remove E	LR			
E XEVPRM Message					
Products	Description Name/Value				
⊟ Insert - Development	Type Development				
- Pharmaceutical Products (-)	Operation Type Insert				
- Drug ATCS (-)	Sender Local Code				
Drug Indications (-)	Sponsor	Field is Mandatory			
- Product Attachments (-)	Product Code	Field is Mandatory Optional			
Substatices	Product Name	Field is Mandatory Optional			
Organisations	Product Other Name				
ATC Codes	Bharmacoutical Broducts ( )	Soction is Mandatony			
- Pharmacoutical Forms	Drug ATCs ()	Section is Manuatory			
- Routes Of Administration	Drug Indications (-)				
- Attachments	Product Attachments (-)				
Master File Locations					

• 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:

WEB Trader Create and Send Product Reports	Medicinal Products MedDRA
Reset Application Reset Section Clear Va	idate Send XML ZIP RTF Duplicate Remove E L R
XEVPRM Message	
Products	Description Name/Value
- Pharmaceutical Products (-)	Type Development
- Drug ATCs (-)	Opperation lype Insert
<ul> <li>Drug Indications (-)</li> </ul>	Sponsor Field is Mandatory
- Product Attachments (-)	Product Code Field is Mandatory Optional
- Substances	Product Name Field is Mandatory Optional Product Other Name Field is Mandatory Optional
Organisations	Comment
ATC Codes	Pharmaceutical Products (-) Section is Mandatory
- Pharmaceutical Forms	Drug AICS (-) Drug tetications (-)
Attachments	Product Attachments (-)
Master File Locations	
	Organisation Name
	Query Mode Begins vi
	Sponsor (DP.5)

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.

 $_{\odot}$  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:

				1	
WEB Trader Create and Send Product Reports Medicinal Products MediCRA					
Heset Application Reset Section Clear Validate Send XML	ZP RIF Duplicate	Remove E L R			
Breducto		Description	NameA/alue		
- Flouders		Type	Development	-	
-Pharmaceutical Products (-)		Operation Type	Insert		
-Drug ATCs (-)	Se	ender Local Code			
Drug Indications (-)		Sponsor		Field is Mandatory	
Product Attachments (-)		Product Code		Field is Mandatory Optional	
Substances	D.	Product Name		Field is Mandatory Optional	
Organisations	Pro	duct Other Name			
ATC Codes		Comment	Pharmaceutical Products (-)	Section is Mandatory	
Pharmaceutical Forms			Drug ATCs (-)	,	
Attachments			Drug Indications (-)		
Master File Locations			Product Attachments (-)		
	Mess	age from webpage	×		
		Lookup returr	ned no results		
			ОК		
	Organisation Name Sponsor X*				
	Query Mode	Begins			
11	1				

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:

WEB Tader       Create and Send Product Reports       Medicinal Products         Reset Application       Reset Section       Clear       Validate       Send       XML       20         > XEVPRM Message       Image: Application       Products       Image: Application       Products       Image: Application       Image: Application	MedDRA P RTF Duplicate Remore E L R Description Name/Value Type Development Operation Type Insert Sender L Sender L Sender L Programmer Senter Senter X Programmer Product Onsert Senter X Comment Pharmaceutical Products (-) Drug ATCs (-) Drug Indications (-) Product Attachments (-)	Field is Mandatory Optional Field is Mandatory Optional Section is Mandatory
--	--	--

 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:

WEB Trader         Create and Send Product Reports         Medicinal Products           Reset Application         Reset Section         Clear         Validate         Send         XML	MedDRA		
□ XEVPRM Message		(	
Products	Description	Name/Value	
Insert - Development	Туре	Development	
Pharmaceutical Products (-)	Operation Type	Insert	
-Drug ATCs (-)	Sender Local Code		
- Drug Indications (-)	Sponsor	Insert - Sponsor - Sponsor X	
Product Attachments (-)	Product Code		Field is Mandatory Optional
Substances	Product Name		Field is Mandatory Optional
Organisations	Product Other Name		
Insert - Sponsor - Sponsor X	Comment		
ATC Codes		Pharmaceutical Products (-)	Section is Mandatory
- Pharmaceutical Forms		Drug ATCs (-)	
-Routes Of Administration		Drug Indications (-)	
Attachments		Product Attachments (-)	
Master File Locations			

#### 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	
Туре	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	
Туре	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 (-)	

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



#### 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 <u>Guidance on the electronic submission of information on investigational medicinal</u> <u>products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD)</u>, 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 <u>Guidance on the electronic submission of information on investigational</u> <u>medicinal products for human use in the Extended EudraVigilance medicinal product dictionary</u>

(XEVMPD) , 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 <u>Guidance on</u> the electronic submission of information on investigational medicinal products for human use in the <u>Extended EudraVigilance medicinal product dictionary (XEVMPD)</u>, 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 XEVMPD.

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

#### **Pharmaceutical product elements**

Each medicinal product entry in the XEVMPD 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 <u>Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD).</u>

#### 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:

WEB Trader         Create and Send Product Reports         Medicinal Products           Reset Application         Reset Section         Clear         Validate         Send         XML	MedDRA ZIP RTF Duplicate Remove E L R		
⊡·XEVPRM Message ⊟·Products	Description	Name/Value	
<ul> <li>Insert - Development         <ul> <li>Pharmaceutical Products (-)</li> <li>Drug ATCs (-)</li> <li>Drug Indications (-)</li> <li>Product Attachments (-)</li> <li>Substances</li> </ul> </li> <li>Organisations         <ul> <li>Insert - Sponsor - Sponsor X</li> <li>ATC Codes</li> <li>Pharmaceutical Forms</li> <li>Routes Of Administration</li> <li>Attachments</li> <li>Master File Locations</li> </ul> </li> </ul>	Type Operation Type Sender Local Code Sponsor Product Code Product Name Product Other Name Comment	Development Insert Insert - Sponsor - Sponsor X ABC001 Pharmaceutical Products (-) Drug ATCs (-) Drug Indications (-) Product Attachments (-)	Section is Mandatory

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:

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		
E XEVPRM Message			
<u>⊨</u> Products	Description	Name/Value	
⊟-Insert - Development	Administrable Pharmaceutical Form		Field is Mandatory
Pharmaceutical Products (1)		Drug Routes (-)	Section is Mandatory
Pharmaceutical Product		Drug Ingredients (-)	Section is Mandatory
Drug Routes (-)		Old Drug Ingredients (-)	
Drug Ingredients (-)		Medical Devices (-)	
Old Drug Ingredients (-)			
Medical Devices (-)			
Drug ATCs (-)			
Drug Indications (-)			
Product Attachments (-)			
Substances			
<u>⊜</u> Organisations			
Insert - Sponsor - Sponsor X			
ATC Codes			
Pharmaceutical Forms			
-Routes Of Administration			
Attachments			
Master File Locations			

- **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:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA					
Reset Application Reset Section Olex Validate Send XML 2P RTF Duplicate Remove E L L R					
Week Application       Reset Application       Res	ZP       RTF       Duplicate       Remove       E       L       R         Description       Administrable       Pharmaceutical	Name/Value Drug Routes (-) Drug Ingredients (-) Old Drug Ingredients (-) Medical Devices (-)	Field is Mandatory Section is Mandatory Section is Mandatory		
	Phamapeutical Form Nat Capsule*				
	Query Mode Begins				
	Num Name		Туре		
	0001 CAPSULE		Standard		
	0002 CAPSULE, SOFT		Standard		
	0003 CAPSULE, HARD		Standard		

 $\circ$   $\;$  Select the required pharmaceutical form, so it is highlighted in blue:

Pharmace	Pharmaceutical Form Nat CAPSULE, SOFT			
QueryMo	Query Mode Begins			
Num	Name	Туре		
0001	CAPSULE	Standard		
0002	CAPSULE, SOFT	Standard		
0003	CAPSULE, HARD	Standard		

• 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 <u>'Extended EudraVigilance product report message (XEVMPD)</u> pharmaceutical dose forms' list].

