EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management

EudraVigilance XCOMP - organisation and user registration documents

Pre-requisites for registering a headquarter organisation

- Organisation details are entered in the EV XCOMP registration application
- Raise a ticket with Service Desk with Subject " Registration of new organisation – EV XCOMP" attaching the below documents, as applicable:

Registration of the headquarter for MAHs

- A **cover letter** signed by the qualified person for pharmacovigilance or a responsible person within the pharmacovigilance department of the organisation. The cover letter should be printed on the organization's headed paper and should indicate that the undersigned is the 'qualified person for pharmacovigilance'. The name and EV XCOMP ORG ID of the new organisation should also be provided as entered via the EV XCOMP registration application
- A **copy of the EV XCOMP online registration form** for 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information will be used to verify the identity of the responsible person and will be treated as confidential and will not be published or included in any user list[i]
- 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 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)

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- **Proof of an EEA marketing authorisation or application for an EEA marketing authorisation** for at least one product

Registration of the headquarter for commercial sponsors and non-commercial sponsors

Sponsors based within the EEA conducting clinical trials within the community

- 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 EV XCOMP ORG ID of the new organisation should also be provided as entered via the EV XCOMP registration application
- A **copy of the EV XCOMP online registration form** for 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)
- **Form A** – signed by the named person on the sponsor's clinical trial application form, appointing the new responsible person, including the name and the contact details of this person (download Form A here)
- A **EudraCT number** for a study the sponsor is conducting

Sponsors based outside the EEA conducting clinical trials within the community

Sponsors should additionally provide the following documents:

- **Form B** should be also sent, appointing the new 'legal representative', including the name and the contact details of this person (download Form B here)
- a **copy of the ID card or driving license or passport** of the new legal representative[1]

Registration of the headquarter of National Competent Authority

- 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 EV XCOMP ORG ID of the new organisation should also be provided as entered via the EV XCOMP registration application

- A **copy of the EV XCOMP online registration form** for 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)

Pre-requisites for registering an affiliate organisation

- Affiliate organisation details are entered in the EV XCOMP Restricted Area
- Raise a ticket with Service Desk with Subject " Registration of new affiliate organisation – EV XCOMP" attaching a **copy of the EV XCOMP online affiliate registration form** for the organisation

Pre-requisites for user registration

- User details are entered under the respective organisation in the EV XCOMP Restricted Area by the QPPV/RP/TD
- Raise a ticket with Service Desk with Subject " User registration in EV XCOMP" listing the organisation name, EV XCOMP ORG ID and full names of users to be registered
- **No registration documents are required for user registration in XCOMP**, unless the user is the main QPPV/ RP of the organisation

[i] *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.*