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

Version 5.9

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Summary of changes

Following the publication of version 5.8 in December 2022, the below sections of this document were updated in this version.

• Please note that although some of the screenshots in this manual show the sections 'Sources' and 'Substances' in the 'Create and Send Product Reports' section of EVWEB:

- The 'Source' section is not available to MAH/sponsor users from January 2024;
- The 'Substances' section is not available to MAH/sponsor users from 28 June 2024.

This is because only the EMA can insert and maintain source and substance entities in the XEVMPD.

The screenshots in this manual will be updated to reflect this change in due course. For the time being, these sections are marked in this manual as follows:

Substances Sources

- New sub-sections were created in section 1.5. EVWEB and 4.11. Export of owned entities for easier orientation
- 1.5.1. User access to EVWEB and multi-factor authentication (MFA) content updated
- 1.6. eXtended EudraVigilance Medicinal Product Report Message (XEVPRM) content updated
- 1.7.2. Data collected in the XEVMPD content updated
- 1.7.7. Data access policy tables updated
- 1.7.2.7. <u>ATC Code</u> content updated
- 1.7.2.8. <u>Pharmaceutical form</u> content updated
- 1.7.2.9. Route of administration
- 1.7.3. XEVMPD terminologies content updated
- 1.7.4. Data ownership and maintenance content updated
- 2. Accessing EVWEB content updated
- 3.5.1.5. Local database look-up tables- content updated
- 4.1. Commands/operation types to be used in an XEVPRM- content updated
- 4.2. Create an XEVPRM with operation type Insert- content updated
- 4.2.3. Insert of an approved substance content updated
- 4.2.4. Insert of a reference source content updated
- 4.2.7. Insert of a proposed or development ATC Code- content updated
- 4.2.8. Insert of a proposed or development pharmaceutical form- content updated
- 4.2.9. Insert of a proposed or development route of administration content updated
- 4.2.10. Insert of an attachment screenshots updated content updated

- 4.6.1. Update of entities in the XEVMPD- content updated
- 4.11.2. Exporting an overview of all owned AMP entities additional details and screenshots included
- 4.11.3. Exporting an overview of all owned DMP entities additional details and screenshots included.

Content changes are highlighted in red.

Editorial changes in this document are not described in the summary of changes.

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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 (EMA) 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, the related documents to be read in conjunction with this user manual include:

- Chapter 3.II: Extended EudraVigilance product report message (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 <u>Reporting requirements for marketing-authorisation holders webpage</u>.

For sponsors of clinical trials, the related documents to be read in conjunction with this user manual include:

- <u>Guidance on the electronic submission of information on investigational medicinal products for</u> <u>human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD);</u>
- <u>Electronic submission of investigational medicinal product (IMP) data to the eXtended</u> <u>EudraVigilance Medicinal Product Dictionary (XEVMPD): Frequently asked questions & answers</u> (FAQs).

Further information related to the electronic submission of un-authorised medicines can be found on the <u>Data submission on investigational medicines: guidance for clinical trial sponsors webpage</u>.

Case and medicinal product examples used in this manual to describe the functionalities and rules of the system are intended for demonstration purposes only.

1.2. About EudraVigilance

<u>EudraVigilance</u> 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.

The main components are:

- EudraVigilance (EV) gateway: a data-processing solution for the secure electronic exchange of adverse reaction data;
- EudraVigilance Post-Authorisation Module (EVPM): dedicated to the collection of ICSRs related to all medicinal products authorised in the EEA in line with Regulation (EC) No 726/2004 and Directive 2001/83/EC;
- EudraVigilance Clinical Trial Module (EVCTM): dedicated to the collection of ICSRs of Suspected Unexpected Serious Adverse Reactions (SUSARs) in accordance with Directive 2001/20/EC and Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC;
- **eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)**: a reference source for the coding of substances and medicinal products reported in ICSRs based on the information provided by MAHs in line with Article 57(2), second subparagraph of Regulation (EC) No 726/2004.
- **EudraVigilance Data Analysis System (EVDAS)**: supporting the EU pharmacovigilance safety monitoring activities with the main focus on signal detection and evaluation of ICSRs;
- **Adrreports.eu portal**: allowing to search and view data on suspected adverse reactions for authorised medicinal products in the EEA and provides general information to aid the understanding of the reports.

The EMA launched a new EudraVigilance system with enhanced functionalities for reporting and analysing suspected adverse reactions in November 2017.

1.3. EudraVigilance system overview



1.4. EudraVigilance ESTRI gateway

The EudraVigilance gateway is a data-processing network which follows the <u>ICH M2 gateway</u> <u>recommendation for the electronic standards (for the) transmission (of) regulatory information (ESTRI)</u> for the secure electronic exchange of data.

The purpose of the EudraVigilance gateway is to operate a single common gateway for receiving regulatory submissions in a fully automated and secure way.

The EudraVigilance gateway allows MAHs, applicants and sponsors of clinical trials to report to a common reporting point within the EEA from where the transactions are re-routed to the addressed competent authorities, the EMA and the WHO.

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, receipt and transmission of ICSRs and 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 <u>EudraVigilance registration</u>

<u>webpages</u> for information on how to register your organisation with EudraVigilance for **medicinal product reporting**.

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.

1.5.1. User access to EVWEB and multi-factor authentication (MFA)

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 using a HTTPS (SSL) protocol. Secure sockets layer (SSL) provides security using 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. The registration process is outlined on the <u>EudraVigilance registration webpage</u>. User registration is manged in the <u>EMA Account Management</u> <u>portal</u>.

Multi-factor authentication was implemented for the production environment on 28 March 2023 and in the XCOMP (test) environment on 30 October 2023. Users can check and manage their EMA MFA credentials through the <u>following link</u>.

Additional guidance on setting up and managing MFA for EMA services is described here.

1.5.2. ActiveX component

EVWEB requires an internet connection, and the application is supported by Internet Explorer 8 and above. EVWEB may require, depending on the software available on the Windows Client, to install an **ActiveX Component for the User Interface** by following the instructions described in <u>this</u> <u>document</u>.

1.5.3. IE Tab

Following Microsoft's announcement that IE11 will be retired from 15 June 2022, the EMA investigated various alternatives and identified IE Tab extension for Google Chrome and Microsoft Edge as the best

alternative to access EVWEB. EMA validated that there is no loss of functionality nor changes in behaviour of EVWEB when accessed via IE Tab.

To access EVWEB with Microsoft Edge or Google Chrome using IE Tab, **registered users** should download the install IE Tab from the Google or Edge web stores and obtain the licence key from the <u>EV</u> restricted area. The steps to follow are described in the <u>'User Support' section, under 'XEVMPD</u> <u>Support'.</u>

For further technical information, please refer to the information available on the <u>'How to submit</u> <u>information on authorised and investigational medicines' webpage</u>.

A version of EVWEB with an XHTML Active Area is available to allow the visualisation and input of the full Unicode Character Set (<u>Production</u> and <u>XCOMP</u>).

1.5.4. Main EVWEB functionalities

The main functionalities of EVWEB are to:

 Create and send eXtended EudraVigilance Product Report Messages (XEVPRMs) 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 XEVPRMs via EVWEB. Gateway users may use the application to create XEVPRMs, but messages can only be sent via their local gateway or via EV Post functionality (see section <u>4.9. Use EV Post</u>), which is available in the restricted area of the EudraVigilance website (accessible by registered users only).

EVWEB automatically displays the complete sections of the hierarchical structure of a typical XEVPRM, 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 XEVPRM Acknowledgment messages (XEVPRM ACKs)

XEVPRM acknowledgement messages are used to inform the sender organisation (i.e. the marketing authorisation holder, sponsor of a clinical trial, EMA) that the XEVPRM has been received and processed by the EMA and of the outcome of validation of an authorised medicinal product entity performed by the Agency. See <u>Chapter 5: eXtended EudraVigilance Product Report</u> <u>Acknowledgement Message</u> for further information.

• Only Web Trader users can receive XEVPRM ACKs via EVWEB. Gateway users will receive their XEVPRM 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 (current and archived) 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 can 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 in use. MedDRA is fully integrated in the EVWEB application.

1.6. eXtended EudraVigilance Medicinal Product Report Message (XEVPRM)

An 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 from companies submitting information.

An XEVPRM can contain:

- product(s): authorised or development;
- approved substance¹;
- source(s)¹;
- organisation(s): MAH or sponsor;
- ATC Code(s)¹;
- pharmaceutical form(s)¹;
- administration route(s)¹;
- attachment(s);
- master file location(s).

When creating an XEVPRM message using EVWEB, 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 must specify only 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 'Message number' can be either a number or a text that will help the sender identify that XEVPRM.

• The **'Medicinal Products' section** is the main section and allows users to create product reports for authorised and development medicinal products that need to be added or maintained in the XEVMPD.

¹ Substances, as well as sources, standard and proposed terms are inserted and maintained in the XEVMPD by the EMA.

- Users can add more than one product entity in the same XEVPRM but for each product entity, the operation type and the medicinal product type ('Authorised' or 'Development') must be specified.
- The 'Substances' section, available only to EMA users, allows users to create substance reports for substances that need to be added or maintained in the substance look-up table in the XEVMPD.
 - More than one substance entities can be added in the same XEVPRM, but for each substance entity, the operation type, and the substance type (i.e., 'Approved') must be specified.
 - MAHs and/or sponsor users cannot insert or maintain substance information in the XEVMPD.
 Substance information is inserted and maintained in the XEVMPD by the EMA as per EMA processes and/or requests from MAHs/sponsors.
- The 'Sources' section, available only to EMA users, allows users to create reference sources that need to be added or maintained in the 'Source' look-up table in the XEVMPD.
 - Users can add more than one source entity in the same XEVPRM but for each source entity, the operation type must be specified.
 - MAHs and/or sponsor users cannot insert or maintain source information in the XEVMPD.
 Source information is inserted and maintained in the XEVMPD by the EMA as per EMA processes and/or requests from MAHs/sponsors.
- The '**Organisations' section** allows users to create organisation entities for marketing authorisation holders and sponsors that need to be added or maintained in the MAH and sponsor look-up tables.
 - Users can add more than one organisation entity in the same XEVPRM but for each organisation but for each organisation entity, the operation type, and the organisation type ('MAH' or 'sponsor') must be specified.
 - Marketing authorisation holders/sponsors are not allowed to send medicinal products for which they do not hold a marketing authorisation or for which they are not the sponsors. Users are only allowed to specify MAHs/sponsors/affiliate/subordinates that belong to their organisation hierarchy (e.g., the headquarter organisation and its affiliates). The organisations that users can specify must be registered in the EudraVigilance system; their 'Organisation Sender ID' must be reported in the 'Sender ID' field of the XEVPRM. Please refer to the <u>Registration with EudraVigilance</u> webpages for further information.
- The 'ATC Codes' section allows users to create ATC Codes that need to be added or maintained in the 'ATC Code' look-up table in the XEVMPD.
 - Standard and proposed ATC Codes are entered and maintained in the XEVMPD by the EMA as per EMA processes and/or requests from MAHs/sponsors.
 - Users can add more than one ATC Code in the same XEVPRM but for each ATC Code the operation type and the term type ('Standard', 'Proposed' or 'Development') must be specified.
 - Development terms can only be referenced in development medicinal products.
- The '**Pharmaceutical Forms' section** allows users to create pharmaceutical forms that need to be added or maintained in the 'Pharmaceutical dose form' look-up table.
 - Standard and proposed pharmaceutical forms are entered and maintained in the XEVMPD by the EMA as per EMA processes and/or requests from MAHs/sponsors.

- Users can add more than one pharmaceutical dose form in the same XEVPRM, but for each pharmaceutical dose form the operation type and the term type ('Standard', 'Proposed' or 'Development') must be specified.
- Development terms can only be referenced in development medicinal products.
- The 'Administration Routes' section allows users to create administration routes that need to be added or maintained in the 'Administration route' look-up table.
 - Standard and proposed routes of administration are entered and maintained in the XEVMPD by the EMA as per EMA processes and/or requests from MAHs/sponsors.
 - Users can add more than one administration route in the same XEVPRM but for each administration route the operation type and the term type ('Standard', 'Proposed' or 'Development') must be specified.
 - Development terms can only be referenced in development medicinal products.
- The '**Attachments**' **section** allows users to create a reference to a printed product information (PPI) and/or printed substance information (PSI) [PSI is currently not in use]. This information will be attached to the message when sending.
 - Users need to specify the file type and name, as well as the language of the file, the version number and version date of the file to be attached.
- The '**Master File Location**' **section** allows users 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 <u>Guidance documents related</u> to data submission for authorised medicines webpage:

- Extended EudraVigilance product report message (XEVPRM) schema;
- Chapter 3.I: Extended EudraVigilance product report message (XEVPRM) technical specifications;
- <u>Chapter 5: Extended EudraVigilance product report acknowledgement message</u>.

1.7. eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) 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 XEVMPD 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 EEA;
- accurately identify medicines, especially medicines included in reports of suspected adverse reactions;
- co-ordinate the regulation and safety monitoring of medicines across the EU and EEA.

The XEVMPD 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); and
- 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 based on their composition, regardless of their different trade names, or their MAHs or sponsors.

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 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 information on 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 consider 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 look-up 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 <u>Chapter 3.II: Extended</u> <u>EudraVigilance product report message (XEVPRM) user guidance</u>, section *1.2.13. AMP – Presentation Name element structure (AP.13).*

The document '<u>European Medicines Agency splitting of the full presentation name of the medicinal</u> product best practice: procedure and principles to handle product name in the EudraVigilance Medicinal <u>Product Dictionary (XEVMPD)</u>' also provides 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 consider 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 contains **medicinal product** information provided by marketing authorisation holders and sponsors of clinical trials.

Marketing authorisation holders, applicants, commercial or non-commercial sponsors may use Clinical research organisations (CROs), IT vendors and third-party service providers to act on behalf of these organisations by providing services related to EudraVigilance. These entities may be registered in EudraVigilance by the MAH, applicant, commercial or non-commercial sponsor as a **third-party service provider** to act on behalf of the MAH applicant, commercial or non-commercial sponsor. Further information can be found on the <u>EudraVigilance: how to register webpage</u>.

1.7.1.1. Marketing authorisation holders (MAHs)

As per <u>Article 57(2) of Regulation (EC) No 726/2004</u> as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012, marketing authorisation holders are required to submit to the EMA 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).

MAHs are also required to submit to the EMA information on all medicinal products for which they hold a marketing authorisation in the 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 <u>Legal Notice on the Implementation of Article 57(2) of Regulation (EC) No. 726/2004.</u>

Medicinal product data must be submitted to 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 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 fulfil new legal obligations. The new XSD schema is available in the EVWEB production environment as of 16 June 2014 and in XCOMP (i.e., the EudraVigilance External Compliance Testing Environment) from 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 (i.e., the SME status information).

For detailed information please refer to the <u>Reporting requirements for marketing-authorisation holders</u> webpage.

If the MAH organisation is a headquarter organisation, they may wish to send information on all medicinal products for which they and their affiliate(s) hold the marketing authorisation. Alternatively, the sending of the medicinal product information may be delegated to the individual affiliate(s), i.e. for those medicinal products for which the affiliate holds the local marketing authorisation.

1.7.1.2. Sponsors

<u>Directive 2001/20/EC</u>, Article 2 (d), provides the following definition of 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.'

Sponsors of clinical trials for human use are required to submit their investigational medicinal product information (IMP) in the XEVMPD as per Article 81(3) of <u>CT Regulation (EU) No 536/2014</u>: "*The EU database shall support the recording and submission to the Medicinal Product Dictionary, contained in the Eudravigilance database, of all the data on medicinal products without a marketing authorisation in the Union and substances not authorised as part of a medicinal product in the Union, that are necessary for the maintenance of that dictionary. To this effect and also with the purpose of enabling the sponsor to cross-refer to prior applications, an EU medicinal product number shall be issued for every medicinal product without a marketing authorisation and an EU active substances code shall be issued for each new active substance not previously authorised as part of a medicinal product in the Union. This shall be done before or during the application for authorisation of the first clinical trial with that product or active substance submitted in accordance with this Regulation. Those numbers shall be mentioned in all subsequent applications for clinical trials and for substantial modifications."*

Also, as stated in the <u>Detailed guidance on the collection, verification and presentation of adverse</u> <u>event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3') (OJ</u> <u>2011/C 172/01</u>) 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')'.

Sponsor organisations and their affiliates/subordinates (e.g., clinical research departments) must be registered with the EudraVigilance system. Registration is a prerequisite to enable the submission of investigational medicinal product information to the XEVMPD.

Sponsors may delegate the sending of medicinal product information to clinical research organisations (CROs) or IT vendors.

1.7.2. Data collected in the XEVMPD

The information collected in the XEVMPD concerns:

- authorised medicinal products (AMPs); and
- un-authorised (referred to in the XEVMPD as 'development') medicinal products (DMPs).

Many fields related to authorised or development medicinal products are coded in look-up tables in the XEVMPD.

Some look-up tables are maintained by the EMA, whilst other look-up tables can be maintained directly by the XEVMPD user (updatable look-up tables).

The look-up tables present in the XEVMPD are maintained as per the overview in the table below:

Look-up	Maintained by	Reference
MAH organisation list	MAH/sponsor	
SME status list	EMA	
QPPV list	MAH (via EV Registration process)	
MFL list	МАН	
Country code list	EMA	ISO
Authorisation procedures	EMA	
Authorisation status	EMA	
Legal basis list	EMA	
Orphan drug designation	EMA	
Additional monitoring designation	EMA	
Medicinal product type	EMA	
Standard pharmaceutical form list	EMA	EDQM
Proposed pharmaceutical form list	User EMA	
Development pharmaceutical form list	MAH/sponsor	
Standard administration route list	EMA	EDQM
Proposed administration route list	User EMA	
Development administration route list	MAH/sponsor	
Approved substance list	EMA	
Development substance list	EMA	
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 EMA	
Development ATC Code list	MAH/sponsor	
MedDRA version	EMA	MSSO
MedDRA level	EMA	MSSO
MedDRA term	EMA	MSSO
Attachments list	MAH/sponsor	
Attachment type list	EMA	
Attachment file type list	EMA	
EEA Language list	EMA	ISO

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

Whilst some data might not be flagged as mandatory via a technical rule, the provision of this data might be required via a business rule is place.

For list of data fields collected for entities in the XEVMPD and the business rules based on which the information needs to be provided for these fields and under which condition MAH/sponsor users should refer to the relevant user guidance document. I.e.:

- MAHs: <u>Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance;</u>
- **Sponsors**: <u>Guidance on the electronic submission of information on investigational medicinal</u> <u>products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD)</u>.

For technical specifications, please see <u>Chapter 3.I: Extended EudraVigilance product report message</u> (XEVPRM) technical specifications.

1.7.2.1. Authorised medicinal product (AMP)

The information regarding an authorised medicinal product includes the below information [the symbol (*) means mandatory]:

- (*) Marketing authorisation holder (MAH) of the AMP
- (*) Qualified Person responsible for Pharmacovigilance (QPPV)
- ^(*) Master File Location
- ^(*) PhV enquiry e-mail
- (*) PhV Phone number
- Sender Local Code
- (*) Info Date (applicable per the relevant business rules)
- (*) Authorisation Country Code
- (*) Authorisation Procedure
- ^(*) Authorisation Status
- (*) Authorisation Number
- ^(*) Authorisation/Renewal Date
- (*) MRP/DCP/EMEA Number (as applicable per the relevant business rules)
- (*) EU Number (as applicable per the relevant business rules)
- (*) Legal basis
- ^(*) Orphan drug status
- (*) Additional Monitoring
- (*) Invalidated MA date (as applicable per the relevant business rules)
- (*) Product Name information
 - (*) Full presentation name
 - (*) Product Short Name (as applicable per the relevant business rules)
 - (*) Product INN/Common Name (as applicable per the relevant business rules)
 - (*) Product Company Name (as applicable per the relevant business rules)
 - (*) Product Strength Name (as applicable per the relevant business rules)
 - (*) Product Form Name (as applicable per the relevant business rules)
- Package description
- (*) Comment (as applicable per the relevant business rules)

- (*) Medicinal Product Type
- (*) Authorised Pharmaceutical Form
- (*) (Administrable) Pharmaceutical Dose Form(s)
- ^(*) Route of Administration(s)
- Ingredients:
 - (*) Active Ingredient(s) substance(s)
 - (*) Strength of the Active Ingredient(s)
 - (*) Excipient(s) substance(s)
 - Strength of the Excipient(s)
 - ^(*) Adjuvant(s) substance(s)
 - (*) Strength of the Adjuvant(s)
- Old Drug Ingredient(s)
- Medical Devices
- ^(*) Product ATC Code(s)
- (*) Product Indication(s) (using MedDRA coding)
 - (*) MedDRA version
 - (*) MedDRA Level
 - (*) MedDRA Term
- (*) Previous EV Code(s) (as applicable per the relevant business rules)
- (*) Product Attachment(s) including validity declaration (as applicable per the relevant business rules)

For details on which information should be provided in the individual fields of an *authorised medicinal product (AMP) entity* MAHs should refer to <u>Chapter 3.II: Extended EudraVigilance product report</u> <u>message (XEVPRM) user guidance</u>.

1.7.2.2. Development medicinal product (DMP)

The information regarding a development medicinal product includes the below information [the symbol ^(*) means mandatory]:

- Sender Local Code
- ^(*) Sponsor of the DMP
- (*) Sponsor's Product Code or Product Name (as per applicable business rules)
- Product's Other Name, if applicable
- (*) Comment (as per applicable business rules)
- (*) (Administrable) Pharmaceutical Dose Form(s)
- ^(*) Route of Administration(s)
- Ingredients:
 - Active Ingredient(s) substance(s)
 - (*) Strength of the Active Ingredient(s)
 - Excipient(s) substance(s)
 - Strength of the Excipient(s)
 - (*) Adjuvant(s) substance(s)
 - (*) Strength of the Adjuvant(s)
- Old Drug Ingredient(s)
- Medical Devices
- Product ATC Code(s)

- Product Indication(s) (using MedDRA coding)
 - MedDRA version
 - MedDRA Level
 - MedDRA Term
- Product Attachment(s) including validity declaration (if applicable and as per relevant business rules)

For details on which information should be provided in the individual fields of a *development medicinal product (DMP) entity* sponsors should refer to the <u>Guidance on the electronic submission of information</u> <u>on investigational medicinal products for human use in the Extended EudraVigilance medicinal product</u> <u>dictionary (XEVMPD)</u> document.

1.7.2.3. Approved substance (AS)

The information collected regarding an approved substance (AS) includes the below information [the symbol ^(*) means mandatory]:

- ^(*) Substance Name in English
- (*) The Substance Class and the reference source for the Substance (e.g. INN, EU Pharmacopoeia)
- ^(*) Source
- CAS² Number / CBD³ / Molecular Formula
- (*) Comment (as per applicable business rules)
- Alias/ Translation(s)
- Substance International Code (including the Source)
- Substance Parent Code (including the Substance Type)
- Previous EV Code(s)
- Substance Attachment(s)

Substance information can be inserted and/or updated in the XEVMPD by the EMA only. The process on how to request the insert/update of substance information in the XEVMPD is described in the relevant guidance document:

MAHs: Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance.

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

1.7.2.4. <u>Source</u>

The information collected regarding a source includes the below information [the symbol ^(*) means mandatory]:

- (*) Source Name
- (*) Comment (as per applicable business rules)

² CAS = Chemical Abstract Service

³ CBD = Chemical/Biological Description

Source information can be inserted and/or updated in the XEVMPD by the EMA only. The process on how to request the insert/update of source information in the XEVMPD is described in the relevant guidance document:

MAHs: <u>Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance</u>.

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

1.7.2.5. MAH organisation

The information collected regarding a marketing authorisation holder organisation includes the below information [the symbol ^(*) means mandatory]:

- ^(*) MAH Name
- ^(*) SME status
- SME number (if applicable)
- MAH Sender ID
- ^(*) Address
- ^(*) City
- Region
- ^(*) Post Code
- ^(*) Country Code
- Tel Number
- Tel Extension
- Tel Country Code
- E-mail Address
- (*) Comment (as per applicable business rules)

For details on what information should be provided in the individual fields of *MAH* entity MAHs should refer to <u>Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance</u>.

1.7.2.6. Sponsor organisation

The information collected regarding a sponsor organisation includes the below information [the symbol ^(*) means mandatory]:

- ^(*) Sponsor Name
- Sponsor Sender ID
- (*) Address
- ^(*) City
- Region
- ^(*) Postcode
- (*) Country Code
- Tel Number
- Tel Extension
- Fax Number
- Fax Extension

- Fax Country Code
- E-mail Address
- (*) Comment (as per applicable business rules)

For details on which information should be provided in the individual fields of a *sponsor organisation entity* sponsors should refer to the <u>Guidance on the electronic submission of information on</u> <u>investigational medicinal products for human use in the Extended EudraVigilance medicinal product</u> <u>dictionary (XEVMPD)</u> document.

1.7.2.7. <u>ATC Code</u>

The information collected for an ATC Code includes the below information [the symbol ^(*) means mandatory]:

- ^(*) ATC Code
- ^(*) ATC Code Description
- ^(*) Version Date
- (*) Comment (as per applicable business rules)

For details on what information should be provided in the individual fields, and/or how to request the addition/amendment of a proposed or standard *ATC Code entity*, MAHs/sponsors should refer to the below documents:

MAHs: <u>Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance</u>.

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

1.7.2.8. 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 EV Code
- (*) Comment (as per applicable business rules)

For details on what information should be provided in the individual fields, and/or how to request the addition/amendment of a proposed or standard *pharmaceutical form entity*, MAHs/sponsors should refer to the below documents:

MAHs: Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance.

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

1.7.2.9. Route of administration

The information collected regarding a development/proposed route of administration includes the below information [the symbol ^(*) means mandatory]:

- ^(*) Administration Route Name
- ^(*) Version Date
- Previous EV Code
- (*) Comment (as per applicable business rules)

For details on what information should be provided in the individual fields, and/or how to request the addition/amendment of a proposed or standard *route of administration entity*, MAHs/sponsors should refer to the below documents:

MAHs: <u>Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance</u>.

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

1.7.2.10. Printed product information (PPI)/printed substance information (PSI)

The information collected regarding the attachment for the printed product information (PPI) includes the below information [the symbol ^(*) means mandatory]:

- ^(*) File Type
- ^(*) Name
- (*) Type (PPI or PSI)
- ^(*) Language
- 2nd Language
- ^(*) Version Number
- ^(*) Version Date

For details on what information should be provided in the individual fields of *a Printed Product Information (PPI) entity* MAHs/sponsors should refer to the below documents:

- MAHs: Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance.
- Sponsors: Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD).

The same rules are applicable to a *printed substance information (PSI)* - the attachment type is however to be specified as 'PSI' (2). Please note that **PSI is not in use**.

1.7.2.11. 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
- Region
- ^(*) Post Code
- ^(*) Country
- (*) Comment (as per applicable business rules)

For details on what information should be provided in the individual fields of *a PSMFL entity* MAHs should refer *to* <u>Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user</u> <u>guidance</u>.

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

- exchanging XML files through an ESTRI gateway or the EV Post function; or
- using EVWEB.

At the end of each procedure, the EudraVigilance system handles and processes the XEVPRM.

Before explaining how to use EVWEB for creating and sending an XEVPRM, 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:

- **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.
- **authorised medicinal product (AMP):** a medicinal product authorised either within or outside the EEA.
- 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.
- **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 referenced in development medicinal products.
- 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).

- 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).
- **proposed term:** term for which there is an application to the maintenance organisation, but the term is not yet approved or published. Until mid-January 2024, these terms are were entered and maintained in the XEVMPD by sponsors and/or MAHs. From 18 January 2024, only the EMA can insert and maintained proposed terms in the XEVMPD. Proposed terms can be used either in development medicinal products or authorised medicinal products. MAHs/sponsors can request the addition and/or amendment of a proposed term in the XEVMPD using the process described in the relevant guidance document.
- **standard term:** term published as a term of standard terminology by an official maintenance body [e.g., European Directorate for the Quality of Medicines (EDQM)] used in the XEVMPD. This information is entered and maintained in the XEVMPD by the European Medicines Agency (EMA). as per EMA processes and/or requests from MAHs/sponsors. Standard terms can be used either in development medicinal products or authorised medicinal products. MAHs/sponsors can request the addition and/or amendment of a standard term in the XEVMPD using the process described in the relevant guidance document.
- **term:** pharmaceutical dose form, administration route, or an ATC Code.

1.7.4. Data ownership and maintenance

Medicinal product information submitted via the XEVPRM is 'owned' by the **EudraVigilance headquarter (HQ) ID** of the sender organisation that submitted the information. For each submitted entity the XEVMPD stores the **sender organisation ID** and the **owner organisation ID** and checks these fields before allowing the modification of such entity.

• Only the owner organisation (registered in EV as a HQ) and/or the affiliate(s) registered under this HQ profile is/are authorised to maintain the data that they submitted in the XEVMPD.

Duplicated or obsolete entities can only be nullified by the owner organisation and or its affiliates and/or the EMA if they are **not** referenced in any other current (i.e., not nullified) entities. With the exception of development medicinal products, which can be nullified even if flagged as validated in the XEVMPD, validated entities can only be nullified by the EMA upon a request received via the <u>EMA</u> <u>Service Desk portal</u>:

- Substance related requests: via <u>'Request SMS services' ticket.</u>
- XEVMPD product data related request: via <u>'Request XEVMPD/Art.57 Services' ticket</u>.

• MAHs and/or sponsors cannot perform maintenance related operation types on substances, sources and proposed or standard terms (ATCs, pharmaceutical forms, routes of administrations); these will

lead to a negative XEVPRM ACK. Amendments to these entities in the XEVMPD can be requested as follows:

- Amendment of substance entity in the XEVMPD: via <u>'Request SMS services' ticket</u> in EMA Service Desk
- Amendment of source entity, proposed or standard ATC Code, proposed or standard pharmaceutical form and/or proposed or standard route of administration in the XEVMPD via a change request submitted in the <u>Referentials Management System (RMS) portal</u> as per instructions in the relevant guidance document.

An overview of the operation types that MAH/sponsor organisations can perform on XEVMPD entities **taking into account the applicable ownership, business and technical rules,** is provided below:

		K (M)	e ⁽²⁾	tion (3	fication	(A) MA (6
	Inser	Upda	Varie	Null	. Inve	
Authorised product	✓	√	X	√	√	
Development product	√	√	X	√	X	
Approved substance	X	x	x	x	x	
Development substance	x	x	x	x	x	
Attachment	v	x	x	x	x	
Master File Location	v	√	x	√	x	
Source	X	x	x	x	x	
MAH organisation	v	✓	x	√	x	
Sponsor organisation	v	✓	x	√	x	
Development Pharmaceutical Form	~	~	x	~	x	
Proposed and Standard Pharmaceutical Form	X	x	x	x	x	
Development Route of Administration	√	√	X	✓	X	
Proposed or Standard Route of Administration	X	X	X	x	X	
Development ATC Code	✓	✓	X	√	X	
Proposed or Standard ATC Code	X	X	x	x	X	

1.7.5. Data quality

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

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

Users will receive an XEVPRM acknowledgement for every XEVPRM sent to the XEVMPD. The acknowledgement informs the sender organisation 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 <u>Chapter 5: Extended</u> <u>EudraVigilance product report acknowledgement message</u> and *Appendix 5 – Element Acknowledgement Codes* of <u>Chapter 3.I: Extended EudraVigilance product report message (XEVPRM)</u> <u>technical specifications</u>.

In July 2014, the Agency began the review of quality and integrity of <u>authorised medicinal product</u> <u>information</u> submitted in line with the amended XEVPRM format and specifications effective as of 16 June 2014.

The EMA performs data integrity assessments (referred to as 'validation') and, where necessary, revisions in accordance with the principles outlined in the published <u>Data Quality Control methodology</u>. Systematic assessment of **the latest version** of the received medicinal product data is performed by checking each data element against the information stated in the provided summary of product characteristics (SmPCs) or equivalent document that facilitates the data quality assurance process by the EMA. When this assessment in completed, the entity is **flagged as 'validated' in the XEVMPD**. The EMA does not perform an assessment of each version of the AMP record. Also, once an AMP is nullified or invalidated, no further assessment is performed by the EMA. For further information please see the Agency's document <u>Quality control of medicinal-product data submitted as per the legal requirement introduced by Article 57(2) of Regulation (EC) No 726/2004</u>.

The EMA does not perform dedicated validation of <u>development product information</u> in the XEVMPD; **DMP entities are automatically flagged as valid by the system** (i.e., the 'Product Validity' field in EVWEB displays 'Valid') upon their initial submission by the sponsor organisation. This is to allow for the DMP to be available for the recoding of suspected unexpected serious adverse reactions reports (SUSARs).

1.7.6. Product status fields

Following a successful submission of a medicinal product entity in the XEVMPD, a version number is assigned (i.e. if a new AMP/DMP is submitted via an operation type 'Insert', the version number will be '1').

When maintenance related operation(s) are applied to this entity, subsequent version numbers will be assigned (e.g., if an 'Update' is performed following the 'Insert', the version number will be '2' and any other subsequent updates will be assigned version numbers '3', '4' etc.).

The following fields are available in EVWEB to provide information on the history and status of the product entity:

Version
Version Status
Version Validity
Version Description
Product Validity
Product Pending
Product Nullified
Version Date
Version by
New Version ?
New Version by
Nullified

• Version

This field indicates the number of the displayed version and the total number of versions for this product (e.g. 1/1).

• Version Status

This field indicates whether the displayed version of the product was:

- Accepted (i.e. it is a correct version of this product),
- Nullified (i.e. it is a nullification version the last correct data is the previous version),
- Rejected (i.e. the update by an MAH is an identical copy of the version created before the validation by the EMA),
- Unassessed (i.e. the version was incorrectly processed; there were issues in the loading process. This would be an exceptional situation).

• Version Validity

This field indicates whether the displayed version of the product:

- Need MAH follow-up (i.e. this version of the product has been assessed by EMA and MAH follow-up is needed); the status is currently not used, MAHs are contacted directly when needed,
- Unassessed (i.e. this version of the product has not been assessed by EMA),
- Valid (i.e. this version of the product has been assessed by EMA as valid).

• Version Description

A one-line description of the status of this product version is included in this field (e.g., 'Current valid version') and it is a concatenation of the above-described terms.

• Product Validity

This field indicates whether the product entity was flagged as:

- Not Assessed (i.e., no version of this product has been assessed by EMA),
- Valid (i.e., a version of this product has been assessed as 'Valid' by EMA),

 Need MAH follow-up (i.e., this version of the product has been assessed by EMA and MAH follow-up is needed); the status is currently not used, MAHs are contacted directly as an when needed.

Product Pending

This field indicates whether the product version was flagged as:

- Not Assessed (i.e., this version has not been assessed by EMA),
- Pending Update (i.e., this Version is an update of a version assessed by EMA),
- Assessed (i.e., this version has been assessed by EMA).

Product Nullified

This field indicates whether the product entity has been nullified. The following field values are available:

- Yes,
- No.

• Version Date

The date and time of the receipt of the message containing this product version is included (e.g., '09/07/2015 13:19:32'.

• Version By

The sender ID (organisation routing ID) of the sender of the message containing this product version is included (e.g., 'EVHUMANWT').

• New Version ?

This field indicates whether there is a newer (more recent) version of this product (e.g., following an update, nullification etc.). The available values are:

- Yes,
- No.

• New Version By

The sender ID (organisation routing ID) of the sender of the message containing a newer version of this product (e.g., update, nullification, etc.) is included ((e.g. 'EVHUMANWT').

Nullified

This field indicates whether this version of the product is a version that nullifies the product entity. The available values are:

- Yes
- No

To compare the current versus the previous version of the same AMP record (excluding nullified products) please refer to section *4.15. Comparing individual versions of a medicinal product entity*.

1.7.7. Data access policy

An organisation registered with the EudraVigilance system, and that is not a national competent authority (NCA), can read:

- data for which they are the owner;
- authorised medicinal products validated by the EMA;
- approved substances, terms and organisations flagged as validated by the EMA/system.

