European Medicines Agency

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WORKSHOP ON DRAFT GUIDELINE ON REQUIREMENTS FOR FIRST-IN-MAN CLINICAL TRIALS FOR POTENTIAL HIGH-RISK MEDICINAL PRODUCTS

The European Medicines Agency (EMEA) will hold a workshop to review and discuss comments received on the draft guideline on 'first-in-man' clinical trials on 12 June 2007. Following adoption by the Committee for Medicinal Products for Human Use, the draft guideline was released for a two-month consultation period ending on 23 May 2007.

The aim of the workshop is to consider - together with key stakeholders from the European Commission, national competent authorities, pharmaceutical industry, patients' and healthcare professionals' organisations, academia and related learned societies - the feedback received in order to ensure the clarity and acceptability of the guideline before it is finalised, shortly after the workshop.

To express your interest in attending the workshop, please use the attached registration form and send it back to the EMEA before **30 April 2007**.

Please note that the number of places available for the workshop is limited, and the EMEA may not be able to register everybody who has expressed an interest in participating at the workshop. Due to the limited space only one participant per organisation can be accepted as a rule. Priority will be given to those organisations that have sent relevant comments on the guideline during the consultation period to allow fruitful discussions.

The EMEA looks forward to welcoming you at the workshop.

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