Important checks for marketing authorisation holders (MAHs) to prepare the transition of post-authorisation procedures in IRIS

1 *ALL Marketing Authorisation Holders (MAHs) need to be registered in OMS*. Check section 4 of **IRIS guide to registration and RPIs** for more information.

2 *Contact persons for all registered MAHs in OMS have **EMA account** and the appropriate **IRIS Industry role (preferably IRIS Industry Manger role)**.*

→ **How to request access?** Via the **EMA Account Management System** for all IRIS Industry affiliated roles.

Instructions are available in the **IRIS guide to registration and RPIs**.

3a ***CAP MAHs** update product contact information:*

Scenario 1

The product contact person remains unchanged, but linked to a functional mailbox - Update contacts currently listed with functional mailbox with personal email addresses associated with responsible contact person having IRIS role.

How do you change the product contact email? Raise a ticket:

- In sub-section 'Service', select 'Identity and access management'
- In sub-section 'Service offering', select 'Eudra Common Directory – ECD'

Scenario 2

The product contact person changes - Submit the updated form using this template: template_letter-change_contact_person_en.doc (live.com)

How to submit the form?

- Human-use products: Contacting EMA: post-authorisation | European Medicines Agency (europa.eu)
- Veterinary-use products: Notifying EMA of changes to contact persons (veterinary medicines) | European Medicines Agency (europa.eu)

Who is the product contact for CAP MAHs?

Person authorised for communication with the Agency (referred in section 2.4.3 of the application form)

The information to be provided as per points 1 to 3 is crucial for the procedures to be created in IRIS and for communication via IRIS to reach the correct MAH contact persons.

EMA

Important checks for marketing authorisation holders (MAHs) to prepare the transition of post-authorisation procedures in IRIS

3b ***Non-CAP MAHs*** *update product contact information:*

- To register as a QPPV and regulatory contact point for a MAH, the process described in the section **Registering individual users of the** EudraVigilance: how to register webpage should be followed;
- To create a link between the authorised medicinal product (AMP) and the QPPV in the Art57 database, the AMP entry must reference the QPPV Code assigned to the QPPV. This is explained in section **1.2.5. Qualified Person responsible for Pharmacovigilance (QPPV) code (AP.5)** of Chapter 3.II: XEVPRM user guidance for MAHs.
- To update QPPV information reference in an AMP entry in the Art57 database, see section 2.1. Maintenance of a Qualified Person responsible for Pharmacovigilance (QPPV) of Chapter 3.II: XEVPRM user guidance for MAHs
- Liaise with NCA to update the MAH contact person at NCA;

→ **For already submitted PSURs and to be started in IRIS:** Via eSubmission Questions form, request the change for the PSUR submission email address to the one indicated when requesting access to IRIS (as per point 2):

- Fill in "Subject" – "Request to change email address for PSUR submissions;
- Fill in "Description" - "Request to change the email address for the MAH contact person from <*email address*> to <*email address*> for PSUR submissions <*PSUSA/XXX/YYY*>. The change to be done in PSUR submission form
- Provide relevant MAH OMS ORG-ID, if related;
- (Optional) Tick "In order to add an attachment please indicate that you agree to the Terms of Use" box and attach relevant files

Who is the product contact for non-CAP MAHs?

- QPPV registered in Art 57 database or UPD;
- Regulatory contact point (RCP) registered in the Eudravigilance database (Human domain);
- MAH contact point at national level;
- MAH contact point assigned to the procedure by the MAH (e.g. referrals triggered by MAH).
- For PSURs, contact person indicated in the PSUR form (Human domain).

The information to be provided as per points 1 to 3 is crucial for the procedures to be created in IRIS and for communication via IRIS to reach the correct MAH contact persons.

Key training resources & support for marketing authorisation holders (MAHs)

1. Industry **training** on post-authorisation procedures in IRIS (12 Nov 2024): presentation & recording available on event web page
2. Industry **FAQ document** (updated): most frequently asked questions from MAHs on post-authorisation procedures management in IRIS
3. **User guide for applicants** (updated, further updates will be included in January)
4. **IRIS Guide for registration** (further updates will be included in January)

Guidance on type of support for questions on IRIS for post-authorisation procedure management