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

2000/0323(COD) - 12/06/2002 - Text adopted by Parliament, 2nd reading

By adopting this draft recommendation for second reading by Mr Giuseppe NISTICO (EPP-Ed, I), the European Parliament approved the common position in principle subject to some amendments. The Parliament proposes to introduce a number of definitions, including "adverse event", "adverse reaction", "haeomovigilance" and "inspection". It also wants haemovigilance data to be kept for at least 30 years. An amendment was adopted which enables Member States to introduce requirements for voluntary unpaid donations, which include the prohibition, and restriction of imports of blood and blood components to ensure a high level of health protection. In addition, Parliament adopted another amendment demanding that a medical examination, comprising at least an interview and blood pressure check by a doctor, shall be carried out before any donation of blood or blood components. The doctor shall be responsible for giving donors the necessary information and gathering information from donors, and shall, on the basis thereof, assess the eligibility of donors. They shall take steps to ensure that tests are carried out in conformity with the latest scientific and technical procedures that reflect current best practices. They must also take advantage of scientific advances in the detection, inactivation and elimination of pathogens which can be transmitted via transfusion. Lastly, the Parliament called for Member States to report to the Commission every two years on the measures taken under the directive.