



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



## eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) user manual

Version 5.2

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# 1. INTRODUCTION

## 1.1. *About this User Manual*

This user manual is part of the official documentation prepared by the European Medicines Agency to support marketing authorisation holders (MAHs) and sponsors of clinical trials using the eXtended EudraVigilance Medicinal Product Dictionary data-entry tool (EVWEB), and focuses on EVWEB functionalities based on the **XEVPRM format published by the Agency on 31 January 2014 and available in the EVWEB production environment as of 16 June 2014.**

For marketing authorisation holders, related documents to be read in conjunction with this User Manual include:

- [Chapter 3.II: XEVPRM User Guidance](#);
- [Legal Notice on the Implementation of Article 57\(2\) of Regulation \(EC\) No. 726/2004](#);
- [Electronic submission of Article 57\(2\) data: Questions & Answers \(Q&As\) document](#).

Further information related to the electronic submission of authorised medicines can be found on the [Reporting requirements for marketing-authorisation holders](#) webpage of the Agency's website.

**The case and medicinal product examples used in this manual to describe the functionalities and rules of the system are fictitious, and are intended for demonstration purposes only.**

## **1.2. About EudraVigilance**

EudraVigilance is the European Union pharmacovigilance database and data-processing network (the 'EudraVigilance database'). It supports the:

- Secure exchange, processing and evaluation of Individual Case Safety Reports (ICSRs) related to medicinal products authorised in the European Union (EU) and investigational medicinal products (IMPs) studied in clinical trials authorised in the EU;
- Signal detection, evaluation and management;
- Proactive release of information on adverse reactions in compliance with personal data protection legislation in the EU;
- Electronic submission of information of medicinal products authorised in the EU;
- Provision of information on IMPs by the sponsor before completing a clinical trials application in the EU.

## **1.3. EudraVigilance Database Management System (EVDBMS)**

The EVDBMS is one of the core elements of EudraVigilance. The web-based information system features:

- A fully integrated organisation and user management synchronised with the EudraVigilance Gateway profile management;
- Proper privacy and security measures to ensure that the principles of data integrity, accountability and availability are adhered to;
- A fully automated message processing mechanism, using XML-based messaging, supporting both asynchronous data interchange and interactive transactions;
- A pharmacovigilance database, which is built by importing and consolidating data from multiple sources, including information on medicinal products and adverse drug reactions;
- An extensive query and tracking/tracing capability, both from a scientific and administrative business perspective.

EVDBMS is based on a three-tier, light client based architecture offering remote access to administrative and scientific users of the European Commission, the EMA, the EU Regulatory Network and pharmaceutical companies via secure connection over the Internet.

Taking into account the pharmacovigilance activities in the pre- and post- authorisation phase, the EudraVigilance Database Management System (EVDBMS) consists of two reporting modules:

- The EudraVigilance Clinical Trial Module (EVCTM) to facilitate the electronic reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) as required by Directive 2001/20/EC.;
- The EudraVigilance Post-Authorisation Module (EVPM) for post-authorisation ICSRs as required by Regulation (EC) No 726/2004, Directive 2001/83/EC as amended.

The reporting of suspected serious adverse reactions (ADRs) is defined in the Community legislation. This process involves healthcare professionals, the European Medicines Agency (EMA), National Competent Authorities (NCAs) and marketing authorisation holders (MAHs), and is applicable to all medicinal products authorised in the EEA. The reporting includes suspected serious adverse reactions occurring both within and outside the EEA.

The reporting of suspected unexpected serious adverse reactions (SUSARs) during clinical trials is defined in the Community legislation. This process involves investigators, sponsors of clinical trials conducted in the EEA, the EMA, NCAs and Ethics Committees. The reporting is applicable to all investigational medicinal products (IMPs), which are studied in the frame of interventional clinical trials conducted in the EEA and includes all SUSARs, which occur either within or outside the EEA.

#### **1.4. EudraVigilance ESTRi Gateway**

EudraVigilance provides an electronic regulatory submission environment, the EudraVigilance Gateway, which follows the ICH M2 Gateway Recommendation for The Electronic Standards (for the Transmission (of) Regulatory Information (ESTRi) Gateway.

The purpose of the EudraVigilance Gateway is to operate a single common EU Gateway for receiving regulatory submissions in a fully automated and secure way including all aspects of privacy, authentication, integrity and non-repudiation of all transactions in pharmacovigilance.

The EudraVigilance Gateway allows marketing authorisation holders (MAHs), applicants and sponsors of clinical trials (sponsors) to report to a common reporting point within the EEA from where the transactions are re-routed to the addressed Competent Authorities and the EMA. It provides the Competent Authorities with a secure reporting mechanism to the MAHs, applicants, and sponsors and to the EMA. The MAHs, applicants and sponsors are responsible for implementing at least one of the multiple ESTRi standards in order to ensure electronic communication with any Regulatory Authority.

The EudraVigilance Gateway supports two transmission modes:

- The Gateway transmission mode;
- The Web Trader transmission mode.

The **Gateway transmission mode** refers to an organization that has a fully ICH E2B(M) compliant pharmacovigilance database available, which permits the generation and receipt of ICSRs and the electronic transmission of ICSRs via a local gateway solution that meets the ICH M2 standards, and that has been successfully tested and connected with the EudraVigilance Gateway.

The **Web Trader transmission mode** is an integrated component of the EudraVigilance Gateway designed to facilitate electronic submissions by Small and Medium Size Enterprises (SMEs) or Regional Pharmacovigilance Centres in a secure way.

The Web Trader transmission mode is applicable to organisations that do not have a local Gateway solution that allows connecting to the EudraVigilance Gateway.



• Only registered organisations are permitted to exchange Safety, Product and Acknowledgement Messages by means of the EudraVigilance Gateway. Please see the [EudraVigilance registration webpages](#) for information on how to register.



## 1.5. EVWEB

In addition to the automated message generation and processing, the EudraVigilance Database Management System also provides interactive tools to allow for a "manual" safety and acknowledgement message, as well as medicinal product report generation and administration by a user via a web interface called EVWEB.

EVWEB can be used by any marketing authorisation holder or sponsor of a clinical trial with reporting or submission obligations in the EU, but has been specifically designed for Small and Medium Size Enterprises (SMEs), which do not have the necessary IT in-house tools available.

EVWEB requires an Internet connection and the application currently only supports Internet Explorer 8. If you cannot use this older version of IE, you can still use EVWEB with IE9 & IE10 using the link [here](#) to access the XHTML version of the application directly. You will need to set your IE browser to compatibility view. More information on how to change Internet Explorer compatibility view settings is available from the [Microsoft website](#).

The electronic submission of information on medicinal products is secure. Security is achieved in a first instance by a username/password combination to access the registered user restricted area of the EudraVigilance website, and in a second instance by the use of a HTTPS (SSL) protocol. Secure Sockets Layer (SSL) provides security by the use of a public key to encrypt data that is then transferred over the SSL connection. In HTTP (S-HTTP), SSL creates a secure connection between a client and a server, through which any amount of data can be sent securely. SSL and S-HTTP are therefore complementary technologies.

Access to EVWEB is personal and non-transferable for each user of each organisation. It is achieved through personal login and password access keys can be obtained following registration with EudraVigilance. The registration process is outlined on the [EudraVigilance registration webpage](#).

One of the main functionalities of EVWEB is the possibility to:

- **Create and send eXtended EudraVigilance Product Report Messages (XEVRMs)** in relation to authorised medicinal products as per Article 57(2) of Regulation (EC) 726/2004 requirements, and investigational medicinal products in accordance with the Commission's detailed guidance CT-3 requirements.



- Only Web Trader users can send XEVRMs via EVWEB. Gateway users may use the application to create XEVRMs but messages can only be sent via their local gateway or via EV Post functionality, which is available on the EudraVigilance website (restricted area accessible for registered users only).

EVWEB automatically displays the complete sections of the hierarchical structure of a typical XEVRM, giving the user an opportunity to insert the information on medicinal products in the various fields as necessary. The application displays mandatory fields and allows detecting errors in complying with business rules before sending the message.

- **Receive XEVRM Acknowledgment messages (XEVRM ACKs)**

XEVRM acknowledgement messages are used to inform a marketing authorisation holder or a sponsor of a clinical trial that the XEVRM has been received and processed by the EMA.



- Only Web Trader users can receive XEVRM ACKs via EVWEB. Gateway users will receive their XEVRM ACKs via their local gateway.

- **Keep track of sent XEVPRMs and received XEVPRM ACKs**, as well as **rejected XEVPRMs** (e.g. due to non-conformity with the XEVPRM schema or non-adherence with the XEVPRM business rules).



- Only Web Trader users can use the 'Web Trader Inbox and Outbox' sections of EVWEB. Gateway users will store their sent and received messages via their local gateway.

- **Export XEVPRMs**

After an XEVPRM has been created, it can be exported in different formats: XML (which is the typical format for electronic submissions of information on medicinal products) and RTF (which are typical "text" document formats).

This is to enable the user to maintain a copy of the XEVPRM submissions locally.

- **Navigate, browse and perform queries throughout the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD )**

EVWEB users are able to insert specific key words and/or combinations of search criteria to run complex queries in the XEVMPD. Results will be displayed on screen.

- **Browse and query MedDRA terminology** in its latest version. MedDRA is fully integrated in the EVWEB application.

## ***1.6. eXtended Medicinal Product Report Message (XEVPRM)***

XEVPRM is an XML file used to insert and maintain information in the XEVMPD. It consists of a set of controlled vocabularies covering a set of codified data elements required by companies submitting information.

An XEVPRM can contain:

- Product (Authorised or Development)
- Substance (Approved or Development)
- Source
- Organisation
- ATC Code
- Pharmaceutical Form
- Administration Route
- Attachments
- Master File Locations

When creating an XEVPRM message using EVWEB (as described in section [3. CREATE AND SEND XEVPRMs](#)), the **"XEVPRM Message" section** allows specifying the Message Header, which is a mandatory section in the XEVPRM. Please note that for the "message header" section, you only have to

specify the "Message Number", since the system will automatically complete the other message header information which is not displayed (i.e. sender ID, receiver ID, etc.).

The **"Medicinal Products" section** is the main section and allows you to create Product Reports both for authorised and development medicinal products that need to be added or maintained in the XEVMPD.

You can add more than one Product Report in the same XEVPRM, but for each Product Report, you must specify the operation type and the medicinal product type ("Authorised" or "Development").

The **"Substances" section** allows you to create Substance Reports for both - development or approved substances that need to be added, updated or deleted in the substance lookup table.

You can add more than one substance report in the same XEVPRM, but for each substance, you must specify the operation type and the substance type ("Approved" or "Development").



● Please note that users cannot currently insert or maintain approved substance information in the XEVMPD. Please refer to the changes related to submission of approved substance information - see [Changes to some business rules of the eXtended EudraVigilance Medicinal Product Dictionary \(XEVMPD\): Submission of substance information](#) or see section [1.7.2.3. Approved Substance \(AS\)](#) for further information.

The **"Sources" section** allows you to create reference sources that need to be added, updated or deleted in the Source lookup table.

You can add more than one source in the same XEVPRM, but for each source you must specify the operation type.

The **"Organisations" section** allows you to create organisations for both – marketing authorisation holders (MAHs) and sponsors that need to be added, updated or deleted in the MAH and sponsor lookup tables.

You can add more than one organisation in the same XEVPRM, but for each organisation you must specify the operation type and the organisation type ("MAH" or "Sponsor").

You cannot send medicinal products of other MAHs or sponsors - you are only allowed to specify MAHs/Sponsors/Affiliate/Subordinates that belong to your organisation hierarchy (e.g. you as the headquarter organisation and your affiliates). The organisations you can specify must be registered in the EudraVigilance system and you should report their "Organisation Sender ID" in the "Sender ID" field. Please refer to the [Registration with EudraVigilance](#) webpages.

The **"ATC Codes" section** allows you to create ATC Codes for both – proposed or development ATC Codes that need to be added, updated or deleted in the ATC Code lookup table.

You can add more than one ATC Code in the same XEVPRM, but for each ATC Code you must specify the operation type and the term type ("Proposed" or "Development"). Development terms can only be used in development medicinal products.

The "**Pharmaceutical Forms**" section allows you to create Pharmaceutical Forms for both – proposed or development pharmaceutical forms that need to be added, updated or deleted in the Pharmaceutical Dose Form lookup table.

You can add more than one Pharmaceutical Dose Form in the same XEVPRM, but for each Pharmaceutical Dose Form you must specify the operation type and the term type ("Proposed" or "Development").

Development terms can only be used in development medicinal products.

The "**Administration Routes**" section allows you to create Administration Routes for both - proposed or development routes of administration that need to be added, updated or deleted in the Administration Route lookup table.

You can add more than one Administration Route in the same XEVPRM, but for each Administration Route you must specify the operation type and the term type ("Proposed" or "Development").

Development terms can only be used in development medicinal products.

The "**Attachments**" section allows you to create a reference to Printed Product Information (PPI) and/or Printed Substance Information (PSI), which will be attached to the message when sending.

You would need to specify the file type and name, as well as the language of the file and the version number of the file to be attached.

The "**Master File Location**" section allows you to provide information about the physical location of the Pharmacovigilance Master File.

For a complete description of the XML schema and the structure of the XEVPRM please refer to the XEVPRM and XEVPRM Acknowledgement Documentation available on the "Guidance Documents" webpage

([http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000336.jsp&mid=WC0b01ac05804d8b2b&jsenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&mid=WC0b01ac05804d8b2b&jsenabled=true)):

- [Extended EudraVigilance product report message \(XEVPRM\) schema;](#)
- [Chapter 3.I: Extended EudraVigilance product report message \(XEVPRM\) technical specifications;](#)
- [Chapter 5: Extended EudraVigilance product report acknowledgement message.](#)

## **1.7. eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD)**

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD) is a database designed to support the collection, reporting, coding and evaluation of medicinal product data in a standardised and structured way.

The main objective of the XEVMPPD is to assist the pharmacovigilance activities in the European Economic Area (EEA), enabling the Agency to:

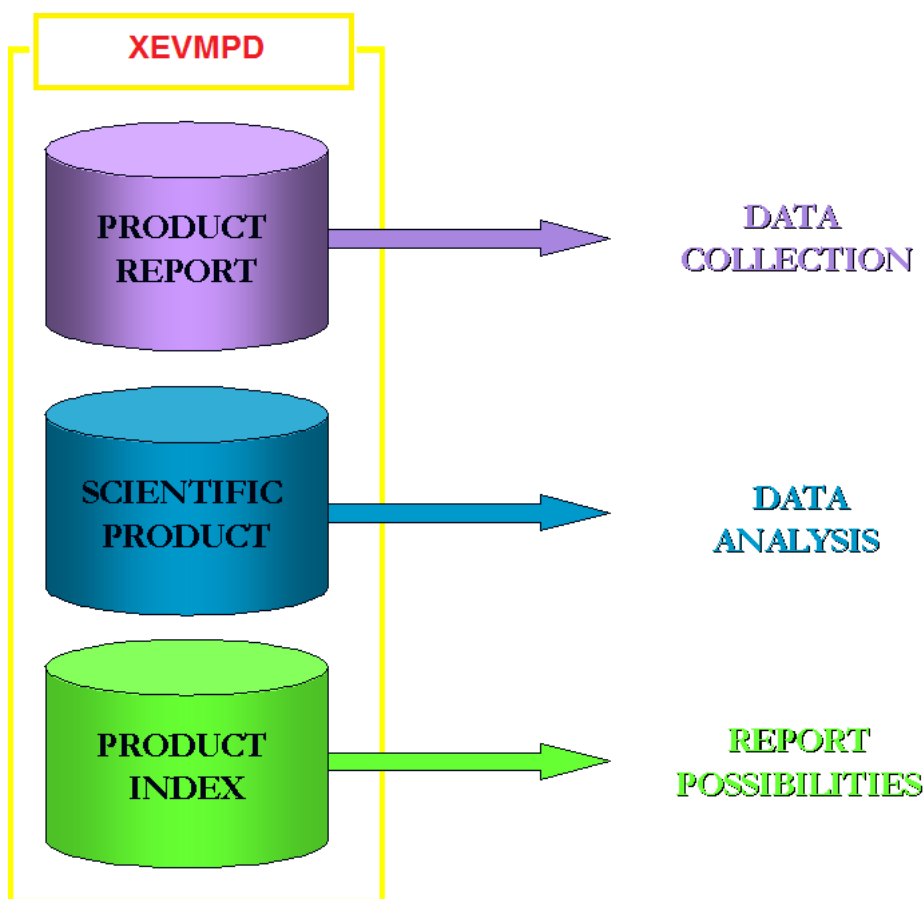
- Create a list of all medicines authorised in the EU;
- Accurately identify medicines, especially medicines included in reports of suspected adverse reactions;
- Co-ordinate the regulation and safety monitoring of medicines across the EU.

The XEVMPPD consists of three different databases designed to support the collection, scientific evaluation and coding of medicinal products authorised worldwide.

Investigational medicinal products, which are subject to a clinical trial in the EEA, are also integrated with the necessary security level to ensure data confidentiality.

The three different databases are:

1. Product Report Database (Product Report)
2. Scientific Product Database (Scientific Product)
3. Product Index Database (Product Index)



The **Product Report Database** is designed to support data collection and contains a key set of information about authorised and development medicinal products, for which the information is provided by MAHs and sponsors of clinical trials.

The **Scientific Product Database** is designed to support data analysis and implements a hierarchy allowing a classification of all medicinal products available in the XEVMPD on the basis of the active ingredient, the concentration and the pharmaceutical form. It allows grouping of medicinal products solely on the basis of their composition, regardless of their different trade names, or their MAHs.

The hierarchy within the scientific Product consists of the following levels:

- **Abstract Composition:** each Abstract Composition represents the set of pharmaceutical products containing the same active ingredient(s);
- **Abstract Strength:** each Abstract Strength represents the set of pharmaceutical products containing the same active ingredient(s) in the same strength(s);
- **Abstract Formulation:** each Abstract Formulation represents the set of pharmaceutical products containing the same active ingredient(s) and the same pharmaceutical dose form;
- **Abstract Pharmaceutical Product:** each Abstract Pharmaceutical Product represents the set of pharmaceutical products with the same active ingredient(s) in the same strength(s) and the same pharmaceutical dose form.

The Product Index Database and the Scientific Product Database and are two data structures maintained by entering or updating medicinal product information in the XEVMPD through data from the Product Report database.

The Product Reports Database collects Authorised Medicinal Products and Development Medicinal Products.

The **Product Index (PI) Database** is designed to provide various reporting possibilities on the same medicinal product. It is very important to take into account the possible vagueness of the reported medicinal product information provided by the original reporting source, which is especially common in spontaneous adverse reaction reporting. It is very important to standardise this information to allow accurate data analysis by scientific experts.

The Product Index Database provides a reference lookup list containing various reporting possibilities generated from the full presentation name of a medicinal product (i.e. the medicinal product name as it has been authorised). Each reporting possibility is generated from the data available in both, the Product Report Database and in the Scientific Product Database.

The combination of the following fields (all part of the full medicinal product presentation name) of the Product Report Database provides the reporting possibilities in the Product Index Database:

- Product Short Name;
- Product INN/Common Name;
- Product Company Name;
- Product Strength Name;
- Product Form Name.

It is therefore very important that the authorised medicinal product name information provided in the "Full Presentation Name" field is correctly entered in the relevant fields (i.e. "Product Short Name" field, "Product INN/Common Name" field, "Product Company Name" field, "Product Strength Name" field and "Product Form Name" field). For related information please refer to [Chapter 3.II: XEVPRM User Guidance](#), section *1.2.13. AMP - Presentation Name element structure (AP.13)*.

The document "[European Medicines Agency substance names best practice: Procedure and principles to handle substance name in the substance management system](#)" is also available providing further information and additional examples.

The reporting possibilities are also generated using the Development Medicinal Product and Development Substance information collected in the Product Report DB for IMPs. These entries take into account the confidentiality of the information related to IMPs.

The reporting possibilities in the Product Index Database are also generated using the Scientific Database. These reporting possibilities enable the system to maintain a valid list of substances, and combination of substances, for the mapping process of equivalent "generic products".

### 1.7.1. Data submission in the XEVMPD

The XEVMPD is populated with information provided by sponsors and Marketing Authorisation Holders (MAHs).

#### 1.7.1.1. Marketing Authorisation Holders (MAHs)

As per [Article 57\(2\) of Regulation \(EC\) No 726/2004](#) as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2010, marketing authorisation holders are required to submit to the Agency information on all medicinal products for which they hold a marketing authorisation in the European Union, i.e. information on:

- Nationally authorised medicinal products (NAPs);
- Centrally authorised medicinal products (CAPs);
- Mutually recognised medicinal products (MRPs);
- De-centrally authorised medicinal products (DCPs).

Marketing Authorisation Holders are also required to submit to the Agency information on all medicinal products for which they hold a marketing authorisation in EEA countries outside the European Union since the Pharmacovigilance legislation has been incorporated into the EEA agreement.

Full details on the legal provisions and requirements for marketing authorisation holders are available in the [Legal Notice on the Implementation of Article 57\(2\) of Regulation \(EC\) No. 726/2004](#) - Electronic Submission of Information on Medicinal Products for Human Use by Marketing Authorisation Holders to the European Medicines Agency.

Medicinal product data shall be submitted to the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) via the eXtended EudraVigilance Medicinal Product Report Message (XEVPRM). EMA first published the data format in July 2011 and the XML Schema Definition (XSD) for the individual data elements in September 2011. This was followed by updated requirements in March 2012, with fewer mandatory data fields, in order to reduce the administrative burden on marketing authorisation holders submitting medicinal product information in the context of Art 57(2) of Regulation (EC) No 726/2004.

The XSD schema was amended and published on 31 January 2014, including additional information on medicines required to fulfill new legal obligations. The new XSD schema is available in the EVWEB production environment as of 16 June 2014 and in the EVWEB test (XCOMP) environment as of 17 June 2014.

From **16 June 2014**, the required data elements for **authorised medicinal product information** increased, and the following new required fields must be included in the data submission format:

- the details of the legal basis of the marketing authorisation;
- description of the medicinal product type;
- information on the authorised pharmaceutical form and, where applicable, before reconstitution into the administered pharmaceutical form;
- description of the size of the organisation.

For detailed information please refer to the [Reporting requirements for marketing-authorisation holders](#) webpage.



Marketing authorisation holders are not allowed to send medicinal products for which they do not hold a marketing authorisation.

If you are a headquarter organisation, you have the option to send all medicinal products for which you and your affiliates hold the marketing authorisation. Alternatively, you may delegate the sending of the medicinal product information to your affiliates, i.e. for those medicinal products for which they hold the local marketing authorisation. For information how to register, please see the [EudraVigilance registration webpage](#).

#### **1.7.1.2. Sponsors**

If a new medicinal product is being developed and tested in a clinical trial and for which Suspected Unexpected Serious Adverse Reactions (SUSARs) will be submitted as required by Directive 2001/20/EC, then it must be entered as Development Medicinal Product (DMP) in the XEVMPD.

If a medicinal product is authorised in the EEA and studied outside the terms of the SmPC (e.g. new concentration of the active ingredients, new indication, new dosage form, new admin route), then it must be entered as Development Medicinal Product (DMP) in the XEVMPD.

Directive 2001/20/EC, Article 2 (d), provides the following definition for an IMP: *"a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form."*

As stated in the [Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use \('CT-3'\) \(OJ 2011/C 172/01\)](#) published by the Commission on 11 June 2001, paragraph 7.9. Format of report, section 104: *"- the Sponsor should provide, before completing the clinical trials application form, information on the IMP in the EudraVigilance Medicinal Product Dictionary ('EVMPD')"*.

Since each development medicinal product (DMP) in a clinical trial needs to be uniquely identifiable, Sponsors, who are testing the same Development Substance in different formulations or strengths, should insert different Development Medicinal Products in the XEVMPD.

If you are a sponsor, you should send information on your IMPs to the XEVMPD. Your affiliates/subordinates (e.g. clinical research departments) must be registered with the EudraVigilance system. Registration is a prerequisite in order to be able to submit investigational medicinal product information to the XEVMPD. Please see the [EudraVigilance registration webpages](#) for information on how to register.

#### **1.7.2. Data collected in the XEVMPD**

The information collected in the EudraVigilance Medicinal Product Report database concerns:

- Authorised Medicinal Products (AMPs);
- Development Medicinal Products (DMPs).

Many fields related to Authorised or Development Medicinal Products are coded in lookup tables in the XEVMPD.

Some lookup tables are maintained by the EMA, whilst other lookup tables can be maintained directly by the XEVMPD user (Updatable Lookup Tables).

The lookup tables present in the XEVMPD are:

Lookup	Maintained by	Reference
MAH organisation list	User	
SME status list <i>(available as of 16 June 2014)</i>	EMA	
QPPV list	User (via EV Registration process)	
MFL list	User	
Country code list	EMA	ISO
Authorisation Procedures	EMA	
Authorisation status	EMA	
Legal basis list <i>(available as of 16 June 2014)</i>	EMA	
Orphan drug designation	EMA	
Additional monitoring designation	EMA	
Medicinal product type <i>(available as of 16 June 2014)</i>	EMA	
Standard Pharmaceutical form list	EMA	EDQM
Proposed Pharmaceutical form list	User	
Development Pharmaceutical form list	User	
Standard Administration Route list	EMA	EDQM
Proposed Administration Route list	User	
Development	User	

Administration Route list		
Approved Substance list	EMA	
Development Substance list	EMA and User	
Substance class list	EMA	ISO
Reference source list	EMA and User	
Role of the Ingredient list	EMA	
Amount value type (i.e. concentration type) list	EMA	UCUM
Concentration unit list	EMA	UCUM
Unit or presentation list	EMA	UCUM
Unit of measure list	EMA	UCUM
Numerator/Denominator prefix list	EMA	
Medical Device list	EMA	
Standard ATC Code list	EMA	WHO
Proposed ATC Code list	User	
Development ATC Code list	User	
MedDRA version	EMA	MSSO
MedDRA level	EMA	MSSO
MedDRA Term	EMA	MSSO
Attachments list	User	
Attachment type list	EMA	
Attachment file type list	EMA	
EEA Language list	EMA	ISO

When you add a new entity (e.g. medicinal product, organisation, term) in the XEVMPD, a set of data/information must be provided, depending on the type of entity.

For the complete list of data fields collected for each individual entity in the XEVMPD and business rules regarding what information needs to be provided for which field and under which condition, please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#).

For technical specifications, please see [Chapter 3.I: Extended EudraVigilance product report message \(XEVPRM\) technical specifications](#).

Please note that Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance does **not** provide information related to submission of development medicinal products, substances and terms.

### **1.7.2.1. Authorised Medicinal Product (AMP)**

The information regarding an Authorised Medicinal Product (AMP) includes the below information (the symbol <sup>(\*)</sup> means mandatory):

- <sup>(\*)</sup> Marketing Authorisation Holder (MAH) of the AMP
- <sup>(\*)</sup> Qualified Person for Pharmacovigilance (QPPV)
- <sup>(\*)</sup> Master File Location
- <sup>(\*)</sup> PhV enquiry e-mail and Phone number
- Sender Local Code
- Info Date - the date of lifting of suspension (as applicable per the relevant business rules)
- <sup>(\*)</sup> Authorisation Country Code
- <sup>(\*)</sup> Authorisation Procedure
- <sup>(\*)</sup> Authorisation Status
- <sup>(\*)</sup> Authorisation Number
- <sup>(\*)</sup> Authorisation/Renewal Date
- <sup>(\*)</sup> MRP/DCP/EMA Number (as applicable per the relevant business rules)
- <sup>(\*)</sup> EU Number (as applicable per the relevant business rules)
- <sup>(\*)</sup> Legal basis
- <sup>(\*)</sup> Orphan drug designation
- If it is under Additional Monitoring or not
- <sup>(\*)</sup> Invalidated MA date (as applicable per the relevant business rules)
- <sup>(\*)</sup> Product Name(s)
- Package description
- <sup>(\*)</sup> Pharmaceutical Dose Form(s)
- <sup>(\*)</sup> Route of Administration(s)
- Ingredients:
  - <sup>(\*)</sup> Active Ingredient(s)
  - <sup>(\*)</sup> Strength of the Active Ingredient(s)
  - <sup>(\*)</sup> Excipient(s)
  - Strength of the Excipient(s)
  - <sup>(\*)</sup> Adjuvant(s)
  - <sup>(\*)</sup> Strength of the Adjuvant(s)
- Old Drug Ingredient(s)
- Medical Devices
- <sup>(\*)</sup> Product ATC Code(s)
- <sup>(\*)</sup> Product Indication(s) (using MedDRA coding)
- <sup>(\*)</sup> Previous EV Code(s) (as applicable per the relevant business rules)
- <sup>(\*)</sup> Product Attachment(s) including validity declaration (as applicable per the relevant business rules)
- <sup>(\*)</sup> Legal Basis
- <sup>(\*)</sup> Medicinal Product Type
- <sup>(\*)</sup> Authorised Pharmaceutical Form

For details on what information should be provided in the individual fields of an *Authorised Medicinal Product (AMP) entry* please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section *1.1. Initial Submission of an Authorised Medicinal Product (AMP)*.

### **1.7.2.2. Development Medicinal Product (DMP)**

The information regarding a Development Medicinal Product (DMP) includes the below information (the symbol (\*) means mandatory):

- The Sender Local Code
- (\*) The Sponsor of the DMP(\*)
- (\*) Sponsor's Product Code may be provided if available. If no Product Name is included, Product code must be provided as mandatory information as per relevant business rules.
- (\*) Sponsor's Product Name may be provided if available. If no Product Code is included, Product Name must be provided as mandatory information, as per relevant business rules.
- Product's Other Name, if applicable
- (\*) Pharmaceutical Dose Form(s)
- (\*) Route of Administration(s)
- Ingredients:
  - (\*) Active Ingredient(s)
  - (\*) Strength of the Active Ingredient(s)
  - (\*) Excipient(s)
  - Strength of the Excipient(s)
  - (\*) Adjuvant(s)
  - (\*) Strength of the Adjuvant(s)
- Old Drug Ingredient(s)
- Medical Devices
- Product ATC Code(s)
- Product Indication(s) (using MedDRA coding)
- Product Attachment(s) including validity declaration (if applicable and as per relevant business rules)

### **1.7.2.3. Approved Substance (AS)**

The information collected regarding an Approved Substance (AS) includes the below information (the symbol (\*) means mandatory):

- (\*) English Name
- (\*) The Substance Class and the reference source for the Substance  
e.g. INN, EU Pharmacopoeia
- CAS<sup>1</sup> Number / CBD<sup>2</sup> / Molecular Formula
- Alias/ Translation(s)
- Substance International Code (including the Source)
- Substance Parent Code (including the Substance Type)
- Previous EV Code(s)
- Substance Attachment(s)

In the context of improvement of the XEVMPD Substance Controlled Vocabulary data quality, the XEVMPD business rules have been revised to reject any operation type related to submission of approved substances.

This implies that any XEVPRM messages containing operation type 'Insert (1)', 'Update (2)' or 'Nullification (4)' of an approved substance will be rejected, and will generate a negative XEVPRM acknowledgement.

Providing that an approved substance is not listed in the [XEVMPD substance controlled vocabulary list](#) (sheets **1\_Substance CV** and **4b\_Invalid substance names**) available in the 'Controlled Vocabularies' section of the [Data submission on authorised medicines - Guidance documents webpage](#),

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<sup>1</sup> CAS = Chemical Abstract Service

<sup>2</sup> CBD = Chemical/Biological Description

or in the XEVMPD substance look-up table, MAHs should submit an email requests to [MDMS@ema.europa.eu](mailto:MDMS@ema.europa.eu).

Guidance on how to handle approved substance names is included in the document [European Medicines Agency substance names best practice: Procedure and principles to handle substance name in the substance management system](#) published in section "Data Quality-control methodology" on the [Agency's webpage](#).

***To requests a new approved substance to be inserted in the XEVMPD:***

- *"Request for an insert of a new approved substance"* should be stated in the email subject;
- The substance name in English, substance class and reference source need to be included in the request.

Please see the [EudraVigilance eXtended Medicinal Product Dictionary \(XEVMPD\) substance classes](#) Controlled Vocabulary published on the [Agency's website](#) for further information on available substance class values.

Please see the [EudraVigilance eXtended Medicinal Product Dictionary \(XEVMPD\) reference sources](#) Controlled Vocabulary published on the [Agency's website](#) for further information on available reference source values. Should the Summary of Product Characteristics (SmPC) be used as the reference source of the product in which the substance is part of, the SmPC should be attached to the request (as a Word or PDF document).

- If requesting that a translation should be added to the substance entry, the translation and the applicable language information should be included in the request. For languages where the grammar uses declined forms, the nominative singular form (i.e. not declined) of the translated substance name should be provided.
- If requesting that an alias should be added to the substance entry, the alias should be included in the request.

The Agency will process the request in the XEVMPD and provide the MAH with the master substance EV Code to be referenced in their product entry as part of the electronic submission of medicinal product information under Article 57(2) provision.

**To requests an update of an existing substance to add substance translation or alias:**

- *"Request for an update of an approved substance"* should be stated in the email subject;
  - The translation and the applicable language information should be included in the request. For languages where the grammar uses declined forms, the nominative singular form (i.e. not declined) of the translated substance name should be provided.
  - If requesting that an alias should be added to the substance entry, the alias and reference source should be included in the request.

The Agency will process the requests in the XEVMPD.

MAHs should use the master EV Code of the approved substance with the preferred name in English in their product entries as part of the electronic submission of medicinal product information under Article 57(2) provision.

#### **1.7.2.4. Development Substance (DS)**

The information collected regarding a **Development Substance (DS)** includes the below information (the symbol (\*) means mandatory):

- (\*) The Substance Name or Code currently used by the Sponsor
- (\*) The Substance Class
- (\*) The Sponsor of the DS
- CAS (Chemical Abstract Service) Number/ CBD (Chemical/Biological Description) Number
- Molecular Formula
- All other Substance Codes or Names previously used by the Sponsor
- Substance International Code (including the Source)
- Substance Parent Code (including the Substance Type)
- Substance Attachment(s)

#### **1.7.2.5. Source**

The information collected regarding a **Source** includes the below information (the symbol (\*) means mandatory):

- (\*) Source Name
- Comment

For details on what information should be provided in the individual fields of an *a reference source entry* please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section *1.5. Initial submission of a Reference Source*.

#### **1.7.2.6. MAH Organisation**

The information collected regarding a **MAH** includes the below information (the symbol (\*) means mandatory):

- (\*) MAH Name
- MAH Sender ID
- (\*) MAH Address
- (\*) MAH City
- MAH Region
- (\*) MAH Post Code
- (\*) MAH Country Code
- MAH Telephone
- MAH Fax
- MAH Email Address
- Comment
- (\*) SME status
- SME number (if applicable)

For details on what information should be provided in the individual fields of *MAH entry* please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section 1.6. *Initial Submission of a Marketing Authorisation Holder (MAH) Organisation*.

#### **1.7.2.7. Sponsor Organisation**

The information collected regarding a **sponsor** includes the below information (the symbol (\*) means mandatory):

- (\*) Sponsor Name
- Sponsor Sender ID
- (\*) Sponsor Address
- (\*) Sponsor City
- (\*) Sponsor State
- (\*) Sponsor Post Code
- (\*) Sponsor Country Code
- (\*) Sponsor Telephone
- Sponsor Fax
- Sponsor Email Address
- Comment

#### **1.7.2.8. Development/Proposed ATC Code**

The information collected regarding a **Development/Proposed ATC Code** includes the below information (the symbol (\*) means mandatory):

- (\*) ATC Code
- (\*) ATC Code Description
- Version Date
- Comment

For details on what information should be provided in the individual fields of a *proposed ATC Code entry* please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section 1.7. *Initial submission of an ATC Code*.

The same rules are applicable to a *development ATC Code entry* - the type of the term is however to be specified as 'Development Term (1)'.

#### **1.7.2.9. Development/Proposed Pharmaceutical Form**

The information collected regarding a **Development/Proposed Pharmaceutical Form** includes the below information (the symbol (\*) means mandatory):

- (\*) Pharmaceutical dose form
- Version Date
- Previous EVCODE
- Comment



For details on what information should be provided in the individual fields of a *proposed pharmaceutical form entry* please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section *1.8 Initial submission of an Authorised/Administrable Pharmaceutical Form*.

The same rules are applicable to a *development pharmaceutical entry* - the type of the term is however to be specified as 'Development Term (1)'.

#### ***1.7.2.10. Development/Proposed Route of Administration***

The information collected regarding a **Development/Proposed Route of Administration** includes the below information (the symbol <sup>(\*)</sup> means mandatory):

- (\*) Administration Route Name
- Version Date
- Previous EVCODE
- Comment

For details on what information should be provided in the individual fields of a *proposed route of administration entry*, please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section *1.9 Initial Submission of a Route of Administration (RoA)*.

The same rules are applicable to a *development route of administration entry* - the type of the term is however to be specified as 'Development Term (1)'.

Pharmaceutical forms, routes of administration and ATC Codes will be referred to as 'Term' in this session. The reference to 'Development Term' indicates either 'Development ATC Code' or 'Development Pharmaceutical Form' or 'Development Route of Administration'.

#### ***1.7.2.11. Printed Product Information (PPI) / Printed Substance Information (PSI)***

The information collected regarding the **Attachment for the Printed Product Information (PPI)** and the **Printed Substance Information (PSI)** includes the below information (the symbol <sup>(\*)</sup> means mandatory):

- (\*) File Type
- (\*) Name
- (\*) Type (PPI or PSI)
- (\*) Language
- (\*) Version Number
- (\*) Version Date

For details on what information should be provided in the individual fields of a *Printed Product Information (PPI)* entry please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section *1.10. Submission of an attachment*.

The same rules are applicable to a *Printed Substance Information (PSI)* - the attachment type is however to be specified as 'PSI' (2).

### 1.7.2.12. Pharmacovigilance System Master File Location (PSMFL)

The information collected regarding the **Master File Location** includes the below information (the symbol (\*) means mandatory):

- Company
- Department
- Building
- (\*) Street
- (\*) City
- State
- (\*) Post Code
- (\*) Country
- (\*) Comment

For details on what information should be provided in the individual fields of a *PSMFL entry*, please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVRPM\) user guidance](#), section [1.11 Initial submission of a Pharmacovigilance System Master File Location \(PSMFL\)](#).

The provision of medicinal product information can be accomplished via one of the following procedures:

- Exchanging XML files through an ESTRIM Gateway or the EV Post Function; or
- Using EVWEB.

At the end of each procedure, the EudraVigilance System handles and processes the EudraVigilance Product Report Message (XEVRPM).

Before explaining how to use EVWEB for creating and sending an XEVRPM, it is important to briefly describe:

- XEVMPD terminologies;
- Data Ownership and Maintenance Rules;
- Data Quality;
- Data Access Policy.

### 1.7.3. XEVMPD terminologies

The following terminologies and definitions apply for the XEVMPD:

- **Medicinal Product (MP):**

Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances, which may be used in or administered to human beings either with the view to restoring, correcting or

modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis (Directive 2004/27/EC).

- **Authorised Medicinal Product (AMP):**

A Medicinal Product authorised either within the EEA (European Economic Area) or outside the EEA.

- **Investigational Medicinal Product (IMP):**

A pharmaceutical form of an active substance or placebo being tested or used as a reference in a Clinical Trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form (Directive 2001/20/EC).

- **Development Medicinal Product (DMP):**

A Medicinal Product under investigation in a Clinical Trial in the EEA which does not have a marketing authorisation in the EEA, and to which special confidentiality arrangements need to be applied.

- **Approved Substance:**

Any substance as defined in Directive 2004/27/EC, which is an ingredient of a medicinal product for which a marketing authorisation was granted.

- **Development Substance:**

Any substance under investigation in a clinical trial in the EEA, and which is not part of any authorised medicinal product (AMP).

- **Term:**

Pharmaceutical Dose Form, Administration Route, or an ATC Code.

- **Standard Term:**

Term published as a term of standard terminology used in the XEVMPD. This information is entered and maintained in the XEVMPD by the EMA.

- **Development Term:**

Confidential term used in a clinical trial. These terms are entered and maintained in the XEVMPD by Sponsors. Development terms can only be used in Development Medicinal Products. An Authorised Medicinal Product cannot reference a Development Term.

- **Proposed Term:**

Term, which has been submitted (there is an application) to the maintenance organisation but it is not yet approved or published in the standard terminology used in the XEVMPD. These terms are entered and maintained in the XEVMPD by Sponsors or MAHs. Proposed term can be used either in Development Medicinal Products or Authorised Medicinal Products.

#### 1.7.4. Data Ownership and Maintenance

The medicinal product information provided via the XEVPRM is "owned" by the Sender Organisation Headquarter (HQ) ID that submitted the information. For each entry (medicinal products or lookup tables), the XEVMPD stores the **Sender Organisation ID** and checks this field before allowing the modification of a particular entry.



- Only the owner organisation of the data is authorised to maintain the submitted information.

Duplicated or obsolete entities can only be nullified if they're **not** referenced in any other entities (i.e. product entries). For related information see section [2.3.4 Nullification of duplicated/obsolete XEVMPD entities](#) of [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#).

MAH organisation entities made "checked" by the European Medicines Agency (EMA) can only be nullified by the EMA.

MAH cannot perform maintenance related operation types on approved substances - please refer to the process described in [Changes to some business rules of the eXtended EudraVigilance Medicinal Product Dictionary \(XEVMPD\): Submission of substance information](#).

The operation types that a Sender Organisation can perform by sending an XEVPRM are (as per [Chapter 3.1: Extended EudraVigilance product report message \(XEVPRM\) technical specifications](#), Version 5.0: Allowable operations changes highlighted in yellow) as follows:

	Insert	Update	Variation	* Nullify	Invalidate MA
Authorised Product	✓	✓	⊘	✓	✓
Development Product	✓	✓	⊘	✓	⊘
Approved Substance	⊘	⊘	⊘	⊘	⊘
Development Substance	✓	✓	⊘	✓	⊘
Attachment	✓	⊘	⊘	⊘	⊘
**Master File Location	✓	✓	⊘	✓	⊘
Source	✓	✓	⊘	✓	⊘
MAH	✓	✓	⊘	✓	⊘
Sponsor	✓	✓	⊘	✓	⊘
Development Pharmaceutical Form	✓	✓	⊘	✓	⊘
Proposed Pharmaceutical Form	✓	⊘	⊘	⊘	⊘
Development Route of Administration	✓	✓	⊘	✓	⊘
Proposed Route of Administration	✓	⊘	⊘	⊘	⊘
Development ATC Code	✓	✓	⊘	✓	⊘
Proposed ATC Code	✓	✓	⊘	✓	⊘

### 1.7.5. Data Quality

During the creation and sending of an XEVPRM, there are technical business rules where the system automatically checks if the mandatory information has been provided or cross-referenced for a medicinal product submission.

If the validation reports no errors, the information is sent and loaded in the XEVMPD.

You will receive an XEVPRM acknowledgement for every XEVPRM sent to the XEVMPD. The acknowledgement informs you whether the information contained in the XEVPRM and sent to the

XEVMPD has been loaded successfully, or if some reports contained in the XEVPRM have not been loaded. In the latter case, the acknowledgement will display the list of errors found in the unloaded reports.

Detailed information related to an XEVPRM Acknowledgement can be found in [Chapter 5: Extended EudraVigilance product report acknowledgement message](#) and [Appendix 5 – Element Acknowledgement Codes](#) of [Chapter 3.1: Extended EudraVigilance product report message \(XEVPRM\) technical specifications](#).

The Agency, with the assistance of a contractor, is planning to process the information on authorised medicinal products submitted by marketing authorisation holders and perform the review of its quality and integrity to ensure that it is accurate and up-to-date. If information is incomplete, missing or erroneous, the Agency will liaise with the marketing authorisation holder in order to obtain the correct information.

For further information please see the Agency's webpage [Reporting requirements for marketing-authorisation holders](#), section "Data Quality Improvement".

### 1.7.6. Data Access Policy

Some information collected in the XEVMPD is strictly confidential.

An organisation registered with the EudraVigilance System and that is not a National Competent Authority (NCA) can read:

- Data for which they are the owners (product data, substance data etc.);
- Authorised Medicinal Products, Approved Substances and Proposed Terms that have been checked by the EMA;
- All Standard Terms present in the lookup tables and maintained by EMA.

**Development Substances, Development Products and Development Terms (not owned by the Organisation, even if checked by EMA, remain strictly confidential and cannot be accessed by other applicants, MAHs or sponsors.**

The general rules applicable to any MAH/Sponsor/Applicant registered with the EudraVigilance System are summarised in the following table:

SPONSOR, MAH or APPLICANT	Entries Owned		Entries Not Owned	
	Not Checked	Checked	Not Checked	Checked
<b>Authorised or Approved*</b>	✓	✓	⊘	✓
<b>Development CONFIDENTIAL</b>	✓	✓	⊘	⊘
<b>Proposed</b>	✓	✓	⊘	✓
<b>Standard</b>	Not Applicable	Not Applicable	Not Applicable	✓

\* approved substances are visible whether or not they are checked by the EMA.

National Competent Authority registered to the EudraVigilance System can read every entry that has been checked by EMA. The general rules applicable to any National Competent Authority registered to the EudraVigilance System are summarised in the following table:

NATIONAL COMPETENT AUTHORITIES	Entries Owned		Entries Not Owned	
	Not Checked	Checked	Not Checked	Checked
<b>Authorised or Approved*</b>	Not Applicable	Not Applicable	⊘	✓
<b>Development CONFIDENTIAL</b>	Not Applicable	Not Applicable	⊘	✓
<b>Proposed</b>	Not Applicable	Not Applicable	⊘	✓
<b>Standard</b>	Not Applicable	Not Applicable	Not Applicable	✓

\* approved substances are visible whether or not they are checked by the EMA.

### 1.7.7. Controlled Vocabularies and Terminologies

Terminologies and Controlled Vocabularies (CVs) are integrated in EudraVigilance, the below CVs are available on the [Agency's website](#), section "Controlled vocabularies":

- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) Anatomical Therapeutic Chemical (ATC) code;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) authorisation procedures;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) - authorisation status;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) concentration types;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) medical devices;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) organisations;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) pharmaceutical dose forms;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) reference sources;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) routes of administration;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) substance classes;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) substances;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) units of measurement;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) units of presentation;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) - Legal basis;
- EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) - Medicinal product types.

In addition to the CVs maintained by the Agency, further information on terminologies and controlled vocabularies integrated in EudraVigilance, which are maintained by external providers, can be obtained from the following websites:

- A copy of MedDRA needs to be obtained from the [MedDRA](#);
- ATC Codes need be obtained from the [WHO Collaborating Centre for Drug Statistics Methodology](#);
- Pharmaceutical forms and routes of administration are based on the standard terms published by the [European Directorate for the Quality of Medicines & HealthCare \(EDQM\)](#);
- [The Unified Code for Units of Measure \(UCUM\)](#) is maintained by the [Regenstrief institute](#);
- The official list of ISO 3166-1 country codes is maintained by the [International Organization for Standardization \(ISO\)](#);
- The official list of ISO 639-1:2002 codes for the representation of names of languages: Part 1: Alpha-2 code is maintained by the [International Organization for Standardization \(ISO\)](#).



## 2. EVWEB

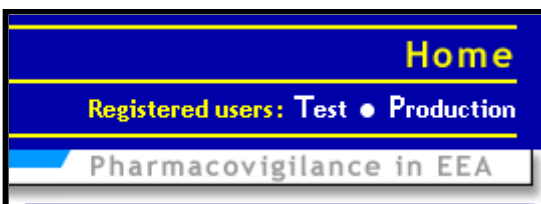
### 2.1. Accessing EVWEB

To access **EVWEB Training Environment**, go to: <https://eudravigilance-training.ema.europa.eu/highres.htm>

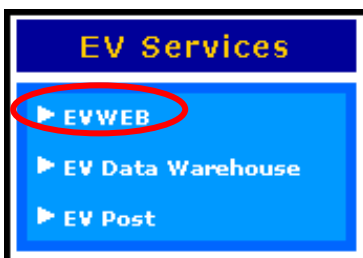
To access **EVWEB Production environment** or **EVWEB test (XCOMP) environment**, go to: <http://eudravigilance.ema.europa.eu:>



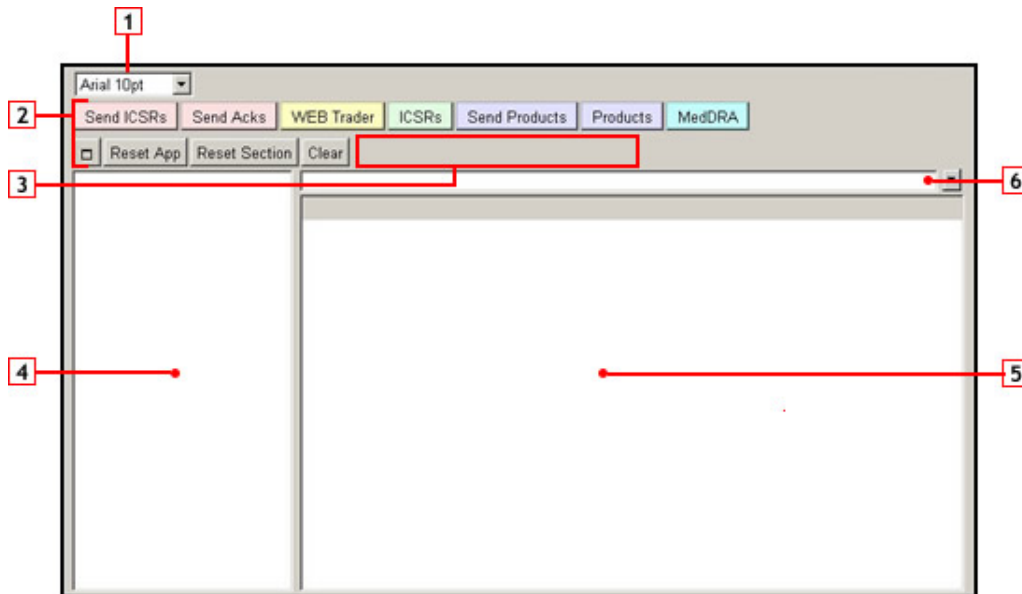
Enter your password to access the restricted area of the selected environment:



EVWEB is accessible by clicking on the "EVWEB" button in the restricted area of the EudraVigilance webpage.



EVWEB will open in a new browser window. The main menu is located at the top of your screen and consists of two sets of buttons: the default and the dynamic sets. Below the main menu, the screen is divided vertically into two parts: on the left side is the tree view area and on the right is the active area.

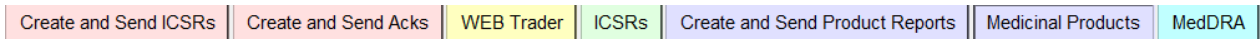


- 1 This drop-down menu allows the user to select the font size to visualize the information on the screen and to customize the screen to the best individual working conditions.  
It also allows to change the active area from XHTML do ActiveX (and vice versa)
- 2 Main menu: The EVWEB-section navigator menu, with the default button set, is always present in every section of the application. EVWEB is divided into different sections according to the kind of information you are going to operate with and your organisation's profile set-up during the registration process.
- 3 Main menu: This area represents the dynamic button set. It will change according to the EVWEB-section of the application you are using
- 4 The tree view
- 5 The active area
- 6 The simple query field

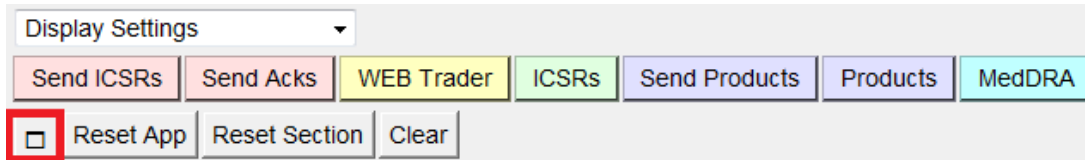
## 2.2. The main menu

### 2.2.1. Sections navigator menu

Depending on your screen settings, the menu is displayed in the "full" version:




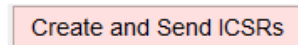
or in the "short" version:




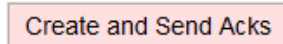
To expand the menu, click on the square button.


The Sections navigator menu consists of the following buttons:

 Allows access to the part of the application dedicated to the creation and sending of ICH ICSR Messages.

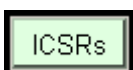



 Allows access to the part of the application dedicated to the creation and sending of ICH ICSR acknowledgements.

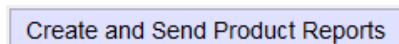


 Allows access to review your own messages, both sent and received. You will be able to see Messages sent to you and by you, in the Inbox and Outbox folders (the last 50 received during the day reference for message archive). The Inbox and Outbox folders will only be available to Web Trader users. Users sending information via their locally established Gateway will not see these folders.

When in this section, you will also be able to import Messages located on your computer.

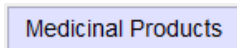
 Allows you to browse and perform searches on the ICSRs submitted by your organisation.

 Allows you to create and send a XEVMPD Product Report Message.



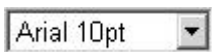


Allows you to browse and perform searches at all levels of the XEVMPD.



This area of the application allows you to browse and perform searches at all levels of MedDRA.

### 2.2.2. Default buttons set



This pop-down menu allows a user to select the type and size of the font used to display the information on the screen, and to customize the interface to individual working conditions.

You can choose the interface of the EVWEB application through an option of this pop-up menu.

ActiveX Interface means that the Active Area is an ActiveX, which allows fast operations but doesn't allow the data entry and display of special Unicode characters.

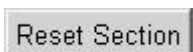
XHTML Interface means that the Active Area is made of standard HTML components, which allows the data entry and display of any Unicode character but it can be slower than the ActiveX Interface. Use this interface when you need to enter Greek or Bulgarian characters.



Maximize: The screen is resizable allowing the interface to be adapted to the user screen size by clicking twice on the button pictured above. The application interface can also be resized by dragging its bottom right corner.



Resets the application, affects all its sections. You will lose all locally entered data up to that point.



Resets only the specific section of the application currently in use. Data entered in that section will be lost if you use the Reset Section button.

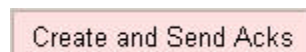
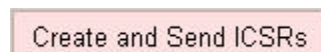


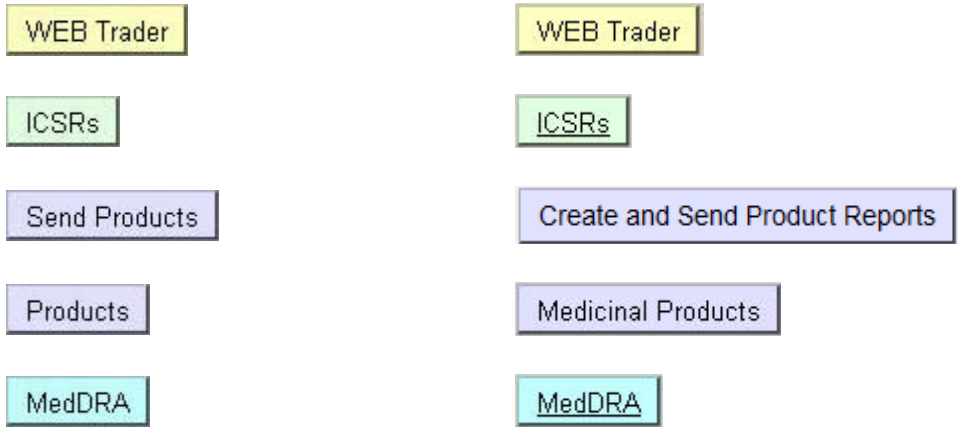
Removes all items marked for deletion in the section of EVWEB currently in use (also unchecked items)

**The buttons displayed on the default set may have different labels, depending on the size of your screen.** Resolutions up to 800x600 will display the buttons' labels just described. Screen resolutions of 1024x768 and higher will display slightly different, more descriptive labels, because there is more space available.

