

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**.*

→ **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](#).

3

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

Scenario 1

The product contact person remains unchanged, but linked to a generic mailbox - Update products currently list generic mailboxes with personal email addresses associated with responsible contact person.

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 \(europa.eu\)](#)



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

