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Information Management

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

Maintenance operations: Update 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 updating our previously submitted DMP with the product name 'ProductX 100ml solution', which is available in the XEVMPD with the assigned EV Code PRD126007.

The following information will be amended using operation type 'Update (2)':

- the product code 'PRX-100' will be entered in the 'Product Code' data element;

- the route of administration (RoA) 'intramuscular use' will be entered as an additional route of administration.
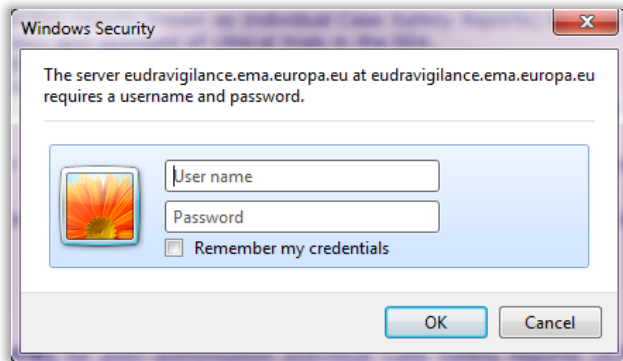
1.2. Retrieve the DMP entity in the XEVMPD

1) Log in to the requested EVWEB environment:

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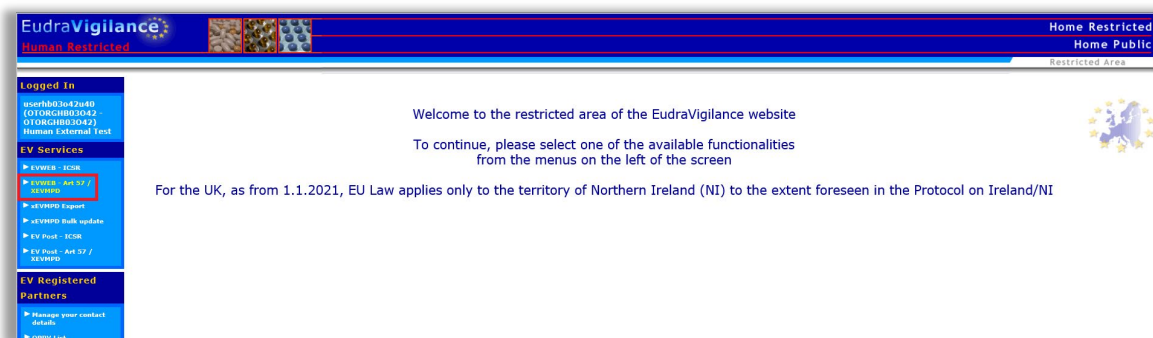
XCOMP (test) environment: https://evtest.ema.europa.eu/x

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 in is shown in the top right 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 the assigned EV Code PRD126007 using a simple query:

5) Select the required medicinal product entity by ticking the relevant 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 visible; click on 'Update':

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 you wish to assign to you XEVPRM:

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

4) Click on the product EV Code/name in the tree-view area; the active area will display the fields of your DMP; the 'Operation type' field displays 'Update (2)' as a default. It is not possible to assign a different operation type:

5) As per our specific example, we wish to add the code of the product to the DMP information. To do so, click on the area next to 'Product Code'. The value of this field will be highlighted in blue:

6) Press 'Enter' on your keyboard or click on the 'E' (Text Edit) button to activate this field. You can now enter the required text in this field:

7) To add the route of administration 'intramuscular use', click on the + sign next to 'Pharmaceutical Products (1) in the tree-view area:

The pharmaceutical product form referenced in the DMP will be displayed. By clicking on the + sign next to the pharmaceutical form name, you will be able to view the details of the pharmaceutical product:

8) To add another route of administration to the pharmaceutical product information, click on the text 'Drug Routes (1); you will be able to add a RoA by selecting 'New Drug Route':

Once you click on the 'New Drug Route' selection field, the tree-view area will display another section under 'Drug Routes' and the number of drug routes referenced in the pharmaceutical product changed from (1) to (2):

9) Press 'Enter' on your keyboard or click on the 'R' (Remote look-up) button to open the 'Route of Administration' look-up list:

10) You can now search for the required term 'intramuscular use':

11) Select the required term by pressing 'Enter' on your keyboard or, in case of multiple results being displayed, make the selection by using your mouse.

