Guidance for registration with EudraVigilance Veterinary

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Annex I: Contact details for submission

1. Summary

Pharmaceutical companies - Marketing Authorisation Holders (MAHs), applicants and National Competent Authorities (NCAs) can register via the veterinary website with the European Medicines Agency in EudraVigilance. The registration process is necessary to identify the partners of the European Medicines Agency in the European Economic Area (EEA) for the secure electronic transmission of adverse event reports (AERs). Only registered partners are permitted to exchange safety or/and acknowledgement messages through the EudraVigilance veterinary gateway and Database Management System (DBMS). A list of registered parties is maintained by the Agency and is accessible in the restricted area of the EudraVigilance veterinary website to all registered partners.
2. Overview of the registration process

<table>
<thead>
<tr>
<th>Industry</th>
<th>Regulatory bodies</th>
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<tbody>
<tr>
<td>Registration of the Headquarter (at European level) of a pharmaceutical company (MAH/applicant) or NCA. Only the respective Headquarter of a pharmaceutical company or NCA will be admitted to this first phase of the registration process. The Qualified Person for Pharmacovigilance (QP)/ Responsible Person (RP) for EudraVigilance Veterinary is registered in this phase as a first user of the system.</td>
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### Phase I

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<thead>
<tr>
<th><strong>Company headquarters of a pharmaceutical company (MAH/applicant)</strong></th>
<th><strong>National Competent Authorities (NCAs)</strong></th>
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<tbody>
<tr>
<td><strong>Step 1</strong>&lt;br&gt;• Choose type of organisation&lt;br&gt;• Define trademark&lt;br&gt;• Choose organisation’s ID&lt;br&gt;• Define organisation’s name&lt;br&gt;• Define organisation’s address</td>
<td><strong>Step 1</strong>&lt;br&gt;• Choose type of organisation&lt;br&gt;• Choose organisation’s ID&lt;br&gt;• Define organisation’s name&lt;br&gt;• Define organisation’s address</td>
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<tr>
<td><strong>Step 2</strong>&lt;br&gt;• Define the name of QP for PhV&lt;br&gt;• Define QP’s contact details</td>
<td><strong>Step 2</strong>&lt;br&gt;• Define the name of RP for PhV&lt;br&gt;• Define RP’s contact details</td>
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<td><strong>Step 3</strong>&lt;br&gt;• Choose transmission mode&lt;br&gt;• Define Third Party Service Provider’s details (name, address, contact person’s name, tel and fax number and email address)&lt;br&gt;• Choose visibility rights</td>
<td><strong>Step 3</strong>&lt;br&gt;• Choose transmission mode&lt;br&gt;• Define Third Party Service Provider’s details (name, address, contact person’s name, tel and fax number and email address)&lt;br&gt;• Choose visibility rights</td>
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<td><strong>Step 4</strong>&lt;br&gt;• Choose security information</td>
<td><strong>Step 4</strong>&lt;br&gt;• Choose security information</td>
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<td><strong>Step 5</strong>&lt;br&gt;• Review, print and submit</td>
<td><strong>Step 5</strong>&lt;br&gt;• Review, print and submit</td>
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Phase II (if applicable)

Registration of affiliates of MAHs/applicants and regional pharmacovigilance centres of NCAs, if applicable.

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<th>Affiliate</th>
<th>Regional PhV Centre</th>
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<tr>
<td>Step 1</td>
<td>Step 1</td>
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<td>- Choose affiliate’s ID</td>
<td>- Choose centre’s ID</td>
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<td>- Define affiliate’s name</td>
<td>- Define centre’s name</td>
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<td>- Define affiliate’s address</td>
<td>- Define centre’s address</td>
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<tr>
<td>Step 2</td>
<td>Step 2</td>
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<tr>
<td>- Appoint Responsible Contact for PhV</td>
<td>- Appoint Responsible Contact for PhV</td>
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<td>- Define Responsible Contact’s details</td>
<td>- Define Responsible Contact’s details</td>
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<td>Step 3</td>
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<td>- Choose transmission mode</td>
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<td>- Review, print and submit</td>
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Phase III (if applicable)

Registration of individual users connected to MAHs/applicants or NCAs or their dependent regional affiliates or pharmacovigilance centres or third party service providers, if applicable.

