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THE TANZANIA MEDICINES AND MEDICAL DEVICES ACT,
(CAP. 219)

REGULATIONS

THE TANZANIA MEDICINES AND MEDICAL DEVICES (CONTROL OF BLOOD AND BLOOD PRODUCTS) REGULATIONS, 2026

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THE TANZANIA MEDICINES AND MEDICAL DEVICES ACT, (CAP. 219)

REGULATIONS

(Made under section 122)

THE TANZANIA MEDICINES AND MEDICAL DEVICES (CONTROL OF BLOOD AND BLOOD PRODUCTS) REGULATIONS, 2026

PART I
PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Tanzania Medicine and Medical Devices (Control of Blood and Blood Products) Regulations, 2026.

Application

2. These Regulations shall apply in all regulatory controls related to blood and blood products including plasma-derived medicinal products in Mainland Tanzania.

Interpretation

3. In these Regulations, unless the context otherwise requires-

Cap. 219

"Act" means the Tanzania Medicine and Medical Devices Act;

"allogeneic donation" means blood and blood components collected from an individual and intended for transfusion to another individual, or for use in medical devices or as starting material or raw material for manufacturing into medicinal products;

"apheresis" means 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;

"applicant" means a natural or legal person, established within or outside Mainland Tanzania, who seek to obtain or has obtained a license to render blood transfusion service under these regulations or who is a marketing authorisation holder of the blood product;

"Authority" has the meaning ascribed to it under the Act;

"autologous donation" means blood or blood components collected from an individual and intended solely for subsequent autologous transfusion or other human application to the same individual;

"autologous transfusion" means a transfusion in which donor and recipient are the same person, using pre-deposited blood or blood components;

"blood" means whole human blood collected from a donor and processed either for transfusion of for further manufacturing, excluding blood specimens intended for pathology testing;

"blood component" means a constituent of blood erythrocytes, leukocytes, platelets, cryoprecipitate and plasma, that can be prepared by various separation methods and under appropriate conditions, may be used directly for therapeutic purposes or for further processing or manufacturing;

"blood donor" means a voluntary, non-remunerated person from whom blood is withdrawn for the subsequent administering to another person or to himself or for the processing into blood products;

"blood establishment" means structure, facility or body that is used for collection, testing, processing, storage, release or distribution of human blood or blood components intended for transfusion or industrial manufacturing;

"blood product" means any therapeutic product derived from human blood or plasma;

"buffy coat" means a blood component prepared by centrifugation of a unit of whole blood, and which

contains a considerable proportion of the leucocytes and platelets;

"cryoprecipitate" means 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" means preservation of blood components by freezing in order to extend their storage life;

"deferral" means permanent or temporary suspension of the individual's eligibility to donate blood or blood components;

"distribution" means an act of delivery of blood and blood components to other blood establishments, hospital blood banks, importers, wholesalers and manufacturers of blood products, other than the issuing of blood or blood components for transfusion;

"directed blood donor" means a blood donor who donates blood intended for transfusion to a specific patient to be transfused to a specific patient; they are normative statements;

"extended phenotyping" means red cell antigen typing other than ABOD but not limited to Kelly, Duffy, Lewis, kelano and MNS system;

"good clinical practice" means a standard for the design, conduct, performance, monitoring, auditing, recording, analysing and reporting of clinical trials, that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected;

"granulocytes apheresis" means a concentrated suspension of granulocytes obtained by apheresis;

"haemovigilance" means 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 donor;

"hospital blood bank" means a unit within a hospital which stores and issues, and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities;

"import" means the entry into Mainland Tanzania of products regulated under the Act;

"inspection" means formal and objective assessment conducted to identify non-conformances in accordance with standards adopted to determine compliance with these Regulations;

"leucapheresis" means the process by which the blood drawn from a donor is processed to separate leukocyte concentrates and the remaining blood components are simultaneously re-transfused into the donor;

"licensing" means authorisation granted by the Authority for the manufacturing, importation, exportation or distribution of blood and blood products;

"lookback haemovigilance system" means a form of haemovigilance system which involves the identification of recipients of blood or blood products from a donor who is subsequently found to have a condition that may pose a risk of transfusion-transmissible infection, and includes quarantine, recall, counselling, testing and management of affected recipients;

"manufacturer" means a natural or legal person responsible for one or more of the following activities in relation to blood products: collection, testing, processing, storage, packaging, labelling, release or distribution;

"Minister" has the meaning ascribed to it under the Act;

"paid blood donor" means a person who donates blood in exchange for money or any other form of payment;

"platelets apheresis" means a concentrated suspension of blood platelets obtained by apheresis;

"platelets apheresis, leucocyte-depleted" means a concentrated suspension of blood platelets, obtained by apheresis, and from which leucocytes have been removed;

"platelets, recovered, pooled" means 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, leucocyte-depleted" means 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 leucocytes are removed;

"platelets, recovered, single unit" means a concentrated suspension of blood platelets, obtained by processing of a single unit of whole blood;

"platelets, recovered, single unit, leucocyte-depleted" means a concentrated suspension of blood platelets, obtained by processing of a single whole blood unit from which leucocytes are removed;

"plasma" means the liquid portion of the blood in which the cells are suspended, separated from the cellular portion of a whole blood for therapeutic use as fresh frozen plasma, or further processing into cryoprecipitate and cryoprecipitate-depleted plasma for transfusion;

"plasma-derived medicinal product" means any therapeutic product derived from human plasma and produced by an industrial-scale manufacturing process involving pooled plasma units;

"plasma, fresh-frozen" means the supernatant plasma separated from a whole blood donation or plasma collected by apheresis, frozen and stored;

"plasma, cryoprecipitate-depleted for transfusion" means a plasma component prepared from a unit of

plasma, fresh-frozen and it comprises the residual portion after removal of cryoprecipitate;

"qualified health professional" means a medical practitioner, nurse or donor carer;

"recall" in relation to blood and blood products, means any action taken by manufacturer, importer, supplier or marketing authorisation holder to remove blood or blood products from the market or a blood bank or to retrieve them from any person to whom they have been supplied, where such blood or blood product may-

(a) be hazardous to health;

(b) fail to conform to any claim made by its manufacturer or importer relating to its quality, safety or efficacy; or

(c) fail to meet the requirements of these Regulations;

"recipient" means a person to whom blood or blood products are administered whether donated by another person or by individual themselves;

"red cells" means the red cells obtained from a single whole blood donation, with majority of plasma removed;

"red cells, buffy coat removed" means the red cells from a single whole blood donation, with majority of plasma remove, and from which the buffy coat containing a large proportion of platelets and leucocytes is removed;

"red cells, leucocyte-depleted" means the red cells from a single whole blood donation, with most of the plasma removed, and from which leucocytes has been removed;

"red cells in additive solution" means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, with a nutrient or preservative solution added;

"red cells, leucocyte-depleted, in additive solution" means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, with leucocytes removed, and a nutrient or preservative solution added;

"red cells, apheresis" means the red cells obtained from an apheresis red cell donation;

"responsible person" mean a person designated to manage a blood establishment in accordance with these Regulations;

"serious adverse event" means any untoward occurrence related to the collection, testing, processing, storage and distribution of blood or blood products, which may cause death or life-threatening, disabling or incapacitating conditions for patients or results in or prolong, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response in a donor or in a recipient associated with the collection or transfusion of blood or blood products that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity;

"site" means any premises at where a blood establishment carries out any of the responsibilities listed in regulation 4(3), but shall not include any premises owned or managed by the blood establishment at which blood is collected, or any mobile blood collection unit;

"standards of practice" means the standards of practice for blood transfusion services as prescribed under these Regulations;

"transfusion reaction" means any adverse reaction as a result of the administration of blood or a blood products;

"transfusion transmissible infection" means an infection that can be transmitted through transfusion of blood or blood products;

"validation" means the establishment of documented and objective evidence that specific requirements for a particular intended use can be consistently fulfilled; and

"washed" means 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.

PART II
CLASSIFICATION OF BLOOD ESTABLISHMENTS

Classification of blood establishments

4.-(1) Blood establishments shall be classified in the following categories:

(a) manufacturing facilities;
(b) hospital blood banks;
(c) National Blood Transfusion Services;
(d) importers and wholesalers of plasma derived medicinal products, blood components, reagents and consumables;
(e) mobile blood collection units or vehicles; and
(f) any other establishment as the Authority may designate.

