EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicines Shortages Activities

Industry Standing Group (ISG) meeting, 21 June 2022

Presented by Monica Dias, Joao Ferreira, Nektaria Varela

Topics for information and discussion

1. Industry single points of contact (i-SPOC) for Marketing Authorisation Holders (MAHs) – *for information*
   - Overview
   - Registration process
2. Lists according to Regulation (EU) 2022/123 – *for information*
   - Critical medicines for COVID-19
   - draft list of Main Therapeutic Groups necessary for emergency care, surgeries and intensive care
3. MAHs reporting obligations – *for information and discussion*
4. European Shortages Monitoring Platform (ESMP)- feasibility study and development plan – *for information*

i-SPOC for MAHs: overview

- Establishment of a list of **single points of contact for MAHs** for <u>all medicinal products authorized in the Union</u> and the deadline to do so is specified in Regulation EU 2022/123:
  - Article 9: *"the agency shall establish and maintain a list of single points of contact for marketing authorisation holders for all medicinal products authorised in the Union"*
  - Article 10: *"Marketing authorisation holders for medicinal products authorised in the Union shall provide the information for the purposes of Article 9(1), point (e), of this Regulation* ***by 2 September 2022****"*

- <u>Primary objective</u>: MAHs to have an identified i-SPOC so that EMA can engage with such contact should the MAH have medicinal products be included in the lists of critical medicines according Regulation (EU) 2022/123;

- To fulfill these requirements, MAHs will be requested to enter the required information into the **IRIS online platform**
  - Registration start **date: 28th June 2022**

i-SPOC for MAHs: IRIS system registration process

- **2 step registration process:**
  - **STEP 1 (IAM, preliminary requirement):** to create an EMA Account and appropriate role in IAM
    - for any type of submission in IRIS, MAH users need an EMA account and an appropriate role in IRIS, to login into IRIS.
  - *Note: Only users with manager role in IAM/IRIS can register an i-SPOC. Incoming rollout: IAM registration to be further improved in Q3 2022*
  - **STEP 2 (IRIS, submission):** Login into the IRIS Portal with EMA account credentials and create a new submission for the registration of an i-SPOC.

- **User guide and video DEMO will be available on EMA's corporate website and IRIS platform**
  - Technical support is available through EMA's service desk
  - Publication of news item is planned for w/c 27 June 2022.
  - Individual communication to all MAHs in the Union (through ServiceDesk).

List of critical medicines for COVID-19

List of critical medicines for COVID-19 (link)

- **Scope**: Medicines included in the list are authorised for COVID-19.
- **Objective**: Supply and demand of these medicines will be closely monitored to identify and manage potential or actual shortages.
- **Adopted** by the MSSG on 07/06/2022
  - Medicines Shortages SPOC WP, ETF, HCPWP/PCWP, Industry Associations have been consulted
- It will be updated on an ongoing basis to reflect changes in the pandemic situation
- **Note:** Triggers reporting obligations for NCAs and MAHs (addressed under item 3)

List of Main Therapeutic Groups (MTGs)

- **Scope**: MTGs of medicinal products that are necessary for emergency care, surgeries and intensive care
  - Includes relevant pharmacological or therapeutic subgroups according to WHO ATC classification (level 3)
  - Takes into account data sources and inclusion criteria defined by the methodology published on EMA website
  - National clinical care practices and expertise in emergency, surgery and intensive care were taken into account (input was sought from Medicine Shortages SPOC WP, Patients and Consumers Working Party, Healthcare Professionals Working Party and Learned Societies)

- **Objective**: The list of MTGs is being developed to inform the preparation of future lists of critical medicines under the Regulation (EU) 2022/123.
- **Publication deadline**: 2 August 2022
  - The MSSG may also update the list of MTGs annually and whenever necessary.
- **Deadline for industry feedback**: cob 24 June 2022.

MAH reporting obligations: critical medicines for COVID-19

Implementation plan:

→ **If <u>NO</u> actual/potential shortages**:

submission of data set (inc. demand/supply forecasts) is deferred to **September 2022.**

→ **<u>ONLY</u> in the event of actual/potential shortages**:

- MAHs are obliged to submit full data starting from **w/c 4 July 2022** (individual communication will follow to the relevant MAHs)
- Request for 6-month forecasts (covering the autumn/winter period).

NOTE: *i-SPOC system deployed in April 2020 (scope: 31 INNs, hospital ICU medicines) was* ***discontinued on 08 June 2022****. EMA notified each iSPOCs of MAHs "in scope" of "old system"*

MAHs in scope of the list of COVID-19 critical medicines

- 85 total MAH HQs. Of those:
  - EMA have records of only 37 MAH i-SPOCs
  - 48 MAHs are pending i-SPOC appointment.
- As soon as all i-SPOCs are identified, **EMA will liaise individually with the MAHs** to inform them of the timelines, processes and tools to collect the required information.

