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

1997/0197(COD) - 26/04/1999 - Modified legislative proposal

The Commission's amended proposal introduces new measures to take into account the European Parliament's opinion. The main amendments focus on the following points : 1) informed consent : with a view to strengthening the guarantees concerning the protection of participants in clinical trials, the Commission introduced an operational definition, as well as procedures for the exercise or withdrawal of consent, particularly in the case of minors or of incapacitated adults. The amended text also lays down clearer conditions for clinical trial subjects who wish to have access to an independent contact able to supply them with further information. To this end, the responsibility of the sponsor to organise the corresponding arrangements is clearly established ; 2) ethics committee : the amended proposal gives the ethics committee a more important role, one that is no longer limited almost exclusively to the phase preceding commencement of the clinical trial. In this way, the content of the information to be submitted to the ethics committee has been widened substantially to cover the entire clinical trial, from before commencement to completion. It has also been made clear that the ethics committee must be consulted again if the sponsor makes substantial amendments to the protocol being followed which could impair subjects' safety, and, therefore, call into question the original favourable opinion ; 3) exchanges of information : the amended proposal reinforces the original text by adding provisions on the practical arrangements for centralisation at Community level of the results of the clinical trials and clearly defining the role played by the Commission in organising and coordinating such exchanges of information vis-à-vis the competent authorities and the sponsor of the clinical trial ; 4) compatibility with existing Community legislation : it is essential that the European Agency for the Evaluation of Medicinal Products receives a copy of the notification of commencement of a clinical trial so that it can assess the content thereof in preparation for subsequent evaluation of the product should it fall under Part A of the Annex to Regulation 2309/93/EEC. If the product falls under Part B of the same Annex, the sponsor has the option of deciding whether or not to notify the Agency ; 5) procedure for the commencement of a clinical trial : the new procedure opts for simplification, which should lead to greater speed and efficiency, by putting the accent on the notification procedure. For the sponsor, this entails informing the competent authorities of any plans to proceed with a clinical trial , by means of a "notification". The notification of the clinical trial must be accompanied by a written authorisation granted by the competent authorities of the Member States concerned within fixed time limits.