



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Medicines Shortages Activities

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**Industry Standing Group (ISG) meeting, 26 September 2022**

Presented by Joao Ferreira, Supply and Availability of Medicines and Devices (TRS-SAM), EMA

An agency of the European Union





# Agenda

- ❖ Industry single points of contact (i-SPOC) for Marketing Authorisation Holders (MAHs) – *for information*
- ❖ ISG operational group: composition and scope of activities – *for information*
- ❖ Public health emergencies: reporting timelines – *for information*



## i-SPOC for MAHs: Update on registration

- As of **2 September 2022**, all MAHs of products authorised in the Union were required to register an i-SPOC for supply and availability issues.
- The Agency's **IRIS platform** is used to collect details of i-SPOCs for all MAHs (registration opened on 28 June 2022).
- Current figures (as of 23 September 2022):
  - Total : **1385** i-SPOC registrations (**~32% compliance**)
    - MAHs of CAPs only = 21
    - MAHs of CAPs + NAPs = 107
    - MAHs of NAPs only = 1257

Parallel distributors:  
Do **not** need to register an i-SPOC on supply and availability.

### Next steps:

- News item planned for W/c September 26<sup>th</sup> at EMA website
- Campaign to raise awareness on registration requirements

The user guide is available on the [IRIS guide for applicants](#), and a video demo is available in the [following link](#).



# ISG operational group – composition and scope of activities (1/2)

## Background:

- Platform for EMA-Industry exchanges on **reporting requirements** defined in Regulation (EU) 2022/123

## Objective:

- Enhance Industry's **submission journey** as per the established tools and processes.

## Workplan:

- **Review and optimisation of guidance/ template** in the context of reporting obligations.



# ISG operational group – composition and scope of activities (2/2)

## Membership:

- EU Industry Trade representatives (7)

## Quarterly meetings:

- Virtual format

## Next steps:

- Kick off call: Friday, October 14<sup>th</sup>
- Draft Terms of Reference
- Survey to MAHs on awareness and usability of guidance and tools (*extended deadline: 30 September 2022*)

Name	Trade Association
Valérie Policar	ACRO
Maria Grazia Sturniolo	Medicines for Europe
Evelina Kozubovska	PPTA
Patrick Costello	EuropaBio
Kasper Ernest	Affordable Medicines Europe
Martin Schoefnagl	EIGA
Annabel Seebohm	COCIR

# Ongoing public health emergencies (PHEs) – reporting timelines

## 1/2

*Monitoring supply/demand for lists of critical medicines under Regulation (EU) 2022/123*

Public Health Emergency (PHE)	No. of Marketing Authorisation Holders “in-scope”	No of monitored authorised MP/ vaccines in EU/EEA	Start of reporting obligations	Submission cadence*	Link (EMA website)
<b>COVID-19</b>	85	<b>13</b> Centrally Authorised Products (CAPs) + all Dexamethasone Nationally Authorised Products (~ <b>140 NAPS</b> )	<b>1 October 2022</b>  <ul style="list-style-type: none"> <li>MAHs experiencing shortages (obligations started on <b>15 July 2022</b>)</li> </ul>	Once-every-month	<a href="#">List of critical medicines for COVID-19 public health emergency (PHE) under Regulation (EU) 2022/123</a>
<b>Monkeypox (MPX)</b>	2	<b>2</b>	<b>22 August 2022</b>	Every-other-week	<a href="#">List of critical medicines for Monkeypox public health emergency (PHE) under Regulation (EU) 2022/123</a>

\*Subject to the **epidemiological situation**



# Ongoing public health emergencies (PHEs) – reporting timelines

## 2/2

### Guidance for MAHs:

- Currently only available for MAHs in scope of the lists of critical medicines
- Not published in EMA website

### Template:

- Required data set (stocks, supply, demand) to be submitted even in the absence of shortages
- If information (e.g. supply deliveries) is not available, a justification needs to be provided.

### Submission tool (interim\*):

- SharePoint Online secure submissions (Excel files)
- i-SPOCs can delegate the reporting of required data set to other MAH users

*\*EMA has implemented a **short-term IT solution, available from July 2022**, to be used for the electronic submissions during a PHEs/MEs, until the ESMP is deployed in 2025.*



# Any questions?

## Further information:

[iSPOC.Secretariat@ema.europa.eu](mailto:iSPOC.Secretariat@ema.europa.eu)

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