The added route of administration will now be displayed in the active area and in the tree-view area:

We have now amended the fields as per our example specifications.

1.4. Validate and send an XEVPRM

1) Validate your XEVPRM by clicking on the 'Validate' button:
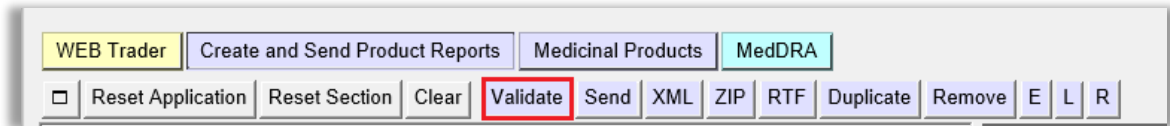
In case of any errors, a warning message will be displayed; the section, where these errors occurred will be highlighted in red and/or the fields where information is missing will contain the text 'Field is Mandatory'/'Field must have a specific value'/'Field is Mandatory Optional'.
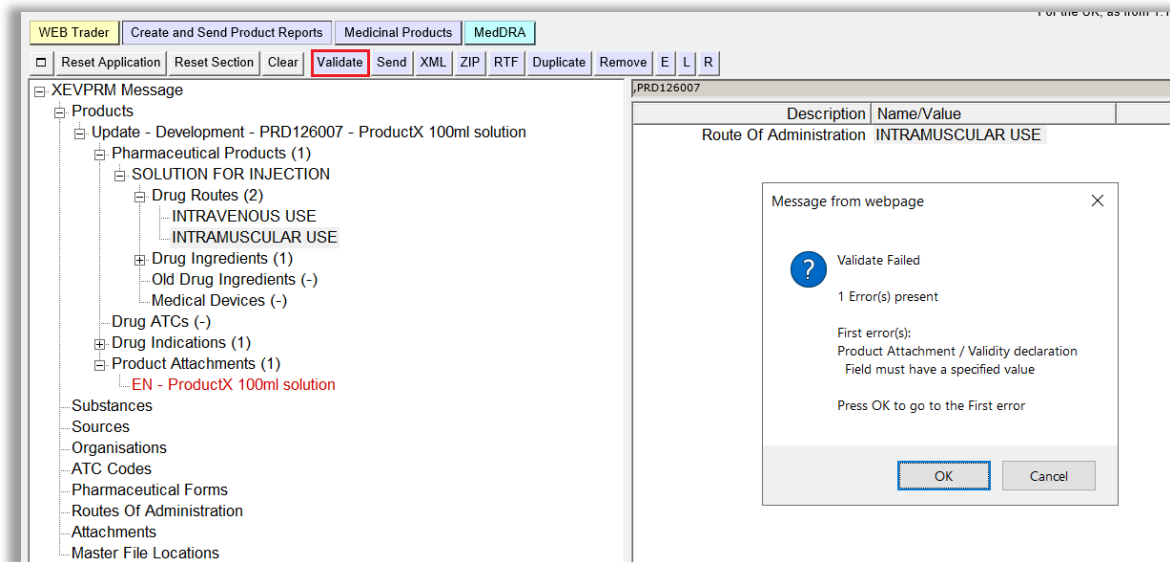
2) To correct the error(s), press 'OK' on the warning message or click on the area highlighted in red in the tree-view area.

Since we are performing an update of a DMP, as per the applicable business rules, we must confirm that the referenced PPI attachment is still valid.