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<th>Individual users</th>
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<td>- Define user’s address</td>
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<td>- Define user’s rights</td>
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3. General information you should familiarise yourself with before proceeding with the EV Veterinary registration:

3.1. EudraVigilance test and production environments

EudraVigilance Veterinary has two different environments:
- The test environment is for the testing of electronic transmission of AERs and to enable users to get used to the system
- The production environment is for the regular electronic transmission of AERs.
Each organisation must provide two different organisation IDs: one for the EudraVigilance Veterinary test environment and one for the EudraVigilance Veterinary production environment. Those two organisation IDs must be different.

3.2. Specification of the transmission mode

When you register, you will be asked to specify the transmission mode that your organisation is going to use to send safety and acknowledgement messages.

There are two transmission modes:

- **Gateway transmission mode**

  This refers to an organisation that has a pharmacovigilance database available. The database permits the generation and receipt of AERs, as well as a gateway solution that meets the ICH M2 standards and that has been successfully tested and connected with the EudraVigilance Veterinary gateway.

- **WEBtrader transmission mode**

  EVWEB allows sending and receiving of safety and acknowledgement messages in compliance with the latest CVMP data elements guideline. It also allows the saving of all messages at the user's local computer as well as the standardisation of message senders and receivers registered with the EMA as part of the EudraVigilance community.

There are two main functionalities that support the secure exchange of safety and acknowledgement messages:

- **WEBtrader**

  The WEBtrader provides a mechanism to compile and to securely send and receive safety and acknowledgement messages, in a semi-automatic way. It provides its users with an inbox where incoming messages can be located, viewed and further processed e.g. stored at the user's local computer. The outbox displays all safety and acknowledgement messages that have been created by WEBtrader users and sent to one or several receivers of the EudraVigilance community. Tracking functions are also available that allow the monitoring of the actual status of a transmitted message.

- **EV Post- the message posting function of EVWEB**

  This allows WEBtrader users to upload safety and acknowledgement messages that have been generated by the sender using their local pharmacovigilance system, to the EudraVigilance Gateway, from where the messages will be re-routed to the specified receiver.

MAHs/applicants and NCAs need to specify their transmission mode at all levels: at Headquarter level and at the level of the regional pharmacovigilance centres or affiliates, if applicable. Different transmission modes may be used at each level.

3.3 Choice of receiver

When a NCA communicates with a MAH, the NCA chooses the organisation ID owned by the MAH of the product(s) involved in the AER(s), which is the receiver ID. If a MAH wishes that AERs for certain products were sent directly to the HQ or a different affiliate, this should be communicated and agreed between the MAH and NCA.
The qualified person of the MAH is responsible for the follow-up of the AERs in line with the Guideline on the Electronic Data Interchange (EDI) of Suspected Adverse Reaction Reports (AERs) in Pharmacovigilance in the European Economic Area (EEA) (EMA/89569/2004).

4. The registration process: step-by-step

Two types of organisations can register with the EudraVigilance Veterinary system: National Competent Authorities (NCA) and pharmaceutical companies (Marketing Authorisation Holders (MAHs) and applicants).

Phase I and III of the registration process have a common form for all organisations. Phase II has two different forms - one for NCAs and another for pharmaceutical companies, however the registration process is analogical.

Please note that the EudraVigilance Veterinary has two different environments: one for testing and another for production (described in section: 3.1. EudraVigilance test and production environments).

4.1 Registration form Phase I

Step 1 – Organisation information

This registration form is identical for both pharmaceutical companies and NCAs.

The first field requires you to declare the type of organisation about to be registered: either a pharmaceutical company or a NCA.
• **National Competent Authority (NCA)**

In relation to this registration process, a NCA is defined as an authority within the EEA responsible for the granting of marketing authorisations for veterinary medicinal products, and the supervision of the marketing of such products, in accordance with the relevant laws and regulations established under community law.