**Up to 800 x 600**

**1024 x 768 +**





The button corresponding to the currently active section of EVWEB will have the appearance of being pressed in.

### 2.2.3. Dynamic buttons set

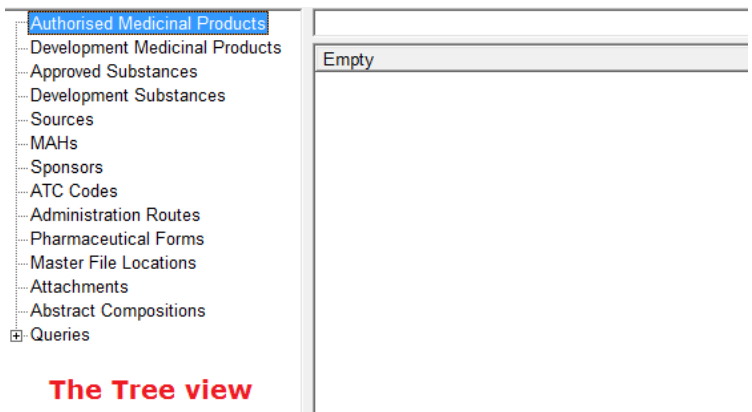
This set of buttons is located on the lower right corner of the main navigation menu and displays a variable number of buttons that changes according to the section of the application and the related item selected in the tree view area.



These buttons will be described in the various sections and functions of EVWEB.

### 2.3. The tree view

The tree view area is located on the left side of the application, below the main navigation menu. It shows elements in a tree view menu style (similar to Windows Explorer).



**The Tree view**

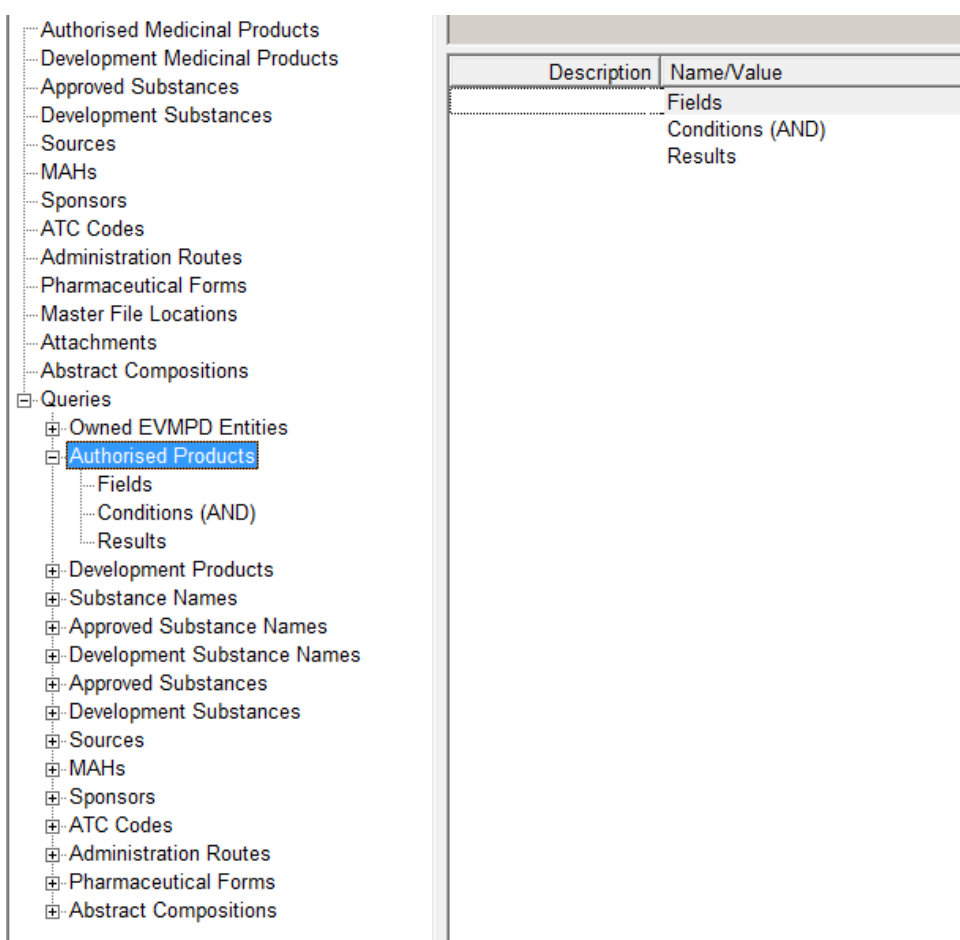
To select an item in the tree view, you have to click on the textual description of the item with your mouse. The selected item will be displayed with a dark background.

When the "+" sign appears on the left of the tree view menu, that item contains a sub-menu that can be expanded by clicking (once) on the little "+".

After a menu is expanded the "+" changes into a "-" sign.

To collapse a menu, just click once on the "-".

Elements in the tree view area can also be expanded by hitting the "Enter" key on the keyboard after they have been selected by clicking once on them with the mouse. To select an item the user has to click once on the text, rather than on the "+" sign. Selected items are always displayed with a dark background.



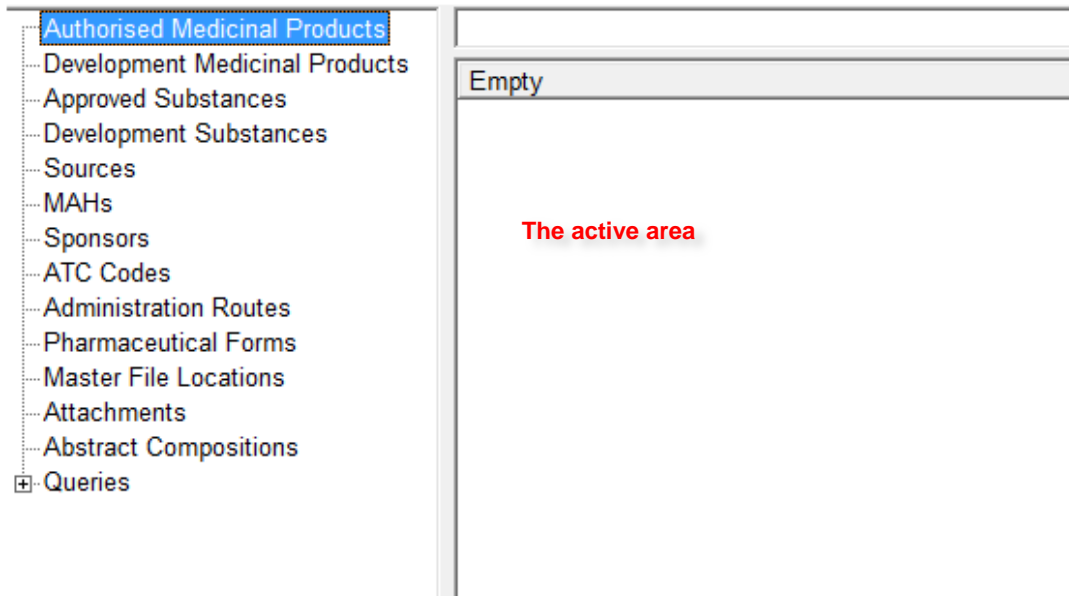
The tree view can grow, expand and become extensive while using the application. The active section of the tree view area is always marked with a dark background.

When the expanded tree grows beyond the size of the tree view area, scroll bars will appear on the side, to allow you to move up and down to reach any part of the tree.

## 2.4. The active area

The active area shows the content of the currently selected item in the tree view.

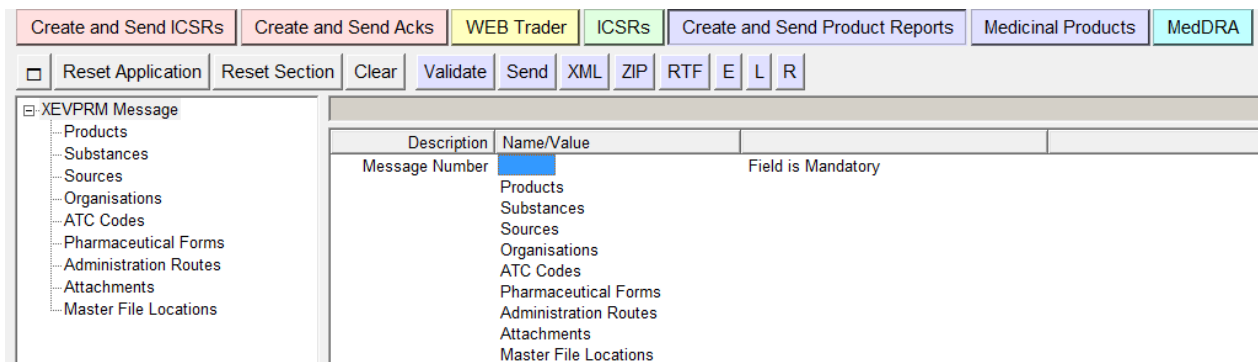
The active area is located on the right side of the application, below the main navigation menu.



The main difference between the tree view and the active area is that the active area is interactive and displays information that can be edited and modified by the user (see section 2.6. Data entry).

The active area displays the information in two different ways:

- **Section view** (which usually displays fields and/or subsections) is used to display information and/or for data entry. A typical example of a section view is the editing of a new XEVPRM:



- **List view** (a detailed list of items of the same kind) is used to display items that can be selected, loaded or just analysed. A typical example of list view is the result of a query.

Num	Source Name	EV Code	Checked	Nullified
<input type="checkbox"/> 0001	PHARMACOPOEIA HELVETICA	SRC870	14/09/2012 10:22:20	
<input type="checkbox"/> 0002	PHARMACOPOEIA BOHEMOSLOVACA	SRC664	23/11/2011 16:03:50	
<input type="checkbox"/> 0003	PHARMACOPOEIA BOHEMICA MCMXCVII	SRC568	01/04/2008 10:01:18	

You can re-arrange the order of presentation of items in the active area by clicking on the header of each column (a click will switch from ascending to descending order and vice versa).

Num	Source Name	EV Code	Checked	Nullified
<input type="checkbox"/> 0003	PHARMACOPOEIA BOHEMICA MCMXCVII	SRC568	01/04/2008 10:01:18	
<input type="checkbox"/> 0002	PHARMACOPOEIA BOHEMOSLOVACA	SRC664	23/11/2011 16:03:50	
<input type="checkbox"/> 0001	PHARMACOPOEIA HELVETICA	SRC870	14/09/2012 10:22:20	

On top of the active area, but still below the main menu, you will find the simple query field (see section 2.7.1. *Simple query*).

Lookup the Authorised Products on: EV Code, Full Presentation Name, Short Name, Generic Name, Company Name, Reporting Names.  
Wildcards ("\*" or "?") can be used in the Query Term. Please note, though, that faster results can be achieved if the Term doesn't BEGIN with a Wildcard.



This search field is not always active. When the search field is locked, the field will appear in grey, indicating that the search is not allowed.

When the simple query is available and selected (clicking inside it), the bottom of the screen will display how the query will work (i.e. on which fields the query will be executed).

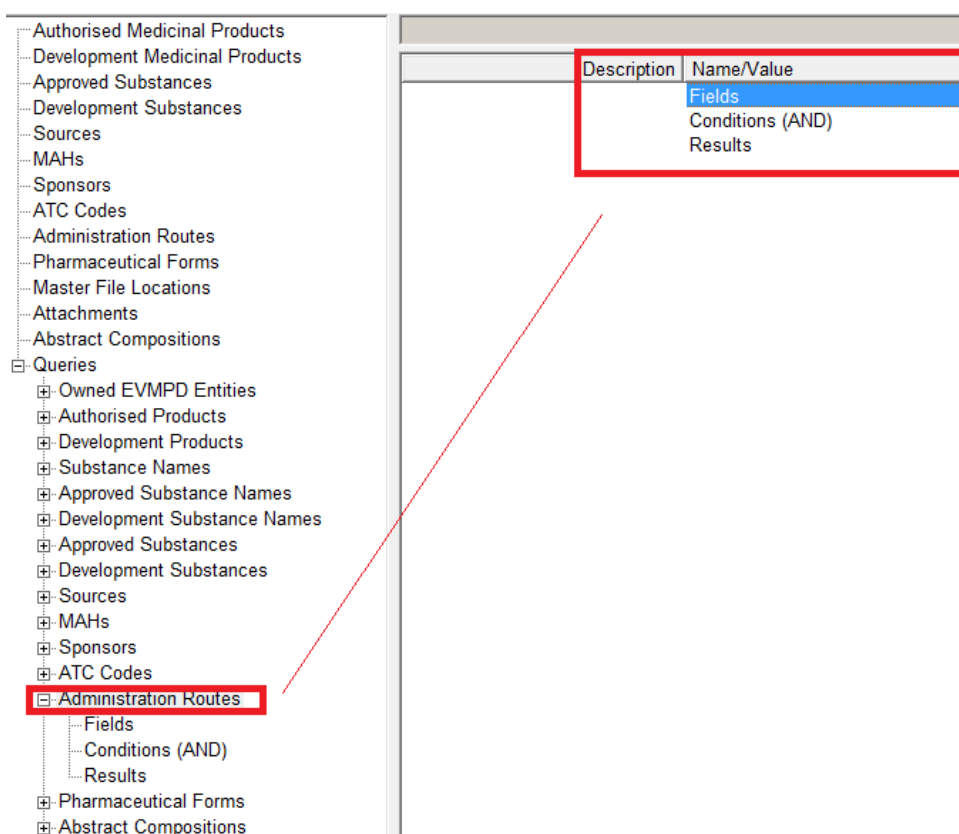
The main body of the active area may display editable or non-editable information.

Sometimes it shows information to the users, other times it requests information or an action from the user.

## 2.5. Interaction between the tree view and active area

The tree view area enables you to browse items by selecting them, and by expanding or closing menus. Functionally, the tree view can be considered as a navigation system.

The active area displays the content of the selected item in the tree view, and allows the user to view, input, amend, modify and nullify information.



The information displayed in the active area can be presented in two different formats: section view and list view. To display the details of any of your items you have two options:

- Double click on the items' name in the active area
- Click once on the items' name in the tree view area

In both cases you will be presented with the same screen.

Please note that the subsections of the item currently selected will be displayed in both screens (in the tree view and at the bottom of the active area).

When a field is selected, a longer description, giving a better indication of the information required, will appear at the bottom of the active area.

Create and Send ICSRs
Create and Send Acks
WEB Trader
ICSRs
Create and Send Product Rep

Reset Application
Reset Section
Clear
XML
RTF
Reinsert
Load

- Authorised Medicinal Products
- Development Medicinal Products
- Approved Substances
- Development Substances
- Sources
- MAHs
- Sponsors
- ATC Codes
- Routes of Administration
  - Standard (3) - ADR00048MIG - ORAL USE
- Pharmaceutical Forms
- Master File Locations
- Attachments
- Abstract Compositions
- Queries

oral use\*

Description	Name/Value
Type	Standard (3)
Deprecated	No (2)
Checked	Checked (14/10/2004 12:05.44)
Nullified	No
EV Code	ADR00048MIG
Administration Route Name	ORAL USE
Version Date	04/04/2013
Previous EV Code	

Administration Route Name (ST.AR.5)

## 2.6. Data entry

This section deals with all the specific actions that you can perform to insert data in the EVWEB application.

### 2.6.1. Input field types

EVWEB contains four different types of fields for the user to input information into the system. These are: **text fields**, **date/time fields**, **look-up fields** and **query fields**. They are explained in detail below. You do not necessarily need to know what type of fields it is when you enter information. The system will take you through the necessary stages for each field type. In some specific situations, a field can be filled in different ways (i.e. a text field that can also be filled as a look-up field).

During the input phase, the application performs a real-time validation of the inserted data.

Fields that contain erroneous or incomplete information have their value (if present) displayed in red, and the relative error message is displayed in the third column of the active area. In addition to that, the section that contains errors is also displayed in red, both in the tree view and the active area.

The most common error message is "Field is mandatory". Mandatory fields require essential information, which needs to be provided to complete the data entry operation successfully.

Some fields are flagged as "Mandatory Optional" which means that they must/may be completed depending on the applicable business rules.

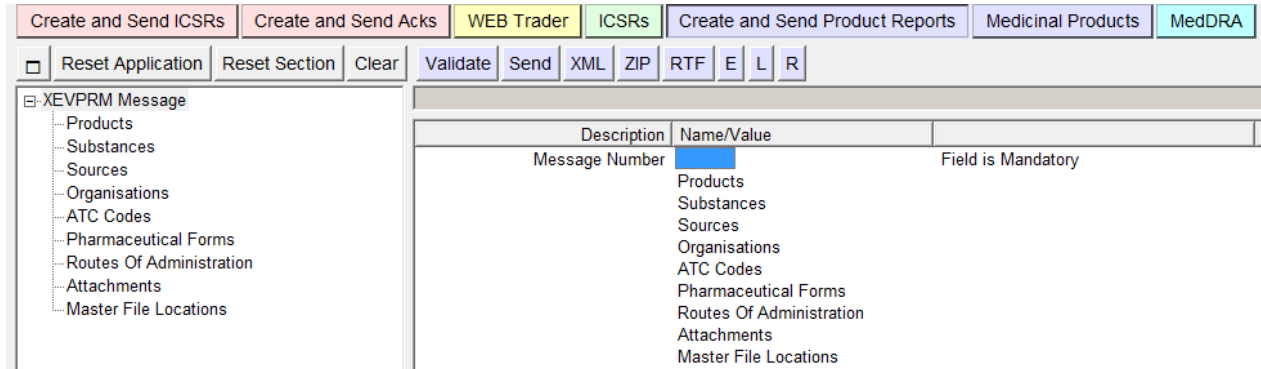
Mandatory sections must be completed.

Description	Name/Value	
Operation Type	Insert (1)	
Type	Authorised (2)	
EV Code	MAH	Field is Mandatory
QPPV		
Master File Location		
PhV enquiry email		Field must have a specified value
PhV enquiry Phone		Field must have a specified value
Sender Local Code		
Info Date		
Authorisation Country Code		Field is Mandatory
Authorisation Procedure		Field is Mandatory
Authorisation Status		
Authorisation Number		Field must have a specified value
Authorisation/Renewal Date		Field must have a specified value
MRP/DCP/EMEA Number		
EU Number		
Legal Basis		
Orphan Drug		
Additional Monitoring		
Invalidated Date		Field must have a specified value
Full Presentation Name		Field is Mandatory
Product Short Name		Field is Mandatory Optional
Product INN/Common Name		Field is Mandatory Optional
Product Company Name		Field must have a specified value
Product Strength Name		
Product Form Name		
Package Description		
Comment		
Medicinal Product Types (-)		Section is Mandatory
Authorised Pharmaceutical Forms (-)		Section is Mandatory
Pharmaceutical Products (-)		Section is Mandatory
Drug ATCs (-)		Section is Mandatory
Drug Indications (-)		Section is Mandatory
Previous EV Codes (-)		
Product Attachments (-)		Section is Mandatory

### 2.6.1.1. Text field

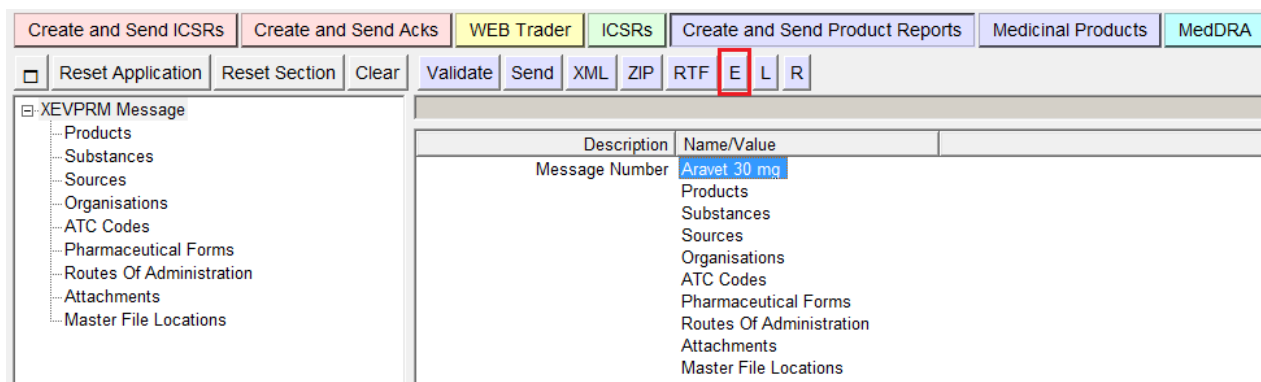
This is the most common type of field that you will find in EVWEB. Text fields require information that is entered using the keyboard.

To enter information in a field text, you need first to select it by clicking once on the field space



and then press "Enter" on your keyboard.

**E** You can also use the "E" button on the dynamic section of the main menu to enter this type of field.



A blank text box appears in the field in order for you to enter the necessary data. Press "Enter" again when you have finished. Press "Esc" on your keyboard if you wish to cancel the input.

You can copy and paste information from/to text fields.

A particular type of text field is the large text field.

This type of field allows you to insert a long text with the help of a specific text area that will be displayed when you activate the editing of this type of field.

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

XEVPRM Message

- Products
  - Insert (1) - Authorised (2)
    - Medicinal Product Types (-)
    - Authorised Pharmaceutical Forms (-)
    - Pharmaceutical Products (-)
    - Drug ATCs (-)
    - Drug Indications (-)
    - Previous EV Codes (-)
    - Product Attachments (-)
  - Substances
  - Sources
  - Organisations
  - ATC Codes
  - Pharmaceutical Forms
  - Routes Of Administration
  - Attachments
  - Master File Locations

Description	Name/Value	
EV Code	MAH	Field is Mandatory
	QPPV	
Master File Location	PhV enquiry email	Field must have a specified value
	PhV enquiry Phone	Field must have a specified value
Sender Local Code	Info Date	
	Authorisation Country Code	Field is Mandatory
Authorisation Procedure	Authorisation Status	Field is Mandatory
	Authorisation Number	Field must have a specified value
Authorisation/Renewal Date	MRP/DCP/EMEA Number	Field must have a specified value
	EU Number	
Legal Basis	Orphan Drug	
Additional Monitoring	Invalidated Date	Field must have a specified value
Full Presentation Name	Product Short Name	Field is Mandatory
	Product INN/Common Name	Field is Mandatory Optional
	Product Company Name	Field is Mandatory Optional
	Product Strength Name	Field must have a specified value
	Product Form Name	
	Package Description	
	Comment	

Value ✓ ✗

You can insert a long text in this field

In this special text area, you are also allowed to enter line breaks. You can do that by pressing, "Shift" + "Enter" on your keyboard (just pressing "Enter" will end the editing process and confirm the text entered).

On top of the text area, two buttons are visible. The first one (Green tick) ends the edit and confirms the text entered. The second one cancels the edit (Red cross).

The large text field is the only one that has a special viewing mode when you are not in a data entry session.

Since this field can contain a very large amount of text (also allowing for line breaks), it can be useful to display the entire content of it. To do so, you can double click on it, and the same text area used for the editing will be displayed. The difference is that in this case, you cannot edit the text.

### 2.6.1.2. Date/time field

This type of field is used in EVWEB to enter the date information in different formats. The information is entered using a graphical interface that recalls a calendar.

To enter information in a date field, you first need to select it by double clicking on the field, or hitting "Enter" on your keyboard after having selected it.

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

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

XEVPRM Message

- Products
  - Insert (1) - Authorised (2)
    - Medicinal Product Types (-)
    - Authorised Pharmaceutical Forms (-)
    - Pharmaceutical Products (-)
    - Drug ATCs (-)
    - Drug Indications (-)
    - Previous EV Codes (-)
    - Product Attachments (-)
  - Substances
  - Sources
  - Organisations
  - ATC Codes
  - Pharmaceutical Forms
  - Routes Of Administration
  - Attachments
  - Master File Locations

Description	Name/Value	
Operation Type	Insert (1)	
Type	Authorised (2)	
EV Code	MAH	Field is Mandatory
MAH	QPPV	
Master File Location	PhV enquiry email	Field must have a specified value
PhV enquiry Phone	Sender Local Code	Field must have a specified value
Sender Local Code	Info Date	
Info Date	Authorisation Country Code	Field is Mandatory
Authorisation Country Code	Authorisation Procedure	Field is Mandatory
Authorisation Procedure	Authorisation Status	
Authorisation Status	Authorisation Number	Field must have a specified value
Authorisation Number	Authorisation/Renewal Date	Field must have a specified value
Authorisation/Renewal Date	MRP/DCP/EMA Number	
MRP/DCP/EMA Number	EU Number	
EU Number	Legal Basis	
Legal Basis	Orphan Drug	
Orphan Drug	Additional Monitoring	
Additional Monitoring	Invalidated Date	Field must have a specified value
Invalidated Date	Full Presentation Name	Field is Mandatory
Full Presentation Name	Product Short Name	Field is Mandatory Optional
Product Short Name	Product INN/Common Name	Field is Mandatory Optional
Product INN/Common Name	Product Company Name	Field must have a specified value
Product Company Name	Product Strength Name	
Product Strength Name	Product Form Name	
Product Form Name	Package Description	
Package Description	Comment	
Comment		

Calendar

yyyyymmdd

2014 May

Su	Mo	Tu	We	Th	Fr	Sa
					1	2
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

Many fields in EVWEB can accept the date/time information in different formats:

Year/month/day

Year/month/

The formats can be selected by clicking on the format button at the top of the calendar.

Calendar

yyyyymm

Format

yyyyymmdd

yyyyymm

2014 May

Su	Mo	Tu	We	Th	Fr	Sa
					1	2
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

Depending on the format selected, the calendar interface will change accordingly.

Calendar

yyyyymm

2014 May

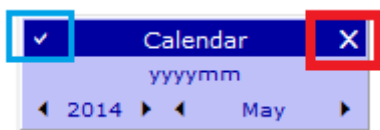
The default calendar will present the current month and year.

If you wish to change the date, just click on a specific date. If you require a change of the month or the year, use the side arrows flanking the month and year.

**Please note that the day selection confirms and enters the date and closes the calendar screen.** Therefore, make sure that the year and the month are correct before you select the day.

When the date format does not require a day (e. g. when entering an incomplete date that does not have a specific day) you can confirm your selection by clicking on the confirmation sign located at the top-left area of the calendar screen ("✓"). This action will also close the calendar screen.

To exit the calendar without selecting a date/time, click on the "x" sign located on the top right corner of the calendar screen.



### **2.6.1.3. Look-up fields (or Look-up tables)**

In this type of field, you are presented with a drop-down menu from where you can select the required information.

By positioning your cursor on the selected field and pressing "Enter" or by double clicking on the field, a list of pre-defined values will be displayed:

Create and Send ICSRs			Create and Send Acks			WEB Trader			ICSRs			Create and Send Product Reports			Medicinal Products			MedDRA																							
Reset Application			Reset Section			Clear			Replicate			Validate			Send			XML			ZIP			RTF			Duplicate			Remove			E			L			R		
<b>XEVPRM Message</b> Products Insert (1) - Authorised (2) Medicinal Product Types (-) Authorised Pharmaceutical Forms (-) Pharmaceutical Products (-) Drug ATCs (-) Drug Indications (-) Previous EV Codes (-) Product Attachments (-) Substances Sources Organisations ATC Codes Pharmaceutical Forms Routes Of Administration Attachments Master File Locations																																									
Description Operation Type Type EV Code MAH QPPV Master File Location PhV enquiry email PhV enquiry Phone Sender Local Code Info Date Authorisation Country Code Authorisation Procedure Authorisation Status Authorisation Number Authorisation/Renewal Date MRP/DCP/EMEA Number EU Number Legal Basis Orphan Drug Additional Monitoring Invalidated Date Full Presentation Name Product Short Name Product INN/Common Name Product Company Name Product Strength Name Product Form Name Package Description Comment												Name/Value Insert (1) Authorised (2) Select option Press A - Z to find initial letter Press Enter to select, Escape to clear Afghanistan (AF) ÅLAND ISLANDS (AX) Albania (AL) Algeria (DZ) American Samoa (AS) Andorra (AD) Angola (AO) Anguilla (AI) Antarctica (AQ) Antigua And Barbuda (AG) Argentina (AR) Armenia (AM) Aruba (AW) Australia (AU) Austria (AT) Azerbaijan (AZ) Bahamas (BS) Bahrain (BH) Bangladesh (BD) Barbados (BB) Belarus (BY) Belgium (BE) Belize (BZ) Benin (BI) Bermuda (BM) Bhutan (BT) Bolivia (BO) BONAIRE, SINT EUSTATIUS AND SABA (BQ) Bosnia And Herzegovina (BA) Botswana (BW) Bouvetisland (BV)												Field is Mandatory Field must have a specified value Field must have a specified value Field is Mandatory Field is Mandatory Field must have a specified value Field must have a specified value Field must have a specified value Field is Mandatory Field is Mandatory Field is Mandatory Optional Field is Mandatory Optional Field must have a specified value Section is Mandatory Section is Mandatory Section is Mandatory Section is Mandatory Section is Mandatory Section is Mandatory																	
Country where the product is auth																																									

Create and Send ICSRs			Create and Send Acks			WEB Trader			ICSRs			Create and Send Product Reports			Medicinal Products			MedDRA																							
Reset Application			Reset Section			Clear			Replicate			Validate			Send			XML			ZIP			RTF			Duplicate			Remove			E			L			R		
<b>XEVPRM Message</b> Products Insert (1) - Authorised (2) Medicinal Product Types (-) Authorised Pharmaceutical Forms (-) Pharmaceutical Products (-) Drug ATCs (-) Drug Indications (-) Previous EV Codes (-) Product Attachments (-) Substances Sources Organisations ATC Codes Pharmaceutical Forms Routes Of Administration Attachments Master File Locations																																									
Description Operation Type Type EV Code MAH QPPV Master File Location PhV enquiry email PhV enquiry Phone Sender Local Code Info Date Authorisation Country Code Authorisation Procedure Authorisation Status Authorisation Number Authorisation/Renewal Date MRP/DCP/EMEA Number EU Number Legal Basis Orphan Drug Additional Monitoring Invalidated Date Full Presentation Name Product Short Name Product INN/Common Name Product Company Name Product Strength Name Product Form Name Package Description Comment												Name/Value Insert (1) Authorised (2) Select option Press A - Z to find initial letter Press Enter to select, Escape to clear EU authorisation procedures - Centralised Procedure (1) EU authorisation procedures - Mutual Recognition Procedure (3) EU authorisation procedures - Decentralised Procedure (7) EU authorisation procedures - National Procedure (4) Non EU authorisation procedure (5) EU authorisation procedures - Traditional use registration for herbal medicinal products (11) EU authorisation procedures - Simplified registration procedure for homeopathic medicinal products (12)												Field is Mandatory Field must have a specified value Field must have a specified value Field is Mandatory Field is Mandatory Field is Mandatory Section is Mandatory Section is Mandatory Section is Mandatory Section is Mandatory																	



### 2.6.1.4. Query fields (Remote database lookup tables)

This type of field requires data that needs to be selected from a predefined list, generated as a result of a query.

A query is a search performed in the XEVMPD (for this reason, a query operation always requires an active internet connection).

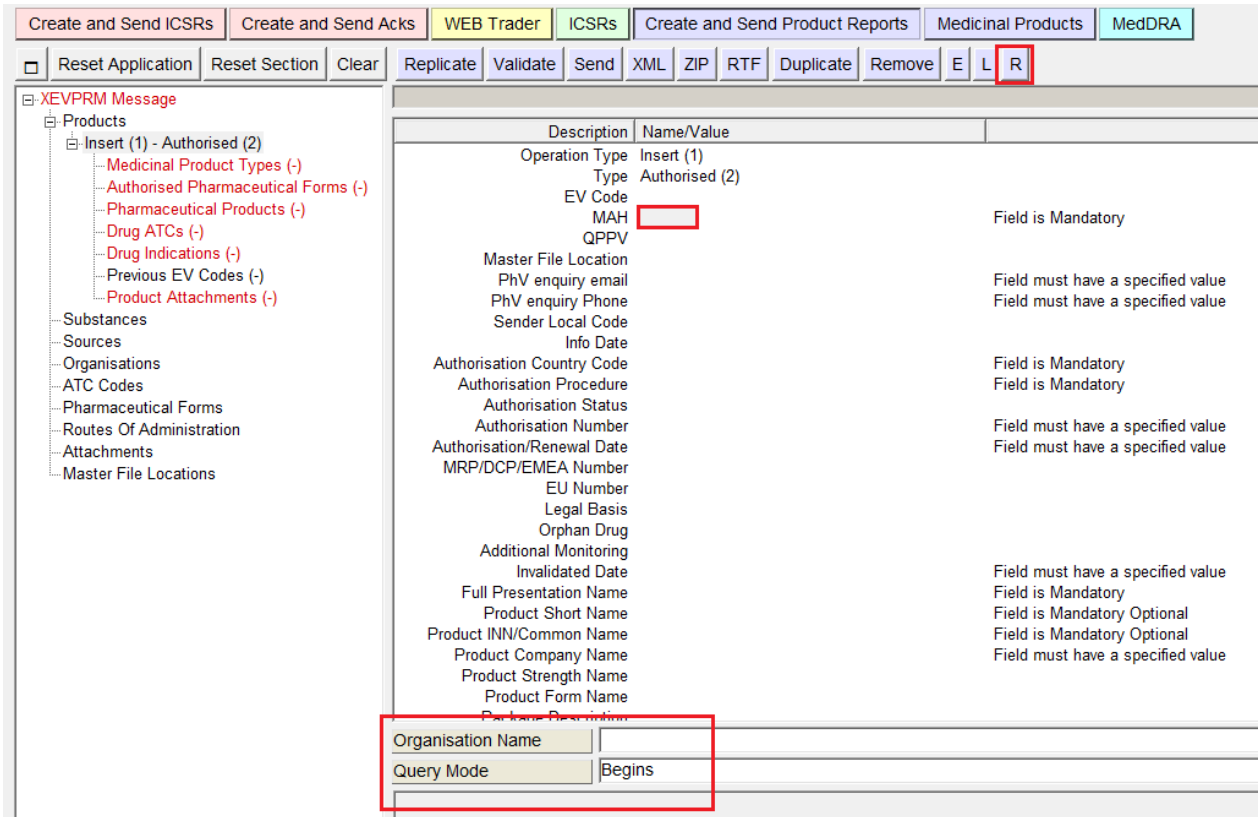
A "query area" will appear in the lower section of the active area. This "query area" always contains at least one search field, one or more "parameter" fields (in this example the one labelled "Query Mode") and an area to display the results.

You can select the field with your cursor and press "Enter" on the keyboard:

The screenshot shows the XEVMPD interface. On the left is a tree view under 'XEVRM Message' with 'Products' expanded to 'Insert (1) - Authorised (2)'. The right pane shows a table with the following data:

Description	Name/Value	
Operation Type	Insert (1)	
Type	Authorised (2)	
EV Code	MAH	Field is Mandatory
	QPPV	
Master File Location		
PhV enquiry email		Field must have a specified value
PhV enquiry Phone		Field must have a specified value
Sender Local Code		
Info Date		
Authorisation Country Code		Field is Mandatory
Authorisation Procedure		Field is Mandatory
Authorisation Status		
Authorisation Number		Field must have a specified value
Authorisation/Renewal Date		Field must have a specified value
MRP/DCP/EMEA Number		
EU Number		
Legal Basis		
Orphan Drug		
Additional Monitoring		
Invalidated Date		Field must have a specified value
Full Presentation Name		Field is Mandatory
Product Short Name		Field is Mandatory Optional
Product INN/Common Name		Field is Mandatory Optional
Product Company Name		Field must have a specified value
Product Strength Name		
Product Form Name		
Package Description		
Organisation Name		
Query Mode	Begins	

Or you can select the field with your cursor and press the "R" (Remote Database Look-up) button:



In both cases, a drop-down menu will be displayed.

You need to search the correct information by typing keywords in the search field. In our example, we are searching for a marketing authorisation holder name. We may know part of the name, or be unsure about the correct spelling. Using the wildcards (e.g.? and \*) we can search the system. In our example, we typed "Nobel" in the search field of the "query area".

The "query mode" field allows us to perform a more restricted search by applying one condition in the query.

You can choose to apply the following conditions in your search: "Matches", "Begins", "Contains", "Sounds like" and "Contains + sounds like" by pressing on the arrow on the right:

The screenshot shows the EVWEB application interface. At the top, there are several tabs: "Create and Send ICSRs", "Create and Send Ack", "WEB Trader", "ICSRs", "Create and Send Product Reports", "Medicinal Products", and "MedDRA". Below the tabs is a menu bar with options: "Reset Application", "Reset Section", "Clear", "Replicate", "Validate", "Send", "XML", "ZIP", "RTF", "Duplicate", "Remove", "E", "L", "R".

The main area is divided into two panes. The left pane shows a tree view of the application structure, including "Products", "Substances", "Sources", "Organisations", "ATC Codes", "Pharmaceutical Forms", "Routes Of Administration", "Attachments", and "Master File Locations". The right pane shows a table with columns "Description" and "Name/Value". The table contains various fields and their values, such as "Operation Type: Insert (1)", "Type: Authorised (2)", "EV Code: MAH", "Master File Location: QPPV", "Authorisation Country Code", "Authorisation Procedure", "Authorisation Status", "Authorisation Number", "Authorisation/Renewal Date", "MRP/DCP/EMEA Number", "EU Number", "Legal Basis", "Orphan Drug", "Additional Monitoring", "Invalidated Date", "Full Presentation Name", "Product Short Name", "Product INN/Common Name", and "Product Company Name".

At the bottom of the right pane, there is a "Query Mode" dropdown menu set to "Begins". A red box highlights the dropdown arrow. A "Select option" menu is open, showing the following options: "Matches", "Begins", "Contains", "Sounds like", and "Contains + Sounds like". Below the menu, there is a note: "Press A - Z to find initial letter. Press Enter to select, Escape to clear".

At the bottom left of the interface, the text "MAH (AP.4)" is displayed.

Press "Enter" on your keyboard to run the search. The search (or query) results will be displayed in the result screen below the search field.

**!** When clicking this arrow and it does not work, it is a sign that EVWEB is about to crash. Save your work, reset the application and delete the temporary internet files from the internet options in the tools menu of the browser. Then reload your file to continue data entry.

You now have to select one of the items displayed in this list by either pressing "Enter" or by double-clicking on the selected value:

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

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

**XEVPRM Message**

- Products
  - Insert (1) - Authorised (2)
    - Medicinal Product Types (-)
    - Authorised Pharmaceutical Forms (-)
    - Pharmaceutical Products (-)
    - Drug ATCs (-)
    - Drug Indications (-)
    - Previous EV Codes (-)
    - Product Attachments (-)
  - Substances
  - Sources
  - Organisations
  - ATC Codes
  - Pharmaceutical Forms
  - Routes Of Administration
  - Attachments
  - Master File Locations

**DrugVero**

Description	Name/Value	
Operation Type	Insert (1)	
Type	Authorised (2)	
EV Code		
MAH		Field is Mandatory
QPPV		
Master File Location		
PhV enquiry email		Field must have a specified value
PhV enquiry Phone		Field must have a specified value
Sender Local Code		
Info Date		
Authorisation Country Code		Field is Mandatory
Authorisation Procedure		Field is Mandatory
Authorisation Status		
Authorisation Number		Field must have a specified value
Authorisation/Renewal Date		Field must have a specified value
MRP/DCP/EMEA Number		
EU Number		
Legal Basis		
Orphan Drug		
Additional Monitoring		
Invalidated Date		Field must have a specified value
Full Presentation Name		Field is Mandatory
Product Short Name		Field is Mandatory Optional
Product INN/Common Name		Field is Mandatory Optional
Product Company Name		Field must have a specified value
Product Strength Name		

Organisation Name: The medicines  
 Query Mode: Begins

Num	Name	Checked	Sender HQ Name	Sender Name
0001	THE MEDICINES COMPANY ...	07/02/2005 15:02:40	EudraVigilance Human	European Medicines Agency (...)

The selected value will be automatically inserted in the relevant (in this case MAH) field:

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

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

**XEVPRM Message**

- Products
  - Insert (1) - Authorised (2)
    - Medicinal Product Types (-)
    - Authorised Pharmaceutical Forms (-)
    - Pharmaceutical Products (-)
    - Drug ATCs (-)
    - Drug Indications (-)
    - Previous EV Codes (-)
    - Product Attachments (-)
  - Substances
  - Sources
  - Organisations
  - ATC Codes
  - Pharmaceutical Forms
  - Routes Of Administration
  - Attachments
  - Master File Locations

**DrugVero**

Description	Name/Value	
Operation Type	Insert (1)	
Type	Authorised (2)	
EV Code		
MAH	THE MEDICINES COMPANY UK LTD	
QPPV		
Master File Location		
PhV enquiry email		Field must have a specified value
PhV enquiry Phone		Field must have a specified value
Sender Local Code		
Info Date		
Authorisation Country Code		Field is Mandatory
Authorisation Procedure		Field is Mandatory
Authorisation Status		
Authorisation Number		Field must have a specified value
Authorisation/Renewal Date		Field must have a specified value
MRP/DCP/EMEA Number		
EU Number		
Legal Basis		
Orphan Drug		
Additional Monitoring		
Invalidated Date		Field must have a specified value
Full Presentation Name		Field is Mandatory
Product Short Name		Field is Mandatory Optional
Product INN/Common Name		Field is Mandatory Optional
Product Company Name		Field must have a specified value
Product Strength Name		
Product Form Name		
Package Description		
Comment		

Medicinal Product Types (-) Section is Mandatory  
 Authorised Pharmaceutical Forms (-) Section is Mandatory  
 Pharmaceutical Products (-) Section is Mandatory  
 Drug ATCs (-) Section is Mandatory  
 Drug Indications (-) Section is Mandatory  
 Previous EV Codes (-) Section is Mandatory  
 Product Attachments (-) Section is Mandatory

### 2.6.1.5. Query fields (Local data lookup tables)

While you are completing an XEVPRM, you will realise that most of the fields are provided as look-up tables.

When an entity that you need to reference in your product report is not included in the lookup tables, you have to add this new information in the XEVPRM.

For example, if you are specifying an Authorised Medicinal Product in an XEVPRM and its MAH "PharmaX Ltd." is not available in the MAH lookup table, you can add the MAH in the same XEVPRM and reference the newly added MAH "PharmaX Ltd." in the AMP using the "L" (**Local Data Lookup**) feature.

As per the below screenshot, you are inserting a new AMP but the MAH organisation you need to reference is not available:

The screenshot displays the XEVPRM Message interface. The top navigation bar includes buttons for 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below this is a toolbar with buttons for 'Reset Application', 'Reset Section', 'Clear', 'Replicate', 'Validate', 'Send', 'XML', 'ZIP', 'RTF', 'Duplicate', 'Remove', 'E', 'L', and 'R'. The left sidebar shows a tree view of 'XEVPRM Message' with 'Products' expanded to 'Insert (1) - Authorised (2)', listing various fields like 'Medicinal Product Types (-)', 'Authorised Pharmaceutical Forms (-)', etc. The main area shows a table with columns 'Description' and 'Name/Value'. The 'MAH' field is highlighted, with a tooltip indicating 'Field is Mandatory'. A modal dialog box titled 'Message from webpage' is overlaid on the table, displaying a warning icon and the text 'Lookup returned no results'. Below the table, there are input fields for 'Organisation Name' (containing 'PharmaX Ltd.') and 'Query Mode' (containing 'Begins').

You will therefore need to create a new MAH entity in the same XEVPRM.

Go to the "Organisations" section of the XEVPRM and create a new marketing authorisation holder organisation (please refer to section 3.2.6. *Insert of MAH organisation*):

The screenshot shows the XEVPRM interface. At the top, there are navigation tabs: 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below these are buttons: 'Reset Application', 'Reset Section', 'Clear', 'Validate', 'Send', 'XML', 'ZIP', 'RTF', 'Duplicate', 'Remove', 'E', 'L', 'R'. The left sidebar shows a tree view under 'XEVPRM Message' with 'Products' expanded to 'Insert (1) - Authorised (2)', and 'Organisations' expanded to 'Insert (1) - MAH (1) - PharmaX Ltd.'. The main area shows a data entry form for 'Insert (1)' with the following fields and values:

Description	Name/Value
Operation Type	Insert (1)
EV Code	
Type	MAH (1)
MAH Name	PharmaX Ltd.
SME Status	Medium (4)
SME Number	
MAH Sender ID	
Address	22 Berry Street
City	London
Region	
Postcode	E22 4HC
Country Code	United Kingdom (GB)
Tel Number	
Tel Extension	
Tel Country Code	
Fax Number	
Fax Extension	
Fax Country Code	
E-mail Address	
Comment	

Once you have created the new MAH organisation, go to the authorised product entity that you started to create, click with your cursor on the field "MAH" and then on the button **L** (Local data lookup).

From the pop-up menu, select the new MAH present in your XEVPRM:

The screenshot shows the XEVPRM interface. At the top, there are navigation tabs: 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below these are buttons: 'Reset Application', 'Reset Section', 'Clear', 'Replicate', 'Validate', 'Send', 'XML', 'ZIP', 'RTF', 'Duplicate', 'Remove', 'E', 'L', 'R'. The left sidebar shows a tree view under 'XEVPRM Message' with 'Products' expanded to 'Insert (1) - Authorised (2)', and 'Organisations' expanded to 'Insert (1) - MAH (1) - PharmaX Ltd.'. The main area shows a data entry form for 'Insert (1)' with the following fields and values:

Description	Name/Value
Operation Type	Insert (1)
Type	Authorised (2)
EV Code	
MAH	
QPPV	
Master File Location	
PhV enquiry email	
PhV enquiry Phone	
Sender Local Code	
Info Date	
Authorisation Country Code	
Authorisation Procedure	
Authorisation Status	
Authorisation Number	
Authorisation/Renewal Date	
MRP/DCP/EMEA Number	
EU Number	
Legal Basis	
Orphan Drug	
Additional Monitoring	
Invalidated Date	
Full Presentation Name	
Product Short Name	
Product INN/Common Name	
Product Company Name	
Product Strength Name	
Product Form Name	
Package Description	
Comment	

A 'Select option' dialog box is open over the 'MAH' field. The dialog box contains the text: 'Select option', 'Press A - Z to find initial letter', 'Press Enter to select. Escape to clear'. The selected option is 'Insert (1) - MAH (1) - PharmaX Ltd. (2)'. The dialog box also shows 'Field is Mandatory' and 'Field must have a specified value'.

At the bottom of the main area, there is a list of sections and their mandatory status:

- Medicinal Product Types (-) Section is Mandatory
- Authorised Pharmaceutical For... Section is Mandatory
- Pharmaceutical Products (-) Section is Mandatory
- Drug ATCs (-) Section is Mandatory
- Drug Indications (-) Section is Mandatory
- Previous EV Codes (-) Section is Mandatory
- Product Attachments (-) Section is Mandatory

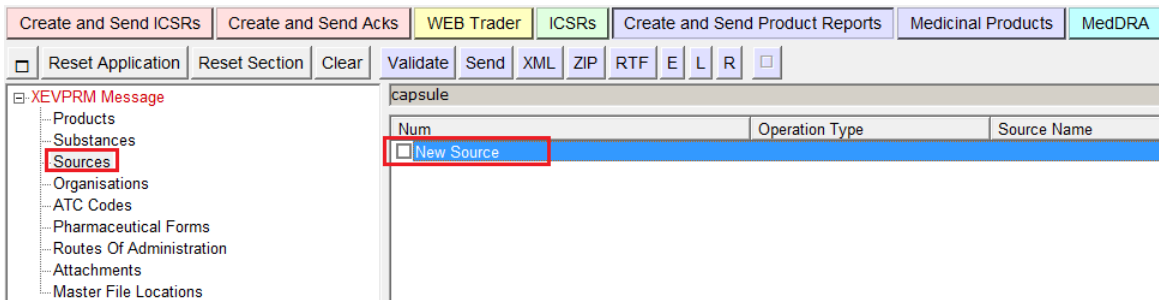
The same process can be used to add information regarding new sponsors, sources, ATC codes (proposed or development), routes of administration (proposed or development), pharmaceutical forms (proposed or development), MFLs, development substances and attachments.

## 2.6.2. Adding and removing items

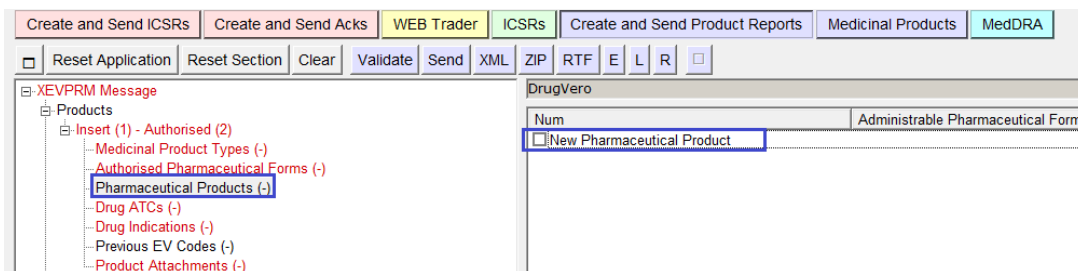
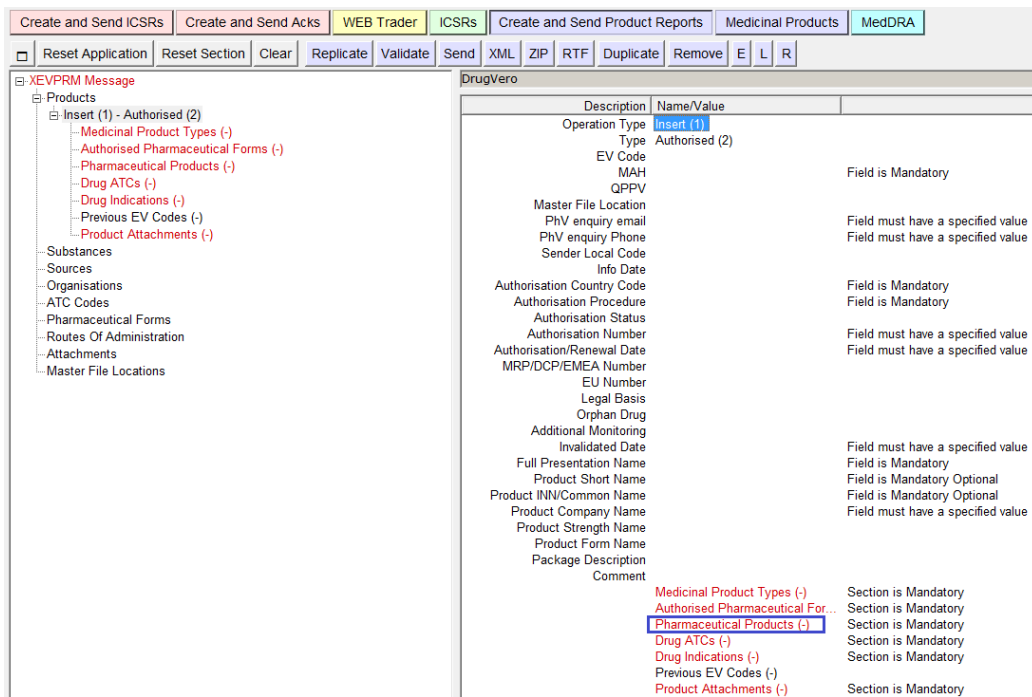
During the data entry process, you may be required to add a new section to the tree view.

This can be done in two different ways:

- In a checklist (see section 2.6.3. *Checklists*) by clicking on the special item called "New ...";



- By double clicking on the item in the list view in the active area.



Some of the sections that you can add are repeatable, which means that you can add several of them. In order to do that, you can click on the "New ..." item more than once. You can also duplicate an already existing item.

**Duplicate** To do this, in the tree view, you have to select the section you wish to duplicate and then click on the "Duplicate button" that becomes available only in these situations:

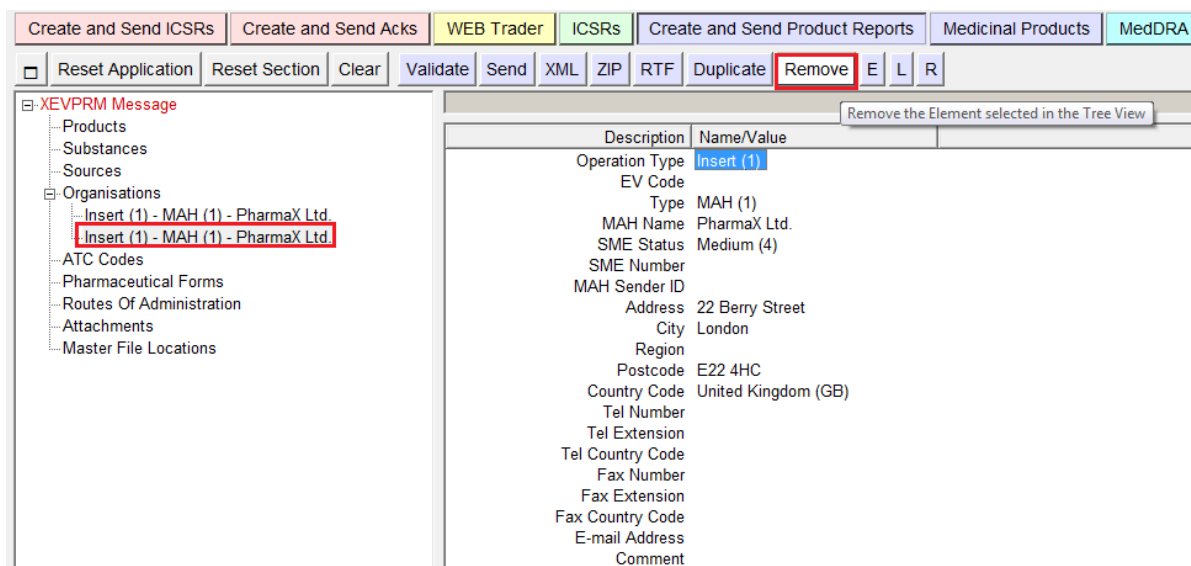
Description	Name/Value
Operation Type	Insert (1)
EV Code	
Type	MAH (1)
MAH Name	PharmaX Ltd.
SME Status	Medium (4)
SME Number	
MAH Sender ID	
Address	22 Berry Street
City	London
Region	
Postcode	E22 4HC
Country Code	United Kingdom (GB)
Tel Number	
Tel Extension	
Tel Country Code	
Fax Number	
Fax Extension	
Fax Country Code	
E-mail Address	
Comment	

Description	Name/Value
Operation Type	Insert (1)
EV Code	
Type	MAH (1)
MAH Name	PharmaX Ltd.
SME Status	Medium (4)
SME Number	
MAH Sender ID	
Address	22 Berry Street
City	London
Region	
Postcode	E22 4HC
Country Code	United Kingdom (GB)
Tel Number	
Tel Extension	
Tel Country Code	
Fax Number	
Fax Extension	
Fax Country Code	
E-mail Address	
Comment	

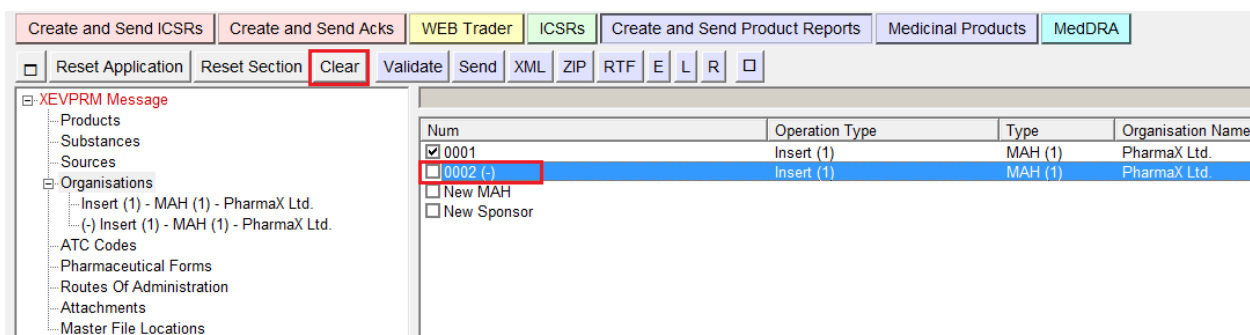
The sections you added can also be removed - to do this, you have two different options:

- To select in the tree view the section you want to remove and click on the "Remove" button that becomes available only in these situations:





- Or in case of multiple sections, uncheck the section you want to remove (see section 2.6.3. Checklists) and press the "Clear" button:



### 2.6.3. Checklists


A checklist is a specific type of **list view** (see section 2.4. *The active area* for related information) displayed in the active area, allowing the user to perform specific actions on the displayed items.

