Survey on the Implementation of the EU Blood and Blood Components Directives 3rd Report

Blood Competent Authority Meeting – 24th April 2015

D4 Substances of Human Origin Team
Legal Background – Directive 2002/98/EC

Article 26 – Reports

1. **Member States** shall send to the Commission, commencing on 31 December 2003 and every three years thereafter, a report on the activities undertaken in relation to the provisions of this Directive, including an account of the measures taken in relation to inspection and control.

2. **The Commission** shall transmit to the European Parliament, the Council, the economic and Social Committee and the Committee of the Regions, the reports submitted by the **Member States** on the experience gained in implementing this Directive.

3. **The Commission** shall transmit to the European Parliament, the Council, the economic and Social Committee and the Committee of the Regions, commencing on July 2004 and every three years thereafter, a report on the implementation of the requirements in this Directive, and in particular those relating to inspection and control.
Transposition of the EU Blood Legislation

- Largely properly transposed
- One infringement procedure ongoing
- Issues requiring clarification:
  - the content and time period for record-keeping,
  - the traceability and reporting requirements for SARE
  - the information required from donors and the eligibility of donors
  - the requirements for testing
Transposition of the EU Legislation - Interpretation Questions

• Issues regarding interpretation of scope
  – bed-side technologies
  – industrial processes falling under pharmaceutical legislation
  – the importance of the eventual use (transfusion, topical use, plasma derivatives, etc.).

• 2 interpretation issues have reached the ECJ

• Call for a structured approach to addressing interpretation questions in collaboration with other authorities
Implementation of the EU legislation

Overall acceptable - but some challenges related to lack of clarity:

• Designation of competent authority or authorities responsible for the implementation of the directive 2002/98/EC

• Obligations of the MS authorities

• Haemovigilance
Designation of competent authority or authorities responsible for the implementation of the directive 2002/98/EC

- All MS have appointed one or more authorities
- In some MS there are multiple authorities with limited role at national/federal level
- Almost all CAs have other regulatory responsibilities
Additional fields of competence for national blood competent authorities (CAs)

- Pharmaceuticals
- Tissues and Cells
- Organs
- Medical Devices
- Other

Graph showing the number of countries with competence in each category.
Issues related to CA responsibilities not addressed in the legislation

• Wherever different activities (authorisation, inspection, haemovigilance) are undertaken by different CAs, good communication and coordination needs to be ensured.

• To facilitate good regulatory communication between MS, as well as to comply with the annual reporting requirements to the Commission, a well-informed national coordinating contact is necessary.

• Independence of the CA from industry must be ensured.

• No specific legal requirement for CAs to authorise new blood component preparation processes or changes to well-established preparation processes.
Obligations of MS - Accreditation, designation, authorisation or licensing of blood establishments

• Some confusion and lack of mutual trust due to:
  – differing procedures for authorisation
  – differing approaches to collection sites
  – different time limits for authorisations

• Some call for common procedures
Obligations of MS – Inspection and Control Measures

• Resource (staffing) issues reported
• Challenge of complying with the 2 year required interval
• Proposals for introducing a risk-based prioritisation approach
• Diversity regarding methodology and classification of deficiencies
• Varying approaches to mobile and satellite sites, hospital blood banks, plasma collection centres and potential 3rd country actors
• Many would welcome greater legal clarity.
Overlapping Inspection Schemes

- Tissues and cells:
- Organs:
- Advanced therapies:
- Pharmaceuticals:
- Medical devices:
- Hospitals:
- Others:
Haemovigilance

- All MS except one have SARE reporting in place
- Most base their system on the EC SARE reporting Common Approach
- One third do not believe that all BEs are reporting SARE appropriately
Haemovigilance: Percentage of Reporting Blood Establishments per Country

- **100%**
  - BE, BG, CY, DK, EE, ES, FI, FR, HR, IE, LI, LT, LU, LV, MT, NL, NO, PL, RO, SI, UK

- **50-69%**
  - SE

- **70-99%**
  - AT, CZ, DE, EL, HU, IT, PT, SK; 8
Comments on Haemovigilance

- All countries have recall procedures in place; 14 reported recalls (1867 in total) – commonly due to information received from the donor after donation
- 2/3 of countries have put in place donor self-exclusion systems
- Most countries organise root cause analyses to understand the reasons behind SARE but - a generally reported interest in developing this approach further
- Good interconnectivity with other health-related vigilance systems, in particular on medical devices and communicable diseases.
- National authorities are well connected to RAB
- Many mention a need to improve communication from RAB to BEs and hospitals
- Clarification of the rules on SARE at European level would be helpful
Import & Export

• While blood and blood components rarely cross borders, plasma and plasma derivatives frequently do.

• Increasing demand for plasma derivatives (6% per year) results in a flow of imports into the EU.

• Most MS have rules for import of blood and blood components but only about half have rules for import of plasma for fractionation.

• Export of plasma is not as restricted as that of blood and blood components although in some cases it is stipulated that the products must be used in the country of donation.

• Without harmonised standards for import/export data, it is difficult to draw conclusions; some call for greater transparency in relation to these flows.
Quality and Safety of Blood and Blood Components
- Donor Screening for Eligibility

• Safety and quality is a major concern for EU citizens, with 56% of respondents to the Eurobarometer survey citing the risk of contracting a disease as a major concern when accepting donated substances.

• About 2/3 have national guidance regarding sexual risk behaviour, including MSM.

• MS wish to discuss further
  – Age limits (increasing the cut-off)
  – History of malignancy
  – Donor risk behaviour
  – Hb levels

• MS indicate support for
  – Mapping the more stringent national criteria for greater transparency
  – Strengthening the legislation to provide protection for donors.
### Main Causes Leading to Deferrals/Country

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<th>Cause</th>
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Quality and Safety of Blood and Blood Components
- Donor Testing and Pathogen Inactivation

• Syphilis, malaria, hepatitis A, hepatitis E and parvovirus B19 are the most frequent additional tests carried out.

• About 2/3 of the countries mention that BEs also use NAT (although some question cost:benefit).

• 16 countries have pathogen inactivation in place for plasma.

• A general call for a common assessment mechanism to understand the impact of changes to donor testing requirements.
Conclusions

• Significant level of application of the current quality and safety requirements of the EU blood legislation in most of the responding EU MS and EEA countries.

• However some gaps and challenges:
  – insufficient harmonisation at EU level of the authorisation/designation/licensing and of inspection practices;
  – the organisation of CAs and their activities vary significantly between and within MS. Lack of a clear and common approach towards inspection and authorisation of mobile and satellite blood collection sites and no provision for risk-based planning of inspections are also mentioned as challenges;
Conclusions contd.

- interpretation questions – lack of a structured approach to address these in close collaboration with other authorities from related sectors (tissues and cells, medicinal products and medical devices);
- differences in additional national requirements for deferral, testing and where appropriate pathogen inactivation, often justified on grounds of local differences in (epidemiological) risks. Lack of transparency on justifications of such measures;
- insufficient requirements for ensuring appropriate national and EU vigilance systems, including reporting of SARE and activity volumes throughout the entire transfusion chain, from donor to recipient and vice-versa.
Thank you!