Medical devices including blood and plasma derivates

1995/0013B(COD) - 30/06/2000 - Commission communication on Council's position

The Commission's proposal, resulting from the COREPER decision of October 1997 and based on Article 95 of the Treaty seeks to harmonise national provisions governing the placing on the market of medical devices incorporating tissues of human origin. During the discussions in the Council, it emerged that it would be advisable to restrict the scope of the proposal to devices containing derivatives of human blood and human plasma, and that devices incorporating other derivatives of human tissues should be the subject of a specific directive. The common position is consequently restricted to amending Directive 93/42/EEC with a view to introducing provisions concerning derivatives of blood and plasma. The Commission accepts the constituent parts of the common position. It notes that the latter is in line with the amendments proposed by the European Parliament. It therefore calls on the two institutions to conclude the legislative procedure as quickly as possible so that the necessary improvement in health protection in the sector concerned can be achieved. In addition, the Commission will begin preliminary work in order to consider the advisability of submitting a proposal for a directive concerning substances other than those derived from human blood and human plasma.