# PROPOSED TECHNICAL REQUIREMENTS BLOOD AND BLOOD COMPONENTS

LABELLING AND TESTING REQUIREMENTS THAT MAY REPLACE THE EXISTING ANNEXES III AND IV of DIRECTIVE 2002/98/EC SHOULD IT BE CONSIDERED NECESSARY

File 2

## DRAFT

## FOR CONSULTATION PURPOSES ONLY

## ANNEX A

## LABELLING REQUIREMENTS

| **Component** | **The label on specimen receptacles and containers should contain at least the following information** |
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| **GENERAL LABELLING REQUIREMENTS** | |
| | **Specify** |
| | • Nature of whole blood or component (or intended component)<br>• Volume of component<br>• Unique numeric or alphanumeric donation identification<br>• Producer's name and address (clear text or code)<br>• ABO group<br>• Rh D group, specifying 'Rh D-positive' if D positive or 'Rh D negative' if D negative<br>• Date of collection/preparation and expiry date<br>• Temperature of storage<br>• Name of anticoagulant (not required for frozen, deglycerolized, rejuvenated, or washed red blood cells)<br>• Approximate volume of blood collected from the donor<br>• That the blood or component must not be used for transfusion if abnormal haemolysis or other deterioration is evident<br>• That blood or component must be administered through a 170-200 μm filter |
| **SUPPLEMENTARY SPECIFIC LABELLING REQUIREMENTS** | |
| | **Specify** |
| **Plasma, fresh frozen** | • Whether component is from whole blood or apheresis donation;<br>• Volume and composition of anticoagulant used;<br>• Whether quarantined or virus inactivated |
| **Platelets, apheresis** | • Volume of content and average number of platelets; if unit does not meet recommended standard, actual number of platelets to be specified;<br>• Whether or not leukocyte depleted |
| **Platelets, recovered** | • Donation number (if platelets are pooled, labelling system must allow identification of original donations);<br>• Whether or not leukocyte depleted;<br>• Composition of anticoagulant solution |
| **Red cells** | • Name and volume of component;<br>• Composition of anticoagulant or additive solution |
| **Red cells, cryopreserved** | • Date and time of preparation and expiry;<br>• Composition and volume of suspending solution;<br>• Extra caution should be applied in identification of frozen bag units |
| **Red cells, buffy coat removed** | • Composition of anticoagulant solution |
| **Red cells, in additive solution** | • Composition and volume of additive solution |

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|---|---|
| **Red cells in additive solution, buffy coat removed** | • Composition and volume of additive solution |
| **Red cells, leukocyte-depleted** | • Composition of anticoagulant solution |
| **Red cells, washed** | • Time of preparation and expiry;<br>• Composition and volume of the suspending solution |
| **Whole blood** | • Volume of preparation;<br>• Composition and volume of anticoagulant solution |
| **Red cells, apheresis** | • Dose of red cells, or the total Hb content;<br>• Number of unit equivalents. Option for split number if a 2 unit collection is administered to more than one recipient;<br>• Whether or not leukocyte depleted;<br>• Composition of anticoagulant solution;<br>• Composition and volume of any additive solution. |

## ANNEX B

## TESTING REQUIREMENTS
## AS REGARDS WHOLE BLOOD AND PLASMA DONATIONS

| Components | Testing Requirements | | Required outcome |
|---|---|---|---|
| **Whole blood/Plasma** | Serological tests | ABO typing * | Determined using approved blood grouping reagents and techniques |
| | | Rh D typing * | Determined using approved anti-D blood grouping reagents and techniques |
| | | Rh C and E typing * | Determined using approved blood grouping reagents and techniques |
| | | HLA typing * (when needed) | Determined using approved reagents and techniques |
| | | Antibodies to red cell antigens | Absence of clinically significant antibodies, using approved reagents and techniques |
| | Surface antigen of Hepatitis B | HbsAg | Negative using an approved ELISA or RIA test |
| | Antibodies to the human immunodeficiency virus 1 | Anti-HIV 1 | Non-reactive for antibodies to HIV-1 using approved screening tests |
| | Antibodies to the human immunodeficiency virus 2 | Anti-HIV 2 | Non-reactive for antibodies to HIV-2 using approved screening tests |
| | Antibodies to the Hepatitis C virus | Anti-HCV | Non-reactive for antibodies to HCV using approved screening tests |
| | | HBc-Ab (when required) | Negative by approved screening test |
| | *Treponema pallidum* (syphilis) | Syphilis (when required) | Negative by screening test |
| | | CMV-Ab (when required) | Negative by screening test |
| | | HTLV-Abs (when required) | Negative by screening test |
| | Malaria for travellers to endemic areas | (when specified by national authorities) | Negative by a validated immunologic or molecular genomic test |

* Not required for apheresis plasma intended only for fractionation.