



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

4 December 2023  
Information Management

## EVVET - EVWEB User Manual

Version 1.8

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

**Telephone** +31 (0)88 781 6000

An agency of the European Union



# Table of Contents

<b>1. INTRODUCTION.....</b>	<b>4</b>
1.1. ABOUT THIS USER MANUAL.....	4
<b>2. EVVET3 EVWEB .....</b>	<b>4</b>
2.1. EVWEB LOGIN .....	4
2.1.1 Login.....	5
2.1.2 Login User Information.....	7
2.1.3 User Interface Layout.....	8
2.1.4 Session Time Out.....	9
<b>3. EVVET3 MAIN MENU .....</b>	<b>10</b>
3.1 MAIN MENU OPTIONS .....	10
<b>4. ADVERSE EVENT REPORTS (AERS) .....</b>	<b>11</b>
4.1 AER TABS.....	11
4.1.1. <i>Create and Send</i> .....	12
<b>4.1.1.1 New</b> .....	12
4.1.1.1.1. VICH Batch.....	23
4.1.1.1.2. AE Report #1.....	24
<b>4.1.1.1.2.1. MAH Information</b> .....	25
<b>4.1.1.1.2.2. Person Acting on Behalf of MAH</b> .....	25
<b>4.1.1.1.2.3. Person(s) involved in AER</b> .....	25
<b>4.1.1.1.2.4. AER information</b> .....	25
<b>4.1.1.1.2.5. Animal Data</b> .....	26
<b>4.1.1.1.2.6. VMP(s) Data and Usage / Registered or Brand name</b> .....	28
<b>4.1.1.1.2.7. Active ingredient(s)</b> .....	31
<b>4.1.1.1.2.8. Lot Number</b> .....	31
<b>4.1.1.1.2.9. Who administered the VMP</b> .....	31
<b>4.1.1.1.2.10. According to Label</b> .....	32
<b>4.1.1.1.2.11. Previous Exposure to the VMP</b> .....	33
<b>4.1.1.1.2.12. Previous AE to VMP</b> .....	34
<b>4.1.1.1.2.13. Dechallenge-Rechallenge Information</b> .....	34
<b>4.1.1.1.2.14. Adverse Event Data</b> .....	35
<b>4.1.1.1.2.15. Assessment of AE</b> .....	36
<b>4.1.1.1.2.16. Report Number(s) of Linked Report(s)</b> .....	36
<b>4.1.1.1.2.17. Supplemental documents</b> .....	37
<b>4.1.1.2. Validate</b> .....	37
<b>4.1.1.3. Validate and Send</b> .....	40
<b>4.1.1.2. Save Draft</b> .....	41
4.1.1.2.1 Resume Drafts.....	43
4.1.1.2.2 Delete Drafts.....	44
<b>4.1.1.3. Save Templates</b> .....	45
4.1.1.3.1 Resume Templates.....	47
4.1.1.3.2 Delete Templates.....	47
<b>4.1.1.2. Import XML</b> .....	48
<b>4.1.1.3. Export XML</b> .....	49
4.1.2. <i>Search AE Reports</i> .....	52
<b>4.1.2.1 Global Search</b> .....	52
<b>4.1.2.2 Advanced Search</b> .....	53
4.1.2.2.1. Criteria Ribbon.....	54
4.1.2.2.1.1. Advanced List Criteria Query.....	57
4.1.2.2.2. MAH Default Criteria Filters.....	58
4.1.2.2.3. NCA Default Criteria Filters.....	59
4.1.2.2.1. Storage of Criteria Filters.....	60
4.1.2.2.2. Fields Ribbon.....	61
4.1.2.2.3. Results Area.....	63

4.1.2.2.3.1.	Export XML in Bulk.....	65
4.1.2.2.3.2.	Export CSV Functionality.....	69
<b>4.1.2</b>	<b>Actions</b> .....	<b>70</b>
4.1.3.1	Open Report.....	71
4.1.3.2	Follow-up / Nullification.....	72
4.1.3.3	Download.....	74
4.1.4	Search VICH Batch.....	74
<b>4.1.4.1</b>	<b>Open VICH Batch</b> .....	<b>75</b>
4.1.5	Bulk Export.....	75
4.1.5	Drafts/ Templates.....	76
<b>5</b>	<b>MAILBOX</b> .....	<b>77</b>
5.1	INBOX SEARCH & VIEW.....	77
5.2	OUTBOX SEARCH & VIEW.....	78
<b>6</b>	<b>ORGANISATION LIST</b> .....	<b>79</b>
<b>7</b>	<b>PROFILE</b> .....	<b>80</b>
<b>8</b>	<b>SYSTEM TIPS</b> .....	<b>81</b>
<b>9</b>	<b>ABBREVIATIONS</b> .....	<b>85</b>
<b>10</b>	<b>AER ENTRY STEP-BY-STEP GUIDE</b> .....	<b>86</b>
<b>10.1</b>	<b>LOG IN</b> .....	<b>86</b>
<b>10.2</b>	<b>CREATE NEW REPORT</b> .....	<b>87</b>
<b>10.2.2</b>	<b>VICH Batch information</b> .....	<b>87</b>
<b>10.2.3</b>	<b>Report information</b> .....	<b>88</b>
<b>10.3</b>	<b>HOW TO IMPORT AN XML TO CREATE A NEW REPORT</b> .....	<b>101</b>
<b>I.</b>	<b>ANNEX 1</b> .....	<b>104</b>
<b>A.</b>	<b>CRITERIA FILTERS IN DETAIL</b> .....	<b>104</b>
<i>i.</i>	<i>MAH Search</i> .....	<i>104</i>
<i>ii.</i>	<i>Sender Search</i> .....	<i>105</i>
<i>iii.</i>	<i>Classification Search</i> .....	<i>106</i>
<i>iv.</i>	<i>Product Name / Substance Name Search</i> .....	<i>107</i>
<i>v.</i>	<i>Occur Country Search</i> .....	<i>109</i>
<i>vi.</i>	<i>Narrative Search</i> .....	<i>109</i>
<i>vii.</i>	<i>Species and Breed Searches</i> .....	<i>110</i>
<i>viii.</i>	<i>Off label use Search</i> .....	<i>110</i>
<i>ix.</i>	<i>Correct report, with warning, errors Search</i> .....	<i>111</i>
<i>x.</i>	<i>Product Recoding Date Search</i> .....	<i>111</i>
<i>xi.</i>	<i>Type of Submission</i> .....	<i>112</i>

# 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 submit 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:** provides information about organisation profile.
- **Chapter 8:** provides list of tips to facilitate navigation through application and submission of AERs.
- **Chapter 9:** List of abbreviations used in this guide.
- **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).

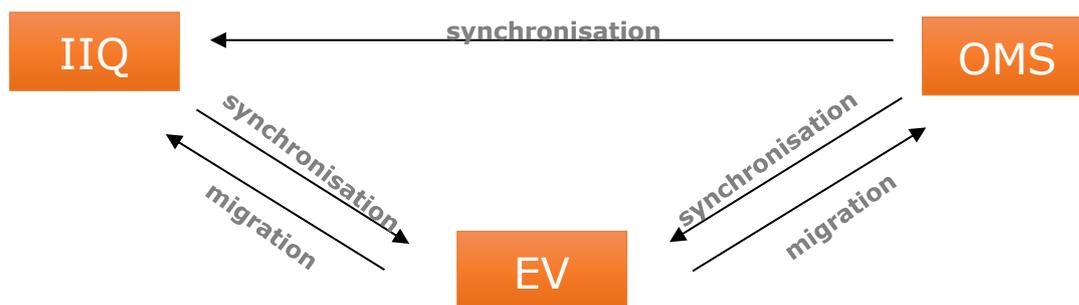


Figure 1: OMS, IIQ and EVWEB synchronisation

### **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/>

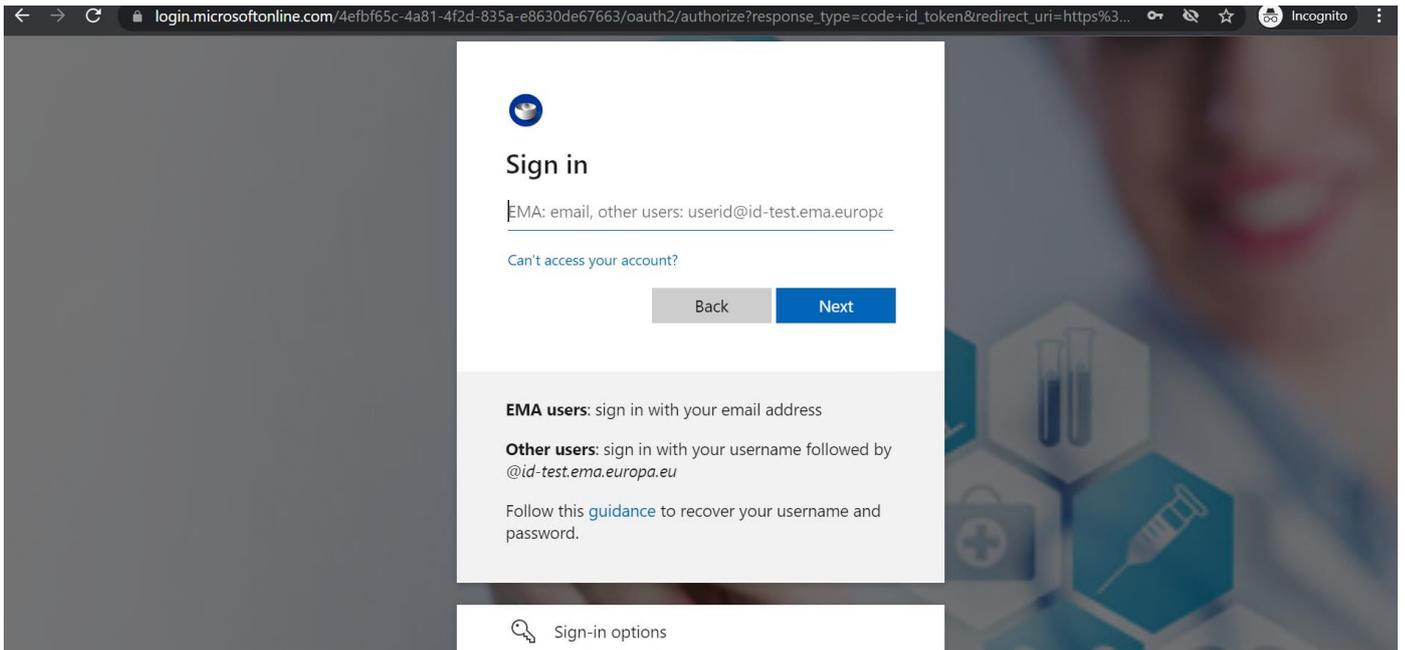


Figure 2: Login to EVVET3 application

User entering password to login

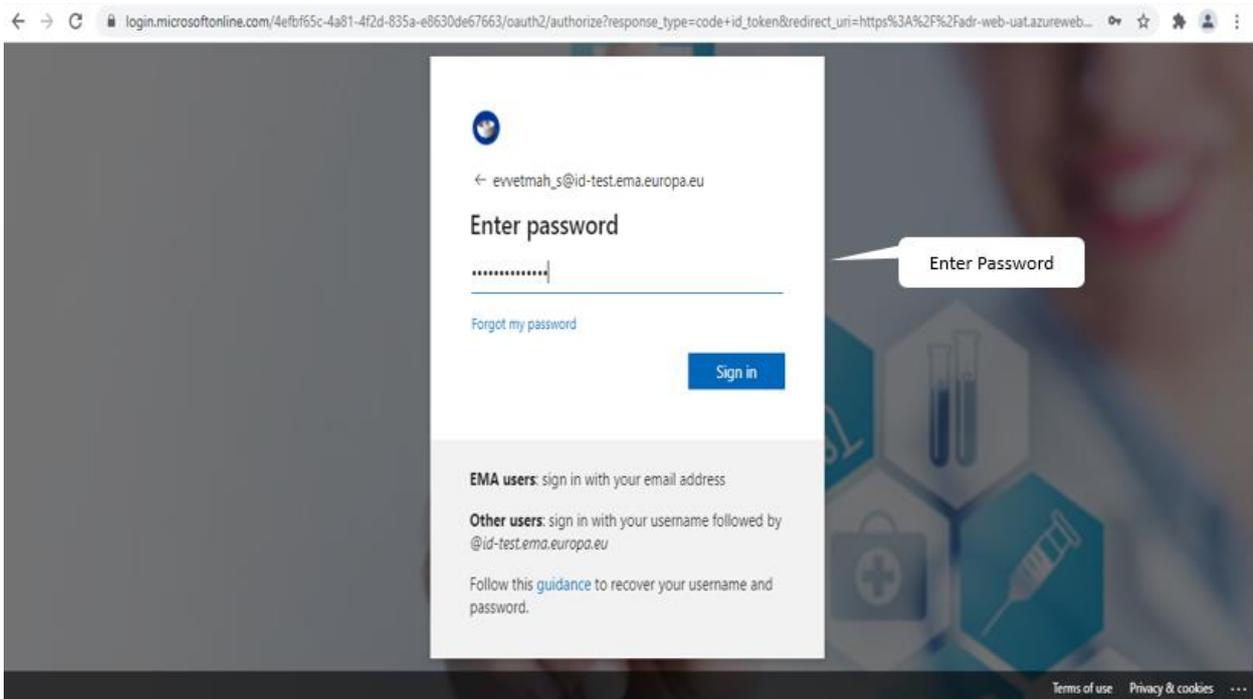


Figure 3: Enter Password

When user logs in, user is prompted to select organisation. The list displays all the organisations to which the user has a role. To facilitate the selection, Routing ID and Organisation Name are visible in the list:

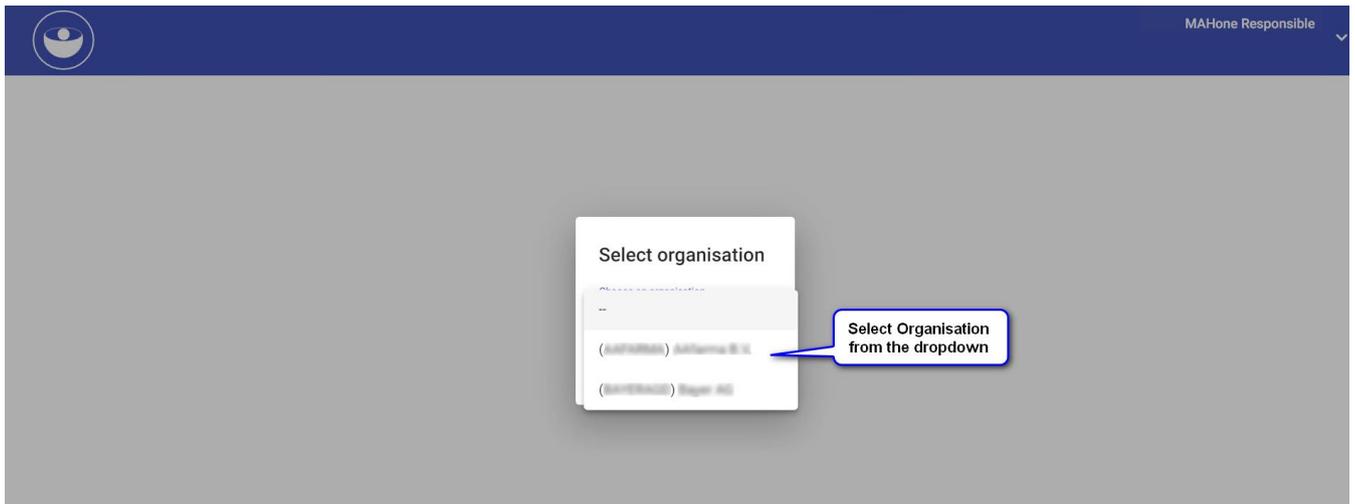


Figure 4: Select Organisation

**NOTE:** Step-by-step guide about how to set up *Multi-factor authentication (MFA)* to access EMA Cloud applications: [Multi-factor authentication \(MFA\) URL](#)

### 2.1.1.1 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.



Figure 5: Log-in information

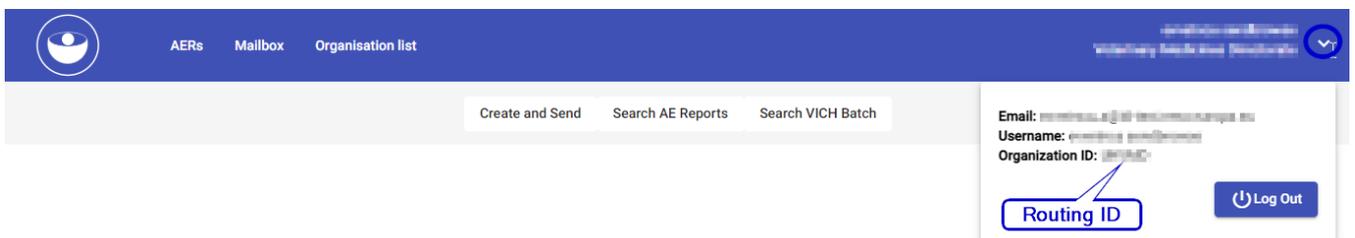


Figure 6: Log-in information details

### 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:



Figure 7: EVVET3 Main screen

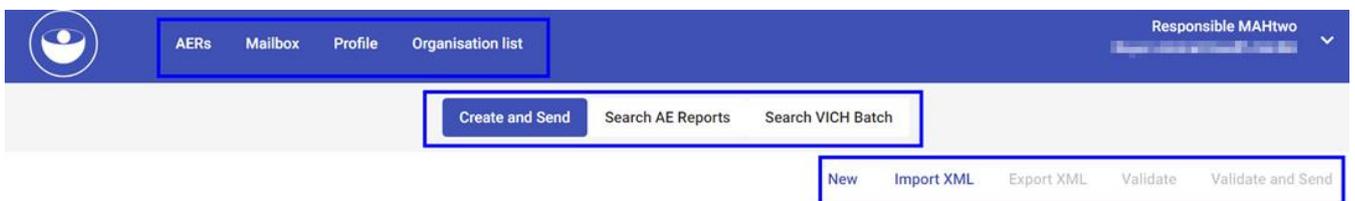


Figure 8: EVVET3 Create and Send

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

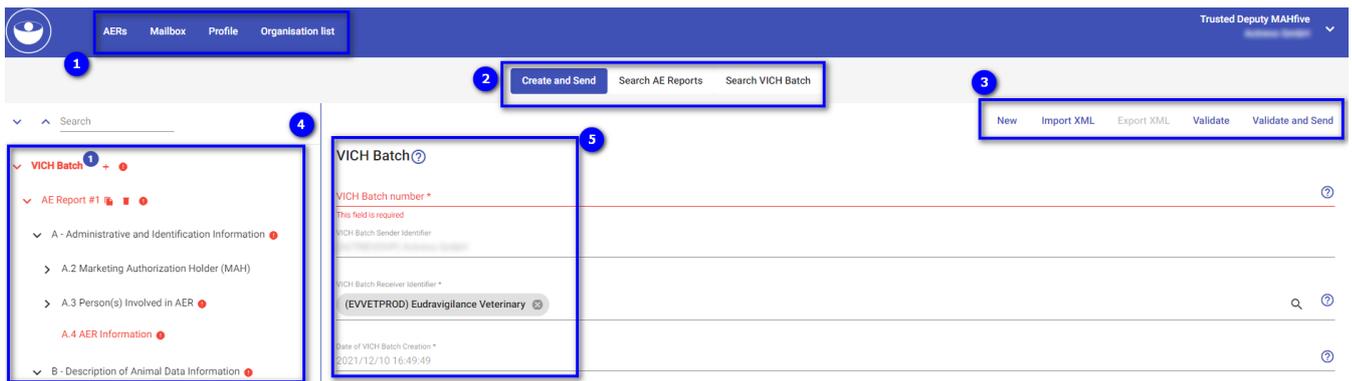


Figure 9: EVVET3 UI Interface display

Interface Option	Description
(1) Main menu	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).

Interface Option	Description
(2) AER tabs	This area represents AER tabs. <b>Create and send, Search AE Reports, Search AE Messages</b>
(3) Actions (regarding the selected option from the main menu)	This area represents dynamic buttons set, New, Import XML, Export XML, Validate, Validate and Send
(4) Tree view area	Displays the hierarchy of the AE Report message sections in a tree view style.
(5) Active area	Displays content of a selected section or search results from a query.

Table 1: User Interface description

### 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.

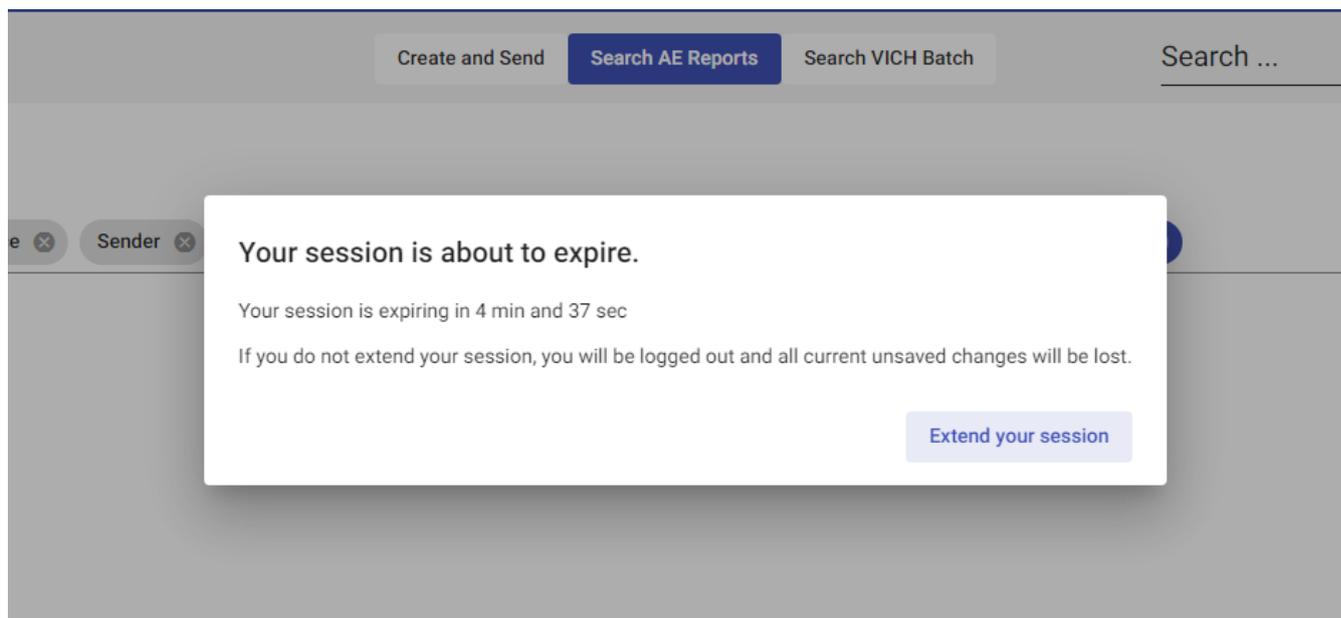


Figure 10: Session expiry warning

**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.

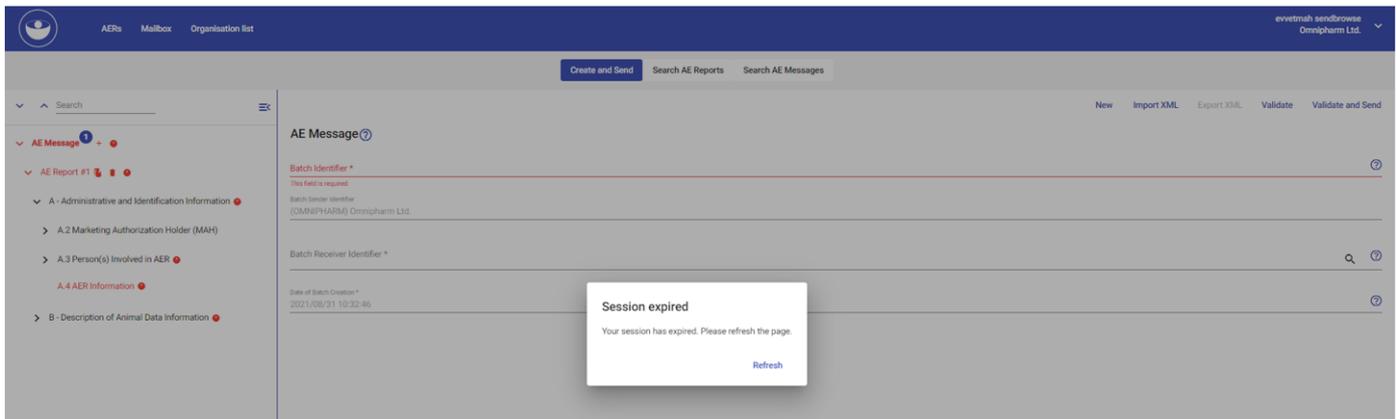


Figure 11: Session expiry warning

### 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.

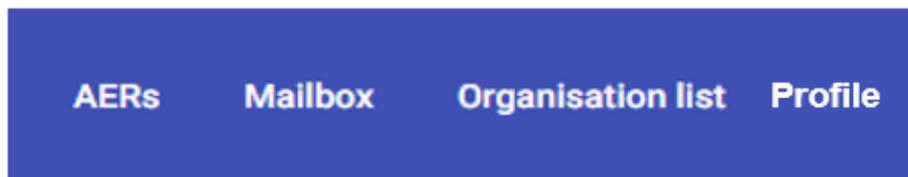
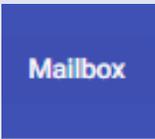


Figure 12: The main menu

Menu Option	Description
	Allows access to the part of the application dedicated to the creation and sending of reports, search for messages and reports.
	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 "Inbox" and "Outbox" views. In the mailbox, the user will be able to see the ACK messages.
	Allows the user to consult the whole organisation list with an associated routing ID.

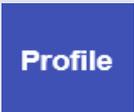
Menu Option	Description
	This feature is reserved just for <i>Responsible person</i> and <i>Trusted Deputy</i> users. This feature will give information about the selected organisation.

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



Figure 13: 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.



Figure 14: AER Tabs

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



Figure 15: Main Menu & AER Tabs

Below table gives brief description of AERs tabs

Menu Option	Description
Create and Send	Allows you to Create and Send adverse event reports.
Search AE Reports	Provides quick search of AE reports by selecting available searching criteria and filtering with required columns.
Search VICH Batch	This provides quick search of AE Messages by selecting available searching criteria and filtering with required columns.
Bulk Export	This option allows you to view all created bulk export requests.
Draft	This allows you to view all drafts (VICH Batch Level) created for the logged organization. All user in the same organization can view, resume and delete drafts through this tab.

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.

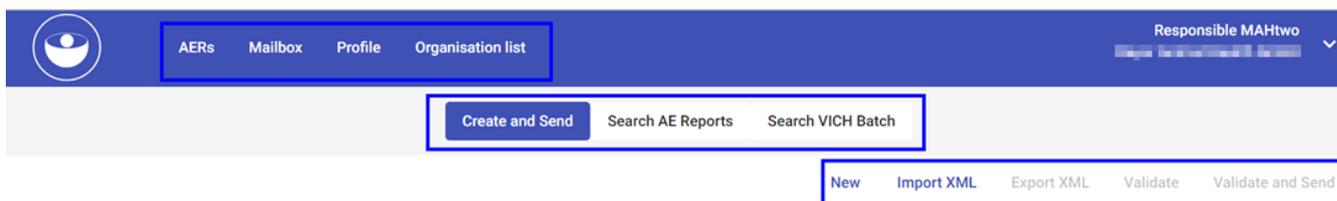


Figure 16: Dynamic buttons set

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.

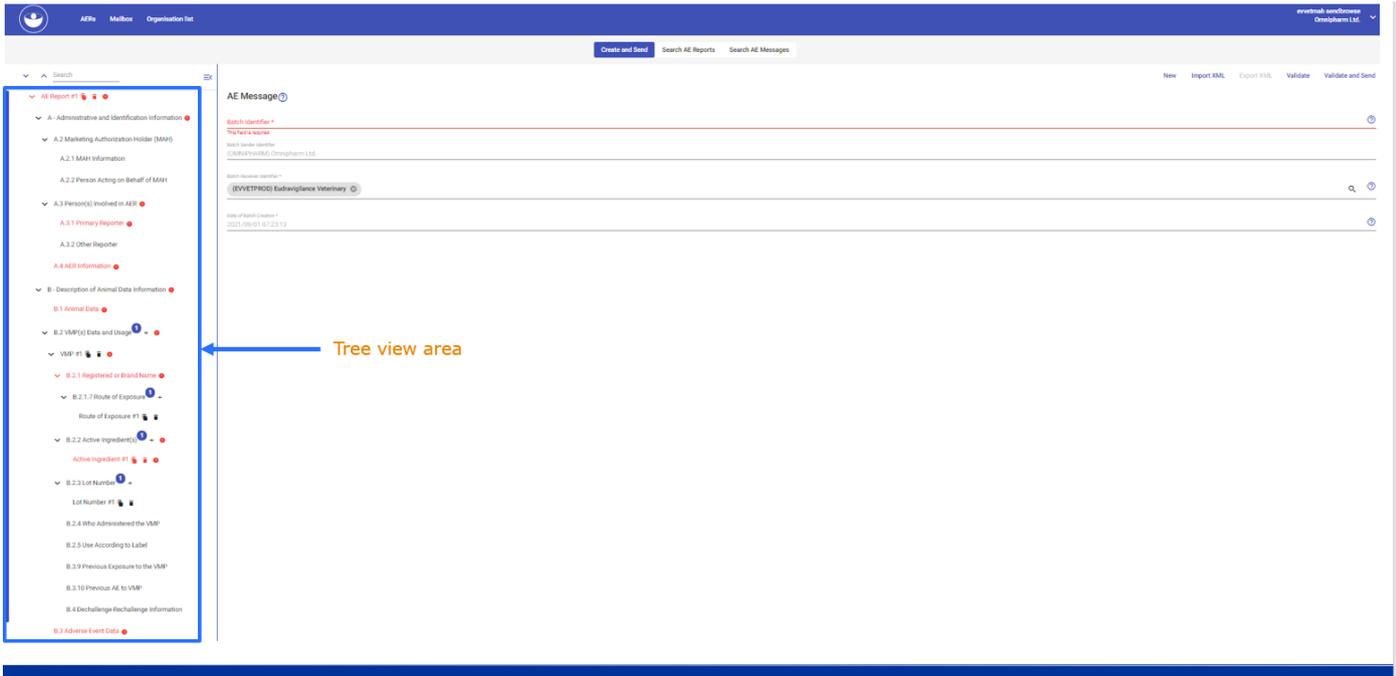


Figure 17: The tree view area

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. <sup>1</sup>) 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.