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

#### If not:

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

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 <u>development</u> 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':

WEB Trader         Create and Send Product Reports         Medicinal Products         MedDRA           Paset Application         Reset Section         Cear         Validate         Send         XML         ZIP         RTF         Duplicate         Remove         E         L         R					
Products	Description	Name/Value			
⊡ Insert - Development	Administrable Pharmaceutical Form		Field is Mandatory		
Pharmaceutical Products (1)		Drug Routes (-)	Section is Mandatory		
Pharmaceutical Product		Drug Ingredients (-)	Section is Mandatory		
- Drug Routes (-)		Old Drug Ingredients (-)			
Drug Ingredients (-)		Medical Devices (-)			
Old Drug Ingredients (-)					

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 <u>Guidance on the electronic submission of information on investigational medicinal products
for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD).
</u>

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

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		1	(
Products	Description	Name/Value	
i⊟ Insert - Development - 2	Administrable Pharmaceutical	CAPSULE. SOFT	
Pharmaceutical Products (1)		Drug Routes (-)	Section is Mandatory
CAPSULE, SOFT		Drug Ingredients (-)	Section is Mandatory
-Drug Routes (-)		Old Drug Ingredients (-)	
Drug Ingredients (-)		Medical Devices (-)	
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			

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

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA	
Reset Application Reset Section Clear Validate Send XML	ZIP RTF E L R	
E XEVPRM Message		
	Num	Route Of Administration
i⊟ Insert - Development - 2	New Drug Route	
Pharmaceutical Products (1)		
Drug Routes (-)		
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		

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:

WEB Trader Create and Send Product Reports	Medicinal Products MedDRA	
Reset Application         Reset Section         Clear         Value	idate Send XML ZIP RTF Duplicate Remove E	LR
XEVPRM Message		
Products	Description Name/Value	
⊡ Insert - Development	Route Of Administration	Field is Mandatory
Pharmaceutical Products (1)		, i i i i i i i i i i i i i i i i i i i
Drug Roules (1)     Route of Administration		
- Drug Ingredients (-)		
- Old Drug Ingredients (-)		
Medical Devices (-)		
Drug ATCs (-)		
Drug Indications (-)		
Product Attachments (-)		
Substances		
- Sources		
⊟"Organisations		
- ATC Codes		
Pharmaceutical Forms		
Routes Of Administration		
Attachments		
Master File Locations		

- **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 lookup) 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:

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			
E XEVPRM Message				
Products	Description	Name/Value		
<ul> <li>Insert - Development - 2</li> <li>Pharmaceutical Products (1)</li> <li>CAPSULE, SOFT</li> <li>Drug Routes (1)</li> <li>Boute of Administration</li> <li>Drug Ingredients (-)</li> <li>Old Drug Ingredients (-)</li> <li>Drug Indications (-)</li> <li>Product Attachments (-)</li> <li>Substances</li> <li>Organisations</li> <li>Insert - Sponsor - 3 - Sponsor X</li> <li>ATC Codes</li> <li>Pharmaceutical Forms</li> <li>Routes Of Administration</li> <li>Attachments</li> <li>Master File Locations</li> </ul>	Route Of Administration		Field is Mandatory	
	Administration Route Narioral use*			
	Query Mode Begins			
	Num Name		Type	
	0001 ORAL USE		Standard	

• Press "Enter".

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

Administra	ion Route Nar	
QueryMod	e Begins	
Num	Name	Туре
0001	ORAL USE	Standard

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

Administration Route Nar ORAL USE	
Query Mode Begins	
Num Name	Туре
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:

WEB Hade Cleate and Send Froduct Reports Medicital Froduc	s MedDRA
Reset Application Reset Section Clear Validate Send XML	ZIP RTF Duplicate Remove E L R
⊡-XEVPRM Message	
⊨ • Products	Description Name/Value
⊡ Insert - Development - 2	Route Of Administration ORAL USE
p · Pharmaceutical Products (1)	
Drug Routes (1)	
ORAL USE	
Drug Ingredients (-)	
Old Drug Ingredients (-)	
Medical Devices (-)	
Drug ATCs (-)	
Drug Indications (-)	
Product Attachments (-)	
Substances	
Insert - Sponsor - 3 - Sponsor X	
AIC Codes	
Pharmaceutical Forms	
Routes Of Administration	
Attachments	
Waster File Locations	

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

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 <u>development</u> 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':

WEB Trader Create and Send Product Reports	Medicinal Products MedDRA	
Reset Application Reset Section Clear Val	idate Send XML ZIP RTF Duplicate Remove E	LR
XEVPRM Message		
□ Products	Description Name/Value	
Insert - Development     Development     Development	Route Of Administration	Field is Mandatory

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.

50	bstances created in the same message are available in the drop down list.
Role of Ingredient	
5	Full Description
Active Ingredient	[Substance] as [role]
Adjuvant	Concise:
ome errors present.	Move the Mouse over a Field highlighted in Red to see the error
Ingredient Stren	ath Information
	Approximately
Amount Value Type	Average Equal Not less than Range T
Amount Value Type	Average Equal Equal Not less than Range T
Amount Value Type	Average Equal Equal Not less than Range T

 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 Query Mo	e Name or Code paracetamol* de Begins				
Num	Name	Language	Туре	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:

1	Substance Name or Code PARACETAMOL				
1	Query Mode Begins				
	Num Name	Language	Туре	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	PARACETAMOL V Remote Lookup
	Substances created in the same message are available in the drop down list.
Role of Ingredient	
	Full Description
Active Ingredient Adjuvant	PARACETAMOL as [role]
Excipient	Concise :
Ingredient Stre	ngth Information
Ingredient Stre	Approximately Average Equal Not less than v 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 <u>Request SMS services</u> form as per the process described in section 8.1. Request for an insert or an amendment of a substance entity of the <u>Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD).</u>

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:

Substance Name	PARACETAMOL   Remote Lookup					
	Substances created in the same message are available in the drop down list.					
Role of Ingredient						
	Full Description					
Active Ingredient	PARACETA MOL as Active Ingredient					
Excipient	Concise:					
Ingre dient Stre	ngth Information					