A checklist always displays a list of items with a white check box beside it. You can check/uncheck one or more items by clicking on the checkboxes with your mouse, or by pressing the "Space" key on your keyboard when the item is selected (dark background).

When dealing with a checklist, you may see two standard buttons in the dynamic buttons area on the main menu:



The button on the left is used to automatically uncheck all the checked items in the checklist. You can use this button instead of manually unchecking all the single items.

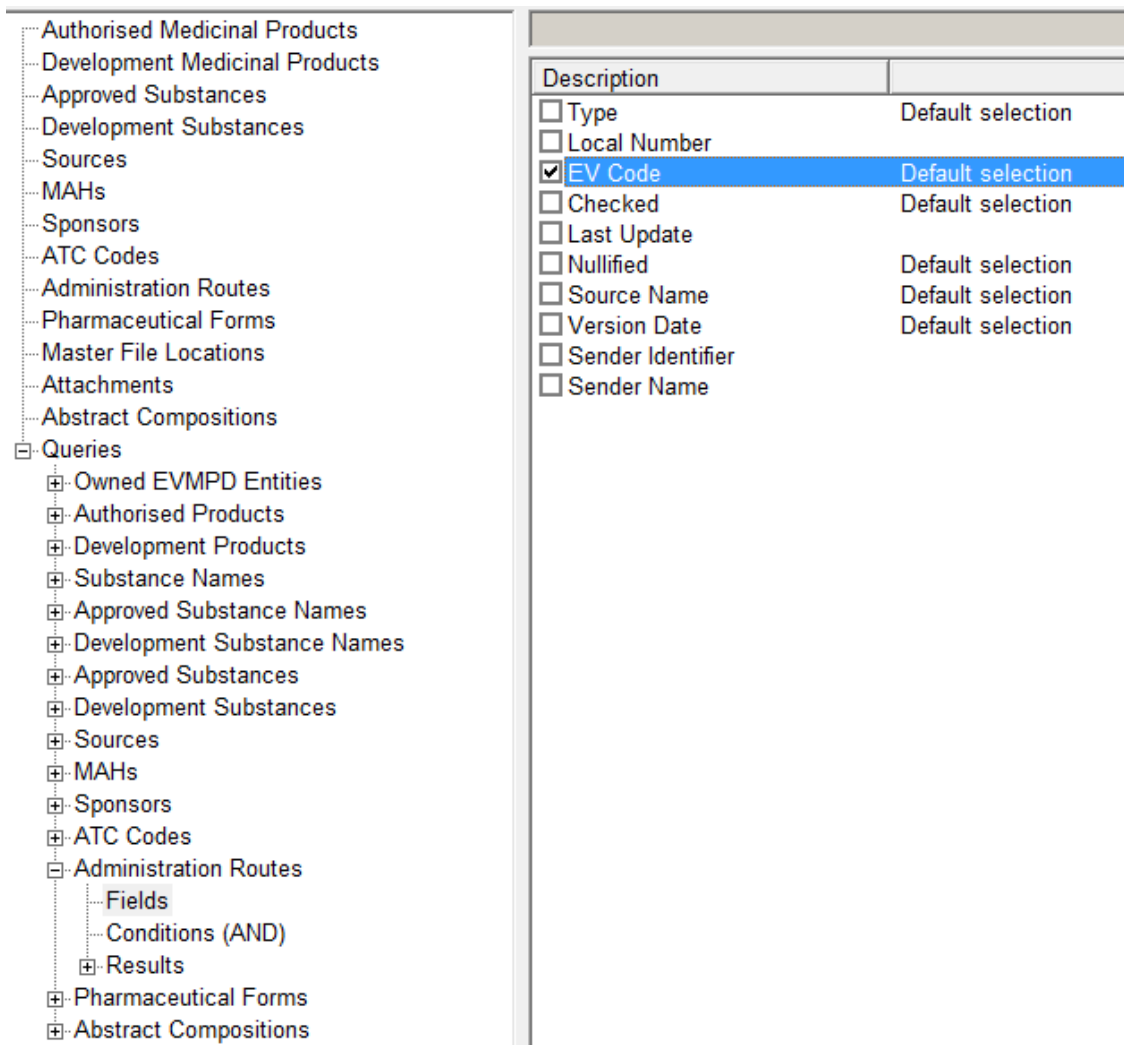
 The button on the right (which is not always displayed) has different functions depending on the operations allowed in each section. These functions will be explained in detail when the EVWEB-sections will be described in the following sessions of the manual (load/unload checklists, fields of a query search, message receivers).

There are three types of checklists, depending on the actions you can perform on the list of items:

- Select/Deselect
- Load/Delete
- Add/Delete

#### 2.6.4. Select/Deselect checklist

This type of checklist allows you to select and deselect one or more items from the list displayed on the screen in the active area. It is used for the Fields, Conditions and Results sections of a query search.



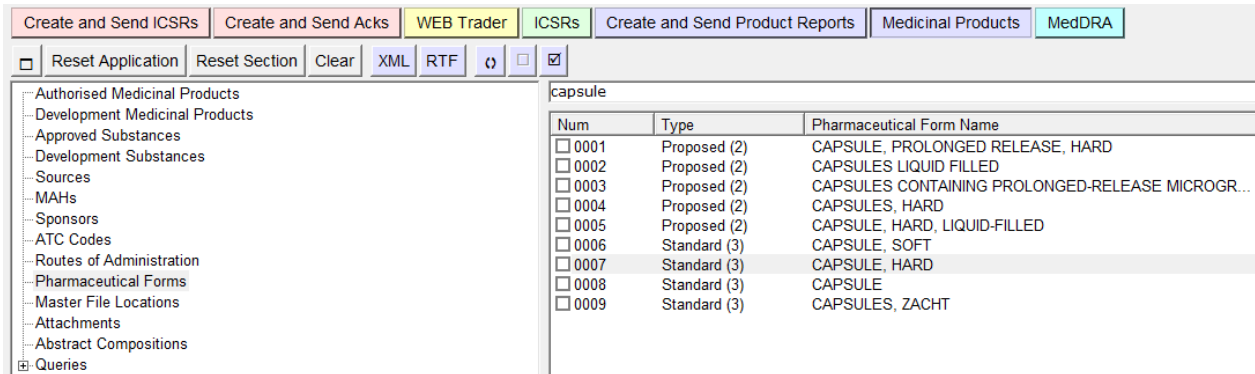
Description	
<input type="checkbox"/> Type	Default selection
<input type="checkbox"/> Local Number	
<input checked="" type="checkbox"/> EV Code	Default selection
<input type="checkbox"/> Checked	Default selection
<input type="checkbox"/> Last Update	
<input type="checkbox"/> Nullified	Default selection
<input type="checkbox"/> Source Name	Default selection
<input type="checkbox"/> Version Date	Default selection
<input type="checkbox"/> Sender Identifier	
<input type="checkbox"/> Sender Name	

In this type of checklist, selected items are displayed only in the active area; nothing changes in the tree view when you select or deselect an item.

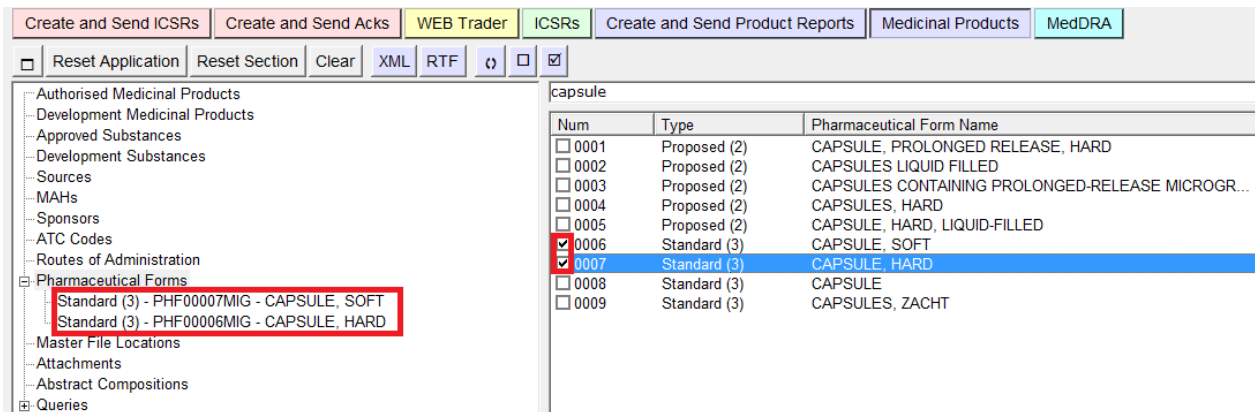
For the Results sections, the purpose of the selection is to mark the entities on which to perform commands.

### 2.6.5. Load/Delete checklist

This type of checklist allows the user to load one or more of the items displayed on the list from the remote system. This type of checklist is used to display the results of a **simple query** and an **advanced query** (see section 2.7. *Search methods*).



By marking one or more of the checkboxes, the EVWEB will load the data from the remote system. This operation may take a few moments to be performed. This means that the result of the operation is not immediate. The loaded data will appear in the appropriate section of the tree view:



The section currently selected in the tree view may not be related to the section where the loaded items will be added. As an example, when you are positioned on the results of an advanced query, the selected item in the tree view is the result of the query itself. The loaded items will be loaded to a different section, depending on the main subject of the query (see section 2.5. *Interaction between the tree view and active area* and section 2.8. *Loading data*).

In case of failure of the loading process, an error message box will be displayed.


The opposite action is to remove one or more of the loaded items. If you unmark one of the items displayed in the list, a negative (-) sign will be displayed in both, the tree view and in the active area. This indicates that that specific item has been marked for deletion and therefore will be no longer considered in the active data. To continue with our example, we unmark "capsule, soft":

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

Authorised Medicinal Products  
 Development Medicinal Products  
 Approved Substances  
 Development Substances  
 Sources  
 MAHs  
 Sponsors  
 ATC Codes  
 Routes of Administration  
 Pharmaceutical Forms  
      Standard (3) - PHF00007MIG - CAPSULE, SOFT  
     Standard (3) - PHF00006MIG - CAPSULE, HARD  
 Master File Locations  
 Attachments  
 Abstract Compositions  
 Queries

capsule

Num	Type	Pharmaceutical Form Name	EV Code
<input type="checkbox"/> 0001 (-)	Standard (3)	CAPSULE, SOFT	PHF00007MIG
<input checked="" type="checkbox"/> 0002	Standard (3)	CAPSULE, HARD	PHF00006MIG

To **permanently delete an unmarked item**, click on the  button on the main menu dynamic section.

The "Clear" button will remove **all of the items unmarked this way**.


Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

Authorised Medicinal Products  
 Development Medicinal Products  
 Approved Substances  
 Development Substances  
 Sources  
 MAHs  
 Sponsors  
 ATC Codes  
 Routes of Administration  
 Pharmaceutical Forms  
      Standard (3) - PHF00007MIG - CAPSULE, SOFT  
     Standard (3) - PHF00006MIG - CAPSULE, HARD  
 Master File Locations  
 Attachments  
 Abstract Compositions  
 Queries

capsule


Num	Type	Pharmaceutical Form Name	EV Code
<input type="checkbox"/> 0001 (-)	Standard (3)	CAPSULE, SOFT	PHF00007MIG
<input checked="" type="checkbox"/> 0002	Standard (3)	CAPSULE, HARD	PHF00006MIG

Message from webpage

 You will remove all the Elements marked as Deleted (-).

Are You sure ?

When using EVWEB, keep in mind that there **is no way to directly delete or modify the data present in the EVDBMS**. All actions performed here only affect the current data present in your personal EVWEB session.

 In this particular type of checklist, this button allows you to load all items displayed in the active area with a single click. The loading operation may take some time, since the result of a query could be very long. For this reason, when you click on this button, the system will ask you to confirm your choice, and will also give you the possibility to stop the loading sequence.

## 2.6.6. Add/Delete checklist

This type of checklist allows the user to add one or more new items during a data entry procedure (i.e. creating a new Authorised Product).

This can be used to display the content of a multiple section. A multiple section is a container of one or more items of the same category. This means that whenever it is possible to insert one or more items of the same category, there is always a section container. As an example, an XEVPRM can contain one or more Authorised Products; to handle this situation in EVWEB, there is a section container called "Products" that contains all the Product Report items.

Num	Operation Type
<input type="checkbox"/>	New Authorised Product
<input type="checkbox"/>	New Development Product

The delete function of this type of checklist works exactly as the one for the Load/delete checklist.

## 2.7. Search methods

To navigate through the information available in the Product Report Database and in the Scientific Product Database, you need to load the product data in EVWEB. The starting point to load data in EVWEB is always a query (simple or advanced).

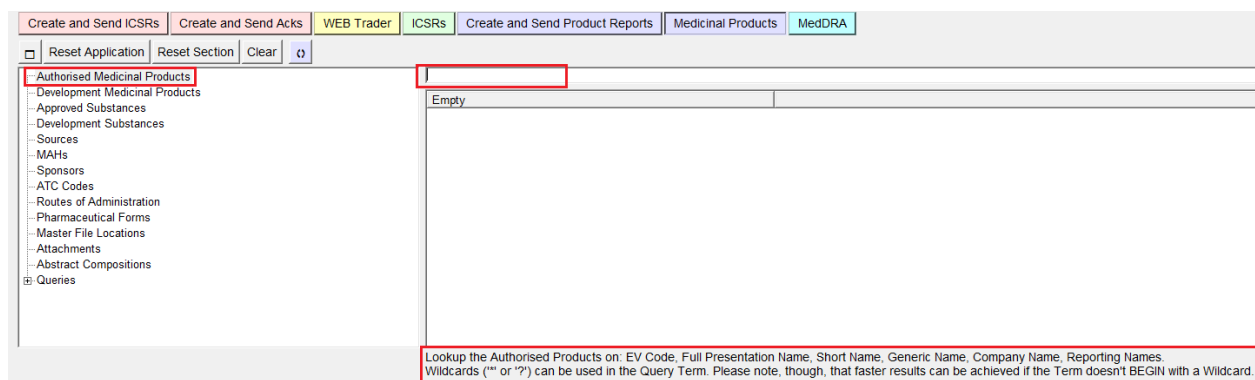
### 2.7.1. Simple query

The simple query field is located at the top of the active area as shown below. Here you can enter key words and activate the search by pressing "Enter" on the keyboard. A pull-down menu on the right of the search field allows you to see a list of previous searches.

Empty
-------

The simple query is available for specific items displayed in the tree view. Selecting one of these items will activate the simple query field.

Clicking inside the simple query field will display the description of the simple query (on which fields the query will be executed).



A simple query is carried out with the simple "contains" clause. You can also use the following wildcards to extend your queries:

**?** is a special character that matches any character (but only one):

T?ST will match: TEST, TAST, but not TEEST

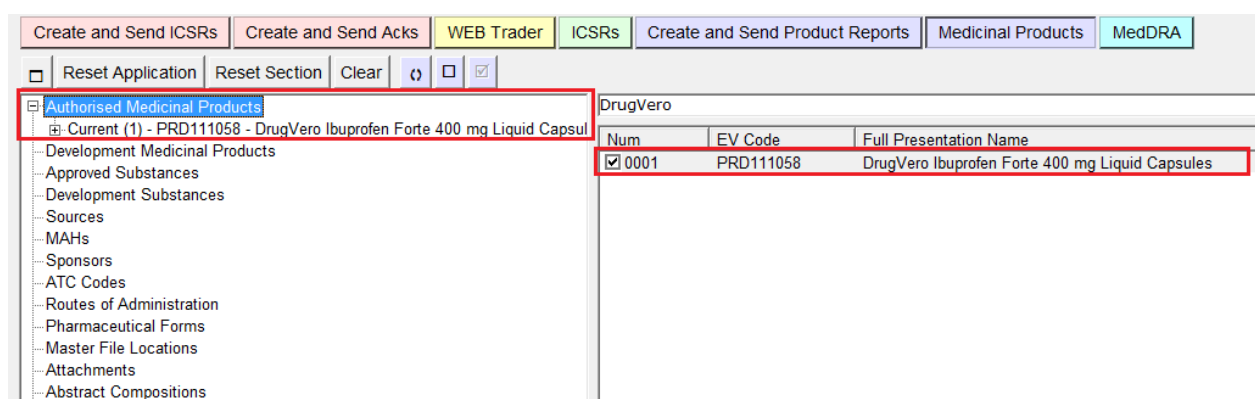
**\*** is a special character that matches any set of characters of any length:

T\*ST will match: TEST, TAST, TST, TEEST

Combined examples for the use of both wildcards:

T?ST\*TERM will return: TEST TERM, TEST of the TERM, TAST – TEARM, TESTTERM

The results of the query will be displayed in the active area, as a Select/Deselect checklist (see section 2.6.3. Checklists). In the tree view area, a new element will appear under the relevant section, containing the results of the query.

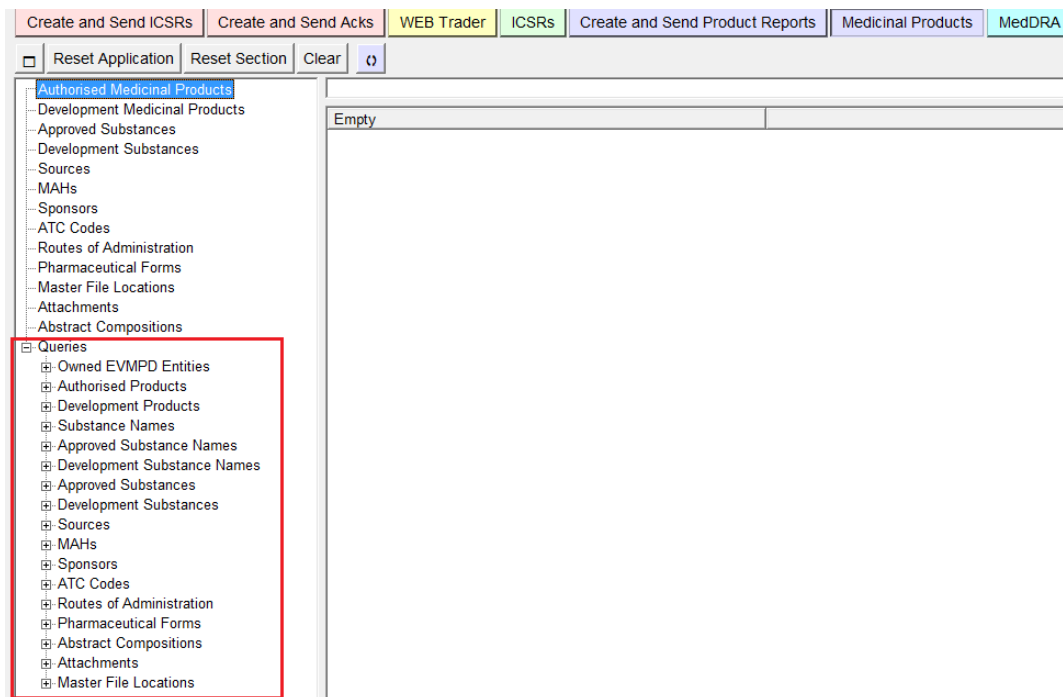


The result of your query may be exported as an Excel spreadsheet, XML file(s) or RTF file(s). See section 4.2.1. Exporting results of a simple query for related information.

## 2.7.2. Advanced Query

EVWEB allows you to perform elaborate queries in the EVDBMS (e.g. Medicinal Products, MedDRA, terms etc.).

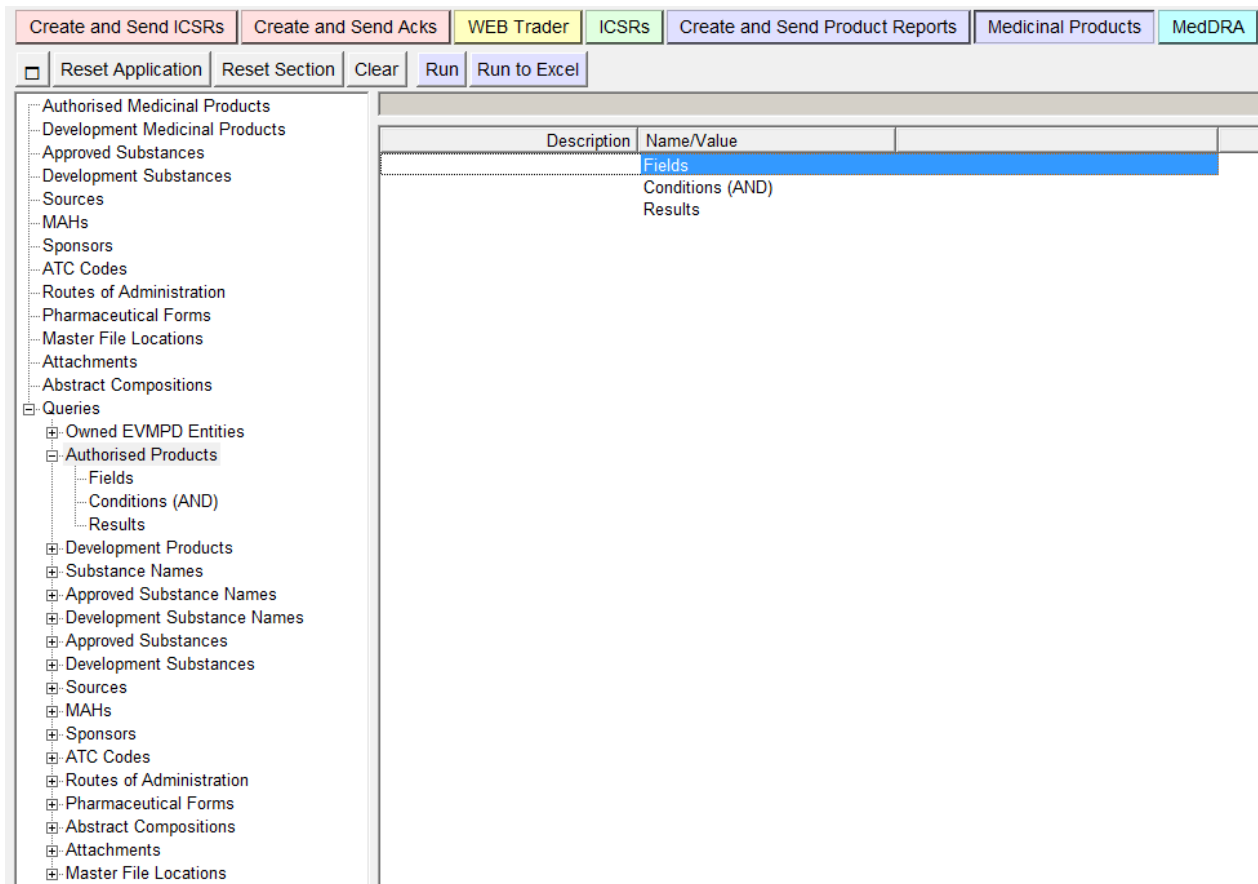
The query items are available as selectable items in the tree view area:



Usually, there will be more than one query available in the Queries section.

Every query is divided in 3 different sections:

- Fields
- Conditions (AND)
- Results



Fields and conditions are used in combination to better target the scope of the query. Both always refer to specific information related to the subject of the query, and will therefore change depending on the subject.

The result of a query is a list of special items displayed as a checklist (see section [2.6.4. Select/Deselect checklist](#)).

#### **2.7.2.1. Fields section**

The "Fields" section is used to define the output of an advanced query. That means that the items displayed in the result checklist will contain only the fields previously selected in this section.

Usually, some of the items displayed in the "Fields" section are marked as "Default selection". This means that if you run the query without selecting any of the items in the "Fields" section, the default ones will be considered as selected.



Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

Reset Application  Reset Section

Description	
<input type="checkbox"/> Local Number	
<input type="checkbox"/> EV Code	Default selection
<input type="checkbox"/> Article 57 Format	
<input type="checkbox"/> Owner Identifier	Default selection
<input type="checkbox"/> Owner Name	
<input type="checkbox"/> Checked	Default selection
<input type="checkbox"/> Cleaned	Default selection
<input type="checkbox"/> Last Update	
<input type="checkbox"/> Nullified	Default selection
<input type="checkbox"/> Category	Default selection
<input type="checkbox"/> Full Presentation Name	Default selection
<input type="checkbox"/> Product Short Name	Default selection
<input type="checkbox"/> Product INN/Common Name	
<input type="checkbox"/> Product Strength Name	
<input type="checkbox"/> Product Company Name	
<input type="checkbox"/> Product Form Name	
<input type="checkbox"/> Authorisation Country	
<input type="checkbox"/> Authorisation Procedure	
<input type="checkbox"/> Authorisation Status	
<input type="checkbox"/> MA Validity	
<input type="checkbox"/> Authorisation Number	
<input type="checkbox"/> MRP/DCP/EMA Number	
<input type="checkbox"/> EU Number	
<input type="checkbox"/> Invalidated Date	
<input type="checkbox"/> MAH Name	Default selection
<input type="checkbox"/> Pharmaceutical Form	
<input type="checkbox"/> Route of Administration	
<input type="checkbox"/> Substance names	
<input type="checkbox"/> Substance Amount Value Types	
<input type="checkbox"/> Is Updatable	
<input type="checkbox"/> Is Nullifiable	
<input type="checkbox"/> Sender Identifier	
<input type="checkbox"/> Sender Name	

If you use your own selection, after having run the query at least once, the "Default selection" will be no longer visible. Instead, the last selection used to run the query will be visible. These items will be labelled as "Last selection".

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

Reset Application  Reset Section

Description	
<input type="checkbox"/> Local Number	
<input type="checkbox"/> EV Code	Last selection
<input type="checkbox"/> Article 57 Format	
<input type="checkbox"/> Owner Identifier	Last selection
<input type="checkbox"/> Owner Name	
<input type="checkbox"/> Checked	Last selection
<input type="checkbox"/> Cleaned	Last selection
<input type="checkbox"/> Last Update	
<input type="checkbox"/> Nullified	Last selection
<input type="checkbox"/> Category	Last selection
<input type="checkbox"/> Full Presentation Name	Last selection
<input type="checkbox"/> Product Short Name	Last selection
<input type="checkbox"/> Product INN/Common Name	Last selection
<input type="checkbox"/> Product Strength Name	Last selection
<input type="checkbox"/> Product Company Name	Last selection
<input type="checkbox"/> Product Form Name	Last selection
<input type="checkbox"/> Authorisation Country	Last selection
<input type="checkbox"/> Authorisation Procedure	
<input type="checkbox"/> Authorisation Status	
<input type="checkbox"/> MA Validity	
<input type="checkbox"/> Authorisation Number	
<input type="checkbox"/> MRP/DCP/EMA Number	
<input type="checkbox"/> EU Number	
<input type="checkbox"/> Invalidated Date	
<input type="checkbox"/> MAH Name	Last selection
<input type="checkbox"/> Pharmaceutical Form	
<input type="checkbox"/> Route of Administration	
<input type="checkbox"/> Substance names	
<input type="checkbox"/> Substance Amount Value Types	
<input type="checkbox"/> Is Updatable	Last selection
<input type="checkbox"/> Is Nullifiable	Last selection
<input type="checkbox"/> Sender Identifier	
<input type="checkbox"/> Sender Name	



In this section a special select button is also available. It will automatically select all items marked as "Default selection" (or "Last selection").

NOTE: When performing a query on authorised medicinal products, whilst it is possible to select all of the "Fields", which you wish to see as part of the result, not all of those fields will be displayed.

### 2.7.2.2. Conditions (AND) section

The "Conditions" section is used to define the criteria of an advanced query.

This section allows you to select one or more items and define their value.

These items are then used as criteria to filter the results of the advanced query.

The conditions section works exactly as a data entry section. The only difference is the checkbox beside the field name.

This is because you have the opportunity to define the value of the criteria, as well as which criteria you want to use (selecting it with the checkbox).

Each item will become active and editable only if it is selected (marked checkbox).

Description	Name/Value
Article 57 Format	<input type="checkbox"/> Article 57 Format (1)
Local Number (Matches)	<input type="checkbox"/>
EV Code (Matches)	<input type="checkbox"/>
Has Been Updated	<input type="checkbox"/>
Owner Identifier (Matches)	<input type="checkbox"/>
Checked	<input type="checkbox"/>
Checked and Updated	<input type="checkbox"/>
Cleaned	<input type="checkbox"/>
Cleaned and Updated	<input type="checkbox"/>
Last Update	<input type="checkbox"/>
Last Update (From)	<input type="checkbox"/>
Last Update (Up to)	<input type="checkbox"/>
Nullified	<input type="checkbox"/>
Category	<input type="checkbox"/>
Full Presentation Name (Matches)	<input type="checkbox"/>
Product Short Name (Matches)	<input type="checkbox"/>
Product INN/Common Name (Matches)	<input type="checkbox"/>
Product Strength Name (Matches)	<input type="checkbox"/>
Product Company Name (Matches)	<input type="checkbox"/>
Product Form Name (Matches)	<input type="checkbox"/>
Authorisation Country	<input type="checkbox"/>
Authorisation Procedure	<input type="checkbox"/>
Authorisation Status	<input type="checkbox"/>
Authorisation/Renewal Date (From)	<input type="checkbox"/>
Authorisation/Renewal Date (Up to)	<input type="checkbox"/>
MA Validity	<input checked="" type="checkbox"/> Valid (1)
Authorisation Number (Matches)	<input type="checkbox"/>
MRP/DCP/EMA Number (Matches)	<input type="checkbox"/>
EU Number (Matches)	<input type="checkbox"/>
Invalidated Date	<input type="checkbox"/>
Invalidated Date (From)	<input type="checkbox"/>
Invalidated Date (Up to)	<input type="checkbox"/>
MAH (Name) (Matches)	<input type="checkbox"/>
MAH (Code) (Matches)	<input type="checkbox"/>
QPPV	<input type="checkbox"/>
Master File Location (Code) (Matches)	<input type="checkbox"/>
Pharmaceutical Form (Matches)	<input type="checkbox"/>
Route of Administration (Matches)	<input type="checkbox"/>
ATC Code	<input type="checkbox"/>
Substance (Code) (Matches)	<input type="checkbox"/>
Substance (Name) (Matches)	<input type="checkbox"/>
Is Updatable	<input type="checkbox"/>
Is Nullifiable	<input type="checkbox"/>
Owned	<input type="checkbox"/>
Sender Identifier (Matches)	<input type="checkbox"/>
Sender Name (Matches)	<input type="checkbox"/>

If a criteria contains a value, but it is not selected (checkbox not marked), then it will not be taken into account when running the query.

For details about the possibilities in dealing with different kind of fields, please refer to section [2.6. Data entry](#)).

### 2.7.2.3. Results section

To launch a query after specifying the fields and conditions, press the "Run" button in the dynamic section of the main menu:

Description	Name/Value
Article 57 Format	<input checked="" type="checkbox"/> Article 57 Format (1)
Local Number (Matches)	<input type="checkbox"/>
EV Code (Matches)	<input type="checkbox"/>
Has Been Updated	<input type="checkbox"/>
Owner Identifier (Matches)	<input type="checkbox"/>
Checked	<input type="checkbox"/>
Checked and Updated	<input type="checkbox"/>
Cleaned	<input type="checkbox"/>
Cleaned and Updated	<input type="checkbox"/>
Last Update	<input type="checkbox"/>
Last Update (From)	<input type="checkbox"/>
Last Update (Up to)	<input type="checkbox"/>
Nullified	<input type="checkbox"/>
Category	<input type="checkbox"/>
Full Presentation Name (Matc...	<input checked="" type="checkbox"/> DrugVero*
Product Short Name (Matches)	<input type="checkbox"/>
Product INN/Common Name (...)	<input type="checkbox"/>
Product Strength Name (Matc...	<input type="checkbox"/>
Product Company Name (Mat...	<input type="checkbox"/>
Product Form Name (Matches)	<input type="checkbox"/>
Authorisation Country	<input type="checkbox"/>
Authorisation Procedure	<input type="checkbox"/>
Authorisation Status	<input type="checkbox"/>
Authorisation/Renewal Date (F...	<input type="checkbox"/>
Authorisation/Renewal Date (...)	<input type="checkbox"/>
MA Validity	<input checked="" type="checkbox"/> Valid (1)
Authorisation Number (Matches)	<input type="checkbox"/>
MRP/DCP/EMA Number (Mat...	<input type="checkbox"/>
EU Number (Matches)	<input type="checkbox"/>
Invalidated Date	<input type="checkbox"/>
Invalidated Date (From)	<input type="checkbox"/>
Invalidated Date (Up to)	<input type="checkbox"/>
MAH (Name) (Matches)	<input type="checkbox"/>
MAH (Code) (Matches)	<input type="checkbox"/>
QPPV	<input type="checkbox"/>

The results of the query will be displayed in the active area, as a Select/Deselect checklist (see section [2.6.3. Checklists](#)). In the tree view area, a new element will appear under the "Results" section, containing the results of the query.

The name of this new element will be the date and time when the query has been launched.

Create and Send ICSRs    Create and Send Acks    WEB Trader    ICSRs    Create and Send Product Reports    Medicinal Products    MedDRA

Reset Application    Reset Section    Clear    ReRun    Modify    Delete    Excel    Export    Reload    Load   

- Authorised Medicinal Products
- Development Medicinal Products
- Approved Substances
- Development Substances
- Sources
- MAHs
- Sponsors
- ATC Codes
- Routes of Administration
- Pharmaceutical Forms
- Master File Locations
- Attachments
- Abstract Compositions
- Queries
  - Owned EVMPD Entities
  - Authorised Products
    - Fields
    - Conditions (AND)
    - Results
      - Result 02 July 2014 10:39:28
- Development Products
- Substance Names
- Approved Substance Names
- Development Substance Names
- Approved Substances
- Development Substances
- Sources
- MAHs
- Sponsors
- ATC Codes
- Routes of Administration
- Pharmaceutical Forms
- Abstract Compositions
- Attachments
- Master File Locations

DrugVero

Num	EV Code	Owner Identifier	Checked	Cleaned	Nullified	Category	Full Presentation Name
<input type="checkbox"/> 0001	PRD111058	DCMTESTMAH	No	No	No		DrugVero Ibuprofen Forte

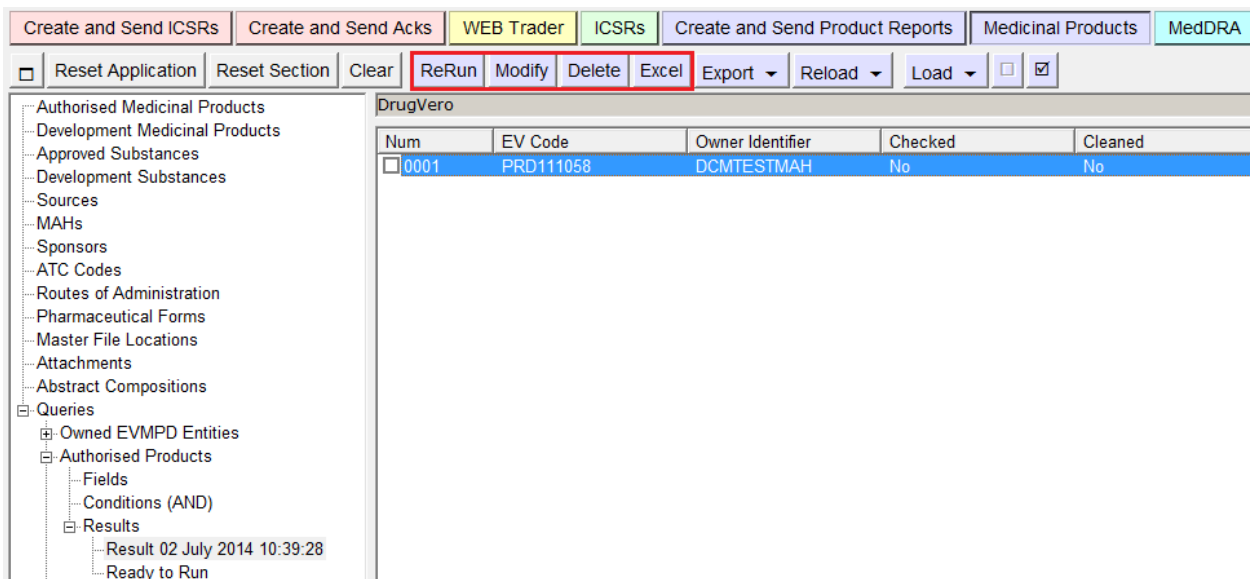
Whilst working with the query elements, at a certain point, a new element may appear under the "Results" section. This new element is called "Ready to Run" and it is just an empty set that will be populated by the results of this query.

- Authorised Medicinal Products
- Development Medicinal Products
- Approved Substances
- Development Substances
- Sources
- MAHs
- Sponsors
- ATC Codes
- Routes of Administration
- Pharmaceutical Forms
- Master File Locations
- Attachments
- Abstract Compositions
- Queries
  - Owned EVMPD Entities
  - Authorised Products
    - Fields
    - Conditions (AND)
    - Results
      - Result 02 July 2014 10:39:28
      - Ready to Run

DrugVero

Description	Name/Value
	Fields
	Conditions (AND)
	Results

When a result set is selected in the tree view, the lower part of left side of the EVWEB screen will display a summary of the conditions used to obtain this result set. This way, when you have different result sets, you can easily understand how the query has been run by just selecting them.



If you then want to modify one of these results without having to set all the fields and conditions again, you can create a new query based on the result set that you want to modify.

**Modify** To modify a result set, you have to select it from the tree view and click on the "Modify" button. Then you will be brought directly to the fields screen already compiled with the previous query criteria so that you can modify them and run a new query.


All the results of the different executions of the query in an active session will be stored until you delete them.

**Delete** To delete a result set, select it in the tree view and then click the "Delete" button on the main menu in the dynamic section.

**ReRun** Another option available within the result set is to launch the same query again. To do that, click on the "ReRun" button after selecting the result set.

When running a query, the system will always return a maximum of 50 rows as a result.

When the number of results exceeds that limit, a message box is displayed.

 When making a more general query, where many results are displayed, this set of buttons is available to navigate among the complete results of an advanced query. They take you 'backwards' and 'forwards' on the results already displayed in your screen. Only 2 pages of 50

results can be displayed. The first two buttons replace the 50 rows displayed with the Previous/Next 50. The third button, with the arrow facing down, adds a new page of results to the results already displayed in your screen without removing them.

The screenshot shows the EVWEB interface with a search results page. A dialog box titled "Message from webpage" is overlaid on the results, displaying a warning icon and the text: "Only 50 Results per page are retrieved. Please make a more specific query." The background shows a search results table with columns for Description and Name/Value, and a left-hand navigation tree.

The screenshot shows the EVWEB interface with a search results page. The table below shows the search results:

Num	EV Code	Owner Identifier	Checked	Cleaned	Nullified
<input type="checkbox"/> 0001	PRD204736	EVHUMAN	Yes (23/02/2011 09:2...	No	Yes (12/04/2012 05:0...
<input type="checkbox"/> 0002	PRD202808	EVHUMAN	Yes (08/02/2011 13:3...	No	Yes (12/04/2012 05:1...
<input type="checkbox"/> 0003	PRD232637	EVHUMAN	Yes (18/07/2011 16:2...	No	Yes (12/04/2012 05:1...
<input type="checkbox"/> 0004	PRD230227	EVHUMAN	Yes (30/06/2011 09:1...	No	Yes (12/04/2012 05:1...
<input type="checkbox"/> 0005	PRD230226	EVHUMAN	Yes (30/06/2011 09:0...	No	Yes (12/04/2012 05:1...
<input type="checkbox"/> 0006	PRD234994	EVHUMAN	Yes (04/08/2011 11:5...	No	Yes (12/04/2012 05:1...
<input type="checkbox"/> 0007	PRD214474	EVHUMAN	Yes (19/04/2011 15:0...	No	Yes (12/04/2012 05:1...
<input type="checkbox"/> 0008	PRD200704	EVHUMAN	Yes (28/01/2011 13:5...	No	Yes (12/04/2012 05:1...
<input type="checkbox"/> 0009	PRD199482	EVHUMAN	Yes (20/01/2011 06:3...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0010	PRD227501	EVHUMAN	Yes (20/06/2011 15:0...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0011	PRD218020	EVHUMAN	Yes (03/05/2011 17:2...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0012	PRD282303	EVHUMAN	Yes (15/02/2012 10:2...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0013	PRD282296	EVHUMAN	Yes (15/02/2012 10:2...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0014	PRD275571	EVHUMAN	Yes (10/01/2012 10:2...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0015	PRD262524	EVHUMAN	Yes (18/11/2011 08:1...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0016	PRD205375	EVHUMAN	Yes (28/02/2011 10:4...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0017	PRD205370	EVHUMAN	Yes (28/02/2011 10:3...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0018	PRD245786	EVHUMAN	Yes (05/09/2011 12:0...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0019	PRD223706	EVHUMAN	Yes (01/06/2011 08:0...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0020	PRD228537	EVHUMAN	Yes (24/06/2011 14:0...	No	Yes (12/04/2012 05:2...
<input type="checkbox"/> 0021	PRD277188	EVHUMAN	Yes (17/01/2012 07:1...	No	Yes (12/04/2012 05:3...
<input type="checkbox"/> 0022	PRD262331	EVHUMAN	Yes (17/11/2011 12:5...	No	Yes (12/04/2012 05:3...
<input type="checkbox"/> 0023	PRD279960	EVHUMAN	Yes (01/02/2012 10:2...	No	Yes (12/04/2012 05:3...
<input type="checkbox"/> 0024	PRD260678	EVHUMAN	Yes (15/11/2011 09:0...	No	Yes (13/04/2012 14:2...
<input type="checkbox"/> 0025	PRD237681	EVHUMAN	Yes (19/08/2011 11:2...	No	Yes (13/04/2012 15:0...
<input type="checkbox"/> 0026	PRD213366	EVHUMAN	Yes (12/04/2011 07:0...	No	Yes (16/04/2012 07:1...

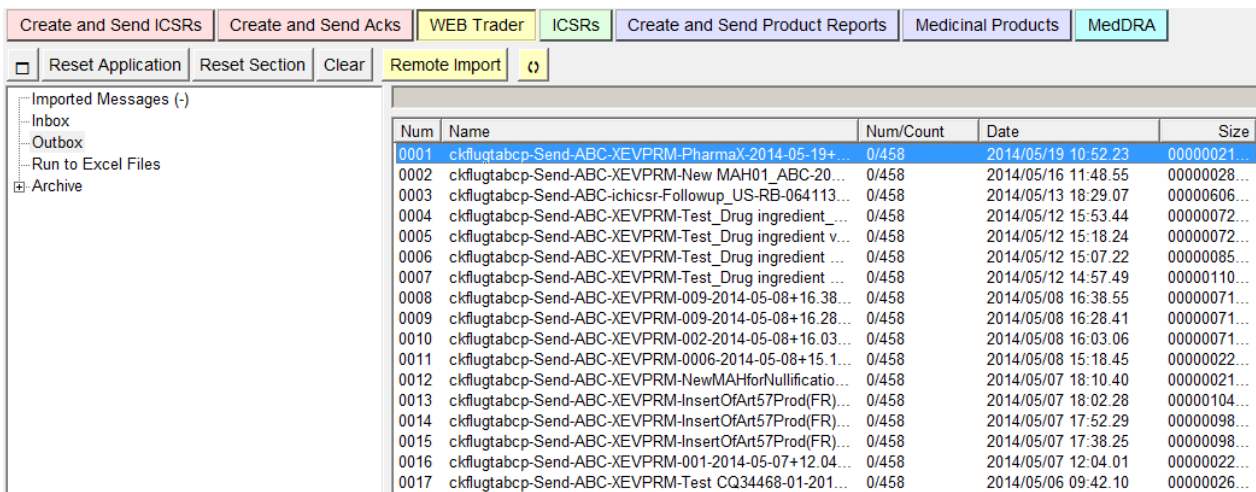
Every result set of every advanced query available in EVWEB may be exported as an Excel spreadsheet, XML file(s) or RTF file(s). See section 4.3.1. *Exporting results of an advanced query* for related information.

### 2.7.3. Immediate Query

An immediate query is a simple query performed automatically by EVWEB without the user input when needed.

As any other query in the system, this will require EVWEB to connect to the remote system to retrieve the data. The difference is that in this situation, the query will be launched simply by selecting the item (no "Run" buttons or specific user input).

The situation, in which this type of query is used in EVWEB is in the "Inbox" and "Outbox" folders in the Web Trader section.



The screenshot shows the EVWEB interface with the 'WEB Trader' tab selected. The main area displays a table of imported messages. The table has columns for 'Num', 'Name', 'Num/Count', 'Date', and 'Size'. The first row is highlighted in blue.

Num	Name	Num/Count	Date	Size
0001	ckflugtabcp-Send-ABC-XEVPRM-PharmaX-2014-05-19+...	0/458	2014/05/19 10:52:23	00000021...
0002	ckflugtabcp-Send-ABC-XEVPRM-New MAH01_ABC-20...	0/458	2014/05/16 11:48:55	00000028...
0003	ckflugtabcp-Send-ABC-ichicr-Followup_US-RB-064113...	0/458	2014/05/13 18:29:07	00000606...
0004	ckflugtabcp-Send-ABC-XEVPRM-Test_Drug ingredient_...	0/458	2014/05/12 15:53:44	00000072...
0005	ckflugtabcp-Send-ABC-XEVPRM-Test_Drug ingredient v...	0/458	2014/05/12 15:18:24	00000072...
0006	ckflugtabcp-Send-ABC-XEVPRM-Test_Drug ingredient ...	0/458	2014/05/12 15:07:22	00000085...
0007	ckflugtabcp-Send-ABC-XEVPRM-Test_Drug ingredient ...	0/458	2014/05/12 14:57:49	00000110...
0008	ckflugtabcp-Send-ABC-XEVPRM-009-2014-05-08+16.38...	0/458	2014/05/08 16:38:55	00000071...
0009	ckflugtabcp-Send-ABC-XEVPRM-009-2014-05-08+16.28...	0/458	2014/05/08 16:28:41	00000071...
0010	ckflugtabcp-Send-ABC-XEVPRM-002-2014-05-08+16.03...	0/458	2014/05/08 16:03:06	00000071...
0011	ckflugtabcp-Send-ABC-XEVPRM-0006-2014-05-08+15.1...	0/458	2014/05/08 15:18:45	00000022...
0012	ckflugtabcp-Send-ABC-XEVPRM-NewMAHforNullificatio...	0/458	2014/05/07 18:10:40	00000021...
0013	ckflugtabcp-Send-ABC-XEVPRM-InsertOfArt57Prod(FR)...	0/458	2014/05/07 18:02:28	00000104...
0014	ckflugtabcp-Send-ABC-XEVPRM-InsertOfArt57Prod(FR)...	0/458	2014/05/07 17:52:29	00000098...
0015	ckflugtabcp-Send-ABC-XEVPRM-InsertOfArt57Prod(FR)...	0/458	2014/05/07 17:38:25	00000098...
0016	ckflugtabcp-Send-ABC-XEVPRM-001-2014-05-07+12.04...	0/458	2014/05/07 12:04:01	00000022...
0017	ckflugtabcp-Send-ABC-XEVPRM-Test CQ34468-01-201...	0/458	2014/05/06 09:42:10	00000026...

This type of query is loaded by EVWEB only once, and then it is retained in the system's memory. If you believe that any change may have occurred in this section, you can tell EVWEB to reload the content of the list by clicking the refresh button.



The refresh button will be available on the dynamic section of the main menu.

### 2.8. Loading data

Loading data is the action of transferring information from different sources into EVWEB.

There are 4 different loading processes available:

- Load from the EVDBMS;
- Load from a remote file;
- Load from a local file;
- Load from inside the EVWEB.

## 2.8.1. Load from the EVDBMS

The load from the EVDBMS is available from the Load/Delete and the Select/Deselect checklists (see section [2.6.3. Checklists](#)).

### 2.8.1.1. Load/Delete checklist

As an example, you will see the checklist result of a simple query for an AMP with the EVCode "PRD111058":

Num	EV Code	Full Presentation Name	Short Name
<input type="checkbox"/> 0001	PRD111058	DrugVero Ibuprofen Forte 400 mg Liquid Capsules	DrugVero Forte

By selecting one or more of the checkboxes, the EVWEB will load the data from the remote system. This operation may take a while to be performed. This means that the result of the operation is not immediate. The data loaded will appear in the appropriate section of the tree view:

Num	EV Code	Full Presentation Name	Short Name
<input checked="" type="checkbox"/> 0001	PRD111058	DrugVero Ibuprofen Forte 400 mg Liquid Capsules	DrugVero Forte

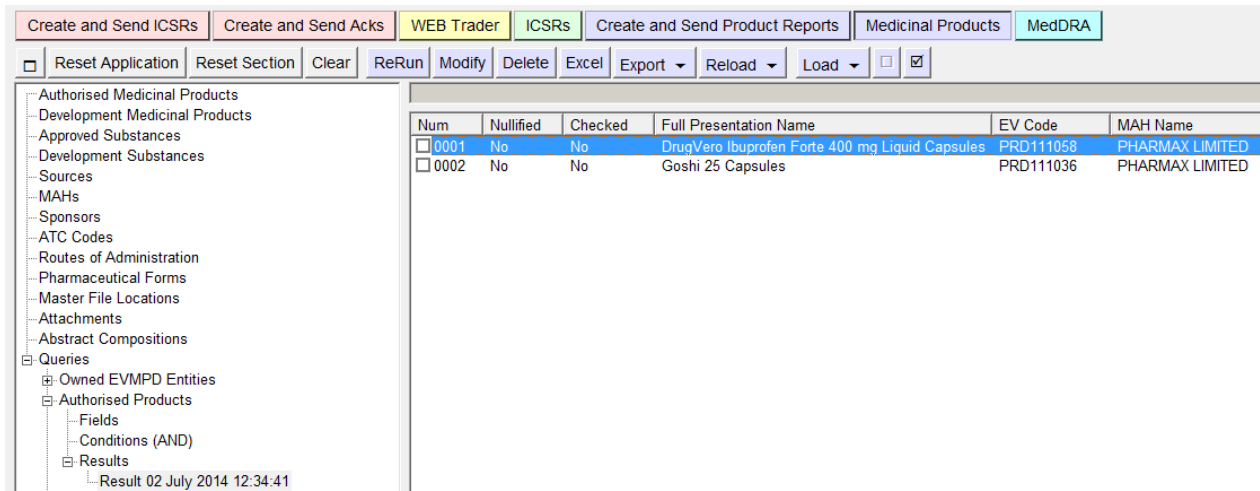
The section currently selected in the tree view may not be related to the section where the loaded items will be added. As an example, when you have the results of an advanced query, the selected item in the tree view is the query result set itself. The loaded items will be loaded to a different section, depending on the main subject of the query (see section [2.5. Interaction between the tree view and active area](#)).

In case of failure of the load process, an error message box will be displayed.

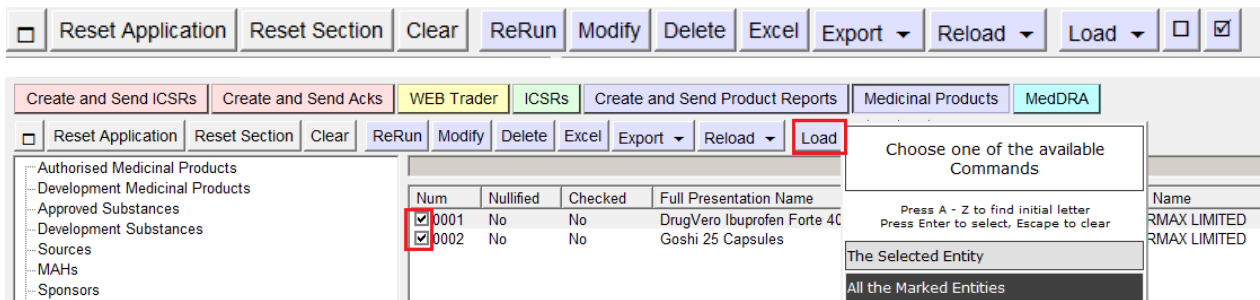


**2.8.1.2. Select/Deselect checklist**

As an example, you will see the checklist result of an advanced query for AMPs referencing the MAH organisation "PharmaX Ltd.":

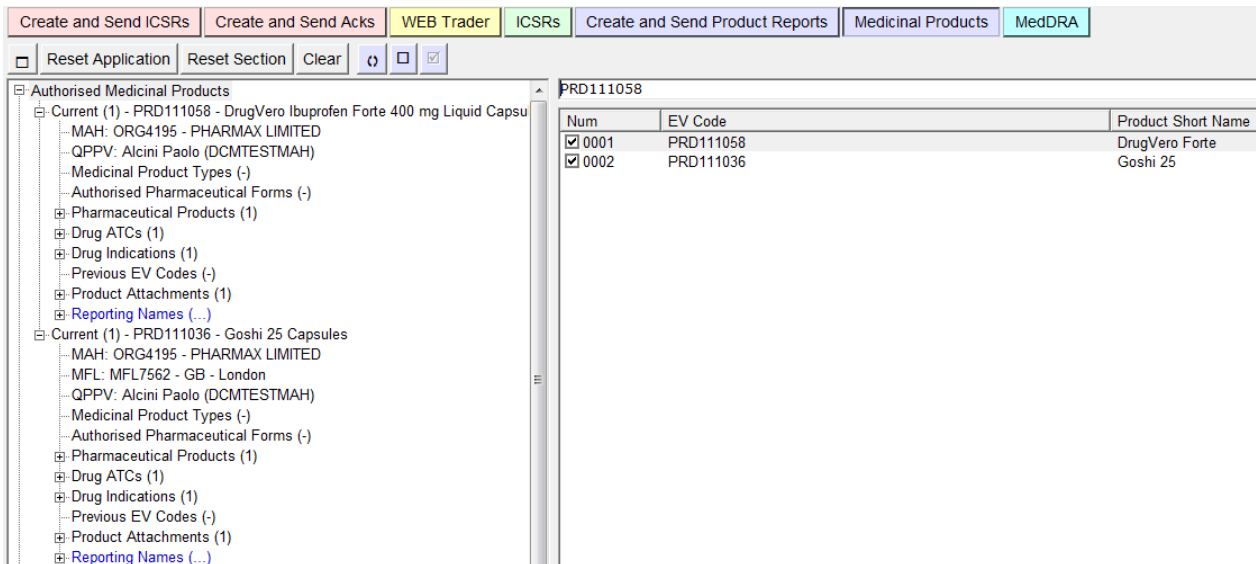


By selecting one or more of the checkboxes, you are indicating for which entries you want to perform a specific command. In this case, we wish to load the products in the tree view and therefore we need to use the "Load" button. A pop-up menu will be displayed, which will allow you to choose which entries to load:



- All the Marked Entities (the ones marked with the checkbox)
- The Selected Entity (the last one selected before pressing the button, which is highlighted with a darker background colour)

After selecting the two options, EVWEB will load the data from the remote system in exactly the same way as for the Load/Delete checklist (see section 2.6.5. Load/Delete checklist).