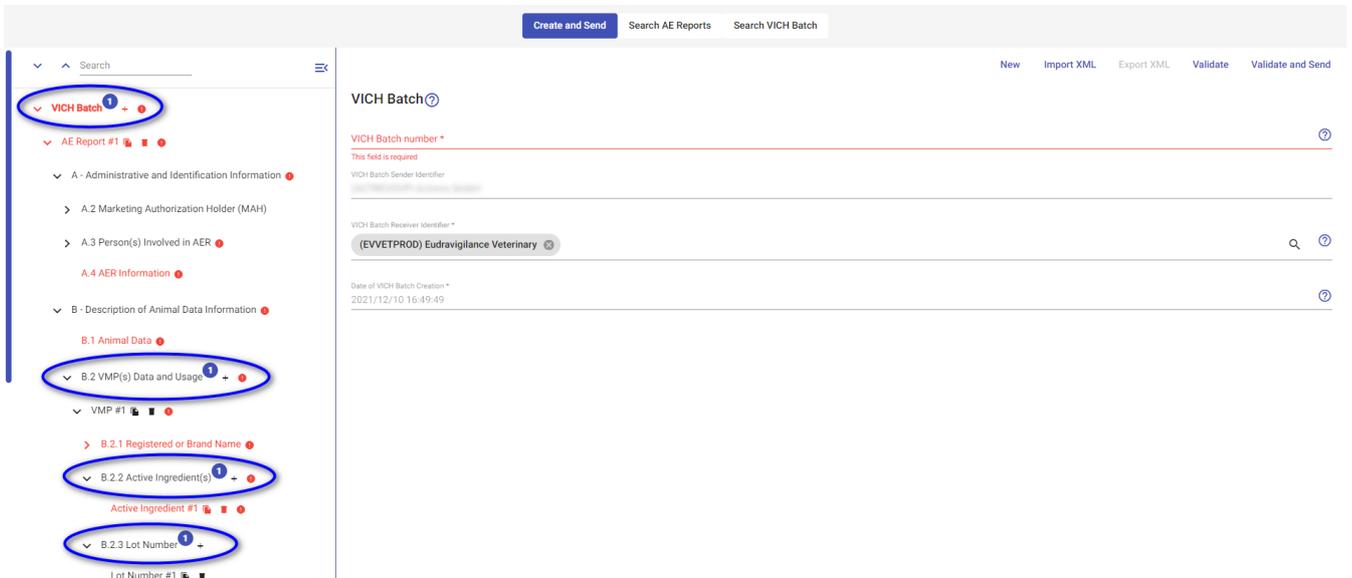


Figure 18: Tree view area with sub-sections

**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.

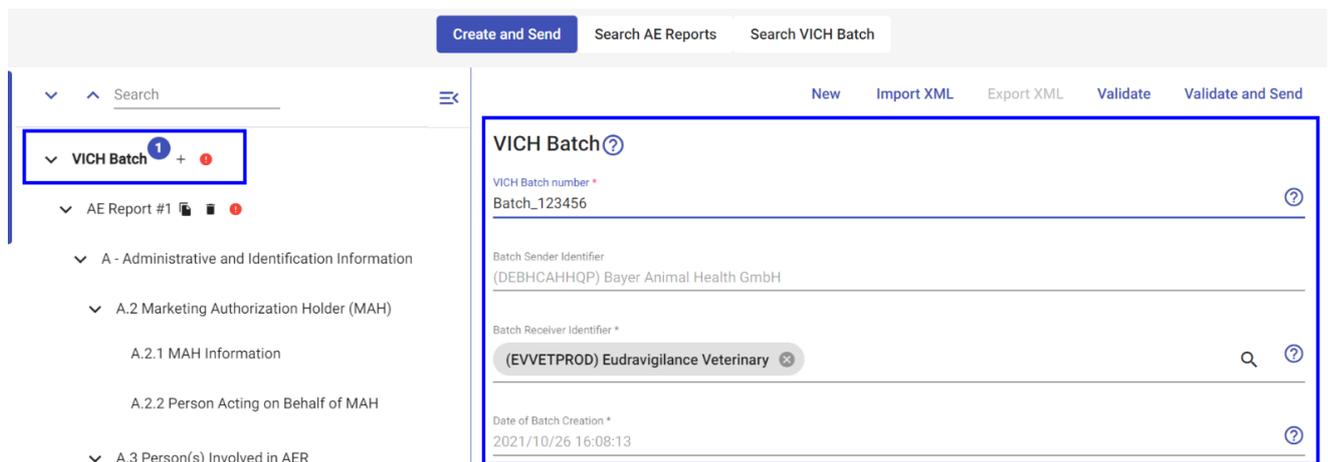


Figure 19: Active area

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.

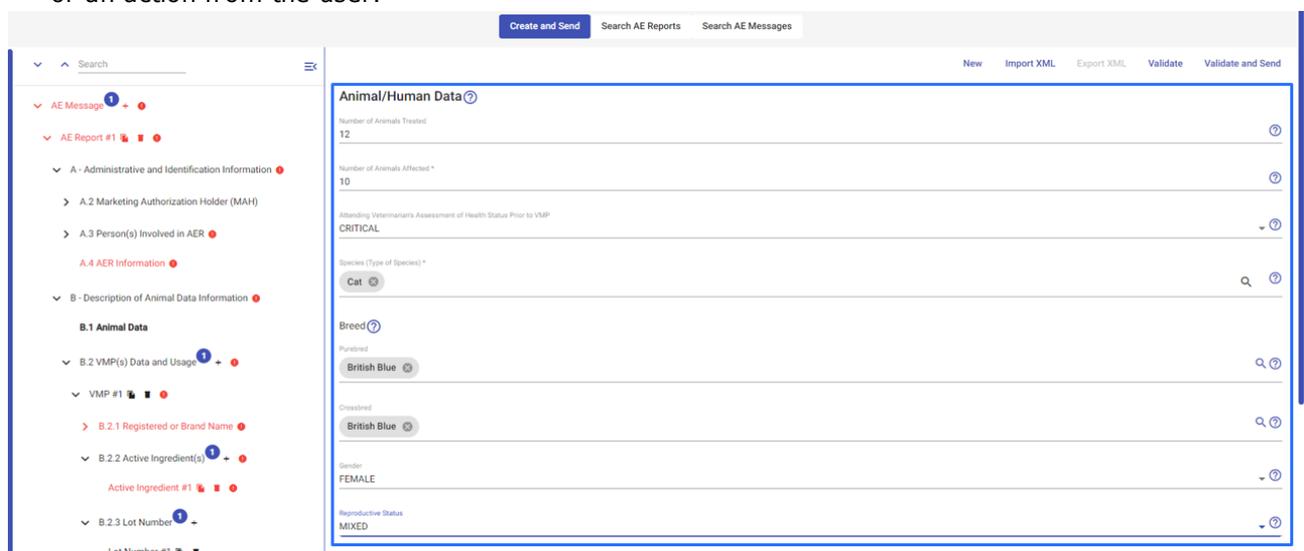


Figure 20: Active area section view

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

Criteria(5)

Message Receive Date Occur Country Sender Species Unique AER Number

Fields(8)

Export XML

Local Report Number	Message Received Date	Occur Country	Results In Death	Message Sender	Species	Type Of Information In Report	Unique AER Number	Actions
20000000016	2021/06/10	Netherlands	0	EVVETWT	Cat	LACK OF EXPECTED EFFECTIVENESS	NLD-GAPINDSY-27318231	👁️ ✎️ ⬇️
20000000021	2021/06/10	Netherlands	0	EVVETWT	Cat	LACK OF EXPECTED EFFECTIVENESS	NLD-GAPINDSY-127016021	👁️ ✎️ ⬇️
20000000027	2021/06/10	Netherlands	0	EVVETWT	Cat	LACK OF EXPECTED EFFECTIVENESS	NLD-GAPINDSY-75727601	👁️ ✎️ ⬇️
20000000028	2021/06/10	Netherlands	0	ZZELANCO	Dog	SAFETY ISSUE	NLD-GAPINDSY-73687134	👁️ ✎️ ⬇️
20000000037	2021/06/10	Netherlands	0	ZZELANCO	Dog	SAFETY ISSUE	NLD-GAPINDSY-73687134	👁️ ✎️ ⬇️
20000000053	2021/06/15	Netherlands	0	EVVETWT	Cat	LACK OF EXPECTED EFFECTIVENESS	NLD-GAPINDSY-123502171	👁️ ✎️ ⬇️
20000000060	2021/06/15	Netherlands	0	EVVETWT	Cat	LACK OF EXPECTED EFFECTIVENESS	NLD-GAPINDSY-116087833	👁️ ✎️ ⬇️
20000000063	2021/06/15	Netherlands	0	EVVETWT	Cat	LACK OF EXPECTED EFFECTIVENESS	NLD-GAPINDSY-50647754	👁️ ✎️ ⬇️

Figure 21: Active area list view

### 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.

Create and Send Search AE Reports Search AE Messages

New Import XML Export XML Validate Validate and Send

Search

- AE Message 1 +
- AE Report #1
- A - Administrative and Identification Information
  - A.2 Marketing Authorization Holder (MAH)
  - A.3 Person(s) Involved in AER
  - A.4 AER Information
- B - Description of Animal Data Information
  - B.1 Animal Data**
  - B.2 VMP(s) Data and Usage 1 +
    - VMP #1
    - B.2.1 Registered or Brand Name
      - Active Ingredient #1
    - B.2.2 Active Ingredient(s) 1 +
      - Active Ingredient #1
    - B.2.3 Lot Number 1 -
      - Lot Number #1

Animal/Human Data

Number of Animals Treated: 12

Number of Animals Affected: 10

Attending Veterinarian's Assessment of Health Status Prior to VMP: CRITICAL

Species (Type of Species): Cat

Breed: British Blue

Purebred: British Blue

Crossbred: British Blue

Gender: FEMALE

Reproductive Status: MIXED

Figure 22: Tree view & active area interaction

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:

[https://www.ema.europa.eu/documents/other/annex-2-evvet3-business-rules\\_en.xls](https://www.ema.europa.eu/documents/other/annex-2-evvet3-business-rules_en.xls)

## 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  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.

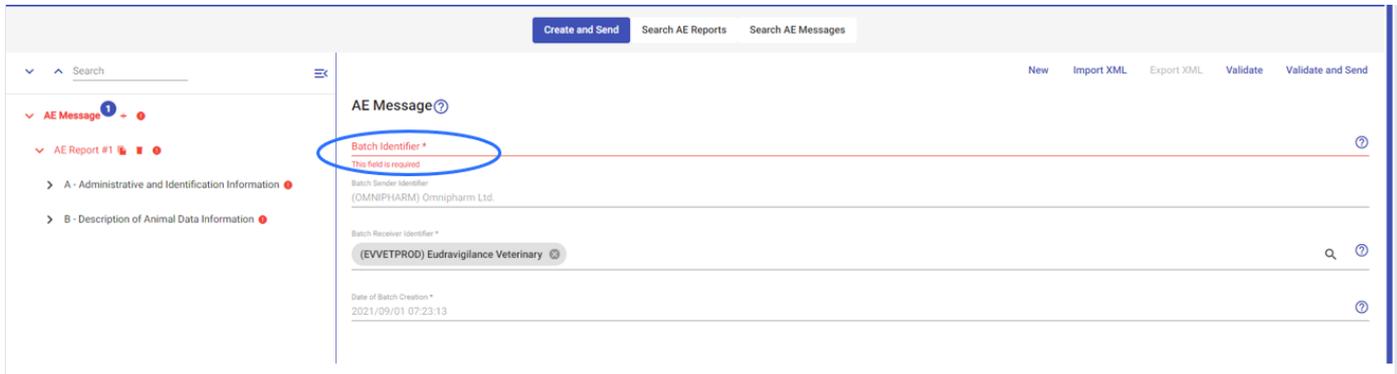


Figure 23: Text fields

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.

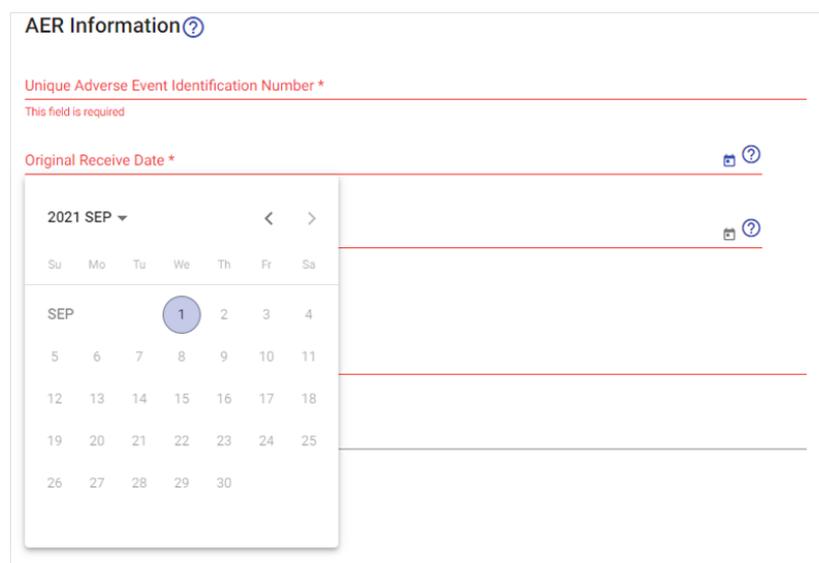


Figure 24: Date field

### 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.

**AER Information** [?](#)

Unique Adverse Event Identification Number \*  
This field is required

Original Receive Date \* [?](#)  
This field is required

Most Recent Info Date \* [?](#)  
This field is required

**Type of Report** [?](#)

Type of Submission \*  
This field is required

Type of Information in Report

- 
- LACK OF EXPECTED EFFECTIVENESS
- BOTH SAFETY AND LACK OF EXPECTED EFFECTIVENESS
- SAFETY ISSUE
- OTHER

Figure 25: Drop down list field

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.

Figure 26: 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-downlist 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 data base 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.

Figure 27: Radio button / Checkbox fields

## 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

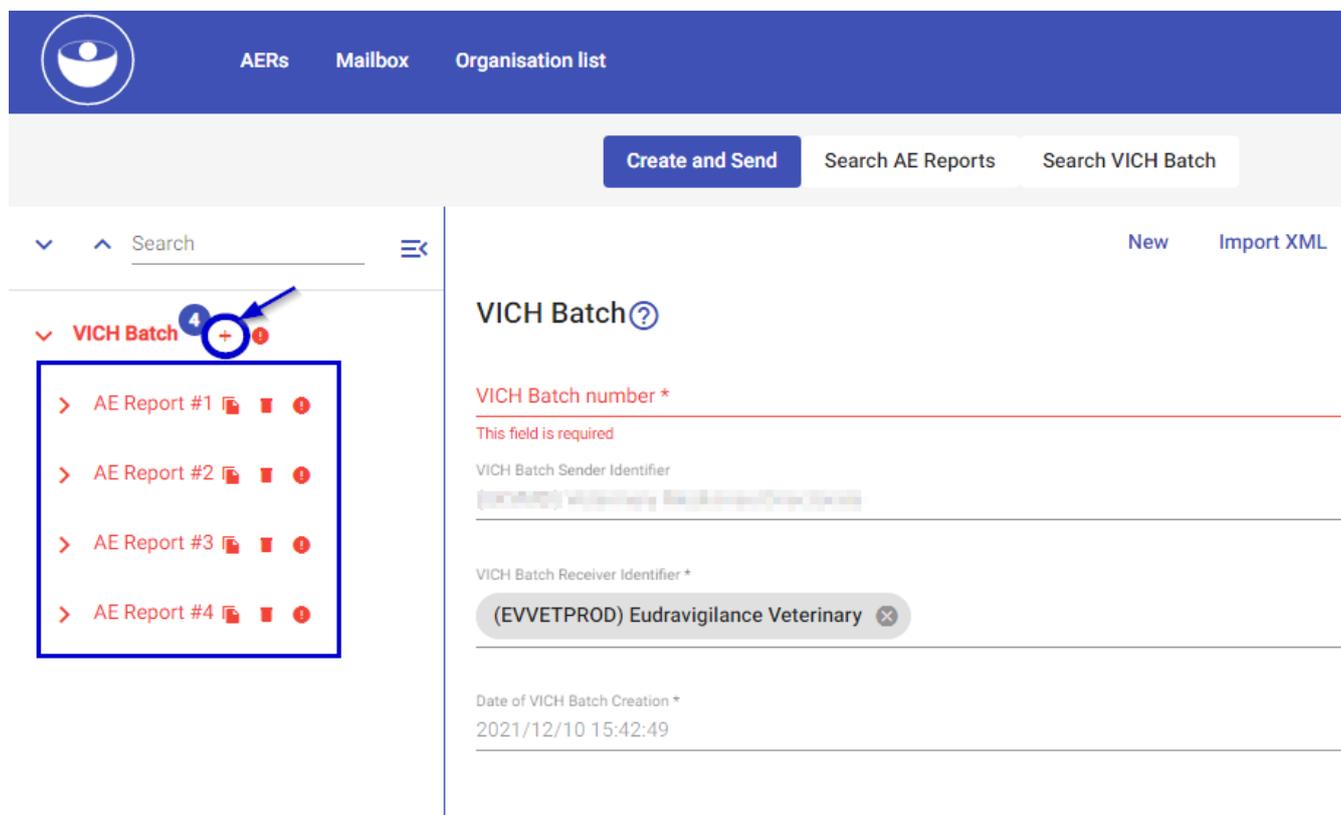


Figure 28: Creating multiple reports

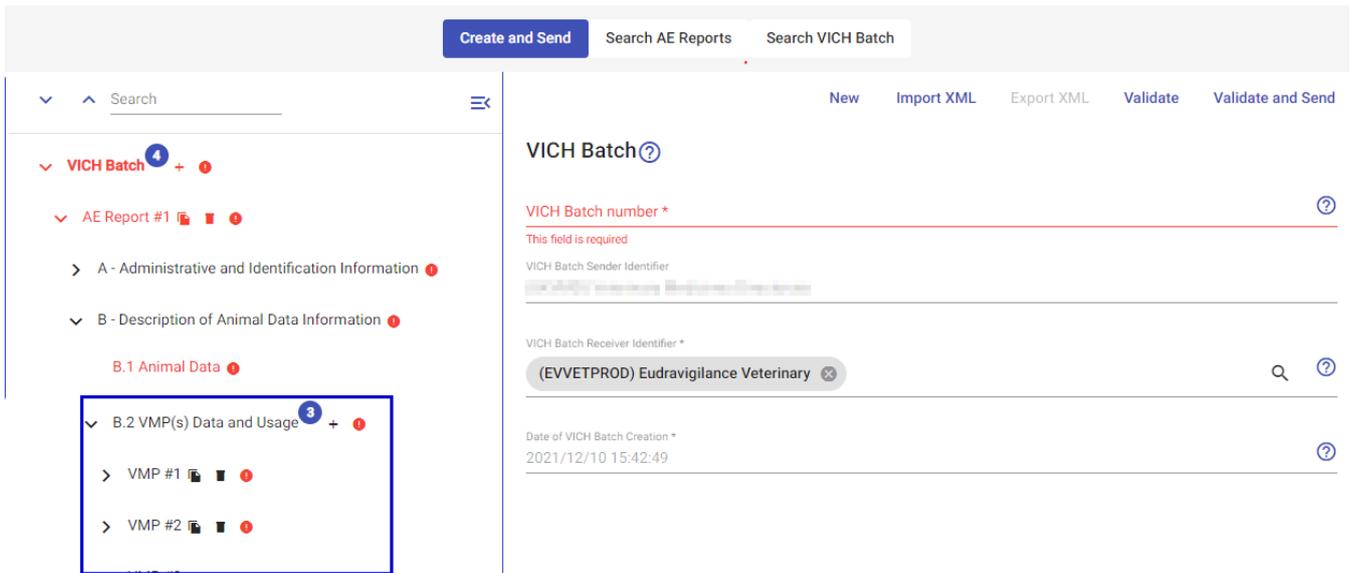


Figure 29: Add multiple VMP Data & Usage

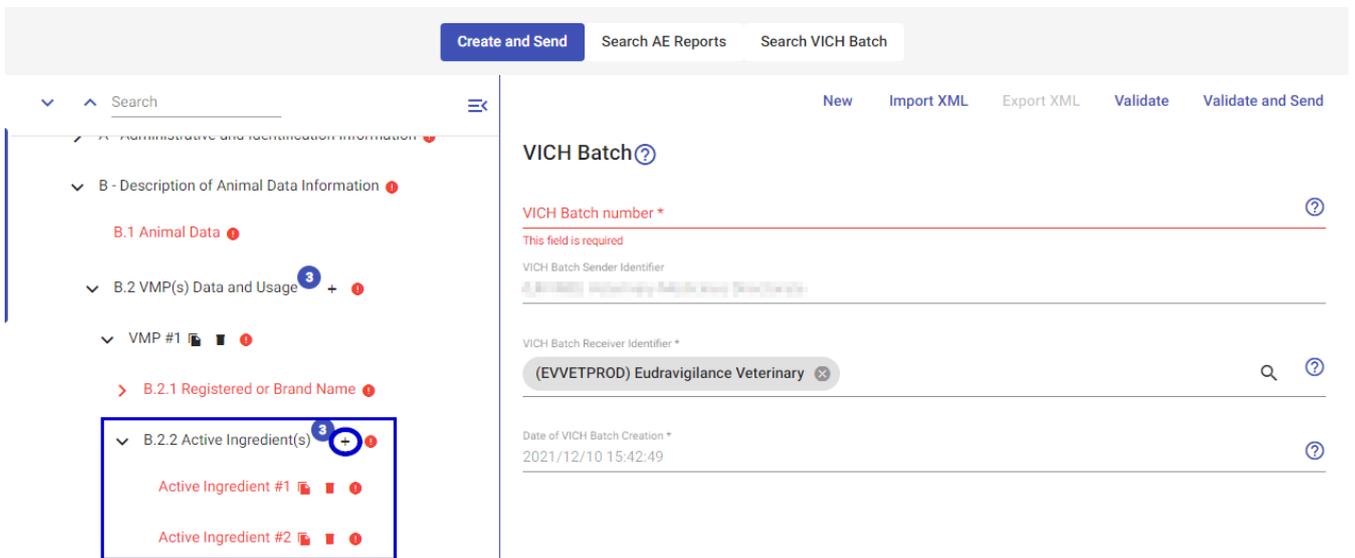


Figure 30: Add multiple Active Ingredient(s)

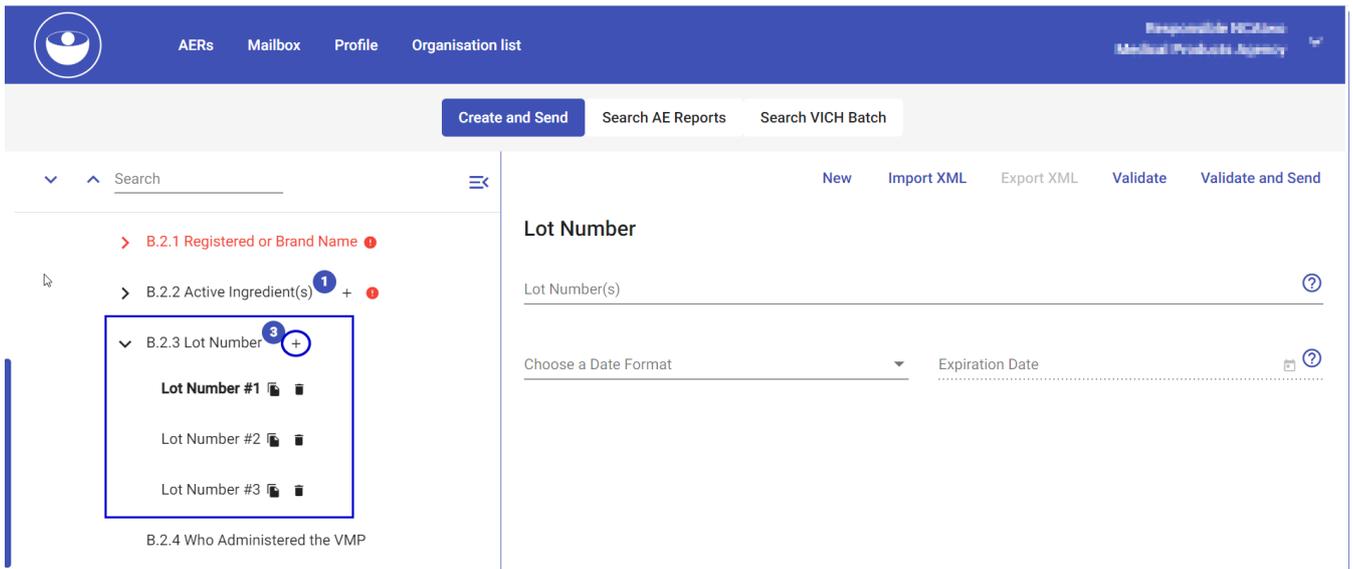


Figure 31: Add multiple Lot Number

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.

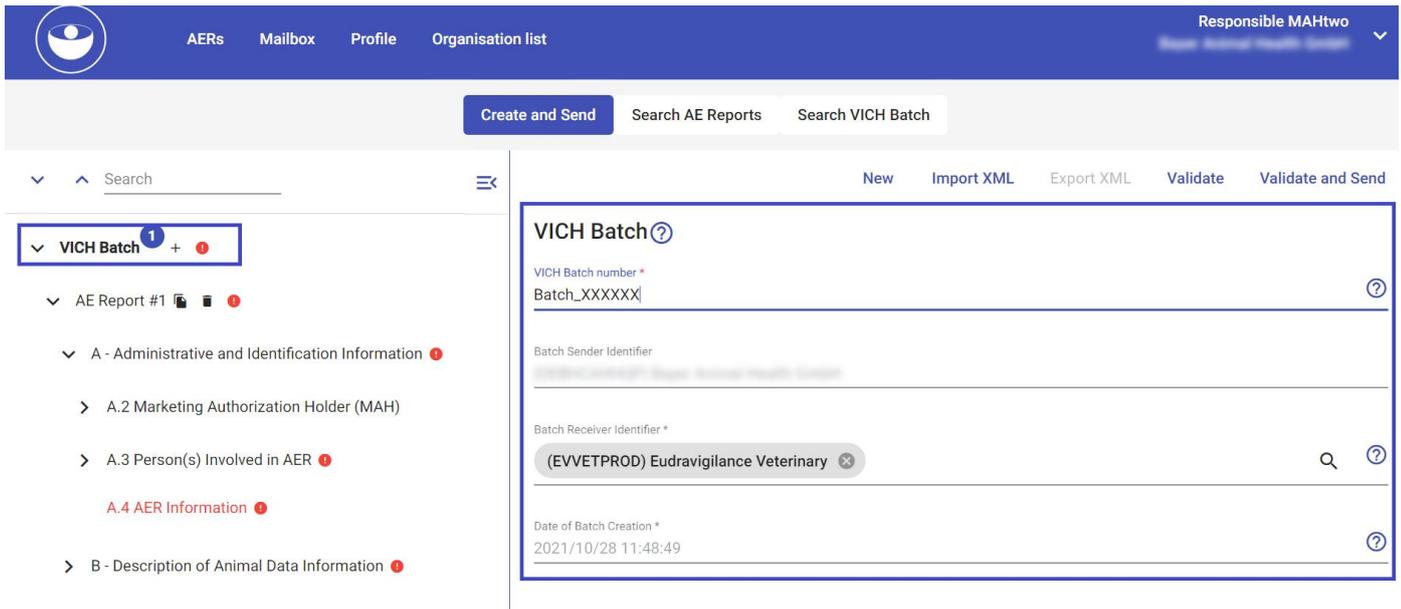


Figure 32: VICH Batch number

#### 4.1.1.1.2. 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.

Figure 33: AE Report level information

#### 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 has been removed from the user interface due to EMA GDPR policy compliance.

#### 4.1.1.1.2.3. Person(s) involved in AER

This section is reserved to introduce the information related to:

- *Primary Reporter* and *Other Reporter* – only Last Name, Country, and Primary Reporter Category fields are visible in the user interface.

As stated in the best practice guide, information in "Last name" field, should be populated by concatenating the initials of the first name and last name, and, if available, the first two digits of the postcode. In case the information is not available, "withheld" or "unknown" should be entered.

Figure 34: Example information populated in Last Name field as best practice.

#### 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 2:** For Northern Ireland cases, ISO code is not defined, therefore code 'XXI'.

**NOTE 2:** The Routing ID can be found in the organisation list feature and also, by clicking on the user information (top right corner of EVWEB).

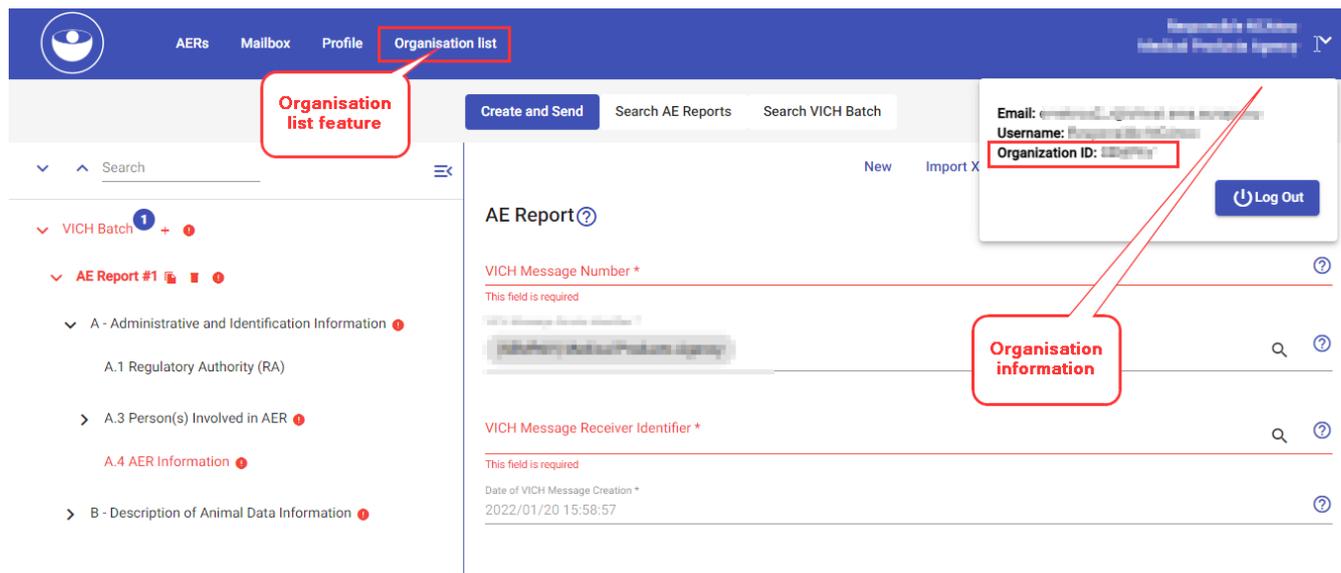


Figure 35: How to know the routing ID

- **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 are only allowed by the sender of the first valid case submitted.
- **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

#### 4.1.1.1.2.5. Animal Data

In this section, the user will be requested to enter the information related the animal/s that suffered de

adverse event.