MAH reporting obligations: submission format and continuous engagement

Submission format:

- **Interim**: SharePoint secure submissions (excel uploads) - available from July 2022
  - Improvements vs. "old" i-SPOC system: replaces emails submissions (addresses info security concerns + CCI exchanges).
  - Usability experience: Other MAH users (i.e. delegates) than i-SPOC can report directly to EMA.
- **Long-term**: secure submission via webform(first release of MVP feature for critical medicines iSPOC shortages submission for ESMP, targeted for end of Q1 2023 – subject to PI planning)

Continuous engagement with Industry on operational/reporting activities:

- Targeted consultation (~10 MAH i-SPOCs)
  - launched by EMA on the use of interim solution
  - only limited feedback received
- "Living guidance"
  - Test experience from subset of "in scope" MAHs on the guidance/template and learn lessons;
- Set up ISG "**reporting operational group**" to facilitate discussion on reporting requirements including optimisation of guidance/template to Industry.
  - **Call for nominations to Trades** (1 nomination per Trade) at ISG. **Deadline: 15 July 2022.**

European Shortages Monitoring Platform (ESMP)

feasibility study and development plan

Content

European shortages monitoring platform (ESMP)

EUROPEAN MEDICINES AGENCY

Implementation date: **2 February 2025 ***

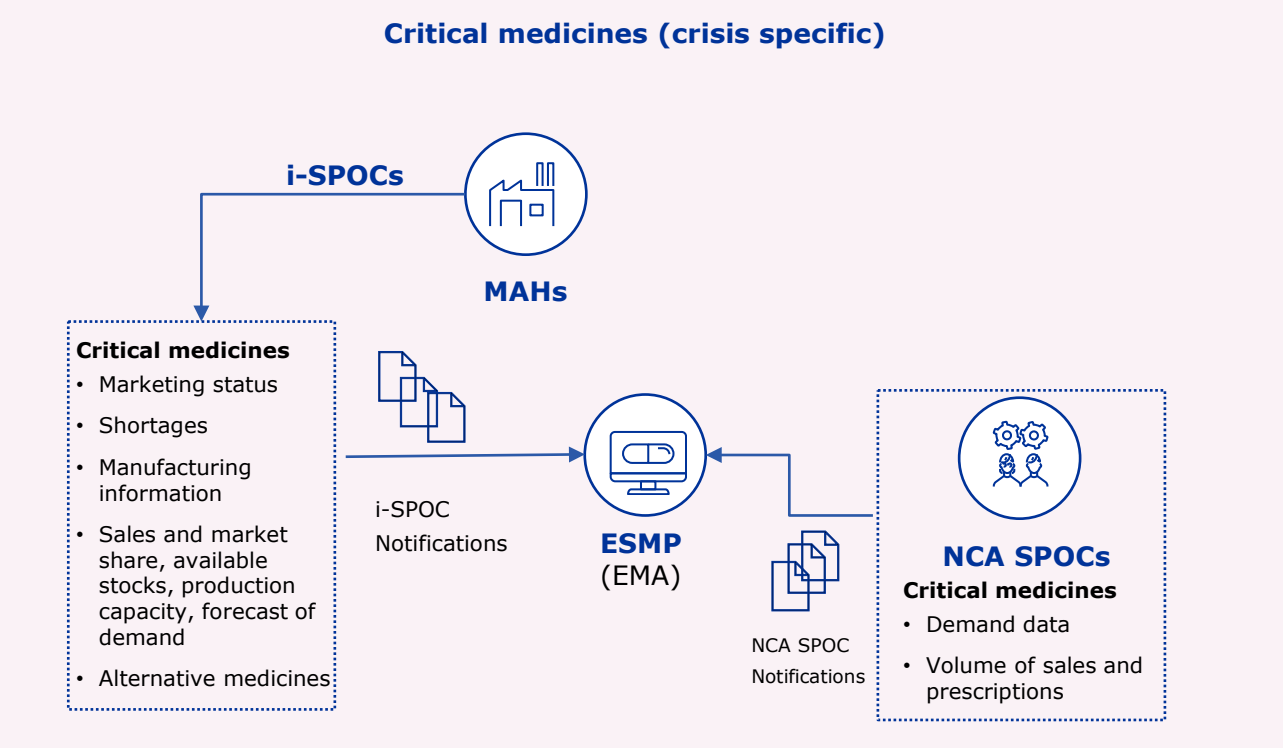
- Article 13 of Regulation (EU) '2022/123' foresees the setting up, maintenance and management of an **IT platform** to facilitate collection of information on **shortages**, **supply** and **demand** for medicinal products, including information on marketing status and marketing cessations, from both Industry's and Member States' SPOCs
- **Scope**: monitoring, management and prevention
  - Shortages (actual or potential) of medicinal products (on the **critical** medicines lists) during a **PHE or a major event**
  - Actual or potential medicines shortages (in a given Member State), that **can lead to** a Major event or a PHE

