Guidelines for the Blood Transfusion Services

Chapter 1: Introduction

http://transfusionguidelines.org/red-book/chapter-1

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1.1: Development of the Red Book

Guidelines for the Blood Transfusion Services in the United Kingdom was first published in 1990 by HMSO. It was compiled by experts from the then Regional Transfusion Centres and the National Institute for Biological Standards and Control (NIBSC), and aimed to define guidelines for all materials produced by the United Kingdom Blood Transfusion Services (UKBTS) for both therapeutic and diagnostic use. The driving force for this joint initiative, which started in 1987, was the imminent European Union (EU) Directive which would bind member states to introduce product liability by July 1988. It was understood that human blood and substances derived from it would be defined as 'products' in terms of this Directive, and guidelines against which manufacturers could be inspected would be required.

Since then seven editions of the Red Book (as the guidelines became known) have been published. They are compiled by a group of experts both from within the Blood Transfusion Services and from the wider NHS and universities, now called the Joint UKBTS/HPA Professional Advisory Committee (JPAC).

The Red Book contains guidelines reflecting best practice, sets standards to be met by the products, describes technical details of the processes involved and states the legally binding requirements introduced in 2005 under the Blood Safety and Quality Regulations, Statutory Instrument 2005 No. 50.[1] More detailed information about the regulatory environment relating to blood and tissues in the UK can be found in Chapter 2.

Guidelines reflect best practice and are developed by professionals in the field. JPAC consists of such professionals in blood transfusion and tissue transplantation, appointed for their expertise from throughout the UK. The Red Book reflects their work as it is implemented in the UK. The book concentrates on the products rather than their use. Clinical use of blood and blood components is outlined in the *Handbook of Transfusion Medicine*,[2] produced by collaboration between JPAC and the British Committee for Standards in Haematology (BCSH).

Professional guidelines are not legally binding but, as they reflect consensus best practice, may be taken into account by the UK judiciary. Such national guidelines have to take into account EU Directives, which have to be transposed into UK law, and these are legally binding.

JPAC, with its Standing Advisory Committees (SACs), undertakes regular review of the guidelines in the light of developments in the field, both scientific and regulatory. The overall aim is to ensure as far as possible the safety of blood transfusion in the UK, for both the donor and the patient. Changes in the guidelines are therefore likely to occur, and these will be notified on the JPAC website, www.transfusionguidelines.org.uk, where an up-to-date version of the guidelines can always be found.

The work of JPAC is conducted through expert SACs. The current SACs of JPAC are shown in Figure 1.1.

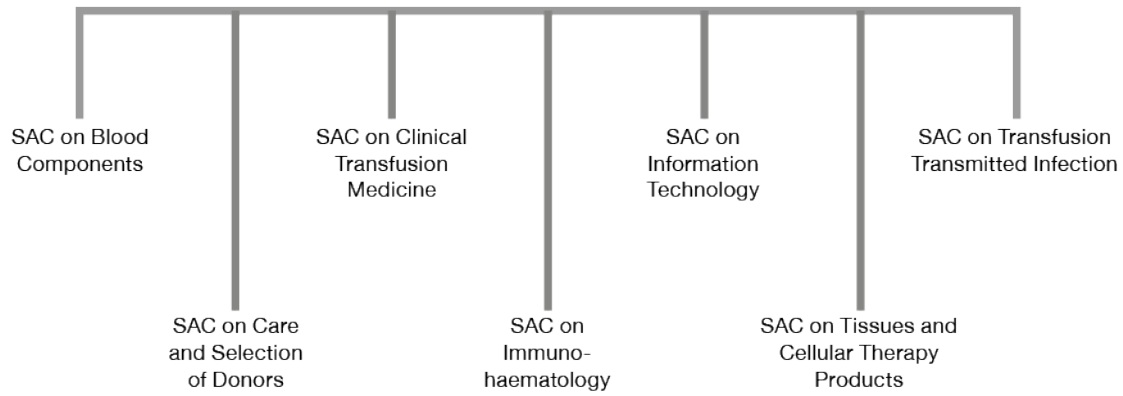

Figure 1.1 Standing Advisory Committees of the Joint UKBTS/HPA Professional Advisory Committee

1.2: Organisation of the UK Blood Services

There are four national Blood Services/Blood Transfusion Services in the UK:

- NHS Blood and Transplant (NHSBT), a Special Health Authority within the NHS, which provides Blood Services and tissues in England and North Wales, and organs for the whole of the UK.
- The Scottish National Blood Transfusion Service (SNBTS), which is managed by NHS National Services Scotland.
- The Northern Ireland Blood Transfusion Service (NIBTS), which is managed by the Northern Ireland Blood Transfusion Special Agency.
- The Welsh Blood Service (WBS), which is provided and managed by Velindre NHS Trust.

These are Blood Establishments.

Following devolution of governments in the UK, the UK Blood Services Forum was established in 1999 comprising the chief executives and medical directors of the four services, and JPAC became accountable to the medical directors, who themselves are accountable to their chief executives. The close working relationship with NIBSC (subsequently part of the Medicines and Healthcare products Regulatory Authority (MHRA) from April 2013) has been maintained through the Director of NIBSC.

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 (EMEA, 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 EMEA coordinates the evaluation and supervision of medicinal products throughout the EU.

The Committee for Medicinal Products for Human Use (CHMP, part of the EMEA) 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 2005[1] under Section 2(5) of the European Community Act (Maastricht 1992) and are binding across the UK.

1.4: References

1. Statutory Instrument 2005 No. 50. The Blood Safety and Quality Regulations 2005. Available at www.legislation.gov.uk.

2. *Handbook of Transfusion Medicine*, third edition. Available at www.transfusionguidelines.org.uk.

3. Council of Europe (2010). *Guide to the Preparation, Use and Quality Assurance of Blood Components*, 16th edition. Council of Europe Publishing.

4. Council of Europe (2010). *Guide to Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells*, fourth edition. Council of Europe Publishing.

5. *Transposition Guide: How to Implement European Directives Effectively*. Available at www.gov.uk/government/publications/implementing-eu-directives-into-uk-law