



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Update on Medicine Shortages Activities

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Industry Standing Group (ISG) meeting, 22 November 2022

Presented by Joao Ferreira, Sofia Zastavnik, EMA

An agency of the European Union





# Agenda

- ❖ Public health emergencies: Industry's submissions – *for information*
- ❖ Industry single points of contact (i-SPOC) for Marketing Authorisation Holders (MAHs) – *for information*
- ❖ ISG operational group: mandate and feedback – *for information*
- ❖ Update on the European Shortages Monitoring Platform (ESMP) – *for information*



# Ongoing public health emergencies (PHEs) –Industry’s submissions (1/3)

*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>               | 86                                                | <b>13</b> Centrally Authorised Products (CAPs)<br>+<br>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) –Industry’s submissions (2/3)

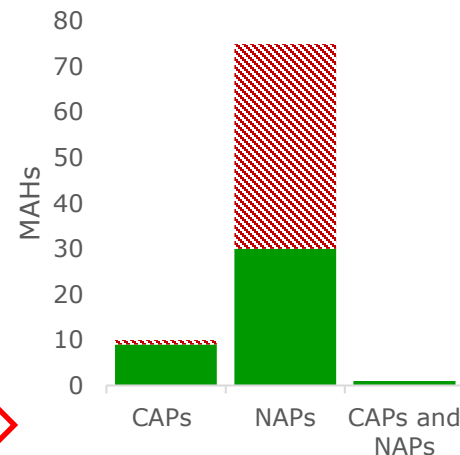
## MAHs – Supply data (*status as of November 7<sup>th</sup>, 2022*):

### Monkeypox

- 2 MAHs submit data set as requested by EMA.

### COVID-19

- Of 86 MAHs, 40 (~47%) submitted information to EMA (“complete” and “incomplete submissions”).
- Of 75 NAP holders (dexamethasone), 45 have not yet submitted info to EMA (“missing submissions”).



## Ongoing public health emergencies (PHEs) –Industry's submissions (3/3)

### Conclusions:

- **Industry's** (supply) **data** is required to undertake the supply & demand matching exercise
  - COVID-19: ~50% (mostly dexamethasone NAP holders) never submitted data to EMA.
- **CAP holders** have put contingency measures in place to prevent potential shortages;
- Reports are provided to the **MSSG** every month;
- EMA in close dialogue with **HERA** to maximise synergies and prevent duplicative actions.

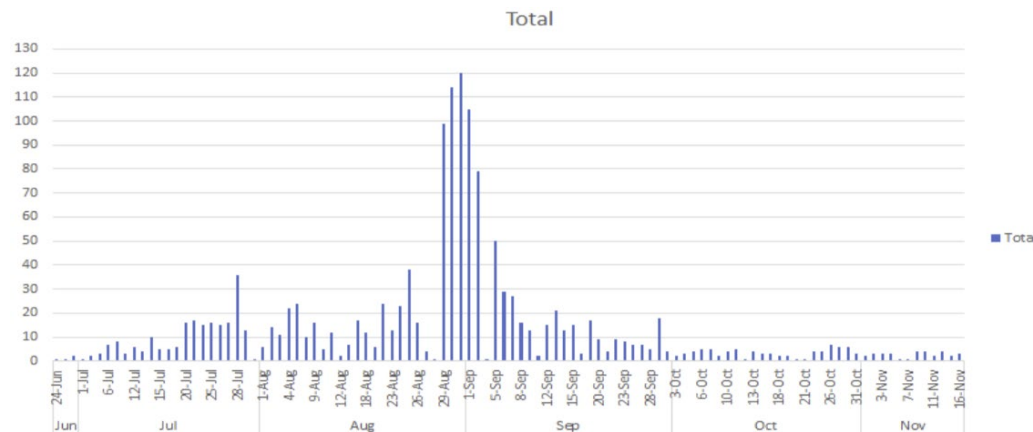
### Next steps:

- EMA is reaching out to MAHs of products in the list of critical medicines for COVID-19 to remind them of their reporting obligations and if necessary to provide dedicated support in the submission process.
- *Request for Support from Industry Trade Associations*: Liaise with member companies (and National Trades) to raise awareness on incomplete/missing submissions and promote reporting compliance



## i-SPOC for MAHs: Update on registration (1/2)

- 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).
- Weekly trends: registrations plateaued (<10 registrations/week)
- Current figures (as of 16 November 2022):
  - Total: **1550 i-SPOC registrations (~37% compliance)**  
**+4% compared to last ISG meeting (26/09)**
    - MAHs with CAP products only = 23 CAP holders
    - MAHs with CAPs & NAPs products = 113 CAP holders
    - MAHs with NAP products only = 1414 NAP holders



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



## i-SPOC for MAHs: Update on registration (2/2)

- Additional planned/ongoing communication activities to raise awareness and promote registration of i-SPOCs on supply and availability in the EU:

*Social Media* – LinkedIn  
campaign

**(ongoing)**

Medicine Shortages  
SPOC Working Party  
(SPOC WP) –  
engagement with local  
pharma companies

**(ongoing)**

NCA's websites – News  
items on each NCA  
website in local  
language

**(ongoing)**

National Trades –  
dissemination by EU  
trade associations

**(planned)**

# ISG operational group on Medicine Shortages (1/2)

## Mandate

Provide input on best solutions to ensure a seamless user experience for submission of data requirements;

Provide input to the template and corresponding external guidance;

Support the on-going activities of EMA in the registration of i-SPOCs for all MAHs in the Union;

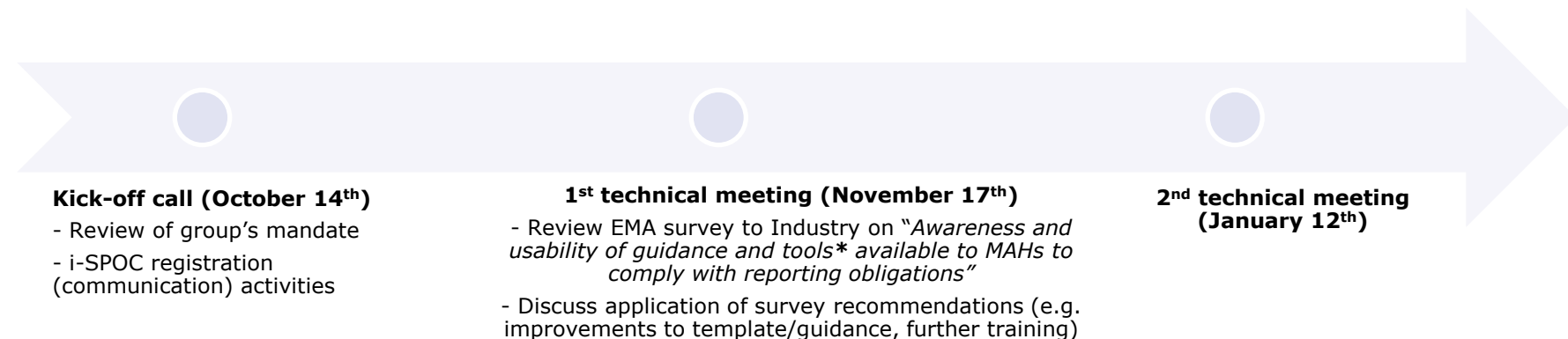
Report back to the ISG on the group activities and provide input when relevant to “awareness session” days to Industry and other training related activities.

The group will be in place while **interim IT solutions** are being used for the collection of data from i-SPOC Networks.

