



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ESMP Development Progress & Roadmap

ISG June 2023

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An agency of the European Union



ESMP Roadmap: Update – focus on Q2 2023



EUROPEAN MEDICINES AGENCY

| Views | Up to Q1 2023 | Q2 2023 | Q3-Q4 2023 | 2024 | 2025 |
|--------------------------|--|---|--|---|---|
| Product Goals | <ul style="list-style-type: none"> iSPOC registration available MAH submit marketing status data for CAPs Establishment and maintenance of critical medicines lists | <ul style="list-style-type: none"> Complete bulk upload using a refined template following consultations with Industry | <ul style="list-style-type: none"> MAH submit crisis data PMS data used to identify CAP and NAP products Data analytics capabilities available | <ul style="list-style-type: none"> NCA submit crisis data MAH submit preparedness data NCA submit preparedness data Interoperability capabilities available | <ul style="list-style-type: none"> Q1: MVP available Q1: Public platform available ESMP improvements Planning the expansion of ESMP |
| Features | <p>Initiation</p> <ul style="list-style-type: none"> F01: iSPOC contacts registration F06, F12: Establish critical medicine list F09: Aggregate demand data* F15: Reporting of Findings & Results* <p><small>*Using interim solution</small></p> | <p>Initiation</p> <ul style="list-style-type: none"> Crisis: Bulk upload of MAH data and download of reporting template with CAP products in scope F16, F17: Security and access management for MAHs F10: Matching of Supply and Demand* <p><small>*Using interim solution data</small></p> | <p>Crisis data management</p> <ul style="list-style-type: none"> F08: Crisis: Evaluate & manage shortages F06: Crisis: MAH reporting F16, F17: Security and access management for NCAs | <ul style="list-style-type: none"> F06: Crisis: MAH reporting, including manufacturing sites and production capacity (PMS integration) F07: Crisis: NCA reporting - demand F11: Crisis: Publication of information on shortages F16, F17: Security and access management for NCAs <p>Preparedness data management</p> <ul style="list-style-type: none"> F02.1: Preparedness: NCA reporting for NAPs F03: Preparedness: MAH reporting for CAPs F04: Preparedness: Data analysis & reporting <p>Interoperability with NCA and MAH</p> <ul style="list-style-type: none"> Interoperability features | <ul style="list-style-type: none"> Improvements |
| Milestones | <ul style="list-style-type: none"> May: Feasibility study concluded May: Governance endorsed, including establishment of MSSG WG Jul 2022: iSPOC registration available Sep 2022: Network PO, MAH and NCA SMEs appointed Q1 2023: ESMP Roadmap concluded & MVP agreed | <ul style="list-style-type: none"> Methodology for matching of supply and demand data concluded Sync with PMS roadmap on NAP manufacturing site data | <ul style="list-style-type: none"> Q2/3: Sync ESMP and HERA roadmaps Q3: Interoperability analysis started | <ul style="list-style-type: none"> Q1: Interoperability approach agreed Q2: Agree on the information to be published | <ul style="list-style-type: none"> Q1: Go-live of MVP Q3: Expansion plan agreed |
| ESMP | Minimum Viable Product | | | | Go Live and Expansion |

Final version of PI objectives to be agreed during PI planning (end of June) according to business value of each item and team capacity

Strategic solution (ESMP platform)

- Improved bulk upload for MAHs and download of reporting template for CAPs (development, bug fixes, user testing)
- Alternative medicines webform for submission of data becomes available (development)
- Marketing status for CAPs is embedded within ESMP (development)
- Security and access features completed for admin role in CRM (development)
- Conclude the functionality for submission of marketing status for NAPs ⁽¹⁾ (development, if analysis completed)
- Improve User Experience of the ESMP: Refinement of the UI (analysis)
- Manuf. sites integration for CAPs and submission of production capacity (analysis)
- Initiate the analysis of the interoperability concept (analysis)
- Integrate NAP data from PMS in ESMP ⁽²⁾ (analysis)

⁽¹⁾ Dependency on previous feature, ⁽²⁾ Dependency on PMS team

Data analytics

- Configure Go Live for crisis data analysis and preparedness
- Refinements and improvements according to new ESMP features as they become available



Any questions?

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