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COVER NOTE

From:	European External Action Service (EEAS)
To:	European Union Military Committee (EUMC)
Subject:	Minimum Technical Requirements for contracted Blood and Blood Products in EU-led military CSDP Operations and Missions

Delegations will find attached the Minimum Technical Requirements for contracted Blood and Blood Products in EU-led military CSDP Operations and Missions.

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To [and/or GSC distribution acronyms]	**Political and Security Committee** **Military representations to the EU** **European Union Military Committee** *CSDP/PSDC; EUMC; EUMC WG*
Title / Subject	**Minimum Technical Requirements for contracted Blood and Blood Products in EU-led military CSDP Operations and Missions**
[Ref. prev. doc.]	**EEAS(2020) 127 REV 2**

Delegations will find attached the document "Minimum Technical Requirements for contracted Blood and Blood Products in EU-led military CSDP Operations and Missions" which was agreed by the EUMC on 20th March 2020.

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1. Introduction

The European Union (EU) Common Security and Defence Policy (CSDP) is an integral part of the EU's integrated approach towards crisis management. Drawing on civilian and military assets, it provides an operational capacity to conduct EU-led CSDP missions and operations with the overarching goal of strengthening international security over the world.

Pursuant to Article 41 of the Treaty of the European Union (TEU), financing of costs arising from European Union operations, having military or defence implications is excluded from EU budget. These operations are funded by contributing Member States (MS). A mechanism with legal capacity, called Athena was established in 2004 (Reference B), designed to administer the financing of common costs thereof.

In general, the financing of EU military operations follows the principle of allocation of expenditure by their author. Nevertheless, costs eligible for the joint financing mechanism by Athena depending on the phase of the operation are defined in a Council Decision. Eligible medical capabilities for common financing are subject to a regular review and defined in the Annexes I-IV of the latest respective Council Decision (Reference C).

The provision of Blood and Blood products is an integral part of the provision of Damage Control Surgery, performed at Role 2 and higher medical treatment facilities, enabling eligibility for common procurement or reimbursement by Athena budget.

Substituting blood for Damage Control Resuscitation (DCR) and Damage Control Surgery (DCS) in austere environments as much forward as possible, including the orphaned whole blood application, is subject to research and strategic assessment in many international organisations as well as on national level in the military but also civilian community.

Since 1989, numerous EU Commission Directives have become effective, setting a minimum European Union Standard for the quality of Blood and Blood Products. As neither the common minimum denominator will satisfy the required standard to be acceptable to the majority of EU MS military actors and Third States Troup Contributing nations (TCN) in military EU-led CSDP missions and operations, nor a NATO Standardised Agreement on the quality of blood and blood products, EU MS agreed to develop standardised minimum technical requirements in the framework of the EU Conceptual Development Implementation Programme (CDIP) (Reference G).

Primary objective though remains the provision of any medical support, including medical logistics on a force generated basis to EU-led military CSDP missions and operations. Contracted alternatives shall only be reverted to, in case of a lack in provision by MS or Third Nation Contribution on the required standard of quality.

2. Aim

2.1. This document shall provide a common, European Union Military Committee (EUMC) agreed standard to facilitate the process of Contractor Support to Operations (CSO) with regard to the procurement and distribution of blood and blood products to be utilised in-theatre to the benefit of EU-led military CSDP Missions and Operations.

2.2. The defined standard provides guidance to Subject Matter Experts (SME), the European Union Military Staff (EUMS), the Military Planning and Conduct Capability (MPCC), EU OHQs (European Union Operation Headquarters), EU FHQs (European Union Force Headquarters) and the Athena mechanism in order to facilitate the definition of technical specifications and minimum requirements for procurement procedures.

2.3. The defined standard shall function as guidance to non-EU Third States TCN if they are willing to offer the service of Blood and Blood Products supply within the remit of a Force Generation Process in the medical Logistics domain.

2.4. The defined standard may be utilised for CSO to Operation providing Blood and Blood Products to EU-led military Missions and Operations in the preparation of a Framework Contract or Specific Contracts[1].

3. Scope

3.1. The scope of the document will be limited to procurement and distribution of Blood and Blood Products and therefore consider two different aspects of the acquisition process

3.1.1. The procurement of Blood and Blood Products on the required quality standard

3.1.2. The distribution and shipping of Blood and Blood Products until hand-over to authorised personal in an EU-led military CSDP Mission or Operation.

3.2. The document will not provide guidance or a policy on handling, storage and the transfusion of Blood and Blood Products in Medical Treatment Facilities (MTF).

3.3. Only Blood and Blood Products with likelihood to be utilised for DCR, DCS and limited Standard Surgery will be subject to the defined standard of the document. The requirements for the individual Blood Products are summarized in the Annexes to this document.

[1] See Chapter Definitions for further information

3.4. The standards might be used as a whole or partially extracted to meet the specific demands occurring in an EU-led military CSDP Mission or Operation. Superseding requirements might always be added, but should never undercut the standard laid out in this document.

4. Specification of the required services

4.1. The Contractor is expected to procure and/ or deliver (Reference 5.4) the required amount of Blood and Blood Products to the meeting point of handover to authorised[1] personal of the requesting military CSDP Missions or Operation observing the technical requirements as laid out in this document.

4.2. The meeting point will in general be the vicinity of an international airport worldwide. Exceptions thereof though may be defined in the specifications of a contract.

4.3. Delivery is expected on a regular and on demand basis, in relation to the required stockpiling of the requesting unit and the Shelf life of the delivered products.

