EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EV Reporting process for users: Export functions in EVWEB

Training Module EV-M3c

Content Summary

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Introduction: Target audience

- Target audience for this training module:
  - National Competent Authorities (NCAs) in the European Economic Area (EEA)
  - Marketing authorisation holders (MAHs)
  - Sponsors of clinical trials (Sponsors)
  - Research institutions/Academia

Introduction: Learning objectives

Following the completion of EV-M3c training module you should be able to understand:

- Implementation of the Access Policy in EVWEB
- ICSR Export – L2A/L2B (Pharmacovigilance obligations)
- ICSR Export - MLM service
- Export previously sent ICSRs

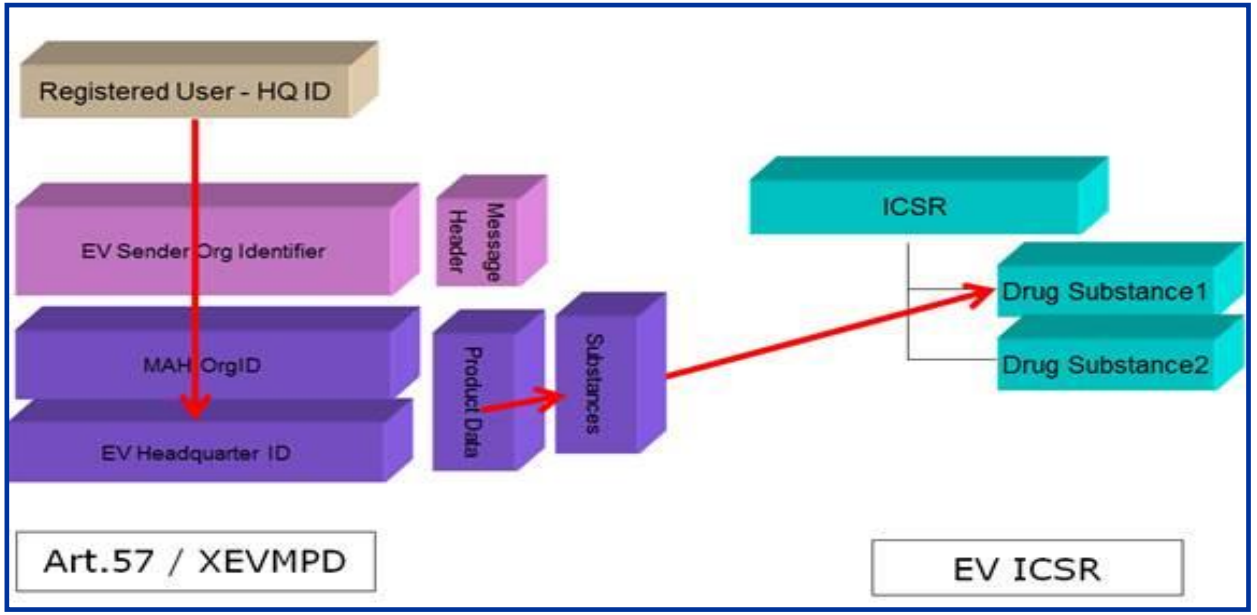
Implementation of the Access Policy in EVWEB

- **National Competent Authorities**
  - Full Access to all data held in EudraVigilance (L3)
- **Marketing Authorisation Holders**
  - Full Access to all data sent by their organisation (Sender based L3)
  - Partially restricted access to ICSRs sent by other organisations where they concern suspect drugs for which they hold Marketing Authorisation. This product must be entered and validated in XEVMPD in order for the access to be granted (Pharmacovigilance obligations – Level L2A & L2B)
  - All other ICSRs that do not fit in the above two categories will have restricted access (L1)
  - No Access to Clinical Trial data apart from sender based

Implementation of the Access Policy in EVWEB

- **Sponsors of clinical trials**
  - Full Access to all data sent by their organisation (Sender based L3)
  - All other ICSRs will have restricted public access (L1)

Pharmacovigilance obligations access - Level L2A & L2B



Pharmacovigilance obligations access - Level L2A & L2B

- The EudraVigilance system updates the list of MAHs that are permitted L2A/L2B access for every ICSR in the database, this is carried out each night.
- MAHs do not need to set filters for substance or products names to perform the Export of ICSRs. Only the dates for extraction need to be set.
- Dates for extraction are based on the date of recoding any suspect drug substance or product names within an ICSR against Art57/XEVMPD

Summary

- Implementation of the Access Policy in EudraVigilance
- ICSR Export – L2A/L2B (Pharmacovigilance obligations)
- ICSR Export - MLM service
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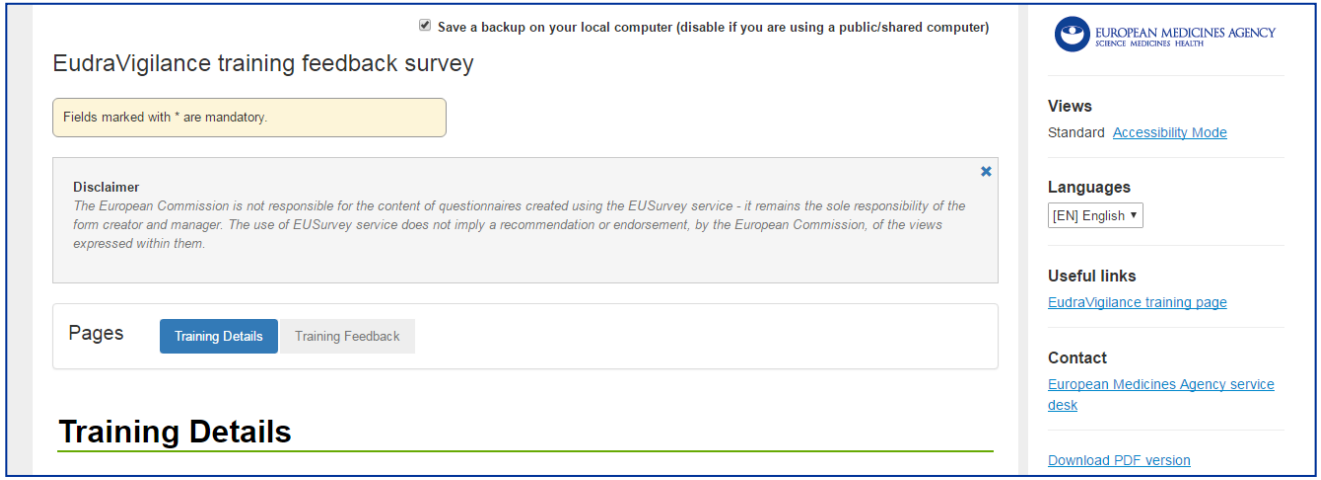
Feedback

- Please provide us with feedback on this E-learning module and any attendant guidance documents you have viewed by taking the EMA training survey.

- The survey is accessible via this link.



Thank you for your attention

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