EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management

Electronic registration process in EudraVigilance XCOMP - registration phases I, II and III

Phase I – Registration of a headquarter profile

Step 1: Fill in the EV XCOMP online registration form

The registration form is the same for all organisation categories: regulators, marketing authorisation holders, commercial and non-commercial sponsors, and vendors.

- **Category:** Indicate the organisation category that is applicable to your organisation.
- **Trademark:** Trademark is any sign, which can be used to distinguish the goods and services of one trader from another. If an organisation does not have a trademark, the name of the organisation can be added in this field.
- **Organisation ID:** Each organisation must specify a unique organisation identifier (organisation ID), which is used to uniquely identify each organisation in the EDI process. The organisation identifier is also used to uniquely identify your organisation as the sender of the extended medicinal product report messages and to assign the ownership of this information for security purposes to your organisation.
  - Use a string formed by upper-case letters (A to Z), a number set (0 to 9) or a combination of both. Special or country-based characters and blank spaces are not allowed. The organisation ID must consist of a minimum of 3 and a maximum of 10 characters.
  - The organisation ID cannot be changed once it has been approved.
  - If a company registers in both environments (external compliance testing environment – XCOMP and production environment), the organisation must have two different organisation identifiers - one for each environment. For example, if your company's Production EV ID is ORG1000XXX, you may choose as your EV XCOMP organisation ID ' ORG1000XXX**T**'
- **Local gateway:** If you plan to perform your transmissions using your own local gateway solution, your organisation IDs for both the EudraVigilance external compliance testing and production environment must be identical to your gateway identifier.

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- **Web trader:** If you plan to perform your transmissions using the Web trader component of EVWEB, your organisation IDs for both the external compliance testing environment and production environment also apply accordingly to identify your organisation in the EDI process at the level of the safety, product and acknowledgement message, the sender or receiver.
- **Organisation name:** The organisation name is the official full name of the organisation, being a national competent authority, a marketing authorisation holder, commercial or non-commercial sponsor, or vendor.
- **Organisation address:** The address details such as street, city, postcode and country must be provided for each organisation.
- **Functional email:** Please enter a generic email address (e.g. IT@company.com) of the service responsible for IT functions of the organisation.
  - This field is mandatory at headquarter level and should not be a personal email address (i.e. firstname.surname@company.com).
  - The functional email address can be provided either from the headquarter or a CRO.
  - The functional email address will mainly be used for communication related to technical updates of the EudraVigilance database.
- **Regulatory Contact Point (for MAHs only):** The Regulatory Contact Point is an individual or a department authorised for communication with the EMA on behalf of the marketing authorisation holder. This communication may involve non-procedural regulatory matters such as changes of the EU QPPV within the organisation. The Regulatory Contact Point must belong to the MAH's organisation, and if it is an individual, he/she must not be the same as the EU Qualified Person for Pharmacovigilance (QPPV). This contact will be used to communicate with the MAH directly when the EU QPPV leaves the organisation.
  Please insert the name, telephone number and email address of an individual or a department, **which is part of the MAH organisation**. The email address may be a personal or a generic email address, such as info@...

  Please note: When you enter the name of an individual here, this person **does not** become a registered user of EudraVigilance.

Step 2: Provide details of the company's qualified person responsible for pharmacovigilance (QPPV) or responsible person (RP) for EudraVigilance

- **Contact details:** The contact details for the QPPV/RP for EudraVigilance include address, direct telephone number, fax number, and e-mail address.
  - No generic entries such as administration@abc.com or info@yahoo.co.uk are accepted.
- **QPPV alternative contact details:** Include the name and telephone number of the alternative QPPV person.
- **Sending reports:** Select the type of reports: safety reports (and product reports if applicable) you wish to register for, using the headquarter profile.

Step 3: Select transmission mode

- **Send directly:** Depending on the transmission mode you intend to use, you must specify one of the following two options:
  - **Local gateway**: This is applicable if you plan to perform your EDI transmissions using your own local gateway solution.
  - **Web trader**: This is applicable if you plan to perform your transmissions using the Web trader component of EVWEB.
- **Send using third party service provider:** If you intend to use a third party service provider to perform the EDI transmissions on your behalf, please enter a contact name and the contact details for the third party service provider.
  - The transmission mode that the third party service provider will be using (either local gateway or Web trader) must also be indicated.