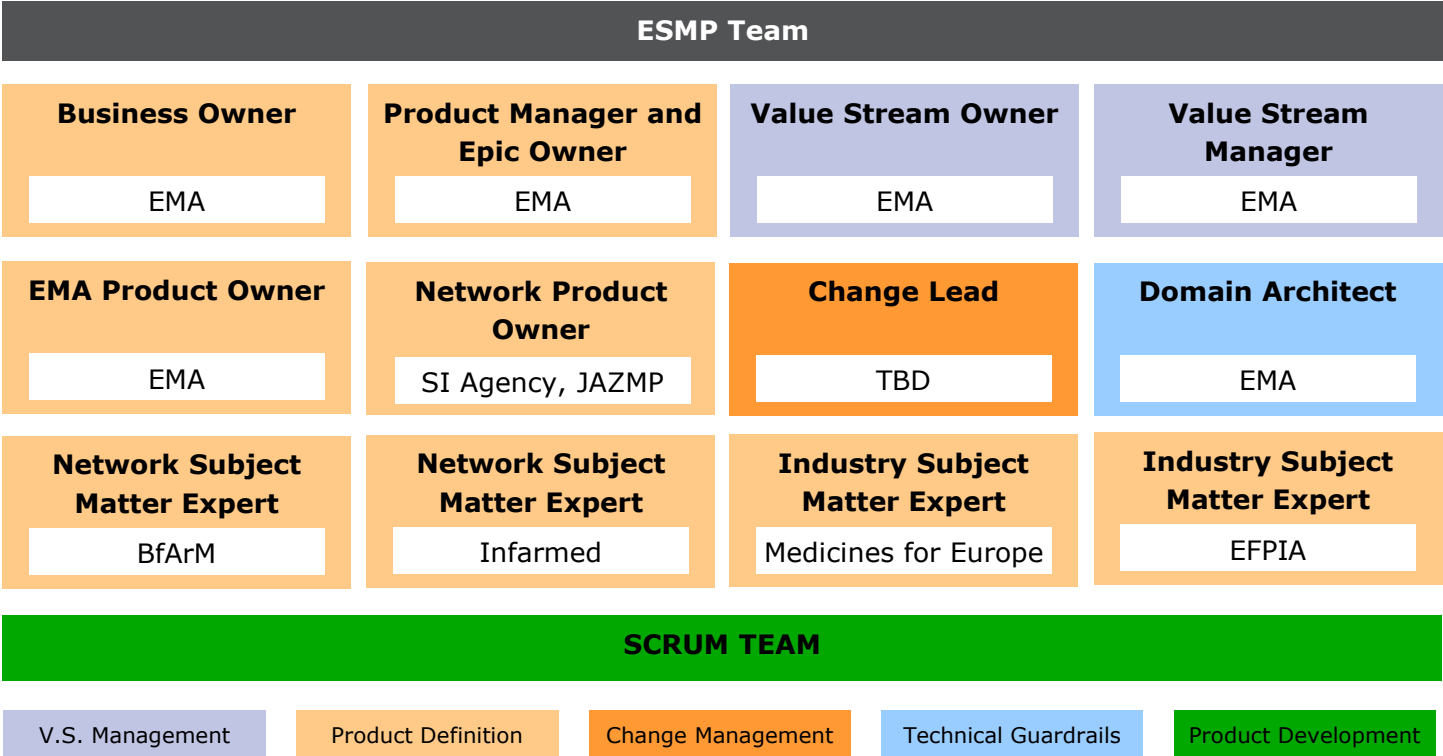


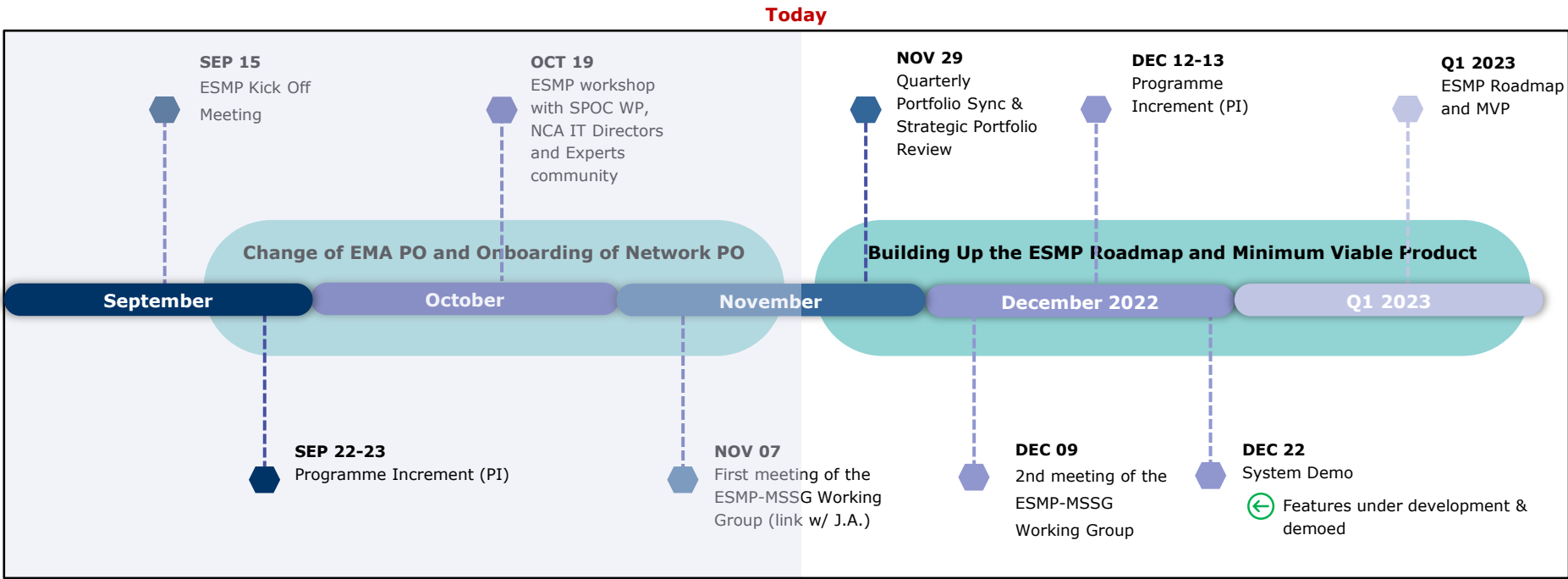
# ISG operational group on Medicines Shortages (2/2)

Reporting back on the group's activities:



*\*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.*





## Background

MSSG requested workshop to be held between SPOC WP and NCA IT Directors and Expert Community

Intended aims:

- to create and strengthen a communication channel that is key for the development of ESMP
- to present and discuss the IT activities required for interoperability and accessibility between local systems and the ESMP
- to give Member States an opportunity to share experiences regarding their capabilities for managing shortages of medicines



## Survey conducted in preparation

Survey focused on 5 key areas

- Shortage notifications and monitoring
- Availability of data (stock, demand, prescription and sales)
- Existing IT systems to gather and analyse data
- Marketing status data collection
- ESMP preparedness check-in

Responses received from all EU/EEA member states

- invaluable context to the discussion
- Critically important baseline information for future discussions