4.4. On demand replacement for unexpected use or higher demand should be met within the requirements laid out in this document.

5. Guidelines and Principles

5.1. CSO should be in line with the respective EU Concept (Reference H).

5.2. Any CSO to EU-led military Missions and Operations initiated or executed by an EU Institution or body should observe the Athena financing regulations (Reference I) or be subject to a mutual acceptance agreement.

5.3. Blood and Blood Products are mainly held by public non-for profit institutions, whereas plasma derived medical products might be controlled additionally by private organisations or even for plasma, on the open market in some EU MS. Whenever possible, without hampering the contractual competition, benefit should be given to non-profit institutions.

5.4. For any CSO in the remit of this document, it is recommended to define common requirements within one contract for the procurement and distribution of Blood and Blood Products, in order to reduce the administrative burden of the respective mission or operation.

5.5. The Contractor should be in the possession of all relevant permits, licenses and logistics (including subcontracting) to export all Blood and Blood Products worldwide without delay to ensure an uninterrupted supply

[1] Authorised personal for the reception of a blood or blood Product delivery must be trained and qualified in accordance with the national requirements of the respective EU MS of origin.

and re-supply chain. This includes especially a profound experience and familiarity with custom regulations in regard of Blood and Blood Products worldwide.

5.6. Solid Quality and Quality Risk Management as well as Good Practice must be essential for all steps from blood collection until the final delivery. The Quality System encompasses quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, non-conformance and self-inspection.

5.7. Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) must be observed to deliver the requested service.

5.8. Blood and Blood Products procured for the purpose of a contract to the benefit of an EU-led CSDP Mission or Operation shall only be purchased if they are produced in a Blood Establishment observing the standards as laid out in this document.

5.9. For Blood and Blood Products imported from third countries and intended for use or distribution in the EU/ in an EU-led military CSDP Mission or Operation, there must be a Quality System for blood establishments in the stages preceding importation equivalent to the Quality System provided for in Article 2 of Directive 2005/62/EC. All quality requirements as laid out in the document need to be observed.

6. Blood Establishment

6.1. Each blood establishment must develop and maintain a Quality System that is based on and/ or observes EU Good Manufacturing Practices (GMP) Directive 2003/94/EC and meet the requirements identified in the Directive 2005/62/EC.

6.2. The Quality System encompasses quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, non-conformance and self-inspection (Directive 2005/62/EC Annex 1.1.2).

6.3. Each actor in the supply chain should establish, document, and fully implement a comprehensively designed Quality System to deliver Quality Assurance based on the principles of Quality Risk management by incorporating Good Practice and Quality Control.

6.4. All procedures, premises and equipment that have an influence on the quality and safety of Blood and Blood Products must be qualified and/ or validated before introduction and must be re-validated at regular intervals,

as determined as a result of these activities.

6.5. Records and data required by Art 13 and Art 14 of DIR 2002/98/EC shall be kept for a minimum of 30 years.

7. Blood collection

7.1. Blood Collection must be in line with GMP, Directives 2002/98/EC and 2005/62/EC.

7.2. Premises used for blood collection should meet the hygiene requirements for this type of activity and should be suitable for the collection of blood, plasma or cells from donors in full-safety.

7.3. The facility should be designed to be used in a rational way including the option for carrying out medical checks in medical confidentiality and in compliance with the EU General Data Protection Regulations (Reference AA).

7.4. Equipment, and in particular collection equipment should be suitable for blood collection.

7.5. Quality Management procedures shall be in place ensuring safe processing, with particular precautions to avoid mixing of samples and/ or contamination.

7.6. The collection of blood should be supervised in responsibility of medically qualified persons.

7.7. Haemovigilance with regard to blood donor management should be in place.

8. Donor selection criteria

8.1. Criteria for Donor selection must at least meet the requirements set out in Directive 2004/33/EC, taking into account the latest legislation releases on temporary deferral criteria (e.g. Directive 2014/110/EC).

8.2. Procedures for safe identification of donors, suitability interview, and eligibility assessment must be implemented and maintained.

8.3. They must take place before each donation and comply with the requirements set out in Annex II and Annex III to Directive 2004/33/EC and Directive 2005/62/EC Annex 6.1.

8.4. Only healthy persons with a good medical history can be accepted as donors of blood or blood Products.

8.5. All donors must undergo a systematic screening process to assess their suitability.

8.6. Relevant acceptance/deferral criteria must be in place at the blood establishment to control acceptance and deferral of donors.

8.7. The selection process must include assessment of each donor carried out by a suitably qualified individual who has been trained to use accepted guidelines and who works under the direction of a physician. This assessment involves an interview, a questionnaire and further direct questions, if necessary.

8.8. Blood and Blood Products shall be collected by Voluntary Non Remunerated Blood Donation (VNRBD).

8.9. Plasma for fractionation collected through plasmapheresis should desirably be collected by Voluntary unpaid donations (VUD).

9. Testing criteria

9.1. General

9.1.1. Blood donations shall be tested by validated procedures to ensure high level of safety to the recipient.

9.1.2. Only test reagents that have been licensed or evaluated and considered to be suitable by a responsible National Health Authority/ Competent Authority must be used. In the EU, these reagents are considered as in vitro diagnostic devices and must be CE-marked (Directives 93/42/EEC and Reference T).

