



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Update on Medicine Shortages Activities

---

Industry Standing Group (ISG) meeting, 26 June 2023



# Agenda

- ❑ Update on Industry's SPOC (iSPOC) COVID-19 and Mpox reporting activities
  - *for information*
- ❑ Update on ISG operational group on Medicine Shortages activities
  - *for information*
- ❑ Update on registration of Industry single points of contact (i-SPOC) for Marketing Authorisation Holders (MAHs)
  - *for information*

# Update on Industry's SPOC (iSPOC) COVID-19 and Mpox reporting activities

## ❑ Industry's reporting obligations ended.

- WHO declared an end to both PHEs in **May 2023**
- Reporting obligations - defined in *Regulation (EU) 2022/123* - ceased to apply:
  - Targeted message sent to i-SPOC Networks confirming end of obligations.
- Process improvement activities will continue throughout **Q3 2023** to prepare for future health emergencies:
  - Voluntary roundtable with incompliant COVID-19 MAHs (NAP holders) planned for September.
- Consider "Lessons learned" in the context of ongoing ESMP agile governance and delivery



# Update on ISG operational group on Medicine Shortages activities

## ❑ **Activities discontinued after end of Public Health Emergencies (PHEs).**

- Operational activities on tactical support to i-SPOC Networks stopped (last meeting held on 31 May 2023)

## ❑ ***Achievements: key insights from “7 months” of Industry’s collaboration :***

1. **Communication/awareness:** support to i-SPOC registration activities towards higher registration compliance.
2. **Data collection initiatives:** input to EMA surveys on “guidance and tools” and review of survey recommendations to Industry
3. **Guidance/reporting template:** targeted consultations on Industry’s reporting template for PHEs/MEs
4. **Training:** review of training to i-SPOC Networks (i.e. technical workshop)
5. **Process improvement:** input on plans to tackle industry’s reporting compliance (e.g. roundtable with non-compliant MAHs)

# Update on registration of Industry single points of contact (i-SPOC) for Marketing Authorisation Holders (MAHs)

- All pharmaceutical companies with a **centrally-** or **nationally-authorized** medicinal product in the EU are required to register an i-SPOC.
- **Objective:** Two-way, rapid communication between EMA and MAHs to detect, report, and prevent or manage 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 June 2023):
  - Total: Of 3958 MAH HQ, **2070** i-SPOC registrations (~52% compliance)
    - **5%+ increase**, compared to March 2023 ISG meeting update
- **Communication activities** to promote MAH i-SPOC registration will continue during 2023:
  - Mass mailing to “incompliant” MAHs in Q3 2023.
  - Disseminate message through EU Industry Trades and national agency websites in Q3-Q4 2023.



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



# Any questions?

## Further information

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Telephone** +31 (0)88 781 6000

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

Follow us on  **@EMA\_News**