



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 January 2026  
Information Management Division

## EVVet3 Production – release notes

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

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## 1. Version 22JANUARY2026

### 1.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database v. **22JANUARY2026**. This version includes new functionalities related to **EVWEB** system.

### 1.2. New improvements from last version

| Issue ID | Description                                                                                  | Component    |
|----------|----------------------------------------------------------------------------------------------|--------------|
| 29656    | EVWEB - Access policy indicator (Report level)                                               | <b>EVWEB</b> |
| 164173   | EVWEB - Update description of option "Search [added text] as new product" in criterion value | <b>EVWEB</b> |

### 1.3. Existing issues in version 22JANUARY2026

| Issue ID                             | Description                                                                                                                                                                        | Component  |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| 110731<br>110732<br>110733<br>110766 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | <b>DWH</b> |

### 1.4. Fixed issues from last version

| Issue ID | Description | Component  |
|----------|-------------|------------|
| N/A      | N/A         | <b>N/A</b> |

## 2. Version 06NOVEMBER2025

### 2.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database v. **06NOVEMBER2025**. This version includes new functionalities related to **EVWEB** system.

### 2.2. New improvements from last version

| Issue ID | Description                                                                                                                                                                                                                | Component    |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 263509   | Business rule: Error 218 (B.3.2) - Improve clarity of the message displayed to users. Message updated to:<br><br>"The field Adverse Clinical Manifestations (AER Term Name(s) & Code(s)) - B.3.2 should have a value which | <b>EVWEB</b> |

| Issue ID | Description                                                                                                 | Component    |
|----------|-------------------------------------------------------------------------------------------------------------|--------------|
|          | matches Veterinary or Common terms when Species (Type of Species) & Code - B.1.3<>'Human'".                 |              |
| 132352   | Search AE Reports - Add "Type of Submission in Report" and "Original Received Date" column to the CSV file. | <b>EVWEB</b> |
| 107693   | Search AE Reports - Disable the download icon for reports with error classification.                        | <b>EVWEB</b> |
| 37883    | Bulk Export - Visual indicator for requests with no reports downloaded (disabled download icon).            | <b>EVWEB</b> |

### 2.3. Existing issues in version 06NOVEMBER2025

| Issue ID                             | Description                                                                                                                                                                        | Component  |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| 110731<br>110732<br>110733<br>110766 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | <b>DWH</b> |

### 2.4. Fixed issues from last version

| Issue ID | Description | Component  |
|----------|-------------|------------|
| N/A      | N/A         | <b>N/A</b> |

## 3. Version 23SEPTEMBER2025

### 3.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database v. **23SEPTEMBER2025**. This version includes new functionalities related to **EVWEB** system.

### 3.2. New improvements from last version

| Issue ID | Description                                                                                                                                                                                                                                           | Component    |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 61743    | Bulk Export - CSV summary to include all columns from results table: <ul style="list-style-type: none"> <li>• Unique AER ID</li> <li>• Local Report Number</li> <li>• VICH Batch Sender Identifier</li> <li>• Type of Submission in Report</li> </ul> | <b>EVWEB</b> |

| Issue ID | Description                                                                          | Component    |
|----------|--------------------------------------------------------------------------------------|--------------|
|          | <ul style="list-style-type: none"> <li>Occur Country</li> <li>Species</li> </ul>     |              |
| 236057   | Search for report by "Product name – as recoded" is not showing scientific products. | <b>EVWEB</b> |

### 3.3. Existing issues in version 23SEPTEMBER2025

| Issue ID                             | Description                                                                                                                                                                        | Component  |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| 110731<br>110732<br>110733<br>110766 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | <b>DWH</b> |

### 3.4. Fixed issues from last version

| Issue ID | Description                                                          | Component    |
|----------|----------------------------------------------------------------------|--------------|
| 244253   | Display in the submitted AER the date precision selected by the user | <b>EVWEB</b> |

## 4. Version 06MARCH2025

### 4.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database v. **06MARCH2025**. This version includes new functionalities related to **EVWEB** system.

### 4.2. New improvements from last version

| Issue ID | Description                               | Component    |
|----------|-------------------------------------------|--------------|
| 226028   | Setup default location in Profile section | <b>EVWEB</b> |
| 204714   | Create and save drafts for follow up AERs | <b>EVWEB</b> |

### 4.3. Existing issues in version 06MARCH2025

| Issue ID                             | Description                                                                                                                                                                        | Component  |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| 110731<br>110732<br>110733<br>110766 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | <b>DWH</b> |

#### 4.4. Fixed issues from last version

| Issue ID | Description | Component |
|----------|-------------|-----------|
| N/A      | N/A         | N/A       |

## 5. Version 28NOVEMBER2024

### 5.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database v. **28NOVEMBER2024**. This version includes new functionalities related to **EVWeb** and **DWH** systems.

### 5.2. New improvements from last version

| Issue ID | Description                                                                                                                                  | Component |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 110101   | [Draft AERs] Drafts/Templates tab: Update date should be added to the result table of Draft tab                                              | EVWeb     |
| 146316   | [Search AER] Multi-Selection Feature for "Unique AER Number" Criteria Filter                                                                 | EVWeb     |
| 199625   | Incidence calculation in Public Reports. A new tab has been created in Public Reports, showing data by species and also by geographic origin | DWH       |

### 5.3. Existing issues in version 28NOVEMBER 2024

| Issue ID                                                                     | Description                                                                                                                                                                        | Component |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 5.4. Fixed issues from last version

| Issue ID | Description | Component |
|----------|-------------|-----------|
| N/A      | N/A         | N/A       |

## 6. Version 31OCTOBER2024

### 6.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database v. **31OCTOBER2024**. This version includes new functionalities related to **IRIS VSM** system.

### 6.2. New improvements from last version

| Issue ID | Description                                                              | Component   |
|----------|--------------------------------------------------------------------------|-------------|
| 206983   | Send a Notification to MAH on re-submission of 'Request for information' | <b>IRIS</b> |
| 209981   | VMPs with Auth. Status pending should be not available for selection     | <b>IRIS</b> |
| 213691   | Correction of ATCvet name that was different in some old cases.          | <b>IRIS</b> |

### 6.3. Existing issues in version 31OCTOBER 2024

| Issue ID                                                                     | Description                                                                                                                                                                        | Component |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 6.4. Fixed issues from last version

| Issue ID | Description | Component |
|----------|-------------|-----------|
| N/A      | N/A         | N/A       |

## 7. Version 16OCT2024

### 7.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database v. **16OCTOBER2024**. This version includes new functionalities related to **DWH** and **EVWeb** system.

### 7.2. New improvements from last version

| Issue ID | Description                                                              | Component |
|----------|--------------------------------------------------------------------------|-----------|
| 207773   | ENTA value has been added to sales data dashboard in sales data section. | DWH       |

| Issue ID | Description                                                                                                                                                                            | Component |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 199623*  | Incidence calculation changes. Incidence calculation values from 'n' year, will be available on 1 <sup>st</sup> March 'n+1' year.                                                      | DWH       |
| 210156   | 'Occurred country' and 'SOC VedDRA term' level have been added to the Precalculations at product shortname level in <i>Signalling for reaction linked to a product or ingredient</i> . | DWH       |
| 206206   | New Criteria and new field organisation functional email                                                                                                                               | EVWeb     |

### 7.3. Existing issues in version 16OCT2024

| Issue ID                                                                | Description                                                                                                                                                                        | Component |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVet3-11272<br>EVet3-11273<br>EVet3-11274<br>EVet3-11275<br>EVet3-14164 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 7.4. Fixed issues from last version

| Issue ID | Description | Component |
|----------|-------------|-----------|
| N/A      | N/A         | N/A       |

## 8. Version 28AUGUST2024

### 8.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database v. **28AUGUST2024**. This version includes new functionalities related to **DWH** system.

