EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

New Organisation First User EU QPPV/RP or Change of EU QPPV/RP

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Introduction

This document describes the actions required by Marketing Authorisation Holders (MAHs), Commercial and Non-commercial Sponsors, and National Competent Authorities (NCAs) for registering or changing EU Qualified Person for Pharmacovigilance (EU QPPV)/Responsible Person (RP). There are, thus, two possible scenarios in described in this document – please choose the one relevant to your case.

Please note that if a change of EU QPPV or RP occurs within your organisation, then the EMA should be notified **within 10 calendar days**.

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.

Change of EU QPPV/RP – i.e. there is still an EU QPPV/RP in the organisation

1. The leaving EU QPPV/RP will need to remove their role via the EMA Account Management Portal by following the steps described in **section 5.6.** of the EudraVigilance Registration Manual. A role removal **Request ID** will be generated and should be provided to the EV Registration team via Service Desk ticket– see step 3.

   Important note: if the EU QPPV/RP has already left the organisation and cannot request the role removal, go to step 2. The EV Registration team will be able to remove the EU QPPV/RP role once all the required documents are provided.

2. The newly appointed EU QPPV/RP needs to remove all the roles they have for the organisation they wish to register as EU QPPV/RP by following the steps described in section **5.6** of the EudraVigilance Registration Manual.

3. A Service Desk ticket should be raised to the Registration team, requesting the validation of the new EU QPPV/RP role, stating the **organisation ID** and **name** in the Description field of the ticket. Moreover, the following documents need also to be attached:

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

     Notes:

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

- For **Marketing Authorisation Holders**, the cover letter should also confirm that the newly appointed EU QPPV resides within the EU/EEA.
- **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.[1]

- The **role removal Request ID** of the current EU QPPV/RP, if available.
- A **copy of the ID card/driving license/passport** of the **new** EU QPPV/RP **AND** 1), for organisations established in the Union/Community, of the person in a position above at headquarters level of the MAH, Sponsor or NCA organisation who co-signed the letter; **OR** 2) for **Sponsor organisations NOT established in the EU/EEA**, of the Sponsor's Legal Representative in the Union/Community.

  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 Union/Community.

  Notes:

  - The full name and signature should be visible; any other information contained on the ID document may be redacted.
  - 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.[2]
- The **User Declaration Form for EU QPPV/RP** (download here), dated and signed, including the organisation type, name of the organisation and the EU QPPV/RP details.
- A **declaration from the EU QPPV/RP that the organisation has a suitably trained person for submission of ICSRs and XEVPRMs**.
  - This declaration can be included in the cover letter or on the description of the Service Desk ticket.

    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.

      The training certificates 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.

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

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 RP/EU QPPV 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.

Commercial and Non-Commercial Sponsors should additionally provide the following document(s):

- **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 Sponsor's level and the RP details.

  Notes:

  - 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.
  - **Sponsors NOT established in the Union/Community** conducting clinical trial within the Union/Community, the form should also include the name, details, and signature of the Legal Representative person within the Union/Community. The addresses of the Responsible Person and Legal Representative should be of the respective organisations they work for.

- For **Sponsors NOT established in the Union/Community**, a **copy of the ID card/driving license/passport** of the Legal Representative must also be provided.

  Notes:

  - The full name and signature should be visible; any other information contained on the ID documents may be redacted.
  - 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.[2]

4. The EMA's EV Registration team will check the documents and confirm the removal of the previous EU QPPV/RP.
5. The new EU QPPV/RP will need to request the EU QPPV/RP role via the EMA Account Management Portal by following the steps described in **section 5.2** of the EudraVigilance Registration Manual. A **role Request ID** will be generated and should be provided to the EV Registration via the Service Desk ticket raised.
6. The EV Registration team will validate the EU QPPV/RP. The EU QPPV/RP will receive an email notification that the role has been approved.

First User EU QPPV/RP registration for new organisations – i.e. there is no EU QPPV/RP in the organisation

1. The appointed EU QPPV/RP needs to register with EMA Account Management Portal by following the steps described in **section 2.1** of the Eudravigilance Registration Manual.
2. The EU QPPV/RP will need to request the EU QPPV/RP role via the EMA Account Management Portal by following the steps described in section 5.2 of the Eudravigilance Registration Manual. A **role Request ID** will be generated and should be provided to EV Registration via Service Desk ticket – see step 3.
3. A Service Desk ticket should be raised to the Registration team, requesting the validation of the EU QPPV/RP role, stating the **organisation ID** and **name** and with the following documents attached:

   - A **cover letter** from the headquarters level of the organisation on a company's headed paper. The cover letter should be co-signed by:
     - the **new** EU QPPV/RP; **AND**
     - A person in a position above at headquarters level (i.e. director of the organisation or similar) of the concerned EEA-based **MAH, Sponsor or NCA organisation**.

       Notes:

       - The cover letter should state the **name**, **position** and **contact details** (including email) of the persons co-signing the letter.
       - For organisations assigning the EU QPPV/RP role for the first time: as there is no former EU QPPV/RP, the letter must also include a statement saying that this is the first time the EU QPPV/RP role is being assigned to a user.
       - **For Marketing Authorisation Holders (MAHs)**, the cover letter should also confirm that the appointed EU QPPV resides within the EU/EEA.
       - **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 Union/Community.[1]
   - **Email confirmation from the OMS** Data Stewards acknowledging the successful creation of the organisation, if available.
   - The **role Request ID** of the EU QPPV/RP, which can be included in the cover letter or on the description of the Service Desk ticket.
   - A **copy of the ID card/driving license/passport** of the **new** EU QPPV/RP **AND** 1) for organisations established in the Union/Community, of the person in a position above at headquarters level of the MAH, Sponsor or NCA organisation 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:

     - The full name and signature are visible; any other information contained on the ID documents may be redacted.

- 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.[2]

- The **User Declaration Form for EU QPPV/RP** (download here), dated and signed, including the organisation type, name of the organisation and the EU QPPV/RP details.
  - A copy 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.
    - The training certificates 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 RP/EU QPPV 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.

Marketing Authorisation Holders should additionally provide the following documents:

- 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 EEA marketing authorisation/application** for at least one product.

Commercial and Non-Commercial Sponsors should additionally provide the following documents:

- **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.
  - 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.
  - For **Sponsors NOT established in the Union/Community** conducting clinical trial within the Union/Community, the form should also include the name, details, and signature of the Legal Representative person within the Union/Community. The addresses of the Responsible Person and Legal Representative should be of the respective organisations they work for.

- For **Sponsors NOT established in the Union/Community**, a **copy of the ID card/driving license/passport** of the Legal Representative must also be provided.

  Notes:

  - The full name and signature should be visible; any other information contained on the ID document may be redacted. 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.[2]

- An **EU CT number** for a study the sponsor is conducting.

4. The EV Registration team will check the documents provided and validate the EU QPPV/RP role. The EU QPPV/RP will receive an email notification that the role has been approved.