

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

2000/0323(COD) - 23/03/2011 - Follow-up document

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.