EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use (Policy 0070)

Follow-up stakeholder meeting on the implementation of EMA policy 0070

Presented by Noël Wathion on 7 September 2015
Chief Policy Adviser

Policy implementation approach

Policy 0070 is composed of two phases:

- Phase 1 of Policy 0070 entered into force on 1st January 2015. Phase 1 pertains to publication of clinical reports only
- Phase 2 will be implemented at a later stage which pertains to the publishing of individual patient data (IPD)2

Clinical reports and IPD are collectively referred to as clinical data

External guidance

- Guidance is needed in order to ensure that Policy 0070 meets its objectives.
- EMA has prepared the following guidance documents:
  - 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 commercially confidential information 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.

Scope (1/2)

- Clinical reports will be published, under Policy 0070, following conclusion of the regulatory decision-making in the frame of centralised marketing authorisation procedures, as follows:
  - as part of a marketing authorisation application (MAA) with the exception of informed consent applications; effective date 1 January 2015, or
  - as part of a procedure under Article 58 of Regulation (EC) No 726/2004; effective date 1 January 2015, or
  - submitted by a third party in the context of a MAA: effective date 1 January 2015, or
  - as part of extension of indication and line extension applications relating to existing centrally authorised medicinal products; effective date 1 July 2015, or

Scope (2/2)

  - requested by the EMA/submitted by the applicant/Marketing Authorisation Holder (MAH) as additional clinical data in the context of the scientific assessment process for the aforementioned situations

- Clinical reports contained in applications where the MAH has notified the EMA of the withdrawal of the MAA are also published under Policy 0070.

- The effective date of Policy 0070 for all other post-authorisation procedures will be decided on by the EMA at a later date.

Topics presented during today's stakeholder meeting

- Types of documents or sections of documents considered not to fall within the scope of policy 0070
- Workflow of the publication process
- Redaction consultation process workflow
- Revisions to External guidance on the identification and redaction of CCI in clinical reports
- Revisions to External guidance on the anonymisation of clinical reports
- Anonymisation report template

Thank you for your attention

Further information

[Insert relevant information sources or contact details as applicable.]

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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