EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Draft Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted outside of the EU/EEA and submitted in marketing authorization applications to the EU Regulatory Authority

Annual Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Group (HCP WG) Joint Meeting – 16 June 11

-released for public consultation (May to September 2010)

-International workshop on 6-7 September 2010, as part of the consultation

-49 written responses received

- Major issues on chapter 3 and 5

-Comments received discussed by the WG members/Draft Reflection Paper amended by EMA according to the discussion

-The document has been shortened

- Introduction amended.

- The scope of the document extended to include clinical trials submitted in Marketing Authorization Application to National Competent Authorities (through decentralized, mutual recognition, or National procedures).

The chapter on the International Cooperation moved at the beginning of the document

Chapter 7 (Summary of regulatory action/action points) removed

The section on access to treatment post trial, vulnerable population, transparency and ethics Committees amended

According to the amendment :

The scope of this Reflection Paper **is to clarify the practical application of ethical standards for clinical trials conducted in third countries** and submitted in Marketing Authorisation Applications **to the EMA** (through the centralised procedure) or **to National competent Authorities (through decentralised, mutual recognition, or National procedures)** and determine the practical steps to be undertaken during the provision of guidance and advice in the drug development phase and during the evaluation of Marketing Authorisation Application.

The final scope of the document is **to strengthen the process** (mainly in an earlier phase) **to assure,** at the time of MAA assessment, **that clinical trials (CTs) in Third Countries have been conducted in accordance with the principles of Good Clinical Practice (GCP) and equivalent ethical standards as those applied/requested in the EU.**

Next steps

-to circulate for comments to PCWP, HCP WG, CHMP, CTFG, COMP, PDCO, CTFG, GCP IWG, CMD etc.- May 11

- Discussion on the comments received/revision of the document by the EMA WG on third Country Clinical Trials

- Final agreement by CHMP, etc. (September 11)

- Management Board – October 2011

- HMA – October 2011

-to prepare list of comments to be sent to EU Commission for considerations (to be taken into account for future legislation)

Comments to be sent to Maria Antonietta Antonelli

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Deadline end of June 2011