

ANNEX III **U.K.**

ELIGIBILITY CRITERIA FOR DONORS OF  
WHOLE BLOOD AND BLOOD COMPONENTS  
(as referred to in Article 4)

2. DEFERRAL CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS **U.K.**

The tests and deferral periods indicated by an asterisk (\*) are not required when the donation is used exclusively for plasma for fractionation.

2.1. Permanent deferral criteria for donors of allogeneic donations **U.K.**

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| <i>Cardiovascular disease</i>  | Prospective donors with active or past serious cardiovascular disease, except congenital abnormalities with complete cure  |
| <i>Central nervous system disease</i>  | A history of serious CNS disease   |
| <i>Abnormal bleeding tendency</i>  | Prospective donors who give a history of a coagulopathy  |
| <i>Repeated episodes of syncope, or a history of convulsions</i>   | Other than childhood convulsions or where at least three years have elapsed since the date the donor last took anticonvulsant medication without any recurrence of convulsions   |
| <i>Gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory system diseases</i>      | Prospective donors with serious active, chronic, or relapsing disease  |
| <i>Diabetes</i>  | If being treated with insulin  |
| <i>Infectious diseases</i>   | Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune   |
|  | Hepatitis C  |
|  | HIV-1/2  |
|  | HTLV I/II  |
|  | Babesiosis (*)   |
|  | Kala Azar (visceral leishmaniasis) (*)   |
|  | Trypanosomiasis cruzi (Chagas' disease) (*)  |
| <i>Malignant diseases</i>  | Except <i>in situ</i> cancer with complete recovery  |
| <i>Transmissible spongiform encephalopathies (TSEs), (e.g. Creutzfeldt Jakob Disease, variant Creutzfeldt Jakob Disease)</i> | Persons who have a family history which places them at risk of developing a TSE, or persons who have received a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands. For variant Creutzfeldt Jakob disease, further precautionary measures may be recommended. |

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| <i>Intravenous (IV) or intramuscular (IM) drug use</i> | Any history of non-prescribed IV or IM drug use, including body-building steroids or hormones                                  |
| <i>Xenotransplant recipients</i>                       |  |
| <i>Sexual behaviour</i>                                | Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood |

## 2.2. Temporary deferral criteria for donors of allogeneic donations **U.K.**

### 2.2.1. Infections **U.K.**

#### Duration of deferral period

After an infectious illness, prospective donors shall be deferred for at least two weeks following the date of full clinical recovery.

However, the following deferral periods shall apply for the infections listed in the table:

|   |   |
|---|---|
| Brucellosis (*)   | 2 years following the date of full recovery   |
| Osteomyelitis   | 2 years after confirmed cured   |
| Q fever (*)   | 2 years following the date of confirmed cured   |
| Syphilis (*)  | 1 year following the date of confirmed cured  |
| Toxoplasmosis (*)   | 6 months following the date of clinical recovery  |
| Tuberculosis  | 2 years following the date of confirmed cured   |
| Rheumatic fever   | 2 years following the date of cessation of symptoms, unless evidence of chronic heart disease   |
| Fever > °C  | 2 weeks following the date of cessation of symptoms   |
| Flu-like illness  | 2 weeks after cessation of symptoms   |
| <b>Malaria (*)</b>  |   |
| — individuals who have lived in a malarial area within the first five years of life | 3 years following return from last visit to any endemic area, provided person remains symptom free; may be reduced to 4 months if an immunologic or molecular genomic test is negative at each donation |
| — individuals with a history of malaria   | 3 years following cessation of treatment <i>and</i> absence of symptoms. Accept thereafter only if an immunologic or molecular genomic test is negative   |
| — asymptomatic visitors to endemic areas  | 6 months after leaving the endemic area unless an immunologic or molecular genomic test is negative   |

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|   |   |
|---|---|
| — individuals with a history of undiagnosed febrile illness during or within six months of a visit to an endemic area | 3 years following resolution of symptoms; may be reduced to 4 months if an immunologic or molecular test is negative                            |
| West Nile Virus (WNV) (*)   | [ <sup>F1</sup> 28 days after leaving a risk area of locally acquired West Nile Virus unless an individual Nucleic Acid Test (NAT) is negative] |

#### Textual Amendments

- F1** Substituted by [Commission Directive 2014/110/EU of 17 December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations \(Text with EEA relevance\)](#).

#### 2.2.2. Exposure to risk of acquiring a transfusion-transmissible infection U.K.

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| — Endoscopic examination using flexible instruments,<br>— mucosal splash with blood or needlestick injury,<br>— transfusion of blood components, tissue or cell transplant of human origin,<br>— major surgery,<br>— tattoo or body piercing,<br>— acupuncture unless performed by a qualified practitioner and with sterile single-use needles,<br>— persons at risk due to close household contact with persons with hepatitis B. | Defer for 6 months, or for 4 months provided a NAT test for hepatitis C is negative  |
| Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood.  | Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests |

#### 2.2.3. Vaccination U.K.

|   |   |
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| Attenuated viruses or bacteria                      | 4 weeks   |
| Inactivated/killed viruses, bacteria or rickettsiae | No deferral if well   |
| Toxoids   | No deferral if well   |
| Hepatitis A or hepatitis B vaccines                 | No deferral if well and if no exposure  |
| Rabies  | No deferral if well and if no exposure<br>If vaccination is given following exposure defer for one year |

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| Tick-borne encephalitis vaccines | No deferral if well and if no exposure |
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#### 2.2.4. Other temporary deferrals **U.K.**

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| Pregnancy        | 6 months after delivery or termination, except in exceptional circumstances and at the discretion of a physician  |
| Minor surgery    | 1 week  |
| Dental treatment | Minor treatment by dentist or dental hygienist — defer until next day (NB: Tooth extraction, root-filling and similar treatment is considered as minor surgery) |
| Medication       | Based on the nature of the prescribed medicine, its mode of action and the disease being treated  |

#### 2.3. Deferral for particular epidemiological situations **U.K.**

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| Particular epidemiological situations (e.g. disease outbreaks) | Deferral consistent with the epidemiological situation (These deferrals should be notified by the competent authority to the European Commission with a view to Community action) |
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#### 2.4. Deferral criteria for donors of autologous donations **U.K.**

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| Serious cardiac disease  | Depending on the clinical setting of the blood collection  |
| Persons with or with a history of<br>— hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune<br>— hepatitis C<br>— HIV-1/2<br>— HTLV I/II | Member States may, however, establish specific provisions for autologous donations by such persons |
| Active bacterial infection   |  |