10 December 2024
EMA/503894/2018
Information Management Division

EudraVigilance registration documents

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

Introduction

This document summarises the pre-requisites and the required documents in order for Marketing Authorisation Holders (MAHs), Commercial Sponsors (CS) and Non-commercial Sponsors (NCS) of Clinical Trials and National Competent Authorities (NCAs) to register with EMA, including for the assignment or reassignment of the role of EU Qualified Person for Pharmacovigilance (EU QPPV)/Responsible Person (RP).

Please also refer to the EMA's webpage EudraVigilance: how to register and to the documents EMA's EV Registration Manual and New Organisation First User EU QPPV/RP or Change of EU QPPV/RP.

Note:

As per the EMA's internal procedures and in order to safeguard the accuracy of the information in EudraVigilance, the Agency reserves the right to contact, if applicable, the former QPPV/RP of the organisation so as to clarify the scope of the change and to validate the change being requested.

Pre-requisites

- User registration in the EMA Account Management Portal – see **section 2.1** of the EudraVigilance Registration Manual.
- Registration of the organisation in the Organisation Management System – see **section 3.3** of the EudraVigilance Registration Manual.
- Request of the role, as applicable, "EV MAH EU QPPV" or "EV CS/NCS Responsible" or "EV NCA Responsible" by the user via the EMA Account Management Portal – see **section 5.2** and **Annex 1** of the EudraVigilance Registration Manual.
- Once the role has been requested in the EMA Account Management Portal, a Service Desk ticket should be raised to the Registration team, quoting the **Request ID number** and attaching the **required documents** listed below.

Registration of the headquarter for Marketing Authorisation Holders (MAHs)

- A **cover letter** from the MAH's headquarters level of the organisation on a company's headed paper. The cover letter should be co-signed by:
  - The **new** EU Qualified Person for Pharmacovigilance (EU QPPV); **AND**
  - The **former** EU Qualified Person for Pharmacovigilance (EU QPPV) if applicable; **AND**
  - A person in a position above at headquarters level (i.e. director of the organisation or similar) of the **MAH organisation**;

  Notes:

  1. The cover letter should state the **name**, **position** and **contact details** (including email) of the persons co-signing the letter.
  2. **For MAHs changing EU QPPVs**: if the former EU QPPV cannot sign the letter, then the letter should also include a statement explaining **why** the **former** EU QPPV is not available to sign the letter.

3. **For MAHs assigning EU QPPV role for the first time**: as there is no former EU QPPV, the letter should also include a statement saying that this is the first time the EU QPPV role is being assigned to a user for this organisation.
4. **The cover letter should also confirm that the newly appointed EU QPPV resides within the EU/EEA**.
5. The **name** and **OMS ORG ID** of the new organisation should also be provided once it has been successfully created by EMA.

- **Email confirmation from the OMS** Data Stewards acknowledging the successful creation of the organisation, if applicable.
- The **role removal Request ID** of the current EU QPPV, if applicable; **OR** the **role Request ID** of the EU QPPV (for organisations assigning the EU QPPV role for the first time). This information can be included in the cover letter or on the Description field of the Service Desk ticket.
- A **copy of the ID card/driver license/passport** of the **new** EU QPPV **AND** of the person in a position above at headquarters level of the MAH organisation who co-signed the letter.

  Notes:

  1. The full name and signature should be visible; any other information contained on the ID document may be redacted.
  2. This information will be used to verify the identity of the registering person and will be treated as confidential and will not be published or included in any user list.[1]
- The **User Declaration Form for EU QPPV/RP** (download here), dated and signed, including the category and the name of the organisation, and the EU QPPV details.
- 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).
- **Proof of an EU/EEA marketing authorisation/application for at least one product.**

Regarding the EudraVigilance ICSR and XEVMPD knowledge evaluation:

- **For MAHs changing their EU QPPV:** A declaration by the EU QPPV that the organisation has a suitably trained person for submission of ICSRs and XEVPRMs. This declaration should be included in the cover letter. *See also the notes below.*
- **For MAHs assigning their first EU QPPV:** Copies of the notification of successful completion of the EudraVigilance ICSR and XEVMPD knowledge evaluation for at least one user.

  Notes:

  Submitting copies of ICSR and XEVMPD training certificates is not necessary when changing the EU QPPV/RP but is required when registering the organisation's first EU QPPV/RP. In any case, the company should ensure that it has a suitably trained person for submission of ICSRs and XEVPRMs at all times.