### 8.2. New improvements from last version

| Issue ID | Description                                                                                     | Component |
|----------|-------------------------------------------------------------------------------------------------|-----------|
| 51079    | Precalculations at Product grouping level <i>Signal detection dashboard</i>                     | DWH       |
| 51095    | Add line listing to precalculations at Product grouping level <i>Signal detection dashboard</i> | DWH       |

### 8.3. Existing issues in version 28AUGUST2024

| Issue ID                                                                     | Description                                                                                                                                                                        | Component |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 8.4. Fixed issues from last version

| Issue ID | Description | Component |
|----------|-------------|-----------|
| N/A      | N/A         | N/A       |

## 9. Version 23AUGUST2024

### 9.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **23AUGUST2024**. This version includes new functionalities related to **EVVET** system

### 9.2. New improvements from last version

| Issue ID | Description                                                   | Component |
|----------|---------------------------------------------------------------|-----------|
| 105857   | [EVWeb profile] Setup functional email in the profile section | EVWeb     |

### 9.3. Existing issues in version 23AUGUST2024

| Issue ID                                                                     | Description                                                                                                                                                                        | Component |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 9.4. Fixed issues from last version

| Issue ID | Description                                                                          | Component |
|----------|--------------------------------------------------------------------------------------|-----------|
| 179468   | Occurrence country filter now retrieving all values properly (e.g. Poland, Finland). | DWH       |

## 10. Version 06JUNE2024

### 10.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **06JUNE2024**. This version includes new functionalities related to **DWH** system.

### 10.2. New improvements from last version

| Issue ID | Description                                                         | Component |
|----------|---------------------------------------------------------------------|-----------|
| 173476   | New dashboard to analyse the trends at product grouping level.      | DWH       |
| 171799   | Product grouping has been added to Adverse event overview dashboard | DWH       |

### 10.3. Existing issues in version 06JUNE2024

| Issue ID                                                                     | Description                                                                                                                                                                        | Component |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 10.4. Fixed issues from last version

| Issue ID | Description                                                                          | Component |
|----------|--------------------------------------------------------------------------------------|-----------|
| 179468   | Occurrence country filter now retrieving all values properly (e.g. Poland, Finland). | DWH       |

## 11. Version 14MAY2024

### 11.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **14MAY2024**. This version includes new functionalities related to **EVVET** system.

### 11.2. New improvements from last version

| Issue ID | Description                                             | Component |
|----------|---------------------------------------------------------|-----------|
| 165293   | [EVWeb] Clear all filters in the search tab on EVWEB.   | EVWeb     |
| 29649    | [EVWEB] UPD and Product Index products (no duplicates). | EVWeb     |

### 11.3. Existing issues in version 14MAY2024

| Issue ID                                                                     | Description                                                                                                                                                                        | Component |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 11.4. Fixed issues from last version

| Issue ID | Description                                                                                                      | Component |
|----------|------------------------------------------------------------------------------------------------------------------|-----------|
| 105343   | Performance issue validating AER before submission, sometimes results is "service call failure" due to time-out. | EVWeb     |

## 12. Version 7MAR2024

### 12.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **7MAR2024**. This version includes new functionalities related to **EVVET** system.

### 12.2. New improvements from last version

| Issue ID | Description                                                                                                                                                | Component |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 146763   | [Search AER] Add " VICH Batch Received Date (Intervals)" and "Product Recoding Date (Intervals)" Criteria Filters.                                         | EVWeb     |
| 146798   | [EVWEB] Display the product name in the menu of "Create and Send" tab.                                                                                     | EVWeb     |
| 148248   | [EVWEB] Display the product name in the menu of "Search AE Reports" tab.                                                                                   | EVWeb     |
| 162760   | Exclude third country product names in Business Rule validation.<br><br><b>Note: Type 8 of productIndexNames is not being used in the recoding process</b> | EVWeb     |

### 12.3. Existing issues in version 7MAR2024

| Issue ID | Description                                                                                                    | Component |
|----------|----------------------------------------------------------------------------------------------------------------|-----------|
| 105343   | Performance issue validating AER before submission, sometimes results is service call failure due to time-out. | EVWeb     |

| Issue ID                                                                     | Description                                                                                                                                                                        | Component |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

#### 12.4. Fixed issues from last version

| Issue ID                                  | Description                                                                                                                    | Component |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612 | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in). | EVWeb     |

## 13. Version 13FEB2024

### 13.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **13FEB2024**. This version includes new functionalities related to **EVVET-DWH** system.

### 13.2. New improvements from last version

| Issue ID | Description                                                                               | Component |
|----------|-------------------------------------------------------------------------------------------|-----------|
| 41002    | Pre-calculations at active substance level on Signalling dashboard.                       | DWH       |
| 50730    | Add 'Line listing' to pre-calculations at active substance level on Signalling dashboard. | DWH       |

### 13.3. Existing issues in version 13FEB2024

| Issue ID                                                                     | Description                                                                                                                                                                        | Component |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| 105343                                                                       | Performance issue validating AER before submission, sometimes results is service call failure due to time-out.                                                                     | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 13.4. Fixed issues from last version

N/A

## 14. Version 25JAN2024

### 14.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **25JAN2024**. This version includes some bug fixes related to **EVVET-EVWEB** system.

### 14.2. New improvements from last version

N/A

### 14.3. Existing issues in version 25JAN2024

| Issue ID                                                                     | Description                                                                                                                                                                        | Component |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| 105343                                                                       | Performance issue validating AER before submission, sometimes results is service call failure due to time-out.                                                                     | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 14.4. Fixed issues from last version

| Issue ID         | Description                                                                                                                                                                                                                          | Component |
|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 85773            | Fixed an issue in the 'Product Name' criteria filter in the Search AE Report section, where a specific product was erroneously retrieved.                                                                                            | EVWeb     |
| 149337           | After entering a text next to criteria filters and saving the input, the entered text remained visible upon restoring the saved criteria. This identified issue has been successfully rectified through the completion of this task. | EVWeb     |
| 149657<br>149664 | Resolved an issue where users were able to send the report by removing both the VMP section and the entire AE report section. The deletion option is now disabled when there is only one section added.                              | EVWeb     |
| 145541           | Current issue in messaging processes that causes some submissions to not be correctly persisted and recoded.                                                                                                                         | Messaging |

| Issue ID     | Description                                                                                                                                     | Component |
|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 143680       | Current issue in messaging process that causes reprocessing of messages not successfully persisted and generation of negative acknowledgements. | Messaging |
| EVVet3-13810 | Line listing in 'Product association' tab from 'Signal evaluation' dashboard now is generated                                                   | DWH       |

## 15. Version 4DEC2023

### 15.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **4DEC2023**. This version introduces the default criteria filters for NCA users in the **EVVET-EVWEB** system.

