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EMA/204890/2017
Information Management Division

# EudraVigilance user declaration for qualified person for pharmacovigilance/responsible person for EudraVigilance

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The undersigned Qualified person responsible for pharmacovigilance (QPPV)/responsible person (RP) declares that he/she:

- will keep the username and password provided by the European Medicines Agency (EMA) for the access to the EudraVigilance database under an adequate regime of security measures; access to the EudraVigilance database refers to access using the EudraVigilance Data Analysis System (EVDAS) and/or the EudraVigilance web application (EVWEB);
- may propose third parties within his/her organisation to have access to the EudraVigilance database for the purpose of pharmacovigilance activities; to that effect, the undersigned must take responsibility to verify the identity of the authorised third parties and communicate their contact details to the responsible EMA Service;
- is responsible for the access and use of the EudraVigilance database system made by the authorised users within his/her organisation;
- remains strictly responsible for any unlawful use or security breaches that may occur to the data stored with EudraVigilance as a result of his/her negligence or the negligence of the authorised third parties within his/her organisation;
- will inform the EMA immediately of any potential compromise to the integrity and confidentiality of password details and other logical security. EMA administrators can be contacted during normal office hours. In such case, the compromised password will be disabled immediately;
- will inform the EMA immediately in writing of any changes in his/her contact details as specified in the online user registration form;
- will inform the EMA immediately in writing about any changes affecting the access rights (e.g. end of employment with the registered organisation, change of department within the registered organisation, etc.) of any registered EudraVigilance user in relation to the organisation as indicated below;
- will inform the EMA immediately in writing about any changes of his/her access rights (e.g. end of employment with the registered organisation, change of department within the registered organisation, etc.);

For security reasons, access to the EudraVigilance database will be denied and suspended if the user enters an incorrect password in the login process three times in a row on the same day.

The EMA can refuse the registration of a user for any valid reason.

**Organisation name (NCA/ MAH/ sponsor)**:

**Organisation type**:

☐ national competent authority (NCA)

☐ marketing authorisation holder (MAH)

☐ applicant

☐ commercial sponsor

☐ non-commercial sponsor

**QPPV users only**:

☐ I declare that I reside within the European Economic Area

Country of residence:

**User details:**

Street:

City:

Postcode:

Country:

User full name:

Telephone number: Fax number:

User E-mail address:

Date: Signature:

*The personal data you provided will be processed in accordance with the provisions of Regulation (EC) No 45/2001 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. These personal data are required to manage the EudraVigilance database set up and maintained by the European Medicines Agency in accordance with Article 24 of Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, also by reference to Article 57(1)(j) of Regulation (EC) No 726/2004, in order to verify the identity of the users of the system and related pharmacovigilance activities. Your address, including e-mail address, will be used to send you technical instructions and other pertinent communications related to the functioning of the EudraVigilance database. The European Medicines Agency and other national competent authorities will process such personal data exclusively for the purpose for which they are collected. You are entitled to access, rectify and block these data in accordance with the provisions of Regulation (EC) No 45/2001. You may exercise these rights by contacting the European Medicines Agency (EudraVigilanceRegistration@ema.europa.eu). You have also the right of recourse to the European Data Protection Supervisor (www.edps.europa.eu) at any time.*