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

2000/0323(COD) - 21/04/2016 - Follow-up document

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.