

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19.6.2006
COM(2006) 313 final

REPORT FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

First report on the application of the Blood Directive

1. INTRODUCTION

Article 26 of Directive 2002/98/EC[1] requires Member States to submit to the European Commission, beginning on 31 December 2003 and every three years thereafter, reports on the activities that they have carried out in relation to the implementation of its provisions. The Commission is required not only to forward these reports to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions but, commencing on 1 July 2004 and every three years thereafter, also to provide them with a report on the implementation of the Directive's requirements, in particular those relating to inspection and control.

This first Commission report provides an overview of the situation in the 15 Member States that belonged to the European Union as of 31 December 2003.[2]

2. IMPLEMENTATION (ART. 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 with measures that ranged from designating blood preparations as medicinal products, requiring additional testing for viruses such as human T-cell lymphotropic virus, introducing nucleic amplification technology for detecting the hepatitis C virus and HIV, to imposing more stringent measures for donor selection, biological control of donations and haemovigilance. Nine of them planned to maintain existing requirements for nine months after 8 February 2005 (Art. 7), in order to give blood establishments additional time to comply with the Directive.

3. OBLIGATIONS ON MEMBER STATES AUTHORITIES

3.1. Blood establishments (Art. 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. Four, however, have more than one – Germany, due to its federal system, has 29; Spain, with its autonomous communities, has 18; and Denmark and Sweden each have two.

The competent authority in 11 of the Member States had designated, authorised, accredited or licensed blood establishments to carry out collection, testing, preparation, storage and distribution activities. Blood establishments in 7 of them had provided the competent authority with information about themselves, the hospital blood banks they supply, as well as

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[1] Directive 2002/98/EC of the European Parliament and of the Council 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 (O.J. L 33, 8.2.2003, p 30).

[2] An overview of the latest state of affairs on certain aspects in relation to Directive 2002/98/EC has been published on the website: http://europa.eu.int/comm/health/ph_threats/human_substance/documents/blood_sum_en.pdf.

details about the responsible person and the quality system in place. Four Member States reported that documentation on the quality system is not always submitted completely.

Six Member States had put in place all provisions for the competent authority to verify blood establishments' compliance with the Directive's requirements and to advise them on which activities could be undertaken and under what conditions.

Blood establishments in 10 Member States were aware that the competent authority's prior approval was needed before any substantial change could be made to their activities. In 9 countries, they were also aware that this authority could suspend or revoke their designation, authorisation, accreditation or licence if inspection and control measures showed non-compliance with the Directive.

3.2. Hospital blood banks (Art. 6)

Hospital blood banks in 7 Member States had been informed of the requirements applicable to them.

3.3. Inspection and control measures (Art. 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. Emergency inspections were carried out when necessary.

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.

In the event of any serious adverse event or reaction or suspicion thereof that could be linked to the quality and safety of blood and blood components, the competent authority must be notified and it must organise inspections and other control measures as appropriate. 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.

4. PROVISIONS FOR BLOOD ESTABLISHMENTS (ART. 9 - 10)

Blood establishments must designate a responsible person with at least the minimum qualifications specified in Article 9.2. Ten Member States comply with the formal academic requirements, however, practical experience was not always required.

The designated person in 5 Member States is responsible for ensuring that every unit of blood or blood components has been collected, tested, processed, stored, and distributed in compliance with the laws in force as well as for providing information to the competent authority in the designation, authorisation, accreditation or licensing procedures.

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. Blood establishments in 6 States have notified the competent authority of the names of the responsible person and others as well as their specific tasks;

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.

5. QUALITY MANAGEMENT (ART. 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. Access to documents was a legislative requirement in 3 Member States and was in compliance with national measures in 4 others.

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. However, the time frame for maintaining these records differs from the 15-year minimum the Directive requires. Three States require records to be kept for 10 years, one stipulates a retention time of 50 years. One Member State indicated that its blood donation centres were not aware that records had to be kept for this length of time.

Eight Member States were aware that the competent authority had to keep records of data received from blood establishments related to their authorisation, provisions for those already existing, inspection and control, the responsible person and adverse events and reactions.

6. HAEMOVIGILANCE (ART. 14 - 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. Eleven Member States indicated that blood establishments had implemented an identification system for each blood donation and each blood unit and its components.

The Directive requires that traceability systems must ensure that each unique donation and type of blood component can be identified and been established in accordance with the requirements set out by the Commission.

For blood and blood components imported from third countries, Member States must ensure that the blood establishment's donor identification system permits an equivalent level of traceability. Four Member States have identification systems to ensure traceability. There were indications that blood components and blood-derived medicinal products were imported from the rare-blood bank in Amsterdam, Nordic countries, Switzerland, and third countries. Two States do not import blood or blood components from third countries.

Nine Member States had taken measures to ensure that the labelling system for the blood and blood components collected, tested, processed, stored, released and/or distributed on its territory complied with the requirements in Annex III.

Ten Member States were aware that data needed for full traceability had to be kept for at least 30 years, although their current national requirements ranged from 10 to 50 years.

7. PROVISIONS FOR QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

7.1. Donors (Art. 16 - 19)

All prospective donors of blood or blood components in the Community must be provided with information about donation and upon their agreement to donate give information related to their identity and their health to the blood establishments.[3] Although these requirements were only adopted through the Comitology procedure (Article 29(b) and (c)) after the reporting date[4], eleven Member States already provided information to donors as normal practice, and 13 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.

Blood establishments are required to document the results of their donor evaluation and testing procedures and report any relevant abnormal findings to the donor. Implementation of these requirements was reported by 11 Member States.

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.

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3 Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components (O.J. L 91, 30.3.2004, p 25).

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7.2. Voluntary and unpaid blood donation (Art. 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.[5]

7.3. Testing of donations (Art. 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.

7.4. Storage, transport and distribution conditions (Art. 22)

Although requirements for storage, transport and distribution conditions for blood and blood components were only adopted through the Comitology procedure (Article 29(e)) after the reporting date[6], 12 Member States already had relevant requirements in place.

7.5. Quality and safety requirements for blood and blood components (Art. 23)

Although the requirements for the quality and safety for blood and blood components were adopted through the Comitology procedure (article 29(f)) after the reporting date[7],7 Member States reported that their blood establishments have to ensure that the quality and safety requirements for blood and blood components meet high standards.

8. DATA PROTECTION (ART. 24)

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.

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5 It is the intention of the Commission to issue a report on the promotion by Member States of voluntary unpaid blood donations in 2006.

6 Commission Directive 2004/33/EC, of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components (O.J. L 91, 30.3.2004, p 25).

7 Commission Directive 2004/33/EC, of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components (O.J. L 91, 30.3.2004, p 25).

9. INFORMATION EXCHANGE, PENALTIES AND TRANSPOSITION

9.1. Information exchange (Art. 25)

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.

9.2. Penalties (Art. 27)

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.

9.3. Transposition (Art. 32)

At the beginning of 2006, 13 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.