22 September 2015
EMA/457830/2015
Chief Policy Adviser

Stakeholder meeting, 6 July 2015

Implementation of EMA policy 0070 (on publication of clinical data for medicinal products for human use): Development of guidance on the identification and redaction of commercially confidential information (CCI) in clinical reports for publication, and on the anonymization of clinical reports for publication – Summary report

1. Introduction

EMA has prepared draft guidance in the context of phase 1 of the implementation of Policy 0070 on publication of clinical data relating to:

- Identifying and redacting CCI in clinical reports for publication
- Anonymising clinical reports for publication

A targeted stakeholder meeting was held with representatives from patients' and healthcare professionals' organisations, academia, pharmaceutical industry associations, National Competent Authorities, NGOs, to gather their views on the draft guidance.

2. Guidance on identifying and redacting CCI in clinical reports for publication

EMA's presentation that sets out the draft guidance is linked here.

2.1. Comments discussed

The draft guidance prepared by EMA was welcomed by stakeholders. Comments raised during the meeting related to:

- Clarification on the use of the justification table and if it will be made publically available.
- Clarification if the clinical reports will be permanently available and if CCI will be periodically reviewed.
- Work to be undertaken by pharmaceutical companies to confirm that information classified as CCI is not in the public domain.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5505
Send a question via our website www.ema.europa.eu/contact

- Need for inclusion in the guidance document of examples of acceptable CCI.

EMA responded to the comments and questions raised and clarification will be included in the revised guidance document.

3. Guidance on anonymising clinical reports for publication

EMA's presentation that sets out the draft guidance is linked here.

3.1. Comments discussed

The draft guidance prepared by EMA in this field was also welcomed by stakeholders. Comments made by stakeholders related to:

- If EMA will review the company's anonymisation report and the company's proposed redaction of personal data, whereby EMA confirmed that EMA will not undertake such review.
- How to best increase data utility and how to define data utility in the context of the publication of CSRs.
- Need for further clarification on the recommendation to publically release patient narratives (with elements of personal information removed).
- Request for EMA to prepare a template for an anonymisation report, which EMA agreed to do.

EMA responded to the comments and questions raised and clarification will be included in the revised guidance document. In addition, a template for an anonymisation report will be prepared by EMA for further discussion with stakeholders.

4. Next steps

EMA emphasised that both guidance documents should be, once finalised, considered "living" documents that will be updated in light of experience obtained. A further targeted stakeholder meeting will be held in early September after EMA has worked further on the documents. The draft guidance documents will be provided in good time of this next stakeholder meeting.