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

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

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1. INTRODUCTION

Article 26 of Directive 2002/98/EC[1] requires Member States to submit to the European Commission, commencing on 31 December 2003 and every three years thereafter, a report on the activities undertaken in relation to the provisions of the Directive, including an account of the measures taken in relation to inspection and control. The Commission is required to transmit these reports to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, and to provide them with a report on the implementation requirements of the Directive, in particular as regards inspection and control.

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. Iceland, Lichtenstein, Norway, Switzerland, Croatia, the Former Yugoslav Republic of Macedonia and Turkey also submitted a report.

2. RESULTS

2.1. Implementing Directives

Directive 2002/98/EC provides that specific technical requirements should be decided in accordance with the 'Comitology' procedure. In this respect, three Commission Directives supplement the provisions of Directive 2002/98/EC:

- Commission Directive 2004/33/EC of 22 March 2004 as regards certain technical requirements for blood and blood components[2].

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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 blood and blood components (OJ L 33, 8.2.2003, p. 30).

2 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 (OJ L 91, 30.3.2004, p. 25).

- Commission Directive 2005/61/EC of 30 September 2005 as regards traceability requirements and notification of serious adverse reactions and events[3].

- Commission Directive 2005/62/EC of 30 September 2005 as regards Community standards and specifications relating to a quality system for blood establishments[4].

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 (for more information, see section 2.6.2).

No Member State indicated particular problems in intra-community exchanges of blood and blood components due to more stringent measures in other Member States.

2.2. Designation of competent authorities (Art. 4 of Directive 2002/98/EC)

Under Article 4(1), Member States must designate the competent authority or authorities responsible for implementing the requirements of the Directive. All Member States have designated a competent authority in accordance with this provision.

2.3. Obligations on Member States' authorities (Art. 5-8 of Directive 2002/98/EC)

2.3.1. Designation, authorisation, accreditation or licensing of blood establishments (Art. 5)

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

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[3] Commission Directive 2005/61/EC of 30 September 2005 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 (OJ L 256, 1.10.2005, p. 32).

[4] Commission Directive 2005/62/EC of 30 September 2005 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 (OJ L 256, 1.10.2005, p. 41).

designation/authorisation/accreditation/licensing process and expect to complete this work in the course of 2009.

The competent authority or authorities may suspend or revoke the designation/authorisation/accreditation/licensing of a blood establishment if it is found to no longer comply with the requirements of the Directives. During 2008, Germany, the Netherlands and Slovakia revoked or suspended initial approvals given to some blood establishments for various reasons such as incorrect donor testing, lack of appropriate donor interview facilities and questionnaires, and general lack of compliance with applicable regulations.

2.3.2. Hospital blood banks (Art. 6)

Article 6 stipulates that Articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 apply to hospital blood banks. Sixteen Member States have specific rules governing hospital blood banks in addition to the provisions covered by the above-mentioned articles (Belgium, Czech Republic, Ireland, Greece, Spain, France, Italy, Latvia, Luxembourg, Hungary, Austria, Poland, Romania, Slovenia, Finland and the United Kingdom). The specific measures relate to authorisation of hospital blood banks and to inspection, quality management and reporting systems. Most Member States have also created specific schemes for cooperation with blood establishments.

According to the Member States' reports, as of 31 December 2008 there were around 4 133 hospital blood banks in the EU. In most Member States hospital blood banks are part of the hospital facilities, while in others, like Italy, they are considered as blood establishments.

2.3.3. Inspection and control measures (Art. 8)

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. Twenty-two 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).

2.3.3.1. Inspection of hospital blood banks

Although not specifically required by the Directive, 20 Member States have systems in place for inspecting hospital blood banks (Belgium, Czech Republic, Denmark, Germany, Ireland, Greece, Spain, France, Italy, Latvia, Luxembourg, Hungary, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Sweden and the United

Kingdom). In most of them, hospital blood banks are inspected in the same way as blood establishments; this is the case of the Czech Republic, Denmark, Germany, Greece, Ireland, Italy, Latvia, Hungary, Romania, Sweden and the United Kingdom.

In six Member States, the inspection of hospital blood banks is performed by regional services (Bulgaria, Greece, Spain, France, Austria and Poland).

In many cases, hospital blood bank inspections are performed by independent scientific societies or transfusion centres, or as part of the hospital facilities general inspections which are performed by other competent authorities.

