Human blood and blood components: quality and safety for the collection, testing, processing, storage and distribution

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The Commission has presented its first report on the implementation of the blood directive (Directive 2002 /98/EC). This report provides an overview of the situation in the 15 Member States that belonged to the European Union as of 31 December 2003. It concerns the implementation of the Directive's requirements, in particular those relating to inspection and control.

Other issues dealt with include :

IMPLEMENTATION (Article 4): Member States may maintain or introduce more stringent protective measures than those of the Directive while ensuring compliance with the Treaty's provisions. Ten Member States avail of this option. Nine of them planned to maintain existing requirements for nine months after 8 February 2005, in order to give blood establishments additional time to comply with the Directive.

OBLIGATIONS ON MEMBER STATES AUTHORITIES :

- Blood establishments (Article 5) : Member States must ensure that an appropriate mechanism is in place so that the activities of blood establishments comply with the Directive's requirements. As of December 2003, 14 Member States had designated a competent authority in accordance with this provision.

- Hospital blood banks (Article 6) : hospital blood banks in 7 Member States had been informed of the requirements applicable to them.

- Inspection and control measures (Article 8) : the competent authority in 7 Member States had organised inspections and control measures in blood establishments in order to ensure compliance with the Directive's requirements. The timeliness of inspections and control measures, however, varied from every six months to every three years. Six Member States have empowered officials representing the competent authority to carry out inspections and control measures in blood establishments and facilities of third parties in their State that have been entrusted by the authorised blood establishment to carry out

evaluation and testing procedures. Eleven confirmed that these officials are empowered to examine any documents related to the inspection, subject to the provisions in force in the Member State at the time of the entry into force of the Directive which place restrictions on these powers. Three Member States had not yet empowered officials to take samples for examination and analysis. Two states had organised such inspections and controls and 4 had not. Five indicated that such notification was part of their haemovigilance procedures. Six Member States indicated that their blood establishments were aware that serious adverse events and reactions had to be notified to the competent authority in accordance with the procedure and notification format. Eight Member States already have procedures in place to enable blood or blood components associated with serious adverse events and reactions to be accurately, efficiently and verifiably withdrawn from distribution.

PROVISIONS FOR BLOOD ESTABLISHMENTS (Articles 9-10) : blood establishments must designate a responsible person with at least the minimum qualifications. Ten Member States comply with the formal academic requirements, however, practical experience was not always required.

Eight Member States already allow for the delegation of tasks specified for the responsible person to other persons qualified by training and experience, although in one the actual responsibility is not assigned. Five Member States had informed their blood establishments that, where the responsible person or such other persons are permanently or temporarily replaced, they must immediately provide the name of the new responsible person and his or her date of commencement to the competent authority. Nine Member States confirmed that personnel directly involved in the collection, testing, processing, storage, and distribution of human blood and blood components is qualified for their tasks and has been provided with timely, relevant and regularly updated training.

QUALITY MANAGEMENT (Articles 11-13) : eleven Member States have ensured that each blood establishment institutes and maintains a quality system based on the principles of good practice. Shortcomings, however, were acknowledged in some Member States. Nine Member States reported that blood establishments are required to maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms and provide access to these documents for officials entrusted with inspection and control. Most Member States have procedures in place to ensure that blood establishments maintain records of their annual activities, basic testing requirements, and the information provided to and obtained from donors as well as donor suitability requirements. **HAEMOVIGILANCE (Articles 13-15) :** all Member States had taken measures to ensure that blood and blood components collected, tested, processed, stored, released and/or distributed on its territory were traceable from donor to recipient and vice versa.

PROVISIONS FOR QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS:

- Donors (Articles 16-19) : eleven Member States already provided information to donors as normal practice, and thirteen required information to be supplied by donors. Nine Member States reported that evaluation procedures and donation deferral criteria were in place in blood establishments for all donors of blood and blood components. Fourteen Member States indicated that provisions are in place for assessing the suitability of individuals to donate blood, including an examination of and an interview with the donor prior to any donation.

- Voluntary and unpaid blood donation (Article 20) : eleven Member States had taken measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible derived from them.

- Testing of donations (Article 21) : fourteen Member States reported that their blood establishments test each donation of blood and blood components in conformity with requirements listed in Annex IV. Eight Member States had procedures in place to ensure that blood and blood components imported into the Community were tested in conformity with these requirements.

- **Storage, transport and distribution conditions (Article 22) :** twelve Member States already had relevant requirements in place.

- Quality and safety requirements for blood and blood components : seven Member States reported that their blood establishments have to ensure that the quality and safety requirements for blood and blood components meet high standards.

DATA PROTECTION : twelve Member States had taken measures to ensure that all data, including genetic information, collated within the scope of the Directive to which third parties have access,

have been rendered anonymous so that the donor is no longer identifiable. Nine have data security measures in place as well as safeguards against unauthorised data additions, deletions or modifications and transfer of information. Procedures to resolve data discrepancies are in place in 6 Member States with improvements required in a few others. Eight have measures in place to ensure no unauthorised disclosure of such information.

INFORMATION EXCHANGE, PENALTIES AND TRANSPOSITION

- **Information exchange :** the Commission has convened a meeting with the competent authorities designated by the Member States, delegations of experts from blood establishments and other relevant parties on 25 September 2005 to exchange information on the experience acquired with regard to the implementation of this Directive.

- **Penalties :** Member States must lay down rules on the penalties for infringements of the national provisions, take all measures necessary to ensure that they are implemented, and notify the Commission of the provisions by 8 February 2005 at the latest and without delay for any subsequent amendments affecting them. Four Member States indicated that penalties and fines already existed.

- **Transposition :** at the beginning of 2006, thirteen Member States subject to the report adopted transposition measures. Two Member States have informed the Commission that procedures for transposition are underway, but that they have not yet informed the European Commission of the laws, regulations and administrative provisions transposing the Directive. The Commission will evaluate the measures of transposition of the Directive in all Member States.