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

1997/0197(COD) - 21/11/2000

The committee adopted the recommendation for second reading under the codecision procedure by Hans-Peter LIESE (EPP-ED, D) amending the Council's common position. The committe retabled, sometimes in slightly modified form, many of the amendments tabled at first reading which had not been taken up by the Council. These concerned in particular the need for written, dated and signed consent to take part in clinical trials, the need for the principal investigator always to be a doctor and the need for special protection for persons incapable of giving their informed consent. The committee also added a number of new points, such as allowing oral consent (in exceptional circumstances) in the presence of witnesses for a person unable to write, and making it clear that the task of balancing benefits against risks in the case of a clinical trial belonged to an Ethics Committee. It also wanted a prior interview to be carried out in order to make sure that trial subjects were properly informed. The committee felt that clinical trials on children should be allowed subject to certain restrictions, including the need for informed consent of the child's parents or legal representative, for the child to be properly informed about the issues, in line with its ability to understand them, and for clinical trials to be designed to minimise pain, discomfort and fear. It also wanted similar requirements to apply to psychiatric patients and other types of patient unable to give consent, who should be included in clinical trials only on a restrictive basis. There should be a justified expectation that the medicinal product to be administered would produce benefits for the patient outweighing the risks, and experts in the type of patients concerned should sit on the Ethics Committees examining the studies in question.