[1] The European Medicines Agency will process this information to verify the identity of the registering person and it will be handled in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. The name of the QPPV/RP and contact details are accessible to the registered organisation in the restricted area of the EudraVigilance and are not made public. For more information, please click here.

If providing the training certificates, please note they do not have to be in the name of the new EU QPPV/RP, but in the name of any active user of the profile who has completed the above courses and is related to the respective organisation. In other words, that the active user is an employee of the organisation OR is an employee of a CRO/Service Provider to which the company has delegated, via written contract, the submission of ICSRs and/or XEVMPRs to EV.

For example, if the ICSR/SUSAR submission to EMA has not been delegated to the CRO/Service Provider, then the company cannot use the ICSR training certificate of the CRO/Service Provider's employee when registering their EU QPPV/RP and, thus, should have an active internal employee who has completed the ICSR training. If the active user leaves the company at some point, then the company should find a replacement, ensuring that at least 1 new active internal user also has successfully completed the ICSR training and has a valid ICSR training certificate. The same logic applies to the XEVMPD training certificate.

Registration of the headquarter for Commercial and Non-commercial Sponsors

- A **cover letter** from the Sponsor's headquarters level of the organisation on a company's headed paper. The cover letter should be signed by:
  - The **new** Responsible Person for EudraVigilance (RP); **AND**
  - The **former** Responsible Person for EudraVigilance (RP), if applicable; **AND**
  - A person in a position above at headquarters level (i.e. director of the organisation or similar) of the **Sponsor organisation**.

  Notes:

  1. The cover letter should state the **name**, **position** and **contact details** (including email) of the persons co-signing the letter.
  2. **For Sponsors changing RPs**: if the former RP cannot sign the letter, then the letter should also include a statement explaining **why** the **former** RP is not available to sign the letter.
  3. **For Sponsors assigning the RP role for the first time**: as there is no former RP, the letter should also include a statement saying that this is the first time the RP role is being assigned to a user.
  4. **For Commercial and Non-Commercial Sponsors NOT established in the Union/Community conducting clinical trial within the Union/Community:** the cover letter should also confirm that the Sponsor's **Legal Representative** in the Union/Community is established in the EU/EEA.[2]
  5. The **name** and **OMS ORG ID** of the new organisation should also be provided once it has been successfully created by EMA.
- **Email confirmation from the OMS** Data Stewards acknowledging the successful creation of the organisation, if applicable.

[2] In accordance with Article 74 of Regulation (EU) 536/2014 and Article 19 of Directive 2001/20/EC as applicable.

- The **role removal Request ID** of the current RP, if applicable; **OR** the **role Request ID** of the RP (for organisations assigning the RP role for the first time). This information can be included in the cover letter or on the Description field of the Service Desk ticket.
- A **copy of the ID card/drive license/passport** of the **new** RP **AND** 1) for **Sponsors established in the Union/Community:** of the person in a position above at headquarters level of the Sponsor who co-signed the letter; **OR** 2) for **Sponsors NOT established in the Union/Community:** of the Sponsor's Legal Representative in the Union/Community.

  Notes:

  1. The full name and signature should be visible; any other information contained on the ID document may be redacted.
  2. This information will be used to verify the identity of the registering person and will be treated as confidential and will not be published or included in any user list.[1]
- The **User Declaration Form for EU QPPV/RP** (download here), dated and signed, including the category and the name of the organisation, and the RP details.
- The **EudraVigilance Human Sponsor Registration Form** (download here), appointing the new RP for EudraVigilance, including the name and the contact details of the person appointing the RP at sponsors level and the RP details.

  Notes:

  1. This document should be signed by the person from the sponsor appointing the RP. The RP address details should be of the organisation the RP works for.
  2. **For Sponsor organisations NOT established in the Union/Community conducting clinical trial within the community:** the form should also include the name, details, and signature of the **Legal Representative** person within the Union/Community. The address of the Legal Representative should be of the respective organisation they work for.
- An **EU CT number** for a study the sponsor is conducting.

Regarding the EudraVigilance ICSR and XEVMPD knowledge evaluation:

- **For Sponsor organisations changing their RP:** A declaration by the RP (or by Legal Representative whenever the Sponsor organisation is **NOT** established in the EU/EEA) that the organisation has a suitably trained person for submission of ICSRs and XEVPRMs. This declaration should be included in the cover letter. *See also the notes below.*
- **For Sponsor organisations assigning their first RP:** Copies of the notification of successful completion of the EudraVigilance ICSR and XEVMPD knowledge evaluation for at least one user.