**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 <u>Guidance on the electronic submission of</u> <u>information on investigational medicinal products for human use in the Extended EudraVigilance</u> <u>medicinal product dictionary (XEVMPD)</u> for further on 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 P	ARACETAMOL   Remote Lookup
Su	ubstances created in the same message are available in the drop down list.
Role of Ingredient	
	Full Description
Active Ingredient Adjuvant	PARACETA MOL as Active Ingredient At [value] [prefix] [unit] per [value] [prefix] [unit]
Excipient	Concise: PARACETAMOL [value] [prefx][unit]/[value] [prefx][unit]
Ingre dient Strengt	h Information
Amount Value Type	Approximately Average Equal Not less than Range
Exact Value	
Value	Prefx Unit
Numerator	
Denominator	ofPresentation

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	PARACET	AMOL			•		Remote Lookup
	Substance	s created i	n the same	e me	essage are available in the drop down list.		
Role of Ingredien	t						
	Full	Descripti	on				
Active Ingredient	PARA	CETAMOL	as Active	e Ingr	redient At [value] [prefix] [unit] per [value] [prefix] [	[unit]	l
Excipient	Con	cise:	PARAG	CET	AMOL [value] [prefix][unit]/[value] [prefix][unit]		
Ingredient St	rength Inf	ormation	l				
Amount Value Ty	pe Approxir Average Equal	than	Expressed	d as	Units of Measure		
Amount Value Ty	pe Approxir Average Equal Not less Range	than	Expressed	d as	Units of Measure		
Amount Value Ty Exact Value	pe Approxir Average Equal Not less Range	than	Expressed	d as	Units of Measure		
Amount Value Ty Exact Value Va	pe Approxir Average Equal Not less Range	hately than Prefix	Expressed	d as U	Units of Measure		
Amount Value Ty Exact Value Va Numerator	Approxin Average Equal Not less Range	than Prefix	Expressed	ed as U	Units of Measure Units of Presentation		•
Amount Value Ty Exact Value Va Numerator	Approxin Average Equal Not less Range	than Prefix	Expressed	d as U	Units of Measure Units of Presentation		•

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

Substance Name	PARACE	TAMOL		- Remote Lookup
	Substanc	es created	in the same i	message are available in the drop down list.
Role of Ingredien	t			
	Ful	l Descripti	ion	
Active Ingredient	PAR	ACETAMO	L as Active I	ngredient At 100 [prefix] [unit] per [value] [prefix] [unit]
Excipient	Co	ncise:	PARAC	ETAMOL 100 [prefix][unit]/[value] [prefix][unit]
Ingredient St	rength In	formation	ı	
Amount Value Ty	Approx Averag Equal Not les Range	s than Ţ	Expressed	as Units of Measure Units of Presentation
Exact Value				
Va	ue	Prefix		Unit
Numerator 10	)		•	▼
Numerator 10	)		•	▼ of Presentation

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

Substance Nam	e PARA	ACETAMOL	✓ Remote Lookup
Role of Ingredie	Substa ent	ance: atto (1x10^-18) centi (1x10^-2)	message are available in the drop down list.
Active Ingredie Adjuvant Excipient	nt F	Full         deci (1x10^-1) deka (1x10^1)           PARA         exa (1x10^18) femto (1x10^-15)           Con(giga (1x10^9))         beto (1x10^2)	ngredient At 100 milli [unit] per [value] [prefix] [unit] ETAMOL 100 m[unit]/[value] [prefix][unit]
Ingredient	Strength	kilo (1x10 <sup>x</sup> 2) Log10 <b>1 Inf(</b> mega (1x10 <sup>x</sup> 6) micro (1x10 <sup>x</sup> -6)	
Amount Value	Fype App Ave Equ Not Rar	mill (1x10 <sup>x</sup> -3) proxin nano (1x10 <sup>x</sup> -9) prage peta (1x10 <sup>x</sup> 15) ual pico (1x10 <sup>x</sup> -12) t less single nge tera (1x10 <sup>x</sup> -12) vocto (1x10 <sup>x</sup> -24)	as Units of Measure Units of Presentation
Exact Value	e /alue	yotta (1x10°-24) yotta (1x10°24) zepto (1x10°-21) zetta (1x10°21)	Unit
Numerator 1	00	milli (1x10^-3)	of Presentation
Denominator			• •

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

Exact Valu	ue		
	Value	Prefix	Unit
Numerator	100	milli (1x10^-3) -	<b>•</b>
			of Presentation
Denominator		-	<b>~</b>

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

				_	
witch view validate	Send XIVIL ZIP F		Gram(s)		
			International Unit(s)		
			Percent	-	
			Litre(s)	=	
Substance Name	PARACETAMOL		Mole(s)		okup
S	ubstances created in	the same n	Allergan Unit	-	
		and barne h	Allergen Unit For Ambrosia Artemisiifolia		
Role of Ingredient			Allergy Unit Equivalent (AUeq)		
	Full Description	1	Allergy Unit Modified (AUM)		
Active Ingredient			Allergy Unit Nominal (AUN) Allergy Unit(s)		
Adjuvant	PARACE TAMOL 8	as Active in	Ampere		
Excipient	Concise:	PARACE	Anti-Thrombin Unit(s)		
			Anti-Xa Activity International Unit(s)		
			Antigen Unit(s)		
Ingredient Stre	noth Information		Arbitary Unit(s)		
			Becquerel(s)		
	A		Bethesda Unit(s)		
	Approximately		Bioequivalent Allergy Unit(s)		
Amount Value Type	Equal E	Expressed a	Biological Allergy Unit (BAU) Bodansky Unit(s)		
	Not less than		British Pharmacopoeia Unit		
	Range 🔹		BU (Biological Unit)		
			Candela		-1
Exact Value			Cell Culture Infective Dose 50		
Value	Prefix		Celsius Temperature	-	
Numerator 100	milli (1x104	3) -		-	
	11111 (1710	~, ·		•	
			of Presentation		
Denominator		•	▼		
)					

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

Exact Valu	Exact Value							
	Value	Prefix	Unit					
Numerator	100	milli (1x10^-3)	Gram(s)					
			of Presentation					
Denominator			• •					

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

Exact Valu	ue			1
	Value	Prefix	Unit	l
Numerator	100	milli (1x10^-3) 🔹	Gram(s) 🔹	l
			of Presentation	l
Denominator	1		•	l

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

Substance Name	PARACET	AMOL	Remote Lookup
	Substance	s created in the sam	e message are available in the drop down list.
Role of Ingredient			
Active Ingredient Adjuvant Excipient	Full PARA Con	atto (1x10^-18) centi (1x10^-2) deci (1x10^-1) (deka (1x10^1) exa (1x10^18) fomto (1x10^15)	ngredient At 100 milli Gram(s) per [prefix] [unit] ETAMOL 100 mg/[prefix][unit]
Ingredient Str	ength Inf	giga (1x10°9) (hecto (1x10°2) kilo (1x10°3)	
Amount Value Typ	Approxit Average Equal Not less Range	mega (1x10^6) micro (1x10^-6) milli (1x10^-3) nano (1x10^-9) peta (1x10^15)	as Units of Measure Units of Presentation
Exact Value		pico (1x10^-12) single tera (1x10^12)	
Valu Numerator 100	le	yocto (1x10 <sup>4</sup> -24) yotta (1x10 <sup>4</sup> 24) zepto (1x10 <sup>4</sup> -21)	Unit Gram(s)
Denominator 1	_	zetta (1x10^21)	of Presentation

