



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management & Business Support

e-Transmission of ICSRs to the EMA

Steps to follow in case of system failure

Fall-back procedures outlined below apply when mechanical, program, electronic or communication failures occur, and electronic reporting of ICSRs is not possible within the expedited reporting timelines as defined in the Community legislation.

The following four scenarios are addressed and are applicable to reporting in the pre- and post-authorisation phase:

1. Failure of transmission of ICH M2 safety or acknowledgement messages at the Sender's gateway
2. Failure of generation of ICH M2 safety or acknowledgement messages at the Sender's database
3. Failure of ICH M2 safety or acknowledgement messages receipt in the event of a prolonged non-availability of the EudraVigilance Gateway at the level of the EMA
4. Failure of EVWEB at the level of the EMA

These scenarios are in line with the [Note for Guidance on the Electronic Data Interchange \(EDI\) of Individual Case Safety Reports \(ICSRs\) and Medicinal Product Reports \(MPRs\) in pharmacovigilance during the pre- and post- authorisation phase in the European Economic Area \(EEA\)](#). For further details always refer to the guideline.

Specific templates (Forms) are available to facilitate the communication during an event of system failure based on the four scenarios outlined above.

The addressee and address for physical media deliveries are specified in the relevant Form(s). The numbering of the Forms is not always consecutive. This is due to additional Forms being used internally by the European Medicines Agency (EMA) or in case of additional information requests.

In case of a system failure that affects your expedited e-reporting of ICSRs to one or more National Competent Authorities (NCAs), please ensure that the Authorities are also informed accordingly in line with the procedures outlined below.



1. Failure of transmission of ICH M2 safety or acknowledgement messages at the Sender's gateway

Timing	Scenario	Action/Event
During Failure	Sender can generate a message but cannot transmit it	<ul style="list-style-type: none"> Notify the Report Receiver (EMA) via fax +44(0) 20 3660 5540 using the appropriate template (Form 1: NFT), Send by <u>recorded delivery</u>: <ul style="list-style-type: none"> - Physical media containing ICSR(s) - The completed Form 2: TPM
Post-Failure	The system is working again	<p>You will receive the automatically generated ICH M2 acknowledgement message(s)* for the reports you sent by physical media via the EudraVigilance Gateway.</p> <p>Resume normal transmission without re-transmitting the ICSRs you transmitted previously by physical media.</p>

*The automatically generated ICH M2 acknowledgement message(s) will contain one of the three below codes and may consequently trigger an action on your side, as outlined in the following table:

Code 01	Code 02	Code 03
<p><i>If you receive an acknowledgement code 01 at message level (ICH M2 A.1.6):</i></p> <p>The reports have been sent correctly and no further action is required on your side.</p>	<p><i>If you receive an acknowledgement code 02 at message level (ICH M2 A.1.6):</i></p> <ul style="list-style-type: none"> Re-submit a corrected electronic version of the specific ICSR identified by code 02 at ICSR level (ICH M2 B.1.8), On receipt of an acknowledgement code 01 at message level (ICH M2 A.1.6), follow instructions as in column 1. 	<p><i>If you receive an acknowledgement code 03 at message level (ICH M2 A.1.6):</i></p> <ul style="list-style-type: none"> Re-submit a corrected electronic version of all reports included in the message. On receipt of an acknowledgement code 01 at message level (ICH M2 A.1.6) follow instructions as in column 1.

2. Failure of generation of ICH M2 safety or acknowledgement messages at the Sender's database

Timing	Scenario	Action/Event
During Failure	Sender cannot generate a message therefore an alternative transmission process is required.	<ul style="list-style-type: none"> Notify failure to the Report Receiver (EMA) via fax +44(0) 20 3660 5540 using the appropriate template (Form 3: NFG). Send paper report(s) in an internationally acknowledged format (CIOM 1) to the dedicated fax line: +44(0) 20 3660 5540 - write "Failure of safety message generation at sender's side" on the paper report(s).
Post-Failure	Generation of messages is working normally again	<ul style="list-style-type: none"> Send a notification by fax (+44 (0) 20 3660 5540) informing that the failure at the sender's side has been resolved, using the appropriate template (Form 5: NCF). Transmit electronically all faxed reports. You will receive the automatically generated ICH M2 acknowledgement message(s)* from the receiver.

