



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Information Management

## eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD) Step-by-Step Guide

Maintenance operations: Invalidation of an authorised medicinal product  
(AMP) entity in the XEVMPPD

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**All examples used in this step-by-step guide are fictitious and intended for demonstration purposes only.**

### **1.1. Invalidate MA example specification**

We are going to withdraw the product "LEVELLE 100 mg" because the marketing authorisation was revoked by the competent authority.

The date of withdrawal is "30/10/2014"

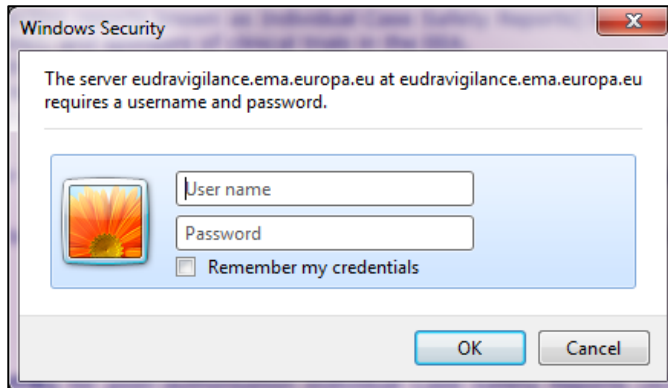
## 1.2. Create an XEVPRM

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/>

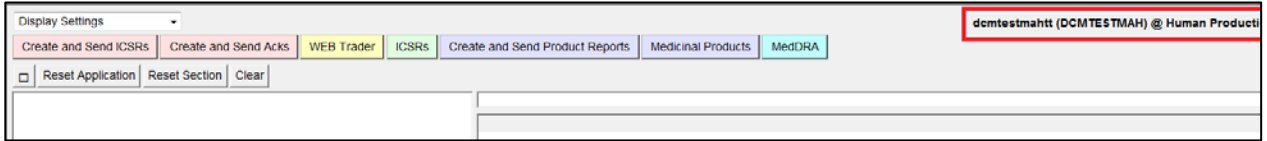


In the restricted area, click on "EVWEB":

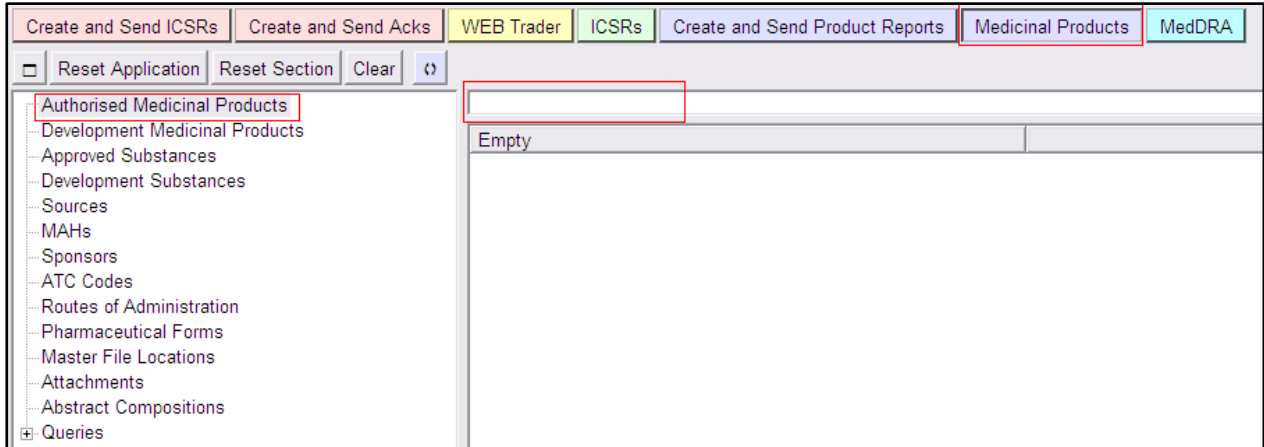
A screenshot of the EudraVigilance Human Restricted portal. The header features the "EudraVigilance" logo and the text "Human Restricted" in red. Below the header is a navigation menu with three main sections: "EV Services", "EV Registered Partners", and "User Support". The "EV Services" section includes "EVWEB" (highlighted with a red box), "xEVMPD Export", and "EV Post". The "EV Registered Partners" section includes "Manage your profile", "QPPV List", and "Organisations List". The "User Support" section includes "Help Desk", "EVWEB Troubleshooting", "XEVMPD Data-Entry Tool (EVWEB) User Manual\_version 5.0", and a "Change Password" button. The main content area is titled "Pharmaceutical Industries and Commercial Sponsors" and contains a prompt: "Please select the initial of the Organisation ID:" followed by a list of letters: "A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | Y | Z | 0-9". Below this is a section titled "Regulators" with a table header: "Organisation Name", "Organisation ID", and "Country".

