



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)