• **Pharmaceutical company (MAH or applicant)**

In relation to this registration process, a pharmaceutical company is defined as a marketing authorisation holder (MAH) or applicant for veterinary medicinal products in the EEA. A marketing authorisation holder is holding a valid marketing authorisation for a veterinary medicinal product in the EEA including any part thereof, independent of the authorisation procedure of this veterinary medicinal product. An applicant is a pharmaceutical company applying for a marketing authorisation for a veterinary medicinal product in the EEA. A marketing authorisation holder (MAH) or applicant in the EEA being a company or a firm, can have a headquarter (HQ) which is the highest level in the organisation (‘headquarter level’) and may have linked to it one or several affiliates in the different Member States (‘affiliate level’). If a MAH has no affiliates it should register itself as HQ.

For transparency purposes the European headquarters of the company will be used as the first point of contact. If you choose ‘pharmaceutical company’ you will be asked for the company’s trademark.

A trademark is any sign that can be used to distinguish the goods and services of one trader from another. The trademark for a pharmaceutical company, registered with EudraVigilance veterinary, should include any letter, word, name, number or a combination of these used by the company as a marketing tool for customer recognition. It should not include any pictures, signatures, symbols etc.

The trademark allows grouping of all entities within a company (e.g. the headquarter and all registered affiliates), which is important for query purposes within EudraVigilance Veterinary, therefore all entities within a company should register with EudraVigilance Veterinary using the same trademark.

• **Organisation identifier (ID)**

Each pharmaceutical company or NCA must specify a unique organisation identifier (organisation ID). The organisation ID must include between 3 and 10 characters, and should consist of upper case letters (A to Z) and/or numbers (0 to 9), not using spaces or special characters. For easy recognition of the organisation and the Member State where it is located, it is further recommended to start the organisation ID with the two-letter country code according to ISO.

Please remember that you will need two different organisation identifiers: one for the test environment and another for the production environment. Those two IDs must be different. For example, if the company is called “VetCompany” and is located in the UK you may choose "UKVETCOMPT" for the test environment and "UKVETCOMP" for the production environment.

If your organisation deals with or produces medicines for both humans and animals, you will need different IDs to register with the veterinary and the human EudraVigilance systems.

• **Organisation name**

The organisation name is the legal name of the company or the exact name of the NCA.
• Organisation address

The address details of the organisation 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 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 and will mainly be used for communication relating to technical updates to the EudraVigilance system.

Step 2 - Qualified Person/Responsible Person for pharmacovigilance

Both pharmaceutical companies and Competent Authorities will be required to enter a Qualified Person (QP)/Responsible Person (RP) for pharmacovigilance. The QP/RP is the agency’s contact within that organisation.
The Qualified Person for pharmacovigilance in a pharmaceutical company is the person responsible for pharmacovigilance as defined in community legislation\(^1\). In a NCA it is the head of the pharmacovigilance department.

The role of the QP/RP in the EudraVigilance Veterinary registration process is to register the headquarter of a pharmaceutical company or a NCA, as well as to register the affiliate(s) or regional pharmacovigilance centres, if applicable, and to register individual users within the organisation. New users can be located at HQ level, the level of the nominated affiliates and/or the nominated third party service providers, when relevant.

The contact details of the QP/RP include address, telephone, fax number, and e-mail. It is essential to provide an email address for the QP/RP. Please note that for the e-mail address no generic entries such as ‘administration@abc.com’ or ‘xyz@yahoo.co.uk’ are accepted as the email address will be used to for sending your personal login credentials.

The QP/RP can delegate the functions related to registration of new users with EudraVigilance to a trusted Deputy within the same organization. The QP/RP should register the trusted Deputy with EudraVigilance as a user in the first instance. The delegation and the registration of the Deputy can be performed simultaneously.

**Step 3 – Transmission mode**

You will be given the choice of sending your electronic messages directly (via the Gateway or EVWEB). If you are planning to use a third party to send your messages, you need to provide their details.

