FUEHRING Stefan (ENTR)

Subject: FW: CCMO response on the clinical trial public consultation

Attachments: Response by Heads of Medicines Agencies221209.doc; Consolidated Comments of the Clinical Trials Facilitation Group final.doc; 2009_10_09_public-consultation-paper.pdf

Dear Madam/Sir,

In response to the public consultation paper of the European Commission on the revision of the Clinical Trials Directive (Directive 200/20EC), we have two remarks we would like to make.

1)
General point. For the review of clinical trials in the Netherlands we have a decentralised system with 27 accredited Medical ethics review committees (aMRECs).
These committees are supervised by the Central Committee for Reseach involving Human Subjects (CCMO). The CCMO acts both as the competent authority and is ethical committee for certain protocols.
In practice, the aMRECs review a protocol as a whole, which means that there is no separation between the scientific review (e.g. the IMPD) and the medical-ethics review.
Only in those cases when a study needs to be carried out in several countries an European decision would lead to a cost and time reduction. However, also in these type of studies an 'national' ethical decision is needed.

2)
Re 3.3.1. We are willing to join the Voluntary Harmonised Procedure (VHP).

Kind regards,

Prof dr GH (Gerard) Koëter
Chairman CCMO

Centrale Commissie Mensgebonden Onderzoek (CCMO)/
Central Committee on Research Involving Human Subjects
Postbus 16302
2500 BH Den Haag
tel: +31 (0)70 340 6700
fax: +31 (0)70 340 6737
e-mail: ccmo@ccmo.nl
website: http://www.ccmo.nl

Dear all,

Please find attached a draft response prepared by the Management Group on the public consultation of the European Commission on the revision of the Clinical Trails directive (Directive 2001/20EC).

The HMA MG is of the opinion that this draft response, mainly focused on some of the Network's general concerns on clinical trials issues, could be sent to the European Commission on behalf of HMA as a response to the public consultation paper together with the detailed CTFG comments to the consultation (attached), as an annex to the HMA letter.

We would like to receive your comments and remarks on this subject by close of business 2nd January 2010 to the HMA Permanent Secretariat email address: hma-ps@imb.ie .

The HMA MG would then send the final version to the European Commission during the first week of January 2010, before the end of the consultation period (8 January 2010).

Best regards,

Birte van Elk
Permanent Secretariat of HMA Management Group

On behalf of Aginus Kalis
Chair of the HMA Management Group