Some information collected in the XEVMPD is however strictly confidential: **Development substances**, **development products and development terms not owned by the organisation**, **even if flagged as** 'Valid' by the EMA/system, **remain strictly confidential in the XEVMPD**, **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 as follows:

MAH/sponsor users	Entities owned organisa	by user's HQ ation	Entities not owr organi	red by user's HQ isation
Read access in EVWEB	Not assessed	Flagged as "Valid"	Not assessed	Flagged as "Valid"
Authorised products	\checkmark	√	X	√
Approved substances	Not applicable	Not applicable	√	√
Development data (products/substances /terms) CONFIDENTIAL	~	~	x	x
Organisations	\checkmark	√	x	√
Proposed terms	√*	√*	√	√
Standard terms	Not applicable	Not applicable	\checkmark	\checkmark
Sources	√*	√*	x	√
PSMFLs	\checkmark	Not applicable		Not applicable
Attachments	\checkmark	Not applicable	Not applicable	Not applicable

* Historically submitted by MAHs/sponsors ** Only limited information is visible

National competent authority registered with the EudraVigilance system can read every entity that has been validated by the EMA. The general rules applicable to any national competent authority registered with the EudraVigilance System are summarised in the following table:

NCAs	Entities owned organisa	by user's HQ ation	Entities not owr organ	red by user's HQ isation
Read access in EVWEB	Not assessed	Flagged as "Valid"	Not assessed	Flagged as "Valid"
Authorised products	Not applicable	Not applicable	√	√
Approved substances	Not applicable	Not applicable	√	✓
Development data (products/substances /terms) CONFIDENTIAL	Not applicable	Not applicable	~	~
Organisations	Not applicable	Not applicable	x	√
Proposed terms	Not applicable	Not applicable	√	√
Standard terms	Not applicable	Not applicable	\checkmark	\checkmark
Sources	Not applicable	Not applicable	x	√
PSMFLs	Not applicable	Not applicable	√	Not applicable
Attachments	Not applicable	Not applicable	x	Not applicable

1.7.8. Controlled vocabularies and terminologies

Terminologies and Controlled Vocabularies (CVs) are integrated in EudraVigilance, the below CVs are available on the <u>Agency's website</u>, 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 MedDRA license can be obtained (purchased) from the <u>MSSO</u>;
- ATC Codes need be obtained from the <u>WHO Collaborating Centre for Drug Statistics Methodology</u>;
- Pharmaceutical forms and routes of administration are based on the standard terms published by the <u>European Directorate for the Quality of Medicines & HealthCare (EDQM);</u>
- 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 <u>International Organization for</u> <u>Standardization (ISO)</u>;
- 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 <u>International Organization for Standardization (ISO)</u>.

2. Accessing EVWEB

Before accessing EVWEB you should have

- multi-factor authentication (MFA) set up;
- approved user access to the required environment for the required organisation via the EMA Account Management portal; and
- ActiveX and IE Tab extension installed on your computer.

To access EVWEB for XEVPRM production or XCOMP (test) environment, go to the <u>'EudraVigilance'</u> <u>webpage</u> and select the required environment:

Login for registered user	S				
ď					
		EudraVigilance XCOMP (Test)	6	-]	
đ	0	EudraVigilance Production	6	-]	

Alternatively, you can click on the below links:

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

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

The organisation/list of organisations, under which you are registered in the <u>EMA Account Management</u> <u>portal</u> as a user, will be displayed.

Please note that the below screenshots show logon to the **XEVMPD production environmen**t.

Organisation Selection Form	× +	- 🗆 X
← → C 😁 eudravigilan	ce.ema.europa.eu/human/restricted/os/org 🍳 🖈 🤤	ඩ 💷 😩 E
Eudra Vigilance Human Restricted		Home Restricted Home Public
		Restricted Area
	Welcome Select organization	
For the UK, as from 1	EV (HQ) - - EV V EV (HQ) - - EV VWT // [EV N (HQ)] EV (AFF) - Web Trader - EV NWT // [EV N (HQ)] Select Cancel .1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/N	41

Select the organisation under which you wish to log on to EVWEB:

Organisation Selection Form	× +	- 🗆 X
← → C 😁 eudravigilar	ce.ema.europa.eu/human/restricted/os/org 🍳 🛧 🤨	ඩ 🛛 😩 :
EudraVigilance: Human Restricted		Home Restricted Home Public
		Restricted Area
	Welcome Select organization	
For the UK, as from	EV WT (AFF) - Web Trader - EV WT /, V I have read and accepted the Terms of Use Select Cancel 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI	

If you are logging on for the first time, confirm that you have read and accepted the Terms of use.

In the restricted area, click on 'EVWEB - Art 57 / XEVMPD':


You will be required to complete a multi-factor authentication. See section *1.5.1. User access to EVWEB and multi-factor authentication (MFA)* for related information.

	hc.htm#url=https://login.microsoftonline.com/bc9dc15c-61bc-4f03-b60b-e5b6d8922839/oauth2/v2.0/authorize?cli 🛠 🧕 🧿
Address: https://login.microsoftonline.com/bc9dc15c-61bc-4f03-b60b-e5b6d8922839/oauth2/v2.0	/authorize?client_id=82c4308b-17d5-4493-beb8-44f9873442c3&response_type=code+id_token&scope=openid+profile&state=OpenIdConnect Authenticat
	0
	Pick an account
	Connected to Windows

Once the MFA is completed, a new window will pop-up, informing you that IE Tab extension is required for EVWEB to work properly:

÷	\rightarrow	×	eudravigilance.ema.europa.eu/human/restricted/x/x.asp
			eudravigilance.ema.europa.eu says Internet Explorer or Chrome/Edge with the installed extension IE tab is required for EVWEB to work properly

Dismiss the window by clicking on 'OK' and access the link to EVWEB production environment using IE Tab:

÷	÷	G	ta eudravigilance.ema.europa.eu/human/restricted/x/x.asp	* 3 5 4 *
			Application Compatibility Test Please wait	

You have now accessed EVWEB; the organisation ID under which you are logged in is shown in the top right corner:



The main menu is located at the top of your screen and consists of two sets of buttons: the default buttons 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.

Display Settings	For the UK, as from 1.1.2021, EU Law applies o
5	6

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 changing the active area from ActiveX (default set up) to XHTML 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 simple query field.
- 5. The tree-view area.
- 6. The active area.

3. Accessing medicinal product section in EVWEB

To access the 'Medicinal Products' section, click on the 'Medicinal Products' or 'Products' button (depending on your screen set up) on the main menu:

Display Settings			
WEB Trader Create and Send Product Reports	Medicinal Products	MedDRA	
Reset Application Reset Section Clear			

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.

3.1. The main menu

3.1.1. Sections navigator menu

Depending on your screen settings and EVWEB chosen font size, the menu is displayed in the 'full' version:

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

or in the 'short' version:

WE	EB Trader	Send Products	Products	MedDRA
	Reset App	Reset Section	Clear 0]

To expand the menu, click on the square button highlighted above.

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

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

Create and Send Product Reports Allows users to create and send an XEVPRM.

Medicinal Products Allows users to browse and perform searches at all levels of the XEVMPD.

MedDRA

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

3.1.2. Default buttons set

Display Settings \succeq 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:

Display Settings
Switch To XHTML Interface
Reset Settings to Default
Font Arial 8pt
Font Arial 9pt
Font Arial 10pt
Font Arial 11pt
Font Arial 12pt
Font Arial 14pt
Font Arial 16pt
Font Tahoma 8pt
Font Tahoma 9pt
Font Tahoma 10pt
Font Tahoma 11pt
Font Tahoma 12pt
Font Tahoma 14pt
Font Tahoma 16pt
Font Verdana 8pt
Font Verdana 9pt
Font Verdana 10pt
Font Verdana 11pt
Font Verdana 12pt
Font Verdana 14pt
Font Verdana 16pt
Color Errors Red
Color Errors Green
Color Errors Blue

ActiveX Interface (default set up) 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 (they will be displayed in the active area, but not on the tree view).

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.

Reset Application

Resets the application, affects all its sections. You will lose all locally entered

data up to that point.

Reset Section 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.

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

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

3.1.3. Dynamic buttons set

Display Settings	
WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Dynamic button area	

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 in which you are working, and the related item(s) selected in the treeview area; and

- the applicable visibility and ownership rules in place.

For example, it can display the following buttons:

XML RTF Other Operations XML RTF Update Other Operations	XML RTF Reinsert Load
ReRun Modify Delete Excel Export - Reload - Load - D	
Local Import Create Ack -	
Version O	

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

3.2. 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).

Display Settings				
WEB Trader Create and Send Product Reports Medicinal Products MedDF	A			
Reset Application Reset Section Clear				
Authorised Medicinal Products Development Medicinal Products The tree-view area	Empty			
Approved Substances Development Substances				
Sources MAHs				
Sponsors ATC Codes				
Routes of Administration				
Master File Locations				
Attachments Abstract Compositions				
🗄 Queries				

To select an item in the tree-view, 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 must 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 area 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.

3.3. 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 area and the active area is that the active area is interactive and displays information that can be edited and modified by the user whilst the tree-view area only displays available items from the XEVPRM (see section <u>3.5. Data entry</u>).

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:

WE	B Trader Create and Send Product Reports Medicinal Products	MedDRA					
	Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R						
	EVPRM Message						
	Products	Description	Name/Value				
	Organisations	Message Number		Field is Mandatory			
	ATC Codes		Products				
	Pharmaceutical Forms		Substances				
	-Routes Of Administration		Organisations				
	Attachments		ATC Codes				
	Master File Locations		Pharmaceutical Forms				
			Routes Of Administration				
			Attachments				
			Master File Locations				

• **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.

WEB Trader Create and Send Product Reports	Medicinal Produc	ts MedDRA					
Reset Application Reset Section Clear XML	RTF 0						
Authorised Medicinal Products	pharmacopoeia	armacopoela*					
- Development Medicinal Products	Num	Source Name	EV Code	Validated	Nullified		
Approved Substances	0001	PHARMACOPOEIA BOHEMOSLOVACA	SRC664	29/02/2012 09:35:00			
Development Substances							
Sources							
MAHs							
Sponsors							
-ATC Codes							
-Routes of Administration							
Pharmaceutical Forms							
Master File Locations							
Attachments							
-Abstract Compositions							
Queries							

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	Validated	Nullified
0001	PHARMACOPOEIA HELVETICA	SRC870	14/09/2012 10:22:20	
0002	PHARMACOPOEIA BOHEMOSLOVACA	SRC664	23/11/2011 16:03:50	

pharmacopoeia*						
Num	Source Name	EV Code	Validated	Nullified		
0002	PHARMACOPOEIA BOHEMOSLOVACA	SRC664	23/11/2011 16:03:50			
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 <u>3.6.1. Simple query</u>).



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.

3.4. Interaction between the tree-view area 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 or a list view, depending on the section selected. To display the details of any of your items you have two options:

- double click on the name of the item in the active area; or
- click once on the name of the item 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.

3.5. Data entry

This section contains information on all the specific actions that you can perform to insert data in the EVWEB application.

3.5.1. 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' or 'Field must have a specified value'. 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 competed⁴.

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) user manual EMA/308954/2012

⁴ In case of 'Invalidated date', the 'Field is mandatory' will continue to appear until some further sections are completed.

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA		
Reset Application Reset Section Clear Replicate Validate Send	XML ZIP RTF Duplicate Remove E	LR	
E-XEVPRM Message			
Products	Description	Name/Value	
- Insert - Authorised	QPPV	F	
-Medicinal Product Types (-)	Master File Location		
-Authorised Pharmaceutical Forms (-)	PhV enquiry email		Field must have a specified value
Pharmaceutical Products (-)	PhV enquiry Phone		Field must have a specified value
	Sender Local Code		
Drug Indications ()	Info Date		
Draginal Caloris (-)	Authorisation Country Code		Field is Mandatory
Previous EV Godes (-)	Authorisation Procedure		Field is Mandatory
Product Attachments (-)	Authorisation Status		
Organisations	Authorisation Number		Field must have a specified value
-ATC Codes	Authorisation/Renewal Date		Field must have a specified value
Pharmaceutical Forms	MRP/DCP/EMEA Number		
Routes Of Administration	EU Number		
Attachments	Legal Basis		
Master File Locations	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 Broduct Turses ()	Castian is Mandatany
		Authorized Deermanoutical Forms ()	Section is Mondatony
		Pharmaceutical Products (-)	Section is Mandatory
			Section is Mandatory
		Drug Indications (-)	Section is Mandatory
		Previous EV Codes (-)	Coolion is Manualory
			o. c



3.5.1.1. 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 must first select it by clicking once on the field space:

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA		
Reset Application Reset Section Clear Validate Send XML ZIF	RTF E L R		
XEVPRM Message			
	Description	Name/Value	
	Message Number		Field is Mandatory
		Products	
		Substances	
		Organisations	
		ATC Codes	
		Pharmaceutical Forms	
		Routes Of Administration	
		Attachments	
		Master File Locations	

and then press 'Enter' on your keyboard:

E

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA		
Reset Application Reset Section Clear Validate Send XML ZIF	PRTFELR		
	Description	Name/Value	
	Message Number		Field is Mandatory
		Products	
		Substances	
		Organisations	
		ATC Codes	
		Pharmaceutical Forms	
		Routes Of Administration	
		Attachments	
		Master File Locations	

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

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA		
Reset Application Reset Section Clear Validate Send XML ZIF	PRTFELR		
E XEVPRM Message			
	Description	Name/Value	
	Message Number		Field is Mandatory
	-	Products	
		Substances	
		Organisations	
		ATC Codes	
		Pharmaceutical Forms	
		Routes Of Administration	
		Attachments	
		Master File Locations	

A blank text box appears in the field 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 and press the 'Delete' key on your keyboard to delete the data (not backspace).

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.

E-XEVPRM Message			
⊟ Products	Description	lame//alue	
□ Insert (1) - Authorised (2)	Description	vame/value	
Medicinal Product Types (-)	EV Code		Field in Mandatan
-Authorised Pharmaceutical Forms (-)			Field is Mandatory
- Pharmaceutical Products (-)	Meeter File Leastion		
-Drug ATCs (-)	DbV onguin ompil		Field must have a specified value
- Drug Indications (-)	Phy enquiry email Phy organic Phone		Field must have a specified value
Previous EV Codes (-)	Sonder Local Code		Tield must have a specified value
Product Attachments (-)	Info Date		
Substances	Authorisation Country Code		Field is Mandatony
Sources	Authorisation Procedure		Field is Mandatory
Organisations	Authorisation Status		i loid lo mandatory
ATC Codes	Authorisation Number		Field must have a specified value
Pharmaceutical Forms	Authorisation/Renewal Date		Field must have a specified value
- Routes Of Administration	MRP/DCP/EMEA Number		
Attachments	EU Number		
Master File Locations	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	Andiaian Devoluent Transa ()	Continu in Mandatan
	Value 🗸 🗙		A ANNUAL TO PROPAGATORY
	You can insert a long text in this f	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.

3.5.1.2. 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 by pressing 'Enter' on your keyboard after having selected it.



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. The available formats are based on the business rules.

Calenda	r X
yyyymn	Format X
◀ 2014 ▶ ◀	yyyymmdd
Su Mo Tu We	yyyymm
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:

• If yyyymmdd is selected, the calendar will appear in the following format:

Calendar						х		
		1	үүү	ymn	ndd			
۹	201	4	•	•	- P	tay		×
	Su	Мо	Тu	We	Th	Fr	Sa	
					1	2	3	
	- 4	5	6	- 7	8	9	10	
	11	12	13	14	15	16	17	
	18	19	20	21	22	23	24	
	25	26	27	28	29	30	31	

• If yyymm is selected, the calendar will appear in the following format:

~	Calendar				X
yyyymm					
•	2014	۲	•	May	•

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 or click on the year and month to allow faster navigation.

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.

To exit the calendar without selecting a date, click on the sign located on the top left corner of the calendar screen.



By doing so, the date will reference only the month and year:

Authorisation/Renewal Date	/05/2014
----------------------------	----------

3.5.1.3. Look-up fields/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:



3.5.1.4. Remote database look-up 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:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA									
Reset Application Reset Section Clear Repitcate Validate XML ZIP RTF Duplicate Remove E L R									
E-XEVPRM Message	oral use	al use							
Products	Description Name	e/Value							
Insert - Authorised	Type Autho	orised							
-Medicinal Product Types (-)	Operation Type Insert	t							
Authorised Pharmaceutical Forms (-)	MAH		Field is Mandatory						
—Pharmaceutical Products (-)	QPPV								
-Drug ATCs (-)	Master File Location		Field m QPPV (AP 5) hifind value						
- Drug Indications (-)	Phy enquiry email Phy organic Phono		Field must have a specified value						
Previous EV Codes (-)	Sender Local Code		rield must have a specified value						
Product Attachments (-)	Info Date								
Substances	Authorisation Country Code		Field is Mandatory						
Sources	Authorisation Procedure		Field is Mandatory						
Organisations	Authorisation Status								
ATC Codes	Authorisation Number		Field must have a specified value						
Pharmaceutical Forms	Authorisation/Renewal Date		Field must have a specified value						
-Routes Of Administration	MRP/DCP/EMEA Number								
Attachments	EU Number								
Master File Locations	Orphan Drug								
	Additional Monitoring								
	Invalidated Date		Field must have a specified value						
	Full Presentation Name		Field is Mandatory						
	Organisation Name								
	Query Mode Begins								

You can also select the field with your cursor and press the '**R**' (**Remote Database Look-up**) button:

WEB Trader Create and Send Product Reports Medicinal Products MedDF Image: Reset Application Reset Section Clear Validate XMI ZIP RTF Dun			1 of an
Reset Application Reset Section Clear Validate XML ZIP RTF Dup XEVPRM Message Products Insert - Development Pharmaceutical Products (-) Drug ATCs (-) Product Attachments (-) Substances Sources Organisations ATC Codes Pharmaceutical Forms Routes Of Administration Attachments	Ilicate Remove E L R oral use Description Type Operation Type Sender Local Code Sponsor Product Code Product Name Product Other Name Comment	Name/Value Development Insert Pharmaceutical Products (-) Drug ATCs (-) Drug Indications (-) Product Attachments (-)	Field is Mandatory Field is Mandatory Optional Field is Mandatory Optional Section is Mandatory
-Master File Locations			

In both cases, a search window 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:

				•
Products	Description	Name/Value		
⊟ Insert (1) - Authorised (2)	Operation Type	Insert (1)		
Medicinal Product Types (-)	Type	Authorised (2)		
Authorised Pharmaceutical Forms (-)	EV Code			
Pharmaceutical Products (-)	MAH		Field is Mandatory	
Drug ATCs (-)	QPPV	,	· · · · · · · · · · · · · · · · · · ·	
Drug Indications (-)	Master File Location	1		
Previous EV Codes (-)	PhV enguiry emai	1	Field must have a specified value	
Product Attachments (-)	PhV enquiry Phone		Field must have a specified value	
Substances	Sender Local Code	8	•	Ξ.
Sources	Info Date	•		
Organisations	Authorisation Country Code	•	Field is Mandatory	
ATC Codes	Authorisation Procedure	•	Field is Mandatory	
- Pharmaceutical Forms	Authorisation Status	1 · · · · · · · · · · · · · · · · · · ·	-	
Routes Of Administration	Authorisation Number	r	Field must have a specified value	
Attachments	Authorisation/Renewal Date	•	Field must have a specified value	
Master File Locations	MRP/DCP/EMEA Number	r		
	EU Number	r		
	Legal Basis	1		
	Orphan Drug	1		
	Additional Monitoring	1		
	Invalidated Date	5	Field must have a specified value	
	Full Presentation Name	1	Field is Mandatory	
	Product Short Name	1	Field is Mandatory Optional	
	Product INN/Common Name	1	Field is Mandatory Optional	
	Product Company Name	1	Field must have a specified value	-
	Product Strength Name			
	Organisation Name			-
	Query Mode Beg	gins		_
				Select option
				Press A - Z to find initial letter Press Enter to select, Escape to clear
				Matches
				Begins
				Contains
				Sounds like
	MAH (AP.4)			Contains + Sounds like

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 on 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 must select one of the items displayed in this list by either pressing 'Enter' or by doubleclicking on the selected value:

-XEVPRM Message	DrugVero						
Products	Descript	tion Name	e/Value		[
i⊟ Insert (1) - Authorised (2)	Operation Ty	vne Insert					
Medicinal Product Types (-)	T	vne Autho	orised (2)				
 Authorised Pharmaceutical Forms (-) 	EV C	ode	011300 (2)				
—Pharmaceutical Products (-)	M			Field is Mandatory			
-Drug ATCs (-)	OP	PV		Tield is Mandatory			
-Drug Indications (-)	Master File Locat	tion					
Previous EV Codes (-)	PhV enquiry en	nail		Field must have a spec	rified value		
-Product Attachments (-)	PhV enquiry Pho	one		Field must have a spec	cified value		
Substances	Sender Local Co	ode		r loid materiale a oper			
Sources	Info D)ate					
	Authorisation Country Co	ode		Field is Mandatory			
-ATC Codes	Authorisation Proced	lure		Field is Mandatory			
Pharmaceutical Forms	Authorisation Sta	itus		, , , , , , , , , , , , , , , , , , , ,			
Routes Of Administration	Authorisation Num	iber		Field must have a specified value			
	Authorisation/Renewal D	ate		Field must have a spec	Field must have a specified value		
Master File Locations	MRP/DCP/EMEA Num	iber					
Master File Elocations	EU Num	iber					
	Legal Ba	asis					
	Orphan D)rug					
	Additional Monitor	ring					
	Invalidated D	ate		Field must have a spec	cified value		
	Full Presentation Na	ime		Field is Mandatory			
	Product Short Na	ime		Field is Mandatory Opt	ional		
	Product INN/Common Na	ime		Field is Mandatory Opt	ional		
	Product Company Na	ime		Field must have a spec	Field must have a specified value		
	Product Strength Na	ime					
	Organisation Name	The medici	ines				
	Query Mode	Begins					
	Num Name		Checked	Sender HQ Name	Sender Name		
	0001 THE MEDICINES CON	MPANY	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:

□ XEVPRM Message	DrugVero		
⊨ Products	Description	Name/Value	
⊡ Insert (1) - Authorised (2)	Operation Type	Insert (1)	
Medicinal Product Types (-)	Type	Authorised (2)	
Authorised Pharmaceutical Forms (-)	EV Code	, (2)	
Pharmaceutical Products (-)	MAH	THE MEDICINES COMPANY UK LTD	
Drug ATCs (-)	QPPV	1	
Drug Indications (-)	Master File Location		
Previous EV Codes (-)	PhV enquiry email		Field must have a specified value
Product Attachments (-)	PhV enquiry Phone		Field must have a specified value
Substances	Sender Local Code		
Sources	Info Date		
Organisations	Authorisation Country Code		Field is Mandatory
-ATC Codes	Authorisation Procedure		Field is Mandatory
Pharmaceutical Forms	Authorisation Status		
Routes Of Administration	Authorisation Number		Field must have a specified value
Attachments	Authorisation/Renewal Date		Field must have a specified value
Master File Locations	MRP/DCP/EMEA Number		
	EU Number		
	Legal Basis		
	Orphan Drug		
	Additional Monitoring		F. 11
	Invalidated Date		Field must have a specified value
	Pull Presentation Name		Field is Mandatory
	Product Short Name		Field is Mandatory Optional
	Product Nov Company Name		Field must have a specified value
	Product Company Name		Tield must have a specified value
	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

3.5.1.5. Local database look-up tables

When an entity that you need to reference in your product report is not included in the look-up tables, you must add this new information in the same XEVPRM.

You may add information regarding new organisations, reference sources, ATC codes (proposed or development), routes of administration (proposed or development), pharmaceutical forms (proposed or development), MFLs and attachments.

Technically, you can also add approved and development substance in your XEVPRM and reference it in your product entry in the same XEVPRM. However, if you do so, upon submission, your XEVPRM will be rejected. The submission of substance information can only be performed in the XEVMPD by the EMA. If you require new substance information to be entered in the XEVMPD, you should follow the process described in the document <u>Changes to some business rules of the eXtended EudraVigilance</u> <u>Medicinal Product Dictionary (XEVMPD): Submission of substance information</u>

To reference an entity not yet present in the XEVMPD (i.e., an EV Code is not assigned to the entity and the entity is not available in the remote look-up table), you must add the entity in the relevant section of the XEVPRM.

Once this entity is added, you can retrieve it from the **Local ('L') look-up table**:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R			
E XEVPRM Message			
-Products	Description	Name/Value	
Substances	Message Number		Field is Mandatory
Sources		Products	
Organisations		Substances	
ATC Codes		Sources	
Pharmaceutical Forms		Organisations	
-Routes Of Administration		ATC Codes	
Attachments		Pharmaceutical Forms	
Master File Locations		Routes Of Administration	
		Attachments	
		Master File Locations	

As an example, we wish to enter a DMP entity in an XEVPRM and reference the sponsor 'SponsorX' in the data field 'Sponsor'. However, the sponsor does not seem to be available in the Sponsor look-up table:



We should therefore add the sponsor information in the same XEVPRM and reference the newly added sponsor 'SponsorX' in the DMP using the 'L' (Local Data Look-up) feature.

You will therefore need to create a new sponsor entity in the same XEVPRM. Please refer to section <u>4.2.6. Insert of a Sponsor organisation</u> for related information.

Once you have created the new sponsor organisation, go to the DMP entity section that you started to create, click in the area next to the field 'Sponsor' and then on the button (Local data look-up):

WEB Trader Create and Send Product Reports Medicinal Products MedD □ Reset Application Reset Section Clear Validate XML ZIP RTF Dup	RA Jlicate Remove E L R		For t
XEVPRM Message Products Insert - Development Pharmaceutical Products (-) Drug Indications (-) Product Attachments (-) Substances Organisations Insert - Sponsor - SponsorX ATC Codes Pharmaceutical Forms Routes Of Administration Attachments Master File Locations	Description Type Operation Type Sender Local Code Sponsor Product Code Product Name Product Other Name Comment	Name/Value Development Insert Pharmaceutical Products (-) Drug ATCs (-) Drug Indications (-) Product Attachments (-)	Field is Mandatory Field is Mandatory Optional Field is Mandatory Optional Section is Mandatory

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



The sponsor will then be referenced in your DMP entity:

WEB Trader Create and Send Product Reports Medicinal Products MedD	RA		
Reset Application Reset Section Clear Validate XML ZIP RTF Du	plicate Remove E L R		
E-XEVPRM Message			
Products	Description	Name/Value	
⊟ Insert - Development	Туре	Development	
Pharmaceutical Products (-)	Operation Type	Insert	
-Drug ATCs (-)	Sender Local Code		
Drug Indications (-)	Sponsor	Insert - Sponsor - SponsorX	
Product Attachments (-)	Product Code		Field is Mandatory Optional
Substances	Product Name		Field is Mandatory Optional
Sources	Product Other Name		
Organisations	Comment	Desmocoutical Products ()	Section is Mandaton
Insert - Sponsor - SponsorX			Section is Manualory
ATC Codes		Drug Indications (-)	
Pharmaceutical Forms		Product Attachments (-)	
Routes Of Administration			
Attachments			
Master File Locations			

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

3.5.2. 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 3.5.3. Checklists) by clicking on the special item called 'New ...', or

WEB Trader Create and Send Product Reports Medicinal Products MedDRA								
Reset Application Reset Section Clear Validate XML ZIP RTF E L R I								
Products	Num	Operation Type						
Substances	New Authorised Product							
Sources	New Development Product							
Organisations								
ATC Codes								
Pharmaceutical Forms								
Routes Of Administration								
Attachments								
Master File Locations								

• by double clicking on the item in the list view in the active area.

WEB Trader Create and Send Product Reports Medicinal Products MedDRA								
Reset Application Reset Section Clear Validate XML ZIP RTF E L R								
E-XEVPRM Message								
Products	Num	Operation Type						
Substances	New Authorised Product							
Sources	New Development Product							
Organisations								
ATC Codes								
Pharmaceutical Forms								
Routes Of Administration								
Attachments								
Master File Locations								

Some of the sections that you can add are repeatable, which means that you can add several of them. 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 must select the section you wish to duplicate and then click on the 'Duplicate button' that becomes available only in these situations:

Reset Application	Reset Section	Clear	Vali	date	Send	XML	ZIP	RTF	Duplicate	Remove	E	L	R	
EVPRM Message Products Substances Sources Organisations Insert (1) - MAH ATC Codes Pharmaceutical For Routes Of Administ Attachments Master File Locatio	(1) - PharmaX Ltd rms tration ns					O M Tel F Fax E	Des peratii E MAH SME SME AH Se P Count Tel Eax Count Fax Eax Count Fax Count Count	scription on Type V Code Type H Name Status Numbe ender IE Address City Region ostcode ry Code Numbe ctension ry Code Numbe ctension ry Code Address ommen	Duplicat Name/van insert (1) MAH (1) PharmaX L Medium (4 2 22 Berry S 22 Berry S 22 Berry S 22 Berry S 22 Berry S 2 Duplication 4 5 5 5 5 5	te the Elemer ae .td.) itreet gdom (GB)	nt sel	ectec		the Tree View

The duplicated entity will appear in the tree-view area:

	Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	Remove	E	LR
<mark>X</mark>	EVPRM Message											
	Products						Des	cription	Name/Valu	Je		
	Substances					0	perati	on Type	Insert (1)			
Г. г.	- Organisations						E	V Code				
`	Insert (1) - MAH	(1) - PharmaX Ltd	_					Туре	• MAH (1)			
	Insert (1) - MAH	(1) - PharmaX Ltd	1					H Name	PharmaX L	.td.		
	ATC Codes						SIVIE	: Status Numbo	iviedium (4)		
	Pharmaceutical For	ms				м	AH Se	ender ID)			
	Routes Of Administ	ration					/ 0	Address	22 Berry S	treet		
	Attachments							City	London			
	Master File Location	ns						Region	1			
							P	ostcode	e E22 4HC			
					Country Coo				 United King 	gdom (GB)		
							Tel	Number	r			
						T -1	Tel Ex	tension	1			
						Ter	Count	ry Code Numbor	•			
				F	Fax Fav Ev	tonsion						
						Fax	Count	rv Code				
						E	-mail /	Address				
							C	omment	t			

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

• you can select in the tree-view area the section you want to remove and click on the 'Remove' button that becomes available only in these situations:

		Reset Application	Reset Section	Clear	Valio	late	Send	XML	ZIP	RTF	Duplicate	Remove	Е	L	R	Ł	
E) · X	EVPRM Message										F	lemo	ve tł	ne E	lement selected in th	e Tree View
		Products							Des	cription	Name/Valu	ie			_		
		Substances						0	peratio	on Type	Insert (1)						
									E	V Code							
		Insert (1) - MAH	(1) - PharmaX I td							Туре	MAH (1)						
		Insert (1) - MAH	(1) - PharmaX Ltd	1					MAł	I Name	PharmaX L	td.					
		ATC Codes	(I)-I Harmax Etu						SME	Status	Medium (4))					
		Pharmaceutical For	me						SME	Number							
		Routes Of Administ	tration					IVI	AH Se	nder ID	00 Dama 0						
		Attachments	lation							Address	22 Derry Si	treet					
		Master File Locatio	00							Degion	London						
		Waster The Locatio	113						D	rtegion	E22 4HC						
									Count	v Code	United Kind	ndom (GB)					
									Tel	Vumber	onicearcing	Juonin (OD)					
									Tel Ex	tension							
								Tel	Count	v Code							
									Fax	Number							
								F	ax Ex	tension							
								Fax	Count	y Code							
								E	mail /	Address							
1					_				C	mment							

• or, in case of multiple sections, un-check the section you want to remove (see section <u>3.5.3.</u> <u>Checklists</u>) and press the 'Clear' button:

Reset Application Reset Section Clear Va	lidate Send XML ZIP RTF E L R			
□ XEVPRM Message				
Products	Num	Operation Type	Type	Organisation Name
Substances	0001	Insert (1)	MAH (1)	PharmaX Ltd.
Organisations Organisations Organisations Organisations Organisations Organisations Organisation Organisation	☐ 0002 (-) ☐ New MAH ☐ New Sponsor	Insert (1)	MAH (1)	PharmaX Ltd.

3.5.3. Checklists

A checklist is a specific type of **list view** (see section <u>3.3. The active area</u> 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:



Deselect all: 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.

Select all: 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

3.5.4. 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.



In this type of checklist, the selected items are displayed only in the active area; nothing changes in the tree-view area 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.

3.5.5. 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 <u>3.6. Search methods</u>).

By marking one or more of the checkboxes, 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.

	WEB Trader Create and Send Product Reports Medicinal Products MedDRA								
	Reset Application Reset Section Clear XML RTF Other • 0 0 2								
Γ	-Authorised Medicinal Products	tablet							
Ш	Development Medicinal Products	Num	Туре	Pharmaceutical Form Name	EV Code	Deprecated	Validated	Nullifie	
ш	- Approved Substances	✓ 0001	Standard	TABLET	PHF00245MIG	No	18/01/2017 10:47:21		
ш	Development Substances	0002	Proposed	TABLETS	PHF2478	No	26/10/2015 11:28:09		
ш	Sources	0003	Proposed	TABLETTEN	PHF2420	No	08/06/2015 14:30:33		
ш	MAHs	0004	Standard	TABLET WITH SENSOR	PHF3170	No	20/11/2019 11:27:09		
ш	Sponsors	0005	Proposed	TABLET FOR SOLUTION	PHF717	Yes	03/12/2014 12:23:25	1. Sec. 1.	
ш	ATC Codes	0006	Proposed	TABLET_EILM-COATED	PHE1219	No		11/10/	

The loaded data will appear in the appropriate section of the tree-view area :

WEB Trader Create and Send Product Reports Medicinal Products Me	dDRA			FOI THE OK, AS ITOHI T. 1.2021, EO LAW			
□ Reset Application Reset Section Clear XML RTF Other - 0 □ □ □							
Authorised Medicinal Products	tablet						
- Development Medicinal Products	Num	Туре	Pharmaceutical Form Name	EV Code			
Approved Substances	✓ 0001	Standard	TABLET	PHF00245MIG			
Development Substances	0002	Proposed	TABLETS	PHF2478			
Sources	0003	Proposed	TABLETTEN	PHF2420			
MAHs	✓ 0004	Standard	TABLET WITH SENSOR	PHF3170			
Sponsors	0005	Proposed	TABLET FOR SOLUTION	PHF717			
ATC Codes	0006	Proposed	TABLET, FILM-COATED	PHF1219			
-Routes of Administration	0007	Proposed	TABLETKI DO ZEBODOLU	PHF1257			
Pharmaceutical Forms	8000	Proposed	TABLET, FOR SUSPENSION	PHF2569			
+ Standard - PHF00245MIG - TABLET	0009	Development	TABLET, EXTENDED RELEASE	PHF2590			
E Standard - PHE3170 - TABLET WITH SENSOR	0010	Standard	TABLET FOR ORAL SUSPENSION	PHF960			
a clandara i in circo indeel vinin centook	0011	Proposod	TABLET CONTROLLED RELEASE	PHE630			

The section currently selected in the tree-view area 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 area 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 <u>3.4. Interaction between the tree-view area</u> <u>and active</u> area and section <u>3.7. Loading data</u>).

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 area 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.

As an example, we unmark 'capsule, soft':

WEB Trader Create and Send Product Reports Medicinal Products Medi	DRA		
Reset Application Reset Section Clear XML RTF Other - 0			
Authorised Medicinal Products	tablet		
Development Medicinal Products	Num	Туре	Pharmaceutical Form Name
Approved Substances	✓ 0001	Standard	TABLET
Development Substances	0002	Proposed	TABLETS
Sources	0003	Proposed	TABLETTEN
MAHs	0004 (-)	Standard	TABLET WITH SENSOR
Sponsors	0005	Proposed	TABLET FOR SOLUTION
ATC Codes	0006	Proposed	TABLET, FILM-COATED
Routes of Administration	0007	Proposed	TABLETKI DO ZEBODOLU
Pharmaceutical Forms	8000	Proposed	TABLET, FOR SUSPENSION
+ Standard - PHF00245MIG - TABLET	0009	Development	TABLET, EXTENDED RELEA
+ (-) Standard - PHF3170 - TABLET WITH SENSOR	0010	Standard	TABLET FOR ORAL SUSPEI
Master File Locations	0011	Proposed	TABLET, CONTROLLED REI
	0012	Droposod	TARI ET FOD ODAL SUSDEL

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

The 'Clear' button will remove all the items unmarked this way:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA							
Reset Application Reset Section Clear XML RTF Other O I I							
Authorised Medicinal Products	tablet						
Development Medicinal Products	Num	Туре	Pharmaceutical Form Name				
-Approved Substances	0001 (-)	Standard	TABLET				
Development Substances	0002	Proposed	TABLETS				
Sources	0003	Proposed	TABLETTEN				
MAHs	0004 (-)	Standard	TABLET WITH SENSOR				
Sponsors	0005	Proposed	TABLET FOR SOLUTION				
ATC Codes	0006	Proposed	TABLET, FILM-COATED				
-Routes of Administration	0007	Proposed	TABLETKI DO ZEBODOLU				
Pharmaceutical Forms	8000	Proposed	TABLET_FOR SUSPENSION				
(-) Standard - PHF00245MIG - TABLET	0009	Development	Message from webpage X				
	0010	Standard					
-Master File Locations		Proposed					
Attachments		Proposed	You will remove all the Elements marked as Deleted (-).				
XEVPRM Messages		Standard					
-Product Status		Proposed	Are fou sure :				
-Product History		Standard					
Legacy Link		Standard					
-Product Index		Standard	OK Cancel				
Abstract Compositions							

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.

3.5.6. Add/Delete checklist

This type of checklist allows the user to add one or more new items during a data entry procedure (e.g., 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.