The 'Validity declaration' field is a field that will allow you to select one of the available pre-defined values.

Using your mouse, click on the area next to 'Validity declaration'. The area will become highlighted in blue:

Press 'Enter' on your keyboard, double-click on the field, or click on the 'R' (Remote look-up) button. The values available for this field will be displayed:

Using your mouse, select the requested value. Once you click on the selected value, it will be displayed in the 'Validity declaration' field:

3) Validate the XEVPRM again; if there are no errors, the below window will be displayed:

You can dismiss the validation message by clicking on '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:
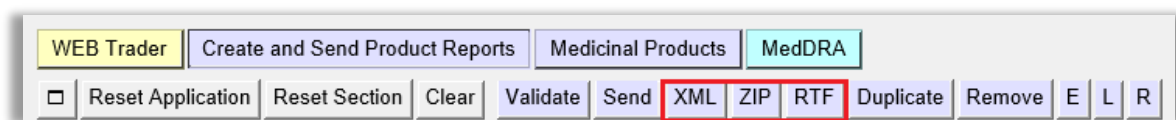
Upon clicking on the required option, a new window will open:
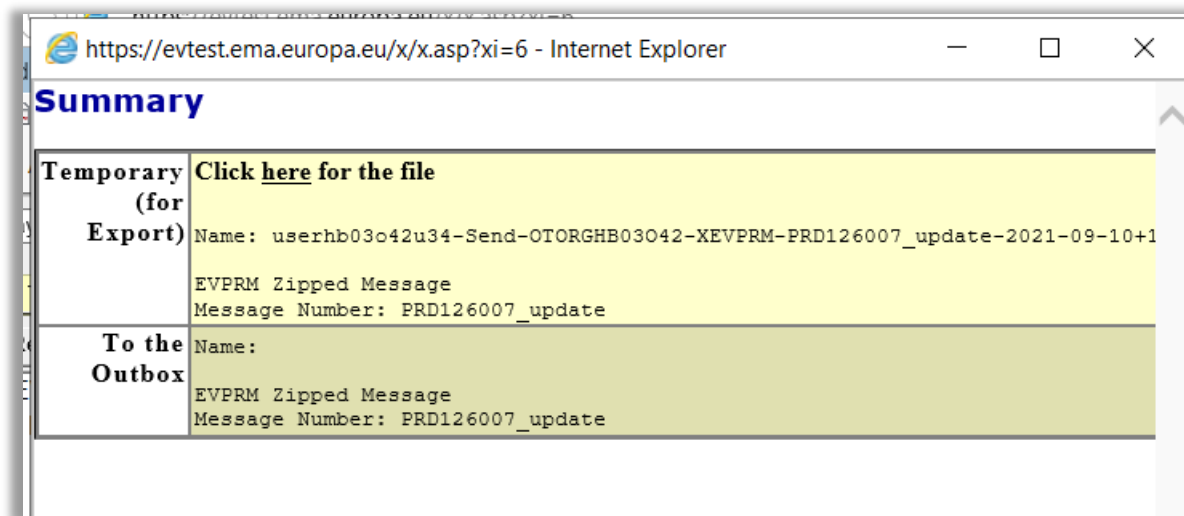
By clicking on 'here', a new window will open, and you will be able to save the file on your computer.

