Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2000/0323(COD)
Human blood and blood components: quality and safety for the collection, testing, processing, storage and distribution Amending Directive 2001/83/EC 1999/0134(COD) Subject 4.20.04.02 Safety of blood and transfusion	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	DELE EP Delegation to Conciliation Committee		26/08/2002
		PPE-DE NISTICÒ Giuseppe	
	Former committee responsible		
	ENVI Environment, Public Health, Consumer Policy		24/01/2001
		PPE-DE NISTICÒ Giuseppe	
	ENVI Environment, Public Health, Consumer Policy		24/01/2001
		PPE-DE NISTICÒ Giuseppe	
	Former committee for opinion		
	BUDG Budgets	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2476	16/12/2002
	Education, Youth, Culture and Sport	2408	14/02/2002
	Health	2384	15/11/2001
European Commission	Commission DG	Commissioner	
	Health and Food Safety		

Key events

13/12/2000	Legislative proposal published	COM(2000)0816	Summary
12/02/2001	Committee referral announced in Parliament, 1st reading		
11/07/2001	Vote in committee, 1st reading		Summary
11/07/2001	Committee report tabled for plenary, 1st reading	A5-0272/2001	

05/09/2001	Debate in Parliament		
06/09/2001	Decision by Parliament, 1st reading	T5-0443/2001	Summary
15/11/2001	Modified legislative proposal published	COM(2001)0692	Summary
14/02/2002	Council position published	14402/1/2001	Summary
28/02/2002	Committee referral announced in Parliament, 2nd reading		
23/04/2002	Vote in committee, 2nd reading		Summary
23/04/2002	Committee recommendation tabled for plenary, 2nd reading	A5-0141/2002	
11/06/2002	Debate in Parliament		
12/06/2002	Decision by Parliament, 2nd reading	T5-0300/2002	Summary
26/08/2002	Parliament's amendments rejected by Council		
19/09/2002	Formal meeting of Conciliation Committee		
26/09/2002	Report tabled for plenary, 3rd reading	A5-0442/2002	
02/10/2002	Final decision by Conciliation Committee		Summary
04/11/2002	Joint text approved by Conciliation Committee co-chairs	3652/2002	
16/12/2002	Decision by Council, 3rd reading		
17/12/2002	Debate in Parliament		
18/12/2002	Decision by Parliament, 3rd reading	T5-0618/2002	Summary
27/01/2003	Final act signed		
27/01/2003	End of procedure in Parliament		
08/02/2003	Final act published in Official Journal		

Technical information

Procedure reference	2000/0323(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Amending Directive 2001/83/EC 1999/0134(COD)
Legal basis	EC Treaty (after Amsterdam) EC 152-p4
Stage reached in procedure	Procedure completed
Committee dossier	CODE/5/16690

Documentation gateway

Legislative proposal		COM(2000)0816 OJ C 154 29.05.2001, p. 0141 E	13/12/2000	EC	Summary

Economic and Social Committee: opinion, report		CES0717/2001 OJ C 221 07.08.2001, p. 0106	30/05/2001	ESC	
Committee report tabled for plenary, 1st reading/single reading		A5-0272/2001	11/07/2001	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0443/2001 OJ C 072 21.03.2002, p. 0235-0289 E	06/09/2001	EP	Summary
Committee of the Regions: opinion		CDR0066/2001 OJ C 019 22.01.2002, p. 0006	20/09/2001	CofR	
Modified legislative proposal		COM(2001)0692 OJ C 075 26.03.2002, p. 0104 E	15/11/2001	EC	Summary
Council position		14402/1/2001 OJ C 113 14.05.2002, p. 0093 E	14/02/2002	CSL	Summary
Commission communication on Council's position		SEC(2002)0233	26/02/2002	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0141/2002	23/04/2002	EP	
Text adopted by Parliament, 2nd reading		T5-0300/2002 OJ C 261 30.10.2003, p. 0150-0290 E	12/06/2002	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2002)0479	23/08/2002	EC	Summary
Report tabled for plenary by Parliament delegation to Conciliation Committee, 3rd reading		A5-0442/2002	26/09/2002	EP	
Joint text approved by Conciliation Committee co-chairs		3652/2002	04/11/2002	CSL/EP	
Text adopted by Parliament, 3rd reading		T5-0618/2002 OJ C 031 05.02.2004, p. 0160-0176 E	18/12/2002	EP	Summary
Implementing legislative act		32004L0033 OJ L 091 30.03.2004, p. 0025-0039	22/03/2004	EU	Summary
Implementing legislative act		32005L0061 OJ L 256 01.10.2005, p. 0032-0040	30/09/2005	EU	Summary
Implementing legislative act		32005L0062 OJ L 256 01.10.2005, p. 0041-0048	30/09/2005	EU	Summary
Follow-up document		COM(2006)0217	17/05/2006	EC	Summary
Follow-up document		COM(2006)0313	19/06/2006	EC	Summary
Follow-up document		C(2009)8541	03/11/2009	EC	
Follow-up document		COM(2010)0003	19/01/2010	EC	Summary
Follow-up document		COM(2011)0138	23/03/2011	EC	Summary
Follow-up document		COM(2016)0224	21/04/2016	EC	Summary
Follow-up document		SWD(2016)0129	21/04/2016	EC	
Follow-up document		SWD(2016)0130	21/04/2016	EC	