Step 4: Specify the visibility at the affiliate/subordinate level for your organisation

You can choose to allow your affiliates/subordinates to be able to view the ICSRs that have been submitted at the headquarter level of your organisation to EV.

Step 5: MedDRA

In order to successfully register in EudraVigilance, a MedDRA licence number is required. There are two types of MedDRA licences available to organisations registering with EV:

- **Full MedDRA licence** (purchased from the MedDRA MSSO); and
- **Special MedDRA licence** (Low Revenue MedDRA EudraVigilance Fee Waiver) only available to micro and small enterprises (as defined by Commission Recommendation 2003/361/EC) and to sponsors of non-commercial clinical trials in the EEA who will only be using MedDRA in EVWEB.
  - To confirm that your company fulfils the criteria for micro or small enterprises, when requesting MedDRA fee waiver access on these grounds, the organisation must confirm its SME status with the Agency's SME office before completing EudraVigilance registration. Please go to EMA SME Office for further information.

Step 6: Specify IP address

The IP address(es) you specify here are not those of an individual computer on your network but refer(s) to the organisation's public IP address(es).

Specifying a single public IP number means that all the computers on your network will be able to access EudraVigilance. It is allowed to specify up to three public IP numbers to provide those organisations with more than one public IP to access EudraVigilance without any problem. If you require remote access or access via your home computer, please select '**all computers**'.

Step 7: Review and print your online EV XCOMP registration form

To modify any data you have inserted before finalising the registration, please use the '**Back**' button. Please note that you need to print this page first in order to enable the '**Submit**' button.

You have completed the first part of the registration process (Phase I). Please see Required registration documents for EV XCOMP to complete the registration process. Your submission will be assessed and, if complete, the QPPV/RP for EudraVigilance will receive a unique username and password to access the EudraVigilance XCOMP environment.

Phase II - affiliates/subordinates/regional level

Phase IIa) Registration of affiliates

If your organisation does not have any affiliates/subordinates, please move directly to Phase III.

Following successful completion of Phase I of the EudraVigilance XCOMP registration process, the qualified person for pharmacovigilance/responsible person for EudraVigilance (QPPV) can now register affiliates/subordinates and individual users for their organisation.

Please note that only the QPPV (or the trusted deputy) at headquarter level will be able to register affiliates/subordinates and new users.

Step 1: Access the restricted area of EudraVigilance XCOMP using your unique username and password.

Step 2: Select 'Manage your profile'

Step 3: Select add affiliate/subordinate

Step 4: Provide organisation information

You will be asked to enter the affiliate identifier (organisation ID), name and address. Please apply the same principle as stated in Phase I, Step 1.

- **Functional email:** Please enter a generic email address (e.g. IT@company.com) of the service responsible for IT functions of the organisation.
  - This field should not be a personal email address (i.e. firstname.surname@company.com).
  - The functional email address can be provided either from the headquarter or a CRO.
  - It will mainly be used for communication related to technical updates of the EudraVigilance database.

Step 5: Select transmission mode

- **Send by headquarter:** If your organisation has decided that the operation of the EDI process is carried out at headquarter level including all affiliate(s)/subordinate(s), the '**Send via Headquarter**' section should be selected.
- **Send directly:** Choose either '**Gateway**' or '**Web trader**' as applicable. If gateway is chosen as a reporting mode, testing will be required (for safety reports only).

The transmission mode of the affiliate does not need to be the same as the transmission mode of the headquarter (e.g. the headquarter can report using the gateway and the affiliate can use the Web trader as a transmission mode).

Phase II b) Register virtual affiliates

If your organisation does not require any virtual affiliates, please move directly to Phase III to register individual users at headquarter level within your organisation.

Following successful completion of Phase I of the EudraVigilance registration process, the qualified person for pharmacovigilance/responsible person for EudraVigilance can now register virtual affiliates for the purpose of third party transmission and individual users for this virtual affiliate.

Please note that only the QPPV (or the trusted deputy) at headquarter level will be able to register virtual affiliates and new users.

Step 1: Access the restricted area of EudraVigilance XCOMP using your unique username and password

Step 2: Select 'Manage your profile'

Step 3: Select add affiliate/subordinate

Step 4: Provide the organisation information

You will be asked to enter the affiliate identifier (organisation ID), name and address. Please complete the name and address of the marketing authorisation holder/sponsor, not the ones of the third party service provider. Please note the organisation ID must in part reflect the name of the headquarter organisation.