### 15.2. New improvements from last version

| Issue ID | Description                                                                                                                                                                                   | Component |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 29674    | Now in EVWEB, when a NCA user logs in the application, predefined criteria filters will be automatically applied based on the logged Organisation/Routing ID in the Search AE Report section. | EVWeb     |
| 145549   | Refresh button to restore the criteria filters to the default in the Search AE Reports section, has been enabled for MAH and NCA users.                                                       | EVWeb     |

### 15.3. Existing issues in version 4DEC2023

| Issue ID                                                                                     | Description                                                                                                                                                                        | Component |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| 105343                                                                                       | Performance issue validating AER before submission, sometimes results is service call failure due to time-out.                                                                     | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164<br>EVVet3-13810 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |
| 145541                                                                                       | Current issue in messaging processes that causes some submissions to not be correctly persisted and recoded.                                                                       | Messaging |

| Issue ID | Description                                                                                                                                     | Component |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 143680   | Current issue in messaging process that causes reprocessing of messages not successfully persisted and generation of negative acknowledgements. | Messaging |

#### 15.4. Fixed issues from last version

N/A

## 16. Version 21NOV2023

### 16.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **21NOV2023**. This version introduces improvements in the **EVVET-EVWEB** system, focusing on improvements regarding criteria filters in the Search AE Reports section and Drafts.

### 16.2. New improvements from last version

| Issue ID         | Description                                                                                                                                                                                    | Component |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 111246<br>105992 | Implemented new functionality to allow the storage of customized criteria filters, which can be retrieved by all users belonging to a same Organisation (Routing ID).                          | EVWeb     |
| 29674            | Now in EVWEB, when an MAH user logs in the application, predefined criteria filters will be automatically applied based on the logged Organisation/Routing ID in the Search AE Report section. | EVWeb     |
| 129775           | Draft AERs allows now the option to delete existing drafts and templates by any user of the organisation.                                                                                      | EVWeb     |

### 16.3. Existing issues in version 21NOV2023

| Issue ID                                                                                     | Description                                                                                                                                                                        | Component |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| 105343                                                                                       | Performance issue validating AER before submission, sometimes results is service call failure due to time-out.                                                                     | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164<br>EVVet3-13810 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

| Issue ID | Description                                                                                                                                     | Component |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 145541   | Current issue in messaging processes that causes some submissions to not be correctly persisted and recoded.                                    | Messaging |
| 143680   | Current issue in messaging process that causes reprocessing of messages not successfully persisted and generation of negative acknowledgements. | Messaging |

#### 16.4. Fixed issues from last version

| Issue ID | Description                                                                                                                                | Component |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 111246   | Fixed issue in the Export CSV that caused some reports from the results table, to not be included in the CSV file and Bulk export.         | EVWeb     |
| 134851   | Draft and Template AERs couldn't be edited when the VICH batch number contains commas.                                                     | EVWeb     |
| 29708    | Business Rules 178 and 148 were triggered as warning although having reported a correct UPD products, Product index or active ingredients. | Messaging |

## 17. Version 5SEP2023

### 17.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **5SEPT2023**. This version introduces improvements in the **EVVET-DWH** system, mainly regarding to the new functionality for pre-calculations at product short name level in signalling dashboard.

### 17.2. New improvements from last version

| Issue ID | Description                                                                                                 | Component |
|----------|-------------------------------------------------------------------------------------------------------------|-----------|
| 50907    | Pre-calculations at Product Short name level in Signalling dashboard (1 year, 6 months, 3 months, 1 month). | DWH       |
| 51379    | Line listing functionality in Pre-calculations at Product Short name level in signalling dashboard.         | DWH       |

### 17.3. Existing issues in version 05SEPT2023

| Issue ID                                  | Description                                                                                                                    | Component |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612 | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in). | EVWeb     |
| 105343                                    | Performance issue validating AER before submission, sometimes results is service call failure due to time-out.                 | EVWeb     |

| Issue ID                                                                                     | Description                                                                                                                                                                        | Component |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164<br>EVVet3-13810 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

#### **17.4. Fixed issues from last version**

N/A

## **18. Version 8AUGUST2023**

### **18.1. Overview**

This release is the next iterative version of the Union Pharmacovigilance Database, v. **8AUGUST2023**. This version introduces improvements in the **EVVET-EVWEB** system, a new functionality for AER templates creation and one bug fix related to advanced product search.

### **18.2. New improvements from last version**

| Issue ID | Description                                                                                                                                          | Component |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 78806    | Templates Creation - This new functionality allows the user to create reusable AER templates that can be used by all users in the same organization. | EVWeb     |

### **18.3. Existing issues in version 8AUGUST2023**

| Issue ID                                                                                     | Description                                                                                                                                                                        | Component |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| 105343                                                                                       | Performance issue validating AER before submission, sometimes results is service call failure due to time-out.                                                                     | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164<br>EVVet3-13810 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

#### 18.4. Fixed issues from last version

| Issue ID | Description                                                                                                                                | Component |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 110273   | The 'Advanced Product Search' in Create and Send section, is now retrieving all available products names, including all language versions. | EVWeb     |

## 19. Version 6JULY2023

### 19.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **6JULY2023**. This version introduces relevant improvements to **EVVET-DWH** system with regards to the pre-calculations at product short name level in Signal detection, bug fixing and product grouping.

### 19.2. New improvements from last version

| Issue ID                         | Description                                                                                                                                                                                                                                                     | Component |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 61340                            | Medically Important events (MIT) filter has been added to the pre-calculations at product short name level in Signal detection dashboard for each of the time frames. Also, the MITs have been highlighted in bold for prioritization purposes in the analysis. | DWH       |
| 105625                           | Product grouping entries with no value informed will be displayed as 'Unknown' in DWH UI.                                                                                                                                                                       | DWH       |
| 54573                            | 'Number of cases by ATC' graph from List of products dashboard shows the lowest level of ATC Vet code.                                                                                                                                                          | DWH       |
| 61356                            | Output from Signal detection dashboard has a unique species filter that affect the three results tables at the same time instead having a filter for each table.                                                                                                | DWH       |
| 29417<br>29416<br>29410<br>29409 | Product grouping level now available in Signal detection dashboard.                                                                                                                                                                                             | DWH       |

### 19.3. Existing issues in version 06JULY2023

| Issue ID                                  | Description                                                                                                                    | Component |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612 | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in). | EVWeb     |
| 105343                                    | Performance issue validating AER before submission, sometimes results is service call failure due to time-out.                 | EVWeb     |

| Issue ID                                                                                     | Description                                                                                                                                                                        | Component |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164<br>EVVet3-13810 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

#### 19.4. Fixed issues from last version

| Issue ID | Description                                                                          | Component |
|----------|--------------------------------------------------------------------------------------|-----------|
| 38583    | 'Total number of cases' table is now loading properly in Signal detection dashboard. | DWH       |
| 102510   | ATC vet code now correctly displayed in List of product dashboard.                   | DWH       |
| 102993   | 'One year' time frame is now considering 12 months instead of 13.                    | DWH       |

## 20. Version 4JULY2023

### 20.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **4JULY2023**. This version introduces improvements in **EVVET-EVWEB** on the searching functionality for products, VeDDRA and MAH, improvements in the "Drafts" section, and a bug fix related to Mailbox ACKs download.