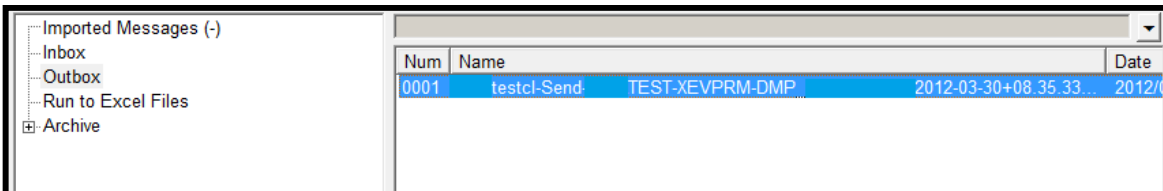


## 2.8.2. Load from a remote file

This loading process is used to import data from an XML file from a remote system into the EVWEB application. It is possible to load any kind of message (product or acknowledgement) handled by the EVWEB from a remote file.

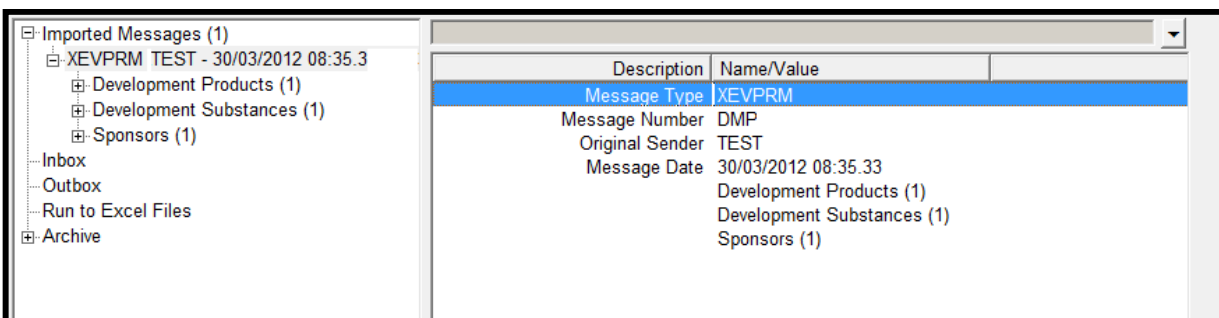
Loading from a remote file does not have a standard procedure to be performed. This depends on the section where this function is available.

As an example, the import function available in the Web Trader section when the "Outbox" folder is selected as shown below.



### Remote Import

By selecting one of the file items in the list view of the active area, you will be able to import it in EVWEB by pressing the "Remote Import" button available on the dynamic section of the main menu.



At the end of the import process, you may be prompted with a warning message saying that some part of the message cannot be decoded. This is because when an XML file is imported in EVWEB, it is decoded and displayed in a user friendlier layout.

The imported data is displayed in a specific section of the tree view. In our example, the data is displayed under "Imported Message (s)" (see section [2.5. Interaction between the tree view and active area](#)).

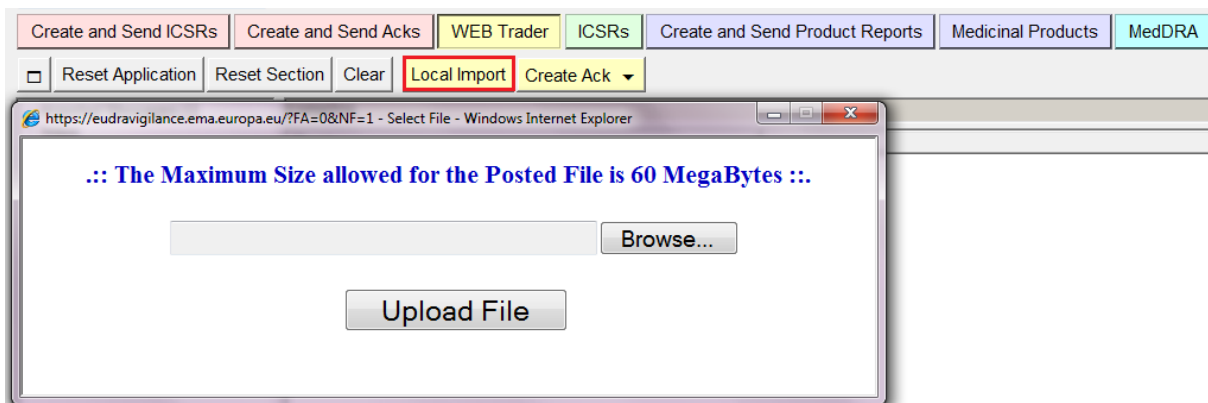
### 2.8.3. Load from a local file

This loading process is used to import data from an XML file available locally (your computer or your local network) into the EVWEB application. It is possible to load any kind of message (product or acknowledgement) handled by the EVWEB from a remote file.

Load from a local file is available in different sections.

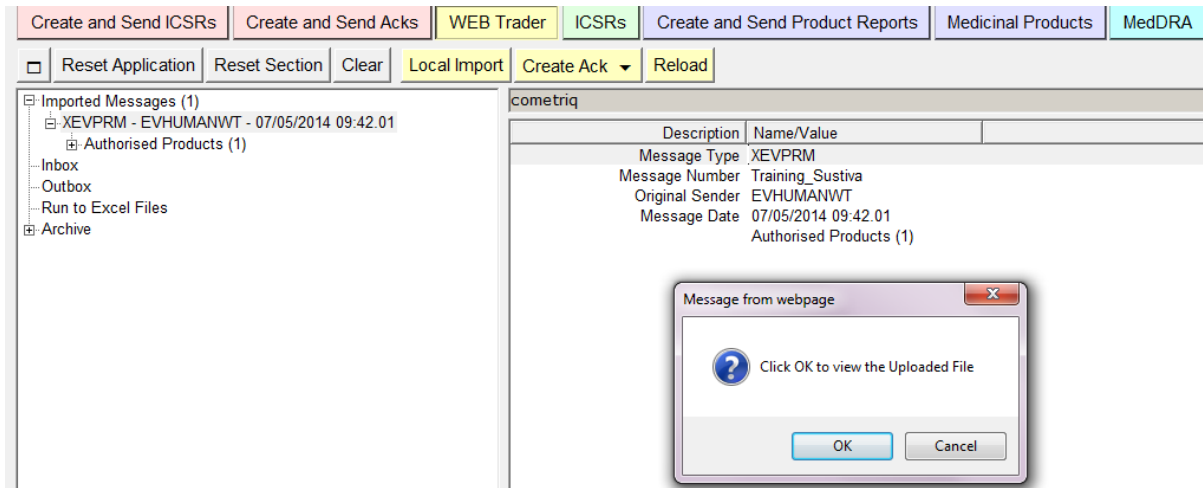
As an example, we show the import function available in the Web Trader section. In this case, the button "Local Import" is always available in the dynamic section of the main menu.

**Local Import** Clicking this button will open a pop-up new window that will allow you to browse and select a local file.



Once you have browsed and selected the file you want to import, clicking on the "Upload File" button will activate the import process.

At the end of the import process, you will be prompted with a pop-up window allowing you to view the original file that has been imported. This is because when an XML file is imported in EVWEB, it is decoded and displayed in a user friendlier layout.

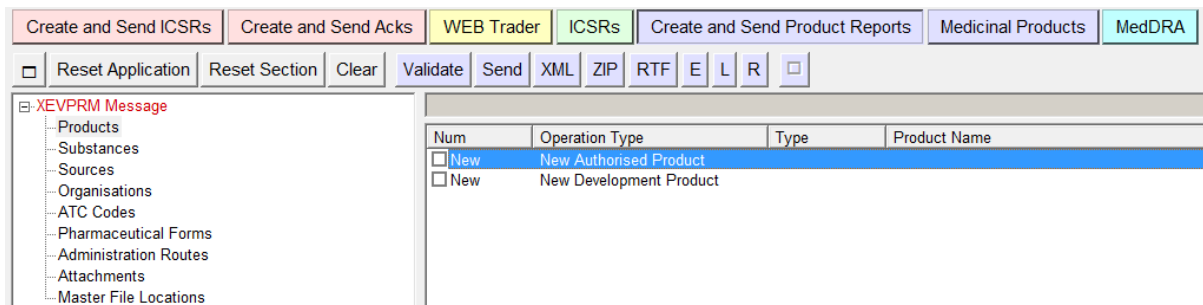


The imported data are displayed in a specific section of the tree view. In our example, the data are displayed under "Imported Message (s)". See section [2.5. Interaction between the tree view and active area](#) and [2.11.3. Reloading an XEVPRM](#) for reloading an imported XEVPRM.

#### 2.8.4. Load from inside the EVWEB

This operation does not actually load any external data. It creates new items in a data entry section (i.e. "Create and Send Products") and eventually completes the newly created items with data taken from others section (i.e. "Medicinal Products" – Update operation).

As an example of this loading process, we will see the creation of a New Authorised Product in the "Create and Send Products" section.



Clicking on the checkbox will create the Authorised Product in the section currently selected in the tree view.

Description	Name/Value	
Operation Type	Insert (1)	
Type	Authorised (2)	
EV Code		
MAH		Field is Mandatory
QPPV		
Master File Location		
PhV enquiry email		Field must have a specified value
PhV enquiry Phone		Field must have a specified value
Sender Local Code		
Info Date		
Authorisation Country Code		Field is Mandatory
Authorisation Procedure		Field is Mandatory
Authorisation Status		
Authorisation Number		Field must have a specified value
Authorisation/Renewal Date		Field must have a specified value
MRP/DCP/EMEA Number		
EU Number		
Legal Basis		
Orphan Drug		
Additional Monitoring		
Invalidated Date		Field must have a specified value
Full Presentation Name		Field is Mandatory
Product Short Name		Field is Mandatory Optional
Product INN/Common Name		Field is Mandatory Optional
Product Company Name		Field must have a specified value
Product Strength Name		
Product Form Name		
Package Description		
Comment		
Medicinal Product Types (-)		Section is Mandatory
Authorised Pharmaceutical Forms (-)		Section is Mandatory
Pharmaceutical Products (-)		Section is Mandatory
Drug ATCs (-)		Section is Mandatory
Drug Indications (-)		Section is Mandatory
Previous EV Codes (-)		
Product Attachments (-)		Section is Mandatory

As you can see, all the fields are empty because in this case, the newly created section is a new Authorised Product (which is supposed to be compiled by the user).

In other situations (e.g. when using the 'Update'(2)' operation type), you may find that some fields are already completed.

## 2.9. Pop-up Commands

In certain sections, commands are grouped together as a single pop-up menu.

In these cases, the command, which triggers the pop-up has a small arrow to the right of the button description name.

By clicking on the button, the pop-up appears, and displays the commands available.

After selecting one of the commands available, the behaviour of the application is exactly the same as any other normal command.

The pop-up can be closed clicking the escape key.

As an example, some of the commands available on the result of the products queries are grouped in three pop-up menus:

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

Reset Application | Reset Section | Clear |  | ReRun | Modify | Delete | Excel | **Export** | Reload | Load |  |

Num	EV Code	Owner Identifier	Checked	Cleaned
<input type="checkbox"/> 0001	PRD04804MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0002	PRD08409MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0003	PRD07741MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0004	PRD04549MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0005	PRD03031MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0006	PRD06468MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0007	PRD04558MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0008	PRD09541MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0009	PRD02460MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0010	PRD06228MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0011	PRD04916MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0012	PRD05089MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0013	PRD03175MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0014	PRD07278MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0015	PRD04615MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0016	PRD06414MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0017	PRD02592MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0018	PRD06558MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0019	PRD02064MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0020	PRD04192MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0021	PRD08571MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0022	PRD07457MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0023	PRD03527MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0024	PRD05311MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0025	PRD06551MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0026	PRD05204MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0027	PRD08514MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0028	PRD05246MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0029	PRD04354MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0030	PRD03177MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0031	PRD03543MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0032	PRD05242MIG		Yes (14/10/2004 12:0...	No
<input type="checkbox"/> 0033	PRD03031MIG		Yes (14/10/2004 12:0...	No

Authorised Medicinal Products  
 Development Medicinal Products  
 Approved Substances  
 Development Substances  
 Sources  
 MAHs  
 Sponsors  
 ATC Codes  
 Administration Routes  
 Pharmaceutical Forms  
 Master File Locations  
 Attachments  
 Abstract Compositions  
 Queries  
 Owned EVMPD Entities  
 Authorised Products  
 Fields  
 Conditions (AND)  
 Results  
 Result 07 May 2014 08:18:18  
 Development Products  
 Substance Names  
 Approved Substance Names  
 Development Substance Names  
 Approved Substances  
 Development Substances  
 Sources  
 MAHs  
 Sponsors  
 ATC Codes  
 Administration Routes  
 Pharmaceutical Forms  
 Abstract Compositions

## 2.10. Batch Commands

When a Select/Deselect checklist is displayed (for example as a result of a query), the commands available to interact with the entities displayed in the checklist have a special behaviour.

The underlying action, instead of being performed on a single entity (the selected one), is performed as a 'batch' on all the entities marked with the checkbox.

As an example, the commands available on the result of the products queries are grouped in three pop-up menus:

The screenshot shows a software interface with a toolbar at the top containing buttons for 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below the toolbar is a table with columns: Num, EV Code, Owner Identifier, Checked, and Cleaned. The table contains 32 rows of data. A red box highlights the 'Export', 'Reload', and 'Load' buttons in the toolbar. Another red box highlights the first ten rows of the table, which are also highlighted in blue. The first ten rows have checkboxes in the 'Num' column that are checked.

Num	EV Code	Owner Identifier	Checked	Cleaned
<input checked="" type="checkbox"/>	0001	PRD04804MIG	Yes (14/10/2004 12:0...	No
<input checked="" type="checkbox"/>	0002	PRD08409MIG	Yes (14/10/2004 12:0...	No
<input checked="" type="checkbox"/>	0003	PRD07741MIG	Yes (14/10/2004 12:0...	No
<input checked="" type="checkbox"/>	0004	PRD04549MIG	Yes (14/10/2004 12:0...	No
<input checked="" type="checkbox"/>	0005	PRD03031MIG	Yes (14/10/2004 12:0...	No
<input checked="" type="checkbox"/>	0006	PRD06468MIG	Yes (14/10/2004 12:0...	No
<input checked="" type="checkbox"/>	0007	PRD04558MIG	Yes (14/10/2004 12:0...	No
<input checked="" type="checkbox"/>	0008	PRD09541MIG	Yes (14/10/2004 12:0...	No
<input checked="" type="checkbox"/>	0009	PRD02460MIG	Yes (14/10/2004 12:0...	No
<input checked="" type="checkbox"/>	0010	PRD06228MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0011	PRD04916MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0012	PRD05089MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0013	PRD03175MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0014	PRD07278MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0015	PRD04615MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0016	PRD06414MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0017	PRD02592MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0018	PRD06558MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0019	PRD02064MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0020	PRD04192MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0021	PRD08571MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0022	PRD07457MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0023	PRD03527MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0024	PRD05311MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0025	PRD06551MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0026	PRD05204MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0027	PRD08514MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0028	PRD05246MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0029	PRD04354MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0030	PRD03177MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0031	PRD03543MIG	Yes (14/10/2004 12:0...	No
<input type="checkbox"/>	0032	PRD05242MIG	Yes (14/10/2004 12:0...	No

After selecting some entities, clicking on the "Reload" button will show the possible commands.

The following commands are available:

**Choose one of the available Commands**

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

Update

Nullify

Invalidate MA

Reinsert

By clicking on the selected command/operation type, the application will load all the selected (marked with the checkbox) entities (products in this case) and then create an XEVPRM for each one of them in the "Create and Send Products" section.

In the below example, the command 'Nullify (4)' was used for all of the selected medicinal products:

The screenshot shows the XEVPRM Message interface. On the left, a tree view lists various medicinal products, with 'Nullification (4) - Authorised (2) - PRD953908' and several other nullified products selected. On the right, the details for PRD294010 are displayed, showing fields like Operation Type (Nullification (4)), Type (Authorised (2)), EV Code (PRD953908), and Product Name (Sustiva tablets). A comment at the bottom indicates 'Field must have a specified value'.

### 2.10.1. Create an XEVPRM with various commands – practical example

In this particular example, we performed an advanced query on all AMP entries referencing MAH "PharmaX" as the MAH with the following result:

Num	Nullified	EV Code	Article 57 Format	Checked	Full Presentation Name	MA Validity
<input type="checkbox"/> 0001	No	PRD111036	Article 57 Format (1)	No	Goshi 25 Capsules	Valid (1)
<input type="checkbox"/> 0002	No	PRD111058	Article 57 Format (1)	No	DrugVero Ibuprofen F...	Valid (1)
<input type="checkbox"/> 0003	No	PRD111081	Article 57 Format (1)	No	ProductX comprimido...	Valid (1)

Two of the AMP entries need to be amended using the command/operation type "Update (2)" and one will need to be invalidated using command/operation type 'Invalidate MA (6)'.



We select the two AMP entries which need to be updated and select the applicable command under "Reload":

The screenshot shows the XEVPRM interface with the 'Reload' button highlighted in the top menu. A dropdown menu is open, showing options: 'Update', 'Nullify', 'Invalidate MA', and 'Reinsert'. The 'Update' option is selected. Below the menu, a table lists AMP entries:

Num	Nullified	EV Code	Article 57 Format	MA Validity
<input checked="" type="checkbox"/> 0001	No	PRD111036	Article 57 Format (1)	Valid (1)
<input type="checkbox"/> 0002	No	PRD111058	Article 57 Format (1)	Valid (1)
<input checked="" type="checkbox"/> 0003	No	PRD111081	Article 57 Format (1)	Valid (1)

Those two AMPs are now available in the "Create and Send Product Reports" with the command/operation type 'Update (2)':

The screenshot shows the XEVPRM interface with the 'Update (2)' operation type selected for two AMPs. The left pane shows a tree view of the AMPs, and the right pane shows the details for the selected AMPs:

- Update (2) - Authorised (2) - PRD111036 - Goshi 25 Capsules
- Update (2) - Authorised (2) - PRD111081 - ProductX comprimido revestido 4 mg

The details pane shows the following information for the selected AMPs:

Description	Name/Value
Operation Type	Update (2)
Type	Authorised (2)
EV Code	PRD111036
MAH	PHARMAX LIMITED
QPPV	John Smith (DCMTESTMAH)
Master File Location	MFL7562 - United Kingdom (GB) - London
PhV enquiry email	pharmacovig@pharmax.co.uk
PhV enquiry Phone	+44 207 2222222
Sender Local Code	
Info Date	
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - National Procedure (4)
Authorisation Status	Valid (1)
Authorisation Number	PL000/00/01
Authorisation/Renewal Date	01/05/2014
MRP/DCP/EMEA Number	
EU Number	
Legal Basis	Full application (Article 8(3) of Directive No 2001/83/EC) (1)
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	Goshi 25 Capsules
Product Short Name	Goshi 25
Product INN/Common Name	
Product Company Name	
Product Strength Name	
Product Form Name	CAPSULES
Package Description	
Comment	25 capsules per pack

To add the AMP to be invalidated in the same XEVPRM, we must go back to the "Medicinal Products" section and select the product to be invalidated:

Num	Nullified	EV Code	Article 57 Format	Checked	Full Presentation Name	MA Validity
<input type="checkbox"/> 0001	No	PRD111036	Article 57 Format (1)	No	Goshi 25 Capsules	Valid (1)
<input checked="" type="checkbox"/> 0002	No	PRD111058	Article 57 Format (1)	No	DrugVero Ibuprofen F...	Valid (1)
<input type="checkbox"/> 0003	No	PRD111081	Article 57 Format (1)	No	ProductX comprimido...	Valid (1)

We then select the applicable command under "Reload":

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

□ Reset Application | Reset Section | Clear | ReRun | Modify | Delete | Excel | Export | Reload

Num	Nullified	EV Code
<input type="checkbox"/> 0001	No	PRD111036
<input checked="" type="checkbox"/> 0002	No	PRD111058
<input type="checkbox"/> 0003	No	PRD111081

Choose one of the available Commands

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

Update

Nullify

**Invalidate MA**

Reinsert

Full Presentation Name	MA Validity
Goshi 25 Capsules	Valid (1)
DrugVero Ibuprofen F...	Valid (1)
ProductX comprimido...	Valid (1)

This AMPs is now available in the "Create and Send Product Reports" with the command/operation type 'Invalidate MA (6)', together with the two AMPs with the assigned command/operation type 'Update (2)':

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

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

XEVPRM Message

- Products
  - Update (2) - Authorised (2) - PRD111036 - Goshi 25 Capsules
    - Medicinal Product Types (-)
    - Authorised Pharmaceutical Forms (-)
    - Pharmaceutical Products (1)
    - Drug ATCs (1)
    - Drug Indications (1)
    - Previous EV Codes (-)
    - Product Attachments (1)
  - Update (2) - Authorised (2) - PRD111081 - ProductX comprimido revestido 4 mg
  - Invalidate MA (6) - Authorised (2) - PRD111058 - DrugVero Ibuprofen Forte 400 mg Liquid Capsules**
    - Medicinal Product Types (-)
    - Authorised Pharmaceutical Forms (-)
    - Pharmaceutical Products (1)
    - Drug ATCs (1)
    - Drug Indications (1)
    - Previous EV Codes (-)
    - Product Attachments (1)
- Substances
- Sources
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Routes Of Administration
- Attachments
- Master File Locations

ProductX

Description	Name/Value
Operation Type	Invalidate MA (6)
Type	Authorised (2)
EV Code	PRD111058
MAH	PHARMAX LIMITED
QPPV	John Smith (DCMTESTMAH)
Master File Location	
PhV enquiry email	pharmacovig@pharmax.co.uk
PhV enquiry Phone	+44 207 2222222
Sender Local Code	
Info Date	
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - ...
Authorisation Status	1 (1) Value not Acceptable
Authorisation Number	1234/5678/111
Authorisation/Renewal Date	07/02/2013
MRP/DCP/EMEA Number	SE/H/1111/222
EU Number	
Legal Basis	Full application (Article 8(3) of ...
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	DrugVero Ibuprofen Forte 400 ...
Product Short Name	DrugVero Forte
Product INN/Common Name	Ibuprofen
Product Company Name	
Product Strength Name	400 MG
Product Form Name	LIQUID CAPSULES
Package Description	
Comment	

Medicinal Product Types (-) Section is Mandatory  
 Authorised Pharmaceutical For... Section is Mandatory  
 Pharmaceutical Products (1)  
 Drug ATCs (1)  
 Drug Indications (1)  
 Previous EV Codes (-)

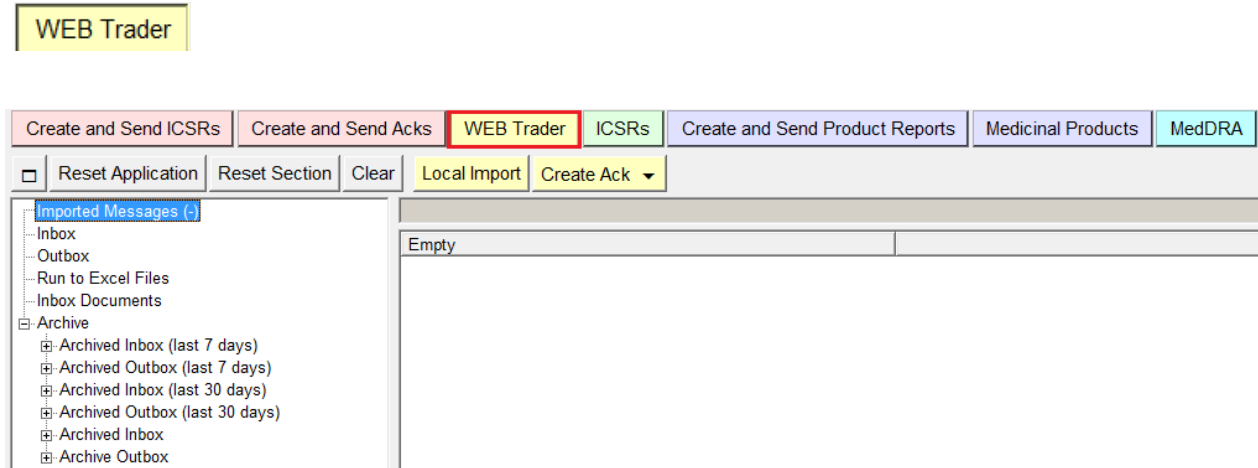
We can now amend all of the AMP entries as applicable, validate and send the XEVPRM.

## 2.11. WEB Trader Functions (Inbox/Outbox/Imported Messages)

Please note that some of these functions will only be available to WEB Trader users.

The WEB Trader section of the application will allow WEB Trader users to keep track of sent product messages and received acknowledgement messages.

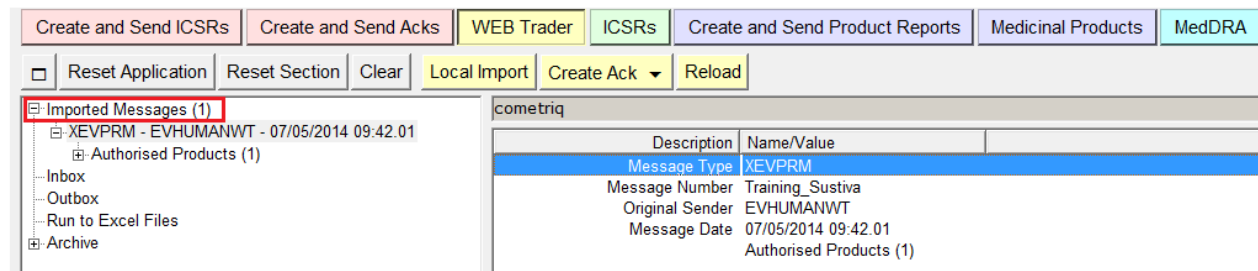
The WEB Trader section of the application will also allow any user to import in the EVWEB safety, product and acknowledgement messages from his/her local computer.



The tree view displays three different sections:

- Imported Message (s)
- Inbox
- Outbox
- Archive

The section "**Imported Message (s)**" will display the imported messages.



The Inbox and Outbox sections are two immediate query items that will display respectively the content of the Inbox and Outbox folder associated to the Web Trader.

Inbox and Outbox sections are only visible to WEB Trader users.

These folders work in a similar way to the Inbox and Outbox folder of almost every email software (such as Microsoft Outlook®).

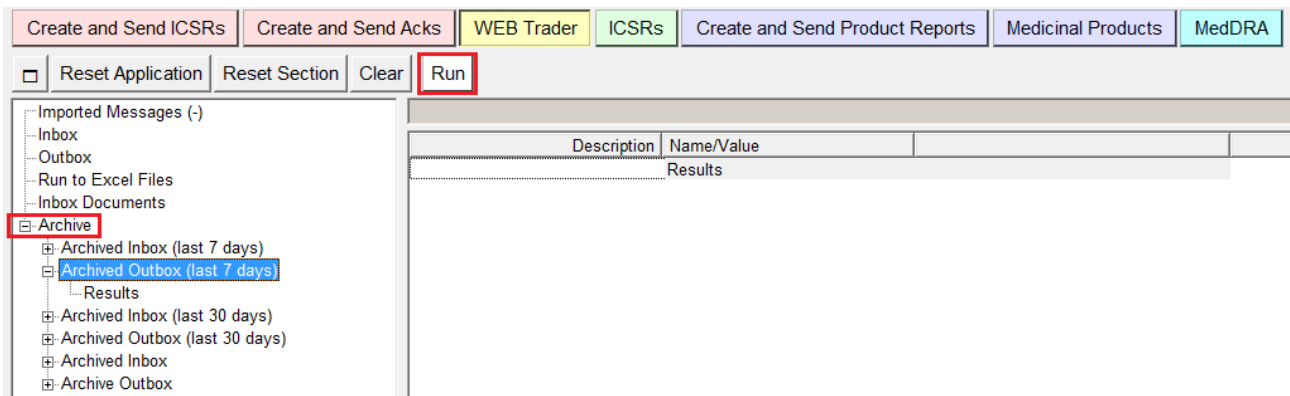
In the **Inbox**, you will find:

- Acknowledgement messages sent to your organisation's ID specified as a receiver. All messages received, regardless of the type, will be displayed in your Inbox;
- Acknowledgement messages that the XEVMPD has sent to you after submitting an XEVPRM. Please refer to section 3. *CREATE AND SEND XEVPRMs* for information on how you can create and send an XEVPRM to the EudraVigilance Medicinal Product Dictionary (XEVMPD).

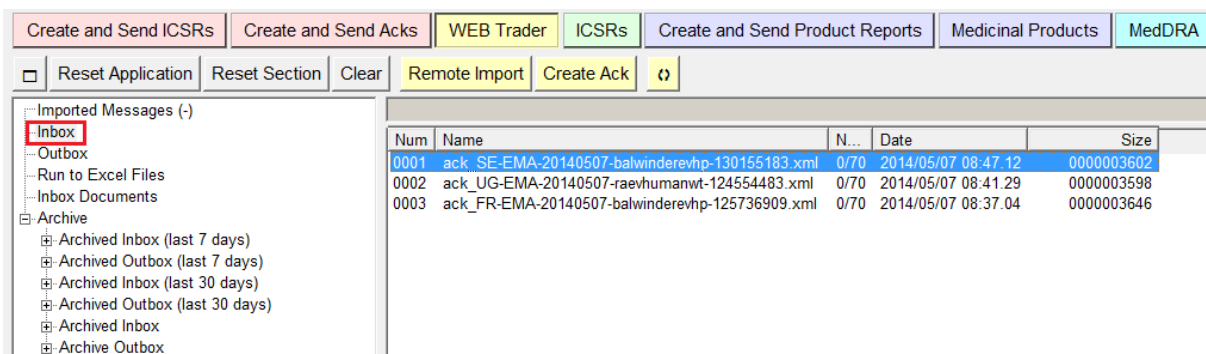
The **Outbox** will display the XEVPRMs sent by your organisation to the XEVMPD.

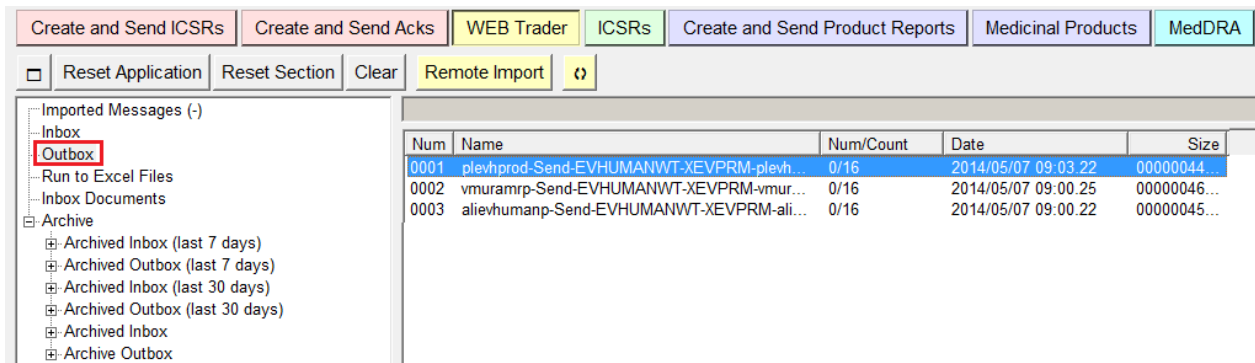
Please note that you **are not able to manage the content of your Inbox/Outbox**.

**The system automatically archives messages in your Inbox and Outbox on a daily basis.** To find messages that have been archived, you will need to **run** queries in the Archive section of WEB Trader.

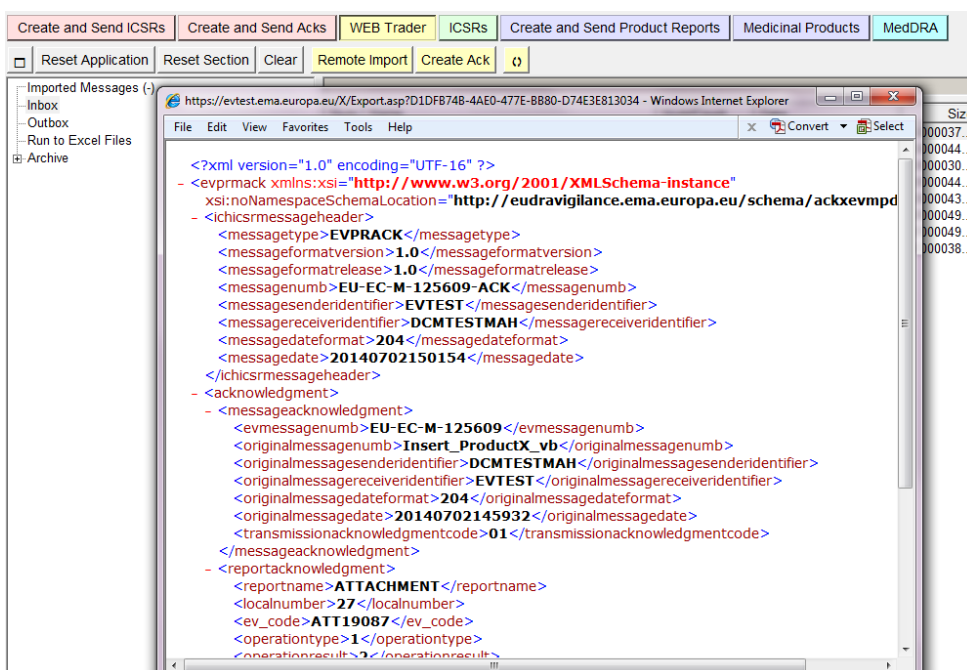


To see the content of your Inbox or Outbox, just select these items in the tree view. Their content will be displayed in the Active area:





To open the individual XEVPRM/XEVPRM ACK, just double click on each item. A new pop-up window will be displayed showing the content of the XEVPRM/XEVPRM ACK:

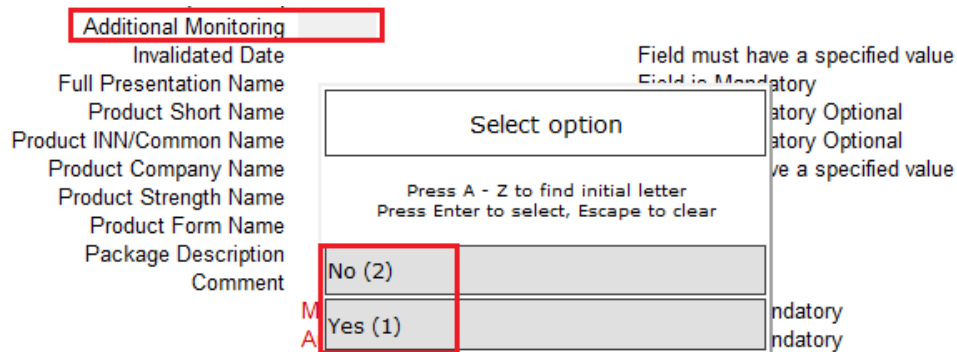


You can perform different actions on these files:

- Show their content in Internet Explorer without any transformation;
- Import them in to EVWEB and decode the content in a user friendly way.

A Product Message (or Acknowledgement Message) in the XML format contains information in a coded form (fields requiring MedDRA terms, pharmaceutical forms, lookup fields, etc.), therefore, when you see the message in its original format, you see the coded information instead of the descriptions used in EVWEB (i.e. 1/2 instead of "Yes"/"No"):

For example, the values for "Additional monitoring" field in EVWEB are displayed as Yes/No:



The values in an XML format are shown as 1 or 2, depending on which value is selected (in our case, the value "No" was selected in EVWEB:

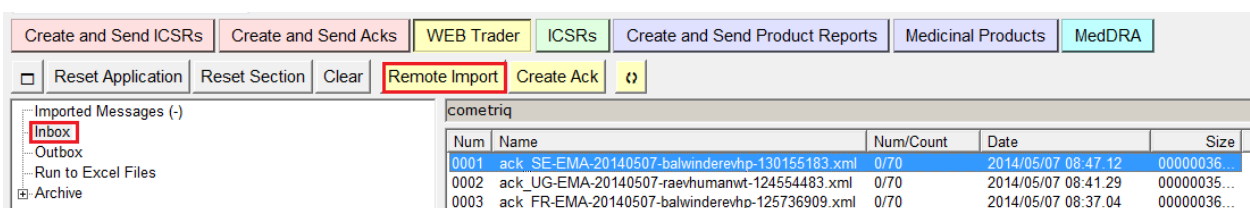
```

- <authorisedproduct operationtype="1">
  <localnumber>9</localnumber>
- <authorisation>
  <intensivemonitoring>2</intensivemonitoring>
</authorisation>
<comments />
</authorisedproduct>
</authorisedproducts>
</evprm>

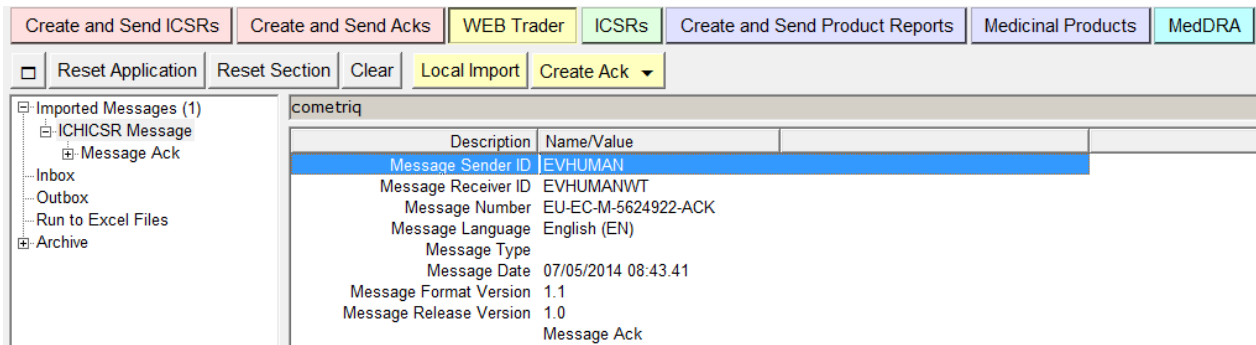
```

### 2.11.1. Importing a Message from Web Trader folders

**Remote Import** To import any of these message and see it decoded, select it in the active area. Then click on the "Remote Import" button that is available in the dynamic area of the main menu.



The message will be loaded in the appropriate section in the tree view ("Imported Message (s)") and it is also automatically selected.



### 2.11.2. Importing a message from the local computer

**Local Import** To import a Safety or Product Message or an Acknowledgement Message from your local computer/network and see it decoded, the "Local Import" button is available in the dynamic area of the main menu of the Web Trader section. As with the "Remote Import function", the message will be loaded in the appropriate section in the tree view ("Imported Message (s)"), and it will also be selected automatically.

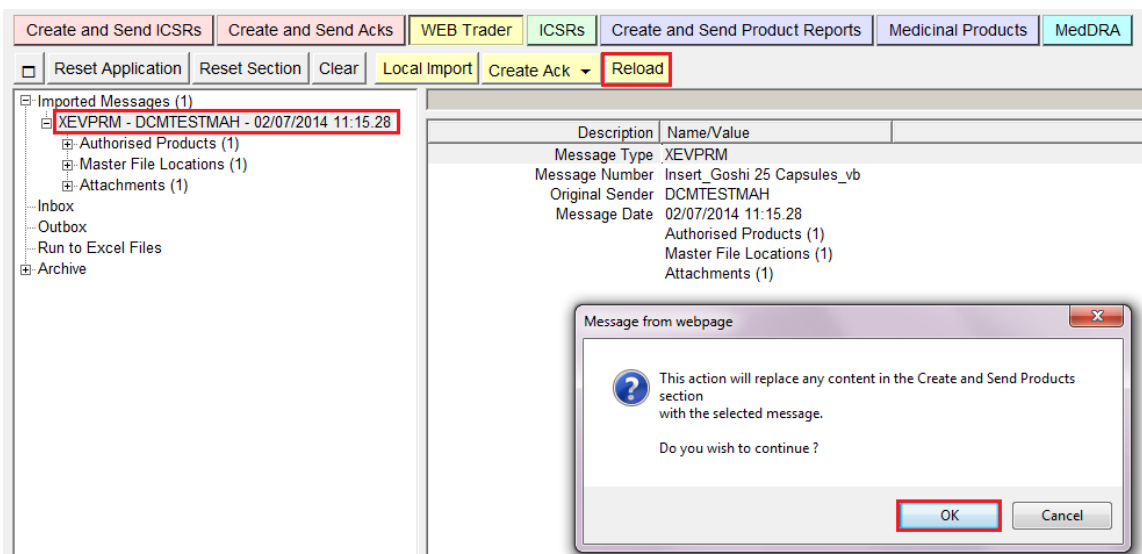
For detailed information about the Local Import function please see section [2.8.3. Load from a local file](#).

### 2.11.3. Reloading an XEVPRM

**Reload** This button can also be used to reload an XEVPRM, which was previously saved on your computer.

When an XEVPRM is selected in the tree view, the "Reload" button becomes available in the dynamic area of the main menu.

By clicking on this button, the EVWEB will copy the content of the product report message in the "Create and Send Products" section, allowing the user to continue and/or complete the creation of the XEVPRM:



Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

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

XEVPRM Message

Products
 

- Insert (1) - Authorised (2) - Goshi 25 Capsules**
  - Medicinal Product Types (-)
  - Authorised Pharmaceutical Forms (-)
  - Pharmaceutical Products (1)
  - Drug ATCs (1)
  - Drug Indications (1)
  - Previous EV Codes (-)
  - Product Attachments (1)
- Substances
- Sources
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Routes Of Administration
- Attachments
- Master File Locations

ProductX

Description	Name/Value	
Operation Type	Insert (1)	
Type	Authorised (2)	
MAH	PHARMAX LIMITED	
QPPV	John Smith (DCMTESTMAH)	
Master File Location	MFL7562 - United Kingdom (GB) - London	
PhV enquiry email	pharmacovig@pharmax.co.uk	
PhV enquiry Phone	+44 207 2222222	
Sender Local Code		
Info Date		
Authorisation Country Code	United Kingdom (GB)	
Authorisation Procedure	EU authorisation procedures - National Procedure (4)	
Authorisation Status	Valid (1)	
Authorisation Number	PL000/00/01	
Authorisation/Renewal Date	01/05/2014	
MRP/DCP/EMEA Number		
EU Number		
Legal Basis	Full application (Article 8(3) of Directive No 2001/83/EC) (1)	
Orphan Drug	No (2)	
Additional Monitoring	No (2)	
Invalidated Date		
Full Presentation Name	Goshi 25 Capsules	
Product Short Name	Goshi 25	
Product INN/Common Name		
Product Company Name		
Product Strength Name		
Product Form Name	CAPSULES	
Package Description		
Comment	25 capsules per pack	
	Medicinal Product Types (-)	Section is Mandatory
	Authorised Pharmaceutical Forms (-)	Section is Mandatory
	Pharmaceutical Products (1)	
	Drug ATCs (1)	
	Drug Indications (1)	
	Previous EV Codes (-)	
	Product Attachments (1)	

The XEVPRM Message number must be assigned again.

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

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

XEVPRM Message

Products
 

- Insert (1) - Authorised (2) - Goshi 25 Capsules**
  - Medicinal Product Types (-)
  - Authorised Pharmaceutical Forms (-)
  - Pharmaceutical Products (1)
  - Drug ATCs (1)
  - Drug Indications (1)
  - Previous EV Codes (-)
  - Product Attachments (1)
- Substances
- Sources
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Routes Of Administration
- Attachments
- Master File Locations

ProductX

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

## 2.12. Export functions and available formats

EVWEB allows several ways to export the loaded information. Each of these buttons will be available on the dynamic section of the main menu, **depending on the section, in which you are working in and on the item(s) selected.**



Data can be exported in the following formats:

#### Excel

Every result set of every advanced query available in EVWEB, may be exported as an Excel spread sheet. To do this click on the “Excel” button when a result set is selected in the tree view.

#### XML

This button allows you to generate an XML version of the message selected in EVWEB.

#### RTF

This button allows you to generate an RTF (which is a typical cross-platform document format) version of the message selected in EVWEB.

Please note that Internet Explorer may handle the RTF format in different ways, depending on the settings of your Windows system (e.g. opening this document inside the browser, launching an external application or asking you to save the document).

#### ZIP

This button allows you to generate a ZIP file also containing the attachment (if present).

Once exported, the document in any of these formats can be printed or saved like any other document on your computer.

### 2.12.1. New Data-export functionality

As of May 2014, new **Data-export functionality** is available to enable marketing authorisation holders to export their own data from EVWEB.

The export tool can be accessed directly via an IE browser at the URL <https://eudravigilance.ema.europa.eu/evmpdex/>.

Alternatively, the application may be accessed via the main EudraVigilance secure home page where a link will be found in the “EV Services” section.

For all related information see the [XEVMPD product export tool: user manual](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/05/WC500166229.pdf) ([http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2014/05/WC500166229.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/05/WC500166229.pdf)).

## 3. CREATE AND SEND XEVPRMs

### 3.1. *Commands/Operation types to be used in an XEVPRM*

You can create a single XEVPRM that contains more than one report for a product (approved or development), for a development substance, for a source, for an organisation (MAH or sponsor), for an ATC code (proposed or development), for a route of administration (proposed or development), for a pharmaceutical form (proposed or development). Moreover, for each report, you can specify different operation types.

Via an XEVPRM, users can:

- Add new information in the XEVMPD;
- Update information already present in the XEVMPD;
- Nullify information already present in the XEVMPD;
- Notify the EMA of extensions of marketing authorisations;
- Notify the EMA of variations to the terms of marketing authorisations;
- Notify the EMA of any changes to the name and the contact details of the qualified person responsible for pharmacovigilance (QPPV);
- Notify the EMA of any changes in the location of the Pharmacovigilance system master file (PSMF);
- Notify the EMA of any changes to the contact information for Pharmacovigilance enquiries;
- Notify the EMA of transfers of marketing authorisations;
- Notify the EMA of any suspension/lifting of the suspension, revocation or withdrawal of a marketing authorisation granted in the Union;
- Notify the EMA of any suspension/lifting of the suspension, revocation or withdrawal of a marketing authorisation granted in the Union;
- Notify the EMA of renewal of the marketing authorisation;
- Notify the EMA of the electronic copy of the latest approved Summary of Product Characteristics (SmPC) where any variations lead to a significant revision of the content.

The below overview provides a description of the available operation types/commands to be used in an XEVPRM:

- **'Insert' (1)**: allows the sender organisation to insert medicinal product information in the XEVMPD.

For EVWEB users, a **'Reinsert'** button is also available, allowing users to re-insert an existing medicinal product in the XEVMPD whilst retaining the previous information. Following the modification of the required data elements, the XEVPRM is then submitted in the XEVMPD with the operation type 'Insert' (1).

- **'Update' (2)**: allows the sender organisation to correct erroneous information previously submitted. Also, as per specific guidance provided in section [2. Maintenance of medicinal product](#)

*data* of [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), this operation type shall be used to maintain some of the medicinal product information. See Chapter 3.II for further details.

- **'Nullification' (4)**: allows users to flag incorrectly submitted information (including duplicated information) as 'non-current'.

See section 2.3.4. *Nullification of duplicated/obsolete XEVMPD entities* of [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#) for the relevant information and processes.

- **'Invalidate MA' (6)**: This operation allows the sender organisation to submit a notification about the withdrawal of an authorised medicinal product from the market via an XEVPRM. The 'Invalidate MA' operation covers a number of scenarios including the transfer of an authorised medicinal product to a third party, and a renewal of the marketing authorisation (MA) by the marketing authorisation holder (MAH) if the marketing authorisation number changes.

See the relevant sections of [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#) for further information and processes:

[2.2.3.3. Transfer of marketing authorisation;](#)

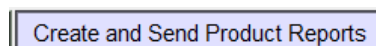
[2.2.3.4. Renewal of marketing authorisation;](#)

[2.2.3.5. Revocation/Withdrawal of Marketing Authorisation \(MA\).](#)

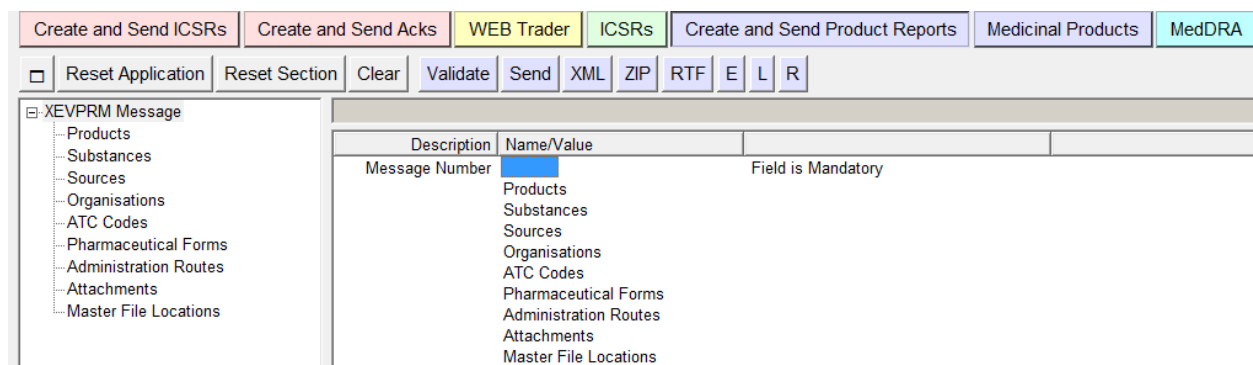
### 3.2. Create an XEVPRM with operation type 'Insert (1)'

If you wish to insert new information in the XEVMPD or to change the information of the updatable lookup tables in the XEVMPD, you have to create and send an XEVPRM.

In order to create an XEVPRM, open the EVWEB and click on the appropriate button in the main menu:



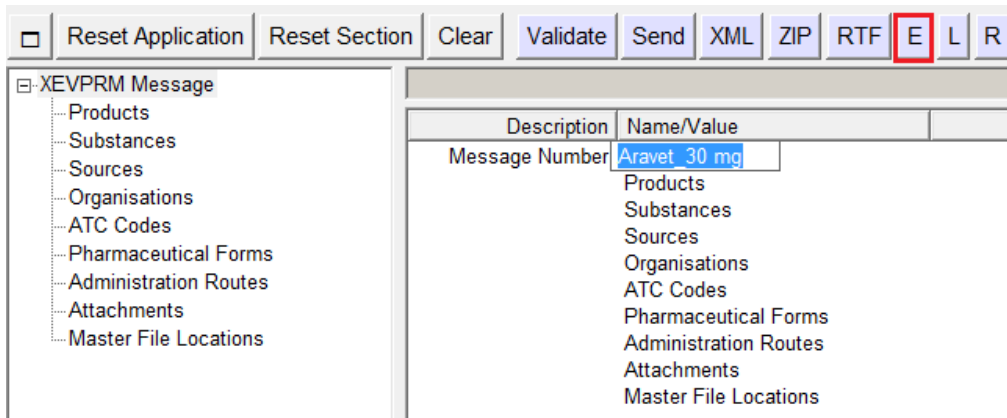
EVWEB will display the sections present in the XEVPRM.



The XEVPRM contains a mandatory section named "message header". EVWEB completes automatically the "message header" section except from the "Message number" field. Therefore you have to type the message number that you wish to assign to your message.

Expand the "XEVRM Message" in the tree view area in order to display the sections of the XEVRM. Enter a message number.

Select the field highlighted on the next screenshot and press 'Enter' on the keyboard or use the "E" button (for text edit) - the field now allows data entry; type the message number then press 'Enter' again to close the field).



To add a new Authorised or Development Medicinal Product in the XEVMPD, you have to add a Product Report in the XEVRM with the operation type 'Insert (1)'.

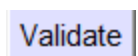
You can also add new development substances, new reference sources, new organisations (MAH or Sponsor), new ATC codes (proposed or development), routes of administration (proposed or development), new pharmaceutical forms (proposed or development), attachments and Master File Locations when this information is not present in the relevant lookup tables you have to create an XEVRM with operation type 'Insert (1)'.

To add new **approved substance name** in English, **approved substance translation or alias**, please refer to the process described in [Changes to some business rules of the eXtended EudraVigilance Medicinal Product Dictionary \(XEVMPD\): Submission of substance information](#).

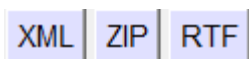
The below examples describe how to create and add a Report with the Operation Type 'Insert' to the XEVRM.

Each Report (Product Report, Substance Report, etc.) contains different fields, but the process for inserting the information does not change. Please refer to [Chapter 3.I: Extended EudraVigilance product report message \(XEVRM\) technical specifications](#) and [Chapter 3.II: Extended EudraVigilance product report message \(XEVRM\) user guidance](#) for a complete list of the fields present in each section and their definition.

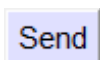
Once you create you report, you can validate, save and send the report:



When you have entered all the necessary information, click on the "Validate" button from the dynamic button set. The system will check the data you have entered and inform you of any missing mandatory information.



To save the XEVPRM you have created, either in "XML" format, "RTF" format, or as a zip file, click on the buttons from the dynamic button set.



After validating the message click on the "Send" button from the dynamic button set to transmit the message to the XEVMPD.

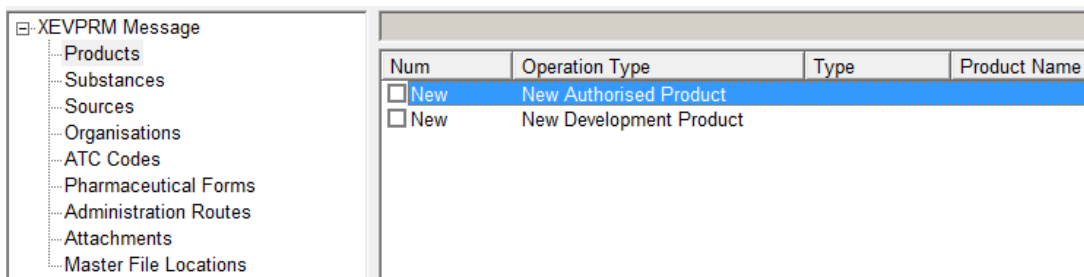
If you wish to insert a new product, select "Products" in the tree view area.

The active area allows you to create a Product Report for an authorised or for a development product by clicking the check box next to the required product type.

The principle of clicking the checkbox to create a new element in the tree-view is the same in all parts of the XEVPRM where applicable, e.g. administration route, Drug ATCs etc.

### 3.2.1. Insert of an authorised medicinal product (AMP)

If you wish to create a Product Report for an authorised product, you have to select "**New Authorised Product**" in the active area.



Once you have selected "New Authorised Product" the tree view area and the active area will display the fields that need to be completed in the product report for an authorised product.

