CREATING AND SENDING ACKNOWLEDGMENT MESSAGES

STEP-BY-STEP GUIDE

This step-by-step guide describes how to create and send acknowledgment messages for SARs received in the WEB Trader Inbox, and for files saved on a Local System.
1 Create an acknowledgement message

You should send an acknowledgment message for each safety message you receive in your inbox. Select the “WEB Trader” section by clicking on the appropriate button in the main menu.

The Web trader section has the following components:
The “Inbox” which contains messages (safety reports and acknowledgements) you have received from others parties. To access the messages that you have received today, just click on “Inbox”. The “Outbox” contains the safety and acknowledgment messages that have been sent by you to others parties. Click on “Outbox”, and the active area will display a list of the messages sent.

To update the information shown in the “Inbox” or the “Outbox” press the “Refresh” button.

To acknowledge a safety message, go to “Inbox”, select the message, and then press the “Create Ack” button.

The Safety Message gets validated against the EudraVigilance business rules. The application moves to the “Send Acks” section, and an acknowledgment is created in accordance with the outcome of the validation.

There are three possible types of outcomes from the validation at the Message level, which are stated on the “Transmission acknowledgement code” field:

01 All Safety Reports Loaded correct.
02 Not All Safety Reports Loaded message have one or more errors.
03 Message or System Error data has been extracted

It means all Safety Reports contained in the message are correct.
It means that one or more Safety Reports contained in the message have one or more errors.
It means that the XML message is not well-formed, and no data has been extracted.
In this Safety Message all the Safety Reports have been loaded successfully.

The “Local Message Number” is a Mandatory field. It is the reference number given to the message received by the receiving organisation of the SAR (the sender of the Acknowledgment). There are no conventions established for this field, the value to be input is determined by the receiving organisation.

Enter in the “Local Message Number”.

Select the “Report Ack (s)” from the tree view area. This section shows the outcome of the validation of each of the SARs within the message.

Click on “Report Acknowledgement”. In our example there is only one SAR in the message. To see the outcome of the validation of this Safety Report, double-click on the safety report.
None of the fields on the “Report Acknowledgment” section are mandatory. Some are automatically filed, like “Safety Report ID”, “Company Number”, “Receipt Date” and “Report Acknowledgement Code”. However, if you track or save the incoming reports on your local database, you may wish to give each report a number. To do so you would use the field “Local Report Number”.

The status of this report is shown on the field “Report Acknowledgement code”. This field is filed automatically when the system performs the validation. There are two possible outcomes of the validation and the report level: Safety Report Loaded, and Safety Report Not Loaded:

In this case, there were no errors on the incoming report, therefore the outcome of the validation was “Safety Report Loaded”.
If there are any errors on the message, there will be reported on the next section, “Report Comment(s)”. In this particular case, there were no errors to report. However, there was a warning. Warnings do not prevent the report from being loaded in the database, but they may mean that there is some further action to be undertaken by the sender.

Double-click on “001 Warning animalsuspectdrug…”. A new section opens, showing details of the warning (or error) detected during validation. The fields are pre-filled with information as an aid for the person sending the acknowledgement, but further details of the error or warning should be added on the “Comment Text” field.

In our report, this warning means that the product (or one of the products) involved in the ADR is not yet included on the Medicinal Product Dictionary. Therefore, the sender of the ADR should also send the product information to EudraVigilance. They may do so either via EVVET or by using the Simple DB.

Once all the necessary information has been entered on the “Acknowledgement message”, the only field remaining to be completed is the “Message Number”.

“Message Number” is a unique tracking number assigned to the acknowledgement message by the sender of the acknowledgment message.
You can validate the Acknowledgment Message before sending it, to make sure that all the mandatory fields have been completed, by clicking the “Local Validation” button.

Once validate, send the Acknowledgment Message by clicking on the “Send” button.

The acknowledgment message can be saved on your local system either as an XML or an RTF file by clicking on the appropriate button.
2 Create an Acknowledgment from a Locally Stored Safety Message

Go to the “ADR” section, and select “Uploaded Messages” on the tree view area, then press “Create Acknowledgement” on the dynamic toolbar.

Click on “Browse”. This will take you to your local system, where you can select a message you had previously saved. Press “Open”, then “Upload file”.

You will get the following message on your screen:

Press “OK”. The message will be imported into the EudraVigilance system. You will be asked if you would like to view the message (this just shows you the XML view of the message you have just imported, so unless you would like to see that, press cancel).
The application will take you to the “Send Acknowledgements” section; the system will validate the Safety Message against the EudraVigilance business rules and provide the results of the validation on the “Transmission Acknowledgement code” field.

In this particular case, unlike on our previous example, the “Transmission Acknowledgment” field indicates that at least one safety message did not meet the business rules, and therefore not all the safety reports were loaded.

From the tree view you can open up the individual case safety report in the safety message and see the results of the validation.

The “Error Comment(s)” field contains the details of why the report was rejected. This report has several errors; these are listed individually; and you can view details of each error by clicking on the respective entry.
Once you have reviewed the results of the validation, you can complete the Acknowledgement Message by filling the mandatory fields as described previously (i.e. “Local Message Number”, etc).

Then, select “Message” from the tree view area and enter the “Message Number”. Now validate the Acknowledgment Message by clicking the “Validate” button.

Finally, you can now send the Acknowledgment Message by clicking on the “Send” button.