Navigation menu:

- ✓ A - Administrative and Identification Information ⓘ
  - A.1 Regulatory Authority (RA)
  - > A.3 Person(s) Involved in AER ⓘ
  - A.4 AER Information ⓘ
- ✓ B - Description of Animal Data Information ⓘ
  - B.1 Animal Data ⓘ**
  - ✓ B.2 VMP(s) Data and Usage ⓘ + ⓘ
  - > VMP #1 ⓘ ⓘ ⓘ ⓘ ⓘ
  - B.3 Adverse Event Data ⓘ
  - B.5 Assessment of AE
  - B.6 Report Number(s) of Linked Report(s)
  - B.7 Supplemental Documents

Form fields:

- Number of Animals Affected \* ⓘ  
This field is required
- Attending Veterinarian's Assessment of Health Status Prior to VMP ⓘ
- Species (Type of Species) \* ⓘ  
This field is required
- Breed ⓘ
- Purebred ⓘ
- Crossbred ⓘ
- Gender ⓘ
- Reproductive Status ⓘ
- Weight ⓘ

Figure 36: Animal data section

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. In case that value of animals affected is greater than animals treated, the final validation of the report will trigger a warning message.
- **Attending Veterinarian's Assessment of Health Status Prior to VMP:** This field will give the user a dropdown list 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'. Information requested in this section is dependent on the Number of Animals Affected: If the number of Affected Animals is 1, then only Minimum Weight and units is requested; if the number of Affected Animals is 2 or more, then the maximum and minimum weight of the group and units are requested.
- **Age:** Introduce the animal/s age and if the value is 'measured', 'estimated' or 'unknown'. Information requested in this section is dependent on the Number of Animals Affected: If the number of Affected Animals is 1, then only Minimum Age and units is requested; if the number of Affected Animals is 2 or more, then the maximum and minimum age of the group and units are requested.

Weight ?

Weight Measured, Estimated or Unknown

ESTIMATED ? Minimum Weight (kg) ?

---

Age ?

Age Measured, Estimated or Unknown

ESTIMATED ? Minimum Age ? Minimum Age Units ?

Figure 37: Weight and Age fields when the number of Animals Affected is 1

Weight ?

Weight Measured, Estimated or Unknown

ESTIMATED ? Minimum Weight (kg) ? Maximum Weight (kg) ?

---

Age ?

Age Measured, Estimated or U...

ESTIMATED ? Minimum Age ? Minimum Age Units ? Maximum Age ? Maximum Age Units ?

Figure 38: Weight and Age fields when the number of Animals Affected is 2 or higher

#### 4.1.1.1.2.6. VMP(s) Data and Usage / Registered or Brand name

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

Figure 39: Registered name or brand name

- **Registered name or brand name:** There are two methods to search products in this field. That is "Generic Product Search" and "Advanced Product Search"
  1. **Generic Product Search** - The user can 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

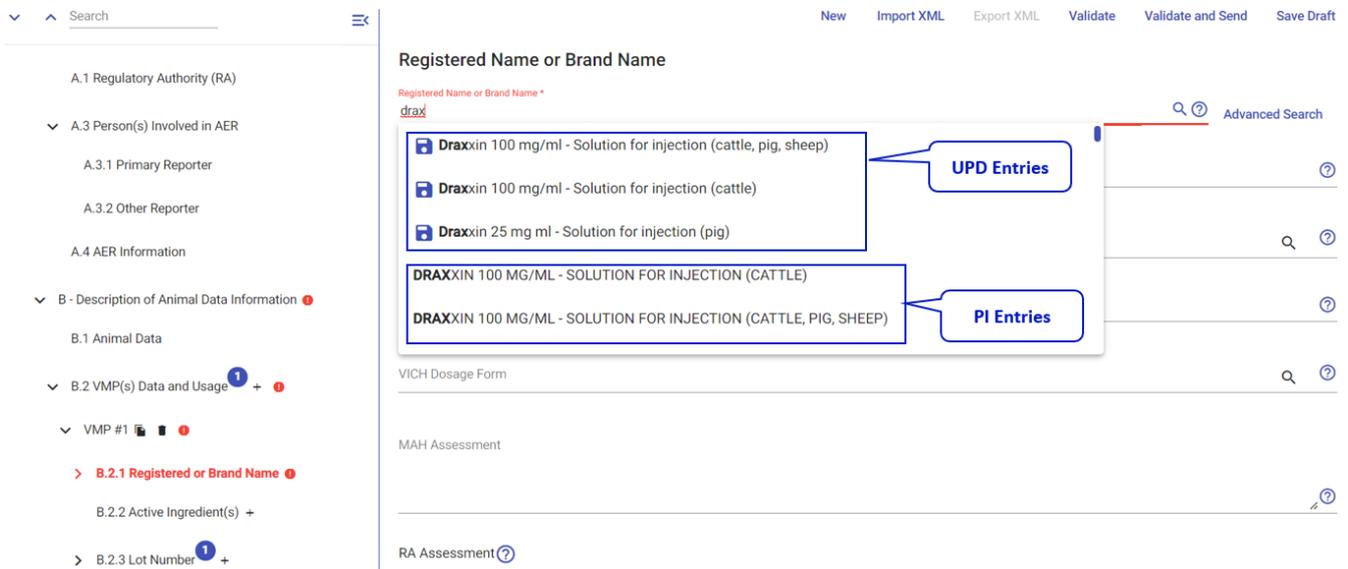


Figure 40: UPD product and PI entries

2. **Advanced Product Search** – The user can Click on the "Advanced Search" button to search the product with multiple product attributes and a separate window will be opened as follows:

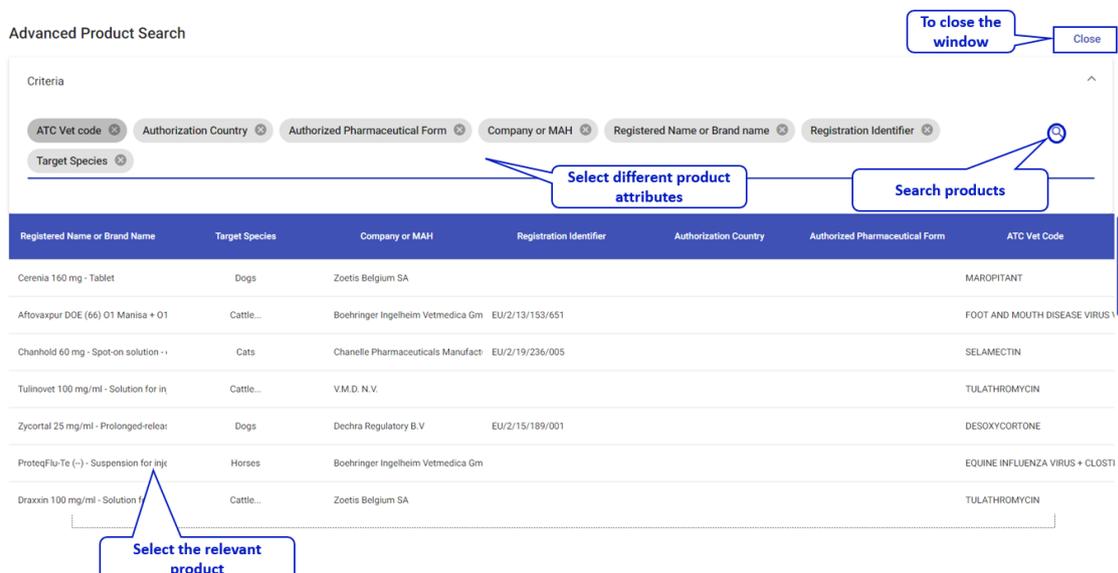


Figure 41: Advanced Product Search

- User can select one or more following criteria filters to identify the relevant product. *ATC Vet Code*

- *Authorization Country*
- *Authorized Pharmaceutical Form*
- *Company or MAH*
- *Registered Name or Brand Name*
- *Registration Identifier*
- *Target Species*

Click on the relevant row in the result table to select the particular product. After the selection, product will be appeared in the screen as follows:

Figure 42: Figure 43 - Product Selection

- **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 county 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>.

**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

- **VICH Dosage form:** This is the VICH 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.

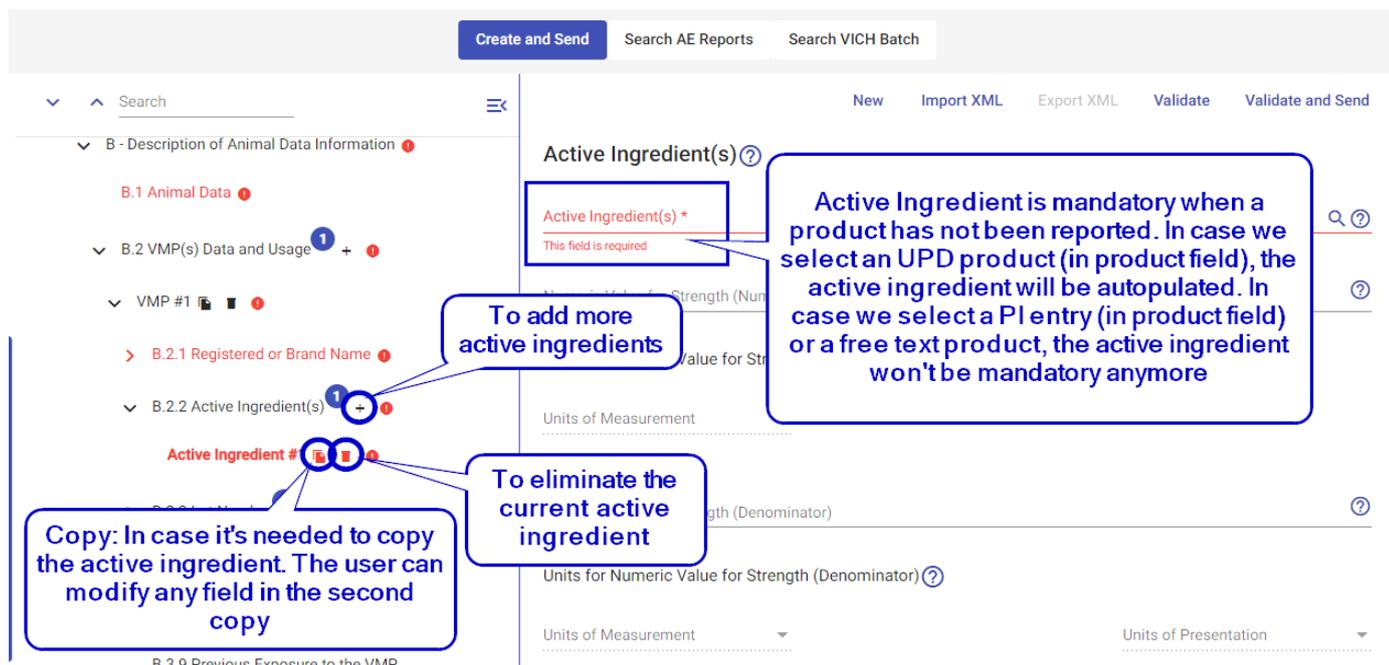


Figure 44: : Active ingredient information

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*.

#### 4.1.1.1.2.8. Lot Number

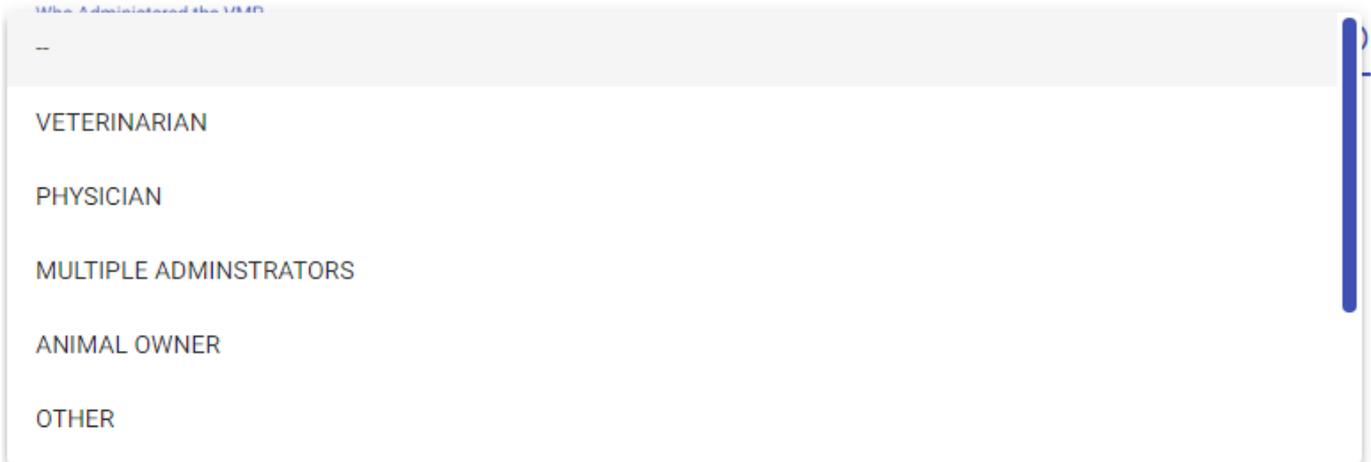
The lot number is not mandatory information. This information is provided in the product container or label. In this section we can find the following fields to be informed:

- *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.

#### 4.1.1.1.2.9. 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

## Who Administered the VMP



Who Administered the VMP

--

VETERINARIAN

PHYSICIAN

MULTIPLE ADMINSTRATORS

ANIMAL OWNER

OTHER

Figure 45: Who administered the VMP information

### 4.1.1.1.2.10. 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

## Label Usage



Use According to Label

Yes  No  Unknown

Figure 46: 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

Use According to Label  Yes  No  Unknown 

Explanation for Off-Label Use 

Was the target species Off-label?	<input type="checkbox"/> Yes <input <="" td="" type="button" value="?"/>
Was the route of administration Off-label?	<input type="checkbox"/> Yes <input <="" td="" type="button" value="?"/>
Was the animal overdosed?	<input type="checkbox"/> Yes <input <="" td="" type="button" value="?"/>
Was the animal underdosed?	<input type="checkbox"/> Yes <input <="" td="" type="button" value="?"/>
Was the treatment regimen Off-label?	<input type="checkbox"/> Yes <input <="" td="" type="button" value="?"/>
Was the indication Off-label?	<input type="checkbox"/> Yes <input <="" td="" type="button" value="?"/>
Was the storage condition Off-label?	<input type="checkbox"/> Yes <input <="" td="" type="button" value="?"/>
Was the product expired?	<input type="checkbox"/> Yes <input <="" td="" type="button" value="?"/>
Was there any other Off-label issue?	<input type="checkbox"/> Yes <input <="" td="" type="button" value="?"/>

NO free text. Select 'Yes' to answer each question

Figure 47: More questions when 'No' is selecting from the menu related to According to label section

**Note:** User can revert selection of any radio button by clicking again on it.

### 4.1.1.1.2.11. 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

Previous Exposure to the VMP  Yes  No  Unknown

Figure 48: Previous Exposure to the VMP options

### 4.1.1.1.2.12. Previous AE to 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

Previous AE to VMP  Yes  No  Unknown

Figure 49: Previous AE to the VMP options

### 4.1.1.1.2.13. Dechallenge-Rechallenge Information

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?  Yes  No  Not Applicable  Unknown

Did AE Reappear After Re-introduction of the VMP?  Yes  No  Not Applicable  Unknown

Figure 50: Dechallenge-Rechallenge Information

#### 4.1.1.1.2.14. 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 for AER Terms (LLT Level, PT Level, HLT Level and SPC Level) from the dropdown list based on the entered text. In addition, the user can see all levels of AER terms and the term type in the dropdown list.

LLT Level	PT Level	HLT Level	SOC Level	Term Type
Sleepiness - neurological disorder	Somnolence	Impaired consciousness	Neurological disorders	C
Implant site lesion	Implant site lesion	Implant site reactions	Application site disorders	V
Barking	Vocalisation	Other behavioural disorders	Behavioural disorders	V
Implant site bruising	Implant site haemorrhage	Implant site reactions	Application site disorders	V

The user can select the relevant LLT level from the list, and it will be displayed in the field.

- **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 options '*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**

#### **4.1.1.1.2.15. 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.

#### **4.1.1.1.2.16. Report Number(s) of Linked Report(s)**

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

## Report Number(s) of Linked Report(s) ?

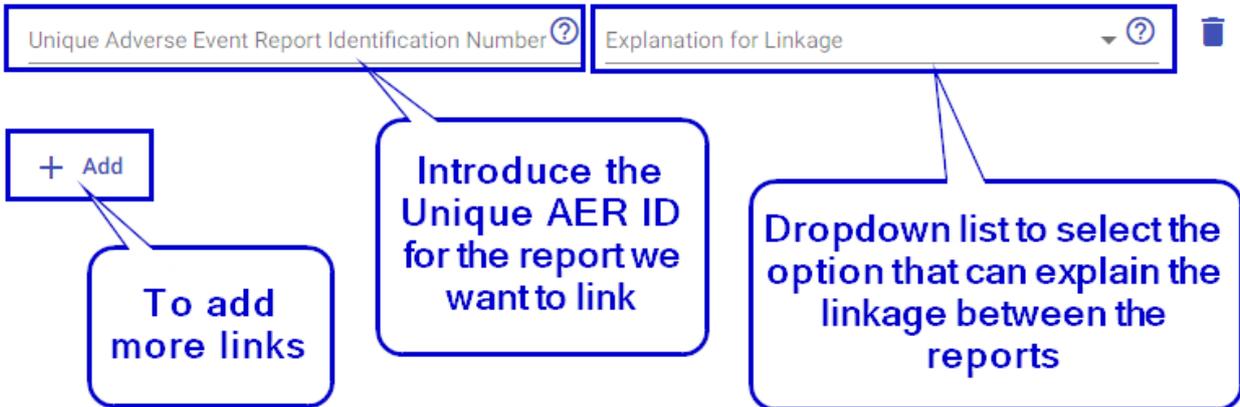


Figure 51: Report Number(s) of Linked Report(s)

### 4.1.1.1.2.17. 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.

New Import XML Export XML Validate Validate and Send

## Supplemental documents ?

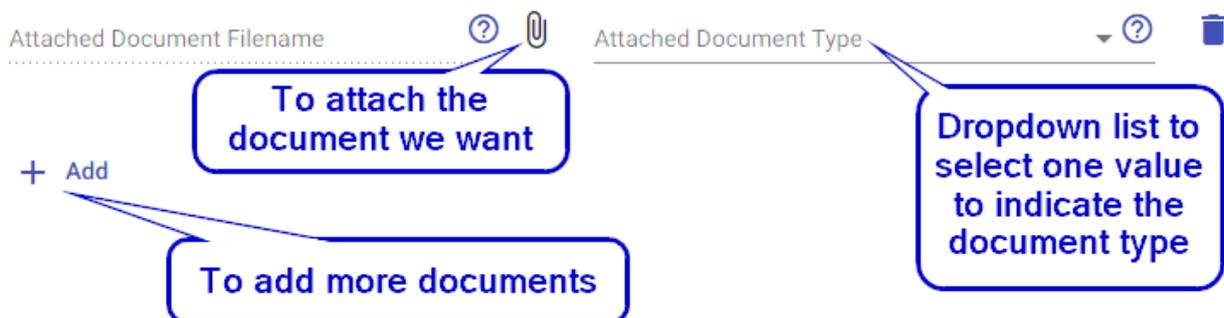


Figure 52: Supplemental documents

### 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).

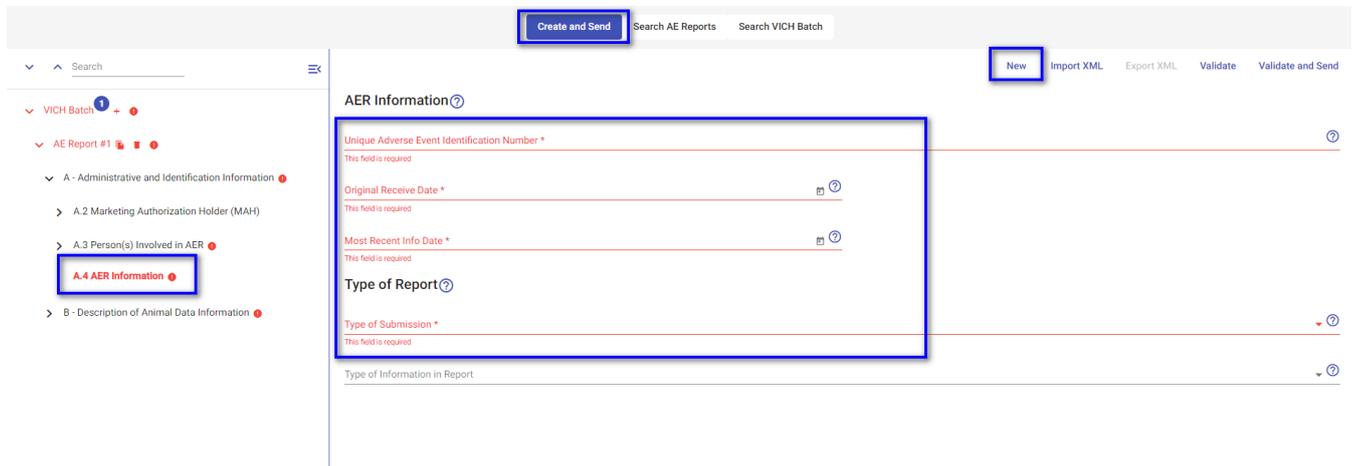


Figure 53: Mandatory fields highlighted in RED

**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](#)

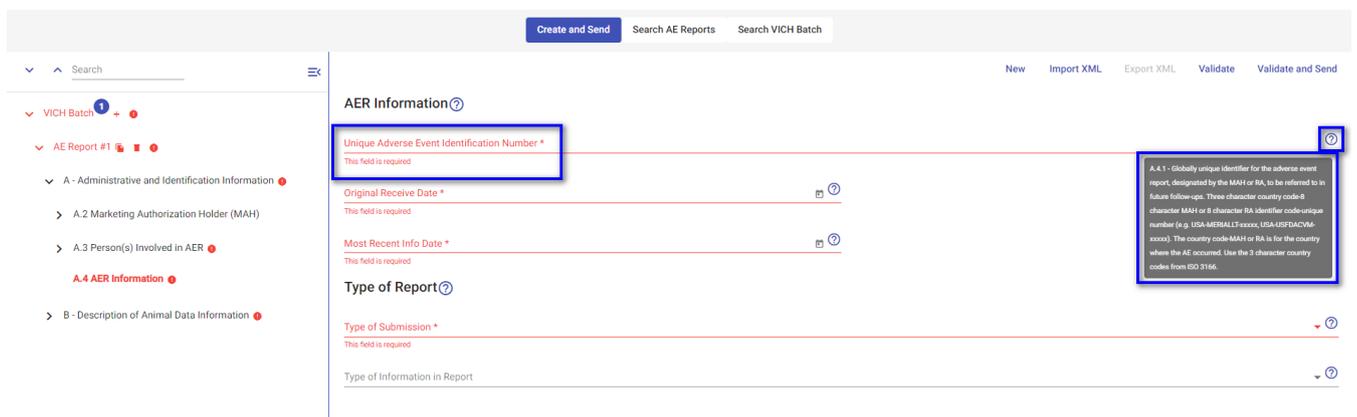


Figure 54: How to display field information

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.

**Validation result** Invalid

**03: Message is rejected in pre-validations**

<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	B.8.1.1.2	<b>Batch Identifier</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	B.8.2.1	<b>Message Number</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	B.8.2.3.1	<b>Message Receiver Identifier</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	A.3.1.3	<b>Last name</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	A.3.1.12	<b>Country</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	A.3.1.1	<b>Primary Reporter Category</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	A.4.1	<b>Unique Adverse Event Identification Number</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	A.4.2	<b>Original Receive Date</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	A.4.3	<b>Most Recent Info Date</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	B.1.2	<b>Number of Animals Affected</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	B.1.3	<b>Species (Type of Species)</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	B.2.1	<b>Registered Name or Brand Name</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	B.2.2.1	<b>Active Ingredient(s)</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	B.3.1	<b>Narrative of AE</b> This field is required
<span style="background-color: red; color: white; padding: 2px;">error (rule)</span>	B.3.2	<b>AER Term Name</b> This field is required

Close

Figure 55: Validation messages from Create and Send

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.

EVVET3 will then proceed to validate the message first on the client-side. If the validation is successful, EVVET3 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, EVVET3 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.

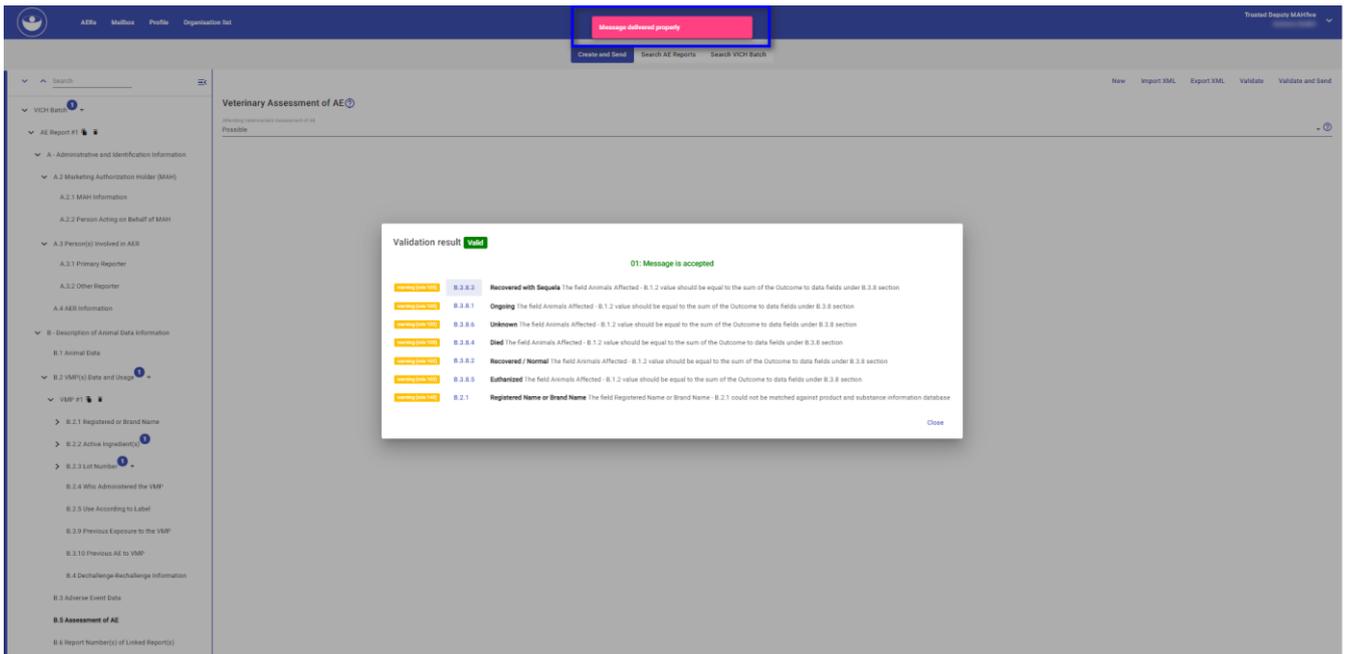


Figure 56: Validation successful

**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

#### 4.1.1.2. Save Draft

The "Save Draft" functionality can be used to save AERs temporary in the EVWEB before the final submission to EVVETPROD or other organisations. Drafts are preliminary versions of incomplete sketches that are being worked on by users. Users can save drafts as they work on them, allowing them to return to them later and continue their work.

Drafts are managed at organisation level (specific routing ID), therefore, all users with Access to EVVET for the same organisation will be able to view, resume and delete the draft.

To save a draft, the VICH Batch Number must be informed, as it will be used as an identifier in the "Drafts" section. Only after having it informed, the "Save Draft" button will be enabled. No other fields are mandatory to save it as a draft.



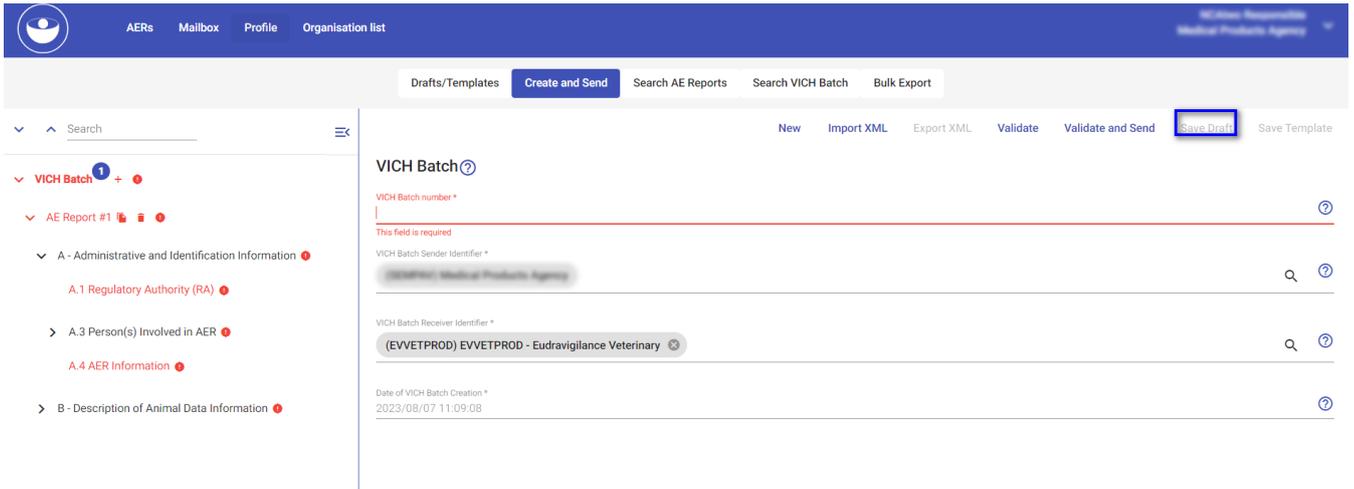


Figure 57: Before informing the VICH Batch number.

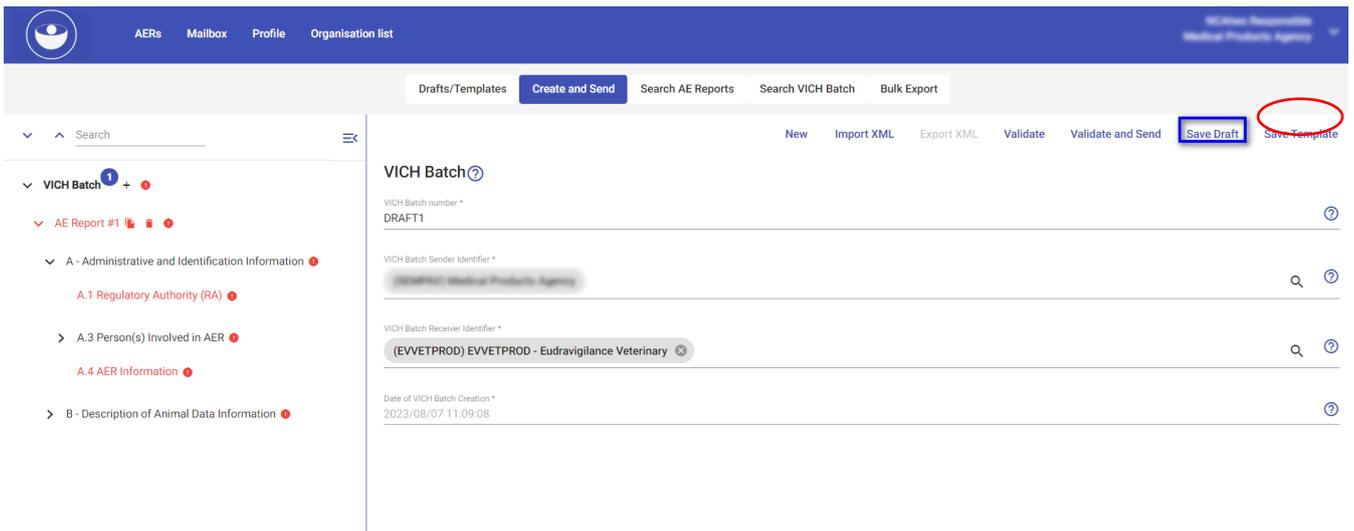


Figure 58: After informing the VICH Batch number.

