



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2.2 Update on ESMP development progress status

Industry Standing Group (ISG) meeting, 23 November 2023

Presented by Pedro Oliveira, Monitoring VS Manager, and
Sofia Zastavnik, ESMP Product Owner
23 November 2023

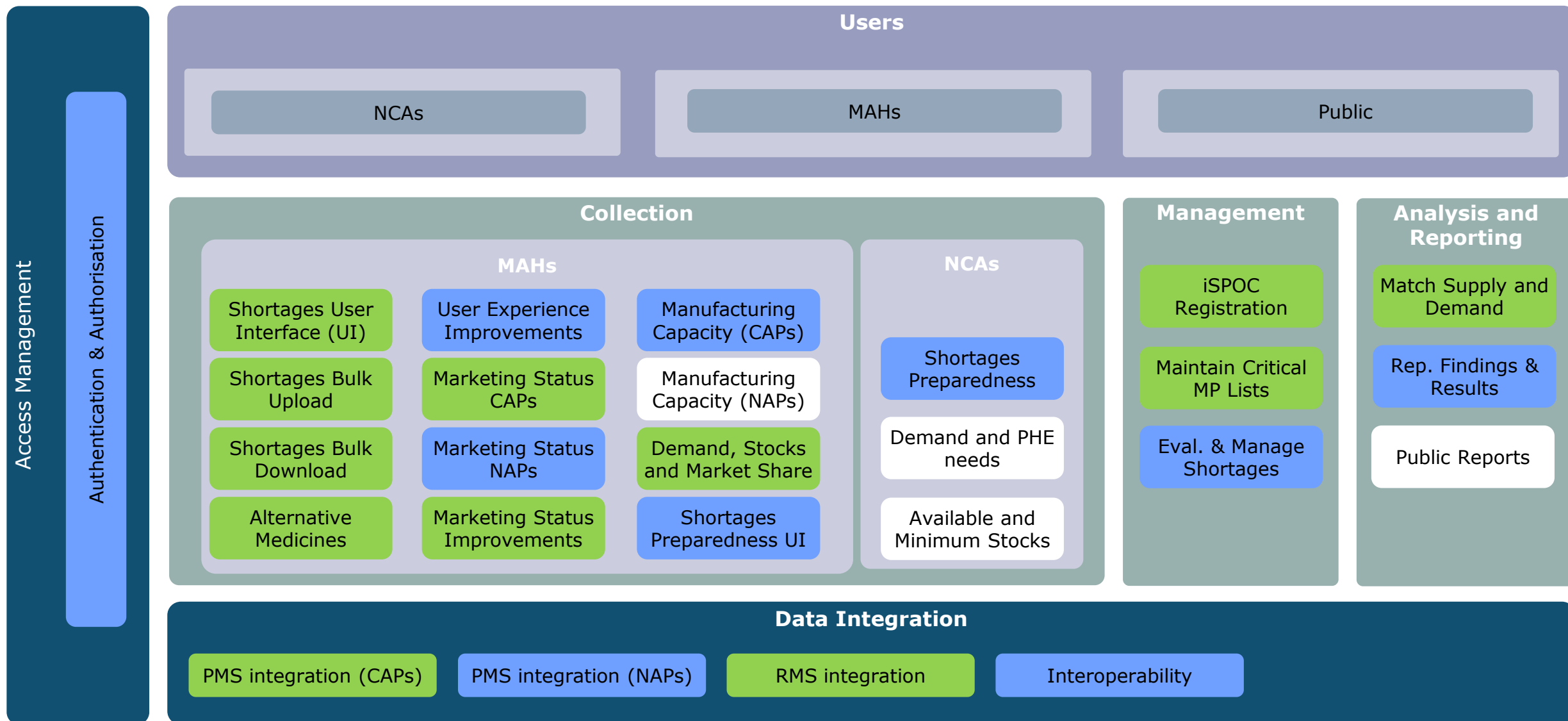
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ESMP High-level Progress Diagram



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Development

Preparedness phase: development of the **pre-filled template, bulk upload functionality** and required webpage(s) to allow **MAHs to submit shortage data for CAPs**

Preparedness phase: development of a **case management flow** to optimise business processes

Fix the identified and prioritised bugs related to submitting the **Marketing Status for CAPs** (incl. the creation of reports for new products and the correction of MAH information)

*Access management in preparation for the planned pilot **go-live in H1 2024***



Business analysis

Business analysis of **interoperability requirements** through **consultations with Industry and NCA** for the definition of MVP requirements and potential post-MVP tasks

