EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Progress update: MLM and EV auditable requirements project

10th industry stakeholder platform – operation of EU pharmacovigilance
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Pharmacovigilance Projects

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Projects & Outputs	Benefits Delivered	Driven By
Medical Literature Monitoring *Delivery of literature monitoring service to MAHs* **Operational**	• **Improved safety monitoring of medicines** through better quality of safety information (reduced duplicates in EV) • **Reduction in MAH literature monitoring activities** as well as duplication between companies	**Effective programme management** which ensures successful delivery of changes
Article 57 Database *European database of all medicinal products* **Operational**	• **Support PV Procedures** (PSUR /Referrals / PASS) which facilitates the coordination of regulatory decisions and actions • **Supports the product index** for EudraVigilance and thus identification of products and substances in Individual Case Safety Reports • **Reduction of duplication** of encoding and maintenance of the same information on medicines	
PSUR Repository *Centralised repository for PSURs and assessment reports* **Operational**	• **Provides a simplification** of PSUR submissions **for industry** • Repository will include all PSURs and assessment reports	
EudraVigilance Auditable Requirements *Enhanced adverse reaction collection and management system* **Go-live in Q4 2017**	• **Simplified reporting** (MAHs report to the NCAs through EudraVigilance) • Data in ISO format will be of higher quality, **improving searchability and analysis of case reports**	

Programme Management of closed projects continues through benefits realisation tracking

Provides public health benefits across Europe

Medical Literature Monitoring (MLM) 1/2

Major achievements

- ✓ An independent audit of the EMA MLM service provider's internal quality management and control systems and of the output of the service was conducted in early 2016. The audit report will be made available on the MLM webpage;

- ✓ 2 stakeholder surveys were conducted in 2016 (March & October) to assess industry and NCAs' experience with the service. The report of these will be made available on the MLM webpage.

Medical Literature Monitoring (MLM) 2/2

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Major achievements

- ✓ 1 Stakeholder workshop was held in September to obtain detailed proposals for future enhancements that would improve the service for stakeholders
  - ✓ The recommendations from this workshop were then included in the October MLM stakeholder survey so that all affected stakeholders could vote on (a) whether they wanted each proposed change & (b) how long they would need to implement each change.
  - ✓ The final outcome from the workshop, surveys & audit will be published together with a road map for enhancements to the MLM service on the MLM webpage in the coming weeks.
  - ✓ Surveys will continue every 6 months and, if there is a continued need once the changes have bedded-in, further workshops will be organised.

EudraVigilance Auditable Requirements (PV-ADR) 1/4

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SCOPE: There is a legal requirement for an **enhanced adverse reaction collection and management system** (EudraVigilance) that delivers better health protection through **simplified reporting, better quality data and better searching, analysis and tracking functionalities**. Enhanced detection of new or changing safety issues allows more rapid action to protect public health.

- ✓ The '**EudraVigilance Auditable Requirements Project**' was set-up to **deliver the new EV system**.
- ✓ Before the move to simplified reporting, the new EudraVigilance system has to undergo an **independent audit** against the functionalities agreed with the EMA Management Board in December 2013.
- ✓ To further strengthen system performance ahead of its launch, in June 2016, the **EMA Management Board approved an updated schedule:**

Independent audit of new EudraVigilance system	**Feb 2017**
Progress update to EMA Management Board	**Mar 2017**
PRAC recommendation on final audit report	**May 2017**
EMA Management Board adoption of final audit outcome – Final audit report to be presented for adoption by written procedure, supported if needed by a dedicated Management Board teleconference	**May 2017**
Release of new EudraVigilance functionalities – Including adoption of revised Access Policy, and the move to simplified reporting.	**Nov 2017**

EudraVigilance Auditable Requirements (PV-ADR) 2/4

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Major achievements/status

- ✓ To support EudraVigilance stakeholders and partners the **EudraVigilance website** has been **redesigned** and enhanced to publish important information on the new and existing EudraVigilance system. This includes: A Stakeholder Change Management Plan; A Communication Plan; A Training Plan and e-learning materials; Technical documentation, such as the EU ICSR Implementation Guide; The EudraVigilance Access Policy.

- ✓ **EV system testing / feedback**
  - ✓ EMA User Acceptance Testing of the auditable system requirements was completed in November 2016.
  - ✓ Testing was conducted to gather feedback from NCA and MAH volunteers on the new EV Gateway solution and EVWEB solution in September and November 2016 respectively.
  - ✓ Testing of the WHO-UMC export functionality was conducted in August and November 2016, with additional volume testing concluded in December 2016.

EudraVigilance Auditable Requirements (PV-ADR) 3/4

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Major achievements/status

- ✓ A minor revision of the **EudraVigilance Access Policy (revision 3)** was published in December 2016 to further strengthen the protection of personal data for reports of suspected adverse reactions related to medicines published on the adrreports.eu web portal;

- ✓ To support Stakeholders / Partners, the PV-ADR project has developed a curriculum of **online training**. An additional set of e-learning modules were published in **January 2017**.

EudraVigilance Auditable Requirements (PV-ADR) 4/4

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What's coming

- ✓ The go-live of the **new external testing system**, namely XCOMP, is scheduled for **June 2017**. All registered organisations with a valid EudraVigilance Test account will be able to start sending E2B(R3) test files and to download E2B(R3) test data. This will provide organisations with a 6 months period to become familiar with the new system before it is launched in production;

- ✓ The **audit of the EV system will take place in February 2017** and its successful completion will be the starting point to the launch of centralised reporting end of 2017;

- ✓ **Before and after the go-live** of the new system in November 2017, **webinars will be organised to support NCAs and MAHs**. This will allow the EMA expert team to answer implementation questions from NCAs and MAHs.

PhV-M0: Introduction to EMA's training offering

Pharmacovigilance	EudraVigilance	EudraVigilance -IT
PhV-M1: New EV functionalities & 2010 pharmacovigilance legislation	EV-M2: Introduction to EV system components and system functionalities	IT-M1: ISO ICSR standard implementation for IT system developers
PhV-M2a: Implementing ISO ICSR/ICH E2B(R3): Impact on adverse reaction reporting	EV-M3a: EV Reporting process for users: EV Gateway, Web-Trader, EV-Post functions	ISO ICSR (E2B(R3)) system implementers workshop
PhV-M2b: Implementing ISO ICSR/ICH E2B(R3): Backwards and forwards conversion	EV-M3b: EV Reporting process for users: Introduction to EVWEB	EV-M5a: EVDAS training for National Competent Authorities
PhV-M3: How to prepare for simplified adverse drug reaction reporting in the European Union	EV-M3c: EV Reporting process for users: Export functions in EVWEB	EV-M5b: EVDAS training for Marketing Authorisation Holders
PhV-M4: Revised EudraVigilance access policy: impact on stakeholders	EV-M3d: EV Reporting process for users: Create and send ICSRs using EVWEB	EV-M6: ADRreports.eu portal

Additional offerings in 2017

Pharmacovigilance	EudraVigilance	EudraVigilance -IT
PhV-M5a: Revision of GVP Module VI 'Management and reporting of adverse reactions to medicinal products' – what's new)	EV-M1: How to register with EudraVigilance and EVDAS	IT-M2: Instructions on how to test ICSR submissions to EV
PhV-M5b: Screening of adverse reaction in EV	EV-M3e: Special reporting scenarios in EVWEB	
PhV-M5c: Revised GVP Module IX 'Signal management' by MAHs including EV data	EV-M4: EudraVigilance Export Manager and ICSR download	EV-M7: Medical Literature Monitoring by EMA
PhV-M5d: Revised GVP Module IX 'Signal management' by NCAs	EV-M5a: EVDAS Training for MAHs	
	EV-M5b: EVDAS training for NCAs	

Guidance and user manuals for 2017

Pharmacovigilance	EudraVigilance
PhV-G1: Methodological guidance for Signal Detection	EV-G1a: MAH's level 1 access via EVDAS
Revision 2 of GVP Module VI	EV-G1b: eRMR for NCA; structure and key activities in screening
Revision 1 of GVP Module IX	EV-G2: EVDAS Report Manual
	EV-G3: ADR website user guide
	EV-G6: ICSR form user manual
	EV-G7: EVWEB user guide

Conclusions

- Medical Literature Monitoring – continuous process improvement
- EudraVigilance Auditable Requirements project is on track
- Comprehensive package is made available ahead of time to support EudraVigilance stakeholders and partners
    - Stakeholder Change Management Plan, Communication Plan, A Training Plan and e-learning materials, Technical documentation, user manuals and Guidance

Thank you for your attention

Further information

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