WEB Trader Create and Send Product Reports Medicinal Products Medicinal Products	IDRA
Reset Application Reset Section Clear Validate Send XML ZIP I	RTF E L R 🗆
□ XEVPRM Message	tablet
Products	Num
Substances	New Authorised Product
Sources	New Development Product
Organisations	
ATC Codes	
Pharmaceutical Forms	
-Routes Of Administration	
Attachments	
Master File Locations	



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

WEB Trader Create and Send Product Reports Medicinal Products MedDRA							
Reset Application Reset Section Clear Validate Send XML ZIP							
E-XEVPRM Message	tablet						
Products	Num	Operation Type	Туре				
🚊 (-) Insert - Authorised	0001 (-)	Insert	Authorised				
Medicinal Product Types (-)	0002 (-)	Insert	Authorised				
Authorised Pharmaceutical Forms (-)	0003	Insert	Authorised				
Pharmaceutical Products (-)	New Authorised Product						
Drug ATCs (-)	New Development Product						
Drug Indications (-)							
Previous EV Codes (-)							
Product Attachments (-)							
🚊 (-) Insert - Authorised							
Medicinal Product Types (-)							
Authorised Pharmaceutical Forms (-)							
Pharmaceutical Products (-)							
Drug ATCs (-)							
Drug Indications (-)							
Previous EV Codes (-)							
Product Attachments (-)							
⊟ Insert - Authorised							
Medicinal Product Types (-)							
Authorised Pharmaceutical Forms (-)							
Pharmaceutical Products (-)							
-Drug ATCs (-)							

Once you deselect your items and click on 'Clear', the deselected entities will be removed from your tree-view area:



WEB Trader Create and Send Product Reports Medicinal Products MedDRA							
Reset Application Reset Section Clear Validate Send XML ZIP I	RTF E L R D						
E XEVPRM Message	tablet						
Products	Num	Operation Type	Туре				
i Insert - Authorised	✓ 0003	Insert	Authorised				
Medicinal Product Types (-)	New Authorised Product						
-Authorised Pharmaceutical Forms (-)	New Development Product						
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							

3.6. 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).

3.6.1. 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.

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

To search for an AMP, you must click on the 'Authorised Medicinal Products' section in the tree-view area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear	
Authorised Medicinal Products	
-Development Medicinal Products	Empty
Approved Substances	
-Development Substances	
Sources	
MAHs	
-Sponsors	
ATC Codes	
-Routes of Administration	
-Pharmaceutical Forms	
-Master File Locations	
Attachments	
Abstract Compositions	
🗄 Queries	

To search for a DMP, you must click on the 'Development Medicinal Products' section in the tree-view area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear	
Authorised Medicinal Products	
Development Medicinal Products	Empty
Approved Substances	
Development Substances	
Sources	
MAHs	
Sponsors	
-ATC Codes	
-Routes of Administration	
-Pharmaceutical Forms	
-Master File Locations	
Attachments	
-Abstract Compositions	

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



WER Trade Create and Sent Products Medicinal Products Medicinal Products Medicinal Products Medicinal Products Country and Sent Products Medicinal						
Reset Application Reset Section Clear						
- Development Medicinal Products	Empty					
- Approved Substances						
Development Substances						
Sources						
MAHs						
Sponsors						
ATC Codes						
-Routes of Administration						
Pharmaceutical Forms						
Master File Locations						
Attachments						
-Abstract Compositions						
Queries						
	Lookup the Development Products on: EV Code, Name, Code, 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.				

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

- A question mark (?) is a special character that matches any character (but only one): T?ST will match: TEST, TAST, but not TEEST
- Asterix (*) 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

To perform a search in the simple query filed, you can enter the EV Code of the entity you are searching for or part of the name of the entity.

In the below example, the search is performed for an AMP with part of the name 'Paracetamol 500'. To Widen our search, * is also added at the end of the text:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear	
Authorised Medicinal Products	Paracetamol 500*
- Development Medicinal Products	Empty
Approved Substances	
Development Substances	
Sources	
MAHs	
Sponsors	
ATC Codes	
-Routes of Administration	
Pharmaceutical Forms	
Master File Locations	
Attachments	
Abstract Compositions	

Once you press 'Enter' on your keyboard to execute the search, the result(s) of your simple query will be displayed:



The result(s) of the query will be displayed in the active area, as a Select/Deselect checklist (see section <u>3.5.3. Checklists</u>). Once you select the entity in the active area, in the tree-view area, a new element will appear under the relevant section, containing the results of the query:

				For the OK, as non-1.1.2021, EO Law applies only to the te
WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Clear				
Authorised Medicinal Products	Paracetamol 500*			
Authorised - PRD126060 - 3/3 - Paracetamol 500 mg Film Coated Tablets	Num	EV Code	Version	Full Presentation Name
Development Medicinal Products	✓ 0001	PRD126060	3/3	Paracetamol 500 mg Film Coated Tablets
Approved Substances				
Development Substances				
Sources				
MAHs				
Sponsors				
ATC Codes				
-Routes of Administration				
Pharmaceutical Forms				
Master File Locations				
Attachments				
Abstract Compositions				
Queries				

3.6.2. Advanced Query

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

The query items in the 'Medicinal product' section of EVWEB are available as selectable items in the tree-view area under 'Queries':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA
Reset Application Reset Section Clear
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
tarres dueries

You can perform queries on the following entities:



Every query is divided in 3 different sections:

- Fields
- Conditions (AND)

Results



3.6.2.1. 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 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.
WEB Trader Create and Send Product Reports Medicinal Products MedDRA						
Reset Application Reset Section Clear E R Run Run to Excel						
Approved Substances						
Development Substances	Description Name/Value					
Sources	Article 57 Format Article 57 Format					
MAHs	Interim Format					
Sponsors	Local Number (Matches)					
ATC Codes	EV Code (Matches)					
Routes of Administration	Has Been Updated 🗌					
Pharmaceutical Forms	Owner HQ ID (Matches)					
-Master File Locations	Product Validity					
Attachments	Product Pending					
-Abstract Compositions						
Owned EVMPD Entities						
Owned Authorised Products						
Authorised Products (Valid Version)						
Fields						
Conditions (AND)	Product INN/Common Name (
Results	Product Strength Name (Matc					
Owned Development Products	Product Company Name (Mat					
E Substance Names	Product Form Name (Matches)					
Approved Substance Names	Authorisation Country					
Development Substance Names	Authorisation Procedure					
Approved Substances	Authorisation Status					
Development Substances	Authorisation/Renewal Date (F					
E Sources	Authorisation/Renewal Date (U					
	MA Validity 🗹 Valid					
	Authorisation Number (Matches)					

To select all items marked as 'Default selection' (or 'Last selection') by the application, select the below highlighted button in the main area:

WEB Trader	Create and Send Product Reports Medicinal Products MedDRA	
Reset App	pplication Reset Section Clear Run Run to Excel	
Authorise	ed Medicinal Products	
Developm	ment Medicinal Products	
Approved	ed Substances	
Developm	ment Substances	
Sources	ò	
MAHs		
Sponsors	ſS	
ATC Cod	des	
Routes of	of Administration	
Pharmac	ceutical Forms	
Master Fi	File Locations	
Attachme	ients	
Abstract	t Compositions	
Queries		
Owner	ed EVMPD Entities	
Owner	ed Authorised Products	
Author	prised Products (Valid Version)	
Fie	elds	
Coi	onditions (AND)	
E Res	esults	

All fields marked as 'default' will become selected:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear Run Run to Excel			
Authorised Medicinal Products	^	Paracetamol 500*	
Development Medicinal Products		Description	
Approved Substances		Local Number	
Development Substances		✓ EV Code	Default selection
Sources		✓ Version	Default selection
MAHs		Version Date	
Sponsors		Article 57 Format	
ATC Codes		Interim Format	
-Routes of Administration		Owner HQ ID	Default selection
Pharmaceutical Forms		Owner Name	
-Master File Locations		Full Presentation Name	Default selection
Attachments		Product Short Name	Default selection
-Abstract Compositions		Product INN/Common Name	
Queries		Product Strength Name	
Owned EVMPD Entities		Product Company Name	
Owned Authorised Products		Product Form Name	
Authorised Products (Valid Version)		Authorisation Country	
Fields		Authorisation Procedure	
Conditions (AND)		Authorisation Status	
		MA Validity	
		Authorisation Number	

To deselect all items marked as 'Default selection' (or 'Last selection') by the application, select the below highlighted button in the main area:



All fields marked as 'default' will become deselected:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear Run Run to Excel			
Authorised Medicinal Products	^	Paracetamol 500*	
Development Medicinal Products		Description	
Approved Substances		Local Number	
Development Substances		EV Code	Default selection
Sources		Version	Default selection
MAHs		Version Date	
Sponsors		Article 57 Format	
ATC Codes		Interim Format	
-Routes of Administration		Owner HQ ID	Default selection
Pharmaceutical Forms		Owner Name	
-Master File Locations		Full Presentation Name	Default selection
Attachments		Product Short Name	Default selection
-Abstract Compositions		Product INN/Common Name	
		Product Strength Name	
Owned EVMPD Entities		Product Company Name	
Owned Authorised Products			
Authorised Products (Valid Version)			
Fields			
Conditions (AND)			
⊞-Results		Authorisation Number	

Aside from the fields selected by default, you can make your own selection by ticking the required fields:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA						
□ Reset Application Reset Section Clear Run Run to Excel □ Ø						
Authorised Medicinal Products	^					
Development Medicinal Products		Description				
Approved Substances		Local Number	F. F.			
- Development Substances		EV Code	Default selection			
Sources		Version	Default selection			
MAHs		Version Date				
Sponsors		Article 57 Format				
ATC Codes		Interim Format				
Routes of Administration		Owner HQ ID	Default selection			
-Pharmaceutical Forms		Owner Name				
Master File Locations		Full Presentation Name	Default selection			
Attachments		Product Short Name	Default selection			
Abstract Compositions		Product INN/Common Name				
		Product Strength Name				
Owned EVMPD Entities		Product Company Name				
Owned Authorised Products						
Authorised Products (Valid Version)		Authorisation Broadura				
-Fields		Authorisation Status				
- Conditions (AND)						
⊞ Results						
Owned Development Products		MRP/DCP/EMEA Number				
Substance Names		FU Number				
Approved Substance Names		Legal Basis				
Development Substance Names		Invalidated Date				
Approved Substances		MAH Name	Default selection			
Development Substances		MAH Code	Default selection			
Sources	Sources QPPV					
MAHs		Master File Location				
Sponsors	Pharmaceutical Form					
ATC Codes		Route of Administration				

NOTE: When performing a query on authorised medicinal products, whilst it is possible to select all the 'Fields', not all of them will be displayed in the results of your query.

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'.

Authorised Medicinal Products		
Development Medicinal Products	Description	
-Approved Substances	Description	
- Development Substances		
Sources		Last selection
MAHs		Last selection
Sponsors	Article 57 Format	Last selection
ATC Codes		
Routes of Administration		Last selection
Pharmaceutical Forms		East selection
Master File Locations	Eull Presentation Name	Last selection
Attachments	Product Short Name	Last selection
-Abstract Compositions	Product INN/Common Name	
Queries	Product Strength Name	
⊡ · Owned EVMPD Entities	Product Company Name	
• Owned Authorised Products	Product Form Name	
Authorised Products (Valid Version)	Authorisation Country	
Fields	Authorisation Procedure	
Conditions (AND)	Authorisation Status	
⊟ Results	MA Validity	
Result 07 September 2015 16:16:29	Authorisation Number	
Ready to Run	MRP/DCP/EMEA Number	
Owned Development Products		
Substance Names	Legal Dasis	
⊕ Approved Substance Names		Last selection
Development Substance Names		Last selection
⊕ Approved Substances		Last selection
Development Substances	Route of Administration	
⊕ Sources	Substance names	
⊞ MAHs	Substance Amount Value Types	
	Is Updatable	Last selection
ATC Codes	Is Nullifiable	Last selection
Routes of Administration	Sender Identifier	
⊕ Pharmaceutical Forms	Sender Name	
Abstract Compositions	Product Validity	Last selection
⊕ Attachments	Product Pending	Last selection
Master File Locations	Product Nullified	Last selection
	Product Last Rejected	Last selection

It is not possible to select all the fields, the system will display an error message if you try to do that.

3.6.2.2. 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 can 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):

• Some fields have their values available as a pre-defined list, e.g.:

Authorisation Procedure	Select option
Authorisation Status	
Authorisation/Renewal Date (From)	Press A - Z to find initial letter
Authorisation/Renewal Date (Up to)	Press Enter to select, Escape to clear
MA Validity 🔽	EU authorisation procedures - Centralised Procedure
Authorisation Number (Matches)	EU authorization procedures - Mutual Recognition Procedure
MRP/DCP/EMEA Number (Matches)	cu authorisation procedures - Mutual Recognition Procedure
EU Number (Matches)	EU authorisation procedures - Decentralised Procedure
Legal Basis	EU authorisation procedures - National Procedure
Invalidated Date	
Invalidated Date (From)	Non EU authorisation procedure
Invalidated Date (Up to)	EU authorisation procedures - Traditional use registration for herbal medicinal products
MAH (Name) (Matches)	n. Tu sakarintin na salara – Cinalifad a sisteria na salar fa kamanatin na isin bara.
MAH (Code) (Matches)	co autorisation procedures - Simplified registration procedure for nomeopathic medicinal products
QPPV	EU other approval/authorisation procedure
Master File Location (Code) (Matches)	

Others are free-text fields, e.g.:



• You can also search for the required value using the remote look-up tables:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear E P Pup Pup to Excel	
Authorised Medicinal Products	
- Development Medicinal Products	Description Name/Value
Approved Substances	Product Short Name (Matches)
- Development Substances	Product INN/Common Name (Matches)
Sources	Product Strength Name (Matches)
MAHs	Product Company Name (Matches)
Sponsors	Product Form Name (Matches)
ATC Codes	Authorisation Country
Routes of Administration	Authorisation Procedure
Pharmaceutical Forms	Authorisation Status
Master File Locations	Authorisation/Renewal Date (From)
Attachments	
-Abstract Compositions	MA Validity Valid
Queries	MDD/DCD/EMEA Number (Matches)
Owned EVMPD Entities	FIL Number (Matches)
Owned Authorised Products	
Authorised Products (Valid Version)	Invalidated Date
-Fields	Invalidated Date (From)
-Conditions (AND)	Invalidated Date (Up to)
Results	MAH (Name) (Matches)
Owned Development Products	MAH (Code) (Matches)
Substance Names	QPPV
Approved Substance Names	
Development Substance Names	
Approved Substances	Query Mode Degins
Development Substances	
Sources	
H MAHs	
Sponsors	
ATC Codes	
Routes of Administration	

If a criterion contains a value, but it is not selected (checkbox not marked), then it will not be considered when running the query.

For details about the possibilities in dealing with different kind of fields, please refer to section <u>3.5.</u> <u>Data entry</u>).

3.6.2.3. Results section

To launch a query after specifying the fields and conditions:

- press the 'Run' button in the dynamic section of the main menu to view the results in the active area; or
- press 'Run to Excel' to view the results in an Excel file⁵.

⁵ For AMPs, this only works if the condition "Owned" is selected.

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear E R Run Run to Excel	
Authorised Medicinal Products	<u>^</u>
Development Medicinal Products	Description Name/Value
-Approved Substances	Product Short Name (Matches)
-Development Substances	Product INN/Common Name (Matches)
Sources	Product Strength Name (Matches)
MAHs	Product Company Name (Matches)
Sponsors	Product Form Name (Matches)
-ATC Codes	Authorisation Country
-Routes of Administration	Authorisation Procedure
-Pharmaceutical Forms	Authorisation Status
-Master File Locations	Authorisation/Renewal Date (From)
Attachments	Authorisation/Renewal Date (Up to)
-Abstract Compositions	MA Validity Any
Queries	Authorisation Number (Matches)
Owned EVMPD Entities	MRP/DCP/EMEA Number (Matches)
Owned Authorised Products	EU Number (Matches)
Authorised Products (Valid Version)	
Fields	
Conditions (AND)	
⊟ Results	MAH (Name) (Matches)
Result 30 September 2021 19:07:41	MAH (Code) (Matches)
Owned Development Products	
Substance Names	Master File Location (Code) (Matches)
Approved Substance Names	Pharmaceutical Form (Matches)
Development Substance Names	Route of Administration (Matches)
Approved Substances	ATC Code
Development Substances	Substance (Code) (Matches)
+ Sources	Substance (Name) (Matches)
⊞ MAHs	Is Updatable
- Sponsors	Is Nullifiable
T ATC Codes	Owned
Routes of Administration	Sender Identifier (Matches)
Pharmaceutical Forms	Sender Name (Matches)
	•

3.6.2.3.1. 'Run' functionality

Once you select the fields that you wish to see as the results of your query and specify the conditions of your advanced query, if you click on the **'Run'** button, the results of the query will be displayed in the active area, as a Select/Deselect checklist (see section <u>3.5.3. Checklists</u>):

WEB Trader Create and Send Product Reports Medicinal Products MedDRA					n 1.1.202
Reset Application Reset Section Clear ReRun Modify Delete Excel Export	Reload - Load	d 🗕 🗆 🗹			
Authorised Medicinal Products					
-Development Medicinal Products	Num	EV Code	Version	Version Date	Owr
Approved Substances	0001	PRD21690	2/2 Valid	2021/07/26 11:16.08	EV
-Development Substances	0002	PRD21689	2/2 Valid	2021/07/26 11:16.08	EV
Sources	0003	PRD21718	1/1 Valid	2005/05/17 15:36.55	EVI
MAHs	0004	PRD109028	4/4 Valid	2021/07/26 11:08.06	EVT
Sponsors	0005	PRD109027	4/4 Valid	2021/07/26 11:08.05	EV
ATC Codes	0006	PRD109030	3/3 Valid	2012/11/06 10:47.29	EV
-Routes of Administration	0007	PRD109029	3/3 Valid	2012/11/06 10:47.29	EVI
-Pharmaceutical Forms	8000	PRD125457	1/1 Valid	2021/05/04 12:12.27	EVI
-Master File Locations	0009	PRD41521	1/1 Valid	2006/09/19 09:10.16	EVI
-Attachments	0010	PRD21863	3/3 Valid	2006/08/02 12:39.00	EVI
-Abstract Compositions	0011	PRD21864	3/3 Valid	2006/08/02 12:39.00	EV
⊖-Queries	0012	PRD21862	3/3 Valid	2006/08/02 12:38.59	EVI
Owned EVMPD Entities	0013	PRD71465	1/1 Valid	2008/02/08 09:14.55	SAA
Owned Authorised Products	0014	PRD05060MIG	1/1 Valid	2004/10/14 12:06.11	EVI
Authorised Products (Valid Version)	0015	PRD05058MIG	1/1 Valid	2004/10/14 12:06.11	EVI
	0016	PRD05059MIG	1/1 Valid	2004/10/14 12:06.11	EVI
Conditions (AND)	0017	PRD69474	2/2 Valid	2008/09/17 11:13.34	EVI
Conditions (AND)	0018	PRD69494	1/1 Valid	2008/01/30 14:46.33	EVI
	0019	PRD69493	1/1 Valid	2008/01/30 14:46.33	EVI
	0020	PRD69492	1/1 Valid	2008/01/30 14:46.33	EVT
Result 30 September 2021 19:09:29	0021	PRD69491	1/1 Valid	2008/01/30 14:46.33	EVI

When a result set is selected in the tree-view area, the lower part of the 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:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Image: Clear	•	Reload 👻 L	oad 🛨 🔲 🗹	
Authorised Medicinal Products	^			
Development Medicinal Products		Num	EV Code	Version
-Approved Substances		0001	PRD21690	2/2 Valid
Development Substances		0002	PRD21689	2/2 Valid
Sources		0003	PRD21718	1/1 Valid
MAHs		0004	PRD109028	4/4 Valid
Sponsors		0005	PRD109027	4/4 Valid
ATC Codes		0006	PRD109030	3/3 Valid
-Routes of Administration		0007	PRD109029	3/3 Valid
Pharmaceutical Forms		8000	PRD125457	1/1 Valid
Master File Locations		0009	PRD41521	1/1 Valid
Attachments		0010	PRD21863	3/3 Valid
Abstract Compositions		0011	PRD21864	3/3 Valid
Queries		0012	PRD21862	3/3 Valid
Owned EVMPD Entities		0013	PRD71465	1/1 Valid
Owned Authorised Products			PRD05060MIG	1/1 Valid
Authorised Products (Valid Version)			PRD05058MIG	1/1 Valid
Fields			PRD05059MIG	1/1 Valid
Conditions (AND)			PRD69474	2/2 Valid
			PRD69494	
Result 30 September 2021 19:07:41			PRD69493	
Result 30 September 2021 19:09:29			PRD09492	1/1 Valid
Owned Development Products			PRD09491	1/1 Valid
			PRD09490	1/1 Valid
Annroved Substance Names			PDD60477	1/1 Valid
			PDD60476	1/1 Valid
			PRD60475	1/1 Valid
			PRD69470	1/1 Valid
			PRD69469	1/1 Valid
		0029	PRD69468	1/1 Valid
		0030	PRD69467	1/1 Valid
	\checkmark	<		
Article 57 Format IN Article 57 Format MA Validity IN Any Substance (Code) LIKE PARACETAMOL				

In the tree-view area, a new element will appear under the 'Results' section, containing the information on the date and time when the query was launched:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA					
Reset Application Reset Section Clear ReRun Modify Delete Excel Export	•	Reload 👻 L	oad 🗕 🗆 🗹		
Authorised Medicinal Products	^				
-Development Medicinal Products		Num	EV Code	Version	Version Date 0
Approved Substances		0001	PRD21690	2/2 Valid	2021/07/26 11:16.08 E
-Development Substances		0002	PRD21689	2/2 Valid	2021/07/26 11:16.08 E
Sources		0003	PRD21718	1/1 Valid	2005/05/17 15:36.55 E
-MAHs		0004	PRD109028	4/4 Valid	2021/07/26 11:08.06 E
Sponsors		0005	PRD109027	4/4 Valid	2021/07/26 11:08.05 E
ATC Codes		0006	PRD109030	3/3 Valid	2012/11/06 10:47.29 E
-Routes of Administration		0007	PRD109029	3/3 Valid	2012/11/06 10:47.29 E
-Pharmaceutical Forms		8000	PRD125457	1/1 Valid	2021/05/04 12:12.27 E
-Master File Locations		0009	PRD41521	1/1 Valid	2006/09/19 09:10.16 E
Attachments		0010	PRD21863	3/3 Valid	2006/08/02 12:39.00 E
-Abstract Compositions		0011	PRD21864	3/3 Valid	2006/08/02 12:39.00 E
E-Queries			PRD21862	3/3 Valid	2006/08/02 12:38.59 E
Owned EVMPD Entities			PRD/1465	1/1 Valid	2008/02/08 09:14.55 S
Owned Authorised Products			PRD05060MIG	1/1 Valid	2004/10/14 12:06.11 E
Authorised Products (Valid Version)			PRD05058MIG	1/1 Valid	2004/10/14 12:06.11 E
Fields			PRD05059MIG	1/1 Valid	2004/10/14 12:06.11 E
Conditions (AND)			PRD69474	2/2 Valid	2008/09/17 11:13.34 E
- Results			PRD09494	1/1 Valid	2008/01/30 14:46.33 E
			PRD09493	1/1 Valid	2000/01/30 14:46.33 E
Besult 30 September 2021 19:09:29			PRD09492	1/1 Valid	2000/01/30 14.40.33 E
Owned Development Products			PRD09491	1/1 Valid	2008/01/30 14.40.33 E
			PRD09490	1/ i Valid	2000/01/30 14:40.33 E

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) user manual EMA/308954/2012

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 must select it from the tree-view area 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. Alternatively, you can select fields or conditions from the tree-view with your mouse.

WEB Trader 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	Num	EV Code	Version	Version Date	Owne			
Approved Substances	0001	PRD21690	2/2 Valid	2021/07/26 11:16.08	EVTE			
Development Substances	0002	PRD21689	2/2 Valid	2021/07/26 11:16.08	EVTE			
Sources	0003	PRD21718	1/1 Valid	2005/05/17 15:36.55	EVTE			
MAHs	0004	PRD109028	4/4 Valid	2021/07/26 11:08.06	EVTE			
Sponsors	0005	PRD109027	4/4 Valid	2021/07/26 11:08.05	EVTE			
ATC Codes	0006	PRD109030	3/3 Valid	2012/11/06 10:47.29	EVTE			
-Routes of Administration	0007	PRD109029	3/3 Valid	2012/11/06 10:47.29	EVTE			
Pharmaceutical Forms	8000	PRD125457	1/1 Valid	2021/05/04 12:12.27	EVTE			
Master File Locations	0009	PRD41521	1/1 Valid	2006/09/19 09:10.16	EVTE			
Attachments	0010	PRD21863	3/3 Valid	2006/08/02 12:39.00	EVTE			
Abstract Compositions	0011	PRD21864	3/3 Valid	2006/08/02 12:39.00	EVTE			
- Queries	0012	PRD21862	3/3 Valid	2006/08/02 12:38.59	EVTE			
Owned EVMPD Entities	0013	PRD71465	1/1 Valid	2008/02/08 09:14.55	SAA			
Owned Authorised Products	0014	PRD05060MIG	1/1 Valid	2004/10/14 12:06.11	EVTE			
Authorised Products (Valid Version)	0015	PRD05058MIG	1/1 Valid	2004/10/14 12:06.11	EVTE			
Fields	0016	PRD05059MIG	1/1 Valid	2004/10/14 12:06.11	EVTE			
Conditions (AND)	0017	PRD69474	2/2 Valid	2008/09/17 11:13.34	EVTE			
	0018	PRD69494	1/1 Valid	2008/01/30 14:46.33	EVTE			
Bosult 30 Sontombor 2021 10:07:41		PRD69493	1/1 Valid	2008/01/30 14:46.33	EVIE			
Deput 20 September 2021 19:07:41	0020	PRD69492	1/1 Valid	2008/01/30 14:46.33	EVIE			
Oursed Development Decluste	0021	PRD69491	1/1 Valid	2008/01/30 14:46.33	EVTE			
	0022	PRD69490	1/1 Valid	2008/01/30 14:46.33	EVTE			

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
		1
Development Medicinal Products	Description	
Approved Substances	Local Number	
Development Substances	EV Code	Last selection
Sources	Version	Last selection
MAHs	Version Date	Last selection
Sponsors	Article 57 Format	
ATC Codes	Interim Format	
Routes of Administration	Owner HQ ID	Last selection
Pharmaceutical Forms	Owner Name	
Master File Locations	Full Presentation Name	Last selection
Attachments	Product Short Name	Last selection
Abstract Compositions	Product INN/Common Name	
Queries	Product Strength Name	
Owned EVMPD Entities	Product Company Name	
Owned Authorised Products	Product Form Name	
Authorised Products (Valid Version)		
Fields	Authorisation Procedure	
Conditions (AND)		
Result 30 September 2021 19:07:41		
Result 30 September 2021 19:00:29		
Ready to Pun		
Owned Development Products		
		Lost coloction
I HESUDSIALCE NAMES	II IMAH Name	Last selection

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 area and then click the 'Delete' button on the
	main menu in the dynamic section.

WEB Trader Create and Send Product Reports Medicinal Products MedDRA								
Reset Application Reset Section Clear Image: Clear								
Authorised Medicinal Products								
Development Medicinal Products	Num	EV Code	Version	Version Date	Owne			
-Approved Substances	0001	PRD21690	2/2 Valid	2021/07/26 11:16.08	EVTE			
Development Substances	0002	PRD21689	2/2 Valid	2021/07/26 11:16.08	EVTE			
Sources	0003	PRD21718	1/1 Valid	2005/05/17 15:36.55	EVTE			
MAHs	0004	PRD109028	4/4 Valid	2021/07/26 11:08.06	EVTE			
Sponsors	0005	PRD109027	4/4 Valid	2021/07/26 11:08.05	EVTE			
ATC Codes	0006	PRD109030	3/3 Valid	2012/11/06 10:47.29	EVTE			
-Routes of Administration	0007	PRD109029	3/3 Valid	2012/11/06 10:47.29	EVTE			
Pharmaceutical Forms	8000	PRD125457	1/1 Valid	2021/05/04 12:12.27	EVTE			
Master File Locations	0009	PRD41521	1/1 Valid	2006/09/19 09:10.16	EVTE			
Attachments	0010	PRD21863	3/3 Valid	2006/08/02 12:39.00	EVTE			
-Abstract Compositions	0011	PRD21864	3/3 Valid	2006/08/02 12:39.00	EVTE			
Queries	0012	PRD21862	3/3 Valid	2006/08/02 12:38.59	EVTE			
- Owned EVMPD Entities	0013	PRD/1465	1/1 Valid	2008/02/08 09:14.55	SAA			
Owned Authorised Products		PRD05060MIG	1/1 Valid	2004/10/14 12:06.11	EVIE			
Authorised Products (Valid Version)	0015	PRD05058MIG	1/1 Valid	2004/10/14 12:06.11	EVTE			
Fields	0016	PRD05059MIG	1/1 Valid	2004/10/14 12:06.11	EVIE			
Conditions (AND)		PRD69474	2/2 Valid	2008/09/17 11:13.34	EVIE			
Results		PRD69494	1/1 Valid	2008/01/30 14:46.33	EVIE			
Posult 30 September 2021 10:00:20		PRD69493	1/1 Valid	2008/01/30 14:46.33	EVIE			
	0020	PRD69492	1/1 Valid	2008/01/30 14:46.33	EVTE			

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.

WEB Trader 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	Num	EV Code	Version	Version Date	Ow
Approved Substances	0001	PRD21690	2/2 Valid	2021/07/26 11:16.08	EV
-Development Substances	0002	PRD21689	2/2 Valid	2021/07/26 11:16.08	EV
Sources	0003	PRD21718	1/1 Valid	2005/05/17 15:36.55	EV
MAHs	0004	PRD109028	4/4 Valid	2021/07/26 11:08.06	EV
Sponsors	0005	PRD109027	4/4 Valid	2021/07/26 11:08.05	EV
ATC Codes	0006	PRD109030	3/3 Valid	2012/11/06 10:47.29	EV
-Routes of Administration	0007	PRD109029	3/3 Valid	2012/11/06 10:47.29	EV
-Pharmaceutical Forms	8000	PRD125457	1/1 Valid	2021/05/04 12:12.27	EV
-Master File Locations	0009	PRD41521	1/1 Valid	2006/09/19 09:10.16	EV
Attachments	0010	PRD21863	3/3 Valid	2006/08/02 12:39.00	EV
-Abstract Compositions	0011	PRD21864	3/3 Valid	2006/08/02 12:39.00	EV
- Queries	0012	PRD21862	3/3 Valid	2006/08/02 12:38.59	EV
Owned EVMPD Entities	0013	PRD71465	1/1 Valid	2008/02/08 09:14.55	SA
Owned Authorised Products	0014	PRD05060MIG	1/1 Valid	2004/10/14 12:06.11	EV
Authorised Products (Valid Version)	0015	PRD05058MIG	1/1 Valid	2004/10/14 12:06.11	EV
Fields	0016	PRD05059MIG	1/1 Valid	2004/10/14 12:06.11	EV
Conditions (AND)	0017	PRD69474	2/2 Valid	2008/09/17 11:13.34	EV
		PRD69494	1/1 Valid	2008/01/30 14:46.33	EV
Bosult 20 Soptember 2021 10:00:20	0019	PRD69493	1/1 Valid	2008/01/30 14:46.33	EV
-Result 50 September 2021 19:09:29	0020	PRD69492	1/1 Valid	2008/01/30 14:46.33	EV

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.

WEB Trader 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	Num	EV Code	Version	Version Date
-Approved Substances	0001	PRD21690	2/2 Valid	2021/07/26 11
Development Substances	0002	PRD21689	2/2 Valid	2021/07/26 11
Sources	0003	PRD21718	1/1 Valid	2005/05/17 15
MAHs	0004	PRD109028	4/4 Valid	2021/07/26 11
Sponsors	0005	PRD109027	4/4 Valid	2021/07/26 11
ATC Codes	0006	PRD109030	3/3 Valid	2012/11/06 10
-Routes of Administration	0007	PRD10902	0/01/-64	0010/11/06 10:
-Pharmaceutical Forms	8000	PRD12545 Message	e from webpage	× 04 12
Master File Locations	0009	PRD41521		19 09:
Attachments	0010	PRD21863	0 1 50 0 1	02 12
Abstract Compositions	0011	PRD21864	Only 50 Results per page	are retrieved. 02 12:
Queries		PRD21862	Flease make a more speci	02 12
Owned EVMPD Entities	0013	PRD71465		08 09
Owned Authorised Products		PRD05060		14 12
Authorised Products (Valid Version)		PRD05058		ОК 14 12
Fields		PRD05059		14 12
Conditions (AND)		PKD09474	2/2 Vallu	2000/09/17 11
- Fields - Conditions (AND)	0017	PRD69474 PRD69494	2/2 Valid 1/1 Valid	2008/09/17 11: 2008/01/30 14

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. 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.

WEB Trader Create and Send Product Reports Medicinal Products MedDRA							
Reset Application Reset Section Clear ReRun Modify Delete Excel Export	▼ Reload ▼ Load ▼ □ Ø						
Authorised Medicinal Products	<u>^</u>						
Development Medicinal Products	Num EV Code Version Ve	ərsio					
Approved Substances	0001 PRD21690 2/2 Valid 20)21/(
- Development Substances	0002 PRD21689 2/2 Valid 20)21/(
Sources	0003 PRD21718 1/1 Valid 20)05/(
MAHs	0004 PRD109028 4/4 Valid 20)21/(
Sponsors	0005 PRD109027 4/4 Valid 20)21/(
ATC Codes	0006 PRD109030 3/3 Valid 20)12/1					

3.6.2.3.2. 'Run to Excel' functionality

Once you select the fields that you wish to see as the results of your query and specify the conditions of your advanced query, if you click on the **'Run to Excel'** button, a new window will open:

🥔 https://evtest.ema.europa.eu/x/x.asp?xi=6 - Internet Explorer − □ ×									
Summary									^
Temporary (for Export)	Click	<u>here</u> for the t	file	(TT- 1 - A		/00.00.0001	10.00 54		
	Name:	Authorised	Froducts	(valid	version)	(30-09-2021	13-36-54)	.X15	l

By clicking on 'here', another window will pop-up, allowing you to open or save the file.

Before the Excel file opens, you might be prompted to re-enter your login credentials.

			Exp	port - Read-Onl	y - Excel		Sear	ch				
Fi	le	Hom	e Insert	Page Layou	ıt Formula	s Data	Review View	Help	Acrobat			
٢	<mark>2</mark> }	5	Verdana	× 6	~ A^ A`	三 三 - 8	or → ab		Text	🗸 🔣 Con	ditional Forma	tting ~
Pa	ste [È ~			0. 0.			Sensitivity	ri v 👘	9 🐺 Forr	mat as Table ~	
	~ <	51	<u>в 1 (</u>	<u>7</u> ~ ⊞ ~ <mark>4</mark>	2 ~ <u>A</u> ~	=== •	<u>-</u> ≡ →= 😫 ~	×	00. 0,→ 0,← 00.	😿 Cell	Styles ~	
Cli	pboard	i L		Font	لاا	Alignm	nent 🛛 🖓	Sensitivity	Number	L.	Styles	
Aut	toSave	• Of	9 🖪 5) ~ (² ~ ⇒								
4.2				f.	0022642							
A3				$\bigvee Jx$	8033043							
<i>(</i>	Inter	nal \ A	II EMA Staf	ff and Contracto	rs 🖋	Private	Public	Inte	ernal 🝷 🕻	Confidential 🔻	Restricted	
	Α	В	С	D	E	F	G			Н		1
1	Aut	horis	sed Prod	lucts (Valid	Version)	(30-09-20	021 19-43-1	L 3)				
2	РК	Туре	EV Code	Version Number	Version	Version Date	Version Sender I	D Entity Typ	e			Owne
3	8033643	3	PRD8017577	3	3/4 Valid	07/05/2020 14:56:28	EVHUMANWT	PRODUCT				SAAVPFI
4	7998493	3 2	PRD330611	71	11/11 Valid	20/04/2020 07:14:42	EVHUMANWT	PRODUCT				VITABALI
5	7998500	2 1	PRD330614	1 0	10/10 Valid	20/04/2020 07:15:42	EVHUMANWT	PRODUCT				VITABALI
6	7998501	1 💈	PRD330612	70	10/10 Valid	20/04/2020 07:15:47	EVHUMANWT	PRODUCT				VITABALI
7	7998503	3 2	PRD330615	10	10/10 Valid	20/04/2020 07:16:42	EVHUMANWT	PRODUCT				VITABALI
8	7998504	4 🔁	PRD330613	71	11/11 Valid	20/04/2020 07:16:48	EVHUMANWT	PRODUCT				VITABALI
9	7969819	2	PRD7954169	2	2/2 Valid	03/04/2020 09:11:22	EVHUMANWT	PRODUCT				6513E 3
10	7994962	2 2	PRD336157	12	12/12 Valid	17/04/2020 08:58:40	EVHUMANWT	PRODUCT				VITABALI
11	7994974	4 2	PRD336156	1 4	14/14 Valid	17/04/2020 09:06:44	EVHUMANWT	PRODUCT				VITABALI
12	8013460	2	PRD2013670	19	9/10 Valid	27/04/2020 10:40:19	POOLPHARMA	PRODUCT				POOLPH
13	8028988	3 2	PRD673062	70	10/10 Valid	05/05/2020 16:28:43	BIOMEDPHAR	PRODUCT				BIOMED
			Recovered	Sheet1 (+	0510510000 10 50 05		DRODUCT		: •		AL TAKE 1

3.6.3. Immediate Query

An immediate query is a simple query performed automatically by EVWEB without the user's 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).

This type of query is used for example in the 'Inbox' and 'Outbox' folders in the Web Trader section:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA Reset Application Reset Section Clear Remote Import Create Ack 0 Imported Messages (-)			1 01 800 011	ио понт т. г. сих т, с. о кин ирри	
Inbox	Num	Name	Num/Count	Date	Size
-Outbox	0001	ack_userhb03o44u40-Send-OTORGHB03	1/2	2021/09/15 13:47.33	00000016
-Run to Excel Files -Bulk Update ⊕ Archive	0002	ack_userhb03o44u40-Send-OTORGHB03	2/2	2021/09/15 12:44.30	00000016

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.

3.7. 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.

3.7.1. Load from the EVDBMS

The load from the EVDBMS is available from the Load/Delete and the Select/Deselect checklists (see section <u>3.5.3. Checklists</u>).

3.7.1.1. Load/Delete checklist

As an example, you will see the checklist result of a <u>simple query</u> for a DMP with part of the name 'ProductY':



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 area:



The section currently selected in the tree-view area 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 area 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 <u>3.4. Interaction between the tree-view area and active</u> area).

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

3.7.1.2. Select/Deselect checklist

As an example, you will see the checklist result of an <u>advanced query</u> for AMPs authorised via the centralise procedure:



Once you select your condition(s), 'RUN' the query:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear E R Run Run to Excel	
Approved Substances	Tasmar
Development Substances	Description Name/Value
Sources	Article 57 Format Article 57 Format
MAHs	Interim Format
Sponsors	Local Number (Matches)
ATC Codes	EV Code (Matches)
Routes of Administration	Has Been Updated
Pharmaceutical Forms	Owner HQ ID (Matches)
Master File Locations	Product Validity
Attachments	Product Pending
Abstract Compositions	Product Nullified
🗄 Queries	Product Last Rejected
Owned EVMPD Entities	
Owned Authorised Products	
Authorised Products (Valid Version)	
Fields	
Conditions (AND)	
Results	Product iniv Common Name (Matches)
Owned Development Products	Product Company Name (Matches)
Substance Names	Product Company Name (Matches)
Approved Substance Names	
Development Substance Names	Authorisation Procedure VEU authorisation procedures - Centralised Procedure

The results of your query will be displayed.

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 area. We therefore need to use the 'Load' button:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Image: Clear Im	▼ Reload ▼ Load ▼ □ ∅
-Approved Substances	Tasmar
- Development Substances	Num EV Code Version Full Presentation Name
-Sources	O001 PRD17002 4/4 Valid CAELYX 2 mg/ml con
MAHs	PRD17003 3/3 Valid CAELYX 2 mg/ml con
Sponsors	PRD17004 3/3 Valid CAELYX 2 mg/ml con
ATC Codes	☑ 0004 PRD17005 3/3 Valid CAELYX 2 mg/ml con
-Routes of Administration	0005 PRD17006 2/2 Valid HYCAMTIN 1 mg pow
Dhormosoutical Forma	D006 PPD17007 2/2 Valid HVCAMTIN 1 mg pow

A pop-up menu will be displayed allowing you to choose which entries to load:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear Image: Clear </td <td>Reload - Load Choose</td> <td>one of the available</td> <td></td>	Reload - Load Choose	one of the available	
-Approved Substances	Tasmar	Commands	
-Development Substances	Num E Press	A - Z to find initial letter	Presentation Name
Sources	✓ 0001 F Press Ent	er to select, Escape to clear	ELYX 2 mg/ml con
MAHs	✓ 0002 F The Selected	Entity	ELYX 2 mg/ml con
-Sponsors	✓ 0003 F All the Marke	d Entities	ELYX 2 mg/ml con
-ATC Codes	✓ 0004 PRD17005	3/3 Valid C	AELYX 2 mg/ml con
-Routes of Administration	0005 PRD17006	2/2 Valid H	YCAMTIN 1 mg pow
-Pharmaceutical Forms	0006 PRD17007	2/2 Valid H	YCAMTIN 1 mg pow
-Master File Locations	0007 PRD17008	2/2 Valid H	YCAMTIN 4 mg pow
Attachmanta	0008 PRD17009	2/2 Valid H	YCAMTIN 4 mg pow

- 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)

In this case, we chose to load 'All the Marked Entities':

WEB Trader Create and Send Product Reports	Medicinal Products	MedDRA						
Reset Application Reset Section Clear	▼ ReRun Modify	Delete Exce	Export -	Reload -	Load 🗕 🗆 🗹			
Approved Substances			^	Tasmar				
Development Substances				Num	EV Code	Version	Full Presentation Name	Product
Sources				0001	PRD17002	4/4 Valid	CAELYX 2 mg/ml con	CAELYX
MAHs				0002	PRD17003	3/3 Valid	CAELYX 2 mg/ml con	CAELYX
Sponsors				✓ 0003	PRD17004	3/3 Valid	CAELYX 2 mg/ml con	CAELYX
ATC Codes				✓ 0004	PRD17005	3/3 Valid	CAELYX 2 mg/ml con	CAELYX
-Routes of Administration				0005	PRD17006	2/2 Valid	HYCAMTIN 1 mg pow	HYCAM
Pharmaceutical Forms				0006	PRD17007	2/2 \/alid	HYCAMTIN 1 mg pow	
Master File Locations				0007	Message from web	page		X (CAM)
Attachments				8000				CAM
-Abstract Compositions				0009				RAMU
Queries				0010	2 The Loadi	ng operation of 4	Entities can be long	RAMU
Owned EVMPD Entities				0011			and All the Medical Fulling 2	smar
Owned Authorised Products				0012	Are tou s	ure fou want to Lo	oad ALL the Marked Entitles (smar
Authorised Products (Valid Version)				0013				smar
Fields						-		smar
Conditions (AND)							OK Cancel	smar
Results								smar

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 <u>3.5.5. Load/Delete checklist</u>).

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear XML RTF Other Operations	
Authorised Medicinal Products	Tasmar
Authorised - PRD17002 - 4/4 Valid - CAELYX 2 mg/ml concentrate for solution for infu	Description Name/Val
MAH: ORG1011 - SP EUROPE	EV Code PRD17005
-Medicinal Product Types (-)	Version 3/3 Valid
-Authorised Pharmaceutical Forms (-)	Type Authorised
Pharmaceutical Products (1)	Version Status Accepted
Drug ATCs (1)	Version Validity Valid
Drug Indications (3)	Version Description Current Va
-Previous EV Codes (-)	Product Validity Valid
-Product Attachments (-)	Product Pending Assessed
Previous Versions ()	Current vs Bravious, Double Cli
Subsequent Versions ()	Version Date 30/01/200
Reporting Names - Presentations ()	Version by EVHUMAN
Reporting Names - Scientific ()	New Version ? No
Authorised - PRD17003 - 3/3 Valid - CAELYX 2 mg/ml concentrate for solution for infu	New Version by
	Nullified No
Medicinal Product Types (-)	PhV enquiry email
Authorised Pharmaceutical Forms (-)	PhV enquiry Phone
Pharmaceutical Products (1)	Sender Local Code RF_20
\oplus Drug ATCs (1)	Info Date 26/06/199
Drug Indications (3)	Authorisation Country Code European
Previous EV Codes (-)	Authorisation Procedure EU author
Product Attachments (-)	Authorisation Number, EU/1/06/0
Previous Versions ()	Authorisation/Renewal Date
Subsequent Versions ()	MRP/DCP/EMEA Number
Reporting Names - Presentations ()	EU Number EU/1/96/0
Penorting Names - Scientific ()	Legal Basis
Authorised - PRD17004 - 3/3 Valid - CAELYX 2 mg/ml concentrate for solution for inful	Orphan Drug No
	Additional Monitoring No
Madiginal Droduct Types ()	Invalidated Date
<pre></pre>	Full Presentation Name CAELYX 2

3.7.2. 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 wish to upload an XML file of an XEVPRM previously saved on our desktop.

In the 'WEB Trader', click on 'Imported Messages' and then 'Local Import':



Local Import

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

WEB Trader Create and Send R	Product Reports Medicinal Products MedDRA							
Reset Application Reset Sec	tion Clear Local Import							
Imported Messages (-)								
Inbox	Empty							
Outbox								
Run to Excel Files								
Bulk Update	🥔 https://evtest.ema.europa.eu/?FA=0&NF=1 - Select File - Int 🚽 🗌 🗙							
Archive								
	.:: The Maximum Size allowed for the Posted File is 60 MegaBytes ::.							
	Browse							
	Upload File							

Once you have browsed and selected the file you want to import, click on the 'Upload File' button to activate the import process:

https://evtest.ema.europa.eu/?FA=0&NF=1 - Select File - Ir	nt —		×					
.:: The Maximum Size allowed for the Posted File is 60 MegaBytes ::.								
L:\ProductX_DMP.xml	Browse							
Upload File								

WEB Trader Create and Send Product Reports	Medicinal Products MedDRA]	
Reset Application Reset Section Clear Local	Import		
Imported Messages (-)			
Inbox			Empty
-Bulk Update		Message fr	om webpage X
Archive		message m	on neopage / /
		F F	ile Successfully Processed. Press OK to Import the Data.
			ОК

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.

In case that some of the information in your XML file has not been decoded properly (for example the information referenced in the product entity could not be found in the environment where the XML file

is uploaded), a pop-up message will be displayed. In our case, the sponsor organisation EV code referenced in the product entity in our XML file does not exist:



You can dismiss the message by clicking on 'OK' or the 'x' in the right-hand corner.

You will be presented with the below message:

Message from webpage	×
? Click OK to view the Uploaded File	
OK Cancel	

By clicking on 'OK', you will be able to view the file in the XML format:



eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) user manual EMA/308954/2012

The imported data are displayed in a specific section of the tree-view area.

In our example, the data are displayed under 'Imported Message (s)':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	N
Reset Application Reset Section Clear Local Import Reload	
Imported Messages (1)	
□ XEVPRM - EVTESTWT - 10/09/2021 12:05:28	Description Name/Value
Development Products (1)	Message Type XEVPRM
Inbox	Message Number
Outbox	Original Sender EVTESTWT
-Run to Excel Files	Message Date 10/09/2021 12:05.28
Bulk Update	Development Products (1)
Archive	

See section <u>3.4. Interaction between the tree-view area and active area</u> and <u>3.10.1.1. Reloading an</u> <u>XEVPRM</u> for reloading an imported XEVPRM.

3.7.3. 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 below screenshots demonstrate the import function available in the **'Outbox'** section. This functionality will allow us to retrieve an <u>XEVPRM already submitted</u>.

In the 'WEB Trader' section, click on 'Outbox'; the list of XEVPRMs submitted from your organisation ID will be displayed:

WEB Trader Create and Send Product Reports Medicinal Product	ucts N	/ledDRA			
Reset Application Reset Section Clear Remote Import					
Imported Messages (-)					
Inbox	Num	Name	Num/Count	Date	Size
Outbox	0001	userhb03o42u34-Send-OTORGHB03O42-XEVP	1/1	2021/09/10 12:33.44	0000057
-Run to Excel Files					
Bulk Update					
⊞ Archive					

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:

WEB Trader Create and Send Product Reports Medicinal Product	ucts N	1edDRA		For the UK, as tro	im 1.1.2021, EU La
Reset Application Reset Section Clear Remote Import 0					
Imported Messages (-)					
-Inbox	Num	Name	Num/Count	Date	Size
-Outbox	0001	userhb03o42u34-Send-OTORGHB03O42-XEVP	1/1	2021/09/10 12:33.44	0000057
-Run to Excel Files					
Bulk Update					
⊞- Archive					

The imported data is displayed in the relevant section of the tree-view area:

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA
Reset Application Reset Section Clear Local Import Reload	
liper Imported Messages (1)	
E XEVPRM - OTORGHB03042 - 10/09/2021 12:33.40	Description Name/Value
Development Products (1)	Message Type XEVPRM
E Sponsors (1)	Message Number ProductX_100ml solution_insert
Attachments (1)	Original Sender OTORGHB03042
Inbox	Message Date 10/09/2021 12:33.40
Outbox	Development Products (1)
-Run to Excel Files	Sponsors (1)
-Bulk Update	Attachments (1)
Archive	

3.7.4. 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 area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			For the OK, as from 1.1.2021, EO Law applies on
Reset Application Reset Section Clear Replicate Validate Send XML ZIP RTF Duplicate Rer	nove E L R		
E XEVPRM Message			
- Products	Description	Name/Value	
E Insert - Authorised	Туре	Authorised	
Medicinal Product Types (-)	Operation Type	Insert	
-Authorised Pharmaceutical Forms (-)	MAH		Field is Mandatory
-Pharmaceutical Products (-)	QPPV		
Drug ATCs (-)	Master File Location		
-Drug Indications (-)	PhV enquiry email		Field must have a specified value
Previous EV Codes (-)	PhV enquiry Phone		Field must have a specified value
Product Attachments (-)	Sender Local Code		
Substances	Info Date		Field in Mandatana
Sources	Authorisation Country Code		Field is Mandatory
Organisations	Authorisation Procedure		Field is Mandatory
ATC Codes	Authorisation Status		Field must have a aposified value
Phormacoutical Forma	Authorisation/Ronowal Date		Field must have a specified value
Pharmaceuucai Forms	MPP/DCP/EMEA Number		Tield must have a specified value
Routes Of Administration	FIL Number		
Attachments	Legal Basis		
Master File Locations	Orphan Drug		
	Additional Monitoring		
	Invalidated Date		Field must have a specified value

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 completed by the user).

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

3.8. 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 the same as any other normal command.

The pop-up can be closed by clicking the escape (ESC) key or by clicking anywhere outside the pop-up.

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

W	EB Trader Creat	Create and Send Product Reports			Medicinal Products M		MedD	RA				
	Reset Application	Reset Section	Clear	ReRun	Modify	Delete	Excel	Export 👻	Reload 👻	Load 👻	□ ∅	

3.9. 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 query are grouped in three popup menus:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	A.			
Reset Application Reset Section Clear ReRun Modify Delete Excel E	Ехро	rt 🕶 Reload 🕶	Load 🛨 🔲	
Development Medicinal Products	^			
Approved Substances		Num	EV Code	Version
Development Substances		0001	PRD126017	1/2 Valid Nullified
Sources		✓ 0002	PRD126023	1/1 Valid
MAHs		✓ 0003	PRD126024	1/1 Valid
Sponsors				
ATC Codes				
Routes of Administration				
Pharmaceutical Forms				
Master File Locations				
Attachments				
-Abstract Compositions				
Owned EVMPD Entities				
Owned Authorised Products				
Authorised Products (Valid Version)				
Owned Development Products				
Fields				
Conditions (AND)				
🖻 Results				
Result 17 September 2021 14:06:09				

After the required product entities, clicking on the 'Reload' button will show the possible commands.

The following commands are available for <u>owned development product entities</u>:

Reload	Choose one of the available Commands
	Press A - Z to find initial letter Press Enter to select, Escape to clear
	Update
	Nullify
	Reinsert

The following commands are available for <u>owned authorised product entities</u>:

Reload	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				

If some of these commands are not available for the products selected as a result of your advanced query, this may be due to the fact that you are not logged on to EVWEB under the ID of the organisation that owns the product entries. You cannot update/nullify DMPs and update/nullify/invalidate AMPs that your organisation does not own in the XEVMPD. In such case, usually only the 'Reinsert' command will be available.

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

In the below example, the command 'Update (2)' was used for the selected development medicinal products:



3.9.1. Create an XEVPRM with various commands - practical example

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

WEB Trader Create and Send Product Report	rts Medicinal P	roducts	ledDRA				
Reset Application Reset Section Clear	ReRun Modify	Delete E	xcel Export 🗸	Reload 🗸 🛛 Load 🗸 🗆			
Authorised Medicinal Products							
- Development Medicinal Products	Num	Nullified	EV Code	Article 57 Format	Checked	Full Presentation Name	MA Validity
Approved Substances		No	DDD111036	Article 57 Format (1)	No	Cochi 25 Canculos	Valid (1)
- Development Substances		No	PRD111050	Article 57 Format (1)	No	DrugVoro Ibuprofon E	Valid (1)
Sources		No	DD111030	Article 57 Format (1)	No	Drugvero ibuproien 1 DroductX comprimido	Valid (1)
MAHs		NU	FRDTTTOT	Anticle 57 Format (1)	NO	Froducts complimited	valiu (1)
Sponsors							
ATC Codes							
-Routes of Administration							
Pharmaceutical Forms							
Master File Locations							
Attachments							
Abstract Compositions							
⊡ Queries							
Authorised Products							
Fields							
Conditions (AND)							
⊟ Results							
Result 02 July 2014 15:05:36							

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':

Reset Application Reset Section C	lear ReRun	Modify	Delete Excel	Export - Reload	Choose one of the available]
Authorised Medicinal Products					Commands	
Development Medicinal Products	Num	Nullified	EV Code	Article 57 Format		MA Validity
- Approved Substances	0001	No	PRD111036	Article 57 Format (1	Press A - Z to find initial letter Press Enter to select, Escape to clear	Valid (1)
Sources	0002	No	PRD111058	Article 57 Format (1		Valid (1)
MAHs	₩ 0003	INO	PRDTTIO	Article 57 Format (1	Update	valid (1)
Sponsors					Nullify	
-AIC Codes					Invalidate MA	ĺ
Pharmaceutical Forms						1
Master File Locations					keinsert	
Attachments						

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

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear Validate Send XML ZIP RTF Remove E L	R	
⊡-XEVPRM Message	ProductX	
	Description	Name/Value
Modicinal Broduct Turoc ()	Operation Type	Update (2)
Authorised Pharmaceutical Forms (-)	Туре	Authorised (2)
- Pharmaceutical Products (1)	EV Code	PRD111036
E-Drug ATCs (1)	MAH	
Drug Indications (1)	QPPV Master File Leastion	John Smith (DOMTESTIMAH) MEL7562 United Kingdom (CP) London
Previous EV Codes (-)	PhV enquiny email	nharmacovig@nharmax.co.uk
	PhV enquiry Phone	+44 207 2222222
Update (2) - Authorised (2) - PRD111081 - ProductX comprimido revestido 4 mg	Sender Local Code	
Medicinal Product Types (-)	Info Date	
Authorised Pharmaceutical Forms (-)	Authorisation Country Code	United Kingdom (GB)
Pharmaceutical Products (1)	Authorisation Procedure	EU authorisation procedures - National Procedure (4)
Drug ATCs (1)	Authorisation Status	Valid (1)
Drug Indications (1)	Authorisation Number	PL000/00/01
Previous EV Codes (-)	Authorisation/Renewal Date	01/05/2014
	WIRP/DCP/EWEA Number	
Substances	Legal Basis	Full application (Article 8(3) of Directive No 2001/83/EC)
Sources	Orohan Drug	No (2)
Organisations	Additional Monitoring	No (2)
-AIC Codes	Invalidated Date	
	Full Presentation Name	Goshi 25 Capsules
- Routes Of Administration	Product Short Name	Goshi 25
Attachments	Product INN/Common Name	
Master File Locations	Product Company Name	
	Product Strength Name	
	Product Form Name	CAPSULES
	Package Description	25 capculae par pack
	Comment	20 capsules per pack Medicinal Product Types (.)
		Authorised Pharmaceutical Forms (-)
		Pharmaceutical Products (1)

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
L	0001	No	PRD111036	Article 57 Format (1)	No	Goshi 25 Capsules	Valid (1)
L	☑)002	No	PRD111058	Article 57 Format (1)	No	DrugVero Ibuprofen F	Valid (1)
	0003	No	PRD111081	Article 57 Format (1)	No	ProductX comprimido	Valid (1)

Then select the applicable command under 'Reload':

WEB Trader Create and Send Product Reports Medici	inal Products	MedDRA		
Reset Application Reset Section Clear ReRun M	odify Delete	Excel Export -	Reload 👻	Choose one of the available
Authorised Medicinal Products				Commands
- Development Medicinal Products	Num	Nullified	EV Code	Press A - Z to find initial letter
Development Substances	0001	No	PRD11103	Press Enter to select, Escape to clear
Sources	0002	No	PRD11105	Update
MAHs	0003	No	PRD11108	Nullify
Sponsors				Invalidate MA
ATC Codes				
Routes of Administration				Reinsert
Pharmaceutical Forms				
Master File Locations				
Attachments				

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)':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear Validate Send XML ZIP RTF Remove E L R		
⊡-XEVPRM Message	ProductX	
⊡-Products	Description	Name/Value
Hodininal Braduet Types ()	Operation Type	Invalidate MA (6)
Authorised Dharmaceutical Forms (.)	Туре	Authorised (2)
Bernaceutical Products (1)	EV Code	PRD111058
$\mathbb{H}_{\mathbb{H}}$ Drug ATCs (1)	MAH	PHARMAX LIMITE
E-Drug Indications (1)	QPPV	John Smith (DCM
Previous EV Codes (-)	Naster File Location	aharmaa uis Qaha
Product Attachments (1)	Phy enquiry email Phy orguin, Phone	+44 207 2222222
T-Update (2) - Authorised (2) - PRD111081 - ProductX comprimido revestido 4 mg	Sender Local Code	144 201 2222222
E Invalidate MA (6) - Authorised (2) - PRD111058 - DrugVero Ibuprofen Forte 400 mg Liquid Capsules	Info Date	
Medicinal Product Types (-)	Authorisation Country Code	United Kingdom (
-Authorised Pharmaceutical Forms (-)	Authorisation Procedure	EU authorisation
Pharmaceutical Products (1)	Authorisation Status	1 (1)
⊕ Drug ATCs (1)	Authorisation Number	1234/5678/111
Drug Indications (1)	Authorisation/Renewal Date	07/02/2013
Previous EV Codes (-)	MRP/DCP/EMEA Number	SE/H/1111/222
Product Attachments (1)	EU Number	

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

3.10. WEB Trader Functions

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 and also to retrieve XML files created as a result of changes performed via the XEVMPD Bulk Update Manager tool (see section *3.10.4. Bulk Update*).

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

The tree-view area displays three different sections:

- Imported Message (s)
- Inbox

- Outbox
- Run to Excel Files
- Bulk Update
- Archive

Display Settings	
WEB Trader Create and Send Product Reports Medicinal Products MedD	ORA
Reset Application Reset Section Clear Local Import	
Imported Messages (-)	
Inbox	Empty
Outbox	
Run to Excel Files	
Bulk Update	
Archive	

3.10.1. Imported messages

The section 'Imported Messages' will display the message(s) that you imported from your local computer or from EVWEB.

For information how to import messages, see sections and *3.7.2. Load from a local file* and *3.7.3. Load from a remote file*.

When you click on the imported file, the 'Reload' button becomes available in the dynamic area of the main menu:



3.10.1.1. Reloading an XEVPRM in the 'Create and Send product reports' section

Reload This button will enable you to reload the content of an XEVPRM in the 'Create and Send Products' section, allowing you to continue and/or complete, validate and send the XEVPRM.

When you click on the 'Reload' button a new window will open informing you that performing this action will replace any content you may have in the 'Create and Send Product Reports' section:

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA		,
Reset Application Reset Section Clear Local Import Reload			
□ Imported Messages (1)	EVHUMAN\sunnyevhp_EVHUMAN_rkg_2021-09-	7_14-23-50-01\New	
E XEVPRM - EVHUMANWT - 17/09/2021 14:23.53	Description	Name/Value	
Authorised Products (15)	Message Type	XEVPRM	
Inbox	Message Number	0001	
Outbox	Original Sender	EVHUMANWT	
Temporary Folder	Message Date	17/09/2021 14:23.53	
Run to Excel Files		Authorised Products (15)	
Bulk Update			
Archive			
		Message from webpage	$\times \mid$
		This action will replace any content in the Create and Send Products section with the selected message. Do you wish to continue ?	
		OK Cancel	

Once you confirm that you wish to continue by clicking on 'OK', the products with the applied changes will be displayed in the 'Create and Send Product Reports' section for your review:

WEB Trader Create and Send	I Product Repo	rts Medi	cinal	l Produ	cts M	ledDRA	\		
Reset Application Reset Se	ction Clear	Replicate	Va	alidate	Send	XML	ZIP	RTF	Remove
E XEVPRM Message			^	EVHU	IMAN\sur	nnyevhp	_EVHU	JMAN_	rkg_2021-09
Products								D	escription
📄 Update - Authori	sed - PRD6	623817 -							EV Code
Medicinal Pro	duct Types	(1)							Туре
Authorised Pl	narmaceutio	al Form	:				l:	s EN	A Owned
Pharmaceutic	al Products	5 (1)					0	pera	tion Type
Drug ATCs (1)						1	Vew	Owner ID
Drug Indication	ons (3)								MAH
Previous EV	Codes (-)						octor	- Eila	QPPV Logotion
Product Attac	hments (1)					IVI	Dh\/		Location
🗄 Update - Authori	sed - PRD6	623815 -				P	PhV e	naui	ry Phone
🕀 Update - Authori	sed - PRD6	623813 -					Sende	erlo	cal Code
🕀 Update - Authori	sed - PRD6	623814 -							Info Date
Update - Authori	sed - PRD6	623812 -			Auth	norisa	tion	Cour	ntry Code
Update - Authori	sed - PRD6	623811 -			1	Autho	risati	on F	rocedure
🕀 Update - Authori	sed - PRD6	623816 -				A	utho	risati	on Status
Update - Authori	sed - PRD6	623824 -				Aut	thoris	satio	n Number
Update - Authori	sed - PRD6	623825 -			Auti	norise	ation/	Ren	ewal Date
🗄 Update - Authori	sed - PRD6	623823 -			IVI	RP/D	CP/E		A Number
Update - Authori	sed - PRD6	623822 -							J Number
🕀 Update - Authori	sed - PRD6	623818 -						Orn	han Drug
🕀 Update - Authori	sed - PRD6	623821 -				Ad	ditio	nal N	Ionitoring
🕀 Update - Authori	sed - PRD6	623820 -				. 10	In	valid	ated Date
🗄 Update - Authori	sed - PRD6	623819 -				Full F	Prese	entat	ion Name

Please note that any products that you may have had in this section prior to re-uploading the imported file will be deleted!

You will be able to review the information in your XEVPRM, assign the XEVPRM Message number (it is not reloaded from the original file), validate, and send the XEVPRM.

3.10.2. Inbox and Outbox

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.

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.

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

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

• The system automatically archives messages in your Inbox and Outbox on daily basis.

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



WEB Trader Create and Send Product Reports Medicinal Products Med	RA			
Reset Application Reset Section Clear Remote Import				
Imported Messages (-)				
Inbox	Num	Name	Num/Count	Date
Outbox	0001	userhb03o44u40-Send-OTORGHB03O44-XEVP	1/4	2021/09/
Run to Excel Files	0002	userhb03o44u40-Send-OTORGHB03O44-XEVP	2/4	2021/09/
Bulk Update	0003	userhb03o44u40-Send-OTORGHB03O44-XEVP	3/4	2021/09/
Archive	0004	userhb03o44u40-Send-OTORGHB03O44-XEVP	4/4	2021/09/
Archived Outbox (last 7 days)				
Archived Outbox (last 30 days)				
Archived Inbox				
Archive Outbox				

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:

Display Settings		
	Ø https://evtest.ema.europa.eu/x/Export.asp?54F5F913-1B65-495F	$\times \mid$
WEB Trader Create and Send Product Repor	× 党Convert ▼ 🗟 Select	
WEB Trader Create and Send Product Report Reset Application Reset Section Clear Imported Messages (-) Inbox Outbox Run to Excel Files Bulk Update Archive Archived Inbox (last 7 days) Archived Outbox (last 30 days) Archived Outbox (last 30 days) Archive Outbox Archive Outbox (last 30 days) Archive Outbox	X @Convert ▼ @Select xml version="1.0" encoding="UTF-8" ? - <evprmack< p=""> xsl:noNamespaceSchemaLocation="http://eudravigilance.ema.europa.eu/schema/ackxxmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"> - <ichicsrmessageteschemalocation="http: ackxxmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" eudravigilance.ema.europa.eu="" schema=""> - < < < <messagetschewelschemats< p=""> < <messagetormatversion>1.0 < <messagetormatversion>1.0 < <messagetormatversion>1.0 < <messagetormatversion>1.0 < <messagetormatversion>2.10 < <messagetormatversion>2.10 < <messagetormatversion>2.10 < <messagetormatversion>2.10 <messagetormatversion>2.10 <messagetormats< p=""> < <messagetormats< p=""> < <messagetormats< p=""> <messagetormats< p=""> <messagetormats< p=""> <td>ev</td></messagetormats<></messagetormats<></messagetormats<></messagetormats<></messagetormats<></messagetormatversion></messagetormatversion></messagetormatversion></messagetormatversion></messagetormatversion></messagetormatversion></messagetormatversion></messagetormatversion></messagetormatversion></messagetschewelschemats<></ichicsrmessageteschemalocation="http:></ichicsrmessageteschemalocation="http:></ichicsrmessageteschemalocation="http:></ichicsrmessageteschemalocation="http:></ichicsrmessageteschemalocation="http:></evprmack<>	ev
	<pre> - <reportacknowledgment> DEVELOPMENTPRODUCT</reportacknowledgment></pre>	\checkmark
		,

In some browsers, the XML file is displayed directly.

You can perform different actions on these files:

- show their content in Internet Explorer without any transformation, or
- import them into 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, look-up 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:

Additional Monitoring Invalidated Date		Field must ha	we a specified value
Full Presentation Name		Field in Mond	atory
Product Short Name Product INN/Common Name		Select option	atory Optional atory Optional
Product Company Name Product Strength Name Product Form Name	Press Press En	ve a specified value	
Package Description Comment	No (2)		
M A	Yes (1)		ndatory ndatory

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:



3.10.3. Run to Excel Files

When you export results in Excel using the 'Run to Excel' button during an advanced query, and the condition selected as "owned", the result of the query will be displayed in this section:

Γ	WEB Trader Create and Send Product Reports Medicinal Products Med	IRA			, , , , , , , , , , , , , , , , , , ,	
L	Reset Application Reset Section Clear					
	-Imported Messages (-)					
Ш	Inbox	Num	Name	Num/Count	Date	Size
Ш	Outbox	0001	userhb03o44u40-Query-[Owned Development Products (22-09-2021 17-39-47)]-2021-09-22 17-39-47-01.xls	1/9	2021/09/22 17:39.49	00000160
Ш	-Run to Excel Files					
L	Bulk Update					

3.10.4. Bulk Update

EVWEB users can use the <u>XEVMPD Bulk update Manager tool</u> to perform bulk data operations on multiple products owned in the XEVMPD by their organisation. The tool facilitates editing key data fields and supports the re-submission of this data to the XEVMPD.

The tool, together with the corresponding <u>XEVMPD bulk update manager user guide</u>, is available in the restricted area of the EudraVigilance website and should be accessed via an IE Tab extension.



Once a user has generated the updated product set using the <u>Bulk Update Manager tool</u>, a series of files will then become available in the 'Bulk Update' sub-section of the Web Trader section of EVWEB:

WEB Trader	Create	and Send Prod	uct Reports	Medicinal P
Reset App	lication	Reset Section	Clear Re	mote Import
Imported	Mess	ages (-)		
Inbox				
Outbox				
Tempor	ary Fo	older		
Run to E	xcel F	iles		
Bulk Upd	late			
Archive				

To retrieve the files in the 'Bulk Update' section, click on 'Bulk Update'. The available files will become visible in the active area:

WEB Trader Create and Send Product Reports Medicinal F	roducts	MedDRA		
Reset Application Reset Section Clear Remote Import	Q			
Imported Messages (-)				
Inbox	Num	Name	Num/Count	Туре
Outbox	0001			FOLDER
Temporary Folder	0002	sunnyevhp_EVHUMAN_rkg_2021-09-17_14-23		FOLDER
Run to Excel Files				
Bulk Update				
Archive				

Select the file you created so it is highlighted in blue:

WEB Trader Create and Send Product Reports Medicinal	Products	MedDRA			
Reset Application Reset Section Clear Remote Impor	t O				
Imported Messages (-)					
Inbox	Num	Name	Num/Count	Туре	Date
Outbox	0001			FOLDER	
Temporary Folder	0002	sunnyevhp_EVHUMAN_rkg_2021-09-17_14-23		FOLDER	2021/09
-Run to Excel Files					
Bulk Update					
. ⊕ Archive					

Double-click on the file; two folders will be displayed in the active area:

- The new file ('New'), generated as a result of the bulk update operations/changes you applied to the selected products;
- The original ('Org') file, containing the product set prior to performing the bulk update operations/changes:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA										
Reset Application Reset Section Clear Remote Import										
EVHUMAI	N\sunnyevhp_EVHUMAN_rkg_2021-09-17_14-23-50-01									
Num	Name	Num/Count	Туре	Date						
0001			FOLDER							
0002	New		FOLDER	2021/09/17 1						
0003	Org		FOLDER	2021/09/17 1						
	Products	MedDRA 0 EVHUMAN\sunnyevhp_EVHUMAN_rkg_2021-09-17_14-23-50-01 Num Name 0001 0002 New 0003 Org	MedDRA O EVHUMAN\sunnyevhp_EVHUMAN_rkg_2021-09-17_14-23-50-01 Num Name 0001 0002 New 0003 Org	MedDRA O EVHUMAN\sunnyevhp_EVHUMAN_rkg_2021-09-17_14-23-50-01 Num Name OO01 FOLDER 0002 New OO03 Org						

Double-click on the 'New' folder and the XML file will be displayed:

WEB Trader Create and Send Product Reports Medicina	I Products	MedDRA						
Reset Application Reset Section Clear Remote Impo	t Q							
Imported Messages (-)	EVHUMA	N\sunnyevhp_EVHUMAN_rkg_2021-09-17_14-23-50-01						
Inbox	Num	Name	Num/Count	Туре				
Outbox	0001			FOLDER				
Temporary Folder	0002	New		FOLDER				
-Run to Excel Files	0003	Org		FOLDER				
-Bulk Update								
Archive								
4 <u></u>								
WEB Trader Create and Send Product Reports Medicinal Products MedDRA								

Reset Application Reset Section Clear Remote Import	0			
Imported Messages (-)	EVHUMA	Nsunnyevhp_EVHUMAN_rkg_2021-09-17_14-23-50-01\New		
Inbox	Num	Name	Num/Count	Туре
Outbox	0001			FOLDER
Temporary Folder	0002	sunnvevhp EVHUMAN rka 2021-09-17 14-23	1/1	XML
-Run to Excel Files				
-Bulk Update				
Archive				

Click on the XML file (so it is highlighted in blue) and the 'Remote Import' functionality will become available:

WEB Trader Create and Send Product Reports Medicinal P	roducts	MedDRA			Former	ок, as irom т. т.202
Reset Application Reset Section Clear Remote Import	0					
Imported Messages (-)	EVHUMAI	N\sunnyevhp_EVHUMAN_rkg_2021-09-17_14-23-50-01\New				
Inbox	Num	Name	Num/Count	Туре	Date	Size
Outbox	0001			FOLDER		
Temporary Folder	0002	sunnyevhp_EVHUMAN_rkg_2021-09-17_14-23	1/1	XML	2021/09/17 14:28.53	00001376
-Run to Excel Files						
Bulk Update						
Archive						

Once you click on the 'Remote Import', the file will become available in the tree-view area:

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA				
Reset Application Reset Section Clear Local Import Reload					
Imported Messages (1)	EVHUMAN\sunnyevhp_EVHUMAN_rkg_2021-09-17_14-23-50-01\New				
E XEVPRM - EVHUMANWT - 17/09/2021 14:23.53	Description Name/Value				
Authorised Products (15)	Message Type XEVPRM				
Inbox	Message Number 0001				
Outbox	Original Sender EVHUMANWT				
Temporary Folder	Message Date 17/09/2021 14:23.53				
Run to Excel Files	Authorised Products (15)				
Bulk Update					
Archive					

To import the products in the 'Create and Send Product Reports' section, click on 'Reload':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA
Reset Application Reset Section Clear Local Import Reload
Imported Messages (1)
E XEVPRM - EVHUMANWT - 17/09/2021 14:23.53
Authorised Products (15)
Inbox
Outbox
Temporary Folder
Run to Excel Files
Bulk Update
Archive

A new window will pop-up asking for confirmation that you wish to re-load the content of the XEVPRM in the 'Create and Send product reports' section:



Once you confirm by clicking on 'OK', the products with the applied changes will be displayed in the 'Create and Send Product Reports' section for your review:

WEB Trader Create	and Send Prod	uct Repo	orts	Medio	inal	Produ	icts I	MedDR	A		
Reset Application	Reset Section	Clear	Rep	olicate	Va	lidate	Send	XML	ZIP	RTF	Remove E
E XEVPRM Mess	age				^	EVHU	JMAN\su	unnyevh	p_EVH	IUMAN_	_rkg_2021-09
Products										D	escription
🚊 Update - /	Authorised -	- PRD	6238	317 -							EV Code
	nal Product	Types	5 (1)								Туре
Author	ised Pharm	aceuti	cal F	Form					I	ls EN	IA Owned
🗄 Pharm	aceutical Pi	roduct	s (1))					C	Opera	tion Type
🕀 Drug A	ATCs (1)									New	Owner ID
⊞ Drug Ir	ndications (3)									MAH
Previou	us EV Code	s (-)								- 53-	QPPV
Produce	t Attachme	nts (1))					IV	DEV		e Location
+ Update - /	Authorised -	- PRD	6238	315 -						onqui	uny eman iny Phono
Update - Authorised - PRD623813 -								Send	ler I r	ny Flione	
Update - /	Authorised -	- PRD	6238	314 -					00110		Info Date
Update - /	Authorised -	- PRD	6238	312 -			Aut	horisa	ation	Cou	ntry Code
Update - Authorised - PRD623811 -				Authorisation Procedu				rocedure			
Update - Authorised - PRD623816 -			316 -		Authorisation Statu				ion Status		
Update - /	Authorised -	- PRD	6238	324 -				Au	thori	satio	n Number
H Update - /	Authorised -	- PRD	6238	325 -			Aut	thoris	ation	/Ren	ewal Date
⊕ Update - /	Authorised -	- PRD	6238	323 -			N	IRP/D	CP/I	EME	A Number
⊕ Undate - /	Authorised -	- PRD	6238	322 -						E	JNumber
Undate - Authorised - PRD623818 -									Le	gal Basis	
Undate - A	Lindate - Authorised - PRD623821 -							Δ.	dditie	Orp	nan Drug Jopitoring
Lindate -	Authorised -		6238	320 -		Auditional Monitorin				ated Date	
⊕ Update - /	Authorised -	- PRD	6238	319 -				Full	Pres	entat	ion Name

Review the product information to confirm that required change was performed.

Assign the XEVPRM Message number to your XEVPRM, then **validate** (using the 'Validate' functionality) and <u>send (using the 'Send' functionality)</u> **the XEVPRM**. The submitted XEVPRM will be available in your WebTrader Outbox/Archived Outbox.

3.10.5. Archive

To find messages that have been archived, you will need to **run** queries in the **Archive section** of EVWEB.

You will need to select the applicable period for which you wish to retrieve your submission of acknowledgement messages:

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

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) user manual EMA/308954/2012

Once you click on the required folder (it will become highlighted in light grey), either 'Run' **and/or** 'Run to Excel' buttons will become available in the dynamic button area, depending on the number of messages in that folder:



If you select **'Run'**, the results will be displayed in the active area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA										
Reset Application Reset Section Clear Reflaw Delete Excel Remote Import Create Ack										
Imported Messages (-)										
-Inbox Num File Name Message Number	Receiver	Sender	Receive Date	Document Ty						
Outbox 0001 ack_userhb03o44u40-Send-OTORGHB0304 EU-EC-M-165174-ACK	OTORGHB03044	EVTEST	2021/09/17 13:56.00	WebTrader I						
Run to Excel Files 0002 ack_userhb03o44u40-Send-OTORGHB03O4 EU-EC-M-165136-ACI	OTORGHB03044	EVTEST	2021/09/15 13:47.33	WebTrader E						
Bulk Update 0003 ack_userhb03o44u40-Send-OTORGHB03O4 EU-EC-M-165125-AC	OTORGHB03044	EVTEST	2021/09/15 12:44.30	WebTrader E						
Archive										
Archived Inbox (last 7 days)										
Results										
Result 17 September 2021 17:39:59										
Archived Outbox (last 7 days)										
Results										
Archived Inbox (last 30 days)										
Results										
Archived Outbox (last 30 days)										
Results										
Archived Inbox										
Archive Outbox										

If 'Run to Excel' is available and you select this option, a new window will open:

https://eudravigilance.ema.europa.eu/x/x.asp?xi=6 - Work - Microsoft Edge	_	×
🧔 🛈 about:blank		Q
Summary		~
Temporary (for Export) Click here for the file Name: Archived Inbox (last 7 days) (17-09-2021 17-42-04).xls		

Once you click on 'here', you will retrieve the results in an Excel file.

3.10.6. Data-export functionality

XEVMPD Export functionality is available to enable organisations to export their own data from EVWEB.

The export tool can be accessed directly via a browser with an IE Tab extension at the URL <u>https://eudravigilance.ema.europa.eu/evmpdex/ExportManager.asp</u>.

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 <u>XEVMPD product export tool: user manual</u>, which is available in the EudraVigilance secure area, under 'User Support':


3.11. 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 set of results 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 area.
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).
Onco ovportod	the document in any of these formats (except for a ZIP file) can be printed or sayed

Once exported, the document in any of these formats (except for a ZIP file) can be printed or saved like any other document on your computer.

See section <u>4.8. Save, Reload and Send an XEVPRM</u> for information.

4. Create and Send XEVPRMs

4.1. 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), a source, an organisation (MAH or sponsor), an ATC code (proposed or development), a route of administration (proposed or development) and 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 <u>Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance</u>, this operation type shall be used to maintain some of the authorised medicinal product information.

- 'Nullification' (4): allows users to flag incorrectly submitted information (including duplicated information) as 'non-current'.
- **'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 by the marketing authorisation holder if the marketing authorisation number changes.

See the relevant sections of <u>Chapter 3.II: Extended EudraVigilance product report message</u> (XEVPRM) user guidance for further information and processes.

• Operation type **'Variation' (3)**: is no longer available in EVWEB as it should not be used to notify the EMA of a variation procedure of an authorised medicinal product in the context of maintenance of medicinal product data during the transition maintenance phase. Gateway users, who will submit an XEVPRM containing an authorised medicinal product assigned with operation type 'Variation' (3) will receive a negative XEVPRM acknowledgement as the entire XEVPRM will be rejected.

The process to be followed to amend an authorised medicinal product entity following a variation procedure is described in section 2.2.3.1. Variations of marketing authorisation of Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance.

4.2. Create an XEVPRM with operation type Insert

To insert new information in the XEVMPD, you must create and send an XEVPRM.

To create an XEVPRM, open EVWEB and go to the 'Create and Send Product Reports' section:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA

EVWEB will display the sections present in the XEVPRM:

WEB Trader Create and Send Product Reports Met	dicinal Products MedDRA		
Reset Application Reset Section Clear Validate	Send XML ZIP RTF E L R		
XEVPRM Message			
	Description	Name/Value	
	Message Number		Field is Mandatory
		Products	
		Substances	
		Sources	
		Organisations	
		ATC Codes	
		Pharmaceutical Forms	
		Routes Of Administration	
		Attachments	
		Master File Locations	

The XEVPRM contains a mandatory section named 'message header' (shown in the below screenshot as present in XML file of the XEVPRM):

<pre><?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"></evprm></pre>
- <ichicsrmessageheader></ichicsrmessageheader>
<messagetype>XEVPRM</messagetype>
<messageformatversion>2</messageformatversion>
<messageformatrelease>0</messageformatrelease>
<messagenumb></messagenumb>
<messagesenderidentifier>OTORGHB03044</messagesenderidentifier>
<messagereceiveridentifier>EVTEST</messagereceiveridentifier>
<messagedateformat>204</messagedateformat>
<messagedate>20210922181311</messagedate>
ichirst messageheader

EVWEB completes automatically the 'message header' section except from the 'Message number' field. Therefore, you must type in the message number that you wish to assign to your message.

You can expand the tree-view area to display the sections of the XEVPRM by moving the separation line to the right:



You must enter a message name of number in the 'Message Number' field, to do so, click on the 'XEVPRM Message' text in your tree-view area:

WEB Trader Create and Send Product Reports Medicinal Products MedD	RA		
Reset Application Reset Section Clear Validate Send XML ZIP R	TF E L R		
	Description	Name/Value	
	Message Number		Field is Mandatory
		Products	
	-	Substances	
	-	Sources	
		Organisations	
		ATC Codes	
		Pharmaceutical Forms	
		Routes Of Administration	
		Attachments	
		Master File Locations	

The active area will show the 'XEVPRM Number' field; the area next to the 'Message Number' will be highlighted in blue:

WEB Trader Create and Send Product Reports Medicinal Products Medi	DRA	
Reset Application Reset Section Clear Validate Send XML ZIP R	RTF E L R	
XEVPRM Message		
	Description Name/Value	
	Message Number	Field is Mandatory
	Products	
	Substances	
	Sources	
	Organisations	
	ATC Codes	
	Pharmaceutical Forms	
	Routes Of Administration	
	Attachments	
	Master File Locations	

Click on the 'E' (Text Edit) button or use 'Enter' on your keyboard to activate the field, and you will be able to write the name/number that you wish to assign to you XEVPRM:

WEB Trader Create and Send Product Reports Medicinal Products MedE	DRA	
Reset Application Reset Section Clear Validate Send XML ZIP R	TFELR	
XEVPRM Message		
	Description Name/Value	
	Message Number	Field is Mandatory
	Products	
	Substances	
	Sources	
	Organisations	
	ATC Codes	
	Pharmaceutical Forms	
	Routes Of Administration	
	Attachments	
	Master File Locations	

Enter the required message number or name and press 'Enter'; the text that you entered will appear in blue:

Description	Name/Value
Message Number	You can assign your XEVPRM name or number here
	Products
	Substances
	Sources
	Organisations
	ATC Codes
	Pharmaceutical Forms
	Routes Of Administration
	Attachments
	Master File Locations

To add a new entity in the XEVMPD, you must add the required entity in the XEVPRM with the operation type 'Insert (1)'.

To do so, you must select the relevant section of the XEVPRM. You can double click on the required section in the active area, or expand the menu (by clicking on the + sign) in the tree-view area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Validate	Send XML ZIP RTF E L R			
XEVPRM Message				
	Description	Name/Value		
	Message Number		Field is Mandatory	
		Products		
		Substances		
		Sources		
		Organisations		
		ATC Codes		
		Pharmaceutical Forms		
		Routes Of Administration		
		Attachments		
		Master File Locations		
	L			

The active area allows you to create the required report by clicking in the check box next to the entity that you wish to insert.

The principle of clicking in 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, pharmaceutical form, ATCs etc.

You can also insert 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 look-up tables.

Please note that whilst you can also add new approved and development substances in your XEVPRM, once you send the XEVPRM, the submission will be rejected. This is because substance information can be inserted and/or updated by the EMA only. Please refer to the information available in the 'Changes to some business rules of the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD): Submission of substance information' document.

The below examples describe how to create and add a report with the operation type 'Insert' to the XEVPRM.

Each report (Product Report, Master File Location Report, etc.) contains different fields, but the process for inserting the information does not change.

Please refer to <u>Chapter 3.I: Extended EudraVigilance product report message (XEVPRM) technical</u> <u>specifications</u> for a complete list of the fields present in each section and their definition and the applicable **technical rules**.

For list of data fields collected for entities in the XEVMPD and the applicable **business rules** please refer to:

- MAHs: <u>Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance</u>; and
- Sponsors: <u>Guidance on the electronic submission of information on investigational medicinal</u> products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD).

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

Validate

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.

XML ZIP RTF

a zip file, click on the buttons from the dynamic button set.

Send

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

4.2.1. Insert of an authorised medicinal product (AMP)

To create a 'Product Report', you must select 'Products' in the tree-view area or in the active area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear Validate	Send XML ZIP RTF E L R		
□ XEVPRM Message			
Products	Description	Name/Value	
Substances	Message Number		Field is Mandatory
Sources		Products	
Organisations		Substances	
ATC Codes		Sources	
Pharmaceutical Forms		Organisations	
-Routes Of Administration		ATC Codes	
Attachments		Pharmaceutical Forms	
Master File Locations		Routes Of Administration	
		Attachments	
		Master File Locations	

You must select the type of product you wish to create by ticking the relevant box in the active area; to create a product report for an authorised product, you must select 'New Authorised Product' in the active area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R				
E XEVPRM Message				
Products	Num			
Substances	New Authorised Product			
	New Development Product			
Organisations				
ATC Codes				
Pharmaceutical Forms				
Routes Of Administration				
Attachments				
Master File Locations				

Once you have selected 'New Authorised Product', the tree-view area and the active area will display the fields that need to be completed for the relevant section of the XEVPRM:

WEB Trader Create and Send Product Reports Medicinal Products MedD	RA		
Reset Application Reset Section Clear Replicate Validate Send XM	L ZIP RTF Duplicate Remove E	LR	
E-XEVPRM Message			
– Products	Description	Name/Value	
□ Insert - Authorised	Type	Authorised	
	Operation Type	Insert	
-Authorised Pharmaceutical Forms (-)	MAH		Field is Mandatory
Pharmaceutical Products (-)	QPPV		,
Drug ATCs (-)	Master File Location		
Drug Indications (-)	PhV enquiry email		Field must have a specified value
Previous EV Codes (-)	PhV enquiry Phone		Field must have a specified value
Product Attachments ()	Sender Local Code		
Substances	Info Date		
SUDSIAILOS	Authorisation Country Code		Field is Mandatory
Sources	Authorisation Procedure		Field is Mandatory
Organisations	Authorisation Status		
ATC Codes	Authorisation Number		Field must have a specified value
-Pharmaceutical Forms	Authorisation/Renewal Date		Field must have a specified value
-Routes Of Administration	MRP/DCP/EMEA Number		
Attachments	EU Number		
Master File Locations	Legal Basis		
	Orphan Drug		
	Additional Monitoring		Field much have a second field only.
	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 Manualory Optional
	Product Company Name		Tielu musi nave a specifieu value
	Product Form Namo		
	Package Description		
	Comment		
	Common	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

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

The 'Operation Type' field displays 'Insert' as default.

Complete the fields as required as per information in <u>Chapter 3.II: Extended EudraVigilance product</u> <u>report message (XEVPRM) user guidance</u>; 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; if the submission was successful, the EV code assigned to the AMP will be provided:



See also <u>Extended EudraVigilance Medicinal Product Report Message step-by-step guide</u>: **Insert of an authorised medicinal product** step-by-step document available on the <u>'Extended EudraVigilance</u> <u>medicinal product dictionary (XEVMPD) training' webpage</u> for step by step instructions.

4.2.2. Insert of a development medicinal product (DMP)

To create a 'Product Report', you must select 'Products' in the tree-view area or in the active area:



To create a product report for a development product, you must select **'New Development Product'** in the active area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R I				
E-XEVPRM Message				
Products	Num	Operation Type		
Substances	New Authorised Product			
Sources	New Development Product			
Organisations				
ATC Codes				
Pharmaceutical Forms				
Routes Of Administration				
Attachments				
Master File Locations				

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 the relevant section of the XEVPRM:

WEB Trader Create and Send Product Reports Medicinal Products Medi	DRA		
Reset Application Reset Section Clear Validate Send XML ZIP R	TF Duplicate Remove E L R		
E XEVPRM Message			
Products	Description	Name/Value	
Insert - Development	Туре	Development	
Pharmaceutical Products (-)	Operation Type	Insert	
Drug ATCs (-)	Sender Local Code		
-Drug Indications (-)	Sponsor		Field is Mandatory
Product Attachments (-)	Product Code		Field is Mandatory Optional
Substances	Product Name		Field is Mandatory Optional
Sources	Product Other Name		
- Organisations	Comment	Destropolytical Braduate ()	Section is Mandatory
ATC Codes			Section is Manualory
-Pharmaceutical Forms		Drug Indications (-)	
-Routes Of Administration		Product Attachments (-)	
Attachments			
Master File Locations			

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

The 'Operation Type' field displays 'Insert' as default.

Complete the fields as required, as per information in the '<u>Guidance on the electronic submission of</u> information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD) document, section *1. Initial submission of a development medicinal product.*

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID; if the submission was successful, the EV code assigned to the DMP will be provided:

- <reportacknowledgment></reportacknowledgment>
<reportname>DEVELOPMENTPRODUCT</reportname>
<localnumber>1</localnumber>
<ev_code>PRD126024</ev_code>
<operationtype>1</operationtype>
<operationresult>2</operationresult>
<pre><operationresultdesc>Entity inserted successfully Version 1</operationresultdesc></pre>

See also <u>Extended EudraVigilance Medicinal Product Report Message step-by-step guide</u>: **Insert of a development medicinal product** step-by-step document available on the <u>'Extended EudraVigilance</u> <u>medicinal product dictionary (XEVMPD) training' webpage</u> for more details.

4.2.3. Insert of an approved substance

Only the EMA can insert, update, or nullify substance information in the XEVMPD. Therefore, this section does not contain information on the insert of this entity in the XEVMPD.

4.2.4. Insert of a reference source

Only the EMA can insert, update, or nullify source information in the XEVMPD. Therefore, this section does not contain information on the insert of this entity in the XEVMPD.

4.2.5. Insert of a marketing authorisation holder organisation

To create an 'Organisation Report', you must select 'Organisations' in the tree-view area or in the active area:

WEB Trader Create and Send Product Reports Mee	dicinal Products MedDRA		
Reset Application Reset Section Clear Validate	Send XML ZIP RTF E L R		
<mark>∋ XEVPRM Message</mark>			
Products	Description	Name/Value	
Substances	Message Number		Field is Mandatory
Sources		Products	
Organisations		Substances	
ATC Codes	_	Sources	
Pharmaceutical Forms	l L	Organisations	
-Routes Of Administration		ATC Codes	
Attachments		Pharmaceutical Forms	
Master File Locations		Routes Of Administration	
		Attachments	
		Master File Locations	

To create an organisation report for an MAH organisation, you must select 'New MAH' in the active area by ticking the relevant box:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R				
E-XEVPRM Message				
Products	Num Operation Type			
Substances	New MAH			
Sources	New Sponsor			
- Organisations				
ATC Codes				
Pharmaceutical Forms				
-Routes Of Administration				
Attachments				
Master File Locations				

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 relevant section of the XEVPRM:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Validate Send XML ZIP R	TF Duplicate Remove E L R			
E-XEVPRM Message				
Products	Description	Name/Value		
Substances	Operation Type	Insert		
Sources	Туре	MAH		
⊟ Organisations	MAH Name	F	ield is Mandatory	
Insert - MAH	SME Status			
ATC Codes	SME Number			
- Pharmaceutical Forms	MAH Sender ID	_		
Routes Of Administration	Address	F	ield is Mandatory	
Attachments	City	F	ield is Mandatory	
Master File Locations	Region	-		
	Postcode	F	ield is Mandatory	
	Country Code	F	ield is Mandatory	
	Tel Country Code			
	For Number			
	Fax Nulliber			
	Fax Extension			
	E-mail Address			
	Comment			

The 'Operation Type' field displays 'Insert' as default.

The 'Type' field displays 'MAH' as default.

Complete the fields as required, as per information in <u>Chapter 3.II: Extended EudraVigilance product</u> <u>report message (XEVPRM) user guidance</u>; 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; if the submission was successful, the EV code assigned to the organisation will be provided:

- <reportacknowledgment></reportacknowledgment>
<reportname>ORGANISATION</reportname>
<localnumber>1</localnumber>
<ev_code>ORG40544</ev_code>
<operationtype>1</operationtype>
<operationresult>2</operationresult>
<pre><operationresultdesc>Entity inserted successfully</operationresultdesc></pre>

See also <u>Extended EudraVigilance Medicinal Product Report Message step-by-step guide</u>: **Insert of an organisation** step-by-step document available on the <u>Extended EudraVigilance medicinal product</u> <u>dictionary (XEVMPD) training' webpage</u> for more details.

4.2.6. Insert of a Sponsor organisation

To create an 'Organisation Report', you must select 'Organisations' in the tree-view area or in the active area:



To create a report for a sponsor organisation, you must select 'New Sponsor' in the active area by ticking the relevant box:

WEB Trader Create and Send Product Reports Medicinal Products Med	DRA			
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R I				
E XEVPRM Message				
Products	Num	Operation Type		
Substances	New MAH			
Sources	New Sponsor			
Organisations				
ATC Codes				
Pharmaceutical Forms				
-Routes Of Administration				
Attachments				
Master File Locations				

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 relevant section of the XEVPRM:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Validate Send XML ZIP R	TF Duplicate Remove E L R			
E XEVPRM Message				
Products	Description	Name/Value		
Substances	Operation Type	Insert		
Sources	Туре	Sponsor		
🖕 Organisations	Sponsor Name		Field is Mandatory	
Insert - Sponsor	Sponsor Sender ID			
ATC Codes	Address		Field is Mandatory	
- Pharmaceutical Forms	City		Field is Mandatory	
-Routes Of Administration	Region			
Attachments	Postcode		Field is Mandatory	
Master File Locations	Country Code		Field is Mandatory	
	Tel Number			
	Tel Country Code			
	For Number			
	Fax Nulliber			
	Eav Country Code			
	F-mail Address			
	Comment			

The 'Operation Type' field displays 'Insert' as default.

The 'Type' field displays 'Sponsor' as default.

Complete the fields as required, as per information in the <u>Guidance on the electronic submission of</u> <u>information on investigational medicinal products for human use in the Extended EudraVigilance</u> <u>medicinal product dictionary (XEVMPD)</u> document, section *3. Initial submission of a sponsor information.*

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID; if the submission was successful, the EV code assigned to the sponsor organisation will be provided:

- <reportacknowledgment></reportacknowledgment>
<reportname>ORGANISATION</reportname>
<localnumber>1</localnumber>
<ev_code>ORG40544</ev_code>
<operationtype>1</operationtype>
<operationresult>2</operationresult>
<pre><operationresultdesc>Entity inserted successfully</operationresultdesc></pre>

See also <u>Extended EudraVigilance Medicinal Product Report Message step-by-step guide</u>: **Insert of an organisation** step-by-step document available on the <u>'Extended EudraVigilance medicinal product</u> <u>dictionary (XEVMPD) training' webpage</u> for more details.

4.2.7. Insert of a proposed or development ATC Code

To create an 'ATC Code Report', you must select 'ATC Codes' in the tree-view area or in the active area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Res et Application Res et Section Clear Validate Send XML	ZIP RTF E L R			
⊡-XEVPRM Message				
Products	Description	Name/Value		
Organisations	Message Number		Field is Mandatory	
ATC Codes		Products		
Pharmaceutical Forms		Organisations		
Routes Of Administration		ATC Codes		
Attachments		Pharmaceutical Forms		
Master File Locations		Routes Of Administration		
		Attachments		
		Master File Locations		

Tick the box next to 'New Development ATC Code':

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA		
Reset Application Reset Section Clear Validate Send XML ZIF	P RTF E L R 🗆		
E-XEVPRM Message			
Products	Num	Operation Type	Туре
Organisations	New Development ATC Code		Development
ATC Codes			
Pharmaceutical Forms			
-Routes Of Administration			
Attachments			
Master File Locations			

Once selected, the tree-view area and the active area will display the fields that need to be completed for the relevant section of the XEVPRM:

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA		
Reset Application Reset Section Clear Validate Send XML 2	IP RTF Duplicate Remove E L R		
E XEVPRM Message			
Products	Description	Name/Value	
Organisations	Operation Type	Insert	
ATC Codes	Туре	Development	
Insert - Development	ATC Code		Field is Mandatory
Pharmaceutical Forms	ATC Code Description		Field is Mandatory
Routes Of Administration	Version Date		
Attachments	Comment		
Master File Locations			

The 'Operation Type' field displays 'Insert' as default.

The 'Type' field displays 'Development' by default.

Complete the fields as required, as per information in the <u>Guidance on the electronic submission of</u> <u>information on investigational medicinal products for human use in the Extended EudraVigilance</u> <u>medicinal product dictionary (XEVMPD)</u> document, section *4.2. Insert of a development ATC Code*.

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID; if the submission was successful, the EV code assigned to the ATC Code will be provided:

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

4.2.8. Insert of a proposed or development pharmaceutical form

To create a 'Pharmaceutical Form Report', you must select 'Pharmaceutical Forms' in the tree-view area or in the active area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
□ Res et Application Reset Section Clear Validate Send XML ZIP RTF E L R			
⊡-XEVPRM Message			
Products	Description	Name/Value	
Organisations	Message Number		Field is Mandatory
ATC Codes		Products	
- Pharmaceutical Forms		Organisations	
Routes Of Administration		ATC Codes	
Attachments		Pharmaceutical Forms	
Master File Locations	Routes Of Administration		
	Attachments		
		Master File Locations	

Tick the box next to 'New Development Pharmaceutical Form':

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA		
Reset Application Reset Section Clear Validate Send XML Z	IP RTF E L R .		
E XEVPRM Message			
Products	Num	Operation Type	Туре
Organisations	New Development Pharmaceutical Form		Development
-ATC Codes			
-Pharmaceutical Forms			
-Routes Of Administration			
Attachments			
Master File Locations			

Once you selected the required type of pharmaceutical form, the tree-view area and the active area will display the fields that need to be completed for the relevant section of the XEVPRM:

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA		
Reset Application Reset Section Clear Validate Send XML ZIF	RTF Duplicate Remove E L R		
E-XEVPRM Message			
Products	Description	Name/Value	
Organisations	Operation Type	Insert	
ATC Codes	Туре	Development	
Pharmaceutical Forms	Pharmaceutical Form Name		Field is Mandatory
Insert - Development	Version Date		
-Routes Of Administration	Previous EV Code		
Attachments	Comment		
Master File Locations			

The 'Operation Type' field displays 'Insert' as default.

The 'Type' field displays 'Development' by default.

Complete the fields as required, as per information in the <u>Guidance on the electronic submission of</u> information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD) document, section *5.2. Insert of a development pharmaceutical form.*

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID; if the submission was successful, the EV code assigned to the pharmaceutical form will be provided:

- <reportacknowledgment></reportacknowledgment>
<reportname>PHARMACEUTICALFORM</reportname>
<localnumber>1</localnumber>
<ev_code>PHF3162</ev_code>
<operationtype>1</operationtype>
<operationresult>2</operationresult>
<operationresultdesc>Entity inserted successfully</operationresultdesc>

4.2.9. Insert of a proposed or development route of administration

To create a 'Route of Administration Report', you must select 'Routes of Administration' in the treeview area or in the active area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Res et Application Reset Section Clear Validate Send XML	Res et Application Res et Section Clear Validate Send XML ZIP RTF E L R			
⊡-XEVPRM Message				
Products	Description	Name/Value		
Organisations	Message Number		Field is Mandatory	
-ATC Codes	-	Products		
Pharmaceutical Forms		Organisations		
-Routes Of Administration		ATC Codes		
Attachments		Pharmaceutical Forms		
Master File Locations		Routes Of Administration		
		Attachments		
		Master File Locations		

Tick the box next to 'New Development Route of Administration':

WEB Trader Create and Send Product Reports Medicinal Products			
Res et Application Res et Section Clear Validate Send XML			
□·XEVPRM Message			
Products	Num	Operation Type	Туре
- Organisations	New Development Route of Administration		Development
-ATC Codes			
Pharmaceutical Forms			
-Routes Of Administration			
Attachments			
Master File Locations			

Once selected, the tree-view area and the active area will display the fields that need to be completed for the relevant section of the XEVPRM:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Res et Application Res et Section Clear Validate Send XML	ZIP RTF Duplicate Remove E L R		
Products	Description	Name/Value	
Organisations	Operation Type	Insert	
- ATC Codes	Туре	Development	
Pharmaceutical Forms	Administration Route Name		Field is Mandatory
Routes Of Administration	Version Date		
Insert - Development	Previous EV Code		
Attachments	Comment		
Master File Locations			

The 'Operation Type' field displays 'Insert' as default.

The 'Type' field displays 'Development' by default.

Complete the fields as required, as per information the <u>Guidance on the electronic submission of</u> information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD) document, section *6.2.* Insert of a development route of administration.

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID; if the submission was successful, the EV code assigned to the route of administration will be provided:



4.2.10. Insert of an attachment

Printed Product Information (**PPI**) is an attachment to be referenced in a produt entity.

Printed Substance Information (**PSI**) is an attachment to be referenced in a substance entity; the submission of PSI is currently not in use.

To create a PPI Attachment Report, you must select 'New PPI Attachment' in the active area:

To insert an attachment in the XEVMPD, you must follow the below described steps:

- 1. Provide the information of the file to be attached in the 'Attachments' section of the XEVPRM;
- 2. Reference the attachment information in the relevant product or substance entity;
- 3. Attach the file at the time of submission of the XEVPRM.

4.2.10.1. Create an Attachment Report

To create an 'Attachment Report', you must select 'Attachments' in the tree-view area or in the active area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear Validate	Send XML ZIP RTF E L R		
■ XEVPRM Message			
Products	Description	Name/Value	
Substances	Message Number		Field is Mandatory
Sources		Products	
Organisations		Substances	
ATC Codes		Sources	
Pharmaceutical Forms		Organisations	
Routes Of Administration		ATC Codes	
Attachments		Pharmaceutical Forms	
Master File Locations		Routes Of Administration	
		Attachments	
		Master File Locations	

You must select 'New PPI Attachment' in the active area:

WEB Trader Create and Send Product Reports Medicinal Products Med	IDRA		
Reset Application Reset Section Clear Validate Send XML ZIP F	RTF E L R 🗆		
E-XEVPRM Message			
Products	Num	Operation Type	Туре
Substances	New PPI Attachment		1
Sources	New PSI Attachment		2
Organisations			
ATC Codes			
-Pharmaceutical Forms			
-Routes Of Administration			
-Attachments			
Master File Locations			

Once you selected the required type of attachment, the tree-view area and the active area will display the fields that need to be completed for the relevant section of the XEVPRM.

For a PPI:

• the 'Type' displays 'PPI' by default;

WE B Trader Create and Send Product Reports Medicinal Produc	ts MedDRA		
Reset Application Reset Section Clear Validate Send XM	L ZIP RTF Duplicate Remove E L R		
E XEVPRM Message			
Products	Description	Name/Value	
Substances	File Type	PDF	
Sources	Name		Field is Mandatory
Organisations	Туре	PPI	
ATC Codes	Language		Field is Mandatory
Pharmaceutical Forms	2nd Language		Fight in Manufactures
-Routes Of Administration	Version Number		Field is Mandatory
⊢ Attachments	Version Date		Field is Mandatory
Insert			
Master File Locations			

• the 'File Type' displays 'PDF' by default; you can change this predefined value by double-clicking on the text in blue, or by using 'Enter' on your keyboard, to view the list of all values available for this field:

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

The list of all values available for this field will be displayed:

Descr	iption	Name/Value	
File Lan		Select option	Field is Mandatory Field is Mandatory Field is Mandatory
Version Ni Versior	DOC	ss Enter to select, Escape to clear	Field is Mandatory Field is Mandatory
	росх		-
	PDF		
	XLS		
	XLSX		

You can select the required value by clicking on the required format:

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

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

With regards to 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 EMA/MAHs will have the assurance that we will be able to open them for many years.

Once you selected the required format of your PPI, complete the fields as required and as per information in the applicable guidance document:

- MAH: <u>Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance;</u> section 1.10. Submission of an attachment, or
- Sponsor: <u>Guidance on the electronic submission of information on investigational medicinal products for human use in the eXtended EudraVigilance Medicinal Product Dictionary</u> (XEVMPD): eXtended EudraVigilance Medicinal Product Report (XEVPRM) user guidance document, section *7. Initial submission of an attachment.*

4.2.10.2. Reference an attachment in a product entity

Once you enter all the required information for your attachment in the 'Attachment' section of your XEVPRM, you must reference the attachment in the product entity, for which the attachment is to be used as a supporting document.



To do so, go to the 'Attachment' section of your AMP and click on 'Product Attachments' in the treeview area; 'New Product Attachment' will become available in the active area:

	1 of the OK, as noni 1.1.2021,
WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R	
E-XEVPRM Message	
- Products	Num Product Attachment
Insert - Authorised - 1 - Paracetamol 500 mg Film Coated Tablets	New Product Attachment
Medicinal Product Types (1)	
Authorised Pharmaceutical Forms (1)	
Pharmaceutical Products (1)	
Drug ATCs (1)	
Drug Indications (14)	
-Previous EV Codes (-)	
Product Attachments (-)	
Substances	
Sources	
Organisations	
ATC Codes	
-Pharmaceutical Forms	
-Routes Of Administration	
Attachments	
Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets	
Master File Locations	

Tick the box next to 'New Product Attachment':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R	□ Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R □			
E XEVPRM Message				
⊢ Products	Num			
E Insert - Authorised - 1 - Paracetamol 500 mg Film Coated Tablets	New Product Attachment			
Medicinal Product Types (1)				
Authorised Pharmaceutical Forms (1)				
Pharmaceutical Products (1)				
Drug ATCs (1)				
Drug Indications (14)				
Previous EV Codes (-)				
Product Attachments (-)				
Substances				
Sources				
⊕ Organisations				
ATC Codes				
Pharmaceutical Forms				
-Routes Of Administration				
– Attachments				
Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets				
An Master File Locations				

The active area will display the information that needs to be provided for the attachment that you wish to reference in your AMP. Since you are referencing a new attachment, which was not yet submitted in the XEVMPD and no attachment EV code is therefore available for the attachment, you must select the attachment from the local look-up table (L).

Click on the button (Local data look-up) in the dynamic buttons section:

	For the OK, as from 1.1.2021, EO Law app
WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate Remove E	R
E- XEVPRM Message	
Products	Description Name/Value
Insert - Authorised - 1 - Paracetamol 500 mg Film Coated Tablets	Product Attachment Field is Mandato
Medicinal Product Types (1)	Validity declaration
Authorised Pharmaceutical Forms (1)	
Pharmaceutical Products (1)	
Drug ATCs (1)	
Previous EV Codes (-)	
Product Attachments (1)	
Product Attachment	
Substances	
Sources	
Organisations	
- ATC Codes	
Pharmaceutical Forms	
-Routes Of Administration	
Attachments	
Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets	
Master File Locations	

The available options will be displayed in the local look-up list of the 'Product Attachment field':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate Remove E	
E XEVPRM Message	
- Products	Description Name/Value
Insert - Authorised - 1 - Paracetamol 500 mg Film Coated Tablets	Product Attaci
Medicinal Product Types (1)	Validity decla Select option
Authorised Pharmaceutical Forms (1)	Brans A - 7 to find initial latter
Pharmaceutical Products (1)	Press Enter to select, Escape to clear
Drug ATCs (1)	Incert English SBC Parasetamal 500 mg Silm Coated Tableta
Drug Indications (14)	Insert - English - SPC_Paracetaniol Soo ing Thin Coated Tablets
Previous EV Codes (-)	
Product Attachments (1)	
Product Attachment	
Substances	
Sources	
Grganisations	
-AIC Codes	
-Pharmaceutical Forms	
-Routes Of Administration	
Attachments	
Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets	
Master File Locations	

Using your mouse, select the required attachment:

Descr	iption Name/Value	
Product Attacl Validity decla	Select option	
	Press A - Z to find initial letter Press Enter to select, Escape to clear	
	Insert - English - SPC_Paracetamol 500 mg Film Coated 1	Tablets

The attachment name will be displayed in the 'Product Attachment' field. The area next to 'Validity declaration' will be highlighted in blue:

Description	Name/Value
Product Attachment Validity declaration	Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets

When you double-click on the area or use 'Enter' on your keyboard, you will be able to view the value applicable for this field:

Descr	iption Name/Value
Product Attach	ment Insert - English - SPC_Paracet
Validity decla	Select option
	Press A - Z to find initial letter Press Enter to select, Escape to clear
	Valid

Using your mouse or 'Enter' on your keyboard, select 'Valid':

Descr	iption Name/Value	
Product Attachment Insert - English - SPC_Paracet.		
Validity decla	Select option	
	Press A - Z to find initial letter Press Enter to select, Escape to clear	
	Valid	

The value will be displayed in the 'Validity declaration' field:

Description	Name/Value
Product Attachment	Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets
Validity declaration	Valid

The validity declaration is only mandatory in case of maintenance operations, not for initial submissions of an attachment.