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\(^1\) Directive 2001/82/EC, Art 74
For the transmission mode of the headquarter you need to choose one of the following two options:

1. **Direct reporting via:**
   - **Local gateway:** this is applicable if electronic data interchange (EDI) transmissions will be done via a gateway solution.
   - or
   - **WEBtrader:** this is applicable if EDI transmissions will occur via the WEBtrader or EV Post components of EVWEB.

If the organisation intends to use a third party service provider to perform the EDI transmissions on their behalf, a contact name and the contact details for the Third Party Service Provider must be also completed.

2. **Reporting using a Third Party Service Provider via:**
   - **Local gateway:** this is applicable if electronic data interchange (EDI) transmissions will be done via a gateway solution.
   - or
   - **WEBtrader:** this is applicable if EDI transmissions will occur via the WEBtrader or EV Post components of EVWEB.

The AERs created within the HQ or by its Third Party Service Provider will all carry the same sender ID (organisation ID).

In addition, the HQ may choose to allow for EDI transmission via affiliate organisations which at their level also may choose to allow for EDI transmission via a Third Party Service Provider.

The affiliate organisations will receive their separate organisation ID, so that safety messages created by the affiliate’s users or its Third Party Service Provider users will carry the organisation ID of the affiliate.

Please note that it is possible to use different options for the transmission mode at HQ level and affiliate level (e.g. a local Gateway at HQ level while at affiliate level a WEBtrader.) However all users within one profile will use the same transmission mode chosen for the organisation.

- **Third Party Service Provider information (if applicable)**

If a pharmaceutical company or NCA chooses to use a Third Party Service Provider, that third party will be responsible for undertaking the operation of the electronic data interchange (EDI) in accordance with the terms and conditions of the interchange agreement on behalf of the pharmaceutical company. Clinical research organisations (CROs), which do not qualify as a MAH, as well as IT vendors, cannot become a registered organisation in the EudraVigilance community on their own. However, CROs or IT vendors may be registered by a MAH as 'Third Party Service Providers' acting on behalf of these organisations by providing services related to EudraVigilance. In this instance the ‘third party’ section in the form needs to be completed. The transmission mode that the third party will be using also needs to be selected.
Visibility - Access rights for affiliates/regional pharmacovigilance centres

The headquarter of a MAH/applicant or NCA can choose to allow its affiliate(s)/regional centre(s) to be able to view the AERs which have been submitted by them to the EudraVigilance Veterinary DBMS. The appropriate option must be selected. Access rights are set in two different ways by the QP/RP of the MAH/NCA:

1) The organisation must first decide whether visibility or access rights would be provided to the affiliates or the Third Party Service Providers registered as ‘virtual’ affiliates for the EDI information being submitted by the HQ to EVVet. Please note that different affiliates will not be able to access each other’s AERs via EVWEB when the HQ visibility is set to 'No'.

The QP will have full access to all AERs sent by the HQ and/or its affiliate organisations. At present this access to the AERs in EVVet is however only limited to the messages being sent by the particular MAH/NCA to EVVet. All other messages in EVVet involving medicinal products from a MAH will not be accessible if these messages did not originate from the particular MAH. Also, when an AER is being sent by a MAH to a National Competent Authority, and this NCA forwards the message to the EVVet central database (after including its causality assessment), this AER will not be available to the MAH. When an AER is being sent by a MAH directly to the EVVet central database and to the NCA, the follow-up message from the NCA to the EVVet central database will still not be visible to the MAH.

Access on the basis of product ownership is being planned and would address this current limited access facility of MAHs to data concerning its products in the EVVet central database. However, when the legal reporting requirements are being followed, the MAH should also receive all AERs in its pharmacovigilance system by NCAs, who would be copying the information to the MAHs.

2) The QP/RP will also decide what specific additional access rights to give to all individual users (please refer to Section: 5. ‘User rights’)
**Step 4 - Security information**

This step is required for security purposes. The requested IP addresses/numbers are public IP numbers used by an organisation to access the Internet.