(2) Subject to provisions of subregulation (1)-

(a) a person operating a manufacturing facility shall be responsible for manufacturing of plasma derived medicinal products;
(b) a person in charge of a hospital blood bank shall be responsible for storage, compatibility testing, blood grouping and issuing of blood and blood products for transfusion;
(c) the authority responsible for National Blood Transfusion Services shall be responsible for donor recruitment, collection, storage, component production, testing and distribution

of blood and blood products intended to be used for transfusion;

(d) an importer or wholesaler shall be responsible for importation, storage and distribution of blood products; and

(e) a person operating a mobile blood collection unit shall be responsible for donation and conveyance of blood and blood products.

Prohibition to carry out activities without authorisation

5. A person shall not carry out any of the activities provided under regulation 4(2) except as authorised under these Regulations.

Authorisation of blood establishment

6.-(1) A person intending to establish and operate a blood establishment shall apply to the Authority for authorisation by filling the form set out in the First Schedule.

(2) The Authority may, upon satisfaction with the application, grant an authorisation for carrying any of the activities referred to under regulation 4.

(3) An application referred to under subregulation (1) shall contain the following:

(a) the name and address of the blood establishment and general information about its activities which shall include:

(i) details of each site at which it wishes to carry out any of the activities;

(ii) a description of the activities which it wishes to carry out at each site;

(iii) where it has or intends to enter into a contractual arrangement with any person to carry out any of the services in respect of which it is seeking authorisation, the name, address of that person and the services which he will carry out;

(iv) the name, qualifications and contact details of the responsible person for the establishment;

(v) the list of hospital blood banks which it supplies; and

(b) description of the quality system in place at each site for each activity in respect of which the application for authorisation is made, which shall include the following information:

(i) documentation, such as an organisation chart, setting out the responsibilities of responsible persons and reporting relationships;

(ii) documentation, such as a site master file or quality manual, describing the quality system and explaining how it meets requirements for quality and safety of blood and blood products as prescribed under these Regulations;

(iii) details of the number and qualifications of personnel;

(iv) details of hygiene provisions;

(v) details of premises and equipment; and

(vi) list of standard operating procedures for-

(aa) recruitment, retention and assessment of donors;

(bb) processing, testing, distribution and recall of blood and blood products;

(cc) the reporting and recording of serious adverse reactions and events; and

(dd) any other procedures as may be designated by the Authority;

(c) proof of payment of the precribed application fee which shall be non-refundable.

Verification of application for authorisation

7.-(1) The Authority shall, on receipt of the application for grant or renewal of authorisation-

(a) verify the statements made in the application form; and

(b) conduct inspection on the blood establishment in accordance with the provisions of these Regulations.

(2) Upon scrutiny of the application and submitted documents, the Authority may grant or refuse the application.

(3) Where the Authority grants the application, the authorisation may be-

(a) in respect of particular a site or activity; or

(b) subject to conditions.

(4) Where the Authority grants an application for authorisation, it shall issue a licence to the blood establishment specifying-

(a) the activities which the blood establishment may undertake at each site in respect of which authorisation is granted; and

(b) the conditions which apply to the undertaking of the activities.

Authority may vary conditions

8.-(1) The Authority may at any time remove or vary any of the conditions or may impose additional conditions as provided for under these Regulations.

(2) Where the Authority removes or varies any condition or imposes any additional condition pursuant to subregulation (1), the Authority shall serve a notice on the blood establishment in question providing-

(a) details of the condition which the Authority intends to remove, vary or impose;

(b) reasons for the decision; and

(c) specific date, which shall be not less than fourteen days from the date on which the notice is served, from which the removal, variation or imposition of the condition shall apply.

(2) A blood establishment shall not make any substantial change in the activities which it undertakes without applying for and obtaining a written approval of the Authority.

(3) Application for approval to make a substantial change in activities shall be accompanied by a fee of the amount prescribed under the applicable fees and charges regulations.

(4) For the purpose of subregulation (2), a substantial change in the activities of blood establishment include changes-

(a) to the sites from which the blood establishment operates or to the activities to be carried out at each site;

(b) which would result to breach of these Regulations or of any condition specified by the Authority pursuant to this regulation; or

(c) to the quality system which may have a substantial impact on the conduct of, or compromise the safety of, any of the activities which the blood establishment has been authorised to undertake pursuant to this regulation.

Duration of authorisation

9.-(1) The licence granted under these Regulations shall, unless sooner suspended, cancelled or revoked, be valid for a period of one year starting from 1st July of each year.

(2) The validity of authorisation may cease to be valid upon-

(a) voluntary withdrawal; or

(b) suspension, revocation or cancellation by the Authority.

Suspension or revocation of license

10-.(1) The Authority may suspend or revoke the license of a blood establishment on one or more of the following grounds:

(a) where the blood establishment fails to comply with the requirements of these Regulations;

(b) where collection, testing, processing, storage or distribution of blood or blood products cannot be carried out safely;

(c) where the establishment fails to supply any blood or blood product in a condition that is safe for administration by transfusion;

(d) where the Authority determines that the information submitted by the blood establishment pursuant to regulation 6(3) is false or incomplete; and

(e) where the blood establishment is found to have collected blood from paid blood donors and engaged in the sale of blood.

(2) Subject to subregulation (3), before suspending or revoking the authorisation of a blood establishment, the Authority shall serve a notice on the establishment stating its intention to suspend or revoke the authorisation. The notice shall specify the date on which the suspension or revocation shall take effect, which shall not be less than thirty days from the date on which the notice is served.

(3) Where the Authority considers that it is necessary in the interests of safety, the Authority may, by a notice served on a blood establishment, suspend or revoke its authorisation with immediate effect.

(4) Where-

(a) the blood establishment has failed to comply with the requirements of these Regulations; or

(b) the information given by the blood establishment pursuant to regulation 6(3) is false or incomplete, and the Authority considers that the default is not serious to warrant suspension or revocation of the authorisation of the blood establishment in the first instance,

the Authority may serve a notice on the responsible person of the blood establishment in accordance with subregulation (5).

(5) A notice served under this subregulation shall-

(a) identify the requirements of the regulations which the blood establishment has breached or, in the case of false or incomplete information, the further information which is required;

(b) identify the action which the blood establishment is required to take; and

(c) state the time within which the blood establishment shall take the action identified in paragraph (b).

(6) Where the blood establishment fails to comply with the requirements set out in the notice within the specified time, the Authority may, by a notice served on the blood establishment, suspend or revoke the authorisation of the blood establishment.

(7) A suspension or revocation pursuant to subregulation (6) shall take effect-

(a) where the Authority considers that it is necessary in the interests of safety, immediately; or

(b) in all other cases, from the date specified in the notice.

(8) Any suspension pursuant to subregulation (1) or (6) shall be for a period as the Authority considers necessary having regard to the reasons for the suspension.

(9) Suspension or revocation of an authorisation under subregulation (1) may be full or partially limited to a particular activity carried out at a particular site or blood product.

PART III
REQUIREMENTS FOR BLOOD ESTABLISHMENTS

National Blood Transfusion Services requirements

11.-(1) National Blood Transfusion Services shall-

(a) ensure that the personnel directly involved in the collection, testing, processing, storage and distribution of human blood and blood products for the blood establishment are qualified to perform those tasks and are provided with timely, relevant and regularly updated training;

(b) establish and maintain a quality system for blood establishments based on the principles of good practice as prescribed by the Authority;

(c) ensure that all testing and processes of the blood establishment which are referred to under these Regulations are validated;

(d) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available;

(e) notify the Authority of-

(i) any serious adverse events related to the collection, testing, processing, storage and distribution of blood and blood product by the blood establishment which may have an influence on their quality and safety, and

(ii) any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood product collected, tested, processed, stored or distributed by the blood establishment as provided for under these Regulations; and

(f) establish and maintain a procedure which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood products associated with any notification referred under this paragraph.

(2) A blood establishment shall, in relation to the donation of blood-

(a) give all prospective donors of blood or blood products information in the manner provided in the Second Schedule;

(b) obtain from all prospective donors of blood or blood products, information in the manner provided in the Third Schedule;

(c) put in place procedures for the evaluation of donors;
(d) apply eligibility criteria for all donors of blood and blood products in the manner provided in the Fourth Schedule;
(e) maintain records of the results of donor evaluations and report to donors any relevant abnormal findings from the evaluations;
(f) ensure that-
(i) an examination of the donor, including an interview, is carried out before any donation of blood or blood products;
(ii) a qualified health professional is responsible for giving to and gathering from donors the information which is necessary to assess their eligibility to donate; and
(iii) on the basis of that information, a qualified health professional assesses the eligibility of all donors to donate;
(g) encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood products are, in so far as possible, provided from such donations, in particular, by-
(i) disseminating information about blood donation; and
(ii) advertising for blood donors.

