EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management

EudraVigilance registration

Questions and answers

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1. Who should register with EudraVigilance

1.1. What type of organisations should register with EudraVigilance?

All marketing-authorisation holders (MAHs), applicants for a marketing authorisation in the EEA and sponsors of clinical trials conducted within the Community should register with EudraVigilance.

1.2. Which person from a marketing-authorisation holder or applicant for a marketing authorisation in the European Economic Area (EEA) organisation should register?

For a marketing-authorisation holder or applicant for a marketing authorisation in the EEA, the QPPV[1] of the organisation's headquarter in the EEA is the organisation's representative who should register with EudraVigilance. That qualified person shall reside in the Community.

1.3. Which person from a sponsor of a clinical trial conducted in the EEA, where the sponsor is also an MAH or an applicant for a marketing authorisation in the EEA should register?

For a sponsor, who is also an MAH or an applicant in the EEA, the QPPV of the organisation's headquarter in the EEA continues to be the organisation's representative in the EudraVigilance registration process. No additional registration of a responsible person for EudraVigilance is required.

1.4. Which person from a sponsor of a clinical trial conducted in the EEA other than a MAH or an applicant for a marketing authorisation in the EEA should register?

For a sponsor, who is not a MAH or an applicant, an organisation's representative for the EudraVigilance registration process (responsible person for EudraVigilance) should be appointed. Only one responsible person for EudraVigilance should be appointed by the sponsor for all clinical trials conducted by the sponsor in the EEA.

This responsible person for EudraVigilance should be appointed by the sponsor's named person - a contact person mentioned in section B.1.2 of the request for authorisation, submitted to the relevant competent authority of a member state, to conduct a clinical trial in at least one centre located in the EEA (hereafter referred to as 'named person').

1.5. Which person from a sponsor of clinical trials conducted in the EEA, not established in the EEA, should register?

If a sponsor is conducting a clinical trial in the EEA but is not established in the EEA, a legal representative of the sponsor has to be established in the EEA. The notion of legal representative refers back to existing national laws and may include natural or legal persons, an authority and/or body provided for by national law.

As a general principle, only one legal representative can act on behalf of one sponsor in one clinical trial.

[1] Article 103 of Directive 2001/83/EC, Regulation (EEC) No. 2309/93

For sponsors not established in the EEA, an organisation's representative for the EudraVigilance registration process (responsible person for EudraVigilance) should be appointed. The responsible person for EudraVigilance does not need to reside in the EEA. Only one responsible person for EudraVigilance should be appointed for the sponsor for all clinical trials conducted by the sponsor in the EEA.

The responsible person for EudraVigilance should be appointed by the legal representative of the sponsor.

1.5.1. What should be done if a sponsor of clinical trials conducted in the EEA, not established in the EEA, has more than one legal representative?

The sponsor is not required to have one single legal representative located in the EEA for all non-EEA sponsored trials that the sponsor is conducting in the EEA. In practice, this means that a sponsor may appoint different single legal representatives for each clinical trial conducted in the EEA.

Where the sponsor has appointed different single legal representatives for non-EU sponsored trials conducted in the EEA, the legal representative appointed for the first clinical trial initiated after 1 May 2004, conducted in the EEA, should appoint the sponsor's responsible person for EudraVigilance as the single entity for all clinical trials conducted by the sponsor in the EEA.

2. EudraVigilance registration process

2.1. How do I update registration details?

- Changes to the organisation registration details should be reported by the qualified person for pharmacovigilance (QPPV) or the responsible person (RP) for EudraVigilance, or the registered trusted deputy. For all changes an email should be sent to the EudraVigilance (EV) Registration team to EudraVigilanceRegistration@ema.europa.eu.
- To cancel the registration of an individual user, an email notification should be sent to the EV Registration team by the QPPV, the RP for EudraVigilance, the trusted deputy or the individual user directly.
- Changes to the transmission mode should be advised well in advance and discussed with the European Medicines Agency.
- Changes to the organisation name should be requested in writing in the form of a cover letter (for sponsors and marketing-authorisation holders) and should be supported by providing a copy of the Trade Register (for marketing-authorisation holders only).
- To change the QPPV or RP for EudraVigilance within the EudraVigilance system please refer to the following document Change of qualified person for pharmacovigilance and responsible person for EudraVigilance.

