22 November 2022
EMA/503894/2018
Information Management Division

EudraVigilance registration documents

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Pre-requisites

- User is registered in the EMA Account Management portal.
- Organisation is registered in the Organisation Management System.
- User has requested the roles of EV MAH EU QPPV or EV NCA Responsible or EV CS/NCS Responsible in the EMA Account Management portal.
- Raise a ticket with Service Desk with the Subject "Registration of new organisation – EV QPPV/Responsible Person validation" attaching the below documents.

Registration of the headquarter for Marketing Authorisation Holders (MAHs)

- A **cover letter** signed by the qualified person for pharmacovigilance (QPPV) of the organisation. The cover letter should be printed on the organisation's headed paper and should indicate that the undersigned is the 'qualified person for pharmacovigilance'. 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.
- A **copy of the ID card or driver's license or passport** of the qualified person for pharmacovigilance at headquarter level.
  - We require that the full name and signature are visible. You may black out any other information contained on the ID document.
  - 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information will be used to verify the identity of the registering person and will be treated as confidential and will not be published or included in any user list.[1]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 QPPV/RP**, including the type and name of the organisation, user's details. The form should be dated and signed by the user (download here).
- 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 or application for an EEA marketing authorisation** 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 to access the production environment, as applicable.

  Please note, this does not have to be in the name of the new 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.

[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.

Registration of the headquarter for commercial and non-commercial sponsors

- A **cover letter** requesting the sponsor's registration with EudraVigilance. The cover letter should be printed on the organisation's headed paper and should indicate that the undersigned is the 'responsible person for pharmacovigilance'. 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.
- A **copy of the ID card or driver's license or passport of the responsible person for EudraVigilance** at headquarter level.
  - We require that the full name and signature are visible. You may black out any other information contained on the ID document.
  - 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 QPPV/RP,** including the type and name of the organisation and user's details. The form should be dated and signed by the user (download here).
- **EudraVigilance Human Sponsor Registration Form** – signed by the sponsor appointing the new Responsible Person for EudraVigilance, including the name and the contact details of this person (download here). The address should be of the organisation the RP works for.
  - For Sponsors based outside the EEA conducting clinical trials within the community, the form must also be signed by the sponsor's Legal Representative established in the Union. The addresses of the Responsible Person and Legal Representative should be of the respective organisations they work for.
  - A **copy of the ID card or driving license or passport** of the Legal Representative must also be provided.[1]
- A **EudraCT number** for a study which 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 to access the production environment, as applicable.

  Please note: this does not have to be in the name of the new 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

Registration of the headquarter of National Competent Authorities

- A **cover letter** signed by the head of the pharmacovigilance department of the national competent authority, stating his/her position. The cover letter should be printed on the organisation's headed paper and should indicate that the undersigned is the 'responsible person for pharmacovigilance'. 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.
- A **copy of the ID card or driver's license or passport** of the head of the pharmacovigilance department of the national competent authority.
  - We require the following information to be visible: full name and signature. You may black out any other information contained on the ID document.
  - 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 QPPV/RP,** including the type and name of the organisation and user's details. The form should be dated and signed by the user (download here).
- A **copy of the notification of successful completion of the EudraVigilance ICSR and XEVMPD knowledge evaluation** for at least one user to access the production environment, as applicable.

  Please note, this does not have to be in the name of the new 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.