Additional information

European Commission	EUR-Lex

Final act

Directive 2002/98
OJ L 033 08.02.2003, p. 0030-0040 Summary

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

PURPOSE : to increase public confidence in the safety of the blood and blood products administered for therapy by establishing Community provisions ensuring the quality and safety of blood and its components whatever the intended purpose. CONTENT : the aims of this proposal are to: - close existing gaps in Community legislation with regard to the setting of standards for the quality and safety of blood and blood components used in therapy; - strengthen requirements related to the suitability of blood and plasma donors and the screening of donated blood in the European Community; - establish at Member State level requirements for establishments involved in the collection, testing, processing, storage and distribution of whole blood and blood components, as well as national accreditation and monitoring structures; - to lay down provisions at Community level for the formulation of a quality system for blood establishments (QSBE); - lay down common provisions at Community level for the training of staff directly involved in the collection, testng, processing, storage and distribution of whole blood components, without prejudice to existing legislation; - establish rules for ensuring the traceability of whole blood and blood components from donor to patient, which are valid through the Community.?

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

The committee adopted the report by Giuseppe NISTICO (EPP-ED, I) broadly approving the proposal under the codecision procedure (1st reading), subject to a large number of mainly technical amendments. MEPs welcomed the proposal but called for blood establishments to ensure that all blood donations were voluntary and non-remunerated, as a means of guaranteeing the safety of blood supplies. They argued that scientific data had shown that blood products from voluntary unpaid donors were far less likely to transmit infectious diseases than blood from paid donors. Member States were also urged to ensure that blood and blood products imported into the EU from third countries met the requirements laid down in the directive. The report made a number of practical recommendations, such as ensuring that a medical examination, consisting of at least an interview and a blood pressure check by a doctor, was carried out before any donation of blood or blood components in order to assess the eligibility of donors. It also emphasised the need to ensure prompt care and full insurance cover for injury to donors when giving blood. Other points raised in the report included the need for the directive to cover the quality and safety of blood derivatives (in addition to blood and blood components) and the need to provide for penalties, such as withdrawal or temporary suspension of accreditation, where accredited blood establishments failed to comply with the prescribed standards.

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

In approving this report drafted by Mr Giuseppe NISTICO (EPP-ED, I), the European Parliament adopted a large number of technical amendments relating to the collection, testing, processing, storage, and distribution of human blood and blood components. (Please refer to the previous text).?

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

The Commission has made a number of amendments to its original proposal bearing in mind parliamentary amendments proposed following the first reading. The main amendments have been grouped into three categories namely, scope of the Directive, establishment of technical standards and voluntary, unpaid donation. Concerning the first category, scope of the Directive, this has now been extended to the collection and testing of blood and blood components for all purposes, including the manufacturing of medicinal products. Council Directive 89/381/EEC has been amended accordingly. In terms of the establishment of technical standards new solutions have been introduced as far as technical implementing provisions are concerned. Rather than including a list of technical annexes to the Directive, the Commission shall develop and up-date the technical implementing provision through the use of a regulatory committee procedure. Lastly, a new amendment has been included which urges Member States to encourage the voluntary and unpaid donation of blood and blood components.?