KEY BENEFIT

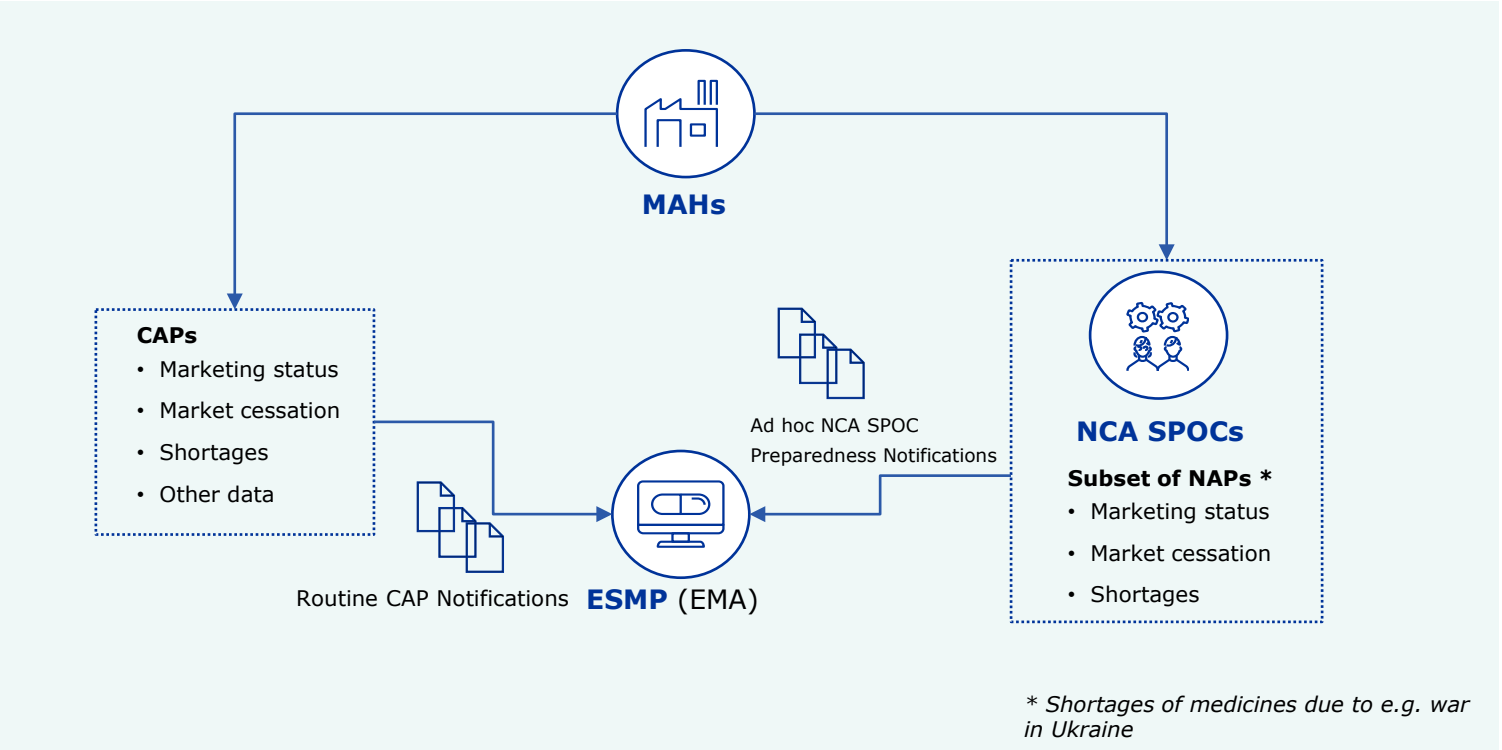
Providing a centralised EU platform to report, monitor, manage and prevent medicine shortages

** Reporting obligations for MAHs/NCAs apply immediately (day 31) and according to Art 9 the Agency needs to develop IT streamlined tools to address the requirements of Articles 4,7,8 and 9 swiftly and earlier than Feb 2025*

ESMP: Public Health Emergency/ Major Event



ESMP: Preparedness



Development requirements

Implementation date: **2 February 2025**

Draw up an **implementation plan**

Develop technical and functional **specifications in collaboration with MSSG**

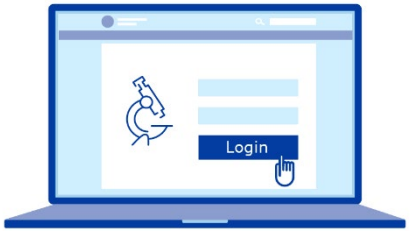
Ensure **compliance** with ISO standards, and Commercially Confidential Information (CCI) protection

Develop standardised reporting terminology and **guidance**

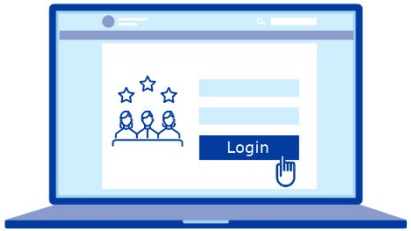
Ensure data interoperability with national IT systems