After clicking on the "Save Draft" button, a confirmation message will appear informing that the draft was successfully saved.

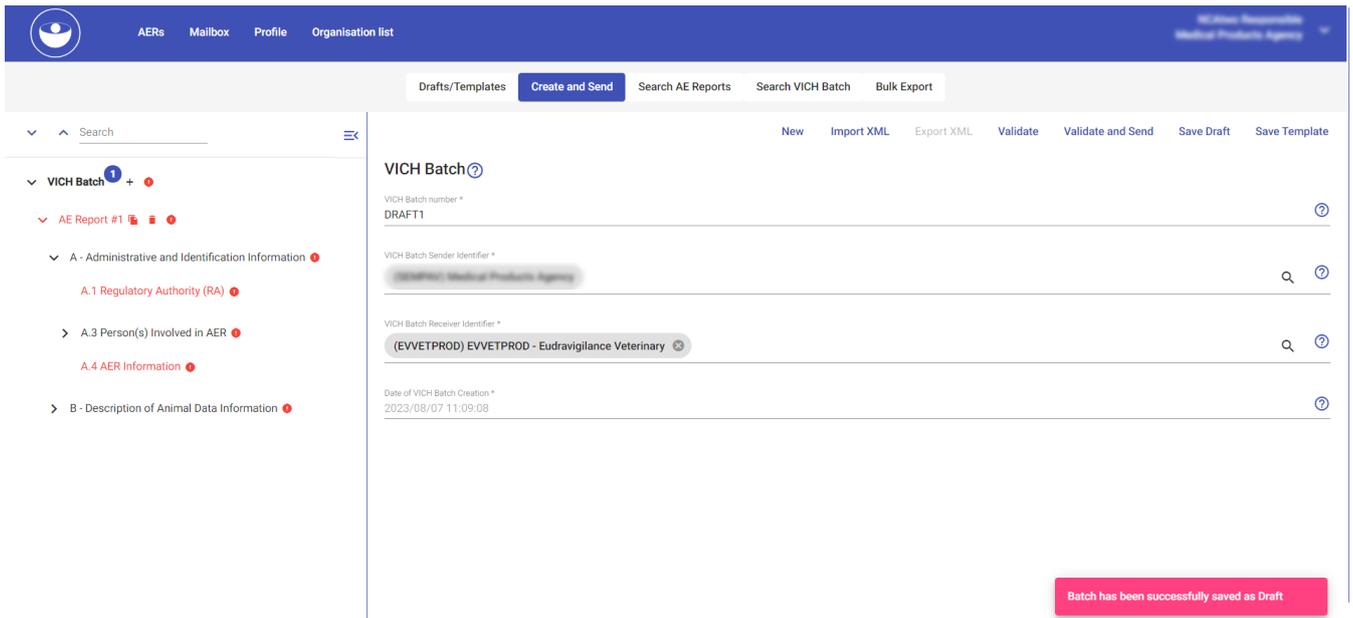


Figure 59 - Saving the Draft

Maximum number of drafts permitted for one organization is 50. After exceeding the maximum number of drafts, the user will get the following message when clicking on "Save Draft" button.

- *Maximum Drafts have been reached. The Draft cannot be saved.*

To view, resume and delete any draft created by users belonging to the logged organization, navigate to the separate menu tab "Drafts/ Templates" (Refer the 4.1.5 section for details about this tab).

VICH Batch Number	Drafts/Templates	Created User	Creation date ↑	Original Receive Date	Product	Actions
DRAFT2	Draft		2023/05/16 11:09 AM		PRODUCT 1	
DRAFT3	Draft		2023/05/16 11:09 AM		PRODUCT 1...	

Figure 60 - Draft Tab

#### 4.1.1.2.1 Resume Drafts

To resume working on the draft AER, click on the pencil icon of the "Draft" and it will be automatically opened in the "Create and Send" tab. Below message will be displayed after opening it

EMA Logo | AERs | Mailbox | Profile | Organisation list | NCAtwo Responsible Medical Products Agency

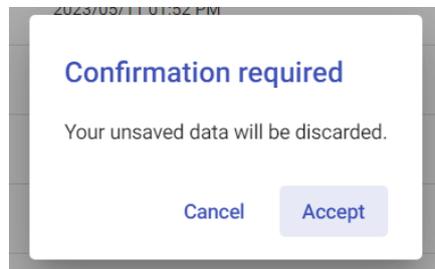
Draft | Create and Send | Search AE Reports | Search VICH Batch | Bulk Export

VICH Batch Number	Created User	Creation date	Original Receive Date	Product	Actions
DRAFT1		2023/05/16 10:59 AM			
DRAFT2		2023/05/16 11:09 AM		PRODUCT 1	
DRAFT3		2023/05/16 11:09 AM		PRODUCT 1...	
Veddrasearch_Many2	NCAtwo Responsible	2023/06/14 01:45 PM	2023/06/14	Draxxin 25 mg/ml - Solution for injection (pig)	
dkdkd	NCAtwo Responsible	2023/06/22 12:35 PM			
draftdemoq1	NCAtwo Responsible	2023/06/22 11:00 AM			
edict	NCAtwo Responsible	2023/06/22 09:21 AM			

The draft has been successfully opened. Go to Create and Send Tab

Figure 61 - Resume Drafts

If there is already a batch opened when resuming a draft, a user will get a confirmation message to discard the unsaved changes.



If a Draft is resumed and the "VICH Batch number" is changed, the information updated will not overwrite the existing draft, but a new Draft will be created instead. In order to update information for an existing draft, the "VICH Batch Number" should not be changed.

After validating and sending the AER, it will be removed from the "Draft" result table.

**4.1.1.2.2 Delete Drafts**

To delete a draft, simply click on the delete button (bin icon). Then, you will get the below message for the confirmation purpose.

- Click on "Delete" button, if you want to delete it permanently.
- Click on "Cancel" button, if you want to cancel the delete action.

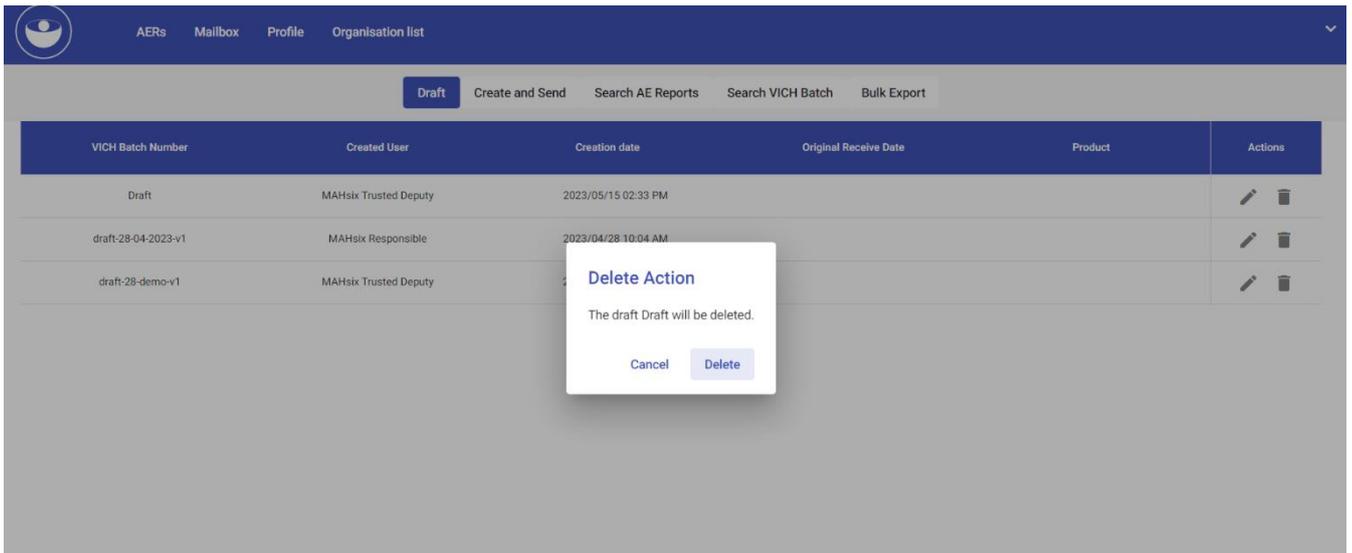


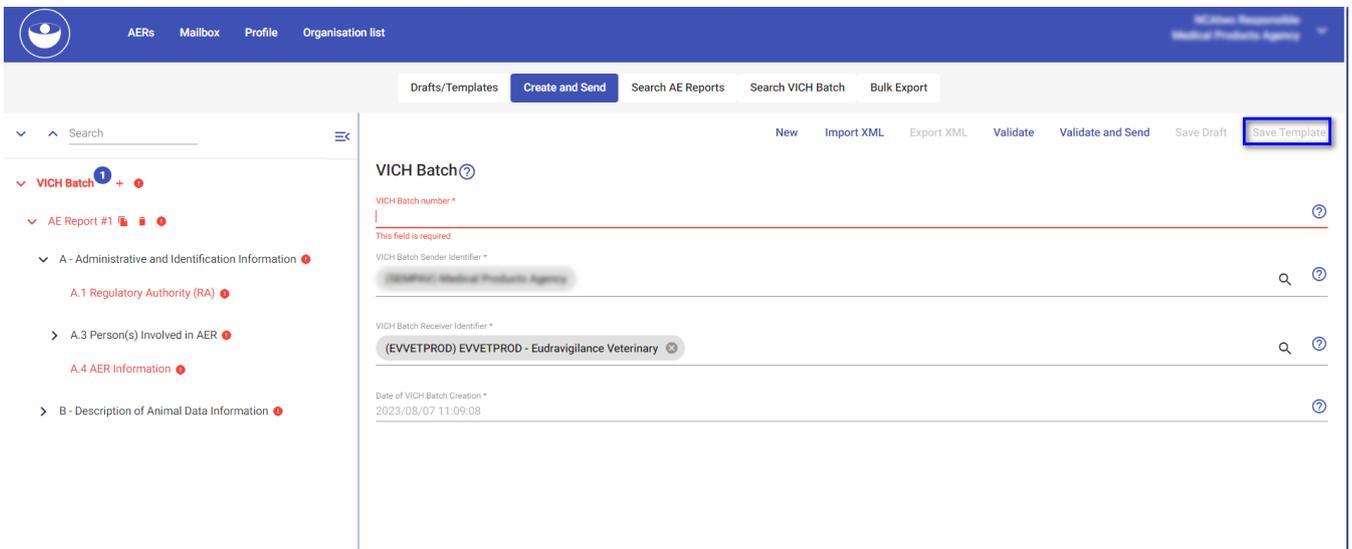
Figure 62 - Delete Drafts

#### 4.1.1.3. Save Templates

The "Save Templates" functionality can be used to create reusable AER layouts in the EVWEB. These reusable templates will facilitate standardized reporting and it will improve the overall efficiency. Templates contain placeholders for various fields or information that need to be filled out when creating reports. In addition, they serve as reusable models for creating drafts. Once a template is created, it can be used repeatedly to create drafts with similar information.

Templates are managed at organisation level (specific routing ID). Therefore, all users with access to EVVET for the same organisation will be able to view and update the templates.

To create a template, the VICH Batch Number must be provided as it will serve as an identifier in the "Drafts/ Templates" section. Only after providing the batch number, the "Save Template" button will be enabled. No other fields are mandatory to save it as a template.



The screenshot shows the 'VICH Batch' creation page. The 'Save Template' button is highlighted with a red box. The form contains the following fields:

- VICH Batch number \*: Template1
- VICH Batch Sender Identifier \*: EMA (European Medicines Agency)
- VICH Batch Receiver Identifier \*: (EUVETPROD) EUVETPROD - Eudravigilance Veterinary
- Date of VICH Batch Creation \*: 2023/08/07 11:09:08

After clicking on the 'Save Template' button, a confirmation message will appear, informing you that the template was successfully saved. You will receive the following message.

The screenshot shows the same 'VICH Batch' creation page, but now a confirmation message is displayed at the bottom right: "Batch has been successfully saved as Template". The 'Save Template' button is no longer highlighted.

Maximum number of templates permitted for one organization is 50. After exceeding the maximum number of templates, the user will get the following message when clicking on "Save Template" button.

- *Maximum templates have been reached. The template cannot be saved.*

To view, resume and delete the templates created by users belonging to the logged organization, navigate to the "Drafts/ Templates" tab (Refer the 4.1.5 section for details about this tab).

VICH Batch Number	Drafts/Templates	Created User	Creation date ↓	Original Receive Date	Product	Actions
Template10	Template	NCAtwo Responsible	2023/08/07 11:25 AM			
testtemp1	Draft	NCAtwo Responsible	2023/08/04 12:11 PM	2023/08/04	Draxxin 25 mg ml - Solution for injection (pig)...	
testtemp1	Template	NCAtwo Responsible	2023/08/04 12:06 PM	2023/08/04	Draxxin 25 mg ml - Solution for injection (pig)...	
testtemplate	Template	NCAtwo Responsible	2023/08/04 11:33 AM		Draxxin 25 mg ml - Solution for injection (pig)	

#### 4.1.1.3.1 Resume Templates

To use the template, click on the pencil icon of the "Template" and it will be automatically opened in the "Create and Send" tab. Below message will be displayed after opening it.

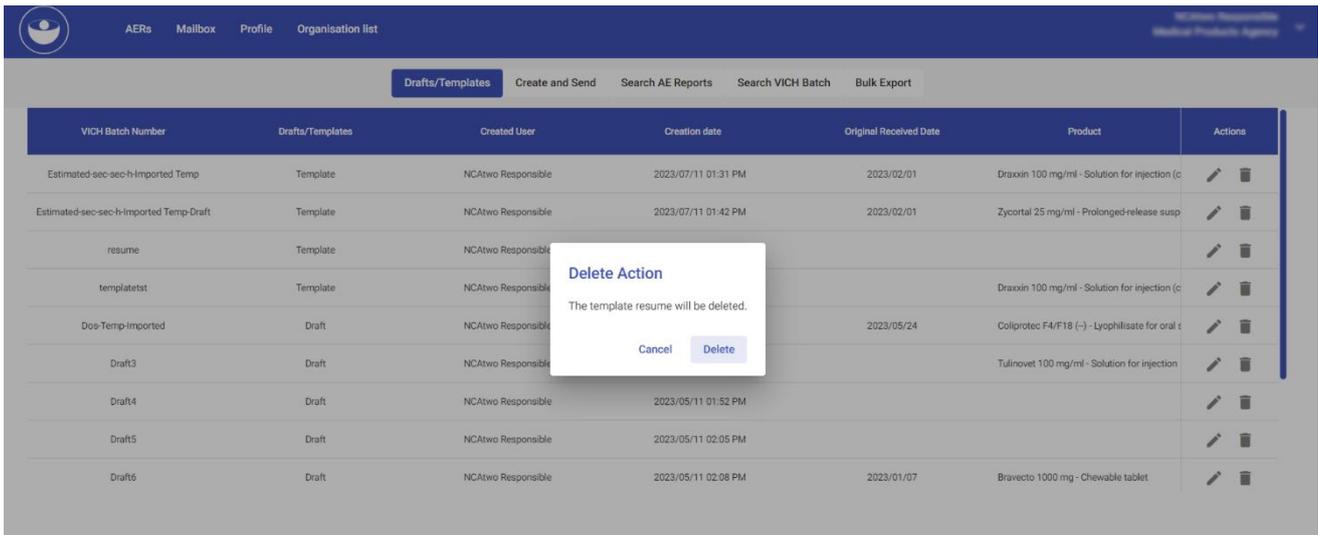
VICH Batch Number	Drafts/Templates	Created User	Creation date ↓	Original Receive Date	Product	Actions
Template10	Template	NCAtwo Responsible	2023/08/07 11:25 AM			
testtemp1	Draft	NCAtwo Responsible	2023/08/04 12:11 PM	2023/08/04	Draxxin 25 mg ml - Solution for injection (pig)...	
testtemp1	Template	NCAtwo Responsible	2023/08/04 12:06 PM	2023/08/04	Draxxin 25 mg ml - Solution for injection (pig)...	
testtemplate	Template	NCAtwo Responsible	2023/08/04 11:33 AM		Draxxin 25 mg ml - Solution for injection (pig)	
templatedemo	Draft	NCAtwo Responsible	2023/07/27 02:07 PM			
templatedemo	Template	NCAtwo Responsible	2023/07/27 02:04 PM			
template	Template	NCAtwo Responsible	2023/07/27 01:10 PM			
Template 6	Draft	NCAtwo Responsible	2023/07/25 02:26 PM		Draxxin 25 mg ml - Solution for injection (pig)	
Template 6	Template	NCAtwo Responsible	2023/07/25 11:56 AM			

The template has been successfully opened. Go to Create and Send Tab

After creating templates, users will be able to use those templates to create drafts. When creating a new draft, they can select a template from the list of available templates, and the predefined fields will be populated automatically. The user can follow the same steps as described in 4.1.1.2 in order to save the draft using the template.

#### 4.1.1.3.2 Delete Templates

To delete a template, simply click on the delete button (bin icon). Then, you will get the message below for the confirmation purpose.



- Click on "Delete" button, if you want to delete it permanently.
- Click on "Cancel" button, if you want to cancel the delete action.

#### 4.1.1.2. 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.

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.

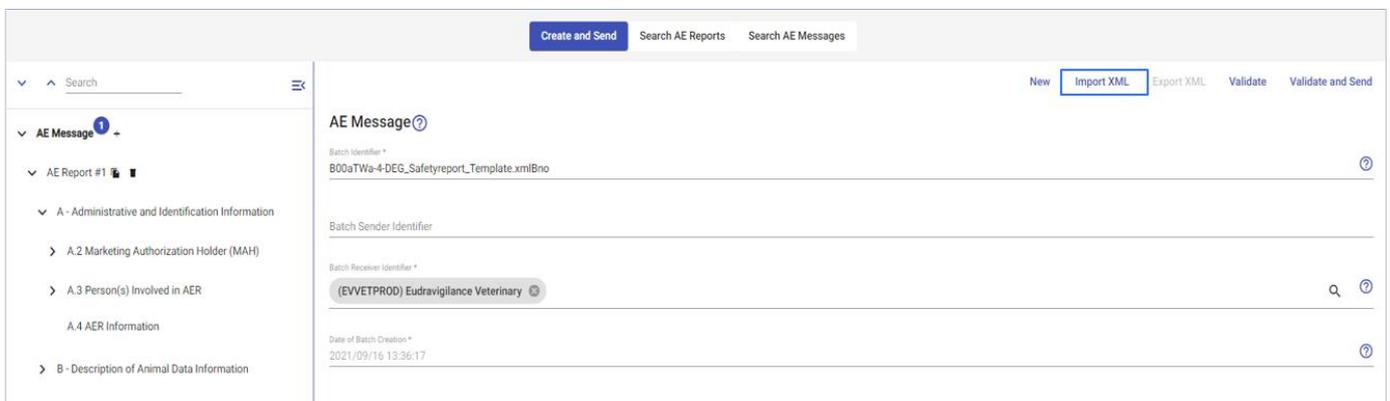


Figure 63: Import XML option

Name	Type
<ul style="list-style-type: none"> <li>Earlier this week (3) <ul style="list-style-type: none"> <li>AER_EVVETPRODBL_20111226151105_twtfQv XML Document</li> <li>AER_EVVETPRODBL_20111226151105_EeDhHE XML Document</li> <li>AER_EVVETPRODBL_20111226151105_UNsSzL XML Document</li> </ul> </li> </ul>	
<ul style="list-style-type: none"> <li>Last month (2) <ul style="list-style-type: none"> <li>act_VICH_GU_Sample_AER_mandatory_deploynt_deploynt XML Document</li> <li>SDAC_AER_2021-07-29T12:44:25+0000_files File folder</li> </ul> </li> </ul>	
<ul style="list-style-type: none"> <li>Earlier this year (1) <ul style="list-style-type: none"> <li>AER_EVVETPRODBL_20111226151105_UNsSzL XML Document</li> </ul> </li> </ul>	

Figure 64: Select XML file to import it in EVWEB

The screenshot shows the EVWEB interface. On the left, a search sidebar is visible with a tree view under 'VICH Batch'. The main content area displays the details of an imported XML file. The fields shown are:

- VICH Batch number \***: VICHBATCH-ImportXMLTest
- VICH Batch Sender Identifier**: (empty)
- VICH Batch Receiver Identifier \***: (EVVETPROD) Eudravigilance Veterinary
- Date of VICH Batch Creation \***: 2021/12/13 09:30:54

Figure 65: Imported XML displayed in tree view

### 4.1.1.3. Export XML

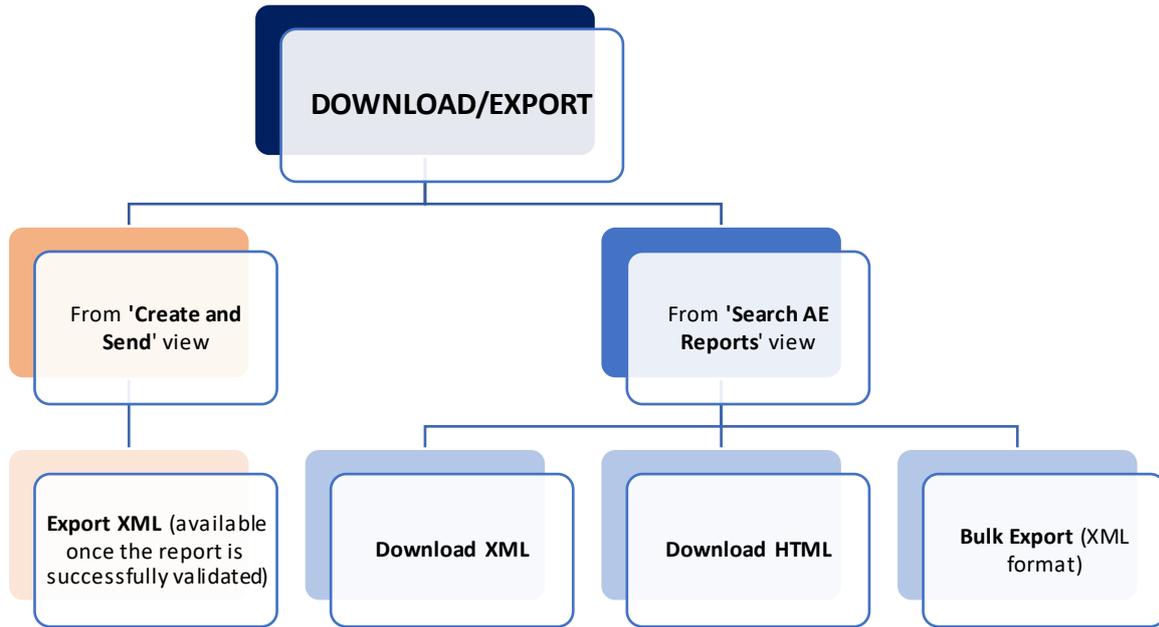


Figure 66: Download overview in EVWEB (both from 'create and send' and 'Search AE reports')

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.

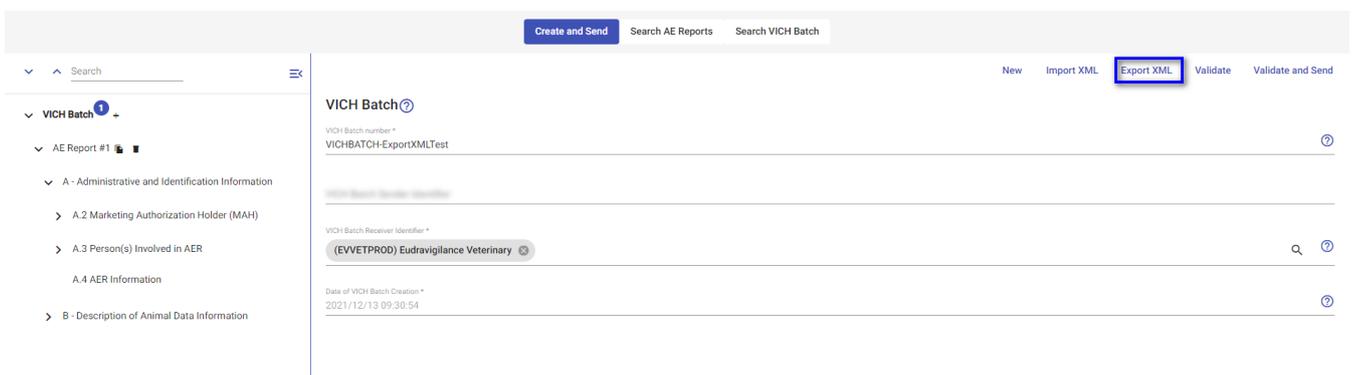


Figure 67: Export XML

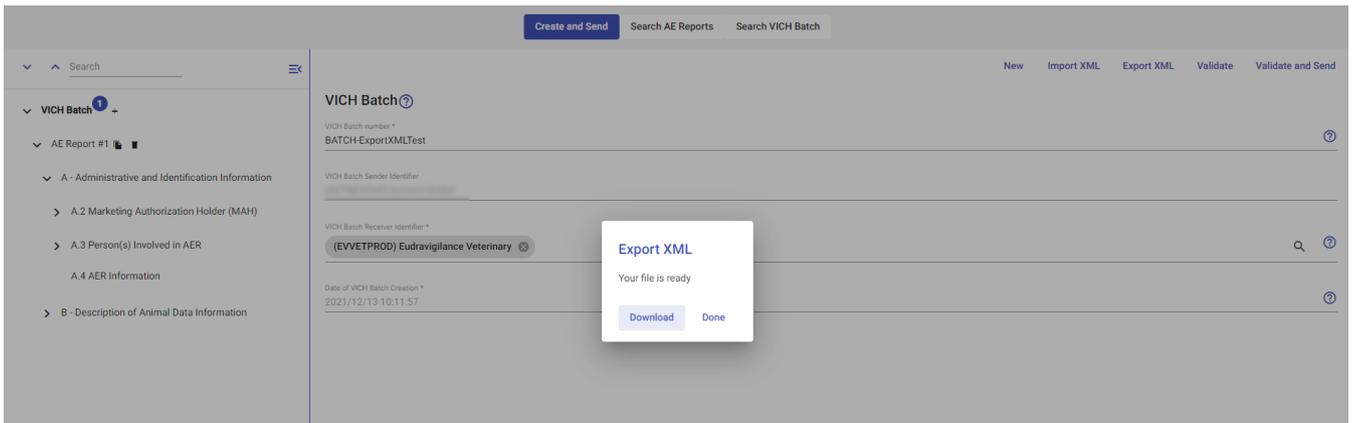


Figure 68: Download Export XML

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.

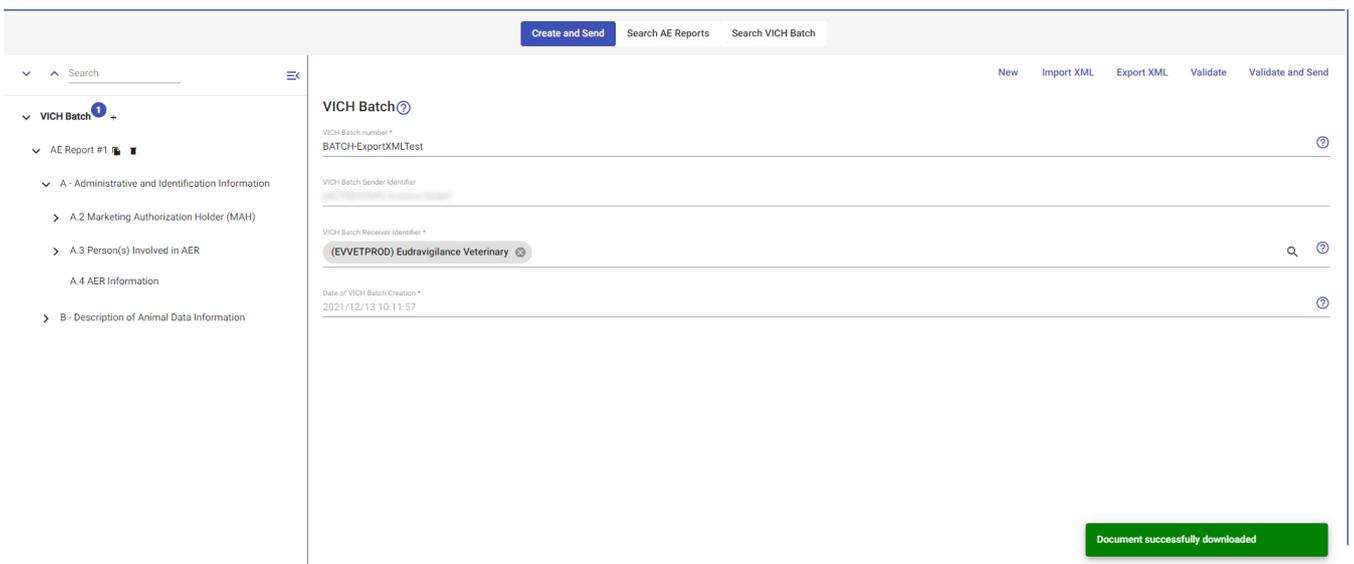


Figure 69: Export XML successful message

The available export file formats are XML & HTML. The below matrix outlines the supported export file formats per these items:

Export File Format	Description
XML	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.

HTML

An HTML file that complies with the Council for International Organizations of Medical Sciences standard (CIOMS).

Table 4: Export formats (XML and HTML)

### 4.1.2. Search AE Reports

There are two different ways to search reports in the Search AE Reports section: using the Global Search, generic and quick; and the Advanced Search, with different criteria filters for a more detailed search.

#### 4.1.2.1 Global Search

The global 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.

