



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EudraVigilance Web Application (EVWEB) XCOMP v.3.0: Release Notes

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About this document

This document lists and briefly describes the following areas for the releases of EVWEB:

- **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: 22 November 2017

Id	Description	Proposed workaround	Status
1	UTC Time zone offset is not stored in the database.	N/A	Open
2	Messages sent to an invalid receiver do not get an error acknowledgment.	N/A	Open
3	R3 messages sent from a Gateway user to another Gateway user are missing the Schema reference information in the XML.	N/A	Open
4	If a test result unit is set to "DF – Dosage Form" an incorrect error message is displayed.	Do not select "DF – Dosage Form" value for Test Result Unit.	Open
5	Reporter's telephone number (C.2.r.2.7) - Masked data not captured correctly.	N/A	Open
6	No error is returned when setting the field Additional documents (C.1.6.1) to "Yes" and Additional documents section (C.1.6.1.r.1/2) empty.	Set Additional documents (C.1.6.1) to "No" if no additional document is included.	Open
7	Age of Parent field (D.10.2.2a) field accepts up to 5 characters without getting a validation error.	N/A	Open
8	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
9	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
10	If an acknowledgment for a re-routed ICSR contains a lower case "ICSR Batch	Acknowledgments sent for re-routed ICSRs should contain upper-case	Open

Id	Description	Proposed workaround	Status
	Number", EVWEB does not stop sending the re-routed original ICSR.	"ICSR Batch Number".	
11	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
12	The "Error Message or Comment" section in acknowledgements sent by EVHUMAN contains the case ID instead of the EV Report ID.	N/A	Open
13	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
14	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 ICSR receiving a negative acknowledgement.	For ICSR 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
15	The bulk download option "PV obligations reports (L2A) & MLM reports" produce unexpected results (either more MLM cases than desired or fewer L2A cases than required).	The 2 bulk downloads should be run separately: L2A without filtering on drugs, MLM with filtering on substances as is performed presently.	Open
16	When reviewing ICSR sent before 8 November 2017 in the Webtrader Outbox, the associated ACKs cannot be viewed from the Outbox.	The ACKs can be viewed from the Webtrader inbox.	Open
17	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 to import ICSR into the workspace area of EVWEB.	Open

Additional points for your consideration:

1. It is recommended to use Google Chrome or Mozilla Firefox as preferred internet browsers.
2. Product data has been loaded for all registered MAH HQ organisations. The product is called "Product-L2A" and contains the substance "Substance-L2A". Any ICSR submitted with these products or substances will be accessible by all MAHs as L2A access.

3. Sample ICH E2B(R3) ICSR data has been uploaded in XCOMP for testing of the ICSR download functionality; for this purpose ICSRs can be requested by selecting the date range to cover from 20 September 2017.
4. ICH regional data elements are not supported. Therefore ICSRs containing these non-EU regional data elements may not receive acknowledgements.
5. Proposed workaround: Do not include non-EU regional data elements.