### 20.2. New improvements from last version

| Issue ID       | Description                                                                                                                                                                                                                                     | Component |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 29662<br>94351 | Improved product search and selection in AERs "Create and send" section. Currently users will be able to use an advanced selection to filter by different product attributes to select the most accurate product to be reported in VMP section. | EVWeb     |
| 60948          | VeDDRA selection has been improved by introducing the corresponding PT, HLT, SOC levels and Term type for each LLT term in the dropdown of "AER Term name (B.3.2)" to enable users to select the most accurate VeDDRA term from the VeDDRA list | EVWeb     |
| 78282          | Improved MAH criteria filter, when the HQ Organisation ID is selected as a value in the MAH filter, reports related to reports related to all organisations in their Hierarchy will be retrieved.                                               | EVWeb     |

| Issue ID       | Description                                                                                                                                                     | Component |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 75725<br>75729 | In Drafts AERs section, new columns have been added in the results table to display the "Original Received Date" (A.4.2) and Created User.                      | EVWeb     |
| 78203          | In "Drafts" section, a confirmation is now required to resume a Draft when it's detected that an unsaved report is already opened in "Create and Send" section. | EVWeb     |
| 53028          | Disabled DEG Standard format Gateway submissions.<br>Rejections to DEG submissions have been setup.                                                             | Messaging |

### 20.3. Existing issues in version 4JULY2023

| Issue ID                                                                                     | Description                                                                                                                                                                        | Component |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| 105343                                                                                       | Performance issue validating AER before submission, sometimes results is service call failure due to time-out.                                                                     | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164<br>EVVet3-13810 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 20.4. Fixed issues from last version

| Issue ID     | Description                                                                                                                         | Component          |
|--------------|-------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| 101027       | Fixed issue in Mailbox, that prevented the successful download of Acknowledgement XMLs.                                             | EVWeb              |
| 95275        | Fixed performance issue related to AER Term Name selections in Create and Send section for Adverse Clinical Manifestations (B.3.2). | EVWeb              |
| 29802        | Fixed the values displayed in Classification column, which were not consistent with the real assigned classification.               | EVWeb<br>Data Jobs |
| EVVet3-12353 | In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results.       | EVWeb              |

## 21. Version 23MAY2023

### 21.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **23MAY2023**. This version introduces in **EVVET-DWH** system improvements related to the pre-calculations at product short name level in Signal detection dashboard.

### 21.2. New improvements from last version

| Issue ID                         | Description                                                                                                                                                                                                | Component |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 53125<br>53126<br>61373<br>61374 | Specific period for each of the time frames has been added in signal detection pre-calculations. Also, the last day of the previous month has been set up as the deadline date to do the pre-calculations. | DWH       |

### 21.3. Existing issues in version 23MAY2023

| Issue ID                                                                                     | Description                                                                                                                                                                         | Component |
|----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                      | EVWeb     |
| EVVet3-12353                                                                                 | In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results.                                                       | EVWeb     |
| 85490<br>29802                                                                               | In the search AER results table, for some reports, the VICH Batch received date and Classification column field values are not displaying the correct information for some reports. | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164<br>EVVet3-13810 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard.  | DWH       |

### 21.4. Fixed issues from last version

N/A

## 22. Version 16MAY2023

### 22.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **16MAY2023**. This version introduces in **EVVET** system a new functionality for Draft AERs, new UPD and product index entries for the different languages of the medicinal products and improvements on Bulks export processing, as well as some bug fixing.

## 22.2. New Improvements from last version

| Issue ID       | Description                                                                                                                                                                    | Component |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 77296          | Draft AER - This new functionality allows to create and save drafts of messages that can be reviewed and edited by all users of one same organization before final submission. | EVWeb     |
| 54636<br>29786 | Full presentation names for all languages registered in UPD for one same product permanent identifier are now included in the product index list.                              | EVWeb     |
| 51951<br>51948 | Bulk export – Improved speed processing of requested bulk exports.                                                                                                             | EVWeb     |

## 22.3. Existing issues in version 16MAY23

| Issue ID                                  | Description                                                                                                                                                                         | Component |
|-------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612 | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                      | EVWeb     |
| EVVet3-12353                              | In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results.                                                       | EVWeb     |
| 85490<br>29802                            | In the search AER results table, for some reports, the VICH Batch received date and Classification column field values are not displaying the correct information for some reports. | EVWeb     |

## 22.4. Fixed issues from last version

| Issue ID | Description                                                                 | Component |
|----------|-----------------------------------------------------------------------------|-----------|
| 51965    | Exported bulks are now being deleted 1 month after the request was created. | EVWeb     |
| 94659    | Fixed some issues affecting the recoding process.                           | Data jobs |

# 23. Version 25APR2023

## 23.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **25APR2023**. This version introduces changes in **DWH** system, mainly with regards to the pre-calculations at Product short name level in Signal detection dashboard.

### 23.2. New Improvements from last version

| Issue ID                         | Description                                                                                                                                                          | Component |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 29431                            | Known VeDDRA terms not to be highlighted in green anymore in Signal detection dashboard.                                                                             | DWH       |
| 29486<br>76274<br>76276          | Pre-calculations at Product short name level in Signal detection dashboard: <ul style="list-style-type: none"><li>• Pre-calculations are done at PT VeDDRA</li></ul> | DWH       |
| 61311                            | 15 days and 1-week timeframes have been removed from the pre-calculations at Product short name level in Signal detection dashboard.                                 | DWH       |
| 51425<br>51427<br>51428<br>61265 | Line listing functionality has been added to the pre-calculations at Product short name level in Signal detection dashboard.                                         | DWH       |
| 86451                            | Pre-calculations option has been set up as the default option in Signal detection dashboard.                                                                         | DWH       |
| 29472                            | 'Un-recodable' and 'Un-recodable reason' dimensions from manual recoding functionality have been added to DWH catalogue for self-service analysis.                   | DWH       |

### 23.3. Existing issues version 25APR23

| Issue ID                                                                                                     | Description                                                                                                                                                                        | Component |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| EVVet3-12353                                                                                                 | In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results.                                                      | EVWeb     |
| EVVet3-11678                                                                                                 | In the search AER results table, for some reports, the VICH Batch received date, Species and classification field values are not displayed.                                        | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164<br>EVVet3-13810<br>EVVet3-13809 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 23.4. Fixed issues from last version

| Issue ID                | Description                                                                                                                                              | Component |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 29503                   | Data in the corresponding graph to analyse the last 10 years was not showing the complete past 10 years data on the 'Adverse event overview' dashboard.  | DWH       |
| 29504                   | Line listing regarding 'Number of cases by time to Onset' in Animal data tab from Signal evaluation dashboard was not generated.                         | DWH       |
| 29506                   | Line listing in Adverse event dashboard was showing more cases than expected.                                                                            | DWH       |
| 29511                   | 'See details' page did not load in 'List of products' dashboard.                                                                                         | DWH       |
| 38714                   | Data in the corresponding graph to analyse the last 5 years was not showing the complete data.                                                           | DWH       |
| 51100                   | 'All cases' and 'new cases' options were not applicable in 'Adverse event comparison between 2 period' dashboard.                                        | DWH       |
| 40835                   | Species dropdown was not showing all values in 'Adverse event overview' dashboard.                                                                       | DWH       |
| 40892<br>75644<br>75016 | Fixed various issues affecting the recoding process.                                                                                                     | EVWEB     |
| 29753                   | Corrected classification for some cases, for which more than one submission was classified as "Case report". This issue affected mainly DEG submissions. | Messaging |

## 24. Version 28FEB2023

### 24.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **28FEB2023**. This version introduces changes in **DWH** system, mainly with regards to the new IRIS line listing (*List of signals*) and 'All cases' and 'New cases' filters.

### 24.2. New Improvements from last version

| Issue ID       | Description                                                                                                                                                                 | Component |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 29441<br>29440 | 'New cases' and 'All cases' to be functionally working.<br><br><b>NOTE: 'New cases' and 'All cases' filters is pending to be implemented in Signal detection dashboard.</b> | DWH       |

| Issue ID | Description                                                                                                                                                                                                                                                                                                                            | Component |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 33011    | IRIS Line listing (List of signals). Implementation of the new line listing regarding the list of signals already registered in IRIS system. List of signals line listing now available in 'Signal detection (with 2 RORs, up to Date 1 and up to Date 2)' tab from Signal detection dashboard, by clicking on the product short name. | DWH       |
| 39286    | Medically important event not shown in all graphs from Adverse event comparison between 2 periods dashboard.                                                                                                                                                                                                                           | EVWEB     |

### 24.3. Existing issues version 28FEB23

| Issue ID                                                                                                     | Description                                                                                                                                                                        | Component |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>VVet3-8613<br>EVVet3-8612                                                                     | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| EVVet3-12353                                                                                                 | In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results.                                                      | EVWeb     |
| EVVet3-11678                                                                                                 | In the search AER results table, for some reports, the VICH Batch received date, Species and classification field values are not displayed.                                        | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-14164<br>EVVet3-13810<br>EVVet3-13809 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |
| EVVet3-13916                                                                                                 | Adverse event overview and Data stratification - Line listing display irrelevant records.                                                                                          | DWH       |
| EVVet3-13122                                                                                                 | Adverse event overview report - Issue with data in the graphs displaying data for last 10 years.                                                                                   | DWH       |

### 24.4. Fixed issues from last version

N/A

## 25. Version 20JAN2023

### 25.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **20JAN2023**. This version introduces amendments for some incorrect breed mappings and Veddra LLT codes, newbusiness rule for Nullifications and Follow-ups and DWH improvements.

## 25.2. New improvements from last version

| Issue ID                     | Description                                                                                                                                                        | Component |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVET3-13201                 | Process of rerouting cases to NCAs has been improved adding a retry process, with up to three additional attempts, when ACK is not received.                       | Messaging |
| EVVET3-13515<br>EVVET3-12906 | New business rule to restrict nullifications and follow-ups of VICH and DEG cases only to the Original sender of the first valid case.                             | Messaging |
| EVVET3-12953                 | DWH-OBIEE Access policy implementation.                                                                                                                            | DWH       |
| EVVET3-13738                 | AER data for NON-CAPS products now available in Public reports website.                                                                                            | DWH       |
| EVVET3-12951                 | Performance improvement: Split results table from Signal detection dashboard into 3 separate tables (Signal detection with 2 RORs, up to Date 1 and up to Date 2). | DWH       |
| EVVET3-13755                 | New tab to retrieve all products and substances that do not have any report associated from List of products' dashboard.                                           | DWH       |
| EVVET3-13631                 | 'Switch to table' functionality has been added to all graphs from Signal evaluation dashboard.                                                                     | DWH       |
| EVVET3-13471                 | Product hierarchy selector has been added to Associated product sub-report from Adverse event overview dashboard.                                                  | DWH       |
| EVVET3-12802                 | Product hierarchy selector has been added to Product association tab from Signal evaluation dashboard.                                                             | DWH       |
| EVVET3-13623                 | 'Switch to table' functionality has been added to all graphs from Adverse event overview dashboard.                                                                | DWH       |

## 25.3. Existing issues version 20JAN2023

| Issue ID                                                     | Description                                                                                                                                                                        | Component |
|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| EVVet3-12353                                                 | In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results.                                                      | EVWeb     |
| EVVet3-11678                                                 | In the search AER results table, for some reports, the VICH Batch received date, Species and classification field values are not displayed.                                        | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

| Issue ID                                     | Description                                                                                      | Component |
|----------------------------------------------|--------------------------------------------------------------------------------------------------|-----------|
| EVVet3-14164<br>EVVet3-13810<br>EVVet3-13809 |                                                                                                  |           |
| EVVet3-13916                                 | Adverse event overview and Data stratification - Line listing display irrelevant records.        | DWH       |
| EVVet3-13122                                 | Adverse event overview report - Issue with data in the graphs displaying data for last 10 years. | DWH       |

#### 25.4. Fixed issues from last version

| .Issue ID                    | Description                                                                                                                                                                    | Component |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVET3-12693<br>EVVET3-12905 | Breed mapping DEG/VICH incorrectly applied by system for 6 breeds.                                                                                                             | Messaging |
| EVVET3-13015                 | DEG dosage form "271 - premix for medicated stuff" has been remapped to VICH "C42969 - PELLET".                                                                                | Messaging |
| EVVET3-13129<br>EVVET3-12497 | Impossible to submit follow-up reports when Unique AER ID contains special character "/".                                                                                      | EVWeb     |
| EVVET3-13129                 | Fixed 4011 affected reports that were incorrectly classified as error although no validity errors were detected.                                                               | Messaging |
| EVVET3-14021                 | Validity errors with LLT Veddra codes 529, 530, 2354, 1909, and 3035.                                                                                                          | Messaging |
| EVVET3-13287                 | Age and Weight information are not displayed in Line Listing.                                                                                                                  | DWH       |
| EVVET3-13203                 | In 'data stratification' dashboard, when using 'And not' operator from VEDDRA filter, the system is incorrectly retrieving thenumber of reports for the excluded Veddra terms. | DWH       |
| EVVET3-12891                 | When 'Date of OnSet' in EVWEB is informed as MM/YYYY or YYYY, DWH is not retrieving the correct date.                                                                          | DWH       |

## 26. Version 8AUG2022

### 26.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **8AUG2022**. This version introduces a new functionality to Export in CSV the results table of a search in "Search AE Reports" section and corrections for some incorrect breed mappings.

### 26.2. New improvements from last version

| Issue ID     | Description                                                                                  | Component |
|--------------|----------------------------------------------------------------------------------------------|-----------|
| EVVET3-12161 | New functionality to export the results table in "Search AE Reports" sections to a CSV file. | EVWeb     |

### 26.3. Existing issues version 8AUG2022

| Issue ID                                                                                     | Description                                                                                                                                                                        | Component |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| EVVet3-12353                                                                                 | In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results.                                                      | EVWeb     |
| EVVet3-11678                                                                                 | In the search AER results table, for some reports, the VICH Batch received date and Species field values are not displayed.                                                        | EVWeb     |
| EVVET3-12693<br>EVVET3-12905                                                                 | Breed mapping DEG/VICH incorrectly applied by system for 6 breeds.                                                                                                                 | Messaging |
| EVVET3-12625                                                                                 | Classification criteria filter does not return the correct results.                                                                                                                | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-11276<br>EVVet3-11681 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |
| EVVET3-13287                                                                                 | Age and Weight information are not displayed in Line Listing.                                                                                                                      | DWH       |
| EVVET3-13203                                                                                 | In 'data stratification' dashboard, when using 'And not' operator from VEDDRA filter, the system is incorrectly retrieving the number of reports for the excluded Veddra terms.    | DWH       |
| EVVET3-12891                                                                                 | When 'Date of OnSet' in EVWEB is informed as MM/YYYY or YYYY, DWH is not retrieving the correct date.                                                                              | DWH       |

### 26.4. Fixed issues from last version

| Issue ID     | Description                                                         | Component |
|--------------|---------------------------------------------------------------------|-----------|
| EVVET3-12551 | Breed mapping DEG/VICH incorrectly applied by system for 17 breeds. | Messaging |

## 27. Version 21JUL2022

### 27.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **21JUL2022**. This version introduces changes in the business rules applicable for AER submissions through EVWEBApplication and Gateway.

### 27.2. New improvements from last version

| Issue ID     | Description                                                                                                                                                                           | Component |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVET3-12743 | Amended rule 92 to allow initial/other submissions with same Unique AER Number when occur country is non-EEA.                                                                         | Messaging |
| EVVET3-12742 | Rule 256 has been changed from Error to Warning, to allow submission of AERs when AER ID in field B.6.1. Linked UniqueAER Number is not in the database and/or not in the same batch. | Messaging |
| EVVET3-12521 | Rule 104 has been changed from Error to Warning, allowing the submission of a AERs when the number of animals affected is higher than the number of animals treated.                  | Messaging |

### 27.3. Existing issues version 21JUL2022

| Issue ID                                                                                     | Description                                                                                                                                                                        | Component |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| EVVet3-12353                                                                                 | In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results.                                                      | EVWeb     |
| EVVet3-11678                                                                                 | In the search AER results table, for some reports, the VICH Batch received date and Species field values are not displayed.                                                        | EVWeb     |
| EVVet3-12551<br>EVVET3-12693<br>EVVET3-12905                                                 | Breed mapping DEG/VICH incorrectly applied by system for 19 breeds.                                                                                                                | Messaging |
| EVVET3-12625                                                                                 | Classification criteria filter does not return the correct results.                                                                                                                | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-11276<br>EVVet3-11681 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 27.4. Fixed issues from last version

N/A

## 28. Version 4JUL2022

### 28.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **4Jul2022**. This version introduces changes in EvWeb report forms, removing any Personal Data information from the

HTML and XML exports and from the EVVet Database, in compliance with EMA GDPR policy. Additionally, minor defects have also been corrected.

## 28.2. New improvements from last version

| Issue ID                     | Description                                                                                                                                                                                                                                                                                                                                                                                                                         | Component |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-12359<br>EVVet3-12322 | <p>In the EvWeb HTML and XML exports, personal data information has been removed, in compliance with GDPR:</p> <ul style="list-style-type: none"> <li>A.2.2 Person Acting on Behalf of MAH</li> <li>A.3.2 Other Reporter</li> <li>A.3.1 Primary Reporter (only Last Name, Country, and Primary Reporter Category fields are visible)</li> </ul> <p>A Datafix has been applied to wipe out this information from EVVet Database.</p> | EVWeb     |
| EVVet3-10941                 | Checkbox as a new filter has been included in all dashboards to get the results based only on the Medical Important Events.                                                                                                                                                                                                                                                                                                         | DWH       |
| EVVet3-13016                 | The minimum of 10 reports for getting results in 'Signalling for reaction linked to a product or ingredient' has been eliminated.                                                                                                                                                                                                                                                                                                   | DWH       |

## 28.3. Existing issues version 4JUL2022

| Issue ID                                                                                     | Description                                                                                                                                                                        | Component |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| EVVet3-12353                                                                                 | In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results.                                                      | EVWeb     |
| EVVet3-11678                                                                                 | In the search AER results table, for some reports, the VICH Batch received date and Species field values are not displayed.                                                        | EVWeb     |
| EVVet3-12551                                                                                 | Breed mapping DEG/VICH incorrectly applied by system for 19 breeds.                                                                                                                | Messaging |
| EVVET3-12625                                                                                 | Classification criteria filter does not return the correct results.                                                                                                                | EVWeb     |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-11276<br>EVVet3-11681 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |
| EVVet3-13205                                                                                 | MAH filter is not working as expected as it is retrieving wrong information (DWH dashboards and Analysis functionality)                                                            |           |

| Issue ID     | Description                                                                                                                                                  | Component |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-13203 | When using 'And not' in VedDRA filter in <i>Data stratification</i> dashboard, it is not excluding the VedDRA terms selected.                                |           |
| EVVet3-13122 | In 'Adverse Event Overview' dashboard, graph regarding Last years is not showing the complete 10 years. It is counting from the exact day the query is done. |           |

#### 28.4. Fixed issues from last version

| Issue ID     | Description                                                                                                                                           | Component |
|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-12544 | In the search AER screen, a classification value has been corrected to "Duplicated" (from "duplicate"), both in the resultstable and criteria values. | EVWeb     |

## 29. Version 7JUN2022

### 29.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **7JUN2022**. This version introduces changes in EvWeb report forms, removing any Personal Data information from the user interface, in compliance with EMA GDPR policy. Additionally, minor defects have also been corrected.

### 29.2. New improvements from last version

| Issue ID                   | Description                                                                                                                                                                                                                                                                                                                     | Component |
|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-12359               | In the EvWeb reporting forms, personal data fields have been removed, in compliance with GDPR: <ul style="list-style-type: none"> <li>A.2.2 Person Acting on Behalf of MAH</li> <li>A.3.2 Other Reporter</li> <li>A.3.1 Primary Reporter (only Last Name, Country, and Primary Reporter Category fields are visible)</li> </ul> | EVWeb     |
| EVVet3-11631               | Both the catalogue and the subject area have been renamed as 'EVVET3 DWH'                                                                                                                                                                                                                                                       | DWH       |
| EVVet3-9876<br>EVVet3-9873 | MAH filter has been added in the following dashboards: <ul style="list-style-type: none"> <li>Data stratification</li> <li>Adverse event comparison between 2 periods</li> </ul>                                                                                                                                                | DWH       |
| EVVet3-9868<br>EVVet3-9867 | Seriousness has been removed both from all dashboards in the(1) Public reports and (2) DWH platform                                                                                                                                                                                                                             | DWH       |
| EVVet3-7232                | Breed filter values will depend on the selected specie in all dashboards                                                                                                                                                                                                                                                        | DWH       |

### 29.3. Existing issues version 7JUN2022

| Issue ID                                                                                     | Description                                                                                                                                                                        | Component |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                     | EVWeb     |
| EVVet3-12353                                                                                 | In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results.                                                      | EVWeb     |
| EVVet3-11678                                                                                 | In the search AER results table, for some reports, the VICH Batch received date and Species field values are not displayed.                                                        | EVWeb     |
| EVVet3-12551                                                                                 | Breed mapping DEG/VICH incorrectly applied by system for 19 breeds.                                                                                                                | Messaging |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-11276<br>EVVet3-11681 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard. | DWH       |

### 29.4. Fixed issues from last version

| Issue ID     | Description                                                                                                                                                                                                  | Component |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11712 | In the search AER results table, for some reports, Age field values are not displayed correctly (no decimals, duplicates values).                                                                            | EVWeb     |
| EVVet3-12101 | When creating a report, it is no possible to link reports (section B.6) contained in the same batch.                                                                                                         | EVWeb     |
| EVVet3-12205 | In the search AER results table, sorting fails for large dataset results.                                                                                                                                    | EVWeb     |
| EVVet3-12163 | When accessing any report, for some fields (i.e., Country, species, AER Term name, ATC, Receiver) a comma is displayed before the actual value in the UI. The defect doesn't impact the download (HTML/XML). | EVWeb     |
| EVVET3-12536 | Classification field names have been corrected in Search AE Reports results table, consistent now with criteria search values.                                                                               | EVWeb     |
| EVVet3-11987 | In the line listing details, when the reported animal age was Unknown, the Datawarehouse reports displayed a '-1'.                                                                                           | DWH       |
| EVVet3-12558 | Line listing from <i>Adverse Event overview</i> dashboard was open in the same window. Now it is open in a new window.                                                                                       | DWH       |

| Issue ID                                     | Description                                                                                                                                                                                                                                                                                                                                            | Component |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-12437<br>EVVet3-12435<br>EVVet3-12434 | The number of records displayed in the line listing does not match the number clicked in the following dashboards: <ul style="list-style-type: none"> <li><i>Data stratification report – Line listing</i></li> <li><i>Adverse event overview – Line listing</i></li> <li><i>Signal evaluation – Product association tab – Line listing</i></li> </ul> | DWH       |
| EVVet3-12358                                 | In <i>Adverse event overview</i> dashboard, the <i>Number of fatal cases (Total all)</i> shows the same value as the <i>Number of fatal cases (period specified)</i>                                                                                                                                                                                   | DWH       |
| EVVet3-11681                                 | In the <i>Product stratification</i> tab from the <i>Data stratification</i> dashboard, graph number 2 is not loaded.                                                                                                                                                                                                                                  | DWH       |

## 30. Version 11MAY2022

### 30.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. **11MAY2022**. This version enhances the searches functionalities in the EvWeb application and improves the SignalEvaluation and Adverse Event Overview dashboards in the EVVet Datawarehouse.

### 30.2. New improvements from last version

| Issue ID                                                                                                                     | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Component |
|------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11676<br>EVVet3-10977<br>EVVet3-11995<br>EVVet3-10758<br>EVVet3-11180<br>EVVet3-11983<br>EVVet3-12193<br>EVVet3-11994 | In the Search AER section, criteria/filter and search results have been improved: <ul style="list-style-type: none"> <li>Sender, Product MAH, Occur country and products/substance criteria filters are now multi select fields, allowing inclusion and exclusion</li> <li>Report Classification has been added as criteria/filter and as field/column</li> <li>Product and Substances criteria have been added as a fields/column in the results table</li> <li>Sorting has been enabled for all the fields/columns where only one value exists</li> <li>Product recoding date has been added as new criteria/filter and new field/column in the results table</li> </ul> | EVWeb     |
| EVVet3-10935                                                                                                                 | The routing ID has been added next to the organisation name within the organisation's selector that is displayed after logging in.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | EVWeb     |
| EVVet3-12120<br>EVVet3-11883                                                                                                 | Analysis by Scientific Product has been improved to retrieve only those reports with the right level of product information.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | DWH       |

| Issue ID                   | Description                                                                                                                                                                                                                                                          | Component |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9402<br>EVVet3-9374 | In the Signal Evaluation dashboard: <ul style="list-style-type: none"> <li>ATC vet name has been added next to the ATC vetcode, for the Product information tab</li> <li>Filtering by 'Unknown' products has been enabled, in the Product association tab</li> </ul> | DWH       |
| EVVet3-9599<br>EVVet3-8888 | In the Adverse Event Overview dashboard: <ul style="list-style-type: none"> <li>Lowest level of ATC vet is now displayed, in the Seedetails section</li> <li>MAH filter has been added, in the filters section</li> </ul>                                            | DWH       |
| EVVet3-9601                | In the Line Listing dashboard, the order of the tabs has beeninterchanged to make it more logical.                                                                                                                                                                   | DWH       |

### 30.3. Existing issues version 11MAY2022

| Issue ID                                                     | Description                                                                                                                                                                                                  | Component |
|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                                               | EVWeb     |
| EVVet3-12101                                                 | When creating a report, it is no possible to link reports (section B.6) contained in the same batch.                                                                                                         | EVWeb     |
| EVVet3-12353<br>EVVet3-12344                                 | In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results.                                                                                | EVWeb     |
| EVVet3-11712                                                 | In the search AER results table, for some reports, Age field values are not displayed correctly (no decimals, duplicates values).                                                                            | EVWeb     |
| EVVet3-11678                                                 | In the search AER results table, for some reports, the VICH Batch received date and Species field values are not displayed.                                                                                  | EVWeb     |
| EVVet3-12163                                                 | When accessing any report, for some fields (i.e., Country, species, AER Term name, ATC, Receiver) a comma is displayed before the actual value in the UI. The defect doesn't impact the download (HTML/XML). | EVWeb     |
| EVVet3-12551                                                 | Breed mapping DEG/VICH incorrectly applied by system for 19 breeds.                                                                                                                                          | Messaging |
| EVVet3-12205                                                 | In the search AER results table, sorting fails for large dataset results.                                                                                                                                    | EVWeb     |
| EVVet3-11987                                                 | In the line listing details, when the reported animal age was Unknown, the Datawarehouse reports displayed a '-1'.                                                                                           | DWH       |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard.                           | DWH       |

| Issue ID                     | Description | Component |
|------------------------------|-------------|-----------|
| EVVet3-11276<br>EVVet3-11681 |             |           |

### 30.4. Fixed issues from last version

| Issue ID                     | Description                                                                                                                                                                                                                                        | Component |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11660<br>EVVet3-11703 | The profile section does not show the correct Responsible Person Information.                                                                                                                                                                      | EVWeb     |
| EVVet3-12189                 | In the Search AER section, searching by products and substances is case sensitive.                                                                                                                                                                 | EVWeb     |
| EVVet3-12164<br>EVVet3-11900 | When filling a new AER, for limited UPD products, the active substance and the procedure number are not retrieved after picking the UPD product.                                                                                                   | EVWeb     |
| EVVet3-11615                 | There are some dosage forms that are missing in the collectionData Base. <ul style="list-style-type: none"> <li>Example product: Ubrolexin intramammary suspension for lactating dairy cows. Missing dosage form: Intramammary solution</li> </ul> | EVWeb     |
| EVVet3-11648                 | For some users it is not possible to download inbox/outbox messages.                                                                                                                                                                               | EVWeb     |
| EVVet3-11142                 | When performing a search (from Search AE Reports) filtering by criteria 'Correct report, with warnings, errors', does not retrieve the correct results.                                                                                            | EVWeb     |
| EVVet3-6581                  | When filling an AER, it is possible to deselect any radio button(e.g., Use according to label).                                                                                                                                                    | EVWeb     |
| EVVet3-12323                 | In the Adverse Event overview, ROR is shown at all VedDRA levels in 'see details' view.                                                                                                                                                            | DWH       |
| EVVet3-12231                 | Some deprecated substances were considered active in the DWH dashboards.                                                                                                                                                                           | DWH       |
| EVVet3-12129                 | In the Adverse Event Overview dashboard, for edge scenarios, the line listing is not retrieving results.                                                                                                                                           | DWH       |
| EVVet3-11896                 | Error message when logging out.                                                                                                                                                                                                                    | DWH       |

## 31. Version 20APR2022

### 31.1. Overview

First release to production environment after Go Live regarding Pharmacovigilance VET3 system.

### 31.2. Existing issues in version 20APR2022

| Issue ID                                                                     | Description                                                                                                                                                                                                                                                | Component |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11142                                                                 | When performing a search (from Search AE Reports) filtering by criteria 'Correct report, with warnings, errors', does not retrieve the correct results.                                                                                                    | EVWeb     |
| EVVet3-9647<br>EVVet3-8613<br>EVVet3-8612                                    | The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in).                                                                                                                             | EVWeb     |
| EVVet3-11660                                                                 | Profile section does not show the correct Responsible Information.                                                                                                                                                                                         | EVWeb     |
| EVVet3-11615                                                                 | There are some dosage forms that are missing in the collection Data Base. <ul style="list-style-type: none"><li>• <i>Example product: Ubrolexin intramammary suspension for lactating dairy cows. Missing dosage form: Intramammary solution</i></li></ul> | EVWeb     |
| EVVet3-11648                                                                 | For some users it is not possible to download inbox/outbox messages.                                                                                                                                                                                       | EVWeb     |
| EVVet3-11900                                                                 | Dropdown menu for UPD products (field B.2.1) should show the Authorisation Identifier instead the procedure number.                                                                                                                                        | EVWeb     |
| EVVet3-12101                                                                 | Impossible to link reports (section B.6).                                                                                                                                                                                                                  | EVWeb     |
| EVVet3-11445                                                                 | Some duplicates values can be found in the list of Primary Source Categorisation (section 6, optional report filter in Adverse event overview dashboard).                                                                                                  | DWH       |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275<br>EVVet3-11276 | The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables).                                                                                                                            | DWH       |

### 31.3. Fixed issues from last version

| Issue ID     | Description                                                                                                                                                                                                                                                                                         | Component |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11469 | Sometimes, when importing a report through an XML file, there are some fields that are not populated in the form. If user clickson 'validate' or 'validate and Send', there are some missing validation messages that should appear regarding these missing fields (e.g., Country - A.1.4.1 field). | Messaging |
| EVVet3-11670 | Warning message (rule 148) 'Registered Name or Brand Name:The field Registered Name or Brand Name - B.2.1 could not bematched against product and substance information database" appearing when selecting some products.                                                                           | Messaging |

| Issue ID     | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Component |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11666 | Domestic vs Foreign Report category field (B.8.2.6) is absent when downloading reports in XML format.                                                                                                                                                                                                                                                                                                                                                              | EVWeb     |
| EVVet3-8615  | VeDDRA terms are not displayed in the UI when opening a report.                                                                                                                                                                                                                                                                                                                                                                                                    | EVWeb     |
| EVVet3-11401 | Download of HTML and XML reports in EVWEB is taking too long.                                                                                                                                                                                                                                                                                                                                                                                                      | EVWeb     |
| EVVet3-11880 | The line listings either takes a long time to appear or does not appear at all.                                                                                                                                                                                                                                                                                                                                                                                    | DWH       |
| EVVet3-11688 | Adverse Event Overview. Concerns the chart Number of cases and fatal cases (Last 10 years). The user can see a line listing report by clicking in any of the bars displayed within this chart (10 years span), but when clicked in a year not included in the filters previously set, line listing's column Number of Cases (Period Specified) is filled with zeros. The solution implemented is that, when the user clicks on those, the report shows no results. | DWH       |
| EVVet3-11650 | Analysis made by the user in the subject area didn't match with the table displayed within the Signal Evaluation dashboard - Product Association tab, link in the far left "Cases with no other products reported". Not all the species shown in the subject area were displayed in this report's dropdown.                                                                                                                                                        | DWH       |

## 32. Version 28JAN2022

### 32.1. Overview of EVVet3 functionality

This release to production environment will bring the new EudraVigilance Veterinary 3 (EVVet3) system live on the 28 of January 2022. The system, that is compliant with VICH guidelines, will be enhanced in future releases. From now the go-live of the system the EVVet2 system will be disabled, so the Adverse Event Reports (AERs) will need to be sent via EVVet3-EVWeb system.

### 32.2. Functionalities

| Deployed features    |              |                                  |
|----------------------|--------------|----------------------------------|
| Access Management    |              | Access policy                    |
|                      |              | Authentication and authorisation |
| Transactional system | EVWeb (AERs) | Create AERs                      |
|                      |              | Submit AERs                      |
|                      |              | View AERs                        |
|                      |              | Import/Export AERs               |
|                      |              | Follow-up / nullify AERs         |

|                        |                                                      |                                                                      |                      |
|------------------------|------------------------------------------------------|----------------------------------------------------------------------|----------------------|
|                        |                                                      | Search AER:<br>Search reports<br>Search Mailbox<br>Search VICH Batch |                      |
|                        | Message processing                                   | Process and load                                                     |                      |
|                        |                                                      | Business rules                                                       |                      |
|                        |                                                      | NCA Re-routing                                                       |                      |
|                        | <b>Data warehouse</b><br>(Analytics & Reporting AER) |                                                                      | Compliance Dashboard |
|                        |                                                      |                                                                      | MAH Dashboard        |
| Signal detection       |                                                      |                                                                      |                      |
| Public Dashboard       |                                                      |                                                                      |                      |
| Signal evaluation      |                                                      |                                                                      |                      |
| Data stratification    |                                                      |                                                                      |                      |
| <b>Data Processing</b> |                                                      | UPD Integration                                                      |                      |
|                        |                                                      | Products and Substance Recoding                                      |                      |

### 32.3. Existing issues in version 28JAN2022

| Issue ID                                                                | Description                                                                                                                                                                                                                                                                                          | Component |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| EVVet3-11469                                                            | Sometimes, when importing a report through an XML file, there are some fields that are not populated in the form. If user clicks on 'validate' or 'validate and Send', there are some missing validation messages that should appear regarding these missing fields (e.g., Country - A.1.4.1 field). | EVWeb     |
| EVVet3-11142                                                            | When performing a search (from Search AE Reports) filtering by criteria 'Correct report, with warnings, errors', the retrieved data is not the correct one.                                                                                                                                          | EVWeb     |
| EVVet3-9648<br>EVVet3-9647<br>EVVet3-8615<br>EVVet3-8613<br>EVVet3-8612 | In the EVWeb, the system may show some minor lower performance when executing some specific actions (e.g., running search by some criteria or log in).                                                                                                                                               | DWH       |
| EVVet3-11445                                                            | Some duplicates values can be found in the list of Primary Source Categorization (section 6, optional report filter in Adverse event overview dashboard).                                                                                                                                            | DWH       |
| EVVet3-11272<br>EVVet3-11273<br>EVVet3-11274<br>EVVet3-11275            | In the DWH, the system may show some minor lower performance when executing some specific actions (e.g., Drop, ordering columns on dashboard tables).                                                                                                                                                | DWH       |

| Issue ID                     | Description | Component |
|------------------------------|-------------|-----------|
| EVVet3-11276<br>EVVet3-11277 |             |           |