



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# ESMP Development progress & Roadmap






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An agency of the European Union



 <p><b>VISION</b></p>	<p>ESMP will enable information exchange for better prevention, identification and management of shortages, and communication between the EMA, National Competent Authorities and Stakeholders in the supply chain medicinal products, in order to ensure medicines are available for patients during PHE and ME.</p>		
 <p><b>TARGET GROUP</b></p> <ul style="list-style-type: none"> <li>- European Commission (EC)</li> <li>- National Competent Authorities (NCA)</li> <li>- Marketing Authorization Holders (MAH)</li> <li>- Emergency preparedness and Response Authority (HERA)</li> <li>- Wholesalers and Distributors</li> <li>- Healthcare Professionals</li> <li>- Patients and Consumers</li> </ul>	 <p><b>NEEDS</b></p> <ul style="list-style-type: none"> <li>- Reliable exchange of information with NCAs, MAHs and relevant actors of the supply chain on medicinal products using ISO-IDMP</li> <li>- Monitoring, prevention and management of shortages of medicines in the critical lists during a Public Health Emergencies (PHE) or Major Event (ME)</li> <li>- Monitoring of actual or a potential shortages in a given MS, that can lead to a ME or a PHE</li> <li>- Match supply and demand data</li> <li>- Due to the sensitive nature of the information collected, the ESMP should ensure that data protection principles are applicable</li> <li>- Ensure a high level of protection against cyber attacks</li> </ul>	 <p><b>PRODUCT</b></p> <ul style="list-style-type: none"> <li>- Monitoring and reporting of actual or potential shortages of medicinal products, supply and demand.</li> <li>- Identify issues relating to supply of and demand for medicinal products</li> <li>- Portal that provides information on actual shortages that can be linked to recommendations to EC, NCA, MAH and to be communicated to healthcare professionals and patients</li> <li>- Process information received from MAHs and NCAs in order to prevent shortages during a PHE or a ME</li> <li>- Enable the use of big data practices and Artificial Intelligence</li> </ul>	 <p><b>BUSINESS GOAL</b></p> <ul style="list-style-type: none"> <li>- Improve crisis preparedness and management with respect to medicinal products shortages to mitigate impact on patients</li> <li>- Strengthened framework for monitoring and reporting on shortages of medicinal products during PHE and ME</li> <li>- Increase efficiency and predictability during public health emergencies and major events, and accelerate the decision-making process</li> <li>- Facilitate availability of critical medicinal products during PHE and ME</li> </ul>



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



## Headlines

- ESMP roadmap done, undergoing review from stakeholders



## Progress against plan

### Progress against plan

- Progress on track
- Progress at risk/not on track – mitigation identified (expect to resolve by end of PI)
- Progress not on track – escalation needed/in progress (PI completion at risk)
- Completed/Achieved

### Status

- Green dot
- Yellow dot
- Red dot
- Blue dot

PI Objective	Status	PI Objective	Status	PI Objective	Status
<p><b>Strategic</b></p> <ul style="list-style-type: none"> <li>Refactoring of Marketing Status, calculation of the Sunset Clause</li> <li>MAHs bulk upload reporting for CAPs (upload &amp; download of files)</li> <li>ESMP portal security and access features (EMA and MAH, admin)</li> <li>Enhancements to MAHs submission data elements</li> <li>UI refinements and NCA demand data submission (Analysis)</li> </ul>	<ul style="list-style-type: none"> <li>Yellow dot</li> <li>Yellow dot</li> <li>Yellow dot</li> <li>Green dot</li> <li>Green dot</li> </ul>	<p><b>Tactical</b></p> <ul style="list-style-type: none"> <li>Enhancements to MAHs + NCAs submissions data collection &amp; mgmt. &amp; reporting</li> <li>Support for functioning of MSSG &amp; MS SPOC WP</li> </ul>	<ul style="list-style-type: none"> <li>Yellow dot</li> <li>Green dot</li> </ul>	<p><b>Data Analytics</b></p> <ul style="list-style-type: none"> <li>Building Data analysis platform for crisis reporting</li> <li>Create reports for MAH and NCA data on shortages, and supply &amp; demand of medicines</li> <li>Data transformations using Art57 data</li> <li>Dashboard: Overview of the situation on the EU market and to point out problem areas requiring further action</li> <li>Matching supply and demand (Analysis)</li> </ul>	<ul style="list-style-type: none"> <li>Green dot</li> <li>Green dot</li> <li>Blue dot</li> <li>Green dot</li> <li>Green dot</li> </ul>



## Risks and issues

- Dependency on other IT delivery teams, high complexity of requirements for pre-population of files for bulk submission of data
- Unplanned business capacity reduction – urgent priorities (antibiotics)



## Comms Summary

Date	Description	Target
Various	<ul style="list-style-type: none"> <li>Quarterly Portfolio Sync (QPS) &amp; Strategic Portfolio Review</li> <li>ESMP MSSG WG</li> <li>SME Forum</li> <li>MSSG</li> <li>ISG</li> </ul>	<ul style="list-style-type: none"> <li>Portfolio Board and NPAG</li> <li>Representative of MSSG and JA 7</li> <li>Product Owners and Subject Matter Ex.</li> <li>Heads of Agency</li> <li>Industry Associations</li> </ul>