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

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

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**.

**CAP MAHs** update product contact information:

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#### 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: <u>template\_letter-change\_contact\_person\_en.doc (live.com)</u>

## How to submit the form?

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

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)

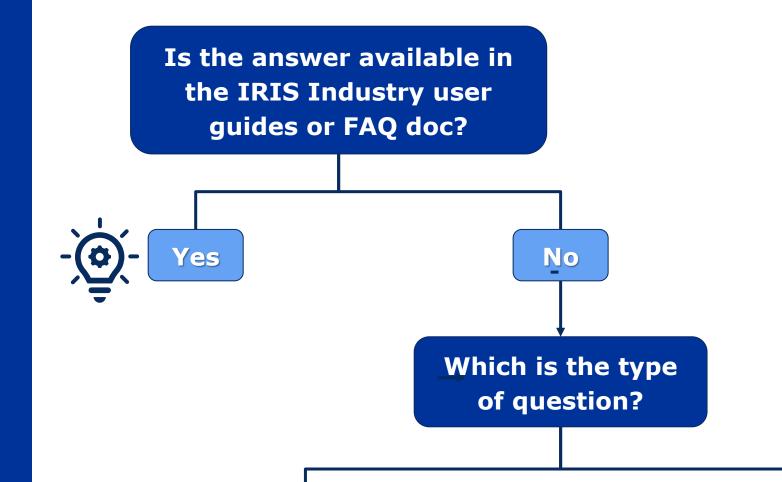
Industry **training** on post-authorisation procedures in IRIS (12 Nov 2024): presentation & recording available on event web page

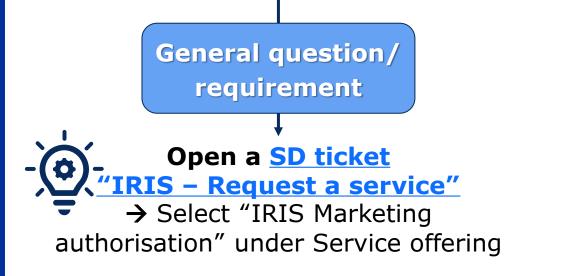
Industry **FAQ document** (updated): most frequently asked questions from MAHs on post-authorisation procedures management in IRIS

<u>User guide for applicants (updated, further updates will be included in January)</u>

**IRIS Guide for registration** (further updates will be included in January)

Guidance on type of support for questions on IRIS for postauthorisation procedure management





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