



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

I-SPOC registration

How marketing authorisation holders (MAHs) for human medicinal products authorised in the EU/EEA can register an Industry Single Point of Contact (i-SPOC) for supply and availability





If you have not done it yet, don't forget to register your Industry Single Point of Contact (i-SPOC) for supply and availability issues





**All MAHs of a CAP or
NAP need to have an
EMA account to
register an i-SPOC in
the IRIS portal**



The i-SPOC will facilitate
the **communication**
between EMA and MAHs
to monitor and prevent
shortages of medicines
during crisis





The i-SPOC will be a key link between the EU and your organisation to ensure..

1

Real-time monitoring of supply and demand of medicines during a crisis

2

Rapid regulatory response to supply issues

3

Prevention of shortages of medicines during crisis

WHEN?

All MAHs in the EU are now required to register an i-SPOC. If not already done, register your i-SPOC now!

WHERE?

[IRIS PLATFORM](#)
[i-SPOC Registration](#)
[Tutorial video](#)
[User Guide](#)



**Not sure about
how to do it?**

Watch the video!



If you are a MAH who already has an EMA Account...

1 Log in to the IRIS portal with EMA account credentials and access the 'Submission' Tab

2 Click on 'Create new submission' to enable the creation of the i-SPOC

3 Select 'Organisation' and insert all the required information in the 'Submission type' tab

4 Select the Organisation in the next screen for which you want to register the i-SPOC

5 In next form, search and select the i-SPOC, fill in the i-SPOC contact details and 'Submit'

6 Review the i-SPOC summary and check if i-SPOC registration was successful



If you don't have an EMA account yet, create one via EMA's Account Management portal to be able to register your i-SPOC in the IRIS portal



If you are a MAH of a NAP who needs to create a new EMA Account...



Complete the 'EMA – Self-service Registration Form' and click on 'Register'

Go to 'EMA Account Management' and click on 'Create a new EMA account'

Enter the value of the 'One-time token' you received by email and complete your request by clicking on 'Confirm'.

Once the self-registration of the account has been completed, you will be notified via email

You can now log in to the IRIS portal with your EMA account credentials and register your i-SPOC

Once you have followed the steps above, please note that creation of the account may take 5-10 business days after the request is submitted.



**Thank you for
registering your i-SPOC
for supply and
availability with the EMA**

