



Public Health Programme – Workplan 2006

Substances of Human Origin

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Unit C6 Health Measures



Article 152 Public Health

4 (a) Measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining of introducing more stringent protective measures.



Safety of blood, tissues and cells, and organs. Legislation

Blood

- Directive 2002/98/EC on the quality and safety of blood
- Commission Directive 2004/33/EC on certain technical requirements
- Commission Directive 2005/61/EC on traceability and notification of serious adverse reactions/events
- Commission Directive 2005/62/EC on a quality system for blood establishments



Safety of blood, tissues and cells, and organs. Legislation

Tissues and cells

- Directive 2004/23/EC on the quality and safety of human tissues and cells
- Directive 2006/17/EC on technical requirements for the donation, procurement and testing of human tissues and cells

Projects Funded 2003

■ JACEI.

Provide impetus to the JACIE programme and ensure its role in standard setting, inspection and accreditation for health institutions and facilities involved in haemotopoietic stem cell collection, processing and transplantation in Europe

■ EUROPEAN QUALITY SYSTEM FOR TISSUE BANKING.

Develop the method to ensure standards of quality and safety in relation to tissue banking activities (standards, tissue registry, training model for tissue bank personnel, pilot model on accreditation)



Projects Funded 2004

■ EU-QMS-Bloodnet.

Implement a quality management programme for blood procurement and processing that provides a consistently high blood product standard throughout Europe, minimizes hazards of blood transfusion and encourages the implementation of the Blood Directive within each member state.

Projects Funded 2005

- European union standards and training for the inspection of tissue establishments
- European training programme on organ donation
 - design a European training programme adapted to different health professional profiles
 - comparative analysis related to organ donation rates before and after implementation of the training programmes

Safety of blood, tissues and cells, and organs. 2006

- Aims to promote the quality, safety and availability of substances of human origin
- To prevent the transmission of diseases
- To give backing to their therapeutic use for the benefit of patients

BLOOD Priorities 2006

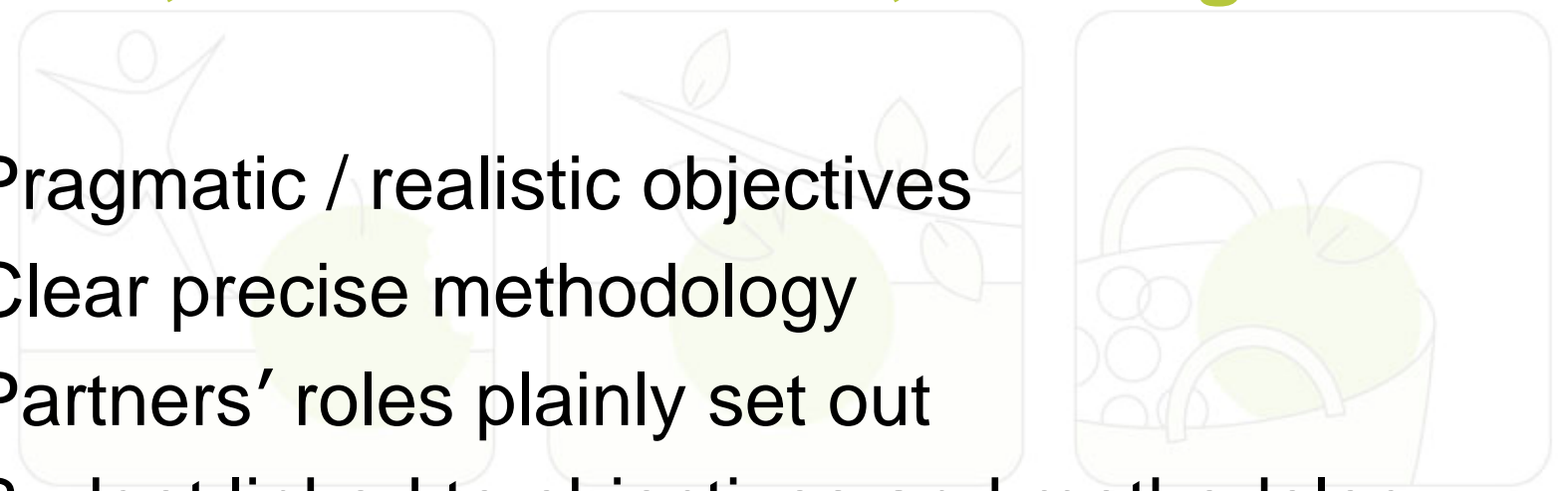
- Ensuring equivalent recognition of inspections of blood establishments among member states through the development and implementation of commonly accepted criteria and standards
- Encourage donation and the optimal use of blood products:
 - sharing of best practice and information on recruitment of donors
 - training in the use of blood components



TISSUES AND CELLS/ORGANS Priorities 2006

- Ensure better therapeutic use of substances of human origin: development of tools that promote evidence-based best practice
- Facilitate the exchange of substances of human origin: improve measures such as common terminologies
- Monitor the health of living donors: improve measures such as development of registers

Safety of blood, tissues and cells, and organs. 2006

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- Pragmatic / realistic objectives
 - Clear precise methodology
 - Partners' roles plainly set out
 - Budget linked to objectives and methodology
 - Community-added value demonstrated
 - Concrete deliverables produced
 - Public health oriented

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