

NMVO Alert Working Group

- Map national guidelines, similarities and reasons for differences
- Map demands from NCAs
- Evolve existing EMVO guidelines
 - SpecificationsDevelopment process

Ref. Ares(2019)7622862 - 11/12/2019

EMVS
and
European Alert
Management
System

Ongoing processes for improving the system

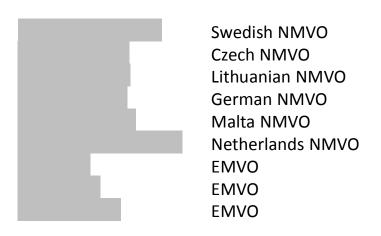
- Stabilisation
- Preventative actions to reduce false alerts
- Alert convergence
- Improved governance of the EMVS as ONE system

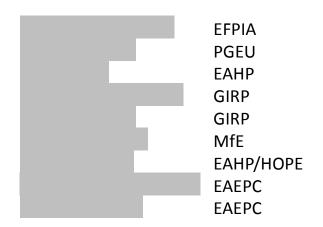
Core functionalities of a European Alert Management System

- Automatic determination of the root causes of alerts, so targeted measures can be put in place.
- Enable a two-way communication conduit between the OBP and end-user (without actually disclosing who the end-user is)



Members







What's next

- The stabilisation of the EMVS must be top priority
- The alert management system should be designed to handle a situation when the alerts have reached an expected level
- Keep the 'additional burden' on all users as little as possible.
- The specification of the European Alert Management System must be outlined as soon as possible.
- The work with European Alert Management System must be done in close cooperation with the NMVOs, EMVO and stakeholders.
- Outline a broad plan and define first actions.



Alert management by each NMVO. Improve by more sharing of best practices and next practices.

Alert harmonisation/convergence by EMVO

Already ongoing

Provide OBPs with 'tips and tricks'

For example 'best practice' workshop with QA.

Could ease and improve alert investigation for OBPs (Based on the presentation from MAH at last NMVO PM meeting.)

Map alert guidelines for all NMVOs and demands from NCAs



Questionnaire sent out

GAP analysis and comparison EMVO guidelines

Differences and similarities explained. Dialogue with NCAs/COM. Input for update of EMVO guidelines. Input for Case mapping.

Update of EMVO guidelines

Towards an European standard alert management

Stakeholder input/expectations on EAMS

Each EMVO stakeholder to provide input on their expectations on Alert mngt system.

Like the EFPIA document. Input for Case mapping

Use Case /scenario mapping

Output: What use cases do the EAMS need to support? Automatic alert mngt? What cases should be handled by procedures not in the system?

Preparation of Technical specifications

Technical specification

Design and implementation



Timelines first step

Who	December	January	February
Working group	 Questionnaire sent out Skype call 12th December: formulating hypothesises for testing with broader audience 	 F2F 13th January: Analyse results/data Drafting scope of EAMS with EMVO Present results to NMVO's 	 Get NCA input on draft of scope Get QA input on scope Present FMD workshop final draft scope
EMVO	Preparation of Technical Specifications of EAMS	 Preparation of Technical Specifications of EAMS Desk research of NCA timelines 	 Present draft technical specification of EAMS for feedback
Stakeholders	 Supply WG with data (questionnaire) Ask stakeholders for expectations (EFPIA plan) 		Validate hypothesis in draft scope





Questions?

