



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

EudraVigilance Checklist for national Competent Authorities in the EEA

In support of the go-live of the enhanced EudraVigilance System

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| Agreement by the Pharmacovigilance Business Team | 18 May 2017 |
| Agreement by the EudraVigilance Expert Working Group (Members of national Competent Authorities) | 18 May 2017 |
| Agreement by the IT Directors of the EU Telematics Governance | 23 May 2017 |
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1. Introduction

Complimentary to the **EudraVigilance Stakeholder Change Management Plan** adopted by the pharmacovigilance governance and published in 2015 on the dedicated [EudraVigilance change management webpage](#), this checklist has been prepared to provide a summary of easy to follow steps to assist national Competent Authorities (NCAs) in preparing for the go-live of the new EudraVigilance (EV) system in November 2017.

Reference is also made to the **e-Learning modules** published on the dedicated [EudraVigilance training webpage](#), which provide detailed instructions on how to prepare for the changes to come.

In addition, the **ICH E2B(R3) Implementation Guide** and the **EU ICSR Implementation Guide with supporting documentation** provide important guidance on how to apply the new ISO Individual Case Safety Report (ICSR) standard and how it should be used for the electronic reporting of suspected adverse reactions related to medicines in the European Economic Area (EEA). These documents can be accessed at [EudraVigilance change management webpage: On the new EudraVigilance database, where can I find detailed information and guidance?](#)

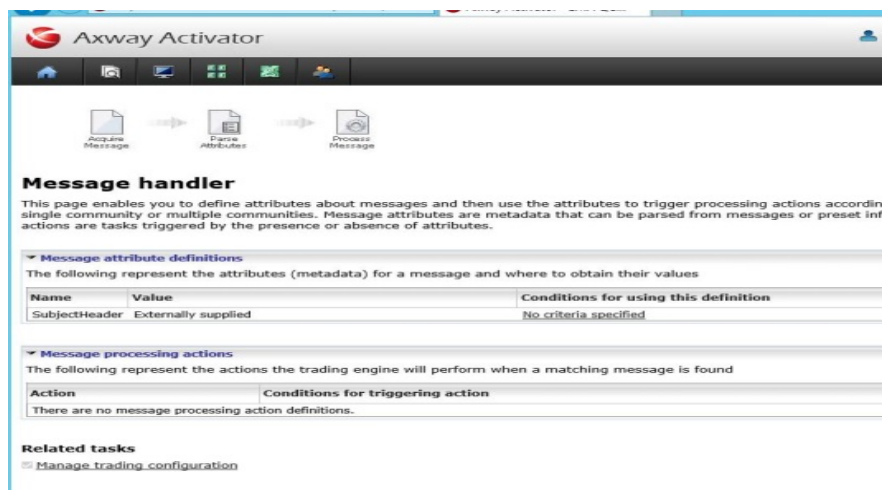
2. Technical checklist

2.1. *IT changes for the exchange of ICSRs and Acknowledgements*

2.1.1. Gateway (Axway Activator) users

NCAs that are using the local gateway connection (Axway Activator) to receive safety and acknowledgement messages electronically should prepare for the following:

- **June 2017:** Update the NCA pharmacovigilance TEST system with the receiver identifiers that should be used when sending ICSR messages for processing by the EVPM and ECTM modules, as described in section I.C.3.1.2 “EudraVigilance Message Receiver Identifiers” of the EU Individual Case Safety Report (ICSR) Implementation Guide.
- **June 2017:** Update the NCA pharmacovigilance TEST system to accepted additional message types used for the re-routing of ICSRs from EudraVigilance to NCAs, as described in section I.C.3.1.1 “Message Type” of the EU Individual Case Safety Report (ICSR) Implementation Guide.
- **June 2017:** Update the NCA gateway configuration in the XCOMP test environment based on the instructions provided below to ensure ICSRs can be transmitted to the new EudraVigilance system. The exact date in June is subject to confirmation by EMA.
 - The update of the configuration for the Axway Activator set-up is provided as follows:



To set the destination of the safety and acknowledgement messages as the EudraVigilance gateway, you will need to include the following two XPATHs to be able to process E2B(R3) files correctly:

- *Direct path:*
 - Sender /MCCI_IN200100UV01/sender/device/id/@extension
 - Receiver /MCCI_IN200100UV01/receiver/device/id/@extension
- *Relative path (Axway activator):*
 - Sender /*/sender/device/id/@extension
 - Receiver /*/receiver/device/id/@extension

IMPORTANT:

- **These paths need to be added in addition to the existing E2B(R2) XPATHs so that you are able to process both E2B(R2) and E2B(R3) ICSRs.**
- There is **no need to change needed to the EV gateway certificates.**
- Note that the **E2B(R3) ICSRs file size can be up to 20Mb**
- **June to November 2017:** Review the default re-routing rules implemented in EVWEB for the re-routing of ICSRs transmitted by marketing authorisation holders (MAHs) to EudraVigilance to define, which ICSRs should be re-routed to your NCA.
Note: the settings of the re-routing rules can be modified by NCAs at any time according to their needs.
- **June to November 2017:** Perform testing of your local pharmacovigilance system to receive ICSRs in the new ICH E2B(R3) format in addition to the current E2B(R2) format:
 - a. More information can be found in the already published e-learning modules:
 - ISO ICSR standard implementation for IT system developers (IT-M1):
<https://www.youtube.com/watch?v=pwA9nYO2VDQ>
 - ISO ICSR (E2B(R3)) system implementers workshop:
<https://www.youtube.com/playlist?list=PL7K5dNgKnawY00IFuSmY4V2zJFehB1BvT>

EMA can provide upon request the logical and messaging models (in power designer format) for the ICH E2B(R3) format. Please send such request to Nick.Halsey@ema.europa.eu.

- b. Refer to the ICH backwards and forwards conversion (BFC) tool available on the dedicated [change management webpage](#) as explained in the e-learning module "[Implementing ISO ICSR/ICH E2B\(R3\): Backwards and forwards conversion](#)" (PhV-M2b)

An example of a free to download program is MSXSL.exe.

This program requires the use of a command line:

```
msxsl <file to be converted> <XSLT location> -o <file name of converted file>
```

Example:

```
msxsl "E2B(R3)_file.XML" downgrade-icsr.xsl -o "E2B(R2)_file_convert.xml"
```

- c. Refer to the "EU reference instances" and "EU example instances" tool available on the dedicated [change management webpage](#), which provides sample ICSRs for testing E2B(R3) transmissions to the EudraVigilance system.

Additional example files will be published in May 2017.

- **By June 2017:** Make sure that your technical experts are registered with EudraVigilance to have access to XCOMP test environment. Existing users of the current EudraVigilance system will be automatically migrated to the new EudraVigilance system. Existing users should check that their XCOMP userid and password are still valid by accessing the current XCOMP test environment. If they are no longer valid, the EudraVigilance Registration team should be contacted at EudraVigilanceRegistration@ema.europa.eu.
- **26 June 2017:** Start using the XCOMP test environment to access the new EudraVigilance functionalities and to start testing the processing of E2B (R2) or E2B (R3) messages. The new URL for the XCOMP environment and the exact date in June is subject to confirmation by EMA.
- **By November 2017:** Update the NCA pharmacovigilance PRODUCTION system with the receiver identifiers that should be used for sending ICSR messages to the EVPM and ECTM modules as described section I.C.3.1.2 "EudraVigilance Message Receiver Identifiers" of the EU Individual Case Safety Report (ICSR) Implementation Guide.
- **By November 2017:** update the NCA pharmacovigilance PRODUCTION system to accepted additional message types used for the retransmission of ICSRs from EV to NCAs, as described section I.C.3.1.1 "Message Type of the EU Individual Case Safety Report (ICSR) Implementation Guide".
- **By November 2017:** Make sure that your experts are registered with EudraVigilance to have access to the PRODUCTION environment. For the registration of new users in PRODUCTION, please follow the registration steps as outlined at the dedicated webpage [EudraVigilance: how to register](#). Existing users of the current EudraVigilance system will be automatically migrated to the new EudraVigilance system. Existing users should check that their userid and password are still valid by accessing the current PRODUCTION environment. If they are no longer valid, the EudraVigilance Registration team should be contacted at EudraVigilanceRegistration@ema.europa.eu. Please also check that the functional e-mail address and e-mail address of Head of Pharmacovigilance Department or appointed deputy are still correct.
- **By November 2017:** Implement a process/functionalities that allow submitting nullification reports to EudraVigilance when a nullification of a pre-existing case has been rerouted by EMA and NCA confirms the nullification, as described in section I.C.6.1.1. "Nullification report" of the EU Individual Case Safety Report (ICSR) Implementation Guide.

- **22 November 2017:** Use the new EudraVigilance functionalities in EVWEB in the PRODUCTION environment as applicable.
- **22 November 2017:** Obtain latest information on NEW organisation IDs to be able to identify these organisations as part of re-routed ICSR. Use the EVDAS report available from Nov.2017 or as published under 'Organisations List' on the restricted area of the EV website (<https://eudravigilance.ema.europa.eu/human/restricted/PublicView/ListWithOrgs.asp>)
- **22 November 2017:** Stop sending ICSRs to WHO-UMC. Detailed guidance will be provided as part of the go-live plan.
- **22 November 2017:** Stop sending/providing ICSR to MAHs. Detailed guidance will be provided as part of the go-live plan.
- **22 November 2017:** Start submitting non-serious ICSRs originating from EEA to EudraVigilance within 90 days.
- **22 November 2017:** Submit serious ICSRs originating from EEA to EudraVigilance within 15 days.
- **22 November 2017:** Send acknowledgements to EudraVigilance for re-routed ICSRs.
- **22 November 2017:** Ensure complying with [security and confidentiality principles](#) that stakeholders using EudraVigilance need to comply with, as published on the EV webpages on EMA website.

