3 February 2026
EMA/389113/2025
Information Management

User manual for the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) user interface (XEVMPDweb)

For marketing authorisation holder and sponsor organisation users

Version 1

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of Content

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 (XEVMPD) also known as 'Article 57 database'.

This user manual provides information about the User Interface (UI) of the XEVMPD made available by the EMA to users from MAH and sponsor organisations in February 2026.

For marketing authorisation holders, the documents recommended 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 Reporting requirements for marketing-authorisation holders webpage.

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

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

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

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

*The screenshots included in this user manual were taken from the **XEVMPDweb UAT and XCOMP environment** accessed via **Google Chrome browser**.*

1.2. About EudraVigilance

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

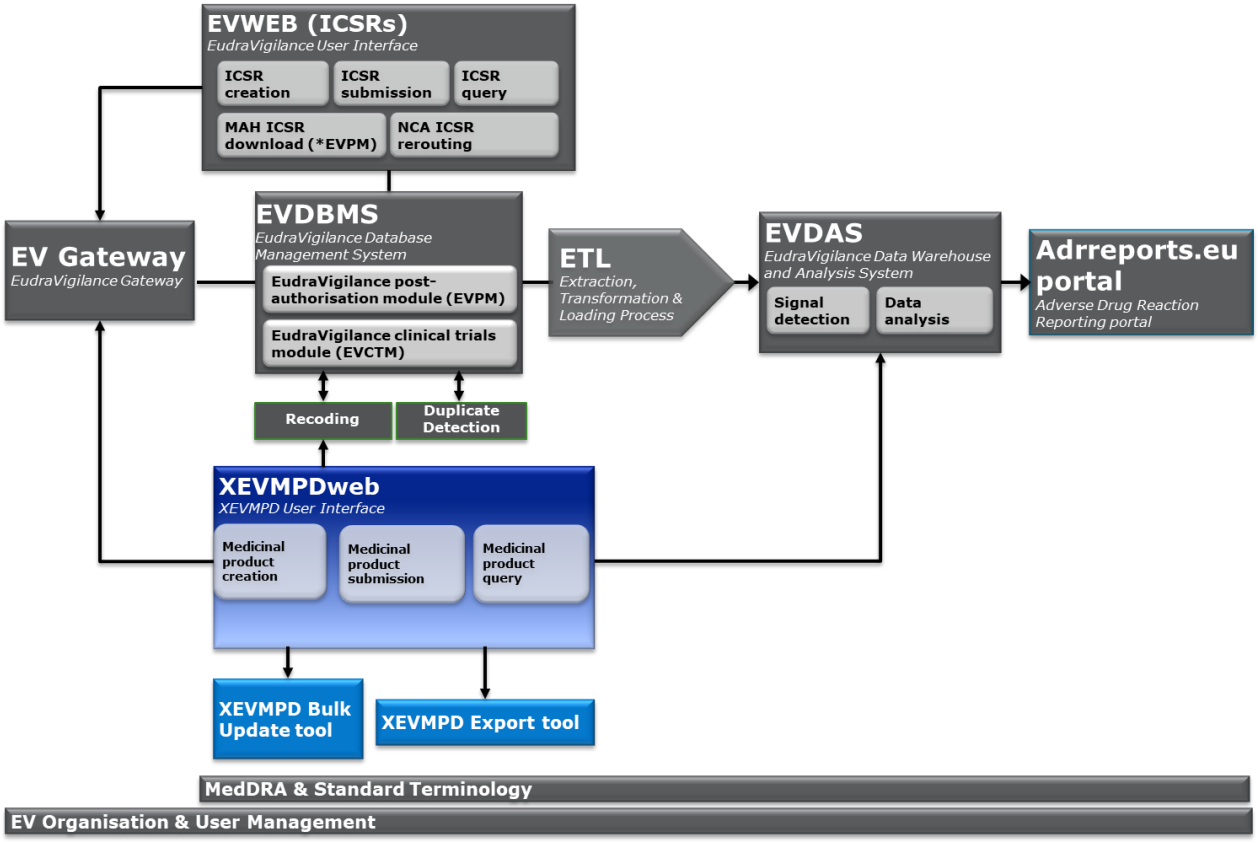
It supports the:

- secure exchange, processing and evaluation of Individual case safety reports (ICSRs) related to medicinal products authorised or studied in clinical trials in the European Economic Area (EEA);
- signal detection, evaluation and management;
- proactive release of information on adverse reactions in compliance with personal data protection legislation in the European Union (EU);
- electronic submission of information of medicinal products authorised in the EU/EEA;
- 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;
- **eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)**: a reference source for the coding of substances and medicinal products authorised in the EU/EEA and un-authorised medicinal products used in clinical trials in the EU/EEA.
- **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.

1.2.1. EudraVigilance system overview



1.2.2. EudraVigilance ESTRI gateway

The EudraVigilance gateway is a data-processing network which follows the formats and standards of the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

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 EudraVigilance registration webpages for information on how to register your organisation with EudraVigilance for **medicinal product reporting**.

1.3. About XEVMPD

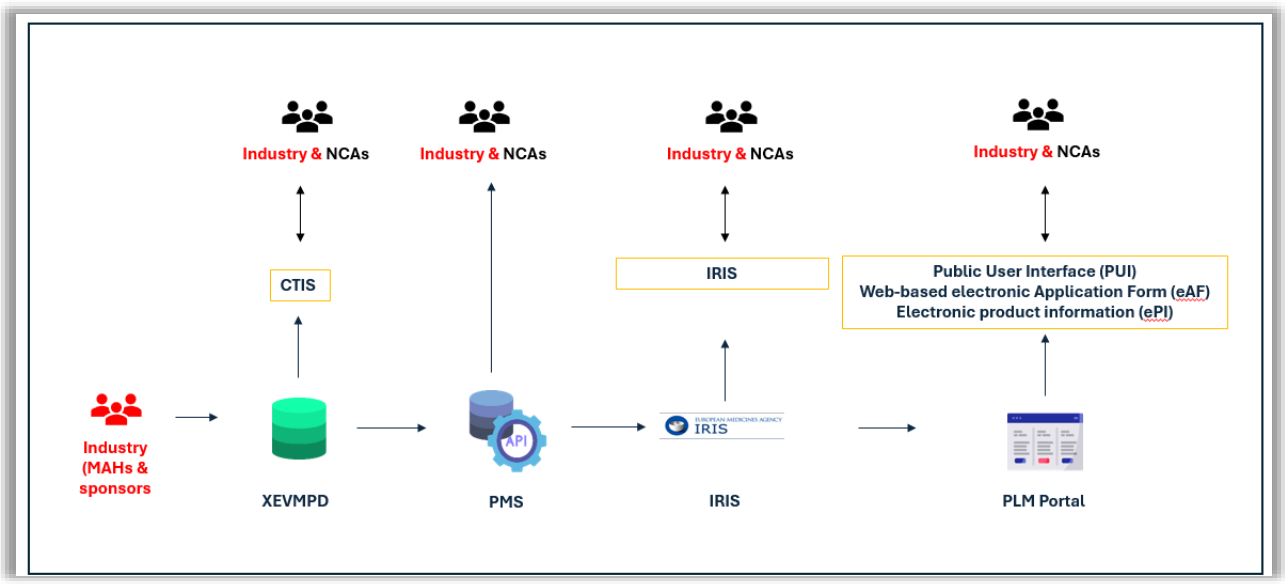
XEVMPD, also known as the 'Article 57 database' is a centralised source of information on authorised and un-authorised medicines.

- Authorised medicinal product data is submitted and maintained in the XEVMPD by marketing authorisation holders, as per Article 57(2) of Regulation 726/2004.
- Un-authorised (referred to in the XEVMPD as 'development') medicinal product data is submitted and maintained in the XEVMPD by sponsors, as per Article 81(3) of Regulation (EU) No 536/2014.
- Substance records and source records are submitted and maintained in the XEVMPD by EMA's Substance Management Service (SMS) data stewards on requests from MAHs, sponsors, national competent authorities (NCAs) etc.
- MAH and sponsor organisation records are submitted and maintained in the XEVMPD by MAHs and sponsors.
- Referential terms (pharmaceutical forms, routes of administration and ATC codes) are submitted and maintained in the XEVMPD by:
  - EMA's Referentials Management Service (RMS) data stewards (standard and proposed terms) on request from MAHs, sponsors, NCAs etc. and
  - MAHs and sponsors (development terms).
- MedDRA terms are maintained by the Maintenance and Support Services Organization (MSSO) and uploaded in the XEVMPD by the EMA.
- Master File Location (MFL) records are submitted and maintained in the XEVMPD by MAHs.
- Attachments are submitted in the XEVMPD by MAHs and sponsors.

Authorised medicinal product data from the XEVMPD is used by the Application Programming Interface (API) of the Product Management Service (PMS) and from there it is further consumed by other EMA systems.

Development medicinal product data from the XEVMPD is consumed by the Clinical Trials Information System (CTIS).

The below picture shows brief overview of where XEVMPD data is used:

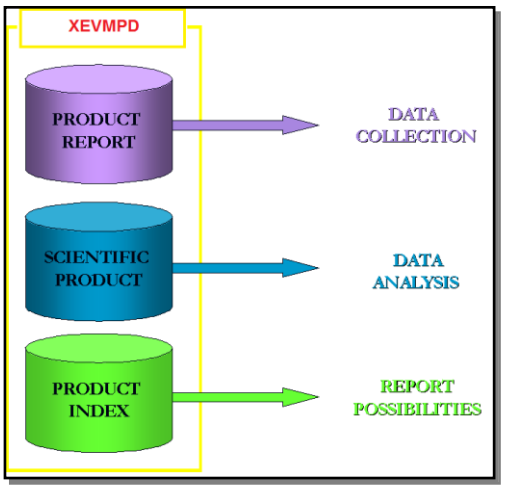


XEVMPD data is therefore used to support:

- the recoding of Individual Case Safety Reports (ICSRs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) in EudraVigilance;
- the registration of clinical trials in CTIS;
- the generation of fees and charges payable to EMA (PharmacoVigilance fees, PSUR fees etc.);
- PharmacoVigilance inspections;
- monitoring of medicines to prevent and manage medicines shortages and availability issues; etc.

The XEVMPD consists of three different databases:

- product report database (product report);
- scientific product database (scientific product); and
- 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 Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance, section *1.2.13. AMP – Presentation Name element structure (AP.13).*

The document 'European Medicines Agency splitting of the full presentation name of the medicinal product best practice: procedure and principles to handle product name in the EudraVigilance Medicinal Product Dictionary (XEVMPD)' 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 development medicinal product data. It is therefore very important that the **development medicinal product name and/or code information** is provided for the DMP correctly**.** For related information please refer to the Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD), section *1.6. Product name, product code, product other name (DP.6).*

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'.

1.3.1. 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 EudraVigilance: how to register webpage.

1.3.1.1. Marketing authorisation holders (MAHs)

As per Article 57(2) of Regulation (EC) No 726/2004 as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012, 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 Legal Notice on the Implementation of Article 57(2) of Regulation (EC) No. 726/2004.

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 Reporting requirements for marketing-authorisation holders 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.

1.3.1.2. Sponsors

Directive 2001/20/EC, 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 CT Regulation (EU) No 536/2014: *"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."*

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.

1.3.2. 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.

1.3.3. 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
Additional monitoring designation	EMA	
Amount value type (i.e., concentration type) list	EMA	UCUM
Approved substance list	EMA	
Attachment file type list	EMA	
Attachment type list	EMA	
Attachments list	MAH/sponsor	
Authorisation procedures	EMA	
Authorisation status	EMA	
Concentration unit list	EMA	UCUM
Country code list	EMA	ISO
Development administration route list	MAH/sponsor	
Development ATC Code list	MAH/sponsor	
Development pharmaceutical form list	MAH/sponsor	
EEA Language list	EMA	ISO
Legal basis list	EMA	
MAH organisation list	MAH/sponsor	
MedDRA level	EMA	MSSO
MedDRA term	EMA	MSSO
MedDRA version	EMA	MSSO
Medical Device list	EMA	
Medicinal product type	EMA	
MFL list	MAH	
Numerator/Denominator prefix list	EMA	
Orphan drug designation	EMA	
Proposed administration route list	EMA	
Proposed ATC Code list	EMA	
Proposed pharmaceutical form list	EMA	
QPPV list	MAH (via EV Registration process)	
Reference source list	EMA	
Role of the Ingredient list	EMA	
SME status list	EMA	
Sponsor organisation list	MAH/sponsor	
Standard administration route list	EMA	EDQM
Standard ATC Code list	EMA	WHO
Standard pharmaceutical form list	EMA	EDQM
Substance class list	EMA	ISO

Look-up	Maintained by	Reference
Unit of measure list	EMA	UCUM
Unit or presentation list	EMA	UCUM

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.

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:** 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).

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

1.3.3.1. 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 and Phone number
- Sender Local Code
- (*) Info Date - the date of lifting of suspension (as 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 designation
- (*) Additional Monitoring
- (*) Invalidated MA date (as applicable per the relevant business rules)
- (*) Product Name information
- Package description
- Comment
- (*) Pharmaceutical Dose Form(s)
- (*) Route of Administration(s)
- Ingredients:
  - (*) Active Ingredient(s)
  - (*) Strength of the Active Ingredient(s)
  - (*) Excipient(s)
  - Strength of the Excipient(s)

  - (*) Adjuvant(s)
  - (*) Strength of the Adjuvant(s)
- Old Drug Ingredient(s)
- Medical Devices
- (*) Product ATC Code(s)
- (*) Product Indication(s) (using MedDRA coding)
- (*) Previous EV Code(s) (as applicable per the relevant business rules)
- (*) Product Attachment(s) including validity declaration (as applicable per the relevant business rules)
- (*) Legal Basis
- (*) Medicinal Product Type
- (*) Authorised Pharmaceutical Form

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

1.3.3.2. 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
- (*) Pharmaceutical Dose Form(s)
- (*) Route of Administration(s)
- Ingredients:
  - (*) Active Ingredient(s)
  - (*) Strength of the Active Ingredient(s)
  - Excipient(s)
  - Strength of the Excipient(s)
  - (*) Adjuvant(s)
  - (*) Strength of the Adjuvant(s)
- Old Drug Ingredient(s)
- Medical Devices
- Product ATC Code(s)
- Product Indication(s) (using MedDRA coding)
- Product Attachment(s) including validity declaration (if applicable and as per relevant business rules)

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

1.3.3.3. 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
- CAS[1] Number / CBD[2] / Molecular Formula
- Alias/ Translation(s)
- Substance International Code (including the Source)
- Substance Parent Code (including the Substance Type)
- Previous EV Code(s)
- Substance Attachment(s)

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

1.3.3.4. Source

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

- (*) Source Name
- Comment

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: 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).

1.3.3.5. 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
- State

1 CAS = Chemical Abstract Service
2 CBD = Chemical/Biological Description

- (*) Postcode
- (*) Country Code
- Telephone Number
- Telephone Extension
- Telephone Country Code
- Fax Number
- Fax Extension
- Fax Country Code
- E-mail Address
- Comment

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

1.3.3.6. Sponsor organisation

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

- (*) Sponsor Name
- Sponsor Sender ID
- (*) Address
- (*) City
- State
- (*) Postcode
- (*) Country Code
- Telephone Number
- Telephone Extension
- Telephone Country Code
- Fax Number
- Fax Extension
- Fax Country Code
- E-mail Address
- Comment

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

1.3.3.7. ATC Code

The information collected for a standard/proposed/development ATC Code includes the below information [the symbol (*) means mandatory]:

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

For details on what information should be provided in the individual fields 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: 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).

Sponsors can insert a development ATC Code entity in the XEVMPD as per information in the above referenced guidance.

1.3.3.8. Pharmaceutical form

The information collected regarding a standard/proposed/development/ pharmaceutical form includes the below information [the symbol (*) means mandatory]:

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

For details on what information should be provided in the individual fields 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: Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD).

Sponsors can insert a development pharmaceutical form entity in the XEVMPD as per information in the above referenced guidance.

1.3.3.9. Route of administration

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

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

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: 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).

Sponsors can insert a development route of administration entity in the XEVMPD as per information in the above referenced guidance.

1.3.3.10. Printed product information (PPI

The information collected regarding the document provided as a 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). **PSI is not in use and should not be provide by MAHs/sponsors.**

1.3.3.11. 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
- State
- (*) Postcode
- (*) 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* Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance.

1.3.4. Data ownership in XEVMPD

Each entity (product, substance, organisation, referential term, MFL or attachment) successfully inserted in the XEVMPD via an XEVPRM is owned in the XEVMPD by the **headquarter (HQ) organisation** to which the sender of the entity belongs to in the EudraVigilance registration database.

If the sender of the entity is an affiliate or virtual affiliate registered in EudraVigilance under a HQ profile of an organisation, the entity is owned in the XEVMPD by the HQ organisation; organisations registered in EV as affiliates or virtual affiliates never own any entities in the XEVMPD.

Entities submitted in the XEVMPD by EMA data stewards (such as all standard referential terms and approved substances) are owned in the XEVMPD by the EMA.

1.3.5. Data validation in XEVMPD

1.3.5.1. Technical validation

When an XEVPRM is created and submitted (either from the user's internal tool, via the 'Post' functionality or via the 'Send' functionality in XEVMPDweb), the system checks if the data within the XEVPRM was entered in accordance with the technical and business rules in place.

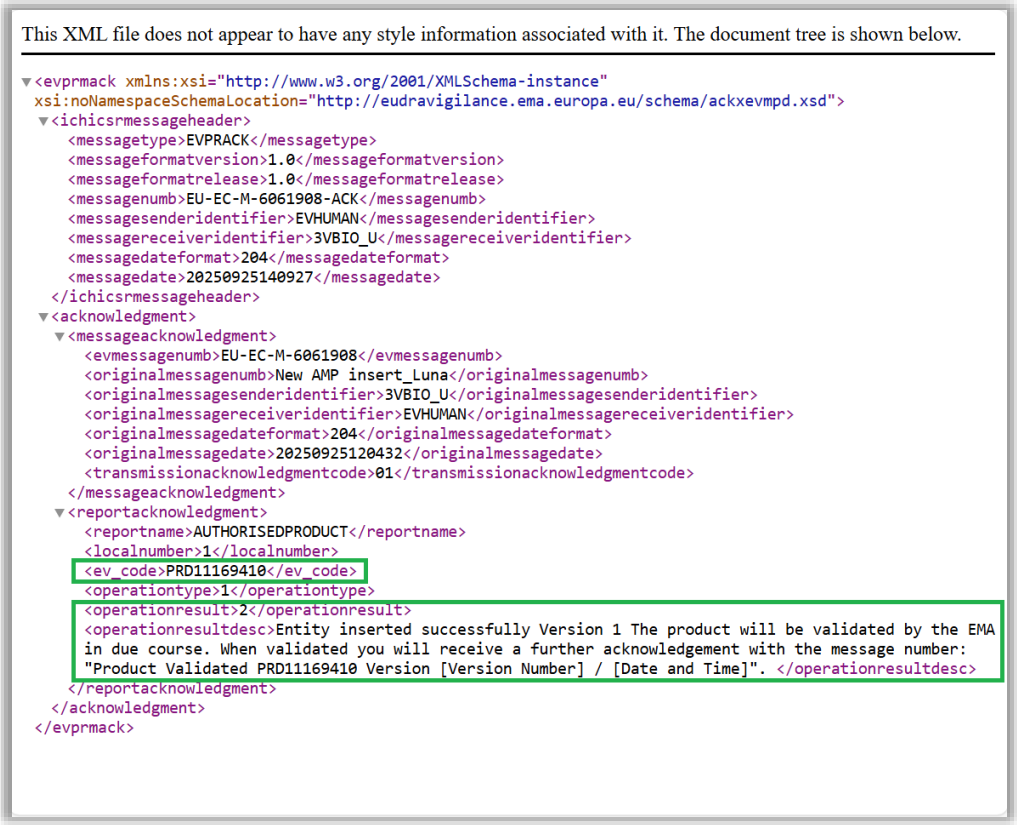
The sender organisation will receive an XEVPRM acknowledgement (ACK) for every XEVPRM sent to the XEVMPD; the receipt of the 1st and 2nd ACK can be expected **within minutes and max withing 48 hours** since the submission XEVPRM was sent.

The XEVPRM ACK will confirm if:

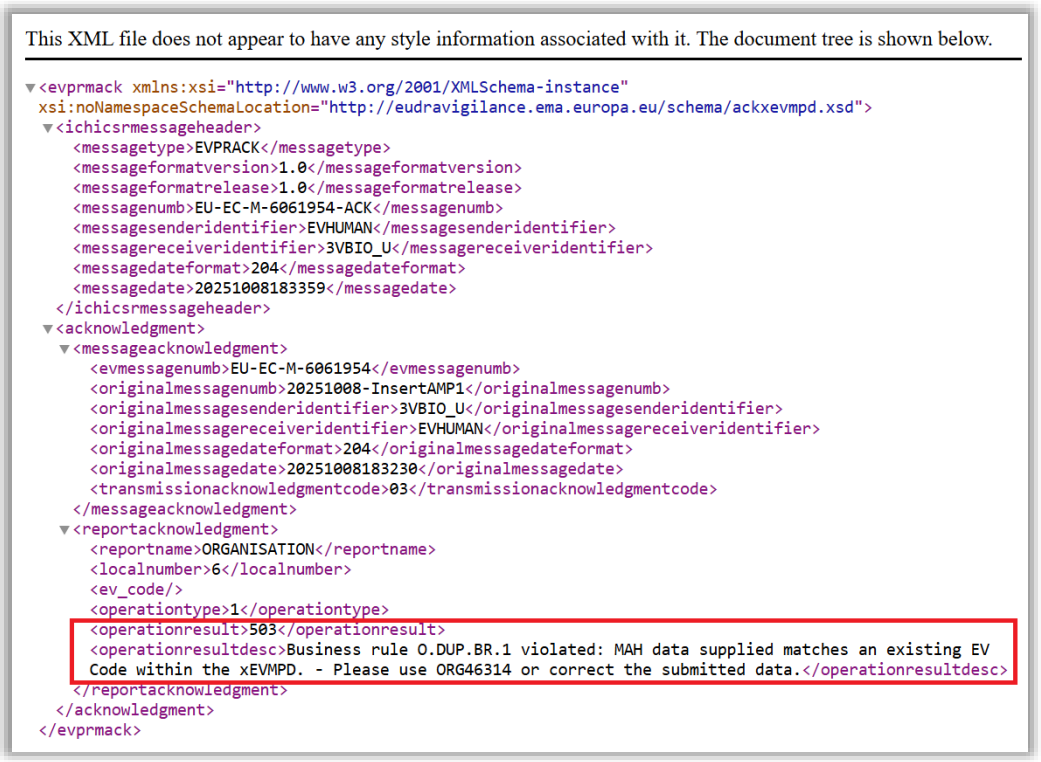
- the medicinal product report was loaded into the database or not (**1st level Acknowledgement**);
- the action performed (insert of a new entity or an amendment of an existing entity) was performed successfully (**2nd level Acknowledgement**);

The 1st and 2nd ACK are combined in one XML file regardless of the transmission mode of the organisation (WEB Trader or Gateway):

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



- If the system validation reports **errors**, the information might be sent but not loaded in the XEVMPD; the ACK will describe the error(s) present in the submitted XEVPRMs. For example:



Detailed information related to an XEVPRM Acknowledgement can be found in Chapter 5: Extended EudraVigilance product report acknowledgement message and *Appendix 5 – Element Acknowledgement Codes* of Chapter 3.I: Extended EudraVigilance product report message (XEVPRM) technical specifications.

The user/organisation should amend the XEVPRM to correct the reported errors and re-submit the file.

1.3.5.2. Content validation

Authorised medicinal products

In July 2014, the EMA began the review of quality and integrity of authorised medicinal product information submitted the XEVMPD. This quality and integrity review is referred to as 'validation'.

An overview of the principles of the validation are outlined in the published Data Quality Control methodology document.

The EMA performs the validation of information referenced in **the latest version** of the received authorised medicinal product data available in the XEVMPD. The information referenced in the XEVMPD data fields is checked against the information stated in the referenced document [i.e. the summary of product characteristics (SmPCs), Module 3 extract, copy of the marketing authorisation approval etc.] and against the business rules described in Chapter 3.II: XEVPRM User Guidance.

The result of the validation is communicated to the sender organisation version of the AMP that is being validated via a **3rd level Acknowledgement.**

- If the there is no need for the EMA validation team to perform any amendments to the data, or to contact the MAH to request amendments/clarification, the validated version is flagged as "Valid" in the XEVMPD as submitted by the MAH:
  - The 'Version Validity' field in the AMP in XEVMPDweb will reference *'Valid'*;

  - The 'Product Validity' field in the AMP in XEVMPDweb will reference *'Valid'*;
  - The 3rd ACK will reference the text: *"Product validated successfully as submitted."*
- Where necessary, the EMA might perform an amendment of the product information as part of the validation; the validated version is flagged as *"Valid"* in the XEVMPD.
  - The 'Version Validity' field in the AMP in XEVMPDweb will reference *'Valid'*;
  - The 'Product Validity' field in the AMP in XEVMPDweb will reference *'Valid'*;
  - The 3rd ACK will reference the text: *"Entity updated successfully" and "Product validated following EMA edit of data. Please note that your product data was not deemed valid as submitted and was edited as part of the validation process as follows…:"* The list of changes made within the AMP will also be provided in the 3rd ACK.

Not every version of an AMP is validated.

The EMA aims to validate newly submitted AMP records **within 2 weeks since the initial submission** of the AMP information.

There is **no defined timeline for the validation of updated product information**; updated product entries are validated as and when required to support a specific business process, or if the updated product entry was validated more than 2 years ago.

No further validation is performed on product information referenced in nullified or invalidated authorised medicinal product records and therefore, no validation related XEVPRM ACK should be expected for such product records.

Further information related to AMP validation can be found in the document Quality control of medicinal-product data submitted as per the legal requirement introduced by Article 57(2) of Regulation (EC) No 726/2004.

For further information related to the different validation related fields, refer to section *1.3.6.* ***Product status fields*** of this manual.

Development medicinal products

The EMA does not perform dedicated content validation of development product information in the XEVMPD; **DMP entities are automatically flagged as validated by the system** (i.e., the 'Product Validity' field in XEVMPDweb displays the text *"Valid"*) upon their initial submission by the sponsor organisation. This is to allow for the DMP to be available for the recoding of SUSARs.

Other XEVMPD entities

- Standard and proposed referential terms submitted in the XEVMPD by the EMA are automatically flagged as validated in the XEVMPD.
- Proposed terms, historically submitted in the XEVMPD by MAHs/sponsors, may be flagged as validated in the XEVMPD, if referenced in validated product entries.
- Development terms, submitted in the XEVMPD by MAHs/sponsors, may be flagged as validated in the XEVMPD, if referenced in validated product entries.
- MAH and sponsor organisations become validated by the system once referenced in an updated version of a product entity that is flagged as validated.

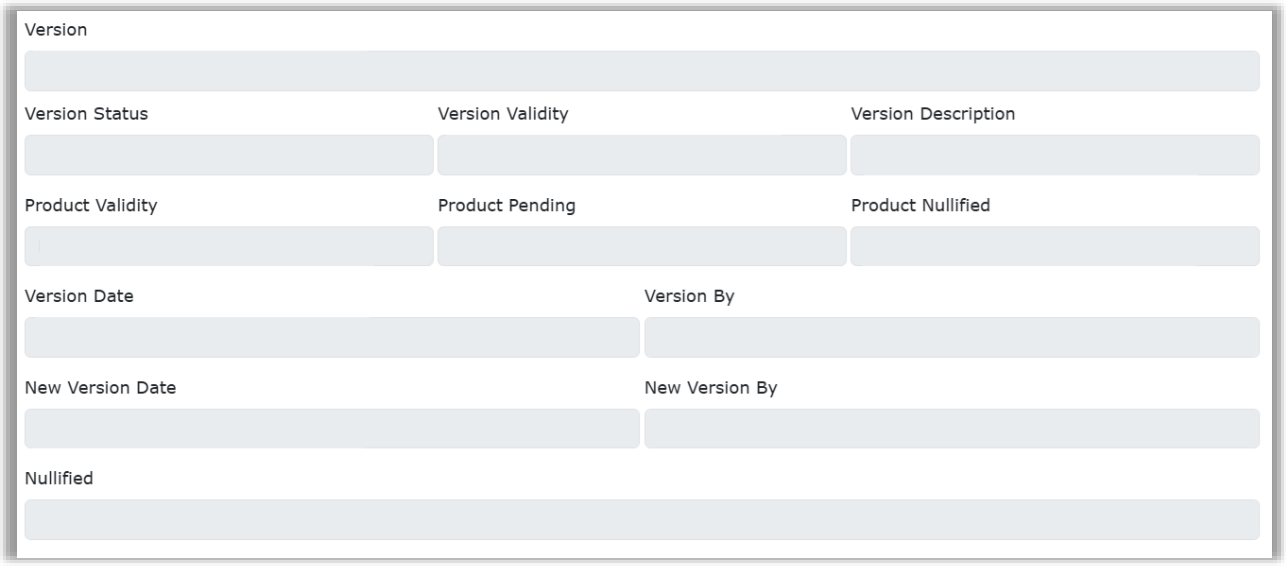
- No validation is performed on MFL entities, although some may have been historically flagged as validated if referenced in a validated AMP.
- No validation is performed on attachment entities.

1.3.6. 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 XEVMPDweb to provide information on the history and status of the **product entity** (i.e. an AMP and/or DMP):



- **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 was 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 was not assessed by EMA),
- *Valid* (i.e. this version of the product was not 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.

This field indicates whether the product entity was flagged as:

- *Not Assessed* (i.e., no version of this product was assessed by EMA),
- *Valid* (i.e., a version of this product was assessed as 'Valid' by EMA),
- *Need MAH follow-up* (i.e., this version of the product was assessed by EMA and MAH follow-up is needed); the status is currently not used, MAHs are contacted directly as an when needed.

- **Product Validity**

This field indicates whether at least one of the product versions was flagged as validated by the EMA or not. The following values are available:

- *Not Assessed* (i.e., no version of this product was assessed by EMA),
- *Valid* (i.e., at least one version of this product was assessed as 'Valid' by EMA),
- *Need MAH follow-up* (i.e., the validation of the product was attempted by EMA but not possible due to missing information; 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**

This field references the date and time of the receipt of the message containing this product version is included (e.g., '09/07/2025 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') in this field.

- **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*

MAH users can also compare the **current versus the previous version** of the same AMP record (excluding nullified products) using the 'Compare' functionality; see section *3.5.1. Compare* for related information.

1.3.7. Data maintenance in XEVMPD

Before a user, or an organisation, is allowed to modify data in the XEVMPD, the system checks who is the owner organisation of the entity and what is the status of the entity.

Only the owner organisation (registered in EV as a HQ) and/or the affiliate(s) registered under this HQ profile and their users, is/are allowed to maintain the data that they submitted in the XEVMPD. The actions that can be performed on the data (such as update, invalidation or nullification) by users from the owner organisation depend on the status of the entity:

- **Update of data** (via 'Update' operation type') can be performed on an XEVMPD entity unless that entity is nullified or invalidated (in case of AMPs).
- **Invalidation of an AMP** (via 'Invalidate MA' operation type) can be performed on an AMP unless that AMP entity is nullified.
- **Nullification of data** (via 'Nullify' operation type) can be performed on an XEVMPD entity unless that entity is referenced in other entities (such as products), validated by the EMA[3] or invalidated.

MAHs and/or sponsors cannot perform maintenance related operations on entities owned in the XEVMPD by the EMA [i.e. substances, sources, proposed or standard terms (ATCs, pharmaceutical forms, routes of administrations)]; these will lead to a negative XEVPRM ACK.

EMA data stewards can perform amendments of information in invalidated AMPs and nullifications of validated entities on behalf of the owner organisation, on request submitted using the 'Request (for) XEVMPD/Art.57 Services' ticket available in the EMA Service Desk.

Amendments to these entities in the XEVMPD can be requested as follows:

[3] This does not apply to DMP entities; these can be nullified by the owner organisation even if flagged as validated in the XEVMPD.

- **Amendment or nullification of substance** entity in the XEVMPD can be requested via 'Request SMS services' ticket submitted via EMA Service Desk.
- **Amendment or nullification of source** entity, **proposed or standard ATC Code**, **proposed or standard pharmaceutical form** and/or **proposed or standard route of administration** in the XEVMPD can be requested via an 'RMS change request' ticket submitted via EMA Service Desk.
- **Amendment of information within an invalidated AMP** or **nullification of validated entities** can be requested via 'Request (for) XEVMPD/Art.57 Services' ticket submitted via EMA Service Desk.

An overview of the operation types that **MAH and/or sponsor users can perform on XEVMPD entities owned by their HQ organsations** in XEVMPDweb is provided below:

	Insert (1)	Update (2)	Nullification (4)	Invalidate MA (6)
Authorised medicinal product (AMP)	yes	yes, unless invalidated or nullified	yes, unless validated by EMA, invalidated, or referenced in an AMP/DMP that is not nullified	yes, unless nullified
Development medicinal product (DMP)	yes	yes	yes	no
Approved substance	no	no	no	no
Development substance	no	no	no	no
Attachment	yes	no	no	no
Master File Location (MFL)	yes	yes	yes, unless referenced in an AMP that is not nullified	no
Source	no	no	no	no
MAH organisation	yes	yes	yes, unless historically validated by the EMA, or referenced in an AMP that is not nullified	no
Sponsor organisation	yes	yes	yes, unless historically validated by the EMA, or unless referenced in a DMP that is not nullified	no
Development Pharmaceutical Form (PhF)	yes	yes	yes, unless referenced in a DMP that is not nullified	no
Proposed PhF	no	no	no	no
Standard PhF	no	no	no	no

	Insert (1)	Update (2)	Nullification (4)	Invalidate MA (6)
Development Route of Administration (RoA)	yes	yes	yes, unless referenced in an DMP that is not nullified	no
Proposed RoA	no	no	no	no
Standard RoA	no	no	no	no
Development ATC Code	yes	yes	yes, unless referenced in a DMP that is not nullified	no
Proposed ATC Code	no	no	no	no
Standard ATC Code	no	no	no	no

1.3.8. Data access

The access to data available in the XEVMPD is granted to the users of the XEVMPD User Interface based on:

- the ownership of the entity and
- the validation status of the entity (see section *1.3.6. Product status fields* for related information).

Access to personal data of the QPPV and commercially sensitive information (such as PSMFL location and all information related to development product entities and other data submitted by sponsors as development) is restricted.

Users from an MAH/sponsor organisation can view the following data in the new XEVMPD UI (XEVMPDweb):

- **AMPs:**

– **All versions of AMPs** (validated or not validated by the EMA) which are **owned** in the XEVMPD by their HQ organisation.

No visibility restrictions apply; users can view:

all available QPPV details,

all available PSMFL details,

all available administrable pharmaceutical product information (incl. concentration of excipients, if provided),

any attachment(s) and their content referenced in the AMP.

– **The last EMA-validated versions of AMPs** which are **not owned** in the XEVMPD by their HQ organisation.

Visibility restrictions apply; users cannot view:

any QPPV details,

all PSMFL information (only EV Code and PSMFL country are visible),

no concentration of excipients, if provided,

any attachment(s) and their content referenced in the AMP.

- **DMPs**:
  - All versions of DMPs owned in the XEVMPD by their HQ organisation.
- **Approved substances:**
  - All approved substances owned in the XEVMPD by the EMA.
- **Development substances:**
  - All development substances owned in the XEVMPD by their HQ organisation[4].
- **Source entities**:
  - All sources owned in the XEVMPD by their HQ organisation[4].
  - All sources owned in the XEVMPD by the EMA or other organisations[4].
- **MAH entities:**
  - All MAH organisations owned in the XEVMPD by their HQ organisation (validated or not validated by the EMA).
  - All MAH organisations not owned in the XEVMPD by their HQ organisation but historically validated by the EMA.
- **Sponsor entities**:
  - All sponsor organisations owned in the XEVMPD by their HQ organisation (validated or not validated by the EMA).
  - All sponsor organisations not owned in the XEVMPD by their HQ organisation but historically validated by the EMA.
- **Standard ATC Codes, standard pharmaceutical forms and standard routes of administration**:
  - All standard ATC Codes, pharmaceutical forms and routes of administration owned in the XEVMPD by the EMA.
- **Proposed ATC Codes, proposed pharmaceutical forms and proposed routes of administration**:
  - All proposed ATC Codes, proposed pharmaceutical forms and proposed routes of administration owned in the XEVMPD by their HQ organisation[4].
  - All proposed ATC Codes, proposed pharmaceutical forms and proposed routes of administration not owned in the XEVMPD by their HQ organisation.
  - All proposed ATC Codes, proposed pharmaceutical forms and proposed routes of administration owned in the XEVMPD by the EMA.
- **Development ATC Codes, development pharmaceutical forms and development routes of administration:**

[4] If submitted historically.

- All development ATC Codes owned in the XEVMPD by their HQ organisation.

- **Master File Location (MFL) entities**:
  - All available PSMFL details owned in the XEVMPD by their HQ organisation.
  - MFL EV Code and MFL country of MFL entities not owned in the XEVMPD by their HQ organisation.

- **Attachment entities**:
  - All attachments owned in the XEVMPD by their HQ organisation.

The table below provides an overview of visibility rules in the XEVMPD:

XEVMPD entity	Users from owner organisation	Non-owner users	Users from national competent authorities
Approved substance	Not applicable	All substance information	All substance information
Attachment	All information	No information	No information
Attachment referenced in AMP	All information	No information	No information
Attachment referenced in DMP	All information	No information	No information
Authorised medicinal product (AMP)	All information from every version of the AMP entity	Restricted information from validated versions of the AMP entity	All information from validated versions of the AMP entity
Development ATC Code	All information	No information	No information
Development medicinal product (DMP)	All information from every version of the DMP entity	No information	All information from validated versions of the DMP entity
Development Pharmaceutical Form (PhF)	All information	No information	No information
Development Route of Administration (RoA)	All information	No information	No information
Development substance	All information	No information	All substance information
MAH organisation	All information	All information from a validated version	All version
Master File Location (MFL)	All information	Restricted information	All information

Proposed ATC Code	All information	All information	All information
Proposed PhF	All information	All information	All information
Proposed RoA	All information	All information	All information
Source	All information	No information	All information
Sponsor organisation	All information	All information from validated version	All version
Standard ATC Code	Not applicable	All information	All information
Standard PhF	Not applicable	All information	All information
Standard RoA	Not applicable	All information	All information

1.3.9. Controlled vocabularies and terminologies

Terminologies and Controlled Vocabularies (CVs) are integrated in EudraVigilance; the below CVs are available on the Agency's website, section 'Controlled vocabularies', although some of the published files are no longer updated:

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

1.4. User interface

In addition to the automated message generation and processing, the EudraVigilance database management system also provides interactive tools to allow for a "manual" creation of safety reports and medicinal product reports by users via a web interface:

- The EudraVigilance user interface (for submission of ICSRs) is called **EVWEB.**
- The XEVMPD/Art.57 user interface (for submission of medicinal products) is called **XEVMPDweb.**

Each of the applicable user interfaces can be used by any marketing authorisation holder or sponsor of a clinical trial with reporting or submission obligations in the EU/EEA but has been specifically designed for small and medium size enterprises (SMEs), which do not have the necessary IT in-house tools available.

1.4.1. Access to XEVMPDweb 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 XEVMPDweb 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 EudraVigilance registration webpage. User registration is manged in the EMA Account Management portal.

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 following link.

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

XEVMPDweb can be accessed via any browser. However, as per the EMA IT policy, support is only provided to users that access the application via Google Chrome or Microsoft Edge.

1.5. 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 substance information[5];
- source(s)[5];
- organisation(s): MAH or sponsor;
- ATC Code(s)[5];
- pharmaceutical form(s)[5];
- administration route(s)[5];
- attachment(s);
- master file location(s).

When creating an XEVPRM message using XEVMPDweb, the **'XEVPRM Message' section** allows specifying the **message header**, which is a mandatory section in the XEVPRM:

Users creating an XEVPRM in XEVMPDweb are required to assign only the *'Message Number'* to the XEVPRM that is being created, since the system will automatically complete the other message header information which is not displayed (i.e., sender ID, receiver ID, message date etc.).

- The **'Medicinal Products' section** allows users with the applicable user rights to create product reports for authorised and development medicinal products that need to be added or maintained in the XEVMPD.

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

- The **'Substances' section is** available only to EMA users and allows EMA users to create substance reports for substances that need to be added or maintained in the substance look-up table in the XEVMPD.
  - 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** is available only to EMA users and allows EMA users to create reference sources that need to be added or maintained in the 'Source' look-up table in the XEVMPD.
  - 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 in the XEVMPD.
  - There is no direct link between organisation entities in the Organisation Management System (OMS) and XEVMPD; if an organisation entity is entered in OMS, and the organisation information should also be available in the XEVMPD, users must insert the organisation information in the XEVMPD via an XEVPRM.
  - The MAH and sponsor organisation list in the XEVMPD is not the same as the list of organisations registered with EudraVigilance; if an organisation entity is registered in the EudraVigilance registration database, and the organisation information should also be available in the XEVMPD, users must insert the organisation information in the XEVMPD via an XEVPRM.
  - 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 Registration with EudraVigilance 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.
  - Non-EMA users can insert only 'Development' ATC Codes in the XEVMPD; these can be referenced only 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 in the XEVMPD.
  - 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.
  - Non-EMA users can insert only 'Development' pharmaceutical forms in the XEVMPD; these can be referenced only 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 in the XEVMPD.

  - 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.
  - Non-EMA users can insert only 'Development' routes of administration in the XEVMPD; these can be referenced only in development medicinal products.
- The '**Attachments**' **section** allows users to submit a document in the XEVMPD; documents can be submitted as printed product information (PPI) and/or printed substance information (PSI); PPI documents should be referenced as an attachment in an authorised and/or development medicinal product.
  - MAH/sponsor users should not submit documents as printed substance information (PSI) in the XEVMPD.
- 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 Guidance documents related 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;
- Chapter 5: Extended EudraVigilance product report acknowledgement message.

2. Access to the XEVMPD user interface (XEVMPDweb)

Before accessing XEVMPDweb, users must have:

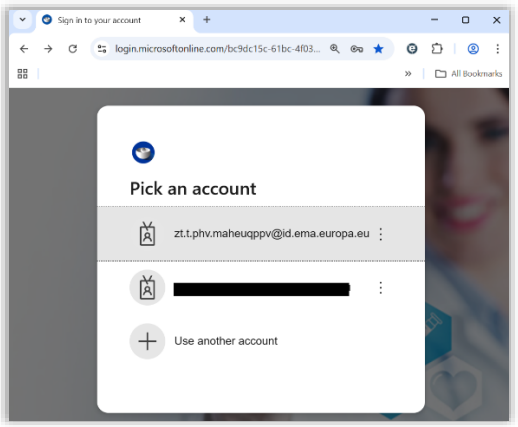
- internet connection;
- multi-factor authentication (MFA) set up;
- approved user access to the required environment for the required organisation via the EMA Account Management portal.

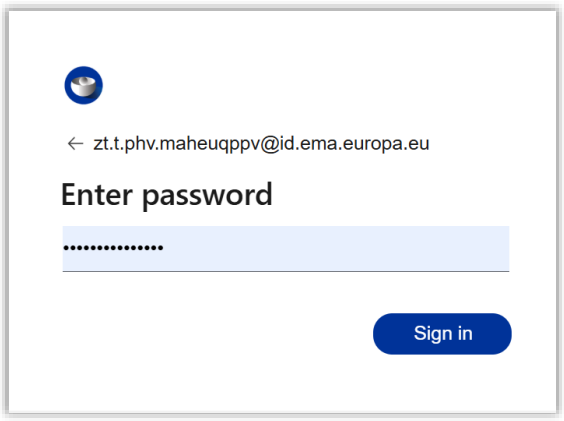
To access XEVMPDweb for XEVMPD production or XCOMP (test) environment, click on the below links, depending on which environment you wish to access:

- XEVMPDweb for **XEVMPD production environment**: https://eudravigilance-xevmpd.ema.europa.eu/
- XEVMPDweb **XEVMPD XCOMP (test) environment**: https://eudravigilance-xevmpd-xcomp.ema.europa.eu/

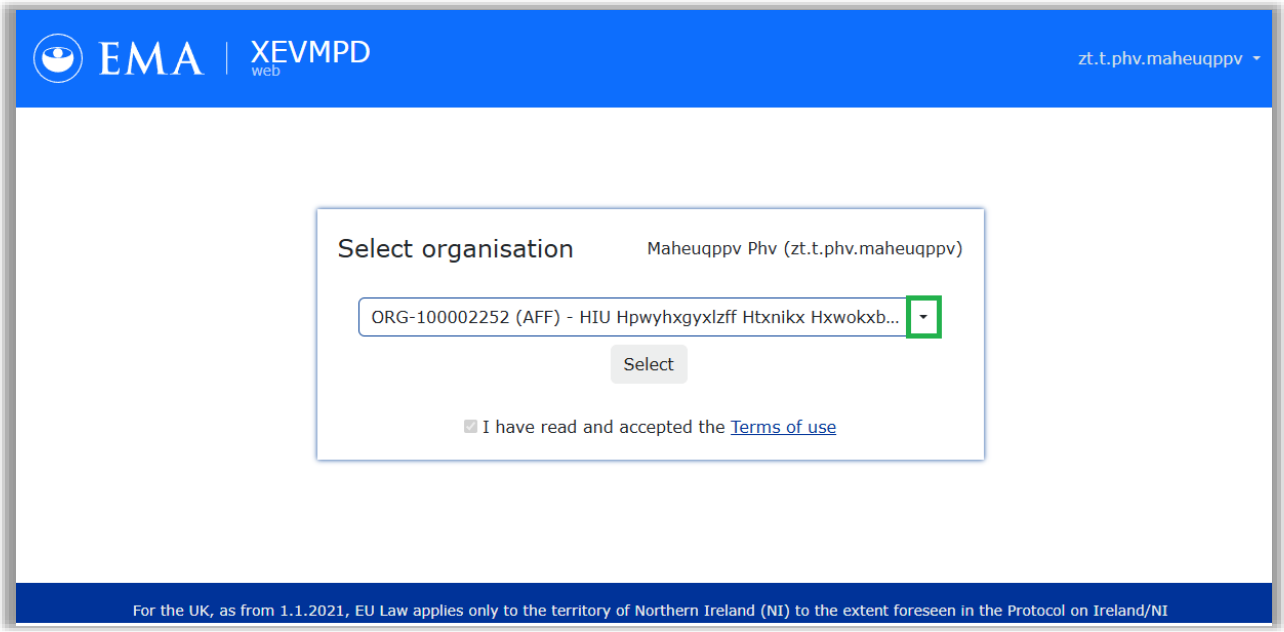
You will be required to complete a multi-factor authentication. See section *1.4.1. Access to XEVMPDweb and multi-factor authentication (MFA)* for related information.

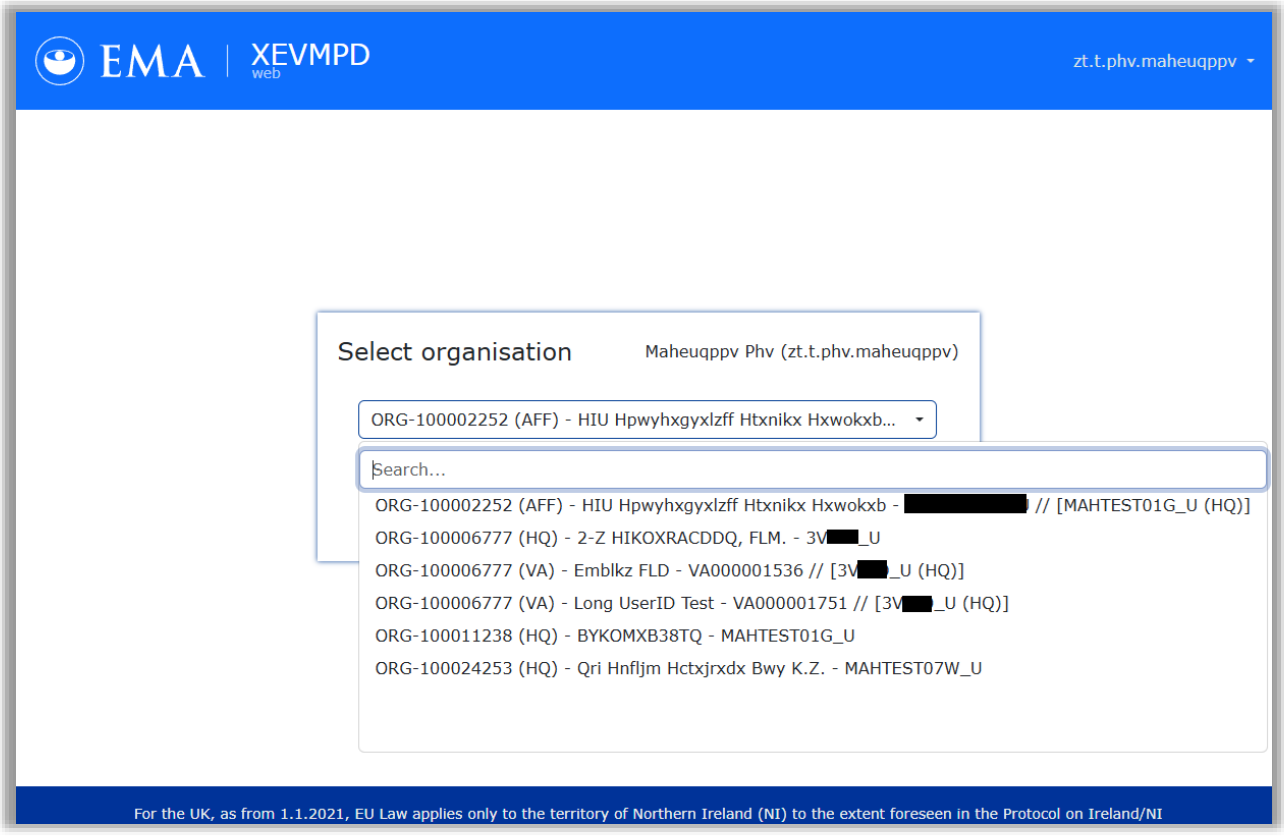
To complete the MFA, select the required user and enter the relevant password:





Once you signed in, the organisation/list of organisations, under which you are registered in the EMA Account Management portal as a user, will be displayed. If you are registered as a user for multiple organisations, you can expand the list of organisations by clicking on the arrow next to the first listed organisation:

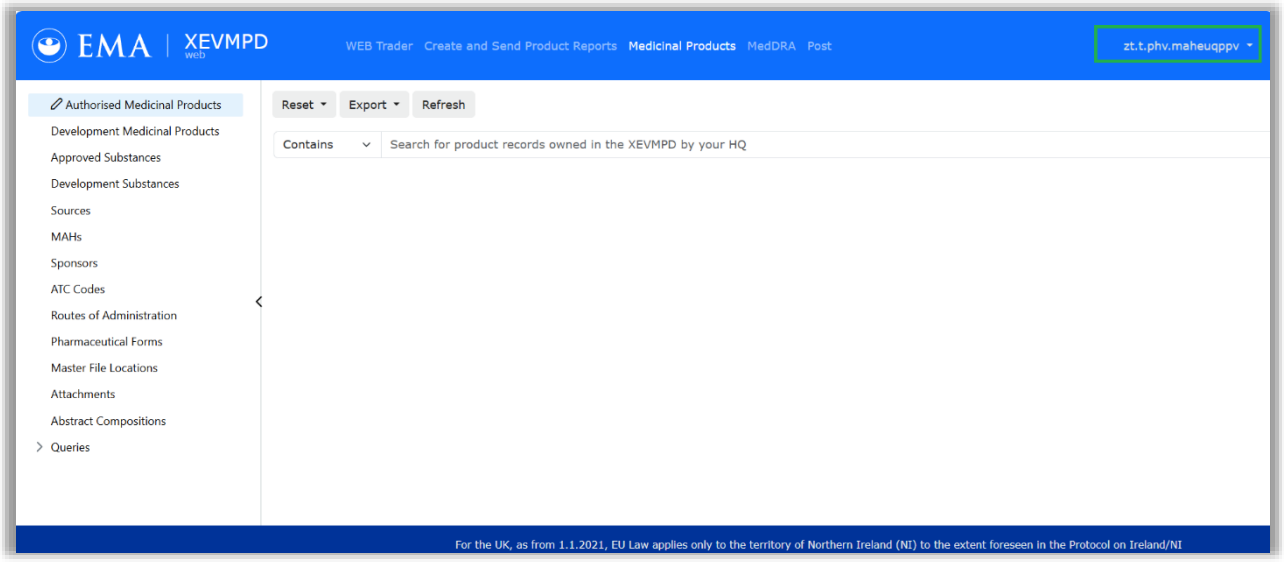




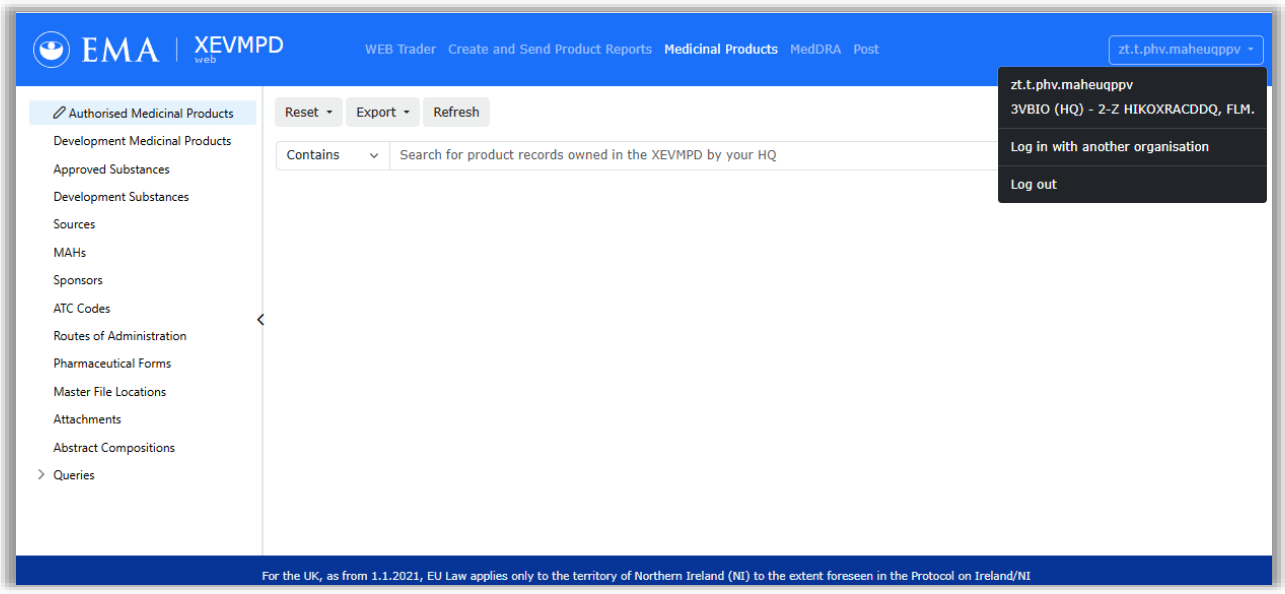
Select the organisation under which you wish to log on to XEVMPDweb:

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

You have now accessed XEVMPDweb; your username is shown in the top right-hand corner:

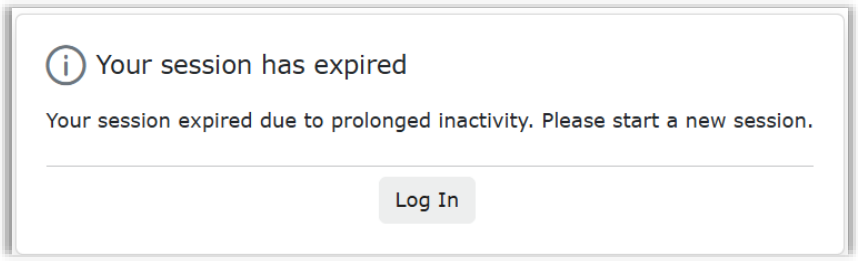


Upon clicking on the down-pointing arrow next to the username, the organisation ID under which you are logged on and the options to 'Log in with another organisation', for which you are registered as a user, and the 'Log out' option, are also displayed:

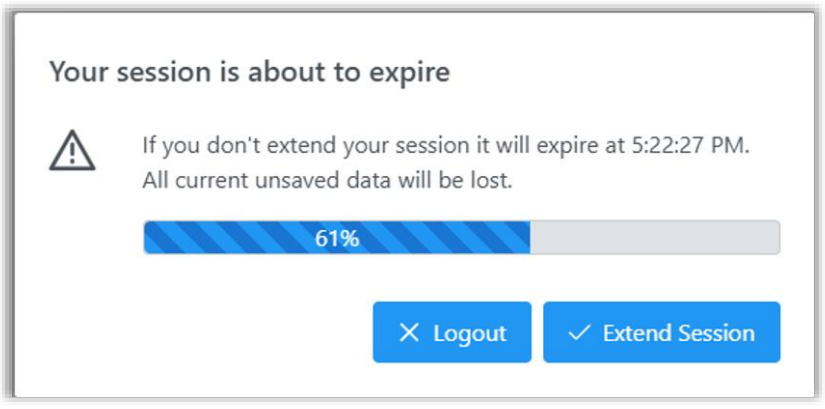


The 'Medicinal Products' section is opened by default.

In case of inactivity, the session will expire after 30 minutes; the below message will appear on the screen:



5 minutes before the session fully expires, the below warning will be displayed:



Users can extend the session by clicking on the 'Extend Session' button.

3. XEVMPDweb structure and functionalities overview

The main functionalities of the XEVMPD/Art.57 user interface are to:

- **Create 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 Article 81(3) of CT Regulation (EU) No 536/2014 requirements.

  XEVMPDweb 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.

- **Send XEVPRMs**
  - Either via the 'Send' functionality available in the 'Create and Send Medicinal Product Reports' section (available to Web Trader organisation users) or
  - Via the 'Post' section (available to Web Trader and Gateway users).

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

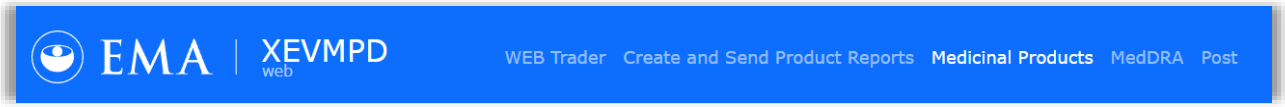
  XEVPRM acknowledgement messages are used to inform the sender organisation (i.e. the marketing authorisation holder, sponsor of a clinical trial, EMA) that the XEVPRM has been received and processed by the EMA, and of the outcome of validation of an authorised medicinal product entity performed by the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

  Only Web Trader users can receive XEVPRM ACKs via EVWEB. Gateway users will receive their XEVPRM ACKs via their local gateway solution.

- **Monitor sent XEVPRMs and received XEVPRM ACKs**, including **XEVPRMs rejected by the system** (e.g., due to non-conformity with the XEVPRM schema or non-adherence with the XEVPRM business and/or technical rules).
- **Export XEVPRMs** to enable the user to maintain a copy of the XEVPRM submissions locally.
- **Navigate, browse, and perform searches in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD).**
- **Export XEVMPD data.**
- **Browse and query MedDRA terminology** in its latest version in use.

3.1. XEVMPDweb structure

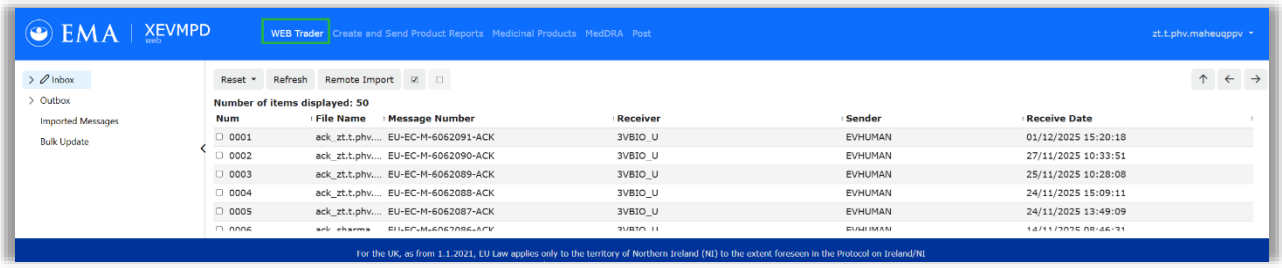
XEVMPD is currently divided into five sections:



These sections are always visible at the top of the screen, allowing users to switch from one section to another.

The 'Medicinal Products' section is displayed by default.

- **Web Trader section**

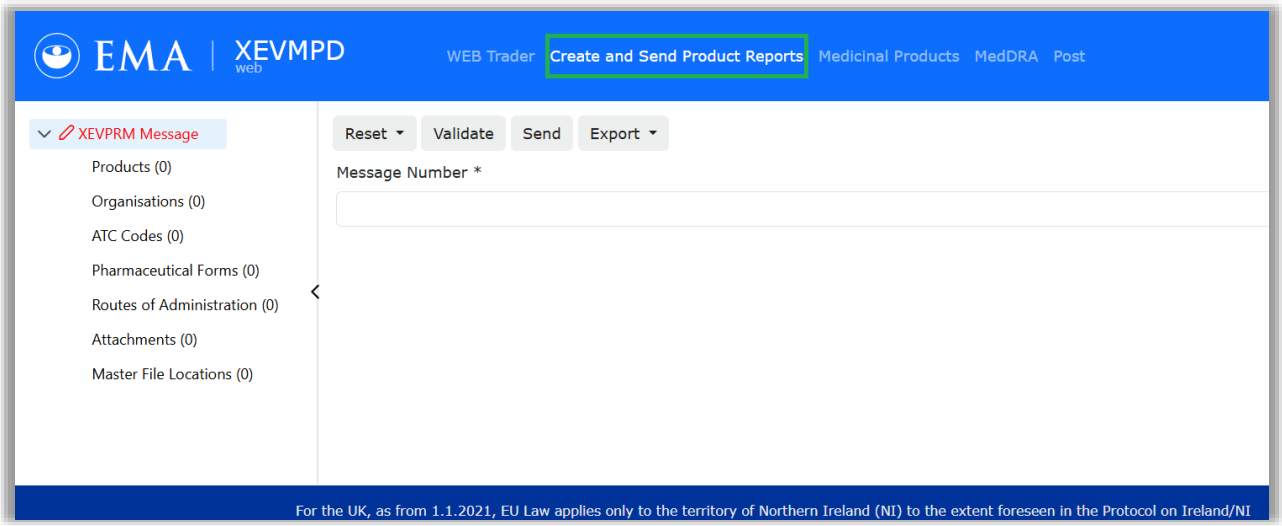


The 'WEB Trader' section allows users to:

- **access to the XEVPRM Acknowledgements** received in the XEVMPD by the organisation under which they are logged on; the received XEVPRM Acknowledgements are available in the 'Inbox' section in the tree-view area;
- **access the XEVPRMs sent in the XEVMPD** by the organisation under which they are logged on; the submitted XEVPRMs are available in the 'Outbox' section in the tree-view area;
- **import XML files** of XEVPRMs located on their computer and upload them in 'Create and Send Product Reports' section;
- **export an overview of the submitted XEVPRMs and/or received XEVPRM acknowledgements** from Inbox/Outbox into an Excel file;
- **load the selected XEVPRMs and/or XEVPRM acknowledgement(s)** into the tree-view area via the 'Remote Import' functionality;
- **access to the XEVPRMs generated via the Bulk Update tool** by the organisation under which they are logged on; these are available in the 'Bulk Update' section of the tree-view area'.

  The Web Trader section is not available to users logged on to XEVMPDweb under the ID of an organisation that is registered in EudraVigilance as a Gateway user.

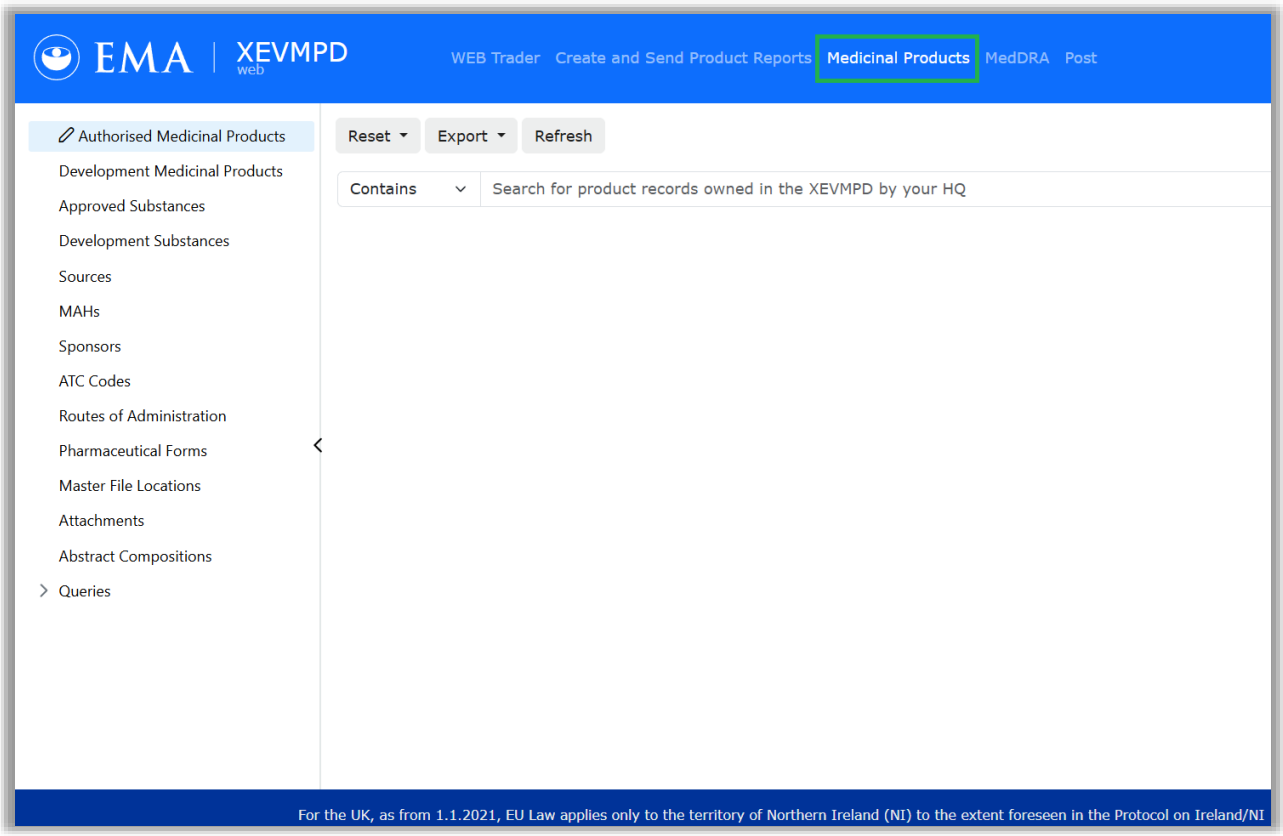
- **Create and Send Product Reports section**



The 'Create and Send Product Reports' section allows users to:

- **create an XEVPRM** containing medicinal product entities, organisations, ATC Codes, Pharmaceutical Forms, Routes of Administrations, Attachments and/or Master File Location entities;
- **validate the information within the XEVPRM** to ensure that mandatory data is provided; the validation of the XEVPRM is performed via the 'Validate' functionality;
- **send an XEVPRM** using the 'Send' functionality; this functionality is only available to users from organisations registered in EudraVigilance as Web Trader users;
- **Export the XEVPRM** using one of the available formats under the 'Export' functionality.

- **Medicinal Products section**

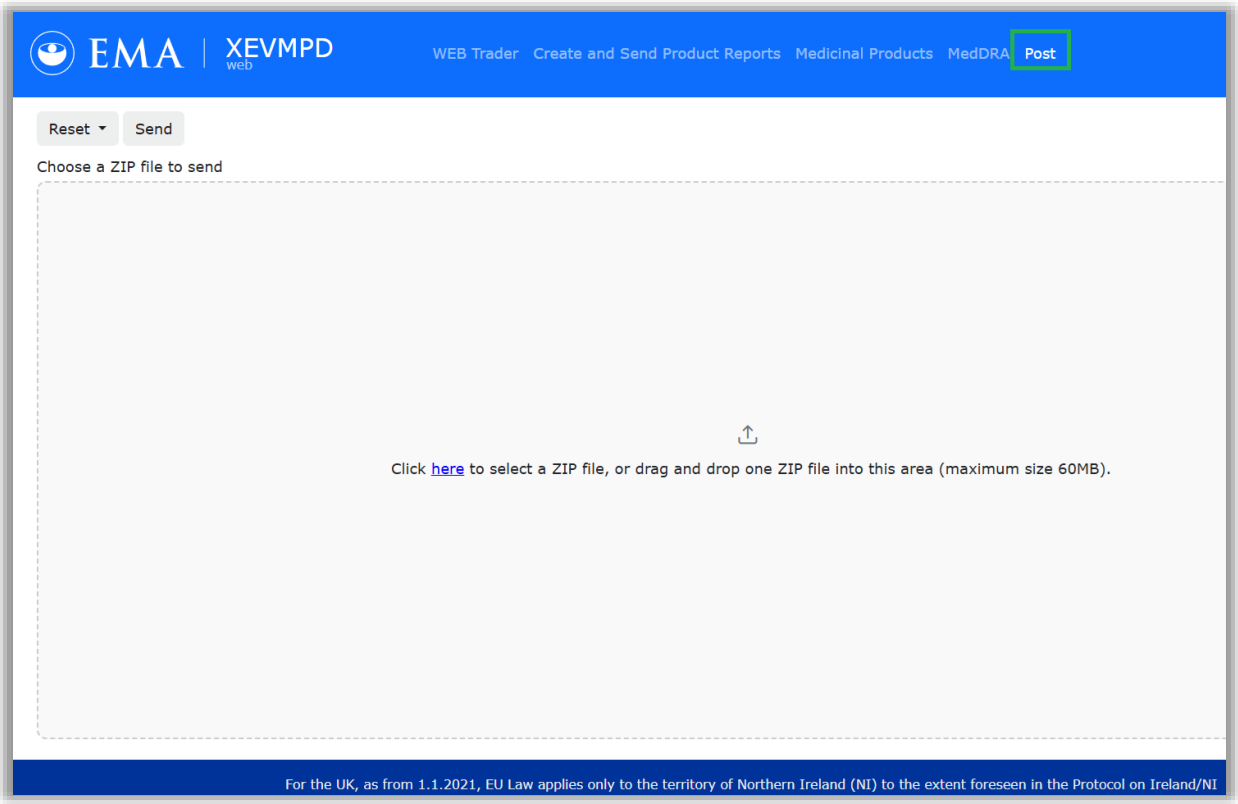


The 'Medicinal Products' section allows users to **browse** and **perform searches** for all available XEVMPD entities, taking into consideration the applicable ownership and visibility rules, and export.

- **MedDRA section**

The MedDRA section allows users to **browse** and **perform searches for MedDRA terms** at all levels of MedDRA.

- **Post**



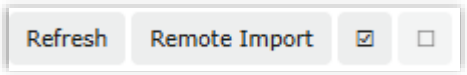
The Post section allows users from organisations registered in EudraVigilance as Gateway and/or Web Trader organisations to **submit ZIP files of XEVPRMs**.

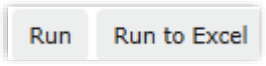
3.2. Default and dynamic buttons

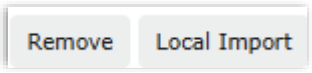
Each section displays a set of buttons for the functionalities applicable to data available in that section. Some buttons will always be available by **default** (such as the 'Reset' button), others will change (**dynamic** buttons) depending on:

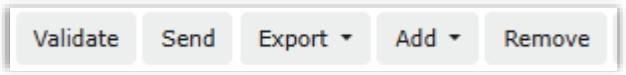
- the section of the application in which the user is working and the item(s) selected and
- the applicable visibility and ownership rules in place.

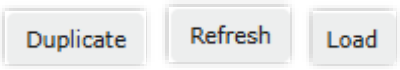
Examples of dynamic buttons include:

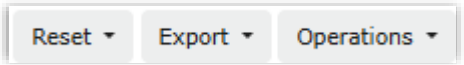








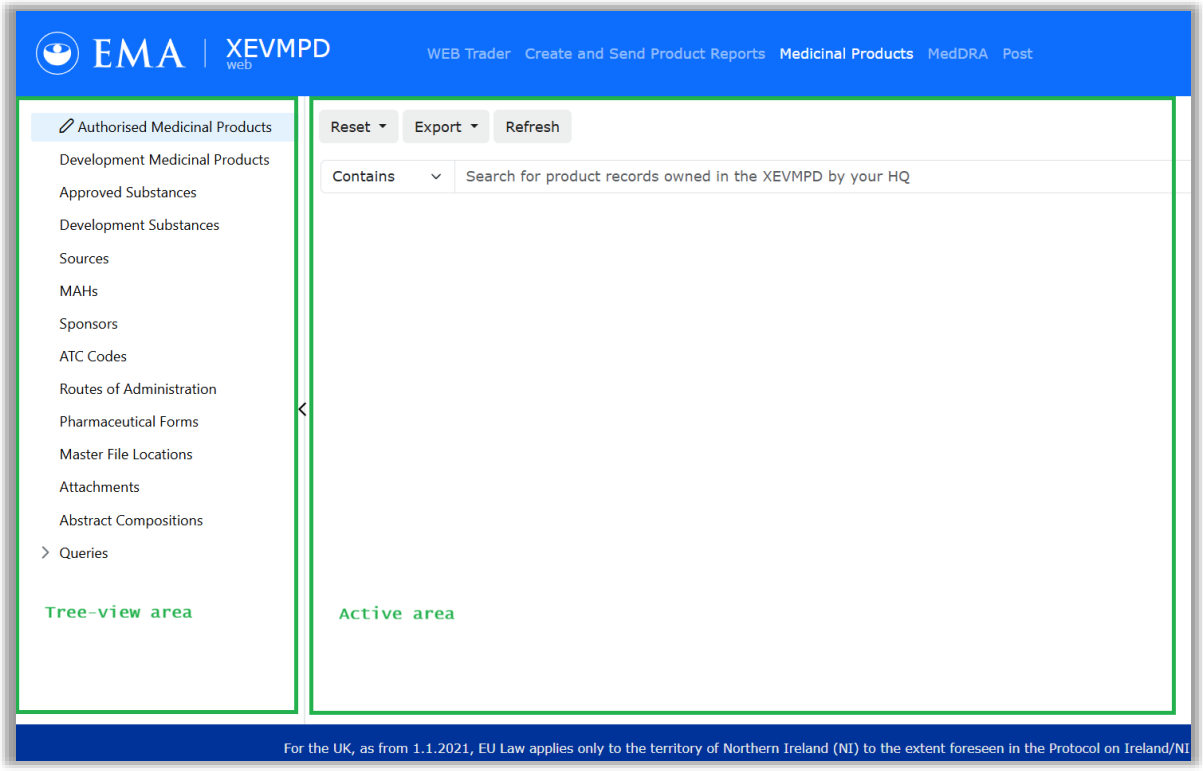




The functionalities related to the use of these buttons are described section *3.5. Functionalities* of this manual.

3.3. Tree-view and active areas

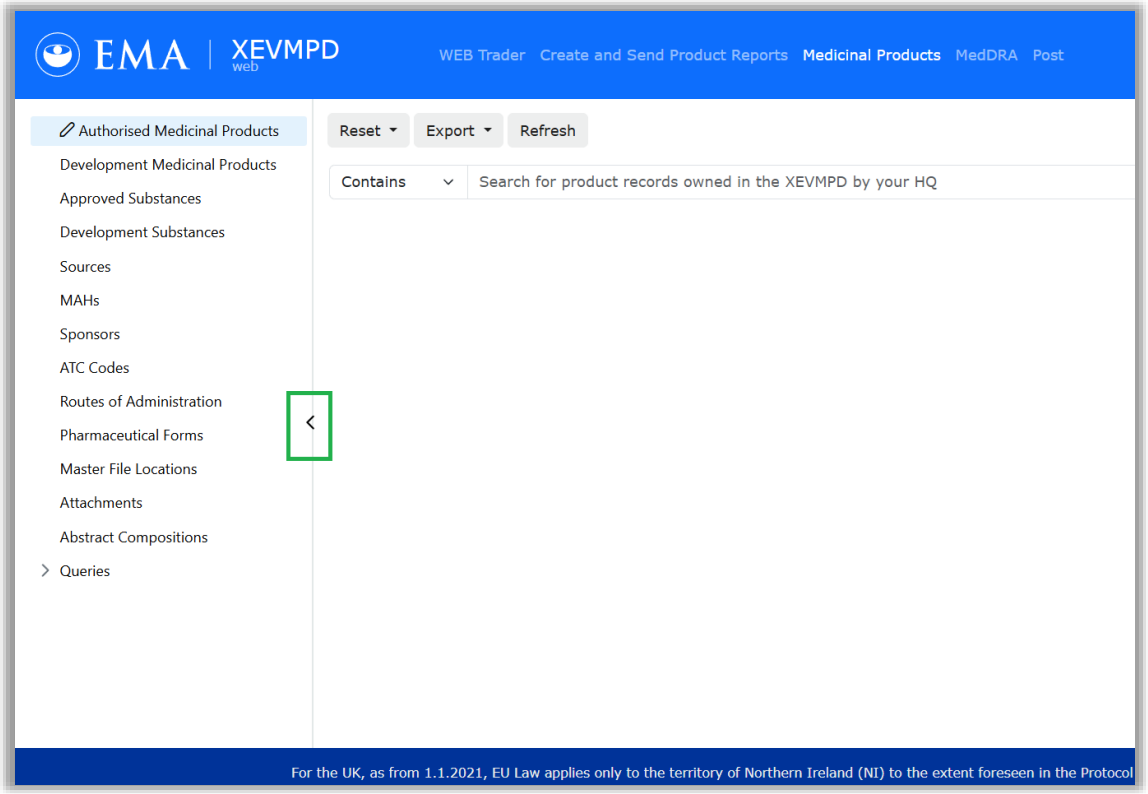
In most sections, except for the 'Post', 'Bulk Export' and 'Bulk Update' sections, the screen is divided vertically into two parts: on the left side is the **tree-view area** and on the right is the **active area**:



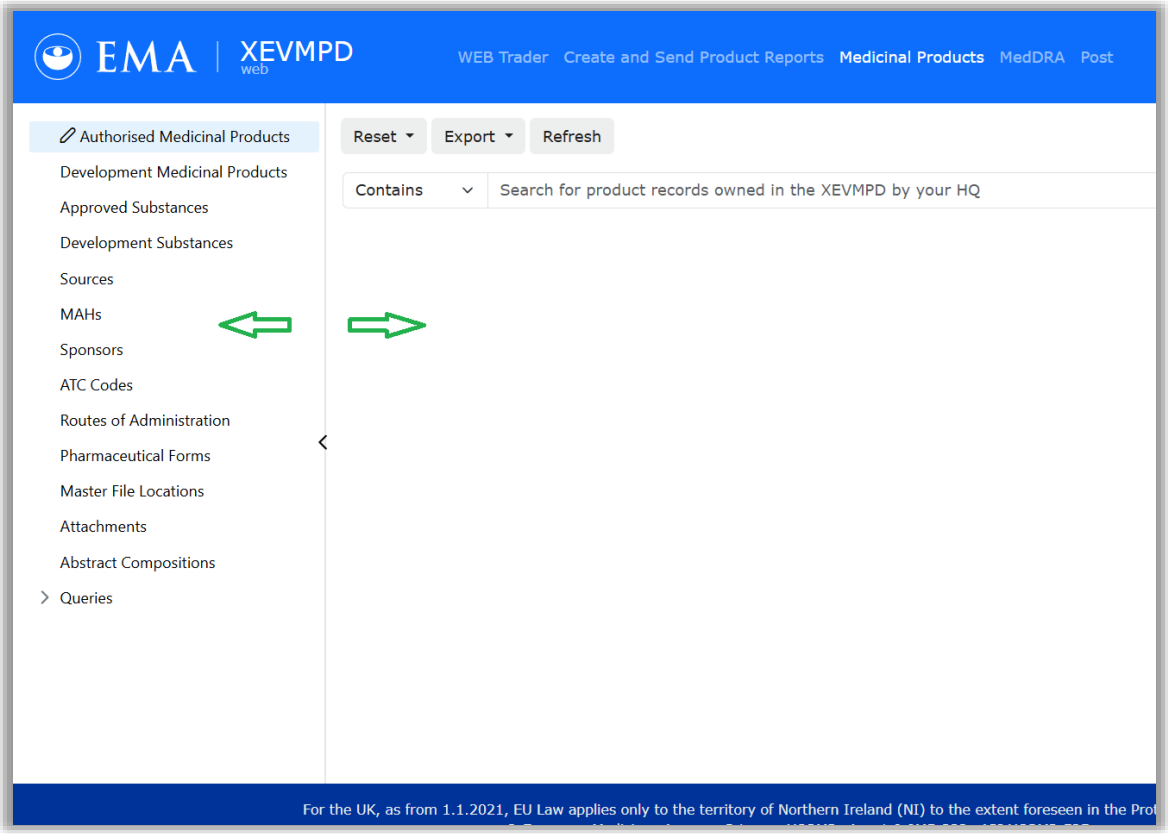
3.3.1. The tree-view area

The tree-view area is located on the left side of the user interface. The tree-view area can be:

- **collapsed** by clicking on the arrow shown on the separating line:

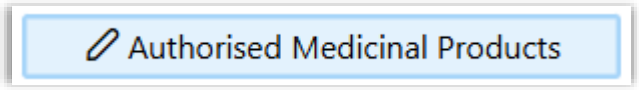


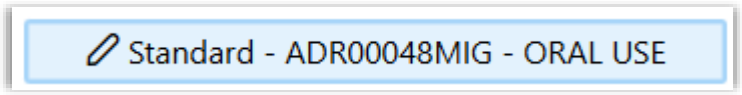
- **expanded/condensed** by moving the separating line to the right or left:

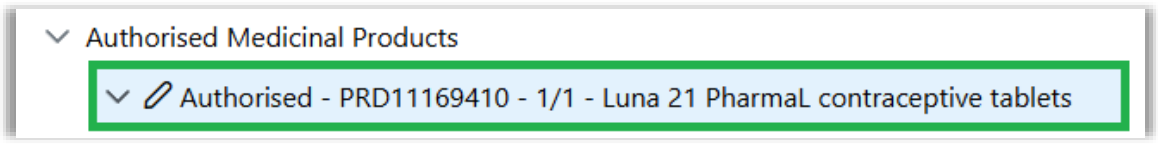


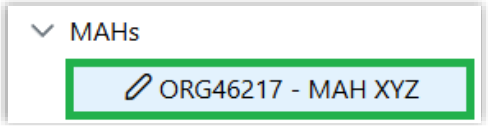
The tree-view area displays the **sections and sub-sections** relevant for each section of the user interface and **items available in the XEVMPD/XEVPRM**.

Sections or items selected in the tree-view area are highlighted with a blue background and a "pencil" symbol:



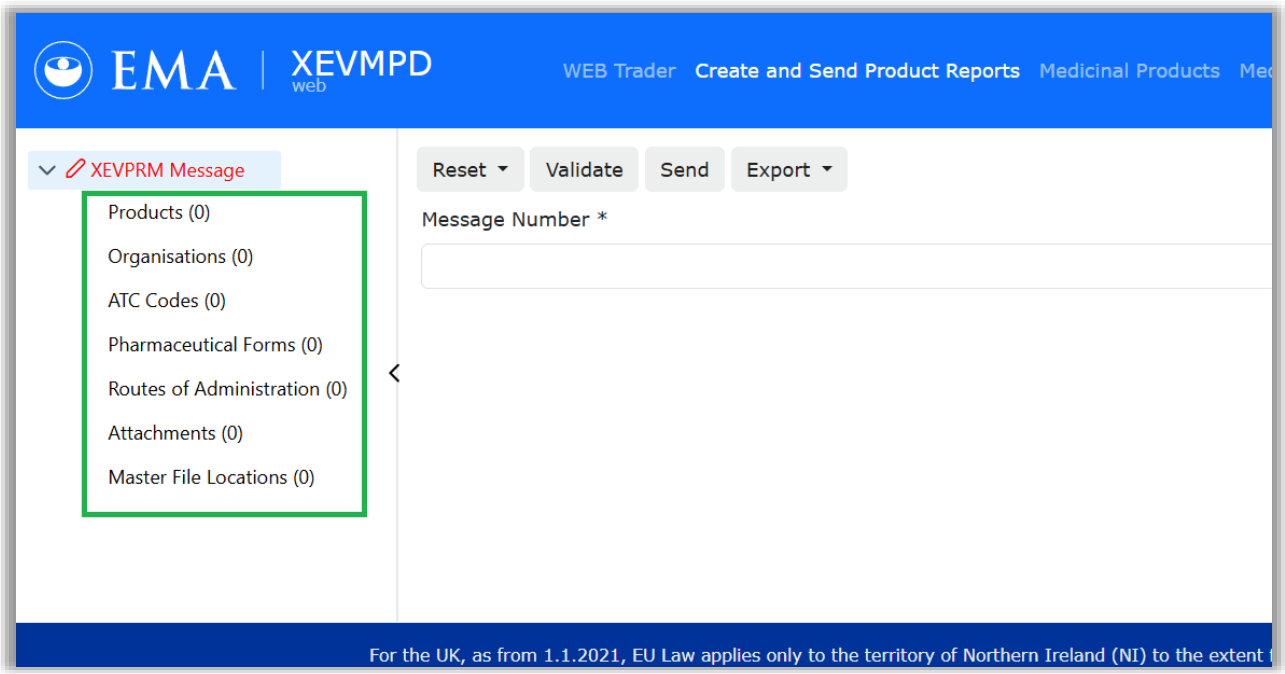




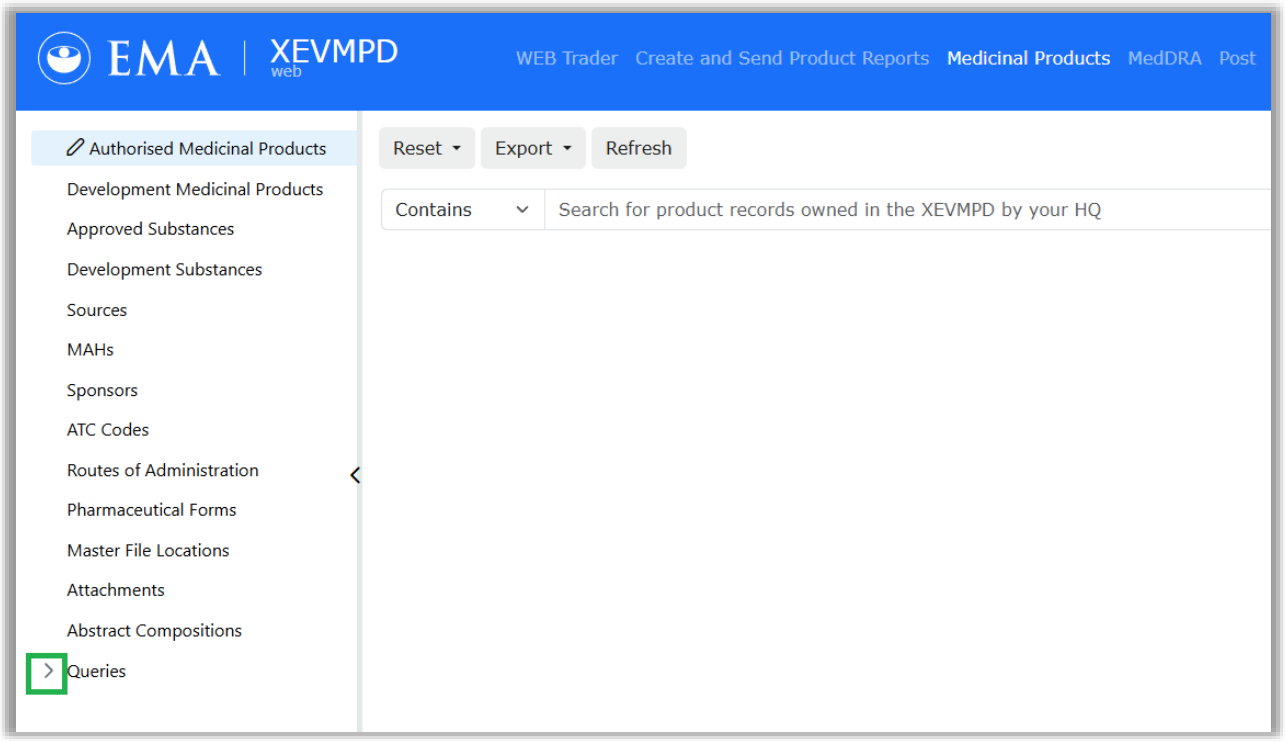


For example, in the 'Medicinal Products' section, the tree-view area displays the following sections available in the XEVMPD:

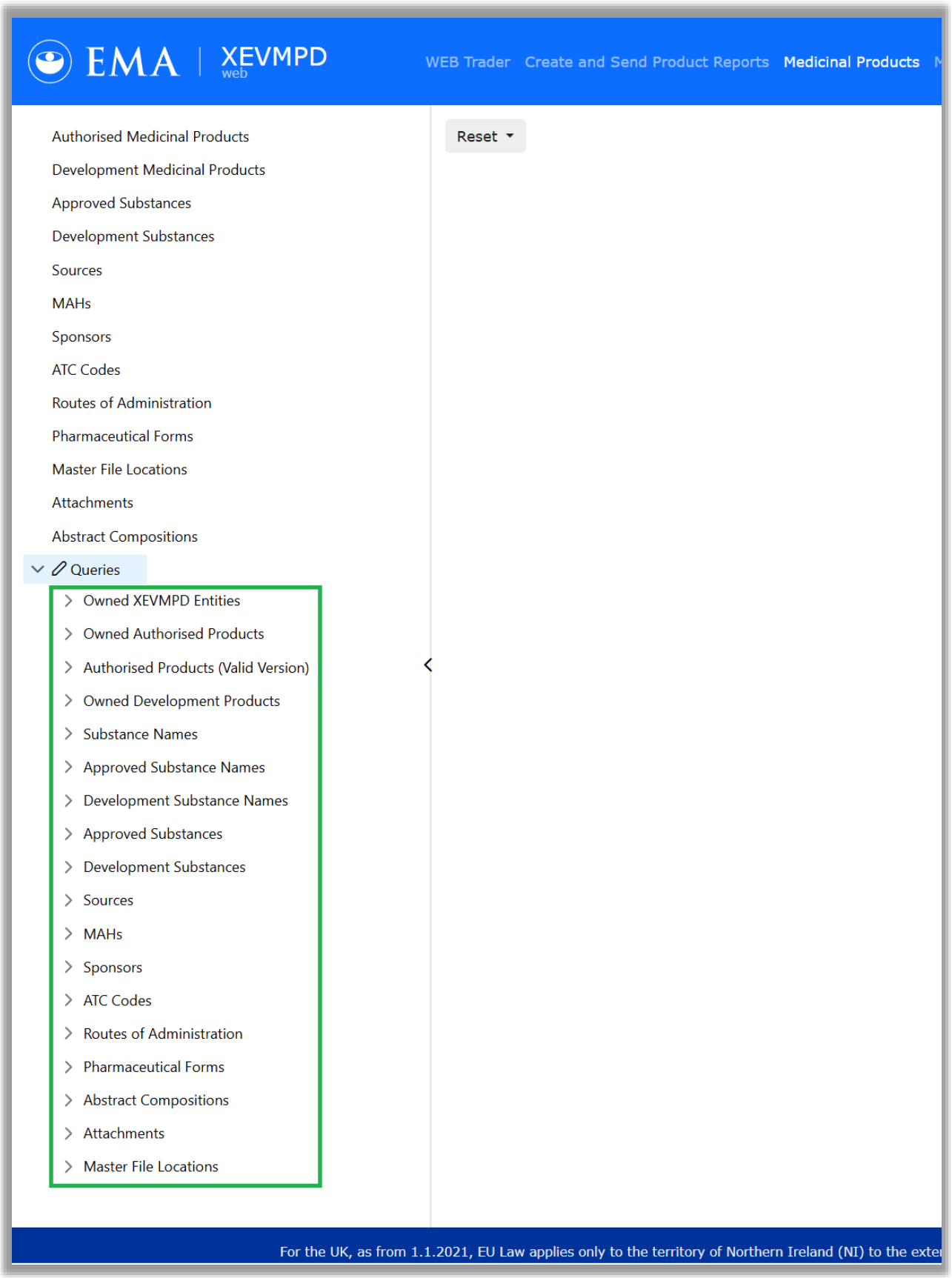
In the 'Create and Send Product Reports' section, the tree-view area displays the following sections available in the XEVPRM:



Sections containing **sub-sections** are marked by the '**>**' sign:

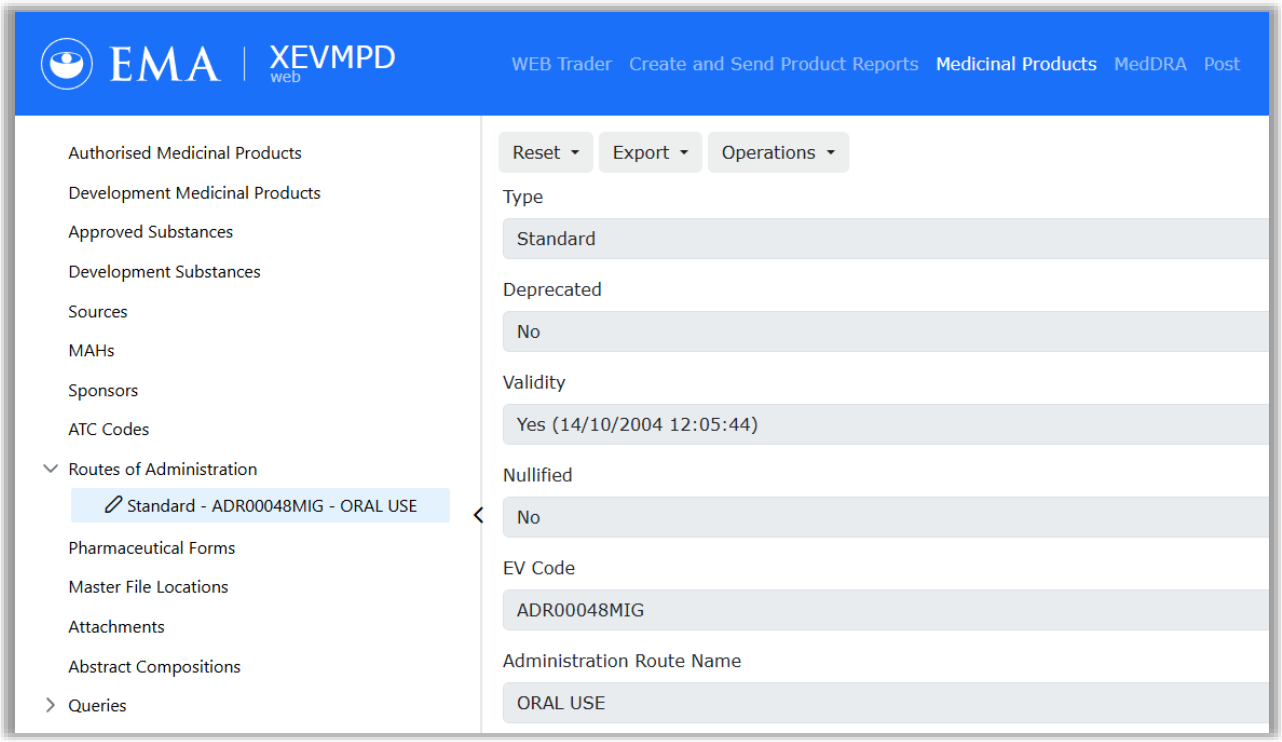


Upon clicking on the '**>**' sign, the sub-sections will become available and the '>' sign changes into a 'v' sign:

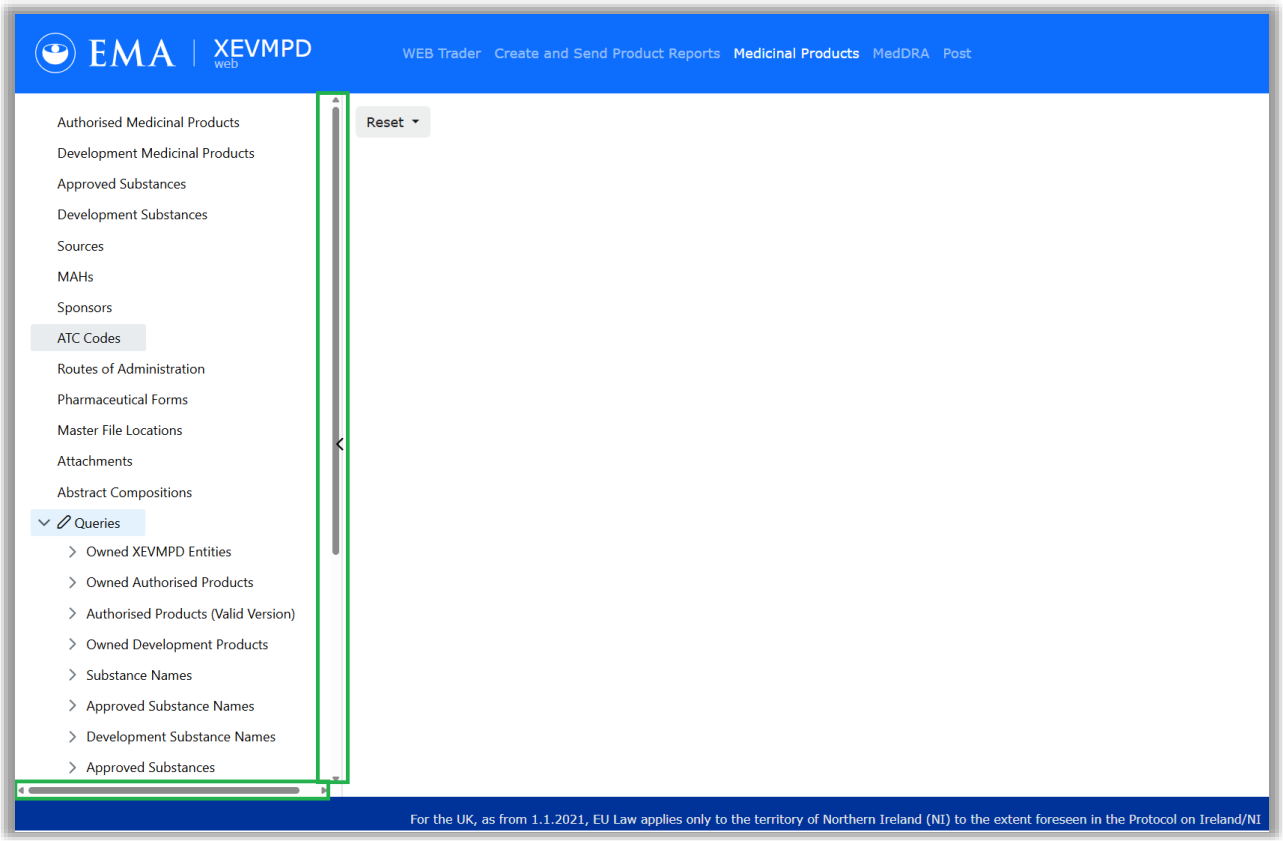


- **To collapse a section**, click once on the 'v' sign.

