EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Organising a EudraVigilance reporting review meeting with stakeholders		
Applies to: Data Collection & Management Section in the Pharmacovigilance and Risk Management Sector		
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1. Changes since last revision

Updated to reflect new organisational names in the Agency.

2. Records

Paper copies of all Reporting Review Meeting documents, including signed copies of any written documents, should be filed in the Company Master Folder, which is stored in DREAM folder Cabinets/13. Projects/EudraVigilance - NEW STRUCTURE/Pharmaceutical Industry and Others/Pharmaceutical Companies.

Electronic copies of all Reporting Review meeting documents, including the meeting agenda, minutes, documents created using the templates and queries described below and all correspondence, should be stored in the DREAM folder "/Cabinets/13. Projects/EudraVigilance - NEW STRUCTURE/Quality Management/QA Checks/QA Check documents" in a subfolder as specified in the following paragraph.

If one does not already exist, a subfolder should be created with the organisation name and a further subfolder should be created entitled "EudraVigilance Reporting Review Meeting Documents" within this subfolder. A copy of the company subfolder should be saved as a link in the DREAM folder Cabinets/13. Projects/EudraVigilance - NEW STRUCTURE/Pharmaceutical Industry and Others.

The Data Collection & Management Section secretary will provide information on the precise location of the documents after each meeting since the organisation under review's name may be different from how it is commonly known or is registered in EudraVigilance.

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3. Instructions

When carring out the processes listed in this document please refer to SOP/H/3194 – EudraVigilance individual case safety report data quality checking and SOP/H/3014 – EudraVigilance business partners testing, because these specify which sections of this working instruction are relevent for the task being carried out.

Once the agenda and meeting details have been agreed with the sending organisation the meeting documents should be circulated at least 2 weeks in advance of the meeting. The documents should be sent to the Qualified Person/Responsible Person as registered in the EudraVigilance Registration Database, at least 1 week in advance of the meeting.

The meeting documents should be prepared as described in Chapter 3.3. below. During the meeting the attending organisation will be requested to produce the minutes and action points agreed to in the meeting.

3.1. Introduction

The SOP/H/3194 "EudraVigilance Data Quality" describes the overall process that should be followed for the review of the quality aspects that need to be followed when reporting to EudraVigilance is performed. This WIN provides details on how to organise a review meeting with an organisation submitting data to EudraVigilance. This relates to all aspects of reporting of Individual Case Safety Reports to the EudraVigilance Post-Authorisation (EVPM) and Clinical Trial Module (EVCTM) as well as the provision of medicinal product information to populate the EudraVigilance Medicinal Product Dictionary (EVMPD) where applicable. In addition, aspects related to the EU-Risk Management Plans (RMPs) and the population of the EudraVigilance Interface are also included.

3.2. Meeting organisation

The EudraVigilance Reporting Review Meeting (EVRRM) Co-ordinator should appoint a member of the EVRRM team, who will be in charge of organising the meeting.

The EVRRM team member should contact the organisation at least four weeks in advance of the meeting to agree on a meeting date.

Meetings are organised at the premises of the Agency and/or via teleconference. In certain instances, not all representatives of an organisation can attend in person but will join the discussions via teleconference. In these instances, when preparing the meeting, it is important to make sure that the meeting room has the necessary teleconference facilities. The invited organisation should be provided with the phone number of the meeting room to ensure the participants to call in for the discussions.

When agreeing on a meeting date, the EVRRM team member should ensure that an appropriate meeting room is available in line with the access control policy for visitors (DREAM Doc. Ref.: EMA/23467/04/3212).

The meeting participants of the invited organisation need to be confirmed to the EVRRM team member at least two days before the meeting. The EVRRM Co-ordinator needs to inform EMA Security accordingly using the appropriate Visitor Request Form accessible via the section "Business Applications" on EMA Plus.

When inviting an organisation to a review meeting, the following representatives of organisation should attend, as applicable:

- The EU QPPV of the MAH and/or the Person Responsible for EudraVigilance for Sponsors of Clinical Trials; for NCAs the Head of the Pharmacovigilance Department or the Clinical Trials Department as applicable.
- System Owner of the organisation's pharmacovigilance database
- The responsible person for maintaining the organisation's medicinal product dictionary (applicable for MAHs and Sponsors)
- Other responsible persons as determined on a case-by-case basis by the organisation or the EMA in accordance with the topics to be discussed.

From the EMA, the Deputy Head of the PhV-RM Sector or appointed backup, the EVRRM Co-ordinator and the EVRRM team member responsible for organising the meeting should attend the meeting. The aforementioned EVRRM team member needs to invite additional experts from the EV team who will attend the meeting depending on the agenda points to be discussed.