[Create and Send ICSRs](#) | [Create and Send Acks](#) | [WEB Trader](#) | [ICSRs](#) | [Create and Send Product Reports](#) | [Medicinal Products](#) | [MedDRA](#)

[Reset Application](#) | [Reset Section](#) | [Clear](#) | [Replicate](#) | [Validate](#) | [Send](#) | [XML](#) | [ZIP](#) | [RTF](#) | [Duplicate](#) | [Remove](#) | [E](#) | [L](#) | [R](#)

XEVPRM Message  
 paracetamol\*

Description	Name/Value	
Operation Type	Insert (1)	
Type	Authorised (2)	
EV Code		
MAH		Field is Mandatory
QPPV		
Master File Location		
PhV enquiry email		Field must have a specified value
PhV enquiry Phone		Field must have a specified value
Sender Local Code		
Info Date		
Authorisation Country Code		Field is Mandatory
Authorisation Procedure		Field is Mandatory
Authorisation Status		
Authorisation Number		Field must have a specified value
Authorisation/Renewal Date		Field must have a specified value
MRP/DCP/EMEA Number		
EU Number		
Legal Basis		
Orphan Drug		
Additional Monitoring		
Invalidated Date		Field must have a specified value
Full Presentation Name		Field is Mandatory
Product Short Name		Field is Mandatory Optional
Product INN/Common Name		Field is Mandatory Optional
Product Company Name		Field must have a specified value
Product Strength Name		
Product Form Name		
Package Description		
Comment		
Medicinal Product Types (-)		Section is Mandatory
Authorised Pharmaceutical Forms (-)		Section is Mandatory
Pharmaceutical Products (-)		Section is Mandatory
Drug ATCs (-)		Section is Mandatory
Drug Indications (-)		Section is Mandatory
Previous EV Codes (-)		
Product Attachments (-)		Section is Mandatory

Products  
 Insert (1) - Authorised (2)  
 Medicinal Product Types (-)  
 Authorised Pharmaceutical Forms (-)  
 Pharmaceutical Products (-)  
 Drug ATCs (-)  
 Drug Indications (-)  
 Previous EV Codes (-)  
 Product Attachments (-)  
 Substances  
 Sources  
 Organisations  
 ATC Codes  
 Pharmaceutical Forms  
 Routes Of Administration  
 Attachments  
 Master File Locations

The "Operation type" field displays "Insert" as default.

The "Type" field displays "Authorised" as default.

Mandatory information is displayed in red in the tree view area.

You can complete the fields as necessary.

For the complete list of data fields collected for an AMP entity in the XEVMPD and business rules regarding what information needs to be provided for which field and under which condition, please refer to [Chapter 3.11: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section *1.1. Initial Submission of an Authorised Medicinal Product (AMP)*.

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the AMP:

```

- <reportacknowledgment>
  <reportname>AUTHORISEDPRODUCT</reportname>
  <localnumber>1</localnumber>
  <ev_code>PRD1576657</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
  
```

### 3.2.1.1. How to reference information not yet present in the XEVMPD in your AMP entry

If some of the information you need to insert in the individual fields of your product entry is not available in the relevant look-up tables, you may add this information in the same XEVPRM, and reference it in the product entry you are creating.

As an example, in the below screenshot, you are inserting a new AMP but the MAH organisation you need to reference is not available:

The screenshot shows the XEVPRM interface with the 'WEB Trader' tab selected. The left sidebar shows a tree view of 'Products' with 'Insert (1) - Authorised (2)' expanded. The main area displays a table of fields for 'paracetamol\*'. A modal dialog box titled 'Message from webpage' is open, displaying a warning icon and the text 'Lookup returned no results'. The dialog has an 'OK' button.

Description	Name/Value	
Operation Type	Insert (1)	
Type	Authorised (2)	
EV Code		
MAH		Field is Mandatory
QPPV		
Master File Location		
PhV enquiry email		Field must have a specified value
PhV enquiry Phone		Field must have a specified value
Sender Local Code		
Info Date		
Authorisation Country Code		Field is Mandatory
Authorisation Procedure		Field is Mandatory
Authorisation Status		
Authorisation Number		Field is Mandatory
Authorisation/Renewal Date		
MRP/DCP/EMA Number		
EU Number		
Legal Basis		
Orphan Drug		
Additional Monitoring		
Invalidated Date		
Full Presentation Name		
Product Short Name		
Product INN/Common Name		
Product Company Name		
Product Strength Name		
Product Form Name		
Package Description		
Organisation Name	Veropharma	
Query Mode	Begins	

You will therefore need to create a new MAH entity in the same XEVPRM.

Go to the "Organisations" section of the XEVPRM and create a new marketing authorisation holder organisation (please refer to section 3.2.6. [Insert of MAH organisation](#)):

The screenshot shows the XEVPRM interface with the 'WEB Trader' tab selected. The left sidebar shows a tree view of 'Products' with 'Organisations' expanded. The main area displays a table of fields for 'paracetamol\*'. The 'MAH' field is now populated with 'Veropharma'.

Description	Name/Value	
Operation Type	insert (1)	
EV Code		
Type	MAH (1)	
MAH Name	Veropharma	
SME Status	Medium (4)	
SME Number		
MAH Sender ID		
Address	43 King's Road	
City	London	
Region		
Postcode	E12 18Z	
Country Code	United Kingdom (GB)	
Tel Number		
Tel Extension		
Tel Country Code		
Fax Number		
Fax Extension		
Fax Country Code		
E-mail Address		
Comment		

Once you have created the new MAH organisation, go to the authorised product entity that you started to create, click with your mouse on the field "MAH" and then on the button **L** (Local data lookup).

From the pop-up menu, select the new MAH present in your XEVPRM:

You can continue to populate the remaining fields in your AMP entry. Any information that is not present in the available look-up fields can be added using the same process described above.

When you enter information in all of the fields as required, validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, it will display the following message including the EV Code of the newly inserted AMP and the MAH organisation:



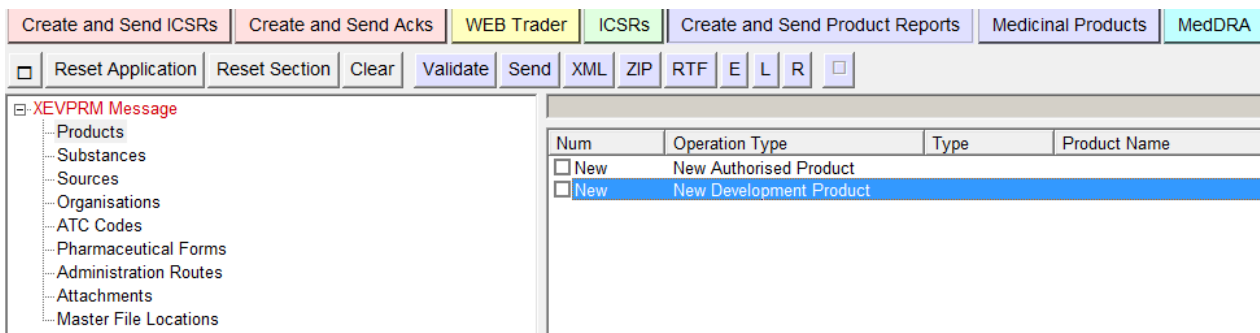
```

- <reportacknowledgment>
  <reportname>ORGANISATION</reportname>
  <localnumber>9</localnumber>
  <ev_code>ORG6741</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted succesfully</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>
  <reportname>AUTHORISEDPRODUCT</reportname>
  <localnumber>2</localnumber>
  <ev_code>PRD180483</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted succesfully</operationresultdesc>
</reportacknowledgment>

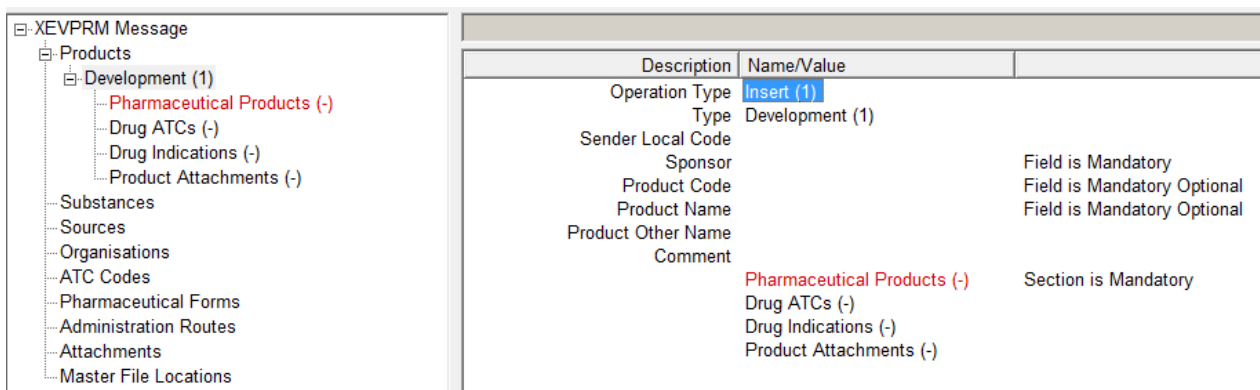
```

### 3.2.2. Insert of a development medicinal product (DMP)

If you wish to create a Product Report for a development product, you have to select "**New Development Product**" in the active area.



Once you have selected "New Development Product" the tree view area and the active area will display the fields that need to be completed in the product report for a development product.



The "Operation type" field displays "Insert" as default.

The "Type" field displays "Development" as default.

Mandatory information is displayed in red.

You can complete the fields as necessary, please refer to the below guidance:

#### **3.2.2.1. Sender Local Code (DP.4)**

*Optional information.*

*The sender local code for the development medicinal product used by the sponsor for internal reference purposes may be specified in this field.*

*The sender local code specified by the sponsor is not used in the XEVMPD for maintenance and it can be any technical code.*

#### **3.2.2.2. Sponsor Code (DP.5)**

*Mandatory information.*

*Sponsor EV Code corresponding to the sponsor organisation of the development medicinal product must be specified, where applicable.*

*If the Sponsor organisation was previously successfully submitted in the XEVMPD and an EV Code has been assigned, the sponsor organisation can be selected from the available look-up table.*

*If the sponsor organisation does not exist in the XEVMPD, the sponsor information can be added using the Organisation section of the XEVPRM and be referenced in the DMP entry using the Local look-up table. Please refer to section [3.2.2.7. How to reference information not yet present in the XEVMPD in your DMP entry.](#)*

#### **3.2.2.3. Product Code (DP.6.1)**

*Mandatory information if product name (in field DP.6.2) is not provided. Optional information if product name (in field DP.6.2) is provided.*

*The code assigned to a development product by the sponsor may/must be specified.*

#### **3.2.2.4. Product Name (DP.6.2)**

*Mandatory information if product code (in field DP.6.1) is not provided. Optional information if product code (in field DP.6.1) is provided.*

*The name assigned to the development product by the sponsor in the clinical trial documentation (e.g. IB) must/may be specified.*

*If the sponsor does not have a specific product name, and only the active substance name or code is available, the product name can be created as a concatenation of the substance code or name and concentration.*

#### **3.2.2.5. Product Other Name (DP.6.3)**

*Optional information.*

*Other descriptive name of the development product may be specified (e.g. if the product has any other name previously used by the sponsor in the clinical trial documentation).*

### 3.2.2.6. Comment (DP.7)

Optional information, which becomes mandatory during nullification – a reason for nullification must be provided in this field (e.g. duplicated product entry).

Validate and send the XEVPRM.

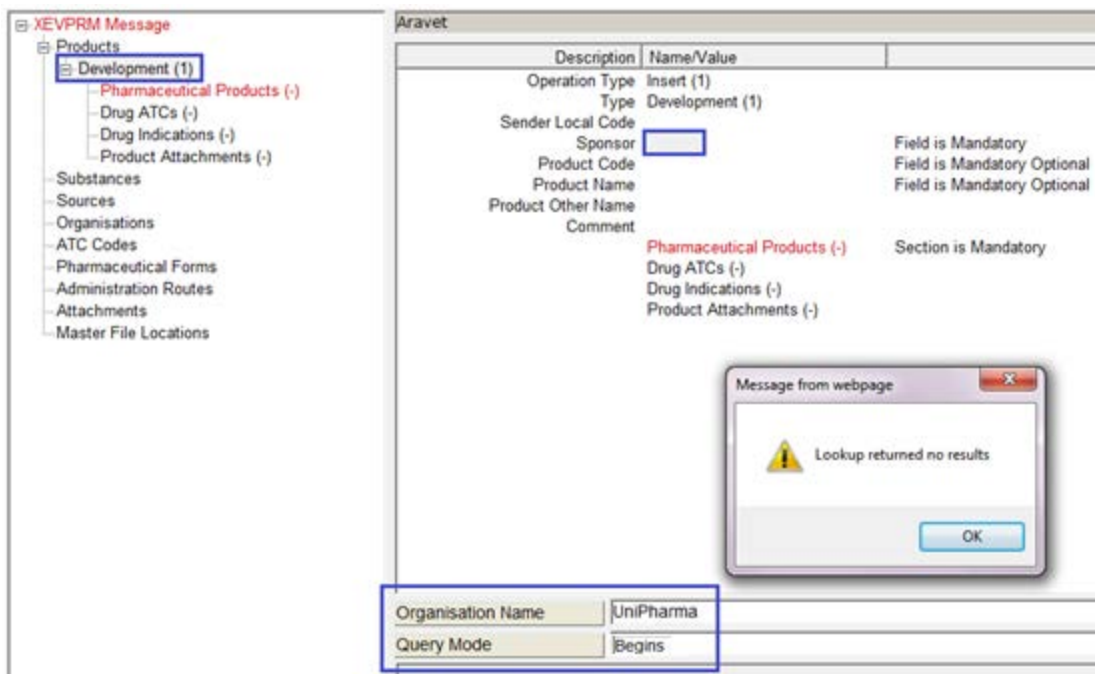
The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the DMP:

```
- <reportacknowledgment>
  <reportname>DEVELOPMENTPRODUCT</reportname>
  <localnumber>1</localnumber>
  <ev_code>PRD 123456</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
```

### 3.2.2.7. How to reference information not yet present in the XEVMPD in your DMP entry

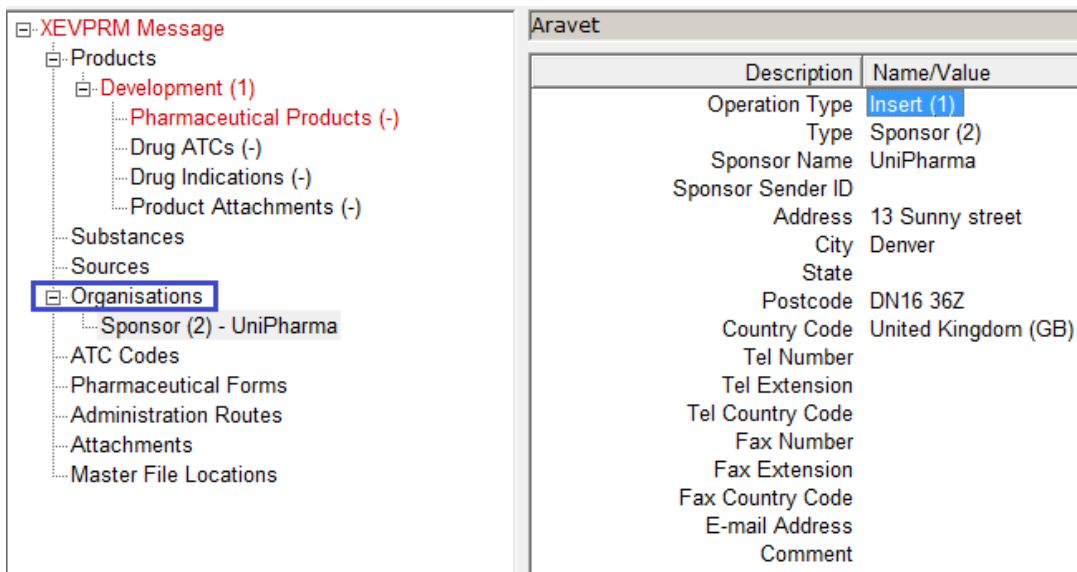
If some of the information you need to insert in the individual fields of your product entry is not available in the relevant look-up tables, you may add this information in the same XEVPRM, and reference it in the product entry you are creating.

As an example, in the below screenshot, you are inserting a new DMP. The sponsor organisation you need to reference is not available in the look-up table:



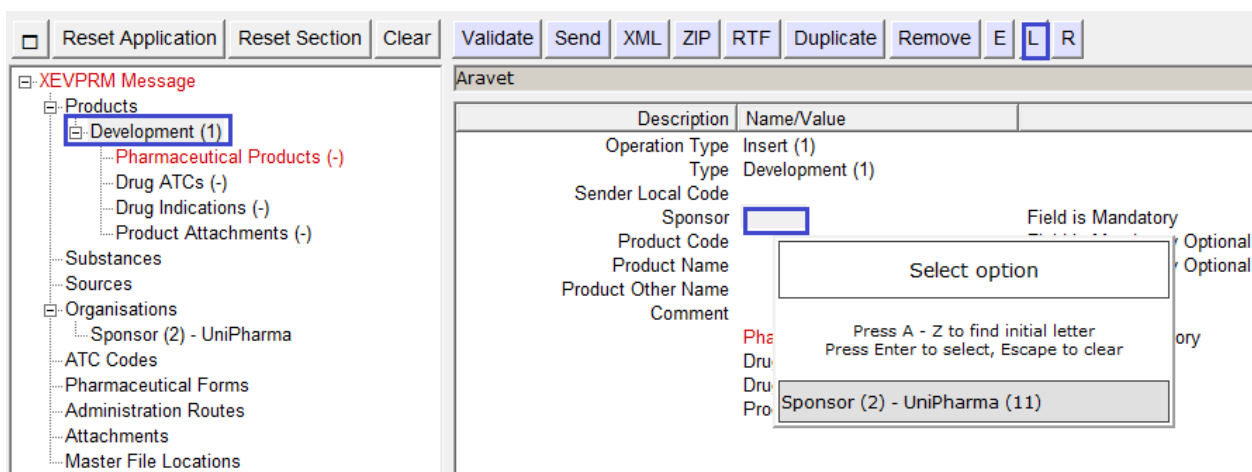
You will therefore need to create a new sponsor entity in the same XEVPRM.

Go to the "Organisations" section of the XEVPRM and create a new sponsor organisation (please refer to section 3.2.7. *Insert of Sponsor organisation*):



Once you have created the new sponsor organisation, go to the development product entity that you started to create, click with your mouse on the field "Sponsor" and then on the button **L** (Local data lookup).

From the pop-up menu, select the new sponsor organisation present in your XEVPRM:



You can continue to populate the remaining fields in your DMP entry. Any information that is not present in the available look-up fields can be added using the same process described above.

When you enter information in all of the fields as required, validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, it will display the following message including the EV Code of the newly inserted DMP and the sponsor organisation:

```

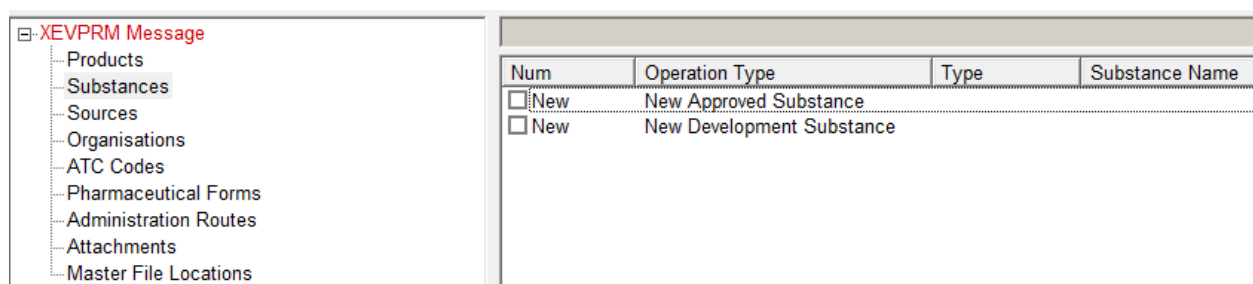
- <reportacknowledgment>
  <reportname>ORGANISATION</reportname>
  <localnumber>11</localnumber>
  <ev_code>ORG6742</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>
  <reportname>DEVELOPMENTPRODUCT</reportname>
  <localnumber>1</localnumber>
  <ev_code>PRD 123456</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>

```

### 3.2.3. Insert of an approved substance

If you wish to create a Substance Report for a new substance, you have to select "Substances" in the tree view area.

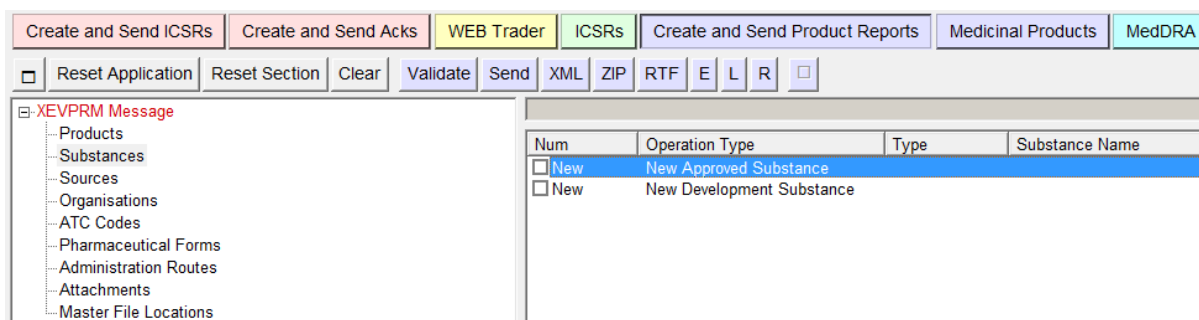
The active area allows you to create a Substance Report for an approved or for a development substance.



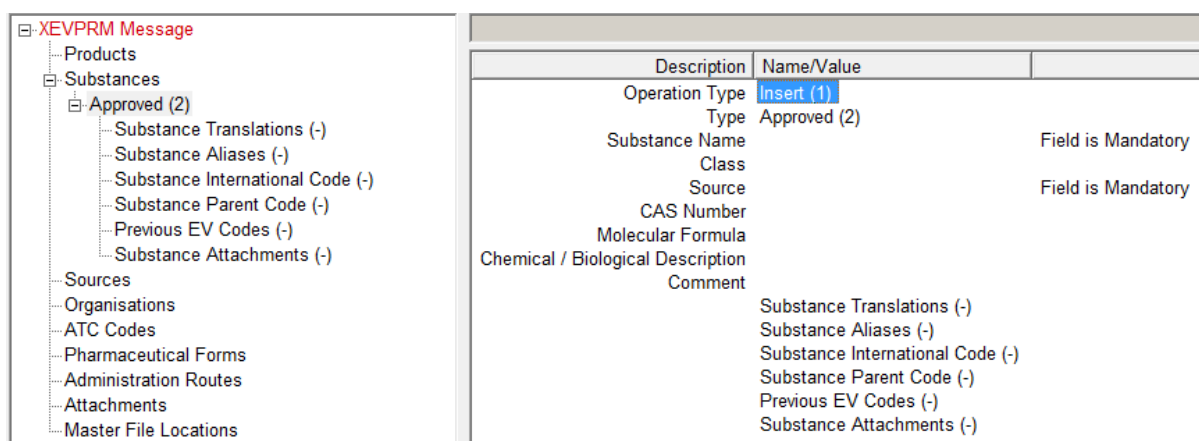
If you wish to create a Substance Report for a new **approved substance**, you have to select "New Approved Substance" in the active area.



Please note that the below screenshot is for the purpose of training only as you should follow the process described in [Changes to some business rules of the eXtended EudraVigilance Medicinal Product Dictionary \(XEVMPD\): Submission of substance information](#) if you wish to add a new approved substance name in English or a new approved substance translation or alias.



Once you have selected "New Approved Substance" the tree view area and the active area will display the fields that need to be completed in the substance report for an approved substance:



You can complete the fields as necessary, then validate and send the XEVPRM.

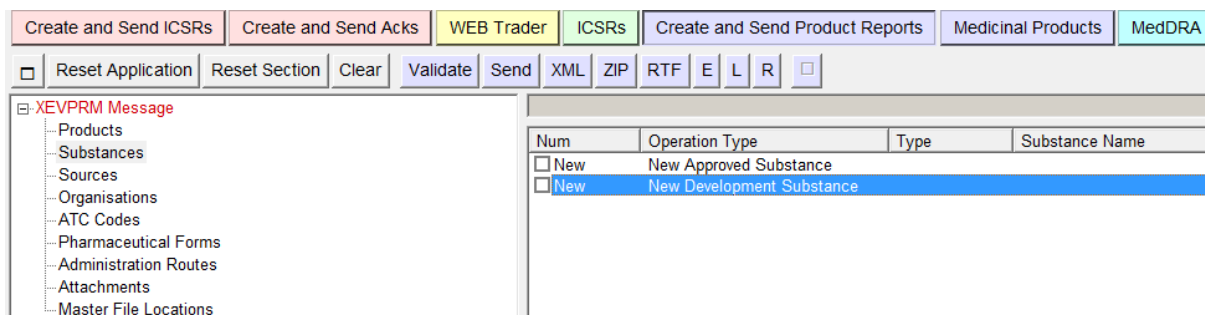
The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the approved substance:

```
- <reportacknowledgment>
  <reportname>APPROVEDSUBSTANCE</reportname>
  <localnumber>1</localnumber>
  <ev_code>SUB166236</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
</acknowledgment>
```

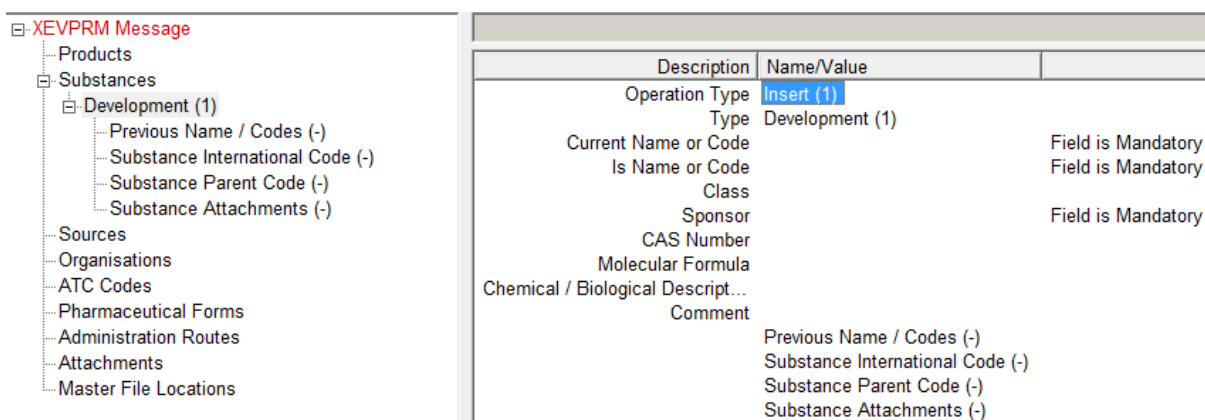
### 3.2.4. Insert of a development substance

Please note that a development term can only be used in development medicinal products.

If you wish to create a Substance Report for a new **development substance**, you have to select "New Development Substance" in the active area.



Once you have selected "New Development Substance" the tree view area and the active area will display the fields that need to be completed in the substance report for a development substance:



You can complete the fields as necessary, please refer to the below guidance:

#### 3.2.4.1.1. Current Name or Code (DS.DSN.1)

*Mandatory information.*

*The current code or name used by the sponsor for this particular development substance must be specified in English.*

*An indication whether the specified information is a name or a code must be provided in field 'Is Name or Code' (DS.DSN.3).*

#### 3.2.4.1.2. Substance class (DS.7)

*Mandatory information.*

*The substance classification must be specified as per available values ([EudraVigilance eXtended Medicinal Product Dictionary \(XEVMPD\) substance classes](#)).*

#### 3.2.4.1.3. Sponsor Code (DS.4)

*Mandatory information.*

Sponsor EV Code corresponding to the sponsor organisation of the development medicinal product must be specified, where applicable.

If the Sponsor organisation was previously successfully submitted in the XEVMPD and an EV Code has been assigned, the sponsor organisation can be selected from the available look-up table.

If the sponsor organisation does not exist in the XEVMPD, the sponsor information can be added using the Organisation section of the XEVPRM and be referenced in the DMP entry using the Local look-up table. Please refer to section [3.2.2.7. How to reference information not yet present in the XEVMPD in your DMP entry.](#)

#### **3.2.4.1.4. Chemical Abstracts Service (CAS) number (DS.5)**

Optional information.

The Chemical Abstracts Service (CAS) number of the development substance may be specified.

#### **3.2.4.1.5. Molecular formula (DS.6)**

Optional information.

The empirical molecular formula of the development substance may be specified.

#### **3.2.4.1.6. Chemical Biological Description (CBD) (DS.8)**

Optional information.

The Chemical Biological Description (CBD) of the Development Substance may be specified.

#### **3.2.4.1.7. Comment (DS.9)**

Optional information, which becomes mandatory during nullification – a reason for nullification must be provided in this field (e.g. duplicated substance entry).

#### **3.2.4.1.8. Previous Name/Codes**

Optional information.

The previous code or name in use by the sponsor for the development substance may be specified.

#### **3.2.4.1.9. International Code (DS.ICs)**

Optional information.



Any internationally recognised code, by which the substance can be identified, may be specified as applicable. For specified substances, the international code section is used to provide a cross reference the appropriate single substance in the XEVMPD or current message.

#### 3.2.4.1.10. Substance Parent Code

No information to be provided in this field, as this field is available for the eventual of ISO compliant structured substance information and is **currently not required** by the EMA. If, however, the field is present, then the content must conform to the published schema. See [Chapter 3.1: Extended EudraVigilance product report message \(XEVPRM\) technical specifications](#) for relevant information.

#### 3.2.4.1.11. (Development) Substance Attachment (DS.ATTs)

It is optional to reference an attachment, as for development substances, attachments may be absent.

The insertion of Attachments will be shown in section [3.2.14.2. Insert of Printed Substance Information \(PSI\)](#).

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the development substance:

```
- <reportacknowledgment>
  <reportname>DEVELOPMENTSUBSTANCE</reportname>
  <localnumber>5</localnumber>
  <ev_code>SUB 12345 </ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>
```

#### 3.2.5. Insert of a reference source

If you wish to insert a new reference source, select "Sources" in the tree view area and create a new Source Report in the active area:

The screenshot shows a tree view on the left with the following items: XEVPRM Message, Products, Substances, Sources, Organisations, ATC Codes, Pharmaceutical Forms, Administration Routes, Attachments, and Master File Locations. The 'Sources' item is selected. On the right, a table displays the following data:

Num	Operation Type	Source Name
<input type="checkbox"/> New	New Source	

You can complete the fields as necessary:

The screenshot shows the 'Source' entity selected in the tree view. The main area displays a table with the following data:

Description	Name/Value	
Operation Type	Insert (1)	
Source Name		Field is Mandatory
Comment		

For the complete list of data fields collected for a reference source entity in the XEVMPD and business rules regarding what information needs to be provided for which field, please refer to [Chapter 3.11: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section 1.5. *Initial submission of a Reference Source*.

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the reference source:

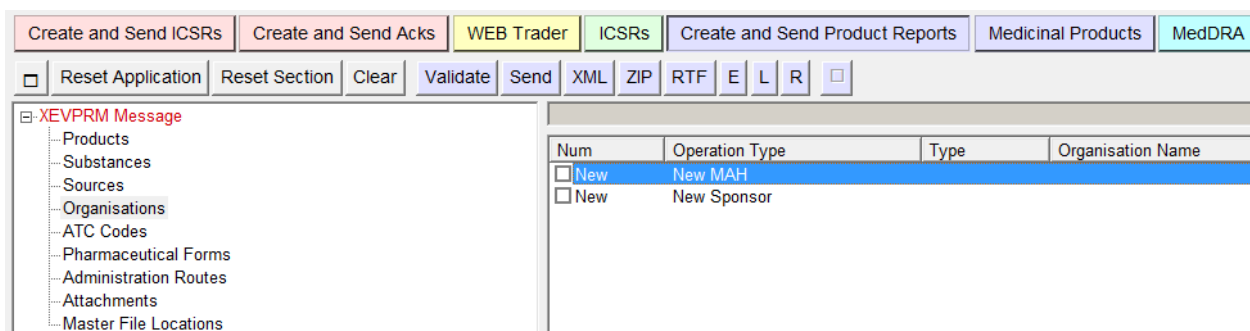
```
- <reportacknowledgment>
  <reportname>SOURCE</reportname>
  <localnumber>10</localnumber>
  <ev_code>SRC1093</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
```

### 3.2.6. Insert of MAH organisation

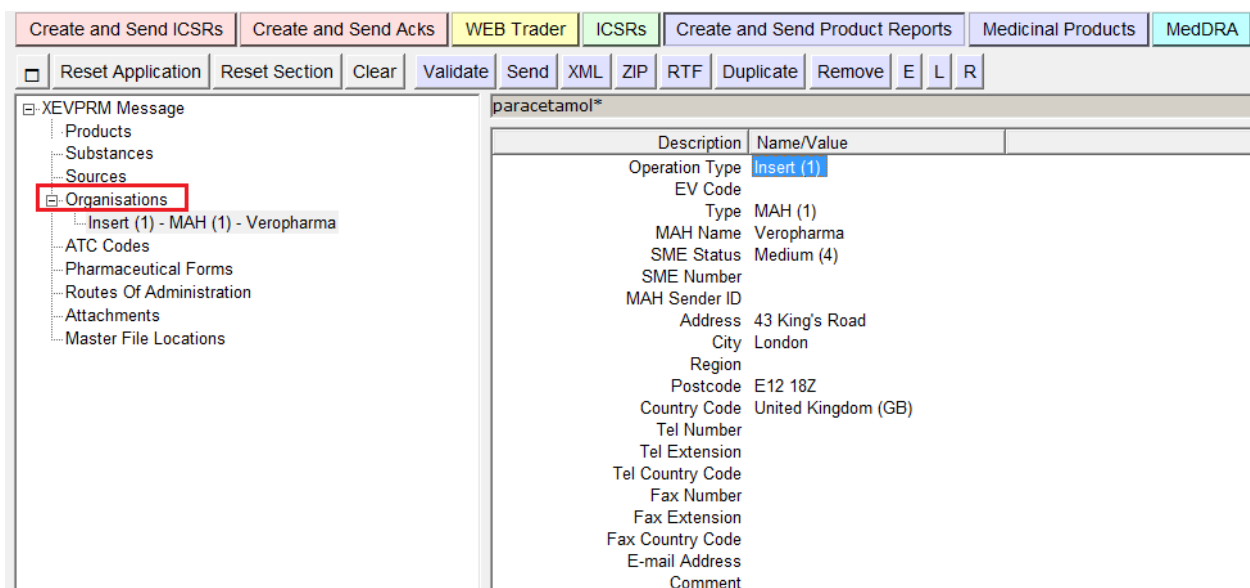
If you wish to insert a new **Organisation**, select "Organisations" in the tree view area.

The active area allows you to create an Organisation Report for a Marketing Authorisation Holder (MAH) or for a sponsor.

If you wish to create an Organisation Report for a **MAH**, you have to select "New MAH" in the active area.



Once you have selected "New MAH", the tree view area and the active area will display the fields that need to be completed for the new MAH:



You can complete the fields as necessary.

For the complete list of data fields collected for a MAH entity in the XEVMPD and business rules regarding what information needs to be provided for which field, please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section 1.6. *Initial Submission of a Marketing Authorisation Holder (MAH) Organisation*.

Validate and send the XEVPRM.

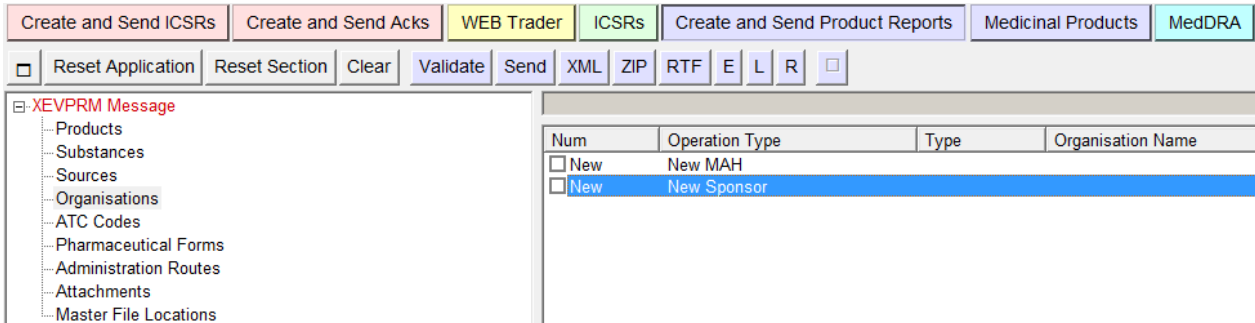
The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the MAH organisation:

```
- <reportacknowledgment>
  <reportname>ORGANISATION</reportname>
  <localnumber>1</localnumber>
  <ev_code>ORG12482</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
```

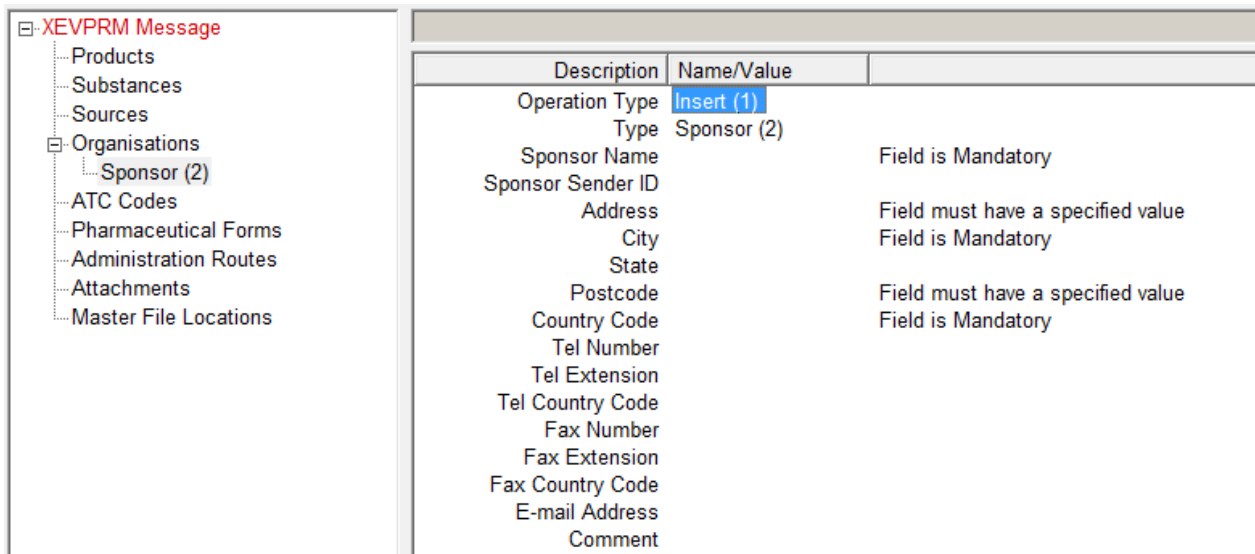
### 3.2.7. Insert of Sponsor organisation

If you wish to insert a new Organisation, select "Organisations" in the tree view area.

If you wish to create an Organisation Report for a **sponsor**, you have to select "New Sponsor" in the active area.



Once you have selected "New Sponsor", the tree view area and the active area will display the fields that need to be completed for the new Sponsor.



You can complete the fields as necessary, then validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the sponsor organisation:

```

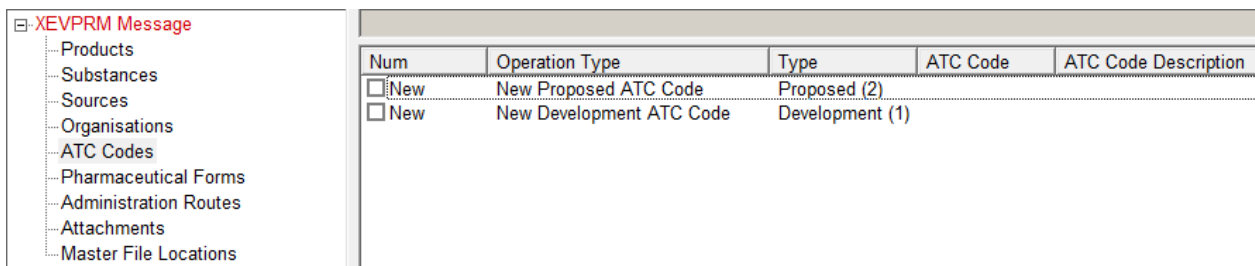
- <reportacknowledgment>
  <reportname>ORGANISATION</reportname>
  <localnumber>2</localnumber>
  <ev_code>ORG6789 </ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>

```

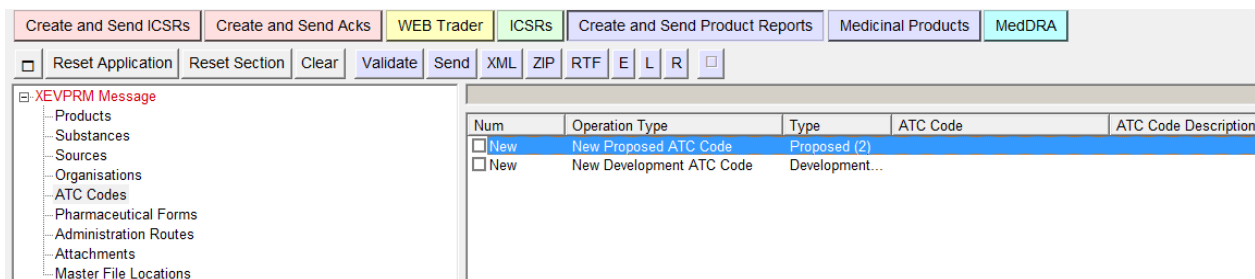
### 3.2.8. Insert of a proposed ATC Code

If you wish to insert a new ATC code, select "ATC codes" in the tree view area.

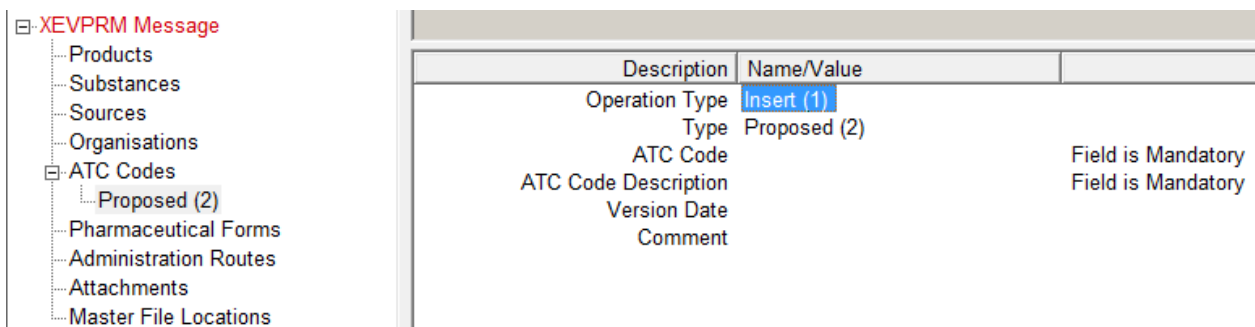
The active area allows you to create an ATC Code Report for a proposed ATC code and for a development ATC code.



If you wish to add information on a new proposed ATC Code you have to select "New Proposed ATC Code" in the active area:



Once you have selected "New Proposed ATC Code", the tree view area and the active area will display the fields that need to be completed for the new proposed ATC code:



You can complete the fields as necessary.

For the complete list of data fields collected for an ATC Code entity in the XEVMPD and business rules regarding what information needs to be provided for which field, please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section 1.7. *Initial submission of an ATC Code*.

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the ATC Code:

```
- <reportacknowledgment>
  <reportname>ATCCODE</reportname>
  <localnumber>L04AA34</localnumber>
  <ev_code>L04AA34</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
```

### 3.2.9. Inset of a development ATC Code

Please note that a development term can only be used in development medicinal products.

If you wish to add information on a new **development ATC Code**, you have to select "New Development ATC Code" in the active area:

The screenshot shows the XEVMPD Data-Entry Tool interface. At the top, there are several tabs: 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below the tabs is a toolbar with buttons for 'Reset Application', 'Reset Section', 'Clear', 'Validate', 'Send', 'XML', 'ZIP', 'RTF', 'E', 'L', 'R', and a help icon. The main area is divided into a tree view on the left and an active area on the right. The tree view shows a hierarchy of entities: Products, Substances, Sources, Organisations, ATC Codes, Pharmaceutical Forms, Administration Routes, Attachments, and Master File Locations. The 'ATC Codes' entity is expanded, and 'New Development ATC Code' is selected. The active area displays a table with the following data:

Num	Operation Type	Type	ATC Code	ATC Cc
<input type="checkbox"/>	New	New Proposed ATC Code	Proposed (2)	
<input type="checkbox"/>	New	New Development ATC Code	Development...	

Once you have selected "New Development ATC Code" the tree view area and the active area will display the fields that need to be completed for the new development ATC code:

The screenshot shows the XEVMPD Data-Entry Tool interface with the 'New Development ATC Code' selected in the tree view. The active area displays a table with the following data:

Description	Name/Value	
Operation Type	Insert (1)	
Type	Development (1)	
ATC Code		Field is Mandatory
ATC Code Description		Field is Mandatory
Version Date		
Comment		

You can complete the fields as necessary.

For the complete list of data fields collected for an ATC Code entity in the XEVMPD and business rules regarding what information needs to be provided for which field, please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section 1.7. *Initial submission of an ATC Code*.

Validate and send the XEVPRM.

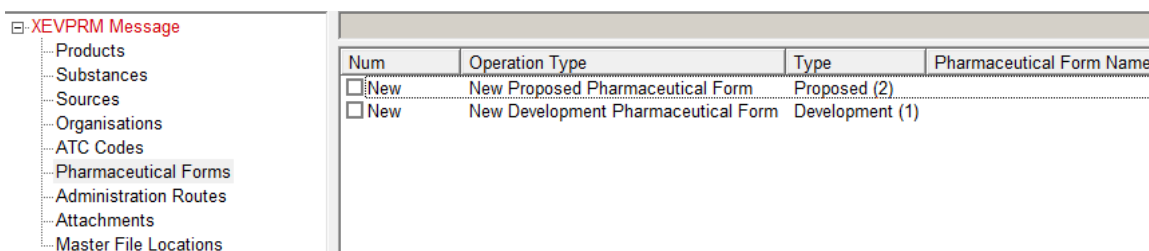
The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the ATC Code:

```
- <reportacknowledgment>
  <reportname>ATCCODE</reportname>
  <localnumber>A10AD06</localnumber>
  <ev_code>A10AD06</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>
```

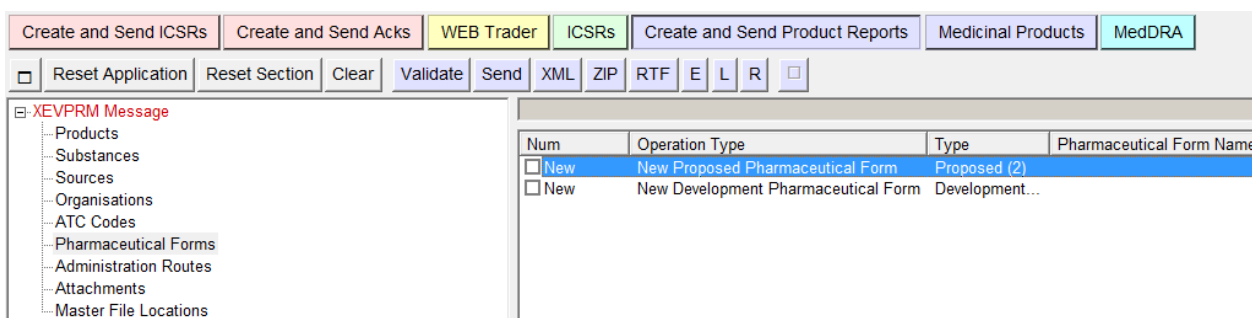
### 3.2.10. Insert of a proposed pharmaceutical form

If you wish to insert a new pharmaceutical form, select "Pharmaceutical Forms" in the tree view area.

The active area allows you to create a Report for a proposed pharmaceutical form and for a development pharmaceutical form.



If you wish to add information on a new **proposed pharmaceutical form** you have to select "New Proposed Pharmaceutical Form" in the active area:



Once you have selected "New Proposed Pharmaceutical Form", the tree view area and the active area will display the fields that need to be completed for the new proposed pharmaceutical form:

You can complete the fields as necessary.

For the complete list of data fields collected for a pharmaceutical form entity in the XEVMPD and business rules regarding what information needs to be provided for which field, please refer to [Chapter 3.11: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section *1.8. Initial submission of an Authorised/Administrable Pharmaceutical Form*.

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the pharmaceutical form:

```
- <reportacknowledgment>
  <reportname>PHARMACEUTICALFORM</reportname>
  <localnumber>3</localnumber>
  <ev_code>PHF2342</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
```

### 3.2.11. Insert of a development pharmaceutical form

Please note that a development term can only be used in development medicinal products.

If you wish to add information on a new **development pharmaceutical form**, you have to select "New Development Pharmaceutical Form" in the active area.

Once you have selected "New Development Pharmaceutical Form", the tree view area and the active area will display the fields that need to be completed for the new development pharmaceutical form:

You can complete the fields as necessary.



For the complete list of data fields collected for a pharmaceutical form entity in the XEVMPD and business rules regarding what information needs to be provided for which field, please refer to [Chapter 3.11: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section 1.8. *Initial submission of an Authorised/Administrable Pharmaceutical Form*.

Validate and send the XEVPRM.

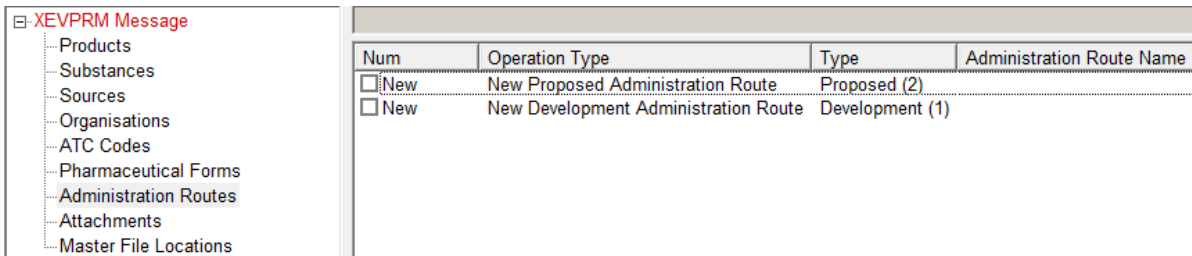
The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the pharmaceutical form:

```
- <reportacknowledgment>
  <reportname>PHARMACEUTICALFORM</reportname>
  <localnumber>3</localnumber>
  <ev_code>PHF2342</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
```

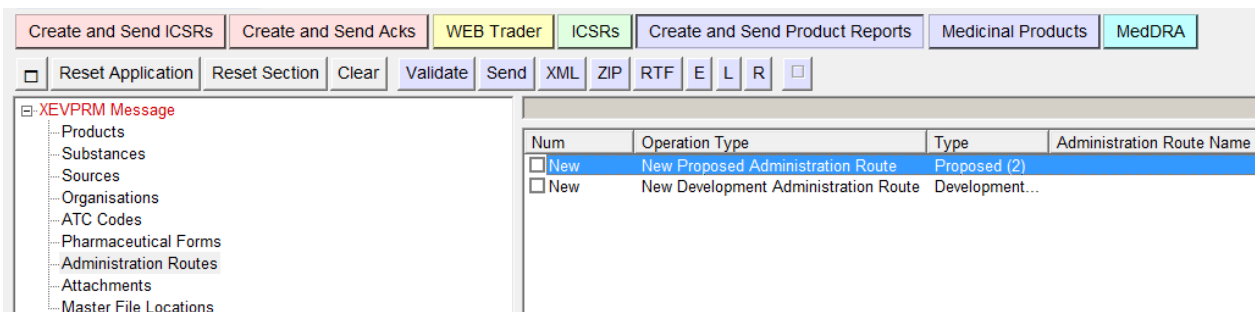
### 3.2.12. Insert of a proposed route of administration

If you wish to insert a new route of administration, select "Administration Routes" in the tree view area.

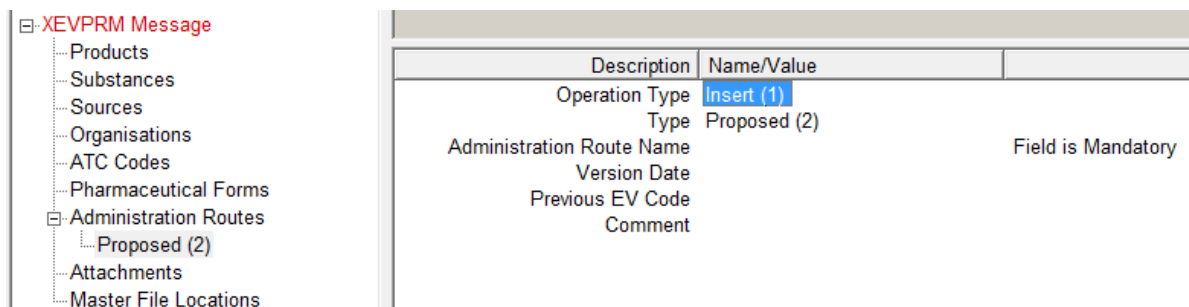
The active area allows you to create a Report for a proposed route of administration and for a development route of administration.



If you wish to add information on a new **proposed route of administration**, you have to select "New Proposed Administration Routes" in the active area:



Once you have selected "New Proposed Administration Routes", the tree view area and the active area will display the fields that need to be completed for the new proposed route of administration:



You can complete the fields as necessary.

For the complete list of data fields collected for a route of administration entity in the XEVMPD and business rules regarding what information needs to be provided for which field, please refer to [Chapter 3.11: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section 1.9. *Initial Submission of a Route of Administration (RoA)*.

Validate and send the XEVPRM.

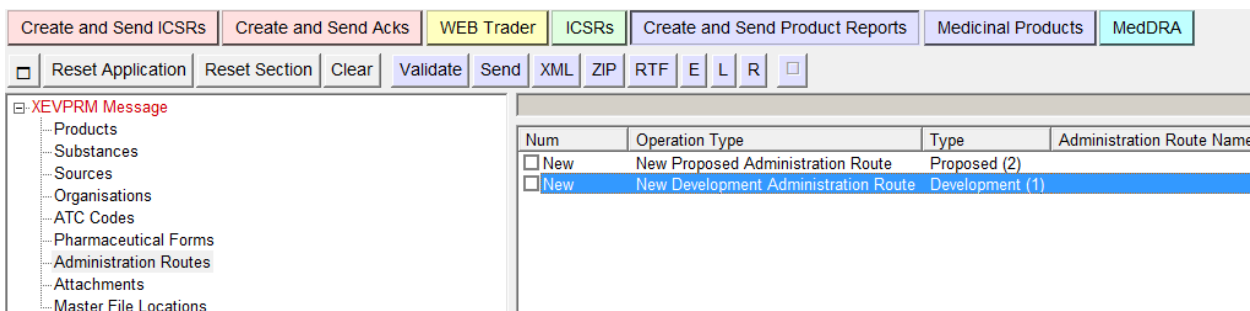
The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the route of administration:

```
- <reportacknowledgment>
  <reportname>ADMINISTRATIONROUTE</reportname>
  <localnumber>4</localnumber>
  <ev_code>ADR620</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
```

### 3.2.13. Insert of a development route of administration

Please note that a development term can only be used in development medicinal products.