(3) The National Blood Transfusion Services shall ensure that, in relation to the collection, processing, storage or distribution of blood and blood products-
(a) each donation of blood and blood products imported into Mainland Tanzania is tested in conformity with-
(i) the basic testing requirements for whole blood and apheresis donations, specified under subregulation (4); and

(ii) any additional tests which may be necessary for specific products, types of donors or epidemiological situations;

(b) the storage, transport and distribution conditions of blood and blood products comply with the requirements specified in the Fifth Schedule; and

(c) quality and safety requirements for blood and blood products meet the standards specified in the Sixth Schedule including any amendments made thereof.

(4) For purposes of subregulation (4)(a)(i), the National Blood Transfusion Services shall ensure basic testing requirements, including-

(a) testing to establish ABO and Rh D group and extended phenotyping;

(b) testing for high alloaglutinin titres in all Group O donations;

(c) testing for red cell antibodies for first-time donors and donors with history of pregnancy or transfusion; and

(d) testing for the following infections in donors:

(i) Hepatitis B (HBs-Ag);

(ii) Hepatitis C (Anti-HCV);

(iii) HIV 1 and 2 (Anti-HIV 1 and 2); or

(iv) Syphilis.

(5) The Authority may issue guidance on the additional tests referred to in subregulation (4), which are necessary in relation to specific products, types of donor or epidemiological situations and blood establishments shall have regard to such guidance.

(6) Subject to subregulation (5), the Authority shall, in issuing such guidance, collaborate with the National Blood Transfusion Services.

(7) The National Blood Transfusion Service shall, as soon as practicable after the end of the reporting year, provide to the Authority a report specifying-

(a) the information referred to in subregulation (4) for that year; and
(b) details of the steps it has taken during that year to comply with subregulation (2)(g).

Hospital blood bank requirements

12.-(1) The person responsible for the management of a hospital blood bank shall-

(a) ensure that personnel directly involved in the testing, storage and distribution of human blood and blood products for the hospital blood bank are qualified to perform those tasks and are provided with timely, relevant and regularly updated training;
(b) establish and maintain a quality system for the hospital blood bank which is based on the principles of good practice;
(c) ensure that all processes under the Fourth Schedule, which are applicable to activities carried out by the hospital blood bank, are valid;
(d) maintain documentation on operational procedures, guidelines, training, reference manuals and reporting forms so that they are readily available;
(e) maintain, for not less than ten years, the data needed to ensure full traceability of blood and blood products, from the point of receipt by the hospital blood bank;
(f) record any serious adverse events related to the testing, storage and distribution of blood and blood products by the hospital blood bank which may have an influence on their quality and safety; and
(g) notify the Director General of-
    (i) any serious adverse events related to the testing, storage and distribution of blood and blood products by the hospital blood

bank which may have an influence on their quality and safety, and

(ii) any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood products issued for transfusion by the hospital blood bank, as provided for under these Regulations;

(h) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood products associated with any notification referred to in paragraph (g);

(i) ensure that the storage, transport and distribution conditions of blood and blood products by the hospital blood bank comply with the requirements in the Fourth Schedule; and

(j) ensure that the following testing requirements are conducted-

(i) testing to establish ABO and Rh D group and extended phenotyping;

(ii) testing for antibody screening and identification; and

(iii) testing for compatibility.

(2) All hospital blood banks stationed within specialised referral hospitals, shall be supervised by a registered medical practitioner.

Manufacturing facility requirements

13. Manufacturing facilities engaged in the manufacturing of blood products shall comply with the current good manufacturing practice requirements set forth in the applicable good manufacturing practice regulations.

Importers and wholesalers' requirements

14. Importers and wholesalers of blood products shall comply with the provisions set out in Part VI of these Regulations.

Mobile blood collection units requirements

15. Mobile blood collection units or vehicles shall meet the following minimum standards:

(a) be designed to undertake blood donation, particularly in hard-to reach areas;
(b) have adequate storage space or cabinets for keeping registers, blood bags, chemicals, reagents, and other consumables;
(c) have donor beds of adequate size;
(d) have sufficient electrical equipment;
(e) be equipped with air conditioning facilities;
(f) have public address system;
(g) have refrigerator for storage of blood and blood products;
(h) have changing rooms with wash basins and chemical toilets conveniently placed;
(i) have cool boxes for collection and transport of blood bags; and
(j) provide donor refreshments.

Person responsible for blood establishment

16.-(1) A blood establishment shall designate a person who is responsible for the following functions:

(a) ensuring that every unit of blood or blood product has been collected and tested in accordance with the requirements of these Regulations;
(b) ensuring that every unit of blood or blood products intended for transfusion has been processed, stored and distributed in accordance with the requirements of these Regulations;
(c) providing information to the Authority relating to the authorisation of the blood establishment; and
(d) the implementation in the blood establishment of the requirements of these Regulations.

(2) A blood establishment shall not designate a person under subregulation (1), unless that person has-

(a) a bachelor degree in the field of medical or biological sciences recognised by relevant professional body;

(b) a diploma or equivalent qualification in the field of medical or biological sciences recognised by relevant professional body; or

(c) a practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under these Regulations for at least two years, in an establishment authorised to undertake activities related to the collection, testing, preparation, storage and distribution of blood and blood products.

(3) The responsible person may delegate any of the functions specified in subregulation (1) to other persons who are qualified and experienced to perform such functions.

(4) The blood establishments shall notify the Authority of the name of any persons to whom functions have been delegated under subregulation (3), and the specific functions which have been delegated.

(5) Where the responsible person or a person to whom functions have been delegated is permanently or temporarily replaced, the blood establishment shall without delay, provide to the Authority the name of the replacement, details of his qualifications and the date on which the replacement began his functions.

(6) Where the Authority finds that the responsible person does not meet the requirements under these Regulations, it may serve a notice to that effect on the blood establishment.

(7) Where, within fourteen days of receiving a notice in accordance with subregulation (6), a blood establishment fails to demonstrate to the reasonable satisfaction of the Authority that the responsible person meets the requirements provided under subregulation (2), the establishment shall, without delay-

(a) relieve such person of the duties of responsible person in respect of the establishment;
(b) appoint a new responsible person in his place; and
(c) notify the Authority of the appointment and provide details of the name and qualifications of the person appointed.

PART IV
CLINICAL TRIALS FOR BLOOD AND BLOOD PRODUCTS

Authorisation of clinical trials for blood and blood products

17. Applications for authorisation of clinical trials involving blood and blood products as investigational products, shall be made in accordance with the provisions of the applicable regulations for control of clinical trials.

Material transfer agreement

18. Subject to regulation 19, transfer of investigational products in form of blood and blood products for clinical trial purpose, shall be done based on material transfer agreement and in accordance with the provisions of the applicable ethical regulations.

Good clinical practice inspections

19. The Authority shall carry out regular good clinical practice inspections as provided for in the applicable regulations for control of clinical trialsa.

Ethical considerations

20. All ethical matters for clinical and non-clinical trials shall be made in accordance with the provisions of the pplicable ethical regulations.

PART V
INSPECTION OF BLOOD AND BLOOD PRODUCTS

Inspections

21.-(1) The Authority shall conduct regular inspections of each blood establishment for the purpose of-

(a) ascertaining compliance with the requirements of these Regulations; and

(b) identifying any non-compliance with these Regulations.

(2) The Authority may serve a notice on a blood establishment requiring it to furnish information concerning its compliance with these Regulations within the period specified in the notice.

(3) A blood establishment which receives a notice in accordance with subregulation (2), shall provide the information requested within the period specified in the notice.

(4) Where a serious adverse event or serious adverse reaction occurs or is suspected to have occured, the Authority may request any information or conduct an inspection under this regulation as it considers appropriate.

(5) A reference in this regulation to an inspection of a site which the Authority is required or empowered to conduct shall include an inspection of premises in Mainland Tanzania at which any activity specified under regulation 4(3) is carried out by a person on behalf of, and pursuant to a contractual arrangement with, a blood establishment.

(6) The Authority may, subject to such terms and conditions as it may deem appropriate, appoint persons to be inspectors for the proper discharge of its functions under these Regulations.

(7) Notwithstanding subregulation (6), the Authority may designate officers from the National Blood Transfusion Services to be inspectors for the purposes of these Regulations.

Powers of inspectors

22.-(1) For the purposes of enforcing compliance or conducting inspections under these Regulations, an inspector shall, upon production of evidence of authorisation, have the power-

(a) at any reasonable time, to enter any premises, other than premises used solely as a private dwelling house, which the inspector has reason to believe it is necessary to enter, including-

(i) any premises owned or managed by a blood establishment;

(ii) any premises of any person who carries out an activity specified under these Regulations on behalf of, and pursuant to a contractual arrangement with a blood establishment;

(iii) any premises, other than a blood establishment, in which a facility for donor evaluation and testing is located.