9.1.3. An external quality assurance programme shall be in place to regularly assess the quality of laboratory testing.

9.1.4. Blood screening programmes should include strategies for confirmatory testing and blood donor management.

9.1.5. Blood donations from countries repetitive endemic (assessed by an international recognized Health Organisation such as WHO, CDC, ECDC and others) for Ebola, Malaria, Chagas disease, Tuberculosis, Q-Fever, and Brucellosis shall be excluded for the purposes of a contract.

9.2. Blood group serological testing of donors and donations

9.2.1. Blood group serology testing must include procedures for testing specific groups of donors (e.g. first-time donors, donors with a history of transfusion) in accordance with Directive 2002/98/EC Annex IV and 2005/62/EC Annex 6.3.

9.2.2. Each subsequent donation should be verified for ABO and RhD blood groups. The manufacturer of such reagents must have a full Quality System certified by an authorised body.

9.2.3. Screening for clinically significant irregular Antibodies shall be performed at least at the first two donations and in addition, depending on the medical history (in particular after pregnancy and transfusion).

9.2.4. Blood collections intended to be processed for plasma should be selected from male donors or consideration should be given to screening female donors for HLA/HNA antibodies, as a TRALI risk reduction measure.

9.3. Testing for infectious markers

9.3.1. All Blood donations must **mandatory** be tested for

- Anti-HIV 1+2, HIV-NAT pool or ID
- HBsAg, HBV-NAT pool or ID
- Anti-HCV, HCV-NAT pool or ID
- Treponema pallidum, TPHA/ EIA

9.3.2. Additional testing requirements have to be in place in case of indications in the personal history of the donor, epidemiological prevalence in the country of origin/ presence and/ or unclear results in routine testing, or according to national requirements, including but not exhaustive:

- HIV p24 Ag
- Anti-HTLV I/ II EIA
- HEV[1]
- HAV
- Anti- HBc
- Malaria, serological marker EIA Antibodies
- Chikungunya Virus
- Anti-T.cruzi EIA
- WNV NAT pool or ID
- Zika
- Creutzfeldt Jacob Disease

10. Processing and validation

10.1. All equipment used must be qualified, validated, calibrated and maintained to suit and efficiently serve the purpose.

10.2. The processing of blood components must be carried out using appropriate and validated procedures, including measures to avoid the risk of contamination and microbial growth in the prepared blood components

[1] HEV NAT mandatory in following EU MS: AT, DE, ES, FR, IR, LU and NL by 2020.

10.3. Systems of sterile blood bags used for the collection of Blood and Blood Products and their processing must be CE-marked or comply with equivalent standards if the Blood and Blood Products are collected in third countries.

10.4. Blood bags shall observe ISO 3826 standards.

10.5. The batch number of the bag must be traceable for each blood component (Directive 2005/62/EC Annex 6.2.2).

10.6. Manufacturers of sterile material such as blood bag systems or anticoagulant solutions should provide a certificate of release for each batch and observe the EU Regulations for Medical Devices.

10.7. Blood collection procedures must minimise the risk of microbial contamination.

10.8. After blood collection, blood bags must be handled in a way that maintains the quality of the blood and at a storage temperature and transport temperature appropriate to the requirements for further processing.

11. Labelling

11.1. At any stage of the process, the labelling should identify clearly the individual components and their nature.

11.2. Labelling system for collected blood, intermediate and finished blood components, and samples must unmistakably identify the type of content, and comply with the labelling and traceability requirements referred to in Article 14 of Directive 2002/98/EC and Directive 2005/61/EC. The label for a final blood component must comply with the requirements of Annex III to Directive 2002/98/EC (Directive 2005/62/EC Annex 6.5.)

11.3. Labelling must contain at a minimum the official name of the component, volume or weight or number of cells in the component (as appropriate), unique numeric or alphanumeric donator identification, name of producing blood establishment and ABO and RhD Group (not required for plasma intended only for fractionation), the date of expiry, temperature of storage and name, composition and volume of anticoagulants and/or additive solution (if applicable) in accordance with Reference K.

11.4. Materiel used for Labelling or in connection thereof shall be suitable for the purpose, especially with regard to resistance to external and environmental impact.

11.5. For Blood and Blood Products supplied to multinational recipients, it is recommended to apply the international labelling system (ISBT 128).

12. Storage, Distribution and Shipping of Blood and Blood Products

12.1. The Quality System of the blood establishment must ensure that the requirements for storage and distribution for Blood and Blood Products intended for the manufacture of medicinal products must comply with Directive 2003/94/EC and Directive 2005/62/EC Annex 7.1.

12.2. Procedures for storage, distribution and transportation shall be validated to ensure blood quality during the entire period and exclude mix-up of blood components.

12.3. Storage conditions must be controlled, monitored and checked. Appropriate alarms must be present and checked regularly; all checks must be recorded until the hand-over to the end recipient in the responsibility of the Contractor. Appropriate actions on alarms must be defined.

12.4. Transport and distribution of Blood and Blood Products must provide conditions to maintain the integrity of the transfusion chain at all stages.

12.5. Logistic planning for transport should be optimised to keep the transport time to a lowest possible.

12.6. Packaging and transportation conditions must be equivalent to storage conditions. Transport containers should be thermally isolated and equipped with a either internal or external cooling mechanism and validated to assure a GDP-conform transportation at all times.

12.7. Transit containers should be equilibrated to their storage temperature prior to filling with components as far as possible.

12.8. Continuous temperature monitoring for blood in transit must be guaranteed throughout the duration of the transit. Digital temperature loggers record continuously and the obtained data must be made available as a documentation (graphic or table) for a GDP compliant transport by the contractor.