*The automatically generated ICH M2 acknowledgement message(s) will contain one of the three below codes and may consequently trigger an action on your side, as outlined in the following table:

Code 01	Code 02	Code 03
<p><i>If you receive an acknowledgement code 01 at the message level (ICH M2 A.1.6):</i></p> <p>Send the fully completed Form 6: NDR via Eudralink¹ or fax +44(0) 20 3660 5540.</p> <p>This will allow for the change of the electronic receipt date of the report by the EudraVigilance system to match the date when the report</p>	<p><i>If you receive an acknowledgement code 02 at the message level (ICH M2 A.1.6):</i></p> <ul style="list-style-type: none"> Re-submit the corrected electronic version of the specific ICSR identified by code 02 at ICSR level (ICH M2 B.1.8). On receipt of an acknowledgement code 01 at message level (ICH M2 A.1.6) follow instructions as in column 	<p><i>If you receive an acknowledgement code 03 at message level (ICH M2 A.1.6) message generation at sender's side*:</i></p> <ul style="list-style-type: none"> Re-submit the corrected electronic version of all reports included in the message. On receipt of an acknowledgement code 01 at message level (ICH M2 A.1.6) follow instructions as in column 1.

Code 01	Code 02	Code 03
was sent by fax.	1.	

3. Failure of ICH M2 safety or acknowledgement messages receipt in the event of a prolonged non-availability of the EudraVigilance Gateway at the level of the EMA

Timing	Scenario	Action/Event
During Failure	A notice informing stakeholders that the EudraVigilance Gateway is not working will be published on the EudraVigilance website (http://eudravigilance.europa.eu)	Send by <u>recorded delivery</u> : <ul style="list-style-type: none"> Physical media containing the ICSR(s) The completed Form 8: TFR.
Post-failure	The system is working normally again. A notice will be published on the EudraVigilance website (http://eudravigilance.europa.eu)	You will receive the automatically generated ICH M2 acknowledgement message(s)* for the reports you sent by physical media via the EudraVigilance Gateway. Resume normal transmission without re-transmitting the ICSRs sent by physical media.

*The automatically generated ICH M2 acknowledgement message(s) will contain one of the three below codes and may consequently trigger an action on your side, as outlined in the following table:

Code 01	Code 02	Code 03
<p><i>If you receive an acknowledgement code 01 at the message level (ICH M2 A.1.6):</i></p> <p>The reports have been sent correctly and no further action is required on your side.</p>	<p><i>If you receive an acknowledgement code 02 at the message level (ICH M2 A.1.6):</i></p> <ul style="list-style-type: none"> Re-submit the corrected electronic version of the specific ICSR identified by code 02 at the ICSR level (ICH M2 B.1.8). On receipt of an acknowledgement code 01 at message level (ICH M2 A.1.6), follow instructions as in column 1. 	<p><i>If you receive an acknowledgement code 03 at message level (ICH M2 A.1.6):</i></p> <ul style="list-style-type: none"> Re-submit a corrected electronic version of all reports included in the message. On receipt of an acknowledgement code 01 at message level (ICH M2 A.1.6), follow instructions as in column 1.

4. Failure of EVWEB at the level of the EMA

Timing	Scenario	Action/Event
During Failure	A notice informing stakeholders that the EudraVigilance EVWEB is not working will be published on the EudraVigilance website (http://eudravigilance.europa.eu)	Send paper report(s) in an internationally acknowledged format (CIOM I) to the dedicated fax line: +44(0) 20 3660 5540 - write " Failure of safety message generation at receiver's side " on the paper report(s).
Post-Failure	The system is working normally again. A notice will be published on the EudraVigilance website (http://eudravigilance.europa.eu).	Transmit electronically all faxed report(s) as usual. You will receive the automatically generated ICH M2 acknowledgement message(s)* from the receiver.

*The automatically generated ICH M2 acknowledgement message will contain one of the three below codes and may consequently trigger an action on your side, as outlined in the following table:

Code 01	Code 02	Code 03
<p><i>If you receive an acknowledgement code 01 at the message level (ICH M2 A.1.6):</i></p> <p>Send the fully completed Form 6: NDR via Eudralink or fax +44(0) 20 3660 5540.</p> <p>This will allow for the change of the electronic receipt date of the report by the EudraVigilance system to match the date when the report was sent by fax.</p>	<p><i>If you receive an acknowledgement code 02 at the message level (ICH M2 A.1.6):</i></p> <ul style="list-style-type: none"> Re-submit the corrected electronic version of the specific ICSR identified by code 02 at the ICSR level (ICH M2 B.1.8). On receipt of an acknowledgement code 01 at the message level (ICH M2 A.1.6) follow instructions as in column 1. 	<p><i>If you receive an acknowledgement code 03 at the message level (ICH M2 A.1.6):</i></p> <ul style="list-style-type: none"> Re-submit the corrected electronic version of all reports included in the message. On receipt of an acknowledgement code 01 at the message level (ICH M2 A.1.6) follow instructions as in column 1.

ⁱ, Eudralink is the secure electronic system designed to enable files to be sent securely over the Internet. To get access to Eudralink contact the EMA helpdesk (+44 203 066 7357; eudralink@ema.europa.eu).