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EVVET - EVWEB User Manual
Version 1.0
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1. Introduction

1.1. About this User Manual

This user manual is part of the official documentation prepared to support the use of the Surveillance Web reporting tool EVVET3-EVWEB. The first 8 chapters will explain how the application works, but the last chapter will give an example and it will guide the user through all the needed steps to fulfill a report.

- **Chapter 2**: presents a Login overview of EVWEB application and should be read before the other chapters. It contains basic login information along with user interface and session timeout information.
- **Chapter 3**: gives brief overview of the EVWEB main menu.
- **Chapter 4**: gives complete insight into Adverse Event Reports (AERs) functionality of creating & sending adverse event report, searching reports and searching report messages. This chapter also details out on how to download, import, export and follow ups and nullifications.
- **Chapter 5**: details out about Mailbox, which includes messages sent and received by user organisations.
- **Chapter 6**: describes about organisation list available
- **Chapter 7**: gives information about user profile.
- **Chapter 8**: can be referred for abbreviations used in the user guide.
- **Chapter 9**: it will give a step-by-step example of how a report could be fulfilled in EVWEB.
- **Chapter 10**: It gives a step-by-step guide to show how to create a report.

2. EVVET3 EVWEB

EVWEB is a tool that provides users a direct and secure access to EudraVigilance veterinary over the internet. It’s designed to transmit AERs (Adverse event reports) to EudraVigilance Veterinary for pharmacovigilance purposes. Allows to follow-up reports and exchange of acknowledgement messages. Contributions to the Medicinal Product database can also be submitted via EVWEB. It provides secure exchange of information, and it is available only to registered users.

EVWEB should be used in Google Chrome navigator.

2.1. EVWEB Login

Only registered organisations and their registered individual users are granted access to the EVWEB. After the integration of IAM2 (Identity and Access Management) to the existing Veterinary Solution, the Organisation management is centralized on OMS - Organisation Management System - (information related to the organisations) and the account/role management is centralized on IIQ (information regarding users and roles).
**Prerequisites to login to EVWEB (new organisations):**

1. Organisation should be registered in Organisation Management System (OMS)
2. User should be registered with the EMA Account Management portal (IAM).
3. User should have at least one valid role to any organisation.

User can find most updated information related to access policy details of EVVET3 application in the EMA website.

**NOTE:** In case one organisation was already registered and working in VET2 system, it will be automatically migrated to VET3 → No need to register again to use VET3. Also, the routing ID associated to each existing organisation will be migrated.

**NOTE:** If one user was already using VET2, it will be automatically migrated to VET3, so the same user will exist in VET3 with the same role(s) and permissions associated. New users (that did not exist in VET2) will need to be registered in IAM (Identity and Access Management) and the required roles need to be approved.

**NOTE:** When starting using VET3, the already existing users (from VET2) will be requested to change their passwords. In case one organisation is not registered/not password, the existing registration process should be followed.

**NOTE:** VET2 system will be closed on 28/01/2022. From this date onwards, VET3 will also be open to send the AERs.

### 2.1.1 Login

EVVET3 is accessible by clicking on the production URL:  [https://eudravigilance-veterinary.ema.europa.eu/adrwebui/](https://eudravigilance-veterinary.ema.europa.eu/adrwebui/)
When user logs in, user is prompted to select organisation. By this selection, in fact, the user is selecting the Routing ID (needed to send reports).
NOTE: Step-by-step guide about how to set up Multi-factor authentication (MFA) to access EMA Cloud applications: Multi-factor authentication (MFA) URL

2.1.1 XCOMP Log In

In order to log in the XCOMP environment, the user should access the following URL https://eudravigilance-veterinary-xcomp.ema.europa.eu/adrwebui/, but first, the organisation should already be registered.
For more information about the registration process, please check the ‘Registration Manual’

2.1.2 Login User Information

On the right top corner of the application, basic information about the logged user is displayed: Username and Organisation Name on first instance. When moving the mouse over the information, an extended information box is displayed with additional information such as Email, Username and Organisation ID.
2.1.3 User Interface Layout

The main menu is located on the top of the screen and below it we can find the dynamic tabs set. The images below, show both the main menu and the actions buttons:

**Image 6 – EVVET3 Main screen**

**Image 7 – EVVET3 Create and Send**

The following image shows the 'Create and Send' screen, and accompanying table provide a general outline of the EVVET3 EVWEB User interface:

**Image 8 – EVVET3 UI Interface display**

<table>
<thead>
<tr>
<th>Interface Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Main menu</td>
<td>EVVET3’s main menu is always present in every screen of the application. EVVET3 is divided into different screens according to the kind of information you are going to operate with (i.e., AER’s, Mailbox, Organisation list, Manage user profile).</td>
</tr>
<tr>
<td>(2) AER tabs</td>
<td>This area represents AER tabs. <strong>Create and send, Search AE Reports, Search AE Messages</strong></td>
</tr>
</tbody>
</table>
### Table 1: User Interface description

<table>
<thead>
<tr>
<th>Interface Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>(3) Actions (regarding the selected option from the main menu)</td>
<td>This area represents dynamic buttons set, New, Import XML, Export XML, Validate, Validate and Send</td>
</tr>
<tr>
<td>(4) Tree view area</td>
<td>Displays the hierarchy of the AE Report messages sections in a tree view style.</td>
</tr>
<tr>
<td>(5) Active area</td>
<td>Displays content of a selected section or search results from a query.</td>
</tr>
</tbody>
</table>

**2.1.4 Session Time Out**

EVWEB allows a maximum period of inactivity of 25 minutes before a user is automatically logged out of the system. Users are therefore advised to save any work if they are going to pause the use of the application. Following image shows the session expiry warning message that will come up when the system is inactive for certain period. User will have 5 mins to extend the session. In order to prevent an automatic log out users can press the **Extend your session** button in order to extend the session.

![Image 9: Session expiry warning](image9.png)

Following image below shows the session expiry warning that will come up when the maximum period of inactivity is being reached. Users can press the "Refresh" button to re-login to the application.
3. EVVET3 Main Menu

3.1 Main Menu Options

EVWEB main menu will have below options. In this user manual it will be described the menu entries and system functionalities available to regular MAH and NCA users of the interface. Below options will navigate to respective default pages.

<table>
<thead>
<tr>
<th>Menu Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AERs</td>
<td>Allows access to the part of the application dedicated to the creation and sending of reports, search for messages and reports.</td>
</tr>
<tr>
<td>Mailbox</td>
<td>Allows access to review your own messages, both sent and received. You will be able to see messages sent to you and by you, in the &quot;Inbox&quot; and &quot;Outbox&quot; views. In the mailbox, the user will be able to see the ACK messages.</td>
</tr>
<tr>
<td>Organisation list</td>
<td>Allows the user to consult the whole organisation list with an associated routing ID.</td>
</tr>
<tr>
<td>Menu Option</td>
<td>Description</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Profile</td>
<td>This feature is reserved just for Responsible person and Trusted Deputy users. This feature will give information about the selected organisation.</td>
</tr>
</tbody>
</table>

Table 2: Main menu description

4. Adverse Event Reports (AERs)

Adverse Event Report button available on main menu will allow the user to create and send adverse event reports, search reports functionality and also you can search messages of reports. You will find detail information about these options in below sections

Image 12- AERs button Main Menu

4.1 AER Tabs

AER tabs will vary in available options, depending on the user’s account access rights. Depending on user account’s rights, you may see all of these options or a limited set of them.

- Users with only Browse permissions, won’t have ‘Create and Send’ option.
- Users with Browse& Send permissions, will have ‘Create and Send’ option.

Image 13– AER Tabs

A typical EVVET3 main menu & AER tabs consists of the following links:

Image 14– Main Menu & AER Tabs
Below table gives brief description of AERs tabs

<table>
<thead>
<tr>
<th>Menu Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create and Send</td>
<td>Allows you to Create and Send adverse event reports.</td>
</tr>
<tr>
<td>Search AE Reports</td>
<td>Provides quick search of AE reports by selecting available searching criteria and filtering with required columns.</td>
</tr>
<tr>
<td>Search VICH Batch</td>
<td>This provides quick search of AE Messages by selecting available searching criteria and filtering with required columns.</td>
</tr>
</tbody>
</table>

*Table 3: Secondary menu AERs tab*

### 4.1.1. Create and Send

In the AER tabs set click on "Create and Send" and on the right side of your window displays a set of dynamic buttons, located under the "Create and Send". Variable number of actions regarding the creation of reports.

These buttons and the different screens and functions of EVVET3 will be described in further detail in the following sections of this user manual.

#### 4.1.1.1. New

a. The Tree View Area

The tree view area is located on the left side of the application, below the main menu and the dynamic buttons set. It shows sections in a tree view style (similar to Windows File Explorer). The tree view will be displayed once the user clicks on "New“ action from "Create and Send“ tab.
Image 16- The tree view area
To select a section in the tree view area, you have to click on section’s name. When you hover the mouse pointer on them mouse pointer becomes hand icon on the sections available for selection and selected section will be highlighted in bold.

