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Statutory Instrument XX of 20XX.

[CAP. 15:03

Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20XX

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SCHEDULES

IT is hereby notified that the Minister of Health and Child Care has, in terms of section 74 and after consultation with the Authority in terms of section 38, of the Medicines and Allied Substances Control Act [*Chapter 15:03*], made the following regulations: —

PART I

PRELIMINARY

Title

1. These regulations may be cited as the Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20XX.

Interpretation

2. In these regulations— [1]

"allogeneic donation" in respect of blood or a blood donation, means that the blood is collected from an individual either for transfusion into another individual or for use in the manufacture of a medicine for human use;

"applicant" means any person, organisation or institution that applies for licensing of a blood establishment;

"approval" means authorisation through licensing in terms of section 7(2) of these regulations or exempted in terms of section 35 of these regulations;

"autologous donation" means the donation of blood by a person for the later administering thereto to the same person;

"blood" means whole human blood collected from a donor and processed either for transfusion or for further manufacturing;

"***blood components"*** means a therapeuti***c*** constituent of blood (red cells, white cells, platelets, cryoprecipitate and plasma) that can be prepared by various separation methods[2];

[1] Acknowledge source of definitions (South Africa Regulations relating to blood and blood products, Directive 2002/98/EC of the EU, Canadian Blood Regulations, US-FDA Blood and blood products regulations, WHO assessment criteria for national blood 1regulatory systems and WHO guidelines on GMP for blood establishments), ISBT 128 STANDARD: Standard Terminology for Medical Products of Human Origin

[2] Revised definition taken from the UK Blood Safety and Quality Regulations 2005

*"**blood donor"*** means any living, voluntary, non-remunerated person from whom blood is withdrawn for the subsequent administering to another living person or to himself or herself or for the processing into blood components;

*"**blood establishment"*** means any structure, facility or body that is responsible for any aspect of the collection, testing, processing, storage, packaging, labelling, release, distribution, import or export of human blood or blood components when intended for transfusion or further industrial manufacturing;

"deferral" means suspension of the eligibility of an individual to donate blood or blood components such suspension being either permanent or temporary;

"distribution" means the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of plasma derived products excluding the issuing of blood or blood components for transfusion;

"emergency circumstances" means that there is an insufficiency of allogeneic blood in Zimbabwe that poses an immediate and substantial risk to public health.

"good manufacturing practices (GMP)" means all elements in the established practice that will collectively lead to final products or services that consistently meet appropriate specifications and compliance with the regulations;

"haemovigilance" means a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in blood donors or recipients of blood and blood components, and the epidemiological follow-up of donors;

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

"imputability" means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process;

"inspection" means formal and objective audit in accordance with standards adopted to assess compliance with these Regulations;

"inspector" means a person appointed in terms of Section 65 (1) (a) of the Act;

"licensing" means approval by the Authority for collection, testing, processing, storage, packaging, labelling, release, importation, exportation, or distribution of blood and blood components;

"quality management system (QMS)" means a management system that directs and controls an organization with respect to quality, and that ensures that steps, processes, procedures and policies related to quality activities are being followed;

*"**recipient**"* means a person to whom blood or a blood component which has been donated by another person or by that person himself or herself is administered;

"Responsible person" means any person approved by the Authority or designated to be the responsible person for a blood establishment[3].

"serious adverse event" means any untoward medical occurrence at collection, testing, processing, storage and distribution, of blood and blood components that is fatal, life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, or results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect. The event does not necessarily have a causal relationship with the collection, testing, processing, storage and distribution, of blood and blood components;

"serious adverse reaction" means an unintended response in a donor or in a recipient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity or which results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect;

*"**standards of practice**"* means the standards of practice for blood transfusion services as determined by the Minister from time to time;

[3] Since the industry is still evolving, the Committee decided to leave the aspect of qualifications of a responsible person.

