



The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE

First EMEA workshop on ethics in clinical trials

Use of placebo in clinical trials

The first EMEA workshop on ethical considerations in clinical trials was held at the EMEA on 26 November 2001. Dr Daniel Brasseur, chairman of the Committee for Proprietary Medicinal Products, led the meeting.

The objective was for the first time in Europe to open dialogue between the ethics committees and the EMEA on ethical considerations relating to the design and conduct of clinical trials for medicinal products for human use.

The workshop brought together members of national and regional ethics committees from throughout the European Union, Iceland, Norway and central and eastern European countries. Other participants included representatives of the European Commission, the Council of International Organisations for Medical Science, the World Medical Association and the European Forum for Good Clinical Practice.

The workshop was welcomed as a unique forum for the exchange of experience on the difficulties that ethics committees across Europe face when reviewing clinical trials. Despite the differences in structures of ethics committees across Europe, a number of common issues were identified. These include independence of ethics committees, excess workloads, scientific training in particular to prepare for new technologies and consistency of opinions given by different ethics committees.

Looking at the current regulatory framework, the workshop considered the new European directive on the conduct of clinical trials, ethical guidelines and the Declaration of Helsinki, including the issue of trials using placebo. The workshop concluded that ethics must be based on good science and that clinical trials that are not scientifically sound are unethical. The use of placebo in a clinical trial may therefore be ethically acceptable, even if a proven therapy is available, if needed for scientific reasons. In all cases, however, the interests of the individual patient should prevail.

Participants requested a follow-up meeting in 2002 as a further opportunity for communication between ethics committees and regulatory bodies.

--ENDS--

NOTES:

1. A public statement from the EMEA Committee for Proprietary Medicinal Products on the use of placebo in clinical trials was published on 28 June 2001 and is available on the EMEA web site.
2. Council Directive 2001/20/EC on good clinical practice is published by the European Commission in the EU Official Journal L 121, 01.05.2001, p. 34.
3. The current European guideline on general considerations for clinical trials was adopted by the CPMP in September 1997 (CPMP/ICH/291/95) and is available on the EMEA web site.

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