12.9. Transport containers intended for air transport must be certified and approved.

12.10. Before distribution and any hand-over, blood components must be visually inspected and the temperature log should be checked. The record thereof shall be provided and controlled by the recipient.

12.11. Shipping and transport containers should be provided without adverse effect on the quality of the products and offer adequate protection from external influences including contamination.

12.12. Safety transport regulations for dangerous goods (e.g. transport materiel like dry ice) have to be adopted and observed.

12.13. Precautions for accidental damage (including e.g. freezing of RBC) and unauthorised access must be taken.

12.14. Without prejudice to manufacturer specification, the following storage conditions in table 1 are recommended for transport packing to keep the optimum range of quality.

Table 1 for liquid and frozen storage[1]

Component	**Temperature of storage**	**Maximum shelf life**
RBC and WB (Whole Blood if used for transfusion)	+ 4 °C ± 2°C	28 to 49 days
Frozen RBC	Below - 65°C	10 to 30 years
Platelets	+ 22 °C ± 2°C	5 to 7 days[2]
Cold-stored Platelets	+ 4 °C ± 2°C	14 days
Frozen Platelets	Below -65°C	2 years
Freeze/ Spray dried Plasma	+ 2°C to + 25 °C	According to Manufacturer
Fresh Frozen Plasma/ Frozen Plasma	Below – 25 °C	3 years

12.15. All transport containers must be properly labelled and marked enabling unique identification and traceability.

13. Blood supply management chain

13.1. Blood and Blood Product deliveries shall be managed to ensure a prompt, smooth, safe delivery without interruption, even over vast distances.

13.2. Blood and Blood Products should in general be available within 7

[1] Extract from Reference M Annex IV

[2] Storage up to 7 days may be applicable in conjunction with detection or reduction of bacterial contamination

working days from the point of order until hand-over to the respective meeting point for hand-over in the mission or operation. Personnel authorised for hand-over and receiving of Blood and Blood Products must be qualified and pre-identified. Specifications on order modalities should be defined in any specific contract.

13.3. In case of an unforeseeable need or unusable distribution, an accelerated provision of the requested Blood or Blood product should be made available within 5 working days from reception of the order until hand-over to the authorised personnel in theatre in case. Depending on the accountability of the extraordinary request, additional costs may be charged by the Contractor.

13.4. The logistic management system of the delivery should be able to compensate innocent delays and obstacles.

13.5. Eligible personal for placing orders are to be defined in each specific contract.

14. Non-conformance, traceability, and recall

14.1. Blood and Blood Products, non-conformant or deviating from the required standard, shall not be acceptable for the purposes of the contract.

14.2. All activities and actions associated with the handling, testing and processing of each donation should be recorded completely and fully linked to the donation, the donor, the fate of the donation and the patient.

14.3. Blood and Blood Products must be traceable (including trace-back) in an uninterrupted chain from the donor to the final recipient. All transportation and storage actions including receipt and distribution shall be defined by written procedures. Appropriate records of distribution shall be kept (Reference N and K).

14.4. The contractor providing the Blood and Blood Products has to assure the correct reception, handling and hand-over of the accompanying documents to the authorised personal of the Contracting Authority.

14.5. The data continuously recorded by digital temperature loggers should be checked as part of the requirements for a safe and secure hand-over of the accompanying documents. The Contractor must ensure the ability to be read on scene.

14.6. An effective recall system, including notification of the Competent Authority must be in place, defining responsibilities and procedures between the Blood Establishment, the Contractor and the receiving party. Recall Operations should be initiated and processed without time-delay.

14.7. Data needed to ensure full traceability shall be kept for 30 years in accordance with Directive 2002/98/EC Article 13.

15. Recommendations for minimum stockholding requirements[1]

15.1. Role 2 Forward MTF/ FST Element:

10 (ten) Units RBC Concentrates	0 RhD neg
10 (ten) Units (lyophilised) Plasma	AB

15.2. Role 2 Basic / Enhanced MTF:

15 (fifteen) Units RBC Concentrates	0 RhD neg
15 (fifteen) Units RBC Concentrates	A and B[2]
20 (twenty) Units (lyophilised/FF) Plasma	AB

15.3. The recommendations provided above are intended to provide figures to estimate overall needs in a Framework contract and in specific contracts. Nevertheless, any specific contract must be tailored to the operational environment, taking into account the risk assessment and casualty estimate rate.

15.4. In the order of numeration, the following components should be considered for stockpiling.

1. RBC (+Fibrinogen concentrate)
2. RBC + Plasma (+ Fibrinogen concentrate)
3. RBC + Plasma + Platelets (+ Fibrinogen concentrate)
4. WB

16. Responsibilities

16.1. The Contractor is responsible for the safe procurement of Blood and Blood Products on the contractual agreed standard and its safe storage and transport until the Point of handover to designated and authorised personnel in the EU-led CSDP Mission or Operation.

16.2. The Contractor may use subcontracting for the management and/ or execution of the logistics to transport the Blood and Blood Products to its designated point of hand-over. The responsibility towards the Contracting Authority remains even in the case of subcontracting with the Contractor.

[1] see Reference Z (Annex IV)

[2] RhD neg/ pos

16.3. The Contractor needs to ensure and guarantee that any subcontracted entity will fulfil the obligations and quality standards of the committed contractual obligations.