(b) to carry out, at the premises such inspections, examinations, tests or analyses as he considers necessary;

(c) to require the production of, and inspect any article or substance found at the premises;

(d) to require the production of, inspect and take copies of, or extracts from, any book, document, data or record in whatever form held, found at the premises or, in the case of computer data or records, accessible at the premises;

(e) to take possession of any samples for examination or analysis, and of any article, substance, book, document, data or record, in whatever form held, found at the premises, or in the case of computer data or records, accessible at the premises;

(f) to question any person found at the premises and whom he has reasonable cause to believe is able to provide relevant information;

(g) to require any person to provide such assistance as the inspector considers necessary in relation to any matter within that person's control or responsibility; and

(h) to require any person to provide such facilities as the inspector may reasonably require, provided that nothing in this subregulation shall be construed as requiring a person to

produce any document which that person would be entitled to withhold on the ground of legal professional privilege in proceedings before a court.

(2) Where a justice of peace is satisfied by any written information on oath that there are reasonable grounds for entry into any premises, other than premises used solely as a private dwelling, for any purpose mentioned in subregulation (1), and-

(a) admission to the premises has been refused or is likely to be refused and notice of intention to apply for a warrant under this subregulation has been given to the occupier;

(b) an application for admission, or the giving of such notice, would defeat the object of the entry; or

(c) the premises are unoccupied or the occupier is temporarily absent and it might defeat the object of the entry to await his return,

the justice may, by warrant signed by him, and which shall continue in force for any reasonable time, authorise an inspector to enter the premises by force.

(3) An inspector entering premises by virtue of subregulation (1) or a warrant under subregulation (2) may take with him when he enters those premises such equipment as may appear to him necessary and be accompanied by any person who is authorised by the Director General to accompany him on that inspection.

(4) Where an inspection is conducted on premises that are unoccupied or in the temporary absence of the occupier, the inspector shall, upon completion of inspection, leave the premises as effectively secured against trespassers as they were found.

(5) Where, during inspection, an inspector takes any article, substance, book, document, data or record, he shall leave, at the premises, a statement specifying particulars sufficient to identify the article, substance, book, document, data or record taken.

(6) The inspector shall leave the statement of particulars with a responsible person at the premises or, where no person is present, in a prominent position on the premises.

(7) Where an inspector takes a sample for analysis pursuant to these Regulations, the Director General may make such arrangements for analysis of that sample as he considers appropriate.

PART VI
HAEMOVIGILANCE

Establishment of haemovigilance system

23. A blood establishment shall set-up a haemovigilance system for receiving, handling, evaluating and reporting adverse events and reactions to the Authority.

Good haemovigilance practices

24. A blood establishment shall ensure that activities are conducted in accordance with the following good haemovigilance practice requirements:

(a) needs of patients, healthcare professionals and the public in relation to the safety of blood transfusion;

(b) assigning tasks and responsibilities to persons involved in implementation of the haemovigilance system;

(c) conducting and maintaining continuous quality improvement by all parties involved in haemovigilance system;

(d) allocating sufficient resources and tasks to support proactive, risk-proportionate, continuous and integrated conduct of haemovigilance;

(e) gathering evidence on the risk-benefit balance of blood products and related factors thay may effect the risk-benefit balance and use of a blood product, to inform decision-making; and

(f) promoting effective cooperation among the National Blood Transfusion Services, hospital blood banks, manufacturers, marketing authorisation holders, patients, healthcare professionals and other relevant bodies.

Requirements for quality system

25. Every blood establishment shall maintain a quality system which consists of the following:

(a) a designated focal person responsible for haemovigilance;

(b) record management system that ensures proper handling, storage, and retrieval of documentation for accurate reporting, interpretation and verification;

(c) document control in relation to their creation, revision, approval and implementation;

(d) continuous training programs relevant to the quality system;

(e) facilities and equipment to support haemovigilance processes which are located, designed, constructed, adapted and maintained to suit their intended purpose;

(f) procedures and processes in place to ensure continuous monitoring of haemovigilance data and scientific evaluation of all information on the risks of blood and blood products; and

(g) procedures and processes to ensure effective communication.

Role of designated focal person

26. The designated focal person responsible for haemovigilance shall have the duty of-

(a) establishing and maintaining haemovigilance and look-back systems;

(b) providing oversight over the functioning of the system in all relevant aspects, including its quality system;

(c) promoting, maintaining and improving compliance with legal requirements;

(d) ensuring and verifying that the information contained is accurate and up-to-date and reflects the status of the haemovigilance system;

(e) being informed and conversant with product safety profiles, emerging safety concerns, risk management plans and risk minimisation measures;

(f) ensuring conduct of haemovigilance and submission of all haemovigilance-related documents in accordance with the legal requirements;

(g) ensuring the necessary quality, including the correctness, and completeness of haemovigilance data submitted to the Authority;

(h) ensuring validation of the adverse reaction database, implementing corrective actions to address any failures, and being informed of significant changes made to the database;

(i) providing to the Authority relevant information on benefit-risk evaluation; and

(j) providing responses to regulatory actions in emerging safety concerns, including variations, urgent safety restrictions, and communication to patients and healthcare professionals.

(2) Notwithstanding the provisions of subregulation (1), the designated person may, in writing, delegate specific roles, under supervision, to appropriately qualified and trained individuals.

Responsibilities of National Blood Transfusion Services

27.-(1) The National Blood Transfusion Services shall be responsibile for monitoring the safety of blood and blood products distributed within their jurisdiction.

(2) Subject to haemovigilance system, the National Blood Transfusion Services shall have the following responsibilities:

(a) identify focal persons to coordinate haemovigilance activities;
(b) plan and budget for haemovigilance activities;
(c) distribute reporting forms, collect data and analyse safety information for blood and blood products used;
(d) manage risk and follow-up for patients;
(e) report adverse events and reactions related to blood and blood products to the Authority, using forms prescribed in the Seventh Schedule;
(f) collaborate with the Authority in implementing haemovigilance activities, including training of healthcare providers on haemovigilance;
(g) promote the rational and safe use of blood and blood products by healthcare providers;
(h) educate and inform patients on the importance of reporting adverse reactions; and
(i) assess and communicate the risks and effectiveness of blood and blood products used.

Roles of hospital blood banks

28.-(1) A hospital blood bank shall establish and maintain a system for collection, management and reporting adverse reactions related to blood and blood products to the Authority.

(2) A hospital blood bank shall appoint a focal person to coordinate haemovigilance activities within the hospital.

(3) A hospital blood bank shall perform the following functions:

(a) receive, distribute and make available adverse event reporting forms to healthcare providers;
(b) report adverse events related to blood and blood products to the Authority, using forms prescribed in the Sixth Schedule these Regulations;

(c) detect, investigate, manage and report adverse events and take appropriate actions to prevent their occurrence;
(d) maintain a register of suspected adverse reactions, adverse events, therapeutic failures, near-miss events, transfusion overload and quality defective blood and blood products;
(e) communicate relevant safety information to health management teams and the community including patients;
(f) implement look-back haemovigilance system;
(g) conduct preliminary identification of safety signals and other risk factors;
(h) organise and conduct staff training and sensitisation on haemovigilance; and
(i) integrate haemovigilance principles into relevant committees including hospital transfusion committees and other health related committees.

Reporting requirements for healthcare providers

29.-(1) Healthcare providers shall report to the Authority all suspected adverse reactions, adverse events or incidents related to blood or blood products reported to them by patients, as well as any quality defect issues that may arise.

(2) The reports referred to under subregulation (1) shall be submitted in the forms prescribed in Sixth Schedule.

Responsibilities of manufacturers and marketing authorisation holders

30.-(1) Manufacturers and marketing authorisation holders shall report to the Authority any adverse reactions or adverse events suspected to be associated with the use of blood or blood products, which are notified to them by healthcare professionals, patients or consumers.

(2) The adverse events report shall include events arising from post-marketing experience, both unsolicited and solicited sources, clinical trials, non-interventional post-registration studies and other post-marketing studies.

(3) Manufacturers and marketing authorisation holders shall systematically assess such reports to establish relationship to blood or blood products.

(4) Manufacturers and marketing authorisation holders shall regularly monitor international and local literature, as well as ongoing safety and efficacy studies, for the identification of adverse reactions or relevant safety findings relating to their blood and blood products.

Expedited reporting and reporting timelines

31.-(1) All serious adverse reactions associated with the use of blood and blood products shall be reported on an expedited basis to the Authority.

