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EVVet3 Production – Release notes

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1. Version 1.4

1.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v 1.4.

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.

1.2. New improvements from last version

Issue ID	Description	Component
EVVet3-12359 EVVet3-12322	In the EvWeb HTML and XML exports, personal data information have been removed, in compliance with GDPR: - A.2.2 Person Acting on Behalf of MAH - A.3.2 Other Reporter - A.3.1 Primary Reporter (only Last Name, Country, and Primary Reporter Category fields are visible) A Datafix has been applied to remove this information from EVVet Database.	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 ' <i>Signalling for reaction linked to a product or ingredient</i> ' has been eliminated.	DWH

1.3. Existing issues version 1.4

Issue ID	Description	Component
EVVet3-9647 EVVet3-8613 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	EVWeb
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276 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

1.4. Issues fixed 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 results table and criteria values.	EVWeb

2. Version 1.3

2.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v 1.3.

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.

2.2. 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: - A.2.2 Person Acting on Behalf of MAH - A.3.2 Other Reporter - A.3.1 Primary Reporter (only Last Name, Country, and Primary Reporter Category fields are visible)	EVWeb
EVVet3-11631	Both the catalog and the subject area have been renamed as 'EVVET3 DWH'	DWH
EVVet3-9876 EVVet3-9873	MAH filter has been added in the following dashboards: - Data stratification - Adverse event comparison between 2 periods	DWH
EVVet3-9868 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

2.3. Existing issues version 1.3

Issue ID	Description	Component
EVVet3-9647 EVVet3-8613 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	EVWeb
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276 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

2.4. Issues fixed 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
EVVet3-12437 EVVet3-12435 EVVet3-12434	The number of records displayed in the line listing does not match the number clicked in the following dashboards: - <i>Data stratification report – Line listing</i> - <i>Adverse event overview – Line listing</i> - <i>Signal evaluation – Product association tab – Line listing</i>	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

3. Version 1.2

3.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v 1.2.

This version enhances the searches functionalities in the EvWeb application and improves the Signal Evaluation and Adverse Event Overview dashboards in the EVVet Datawarehouse.

3.2. New improvements from last version

Issue ID	Description	Component
EVVet3-11676 EVVet3-10977 EVVet3-11995 EVVet3-10758 EVVet3-11180 EVVet3-11983 EVVet3-12193 EVVet3-11994	In the Search AER section, criteria/filter and search results have been improved: <ul style="list-style-type: none"> - Sender, Product MAH, Occur country and Products/substance criteria filters are now multi select fields, allowing inclusion and exclusion - Report Classification has been added as criteria/filter and as field/column - Product and Substances criteria have been added as a fields/column in the results table - Sorting has been enabled for all the fields/columns where only one value exists - Product recoding date has been added as new criteria/filter and new field/column in the results table 	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 EVVet3-11883	Analysis by Scientific Product has been improved to retrieve only those reports with the right level of product information.	DWH
EVVet3-9402 EVVet3-9374	In the Signal Evaluation dashboard: <ul style="list-style-type: none"> - ATC vet name has been added next to the ATC vet code, for the Product information tab - Filtering by 'Unknown' products has been enabled, in the Product association tab 	DWH
EVVet3-9599 EVVet3-8888	In the Adverse Event Overview dashboard: <ul style="list-style-type: none"> - Lowest level of ATC vet is now displayed, in the See details section. - MAH filter has been added, in the filters section 	DWH
EVVet3-9601	In the Line Listing dashboard, the order of the tabs has been interchanged to make it more logical.	DWH

3.3. Existing issues version 1.2

Issue ID	Description	Component
EVVet3-9647 EVVet3-8613 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 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

Issue ID	Description	Component
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	EVWeb
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 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276 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

3.4. Issues fixed from last version

Issue ID	Description	Component
EVVet3-11660 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 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 collection Data Base. Example product: Ubrolexin intramammary suspension for lactating dairy cows Missing dosage form: Intramammary solution	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

4. Version 1.1

4.1. Overview

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

4.2. Existing issues in version 1.1

Issue ID	Description	Component
EVVet3-11142	When performing a search (from Search AE Reports) filtering by criteria ' <i>Correct report, with warnings, errors</i> ', does not retrieve the correct results	EVWeb
EVVet3-9647 EVVet3-8613 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. Example product: Ubrolexin intramammary suspension for lactating dairy cows Missing dosage form: Intramammary solution	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 Authorization 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 <i>Primary Source Categorization</i> (section 6, optional report filter in Adverse event overview dashboard)	DWH
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276	The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables)	DWH

4.3. Issues fixed 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 clicks on ' <i>validate</i> ' or ' <i>validate and Send</i> ', there are some missing validation messages that should appear regarding these missing fields (e.g., <i>Country - A.1.4.1</i> field)	EVWeb
EVVet3-11670	Warning message (rule 148) ' <i>Registered Name or Brand Name: The field Registered Name or Brand Name - B.2.1 could not be matched against product and substance information database</i> ' appearing when selecting some products.	EVWeb

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

5. Version 1.0

5.1. 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.

5.2. Functionalities

Deployed features		
Access Management		Access policy
		Authentication and authorisation
Transactional system	<i>EVWeb (AERs)</i>	Create AERs
		Submit AERs
		View AERs
		Import/Export AERs
		Follow-up / nullify AERs
		Search AER: <ul style="list-style-type: none"> • Search reports • Search Mailbox • Search VICH Batch
	<i>Message processing</i>	Process and load
		Business rules
		NCA Re-routing
	Data warehouse <i>(Analytics & Reporting AER)</i>	Compliance Dashboard
MAH Dashboard		
Signal detection		
Public Dashboard		
Signal evaluation		
Data stratification		
Data Processing	UPD Integration	
	Products and Substance Recoding	

5.3. Existing issues in version 1.0

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

Issue ID	Description	Component
EVVet3-9648 EVVet3-9647 EVVet3-8615 EVVet3-8613 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 <i>Primary Source Categorization</i> (section 6, optional report filter in Adverse event overview dashboard)	DWH
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276 EVVet3-11277	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