Organisation Name	Organisation ID	Country
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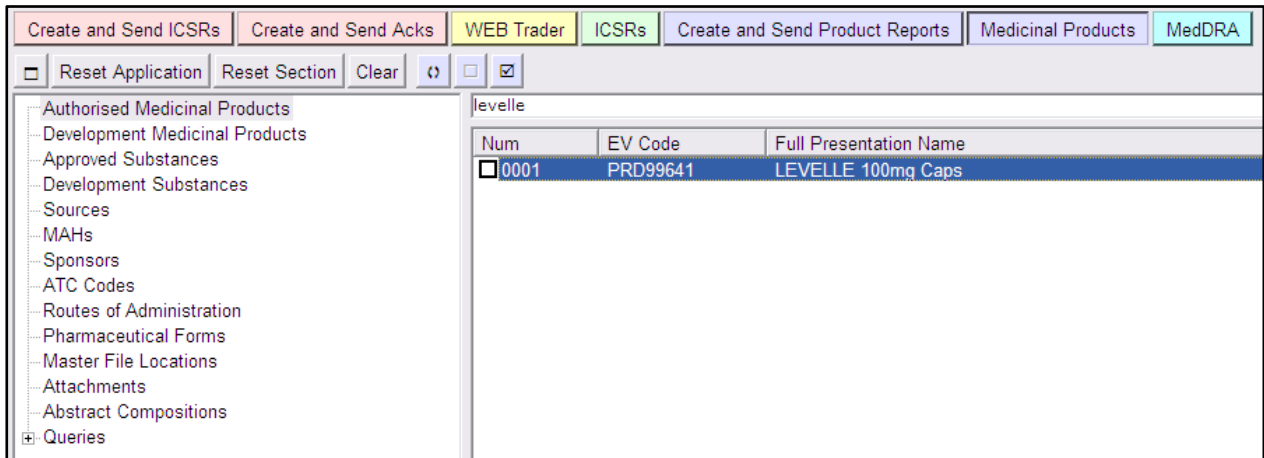
You are now logged in EVWEB – the organisation ID under which you are logged in is shown in the top right corner:



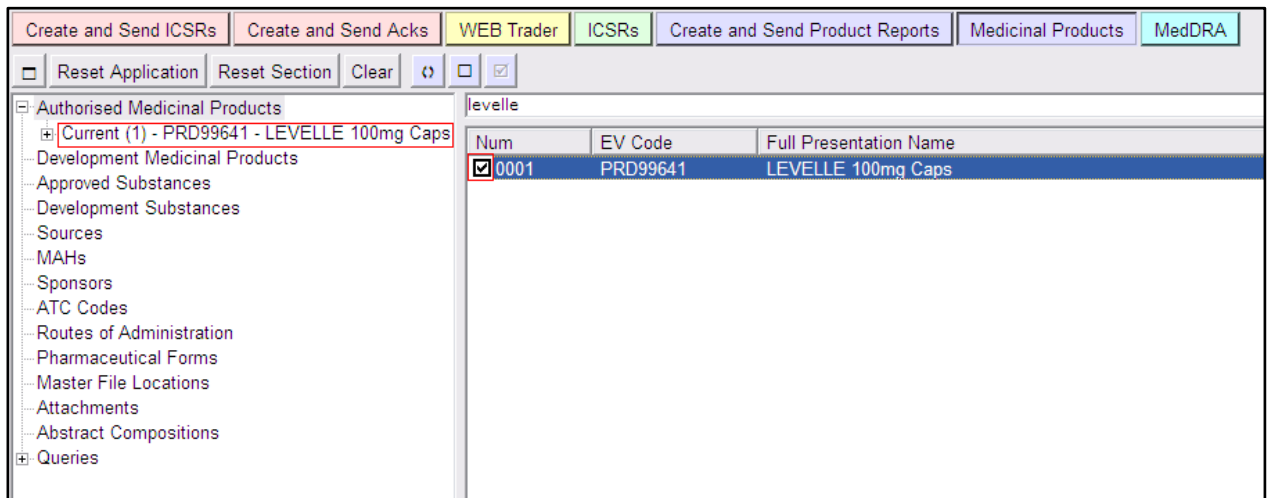
2) Go to "Medicinal Products" section, select "Authorised Medicinal Products" in the tree view, place your mouse in the search field:



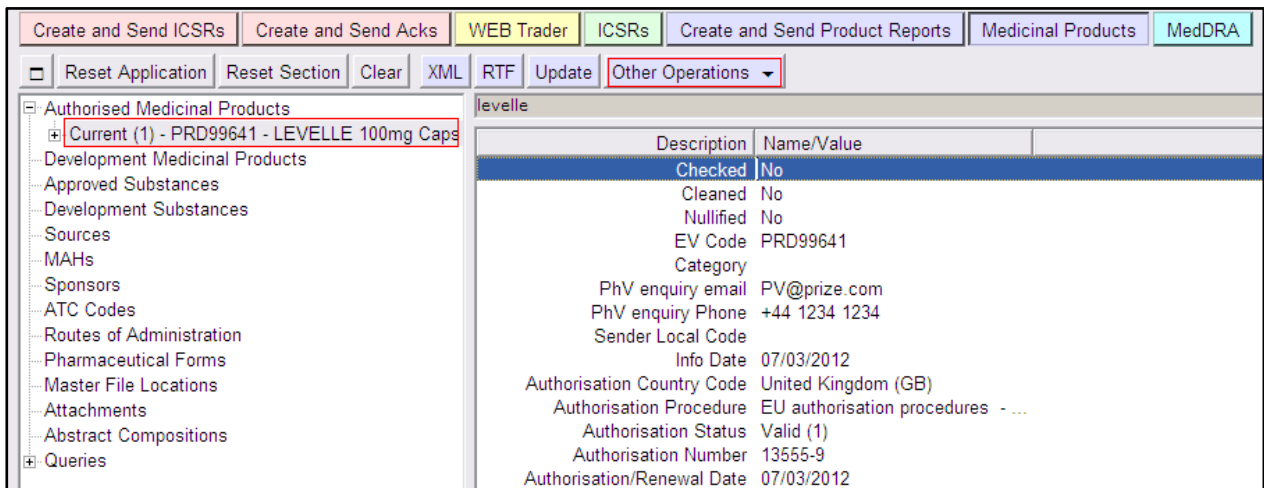
3) Type "Levelle" and press enter; the result(s) of your search will be displayed in the active area:



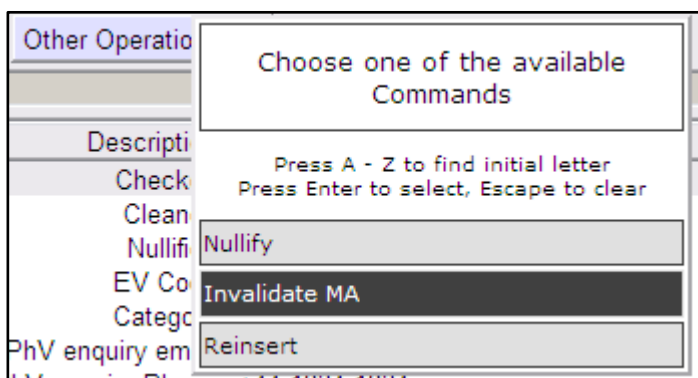
- 4) Click inside the box of the result (i.e. the AMP that you wish to invalidate); the information for the AMP will be loaded in the tree view.



