



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management

Introduction of a 'regulatory contact point' for marketing authorisation holders

The European Medicines Agency is implementing a 'regulatory contact point' within the EudraVigilance registration database.

The regulatory contact point is an individual or department authorised for communication with the EMA on behalf of the 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.

The EMA is implementing this feature in the week commencing on 13 June 2016.

MAH organisations are required to provide at a headquarter level the name of an individual or a department who belongs to the MAH, a telephone number and an email address. The email address can be an individual's email address or a generic email address (e.g. info@..).

This feature will facilitate the change of QPPV process within the EudraVigilance registration database. The regulatory contact point will be used by the EudraVigilance registration team to contact the MAH directly when their registered EU QPPV leaves and a new EU QPPV has not been registered. This will help MAH organisations and the EMA to follow up on the MAH's legal obligations to have permanently and continuously a registered EU QPPV in line with *Article 104(3)(a) of Directive 2001/83/EC*.

The registered EU QPPV and trusted deputy users of existing MAH organisations in EudraVigilance will be able to provide this information by logging in to the secure area of EudraVigilance and by completing the relevant fields under the new "*Edit organisation*" option. When the "*Edit organisation*" option has been selected, the regulatory contact point fields will become mandatory. Newly registering MAH organisations will need to provide this mandatory information as part of the organisation's EudraVigilance online registration form.

Registered MAH organisations are required to provide this information at their earliest convenience. The EMA will be sending out quarterly reminders to organisations who have not updated this information. Please note that if your organisation does not update this information your users' access to EudraVigilance **will not** be restricted.



The introduction of the regulatory contact point is an update of the EV Registration database.

No update of AMPs will need to be performed by the MAH organisations in the Article 57 database.

Any questions related to the new regulatory contact point feature should be directed to the EudraVigilance registration team: EudraVigilanceRegistration@ema.europa.eu.