"standard operating procedures" in respect of an establishment or blood bank, means the component of the establishment's quality management system that is composed of instructions that set out the processes to follow in conducting its activities;

"***traceability"*** means 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.

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

"transmissible infection" means an infection that can be transmitted by the transfusion of blood or a blood component.

Application

Scope of Regulations

3. These Regulations apply to the collection and testing of blood and blood components, and to their processing, storage and distribution when they are intended to be used for transfusion or for use in the manufacture of a medicine for human use.

PART II

FORMS

Particulars

4. Any person who is required to make an application shall complete the appropriate form in the **Second Schedule** and shall furnish the Director-General, or some other person appointed by him or her, with such further information or particulars as may be required.

Forms to be completed in English

5. All forms shall be completed in the English language.

Illegible or incomplete forms

6. The Director-General may reject any form if any part of such form is illegible or not properly completed.

PART I1I

Licensing of blood establishments and responsible person

Requirement for licensing

7. (1) No person may carry on any of the activities listed in subsection (2) otherwise than in accordance with a licence issued in terms of Section 14 of these regulations.

(2) The activities referred to in subsection (1) are –

(a) the collection and testing of blood or blood components, whatever their intended purpose; and

(b) the processing, storage, packaging, labelling, release and distribution of blood and blood components.

Application for issue of licence for blood establishment

8. (1) An application for the issue of a licence, in terms of subsection (2) of section 55 of the Act shall be made to the Director-General in **Form BB1** in the **Second Schedule** and shall be accompanied by –

(a) the appropriate fee; and

(b) three copies of a plan of the premises proposed to be licensed which shall comply with the requirement specified in the **Fourth Schedule**; and

(c) in the case of an individual, proof of citizenship or proof of being ordinarily resident in Zimbabwe or proof of an exemption by the Minister; or

(d) in the case of a company, proof of citizenship or proof of being ordinarily resident in Zimbabwe of the majority of directors or proof of an exemption by the Minister.

(2) the applicant must meet the minimum requirements for a blood establishments specified in the **Third Schedule** of these Regulations.

Application for amendment of licence for blood establishment

9. (1) A blood establishment shall not make any substantial change in the activities and structure which it undertakes without making an application and obtain a prior written approval of the Authority.

(2) Any application for approval to make a substantial change in its activities shall be accompanied by a fee of the amount prescribed in the **First Schedule**.

(3) Upon receipt of such application, the Authority shall consider the application and where the application is approved the Director–General shall request the holder of the licence to produce such licence within such period as he or she may specify and the holder thereof shall produce such licence within the specified period.

(4) Whenever the Authority approves the variation or amendment in terms of subsection (2) on any licence, the Authority shall reissue such licence in accordance with its decision within a reasonable time.

(5) For the purposes of subsection (1), a substantial change in a blood establishment's activities is any change-

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

(b) which would result in breach of these Regulations or of any condition specified in the license or as determined by the Authority from time to time; or

(c) to the quality system which is likely to have a substantial impact on the conduct of, or might compromise the safety of, any of the activities which the blood establishment has been-licensed to undertake pursuant to these regulations.

Change other than substantial change

10. (1) For any other change other than a substantial change, a blood establishment must file with the Authority an annual report that describes any changes –

(a) made that are not described in Section 9(3); or

(b) that could compromise human safety or the safety of blood**.**

(2) On receipt of the report, the Authority shall consider the changes, and where the changes are approved and require reissue of a licence, the Director-General shall request the holder of the licence to produce such licence within such period as he or she may specify and the holder thereof shall produce such licence within the specified period;

(3)Whenever the Authority approves the changes in terms of subsection (2) on any licence, the Authority shall reissue such licence in accordance with its decision.

(4)Where the Authority is of the view that a change that was included in a report under subsection (1) is a substantial change, the Authority may notify the establishment in writing and may require the establishment to cease or reverse the implementation of the change.

