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SCIENCE MEDICINES HEALTH

Finalisation of EMA policy on publication of and access to clinical trial data

Targeted consultation with key stakeholders
May 2014

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An agency of the European Union

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Aim of today's meeting/teleconference

- Provide an update on progress made since the end of the public consultation on the draft policy
- Clarify and fine-tune specific aspects of the policy prior to finalisation of the policy at the June 2014 MB meeting
- In particular, consult on the principles set for possible redaction of the Clinical Study Reports (CSRs) to be published, and the technical measures to make the data available under the policy, including their terms of use

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Background information: Rationale for EMA policy

- EMA has since its creation launched several initiatives to increase transparency of information on medicinal products
- Documents submitted as part of Marketing Authorisation Applications (MAAs) have been released since November 2010 (under the EMA Access to Documents (AtD) policy)
- EMA is committed to continuously extend its approach to transparency, hence the development of a policy on publication of Clinical Trial (CT) data
- Release of data is about
  - Establishing trust and confidence
  - Enabling independent re-analysis of the evidence used by the EMA scientific committees to determine the benefits and risks of medicines

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Outcome of public consultation (1/5)

- 3 months consultation period ended on 30 September 2013
- Exceptional contribution from stakeholders: a total of 1,138 individual comments submitted by 169 entities (including NCAs; pharmaceutical industry associations and individual pharmaceutical companies; academia, healthcare professionals associations and individual doctors; clinical research organisations; patients organisations and individual citizens; drug bulletins; HTA bodies)

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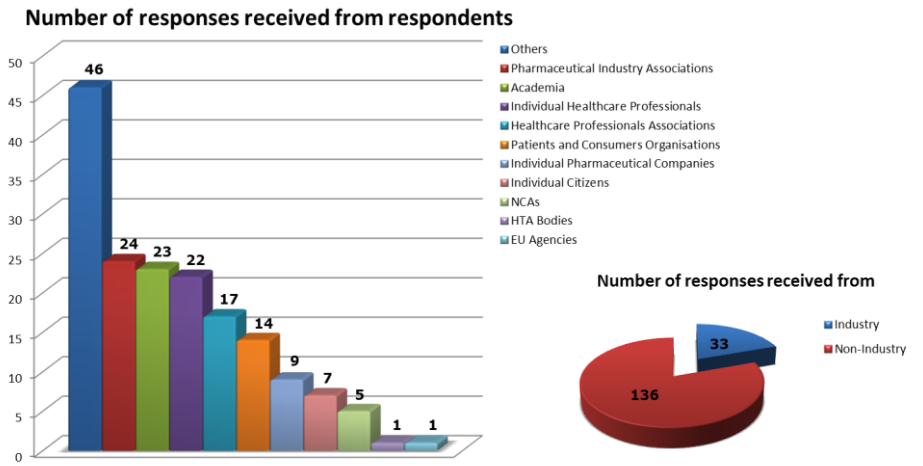
Outcome of public consultation (2/5)



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Outcome of public consultation (3/5)

- The main comments made relate to the following areas:
  - Protecting patient confidentiality
  - Rules of engagement
  - Legal aspects
- Furthermore, there have been requests to clarify a number of statements in the draft policy, such as the concept of raw data

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Outcome of public consultation (4/5)

- Comments relating to protecting patient confidentiality:
  - Extent of informal consent in view of secondary analysis of the data
  - Study personnel data should be classified as confidential
  - Current absence of common de-identification standards
- Comments relating to rules of engagement:
  - Concept of Commercial Confidential Information (CCI) for the purpose of the policy and its application to protect from inappropriate use
  - Timing of release of CSRs including release of data from withdrawn applications/ applications with a negative outcome

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Outcome of public consultation (5/5)

- Comments relating to legal aspects (not yet addressed in the 2 aforementioned areas):
  - No legal basis to request additional set of (de-identified) data
  - Legality and enforceability of the data-sharing agreement between the EMA and the requestor for the proposed Category 3 ("C") data
  - Policy is only applicable to Centrally Authorised Products (CAPs) and not to non-CAPs and therefore it introduces different standards depending on the authorisation route

