Joint Annual Congress of the DGTI and ESFH in cooperation with the SFTS
Düsseldorf, 16.-19. September 2008
Workshop: Seltene Blutgruppen

Differences and communalities leading to pan-European standards (The EuBIS Project): Perspectives of procurement and transfusion of rare blood in Europe

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TREATY PROVISIONS

Article 152 - EU Treaty (Amsterdam 1997)

Article 152 (4) (a) (ex Article 129, EU Treaty-Maastricht 1992)
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.

EU-TREATY PROVISIONS

Substances of human origin: the legal basis for EU law

- Article 152: public health
  - Objective: health protection → minimum standards
  - Tissue Directive 2004/23/EC

- Article 95: internal market
  - Objective: free circulation → harmonisation
  - Example: Medicinal Products Directive 2001/83/EC

"The European Commission" supporting the implementation of the blood legislation

The European Commission
Co-funded by the EC – GA No. 2006202
EuBIS
European Blood Inspection System
Co-funded by the EC – GA No. 2006202
Optimal Donor Management (2007)

Optimal Donor Management

- Standard operating procedures for collection and processing (2008)
- Standards for inspections (2008)
- Optimal use of blood (2008)

EU-Q-Blood-SOP
Methodology for standard operational procedures
Co-funded by the EC GA2004217
Develop a Manual describing a methodology based on good practice that will
(1) assist blood establishments to implement or expand their standard operating
procedures (SOPs).
(2) contribute to the understanding and management of quality processes in blood
services.
(3) assist blood establishments in preparing for the inspection of their services
related to the implementation of quality relevant elements required by the EU
directive 2002/98/EC.

**Project objectives**

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  procedures (SOPs).
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  services.
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  related to the implementation of quality relevant elements required by the EU
directive 2002/98/EC.

**Project Structure**

**European Commission – Directorate C**

- Dr. Tapani Piha (DG Sanco)
- Mr. Thomas Bregeon (DG Sanco)
- Ms. Ann Thuvander (PHEA)

**Project Coordination (DE):**

- Prof. Dr. C. Seidl and
- Prof. Dr. E. Seifried (Leader)

**Participants**

- from 20 EU Member / EFTA states:
  - AT, DE, MT, HU, CZ, NL, CY, IT, UK, BE, BG, RO, FR, ES, EE, IE, PL, LU, SLO, IS

**EuBIS - General Objectives**

(1) define requirements for quality management systems of blood
(2) develop pan-European standards and criteria for the inspection of blood
establishments based on GMP guidelines to assist national inspections in
(3) establish a common benchmark system for continual improvement. This
benchmark system should develop practical assistance and advice to optimise
processes based on good practice among blood establishments.
(4) develop a training programme for inspectors

**Survey Questionnaire**

The specific objectives of this survey are

to define the current situation of standards and criteria used for inspections of
blood establishments among the participants from 17 established, new, applicant
and EFTA states in order to identify

- (A) international and national inspection guidelines in place and
- (B) the current inspection practice.
Section I - Common standards used for quality systems of blood establishments

- ISO standards used
- GMP
- ISO certified or accredited
- GLP
- national standards / guidelines
- WHO

EuBIS Inspection manual

Member Consultation:
Movement of labile blood products

As of: August/September 2007

Questionnaire:
1. Do you have a legal system regulating the self-sufficiency in labile blood products in your country? Yes / No
2. If there is a legal basis please could you send a copy of the corresponding laws; please indicate when this law was installed.
3. If there is no legal basis please let us know whether or not your government allows the importation of labile blood products. Yes it allows importation / No it does not allow importation
SEE Blood safety project

The project comprises two components.

Component one (focused on the harmonization of national blood safety policies/strategies; to ensure the basis for further technical developments)

**Objectives:**

a) The development of national policies on blood safety in accordance with EU directives and international recommendations in the field.

b) Increasing the availability of blood and blood components through sustainable promotion of voluntary non-remunerated blood donations.

Component two (focused on some specific technical issues)

**Objectives:**

a) Building a regional network of institutions and professionals able to respond to both national and regional needs.

b) Establishing a regional information system (E-network) for a rapid identification of blood availability.

c) Setting up mechanisms for rapid transportation of blood and blood components.