Local Report Number	Vich Batch Received Date	Occur Country	Results In Death	Vich Batch Sender	Type Of Submission In Report	Species	Type Of	Actions
1554	2005/02/15	Sweden	0	EVVETPRODBL	OTHER	Dog	SAFETY ISSUE	👁️ ✎️ ⬇️
4603	2005/07/11	Sweden	0	EVVETPRODBL	OTHER	Dog	SAFETY ISSUE	👁️ ✎️ ⬇️
1851	2005/02/25	Sweden	0	EVVETPRODBL	OTHER	Pig	SAFETY ISSUE	👁️ ✎️ ⬇️
11921	2006/12/07	Sweden	0	EVVETPRODBL	PERIODIC	Dog	SAFETY ISSUE	👁️ ✎️ ⬇️
13365	2007/03/28	Sweden	0	EVVETPRODBL	OTHER	Horse	SAFETY ISSUE	👁️ ✎️ ⬇️

Figure 70: Global Search field

Criteria(5) SE-MPA-203/2003

Fields(9)

Export Selected XML  Export All XML  Export CSV

Occur Country	Results In Death	Vich Batch Sender	Type Of Submission In Report	Species	Type Of Information In Report	Unique Aer Number	Actions
Sweden	0	EVVETPRODBL	OTHER	Dog	SAFETY ISSUE	SE-MPA-203/2003	
Sweden	0	EVVETPRODBL	OTHER	Dog	SAFETY ISSUE	SE-MPA-203/2003	
Sweden	0	EVVETPRODBL	OTHER	Dog	SAFETY ISSUE	SE-MPA-203/2003	
Sweden	0	EVVETPRODBL	OTHER	Dog	SAFETY ISSUE	SE-MPA-203/2003	
Sweden	0	EVVETPRODBL	OTHER	Dog	SAFETY ISSUE	SE-MPA-203/2003	
Sweden	0	EVVETPRODBL	OTHER	Dog	SAFETY ISSUE	SE-MPA-203/2003	

Figure 71: Global Search

#### 4.1.2.2 Advanced Search

EVVET3 allows to perform advanced search in the data base. By default, "Search AE Reports" section will have some search criteria and fields options set as default. To add new criteria filters, you can click on the criteria search panel (next to the last criteria field) and select available criteria from the dropdown list 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.

The screenshot displays the advanced search interface with three numbered callouts:

- 1**: Points to the **Criteria(5)** ribbon, which includes filters for Occur Country, Sender, Species, Unique AER Number, and VICH Batch Received Date.
- 2**: Points to the **Fields(9)** ribbon, which includes filters for Local report Number, VICH Batch Received Date, Occur Country, Results in Death, VICH Batch Sender, Type of Submission in Report, Species, Type of Information in Report, and Unique AER Number.
- 3**: Points to the **Result Area**, which contains a table of search results.

The **Result Area** table is as follows:

Local Report Number	Vich Batch Received Date	Occur Country	Results In Death	Vich Batch Sender	Type Of Submission In Report	Species	Type O	Actions
8907	2006/06/19	United Kingdom	0	UKVMD	EXPEDITED	Cat	SAFETY ISSUE	[Eye] [Pencil] [Download]
1384027		Australia	0	NLINTVINT	EXPEDITED	Dog	LACK OF EXPECTEE	[Eye] [Pencil] [Download]
1379144		Canada	0	BIAHPVIP	EXPEDITED	Dog	SAFETY ISSUE	[Eye] [Pencil] [Download]

Figure 72: Advanced Search Criteria

**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.

Every advanced query is divided in 3 different areas (see above screenshot for reference):

- a) Criteria ribbon
- b) Fields ribbon
- c) 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.

#### 4.1.2.2.1. 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.

The screenshot shows the **Criteria(5)** ribbon with the following filters selected:

- Occur Country
- Sender
- Species
- Unique AER Number
- VICH Batch Received Date

Figure 73: Criteria ribbon

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".

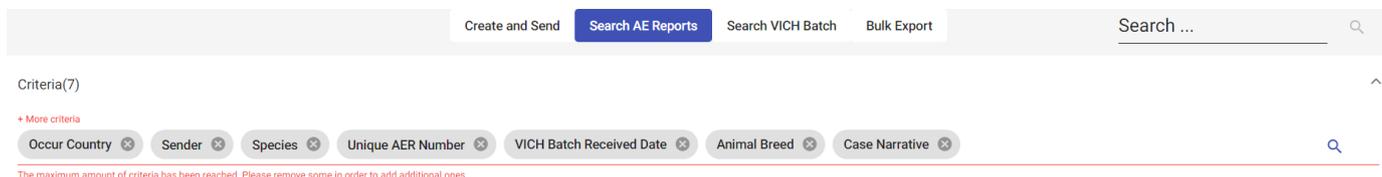


Figure 74: Maximum Criteria

To add a criteria item, users need to click on the criteria search panel . 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.

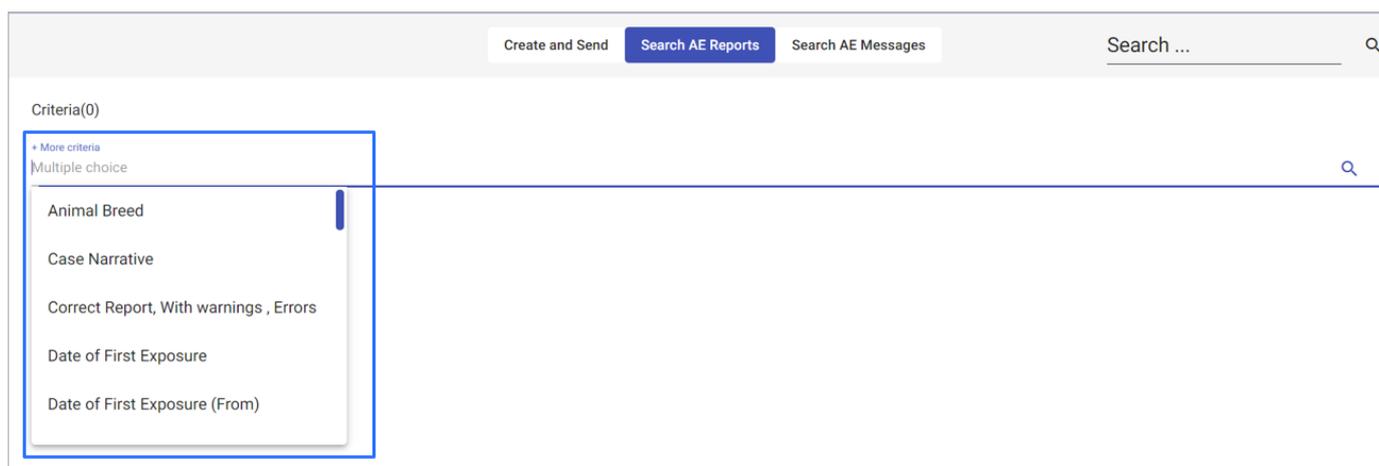


Figure 75: Adding a criteria item

**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, 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.

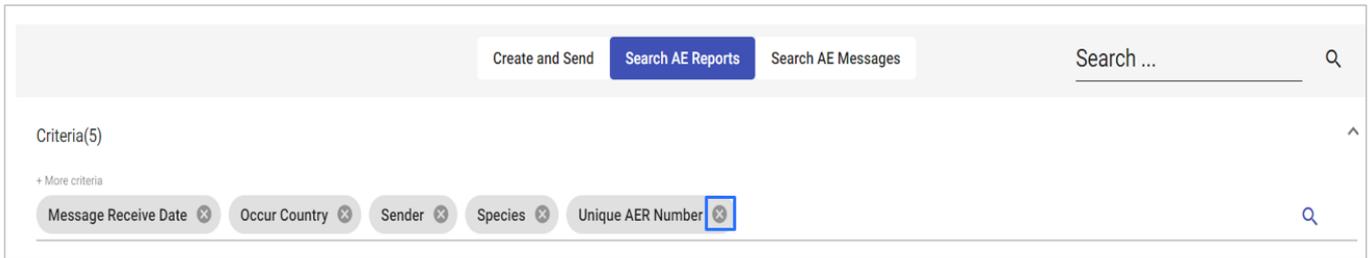


Figure 76: Remove Criteria item

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:

CRITERIA FILTER	VALUE TYPE
Animal Breed	Free Text (with suggestion list available only when Species is informed)
Case Narrative	Free Text
Classification	Dropdown Selection
Correct Report, with warnings, errors	Option list selection
Date of First Exposure	Date (YYYY/MM/DD)
Date of first Exposure (From)	Date (YYYY/MM/DD)
Date of first Exposure (Up To)	Date (YYYY/MM/DD)
Date of Onset of AE	Date (YYYY/MM/DD)
MAH	Organization ID or Organisation Name
Most recent Info Date	Date (YYYY/MM/DD)
Most recent Info Date (From)	Date (YYYY/MM/DD)
Most recent Info Date (Up To)	Date (YYYY/MM/DD)
Occur Country	Free Text (with suggestion list available)
Off label use	Dropdown Selection
Original Received Date	Date (YYYY/MM/DD)
Original Received Date (From)	Date (YYYY/MM/DD)
Original Received Date (Up To)	Date (YYYY/MM/DD)
Outcome Died	Yes / No selection
Outcome Euthanized	Yes / No selection
Product Name	Free Text (with suggestion list available)
Product Name – as Recoded	Free Text (with suggestion list available)
Product Recoding Date	Date (YYYY/MM/DD)
Product Recoding Date (From)	Date (YYYY/MM/DD)
Product Recoding Date (Up to)	Date (YYYY/MM/DD)
Sender	Routing ID
Species	Free Text (with suggestion list available)
Substance Name	Free Text (with suggestion list available)
Substance Name – as recoded	Free Text (with suggestion list available)
Type of Submission	Dropdown Selection

CRITERIA FILTER	VALUE TYPE
Unique AER Number	Free Text
Use According to Label	Dropdown Selection
VICH Batch Received Date	Date (YYYY/MM/DD)
VICH Batch Received Date (From)	Date (YYYY/MM/DD)
VICH Batch Received Date (Up To)	Date (YYYY/MM/DD)
VeDDRA Name	Free Text (with suggestion list available)

*Table 5: Criteria filters and value types*

#### **4.1.2.2.1.1. 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:

Criteria operator	Description
Begins	Finds only matches which start with the search term.
Contains	Finds the search term anywhere in the name – beginning, middle, or end.
Matches	Finds reports that contain only the exact values specified in criteria filter.
Does Not Match	Excludes from results list those reports that match the exact values specified in criteria filter.
In	Finds reports that contain at least one of the exact values specified in criteria filter.
Not In	Excludes reports that contain at least one of the exact values specified in criteria filter.

*Table 6: Criteria operators*

Once you add such an item in the criteria ribbon and click on it, you’ll be presented with the available options to select the query mode for the specific criteria and enter your search term. Please, note that not all criteria filters will present the same query options. For more detailed information on each criteria filter and options, refer to Annex 1.

In the following screenshot the user has selected the “Contains” query mode and has inserted the search term “act” and dropdown list presents all product options that contain in its name the specified value:

Criteria(1)

+ More criteria

The screenshot shows a search criteria filter for 'Product Name'. The operator is set to 'Contains' and the value is 'act'. A dropdown menu is open, displaying a list of search results:

- Zactran 150 mg/ml - Solution for injection (cattle, pigs, sheep)
- Preotact (SRD) 100 µg - Powder and solvent for solution for injection
- Nyracta (SRD) 1 mg - Film-coated tablet
- Sildenafil Actavis 100 mg - Film-coated tablet
- Imatinib Actavis 400 mg - Capsule, hard

Figure 77: Advance Search Criteria ('contains' operator)

Another option available for some criteria filters is the multiselection of terms, that means that user can filter reports that match more than 1 value. To do this, user will need to select first one value and then search for the second value in same line. Once all values are entered, then click on Update button to save the values for the criteria filter:

Criteria(6)

+ More criteria

The screenshot shows a search criteria filter for 'Sender'. The operator is set to 'In' and the value is '(EVVETPROD) Eudravigilanc...' and '(EVVETPRODBL) Eudravigila...'. The 'Update' button is visible.

Figure 78: Multiple values for one criteria filter

#### 4.1.2.2.2. MAH Default Criteria Filters

If a user logs in as an MAH user (Marketing Authorization Holder), they will access a predefined set of criteria filters by default. This functionality streamlines the user experience by providing immediate access to the most frequently used criteria filters, eliminating the need for manual addition.

- Those criteria filters include; Sender – exclude the routing ID of the logged user (Not In {Routing ID of the logged user})
- MAH – OMS ID of the logged user (In {OMS ID of the logged user})
- Batch Receive Date – Last working date (Monday to Friday)
- Classification – Case reports



Figure 79 - MAH Default Criteria Filters

If the user modifies the available default criteria and wants to restore them, they can click on the specified icon.

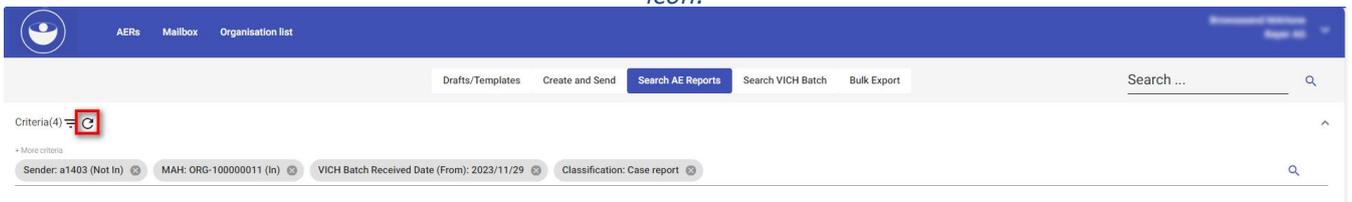


Figure 80 - MAH Default Criteria Filters

#### 4.1.2.2.3. NCA Default Criteria Filters

If a user logs in as an NCA user (National Competent Authorities), they will access a predefined set of criteria filters by default. This functionality streamlines the user experience by providing immediate access to the most frequently used criteria filters, eliminating the need for manual addition.

- Those criteria filters include.
- Occur Country – NCAs default country.
- VICH Batch Received Date (From) – Last working date (Monday to Friday)
- Classification – Case reports

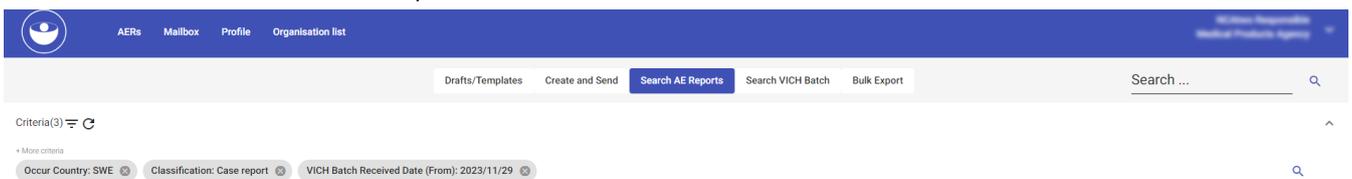


Figure 81 – NCA Default Criteria Filters

If the user modifies the available default criteria and wants to restore them, they can click on the specified icon.

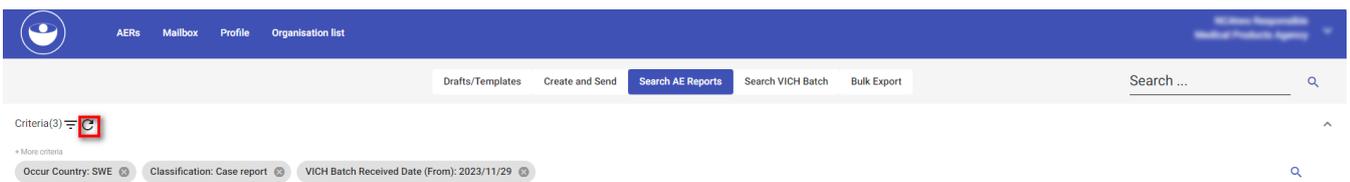
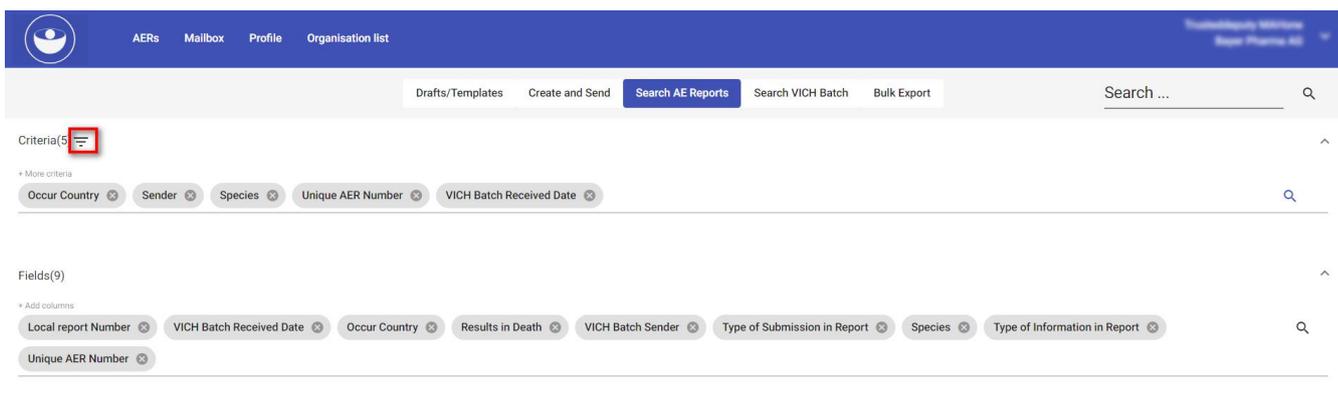


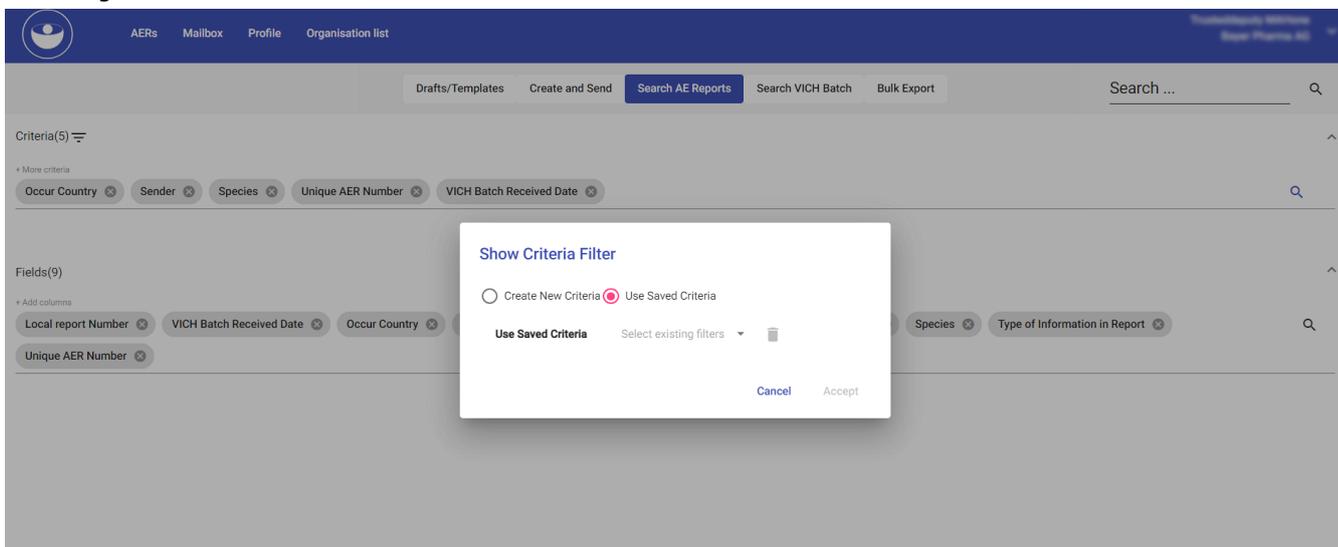
Figure 82 – NCA Default Criteria Filters

#### 4.1.2.2.1. Storage of Criteria Filters

This functionality enables users to generate and save custom criteria filters for future use, and thereafter any user within the same organization will be able to select these filters and automatically retrieve all pre-defined values for conducting searches.

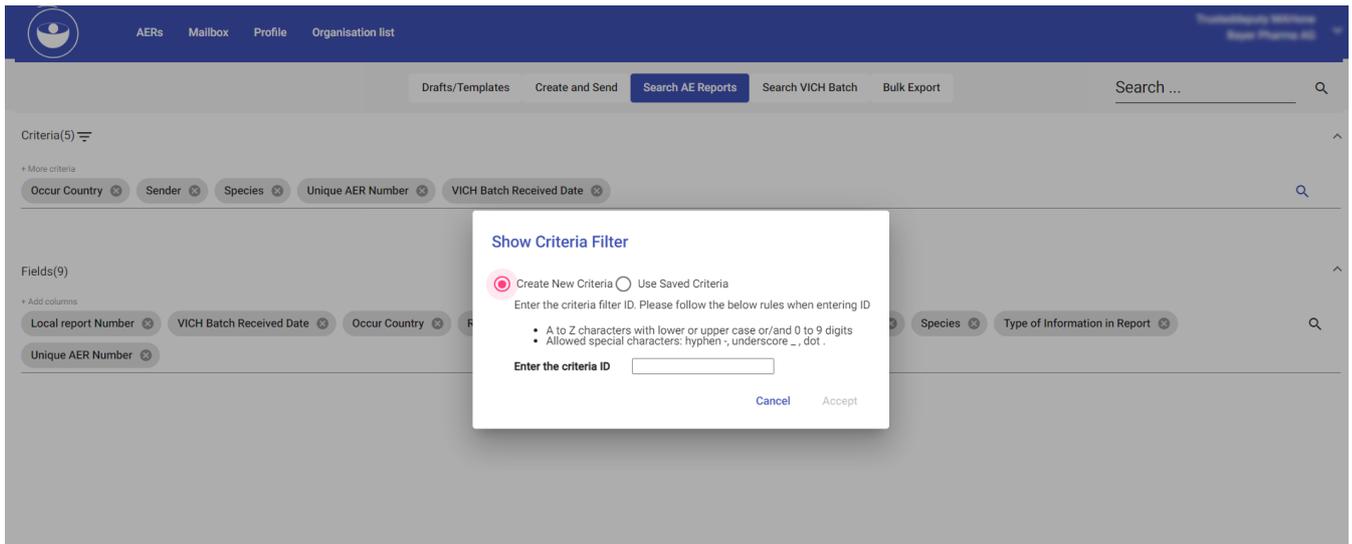


Select the small icon adjacent to the "Criteria". Subsequently, the user will be presented with the following window.



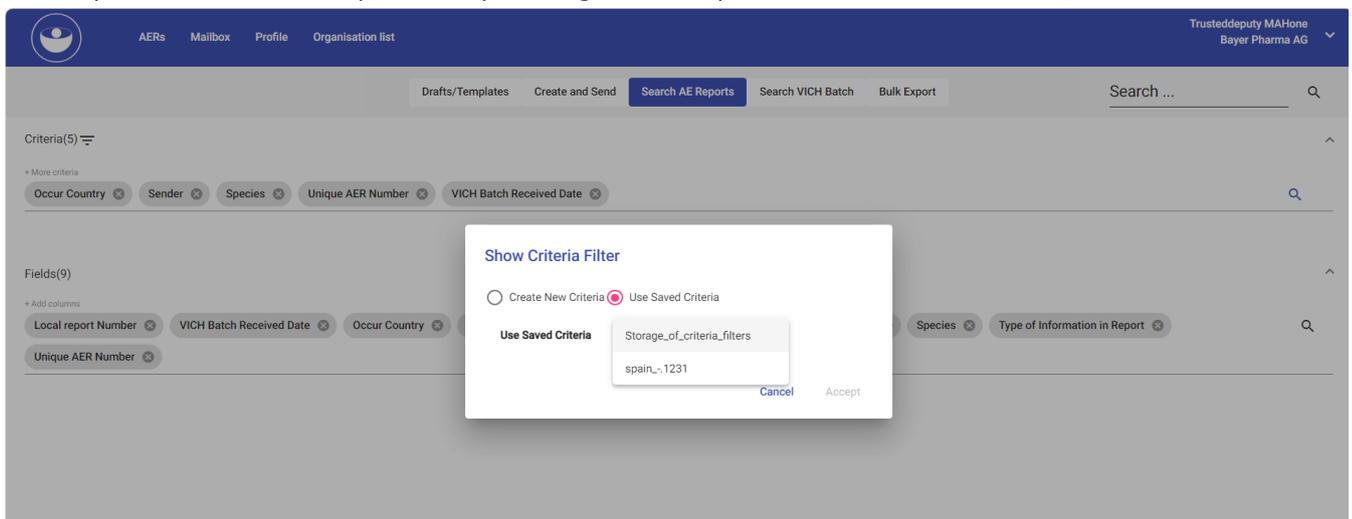
Within this window, users will find two options: "Create New Criteria" and "Use Saved Criteria." The default selection is "Use Saved Criteria," allowing any user within the same organization to choose previously saved criteria from the dropdown field.

If the user intends to create a new set of criteria, they can click on the "Create New Criteria" radio button, after which the window should appear as follows:



The user can enter the criteria ID as instructed in the window and proceed to click the "Accept" button. This information will then be stored in the database for future reference, accessible for use by other users within the same organization.

If the user desires to utilize a previously saved criteria filter, they can easily select the criteria ID from the dropdown field and then proceed by clicking the "Accept" button.



To remove saved criteria, the user can simply choose the desired criteria from the dropdown field and then click on the delete (Bin) icon.

#### 4.1.2.2.2. 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.

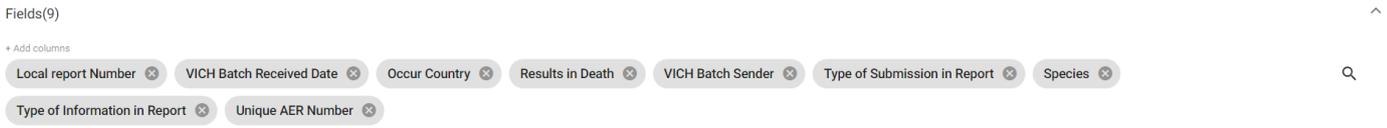


Figure 83: Add Fields item

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.

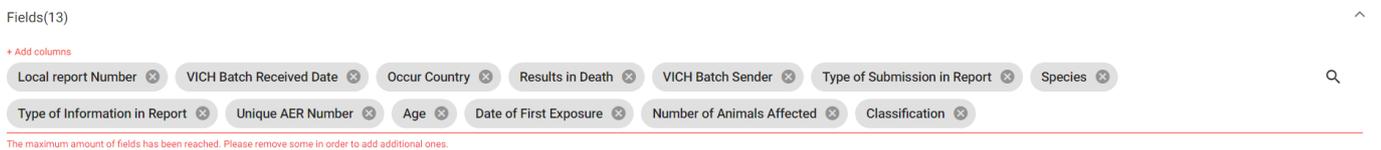


Figure 84: Maximum Fields item

To add a field item, you need to click on the field search panel. This will produce a drop-down list from which you can select the desired field item. You can repeat this process to obtain a 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.

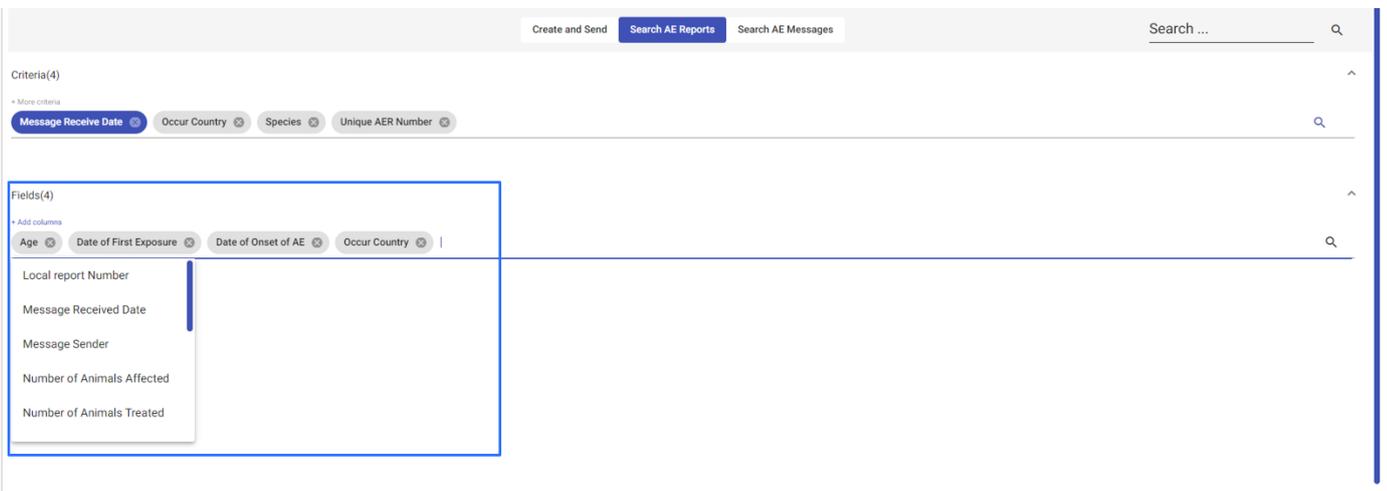


Figure 85: Fields item dropdown list

**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.

Available field columns are listed in below table:

CRITERIA FILTER	COMMENTS
Age	Can displays single value or minimum and maximum ages. Columns ordering not applicable.
Classification	Columns ordering applicable.
Date of first Exposure	Date (YYYY/MM/DD). Columns ordering applicable.
Date of Onset of AE	Date (YYYY/MM/DD). Columns ordering applicable.
Local report number	Internal serialization number. Columns ordering applicable.
Number of animals affected	Columns ordering applicable.
Number of animals treated	Columns ordering applicable.
Occur Country	Columns ordering applicable.
Product Name	For multiple Products informed in AER, field will display the first product and when hovering with the mouse over the filed, a tooltip with full list of products will be displayed.
Product Recoding Date	Date (YYYY/MM/DD). Columns ordering applicable.
Results in death	Columns ordering applicable.
Serious AE	Yes/No. Columns ordering applicable.
Species	Columns ordering applicable.
Substance name	For multiple Substances informed in AER, field will display the first substance and when hovering with the mouse over the filed, a tooltip with full list of active substances will be displayed.
Type of information in report	Columns ordering applicable.
Type of submission in report	Columns ordering applicable.
Unique AER Number	Columns ordering applicable.
Use according to label	Columns ordering applicable.
VICH Batch received date	Date (YYYY/MM/DD). Columns ordering applicable.
VICH Batch sender	Date (YYYY/MM/DD). Columns ordering applicable.
VeDDRA term	For multiple VEDDRA terms informed in AER, field will display the first VEDDRA and when hovering with the mouse over the filed, a tooltip with full list of active substances will be displayed.
VeDDRA Version..	Numeric value. Columns ordering applicable.

*Table 7: List of Fields available for results table*

#### 4.1.2.2.3. 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 EVVET3 screen in a list view layout.

[Create and Send](#)
[Search AE Reports](#)
[Search VICH Batch](#)
[Bulk Export](#)

Criteria(5)

+ More criteria

[Occur Country](#)
[Sender](#)
[Species](#)
[Unique AER Number](#)
[VICH Batch Received Date](#)

---

Fields(9)

+ Add columns

[Local report Number](#)
[VICH Batch Received Date](#)
[Occur Country](#)
[Results in Death](#)
[VICH Batch Sender](#)
[Type of Submission in Report](#)
[Species](#)

[Type of Information in Report](#)
[Unique AER Number](#)

---

Export Selected XML
 [Export All XML](#)
[Export CSV](#)

Local Report Number	Vich Batch Received Date	Occur Country	Results In Death	Vich Batch Sender	Type Of Submission In Report	Species	Type Of	Actions	
<input type="checkbox"/>	8907	2006/06/19	United Kingdom	0	UKVMD	EXPEDITED	Cat	SAFETY ISSUE	
<input type="checkbox"/>	1384027		Australia	0	NLINTVINT	EXPEDITED	Dog	LACK OF EXPECTED	
<input type="checkbox"/>	1379144		Canada	0	BIAHPV1P	EXPEDITED	Dog	SAFETY ISSUE	

Figure 86: Result Area

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.