16.4. The transport process to the agreed point and time for handing over is at risk of the Contractor.

16.5. Complaints because of damaged, faulty or wrong delivery have to be announced immediately at the time of handover. If the electronic temperature logging device can only be read out with special IT, the announcement has to be made as soon as possible. In this case the Contractor will be held reliable for a free-of-charge substitute delivery.

16.6. In- and Export Management including authorisation and permissions of the Blood and Blood Products from its Origin to its designated point lies within the responsibility of the Contractor.

16.7. The Contractor is encouraged to make arrangements with other local, regional or global stakeholders on a non-profit basis and in close coordination with the Contracting Authority to reduce the disposal of unused Blood and Blood Products at the end of shelf life. The Contractor needs to ensure for this process compliance with the minimum technical requirements within his area of responsibility.

16.8. Non-compliance to the contractual commitments will result in a penalty fee to be defined in the specific implementing contracts.

17. Selection Criteria

17.1. Contractors must mandatory observe the Good Distribution Practice (Certification issued by a competent national authority)

17.2. Contractors must mandatory observe the Good Manufacturing Practice (Certification issued by a competent national authority)

17.3. Contractors must mandatory provide a proof of sufficient logistic capability and experience for provision of Blood and Blood products worldwide.

17.4. Contractors must mandatory verify compliance of the procurement source for Blood and Blood Products with the Quality requirements laid out in this document.

18. Exclusion Criteria

18.1. Failure to provide a Declaration on Honour, duly signed and dated, stating that they are not in one of the situations referred to in Article 16 of the Athena Financial Rules - Part II.

18.2. Non-compliance with the requirements provided for in Article 9.1.5

19. Definitions[1]

Accreditation

Formal acknowledgement of compliance with accepted standards for procedures, activities or services following an audit by an authorised institute or organisation. See also Certification and Licensing.

Additive solution

A solution specifically formulated to maintain beneficial properties of cellular components during storage.

Apheresis

A method of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process.

Blood

Whole blood collected from a donor and processed either for transfusion or for further manufacturing.

Blood component

A therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods.

Blood donation

Action where a healthy person is at disposal for blood collection.

Blood establishment

Any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks.

Blood product

Any therapeutic product derived from human blood or plasma.

CE marking of conformity' or 'CE marking'

marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in EU Regulation 2017/746 an 2017/745 as well as other applicable Union harmonisation legislation providing for its affixing.

[1] Extract from European Standard Operating Procedure (SOP) Manual, Edition 1.0, 2007

Certification

Formal acknowledgement of compliance with accepted standards for procedures, activities or services following an audit by an organisation accredited by an officially recognised accrediting body.

Cryoprecipitate

A plasma component prepared from plasma, fresh-frozen, by freeze-thaw precipitation of proteins and subsequent concentration and re-suspension of the precipitated proteins in a small volume of the plasma.

Cryopreservation

Prolongation of the storage life of blood components by deep freezing.

Deferral

Suspension of the eligibility of an individual to donate blood or blood components such suspension being either permanent or temporary.

Distribution

The act of delivery of Blood and Blood Products to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusion.

Donor

A person in normal health with a good medical history who voluntarily gives blood or plasma for therapeutic use.

Dried Plasma

Freeze Dried Plasma/ Lyophilised Plasma

Lyophilisation of plasma is performed by freezing under vacuum for several days until the water content is reduced to approximately 1-2%.

Spray Dried Plasma

Spray-drying of plasma is performed by atomising the liquid plasma to droplets and brief exposure to hot (up to 150°C) gas, followed by rapid evaporative cooling.

Framework Contract

This type of contract is chosen to set out the general terms and conditions preparing for specific contracts. It usually is concluded with more than one contractor and remains dormant (cost-free or stand-by fee) until it becomes effective utilising a specific contract.

FFP

See Plasma, fresh-frozen

Good Distribution Practice (GDP)

A code of standards ensuring that the quality of a medicine is maintained throughout the distribution network, so that authorised medicines are distributed to retail pharmacists and others selling medicines to the general public without any alteration of their properties.

Good Manufacturing Practice (GMP)

That part of quality assurance that ensures products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorisation or product specification.

Good Practice

All elements in established practice that collectively will lead to final blood or blood components that consistently meet predefined specifications and compliance with defined regulations.

Haemovigilance

A set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors.

Labelling

Information that is required or selected to accompany a product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.

Licensing

The granting by a national competent authority of an authorisation to manufacture blood components.

Manufacturing

A process by which product characteristics may be modified by established means to give a product of defined characteristics.

Non-conformance

Failure to meet requirements.

Plasma

The liquid portion of the blood in which the cells are suspended. Plasma may be separated from the cellular portion of a whole blood collection for therapeutic use as fresh-frozen plasma or further processed to cryoprecipitate and cryoprecipitate-depleted plasma for transfusion. It may be used for the manufacture of medicinal products derived from human blood and human plasma or used in the preparation of pooled platelets, or pooled, leukocyte-depleted platelets. It may also be used for

resuspension of red cell preparations for exchange transfusion or perinatal transfusion.

Plasma, fresh-frozen (FFP) or frozen (FP)

The supernatant plasma separated from a whole blood donation or plasma collected by apheresis, frozen and stored. FFP is human donor plasma frozen in a short period after the process of collection (often 8h); whereas FP (Frozen Plasma) is referred to if the interval until freezing is up to 24 hours.

Platelets

A component prepared from whole blood preferably within 8 hours of venepuncture, which contains platelets as the major cellular product.

Platelets, apheresis

A concentrated suspension of blood platelets obtained by apheresis.