4) To send the XEVPRM, click on the 'Send' button. The below message will be displayed on your screen:
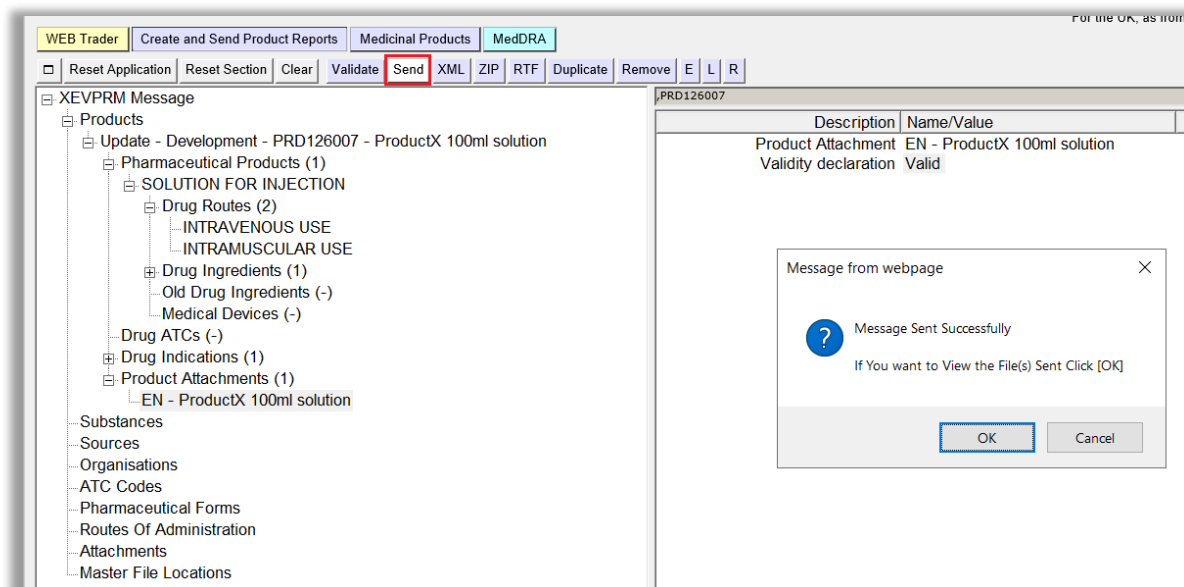
If you wish to dismiss the message, click on 'Cancel' or 'x' in the right-hand corner of the message:
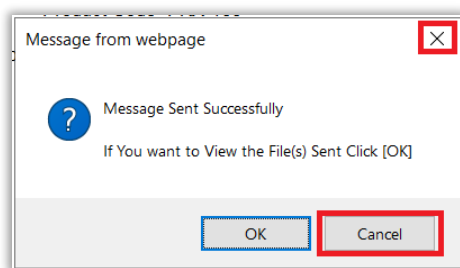
To view/save the **submitted file**, click on 'OK'; the below message will be displayed, enabling you to save your XEVPRM file on your computer:
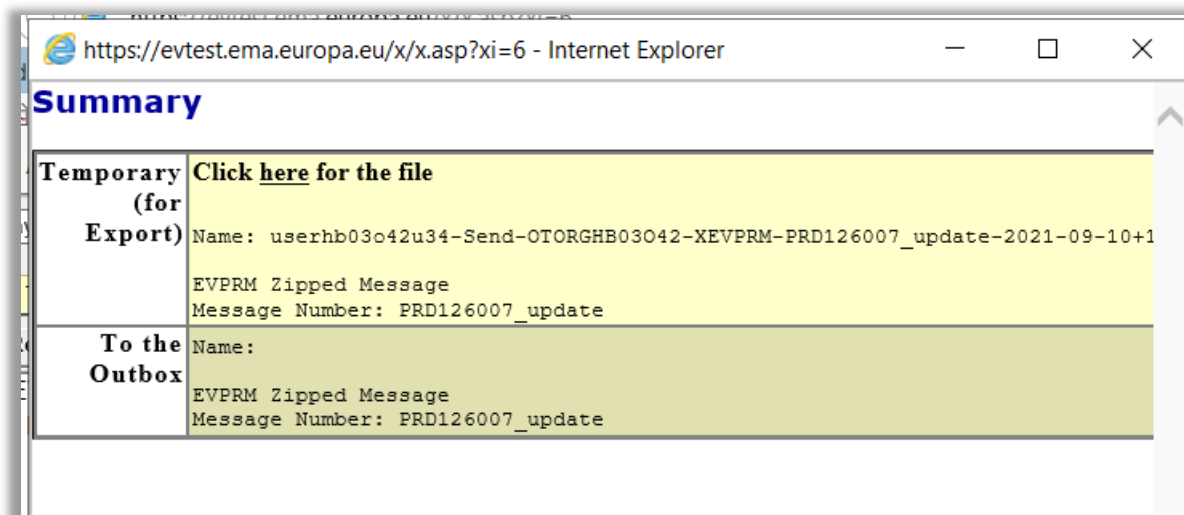
By clicking on 'here', a new window with the XML file of your submitted XEVPRM will open:

```xml
<?xml version="1.0" encoding="UTF-8" ?>
<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>ProductX_100ml solution_insert</messagenumb>
        <messagesenderidentifier>OTORGHB03O42</messagesenderidentifier>
        <messagereceiveridentifier>EVTEST</messagereceiveridentifier>
        <messagedateformat>204</messagedateformat>
        <messagedate>20210910123340</messagedate>
    </ichicsrmessageheader>
    <organisations>
        <organisation operationtype="1">
            <type_org>2</type_org>
            <name_org>Sponsor ABC Ltd</name_org>
            <localnumber>3</localnumber>
            <address>Narrow street 5</address>
            <city>Dublin</city>
            <postcode>D12 34K</postcode>
            <countrycode>IE</countrycode>
        </organisation>
    </organisations>
    <attachments>
        <attachment operationtype="1">
            <localnumber>4</localnumber>
            <filename>Attachment01.DOCX</filename>
            <filetype>3</filetype>
            <attachmentname>ProductX 100ml solution</attachmentname>
            <attachmenttype>1</attachmenttype>
            <languagecode>EN</languagecode>
            <attachmentversion>1.0</attachmentversion>
            <attachmentversiondate>20210901</attachmentversiondate>
            <versiondateformat>102</versiondateformat>
        </attachment>
    </attachments>
    <developmentproducts>
        <developmentproduct operationtype="1">
            <localnumber>1</localnumber>
            <sponsorcode resolutionmode="1">3</sponsorcode>
            <developmentpresentationname>
                <productname>ProductX 100ml solution</productname>
            </developmentpresentationname>
            <productindications>
```