(2) Any serious suspected adverse reactions occurring in post-marketing studies, which the manufacturer is aware of, shall be reported to the Authority on an expedited basis.

(3) Where a case initially classified as a non-expedited report qualifies for expedited reporting upon receipt of follow-up information, the case shall be reclassified accordingly.

(4) Where medically relevant information is received in respect of a previously reported case, the reporting timeframe for submission of the follow-up report shall commence form the date of receipt of that information.

(5) A person responsible for managing adverse reactions shall apply good case management practices to ensure that the information is authentic, accurate, as complete as possible and non-duplicative.

(6) For purposes of this regulation, expedited reporting means reporting made as soon as practicable, and in any case, not later than fifteen days from the date of initial receipt of the minimum required information.

PART VII
STANDARDS OF PRACTICE

Labelling of blood and blood products

32.-(1) A blood establishment shall ensure that the label on each unit of blood or blood product it supplies or receives contains the following information:

(a) official name of the product;
(b) volume, weight or number of cell count in the component, as appropriate;
(c) unique numeric or alphanumeric donation indication code;
(d) name and address of the blood establishment responsible for the production;
(e) ABO Group, except in the case of plasma intended solely for fractionation;
(f) Rh D Group, indicated as Rh D positive or Rh D negative, except in the case of plasma intended solely for fractionation;
(g) date and, where applicable, time of expiry;
(h) storage and transportation temperature conditions; and
(i) name, composition and volume of any anticoagulant and any additive solution.

(2) A blood establishment shall keep records of the information referred to in subregulation (1) and any additional records as are necessary-

(a) for the identification of each single blood donation and each single blood unit and blood or blood products which are imported into Mainland Tanzania; and
(b) to ensure full traceability to the point of delivery to a donation center for a period of not less than ten years.

Norms and standards for blood donation

33.-(1) A blood establishment shall not provide or promise to provide any monetary compensation, benefit, or any other interest to a blood donor.

(2) A blood establishment shall not discriminate against a blood donor on the basis of race, gender, nationality, ethnicity, religion, belief or any other prohibited ground.

(3) A blood establishment shall ensure that protection of blood donor identity is secured in all blood collection procedures.

(4) A blood establishment shall ensure that identification of blood donor and laboratory tests are carried out in accordance with professional and medical ethics except in court trials.

(5) A blood establishment shall ensure that-

(a) at all times, a blood donor is cared for, safeguarded, dignified and recognised;

(b) a blood donor honestly and conscientiously provides information on his medical history and physical conditions in order to ensure the collection and supply of safe blood;

(c) blood donation is done at a pleasant and safe environment;

(d) all matters related to donation procedures, anticipated adverse reactions, post-donation care, tests to be carried out and notification of results are communicated to donors for consent before blood donation;

(e) interview of blood donors for eligibility purpose is done and recorded in a private environment; and

(f) it carefully observes whether a side effect from blood collection occurs, takes necessary measures to prevent any side effects from blood collection and reports any reactions to the Authority as provided for in Part IX of these Regulations.

Compensation for donated blood

34.-(1) A blood establishment shall ensure that-

(a) the donation of blood is, at all times and in all circumstances, voluntary, non-remunerated or not obtained through coercion, force or undue influence; and

(b) donors are not offered any financial gain, whether in cash, or in kind, which may be regarded as a substitute for money.

(2) Without prejudice to subregulation (1), a blood establishment may offer reasonable non-monetary incentives to donors, including pins, plaques, badges, medals, commendation certificates, time off from work, membership in a blood transfusion programme, gifts, small tokens, snacks, meals, refreshments, and reimbursement of direct travel costs.

Standards for blood transfusion

35. A blood establishment shall ensure that-

(a) prior to blood transfusion, patients are fully informed of the known risks, benefits and alternatives of therapy and consent to be transfused;

(b) patients are afforded the right to accept or refuse transfusion, and where is unable to give informed consent, the transfusion shall be administered only if it is in the best interest of the patient;

(c) as far as practicable, a patient receives blood components, including packed RBCs, plasma, platelets and cryoprecipitates which are clinically appropriate and afford optimal safety;

(d) transfusions are administered based on established transfusion triggers; and

(e) blood transfusion committees are created and operationalised in accordance with guidelines issued by National Blood Transfusion Services.

PART VIII
DISCLOSURE OF INFORMATION AND RECORD KEEPING

Disclosure of information by blood establishment

36.-(1) A blood establishment shall ensure that information collected for the purposes of these Regulations is held securely.

(2) The information held under subregulation (1) shall-

(a) be kept available for the purpose of tracing donations;

(b) not be disclosed except-

(i) in accordance with the requirements of subregulation (3); or

(ii) where they have been rendered anonymous so that a donor is no longer identifiable, subject to safeguards against unauthorised additions, deletions or modifications.

(3) For purposes of this subregulation-

(a) disclosure shall be made in accordance with an order of a court or as otherwise required by law;

(b) disclosure shall be made to an inspector appointed by the Director General in accordance with the provisions of these Regulations; or

(c) disclosure shall be for the purpose of tracing a donation from donor to recipient or recipient to donor.

(4) Where disclosure is made to an inspector pursuant to subregulation (2)(b), the inspector shall not further disclose the information received unless-

(a) disclosure is made in accordance with an order of a court or as otherwise required by law;
(b) disclosure is made to another officer of the Authority where it is necessary for the proper performance of the officer's duties; or
(c) information has been rendered anonymous so that a donor is no longer identifiable.

(5) Where a disclosure is made by an inspector to another officer of the Authority pursuant to subregulation (4), the officer shall not further disclose the information he receives other than in accordance with the requirements of subregulation (4).

Data discrepancy

37. The responsible person of the blood establishment shall establish a procedure to promptly resolve any discrepancy in data brought to their attention.

Record keeping by blood establishment

38.-(1) A blood establishment shall keep and maintain records for at least ten years in relation to the activities specified under these Regulations.

(2) The information to be maintained includes-
(a) number of donors who give blood and blood products;
(b) number of donations;
(c) number of recipients of blood transfusions and unit numbers;
(d) updated list of the hospital blood banks which it supplies;
(e) number of whole donations not used;
(f) number of each product produced and distributed;
(g) incidence and prevalence of transfusion-transmissible infectious markers in donors of blood or blood products;
(h) number of product recalls; and
(i) number of serious adverse events and serious reactions reported.

Records to be kept by Authority

39. The Authority shall keep records of information received from, or relating to, a blood establishment as it considers appropriate, and shall, including records relating to-

(a) authorisations granted under these Regulations;
(b) notifications of serious adverse events and serious adverse reactions submitted by blood establishments;
(c) inspections conducted or requests for information made under these Regulations; and
(d) any other matter as the Authority may deem appropriate.

PART IX
GENERAL PROVISIONS

Objections to suspensions or revocations

40.-(1) A blood establishment which objects to-

(a) the suspension or revocation of authorisation, or to any notice served;
(b) the refusal of authorisation or imposition of any condition,

may notify the Director General of the intention to make written representations, or to appear before and be heard by a person appointed by the Director General for that purpose.

(2) A notification of objection under subregulation (1) shall be made within fourteen days from the date of service of the relevant notice on the blood establishment.

(3) Where the Authority receives a notification pursuant to subregulation (1), it shall appoint a person to consider the objection.

(4) A person appointed to consider an objection shall-

(a) determine the procedure for consideration of the objection; and

(b) consider any written or oral representations made by the blood establishment in support of the objection, and shall make a recommendation to the Authority.

(5) A recommendation to the Authority shall be made in writing, and a copy of it shall be sent to the respective blood establishment or its nominated representative.

(6) The Authority shall take into account any recommendation made pursuant to subregulation (5).

(7) Within fourteen days of receipt of a recommendation, the Director General shall inform the blood establishment whether he accepts the recommendation and, where he does not accept it, he shall state the reasons for his decision.

(8) Where the Director General is notified of an objection pursuant to subregulation (1)(a) before the date on which the suspension or revocation or notice is due to take effect, such suspension or revocation or notice shall not take effect until-

(a) a person appointed pursuant to subregulation (3), has considered the matter in accordance with the provisions of this regulation and made a recommendation; and

(b) the Director General has informed the respective blood establishment of his decision regarding the recommendation pursuant to subregulation (8).

(9) Subject to subregulation (9), where the Director General is notified of an objection pursuant to subregulation (1)(a), within the period specified in subregulation (2), regarding the suspension, revocation or other notice which has already taken effect, such suspension, revocation or notice shall cease to have effect until-

(a) the person appointed pursuant to subregulation (3) has considered the matter in accordance with the provisions of this regulation and made a recommendation; and

(b) the Director General has informed the respective blood establishment of his decision regarding the recommendation pursuant to subregulation (8).

