ANNEX III

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ANNEX III

ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

(as referred to in Article 4)

1. ACCEPTANCE CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

Under exceptional circumstances, individual donations from donors who do not comply with the following criteria may be authorised by a qualified healthcare professional in the blood establishment. All such cases must be clearly documented and subject to the quality management provisions in Articles 11, 12, and 13 of Directive 2002/98/EC.

The following criteria do not apply to autologous donations.

1.1. Age and body weight of donors

Age	18 to 65 years		
	17 to 18 years	_	unless classified as a minor by law, or with written consent of parent or legal guardian in accordance with law
	First time donors over 60 years	_	at the discretion of the physician in the blood establishment
	Over 65 years	_	with permission of the physician in the blood establishment, given annually
Body weight	≥ 50 kg for donors either of w components	≥ 50 kg for donors either of whole blood or apheresis blood components	

1.2. Haemoglobin levels in donor's blood

Haemoglobin for female. ≥ 125 g/l	for males ≥ 135 g/l	Applicable to allogeneic donors of whole blood and cellular components
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1.3. Protein levels in donor's blood

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Protein	≥ 60 g/l	The protein analysis for apheresis plasma donations must be performed at least
		annually

1.4. Platelet levels in donor's blood

Platelets	Platelet number greater than	Level required for apheresis
	or equal to $150 \times 10^9/l$	platelet donors