Medicinal products for human use: implementation of good clinical practice in the conduct of clinical trials

1997/0197(COD) - 04/04/2001 - Final act

PURPOSE : to establish specific provisions regarding the conduct of clinical trials of medicinal products on human subjects, particularly in relation to the implementation of good clinical practice. COMMUNITY MEASURE : Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. CONTENT : This directive obliges Member States to adopt detailed rules to protect from abuse individuals who are incapable of giving their informed consent. This includes minors, and incapacitated adults. Such persons should not participate in trials if the same results would be obtained from persons who are capable of giving consent. The directive sets out the preconditions under which trials may take place. The foreseeable risks and inconveniences must be weighed against the anticipated benefits for the individual trial subject and other patients. A trial may only be initiated by the Ethics Committees, the establishment and duties of which are set out in the directive. The trial subject or his legal representative must be given certain information about the trial, including the right of withdrawal. The directive establishes rules on the commencement and conduct of trials, suspension of the trials or infringements, the manufacture and import of investigational medicinal products, labelling, and verification of compliance with good clinical and manufacturing practice. ENTRY INTO FORCE : 01/05/2001 DATE OF APPLICATION : Member States shall adopt and publish before 1 May 2003 the laws to comply with the Directive. The provisions will apply at the latest with effect from 1 May 2004.