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

Exact Valu	ue		
	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	PARACE	TAMOL	Tablet Capsule Vial		▼ Remote Lookup
Role of Ingredient	Substances created in the same n				e drop down list.
Active Ingredient Adjuvant Excipient	Active Ingredient Adjuvant Excipient Full Description PARACETAMOL as Active In Excipient Concise: PARACE		Applicator Bag e In Bar Bead ACE Blister	н	s) per [unit]
Ingredient Str	Ingredient Strength Information				
Amount Value Typ	Approx Averag Equal Not less Range	e Express	Can Carton Cartridge Container Cup Cylinder Disk		
Exact Value Value	ue	Prefix	Drop Film Globule		
Numerator 100		milli (1x10^-3)	<ul> <li>Homeopathic Dilution Implant Impregnated Dressing</li> </ul>	-	•
Denominator 1		single	•	•	

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:

Substance Nam	ne PARA	PARACETAMOL    Remote Lool				
	Substa	Substances created in the same message are available in the drop down list.				
Role of Ingredi	ent					
		Full Description				
Active Ingredie	ent P	ARACETAMOL a	as Active Ingredient At 100 milli Gram(s) per Capsule (1{CAPSULE})			
Excipient		Concise:	PARACETAMOL 100 mg/Capsule			
	_					
Ingredient	Strength	Information				
Ingredient : Amount Value Exact Valu	Strength App Ave Equ Not Rar	roximately rage less than ige	Expressed as Units of Measure Units of Presentation			
Ingredient : Amount Value Exact Valu	Strength Type App Ave Equ Not Rar	Information roximately rage less than ge Prefix	Expressed as Units of Measure Units of Presentation			
Ingredient : Amount Value : Exact Valu Numerator :	Strength Type Ave Equ Not Rar Value 100	Prefix milli (1x10^-	Expressed as Units of Measure Units of Presentation			
Ingredient : Amount Value Exact Valu Numerator	Strength Type Ave Equ Not Rar Value	Prefix milli (1x10^-	Expressed as Units of Measure Units of Presentation			

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":

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Switch View Validate Send XML 2P	RTF Duplicate Remove E L R
⊡-XEVPRM Message	Substance Name PARACETAMOL V Remote Lookup
□-Insert - Development - 2 □-Pharmaceutical Products (1) □-CAPSULE, SOFT □-Drug Routes (1) □-ORAL USE □-Drug Ingredients (1) □-Drug Ingredients (1)	Substances oreated in the same message are available in the drop down list. Role of Ingredient Park CETA MOL as Active Ingredient At 100 milli Gram(s) per Capsule Concise: PARACETAMOL 100 mg/Capsule
PARACETAMOL - Active Ingredient     Old Drug Ingredients (-)     Medical Devices (-)     Drug ATCs (-)     Drug Indications (-)	Ingre dient Strength Information Approximately Amount Value Type Average Equal Not less than Range
Product Attachments (-) Substances Substances Insert - Sponsor - 3 - Sponsor X ATC Codes Pharmaceutical Forms Routes Of Administration Attachments Master File Locations	Exact Value     Value     Prefix     Unit       Numerator     Irolling     (Gram(a))     Irolling       Openominator     Irolling     Irolling     Irolling

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

WEB Trader Ceate and Send Product Reports Medicinal Products MedORA.  C Reset Application Reset Section Cear Validate Send XML 2P RTF E L	R 0								
XEVPRM Message							,		
Products	Num	Substance	Role	Amou	Numerator Value (Low limit)	Numerator Prefix (Low Limit)	Numerator Unit (Low Limit)	Denominator Value (Low limit)	Denominator Prefix (Low Limit)
insert - Development - 2	☑ 0001	PARACETAMOL	Active	Equal	100	milli (1x10^-3)	Gram(s)	1	single
<ul> <li>Pharmaceutical Products (1)</li> </ul>	New Drug Ingredient								
CAPSULE, SOFT									
Drug Routes (1)									
-ORAL USE									
⊖ Drug Ingredients (1)									
PARACETAMOL - 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									

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

WEB Trader Create and Send Product Reports Medicinal Products MedDRA					
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L					
E XEVPRM Message		1			1
Products	Num	Substance	Role	Amou	Numerator \
⊡ Insert - Development - 2	0001	PARACETAMOL	Active	Equal	100
Pharmaceutical Products (1)	New Drug Ingredient				
⊡ CAPSULE, SOFT					
⊡ Drug Routes (1)					
ORAL USE					
⊡ Drug Ingredients (1)					
PARACETAMOL - 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					

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

Substance Name	Remote Lookup  Substances created in the same message are available in the drop down list.							
Role of Ingredient	Role of Ingredient							
Active Ingredient Adjuvant Excipient Some errors preser	Full Description         [Substance] as [role]         Concise:         nt. Move the Mouse over a Field highlighted in Red to see the error							
Ingredient Strength Information								
Amount Value Typ	e Approximately E Average E Equal Not less than Range T							

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	Remote Lookup      Substances created in the same message are available in the drop down list.						
Role of Ingredient							
Active Ingredient Adjuvant Excipient	Full Description [Substance] as [role] Concise:						
Some errors prese	Some errors present. Move the Mouse over a Field highlighted in Red to see the error Ingredient Strength Information						
Amount Value Typ	Approximately Average Equal Not less than Range						
Substance Name or C	ode						
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 di	op down list.
Role of Ingredient	
Full Description	
Active Ingredient (Substance) as (role)	
Adjuvant Consistent	
Exapleint Concise.	
Some errors present. Move the Mouse over a Field highlighted in Red to see the error	иr
Ingredient Strength Information	
Apploximately · · · Average	
Not less than by	
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:
Substance Name Remote Lonkun
Substances created in the same message are available in the drop down list.
Role of Ingredient
Full Description
Active Ingredient ISubstance] as [rde]
Adjuvant Excipient Concise:
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 Range
Message from webpage × Lookup returned no results
Substance Name or Code SubstanceXY2
cuery mode pegins

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 <u>Guidance on the</u> <u>electronic submission of information on investigational medicinal products for human use in the</u> <u>Extended EudraVigilance medicinal product dictionary (XEVMPD)</u>.

