

The European Commission Unit SANCO/C/8, BREY 10/114, BE-1049 Brussels sanco-pharmaceuticals@ec.europa.eu

Brussels, 12 May 2011

Dear Sir,

I am pleased to send you the submission of the Federation of the European Academies of Medicine (FEAM) to the 2011 European Commission concept paper on the revision of the 'Clinical Trials Directive' 2001/20/EC.

This submission was endorsed by the FEAM membership, which includes the following Academies: Austrian Academy of Sciences (Austria), Académie Royale de Médecine de Belgique and Koninklijke Academie voor Geneeskunde van Belgie (Belgium), Czech Medical Academy (Czech Republic), Académie Nationale de Médecine (France), German National Academy of Sciences Leopoldina (Germany), Academy of Athens (Greece), Hungarian Academy of Sciences (Hungary), Accademia Nazionale di Medicina (Italy), Academia portuguesa da Medicina (Portugal), Academia de Stiinte Medicale din Romania (Romania), Real Academia Nacional de Medicina (Spain), Royal Netherlands Academy of Arts and Sciences (The Netherlands), Academy of Medical Sciences (The United Kingdom).

We hope that you will find this submission useful and we look forward to receiving your comments in due course.

Yours sincerely,

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Professor Hubert E. Blum President of FEAM