To ensure **access** to the information for the EC, the EMA, NCAs

ESMP secure and public interfaces



An interface for Industry to submit the iSPOC notifications on Critical Medicines during PHE/ME and during Preparedness as needed



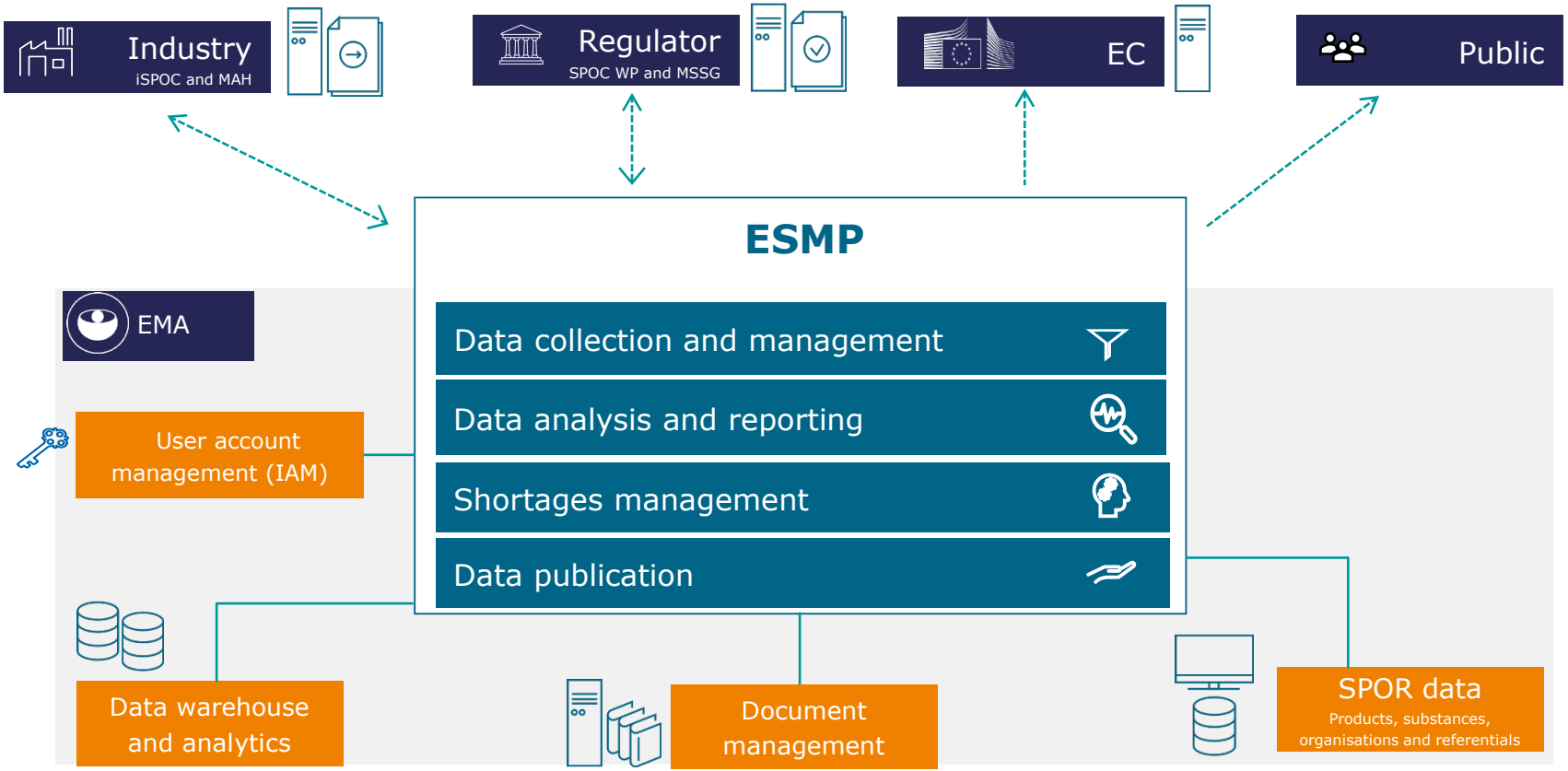
An interface for Regulatory Authorities to submit the SPOC notifications, retrieve reports and manage shortages (EMA)

Secure access

A **public website** where anyone can search for information on critical medicines shortages

Open access

ESMP High Level View



How to deliver the ESMP

Focus on feasible IT Architecture and delivery approach for **2 Feb 2025**

- Build on existing IT Architecture and EMA IT systems (including **existing functionalities** of Marketing status, Market Cessation for CAPs);
- Deliver ESMP **incrementally** (**M**inimum **V**iable **P**roduct approach) **using SAFe Agile** allowing gradual delivery of features and value;
- Invest in **interoperability** and **security by design**;
- SPOR(1) interoperability (ensuring ISO IDMP(2) compliance);
- Clear sources of information per data set, no duplication of reporting;
- Design reusability for similar features in medicines and devices domain;
- Scalable IT Architecture to allow ESMP to be extended as necessary after 2025.

Continuous consultation with Technical and Business Governance bodies

10 March 2022	18 May 2022	25 May 2022
Enterprise **A**dvisory **B**oard	**N**etwork **ICT** **A**dvisory **C**ommittee	**M**edicines **S**teering **G**roup on Shortages

(1) SPOR :Substances, Products, Organisations, Referential Master Data Management
(2) ISO IDMP: ISO for Identification of Medicinal Product.

Industry Standing Group (ISG) meeting, 21 June 2022

Feedback from consultation with governance bodies

MSSG

Main recommendations

- Continued engagement on the ESMP roadmap and delivery with the European Medicines Regulatory Network is of utmost importance
- Interaction with the Joint Action on Shortages to be established from the onset of the development of the ESMP

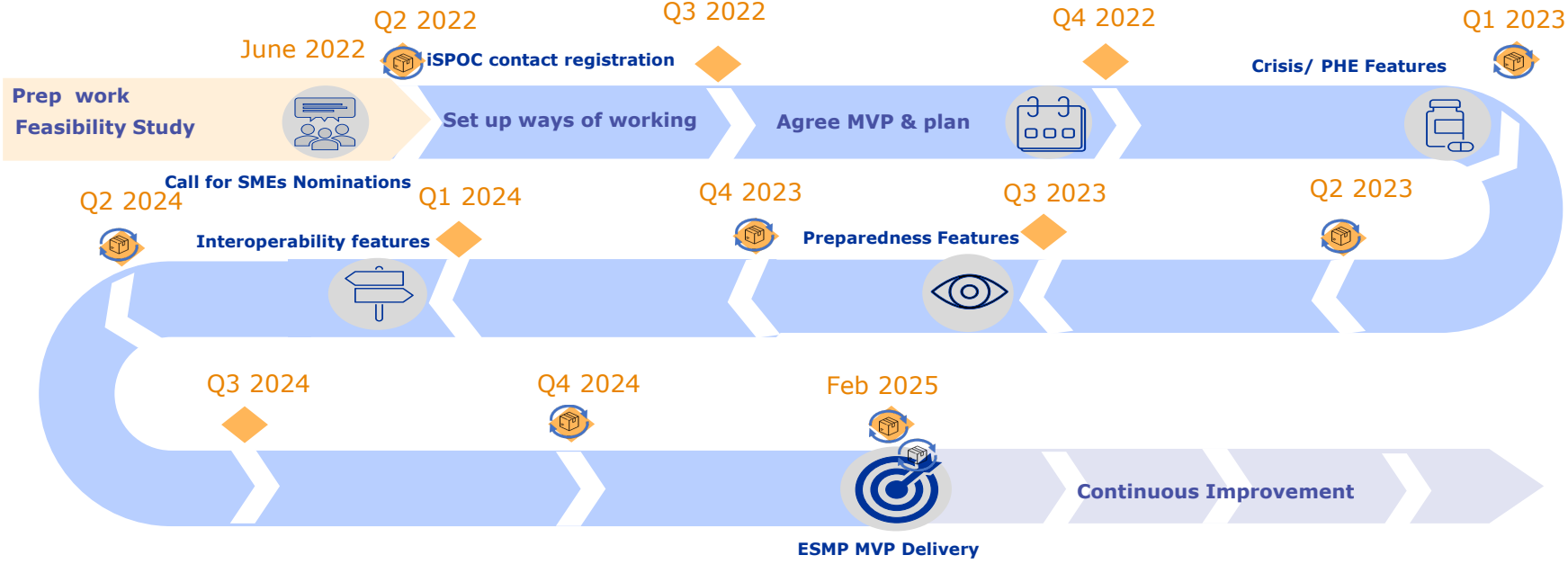
NICTAC

The approach to deliver ESMP should emphasize the following principles

- Data re-use and data standardisation
- Processes standardisation across MSs
- Clarity of actors and their roles
- Re-use of existing components
- Use of ISO IDMP(1)
- Foresee an API(2) to provide interested NCAs a machine to machine interface for exchanging data

(1) ISO IDMP: ISO for Identification of Medicinal Product.
(2) Application Programming Interface.

High level ESMP Roadmap



Feasibility Study: strategic alignment on delivery approach, consideration of possible enablers and data sources for ESMP, readiness survey of the national IT landscape

Incremental Delivery per Quarter

Quarterly milestones/scope is subject to Agile ceremonies and PI [1] planning

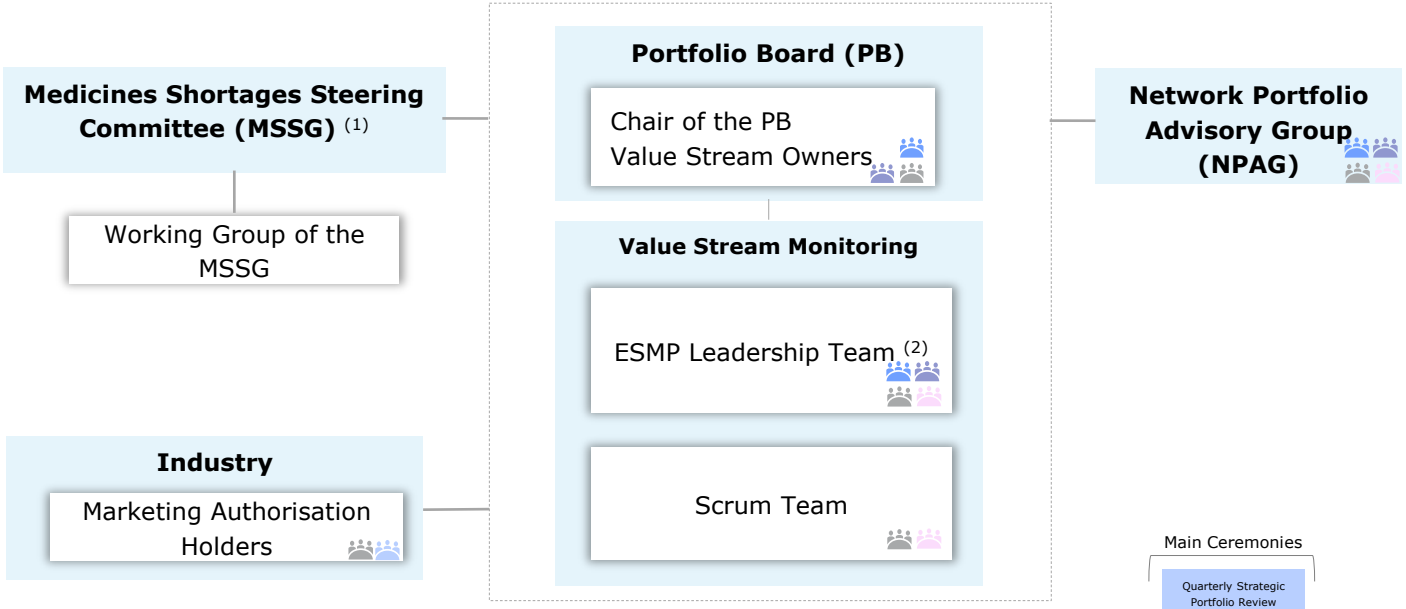
Delivery of Features to production

(1) PI: Program Increment

Feasibility study conclusion

- National IT landscape is very diverse, and systems maturity is foreseen to change over time and in parallel to the delivery of the ESMP:
  - Considering the Joint Action on Shortages that aims at developing an IT concept platform to monitor and manage medicine shortages and harmonization of national systems.
- EMA requires a focused approach to deliver a fully operational platform by 2025, as per the requirements described in the Regulation, minimising dependencies and maximising synergies with other EU projects (i.e., DG HERA, JA on shortages).
- The Regulation foresees the possible extension of the ESMP after 2025. Opportunities to integrate ESMP with other data sources after this date to optimise certain data and extend data analysis capabilities over time should continue be explored from the onset of the delivery of the MVP.
- EMA Architecture principles and delivery approach for the ESMP were validated.
- Need for open dialogue, harmonisation of reporting and continuous engagement with Industry and NCAs through the agile governance structure.

ESMP Governance **Model for the Development of ESMP**

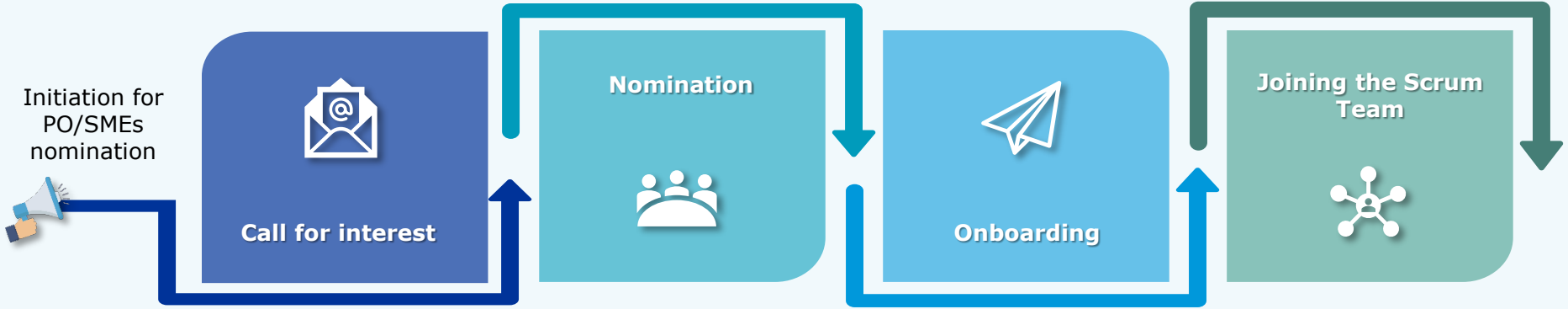


Main Ceremonies

- Quarterly Strategic Portfolio Review
- Quarterly Portfolio Sync
- System demo
- PI Planning

(1) Role as laid out in the Regulation, Article 3.
(2) Represents the Value Stream Leadership Team for the European Shortages Monitoring Platform (ESMP).