2.2. Can the registration process be delegated by the QPPV?

Following initial registration, the MAH's or applicant's QPPV in the EEA can delegate the functions related to registration of new users and affiliates with EudraVigilance to a trusted deputy user within the same organisation. The steps on how to delegate the registration functions are described in the following document Delegating the EudraVigilance registration process.

2.3. What documents are required for registration of a sponsor of a clinical trial conducted in the EEA other than a MAH or an applicant for a marketing authorisation in the EEA, where the sponsor is established in the EEA?

The following documents should be provided by the named person to the Agency in order to appoint a responsible person for EudraVigilance:

- Form A – appointment of the responsible person for EudraVigilance by the named person from the sponsor;
- all other supporting documents related to the responsible person for EudraVigilance as outlined in the document EudraVigilance registration documents.

2.4. What documents are required for registration of a sponsor of a clinical trial conducted in the EEA not established in the EEA?

The following documents should be provided to the Agency by the legal representative of the sponsor in order to appoint a responsible person for EudraVigilance:

- a EudraCT number for a study conducted by the sponsor or a copy of the clinical trial application form submitted to the relevant competent authority of a member state to conduct a clinical trial in at least one centre located within the Community, including the identification and contact details of the named person, stated on the application form;
- Form A – appointment of the responsible person for EudraVigilance by the organisation/ individual, acting as the legal representative;
- Form B – notification of the sponsor's legal representative;
- signed and dated copy of an ID card, driving license or passport of the legal representative of the sponsor:
  - full name and signature must be visible,
  - any other information contained on the ID document may be blacked out;
- all other supporting documents related to the responsible person for EudraVigilance are outlined in the document EudraVigilance registration documents.

2.5. How soon can I expect a response following the submission of registration documents?

The EV Registration team will aim to reply as soon as possible but please allow a maximum of 25 working days for your registration request to be processed.

3. Introduction of a 'regulatory contact point' for marketing authorisation holders

3.1. What is the 'regulatory contact point' for MAHs?

The EMA has implemented a 'regulatory contact point' within the EudraVigilance registration database.

The "Regulatory Contact Point" is an individual authorised for communication with the EMA on behalf of the marketing authorisation holder. This communication may involve procedural regulatory matters

(e.g. non-pharmacovigilance referrals) or non-procedural issues (e.g. processes related to the electronic submission within the EudraVigilance system such as changes to the EU QPPV). This individual should be part of the MAH's organisation and should not be the same as the EU QPPV. If it is an individual, he/she will not become a registered user of EudraVigilance by entering their contact details in this section.

3.2. When is the 'regulatory contact point' feature going to be implemented?

The EMA implemented this feature in June 2016. From 10 April 2017 the EMA will use the regulatory contact point email address as the main contact point for non-pharmacovigilance referral procedures under Article 31 of Directive 2001/83/EC.

3.3. What information is required?

MAH organisations are required to provide at a headquarter level the name of an individual or a department who belongs to the MAH, a telephone number and an email address. The email address can be an individual's email address or a generic email address (e.g. info@..)

3.4. Why was the 'regulatory contact point' introduced?

This feature facilitates the change of QPPV process within the EudraVigilance registration database. The regulatory contact point is used by the EudraVigilance registration team to contact the MAH directly when their registered EU QPPV leaves and a new EU QPPV has not been registered. This helps MAH organisations and the EMA to follow up on the MAH's legal obligations to have permanently and continuously a registered EU QPPV in line with *Article 104(3)(a) of Directive 2001/83/EC*.

For non-pharmacovigilance referral procedures all correspondence from the Agency related to the start of a non-pharmacovigilance referral procedure, as well as all subsequent documents provided to the MAHs/applicants during the procedure, will be sent electronically to the regulatory contact point email address (via Eudralink).

3.5. How are MAH organisations required to provide the 'regulatory contact point' information?

The registered EU QPPV and trusted deputy users of existing MAH organisations in EudraVigilance are able to provide this information by logging in to the secure area of EudraVigilance and by completing the relevant fields under the *"Edit organisation"* option. When the *"Edit organisation"* option has been selected, the regulatory contact point fields become mandatory. Newly registering MAH organisations will need to provide this mandatory information as part of the organisation's EudraVigilance online registration form.

3.6. When are MAH organisations required to provide the 'regulatory contact point' information?

Registered MAH organisations are required to provide this information at their earliest convenience. The EMA sends out quarterly reminders to organisations who have not updated this information. Please note that if your organisation does not update this information your users' access to EudraVigilance ***will not*** be restricted.