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

The Council has taken up two thirds of the amendments proposed by the EP and accepted by the Commission even if in many cases not literally but in substance or in principle. The Council carried out a relatively extensive revision of the text of the proposal in order to better structure and clarify its provisions and to address more fully and systematically certain key issues of particular concern to the Member States. The Council introduced the following main changes: - Scope: there is a general agreement that the Directive should apply also to collection and testing of starting materials for medicinal products; - Hospital blood banks: the Council introduced a definition of hospital blood banks and an Article specifying which provisions of the Directive would apply to them; - Designation, authorisation, accreditation or licensing of blood establishments: the Council extended the concept of accreditation to cover all different modalities of recognition of a blood establishment existing in the Member States; - Responsible person and personnel: the Council considered that the question of appropriate qualifications and timely, relevant and regularly updated training is to be dealt with according to the principle of subsidiarity; - Voluntary unpaid donation : No provision on this issue was included in the Commission's proposal, as the Commission considered that such a provision is not compatible with the Treaty. The Council included instead a provision for the encouragement of voluntary and unpaid blood donations by Member States. The Council has added a provision on information thereon to the other Member States and the Commission as well as a recital referring inter alia to the Council of Europe's efforts in this area. Furthermore, the Council has added an explicit reference to the possibility for a Member State to maintain or implement more stringent protective measures, and in particular, to introduce requirements for voluntary unpaid donations, including the prohibition or restriction of imports of blood and blood components which do not satisfy such requirements. - Structure and content: the Council considered it useful to maintain a number of the Annexes originally proposed by the Commission, albeit in a simplified form, in order to set key reference points defining the framework for the implementation of some important provisions of the Directive which constitutes the basis of the quality and safety system at Community level. Lastly, the Council deleted the Article on clinical tests to be carried out before blood donation and new recitals were added, clarifying certain rpovisions relating to autologous transfusion, hospital blodd banks, quality system and traceability of imported blood and blood components.?

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

The Commission considers the Common Position a good compromise, which takes on board most of the key amendments of the European Parliament, and is also in line with the Amended Proposal on all essential questions. However, the Commission regrets that the Council decided not to accept a number of amendments which aim to strengthen the protection of donors and patients and which aim to clarify administrative provisions of the Directive. The Commission maintains that these provisions would strengthen and complement the Directive, and are justified under the framework of Article 152 of the EC Treaty. However, as most of these standards are already fixed in national legislation in Member States, or can be established afterwards by the Commission using the"comitology" regulatory procedure, on balance the Commission is able to accept the approach put forward in the Common Position. The Commission made three statements for the minutes, which are annexed to this Communication. In its first statement, it confirms its intention to analyse actions taken to encourage voluntary and unpaid donations with a view to spreading best practices. The second statement refers to the views of the Commission regarding two possibilities for implementing a traceability system. The third statement indicates that the Commission will review a labelling requirement listed in Annex III.?

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

The committee adopted the report by Giuseppe NISTICO (EPP-ED, I) amending the Council's common position under the second reading of the codecision procedure. It reinstated, wholly or in part, some amendments adopted by Parliament at first reading which had not been taken up by the Council. These proposed a number of definitions, including "adverse event", "adverse reaction", "haeomovigilance" and "inspection". The committee also wanted haemovigilance data to be kept for at least 30 years. A key amendment reinstated from first reading proposed a definition of "voluntary unpaid blood donation". The amendment stipulated that this would mean the donation of blood or blood components by a person of his/her own free will and without receiving payment in cash or in kind in return which could be considered a substitute for money. The committee said, however, that small tokens, gratuities, refreshments and the reimbursement of direct costs and direct travel expenses should be allowed, as should time off work reasonably required for donation and travel. Another amendment stipulated that the 'responsible person' at the blood collecting establishment should be a doctor with a specialisation in a relevant field, e.g. haematology. Lastly, the committee called for Member States to report to the Commission every two years on the measures taken under the directive. ?

