2nd MDR Eudamed Market Surveillance ad hoc WG Meeting

Implementation plan update for Market Surveillance Module – Planning - Roadmap

25/10/2018

Meetings

Planned Meetings:

- 25/10/18 – 2nd Market Surveillance WG
- 29/11/18 – 4th Data Exchange WG
- 13/12/18 – Steering Committee
- 29/01/19 – 9th Actor Registration WG
- 07/02/19 – 4th Clinical Investigations WG
- 14/02/19 – 4th Vigilance WG
- 21/02/19 – 6th NB & Certificates WG
- 14/03/19 – 6th UDI & Device WG
- 21/03/19 – 5th Data Exchange WG
- 28/03/19 – 3rd Market Surveillance WG

Working Documents

- Functional Specifications document contains
  - Legal requirements
  - Functional specifications
  - Non-functional specifications
- Process overviews / use cases
- Wireframes / Mock-ups
- Business rules
- Data models
- Implementation plan

Analysis Overview

Domain	Stakeholders	Status	Description
Secure			
Legal Requirements	EC, WG, MDCG	Version 2.0	
High Level Specification	EC, WG, MDCG	Version 2.0	
Detailed Requirement gathering	EC, WG	Ongoing	
Business Process	EC, WG	Ongoing	
Entity Model	EC, WG	Ongoing	
Business Rules	EC, WG	Ongoing	
Wireframes	EC, WG	Not Started	
Mock-ups	EC, WG	Not Started	
Validation	EC	Not Started	
Public			
Legal Requirements	EC, WG, MDCG	Version 2.0	
High Level Specification	EC, WG, MDCG	Version 2.0	
Detailed Requirement gathering	EC, WG	Ongoing	
Business Process	EC, WG		Not required, read only for public for one use case
Business Rules	EC, WG	Ongoing	
Wireframes	EC, WG	Not Started	
Mock-ups	EC, WG	Not Started	
Validation	EC	Not Started	
Machine-to-Machine			
Legal Requirements	EC, WG, MDCG	Version 2.0	
High Level Specification	EC, WG, MDCG	Version 2.0	
Services	EC, WG	Not Started	
XML Samples	EC, WG	Not Started	
Business Rules	EC, WG	Not Started	
Validation	EC	Not Started	

MSU- State of Play

- Functional Specifications document V2.0
  - LR-MSU-012 : Non-compliant measures definition modification
  - LR-MSU-021 : Non-compliant measures definition modification
  - LR-MSU-026 : Notified body access to MSU
  - LR-MSU-027 : Notifications to be sent to notified bodies
  - LR-NFS-002 : Reformulate description

- Implementation plan
  - Update will be sent after inclusion of the new version of the functional specifications

MSU - State of Play

Legend for the following slides:

Priority in High Functional Specs – Status of analysis – Analysis Finalized

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MSU - State of Play

MSU Restricted FS – sorted by Priority

1. FS-MSU-002 : Manage the final inspection reports of the MS

   High – Collect Requirements – Define Template – 11/18

2. FS-MSU-008 : Search and view information on market surveillance

   High – Collect Requirements - 3/19 (Functionality added for each FS)

3. FS-MSU-005 : Manage notification and exchange information on devices presenting an unacceptable risk to health and safety

   High – Collect Requirements – 1/19

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MSU - State of Play

MSU Restricted FS – sorted by Priority

4. FS-MSU-006 : Manage information on measures taken for a non-compliant device not presenting an unacceptable risk to health or safety or other aspects of the protection of public health

   High – Collect Requirements – 1/19

5. FS-MSU-007 : Manage notification on preventive health protection measures

   High – Collect Requirements – 1/19

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MSU - State of Play

MSU Restricted FS – Further release

6. FS-MSU-001 : Manage the annual summaries of the results of the surveillance activities of the MS

    Medium– Collect Requirements – Define Template – Further Release

7. FS-MSU-003 : Manage the summaries of the results of the reviews and assessment of the market surveillance activities of the MS

    Medium– Collect Requirements – Define Template – Further release

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MSU - State of Play

MSU Restricted FS – Further release

8. FS-MSU-004 : Communicate results of the review and assessment by the MS of the functioning of its market surveillance activities

   Medium– Collect Requirements – Define Template – Further release

9. FS-MSU-011 : Platform for cooperation and collaboration between MS and between MS and the Commission

   Medium – Collect Requirements – Further release

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State of Play

MSU Machine to Machine FS – sorted by Priority

1. FS-MSU-009 : Machine to machine (M2M) market surveillance data Download

   High – Collect Requirements / Services – 2/19

2. FS-MSU-010 : Machine to machine (M2M) market surveillance data Upload

   High – Collect Requirements / Services – 3/19

State of Play

MSU Public FS

FS-PUB-MSU-001 : Search and view a summary of the results of the reviews and assessments of the market surveillance activities of a MS

Medium – Collect Requirements / Services – Further Release

Moving Forward

- Establish a communication channel with COEN Eudamed TF
- COEN to provide feedback on provided detailed analysis
- COEN to provide meta-data for form content
- Collaboration with COEN in defining requirements
- Finalize all Detailed Requirements by next WG (03/19)

Questions?