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

1997/0197(COD) - 29/10/1998

The Committee adopted a report by Mr Amedeo AMADEO (independent, It) on a Commission proposal designed to ensure that similar standards of good clinical practice are observed throughout the union when trials are carried out on human beings with a view to developing new medicines. There are two main concerns: (1) to ensure the safety of those who have volunteered to take part in the trials (thousands of people may be involved in more than one Member State) and (2) to eliminate red-tape so that patients suffering from serious diseases such as Aids or cancer have access to new pharmacological discoveries as early as possible. The committee adopted a number of amendments with this in mind. In particular, it insisted on the right of participants to physical and mental integrity as well as to privacy and stipulated that they give written consent to their participation. Compensation should be available in the event of death or injury. Recruitment of volunteers must be suspended in the event of unexpected side-effects. Medicines used in trials ("investigational medicinal products") must accord with good manufacturing practices, regardless of whether they have been produced in a Member State or imported from a third country. Those responsible for approving such medicines must have received appropriate training. Trials should not begin before the relevant ethics committee has given a favourable opinion. They may be deferred or terminated if good clinical practice is not respected. Detailed rules must be adopted to protect the mentally handcapped and children. The person responsible for a clinical trial must be a doctor. The committee also deleted from the proposal a reference to a related Council of Europe convention. Under the Commission proposal a database is to be set up in connection with such trials. The committee insisted that the confidentiality of the data recorded be strictly observed. Moreover, no information must be included which would adversely affect the industrial property rights or competitiveness of a trial's sponsor. With a view to cutting red-tape, the committee criticised the existence of several diverse procedures for obtaining opinions from ethics committees: a single opinion for each Member State concerned would normally suffice. The committee also accepted the rapporteur's view that those sponsoring a clinical trial could simply notify the authorities of their intention: they did not need to submit a prior application for authorization.