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 'Update' (2) for a development medicinal product entity.

1.5. Retrieve the XEVPRM Acknowledgement (XEVPRM ACK)

1)   In EVWEB, go to the 'Web Trader' section:
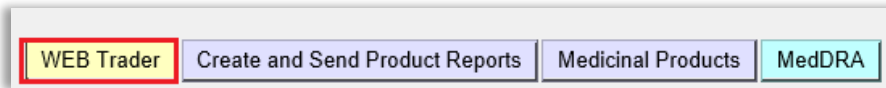
2)   Click on 'Inbox' (or 'Archived Inbox' under 'Archive', depending on when you decide to retrieve your XEVPRM ACK). The application will appear 'frozen' for a second or two:
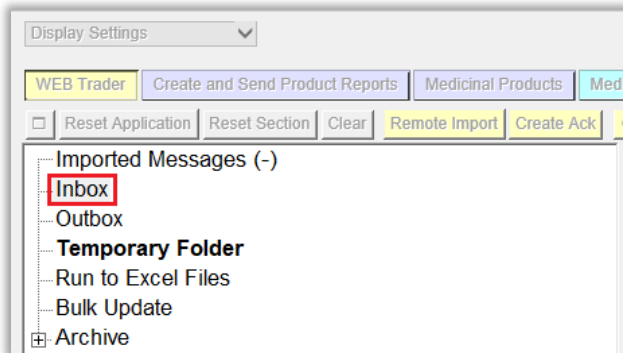
After a few seconds, the active area will display XEVPRM ACKs sent to your organisation's ID; the first message will be automatically highlighted in blue:
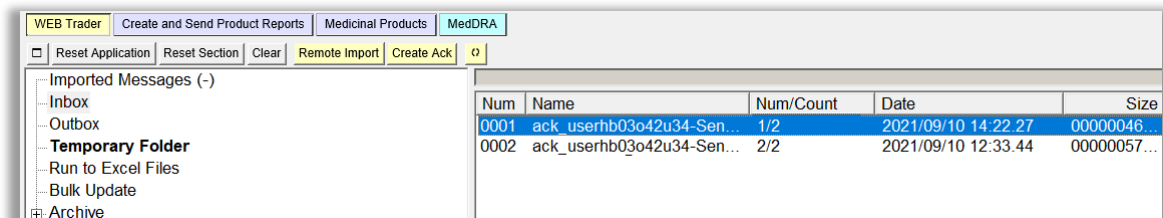
To view the ACK name in full, expand the section by placing your cursor on the separator line between 'Name' and 'Num/Count', click and drag towards the right until the full name is visible:
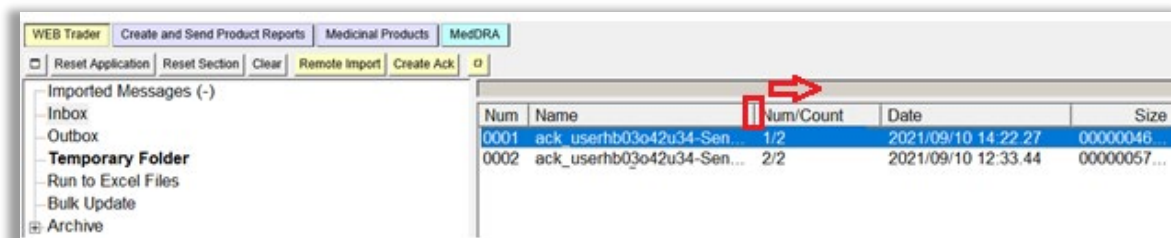
3)   Based on the XEVPRM number, which you assigned to your message, find the XEVPRM ACK. Click on the relevant row with your mouse (the message will be highlighted in blue). Press 'Enter' on your keyboard or double-click with your mouse, and the XML of the XEVPRM ACK will be displayed on your screen, showing the operation result for the relevant entity:

```
<?xml version="1.0" encoding="UTF-8" ?>
- <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-165051-ACK</messagenumb>
      <messagesenderidentifier>EVTEST</messagesenderidentifier>
      <messagereceiveridentifier>OTORGHB03O42</messagereceiveridentifier>
      <messagedateformat>204</messagedateformat>
      <messagedate>20210910142421</messagedate>
    </ichicsrmessageheader>
  - <acknowledgment>
    - <messageacknowledgment>
        <evmessagenumb>EU-EC-M-165051</evmessagenumb>
        <originalmessagenumb>PRD126007_update</originalmessagenumb>
        <originalmessagesenderidentifier>OTORGHB03O42</originalmessagesenderidentifier>
        <originalmessagereceiveridentifier>EVTEST</originalmessagereceiveridentifier>
        <originalmessagedateformat>204</originalmessagedateformat>
        <originalmessagedate>20210910142223</originalmessagedate>
        <transmissionacknowledgmentcode>01</transmissionacknowledgmentcode>
      </messageacknowledgment>
    - <reportacknowledgment>
        <reportname>DEVELOPMENTPRODUCT</reportname>
        <localnumber />
        <ev_code>PRD126007</ev_code>
        <operationtype>2</operationtype>
        <operationresult>4</operationresult>
        <operationresultdesc>Entity updated successfully Version 2</operationresultdesc>
      </reportacknowledgment>
    </acknowledgment>
  </evprmack>
```

The ACK confirmed that the update of the DMP in our example 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 updated successfully.

In case the update 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.