Specifying a single public IP number means that all the computers within the registering organisation will be able to access EudraVigilance Veterinary.

You can choose from the following options:

- ‘Grant access to’: Please enter up to 3 public IP numbers for the Headquarter to enable access EudraVigilance Veterinary from 3 different locations. Contact your network administrator for the required information.

  or

- ‘All computers (no control on IP address)’: this option allows access to EV Veterinary from all computers
Step 5 - Review, print and submit

This last step allows you to review and print the information before proceeding with the submission of your organisation registration information to EudraVigilance Veterinary. In case of any errors, you are able to go back to the completed forms and modify any data that you have inserted before finalising the registration by pressing the <Submit> 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).

To finalise the registration process, you must complete and send documentation to the EudraVigilance Registration Office (contact details in Annex I). For guidance on what documents are required for registration please refer to Section: 6. Documents required for EV Veterinary Registration. Your submission will be assessed and, if accepted, the QP/RP identified by you will receive a unique user name and password to enter the EudraVigilance Veterinary system.
4.2 Registration Form Phase II (if applicable) for Affiliate/Subordinate

**Step 1 – Affiliate/Subordinate information**

The QP/RP of a MAH/applicant or a NCA can now register affiliates, pharmacovigilance centres and individual users. If your organisation does not have any affiliates and you want to register individual users, please skip this phase and refer to section: 4.3. Registration form phase III – Individual users.

You must first enter the restricted area of the system via the ‘login’ link on the EudraVigilance veterinary homepage [http://eudravigilance.ema.europa.eu/veterinary/register.html](http://eudravigilance.ema.europa.eu/veterinary/register.html). You will be asked to enter your username and password. Go to <manage your profile> and EudraVigilance veterinary will recognise your identity from your login details and will grant you access to your organisation details.

Clicking on the ‘add new affiliate/regional centre’ button in the left-hand side navigation area will start the second phase of the registration process. Please note that affiliates/regional pharmacovigilance centres will not be able to register themselves. The QP/RP at headquarter level will be the only person able to add new users to the EudraVigilance Veterinary system.

You will be asked to enter the affiliate identifier (ID), name and address.
- **Affiliate identifier (ID)**

Please specify a unique affiliate ID for each affiliate that you register. The ID must contain between 3 and 10 characters, and should consist of upper case letters (A to Z) and/or numbers (0 to 9), not using spaces or special characters. For easy recognition of the organisation and the Member State where it is located, it is further recommended to start the organisation ID with the two-letter country code according to ISO.

Each affiliate must have two different IDs: one for the EudraVigilance Veterinary test environment and one for the EudraVigilance Veterinary production environment.

- **Affiliate name**

The affiliate name should be the full and precise name of the pharmaceutical company’s affiliate. The exact address should be also specified.

- **Functional email**

Please enter a generic email address (e.g. IT@company.com) of the service responsible for IT functions of the organisation 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 and will mainly be used for communication relating to technical updates to the EudraVigilance system.
Step 2 - Responsible Contact person for pharmacovigilance for an affiliate

The Responsible Contact person for EudraVigilance of an affiliate is the person responsible for pharmacovigilance nominated for this affiliate. Please be aware that the Responsible Contact person can be identical with the QP/RP at HQ level. The form and its field requirements are identical to the one in phase I step 2 – the address, direct telephone number, fax number and e-mail address should be provided. Please note that for the e-mail address no generic entries such as 'administration@abc.com' or 'xyz@yahoo.co.uk' are accepted as the email address will be used to for sending your personal login credentials.
**Step 3 – Transmission mode**

A new form will be presented to you. You will be asked to choose the transmission mode by which the affiliate will be sending the reports to EudraVigilance Veterinary. Three options are presented:

- **Send via headquarter:** If the pharmaceutical company has decided that the headquarter will undertake the operation of electronic data interchange (EDI) on behalf of the affiliate(s), this section should be selected.