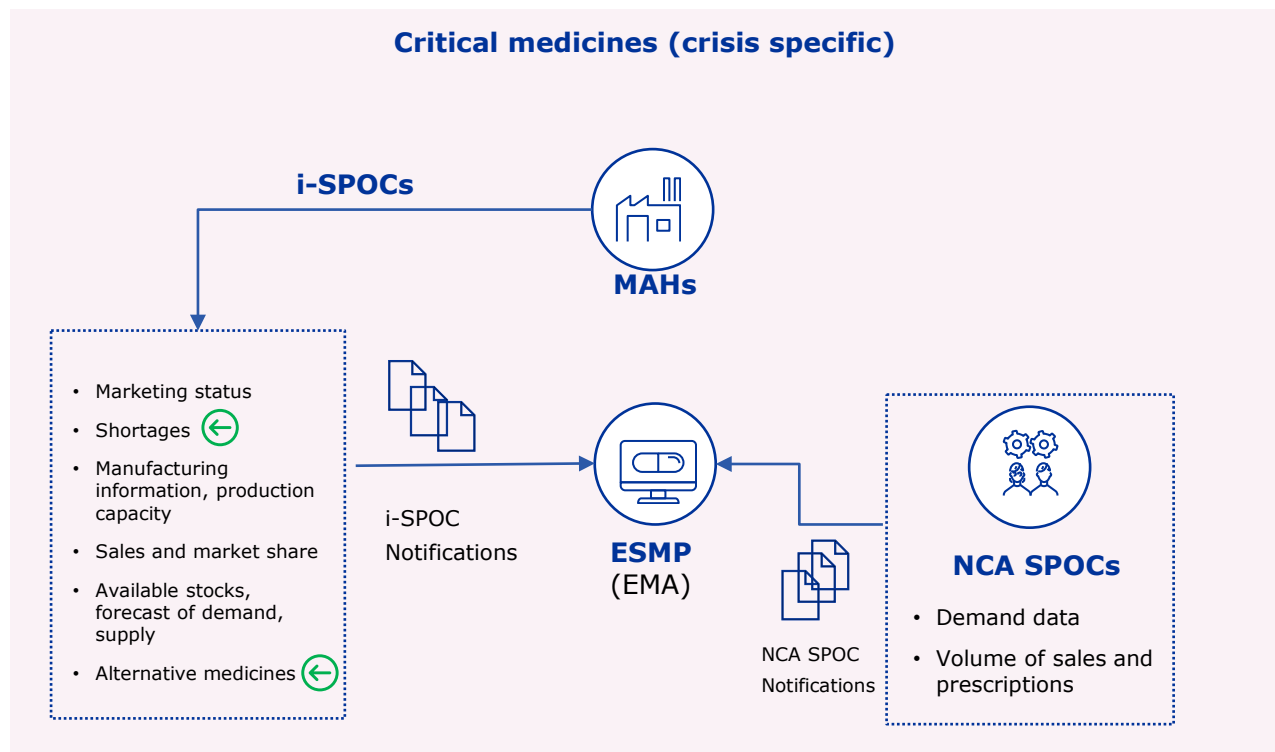


## Agenda highlights

- EMA ESMP team presented on
  - Agile transformation
  - Feasibility study undertaken earlier this year to define path forward
  - Current status of ESMP development and upcoming milestones
- 3 Member states (Portugal, Belgium, and Denmark) provided demonstrations of their national shortage management systems
- The workshop concluded with a technical discussion on interoperability in order to address the comments and suggestions made by NICTAC in May.