If you wish to add information on a **new development route of administration**, you have to select "New Development Administration Routes" in the active area.



Once you have selected "New Development Administration Routes", the tree view area and the active area will display the fields that need to be completed for the new development route of administration:

XEVPRM Message	
Description	Name/Value
Operation Type	Insert (1)
Type	Development (1)
Administration Route Name	Field is Mandatory
Version Date	
Previous EV Code	
Comment	

You can complete the fields as necessary.

For the complete list of data fields collected for a route of administration entity in the XEVMPD and business rules regarding what information needs to be provided for which field, please refer to [Chapter 3.11: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#); section *1.9. Initial Submission of a Route of Administration (RoA)*.

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the route of administration:

```
- <reportacknowledgment>
  <reportname>ADMINISTRATIONROUTE</reportname>
  <localnumber>4</localnumber>
  <ev_code>ADR620</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
```

### 3.2.14. Insert of an attachment

If you wish to insert an Attachment in, you would need to do it in three steps:

- Provide the information of the file to be attached in the Attachments section;
- Reference the attachment information to the applicable Product or Substance;
- Attach the file at the moment of sending the XEVPRM.

Select "Attachment" in the tree view area:

XEVPRM Message

- Products
- Substances
- Sources
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Administration Routes
- Attachments
- Master File Locations

Num	Operation Type	Type	Attachment Name
<input type="checkbox"/> New	New PPI Attachment	1	
<input type="checkbox"/> New	New PSI Attachment	2	

### 3.2.14.1. Insert of Printed Product Information (PPI)

If you wish to add a new Printed Product Information (PPI) in the XEVMPD, select "New PPI Attachment" in the active area:

Create and Send ICSRs   Create and Send Acks   WEB Trader   ICSRs   Create and Send Product Reports   Medicinal Products   MedDRA

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

XEVPRM Message

- Products
- Substances
- Sources
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Administration Routes
- Attachments
- Master File Locations

Num	Operation Type	Type	Attachment Name
<input type="checkbox"/> New	New PPI Attachment	1	
<input type="checkbox"/> New	New PSI Attachment	2	

Once you have selected "New PPI Attachment", the tree view area and the active area will display the fields that need to be completed for entering the Attachment information:

XEVPRM Message

- Products
- Substances
- Sources
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Administration Routes
- Attachments
  - Attachment
- Master File Locations

Description	Name/Value	
File Type	PDF (1)	
Name		Field is Mandatory
Type	PPI (1)	
Language		Field is Mandatory
Version Number		Field is Mandatory
Version Date		Field is Mandatory

By default, the File Type is "PDF", but you can change this value.

For PPI the values accepted are .pdf, .doc and .docx.

Description	Name/Value
File Type	PDF (1)
Name	
Type	PPI (
Language	
Version Number	
Version Date	

Select option

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

DOC (2)
DOCX (3)
<b>PDF (1)</b>
XLS (4)
XLSX (5)

For PDF attachments, only "genuine" PDF documents should be attached (not scanned documents). PDF file version 1.4 or 1.7 should be used as these are the only two versions that are ISO standards compliant. They are used for long term preservation of information and therefore the Agency/MAHs will have the assurance that we will be able to open them for many years.

You can complete the fields as necessary.

For details on what information should be provided in the individual fields of a Printed Product Information (PPI) entry please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section *1.10. Submission of an attachment*.

The PPI attachment must be referenced in at least one product entity in the same XEVPRM, as it is not possible to submit a standalone PPI attachment in an XEVPRM.

#### **3.2.14.1.1. How to reference a PPI attachment in an AMP entry – operation type 'Insert (1)'**

A copy of the SmPC as authorised by the Authorising Body must be provided as a PPI attachment to the authorised medicinal product entry. Where, in exceptional circumstances, the SmPC is not available as part of the marketing authorisation, an equivalent document that facilitates the data quality assurance process by the Agency (e.g. English common text, package insert or other similar text as authorised by the Authorising Body) should be provided.

After you created your authorised medicinal product entry in the "Products" section of the XEVPRM [see section *3.2.1. Insert of an authorised medicinal product (AMP)*], create your PPI attachment in the "Attachments" section of the same XEVPRM:

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

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

XEVPRM Message

- Products
  - Insert (1) - Authorised (2) - Aravet 30 mg
    - Medicinal Product Types (1)
      - Conditional Marketing Authorisation (Article 14 (7) of Regulation (EC) No 726/2004 (1)
    - Authorised Pharmaceutical Forms (1)
      - TABLET
    - Pharmaceutical Products (1)
    - Drug ATCs (1)
    - Drug Indications (5)
    - Previous EV Codes (-)
    - Product Attachments (-)
  - Substances
  - Sources
  - Organisations
  - ATC Codes
  - Pharmaceutical Forms
  - Routes Of Administration
  - Attachments
    - Insert (1) - Czech (CS) - Aravet 30 mg
  - Master File Locations

paracetamol\*

Description	Name/Value
File Type	DOC (2)
Name	Aravet 30 mg
Type	PPI (1)
Language	Czech (CS)
Version Number	1
Version Date	07/05/2014

In the authorised product entity (in section "Products"), click on "Product Attachments". Using the button **L** (Local data lookup), select the new product attachment:

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

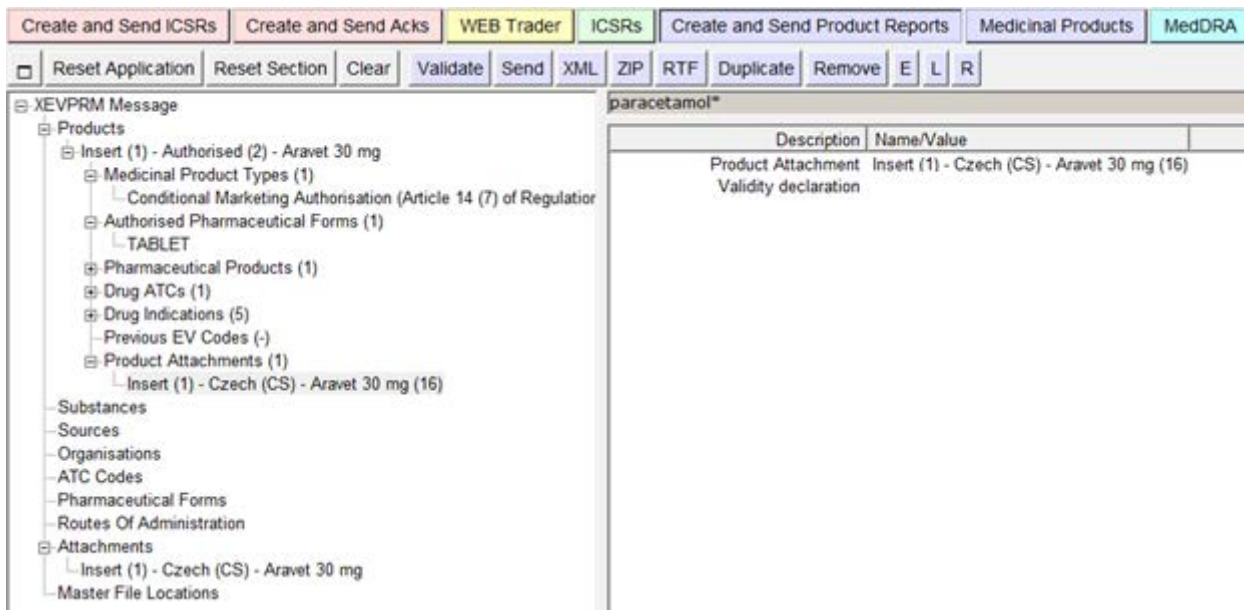
Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate Remove E L R

XEVPRM Message

- Products
  - Insert (1) - Authorised (2) - Aravet 30 mg
    - Medicinal Product Types (1)
      - Conditional Marketing Authorisation (Article 14 (7) of Regulation (EC) No 726/2004 (1)
    - Authorised Pharmaceutical Forms (1)
      - TABLET
    - Pharmaceutical Products (1)
    - Drug ATCs (1)
    - Drug Indications (5)
    - Previous EV Codes (-)
    - Product Attachments (1)
      - Product Attachment
  - Substances
  - Sources
  - Organisations
  - ATC Codes
  - Pharmaceutical Forms
  - Routes Of Administration
  - Attachments
    - Insert (1) - Czech (CS) - Aravet 30 mg
  - Master File Locations

paracetamol\*

Description	Name/Value
Product Attachment	
Validity declaration	Field is Mandatory
Select option Press A - Z to find initial letter Press Enter to select, Escape to clear	
Insert (1) - Czech (CS) - Aravet 30 mg (16)	



Validate your file using the "Validate" button. Any mandatory fields, which are mandatory and which were not populated will be highlighted in red. Once you amend the XEVPRM file so that it contains all of the mandatory information, press "Send".

A new window will appear, prompting you to upload your attachment file. Please note that the name of the file has to be the same as the name provided in the Attachments section:



This item is repeatable according to the number of attachments to be sent.

After you upload the file, the XEVPRM is sent.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the newly inserted AMP and the PPI attachment:

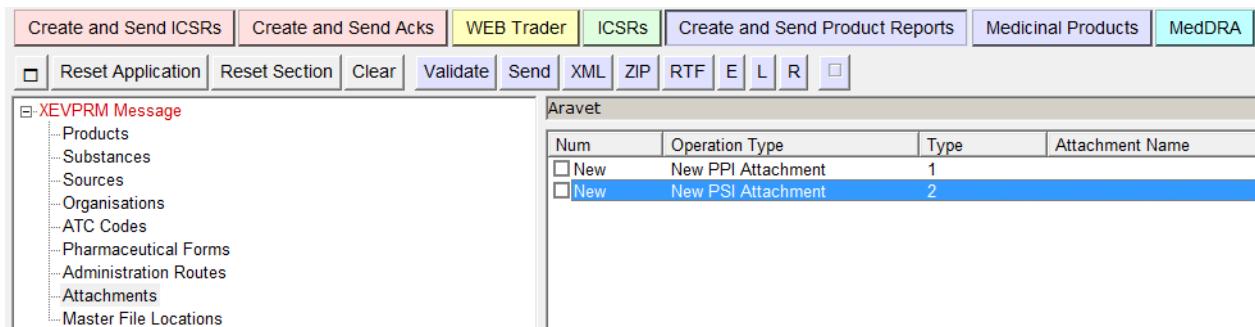
```

- <reportacknowledgment>
  <reportname>ATTACHMENT</reportname>
  <localnumber>28</localnumber>
  <ev_code>ATT6</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted succesfully</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>
  <reportname>AUTHORISEDPRODUCT</reportname>
  <localnumber>24</localnumber>
  <ev_code>PRD180481</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted succesfully</operationresultdesc>
</reportacknowledgment>

```

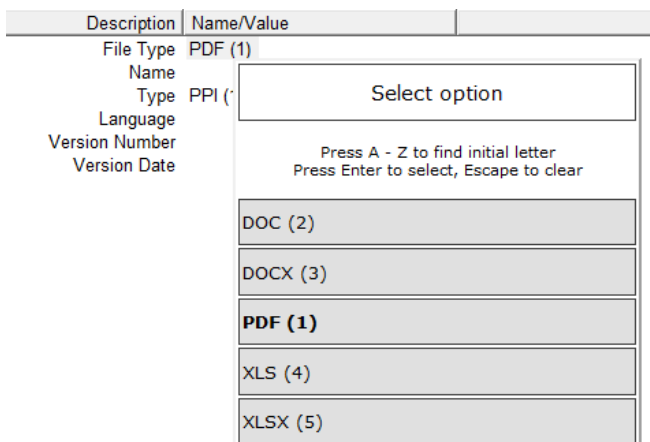
### 3.2.14.2. Insert of Printed Substance Information (PSI)

If you wish to add a new Printed Substance Information (PSI) in the XEVMPD, select "New PPI Attachment" in the active area:



By default, the File Type is "PDF", but you can change this value.

For PSI the values accepted are .pdf, .doc, .docx.





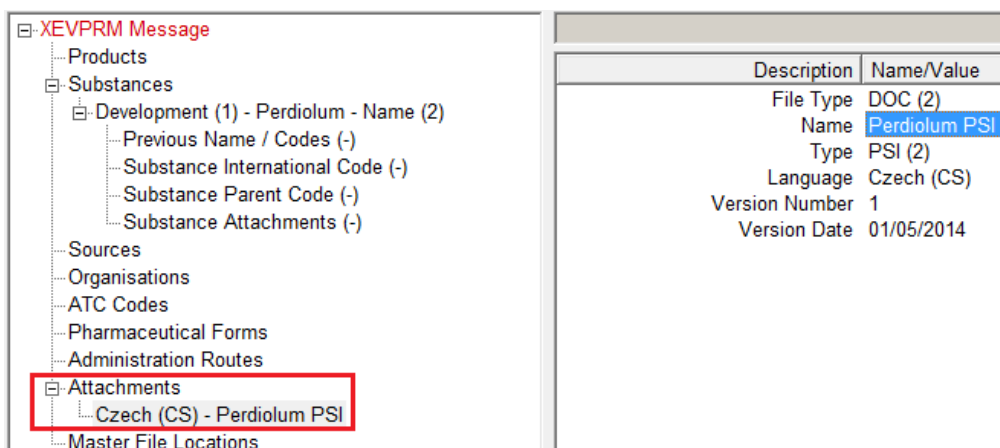
For PDF attachments, only "genuine" PDF documents should be attached (not scanned documents). PDF file version 1.4 or 1.7 should be used as these are the only two versions that are ISO standards compliant. They are used for long term preservation of information and therefore the Agency/MAHs will have the assurance that we will be able to open them for many years.

You can complete the fields as necessary.

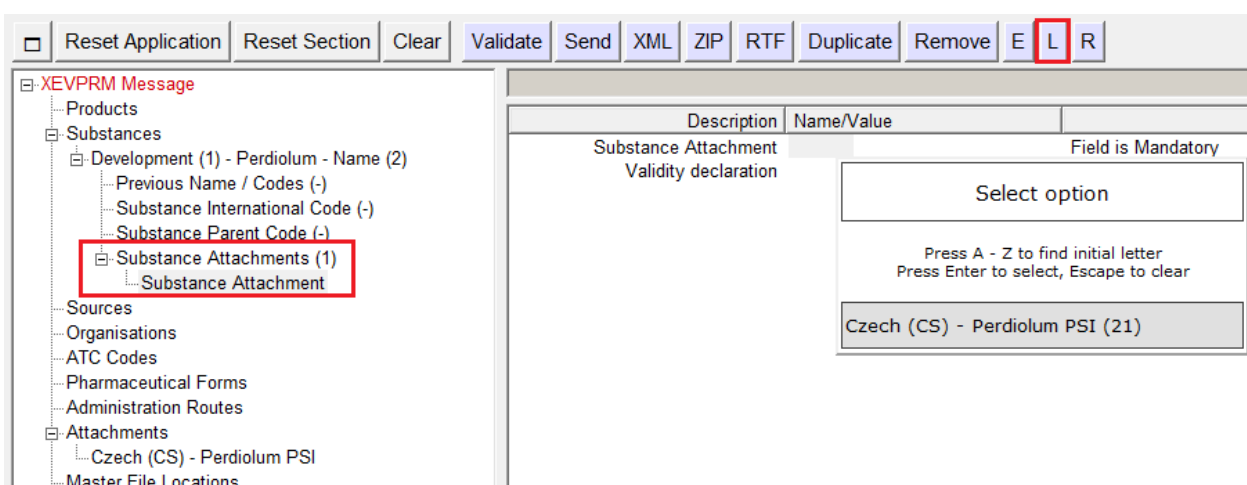
The PSI attachment must be referenced in at least one substance entity in the same XEVPRM, as it is not possible to submit a standalone PSI attachment in an XEVPRM.

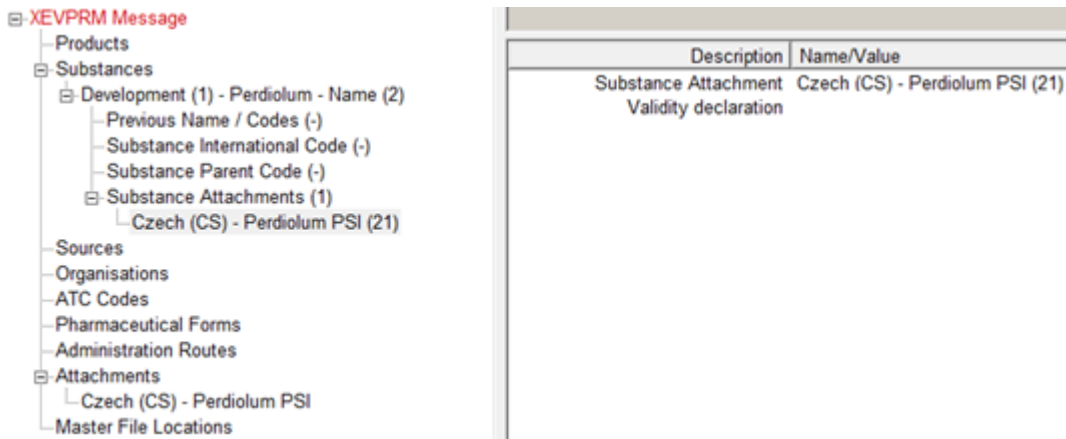
### 3.2.14.2.1. How to reference a PSI attachment in a development substance entry – operation type 'Insert (1)'

Once you create your development substance entry in the "Products" section of the XEVPRM (see section 3.2.4. *Insert of a development substance*), you can create your PSI attachment entity in the "Attachments" section of your XEVPRM:



Reference the attachment in the development substance entity - go to the "Substances" section (where you have the information for the development substance to be entered in the XEVMPD) and go to "Substance attachment". Using the button **L** (Local data lookup), select the new substance attachment:

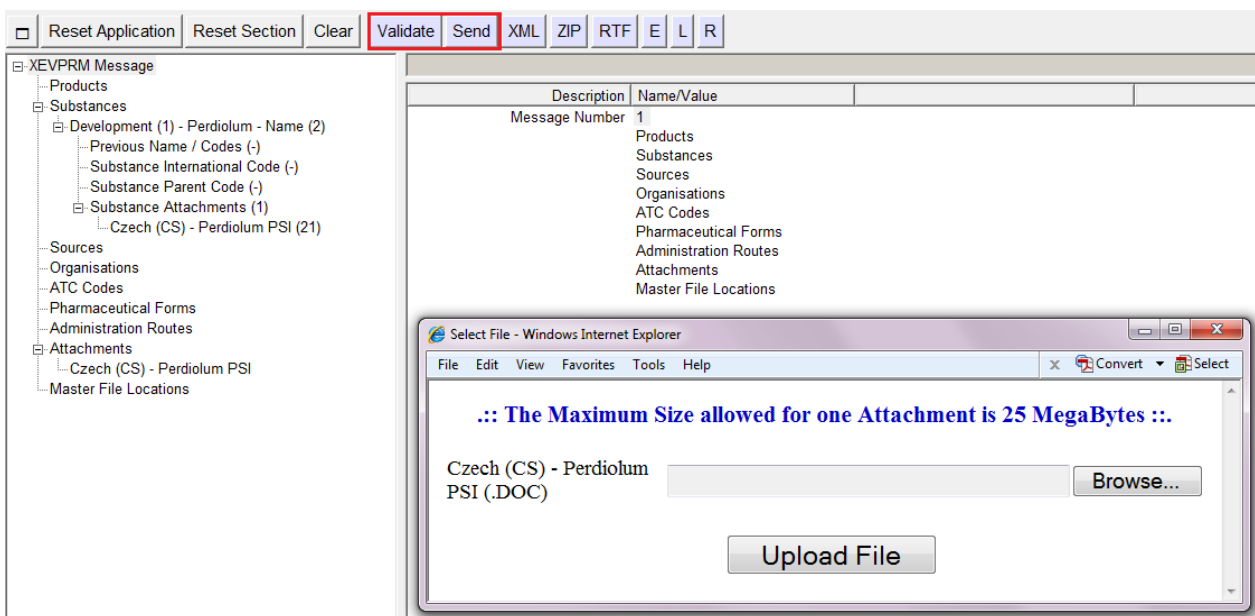




Validate your file using the "Validate" button. Any mandatory fields, which are mandatory and which were not populated will be highlighted in red.

Once you amend the XEVPRM file so that it contains all of the mandatory information, press "Send".

A new window will appear, prompting you to upload your attachment file. Please note that the name of the file has to be the same as the name provided in the Attachments section:



This item is repeatable according to the number of attachments to be sent.

After you upload the file the XEVPRM is sent.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the development substance and the PSI attachment:

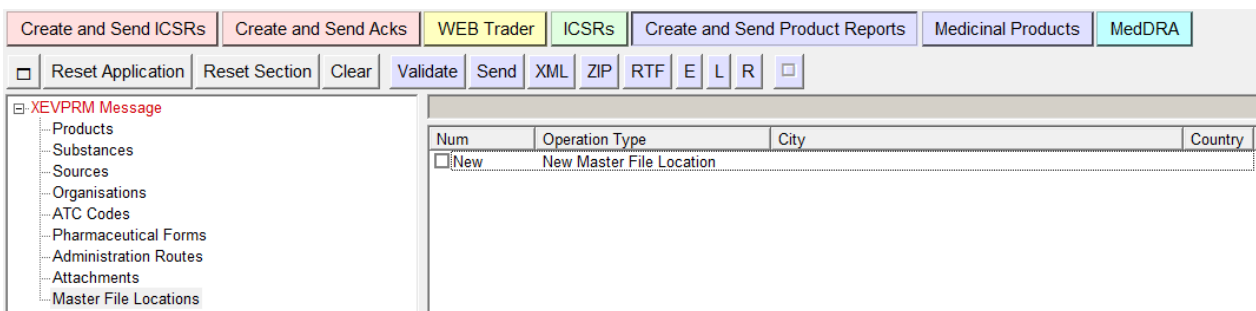
```

- <reportacknowledgment>
  <reportname>ATTACHMENT</reportname>
  <localnumber>19</localnumber>
  <ev_code>ATT510793</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>
  <reportname>DEVELOPMENTSUBSTANCE</reportname>
  <localnumber>5</localnumber>
  <ev_code>SUB 12345 </ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
- <reportacknowledgment>

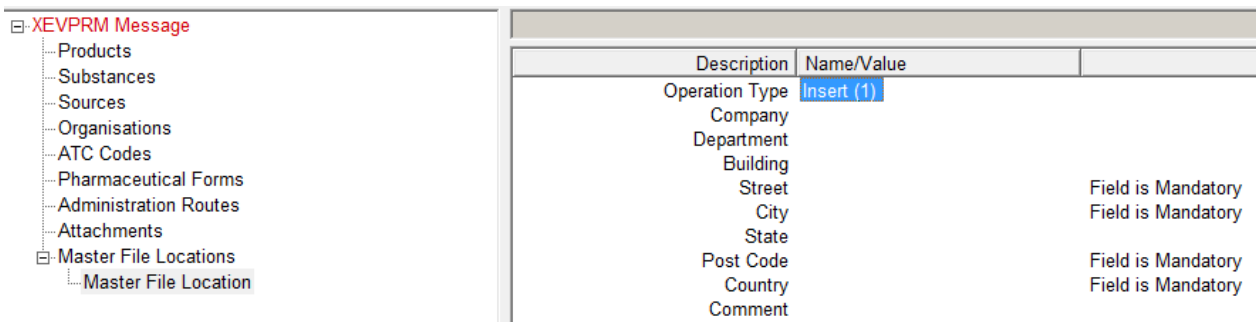
```

### 3.2.15. Insert of a Master File Location

If you wish to insert a new Master File Location, select "Master File Locations" in the tree view area. In the active area select "New Master File Locations":



The tree view area and the active area will display the fields that need to be completed for the new MFL:



You can complete the fields as necessary.

For details on what information should be provided in the individual fields of a Master File Location entry please refer to [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section 1.11. Initial submission of a Pharmacovigilance System Master File Location (PSMFL).

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, will display the following message, including the EV Code of the MFL:

```
- <reportacknowledgment>
  <reportname>MFL</reportname>
  <localnumber>3</localnumber>
  <ev_code>MFL5312</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
```

### 3.2.15.1. How to reference a Master File Location entity in an AMP entry - operation type 'Insert (1)'

After you created your authorised medicinal product entry in the "Products" section of the XEVPRM [see section 3.2.1. *Insert of an authorised medicinal product (AMP)*], create Master File Location (MFL) entity in the "Master File Locations" section of the same XEVPRM:

The screenshot shows the XEVPRM interface. The top navigation bar includes buttons for 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below this is a secondary bar with 'Reset Application', 'Reset Section', 'Clear', 'Validate', 'Send', 'XML', 'ZIP', 'RTF', 'Duplicate', 'Remove', 'E', 'L', and 'R'. The main area is split into two panes. The left pane shows a tree view of the XEVPRM Message structure, with 'Master File Locations' highlighted in red. The right pane shows the details for 'paracetamol\*' with a table of fields and values.

Description	Name/Value
Operation Type	Insert (1)
EV Code	
Company	
Department	
Building	
Street	Nova ulice 12
City	Prague 4
Region	
Post Code	140 00
Country	Czech Republic (CZ)
Comment	

In the authorised product entity (in section "Products"), click on "Master File Location" field. Using the button **L** (Local data lookup), select the new product attachment:

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

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

XEVPRM Message

- Products
  - Insert (1) - Authorised (2) - Aravet 30 mg
    - Medicinal Product Types (1)
      - Conditional Marketing Authorisation (Article 14 (7) of Regulation)
    - Authorised Pharmaceutical Forms (1)
      - TABLET
    - Pharmaceutical Products (1)
    - Drug ATCs (1)
    - Drug Indications (5)
    - Previous EV Codes (-)
    - Product Attachments (1)
      - Insert (1) - Czech (CS) - Aravet 30 mg (16)
  - Substances
  - Sources
  - Organisations
  - ATC Codes
  - Pharmaceutical Forms
  - Routes Of Administration
  - Attachments
    - Insert (1) - Czech (CS) - Aravet 30 mg
  - Master File Locations
    - Insert (1) - Czech Republic (CZ) - Prague 4

paracetamol\*

Description	Name/Value
Operation Type	Insert (1)
Type	Authorised (2)
MAH	NOBEL PHARMA CO., LTD.
QPPV	
Master File Location	<input type="text"/>
PhV enquiry email	tr:
PhV enquiry Phone	+: <input type="text"/>
Sender Local Code	
Info Date	12
Authorisation Country Code	C:
Authorisation Procedure	El
Authorisation Status	V: (18)
Authorisation Number	07
Authorisation/Renewal Date	22/10/1987
MRP/DCP/EMA Number	
EU Number	
Legal Basis	
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	Aravet 30 mg
Product Short Name	Aravet
Product INN/Common Name	
Product Company Name	
Product Strength Name	30 mg
Product Form Name	
Package Description	
Comment	

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

Insert (1) - Czech Republic (CZ) - Prague 4

Medicinal Product Types (1)  
 Authorised Pharmaceutical Forms (1)  
 Pharmaceutical Products (1)  
 Drug ATCs (1)  
 Drug Indications (5)  
 Previous EV Codes (-)  
 Product Attachments (1)

Validate your file using the "Validate" button. Any mandatory fields, which are mandatory and which were not populated will be highlighted in red. Once you amend the XEVPRM file so that it contains all of the mandatory information, press "Send".

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, it will show the EV Codes of all the newly inserted entities.

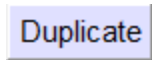
### 3.2.15.2. How to reference a Master File Location entity in an AMP entry - operation type 'Update (2)'

If you submitted an AMP entity in the XEVMPD without specifying the Master File Location or you wish to amend the specified MFL, you can add this information/amend the information by following the process described in [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section 2.3.2. *Amendment of an AMP entry following a change in the referenced PSMFL information*.

### 3.3. Duplicate an entity in an XEVPRM

To accelerate the data entry process during the creation of an XEVPRM in EVWEB, it can be useful to duplicate any entity present in you XEVPRM and modify it as appropriate.

Once you have created an AMP entity or any other entity (substance, source, organisation, ATC code, administration route or pharmaceutical form) with the operation type "Insert", by selecting the item in the tree view area, the main menu displays the "Duplicate" button.



By clicking on the "Duplicate" button, EVWEB automatically adds a copy of the previously entered item. In the tree view area, a new entity is displayed. The operation type for the new entity is "Insert":

The screenshot shows the EVWEB interface. At the top, there are several tabs: 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below these is a main menu with buttons: 'Reset Application', 'Reset Section', 'Clear', 'Replicate', 'Validate', 'Send', 'XML', 'ZIP', 'RTF', 'Duplicate' (highlighted with a red box), 'Remove', 'E', 'L', and 'R'. On the left, a tree view shows a hierarchy of entities under 'XEVPRM Message'. The 'Products' folder is expanded, and 'Insert (1) - Authorised (2) - Aravet 30 mg' is selected and highlighted with a red box. The main panel on the right displays the details for 'paracetamol\*'. It has a table with two columns: 'Description' and 'Name/Value'. The table contains the following data:

Description	Name/Value
Operation Type	Insert (1)
Type	Authorised (2)
MAH	NOBEL PHARMA CO., LTD.
QPPV	John Smith
Master File Location	Insert (1) - Czech Republic (CZ) - Prague 4 (18)
PhV enquiry email	nobelpharma@nobelpharma.com
PhV enquiry Phone	+420 2222 1234
Sender Local Code	
Info Date	12/11/2013
Authorisation Country Code	Czech Republic (CZ)
Authorisation Procedure	EU authorisation procedures - National Procedure (4)
Authorisation Status	Valid (1)
Authorisation Number	01/237/87-C
Authorisation/Renewal Date	22/10/1987
MRP/DCP/EMEA Number	
EU Number	
Legal Basis	Full application (Article 8(3) of Directive No 2001/83/EC) (1)
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	Aravet 30 mg
Product Short Name	Aravet
Product INN/Common Name	
Product Company Name	
Product Strength Name	30 mg
Product Form Name	
Package Description	
Comment	Medicinal Product Types (1) Authorised Pharmaceutical Forms (1) Pharmaceutical Products (1) Drug ATCs (1) Drug Indications (5) Previous EV Codes (-) Product Attachments (1)

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

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

XEVPRM Message

paracetamol\*

Description	Name/Value
Operation Type	Insert (1)
Type	Authorised (2)
MAH	NOBEL PHARMA CO., LTD.
QPPV	John Smith
Master File Location	Insert (1) - Czech Republic (CZ) - Prague 4 (18)
PhV enquiry email	nobelpharma@nobelpharma.com
PhV enquiry Phone	+420 2222 1234
Sender Local Code	
Info Date	12/11/2013
Authorisation Country Code	Czech Republic (CZ)
Authorisation Procedure	EU authorisation procedures - National Procedure (4)
Authorisation Status	Valid (1)
Authorisation Number	01/237/87-C
Authorisation/Renewal Date	22/10/1987
MRP/DCP/EMA Number	
EU Number	
Legal Basis	Full application (Article 8(3) of Directive No 2001/83/EC) (1)
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	Aravet 30 mg
Product Short Name	Aravet
Product INN/Common Name	
Product Company Name	
Product Strength Name	30 mg
Product Form Name	
Package Description	
Comment	
	Medicinal Product Types (1)
	Authorised Pharmaceutical Forms (1)
	Pharmaceutical Products (1)
	Drug ATCs (1)
	Drug Indications (5)
	Previous EV Codes (-)
	Product Attachments (1)

By expanding the menu, you can go through the individual fields and modify the information as necessary (in the below example, we modified the Authorisation Number, Full Presentation Name and the Product Strength Name):

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

XEVPRM Message

- Products
  - Insert (1) - Authorised (2) - Aravet 30 mg
    - Medicinal Product Types (1)
    - Authorised Pharmaceutical Forms (1)
    - Pharmaceutical Products (1)
    - Drug ATCs (1)
    - Drug Indications (5)
    - Previous EV Codes (-)
    - Product Attachments (1)
  - Insert (1) - Authorised (2) - **Aravet 60 mg**
    - Medicinal Product Types (1)
    - Authorised Pharmaceutical Forms (1)
    - Pharmaceutical Products (1)
    - Drug ATCs (1)
    - Drug Indications (5)
    - Previous EV Codes (-)
    - Product Attachments (1)
- Substances
- Sources
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Routes Of Administration
- Attachments
- Master File Locations

paracetamol\*

Description	Name/Value
Operation Type	Insert (1)
Type	Authorised (2)
MAH	NOBEL PHARMA CO., LTD.
QPPV	John Smith
Master File Location	Insert (1) - Czech Republic (CZ) - Prague 4 (18)
PhV enquiry email	nobelpharma@nobelpharma.com
PhV enquiry Phone	+420 2222 1234
Sender Local Code	
Info Date	12/11/2013
Authorisation Country Code	Czech Republic (CZ)
Authorisation Procedure	EU authorisation procedures - National Procedure (4)
Authorisation Status	Valid (1)
Authorisation Number	<b>02/333/87</b>
Authorisation/Renewal Date	22/10/1987
MRP/DCP/EMEA Number	
EU Number	
Legal Basis	Full application (Article 8(3) of Directive No 2001/83/EC) (1)
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	<b>Aravet 60 mg</b>
Product Short Name	Aravet
Product INN/Common Name	
Product Company Name	
Product Strength Name	<b>60 mg</b>
Product Form Name	
Package Description	
Comment	

Medicinal Product Types (1)  
Authorised Pharmaceutical Forms (1)  
Pharmaceutical Products (1)  
Drug ATCs (1)  
Drug Indications (5)  
Previous EV Codes (-)  
Product Attachments (1)

Validate your file using the "Validate" button. Any mandatory fields, which are mandatory and which were not populated will be highlighted in red. Once you amend the XEVPRM file so that it contains all of the mandatory information, press "Send".

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, it will show the EV Codes of all the newly inserted entities.

### 3.4. Create an XEVPRM with maintenance related operation types/commands

#### 3.4.1. Update of entities in the XEVMPD

**The information concerning medicinal products** (authorised or development), **substances** (approved or development), **sources**, **organisations** (MAH or sponsor), **ATC codes** (proposed or development), **routes of administration** (proposed or development), **pharmaceutical forms** (proposed or development), **attachments and Master File Locations, can be modified only by the owner of the entity in the XEVMPD (i.e. the organisation that has provided the initial information).**

XEVMPD will check the ownership of the information before allowing any modification to the information in the XEVMPD.



Operation type 'Update (2)' shall be used cover several scenarios related to the maintenance of data submitted in the XEVMPD, for example:

- To amend information submitted incorrectly or by mistake (e.g. spelling mistake, incorrect information etc.) in an XEVMPD entity (e.g. medicinal products, organisations, MFLs, pharmaceutical forms; routes of administration, ATC Codes, sources etc.);
- To amend an AMP entry following a variation procedure, lifting of suspension of marketing authorisation or a renewal or marketing authorisation, extension to the terms of marketing authorisation changing the route of administration where the MA number doesn't change;
- To amend an AMP entry to reference a new OPPV, MAH organisation, SmPC, MFL etc.

For detailed information on the individual processes to be followed, please refer to section 2. [Maintenance of medicinal product data](#) of [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#).

### 3.4.1.1. Create an XEVPRM with operation type 'Update (2)'

The update an entity, the entity:

- must be already present in the XEVMPD (i.e. an EV Code has been assigned); and
- must not be nullified.

Retrieve the entity you need to update in the XEVMPD either using a simple or an advanced query:

The screenshot shows the XEVMPD interface with a search for 'ProductX'. The interface includes a top navigation bar with buttons for 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. Below this is a toolbar with 'Reset Application', 'Reset Section', 'Clear', and other icons. A tree view on the left shows a hierarchy of categories, with 'Current (1) - PRD111081 - ProductX comprimido revestido 4 mg' selected under 'Authorised Medicinal Products'. On the right, a table displays the search results:

Num	EV Code	Full Presentation Name
<input checked="" type="checkbox"/> 0001	PRD111081	ProductX comprimido revestido 4 mg

Select the entity which you wish to modify and click on operation type "Update":

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

Reset Application | Reset Section | Clear | XML | RTF | Update | Other Operations ▾

Authorised Medicinal Products
 

- Current (1) - PRD111081 - ProductX comprimido revestido 4 mg
- Development Medicinal Products
- Approved Substances
- Development Substances
- Sources
- MAHs
- Sponsors
- ATC Codes
- Routes of Administration
- Pharmaceutical Forms
- Master File Locations
- Attachments
- Abstract Compositions
- Queries

ProductX

Description	Name/Value
Checked	No
Cleaned	No
Nullified	No
EV Code	PRD111081
Category	
PhV enquiry email	pharmacovig@pharmax.co.uk
PhV enquiry Phone	+44 207 2222222
Sender Local Code	
Info Date	
Authorisation Country Code	Portugal (PT)
Authorisation Procedure	EU authorisation procedures - National Procedure (4)
Authorisation Status	Valid (1)
Authorisation Number	8888/222/333
Authorisation/Renewal Date	30/06/2014
MRP/DCP/EMA Number	
EU Number	
Legal Basis	Medicinal product authorised according to Article 126a of Directive No 2001/83/EC (10)
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	ProductX comprimido revestido 4 mg
Product Short Name	ProductX
Product INN/Common Name	
Product Company Name	
Product Strength Name	4 MG
Product Form Name	COMPRIMIDO REVESTIDO

Your product entity is moved from the "Medicinal product" section to the "Create and Send Product Reports" section. The operation type is selected as "Update":

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

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

XEVPRM Message
 

- Products
  - Update (2) - Authorised (2) - PRD111081 - ProductX comprimido revestido 4 mg
    - Medicinal Product Types (-)
    - Authorised Pharmaceutical Forms (-)
    - Pharmaceutical Products (1)
    - Drug ATCs (1)
    - Drug Indications (1)
    - Previous EV Codes (-)
    - Product Attachments (1)
  - Substances
  - Sources
  - Organisations
  - ATC Codes
  - Pharmaceutical Forms
  - Routes Of Administration
  - Attachments
  - Master File Locations

ProductX

Description	Name/Value
Operation Type	Update (2)
Type	Authorised (2)
EV Code	PRD111081
MAH	PHARMAX LIMITED
QPPV	John Smith (DCMTESTMAH)
Master File Location	
PhV enquiry email	pharmacovig@pharmax.co.uk
PhV enquiry Phone	+44 207 2222222
Sender Local Code	
Info Date	
Authorisation Country Code	Portugal (PT)
Authorisation Procedure	EU authorisation procedures - ...
Authorisation Status	Valid (1)
Authorisation Number	8888/222/333
Authorisation/Renewal Date	30/06/2014
MRP/DCP/EMA Number	
EU Number	
Legal Basis	Medicinal product authorised a...
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	ProductX comprimido revestido ...
Product Short Name	ProductX

Modify the information within the entity as requested, validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID and if the update submission was successful, will display the following message:

```

<operationtype>2</operationtype>
<operationresult>4</operationresult>
<operationresultdesc>Entity updated successfully</operationresultdesc>
</reportacknowledgment>
  
```

### 3.4.2. Variation of a medicinal product in the XEVMPD

To notify the EMA of a variation of an authorised medicinal product entry in the XEVMPD, you have to be the XEVMPD owner of the medicinal product information (i.e. you are the organisation that has submitted the initial information on the authorised product). The system will check the ownership of the information before allowing you to perform the variation.

Variations on medicinal product entries are currently to be performed using operation type 'Update (2)' as per the individual processes and principles described in [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section 2. *Maintenance of medicinal product data*, and specifically section [2.2.3.1. Variations of marketing authorisation](#).

### 3.4.3. Nullification of an entity in the XEVMPD

Operation type 'Nullification (4)' should be used whenever an entity that you previously submitted and for which an EV Code exists, needs to be nullified.

Operation type 'Nullification (4)' should be used when:

- An entity was submitted by a mistake;
- An entity was identified as a duplicate;
- An entity is obsolete and will not be used in any future submissions.

The information concerning medicinal products (authorised or development), substances (approved or development), sources, organisations (MAH or sponsor), ATC codes (proposed or development), routes of administration (proposed or development), pharmaceutical forms (proposed or development), master file locations, can be only nullified by the organisation (MAH or sponsor) that has provided the initial information. The XEVMPD will check the ownership of the information before allowing any modification in the dictionary.

Nullification of approved substances can only be performed by the EMA upon request sent to [MDMS@ema.europa.eu](mailto:MDMS@ema.europa.eu).

The nullification of XEVMPD entities is not allowed in the XEVMPD if the entity is referenced in any other entry (e.g. AMP).

Please note that entries are never deleted from the XEVMPD, they are flagged as "nullified", which means "non current".

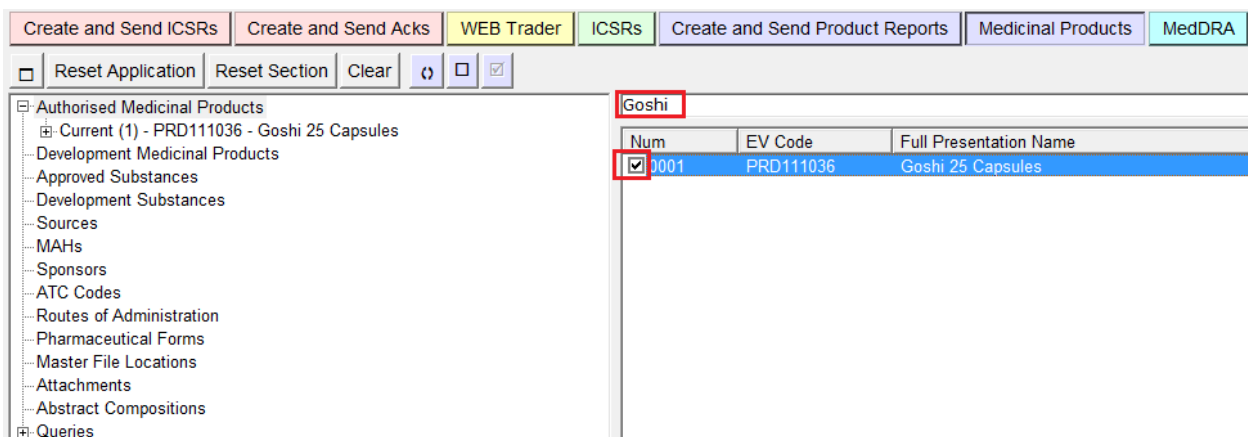
For related information, please see [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section [2.3.4. Nullification of duplicated/obsolete XEVMPD entities](#).

#### 3.4.3.1. Create an XEVPRM with operation type "Nullification (4)"

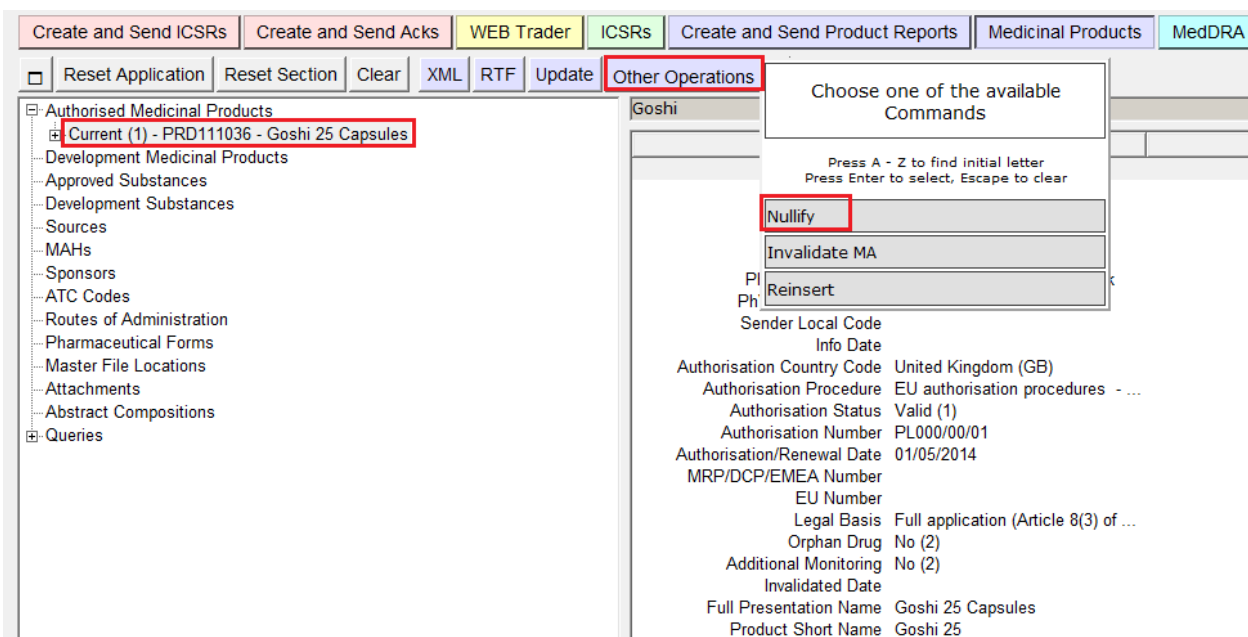
To nullify an entity, the entity:

- must be already present in the XEVMPD (i.e. an EV Code has been assigned);
- must not be referenced in any other entity;
- must not be already nullified.

Retrieve the entity you wish to nullify in the XEVMPD using either simple or advanced query. In the below example, we will be nullifying an AMP entity as it was submitted as a duplicate of another AMP by mistake:



Select the entity which you wish to nullify and in "Other Operations", click on operation type "Nullify":



Your AMP entity is moved from the "Medicinal product" section to the "Create and Send Product Reports" section. The operation type is selected as "Nullification".

[Create and Send ICSRs](#) | [Create and Send Acks](#) | [WEB Trader](#) | [ICSRs](#) | [Create and Send Product Reports](#) | [Medicinal Products](#) | [MedDRA](#)

[Reset Application](#) | [Reset Section](#) | [Clear](#) | [Replicate](#) | [Validate](#) | [Send](#) | [XML](#) | [ZIP](#) | [RTF](#) | [Remove](#) | [E](#) | [L](#) | [R](#)

**XEVPRM Message**

- Products
  - Nullification (4) - Authorised (2) - PRD111036 - Goshi 25 Capsules
    - Medicinal Product Types (-)
    - Authorised Pharmaceutical Forms (-)
    - Pharmaceutical Products (1)
    - Drug ATCs (1)
    - Drug Indications (1)
    - Previous EV Codes (-)
    - Product Attachments (1)
  - Substances
  - Sources
  - Organisations
  - ATC Codes
  - Pharmaceutical Forms
  - Routes Of Administration
  - Attachments
  - Master File Locations

**Goshi**

Description	Name/Value
Operation Type	Nullification (4)
Type	Authorised (2)
EV Code	PRD111036
MAH	PHARMAX LIMITED
QPPV	John Smith (DCMTESTMAH)
Master File Location	MFL7562 - United Kingdom (G...
PhV enquiry email	pharmacovig@pharmax.co.uk
PhV enquiry Phone	+44 207 2222222
Sender Local Code	
Info Date	
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - ...
Authorisation Status	Valid (1)
Authorisation Number	PL000/00/01
Authorisation/Renewal Date	01/05/2014
MRP/DCP/EMEA Number	
EU Number	
Legal Basis	Full application (Article 8(3) of ...
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	Goshi 25 Capsules
Product Short Name	Goshi 25

Enter the reason for nullification in the "Comment" field, enter the XEVPRM Message number, validate the XEVPRM and send:

[Create and Send ICSRs](#) | [Create and Send Acks](#) | [WEB Trader](#) | [ICSRs](#) | [Create and Send Product Reports](#) | [Medicinal Products](#) | [MedDRA](#)

[Reset Application](#) | [Reset Section](#) | [Clear](#) | [Replicate](#) | [Validate](#) | [Send](#) | [XML](#) | [ZIP](#) | [RTF](#) | [Remove](#) | [E](#) | [L](#) | [R](#)

**XEVPRM Message**

- Products
  - Nullification (4) - Authorised (2) - PRD111036 - Goshi 25 Capsules
    - Medicinal Product Types (-)
    - Authorised Pharmaceutical Forms (-)
    - Pharmaceutical Products (1)
    - Drug ATCs (1)
    - Drug Indications (1)
    - Previous EV Codes (-)
    - Product Attachments (1)
  - Substances
  - Sources
  - Organisations
  - ATC Codes
  - Pharmaceutical Forms
  - Routes Of Administration
  - Attachments
  - Master File Locations

**Goshi**

Description	Name/Value
Type	Authorised (2)
EV Code	PRD111036
MAH	PHARMAX LIMITED
QPPV	John Smith (DCMTESTMAH)
Master File Location	MFL7562 - United Kingdom (GB) - London
PhV enquiry email	pharmacovig@pharmax.co.uk
PhV enquiry Phone	+44 207 2222222
Sender Local Code	
Info Date	
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - National Procedure (4)
Authorisation Status	Valid (1)
Authorisation Number	PL000/00/01
Authorisation/Renewal Date	01/05/2014
MRP/DCP/EMEA Number	
EU Number	
Legal Basis	Full application (Article 8(3) of Directive No 2001/83/EC) (1)
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	Goshi 25 Capsules
Product Short Name	Goshi 25
Product INN/Common Name	
Product Company Name	
Product Strength Name	
Product Form Name	CAPSULES
Package Description	
Comment	Duplicate Medicinal Product Types (-)

[Create and Send ICSRs](#)
[Create and Send Acks](#)
[WEB Trader](#)
[ICSRs](#)
[Create and Send Product Reports](#)
[Medicinal Products](#)
[MedDRA](#)

XEVPRM Message
 

Description	Name/Value
Message Number	Nullification PRD111036
	Products
	Substances
	Sources
	Organisations
	ATC Codes
	Pharmaceutical Forms
	Routes Of Administration
	Attachments
	Master File Locations

Products
 

- Nullification (4) - Authorised (2) - PRD111036 - Goshi 25 Capsules
  - Medicinal Product Types (-)
  - Authorised Pharmaceutical Forms (-)
  - Pharmaceutical Products (1)
  - Drug ATCs (1)
  - Drug Indications (1)
  - Previous EV Codes (-)
  - Product Attachments (1)
- Substances
- Sources
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Routes Of Administration
- Attachments
- Master File Locations

The XEVPRM acknowledgement will be sent to the sender organisation ID and if the nullification submission was successful, the following message will be displayed:

```

- <reportacknowledgment>
  <reportname>AUTHORISEDPRODUCT</reportname>
  <localnumber />
  <ev_code>PRD111036</ev_code>
  <operationtype>4</operationtype>
  <operationresult>3</operationresult>
  <operationresultdesc>Entity nullified successfully</operationresultdesc>
</reportacknowledgment>
  
```

### 3.4.4. Revocation/Withdrawal of product entity in the XEVMPD

This function applies only to Authorised Medicinal Products.

This function should be used whenever an authorised medicinal product that you have previously transmitted is revoked/withdrawn. You can provide the information on the revocation/withdrawal by sending an XEVPRM with the operation type 'Invalidate MA (6)'.

The information on the revocation/withdrawal of an authorised medicinal product can be only provided by the organisation that has sent the initial information. The XEVMPD will check the ownership of the information before allowing any modification in the XEVMPD.

Please note that withdrawn entries are never deleted from the XEVMPD – their authorisation status is set as "Not valid".

For related information, principles and processes to be followed please refer to [Chapter 3.11: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section 2. *Maintenance of medicinal product data* and specifically section 2.2.3.5. *Revocation/Withdrawal of Marketing Authorisation (MA)*.

#### 3.4.4.1. Create a Product Report with Operation Type 'Invalidate MA (6)'

In the below example, we will modify an AMP to flag that the medicinal product was withdrawn from the market by the marketing authorisation holder.

Retrieve and select the AMP entity you wish to flag as "withdrawn from the market":

The screenshot shows the XEVPRM interface with the 'Medicinal Products' section selected. The 'Current (1) - PRD111058 - DrugVero Ibuprofen Forte 400 mg Liquid Capsules' entity is highlighted in the list. The 'DrugVero' table below shows the following data:

Num	EV Code	Full Presentation Name
<input checked="" type="checkbox"/> 0001	PRD111058	DrugVero Ibuprofen Forte 400 mg Liquid Capsules

Select the entity and click on operation type "Invalidate MA" under "Other operations":

The screenshot shows the XEVPRM interface with the 'Other Operations' menu open. The 'Invalidate MA' option is selected. The 'Current (1) - PRD111058 - DrugVero Ibuprofen Forte 400 mg Liquid Capsules' entity is highlighted in the list. The 'Other Operations' menu shows the following options:

- Nullify
- Invalidate MA**
- Reinsert

The 'DrugVero' table below shows the following data:

Sender Local Code	Info Date
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - ...
Authorisation Status	Valid (1)
Authorisation Number	1234/5678/111
Authorisation/Renewal Date	07/02/2013
MRP/DCP/EMA Number	SE/H/1111/222
EU Number	
Legal Basis	Full application (Article 8(3) of ...
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	DrugVero Ibuprofen Forte 400 ...
Product Short Name	DrugVero Forte

Your AMP entity is moved from the "Medicinal product" section to the "Create and Send Product Reports" section. The operation type is selected as 'Invalidate MA (6)'.

As per the principles and processes to be followed in case of a withdrawal of an AMP provided in [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#), section 2. *Maintenance of medicinal product data* and specifically section 2.2.3.5. *Revocation/Withdrawal of Marketing Authorisation (MA)*:

- The date of revocation or withdrawal must be specified in the data element "Invalidated date" (AP.12.12);
- One of the "Not Valid" statuses must be specified (as applicable) in the data element "Authorisation status" (AP.12.3) before sending the XEVPRM.

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

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

XEVPRM Message

Products
 

- Invalidate MA (6) - Authorised (2) - PRD111058 - DrugVero Ibuprofen Forte 400 m
  - Medicinal Product Types (-)
  - Authorised Pharmaceutical Forms (-)
  - Pharmaceutical Products (1)
  - Drug ATCs (1)
  - Drug Indications (1)
  - Previous EV Codes (-)
  - Product Attachments (1)
- Substances
- Sources
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Routes Of Administration
- Attachments
- Master File Locations

DrugVero

Description	Name/Value
Operation Type	Invalidate MA (6)
Type	Authorised (2)
EV Code	PRD111058
MAH	PHARMAX LIMITED
QPPV	John Smith (DCMTESTMAH)
Master File Location	
PhV enquiry email	pharmacovig@pharmax.co.uk
PhV enquiry Phone	+44 207 2222222
Sender Local Code	
Info Date	
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - Mutual Recognition Procedure (3)
Authorisation Status	1 (1) Value not Acceptable
Authorisation Number	1234/5678/111
Authorisation/Renewal Date	07/02/2013
MRP/DCP/EMEA Number	SE/H/1111/222
EU Number	
Legal Basis	Full application (Article 8(3) of Directive No 2001/83/EC) (1)
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	
Full Presentation Name	DrugVero Ibuprofen Forte 400 mg Liquid Capsules
Product Short Name	DrugVero Forte
Product INN/Common Name	Ibuprofen
Product Company Name	
Product Strength Name	400 MG
Product Form Name	LIQUID CAPSULES
Package Description	
Comment	

As per our specific example (i.e. withdrawal from the market by the MAH), the following fields must be modified:

- The "Authorisation Status" field must be amended to 'Not valid - Withdrawn by marketing authorisation holder (3)';
- The "Invalidated date" field must be amended to contain the date of expiry of the marketing authorisation.

Modify the fields, enter the message number, validate and send the XEVPRM.

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

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

XEVPRM Message

Products
 

- Invalidate MA (6) - Authorised (2) - PRD111058 - DrugVero Ibuprofen Forte 400 m
  - Medicinal Product Types (-)
  - Authorised Pharmaceutical Forms (-)
  - Pharmaceutical Products (1)
  - Drug ATCs (1)
  - Drug Indications (1)
  - Previous EV Codes (-)
  - Product Attachments (1)
- Substances
- Sources
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Routes Of Administration
- Attachments
- Master File Locations

DrugVero

Description	Name/Value
Operation Type	Invalidate MA (6)
Type	Authorised (2)
EV Code	PRD111058
MAH	PHARMAX LIMITED
QPPV	John Smith (DCMTESTMAH)
Master File Location	
PhV enquiry email	pharmacovig@pharmax.co.uk
PhV enquiry Phone	+44 207 2222222
Sender Local Code	
Info Date	
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - Mutual Recognition Procedure (3)
Authorisation Status	Not Valid - Withdrawn by Marketing Authorisation Holder (3)
Authorisation Number	1234/5678/111
Authorisation/Renewal Date	07/02/2013
MRP/DCP/EMEA Number	SE/H/1111/222
EU Number	
Legal Basis	Full application (Article 8(3) of Directive No 2001/83/EC) (1)
Orphan Drug	No (2)
Additional Monitoring	No (2)
Invalidated Date	08/04/2014
Full Presentation Name	DrugVero Ibuprofen Forte 400 mg Liquid Capsules
Product Short Name	DrugVero Forte
Product INN/Common Name	Ibuprofen
Product Company Name	
Product Strength Name	400 MG
Product Form Name	LIQUID CAPSULES
Package Description	
Comment	

Medicinal Product Types (-) Section is Mandatory  
 Authorised Pharmaceutical Forms (-) Section is Mandatory  
 Pharmaceutical Products (1)  
 Drug ATCs (1)  
 Drug Indications (1)  
 Previous EV Codes (-)

The XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, the following message will be displayed:



```
- <reportacknowledgment>
  <reportname>AUTHORISEDPRODUCT</reportname>
  <localnumber />
  <ev_code>PRD111068</ev_code>
  <operationtype>6</operationtype>
  <operationresult>29</operationresult>
  <operationresultdesc>Entity withdrawn successfully</operationresultdesc>
</reportacknowledgment>
```

### 3.4.5. Transfer of marketing authorisation of a product entity


This function applies to Authorised Medicinal Products.

Only the owner of the AMP entity in the XEVMPD (i.e. the organisation that has provided the initial information) can modify an existing AMP entry to notify a transfer of marketing authorisation.

Please refer to the detailed information and processes described in [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance, section 2.2.3.3. Transfer of marketing authorisation.](#)

### 3.5. Validation of an XEVPRM

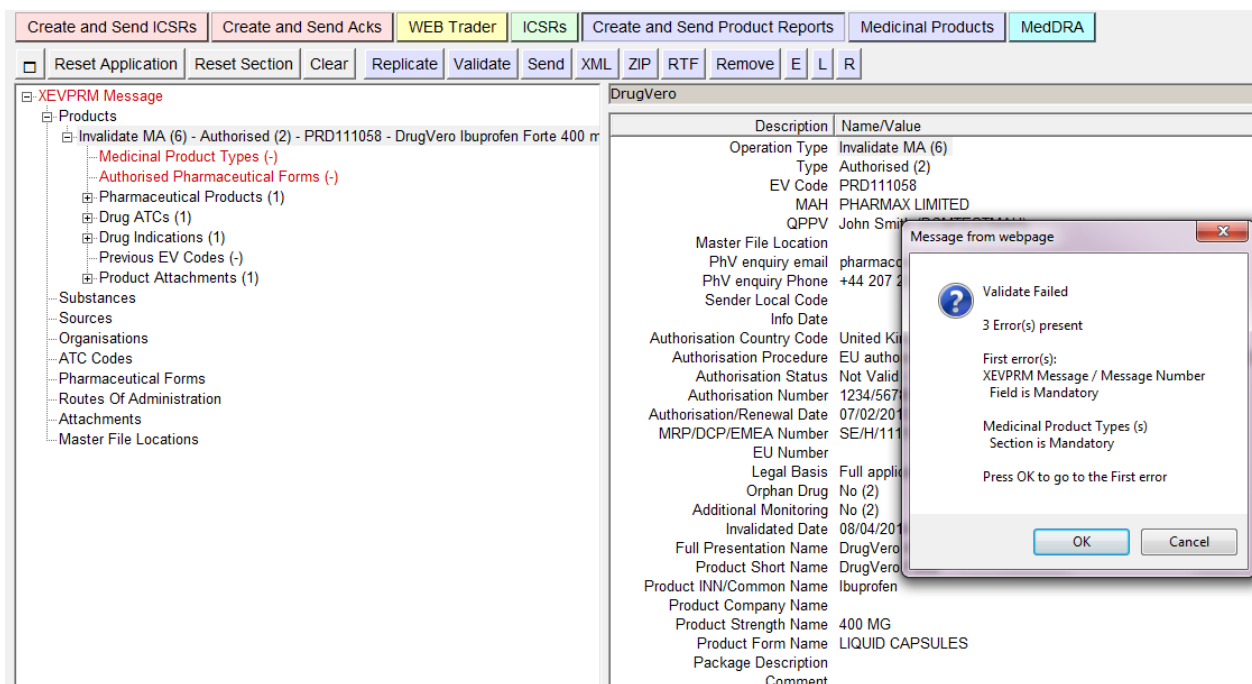
Once you have created an XEVPRM containing all the information that you wish to send, you should validate the information.

 Click on "validate" button from the dynamic button set. The system automatically checks all the information in the message.

A pop-up window will confirm the correct validation or highlight errors or missing information.

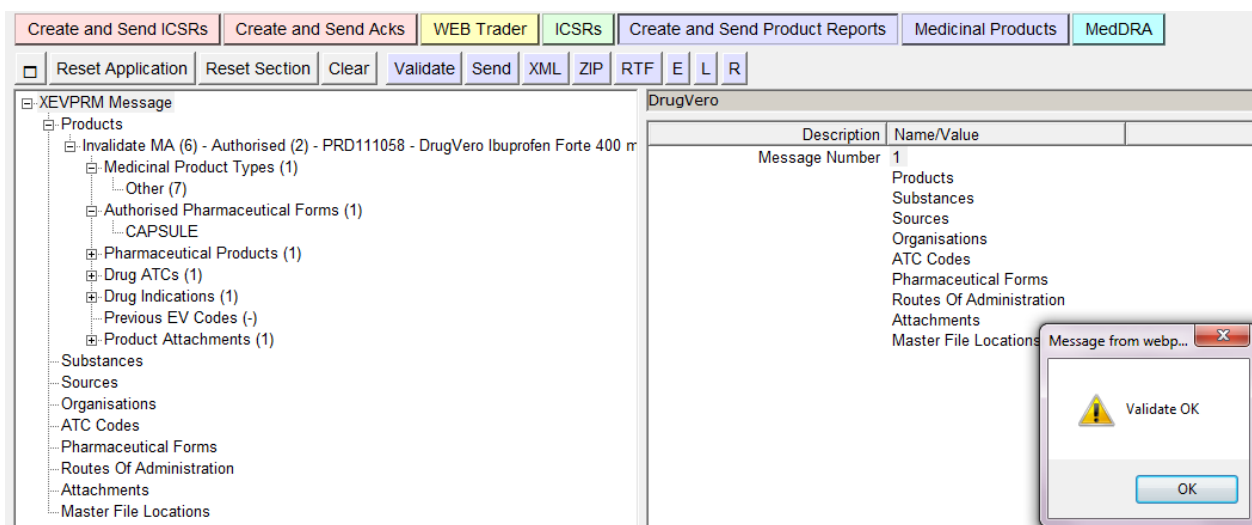
If the message does not contain all the mandatory information or errors are detected, EVWEB will automatically present a pop-up window listing them.

The pop-up window will describe the total number of errors detected and the description of the first error encountered.



After the correction of the first error, by clicking on the "validate" button from the dynamic button set, EVWEB will show the next error encountered. This way, the EVWEB takes you through the mandatory fields where information is missing and the errors occurred.

When the XEVPRM does not contain any errors and all the mandatory fields have been specified, the validation will be declared successful.



### 3.6. Save, Reload and Send an XEVPRM

Once you have created and validated XEVPRM, you have the possibility to save the message as an XML file or a RTF file.

Click on "XML" button from the dynamic button set and save the XEVPRM as XML file.



Alternatively, click on the "RTF" button from the dynamic button set as RTF file.



If you have created but not completed an XEVPRM and you have saved the XML file locally, you can reload the incomplete XEVPRM and then continue with the completion of the data. Please refer to 2.11.3. *Reloading an XEVPRM*, for a detailed description on how you can reload an incomplete XEVPRM in the "Send Product" section.

Once you have completed the XEVPRM you can submit it to the XEVMPD.

To send the XEVPRM to XEVMPD, click on the "send" button from the dynamic button set.



### **3.7. How to Use EV Post**

If you are a Web Trader– Post Function User, it is possible to send XEVPRM using the EVPost function.

Log in to EudraVigilance restricted area with your username and password.

Click on EVPost.



Select the XEVPRM xml or ZIP file from your computer:

**::: Choose the file to send :::**

[➤ Send](#)

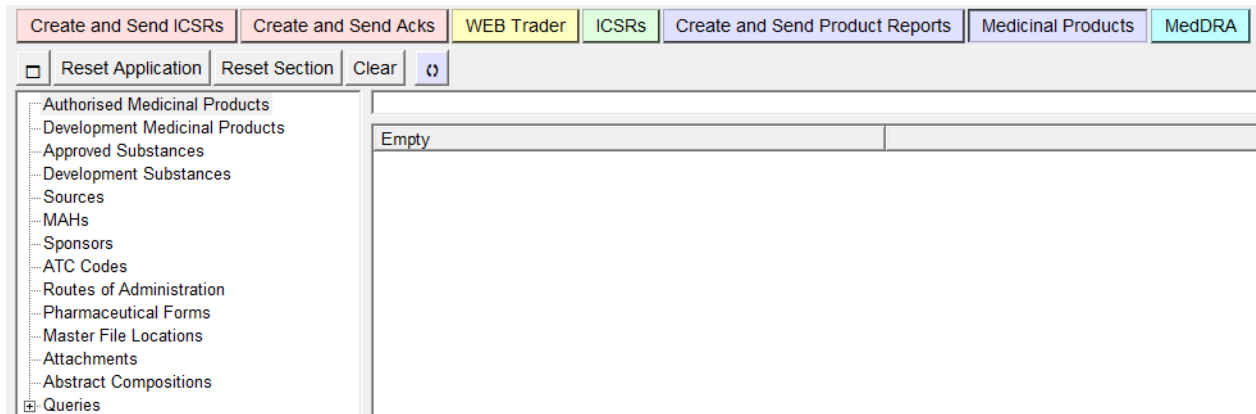
## 4. XEVMPD

### 4.1. Accessing the XEVMPD

To access the XEVMPD click on the "Medicinal Products" or "Products" button (depending on your screen set up) on the main menu.



The Medicinal Products section displays a tree view area on the left side of your screen, and an active area on the right side of the screen.



The tree view area displays a list of items you can use to navigate the information in the Product Report Database and in the Scientific Product Database.

### 4.2. Simple queries in the XEVMPD

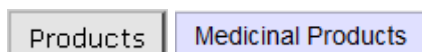
Information on how to perform simple queries is available in section [2.7.1. Simple query](#).

The following example shows how to perform a simple query in the "Medicinal Products" section of the application.



When searching for an **authorised medicinal product** using a simple query, please note that only authorised medicinal products submitted in the XEVPRM (i.e. Article 57) format, as per 57(2) requirements, will be displayed. To search for authorised medicinal products submitted to the XEVMPD in the EVPRM (i.e. Pre-Article 57) format, please use the "Advanced Queries" section - the condition "Pre Article 57 format (2)" must be selected.

Click on the "Medicinal Products" (or "Products", depending on your set-up) button on the main menu to enter the section.



Type the name (or part of the name) of the medicinal product you are searching for in the simple query field and press the "Enter" key on your keyboard. The active area will display your results as a checklist.

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

Reset Application  Reset Section

- Authorised Medicinal Products
- Development Medicinal Products
- Approved Substances
- Development Substances
- Sources
- MAHs
- Sponsors
- ATC Codes
- Routes of Administration
- Pharmaceutical Forms
- Master File Locations
- Attachments
- Abstract Compositions
- Queries

DrugVero		
Num	EV Code	Full Presentation Name
<input type="checkbox"/> 0001	PRD111058	DrugVero Ibuprofen Forte 400 mg Liquid Capsules

To view the item(s) in the tree view area, the item(s) must be selected:

Num	EV Code	Full Presentation Name	Short Name
<input checked="" type="checkbox"/> 0001	PRD111058	DrugVero Ibuprofen Forte 400 mg Liquid Capsules	DrugVero Forte

Following the selection, the item is displayed in the tree view area. Expanding the menu on the left side of the items allows you to navigate through the information available in the Product Report Database.

If you keep expanding the menus of each item in the tree view area, you can access all the information available on that product.

Clicking on each item in the tree view area displays the relevant information in the active area:

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

Reset Application  Reset Section

- Authorised Medicinal Products
  - Current (1) - PRD111058 - DrugVero Ibuprofen Forte 400 mg Liquid Capsules
    - MAH: ORG4195 - PHARMAX LIMITED
    - QPPV: John Smith (DCMTESTMAH)
    - Medicinal Product Types (-)
    - Authorised Pharmaceutical Forms (-)
    - Pharmaceutical Products (1)
      - CAPSULE, SOFT
        - Drug Routes (1)
          - ORAL USE
        - Drug Ingredients (2)
          - IBUPROFEN - Active Ingredient (1)
          - PINK COLOUR (E127) - Excipient (2)
        - Old Drug Ingredients (-)
        - Medical Devices (-)
        - Original Abstract Pharmaceutical Products (...)
        - Original Abstract Pharmaceutical Products (Sym) (...)
        - Abstract Pharmaceutical Products (...)
        - Abstract Pharmaceutical Products (Sym) (...)
      - Drug ATCs (1)
      - Drug Indications (1)
      - Previous EV Codes (-)
      - Product Attachments (1)
      - Reporting Names (...)

DrugVero		
Num	EV Code	Full Presentation Name
<input checked="" type="checkbox"/> 0001	PRD111058	DrugVero Ibuprofen Forte 400 mg Liquid Capsules

By following the steps described above, you can navigate through the information in the Product Report Database and in the Scientific Database from different starting points (Substances, MAHs, Sources, Abstract Compositions).

### 4.2.1. Exporting results of a simple query

There are two options how to export the AMP entity/entities displayed as a result of a simple query:

- XML file
- RTF file

See section 2.12. *Export functions* for related information.

As an example, following a simple query, our AMP is displayed in the tree view area:

The screenshot shows the EMA interface with a tree view on the left and a detailed view on the right. The tree view is expanded to show 'Current (1) - PRD111058 - DrugVero Ibuprofen Forte 400 mg Liquid Capsules'. The detailed view shows the following information:

Description	Name/Value
Checked	No
Cleaned	No
Nullified	No
EV Code	PRD111058
Category	
PhV enquiry email	pharmacovig@pharmax.co.uk
PhV enquiry Phone	+44 207 2222222
Sender Local Code	
Info Date	
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - ...
Authorisation Status	Valid (1)

To export the AMP as an **XML file**, select the "XML" from the main menu. A pop-up window will be displayed:

The pop-up window titled "Summary" has a yellow background. It contains the following text:

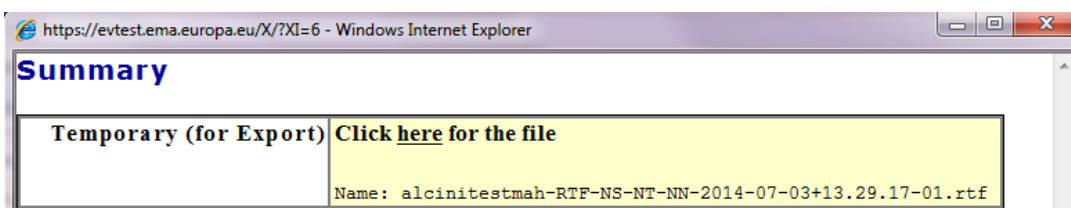
**Temporary (for Export)** [Click here for the file](#)  
Name: alcinitestmah-Export-DCMTESTMAH-XEVPRM-ProductMessage-2014-07-03+13.25.42-C

Clicking on "here" will enable you to view and save the file on your computer in an XML format:

The screenshot shows a web browser displaying the XML content of the exported file. The XML is as follows:

```
<?xml version="1.0" encoding="UTF-16" ?>
- <evprm xmlns="http://eudravigilance.ema.europa.eu/schema/emaxevmpd"
  xmlns:ssi="http://eudravigilance.ema.europa.eu/schema/emaxevmpd_ssi"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xsi:schemaLocation="http://eudravigilance.ema.europa.eu/schema/emaxevmpd
  http://eudravigilance.ema.europa.eu/schema/emaxevmpd.xsd">
- <ichicsrmessageheader>
  <messagetype>XEVPRM</messagetype>
  <messageformatversion>2</messageformatversion>
  <messageformatrelease>0</messageformatrelease>
  <messagenumb>ProductMessage</messagenumb>
  <messagesenderidentifier>DCMTESTMAH</messagesenderidentifier>
  <messagereceiveridentifier>EVTEST</messagereceiveridentifier>
  <messagedateformat>204</messagedateformat>
  <messagedate>20140703132542</messagedate>
```

To export the AMP in an **RTF format**, select the "RTF" from the main menu. A pop-up window will be displayed:



Clicking on "here" will enable you to view and save the file on your computer in an RTF format:



Authorised Product	
Checked	No
Cleaned	No
Nullified	No
EV Code	PRD111058
PhV enquiry email	pharmacovig@pharmacx.co.uk
PhV enquiry Phone	+44 207 222222
Authorisation Country Code	United Kingdom
Authorisation Procedure	EU authorisation procedures - Mutual Recognition Procedure
Authorisation Status	Valid
Authorisation Number	1234/5678/111
Authorisation/Renewal Date	07/02/2013
MRP/DCP/EMA Number	SE/H/1111/222
Legal Basis	Full application (Article 8(3) of Directive No 2001/83/EC)

### 4.3. Advanced Queries in XEVMPD

Information on how to perform advanced queries is available in section [2.7.2. Advanced Query](#).

The following example shows how to perform an advanced query in the "Authorised Products" sub-section of the "Queries" section of the application.

In this particular example, we will retrieve all medicinal products submitted in Article 57 format and referencing the MAH organisation "PharmaX Ltd.".

- In "Queries", select "Authorised Products"
- In "Conditions", the relevant fields must be selected:
  - In "Article 57 format" field select "Article 57 format (1)":



Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

Reset Application Reset Section Clear E R Run Run to Excel

- Authorised Medicinal Products
- Development Medicinal Products
- Approved Substances
- Development Substances
- Sources
- MAHs
- Sponsors
- ATC Codes
- Routes of Administration
- Pharmaceutical Forms
- Master File Locations
- Attachments
- Abstract Compositions
- Queries
  - Owned EVMPD Entities
  - Authorised Products
    - Fields
    - Conditions (AND)**
    - Results
  - Development Products
  - Substance Names
  - Approved Substance Names
  - Development Substance Names
  - Approved Substances
  - Development Substances
  - Sources
  - MAHs

Description	Name/Value
Article 57 Format	<input checked="" type="checkbox"/> Article 57 Format (1)
Local Number (Matches)	<input type="checkbox"/>
EV Code (Matches)	<input type="checkbox"/>
Has Been Updated	<input type="checkbox"/>
Owner Identifier (Matches)	<input type="checkbox"/>
Checked	<input type="checkbox"/>
Checked and Updated	<input type="checkbox"/>
Cleaned	<input type="checkbox"/>
Cleaned and Updated	<input type="checkbox"/>
Last Update	<input type="checkbox"/>
Last Update (From)	<input type="checkbox"/>
Last Update (Up to)	<input type="checkbox"/>
Nullified	<input type="checkbox"/>
Category	<input type="checkbox"/>
Full Presentation Name (Matches)	<input type="checkbox"/>
Product Short Name (Matches)	<input type="checkbox"/>
Product INN/Common Name (Matches)	<input type="checkbox"/>
Product Strength Name (Matches)	<input type="checkbox"/>
Product Company Name (Matches)	<input type="checkbox"/>
Product Form Name (Matches)	<input type="checkbox"/>
Authorisation Country	<input type="checkbox"/>
Authorisation Procedure	<input type="checkbox"/>
Authorisation Status	<input type="checkbox"/>
Authorisation/Renewal Date (From)	<input type="checkbox"/>
Authorisation/Renewal Date (Up to)	<input type="checkbox"/>
MA Validity	<input checked="" type="checkbox"/> Valid (1)

**!** **NOTE:** As a default, the field "MA validity" is automatically set as "Valid (1)". Should you wish to see also medicinal product entries, which were invalidated, another query must be performed, where the "MA Validity" field is set as "Invalid (2)":

- Authorised Medicinal Products
- Development Medicinal Products
- Approved Substances
- Development Substances
- Sources
- MAHs
- Sponsors
- ATC Codes
- Routes of Administration
- Pharmaceutical Forms
- Master File Locations
- Attachments
- Abstract Compositions
- Queries
  - Owned EVMPD Entities
  - Authorised Products
    - Fields
    - Conditions (AND)
    - Results
  - Development Products
  - Substance Names
  - Approved Substance Names
  - Development Substance Names
  - Approved Substances
  - Development Substances
  - Sources
  - MAHs

Description	Name/Value
Article 57 Format	<input checked="" type="checkbox"/> Article 57 Format (1)
Local Number (Matches)	<input type="checkbox"/>
EV Code (Matches)	<input type="checkbox"/>
Has Been Updated	<input type="checkbox"/>
Owner Identifier (Matches)	<input type="checkbox"/>
Checked	<input type="checkbox"/>
Checked and Updated	<input type="checkbox"/>
Cleaned	<input type="checkbox"/>
Cleaned and Updated	<input type="checkbox"/>
Last Update	<input type="checkbox"/>
Last Update (From)	<input type="checkbox"/>
Last Update (Up to)	<input type="checkbox"/>
Nullified	<input type="checkbox"/>
Category	<input type="checkbox"/>
Full Presentation Name (Matches)	<input type="checkbox"/>
Product Short Name (Matches)	<input type="checkbox"/>
Product INN/Common Name (Matches)	<input type="checkbox"/>
Product Strength Name (Matches)	<input type="checkbox"/>
Product Company Name (Matches)	<input type="checkbox"/>
Product Form Name (Matches)	<input type="checkbox"/>
Authorisation Country	<input type="checkbox"/>
Authorisation Procedure	<input type="checkbox"/>
Authorisation Status	<input type="checkbox"/>
Authorisation/Renewal Date (From)	<input type="checkbox"/>
Authorisation/Renewal Date (Up to)	<input type="checkbox"/>
MA Validity	<input checked="" type="checkbox"/> Invalid (2)

- In "MAH (Code) (Matches)" type in the name of the MAH organisation and select the organisation from the available look-up list:

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

Reset Application Reset Section Clear E R Run Run to Excel

Authorised Medicinal Products  
 Development Medicinal Products  
 Approved Substances  
 Development Substances  
 Sources  
 MAHs  
 Sponsors  
 ATC Codes  
 Routes of Administration  
 Pharmaceutical Forms  
 Master File Locations  
 Attachments  
 Abstract Compositions  
 Queries

Owned EVMPD Entities  
 Authorised Products  
   Fields  
   Conditions (AND)  
   Results  
 Development Products  
 Substance Names  
 Approved Substance Names  
 Development Substance Names  
 Approved Substances  
 Development Substances  
 Sources  
 MAHs  
 Sponsors  
 ATC Codes  
 Routes of Administration  
 Pharmaceutical Forms  
 Abstract Compositions  
 Attachments  
 Master File Locations

DrugVero

Description	Name/Value
Cleaned	<input type="checkbox"/>
Cleaned and Updated	<input type="checkbox"/>
Last Update	<input type="checkbox"/>
Last Update (From)	<input type="checkbox"/>
Last Update (Up to)	<input type="checkbox"/>
Nullified	<input type="checkbox"/>
Category	<input type="checkbox"/>
Full Presentation Name (Matches)	<input type="checkbox"/>
Product Short Name (Matches)	<input type="checkbox"/>
Product INN/Common Name (Matches)	<input type="checkbox"/>
Product Strength Name (Matches)	<input type="checkbox"/>
Product Company Name (Matches)	<input type="checkbox"/>
Product Form Name (Matches)	<input type="checkbox"/>
Authorisation Country	<input type="checkbox"/>
Authorisation Procedure	<input type="checkbox"/>
Authorisation Status	<input type="checkbox"/>
Authorisation/Renewal Date (From)	<input type="checkbox"/>
Authorisation/Renewal Date (Up to)	<input type="checkbox"/>
MA Validity	<input checked="" type="checkbox"/> Valid (1)
Authorisation Number (Matches)	<input type="checkbox"/>
MRP/DCP/EMA Number (Matches)	<input type="checkbox"/>
EU Number (Matches)	<input type="checkbox"/>
Invalidated Date	<input type="checkbox"/>
Invalidated Date (From)	<input type="checkbox"/>
Invalidated Date (Up to)	<input type="checkbox"/>
MAH (Name) (Matches)	<input type="checkbox"/>
MAH (Code) (Matches)	<input checked="" type="checkbox"/>
OPPV	<input type="checkbox"/>

Organisation Name: PharmaX\*  
 Query Mode: Begins

Num	Name	Checked	Sender HQ Name	Sender Name
0001	PHARMAX LIMITED		EMA	EMA

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

Reset Application Reset Section Clear E R Run Run to Excel

Authorised Medicinal Products  
 Development Medicinal Products  
 Approved Substances  
 Development Substances  
 Sources  
 MAHs  
 Sponsors  
 ATC Codes  
 Routes of Administration  
 Pharmaceutical Forms  
 Master File Locations  
 Attachments  
 Abstract Compositions  
 Queries

Owned EVMPD Entities  
 Authorised Products  
   Fields  
   Conditions (AND)  
   Results  
 Development Products  
 Substance Names  
 Approved Substance Names  
 Development Substance Names  
 Approved Substances  
 Development Substances  
 Sources  
 MAHs  
 Sponsors  
 ATC Codes  
 Routes of Administration  
 Pharmaceutical Forms  
 Abstract Compositions  
 Attachments  
 Master File Locations

DrugVero

Description	Name/Value
Article 57 Format	<input checked="" type="checkbox"/> Article 57 Format (1)
Local Number (Matches)	<input type="checkbox"/>
EV Code (Matches)	<input type="checkbox"/>
Has Been Updated	<input type="checkbox"/>
Owner Identifier (Matches)	<input type="checkbox"/>
Checked	<input type="checkbox"/>
Checked and Updated	<input type="checkbox"/>
Cleaned	<input type="checkbox"/>
Cleaned and Updated	<input type="checkbox"/>
Last Update	<input type="checkbox"/>
Last Update (From)	<input type="checkbox"/>
Last Update (Up to)	<input type="checkbox"/>
Nullified	<input type="checkbox"/>
Category	<input type="checkbox"/>
Full Presentation Name (Matches)	<input type="checkbox"/>
Product Short Name (Matches)	<input type="checkbox"/>
Product INN/Common Name (Matches)	<input type="checkbox"/>
Product Strength Name (Matches)	<input type="checkbox"/>
Product Company Name (Matches)	<input type="checkbox"/>
Product Form Name (Matches)	<input type="checkbox"/>
Authorisation Country	<input type="checkbox"/>
Authorisation Procedure	<input type="checkbox"/>
Authorisation Status	<input type="checkbox"/>
Authorisation/Renewal Date (From)	<input type="checkbox"/>
Authorisation/Renewal Date (Up to)	<input type="checkbox"/>
MA Validity	<input checked="" type="checkbox"/> Valid (1)
Authorisation Number (Matches)	<input type="checkbox"/>
MRP/DCP/EMA Number (Matches)	<input type="checkbox"/>
EU Number (Matches)	<input type="checkbox"/>
Invalidated Date	<input type="checkbox"/>
Invalidated Date (From)	<input type="checkbox"/>
Invalidated Date (Up to)	<input type="checkbox"/>
MAH (Name) (Matches)	<input type="checkbox"/>
MAH (Code) (Matches)	<input checked="" type="checkbox"/> PHARMAX LIMITED

➤ Click "Run"

The list of valid AMP entries referencing "PharmaX Limited" will be displayed:

The screenshot shows the XEVMPD Data-Entry Tool interface. At the top, there are several tabs: "Create and Send ICSRs", "Create and Send Acks", "WEB Trader", "ICSRs", "Create and Send Product Reports", "Medicinal Products", and "MedDRA". Below the tabs is a menu bar with options: "Reset Application", "Reset Section", "Clear", "ReRun", "Modify", "Delete", "Excel", "Export", "Reload", "Load", and a search icon. On the left side, there is a tree view of the application structure, including "Authorised Medicinal Products", "Development Medicinal Products", "Approved Substances", "Development Substances", "Sources", "MAHs", "Sponsors", "ATC Codes", "Routes of Administration", "Pharmaceutical Forms", "Master File Locations", "Attachments", "Abstract Compositions", "Queries", "Owned EVMPD Entities", "Authorised Products", "Fields", "Conditions (AND)", "Results", and "Result 02 July 2014 12:15:23". The main area displays a table of AMP entries:

Num	EV Code	Owner Identifier	Checked	Cleaned	Nullified	Category	Full Presentation Name	Product Short Name	MAH Name
<input type="checkbox"/> 0001	PRD111036	DCMTESTMAH	No	No	No		Goshi 25 Capsules	Goshi 25	PHARMAX LIMITED
<input type="checkbox"/> 0002	PRD111058	DCMTESTMAH	No	No	No		DrugVero Ibuprofen F...	DrugVero Forte	PHARMAX LIMITED

The fields visible in the active area will display the fields set up as default (see section [2.7.2.1. Fields section](#)):

Num	EV Code	Owner Identifier	Checked	Cleaned	Nullified	Category	Full Presentation Name	Product Short Name	MAH Name
<input type="checkbox"/> 0001	PRD111036	DCMTESTMAH	No	No	No		Goshi 25 Capsules	Goshi 25	PHARMAX LIMITED
<input type="checkbox"/> 0002	PRD111058	DCMTESTMAH	No	No	No		DrugVero Ibuprofen F...	DrugVero Forte	PHARMAX LIMITED

As a follow-up, we would also like to see the authorisation country/procedure/status/number in our overview. In order to achieve this, we must go back to the "Fields" section and on top of our last selection, select those additional fields:

The screenshot shows the 'Fields' selection panel in the XEVMPD interface. The 'Fields' section is highlighted in red. The following fields are checked:

- EV Code (Last selection)
- Owner Identifier (Last selection)
- Checked (Last selection)
- Cleaned (Last selection)
- Nullified (Last selection)
- Category (Last selection)
- Full Presentation Name (Last selection)
- Product Short Name (Last selection)
- Authorisation Country
- Authorisation Procedure
- Authorisation Status
- Authorisation Number
- MAH Name (Last selection)
- Is Updatable (Last selection)
- Is Nullifiable (Last selection)

We then run the query again. The result now shows the additionally selected fields:

Num	EV Code	Owner Identifier	Checked	Cleaned	Nullified	Category	Full Presentation Name	Product Short Name	MAH Name	Authorization Country	Authorisation Proceed	Authorisation Status	Authorisation Number
E 001	PRD111058	DCMESTMAH	No	No	No		Gosh 25 Capsules	Gosh 25	PHARMAX LIMITED	United Kingdom (GB)	EU authorization proc.	Valid (1)	PL000/00/01
	0002	PRD111036	DCMESTMAH	No	No		Gosh 25 Capsules	Gosh 25	PHARMAX LIMITED	United Kingdom (GB)	EU authorization proc.	Valid (1)	PL000/00/01

### 4.3.1. Exporting results of an advanced query

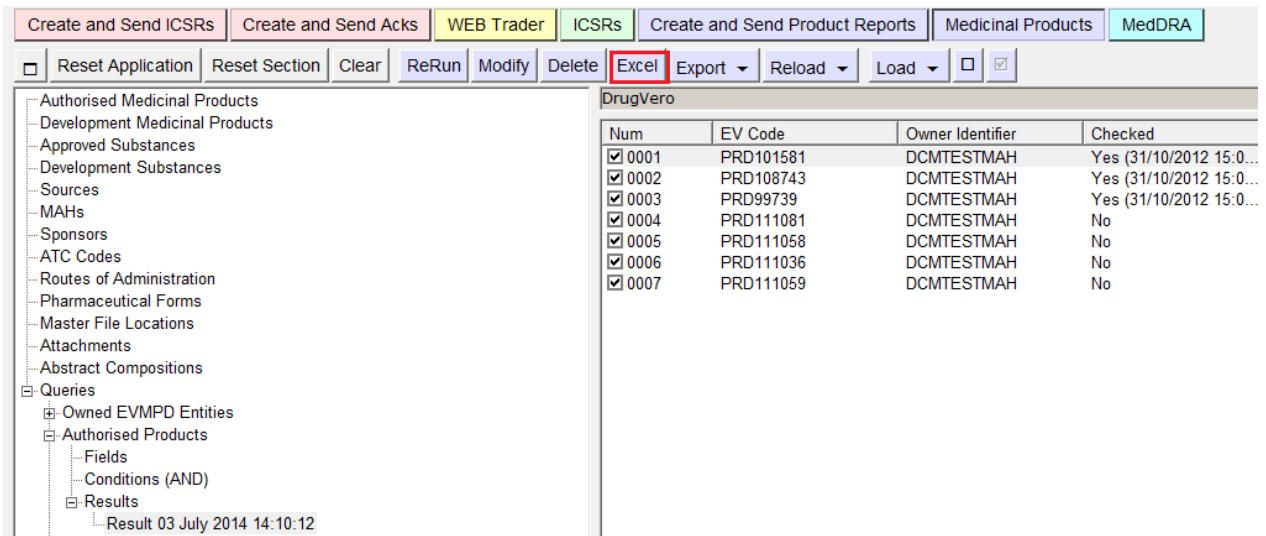
There are several options how to export the AMP entity/entities displayed as a result of an advance query:

- Excel spread sheet
- One or multiple XML file(s)
- One or multiple RTF file(s)

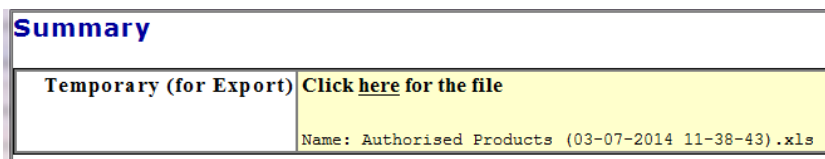
See section 2.12. *Export functions* for related information.

As an example, following an advanced query, list of AMPs is displayed in the active area.

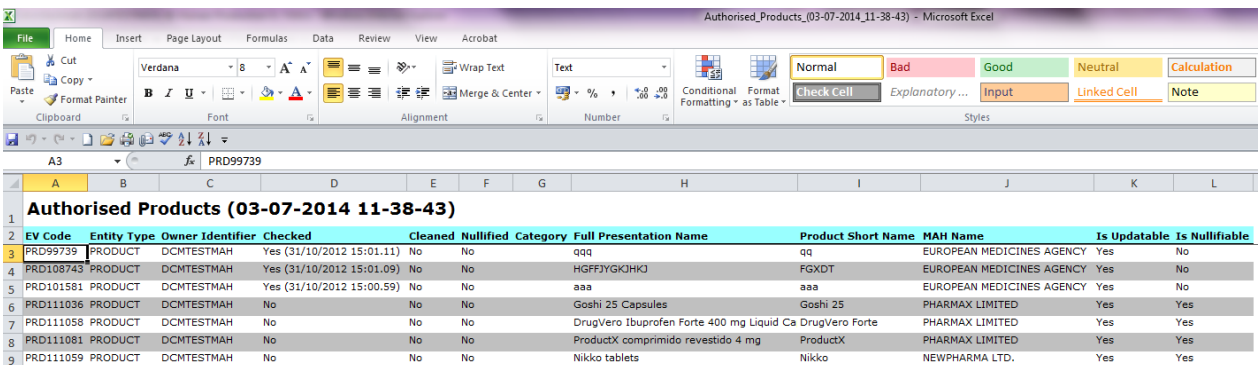
To export the selected AMP entities in an **Excel spreadsheet** select "Excel" from the main menu.



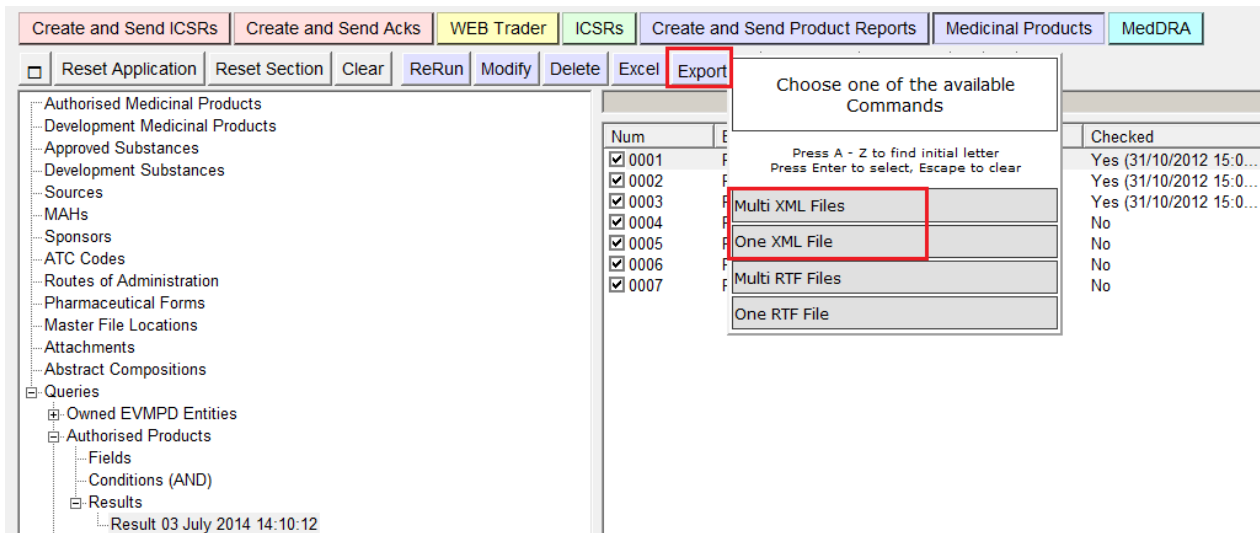
A pop-up window will be displayed:



You can then download the file to view or save on your computer:



To export the selected AMP entities as an **XML file** select "One XML File" (one XML file will be created for all selected entities) or "Multi XML Files" (one XML file will be created for each selected entity) from the main menu, under "Export":



Depending on the selected option, a pop-up window with multiple files or one file will be displayed:

If "Multi XML Files" was selected:

#### Summary

Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinitestmah-Export-DCMTESTMAH-XEVPRM-ProductMessage-2014-07-03+14.19.21-01.xml
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinitestmah-Export-DCMTESTMAH-XEVPRM-ProductMessage-2014-07-03+14.19.21-02.xml
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinitestmah-Export-DCMTESTMAH-XEVPRM-ProductMessage-2014-07-03+14.19.21-03.xml
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinitestmah-Export-DCMTESTMAH-XEVPRM-ProductMessage-2014-07-03+14.19.21-04.xml
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinitestmah-Export-DCMTESTMAH-XEVPRM-ProductMessage-2014-07-03+14.19.21-05.xml
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinitestmah-Export-DCMTESTMAH-XEVPRM-ProductMessage-2014-07-03+14.19.21-06.xml
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinitestmah-Export-DCMTESTMAH-XEVPRM-ProductMessage-2014-07-03+14.19.21-07.xml

If "One XML file" was selected:

#### Summary

Temporary (for Export)	Click <a href="#">here</a> for the file Name: Authorised Products.xls
------------------------	--

You can then download the file/files to view or save on your computer:

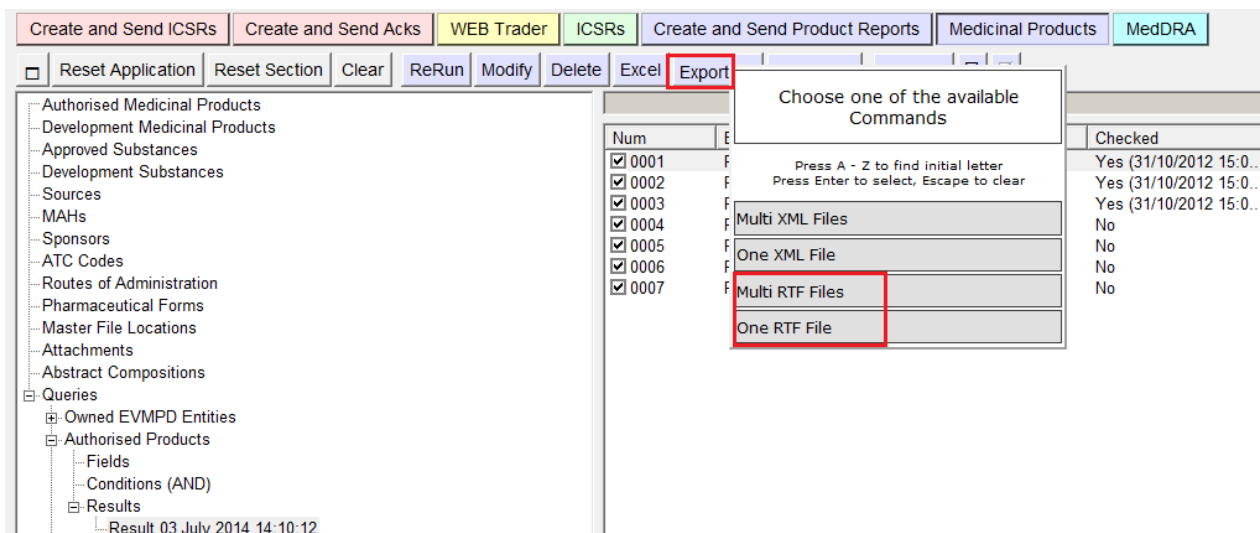
```

https://evtest.ema.europa.eu/X/Export.asp?EBC7F98C-3700-402F-BDDF-1B6210D7124A - Windows Internet Explorer
File Edit View Favorites Tools Help

<?xml version="1.0" encoding="UTF-16" ?>
- <evprm xmlns="http://eudravigilance.ema.europa.eu/schema/emaxevmpd"
  xmlns:ssi="http://eudravigilance.ema.europa.eu/schema/emaxevmpd_ssi"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xsi:schemaLocation="http://eudravigilance.ema.europa.eu/schema/emaxevmpd
  http://eudravigilance.ema.europa.eu/schema/emaxevmpd.xsd">
- <ichicrsmessageheader>
  <messagetype>XEVPRM</messagetype>
  <messageformatversion>2</messageformatversion>
  <messageformatrelease>0</messageformatrelease>
  <messagenum>ProductsMessage</messagenum>
  <messagesenderidentifier>DCMTESTMAH</messagesenderidentifier>
  <messagereceiveridentifier>EVTEST</messagereceiveridentifier>
  <messageformat>204</messageformat>
  <messageformat>204</messageformat>
  <messageformat>204</messageformat>
  <messageformat>204</messageformat>
  </ichicrsmessageheader>
- <authorisedproducts>

```

To export the selected AMP entities as an **RTF file** select "One RTF File" (one RTF file will be created for all selected entities) or "Multi RTF Files" (one RTF file will be created for each selected entity) from the main menu, under "Export":



Depending on the selected option, a pop-up window with multiple files or one file will be displayed:

If "Multi RTF Files" was selected:

**Summary**

Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinittestmah-RTF-NS-NT-NN-2014-07-03+14.44.58-01.rtf
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinittestmah-RTF-NS-NT-NN-2014-07-03+14.44.58-02.rtf
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinittestmah-RTF-NS-NT-NN-2014-07-03+14.44.58-03.rtf
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinittestmah-RTF-NS-NT-NN-2014-07-03+14.44.58-04.rtf
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinittestmah-RTF-NS-NT-NN-2014-07-03+14.44.58-05.rtf
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinittestmah-RTF-NS-NT-NN-2014-07-03+14.44.58-06.rtf
Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinittestmah-RTF-NS-NT-NN-2014-07-03+14.44.58-07.rtf

If "One RTF file" was selected:

**Summary**

Temporary (for Export)	Click <a href="#">here</a> for the file Name: alcinittestmah-RTF-NS-NT-NN-2014-07-03+14.49.17-01.rtf
------------------------	---

You can then download the file/files to view or save on your computer:



Authorised Product	
Checked	No
Cleaned	No
Nullified	No
EV Code	PRD111058
PhV enquiry email	pharmacovig@pharmax.co.uk
PhV enquiry Phone	+44 207 2222222
Authorisation Country Code	United Kingdom
Authorisation Procedure	EU authorisation procedures - Mutual Recognition Procedure
Authorisation Status	Valid
Authorisation Number	1234/5678/111
Authorisation/Renewal Date	07/02/2013
MRP/DCP/EMA Number	SE/H/1111/222
Legal Basis	Full application (Article 8(3) of Directive No 2001/83/EC)



#### 4.4. Exporting entities to an Excel spread sheet

An Excel spread sheet containing data submitted to EVWEB can be created following an advanced query on the selected entity (per the applicable visibility rules). Please refer to section 2.7.2.3. Results section for related information.

##### 4.4.1. Exporting an overview of all owned entities to an Excel spread sheet

To view/save an overview of all owned entities in EVWEB, go to "Queries" and click on "Owned EVMPD entities". An overview will be listed in the active area:

The screenshot shows the EVWEB interface with a navigation tree on the left and a data table on the right. The 'Owned EVMPD Entities' query is selected in the tree. The table displays the following data:

Num	Entity	Article 57 Format	Type	Status	Number
0001	Attachment	Article 57 Format (1)			11
0002	Master File Location	Article 57 Format (1)		Awaiting Check (1)	7
0003	Organisation	Article 57 Format (1)	Sponsor (7)	Awaiting Check (1)	1
0004	Organisation	Article 57 Format (1)	MAH (6)	Awaiting Check (1)	6
0005	Pharmaceutical Form	Article 57 Format (1)	Proposed (9)	Awaiting Check (1)	1
0006	Product	Article 57 Format (1)	Authorised (2)	Awaiting Check (1)	4
0007	Product	Article 57 Format (1)	Authorised (2)	Checked (2)	3

To save this overview in Excel spread sheet, click on "Excel".

A pop-up window will be displayed. You can then download the file to view or save on your computer.

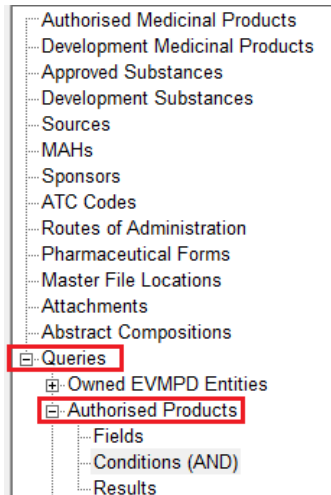
**Summary**

<b>Temporary (for Export)</b>	<b>Click <a href="#">here</a> for the file</b>
	Name: Owned EVMPD Entities.xls

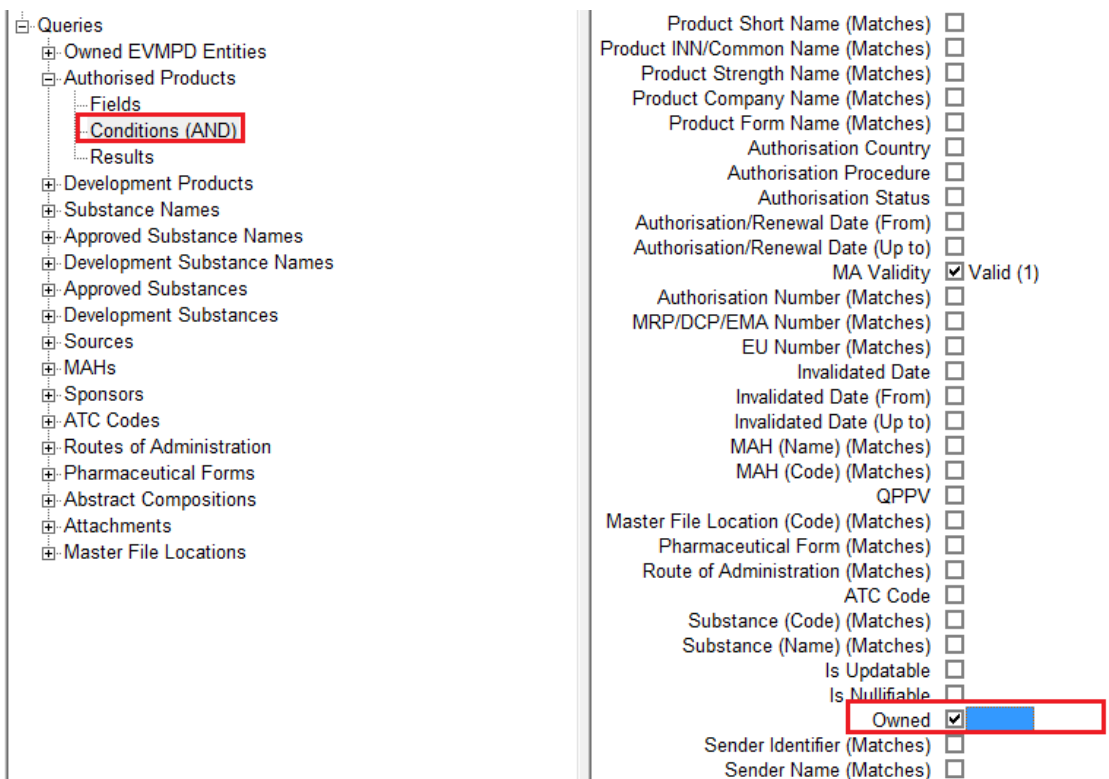
## 4.4.2. Exporting an overview of all owned AMPs to an Excel spread sheet

To create an Excel spread sheet containing all AMP entities owned by your HQ organisation ID, you can perform an advanced query and export the results in Excel.

Open the "Queries" section in the tree view area and select "Authorized Products":



In the "Conditions" select "Owned" and then press the button "Run to Excel".



## 4.5. Displaying/printing and saving information from XEVMPD

The information available in the XEVMPD can be displayed, saved and printed in various formats.

**Depending on the section, in which you are working in and on the item(s) selected**, individual entities and/or results of queries can be saved as an Excel spread sheet, XML file, RTF file or a ZIP file.

See section 2.12. *Export functions and available formats* for related information.

### Excel

This button allows you to save the result of your queries as a spread sheet in an Excel format:

The screenshot shows the XEVMPD interface with the 'Excel' button highlighted in the top toolbar. The interface includes a navigation pane on the left with categories like 'Authorised Medicinal Products', 'Development Medicinal Products', 'Approved Substances', etc. The main area displays a table of 'DrugVero' data with columns: Num, EV Code, Owner Identifier, and Checked. The 'Checked' column contains dates like 'Yes (31/10/2012 15:00:00)'.

The screenshot shows a Microsoft Excel spreadsheet titled 'Authorised\_Products\_03-07-2014\_11-38-43'. The spreadsheet contains a table with the following data:

EV Code	Entity Type	Owner Identifier	Checked	Cleaned	Nullified	Category	Full Presentation Name	Product Short Name	MAH Name	Is Updatable	Is Nullifiable
PRD99739	PRODUCT	DCMTESTMAH	Yes (31/10/2012 15:01:11)	No	No	ccc	ccc	ccc	EUROPEAN MEDICINES AGENCY	Yes	No
PRD108743	PRODUCT	DCMTESTMAH	Yes (31/10/2012 15:01:09)	No	No	HGFFJYGKHKQ	HGFFJYGKHKQ	FGXDT	EUROPEAN MEDICINES AGENCY	Yes	No
PRD101581	PRODUCT	DCMTESTMAH	Yes (31/10/2012 15:00:59)	No	No	aaa	aaa	aaa	EUROPEAN MEDICINES AGENCY	Yes	No
PRD11036	PRODUCT	DCMTESTMAH	No	No	No	Goshi 25 Capsules	Goshi 25 Capsules	Goshi 25	PHARMAX LIMITED	Yes	Yes
PRD11058	PRODUCT	DCMTESTMAH	No	No	No	DrugVero Ibuprofen Forte 400 mg Liquid Ca	DrugVero Ibuprofen Forte 400 mg Liquid Ca	DrugVero Forte	PHARMAX LIMITED	Yes	Yes
PRD11081	PRODUCT	DCMTESTMAH	No	No	No	ProductX comprimido revestido 4 mg	ProductX comprimido revestido 4 mg	ProductX	PHARMAX LIMITED	Yes	Yes
PRD11059	PRODUCT	DCMTESTMAH	No	No	No	Nikko tablets	Nikko tablets	Nikko	NEWPHARMA LTD.	Yes	Yes

### XML

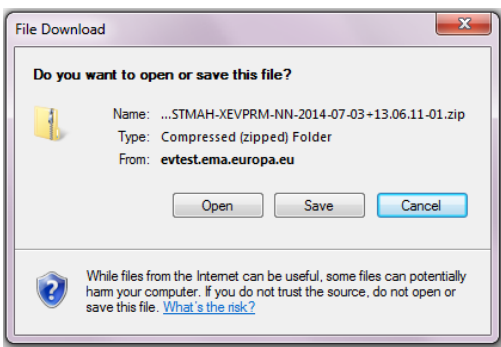
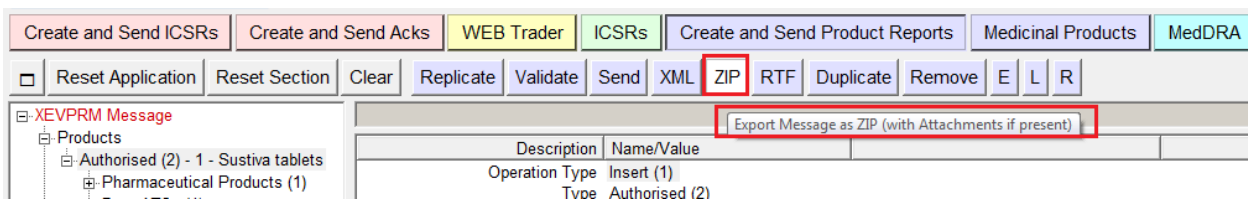
This button allows you to generate an XML version of the message selected in EVWEB:

The screenshot shows the XEVMPD interface with the 'XML' button highlighted in the top toolbar. The interface includes a navigation pane on the left with categories like 'Authorised Medicinal Products', 'Development Medicinal Products', 'Approved Substances', etc. The main area displays a table of 'DrugVero' data. The 'XML' button is highlighted in the top toolbar.

