EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

EU legislation on

Blood
&
Blood Components

The legal basis: Article 152 Public Heath

4 ...Shall contribute to the achievement of the objectives referred to in this Articles through adopting:

(a) Measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives, these measures not prevent any member States from maintaining or introducing more stringent protective measures.

Regulatory framework

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

- Codecision: adopted by Parliament and Council on 27 January 2003
- Transposed in all Member States by 8 February 2005
- Basic principles

Regulatory framework

Commission Directive 2004/33/EC

of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and the Council as regards certain technical requirements for blood and blood components

- transposed in all Member States by 8 February 2005
- Technical requirements

Regulatory framework

Commission Directive 2005/61/EC

of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and the Council as regards traceability requirements and notification of serious adverse reactions and events

Commission Directive 2005/62/EC

of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and the Council as regards Community standards and specifications relating to a quality system for blood establishments

- To be transposed in all Member States by 31 August 2006
- Technical requirements

Directive 2002/98/EC

GENERAL PROVISIONS

- Objective (article 1)

lay down standards of quality and safety for human blood and of blood components in order to ensure a high level of protection of human health

Directive 2002/98/EC

Directive 2004/33/EC

GENERAL PROVISIONS

- Scope (Article 2)
  - Includes autologous donations
    - they shall be clearly identified as such (art. 7 Directive 2004/33/EC)
    - they shall be kept separate from allogeneic donations (art. 7 Directive 2004/33/EC – annex IV Directive 2004/33/EC)
  - Directive does not apply to blood stem cells → Directive 2004/23/EC on tissues and cells

Directive 2002/98/EC: SCOPE

SOURCE

Collection and testing of human blood and blood components whatever their intended purpose (including starting materials for medicinal products)

Blood Directive

PROCESSING

Processing, Storage and Distribution

When intended for transfusion

Blood Directive

Proprietary industrially-prepared medicinal products derived from human blood or plasma

Directive 2001/83/EC Community Code relating to Medicinal Products for human use

Directive 2002/98/EC

GENERAL PROVISIONS

- Definitions (article 3)

- Implementation (article 4)

  Designation of Competent authority(ies) responsible for implementing the requirements of the Directive

  Directive shall not prevent MS from maintaining or introducing more stringent protective measures which comply with the provisions of the Treaty

Directive 2002/98/EC

OBLIGATIONS ON MEMBER STATES AUTHORITIES

- Designation, authorisation, accreditation or licensing of Blood Establishments (BE) (article 5)
  - Activities relating to the collection, testing, preparation, storage and distribution (see scope) can only be undertaken by blood establishments which have been designated for that purpose by the competent authority (CA)

  →BE submits info to CA (annex I):
    - part A: general information
    - part B: a description of the quality system
  - No substantial change in activities without prior written approval by CA
  - CA may suspend or revoke if inspection or control measures demonstrate that the BE does not comply with the Directive's requirements

Directive 2002/98/EC

OBLIGATIONS ON MEMBER STATES AUTHORITIES

- Hospital blood banks (Article 6)
  - Personnel, quality system, documentation, traceability, notification SAE/SAR, storage, transport and distribution conditions, data protection and confidentiality
- Provisions for existing establishments
  - 9 months to comply after the entry into force of the Directive

Directive 2002/98/EC

OBLIGATIONS ON MEMBER STATES AUTHORITIES

- Inspection and control measures (article 8)
  - MS shall ensure that the CA organise inspections and appropriate control measures in blood establishments
  - on a regular basis – interval shall not exceed two years
  - by officials representing the CA empowered to
    - inspect BE and facilities of any third parties on its own territory
    - take samples for examination and analysis
    - examine any documents relating to the object of the inspection
  - as appropriate in the event of any serious adverse event or reaction or suspicion thereof

Directive 2002/98/EC

PROVISIONS FOR BLOOD ESTABLISHMENTS

- Responsible person (article 9)
  - BE shall designate a responsible person, responsible for:
    - ensuring that every unit of blood has been collected and tested/processed, … in compliance with the laws in force in the MS
    - providing info to the CA in the designation procedures
    - implementation of requirements on personnel, quality system, documentation, record keeping, traceability, notification SAR/SAE
  - minimum conditions of qualification: diploma + 2 year practice
  - tasks may be delegated to other persons who shall be qualified by training and experience

Directive 2002/98/EC

PROVISIONS FOR BLOOD ESTABLISHMENTS

- Personnel (article 10)

Personnel directly involved in collection, testing, processing, storage and distribution shall be qualified and be provided with timely, relevant and regularly updated training

Directive 2002/98/EC

Directive 2005/62/EC

QUALITY MANAGEMENT

- Quality system (article 11)
  - MS take all measures to ensure that each BE establishes and maintains a quality system based on principles of good practice
  - Community standards and specifications (Directive 2005/62/EC)
    - personnel and organisation
    - premises, equipment and materials
    - documentation
    - blood collection, testing and processing
    - storage and distribution
    - contract management
    - non-conformance
    - audits and improvement

Directive 2002/98/EC

QUALITY MANAGEMENT

- Documentation (article 12)
  - MS take all measures to ensure that BE maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms
  - MS take all measures to ensure that access is provided for inspection officials

Directive 2002/98/EC

QUALITY MANAGEMENT

- Record keeping (article 13)
  - MS take all measures to ensure that BE maintain records of:
    - the information required in Annex II (year report) and IV (basic testing requirements)
    - information to be provided to donors
    - information to be obtained from donors
    - suitability of blood and plasma donors and the screening of donated blood
  - records shall be kept for a minimum of 15 years
  - CA shall keep records of the data received from the BE (designation, inspection, responsible person, SAR/SAE)