You will notice that most section names are followed by a numbered Blue circle icon (i.e. 1) and ‘+’ sign. On click of ‘+’ sign, the user can add additional sub-section and Blue circle icons indicate how many additional sub-sections are available under the main section.

When the icon   appears on the left of a tree view section, this indicates it contains a sub-section that can be expanded by clicking on it.

![Image 17- Tree view area with sub-sections](image)

**Tip:** You can expand or collapse at once all tree view sections by clicking on the corresponding icons (   ) located at the top of the tree view area.

After a tree view section is expanded, the icon   changes into   . To collapse the section again, click on the   icon.

The tree view can grow, expand and become extensive while using the application. The active section of the tree view area is always marked on a white background.

**Note:** On the top of the tree, you can find a "Search" field that you can use as a query for search any section/sub-section or field in the current tree view area.

When the expanded tree grows beyond the size of the tree view area, scroll bars will appear on the side, to allow you to move up and down and reach any part of the tree.
b. The Active Area

The active area displays the content of the currently selected section in the tree view area.

The active area is located below the main menu and the dynamic buttons set. If a tree view area is selected, the active area appears on the right side of the application.

Image 18- Active area

The main difference between the tree view area and the active area is that the active area is interactive and displays information that can be edited and modified by the user (see section 3.5 Data Entry of this User Guide).

The active area displays information in 2 different ways:

- **Section view**: Used for displaying information and/or data entering. A typical example of a section view is the editing of a new report. The main body of the active area may display editable or non-editable information. Sometimes it shows information to the user, other times it requests information or an action from the user.

Image 19- Active area section view
List view: Used for displaying items that can be selected. A typical example of a list view is the result of a query/search.

c. Interaction Between the Tree View & Active Area

The tree view area enables you to browse sections by selecting them, and by expanding or collapsing them into sub-sections. Functionally, the tree view area can be considered a navigation system. The active area displays the content of the selected section in the tree view area and allows the user to view, input, modify and nullify information.
The information displayed in the active area can be presented in two different formats: section view and list view (see section b. The Active Area of this manual). To display the details of any of the sections you have to click once on the section’s name in the tree view area.

d. Data Entry

This part deals with all specific actions that you can perform to insert data in the EVVET3 application.

You can find all the data entry fields and business rules around them in the following URL:


e. Input Field Types

EVWEB has basically five different types of fields for the user to input information into the system. These are:

1. Text fields
2. Date fields
3. Drop-down list fields
4. Immediate query fields
5. Checkbox/radio button fields

These are explained in detail below. You do not necessarily need to know what type of field you are dealing with when you are entering information. The system will guide you through the necessary steps for each type of field.

During the input phase the application performs a real-time validation of the inserted data. Fields that contain erroneous or incomplete information have their title/description and field box highlighted in red. The relative error message is displayed when you hover the mouse pointer over the caution icon which appears on the far right of the invalid field. In addition to that, the section that contains errors is also displayed in red both in the tree view area and the active area.
1. Text Field

This is one of the common type of field that you will find in EVWEB. Text fields require information that is entered using the keyboard.

To enter information in a text field, you first need to select it by clicking in its text box.

Once you enter the required data, you can click anywhere outside of the text field to finish the input process for that field. You also have the ability to copy and paste information from/to text fields.

**Tip:** To quickly move to the next field, you can press the TAB key on your keyboard. This will activate the next field for you. Similarly, you can press SHIFT+TAB to activate the previous field.

This type of field is used in EVWEB to enter date information using either a graphical interface that resembles a calendar, or by typing it in the available date field text box.

2. Date

Using the graphical interface, clicking on the icon displays the calendar. The calendar provides a grid layout for the successive selection of year, month and day.
3. Drop-Down List Field

In this type of field you are presented with a drop-down list from which you can select the required information.

Select the field by clicking on it, in the same way you do to complete a text field. A drop-down list will be displayed. Choose the required information from the list by clicking on any element using your mouse pointer.
4. Immediate Query Field

This type of field, which is also known as a look-up field, automatically acquires data from the database as a result of the query performed in it.

![Image 25- Immediate query field]

Proceed as you do with a text field, by clicking in the field’s box to activate it. Now start typing a few characters or words that are part of the entry you would like to insert in this field. Soon, a drop-down list will appear with all entries that match the characters/words you have typed in. You can now click on the suitable entry and it will be inserted into the immediate query field.

**Tip:** The characters or words you type into an immediate query field are also called keywords. A keyword is text that indicates to information retrieval systems (or search engines) what to look for and, thus, allow for the best possible match upon retrieval of that information.

Your keyword(s) can be any part of a database entry. For example, if you type **na** as a keyword in species immediate query field will include the following entries for you to select from:

- Common Canary
- Iguana
- Snake

Also evident in the above immediate query field results example is that the search is not case sensitive. This means that you can query the following keywords **NA, nA, Na**, and still obtain the same search results.

5. Checkbox/Radio Button Fields

The checkbox/radio button fields allow the selection of a true or false state (checkbox field) or the selection of a mutually exclusive state (radio button field). Consequently, the checkbox field usually contains a single item for you to state as true (ticked box) or false (unticked box), whereas the radio button field always contains two or more items of which only one can be selected.
f. Adding & Removing Tree View Area Sections/Sub-sections

During the data entry process, you may be required to add a new sub-section to the tree view area. This can be done by clicking on the icon that appears at the section where sub section can be added and allows such an action. An example of this process can be found in the Create and Send screen of the EVVET3 application.

Tree view area sections also allow the creation of multiple sub-sections within them. In order to do this you should click on the icon more than once, depending on the number of sub-sections required.

Another useful option when dealing with sub-sections is the ability to create a copy of them within the same section. This is very handy when data is quite similar (or identical) between multiple sub-sections.

To create a copy of a sub-section, hover the mouse pointer over it and click on the icon that appears on the right side of the sub-section.

The sub-sections you add can, of course, be removed. To do this you have to hover the mouse pointer over the sub-section you need to remove in the tree view area and click on the icon that becomes available in these situations.

g. Creating Multiple reports

User can add multiple reports as explained above by using icon existing next to VICH Batch on the tree view section. Similarly, user can also add multiple “B.2 VMP Data Usage”, “B.2.2 Active ingredient(s) and Lot Number”, “B.2.1.7 Route of exposure” inside each of the report
Image 27 – Creating multiple reports

Image 28 – Add multiple VMP Data & Usage
Image 29– Add multiple Active Ingredient(s)

Image 30– Add multiple Lot Number
AE Reports contain, in general view, information regarding Reporting Organisations, affected products and information of Onsets. This is divided in different sections.

4.1.1.1.1. VICH Batch

VICH Batch includes the necessary information to identify the batch submission. This section is referred to the whole batch, that could contain one or more reports (up to 100). Following fields should be informed:

- **VICH Batch number**: helps identifying the AER submission or group of AERs. It’s a free text and it’s the sender’s responsibility to define and assign this identifier, as each batch submission should have a unique identifier.

- **VICH Batch Sender**: its automatically populated based on the Organisation logged in. Includes the Routing ID and the Organisation Name.

- **VICH Batch Receiver Identifier**: The responsible organization to which the report is sent. Correct procedure is to assign here the (EVVETPROD) Eudravigilance Veterinary identifier. Currently the system can not send at once the same report to several receivers, so in case it’s needed to send the same report to more than one organisation, it’s required to send the report twice (one report to the EMA and the other one to the desired organisation).

  **NOTE**: VICH Batch Receiver Identifier should be the same in:
  - VICH Batch level
  - AE Report level

- **Date of VICH batch Creation**: Automatically taking the date and time from system.

![Image 31: VICH Batch number](image)

4.1.1.2. AE Report #1

One VICH batch can be used to submit one or more AE Reports (Up to 100 reports in case the 2MB maximum size). When user selects one of the reports, following information is requested:

- **VICH Batch number**: The "Message Number" information identifies the message. The concatenation of Message Number Root and Extension uniquely identifies each message. The message creator should ensure that this uniquely assigned identifier will never be used in another
message. It is the sender’s responsibility to define and assign this number, as each message should have a unique number.

**NOTE:** VICH Batch Number and VICH Message number can be the same

- **VICH Batch Sender Identifier:** its automatically populated based on the Organisation logged in. Includes the Routing ID and the Organisation Name.

- **VICH Batch Receiver Identifier:** It should match with the Batch Receiver Identifier from previous section. Correct procedure is to assign here the (EVVETPROD) Eudravigilance Veterinary identifier.

- **Date of VICH Message Creation:** Automatically taking the date and time from system.

