HMA
Heads of Medicines Agencies
Management Group

12th May 2011

To: European Commission
DG SANCO/C8, Brey 10/114/BE-1049 Brussels
Email: sanco-pharmaceuticals@ec.europa.eu

**Subject: RESPONSE of the HEADS OF MEDICINES AGENCIES (HMA) and the Clinical Trials Facilitation Group (CTFG) TO THE COMMISSION'S CONSULTATION ON REVIEW OF THE CLINICAL TRIALS DIRECTIVE**

Following the announcement of the European Commission on 9 February 2011 regarding the public consultation on the Clinical Trials Directive 2001/20/EC, the Heads of Medicines Agencies (HMA) and in particular its Clinical Trials Facilitation Group (CTFG) have discussed the questions put forward by the European Commission and agreed a common position paper.

On behalf of HMA I would like to thank you for raising such relevant questions which are extremely important for the future of pharmaceutical innovation in Europe and a sector which national regulatory agencies are focused on, as stated in the HMA Strategy Paper for 2015 "HMA envision the creation of an efficient and unified regulatory environment for clinical trials in Europe that encourages innovation and high quality clinical research (...)". Attached you may find the agreed common paper by the CTFG as relevant input for the European Commission.

In the concept paper under consultation the Commission introduced several options regarding the cooperation in "assessing and following up applications for Clinical Trials". Those options, although not currently described in the Clinical Trials Directive, have been voluntary introduced by the Member States themselves, at least at the National Competent Authorities (NCAs) level. The HMA has realised from the beginning that harmonisation between NCAs needs to be promoted with the aim to reduce the sponsors' workload, to ensure the same level of protection for participants and to avoid discrepancies between NCAs. For those reasons, the CTFG was created in 2004 as a Working Group of the NCAs in charge of CT assessment and follow up.

Since then the CTFG has proposed different procedures to promote harmonisation, among which is the Voluntary Harmonisation Procedure (VHP) for a coordinated assessment of multinational Clinical Trials Applications (CTA) (2008) and a pilot of an internal worksharing of safety data assessment (2010). These procedures, which are not based on the current legislation and therefore are of voluntary nature, could be taken into account while reviewing the Directive.

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Regarding the cooperation in assessing and following up CTA, the HMA generally welcomes the Centrally Assessment Procedure (with a different acronym than CAP to avoid unnecessary misunderstandings) and focuses on the Multinational Clinical Trials. The single submission assessed through the Centrally Assessment Procedure should be dealt with via worksharing and coordinated by the secretariat of the CTFG. To cooperate in assessing CTAs, the responsibilities within the process (process - assessing CT safety data (as SUSAR, DSUR, signalling)) could be taken up as a task by the CTFG. Additionally, HMA considers that Clinical Trials safety data assessment should also be coordinated under the Centrally Assessment Procedure.

Furthermore, the HMA is of the opinion that at this stage there should be a possibility for a NCA to 'opt out' if a decision can not be reached by consensus.

In case you may need further information please do not hesitate in contacting us.

Yours sincerely,

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Chair of the HMA Management Group

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