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

1997/0197(COD) - 20/07/2000 - Council position

The Council's common position is essentially based on the amended Commission proposal, and therefore includes the letter or spirit of most of the amendments suggested by Parliament and taken up by the Commission. An important exception concerns the procedure for starting a clinical trial, which has been substantially amended by the Council in order to simplify and speed up decision-making by the competent authorities of the Member States. Another exception concerns the provisions for the subjects in clinical trials, in particular certain aspects to minors and incapacitated adults which could only be partly accepted by the Council and the Commission, both institutions nevertheless considering that the protection guarantees for subjects in clinical trials would not be reduced as a result. In addition, the Council has also introduced a number of editorial changes to the text of the common position. Some original provisions to which the European Parliament's proposals for amendments refer have consequently undergone subsequent re-drafting or re-editing. The amendments accepted by the Council without modification, with minor editorial modifications or in principle relate in particular to: - the definition of "informed consent". The definition selected by the Council differs from that proposed by the Parliament in that it also covers persons who are not in a position to give their consent with full knowledge of the facts; - the definition of "unexpected adverse reaction"; - the extension of the 60-day period for the Ethics Committee to give its opinion in cases where trials involve medicinal products for gene therapy was accepted by the Council and extended to include somatic cell therapy, including xenogenic cell therapy; - the strict observance of the confidentiality of data to be entered in the European databases; - the obligation to inform the sponsor, the competent authorites, the Ethics Committee and the Commission in cases where a suspension of clinical trials must be contemplated; - provisions relating to the manufacture and importation of investigational medicinal products. In relation to the amendments which were partly accepted by the Council, these concern the protection of trial subjects in clinical trials. Moreover, they also concern the trial subject's right to have his mental and physical integrity safeguarded. On the other hand, the amendments not accepted by the Council relate in particular to: - replacing the idea of "person responsible" in the definition of "investigator" by "doctor responsible"; - the deletion of the provision on the arrangements for rewarding or compensating investigators and trial subjects as one of the elements to be considered when the Ethics Committee prepares its opinion; - the indication on the packaging that the medicinal product is being used in the framework of a clinical trial and that it cannot be sold. Lastly, the Council did not accept the amendment whichprovides for the deletion of the indication that inspections for the purpose of verifying compliance with good clinical and manufacturing practice are carried out on "behalf of the Community".