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EudraVigilance System v.1.3 Release Notes

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About this document

This document lists and briefly describes the following areas for the releases of the EudraVigilance system. This includes the EudraVigilance messaging system, the EVWEB interface and the EV post function:

- **What's New:** The enhancements and other changes released (new feature).
- **Known Issues:** The issues that exist (open issue).
- **Fixed Issues:** The issues that are fixed (fixed issue).
- **Points to Note:** The important aspects to keep in mind (point to note).

Release date: 18th December 2017

Fixed Issues:

Id	Description	Status
1	When using the ICSR Download functionality, limiting the search to non-serious ICSRs did not always work as expected and users had sometimes retrieve serious ICSRs in their results too. (Note: no ICSRs were missing from the downloaded files but are rather duplicated, i.e. present in both search for non-serious and serious ICSRs)	Closed
2	Country filter in ICSR Download should allow entering more than one country.	Closed
3	Business Rules 109 and 696 need to be enabled to correctly validate consistency between Primary Source Country, Reporter Country and Reporter State for Spain.	Closed
4	Webtrader Users: not able to open a message received from another user.	Closed
5	When reviewing ICSRs sent before 8 November 2017 in the Webtrader Outbox, the associated ACKs could not be viewed from the Outbox.	Closed
6	Webtrader users were not able to open an ICSR message submitted before 8 November 2017.	Closed

Known Issues:

Id	Description	Proposed workaround	Status
1	UTC Time zone offset is not stored in the database.	N/A	Open
2	If a test result unit is set to "DF – Dosage Form" an incorrect error message is displayed.	The "DF – Dosage Form" value for Test Result Unit should not be selected.	Open
3	Age at Time of Onset of Reaction / Event (D.2.2a) and Age of Parent (D.10.2.2a) fields may accept values greater than the limit of 150 and longer than 3 characters without returning a validation error. This causes the message not to be processed correctly.	Age at Time of Onset of Reaction / Event (D.2.2a) and Age of Parent (D.10.2.2a) should be set <=150.	Open

Id	Description	Proposed workaround	Status
4	If an acknowledgment for a re-routed ICSR contains a lower case "ICSR Batch Number", EVWEB does not stop sending the re-routed original ICSR.	Acknowledgments sent for re-routed ICSRs should contain upper-case "ICSR Batch Number".	Open
5	The "World Wide Case ID" field is case- sensitive when nullifying an ICSR and when filtering is applied in the ICSR download screen.	When nullifying an existing ICSR and when performing a search using the ICSR Download screen, the "World Wide Case ID" should match exactly the one in the original message.	Open
6	The "Error Message or Comment" section in acknowledgements sent by EVHUMAN contains the case ID instead of the EV Report ID.	N/A	Open
7	If the field Parent Identification (D.10.1) is masked in the ICSR, it appears as blank in the exported RTF file.	N/A	Open
8	ICSRs submitted in ICH E2B(R3) format where the reaction or drug end date is provided (in the same year of the reaction or drug start date) as an incomplete format may result in the ICSRs receiving a negative acknowledgement.	For ICSRs that have this issue, the end date should be left blank. The incomplete end date should then be provided in the field "Additional Information on Drug" for the drug end date or the "case narrative" field for the reaction end date.	Open
9	The ICSR download option "PV obligations reports (L2A) & MLM reports" produce unexpected results (either more MLM cases than desired or fewer L2A cases than required).	The ICSR download option "PV obligations reports (L2A) & MLM reports" have been disabled. The 2 ICSR download functionality should be run separately: L2A without filtering on drugs, MLM with filtering on substances as is performed presently.	Open
10	An error may occur when importing ICH ICSR messages into the workspace area of EVWEB from the ICSR search section. Other imports into the workspace are not affected by this.	The "Safety reports" search option in the ICSR section of EVWEB should be used instead of importing ICSRs into the workspace area of EVWEB.	Open

Id	Description	Proposed workaround	Status
11	For XML files created by EudraVigilance the non-mandatory field Reporter's telephone number (C.2.r.2.7) - is not created as recommended by the ICH E2B technical document when the data is marked as masked. When this field is masked it will be provided as follows: <telecom nullFlavor="MSK"/>	N/A	Open
12	Performance of ICSR Download functionality for MAH can vary during the day.	N/A	Under monitoring by EMA
13	The L2B access to case narratives is currently under final validation and will be enabled at the same time as the MAH eRMR is made available to users.	N/A	Open
14 - New	Saved L2A requests (json file) using filter for primary source country, generates list of all countries apart from those countries that are part of the request.	When manually creating/changing L2A filters that include primary source country users need to be aware that the full list of countries needs to be used and the ones of interest should be removed.	Open

Points to Note:

1. It is recommended to use Google Chrome, Mozilla Firefox or Internet Explorer 11 as preferred internet browsers.
2. ICH regional data elements are not supported. Therefore ICSRs containing these non-EU regional data elements may not receive acknowledgements.

Proposed workaround: Do not include non-EU regional data elements.
3. ICSR download requests pending for more than 2 days will be cancelled by EMA. Users are advised to re-run the ICSR down-load requests.