3.3. Agenda and Meeting documents

A standard meeting agenda is located in the following folder: X:/Templates/Others/Eudravigilance, with a copy in the following DREAM folder: Cabinets/13. Projects/EudraVigilance - NEW STRUCTURE/Quality Management/WINs/EudraVigilance WINs - LINKS TO IQM/Documents required for WIN 3209 (Doc. Ref.: EMA/557880/2008) which addresses the topics that would normally be discussed at the review meetings. This agenda can be amended depending on specific issues to be discussed with the organisation invited.

In preparation of the draft agenda, the EVRRM team member should contact the organisation to see if there are additional points they wish to discuss at the meeting.

In preparation of the EVRRM with an organisation, a review of the data transmitted to EudraVigilance for a defined time period should be carried out. The end-date should always be the date on which the analysis is carried out. The start-date for the first review meeting should be the date when electronic reporting of ICSRs was initiated by the organisation. For any following review meetings the review period should cover the time period since the conduct of the previous review. If the organisation had committed to solve identified problems following the previous meeting, then the start-date of the review for the relevant queries should be the date by which the problem should have been solved.

The discussions at the meeting should include a review of the status of the action points agreed at the time of approving the organisation to move in production with the electronic reporting of ICSRs to EudraVigilance and any other follow-up actions agreed thereafter as applicable.

Once the agenda and meeting details have been agreed with an organisation, the meeting documents should be prepared and provided in advance to the organisation concerned. As some documents will take time to be produced by different members of the Data Collection & Management Section, the preparation of the meeting should normally be initiated as soon as the date of the meeting has been agreed. It is the responsibility of the EVRRM team member, in liaison with the EVRRM co-ordinator to take care of all these aspects.

The meeting documents should be prepared as described below. After the meeting the attending organisation should produce the draft minutes and action points agreed to following the meeting.

The draft meeting minutes should be submitted by the organisation within 4 weeks of the meeting to the EVRRM team member and co-ordinator. The meeting minutes should be agreed and finalised with the organisation via email within two weeks of receipt.

The meeting documents should be prepared according to the topics be discussed as set out in the agenda. In most situations these will consist of the following:

- The (draft) Agenda
- A copy of the agreed action points and minutes of the previous meeting, where applicable
- The documents produced according to WIN/H/3201 – 'EudraVigilance how to check the quality of data'
- The Graph and Excel spreadsheets produced according to section 3.4. 'Database Queries'
- The questions relating to duplicates and a list of identified duplicates (see section 3.5.)
- RMP templates and related questions (see section 3.6.)
- EVMPD issues produced in section 3.7.
- List of registered users of the organisation in EudraVigilance (see section 3.8.)
- Parallel reporting questions and sample table (see section 3.9.)
- Documents related to points raised by the organisation (if applicable)

The organisation should be invited to submit any documents, they wish to discuss in relation to the meeting agenda at least one week in advance of the meeting. The EVRRM, with the support of an EV Team Secretary should ensure that enough copies of the document are prepared for the meeting attendees; the pages of the documents should be numbered where possible. If it is not possible to number all pages consecutively the document should be divided into sections in order to aid the readability of the document.

All correspondence with the organisation under review and all meeting-related documents should be stored in DREAM as described in section 2. – Records.

3.4. Database Queries

Prior to the meeting the queries described in the document "Database Queries for WIN/H/3209" (Doc. Ref.: EMA/646183/2008, located in the following DREAM folder: Cabinets/13. Projects/EudraVigilance - NEW STRUCTURE/Quality Management/WINs/EudraVigilance WINs - LINKS TO IQM/Documents required for WIN 3209) should be run according to the instructions contained therein.

The output of these queries (graphs and Excel spreadsheets) should be provided to the organisation in advance of the meeting along with the other meeting documents. The organisation will be expected to investigate the cases listed in the spreadsheets and, where necessary, submit corrected versions or nullify the cases as appropriate. These corrected versions should be transmitted as the same message type as the erroneous versions.

3.5. Duplicate management

The organisation should be requested to provide details on the local handling of duplicate reports through the following questions:

- How are potential duplicates identified?
- What steps are taken when a duplicate is identified?
- How are the relevant authorities informed of the duplicate cases?
- The organisation should also provide information on co-licensing agreements that may be potential sources of duplicates.

The organisation will be provided with figures on how many confirmed duplicates they have sent to EudraVigilance and will also be provided with Worldwide Unique Case Safety Identifiers of suspected duplicates that they have transmitted to EudraVigilance. This information will come from the Duplicate Detection Client. If the EVRRM team member does not have access to the duplicate detection client, they should contact the EVRRM co-ordinator, who should liaise with a DCM section staff member with access to it. This DCM section staff member should then provide the list to the EVRRM co-ordinator, who should, in turn, provide it to the DCM section staff Member.

3.6. Risk Management Plan templates

The required information to check this topic is available in DREAM (Cabinets/13. Projects/EudraVigilance – NEW STRUCTURE/Pharmacovigilance /Risk Management/EV - RMP Interface).