- **To view an item in the tree-view area**, a search must be performed for the required entity (e.g. a medicinal product, organisation entity, pharmaceutical form etc.) first. The entity should then be uploaded in the tree-view area under the relevant section using the 'Load' button. Upon clicking on the textual description of the item, the information relevant to the entity will be displayed:



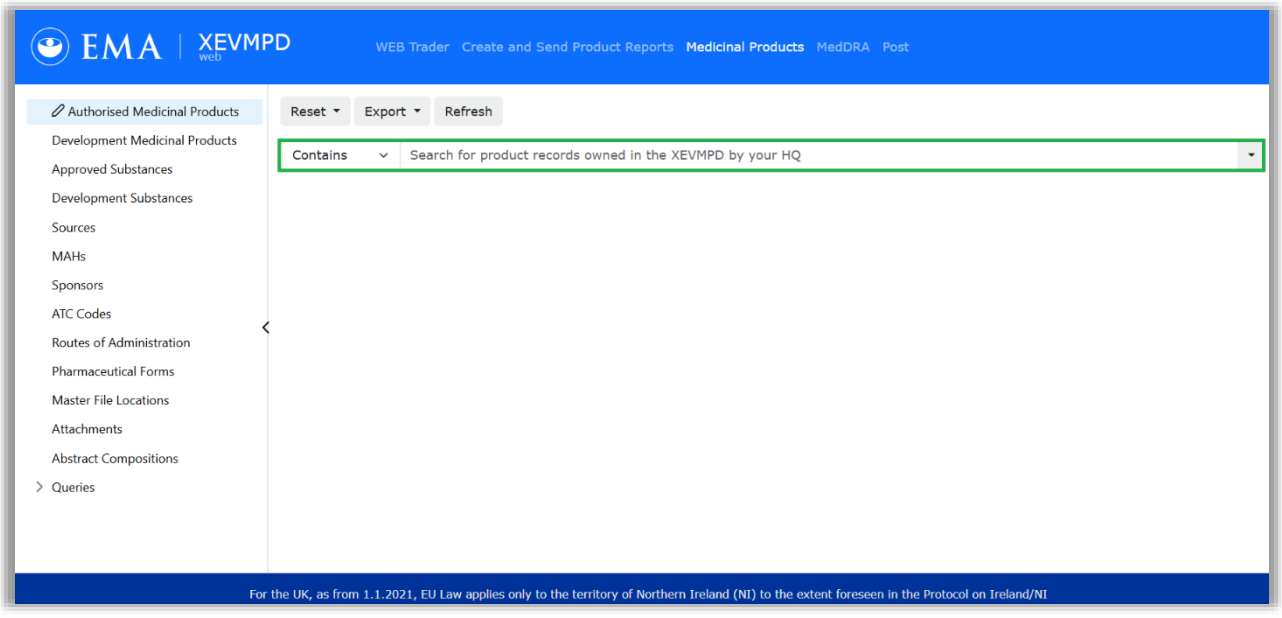
Depending on the size of the user's screen set-up, a scroll bar might become available at the bottom of the screen, or the right-hand side, of the tree-view area to allow users to scroll right or left to view all the displayed information:

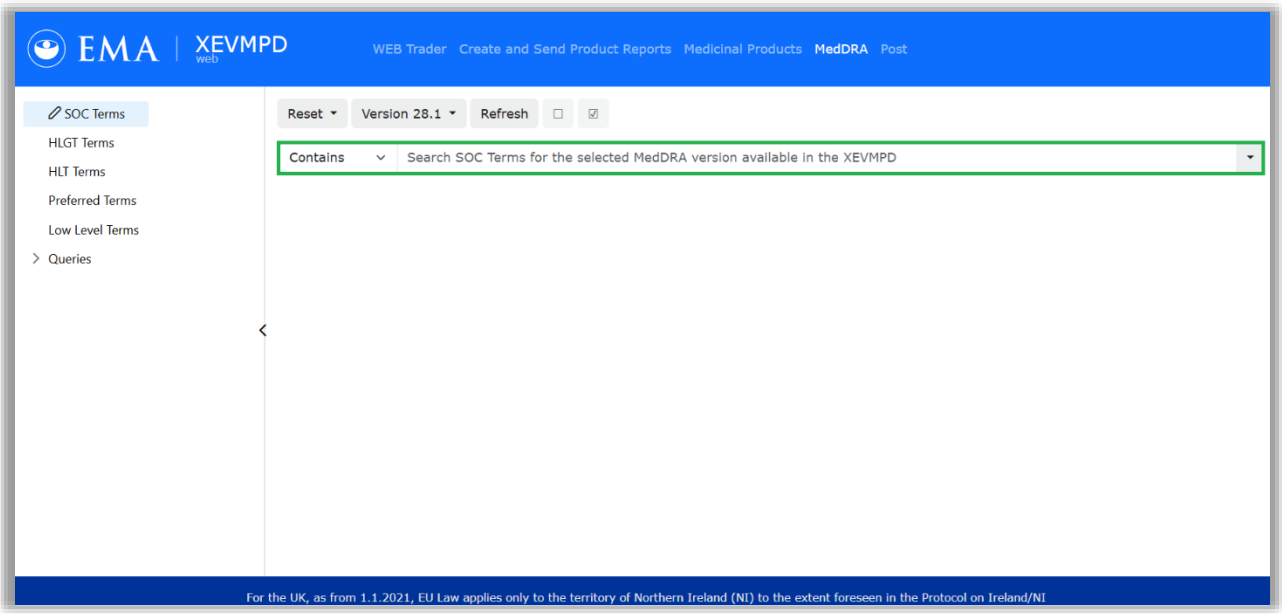


3.3.2. The active area

The active area is located on the right side of the user interface.

A **'simple query' search field** is available on top of the active area, under the dynamic/default buttons in the 'Medicinal Products' and 'MedDRA' sections, for all the sections listed in the tree-view area, except for 'Queries':



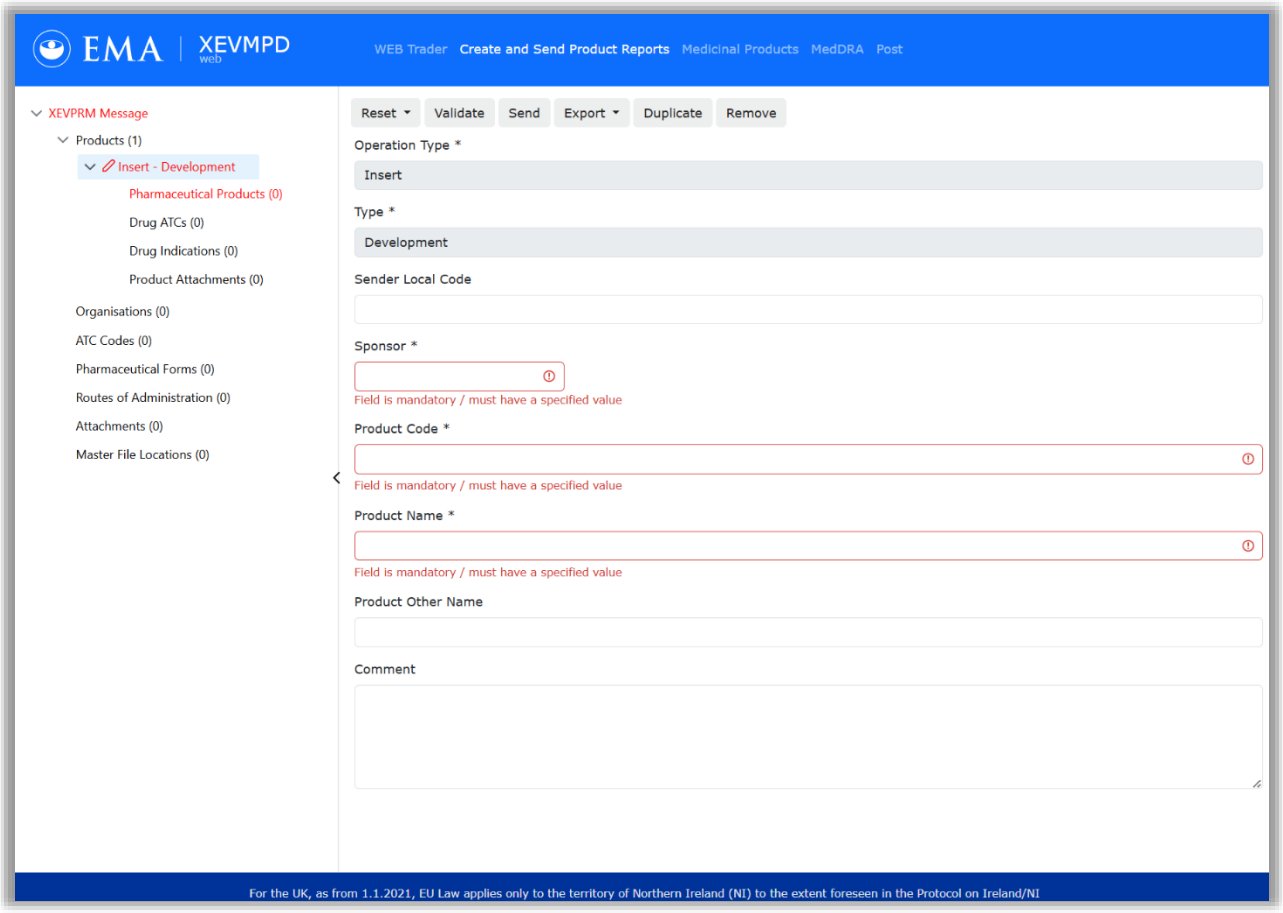


In general, the active area shows the **content of the item or section selected in the tree-view area**.

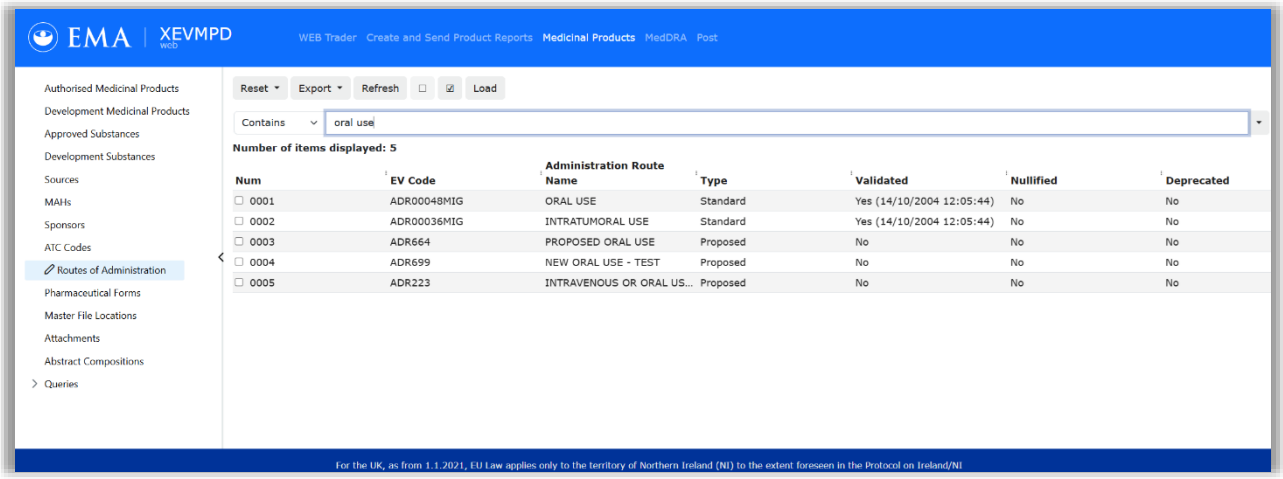
The active area is interactive and displays information that can be edited and modified by the user, **depending on their user rights and the applicable visibility and ownership rules in place**.

The active area displays information in two different ways:

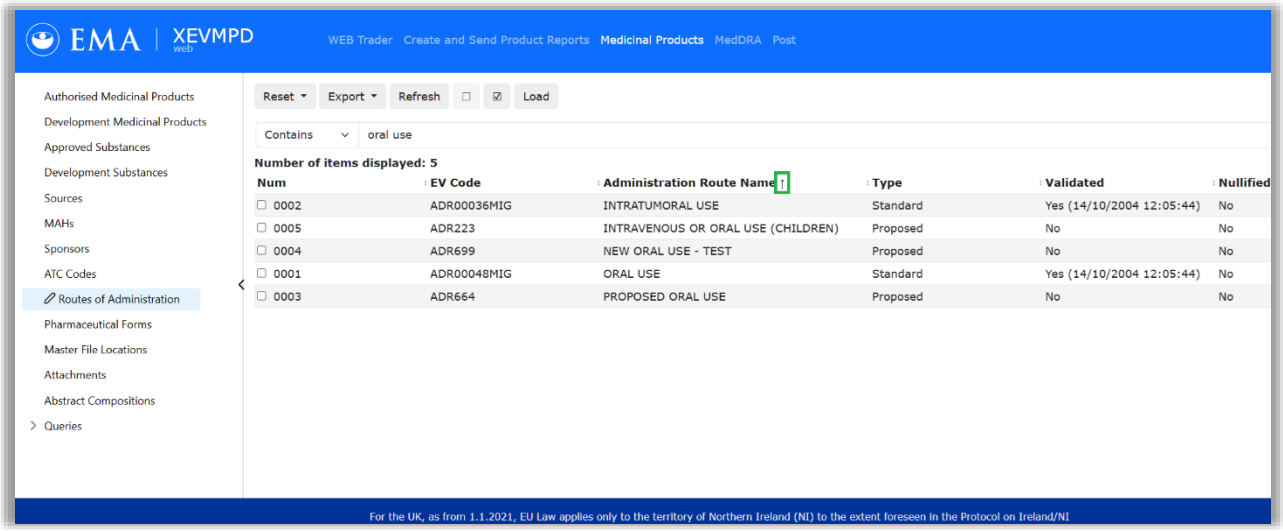
- **Section view** (which usually displays fields and/or subsections) used to display information for data entry. A typical example of a section view is the editing of an XEVPRM:

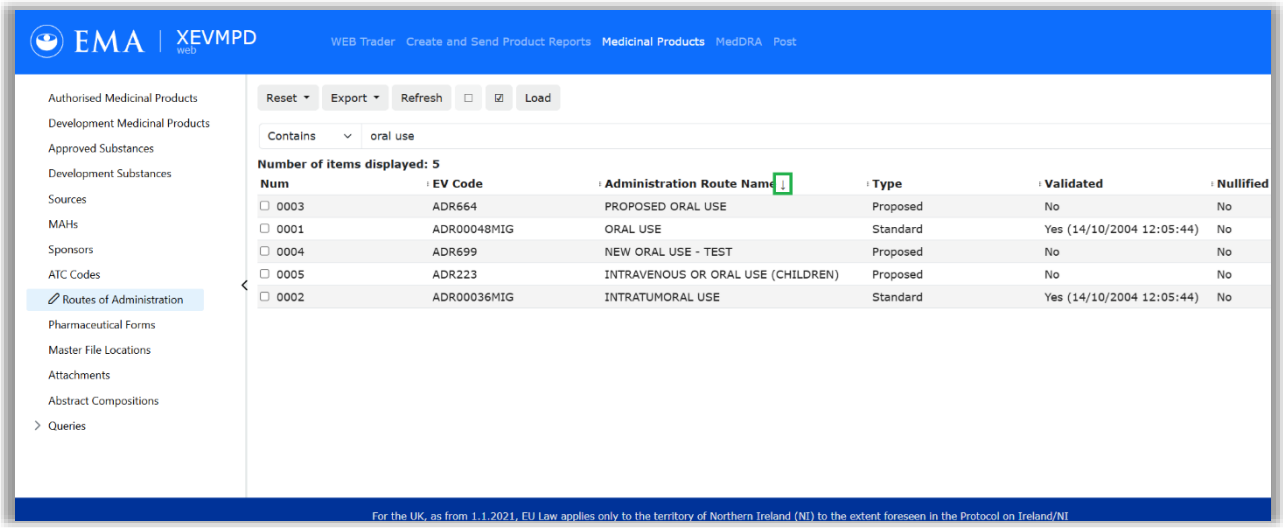


- **List view** (a detailed list of items) used to display items that can be selected, loaded, or just analysed. A typical example of a list view is the list of items retrieved as a result of a query:

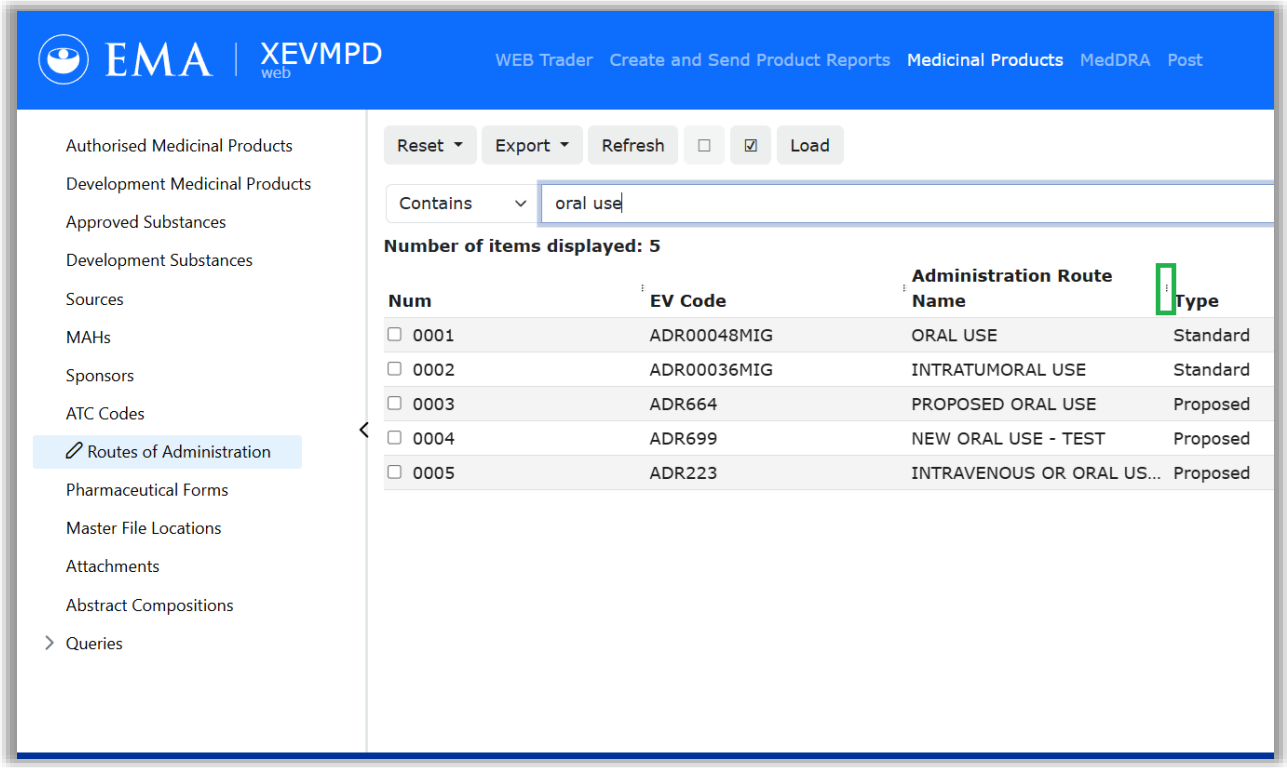


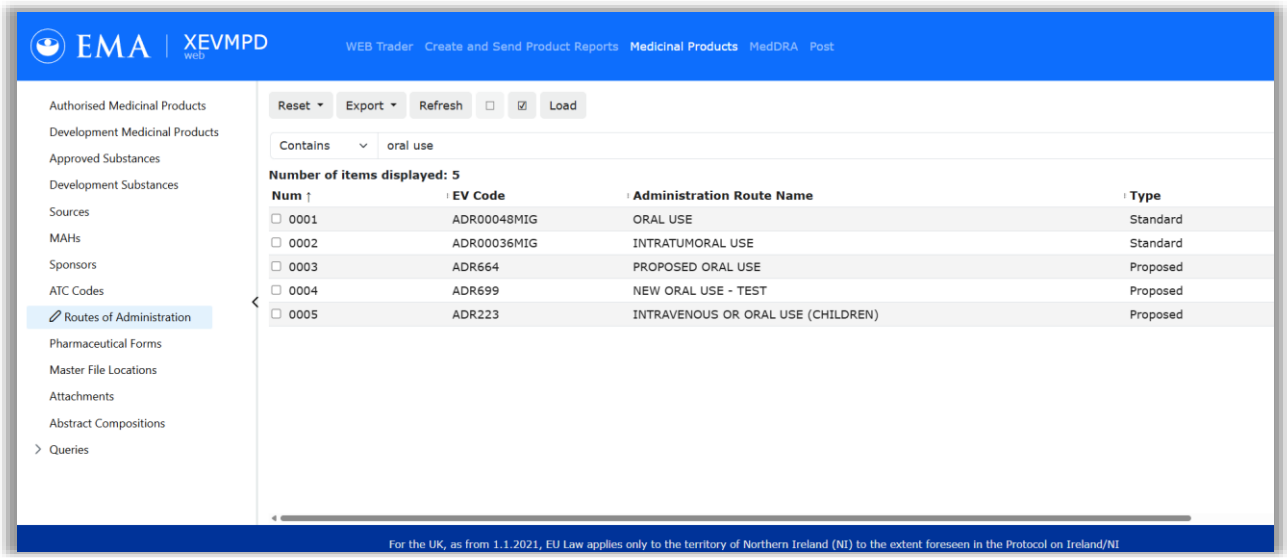
The order of presentation of the items retrieved as a result of a query and displayed in the active area can be re-arranged by clicking on the header of each column; an arrow will be displayed next to the header, allowing users to sort the items in that column from ascending to descending order and vice versa:



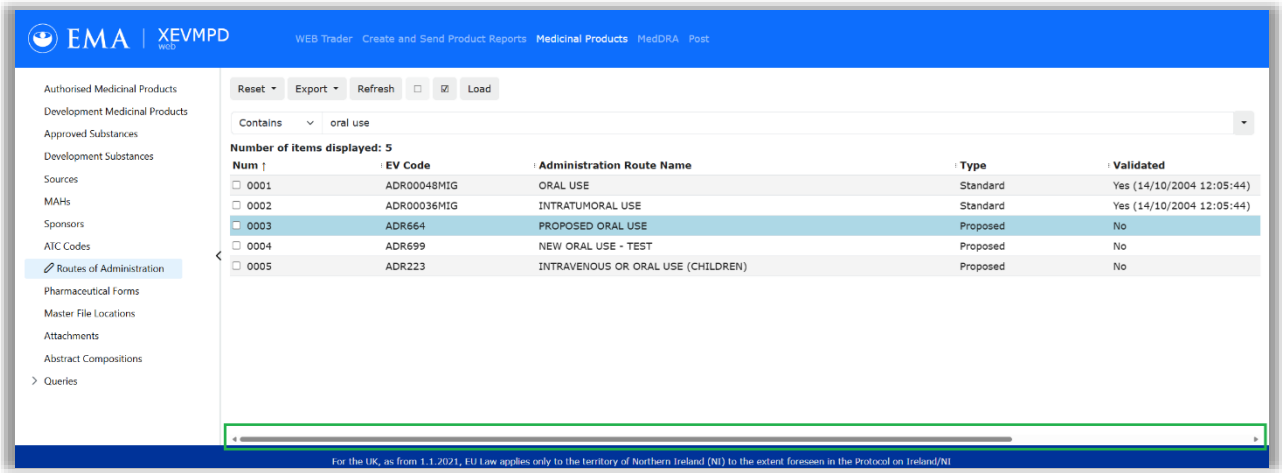


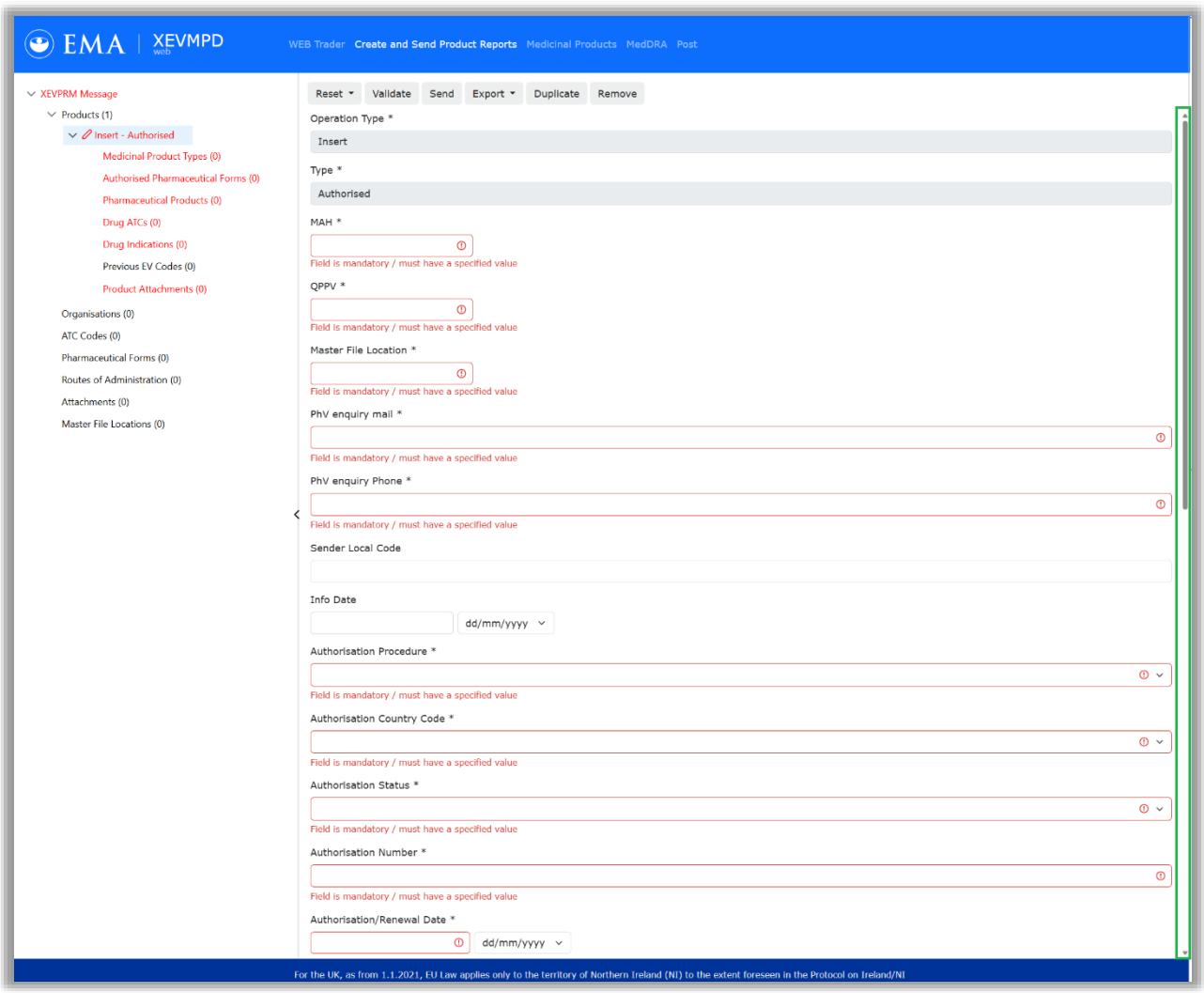
Users can also expand or collapse the displayed columns by placing the mouse over the three vertical dots in front of each column until the symbol **<-||->** appears. Upon clicking on this symbol, users can then move the width of the column to the left or right, as required:





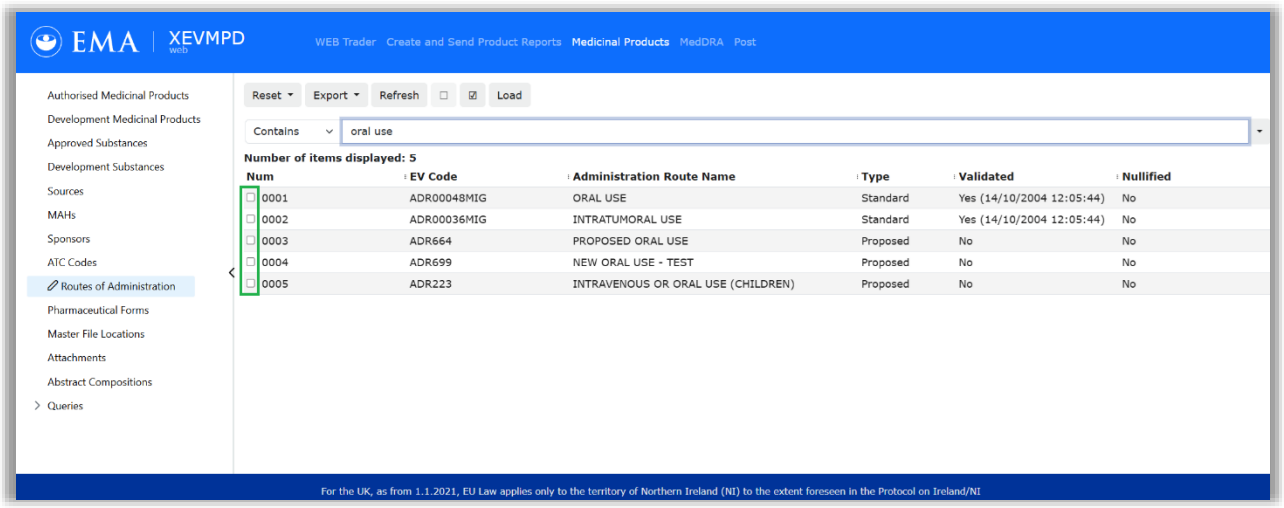
Depending on the size of the user's screen set-up, a **scroll bar** might become available at the bottom of the screen or at the right-hand side of the screen to allow users to scroll right/left or up/down to view all the displayed information:

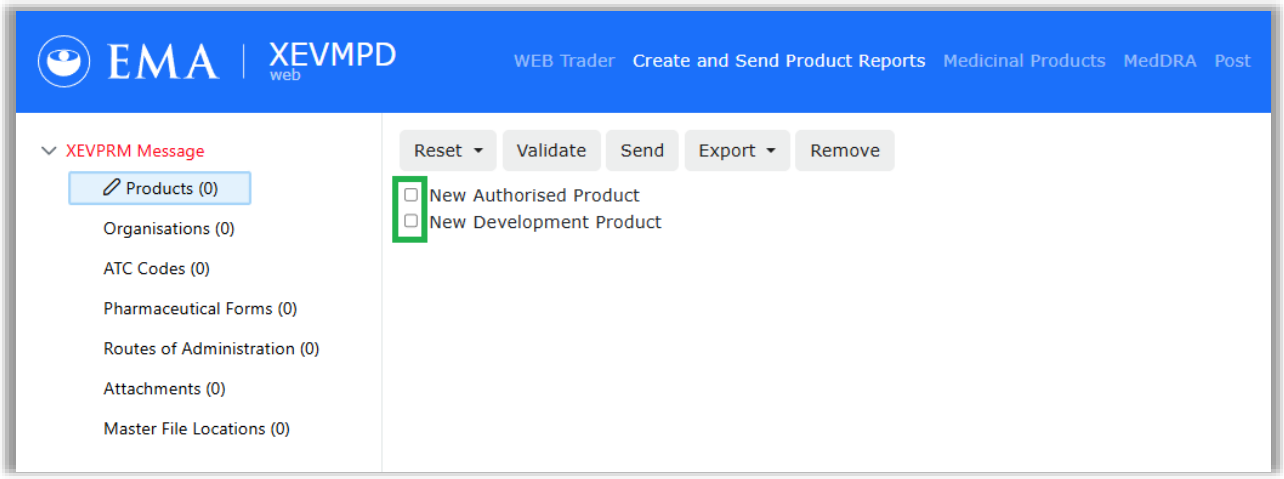


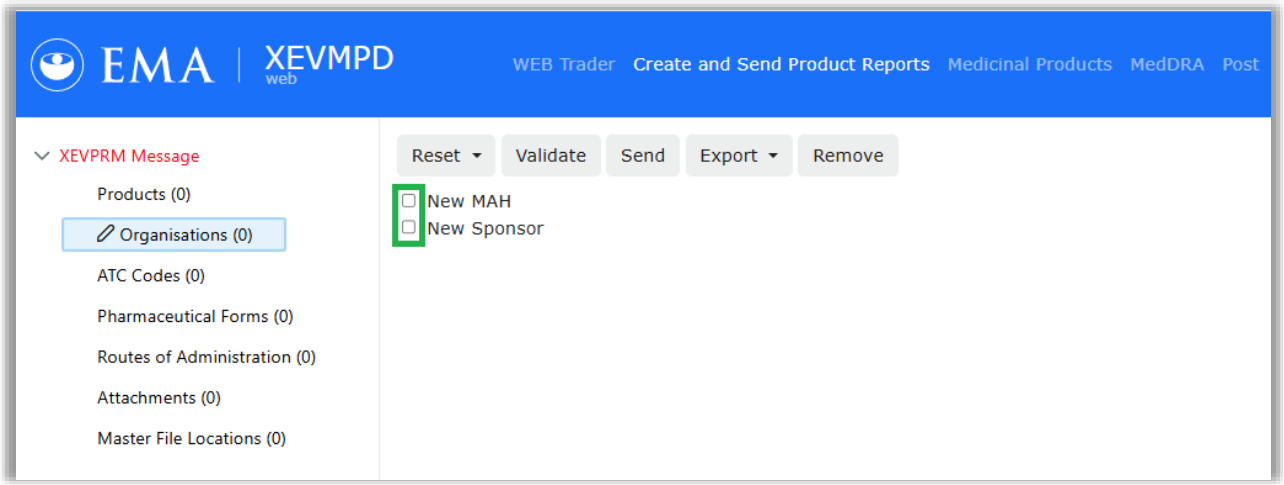


3.4. Checklists

When results are displayed in the active area, or when different type of entity can be added during a creation of an XEVPRM, a checkbox will become available for each item in the active area:







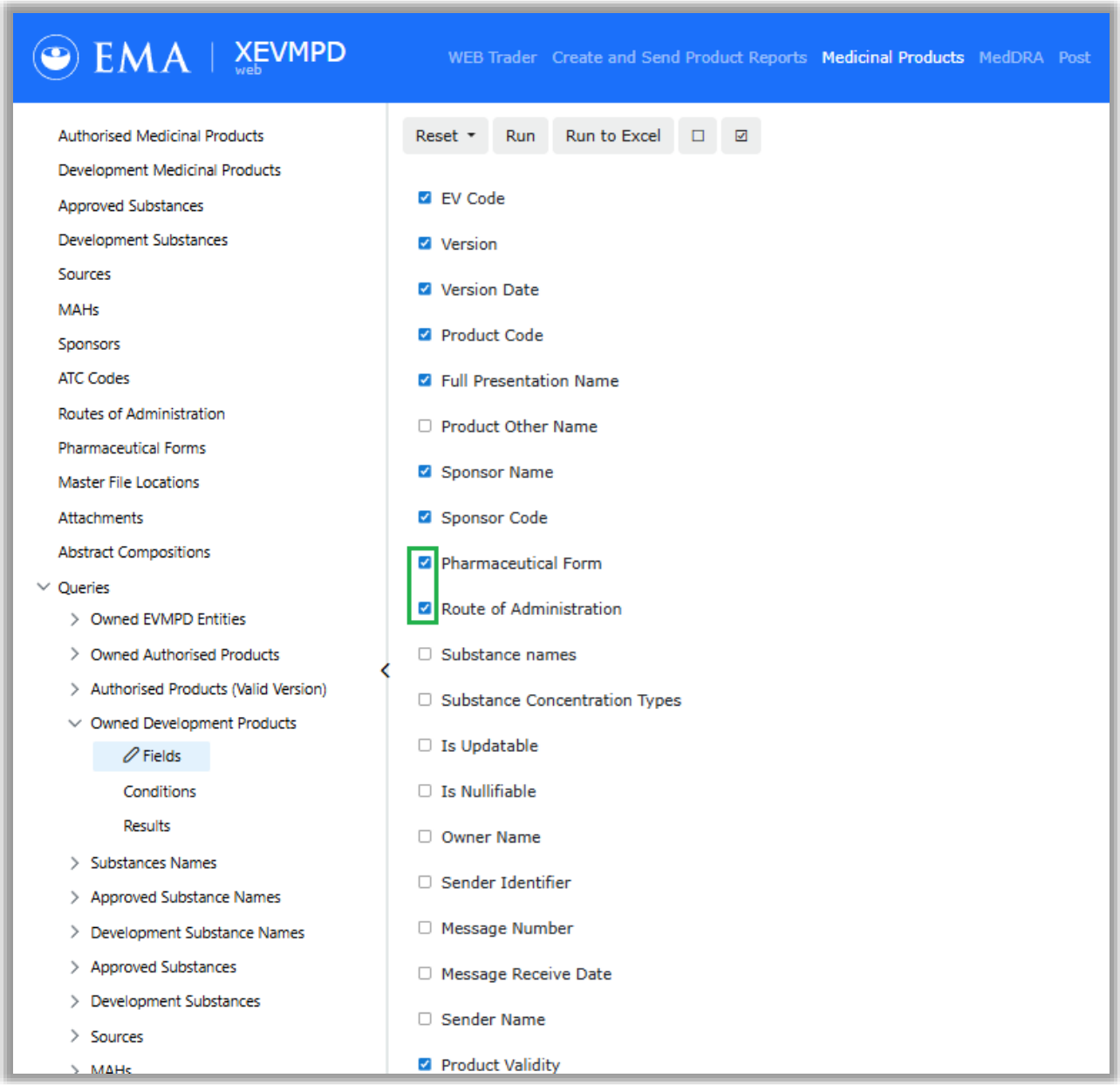
By selecting or de-selecting these checkboxes, the user will indicate for which item the applicable action should be performed. They type of action which can be performed on the selected/de-selected item depends on:

- the section where the item is available (e.g. 'Medicinal products' section versus 'Create and Send Product Reports' section);
- the user rights assigned to the user (e.g. browse or send XEVMPD data);

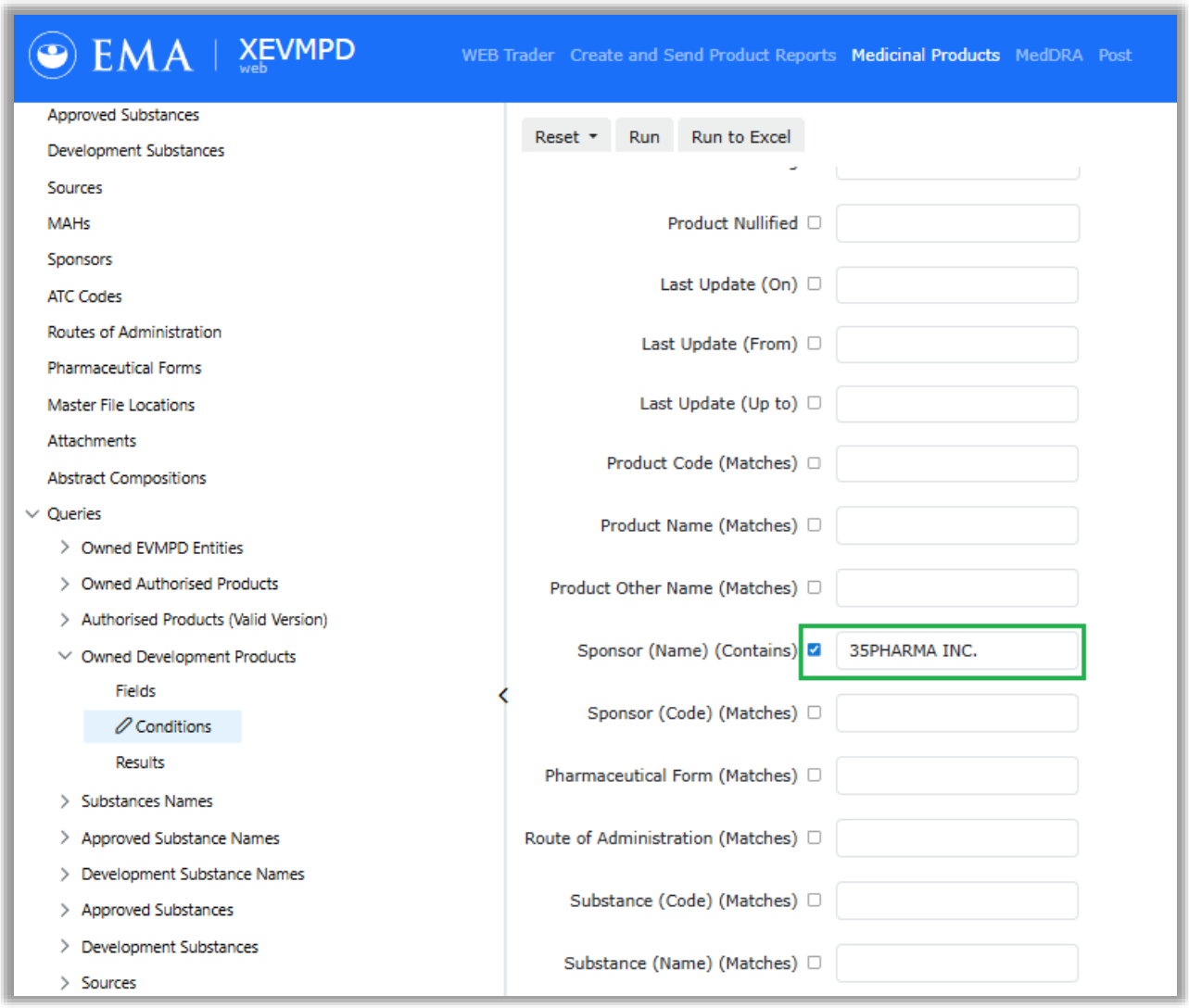
- the ownership of the item (e.g. owned by the user's HQ organisation or not);
- the status of the item (e.g. nullified and/or validated entity versus not-nullified and not assessed).

The checkbox option is also used to indicate which fields and conditions should be considered when running and advanced query.

- **In the 'Fields' section** of an advanced query, certain fields are already selected by default. By selecting further fields, the user can indicate additional fields, from which information should be displayed as a result:



- **In the 'Conditions' section** of an advanced query, by selecting any of the available fields, the user can indicate which condition(s) within which field(s) should be taken into consideration to perform the search:

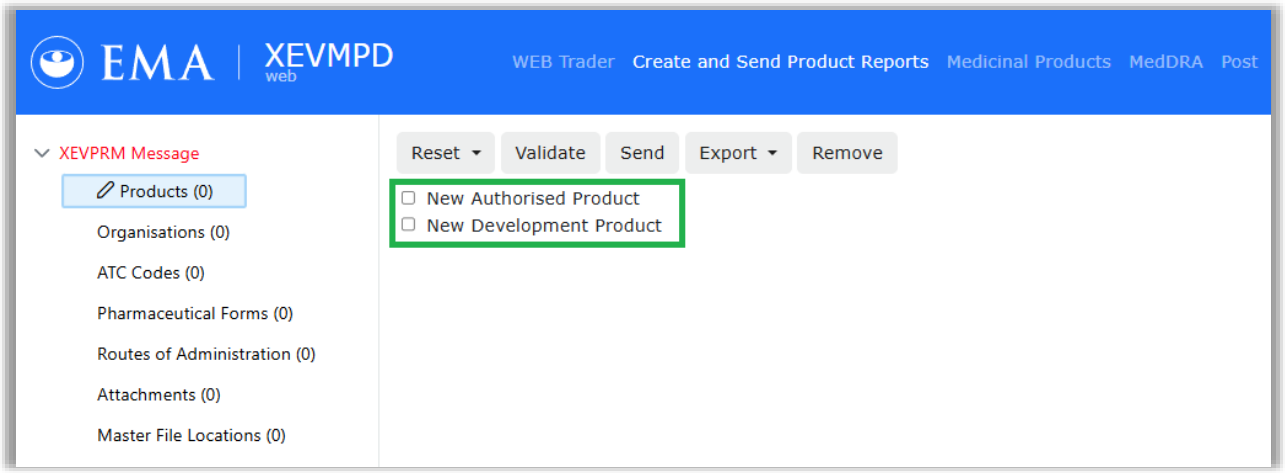


3.4.1. Adding and removing items during data entry or maintenance process

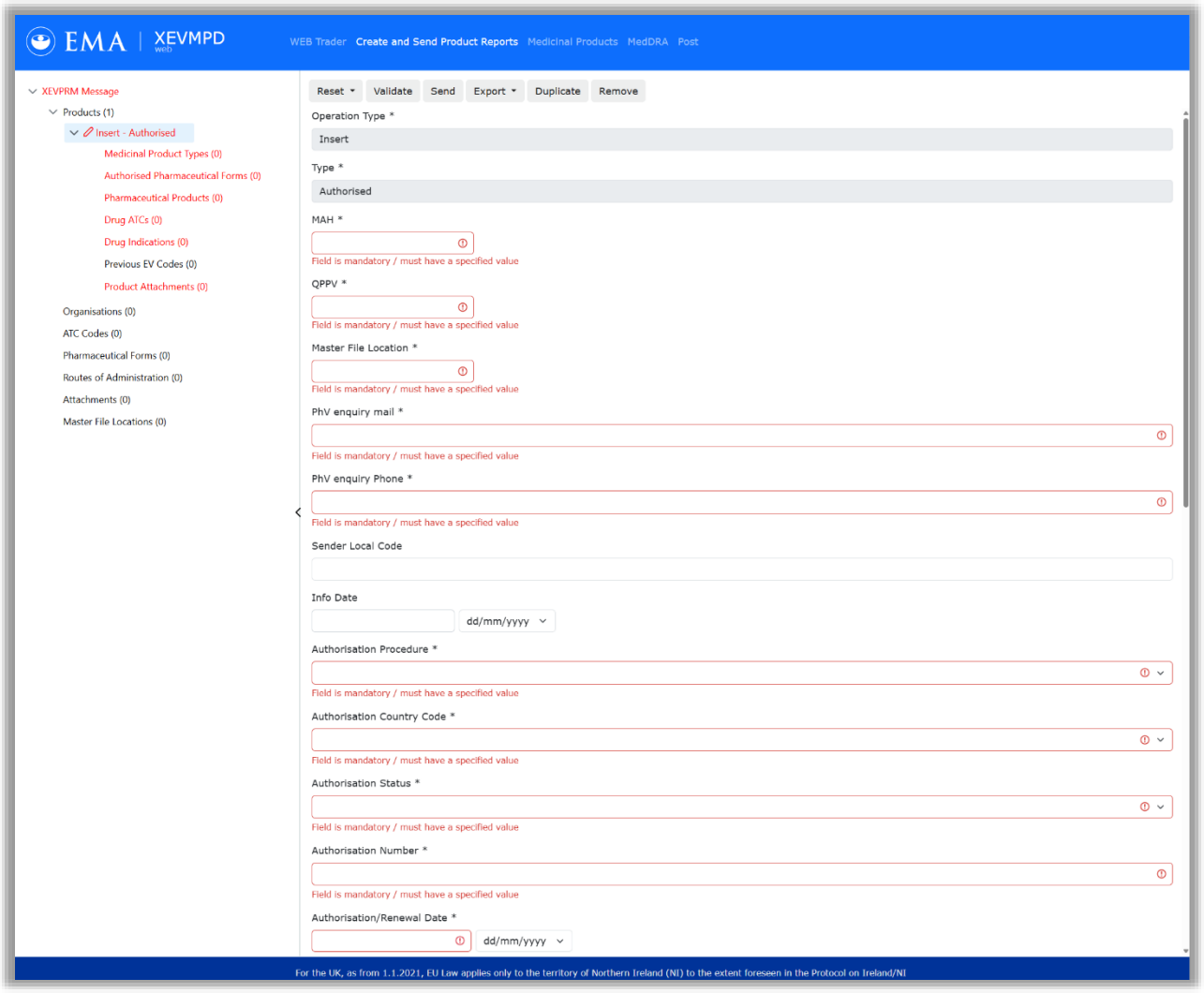
3.4.1.1. Adding items during data entry or maintenance process

During the data entry or maintenance process, users may be required to **add an entity** in the XEVPRM. This can be achieved by using the checklist option, which will become available in the active area when the appropriate section of the required entity to be added is selected in the tree-view.

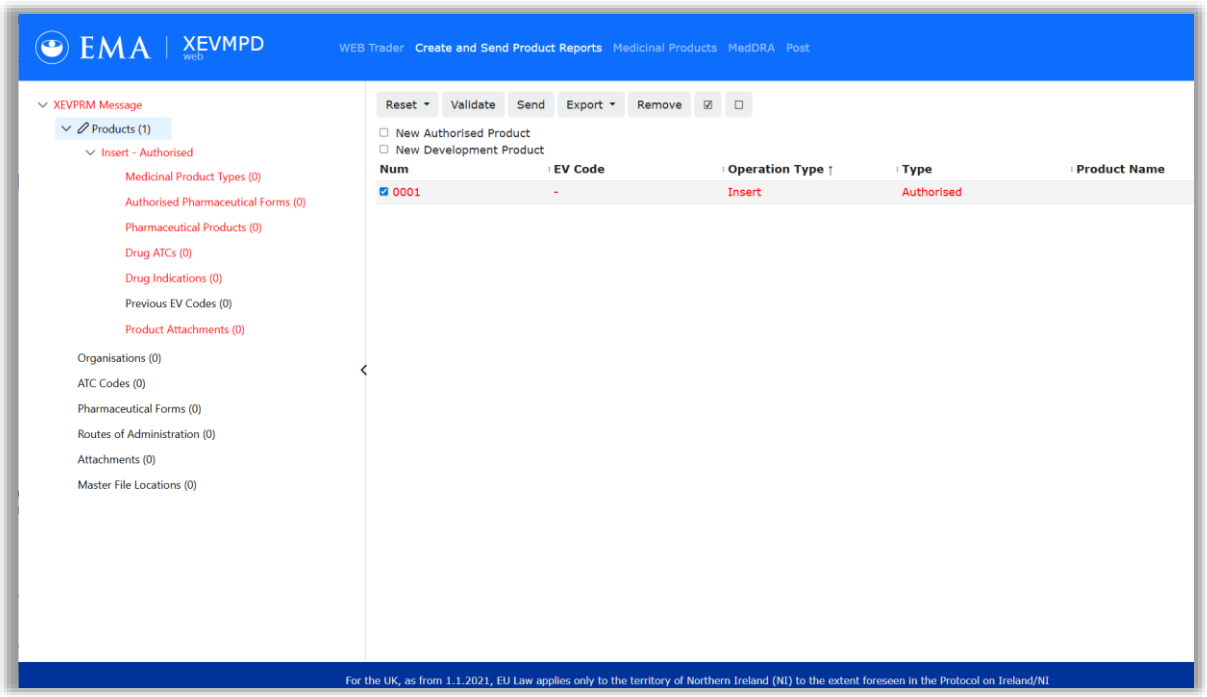
For example, during the creation of an XEVPRM, the user can indicate if they wish to add information for an authorised or development medicinal product by selecting the relevant item in the active area:



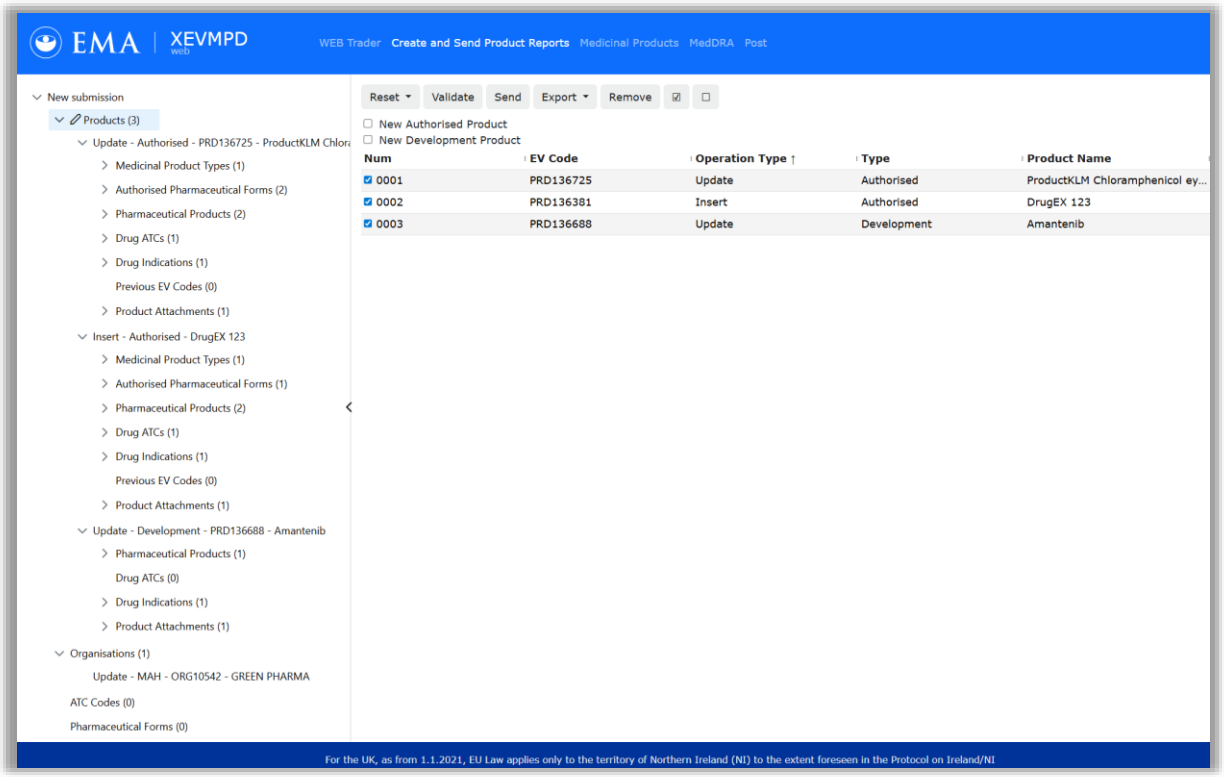
Upon clicking inside the checkbox next to the 'New Authorised Product', the section related to an insert of an authorised medicinal product will become available in the tree-view area, and the active area will display the fields applicable to that section within the AMP:



Upon clicking on the 'Products' section in the tree-view area, the active area will display the number of entities added in that section and some of the details related to that entity; the checkbox will be selected by default:



For example, if a user is performing an insert of new entity/entities together with maintenance of existing entities in the same XEVPRM, when clicking on 'Products' in the tree-view area, the active area will list the entities that are being added/maintained in that XEVPRM; the checkbox es will be selected by default:

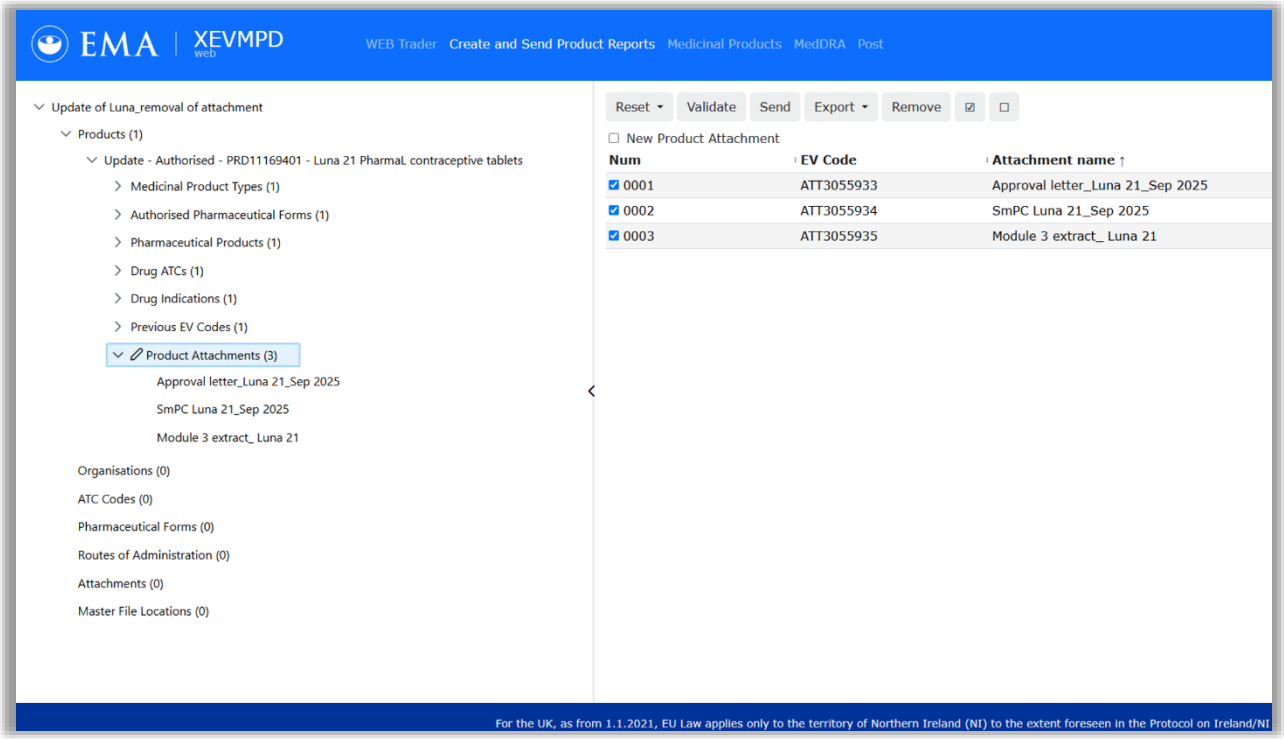


3.4.1.2. Removing items during data entry or maintenance process

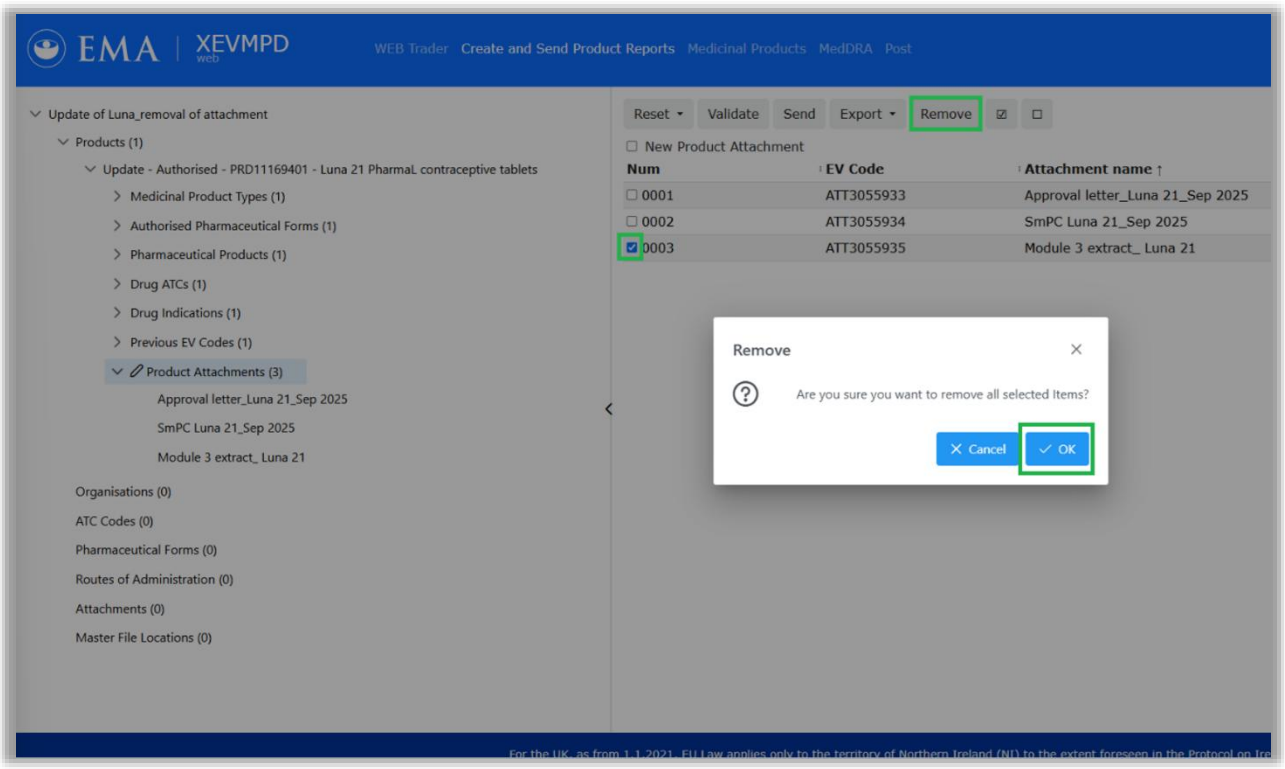
During the data entry or maintenance process, users may be required to **remove an entity** from the XEVPRM. This can be achieved by using the checklist option, which will become available in the active area when the appropriate section of the required entity to be removed is selected in the tree-view.

Example 1:

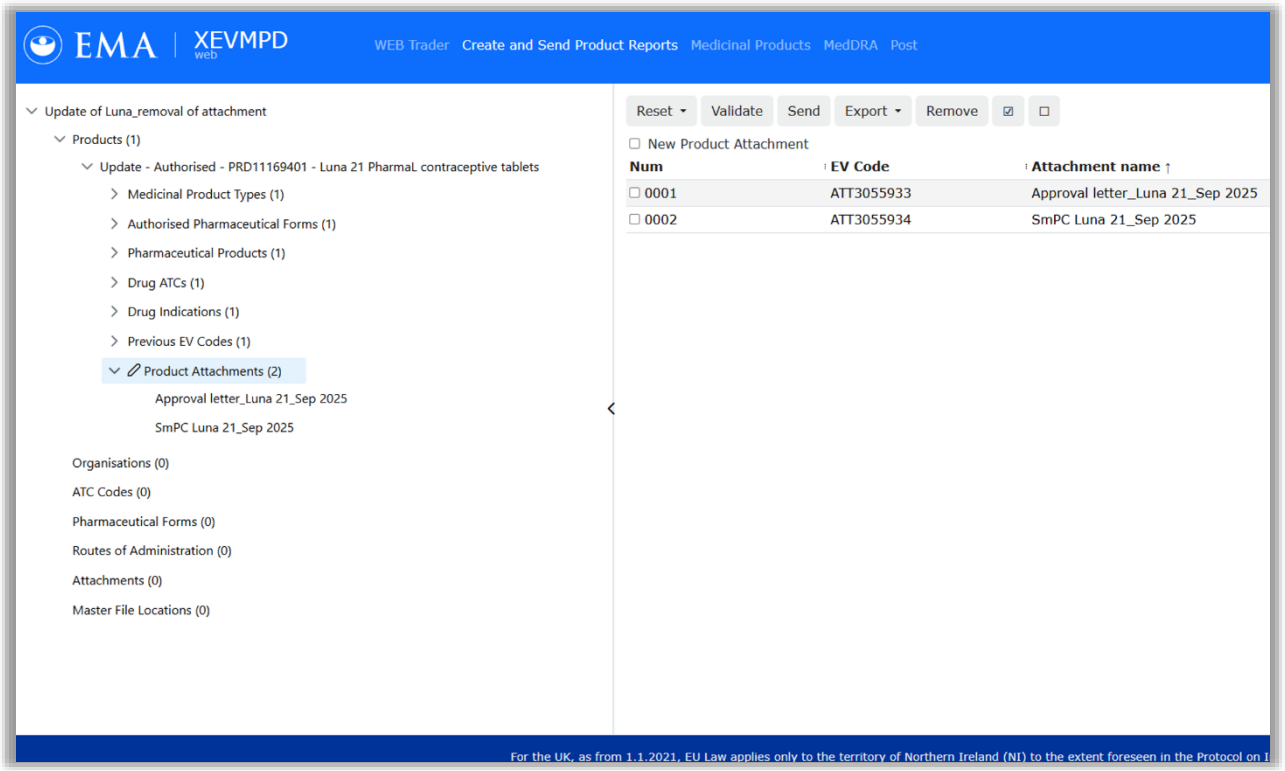
During the creation of an XEVPRM with an update of an existing authorised medicinal product, the user wishes to remove one of the attachments referenced in the AMP that is being updated. To achieve this, the user should click on the 'Product Attachments' section of the AMP entity on the tree-view area to view the list of attachments referenced in that AMP in the active area; all attachments are selected by default:



To remove the last attachment, the user should de-select the first two attachment entities. Only the last attachment should continue to be selected to indicate that the required action (i.e. removal) should be applied only to that entity. The user should then click on the 'Remove' button and, when the confirmation message is displayed on the screen, click on 'OK' to proceed with the removal of the attachment entity from that AMP:



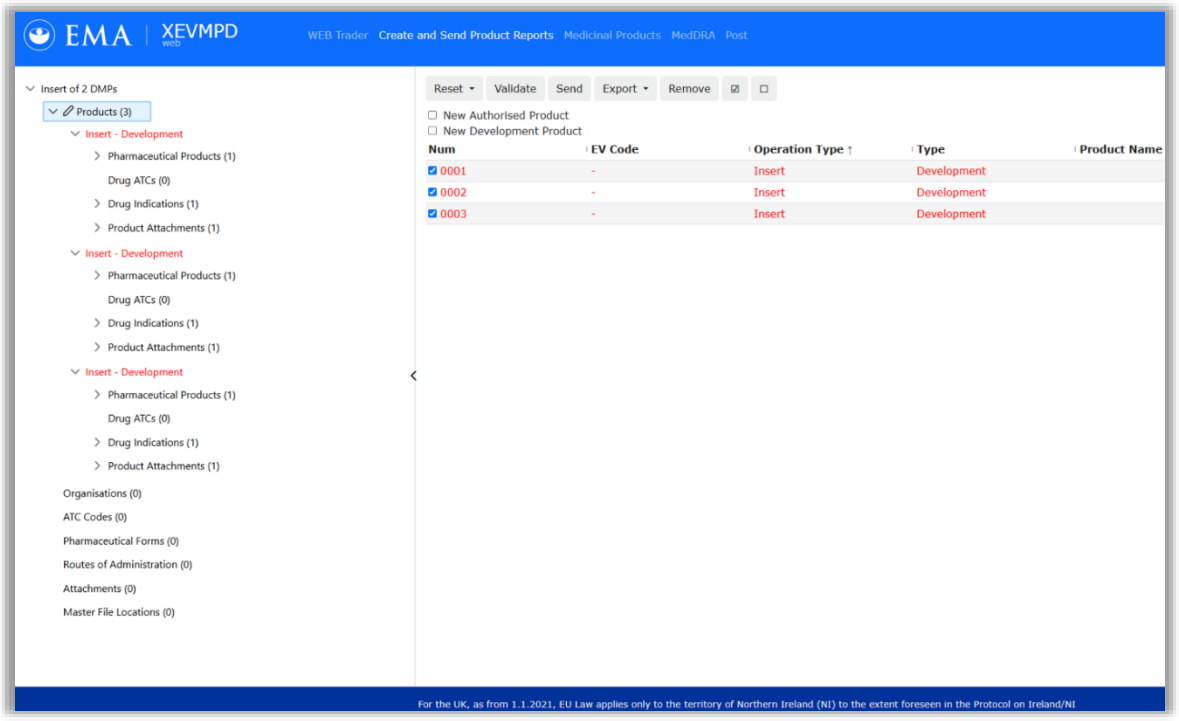
Once confirmed, the third attachment entity is removed from the product entity and only two items are listed in the 'Product Attachments' section of the AMP:



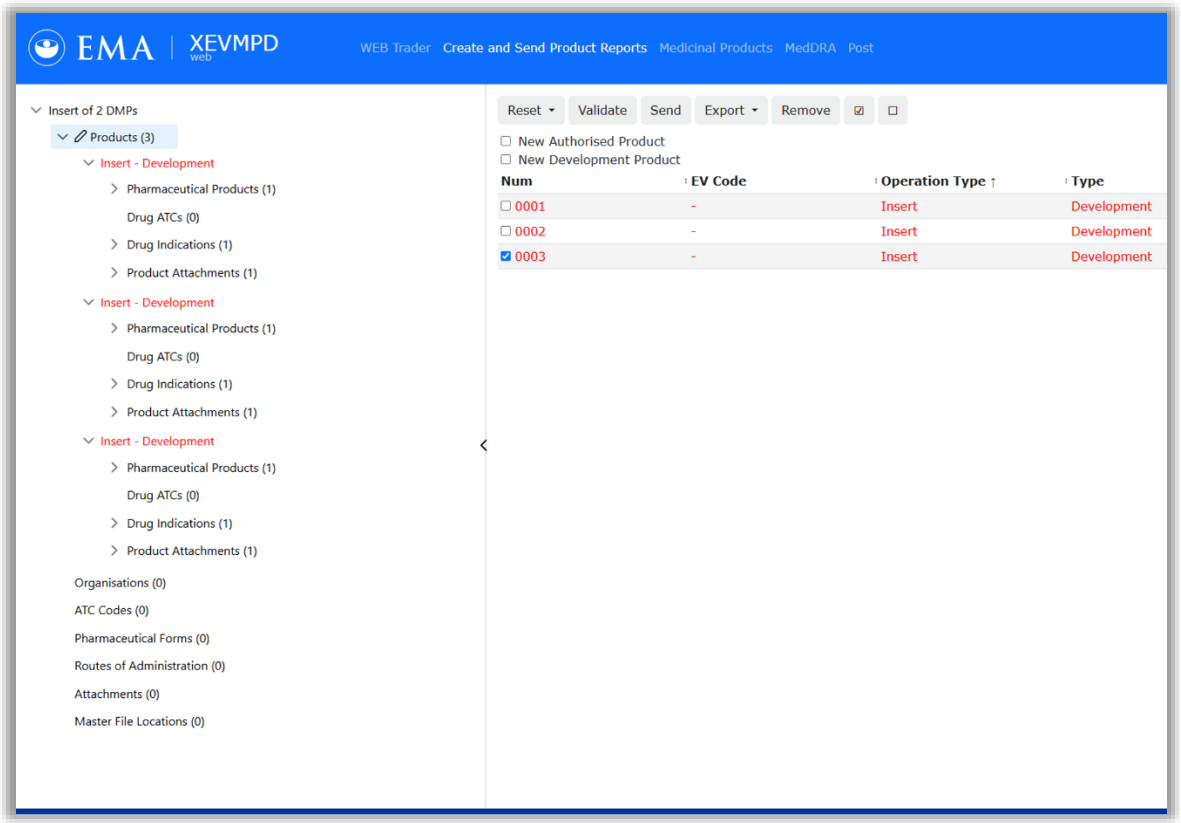
Example 2:

During the creation of an XEVPRM the user added three development medicinal product entities in the XEVPRM that is being created instead of two and therefore wishes to remove one of them. To achieve

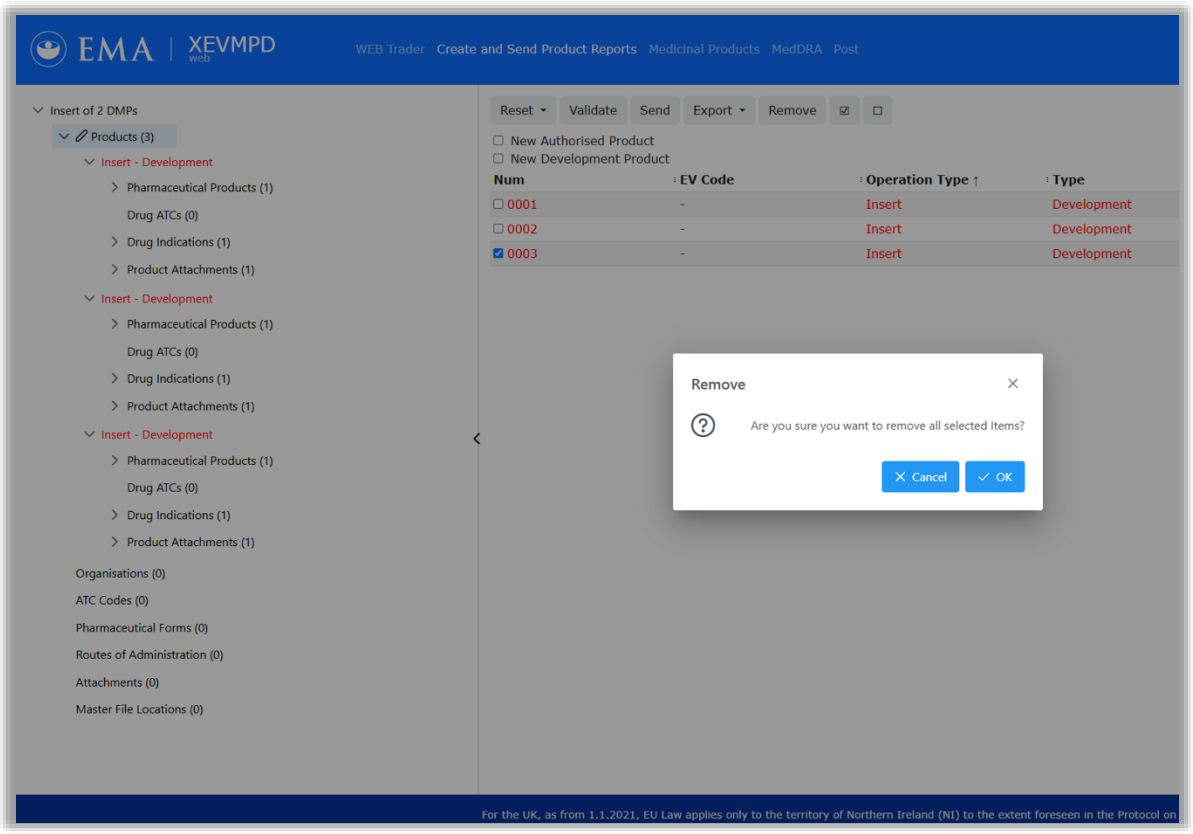
this, the user should click on the 'Products' section in the tree-view area to view the list of entities referenced within that section in the active area; all product entities are selected by default:



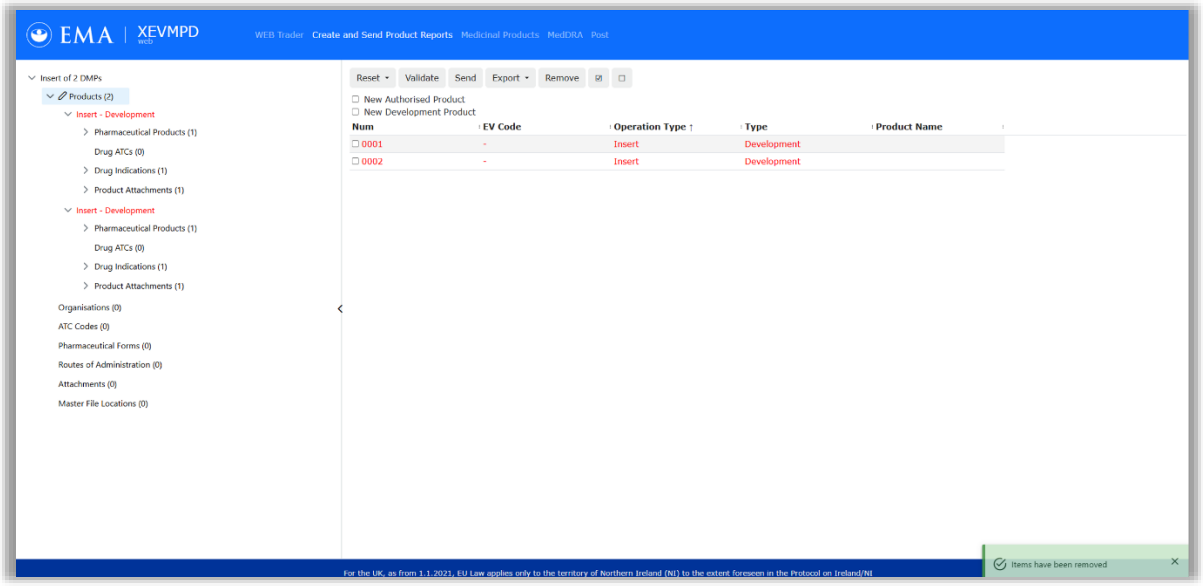
To remove one of the items, the user should de-select the items that should remain, so that only the item to be removed is selected:



The user should then click on the 'Remove' button to proceed with the removal of the DMP entity from the XEVPRM:



Once confirmed, the DMP entity is removed from the XEVPRM and only two items are listed in the 'Products' section of the XEVPRM:

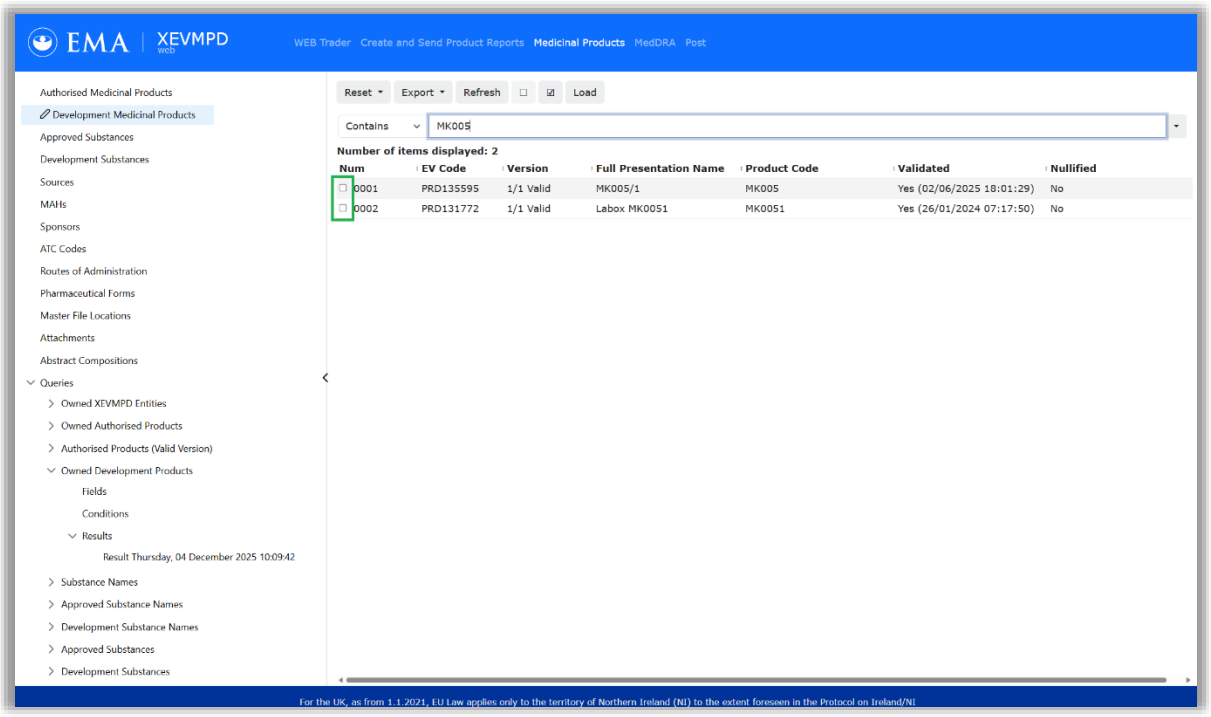


3.4.2. Adding and removing items retrieved as a result of a search

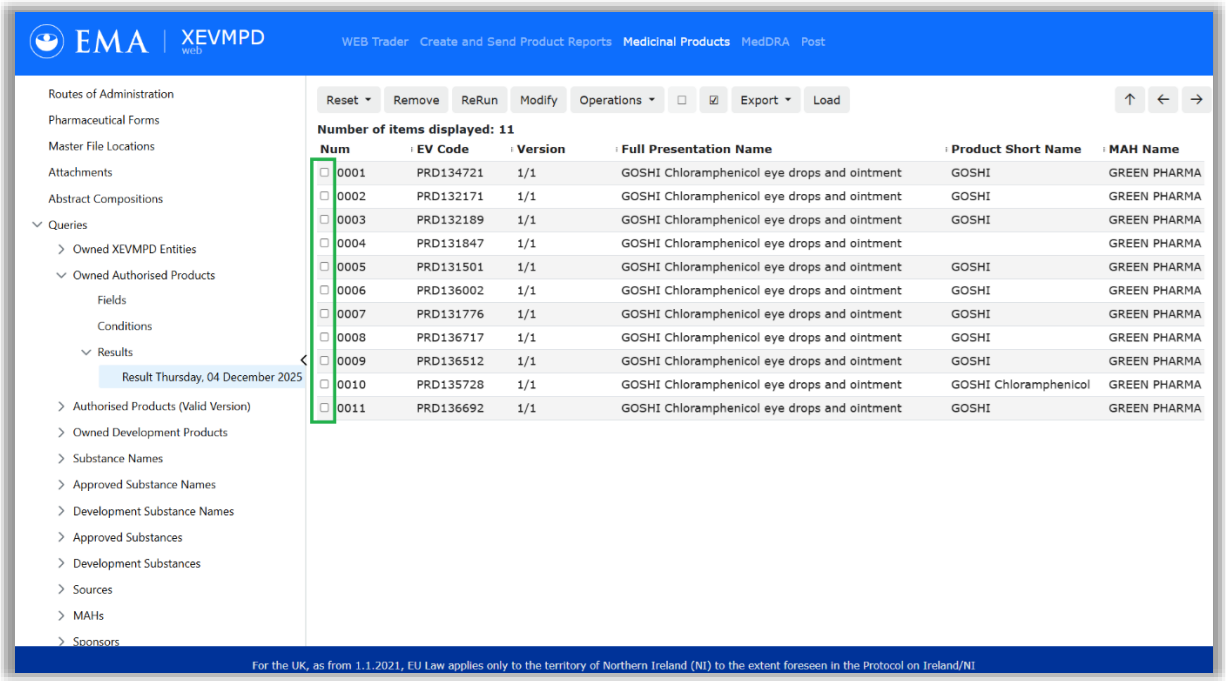
3.4.2.1. Adding items retrieved as a result of a search

The checklist option also allows users to indicate which item(s) should be selected for further action when results of a query are displayed in the active area.

Example 1: Simple query results:



Example 2: Advanced query results:

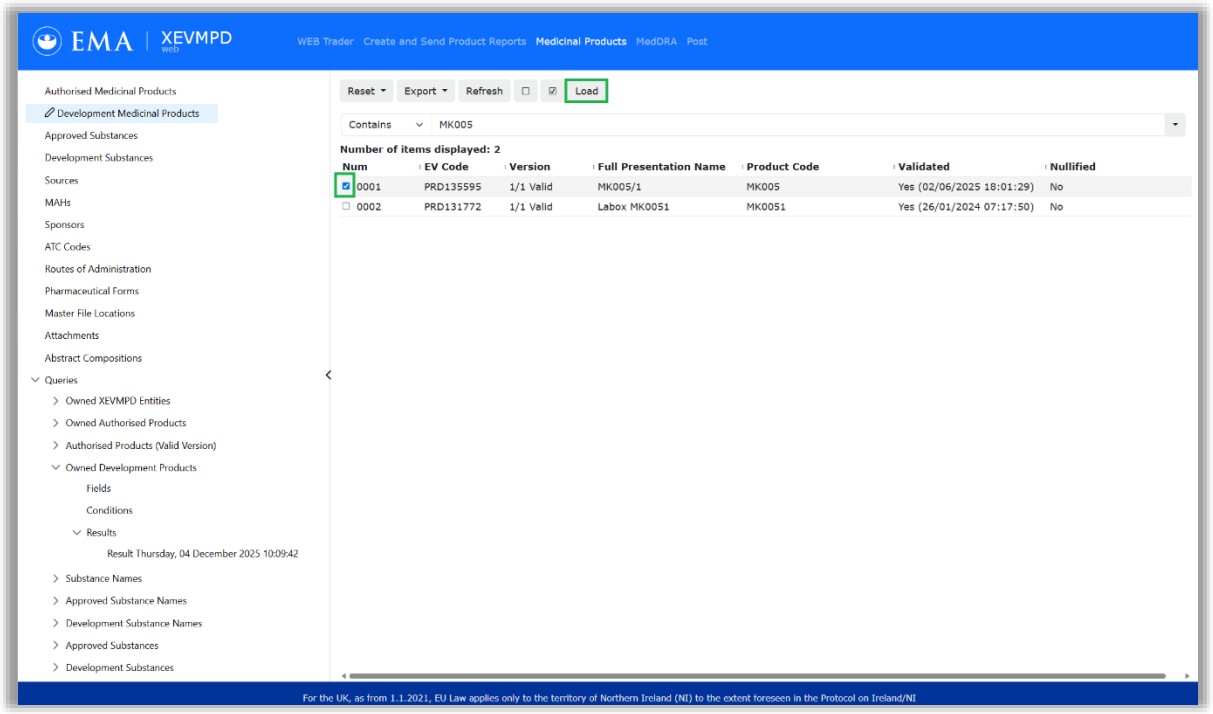


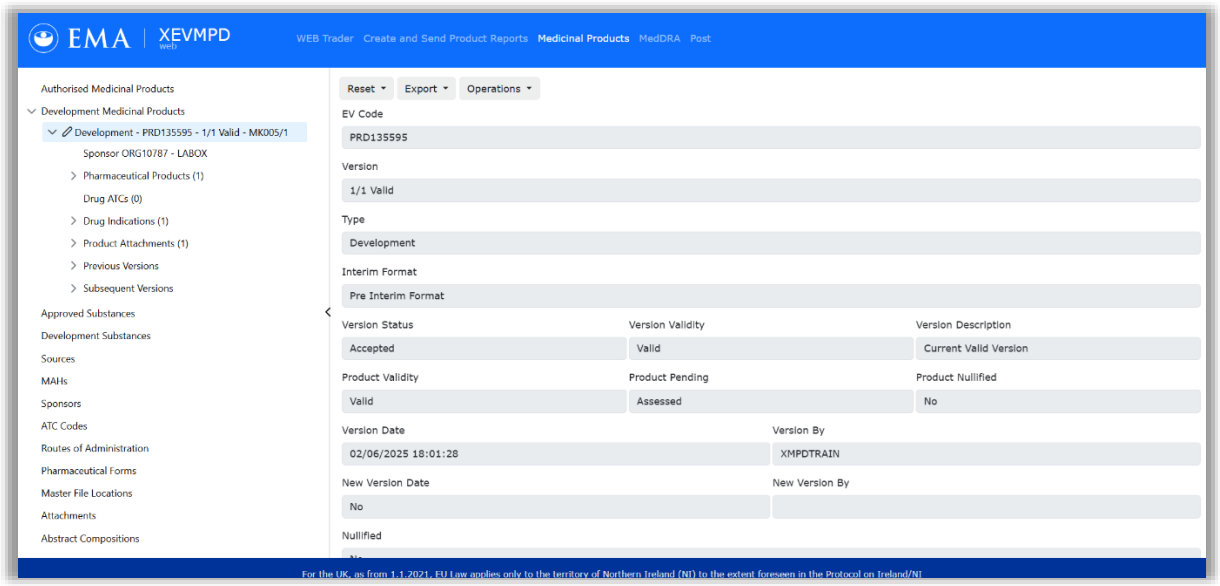
Users can select/de-select **one, multiple or all items** listed in the active area by clicking inside the checkboxes next to the items, or by clicking on the "Select all" button:

.