- 5) Click on the AMP information "Levelle 100mg Caps" loaded in the tree view, the dynamic button containing "Other Operations" will appear:



- 6) Click on "Other Operations" and select "Invalidate MA":



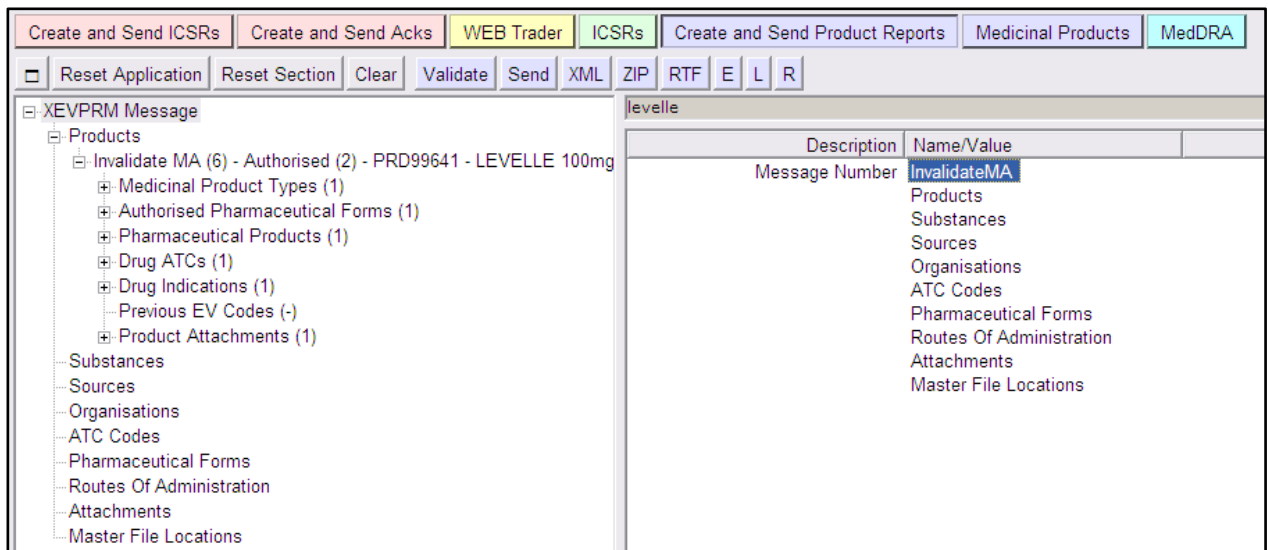
- 7) You will be prompted to the "Create and Send Product Reports" section. An XEVPRM with an AMP with the assigned operation type "Invalidate MA" will be displayed:

Description	Name/Value
Operation Type	Invalidate MA (6)
Type	Authorised (2)
EV Code	PRD99641
MAH	PRIZE COMPANY
QPPV	
Master File Location	
PhV enquiry email	PV@prize.com
PhV enquiry Phone	+44 1234 1234
Sender Local Code	
Info Date	07/03/2012
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - ...
Authorisation Status	1 (1) Value not Acceptable
Authorisation Number	13555-9
Authorisation/Renewal Date	07/03/2012
MRP/DCP/EMA Number	
EU Number	

- 8) As per the applicable business and technical rules, you must change the value in the "Authorisation Status" field:

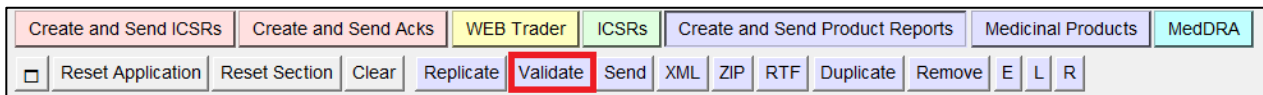
- 9) You must also enter information in the "Invalidated date" field:

10) Populate the "Message number" field:

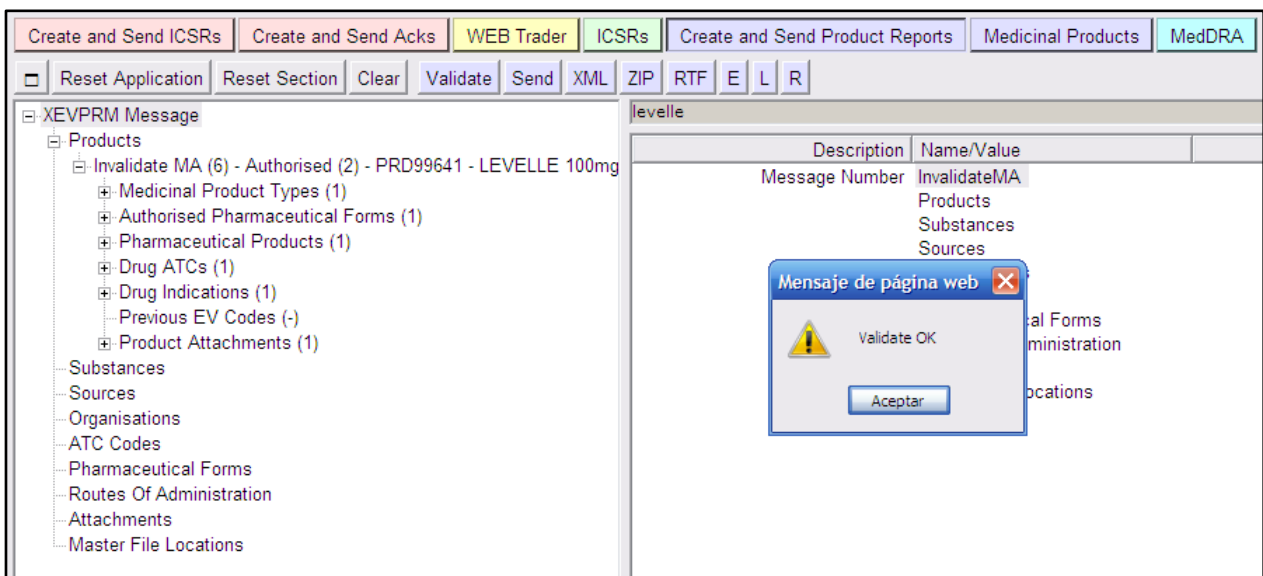


### 1.3. Validate and send an XEVPRM

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

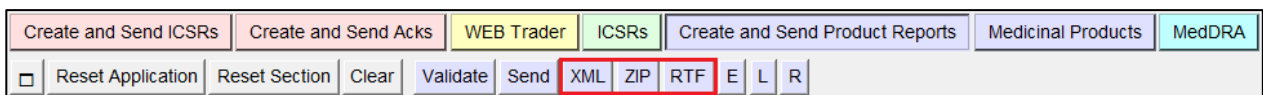


New window will be displayed on your screen, showing the result of your validation.



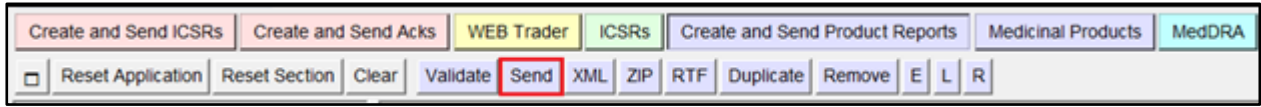
You can dismiss the message by clicking on "OK".

2) Save the XEVPRM for your reference by clicking on the relevant button:

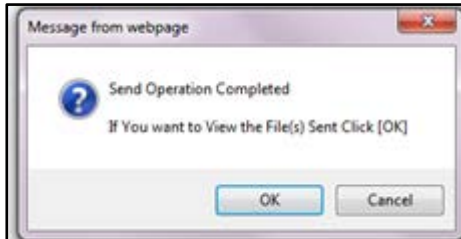




3) Send the XEVPRM by clicking on the "Send" button:



The below message will confirm that your XEVPRM has been sent:



If you want to view/save your file, click on "OK".

The below message will be displayed, enabling you to save your XEVPRM file on your computer:

