

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3.2 Update on ESMP development progress status

Medicine shortages and Medical Devices - ISG September 2023

Presented by Pedro Pina Ferreira, Monitoring VS Owner, and
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21 September 2023



Objectives	Status
Strategic	
• Finalisation of the functionality for the bulk submission of data of CAPs in scope of MAH reporting requirements	●
• Functionality for the submission of alternative therapies by MAHs for medicines in scope of crisis reporting	●
• Embedding data on Marketing Status for CAPs	●
• Security features to protect access to the ESMP's data	●
• Incident management and bug fixing for Marketing status	●
Tactical	
• Assist MSSG-led preparedness actions for antibiotics ahead of 2023/2024 winter season: retrieve data on manufacturers of antibiotics marketed in at least one EU MS to establish communication channels	●
Analytical	
• Finalisation dashboards for crisis data, including matching supply and demand data in Q1 2024	●

Progress against plan	Status
Progress on track	●
Delay risk	●
Delayed	●
Completed/Achieved	●

Development

Preparedness phase: Functionality for the **submission of shortage data for CAPs by MAHs**

Preparedness phase: Functionality for **shortage case management** to optimise business processes

Functionality for the **submission of Marketing Status data for NAPs by MAHs**

Improve implemented features (e.g., Marketing Status)

Business analysis

Preparedness phase: Functionality for the **submission of data from NCAs**

Crisis phase: Functionality for the **submission of data from NCAs**

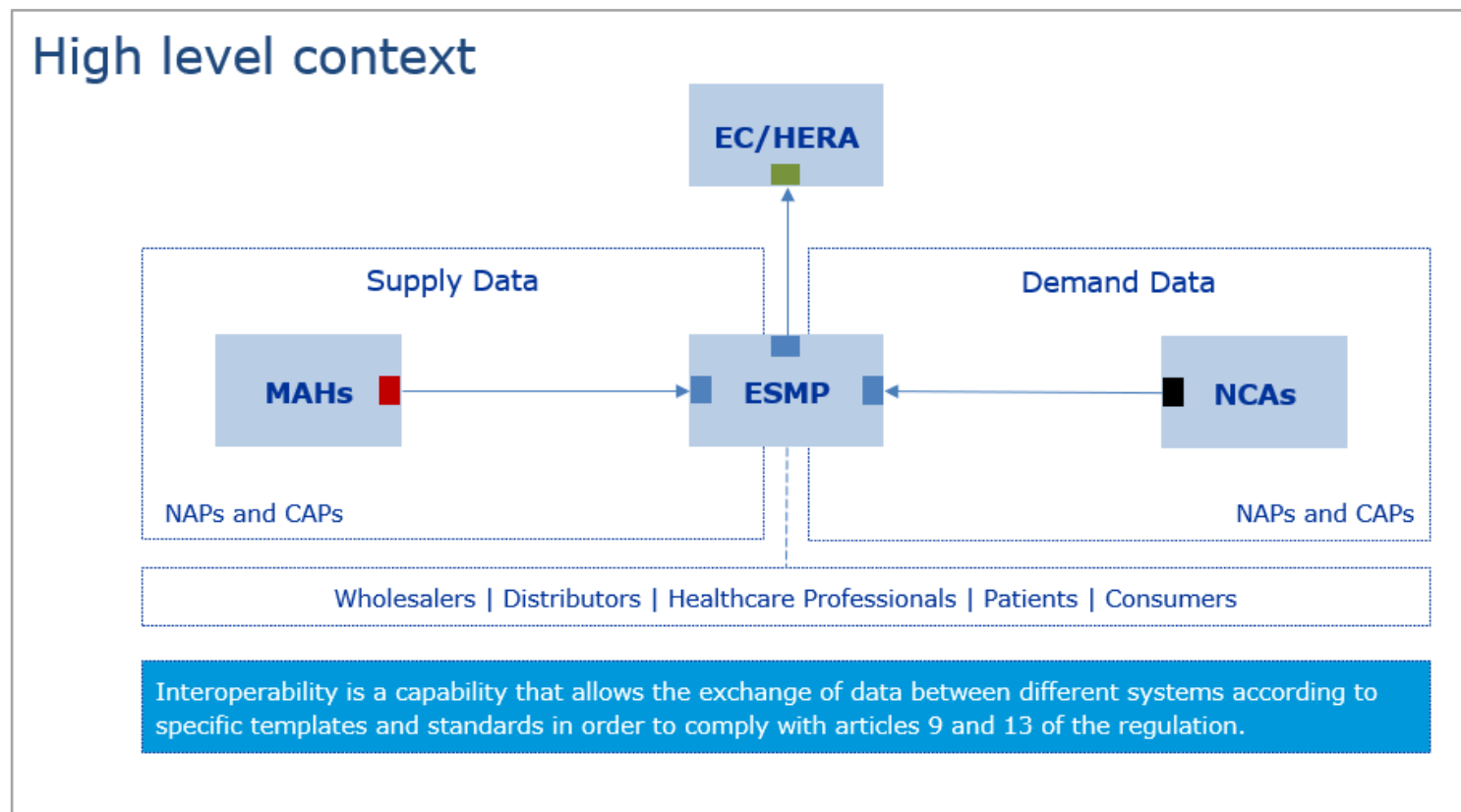
Integration of NAP data from SPOR Product Management Services

Interoperability requirements for both NCAs and MAHs

Data Analytics

Developing **NCA-specific PHE monitoring dashboards** including relevant PHE data per country

Define, agree and implement a phased solution between ESMP and stakeholders for data submission and validation.



Phase 1 : Q3/23 - Q1/24

Dataset Requirements

- Workshops with ESMP-MSSG-WG, PO, SMEs, DG HERA
- Analyse constrains and risks
- Define priorities

IT Solutions

- Analyse potential solutions

Plan

- Propose MVP for Feb25
- Propose Post MVP after Feb25

Phase 2 : MVP Q1/24 – Q2/25

Implement MVP

Start Phase 1

July 2023

NCA PO/SMEs

4 & 5 Oct 23

IND SMEs

8 Nov 23

NCA PO/SMEs

TBD

IND SMEs

TBD

End Phase 1

Q1 2024

Note: Workshop schedule

MVP : Minimum Viable Product
SME : Subject Matter Experts
PO: Product Owner



Any questions?

Further information

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