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	SUB STANCEXYZ V Remote Lookup				
	Substances created in the same message are available in the drop down list.				
Role of Ingredient					
	Full Description				
Active Ingredient Adjuvent	SUBSTA NCEXYZ as Active Ingredient At 100 milli Gram(s) per Capsule				
Excipient	Concise: SUBSTANCEXYZ100 mg/Capsule				
Ingradiant Stree	orth Information				
ingreateric otter					
Amount Value Typ	Approximately Average Equal Not less than Range				
Exact Value					
Val	ue Prefix Unit				
Numerator 100	milli (1x10^-3) V Gram(s) V				
	of Presentation				
Denominator 1	single V Capsule V				

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

WEB Trader Ceate and Send Product Reports Medicinal Products MedDRA						
Reset Application Reset Section Clear Validate Send XIIL ZP RTF E						
XEVPRM Message						-
Products	Num	Substance	Role Amou	Numerator Value (Low limit)	Numerator Prefix (Low Limit)	Numerato
Insert - Development - 2	☑ 0001	PARACETAMOL	Active Equal	100	mili (1x10^-3)	Gram(s)
Pharmaceutical Products (1)	0002	SUBSTANCEXYZ	Active Equal	100	mili (1x10^-3)	Gram(s)
B-CAPSULE, SOFT	New Drug Ingredient					
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 <u>Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD).</u>

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:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L	R	
E XEVPRM Message		
Products	Num	ATC Code
⊡ Insert - Development - 2	New Drug ATC	
Pharmaceutical Products (1)		
Drug Routes (1)		
- ORAL USE		
Drug Ingredients (2)		
PARACETAMOL - Active Ingredient		
SUBSTANCEXYZ - Active Ingredient		
Old Drug Ingredients (-)		
Medical Devices (-)		
Drug ATCs (-)		
Drug Indications (-)		
t Product Attachments (-)		
Substances		
. ⊡ Organisations		
Insert - Sponsor - 3 - Sponsor X		
ATC Codes		
Pharmaceutical Forms		
Routes Of Administration		
Attachments		
Master File Locations		

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		Field is Mandatory
ATC Code			
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	N02BE 01		
QueryMo	de Begins		
Num	ATC Code	Name	Туре
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:

1	ATC Code	N02BE 01	1	
4	QueryMo	de Begins		
	Num	ATC Code	Name	Туре
	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:



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

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

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 <u>development</u> 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		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 <u>Guidance on the electronic</u> <u>submission of information on investigational medicinal products for human use in the Extended</u> <u>EudraVigilance medicinal product dictionary (XEVMPD).</u>

### 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:

De	scription	Name/Value	
MedDR/ MedD		Select option	Field is Mandatory Field is Mandatory
MedD	Press A Press Ente	A-Z to find initial letter er 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:

De	scription	Name/Value	
MedDR/ MedD		Select option	Field is Mandatory
MedD	Press / Press Ente	A-Z to find initial letter erto select, Escape to dear	Field is Mandatory
	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:

De	escription	Name/Value		
MedDR/	A Version	26.1	1	
MedD MedD		Select option		Field is Mandatory
Mean	Press A Press Ente	A-Z to find initial letter erto select, Escape to dear		i loid is Manualory
	Low Level Te	rm		
	Preferred Te	rm		
	High Level Te	erm		
	High Level G	roup Term		
	System Orga	an Class		

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

De	escription Name/Value	
MedDRA	Version 26.1	
MedD MedD	Select option	Field is Mandatory Field is Mandatory
	Press A- Z to find initial letter Press Enter to select, Escape to dear	2
	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	
M	edDRA Version	26.1	
	MedDRA Level	Low Level Term	
	MedDRA Term		Field is Mandatory
			-
Name	1		
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	
M	edDRA 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 rad	liation)	10024892

Select the requested value, double-click or press "Enter" on your keyboard. The selected value will be displayed in the "MedDRA Term" 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	
	Description Name/Value
⊡ Insert - Development - MK005	MedDRA Version 26.1
Pharmaceutical Products (1)	MedDRA Level Low Level Term
	MedDRA Term Low back pain
⊟- Drug Routes (1)	
ORAL USE	
Drug Ingredients (3)	
PARACETAMOL - Active Ingredient	
ORANGE FLAVOUR - Excipient	
MEPHENESIN NICOTINATE - Active Ingredient	
Old Drug Ingredients (-)	
Medical Devices (-)	
Drug ATCs (-)	
prug Indications (1)	
Low back pain - Ver. 26.1 - Low Level Term	

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:

IC	Π.			
H		Description	Name/Value	
L		Product Attachment		Field is Mandatory
L		Validity declaration		
		-		
L				
H				
L				
L				
Ш	13			
		Product Attachments		
Ш				

 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:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear Validate Send XML ZIP RTP Dupin			
	Description Name/Value		
Incert - Development - 2	Product Attachment	Field is Mandaton/	
Pharmaceutical Products (1)     G-CAPSULE, SOFT     Drug Routes (1)	Validity declaration	,	
ORAL USE     ORAL USE     ORAL USE     Orug Ingredients (2)     Orug Ingredients (2)     Orug Ingredients (2)     Orug Ingredients (-)     Orug ATCs (1)     Orug ATCs (1)     Orug Indications (1)			
	Message from webpage X		
Routes Of Administration Attachments Master File Locations	ОК		
	Product áttachmente ABC001 IB		
	l		

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:

XEVPRM Message	Description	Norma O Colum	[		
- Products	Description	Name/Value			
E-Insert - Development - 2	Product Attachment		Field is Mandator		
□-Pharmaceutical Products (1)	Validity declaration				
E-CAPSULE, SOFT					
Drug Routes (1)					
ORAL USE					
Drug Ingredients (2)					
PARACETAMOL - Active Ingredient					
SUBSTANCEXYZ - Active Ingredient					
Old Drug Ingredients (-)					
Medical Devices (-)					
E-Drug ATCs (1)					
N02BE01					
-Drug Indications (1)					
-Low back pain - Ver. 26.1 - Low Level Term					
Product Attachments (1)					
Product Attachment					
Substances					
Organisations					
Insert - Sponsor - 3 - Sponsor X					
ATC Codes					
- Pharmaceutical Forms					
- Routes Of Administration					
- Attachments					
Insert - English - ABC001 IB					
Master File Locations					

 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:

WEB Trader Create and Send Product Reports Medicinal Products MediCRA					
Reset Application Reset Section Clear Validate Send XML ZP RTF Duplicate Remove E L R					
⊡ XEVPRM Message			1		
	Description	Name/Value			
⊟ Insert - Development - 2	Product Attachment		Field is Mandatory		
Pharmaceutical Products (1)	Validity declaration				
🖻 CAPSULE, SOFT					
Drug Routes (1)					
- ORAL USE					
Drug Ingredients (2)					
PARACETAMOL - Active Ingredient					
SUBSTANCEXYZ - Active Ingredient					
Old Drug Ingredients (-)					
Medical Devices (-)					
⊡ Drug ATCs (1)					
- Drug Indications (1) - Low back asia, Max 20 1, Low Level Term					
Development Attachments (1)					
E-Product Attachments (1)					
Substances					
Insert - Sponsor - 3 - Sponsor X					
ATC Codes					
Pharmaceutical Forms					
-Routes Of Administration					
□ Attachments					
Insert - English - ABC001 IB					
Master File Locations					
	l				