Platelets, apheresis, leukocyte-depleted

A concentrated suspension of blood platelets, obtained by apheresis, and from which leukocytes are removed.

Platelets, recovered, pooled

A concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation.

Platelets, recovered, pooled, leukocyte-depleted

A concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation, and from which leukocytes are removed.

Platelets, recovered, single unit

A concentrated suspension of blood platelets, obtained by processing of a single unit of whole blood.

Platelets, recovered, single unit, leukocyte-depleted

A concentrated suspension of blood platelets, obtained by processing of a single whole blood unit from which leukocytes are removed.

Policy

A documented general principle that guides present and future decisions.

Procedure

A series of tasks usually performed by one person according to instructions.

Process

A set of related tasks and activities that accomplish a work goal.

Processing

Any step in the preparation of a blood component that is carried out between the collection of blood and the issuing of a blood component.

Qualification

As part of validation, the action of verifying that any personnel, premises, equipment or material works correctly and delivers the expected results.

Quality

Manufacture of medicinal products so as to ensure that they are fit for their intended use, comply with the requirements of the Marketing Authorisation and do not place patients at risk due to inadequate safety, quality or efficacy. (According to EN ISO 9000:2005; quality is defined as the 'degree to which a set of inherent qualities are met').

Quality assurance

All the activities from blood collection to distribution made with the object of ensuring that Blood and Blood Products are of the quality required for their intended use.

(EC GMP Guidelines: quality assurance is defined as 'A wide-ranging concept that covers all matters, which individually or collectively influences the quality of a product. It is the total sum of the organised arrangements made with the object of ensuring that medicinal products are of the quality required for their intended use. Quality assurance therefore incorporates Good Manufacturing Practice (GMP) plus other factors outside the scope of this document.

Quality assurance system

Establishment and implementation of an effective pharmaceutical quality assurance system, involving the active participation of the management and personnel of active participation of the management and personnel of the different departments.

Quality control

Part of a quality system focussed on fulfilling quality requirements.

(EC GMP Guidelines: quality control is defined as 'That part of GMP that is concerned with sampling, specifications and testing; and with the organisation, documentation and release procedures, which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory'.)

Quality management

The co-ordinated activities to direct and control an organisation with regard to quality at all levels within the blood establishment.

(EC GMP Guidelines: quality management is defined as ‘achieving through a process of quality assurance medicinal products that do not place patients at risk with respect to safety, quality and efficacy’.)

Quality system

The organisational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Quarantine

The physical isolation of blood components or incoming materials/reagents over a variable period of time while awaiting acceptance, issuance or rejection of the blood components or incoming materials/reagents.

Recipient

Someone who has been transfused with blood or blood components.

Red cells

The red cells from a single whole blood donation or erythrocyte apheresis, with a large proportion of the plasma from the donation removed.

Red cells, leukocyte-depleted

The red cells from a single whole blood donation or erythrocyte apheresis, with a large proportion of the plasma from the donation removed, and from which leukocytes are removed.

Red cells, leukocyte-depleted, in additive solution

The red cells from a single whole blood donation or erythrocyte apheresis, with a large proportion of the plasma from the donation removed, and from which leukocytes are removed. A nutrient/ preservative solution is added.

Specific contract

Within a Framework contract, several specific contracts can be concluded, based on the general terms and conditions, tailored to the specific requirements of the executing area.

Traceability

The ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal, and vice versa.

Trace-back

The process of investigating a report of a suspected transfusion-associated adverse reaction in a recipient in order to identify a potentially implicated donor.

VNRBD/ VUD

Voluntary non-remunerated blood donation/ Voluntary unpaid donation

"Donation is considered voluntary and non-remunerated if the person who gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation". [1]

Washed

A process of removing plasma or storage medium from cellular products by centrifugation, decanting of the supernatant liquid from the cells and addition of an isotonic suspension fluid, which in turn is generally removed and replaced following further centrifugation of the suspension. The centrifugation, decanting, replacing process may be repeated several times.

Whole blood

A single blood donation.

Whole Blood for transfusion is only available in a limited number of EU MS. In exceptional circumstances and in accordance with increasing scientific data, it might be advisable to stockpile Whole blood. This decision shall be made in agreement with the participating EU MS and TCN of an EU-led military CSDP operation or mission.

[1] Definition of the Council of Europe in Recommendation No. 95 (14), endorsed by the European Union, the WHO, International Society of Blood Transfusion, International Federation of Red Cross and Red Crescent Societies and International Federation of Blood Donor Association.

20. Abbreviations

Athena	Financing mechanism for EU-led CSDP military Missions and Operations
CSDP	Common Security and Defence Policy
CDC	Centers for Disease Control and Prevention
CDIP	Conceptual Development Implementation Programme
CSO	Contractor Support to Operations
DCR	Damage Control Resuscitation
DCS	Damage Control Surgery
EIA	Enzyme Immuno Assays
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EU	European Union
EUMC	European Union Military Committee
EUMS	European Union Military Staff
EU MS	European Union Member States
EU OHQ	European Union Operational Headquarter
FFP	Fresh Frozen Plasma
GMP	Good Manufacturing Practice
GDP	Good Distribution Practice
HAV	Hepatitis A Virus
HBV	Hepatitis B Virus
HBsAg	Hepatitis B surface Antigen
HBc	Hepatitis B core Antigen
HCV	Hepatitis C Virus
HEV	Hepatitis E Virus
HIV	Human Immunodeficiency Virus
HLA	Human Leukocyte Antigen