3.7. Does the addition of a 'regulatory contact point' in the EV Registration database result in an update of AMP data in the Article 57 database?

No. This is an update of the EV Registration database. No update of AMPs will need to be performed by the MAH in the Article 57 database.

3.8. Whom shall we contact with questions?

Any questions related to the use of the regulatory contact point feature for QPPV changes should be directed to the EudraVigilance registration team: EudraVigilanceRegistration@ema.europa.eu

For queries related to the use of the regulatory contact point for non-pharmacovigilance referral procedures, please use the EMA website: Home> About Us> Contact> Send a question, quoting the keyword “REF-non PhV” in the subject line.

4. Delegation of reporting tasks

4.1. Can sponsors delegate their clinical trial-related reporting tasks?

Where trial-related electronic reporting duties are delegated by the sponsor to a third party, such third party should be registered by the responsible person for EudraVigilance as a third party service provider. For further details, please refer to the following document Electronic registration process – EudraVigilance registration phases I, II and III.

5. Merge of organisations

5.1. What should be done if an MAH/sponsor organisation acquires another organisation which is already registered with EudraVigilance?

The organisation changes need to be processed in the format of an organisation merge in the EudraVigilance registration database by moving the acquired company to the registration of the acquiring organisation (MAH, sponsor or non-commercial sponsor).

- A cover letter must be sent to the Registration team (EudraVigilanceRegistration@ema.europa.eu) confirming which organisation should maintain their registration as headquarter (HQ) and which organisation should become a registered affiliate.
- The affiliate’s transmission mode and other possible organisation changes should be detailed in the cover letter. The qualified person for pharmacovigilance/responsible person for EudraVigilance of both organisations must sign this letter.

In relation to the visibility and maintenance of AMPs/DMPs submitted in the Article 57 database/XEVMPD, both organisations will be able to see and maintain data submitted from the other organisations (i.e. the HQ’s and the affiliate’s) profile.

6. Separation of organisations

6.1. What should be done if an affiliate separates from a headquarter (HQ) organisation?

- If an affiliated company separates from a HQ organisation (MAH, commercial sponsor or non-commercial sponsor) the former qualified person for pharmacovigilance/responsible person for EudraVigilance should request the affiliate profile to be disabled.
  - A cover letter must be sent to the Registration team (EudraVigilanceRegistration@ema.europa.eu) requesting disabling of the relevant affiliate.
  - The affiliated company should then be re-registered under a new organisation or as a stand-alone entity, as applicable.
- If an affiliated company has ceased to exist, the qualified person for pharmacovigilance/responsible person for EudraVigilance of the organisation should request a disconnection of the relevant affiliated company in writing.

In relation to the medicinal product entities submitted in the Article 57 database/XEVMPD, the AMPs/DMPs submitted from the affiliate's ID should be nullified and inserted as new under the new organisation's ID.

7. Updating an organisation category

7.1. What should be done if an organisation changes its category from a sponsor to a MAH / applicant?

- If a sponsor organisation becomes a marketing authorisation holder or an applicant for marketing authorisation, the following documents should be provided to the Registration team (EudraVigilanceRegistration@ema.europa.eu):
  - A cover letter requesting change of category.
  - Proof of marketing authorisation (MA) or a copy of the MA application form.
  - A copy of the trade register for pharmaceutical companies. This document proves that the company has been registered in the Member State in which it has its registered office, according to the law of that Member State (Council Regulation (EC) No 2157/2001).
  - A EU QPPV must be registered, replacing the previously registered responsible person for EudraVigilance unless this is the same person.

7.2. What should be done if an organisation changes its category from a MAH to a sponsor?

- If a MAH organisation becomes a sponsor of clinical trials, the following documents should be provided to the Registration team (EudraVigilanceRegistration@ema.europa.eu):
  - A cover letter requesting change of category.
  - A EudraCT number for a study the sponsor is conducting on the territory of the European Economic Area (EEA).

- Completed form A if the sponsor is based within the EEA.
- Completed forms A and B if the sponsor is based outside of the EEA.
- A responsible person for EudraVigilance must be registered, replacing the previously registered EU QPPV unless this is the same person.

Please note, if the organisation is both a MAH and a sponsor, no action is required. MAH organisations can perform clinical trial reporting via their existing MAH profile.