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

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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.