4.1.1.1.2.1. MAH Information

This section includes all the information related to the MAH reporting organization. It’s automatically populated by the system, taking the data that has been registered in the OMS systems. Business name and Country are visible for all organizations with permissions to access the report but contact details will be only visible to the NCAs, EMA and reporting organization.

4.1.1.1.2.2. Person Acting on Behalf of MAH

This section includes the details of the person acting on behalf of the Marketing Authorisation Holder for the products reported in this AE Report.

4.1.1.1.2.3. Person(s) involved in AER

This section is reserved to introduce the information related to:

- Primary Reporter
- Other Reporter

4.1.1.1.2.4. AER information

This section is used to introduce the following information:

- **Unique Adverse Event Identification Number:** Globally unique identifier for the adverse event report, designated by the MAH or RA, to be referred to in future follow-ups. Three character country
code-8 character MAH or 8 character RA identifier code-unique number (e.g. USA-MERIALLT-xxxxx, USA-USFDACVM-xxxxx). The country code-MAH or RA is for the country where the AE occurred. Use the 3-character country codes from ISO 3166.

**NOTE:** The Routing ID can be found in the organisation list feature and also, by clicking on the user information (top right corner of EVWEB)

- **Original Receive Date:** This is the date of first communication of an AER from the primary reporter to the MAH or RA. This date is fixed and cannot be changed in future submissions.

- **Most Recent Info Date:** Date current AER submitted to RA

- **Type of Submission:** When clicking on this field, a dropdown menu will be displayed with the following values:
  - Nullification (Only possible by the organisation that did the last follow-up).
  - Expedited (For submission of original reports)
  - Other
  - Periodic
  - Follow-up (not available when creating a new report). Please, consider that the follow ups will be possible to be done only by those users that have L2 and L3 access over one report.

- **Reason for Nullification Report:** This field is reserved to introduce the reason why the AER was nullified. This field will be available when Nullification was selected in Type of submission field.

- **Type of Information in Report:** Some options will be displayed to be selected regarding this field:
  - Lack of expected effectiveness
  - Other
  - Safety issue
  - Both safety and lack of expected effectiveness

**4.1.1.2.5. Animal Data**

In this section, the user will be requested to enter the information related the animal/s that suffered adverse event.
The fields to be fulfilled are the following:

- **Number of animals treated**: The user will have to introduce the number of animals that were treated with the VMP.
- **Number of animals affected**: The user will have to introduce the number of animals affected by the VMP, but the number introduced should NOT be greater than the previous one introduced in **Number of animals treated**. In case a greater number is introduced in this field, the final validation of the report will give an error message to the user.
- **Attending Veterinarian’s Assessment of Health Status Prior to VMP**: This field will give the user a dropdown list in order to select any of them.
- **Species (Type of Species)**: Dropdown list displays all available species to select the one that suffered the AE.
- **Breed/Purebred**: Dropdown list based on the previous selected species. More than one entry can be selected if animals of several breeds are affected.
- **Breed/Crossbred**: Dropdown list based on the selected species. This field is used for crossbred animals.
- **Gender**: Dropdown list. If ‘female’ option is selected, field ‘female physiological status’ will be displayed to be fulfilled.
- **Weight**: Enter the animal weight and if the value is ‘measured’, ‘estimated’ or ‘unknown’.
- **Age**: Introduce the animal/s age and if the value is ‘measured’, ‘estimated’ or ‘unknown’.
4.1.1.2.6. VMP(s) Data and Usage / Registered or Brand name

This section is used to reflect the product(s) that are involved in the AER.

Image 35: Registered name or brand name

- **Registered name or brand name**: The user is able to start typing in the field and suggestions will appear based on the entered text. There are some different values available:
  - **UPD entries (Union product database entries)**: With a record/disc icon next to the product name
  - **PI entries (Product Index entries)**: With no record/disc icon next to the product name

Image 36: UPD product and PI entries

- **Registration identifier**: Mandatory for MAH’s product(s) unless cannot be determined due to insufficient information from reporter, then “Cannot Be Determined” is entered. Optional for other MAHs’ VMP(s). The Registration Identifier consists of the (3 character country code)-(8 character RA Identifier Code)-(registration number of the VMP involved in the AE). The country code is for the country where the product is approved. Use the 3-character country codes from ISO 3166. (For EU centrally authorized products use GBR for the character country code and EUEMA000 for the 8-
character RA Identifier Code.

**NOTE:** When selecting an UPD product, this information in automatically fulfilled

- **Anatomical Therapeutic Chemical Vet (ATCvet) Code:** Mandatory for MAH product(s). To be used for RA searching purposes. For purposes of AER submission this is not to be used to define “same” or “similar” VMPs. If cannot be determined, then “Unknown” may be entered. More information is available about the ATCvet Code at the following website: [http://www.whocc.no/atcvet](http://www.whocc.no/atcvet).

**NOTE:** When selecting an UPD product, this information in automatically fulfilled

- **Company or MAH:** MAH associated with the VMP involved in the AE.

**NOTE:** When selecting an UPD product, this information in automatically fulfilled

- **Dosage form:** This is the dosage form of the VMP involved in the AE. The MAH should choose from the list the labeled dosage form of the VMP(s).

### 4.1.1.1.2.7. Active ingredient(s)

This section is used to indicate the information related to the active ingredient involved in the AER.

- Active ingredient will be mandatory in case a product has not been reported in the previous section
- Active ingredient will be autopopulated when the user selects an UPD product in the previous section
- It’s mandatory to enter information about the Product or the Active substance. When entering any of them, the other won’t be mandatory anymore.

The rest of information in the active ingredient screen, can be fulfilled and it will be referred to the strength:

- **Units (measurement or presentation) and numeric value for strength (numerator)**
- **Units (measurement or presentation) and numeric value for strength (denominator)**

Both for the numerator and denominator, the units will be active to be fulfilled once the numeric value
(both cases) is fulfilled. Once the numeric value is introduced, the user must select or *Units of measurement* or *units of presentation*.

### 4.1.1.2.8. Lot Number

The lot number is not mandatory information. This information is provided in the product container or label. In this section we can find the following fields to be informed:

- **Lot Number**
- **Choose a Date Format**: The user can select the date format of the expiration date.
- **Expiration date**: Expiration date that can be consulted in the product package or label.

### 4.1.1.2.9. Who administered the VMP

In this section the user will be able to open a dropdown menu with some options available. This field is not mandatory.

*Image 38: Who administered the VMP information*

### 4.1.1.2.10. According to Label

This is an option field, and it is used to give information on whether the VMP was used according to its label recommendations.

When accessing this section, there are three different options to be selected:

- Yes
- No
- Unknown

*Image 39: Label usage options*
If 'No' is selected, then more questions will be displayed to be answered (only by clicking on 'yes'). There is no mandatory information in this section. Also, there is no requirement to answer any question:

**Label Usage**

[Image 40: More questions when 'No' is selecting from the menu related to According to label section]

**4.1.1.2.11. Previous Exposure to the VMP**

This section is not mandatory to be answered. This field applies only to exposures outside the dates mentioned in Date of First Exposure (B.2.1.7.1.3.2) and Date of Last Exposure (B.2.1.7.1.3.3). If there was a previous exposure to the VMP, choose "YES" and provide the dates of previous exposure in the
Narrative of AE (B.3.1). Choose “NO” if there was no previous exposure. Choose “UNKNOWN” if the information was not available from the reporter.

**Previous Exposure to the VMP**

This section is not mandatory to be answered. This field refers only to clinical manifestations that occurred during the previous exposure mentioned in B.3.9. Choose “YES” if there was previous AE(s) from an exposure to the VMP and “NO” if there was not a previous AE(s) to the VMP. If “YES” is chosen, describe the clinical 16 signs of in the Narrative of AE (B.3.1). Choose “UNKNOWN” if the information is not available from the reporter.

**Previous AE to VMP**

This section is not mandatory to be answered. In this section, we can find two questions with the same available answers: ‘Yes’, ‘No’, ‘Not Applicable’, ‘Unknown’.

The information in this section relates to affected animal(s). This set of fields will be used for cases where dechallenge or rechallenges occur in single VMP events. Dechallenge-Rechallenge information for multiple VMP events should be described in the narrative to the best detail possible.

**Dechallenge - Rechallenge Information**

Did AE Abate After Stopping the VMP?

Did AE Reappear After Re-introduction of the VMP?
4.1.1.2.14. Adverse Event Data

In this section we can give information about the adverse reaction, the VEDDRA terms, and the narrative to explain any detail.

The following fields are the ones related to this section (Adverse Event Data):

- **Narrative of AE**: The narrative should describe the sequence of events, where information is available, including:
  - administration of VMP(s)
  - clinical signs
  - sites of responses
  - severity
  - pertinent laboratory test results
  - necropsy results (accurate description of gross pathology and accurate description of histopathologic findings including a pathologists assessment)
  - possible contributing factors
  - treatment of AE
  - relevant medical history
  - reason for use of VMP
  - comment on assessment (veterinarian’s or MAH’s)
  - chronological sequence of events

Apart from this information, we can add anymore data/detail to the narrative. Also, in case we want to give more details about a specific field, we can do it in the narrative.

