EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management

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

Regulatory contact point for QPPV changes in EudraVigilance

The European Medicines Agency has implemented 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 implemented this feature 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 facilitates the change of QPPV process within the EudraVigilance registration database. The regulatory contact point is 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 helps 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 are able to provide this information by logging in to the secure area of EudraVigilance and by completing the relevant fields under the *"Edit organisation"* option. When the *"Edit organisation"* option has been selected, the regulatory contact point fields will become mandatory. Newly registering MAH organisations 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 aims to send out quarterly reminders to organisations who have not updated this information.

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Send a question via our website www.ema.europa.eu/contact

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 AskEMA.

Regulatory contact point for non-pharmacovigilance referrals

The European Medicines Agency is changing the way it communicates with marketing authorisation holders (MAHs) and applicants involved in non-pharmacovigilance referral procedures under Article 31 of Directive 2001/83/EC.

From 10 April 2017 the Agency will use the regulatory contact point email address provided in the EudraVigilance registration system as the main contact point for the concerned products throughout the procedure. All correspondence from the Agency related to the start of a non-pharmacovigilance referral procedure, as well as all subsequent documents provided to the MAHs/applicants during the procedure, will be sent electronically to the regulatory contact point email address (via Eudralink).

Therefore, MAHs need to ensure that the regulatory contact point listed in the EudraVigilance registration system is up to date.

Whenever possible and provided an email address for the regulatory contact point is available, MAHs/applicants will be informed on the Wednesday before the CHMP meeting of new non-pharmacovigilance Article 31 procedures that the CHMP will consider the following week. This communication will be provided for information only.

Note that notifications for referrals can be received at any time, including during the CHMP meeting, and it may not always be possible to provide MAHs/applicants with advance information on the Wednesday before the CHMP plenary meeting.

Following the CHMP meeting, all concerned MAHs/applicants will receive further information from the EMA, including the details of the EMA procedure manager and assistant.

For currently ongoing non-pharmacovigilance referrals, the Agency will continue to use the contact details established for those procedures.

For queries related to this process, please use the EMA website: Home> About Us> Contact> Send a question, quoting the keyword "REF-non PhV" in the subject line.