EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSUR Repository

Mandatory use of the PSUR Repository

7th industry stakeholder platform - operation of EU pharmacovigilance legislation

Presented by Ana Zanoletty on 4th April 2016
Procedure Management Department

Key points to remember

- Use of PSUR Repository for PSUR submissions across the EU will become mandatory on the **13 June 16** for CAPs and NAPs, whether they fall under the EU Single assessment or are assessed only at national level.
- There will no longer be any requirement to submit to National Competent Authorities. Only 1 submission will be required to EMA.
- Users must be registered to the eSubmissions Gateway to submit.
- Users must have their products correctly included (legal basis!) in Art. 57.
- Submissions must be structured electronic formats (eCTD or NeeS). It is not possible to submit single pdfs via email or Eudralink.
- More info? Problems? Check eSubmissions PSUR Repository webpage or contact psurrepository@ema.europa.eu

How we will facilitate transition

- General and targeted communication via Industry associations and direct mailings to QPPVs:
  - At time of advice note (DLP)
  - 1 month prior to submission deadline
- Active collaboration with NCAs to ensure the information on the mandatory use and required technicalities is far-reaching at national level
- Webinars & Q&A sessions prior to mandatory use (see eSubmissions webpage)

Thank you for your attention

Further information

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