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

D	escription	Name/Value				
Product A Validity (	Select option			Field is Mandatory		
	Press A - 1 Press Enter to	ess A - Z to find initial letter Enter to select, Escape to dear				
	Insert - English	- ABC001_18				

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:



# 3. Validate the XEVPRM

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

WEB Trader Create and Send Product Reports				Medicinal Products			MedDRA					
Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	Remove	EL	. R	

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:

Message fro	om webpage
?	Validate Failed 1 Error(s) present First error(s):
	XEVPRM Message / Message Number Field is Mandatory Press OK to go to the First error
	OK Cancel

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		Field is Mandatory
	Products	
	Substances	
	Sources	
	Organisations	
	ATC Codes	
	Pharmaceutical Forms	
	Routes Of Administration	
	Attachments	
	Master File Locations	
	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:



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

# 4. Send the XEVPRM

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

W	WEB Trader Create and Send Product Reports			orts Medi	cinal Pr	oducts	M	edDRA					
	Reset Applicati	n Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	Remove	E	L	R

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 <u>XEVMPD Data-Entry Tool</u> (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 <u>EMA Service Desk</u> for assistance, if needed.

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

9	Address: https://evtest.ema.europa.eu/human/restricted/x/LoadPost.asp?FA=1&NF=1							
	.:: The Maximum Size allowed for one Attachment is 25 MegaBytes ::.							
	English - ABC001_IB (DOCX)		Browse					
		Upload File						

**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:

Message f	rom webpage	×
?	Message Sent Successfully If You want to View the File(s) Sent Click [OK]	
	OK Cancel	

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:

Address: https://evtest.em	a.europa.eu/human/restricted/x/x.asp?xi=6	►
Summary		
Temporary (for Export)	Click here for the file	٦
	Name: V@xmpdtrain-Send-XMPDTRAIN-XEVPRM-Insert of DMP ABC001-2024-01-23+16.33.10-01.xr	nl
	EVPRM Zipped Message	
To the Outbox	Name:	
	EVPRM Zipped Message	
	Message Number: Insert of DMP ABCUUI	

Click on 'here':

Address: https://evtest.em	Address: https://evtest.ema.europa.eu/human/restricted/x/x.asp?xi=6							
Summary								
Temporary (for Export)	Click here for the file							
	Name: v@xmpdtrain-Send-XMPDTRAIN-XEVPRM-Insert of DMP ABC001-2024-01-23+16.33.10-01.xmJ							
	EVPRM Zipped Message							
	Message Number: Insert of DMP ABC001							
To the Outbox	Name :							
	EVPRM Zipped Message							
	Message Number: Insert of DMP ABC001							

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

Importation and a current and	
xml version="1.0" encodina="UTF-16" ?>	
vprm xmlns="http://eudraviailance.ema.europa.eu/schema/emaxevmpd"	
xmlns:ssi="http://eudravigilance.ema.europa.eu/schema/emaxevmpd_ssi" xmlns:xsi="http://www.w3.org/200	)1/XMLSchema-instance"
xsi:schemalocation="http://eudravigilance.ema.europa.eu/schema/emaxevmpd	-,
http://eudravigilance.ema.europa.eu/schema/emaxevmpd.xsd">	
<ichicsrmessageheader></ichicsrmessageheader>	
<messagetype>XEVPRM</messagetype>	
<messageformatversion>2</messageformatversion>	
<messageformatrelease>0</messageformatrelease>	
<messagenumb>Insert of DMP ABC001</messagenumb>	
<messagesende ridentifier="">XMPDTRAIN</messagesende>	
<messagereceiveridentifier>EVTEST</messagereceiveridentifier>	
<messagedat eformat="">204</messagedat>	
<messagedate>20240123163310</messagedate>	
organisations>	
- <pre>- </pre> - <pre>- </pre> - <pre>- </pre>	
<type_org>2</type_org>	
<pre><name org="">Sponsor X</name></pre>	
<li>localnumber&gt;3</li>	
<address>Blue_street</address>	
<city>Dublin</city>	
<pre>cnstcode.plil2_SNN</pre> /cnstcode.>	
<pre>countrycode&gt;LEs/countrycode&gt;</pre>	
attachments >	
- attachment operationtype="1">	
-filearman Attackment DOCX -/filearman	
statestantesteres APC001 IP s(stachmentesteres)	
<pre>cattachmentname&gt;Abcovi_ib</pre>	
<a attachmentry="" mentry="" pes<="" pests="" tach="" td=""><td></td></a>	
<pre>statiguagecode&gt;En</pre> /inguagecode>	
<actachmentversion attachmentversion="" s<="" sit="" td=""><td></td></actachmentversion>	
<attachmentversiondate>20240119</attachmentversiondate>	
<versiondaterormat>102</versiondaterormat>	
<pre>valuestance.com/size</pre>	
<pre>caeveipment products &gt;     description description = """ </pre>	
- <developmentproduct operationtype="1"></developmentproduct>	
<li>localnumber&gt;2</li>	
<sponsorcode resolutionmode="1">3</sponsorcode>	
- <developmentpresentationname></developmentpresentationname>	
<pre><pre>cproduct code &gt; ABC001 </pre></pre>	
development present at ionname	
- <productat cs=""></productat>	
- <product atc=""></product>	
<at ccode="" resolutionmode="2">N02BE01</at>	
- <productindications></productindications>	
- <pre>cproduct indication&gt;</pre>	
<meddraversion>26.1</meddraversion>	
<pre>cmeddralevel&gt;UTc/meddralevel&gt;</pre>	

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 <u>XEVMPD</u> <u>Data-Entry Tool (EVWEB) User Manual</u>, 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:

WEB Trader	Create and Send Product Reports			te and Send Product Reports Medicinal Pro			
Reset App	Reset Application Reset Section Clear Local Import						

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:

WEB Trader Create and	I Send Product Reports Medicinal Products MedDRA
□ Reset Application Re	set Section Clear Remote Import Create Ack
Imported Messages (-) Inbox Outbox Run to Excel Files Bulk Update Archive	

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

Address: https://evtest.ema.europa.eu/human/restricted/x/x.as	sp?xi=6					
Display Settings V						
WEB Trader Create and Send Product Reports Medicinal Products MedDRA						
Reset Application Reset Section Clear Remote Import 0						
Imported Messages (-)						
Inbox	Num	Name		Num/Count	Date	Size
Outbox	0001	ack	v@xmpdtrain-Send-XMPDTRAIN-XEV	1/1	2024/01/23 16:37.21	0000023
-Run to Excel Files						
-Bulk Update						
i Archive						

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" <u>for the relevant period</u>:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA
Reset Application Reset Section Clear Run Run to Excel
Imported Messages (-)
Inbox
Outbox
Run to Excel Files
Bulk Update
Archive
Archived Inbox (last 7 days)
Results
Archived Outbox (last 7 days)
Archived Outbox (last 30 days)
Archived Inbox
Archive Outbox

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 <u>for that period</u>.

