EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of the EMA policy on the publication of clinical data – Status report

Management Board, 2 October 2015
Agenda point B.6

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Background information

- Policy adopted by the Management Board on 2 October 2014
- Implementation currently limited to publication of clinical reports only (phase 1), i.e.:
  - Clinical overviews
  - Clinical summaries
  - Clinical study reports with some appendices
- Date of coming into effect:
  - 01/01/2015 for any new MAAs and Article 58 applications, submitted after this date
  - 01/07/2015 for extension of indication applications and line extension indications for existing CAPs, submitted after this date
  - TBD for all other post-authorisation applications for existing CAPs

Preparing for implementation (1/2)

- Completely new activity for EMA requiring several new arrangements to be put into operation in the most cost-efficient way
- Also important consequences for pharmaceutical industry
- Continued involvement of all stakeholders in preparing for the implementation, albeit through a more targeted stakeholder consultation (due to the complexity of the project and the available timeframe)

Preparing for implementation (2/2)

- Five workstreams:
  1. Data receipt and filing
     - Focus on receipt, validation and internal distribution of a "Redaction proposal"[1] version at the EMA
  2. Redaction consultation
     - Focus on EMA assessment of the pharmaceutical company's proposals for redaction, followed by the final "conclusion" by the EMA
  3. Publication
     - Focus on the publication by the EMA of the "Final redacted" version
  4. Presentation
     - Focus on public access to the clinical reports for the users while such clinical reports are protected through redaction and watermarking
  5. Management of the external users
     - Focus on user registration, user account management, acceptance of the Terms of Use (ToU)

[1] "Redaction proposal" version refers to the version with redactions proposed by the pharmaceutical company

Main deliverables (1/2)

- New end-to-end business processes:
  - For each of the 5 workstreams one or more business processes have been developed
- Guidance documents on the following aspects:
  - External guidance on the procedural aspects related to the submission of clinical reports for the purpose of publication in accordance with EMA policy 0070
  - External guidance on the identification and redaction of CCI in clinical reports submitted to the EMA for the purpose of publication in accordance with EMA policy 0070
  - External guidance on the anonymisation of clinical reports for the purpose of publication in accordance with EMA policy 0070

Main deliverables (2/2)

- IT systems:
  - User registration system
  - Publishing system
  - Workflow and case management system
  - Digital rights management system
  - Watermark system

Current status

- Meetings with all European Industry Associations held on 8 May and 23 June 2015; overall broad support from pharmaceutical industry; comments and suggestions made have been considered
- Webinar held on 24 June to present the current status of implementation and obtain first feedback from all stakeholders
- Face to face meetings (with MS representation) held on 6 July and 7 September with all stakeholders to discuss guidance on redacting CCI in clinical reports and anonymising clinical reports for publication

Next steps

- External guidance on the procedural aspects related to the submission of clinical reports will be subject to 3 weeks consultation with European Industry Associations
- Meeting with the EO and the EDPS on the implementation of the EMA policy (19 October 2015)
- All external guidances to be afterwards published on the EMA website (“living documents”) and to be updated once more experience is obtained

Thank you for your attention

Further information

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