2.1.2. EVWEB users

NCA's that are using EVWEB to receive safety and acknowledgement messages electronically should prepare for the following:

- **By June 2017:** Make sure that your experts are registered with EudraVigilance to have access to the XCOMP test environment. For the registration of new users in the XCOMP test environment, follow the registration steps as outlined at the dedicated webpage [EudraVigilance: how to register](#).
- **26 June 2017:** Start using the XCOMP test environment to access the new EudraVigilance functionalities in EVWEB. The new URL for the XCOMP environment is <https://eudravigilance-human-xcomp.ema.europa.eu>
- **June to November 2017:** Review the default re-routing rules implemented in EVWEB for the re-routing of ICSRs transmitted by MAHs to EudraVigilance to define which ICSRs should be re-routed to your NCA.
- **By November 2017:** Make sure that your experts are registered with EudraVigilance to have access to the PRODUCTION environment. For the registration of new users in PRODUCTION, please follow the registration steps as outlined at the dedicated webpage [EudraVigilance: how to register](#). Existing users of the current EV system will be migrated to the new EudraVigilance system. Existing users should check that their userid and password are still valid by accessing the current PRODUCTION environment. If they are no longer valid, the EudraVigilance Registration team should be contacted at EudraVigilanceRegistration@ema.europa.eu. Check also that the functional e-mail address and e-mail address of the Head of the Pharmacovigilance Department and appointed deputy are still correct.
- **22 November 2017:** Use the new EudraVigilance functionalities in EVWEB in the PRODUCTION environment as applicable.

- **22 November 2017:** Stop sending ICSRs to WHO-UMC. Detailed guidance will be provided as part of the go-live plan.
- **22 November 2017:** Stop sending/providing ICSR to MAHs. Detailed guidance will be provided as part of the go-live plan.
- **22 November 2017:** Start submitting non-serious ICSRs originating from EEA to EudraVigilance within 90 days.
- **22 November 2017:** Submit serious ICSRs originating from EEA to EudraVigilance within 15 days.
- **22 November 2017:** Send acknowledgements to EudraVigilance for re-routed ICSRs.
- **22 November 2017:** Ensure complying with [security and confidentiality principles](#) that stakeholders using EudraVigilance need to comply with, as published on the EV webpages on EMA website.

2.2. IT changes for data analysis

2.2.1. EVDAS users

- **By November 2017:** Use the new EudraVigilance functionalities in EVDAS in the PRODUCTION environment.
- **By November 2017:** Make sure that new users are registered with EVDAS (see also chapter 3.1.2.)
- **22 November 2017:** Start using new reports/functionalities available from the day of the go-live of the new system.
- **22 November 2017:** From the day of the go-live of the new system, ensure they comply with [security and confidentiality principles](#) that stakeholders using EudraVigilance need to comply with, as published on the EV webpages on EMA website.

3. Business process checklist

3.1.1. Business Process Changes

- **By November 2017:** Implement an internal process to receive from EMA confirmation requests (via email) for nullification of ICSRs submitted by MAHs.
- **By November 2017:** Implement an internal process to support the MAH signal validation and management activities as per GVP module IX.

3.1.2. Registration of users

- **By October 2017:** Send registration requests for new users to the EudraVigilance Registration Team at EudraVigilanceRegistration@ema.europa.eu. This applies to new EVDAS and EVWEB user registrations.

3.1.3. Stakeholder Communication

- Establish internal and external communication plans to facilitate the communication within your authority and with external stakeholders at national level on the changes to come.

3.1.4. Training/support webinar

- Follow the learning pathways recommended by EMA as part of the e-learning module **“Introduction to EMA’s training offering (PhV-M0)”** (<https://www.youtube.com/watch?v=qvHZrmfZj80&feature=youtu.be>)
- Attend face to face trainings and Information Days organised by EMA as announced at the dedicated webpage [EudraVigilance Training](#) and the EU NTC learning platform.
- Attend support webinars organised by EMA as announced at the dedicated [EudraVigilance Training](#) webpage.

4. EMA Support

- If you have pharmacovigilance questions and other general enquiries: [Send a question to the European Medicines Agency.](#)
- If you require technical support using EudraVigilance and the gateway/web client contact the: [EMA IT Service Desk](#) (or Tel. +44 (0)20 3660 7523).