The first message will be automatically highlighted in blue:

Address: https://evtest.ema.europa.eu/human/restricted/x/x.as	p?xi=6							
Display Settings								
WEB Trader Create and Send Product Reports Medicinal Products MedDRA								
Reset Application Reset Section Clear ReRun Delete Excel Remote Import								
Imported Messages (-)		t.	1	1	1	1	1	
Inbox	Num	File Name	Message Number	Receiver	Sender	Receive Date	Document Type	ID
Outbox	0001	ack v@xmpdtr	EU-EC-M-177500-ACK	XMPDTRAIN	EVTEST	2024/01/23 16:37.20	WebTrader EVPRMA	3451355
Run to Excel Files								
Bulk Update								
Archive								
Archived Inbox (last 7 days)								
Results								
Result 23 January 2024 16:38:59								
Archived Outbox (last 7 days)								
Archived Inbox (last 30 days)								
<ul> <li>Archived Outbox (last 30 days)</li> </ul>								
Archived Inbox								
Archive Outbox								

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:

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 Remote Import							
Imported Messages (-)		-	_	1			
Inbox	Num	Name		Num/Count	Date	Size	
Outbox	0001	ack www.ack www.ack.ack.ack.ack.ack.ack.ack.ack.ack.ack		1/1	2024/01/23 16:37.21	0000023	
-Run to Excel Files							
Bulk Update							

You can also double click on the separator line:

Num	Name		Num/Count	Date	Size
0001	ack I	v@xmpdtrain-Send-XMPDTRAIN-XEVPRM-Insert of DMP ABC001-2024-01-23+16.33.10-01 73lpwo.xml	1/1	2024/01/23 16:37.21	00000023

**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), ten press "Enter" on your keyboard or doubleclick 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):



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:



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:

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

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

WEB Trader Create and Send Product Reports	Medicinal Products MedDRA	
Reset Application Reset Section Clear Va	alidate Send XML ZIP RTF Duplicate Remove E L R	
E XEVPRM Message		
Products	Description Name/Value	_
Insert - Development	Operation Type Insert	
Pharmaceutical Products (-)	Type Sponsor	
Drug ATCs (-)	Sponsor Name Field is Mandatory	
Drug Indications (-)	Sponsor Sender ID	
Product Attachments (-)	Address Field is Mandatory	
Substances	City Field is Mandatory	
Sources	Region	
	Postcode Field is Mandatory	
Insert - Sponsor	Country Code Field is Mandatory	
ATC Codes	lelNumber	
- Pharmaceutical Forms	lel Extension	
-Routes Of Administration	Tel Country Code	
Attachments	Fax Number	
Master File Locations	Fax Extension	
	Fax Country Code	
	E-mail Address	
	Comment	

- The "Operation type" field displays "Insert (1)" as a default. It is not possible to assign a different operation type.
- Mandatory fields that must be populated are highlighted with the text "Field is Mandatory".

- Please note that not all mandatory fields are highlighted this way (some fields are business rules dependent). Additional mandatory fields/fields that must contain specific value may be highlighted during the validation process (see section 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 <u>Guidance on the electronic</u> <u>submission of information on investigational medicinal products for human use in the Extended</u> <u>EudraVigilance medicinal product dictionary (XEVMPD)</u>.

### 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.

### Туре

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:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA						
Reset Application Reset Section Clear Val	lidate Send XML ZIP RTF Duplicate Remove E	LR				
□ XEVPRM Message						
⊟ Products	Description Name/Value					
⊟-Insert - Development	Operation Type Insert					
Pharmaceutical Products (-)	Type Sponsor					
Drug ATCs (-)	Sponsor Name	Field is Mandatory				
Drug Indications (-)	Sponsor Sender ID					
Product Attachments (-)	Address	Field is Mandatory				
Substances	City	Field is Mandatory				
Sources	Region					
Organisations	Postcode	Field is Mandatory				
Insert - Sponsor	Country Code	Field is Mandatory				
- ATC Codes	Tel Number					
- Pharmaceutical Forms	Tel Extension					
- Routes Of Administration	Tel Country Code					
Attachments	Fax Number					
Master File Locations	Fax Extension					
	Fax Country Code					
	E-mail Address					
	Comment					

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

WEB Trader Create and Send Product Reports	Medicinal Products MedDRA	Ŭ
Reset Application Reset Section Clear Va	lidate Send XML ZIP RTF Duplicate Remove E	LR
XEVPRM Message		
Products	Description Name/Value	
Insert - Development	Operation Type Insert	
Pharmaceutical Products (-)	Type_Sponsor	
Drug ATCs (-)	Sponsor Name	Field is Mandatory
Drug indications (-)	Sponsor Sender ID	
Product Attachments (-)	Address	Field is Mandatory
Substances	City	Field is Mandatory
	Region	Field in Mandatany
	Posicode Country Code	Field is Mandatory
ATC Codes	Tal Number	FIEID IS Manualory
- Dharmacoutical Forms	Tel Extension	
Poutes Of Administration	Tel Country Code	
Attachments	Fax Number	
Master File Locations	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:



### 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	
Туре	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:

E Dent Assistantia Dent Partice Dent VIII 200 DEC Dented Dented Dented Dented	
Reset Application Reset Section Gear Validate Send XML 2/P RIF Duplicate Remove E L R	
E-XEVPRM Message	
Insert - Development     Operation Type Insert	
Pharmaceutical Products (-)     Type Sponsor	
Drug ATCs (-) Sponsor Name Sponsor X	
Drug Indications (-)     Sponsor Sender ID	
Product Attachments (-) Address Blue street	
Substances City Dublin	
Region	
Insert - Sponsor X Postcode DU12 5NN	
ATC Codes Country Code Field is Ma	andatory
- Pharmaceutical Forms Tel Number	
Routes Of Administration Tel Extension	
Attachments Tel Country Code	
Matter File Locations 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 Va	lidate Send XML ZIP R	Select option			
E XEVPRM Message		Press A - Z to find initial letter Press Enter to select, Escape to clear			
□ Products	Description				
☐ Insert - Development	Operation Type	Afghanistan	^		
- Pharmaceutical Products (-)	Type	ÅLAND ISLANDS			
Drug ATCs (-)	Sponsor Name	Albania			
Drug Indications (-)	Sponsor Sender ID	Algeria			
Product Attachments (-)	Address	American Samoa			
Substances	City	Andorra			
Sources	Region	Angola			
Organisations	Postcode	Anguilla			
Insert - Sponsor - Labox	Country Code	Antarctica	datory		
ATC Codes	Tel Number	Antigua And Barbuda			
Pharmaceutical Forms	Tel Extension	Argentina			
Routes Of Administration	Tel Country Code	Armenia			
Attachments	Fax Number	Aruba			
Master File Locations	Fax Extension	Australia			
	Fax Country Code	Austria			
	E-mail Address	Azerbaijan			
	Comment	Bahamas			