Items per page: 10  1 - 10 of 31040

Figure 87: Pagination

All fields in the results table that can have in its content only one value (that means that products, substances, Veddra terms and age are excluded as they can have more than 1 value informed), can be used to order in ascending or descending mode the results list. To do this, an arrow will appear next to each column header which will change the order each time that it's clicked. Order of results table is limited to 10000 results. If the results retrieve are higher than this limit, then sorting is disabled for all columns.

Criteria(5)

+ More criteria

Occur Country Sender Species Unique AER Number VICH Batch Received Date

Fields(9)

Export Selected XML Export All XML Export CSV

Local Report Number	Vich Batch Received Date	Occur Country	Results In Death	Vich Batch Sender	Type Of Submission In Report	Species	Type Of	Actions
<input type="checkbox"/>	20000001761	2022/12/01	Sweden	0	DEBHCAHHQP	NULLIFICATION	Bat	
<input type="checkbox"/>	20000001760	2022/12/01	Sweden	0	DEBHCAHHQP	EXPEDITED	Bat	
<input type="checkbox"/>	20000001762	2022/12/01	Sweden	0	DEBHCAHHQP	FOLLOW-UP	Bat	
<input type="checkbox"/>	20000001756	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat	
<input type="checkbox"/>	20000001757	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat	

Figure 88: Ordering of the results table

In some cases, when field information is longer than the space in results table, the information is cut, but can be easily displayed without opening the report, by hovering the mouse over the text. A pop-up text box appears with the extended information:

Vich Batch Received Date	Product Name	Substance Name
	Amoxicillin...	
2018/09/24	FRONTLINE SPOT ON CHAT	
2016/09/20	Loxicom 1.5 mg/ml Oral Suspension for Dogs...	Meloxicam...
	Neosel	Neomycinsulfat...
2016/10/03	Deramaxx 25 mg...	deracoxib...
2016/09/09	Deramaxx 25 mg,K9 Immunity,Adequan Canine 100 mg/ml,Dasuquin Advanced,Sentinel,Interceptor Plus Chews 5.75 mg	Diphenhydramine...

Items per page: 10 101 – 110 of 599369

Figure 89: Pop-up information text box for extended column field information

Furthermore, EVWEB enables users to export the searched result as an XML and a CSV file.

#### 4.1.2.2.3.1. Export XML in Bulk

In "Search AE Reports" section, users have the option to export case reports in XML format in a bulk.

There are two different ways to export the bulk: By selecting specific reports or exporting all reports as result of the search criteria.

- **Export Selected reports:** If only a selection of reports want to be added in the exported bulk, then the user can select the relevant reports from the result table and then click on the "Export Selected XML" button. The button is enabled only when 2 or more reports are selected to be exported. Export XML button will also show number of reports selected for export when check box is selected.

The screenshot shows a search interface with the following elements:

- Buttons: "Create and Send", "Search AE Reports", "Search VICH Batch", "Bulk Export", and a search input field.
- Criteria: "Criteria(5)" with filters for "Occur Country: SWE", "Sender", "Species", "Unique AER Number", and "VICH Batch Received Date".
- Fields: "Fields(9)" with export options: "Export Selected XML" (checked), "Export All XML", and "Export CSV".
- Table: A table with columns: Local Report Number, Vich Batch Received Date, Occur Country, Results In Death, Vich Batch Sender, Type Of Submission In Report, Species, Type Of, and Actions. The first two rows have their checkboxes selected.

Local Report Number	Vich Batch Received Date	Occur Country	Results In Death	Vich Batch Sender	Type Of Submission In Report	Species	Type Of	Actions
<input checked="" type="checkbox"/>	20000001761	2022/12/01	Sweden	0	DEBHCAHHQP	NULLIFICATION	Bat	
<input checked="" type="checkbox"/>	20000001760	2022/12/01	Sweden	0	DEBHCAHHQP	EXPEDITED	Bat	
<input type="checkbox"/>	20000001762	2022/12/01	Sweden	0	DEBHCAHHQP	FOLLOW-UP	Bat	
<input type="checkbox"/>	20000001756	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat	
<input type="checkbox"/>	20000001757	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat	

Figure 90: Export Selected XML (specific reports in one page)

If the user wants to select all reports in the 1<sup>st</sup> view page of the result table, user can click on the generic checkbox. By default check boxes are unselected. When user selects this checkbox, all the reports in view in that page get selected.

Create and Send Search AE Reports Search VICH Batch Bulk Export Search ...

Criteria(5)  
+ More criteria  
Occur Country: SWE Sender Species Unique AER Number VICH Batch Received Date

Fields(9)  
 Export Selected XML <sup>10</sup>  Export All XML <sup>9...</sup>  Export CSV

Local Report Number	Vich Batch Received Date ↓	Occur Country	Results In Death	Vich Batch Sender	Type Of Submission In Report	Species	Type Of	Actions
<input checked="" type="checkbox"/>	20000001761	2022/12/01	Sweden	0	DEBHCAHHQP	NULLIFICATION	Bat	
<input checked="" type="checkbox"/>	20000001760	2022/12/01	Sweden	0	DEBHCAHHQP	EXPEDITED	Bat	
<input checked="" type="checkbox"/>	20000001762	2022/12/01	Sweden	0	DEBHCAHHQP	FOLLOW-UP	Bat	
<input checked="" type="checkbox"/>	20000001756	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat	
<input checked="" type="checkbox"/>	20000001757	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat	
<input checked="" type="checkbox"/>	20000001755	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat	
<input checked="" type="checkbox"/>	20000001758	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat	

Figure 91: Export Selected XML (all items in one page)

- **Export All reports from the results table:** Clicking on “Export All XML” button, the export will be automatically including all the reports that were obtained as results from the applied search, currently with a limit of 500 reports.

Create and Send Search AE Reports Search VICH Batch Bulk Export Search ...

Criteria(5)  
+ More criteria  
Occur Country: SWE Sender Species Unique AER Number VICH Batch Received Date

Fields(9)  
 Export Selected XML  Export All XML <sup>9...</sup>  Export CSV

Local Report Number	Vich Batch Received Date ↓	Occur Country	Results In Death	Vich Batch Sender	Type Of Submission In Report	Species	Type Of	Actions
<input type="checkbox"/>	20000001761	2022/12/01	Sweden	0	DEBHCAHHQP	NULLIFICATION	Bat	
<input type="checkbox"/>	20000001760	2022/12/01	Sweden	0	DEBHCAHHQP	EXPEDITED	Bat	
<input type="checkbox"/>	20000001762	2022/12/01	Sweden	0	DEBHCAHHQP	FOLLOW-UP	Bat	
<input type="checkbox"/>	20000001756	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat	
<input type="checkbox"/>	20000001757	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat	

Figure 92: Export all XML

If the search result it is more than 500, then the user will get below error message.

Criteria(5)

+ More criteria

Occur Country: SWE Sender Species Unique AER Number VICH Batch Received Date

Fields(9)

Export Selected XML Export All XML Export CSV

Local Report Number	Vich Batch Received Date	Occur Country	Results In Death	Vich Batch Sender	Type Of Submission In Report	Species	Type Of	Actions
20000001761	2022/12/01	Sweden	0	DEBHCAHHQP	NULLIFICATION	Bat		
20000001760	2022/12/01	Sweden	0	DEBHCAHHQP	EXPEDITED	Bat		
20000001762	2022/12/01	Sweden	0	DEBHCAHHQP	FOLLOW-UP	Bat		
20000001756	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat		
20000001757	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat		

XML export is disabled, results exceed the limit of 500 rows

Figure 93: The message when the maximum limit is exceeded

After, fulfilling above criteria and clicking on "Export Selected XML" button or "Export All XML" button, user will get below popup to enter the request name.

Criteria(5)

+ More criteria

Occur Country: SWE Sender Species Unique AER Number VICH Batch Received Date

Fields(9)

Export Selected XML Export All XML Export CSV

**Bulk Export Request ID**

Note: Reports applying access policy level 1 will be excluded from the Bulk report.

Request ID:  1

Add CSV Summary list  2

Cancel Accept

Local Report Number	Vich Batch Received Date	Occur Country	Results In Death	Vich Batch Sender	Type Of Submission In Report	Species	Type Of	Actions
20000001761	2022/12/01	Sweden	0	DEBHCAHHQP	NULLIFICATION	Bat		
20000001760	2022/12/01	Sweden	0	DEBHCAHHQP	EXPEDITED	Bat		
20000001762	2022/12/01	Sweden	0	DEBHCAHHQP	FOLLOW-UP	Bat		
20000001756	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat		
20000001757	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat		

Figure 94: A popup to enter the request details

Following information is required in order to proceed with the export execution:

- Request ID – Enter the unique request name in the text field. Following restrictions are applied:
  - o A to Z characters accepter with lower or upper case
  - o Only following special characters are accepted: hyphen -, underscore \_, dot.
  - o 0 to 9 digits accepted
  - o Request ID should not be repeated if another request was already done.
- Add CSV Summary List –If the user wants to add a summary of the reports contained in the ZIP file, user can select this option.

After clicking on the "Accept" button, bulk export request will create and user can search the request in the "Bulk Export" tab (Refer the section 4.1.5).

**NOTE:** It's important to highlight that access policy is applied to the reports included in the XML bulk, therefore, if the request contained any report were access policy 1 was applied, this will be excluded from the export process.

#### 4.1.2.2.3.2. Export CSV Functionality

The screenshot shows a web interface for bulk export. At the top, there are navigation buttons: "Create and Send", "Search AE Reports", "Search VICH Batch", and "Bulk Export". A search bar is on the right. Below this, there are filter criteria: "Occur Country", "Sender", "Species", "Unique AER Number", and "VICH Batch Received Date". Under the "Fields(9)" section, there are three options: "Export Selected XML", "Export All XML", and "Export CSV". The "Export CSV" button is highlighted with a red box. Below the filters is a table with the following data:

Local Report Number	Vich Batch Received Date ↓	Occur Country	Results In Death	Vich Batch Sender	Type Of Submission In Report	Species	Type Of	Actions
<input type="checkbox"/> 20000001761	2022/12/01	Sweden	0	DEBHCAHHQP	NULLIFICATION	Bat		
<input type="checkbox"/> 20000001760	2022/12/01	Sweden	0	DEBHCAHHQP	EXPEDITED	Bat		
<input type="checkbox"/> 20000001762	2022/12/01	Sweden	0	DEBHCAHHQP	FOLLOW-UP	Bat		
<input type="checkbox"/> 20000001756	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat		
<input type="checkbox"/> 20000001757	2022/11/22	Sweden	0	SEMPAV	EXPEDITED	Cat		

Figure 95: Export CSV Functionality

Once the user clicks on the "Export CSV" button, CSV file will be downloaded if the row count is less than or equal to 5000 in the result table.

If the row count exceeds the 5000 rows, then the user will get an error message as below.

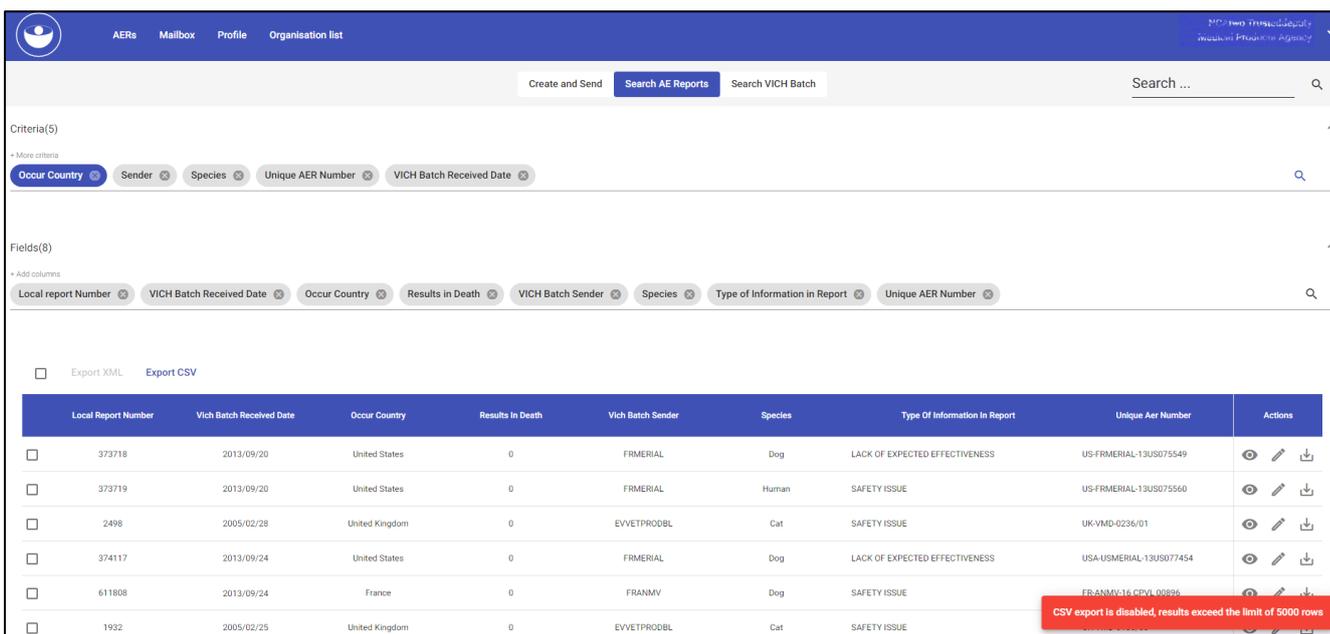


Figure 96: Export CSV Functionality when the maximum row count is exceeded

When downloading the CSV file, all entries that are available under the searched criteria will be downloaded and all columns will be added to the CSV file (Not only the selected columns in the "Fields" section).

If there is no result found based on the search criteria defined, then the "Export CSV" function will be disabled.

#### 4.1.2 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.

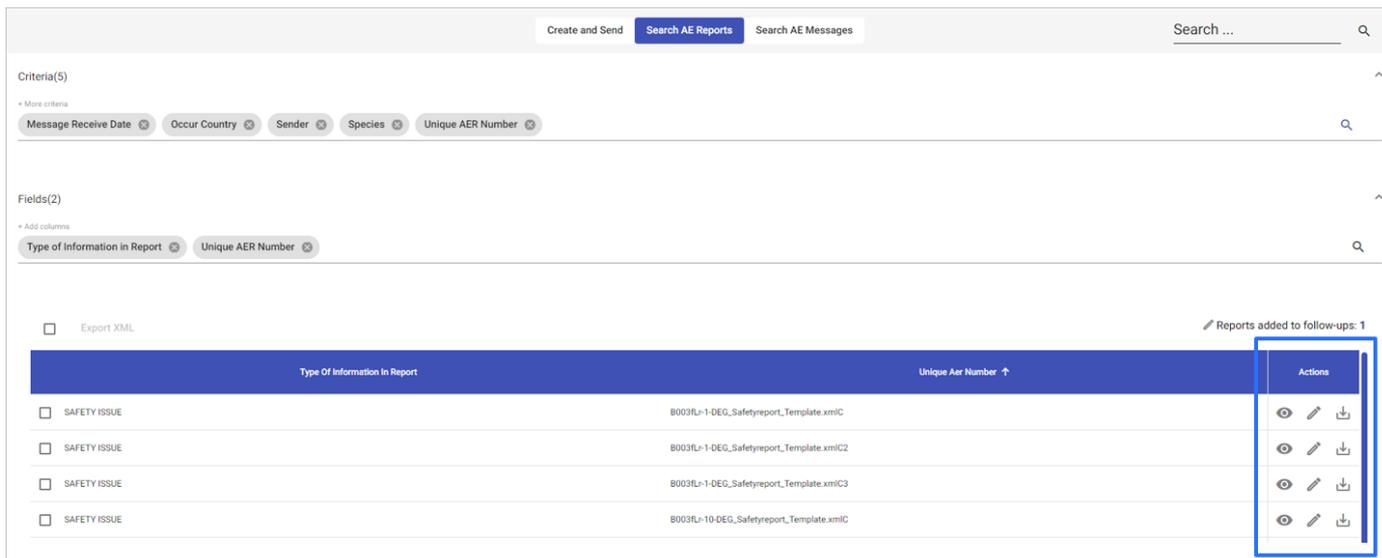


Figure 97: Actions from Search AE reports

#### 4.1.3.1 Open Report

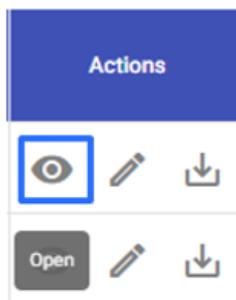


Figure 98: Open action

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

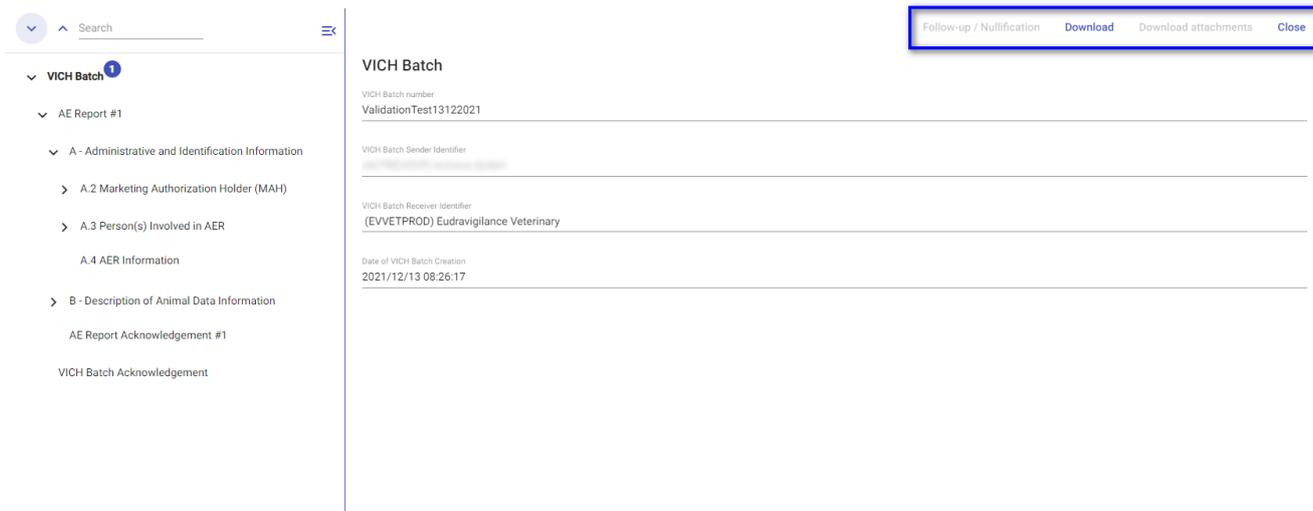


Figure 99: Actions from an open report

#### 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**.

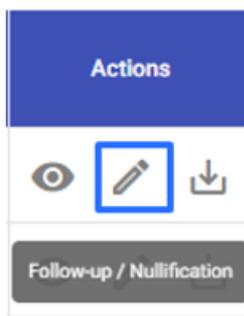


Figure 100: Follow up/nullification action icon

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".

[Create and Send](#)
[Search AE Reports](#)
[Search VICH Batch](#)
DEU-ABCDEF GH-123456

Criteria(4) ^

+ More criteria

Occur Country 
Sender 
Species 
VICH Batch Received Date

---

Fields(8) v

✎ Reports added to follow-ups: 1

Local Report Number	Vich Batch Received Date	Occur Country	Results In Death	Vich Batch Sender	Species	Type	Actions
20000000005	2021/10/26	Germany	0	DEBHCAHHQP	Alpaca		<input type="checkbox"/> <input type="text"/>

Report added to follow-ups

Figure 101: Follow-up action from Search AE report

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.

[Create and Send](#)
[Search AE Reports](#)
[Search VICH Batch](#)

[New](#)
[Import XML](#)
[Export XML](#)
[Validate](#)
[Validate and Send](#)

Search

- VICH Batch 1 + ●
- ✎ AE Report #1 ● ● ●
- A - Administrative and Identification Information ●
    - > A.2 Marketing Authorization Holder (MAH)
    - > A.3 Person(s) Involved in AER
    - A.4 AER Information ●
    - > B - Description of Animal Data Information ●

**AER Information** ?

Unique Adverse Event Identification Number  
DEU-ABCDEF GH-123456 ?

Original Receive Date \*  
2021/10/26 ?

Most Recent Info Date \*  
2021/10/26 ?

**Type of Report** ?

Type of Submission \*  
NULLIFICATION v ?

Reason for Nullification Report \* ?

This field is required

Type of Information in Report v ?

Figure 102: How to nullify one report (from a follow up)

**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.

### 4.1.3.3 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.

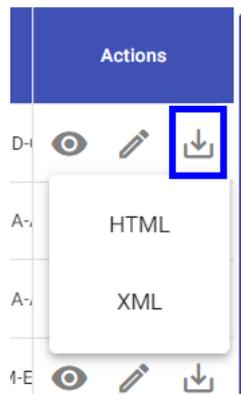


Figure 103: Download (from search AE Report – Actions)

### 4.1.4 Search VICH Batch

Search VICH Batch allows user to search for a Specific batch number. The difference in this case between 'Search AE Reports' or 'Search VICH Batch' is that 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.

Criteria(4) GBR-ABCDEFGH-123456\_

+ More criteria

Received Date  Received Date (From)  Received Date (Up To)  VICH Batch Number: Batch\_123456\_2 (Matches)

Fields(5)

Vich Batch Creation Date	Vich Batch Number	Vich Batch Received Date	Number Of Reports	Sender	Actions
2021/10/26	Batch_123456_2	2021/10/26	2	DEBHCAHHQP	<input type="button" value="Open"/> <input type="button" value="Download"/>

Items per page: 10 1 - 1 of 1

Figure 104: Search VICH Batch

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 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.

Figure 105: Actions from an open message (with several reports)

#### 4.1.5 Bulk Export

This section is listing the different request for XML export in bulk (*Described in section 4.1.2.2.3.1. Export XML in bulk*) created at organisation level. This means users from one organisation can track the requests and download the files generated by other colleagues within the same organisation.

The following information is displayed in the results table for each request:

- Requested on: the date when the bulk export was requested.
- Requested ID: The request name that was entered in the popup.
- Status: the status of the request is updated in while processing and after export completion:
  - o Started – Requests pending or in progress to be exported.
  - o Completed - Requests completed. Download available for 5 days.
  - o Archived - Only for the history of exported Bulks. Under this status, file are not longer available for download. There Archived records will be deleted after 1 month.
  - o Failed: An error occurred while during export process that could not generate the ZIP file.
- File Size: The size of the ZIP file.
- Total Reports: Number of reports that were selected during the request.
- Has CSV summary: Informs with True or False, if the CSV summary of the reports in included in the ZIP file, as required by the user at the moment to trigger the request.
- Action: Downloadable ZIP file including all AERs and optionally CSV summary.

Requested On	Request Id	Status	File Size	Total Reports	Has Csv Summary	Actions
2023-02-03	Export1	COMPLETED	16.5 KIB	7	true	

Figure 106: Bulk export tab

### 4.1.5 Drafts/ Templates

The Draft / Template tab allows users to manage drafts and templates created at the organization level. (Described in section 4.1.1.3). All the users with access to EVVET for the same the same organization can view, edit and delete any draft or templates listed in this section.

VICH Batch Number	Drafts/Templates	Created User	Creation date ↓	Original Receive Date	Product	Actions
Template10	Template	NCAtwo Responsible	2023/08/07 11:25 AM			
testtemp1	Draft	NCAtwo Responsible	2023/08/04 12:11 PM	2023/08/04	Draxxin 25 mg ml - Solution for injection (pig)	
testtemp1	Template	NCAtwo Responsible	2023/08/04 12:06 PM	2023/08/04	Draxxin 25 mg ml - Solution for injection (pig)	
testtemplate	Template	NCAtwo Responsible	2023/08/04 11:33 AM		Draxxin 25 mg ml - Solution for injection (pig)	

Figure 107 - Drafts Section

The following information is displayed in the results table for each draft:

- VICH Batch Number – The batch number that was entered when creating the draft or template. This will be unique.
- Draft/ Templates – This column indicates whether the record is a draft or a template.
- Created User – The username of the draft or template creator, who initiated the draft.
- Created Date – The date when the draft or template was created.
- Original Received Date – The original received date of the batch, as entered during the draft or template creation.
- Products – If available, the names of products associated with the batch will be shown.
- Edit (Pencil icon) – Click on this icon to resume the draft or template. After clicking on it, the batch will open in the “Create and Send” tab for further editing.

- Delete (Bin icon) – Click on this icon to delete the batch. The user will receive a confirmation message before the batch is permanently deleted.

## 5 Mailbox

The Mailbox screen of the EVVET3 application allows users to keep track of sent and received messages and Acknowledgement messages and search messages. In EVVET3’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.

Menu Option	Description
Inbox	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.
Outbox	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.

Table 8: Inbox/Outbox

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

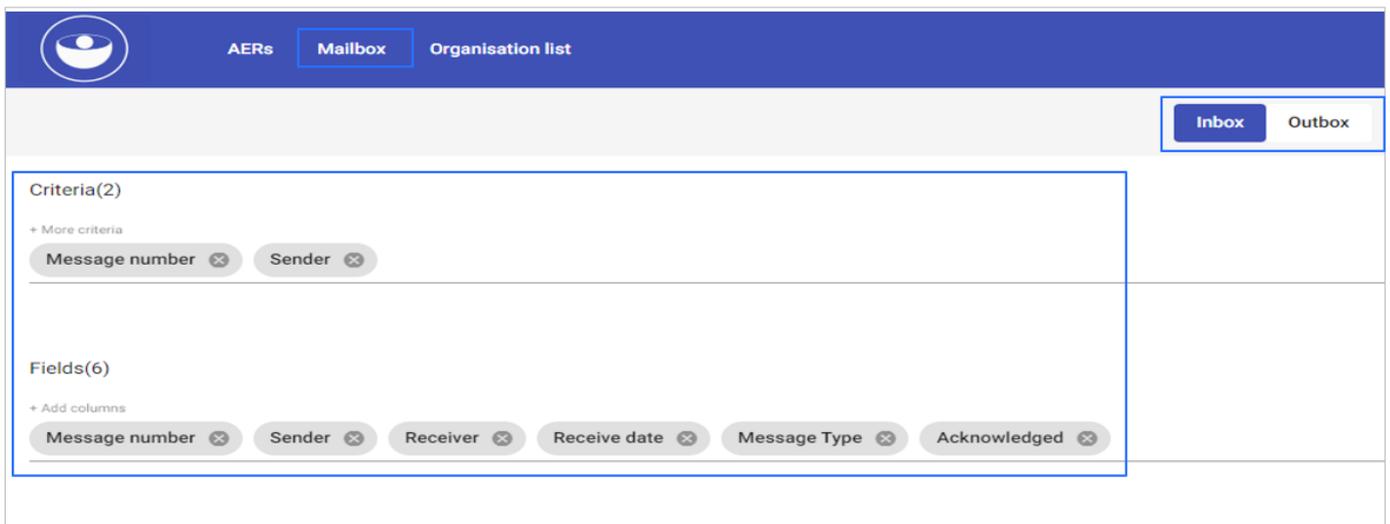


Figure 108: Mailbox

### 5.1 Inbox Search & View

Enabled by default, “Inbox” allows the user to view all the messages and Acknowledgement messages received by the user’s organisation. A set of defined criteria and fields can be found on the screen to filter the search results.

To add a criteria item, you need to click on the criteria section, right to the last selected criteria that is

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. To differentiate the Acknowledgement messages from the messages received by other Organisations, the field VICH Batch type will display this information.

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.

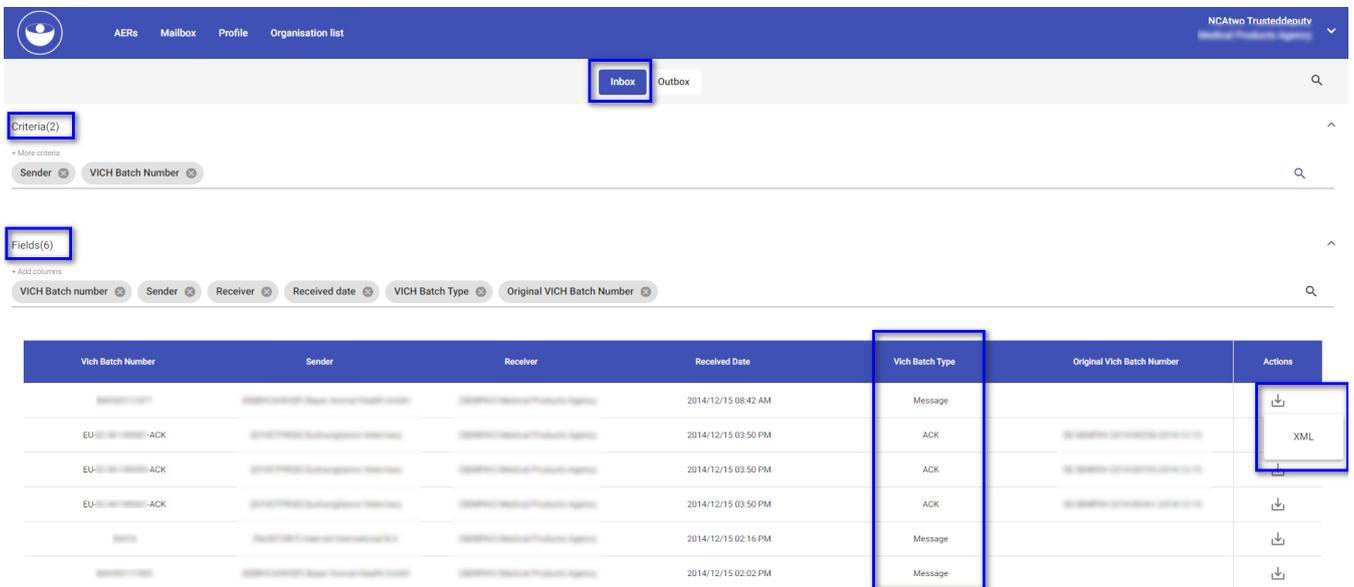


Figure 109: Inbox menu

## 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.

**Note:** Acknowledgements will be visible in Inbox only for messages that have been sent to EVVETPROD. However, in the case that an MAH or NCA organisation forwards a report to another NCA or MAH, this acknowledgement won't be received for both Webtrader or Gateway transmission modes.