Validate your XEVPRM before proceeding with sending the attachment file and the XEVPRM:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate Remove E L	R
E-XEVPRM Message	
Products	Description Name/Value
Insert - Authorised - 1 - Paracetamol 500 mg Film Coated Tablets	Product Attachment Insert - English - SPC_Paracet
Medicinal Product Types (1)	Validity declaration Valid
Authorised Pharmaceutical Forms (1)	
Pharmaceutical Products (1)	
Drug ATCs (1)	
Drug Indications (14)	
-Previous EV Codes (-)	
Product Attachments (2)	
Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets	
Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets	
Substances	
Sources	
AIC Codes	
Pharmaceutical Forms	
Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets	
Master File Locations	

New pop-up window will inform you of the validation status. If there are no errors in your XEVPRM, the below message will be displayed:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate Remove E	L R
E-XEVPRM Message	
Products	Description Name/Value
Insert - Authorised - 1 - Paracetamol 500 mg Film Coated Tablets	Product Attachment Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets
Medicinal Product Types (1)	Validity declaration Valid
Authorised Pharmaceutical Forms (1)	
Pharmaceutical Products (1)	
Drug ATCS (1) Drug Indiactions (14)	
Erovious EV Codes ()	
Product Attachments (1)	Message from webpage X
Insert - English - SPC Paracetamol 500 mg Film Coated Tablets	
Substances	
Sources	
Organisations	
-ATC Codes	
Pharmaceutical Forms	ОК
Routes Of Administration	
Attachments	
Master File Leastions	
H-Master File Locations	

You can dismiss the message by clicking on 'OK' or 'x' in the right-hand corner of the window:



4.2.10.3. Submission of a file attachment at the time of XEVPRM submission

To send the XEVPRM, click on the 'Send' button:

WEB Trader Create and Send Product Reports Medicinal Products Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate Remove E L R Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate Remove E L R Products Products Medicinal Product Types (1) Authorised Pharmaceutical Pharmaceutical Products (1 Browse (2) Previous EV Codes (-) Product Attachments (1) Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets (PDF) Upload File Upload File Upload File Organisations ATC Codes Pharmaceutical Forms Route Of Administration Route Of Administr		Torme	ok, as nom 1.1.2021, LO Law applies only to the ter
Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate Remove E L R EXEVPRM Message Products Medicinal Product Types (1) Authorised Pharmaceutical Pharmaceutical Products (1) Provide Attachments (1) Product Attachments (2) Product Attachm	WEB Trader Create and Send Product Reports	s Medicinal Products MedDRA	
EXEVPRM Message Products Image: Authorised - 1 - Parace Medicinal Product Types (1) Authorised Pharmaceutical Pharmaceutical Products (1) Providuct Attachments (1) Previous EV Codes (-) Product Attachments (1) Insert - English - SPC_Pe Upload File Browse	Reset Application Reset Section Clear	Validate Send XML ZIP RTF Duplicate Remove E L R	
Products Insert - Authorised - 1 - Paracet Medicinal Product Types (1) Authorised Pharmaceutical Authorised Pharmaceutical Pharmaceutical Products (1) Previous EV Codes (-) Product Attachments (1) Insert - English - SPC_Pe Substances Sources Sources Pramaceutical Forms Routes Of Administration	E-XEVPRM Message		
 Insert - Authorised - 1 - Parace Insert - Authorised - 1 - Parace Medicinal Product Types (1) Authorised Pharmaceutical Products (1) Pharmaceutical Products (1) Drug ArTCs (1) Drug Indications (14) Previous EV Codes (-) Product Attachments (1) Insert - English - SPC_Paracetamol 500 mg Film Coated Browse 	Products		
Medicinal Product Types (1) Medicinal Product Types (1) Medicinal Product Types (1) Medicinal Product Types (1) Medicinal Product Attachment Size Allowed for one Attachment is 25 MegaBytes ::. Drug ATCs (1) Drug Indications (14) Previous EV Codes (-) Product Attachments (1) Insert - English - SPC_Pe Substances Morganisations ATC Codes Pharmaceutical Forms Routes Of Administration	Insert - Authorised - 1 - Parace	e nttps://evtest.ema.europa.eu//FA=1&NF=1 - Select File - Internet Explorer — Ц X	Paracetamol 500 mg Film Coated Tablets
Authorised Pharmaceutical f Authorised Pharmaceutical f Pharmaceutical Products (1 Drug ATCs (1) Previous EV Codes (-) Product Attachments (1) Insert - English - SPC_Pe Substances Organisations ATC Codes Pharmaceutical Forms Routes Of Administration	Medicinal Product Types (1)	🗴 宛 Convert 🔻 🗟 Select	
Pharmaceutical Products (1 Provide TCS (1) Provide TCS (1) Previous EV Codes (-) Provide T - English - SPC_Pe Substance Sources Organisations -ATC Codes -Pharmaceutical Forms -Routes Of Administration	Authorised Pharmaceutical F		
Brug ATCs (1) Drug Indications (14) Previous EV Codes (-) Product Attachments (1) Insert - English - SPC_Pa Substances Solutions ArtC Codes Pharmaceutical Forms Routes Of Administration	Pharmaceutical Products (1)	.:: The Maximum Size allowed for one Attachment is 25 MegaBytes ::.	
Drug Indications (14) Previous EV Codes (-) Product Attachments (1) Insert - English - SPC_Pe Substancee Organisations ATC Codes Pharmaceutical Forms Routes Of Administration	Drug ATCs (1)	E L'I CRO D (1500 E'I C) I	
Provous EV Codes (-) Provous EV Codes (-) Provous EV Codes (-) Upload File Upload File Upload File Organisations ATC Codes Pharmaceutical Forms Routes Of Administration	Drug Indications (14)	English - SPC_Paracetamol 500 mg Film Coated Browse	
Product Attachments (1) Insert - English - SPC_Pa Substances Sources Organisations - ATC Codes - Pharmaceutical Forms - Routes Of Administration	Previous EV Codes (-)		
Insert English - SPC_Pe Substances Sources Organisations ATC Codes Pharmaceutical Forms Routes Of Administration	⊟ Product Attachments (1)	Linlood File	
Studsances Sources ⊕ Organisations – ATC Codes – Pharmaceutical Forms – Routes Of Administration	Insert - English - SPC_Pa	Opidad File	
Gorganisations ATC Codes —Pharmaceutical Forms —Routes Of Administration	Substances		
Organisations Art Codes Pharmaceutical Forms Routes Of Administration	Sources		
- Pharmaceutical Forms Routes Of Administration			
- Routes of Administration	Dharmanautical Forma		
	Poutes Of Administration		
Attachments	Attachments		
Linsert - English - SPC Paranet	Insert - English - SPC Paracet		
	Master File Locations		
\sim			
		<	

• The 'Send' button will only be available for users from organisations registered for product reporting via Web Trader. Whilst users from organisations registered for product submissions via Gateway can create XEVPRMs using EVWEB, the 'Send' button will not be available to them. Gateway organisation users can submit XEVPRMs as 'ZIP' files using EV Post. See section *4.9. Use EV Post* of this document for further information.

Once you click on the 'Send' button a new window will open, allowing you to browse your computer and select the file that you wish to submit in the XEVMPD. Once you make the selection, click on 'Upload File':

Attps://evtest.ema.europa.eu/?FA=1&NF=1 - Select File - Internet Explorer —			\times
× 党Convert ▼ 🗟 Select			
.:: The Maximum Size allowe	d for one Attachment is 25 MegaBytes ::.		^
English - SPC_Paracetamol 500 mg Film Coated Tablets (.PDF)	L:\SPC_Paracetamol 500 mg Film Coated	Browse	
	Upload File		

If the attachment was successfully posted, a new window will open confirming the result of your action:



Click 'OK' to dismiss the message; another pop-up window will open informing you that your XEVPRM was sent successfully:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Image: Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate Remove E	LR
E-XEVPRM Message	
Products	Description Name/Value
Insert - Authorised - 1 - Paracetamol 500 mg Film Coated Tablets	Product Attachment Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets
	Validity declaration Valid
Authorised Pharmaceutical Forms (1)	
Pharmaceutical Products (1)	
Drug ATCs (1)	
Drug Indications (14)	
Previous EV Codes (-)	Message from webpage X
Product Attachments (1)	
Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets	Marrana Sant Summafully
Substances	Viessage sent successiony
Sources	If You want to View the File(s) Sent Click [OK]
Organisations	
-ATC Codes	
Pharmaceutical Forms	
Routes Of Administration	OK Cancel
Attachments	
Insert - English - SPC_Paracetamol 500 mg Film Coated Tablets	
⊞ Master File Locations	

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) user manual EMA/308954/2012

An XEVPRM acknowledgement will be sent to the sender organisation ID, and if the submission was successful, it will include the EV Codes assigned to the attachment, as well as to the product entity:



4.2.11. Insert of a Master File Location

To create a 'Master File Location Report', you must select 'Master File Locations' in the tree-view area or in the active area:

WEB Trader Create and Send Product Reports Me	dicinal Products MedDRA		
Reset Application Reset Section Clear Validate	Send XML ZIP RTF E L R		
B XEVPRM Message			
Products	Description	Name/Value	
Substances	Message Number		Field is Mandatory
Sources		Products	
Organisations		Substances	
-ATC Codes		Sources	
Pharmaceutical Forms		Organisations	
Routes Of Administration		ATC Codes	
Attachments		Pharmaceutical Forms	
Mastor File Locations		Routes Of Administration	
		Attachments	
		Master File Locations	

You must select 'New Master File Location' in the active area by ticking the relevant box:

WEB Trader Create and Send Product Reports Mee	dicinal Products MedDRA	
Reset Application Reset Section Clear Validate	Send XML ZIP RTF E L R	
E XEVPRM Message		
Products	Num	Operation Type
Substances	New Master File Location	
Sources		
Organisations		
-ATC Codes		
Pharmaceutical Forms		
Routes Of Administration		
Attachments		
Master File Locations		

Once you have selected 'New Master File Location', the tree-view area and the active area will display the fields that need to be completed for the relevant section of the XEVPRM:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate Remove E L R		
E-XEVPRM Message		
Products	Description Name/Value	
Substances	Operation Type Insert	
Sources	Company	
Organisations	Department	
ATC Codes	Building	
Pharmaceutical Forms	Street	Field is Mandatory
Routes Of Administration	City	Field is Mandatory
Attachments	Region	
Master File Locations	Post Code	Field is Mandatory
	Country	Field is Mandatory
Insert	Comment	

The 'Operation Type' field displays 'Insert' as default.

Information to be provided as mandatory is highlighted as 'Field is Mandatory'.

Complete the fields as required.

For the complete list of data fields collected for a Master File Location entity in the XEVMPD and the applicable business rules please refer to <u>Chapter 3.II</u>: <u>Extended EudraVigilance product report</u> <u>message (XEVPRM) user guidance</u>; section *1.11*. *Initial submission of a Pharmacovigilance System Master File (PSMF) information*.

Validate and send the XEVPRM.

The XEVPRM acknowledgement will be sent to the sender organisation ID; if the submission was successful, the EV code assigned to the MFL will be provided:

- <reportacknowledgment></reportacknowledgment>
<reportname>MFL</reportname>
<localnumber>2</localnumber>
<ev_code>MFL17273</ev_code>
<operationtype>1</operationtype>
<operationresult>2</operationresult>
<pre><operationresultdesc>Entity inserted successfully</operationresultdesc></pre>

See also <u>Extended EudraVigilance Medicinal Product Report Message step-by-step guide</u>: **Insert of a pharmacovigilance master file location entity** step-by-step document available on the <u>'Training'</u> <u>webpage</u> for more details.

4.3. Duplicate an entity in an XEVPRM

To accelerate the data entry process during the creation of an XEVPRM in EVWEB, it is possible to duplicate any entity present in you XEVPRM and modify it as appropriate.

Once you have created an entity (e.g., a product, a source, an organisation, an ATC code, route of administration, pharmaceutical form etc.) with operation type 'Insert' in your XEVPRM, and you **select the item in the tree-view area**, the main menu will display the 'Duplicate' button:

4.3.1. Duplication of a product entity information in an XEVPRM

To duplicate a product entity in an XEVPRM, select the product entity in the tree-view area:



Click on the 'Duplicate' button:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate	Remove E L R	
E-XEVPRM Message		
Products	Description	Name/Value
Insert - Development - ProductY 20ml solution for injection	Туре	Development
Pharmaceutical Products (1)	Operation Type	Insert
Drug ATCs (-)	Sender Local Code	
⊕ Drug Indications (1)	Sponsor	SPONSOR ABC LTD
Product Attachments (-)	Product Code	PRX-100
Substances	Product Name	ProductY 20ml solution for inje
Sources	Product Other Name	
Organisations	Comment	
ATC Codes		Pharmaceutical Products (1)
Dharmanautical Forms		Drug ATCs (-)
Pharmaceulical Forms		Drug Indications (1)
-Routes Of Administration		Product Attachments (-)
Attachments		
Master File Locations		

EVWEB automatically adds a copy of the previously entered item in the tree-view area; a new entity is displayed with the operation type assigned as 'Insert':



4.3.2. Duplication of a pharmaceutical product information of a product entity in an XEVPRM

To duplicate pharmaceutical product information of a product entity in an XEVPRM, select the pharmaceutical product information in the tree-view area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate	Re
E-XEVPRM Message	
⊨ Products	
Insert - Development - ProductY 20ml solution for injection	A
⊨ Pharmaceutical Products (1)	
E SOLUTION FOR INJECTION	
Drug ATCs (-)	
Drug Indications (1)	
Product Attachments (-)	
Substances	
Sources	
Organisations	
ATC Codes	
-Pharmaceutical Forms	
-Routes Of Administration	
Attachments	
Master File Locations	

Click on the 'Duplicate' button:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Validate Send XML ZIP RTF Duplicate	Remove E L R
E-XEVPRM Message	
Products	Description Name/Value
Insert - Development - ProductY 20ml solution for injection	Administrable Pharmaceutical SOLUTION FOR INJECTION
Pharmaceutical Products (1)	Drug Routes (2)
BOLUTION FOR INJECTION	Drug Ingredients (1)
Drug ATCs (-)	Old Drug Ingredients (-)
Drug Indications (1)	Medical Devices (-)
Product Attachments (-)	
Substances	
Sources	
Organisations	
ATC Codes	
Pharmaceutical Forms	
-Routes Of Administration	
Attachments	
Master File Locations	

EVWEB automatically adds a copy of the previously entered item in the tree-view area; a new entity is displayed with the operation type assigned as 'Insert':

XEVPRM Message					
⊨ Products					
Insert - Development - ProductY 20ml solution for injection					
Pharmaceutical Products (2)					
SOLUTION FOR INJECTION					
E SOLUTION FOR INJECTION					
Drug Routes (2)					
Drug Ingredients (1)					
Old Drug Ingredients (-)					
Medical Devices (-)					
Drug ATCs (-)					
Drug Indications (1)					
Product Attachments (-)					
Substances					
Sources					
Organisations					
-ATC Codes					
Pharmaceutical Forms					
-Routes Of Administration					
Attachments					
Master File Locations					

You can expand the items and modify the information of each of the items as required:



4.4. Remove an entity from an XEVPRM

To remove one or more items from your XEVPRM, you need to mark the item to be removed by unmarking the item in the list displayed in the active area.

As an example, we wish to remove one of the DMP entities currently present in our XEVPRM:

W	EB Trader	Create	and Send Produ	uct Repo	rts Med	licinal P	roducts	М	edDRA		
Reset Application Reset Section Clear Validate Send XML ZIP RTF						RTF	E	LR			
	XEVPRM M	lessa	ge								
	Products										
	🖻 Insert	- Dev	/elopment - P	roduct	Y 20ml so	olution	for inj	ectio	n		
	🕀 Pha	arma	ceutical Produ	ucts (2))						
	Dri	ug AT	Cs (-)								
	🕀 Dri	ug Ind	lications (1)								
	Pro	oduct	Attachments	(-)					_		
	🖻 Insert	- De	/elopment - P	roduct	Y 20ml so	olution	for inj	ectio	n		
	🕀 Pha	arma	ceutical Produ	ucts (2))						
	Dri	ug AT	Cs (-)								
	🗄 Dri	ug Ind	lications (1)								
	- Pro	oduct	Attachments	(-)							
	Substance	ces									
	Sources	`									
	Organisations										
	ATC Codes										
	Pharmaceutical Forms										
	Routes Of Administration										
	Attachme	ents									
	Master F	ile Lo	cations								

To do so, we must click on the 'Product' section in the tree-view area:



By doing so, the active area will display the list of entities present in our XEVPRM:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA					
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R					
XEVPRM Message					
Products	Num	Operation Type	Type	Authorisation Status	Product Name
Insert - Development - ProductY 20ml solution for injection	✓ 0001	Insert	Development		ProductY 20ml solution for injection
Pharmaceutical Products (2)	0002	Insert	Development		ProductY 20ml solution for injection
Drug ATCs (-)	New Authorised Product				
Drug Indications (1)	New Development Product				
Product Attachments (-)					
Insert - Development - ProductY 20ml solution for injection					
Pharmaceutical Products (2)					
Drug ATCs (-)					
Drug Indications (1)					
Product Attachments (-)					
Substances					
Sources					
Organisations					
ATC Codes					
Pharmaceutical Forms					
Routes Of Administration					
Attachments					
Master File Locations					

If you unmark one of the items displayed in the list, a negative (-) sign will be displayed in both, the tree-view area 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:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R			
E-XEVPRM Message			
Products	Num	Operation Type	Туре
Insert - Development - ProductY 20ml solution for injection	0001	Insert	Development
Pharmaceutical Products (2)	0002 (-)	Insert	Development
Drug ATCs (-)	New Authorised Product		
	New Development Product		
Product Attachments (-)			
[-] Insert - Development - ProductY 20ml solution for injection			
Pharmaceutical Products (2)			
Drug ATCs (-)			
Drug Indications (1)			
Product Attachments (-)			
Substances			
Sources			
Organisations			
ATC Codes			
Pharmaceutical Forms			
Routes Of Administration			
Attachments			
Master File Locations			

Once you unmark the item you wish to remove from your XEPRM, click on 'CLEAR' in the main menu:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			1 01 110
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R			
E-XEVPRM Message			
Products	Num	Operation Type	Туре
Insert - Development - ProductY 20ml solution for injection	0001	Insert	Development
Pharmaceutical Products (2)	0002 (-)	Insert	Development
Drug ATCs (-)	New Authorised Product		
Drug Indications (1)	New Development Product		
Product Attachments (-)			
(-) Insert - Development - ProductY 20ml solution for injection			
Pharmaceutical Products (2)			
Drug ATCs (-)			
Drug Indications (1)			
Product Attachments (-)			
Substances			
Sources			
Organisations			
ATC Codes			
-Pharmaceutical Forms			
Routes Of Administration			
Attachments			
Master File Locations			

The below message will be displayed:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R	
E-XEVPRM Message	
Products	Num Operation Type Type Autho
Insert - Development - ProductY 20ml solution for injection	☑ 0001 Insert Development
Pharmaceutical Products (2)	0002 (-) Insert Development
-Drug ATCs (-)	New Authorised Product
⊡ Drug Indications (1)	New Development Product
Product Attachments (-)	
(-) Insert - Development - ProductY 20ml solution for injection	
Pharmaceutical Products (2)	Message from webpage X
-Drug ATCs (-)	
Drug Indications (1)	
Product Attachments (-)	? You will remove all the Elements marked as Deleted (-).
Substances	Are You sure ?
Sources	
Organisations	
-ATC Codes	
-Pharmaceutical Forms	OK Cancel
-Routes Of Administration	
-Attachments	
Master File Locations	

By clicking on 'OK', you will confirm that you wish to remove the de-selected item(s); the item will be removed from the tree-view area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Image: Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R			
E-XEVPRM Message			
- Products	Num	Operation Type	Туре
Insert - Development - ProductY 20ml solution for injection	✓ 0001	Insert	Development
Pharmaceutical Products (2)	New Authorised Product		
Drug ATCs (-)	New Development Product		
Drug Indications (1)			
Product Attachments (-)			
Substances			
Sources			
Organisations			
-ATC Codes			
-Pharmaceutical Forms			
-Routes Of Administration			
Attachments			
Master File Locations			
	1		

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) user manual EMA/308954/2012

The same process described above can be used remove other entities from your XEVPRM (pharmaceutical products, organisations, attachments referenced in product entries etc.).

4.5. Reference information not yet present in the XEVMPD in a product entity in an XEVPRM

To reference an entity not yet present in the XEVMPD (i.e., an EV Code is not assigned to the entity and the entity is not available in the remote look-up table), you must add the entity in the relevant section of the XEVPRM.

Once this entity is added, you can retrieve it from the Local ('L') look-up table:

W	EB Trader	Create and Send Product Reports			Medicinal Products			М	edDRA				
	Reset App	lication	Reset Section	Clear	Val	idate	Send	XML	ZIP	RTF	Е	L	R

See section 3.5.1.5. Local database look-up tables of this document for related information.

As an example, we wish to reference in an AMP entity, which is a subject to an insert, a new Master File location entity, which is not yet present in the XEVMPD.

First, we must enter the master file location information in the 'Master File Location' section of the XEVPRM:



When done, go to your AMP entity, click in the area next to the field 'Master file location' (so it becomes highlighted in blue) and then on the button \Box (Local data look-up):

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear Replicate Validate Send XML ZIP RTF Duplicate F	Remove E L R	
E-XEVPRM Message		
Products	Description	Name/Value
Insert - Authorised - Paracetamol 500 mg Film Coated Tablets	Туре	Authorised
Medicinal Product Types (1)	Operation Type	Insert
Authorised Pharmaceutical Forms (1)	MAH	XYZ PHARMA LTD
	QPPV	User HB03044 Num 01 (OTORGHB03044)
Drug ATCs (1)	Master File Location	
Drug Indications (14)	PhV enquiry email	pharmacovigilance@xyzpharma.ie
Previous EV Codes (-)	PhV enquiry Phone	+353 1234 5678
Product Attachments (1)	Sender Local Code	
Substances	Authorisation Country Code	Iroland
Sources	Authorisation Procedure	ELL authorisation procedures - National Procedure
Organisations	Authorisation Status	Valid
ATC Codes	Authorisation Number	PA1234/567/001
Pharmaceutical Forms	Authorisation/Renewal Date	30/10/2020
Routes Of Administration	MRP/DCP/EMEA Number	
Attachments	EU Number	
Additional Additions	Legal Basis	Well-established use application (Article 10a of Directive No 2001/83/EC)
Insert - Germany - Bonn	Orphan Drug	No
insolt comany boint	Additional Monitoring	No
WEB Trader Create and Send Product Reports Medicinal Products MedDRA		

WED Tader Create and Send Floduci Reports Medicinal Floducis Medicinal Floducis							
Reset Application Reset Section Clear Replicate Validate Send XML ZIP RTF Duplicate Remove E L R							
E-XEVPRM Message							
- Products	Description	Name/Value					
Insert - Authorised - Paracetamol 500 mg Film Coated Tablets	Туре	Authorised					
Medicinal Product Types (1)	Operation Type	Insert					
Authorised Pharmaceutical Forms (1)	MAH	XYZ PHARMA LTD					
Pharmaceutical Products (1)	QPPV	User HB03O44 Num 01 (OTORGHB03O44)					
T Drug ATCs (1)	Master File Location						
Drug Indications (14)	PhV enquiry email	pharmacovigilance@xyzpharma.ie					
Draginateations (11)	PhV enquiry Phone	+353 1234 5678					
Dreduet Attentmente (1)	Sender Local Code						
	Info Date						

From the pop-up menu, select MFL location and click on the entity or press 'Enter' on your keyboard:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Replicate Validate Send XML ZIP RTF Duplicate F	Remove E L R
E-XEVPRM Message	
Products	Description Name/Value
Insert - Authorised - Paracetamol 500 mg Film Coated Tablets	Type Authorised
Medicinal Product Types (1)	Operation Type Insert
Authorised Pharmaceutical Forms (1)	MAH XYZ PHARMA LTD
Pharmaceutical Products (1)	OTORGHB03044)
Drug ATCs (1)	Master File Li Select option
Drug Indications (14)	PhV enquir Press A - Z to find initial letter
Previous EV Codes (-)	PNV ENQUITY Press Enter to select, Escape to clear
	Sender Loca In Insert - Germany - Bonn
Substances	Authorisation Country Code Ireland
Sources	Authorisation Procedure EU authorisation procedures - National Procedure
Organisations	Authorisation Status Valid
ATC Codes	Authorisation Number PA1234/567/001
Pharmaceutical Forms	Authorisation/Renewal Date 30/10/2020
Routes Of Administration	MRP/DCP/EMEA Number
Attachments	EU Number
Aaster File Locations	Legal Basis Well-established use application (Article 10a of Directive
Insert - Germany - Bonn	Orphan Drug No

The MFL entity will then be referenced in your AMP entity:
WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear Replicate Validate Send XML ZIP RTF Duplicate I	Remove E L R	
E XEVPRM Message		
Products	Description	Name/Value
Insert - Authorised - Paracetamol 500 mg Film Coated Tablets	Туре	Authorised
Medicinal Product Types (1)	Operation Type	Insert
Authorised Pharmaceutical Forms (1)	MAH	XYZ PHARMA LTD
Pharmaceutical Products (1)	QPPV	User HB03O44 Num 01 (OTORGHB03O44)
Drug ATCs (1)	Master File Location	Insert - Germany - Bonn
Drug Indications (14)	PhV enquiry email	pharmacovigilance@xyzpharma.ie
Previous EV Codes (-)	PhV enquiry Phone	+353 1234 5678
Product Attachments (1)	Sender Local Code	
Substances	Into Date	laster d
Sources	Authorisation Broadura	ELL authorization procedures – National Procedure
Organisations	Authorisation Status	Valid
ATC Codes	Authorisation Number	PA1234/567/001
Pharmaceutical Forms	Authorisation/Renewal Date	30/10/2020
Poutos Of Administration	MRP/DCP/EMEA Number	
Attachmonts	EU Number	
Master File Leastions	Legal Basis	Well-established use application (Article 10a of Directive No 2001/83/EC)
- Master File Locations	Orphan Drug	No
misert - Germany - Bonn	Additional Monitoring	No
	Invalidated Date	
	Full Presentation Name	Paracetamol 500 mg Film Coated Tablets
	Product Short Name	

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

4.6. Create an XEVPRM with maintenance related operation types/commands

4.6.1. Update of entities in the XEVMPD

The information concerning medicinal products (authorised 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 and/or the HQ organisation under which the sender organisation is registered in EV) and the EMA.

XEVMPD will check the ownership of the information before allowing any modification to the information in the XEVMPD.

Information of substance entities can only be modified by the EMA.

Operation type 'Update (2)' shall be used cover several scenarios related to the maintenance of data submitted in the XEVMPD, for example:

- To amend in an XEVMPD entity (e.g., medicinal products, organisations, MFLs, pharmaceutical forms; routes of administration, ATC Codes, sources etc.) information submitted incorrectly or by mistake (e.g., spelling mistake, incorrect information).
- 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 QPPV, MAH organisation, SmPC, MFL etc.

4.6.1.1. 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;
- must not be an invalidated entity.

Retrieve the entity you need to update in the XEVMPD either using a simple or an advanced query and select the entity so that it is displayed in your tree-view area:



WEB Trader Create and Send Product Reports Medicinal Products MedDRA				1 61 810 614 80 8011 1.1.2621, 20 281 8
Reset Application Reset Section Clear O D E				
Authorised Medicinal Products	Paracetamol 500*			
Authorised - PRD126060 - 1/1 - Paracetamol 500 mg Film Coated Tablets	Num	EV Code	Version	Full Presentation Name
Development Medicinal Products	✓ 0001	PRD126060	1/1	Paracetamol 500 mg Film Coated Tablets
-Approved Substances				
Development Substances				
Sources				
MAHs				
Sponsors				
ATC Codes				
Routes of Administration				
Pharmaceutical Forms				
Master File Locations				
Attachments				
-Abstract Compositions				
🕀 Queries				
<u> </u>				

Click on the EV Code or name of the medicinal product entry in the tree-view area so the product information is visible in the active area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				For the UK, as from 1.1.2021, EU Law app
Reset Application Reset Section Clear	_			
Authorised Medicinal Products	Paracetamol 500*			
Authorised - PRD126060 - 1/1 - Paracetamol 500 mg Film Coated Tablets	Num	EV Code	Version	Full Presentation Name
- Development Medicinal Products	✓ 0001	PRD126060	1/1	Paracetamol 500 mg Film Coated Tablets
Approved Substances				
Development Substances				
Sources				
MAUG				

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear XML RTF Update Other Operations		
Authorised Medicinal Products	Paracetamol 500*	
+ Authorised - PRD126060 - 1/1 - Paracetamol 500 mg Film Coated Tablets	Description	Name/Value
Development Medicinal Products	EV Code	PRD126060
Approved Substances	Version	1/1
Development Substances	Туре	Authorised
Sources	Version Status	Accepted
MAHs	Version Validity	Unassessed
Sponsors	Version Description	Current Not Assessed Version
	Product Validity	Not Assessed
AIC Codes	Product Pending	Not Assessed
-Routes of Administration	Product Nullified	No
-Pharmaceutical Forms	Current vs Previous	No Previous Version
Master File Locations	Version Date	30/09/2021 12:19:55
Attachments	Version by	OTORGHB03O44
-Abstract Compositions	New Version ?	No
- Oueries	New Version by	
	Nullified	No
	PhV enquiry email	pharmacovigilance@xyzpharm

To perform and update, click on operation type 'Update' in the main menu:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
□ Reset Application Reset Section Clear XML RTF Update Other Operations -		
P Authorised Medicinal Products	Paracetamol 500*	
Authorised - PRD126060 - 1/1 - Paracetamol 500 mg Film Coated Tablets	Description	Name/Value
-Development Medicinal Products	EV Code	PRD126060
Approved Substances	Version	1/1
Development Substances	Туре	Authorised
Sources	Version Status	Accepted
MAHs	Version Validity	Unassessed
Sponsors	Version Description	Current Not Assessed Version
ATC Codec	Product Validity	Not Assessed
ATC Codes	Product Pending	Not Assessed
Routes of Administration	Product Nullified	No
Pharmaceutical Forms	Current vs Previous	No Previous Version
Master File Locations	Version Date	30/09/2021 12:19:55
Attachments	Version by	OTORGHB03044
-Abstract Compositions	New Version ?	No
- Queries	New Version by	
	Nullified	No
	PhV enquiry email	pharmacovigilance@xyzpharm
	PhV enguiry Phone	+353 1234 5678

Your product entity is moved from the 'Medicinal product' section to the 'Create and Send Product Reports' section. The operation type displayed is 'Update':

	For the UK, as from 1.1.2021, EU Law
WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Image: Constraint of the section Clear Replicate Validate Send XML ZIP RTF Remove E L R	
E-XEVPRM Message	Paracetamol 500*
Products	Description Name/Value
Update - Authorised - PRD126060 - Paracetamol 500 mg Film Coated Tablets	EV Code PRD126060
Medicinal Product Types (1)	Type Authorised
Authorised Pharmaceutical Forms (1)	Operation Type Update
Pharmaceutical Products (1)	MAH XYZ PHARMA LTD
+ Drug ATCs (1)	QPPV User HB03O44 Num 01 (OTORGHB03O44)
Drug Indications (14)	Master File Location MFL8/80 - Ireland - Dublin
Previous EV Codes (-)	Phy enquiry email pharmacovigliance@xyzpharma.le
Product Attachments (1)	Priveriquity Priorie +353 1234 5076 Sender Local Code
Substances	Info Date
Sources	Authorisation Country Code Ireland
Organisations	Authorisation Procedure EU authorisation procedures - National Procedure
ATC Codes	Authorisation Status Valid
- Pharmaceutical Forms	Authorisation Number PA1234/567/001
Routes Of Administration	Authorisation/Renewal Date 30/10/2020
Attachments	MRP/DCP/EMEA Number
Master File Locations	EU Number
	Legal Basis Well-established use application (Article 10a of Directive No 2001/8
	Orphan Drug No

Modify the information within the entity as requested, enter the message number, 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 a message similar to the following message:



• Please note that not every version of a medicinal product entity is validated by the EMA in the Article 57 database.

See also the <u>Extended EudraVigilance Medicinal Product Report Message step-by-step guide</u>: **Update** <u>of an authorised medicinal product document</u> available on the <u>'Training' webpage</u> for more details.

4.6.2. Nullification of entities in the XEVMPD

Operation type 'Nullification (4)' should be used whenever an entity 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 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), sources, organisations (MAH or sponsor), ATC codes (proposed or development), routes of administration (only development), pharmaceutical forms (only development) and master file locations, can be nullified by the owner organisation that has provided the initial information and the EMA. The XEVMPD will check the ownership of the information before allowing any modification in the dictionary.

Nullification of validated entities can only be performed by the EMA upon request submitted via the <u>EMA Service Desk portal</u>:

 Substance related requests: https://support.ema.europa.eu/esc?id=sc_cat_item&sys_id=6fac4352c3195d10e68bf1f4e4013_1a5
 XEVMPD product data related request: https://support.ema.europa.eu/esc?id=sc cat item&sys id=5cd0ff1ec3995d10e68bf1f4e4013 1bb

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'.

4.6.2.1. Create an XEVPRM with operation type 'Nullification (4)'

For an entity to be nullified by the MAH/Sponsor, 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;
- must not be flagged as 'Valid' by the EMA. Nullification of validated entities can only be performed by the EMA upon request submitted via the <u>EMA Service Desk portal</u>:
 - Substance related requests: <u>https://support.ema.europa.eu/esc?id=sc_cat_item&sys_id=6fac4352c3195d10e68bf1f4e4013</u> <u>1a5</u>
 - XEVMPD product data related request: <u>https://support.ema.europa.eu/esc?id=sc_cat_item&sys_id=5cd0ff1ec3995d10e68bf1f4e4013</u> <u>1bb</u>

and the reason for nullification must be provided.

• This rule is not applicable for development product entities; DMPs can be nullified by the owner organisation even if flagged as 'Valid' by the system.

Retrieve the entity you need to nullify in the XEVMPD either using a simple or an advanced query and select the entity so that it is displayed in your tree-view area:



WEB Trader Create and Send Product Reports Medicinal Products MedDRA				· · · · · · · · · · · · · · · · · · ·
Reset Application Reset Section Clear				
Authorised Medicinal Products	Paracetamol 500*			
Authorised - PRD126060 - 2/2 - Paracetamol 500 mg Film Coated Tablets	Num	EV Code	Version	Full Presentation Name
- Development Medicinal Products	✓ 0001	PRD126060	2/2	Paracetamol 500 mg Film Coated Tablets
Approved Substances				
Development Substances				
Sources				
MAHs				
Sponsors				
ATC Codes				
Routes of Administration				
Pharmaceutical Forms				
-Master File Locations				
Attachments				
- Abstract Compositions				
Queries				

Click on the EV Code or name of the medicinal product entry in the tree-view area so the product information is visible in the active area:



WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear ANL RTP Opdate Other Operations -		
Authorised Medicinal Products	Paracetamol 500*	
Authorised - PRD126060 - 2/2 - Paracetamol 500 mg Film Coated Tablets	Description	Name/Value
Development Medicinal Products	EV Code	PRD126060
Approved Substances	Version	2/2
Development Substances	Туре	Authorised
Sources	Version Status	Accepted
MAHs	Version Validity	Unassessed
Spansore	Version Description	Current Not Assessed Version
	Product Validity	Not Assessed
Alt Codes	Product Pending	Not Assessed
Routes of Administration	Product Nullified	No
Pharmaceutical Forms	Current vs Previous	Double Click to Compare
Master File Locations	Version Date	30/09/2021 14:19:03
Attachments	Version by	OTORGHB03O44
Abstract Compositions	New Version ?	No
- Queries	New Version by	
	Nullified	No
	PhV enquiry email	pharmacovigilance@xyzpharm
	PhV onquiry Phono	+353 1234 5680

To perform the nullification, click on 'Other Operations' in the main menu and select 'Nullify':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear XML RTF Update Other Operations	Choose one of the available	1	
Authorised Medicinal Products	Commands	Paracetamol 500*	
Authorised - PRD126060 - 2/2 - Paracetamol 500 mg F	Press A - Z to find initial letter	Description	Name/Value
Development Medicinal Products	Press Enter to select, Escape to clear	EV Code	PRD126060
Approved Substances	Nullify	Version	2/2
Development Substances	Invalidate MA	Туре	Authorised
Sources	Reinsert	Version Status	Accepted
MAHs		Version Validity	Unassessed
Sponsors		Version Description	Current Not Assessed Version
ATC Cadaa		Product Validity	Not Assessed
ATC Codes		Product Pending	Not Assessed
Routes of Administration		Product Nullified	No
Pharmaceutical Forms		Current vs Previous	Double Click to Compare
Master File Locations		Version Date	30/09/2021 14:19:03
Attachments		Version by	OTORGHB03044
Abstract Compositions		New Version ?	No
		New Version by	
		Nullified	No
		PhV enquiry email	pharmacovigilance@xyzpharm.

Your product entity is moved from the 'Medicinal product' section to the 'Create and Send Product Reports' section. The operation type displayed is 'Nullification':

WEB Trader 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	Paracetamol 500*	
Products	Description	Name/Value
Nullification - Authorised - PRD126060 - Paracetamol 500 mg Film Coated Tablets	EV Code	PRD126060
Medicinal Product Types (1)	Type	Authorised
Authorised Pharmaceutical Forms (1)	Operation Type	Nullification
Pharmaceutical Products (1)	MAH	XYZ PHARMA LID
Drug ATCs (1)	QPPV Master File Leastien	User HB03044 Num 01 (010R
Drug Indications (14)	BbV onguin (omoil	MFL0700 - ITelana - Dublin
Previous EV Codes (-)	PhV enquiry Phone	+353 1234 5680
Product Attachments (1)	Sender Local Code	- 333 1234 3003
Substances	Info Date	
Sources	Authorisation Country Code	Ireland
Organisations	Authorisation Procedure	EU authorisation procedures
ATC Codes	Authorisation Status	Valid
-Pharmaceutical Forms	Authorisation Number	PA1234/567/001
-Routes Of Administration	Authorisation/Renewal Date	30/10/2020
Attachments	MRP/DCP/EMEA Number	
Master File Locations	EU Number	
	Legal Basis	vveil-established use applicatio

Enter the reason for nullification in the 'Comment' field of the entity, enter the message number, 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 a message similar to the following message:

See also <u>Extended EudraVigilance Medicinal Product Report Message step-by-step guide: Maintenance</u> operations: **Nullification of development medicinal product (DMP) entity** in the XEVMPD available on the <u>'Training' webpage</u> for more details.

4.6.3. Invalidation of an AMP entity in the XEVMPD

Invalidation can only be performed on Authorised Medicinal Products.

This function should be used when a marketing authorisation of an authorised medicinal product was revoked, withdrawn, transferred, or expired, and this change must be reflected in the Article 57 database. You can provide the information on the revocation/withdrawal/transfer/expiry of the AMP by sending an XEVPRM with the operation type 'Invalidate MA (6)'.

AMPs can be invalidated by the owner organisation that has provided the initial information and the EMA. The XEVMPD will check the ownership of the information before allowing any modification in the dictionary.