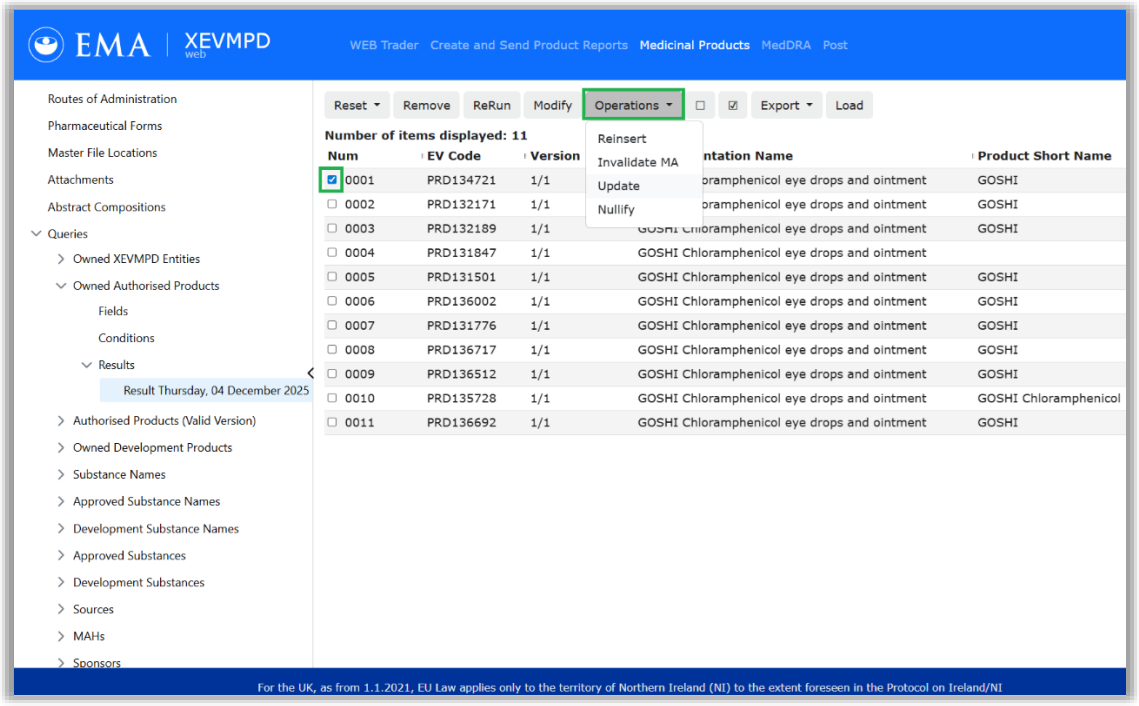
When the required items are selected, the user can:

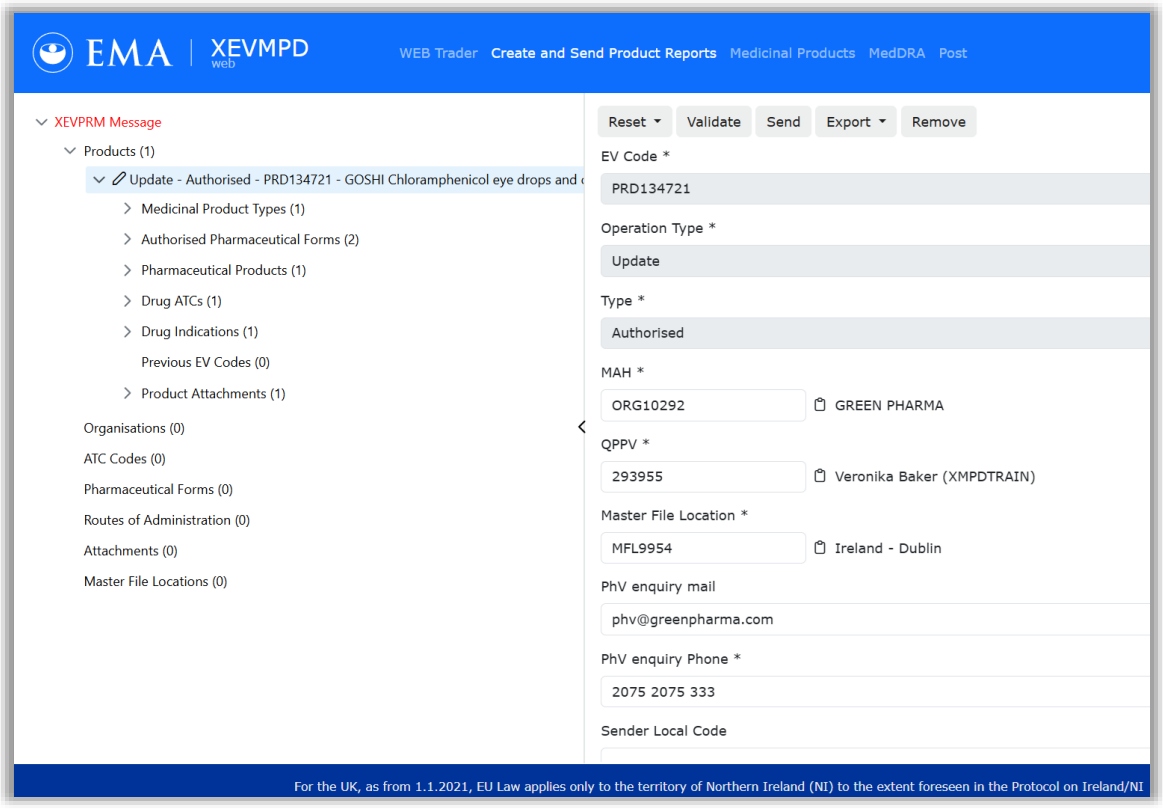
- **Load the items from the active area into the tree-view area** using the **'Load'** functionality:



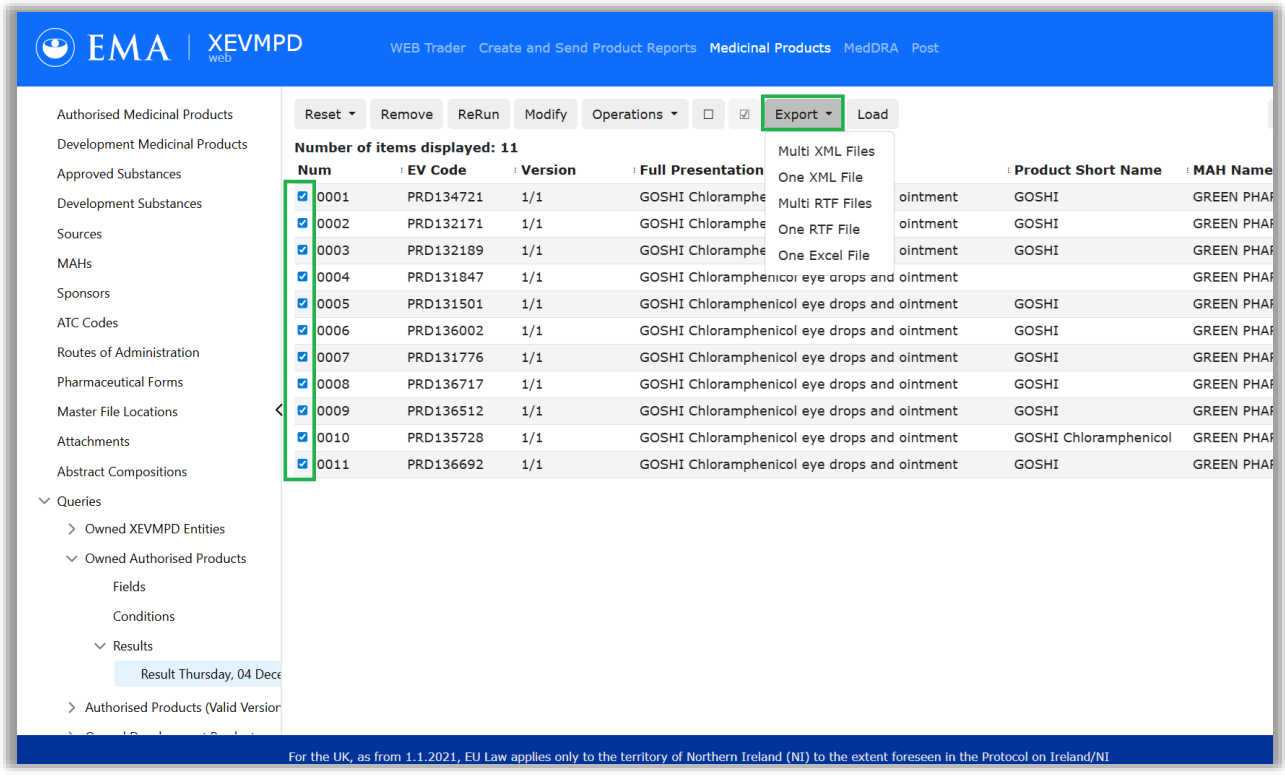


- **Load the items from the active area into the 'Create and Send Product Reports' area** using the 'Operations' functionality (available for results of an advance query):





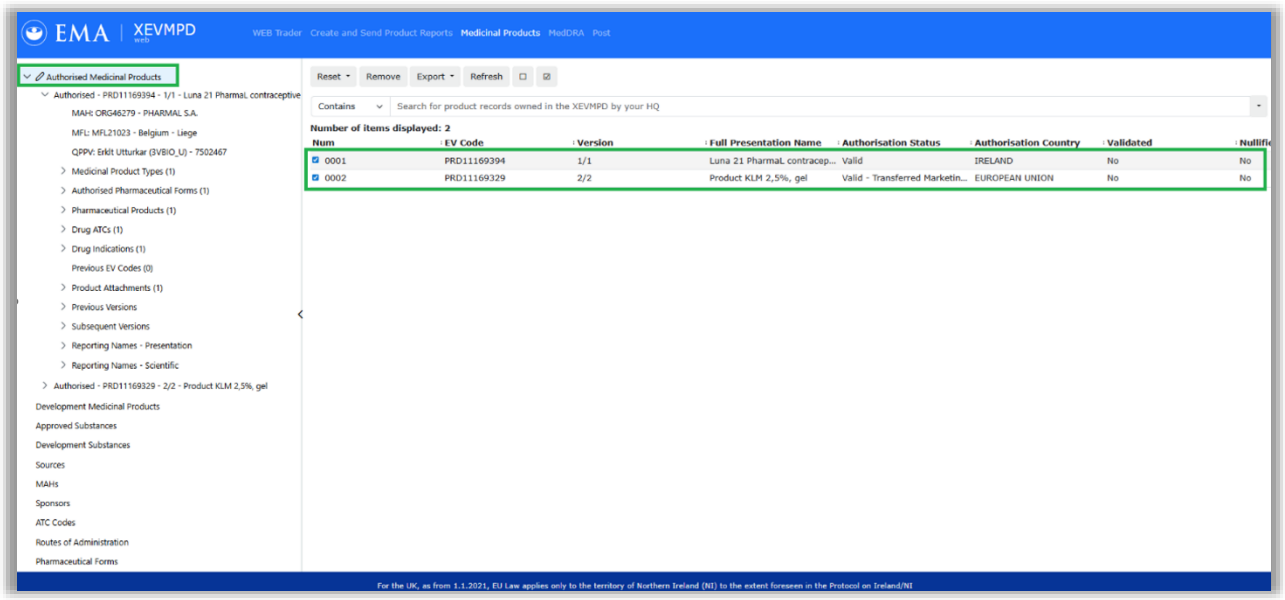
- **Export the selected items from the active area into XML, RTF or Excel file(s)** using the 'Export' functionality:



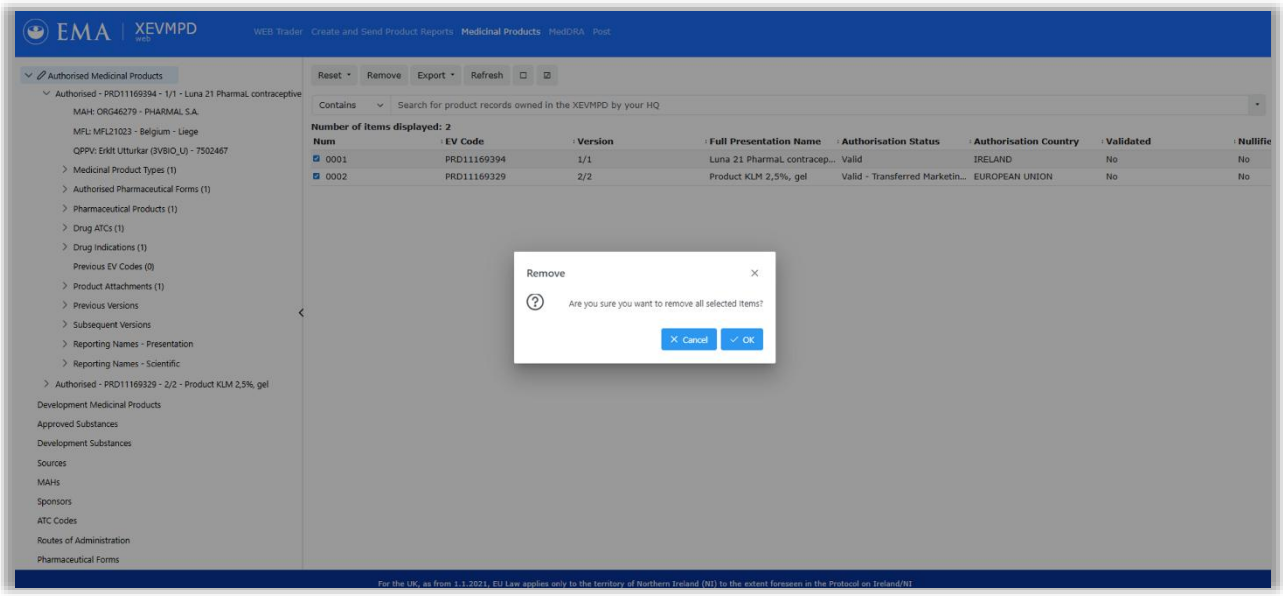
3.4.2.2. Removing items retrieved as a result of a search

Items that were loaded into the tree-view under their respective sections can also be removed from the tree-view and active area using the 'Remove' functionality and the checklist option:

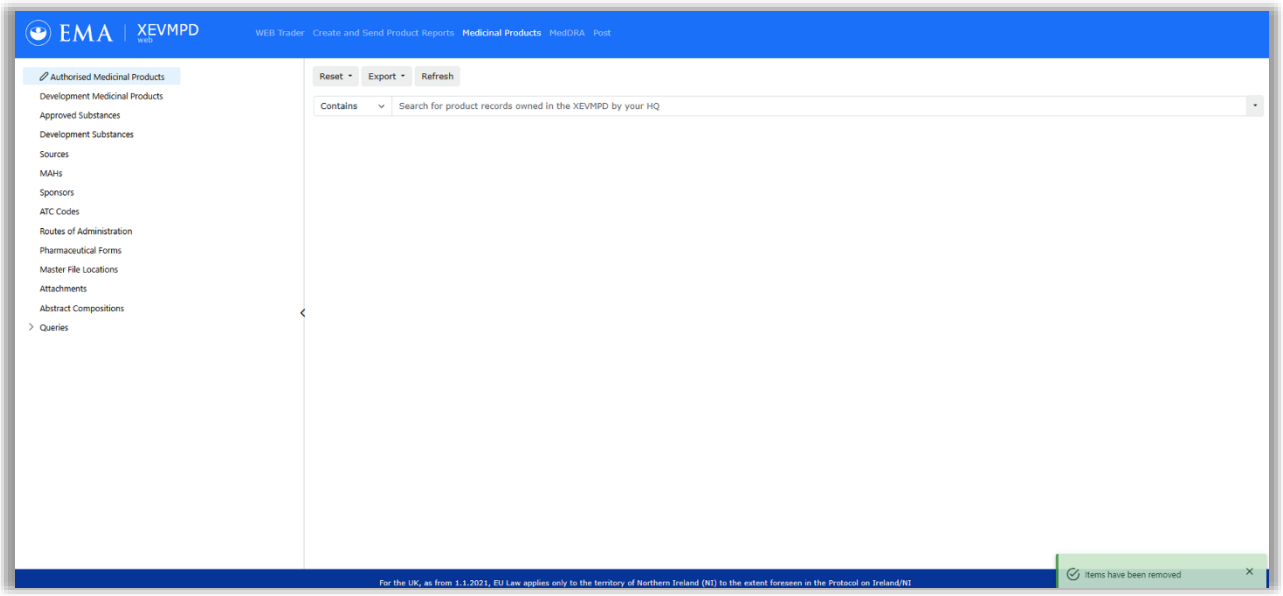
- **To remove an item added in the tree-view**, click on the section under which these items are listed in the tree-view area; the active area will display the items available in that section and the checkbox next to those items will be automatically selected:



Once you click on the 'Remove' button, which is now available, you will be prompted to confirm if all items under that section should be removed:



Once confirmed by selecting 'OK' in the displayed message, the items available in that section will be removed from the tree-view and active area:

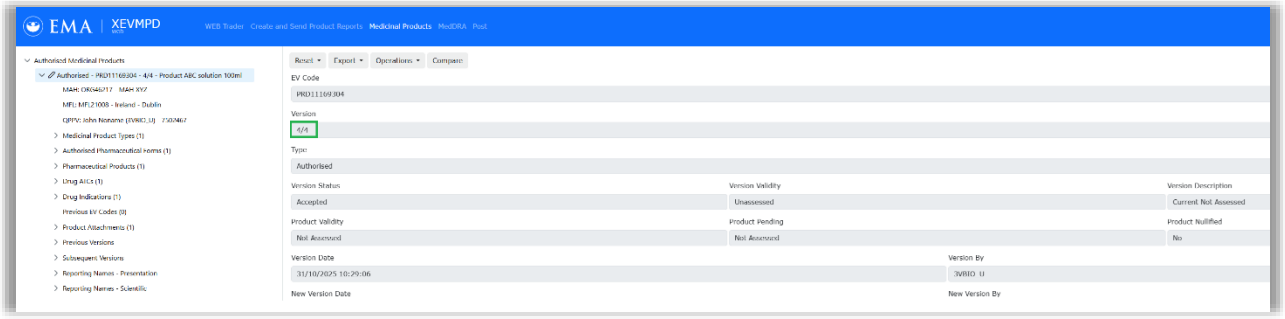


3.5. Functionalities

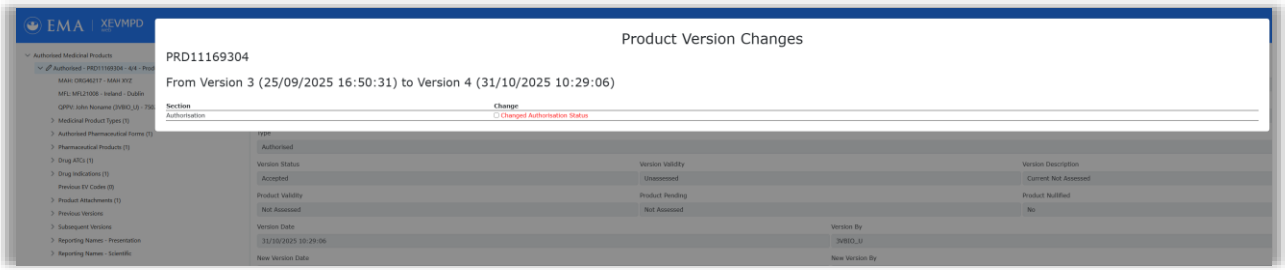
3.5.1. Compare

The 'Compare' functionality available in the 'Medicinal Products' section, allows users from the organisation that owns the AMP record in the XEVMPD, to compare the **current versus previous version** of an **AMP entity**.

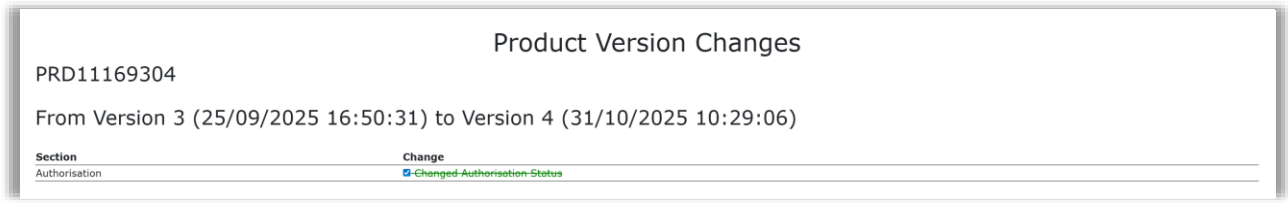
To compare individual versions of the medicinal product entity, retrieve the AMP entity so that it is available in the active area of EVWEB; as an example, in the below product, there are 4 versions:



By clicking on the 'Compare' functionality, a new window will open, providing a short description of the changes made between the current (i.e. the latest) and the previous version:

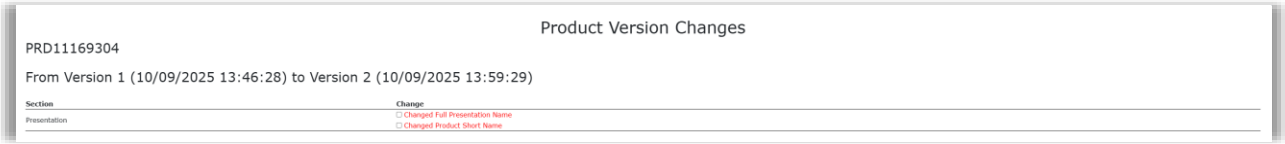


In this specific example, a change was made in the 'Authorisation status' field. The square box next to the field(s) is there to help the end user keep on track of the reviewed changes in case that multiple changes were made within one AMP entity. By selecting the box(es), the user can see which changes were reviewed and which are yet to be done:



Selecting/not selecting the relevant boxes has no impact on the changes made in the AMP or indeed the EVWEB.

The compare functionality can be used to compare also previous versions of the same entry. For example, the changes made between version 1 and 2 of the AMP are as follows:



3.5.2. Copy and paste functionality

It is possible to copy and paste information from free-text fields using Ctrl+C and Ctrl+V keyboard functionalities.

For look-up fields (remote and local), it is possible to copy the information within the field by using the "Clipboard" functionality:

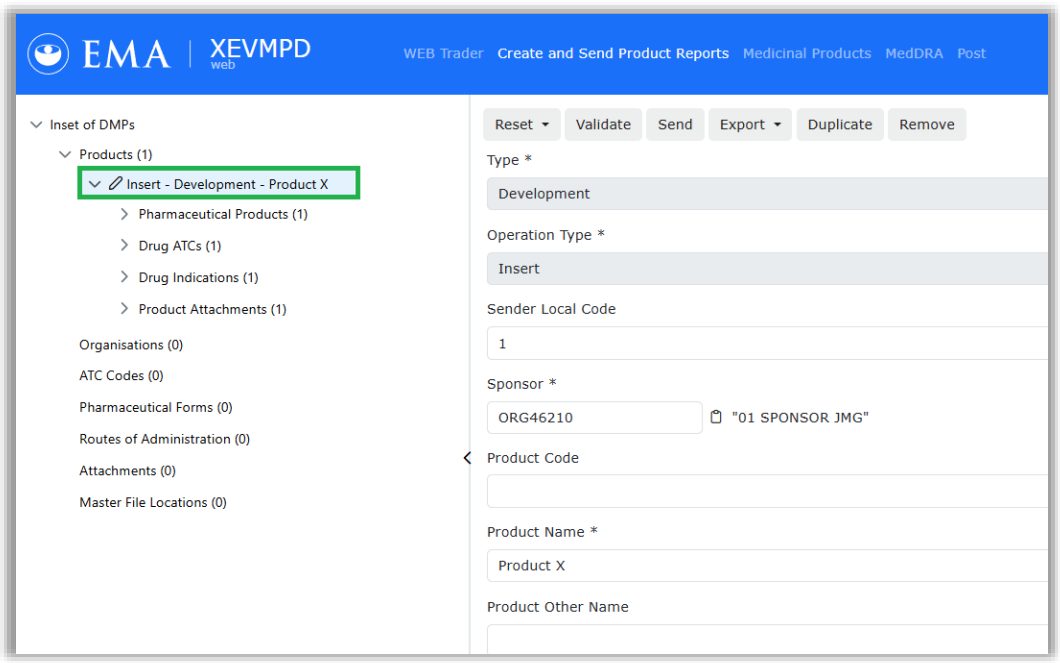
3.5.3. Duplicate

The 'Duplicate' functionality available in the 'Create and Send Product reports' section allows users to clone an item which already exists in the XEVPRM that is being created.

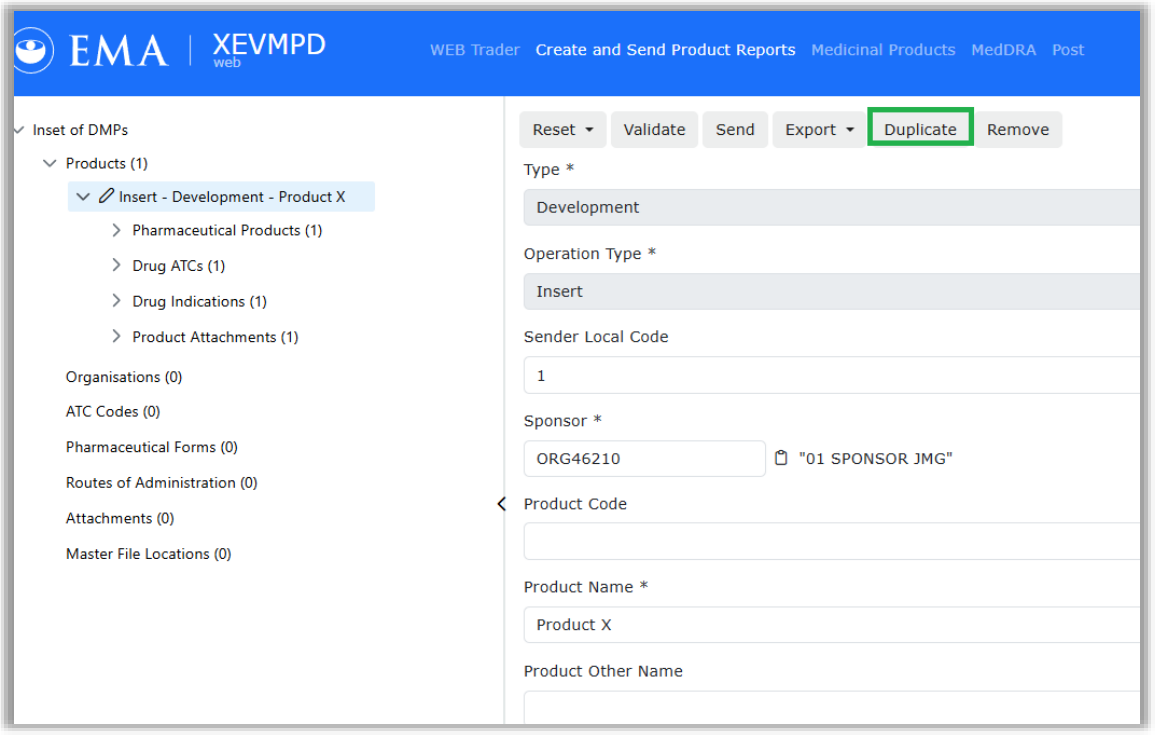
It is possible to duplicate entities that are being **inserted** in the XEVPRM or information within entities that are being **inserted**. It is not possible to duplicate entities that are being **maintained** (i.e. updated, invalidated or nullified).

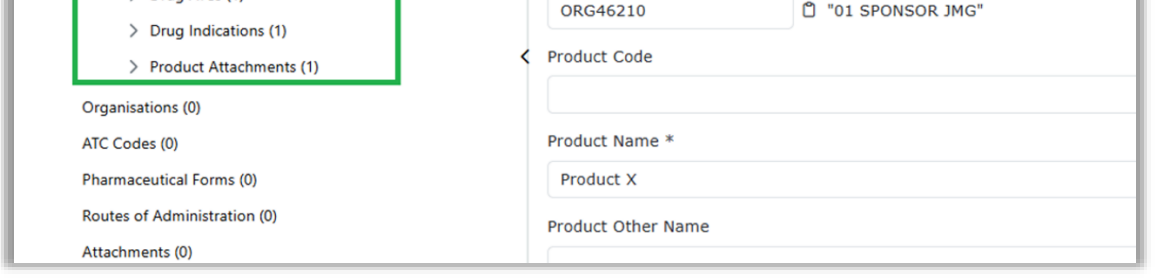
Duplicate detection is also in place to prevent users from submitting duplicated information and receiving a negative acknowledgement.

To use the 'Duplicate' functionality, users must click on the item to be cloned (product, organisation, MFL etc.) in the tree-view area, so that the entity is highlighted in the tree-view area in blue; the below screenshot shows a duplication of a DMP entity:



By clicking on the 'Duplicate' functionality, the product entity will be duplicated in the tree-view area, thus resulting in the XEVPRM containing two DMP entities with the operation type 'Insert':

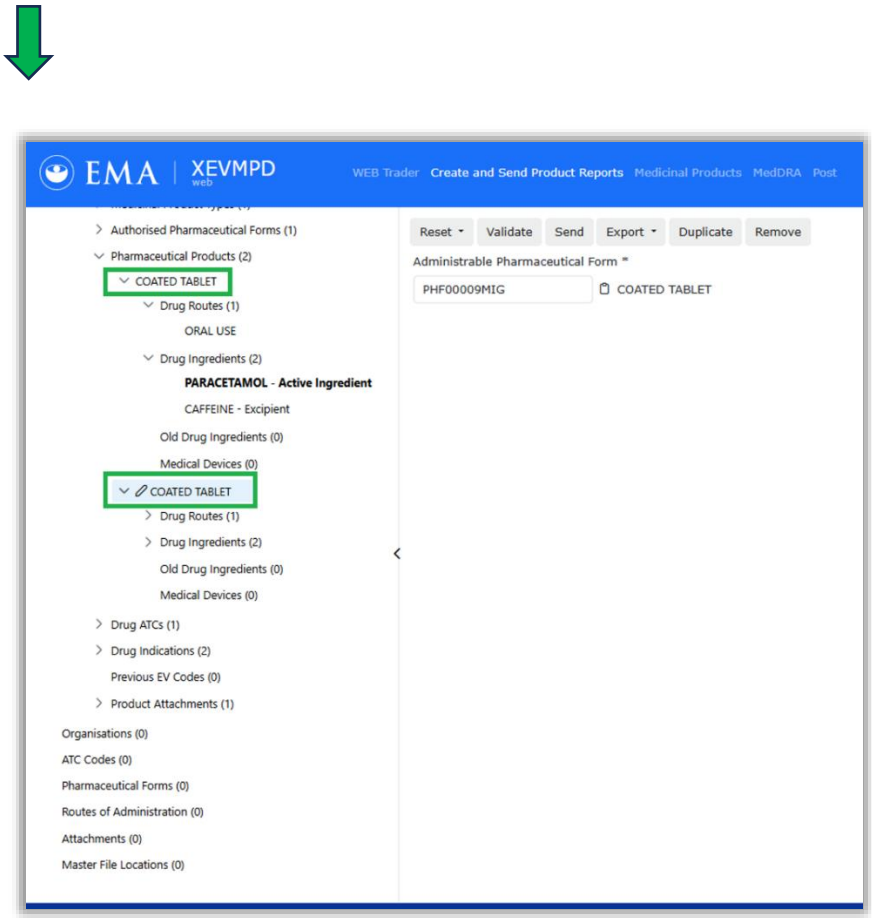




The user can then further modify the information within the entities before submission.

Users can also duplicate sub-sections within the product entities, such as the 'Pharmaceutical Product' section.

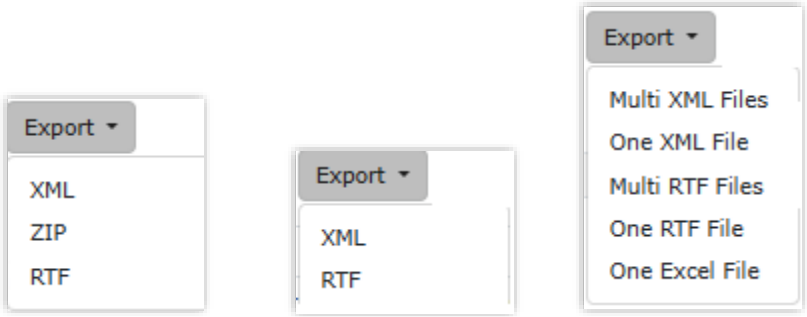
The below screenshot shows a duplication of the pharmaceutical product section (coated tablet) present within an AMP entity, resulting in the AMP containing two pharmaceutical products:



3.5.4. Export

XEVMPDweb allows several ways to export the loaded information. Each of these buttons will be available under the 'Export' functionality.

The formats that are available within the 'Export' functionality depend on the section in which the user is working, and on the item(s) selected.

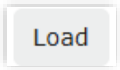


- **XML:** Allows users to generate an XML version of an XEVPRM message or the results of a query available in the active area.
- **RTF:** Allows users to generate an RTF (which is a typical cross-platform document format) version of the XEVPRM or results of a query selected in the active area.
- **ZIP:** Allows users to generate a ZIP file of the XEVPRM with an attachment (if present).
- **Excel:** Allows users to generate an Excel file of the results of a query selected in the active area.

The exported file(s) will become available in the 'Downloads' folder of the browser used to access XEVMPDweb by the user.

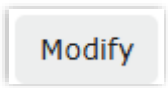
3.5.5. Load

The 'Load' functionality allows users to load items selected in the active area into the tree-view area.



3.5.6. Modify

This functionality will become available when results of a search are displayed in the active area; it allows users to modify the conditions of an existing search by redirecting the user back to the 'Conditions' section of the advanced query.



3.5.7. Operations

From technical point of view:

- **Reinsert**: Allows users to re-insert an existing XEVMPD entity (e.g. product, organisation, master file location etc., as per the applicable accessibility rules) whilst retaining the previous information. The existing entity will be moved to the 'Create and Send Product Reports' section, with the

assigned operation type 'Insert', where the user can further modify the information before submission.

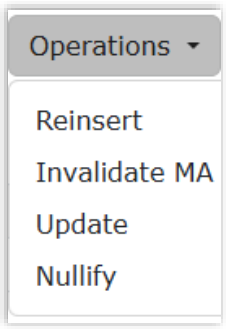
- **Update**: Allows users to update an existing XEVMPD entity owned in the XEVMPD by their headquarter organisation (e.g. product, organisation, master file location etc.) providing that this entity is not invalidated or nullified. The existing entity will be moved to the 'Create and Send Product Reports' section, with the assigned operation type 'Update', where the user can further modify the information before submission.
- **Nullify**: Allows users to nullify an existing XEVMPD entity owned in the XEVMPD by their headquarter organisation (e.g. product, organisation, master file location etc.) providing that this entity is not:
  - already nullified;
  - invalidated (in case of an authorised medicinal product);
  - validated by the EMA (this does not apply for DMPs, which are flagged as validated by default upon their initial submission).

  If the nullification is allowed, the existing entity will be moved to the 'Create and Send Product Reports' section, with the assigned operation type 'Nullify', where the user can further modify the information (e.g. to provide the reason for nullification in the 'Comment' field of the entity) before submission. If the entity to be nullified is however referenced in other not-nullified entities (such as AMPs or DMPs), the nullification will be rejected by system, and the user will receive a negative acknowledgement.

  Nullified entities are never deleted from the XEVMPD; when the nullification related status field references 'Yes', this indicates that the entity is no longer current, and no future use of this entity within any submissions is possible.
- **Invalidate MA**: Allows users to invalidate an existing AMP record owned in the XEMVPD by their headquarter organisation providing that the AMP is not:
  - already invalidated;
  - nullified in the XEVMPD.

  If the invalidation is allowed, the existing AMP entity will be moved to the 'Create and Send Product Reports' section, with the assigned operation type 'Invalidated MA', where the user can further modify the information and assign the required 'Not-valid' marketing authorisation status and invalidated date before submission.

  Invalidated AMP entities are never deleted from the XEVMPD; their authorisation status is set as 'Not valid' to indicate that the marketing authorisation of the medicinal product is not valid.



From business point of view, the above referenced operation types are to be used to cover wide range of scenarios; for this reason:

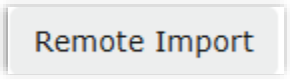
- MAHs users should refer to Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance and
- Sponsor users should refer to the Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD) to check how/which operation type should be used to notify a change related to their data in the XEVMPD.

3.5.8. Refresh

The 'Refresh' functionality allows users to refresh the search within the section that they are working in.

3.5.9. Remote import

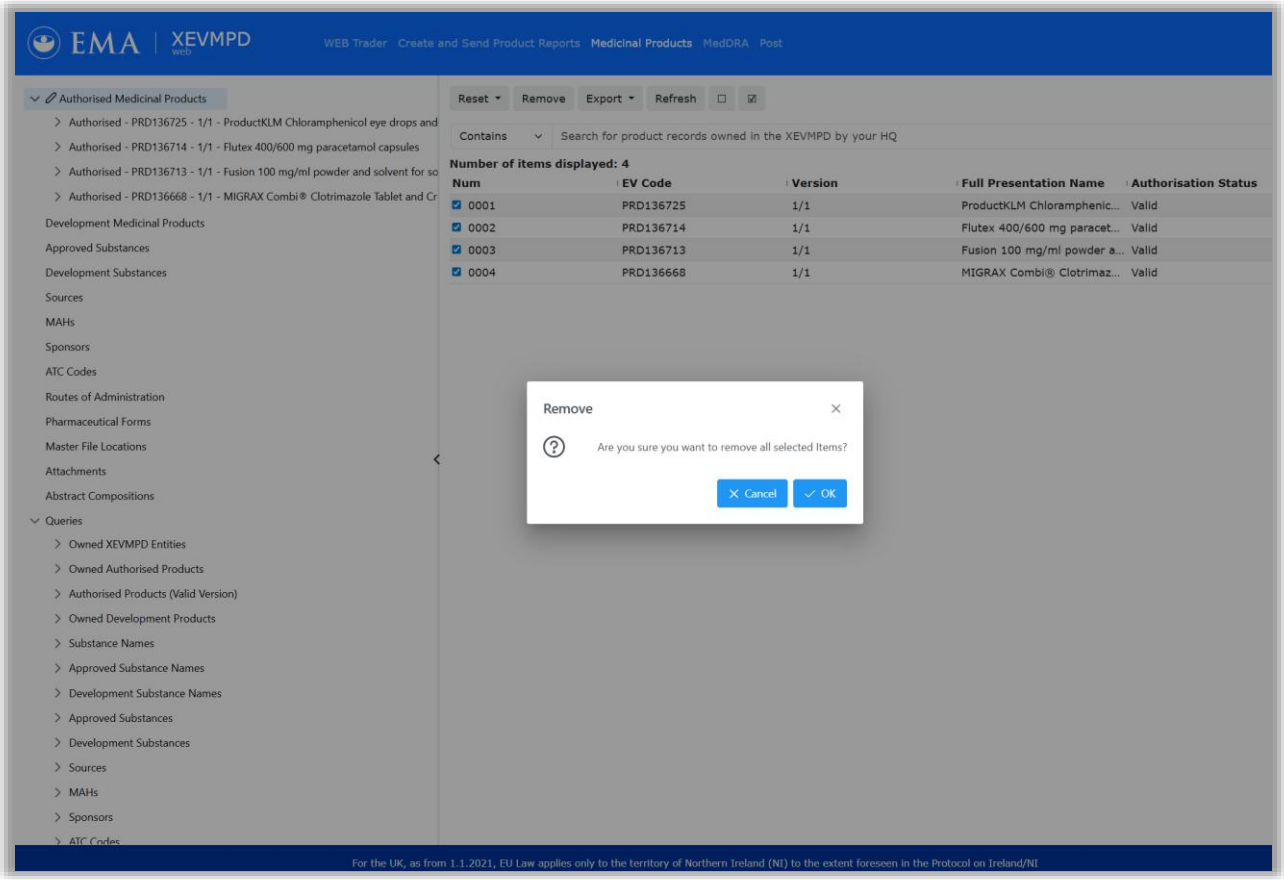
The 'Remote Import' functionality available in the 'Web Trader' section allows users to import a message (submitted or received) from the active area into the tree-view area.



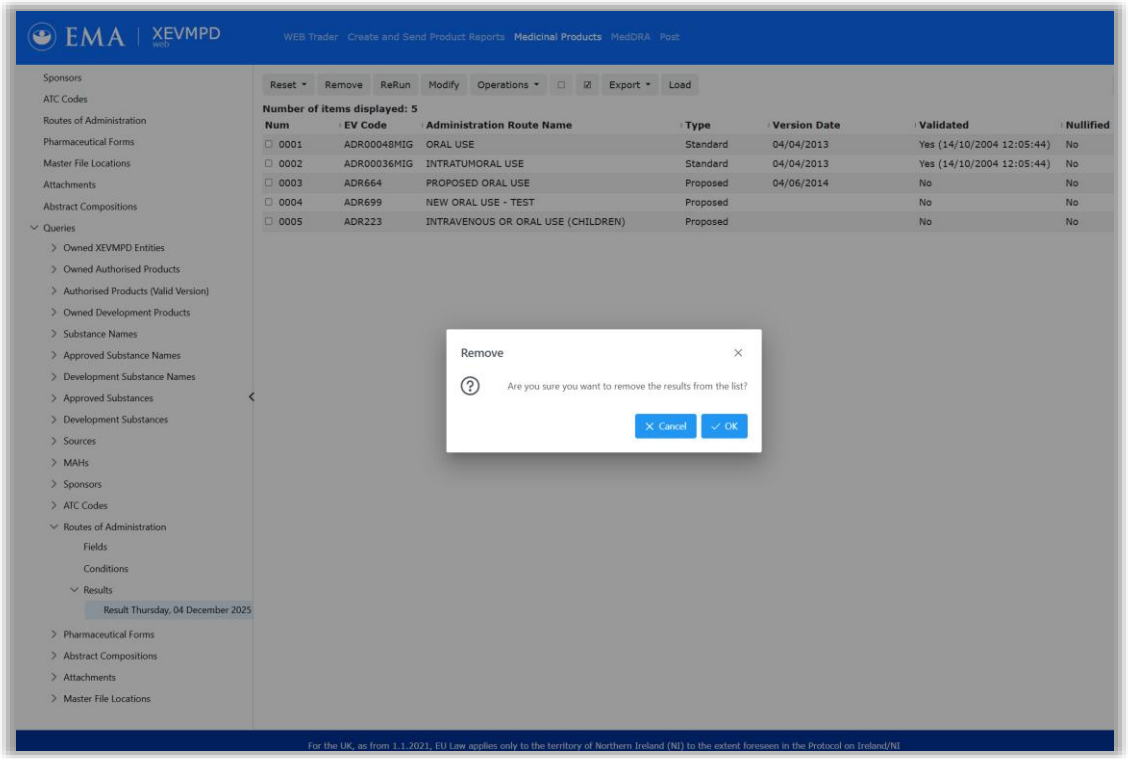
3.5.10. Remove

This functionality should be used to delete item(s) from the tree-view and/or active area of the user interface. This functionality **will not remove the item(s) from the XEVMPD** as this action will only affect the current data present in the user's personal session in the user interface.

- When removing results of a simple query from the tree-view area, all results listed in the active area will be selected (via the checkbox option) by default. Uless the user de-selects the results that should remain, these will be removed just by clicking on the 'Remove' functionality and confirming 'OK' when the below message is displayed

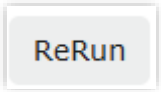


- When removing <u>results of an advanced query</u> it is not possible to select any results to be removed. **All results** listed in the active area will be removed upon clicking on the 'Remove' functionality and confirming 'OK' when the below message is displayed:



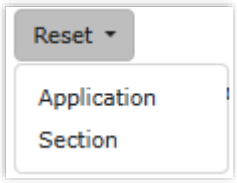
3.5.11. ReRun

This functionality will become available when results of an advanced search are displayed in the active area; it allows users to run an existing search, based on the already specified conditions, again.



3.5.12. Reset

The 'Reset' button is available by default in each section of the user interface; by clicking on this functionality, two options are revealed:



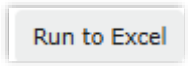
- Upon selecting **'Application'**, the entire user interface will re-set, resulting in losing any data available in each of the sections at that point.
- Upon selecting **'Section'**, only the specific section of the user interface will be affected, resulting in losing any data available in that section at that point.

3.5.13. Run

The 'Run' functionality allows users to run their advanced query; the results will be displayed in the active are.

3.5.14. Run to Excel

The 'Run to Excel' functionality allows users to run their advanced query directly to an Excel file without viewing the results in the active area first. The exported file(s) will become available in the 'Downloads' folder of the browser used to access XEVMPDweb by the user.



3.5.15. Select/De-select all

When items are loaded in the active/tree-view area, it is also possible to select/de-select all items available in the active area by using the following functionalities, which will become available next to the dynamic buttons:

 **Select all:** This button allows the user to select all entities displayed in the active area/tree-view (maximum of 50 results is shown per page). Users can use this button instead of manually checking each single item:

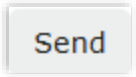
 **Deselect all:** Allows the user to de-select all entities displayed in the active area/tree-view (maximum of 50 results are shown per page). Users can use this button instead of manually unchecking each single item:

3.5.16. Send

The 'Send' functionality is available in the 'Create and Send Product reports' section to users from organisations registered in EudraVigilance as WebTrader organisations.

If the user is from an organisation registered in EudraVigilance as Gateway user, the 'Send' button will be missing.

This functionality allows users to submit the XEVPRM which is being created into the system.



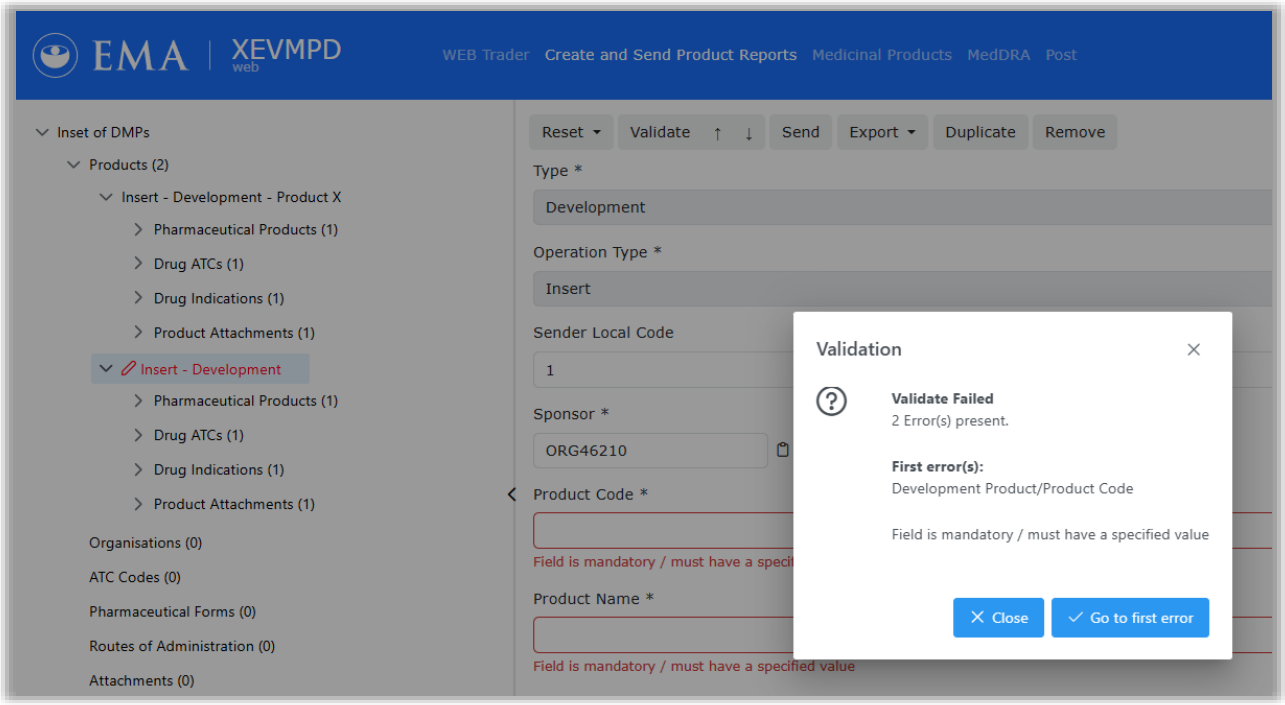
3.5.17. Sort conditions alphabetically

The 'Sort conditions alphabetically' functionality allows users to alphabetically sort the condition fields of an advanced query in the active area in an alphabetical order.

3.5.18. Validate

The 'Validate' functionality available in the 'Create and Send Product reports' section allows users to perform a check of the information in the XEVPRM that is being created and flag any possible errors (such as missing mandatory data etc).

The system will confirm the result of the check via a pop-up message that will be displayed on the screen and the fields/sections with errors will be highlighted in red:

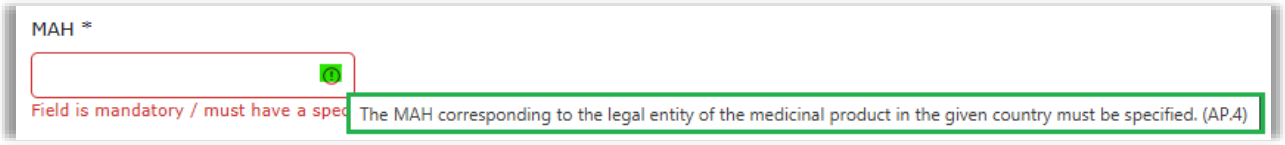


3.6. Data entry input fields

There are four types of fields for users to enter information into the system:

- text fields;
- date field/time fields;
- look-up fields (local and remote); and
- query fields.

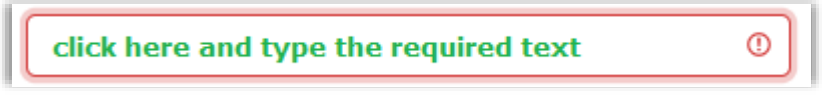
Most of the fields reference a tooltip, which provides a brief overview of the type of information that is expected for that field. The tooltip can be viewed by hovering over the ⓘ symbol:



3.6.1. Free-text fields

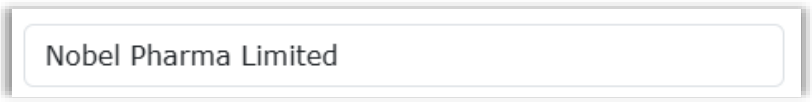
This is the most common type of field in XEVMPDweb. Free-text fields require information that must be entered using the keyboard.

To enter information in a free-text field, users must click inside the field space and type in the required information:



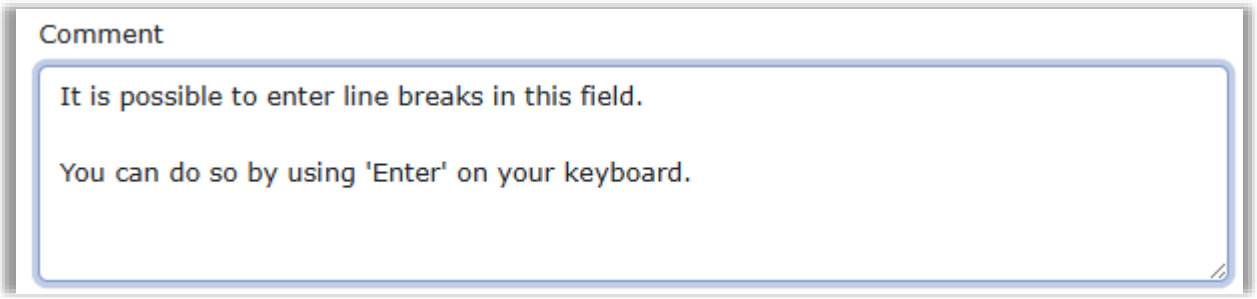
Once you start typing, the colour of the field changes from red to blue:

When you finish typing the required text and click outside the field, the field will display the text that you entered:



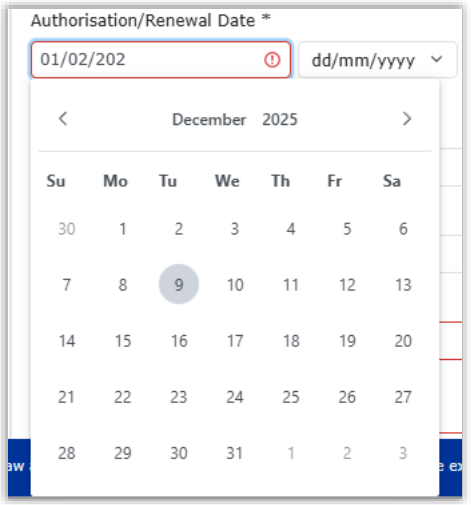
It is possible to copy and paste information to and from text fields.

Each text field has a defined number of characters that can be entered in that field; many fields in the XEVMPD allow up to 2000 characters to be entered. In some fields [for example in the 'Comment' field of an AMP (AP.14)], users are also allowed to enter line break(s). These can be added by using 'Enter' on your keyboard:



3.6.2. Date/time fields

This type of field is used in XEVMPDweb to enter the date information in different formats. The information is entered using a graphical interface that recalls a calendar or can be entered (in the required format) using your keyboard:

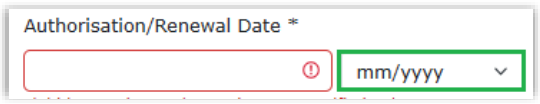


Many fields in XEVMPDweb can accept the date information in different formats; **the options that are available depend on the business rules set up for the specific field**:

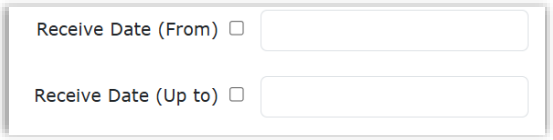
- date/month/year; i.e.: **dd/mm/yyyy**

- month/year; i.e.: **mm/yyyy**

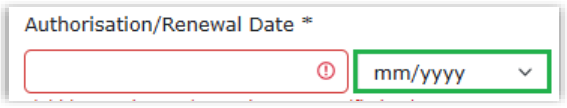
If it is possible for a field to choose the format in which the date should be provided, the field will display the format next to the field:

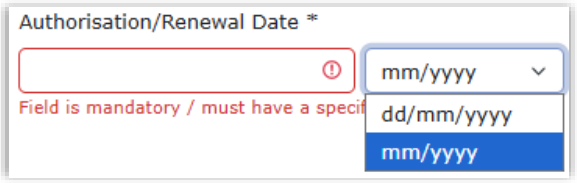


If it is not possible to choose the format in which the date should be provided, the field will not display the format option next to the field:

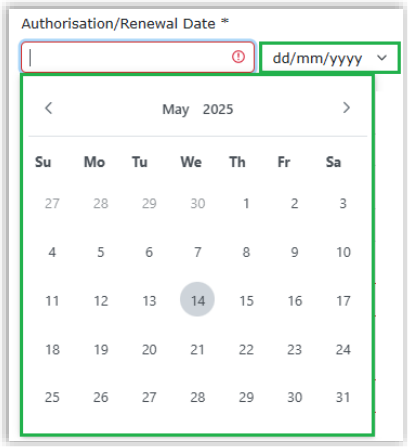


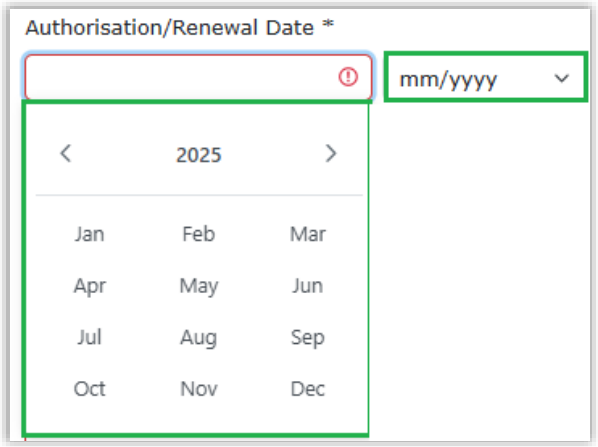
The formats can be selected by clicking on the format button next to the calendar and selecting the required option:



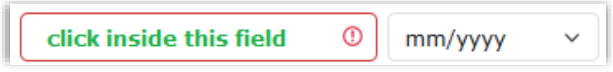


The calendar will then be displayed as per the selected option:

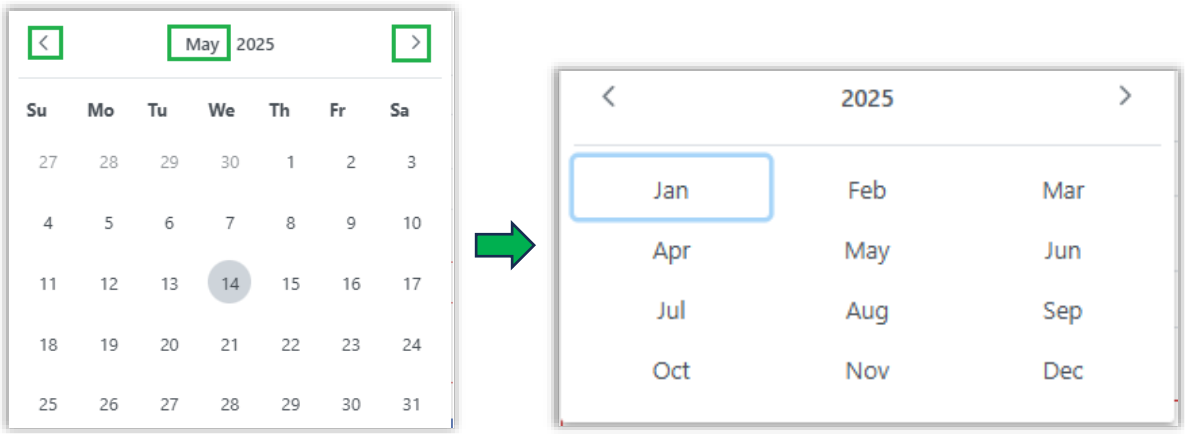




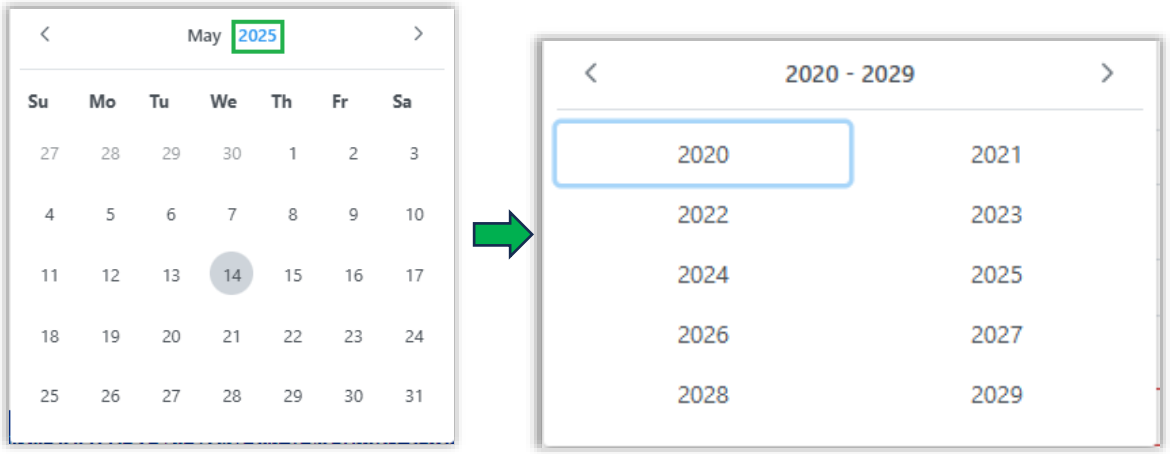
To enter information in a date field, click inside the field, and the calendar option will be presented for the selected format (i.e. either date/month/year or month/year). By default, it displays that current date, month and year:



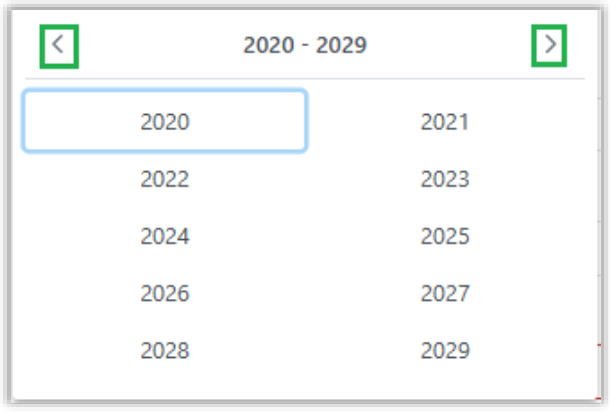
- To change the **month**, click on the month to view the other months, or use the side arrows for navigation:



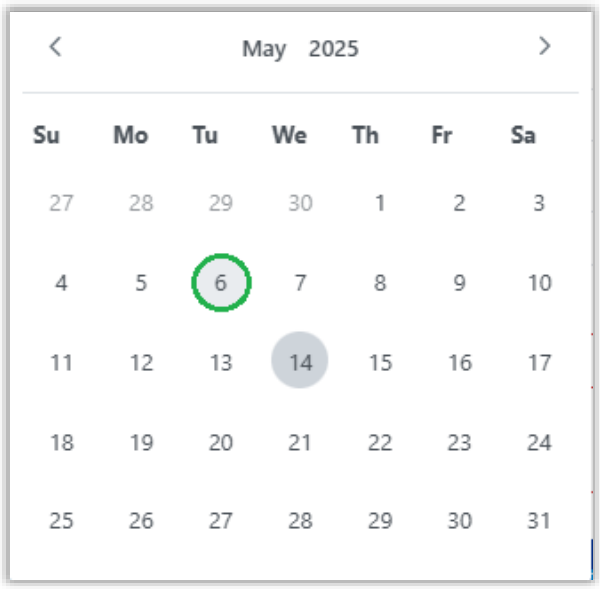
- To change the **year**, click on the year to view other years:



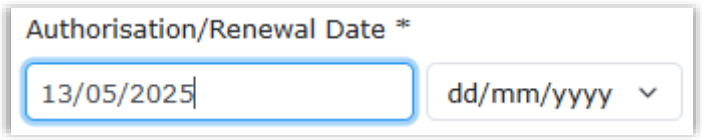
You can then navigate to different years by using the side arrows:



- To change the **date**, click on the specific date:



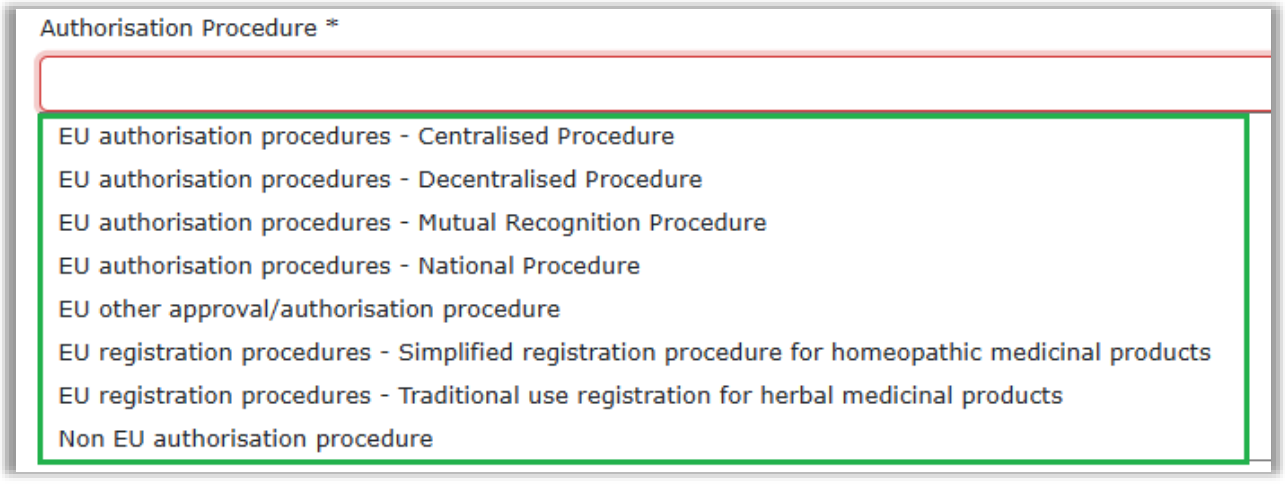
The day selection confirms and enters the date and closes the calendar screen:



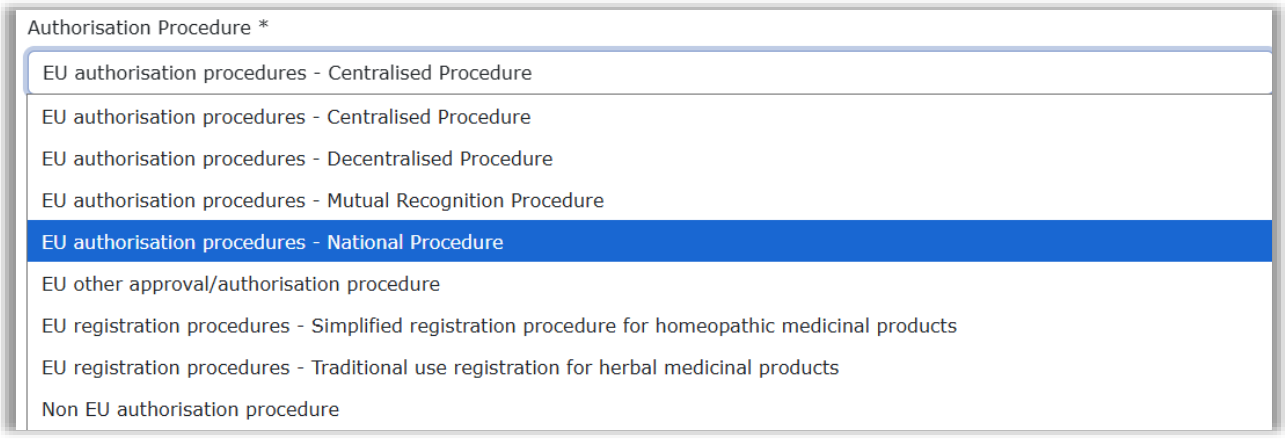
3.6.3. Look-up fields/tables

In this type of field, users are presented with a drop-down menu of available options.

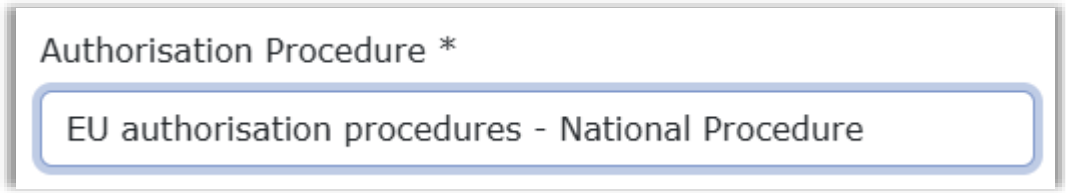
By clicking inside the field, the list of pre-defined values will be displayed:



Users provide the input for that field by selecting **one of the available values**; the value that is being selected in highlighted in blue:



By clicking on the required value, the value is then presented in the field:

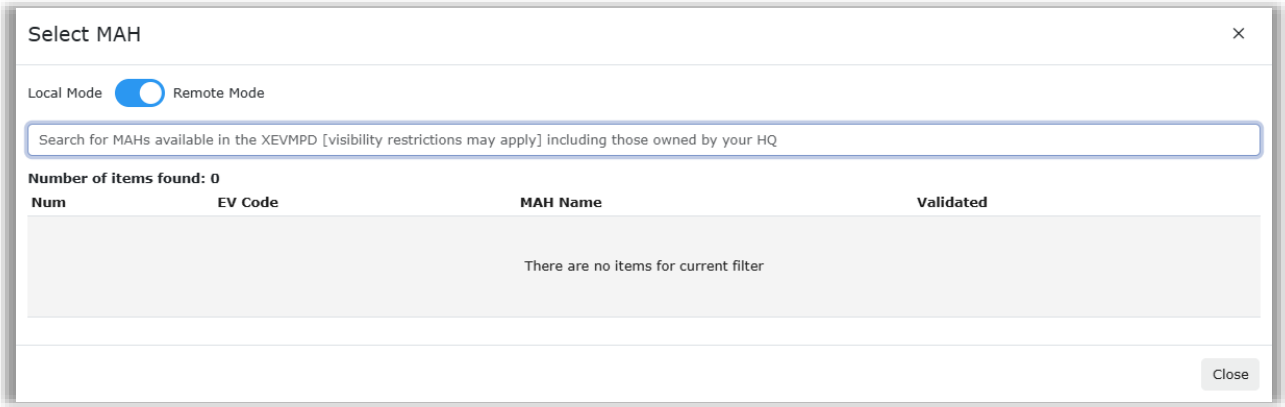


- To change the referenced value for another value, you can repeat the above-described steps.
- To remove the selected value so that the field is completely empty:
  - click inside the field again, so that all available options from the drop-down menu are visible,
  - then click inside the field again and press the 'Delete' or 'Backspace' buttons on your keyboard.

3.6.4. Remote database look-up tables

This type of field requires data that needs to be selected from a predefined **list already available in the XEVMPD** (i.e. an EV Code is already assigned to that entity). The data is generated as a result of a query.

To search remote look-up table within a field, users must click inside the field; a new pop-up window will be displayed:

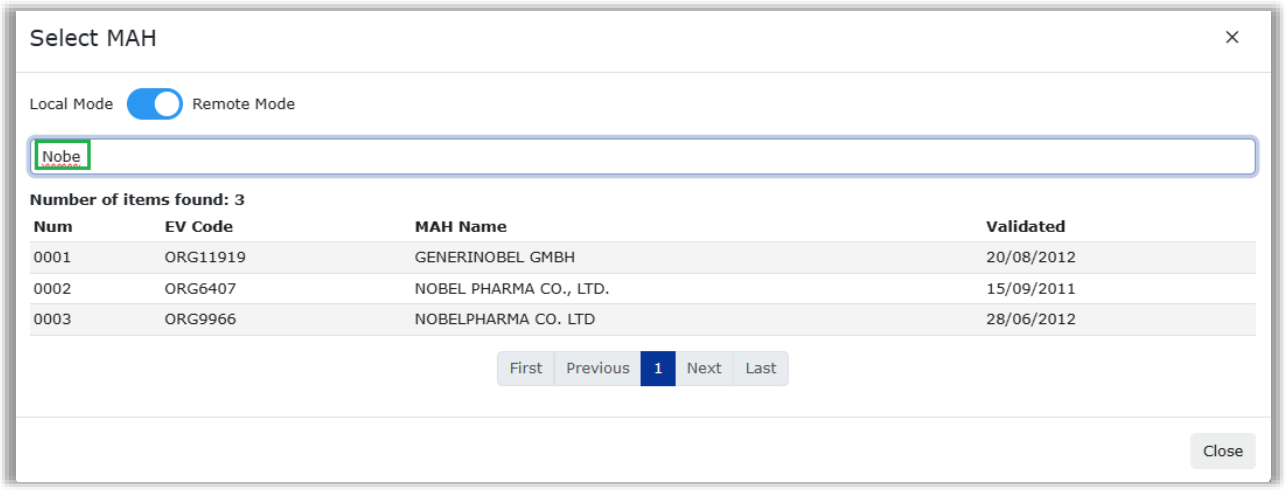


The search mode is set to **'Remote Mode' by default**:

- If it is possible to switch the look-up from Remote to Local, the button will be highlighted in blue:

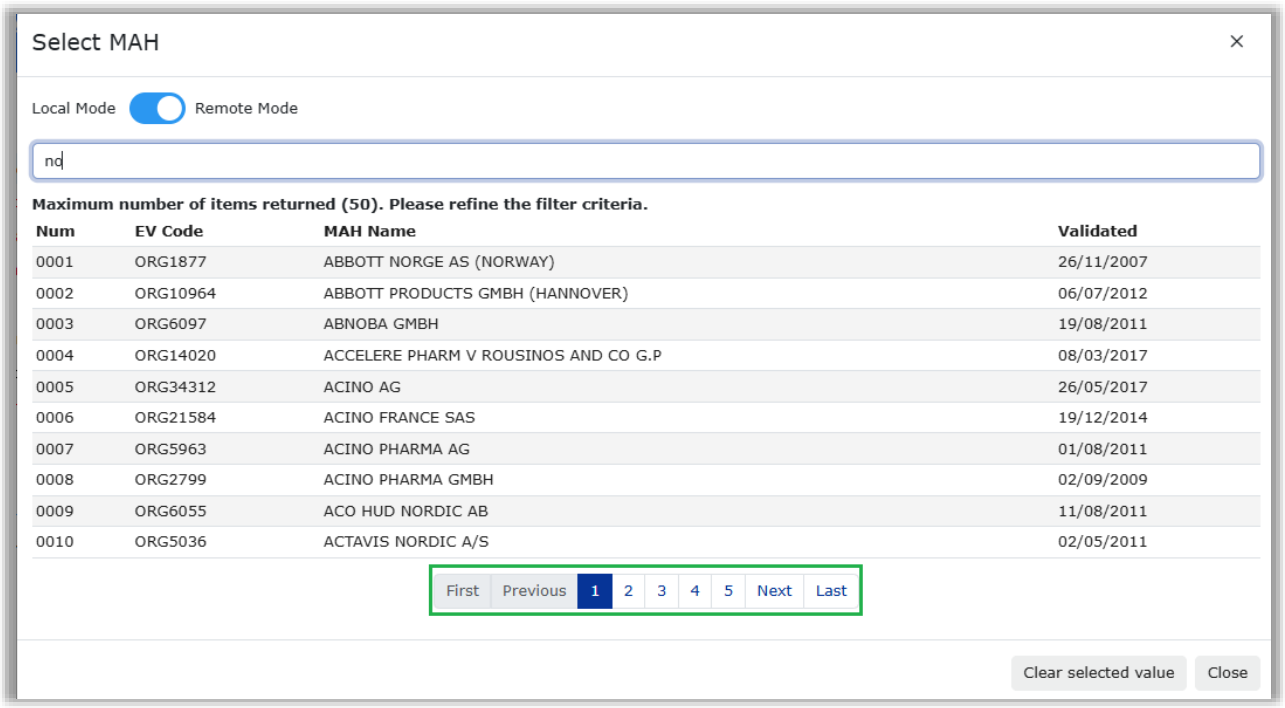
- If it is not possible to switch the look-up from Remote to Local, the button will be highlighted in grey:

By typing in the required text, the system will perform a search for entities that **contain** the typed text and display the retrieved results:

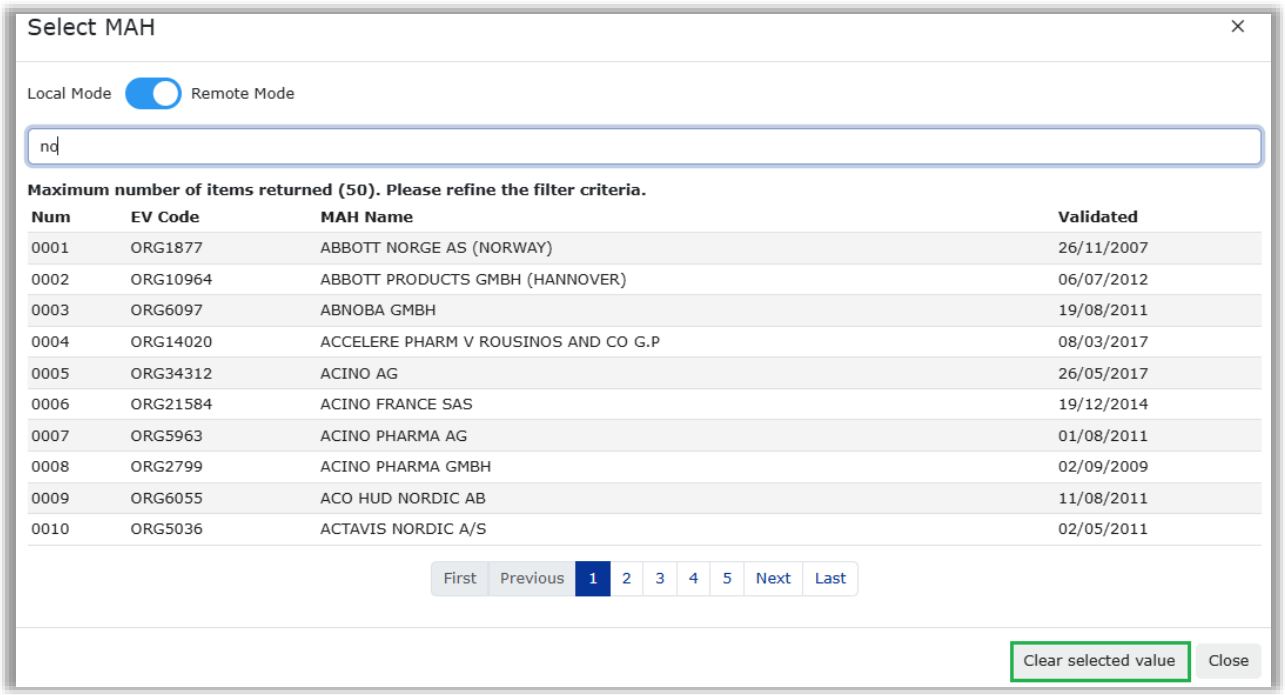


The more text is typed into the search field, the more the system restricts the search.

If multiple results are found, the results are paginated; each page will display 10 results. **Maximum of 50 results can be displayed** as a result of a query. To move between pages, users can click on the individual page numbers or go straight to the first, previous, next or last page:

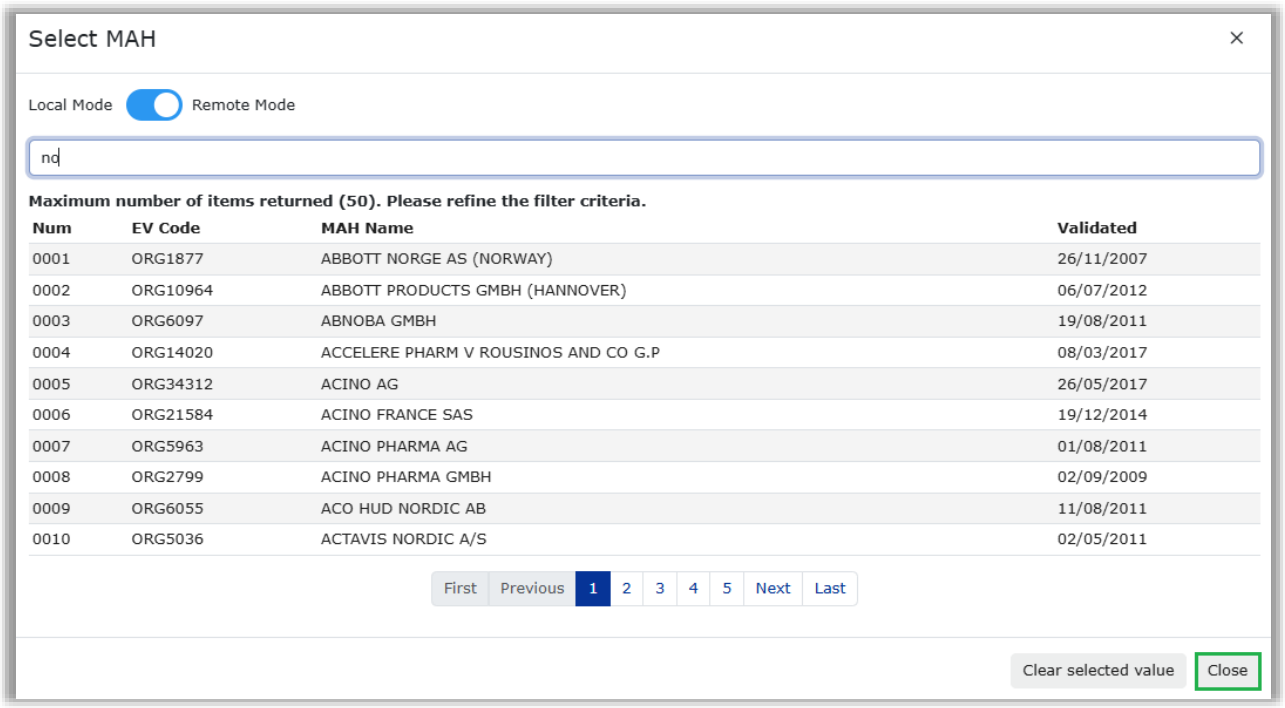


To **clear the search**, users can either remove the text from the search field by selecting the text and using 'Delete' or the 'Backspace' functionality on their keyboard, or by using the **'Clear selected value'** option within the window:

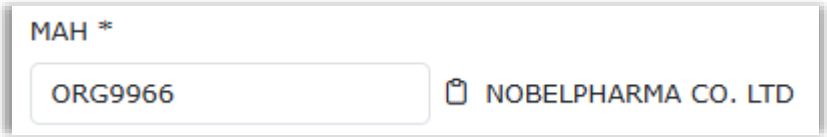


The **'Clear selected value'** option within the window will also close the look-up window.

To close the look-up window without clearing the values, the **'Close'** option within the window can also be used:



Once you select the required value from the displayed results, the information is entered in the field:



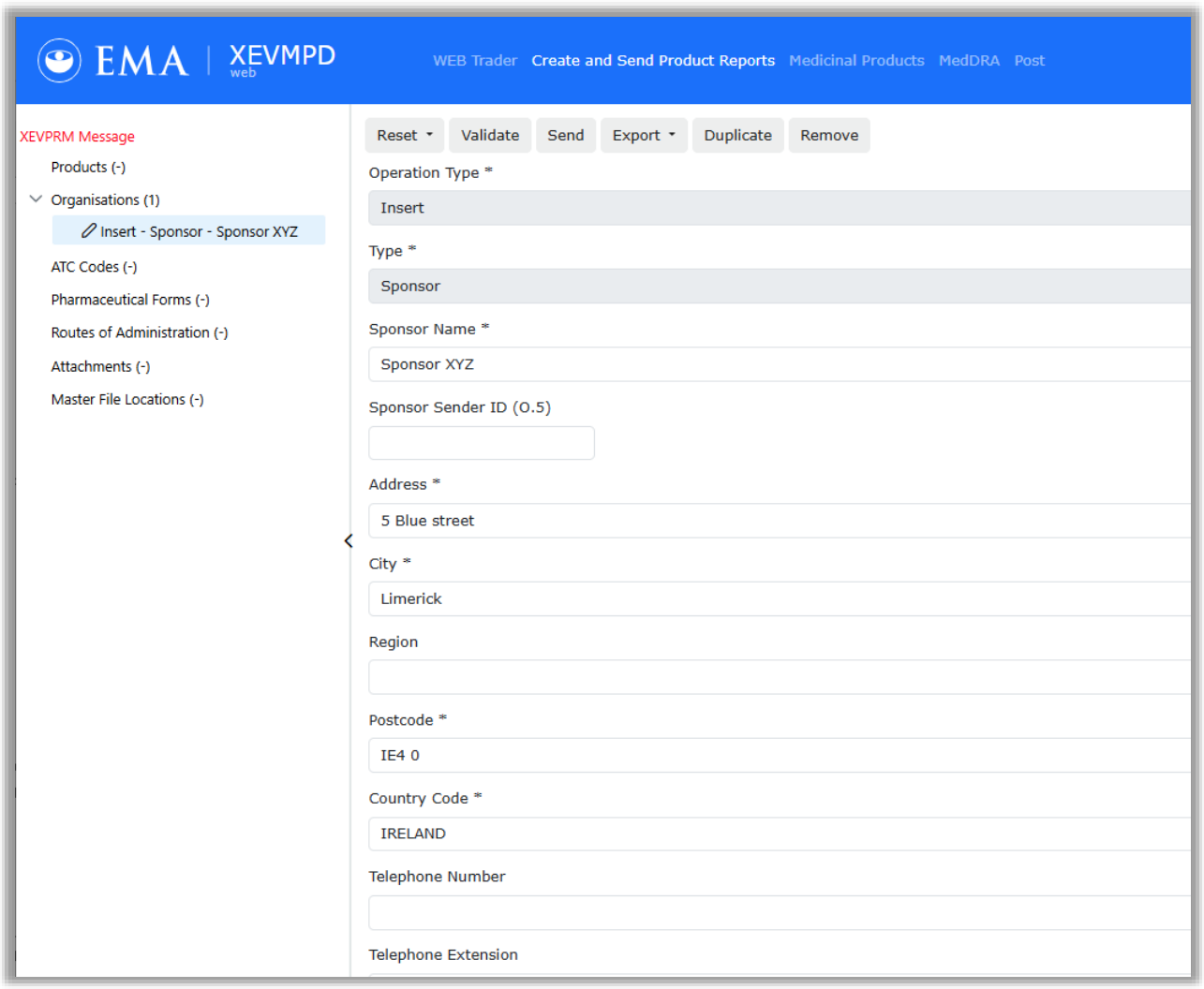
3.6.5. Local database look-up tables

When an entity, which needs to be referenced in a product entity (AMP or DMP), is not included in the (remote) look-up tables already present in the XEVMPD, users can add this new information in the same XEVPRM.

To reference an entity not yet present in the XEVMPD (i.e., an entity without an assigned EV Code), users must add the information for that entity in the relevant section of the XEVPRM and then reference this entity in the required field by retrieving it from the **'Local Mode'** look-up table.

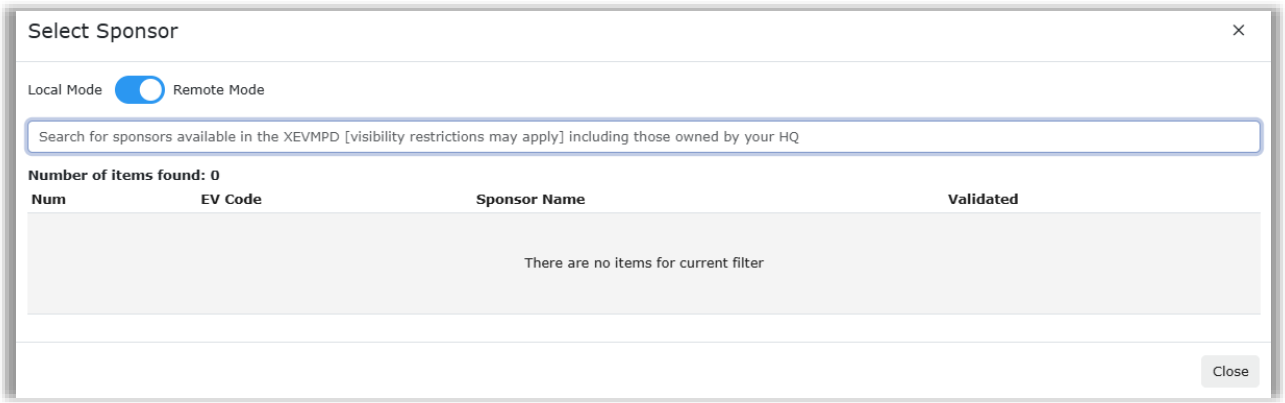
Example:

An organisation with the name "Sponsor XYZ" must be referenced as the 'Sponsor' within a development medicinal product. This sponsor organisation does not exist in the XEVMPD. The sponsor information is therefore entered in the 'Organisation' section of the XEVPRM that is being created:

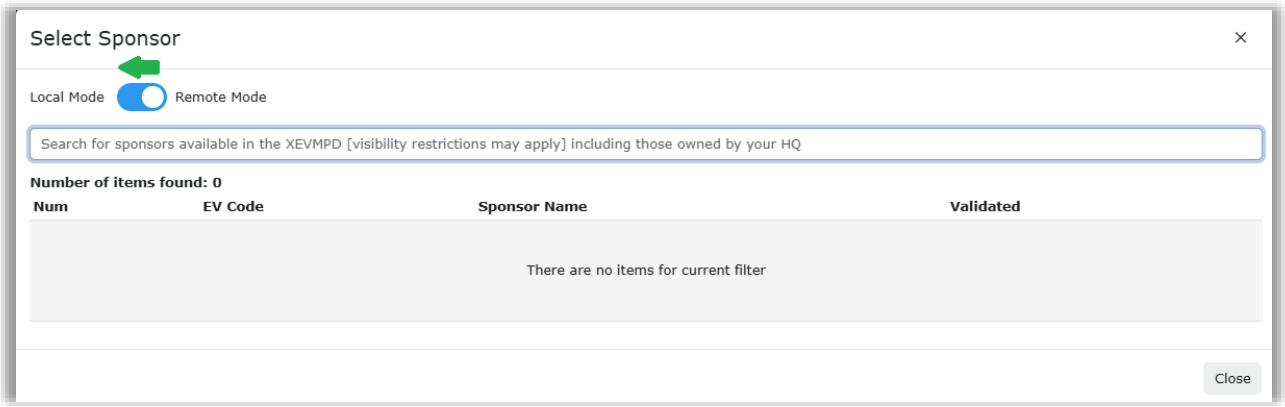


Once the sponsor information is provided in the 'Organisations' section of the XEVPRM, the sponsor organisation will be available for selection from the local look-up table in the 'Sponsor' field within the development medicinal product entity.

