13 March 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

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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 NCA Responsible" or "EV CS/NCS 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 headquarters level of the organisation on a company's headed paper.
  - The cover letter should be signed by the EU Qualified Person for Pharmacovigilance (EU QPPV) or by a person in a position above at headquarters level (i.e. director of the organisation or similar);
  - The cover letter should state the **name**, **position** and **contact details** of the EU QPPV;
  - 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 available.
- A **copy of the ID card/driver license/passport** of the EU QPPV
  - We require that the full name and signature are 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information will be used to verify the identity of the registering person and will be treated as confidential and will not be published or included in any user list.[1]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 EEA marketing authorisation/application** for at least one product.
- A copy of the **notification of successful completion of the EudraVigilance ICSR and XEVMPD knowledge evaluation** for at least one user. Please note that the training certificates do not have to be in the name of the new EU QPPV, but in the name of any active user of the

[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.

profile who has completed the courses and is related to the respective organisation. In other words, that is active user is an employee of the organisation OR is an employee of a CRO/Service Provider to which the company has delegated, via contract, the submission of ICSRs and/or XEVMPRs to EV.

Registration of the headquarter for Commercial and Non-commercial sponsors

- A **cover letter** from the headquarters level of the organisation on a company's headed paper.
  - The cover letter should be signed by the Responsible Person for PharmacoVigilance (RP) or by a person in a position above at headquarters level (i.e. director of the organisation or similar);
  - The cover letter should state the name, position and contact details of the RP;
  - 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 available.
- A **copy of the ID card/drive license/passport** of the RP
  - We require that the full name and signature are 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.[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.
  - 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 based outside EU/EEA conducting clinical trial within the community, the form should also include the name, details, and signature of the Legal Representative person within the EU/EEA. 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.
- A copy of the **notification of successful completion of the EudraVigilance ICSR and XEVMPD knowledge evaluation** for at least one user. Please note that the training certificates do not have to be in the name of the new RP, but in the name of any active user of the profile who has completed the courses and is related to the respective organisation. In other words, that is active user is an employee of the organisation OR is an employee of a CRO/Service Provider to which the company has delegated, via contract, the submission of ICSRs and/or XEVMPRs to EV.

Registration of the headquarter of National Competent Authorities

- A **cover letter** on organisation's headed paper.
  - The cover letter should be signed by the Head of the Pharmacovigilance Department/Responsible Person (RP) of the National Competent Authority;
  - The cover letter should state the name, position and contact details of the RP;
  - 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 available.
- A **copy of the ID card/driver license/passport** of the RP
  - We require the following information to be visible: full name and signature. 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.[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.
- A **copy of the notification of successful completion of the EudraVigilance ICSR and XEVMPD knowledge evaluation** for at least one user. Please note that the training certificates do not have to be in the name of the new RP, but in the name of any active user of the profile who has completed the courses and is related to the respective organisation. In other words, that is active user is an employee of the organisation OR is an employee of a CRO/Service Provider to which the company has delegated, via contract, the submission of ICSRs and/or XEVMPRs to EV.