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Registration of an Industry Single Point Of Contact (i-SPOC): Frequently asked questions

This document provides answers to the most frequently asked questions received on the i-SPOC registration process in EMA's IRIS online platform.

If the answer to your question is not here, please contact the Service Desk using the user credentials for a system hosted by EMA. Non-registered users can refer to this link and click on "Create an EMA account".

The entire process of registration of an i-SPOC in the EMA's online platform is described in the IRIS guidance for Marketing Authorisation Holders (MAHs).

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Table of Contents

Table of definitions

EMA Account Management Portal (IAM)	The European Medicines Agency's (EMA) secure online platform where you can request and manage access to EMA applications.
IRIS	A secure online platform for handling product-related scientific and regulatory procedures with EMA.
Industry Single Point Of Contact (i-SPOC)	Industry Single Point Of Contact who will inform EMA about the supply and availability of critical medicines identified in the context of a 'public health emergency' or a 'major event'.
Marketing Authorisation Holder (MAH)	The company or other legal entity that has the authorisation to market a medicine in one, several or all European Union Member States.

Background

Regulation (EU) 2022/123 reinforces EMA's role in crisis preparedness and the management of medicinal products. The Regulations sets out a framework for the monitoring and management of medicinal shortages during public health emergencies and major events. As part of this framework, industry and Member States will be required to provide information at both the product, as well as the supply and demand, level.

Under the new Regulation, Marketing Authorisation Holders (MAHs) must now register an Industry Single Point of Contact (i-SPOC) for all medicinal products authorised in the Union. The i-SPOC will facilitate rapid communication between EMA and MAHs to detect, report, and prevent or manage supply and availability issues of medicines included in a list of critical medicines for a 'public health emergency' or a 'major event'.

General questions

Why do I need to register an i-SPOC?

Regulation (EU) 2022/123 reinforces EMA's role in crisis preparedness, including the monitoring and management of medicinal products, during a public health emergency or a major event, with the reporting of shortages, information on supply and demand, and coordinating responses of EU countries to shortages of critical medicines. All MAHs with a centrally- or nationally-authorised medicinal product in the EU are required to register an i-SPOC. This will facilitate future communication with those MAHs of identified critical medicines during public health emergencies or major events.

What is the role of an i-SPOC?

The i-SPOC will facilitate rapid communication between EMA and MAHs to detect, report, and prevent or manage supply and availability issues of medicines included in a list of critical medicines for a 'public health emergency' or a 'major event'.

Who needs to register an i-SPOC?

Marketing authorisation holders (MAH) for all authorised medicines in the EU regardless of marketing status or licensing route, are required to appoint an industry Single Point Of Contact (i-SPOC).

What expertise should an i-SPOC have?

An i-SPOC should be able to provide information directly to EMA about the supply and availability of critical medicines identified in the context of a major event or a public health emergency. The i-SPOC should oversee the product supply chain, manufacturing capacity management and shortages.

For what products do I need to register an i-SPOC?

All MAHs in the Union regardless of authorisation route, indication, product type, or marketing status are required to appoint an i-SPOC.

Does the requirement to register an i-SPOC also apply to veterinary medicinal products?

At this time, only MAHs of authorised medicinal products for human use are required to register an i-SPOC.

When should an i-SPOC be registered?

MAHs are required to register an i-SPOC with the Agency by **2 September 2022**.

Questions on how to register an i-SPOC

Where do I register an i-SPOC?

An i-SPOC should be registered through the IRIS portal.

What are preliminary requirements for registering an i-SPOC?

For any type of submission in the IRIS portal, you first need an EMA account (IAM registration) and an appropriate role in IRIS to be able to login.

IAM registration needs to be done only once; and this will allow you to register an MAH i-SPOC in IRIS.

How do I request an EMA account and/or appropriate IRIS role?

For information on how to request an EMA account and an appropriate IRIS role, please consult the separate IRIS guide to registration and the quick interactive guide to IRIS registration process on the IRIS home page.

How long does the registration of an i-SPOC take?

Registration of an i-SPOC is a two-step process. Initial registration of an EMA account may take 5-10 days for authorisation. Once that has been completed and the user has been granted an appropriate IRIS role, i-SPOC registration can be completed in i-SPOC which is effective immediately.

Who can be an i-SPOC?

The i-SPOC can be any MAH user with a "MANAGER" or a "CONTRIBUTOR" role in IAM/IRIS.

Who can register an i-SPOC?

Only a user with a "MANAGER" role in IAM/IRIS can successfully register an MAH i-SPOC within the IRIS portal.

Who can update an i-SPOC?

Only a user with a "MANAGER" role in IAM/IRIS can update or change an i-SPOC.

How can I register an i-SPOC?

EMA has updated the IRIS user guide and published a video demo to support companies with the registration process.

Can the same i-SPOC be registered for multiple local affiliates?

MAHs may wish to register their i-SPOC at company Headquarter level, instead of an i-SPOC at each individual company affiliate level. Hence, during the registration process, the system will allow MAH users to create or maintain a single i-SPOC persona for multiple, local affiliates (or organisations).

Please be aware that in order to have a MAH centralised at Headquarter level, the MAH user must be affiliated in IAM/IRIS to multiple local organisations.

Can a MAH who already has an "Industry Manager" role in IRIS nominate themselves as i-SPOC?

Yes, a person with the "Industry Manager" role in IRIS can nominate themselves for MAH i-SPOC (the only consideration is that the user should be affiliated in IAM).

Can a person without any IRIS role be registered as an i-SPOC?

No, unfortunately, in order to register a user as an i-SPOC, this individual needs to have either the "MANAGER" or "Contributor" role.

Do MAHs who have assigned a contact person with regards to the critical medicines for COVID-19 in 2020 need to assign an i-SPOC again?

EMA has individually contacted MAHs of products in the list of the critical medicines to inform them of the timelines, processes and tools to collect the required information. If you believe that your company has a product in scope but has not been contacted, please contact the EMA as soon as possible by submitting a ticket to the helpdesk.

Do MAHs based in the United Kingdom have to register an i-SPOC? Considering that they have products marketed in Northern Ireland.

Only those MAHs with products authorised in the EU are required to register an i-SPOC. Therefore MAHs whose products are only authorised in the United Kingdom are not in scope of this requirement, even if the product is also distributed to Northern Ireland.

Questions related to the IRIS portal

What are supported browsers for using the IRIS portal?

IRIS can be accessed on any modern Web Browser, including but not limited to Google Chrome (latest version), Internet Explorer 11 and above, Edge (including the new, Chromium-based Edge), Safari 12 and above, Firefox, and Vivaldi.