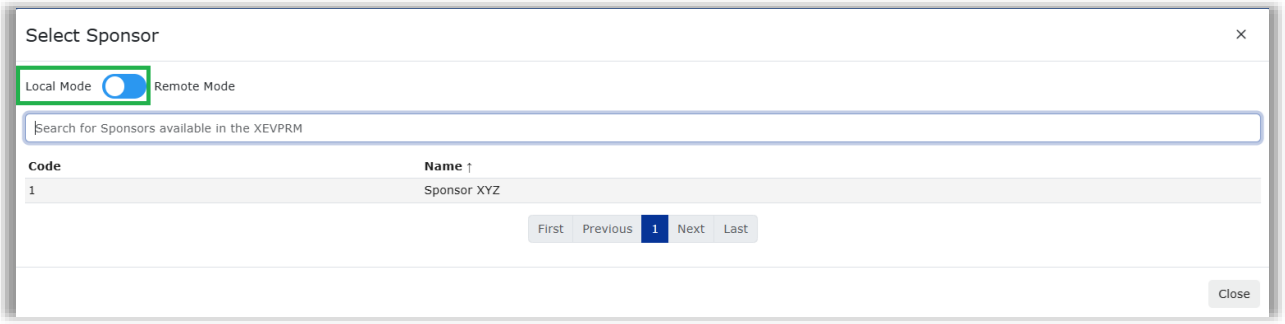
To search local look-up table **within the required field**, users must click inside the field; a new pop-up window will be displayed:



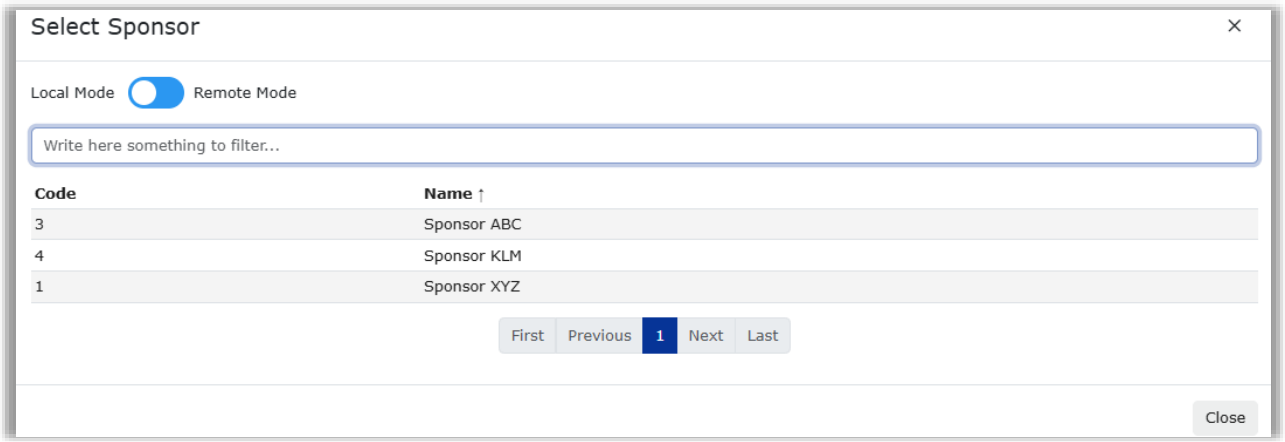
The search mode is set to **'Remote Mode' by default**. The search mode must therefore be switched to the **'Local Mode'** by moving the toggle to the left:



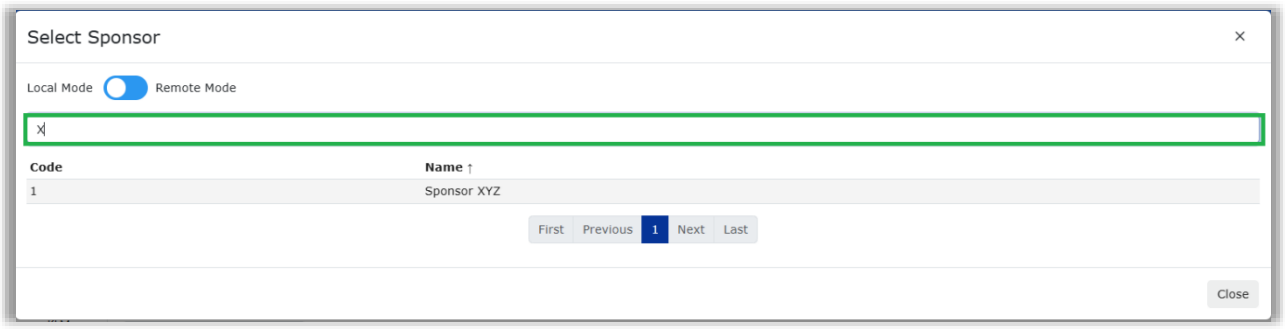
By doing so, the system will display the retrieved results **for that entity** (in this case, a sponsor organisation):



The search panel is also available to allow users to query the local look-up list; this is useful when multiple records for the same type of entity were inserted via the same XEVPRM:



By typing in the required text, the system will perform a search for entities that **contain** the typed text and display the retrieved results:



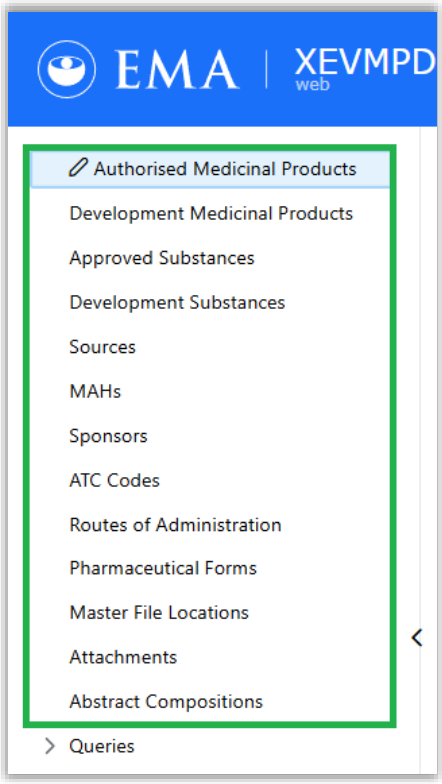
Once you select the required value from the displayed results, the information is entered in the field:

3.7. Search methods

To search the XEVMPD, users can perform a simple search (using the simple query field) or an advanced search (using the advanced query section).

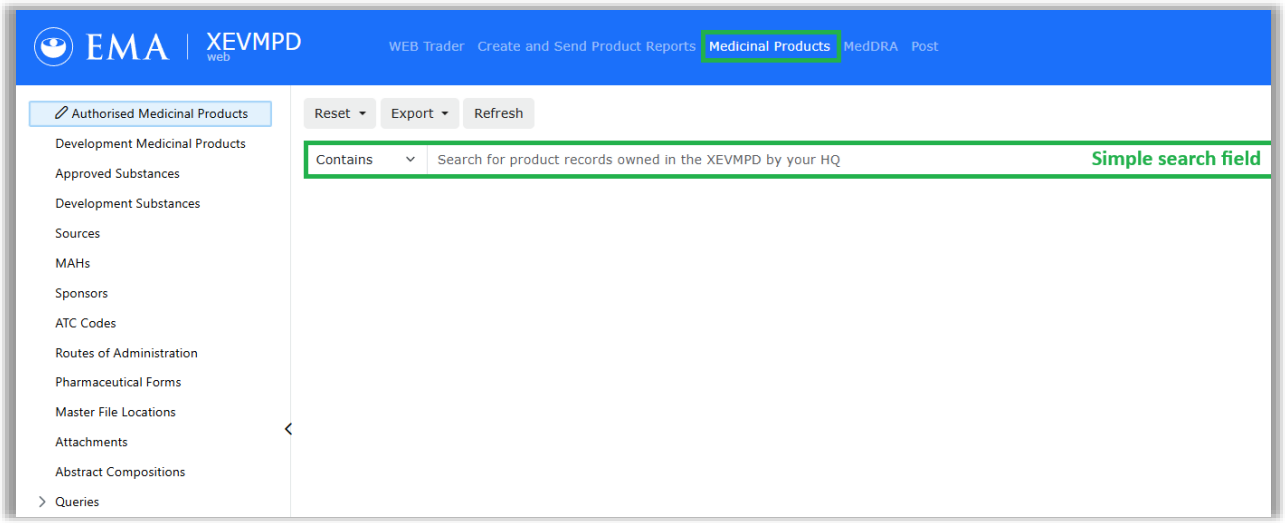
3.7.1. Simple query

The simple query field is available for each of the below shown sub-section of the 'Medicinal products' section of XEVMPDweb.

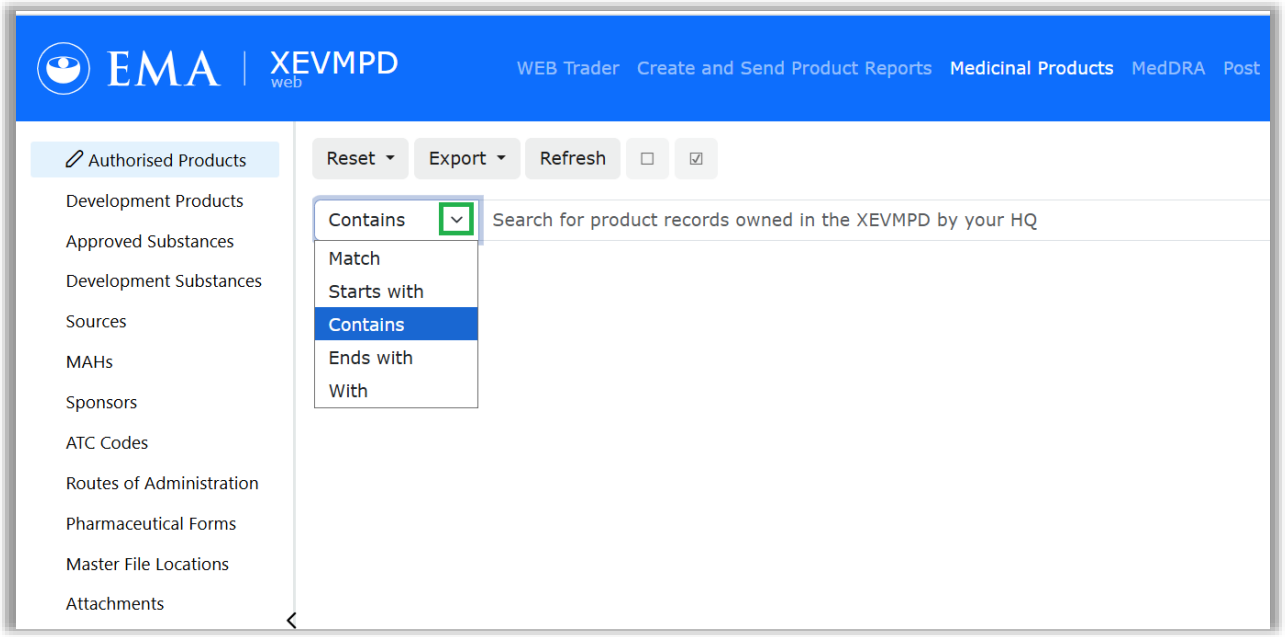


The simple search field is located at the top of the active area for each of the individual sections referenced in the tree-view area.

Example: Simple search field for 'Authorised Medicinal Products' sub-section:

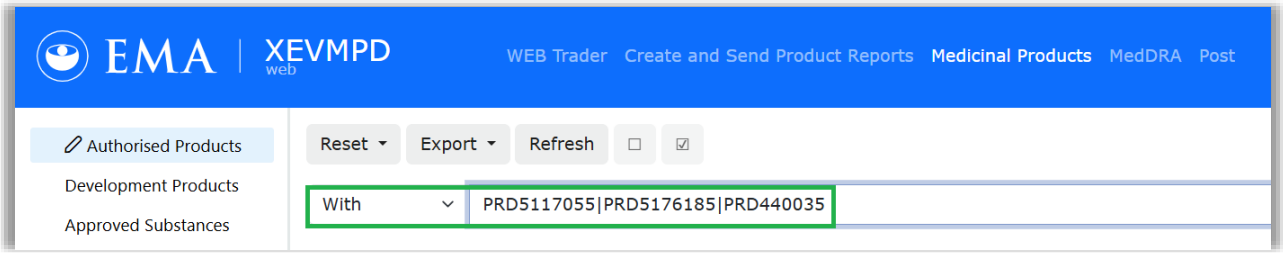


By default, the search is carried out with the simple 'Contains' clause however, it is possible to select other options by clicking on the downwards arrow next to 'Contains':



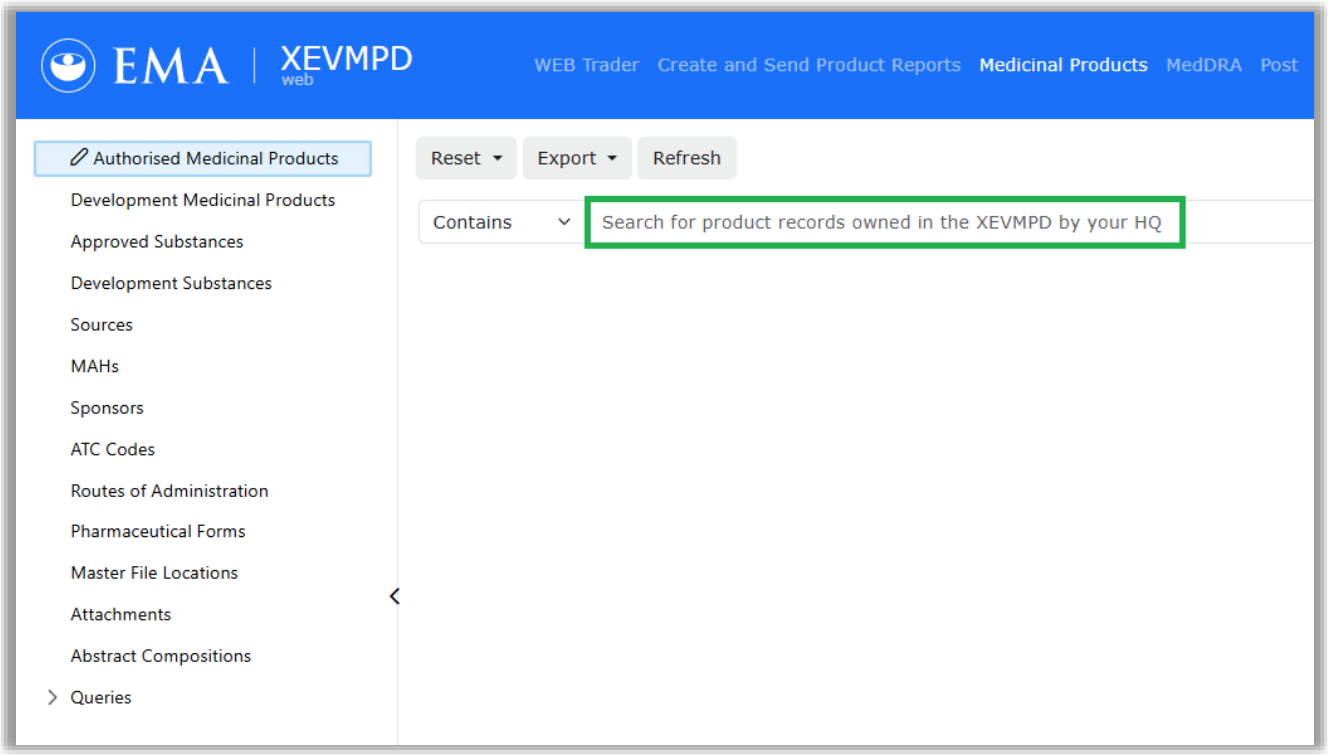
- '**Match**' will indicate that the search should be performed for items that are an exact match of the entered value.
- '**Starts with**' will indicate that the search should be performed for items that begin with the entered value.
- '**Contains**' will indicate that the search should be performed for items that reference the entered value.
- '**Ends with**' will indicate that the search should be performed for items that end with the entered value.

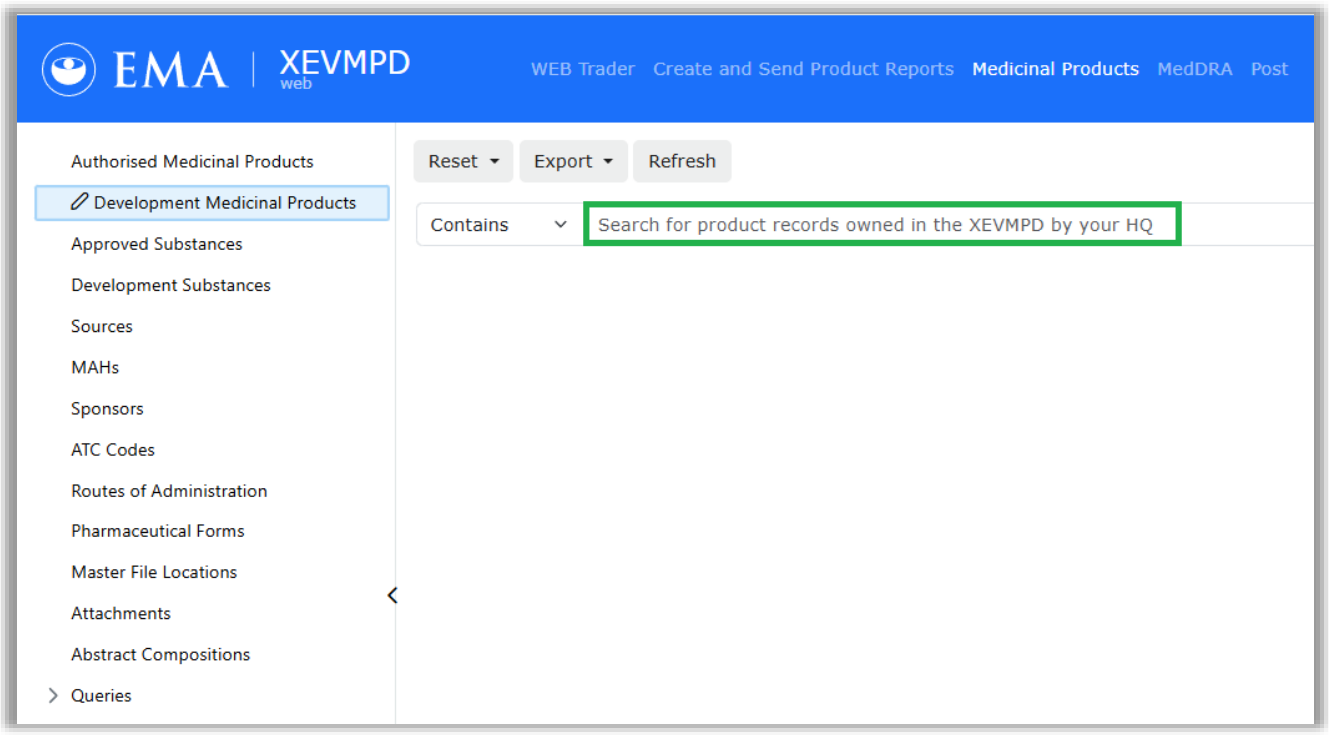
- '**With**' will indicate that the search should be performed for specific items only, such as EV Codes. These must be separated in the search field by a pipe symbol (|):

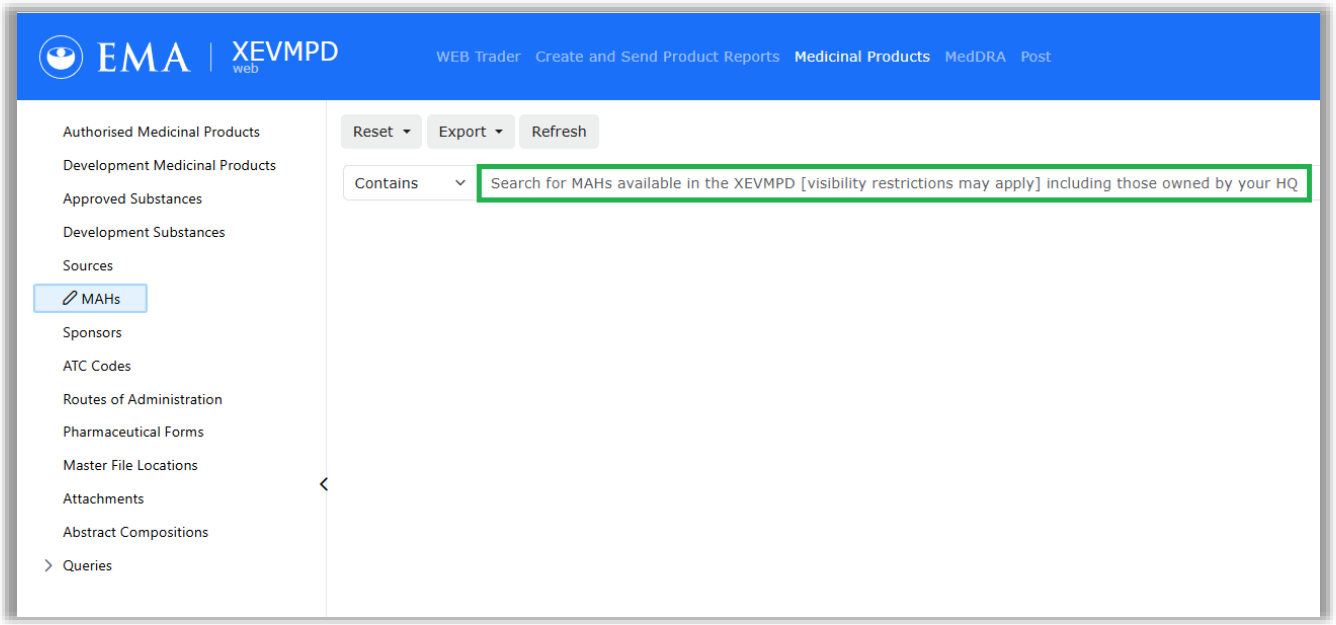


For each sub-section, the simple search field provides a brief description of the information that can be found in that sub-section.

Examples:

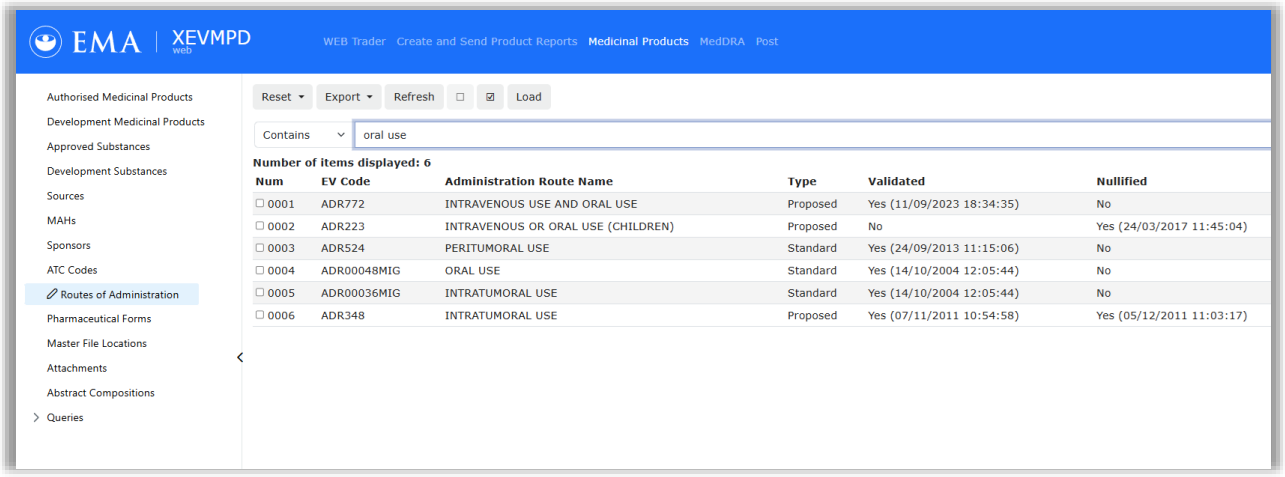




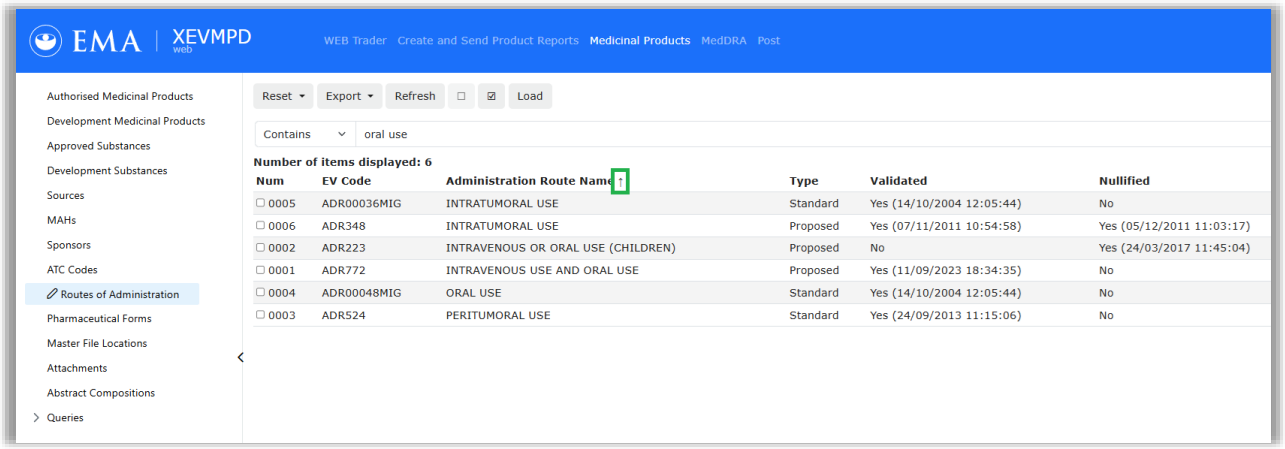


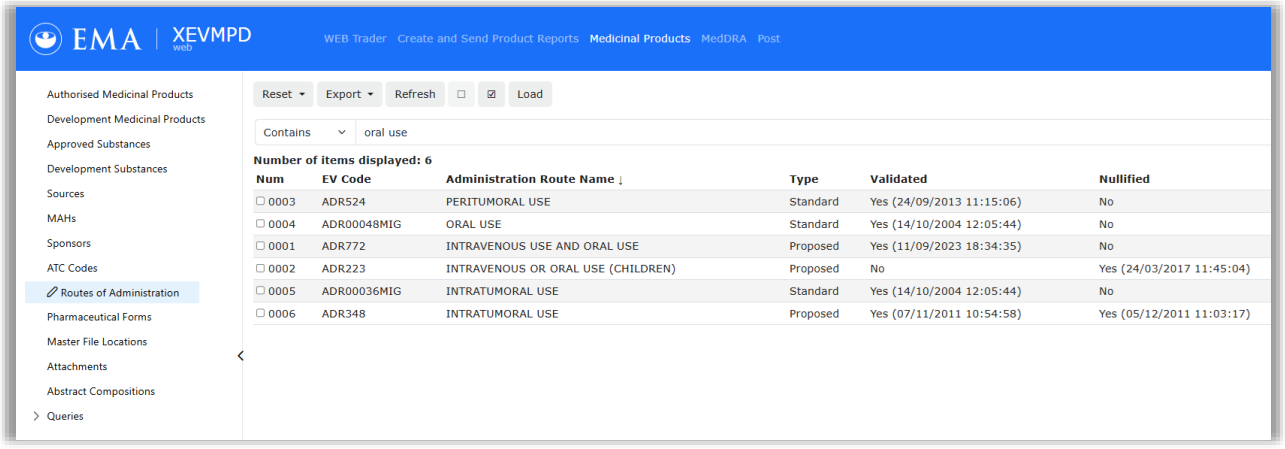
Here users can enter key words or EV Codes and activate the search by pressing 'Enter' on their keyboard.

The results will be displayed in the active area, under the search field:



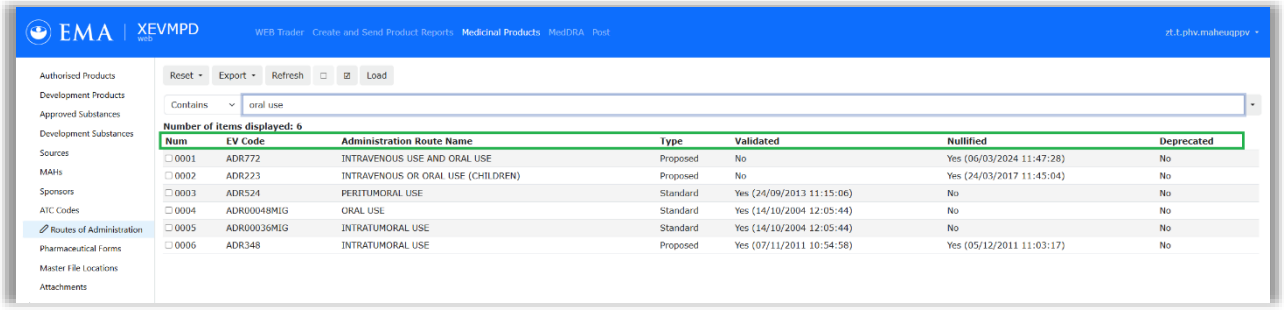
The order of presentation of the items retrieved as a result of a query and displayed in the active area can be re-arranged by clicking on the header of each column. An arrow will be displayed next to the header of each column, allowing you to sort the items in that column from ascending to descending order and vice versa:





The simple search does not allow users to apply filters for their search or to specify which information should be displayed for the items retrieved; the information displayed for the retrieved results is provided by default and depends on the type of entity that is being searched for.

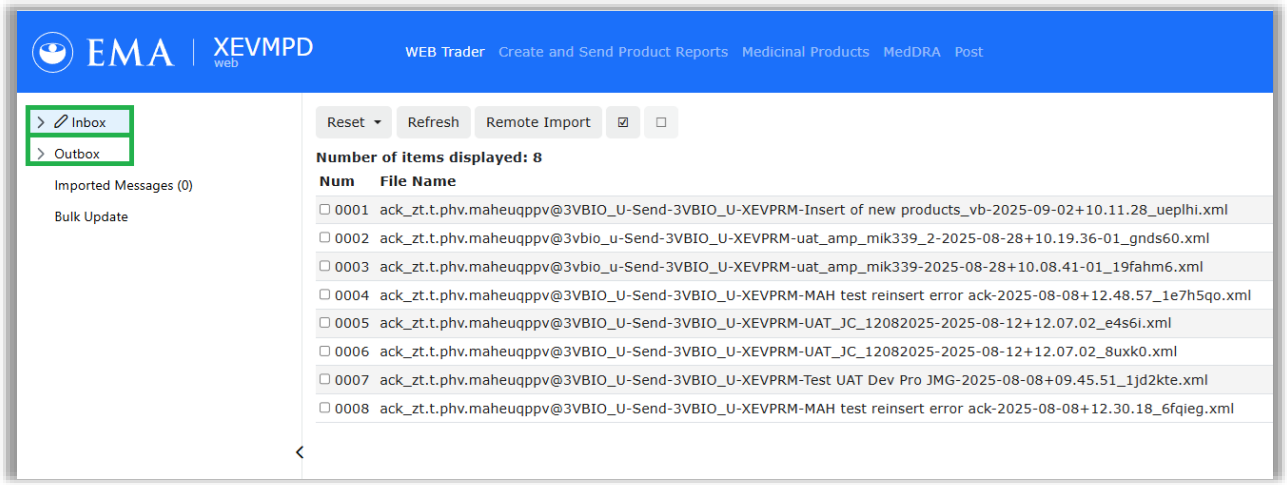
For example, for routes of administration, the results will display the following information:



3.7.2. Advanced query

XEVMPDweb allows users to perform elaborate queries for the various XEVMPD entities. These queries are referred to as 'advanced queries' and are available:

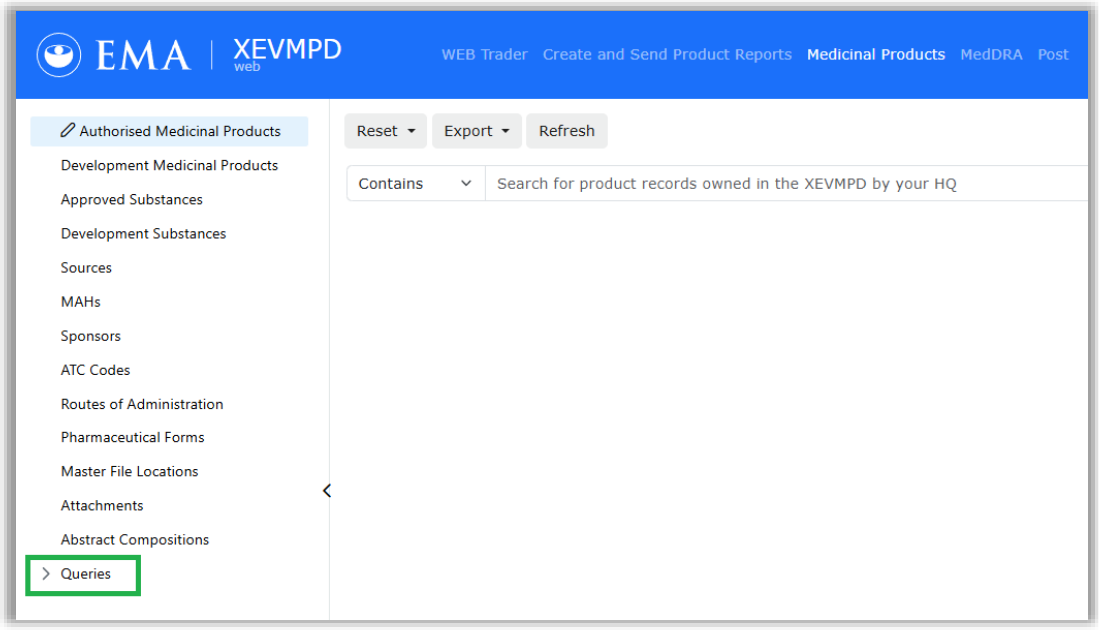
- In the tree-view area within the **'WEB Trader'** section, **under 'Inbox' and 'Outbox'**:



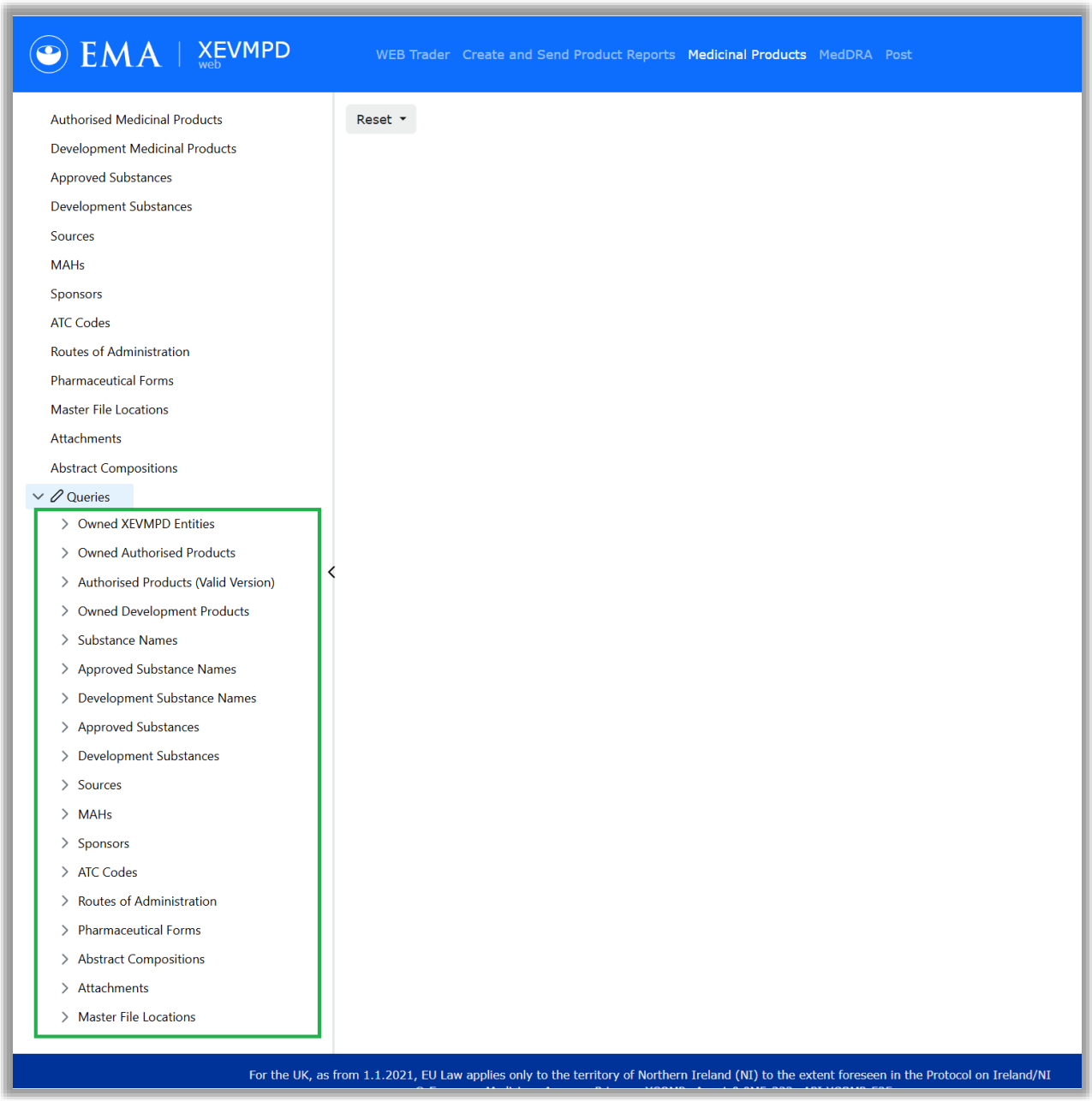
In the 'WEB Trader' section, users can perform queries on:

- Received XEVPRM Acknowledgements (in the 'Inbox' section) and
- Submitted XEVPRMs (in the 'Outbox' section).

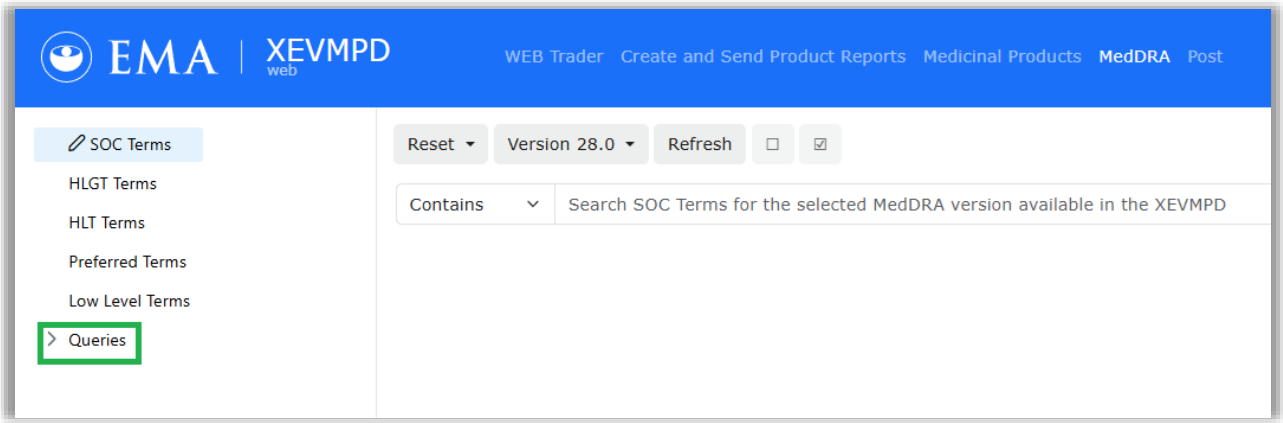
- In the tree-view area within the '**Medicinal Products**' section **under 'Queries'**:



In the 'Medicinal Products' section within XEVMPDweb, users can perform queries on:



- in the tree-view area within the '**MedDRA**' section **under 'Queries'**:



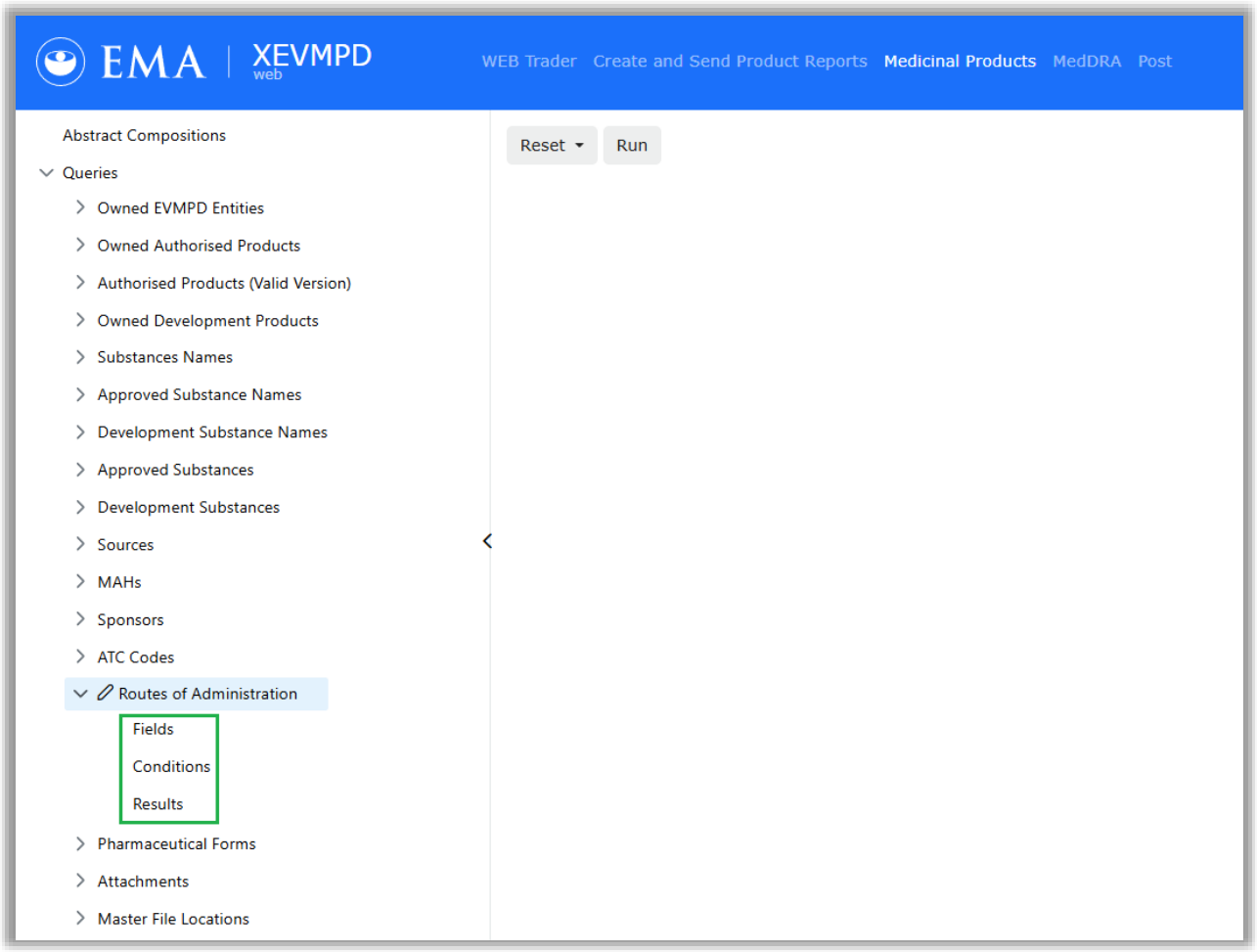
In the 'MedDRA' section, users can perform queries on:

- SOC Terms;
- HLGT Terms;
- HLT Terms;
- Preferred Terms;
- Low Level Terms.

An advanced query is divided in 3 different sections:

- Fields
- Conditions
- Results

The below example shows an advanced query section for 'Routes of Administration':

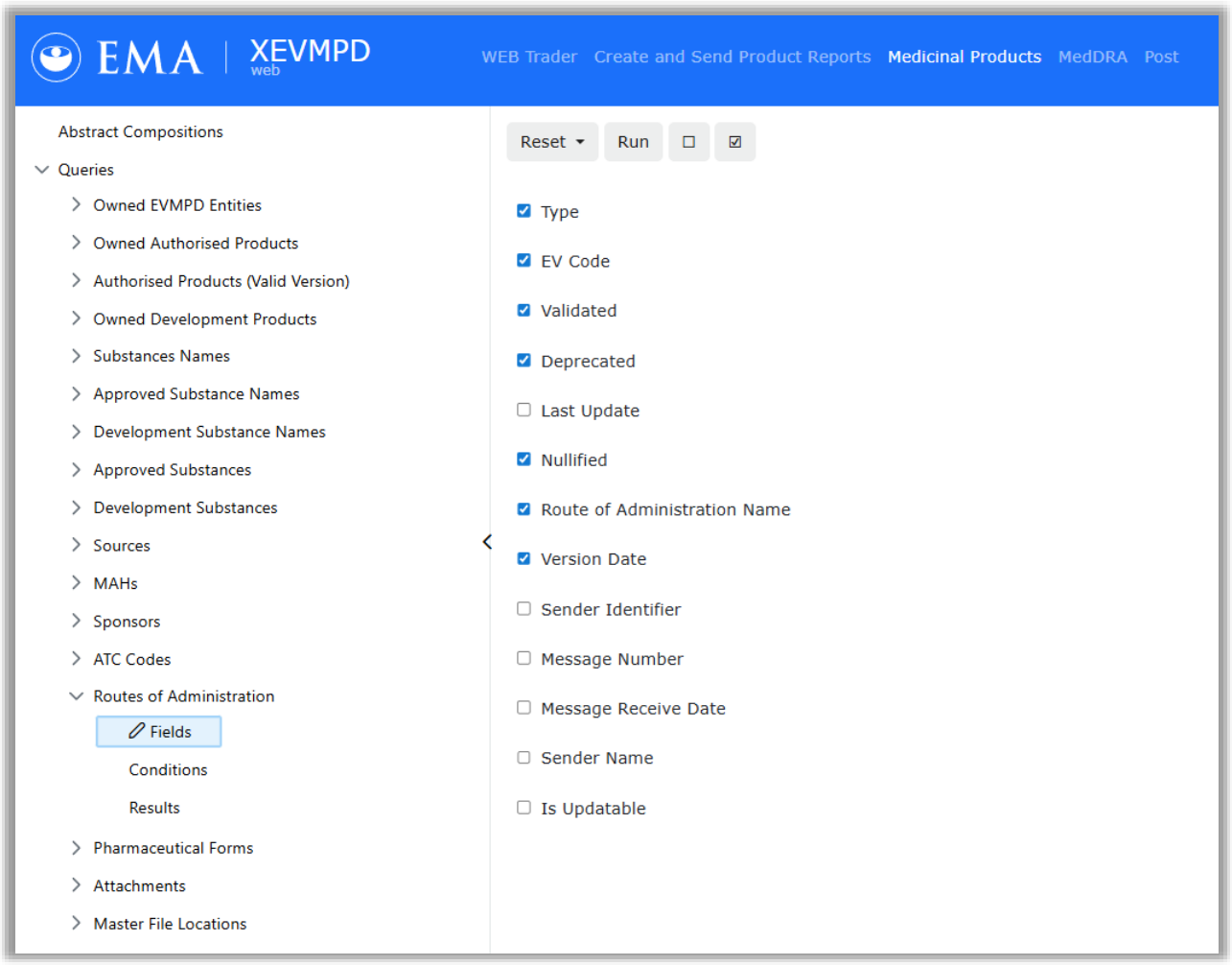


3.7.2.1. Fields section

The 'Fields' section is used to define the output of an advanced query. That means that the items displayed in the result list will contain information for the fields selected (by default of manually) in this section.

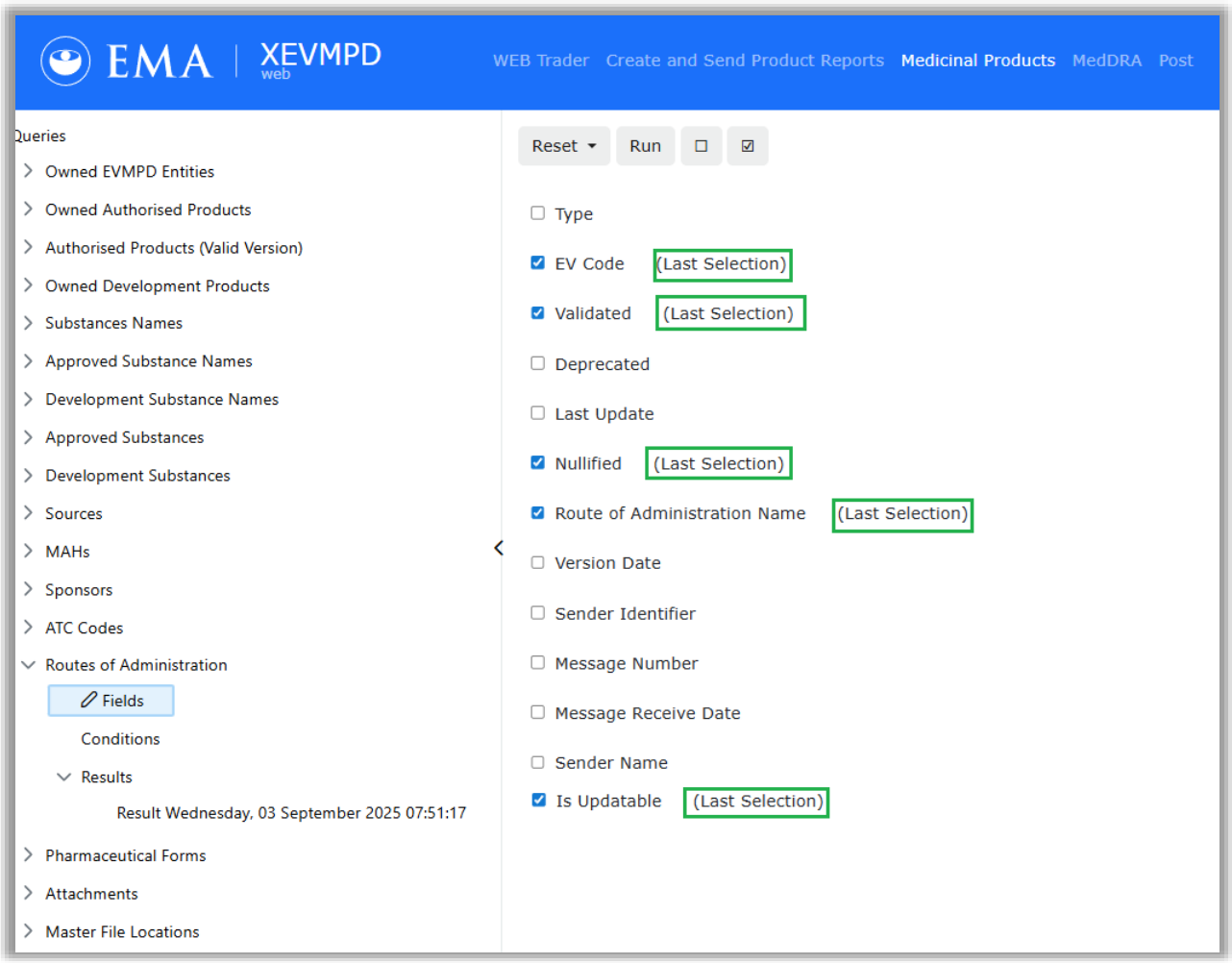
Usually, some of the items displayed in the 'Fields' section are marked as **default** (i.e. the checkbox next to the field is already selected). This means that if users run the query without selecting any additional fields in the 'Fields' section, only the default ones will be considered as selected.

For example, the fields for the 'Route of Administration' advanced query selected as default are:



The user can select or de-select any or all the fields available.

If the user made their own selection of fields and run the query, the fields previously selected will be labelled as 'Last selection'.



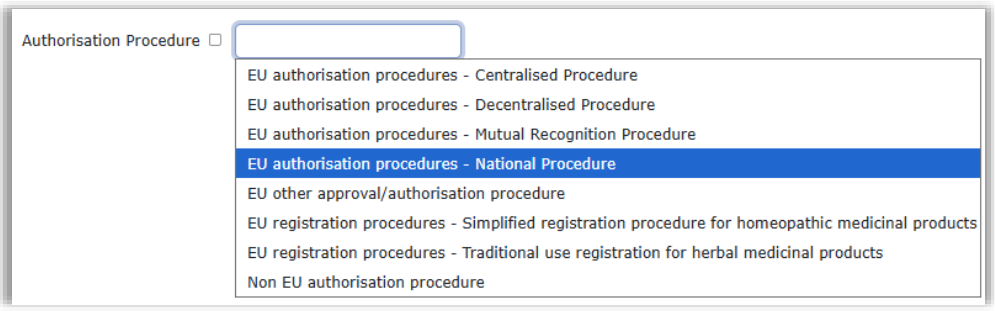
3.7.2.2. Conditions section

The 'Conditions' section is used to define the criteria of an advanced query. This section allows users to select one or more condition and, within this/these condition(s), define the criteria to be used as filter(s) for the search.

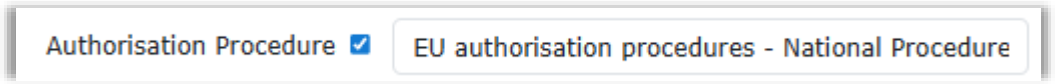
3.7.2.2.1. Conditions with a list of pre-defined values

In this type of condition, the user can select **one of the values from the pre-defined list**; multiple selection is not possible.

For example:

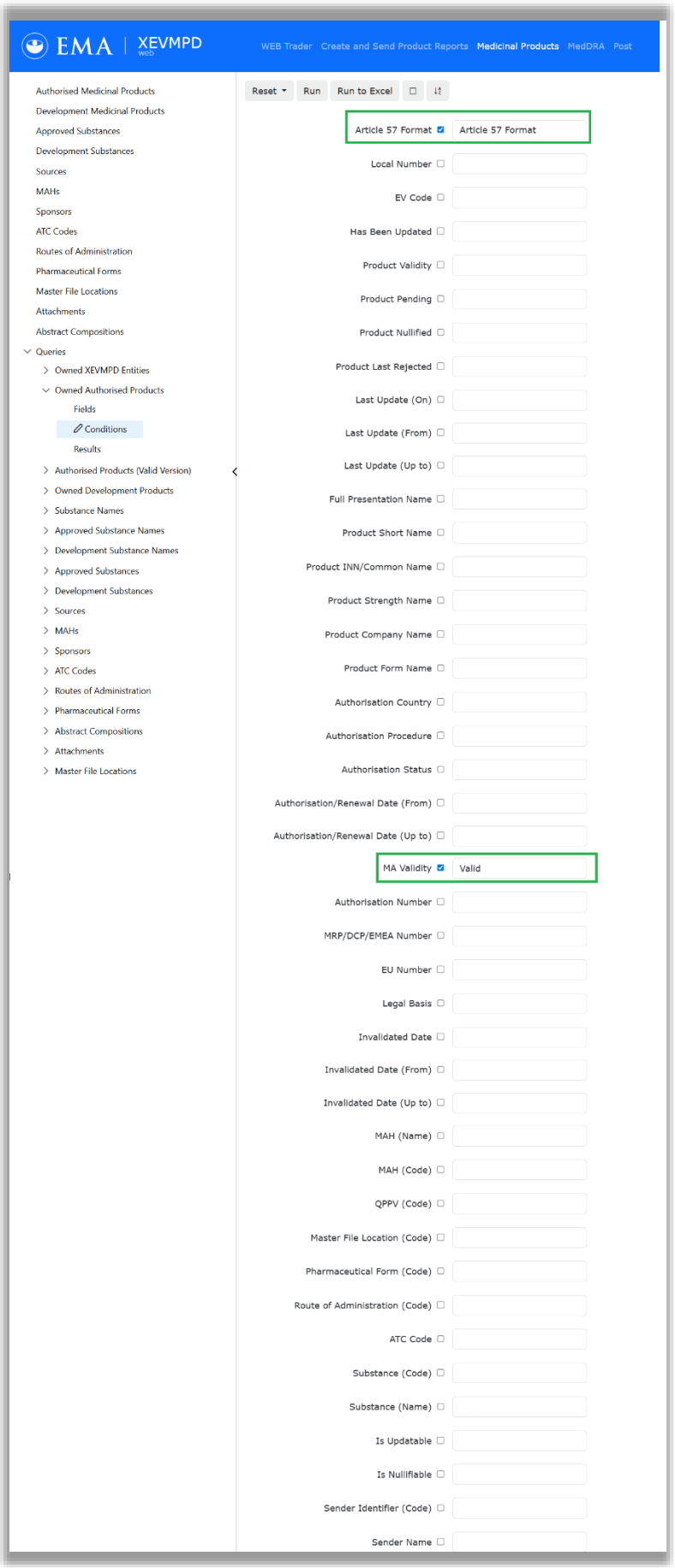


Upon selection, the value will be displayed in the field for that condition:

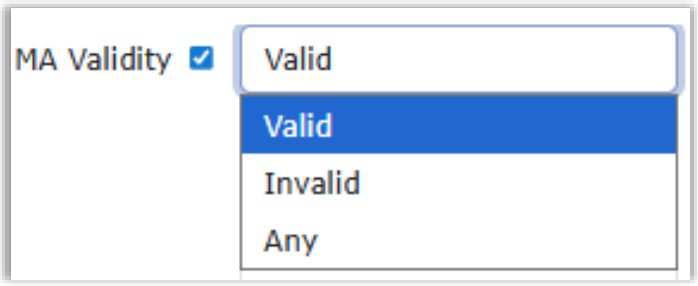


Some of the conditions already have one of the available values selected by default.

For example, within the 'Owned Authorised Products' advanced query, the condition 'Article 57 Format' and 'MA Validity' = 'Valid' are selected by default:


EMA | XEVMPD web
WEB Trader
Create and Send Product Reports
Medicinal Products
MedDRA
Post
Authorised Medicinal Products
Development Medicinal Products
Approved Substances
Development Substances
Sources
MAHs
Sponsors
ATC Codes
Routes of Administration
Pharmaceutical Forms
Master File Locations
Attachments
Abstract Compositions
Queries
Owned XEVMPD Entities
Owned Authorised Products
Fields
Conditions
Results
Authorised Products (Valid Version)
Owned Development Products
Substance Names
Approved Substance Names
Development Substance Names
Approved Substances
Development Substances
Sources
MAHs
Sponsors
ATC Codes
Routes of Administration
Pharmaceutical Forms
Abstract Compositions
Attachments
Master File Locations
Reset
Run
Run to Excel
Article 57 Format
Article 57 Format
Local Number
EV Code
Has Been Updated
Product Validity
Product Pending
Product Nullified
Product Last Rejected
Last Update (On)
Last Update (From)
Last Update (Up to)
Full Presentation Name
Product Short Name
Product INN/Common Name
Product Strength Name
Product Company Name
Product Form Name
Authorisation Country
Authorisation Procedure
Authorisation Status
Authorisation/Renewal Date (From)
Authorisation/Renewal Date (Up to)
MA Validity
Valid
Authorisation Number
MRP/DCP/EMEA Number
EU Number
Legal Basis
Invalidated Date
Invalidated Date (From)
Invalidated Date (Up to)
MAH (Name)
MAH (Code)
QPPV (Code)
Master File Location (Code)
Pharmaceutical Form (Code)
Route of Administration (Code)
ATC Code
Substance (Code)
Substance (Name)
Is Updatable
Is Nullifiable
Sender Identifier (Code)
Sender Name

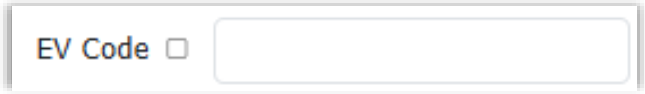
Users cannot de-select these conditions; they can however select a different value available within this condition:



3.7.2.2.2. Free-text conditions

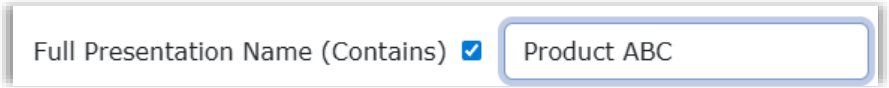
In these conditions, users can enter the information themselves using their keyboard. It is possible to specify **multiple values**, providing that the values are separated by a vertical line (|).

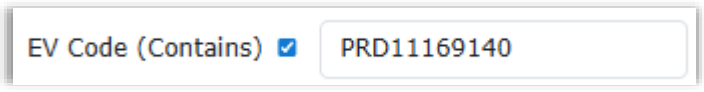
For example:

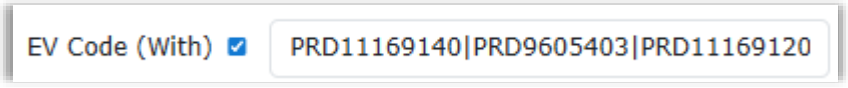


Whilst the free-text condition descriptions do not initially reference the search option to be used, the condition name might be appended with the text '(Contains)' or '(With)' once a text is entered in the condition field, depending on what type of criteria the user entered [single value or multiple values separated by a vertical line (I) etc.]:

For example:



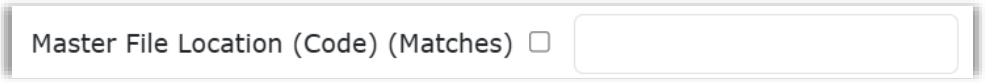




3.7.2.2.3. Remote look-up conditions

Within these conditions, users can search for an entity already present in the XEVMPD (i.e. an EV Code is assigned to that entity) using the remote look-up tables, and by entering the required condition (i.e. an EV Code) directly into the field, either **as a single value or as multiple values** separated by a vertical line (|):

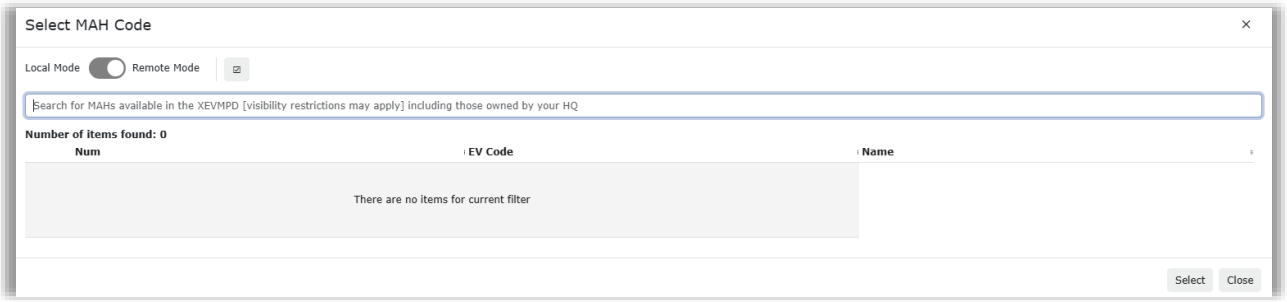
For example:



Whilst the condition descriptions text does not initially reference the search option to be used, the condition name might be appended with the text '(Matches)' or '(With)' once the required value(s) is/are entered in the condition field, depending on what type of criteria the user entered [single value or multiple values separated by a vertical line (I) etc.]:

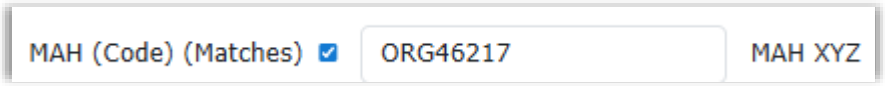
For example:

To specify an EV Code of a single MAH entity that should be used in the 'MAH (Code)' condition, the user should click within the field and press ENTER on their keyboard. The search section will open:

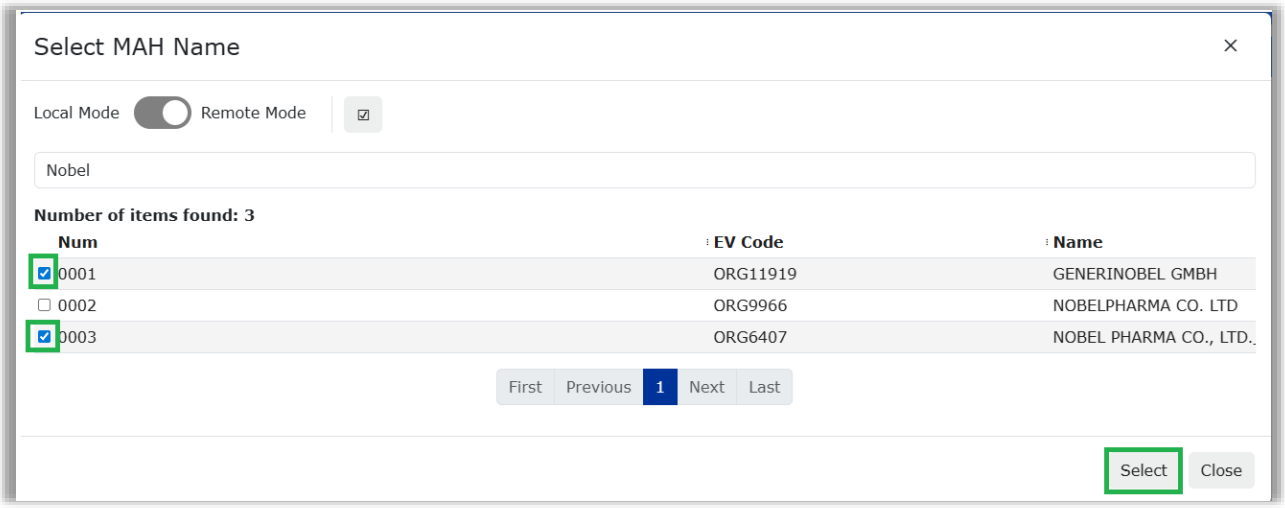


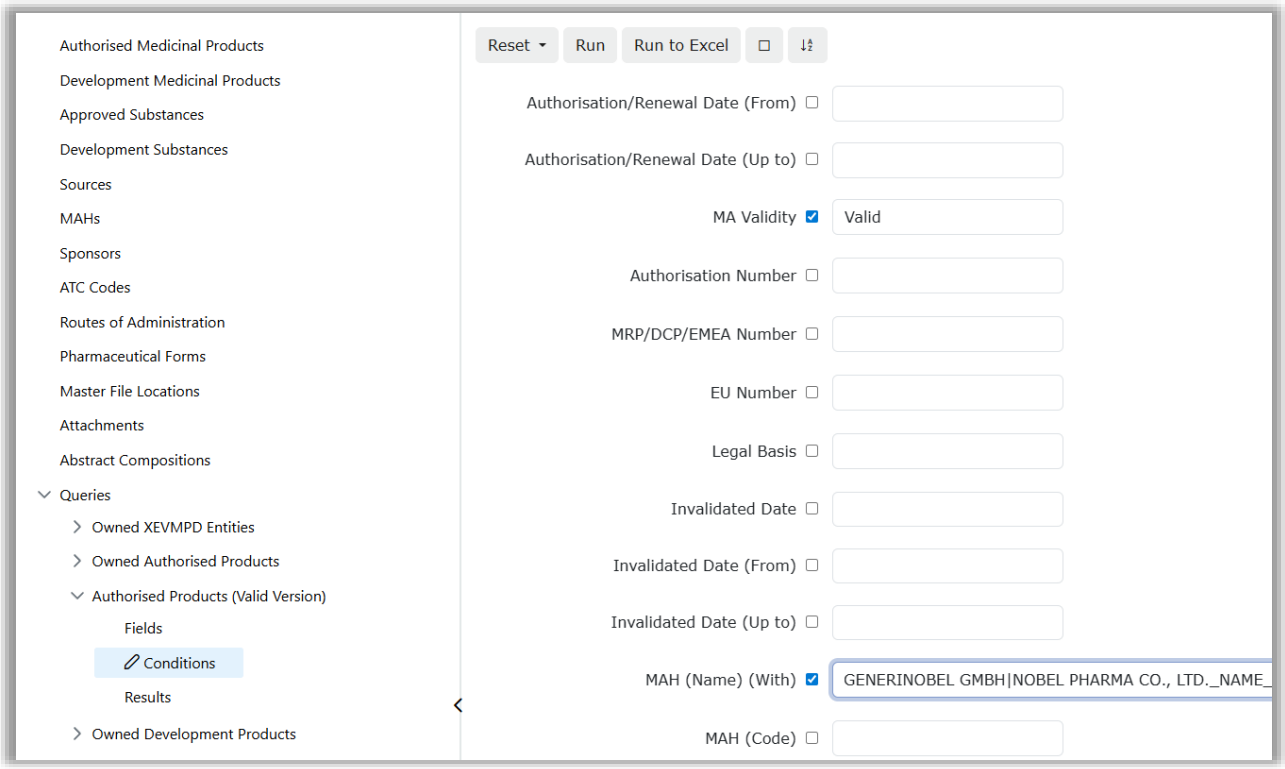
The 'Remote Mode' is selected by default.

Once the required entity is retrieved and selected (via the check-box), the EV Code of that entity will be present in the condition field:



It is also possible to select multiple entities to be considered for the search by ticking the checkboxes next to the retrieved entities and using the 'Select' option:





If the user knows the EV Code(s) of the entity/entities that should be used as basis for the search, the EV Code(s) can be entered directly in the field either as a single value, or as multiple values separated by a vertical line (|).

For example:

Once the 'Conditions' and the values within these conditions are selected, the advanced query can be executed via the 'Run' or 'Run to Excel' functionality.

The 'Run to Excel' functionality is not available in advanced queries for:

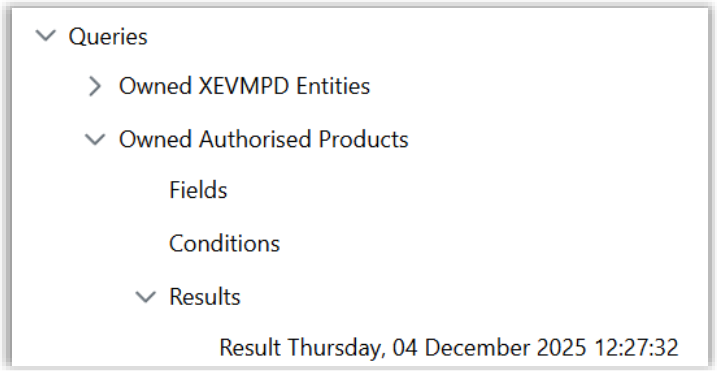
- Owned XEVMPD Entities

- Substance Names
- Approved Substance Names
- Development Substance Names
- Sources
- MAHs
- Sponsors
- ATC Codes
- Routes of Administration
- Pharmaceutical Forms
- Abstract Compositions
- Attachments
- Master File Locations

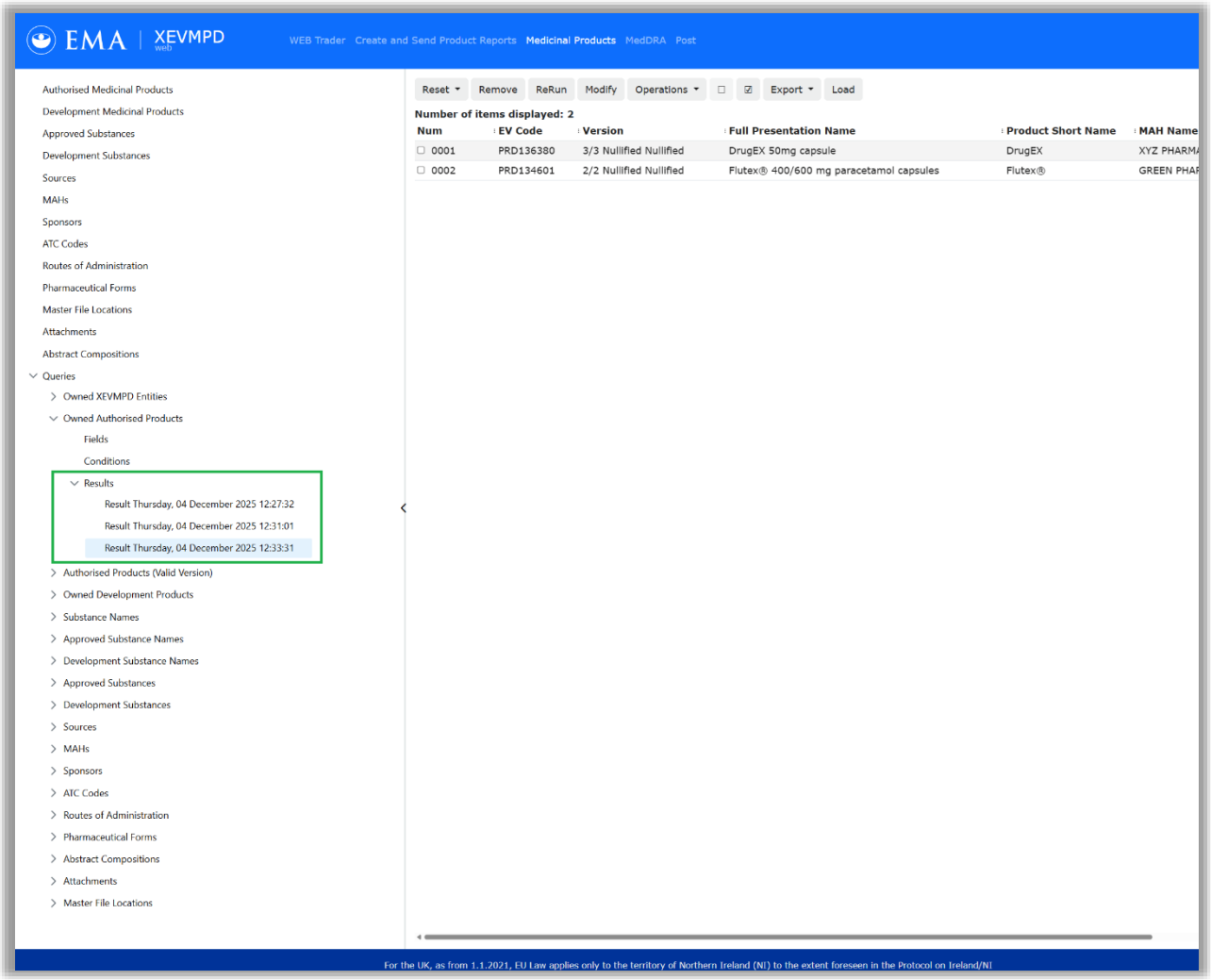
The user must run the query first and then extract the results into Excel using the '*Export*' functionality.

3.7.2.3. Results section

If the advanced query was run using the *'Run'* functionality, and the results are therefore available in the active area, a brief overview of when the query was run will be displayed under the 'Results' section:

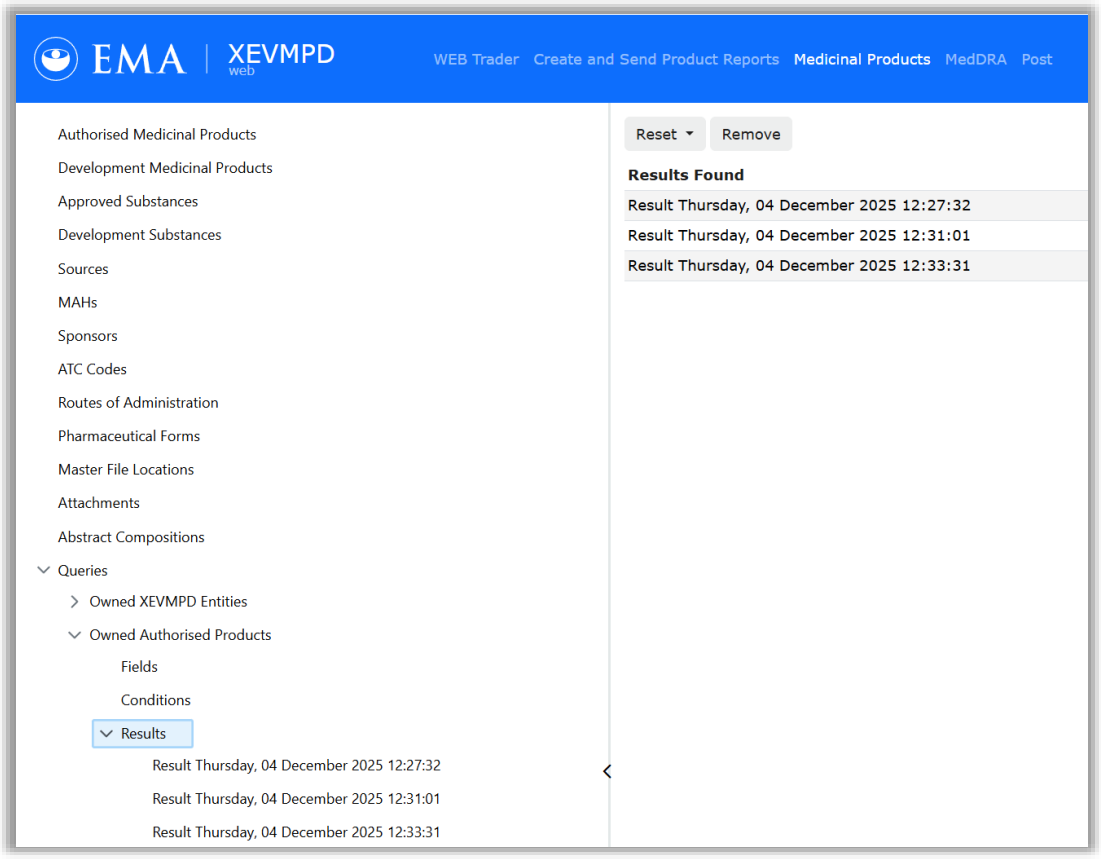


In case of multiple searches, the overview of when each of the searches was run, will be listed; the active area will display the results retrieved for the search highlighted in the tree view area in blue:

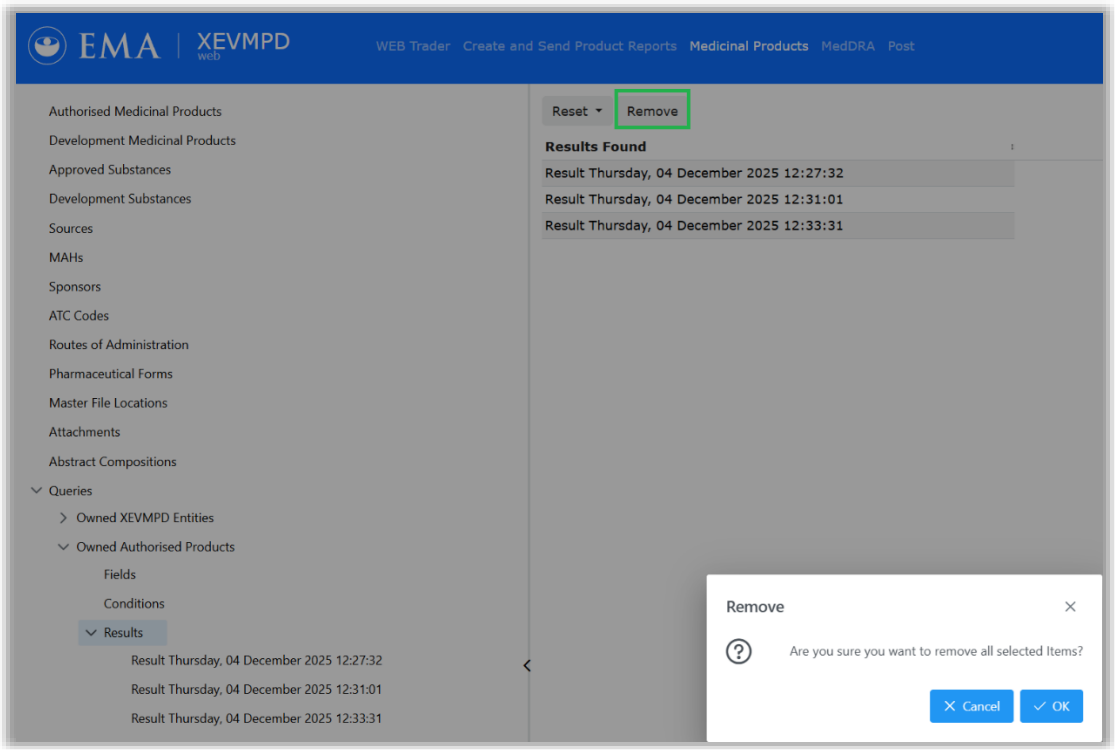


Users can swich between viewing the results for each search by clicking on the relevant result overview in the tree view.

By clicking on the section title 'Results', the active area will display the overview of when each of the searches was run:



To clear the 'Results' section and remove all results for each search, the 'Remote import' functionality should be used. Once confirmed, the results will be deleted:



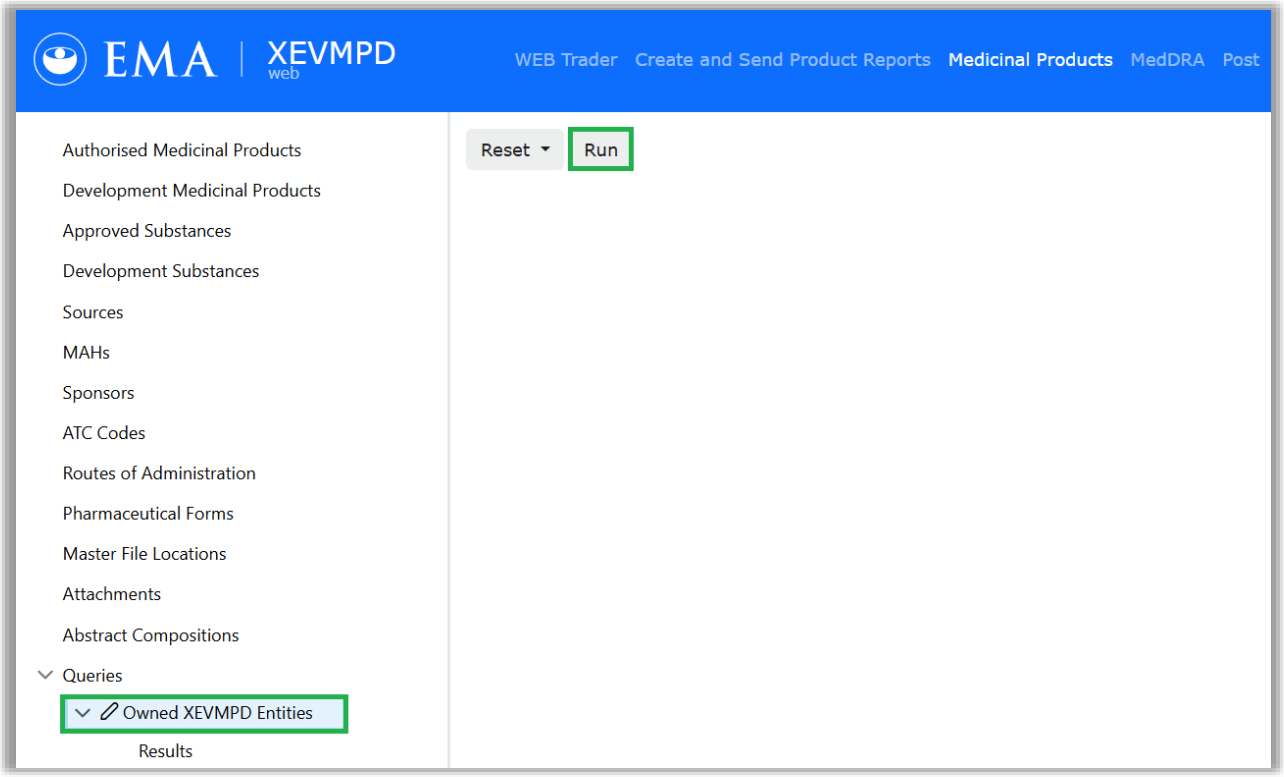
It is also possible to remove the results by re-setting the whole section/application using the 'Reset' functionality.

3.7.3. Immediate query

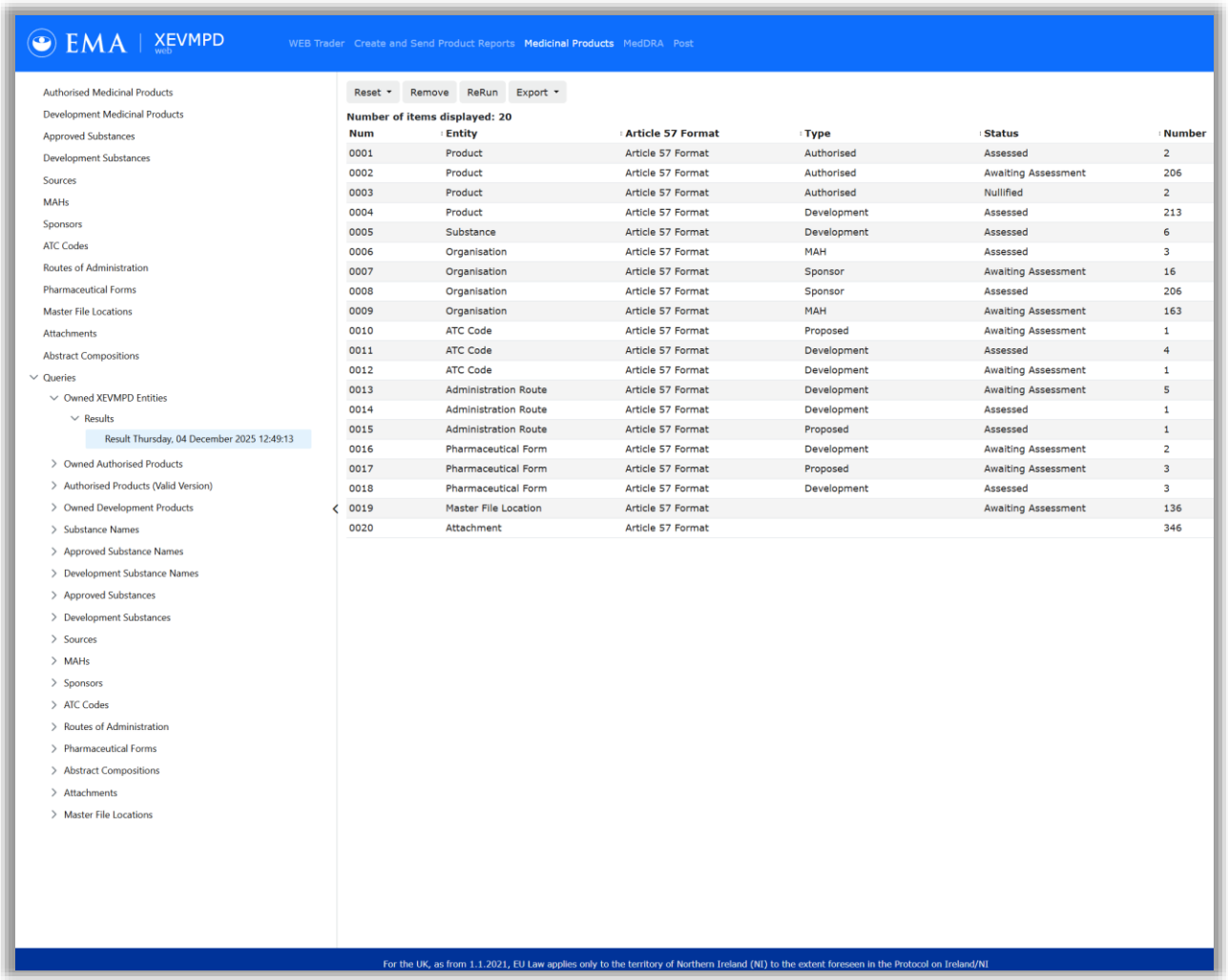
An immediate query is a simple query performed automatically by XEVMPDweb without the user specifying any condition(s) to be used as a base for the search.

This type of query is used for example in the 'Medicinal Products' section, on '**Owned EVMPD Entities**' under 'Queries'.

To launch an immediate query, the user should simply select the item and run the search using the 'Run' functionality:



The results will be displayed in the active area, showing information in fields set by default by the system:


EMA | XEVMPD WEB
WEB Trader
Create and Send Product Reports
Medicinal Products
MedDRA
Post
Authorised Medicinal Products
Development Medicinal Products
Approved Substances
Development Substances
Sources
MAHs
Sponsors
ATC Codes
Routes of Administration
Pharmaceutical Forms
Master File Locations
Attachments
Abstract Compositions
Queries
Owned XEVMPD Entities
Results
Result Thursday, 04 December 2025 12:49:13
Owned Authorised Products
Authorised Products (Valid Version)
Owned Development Products
Substance Names
Approved Substance Names
Development Substance Names
Approved Substances
Development Substances
Sources
MAHs
Sponsors
ATC Codes
Routes of Administration
Pharmaceutical Forms
Abstract Compositions
Attachments
Master File Locations
Reset
Remove
ReRun
Export
Number of items displayed: 20
Num
Entity
Article 57 Format
Type
Status
Number
0001 Product Article 57 Format Authorised Assessed 2
0002 Product Article 57 Format Authorised Awaiting Assessment 206
0003 Product Article 57 Format Authorised Nullified 2
0004 Product Article 57 Format Development Assessed 213
0005 Substance Article 57 Format Development Assessed 6
0006 Organisation Article 57 Format MAH Assessed 3
0007 Organisation Article 57 Format Sponsor Awaiting Assessment 16
0008 Organisation Article 57 Format Sponsor Assessed 206
0009 Organisation Article 57 Format MAH Awaiting Assessment 163
0010 ATC Code Article 57 Format Proposed Awaiting Assessment 1
0011 ATC Code Article 57 Format Development Assessed 4
0012 ATC Code Article 57 Format Development Awaiting Assessment 1
0013 Administration Route Article 57 Format Development Awaiting Assessment 5
0014 Administration Route Article 57 Format Development Assessed 1
0015 Administration Route Article 57 Format Proposed Assessed 1
0016 Pharmaceutical Form Article 57 Format Development Awaiting Assessment 2
0017 Pharmaceutical Form Article 57 Format Proposed Awaiting Assessment 3
0018 Pharmaceutical Form Article 57 Format Development Assessed 3
0019 Master File Location Article 57 Format Awaiting Assessment 136
0020 Attachment Article 57 Format 346
For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI

4. 'WEB Trader' section

The 'WEB Trader' section is available to users from organisations registered in EudraVigilance as Web Trader organisations.

Within this section, users can:

- access their WEB Trader Inbox and Outbox;
- import XEVPRMs available in their WEB Trader Inbox and/or Outbox (i.e. via the 'Remote Import' functionality);
- import XEVPRMs stored locally on their computer (via the 'Local Import' functionality available in the 'Imported Messages' section);
- retrieve the XML files generated via the 'XEVMPD Bulk Update tool'.

The 'Inbox' section is displayed by default.

4.1. Inbox

The 'Inbox' displays XEVPRM Acknowledgement messages in an XML format sent to the organisation ID of an organisation registered in EudraVigilance with a WEB Trader submission mode.

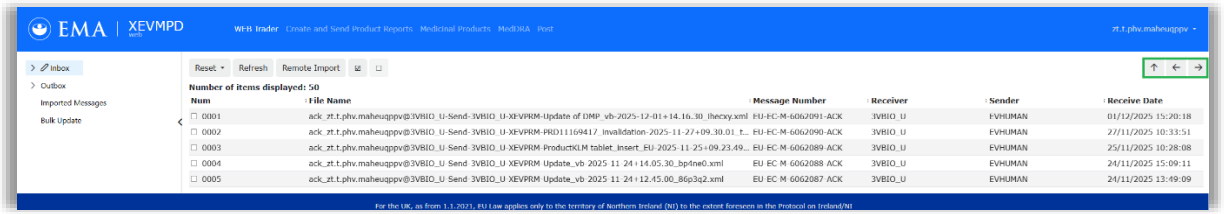
Organisations registered in EudraVigilance with a Gateway submission mode will find their XEVPRM acknowledgement in the location specified by their Gateway provider.

The sender of the XEVPRM acknowledgment will always be specified as EVHUMAN, which corresponds to the EMA Gateway.

The timelines for the receipt of the XEVPRM Acknowledgement depend on the type of acknowledgement that is expected:

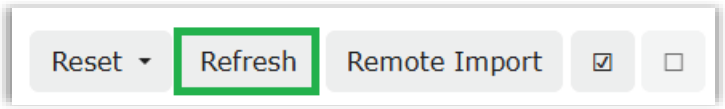
- 1st and 2nd ACK (in one file) can be expected **within minutes and max withing 48 hours** since the submission XEVPRM was sent;
- 3rd ACK can be expected as per information provided in section *1.3.5.2. Content validation* of this document.

By default, the 'Inbox' section will display the last 50 XEVPRM ACKs sent to the organisation ID under which the user is logged on to XEVMPDweb. However, the user can view the remaining messages by using the arrows at the top of the active area:

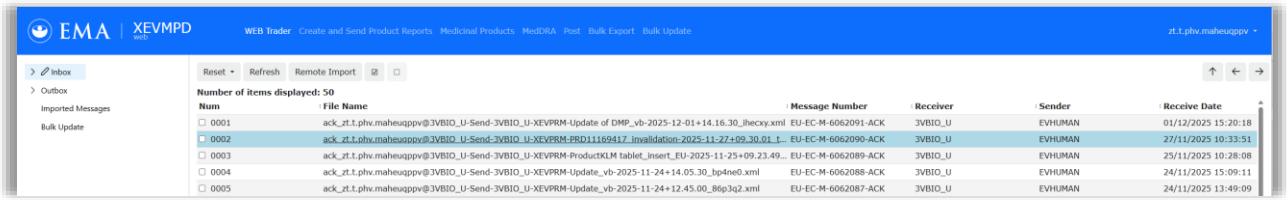


Users cannot modify the content of their Inbox.