2.4. Quality management (Art. 11-13 of Directive 2002/98/EC)

2.4.1. Quality system for blood establishments (Art. 11)

Under Article 11(1), Member States must take all necessary measures to ensure that each blood establishment sets up and maintains a quality system for blood establishments based on principles of good practice.

The minimum standards and specifications relating to a quality system for blood establishments were adopted by Commission Directive 2005/62/EC.

Article 2 of Directive 2005/62/EC provides that good practice guidelines are to be developed by the Commission in accordance with the 'Comitology' procedure for the interpretation of the Community standards and specifications established in the annex to the Directive.

The Commission is currently working on the development of such guidelines.

2.4.2. Record keeping (Art. 13)

Under Article 13(1), Member States must ensure that blood establishments maintain records of: the preceding year's activity; testing performed; information provided to donors; information obtained from donors; and information regarding the suitability of blood and plasma donors and the screening of donated blood.

As a good practice, 22 Member States receive annual reports from blood establishments on the previous year's activities in accordance with Annex II to Directive 2002/98/EC (Belgium, Bulgaria, Czech Republic, Denmark, Germany, Ireland, Greece, Spain, France, Italy, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia and Finland). Twelve Member States have made the reports public through their web pages on a voluntary basis (Denmark, Germany, Spain, France, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Slovenia, Slovakia and Finland).

2.5. Haemovigilance (Art. 14-15 of Directive 2002/98/EC)

Under Article 14(1), Member States must ensure that blood establishments implement a system for identifying each single blood donation and each single blood unit and components thereof, enabling full traceability to the donor as well as to the transfusion and the recipient thereof.

Under Article 15, Member States must ensure that any serious adverse events[5] (accidents and errors) related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious adverse reactions[6] observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components, are notified to the competent authority,

All Member States, except Cyprus and Bulgaria, have a system in place for notifying serious adverse events and reactions to the competent authority or delegated body.

In some Member States haemovigilance systems are linked to other national vigilance systems:

- vigilance systems for human tissues, cells or organs in 13 Member States;
- the pharmacovigilance system in 12 Member States;
- the medical devices vigilance system in 15 Member States;
- the communicable diseases vigilance system in 15 Member States.

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.

2.6. Provisions for quality and safety of blood and blood components (Art. 16-23 of Directive 2002/98/EC)

2.6.1. Voluntary and unpaid blood donation (Art. 20)

Under Article 20, Member States must take the necessary measures to encourage voluntary and unpaid donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations. Member States must regularly submit reports on these measures to the Commission. On the basis of

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[5] According to Article 3(g) of Directive 2002/98/EC, 'Serious adverse event' means any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients, or which results in, or prolongs, hospitalisation or morbidity.

[6] According to Article 3 (h) of Directive 2002/98/EC, 'Serious adverse reaction' means an unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

these reports the Commission will inform the European Parliament and the Council of any necessary measures it intends to take.

The latest Commission report to the European Parliament and the Council is available on the Commission website[7].

2.6.2. Testing of donations (Art. 21)

Under Article 21, blood establishments must ensure that each donation is tested in conformity with the requirements of the Directive. In this respect, all Member States comply with the minimum testing requirements as laid down in the Directive.

Some Member States apply other tests in addition to those established as minimum requirements in the Directive, in particular:

- Anti-HBc testing[8]: Nine Member States (Germany, France, Lithuania, Luxembourg, Hungary, Malta, Portugal, Slovakia and Sweden).
- NAT HBV testing[9]: Thirteen Member States (Denmark, Greece, Spain, France, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal Slovenia and Finland).
- NAT HCV testing[10]: Eighteen Member States (Belgium, Denmark, Germany, Ireland, Greece, Spain, France, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Poland, Portugal, Slovenia, Finland and the United Kingdom).
- Ag HIV testing[11]: Ten Member States (Bulgaria, Czech Republic, Greece, Italy, Cyprus, Luxembourg, Portugal, Slovenia, Slovakia and Finland).
- NAT HIV1 testing[12]: Seventeen Member States (Belgium, Denmark, Germany, Ireland, Greece, Spain, France, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Poland, Portugal, Slovenia and Finland).
- *Treponema Pallidum*[13] testing: Twenty-two Member States (Belgium, Bulgaria, Czech Republic, Germany, Spain, France, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Sweden and the United Kingdom).
- HTLV testing[14]: Nine Member States (Denmark, Greece, France, Luxembourg, the Netherlands, Romania, Portugal, Sweden and the United Kingdom).