Directive 2002/98/EC

Directive 2005/61/EC

HAEMOVIGILANCE

- Traceability (article 14 + art. 2 Directive 2005/61/EC)
  - MS take measures to ensure that blood collected, tested, processed, stored, released and/or distributed on their territory can be traced from donor to recipient and vice versa
    - identification procedures
    - record maintenance
    - labelling system

Directive 2002/98/EC

Directive 2005/61/EC

HAEMOVIGILANCE

- Traceability (article 14 + art. 2 Directive 2005/61/EC)
  - BE implement a system for identification of each single blood donation and each single blood unit and components thereof, blood establishments
  - blood imported from third countries: donor identification system must permit equivalent level of traceability
  - labelling system must comply with the identification system and the labelling requirements of Annex III Directive 2002/98/EC
  - data for full traceability (annex I Directive 2005/61/EC) must be kept for at least 30 years

Directive 2002/98/EC

Directive 2005/61/EC

HAEMOVIGILANCE

- Traceability: labelling requirements
  - official name of the component
  - volume or weight or number of cells in the component
  - unique numeric or alphanumeric donation identification
  - name of producing BE
  - the ABO group (not required for plasma intended for fractionation)
  - the Rh D group (‘’ ‘’ ‘’ ‘’ ‘’)
  - the date or time of expiry
  - the temperature of storage
  - the name, composition and volume of anticoagulant and/or additive solution

Directive 2002/98/EC

Directive 2005/61/EC

HAEMOVIGILANCE

- Notification of serious adverse events and reactions (article 15)
  - MS shall ensure that
    - any SAE (accidents and errors - article 5 Directive 2005/61/EC)
      - related to the collection, testing, processing, storage and distribution of blood
      - which may have an influence on their quality and safety
    - as well as any SAR (article 6 Directive 2005/61/EC)
      - observed during or after transfusion
      - which may be attributed to the quality and safety of blood

    are notified to the CA

Directive 2002/98/EC

Directive 2005/61/EC

HAEMOVIGILANCE

- Notification of serious adverse events and reactions (article 15)
  - MS shall ensure that BE have in place a procedure to withdraw from distribution blood associated with the notification of SAE/SAR
  - notification in accordance with procedure and notification format (annex II and III Directive 2005/61/EC)
  - BE have an equivalent notification system in place for imports of blood from third countries
  - annual report by MS to be submitted to Commission (annex II and III Directive 2005/61/EC)
  - CA communicate to each other information on SAE/SAR in order to guarantee that defective blood is discarded (art. 9 Directive 2005/61/EC)

Directive 2002/98/EC

Directive 2004/33/EC

PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

- Provision of information to prospective donors (article 16 - annex II A, Directive 2004/33/EC):
  - accurate educational materials on blood, donation procedure, benefits to patient…
  - protection of personal data
  - nature of the procedures involved and associated risks
  - option for donors to change their mind/withdrawing at any time
  - …

Directive 2002/98/EC

Directive 2004/33/EC

PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

- Information required from donors (article 17 – annex II, B Directive 2004/33/EC):
  - upon agreement of a willingness to commence donation, all donors provide the following information:
    - identification of the donor (and contact data)
    - health and medical history of the donor (provided on questionnaire and through a personal interview by a qualified healthcare professional)
    - signature of the donor on the questionnaire countersigned by the staff member responsible for obtaining the health history, confirming a number of facts

Directive 2002/98/EC

Directive 2004/33/EC

PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

- Eligibility of donors (article 18)
  - BE ensure that evaluation procedures are in place for all donors and that criteria for donation are met (Annex III of Directive 2004/33/EC):
  - the results of the donor evaluation and testing procedures shall be documented, any relevant abnormal findings shall be reported to the donor
- Examination of donors (article 19)
  - before donation: an examination, including an interview
  - qualified health professional shall give and gather information and assess the eligibility of donors

Directive 2002/98/EC

PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

- Voluntary and unpaid blood donations (article 20)
  - MS take measures to encourage voluntary and unpaid donations ensuring that blood is in so far as possible provided from such donations
  - MS submit reports to the Commission on these measures two years after entry into force and every three years thereafter
- Testing of donations (article 21)
  - BE ensure that each donation is tested in conformity with requirements annex IV Directive 2002/98/EC (ABO, Rh D, Hepatitis B/C, HIV 1-2)
  - MS ensure that blood imported into the Community is tested in conformity with annex IV Directive 2002/98/EC

Directive 2002/98/EC

Directive 2004/33/EC

PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

- Storage, transport and distribution conditions (article 22 - annex IV Directive 2004/33/EC):
- Quality and safety requirements (article 23 – annex V Directive 2004/33/EC)
  - blood and blood components must comply with technical quality measurements
  - MS must ensure that all imports from third countries meet equivalent standards of quality and safety

Directive 2002/98/EC

DATA PROTECTION

- Data protection and confidentiality (article 24)
  - MS take measures to ensure that all data, including genetic information, to which third parties have access have been rendered anonymous (donor no longer identifiable)
  - data security measures – safeguards against unauthorised data additions, deletions or modifications
  - procedures to resolve data discrepancies
  - no unauthorised disclosure of information

  Whilst guaranteeing the traceability of donations

Directive 2002/98/EC

EXCHANGE OF INFORMATION, REPORTS AND PENALTIES

- Information exchange (article 25)
  - Commission holds regular meetings with CA, delegations of experts from BE and other relevant parties
  - exchange information on experience acquired on implementation
- Reports (article 26)
  - MS send report on 31/12/2003 and every three years after
  - Commission transmits these and a commission report on the implementation to EP, Council, Ecosoc Committee, Committee of Regions
- Penalties (article 27)

Directive 2002/98/EC

COMMITTEES

- Regulatory Committee (article 28)

- Technical requirements and their adaptation to Scientific and technical progress (article 29)

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Thank You