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Information Management

EudraVigilance Data Analysis System (EVDAS)

User registration steps for EU QPPVs or trusted deputies (for the purpose of the EudraVigilance registration process)

As of 22 November 2017, users from marketing authorisation holder (MAH) organisations in the European Economic Area have been granted access to the EudraVigilance Data Analysis System (EVDAS).

EVDAS users appointed by the European Qualified Person responsible for Pharmacovigilance (EU QPPV) are registered both in EVDAS and in the XEVMPD Data-Entry Tool (EVWEB) as part of the EudraVigilance system and:

- receive login details to access the EVDAS system to view the active substance grouping reports, electronic reaction monitoring reports (e-RMRs) and line listings; and
- receive login details for EVWEB to access individual case safety reports (ICSRs) directly from the line listings.

Note: signal management experts, who do not have an EVDAS account, can access individual cases using their EVWEB account by searching via the world-wide unique case identification number(s).

EVDAS user registration

Step 1

The EU QPPV/trusted deputy submits the user details in the EudraVigilance registration system under the headquarter profile of the organisation. The EVWEB user rights and EVDAS roles should be specified for the following parameters:

- EVDAS Scientific (EVDAS with access to individual case report forms)
- EVDAS Administrator (EVDAS without access to individual case report forms)

EVDAS access via EudraVigilance can be provided **only at HQ level**.

For users associated with the role *"EVDAS Scientific"* login details for EVWEB and login details for EVDAS are provided.

For users associated with the role *"EVDAS Administrator"* only EVDAS login details are provided.

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Step 2

The EU QPPV/trusted deputy submits a request for EVDAS user access by sending an email to the dedicated EVDAS registration inbox EudraVigilanceRegistration@ema.europa.eu.

The email request should contain the following information for the EVDAS user(s) to be registered:

- number of users, organisation ID and organisation name must be specified in the subject line of the email;
- user(s) full name, user(s) email address, EV HQ ID and the name of the organisation must be specified in the body of the email.

If the user requiring EVDAS access is already registered as an EVWEB user, the relevant EVDAS role should be requested by sending an email to EudraVigilanceRegistration@ema.europa.eu.

Step 3

The EU QPPV/trusted deputy are notified by email of the completion of the user registration request and the respective **EVWEB and EVDAS login details** are sent to the user.

From 22 November 2017 users can log in to the EVDAS system in the following two ways:

- via the EudraVigilance registration page on the EMA corporate website - http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000687.jsp&mid=WC0b01ac0580a69262
- via the EVDAS welcome page - https://bi.ema.europa.eu/analytics/saw.dll?Dashboard&PortalPath=%2Fshared%2FMAH%20Pharmacovigilance%20Query%20Library%2F_portal%2FMAH%20Pharmacovigilance%20Queries

Removal of a user's EVDAS access

If the user access to EVDAS needs to be removed (e.g. the person is moving to a different department or is leaving the company), the EU QPPV/trusted deputy must send immediately an email to the dedicated EVDAS registration inbox EudraVigilanceRegistration@ema.europa.eu requesting the removal of relevant access of the user.

The email request should contain the following information:

- user(s) full name;
- user(s) email address;
- **EV HQ ID** and name of organisation;
- type of access rights/ roles to be removed (EVWEB and EVDAS);
- date as of when the access has to be removed.