



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Information Management

## EudraVigilance Release Notes v.1.12



## 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: 11 April 2018

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## What is New?

The new release of EudraVigilance includes a number of improvements that increase the performance and usability of the system by all stakeholders. Some of these improvements will also enhance aspects of the functionality of the system, which are highlighted below.

Id	Description
1 -	<p>Since 14 February 2018, MAH are now able to filter and download ICSRs based on the sender organisation type: National Competent Authorities (EEA Member States), Other sender organisations (excluding NCAs), All sender organisations.</p> <p>Note that organisations should update their pre-defined filters saved as Json files to incorporate this new filter.</p>
2 -	<p>L2A &amp; L2B downloads filtering added "Current report only"</p> <p>This new filter will exclude ICSRs for download if a newer version of the case has been subsequently received from the same original Sender</p> <p>Note: The newer version of the case will only become available after it has been classified against the XEVMPD data. Therefore first access to an ICSR by an MAH may be delayed if several follow-up versions are received during a short period of time.</p>
3 -	<p>L2A ICSR download "Report type" filter added. User can now select "Spontaneous", "Report from studies", "Other" or "Not available to sender (unknown)"</p>

## Fixed Issues

Id	Description	Status	PHV issue
1	As part of the automatic classification of medicinal product information reported in ICSRs, a number of reports are pending for download by the dedicated EudraVigilance download functionality.	Closed	PHV-6991 PHV-6938
2	Date fields populated as year, month, day or minute are being displayed in EVWEB as though they were entered to the second.  In addition, if a user obtains a case from the ICSR section and then clicks "follow-up", this incorrect level of precision is transposed into the follow-up case and would require correcting.	Closed	PHV-7049
3	When using the ICSR download functionality, 'Study type code' is missing from Study reports when neither the study name nor protocol number are provided by the sender organisation	Closed	PHV-6541
4	EVWEB & L2A downloads are not displaying/providing study type for ICSRs with report type "Reports from studies" where study name is not provided.	Closed	PHV-7042
6	EVWEB: SUSAR Validation process misses check on mandatory drug reaction assessments	Closed	PHV-7170
7	EVWEB: Missing study type information in ICSRs imported into EVWEB are not detected during validation checks	Closed	PHV-6681

## Known Issues

Id	Description	Proposed workaround	Status	PHV issue
1	Processing time out of ICSR messages that contain over 100 ICSRs or ICSRs that contain many reactions, drugs and drug-reaction assessments	Organisations should not put more than 100 ICSRs within a single message. In addition, organisations should follow the MedDRA points to consider term selection when creating ICSRs and the ICH E2B guidance on entering relevant information. ICSRs listing over 50 suspected adverse reactions, 50 drugs and 100 lab test results can cause parsing timeouts.	Open	PHV-6612

Id	Description	Proposed workaround	Status	PHV issue
2	For invalid ICSR messages submitted in E2B (R2) format, negative ack messages may not be returned to the sender organisation by the EudraVigilance system	If no ACK message is received after 48h, please contact EMA service desk.	Open	PHV-6643
3	EV business rule BR538 for E2B (R3) data element F.r.3.4 (Result Unstructured Data (free text)) is not applied, when blank information provided	N/A	Open	PHV-6652
4	E2B(R3) messages containing corrupted attachments do not receive negative acknowledgements	Sender organisations should ensure that they implement the RFC1951 deflate algorithm correctly. If no ACK message is received after 48h, please contact EMA service desk.	Open	PHV-7006
5	The Error message/ comments in the Acknowledgement is not ordered first by Error comments and then by warnings. This means that the Error comments might be truncated from the Acknowledgement message.	Please contact EMA service desk for support if a rejection acknowledgment is received with a truncated error comment.	Open	PHV-6669
6	Sender organisation type is not displaying correctly in the EVWEB interface and ICSR form for some sponsor organisations of clinical trials	No action required. This is a display issue in EV, EMA confirm that the underlying data is correct.	Open	PHV-6930
7	EVWEB users cannot log in when they have used special characters such as '&' and '+' in their EV password	EV password setting page will be updated to prevent this. Latin standard characters [a-z][A-Z][0-9] should be used instead of the listed special characters; accented characters should also not be used.	Open	PHV-6948

Id	Description	Proposed workaround	Status	PHV issue
9	For ICSRs submitted in E2B(R3) format and displayed in the EVWEB interface, the time in the date/time fields is wrongly displayed and do not take into account the two 12-Hour Periods 'AM' and 'PM', e.g. display as 2018/01/30 2:24:26 instead of 2018/01/30 14:24:26.	This only affects the EVWEB interface. In case of any doubt, users are advised to check the row data in the download xml or the ICSR form.	Open	PHV-7113
10 - New	The following business rule is not working as expected: If G.k.7.r.1 is populated, then G.k.7.r.2b Indication (MedDRA code) is Mandatory entry		Open	PHV-7201

## Points to Note

1. It is recommended to use recent version of Google Chrome, Mozilla Firefox or Internet Explorer 11 as preferred internet browsers (see issue 8 above).
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.
4. MAHs should not send acknowledgements for any ICSRs downloaded from EudraVigilance.
5. The EVWEB application is available during EMA office hours 08:30 – 18:00 (UK time), Monday to Friday. EVWEB is also available outside of these hours apart from scheduled maintenance and routine data management tasks.

The following tasks are performed outside of EMA office hours in order to support the operation of EudraVigilance:

- classification of ICSRs against the xEVMPD/Art.57 database;
- detection and management of duplicate ICSRs;
- assignment of the substance based access (Level 2) for MAHs.

These scheduled activities run every day Monday to Sunday between 11:59 p.m. and 04:00 a.m. (UK time). EVWEB services resume as soon as these automated tasks have completed. Access to EVWEB is not possible whilst these activities are being performed and during which a maintenance page is displayed.

If a larger than normal number of ICSRs is received within a day, the system may become available again later than 04:00 a.m. UK time. However, in such situations EVWEB should still be accessible from 08:30 a.m. (UK time) (EMA office hours).

- ICSR download requests launched by MAHs that have not completed before the scheduled maintenance and data management activities start, are made available as soon as the EVWEB interface is available again.
  - Submissions made via the EudraVigilance gateway are not affected by the scheduled maintenance and data management activities, however acknowledgements will be returned after these processes have finished.
6. All service issues/outages are reported on the EMA service desk homepage at <https://servicedesk.ema.europa.eu>. Please consult this page to check on the EudraVigilance service availability