- **Send directly via:**
  
  If your organisation has decided that the operation of EDI processes is carried out at affiliate/subordinate level, you have to indicate the transmission mode that the affiliate/subordinate is going to use:

  - **Local gateway** - if your affiliates/subordinates plan to perform your EDI transmissions using your own local gateway solution
  
  - **WEBtrader** - if your affiliates/subordinates plan to perform your transmissions using the EVWeb or EV Post components of EVWEB
• Send using Third Party Service Provider via:

If your affiliate/subordinate chooses to use a Third Party Service Provider to perform the EDI transmissions on their behalf, a contact name and the contact details for the Third Party Service Provider must also be completed.

The transmission mode that the third party service provider will be using:

• **Local gateway** - if your affiliates/subordinates plan to perform your EDI transmissions using your own local gateway solution

• **WEBtrader** - if your affiliates/subordinates plan to perform your transmissions using the EVWeb or EVPost components of EVWEB

### Step 4 - Security information

Please refer to the ‘Security Information’ section of Phase I.

### Step 5 - Review, print and submit

This step corresponds to the ‘Review, print and submit’ section of phase I. Please send the documentation identified in Section: 6. Document required for EV Veterinary registration to the EudraVigilance registration office (contact details in Annex I) to finalise the registration process for your affiliate. After validation, the Responsible Contact person for pharmacovigilance at affiliate level will then receive their unique user name and password to access EudraVigilance Veterinary.

#### 4.2.1 Pharmacovigilance centre

If the National Competent Authority does not have regional pharmacovigilance centres, you can skip this phase. You can still register individual users (see Phase III). Follow the steps identically to the steps for affiliate registration described in section- 4.2 Registration Form Phase II. The registration process of a Pharmacovigilance centre is identical to the Affiliate/Subordinate registration.

### 4.3 Registration form phase III – Individual users (if applicable)

#### Step 1

The QP/RP of a MAH/applicant or a NCA can also register individual users.


There are two environments you can choose from by clicking on the appropriate links.

You will be asked to enter your username and password. Go to <Manage your profile> and EudraVigilance Veterinary will recognise your identity from your login details and will grant you access to your organisation details.

Clicking on the <add new user> button in the left-hand side navigation area will start this phase of the registration process of an individual user.
The individual user registration form requires the name and contact details for the new user.

- **Individual user name and contact details**

The contact details for this person including address, telephone, fax number and e-mail must be specified. Please note that for the e-mail address no generic entries such as ‘administration@abc.com’ or ‘xyz@yahoo.co.uk’ are accepted as the email address will be used to for sending your personal login credentials.

- **Define user rights**

You will also be asked to specify the user rights for each new user. For further information please refer to Section: 5. User Rights.

Please submit the form online and then provide the documentation and information identified in Section: 6. Documents required for EV Veterinary registration in order to finalise the registration process for the new user. After validation, the new user will receive their unique user name and password to access EudraVigilance Veterinary.
5. User Rights

The user rights of each individual user, within an organisation must be defined by the head of the pharmacovigilance department of the NCA or the Qualified Person of the MAH/applicant with whom the individual is associated.

One of the following access rights can be assigned to an individual user:

- **No Access Right:**
  
  This does not allow the individual user to access the EudraVigilance Veterinary DBMS. This status should be chosen for example if a user is no longer allowed to use the DBMS because he/she is no longer employed at the organisation or has changed departments.

- **Browse:**
  
  This allows the individual user to access the EudraVigilance Veterinary DBMS to make queries on a “read only” basis. Please note that the access rights of users depend on the authorisation given to them by their headquarters (visibility for affiliates section) and that in principle an organisation can only access its own submitted data. This status allows the user also to view an AER and a medicinal product report but **not** to create and send it via the WEBtrader (transmission can only take place via the locally established gateway).

- **Send AERs:**
  
  This applies to individual users of an organisation using the WEBtrader transmission mode. The user can create and send AERs using EVWEB.

- **Send Medicinal Product Report:**
  
  This applies to individual users of an organisation using the WEBtrader transmission mode. The user can create and send a Medicinal Product Report using EVWEB.