Application for issue of licence for responsible person

11. (1) An application for the issue of a licence in terms of Section 58 of the Act shall be made to the Director- General in **Form BB2** in the **Second Schedule** and shall be accompanied by–

(a) the appropriate fee;

(b) proof of citizenship or proof of being ordinarily resident in Zimbabwe, or proof of an exemption by the Minister; and

(c) proof of registration by the Health Professions Authority.

Requirements for the issue of a licence to a responsible person for a blood establishment

12. (1) Subject to subsection (2), no person shall be issued with a licence unless such person –

(a) is registered by-

i. the Medical and Dental Practitioners Council of Zimbabwe; or
ii. the Nurses Council of Zimbabwe; or
iii. the Medical Laboratory and Clinical Scientists Council of Zimbabwe established by the Health Professions Act (Chapter 27:19)

(b) satisfies the Authority that he or she is familiar with the regulations and standards of practice relating to the collection, testing, processing, storage, release or distribution of human blood or blood components when intended for transfusion or further industrial manufacturing and such other matter as the Authority may determine from time to time; or

(c) has practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under these Regulations for at least 5 years, in an establishment (or more than one establishment) licensed to undertake activities related to the collection or testing (or both) of blood and blood components, or to their preparation, storage and distribution.

(2) The Authority may exempt any person from any of the requirements referred to in subsection (1) if it is satisfied that such person has —

(a) passed other examinations in the course of such person's studies; or
(b) has such other practical experience as the Authority considers justifies the grant of such exemption.

(3) The responsible person may delegate any of the tasks specified in subsection (1) to other persons who shall be qualified by training and experience to perform such tasks.

(4) A blood establishment shall notify the Authority of the name of any persons to whom tasks have been delegated by the responsible person under subsection (3), and the specific tasks which have been delegated to such persons.

(5) Where the responsible person or a person to whom tasks have been delegated under subsection (3) is permanently or temporarily replaced, the blood establishment shall without delay provide the Authority with the name of the replacement, details of his qualifications and the date on which the replacement began his duties.

Application for renewal of licences

13. (1) An application for the renewal of a licence in terms of subsection (2) of Section 60 of the Act shall be lodged with the Director-General, in **Form BB3** for the renewal of a licence for premises and in **Form BB4** for the renewal of a licence for a person—

(a) before the expiry of such licence; and

(b) shall be accompanied by the appropriate fee in respect of each licence.

(2) Where an application for the renewal of a licence has been lodged with the Director-General, the validity of the licence shall, where the applicant has not been given notice of the renewal or refusal of the application by the date of expiry of such licence, continue after the date of expiry until the decision of the Authority on the application is notified to the applicant by the Director-General.

Issue of licences

14. The Authority may issue a licence for-

a) a blood establishment in **Form BB 5**
b) or for a responsible person for a blood establishment in **Form BB 6**

and in issuing such licence the Authority may impose such conditions, as it may consider necessary or desirable.

Duration of licences

15. Any licence, which is issued in respect of premises or persons, shall be valid for a period of twelve (12) months, commencing on the 1st of January in each year, and may be renewed annually thereafter, before its expiry.

Production and return of licences

16. (1) Whenever the Authority—

(a) cancels any licence; or
(b) varies or amends the conditions of any licence; or
(c) imposes new conditions on the renewal of any licence;

the Director-General shall request the holder of the licence to produce such licence within such period as he may specify and the holder thereof shall produce such licence within the specified period.

(2) Any person who fails to comply with a request in terms of subsection (1) shall be guilty of an offence.

(3) Whenever the Authority varies, amends or imposes any new conditions on any licence, the Authority shall return such licence duly endorsed to the holder thereof within a reasonable time.

Fee payable for temporary renewal of licences

17. The Authority may issue a temporary renewal of a licence in terms of Section 60(7) of the Act to any blood establishment or responsible person who has satisfied the provisions of that subsection.

Suspension or cancellation* of *licences

18. (1) The Authority may suspend or cancel a licence of a blood establishment or for a responsible person on one or more of the following grounds –

(a) that the blood establishment or the responsible person of the blood establishment, in any material respect, fails to comply with the requirements of these regulations;

(b) that the collection, testing, processing, storage or distribution of blood or blood components by the establishment cannot be carried out safely;

(c) that any blood or blood components cannot be supplied to hospital blood banks or to transfusing units in such a state that they could be safely administered for transfusion; or

(d) that the information given by the blood establishment pursuant to Section 8 or Section 11 was false or incomplete in any material respect.

19. (1) Any suspension pursuant to Section 18 shall be for such period as the Authority shall consider necessary having regard to the reasons for the suspension.
(2) The suspension or cancellation of a licence under Section 18**,** may be total, or may be limited to a particular activity or to one or more activities carried out at a particular site or sites, or to a particular blood component.

Record-keeping

20. (1) A blood establishment shall, in relation to the activities specified in Section 7 (2) for which it is responsible, maintain records, for a minimum period of 10 years or any other time period stipulated by the Authority, of –

(a) the information specified in subsections (2), (3); and

(b) the conduct of the tests conducted on each donation of blood and blood components.

(2) The information specified in this subsection is –

(a) the total number of donors who give blood and blood components;
(b) the total number of donations;
(c) an updated list of the hospital blood banks which it supplies;
(d) the total number of whole donations not used;
(e) the number of each component produced and distributed;
(f) the incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood components;
(g) the number of product recalls;
(h) the number of serious adverse events and serious adverse reactions reported, including the investigation reports; and

(3) The information which is to be kept in terms of subsection 1(a) shall be –

(a) provided to donors by the blood establishment in accordance with subsection (2)(a);
(b) obtained from donors by the blood establishment in accordance with subsection (2)(b); and
(c) relating to the suitability of blood and plasma donors in accordance with the eligibility criteria specified in the **Sixth Schedule**, Part (c) .

21. A blood establishment shall retain the records set out in subsection 1 for at least ten(10) years in an appropriate and readable storage medium in order to ensure traceability-

(1) (a) blood establishment identification;

(b) blood donor identification;

(c) blood unit identification

(d) individual blood component identification;

(e) date of collection(year/month/day); and

(f) facilities to which blood units or blood components are distributed, or subsequent disposition.

(2) in the case of hospital blood banks-

(a) blood component supplier identification;

(b) issued blood component identification;

(c) transfused recipient identification

(d) for blood units not transfused, confirmation of subsequent disposition;

(e) date of transfusion or disposition)year/month/day); and

(f) lot number of the component, if relevant.

PART IV

Inspections

22. (1) The Authority shall conduct regular inspections of each site of a blood establishment, for the purpose of ensuring that –

(a) blood establishments comply with the requirements of these Regulations;

(b) responsible persons of such blood establishments comply with the requirements of these Regulations; and

(2) The Authority may also require a blood establishment to submit any information concerning its compliance with these Regulations.

(3) Any blood establishment which receives a request of information in accordance with subsection (2) shall provide the information requested within the period specified in the request.

(4) In the event of any serious adverse event or any serious adverse reaction or suspicion thereof, the Authority shall request such information or conduct such inspections in accordance with these regulation***s*** as it shall consider appropriate.

(5) For the purposes of enforcing compliance with these Regulations or conducting inspections pursuant to subsection 1, an inspector shall, upon production of evidence that he or she is so authorised, have the rights and powers specified in terms of Section 66 of the Act.

PART V

Haemovigilance

23. (1) Every blood establishment shall set up a haemovigilance system for receiving, handling, evaluating and reporting adverse events and reactions to the Authority.

(2) Every blood establishment shall designate an individual to be in charge of the haemovigilance system

24. Every blood establishment shall ensure that activities are conducted in accordance with but not limited to 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 implementing the haemovigilance system;

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

(e) seeking evidence on the risk-benefit balance of blood or blood component and all relevant aspects, which could impact on the risk benefit balance and the use of a blood or blood component to be considered for decision-making.

(f) evaluation of suspected serious adverse reactions according to the imputability levels set out by the Authority from time to time

PART VI

GENERAL

Import and Export of blood and blood components

25. (1) No person shall import into Zimbabwe or export out of Zimbabwe any blood or blood components intended for use in the manufacture of medicinal products for human use or for transfusion without prior written authorisation of the Authority.

(2) Each blood establishment shall have in place a system of traceability for imports of blood and blood components from blood establishments outside Zimbabwe equivalent to that provided for in Section 21.

(3) Each blood establishment shall have in place a system of notification for imports of blood and blood components from outside Zimbabwe equivalent to that provided for in Section 1 (e) of the Third Schedule.

Labelling of blood and blood components

26. (1) A blood establishment shall ensure that each unit of blood or blood component supplied by it shall, unless otherwise directed by the Authority, bear or incorporate a label on the package in which such blood or blood component is distributed, on which is printed in clear and indelible letters, using only adhesives and inks that will not permeate the container, in English language, the following particulars which relate to the blood or blood component only –

(a) the official name of the component;

(b) the volume or weight or number of cells in the component, as appropriate;

(c) a unique numeric or alphanumeric donation code;

(d) the name and address of the producing blood establishment;

(e) the ABO Group, except in the case of plasma intended only for fractionation;

(f) the Rh D Group, either Rh D positive or Rh D negative, except in the case of plasma intended only for fractionation;

(g) the date or time of expiry, as appropriate;

(h) the recommended storage conditions;

(i) the name, composition and volume of any anticoagulant and any additive solution;

(j) in the case of blood for transfusion, a warning that the blood could transmit infectious agents;

(k) in the case of autologous blood, the statement “For Autologous Use Only”; and

(l) any other particulars or warning notices as may be directed by the Authority.

(2) A blood establishment shall keep such records of the information referred to in subsection (1) above and such additional records as are necessary—

(a) for the identification of each single blood donation and each single blood unit and its components; and

(b) to ensure full traceability to the point of delivery to a hospital, for a period of not less than 10 years or as stipulated by the Authority based on current standards.

Traceability

27. (1) A blood establishment shall ensure the traceability of blood and blood components through accurate identification procedures, record maintenance and an appropriate labelling system.

(2) A blood establishment shall ensure that it has in place a traceability system that enables the tracing of blood components to their location and processing stage.

(3) A blood establishment shall ensure that it has in place a system to uniquely identify each donor, each blood unit collected and each blood component prepared, whatever its intended purpose, and the facilities to which a given blood component has been delivered.

(4) A facility shall have a system in place to record each blood unit or blood component received, whether or not locally processed, and the final destination of that received unit, whether transfused, discarded or returned to the distributing blood establishment

(5) A blood establishment shall have a unique identifier that enables it to be precisely linked to each unit of blood that it has collected and to each blood component that it has prepared.

Disclosure of information

28. (1) Subject to Section 73 of the Act and any other relevant laws of the country, a blood establishment and the responsible person of a blood establishment shall ensure that all information which is collected for the purposes of these Regulations is held securely so that it is –

(a) available for the purpose of tracing donations;

(b) not disclosed except—

(i) in accordance with one or more of the requirements of subsection (2), or

(ii) where they have been rendered anonymous so that donors or recipients are no longer identifiable.

(c) subject to safeguards against unauthorised additions, deletions or modifications;

(2) The authorised disclosures in terms of this section may include-

(a) the disclosure made in accordance with an order of a court or is otherwise required by law; or

(b) the disclosure to an inspector appointed in terms of Section 65 of the Act; or

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

(d) any other disclosures as may be authorised by the Authority from time to time.