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

By adopting this draft recommendation for second reading by Mr Giuseppe NISTICO (EPP-Ed, I), the European Parliament approved the common position in principle subject to some amendments. The Parliament proposes to introduce a number of definitions, including "adverse event", "adverse reaction", "haeomovigilance" and "inspection". It also wants haemovigilance data to be kept for at least 30 years. An amendment was adopted which enables Member States to introduce requirements for voluntary unpaid donations, which include the prohibition, and restriction of imports of blood and blood components to ensure a high level of health protection. In addition, Parliament adopted another amendment demanding that a medical examination, comprising at least an interview and blood pressure check by a doctor, shall be carried out before any donation of blood or blood components. The doctor shall be responsible for giving donors the necessary information and gathering information from donors, and shall, on the basis thereof, assess the eligibility of donors. They shall take steps to ensure that tests are carried out in conformity with the latest scientific and technical procedures that reflect current best practices. They must also take advantage of scientific advances in the detection, inactivation and elimination of pathogens which can be transmitted via transfusion. Lastly, the Parliament called for Member States to report to the Commission every two years on the measures taken under the directive.?

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

The Commission is in favour of the eight amendments to the Common Position voted by the European Parliament. These amendments aim to: - introduce a definition of 'inspection'; - require haemovigilance data be maintained for at least 30 years (the Commission finds this acceptable even though onerous. A less onerous but also effective alternative could be to limit the application of the 30-year time period only to traceability data (a major component of haemovigilance data); - require Member States to report on voluntary unpaid donations to the Commission every three years; - require that blood-donation testing is conducted in line with procedures reflecting best practices as defined, reviewed and updated in consultation with experts; - provide for meetings of the Commission with delegations of experts; - provide that voluntary unpaid donations ensure a high level of health protection; - oblige an examination of donors; - present a definition of 'haemovigilance'.?

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

The Conciliation Committee reached agreement on a joint text for the directive. The negotiations had centred on the one remaining point of dispute, namely, the examination of blood donors. Parliament had proposed that this should be done by a "doctor", whereas the Council considered that a "health professional" would be a sufficient requirement. Eventually both Parliament and Council agreed that a "qualified health professional" should be responsible for the examination of donors.?

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

The European Parliament adopted a resolution approving the joint text by the Conciliation Committee. (Please refer to the document dated 08/11/02).?

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

PURPOSE : to establish high standards of quality and safety for human blood and blood components. COMMUNITY MEASURE : Directive 2002/98/EC of the European Parliament and of the Council 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. CONTENTS : the safety requirements of proprietary industrially prepared medicinal products derived from human blood or plasma were ensured through Directive 2001/83/EC. The specific exclusion of whole blood, plasma and blood cells of human origin from that directive, however, has led to a situation whereby their quality and safety, in so far as they are intended for transfusion and not processed as such, are not subject to any binding Community legislation. This Directive, therefore, contains provisions to ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain in all Member States. It applies to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for transfusion. The main provisions of the Directive are as follows: - Member States must designate the competent authority responsible for implementing the provisions of the Directive. Member States may introduce more stringent protective measures, including requirements for voluntary and unpaid donations; - activities relating to collection and testing, preparation, storage and distribution must be undertaken only by the blood establishments which have been authorised by the competent authority; - the competent authority must organise inspection and control measures at least every two years. Officials from the competent authority must be empowered to take samples and examine documents; - blood establishments must designate a responsible person to ensure that every unit of blood or blood components has been collected, tested, processed, stored and distributed in compliance with the law. The responsible person must fulfil prescribed minimum conditions of qualification; - each blood establishment must establish a quality system based on the principles of good practice. They must also maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms. Records of information must be kept for a minimum of 15 years; - there are provisions to ensure that blood can be traced from donor to recipient and vice versa. Data needed for full traceability must be kept for at least 30 years; - adverse events must be notified to the competent authority and blood associated with the event must be withdrawn; - there must be evaluation procedures for all donors; - a qualified health professional is responsible for examining donors and assessing eligibility; - Member States must encourage voluntary and unpaid donations and report on the measures taken to do so two years after the Directive enters into force; - donations must be tested in conformity with the Directive. DATE OF TRANSPOSITION : 08/02/05. ENTRY INTO FORCE : 08/02/03.?