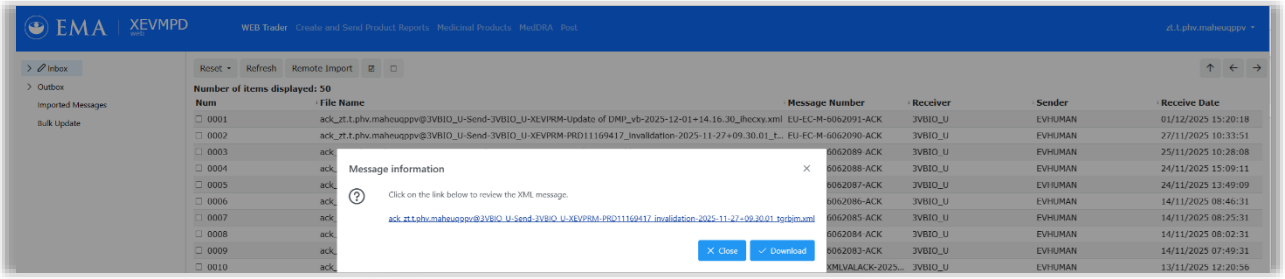
Users can however refresh the results shown by clicking on the 'Refresh' button:



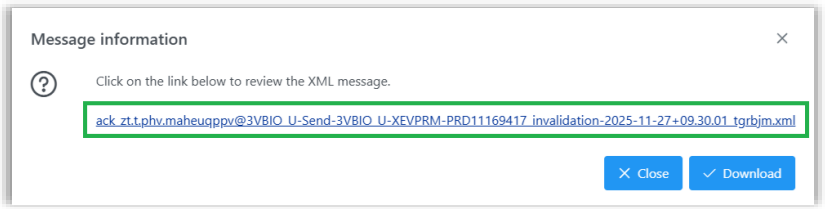
To view the content of an XEVPRM ACK or to download the file, select the required file name in the active area; the selected file will be highlighted in blue:



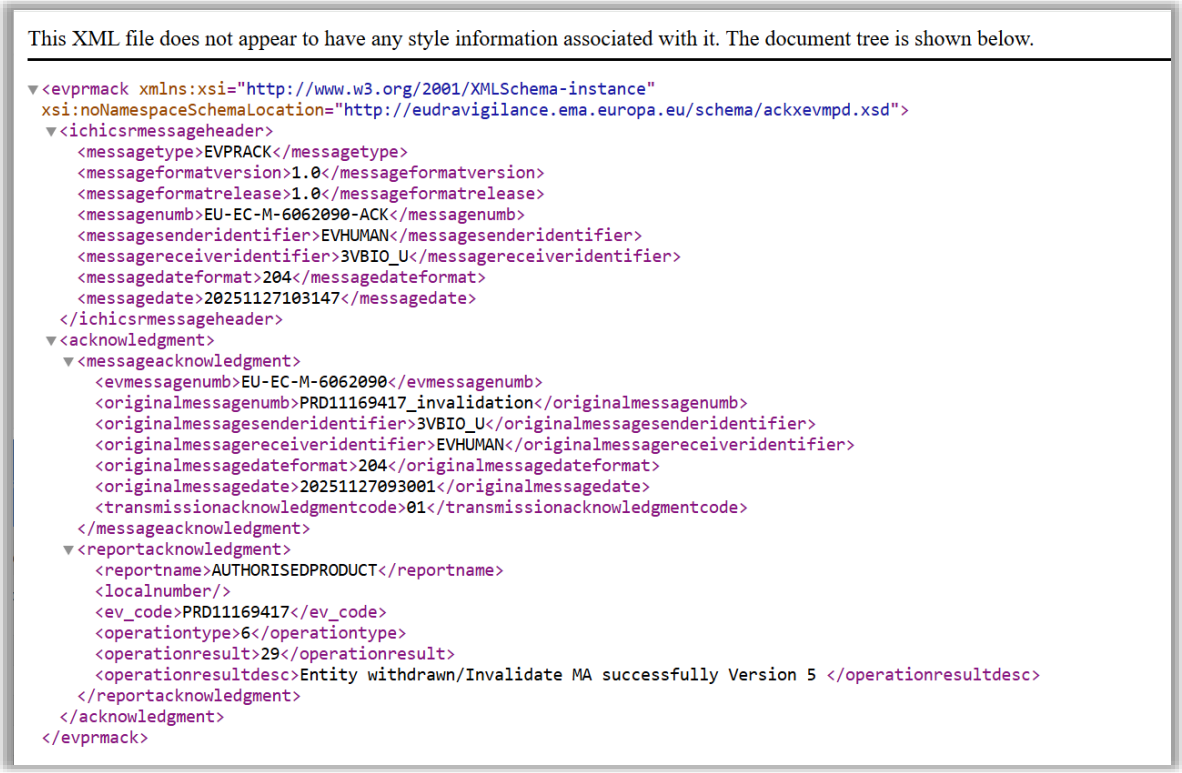
Click on the selected file and a new pop-up window will be displayed, containing the link to the XML file of the XEVPRM ACK and the option to download the file:



- **To view the information in the file**, click on the hyperlink in blue:



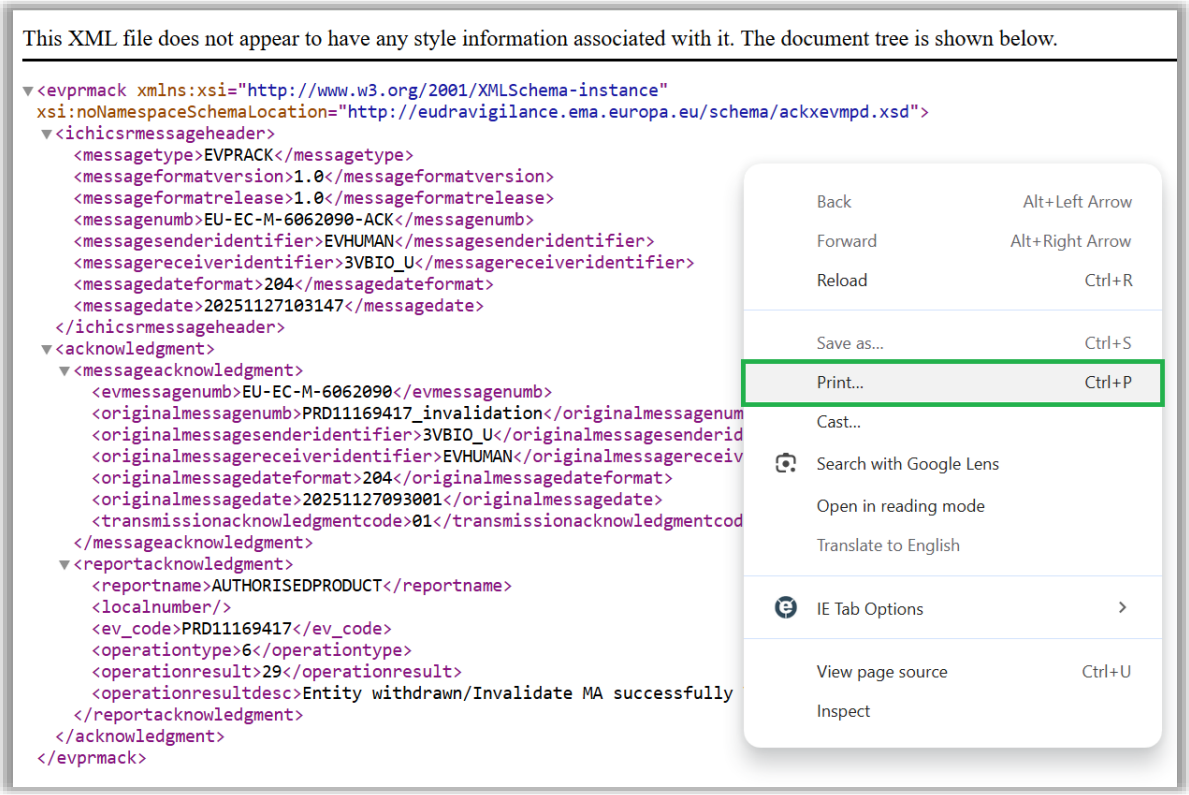
  A new window will open and display the content of the message:



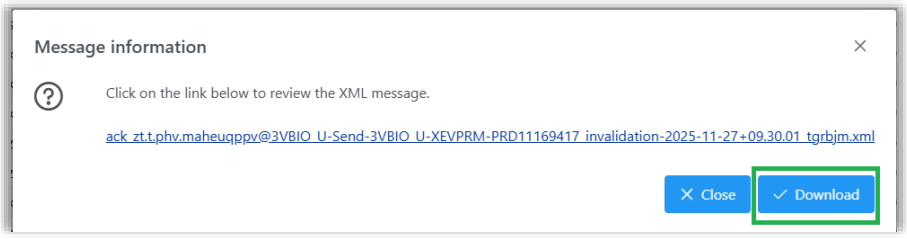
This XML file does not appear to have any style information associated with it. The document tree is shown below.


```
<evprmack xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xsi:noNamespaceSchemaLocation="http://eudravigilance.ema.europa.eu/schema/ackxevmpd.xsd">
  <ichicsrmessageheader>
    <messagetype>EVPRACK</messagetype>
    <messageformatversion>1.0</messageformatversion>
    <messageformatrelease>1.0</messageformatrelease>
    <messagenumb>EU-EC-M-6062090-ACK</messagenumb>
    <messagesenderidentifier>EVHUMAN</messagesenderidentifier>
    <messagereceiveridentifier>3VBIO_U</messagereceiveridentifier>
    <messagedateformat>204</messagedateformat>
    <messagedate>20251127103147</messagedate>
  </ichicsrmessageheader>
  <acknowledgment>
    <messageacknowledgment>
      <evmessagenumb>EU-EC-M-6062090</evmessagenumb>
      <originalmessagenumb>PRD11169417_invalidation</originalmessagenumb>
      <originalmessagesenderidentifier>3VBIO_U</originalmessagesenderidentifier>
      <originalmessagereceiveridentifier>EVHUMAN</originalmessagereceiveridentifier>
      <originalmessagedateformat>204</originalmessagedateformat>
      <originalmessagedate>20251127093001</originalmessagedate>
      <transmissionacknowledgmentcode>01</transmissionacknowledgmentcode>
    </messageacknowledgment>
    <reportacknowledgment>
      <reportname>AUTHORISEDPRODUCT</reportname>
      <localnumber/>
      <ev_code>PRD11169417</ev_code>
      <operationtype>6</operationtype>
      <operationresult>29</operationresult>
      <operationresultdesc>Entity withdrawn/Invalidate MA successfully Version 5 </operationresultdesc>
    </reportacknowledgment>
  </acknowledgment>
</evprmack>
```

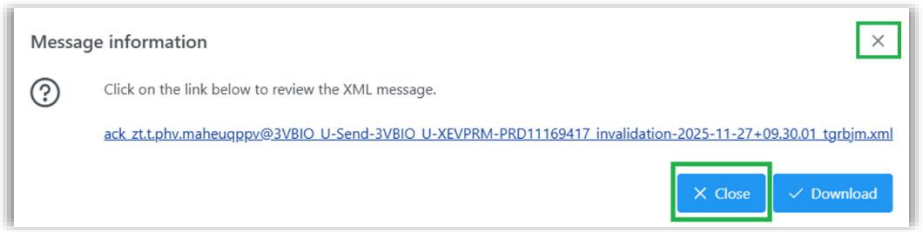

- Depending on the browser that is used to access XEVMPDweb, users might be able to **save the file as a PDF file** using the **'Print'** option available upon using a right click on the user's mouse:



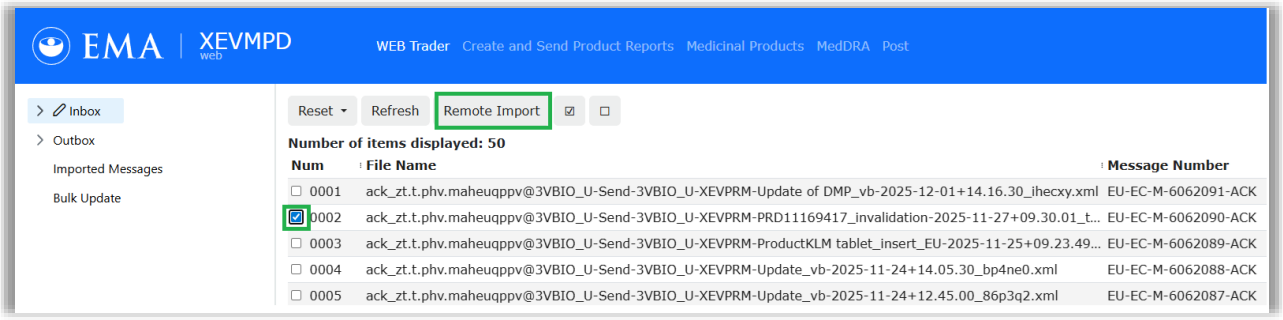
- **To download the XML file**, the 'Download' option should be used:



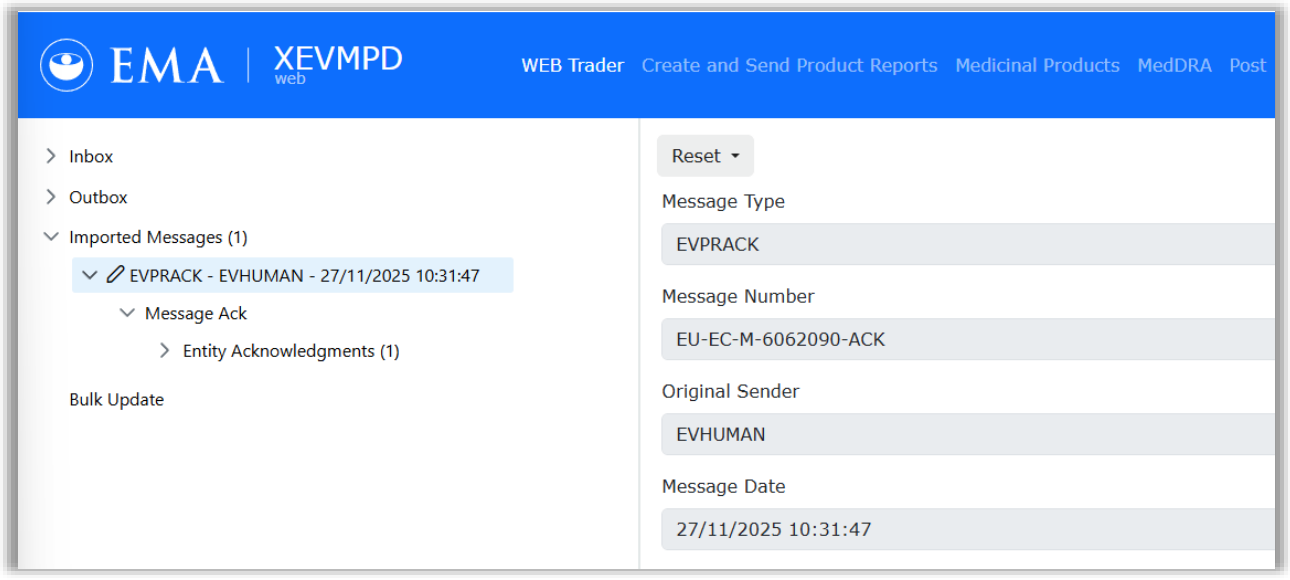
- **To close the pop-up window**, either of the 'Close' options should be used:



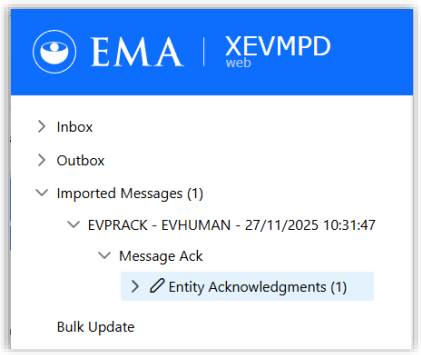
- **To view the information of the required ACK in user-friendly format** in XEVMPDweb, the ACK should be selected (by ticking the box next to the item in the active area) and then uploaded in the tree-view area via the **'Remote Import'** functionality:



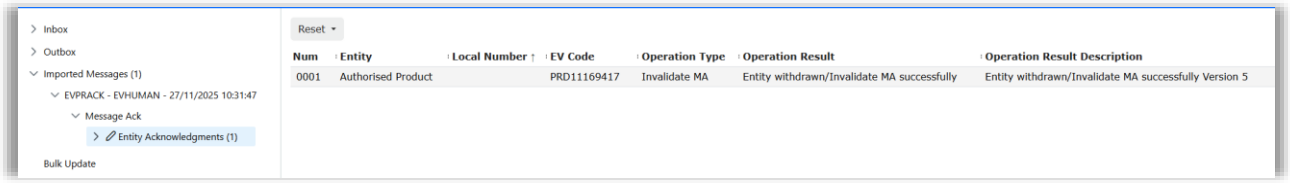
The information related to the **content of the received ACK** will then be displayed in the tree-view area under the 'Imported Messages' section, whilst the active area will display the information related to **the identification of the received acknowledgement file**:



To check if the action performed on the item referenced in the submission XEVPRM (for example an insert of a new entity or an amendment of an existing entity) was performed successfully, click on the 'Entity Acknowledgement' section in the tree-view area:



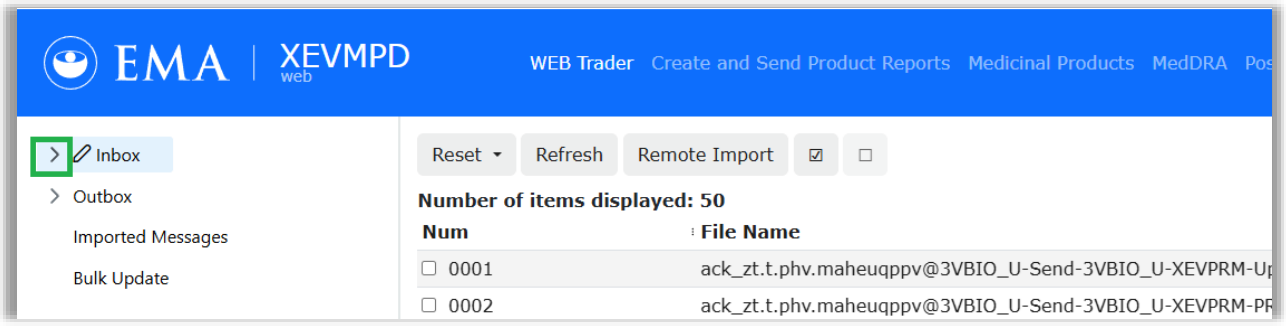
A summary will then be displayed in the active area:



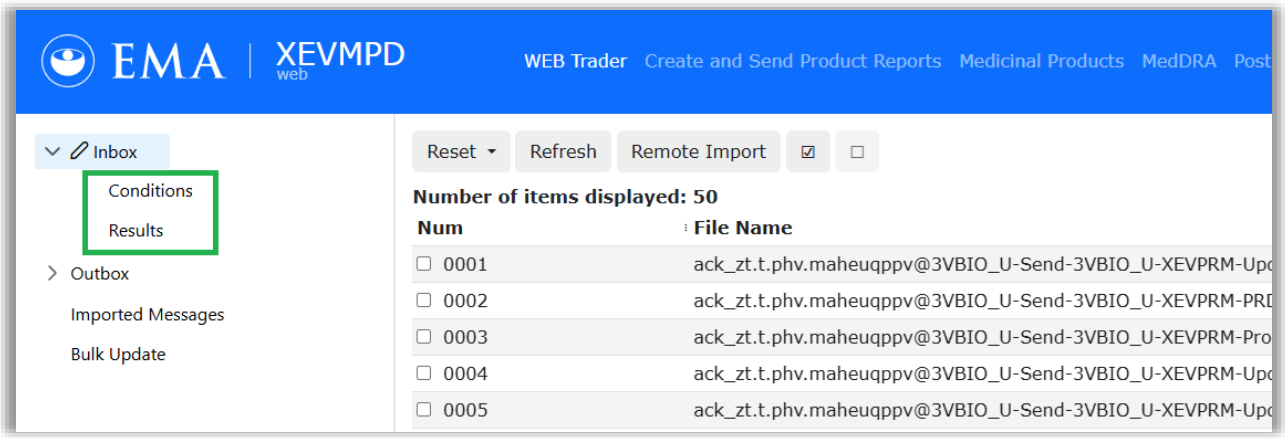
4.1.1. Search within the 'Inbox' section

Within the 'Inbox', it is possible to perform a search related to the XEVPRM ACKs received. The search is based on specifying the conditions that should be used as criteria for the search.

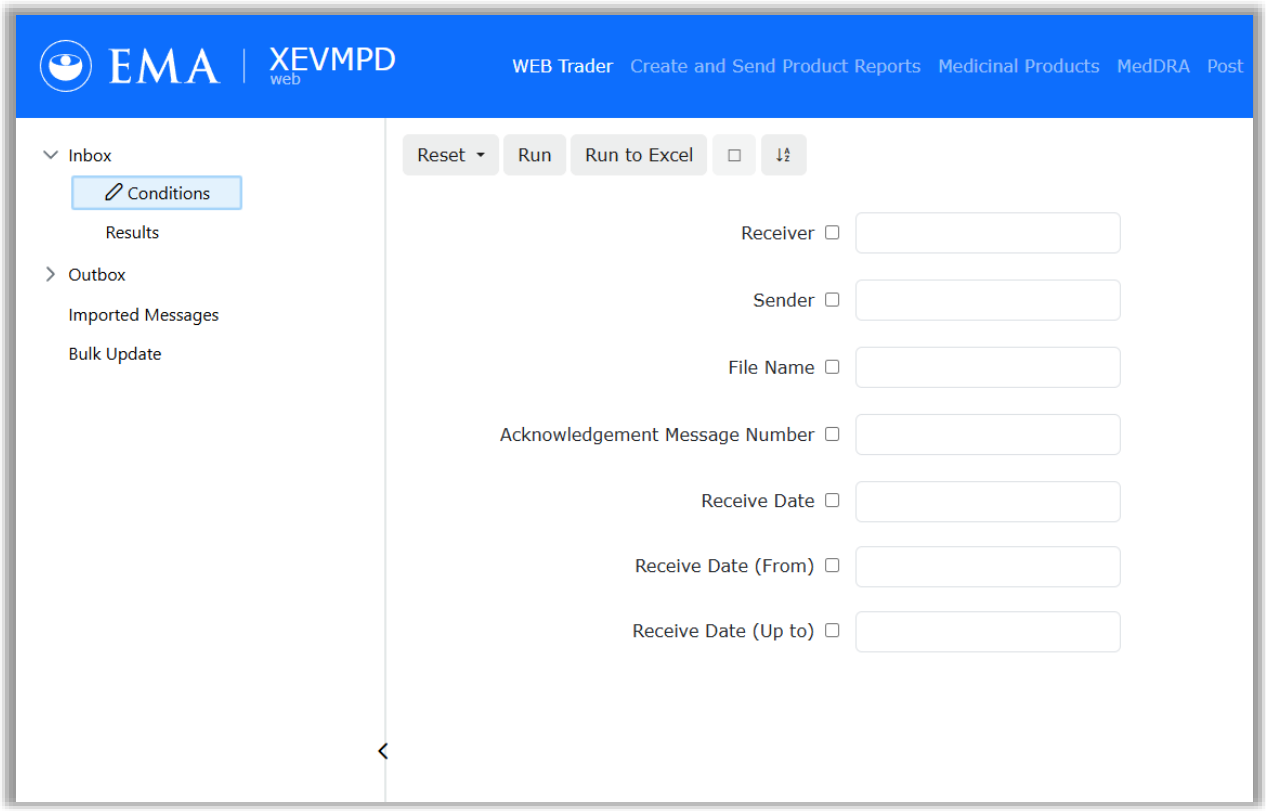
To specify the search conditions, expand the 'Inbox' section in the tree-view area by clicking on the arrow next to 'Inbox':



The tree-view area will show 'Conditions' and 'Results' under the 'Inbox' header:



By clicking on 'Conditions', the active area will display the conditions that the user can use to specify the filters and conditions for the search:



Aside from the date related condition, the fields are free-text fields, which means that users can type in or copy the information that should be used to restrict the search.

For example:

To find XEVPRM acknowledgements received during a specific **period**, users should use the date fields available to restrict the time frame to be used for the search.

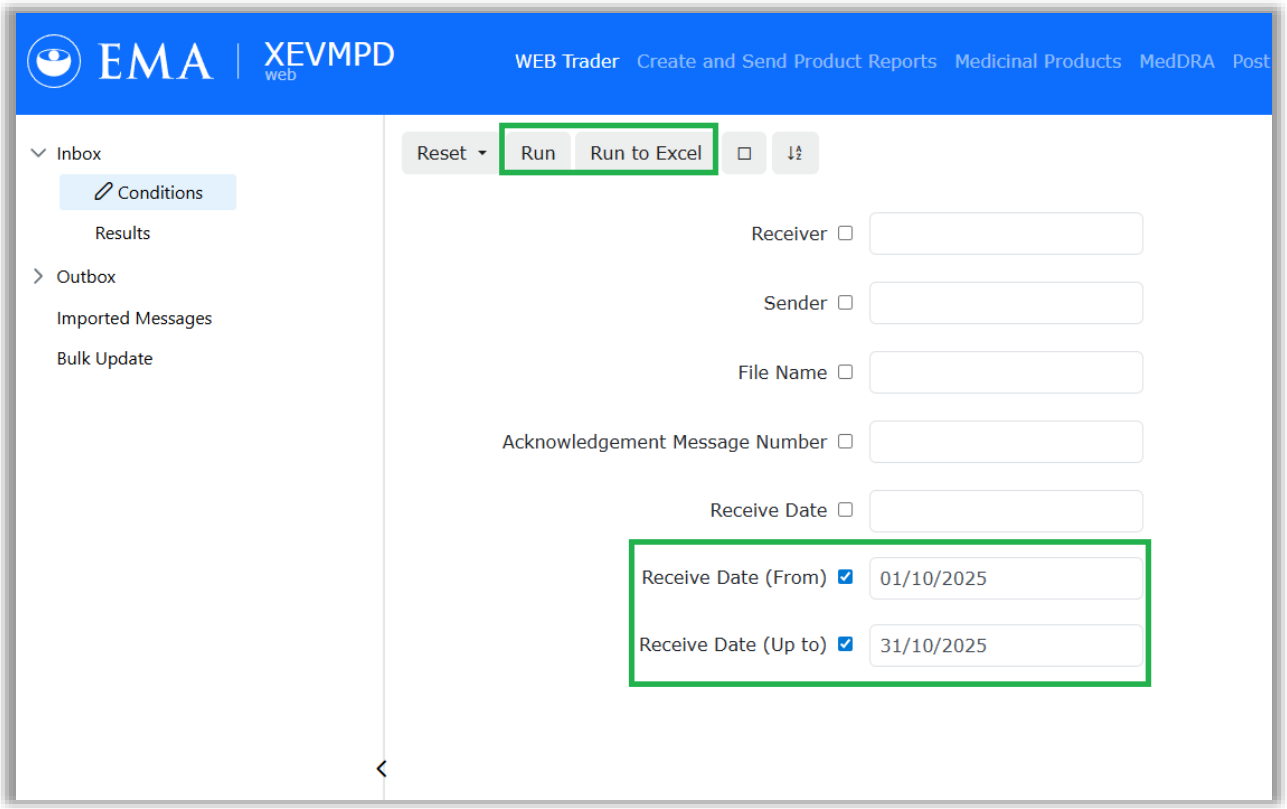
- the '**Received Date**' query field should be used when the user is searching for XEVPRM ACKs received on a specific date.

- the '**Received Date (From)**' should be used to search for XEVPRM ACKs received from a certain date onwards.

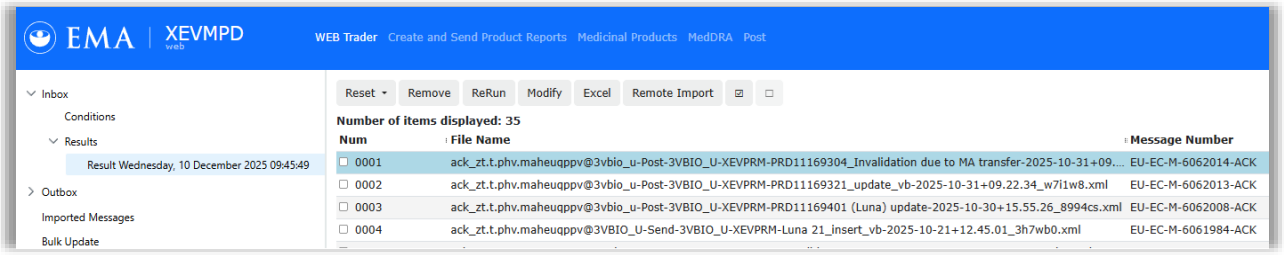
- the '**Received Date (Up to)**' should be used to search for XEVPRM ACKs received up to a certain date.

- Combination of 'Received Date (From)' and 'Received Date (Up to)' should be used to search for XEVPRM ACKs received during a specific period (for example a month). The start and end of the period should be entered into the 'Receive Date (From)' and 'Receive Date (Up to)' fields using the calendar option.

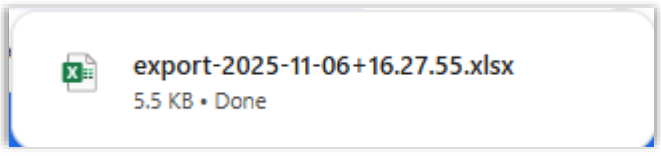
Once the required conditions for the search were specified, users can select if they wish to run the search via the '**Run**' or '**Run to Excel**' functionality:



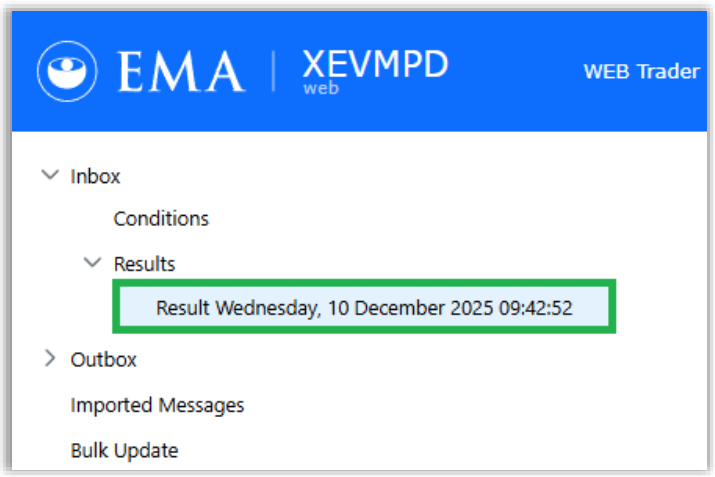
By selecting '**Run**', the results of the search will be displayed in the active area:



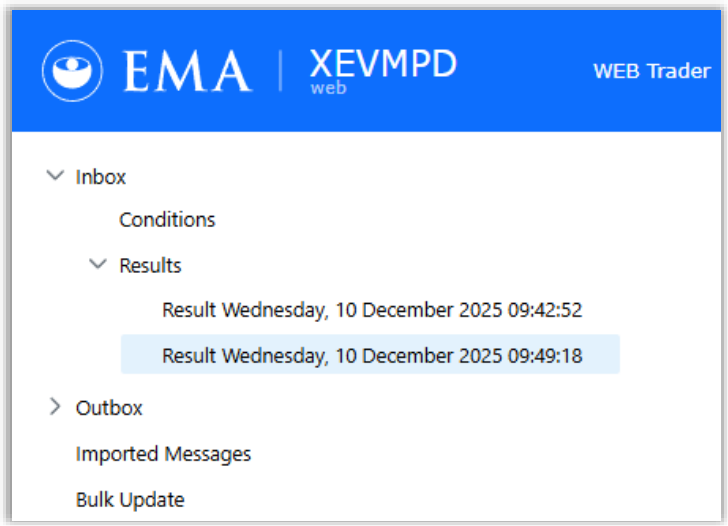
By selecting '**Run to Excel**', the results of the search will be sent to an Excel file, which will be sent to the 'Downloads' folder of the browser in which the user is viewing XEVMPDweb:



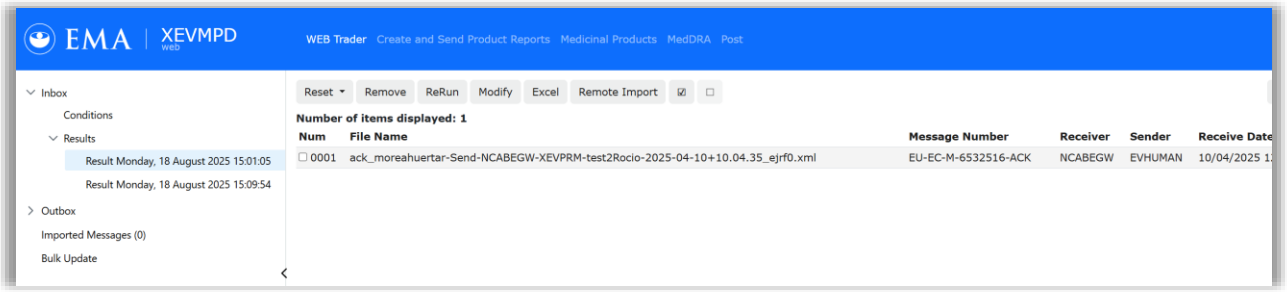
Once the search was executed, a time stamp (with the date and time) will be displayed under 'Results' in the tree-view area:



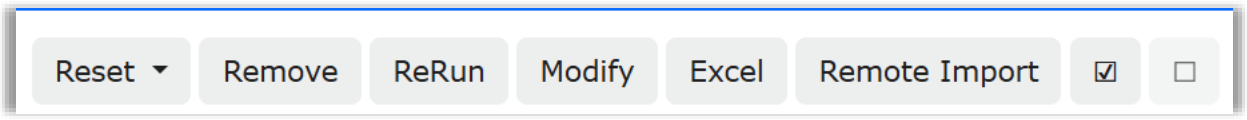
If multiple searches were performed, the time stamp for each of the searches will show in the 'Results' section:



Users can **view the results for each of the searches performed** by clicking on the required time stamp; the results of that search will then be displayed in the active area:

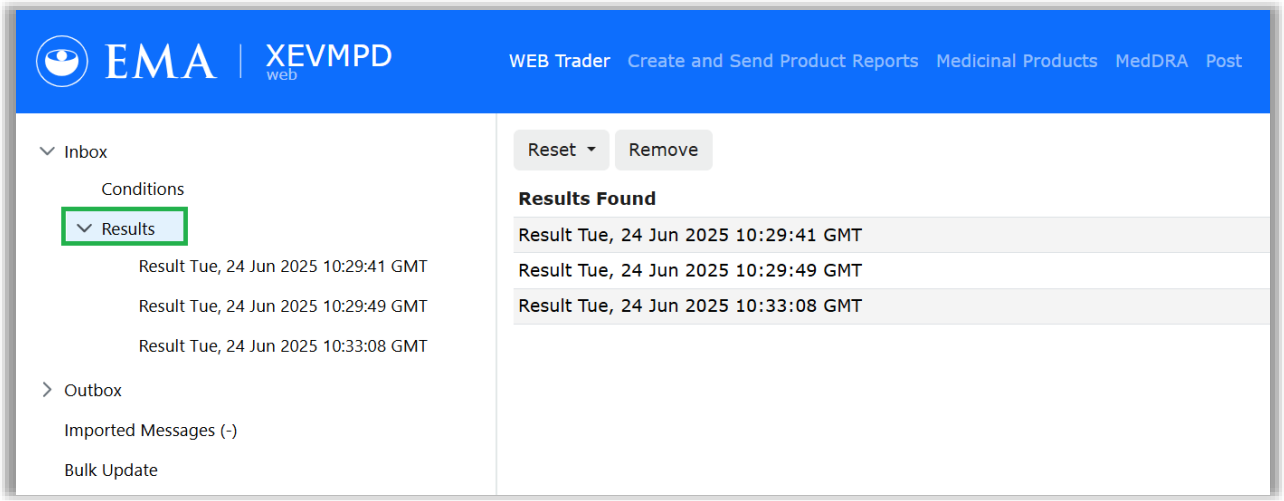


Once results are available in the active area, several functionalities will become available in the active area:

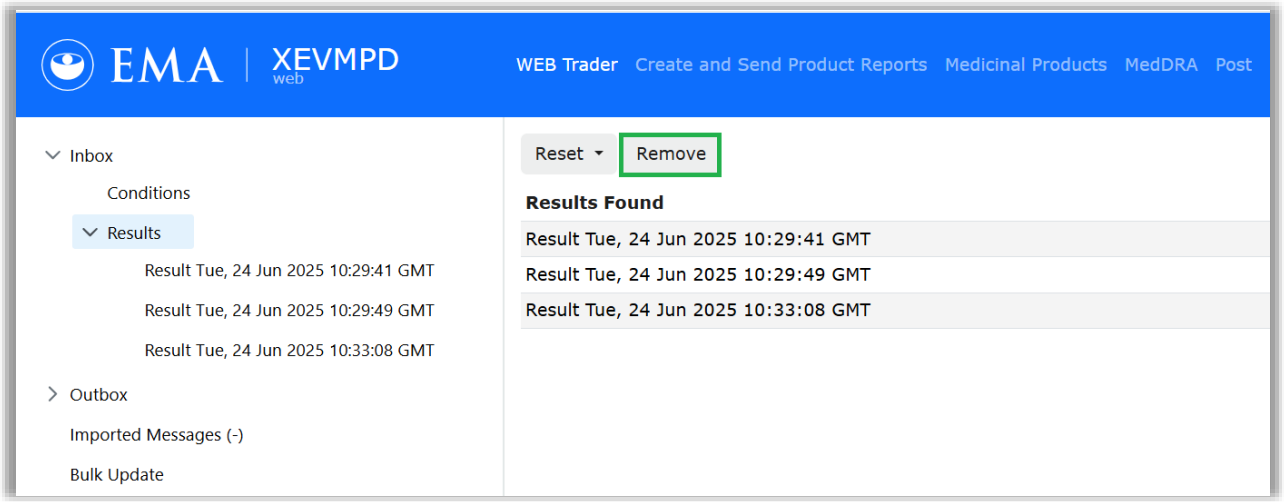


These functionalities can be used on the items selected in the active area:

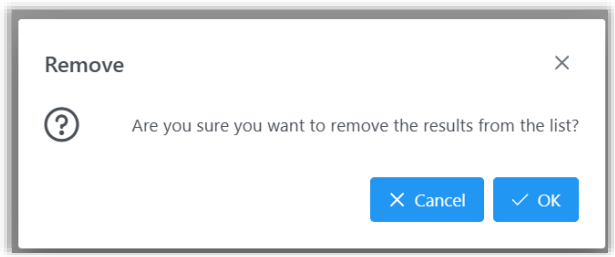
To **remove all results from each of the searches**, users should click on the 'Result' section in the tree-view area; an overview of the searches performed will be displayed in the active area:



You can remove **all results** by clicking on the 'Remove' functionality:



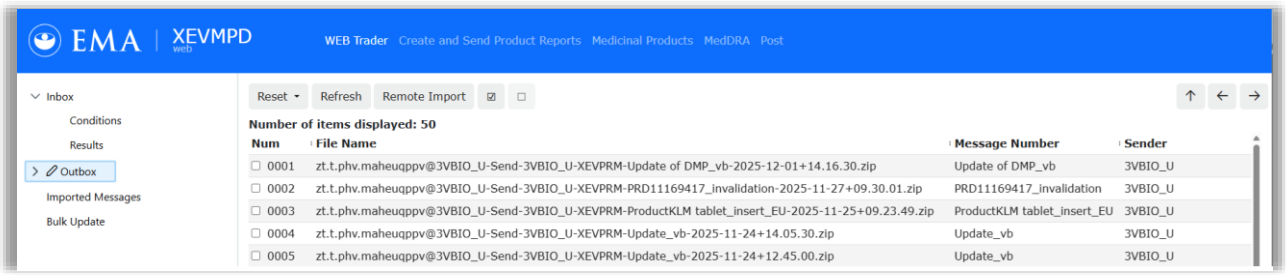
A pop-up window will be displayed asking the user to confirm that all items should be removed:



Once confirmed, the results will be removed.

4.2. Outbox

The 'Outbox' displays XEVPRMs (in a ZIP file) sent in the XEVMPD from the user's organisation (i.e. the ID of an organisation registered in EudraVigilance with a WEB Trader submission mode):



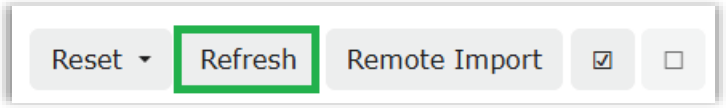
Organisations registered in EudraVigilance with a Gateway submission mode will find their submitted XEVPRMs in the location specified by their Gateway provider.

The ZIP file with the submitted XEVPRM will be available in the in the WEB Trader Outbox **within minutes and max 48 hours** since the XEVPRM was submitted.

By default, the 'Outbox' section will display the last 50 XEVPRMs **sent from the organisation ID under which the user is logged on** to XEVMPDweb.

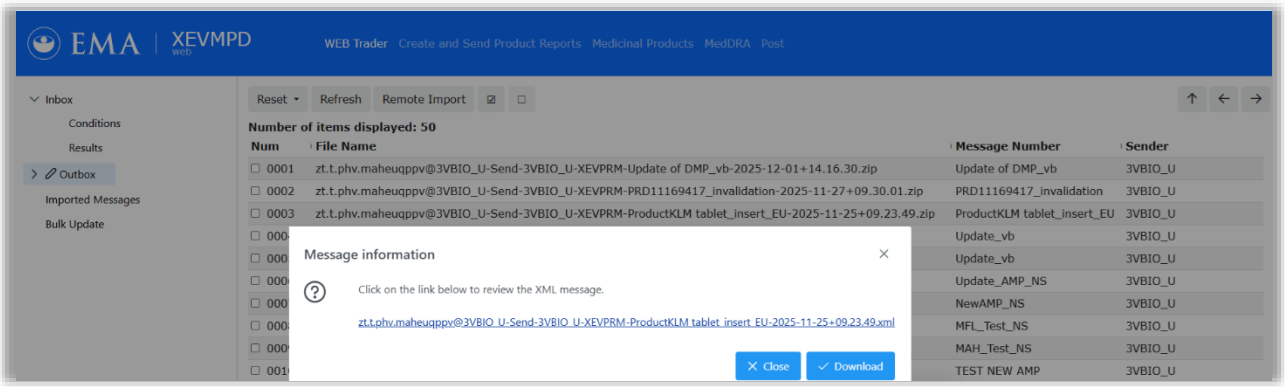
Users cannot modify the content of their Outbox.

Users can however refresh the results show by clicking on the 'Refresh' button:

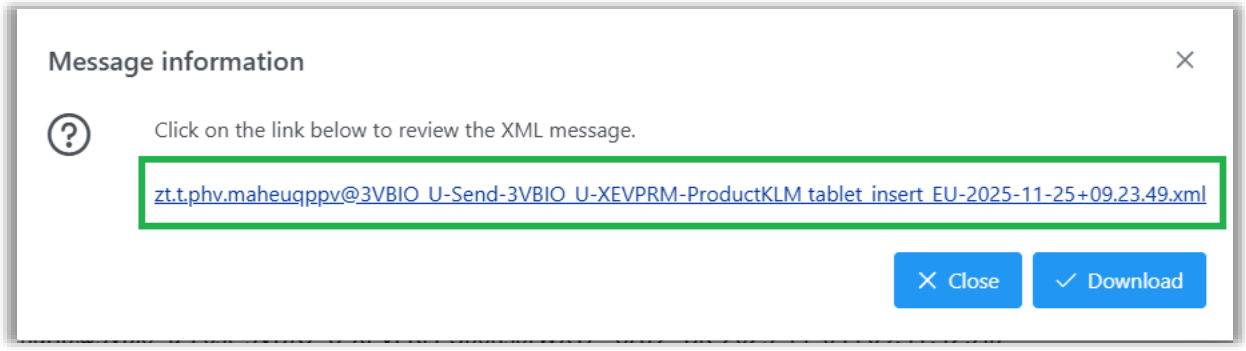


To view the content of the submitted XEVPRM, or to download the file, select the required file name in the active area; the selected file will be highlighted in blue:

Click on the selected file and a new pop-up window will be displayed, containing the link to the XML file of the XEVPRM that was sent, and the option to download the file:



- To **view the information in the file**, click on the hyperlink in blue:

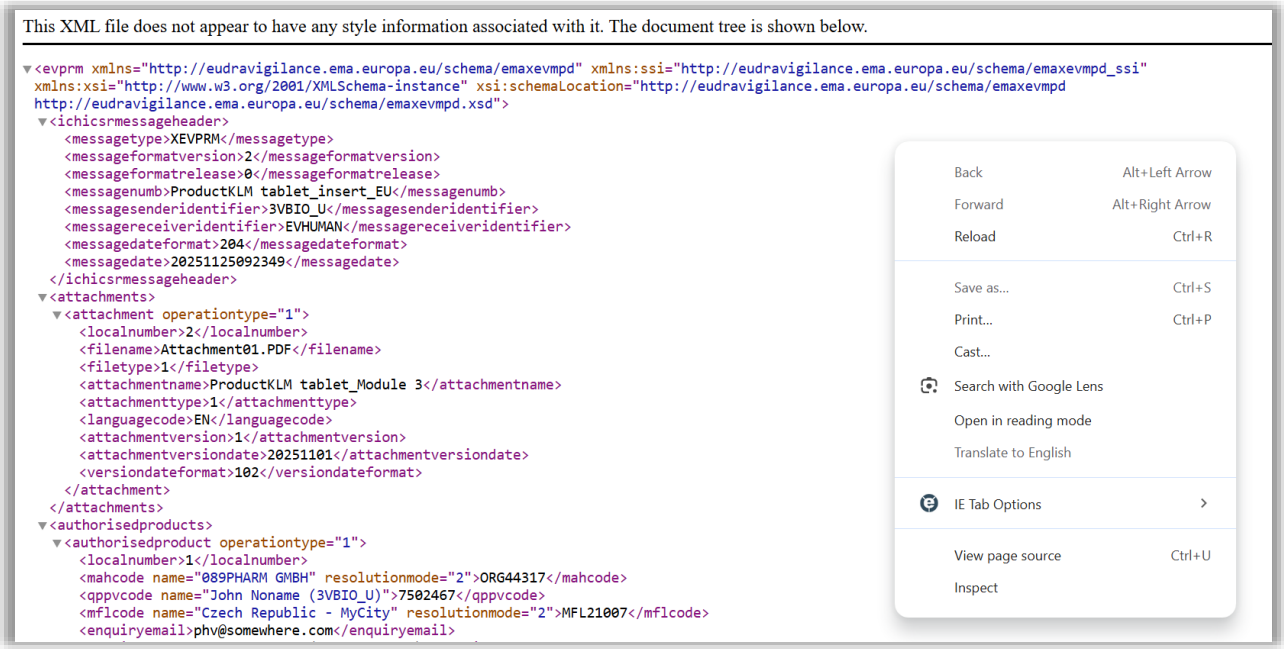


A new window will open and display the content of the message:

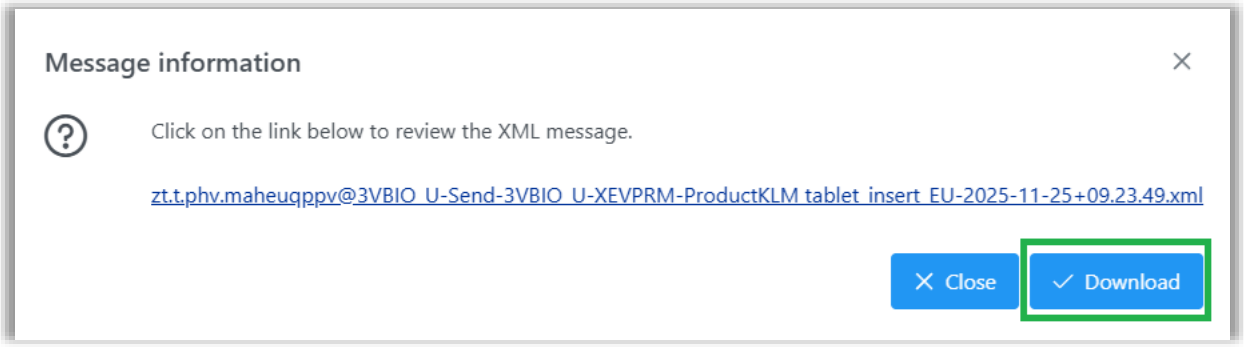
This XML file does not appear to have any style information associated with it. The document tree is shown below.


```
<evprm xmlns="http://eudravigilance.ema.europa.eu/schema/emaxevmpd" xmlns:ssi="http://eudravigilance.ema.europa.eu/schema/emaxevmpd_ssi"
 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="http://eudravigilance.ema.europa.eu/schema/emaxevmpd
 http://eudravigilance.ema.europa.eu/schema/emaxevmpd.xsd">
  <ichicsrmessageheader>
    <messagetype>XEVPRM</messagetype>
    <messageformatversion>2</messageformatversion>
    <messageformatrelease>0</messageformatrelease>
    <messagenumb>ProductKLM tablet_insert_EU</messagenumb>
    <messagesenderidentifier>3VBIO_U</messagesenderidentifier>
    <messagereceiveridentifier>EVHUMAN</messagereceiveridentifier>
    <messagedateformat>204</messagedateformat>
    <messagedate>20251125092349</messagedate>
  </ichicsrmessageheader>
  <attachments>
    <attachment operationtype="1">
      <localnumber>2</localnumber>
      <filename>Attachment01.PDF</filename>
      <filetype>1</filetype>
      <attachmentname>ProductKLM tablet_Module 3</attachmentname>
      <attachmenttype>1</attachmenttype>
      <languagecode>EN</languagecode>
      <attachmentversion>1</attachmentversion>
      <attachmentversiondate>20251101</attachmentversiondate>
      <versiondateformat>102</versiondateformat>
    </attachment>
  </attachments>
  <authorisedproducts>
    <authorisedproduct operationtype="1">
      <localnumber>1</localnumber>
      <mahcode name="089PHARM GMBH" resolutionmode="2">ORG44317</mahcode>
      <qppvcode name="John Noname (3VBIO_U)">7502467</qppvcode>
      <mflcode name="Czech Republic - MyCity" resolutionmode="2">MFL21007</mflcode>
      <enquiryemail>phv@somewhere.com</enquiryemail>
      <enquiryphone>01234 567 890 (9:00 - 17:00)</enquiryphone>
      <authorisation>
        <authorisationcountrycode name="European Union">EU</authorisationcountrycode>
        <authorisationprocedure name="EU authorisation procedures - Centralised Procedure">1</authorisationprocedure>
        <authorisationstatus name="Valid">1</authorisationstatus>
        <authorisationnumber>EU 132456/001</authorisationnumber>
        <authorisationdate>20251006</authorisationdate>
        <authorisationdateformat>102</authorisationdateformat>
        <mrpnumber>EMEA 1234/001</mrpnumber>
        <eunumber>EU 132456/001</eunumber>
        <legalbasis name="Application according to Article 58 of Regulation (EC) No 726/2004">11</legalbasis>
        <medicinalproducttypes>
          <medicinalproducttype>
            <producttypecode name="Other">7</producttypecode>
          </medicinalproducttype>
        </medicinalproducttypes>
        <orphandrug name="No">2</orphandrug>
        <intensivemonitoring name="Yes">1</intensivemonitoring>
      </authorisation>
      <presentationname>
        <productname>ProductKLM tablet</productname>
        <productshortname>ProductKLM</productshortname>
        <productform>TABLET</productform>
      </presentationname>
      <authpharmforms>
        <authpharmform>
          <authpharmformcode name="FILM COATED TABLET" resolutionmode="2">PHF2355</authpharmformcode>
        </authpharmform>
      </authpharmforms>
      <productatcs>
        <productatc>
          <atccode name="ACETYLCARNITINE " resolutionmode="2">N06BX12</atccode>
        </productatc>
      </productatcs>
      <productindications>
        <productindication>
          <meddraversion>28</meddraversion>
          <meddralevel>LLT</meddralevel>
          <meddracode name="Abnormal complement fixation">10000123</meddracode>
        </productindication>
      </productindications>
      <pharmaceuticalproducts>
        <pharmaceuticalproduct>
          <pharmformcode name="FILM COATED TABLET" resolutionmode="2">PHF2355</pharmformcode>
```

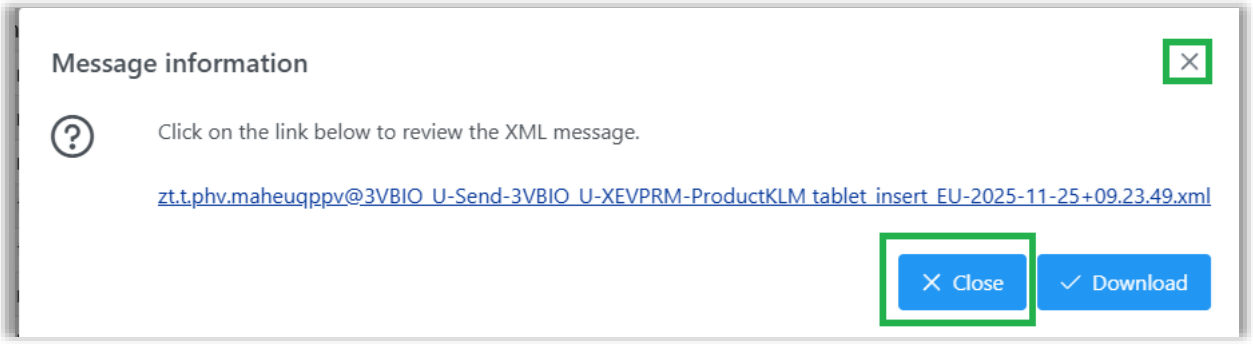

- Depending on the browser that is used to access XEVMPDweb, users might be able to **save the file as a PDF file** using the **'Print'** option available upon using a right click on the user's mouse:



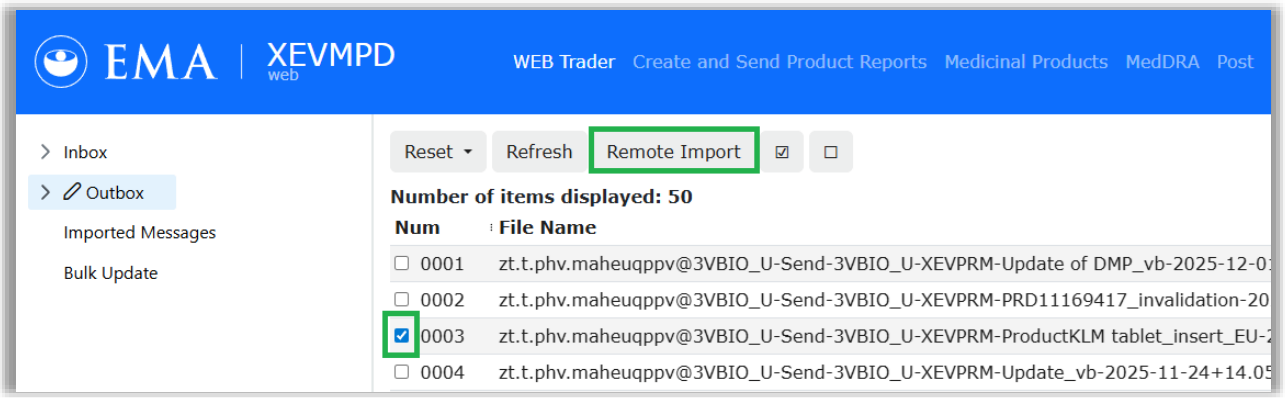
- To **download the XML file**, the **'Download'** option should be used:



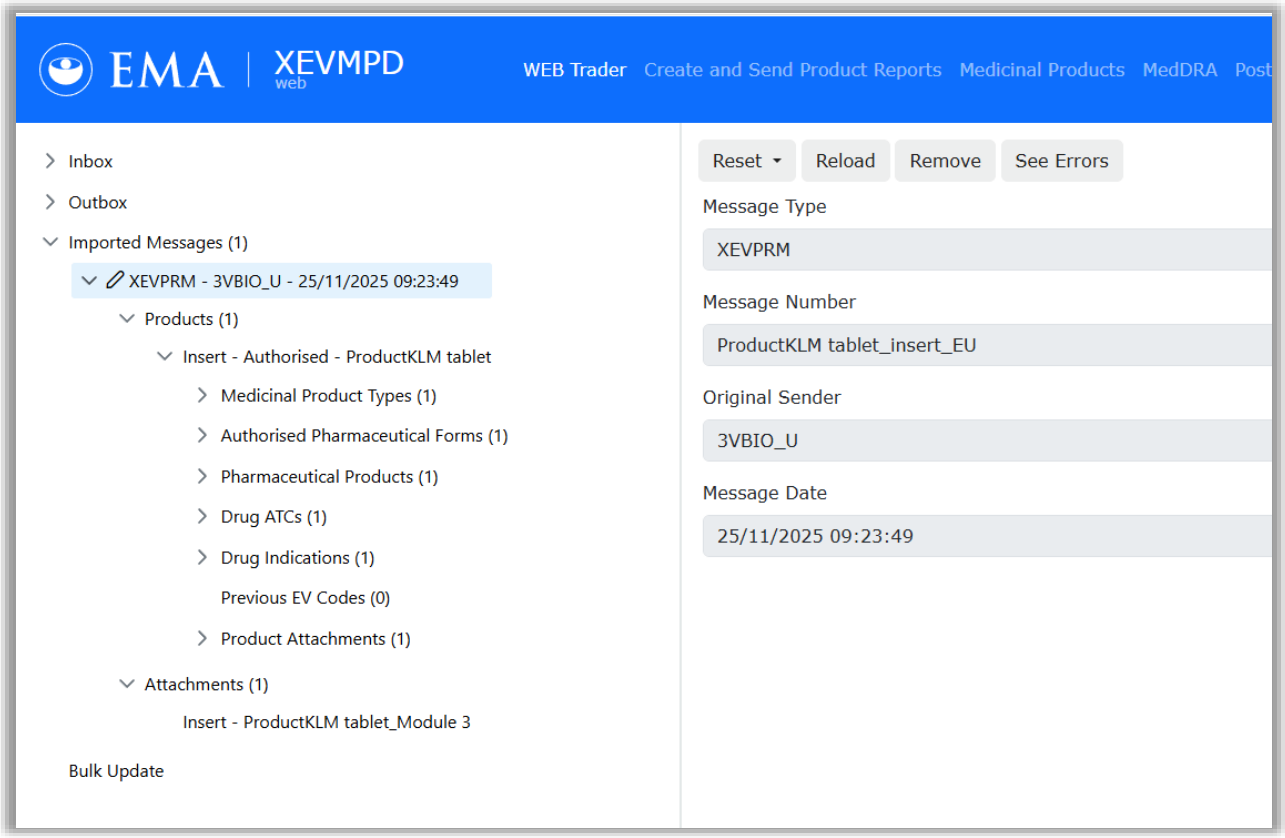
- To **close the pop-up window**, either of the 'Close' options should be used:



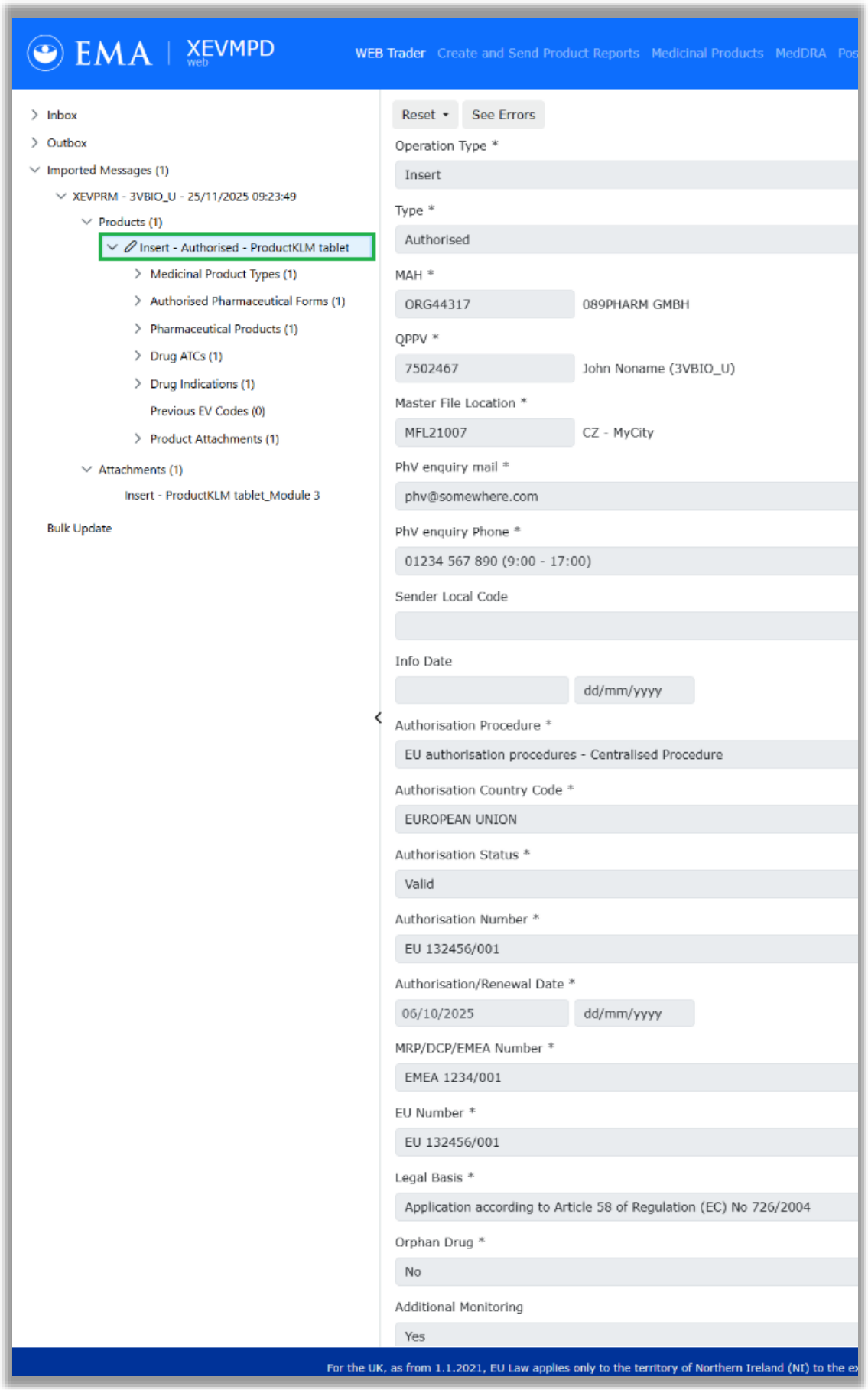
To view the information of the submitted XEVPRM in user-friendly format in XEVMPDweb, the XML file should be selected (by ticking the box next to the item in the active area), and then uploaded in the tree-view area via the **'Remote Import'** functionality:

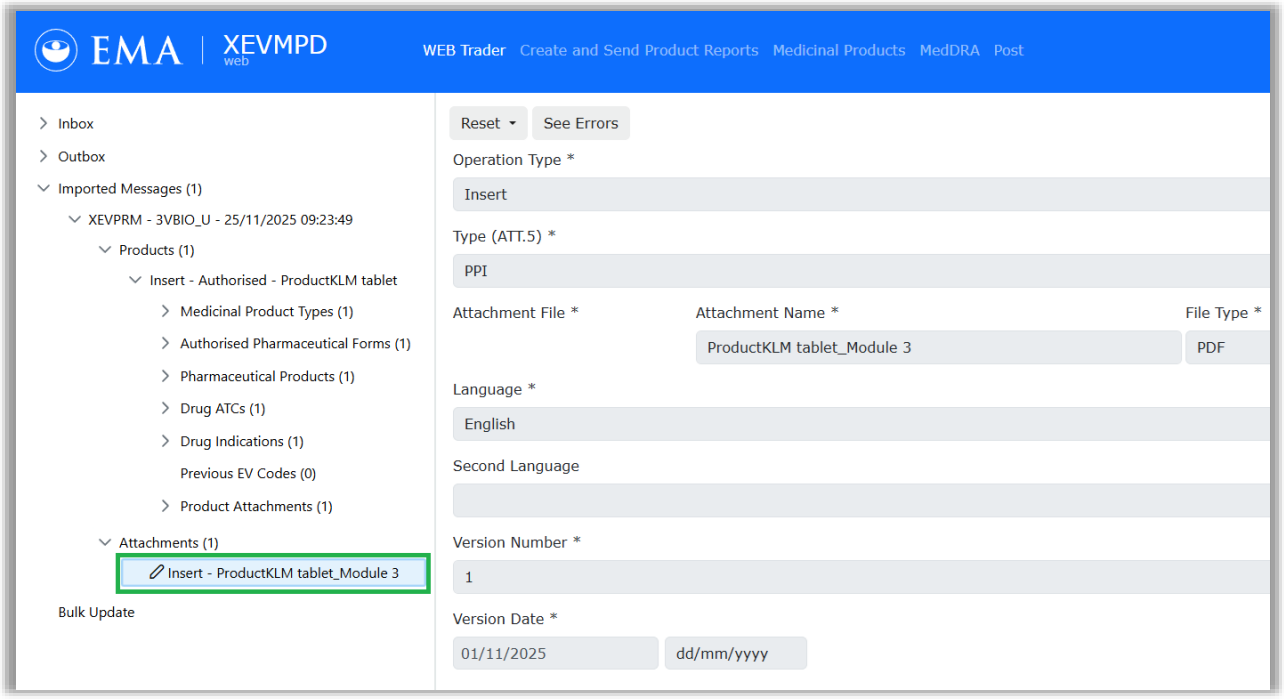


The tree-view area will then display information related to the **content of the submitted file** whilst the active area will display the information related to the **identification of the submitted file**:



To check the details of the items submitted in the XEVPRM, click on the relevant section(s) in the tree-view area; upon doing so, the details of the selected entity will be displayed in the active area:

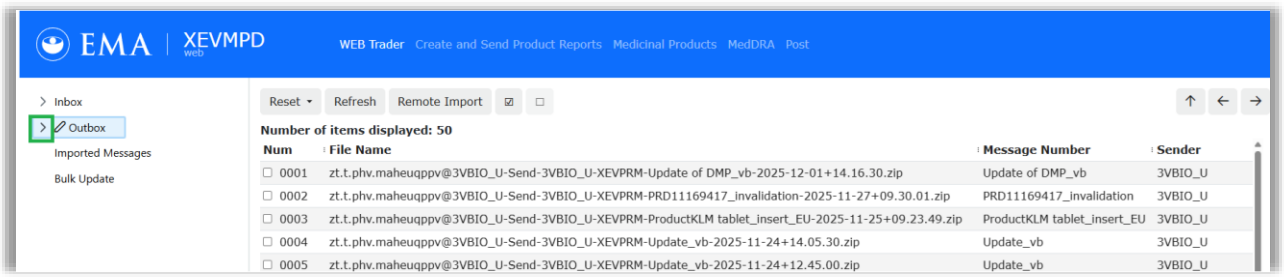

EMA | XEVMPD web
WEB Trader
Create and Send Product Reports
Medicinal Products
MedDRA
Inbox
Outbox
Imported Messages (1)
XEVPRM - 3VBIO_U - 25/11/2025 09:23:49
Products (1)
Insert - Authorised - ProductKLM tablet
Medicinal Product Types (1)
Authorised Pharmaceutical Forms (1)
Pharmaceutical Products (1)
Drug ATCs (1)
Drug Indications (1)
Previous EV Codes (0)
Product Attachments (1)
Attachments (1)
Insert - ProductKLM tablet_Module 3
Bulk Update
Reset
See Errors
Operation Type *
Insert
Type *
Authorised
MAH *
ORG44317
089PHARM GMBH
QPPV *
7502467
John Noname (3VBIO_U)
Master File Location *
MFL21007
CZ - MyCity
PhV enquiry mail *
phv@somewhere.com
PhV enquiry Phone *
01234 567 890 (9:00 - 17:00)
Sender Local Code
Info Date
dd/mm/yyyy
Authorisation Procedure *
EU authorisation procedures - Centralised Procedure
Authorisation Country Code *
EUROPEAN UNION
Authorisation Status *
Valid
Authorisation Number *
EU 132456/001
Authorisation/Renewal Date *
06/10/2025
dd/mm/yyyy
MRP/DCP/EMEA Number *
EMEA 1234/001
EU Number *
EU 132456/001
Legal Basis *
Application according to Article 58 of Regulation (EC) No 726/2004
Orphan Drug *
No
Additional Monitoring
Yes
For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the ex



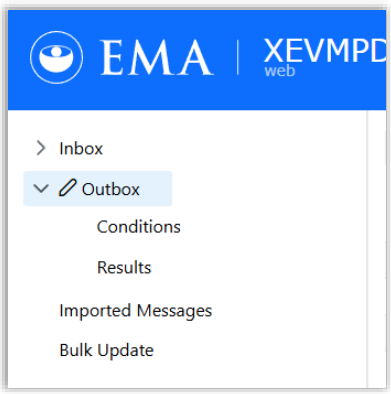
4.2.1. Search within the 'Outbox' section

Within the 'Outbox', it is possible to perform a search related to the XEVPRMs that were sent from the user's organisation (i.e. from the organisation ID under which the user is logged on to XEVMPDweb).

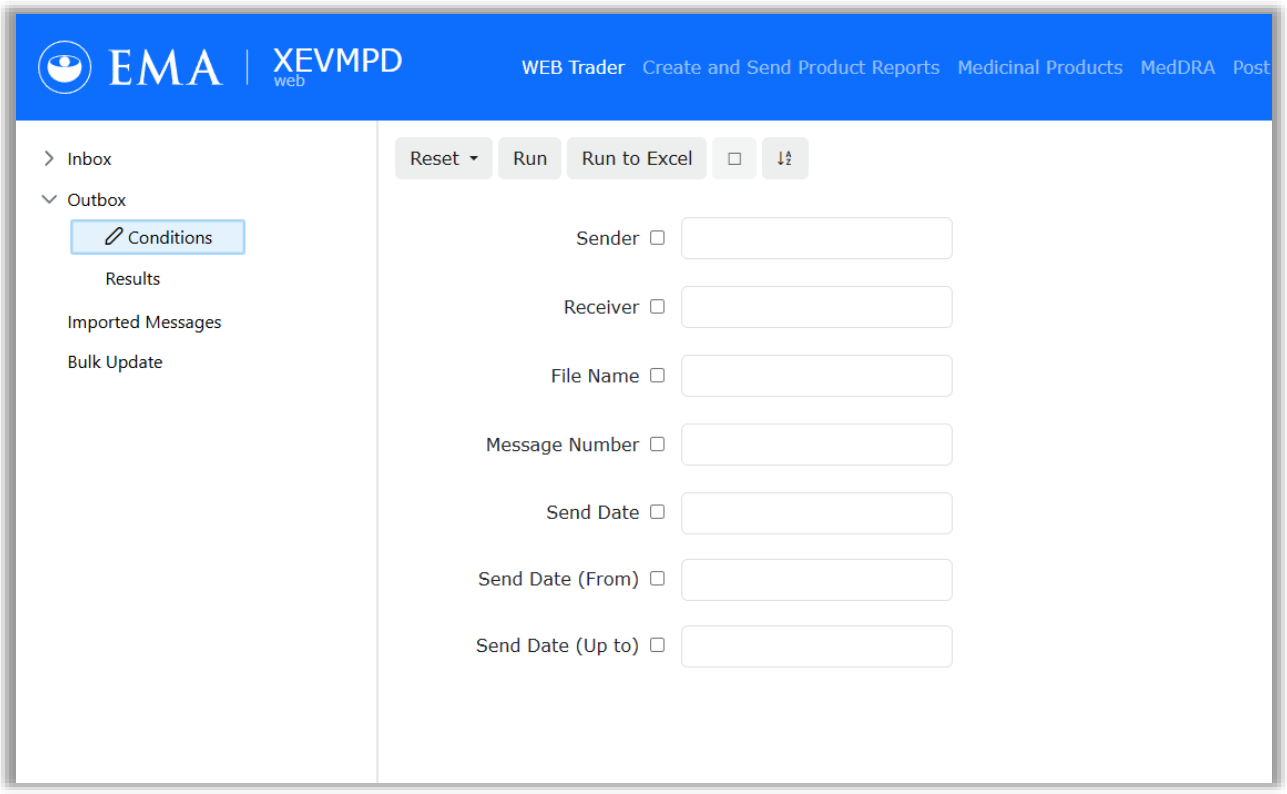
To specify the search conditions, expand the 'Outbox' section in the tree-view area by clicking on the arrow next to the 'Outbox':



The 'Outbox' text will become highlighted in blue, and the tree-view area will show the 'Conditions' and 'Results' under the 'Outbox' header:



By clicking on 'Conditions', the active area will display the conditions that the user can use to specify the filters and conditions for the search:



The user can then select and specify the conditions of the search, and run the search, in similar manner as described in section *4.1.1. Search within the 'Inbox' section* of this document.

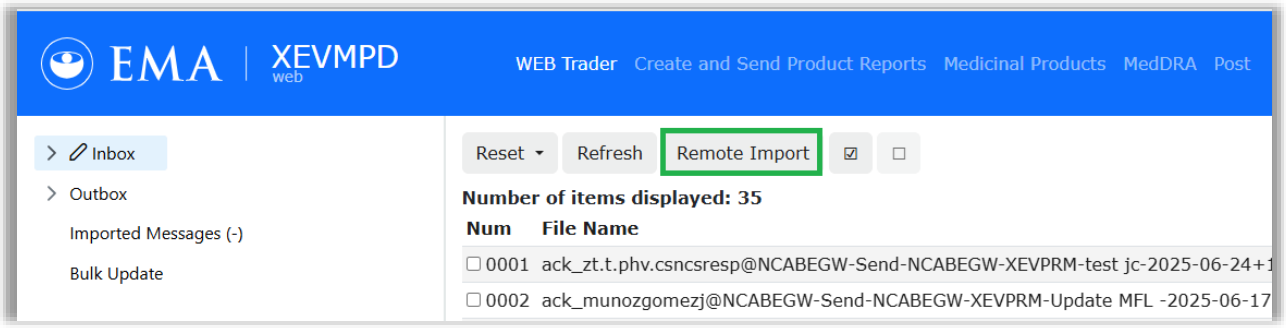
4.3. Imported Messages

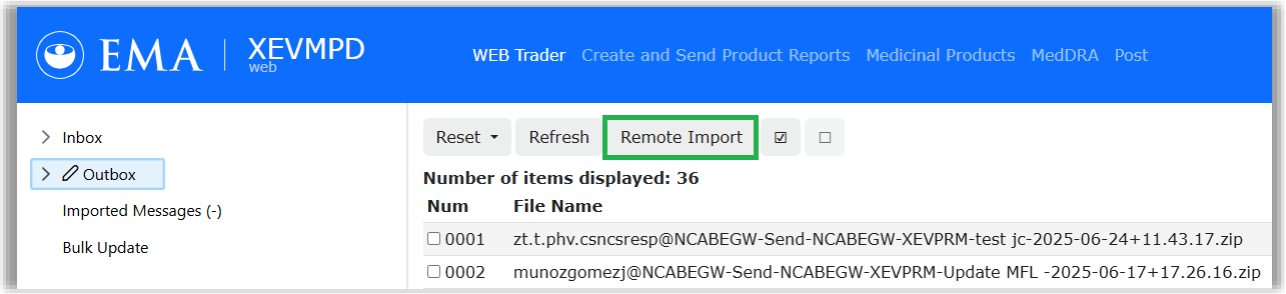
The section 'Imported Messages' will display:

- messages received (i.e. XEVPRM Acknowledments available in the WEB Trader 'Inbox') and imported by the user from the 'Inbox' section using the **'Remote Import'** functionality;
- messages submitted in the XEVMPD (i.e. messages available in the WEB Trader 'Outbox') and imported by the user from the 'Outbox' section using the **'Remote Import'** functionality; and
- messages uploaded by the user from their local computer using the **'Local Import'** functionality.

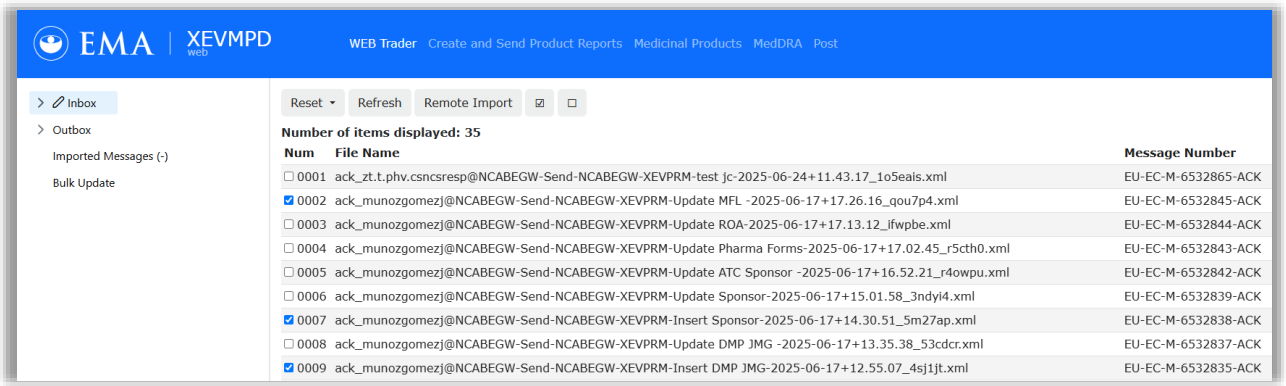
4.3.1. Remote Import

The **'Remote Import'** functionality is available for items that are displayed in the active area (by default of as a result of a search) either within the 'Inbox' or within the 'Outbox' of the Web Trader section:



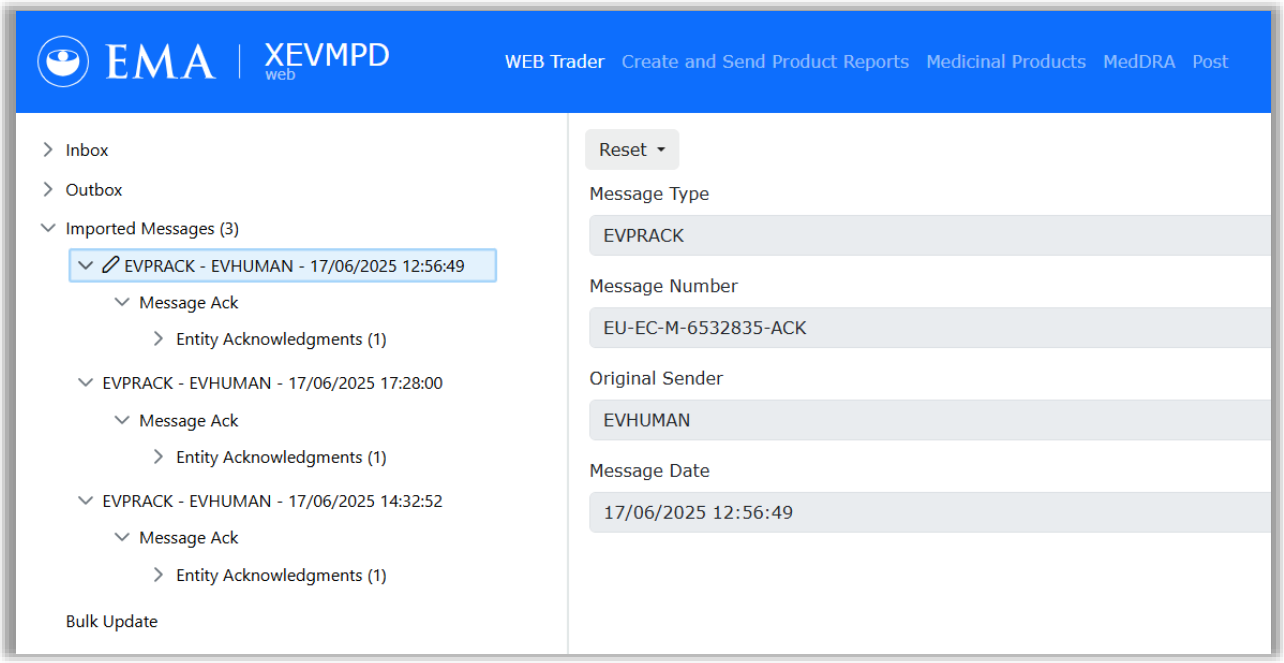


Users must first select the files they wish to import from the active area (one, multiple or all) into the tree-view area by using the checkbox available for each item:

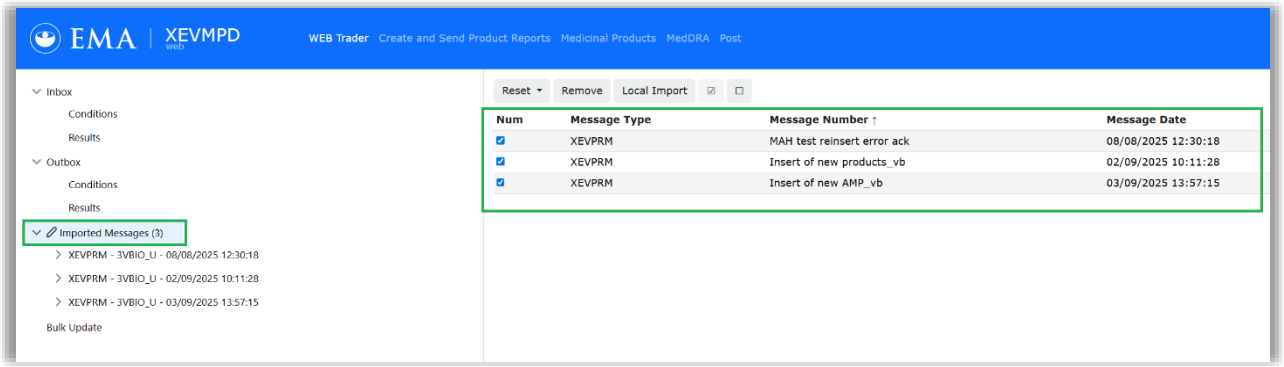


Once the files are selected, upon clicking on the 'Remote Import' functionality, the files will be loaded in the tree-view area, under the 'Imported Messages' section:

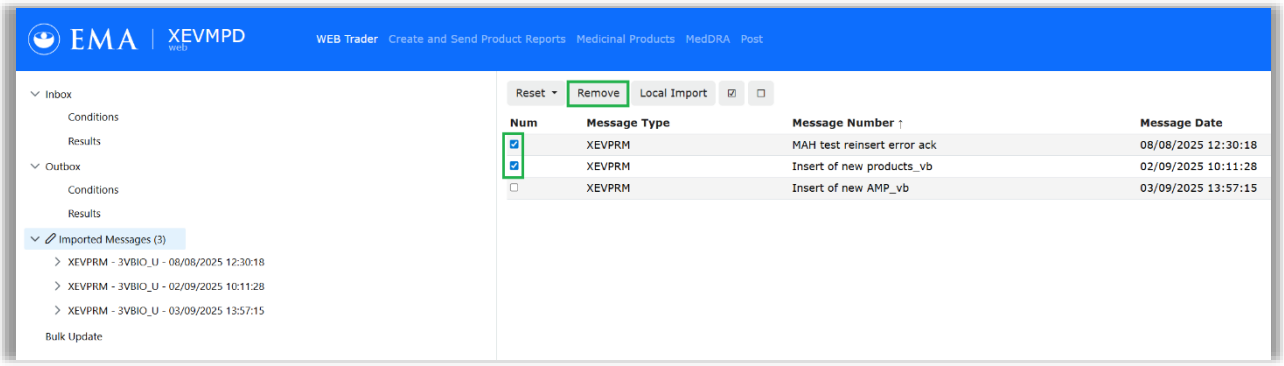
- the tree-view area will display information related to the **content of the submitted file** and;
- the active area will display the information related to the **identification of the file(s)**.



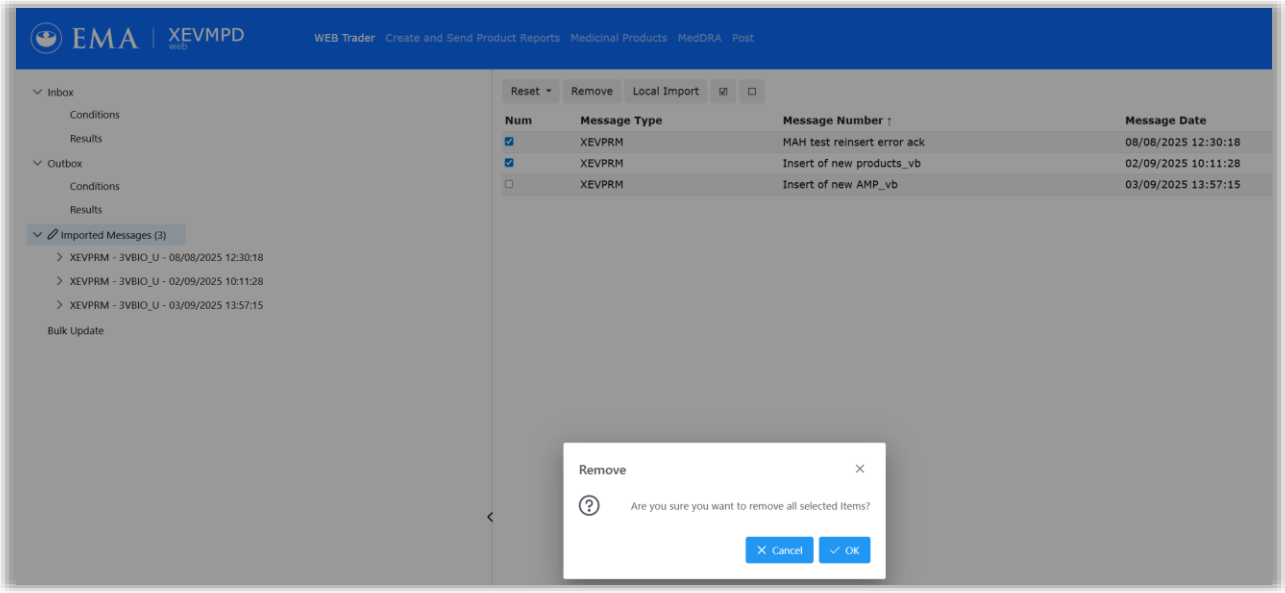
If multiple files are listed in the tree-view area, when clicking on the 'Imported Messages' section, the active area will display an overview of information for all the of the files listed:



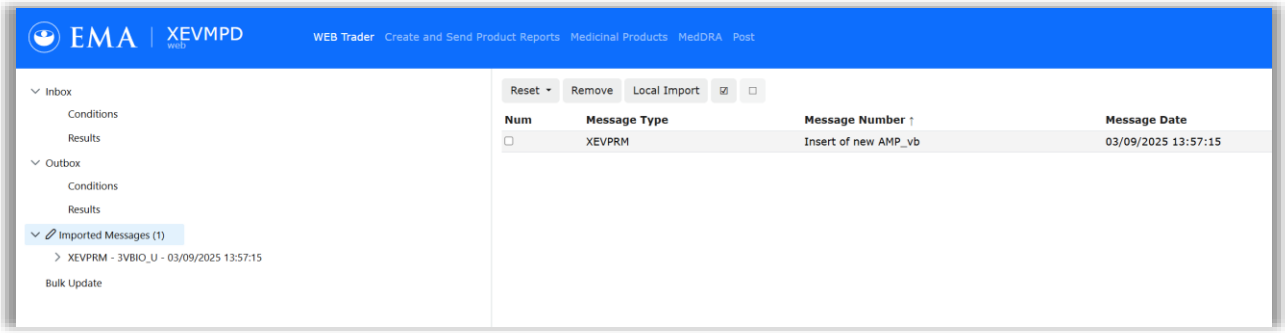
The checkbox for each of the files in the active area will be selected by default; users can remove the files that are selected from the list in the active area and from the tree-view area by using the 'Remove' functionality:



A pop-up window will be displayed asking the user to confirm or cancel the action:

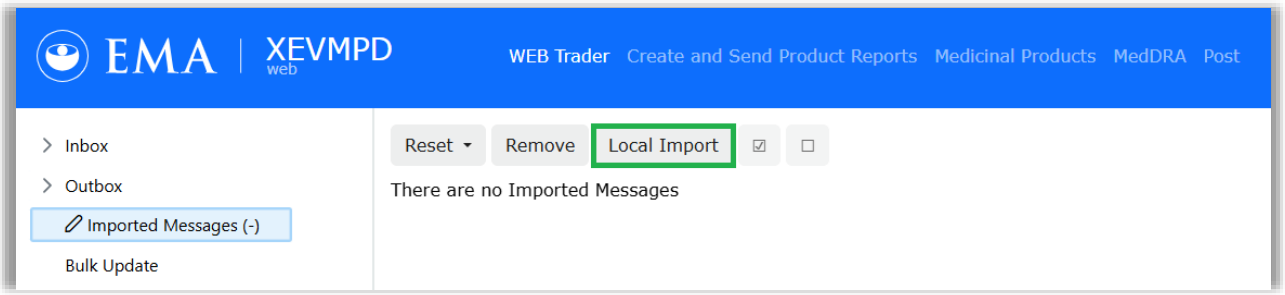


Once confirmed, only the file(s) that were de-selected will remain in the active and tree-view area:



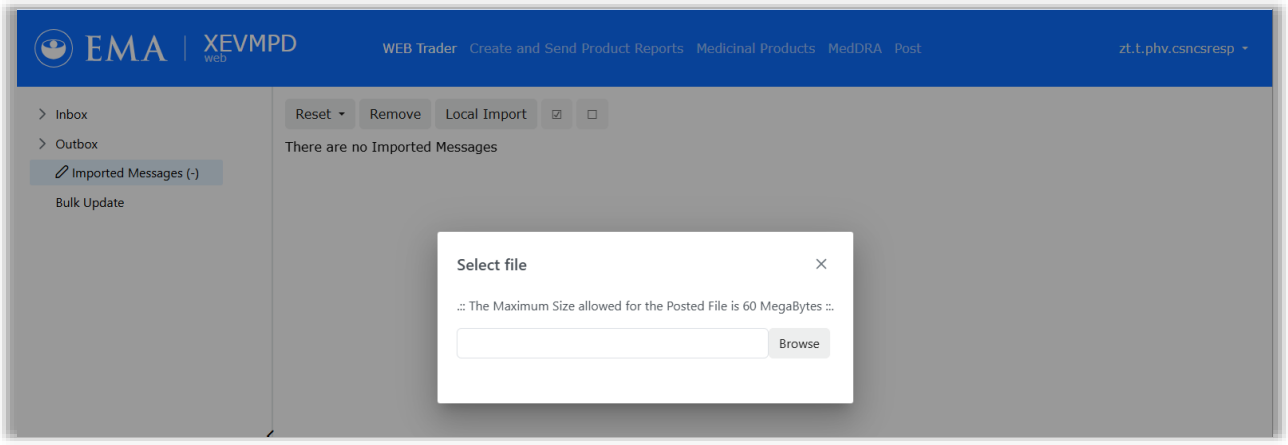
4.3.2. Local Import

The **'Local Import'** functionality available within the 'Imported Messages' section of WEB Trader allows users from Web Trader organisations to import an XML file stored on their computer into XEVMPDweb.

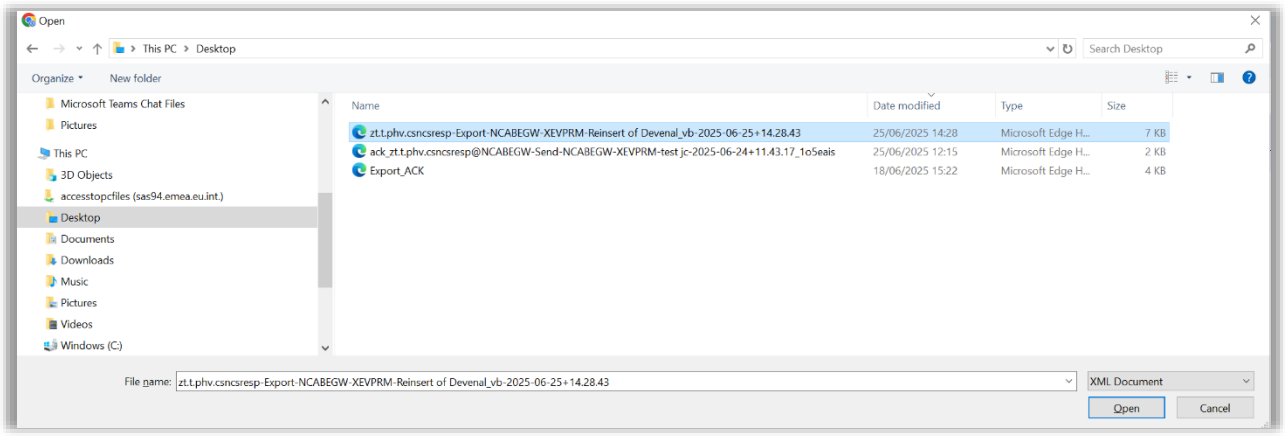


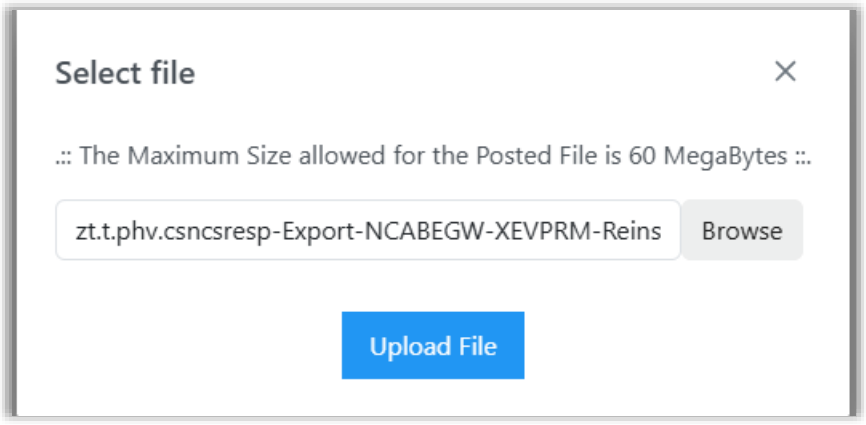
This loading process is used to import data from an XML file available locally (on user's computer or local network) into XEVMPDweb. It is possible to load any kind of message (submission or acknowledgement) that is in an XML file.

To upload an XML file of an XEVPRM saved on user's computer/local network, click on the **'Local Import'** functionality; a new pop-up window will be displayed, prompting the user to browse the location of the file:

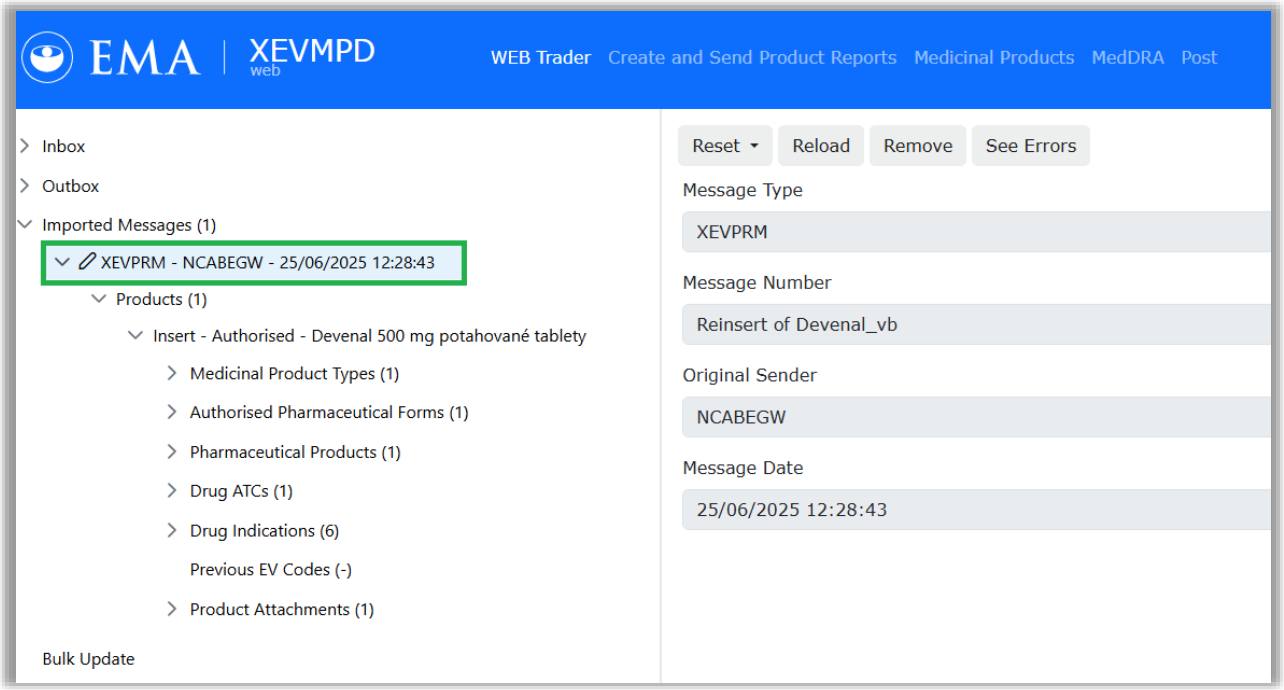


Retrieve the file, select it and upload it:

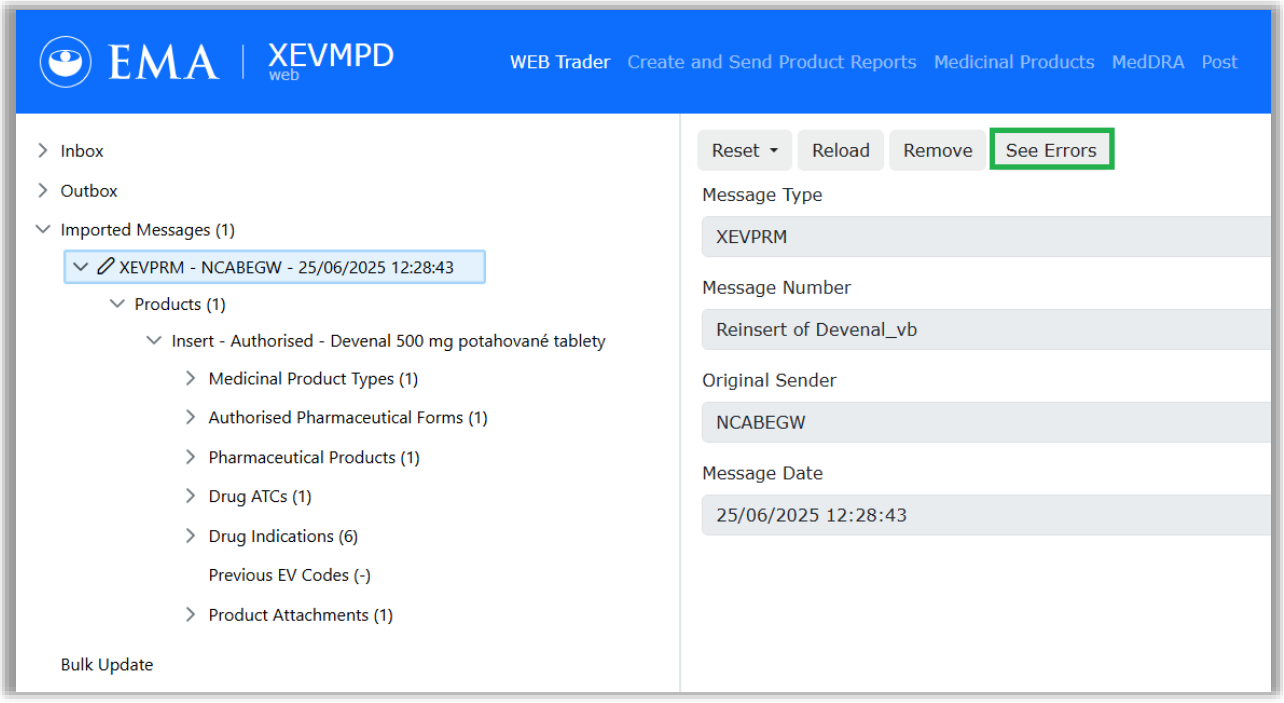




The information related to the content and identification will then be displayed in the tree-view and active area, as applicable:

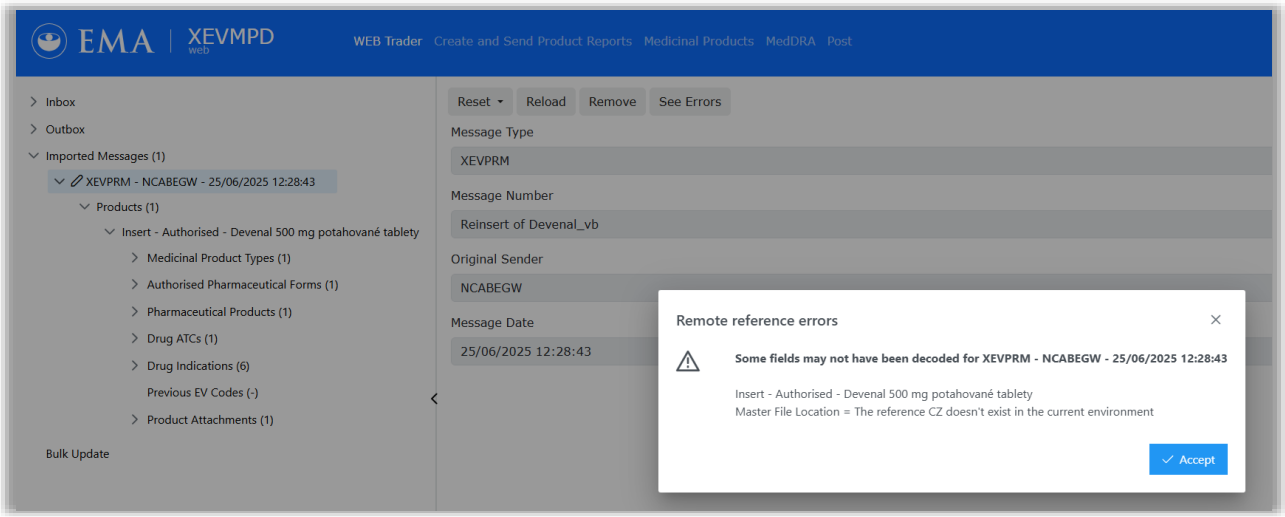


It is possible to check for errors in the uploaded file. This can be achieved by clicking on the 'See Errors' functionality:



In case that some of the information in the XML file was not 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.

As an example, in the file uploaded in the above screenshot, MFL EV Code referenced in the product entity in our XML file does not exist in the environment in which the XML file was uploaded:



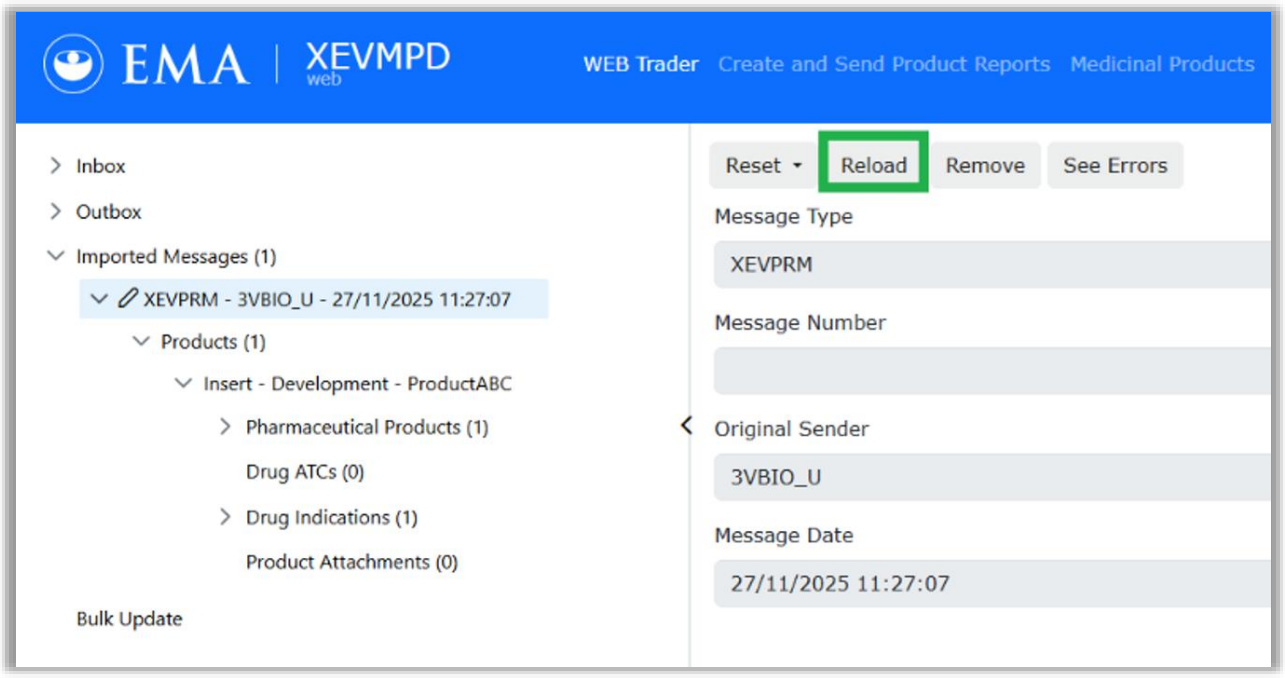
You can dismiss the message by clicking on 'Accept' or close the message by clicking on the 'x' in the right-hand corner of the pop-up window.

XML files of XEVPRMs imported via the 'Local Import' option can be reloaded in the 'Create and Send Product Reports' section via the 'Reload' functionality.

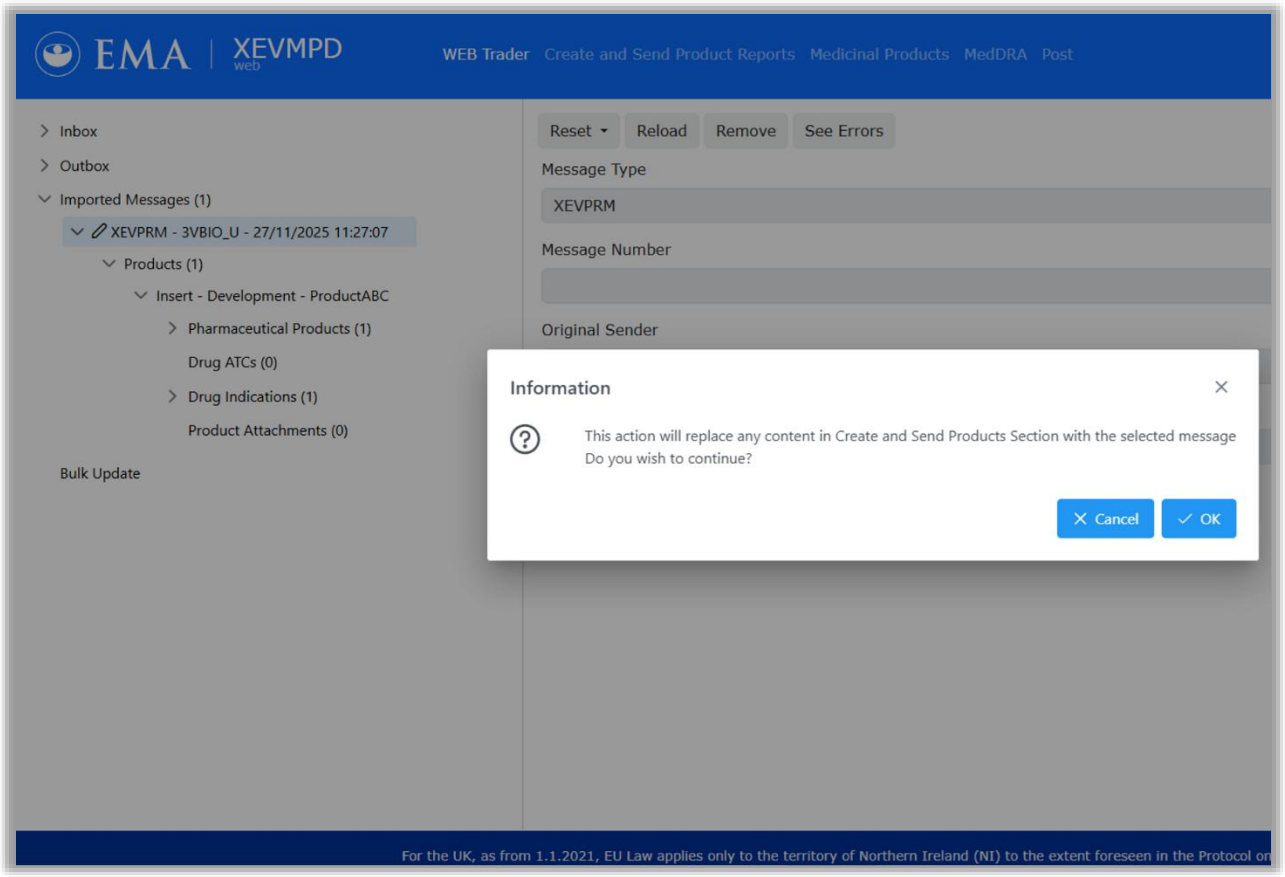
4.3.2.1. Import of XEVPRMs into the 'Create and Send Product Reports' section

XML files imported in the 'Web Trader' section via the 'Local Import' option can be reloaded in the 'Create and Send Product Reports' section where the information within the XEVPRM can be further modified, validated and submitted, if required.

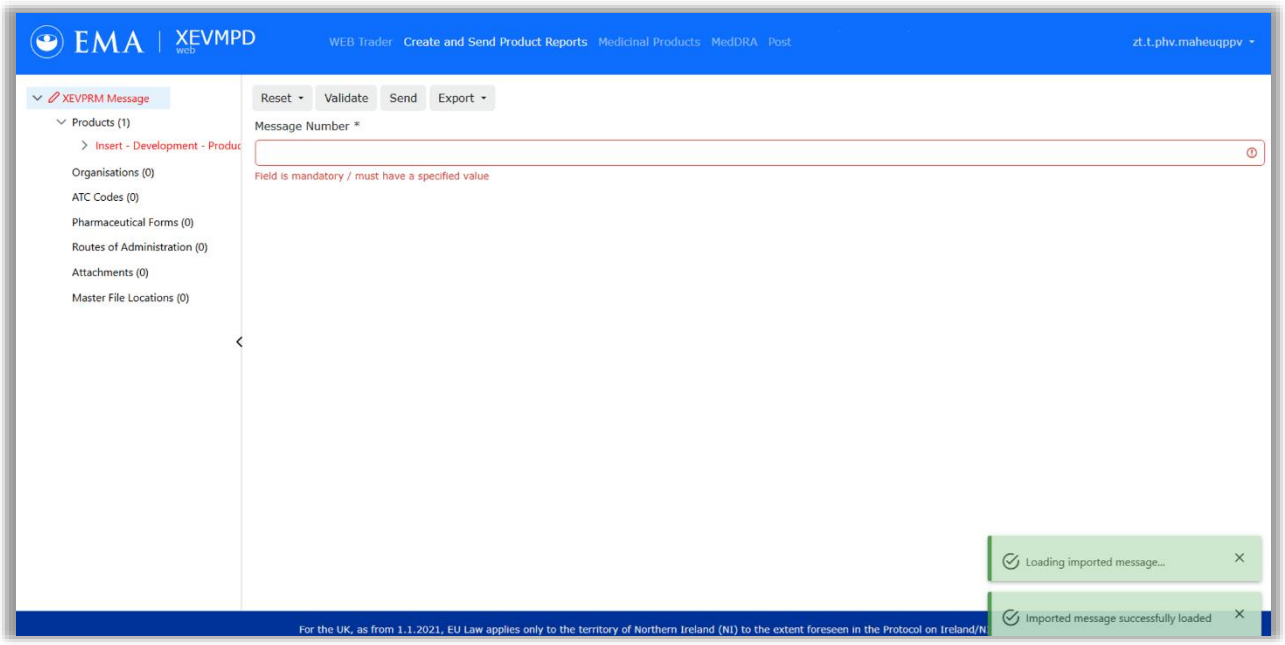
Such import can be achieved via the **'Reload'** function:



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

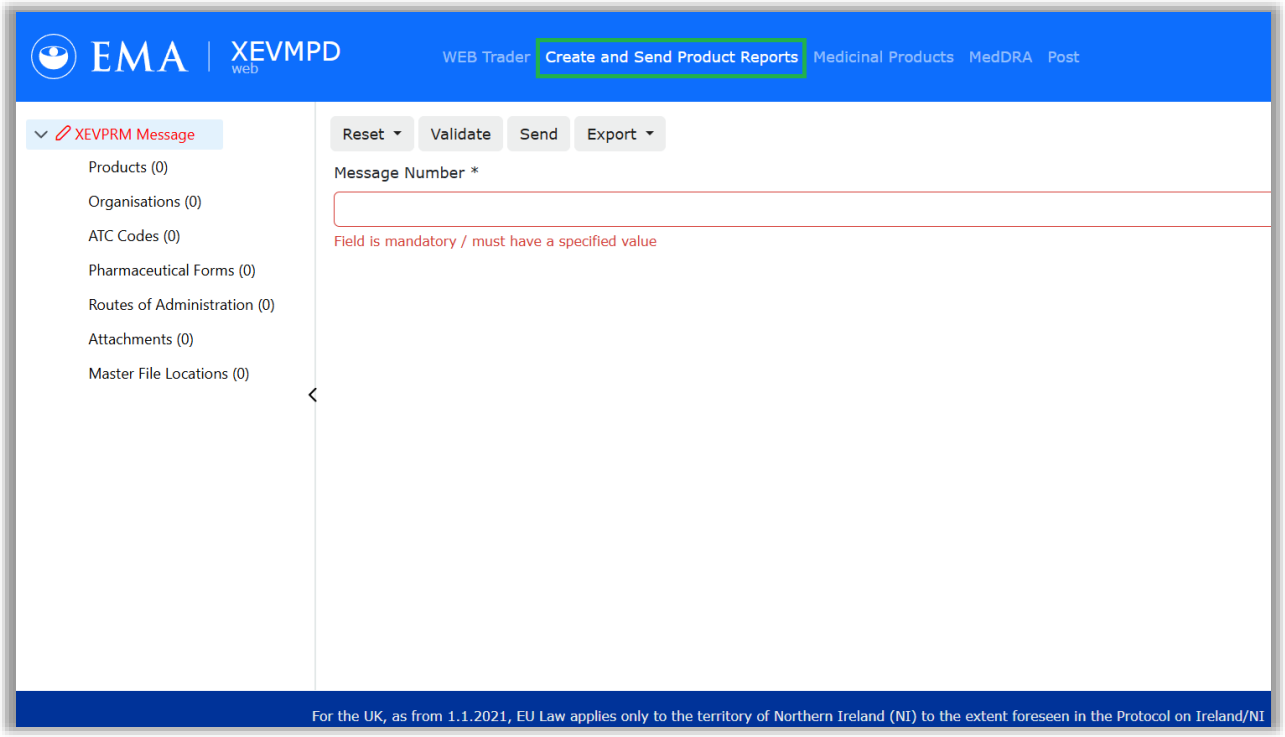


Once you confirm that you wish to continue by clicking on 'OK', the system will proceed with loading the XEVPRM in the 'Create and Send Product Reports' section:



You can then further modify the information within the XEVPRM, assign the message number, validate and send the XEVPRM.

5. 'Create and Send Product Reports' section



This section is used to **create XEVPRMs** thorough which medicinal product information is inserted in the XEVMPD as new or maintained (updated, invalidated or nullified).

Users from organisations registered in EudraVigilance as Web Trader users can also **submit the created XEVPRM** in the XEVMPD using the 'Send' functionality. The 'Send' functionality will not be available to users from organisations registered in EudraVigilance as Gateway users; such users should either submit the created XEVPRM using their internal database or using the 'Post' functionality.

Each XEVPRM can contain up to 100 XEVMPD entities for each of the entity type that is being inserted or maintained.

Users from an MAH and/or sponsor organisations can create an XEVPRM that contains medicinal products (authorised or development), organisations (MAH or sponsor), ATC codes (development), routes of administration (development), pharmaceutical forms (development), attachments and master file locations.

Each of the entity referenced in the XEVPRM will have an operation type (insert, update, invalidate or nullified) assigned to that entity, depending on the type of action that the user is performing.

5.1. Creation of an XEVPRM with operation type 'Insert'

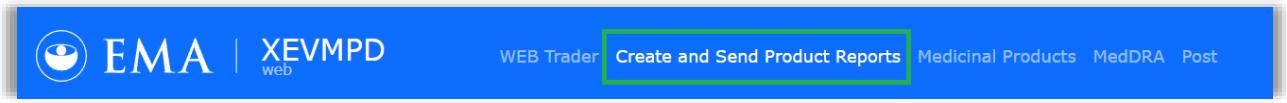
To create an XEVPRM through which an entity is **inserted** in the XEVMPD, users can do so by:

- going to the 'Create and Send Product Reports' section of XEVMPDweb, where they can select the required entity to be added in the tree-view area and **insert** the information for such entity, or by
- finding an entity, which is already present in the XEVMPD in the 'Medicinal Products' section and, using the operation type **'Reinsert'**, to re-load the entity in the 'Create and Send Product Reports' section, where they can further modify the existing information.

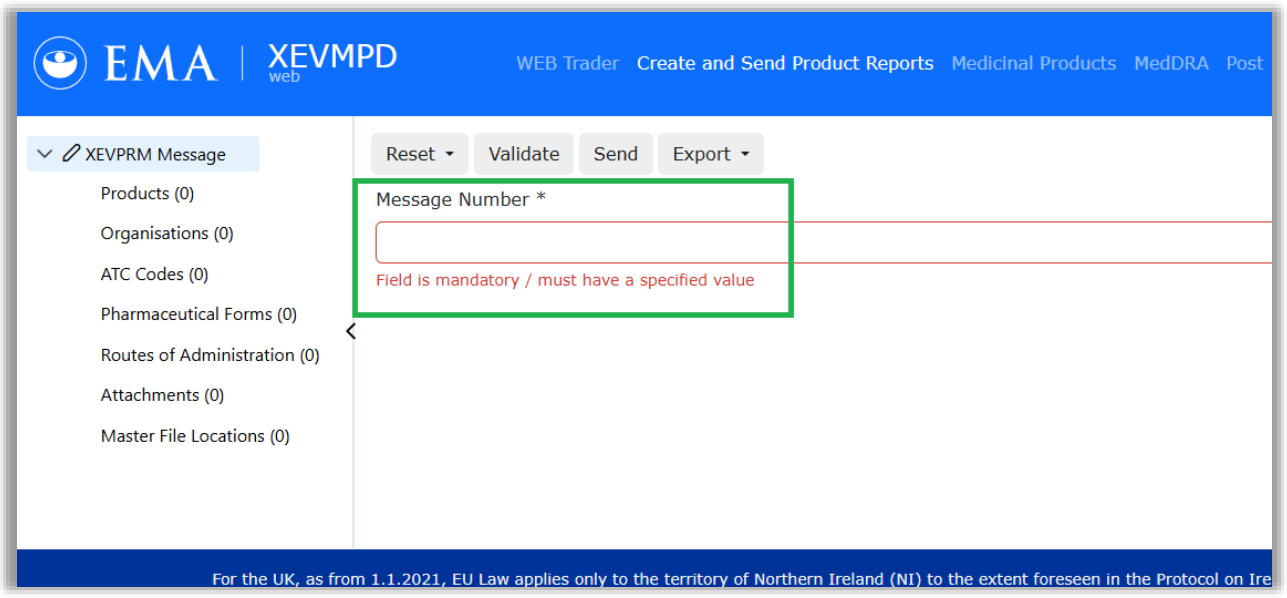
5.1.1. Insert of an AMP or DMP using operation type 'Insert'

To create an XEVPRM with an insert of an AMP or DMP:

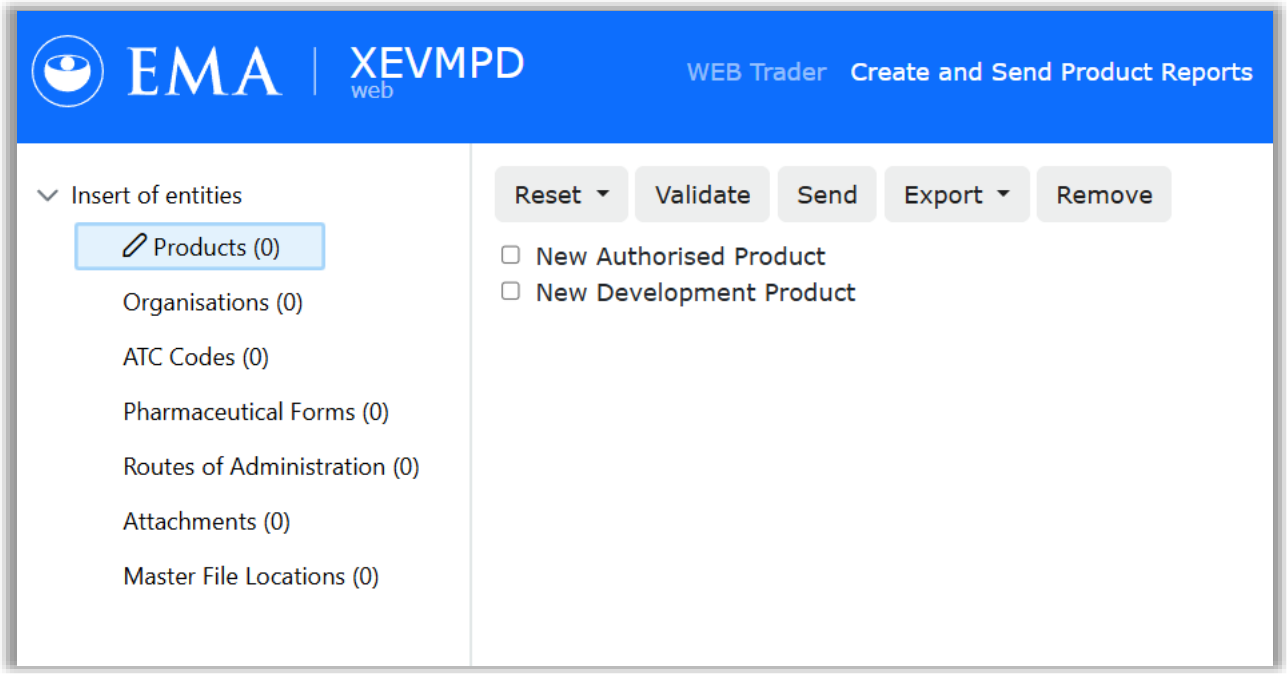
1. Go to the 'Create and Send Product Reports' section of XEVMPDweb:



2. In the 'Message Number' field, assign a number, or a name, to your XEVPRM:



3. In the tree-view area, click on 'Products'; the text will become highlighted in blue, and the active area will display the available options:



4. Click inside the box next to 'New Authorised Product' or 'New Development Product', as required, and:

    a. the tree-view area will display the sections applicable to an AMP/DMP entity;

    b. the active area will display fields to be completed for the AMP/DMP; the 'Operation Type' field displays 'Insert' as default and the 'Type' field displays 'Authorised' or 'Development', as applicable.

5. Complete the fields as required as per information in:

    a. Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance; section *1.1. Initial Submission of an Authorised Medicinal Product (AMP) or*

    b. Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD), *section 1. Initial submission of a development medicinal product.*

    c. If an entity that is required for the submission (such as MFL, MAH or sponsor organisation etc.) is not available in the XEVMPD and therefore cannot be found in the **remote look-up tables**, you should insert the entity in the same XEVPRM and use the **local look-up table**s to find it and reference it in the applicable field. See section *3.6.5. Local database look-up tables* for related information.

6. Validate the XEVPRM; if any errors are reported, review the sections/fields where the errors are present and correct them as required.

7. Send the XEVPRM via the 'Send' (WebTrader users) or 'Post' (Gateway users) functionality.

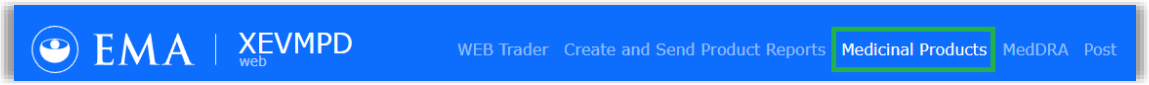
8. Retrieve the XEVPRM acknowledgement in you WebTrader Inbox (WebTrader users) or in your internal system (Gateway users).

    If the submission was successful, the XEVPRM Acknowledgement will reference the EV Code of the entity that was being inserted (i.e. an AMP or DMP) and the text: *"Entity inserted successfully…".*

5.1.2. Insert of an AMP or DMP using operation type 'Reinsert'

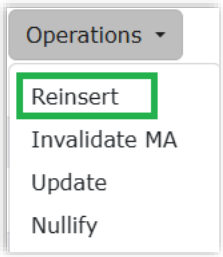
To use an AMP entity or a DMP entity already available in the XEVMPD (i.e. an EV Code is assigned) as a "template" for the creation of a new AMP/DMP entity, the 'Reinsert' operation should be used.

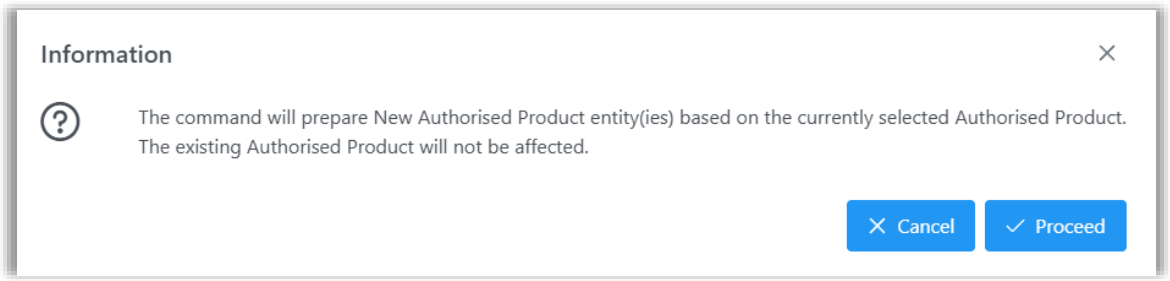
1. Go to the Medicinal Products' section of XEVMPDweb:

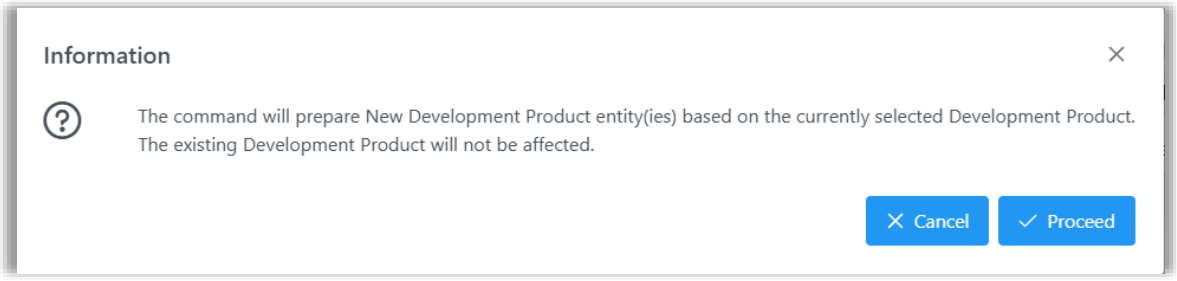


2. Using the simple query or advanced query search (see sections *3.7.1. Simple query* and *3.7.2. Advanced query* for details), find the AMP/DMP to be used as a "template" for your new product record.

3. Once retrieved, perform a 'Reinsert' operation type on this entity; the system will inform you that the entity will be loaded in the 'Create and Send Product Reports section' as a new AMP/DMP:







The AMP/DMP information will be loaded in the 'Create and 'Send Medicinal Product reports'; in the active area, the 'Operation Type' field displays 'Insert' as default and the 'Type' field displays 'Authorised' or 'Development', as applicable.

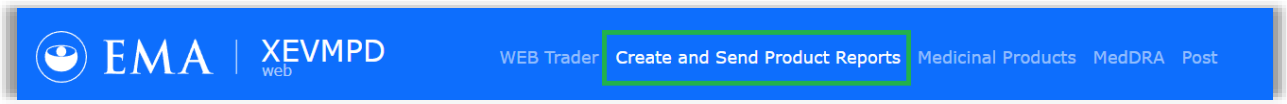
4. In the 'Message Number' field, assign a number, or a name, to your XEVPRM.
5. Review and amend the information in the individual fields/sections, as required for the new AMP or DMP entity.
    a. If an entity that is required for the submission (such as MFL, MAH or sponsor information etc.) is not available in the XEVMPD and therefore cannot be found in the remote look-up tables, you should insert the entity in the same XEVPRM and use the local look-up tables to find it and reference it in the applicable field. See section *3.6.5. Local database look-up tables* for related information.
6. Validate the XEVPRM; if any errors are reported, review the sections/fields where the errors are present and correct them as required.
7. Send the XEVPRM via the 'Send' (WebTrader users) or 'Post' (Gateway users) functionality.
8. Retrieve the XEVPRM acknowledgement in you WebTrader Inbox (WebTrader users) or in your internal system (Gateway users).

    If the submission was successful, the XEVPRM Acknowledgement will reference the EV Code of the entity that was being inserted (i.e. an AMP or DMP) and the text: "*Entity inserted successfully…".*

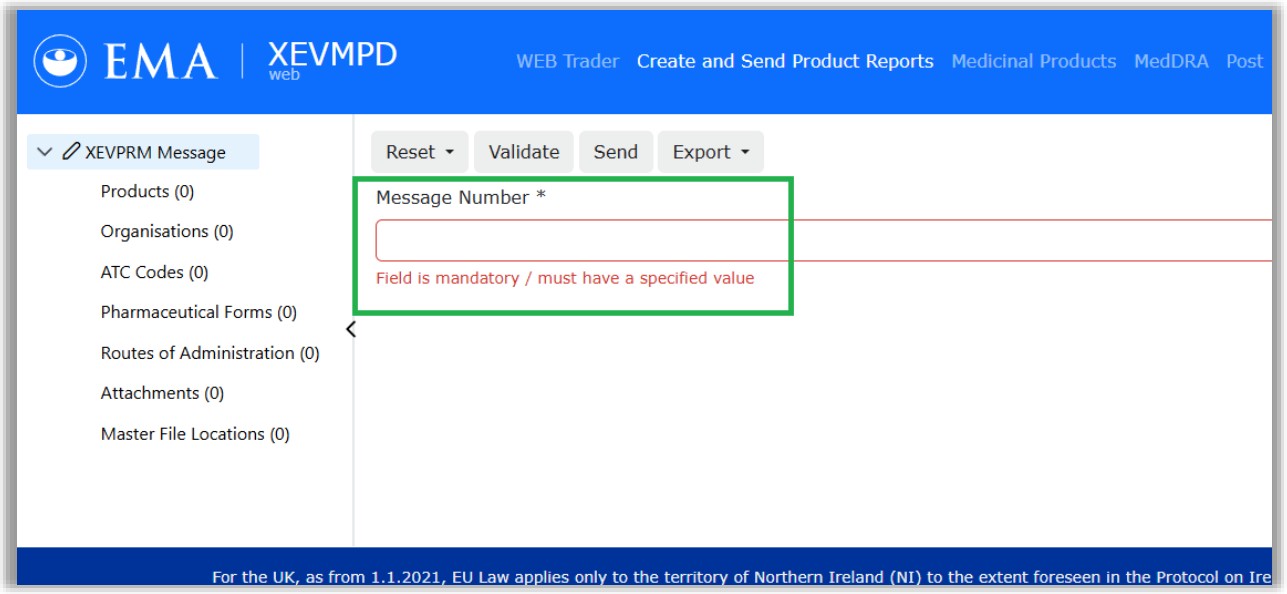
5.1.3. Insert of an MAH or sponsor organisation

To create an XEVPRM with an insert of an MAH:

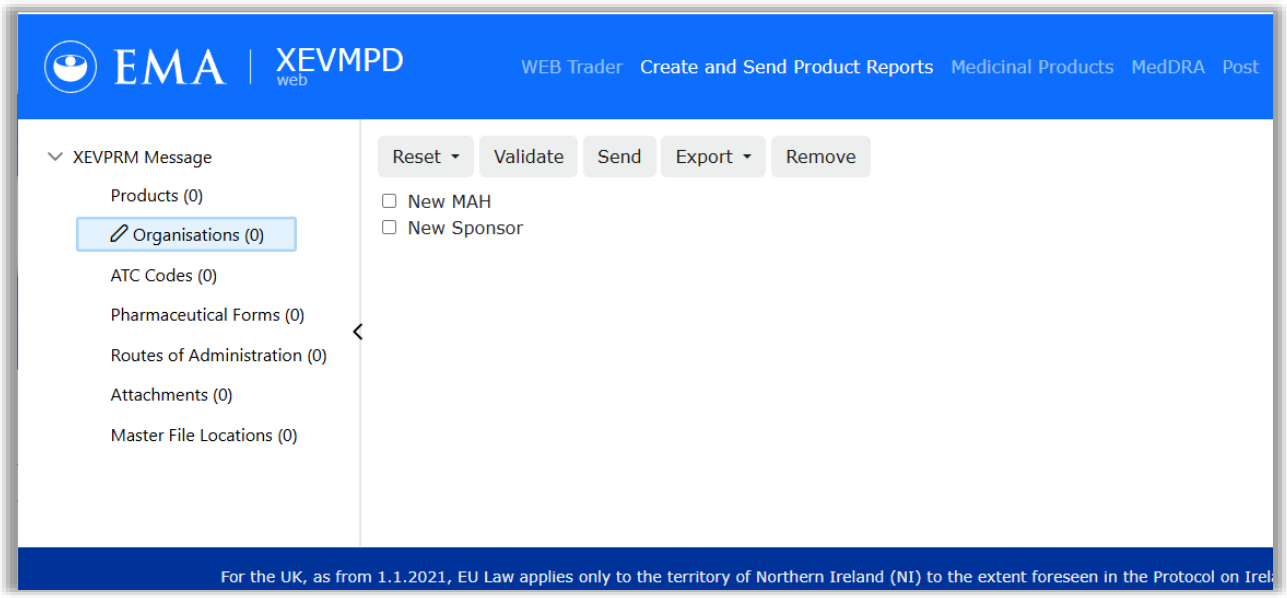
1. Go to the 'Create and Send Product Reports' section of XEVMPDweb:



2. In the 'Message Number' field, assign a number, or a name, to your XEVPRM:



3. In the tree-view area, click on 'Organisations'; the text will become highlighted in blue, and the active area will display the available options:



4. Click inside the box next to 'New MAH' or 'New Sponsor', as required and:

    a. the tree-view area will display the sections applicable to an MAH/sponsor entity;

    b. the active area will display fields that need to be completed for each of the sections; the 'Operation Type' field displays 'Insert' as default and the 'Type' field displays 'MAH' or 'Sponsor' as selected.

5. Complete the fields as required, as per information in:

    a. Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance; section *1.6. Initial submission of a marketing authorisation holder (MAH) organisation* or

    b. Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD), section *3. Initial submission of a sponsor information*.

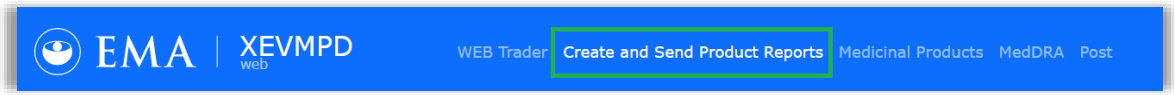
6. Validate the XEVPRM; if any errors are reported, review the sections/fields where the errors are present and correct them as required.
7. Send the XEVPRM via the 'Send' (WebTrader users) or 'Post' (Gateway users) functionality.
8. Retrieve the XEVPRM acknowledgement in you WebTrader Inbox (WebTrader users) or in your internal system (Gateway users).

    If the submission was successful, the XEVPRM Acknowledgement will reference the EV Code of the entity that was being inserted (i.e. an MAH or sponsor organisation) and the text: *"Entity inserted successfully…".*

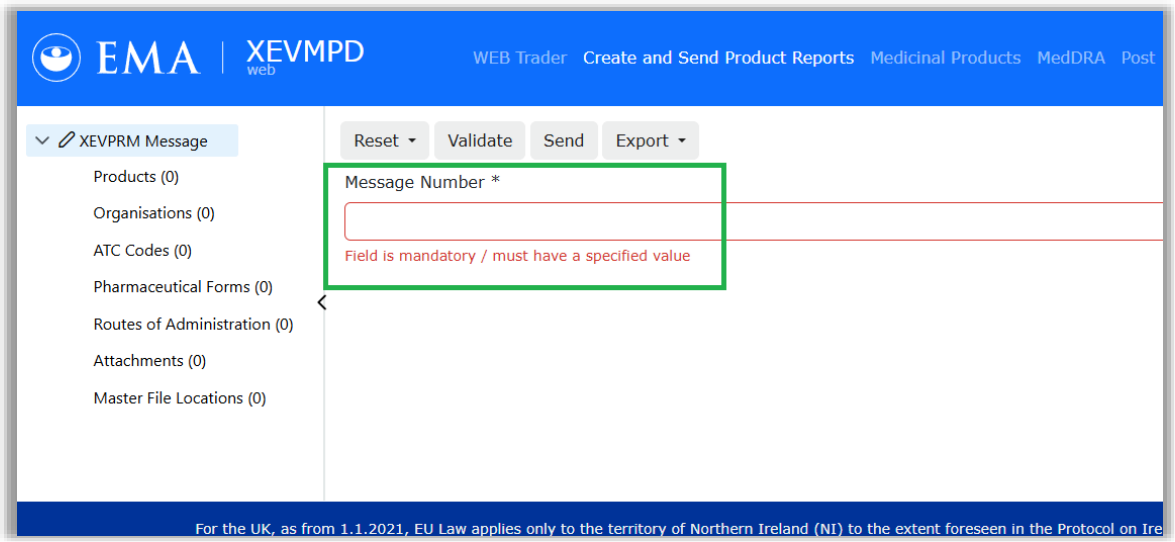
5.1.4. Insert of a development ATC Code

To create an XEVPRM with an insert of a development ATC Code:

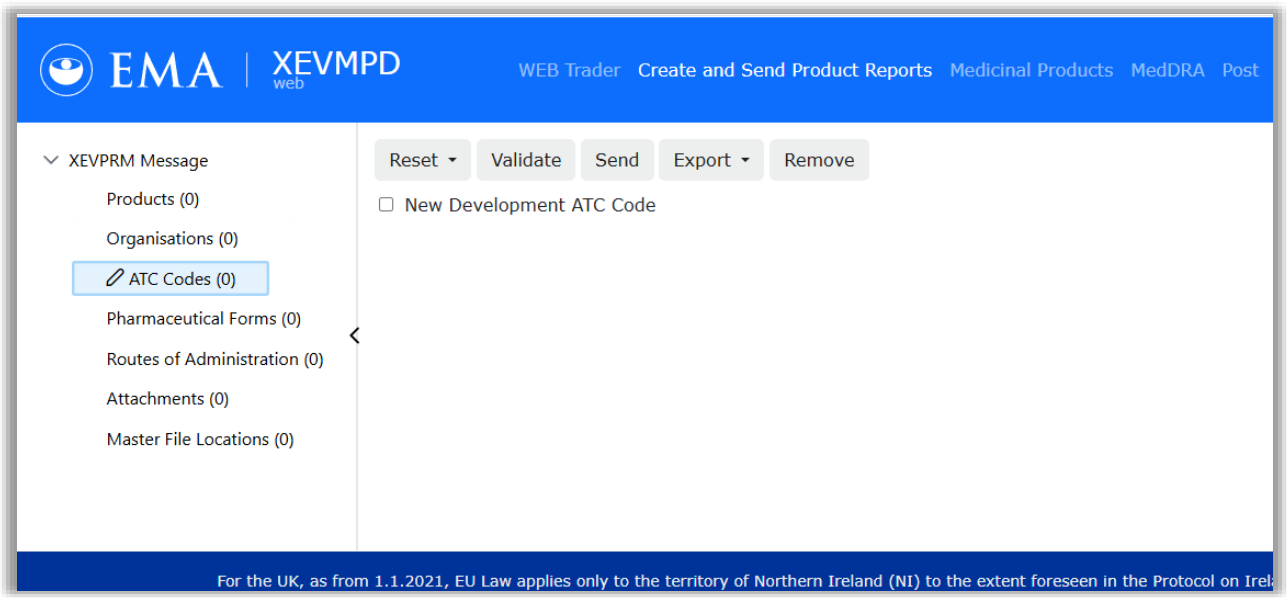
1. Go to the 'Create and Send Product Reports' section of XEVMPDweb:



2. In the 'Message Number' field, assign a number or a name to your XEVPRM:



3. In the tree-view area, click on 'ATC Codes'; the text will become highlighted in blue, and the active area will display the available option:



4. Click inside the box next to 'New Development ATC Code' and:

    a. the tree-view area will display the sections applicable to an ATC Code entity;

    b. the active area will display fields that need to be completed for each of the sections; the 'Operation Type' field displays 'Insert' as default and the 'Type' field displays 'Development' as default.

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

6. Validate the XEVPRM; if any errors are reported, review the sections/fields where the errors are present and correct them as required.

7. Send the XEVPRM via the 'Send' (WebTrader users) or 'Post' (Gateway users) functionality.

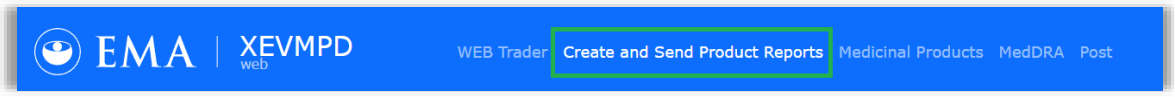
8. Retrieve the XEVPRM acknowledgement in you WebTrader Inbox (WebTrader users) or in your internal system (Gateway users).

    If the submission was successful, the XEVPRM Acknowledgement will reference the EV Code of the entity that was being inserted (i.e. an ATC Code) and the text: *"Entity inserted successfully…"*..

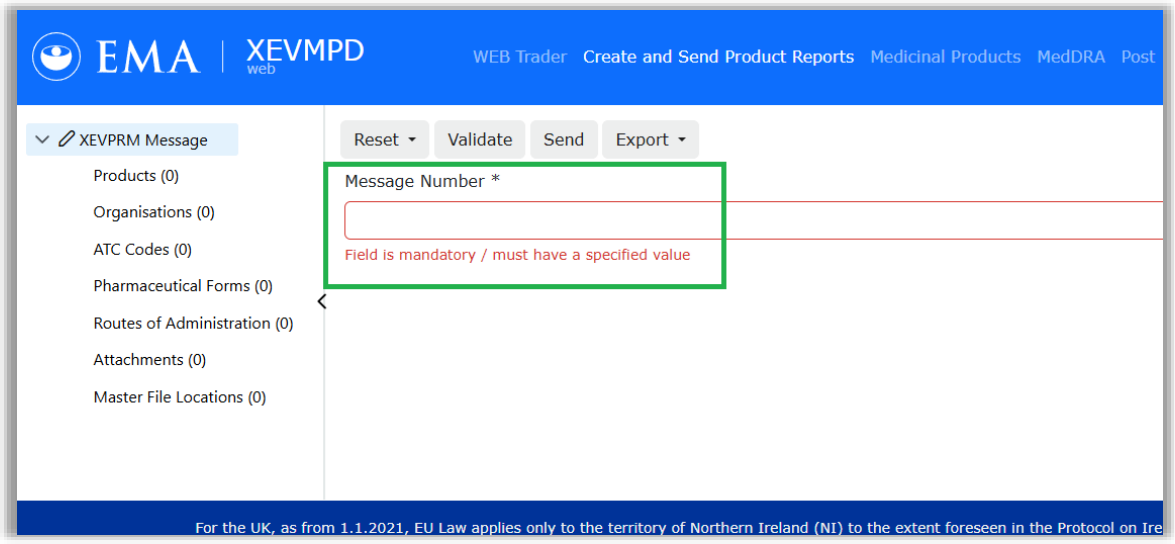
5.1.5. Insert of a development pharmaceutical form

To create an XEVPRM with an insert of a development pharmaceutical form:

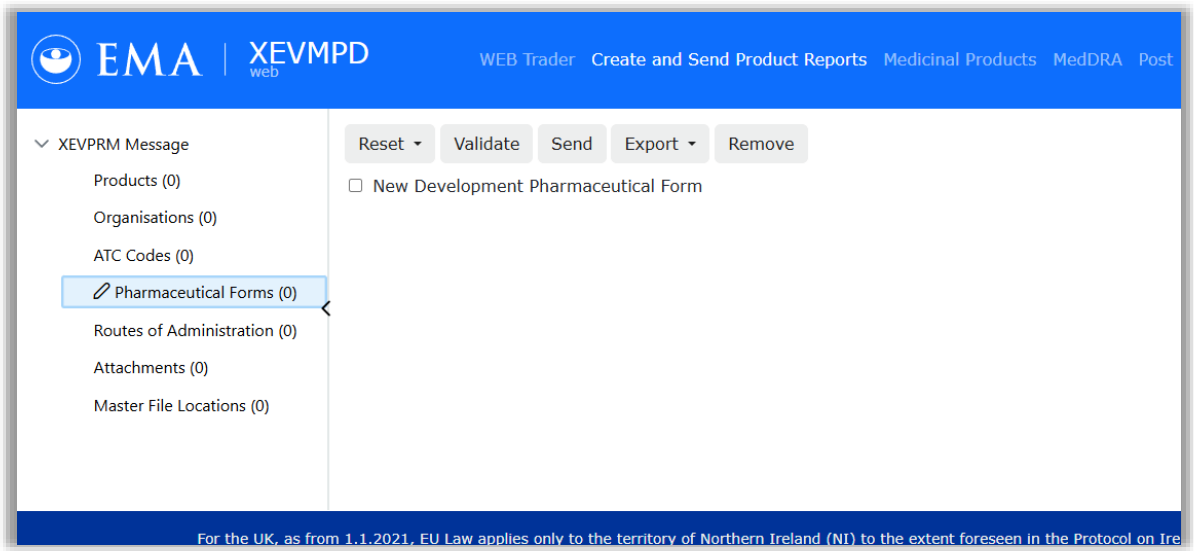
1. Go to the 'Create and Send Product Reports' section of XEVMPDweb:



2. In the 'Message Number' field, assign a number, or a name, to your XEVPRM:



3. In the tree-view area, click on 'Pharmaceutical Forms'; the text will become highlighted in blue, and the active area will display the available options:



4. Click inside the box next to 'New Development Pharmaceutical Form' and:
    a. the tree-view area will display the sections applicable to a pharmaceutical form entity;
    b. the active area will display fields that need to be completed for each of the sections; the 'Operation Type' field displays 'Insert' as default and the 'Type' field displays 'Development' as default.
5. Complete the fields as required, as per information in the 'Guidance on the electronic submission of 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.*
6. Validate the XEVPRM; if any errors are reported, review the sections/fields where the errors are present and correct them as required.
7. Send the XEVPRM via the 'Send' (WebTrader users) or 'Post' (Gateway users) functionality.

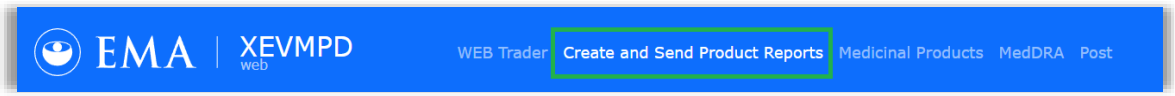
8. Retrieve the XEVPRM acknowledgement in you WebTrader Inbox (WebTrader users) or in your internal system (Gateway users).

   If the submission was successful, the XEVPRM Acknowledgement will reference the EV Code of the entity that was being inserted (i.e. a development pharmaceutical form) and the text: *"Entity inserted successfully…"*.

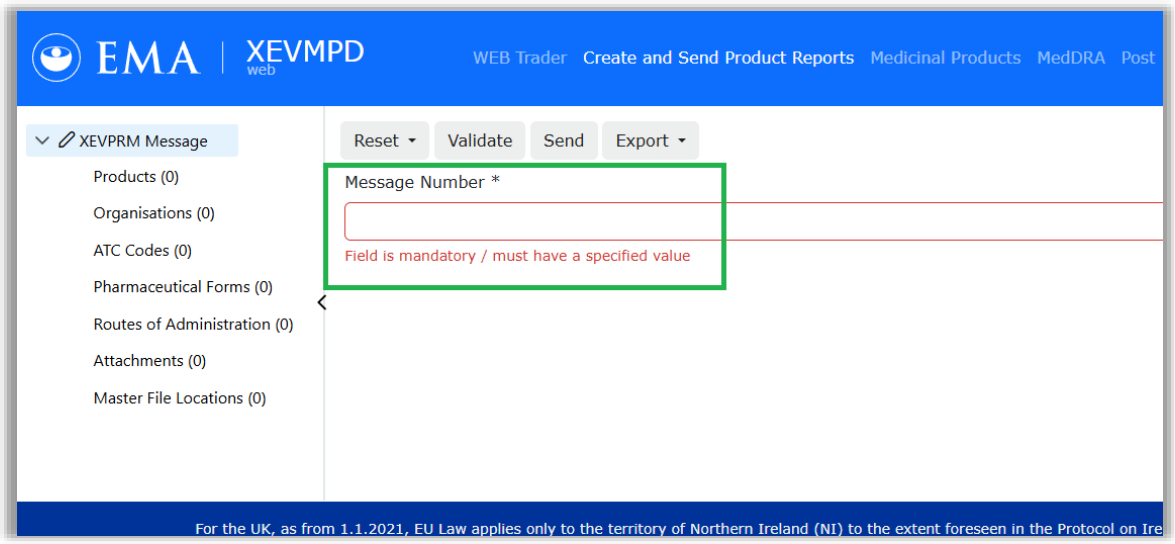
5.1.6. Insert of a development route of administration

To create an XEVPRM with an insert of a DMP:

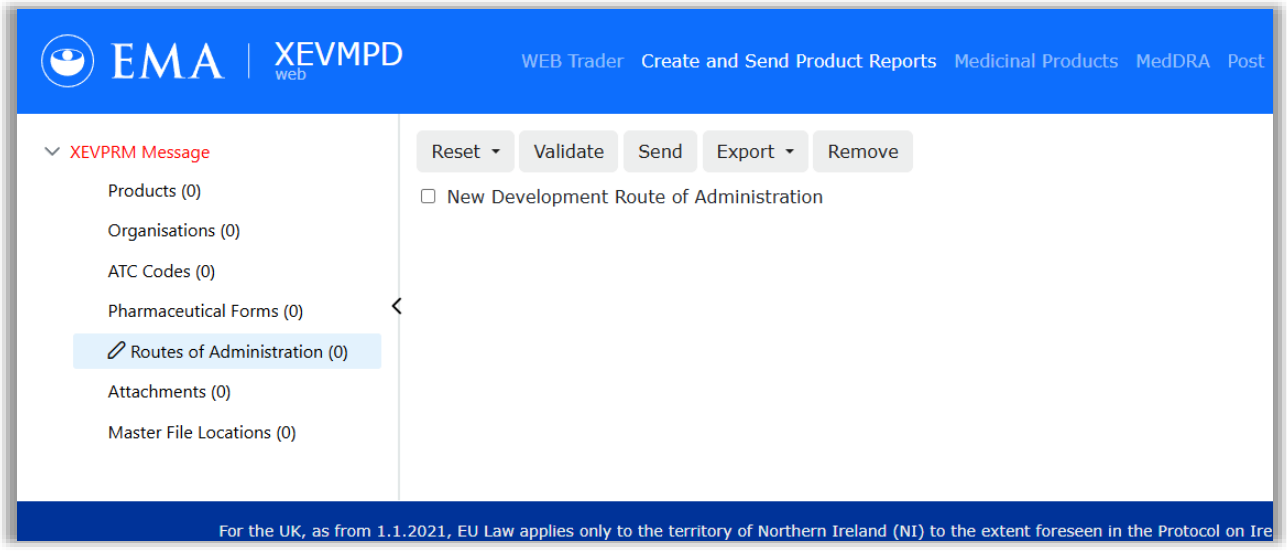
1. Go to the 'Create and Send Product Reports' section of XEVMPDweb:



2. In the 'Message Number' field, assign a number or a name to your XEVPRM:



3. In the tree-view area, click on 'Routes of Administration'; the text will become highlighted in blue, and the active area will display the available option:



4. Click inside the box next to 'New Development Route of Administration' and:

    a. the tree-view area will display the sections applicable to a route of administration entity;

    b. the active area will display fields that need to be completed for each of the sections; the 'Operation Type' field displays 'Insert' as default and the 'Type' field displays 'Development' as default.

5. Complete the fields as required, as per information in the 'Guidance on the electronic submission of 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.*

6. Validate the XEVPRM; if any errors are reported, review the sections/fields where the errors are present and correct them as required.

7. Send the XEVPRM via the 'Send' (WebTrader users) or 'Post' (Gateway users) functionality.

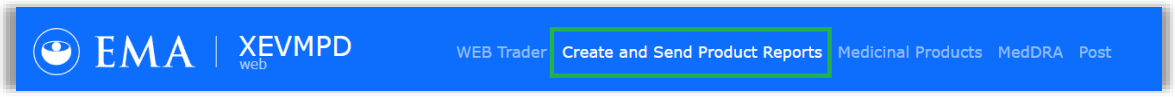
8. Retrieve the XEVPRM acknowledgement in you WebTrader Inbox (WebTrader users) or in your internal system (Gateway users).

    If the submission was successful, the XEVPRM Acknowledgement will reference the EV Code of the entity that was being inserted (i.e. a development route of administration) and the text: *"Entity inserted successfully…".*

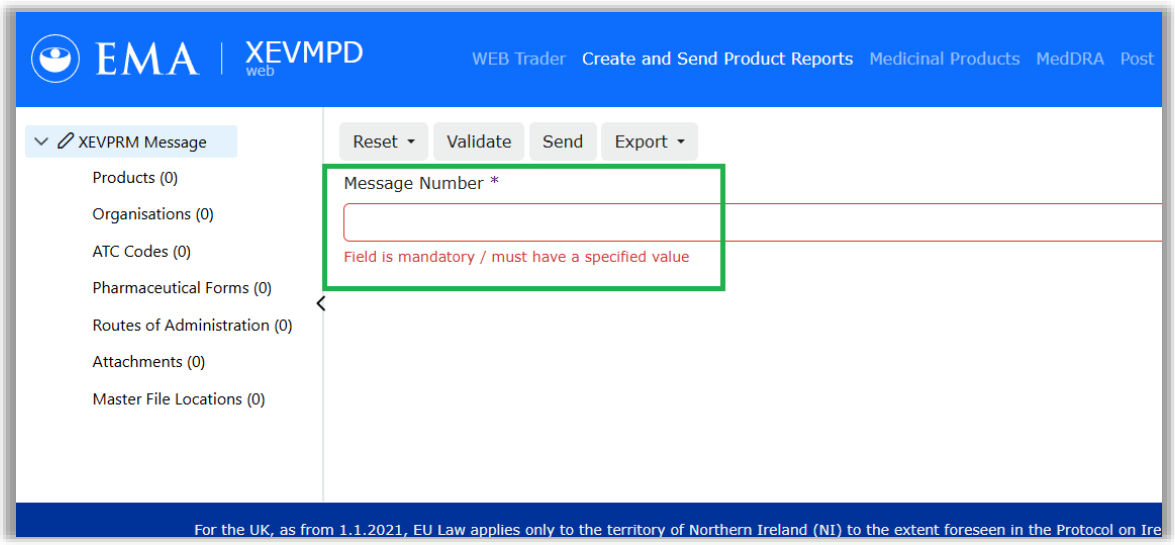
5.1.7. Insert of a product related attachment

To create an XEVPRM with an insert of a product related attachment (PPI):

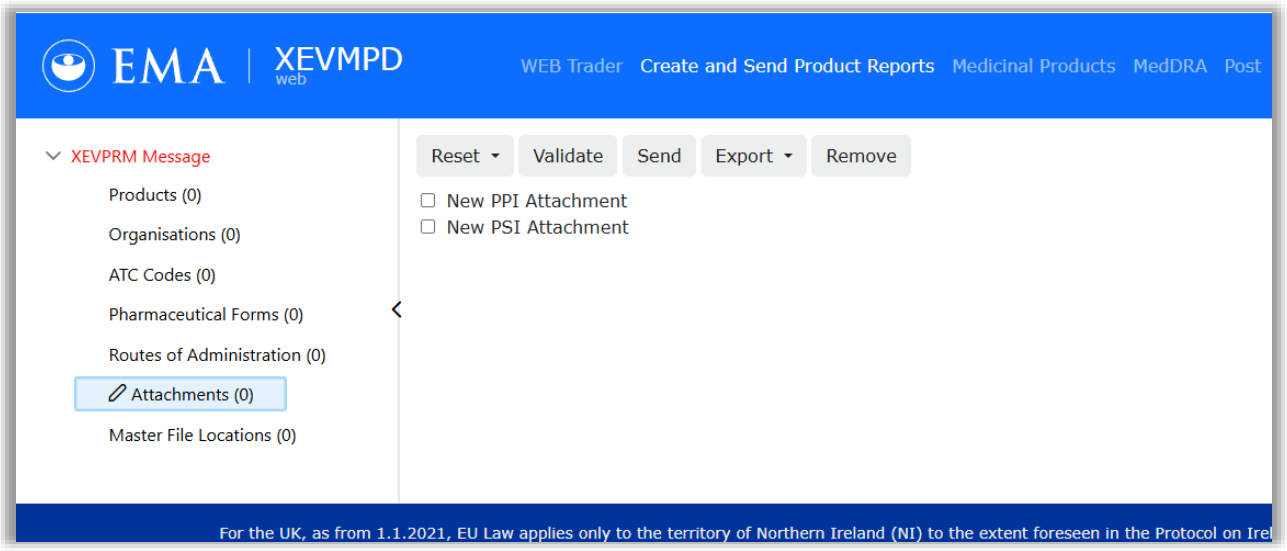
1. Go to the 'Create and Send Product Reports' section of XEVMPDweb:



2. In the 'Message Number' field, assign a number, or a name, to your XEVPRM:



3. In the tree-view area, click on 'Attachments'; the text will become highlighted in blue, and the active area will display the available options:

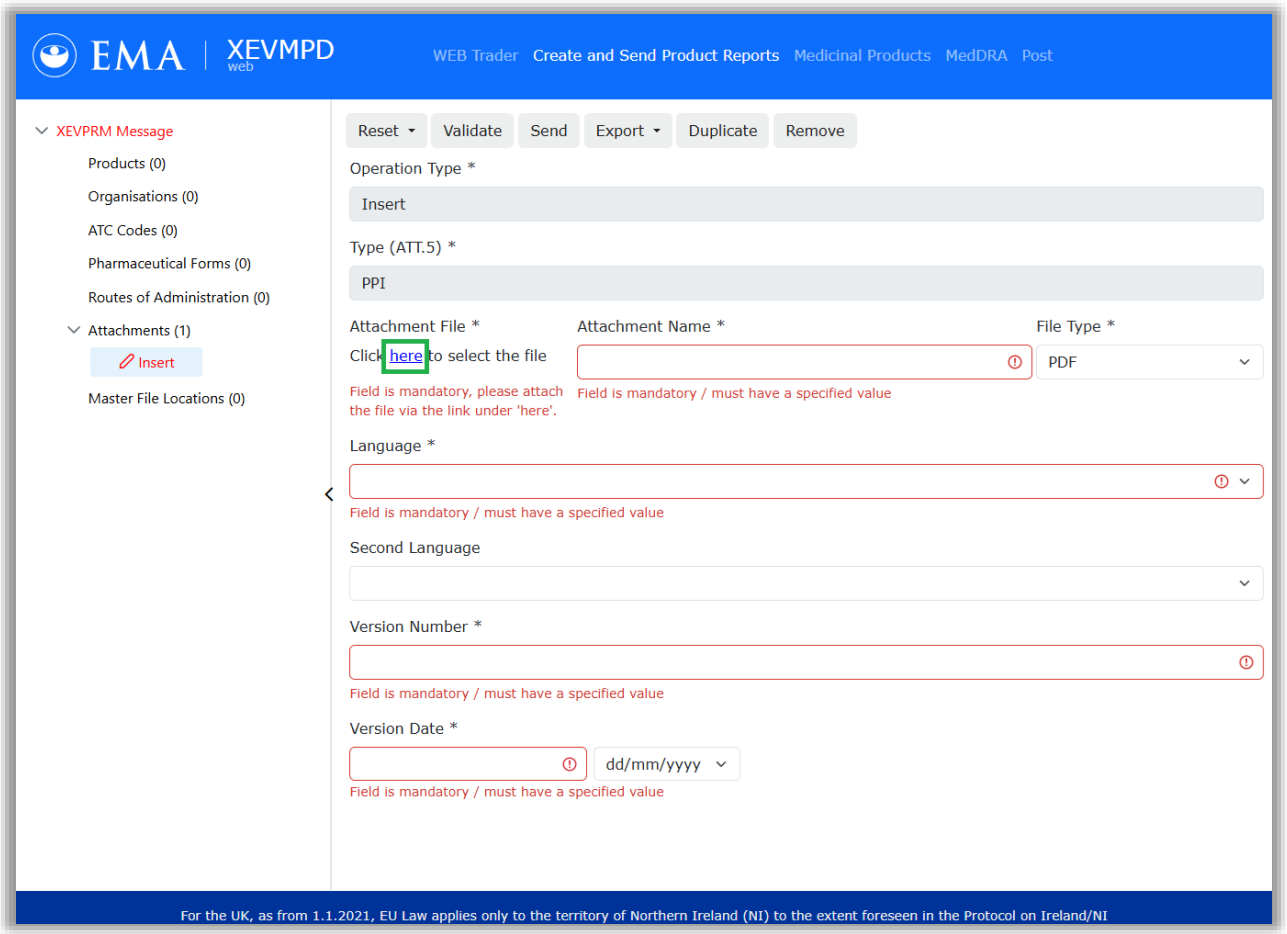


4. Click inside the box next to New **PPI** Attachment' and:

    a. the tree-view area will display the sections applicable to a PPI attachment entity;

    b. the active area will display fields that need to be completed for each of the sections; the 'Operation Type' field displays 'Insert' as default, the 'Type' field displays 'PPI' as default, the 'File Type' displays 'PDF' as default.

5. Add the attachment file by clicking on the 'here' text in the active area:



The 'Attachment Name' field and the 'File Type' field will automatically reference the name of the file and the format of the file that was selected.

6. Complete the remaining fields as required, as per information in:

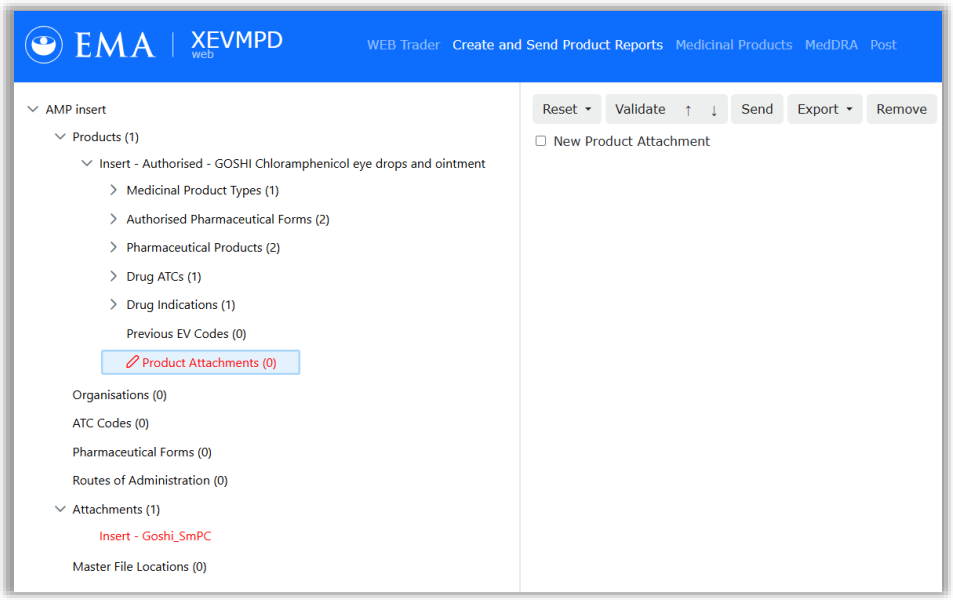
    a. Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance; section *1.10. Submission of an attachment* or

    b. 'Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD) document, section *7. Initial submission of an attachment.*

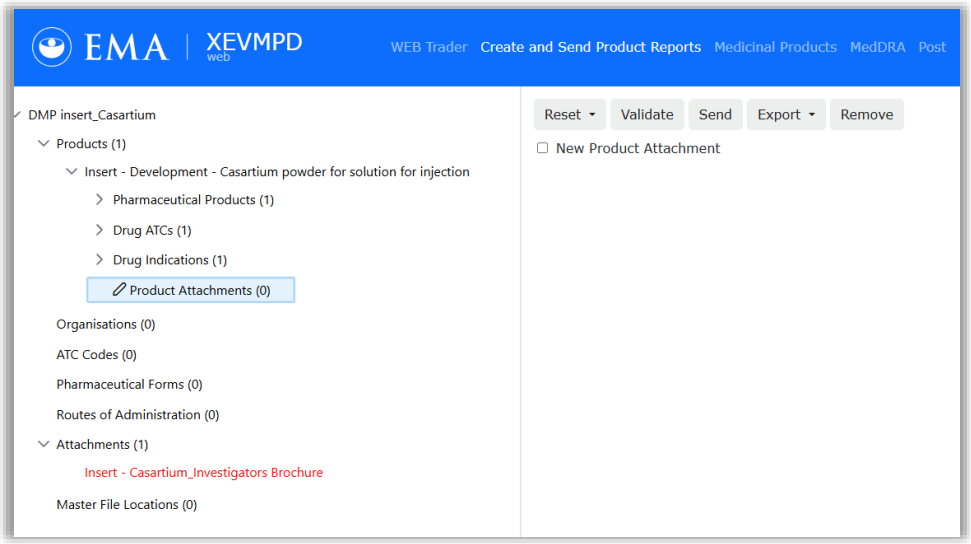
7. Reference the attachment in the relevant AMP or DMP entity:

    a. Go to your AMP or DMP and click on 'Product Attachments' within the AMP/DMP in the tree-view area; 'New Product Attachment' will be displayed in the active area:

    AMP:



    DMP:

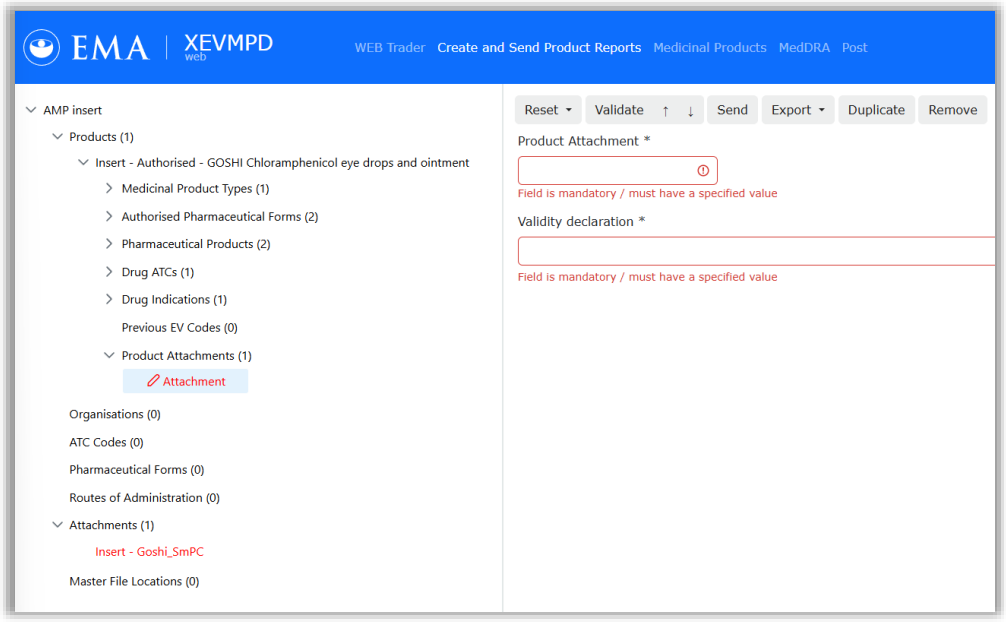


b. Click inside the box next to 'New Product Attachment' and:

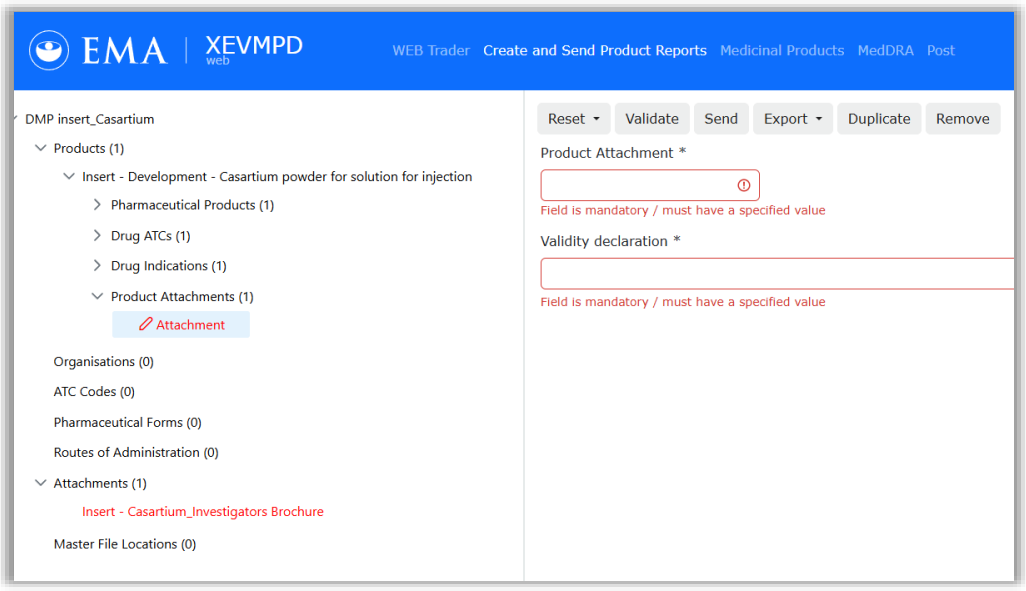
- the tree-view area will display 'Attachment' under the 'Product Attachments' section

- the active area will display a 'Product Attachment' and 'Validity Declaration' fields:

AMP:

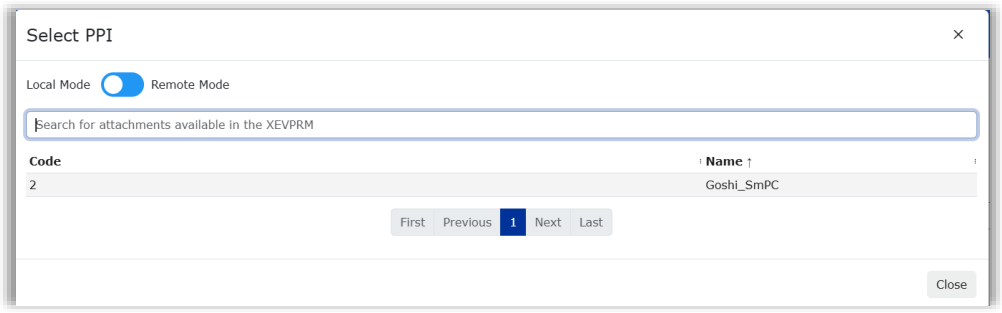


DMP:

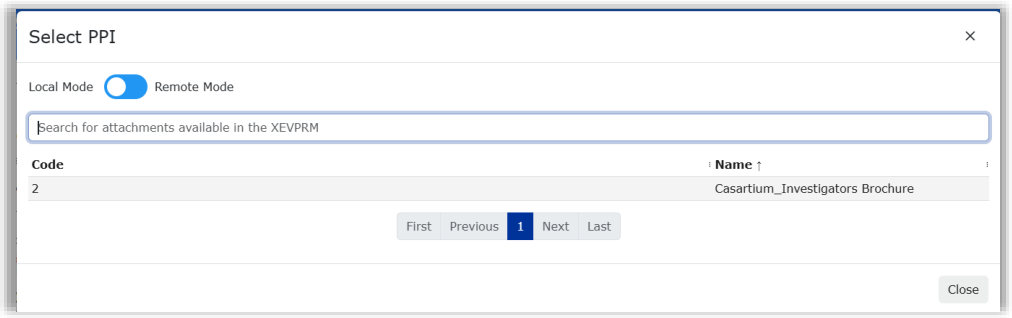


c. Click inside the 'Product Attachment' field and select the **'Local Mode'** option; the attachment(s) inserted in the same XEVPRM, with the local code assigned by the system, will be displayed:

AMP:

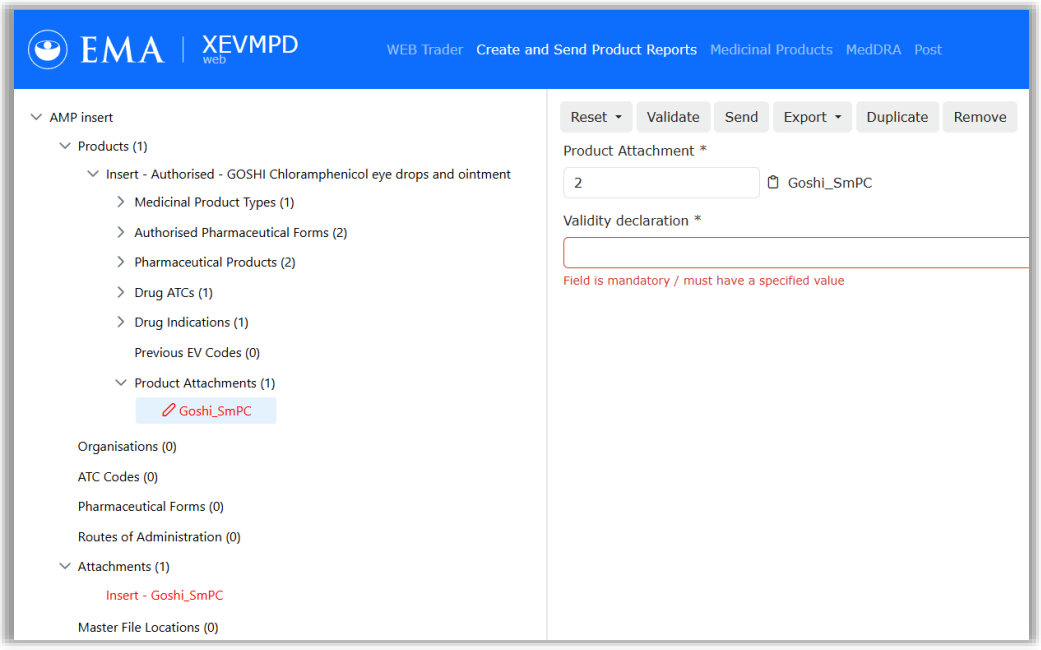


DMP:

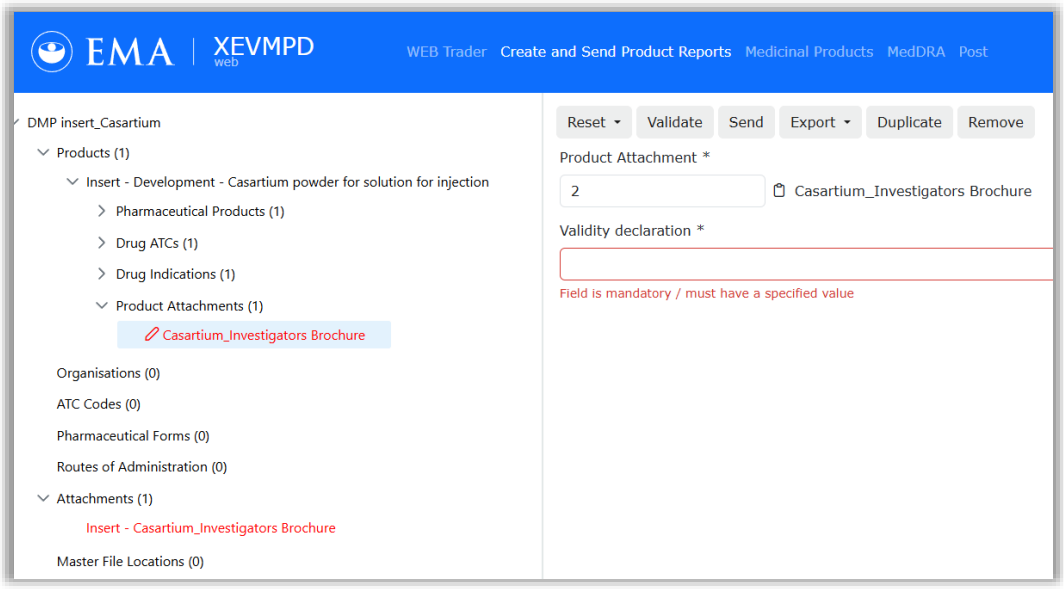


d. In the displayed result, click on the attachment you wish to reference; the local code, will be referenced in the 'Product Attachment' field:

AMP:



DMP:



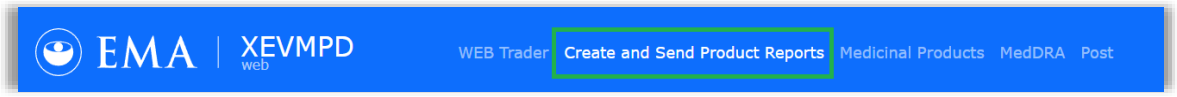
e. In the 'Validity declaration' field select 'Valid'.

8. Validate the XEVPRM; if any errors are reported, review the sections/fields where the errors are present and correct them as required.
9. Send the XEVPRM via the 'Send' (WebTrader users) or 'Post' (Gateway users) functionality.
10. Retrieve the XEVPRM acknowledgement in your WebTrader Inbox (WebTrader users) or in your internal system (Gateway users).

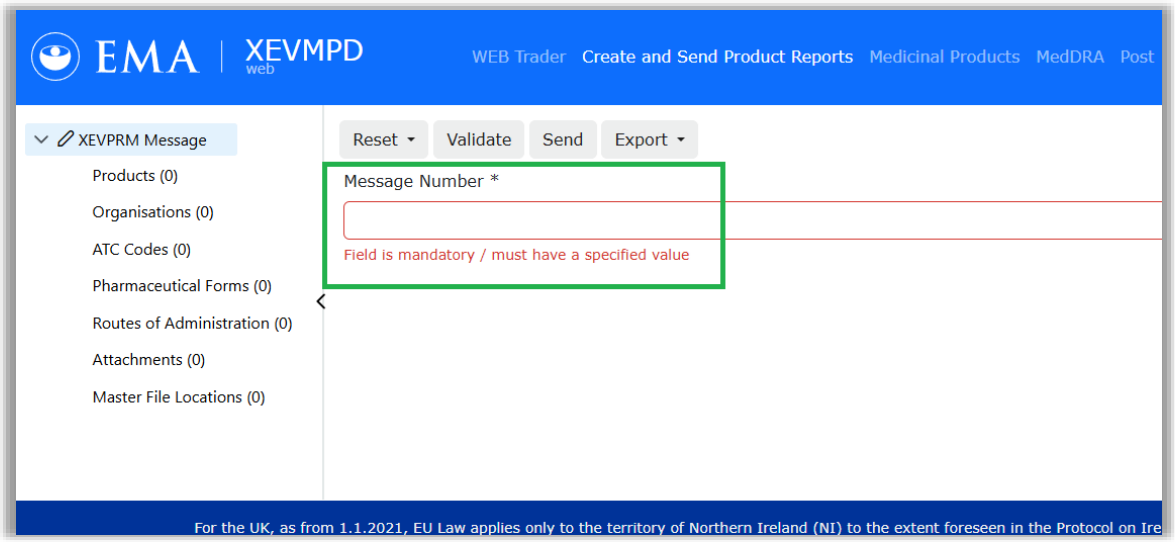
    If the submission was successful, the XEVPRM Acknowledgement will reference the EV Code of the entity that was being inserted (i.e. an attachment) and the text: *"Entity inserted successfully"*, together with any other EV Codes of any other entities that were being inserted or maintained via the same XEVPRM.

5.1.8. Insert of a Master File Location

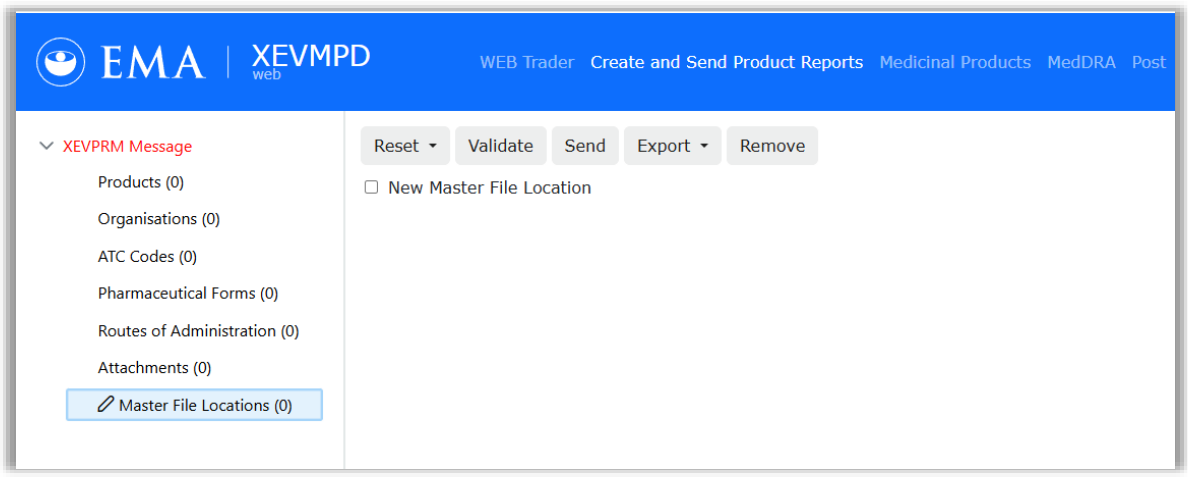
1. Go to the 'Create and Send Product Reports' section of XEVMPDweb:



2. In the 'Message Number' field, assign a number, or a name, to your XEVPRM:



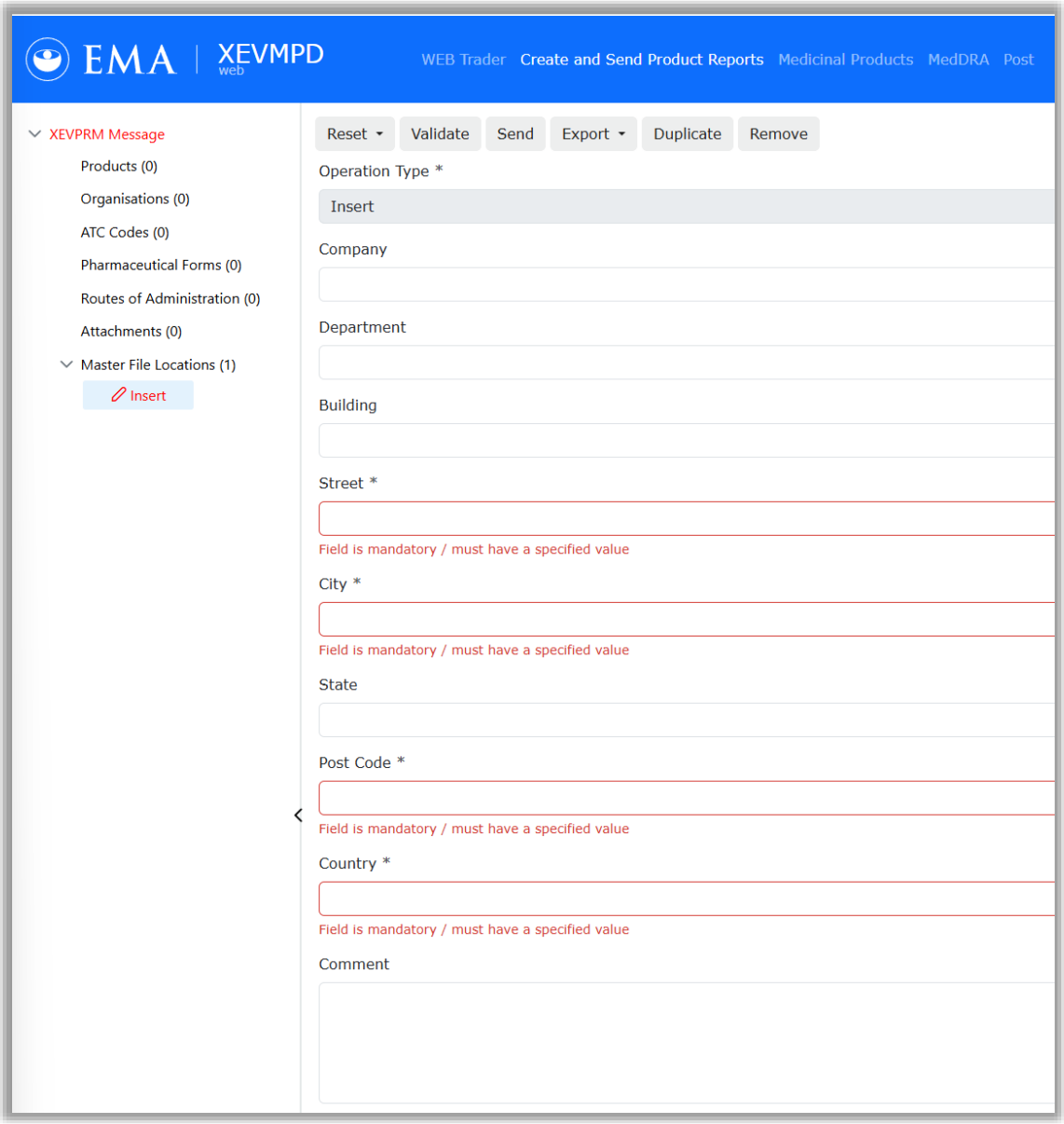
3. In the tree-view area, click on 'Master File Locations'; the text will become highlighted in blue, and the active area will display the available option:



4. Click inside the box next to New Master File Location' and:

   - the tree-view area will display the sections applicable to a MFL entity;

   - the active area will display fields that need to be completed for each of the sections; the 'Operation Type' field displays 'Insert' as default:



5. Complete the fields as required, as per information in the '[Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance]; section *1.11. Initial submission of a Pharmacovigilance System Master File (PSMF) information*.

6. Validate the XEVPRM; if any errors are reported, review the sections/fields where the errors are present and correct them as required.

7. Send the XEVPRM via the 'Send' (WebTrader users) or 'Post' (Gateway users) functionality.

8. Retrieve the XEVPRM acknowledgement in you WebTrader Inbox (WebTrader users) or in your internal system (Gateway users).

   If the submission was successful, the XEVPRM Acknowledgement will reference the EV Code of the entity that was being inserted (i.e. a MFL) and the text: *"Entity inserted successfully…"*.

5.2. Creation of an XEVPRM with operation type 'Update (2)'

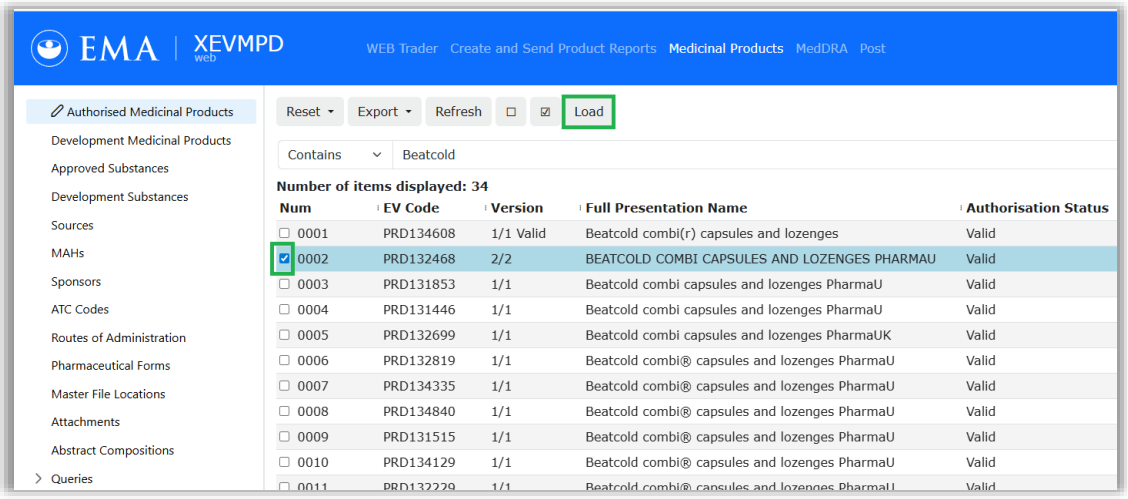
To update an entity in the XEVMPD:

- the entity must be present in the XEVMPD (i.e., an EV Code is assigned);
- the entity must be owned in the XEVMPD by the user's HQ organisation and the entity;
- the entity must not be nullified;
- the entity must not be an invalidated entity (in case of an AMP).

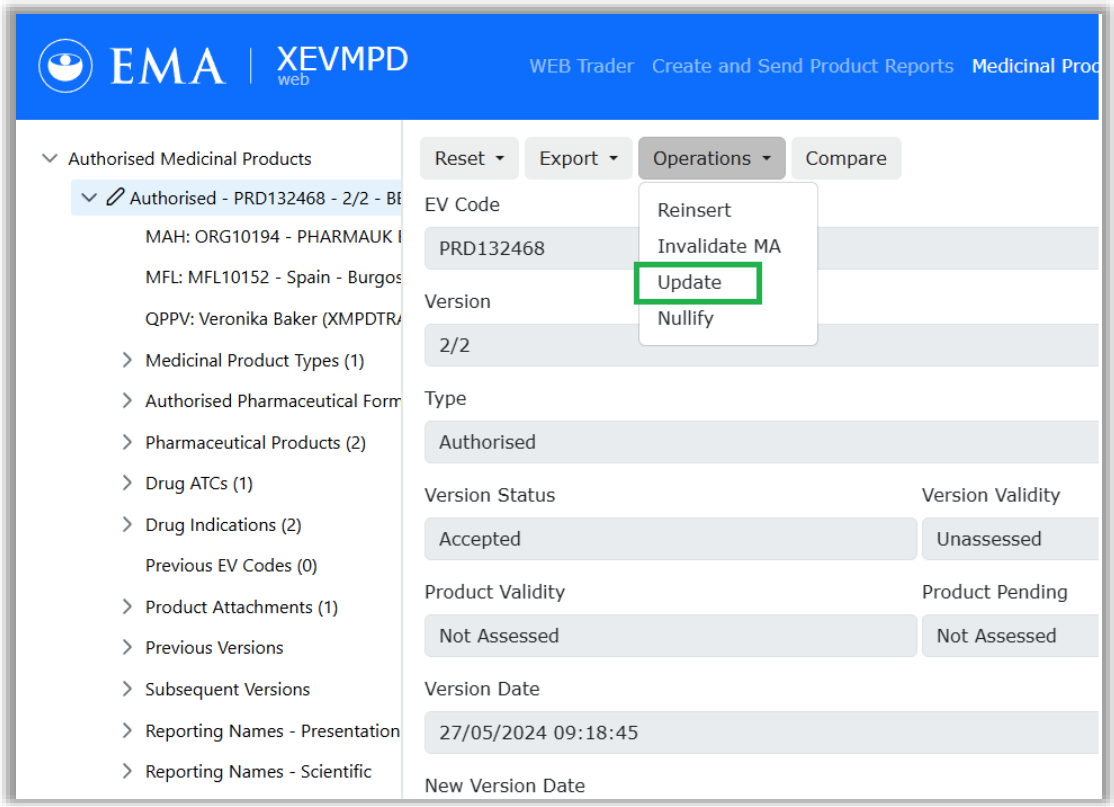
The below instructions describe the update of an AMP, but the process is the same for any other entity (except for an attachment, which cannot be updated) owned in the XEVMPD by the user's HQ organisation.

1. Retrieve the entity to be updated in the XEVMPD using either a simple query or an advanced query in XEVMPDweb:

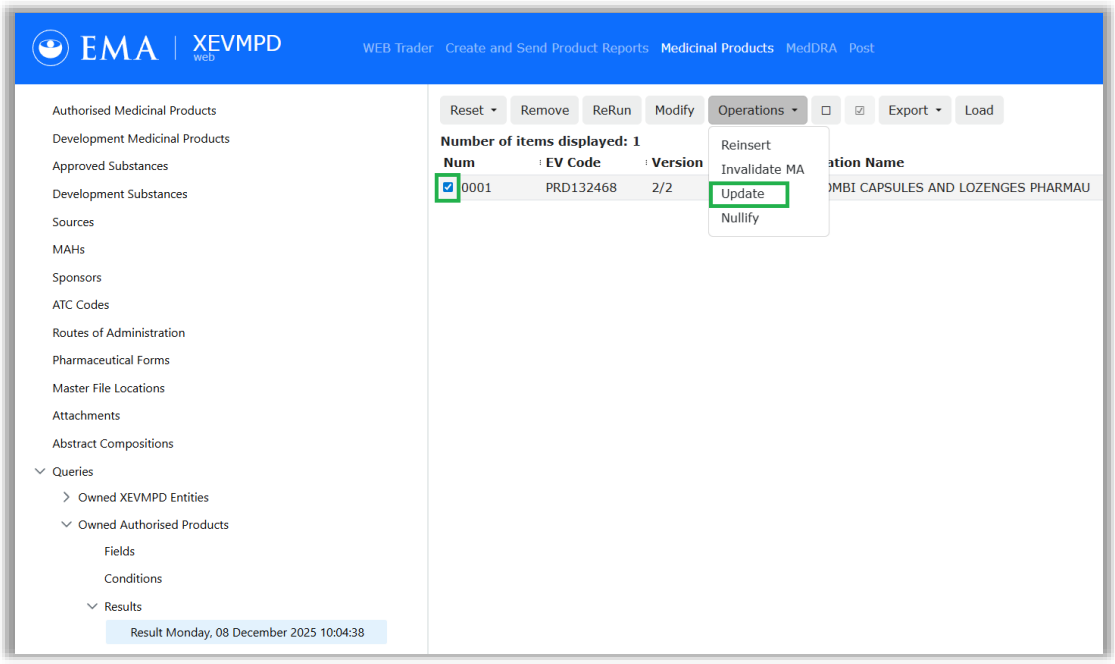
   - If retrieving the AMP via the **simple query**, load the AMP in the tree-view area using the check box and 'Load' functionality:



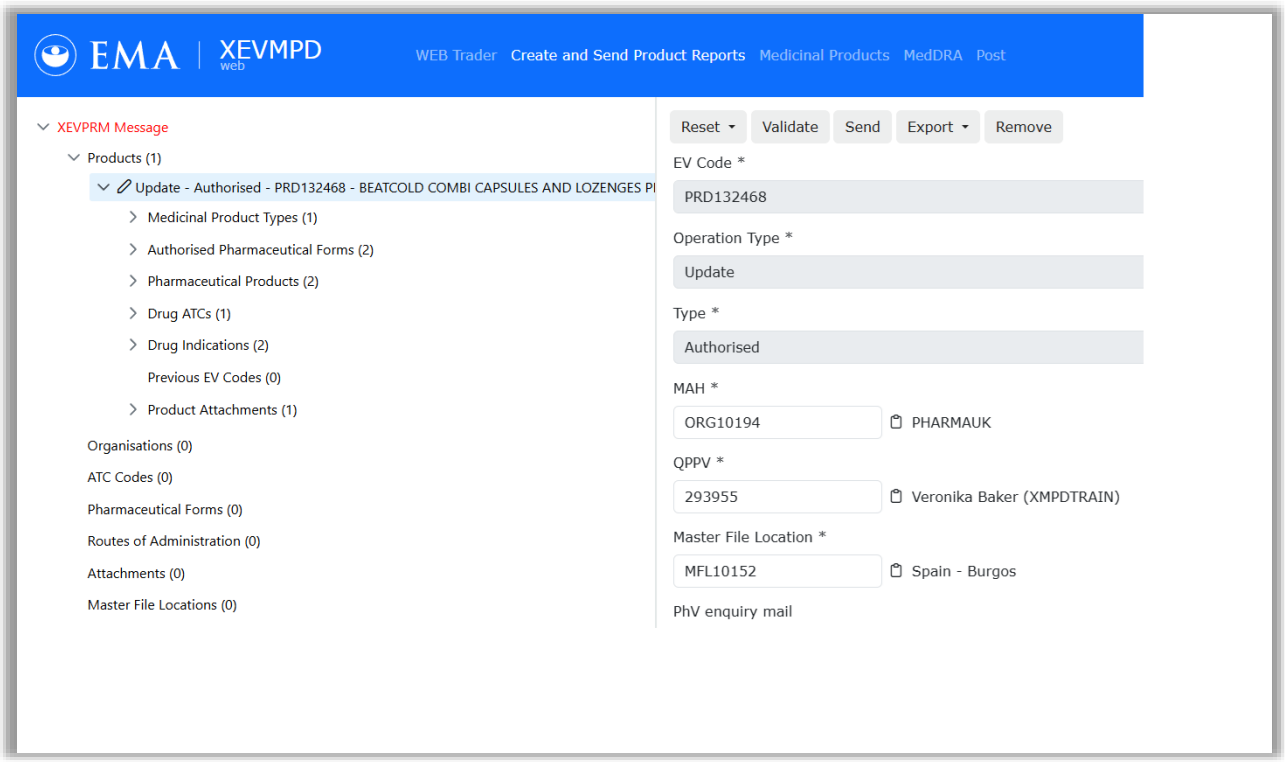
   Once loaded in the tree-view area, go to 'Operations' and select 'Update':



- If retrieving the AMP via the **advanced query**, select the entity in the active area, then go to 'Operations' and select 'Update':



The entity will be loaded in the 'Create and Send Product Reports' section:



2. Modify the information as required.
3. In the 'Message Number' field, assign a number, or a name, to your XEVPRM.
4. Validate the XEVPRM; if any errors are reported, review the sections/fields where the errors are present and correct them as required.
5. Send the XEVPRM via the 'Send' (WebTrader users) or 'Post' (Gateway users) functionality.
6. Retrieve the XEVPRM acknowledgement in you WebTrader Inbox (WebTrader users) or in your internal system (Gateway users).

   If the submission was successful, the XEVPRM Acknowledgement will reference the EV Code of the entity that was being updated and the text: *"Entity updated successfully…".*

5.3. Creation of an XEVPRM with operation type 'Nullification (4)'

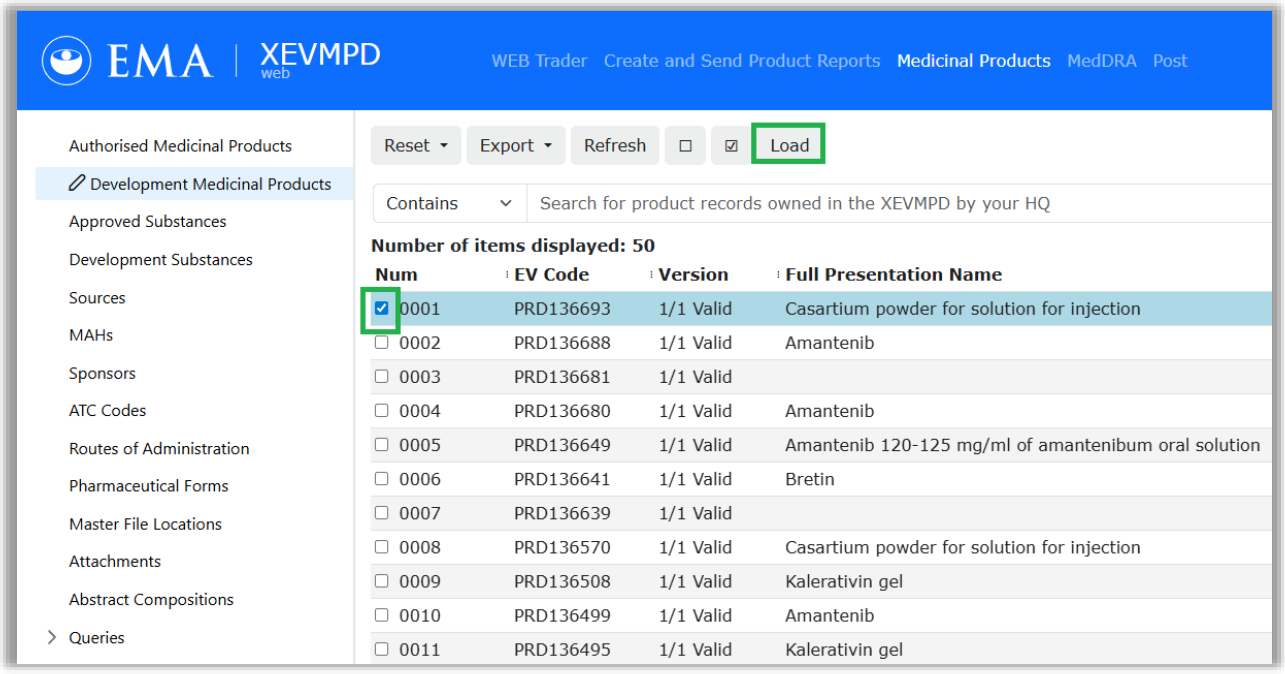
To nullify an entity in the XEVMPD:

- the entity must be present in the XEVMPD (i.e., an EV Code is assigned);
- the entity must be owned in the XEVMPD by the user's HQ organisation and the entity;
- the entity must not already be nullified;
- the entity must not be an invalidated entity (in case of an AMP);
- the entity must not be flagged as validated by the EMA[3] (i.e. the 'Product Validity' field must not reference 'Valid');
- the entity must not be referenced in other entities (such as AMPs or DMPs).

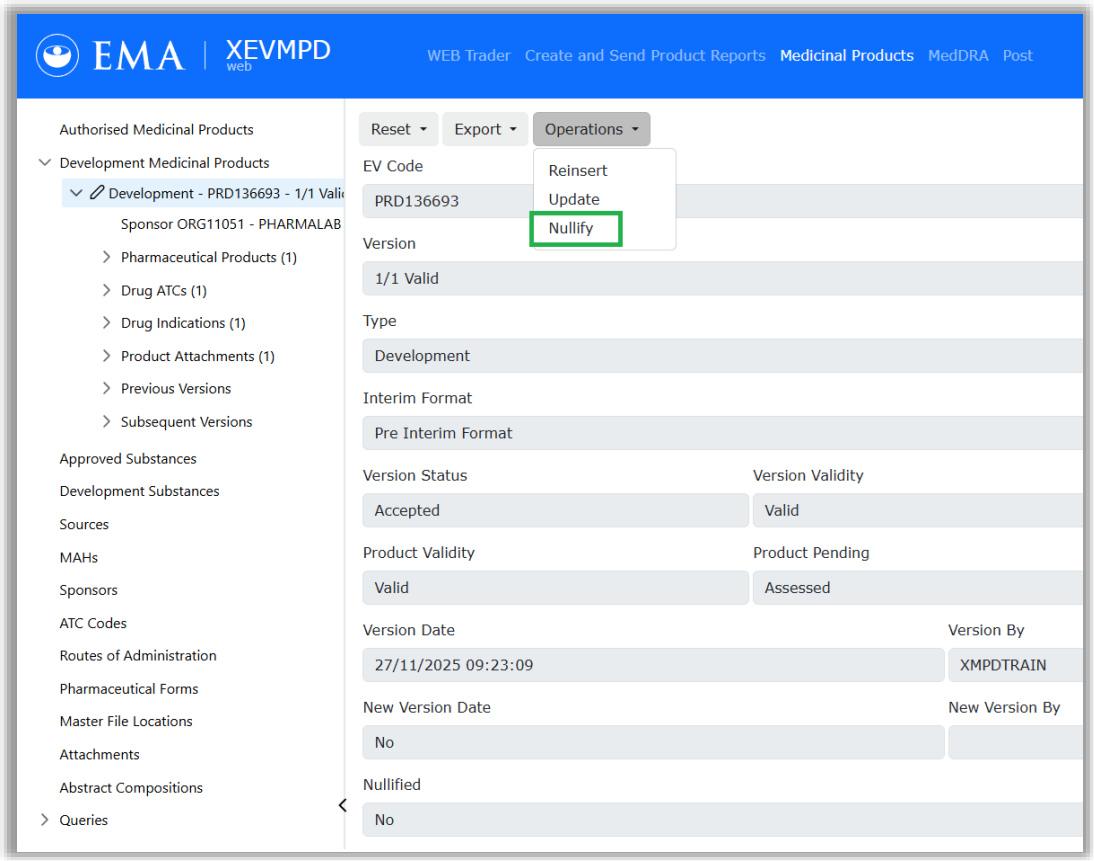
The below instructions describe the nullification of a DMP, but the process is the same for any other XEVMPD entity (except for attachments) owned in the XEVMPD by the user's HQ organisation.

1. Retrieve the entity to be nullified in the XEVMPD either using a simple or an advanced query in XEVMPDweb:

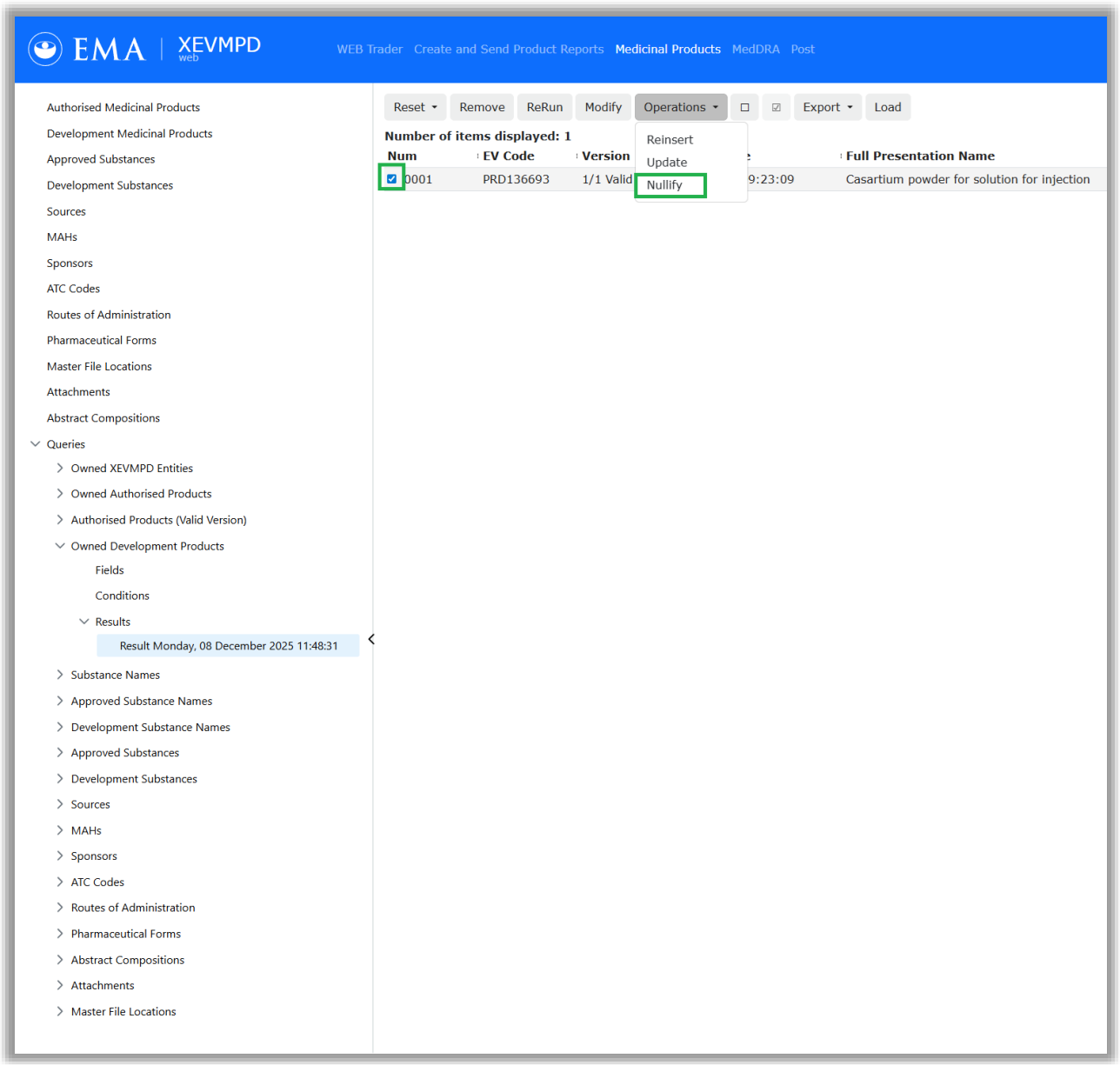
   - If retrieving the DMP via the **simple query**, load the DMP in the tree-view area using the check box and 'Load' functionality:



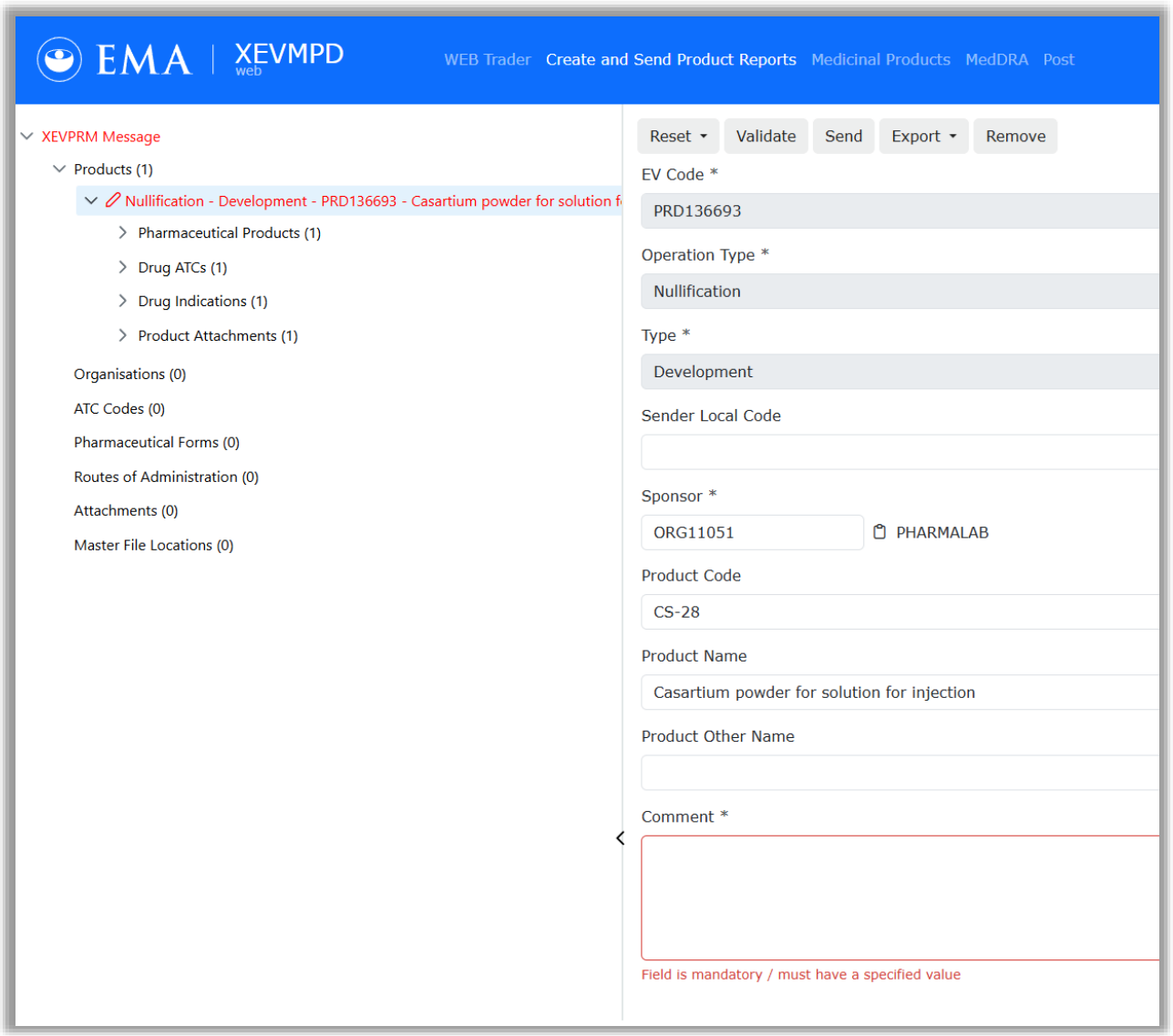
   Once loaded in the tree-view area, go to 'Operations' and select 'Nullify':



- If retrieved via the **advanced query**, select the entity in the active area, then go to 'Operations' and select 'Nullify':



The entity will be loaded in the 'Create and Send Product Reports' section:



2. Modify the information as required (i.e. enter the reason for nullification in the 'Comment' field).
3. In the 'Message Number' field, assign a number, or a name, to your XEVPRM.
4. Validate the XEVPRM; if any errors are reported, review the sections/fields where the errors are present and correct them as required.
5. Send the XEVPRM via the 'Send' (WebTrader users) or 'Post' (Gateway users) functionality.
6. Retrieve the XEVPRM acknowledgement in you WebTrader Inbox (WebTrader users) or in your internal system (Gateway users).

   If the submission was successful, the XEVPRM Acknowledgement will reference the EV Code of the entity that was being nullified and the text: *"Entity nullified successfully…".*

5.4. Creation of an XEVPRM with Operation Type 'Invalidate MA (6)'

To invalidate an AMP entity in the XEVMPD:

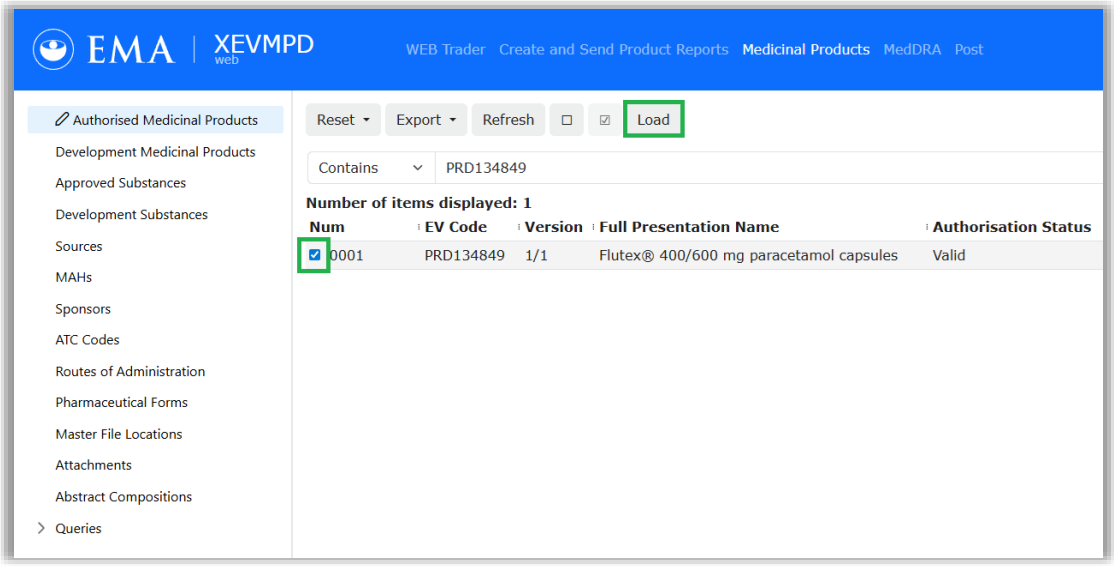
- the entity must be present in the XEVMPD (i.e., an EV Code is assigned);
- the entity must be owned in the XEVMPD by the user's HQ organisation and the entity;

- the entity must not be already nullified;
- the entity must not be an invalidated entity;
- the entity must not be referenced in other entities (such as other AMPs).

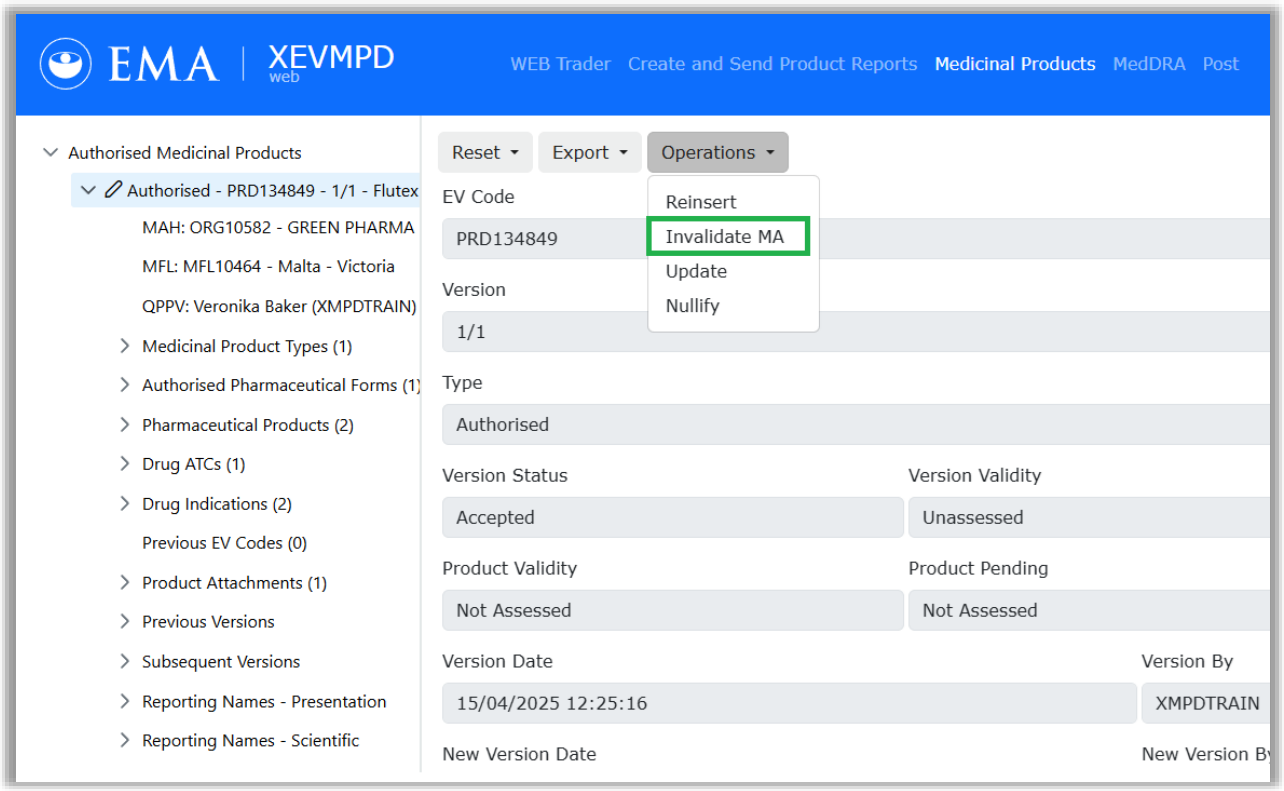
The below instructions describe the invalidation of an AMP due to marketing authorisation withdrawal, but the process is similar for any other AMPs where the marketing authorisation is no longer valid, owned in the XEVMPD by the user's HQ organisation.

1. Retrieve the AMP entity to be invalidated in the XEVMPD either using a simple or an advanced query in XEVMPDweb:

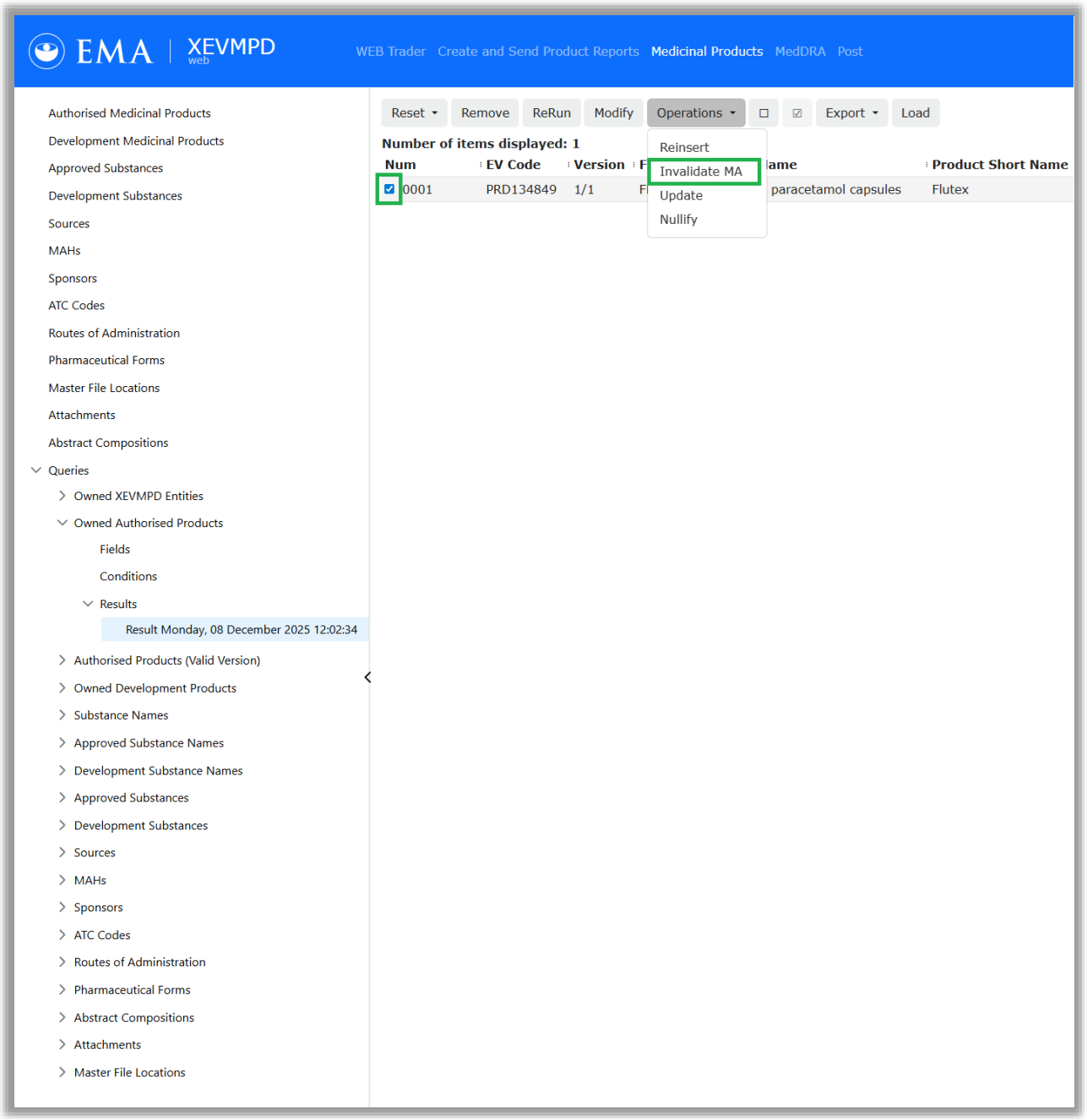
   - If retrieved via the **simple query**, load the entity in the tree-view area using the check box and 'Load' functionality:



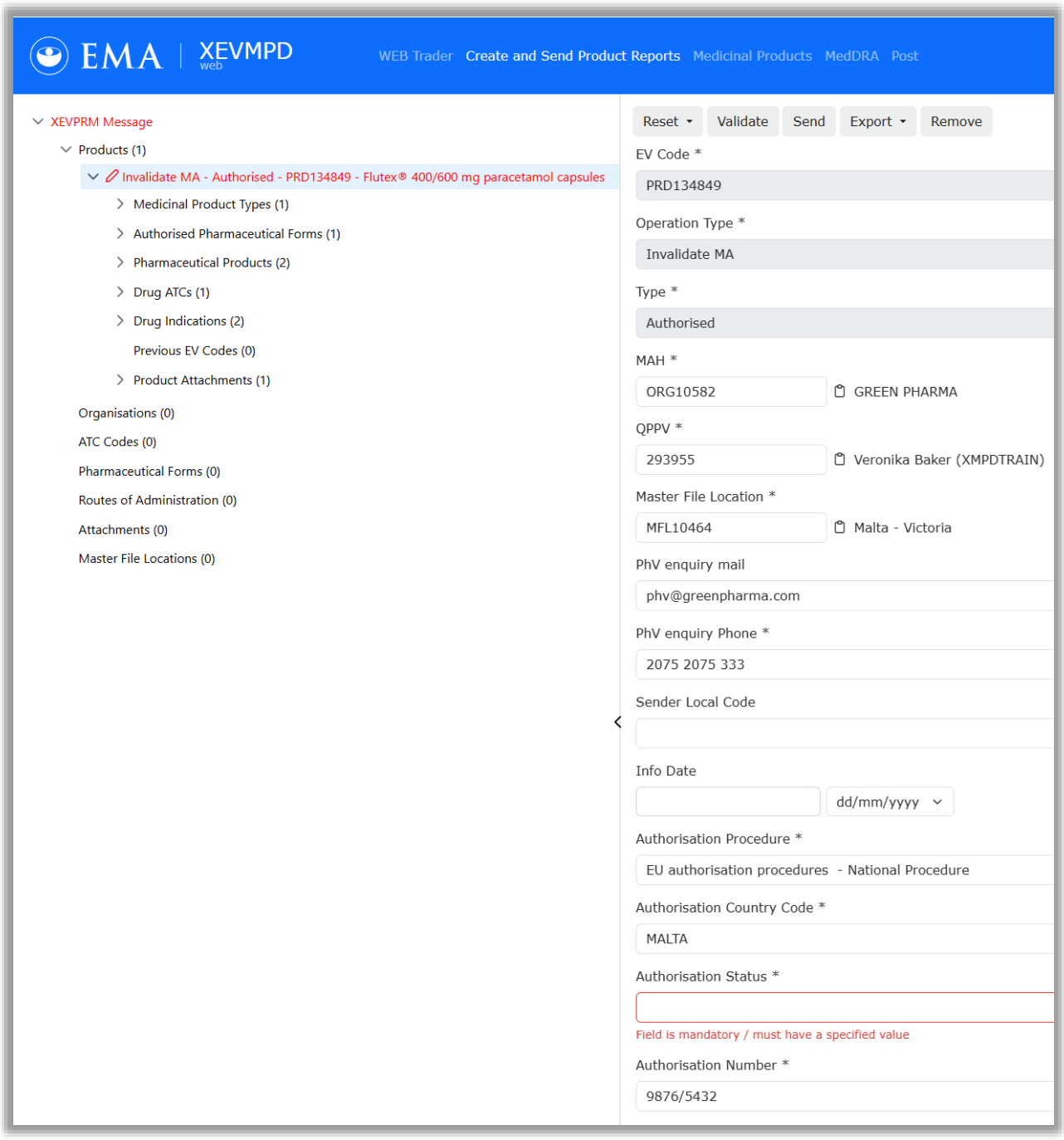
   Once loaded in the tree-view area, go to 'Operations' and select 'Invalidate MA':



- If retrieved via the **advanced query**, select the entity in the active area, then go to 'Operations' and select 'Invalidate MA':



The entity will be loaded in the 'Create and Send Product Reports' section:



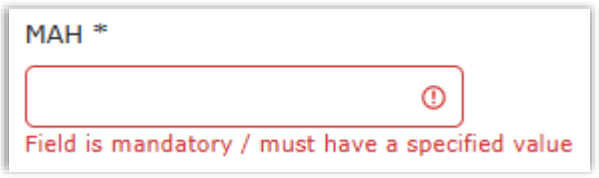
2. Modify the information as required (i.e. enter the applicable not-valid marketing authorisation status in the 'Authorisation Status' field and the applicable date in the 'Invalidated Date' field).
3. In the 'Message Number' field, assign a number, or a name, to your XEVPRM.
4. Validate the XEVPRM; if any errors are reported, review the sections/fields where the errors are present and correct them as required.
5. Send the XEVPRM via the 'Send' (WebTrader users) or 'Post' (Gateway users) functionality.
6. Retrieve the XEVPRM acknowledgement in you WebTrader Inbox (WebTrader users) or in your internal system (Gateway users).

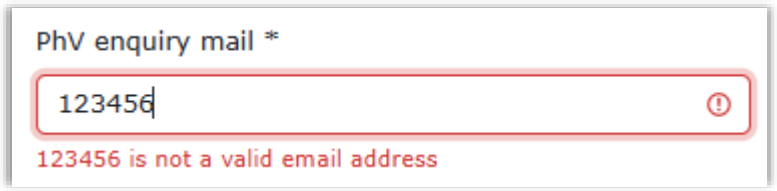
If the submission was successful, the XEVPRM Acknowledgement will reference the EV Code of the entity that was being invalidated and the text: *" Entity withdrawn/Invalidate MA successfully…".*

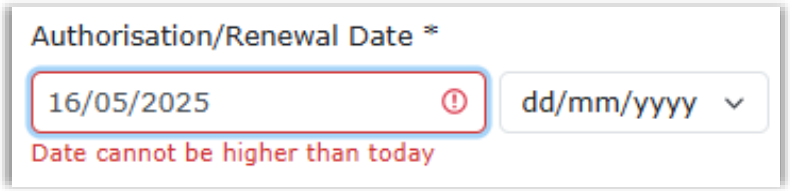
5.5. Validation of an XEVPRM

During the creation of an XEVPRM, the application performs a real-time validation of the inserted data by applying technical and business rules in use. Fields that contain erroneous or incomplete information will be flagged in red colour and an error message applicable for that field will be displayed under the field.

Examples of such error messages are included below:

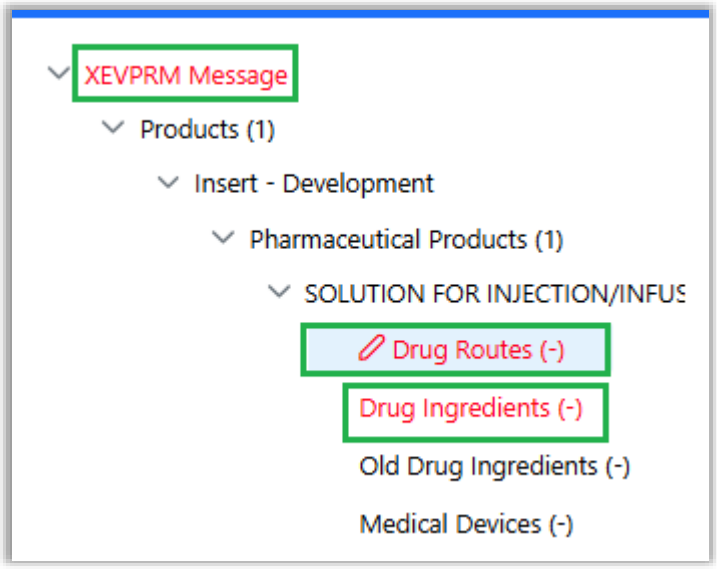






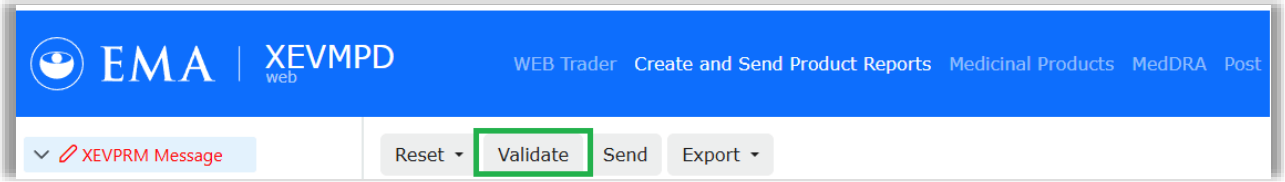
The most common error message is "Field is mandatory/must have a specified value". This type of field requires essential information, which needs to be provided to complete the data entry operation successfully and is dependable on technical and/or business rules in place.

Sections with missing mandatory information or errors will be highted in the tree-view area in red font, as shown in the screenshot below:



Mandatory sections must be completed[6]. An XEVPRM will not be sent, if a field highlighted as mandatory does not contain any information.

Once users create an XEVPRM containing all the information that they wish to send in the XEVMPD, they should perform a validation check of the information present in the XEVPRM using the 'Validate' functionality before submitting the XEVPRM.



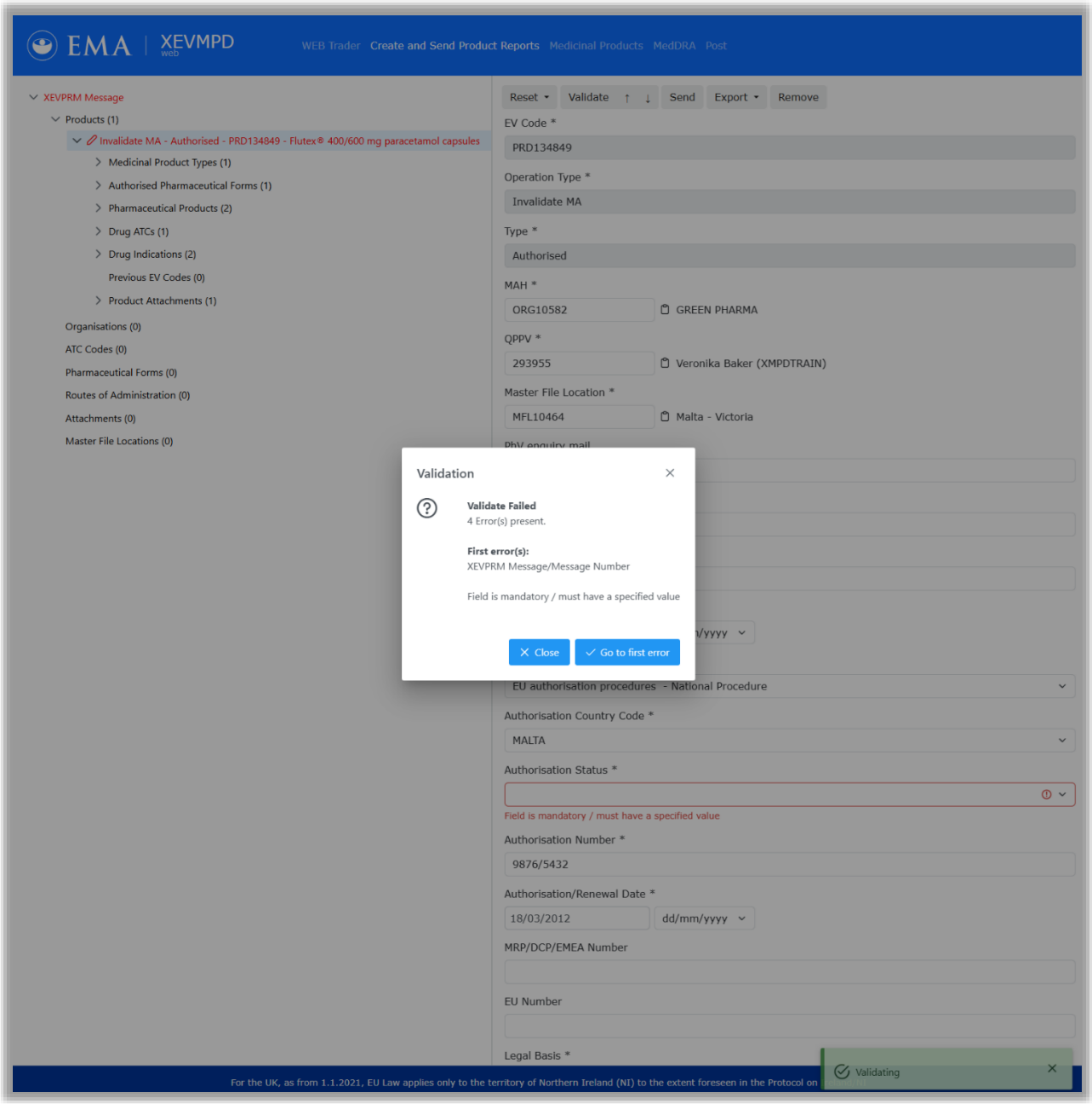
By clicking on the 'Validate' button from the dynamic button set, the system checks the information in the message. This includes checking that information is provided in the mandatory fields and, in some cases, also in accordance with the applicable business rules.

A pop-up window will confirm if the XEVPRM contains any error or not:

- If errors are present, 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.

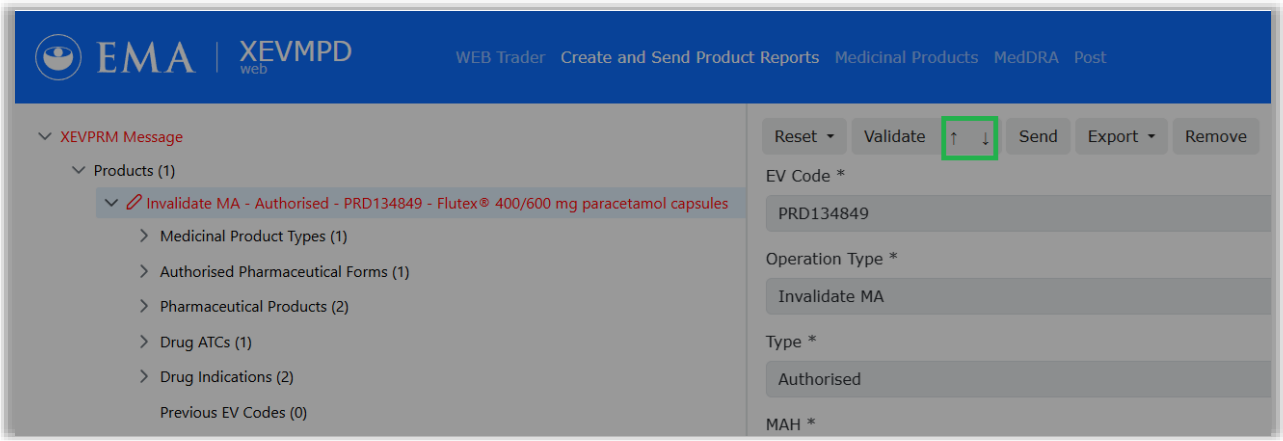
  For example:

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

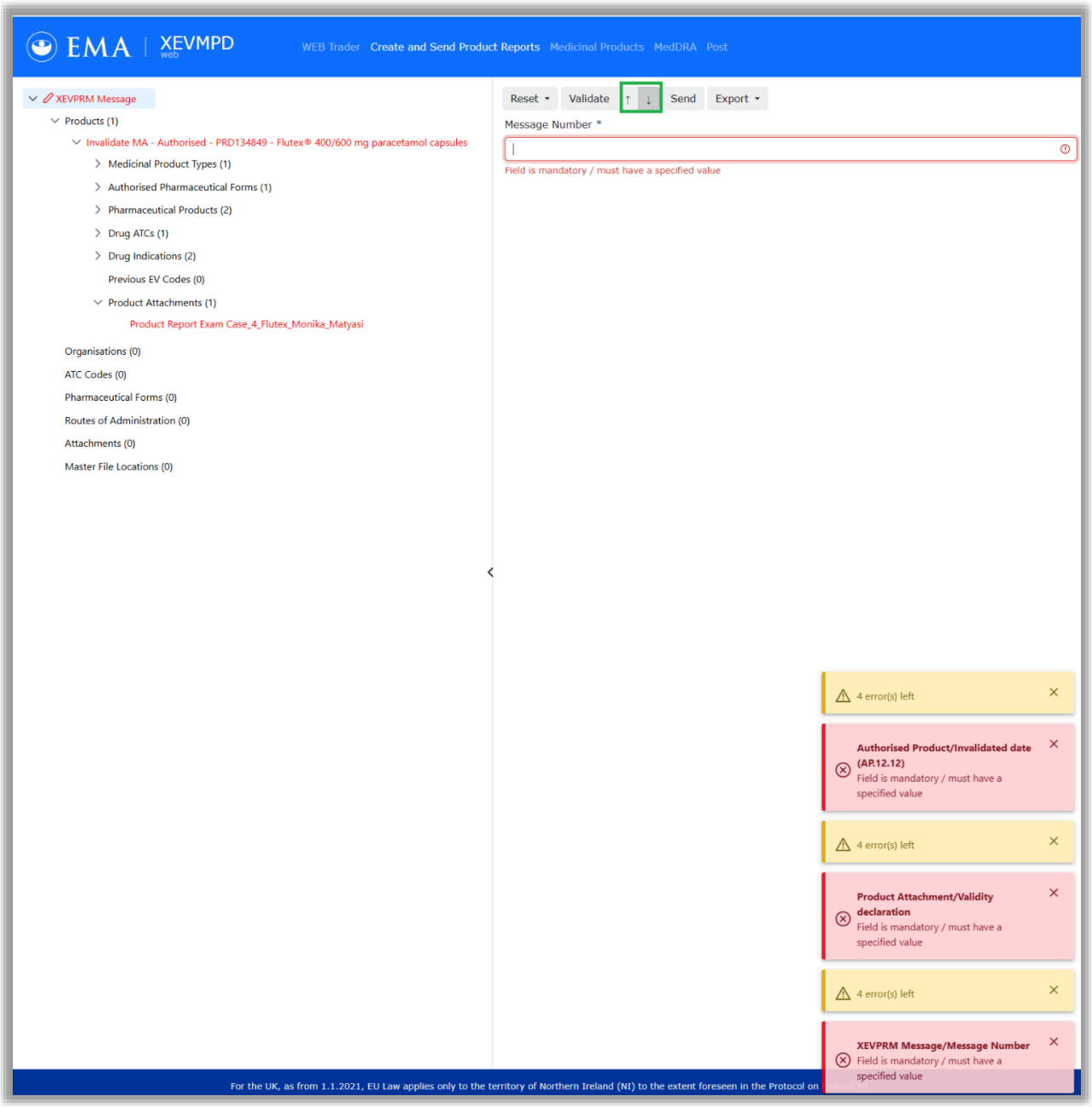


You can either close the window and go to the fields highlighted in red, indicating where the error is, or you can select 'Go to first error' and the system will re-direct you to the first available error.

In case of multiple errors in the XEVPRM, you can use the up and down arrows, which will appear next to the 'Validate' button, to navigate from one error to another:

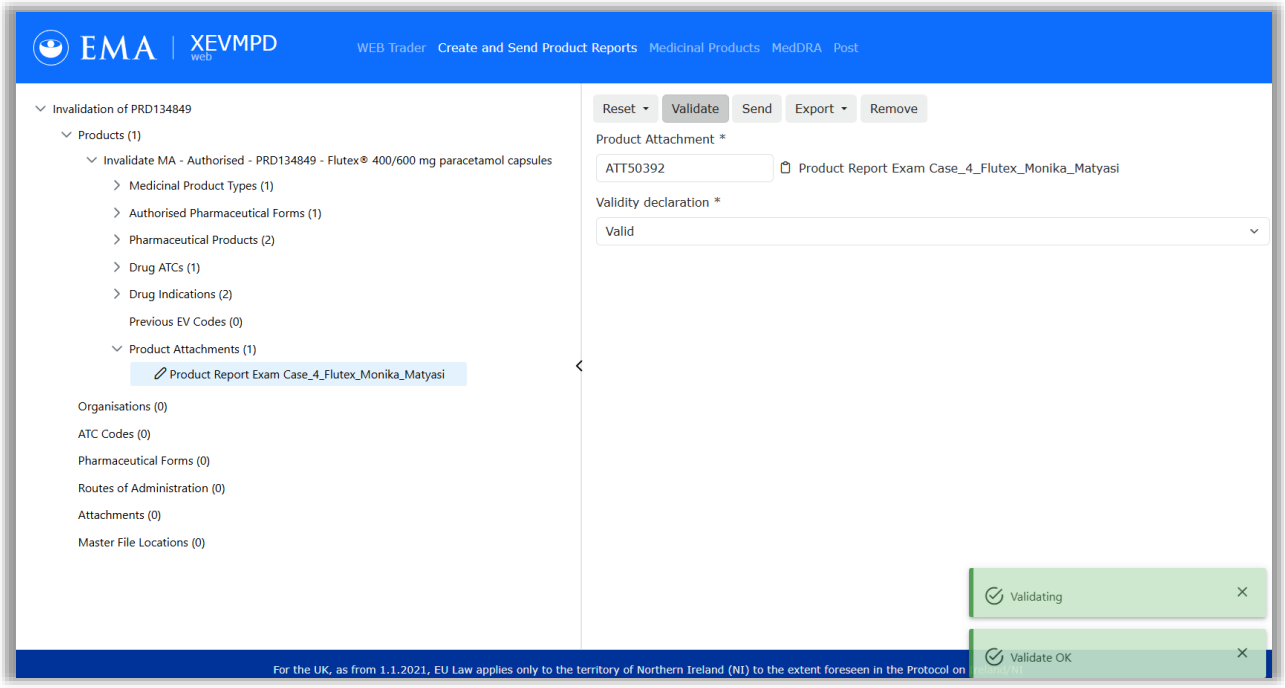


Validation related messages will appear in the right-hand corner of the window providing further information related to the error(s):



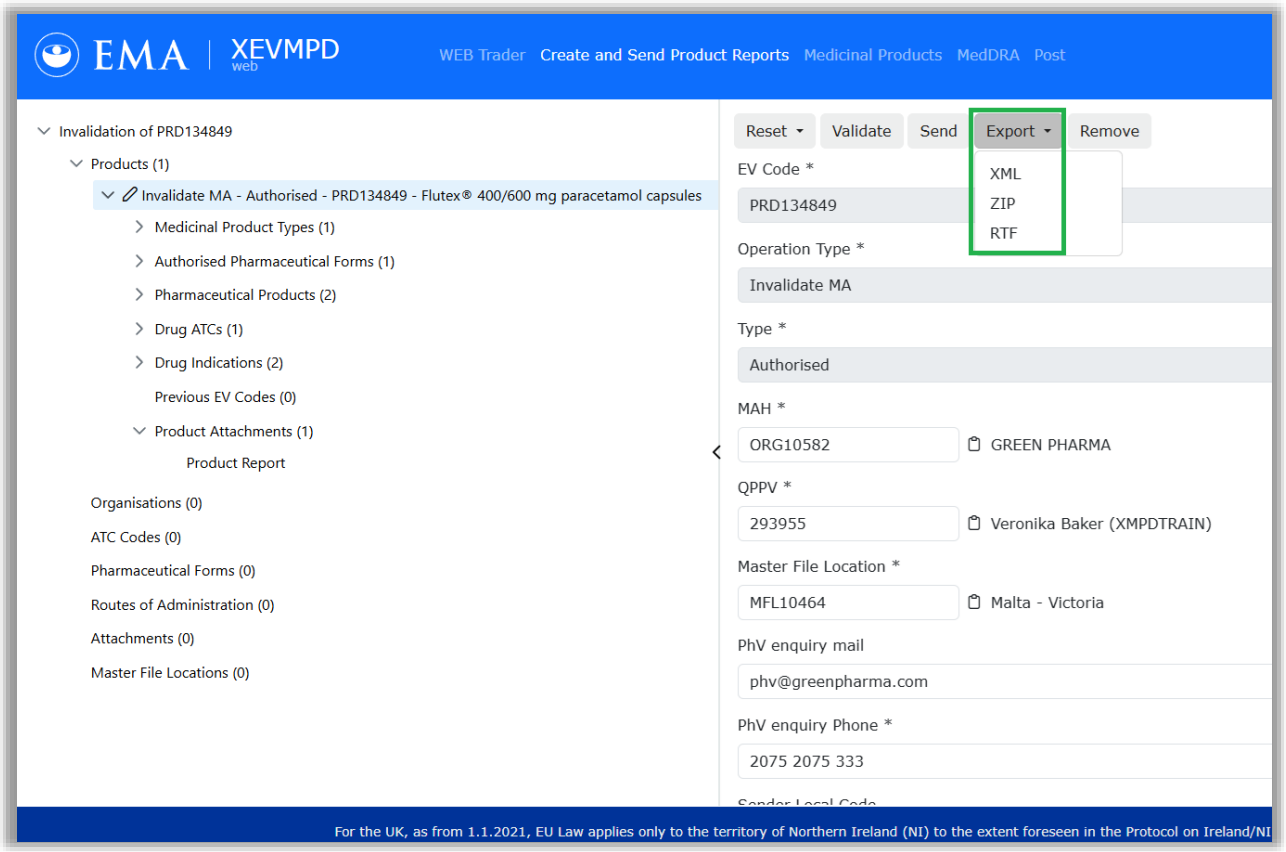
After the correction of the error(s) reported, 'Validate' the XEVPRM again.

- If no errors are present, the validation related message that appears in the right-hand corner of the window will state: "Validate OK".



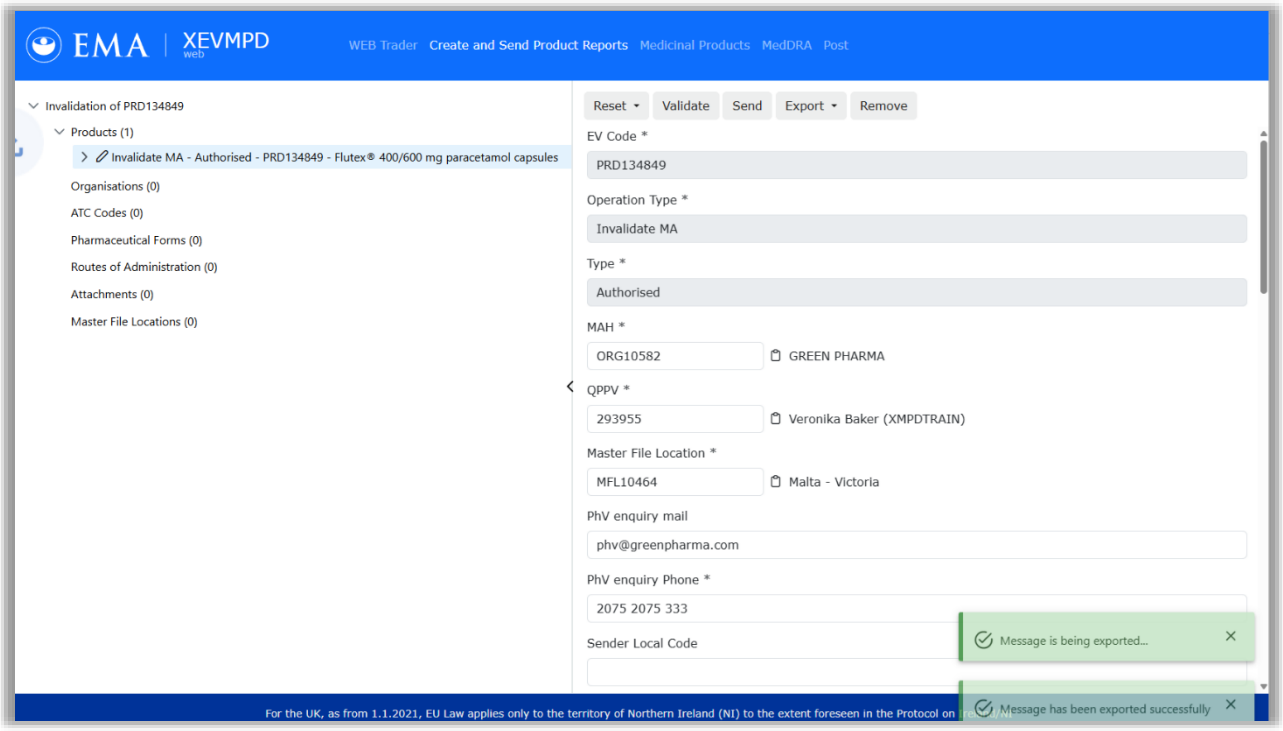
5.6. Saving of an XEVPRM before submission

Once you created and validated your XEVPRM, and before the submission of your XEVPRM, you have the possibility to export the XEVPRM as an **XML file**, **ZIP file** or an **RTF file** using the 'Export' functionality:



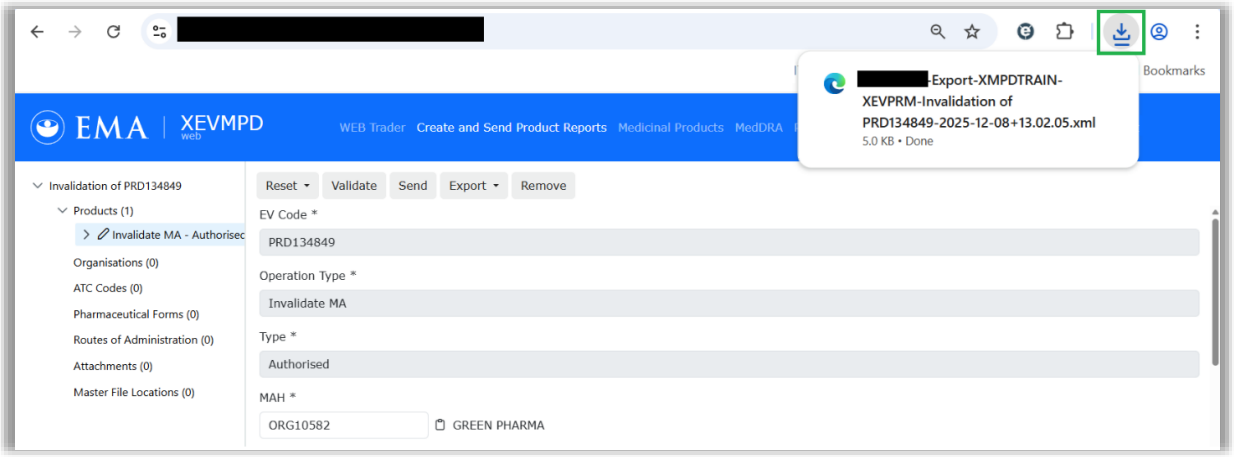
To save the XEVPRM in the 'XML', 'ZIP' or 'RTF' format, click on the required option within the 'Export' functionality:

- The system will confirm that the file is being exported via a message in the right-hand corner of the screen:

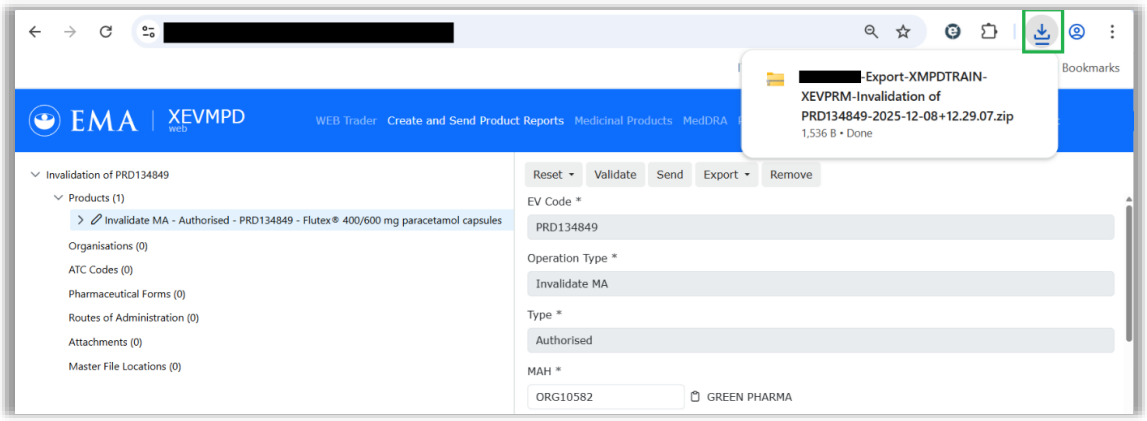


- The exported file(s) will become available in the 'Downloads' folder of the browser used to access XEVMPDweb:

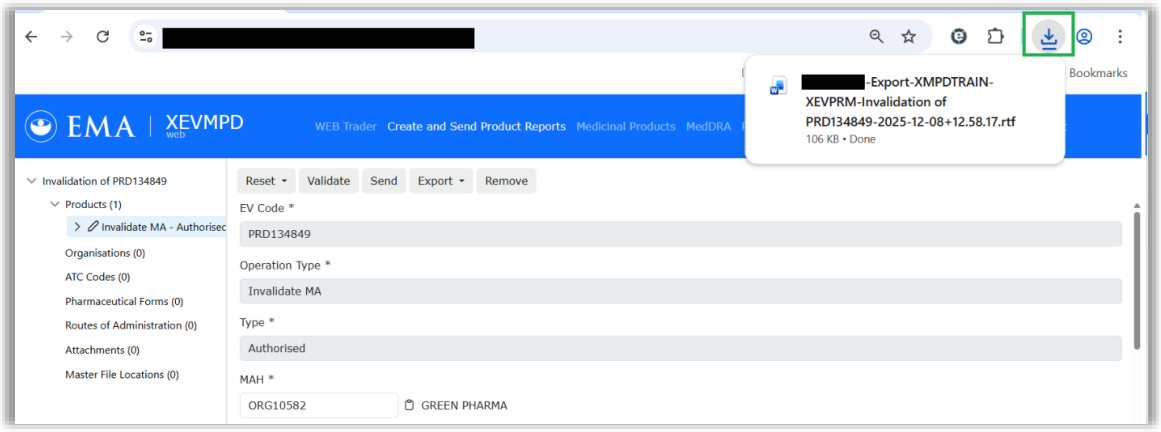
  - **XML**:



  - **ZIP**:



– **RTF**:



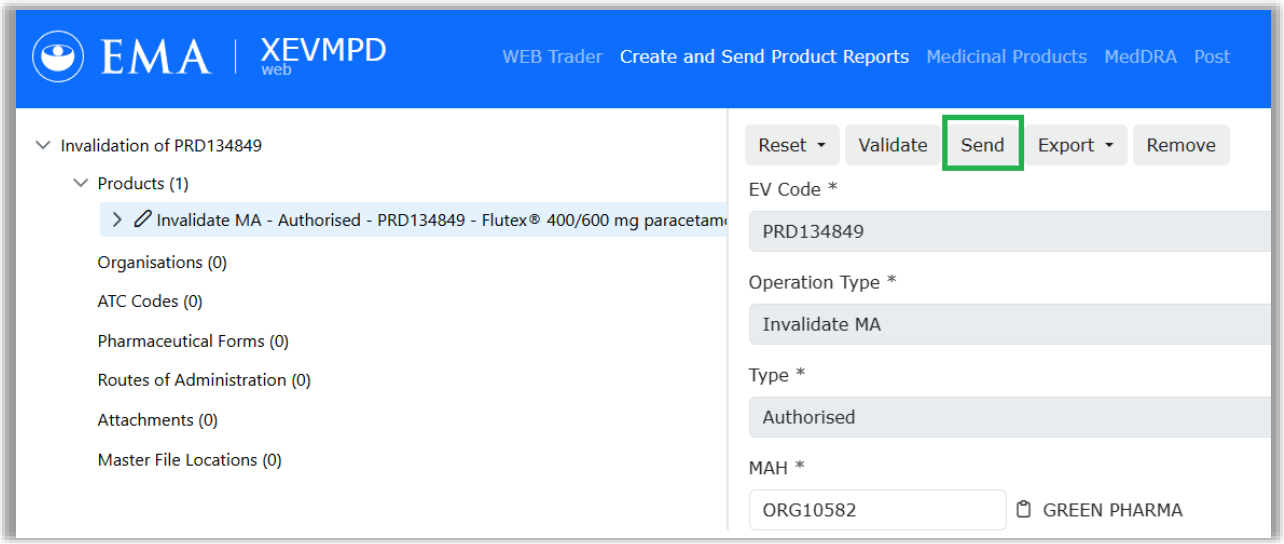
5.7. Sending of an XEVPRM

To send an XEVPRM:

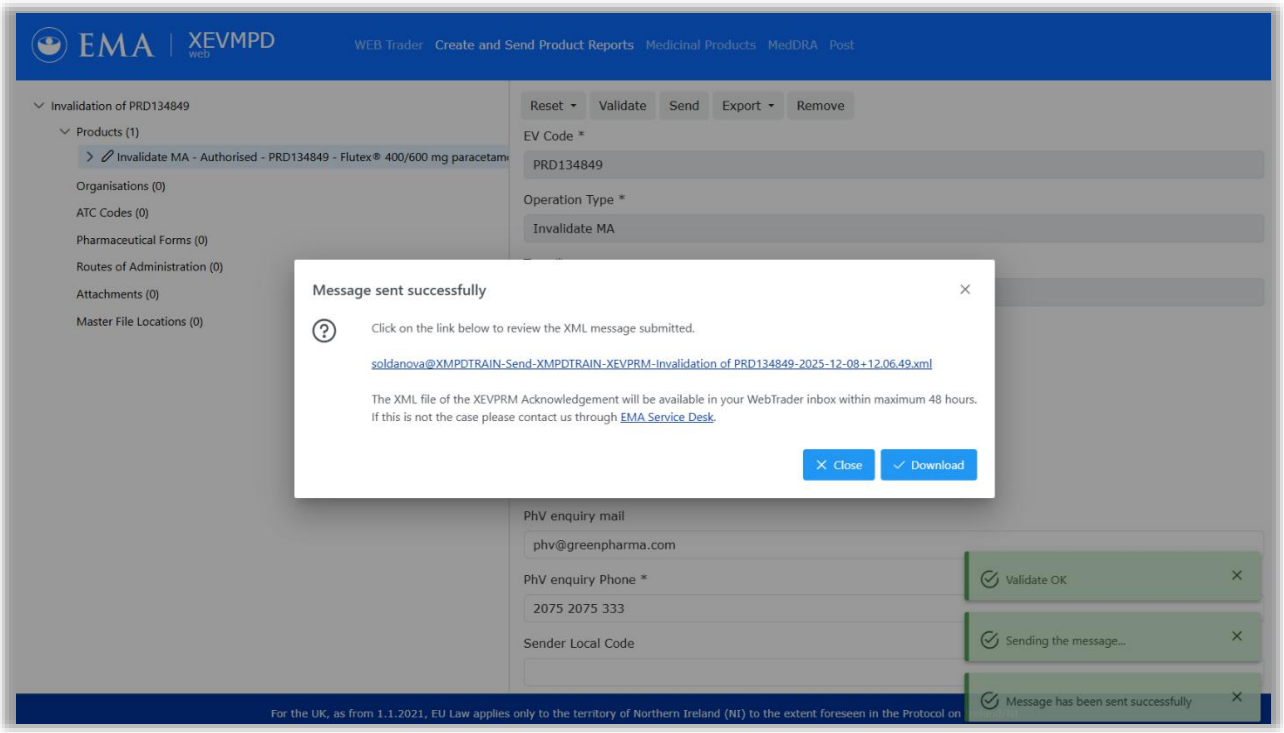
- Users from organisations registered in EudraVigilance as **Web Trader organisations** can submit XEVPRMs:
  - via the **'Send'** functionality available in the 'Create and Send Product Reports' section, which automatically converts the XEVPRM in a ZIP file, or
  - via the **'Post'** section of XEVMPDweb, where the user uploads the ZIP file with the XEVPRM.
- Users from organisations registered in EudraVigilance as **Gateway organisations** can submit:
  - XEVPRMs as 'ZIP' files using their **in-house solution**, or
  - via the **'Post'** section of XEVMPDweb, where the user uploads the ZIP file with the XEVPRM.

5.7.1. Sending an XEVPRM via the 'Send' functionality

Once the validation of an XEVPRM is completed and the XEVPRM contains no errors, the user can submit the XEVPRM via the 'Send' functionality by clicking on 'Send':



A new message will appear on the screen, allowing the user to view or download the submitted XEVPRM:



The submitted XEVPRM will be available in the in the WEB Trader Outbox **within minutes and max 48 hours** since the XEVPRM was submitted.

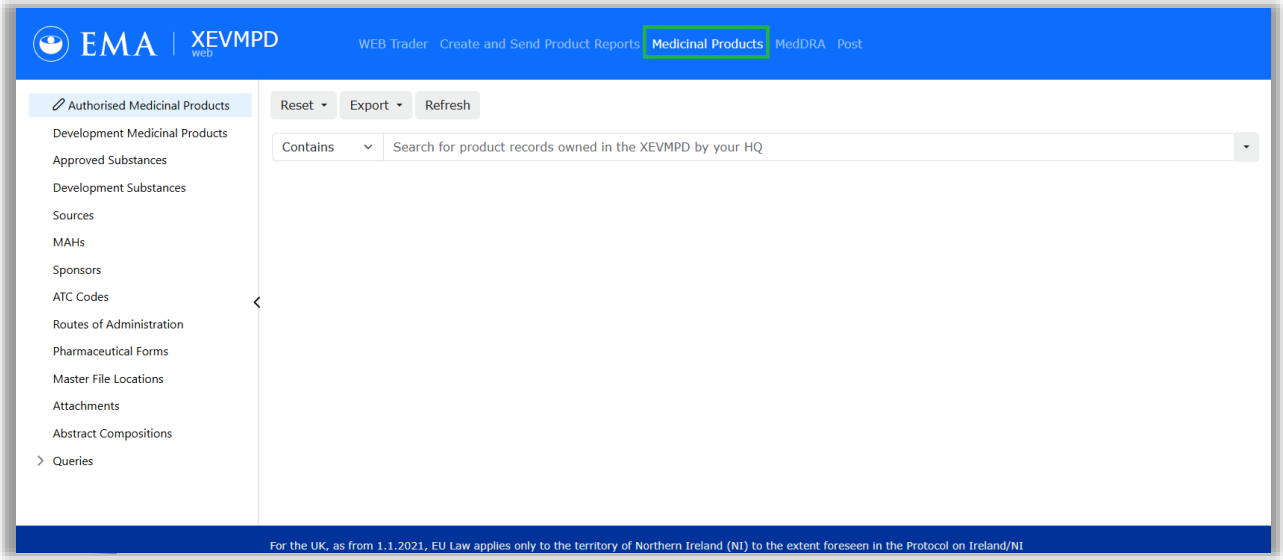
5.7.2. Sending an XEVPRM via the 'Post' functionality

Once the validation of an XEVPRM is completed and the XEVPRM contains no errors, the user must save the XEVPRM in a 'ZIP' file.

To submit a ZIP file containing an XML file of an XEVPRM with or without any attachment(s), go to the *'Post'* section of XEVMPDweb and follow instructions described in section *0*

'Post' section of this manual.

6. 'Medicinal Products' section



The 'Medicinal Products' section allows users to:

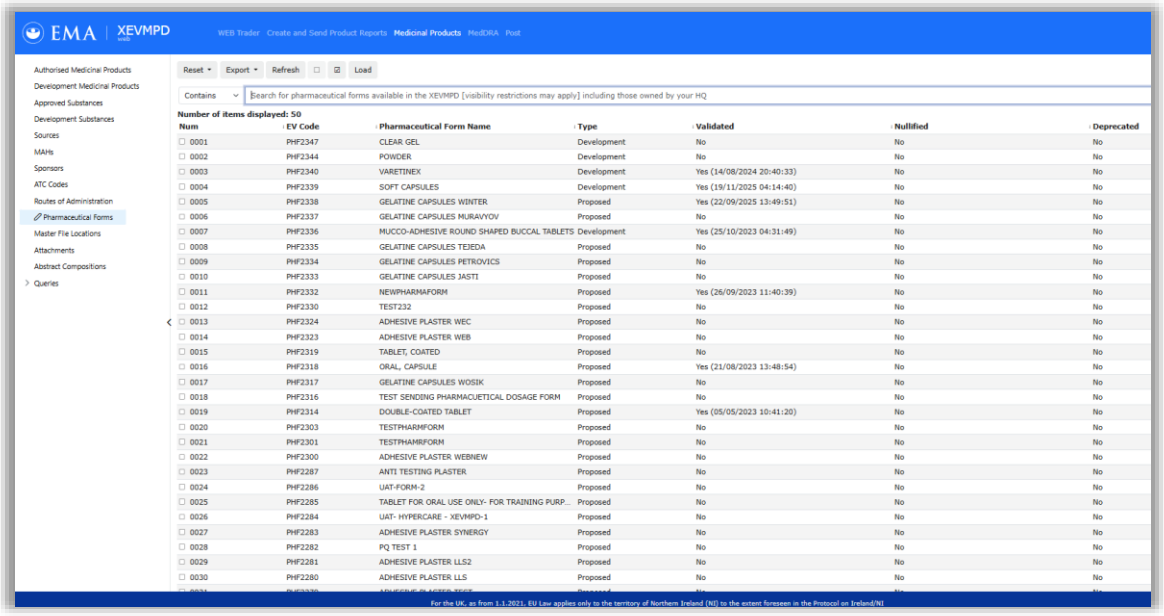
- **browse** the data available in the XEVMPD;
- **perform searches** for all available XEVMPD entities either via the simple query or via advanced queries, taking into consideration the applicable ownership and visibility rules;
- **export data** in any of the available formats.

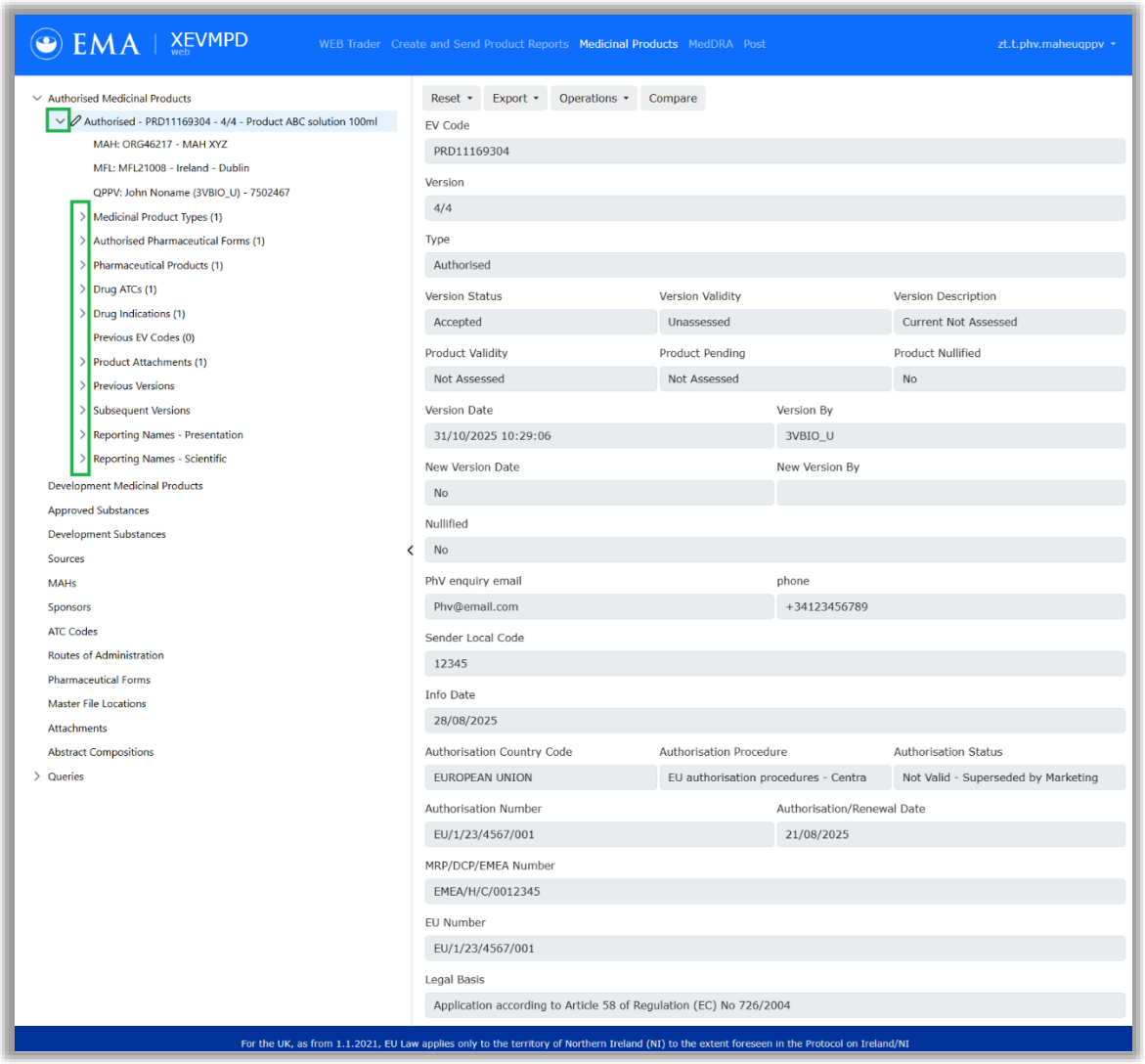
6.1. Browsing data

Users can browse data in the 'Medicinal Products' section. Visibility restrictions apply, as per information in section *1.3.8. Data access*.

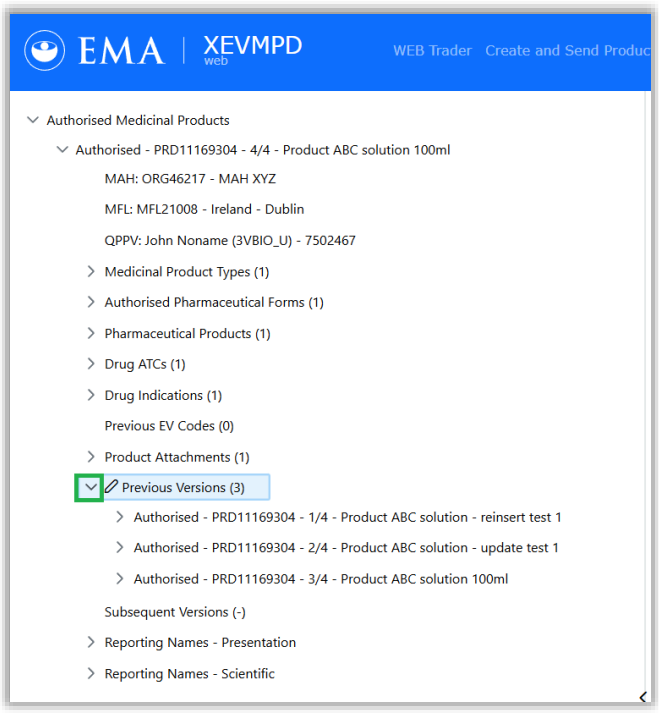
The tree-view area enables users to browse items by selecting them, and by expanding or closing menus.

The active area displays the results of a search (simple or advanced) and the content of the selected item in the tree-view.

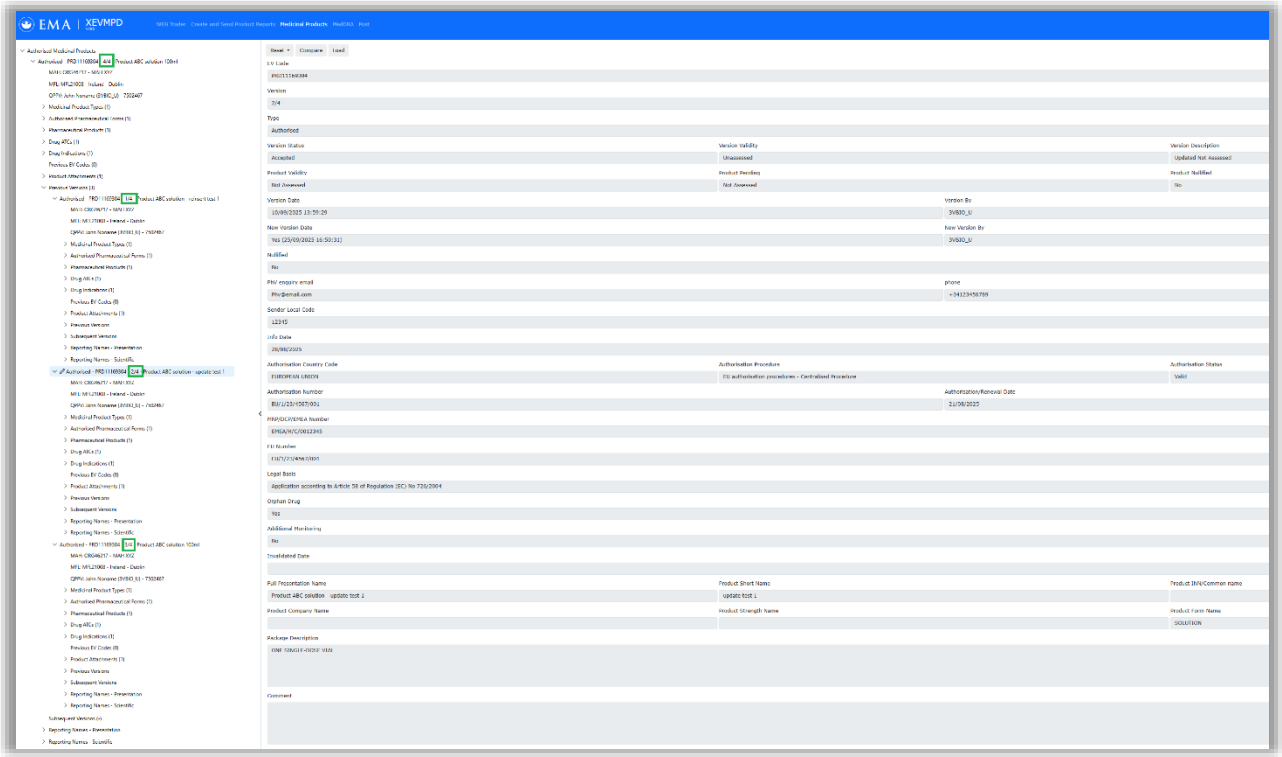




For example, to view the previous or subsequent version(s) of an AMP entity, the user should expand the section 'Previous Versions' or 'Subsequent Versions', as required, in the tree-view area:



The previous/subsequent version(s) of the AMP record will then be listed in the tree-view area where they can be further viewed; the active area will display the information for the version that is highlighted in the tree-view area in blue:



6.2. Searching for data

In the 'Medicinal Products' section, users can search for XEVMPD data as per the applicable accessibility rules described in section *1.3.8. Data access.*

6.2.1. Search for medicinal product data via a simple query

Via the **simple search**, users can search for:

- **Authorised medicinal product** entities owned in the XEVMPD by their HQ organisation
- **Development medicinal product** entities owned in the XEVMPD by their HQ organisation
- **Approved substances** available in the XEVMPD
- **Development substances** owned in the XEVMPD by their HQ organisation
- **Sources** available in the XEVMPD:
  - All sources owned in the XEVMPD by their HQ organisation.
  - All sources owned in the XEVMPD by the EMA or other organisations.
- **MAH** and **sponsor** organisations available in the XEVMPD:
  - MAH and sponsor entities owned in the XEVMPD by their HQ organisation
  - MAH and sponsor entities owned in the XEVMPD by other HQ organisations but flagged as validated by the EMA
- **Development terms (ATC codes**, **routes of administration** and **pharmaceutical forms)** owned in the XEVMPD by their HQ organisation
- **Proposed terms (ATC codes**, **routes of administration** and **pharmaceutical forms):**
  - All proposed terms owned in the XEVMPD by their HQ organisation.
  - All proposed terms not owned in the XEVMPD by their HQ organisation.
  - All proposed terms owned in the XEVMPD by the EMA.
- **Standard terms (ATC codes**, **routes of administration** and **pharmaceutical forms)** owned in the XEVMPD by the EMA and flagged as validated
- **Master file location** entities available in the XEVMPD:
  - owned in the XEVMPD by their HQ organisation (all available information)
  - owned in the XEVMPD by other HQ organisations (restricted information only: EV Code and Country)
- **Attachment** entities owned in the XEVMPD by their HQ organisation
- **Abstract Compositions**, terms derived from the combination of the pharmaceutical forms' active substance(s) to support ICSR recoding and the scientific product hierarchy.

See section *3.7.1. Simple query* for information how to perform simple query search in XEVMPDweb.

6.2.2. Search for medicinal product data via advanced queries

Via the **advanced query search**, users can search for:

- An overview of how many entities are owned in the XEVMPD by their HQ organisation using the '**Owned XEVMPD Entities**' query
- Authorised medicinal product entities owned in the XEVMPD by their HQ organisation using the **'Owned Authorised Products'** query
- Last EMA validated version of authorised medicinal products owned in the XEVMPD by other HQ organisations via the **'Authorised Products (Valid Version)**:
  - Access to some information within the AMP entities is restricted to MAH and sponsor users
- **Development medicinal product** entities owned in the XEVMPD by their HQ organisation
- All approved substance names available in the XEVMPD and development substance names owned by the user's HQ organisation via the **'Substance Names'** query
- All approved substance names available in the XEVMPD via the **'Approved Substance Names'** query
- All development substance names of substances owned in the XEVMPD by their HQ organisation via the **'Development Substance Names'**
- Approved substances available in the XEVMPD via the **'Approved Substances'** query
- Development substances owned in the XEVMPD by their HQ organisation via the **'Development Substances'** query
- Sources available in the XEVMPD via the **'Sources'** query:
  - All sources owned in the XEVMPD by their HQ organisation.
  - All sources owned in the XEVMPD by the EMA or other organisations.
- MAH and sponsor organisations owned in the XEVMPD by their organisation, and organisations owned by other HQs and flagged as validated by the EMA, via the **'MAHs'** and '**Sponsors**' queries
- Standard ATC Codes, proposed ATC Codes flagged as validated by the EMA, and development ATC Codes owned by their HQ organisation via the **'ATC Codes'** query
- Standard routes of administration (RoA), proposed RoA flagged as validated by the EMA, and development RoA owned by their HQ organisation via the **'Routes of Administration'** query
- Standard pharmaceutical forms (PF), proposed PF flagged as validated by the EMA, and development PF owned by their HQ organisation via the **Pharmaceutical Forms'** query
- Abstract Compositions: terms derived from the combination of the pharmaceutical forms' active substance(s) to support ICSR recoding and the scientific product hierarchy.
- Attachment entities owned in the XEVMPD by their HQ organisation via the **'Attachments'** query
- Master file locations (MFLs) owned in the XEVMPD by their organisation, and MFLs owned by other HQs and flagged as validated by the EMA (restricted information only), via the **'Master File Locations'** query

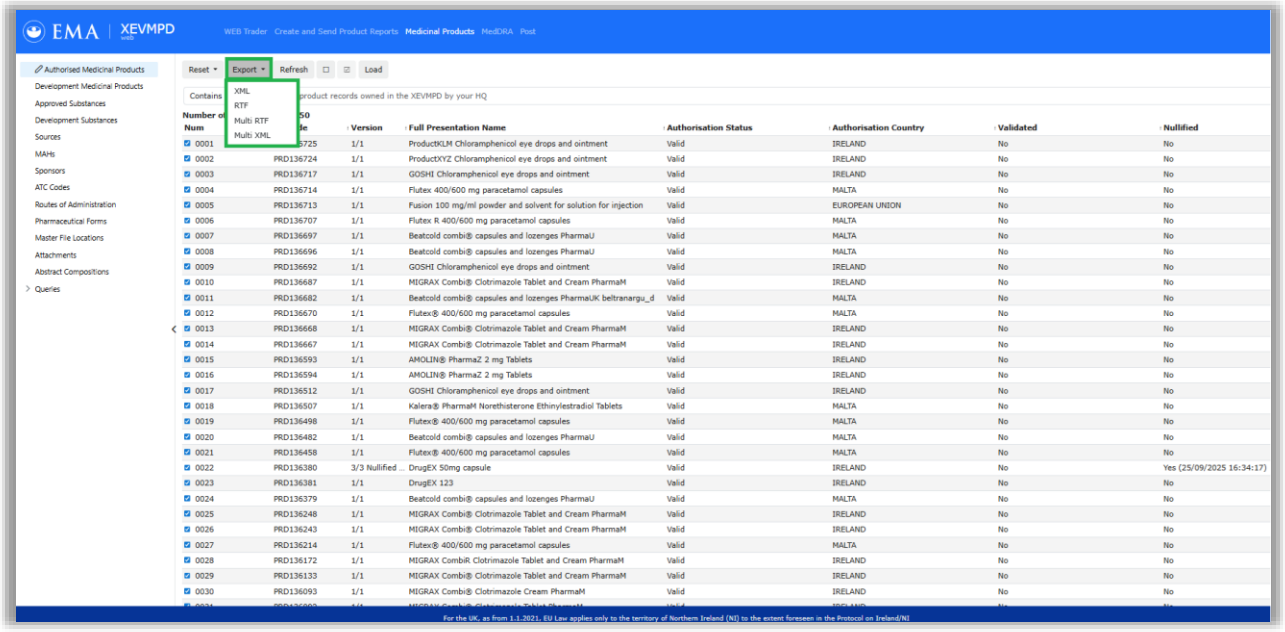
See sections *3.7.2. Advanced query* and *3.7.3. Immediate query* for information how to perform advanced queries in XEVMPDweb.

6.3. Export of data

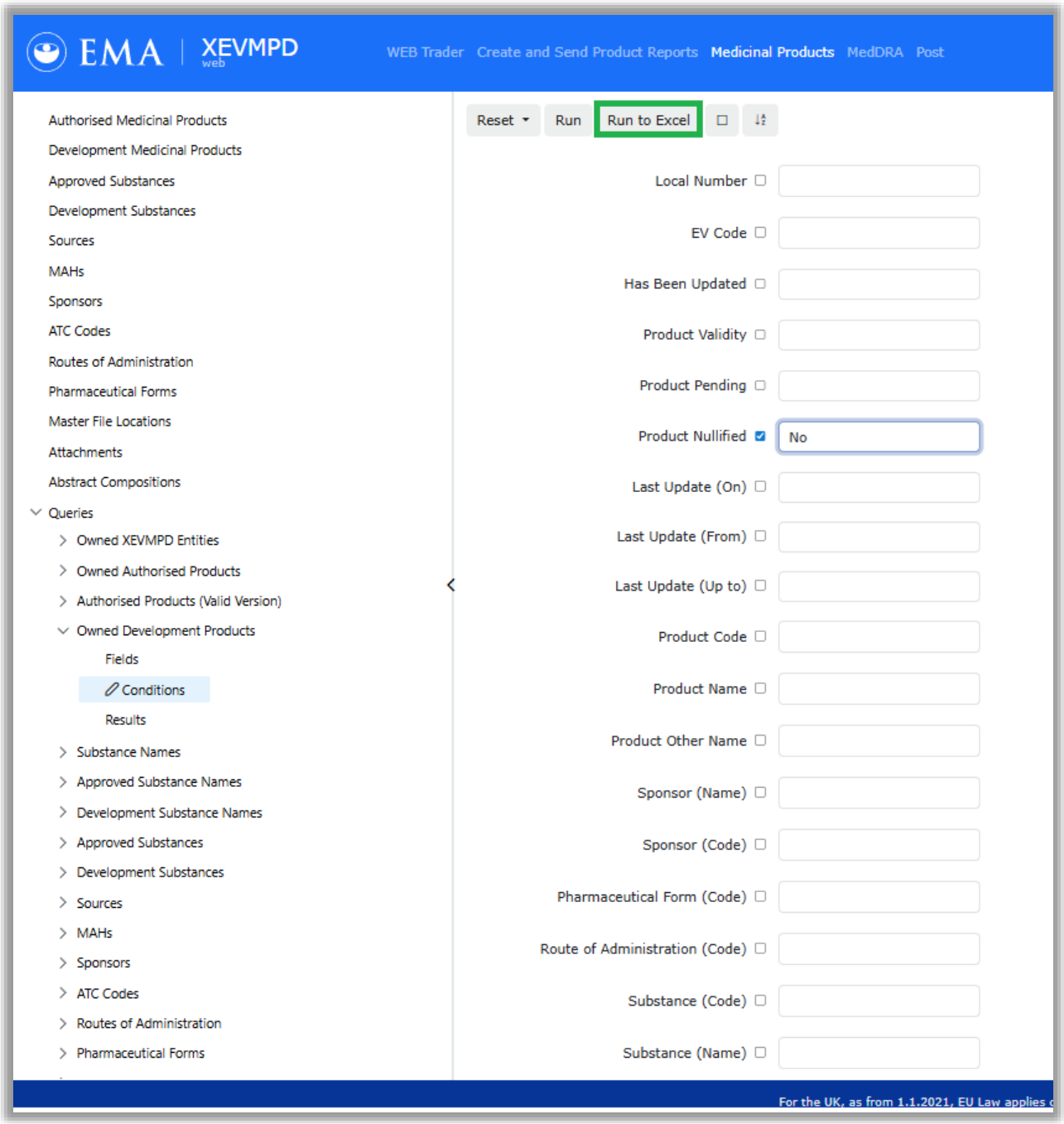
To export results of a simple query, the results displayed in the active area must be selected (i.e. the checkbox must be ticked).

The **selected result(s)** of a simple query can then be exported into:

- a single or multiple XML file(s) or
- a single or multiple RTF file(s) using the **'Export'** functionality:

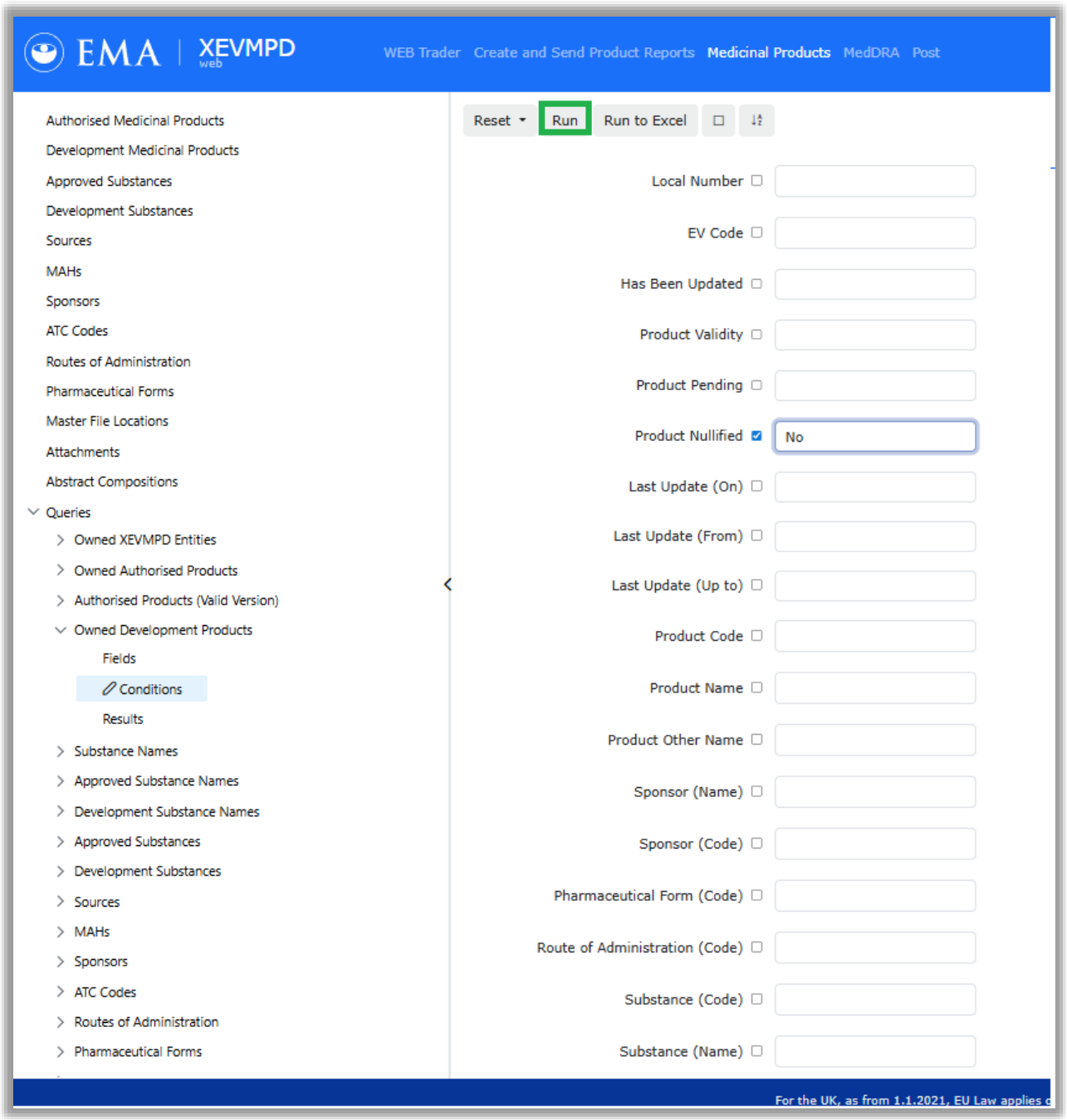


Results of advanced query can be sent directly to an Excel spreadsheet, without being displayed in the active area first, via the 'Run to Excel' functionality:



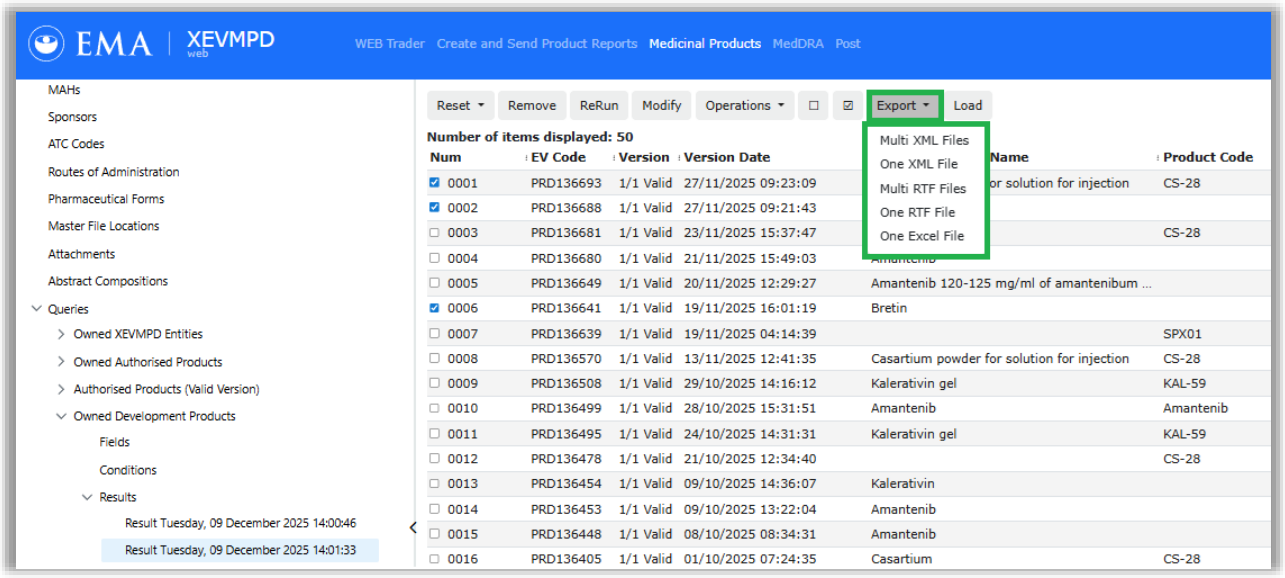
The exported Excel file(s) will become available in the 'Downloads' folder of the browser used to access XEVMPDweb by the user.

If the user wishes to view the results in the active area first and then export some, or all, of the displayed results into one of the available formats, the query should be executed via the **'Run'** functionality:



Using the 'Export' functionality, the **selected result(s)** of an advanced query can then be exported into:

- single or multiple XML file(s);
- single or multiple RTF file(s) or
- one Excel File.



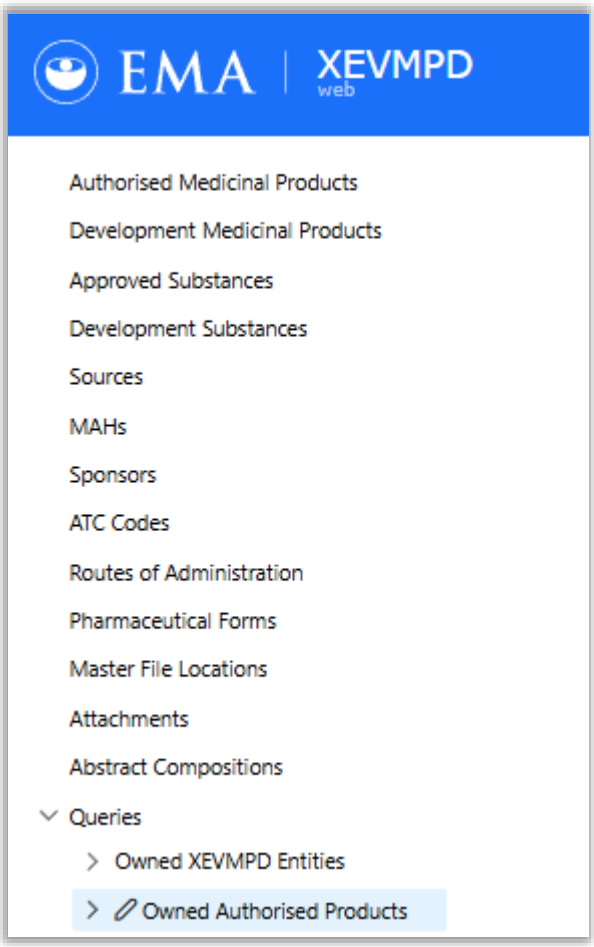
The exported file(s) will become available in the 'Downloads' folder of the browser used to access XEVMPDweb by the user.

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).

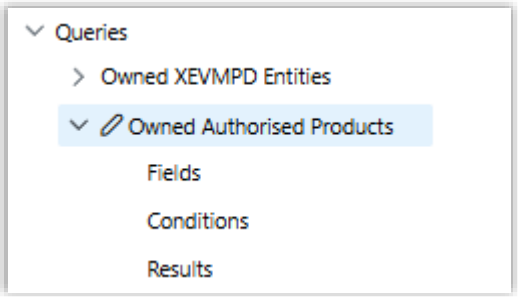
6.3.1. Exporting an overview of all owned AMP entities

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.

1. Open the 'Queries' section in the tree-view area and select 'Owned Authorised Products':

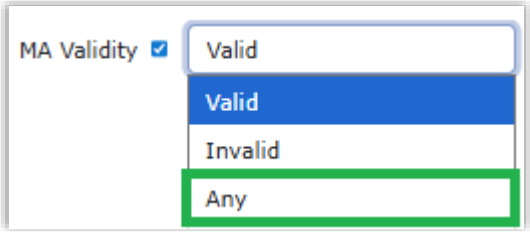


2. Expand the section so you can view the 'Fields' and 'Conditions':



3. Select which fields you wish to see as the result of your query in the **'Fields'** section.
4. Specify the conditions for your search. Please note that for AMPs, 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:



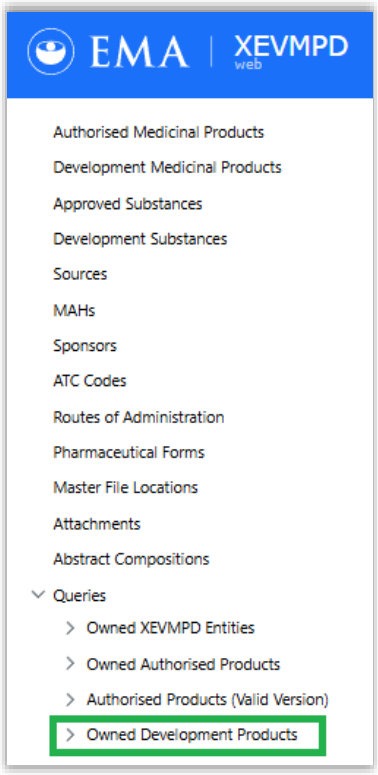
5. Once you select the conditions of your query, click on **'Run'** to view the results of your query on the screen, in the active area, or select **'Run to Excel'** to export the results of your query directly in an Excel file.

   If you opted to run the results directly in an Excel file, the exported Excel file(s) will become available in the 'Downloads' folder of the browser that you used to access XEVMPDweb.

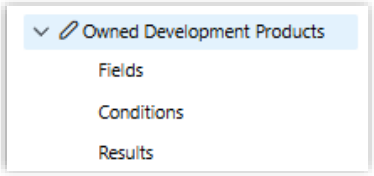
6.3.2. Exporting an overview of all owned DMP entities

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.

1. Open the 'Queries' section in the tree-view area and select 'Owned Development Products':



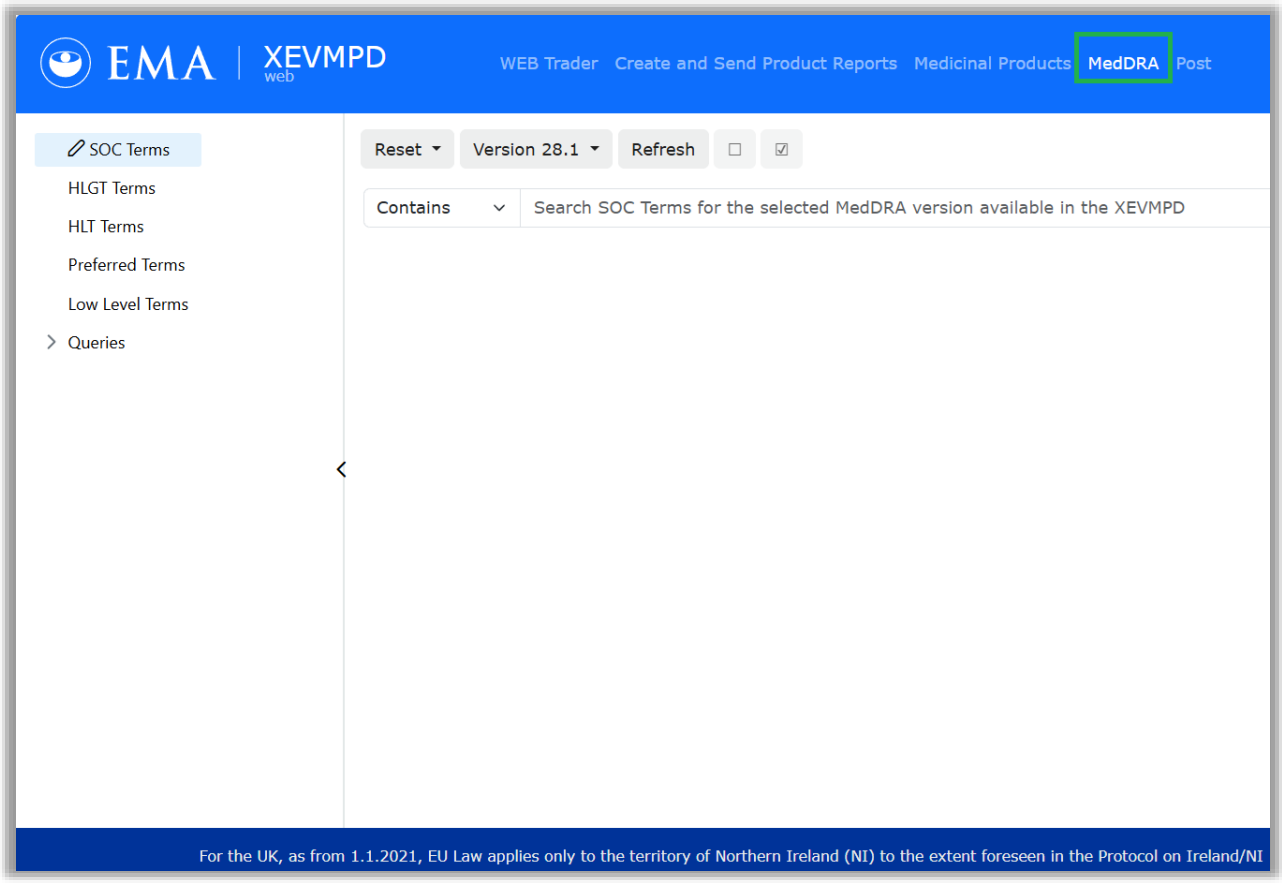
2. Expand the section so you can view the 'Fields' and 'Conditions':



3. Select which fields you wish to see as the result of your query in the 'Fields' section.
4. Specify the conditions for your search.
6. Once you select the conditions of your query, click on 'Run' to view the results of your query on the screen, in the active area, or select 'Run to Excel' to export the results of your query directly in an Excel file.

   If you opted to run the results directly in an Excel file, the exported Excel file(s) will become available in the 'Downloads' folder of the browser that you used to access XEVMPDweb.

7. 'MedDRA' section

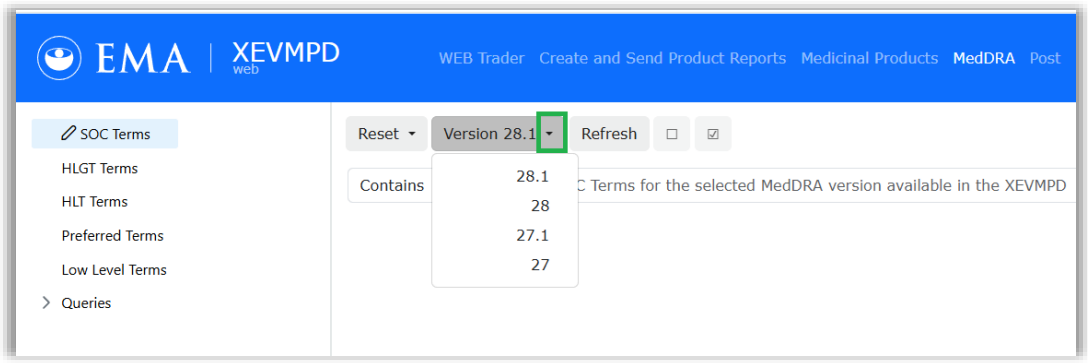


The 'MedDRA section allows users to:

- **browse** the MedDRA terms available in the XEVMPD;
- **perform searches** for all available MedDRA terms either via the simple queries or via advanced queries and
- **export data** in any of the available formats.

7.1. Browsing data

The latest available MedDRA version is referenced by default, but users can select to view data from that last three versions available before the latest version, by clicking expanding the version window shown in the below screenshot:



The EMA uploads the latest version of MedDRA on the first Monday of May and on the first Monday of November each year.

The tree-view area enables users to browse items by selecting them, and by expanding or closing menus.

The active area displays the results of a search (simple or advanced) and the content of the selected item in the tree-view.

7.2. Searching for MedDRA terms

As in other sections of XEVMPDweb, searches can be performed using simple or advanced queries.

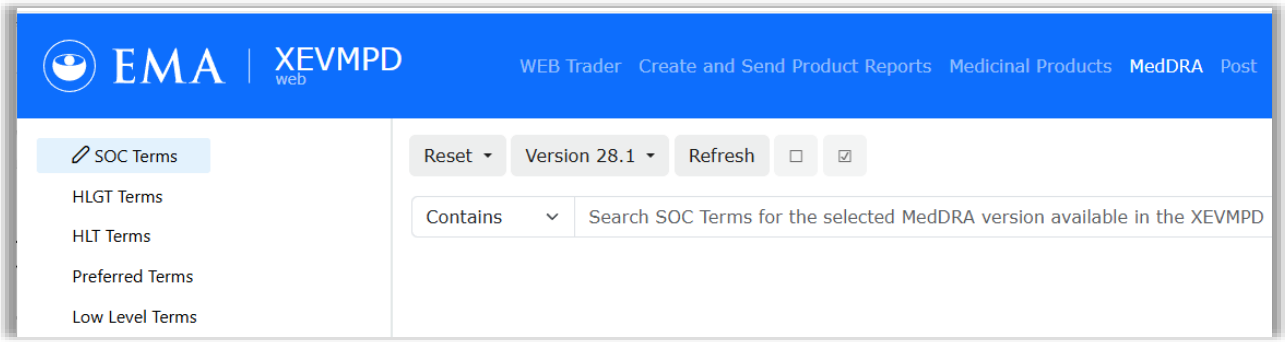
If users to not select a specific MedDRA version to perform their query, the simple and advanced queries are performed with the current MedDRA version set as default.

7.2.1. Search for MedDRA terms via simple query

Via the simple search, users can search for:

- SOC (System Organ Class) Terms
- HLGT (High Level Group Terms)
- HLT (High Level Terms)
- PT (Preferred Terms)
- LLT (Low Level Terms)

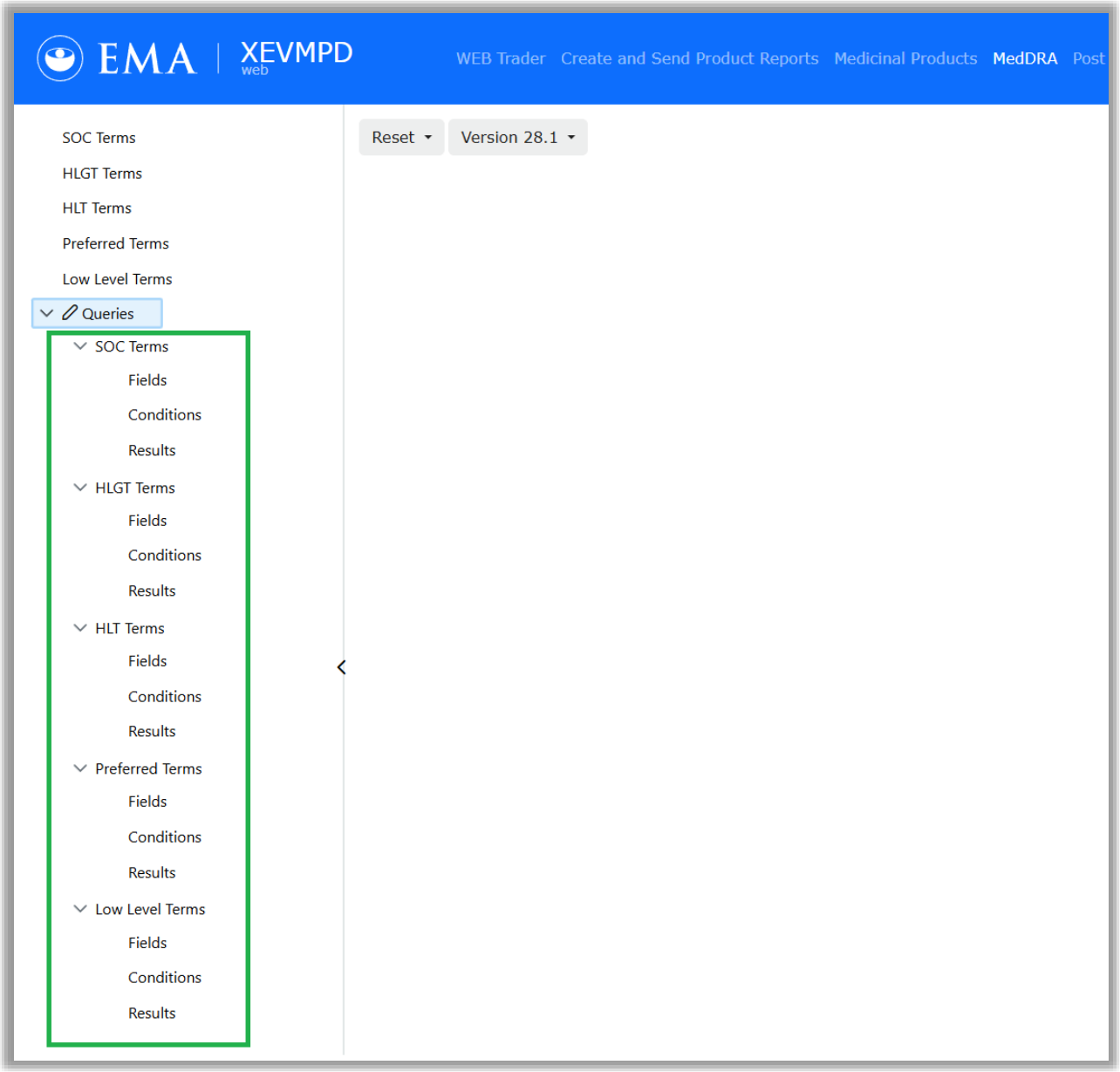
The simple search window is present in the active area for each of the sections:



See section *3.7.1. Simple query* for information how to perform simple query search in XEVMPDweb.

7.2.2. Search for MedDRA terms via advanced queries

Via the advanced query search, users can also search for System Organ Class terms, High Level Group Terms, High Level Terms, Preferred Terms and Low Level Terms:



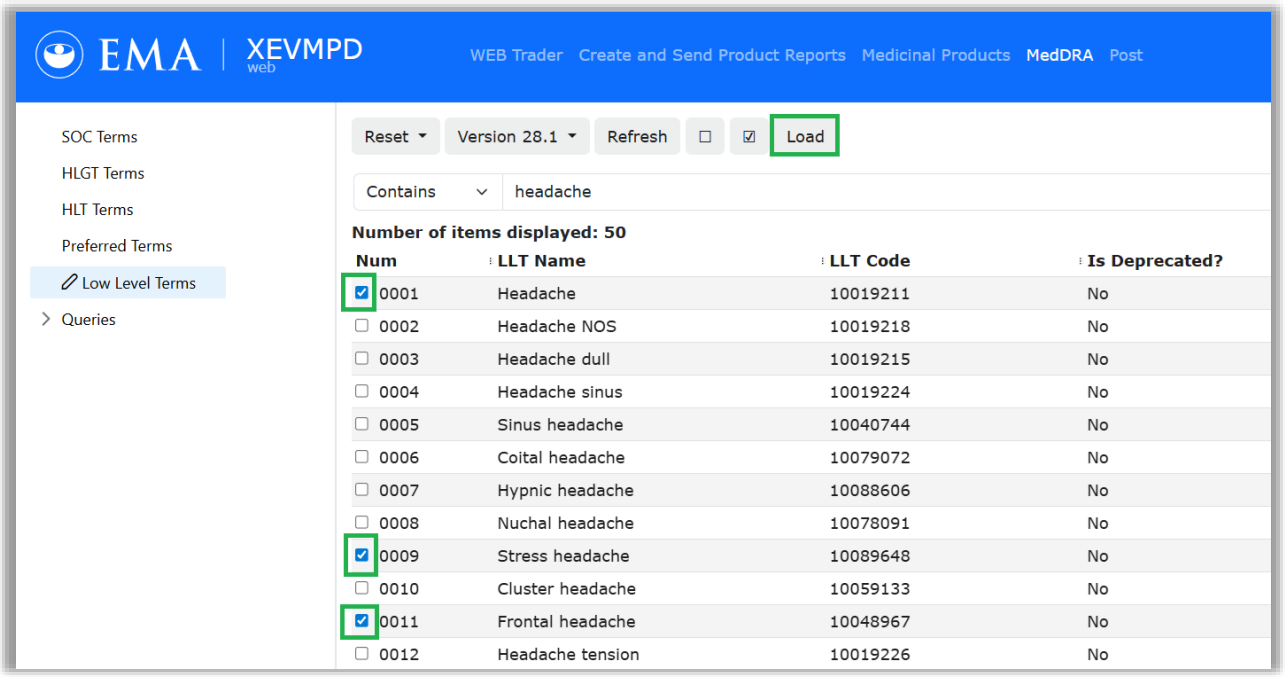
The filter(s) for the search within the required section, and the fields for which information should be provided as a result, can be selected via the 'Conditions' and 'Fields' sections.

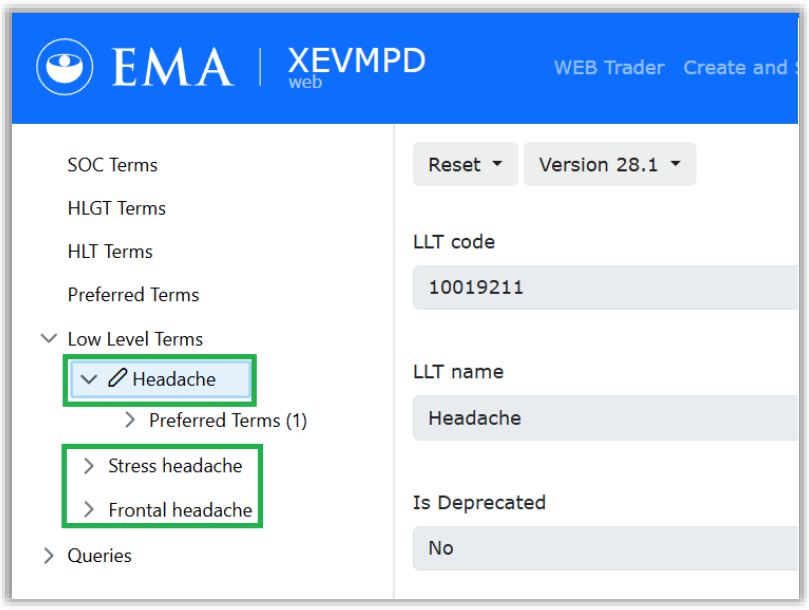
See section *3.7.2. Advanced query* for further information.

7.3. Export of MedDRA terms

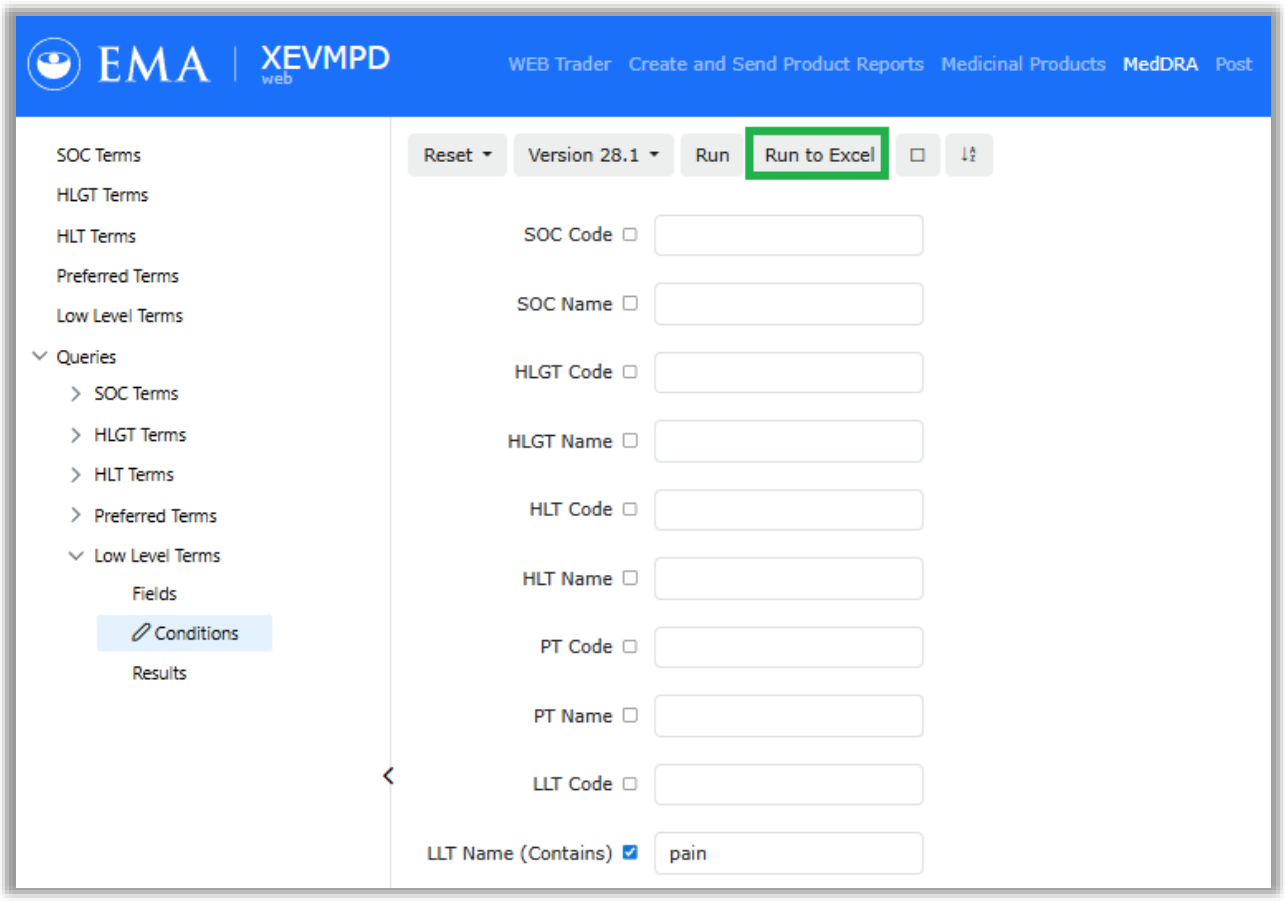
It is not possible to export results of a simple query performed in the MedDRA section.

When a simple query is performed, the results will be displayed in the active area, from where they can be uploaded in the tree-view area using the check-box option and 'Load' functionality combination:



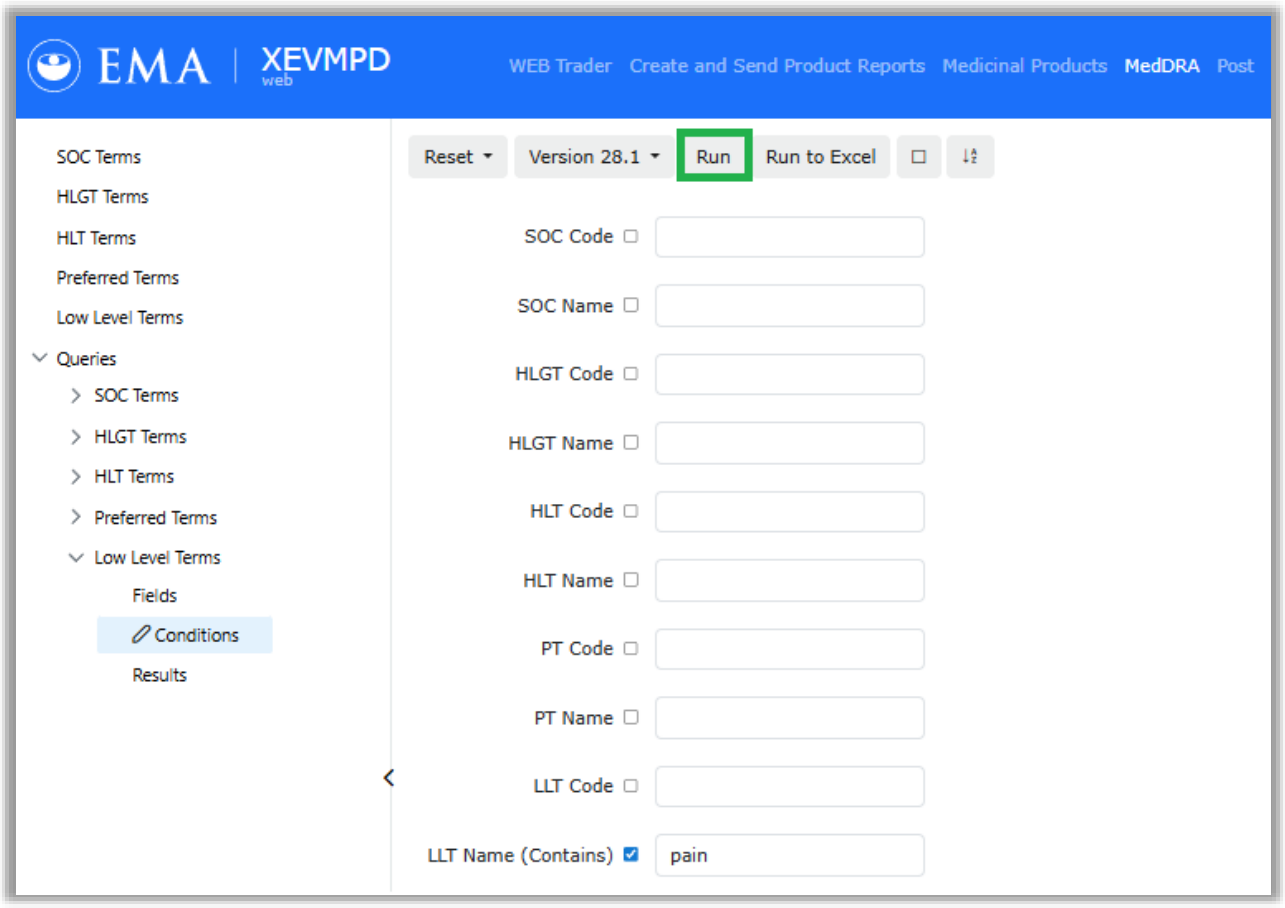


Results of advanced query can be sent directly to an Excel spreadsheet, without being displayed in the active area first, via the **'Run to Excel'** functionality:

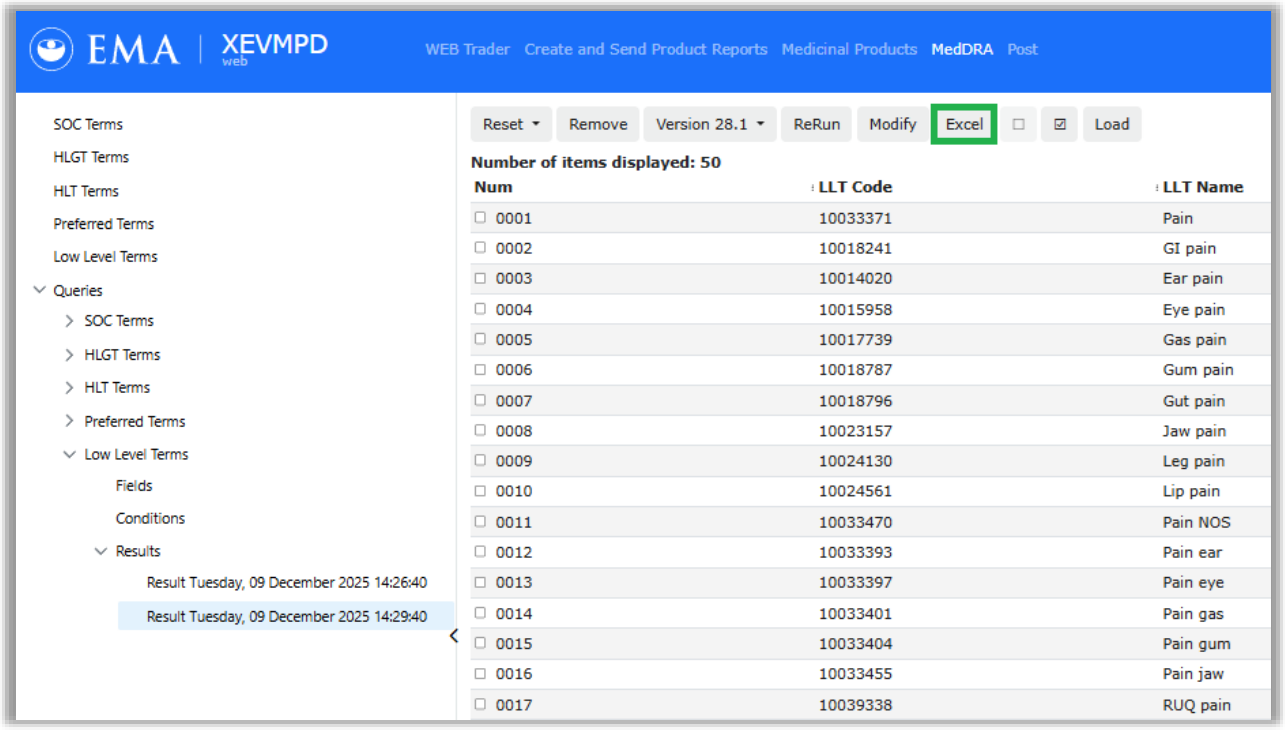


The exported Excel file(s) will become available in the 'Downloads' folder of the browser used to access XEVMPDweb by the user.

If the user wishes to view the results in the active area first and then export some, or all, of the displayed results into one of the available formats, the query should be executed via the **'Run'** functionality:

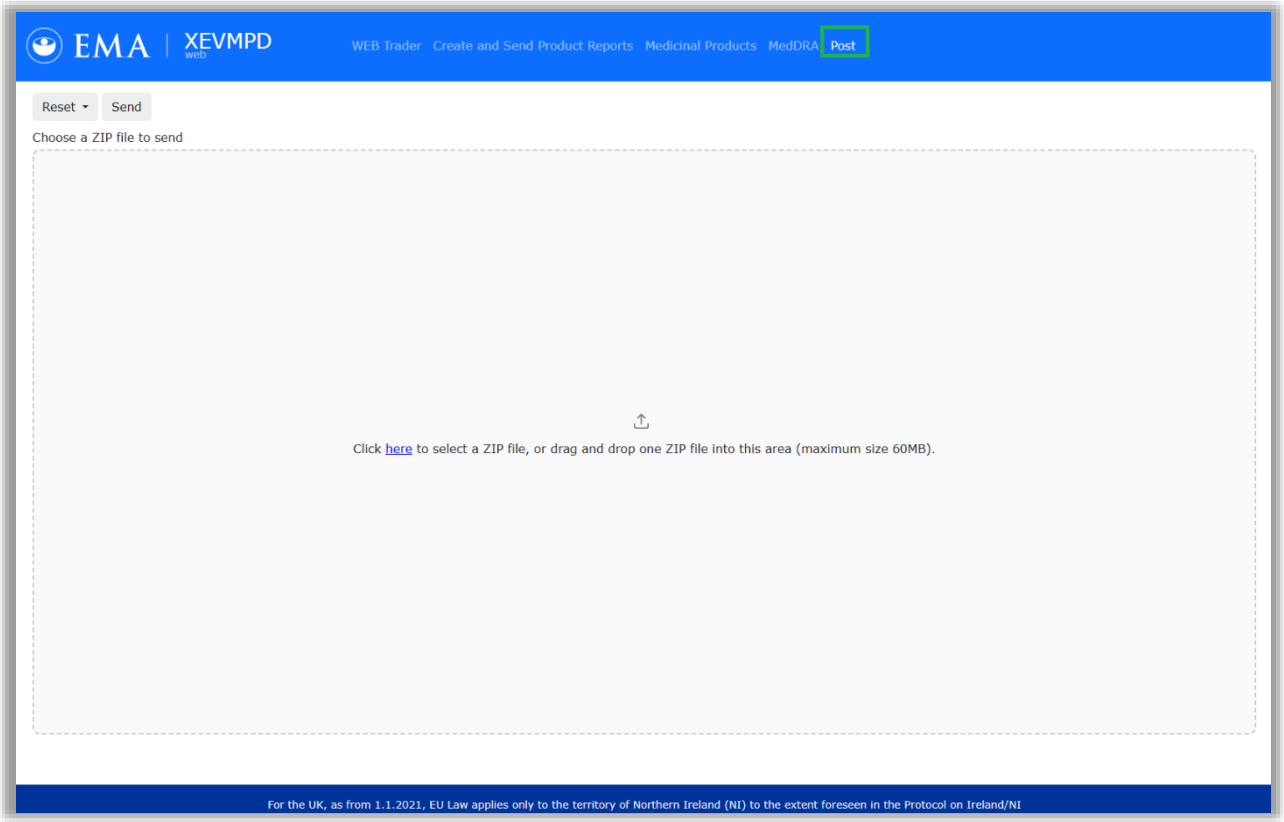


Once the results are displayed in the active area, the results (50 max) can be exported into one Excel File:



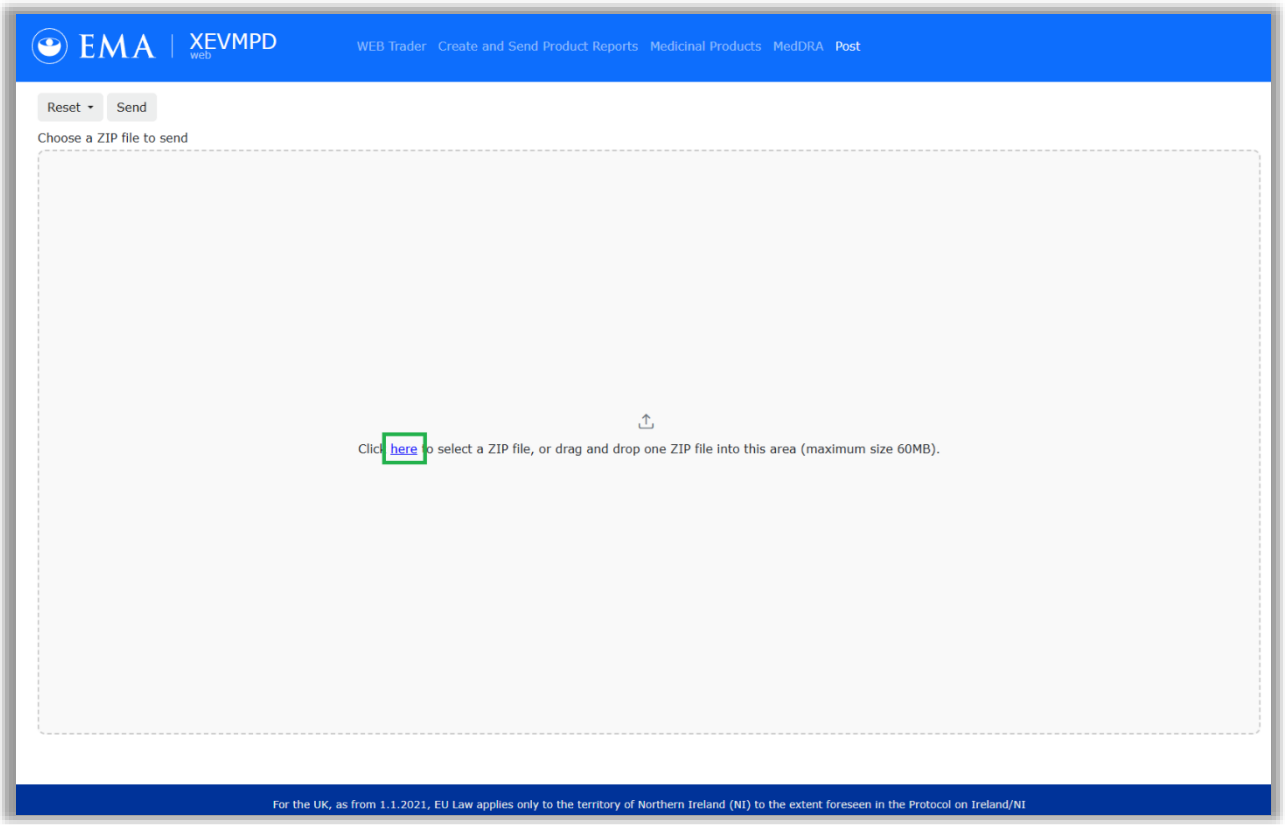
The file can then be retrieved from the 'Downloads' folder of the browser used to access XEVMPDweb by the user.

8. 'Post' section

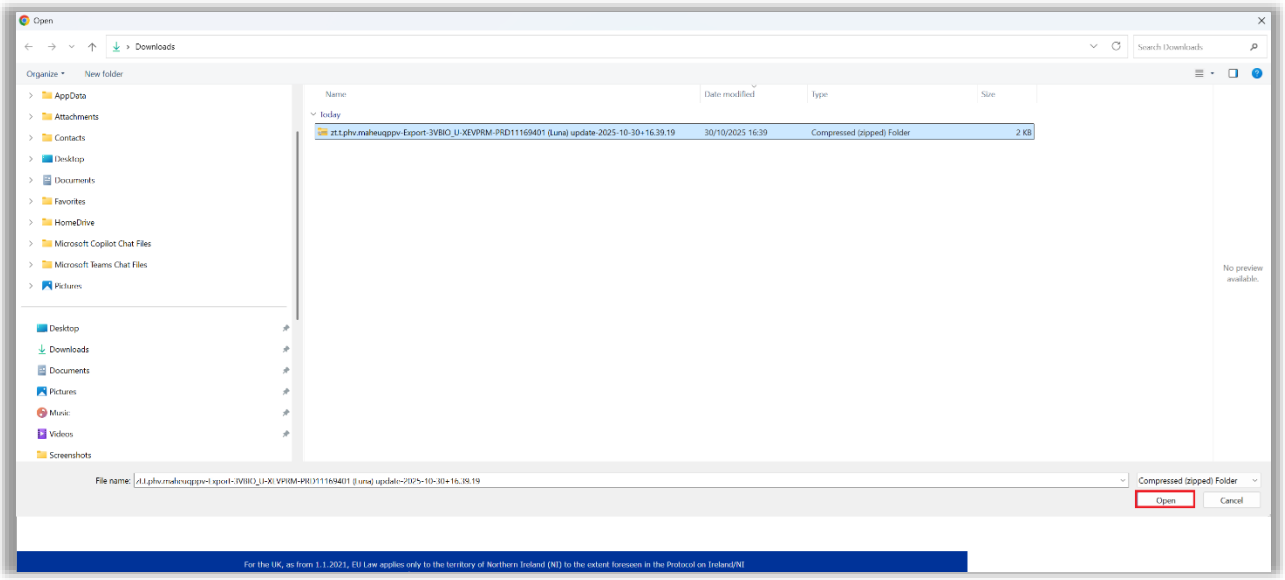


To submit a ZIP file containing an XML file of an XEVPRM with or without any attachment(s), go to the *'Post'* section of XEVMPDweb. The size of the ZIP file must be maximum 60MB.

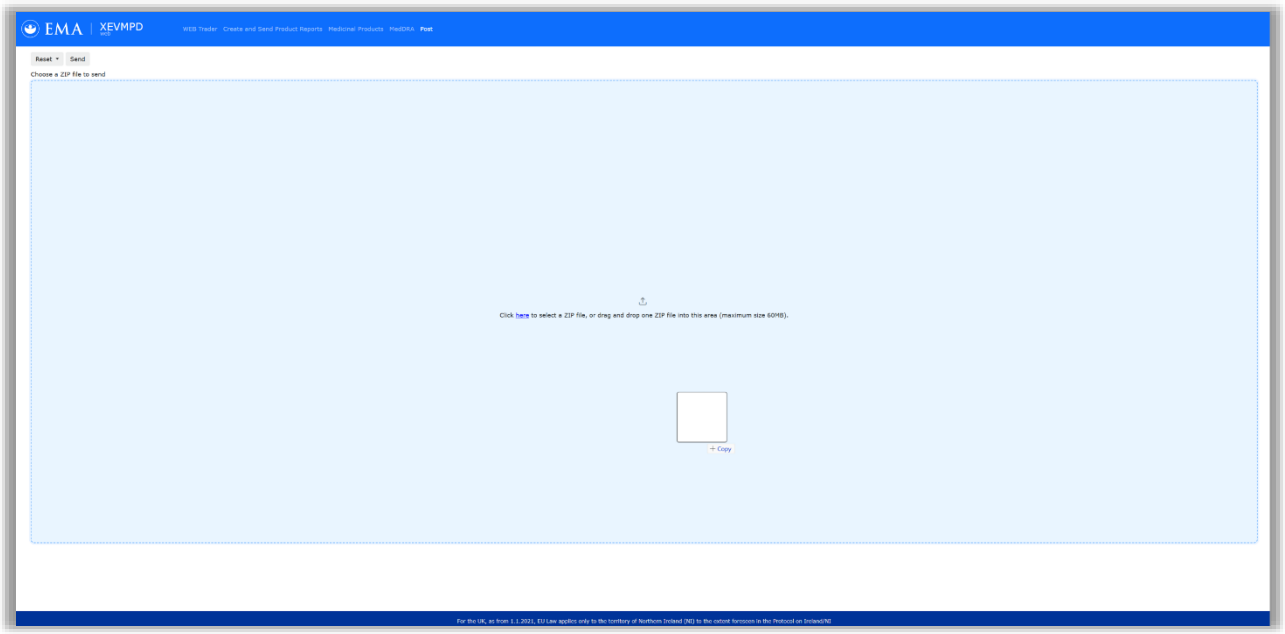
Click on the text 'here':



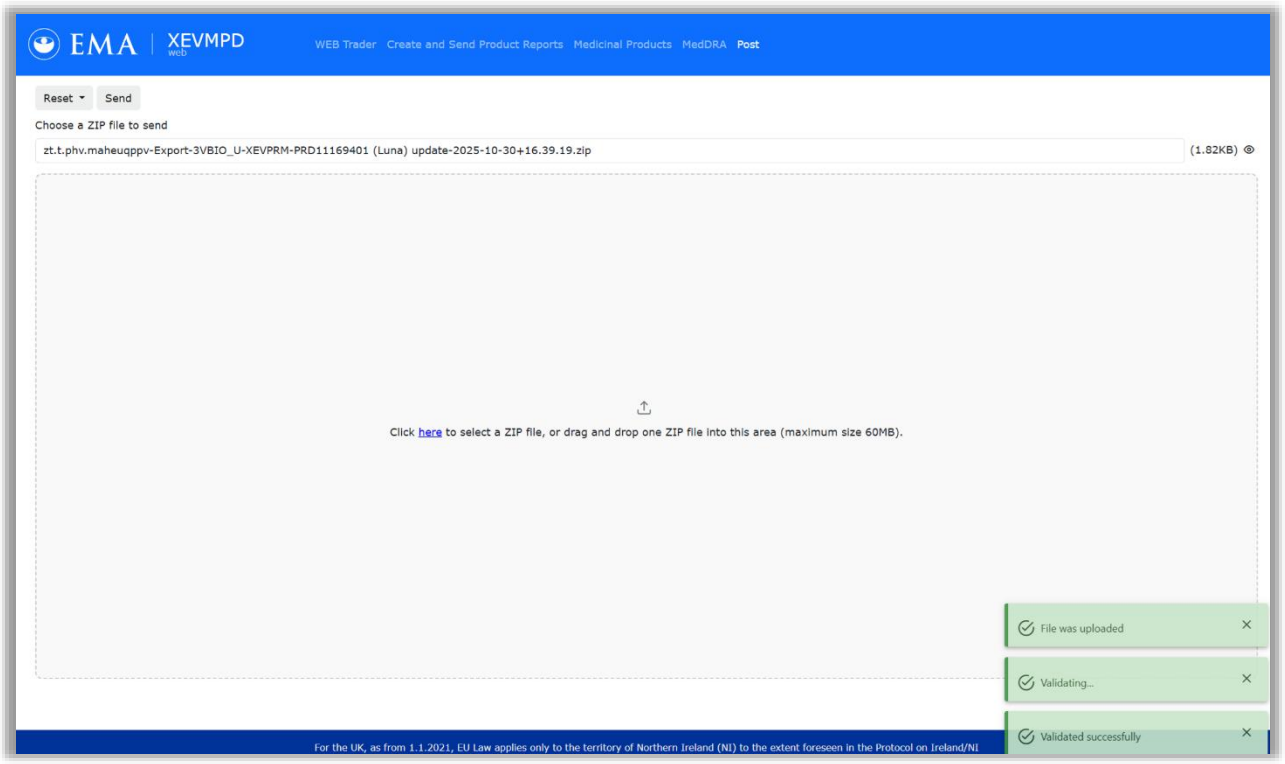
When a new window opens, select the Zip file that you wish to submit and then click on 'Send':



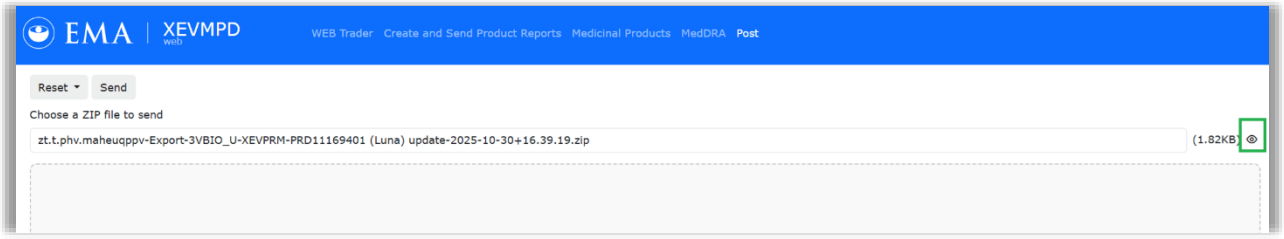
You can also use the "drag and drop" method, where you select a file on your computer, drag it to the 'Post' screen and drop it in the middle of the screen:



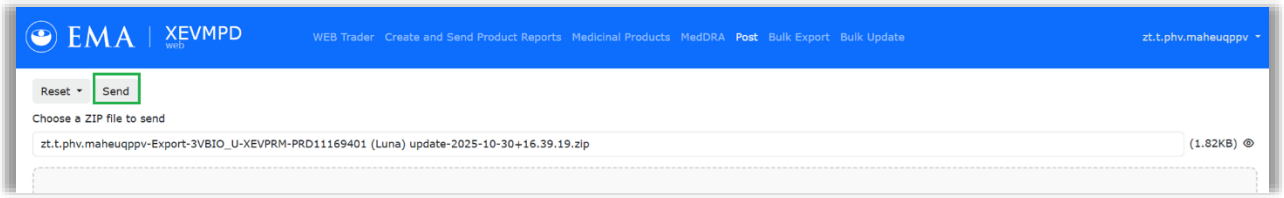
The Zip file name will be displayed at the top of the section, and the system will perform a validation of the selected file. The result of the validation will be displayed in the right-hand corner of the screen:



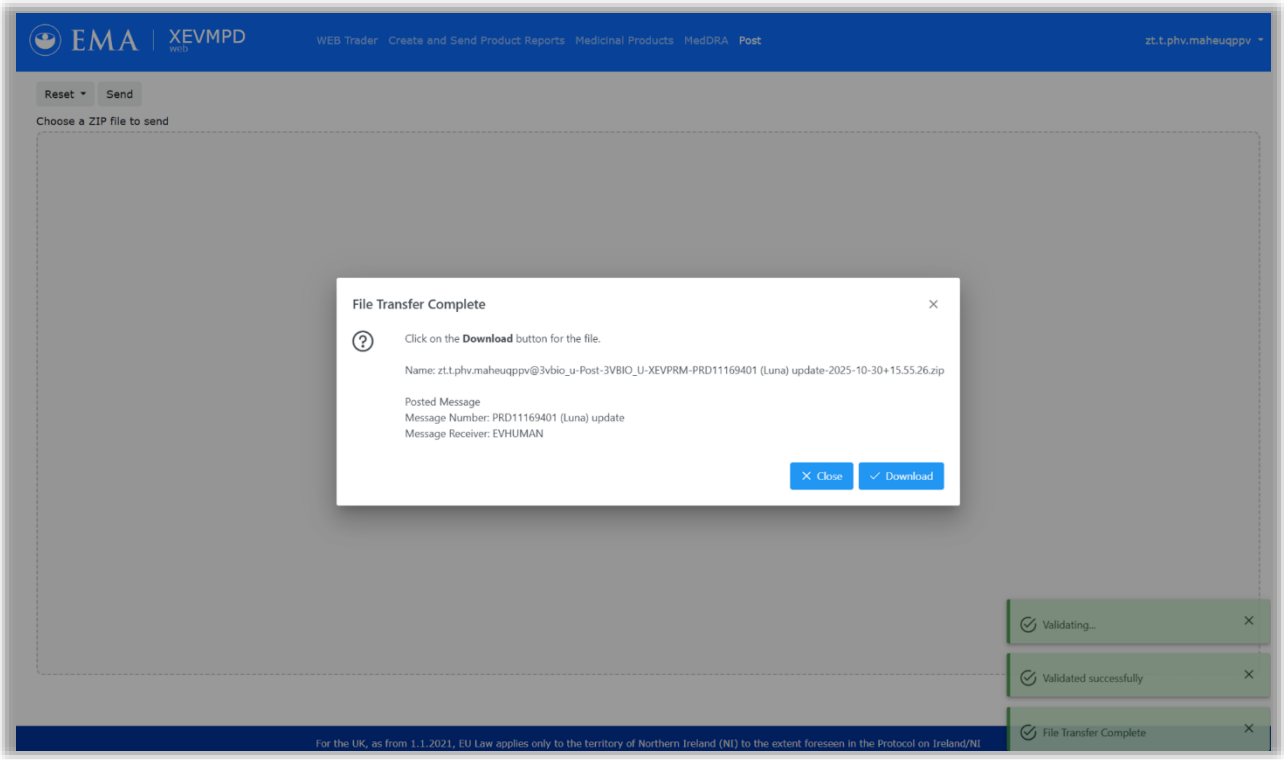
It is possible to review the file by clicking on the eye symbol next to the file name; the system will send the file to the 'Downloads' folder in the user's browser, where it can be reviewed:



If no errors are reported, the file can be submitted by clicking on the 'Send' functionality:



The system will perform another validation and a new window will appear on the screen confirming if the file transfer was completed and enabling the user to download the submitted ZIP file or to close the message:



- Web Trader users can retrieve the submitted ZIP file in the 'Web Trader' Outbox.
- Gateway users should check with their Gateway provider where the submitted file can be found.

9. EMA Contact points

Support related to submission of information in the XEVMPD is provided via the EMA Service desk[7].

- Request (for) XEVMPD/Art.57 Services should be submitted to request:
  - **XEVMPD data**, such as an EV Code of an AMP, a copy of an XEVPRM ACK if not received by the MAH etc.
  - **Support with XEVMPD data management**, such as: nullification of validated entries, amendment of data in the XEVMPD on behalf of the MAH organisation (e.g. a correction of information in invalidated AMPs, change of authorisation status of an AMP record back to valid in case of incorrect invalidation of the AMP entity), data correction in case the MAH does not agree with the change(s) made as part of the validation the AMP performed by EMA data stewards.
  - **Registration for XEVMPD e-learning training**, e.g. initial registration for the knowledge evaluation, assessment of knowledge evaluation.

  The timeframe applicable to the XEVMPD support team/EMA data stewards to address such request is 5 working days since the ticket was assigned to the XEVMPD support team.
- Request for information referencing *"SPOR"* as the 'Service' and *"XEVMPD/Art.57"* as the 'Service Offering' should be raised to:
  - Submit notification of delay in the submission of AMP information in the XEVMPD within the 15/30 calendar day timeframe;
  - request information related to XEVMPD processes in use or guidance on how to submit data in XEVMPD;
  - request information on where to find XEVMPD submissions related information;
  - ask information about how to use XEVMPDweb;
  - enquire about XEVMPD e-learning training process (questions related to the initial registration, assessment evaluation, access to XCOMP for e-learning training purposes).

The timeframe applicable to the XEVMPD support team to respond to such request is 22 working days since the ticket was assigned to the XEVMPD support team.

- Report (of) a technical issue referencing *"SPOR"* as the 'Service' and the applicable 'Service Offering' should be submitted to notify the EMA of a **technical issue** with:
  - XEVMPD (production or XCOMP environment);
  - XEVMPD user interface;
  - XEVMPD additional tools (e.g., XEVMPD Data Export tool, XEVMPD Bulk update tool);
- Incident on Gateway Service should be submitted to report issues with EMA Gateway Services, including connection issues and delayed acknowledgments.

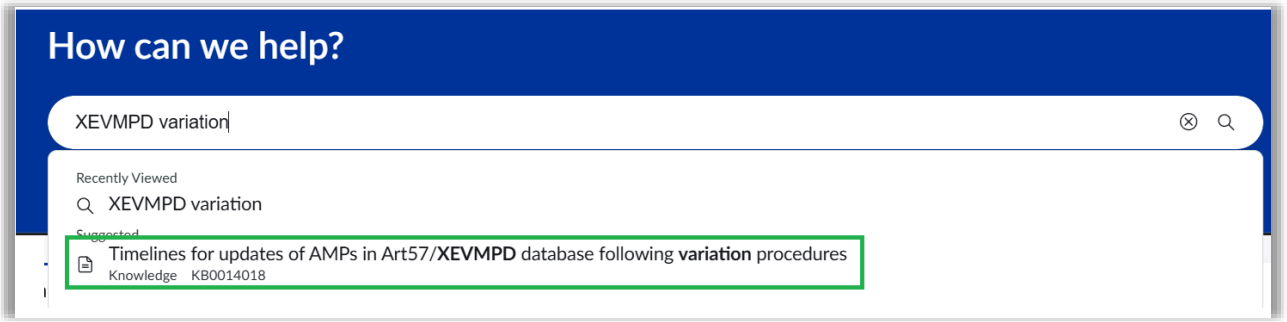
  The timeframe applicable to the responsible team to respond to such report is 5 working days since the ticket was assigned to the responsible team.

[7] As per EMA IT policy, IT support is only provided to users who use Edge or Chrome to access the XEVMPD User Interface.

Before submitting requests or questions via the Service Desk, users are encouraged to:

- search the available **knowledge articles** and **question and answers articles** in the ServiceNow portal to see if the required information is already available using the 'Search' panel in ServiceNow:

For example, searching for the keywords "XEVMPD variation" will retrieve the following result:



By clicking on the displayed results, users can view the whole article:

KB0014018

Timelines for updates of AMPs in Art57/XEVMPD database following variation procedures

• 11d ago • 5 Views • ☆☆☆☆☆

This article explains the timelines for updating authorised medicinal product (AMP) records in the Article 57 database following the approval of variations, and specifically Type IA variations and other variation types, for national authorisation procedures (NAPs) and mutual recognition procedures/decentralised procedures (MRPs/DCPs).

Variation Type IA

For NAPs:

- If the national competent authority **(NCA) provides an approval letter**: The 30-day timeline starts after the day the MAH receives the approval letter.
- If the **NCA does not provide an approval letter:** According to the variation legislation, the variation is considered approved 30 days after submission. Therefore, MAHs have 30 calendar days to update the product data in the Article 57 database after the 30 calendar days have passed since the submission.

For MRPs/DCPs:

- The same legislation applies as for NAPs (see above).

Best Practice Guidance:

- The reference member state (RMS) should notify the MAH when the variation is approved.
- If notification is not received within 30 days after the procedure starts (submission date), the variation can be deemed approved.

Additional Notes:

- The concerned member state(s) (CMSs) might not notify the MAH; however, if the RMS approved the variation (or has not indicated otherwise), the CMSs cannot reject the variation.
- Therefore, if the RMS has approved the variation, **all AMP EV Codes for all countries can be updated** (submit the English version of the SmPC and update with translated versions of the SmPC once approved).

Variation IAIN

For NAPs:

- The NCA should notify the MAH about the approval of the variation; therefore, the date of the notification marks the start of the 30-calendar day timeline for the update of the product data in the Article 57 database.

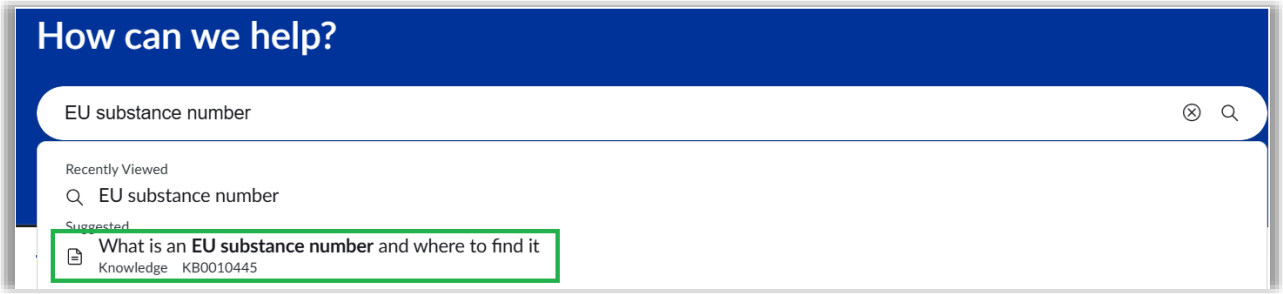
For MRPs/DCPs:

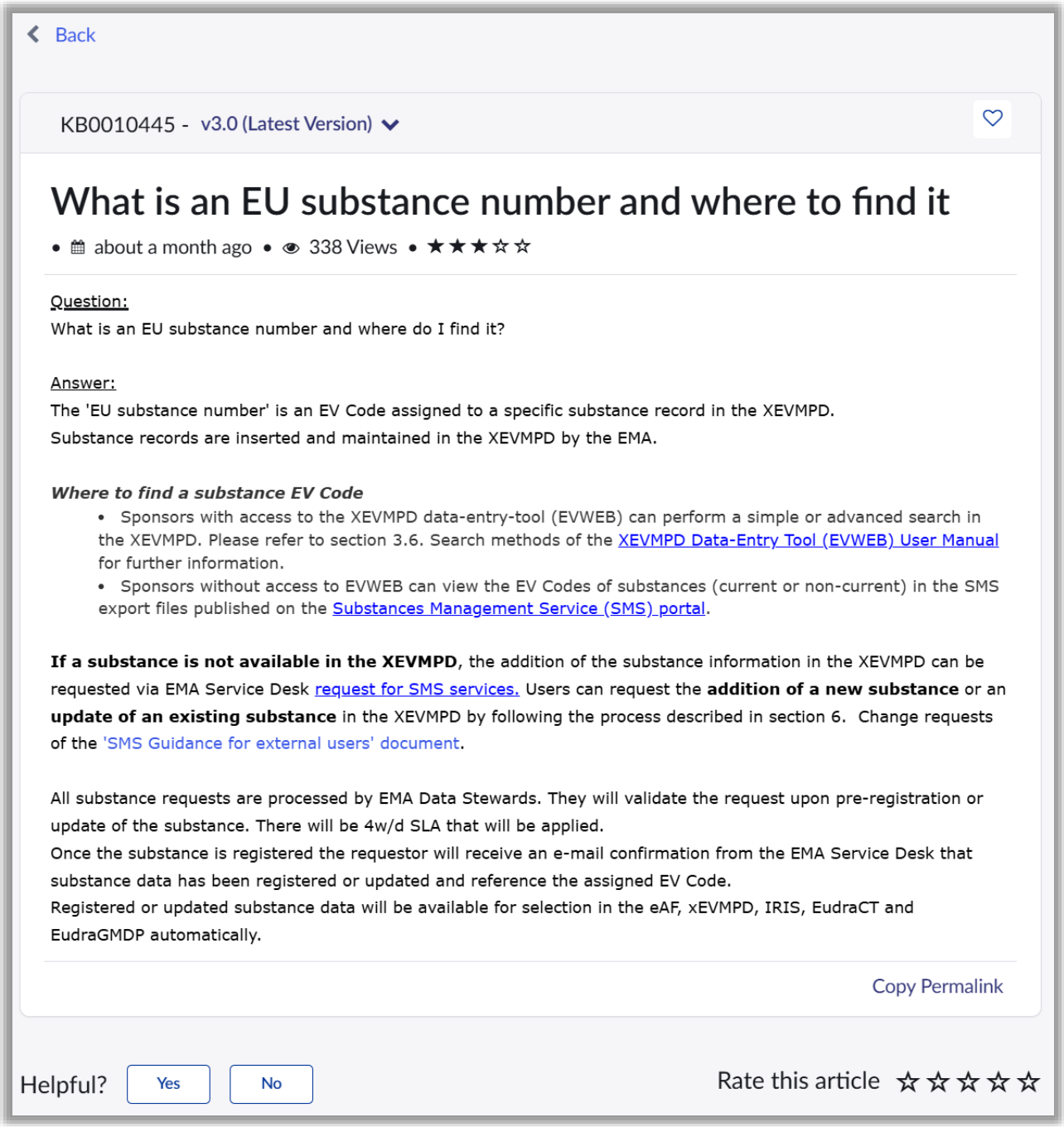
- The RMS should notify the MAH about the approval, which starts the 30-calendar day clock for the update of the product data in the Article 57 database.
- As before, since the CMSs cannot reject the variation, the MAH can **update all product records for all countries** in the Article 57 database with the common SmPC and later update the product records to reference the translated SmPC when authorised.

Copy Permalink

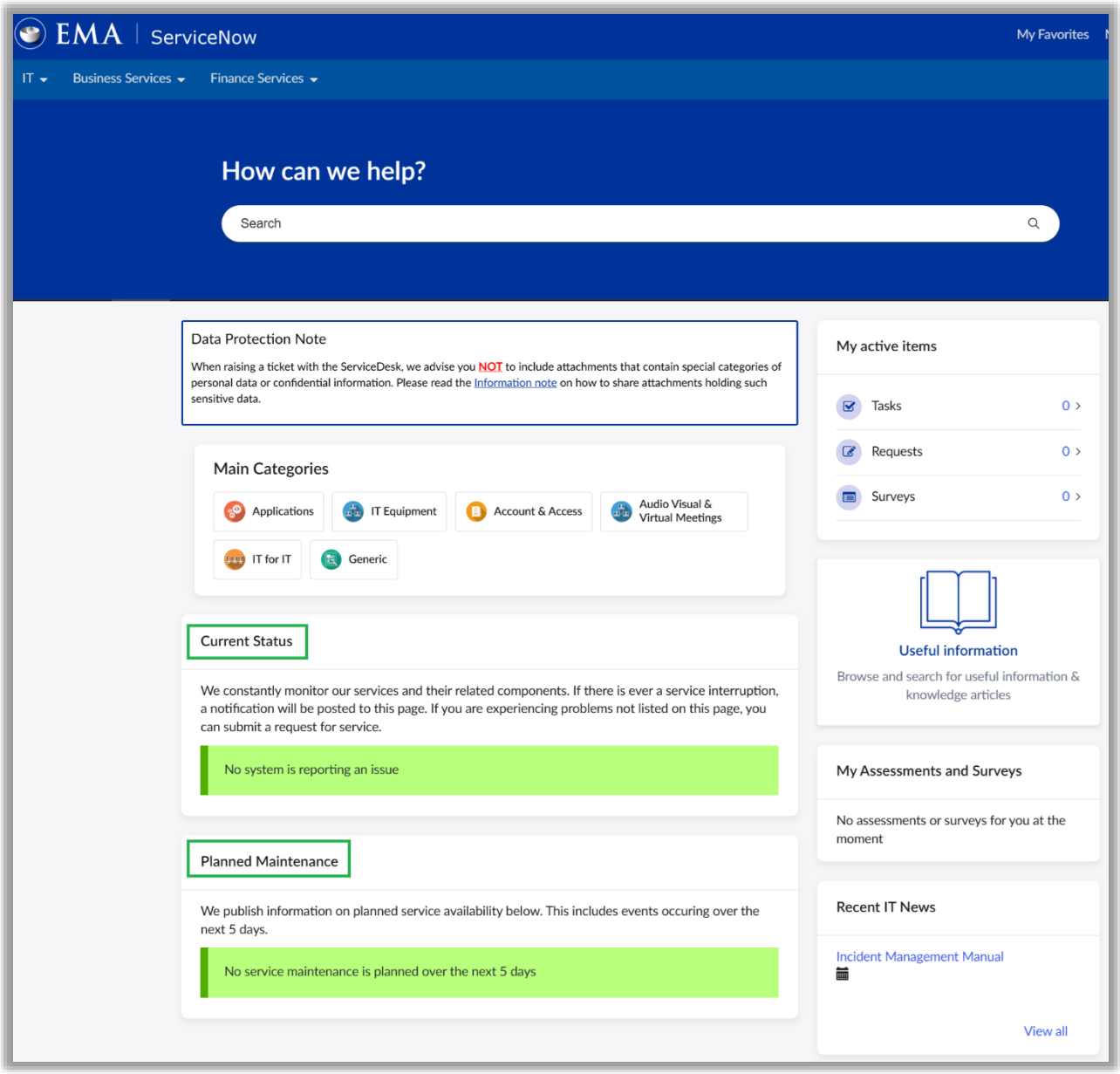
Helpful? Yes No

Rate this article ☆☆☆☆☆


How can we help?
EU substance number
Recently Viewed
EU substance number
Suggested
What is an EU substance number and where to find it
Knowledge KB0010445


Back
KB0010445 - v3.0 (Latest Version)
What is an EU substance number and where to find it
about a month ago
338 Views
Question:
What is an EU substance number and where do I find it?
Answer:
The 'EU substance number' is an EV Code assigned to a specific substance record in the XEVMPD.
Substance records are inserted and maintained in the XEVMPD by the EMA.
Where to find a substance EV Code
Sponsors with access to the XEVMPD data-entry-tool (EVWEB) can perform a simple or advanced search in the XEVMPD. Please refer to section 3.6. Search methods of the XEVMPD Data-Entry Tool (EVWEB) User Manual for further information.
Sponsors without access to EVWEB can view the EV Codes of substances (current or non-current) in the SMS export files published on the Substances Management Service (SMS) portal.
If a substance is not available in the XEVMPD, the addition of the substance information in the XEVMPD can be requested via EMA Service Desk request for SMS services. Users can request the addition of a new substance or an update of an existing substance in the XEVMPD by following the process described in section 6. Change requests of the 'SMS Guidance for external users' document.
All substance requests are processed by EMA Data Stewards. They will validate the request upon pre-registration or update of the substance. There will be 4w/d SLA that will be applied.
Once the substance is registered the requestor will receive an e-mail confirmation from the EMA Service Desk that substance data has been registered or updated and reference the assigned EV Code.
Registered or updated substance data will be available for selection in the eAF, xEVMPD, IRIS, EudraCT and EudraGMDP automatically.
Copy Permalink
Helpful?
Yes
No
Rate this article

- Check the 'Current Status' and 'Planned Maintenance' sections for announcements related to the EMA applications in use:



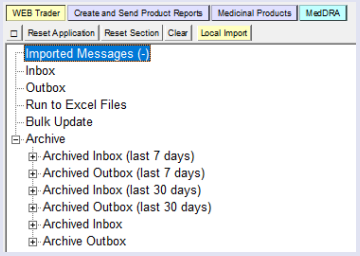
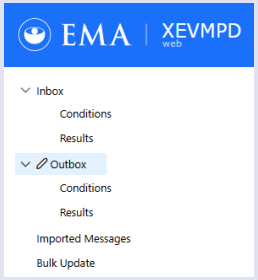
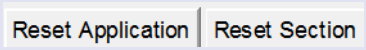
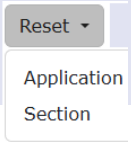
10. List of Abbreviations and Acronyms

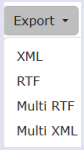
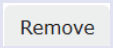
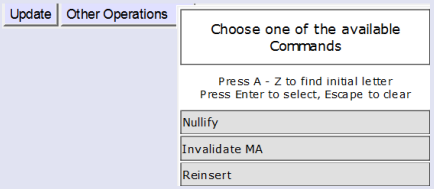
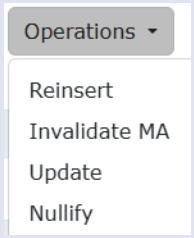
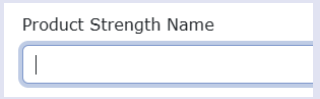
AMP	Authorised Medicinal Product
AS	Approved Substances
ATC	Anatomic Therapeutic Chemical (details at www.whocc.no)
CAS	Chemical Abstract Service (Number)
CAP	Centrally Approved Product
CBD	Chemical Biological Description
CV	Controlled Vocabulary
DBMS	Database Management System
DCP	Decentralised Procedure
DMP	Development Medicinal Product
DS	Development Substances
EEA	European Economic Area
EDI	Electronic Data Interchange
EDQM	European Directorate for the Quality of Medicines
EMA	European Medicines Agency
ESTRI	Electronic Standards for Transmission of Regulated Information (gateway technical specification)
EU	European Union
EVDBMS	EudraVigilance Database Management System
EVHUMAN	Unique Identifier of the EMA (for XEVMPD transmissions)
EVWEB	EudraVigilance web-based reporting application (XEVMPD Data Entry Tool)
EWG	Expert Working Group (in ICH or at the EMA)
FDIS	Final Draft International Standard (in ISO)
https	Hypertext Transfer Protocol Secure
ICSR	Individual Case Safety Report
ISO	International Standardization Organization
IM	Implementation Measure
IMP	Investigational Medicinal Product
INN	International Non-Proprietary Name
MAH	Marketing Authorization Holder

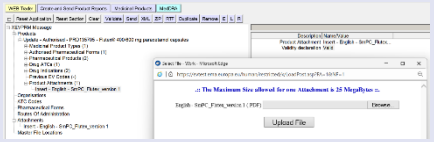
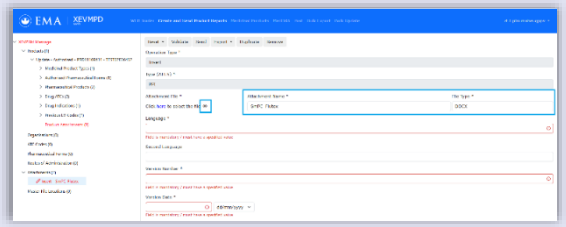
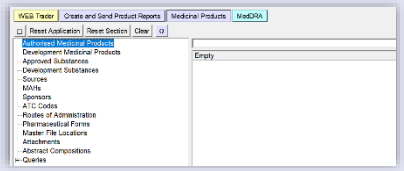
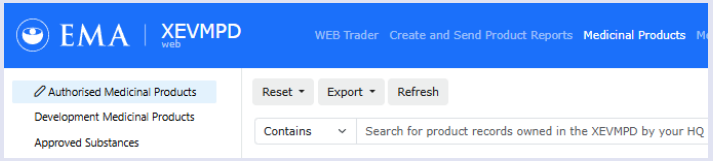
MDN	Message Disposition Notification
MedDRA	Medical Dictionary for Regulatory Activities
MFL	[Pharmacovigilance] Master File Location
MRP	Mutual Recognition Procedure
MS	Member State (in the EU)
MSSO	MedDRA Services and Support Organisation
NAP	Nationally Authorised Product
NCA	National Competent Authority
PF	Pharmaceutical Form
PIL	Product Information Leaflet
PL	Package Leaflet
PPI	Printed Product Information
PSI	Printed Substance Information
QPPV	Qualified Person responsible for Pharmacovigilance Activities
SME	Small and Medium Size Enterprise
SmPC or SPC	Summary of Product Characteristics
SSI	Structured Substance Information
SSL	Secure Socket Layer
UCUM	Unified Code for Units of Measure
XCOMP	EudraVigilance External Compliance Testing Environment (aka Test or Pre-Production Environment)
XHTML	eXtensible HyperText Markup Language
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary
XEVPRM	eXtended EudraVigilance Product Report Message
WHO	World Health Organisation
XSD	XML Schema Definition
ZIP file	Zipped compressed file

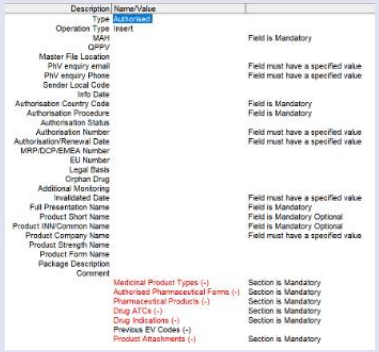
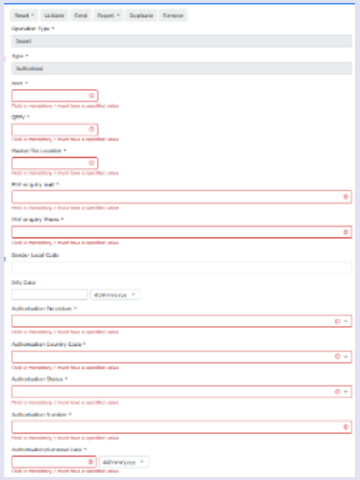
Annex I: Overview of main differences between the current and new UI

This section provides an overview of some the main differences between the XEVMPD User Interface (EVWEB - Art 57 / XEVMPD) in use since 2004 and the new XEVMPD User Interface (XEVMPDweb) in use since February 2026.

Change description	Current	New
ActiveX and IE Tab extension are no longer required to access the new user interface		
'EV Post – Art57/XEVMPD' functionality is now also available as a new section within XEVMPDweb. Users can either continue to use the functionality in the EV Restricted area or use the functionality in the new XEVMPDweb.		
'Archive' section within the Web Trader section was removed; users can search for all of the XEVPRMs and XEVPRM Acknowledgemets submitted and received by their organisation, via the advanced queries option.		
'Reset Application' and 'Reset Section' are available under 'Reset'		

Change description	Current	New
XML/ZIP/RTF export options are now available under 'Export'		
'Replicate' functionality removed, as it shares the same functionality as 'Duplicate'		
'Clear' is replaced by 'Remove'		
'Other Operations' is now re-named to 'Operations' and 'Update' is moved under 'Operations'		
'L' (for Local look-up) and 'R' (for Remote look-up) are now presented within the look up field		
'E' (for Edit) was removed as no longer required; free-text fields are activated by clicking inside the field and typing		

Change description	Current	New
The Master File Location field has been flagged as a mandatory field by a technical rule (not just a business rule, as it was to date)	Master File Location	Master File Location * Field is mandatory / must have a specified value
An attachment file is added to the XEVPRM during the insert of the attachment entity (not as the last step post-XEVPRM submission); the attachment details (name and format) are automatically populated by the system based on the information of the actual file, when uploaded		
The simple search field provides a tool tips on the information that can be retrieved for the selected entity type		
Remote look-up fields referenced within product entities now reference also the codes (EV Code, QPPV Code) and not only the name of the referenced entity	MAH MAHNEWX QPPV Veronika Baker (XMPDTRAIN) Master File Location ES - Burgos	MAH * ORG46211 NEW ORG DELTA MAH QPPV * 7502467 John Noname (3VBIO_U) Master File Location * MFL21007 CZ - MyCity

Change description	Current	New
Export files (XML, ZIP, RTF, Excel) must be retrieved from the 'Downloads' folder of the browser used to access the UI		
The layout of the active area in the 'Create and Send Product Reports' has changed due to the format used to create the new UI		
Excel files with exported data are no longer retrievable via a pop-up window displayed on the screens, these are sent to the 'Downloads' folder of the browser used by the user