EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on EudraVigilance Auditable Requirements project

11th industry stakeholder platform – operation of EU pharmacovigilance - 02 June 2017

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EudraVigilance - achievement of the full functionality

- Based on an independent audit report and a favourable PRAC recommendation, on 22 May the EMA Management Board confirmed and announced that full functionality of the new EudraVigilance database has been achieved and the system meets the defined functional specifications.
- **The enhanced EudraVigilance system will be launched on 22 November 2017.** Together with the launch, further legal obligations will become applicable to the mandatory electronic reporting through EudraVigilance as stated in the announcement of the EMA Management Board.
- Users of the system, i.e. marketing authorisation holders and sponsors of clinical trials, have to make final preparations to ensure that their processes and local IT infrastructure are compatible with the new system and the internationally agreed format.

Expected benefits

- Simplified reporting of individual case safety reports (ICSRs) and the re-routing of ICSRs to Member States as marketing authorisation holders will no longer have to provide these reports to national competent authorities, but directly to EudraVigilance;
- Better detection of new or changing safety issues, enabling rapid action to protect public health;
- Increased transparency based on broader access to reports of suspected adverse reactions by healthcare professionals and general public via the adrreports.eu portal;
- Enhanced search and more efficient data analysis capabilities;
- Increased system capacity and performance to support large volumes of users and reports (including non-serious adverse reactions originating from the EEA);
- More efficient collaboration with the World Health Organization (WHO) as EMA will make the reports of individual cases of suspected adverse reactions within the EEA available to the WHO Uppsala Monitoring Centre (UMC) directly from EudraVigilance;

EudraVigilance Training and Support

- **E-Learning**: training via e-learning videos; user guides for EVWEB and EVDAS will be made available shortly
- **Face-to-Face trainings**: focus on the new EVWEB functionalities, use of the ICH E2B(R3) ICSR format based on various case scenarios, principles of EVDAS and use of e-RMRs, line listings and ICSR forms
- **"Pharmacovigilance and EudraVigilance" support webinars**: business oriented – 13 webinars (2017)
- **"Technical" support webinars**: IT oriented – 13 webinars (2017)
- **"Information Days"**: 3 EudraVigilance, 1 Signal Management (2017)

Please visit EudraVigilance Training and Support webpage

EudraVigilance Registration

- **EVDAS registration:**
  - Phased registration of MAHs (HQ level) from June to October 2017
  - ~ 600 MAH HQs to be registered per month
  - Registration of 5 users per MAH HQ
- **EVWEB registration (test and production environment):**
  - Ensure that login credentials of users are valid
  - Start registration of new EVWEB users if required

Please visit EudraVigilance: how to register webpage

For assistance contact: EudraVigilanceRegistration@ema.europa.eu

Thank you for your attention

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