Medical devices including blood and plasma derivates

1995/0013B(COD) - 29/06/2000 - Council position

The Commission included in its amended proposal almost all of the amendments suggested by the Parliament. More importantly, during the legislative procedure on the proposal, the Council in agreement with the Commission, decided to make a split and initially to draw up a common position only on in vitro diagnostic medical devices. For that part of the proposal, all the amendments proposed by the Parliament were adopted by the Council. The European Parliament approved the split and proposal at second reading an amendment to that effect, stressing the need to legislate rapidly on medical devices manufactured from substances of human origin. That amendment was incorporated in Recital no 35 of Directive 98/79/EC on in vitro diagnostic medical devices, adopted on 27 October 1998. The text of the present common position is the result of the continuation of work at Council level on the part of the proposal still outstanding. However, agreement could be reached only on a Directive limited to devices containing derivatives of human blood or plasma. Devices incorporating other substances derived from human tissue will have to be the subject of a specific Directive. Accordingly, the text of the common position is limited to amending Directive 93/42/EEC to incorporate provisions on substances derived from human blood or plasma. Consequently, two of the five amendments relating to the inclusion of medical devices made from products derived from tissues and cells from the human body in Directive 93/42/EEC, proposed by the Parliament and adopted by the Commission have become irrelevant because the scope of the common position is limited. Furthermore, amendments concerning an addition to the labelling requirements, requirements on the EU conformity declaration and the addition of medical devices covered by this Directive to class III of the classification system were all adopted by the Council with necessary adjustment to take account of the fact that the scope is limited to devices incorporating stable derivatives of human blood or plasma. Since derivatives of human blood are considered to be a medicinal product within the meaning of Directive 89/381/EEC on special provisions for medicinal products derived from human blood or plasma, and, accordingly, medical devices containing those derivatives must guarantee the same level of quality and safety as medicinal products when used, they must be subject to the existing Community evaluation and verification procedures for medicinal products.