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

ACT : Commission Directive 2004/33/EC implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components. CONTENT : in order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements. This Directive lays down those technical requirements, which take account of Council Recommendation 98/463/EC of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community, certain recommendations of the Council of Europe, the opinion of the Scientific Committee for Medicinal Products and Medical Devices, the monographs of the

European Pharmacopoeia, particularly in respect of blood or blood components as a starting material for the manufacture of proprietary medicinal products and recommendations of the World Health Organisation (WHO), as well as international experience in this field. ENTRY INTO FORCE : 19/04/2004. IMPLEMENTATION : 08/02/2005.?

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

LEGISLATIVE ACT : Commission Directive 2005/61/CE implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events.

CONTENT : In order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements dealing with traceability, a Community procedure for notifying serious adverse reactions and events and the notification format. Notification of suspected serious adverse reactions or serious adverse events should be submitted to the competent authority as soon as known. This Directive therefore establishes the notification format defining the minimum data needed, without prejudice to the faculty of Member States to maintain or introduce in their territory more stringent protective measures.

The Directive lays down those technical requirements, which take account of: Council Recommendation 98/463/EC on the suitability of blood and plasma donors and the screening of donated blood in the European Community; Directive 2001/83/EC on the Community code relating to medicinal products for human use; Commission Directive 2004/33/EC implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components, and certain recommendations of the Council of Europe.

Accordingly, blood and blood components imported from third countries, including those used as starting material or raw material for the manufacture of medicinal products derived from human blood and human plasma, intended for distribution in the Community, should meet equivalent Community standards and specifications relating to traceability and serious adverse reaction and serious adverse event notification requirements as set out in this Directive.

The Directive also determines common definitions for technical terminology in order to ensure the consistent implementation of Directive 2002/98/EC.

ENTRY INTO FORCE : 21/10/2005.

TRANSPOSITION : 31/08/2006.

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

LEGISLATIVE ACT : Commission Directive 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments.

CONTENT : In order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements including Community standards and specifications with regard to a quality system for blood establishments. A quality system for blood establishments must embrace the principles of quality management, quality assurance, and continuous quality improvement, and should include personnel, premises and equipment, documentation, collection, testing and processing, storage and distribution, contract management, non-conformance and self-inspection, quality control, blood component recall, and external and internal auditing.

This Directive lays down those technical requirements, which take account of: Council Recommendation 98/463/EC on the suitability of blood and plasma donors and the screening of donated blood in the European Community; Directive 2001/83/EC on the Community code relating to medicinal products for human use; Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use; Commission Directive 2004/33/EC implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components, certain recommendations of the Council of Europe, the monographs of the European Pharmacopoeia, particularly in respect of blood or blood components as a starting material for the manufacture of proprietary medicinal products, recommendations of the World Health Organisation, as well as international experience in this field.

The Directive provides that guidance on good practice must be developed by the Commission to support the quality system requirements for blood establishments taking fully into account the detailed guidelines referred to in Article 47 of Directive 2001/83/EC so as to ensure that the standards required for medicinal products are maintained.

Blood and blood components imported from third countries, including those used as starting material or raw material for the manufacture of medicinal products derived from human blood and human plasma intended for distribution in the Community, must meet equivalent Community standards and specifications relating to a quality system for blood establishments as set out in this Directive.

The Directive provides that a quality system is to be applied for any blood and blood components circulating in the Community and that Member States must ensure that for blood and blood components coming from third countries, there is a quality system in place for blood establishments in the stages preceding importation equivalent to the quality system provided under this Directive.

Finally, the Directive also determines common definitions for technical terminology in order to ensure the consistent implementation of Directive 2002/98/EC.

ENTRY INTO FORCE : 20/10/2005.

TRANSPOSITION : 31/08/2006.

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

In accordance with Directive 2002/98/EC on setting standards relating to human blood and blood components, this report summarises the measures taken by the Member States to encourage voluntary unpaid donations and identifies the measures the Commission intends to take in order to promote self-sufficiency in the EU through voluntary unpaid donations. This is a comprehensive report examining and analysing in detail measures taken in the Member States.

