

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

2000/0323(COD) - 23/04/2002

The committee adopted the report by Giuseppe NISTICO (EPP-ED, I) amending the Council's common position under the second reading of the codecision procedure. It reinstated, wholly or in part, some amendments adopted by Parliament at first reading which had not been taken up by the Council. These proposed a number of definitions, including "adverse event", "adverse reaction", "haemovigilance" and "inspection". The committee also wanted haemovigilance data to be kept for at least 30 years. A key amendment reinstated from first reading proposed a definition of "voluntary unpaid blood donation". The amendment stipulated that this would mean the donation of blood or blood components by a person of his /her own free will and without receiving payment in cash or in kind in return which could be considered a substitute for money. The committee said, however, that small tokens, gratuities, refreshments and the reimbursement of direct costs and direct travel expenses should be allowed, as should time off work reasonably required for donation and travel. Another amendment stipulated that the 'responsible person' at the blood collecting establishment should be a doctor with a specialisation in a relevant field, e.g. haematology. Lastly, the committee called for Member States to report to the Commission every two years on the measures taken under the directive.