- **Functional email:** Please enter a generic email address (e.g. IT@company.com) of the service responsible for IT functions of the organisation. Please note that this field should not be a personal email address (i.e. firstname.surname@company.com). The functional email address can be provided either from the headquarter or a CRO. The functional email address will mainly be used for communication relating to technical updates to the EudraVigilance database.

Step 5: Select transmission mode

- Select '**Send via third party**' and insert the name and contact details of the third party service provider in the relevant fields. The transmission mode of the affiliate does not need to be the same as the transmission mode of the headquarter (e.g. the headquarter can report using the gateway and the affiliate can use the Web trader as a transmission mode).

Please refer to the Required registration documents for EV XCOMP to complete the affiliate registration process.

Phase III – Registration of a new user

Please note that only the qualified person for pharmacovigilance/responsible person for EudraVigilance (or the trusted 'deputy') at headquarter level will be able to register new users.

Step 1: Access the restricted area of EudraVigilance XCOMP using your unique username and password

Step 2: Select 'Manage your profile' and select 'Add user'

By clicking on the '**Add user**' button, the qualified person for pharmacovigilance/responsible person for EudraVigilance (or the trusted deputy) will be able to register new users at headquarter level.

To add a new user at an affiliate/subordinate level, click on '**Manage your profile**' to see full details of your organisation including a list of your registered affiliates and users, then click on the organisation ID of the relevant affiliate/subordinate. A new window with the details of that affiliate/subordinate will appear. At the top of that new window you will find an '**Add user**' button. By clicking on that button you will reach the registration form required to add a new user to the affiliate/subordinate.

Step 3: Set as QPPV

Please ensure that you indicate if the new user is a QPPV for a product by choosing the relevant tick box when creating the new user.

Step 4: Set individual user rights

The individual user rights depend on the overall access policies in EudraVigilance for the various registered partners.

- **National competent authorities** have full access to all ICSRs stored in EudraVigilance. During the registration process national competent authorities can decide what level of access they will grant to regional pharmacovigilance centres, where this is applicable.
- **Marketing authorisation holders** have restricted access to all ICSRs they have submitted to EudraVigilance. They can decide what level of access they will grant to their affiliates, where this is applicable.
- **Commercial and non-commercial sponsors** currently have access to any ICSRs that qualify as suspected unexpected serious adverse reactions (SUSARs), occurring in clinical trials and qualifying for reporting to the EudraVigilance clinical trial module (EVCTM) in accordance with the appropriate note for guidance as published by the European Commission.

Taking into account the overall EudraVigilance access policy, one of the following access rights can be assigned to an individual user:

- **Browse:** This allows the individual user to access EudraVigilance and to perform queries on a read only basis. Please note that the access rights of affiliate/subordinate users depend on the authorisation granted by the organisation headquarter (section '**Visibility for affiliates/subordinates'**).
- **Send ICSRs:** This applies to individual users of organisations at headquarter level or affiliate/subordinate level that are using the Web trader transmission mode for the EDI process.

The user can send ICSRs using EVWEB. In addition, the user can receive safety messages with one or several ICSRs, store the safety messages locally and generate acknowledgement messages.

- **Send extended medicinal product reports:** This applies to individual users of organisations at headquarter level or affiliate/subordinate level independently if they are using the Web trader or local gateway transmission mode. The user can create and send extended medicinal product reports by means of extended medicinal product report messages using EVWEB.
- **Browse and send ICSRs:** This allows the individual user to access EudraVigilance to perform queries. Please note that the access rights of affiliate/subordinate users depend on the authorisation granted by the organisation headquarter (section '**Visibility for affiliates/subordinates**'). The '**Browse and send ICSRs**' status allows the user also to create and send ICSRs via the Web trader. In addition, the user can receive safety messages with one or several ICSRs, store the safety essages locally and generate acknowledgement messages.
- **Browse and send extended medicinal product reports:** This allows the individual user to access EudraVigilance to perform queries. Note that the access rights of affiliate/subordinate users depend on the authorisation granted by the organisation headquarter (section '**Visibility for affiliates/subordinates**'). This status allows the user also to send extended medicinal product reports via the Web trader. In addition, the user can receive safety messages with one or several ICSRs, store the safety messages locally and generate acknowledgement messages.
- **No access rights:** The '**No access rights**' status does not allow the individual user to access EudraVigilance. This status may be assigned if the user goes on long-term leave (e.g. maternity leave, long-term absence etc.).

Please refer to the Required registration documents for EV XCOMP to complete the user registration process.