**NOTE**: In the migrated reports from VET2 (DEG format), we could find some fields (with no mapping between DEG format and VICH format) in the narrative.

- **Adverse Clinical manifestation**:
  - **AER Term Name**: The VEDDRA term is indicated in this field. This field is a dropdown menu and the user will get suggestions from the dropdown list based on the entered text.
  - **Number of animals**: Number of animals that suffered the clinical manifestation (VEDDRA term indicated in the previous field ‘AER Term Name’).
  - **Accuracy of the Number of Animals**: Mandatory field when ‘Number of animals’ is indicated. Dropdown list with two options ‘Actual’ or ‘Estimated’.
  - **Date format**: Dropdown list with three option ‘Day, month and year’, ‘Month and year’, ‘Year’.
  - **AE Start Date**: Click on the calendar icon to select the specific date based on the selected format in the previous field.
  - **Length of Time between Exposure to VMP & Onset of AE**: Dropdown list with available option to be selected. Generally, this field would be for single VMP cases or when multiple VMPs are given at the same time. When a clear time picture is difficult to ascertain or not coded easily, particularly in cases where multiple VMPs are involved; or, in single/multiple VMP cases where more explanation is necessary, the time relationship should be described in the narrative to the best detail possible.

- **Duration of AE**:
  - **Duration (Time)**: This is the length of time the adverse reaction lasted
  - **Duration Time Units**: Dropdown list to select one of the available options
  - **Serious AER Reported**: Select ‘Yes’ or ‘No’.
  - **Treatment of AE**: Select one of the available options ‘Yes’, ‘No’ or ‘Unknown’.

- **Outcome to Date**: The following fields in this section can be answered by introducing a number (equal or less than the total of animals affected)
  - Ongoing
  - Recovered/Normal
  - Recovered with sequela
  - Died
  - Euthanized
  - Unknown
**4.1.1.2.15. Assessment of AE**

Assessment by the attending veterinarian on the association between the VMP(s) and the AE (other than human). The MAH should choose from the list the Attending Veterinarian’s assessment on the association between the VMP(s) and the AE. The definitions of these values will be left to the veterinarian’s medical opinion.

**4.1.1.2.16. Report Number(s) of Linked Report(s)**

This section should be used to identify reports that warrant being evaluated together.

**4.1.1.2.17. Supplemental documents**

Utilized by MAH upon request from RA for additional information on a specific AER, or voluntarily by the MAH. This field is a file attachment to be used for pathology, radiology, laboratory analysis, etcetera. The MAH should provide a description of the contents in the files and a listing of the files. This section is repeatable for each supplemental document. The description of the contents of the file should be given in the B.3.1 Narrative of AE.
4.1.1.2. Validate

By default, any mandatory fields in the active area will be highlighted in red denoting that they are invalid or incomplete. This is also the case for sections in the tree view area, which will appear in red text and background (this indicates that these invalid tree view sections contain invalid active area fields).

Note: EVVET3 uses an internal auto-validation process that determines whether a field contains correct input or not. This process is also responsible for providing a descriptive error message when field value is invalid.

On hovering mouse pointer over the icon that appears at the right edge of the field you will see description of field and VICH reference number. e.g., below Image shows description of field "Unique Adverse Event Identification Number" when hovered mouse pointer on icon at the right of the field. In case you need more information apart from existing information on the screen, you can visit the following URL in order to check the VICH guideline documents: VICH guidelines
Thus, at this stage, you should correctly complete all invalid/incomplete fields and fill in any other necessary ones before proceeding with the creation process. When successfully done, all sections in the tree view and active area should appear in blue text, indicating that no errors are present in the Adverse Event Report.

All populated sections should appear in bold text, indicating clearly which sections you have entered data in.

The next step involves validating the entire Safety message (to apply the business rules). EVVET3 provides two methods for this function:

- Validate
- Validate & Send

These two methods appear in the dynamic buttons set of the “Create and Send” screen.

While the “Validate” button might seem redundant, since it is already part of the “Validate & Send” method, it has been included for specific validation scenarios. This button should be used when a message only needs to be validated but not sent to any receiver. For all other regular AER creation cases, you can choose “Validate & Send”.

If there are errors when running the validation process on the Created and Send AER, you will be presented with a validation result window in which all invalid fields will be listed, along with a description of their errors.
The errors displayed in the validation result window are grouped per tree view section of the validated AE Message. To correct a reported validation error you can either close the validation result window (by clicking on the "Close" button) and fix the issue in the Create and Send screen, or click on the specific field for each error message in the validation screen (the bold blue text); this will take you directly to the invalid fields of that tree view section. If there are no errors, the "Close" button will be replaced by an "OK" button.

4.1.1.3. Validate and Send

To send a completed Safety message you need to click on the "Validate & Send" button which is located in the dynamic buttons set.
EVET3 will then proceed to validate the message first on the client-side. If the validation is successful, EVET3 will proceed and apply the server-side validation process. If any of these validation checks is unsuccessful, you will be presented with the validation result window which will contain the errors that need correction.
If both validation steps are successful, EVET3 will send the AE message to the Cosmo DB and place a copy of the message in the "Outbox" view area of the Mailbox screen.
NOTE: Once the validation has been correctly done, we could export the report in XML format in order to save the data to keep working later. For more information about how to export, please refer to section 4.1.1.5 Export XML.

4.1.1.4. Import XML

Import XML feature in EVWEB can be used in case you want to create a report which is almost similar to previously created report with small modifications to few fields. Also, it can be used when the user has the report information in XML format, so it will be possible to create one report by importing the XML file in EVWEB.

NOTE: For a transitional period (6 months), it is possible to upload reports in the old DEG format via Gateway. These reports will be automatically converted to VICH format. EVWEB will only accept reports in VICH format from 28/01/2022 onwards.

Import XML dynamic button allows user to select XML file to be imported from local system. It opens file selection window to select the file. User is allowed to select only one XML file at a time. After the selection of XML, it appears in the tree view section of the EVWEB application.
Image 50: Import XML option

Image 51: Select XML file to import it in EVWEB

Image 52: Imported XML displayed in tree view
4.1.1.5. Export XML

EVWEB provides a framework to export adverse event report as electronic files enabling, thus, the distribution and storing of such items outside the EVWEB. These export functions are available as selectable options in various locations in the application, one in “Create and Send” and also in “Search AE Reports”. “Export XML” button is disabled by default in “Create and Send” screen, as from this view it’s needed to have a correct validation for the report. Once the report is correctly validated, the Export XML will be available to be selected.

Image 53: Download overview in EVWEB (both from ‘create and send’ and ‘Search AE reports’)

Image 54: Export XML
Once you initiate the export function, and regardless of the function’s location (i.e. dynamic buttons set or contextual actions menu), a window will appear requesting you to download the generated file.

Also, in "Search AE Reports" screen you can see Export XML check box on top of the search result table. By default check box is unselected. When user selects this checkbox, all the reports in that page gets selected. Click on Export XML button will export all the reports at once. It is also possible to export individual report by selecting check box individually for the specific report(s). Export XML button will also show number of reports selected for export when check box is selected.
The available export file formats are XML & HTML. The below matrix outlines the supported export file formats per these items:

<table>
<thead>
<tr>
<th>Export File Format</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>XML</td>
<td>Abbreviation for Extensible Markup Language. A markup language that defines a set of rules for encoding documents in a format which is both human-readable and machine-readable.</td>
</tr>
<tr>
<td>HTML</td>
<td>An HTML file that complies with the Council for International Organizations of Medical Sciences standard (CIOMS).</td>
</tr>
</tbody>
</table>

*Table 4: Export formats (XML and HTML)*
4.1.2. Search AE Reports

4.1.2.1 Global Search

When applicable, the search field is located below the dynamic tabs as shown in the screenshot below. Here you can either search for any specific report or just click on magnifying glass to search ( ). Search without any specific data will show all the results and when searched with specific data like Unique AER number will show only specific record.

Image 59- Global Search field

Image 60- Global Search

4.1.2.2 Advanced Search

EVET3 allows you to perform elaborate search in the data base. The advanced search parameters that describe and define search are available as separate ribbons under the Search ribbon. As an example, the advanced search parameters available for EVET3 screen are displayed.
Every advanced query is divided in 3 different areas (see above screenshot for reference):

1. **Criteria ribbon**
2. **Fields ribbon**
3. **Results area**

Criteria and fields are used in combination, to better target the scope of the search. The results area in this search case is actually the active area of the **EVWEB** screen.

1. **Criteria Ribbon**

The criteria ribbon is used to define the conditions of an advanced search. This area allows you to select one or more items and define their value. These items are then used as criteria to filter the results of the advanced query.

