European Medicines Agency
Press office

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Press release
European Medicines Agency workshop on first-in-man clinical trials draft guideline

The European Medicines Agency held a workshop on 12 June 2007 as part of the public consultation on the draft guideline on requirements for first-in-man clinical trials for potential high-risk medicinal products.

Attended by some 150 people, the workshop complements the extensive written comments already received from 57 organisations representing pharmaceutical industry, contract research organisations, clinical research organisations, ethical committees, academia, healthcare professionals, animal welfare organisations and patients' organisations.

The draft guideline gives guidance on managing the transition from non-clinical studies, e.g. studies in animals or *in vitro* studies, to first tests in humans. It describes the principles of a science-based approach ensuring the safety of subjects and respecting ethical principles while allowing for flexibility.

While the criteria described in the draft guideline to be taken into account in the non-clinical area for identifying potential risks and for implementing risk management strategies for the phase I clinical trials were generally supported, one main area of debate emerged from the public consultation.

This was the concept of classification of high-risk versus non-high-risk medicinal products. Proposals were made to replace it with a risk management and risk mitigation approach based on the concept of risk as a continuum for all medicinal products. These suggestions will be taken into account in the finalisation of the guideline planned in the coming weeks.

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NOTES:

1. The Agenda of the workshop and presentations given can be found here.
2. The draft guideline can be found here. It was released for a two-month public consultation period from 22 March to 23 May 2007. A press release was issued and is available here.
3. A Community guideline is a document considered to provide advice to sponsors, applicants or marketing authorisation holders, national competent authorities and/or other interested parties on the best way to fulfil an obligation laid down in the Community pharmaceutical legislation. Scientific guidelines are Community guidelines that relate to specific scientific issues and reflect a harmonised EU approach, based on the most up-to-date scientific knowledge. Guidelines are not binding. Sponsors may deviate from the recommendations of the guideline provided they can substantiate their approach.
4. Clinical trials are undertaken to allow data on the safety and efficacy of new medicinal products to be collected. The first-in-man trial is the initial step of the clinical development of a medicine in humans and is part of the Phase-I or early-development clinical trials. Phase-I trials are designed to look at the initial safety and tolerability, as well as the pharmacology and pharmacokinetics of the medicinal product concerned. Studies in this phase of development usually have non-therapeutic objectives and may be conducted in healthy volunteer subjects.

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5. Clinical trials are regulated by European Union Directive 2001/20/EC, of 4 April 2001. The Directive harmonises across EU Member States the administrative provisions governing clinical trials, as well as the standards of good clinical practice (GCP) and good manufacturing practice (GMP) to which they are conducted. It is the responsibility of national competent authorities to assess applications to conduct clinical trials with medicinal products.
6. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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