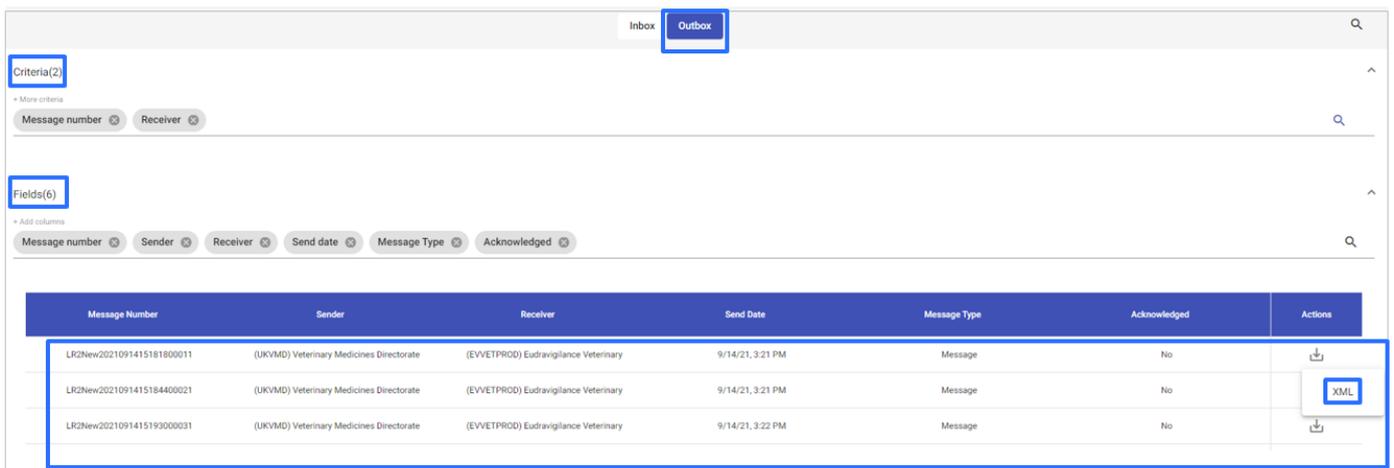


Figure 110: Outbox – Download message

## 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.

The screenshot shows the 'Organisation list' interface. At the top, there are navigation tabs: 'AERs', 'Mailbox', and 'Organisation list' (highlighted with a red circle 1). Below the tabs, there is a 'Criteria(3)' section with a search icon (red circle 3). The criteria section contains three filters: 'Organisation ID', 'Organisation Name', and 'Organisation Routing ID' (highlighted with a red circle 2). A callout box points to this section with the text: 'Criteria section to be used in case we want to filter the data to be consulted'. Below the criteria section is a table with the following columns: 'Organisation id', 'Organisation Name', 'Country', and 'Organisation Routing id'. The table contains five rows of data. A callout box points to the table with the text: 'To select the items per page in the results table'. Below the table, there is a pagination control showing 'Items per page: 10' and '1 - 10 of 459'. A callout box points to the pagination control with the text: 'To navigate through all pages in the results table'.

Organisation id	Organisation Name	Country	Organisation Routing id
ORG-100014106	AA-Vet Diergeneesmiddelen NV	Netherlands	AAVETP
ORG-100014105	AAFarma B.V.	Netherlands	AAFARMA
ORG-100014114	ABBEYVET EXPORT LLP	United Kingdom	UKABBVETP
ORG-100000132	Ab Science	France	
ORG-100014107	Ab7 Sante	France	

Figure 111: Organisation list

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.

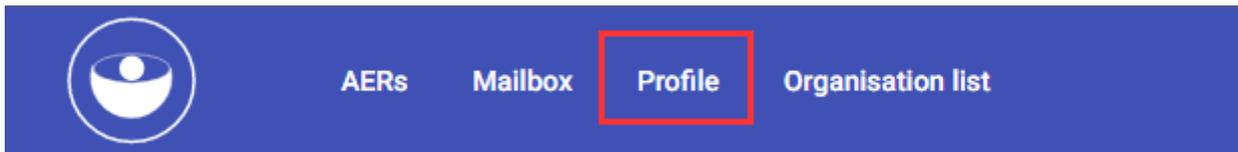


Figure 112: Profile feature (EVWEB main menu)

Once inside 'Profile' feature, the user will display the following information:

Name (Headquarter User)	User Name
MAHone Responsible	evvetmah1_r

Affiliate Id	Affiliate Name	Name	User Name
ORG-100000104	Delegated access for Bayer Pharma AG	MAHthree Responsible	evvetmah3_r
ORG-100000090	Delegated access for Bayer Animal Health GmbH	MAHtwo Responsible	evvetmah2_r

Figure 113: Profile information

- Organisation information:** This section will retrieve data from OMS (Organisation Management Service) and it will be referred to the main information of the organisation.
- 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.
- 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 + Las name
  - User name* in the system
- 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

## 8 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'.

The screenshot shows the 'Search AE Reports' interface. At the top, there are buttons for 'Create and Send', 'Search AE Reports', and 'Search VICH Batch', along with a search bar. Below this, there are search criteria: 'Ocur Country', 'Sender', 'Species', 'Unique AER Number', and 'VICH Batch Received Date'. Underneath, there are fields for 'Local Report Number', 'Vich Batch Received Date', 'Ocur Country', 'Results In Death', 'Vich Batch Sender', and 'Species'. A table of results is displayed with two rows. The first row has a checkbox, '2000000076', '2020/01/31', 'Netherlands', '5', 'EVVETWT', 'Cat', and 'LACK C'. The second row has a checkbox, '2000000077', '2020/01/31', 'United States', '9', 'ACMEDRUGCOX4P', 'Parrot', and 'SAFET'. To the right of the table, there is a dropdown menu with 'HTML' and 'XML' options, and a download icon (1) is highlighted. A red circle (2) is also present near the dropdown menu.

Figure 114: HTML download format (from Search AE Reports)

- 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).

Substances Products **Organisations** Referentials Help

SPOR Home **Organisations** Documents

Home / Search Organisations

Hide search

Organisation ID  Contains

Organisation name  Contains

Location ID  Contains

Address  Contains

City  Contains

Postcode  Contains

Country 0 Selected

Modified Since yyyy-MM-dd

Location status \* ACTIVE, INACTIVE

Reset Search

Use any desired criteria to search the organisation we want

Figure 116: OMS (Organisations Management System)

Substances Products Organisations Referentials Help

SPOR Home Organisations Documents

Home / Search Organisations

Show search

Reset Search

Page 1 of 4

Showing 20 of 71 results

Organisation ID	Organisation Name	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-100006311	Abylnx	Belgium	LOC-100011958	Zwijnaarde	Technologiepark-Zwijnaarde 4	9052	INACTIVE	2019-08-28T17:37:51	Q
ORG-100005530	Air Liquide Medical	Belgium	LOC-100008228	Genk	Munsterenstraat 2	3600	INACTIVE	2019-08-28T17:37:51	Q
ORG-100005530	Air Liquide Medical	Belgium	LOC-100010033	Machelen	Beaulieustraat 4	1830	INACTIVE	2019-08-28T17:37:51	Q
ORG-100005530	Air Liquide Medical	Belgium	LOC-100008135	Baudour	Route De Wallonie	7331	INACTIVE	2019-08-28T17:37:51	Q
ORG-100003155	Air Products	Belgium	LOC-100009992	Auderghem	Chaussee De Wavre 1789	1160	INACTIVE	2020-09-15T08:42:08	Q
ORG-100021188	Allergan	Belgium	LOC-100042507	Hoellaart	Terhulpesteenweg 6d	1560	INACTIVE	2020-09-15T17:09:42	Q
ORG-100021188	Allergan	Belgium	LOC-100029891	Machelen	Pegasuslaan 5	1831	INACTIVE	2021-09-14T12:40:06	Q
ORG-100009995	Antwerp University Hospital	Belgium	LOC-100014858	Wilrijk	Universiteitsplein 1	2610	INACTIVE	2021-02-01T14:34:36	Q
ORG-100009995	Antwerp University Hospital	Belgium	LOC-100019861	Edegem	Wilrijkstraat 10	2650	INACTIVE	2021-12-08T20:41:17	Q

Figure 117: OMS results table

- 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

Criteria(5)

+ More criteria

Occur Country Sender Species Unique AER Number VICH Batch Received Date

Fields(8)

Export XML

Local Report Number	Vich Batch Received Date	Occur Country	Results In Death	Vich Batch Sender	Species	Actions
<input type="checkbox"/> 2000000076	2020/01/31	Netherlands	5	EVVETWT	Cat	LACK C   
<input type="checkbox"/> 2000000077	2020/01/31	United States	9	ACMEDRUGCOX4P	Parrot	SAFET   
<input type="checkbox"/> 2000000078	2020/01/31	United States	5	ACMEDRUGCOX4P	Parrot	SAFET   

Figure 118: Search report to open it

Search

- AE Report #1
  - A - Administrative and Identification Information
    - A.2 Marketing Authorization Holder (MAH)
    - A.3 Person(s) Involved in AER
    - A.4 AER Information
  - B - Description of Animal Data Information
- AE Report Acknowledgement #1
- VICH Batch Acknowledgement**

Acknowledgment Date of VICH Batch Transmission  
2021/09/28 13:08:29

VICH Batch Number  
Batch1\_17777-87777

Acknowledgement Local VICH Batch Number  
EU-EC-M-20000000059

Date of VICH Batch Transmission  
2020/01/31 06:02:53

Transmission Acknowledgement Code  
AE

VICH Batch Validation Error

Three different values:  
-AA  
-AR  
-AE

Figure 119: VICH ACK transmission mode (AA, AE, AR)

- 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
  - 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:
  - o If **one single batch** contains only **1 report**, the narrative could contain up to **20,000 characters**.
  - o 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

Abbreviation/ Acronym	Description
AER	Adverse Event Report [Veterinary]
AE	Adverse Event
Business Rules	The validation rules applicable to individual fields and between fields in the Adverse Event Report.
DB	Data Base
EU	European Union
EV	EudraVigilance
EVWeb	EudraVigilance Web System
HTML	Hypertext Markup Language. Commonly used to format Web pages.

Abbreviation/ Acronym	Description
WHO	World Health Organisation
MAH	Marketing Authorization Holder
MP	Medical Product
MS	Member State
NCA	National Competent Authority A regulatory authority in a MS
Vet	Veterinarian. In EV Vet terms this references any Veterinarian who resides within the EEA.
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 9 - 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

1. Access production EVWEB Production URL: <https://eudravigilance-veterinary-.ema.europa.eu/adrwebui/>
2. Introduce credentials (user and password)
3. Click on 'Next'.
4. Select the organisation and once it's selected, click on 'Select'

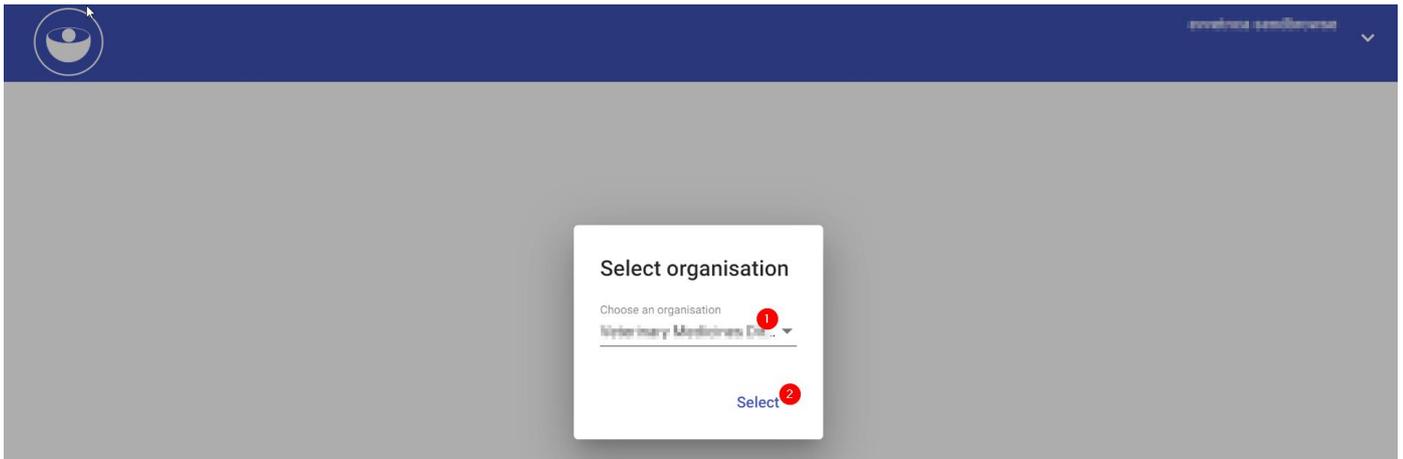


Figure 120: Select organisation (EVWEB Log In)

5. Home page is displayed



Figure 121: EVWEB landing/home page

## 10.2 Create new report

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

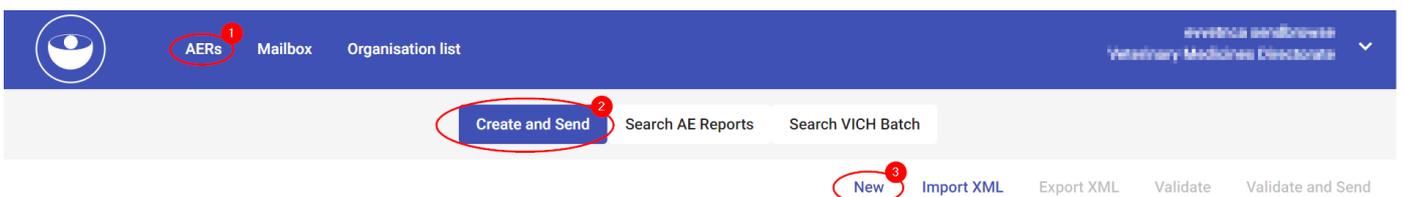


Figure 122: Create new report

### 10.2.2 VICH Batch information

7. Populate **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.

The screenshot displays a web application interface for creating a VICH Batch. At the top, there are buttons for 'Create and Send', 'Search AE Reports', and 'Search VICH Batch'. Below this, a sidebar on the left contains a search bar and a tree view with categories: 'VICH Batch', 'AE Report #1', 'A - Administrative and Identification Information', and 'B - Description of Animal Data Information'. The main content area is titled 'VICH Batch' and features several input fields:
 

- VICH Batch number \***: A text field containing 'SE-SEMPAV-2013-081'.
- Batch Sender Identifier**: A text field with a blurred value.
- Batch Receiver Identifier \***: A dropdown menu showing '(EVVETPROD) Eudravigilance Veterinary'.
- Date of Batch Creation \***: A text field showing '2021/11/05 17:17:10'.

 At the top right of the main area, there are buttons for 'New', 'Import XML', 'Export XML', 'Validate', and 'Validate and Send'.

Figure 123: Populate VICH Batch information

### 10.2.3 Report information

In this section, it's requested to populate 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. Marketing Authorization Holder (MAH)
    - A.2.1 MAH Information
  - 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

8. 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.
  - o When clicking on '+' icon next *VICH Batch* in the tree, we will be able to create more reports inside the same VICH Batch.

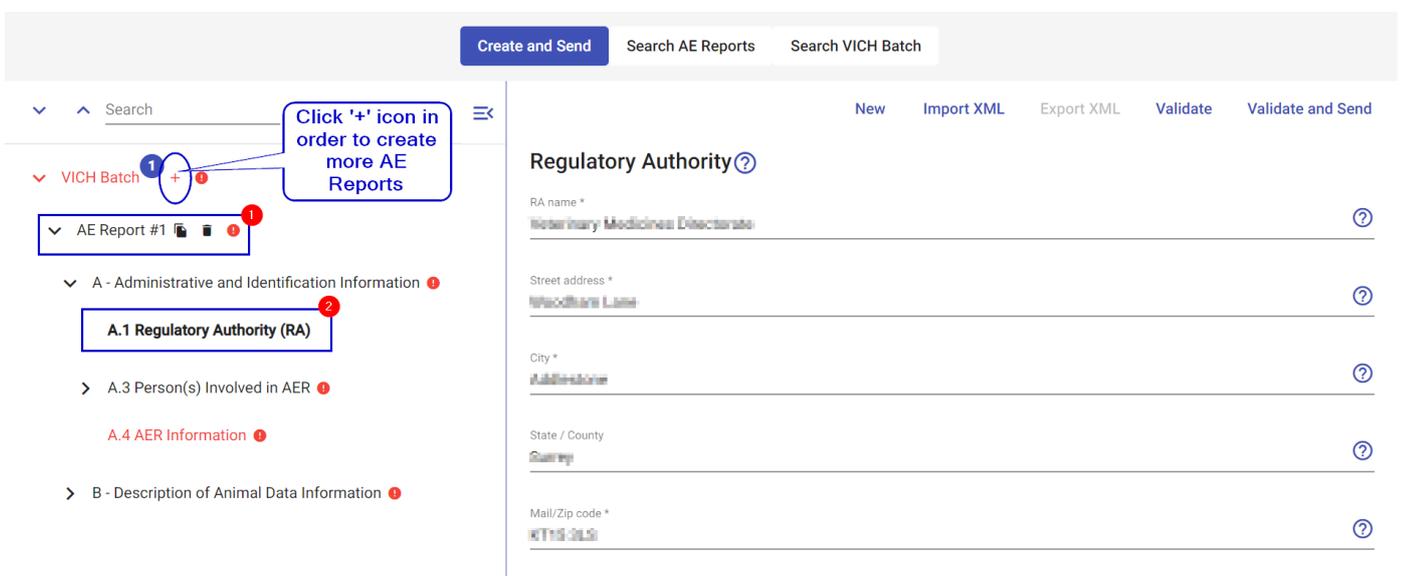


Figure 124: RA information

9. Populate 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:
- Last name (mandatory): Both for primary reporter and other reporter, introduce the letter of the surname.
  - Country (mandatory)
  - Primary/Other Reporter Category (dropdown menu) (mandatory)

The screenshot shows a web application interface for entering 'Primary Reporter Information'. On the left, a sidebar menu is visible with the following structure:

- VICH Batch
- AE Report #1
- A - Administrative and Identification Information
  - A.1 Regulatory Authority (RA)
  - A.3 Person(s) Involved in AER** (highlighted with a blue box)
    - A.3.1 Primary Reporter** (highlighted with a blue box)
    - A.4 AER Information
  - B - Description of Animal Data Information

The main form area is titled 'Primary Reporter Information' and includes a 'Withhold' toggle switch. Below it, there are three input fields:

- 'Last name \*': A text input field containing the letter 'L'.
- 'Country \*': A dropdown menu with 'Netherlands' selected.
- 'Primary Reporter Category \*': A dropdown menu with 'VETERINARIAN' selected.

Figure 125: Person(s) involved in AER - 'Primary Reporter'

## 10. Populate **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.

The screenshot displays a web application interface for entering Adverse Event Report (AER) information. The top navigation bar includes a 'Create and Send' button and search options for 'AE Reports' and 'VICH Batch'. The left sidebar shows a hierarchical menu with 'A.4 AER Information' selected. The main content area is titled 'AER Information' and contains the following fields:

- Unique Adverse Event Identification Number \*: SWE-SEMPAVV-2013-081
- Original Receive Date \*: 2020/11/02
- Most Recent Info Date \*: 2020/11/02
- Type of Report: EXPEDITED
- Type of Information in Report: SAFETY ISSUE

Figure 126: AER information

11. Populate 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.
- 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 populated (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.

Search

[Create and Send](#)
[Search AE Reports](#)
[Search VICH Batch](#)

[New](#)
[Import XML](#)
[Export XML](#)
[Validate](#)
[Validate and Send](#)

- ▼ VICH Batch 1 + ●
  - ▼ AE Report #1 ■ ■ ●
    - ▼ A - Administrative and Identification Information
      - A.1 Regulatory Authority (RA)
      - ▼ A.3 Person(s) Involved in AER
        - A.3.1 Primary Reporter
        - A.3.2 Other Reporter
      - A.4 AER Information
    - ▼ B - Description of Animal Data Information ●
      - B.1 Animal Data
      - > B.2 VMP(s) Data and Usage 1 + ●
        - B.3 Adverse Event Data ●
        - B.5 Assessment of AE
        - B.6 Report Number(s) of Linked Report(s)
        - B.7 Supplemental Documents

### Animal/Human Data ?

Number of Animals Treated ?

1

---

Number of Animals Affected \* ?

1

---

Attending Veterinarian's Assessment of Health Status Prior to VMP ?

GOOD ▼

---

Species (Type of Species) \* ?

Horse 🔍 ?

---

Breed ?

Purebred ?

Warmblood - Swedish 🔍 ?

---

Crossbred 🔍 ?

---

Gender ?

FEMALE ▼

---

Reproductive Status ?

NEUTERED ▼

---

Female Physiological Status ?

UNKNOWN ▼

---

Weight ?

Weight Measured, Estimated or Unknown \* ? Weight (kg) ?

MEASURED ▼ 340

---

Age ?

Age Measured, Estimated or Unknown \* ? Age ? Age Units \* ?

MEASURED ▼ 4 ? Year ▼

*Figure 127: Animal data*

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
  - ATCVet 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:

New Import XML Export XML Validate Validate and Send

### Registered Name or Brand Name

Registered Name or Brand Name \*

EXAMPLEproduct 🔍 ?

---

! No suggestions found for "EXAMPLEproduct" ?

+ Add "EXAMPLEproduct" as a new product ?

Figure 128: 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.

Create and Send Search AE Reports Search VICH Batch

New Import XML Export XML Validate Validate and Send

Search

- A.3 Person(s) Involved in AER
    - A.3.1 Primary Reporter
    - A.3.2 Other Reporter
  - A.4 AER Information
- B - Description of Animal Data Information
  - B.1 Animal Data
  - B.2 VMP(s) Data and Usage 1 +
    - VMP #1 +
    - > B.2.1 Registered or Brand Name

### Registered Name or Brand Name

Registered Name or Brand Name \*

equilis Prequenza, suspension for injection, for horses 🔍 ?

---

Registration Identifier

EU/2/05/056 ?

---

Anatomical Therapeutic Chemical Vet (ATCvet) Code

EQUINE INFLUENZA VIRUS 🔍 ?

---

Company or MAH

Intervet International BV ?

---

Dosage Form

INJECTION, SUSPENSION ?

Figure 129: 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): Populate one of the fields (or Units of measurement or units of presentation). When trying to inform both, one will be erased.
- Units value for Dose (Denominator) (mandatory if numeric value for dose is informed): Populate one of the fields (or Units of measurement, Units of presentation or Dose denominator qualifiers). When trying to Inform 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.

Figure 130: Route of exposure information

1

14. **Active ingredient** must be informed. 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 populated.

- 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 inform 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 populated until Numeric values are introduced.

**Active Ingredient(s)** ?

Active Ingredient(s) \*

EXAMPLEIngredient 🔍 ?

! No suggestions found for "EXAMPLEIngredient"

+ Add "EXAMPLEIngredient" as a new substance ?

Units for Numeric Value for Strength (Numerator) ?

Figure 131: Add a new substance

2

Search

- A.3.1 Primary Reporter
- A.3.2 Other Reporter
- A.4 AER Information
- ▼ B - Description of Animal Data Information ●
- B.1 Animal Data
- ▼ B.2 VMP(s) Data and Usage 1 +
- ▼ VMP #1 📄 ■
- ▼ B.2.1 Registered or Brand Name
- ▼ B.2.1.7 Route of Exposure 1 +
- Route of Exposure #1 📄 ■
- ▼ B.2.2 Active Ingredient(s) 1 +
- Active Ingredient #1 📄 ■

New Import XML Export XML Validate Validate and Send

**Active Ingredient(s)** ?

Active Ingredient(s)

CORTISONE ✕ 🔍 ?

---

Numeric Value for Strength (Numerator)

1 ?

Units for Numeric Value for Strength (Numerator) ?

Units of Measurement

Millimeter ▼

Numeric Value for Strength (Denominator)

1 ?

Units for Numeric Value for Strength (Denominator) ?

Units of Measurement ▼

Units of Presentation

vial ▼

Figure 132: Active ingredient information

15. **Lot number** information to be populated (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

Figure 133: Lot number

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).

Figure 134: Who administered the VMP

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.

The screenshot shows a web application interface. At the top, there are buttons for 'Create and Send', 'Search AE Reports', and 'Search VICH Batch'. Below this is a navigation menu with 'A.4 AER Information', 'B - Description of Animal Data Information' (which is expanded to show 'B.1 Animal Data'), and a search bar. On the right side, there are buttons for 'New', 'Import XML', 'Export XML', 'Validate', and 'Validate and Send'. The main content area is titled 'Label Usage' and contains the text 'Use According to Label' followed by three radio buttons: 'Yes', 'No', and 'Unknown'. The 'No' radio button is selected, indicated by a red dot in the center.

Figure 135: Label use ('No' selection)

18. **Previous Exposure to the VMP:** 'yes', 'No' or 'Unknown' are the possible values.

### Previous Exposure to the VMP

The screenshot shows a web application interface. At the top, there are buttons for 'New', 'Import XML', 'Export XML', 'Validate', and 'Validate and Send'. Below this is a navigation menu with 'A.4 AER Information', 'B - Description of Animal Data Information' (which is expanded to show 'B.1 Animal Data'), and a search bar. The main content area is titled 'Previous Exposure to the VMP' and contains three radio buttons: 'Yes', 'No', and 'Unknown'. The 'No' radio button is selected, indicated by a red dot in the center.

Figure 136: Previous Exposure to the VMP

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

The screenshot shows a web application interface. At the top, there are buttons for 'New', 'Import XML', 'Export XML', 'Validate', and 'Validate and Send'. Below this is a navigation menu with 'A.4 AER Information', 'B - Description of Animal Data Information' (which is expanded to show 'B.1 Animal Data'), and a search bar. The main content area is titled 'Previous AE to VMP' and contains three radio buttons: 'Yes', 'No', and 'Unknown'. The 'No' radio button is selected, indicated by a red dot in the center.

Figure 137: Previous AE to VMP

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.

## Dechallenge - Rechallenge Information ?

Did AE Abate After Stopping the VMP?  Yes  No  Not Applicable  Unknown ?

Did AE Reappear After Re-introduction of the VMP?  Yes  No  Not Applicable  Unknown ?

Figure 138: Dechallenge - Rechallenge Information

### 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 populate 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

- ▼ VICH Batch 1 + ●
- ▼ AE Report #1 1 1 1 ●
- ▼ A - Administrative and Identification Information
  - A.1 Regulatory Authority (RA)
  - ▼ A.3 Person(s) Involved in AER
    - A.3.1 Primary Reporter
    - A.3.2 Other Reporter
  - A.4 AER Information
- ▼ B - Description of Animal Data Information ●
  - B.1 Animal Data
  - ▼ B.2 VMP(s) Data and Usage 1 +
    - ▼ VMP #1 1 1
      - ▼ B.2.1.7 Route of Exposure 1 +
        - Route of Exposure #1 1 1
      - ▼ B.2.2 Active Ingredient(s) 1 +
        - Active Ingredient #1 1 1
      - > B.2.3 Lot Number 1 +
        - 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

## Adverse Event Data ?

**Narrative of AE \***  
 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 dl of paraffin oil within 20 minutes. The horse recovered fully. The horse had, prior to this event, had a reaction to the Duvaxyn vaccine. 2020-11-02: Swedish MPA has decided to submit all adverse event reports from 2013 to EVVet, to facilitate signal detection.

### Adverse Clinical Manifestations ?

AER Term Name *	Number of Animals	Accuracy of the Number of Animals *
Fever <span style="color: grey;">✕</span>	1 <span style="color: blue;">?</span>	Actual <span style="color: blue;">?</span> <span style="color: blue;">?</span>
Decreased appetite <span style="color: grey;">✕</span>	1 <span style="color: blue;">?</span>	Actual <span style="color: blue;">?</span> <span style="color: blue;">?</span>
Decreased drinking <span style="color: grey;">✕</span>	1 <span style="color: blue;">?</span>	Actual <span style="color: blue;">?</span> <span style="color: blue;">?</span>
Injection site stiffness <span style="color: grey;">✕</span>	1 <span style="color: blue;">?</span>	Actual <span style="color: blue;">?</span> <span style="color: blue;">?</span>

[+ Add](#)

Choose a Date Format \* ?      Date of Onset of AE (AE Start Date) \* ?  
 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  No

Treatment of AE ?       Yes  No  Unknown

### Outcome to Date ?

Ongoing ?

Recovered / Normal ?  
 1

Recovered with Sequela ?

Died ?

Euthanized ?

Unknown ?

Figure 139: AER Data

22. **Veterinary Assessment of AE:** Dropdown list

**Veterinary Assessment of AE** 

Attending Veterinarian's Assessment of AE

Possible



Figure 140: Veterinary Assessment of AE

3

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.

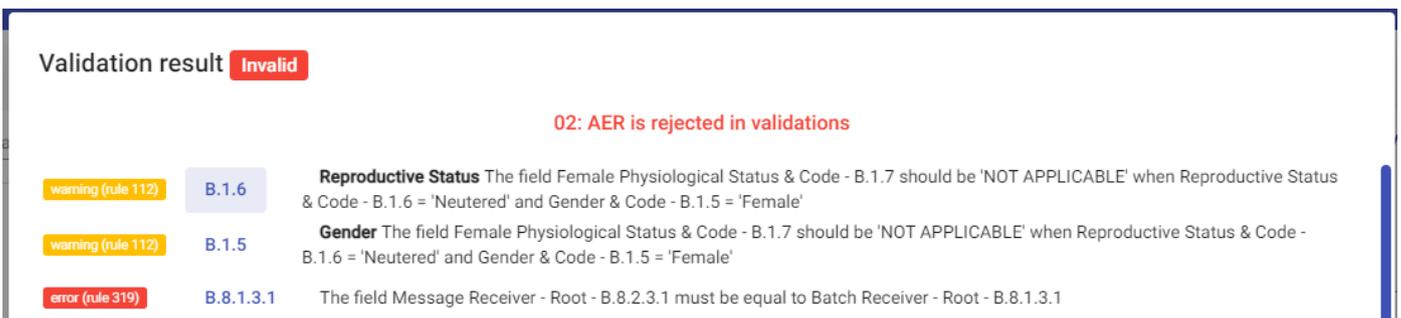
**NOTE:** To create additional links, the user must click on '+ Add'

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.



