10th European Haemovigilance Seminar (EHS)
February 28 Frankfurt/Main, Germany

EU BLOOD AND TISSUES DIRECTIVES

European Commission
Health and Consumer Protection Directorate General
Public Health and Risk Assessment Directorate
Health Measures Unit
Article 152 (4) (a)

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.
Legislation and policy on human substances

  - Three Commission Directives
  - Two Commission reports

  - Two Commission Directives
  - Two Commission reports

- Open consultation on policy options on organ donation and transplantation (2006)
  - Communication in 2007
SoHO Committees/Groups

1. Regulatory Committee
   - Working group on European Coding System
   - Working group on Ethical related aspects

2. Meeting of Competent Authorities
   - SAR/SAE reporting group

3. National Experts Technical Meetings
The blood and blood components Legal Framework


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

COMMISSION DIRECTIVE 2004/33/EC

of 22 March 2004


(Text with EEA relevance)

COMMISSION DIRECTIVE 2005/61/EC

of 30 September 2005


(Text with EEA relevance)

COMMISSION DIRECTIVE 2005/62/EC

of 30 September 2005


(Text with EEA relevance)
TRANSPOSITION TO DATE (February 2008)

Notifications received by the Commission

- 2002/98: 27
- 2004/33: 26
- 2005/61: 25
- 2005/62: 25
The Blood Legal Framework

• Competent authorities
• Accreditation, designation, authorisation, or licensing of blood establishments
• Quality systems/ Quality standards
• Inspection and control measures
• Traceability
• Import/export of blood/blood components
• Notification of Serious adverse events and reactions
THE LEGAL CONTEXT

- System in place in Member States on SAE/SAR reporting

- Article 8 of Directive 2005/61/EC: the Member States shall submit to the Commission an annual report,

- First reporting to the Commission: 30 June 2008, concerning information collected during the complete year 2007 (from 1st January to 31st of December)
Serious Adverse Events and Reactions (October 2006)

Is there a SAE/R reporting system in place?

- Yes: 26
- No: 3

N = 29
Serious Adverse Events and Reactions (October 2006)

Is there a link with pharmacovigilance systems?
- Yes
- No

N= 29

Is there a link with medical devices vigilance?
- Yes
- No
- N/A
Definitions of Serious Adverse Events
Serious Adverse Reactions

Any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood component that...

Unintended response in donor or in patient associated with the collection or transfusion of blood and blood components that...

... (or,/) life-threatening, disabling (or,/) incapacitating (conditions for patients) or which results in, or prolongs, hospitalisation or morbidity.
Haemovigilance in the Blood Directive
What falls in?

Blood and blood components when intended for
TRANSFUSION

SAE

SAR

Attributed to the QUALITY and SAFETY of blood and blood components

COLLECTION, testing, processing, storage and DISTRIBUTION
### Reporting establishment

### Reporting period

<table>
<thead>
<tr>
<th>Blood component</th>
<th>Number of units transfused (total number of recipients transfused with a given number of blood components)</th>
<th>Number of recipients transfused (total number of recipients transfused with a given number of blood components) (if applicable)</th>
<th>Number of units transfused (the total number of blood components units transfused over the reporting period) (if available)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red blood cells</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelets</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Number of deaths

<table>
<thead>
<tr>
<th>Number of deaths</th>
<th>Number of serious adverse reactions with immortality level 0 to 3 after transfusion (per annual unit)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Level 0</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Immunological haemolys

<table>
<thead>
<tr>
<th>Due to ABO incompatibility</th>
<th>Total</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Due to other alloantibody</th>
<th>Total</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

#### Non-immunological haemolys

<table>
<thead>
<tr>
<th>Total</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

#### Transfusion-transmitted bacterial infection

<table>
<thead>
<tr>
<th>Total</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

#### Anaphylaxis/hypersensitivity

<table>
<thead>
<tr>
<th>Total</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

#### Transfusion related acute lung injury

<table>
<thead>
<tr>
<th>Total</th>
<th>Deaths</th>
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<tbody>
<tr>
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</tbody>
</table>

#### Transfusion-transmitted viral infection

<table>
<thead>
<tr>
<th>HBV</th>
<th>Total</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>HCV</th>
<th>Total</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>HIV(+)</th>
<th>Total</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Other (specify)</th>
<th>Total</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