User can add maximum of 7 criteria to search reports, after that an error message is displayed to let the user know “The maximum amount of criteria has been reached. Please remove some in order to add additional ones.”
To add a criteria item, users need to click on criteria section (under ‘’More criteria’’). This will produce a drop-down list from which you can select the desired criteria item. You can repeat this process as many times as necessary to obtain all criteria items required for your advanced query.

**Tip:** If the criteria section is not visible in the criteria ribbon then this means that the ribbon is in collapsed mode. You should click on the 📈 icon which will expand the ribbon, allowing access to add the desired criteria.

Once you have selected your criteria items, and before you run the query, you should define their values. This is accomplished by clicking on each criteria item that you have inserted in the criteria ribbon, and defining their value using the available options presented.

Depending on criteria type, when you click on an inserted criteria item you will be presented with a drop-down list (or a calendar in the case of date criteria items) from which you can choose the required option.

To remove a criteria item, you simply need to click on the ✗ icon located on the right-hand side of the item.

The table below is listing all the available criteria and the value definitions that each one accepts:
<table>
<thead>
<tr>
<th>CRITERIA FILTER</th>
<th>VALUE TYPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Breed</td>
<td>Free Text (with suggestion list available only when Species is informed)</td>
</tr>
<tr>
<td>Case Narrative</td>
<td>Free Text</td>
</tr>
<tr>
<td>Correct Report, with warnings, errors</td>
<td>Option list selection</td>
</tr>
<tr>
<td>Date of First Exposure</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>Date of first Exposure (From)</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>Date of first Exposure (Up To)</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>Date of Onset of AE</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>MAH</td>
<td>Organization ID</td>
</tr>
<tr>
<td>Most recent Info Date</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>Most recent Info Date (From)</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>Most recent Info Date (Up To)</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>Occur Country</td>
<td>Free Text (with suggestion list available)</td>
</tr>
<tr>
<td>Off label use</td>
<td>Dropdown Selection</td>
</tr>
<tr>
<td>Original Received Date</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>Original Received Date (From)</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>Original Received Date (Up To)</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>Outcome Died</td>
<td>Yes / No selection</td>
</tr>
<tr>
<td>Outcome Euthanized</td>
<td>Yes / No selection</td>
</tr>
<tr>
<td>Product Name</td>
<td>Free Text (with suggestion list available)</td>
</tr>
<tr>
<td>Product Name – as Recoded</td>
<td>Free Text (with suggestion list available)</td>
</tr>
<tr>
<td>Sender</td>
<td>Routing ID</td>
</tr>
<tr>
<td>Species</td>
<td>Free Text (with suggestion list available)</td>
</tr>
<tr>
<td>Substance Name</td>
<td>Free Text (with suggestion list available)</td>
</tr>
<tr>
<td>Substance Name – as recoded</td>
<td>Free Text (with suggestion list available)</td>
</tr>
<tr>
<td>Type of submission</td>
<td>Free Text (with suggestion list available)</td>
</tr>
<tr>
<td>Unique AER Number</td>
<td>Free Text</td>
</tr>
<tr>
<td>Use According to Label</td>
<td>Dropdown Selection</td>
</tr>
<tr>
<td>VICH Batch Received Date</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>VICH Batch Received Date (From)</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>VICH Batch Received Date (Up To)</td>
<td>Date (YYYY/MM/DD)</td>
</tr>
<tr>
<td>VeDDRA Name</td>
<td>Free Text (with suggestion list available)</td>
</tr>
</tbody>
</table>

*Table 5: Criteria filters and value types*

2. **Fields Ribbon**

The fields ribbon is used to define the output of an advanced query. This means that the items displayed in the results area will contain only the fields previously inserted in this ribbon.
Usually, some of the items displayed in the fields ribbon are the default ones. If you run the query without inserting any items in the fields ribbon there is an error message displayed "Error occurred while retrieving a data” no results come up.

To add a field item, you need to click on the criteria section (under “+More fields”). This will produce a drop-down list from which you can select the desired field item. You can repeat this process to obtain maximum of 13 field items required for your advanced query. After 13 items are selected and you still wish to add more, an error message is displayed that forces you to remove fields in order to add the desired ones.

**Tip:** If the field section is not visible in the field ribbon, then this means that the ribbon is in collapsed mode. You should click on the icon which will expand the ribbon, allowing access to add the desired fields.
3. **Results Area**

To initiate a query, after having specified the criteria and fields, you need to click on any magnifying glass icon. The results of the query will be displayed in the active area of the current EVET3 screen in a list view layout.

![Image 69 - Result Area](image)

When running a query, the system will always return, as the result, a maximum of 50 search items. When the number of items exceeds that limit then one of the following options becomes available to the user, a set of pages to navigate will appear at the bottom right of the active area.

Numeric indicators of the displayed search items’ range, along with the total number of items resulting from the query, appear at the top and bottom left of the active area.

![Image 70 - Pagination](image)

### 4.1.2.3 **Advanced List Criteria Query**

This special search method deserves its own paragraph, despite belonging to the criteria ribbon functionality. The advanced list criteria query method provides a more refined way of looking up EV data within a criteria item, leading in turn to a quicker and easier set up of a simple or advance query. Furthermore, this search method offers extra query modes and, thus, is not restricted to EVWEB’s regular “Contains” clause which is used in simple and advanced queries. These modes are as follows:
<table>
<thead>
<tr>
<th>Criteria operator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Begins</td>
<td>Finds only matches which start with the search term.</td>
</tr>
<tr>
<td>Matches</td>
<td>Finds only matches which are identical with the search term.</td>
</tr>
<tr>
<td>Contains</td>
<td>Finds the search term anywhere in the name – beginning, middle, or end.</td>
</tr>
</tbody>
</table>

*Table 6: Criteria operators*

Once you add such an item in the criteria ribbon and click on it, you’ll be presented with options to select the query mode and enter your search term. In the following screenshot the user has selected the “Begins” query mode and has inserted the search term “Act”:

![Image 71 – Advance Search Criteria ("contains" operator)](image)

Reports once validated and sent can be searched from "Search AE Reports" screen. By default this screen will have search criteria and fields options to search. You can add criteria by clicking on “+More criteria” in the criteria field and select available criteria from dropdown to search for reports, user can choose fields to see in the result table by selecting from fields dropdown. To remove criteria or field selected you can click on “X” icon on selected value. This will refresh the table list and results are updated as per selected criteria (Further detailed in section 4.1.2.2 Advance Search)
NOTE: The users can find cases related to all their products by searching under criteria ‘Product Name’ (‘Product name’ criteria is used to filter by the reported product. On the other hand, ‘Product name (as recoded)’ is used to filter by the recoded product after the recoding process has been executed) but if the product is not recoded, the users won’t have L2 access. If the users need urgent access to the case narrative due to a potential signal related to a product not yet recoded, they should contact the relevant NCA/EMA to request for the product to be added to the UPD.

4.1.3 Actions

Search result table in “Search AE Reports” screen shows “Action” column which contains below functional icons, each of these icons perform specific actions. Leaving the mouse on the Icon, you can see a pop-up with the icon description.
4.1.3.1 Open Report

When you click on open icon a pop-up window opens up with tree view and action area and on the top you will see buttons like “Follow up/Nullification”, “Download”, “Download attachments”

**Follow up/Nullification**: This will be disabled in this screen as user can perform this action from “Create and Send” screen. Nullifications and follow ups can only be created from one previous report (cannot be created from scratch). Nullification or follow up action can be performed by clicking on the pencil icon under actions column in the results table from the search view. Afterwards you can go to the “Create and Send” screen and process the FU/nullification.

**Download**: User can download Report from here, file gets saved to local system/network

**Download attachment**: User will be able to download Report with attachments from here

**Close**: This allows user to close the popup window

4.1.3.2 Follow-up / Nullification

EVWEB does not allow the user to remove any report. In case we need to do any correction, we need to create a follow-up of the case report, this way the last follow-up will be the last version of the original report. In case we need to nullify a report, we need to do a follow-up and select NULLIFICATION as the
Type of Submission from section **A.4 AER Information**.

![Image 76: Follow up/nullification action icon](image)

User will be able to mark any report for Follow-up/Nullification by clicking the edit pencil icon in actions column (from 'Search AE reports' view). After doing this, the icon gets highlighted in blue for the report selected and a pop-up message appears on the bottom of the site: “Report added to follow-ups”.

![Image 77 - Follow-up action from Search AE report](image)

The reports which are marked for follow-up are visible in “Create and Send” screen and user can modify these reports by navigating through each section.

In section A.4 AER Information, we can specify the type of report in field **Type of submission**. By default, this value is set with option FOLLOW-UP, however, to nullify a report we can change this value in field (A.4.4.1) selecting NULLIFICATION from the dropdown list. After selecting this option, a new mandatory field appears in section to inform the **Reason for Nullification Report**.