Integrate NAP data from PMS in ESMP and assess the adaptability of existing functionalities* (analysis, development)

Create the required Feature(s)/User Stories, incl. their description and definition of acceptance criteria for the **submission of data by NCAs during a Crisis phase**

Create the required Feature(s)/User Stories, incl. their description and definition of acceptance criteria for the **submission of data by NCAs during the Preparedness phase**



UAT

Crisis phase: Prepare and conduct a **UAT with MAH users** on:

- **The bulk upload and download of reporting template for CAPs**
- The **webform** for submission of **alternative medicines** data



Data Analytics

Test the Public healthcare emergency (PHE) **monitoring tool**, bug fixing

Further **refinement** of the already implemented sections of the PHE monitoring tool

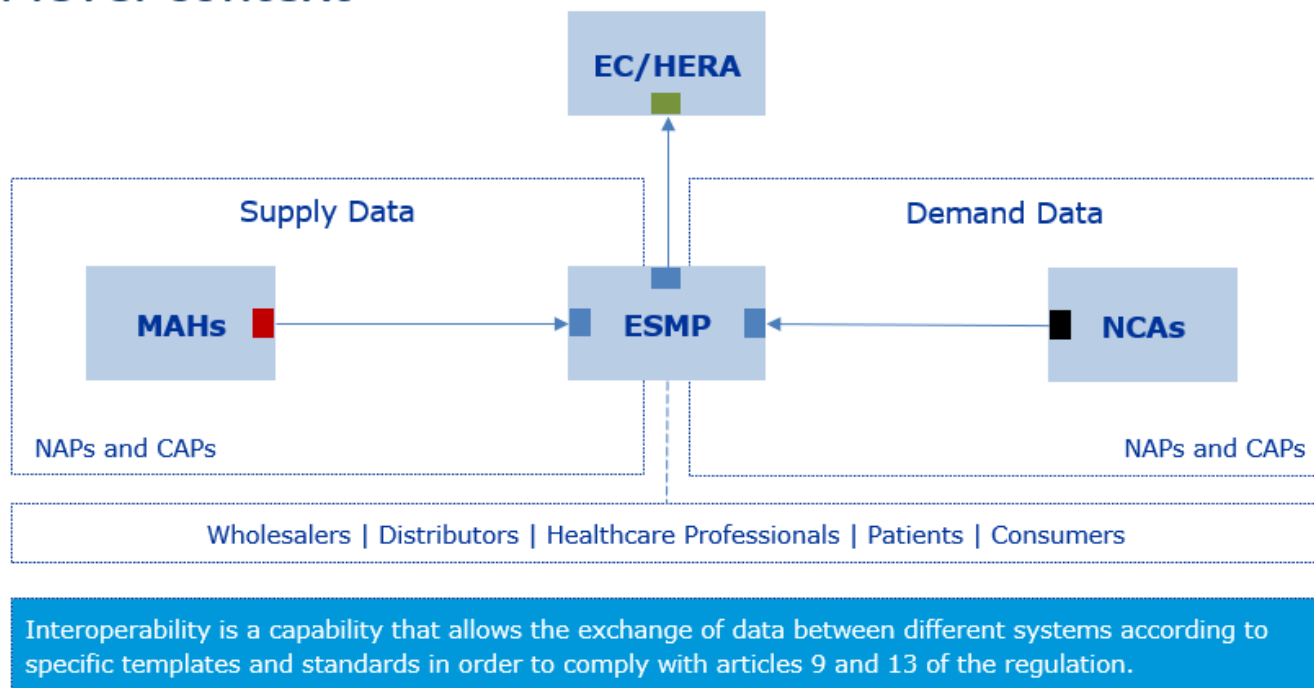
Creation of a new section in the PHE monitoring tool with **country relevant PHE data for NCAs**



Progress on track

Objective: define, agree, and implement a phased solution between ESMP and stakeholders for data submission and validation.

High level context



Phase 1 : Q3/23 - Q1/24

Dataset Requirements

- Workshops with ESMP-MSSG-WG, PO, SMEs, DG HERA
- Analyse constraints 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 + IND

TBC 15-19 Jan

End Phase 1

Q1 2024

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



The **first workshops** between the EMA and NCAs/Industry Subject Matter Experts took place in October and November 2023 respectively, in which participants discuss the **processes for the submission of data** from NCAs/MAHs to the ESMP, including **data elements and datasets** to be submitted, **availability of data** and data sources, **priorities for IT solutions**.