#### Transfusion-transmitted parasitical infection

<table>
<thead>
<tr>
<th>Malaria</th>
<th>Total</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Other (specify)</th>
<th>Total</th>
<th>Deaths</th>
</tr>
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<tbody>
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</tbody>
</table>
PART C

Annual Notification Format for Serious Adverse Events

<table>
<thead>
<tr>
<th>Reporting establishment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting period</td>
<td>1 January-31 December (year)</td>
</tr>
</tbody>
</table>

Total number of blood and blood components processed:

<table>
<thead>
<tr>
<th>Serious adverse event, affecting quality and safety of blood component due to a deviation in:</th>
<th>Total number</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apheresis collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Testing of donations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distribution</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others (specify)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
COMPETENT AUTHORITES WORKING GROUP

- How to ensure that the reported information is exploitable?
- How to optimise the gathering exercise to avoid unnecessary burden at all stages?

Need to ensure that everyone is clear on WHAT should be reported.
What is the information to report to the Commission?


- Feed back from stakeholders and Competent Authorities: lack of clarity, risk of mistake or misreporting, long internal discussions…

- Necessity to clear up as much questions as possible IN ADVANCE to the first collection… keeping in mind that we remain in a learning by experience exercise
Next steps?

- Written comments on the working document by 30 November
- Working group to outline the common approach – 19 December 2007
- Finalisation of the common approach by the Commission - early 2008
The Tissues and Cells Legal Framework


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

COMMISSION DIRECTIVE 2006/17/EC

of 8 February 2006


(Text with EEA relevance)

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

(Text with EEA relevance)
TRANSPOSITION TO DATE (February 2008)
The Tissues and Cells Legal Framework

- Competent authorities
- Supervision of human tissues and cells procurement
- Accreditation, designation, authorisation, or licensing of tissue establishments and tissues and cells preparation processes
- Quality systems/Quality standards
- Inspection and control measures
- Traceability/Coding system
- Import/export of human tissues and cells
- Register of Tissue establishment
- Notification of Serious adverse events and reactions
THE LEGAL CONTEXT

- System in place in Member States on SAE/SAR reporting

- Article 7 of Directive 2006/86/EC: the Member States shall submit to the Commission an annual report, by 30 June of the following year, on the notification of serious adverse events and reactions received by the competent authority.

- First reporting to the Commission: 30 June 2008, concerning information collected during the complete year 2007 (from 1st September to 31st of December)
SAE/SAR (February 2006)

- Yes, reporting system for SAE/SAR is in place: 14 (58%)
- No, reporting system is not in place: 10 (42%)

n = 24
Definition of SAR (February 2006)

1. Serious adverse reactions in the recipient which may be linked to the quality and safety of tissues/cells
2. Serious adverse reactions in the donor which may influence the quality and safety of tissues/cells
3. Serious adverse reactions that cannot be attributed to the quality and safety of tissues/cells
4. Serious adverse reactions in the donor that do not influence the quality and safety of tissues/cells

Additional definitions used in MS: adverse reaction which occur with abnormal frequency; adverse reaction possibly linked to the ancillary product; disease transmission, serious infection; a) Perte accidentelle avant la greffe d’un greffon autologue (réactions indésirables graves chez le patient déjà conditionné pour la greffe) b) Mauvaise qualité d’un produit annexe découverte après la délivrance ou la distribution de ce produit Contamination bactérienne ou fongique d’un greffon découverte après la greffe
Definition of SAE (February 2006)

1. The administration or the use of tissues/cells that did not fulfill the safety and quality requirements
2. A near miss: the distribution of tissues/cells that did not fulfill the safety or quality requirements at the time (but that was not administered or used)
3. The release of tissues/cells (even if not distributed), that did not fulfill the release requirements, due to a procedural problem of the release process

Additional definitions used in MS: An event that might put the life of a donor in danger, seropositivity,
European Union Standards and Training in the Inspection of Tissue Establishments: EUSTITE

In 2009 a system for the definition, classification and reporting of adverse reactions and events associated with safety and quality of tissues and cells applied to the human body will have been proposed by the project and established on a pilot basis. The system will have links to developing surveillance systems in the field outside the EU.
Thank you