Engagement plan for Product Owner/Subject



- Profile requirements
- Knowledge and expertise
- Time commitment

- Selection of the PO/SME's
- Appointment
- Communication

- Confidentiality agreement
- System access
- Coaching and training

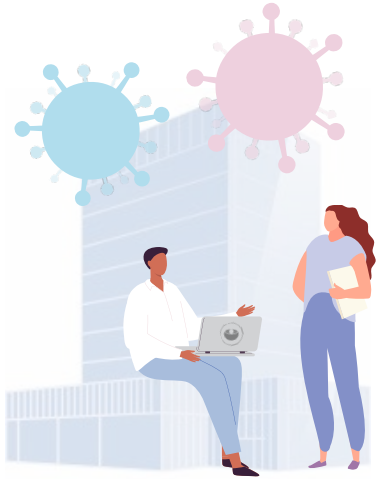
- Play an active role in the design and development of the ESMP in a scrum team coordinated by the EMA PO

Benefits

- Direct influence in the development of the ESMP.
- Bring the NCA's and Industry perspective, in particular submitting and retrieving information from the ESMP.
- Become key elements (expertise) in the improvement initiatives of NCA/MAH's systems.

Next Steps/ Engagement with Industry

- EMA to launch a call for nominations for Industry SMEs in June 2022.
- ESMP delivery starts formally under the SAFe Agile way of working in Q3 2022 (PI planning).
- Need for open/early dialogue on the potential expansion of the ESMP after 2025.



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

Follow us on **@EMA_News**

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Monitoring and mitigating shortages of critical medical devices in the context of a public health emergency

Industry Standing Group (ISG) meeting, 21 June 2022

Presented by Monica Dias, Klaus Kruttwig

Monitoring and mitigating shortages of critical medical devices

Implementation date: 2 Feb 2023

*Within the provisions of **Regulation (EU) 2022/123**, EMA has a central role in monitoring and mitigating shortages of critical medical devices in the context of a public health emergency (PHE).*

The **Executive Steering Group on Shortages of Medical Devices** (MDSSG) will be set up as part of the agency responsible for:

- Adopting a list of categories of critical medical devices, i.e. the PHE **critical medical devices list.** The list will be updated whenever necessary until the termination of the PHE.
- Defining the set of info to be provided, **monitor the supply of and demand for medical devices** included on the PHE critical medical devices list, with a view to identifying any actual or potential shortages of those medical devices.
- Report and provide recommendations (and coordinate) on measures to **prevent or mitigate potential or actual shortages**, and **provide aggregated data and forecasts of demand**.

EUROPEAN MEDICINES AGENCY

Definition of a public health emergency

- ***Article 2(a)*** public health emergency' means a situation of public health emergency recognised by the Commission in accordance with Article 12(1) of Decision No 1082/2013/EU

- Monitoring and mitigating shortages of critical medical devices only in the context of a public health emergency.

Definition of medical devices as provided in the Regulation 2022/123?

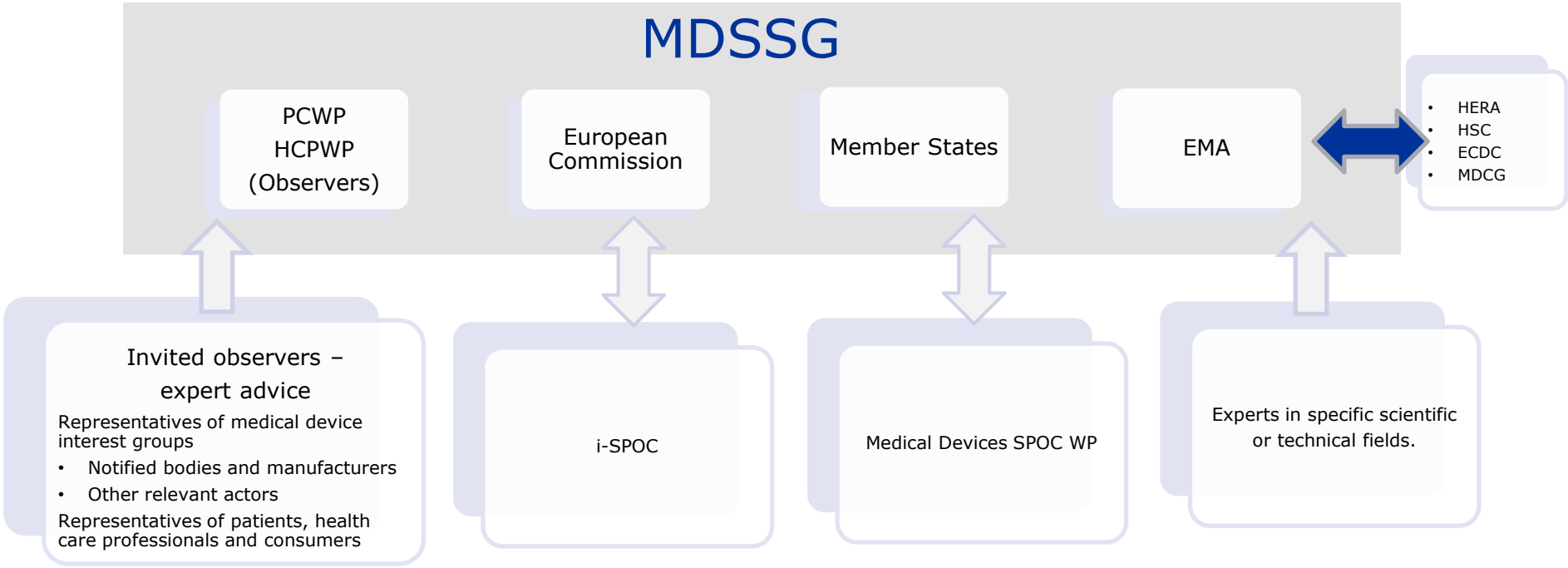
- ***Article 2(e)*** 'medical device' means a medical device as defined in Article 2, point (1), of Regulation (EU) 2017/745 or an in vitro diagnostic medical device as defined in Article 2, point (2), of Regulation (EU) 2017/746, and includes **accessories for such devices** within the meaning of Article 2, point (2), of Regulation (EU) 2017/745, and Article 2, point (4), of Regulation (EU) 2017/746, respectively

