Guidelines for the Blood Transfusion Services

2.2: Key initiatives

http://www.transfusionguidelines.org/red-book/chapter-2-quality-in-blood-and-tissue-establishments-and-hospital-blood-banks/2-2-key-european-initiatives

2.2: Key initiatives

2.2.1: European Union Blood Safety and Quality Directives

- Commission Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.[3]
- Commission Directive 2004/33/EC of the European Parliament and the Council of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.[4]
- Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events.[5]
- Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for Blood Establishments.[6]

The first two Directives came into force in UK law on 8 February 2005 as the Blood Safety and Quality Regulations 2005 (BSQR),[1] with their requirements becoming effective in November 2005. They set standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion. The regulations also cover the collection and testing of blood and blood components for autologous use. In effect, therefore, they cover the whole process from donor to patient – from ‘vein to vein’.

The latter two Directives came into force in August 2006 and relate specifically to traceability requirements and notification of adverse reactions and events, and introduce EC standards and specifications relating to a quality system for Blood Establishments. They also added provisions relating to record keeping and traceability of blood and blood components to a new category of facility, defined as a hospital, another facility or service owned or managed by a health service body, a care home, an independent clinic, a manufacturer or a biomedical research institute.

The Directives define certain activities which can only be undertaken by Blood Establishments, namely:

- the collection and testing of blood or blood components, whatever their intended purpose
- the processing, storage and distribution of blood and blood components when they are intended to be used for transfusion.

Hospital blood banks are not permitted to undertake these activities unless licensed as Blood Establishments, but are able to store, distribute and perform compatibility tests on blood and blood components for use within hospital facilities.

2.2.2: Medical devices legislation

Blood and Tissue Establishments and Hospital Blood Banks are key users of medical devices such as blood bags and in vitro diagnostic medical devices such as test kits for blood grouping. Some establishments also manufacture CE or UKCA marked in vitro diagnostic medical devices (guidelines for reagent manufacture are included in Chapter 11). The Good Practice Guidelines for Blood Establishments and the HTA Guide Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment mandate the use of CE or UKCA marked medical devices wherever possible. Knowledge of medical devices legislation is therefore important for Blood and Tissue Establishments and Hospital Blood Banks.

The Medicines and Healthcare products Regulatory Agency (MHRA) is the designated authority that administers and enforces the law on medical devices in the UK. It has a range of investigatory and enforcement powers to ensure the safety and quality of medical devices placed on the UK market. Different regulatory requirements apply to Great Britain (England, Wales and Scotland) and Northern Ireland and these are set out below.

2.2.2.1: Regulation of medical devices in Great Britain

Medical devices are regulated under theMedical Devices Regulations 2002(SI 2002 No 618, as amended) (UK MDR 2002) which is based on requirements derived from the following EU Directives:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on *in vitro* diagnostic medical devices (EU IVDD)

The UKCA (UK Conformity Assessed) marking is a UK product marking used for certain goods, including medical devices, being placed on the Great Britain market. UKCA marking is not recognised in the Northern Ireland or the EU. UKCA marking requirements are based on the requirements of the relevant Annexes to the EU Directives listed above, which have been modified by Schedule 2A to the UK MDR 2002.

Under the UK MDR 2002, a CE marked device with a valid declaration of conformity or EC certificate is viewed as meeting the UKCA marking requirements whilst CE marking continues to be recognised in Great Britain - until 30 June 2023. This applies to devices that have been CE marked under and fully conform with the following applicable EU legislation:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD) (for devices that have been CE marked prior to 26 May 2021)
- Directive 93/42/EEC on medical devices (EU MDD) (for devices that have been CE marked prior to 26 May 2021)
- Directive 98/79/EC on *in vitro* diagnostic medical devices (EU IVDD) (for devices that have been CE marked prior to 26 May 2022)
- Regulation (EU) 2017/745 on medical devices (EU MDR)
- Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (EU IVDR)

From 1 July 2023, devices that are placed on the Great Britain market will need to conform with UKCA marking requirements.