National Competent Authorities

- 1. Lessons learned** : Interoperability of national systems with UPD and UPHV systems (*Suggested in Bonn Meeting*)
- 2. Datasets required by ESMP** : A general understanding of the datasets and processes for the submissions in times of crisis and preparedness was obtained
- 3. Data collection from NCAs** : NCAs often gather information from other public health bodies and health ministries to incorporate into their internal systems
- 4. Joint Action 7** : The findings indicated a significant variation among NCAs in terms of their IT solutions and data collected for managing shortages
- 5. Data Exchange Formats** : Will be the basis for the development of the IT solution for interoperability between ESMP and NCAs

Industry

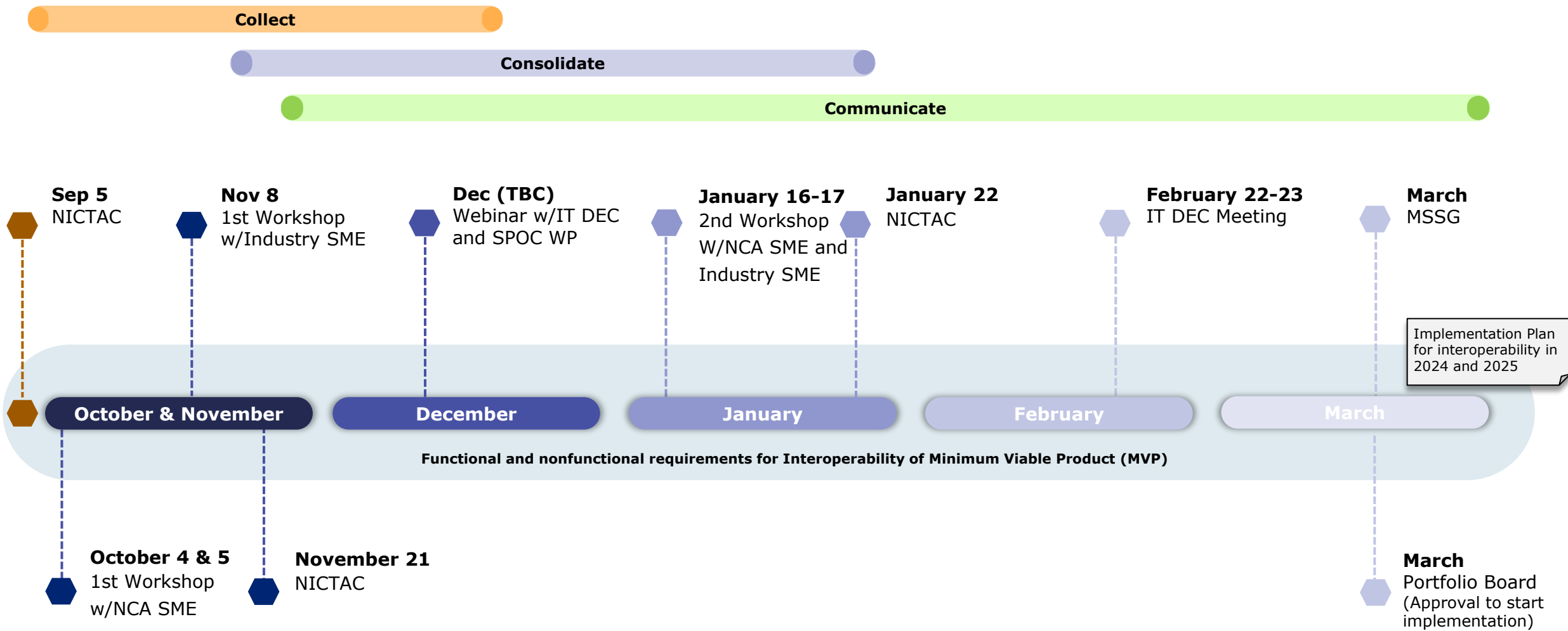
1. Datasets Required by ESMP:

- The granularity of data submission put in place aligns well with Industry requirements
- Most data elements requested in the ESMP are owned by Industry

2. Data Mapping from MAHs : MAHs use stock keeping unit (SKU) identifiers, facilitating consistent mapping with EMA PMS identifiers at package level + country

3. Data Aggregation from MAHs : Data submission is preferable through Excel templates, to facilitate (semi-) automatic population of their data

4. Leveraging Existing Systems : Industry SMEs suggested the possibility to use EMVS as a source of supply data to complement the datasets in ESMP





Any questions?

Further information

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