Voluntary and unpaid donations: Voluntary unpaid donations have a long tradition in many of the EU Member States, notably France, Luxembourg, Northern Ireland, Slovenia, the former Czechoslovakia, Belgium, Denmark, the UK, Finland and the Netherlands. The report notes that interpretation of the principle of voluntary and unpaid donations varies across the Member States. This is illustrated in the level of expenses covered or time given off work to donate blood.

Promotion of voluntary unpaid blood donations: The promotion of voluntary unpaid blood donations is vital for donations to succeed. Activities vary and include publications such as guides or advertising to specific target groups and student awareness programmes. Events include ?World Blood Donor Day?, which generated a lot of publicity. Student awareness campaigns have been developed in the UK, with Scotland designing an extensive school and university recruitment programme. Ireland produced an educational video and Latvia provided explanations on the processing of blood and donor requirements. The Report finds that different initiatives exist to promote the principle of voluntary and unpaid donations, using techniques as diverse as marketing actions, student programmes and e-initiatives. Some of the actions are related to the promotion of donations, others are more specific and relate to the promotion of unpaid donations. The Commission suggests there is a growing need to determine best practices.

Commission Action: The Commission will continue to encourage Member States to promote voluntary, unpaid donations. Under the Community Health Programme it will commission a European wide study to determine best practices for promoting voluntary and unpaid donations. Lastly, the Commission intends to continue discussions on EU blood donation self-sufficiency.

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

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.

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

The Commission presents its report on the application of Directive 2002/98/EC 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. Three Commission implementing Directives supplement the provisions of Directive 2002/98/EC: Commission Directive 2004/33/EC as regards certain technical requirements for blood and blood components; Commission Directive 2005/61/EC as regards traceability requirements and notification of serious adverse reactions and events; and Commission Directive 2005/62/EC as regards Community standards and specifications relating to a quality system for blood establishments. Member States may maintain or introduce more stringent protective measures than those of the Directive 2002/98/EC, provided that they comply with the provisions of the Treaty. For instance, 26 Member States apply additional testing requirements to take into account their specific national epidemiological situation. No Member State indicated particular problems in intra-community exchanges of blood and blood components due to more stringent measures in other Member States.

This report is based on the replies to questionnaires on transposition and implementation that Member States send to the Commission on a yearly basis upon request. All Member States except Estonia have submitted a report on the activities undertaken in relation to the provisions of the Directive in 2008.

The Commission reports that overall, the implementation of the Directives is satisfactory. This concerns in particular the following measures:

- the requirement to designate a competent authority or authorities;
- the establishment of inspection systems and control measures;
- haemovigilance systems to report, investigate, register and transmit information about serious adverse events and reactions; and testing requirements.

The degree of implementation of some other measures suggests that further efforts and actions by Member States are needed. This concerns:

1) the finalisation of the accreditation/designation/authorisation/licensing process in respect of each individual blood establishment: under Article 5(1), Member States must ensure that activities relating to the collection and testing of human blood and blood components, whatever the intended purpose, and to their preparation, storage and distribution when intended for transfusion, are undertaken only by the blood establishments which have been designated/authorised/accredited/licensed by the competent authority for that purpose.

As of December 2008, 21 Member States had completed the designation/authorisation/accreditation/licensing of all existing blood establishments in their respective territories (Belgium, Czech Republic, Denmark, Germany, Ireland, Greece, Spain, France, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, the Netherlands, Austria, Poland, Slovakia, Finland, Sweden and the United Kingdom). This means that 775 blood establishments (?BE?) were already authorised in the EU at the end of 2008. Bulgaria (5 BE), Malta (1 BE), Portugal (24 BE) Romania (42 BE) and Slovenia (3 BE) are currently finalising the designation/authorisation/accreditation/licensing process and expect to complete this work in the course of 2009;

2)the carrying out of inspections in all Member States: under Article 8(1), Member States must ensure that the competent authority organises inspections and appropriate control measures in blood establishments to check that the requirements of the Directive are complied with. All

Member States except Cyprus have inspection and control systems in place. 22 Member States conducted regular inspections of blood establishments in 2008.