Please note that invalidated AMP entities are never deleted from the XEVMPD; their authorisation status is set as 'Not valid'.

4.6.3.1. Create an XEVPRM 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 the entity you need to flag as 'withdrawn' in the XEVMPD either using a simple or an advanced query and select the entity so that it is displayed in your tree-view area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Image: Clear Image: Clear				
Authorised Medicinal Products	Paracetamol 500*			
- Development Medicinal Products	Num	EV Code	Version	Full Presentation Name
-Approved Substances	0001	PRD126060	2/2	Paracetamol 500 mg Film Coated Tablets
- Development Substances				
Sources				
MAHs				
Sponsors				
-ATC Codes				
-Routes of Administration				
Pharmaceutical Forms				
-Master File Locations				
Attachments				
-Abstract Compositions				
. dueries				



Click on the EV Code or name of the medicinal product entry in the tree-view area so the product information is visible in the active area:

	WEB Trader Create and Send Product Reports Medicinal Products MedDRA
	Reset Application Reset Section Clear XML RTF Update Other Operations
	-Authorised Medicinal Products
	Authorised - PRD126060 - 2/2 - Paracetamol 500 mg Film Coated Tablets
	Development Medicinal Products
	Approved Substances
	Development Substances
	Sources
	MAHs
	Sponsors
	ATC Codes
	-Routes of Administration
	-Pharmaceutical Forms
	-Master File Locations
	Attachments
	-Abstract Compositions
	Queries
l	1-

WEB Trader Create and Send Product Reports Medicinal Products MedDRA								
Reset Application Reset Section Clear XML RTF Update Other Operations								
Authorised Medicinal Products	Paracetamol 500*							
Authorised - PRD126060 - 2/2 - Paracetamol 500 mg Film Coated Tablets	Description	Name/Value						
-Development Medicinal Products	EV Code	PRD126060						
Approved Substances	Version	2/2						
- Development Substances	Туре	Authorised						
Sources	Version Status	Accepted						
MAHs	Version Validity	Unassessed						
Sponsors	Version Description	Current Not Assessed Version						
ATC Codes	Product Validity	Not Assessed						
ATC Codes	Product Pending	Not Assessed						
Routes of Administration	Product Nullified	No						
Pharmaceutical Forms	Current vs Previous	Double Click to Compare						
Master File Locations	Version Date	30/09/2021 14:19:03						
Attachments	Version by	OTORGHB03O44						
Abstract Compositions	New Version ?	No						
- Queries	New Version by							
	Nullified	No						
	PhV enquiry email	pharmacovigilance@xyzpharm						
	PhV onguiny Phono	+353 1234 5680						

To perform the invalidation, click on 'Other Operations' in the main menu and select 'Invalidate MA':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA									
Reset Application Reset Section Clear XML RTF Update Other Operations Checke age of the sublicities									
Authorised Medicinal Products	Commands	Paracetamol 500*							
⊕ Authorised - PRD126060 - 2/2 - Paracetamol 500 mg F	Press A - Z to find initial letter	Description	Name/Value						
Development Medicinal Products	Press Enter to select, Escape to clear	EV Code	PRD126060						
Approved Substances	Nullify	Version	2/2						
Development Substances	Invalidate MA	Туре	Authorised						
Sources	Reinsert	Version Status	Accepted						
MAHs		Version Validity	Unassessed						
Sponsors		Version Description	Current Not Assessed Version						
ATC Cadaa		Product Validity	Not Assessed						
ATC Codes		Product Pending	Not Assessed						
Routes of Administration		Product Nullified	No						
- Pharmaceutical Forms		Current vs Previous	Double Click to Compare						
Master File Locations		Version Date	30/09/2021 14:19:03						
Attachments		Version by	OTORGHB03044						
Abstract Compositions		New Version ?	No						
- Oueries		New Version by							
		Nullified	No						

Your product entity is moved from the 'Medicinal product' section to the 'Create and Send Product Reports' section. The operation type displayed is 'Invalidate MA':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			,
Reset Application Reset Section Clear Replicate Validate Send XML ZIP RTF Remove E L R			
EVPRM Message	Paracetamol 500*		
Products	Description	Name/Value	
Invalidate MA Authorised - PRD126060 - Paracetamol 500 mg Film Coated Tablets	EV Code	PRD126060	
Medicinal Product Types (1)	Туре	Authorised	
Authorised Pharmaceutical Forms (1)	Operation Type	Invalidate MA	
Pharmaceutical Products (1)	MAH	XYZ PHARMA LTD	
Drug ATCs (1)	QPPV	User HB03044 Num 01 (OTORGHB03044)	
Drug Indications (14)	Master File Location	MFL8780 - Ireland - Dublin	
Previous EV Codes (-)	Phy enquiry email Db)(opquiry Dopp	+252 4024 6690	
Product Attachments (1)	Sender Local Code	+333 1234 3009	
Substances	Info Date		
Sources	Authorisation Country Code	Ireland	
Organisations	Authorisation Procedure	EU authorisation procedures - National Procedure	
ATC Codes	Authorisation Status	1	Value not Acceptable
- Pharmaceutical Forms	Authorisation Number	PA1234/567/001	
-Routes Of Administration	Authorisation/Renewal Date	30/10/2020	
Attachments	MRP/DCP/EMEA Number		
-Master File Locations	EU Number		
	Legal Basis	vveil-established use application (Article 10a of Directive No 2001/83/	
	Additional Monitoring	No	
	Invalidated Date	no	
	Full Presentation Name	Paracetamol 500 mg Film Coated Tablets	

Enter the required authorisation status and the invalidated date, assign the message number, 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 a message similar to the following message:

- <reportacknowledgment></reportacknowledgment>
<reportname>AUTHORISEDPRODUCT</reportname>
<localnumber></localnumber>
<ev_code>PRD126060</ev_code>
<pre><operationtype>6</operationtype></pre>
<pre><operationresult>29</operationresult></pre>
<pre><operationresultdesc>Entity withdrawn/Invalidate MA successfully</operationresultdesc></pre>
Version 3 The product will be validated by the EMA in due
course. When validated you will receive a further
acknowledgement with the message number: "Product
Validated PRD126060 Version [Version Number] / [Date and
Time]".

• Please note that no further validation is performed by the EMA on AMPs that are invalidated in the Article 57 database.

See also <u>Extended EudraVigilance Medicinal Product Report Message step-by-step guide: Maintenance</u> operations - **Invalidation of an authorised medicinal product (AMP) entity** in the XEVMPD available on the <u>'Training' webpage</u> for more details.

4.7. 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 the 'Validate' button from the dynamic button set. The system automatically checks all the information in the message.

WEB Trader Create and Send Product Reports Medicinal Products MedDRA								
Reset Application Reset Section Clear Replicate Validate Send XML ZIP RTF Remove E L R								
E-XEVPRM Message	Paracetamol 500*							
Products	Description	Name/Value						
Update - Authorised - PRD126060 - Paracetamol 500 mg Film Coated Tablets	EV Code	PRD126060						
Medicinal Product Types (1)	Туре	Authorised						
Authorised Pharmaceutical Forms (1)	Operation Type	Update						
Pharmaceutical Products (1)	MAH	XYZ PHARMA LTD						
E Drug ATCs (1)	QPPV	User HB03O44 Num 01 (OTOR						
Drug Indications (14)	Master File Location	MFL8780 - Ireland - Dublin						
Provious EV Codes (-)	PhV enquiry email	pharmacovigilance@xyzpharm						
- Devide L Vecherster (1)	PhV enquiry Phone	+353 1234 5689						
	Sender Local Code							
Substances	Info Date							
Sources	Authorisation Country Code	Ireland						
Organisations	Authorisation Procedure	EU authorisation procedures						
ATC Codes	Authorisation Status	Valid						
Pharmaceutical Forms	Authorisation Number	PA1234/567/001						
Routes Of Administration	Authorisation/Renewal Date	30/10/2020						
Attachments	MRP/DCP/EMEA Number							
Mactor File Loadiana	EU Number							
	Legal Basis	Well-established use applicatio						

A pop-up window will confirm if the XEVPRM contains any error; if so, the errors or missing information will be highlighted. 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 error(s), 'Validate' the XEVPRM again.

When the XEVPRM does not contain any errors and all the mandatory fields have been specified, the validation will be declared successful:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear Replicate Validate Send XML ZIP RTF Remove E L R				
E XEVPRM Message	Paracetamol 500*			
Products		Description	Name/Value	
Update - Authorised - PRD126060 - Paracetamol 500 mg Film Coated Tablets		EV Code	PRD126060	
Medicinal Product Types (1)		Туре	Authorised	
Authorised Pharmaceutical Forms (1)	0	peration Type	Update	
Pharmaceutical Products (1)		MAH	XYZ PHARMA	LTD
Drug ATCs (1)		QPPV	User HB03044	Num 01 (OTOR.
Drug Indications (14)	Master	File Location	MFL8/80 - Ire	land - Dublin
Previous EV Codes (-)	Priv Db)/ or	enquiry email	pharmacovigila	ance@xyzpnarm.
Product Attachments (1)	Sonde	Message from	webpage X	9
EN - SPC_Paracetamol 500 mg Film Coated Tablets	Jenu	message nom	nebpage //	
Substances	Authorisation			
Sources	Authorisati	A Valid	lata OK	n procedures -
Organisations	Author			
ATC Codes	Authoris			01
-Pharmaceutical Forms	Authorisation/			
-Routes Of Administration	MRP/DCP/E		ОК	
Attachments				d uso applicatio
Master File Locations	'	Orphan Drug	No	u use applicatio.

4.8. Save, Reload and Send an XEVPRM

Once you created and validated your XEVPRM, you have the possibility to save the XEVPRM as an **XML** file, **RTF file** or a **ZIP file**.

• To save the XEVPRM as an **XML file**, click on 'XML' button from the dynamic button set:

WEB Trader	Create and Send Product Reports			rts Medi	Medicinal Products MedE			A					
Reset App	lication	Reset Section	Clear	Replicate	Validate	Send	XML	ZIP	RTF	Remove	E	LF	R

Once you click on the 'XML' button a new window will open:

Summary	
Temporary (for Export)	Click <u>here</u> for the file
	Name: ·Export-EVHUMANWT-XEVPRM-NN-2022-06-03+09.53.51-01.xml

After clicking on 'here', the 'Save' options will become available to you.

<u>If you are accessing EVWEB via Edge or Chrome using the IE Tab</u>, once you click on 'here', a new window will open, displaying the content of your XEVPRM.



To save the file, you must select '**Ctrl+S**' on your keyboard, which will then allow you to save the file on your computer:

<pre></pre>	Address: https://eudrav nl version="1.0" encodin rm xmlns="http://eudrav is:sis="http://eudravigilance.e. http://eudravigilance.e. https://eudravigi	vigilance.ema.europa.eu/x/E ravigilance.ema.europa.eu vigilance.ema.europa.eu o://eudravigilance.ema.eu ema.europa.eu/schema/e 4 >2 >0	xport.asp?F9EA955D-6 u/schema/emaxevmpd uropa.eu/schema/em emaxevmpd.xsd">	75E-4B0E-B8D8-D pd" _ssi" xmlns:xsi="h axevmpd	1155586F001	9 w3.org/2001/XMLSch	▶ 🕉 @	e"
</th <th>C Save As $\leftarrow \rightarrow \checkmark \uparrow$</th> <th>> This PC > Desktop ></th> <th></th> <th>~</th> <th>ک ک</th> <th>) Search Desktop</th> <th>×</th> <th></th>	C Save As $\leftarrow \rightarrow \checkmark \uparrow$	> This PC > Desktop >		~	ک ک) Search Desktop	×	
	 ✓ I Quick access Desktop Documents ↓ Downloads ➡ Pictures 	ر و ر	Name	^		Date modified	Ty ^	
	File <u>n</u> ame: Save as <u>type</u> : Hide Folders	Export All Files (*.*)				Save Car	~ ~	

• Alternatively, you can save the XEVPRM as an **RTF file** by clicking on the 'RTF' button from the dynamic button set:

WEB Trader	Trader Create and Send Product Reports			orts Media	Medicinal Products MedDRA			A					
Reset App	olication	Reset Section	Clear	Replicate	Validate	Send	XML	ZIP	RTF	Remove	Е	L	R

Once you click on the 'RTF' button a new window will open:

	Summary	
1	Temporary (for Export)	Click <u>here</u> for the file
		Name: ·Export-EVHUMANWT-XEVPRM-NN-2022-06-03+09.53.51-01.xml

Once you click on 'here', the 'Open' and 'Save' options will become available to you.

<u>If you are accessing EVWEB via Edge or Chrome using the IE Tab</u>, once you click on 'here', a new window will open, prompting you to open or save the file:

e	Address:	ss: https://eudravigilance.ema.europa.eu/x/Export.asp?7CEC38CF-970B-46A4-BC41-403BADE66FE8	Þ	ð	۵ ک
		File Download		×]
		Do you want to open or save this file? Image: RTF-NS-NT-NN-2022-06-03+11.15.35-01.rtf Type: Microsoft Word 97 - 2003 Document From: eudravigilance.ema.europa.eu Image: Open	Cancel		
		While files from the Internet can be useful, some files can po your computer. If you do not trust the source, do not open or What's the risk?	otentially har save this file	m e.	

• To save the file as a **ZIP file**, click on the 'ZIP' button from the dynamic button set:

WEB Trader Create and Send Product Reports				orts Med	Medicinal Products			MedDRA			
Reset Ap	plication	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Е	L	R

Once you click on the 'ZIP' button a new window will open:

Summary	
Temporary (for Export)	Click <u>here</u> for the file
	Name: ·Export-EVHUMANWT-XEVPRM-NN-2022-06-03+09.53.51-01.xml

Once you click on 'here', the 'Open' and 'Save' options will become available to you.

<u>If you are accessing EVWEB via Edge or Chrome using the IE Tab</u>, once you click on 'here', a new window will open, promting you to open or save the file:

θ	Address: https://eudravigilance.ema.europa.eu/x/Export.asp?60865B7A-6E88-4976-9F57-FAF75B7DB1FA	▶ 💥 🕡	×
			as from 1.1.
	0% of Export.asp from eudravigilance.em File Download Do you want to open or save this file Name:EVHUMANWT- Type: zip Archive From: eudravigilance.em Qpen	a.europa.eu a? XEVPRM-NN-2022- ma.europa.eu Save	- X
	While files from the Internet can your computer. If you do not true What's the risk?	be useful, some file at the source, do not	es can potentially harm open or save this file.

If you 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 *3.10.1.1. 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 in the XEVMPD, click on the 'Send' button from the dynamic button set:

WEB Trader C	reate	e and Send Prod	uct Repo	orts Medi	cinal Produ	icts I	MedDR.	A					
Reset Applica	tion	Reset Section	Clear	Replicate	Validate	Send	XML	ZIP	RTF	Remove	Е	L	R

The below message will be displayed on your screen:



• The 'Send' button will only be available for users from organisations registered for product reporting via Web Trader. Whilst users from organisations registered for product submissions via Gateway can create XEVPRMs using EVWEB, the 'Send' button will not be available to them. Gateway organisation users can submit XEVPRMs as 'ZIP' files using EV Post. See section *4.9. Use EV Post functionality* of this document for further information.

4.9. Use EV Post functionality

- If you are a Web Trader user, you can send XEVPRMs either from the 'Create and Send Product Reports' section of EVWEB, or by using the EV Post function.
- Gateway users can send XEVPRMs via their Gateway or by using the EV Post function.
 - Gateway organisation users can also create XEVPRMs using EVWEB (you may need to check that your organisation's profile in the EV registration system is set-up to allow this), however, since no 'Send' button is available to them in the 'Create and Send Product Reports' section, these XEVPRMs can only be submitted via EV Post.

XEVPRMs must be submitted via EV Post as a ZIP file.

Create your XEVPRM in the 'Create and Send' product report section of EVWEB and click on 'ZIP' in the main menu; a new window will open:

WEB Trader Create and Send Product Reports Medicinal Pro	ducts MedDRA		
Reset Application Reset Section Clear Replicate Validat	e Send XML ZIP RTF Remove E L R		
E XEVPRM Message	Parace	tamol 500*	
Products	https://evtest.ema.europa.eu/x/x.asp?xi=6 - Internet Ex	- 🗆	\times
Update - Authorised - PRD126060 -	Summary		
Medicinal Product Types (1)	Summary		
Authorised Pharmaceutical Forms	Temporary Click <u>here</u> for the file		
Pharmaceutical Products (1) Drug ATCo (1)	(for Export) Name: userhb03044u40-Export-OTORGHB03044-XEVPRM-PF	012606 update-2021-09	-30.
Drug ATCS (1)			ht
Previous EV Codes (-)			r
□ Product Attachments (1)			
EN - SPC Paracetamol 500 m			h
Substances			Ĩ
Sources			t I
Organisations			a
-ATC Codes			ľ
Pharmaceutical Forms			Ľ
Routes Of Administration			h
Attachments			2
Master File Locations			þ
			\sim
	<)	

Click on 'here' and save your file on your computer:

https://evtest.ema.europa.eu/x/x.asp?xi=6 -	Internet Ex	- 🗆	×
Summary			~
Temporary Click here or the file (for Export) Name: userhb03044u40-Export-OIORGHB03	044-XEVPRM-PRD126	06 update-202	1-09-30-
-			
			×
userhb03o44u40-Export-OTzip	evtest.ema.	europa.eu	
<u>♦</u>	<u>S</u> ave •	<u>C</u> ancel	>
	Save Save as		
	Save and <u>o</u>	ben	

<u>If you are accessing EVWEB via Edge or Chrome using the IE Tab</u>, once you click on 'here', a new window will open, displaying the content of your XEVPRM.

Address: https://eudravigilance.ema.europa.eu/x/Export.asp?F9EA955D-67	5E-4B0E-B8D8-D155586F0019
<pre><?xml version="1.0" encoding="UTF-16" ?> - <evprm <="" th="" xmlns="http://eudravigilance.ema.europa.eu/schema/emaxevmp</pre></td><th>d"></evprm></pre>	
<pre>xmins:ssi="http://eudravigilance.ema.europa.eu/schema/emaxevmpd_ xsi:schemaLocation="http://eudravigilance.ema.europa.eu/schema/ema http://eudravigilance.ema.europa.eu/schema/emaxevmpd.xsd"></pre>	ssi" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" pxevmpd
 - <ichicsrmessageheader> <messagetype>XEVPRM</messagetype> <messagetype></messagetype> <messagetype></messagetype> </ichicsrmessageheader> 	
<pre><messageformativersion>z</messageformativersion> </pre>	

To save the file, you must select '**Ctrl+S**' on your keyboard, which will then allow you to save the file on your computer:

Θ	Address: https://eudrav	/igilance.ema.europa.eu/x/E	xport.asp?F9EA955D-67	75E-4B0E-B8D8-D	155586F0019		▶ 💥 🕖	×
<pre><?xml version="1.0" encoding="UTF-16" ?></pre>								
	💽 Save As						×	
	\leftarrow \rightarrow \checkmark \uparrow	> This PC > Desktop >		~	Q O	Search Desktop		
- <-	Organize 🔹 Nev	v folder				↓ 	()	- 1
	 Quick access Desktop 		▲ Name	^		Date modified	Ту	
	Documents Downloads	:	*					
	Pictures		*			_		
	File <u>n</u> ame:	Export					\sim	
	Save as type:	All Files (*.*)					~	
	∧ Hide Folders					<u>S</u> ave Can	cel	

In the secure area of the EudraVigilance website click on EV Post:



Select the ZIP file from your computer:

.:: Choose the file to send ::.			
Browse			

Press 'Send':

.:: Choose the file to send ::.						
L:\emamahprod-E	xport-E Browse					
≻Send						

The below message will be displayed if the file was successfully posted:

```
.:: File Transfer Complete ::.
```

4.10. Export functions

4.10.1. Exporting results of a simple query

The result of your query may be exported as an Excel spread sheet, XML file(s) or RTF file(s).

There are two options how to export entities displayed as a result of a simple query:

- XML file
- RTF file

As an example, following a simple query, our AMP is displayed in the tree-view area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear XML RTF Other Operations	
P Authorised Medicinal Products	Paracetamol 500*
Authorised - PRD126060 - 3/3 - Paracetamol 500 mg Film Coated Tablets	Description Name/Value
-Development Medicinal Products	EV Code PRD126060
Approved Substances	Version 3/3
- Development Substances	Type Authorised
Sources	Version Status Accepted
MAHs	Version Validity Unassessed
Sponsors	Version Description Current Not Assessed Version
ATC Codes	Product Validity Not Assessed
Poutos of Administration	Product Pending Not Assessed
	Product Nullified No
- Pharmaceutical Forms	Current vs Previous Double Click to Compare
-Master File Locations	Version Date 30/09/2021 15:02:07
Attachments	Version by OTORGHB03O44
-Abstract Compositions	New Version ? No
⊕ Queries	New Version by

To export the AMP as an **XML file**, select the 'XML' from the main menu:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		'
Reset Application Reset Section Clear XML RTF Other Operations		
Authorised Medicinal Products	Paracetamol 500*	
Authorised - PRD126060 - 3/3 - Paracetamol 500 mg Film Coated Tablets	Description	Name/Value
Development Medicinal Products	EV Code	PRD126060
Approved Substances	Version	3/3
- Development Substances	Туре	Authorised
Sources	Version Status	Accepted
MAHs	Version Validity	Unassessed
Sponsors	Version Description	Current Not Assessed Version
ATC Codes	Product Validity	Not Assessed
-Routes of Administration	Product Pending	Not Assessed
Pharmaceutical Forms	Product Nullified	No
Master File Locations	Current vs Previous	Double Click to Compare
Attachmenta	Version Date	30/09/2021 15:02:07
	Version by	OTORGHB03044
Abstract Compositions	New Version ?	NO
⊞-Queries	New Version by	No
	DbV anguin (amail	NU phormosovigilopeo@vugphorm
	Privenquiry email	+252 1224 5690
	Priv enquiry Phone	+303 1234 0009

A pop-up window will be displayed:

\$	Summary	
ł	Temporary (for Export)	Click <u>here</u> for the file
H.		Name: userhb03o44u40-Export-OTORGHB03O44-XEVPRM-ProductMessage-2021-09-30+21.15.16-01.xml
ľ		

Clicking on 'here' will enable you to view and save the file on your computer in an XML format.

<u>If you are accessing EVWEB via Edge or Chrome using the IE Tab</u>, once you click on 'here', a new window will open, displaying the content of your XEVPRM. To save the file, you must select '**Ctrl+S**' on your keyboard, which will then allow you to save the file on your computer.

To export the AMP retrieved as a result of a simple query in an **RTF format**, select the 'RTF' from the main menu.

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		10
Reset Application Reset Section Clear XML RTF Other Operations -		
Authorised Medicinal Products	Paracetamol 500*	
Authorised - PRD126060 - 3/3 - Paracetamol 500 mg Film Coated Tablets	Description	Name/Value
Development Medicinal Products	EV Code	PRD126060
-Approved Substances	Version	3/3
Development Substances	Туре	Authorised
Sources	Version Status	Accepted
MAHs	Version Validity	Unassessed
Sponsors	Version Description	Current Not Assessed Version
ATC Codes	Product Validity	Not Assessed
Poutos of Administration	Product Pending	Not Assessed
	Product Nullified	No
Pharmaceutical Forms	Current vs Previous	Double Click to Compare
Master File Locations	Version Date	30/09/2021 15:02:07
Attachments	Version by	OTORGHB03044
-Abstract Compositions	New Version ?	No
Queries	New Version by	
	Nullified	No
	PhV enquiry email	pharmacovigilance@xyzpharm
	PhV enquiry Phone	+353 1234 5689

A pop-up window will be displayed:

https://evtest.ema.euro	🥖 https://evtest.ema.europa.eu/x/x.asp?xi=6 - Internet Explorer − 🛛 🗙						(
Summary								^
Temporary (for Export)	Click	ere for the file						
	Name:	userhb03o44u40-1	RTF-NS-NT-NN-	2021-09-:	30+21.0	9.38-01.	rtf	l

After clicking on 'here', another window will open enabling you to open or save the file on your computer.

If you choose to open the file, the file will be displayed in an RTF format. You can then save the file, if required.

ener Eu	IdraVigilance
EV Code	PDD126060
Ly Code Version	2/2
Version Tema	
Type	Authorised
Version Status	Accepted
Version Validity	Unassessed
Version Description	Current Not Assessed Version
Product Validity	Not Assessed
Product Pending	Not Assessed
Product Nullified	No
Current vs Previous	126061-126062
Version Date	30/09/2021 15:02:07
Version by	OTORGHB03O44
New Version ?	No
Nullified	No
PhV enquiry email	pharmacovigilance@xyzpharma.ie
PhV enquiry Phone	+353 1234 5689
Authorisation Country Code	Ireland
Authorisation Procedure	EU authorisation procedures - National Procedure
Authorisation Status	Not Valid - Withdrawn by Marketing Authorisation
	Holder
Authorisation Number	PA1234/567/001
Authorisation/Renewal Date	30/10/2020
Legal Basis	Well-established use application (Article 10a of

4.10.2. Exporting results of an advanced query

Results of an advanced query, which are available in the active area, may be exported as:

- an Excel spread sheet;
- one or multiple XML file(s);

• one or multiple RTF file(s).

The results to be exported must be selected by ticking the check box next to the result. You can select each product manually:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA				
Reset Application Reset Section Clear ReRun Modify Delete Excel Export	Reload - As	ssessment ▾ Load ▾ □ i	2	
Legacy Link	,PRD320712			
Product Index	Num	EV Code	Version	Version Date
-Abstract Compositions	✓ 0001	PRD8017577	3/4 Valid	2020/05/07 14:56.28
-Scientific Products	✓ 0002	PRD330611	11/11 Valid	2020/04/20 07:14.42
Manual Scientific Products	⊘ 0003	PRD330614	10/10 Valid	2020/04/20 07:15.42
-Product Misspellings (-)	0004	PRD330612	10/10 Valid	2020/04/20 07:15.47
Substance Misspellings (-)	0005	PRD330615	10/10 Valid	2020/04/20 07:16.42
Entity Reference Lookups	0006	PRD330613	11/11 Valid	2020/04/20 07:16.48
E Queries	✓ 0007	PRD7954169	2/2 Valid	2020/04/03 09:11.22
Owned EVMPD Entities	≥ 0008	PRD336157	12/12 Valid	2020/04/17 08:58.40
Owned By EVMPD Entities	✓ 0009	PRD336156	14/14 Valid	2020/04/17 09:06.44
TH Validation	0010	PRD2013670	9/10 Valid	2020/04/27 10:40.19
Authorised Products (Last Version)	0011	PRD673062	10/10 Valid	2020/05/05 16:28.43
Authorised Products (Valid Version)	0012	PRD2907651	4/6 Valid	2020/05/05 13:50.25
Fields	0013	PRD359936	13/13 Valid	2020/04/17 12:01.37
Conditions (AND)	0014	PRD8019113	1/1 Valid	2020/04/29 12:02.14
Besults	0015	PRD330421	9/9 Valid	2020/04/17 12:10.44
Result 30 September 2021 19:51:16	0016	PRD8008974	3/5 Valid	2020/04/30 08:41.28
Result 30 September 2021 19:51:16	0017	PPD8008005	3/5 Valid	2020/04/30 08:41 28

Or you can select all products by clicking on the checked box highlighted in the below screenshot in red:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA					FOI THE OK, AS ITO
Reset Application Reset Section Clear ReRun Modify Delete Excel Expo	rt 🔻	Reload - As	sessment ▾ Load ▾ □ E	Z	
Legacy Link	^	,PRD320712			
Product Index		Num	EV Code	Version	Version Date
Abstract Compositions		0001	PRD8017577	3/4 Valid	2020/05/07 14:56.28
Scientific Products		0002	PRD330611	11/11 Valid	2020/04/20 07:14.42
🖽 Manual Scientific Products		0003	PRD330614	10/10 Valid	2020/04/20 07:15.42
Product Misspellings (-)		0004	PRD330612	10/10 Valid	2020/04/20 07:15.47
Substance Misspellings (-)		0005	PRD330615	10/10 Valid	2020/04/20 07:16.42
Entity Reference Lookups		0006	PRD330613	11/11 Valid	2020/04/20 07:16.48
		0007	PRD7954169	2/2 Valid	2020/04/03 09:11.22
Owned EVMPD Entities		8000	PRD336157	12/12 Valid	2020/04/17 08:58.40
Owned By EVMPD Entities		0009	PRD336156	14/14 Valid	2020/04/17 09:06.44
		0010	PRD2013670	9/10 Valid	2020/04/27 10:40.19
Authorised Products (Last Version)		0011	PRD673062	10/10 Valid	2020/05/05 16:28.43
Authorised Products (Valid Version)		0012	PRD2907651	4/6 Valid	2020/05/05 13:50.25
Fields		0013	PRD359936	13/13 Valid	2020/04/17 12:01.37
Conditions (AND)		0014	PRD8019113	1/1 Valid	2020/04/29 12:02.14
		0015	PRD330421	9/9 Valid	2020/04/17 12:10.44
Result 30 Sentember 2021 10:51:16		0016	PRD8008974	3/5 Valid	2020/04/30 08:41.28
		0017	PRD8008995	3/5 Valid	2020/04/30 08:41.28

The required format in which you wish to export you results can be selected from the main menu by clicking on the 'Excel' button or on 'Export':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear ReRun Modify Delete Excel Expor	Choose one of	the available	
Legacy Link	Comm	ands	
Product Index	Press A - 7 to fin	d initial letter	Version Version Date
Abstract Compositions	Press Enter to selec	, Escape to clear	7 3/4 Valid 2020/05/07 14:56.28
Scientific Products	Multi XML Files		11/11 Valid 2020/04/20 07:14.42
🖽 Manual Scientific Products	One XML File		10/10 Valid 2020/04/20 07:15.42
Product Misspellings (-)	Multi PTE Filos		10/10 Valid 2020/04/20 07:15.47
Substance Misspellings (-)			10/10 Valid 2020/04/20 07:16.42
Entity Reference Lookups	One KTF File		11/11 Valid 2020/04/20 07:16.48
Queries	0007	PRD795416	169 2/2 Valid 2020/04/03 09:11.22
Owned EVMPD Entities	8000	PRD33615	57 12/12 Valid 2020/04/17 08:58.40
Owned By EVMPD Entities	0009	PRD336156	56 14/14 Valid 2020/04/17 09:06.44
Validation	0010	PRD20136	670 9/10 Valid 2020/04/27 10:40.19
Authorised Products (Last Version)	0011	PRD673062	10/10 Valid 2020/05/05 16:28.43
Authorised Products (Valid Version)	0012	PRD29076	651 4/6 Valid 2020/05/05 13:50.25
Fields	0013	PRD359936	13/13 Valid 2020/04/17 12:01.37
Conditions (AND)	0014	PRD80191	113 1/1 Valid 2020/04/29 12:02.14
⊨-Results	0015	PRD33042	21 9/9 Valid 2020/04/17 12:10.44
Result 30 September 2021 19:51:16		PRD80089	9/4 3/5 Valid 2020/04/30 08:41.28
Authorised Products (MAH Follow-Up Version)		PRD80089	3/5 Valid 2020/04/30 08:41.28
Development Products (Last Version)		PRD80089	3/5 Valid 2020/04/30 08:41.28
Development Products (Valid Version)		PKD/99/6	06Z Z/Z Valid 2020/04/23 03:49.41
	11 10020	PKD80089	i997 3/5 Valid 2020/04/30 08:41.29

To export the selected results 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':

Display Settings		
WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear ReRun Modify Delete Excel Expo	Choose one of the available	
MAHs	Commands	
Sponsors	Press A - Z to find initial letter	EV Code
ATC Codes	Press Enter to select, Escape to clear	MFL1
Routes of Administration	Multi XML Files	MFL2
Pharmaceutical Forms	One XML File	MFL3
Master File Locations	Multi RTF Files	MFL238
Attachments	One RTF File	MFL258
Abstract Compositions	0000	- MFL170
	0007	MFL242
Owned EVMPD Entities	0008	MFL243
Owned Authorised Products	0009	MFL247
Authorised Products (Valid Version)	0010	MFL248
Owned Development Products		MFL252
		MFL253
Approved Substance Names	0013	MFL262

Depending on the selected option (we selected multiple RTF File), a pop-up window will be displayed:

Summary		~
Temporary (for Export)	Click <u>here</u> for the file	
	Name: userhb03o44u40-Export-OTORGHB03044-XEVPRM-MFLMessage-2021-09-30+21.19.49-01.xml	
Temporary (for Export)	Click <u>here</u> for the file	
	Name: userhb03044u40-Export-OTORGHB03044-XEVPRM-MFLMessage-2021-09-30+21.19.49-02.xml	
Temporary (for Export)	Click <u>here</u> for the file	
	Name: userhb03044u40-Export-OTORGHB03044-XEVPRM-MFLMessage-2021-09-30+21.19.49-03.xml	
Temporary (for Export)	Click <u>here</u> for the file	
	Name: userhb03o44u40-Export-OTORGHB03044-XEVPRM-MFLMessage-2021-09-30+21.19.49-04.xml	
Temporary (for Export)	Click <u>here</u> for the file	
	Name: userhb03o44u40-Export-OTORGHB03044-XEVPRM-MFLMessage-2021-09-30+21.19.49-05.xml	
Temporary (for Export)	Click <u>here</u> for the file	
	Name: userhb03044u40-Export-OTORGHB03044-XEVPRM-MFLMessage-2021-09-30+21.19.49-06.xml	
Temporary (for Export)	Click <u>here</u> for the file	
	Name: userhb03044u40-Export-OTORGHB03044-XEVPRM-MFLMessage-2021-09-30+21.19.49-07.xml	
		\sim

After clicking on 'here', another window will open enabling you to open or save the file on your computer, as required.

🗴 🔁 Convert 👻 👼 Select
<pre>X</pre>
 <masterfilelocations></masterfilelocations>
- <masterfilelocation operationtype="1"> <localnumber>MFL1</localnumber></masterfilelocation>

If you wish to view/save the file in an RTF format, select the 'RTF' from the main menu:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear ReRun Modify Delete Excel Excel	Choose one of the available	
MAHs	Commands	
Sponsors	Press A - Z to find initial letter	EV Code
ATC Codes	Press Enter to select, Escape to clear	MFL1
Routes of Administration	Multi XML Files	MFL2
Pharmaceutical Forms	One XML File	MFL3
Master File Locations	Multi RTE Files	MFL238
Attachments		MFL258
Abstract Compositions		MFL170
	☑ 0007	MFL242
Owned EVMPD Entities	☑ 0008	MFL243
Owned Authorised Products	☑ 0009	MFL247
Authorised Products (Valid Version)	0010	MFL248
Owned Development Products	0011	MFL252
	0012	MFL253

A pop-up window will be displayed:

Summary		^
Temporary (for Export)	Click here for the file Name: userhb03044u40-RTF-NS-NT-NN-2021-09-30+21.26.25-01.rtf	

After clicking on 'here', another window will open enabling you to open or save the file on your computer.

If you choose to open the file, the file will be displayed in an RTF format. You can then save the file, if required:

EudraVigilance					
Master File Location					
Validity	No				
	No				
Nullified	140				

4.11. Export of owned entities

MAH or sponsor users can view and export the overview of the entities owned in the XEVMPD by their HQ organisation profile using the 'Queries' section.

4.11.1. 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':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA
Reset Application Reset Section Clear
Development Medicinal Products
Approved Substances
Development Substances
Sources
MAHs
Sponsors
ATC Codes
Routes of Administration
Pharmaceutical Forms
Master File Locations
Attachments
Abstract Compositions
Owned EVMPD Entities
Owned Authonised Products Authorized Draduate (Valid Version)
Authonised Products (Valid Version)
E Sources
A MAHs
E Sponsors
ATC Codes
Routes of Administration
Pharmaceutical Forms
Abstract Compositions
Master File Locations

An overview will be listed in the active area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA							
Reset Application Reset Section Clear ReRun Delete Excel							
Development Medicinal Products	~ [
Approved Substances		Num	Entity	Article 57 Format	Туре	Status	Number
Development Substances		0001	Attachment	Pre Article 57 Format			
Sources		0002	Master File Location	Pre Article 57 Format		Awaiting Assessment	2
MAHs		0003	Organisation	Article 57 Format	Sponsor	Awaiting Assessment	1
Sponsors		0004	Organisation	Article 57 Format	MAH	Awaiting Assessment	2
-ATC Codes		0005	Product	Article 57 Format	Authorised	Awaiting Assessment	1
Routes of Administration		0006	Product	Article 57 Format	Development	Assessed	2
Pharmaceutical Forms	1	0007	Product	Article 57 Format	Development	NUIIMed	1
Master File Locations							
Attachments							
Abstract Compositions							
🗄 Queries							
Owned EVMPD Entities							
Results							
Result 01 October 2021 17:08:35							

You can save this overview in Excel spread sheet by clicking on 'Excel':

WEB Trader Create and Send Product Reports Medicinal Products MedDRA							,
Reset Application Reset Section Clear ReRun Delete Excel							
- Development Medicinal Products	~ [
- Approved Substances		Num	Entity	Article 57 Format	Туре	Status	Number
- Development Substances		0001	Attachment	Pre Article 57 Format			2
Sources		0002	Master File Location	Pre Article 57 Format		Awaiting Assessment	2
MAHs		0003	Organisation	Article 57 Format	Sponsor	Awaiting Assessment	1
Sponsors		0004	Organisation	Article 57 Format	MAH	Awaiting Assessment	2
ATC Codes		0005	Product	Article 57 Format	Authorised	Awaiting Assessment	1
Routes of Administration		0006	Product	Article 57 Format	Development	Assessed	2
Pharmaceutical Forms		0007	Product	Article 57 Format	Development	Nullified	1
Master File Locations							
Attachments							

4.11.2. Exporting an overview of all owned AMP entities

To view all AMP entities owned in the XEVMPD by your HQ organisation ID or to create an Excel spread sheet containing all AMP entities owned in the XEVMPD 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 'Owned Authorised Products':



Expand the section by clicking on the + sign:

Owned EVMPD Entities
Owned Authorised Products
Authorised Products (Valid Version)
Owned Development Products
🗄 Substance Names
Approved Substance Names
Development Substance Names
Approved Substances
Development Substances
E Sources
. ∰. MAHs
ATC Codes
Routes of Administration
Pharmaceutical Forms
Abstract Compositions

h Attachmonte

Click on 'Conditions' and tick the box next to the field 'Owned':



• Please note that <u>for AMPs</u>, the condition 'Valid' in 'MA validity' is selected **by default**. This means, that the query will be run for all AMPs referencing a valid marketing authorisation status.