HNA	Human Neutrophil Antigen
HTLV	Human T-cell Lymphotropic Virus type 1
ID	Individual
ISBT	International Society of Blood Transfusion
OHQ	Operation Head Quarter
MPCC	Military Planning and Conduct Capability
MTF	Medical Treatment Facility
NAT	Nucleic Acid Amplification Techniques
PCR	Polymerase Chain Reaction
RBC	Red Blood Cells
RhD neg	Rhesus Factor (D) negative
RhD pos	Rhesus Factor (D) positive
SME	Subject Matter Experts
TCN	Troup Contributing Nation
TEU	Treaty of the European Union
TRALI	Transfusion Related Acute Lung Injury
TPHA	Treponema Pallidum Haemagglutination Assay
VNRBD	Voluntary Non Remunerated Blood Donation
VUD	Voluntary unpaid donations
WNV	West Nile Virus
WHO	World Health Organisation
WB	Whole Blood

21. References

A. Consolidated versions of the Treaty on European Union (TEU) and the Treaty on the functioning of the European Union (TFEU) (Treaty of Lisbon 13/12/2007 plus amendments, Council Doc 655/08), dated 15/04/2008.

B. Council Decision 2004/197/CFSP of 23 February 2004 (O.J. No L 63, 28 February 2004, p. 68).

C. Council Decision 2015/528/CFSP of 27 March 2015 (O.J. No L 84, 28 March 2015, p.39-63).

D. Comprehensive Health and Medical Support Concept for EU-led Crisis Management Operations of 3rd June 2014 (10530/14).

E. EU Concept for Logistic Support for EU-led Military Operations and Missions of 1 October 2018 (12628/18).

F. EUMC Glossary of Acronyms and Definitions - Revision 2018 of 22 February 2019 (6763/19).

G. EU Conceptual Development Implementation Programme 2019-2020 (CDIP 19-20) of 2 May 2019 (8980/19).

H. EU Concept for Contractor Support to EU-led military operations of 7 April 2014 (8628/14)

I. Financial Rules Applicable to expenditure financed through ATHENA, Act of the Special Committee 16-0139 of 16 March 2016

J. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67–128).

K. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human Blood and Blood Components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30–40).

L. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice (GMP) in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22–26).

M. Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components (OJ L 91, 30.3.2004, p. 25–39).

N. Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events (OJ L 287M, 18.10.2006, p. 350–358 (MT); OJ L 256, 1.10.2005, p. 32–40).

O. Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments (OJ L 256, 1.10.2005, p. 41–48; OJ L 287M, 18.10.2006, p. 359–366).

P. Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life (OJ L 97, 12.4.2011, p. 28–29).

Q. 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 (OJ L 366, 20.12.2014, p. 81–82).

R. Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments (OJ L 199, 26.7.2016, p. 14–15)

S. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1–33).

T. Regulation (EU) No 2017/ 746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices (OJ L 117, 5.5.2017, p. 176 – 332)

U. Guidelines of 5 November 2013 on Good Distribution Practice (GDP) of medicinal products for human use (OJ C 343, 23.11.2013, p. 1–14).

V. Good Practice Guidelines (GPG) for Blood Establishment required to comply with Directive 2005/62/EC of 15 February 2018.

W. Guide to the preparation, use and quality assurance of blood components, 19th Edition as of 2017, European Commission and Council of Europe, European Directorate for the Quality of Medicines (EDQM)

X. The collection, testing and use of blood and blood components in Europe, 2015. European Directorate for the Quality of Medicines and Health Care-Council of Europe

Y. WHO, Screening Donated Blood for Transfusion-Transmissible Infections, Recommendations, 2010.

Z. Minimum technical requirements for contracted in-theatre Role 2 Basic services for EU Operations and Missions of 13 March 2018 (7138/18)

AA. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1–88)

BB. 10th Edition of the European Pharmacopoeia (Ph.Eur.), released July 2019

ANNEX A **Whole Blood (WB)** [1]

Specific requirements:

Single donor

Low Titre Whole Blood (LTWB)

Leukocyte depleted (desirable)

1 Unit 450ml +/- 10 %

In a sterile plastic bag system (CE marked)

Including sterile transfusion sets (150-250µm filter; ISO 1135-4:2015 or equivalent)

Haemoglobin not less than 45 g per unit

Haematocrit between 50 – 70 %

Haemolysis less than 0, 8% of red cell mass at the end of the shelf life

Titre anti-A/B IgM < 1:256

Testing: According to Paragraph 9

Shelf life Minimum of 21 days at the day of delivery and/ or until the next planned delivery[2]

[1] Whole Blood delivery will only be required under exceptional circumstances.

[2] Shelf life must be proven by scientific data comparable to components.

ANNEX B **Red Blood Cells (RBC)**

Specific requirements:

Single donor

Leukocyte depleted with or without additive solution[1]

Liquid or frozen[2]

1 Unit 280ml +/- 20%

In a sterile plastic bag system (CE marked)

Including sterile transfusion sets (150-250µm filter; ISO 1135-4:2015 or equivalent)

Haemoglobin not less than 40 g per unit

Haematocrit between 50 – 70 %

Haemolysis less than 0, 8% of red cell mass at the end of the shelf life

Leukocyte content less than $1x10^6$ per unit

Testing: According to Paragraph 9

Shelf life Minimum of 28 days at the day of delivery and/ or until the next planned delivery[3]

[1] Only additive solutions listed in the European Pharmacopeia (http://online.edqm.eu/EN/entry.htm)

[2] An appropriate amount of liquid RBC for immediate transfusion shall be held in stock as post- thaw RBC shall not be utilised >24hours.

