

European self-sufficiency for blood components and plasma for fractionation - Summary

Context

The European Directive 2002/98/EC on blood and blood components¹ calls for a blood strategy to reinforce confidence in the safety of the blood transfusion chain and to promote self-sufficiency.

Issues

Self-sufficiency for blood components

Keeping a representative donor base in a changing environment

Reduced demand for red blood cells and greater personalization of components for patients of increasingly diverse ethnicity pose a challenge to blood establishments. To match these needs a sustainable donor base reflecting patients' diverse ethnic backgrounds is required.

Outbreaks of emerging infectious diseases may overwhelm a local donor base, and create the need for collaboration between European blood establishments to ensure continuity of supply.

The risk of "cherry picking" in a context of competition

Commercial suppliers of labile products entering and leaving a market left some blood supply systems disrupted. In this unfair competition or 'cherry-picking' environment, some providers choose to only provide the most profitable blood products to the most convenient clients. The supply of less profitable or more complex/rare products, delivered to all hospitals including those of small size or located in remote areas is left to not-for-profit blood operators.

Plasma for fractionation into plasma-derived medicinal products

All stakeholders recognize that the EU is not self-sufficient in plasma for fractionation (PfF) and plasma derived medicinal products (PDMP). The EU is dependent mainly on one country (USA), which poses a risk in terms of continuity of supply in crises situations². A 2012 Presidential order on USA national defence resources preparedness foresees that national use health resources be prioritized over the supply of foreign needs and contracts³. Should this Presidential order be put

¹ DIRECTIVE 2002/98/EC of the European Parliament and of the Council of 27 January 2003 [...] amending Directive 2001/83/EC

² According to market data, in 2014, 45 million litres of PfF were collected worldwide, including 32.6 million litres of source plasma and 8.7 million litres of recovered plasma; 64% of the total was collected in the USA.

³ [Executive Order](#) - National Defense Resources Preparedness, 16 March 2012, Part II, Section 201 (a), specifically sub a and Part VIII, General Provisions, section 801, sub (i)

into practice for health resources to deal with a major crisis in the USA, the supply of PfF and PDMP in the EU would be threatened.

EBA recommendations on self-sufficiency in future Blood Directives

Self-sufficiency in labile blood components

- Blood and blood components, including plasma should be considered a strategic resource, and blood products supply recognized as a service of general interest. European law should require the development and maintenance of adequate infrastructures and broad donor base.
- Blood service(s) should provide the full spectrum of labile blood components to match the patients' needs. Furthermore, the obligation of supply to special groups of recipients should be shared by all licensed blood establishments.

Self-sufficiency in plasma for fractionation and plasma derived medicinal products

- Blood establishments should be encouraged to develop efficient plasmapheresis collection programmes based on voluntary non-remunerated donors in the EU Member States.
- Guidance and training should be provided to reduce wastage of plasma.
- The EU should stimulate research on the optimal use of blood, blood components and PDMPs.