2.2.2.2: Regulation of medical devices in Northern Ireland

Under the terms of the Northern Ireland Protocol, the rules for placing medical devices on the Northern Ireland market differ from those applicable to Great Britain. CE marking is needed for medical devices placed on the Northern Ireland market and the following EU Regulations apply:

- Regulation (EU) 2017/745 on medical devices (EU MDR)
- Regulation (EU) 2017/746 on in vitro diagnostic medical devices (EU IVDR)

In addition, the UKNI indication is required if a UK Notified Body undertakes mandatory third-party conformity assessment.

2.2.2.3: In-house manufacture of medical devices by Health Institutions

Health Institutions are exempt from the provisions of the UK MDR 2002 for products manufactured and used within the same Health Institution and either on the premises of their manufacture or on premises in the immediate vicinity without having been transferred to another legal entity. Additional requirements apply to Health Institutions in Northern Ireland and the requirements for Health Institution Exemption (HIE) set out in Article 5 of the EU MDR and IVDR must be complied with.

2.2.2.4: Off-label use and exceptional use of non-complying medical devices

Medical devices should be used as described by the manufacturer in the instructions for use. If a device is used in any other way, it is considered ‘off-label’ use. Without the manufacturer’s approval this will be at your own risk and you or your employer could become liable for civil claims for damages from injured patients or their families if something goes wrong with the device. Modification of a device where this is not described in the manufacturer’s instructions for use is also considered to be off-label use. Use of a non-CE or UKCA marked product for a medical purpose also carries risk and should be avoided; this includes use of products labelled as ‘Research Use Only’. Although rare, there may be occasions where there is no option but to use a device off-label; the MHRA may authorise the use of a non-complying device on humanitarian grounds if they are satisfied that such use would be in the best interests of the patient and the protection of health. Further information on off-label use and exceptional use of non-complying medical devices is available on the MHRA web site.

2.2.2.5: Future regulation of medical devices in the UK

The MHRA are planning significant changes to how medical devices will be regulated in the UK. This will be implemented through amendments to the UK MDR 2002, and it is anticipated that these will enter in to force on 1st July 2023. Furthermore, changes to how the Northern Ireland Protocol will apply may have an impact on how medical devices are regulated. Readers are advised to check the MHRA website for up-to-date guidance on regulation of medical devices in Great Britain and Northern Ireland.

2.2.3: Human Tissue Act 2004[11]

The Human Tissue Act 2004 replaced the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they relate to England and Wales, and the corresponding Orders in Northern Ireland.

The Human Tissue Act 2004 covers England, Wales and Northern Ireland. It established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The Human Tissue Act 2004 lists the purposes for which consent is required (these are called Scheduled Purposes).

There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006.

While provisions of the Human Tissue (Scotland) Act 2006 are based on authorisation rather than consent, these are essentially both expressions of the same principle.

2.2.4: The European Union Tissues and Cells Directives

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.[12]
- Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.[13]
- Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events, and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.[14]
- Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells.[15]

These Directives establish a harmonised approach to the regulation of tissues and cells across Europe. They set a benchmark for the standards that must be met when carrying out any activity involving tissues and cells for human application (patient treatment). The Directives also require that systems are put in place to ensure that all tissues and cells used in human application are traceable from donor to recipient.

The HTA, as one of the Competent Authorities in the UK under the EU Tissues and Cells Directives, has responsibility for regulating tissues and cells (other than gametes and embryos) for human application.

2.2.5: Human Tissue (Quality and Safety for Human Application) Regulations 2007[2]

The Directives were fully implemented into UK law on 5 July 2007, via the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The HTA's remit includes the regulation of:

- procurement
- testing
- processing
- storage
- distribution
- import/export

of tissues and cells for human application.

Establishments where these activities are carried out will normally need a licence. To obtain this, establishments carrying out the above activities are required to meet the standards which are detailed in the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment[14] as implemented by HTA Directions 001/2021.

The HTA also publishes Codes of Practice, which provide guidance and lay down expected standards for each of the sectors it regulates (see www.hta.gov.uk).