

## **EXPLANATORY MEMORANDUM ON A EUROPEAN COMMUNITY DOCUMENT**

### **Commission Communication on Blood Safety and Self Sufficiency in the European Community**

**Submitted by the Department of Health**

#### **SUBJECT MATTER**

The Communication is a follow up to the Council's request for a report to be prepared relating to the legal provisions and current practices in the Member States on the collection, control and treatment of blood, and the distribution and trade in blood and blood products with a view to proposing common safety criteria. The communication also specifies the need for Community action in this area particularly in the context of the Council's Resolution concerning the field of public health and the Commission communication on AIDS and certain other communicable diseases (COM(94) 413 final).

#### **MINISTERIAL RESPONSIBILITY**

The Secretary of State for Health and the other UK Health Ministers

#### **LEGAL AND PROCEDURAL ISSUES**

##### **(i) Legal Basis**

Articles 3(o) and 129 of the Treaty establishing the European Community, as amended and Directive 89/381.

##### **(ii) European Parliament Procedure**

Co-decision procedure (Article 189b). Consultation with the Economic and Social Committee and with the Committee of the Regions is also required.

##### **(iii) Voting Procedure**

Qualified majority.

##### **(iv) Impact on United Kingdom law**

There is no impact on UK law in respect of the references to blood. The references to blood products may have some impact on the provisions of the Consumer Protection Act. [D.N Andrzej - can we say what the likely impact is here?]

#### **APPLICATION TO THE EUROPEAN ECONOMIC AREA**

None

#### **SUBSIDIARITY**

The communication was prepared in response to a request from the council. Its recommendations take the form of suggestions for measures the Commission could take. Insofar as they relate to blood products are consistent with the principle of subsidiarity. The references to blood will require clarification as they imply community competence in an area which is beyond the scope of article 129.

#### **POLICY IMPLICATIONS**

The Government welcomes the proposals in relation to the harmonisation of safety of blood

products and self sufficiency. The Government will wish to ensure however that, in accordance with Article 129, the references to blood and clinical practice are clarified so as not to imply community competence in this area. The Government would be concerned should any attempt at compulsion of self sufficiency interfere with the principle of clinical freedom.

#### **FINANCIAL IMPLICATIONS**

As they the proposals in the Communication appear to hold no financial implications for the UK.

#### **TIMETABLE**

The Presidency has asked that ideas for Community action be provided for consideration at the health group's meeting on 22/23 February 1995.