## Features under development & demoed



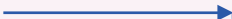
## Features under development & demoed

**MAHs**



**i-SPOCs**







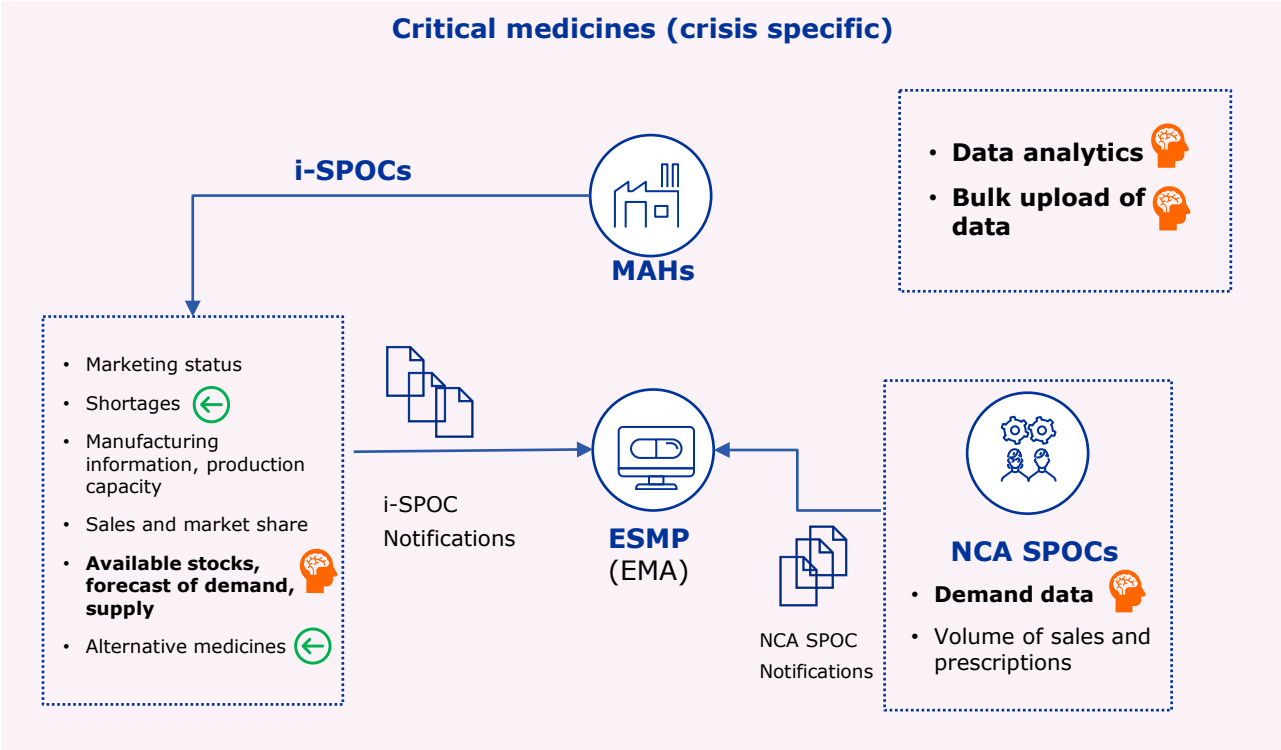
**ESMP**  
(EMA)

| iSPOC Notification form                                                                                         |                 |                                                       |                                                                                                                              |                                        |                    |
|-----------------------------------------------------------------------------------------------------------------|-----------------|-------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|
| Medicinal Product information  |                 |                                                       |                                                                                                                              |                                        |                    |
| MAH                                                                                                             | Product name    | Active substance                                      | Authorisation status                                                                                                         | Marketing status                       |                    |
|                                                                                                                 |                 |                                                       |                                                                                                                              |                                        |                    |
| Shortage information           |                 |                                                       |                                                                                                                              |                                        |                    |
| Start of shortage                                                                                               | End of shortage | Root cause                                            | Point in supply chain at which disruption occurs                                                                             |                                        |                    |
|                                                                                                                 |                 |                                                       |                                                                                                                              |                                        |                    |
| Manufacturing information                                                                                       |                 |                                                       |                                                                                                                              |                                        |                    |
| Active manufacturing site for finished product and API                                                          |                 | Approved production sites of finished product and API |                                                                                                                              | Potential alternative production sites |                    |
|                                                                                                                 |                 |                                                       |                                                                                                                              |                                        |                    |
| Shortage mitigation and prevention information                                                                  |                 |                                                       |                                                                                                                              |                                        |                    |
| Market share data                                                                                               | Sales volume    | Available stocks                                      | Available alternative medicinal products  | Forecast of demand                     | Forecast of supply |
|                                                                                                                 |                 |                                                       |                                                                                                                              |                                        |                    |