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

Select option	٦		
Press Enter to select, Escape to clear			
[			
Gabon	~		
Gambia			
Georgia			
Germany			
Ghana			
Gibraltar			
Greece			
Greenland			
Grenada			
Guadeloupe			
Guam			
Guatemala			
Guernsey			
Guinea			
Guinea-Bissau			
Guyana			
Haiti			
Heard And Mcdonald Islands			
Honduras			
Hongkong			
Hungary			
Iceland			
India			
Indonesia			
Iran			
Iraq			
Ireland			
Isle of Man			
Israel			
Italy			
lamaica	$\sim$		
20marca			

Once you click on the selected value, it will be displayed in the "Country Code" 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					
	Description Name/Value				
- Insert - Development	Operation Type Insert				
Pharmaceutical Products (-)	Type Sponsor				
Drug ATCs (-)	Sponsor Name Sponsor X				
Drug Indications (-)	Sponsor Sender ID				
Product Attachments (-)	Address Blue street				
Substances	City Dublin				
	Region				
Insert - Sponsor - Sponsor X	Postcode DU12 5NN				
-ATC Codes	Country Code Ireland				
Pharmaceutical Forms	Tel Number				
-Routes Of Administration	Tel Country Code				
Attachments	Fax Number				
Master File Locations	Fax Extension				
	Fax Country Code				
	E-mail Address				
	Comment				

#### Tel Number, Extension, Country Code, Fax Number, Fax Extension, Fax Country Code and Email 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:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Validate Send XML ZIP RTF Dupt				
E XEVPRM Message				
Products				
insert - Development - 2				
Pharmaceutical Products (-)				
Drug ATCs (-)				
Drug Indications (-)				
Product Attachments (-)				
Substances				
Organisations				
ATC Codes				
Pharmaceutical Forms				
Routes Of Administration				
Attachments				
Master File Locations				

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	
Туре	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 <u>Guidance on the electronic</u> <u>submission of information on investigational medicinal products for human use in the Extended</u> <u>EudraVigilance medicinal product dictionary (XEVMPD).</u>

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 predefined 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:

WER Taxes Court and Sent Design Design Multiple Design 1 Mar Dia				
Res et Application Reset Section Clear Validate Send XML ZP RTF E L				
R XEVPRM Message				
Products	Num	Operation Type	Туре	Administration Route Name
🗄 Insert - Development - 2	New Development Route of Administration		Development	
Pharmaceutical Products (1)				
CAPSULE, SOFT				
Drug ATCs (-)				
Drug Indications (-)				
Product Attachments (-)				
Substances				
Organisations				
-ATC Codes				
Pharmaceutical Forms				
Routes Of Administration				
Attachments				
Master File Locations				

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

Description	Name/Value	
Operation Type	Insert	
Туре	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 <u>Guidance on the electronic</u> submission of information on investigational medicinal products for human use in the Extended <u>EudraVigilance medicinal product dictionary (XEVMPD).</u>

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 predefined 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:

Field is Mandatory
Field is Mandatory

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 <u>Guidance on the electronic submission of</u> 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 predefined 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 are, 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 <u>Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD).</u>

### 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
Туре	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:

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

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

0	)escription	Name/Value		
	Select option			
	Press A - Z to find initial letter Press Enter to select, Escape to dear			
2nd	DOC			
Versio	i( pocx			
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
Туре	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		Field is Mandatory
Туре	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	221	Field is Mandatory
language	PPI	Field is Mandaton/
2nd Language		Tield is Manualory
Version Number		Field is Mandatory
Version Date		Field is Mandatory
J		
Value * X		

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

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Olear Validate Send XML ZP RTF Duplicate Remove E L R				
⊡-XEVPRM Message			,	
⊟ Products	Description	Name/Value		
⊟ Insert - Development - 2	File Type	DOCX		
Pharmaceutical Products (1)	Name	ABC001_IB		
i⊟ CAPSULE, SOFT	Туре	PPI		
⊡ Drug Routes (1)	Language		Field is Mandatory	
ORAL USE	2nd Language			
□ Drug Ingredients (2)	Version Number		Field is Mandatory	
PARACETAMOL - Active Ingredient	Version Date		Field is Mandatory	
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)				
Product Attachment				
Substances				
□ Organisations				
Insert - Sponsor - 3 - Sponsor X				
ATC Codes				
Pharmaceutical Forms				
Routes Of Administration				
- Attachments				
Insert - ABC001_IB				
Master File Locations				
	J Value * X			
	ABC001_IB			

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

Description	Name/Value	
File Type	DOCX	
Name	ABC001 IB	
Туре	PPI	
Language		Field is Mandatory
2nd Language		
Version Number		Field is Mandatory
Version Date		Field is Mandatory

### Туре

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

Description	Name/Value	
File Type	DOCX	
Name	ABC001 IB	
Туре	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	
Туре	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:

		1		,
D	escription	Name/Value		
	File Type	DOCX		
	Name	ABC001 IB		
	- Tunio	1.00001_10		
	Se	elect option		
	Press A - Press Enter to	Z to find initial letter o select, Escape to dear	,	Field is Mandatory
2nd				
Versic	Bulgarlan		~	Field is Mandatory
Ve	Croatian			Field is Mandatory
	Czech			
	Danish			
	Dutch			
	English			
	Estonian			
	Finnish			
	French			
	German			
	Greek			
	Hungarian			
	Icelandic			
	Irish			
	Italian			
	Latin			
	Latvian			
	Lituanian			
	Maltese			
	Norweglan			
	Polish			
	Portuguese			
	Romanian			
	Slovaklan			
	Slovene			
	Spanish			
	Standard			
	Swedish		V I	

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

escription Name/Value	
File Type DOCX Name ABC001_IB	
Select option Press A - Z to find initial letter Press Enter to select, Escape to dear	Field is Mandatory
Bulgarian Croatian Czech	Field is Mandatory Field is Mandatory
Danish Dutch English	
Estonian Finnish	
	Pescription Name/Value File Type DOCX Name ABC001_IB Select option Press A - Z to find initial letter Press Enter to select, Escape to dear Bulgarian Croatian Croatian Czech Danish Dutch English Estonian Finnish French

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

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

#### 2<sup>nd</sup> 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	
Туре	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	
Туре	PPI	
Language	English	
2nd Language		
Version Number		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	
Туре	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	
Туре	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:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear Validate Send XML ZIP RTF Dupli	cate Remove E L R		
⊡-XEVPRM Message			
- Products	Description	Name/Value	
insert - Development - 2	File Type	DOCX	
Pharmaceutical Products (1)	Name	ABC001_IB	
CAPSULE, SOFT	Туре	PPI	
Drug Routes (1)	Language	English	
ORAL USE	2nd Language		
Drug Ingredients (2)	Version Number	1	
PARACETAMOL - Active Ingredient	Version Date		Field is Mandatory
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)			
Product Attachment			
Substances			
Organisations			
Insert - Sponsor - 3 - Sponsor X			
ATC Codes			
-Pharmaceutical Forms			
-Routes Of Administration			
Attachments			
Insert - English - ABC001_IB			
Master File Locations	Colordar X		
	yyyymmdd		
	C 2024 C January		
	1 2 3 4 5 6		
	7 8 9 10 11 12 13 14 15 16 17 18 19 20		
	21 22 23 24 25 26 27 28 29 30 31		

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**.