[3] In emergency cases a reduced shelf life may be accepted (if agreed by the Contracting authority) but should not be less than 21 days.

ANNEX C **Platelet Concentrates**[1]

Specific requirements:

Single donor/ Pooled/ Apheresis/ Recovered

Pathogen inactivation (desirable)

Fresh/ Cold or frozen[2]

1 Unit approx. 300ml plasma

In sterile plastic bag system (CE marked)

Including sterile transfusion sets (large pore filter; ISO 1135-4:2015 or equivalent)

Platelet content $300x10^9$ to $350x10^9$

pH value at the end of shelf life not less than 6, 4

Testing: According to Paragraph 9

Shelf life Minimum of 75% of the manufacturer guarantee

[1] Due to the limited shelf life of fresh platelet concentrates (5-7 days) and logistic constraints for transport in austere environments, fresh platelets will only be required for delivery in exceptional operational settings.

[2] Or alternates in accordance with present product development

ANNEX D **Fresh Frozen Plasma (FFP)/ Frozen Plasma (FP)**

Specific requirements:

Whole Blood (recovered plasma) or via apheresis

Leukocyte-depleted

Fresh frozen (temperature -25°C) as soon as possible but NLT 24 h after collection

Storage temperature at least -25°C

1 Unit 200 to 360 ml

In a sterile plastic bag system (CE marked)

Including sterile transfusion sets (150-250µm filter; ISO 1135-4:2015 or equivalent)

Total protein	> 50 g/l
Factor VIII	> 70IU/ 100ml
	> 50 IU/ 100ml if PR[1]

Residual cellular content:

Red cells:	< 6.0 x 10^9 /l
Leukocytes:	< 0.1 x 10^9 /l
Platelets:	< 50 x 10^9 /l

Testing: According to Paragraph 9

Additional labelling:

Warning that the component must be used within 4 hours of thawing if maintained at 22 ±2°C, or up to a maximum of 120 hours of thawing if stored at 4 ±2°C, depending on indication

Shelf life Minimum of 12 months at the day of delivery and/ or until the next planned delivery[2]

[1] PR: Pathogen reduced

[2] In emergency cases (or in reference to a reduced shelf life may be accepted but should not be less than 3 months.

ANNEX E **Dried Plasma**

(Freeze dried (lyophilised)/ spray dried)

The market of dried plasma in the European Union is limited and the available products are not licensed in all EU MS. Manufacturer specification of the two products with marketing authorisation can be found below.

French Lyophilised Plasma (FLyP®)

Licensed for use outside the United States[1]

Pathogen reduced leukocyte depleted freeze dried plasma

Pooled apheresis FFP from small donor-pools (<12)

Voluntary donation with strict medical selection

Amotosalen based pathogen attenuation

Normal factor levels

ABO universal

Testing:

All:

- Haemoglobin
- ABO Rh Kell
- HIV 1/2 antibodies & PCR
- HCV antibodies & PCR
- HBV antigen & PCR
- HTLV antibodies
- Syphilis antibodies

Some:

- Chagas antibodies
- Malaria antibodies

Only for plasma

- HLA antibodies
- Haemostasis tests
- HEV PCR

Shelf life 2 years at room temperature

[1] 9th July 2018, FDA authorisation for emergency use in military operations (treatment of haemorrhage or coagulopathy when FFP is not available or practical)

LyoPlas N-W®

Lyophilised leuko-reduced plasma

Apheresis single donor (frozen 4 months quarantine for donor retest)

TRALI prevention (male or leukocyte-antibody negative donors)

Normal factor levels

ABO type specific (0, A, B, AB)

1 Unit 200 ml

Sterile bottle (CE marked) plus transfer fluid and devices

Including sterile transfusion sets (170-230µm filter)

Coagulation Active Factors:

aPTT	26 – 45 s
Fibrinogen	≥ 1, 7 g/l
F VIII	≥ 0, 7 IE/ml (testing in pools of 6 units)
pH	6, 8 – 8, 0
Erythrocyte	below the detection limit
Leukocyte	below the detection limit
Thrombocytes	below the detection limit

Testing:

Routine Testing according to DE legislation[1] including

- HIV (HIV 1/2 antibodies, HIV-1 RNA)
- HBV (HBsAg, HBV DNA)
- HCV (HCV antibodies, HCV RNA)
- HAV RNA
- Treponema pallidum (Anti-Treponema pallidum-antibodies)
- PVB-19 DNA

Retesting after 4 months quarantine frozen storage

Shelf life 15 months at +2° to +25°C

[1] DE legislation includes mandatory testing for HEV NAT from 1/2020 and WNV PCR from 6/2020

ANNEX F **Fibrinogen Concentrates**[1]

Specific requirements:

Lyophilised and purified from pooled Human Plasma

Virus/ dual-pathogen inactivated

Human albumin (stabiliser)

1 Unit Human Plasma Fibrinogen

Powder for solution plus sterile water

Quality requirements according to the latest monographs of European Pharmacopoeia (Reference BB) related to Human Plasma for fractionation (0853) and Human Fibrinogen (0024)

Marketing authorization (preferably in an EU member state)

[1] Licensing of Fibrinogen Concentrates for acquired fibrinogen deficiency in the EU limited to Haemocomplettan® and Fibryga®