 Under development & demoed



Draft plans for Q4 2022 – to be finalised at next PI Planning

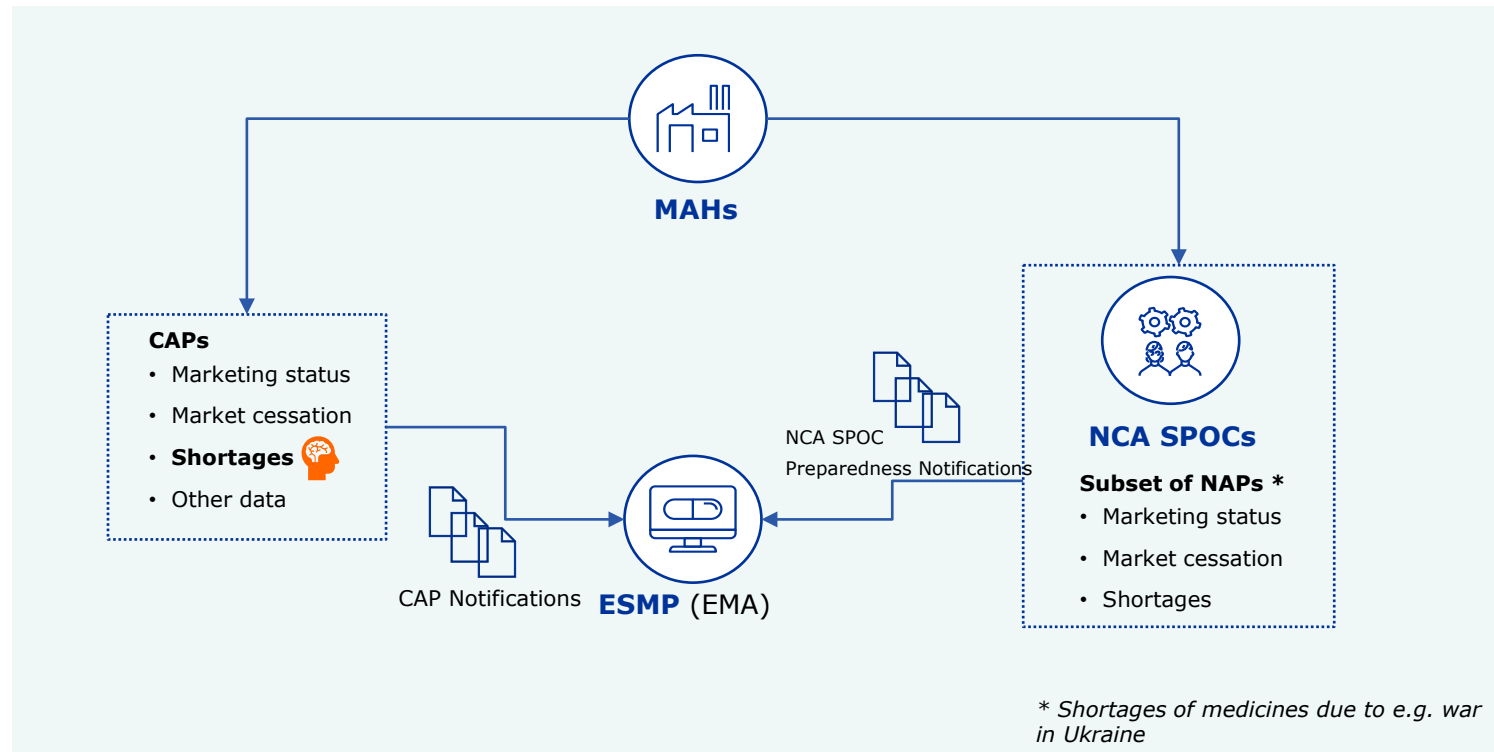


Analysis & design



Under development & demoed

## Draft plans for Q4 2022 – to be finalised at next PI Planning



Analysis & design



# Any questions?

## Further information

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