

13 June 2016
EMA/410776/2016
Information Management Division

EudraVigilance registration system

Introduction of new functionalities

The European Medicines Agency is implementing the following changes to the EudraVigilance registration system with effect from Monday 13 June 2016:

- **Introduction of a 'regulatory contact point' for marketing authorisation holders only**

The 'regulatory contact point' is an individual or department at headquarter level authorised for communication with the EMA on behalf of the marketing authorisation holder (MAH). This communication may involve non-procedural issues (e.g. processes related to the change of EU QPPV). The 'regulatory contact point' should be part of the MAH's organisation and if it is an individual, he/she should not be the same as the EU QPPV. If it is an individual, he/she will not become a registered user of EudraVigilance by entering their contact details in this section.

Existing registered MAH organisations are required to update their EudraVigilance profiles with these details at their earliest convenience.

- **Mandatory password change functionality for first time users**

Users will be required to change their password immediately after they log in to EudraVigilance for the first time. A password change will also be required if an existing user's password has been reset.

- **Introduction of editable fields and affiliate categories**

The registered responsible users of headquarter organisations (QPPVs, RPs and trusted deputy users) will be able to edit a number of fields within their organisation and user profiles accessible via the "Restricted area" of EudraVigilance. Affiliate profiles will have a category which the responsible users from the headquarter are required to update at their earliest convenience.

- **Introduction of a new troubleshooting functionality**

Registered EudraVigilance users will be able to see that the EMA is troubleshooting their user account. This will be visible within the EudraVigilance restricted area and EVWEB. This will not result in restriction of user access.

- **Introduction of separate ADR and XEVMPD user rights**

The EudraVigilance system will be upgraded to support the ISO/HL7 27953-2:2011 (E2B(R3)) ICSR format in 2017. In preparation for this, a change has been made to the Eudravigilance Registration system to enable roles to be assigned separately in the future to the Human ICSR and Human XEVMPD (Product) EudraVigilance applications.

Should you have any questions in relation to the above changes, please contact the EudraVigilance registration team: EudraVigilanceRegistration@ema.europa.eu