In both cases, the Unique AER identification number is frozen and cannot be changed. Follow-ups and Nullification always maintain this value and can be identified because of new VICH Batch Number and Message Number assigned.
**NOTE**: Follow ups are only available to be done by the following access policy levels:

- L2
- L3

It means that an organisation with Access policy L1 regarding one report cannot do a follow up. Also, when an organisation with access policy L2 does a follow up, it won't be needed to fulfil the information related to the primary reporter (this information will be retrieved from the case report).

**NOTE**: Nullifications are only available to be done by the organisation that did the last follow up. If any other organisation tries to do the nullification, an error message will appear when report validation is done.

### 4.1.3 Download

Individual report can be downloaded by using this button and file gets downloaded into local system/network. Two types of formats can be downloaded from ‘Search AE Reports’ view: HTML and XML.
4.1.4 **Search VICH Batch**

Search VICH Batch allows users to search for a specific batch number. The difference in this case between ‘Search AE Reports’ or ‘Search VICH Batch’ is that the first option will return only the information for the single selected report, while searching for VICH Batch will return information for the multiple reports that could have been added to one VICH Batch.

![Image 80 - Search VICH Batch](image)

In “Actions” column, only options to Open and Download are available. This is because Follow-Up/Nullification can be done only for a single AER Report and not a group of reports.

4.1.4.1 **Open VICH Batch**

When you click on open icon a pop-up window opens up with tree view and action area and on the top, you will see buttons like “Follow-up/Nullification”, “Download”, “Download attachments” and “Close”. For the entire VICH batch, “Follow-up/Nullification” and “Download attachments” are disabled. These actions are only possible for a single report and are activated when user clicks on the specific AE Report in the left panel menu.

![Image 81 - Actions from an open message (with several reports)](image)
5 Mailbox

The Mailbox screen of the EVET3 application allows users to keep track of sent and received messages and Acknowledgement messages and search messages. In EVET3's main menu you see "Mailbox" option. To access the Mailbox screen, click on Mailbox on the main menu. By default, when you enter this screen, you will be presented with "Inbox" view.

<table>
<thead>
<tr>
<th>Menu Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inbox</td>
<td>This provides quick search of AE Messages which received by user organisation by selecting available searching criteria and filtering with required columns. In Inbox we can also find the ACKs.</td>
</tr>
<tr>
<td>Outbox</td>
<td>This provides quick search of AE Messages which are sent by the logged organisation. Available searching criteria and fields (to get the results table) are available to be used.</td>
</tr>
</tbody>
</table>

Table 7: Inbox/Outbox

The following screen will be displayed when you click on Mailbox from main menu

![Image 82 – Mailbox](image)

5.1 Inbox Search & View

Enabled by default, allows the user to view all the messages and Acknowledgement messages received by the user’s organisation.

If the "Inbox" view option is active, you will find criteria and Fields options on the screen to search for messages and Acknowledgement with a set of defined criteria and fields.

To add a criteria item, you need to click on the criteria section, right to the last selected criteria that is located in the criteria ribbon. This will produce a drop-down list from which you can select the desired criteria item. You can repeat this process as many times as necessary to obtain all required criteria items.
required for your query.

Once you have selected your criteria items, and before you perform the query, you should define their values. This is accomplished by clicking on each criteria item that you have inserted in the criteria ribbon, and defining their value using the available options presented.

To remove a criteria item, you simply need to click on the icon located on the right side of the item. To initiate the search, after having specified the criteria items, you need to click on any magnifying glass icon . The results of the search will be displayed in the active area of the inbox screen in a list view layout.

Search results are displayed in table format with columns as selected in "Fields" option and along with Action column.

Action column allows user to download message individually by using "Download" icon present at each message row. When user clicks on download icon, a dropdown with XML option pops up and user will be able to download message in XML format into local system/network.

5.2 Outbox Search & View

Outbox allows the user to view all the messages and Acknowledgement messages sent by the user’s organisation. These are messages that you have sent to another organisation. All sent messages and acknowledgements, will be displayed search result table with a set of defined criteria and fields.

Outbox screen will have search option with Criteria and Fields. To add a criteria item, you need to click on the criteria section that is located in the criteria ribbon. This will produce a drop-down list from which you can select the desired criteria item. You can repeat this process as many times as necessary to obtain all required criteria items for your query.

Once you have selected your criteria items, and before you perform the query, you should define their values. This is accomplished by clicking on each criteria item that you have inserted in the criteria ribbon and defining their value using the available options presented.
To remove a criteria item, you simply need to click on the icon located on the right side of the item. To initiate the search, after having specified the criteria items, you need to click on the magnifying glass icon in the criteria ribbon. The results of the search will be displayed in the active area of the inbox screen in a list view layout.

Search results are displayed in table format with columns as selected in "Fields" option and along with Action column.

Action column allows user to download message individually by using "Download" icon present at each message row. When user clicks on download icon, a dropdown with XML option pops up and user will be able to download message in XML format into local system/network.

Image 84 - Outbox – Download message

6 Organisation List

This feature will be available for all users in EVWEB and through this feature, it’s possible to consult the following information for any organisation that has a routing ID associated:

- Country
- Organisation ID (OMS ID)
- Organisation Name
- Routing ID

The information indicated above are also the available criteria to be used.
You can select any criteria from dropdown list, however, result table shows all columns i.e. "Organisation id", "Organisation Name", "Country" and "Routing id" irrespective of selected criteria. You can either select single criteria from drop down list i.e. "Organisation id", "Organisation Name" and "Routing id" or combination of these criteria. However, you cannot combine these criteria’s with "Country" criteria, it needs to be selected as single criteria.

**NOTE:** Only organisations with Routing ID associated will be retrieved by Organisation list feature, so in case we want to look for an organisation with no routing ID, we need to use OMS (Organisation Management system) to get it (please, see ‘System Tips’ section for more information about this issue).

### 7 Profile

This feature is reserved only for:

- **Responsible person** of each organisation
- **Trusted deputy** users

Through this feature, the above indicated users could consult the information related their organisations. In case one user is Responsible (RP) or Trusted deputy (TD) for more than one organisation, a dialog window will appear to select the organisation for which the user wants to display the information.

Once inside ‘Profile’ feature, the user will display the following information:
2. **Organisation information**: This section will retrieve data from OMS (Organisation Management Service) and it will be referred to the main information of the organisation.

3. **Responsible information**: This section will retrieve data from IAM (Identity and Access Management). And it will be referred to the responsible for the selected organisation.

4. **Headquarter info.**: This table/section will give information about the Headquarter. In this table the user will see two columns regarding the HQ:
   - **Name(Headquarter user)**: Name + Last name
   - **User name in the system**

5. **Affiliates info.**: This table/section will give information about all affiliated linked to a headquarter (HQ). The user will see the following columns regarding each of the affiliates:
   - **Affiliate ID**: The affiliate ID will be the OMS ID
   - **Affiliate name**: This column will give the name of the organisation (affiliate)
   - **Name**: This column will give the Name + Last name of each user in each of the affiliates.
   - **User name**: User name in the system for each user

### System tips

In order to collect some helpful information with regards to the system, this section will give some tips regarding some key points:

- As the system cannot save a draft to keep working later, it will be helpful to download (export XML) the report. To make the ‘Export XML’ available we should validate the report, and once it’s validated, we will be able to export it. If we get error message from the validation, we won’t be able to export the report.
- In case we want to print the report, we should use the HTML downloadable version from the result table in ‘Search AE Reports’.

![Image 88 - HTML download format (from Search AE Reports)](image)

- In case one organisation was already registered and working in VET2 system, it will be automatically migrated to VET3 → No need to register again to use VET3. Also, the routing ID associated to each existing organisation will be migrated.

- If one user was already using VET2, it will be automatically migrated to VET3, so the same user will exist in VET3 with the same role(s) and permissions associated. New users (that did not exist in VET2) will need to be registered in IAM (Identity and Access Management) and the required roles need to be approved.

- When starting using VET3, the already existing users (from VET2) will be requested to change their passwords through IAM (https://register.ema.europa.eu/identityiq/login.jsf?prompt=true)

- To look for one specific organisation and get, for example, the ORG ID (OMS ID) we can use the following SPOR URL https://spor.ema.europa.eu/omswi/#/searchOrganisations. Once inside, please use the criteria to look for the desired organisation. This tip is useful when we need to look for an specific OMS to use the MAH criteria in search mode in EVWEB (as Organisation list feature only shows organisations that have a routing ID associated).
- In case we want to check the VICH ACK Transmission codes, we can open one report once it has been already sent and open the VICH Batch Acknowledgement and check the field ‘Transmission Acknowledgement code’.

There are three different values regarding this field:

- **AA** when the XML is valid, attachments have no virus, the message size is under 20MB, and there are no pre-validation errors, no batch level errors, and no error reports. There could be reports with warnings.