Follow-up to public consultation

- EMA has carefully reviewed the comments made
- Clarifications on certain aspects have been undertaken
- EMA Management Board (MB) has regularly been updated on progress made
- EMA MB at its December 2013 meeting endorsed the principles proposed by EMA to revise the draft policy, in terms of
  - Scope of the policy
  - Stepwise approach for its implementation
- In addition, the recently adopted CT legislation reinforces the need for transparency in this area

Revision of the draft EMA policy: Main characteristics (1/8)

- Clarification on the scope of the EMA policy:
  - Scope relates to CT data, composed of CSRs and Individual Patient Data (IPD)
  - Scope relates to CT data submitted under the centralised procedure after the "effective" date,
    - as part of a MAA
    - as part of a variation procedure
    - or requested as additional CT data

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Revision of the draft EMA policy: Main characteristics (2/8)

- Clarification on the scope of the EMA policy (cont'd):
  - Scope does not relate to (legacy) data submitted under arbitration/referral procedures → these continue to be handled under the EMA AtD policy
  - Scope does not relate to legacy data submitted under the centralised procedure → continue to be handled under the EMA AtD policy unless the MAH takes the initiative to resubmit the CT data in view of publication

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Revision of the draft EMA policy: Main characteristics (3/8)

- Clarification on the implementation of the policy, to be undertaken in a stepwise manner:
  - First phase: publication of CSRs only, subject to certain preliminary steps
  - Second phase: discuss with stakeholders the concept of IPD (this second phase will, therefore, not yet be further elaborated upon at this stage in the EMA policy)
  - Envisaged "effective" date: 1 October 2014 (for MAAs submitted as of that date) and 1 January 2015 (for any legacy CSRs resubmitted by MAHs)

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Revision of the draft EMA policy: Main characteristics (4/8)

- Particular aspects relating to the first phase:
  - Introduction of a managed publication process for CSRs
  - Clarification on the application of CCI in CSRs

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Revision of the draft EMA policy: Main characteristics (5/8)

- Particular aspects relating to the first phase (cont'd):
  - Introduction of a managed publication process for CT data through:
    - Terms of Use (ToU) which govern the access to and use of CT data
    - Technical tool allowing access to CT data

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Revision of the draft EMA policy: Main characteristics (6/8)

- Particular aspects relating to the first phase (cont'd):
  - ToU characteristics:
    - Definition of CT data: CSRs (Module 5) + Clinical Overviews (Module 2.5) + Clinical Summaries (Module 2.7) + Appendices to CSRs No. 16.1.1, 16.1.2 and 16.1.9
    - Information available in "view-on-screen-only" mode
    - Information may be used for information, research and other non-commercial purposes
    - Information may not be used to support a MAA or make any unfair commercial use of information

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Revision of the draft EMA policy: Main characteristics (7/8)

- Particular aspects relating to the first phase (cont'd):
  - Technical tool characteristics:
    - Very user-friendly system
    - Simple procedural requirements
      - User ID/password
      - Acceptance of ToU ("view-on-screen-only", not downloadable, not printable)
      - Watermark to emphasise the proprietary nature of the information
    - Basically, all means foreseen aiming at preventing commercial/regulatory use of the information

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Revision of the draft EMA policy: Main characteristics (8/8)

- Particular aspects relating to the first phase (cont'd):
  - Clarification on the application of CCI in CSRs through:
    - Elaboration of redaction principles, complementing the use controls that need to be accepted:
      - Large majority of info in CT data is not CCI
      - Limited circumstances may lead to exceptions (examples listed in EMA policy)
    - Procedural mechanism for redaction:
      - Simple process based on the aforementioned redaction principles
      - Consultation phase with pharmaceutical companies is foreseen

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Next steps

- Following targeted discussions with key stakeholders:
  - Patients and Consumers Organisations/Healthcare Professionals Organisations (6 May 2014)
  - Pharmaceutical Industry Associations (8 May 2014)
  - Academia/Medical Journals (16 May 2014)

  EMA will review the feedback received in order to finalise its draft policy
- Summary reports of these meetings will be published once all meetings have been held (w/c 19 May 2014)
- EMA will present the revised draft policy for endorsement by the MB at its 12 June 2014 meeting
- Endorsed policy will subsequently be published and the "effective" date will be announced