Validation result **Invalid**

**02: AER is rejected in validations**

warning (rule 112)	B.1.6	<b>Reproductive Status</b> The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'
warning (rule 112)	B.1.5	<b>Gender</b> The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'
error (rule 319)	B.8.1.3.1	The field Message Receiver - Root - B.8.2.3.1 must be equal to Batch Receiver - Root - B.8.1.3.1

Figure 141: Report validation (with errors – red messages)

Validation result **Valid**

01: Message is accepted

warning (rule 112)

B.1.6

**Reproductive Status** The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'

warning (rule 112)

B.1.5

**Gender** The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'

Figure 142: Report validation without errors

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

Validation result **Valid**

Message sent

01: Message is accepted

warning (rule 112)

B.1.6

**Reproductive Status** The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'

warning (rule 112)

B.1.5

**Gender** The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'

Figure 143: Successful message (Validate and Send)

### 10.3 How to import an XML to create a new report

1. Access production EVWEB Production URL.
2. Introduce credentials (user and password).  
Click on 'Next'.
3. Select the organisation and once it's selected, click on 'Select'

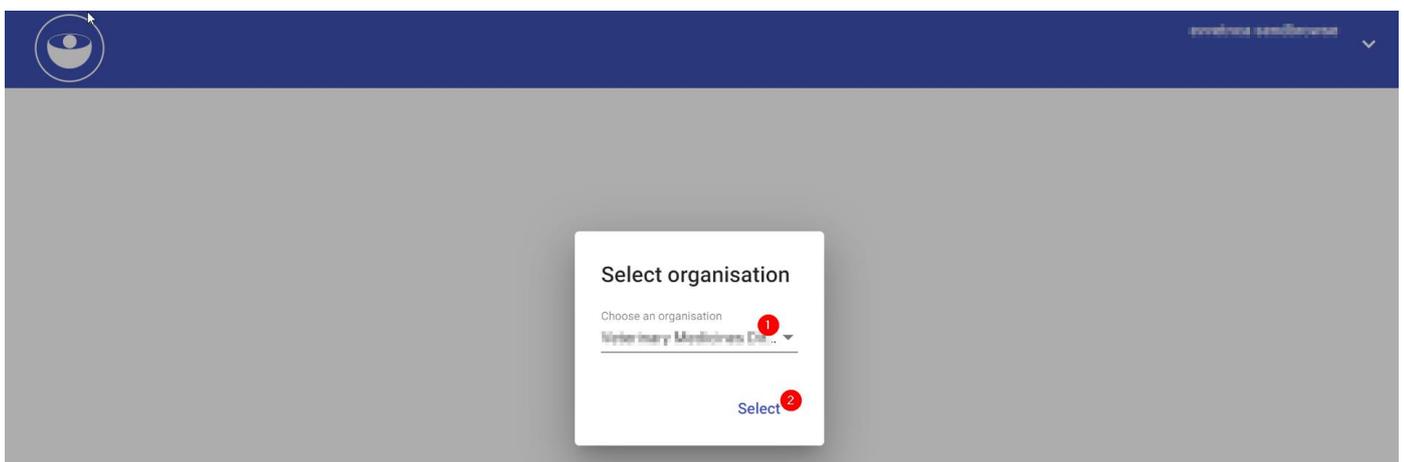


Figure 144: Select organisation (EVWEB Log In)

4. Home page is displayed



Figure 145: EVWEB landing/home page

5. Click on AERs
6. Click on 'Create and Send'
7. Click on 'Import XML'

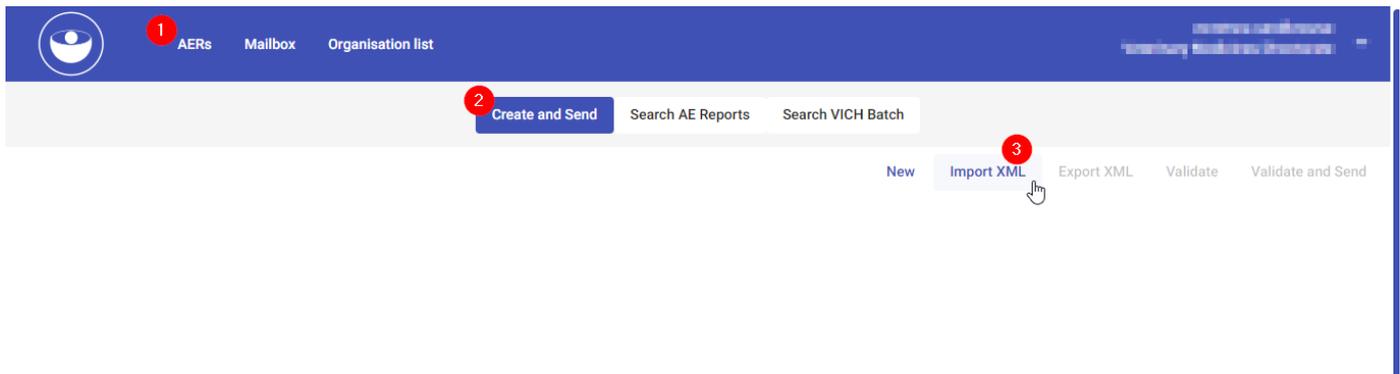


Figure 146: Import XML

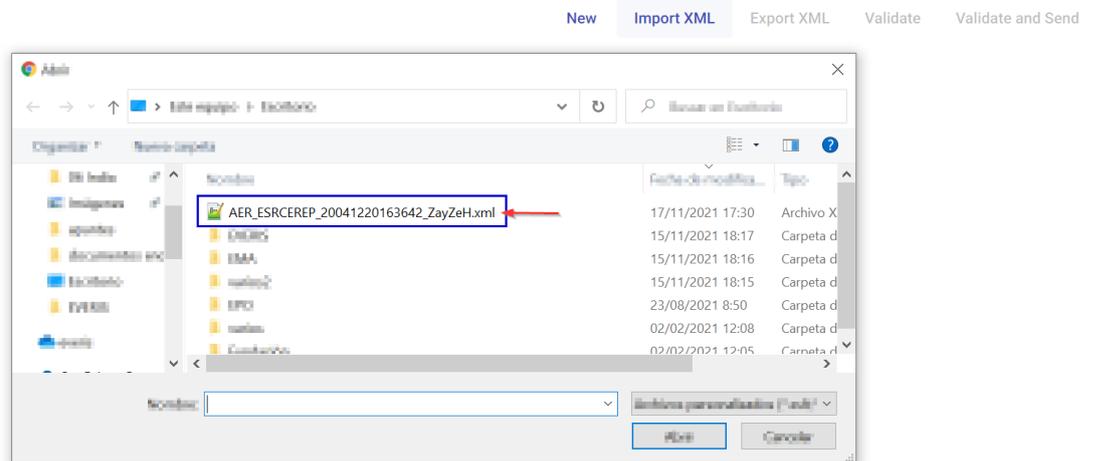


Figure 147: Select XML to be imported in EVWEB

8. Once it's imported, make the needed changes or modifications
9. 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.

**Validation result** Invalid

**02: AER is rejected in validations**

warning (rule 112)	B.1.6	<b>Reproductive Status</b> The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'
warning (rule 112)	B.1.5	<b>Gender</b> The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'
error (rule 319)	B.8.1.3.1	The field Message Receiver - Root - B.8.2.3.1 must be equal to Batch Receiver - Root - B.8.1.3.1

Figure 148: Report validation (with errors – red messages)

Validation result **Valid**

01: Message is accepted

warning (rule 112)

B.1.6

**Reproductive Status** The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'

warning (rule 112)

B.1.5

**Gender** The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'

Figure 149: Report validation without errors

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

Validation result **Valid**

Message sent

01: Message is accepted

warning (rule 112)

B.1.6

**Reproductive Status** The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'

warning (rule 112)

B.1.5

**Gender** The field Female Physiological Status & Code - B.1.7 should be 'NOT APPLICABLE' when Reproductive Status & Code - B.1.6 = 'Neutered' and Gender & Code - B.1.5 = 'Female'

Figure 150: Successful message (Validate and Send)

## I. ANNEX 1

### a. Criteria Filters in Detail

#### i. MAH Search

MAH Criteria filter is used to search cases containing products from a specific MAH. Product MAH is only identified when recoding is completed, that means that if the product reported was not a UPD value, the report will not appear under this criteria search until recoding is completed.

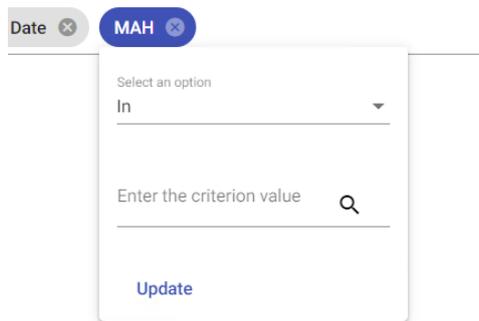


Figure 151: MAH Criteria filter

MAH filter has only 2 option filters available: In and Not In.

- “In” option, will allow the user to multiselect different organisations to retrieve, for example, the list of reports affecting all organisations of a same hierarchy.
- “Not in” option, will exclude from results all MAH entered in filter. This option also admits multiselect functionality.

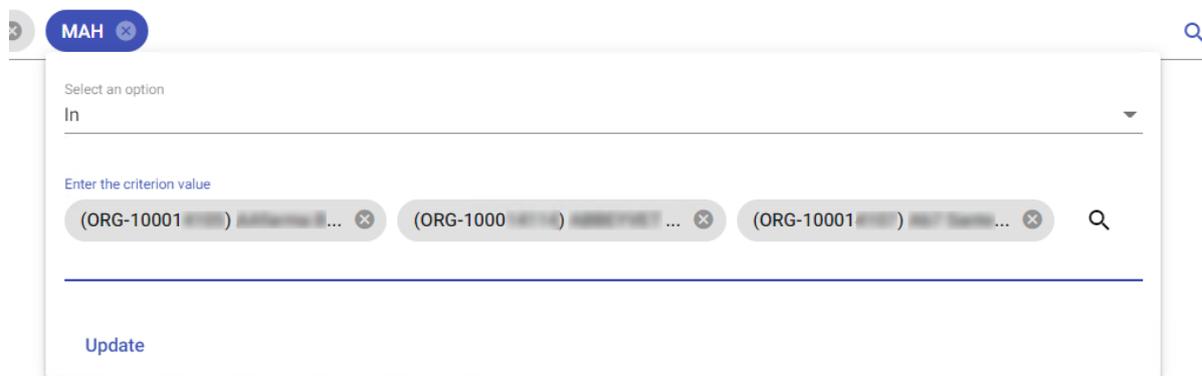


Figure 152: MAH multiselect functionality

If you don't know the ORG ID, go to OMS <https://spor.ema.europa.eu/omswi/#/searchOrganisations> or check it in the Organisation List section in EVWEB. For those organizations for which ORG ID has not yet been registered in OMS, is also possible to find the report by adding the ORG ID as free texts in the search filter.

## ii. Sender Search

Sender Search criteria allows the user to filter those reports that have been sent by a specific organisation. In the value area, the user can specify both the Routing ID or Organisation Name, and the system automatically will display the list of available options that contain the entered value. Similar to the MAH filter explained before, the Sender filter has 2 options to filter: “In” and “Not In”, both with multiselect functionality.

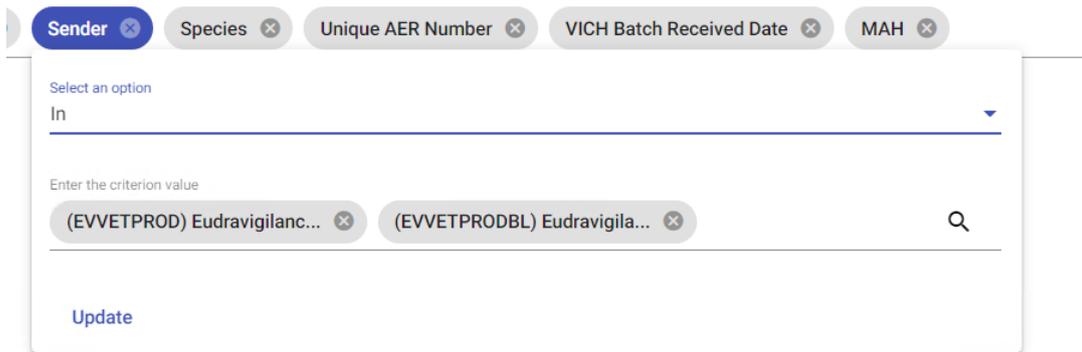


Figure 153: Sender Search filter

### iii. Classification Search

This criteria search allows to filter out the list of reports based on its classification. Following classification values are included:

- **Case report:** The current case report is the AER submission within the case that was determined to be the latest valid submission. There can only be 1 Safety Report within the case, marked as the current case report. These reports are sent to the DWH.
- **Error report:** Any report can be flagged as in-error, if mandatory fields are missing, or any other business rule generates an error. Individual reports in error are skipped by ETL and not used in the DWH. Other valid reports in the same case can be used for the DWH.
- **Nullified report:** A report specified by the sender as a Nullification. This report submission consequently nullifies the whole case, excluding them for the DWH.
- **Duplicated report:** This is used to mark an AER as a duplicate. This might be specified by the sender or by the DD Algorithm. These reports are excluded for the DWH.
- **Replaced report:** All other reports, which are not current, duplicate, nullification or in error are marked as replaced. These reports are excluded for the DWH.

This filter is not multiselect, so results table will only display the list of reports matching one of the classification selected.

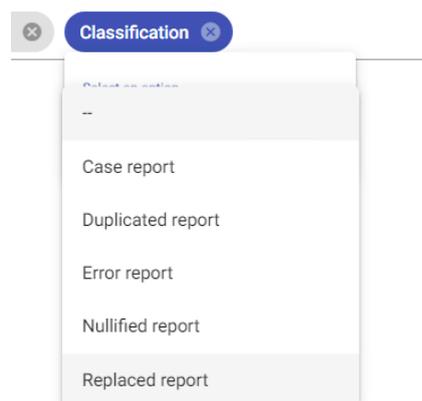


Figure 154: Classification search options

In addition to the criteria filter, the results table also displays the same criteria as a field value:

The screenshot shows a search interface with a top navigation bar containing 'Create and Send', 'Search AE Reports', and 'Search VICH Batch'. Below this, there are sections for 'Criteria(6)' and 'Fields(6)'. The 'Criteria' section includes 'Occur Country', 'Sender', 'Species', 'Unique AER Number', 'VICH Batch Received Date', and 'Classification: Case Report'. The 'Fields' section includes 'Local report Number', 'VICH Batch Received Date', 'Occur Country', 'Results in Death', 'VICH Batch Sender', and 'Classification'. A table below displays search results with columns for 'Local Report Number', 'Vich Batch Received Date', 'Occur Country', 'Results In Death', 'Vich Batch Sender', 'Classification', and 'Actions'. The 'Classification' column shows 'Case Report' for three entries. A red box highlights the 'Classification: Case Report' criterion and the 'Classification' column in the table.

Local Report Number	Vich Batch Received Date	Occur Country	Results In Death	Vich Batch Sender	Classification	Actions
1229695	2018/09/14	United States	0	BIAHPV1P	Case Report	[Icons]
3937	2005/03/29	Netherlands	0	NLBBD	Case Report	[Icons]
375164	2013/10/07	Poland	0	PLMEDVET01	Case Report	[Icons]

Figure 155: Results obtained applying classification criteria and field

#### iv. Product Name / Substance Name Search

Searches based on “**Product name**” (see below) will return all AERs in which the selected product has been reported in field B.2.1. Registered Name or Brand Name (so, this criteria could also be entered as free text as it is used to filter by reported product). Once the product is entered in the criteria, please click on the ‘Update’ button, then click on any magnifying glass to run the search.

**Note:** The results may include reports where the access levels are not yet defined, so only L1 access will be granted

The screenshot shows a search interface with a top navigation bar containing 'Create and Send', 'Search AE Reports', and 'Search VICH Batch'. Below this, there are sections for 'Criteria(5)' and 'Fields(8)'. The 'Criteria' section includes 'Occur Country', 'Sender', 'Species', 'Unique AER Number', and 'Product Name'. The 'Product Name' criterion is expanded to show a dropdown menu with 'In' selected, a search input field labeled 'Enter the criterion value', and an 'Update' button. The 'Fields' section includes 'Local report Number', 'VICH Batch Received Date', 'Occur Country', 'Results in Death', 'VICH Batch Sender', and 'Classification'. An 'Export CSV' button is visible on the right side.

Figure 156: Product Name search

Add **"Product name – as recoded"** to get access to all reports for the selected Product which have been already assigned the correct access levels for the organisation. Once the product is entered in the criteria (dropdown list), please click on 'Update' button, then on any magnifying to run the search:

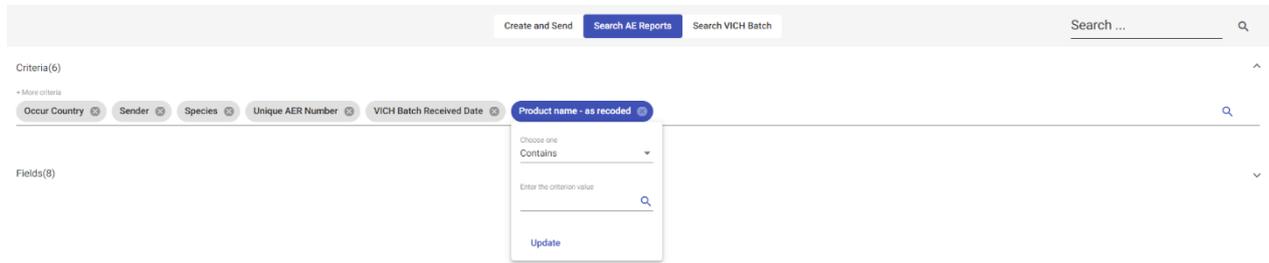


Figure 157: Product Name - As recoded search

The four criteria filters, have available the following search options: "In", "Not in", "Contains" and "Begins". As an example, "In" will retrieve in results table all reports that contain the specified products as one of the VMPs informed.

"In" and "Not in" options, also accept multiple values in the search, which allows to find all reports that contain at least one of the specified products from the filter.

Criteria(4)

+ More criteria

Occur Country Sender Species Product Name: Ewweb3 testing pills 125mg,EvWeb 5 mg/ml -...

Fields(5)

Export CSV

Export XML

Local Report Number	Species	Type Of Information In Report	Unique Aer Number	Product Name	Actions
<input type="checkbox"/> 20000000092	Dog	OTHER	GBR-GBRUKVMD-123456789	Draxxin...	<input type="checkbox"/> <input type="edit"/> <input type="download"/>
<input type="checkbox"/> 20000001177	Cat	BOTH SAFETY AND LACK OF EXPECTED EFFECTIVENESS	DEU-ACTREVOG-AP2-101120212	Draxxin,EvWeb 50 mg/ml - Solution for injection,EvWeb 5 mg/ml - Solution for injection	<input type="checkbox"/> <input type="edit"/> <input type="download"/>
<input type="checkbox"/> 20000000077	Cat	BOTH SAFETY AND LACK OF EXPECTED EFFECTIVENESS	DEU-ACTREVOG-AP2-10112021	EvWeb 5 mg/ml - Solution for injection...	<input type="checkbox"/> <input type="edit"/> <input type="download"/>
<input type="checkbox"/> 20000000051	Alpaca		GBR-GBRUKVMD-TestReportSend	EvWeb 5 mg/ml - Solution for injection	<input type="checkbox"/> <input type="edit"/> <input type="download"/>

Figure 158: Results obtained applying "In" option for Product Name search

As accepted criteria values, Products Name and Product Name – As recoded, present the list of UPD and Product index entries available, although the user is also able to enter a free text value. Same happens for Substance Name and Substance Name – As recoded, the available substances are listed in the dropdown list of values.

Additionally, the four searches have also available the option "Not reported", which will return all those reports that do not have either any product or substance informed.

Criteria(4) ^

+ More criteria

Occur Country × Sender × Species × Product Name: Not Reported (In) × Q

---

Fields(4) v

[Export CSV](#)

Export XML

	Local Report Number	Species	Type Of Information In Report	Product Name	Actions
<input type="checkbox"/>	379014	Cat	LACK OF EXPECTED EFFECTIVENESS		
<input type="checkbox"/>	15243	Dog	SAFETY ISSUE		
<input type="checkbox"/>	380667	Dog	LACK OF EXPECTED EFFECTIVENESS		
<input type="checkbox"/>	282583	Chicken	SAFETY ISSUE		
<input type="checkbox"/>	19494	Cat	SAFETY ISSUE		
<input type="checkbox"/>	1316835	Dog	SAFETY ISSUE		

Figure 159: "Not informed" search applied to products, retrieves reports where only substances are informed.

## v. Occur Country Search

This filter displays the list of available countries for report submission. The country selected will correspond to the country of occurrence, retrieved from the first 3-digits of the Unique AER number. This search criteria accepts multiple values.

Create and Send [Search AE Reports](#) [Search VICH Batch](#)

Criteria(3) ^

+ More criteria

Occur Country × Sender × Species ×

Enter the criterion value

Afghanistan... × Algeria... × | Q

- Aland Islands
- Albania
- American Samoa
- Andorra
- Angola

	Species	Type Of Information In Report	Product Name	Actions
<input type="checkbox"/>	Cat	LACK OF EXPECTED EFFECTIVENESS		

Figure 160: Occur country Search

## vi. Narrative Search

Narrative filter is a free text that allows user to find reports that contain the match of the text entered in the

criteria value. Case sensitiveness is not applicable for this field.

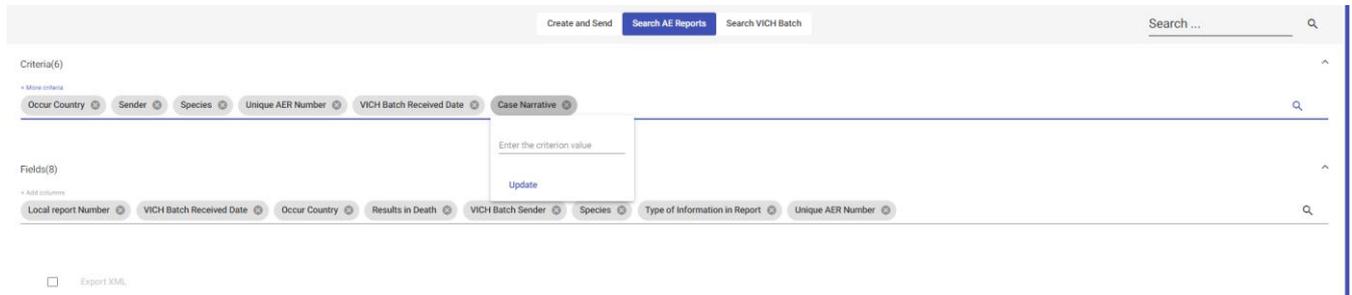


Figure 161: Narrative search

### vii. Species and Breed Searches

System also allows to filter by specific species and breeds. These filters do not allow multiple criteria values for the moment, that means, that search will retrieve those reports where breed is informed in both purebred and crossbred fields. Specific crossbred combination is not possible to search in option.

To specify the breed value, the user will need to mandatorily specify first the Species. Once, species is informed, a dropdown list will be displayed with all available breed for that species.

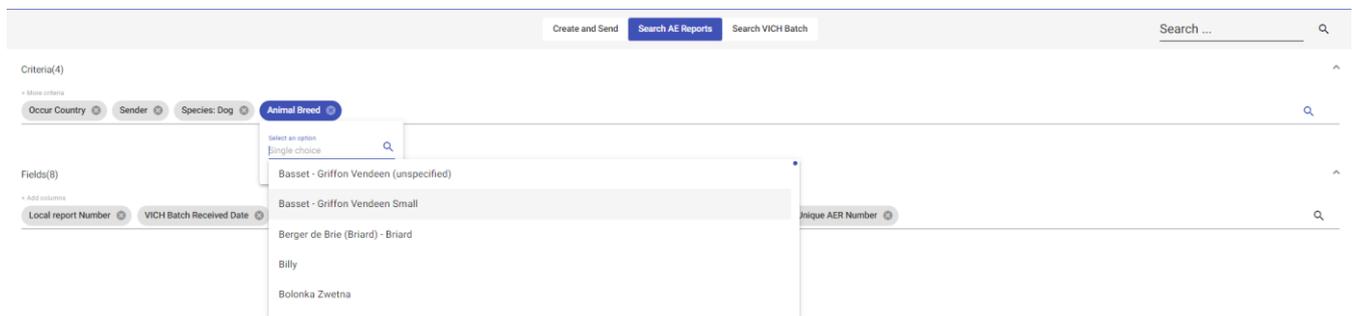


Figure 162: Species and Breed search

### viii. Off label use Search

This criteria filter displays the list of options from section B.2.5 Usage according to label from report, when user has selected option "use according to label" as No. The listed options will filter out those reports where off label use option was meeting the selected explanation. Multiple selection is not available for this criteria filter.

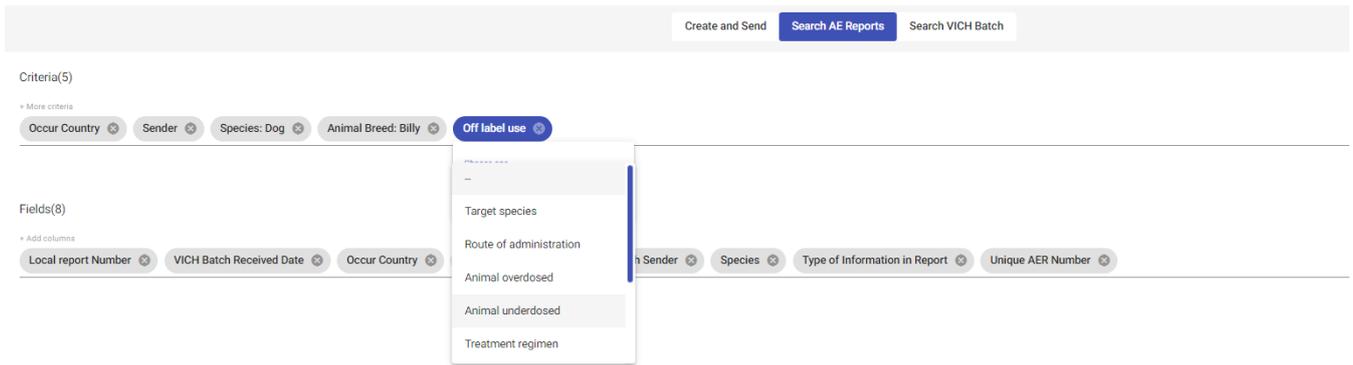


Figure 163: Off label use Search

### ix. Correct report, with warning, errors Search

Based on validation after submission, user can filter out those reports that presented warnings or were classified as error. The information is visible in the AE Report acknowledgement section of the submitted report.

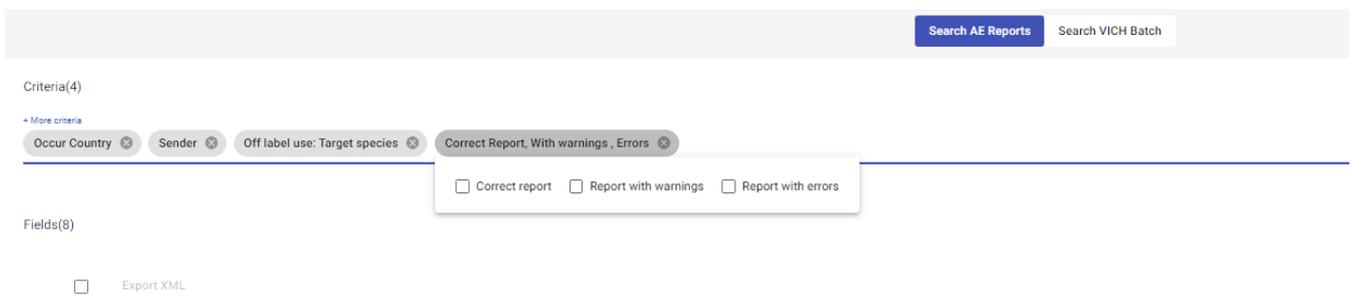


Figure 164: Correct report, with warnings errors Search

### x. Product Recoding Date Search

The criteria filter "Product recoding date" will help organisations to retrieve all reports for which recoding has been completed or updated at the specified time in filter.

Unlike to the MAH filter, this filter retrieves the reports with recoded products, independently to the MAH assigned to the products.

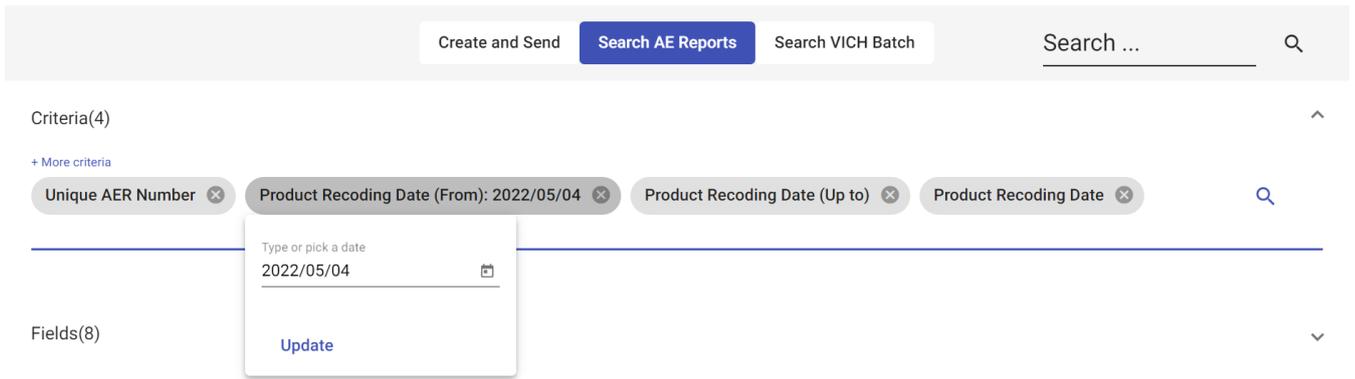


Figure 165: Product Recoding Date Search

The Product recoding date is applicable to the report and is considering the most recent recoding date of all its products informed. Therefore, each time that one of the products is updated in UPD or a manual recoding is done, the Product Recoding date of the report will be updated to that most recent date.

## xi. Type of Submission

The criteria filter "Type of submission" allows the user to retrieve the reports based on the report submission type assigned. Available types are: EXPEDITED, OTHER, NULLIFICATION, FOLLOW-UP and PERIODIC.

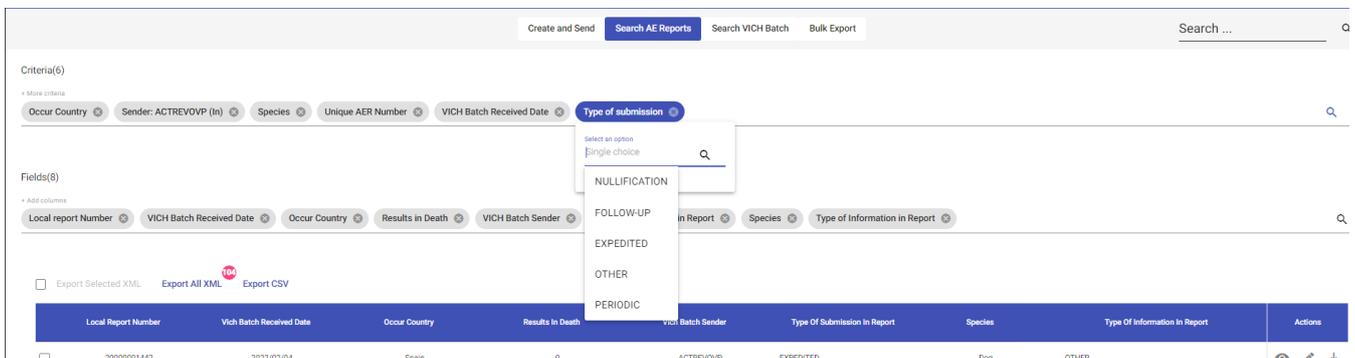


Figure 166: Type of submission