1. Open the tracking table 'EU-RMP Annex 1 Tracking.xls' and check if the company has an EU-RMP for any of its products in place and has previously submitted the EU-RMP Annex 1 to EudraVigilance. Alternatively check in Outlook the Chrono-In Emailbox H-EURMP-EVINTERFACE for latest submissions which may not yet have been entered into the tracking table.
2. If an EU-RMP Annex 1 was submitted and a EU-RMP Annex 1 Report had been prepared for discussion with the company (identified by a data in the column 'validation' of the tracking table), this report should be discussed in the meeting. The report can be found in the corresponding product folder in DREAM under the path as indicated above. The attendance of the EV team member in charge of the report is decided on a case-by-case basis.
3. If no such report is available the company may have submitted questions referring to the EU-RMP Annex 1 in advance of the meeting. Any such questions should be forwarded to the Data Collection & Management Section staff member in advance of the meeting in order to provide the answers.
4. If there is no EU-RMP Annex 1 in place no action is required.

3.7. EVMPD data

The organisation should be presented with the following information regarding medicinal product data:

- A full list of all products and substances contained in ICSRs transmitted by the organisation that have not been recoded

- The number of Authorised Products that the Organisation has entered in the EVMPD
- The number of Development Products that the Organisation has entered in the EVMPD

This data should be obtained from EVDAS following the instructions laid out in the document "Database Queries for WIN/H/3209" (Doc. Ref.: EMA/646183/2008, located in the following DREAM folder: Cabinets/13. Projects/EudraVigilance - NEW STRUCTURE/Quality Management/WINs/EudraVigilance WINs - LINKS TO IQM/Documents required for WIN 3209)

The organisation will be asked to outline its policy for the Drug section of ICSRs. Regarding the population of field B.4.k.2.2, the organisation should describe the reference sources they use (e.g. INN, European Pharmacopoeia, USAN, BAN, JAN) and also the policy regarding products containing multiple substances.

The organisation should also be asked to explain policy regarding recording in ICSRs therapeutic actions, interventions of products which are not classed as drugs (e.g. radiotherapy, acupuncture, foods) and also the entering of information where only a drug class is known.

If the database queries raise drug-class specific issues (e.g. vaccines, insulins, herbal medicinal products), the Data Collection & Management Section staff member in charge of this drug class in the EVMPD should attend the meeting.

3.8. Registration Information

The EVRRM team member should contact the EudraVigilance registration team (eudravigilaceregistration@EMA.europa.eu) and request a list of the registered users within the organisation being reviewed and all affiliates. This list should be provided to the organisation in advance of the meeting along with the other meeting documents. In the review meeting the organisation will be asked to confirm that the list is complete, accurate and up to date and, if it is not, the organisation will be expected to correct the information within 1 week of the meeting.

3.9. Reporting EEA ICSRs to both NCAs and EudraVigilance

If this has not already been addressed at a previous meeting, then this should form point 5.4 of the draft agenda and the following questions should be submitted to the organisation along with a table giving the start-dates of transmission of ICSRs by the EEA NCAs, which is stored at the following location: Cabinets/13. Projects/EudraVigilance - NEW STRUCTURE/Quality Management/WINs/EudraVigilance WINs - LINKS TO IQM/Documents required for WIN 3209 (Doc. Ref.: EMA/647142/2008).

- Is [Organisation] currently transmitting post-marketing reports of EEA origin to EudraVigilance?
- Was [Organisation] previously transmitting reports of EEA origin to EudraVigilance?

If the answer to either of the above questions is yes, the organisation should provide a table listing the country, the start and end dates between which the organisation transmitted these cases to EudraVigilance and stating whether or not cases were transmitted electronically to the NCA during this period. A sample table is located in the following folder: X:/Templates/Others/Eudravigilance, with a copy in the following DREAM folder: Cabinets/13. Projects/EudraVigilance - NEW STRUCTURE/Quality Management/WINs/EudraVigilance WINs - LINKS TO IQM/Documents required for WIN 3209 (Doc. Ref.: EMA/646374/2008).

If there is overlap between the organisation's transmission of EEA-ICSRs and a NCA entering into production, then the organisation should provide an electronic copy of an Excel spreadsheet giving the Worldwide Case Safety IDs (ICH E2B(R2) A.1.10.1), Sender's case Safety Unique Report Identifier (ICH E2B(R2) A.1.0.1) and transmission date of the cases transmitted during this overlap period so that the EMA can query EudraVigilance to see if there has been duplicate reporting.

3.10. Pharmacovigilance in post-authorisation safety studies

The organisation will be asked to outline their policy on the reporting of ICSRs arising from non-interventional studies and from compassionate use, to ensure that all such ICSRs of which they are notified will be correctly transmitted to the EudraVigilance Post-Authorisation Module.

The QPPV will also be asked to confirm that they, or a nominated person, are involved in the review of protocols for all post-authorisation safety studies, in order to ensure compliance with pharmacovigilance requirements.