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Chief Policy Adviser

Second stakeholder meeting, 7 September 2015

Implementation of EMA policy 0070 (on publication of clinical data for medicinal products for human use)

EMA held a second stakeholder meeting on 7 September with patient associations, academia, representatives of National Competent Authorities and pharmaceutical industry associations. The purpose of the meeting was to inform stakeholders about the revisions to the guidance on which the stakeholders were previously consulted at the earlier stakeholder meeting on 6 July 2015:

- External guidance on the identification and redaction of commercially confidential information in clinical reports submitted to the EMA for publication.
- External guidance on the anonymisation of clinical reports for publication.

The views expressed demonstrate the evolving nature of anonymisation taking account of the objective of data utility and the legal requirements for personal data protection in publically available documents. Pharmaceutical industry associations argued that a straightforward and efficient process for anonymisation of documents was needed. In their view, EMA should describe a clear approach based on redaction of the original CSR rather than propose the use of a quantitative assessment of the risk of re-identification. Academia highlighted the challenge with non-analytical or qualitative approaches that can lead to two different outcomes depending on the extent of redaction. On one hand, if large sections of a clinical study report are removed, the risk of re-identification is likely to be very low but data utility will be compromised. On the other hand, if a clinical study report is 'under' redacted this could lead to the publication of documents that have a high risk of re-identification.

In addition, the EMA has prepared

- External guidance on the procedural aspects related to the submission of clinical reports for the purpose of publication in accordance with EMA Policy 0070.

The main points of this technical guidance were presented together with the workflow of the redaction consultation process and the overall process to publication. It will be sent shortly to pharmaceutical industry associations for consultation over a three-week period.

As part of its preparation for the implementation of this policy, the EMA will meet in October with both the European Ombudsman and the European Data Protection Supervisor in order to consult with these Institutions. Following this further step of consultation the guidance will be finalised for publication. All

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guidance documents should be considered “living” documents that will be updated in light of experience obtained.