- **Browse and Send AERs:**
  
  This allows the individual user to access the EudraVigilance Veterinary DBMS in order to make queries and create and send AERs via the WEBtrader.

- **Browse and Send Medicinal Product Reports:**
  
  This allows the individual user to access the EudraVigilance Veterinary DBMS to make queries and create and send Medicinal Product Reports.

- **Browse and Send AERs and Medicinal Product Reports:**
  
  This allows the individual user to access the EudraVigilance Veterinary DBMS to make queries. This status also allows the user to create and send AERs and Medicinal Product Reports via the WEBtrader.

*Note: The access rights of users registered under an affiliate/pharmacovigilance centre’s routing ID additionally depend on the authorisation given to them by their headquarters (refer to section: 4.1 Registration form phase I- ‘Visibility- Access rights for affiliates/regional pharmacovigilance centres’).*
6. Documents required for EV Veterinary registration

To successfully complete the registration process you are required to post several documents to the Agency, see Annex I: Contact details for submission for the postal address details.

6.1 Documents required for Headquarter registration

The following documents are required to be sent to the indicated address:

- **Cover letter** requesting registration of the MAH/applicant/NCA, signed by the Qualified Person for Pharmacovigilance/Responsible Person for EudraVigilance Veterinary (main user). The letter should indicate that the person signing it is in fact the QP/RP of the organisation and should be printed on the company’s letter-headed paper.

- Printed copy of the completed *Online registration* form. This form should be signed and dated by the QP/RP.

- Signed and dated *EudraVigilance Veterinary User Declaration* form. This form is to be signed by the QP/RP registering in this process. You can download the template from our website: http://eudravigilance.ema.europa.eu/veterinary/register.html

- Signed and dated *EudraVigilance Veterinary Access Security Declaration* form. This form is to be signed by the Responsible Contact person who is being registered as a user for this affiliate. You can download the template from our website: http://eudravigilance.ema.europa.eu/veterinary/register.html

- Signed and dated copy of the **ID card/drivers license or passport** of the QP/RP registering in this process. These documents are necessary to verify the identity of the registered person. They are securely kept and they will not be published or included in any user list. The European Medicines Agency processes your personal data in accordance with Regulation (EC) 45/2001. For more information, please visit: [http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000178.jsp&murl=&mid=#data](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000178.jsp&murl=&mid=#data)

- Copy of the **trade register** for the MAH/applicant only. 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 the respective Member State.

6.2 Documents required for Affiliate:

The following documents are required to be sent to the indicated address:

- **Cover letter** requesting the registration of that affiliate, signed by the QP/RP (main user)

- Printed copy of the completed *Online registration* form. This form should be signed and dated by the QP/RP of the headquarter.

- Signed and dated *EudraVigilance Veterinary User Declaration* form. This form is to be signed by the Responsible Contact person who is being registered as a user for this affiliate. You can download the template from our website: http://eudravigilance.ema.europa.eu/veterinary/register.html

- Signed and dated *EudraVigilance Veterinary Access Security Declaration* form. This form is to be signed by the Responsible Contact person who is being registered as a user for this affiliate. You can download the template from our website: http://eudravigilance.ema.europa.eu/veterinary/register.html
• Signed and dated copy of the **ID card/drivers license or passport** of the Responsible Contact person to be registered. The document of identification should be of the actual person who is being registered. The copy of your document is necessary in order to verify the identity of the registered person. It will be kept securely and processed in a confidential manner. At no time, these documents will be published or included in any user list. The Agency processes your data in accordance with the provisions of Regulation (EC) 45/2001. For more information, please visit: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000178.jsp&murl=&mid=#data

6.3 Documents required for trusted Deputy registration (if applicable)

The Qualified Person/Responsible Person for pharmacovigilance at headquarter level can delegate the functions related to the registration of new users or affiliates in EudraVigilance Veterinary to a trusted Deputy within the same organisation.