(10) The provisions of subregulation (10) shall not apply-

(a) in relation to a suspension or revocation, or a notice served, which takes immediate effect in accordance with these Regulations; or

(b) in any other case, where the Director General determines that it is necessary in the interests of public safety for the suspension, revocation or notice to take effect on the date originally specified, and serves a notice in writing to that effect on the respective blood establishment.

Marketing authorisation of blood and blood products

41. Blood products shall be subject to marketing authorisation procedures in accordance with the requirements prescribed under the the applicable regulations for registration of medicinal products and medical devices, including in-vitro diagnostics.

Importation or exportation of blood and blood products

42. A person shall not import into, or export from, Mainland Tanzania any blood or blood product, including blood or blood products intended for use as starting materials or raw materials in the manufacture of medicinal products, except in accordance with the requirements prescribed under the applicable regulations for control of import and export.

Recall and disposal

43. (1)A person shall not sell, offer or expose for sale any blood or blood product which has been subjected to recall.

(2) Recall of blood or blood products shall be in accordance with the applicable regulations doverning the recall of medicines.

(3) Disposal of blood or blood products shall be in accordance with the applicable regulations governing the disposal of medicines.

Appeals

44.-(1) Notwithstanding the provisions of regulation 40, a person aggrieved by a decision of the Authority may, within sixty days appeal in writing to the Minister.

(2) The appellant shall send a copy of the notice of the appeal to the Authority which shall within fourteen days submit a written response to the Minister and provide a copy to the appellant.

(3) Where the Minister is of the opinion that a case has been made, he may summon the parties for additional information or make a decision to allow or dismiss the appeal.

Offences and penalties

45. A person who contravenes or aids any other person to contravene the provisions of these Regulations commits an offence and on conviction, shall be liable to the penalty prescribed by the Act.

Compounding of offences

46.-(1) The Director General, inspector or any other authorised person may, subject to and in accordance with the provisions of these Regulations, is satisfied that a person has committed an offence against these Regulations, compound such offence by accepting from that person a sum of money in respect of which the offence was committed.

(2) The sum of money payable under subregulation (1) shall not exceed five times the maximum amount of the fine prescribed for such offence.

(3) The power conferred by this section shall be exercised only where a person admits that he has committed an offence and agrees in writing in the

prescribed form to the offence being dealt with under this regulation.

(4) The Director General or officer exercising powers under this regulation shall provide the person from whom any sum of money is received under subsection (2) with a receipt in a prescribed form.

(5) Any sum of money received under this regulation shall be paid to the Authority.

(6) Where any proceedings are brought against any person for an offence against these Regulations, it shall be a good defence if such person proves that the offence with which he is charged has been compounded under this regulation.

FIRST SCHEDULE

(Made under regulation 6(1))

APPLICATION FOR A BLOOD ESTABLISHMENT AUTHORISATION

(Please complete all relevant Sections in this form typed or in block capitals)

Section 1: Applicant Details

Blood Establishment Name:	
Applicant Name:	
Address:	
Postcode:	
Telephone:	
Mobile	
E-mail address:	

Section 2: Establishment/Site Information.

Site Name:	
Site Address:	
Postcode:	

Site Contact Name	
Telephone:	
Mobile	
E-mail address:	
Add as many rows as possible (if more than one site)	

ESTABLISHMENT/SITE ACTIVITY: Please detail below site activity, for clarity please write 'Yes' or 'No' against each proposed activity type:		
	YES	**NO**
Collecting blood		
Testing blood		
Storing blood		
Distributing blood		
Processing blood into blood components		
Storage of blood products		
Distribution of blood products		

Section 3: Establishment or Site Processes.

Proposed processes to be conducted at this site: Please write Yes or No as required in the relevant column for each of the processes proposed to be conducted:

	YES	**NO**
Whole blood collection		
Autologous whole blood collection		
Testing donor samples		
Apheresis collection of components		
Please specify apheresis component type collected:		
Whole Blood Processing into:	**YES**	**NO**
Red cells		
Platelets		
Granulocytes		
Fresh frozen plasma		
Recovered plasma (for discard)		
Cryoprecipitate		
Cryoprecipitate depleted plasma		
Buffy coats		
Other (please specify):		

Components Processed into:	**YES**	**NO**
Methylene blue treated plasma		
Irradiated components		
Washed components		
Leucocyte depleted components		
Splitting into small volume packs		
Pooling cryoprecipitate		
Manipulation of haematocrit		
Other (please specify):		

Section 4: Site Personnel.

Please list below the names of Responsible Person (Blood) and other site personnel:

S/N	Name	Qualification	Responsible for

Section 5: Declaration.

I/we apply for the grant of a Blood Establishment Authorisation to the proposed holder named in this application form in respect of the activities to which the application refers.

Signed: _____
Date:_____
Name: _____
Position: _____
Stamp/Seal: _____

SECOND SCHEDULE

(Made under regulation 11 (2) (a))

INFORMATION TO BE PROVIDED TO PROSPECTIVE DONORS OF BLOOD OR BLOOD COMPONENTS

1. Accurate educational materials, which are written in terms that can be understood by members of the general public, about the essential nature of blood, the blood donation procedure, and the components derived from whole blood and apheresis donations, and the important benefits to patients.

2. For both allogeneic and autologous donations, the reasons for requiring a medical examination, health and medical history, and the testing of donations, and the significance of "informed consent".

3. For allogeneic donations, the criteria for self-deferral, temporary and permanent deferral, and the reasons why individuals should not donate blood or blood components if there could be a risk to the recipient.

4. For autologous donations, the possibility of deferral and the reasons why the donation procedure would not proceed in the presence of a health risk to the individual, whether as donor or recipient of the autologous blood or blood components.

5. Information on the protection of personal data, including confirmation that there will be no disclosure of the identity of the donor, information concerning the donor's health, or the results of the tests performed, other than in accordance with the requirements of these Regulations.

6. The reasons why individuals should not make donations which may be detrimental to their health.

7. Specific information on the nature of the procedures involved either in the allogeneic or autologous donation processes and their respective associated risks. For autologous donations, the possibility that the autologous blood and blood components may not be sufficient for the intended transfusion requirements.

8. Information on the option for donors to change their mind about donating prior to proceeding further, or the possibility of withdrawing or self-deferring at any time during the donation process, without undue embarrassment or discomfort.

9. The reasons why it is important that donors inform the blood establishment of any subsequent event that may render prior donation unsuitable for transfusion.

10. Information on the responsibility of the blood establishment to inform the donor, through an appropriate mechanism, if test results show any abnormality significance to the donor's health.

11. Information as to why unused autologous blood and blood components will be discarded and not transfused to other patients.

12. Information that test results detecting markers for viruses, such as HIV, HBV, HCV or other relevant blood transmissible microbiologic agents will result in donor deferral and destruction of the collected unit.

13. Information on the opportunity for donors to ask questions at any time.

THIRD SCHEDULE

(Made under regulation 11 (2) (b))

INFORMATION TO BE OBTAINED FROM DONORS BY BLOOD ESTABLISHMENTS AT EVERY DONATION

1. Personal data that uniquely identify the donor, and without any risk of mistaken identity, as well as relevant contact details.

2. Health and medical history, provided through a questionnaire and a personal interview conducted by a qualified health professional, including relevant factors that may assist in identifying and screening out individuals whose donation could present a health risk to others, such as the possibility of disease transmission, or health risks to themselves.

3. The donor's signature on the donor questionnaire, countersigned by the qualified health professional responsible for obtaining the health history, confirming that the donor has:

   (a) read and understood the educational materials provided;

   (b) had the opportunity to ask questions;

   (c) received satisfactory responses to any questions asked;

   (d) given informed consent to proceed with the donation process; and

   (e) been informed, in the case of autologous donations, that the donated blood and blood components may not be sufficient for the intended transfusion requirements; and has acknowledged that all information provided by the donor is true to the best of his knowledge.

FOURTH SCHEDULE

(Made under regulation 11 (2) (d))

ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD PRODUCTS

1. Acceptance criteria for donors of whole blood and blood products

Under exceptional circumstances, individual donations from donors who do not comply with following criteria may be authorised by a qualified healthcare professional in the blood establishment.

The criteria set out in this paragraph do not apply to autologous donations.

Age	18 to 65 years		
	16 to 17 years	Where, in the opinion of a qualified health professional, the donor has sufficient knowledge and understanding of what is involved in the process of blood donation to give informed consent, or alternatively, where written consent has been obtained from a person with parental responsibility.	
	First time donors over 60 years	At the discretion of the medical practitioner in the blood establishment.	
	Over 65 years	With permission of the medical practitioner in the blood establishment, given annually.	
Body weight	≥50 kg for donors either of whole blood or apheresis blood components.		
Haemoglobin	For females ≥12.5 g/dl	For males ≥ 13.5 g/dl	Applicable to allogeneic donors of whole blood and cellular components.
Blood Pressure	Acceptable range of BP should be (90/60-140/90) that means Systolic BP90-140mmHg and Diastolic BP 60-90mmHg.		
Pulse rate	Acceptable pulse rate shall regular and not <60 or >100 beats/minute.		
Protein levels in donor's blood	≥60g/dl	The protein analysis for apheresis plasma donations must be performed at least annually.	

Platelet levels in donor's blood	Platelets Platelet number greater than or equal to 150 x 10^9/L	Level required for apheresis platelet donors.
Blood Donation Interval	**Male:** The normal interval between whole blood donations is 12 weeks (three months)	**Female:** The normal interval between whole blood donations is 16 weeks (four months).

2. Deferral Criteria for Donors of Whole Blood and Blood Components

2.1 Permanent deferral criteria for donors of allogeneic donations

Cardiovascular disease	Prospective donors with active or past serious cardiovascular disease, except congenital abnormalities with complete cure.
Central nervous system disease	A history of serious CNS disease.
Abnormal bleeding tendency	Prospective donors who give a history of a coagulopathy.
Repeated episodes of syncope, or a history of convulsions	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.
Gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory system diseases	Prospective donors with serious active, chronic, or relapsing disease.
Diabetes	All diabetics patients are permanently deferred from donating blood except for a female who had diabetes during pregnancy may donate provided the diabetes has resolved.
Infectious diseases	Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune Hepatitis C HIV1&2, Babesiosis Visceral, Leishmaniasis, Chagas' disease and Lyme disease.
Malignant diseases	Defer permanently all Leukemia, Lymphoma, Kaposi Sarcoma and Malignant Melanoma, Except in situ cancer with complete recovery.
Transmissible spongiform encephalopathies (TSEs) (e.g. Creutzfeldt Jakob Disease, variant Creutzfeldt Jakob Disease)	All blood donors with a history of CJD diagnosis found at increased risk or if any relatives have been diagnosed with CJD are deferred indefinitely.
Intravenous (IV) or intramuscular (IM) drug use and oral drugs	Anti-epileptic drugs, anti-convulsant drugs such Tegratol, Pituitary Growth Hormone, body-

	building steroids or hormones Xenotransplant recipients.
Sexual behaviour	Persons whose sexual behaviour places them at high risk of acquiring severe infectious diseases that are transmissible through blood.

2.2. Temporary deferral criteria for donors of allogeneic donations

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 cure
Syphilis	1 years following the date of confirmed cure
Toxoplasmosis	6 years following the date of clinical recovery
Tuberculosis	2 years following the date of confirmed cure
Rheumatic fever	2 years following the date of cessation of symptoms, unless evidence of chronic heart disease
Fever >38°C	2 weeks following the date of cessation of symptoms
West Nile Virus (WNV)	28 days after leaving an area with ongoing transmission of WNV to humans

2.3 Exposure to risk of acquiring a transfusion-transmissible infection

- Endoscopic examination using flexible instruments - Mucosal splash with blood or needle stick injury - transfusion of blood components - tissue or cell transplant of human origin - major surgery - tattoo or body piercing - acupuncture unless performed by a qualified practitioner and with sterile single-use needles - persons at risk due to close household contact with persons with hepatitis B	Defer 6 months, or 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 are transmissible by blood.	Defer after donation after cessation of risk behaviour for a period determined by the disease in question and by the availability of appropriate testing methods.

2.4 Vaccination

Killed and inactivated vaccines	
Inactivated/killed viruses, bacteria or rickettsiae vaccine Tetanus, Meningococcal Rabies Tetanus vaccine-accept individuals who Toxoids Hepatitis A or B vaccine Tick borne encephalitis vaccines	No deferral is required for killed or inactivated vaccines provided that the donor feels well.
Live attenuated vaccines, examples	
BCG (Bacillus Chalmette-Guerin) Herpes Zoster, Varicella zoster Measles, Mumps, Rubella (MMR) Polio (Sabin, oral) Rubella that is German Measles (MMR) Typhoid (Oral) Yellow Fever Botulism Toxin Pertussis Immune Globulin Rabies - Treatment after with Immune Globulin Rh Immune Globulin (RhoGAM) Smallpox Tetanus Antitoxin Tetanus Immune Globulin Chickenpox (Varivax & immune globulin,) Hepatitis A and Hepatitis B (Twinrix) Hepatitis B (Engerix B, Recombivax–HB) Hepatitis B Immune Globulin (HBIG)	Defer for 4 weeks

2.5 Other temporary deferrals

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. Refer to donor selection guideline.

2.6 Deferral for particular epidemiological situations

Particular epidemiological situations (e.g. disease outbreaks)	Deferral consistent with the epidemiological situation

2.7 Deferral criteria for donors of autologous donations

Serious cardiac disease	Depending on the clinical setting of the blood collection
Active bacterial infection	
Additional requirements for autologous donations	Autologous blood and blood components must be clearly identified as such and stored, transported and distributed separately from allogeneic blood and blood components. The candidate for autologous blood donation must meet all routine requirements for allogeneic donation and should donate one unit per week and no more than one unit every three days.
	Autologous blood and blood components must be labelled as required by these regulations, and, in addition, the label must include the identification of the donor and the warning "FOR AUTOLOGOUS TRANSFUSION ONLY".

	The unused blood for auto-transfusion cannot be used for other purposes, except by approval of the person who donated blood for autologous transfusion.

FIFTH SCHEDULE

(Made under regulation 11 (3) (b))

STORAGE, TRANSPORT AND DISTRIBUTION CONDITIONS FOR BLOOD AND BLOOD COMPONENTS

1. Storage.

Component	Temperature of storage	Maximum storage time
Packed Red cell and whole blood (if used for transfusion as whole blood)	+2 to +6°C	28 to 49 days according to the processes used for collection, processing and storage.
Platelet	+20 to +24°C	3-5 days after blood collection, may be stored for 7 days in conjunction with detection or reduction of bacterial contamination.
Granulocytes	+20 to +24°C	24 hours

2. Cryopreservation.

Component	Storage conditions and duration
Red blood cells	Up to 30 years according to processes used for collection, processing and storage.
Platelets	Up to 24 months according to processes used for collection, processing and storage.
Plasma and cryoprecipitate	Up to 36 months according to processes used for collection, processing and storage.

Cryopreserved red blood cells and platelets must be formulated in a suitable medium after thawing. The allowable storage period after thawing to depend on the method used.

3. Transport and Distribution .

Transport and distribution of blood and blood components at all stages of the transfusion chain shall be under conditions that maintain the integrity of the product.

SIXTH SCHEDULE

(Made under regulation 11 (3) (c))

QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD PRODUCTS

1. Blood and blood products shall comply with the following technical quality measurements and meet the acceptable results.

2. Appropriate bacteriological control of the collection and manufacturing process shall be performed.

Component	Quality measures required	Acceptable results for quality measures.
Whole Blood	Volume	Volume of whole blood should be 405 – 495 ml (450mls ± 10%).
	Haemoglobin	Haemoglobin should be 45 g/dl per unit.
	Haemolysis	Less than 0.8% of red cell mass at end of shelf life.
	Haematocrit	35-45%
Packed Red Blood Cells	Preparation	Separate red cells and plasma within 6 to 18 hours after collection (if platelets are not being produced). Prepare components within 72 hours preferably but not more than 7 days after collection.
	Volume	155 – 270 ml.
	Haemoglobin	Haemoglobin should be more than 45g/dL per unit.
	Haematocrit	Haematocrit for PRC should be 60-80%.
	Haemolysis	Less than 0.8% of red cell mass at end of shelf life
	Leucocyte	For leucocyte depleted PRBC-Leukocyte count should be ≤2.4 x 10^9/unit for red cells in additive solution and buffy-coat removed.