In four Member States inspections of blood establishments are performed by regional or autonomous communities? services (Germany, Spain, Italy and Poland). In the rest of the Member States, inspections are performed by the central competent authority. In eleven Member States, the authority granting the designation/authorisation/ accreditation/licensing is the same as the one performing inspections (Czech Republic, Denmark, Germany, Ireland, Greece, Latvia, Luxembourg, Hungary, Finland, Sweden and the United Kingdom);

3) the annual report on adverse events and reactions for the Commission: Member States must submit an annual report to the Commission on the adverse reactions and events notified to the competent authority or authorities in accordance with Article 8 of Directive 2005/61/EC. The annual report on haemovigilance covering the period from 1 January to 31 December 2007 was submitted to the Commission by 23 Member States (Belgium, Bulgaria, Czech Republic, Germany, Denmark, Estonia, Greece, Spain, France, Hungary, Ireland, Italy, Lithuania, Latvia, Malta, the Netherlands, Poland, Portugal, Romania, Slovenia, Sweden, Finland and the United Kingdom). The competent authority or authorities should organise inspections and carry out control measures as appropriate whenever there is a serious adverse reaction or event. Four inspections were conducted in this respect during 2008.

Furthermore, the collection of reports on blood establishments? activity in the preceding year is a good practice that should be encouraged as it is a valuable source of information for both regulators and citizens.

The Commission is working with the Member States to help them develop operational solutions in response to the remaining challenges.

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

In accordance with the requirements of Directive 2002/98/EC the Commission presents its 2nd report on voluntary and unpaid donation of blood and blood components. The report is based on the Members States' responses to a report template on voluntary and unpaid donation of blood and blood components, which was sent to the competent authorities for blood and blood components during the spring of 2010. All Member States submitted a report to the Commission, together with Croatia and Norway.

This second report aims to provide an overview of the practice of voluntary and unpaid donation of blood and blood components in the EU, focusing on legislative provisions/guidelines and policies; incentives; promotion, and collection and supply. It should, however, be noted that although the report touches on areas related to pharmaceuticals, its focus is on blood and blood components.

The report shows that Member States overall comply with Directive 2002/98/EC, requiring Member States to take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensure that blood and blood components are in so far as possible provided from such donation. Largely in line with the findings of the first report on voluntary and unpaid blood donation (issued 2006), this report shows that legislative provisions and guidelines on voluntary and unpaid blood donation are well established across the EU. All but one of the 29 reporting countries have such provisions in place. Ireland has no legislative provisions or guidelines governing the principle of voluntary and unpaid donation of blood and blood components.

Most reporting countries have some form of incentive structures for blood donors, such as refreshments, small token and reimbursement of travel costs. Several countries also offer blood donors employed in the public sector time off work. The study indicates that there are no major differences in incentives for whole blood donors and apheresis (plasma, platelets?) donors. 27 out of the 29 reporting countries have undertaken some form of measures to promote voluntary and unpaid blood donation, such as awareness raising and information campaigns.

Concerning collection and supply of blood and blood components, the report shows that collectors/suppliers of whole blood and plasma are predominately public in the EU, Norway and Croatia. About half of the reporting countries have the capacity for plasma fractionation. In these countries, actors in the field of plasma fractionation are mainly private (71%). With regards to supply, the competent authorities for blood and blood components report relatively limited shortages of blood and blood components, ranging from around 14% (for whole blood) to 0% for white blood cells. About 75% of the countries have policies in place to contain or ensure the effective clinical use of blood, as well as to promote self-sufficiency of blood and blood components.

Based on the findings of the report, the Commission will now, together with the Member States, reflect on the potential need for further measures, keeping in mind that the Commission's mandate is limited to quality and safety of blood and blood components.

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

The Commission presented a report on the implementation of the Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC setting standards of quality and safety for human blood and blood components.

This overarching report is a summary, drawing from the replies to questionnaires that the Commission sent to Member States in 2012 (verification of the completeness of transposition), 2013 (implementation survey) and 2014 (implementation of the VUD principle) and follows up on the Report in 2006 and the Commission Communication in 2010, as well as on the two Reports on the application of the principle of VUD for blood and blood components issued in 2006 and 2011.