- **AE** when the XML is valid, attachments have no virus, the message size is under 20MB, and there are no pre-validation errors, no batch level errors, and one or more
report has an error

- **AR** when the XML is not valid, or, one attachment has a virus, or the message size is above 20MB, or, there are a pre-validation error, or, there is a batch level error

---

- As it was mentioned in before, only organisations with an already Routing ID associated will be retrieved and displayed in 'Organisation list' feature. So, if the organisation that we are looking for is not retrieved in 'Organisation list' feature, it’s because that specific organisation does not have any routing ID associated so to get the ORG ID (OMS) we need to go to OMS URL as it was mentioned in the previous tip (https://spor.ema.europa.eu/omswi/#/searchOrganisations).

- *Follow ups* are only available to be done by the following access policy levels:
  - L2
  - AR
  - L3
It means that an organisation with Access policy L1 regarding one report cannot do a follow up. Also, when an organisation with access policy L2 does a follow up, it won’t be needed to fulfil the information related to the primary reporter (this information will be retrieved from the case report).

- Nullifications are only available to be done by the organisation that did the last follow up. If any other organisation tries to do the nullification, an error message will appear when report validation is done.

- One single batch could contain several reports (up to 100 reports) but we also should take into account the size of the narrative:
  - If one single batch contains only 1 report, the narrative could contain up to 20,000 characters.
  - If one single batch contains multiple reports, the narrative for each of the reports should not exceed 5000 characters.

- Any organisation configured as Headquarter will have Level 3 access on the cases sent by their hierarchy.

- The fact that reports come in the same batch does not mean that they are related. Field B.6 (Report number(s) of linked Report(s)) should be used to link reports.

9 Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation/Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AER</td>
<td>Adverse Event Report [Veterinary]</td>
</tr>
<tr>
<td>AE</td>
<td>Adverse Event</td>
</tr>
<tr>
<td>Business Rules</td>
<td>The validation rules applicable to individual fields and between fields in the Adverse Event Report.</td>
</tr>
<tr>
<td>DB</td>
<td>Data Base</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>EV</td>
<td>EudraVigilance</td>
</tr>
<tr>
<td>EVWeb</td>
<td>EudraVigilance Web System</td>
</tr>
<tr>
<td>HTML</td>
<td>Hypertext Markup Language. Commonly used to format Web pages.</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>MAH</td>
<td>Marketing Authorization Holder</td>
</tr>
<tr>
<td>MP</td>
<td>Medical Product</td>
</tr>
<tr>
<td>MS</td>
<td>Member State</td>
</tr>
<tr>
<td>NCA</td>
<td>National Competent Authority</td>
</tr>
<tr>
<td>Vet</td>
<td>Veterinarian. In EV Vet terms this references any Veterinarian who resides within the EEA.</td>
</tr>
</tbody>
</table>
### Abbreviation/Acronym | Description
--- | ---
VICH | International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products
VMP | Medicinal Products for Veterinary User
XML | EXtensible Markup Language
OMS | Organisation management system

*Table 8 - Abbreviations*

## 10 AER entry step-by-step guide

This step-by-step guide describes the process of creating an AE report received from the primary source.

The information in the fictitious “European Veterinary Pharmacovigilance Reporting Form for MAHs” shown below will be used as an example to complete the AE report.

### 10.1 Log In


7. Introduce credentials (user and password)
8. Click on ‘Next’.
9. Select the organisation and once it’s selected, click on ‘Select’

![Image 93: Select organisation (EVWEB Log In)](image)

10. Home page is displayed
10.2 Create new report

1. Access to 'Create and Send' option and click on 'New'

10.2.2 VICH Batch information

2. Fulfill VICH batch information. This information is referred to the whole Batch, that could contain several reports (even if they are related to each other).

   - **VICH Batch number (mandatory):** Open text field to type the desired VICH Number.
   - **VICH Batch Sender Identifier:** VICH Batch Sender Identifier will be auto populated based on our Log In credentials.
   - **VICH Batch Receiver Identifier (mandatory):** From the dropdown, select the Receiver (commonly EVVETPROD – EudraVigilance Veterinary).
   - **Date of VICH Batch creation:** This field is auto populated.
10.2.3 Report information

In this section, it’s requested to fulfill the information related one specific report in the batch. The information in the report has several sections and subsections:

- **Section A – Administrative and Identification Information.** Information related to the Regulatory Authority/Marketing Authorization Holder and the person(s) involved in AER (sending the AER).
  - A.1 Regulatory Authority (RA)
    - A.2.1 MAH Information
    - A.2.2 Person Acting on Behalf of MAH
  - A.3 Person(s) Involved in AER
    - A.3.1 Primary Reporter
    - A.3.2 Other Reporter
  - A.4 AER Information

- **Section B – Description of Animal Data Information**
  - B.1 Animal Data
  - B.2 VMP(s) Data and Usage
    - VMP #n
      - B.2.1 Registered or Brand name
      - B.2.1.7 Route of Exposure
- **B.2.2 Active Ingredient(s)**
- **B.2.3 Lot Number**
- **B.2.4 Who Administered the VMP**
- **B.2.5 Use according to Label**
- **B.3.9 Previous Exposure to the VMP**
- **B.3.10 Previous AE to VMP**
- **B.4 Dechallenge-Rechallenge Information**
  - **B.3 Adverse Event Data**
  - **B.5 Assessment of AE**
  - **B.6 Report Number(s) of Linked Report(s)**
  - **B.7 Supplemental Documents**

3. Click on section **A.1 or A.2** (depending if the logged user is a NCA or a MAH) and the information relating this section should be auto-populated based on the logged user.

   - When clicking on ‘+’ icon next **VICH Batch** in the tree, we will be able to create more reports inside the same VICH Batch.

4. Fulfill the information related the **Person(s) involved in AER**. Please, consider activating ‘Withhold’ option to hide some fields and to enter only the information for:
   - **a. Last name (mandatory)**: Both for primary reporter and other reporter, introduce the letter of the surname.
   - **b. Country (mandatory)**
   - **c. Primary/Other Reporter Category (dropdown menu) (mandatory)**
5. Fulfill **AER information**.

- **Unique Adverse Event Identification Number (mandatory)**: Please, consider that the Unique AER Number must follow the following structure:

  **MAH:**

  *Country of occurrence code (3 digits) – MAHORID (8 digits) -ROUTING ID + remaining text (up to 47 digits)*

  **Example:**

  **RA:**

  *Country of occurrence code (3 digits) – VICH RA Identifier Code (8 digits) – Internal case reference*

- **Original receive date (mandatory)**: Introduce date.
- **Original Recent info date (mandatory)**: Introduce date.
- **Type of submission (mandatory)**: Click and select the desired option from the dropdown list (Follow up option won't be available when creating new reports).
- **Type of Information in report**: Click and select the desired option from the dropdown list.
11. Fulfill the **Animal data**: Enter the information related to the animal(s) that suffered the AE

- **Number of Animals treated**: Introduce the total number of animals that were treated with the corresponding product related to this report. To avoid future validation error message, please check that *Number of animals affected* is <= *Number of animals treated*.
- **Number of Animals affected (mandatory)**: Introduce the number of animals that were affected by the AE.
- **Attending Veterinarian’s Assessment of Health Status Prior to VMP**: Dropdown list to select an option.
- **Species (type of Species) (mandatory)**: Select an option from the dropdown list.
- **Breed**: Select an option from the dropdown list. The available list will depend on the previous selected species.
- **Crossbred**: Select an option from the dropdown list. The available list will depend on the previous selected species.
- **Gender**: Select an option from the dropdown list. If ‘female’ is selected, then ‘Female physiological status’ field will be displayed to be fulfilled (dropdown list).
- **Reproductive status**: Select an option from the dropdown list.
- **Weight (mandatory)**:
  - **Weight measured, estimated or Unknown**: Dropdown list
  - **Weight (kg)**: Introduce the weight of the animal.

- **Age (mandatory)**:
  - **Age measured, Estimated or Unknown**: Dropdown list
  - **Age**: Age number
  - **Age units**: Dropdown list.
12. Enter the information related to the **product**. When selecting a UPD product, the following fields and the active ingredients should be auto populated:

- Registration identifier
- ATC Vet code
- Company or MAH
- Active ingredients (different subsection in the tree)

- Registered name or brand name (mandatory if active ingredient is not reported): It’s possible to start typing the name of the product and the system will give suggestions based on the entered text. Also, a new product could be added as free text:
101: Add a new product option (Field B.2.1)

- **Registration Identifier**: Introduce the registration number. When selecting an UPD product, this field will be auto populated.
- **Anatomical Therapeutic Chemical Vet (ATCvet) Code**: Dropdown list. When selecting an UPD product, this field will be auto populated.
- **Company or MAH**: Introduce the company or MAH product holder. When selecting an UPD product, this field will be auto populated.
- **Dosage form**: Dropdown list.
- **MAH Assessment**: In those regions where required, assessment by the MAH of the association between the use of the VMP and the AE based on a hierarchical system. For the purposes of 3rd country reports of an AE, the assessment originally conducted by the MAH will be sufficient for subsequent RAs.
- **RA assessment Term**: Dropdown list.
- **Explanation Relating to Assessment**: RA assessment explanation. Assessment of the association between the use of the VMP and the AE(s). Each VMP is evaluated and assigned to one of the categories as defined within regions.