Plasma (FFP)	Preparation	Separated from whole blood within 6 to 18 hours of collection and freeze solid at minus 18°C or, preferably, at minus 25°C or lower as early as possible.
	Volume	225 – 250 ml.
	Coagulation factor	FVIII: should be 80IU.
Platelets	Preparation	Separate platelet concentrates from whole blood by centrifugation at +20°C to +24°C from either platelet rich plasma or buffy-coats using validated methods.
	Volume	Suspend platelets in 50-70ml of plasma.
	Leucocyte count	Platelet production methods adopted shall ensure that leucocyte is less than 5×10^6/L per pool.
	Platelet count	Whole blood derived platelet unit should contain $\geq 5.5 \times 10^9$ platelets per unit in 50-70mls, pooled platelets (from random donors) should contain $\geq 2.4 \times 10^{11}$ platelets per pool (200-300ml and apheresis platelet unit should contain $\geq 3 \times 10^{11}$ platelets per unit.
	pH	The pH shall be 6.4 - 7.4 corrected for 22^0C at the end of shelf life.
	Glucose	27 mmol/L
Cryoprecipitate	Volume	10 -15 ml
	Factor VIII	80-100U per unit
	Fibrinogen	200-300mg per unit
	Von Willebrand's factor	80U

SEVENTH SCHEDULE

(Made under regulation 29(2)(e))

ADVERSE REACTION REPORTING FORMS

Form No. 1

BLOOD DONATION ADVERSE EVENT REPORTING FORM Scope: To be filled in by the donation team					
Donor Information:					
Donation site		Donor Number		Donation Number	
Donation Date		Type of Donation: Whole blood or Apheresis (Circle the appropriate)			
Donor Name				DOB	
Sex M/F		Donor status: First time/Repeat		Ethnic Group	
Donor weight		Donor Hb			
Phone No: Mobile		Phone no: Work		Phone No: Home	
Reaction/Injury Information.					
Date of Incident/ Reaction began			Time of Incident/Reaction began		
Time incident/Reaction ended					
Type of Reaction/Injury (mark all signs and symptoms that apply).					
Donor Reaction with Generalized Symptoms – Vasovagal Reaction:					**Tick √**
• Cold extremities/chills					
• Convulsions					
• Feeling of warmth					
• Hypotension					
• Light-headedness/dizziness					
• Loss of bladder and/or bowel control					
• LOC <60seconds					
• LOC >60seconds					
• Nausea/vomiting					

• Pallor(pale skin or lips)					
• Rapid pulse					
Hyperventilation. Hyperventilation causes the **CO_2** level in the blood to decrease. This lower level of **CO_2** and reduction of blood flow to the brain, may result in the below nervous system and emotional symptoms. Over breathing can also cause the calcium levels to drop in your blood, which may result in the below nervous system symptoms:					
• Over breathing					**Tick √**
• Weakness					
• Fainting					
• Dizziness					
• Numbness and tingling both arm and mouth					
• Tetany (spasm or cramps of hand and feet)					
Then record vital signs after every 15mins in case of Vasovagal Reaction and Hyperventilation.					
Pre-donation BP:			Pre donation Pulse rate		
Time recorded:					
Respiratory rate R/Min	Start	After 15min	After 15min	After 15min	After 15min
B/P mmHg					
Pulse (Beats/Minute)					
Rhythm: Regular/Irregular					
Respiratory rate R/Min					
Record Therapy Provided:					
Type of Therapy		Route of Administration	Dose/Volume	Frequency/Times	Signature
Donor Reaction with localized Symptoms (mark all signs and symptoms that apply).					

Nerve Irritation:				**Tick √**
• Immediate intense pain at site				
• Numbness or tingling of fingers, hand or arm				
• Shooting pain down arm				
• Weakness of arm				
Hematoma/Infiltration:				
• Pain				
• Swelling				

Discharge/Release:	**Tick √**
Was Medical Practitioner notified	
Donor condition on leaving the premises	
Blood Centre instruction on the referral note	
Donor released to: Self others, if other, relationship to donor	
Donor released to Home Hospital specify	
Donor refused treatment/medical advice (please explain)	
Additional Information/Details: (i.e. parents phone calls, any information not on the check list)	
Person Incharge of the blood collection team Name.....Signature.....Date.....	

Form No. 2

ADVERSE TRANSFUSION EVENT NOTIFICATION FORM (Scope: To be filled by blood establishment and sent to the Authority)
Confidentiality of this information is fundamental to the success of this program; we will contact you to obtain additional information, if necessary, once the initial reaction has been reported. Report one adverse reaction per form. Thank you for taking the time to complete this form. Please feel free to contact TFDA should you require additional information.
To be reported from Wards by Nurse:
Report made by: Name (Full name) …… Title:…… Facility name…….....Mobile number:……...
Patient Details Surname:.....First name…….....Middle name…….. Hospital:..... Sex: F M

File number:..... Date of birth:...../...../.....
Diagnosis:.....
Reason for Transfusion…….....
Blood Component Details:
Type of Blood Component implicated (Whole Blood, Red Cells, Plasma, Platelets, Cryoprecipitate).
Blood Unit Number……Blood Unit ABO & Rh Group……Expiry date……..
Patient ABO & Rh Group……
Date of implicated transfusion ……../…... /….. Time transfusion started……
Time reaction noticed…… hrs.
Findings of physical inspection of the blood unit……

Any Transfusion or Obstetrical History in the past (Circle the appropriate):

Transfusions: Yes <3 month. Yes >3 month. No Unknown
Pregnancy: Yes <3 month. Yes >3 month. No Unknown

Any history of Pre-medication during blood transfusion:
If yes, Specify Drug(s) or fluid used……

Please tick the Transfusion adverse reaction, Near miss or Error:

	Suspected *Please Tick*	Certain & confirmed *Please Tick*
Adverse Reaction:		
Acute Haemolytic Reaction (AHTR)		
Delayed Haemolytic Reaction (DHTR)		
Febrile non-Haemolytic TR (FNHTR)		
Allergic/Anaphylactic Transfusion Reaction (ATR)		
Transfusion-related acute lung injury (TRALI)		
Post-transfusion purpura (PTP)		
Transfusion-associated graft-versus-host disease (TA-GVHD)		
Transfusion associated circulatory overload (TACO)		
Transfusion-associated dyspnoea (TAD)		
Hypotensive (HT)		
Bacterial contamination (BC)		
Transfusion-transmitted infection (TTI)		

Clinical Signs and Symptoms in case of a reaction: *Please Circle*
Chills/Rigors: Haemoglobinuria: Tachycardia: Falling urinary output : Oliguria, Urticarial: Back pain: Nausea/Vomiting: Hypertension: Hypotension: Shock Fever: Jaundice: Dyspnoea: Dyspnoea Haemorrhage: Bradycardia: Pain along infusion site: Rising pCO_2: Hypoxemia (PaO_2 or SaO_2)
Sub-Sternal discomfort: Stridor / Wheeze: GI symptoms, including cramps: Cyanosis: Falling O_2 saturation: Falling haemoglobin: Restlessness/anxiety: Chest x-ray changes: Other:

Measures Taken: *Please Circle*

None Required: Diuretics: Supplementary O_2: Antipyretics: Chest X-ray: Analgesics Antihistamines: Mechanical Ventilation :Transfusion Stopped: Steroids: ICU Required Transfusion Restarted: Vasopressors: Blood (Component Cultures Ordered): Patient Blood Culture Ordered: Other, Specify:

Patient outcome: *Please Circle*

Relationship of adverse reaction to transfusion

Definite Probable Doubtful Ruled Out Not determined

Severity of adverse reaction

Non-Severe Severe Life-threatening Death Not determined

Outcome of the patient

Death Major Long-term sequela Minor (no sequela) Not determined

To be reported by the Transfusing Nurse and Laboratory officer, where applicable:

	Please Tick	
Near Miss and Errors		
Mix-up of donors or donated blood unit numbers		
Incorrect labelling		
Release of blood products that do not conform to specifications		
Incorrect testing		
Detection of a transfusion-transmissible infection in a blood donor		
Incorrect blood release to wrong patient(if no reaction)		
Incorrect ABO and Rh D group transfused (if no reaction)		
Transfusion of expired component		
Transfusion of incorrectly stored component		

Transfusion Reaction Sample Collected from:

Ward/Unit ……..

Clerical error (unit labelling, check findings…….

Please state the blood group of the patient: Pre transfusion ABO/Rh……Post transfusion ABO/Rh…….....

Please state the compatibility test results on Pre transfusion sample with Donor blood ……Post transfusion sample with Donor blood …….....

Please state if any post-transfusion antibody screen was positive.…….……

What antibody (ies) were identified?.....

Was DAT performed? Yes/No If yes, what was the result?.....

State pre transfusion haemoglobin level ……..and post transfusion haemoglobin level……

State macroscopic and microscopic urinalysis results…….

Blood Culture and other Bacteriological findings……..

State any other investigational results……..
Facility Lab Clerical Check: Reported by: Name……...Date/Time……. Discrepancies…… Yes No If yes, Specify……

Dodoma,
4th June, 2026

MOHAMED OMARY MCHENGERWA
Minister for Health