Human blood and blood components: quality and safety for the collection, testing, processing, storage and distribution

2000/0323(COD) - 14/02/2002 - Council position

The Council has taken up two thirds of the amendments proposed by the EP and accepted by the Commission even if in many cases not literally but in substance or in principle. The Council carried out a relatively extensive revision of the text of the proposal in order to better structure and clarify its provisions and to address more fully and systematically certain key issues of particular concern to the Member States. The Council introduced the following main changes: - Scope: there is a general agreement that the Directive should apply also to collection and testing of starting materials for medicinal products; - Hospital blood banks: the Council introduced a definition of hospital blood banks and an Article specifying which provisions of the Directive would apply to them; - Designation, authorisation, accreditation or licensing of blood establishments: the Council extended the concept of accreditation to cover all different modalities of recognition of a blood establishment existing in the Member States; - Responsible person and personnel: the Council considered that the question of appropriate qualifications and timely, relevant and regularly updated training is to be dealt with according to the principle of subsidiarity; - Voluntary unpaid donation : No provision on this issue was included in the Commission's proposal, as the Commission considered that such a provision is not compatible with the Treaty. The Council included instead a provision for the encouragement of voluntary and unpaid blood donations by Member States. The Council has added a provision on information thereon to the other Member States and the Commission as well as a recital referring inter alia to the Council of Europe's efforts in this area. Furthermore, the Council has added an explicit reference to the possibility for a Member State to maintain or implement more stringent protective measures, and in particular, to introduce requirements for voluntary unpaid donations, including the prohibition or restriction of imports of blood and blood components which do not satisfy such requirements. - Structure and content: the Council considered it useful to maintain a number of the Annexes originally proposed by the Commission, albeit in a simplified form, in order to set key reference points defining the framework for the implementation of some important provisions of the Directive which constitutes the basis of the quality and safety system at Community level. Lastly, the Council deleted the Article on clinical tests to be carried out before blood donation and new recitals were added, clarifying certain rpovisions relating to autologous transfusion, hospital blodd banks, quality system and traceability of imported blood and blood components.