List of critical medical devices and information to be provided

- ***Article 22(1)*** Immediately following the recognition of a public health emergency, the MDSSG shall consult the working party referred to in Article 21(5). Immediately following that consultation, the MDSSG shall adopt a list of categories of critical medical devices which it considers to be critical during the public health emergency ('public health emergency critical devices list').

- **The MDSSG shall adopt and make publicly available the set of information referred to in Article 25(2), points (b) and (c),** that is necessary to monitor the supply of and demand for medical devices included on the public health emergency critical devices list.

Executive Steering Group on Shortages of Medical Devices



Role of the Member States in the monitoring and mitigation of shortages

Medical Devices Shortages SPOC WP

- **Operational group**
- consists of one representatives from each NCAs responsible for shortage monitoring and management of medical devices

Role:

Submission of the information specified in Article 27(1), point (a) and Article 27(3):

- Available and estimated data on volume of demand and demand forecasts.
- Any information which provides evidence of an actual or potential shortages of medical devices

Role of the economic operators & notified bodies in the monitoring and mitigation of shortages

Single points of contact

(for devices in the critical list)

Distributors*

Manufacturers

Notified Bodies

Importers*

Authorised Representatives

**where appropriate*

Role: Submission of the information specified in Article 26 and Article 25(2),point (c):

- **Mandatory reporting**, including:
  - Details of the manufacturer, medical device & if applicable notified body
  - Details on the shortage
  - Sales and market share data
  - Available stocks
  - forecast of supply, including information on the potent vulnerabilities in the supply chain
  - Forecast of demand
  - Quantities already delivered & projected deliveries
  - Shortage prevention and mitigation plans
  - **notified bodies** - information on status, number of applications & capacity to process applications

EMA extended mandate: main actions for device shortages

Establishment of a **drafting group** to support the preparatory work for the monitoring of shortages

Establishment of interactions with relevant existing groups responsible for medical devices

- Set up interaction with e.g. HMA core group, CAMD and MDCG
- Set up interactions with manufacturers and other relevant actors

Preparatory work for the monitoring of shortages (list of critical devices)

- Establish methodology to create list of categories of critical devices
- Establish procedures and processes for reporting of shortages of devices, demand and supply data

Preparatory work for formal establishment of the Medical devices Shortages Steering Group (**MDSSG**) and the Medical Device shortages SPOC **WP**

Identification of existing data sources for medical devices

- Set up interactions with NCAs to facilitate information exchange

Develop **electronic monitoring and reporting systems for devices**

- Leverage from EMA IT developments for medicines
- leverage from national IT systems until integration in EUDAMED is possible

Ad-hoc drafting group on medical devices shortages

Main tasks of the drafting group in the preparatory phase:

- Share experiences from the COVID-19 public health emergency
- Support the preparatory work for the establishment of the MDSSG and supporting Working Party
- Develop draft methodology to create list of categories of critical devices
- Develop draft processes for reporting of shortages of critical medical devices, analysing demand and supply data.
- Support interactions with industry and trade associations and other relevant groups

Conclusion and next steps

- For the monitoring and mitigation of shortages of critical medical devices, although the date of application is 2 Feb 2023, the preparatory work is ongoing in order to set up the necessary structures (MDSSG and its supporting WP) and processes by that date.
- Establishment of the *ad hoc* drafting group on medical device shortages
- Establishment of necessary interactions with stakeholders in the field of medical devices.
- Continue ongoing interactions with the EC on the learnings from the COVID-19 pandemic.

Thank you for your attention

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

Follow us on **@EMA_News**