**European Commission**
**Health and Consumers Directorate General**
**Directorate C - Public Health and Risk Assessment**
**Ms Patricia Brunko, Head of Unit Pharmaceuticals**
**sanco-pharmaceuticals@ec.europa.eu**

The Hague, May 13, 2011

**Re: Response to the Public Consultation on the Concept Paper *Revision of the 'Clinical Trials Directive' 2001/20/EC***

Dear Ms Patricia Brunko,

I am writing on behalf of the European Hematology Association (EHA) in response to the Public Consultation on the Concept Paper *Revision of the 'Clinical Trials Directive' 2001/20/EC.* EHA welcomes the opportunity to participate in this consultation process and appreciates the European Commission's effort to seek views on more concrete ideas on the issues that have been presented in a rather general way during the 2009/2010 public consultation, to which EHA responded as well.

EHA is an NGO that aims to promote excellence in clinical practice, research and education in European haematology, the medical specialty that concerns blood diseases and blood related diseases. With a membership in access of 3000, an annual congress that attracts, in its latest instalment, more than 9000 haematologists, and a journal (Haematologica/The Hematology Journal – impact factor: 6.416) that is the primary general haematology journal in Europe, EHA is *the* representative of haematologists in Europe.

EHA has coordinated three projects, funded by the European Commission (DG Education and Culture) which were and are focused on the harmonisation of education in haematology in Europe.[1]

We would like to contribute to the revision of the Clinical Trials Directive by emphasizing the following points:

First, the primary concern of clinical trials is patient safety, both during and after the appraisal of the medicine. At all times, the approach to be taken towards the modification of the directive must be patient-centered.

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[1] ECAH – Establishment and accreditation of a system of speciality training and continuing education in the haematology across EU countries – Leonardo da Vinci 2002-4545 / 001-001 LE2-22ACTH; EurETAH – European Education, Training and Accreditation in Haematology Online – Leonardo da Vinci UER/02/C/F/PP-84703; and H-Net – European Network for Harmonisation of Training in Haematology – Leonardo da Vinci 2008 – 1941 / 001 – LE3 LENETW.

Second, EHA supports the Commission's aim towards establishing a single submission system, administered by the European Medicines Agency. As to the assessment procedure, EHA supports a coordinated approach albeit conditionally (see EHA's response to the questionnaire).

Third, life threatening diseases need special rules. The risks associated with the treatment of such diseases must be offset against the risk of death.

For more specific comments I refer you to the responses to the separate consultation items. I would like to thank you for the opportunity to share our views on your Concept Paper. EHA is at your disposal for any elaboration or advice you wish to attain.

Yours sincerely,

Robin Foà
President EHA

Annex:

EHA's Response to the consultation items