- <presentationname>  
 <productname>DrugVero Ibuprofen Forte 400 mg Liquid Capsules</productname>  
 <productshortname>DrugVero Forte</productshortname>  
 <productgenericname>Ibuprofen</productgenericname>  
 <productstrength>400 MG</productstrength>  
 <productform>LIQUID CAPSULES</productform>

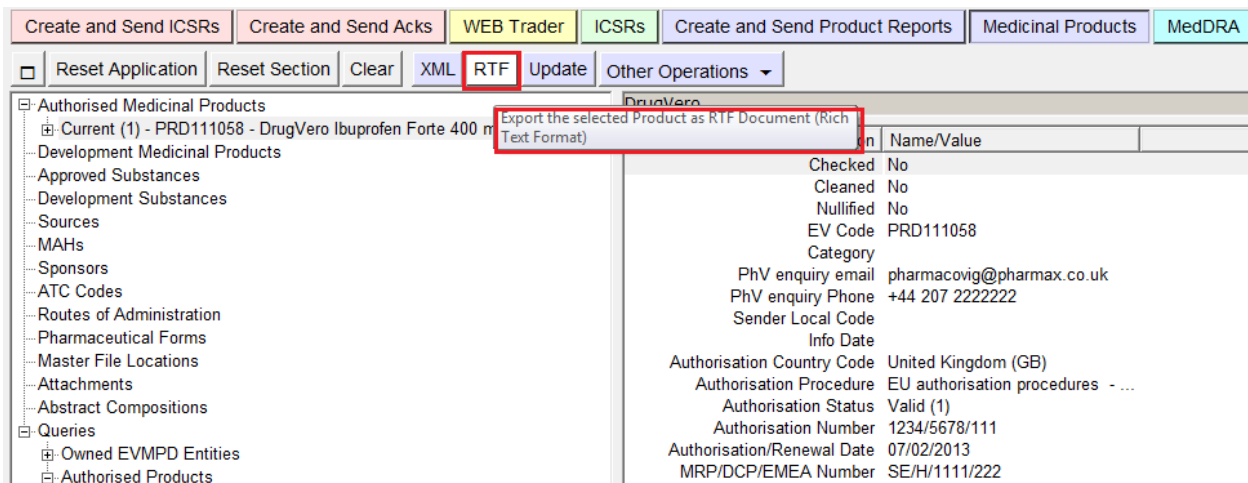
## ZIP

This button allows you to generate a ZIP file also containing the attachment (if present):



## RTF

This button allows you to generate an RTF file (a typical cross-platform document format) version of the message selected in EVWEB.



**XEVPRM Message****Products****Authorised Product**

<b>Operation Type</b>	<b>Insert</b>
<b>Type</b>	<b>Authorised</b>
<b>MAH</b>	<b>PHARMAX LIMITED</b>
<b>QPPV</b>	<b>Alcini Paolo (DCMTESTMAH)</b>
<b>PhV enquiry email</b>	<b>pharmacovig@pharmax.co.uk</b>
<b>PhV enquiry Phone</b>	<b>+44 207 2222222</b>
<b>Authorisation Country Code</b>	<b>Portugal</b>
<b>Authorisation Procedure</b>	<b>EU authorisation procedures - National Procedure</b>
<b>Authorisation Status</b>	<b>Valid</b>
<b>Authorisation Number</b>	<b>8888/222/333</b>
<b>Authorisation/Renewal Date</b>	<b>30/06/2014</b>
<b>Legal Basis</b>	<b>Medicinal product authorised according to Article 126a of Directive No 2001/83/EC</b>

Once exported, the document in any of these formats can be printed or saved like any other document on your computer.

## 5. MedDRA

MedDRA is the Medicinal Dictionary for Regulatory Activities. It has been developed as a clinically validated international medical terminology for regulatory authorities and the pharmaceutical industry. MedDRA is intended to be used throughout the entire regulatory processes, from pre- marketing to post- marketing phases, for data entry, retrieval, evaluation and presentation.

This section describes the principal aspects of MedDRA, its structure and how to access and use MedDRA in EVWEB. This section also explains the process necessary to perform both simple and advanced queries on MedDRA through EVWEB.

Every user of EVWEB should hold a valid MedDRA license. The license details should be provided as part of the registration process with EudraVigilance.

For further details about the MedDRA license policies, please refer to the official Website of the MedDRA MSSO and the specific EudraVigilance license policy for Small and Medium Size Enterprises (SMEs) published at the EudraVigilance Website.

### 5.1. Introduction

MedDRA has been developed as a clinically validated international medical terminology for regulatory authorities and the pharmaceutical industry for use in data entry, retrieval, evaluation and presentation during all phases of the regulatory processes, from pre- to post- marketing phases. These processes include:

- Clinical studies
- Reports of spontaneous adverse reactions and events
- Regulatory submissions
- Regulated product information.

The dictionary provides terminology intended to be used in the following areas:

- Diseases
- Diagnosis
- Signs
- Symptoms
- Therapeutic indications
- Investigations names and qualitative results
- Medical, social, family history.

Nevertheless, there are some areas excluded from MedDRA terminology:

- Population level qualifiers (e.g. "rare" and "frequent" fail to focus on the individual patient)
- Numerical values for results (numeric representations cannot be universalized, especially in terms of the measurement parameter)
- Severity descriptors (typically, terms such as "severe" or "mild" are not found in the terminology, with some exception when their presence is medically relevant, e.g., aggravated conditions are different than the condition itself)
- Patient demographics (aside from very few occasions where sex is a pertinent descriptor, terms like age, race and religion are not included in the terminology)
- Equipment, device and diagnostic product terms (e.g. the term "catheter" would not be include in the terminology whereas the failure and its health effects would be)
- Drug product terms
- Device failure terms
- Clinical trial study designs terms.

## **5.2. MedDRA Structure**

MedDRA is organized in a hierarchical structure. MedDRA terms are grouped at different levels thus allowing searches to be performed with several degrees of specificity.

The hierarchical structure provides vertical links between superordinate terms (broad grouping) and subordinate descriptors (higher level of specificity):

*System Organ Class (SOC)*

*High Level Group Term (HLGT)*

*High Level Term (HLT)*

*Preferred Term (PT)*

*Lowest Level Term (LLT)*

*System Organ Class (SOC)*

The System Organ Class (SOC) is the highest level of the hierarchy and provides the broadest concepts for data retrieval.

There are SOC's, and they represent parallel axes, which are not mutually exclusive. This allows terms to be represented in more than one SOC, and therefore grouped by different classifications.

*High Level Group Term (HLGT)*

A High Level Group Term (HLGT) is subordinate only to System Organ Classes (SOCs) and superordinate for one or more High Level Terms.

*High Level Term (HLT)*

A High Level Term (HLT) is subordinate to High Level Group Terms and is superordinate for the Preferred Terms (PTs) linked to it.

The specificity of HLTs is not uniform. HLT groupings reflect the relative importance of terms dependent on the individual SOC.

#### *Preferred Term (PT)*

A Preferred Term (PT) is subordinate to High Level Terms and groups together the Lowest Level Terms (LLTs).

There is no limit to the number of LLTs that can be linked to a single PT. For every new PT, an identical LLT is created for data entry purposes. A PT contained in a particular SOC can only be linked to that individual SOC via one route. PTs represent a single medical concept and are internationally agreed.

Although a PT can be linked to more than one SOC, each PT is assigned to a Primary System Organ Class. The purpose for the Primary SOC is to determine which SOC will represent a PT during cumulative data output. This will prevent a PT from being represented more than once during data retrieval from all SOCs.

#### *Lowest Level Term (LLT)*

A Lowest Level Term (LLT) constitutes the bottom level of the hierarchy and is linked to a PT.

Culturally unique terms that have been internationally agreed upon are found at this level. LLTs facilitate the transfer of historical data; terms from other terminologies are also stored here.

LLTs have one of the following three relationships to PTs:

Synonyms – different term for the same descriptor

Lexical variant – different word forms for same expression

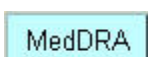
Quasi-synonyms – terms with meanings generally regarded as different, but which in practice are treated as equivalent

#### *Special Search Categories (SPEC CAT(s))*

Special Search Categories (*SPEC CAT(s)*) allow linkage of terms that are neither equivalent nor hierarchically related, but share clinical concepts that cross SOC hierarchies. This is accomplished by grouping terms at the PT level that are all relevant to the same, singular issue. This is usually a disease or syndrome.

### **5.3. MedDRA in EVWEB**

You can access the MedDRA section of EVWEB by clicking on the "MedDRA" button on the main menu.



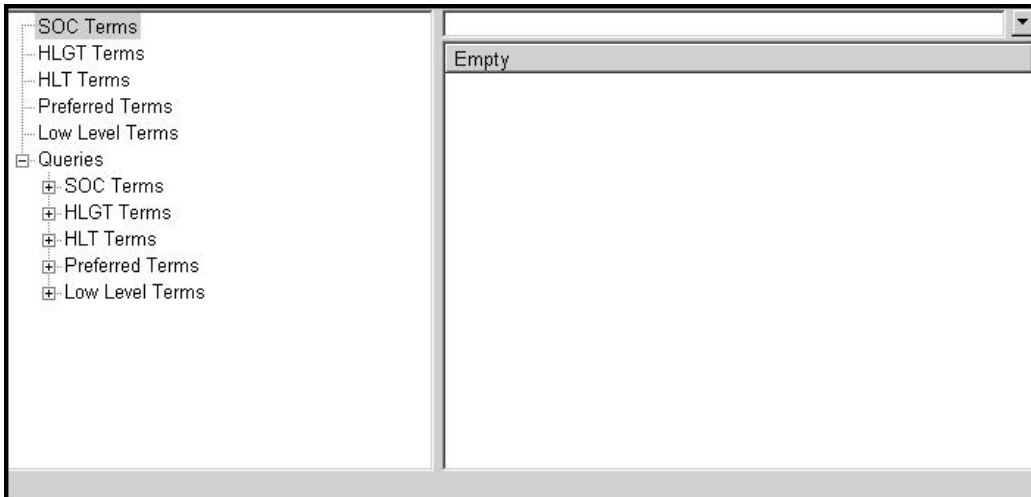
The MedDRA section allows you to perform searches among SOC Terms, HLG T Terms, HLT Terms, Preferred Terms and Low Level Terms.



As in other sections of EVWEB, searches can be performed in two different ways:

- Simple query
- Advanced query.

To perform an advanced query, you have to expand the "Queries" section in the tree view.



Each query term has its own sub-menu, allowing to choose between "Fields" and "Conditions" to perform a query.

**Fields for SOC Terms:**

*SOC Code*

*SOC Name*

*SOC Abbreviation*

**Conditions for SOC Terms:**

*SOC Code*

*SOC Name*

*HLGT Code*

*HLGT Name*

*HLT Code*

*HLT Name*

*PT Code*

*PT Name*

*LLT Code*

*LLT Name*

**Fields for HLGT Terms:**

*HLGT Code*

*HLGT Name*

**Conditions for HLGT Terms:**

*SOC Code*

*SOC Name*

*HLGT Code*

*HLGT Name*

*HLT Code*

*HLT Name*

*PT Code*

*PT Name*

*LLT Code*

*LLT Name*

**Fields for HLT Terms:**

*HLT Code*

*HLT Name*

**Conditions for HLT Terms:**

*SOC Code*

*SOC Name*

*HLGT Code*

*HLGT Name*

*HLT Code*

*HLT Name*

*PT Code*

*PT Name*

*LLT Code*

*LLT Name*

**Fields for Preferred Terms:**

*PT Code*

*PT Name*

**Conditions for Preferred Terms:**

*SOC Code*

*SOC Name*

*HLGT Code*

*HLGT Name*

*HLT Code*

*HLT Name*

*PT Code*

*PT Name*

*LLT Code*

*LLT Name*

**Fields for Low Level Terms:**

*LLT Code*

*LLT Name*

*LLT is current?*

**Conditions for Low Level Terms:**

*SOC Code*

*SOC Name*

*HLGT Code*

*HLGT Name*

*HLT Code*

*HLT Name*

*PT Code*

PT Name

LLT Code

LLT Name

In all cases, query search allow you to select one or more "Fields" and one or more "Conditions" to restrict the results of the search.

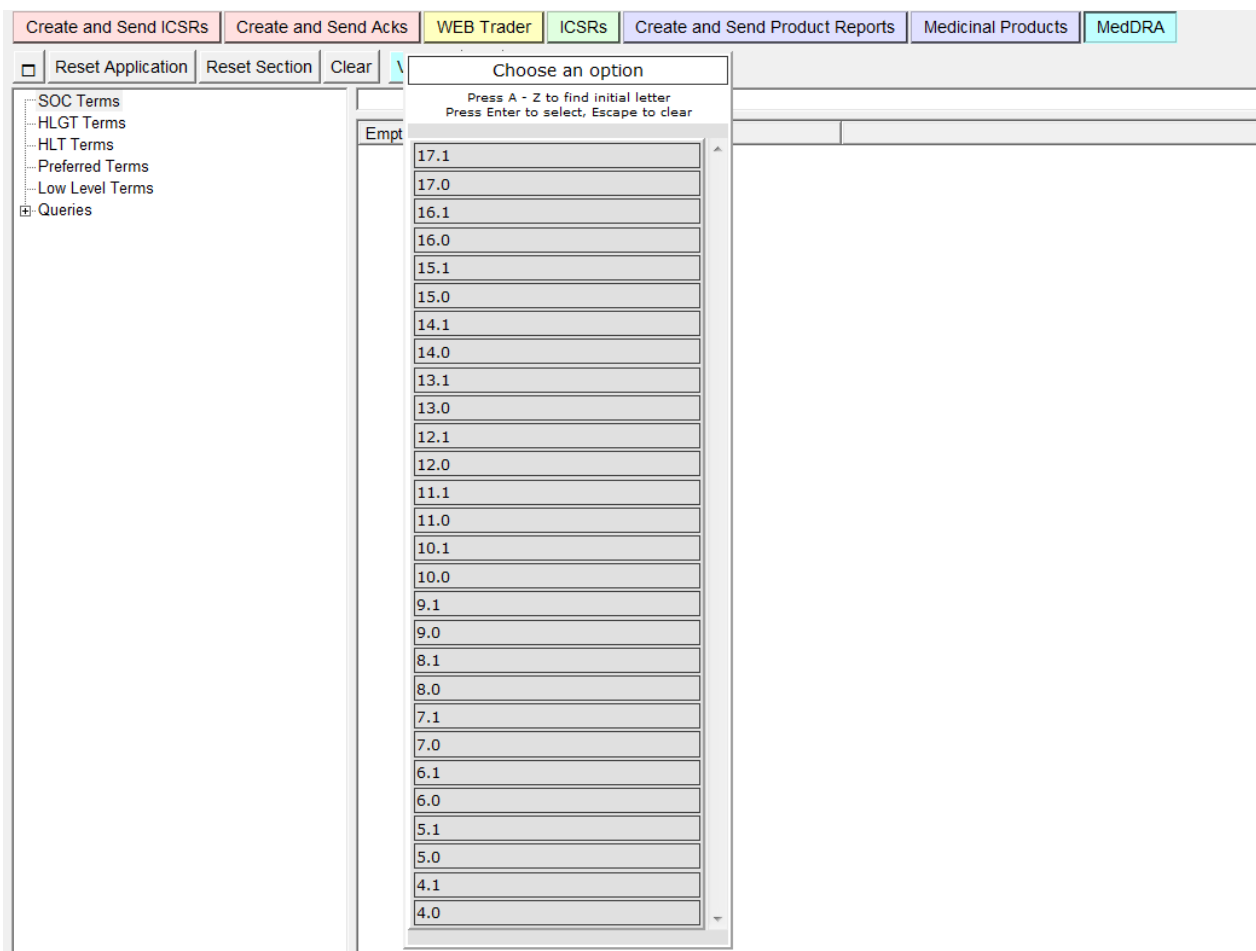
MedDRA version

EVWEB allows you to select a specific version of MedDRA to perform your simple and advanced queries.



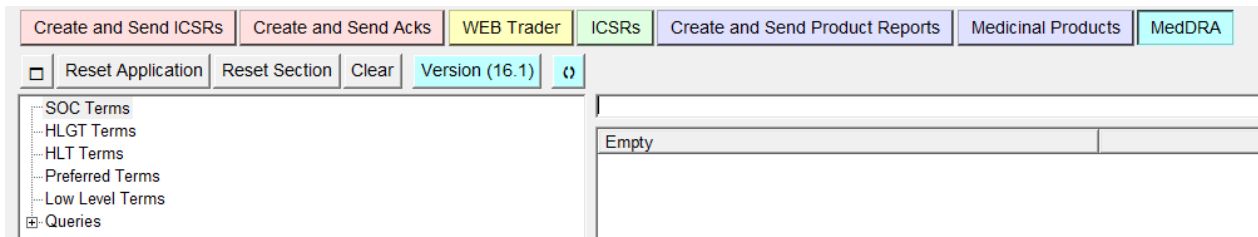
Click on the button "Version" that will be displayed in the dynamic button set on the main menu.

A drop down menu will be displayed allowing you to select a MedDRA version as required.



The screenshot shows the EVWEB interface with a navigation bar at the top containing buttons for 'Create and Send ICSRs', 'Create and Send Acks', 'WEB Trader', 'ICSRs', 'Create and Send Product Reports', 'Medicinal Products', and 'MedDRA'. The 'MedDRA' button is highlighted. Below the navigation bar, there are buttons for 'Reset Application', 'Reset Section', and 'Clear'. A dropdown menu is open, titled 'Choose an option', with instructions: 'Press A - Z to find initial letter' and 'Press Enter to select, Escape to clear'. The dropdown list contains the following MedDRA versions: 17.1, 17.0, 16.1, 16.0, 15.1, 15.0, 14.1, 14.0, 13.1, 13.0, 12.1, 12.0, 11.1, 11.0, 10.1, 10.0, 9.1, 9.0, 8.1, 8.0, 7.1, 7.0, 6.1, 6.0, 5.1, 5.0, 4.1, and 4.0. On the left side of the dropdown, there is a tree view with categories: 'SOC Terms', 'HLGT Terms', 'HLT Terms', 'Preferred Terms', 'Low Level Terms', and 'Queries'.

Once a version is selected, you can start performing simple and advanced queries for that specific MedDRA version.



If you do not specify any version, the simple and advanced queries are performed with the current MedDRA version.

#### **5.4. How to perform a Simple query**

You can start a simple query from any MedDRA level listed in the tree view:

*SOC (System Organ Class Terms)*

*HLGT (High Level Group Terms)*

*HLT (High Level Terms)*

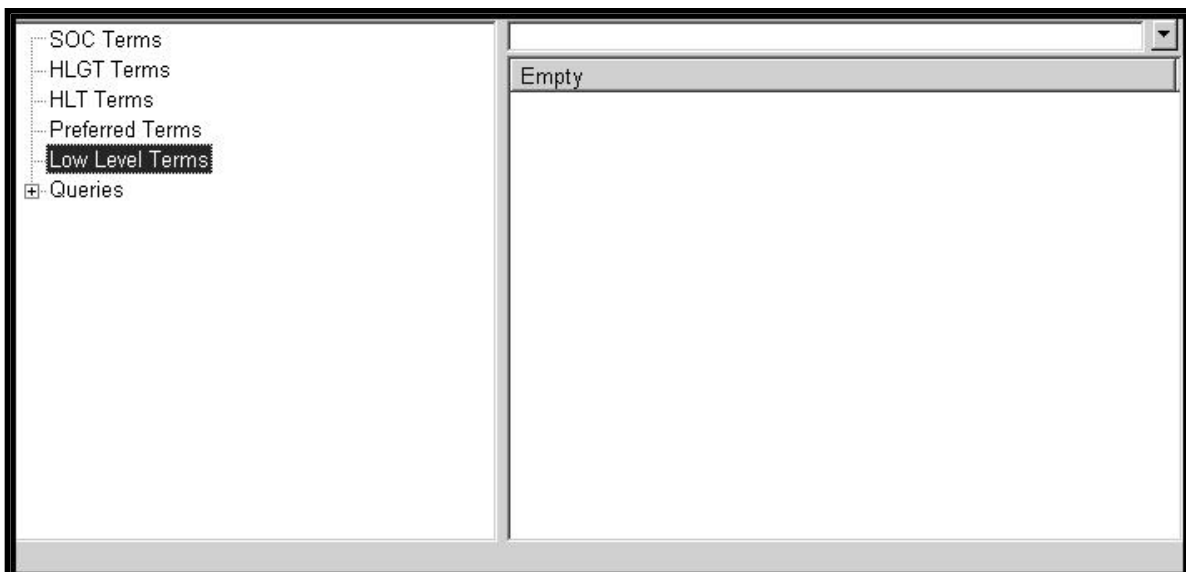
*PT (Preferred Terms)*

*LLT (Low Level Terms)*

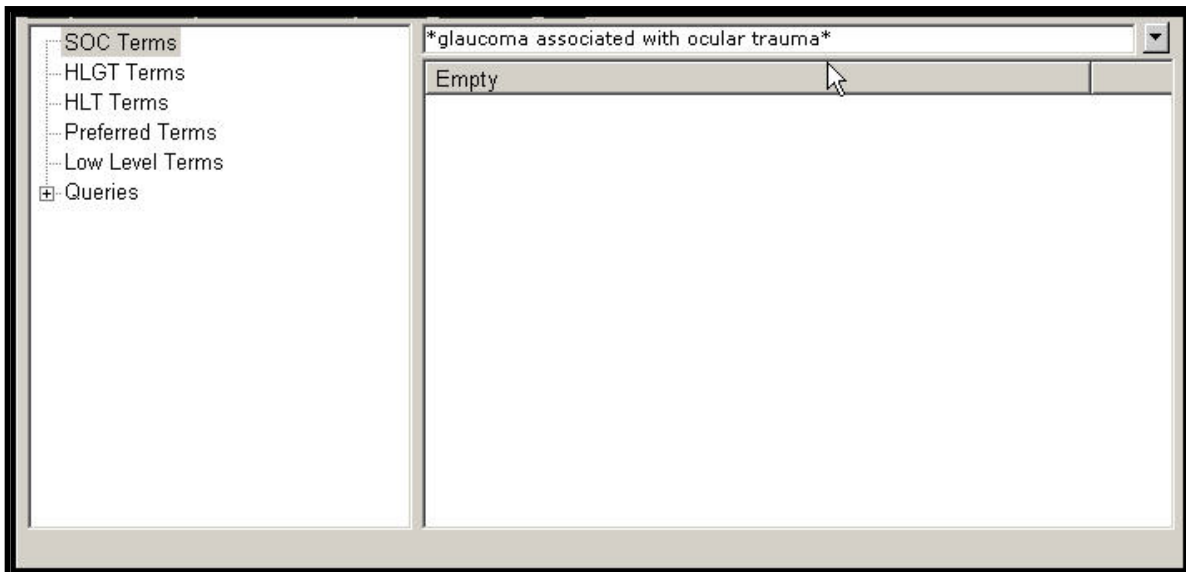
"SOC Terms" is the default selection presented by the system.

As an example, we will perform a simple query starting from the Low Level Term "Glaucoma associated with ocular trauma".

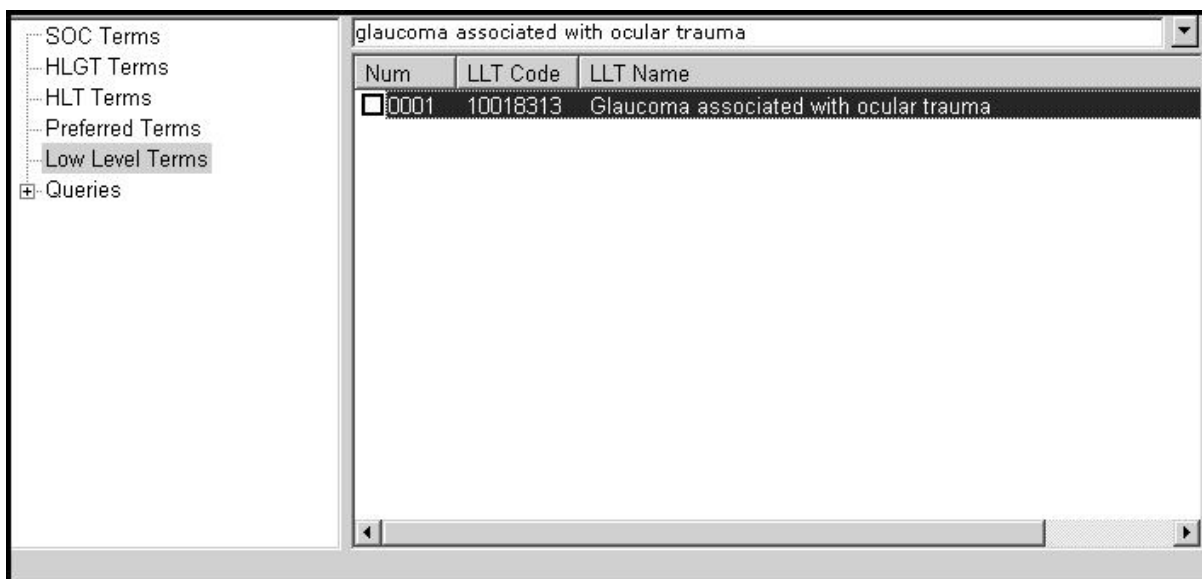
Select "Low Level Terms" in the tree view.



Type "\*glaucoma associated with ocular trauma\*" in the simple query field on the top of the active area.



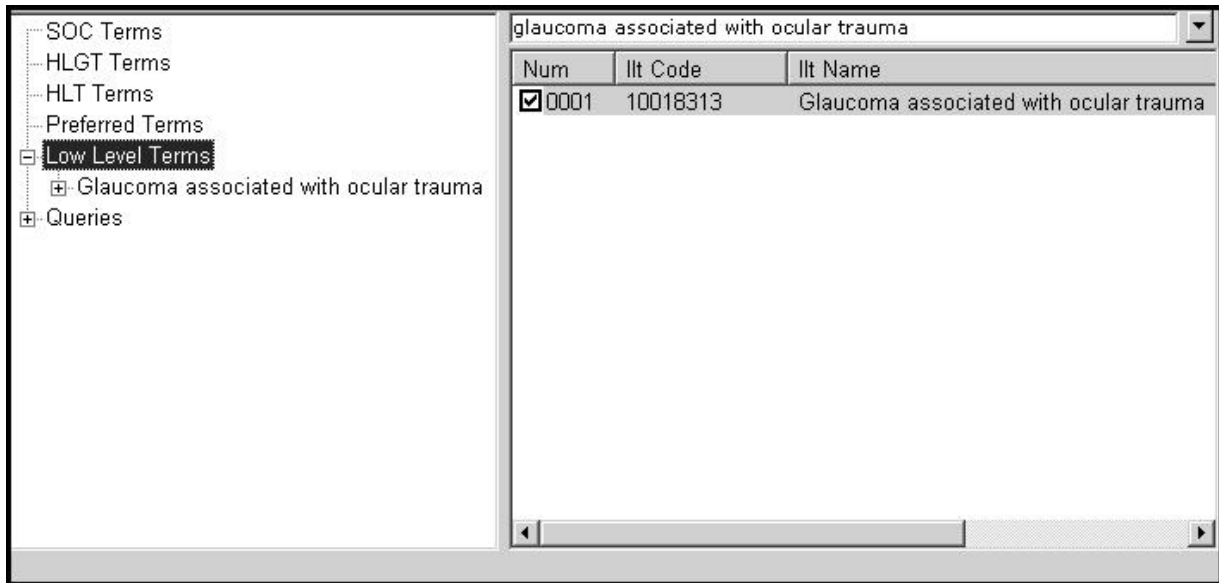
Press "Enter" on your keyboard to perform the query. The results are displayed in the active area.



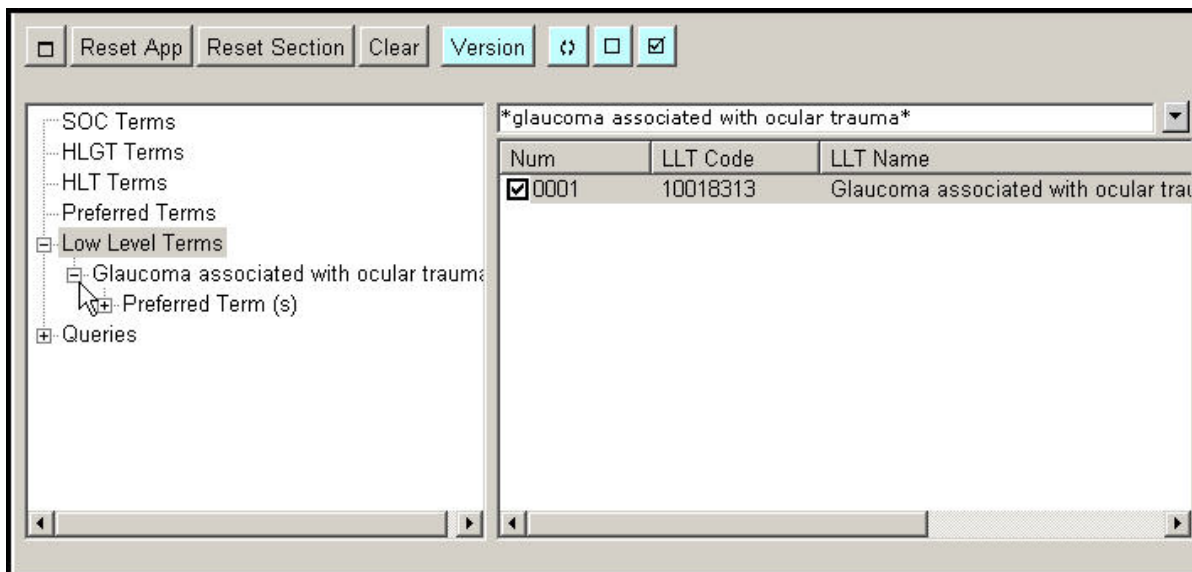
The columns heading in the active area will provide the following information: "Num" (number of items found), "LLT Code" and "LLT Name".

To go into further details, just click on the little white square in the "Num" column. It may take a few seconds in order to have the item selected, please wait.

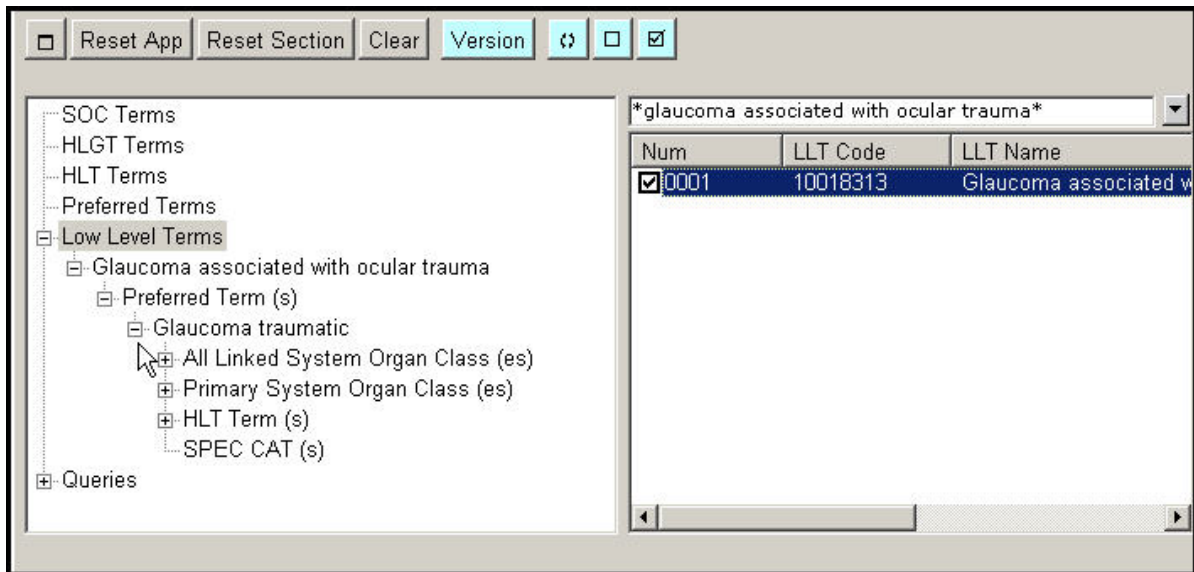
The results of our search will be displayed under "Low Level Terms" in the tree view.



Click on "+" at the left side of "Glaucoma associated ..." in the tree view, in order to move from "Low Level Term" up to "Preferred Terms".

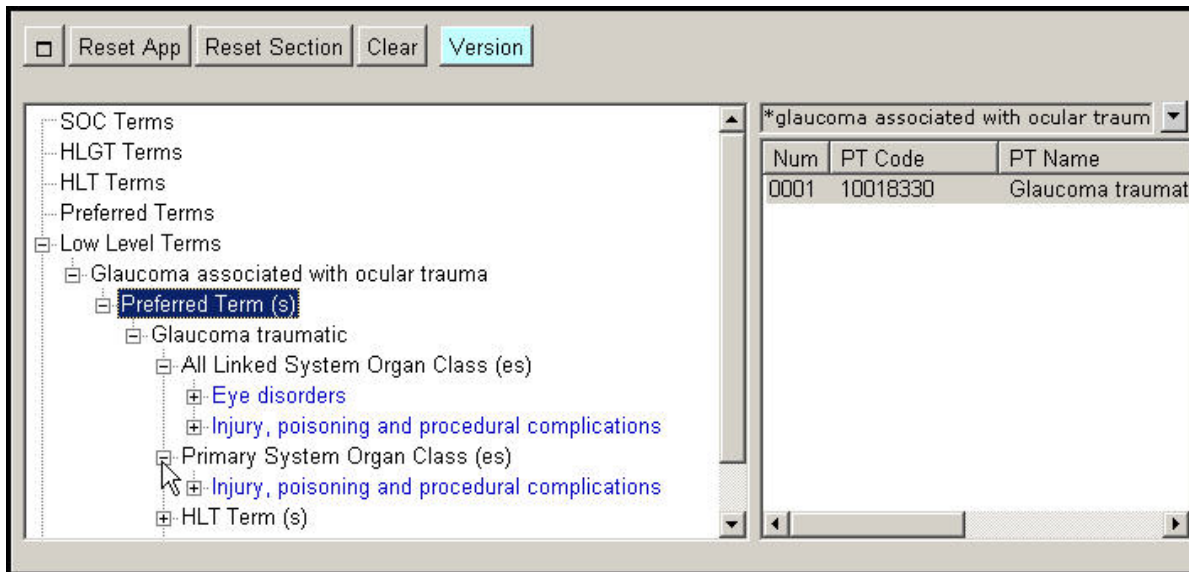


Click on "+" next to "Preferred Term (s)" in order to drill up to the SOC, HLT and SPEC CAT(s).

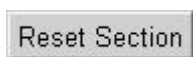


As far as the SOC Terms are concerned, EVWEB displays "All Linked System Organ Class" and "Primary System Organ Class".





To delete the queries performed in the MedDRA section, click on the "Reset Section" button on the main menu. This operation does not delete any queries performed in other sections of EVWEB.



### 5.5. How to perform an Advanced Query

You can perform advanced queries through the query function, located in the tree view. An advanced query performs a more customized and structured search than the generic one.

Click on "+" next to "Queries" in the tree view. The MedDRA hierarchical terminology levels will be displayed:

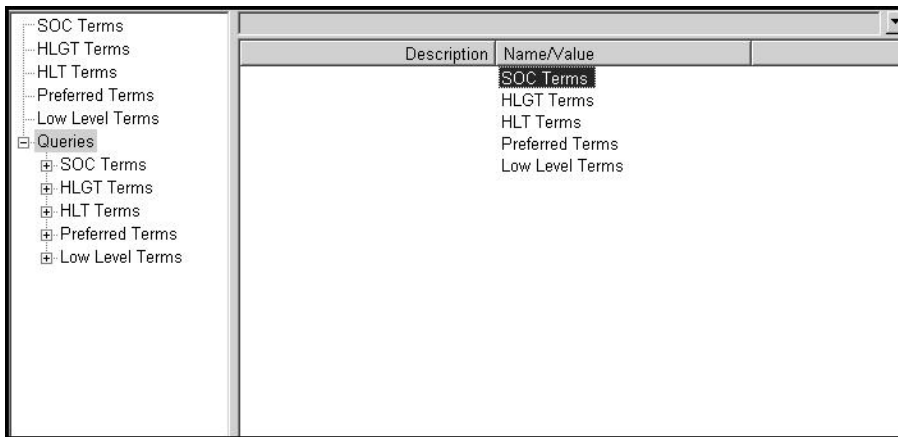
*SOC (System Organ Class Terms)*

*HLGT (High Level Group Terms)*

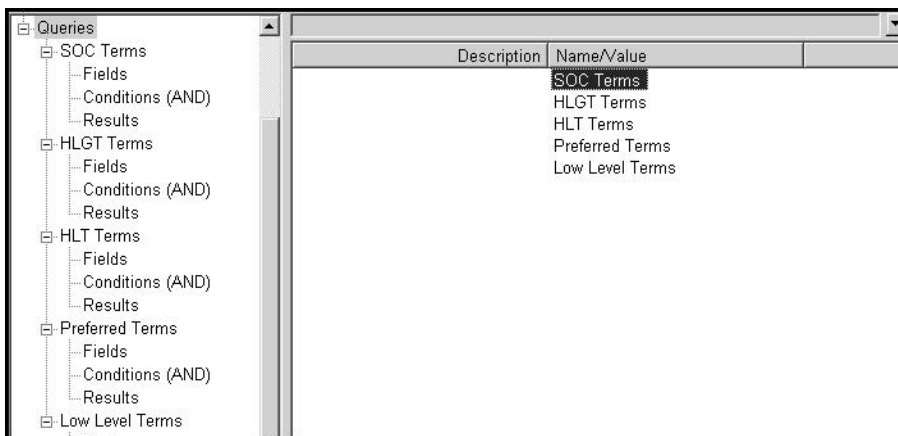
*HLT (High Level Terms)*

*PT (Preferred Terms)*

*LLT (Low Level Terms)*



You can now expand each item by clicking on "+" at the left side of each single item.



At each level, "Fields", "Conditions" and "Results" will be displayed.

"Fields" and "Conditions" are the two variables that you will have to choose in order to carry out an advanced query. The "Results" sub-section will display the results of your query. For more details about how to perform an advanced query see section [2.7.2. Advanced Query](#).

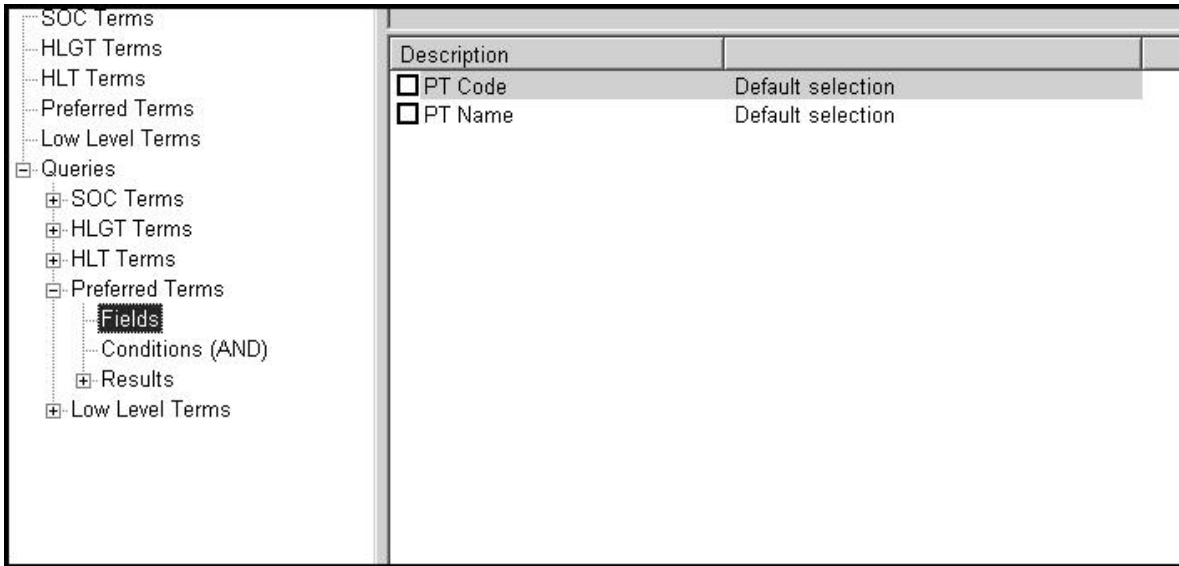
The following example describes how to perform an advanced query. We will search all Preferred Terms (with their relevant codes) linked to the High Level Terms containing the word "glaucoma".

**Fields:** Preferred Terms

**Conditions:** High Level Terms containing "glaucoma"

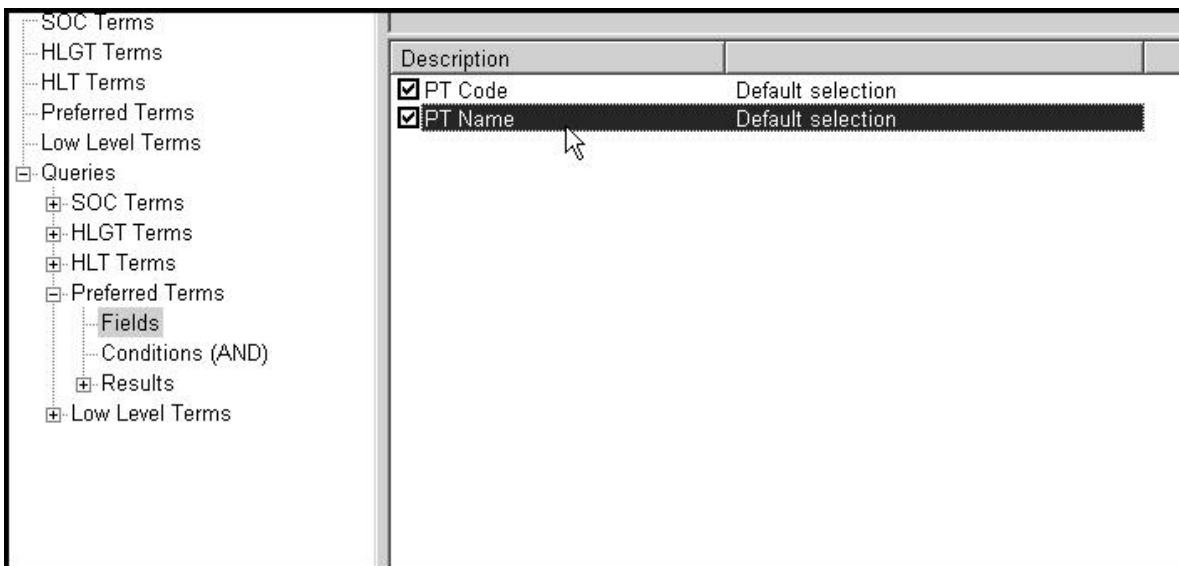
Click on "+" at the left side of the "Queries" in the tree view. Then, click on "+" at the left side of "Preferred Terms" that appears under the "Query" item in the tree view.

Now click on "Fields". "PT Code" and "PT Name" are now displayed in the active area.



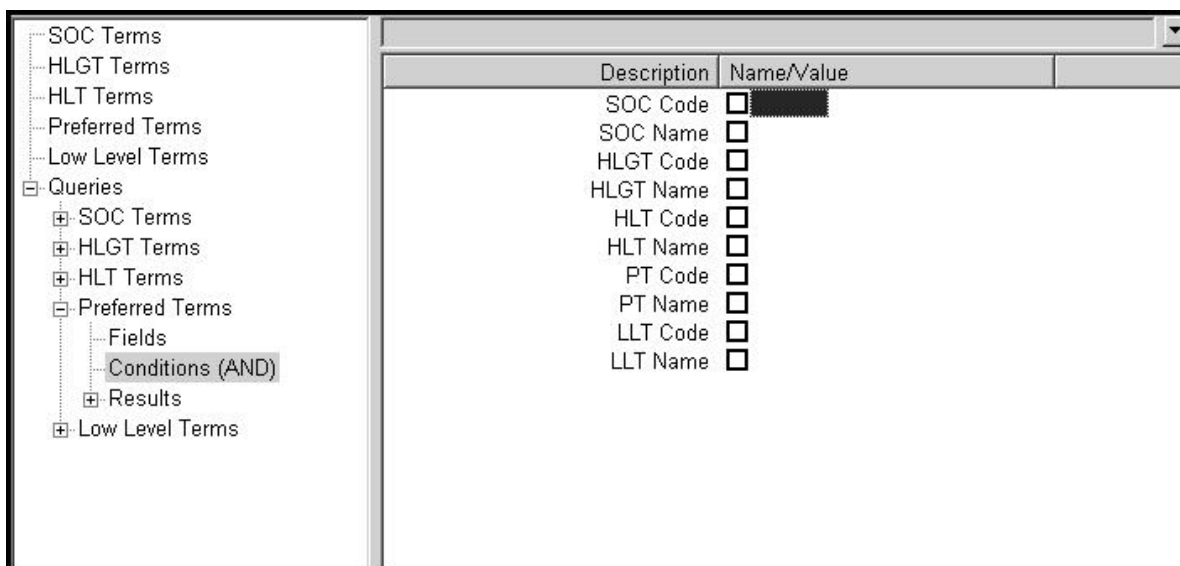
To see both the codes and the names of the "Preferred terms", select "PT Code" and "PT Name" in the active area.

Both "PT Code" and "PT Name" items appear now as checked.



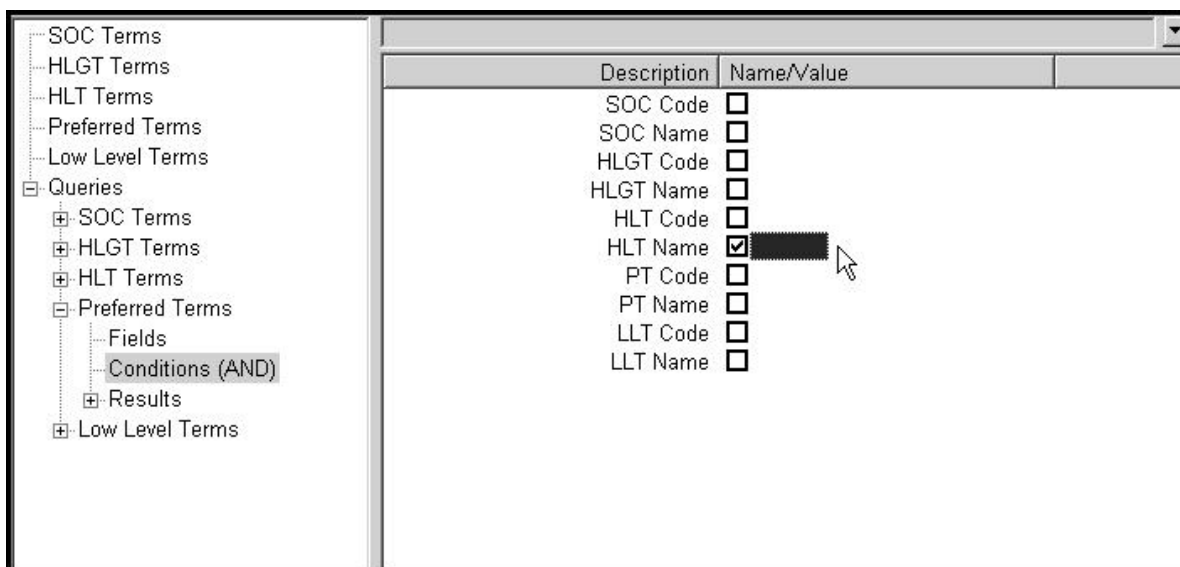
Now select "Conditions" in the tree view, to define the conditions of the search.

The two columns in the active area will provide the following information: "Description" and "Name/Value".



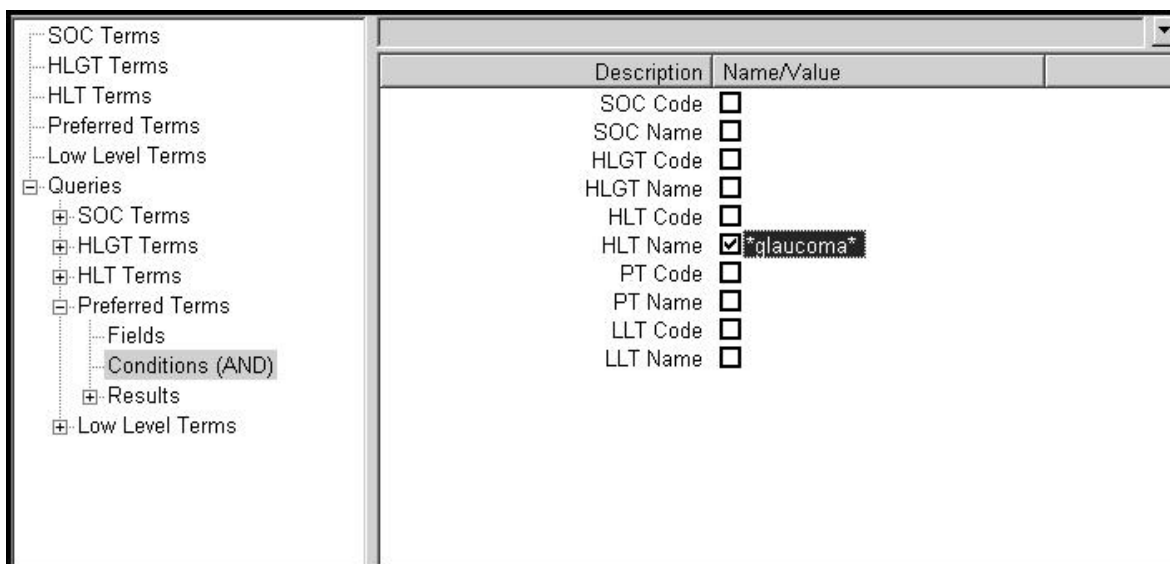
To find the Preferred Terms related to the HLT terms containing the word "Glaucoma", we need to specify as a condition for this query "HLT Name" contains "Glaucoma".

Click on the white square displayed in the active area next to "HLT Name".



The condition of our query deals with HLT Terms containing the word "glaucoma". Press "Enter" on the keyboard and type "\*glaucoma\*" in the text field just on the right side of the selected item. Finally press "Enter" on the keyboard in order to have the information available in the active area.

**Remember to put an asterisk (\*) at the beginning and at the end of the word that you are entering.** That will extend the search to all High Level Terms containing the word glaucoma.

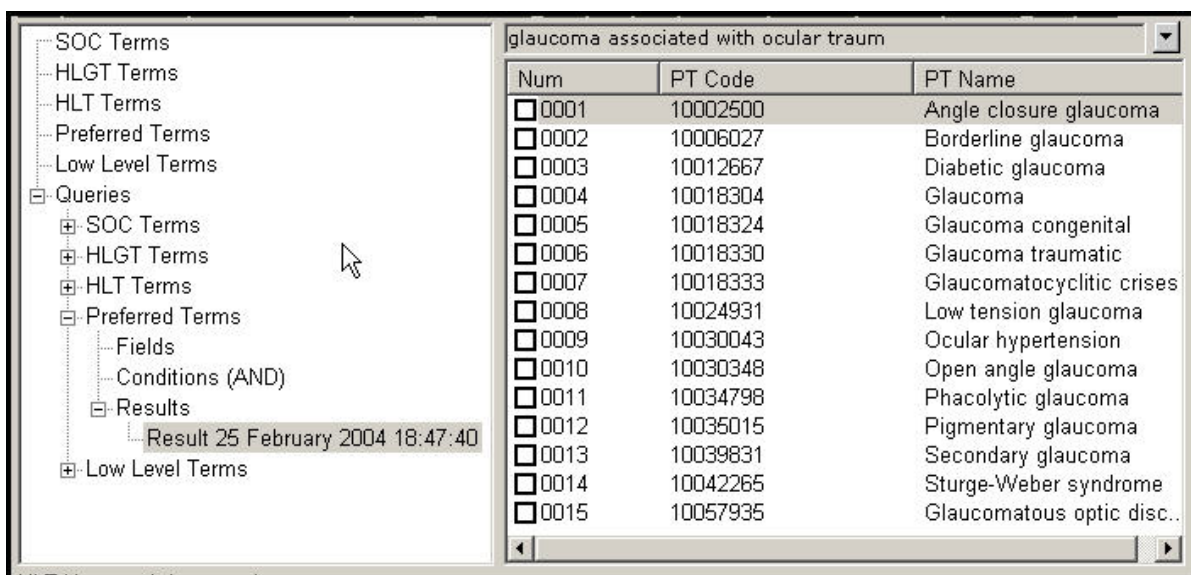


Run

A new dynamic button ("Run") has appeared on the main menu. Click on "Run" in order to perform the query.

You may have to wait a few seconds before the results of your query are displayed.

The result will appear in the active area.



The results are displayed in the form of a list of Preferred Terms that are linked to the High Level Term containing the word "glaucoma". The two columns in the active area will provide the information concerning "PT Code" and "PT Name" as we had selected these two fields in the advanced query.

The results will be recorded in the tree view under "Results". You can now select and analyse one or more of the Preferred Terms displayed in the list by clicking on the little white square under the "Num" column.

Please see [2.6.3. Checklists](#) for details on how to manage and navigate a checklist in EVWEB.

## **5.6. Current status for LLT**

EVWEB provides information whether a Low Level Term is current or not in the selected version. When you browse information on LLTs, the active area displays information on the current status of LLT.

The information on the "current status" of the LLT is based on the MedDRA version selected.

## 6. List of Abbreviations and Acronyms

AMP	Authorised Medicinal Product
AS	Approved Substances
ATC	Anatomic Therapeutic Chemical (details at <a href="http://www.whooc.no">www.whooc.no</a> )
CAS	Chemical Abstract Service (Number)
CAP	Centrally Approved Product
CBD	Chemical Biological Description
CV	Controlled Vocabulary
DBMS	Database Management System
DCP	Decentralised Procedure
DMP	Development Medicinal Product
DS	Development Substances
EEA	European Economic Area
EDI	Electronic Data Interchange
EDQM	European Directorate for the Quality of Medicines
EMA	European Medicines Agency
ESTRI	Electronic Standards for Transmission of Regulated Information (gateway technical specification)
EU	European Union
EVDBMS	EudraVigilance Database Management System
EVHUMAN	Unique Identifier of the EMA (for XEVMPD transmissions)
EVWEB	EudraVigilance web-based reporting application (XEVMPD Data Entry Tool)
EWG	Expert Working Group (in ICH or at the EMA)
FDIS	Final Draft International Standard (in ISO)
https	Hypertext Transfer Protocol Secure
ICSR	Individual Case Safety Report
ISO	International Standardization Organization
IM	Implementation Measure
IMP	Investigational Medicinal Product
INN	International Non-Proprietary Name

MAH	Marketing Authorization Holder
MDN	Message Disposition Notification
MedDRA	Medical Dictionary for Regulatory Activities
MFL	[Pharmacovigilance] Master File Location
MRP	Mutual Recognition Procedure
MS	Member State (in the EU)
MSSO	MedDRA Services and Support Organisation
NAP	Nationally Authorised Product
NCA	National Competent Authority
PF	Pharmaceutical Form
PIL	Product Information Leaflet
PL	Package Leaflet
PPI	Printed Product Information
PSI	Printed Substance Information
QPPV	Qualified Person responsible for Pharmacovigilance Activities
SME	Small and Medium Size Enterprise
SmPC or SPC	Summary of Product Characteristics
SSI	Structured Substance Information
SSL	Secure Socket Layer
UCUM	Unified Code for Units of Measure
XCOMP	EudraVigilance External Compliance Testing Environment (aka Test or Pre-Production Environment)
XHTML	eXtensible HyperText Markup Language
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary
XEVPRM	eXtended EudraVigilance Product Report Message
WHO	World Health Organisation
XSD	XML Schema Definition