102: Product information

13. Enter the information related to the **Route of Exposure**.
   - **Route of Exposure (Route of Administration)**: Dropdown list
   - **Dose per administration (numerator)**:
     - **Numeric value for Dose (Numerator)**: Introduce numeric value
○ **Units of Value for dose (Numerator):** Fulfill one of the fields (or **Units of measurement** or **units of presentation**). When trying to fulfill both, one will be erased.

- **Units value for Dose (Denominator) (mandatory if numeric value for dose is fulfilled):** Fulfill one of the fields (or **Units of measurement**, **Units of presentation** or **Dose denominator qualifiers**). When trying to fulfill all of them, the other two fields will be erased.

- **Numeric value for interval of Administration:** Introduce numeric value.

- **Units of Value for the Interval of Administration** (mandatory if Numerical value is entered): Dropdown list.

- **Date of first exposure:** Enter a date.

- **Date of last exposure:** Enter a date.

---

**Image 103: Route of exposure information**

14. **Active ingredient** must be fulfilled. If an UPD product was selected (in the previous step – B.2.1 Registered or Brand name), the active ingredient is auto populated automatically. If not, the active ingredient and the rest of the fields should be fulfilled.

- **Active ingredient** (mandatory if a product has not been introduced): Start typing the substance/active ingredient and the system will give suggestions based on the entered text. Also, it’s possible to add a new active ingredient by clicking on ‘Add as new substance’ (when the system does not recognize the entered text). When an UPD product has been selected (field B.2.1), the active ingredient is auto populated.

**NOTE:** When a product has been entered (field B.2.1), is not mandatory to fulfill the active ingredient.

- **Numeric value for strength (Numerator):** Enter a numeric value

- **Units for Numeric value for strength (Numerator):**  
  - **Units of measurement**: Dropdown list

- **Numeric value for strength (Denominator):** Enter a numeric value

- **Units of Numeric value for Strength (Denominator):**  
  - **Units of measurement**: Dropdown list.
  - **Units of presentation**: Dropdown list.
**NOTE:** Units of measurement won’t be able to be fulfilled until Numeric values are introduced.

**Image 104: Add a new substance**

**Image 105: Active ingredient information**

15. **Lot number** information to be fulfilled (Lot number and Expiration date. This information could be found in the product label)
   - **Expiration date:**
Choose a date format: Select an option from the dropdown
Expiration date: Enter a specific date

16. Through this field, the user will select an option from the dropdown list to give information about the person who administered the VMP (dropdown list).

17. B.2.5 field is referred to the Label use. If the user selects 'No', some fields will appear in order to give more information about the off-label use. If applicable, several of these new fields can be answered:

- Was the target species off-label?: Select ‘Yes’ if so.
- Was the route of administration off-label?: Select ‘Yes’ if so.
- Was the animal overdosed?: Select ‘Yes’ if so.
- Was the animal underdosed?: Select ‘Yes’ if so.
- Was the treatment regimen off-label?: Select ‘Yes’ if so.
- Was the indication off-label?: Select ‘Yes’ if so.
- Was the product expired?: Select ‘Yes’ if so.
- Was the any other off-label use?: Select ‘Yes’ if so.

NOTE: To give more details about off-label use, it could be done in the narrative.
18. **Previous Exposure to the VMP**: ‘yes’, ‘No’ or ‘Unknown’ are the possible values.

19. **Previous AE to VMP**: ‘yes’, ‘No’ or ‘Unknown’ will be the possible values.

20. **Dechallenge - Rechallenge Information**:  
   - **Did AE Abate after stopping the VMP**: ‘Yes’, ‘No’, ‘Not applicable’, ‘Unknown’ are the possible values.  
   - **Did AE Reappeared after Re-introduction of the VMP?**: ‘Yes’, ‘No’, ‘Unknown’ are the possible values.

21. **Adverse Event Data**:  
   - **Narrative of AE (mandatory)**: Enter any desired information in the narrative. In case it’s necessary to give more details about the AE or any
field, it can be done in this open field. In this field, it’s possible to introduce the full information of the case.

- **Adverse clinical Manifestations:**
  - **AER Term Name (mandatory):** Click on the field and a dropdown list will appear to select one of the terms (VEDDRA Terms).
  - **Number of animals:** Introduce the number of animals that suffered the VEDDRA Term selected.
  - **Accuracy of the Number of Animals:** Dropdown list

**NOTE:** If more than one VEDDRA Term is needed, click on ‘+Add’. For each entry (VEDDRA Term) it’s possible to fulfill the information mentioned above (*AER Term name, Number of animals, Accuracy of the number of animals*).

**Date of Onset of AE (AE Start Date) (mandatory):** Enter both the date format and the specific date when the AE started.

- **Duration of AE:**
  - **Duration (Time):** Enter a numeric value
  - **Duration Time Units:** Dropdown list
  - **Serious AER Reported (mandatory):** ‘Yes’ or ‘No’ are the possible values.
  - **Treatment of AE:** ‘Yes’, ‘No’ or ‘Unknown’ are the possible values.

- **Outcome to Date:**
  - **Ongoing:** Enter a numeric value
  - **Recovered/normal:** Enter a numeric value (recovered animals from the AE)
  - **Recovered with Sequela:** Enter a numeric value (how many animals recovered with sequela from the AE)
  - **Died:** Enter a numeric value (animals that died due to the AE)
  - **Euthanized:** Enter a numeric value (animals that were euthanized)
  - **Unknown:** Enter a numeric value
Adverse Event Data

Narrative of AE:

A horse was administered, became very stiff, and could barely get his head down to the ground and ate and drank less than usual. The horse was brought to the clinic the following day, by then the horse had no fever and the general health conditions were without remarks. The horse was given 5 liters of water + 5 ml of paraffin oil within 20 minutes. The horse recovered fully. The horse had, prior to this event, had a reaction to the Duvayve vaccine. 2020-11-02: Swedish MPA has decided to submit all adverse event reports from 2013 to EVMet, to facilitate signal detection.

Adverse Clinical Manifestations:

- Fever: 1 Actual
- Decreased appetite: 1 Actual
- Decreased drinking: 1 Actual
- Injection site stiffness: 1 Actual

Choose a Date Format:

- Day, Month and Year: 2013/03/19

Length of Time between Exposure to VMP & Onset of AE:

- <24 hours

Duration of AE:

- Duration (Time): 1
- Duration Time Units: Day

Serious AER Reported:

- Yes

Treatment of AE:

- Yes

Outcome to Date:

- Ongoing
- Recovered / Normal: 1
- Recovered with Sequella
- Died
- Euthanized
- Unknown
22. **Veterinary Assessment of AE**: Dropdown list

**Image 113: Veterinary Assessment of AE**

23. **Report Number(s) of Linked Report(s)**: It’s possible to add as many links as needed. For each entry it’s possible to enter the following information:
   - **Unique Adverse Event Report Identification Number**: Enter the Unique AER number of the report we want to link to.
   - **Explanation for Linkage**: Reason of the link.

   **NOTE**: In order to create some links, the user must click on ‘+ Add’

24. **Supplemental documents**: It’s possible to upload documents related to the AER (both to upload the document and indicate the type of document).

   **NOTE**: In order to upload some documents, it’s necessary to click on ‘+Add+

25. Click on ‘Validate’ from the top right corner and check if there is any error message. If so, check that corresponding field and modify the information in order to correct any mistake in the report.

   - Orange message → The validation could run successfully
   - Red messages → The user needs to correct the fields/data.

   **Image 114: Report validation (with errors – red messages)**

26. Once the validation is OK, click on **Validate and Send**. A successful message will be displayed:

   **Image 115: Report validation without errors**
10.3 How to import an XML to create a new report


2. Introduce credentials (user and password)
3. Click on 'Next'.
4. Select the organisation and once it's selected, click on 'Select'

5. Home page is displayed
6. Click on AERs
7. Click on ‘Create and Send’
8. Click on ‘Import XML’

Image 119: Import XML

9. Once it’s imported, make the needed changes or modifications
10. Click on ‘Validate’ from the top right corner and check if there is any error message. If so, check that corresponding field and modify the information in order to correct any mistake in the report.
   - Orange message → The validation could run successfully
   - Red messages → The user needs to correct the fields/data.

Image 120: Select XML to be imported in EVWEB
11. Once the validation is OK, click on 'Validate and Send'. A successful message will be displayed: