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Information Management

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

Maintenance operations: Nullification of development medicinal product (DMP) entity in the XEVMPD

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Product and sponsor information used in this step-by-step guide is fictitious and intended for demonstration purposes only.

1.1. Example specifications

For the purpose of this step-by-step exercise, we will be nullifying our previously submitted DMP with the product name 'ProductX 100ml solution' available in the XEVMPD with the assigned EV Code PRD126017, as it is a duplicate of the same medicinal product with the assigned EV Code PRD126007.

The product information was submitted in the XEVMPD twice, due to error.

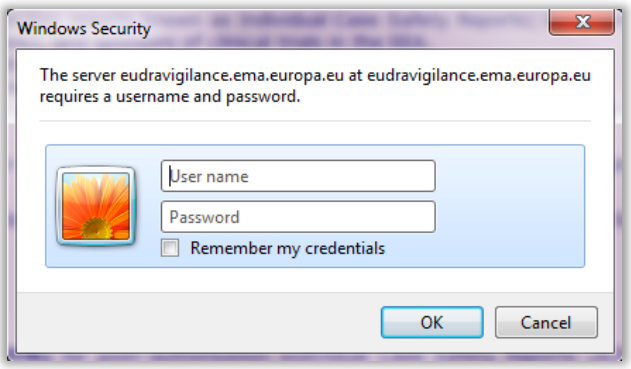
1.2. Retrieve the DMP entity in the XEVMPD

1) Log in to the requested EVWEB environment:

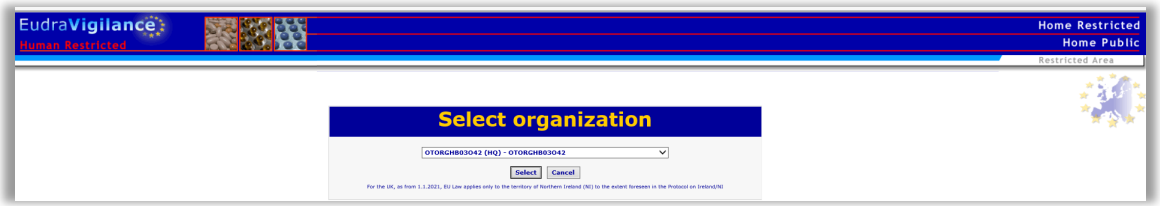
EVWEB production: https://eudravigilance.ema.europa.eu/x

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

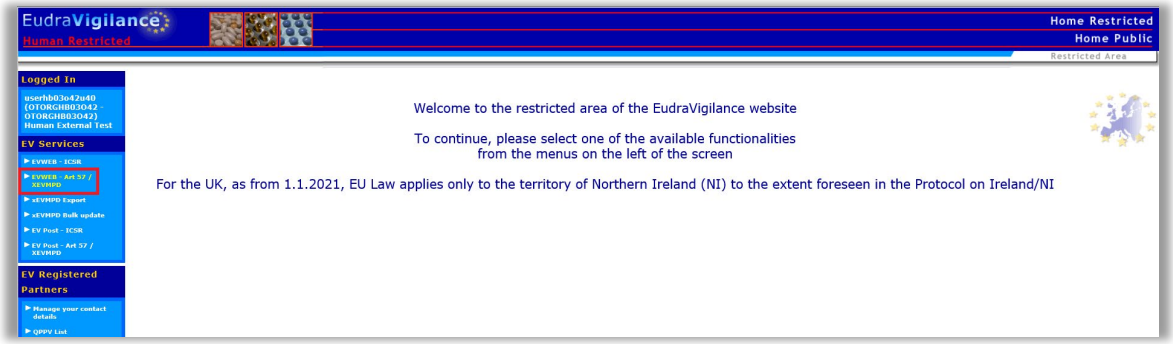
EVWEB training environment: https://eudravigilance-training.ema.europa.eu/x/



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



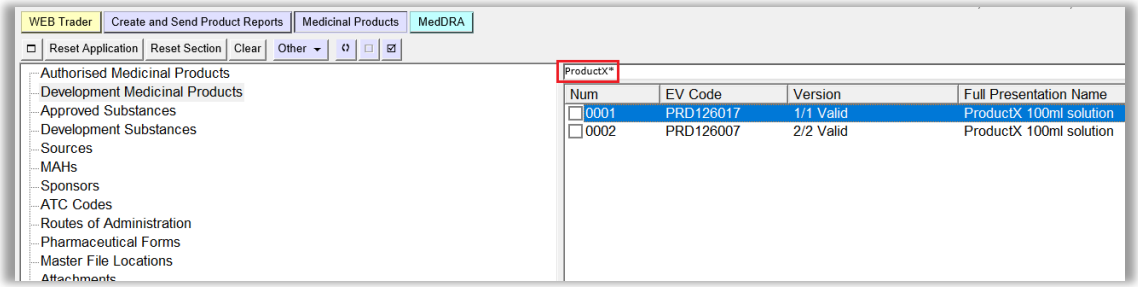
3) In the restricted area, click on 'EVWEB - Art 57 / XEVMPD':



You are now logged in EVWEB; the organisation ID, under which you are logged on, is shown in the top right-hand corner:

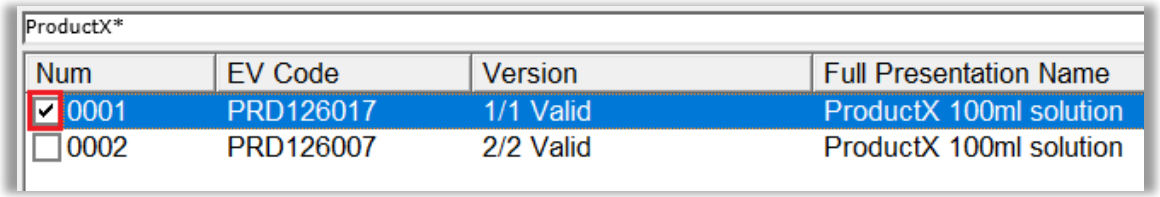
4) Go to the 'Medicinal Products' section and using the simple or advanced query, retrieve the specific product entry.

For this demonstration, the search is performed for a DMP with part of the name 'ProductX' using the simple query field:

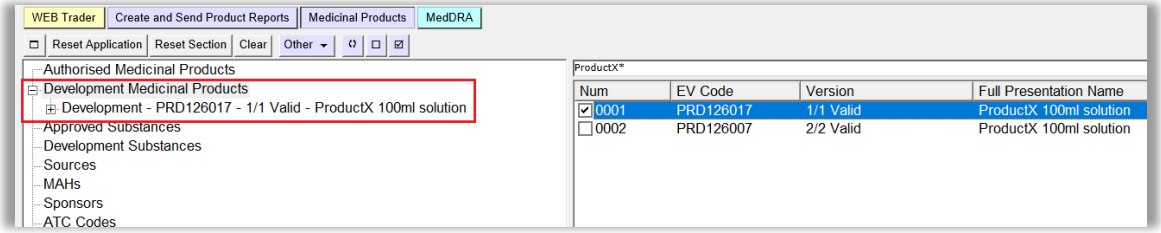


5) The search brings up two DMP records; PRD126017 and PRD126007. As per our example, PRD126017 is a duplicate of PRD126007 and must therefore be nullified.

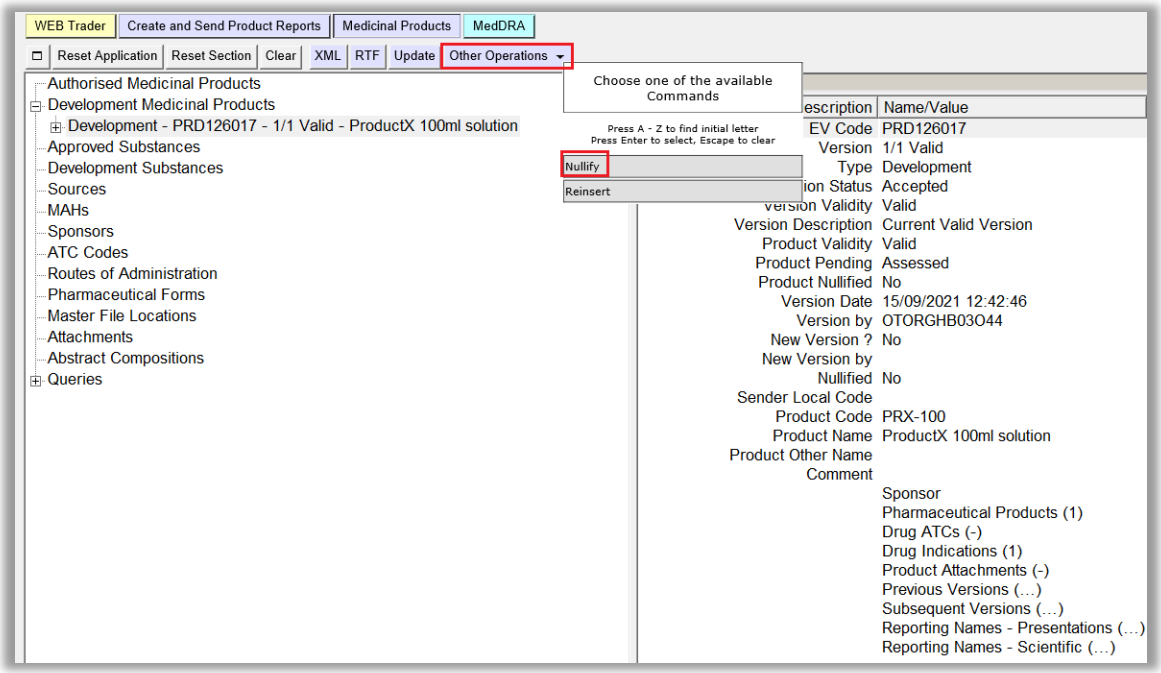
Select the required medicinal product entity for nullification by ticking the relevant tick-box in the active area:



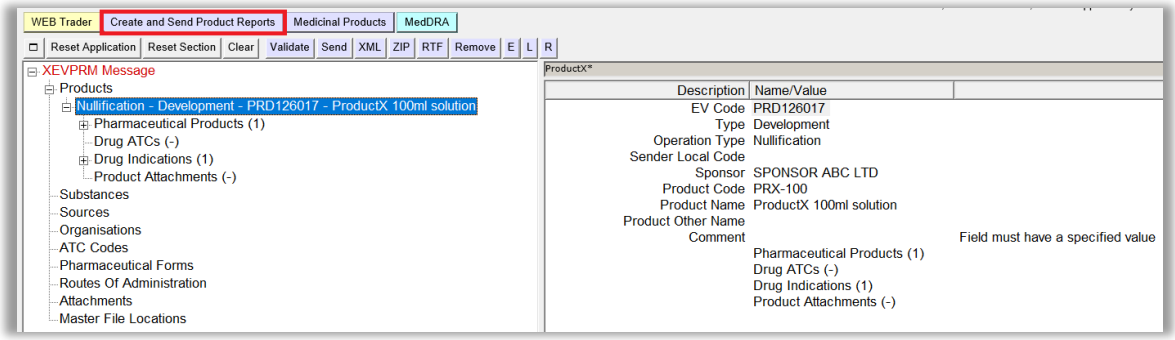
The product will become available in the tree-view area:



6) Click on the product EV Code in the tree-view area; the product details will be displayed in the active area and the operation type buttons, applicable for this DMP, will also become available. In 'Other Operations' select operation type 'Nullify':

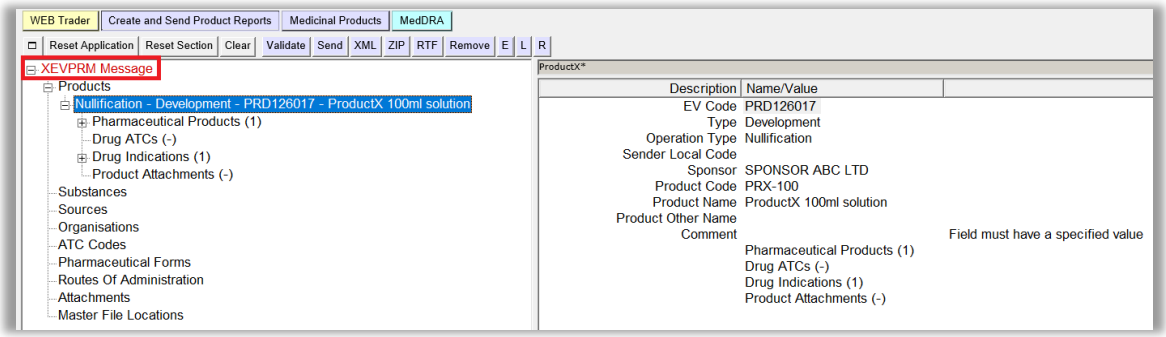


By clicking on the 'Nullify' option, the DMP entity will be moved from the 'Medicinal Products' section to the 'Create and Send Product Reports' section:

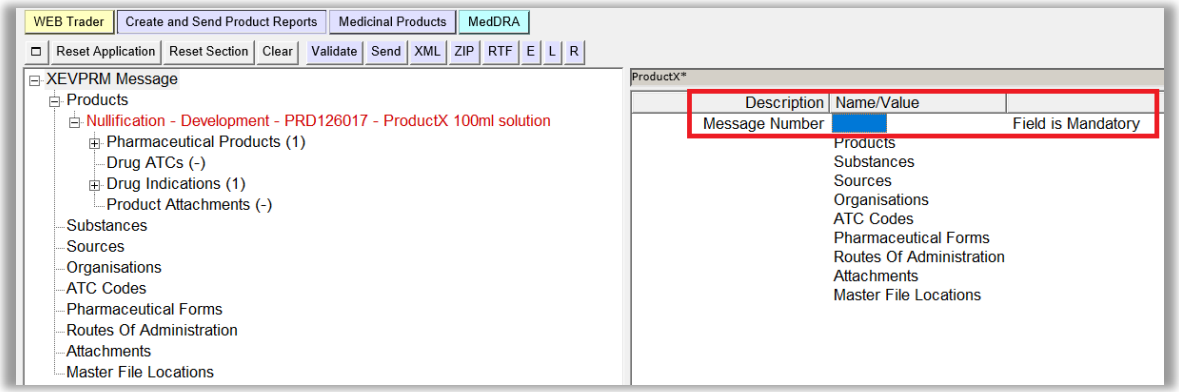


1.3. Create an XEVPRM

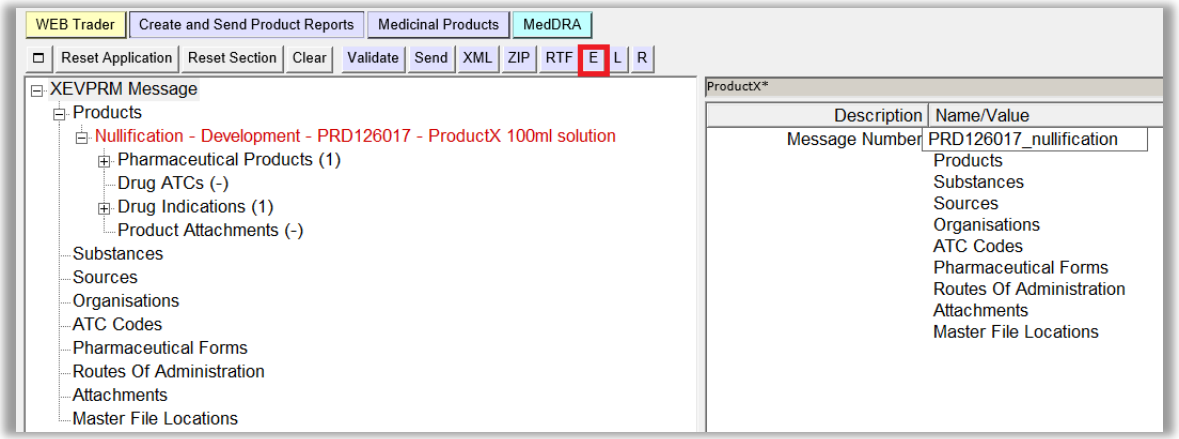
1) Click on the 'XEVPRM Message' text in your tree-view area:



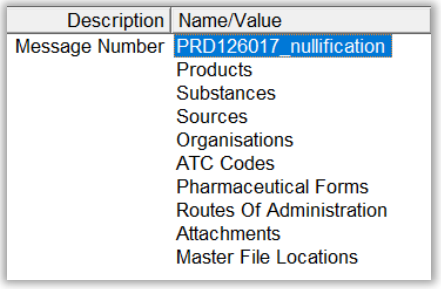
The active area will show the 'XEVPRM Number' field; the area next to the 'Message Number' will be highlighted in blue:



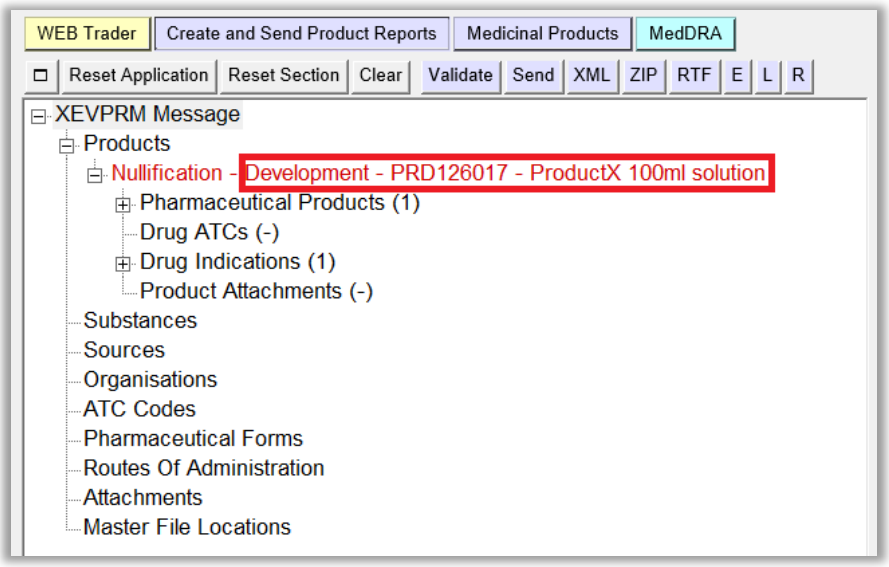
2) Click on the 'E' (Text Edit) button or use 'Enter' on your keyboard to activate the field, and you will be able to write the name/number that you wish to assign to you XEVPRM:



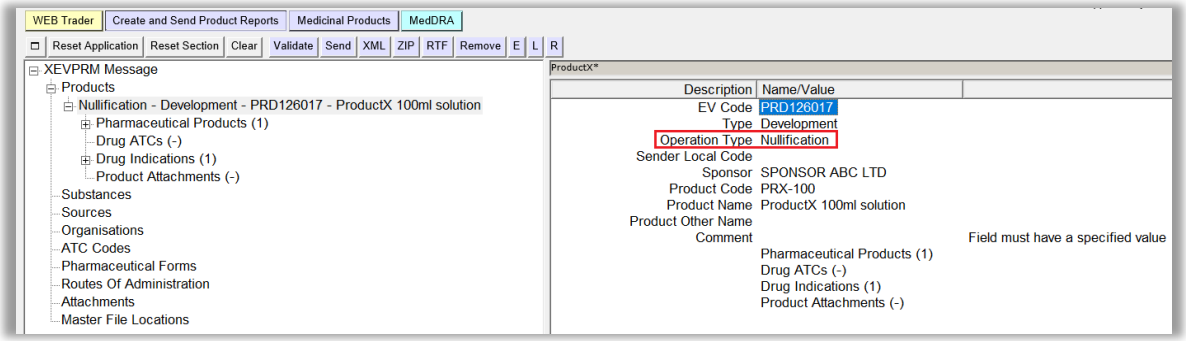
3) Once you enter the required message number press 'Enter'; the text that you entered will appear in blue:



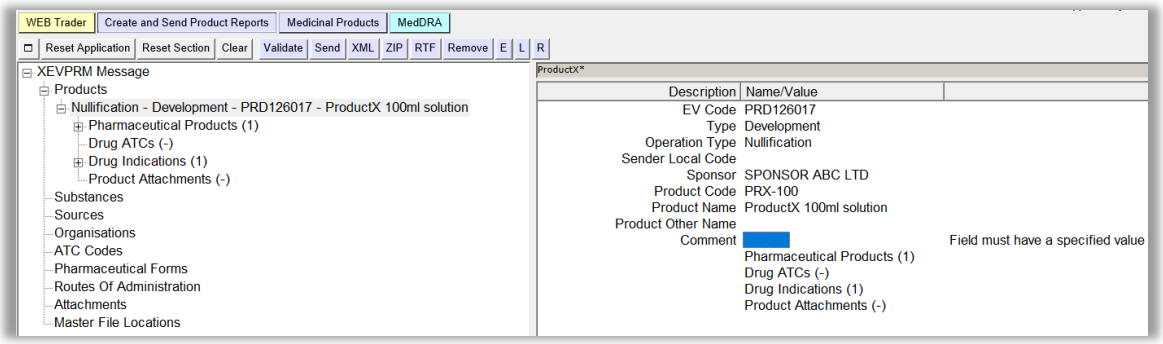
4) In the tree-view area, click on the product EV Code/name:



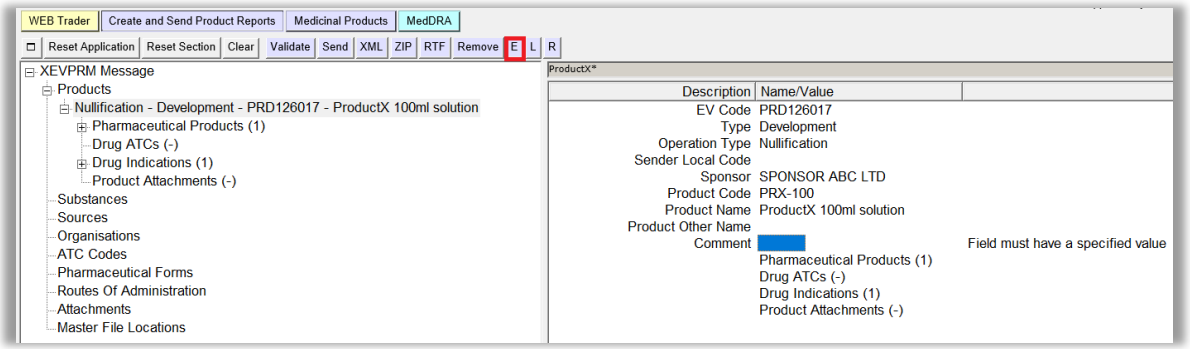
The active area will display the fields of your DMP; the 'Operation type' field displays 'Nullification' as default. It is not possible to assign a different operation type.



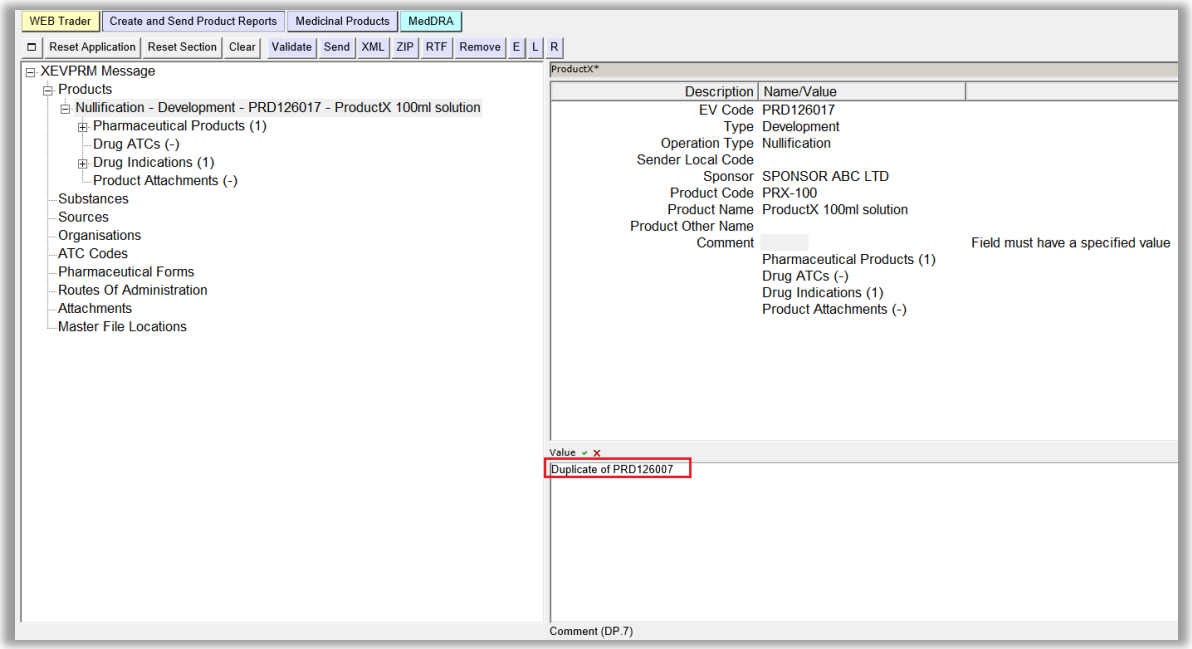
5) As per our specific example, we are nullifying the product entity. In accordance with the applicable business rules, we must enter the reason for nullification in the 'Comment' field. To do so, click on the area next to the 'Comment' field. The area will be highlighted in blue:

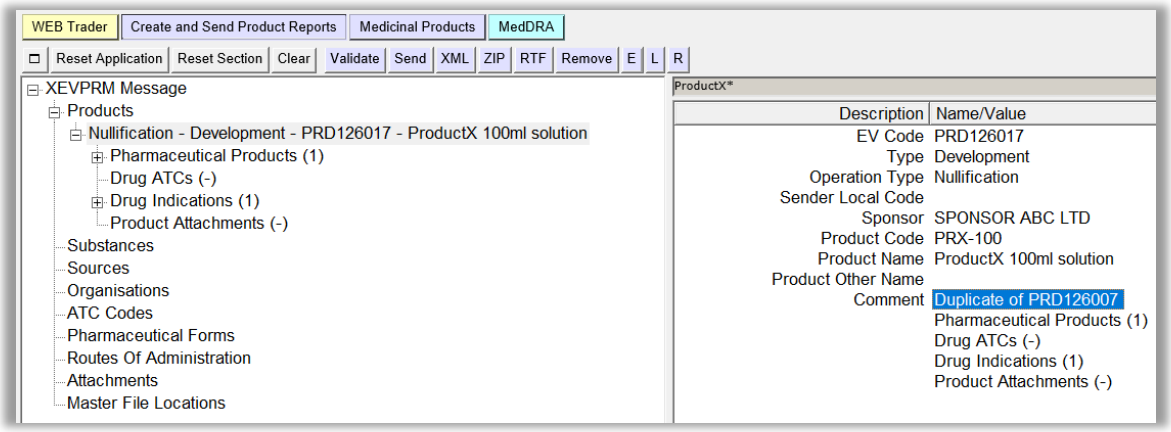


6) Press 'Enter' on your keyboard or click on the 'E' (Text Edit) button:



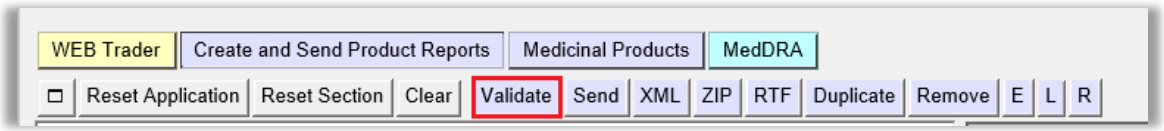
7) Type in the required text, then press 'Enter' on your keyboard; the text will be displayed in the relevant field:




WEB Trader
Create and Send Product Reports
Medicinal Products
MedDRA
Reset Application
Reset Section
Clear
Validate
Send
XML
ZIP
RTF
Remove
E
L
R
XEVPRM Message
Products
Nullification - Development - PRD126017 - ProductX 100ml solution
Pharmaceutical Products (1)
Drug ATCs (-)
Drug Indications (1)
Product Attachments (-)
Substances
Sources
Organisations
ATC Codes
Pharmaceutical Forms
Routes Of Administration
Attachments
Master File Locations
ProductX*
Description
Name/Value
EV Code PRD126017
Type Development
Operation Type Nullification
Sender Local Code
Sponsor SPONSOR ABC LTD
Product Code PRX-100
Product Name ProductX 100ml solution
Product Other Name
Comment Duplicate of PRD126007
Pharmaceutical Products (1)
Drug ATCs (-)
Drug Indications (1)
Product Attachments (-)

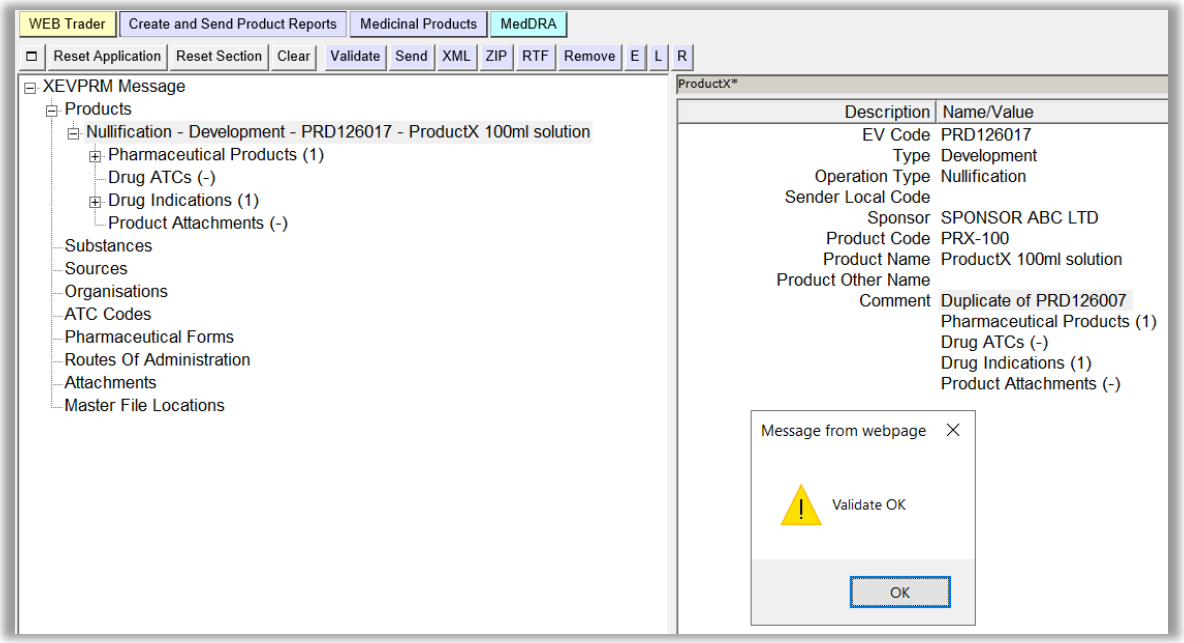
1.4. Validate and send an XEVPRM

1) Validate your XEVPRM by clicking on the 'Validate' button:



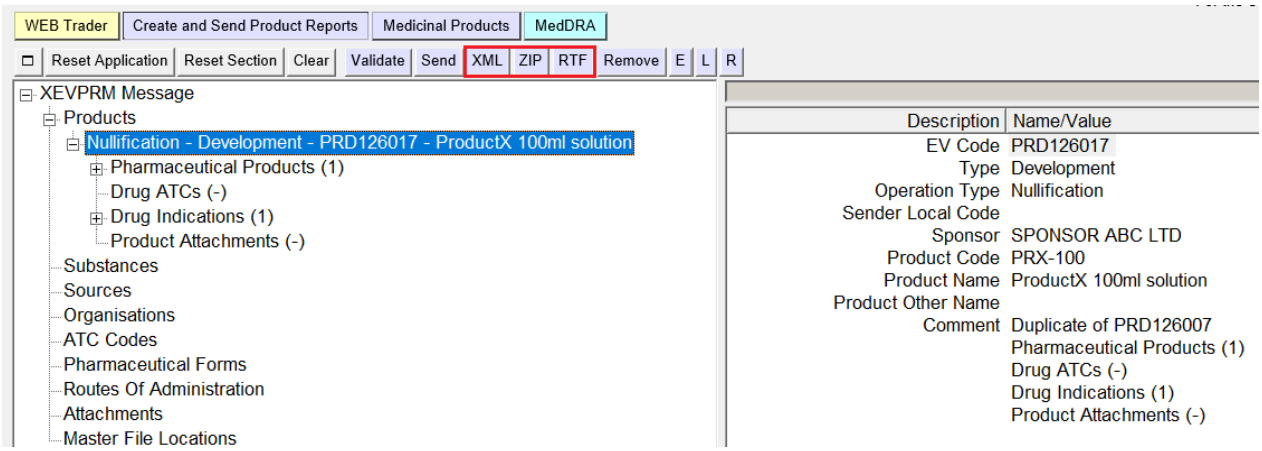
In case of any errors, a warning message will be displayed. The section(s), where the error(s) occurred will be highlighted in red and/or the fields where information is missing will contain the text 'Field is Mandatory'/'Field must have a specific value'/'Field is Mandatory Optional'. To correct the error(s), you should press 'OK' on the warning message or click on the area highlighted in red in the tree-view area.

2) Since we are performing a nullification of a DMP entity and we provided the required information for the 'Comment' field, the validation did not report any errors:

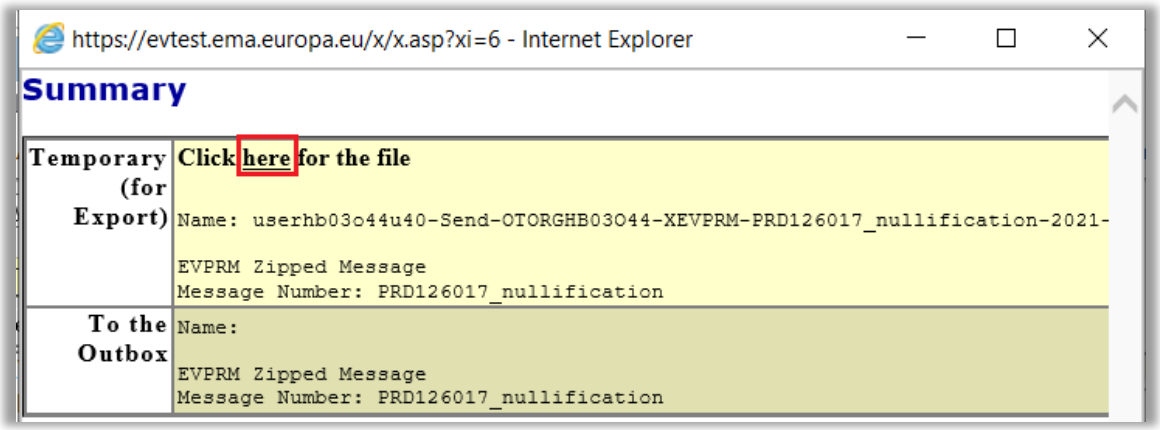


To dismiss the validation message, press 'OK' or 'x' in the right-hand corner of the window.

If you wish, you can save the XEVPRM (**prior to its submission**) for your reference by selecting the relevant button:

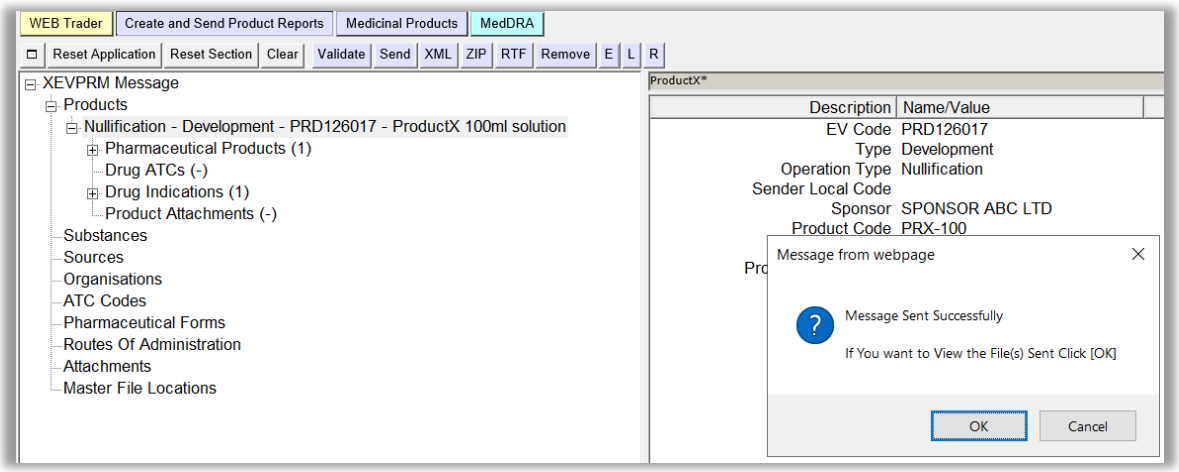


Upon clicking on the required option, a new window will open:

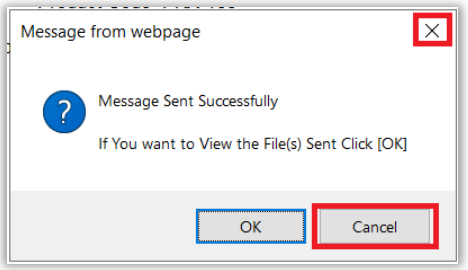


By clicking on 'here', another window will open, and you will be able to save the file on your computer.

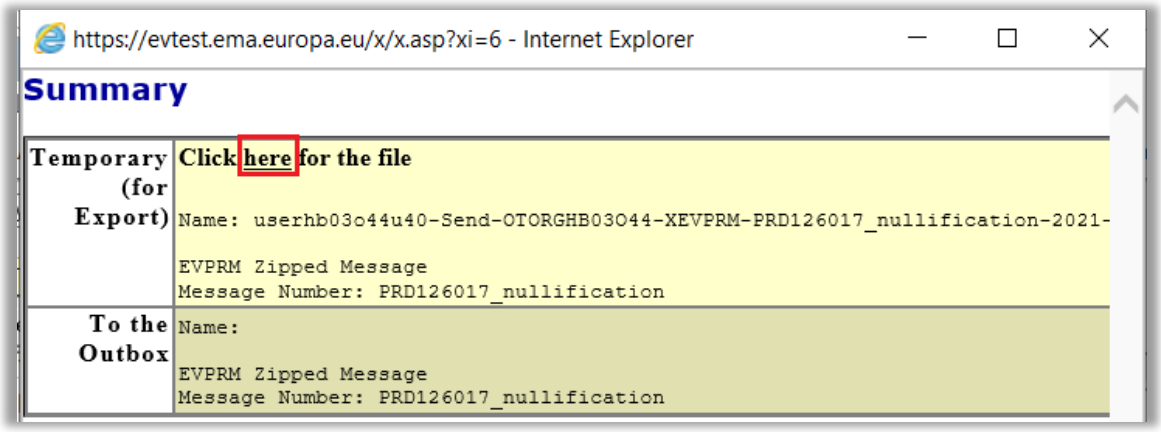
3) To send the XEVPRM, click on the 'Send' button. The below message will be displayed on your screen:



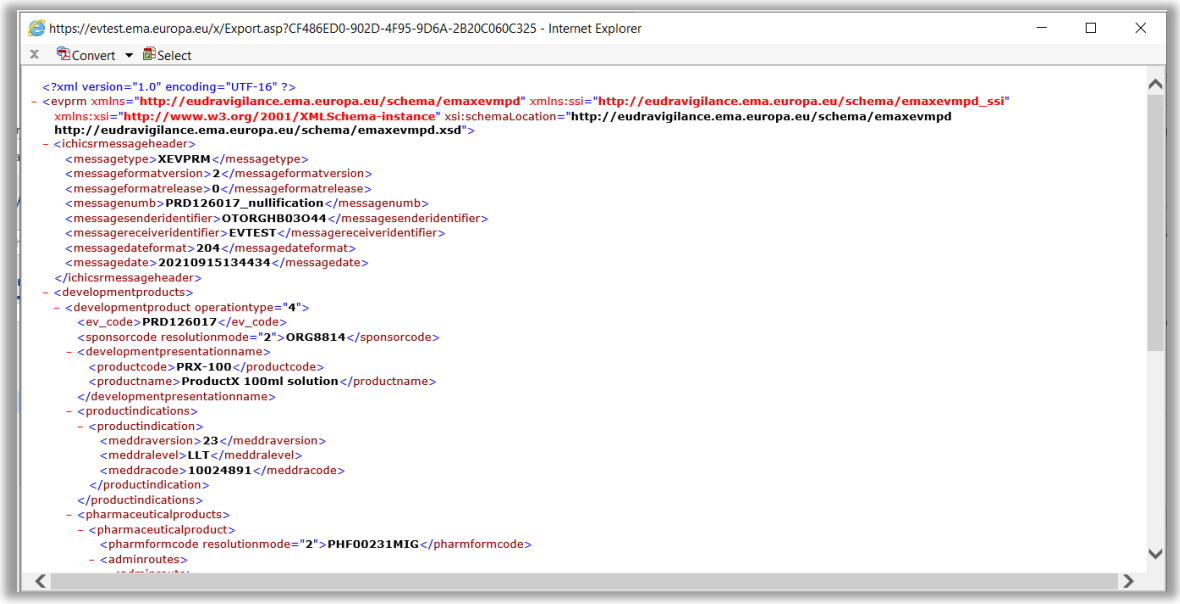
If you wish to dismiss the message, click on 'Cancel' or 'x' in the right-hand corner of the message:



To view/save **the submitted file**, click on 'OK'; the below window will pop-up, enabling you to save your XEVPRM file on your computer:



By clicking on 'here', a new window with the XML file of your submitted XEVPRM will open:

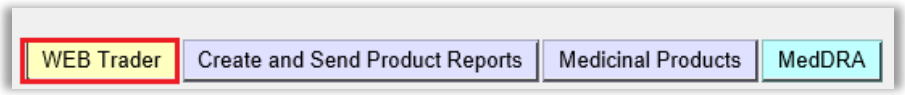


You can save the XML file of the submitted XEVPRM on your computer either by using the 'File'/'Save As' option (if available) or by using Ctrl+S on your keyboard.

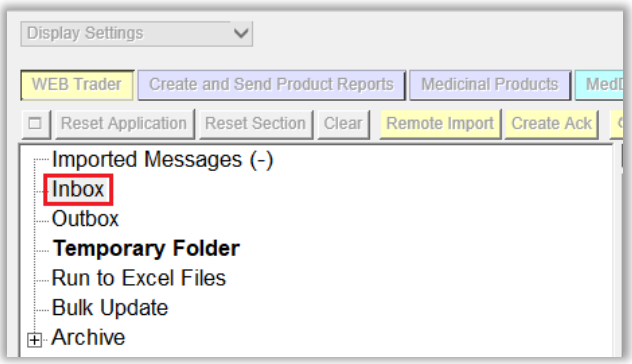
You have now successfully submitted an XEVPRM with operation type 'Nullify'(4) for a development medicinal product entity.

1.5. Retrieve the XEVPRM Acknowledgement (XEVPRM ACK)

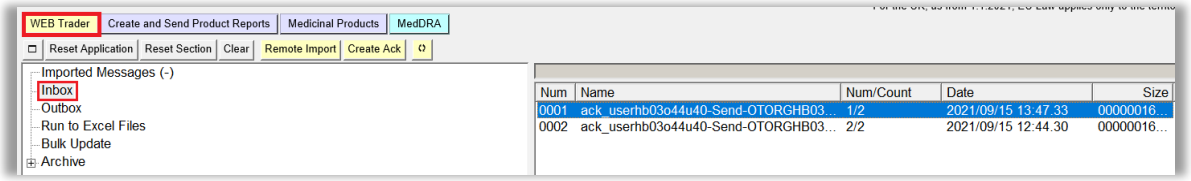
1) In EVWEB, go to the 'Web Trader' section:



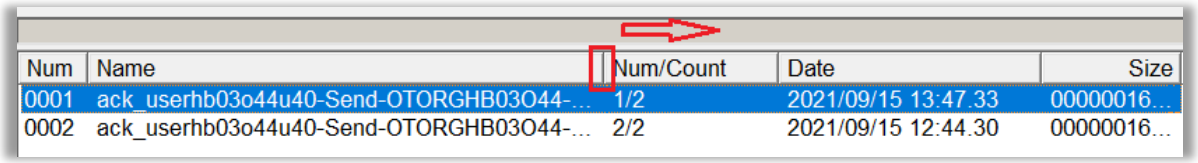
2) Click on 'Inbox' (or 'Archived Inbox' under 'Archive', depending on when you decide to retrieve your XEVPRM ACK). The application will appear 'frozen' for a second or two:

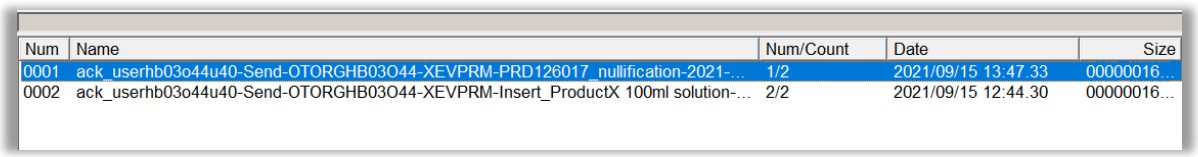


After a few seconds, the active area will display XEVPRM ACKs sent to your organisation's ID; the first message will be automatically highlighted in blue:

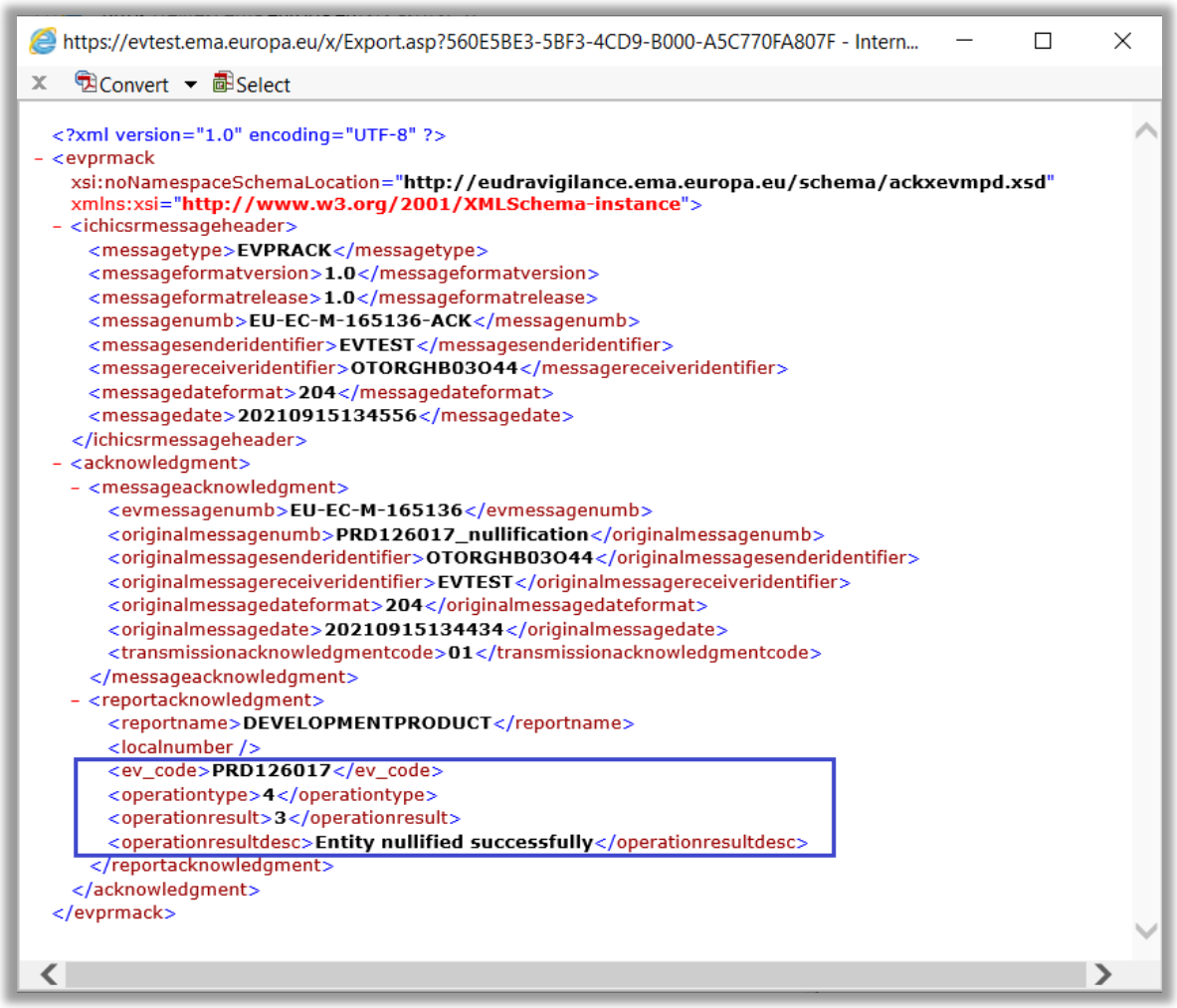


To view the ACK name in full, expand the section by placing your cursor on the separator line between 'Name' and 'Num/Count', click and drag towards the right until the full name is visible:





3) Based on the XEVPRM number, which you assigned to your message, find the XEVPRM ACK. Click on the relevant row with your mouse (the message will be highlighted in blue). Press 'Enter' on your keyboard or double-click with your mouse, and the XML of the XEVPRM ACK will be displayed on your screen, showing the operation result for the relevant entity:



The ACK confirmed that the nullification of the DMP was successful.

4) You can save the XML file of the submitted XEVPRM on your computer either by using the 'File'/'Save As' option (if available) or by using Ctrl+S on your keyboard.

You have now successfully retrieved the XEVPRM Acknowledgement confirming that your product entity was successfully nullified.

In case the nullification would not be successful, the operation result would contain a different message, indicating why the required operation was not performed on the entity.

- The list of negative operation results is available in the **'Ack - Failure codes'** spread sheet of the EudraVigilance eXtended medicinal product dictionary acknowledgment codes Excel file published on the 'Guidance documents' webpage.
  - Based on the acknowledgment, you should amend the information that led to the negative acknowledgement as per the 'operation result' message and resubmit the XEVPRM.
  - In case that the nullification was rejected because the product entity is referred to by others, you can request further information via the EMA Service Desk portal.