The QP/RP at headquarter level should first enter the trusted Deputy’s details in EudraVigilance Veterinary as an individual user (see Section: 4.3. Registration form phase III – Individual users). The delegation and the registration of a Deputy can be performed simultaneously by sending the following required documents:

• A **cover letter** indicating that the QP/RP wishes to delegate the functions related to EudraVigilance Veterinary registrations of individual users and/or affiliates in the organisation to the named trusted Deputy.

• A completed **‘EudraVigilance Veterinary Registration Delegation’** form signed by the QP/RP. The form is available for download on the website: http://eudravigilance.ema.europa.eu/veterinary/register.html

6.4. Documents required for registration of new Users:

• A **request** to complete the registration of new users by email, by the QP/RP or the trusted Deputy (specifying the organisation name and ID, the Test Environment and/or Production Environment in which the user should be registered and the complete name of the user)

For every new user registration in EV Veterinary, the process should be as such:

• the QP/RP will log into the “manage your profile” section, and will create the user profile in the system,

• the QP/RP will send a **request** to complete the registration of this new user by email to EudraVigilance registration general inbox at EudraVigilanceRegistration@ema.europa.eu (the organisation name and ID and the complete name of the user must be specified in this request)

• the EudraVigilance registration team will process the registration in the EudraVigilance system and will send the login credentials to the user, via a secure link email

Consequently, there is no need to provide the EMA with the following original documents:

• ‘Individual online registration’ form signed by the QP/RP
• ‘EudraVigilance Veterinary User Declaration’ form signed by the user
• Copy of the ID of the user, signed and dated by the user
6.5. Documents required for change of Qualified Person/Responsible Person

If a change of Qualified Person for Pharmacovigilance/Responsible Person for EudraVigilance/ within your organisation occurs, you need to notify the EudraVigilance team in writing of that change.

- A **cover letter** should be sent from the ‘headquarters’ level of the organisation. That cover letter should be signed by the ‘new’ QP/RP, or by a person in a position above that at ‘headquarters’ level (i.e. the Director of the organisation or similar). The letter should state the name and position of the ‘old’ QP/RP, and the name, position and complete contact details of the ‘new’ QP/RP. It should also say if the ‘old’ QP/RP should be disconnected from the system or should remain active as a regular user.

Please do not repeat the online registration form for headquarters of your organisation with the new details. The QP/RP will be replaced in the system by the EudraVigilance database administrator here at the European Medicines Agency.

In addition, the ‘new’ QP/RP should be registered in the system, if not already so. For that purpose he/she should send the following documents:

- Signed and dated copy of the **ID card/drivers license or passport** of the QP/RP registering in this process. These documents are necessary to verify the identity of the registered person. They are securely kept and they will not be published or included in any user list. The European Medicines Agency processes your personal data in accordance with Regulation (EC) 45/2001. For more information, please visit: [http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000178.jsp&murl=&mid=#data](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000178.jsp&murl=&mid=#data)

- **EudraVigilance Veterinary Access Security Declaration** signed and dated by the QP/RP. You can download the template from our website: [http://eudravigilance.ema.europa.eu/veterinary/register.html](http://eudravigilance.ema.europa.eu/veterinary/register.html)

- **EudraVigilance Veterinary User Declaration** form, signed and dated by the QP/RP. You can download the template from our website: [http://eudravigilance.ema.europa.eu/veterinary/register.html](http://eudravigilance.ema.europa.eu/veterinary/register.html)

**Annex I: Contact details for submission**

The complete documentation should be sent as scanned PDF-files via e-mail to: [EudraVigilanceRegistration@ema.europa.eu](mailto:EudraVigilanceRegistration@ema.europa.eu)

If you have questions regarding the registration process, please contact us via the helpdesk accessible via the EudraVigilance Veterinary webpage: [http://eudravigilance.ema.europa.eu/veterinary/contactus.html](http://eudravigilance.ema.europa.eu/veterinary/contactus.html) or by sending an email directly to [EudraVigilanceRegistration@ema.europa.eu](mailto:EudraVigilanceRegistration@ema.europa.eu).

You can also contact us directly by tel: +44 (0) 20 7523 7523.