  Notes:

  Submitting copies of ICSR and XEVMPD training certificates is not necessary when changing the EU QPPV/RP but is required when registering the organisation's first EU QPPV/RP. In any case, the company should ensure that it has a suitably trained person for submission of ICSRs and XEVPRMs at all times.

  If providing the training certificates, please note they do not have to be in the name of the new EU QPPV/RP, but in the name of any active user of the profile who has completed the above courses and is related to the respective organisation. In other words, that the active user is an employee of the organisation OR is an employee of a CRO/Service Provider to which the company has delegated, via written contract, the submission of ICSRs and/or XEVMPRs to EV.

For example, if the ICSR/SUSAR submission to EMA has not been delegated to the CRO/Service Provider, then the company cannot use the ICSR training certificate of the CRO/Service Provider's employee when registering their EU QPPV/RP and, thus, should have an active internal employee who has completed the ICSR training. If the active user leaves the company at some point, then the company should find a replacement, ensuring that at least 1 new active internal user also has successfully completed the ICSR training and has a valid ICSR training certificate. The same logic applies to the XEVMPD training certificate.

Registration of the headquarter of National Competent Authorities

- A **cover letter** from the NCA organisation on an organisation's headed paper. The cover letter should be co-signed by the:
  - The **new** Responsible Person for EudraVigilance (RP); **AND**
  - The **former** Responsible Person for EudraVigilance (RP), if applicable; **AND**
  - A person in a position above at headquarters level (i.e. Head of the Pharmacovigilance Department, director of the organisation or similar) of the **NCA organisation**.

  Notes:

  1. The cover letter should state the **name**, **position** and **contact details** (including email) of the persons co-signing the letter.
  2. For NCAs changing RPs: if the former RP cannot sign the letter, then the letter should also include a statement explaining **why** the **former** RP is not available to sign the letter.
  3. For NCAs assigning the RP role for the first time: as there is no former RP, the letter should also include a statement saying that this is the first time the RP role is being assigned to a user.
  4. The **name** and **OMS ORG ID** of the new organisation should also be provided once it has been successfully created by EMA.
- The **email confirmation from the OMS Data Stewards** acknowledging the successful creation of the organisation, if applicable.
- The **role removal Request ID** of the current RP, if applicable; **OR** the **role Request ID** of the RP (for organisations assigning the RP role for the first time). This information can be included in the cover letter or on the Description field of the Service Desk ticket.
- A **copy of the ID card/driver license/passport** of the **new** RP **AND** of the person in a position above at headquarters level of the NCA organisation who co-signed the letter.

  Notes:

  1. The full name and signature should be visible; any other information contained on the ID document may be redacted.
  2. This information will be used to verify the identity of the registering person and will be treated as confidential and will not be published or included in any user list.[1]
- The **User Declaration Form for EU QPPV/RP** (download here), dated and signed, including the category and the name of the organisation, and the RP details.

Regarding the EudraVigilance ICSR and XEVMPD knowledge evaluation:

- **For NCAs changing their RP:** A declaration by the RP that the organisation has a suitably trained person for submission of ICSRs and XEVPRMs. This declaration should be included in the cover letter. *See also the notes below.*
- **For NCAs assigning their first RP:** Copies of the notification of successful completion of the EudraVigilance ICSR and XEVMPD knowledge evaluation for at least one user.

  Notes:

  Submitting copies of ICSR and XEVMPD training certificates is not necessary when changing the EU QPPV/RP but is required when registering the organisation's first EU QPPV/RP. In any case, the company should ensure that it has a suitably trained person for submission of ICSRs and XEVPRMs at all times.

  If providing the training certificates, please note they do not have to be in the name of the new EU QPPV/RP, but in the name of any active user of the profile who has completed the above courses and is related to the respective organisation. In other words, that the active user is an employee of the organisation OR is an employee of a CRO/Service Provider to which the company has delegated, via written contract, the submission of ICSRs and/or XEVMPRs to EV.

  For example, if the ICSR/SUSAR submission to EMA has not been delegated to the CRO/Service Provider, then the company cannot use the ICSR training certificate of the CRO/Service Provider's employee when registering their EU QPPV/RP and, thus, should have an active internal employee who has completed the ICSR training. If the active user leaves the company at some point, then the company should find a replacement, ensuring that at least 1 new active internal user also has successfully completed the ICSR training and has a valid ICSR training certificate. The same logic applies to the XEVMPD training certificate.