

Guidelines for the Blood Transfusion Services

1.3: Other institutions involved in developing guidelines and regulations relevant to the UK

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1.3: Other institutions involved in developing guidelines and regulations relevant to the UK

A brief description of some international organisations and their interrelationships is required for an understanding of the regulatory environment in the UK.

1.3.1: World Health Organization

www.who.int

Established in 1948 as the United Nations' specialised agency for health, the World Health Organization (WHO) is governed by 194 member states through the World Health Assembly. Its aim is the attainment of the highest possible levels of health by all people, and clearly the availability of safe blood contributes to this aim.

The WHO produces recommendations, programmes and educational materials. The Global Collaboration in Blood Safety programme started in 1995. It was recognised that with the increased movement of populations and plasma and plasma-derived medicinal products, blood safety could only be improved through global collaboration. Consensus proposals and recommendations are addressed to the participant countries.

WHO guidelines and recommendations are not legally binding in any of the 194 countries; however, EU legislation in this field states that the advice emanating from the WHO has to be taken into account by the member states when formulating their own legislation.

1.3.2: The Council of Europe and the European Union

The Council of Europe (CoE) and the EU are two totally distinct organisations. They are easily and often confused as much of the same terminology is used. In 2012 the CoE had 47 member states with approximately 800 million inhabitants and the EU had 27, with a population of 502 million. All member states of the EU are member states of the CoE.

1.3.2.1: Council of Europe

www.coe.int

Founded in 1949, one of the Council of Europe's founding principles was the promotion of increased cooperation between member states to improve the quality of life for the population of Europe. In the field of health the CoE has consistently addressed ethical issues; the most important of these is the non-commercialisation of human substances: blood, tissues and organs. In the 1950s member states started to cooperate in blood transfusion activities. Through its committees and working parties composed of national experts, including representation from JPAC, the CoE has produced recommendations to ensure the quality

of blood components and tissues and publishes guidelines as annexes to the recommendations – *Guide to the Preparation, Use and Quality Assurance of Blood Components*³ and *Guide to Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells*.⁴ These annexes are updated regularly to take account of advances in worldwide knowledge and technology.

Neither the recommendations nor the guidelines are legally binding but they are generally regarded as constituting basic best practice and many form the basis of EU Directives, which are legally binding in EU member states.

1.3.2.2: European Union

www.europa.eu

The EU was first proposed by the French Foreign Minister Robert Schuman in 1950, following the devastation of the Second World War. It was conceived to prevent further such wars. Initially it consisted of six countries. The European Coal and Steel Community (ECSC) was created in 1951: coal and steel had played a major role in the Second World War and cooperation over these assets was seen as a means of preventing further such cataclysms. The European Atomic Energy Community (EAEC or Euratom) came into force in 1958, as did the European Economic Community (EEC) created by the Treaty of Rome in 1957. The Treaty of Maastricht 1992 (the Treaty on the European Union) amended the three existing treaties giving the three Communities (ECSC, EAEC and EEC) increased powers. The EEC was renamed the European Community (EC). A 'competence' in EU terminology is a subject over which it has legislative powers. These competences are agreed by the treaties and outlined in the *acquis communautaire*. Competence in the field of blood and blood components was conferred on the EU by the Treaty of Amsterdam 1999 Article 152. It is important to note that this Article stipulates that 'member states cannot be prevented from maintaining or introducing more stringent protective measures as regards standards of quality and safety of blood and blood components'.

In 2012 the EU does not have competence over member states' healthcare services or clinical practice. This means that the laws governing blood, blood components and tissues extend only to cover the safety of the products and not their clinical use.

The five key EU institutions are:

- Parliament: elected by the peoples of the member states.
- Council of the European Union: representing the governments of the member states.
- European Commission: the driving force and executive body.
- European Court of Justice: ensuring compliance with EU law.
- European Court of Auditors: controlling sound and lawful management of the European budget.

The European Commission is the only body that can initiate legislation; the processes whereby legislation is proposed and finally adopted are complex.

Issues regarding health come under a Co-decision Procedure, which means that both the European Parliament and Council (European Council not Council of Europe) have to agree the Commission proposals.

There is open consultation on any proposed legislation. The texts of the Directives and stages in the consultation process can be found online at www.europarl.eu

Directives come into force on the day they are published in the *Official Journal of the European Union (OJ)* but defined time for transposition and implementation is allowed.

EU member states in 2012 were: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

Candidate countries in 2012 were: Croatia, FYR Macedonia and Turkey.

1.3.3: European Pharmacopoeia

www.pheur.org

This CoE initiative was ratified by the EU and 30 participating member states. Pharmacopoeias are collections of standardised specifications that define the quality of pharmaceutical preparations, their constituents and even their containers. The European Pharmacopoeia (Ph Eur) monographs are binding on the EU and the participating member states.

The success of the Biological Standardisation Programme for medicines for human use of the European Pharmacopoeia Secretariat led to further collaboration between the Commission of the EU and the CoE. The European Pharmacopoeia Secretariat changed its name to the European Directorate for the Quality of Medicines & HealthCare (EDQM).

Blood transfusion activities in the EDQM are managed by the Department of Biological Standardisation, Network of Official Medicines Control Laboratories (OMCL) and Healthcare Department.

The European Medicines Agency (EMA, www.ema.europa.eu) is a decentralised body of the EU based in London. Its main responsibility is the protection and promotion of public health through the evaluation and supervision of medicines for human and veterinary use. The EMA coordinates the evaluation and supervision of medicinal products throughout the EU.

The Committee for Medicinal Products for Human Use (CHMP, part of the EMA) is involved in evaluating industrially prepared plasma derivatives.

The CoE and EU work together in this field. Industrially prepared, fractionated plasma products are medicinal products and the Ph Eur monographs are mandatory.

Blood components are not 'medicinal products' and are now regulated by the EU Blood Safety and Quality Directives (see Chapter 2).

1.3.4: United Kingdom

www.cabinetoffice.gov.uk

The UK is one member state in the EU, although since 1997 there has been devolved government in Wales and Scotland and sporadically in Northern Ireland. EU legislation must be transposed into member states' own legislation within a defined time frame.

An account of European decision-making and transposition is given in the *Transposition Guide: How to Implement European Directives Effectively*.⁵ This is available at www.bis.gov.uk.

The EU Directives regarding blood and blood components are transposed into The Blood Safety and Quality Regulations 2005¹ under Section 2(5) of the European Community Act (Maastricht 1992) and are binding across the UK.