Implementation of the EU blood legislation: the report revealed an overall adequate level of application of the current quality and safety requirements of the EU blood legislation. The implementation of the EU blood legislation by Member States is considered adequate and the legislation has resulted in the establishment of a network of competent authorities that oversee the field through authorisation, inspection, and vigilance.

Significant progress has been made in many areas, often through the active support of Commission funded projects and other initiatives:

- since 2003, a number of projects have been funded under the multi-annual programmes for Union action in the field of health addressing the area of blood and blood components. These actions brought improvements in areas of common interest such as

quality management and inspection and donor selection and included training courses for Member States Competent Authorities and their inspectors;

- as regards the risk of transmission of communicable diseases thorough blood and blood components, the collaboration with ECDC proved extremely valuable. In addition to providing regular updates during the bi-annual meeting of the blood expert sub-group on the epidemiological situation relevant to the blood sector, the development of risk assessments (e.g. for HTLV, malaria, dengue and chikungunya) and preparedness plans (e.g. for WNV outbreaks) provide a valuable contribution to policy and decision making in this sector at both national and EU level.;
- the Commission developed, in close cooperation with the Member States, a Rapid Alert Platform for Blood (RAB) which facilitates web-based communications between Member States in case of alerts with relevance in two or more Member States.

However, the report also points to some gaps and difficulties in relation to the application and enforcement of the existing provisions (e.g. definitions, provisions for donor safety, inspections framework), some due to different approaches taken by the Member States and others due to technological advances and changing risks observed since the legislation was adopted.

Whilst overall Member States seem to correctly implement the provisions concerning inspections, a number of Member States reported difficulties related to staffing, which makes compliance with the required 2-year inspection interval challenging. Several Member States expressed interest in applying instead a risk-based prioritisation planning for inspections. There is diversity between Member States in organisation (e.g. desk-based versus on-site), and outcome (i.e. classification and follow-up of deficiencies) of inspections. Also the inspection approaches vary significantly towards mobile and satellite sites, hospital blood banks, plasma collection centres and potential third country players.

The Commission will follow-up with Member States to address situations where the legislation might not have been fully or correctly implemented.

Voluntary and unpaid donation (VUD): the VUD survey shows that Member States overall comply with Article 20 of Directive 2002/98/EC requiring them to take the necessary measures to encourage VUD. However, Member States' perceptions of what is considered compensation and incentive vary.

The maximum reported values of compensation and incentives are around EUR 25-30 per donation while the reported values of refreshments and small tokens are between EUR 1 and EUR 10 per donation. Reimbursement of travel costs can cover the actual costs or be a standard lump sum. Time off work varies from less than half a day to up to two days. Some countries foresee compensation for loss of earnings in some circumstances.

Less than half of the countries reported having national guiding principles to define what form of compensation or other practice is allowed and under which circumstances.

Quality and safety of blood and blood components: safety and quality of the blood supply is an important issue for EU citizens, with 56% of respondents to the Eurobarometer survey on Blood and Cell and Tissue Donation citing the risk of contracting a disease as a major concern when accepting donated substances.

As regards the selection of eligible donors, Member States expressed interest in an increased level of donor protection and in an overview of additional national eligibility criteria in order to increase transparency and mutual trust in exchanges.

As regards testing and inactivation technologies, the report noted that the minimum serological testing for human immunodeficiency virus (HIV) 1/2, hepatitis B and hepatitis C carried out for every whole blood and apheresis donation are performed by authorised laboratories. Member States can add tests for specific components or epidemiological situations. They reported conducting additional tests for syphilis, malaria, hepatitis A, hepatitis E and Parvovirus B19.

Sixteen countries report having pathogen inactivation technologies in place. Inactivation techniques are mainly used for plasma although pathogen inactivation of platelets is likely to be more common going forward. Member States also highlight the need for good validation of testing technologies, and also pathogen inactivation technologies, in order to achieve an effective level of safety and quality.

In conclusion, the gaps and difficulties identified may suggest that a further in-depth evaluation might be useful. The Commission will consider the need for an evaluation in order to assess the relevance, effectiveness, efficiency, coherence and the EU added value of Directive 2002/98/EC and its implementing Directives.