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7 http://ec.europa.eu/health/ph_threats/human_substance/documents/blood_com_0217_en.pdf.
8 Testing for presence of Hepatitis B antibodies.
9 Nucleic acid amplification technique for testing Hepatitis B.
10 Nucleic acid amplification technique for testing Hepatitis C.
11 Testing for presence of HIV antigens.
12 Nucleic acid amplification technique for testing HIV1.
13 Bacteria generally acquired by close sexual contact giving rise to congenital syphilis.
14 Human T-lymphotropic virus.

2.7. Import/export (Art. 14 of Directive 2002/98/EC, Art. 7 of Directive 2005/61/EC, Art. 2(3) of Directive 2005/62/EC)

Under Article 14(1) of Directive 2002/98/EC, Member States must ensure that, with regard to blood and blood components imported from third countries, the donor identification system to be implemented by blood establishments permits an equivalent level of traceability.

Under Article 7 of Directive 2005/61/EC, Member States must ensure that third countries' blood establishments have in place a system for notification of serious adverse events and reactions equivalent to that of the EU Member States.

Under Article 2(3) of Directive 2005/62/EC, Member States must ensure that for blood and blood components imported from third countries and intended for use or distribution in the Community, there is a quality system for blood establishments in the stages preceding importation equivalent to that provided for in Commission Directives 2005/61/EC and 2005/62/EC.

(a) Import

Twenty-five Member States have clear rules in place for the authorisation and control of the import of blood and blood components for transfusion and fractionation from EU Member States and third countries (Belgium, Bulgaria, Czech Republic, Denmark, Germany, Ireland, Greece, Spain, France, Italy, Cyprus, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland, Sweden and the United Kingdom).

The rules are either part of the implementing legal measures or are established in separate protocols. In the majority of Member States imports are approved by the competent authorities. In the other Member States, blood establishments are responsible for authorising and verifying the equivalence of standards for quality and safety of blood and blood components as well as of traceability requirements. Ten Member States use bilateral agreements for assuring equivalent standards of quality and safety. Only one Member State performs inspections in third countries before authorising the importation of blood or blood components.

(b) Export

Seventeen Member States have rules in place for the authorisation and control of the export of blood and blood components for transfusion or fractionation to EU Member States or third countries (Bulgaria, Czech Republic, Denmark, Germany, Spain, France, Italy, Lithuania, Hungary, the Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia, Sweden and the United Kingdom). In most Member States, the competent authorities are responsible for ensuring that exports comply with the same quality and safety standards as those established by the Directives.

Although many competent authorities collect the annual report from the blood establishments on the previous year's activities, only a very limited number of

Member States have data on the imported and exported volumes of blood and blood components.

2.8. Exchange of information, reports and penalties, transposition (Art. 25-32 of Directive 2002/98/EC)

2.8.1. Information exchange (Art. 25)

The Commission has convened four meetings with the competent authorities designated by the Member States to exchange information on the experience acquired with regard to the implementation of Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC. The last meeting took place on 27-28 January 2009.

2.8.2. Penalties (Art. 27)

Under Article 27, Member States must lay down rules on penalties applicable to infringements of the national provisions.

Only France reported that it had imposed penalties on blood establishments in this respect.

2.8.3. Transposition (Art. 32)

All Member States have notified to the Commission their national transposition measures in relation to Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC.

On 6 March 2009 the Commission sent a template for a concordance table for Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC to the Member States for completion. Twenty-two Member States have sent back completed tables to the Commission (Belgium, Bulgaria, Czech Republic, Germany, Estonia, Ireland, Greece, Spain, France, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovenia, Slovakia, Finland and the United Kingdom). Based on the tables, the Commission will assess the level of transposition of the blood Directives.

3. CONCLUSIONS

Overall, the implementation of the Directives is satisfactory.

This concerns in particular the requirement to designate a competent authority or authorities and 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 the finalisation of the accreditation/designation/authorisation/licensing process in respect of each individual blood establishment, the carrying out of inspections in all Member States, and the annual report on adverse events and reactions for the Commission. 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.