If you wish to also include AMPs with an invalid marketing authorisation status, you must change the value to 'Any' in that field:

MA Validity	Select option
Authorisation Number (Matches)	
MRP/DCP/EMEA Number (Matches)	Press A - Z to find initial letter
EU Number (Matches)	
Legal Basis	Valid Valid
Invalidated Date	
Invalidated Date (From)	
Invalidated Date (Up to)	Any

Define other filters for your query in the **'Conditions'** section as required.

You can select which fields you wish to see as the result of your query in the 'Fields' section:

Owned EVMPD Entities
Owned Authorised Products
Fields
Conditions (AND)

Once you select the conditions of your query, click on **'Run'** to view the results of your query on the screen or **'Run to Excel'** to export the results of your query in an Excel file:



If you opted to view the results of your query on the screen, the list of products will be displayed in the active area:

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA			
Reset Application Reset Section Clear ReRun Modify	Delete Excel E	(port ▼ Reload ▼ Lo	oad 👻 🗆 🗹	
Authorised Medicinal Products				
Development Medicinal Products	Num	EV Code	Version	Version Date
Approved Substances	0001	PRD131811	1/1	2024/02/05 21:41.04
Development Substances	0002	PRD131812	1/1	2024/02/05 22:34.22
Sources	0003	PRD131814	1/1	2024/02/06 12:39.05
MAHs	0004	PRD131203	2/2	2023/10/04 18:13.01
Sponsors	0005	PRD131423	1/1	2023/10/24 13:25.35
ATC Codes	0006	PRD131515	1/1	2023/11/14 11:22.35
-Routes of Administration	0007	PRD131748	1/1	2024/01/24 10:47.33
Pharmaceutical Forms	8000	PRD131753	1/1	2024/01/24 12:00.37
Master File Locations	0009	PRD131754	1/1	2024/01/24 12:00.37
Attachments	0010	PRD131770	1/1	2024/01/25 12:05.50
Abstract Compositions	0011	PRD131776	1/1	2024/01/26 15:36.13
	0012	PRD131777	1/1	2024/01/26 15:44.13
Owned EVMPD Entities	0013	PRD131789	1/1	2024/01/31 10:09.39
	0014	PRD131791	1/1	2024/02/01 11:46.56
	0015	PRD131581	1/1	2023/12/01 17:27.01
Conditions (AND)	0016	PRD131651	1/1	2023/12/19 10:50.43
	0017	PRD131652	1/1	2023/12/19 10:50.43
	0018	PRD131664	1/1	2023/12/28 03:41 18

If you opted to view the results of your query in an Excel file, a new window will open; you will be able to retrieve the Excel file by clicking on the text 'here':

Jummary	
Temporary (for Export) Click <u>here</u> for the file	
Name: Authorised Products (Valid Version) (07-11-2023 09-46-27).xls	

4.11.3. Exporting an overview of all owned DMP entities

To view all DMP entities owned in the XEVMPD by your HQ organisation ID or to create an Excel spread sheet containing all DMP entities owned in the XEVMPD 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 'Owned Development Products':

WEB Trader Create and Send Product Reports	Medicinal Products	MedDRA				
Reset Application Reset Section Clear Ru	Run to Excel					
-Development Medicinal Products						
Approved Substances						
Development Substances						
Sources						
MAHs						
Sponsors						
ATC Codes						
Routes of Administration						
Pharmaceutical Forms						
Master File Locations						
Attachments						
Abstract Compositions						
Owned EVMPD Enulies Owned Authorized Products						
Owned Authorised Products	(n)					
Authorised Products (Valid Versic	лт <i>)</i>					
Substance Names						
Development Substance Names						
Approved Substances						
Development Substances						
Sources	B Sources					
A MAHs						
- Sponsors						
ATC Codes						
Routes of Administration						
Pharmaceutical Forms						
Abstract Compositions						
Attachments						
Master File Locations						

Expand the section by clicking on the + sign:

- - Owned EVMPD Entities
 - Owned Authorised Products
 - Authorised Products (Valid Version)
 - Owned Development Products

E Substance Names

- Approved Substance Names
- Development Substance Names

Click on 'Conditions' and tick the box next to the field 'Owned':

WEB Trader 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	Description Name/Value
Approved Substances	Local Number (Matches)
Development Substances	EV Code (Matches)
Sources	Has Been Updated 🗌
MAHs	Owner HQ ID (Matches)
Sponsors	Product Validity
ATC Codes	Product Pending
-Routes of Administration	Product Nullified
-Pharmaceutical Forms	Last Update
-Master File Locations	Last Update (From)
Attachments	Last Update (Up to)
Abstract Compositions	Product Code (Matches)
Queries	
Owned EVMPD Entities	
Owned Authorised Products	Sponsor (Name) (Matches)
Authorised Products (Valid Version)	Sponsor (Code) (Matches)
- Owned Development Products	Pharmaceutical Form (Matches)
Fields	
Conditions (AND)	Substance (Name) (Matches)
– – substance Names	
Approved Substance Names	Is Nullifiable
Development Substance Names	Owned
Approved Substances	Sender Identifier (Matches)
Development Substances	Sender Name (Matches)

Define other filters for your query in the **'Conditions'** section as required.

You can select which fields you wish to see as the result of your query in the **'Fields'** section; some fields are already selected by default:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA					
Reset Application Reset Section Clear Run Run to Excel					
Authorised Medicinal Products	^				
Development Medicinal Products		Description			
Approved Substances		Local Number			
Development Substances		EV Code	Default selection		
Sources		✓ Version	Default selection		
MAHs		Version Date	Default selection		
Sponsors		Owner HQ ID	Default selection		
ATC Codes		Product Code	Default selection		
-Routes of Administration		Full Presentation Name	Default selection		
Pharmaceutical Forms		Product Other Name			
Master File Locations		Sponsor Name	Default selection		
Attachments		Sponsor Code	Default selection		
-Abstract Compositions		Pharmaceutical Form			
Queries					
Owned EVMPD Entities		Substance names			
Owned Authorised Products		Substance Concentration Ty			
Authorised Products (Valid Version)					
Owned Development Products					
Fields					
Conditions (AND)					
Results		Message Receive Date			
Substance Names		Sender Name			
Approved Substance Names		Product Validity			
Development Substance Names		Product Pending			
Approved Substances		Product Nullified			
Development Substances					
⊞ MAHs					

Once you select the conditions of your query, click on **'Run'** to view the results of your query on the screen or **'Run to Excel'** to export the results of your query in an Excel file:

WEB Trader 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	Description Name/Value
Approved Substances	Local Number (Matches)
Development Substances	EV Code (Matches)
Sources	Has Been Updated 🗌
MAHs	Owner HQ ID (Matches)
Sponsors	Product Validity
ATC Codes	Product Pending
-Routes of Administration	Product Nullified
Pharmaceutical Forms	Last Update
Master File Locations	Last Update (From)
Attachments	
Abstract Compositions	Product Code (Matches)
	Product Other Name (Matches)
Owned EVMPD Entities	Sponsor (Name) (Matches)
Owned Authorised Products	Sponsor (Code) (Matches)
Authorised Products (Valid Version)	Pharmaceutical Form (Matches)
Owned Development Products	Route of Administration (Matc
Fields	Substance (Code) (Matches)
Conditions (AND)	Substance (Name) (Matches)
Results	ATC Code
E Substance Names	Is Updatable
Approved Substance Names	Is Nullifiable
Development Substance Names	Owned 🔽
Approved Substances	Sender Identifier (Matches)
Development Substances	Sender Name (Matches)
⊕ Sources	
⊕ MAHs	
Sponsors	
the ATC Codes	

If you opted to view the results of your query on the screen, the list of products will be displayed in the active area:

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA			
Reset Application Reset Section Clear ReRun Modify	Delete Excel	Export - Reload - Load	i 🗕 🔲	
Authorised Medicinal Products				
- Development Medicinal Products	Num	EV Code	Version	Version Date
-Approved Substances	0001	PRD131268	1/1 Valid	2023/10/09 14:56.45
Development Substances	0002	PRD131818	1/1 Valid	2024/02/07 09:26.10
Sources	0003	PRD131210	1/1 Valid	2023/09/28 11:50.57
MAHs	0004	PRD131681	1/1 Valid	2024/01/09 00:48.46
Sponsors	0005	PRD131704	1/1 Valid	2024/01/11 13:30.52
ATC Codes	0006	PRD131422	1/1 Valid	2023/10/24 13:25.35
-Routes of Administration	0007	PRD131519	1/1 Valid	2023/11/16 17:22.18
Pharmaceutical Forms	8000	PRD131743	1/1 Valid	2024/01/23 16:34.37
-Master File Locations	0009	PRD131751	1/1 Valid	2024/01/24 11:25.35
Attachments	0010	PRD131760	1/1 Valid	2024/01/24 12:26.38
Abstract Compositions		PRD131769	1/1 Valid	2024/01/25 11:38.48
Queries		PRD131772	1/1 Valid	2024/01/26 07:17.49
Owned EVMPD Entities		PRD131773	1/1 Valid	2024/01/26 08:27.52
Owned Authorised Products		PRD131774		2024/01/26 09:14.54
Authorised Products (Valid Version)		PRD131787		2024/01/30 16:40.10
- Owned Development Products		PRD131788		2024/01/31 08:59:35
Fields		PRD 131790	1/1 Valid	2024/02/01 10.18.52
Conditions (AND)		PRD 131300	1/1 Valid	2023/12/01 17.27.01
⊟- Results		PRD131655	1/1 Valid	2023/12/20 10:09:55

If you opted to view the results of your query in an Excel file, a new window will open; you will be able to retrieve the Excel file by clicking on the text 'here':

Summary						
Temporary (for Export)	Click	here for	the file			
	Name:	Owned	Development	Products	(07-11-2023	09-47-55).xls

4.12. 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 (in 'Create and Send Product Reports' section only).

See section <u>3.11. Export functions and available formats</u> of this document for related information.

Excel This button allows you to save the result of your queries as a spread sheet in an Excel format.

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

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

This button in the 'Create and Send Product Reports' section allows you to generate a ZIP file also containing the attachment (if present) and save it on your computer.

See section <u>4.8. Save, Reload and Send an XEVPRM</u> for information.

4.13. Retrieving previous version(s) of medicinal product entity

In EVWEB, users can view each individual version available for the EV Code of their AMP/DMP entity in the sections 'Previous Versions'/'Subsequent Versions' within the AMP/DMP entity.

To achieve this, load the product in the tree-view area, then click on 'Previous Versions' or 'Subsequent Versions' as required:



To view the versions in each section, click on the '+' sign:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA
Reset Application Reset Section Clear XML RTF Other Operations -
P Authorised Medicinal Products
Authorised - PRD126060 - 3/3 - Paracetamol 500 mg Film Coated Tablets
MAH: ORG8828 - XYZ PHARMA LTD
MFL: MFL8780 - IE - Dublin
⊕ Medicinal Product Types (1)
⊕ Authorised Pharmaceutical Forms (1)
□ Drug ATCs (1)
Previous EV Codes (-)
Product Attachments (1)
Previous Versions ()
Subsequent Versions ()

The individual versions of your product entry will be displayed:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA			
Reset Application Reset Section Clear			
Authorised Medicinal Products			
Authorised - PRD126060 - 3/3 - Paracetamol 500 mg Film Coated Tablets			
MAH: ORG8828 - XYZ PHARMA LTD			
MFL: MFL8780 - IE - Dublin			
QPPV: User HB03044 Num 01 (OTORGHB03044) - 211696			
Medicinal Product Types (1)			
Authorised Pharmaceutical Forms (1)			
Pharmaceutical Products (1)			
Drug ATCs (1)			
Drug Indications (14)			
Previous EV Codes (-)			
Product Attachments (1)			
Previous Versions (2)			
-1/3 - Paracetamol 500 mg Film Coated Tablets			
2/3 - Paracetamol 500 mg Film Coated Tablets			
Subsequent Versions (-)			
Reporting Names - Presentations ()			
Reporting Names - Scientific ()			

To view the required version, click on the version you wish to view so it becomes available in the active area:
WEB Trader Create and Send Product Reports Medicinal Products MedDRA		
Reset Application Reset Section Clear Load		
Authorised Medicinal Products	Paracetamol 500*	
Authorised - PRD126060 - 3/3 - Paracetamol 500 mg Film Coated Tablets	Description	Name/Value
	EV Code	PRD126060
MFL: MFL8780 - IE - Dublin	Version	1/3
	Туре	Authorised
Medicinal Product Types (1)	Version Status	Accepted
Authorised Pharmaceutical Forms (1)	Version Validity	Unassessed
Pharmaceutical Products (1)	Version Description	Updated Not Assessed Version
	Product Validity	Not Assessed
Drug Indiactions (14)	Product Pending	Not Assessed
	Product Nullified	No
Previous EV Codes (-)	Current vs Previous	No Previous Version
Product Attachments (1)	Version Date	30/09/2021 12:19:55
Previous Versions (2)	Version by	OTORGHB03O44
1/3 - Paracetamol 500 mg Film Coated Tablets	New Version ?	Yes (30/09/2021 14:19:03,000)
2/3 - Paracetamol 500 mg Film Coated Tablets	New Version by	OTORGHB03O44
-Subsequent Versions (-)	Nullified	No
Reporting Names - Presentations ()	PhV enquiry email	pharmacovigilance@xyzpharm
Reporting Names - Scientific ()	PhV enquiry Phone	+353 1234 5678
Entroporting frames Colonate ()	Sondor Local Code	

Click on 'Load' in the main menu and the version will be displayed in the tree-view area and in the active area of EVWEB:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA		10
Reset Application Reset Section Clear Load		
Authorised Medicinal Products	Paracetamol 500*	
Authorised - PRD126060 - 3/3 - Paracetamol 500 mg Film Coated Tablets	Description	Name/Value
MAH: ORG8828 - XYZ PHARMA LTD	EV Code	PRD126060
MFL: MFL8780 - IE - Dublin	Version	1/3
QPPV: User HB03O44 Num 01 (OTORGHB03O44) - 211696	Туре	Authorised
Medicinal Product Types (1)	Version Status	Accepted
Authorised Pharmaceutical Forms (1)	Version Validity	Unassessed
Pharmaceutical Products (1)	Version Description	Updated Not Assessed Version
	Product Validity	Not Assessed
Drug Indiactions (14)	Product Pending	Not Assessed
	Product Nullified	No
Previous EV Codes (-)	Current vs Previous	No Previous Version
Product Attachments (1)	Version Date	30/09/2021 12:19:55
Previous Versions (2)	Version by	OTORGHB03O44
 – 1/3 - Paracetamol 500 mg Film Coated Tablets 	New Version ?	Yes (30/09/2021 14:19:03,000)
2/3 - Paracetamol 500 mg Film Coated Tablets	New Version by	OTORGHB03O44
	Nullified	No
Reporting Names - Presentations ()	PhV enquiry email	pharmacovigilance@xyzpharm
Deporting Names - Scientific ()	PhV enquiry Phone	+353 1234 5678
Herebolung rames - Ocientine ()	Sender Local Code	

For the T WEB Trader Create and Send Product Reports Medicinal Products MedDRA							
Reset Application Reset Section Clear XML RTF Update Other Operations -							
Authorised Medicinal Products	Paracetamol 500*						
Authorised - PRD126060 - 3/3 - Paracetamol 500 mg Film Coated Tablets	Description	Name/Value					
-MAH: ORG8828 - XYZ PHARMA LTD	EV Code	PRD126060					
-MFL: MFL8780 - IE - Dublin	Version	1/3					
-QPPV: User HB03O44 Num 01 (OTORGHB03O44) - 211696	Туре	Authorised					
Medicinal Product Types (1)	Version Status	Accepted					
Authorised Pharmaceutical Forms (1)	Version Validity	Unassessed					
Pharmaceutical Products (1)	Version Description	Updated Not Assessed Version					
Drug ATCs (1)	Product Validity	Not Assessed					
Drug Indications (14)	Product Pending	Not Assessed					
Previous EV Codes (-)	Product Nullified	No					
Product Attachments (1)	Current vs Previous	No Previous Version					
	Version by	30/09/2021 12.19.35 OTODOLIB02044					
1/2 Paraostamol 500 mg Film Costod Tablete	New Version 2	Voc (20/00/2021 14:10:02 000)					
2/2 Derestamel 500 mg Film Costed Tablets	New Version by	OTOPCH803044					
	Nullified	No					
-Subsequent versions (-)	PhV enquiry email	nharmacovigilance@xvzpharm					
Reporting Names - Presentations ()	PhV enguiry Phone	+353 1234 5678					
Reporting Names - Scientific ()	Sender Local Code						
□ Authorised - PRD126060 - 1/3 - Paracetamol 500 mg Film Coated Tablets	Info Date						
	Authorisation Country Code	Ireland					
MFL: MFL8780 - IE - Dublin	Authorisation Procedure	EU authorisation procedures					
-QPPV: User HB03O44 Num 01 (OTORGHB03O44) - 211696	Authorisation Status	Valid					
Medicinal Product Types (1)	Authorisation Number	PA1234/567/001					

4.14. Retrieving 'Valid' versions of medicinal product entities

In EVWEB, you can perform an advanced query to retrieve only valid versions of your **AMP entities**.

Go to 'Advanced Queries' and select 'Authorised Products (Valid version)'.

In the 'Conditions (AND)', select 'Owned' and run the query (using 'Run' or 'Run to Excel'):

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear E R Run Run to Excel	
Development Medicinal Products	Paracetamol 500*
Approved Substances	Description Name/Value
Development Substances	Product Strength Name (Matc
Sources	Product Company Name (Mat
MAHs	Product Form Name (Matches)
Sponsors	Authorisation Country
ATC Codes	Authorisation Procedure
-Routes of Administration	Authorisation Status
-Pharmaceutical Forms	Authorisation/Renewal Date (F
Master File Locations	Authorisation/Renewal Date (U
Attachments	MA Validity 🔽 Valid
Abstract Compositions	Authorisation Number (Matches)
	MRP/DCP/EMEA Number (Ma
Owned EVMPD Entities	EU Number (Matches)
Owned Authorised Products	Legal Basis
Authorised Products (Valid Version)	Invalidated Date
-Fields	Invalidated Date (From)
Conditions (AND)	Invalidated Date (Up to)
Results	
Owned Development Products	
Substance Names	
Approved Substance Names	Dermacoutical Form (Matchos)
Development Substance Names	Pouto of Administration (Mate
Approved Substances	
Pevelopment Substances	Substance (Code) (Matches)
Bources	Substance (Name) (Matches)
H MAHS	
E Sponsors	
ATC Codes	Owned V
Routes of Administration	Sender Identifier (Matches)
Pharmaceutical Forms	Sender Name (Matches)

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) user manual EMA/308954/2012

A list of AMPs which have a product validity set to 'Valid' will become available either in the active area or in an Excel file, depending on how you run the query:

Reset Application Reset Section Clear ReR	un Modify	Delete Excel Export	✓ Reload ✓ Loa	ad 🗕 🗆				
Authorised Medicinal Products								
Development Medicinal Products	Num	EV Code	Version	Version Date	Owner Identifier	Full Presentation Name	Product Short Name	MAH Name
Approved Substances	0001	PRD99739	4/4 Valid	2012/10/31 15:01.15	DCMTESTMAH	999	99	EUROPEAN MEDICI.
Sources	0002	PRD101581	3/3 Valid	2012/10/31 15:01.14	DCMTESTMAH	aaa	aaa	EUROPEAN MEDICI.
MAHs	0003	PRD108743	3/3 Valid	2012/10/31 15:01.15	DCMTESTMAH	HGFFJYGKJHKJ	FGXDT	EUROPEAN MEDICI.
Sponsors		PRD111056	2/2 Valid	2015/06/05 12:57.40 2014/10/03 14:05 23	DOMTESTMAN	DrugVero Ibuprofen F	DrugVero Forte	PHARMAX LIMITED
ATC Codes	0006	PRD111059	1/1 Valid	2014/07/02 10:05.23	DCMTESTMAH	Nikko tablets	Nikko	NEWPHARMA LTD.
-Routes of Administration	0007	PRD111081	2/6 Valid	2015/07/02 12:55.02	DCMTESTMAH	ProductX comprimido	ProductX	PHARMAX LIMITED
Pharmaceutical Forms	0008	PRD112205	3/3 Valid	2015/02/25 17:28.16	DCMTESTMAH	Luna 21 PharmaL co	Luna 21	PHARMAL LTD
Master File Locations	0009	PRD114960	1/3 Valid	2015/04/23 13:03.17	DCMTESTMAH	TabletsX	TabletsX	PHARMAL LTD
Attachments	0010	PRD114962	2/2 Valid	2015/04/24 11:47.41	DCMTESTMAH	Product Y Ibuprofen	DrugVero Forte	PHARMAX LIMITED
-Abstract Compositions								

- To identify AMPs, which were not updated (i.e. operation type 'Update' was not applied for that AMP) by the MAH following a validation by the Agency:
 - In EVWEB, go to 'Advanced Queries' and select 'Owned Authorised Products';
 - In the 'Conditions (AND)', select the field 'Product Validity' and set the value to 'Valid'. Also, select the field 'Product Pending' and set the value to 'Assessed';
 - Then run the query (using 'Run' or 'Run to Excel').
- To identify AMPs, which were updated (i.e., operation type 'Update' was applied for that AMP) by the MAH following a validation by the Agency:
 - In EVWEB, go to 'Advanced Queries' and select 'Owned Authorised Products';
 - In the 'Conditions (AND)', select the field 'Product Validity' and set the value to 'Valid'. Also, select the field 'Product Pending' and set the value to 'Pending Update';
 - Then run the query (using 'Run' or 'Run to Excel').

4.15. Comparing individual versions of a medicinal product entity

To compare individual versions of the medicinal product entity, retrieve the AMP entity so that it is available in the active area of EVWEB:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA							
□ Reset Application Reset Section Clear XML RTF Other Operations -							
E-Authorised Medicinal Products							
⊕ Authorised - PRD4334370 - 3/3 Valid - Ibuproten 400 tablety Development Medicinal Products	Description	Name/Value					
	EV Code	PRD4334370					
- Development Substances	Version	3/3 Valid					
Sources	Туре	Authorised (2)					
MAHe	Version Status	Accepted (1)					
C	Version Validity	Valid (1)					
Sponsors	Version Description	Current Valid Version					
AIC Codes	Product Validity	Valid (1)					
-Routes of Administration	Product Pending	Assessed (2)					
Pharmaceutical Forms	Product Nullified	No (0)					
Master File Locations	Current vs Previous	Double Click to Compare					
Attachments	Version Date	01/09/2016 14:59:24					
-Abstract Compositions	Version by	EMAMAHP					
. Queries	New Version ?	No					
	New Version by						
	Nullified	No					

In this specific product entity, there are 3 versions.

Double-click on the 'Double Click to Compare' text in the 'Current vs Previous' field:

Description	Name/Value
EV Code	PRD4334370
Version	3/3 Valid
Туре	Authorised (2)
Version Status	Accepted (1)
Version Validity	Valid (1)
Version Description	Current Valid Version
Product Validity	Valid (1)
Product Pending	Assessed (2)
Product Nullified	No (0)
Current vs Previous	Double Click to Compare
Version Date	01/09/2016 14:59:24
Version by	EMAMAHP
New Version ?	No
New Version by	
Nullified	No

A new window will open, providing a short description of the changes made between the current (i.e. the latest) and the previous versions:

https://eudravigilance.ema.europa.eu/?7CCDF184-2303-4978-	-88FE-94C662254EF0 - Product Versions C - Internet Explorer 🗖 🔳 🗮							
File Edit View Favorites Tools Help	x 📆 Convert 👻 🗃 Select							
Product Ve	rsions Changes							
PRD4334370								
From Version 2 Valid (20) (2016/09/01 14:59:24)	16/09/01 13:10:51) to 3 Valid							
Section	Changes							
Authorised Product	Changed PhV enquiry email							
	~							

In this specific example, a change was made in the 'PhV enquiry email' field. The square box next to the field(s) is there to help the end user keep on track of the reviewed changes in case that multiple changes were made within one AMP entity. By ticking off the box(es), the user can see which changes were reviewed and which are yet to be done.

🥭 h	ttps://e	udravigi	lance.ema.e	uropa.eu	/?7CCDF184-230)3-497B-88	FE-94C662254	FO - Product	Versions C -	Intern	et Explorer		• X
File	Edit	View	Favorites	Tools	Help					Х	📆 Conv	ert 🔻	🐻 Select
Product Versions Changes													
	Fra (20	om \ 16/(Versi 09/01	on 2 14:	2 Valid 59:24)	(2010	5/09/01	13:1():51) 1	to 3	3 Val	id	
	Sec	tio	1				Chan	ges					
			Auth	orise	ed Produ	ct	⊡ Chang	ed PhV-	enquiry	emai	ł		

Selecting/not selecting the relevant boxes has no impact on the changes made in the AMP or indeed the EVWEB.

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 included 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 SOCs, 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.

WE	B Trader	Create	Create and Send Product Reports				al Products	MedDRA	
	Reset App	lication	Reset Section	Clear	XMI	RTF	Other Opera	ations 👻	

The MedDRA section allows you to perform searches among SOC Terms, HLGT 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, expand the 'Queries' section in the tree-view area:

WEB Trader Create and Send Product Reports Medicinal Products MedDRA	
Reset Application Reset Section Clear Version	
SOC Terms	
HLGT Terms	
HLT Terms	
Preferred Terms	
Low Level Terms	
Queries	

WEB Trader Create and Send Product Reports Medici	Products MedDRA
Reset Application Reset Section Clear Version	
SOC Terms	
HLGT Terms	
HLT Terms	
Preferred Terms	······
Low Level Terms	
⊞ SOC Terms	
⊞ HLGT Terms	
⊞ HLT Terms	
Preferred Terms	
Low Level Terms	

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 allows 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.

Version

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:

WEB Trader Create and Send Product Reports N	Medicinal Products MedDRA	
WEB Trader Create and Send Product Reports N Reset Application Reset Section Clear Version SOC Terms HLGT Terms HLGT Terms HLT Terms Preferred Terms Low Level Terms SOC Terms HLGT Terms HLGT Terms Preferred Terms Preferred Terms HLGT Terms HLGT Terms HLGT Terms HLGT Terms HLGT Terms HLGT Terms HLT Terms HLT Terms Preferred Terms HLT Terms Preferred Terms HLT Terms Preferred Terms Low Level Terms Low Level Terms	Medicinal Products MedDRA Choose an option Press A - Z to find initial letter Press Enter to select, Escape to clear 24.0 23.1 23.0 22.1 22.0 21.1 21.0 20.1	Des
	19.1	
	19.1	
	19.0	

Once a version is selected, you can start performing simple and advanced queries for that specific MedDRA version.

WEB Trader Create and Send Product Reports Medi	icinal Products MedDRA
Reset Application Reset Section Clear Version (2)	24.0) Run
SOC Terms	
HLGT Terms	Description Name/Value
HLT Terms	Fields
Preferred Terms	Conditions (AND)
Low Level Terms	Results
Queries	
SOC Terms	
HLGT Terms	
HLT Terms	
Preferred Terms	
Low Level Terms	
Fields	
Conditions (AND)	
Results	

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 area:

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 area:

WEB Trader Create and Send Product Reports Med					
Reset Application Reset Se	ection Clear Version	ı (:			
SOC Terms		-			
HLGT Terms					
HLT Terms					
Preferred Terms					
Low Level Terms					
Queries					
SOC Terms					
HLGT Terms					
HLT Terms					
Preferred Terms					
E Low Level Terms					
Fields					
Conditions (AND)					
Results					

Type: "*glaucoma associated with ocular trauma*" in the simple query field on the top of the active area and press 'Enter' on your keyboard to perform the query. The results are displayed in the active area:

WEB Trader Create and Send Product Reports Med	ficinal Products	MedDRA		
Reset Application Reset Section Clear Version	0 🗆 🗹			
SOC Terms	*glaucoma assoc	iated with ocular tra	auma*	
HLGT Terms	Num	LLT Code	LLT Name	Is Deprecated
-HLT Terms	0001	10018313	Glaucoma associated with ocular trauma	No
Preferred Terms				
Low Level Terms				
Queries				

The columns' heading in the active area will provide the following information: 'Num' (number of items found), 'LLT Code' and 'LLT Name'.

To see further details of the result of your query, select the result in the active area and the result of our search will be displayed under 'Low Level Terms' in the tree-view:

WEB Trader Create and Send Product Reports Med	icinal Products	MedDRA		,,,,,,,, .
Reset Application Reset Section Clear Version	0 🗆 🗹			
SOC Terms	*glaucoma associ	iated with ocular tra	uma*	
HLGT Terms	Num	LLT Code	LLT Name	Is Deprecated
HLT Terms	✓ 0001	10018313	Glaucoma associated with ocular trauma	No
Preferred Terms				
Low Level Terms				
Glaucoma associated with ocular trauma				
<u>⊕</u> Queries				

Click on '+' at the left side of 'Glaucoma associated ...' in the tree-view area to move from 'Low Level Term' up to 'Preferred Terms'. Follow the same principle to view the SOC, HLT and SPEC CAT(s):

WEB Trader Create and Send Product Reports Media	inal Products	MedDRA		
Reset Application Reset Section Clear Version Clear				
SOC Terms	*glaucoma asso	ciated with ocular tra	uma*	
HLGT Terms	Num	LLT Code	LLT Name	Is Deprecated
HLT Terms	✓ 0001	10018313	Glaucoma associated with ocular trauma	No
Preferred Terms				
Low Level Terms				
Glaucoma associated with ocular trauma				
Preferred Terms (1)				
🖻 Glaucoma traumatic				
HLT Terms (2)				
Primary System Organ Class (es)				
All Linked System Organ Class (es)				

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA	
Reset Application Reset Section Clear Version Image: Clear		
-SOC Terms	*glaucoma associated with ocular trauma*	
HLGT Terms	Num LLT Code LLT Name Is	s Deprecated
HLT Terms	O001 10018313 Glaucoma associated with ocular trauma N	vo
Preferred Terms		
E Low Level Terms		
⊟ Glaucoma associated with ocular trauma		
Preferred Terms (1)		
🖻 Glaucoma traumatic		
🖻 HLT Terms (2)		
Glaucomas (excl congenital)		
⊨ Primary System Organ Class (es)		
Injury, poisoning and procedural complications		
⊟ All Linked System Organ Class (es)		
Eye disorders		
Injury, poisoning and procedural complications		
🗄 Queries		

To delete the queries performed in the MedDRA section, you can either deselect all items in your active area and use the 'Clear' functionality in the main menu, or click on the 'Reset Section' button:

WEB Trader	Create	reate and Send Product Reports			Medicina	I Products	MedDRA
Reset App	olication	Reset Section	Clear	Vers	ion 🗘		

5.5. How to perform an Advanced Query

You can perform advanced queries through the query function, located in the tree-view area. An advanced query performs a more customized and structured search than the generic one.

Click on '+' next to 'Queries' in the tree-view area. 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)

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA
Reset Application Reset Section Clear Version Run	
SOC Terms	
HLGT Terms	
HLT Terms	
Preferred Terms	
Low Level Terms	
E SOC Terms	
HLGT Terms	
HLT Terms	
Preferred Terms	
E. 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 <u>3.6.2. Advanced Query</u>.

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 area. Then, click on '+' at the left side of 'Preferred Terms' that appears under the 'Query' item in the tree-view area.

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.

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA	
Reset Application Reset Section Clear Version Run Run		
SOC Terms		
HLGT Terms	Description	
HLT Terms	✓ PT Code	Default selection
Preferred Terms	✓ PT Name	Default selection
Low Level Terms		
⊕ SOC Terms		
⊞ HLGT Terms		
HLT Terms		
Preferred Terms		
Fields		
Conditions (AND)		
⊞ Low Level Terms		

Now select 'Conditions' in the tree-view area, to define the conditions of the search.

The two columns in the active area will provide the following information: 'Description' and 'Name/Value'.

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA
Reset Application Reset Section Clear Version E R Run	
SOC Terms	
HLGT Terms	Description Name/Value
HLT Terms	SOC Code
Preferred Terms	SOC Name (Matches)
-Low Level Terms	HLGT Code
	HLGT Name (Matches)
B SOC Terms	HLT Code
HLGT Terms	HLT Name (Matches)
HLT Terms	PT Code 🗌
Preferred Terms	PT Name (Matches)
Fields	LLT Code 🗌
Conditions (AND)	LLT Name (Matches)
⊕ Results	

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', Press 'Enter' on the keyboard and type '*glaucoma*' in the text field just on the right side of the selected item. Then press 'Enter' on the keyboard in order to have the information available in the active area

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA
Reset Application Reset Section Clear Version E R Run	
SOC Terms	
HLGT Terms	Description Name/Value
HLT Terms	SOC Code
Preferred Terms	SOC Name (Matches)
Low Level Terms	HLGT Code
	HLGT Name (Matches) 🗹 Glaucoma
BOC Terms	HLT Code
HLGT Terms	HLT Name (Matches) 🗌
⊞ HLT Terms	PT Code 🗌
Preferred Terms	PT Name (Matches) 🗌
Fields	LLT Code 🗌
Conditions (AND)	LLT Name (Matches) 🗌
Results	
E Low Level Terms	

To extend the search to all High Level Terms containing the word glaucoma, you should enter an asterisk (*) at the beginning and at the end of the word that you are entering:

Description	Name/Value
SOC Code	
SOC Name (Matches)	
HLGT Code	
HLGT Name (Matches)	*Glaucoma*
HLT Code	
HLT Name (Matches)	
PT Code	
PT Name (Matches)	
LLT Code	
LLT Name (Matches)	

Run A new dynamic button ('Run') has appeared on the main menu. Click on 'Run' 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.

WEB Trader Create and Send Product Reports Medicinal Products	MedDRA
Reset Application Reset Section Clear Version E R Run	
SOC Terms	
HLGT Terms	Description Name/Value
HLT Terms	SOC Code
Preferred Terms	SOC Name (Matches)
Low Level Terms	HLGT Code
	HLGT Name (Matches) 🗹 *Glaucoma*
SOC Terms	HLT Code
HLGT Terms	HLT Name (Matches)
HLT Terms	PT Code
Preferred Terms	PT Name (Matches)
Fields	LLT Code
Conditions (AND)	LLT Name (Matches)
Results	
⊞ Low Level Terms	

WEB Trader Create and Send Product Reports Medicinal Product	MedDRA		
Reset Application Reset Section Clear Version Reset Res	Run Modify	Delete Excel	
SOC Terms			
-HLGT Terms	Num	PT Code	PT Name
HLT Terms	0001	10002532	Aniridia
-Preferred Terms	0002	10009934	Coloboma
Low Level Terms	0003	10026829	Marfan's syndrome
	0004	10002640	Anophthalmos
B SOC Terms	0005	10044686	Trisomy 13
⊞ HLGT Terms	0006	10048734	Phakomatosis
⊞ HLT Terms	0007	10049066	Cohen syndrome
Preferred Terms	8000	10061528	Congenital optic nerve anomaly
Fields	0009	10062766	Stargardt's disease
Conditions (AND)	0010	10062940	Neuropathy, ataxia, retinitis pigmentosa syndrome
⊟- Results	0011	10067159	Septo-optic dysplasia
Result 01 October 2021 19:02:39	0012	10018330	Glaucoma traumatic
Low Level Terms	0013	10035015	Pigmentary glaucoma
	0014	10078211	Pseudophakic glaucoma
	0015	10011005	Corneal dystrophy
	0016	10083306	Galactosialidosis
	0017	10024202	Lens abnormality, congenital
	0018	10041513	Spherophakia
	0019	10052642	Iris coloboma
	0020	10057411	Congenital iris anomaly

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 3.5.3. 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 <u>www.whocc.no</u>)
CAS	Chemical Abstract Service (Number)
САР	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

МАН	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
ZIP file	Zipped compressed file