(3) Where a disclosure is made to an inspector pursuant to subsection (2)(b), the inspector shall not further disclose the information received unless –

(a) the disclosure is made in accordance with an order of a court or is otherwise required by law; or

(b) the disclosure is to an inspector or an analyst appointed in terms of Section 65 of the Act where this is necessary for the proper performance of the inspector or officer's duties; or

(c) the information has been rendered anonymous so that that donors or recipients are no longer identifiable.

(4) The responsible person shall ensure that they put in place ~~a~~ procedure**s** to ensure that any discrepancies relating to data which are brought to their attention are resolved without delay.

Recall and Withdrawal

29. (1) Where the Authority is of the opinion that the recall and withdrawal of any blood or blood component is necessary for the protection of the public, the Authority may require any person to recall or withdraw such blood or blood component in accordance with the procedure for the recall or withdrawal of any blood or blood component as determined by the Authority from time to time.

(2) Every person who is in possession of a blood and blood component required to be recalled and withdrawn in terms of subsection (1) shall comply with the procedure for the recall or withdrawal of any medicine as determined by the Authority from time to time.

Exceptional Distribution and Importation of blood and blood components in emergency circumstances

30. (1) A blood establishment may, in emergency circumstances, import allogeneic blood that was not processed in accordance with these regulations if it provides the Authority with the following information before the importation-

(a) a written justification that demonstrates the existence of emergency circumstances;

(b) the full name and physical address of the blood establishments from which it intends to import blood or blood components from;

(c) evidence that blood establishments from which it intends to import blood or blood components from is licensed by the competent authority of the country the blood establishment is domiciled;

(d) proof that the blood establishment from which it intends to import blood or blood components from complies with current Good Manufacturing Practices;

(e) a description of how the establishment proposes to identify the blood as having been imported in emergency circumstances; and

(f) a description of any further processing or labelling that may need to be done to the blood before its transfusion.

(2) A blood establishment may distribute or transfuse allogeneic blood for transfusion for which the test results for ABO group, Rh factor and transmissible infections or infectious agents are not yet available if both of the following conditions are met-

(a) blood that has been determined safe for distribution is not immediately available; and

(b) the recipient's physician requests the blood for use in the emergency treatment of their patient.

(3) An establishment that distributes blood under subsection (2) must complete a notice of exceptional distribution that contains all of the following information-

(a) the name of the blood establishment and the signature of the responsible person;

(b) the donation code;

(c) a statement of whether the blood was whole blood or a blood component, and if it was a component, its name;

(d) a list of the test results that were not available at the time of the distribution;

(e) the name and signature of the recipient's physician;

(f) the justification for the distribution;

(g) the name of the hospital blood bank to which it distributed the blood; and

(h) the date and time of the distribution.

(4) A blood establishment that distributes blood under subsection (2) must label it to indicate that the testing required by these Regulations is incomplete or that all of the test results are not yet available, as the case may be.

(5) The blood establishment must keep the notice of exceptional distribution in its records and send a copy of it to the hospital blood bank to which it distributed the blood

(6) If the hospital blood bank to which the blood is distributed does not perform the transfusion, it must send a copy of the notice of exceptional distribution to the establishment where the transfusion is performed.

(7) The establishment where the transfusion is performed must keep the notice in the recipient's file.

(8) A blood establishment that distributes blood under subsection (2) either before the testing is complete or before the test results are all available must, after the distribution, conduct any remaining testing and provide the hospital blood bank to which it distributed the blood with all of the relevant test results as soon as they become available.

(9) If the hospital blood bank to which the blood was distributed did not perform the transfusion, it must send a copy of the test results to the establishment where the transfusion was performed.

(10) If blood that is the subject of an exceptional distribution is not transfused into the intended recipient in the emergency, the establishment that was to perform the transfusion must not store the blood or transfuse it into another recipient.

Disposal

31. In case of disposal of blood and blood components, the appropriate regulations for disposal of biomedical waste in force shall be applicable.

Fees

32. (1) The fees payable in terms of these regulations shall be the appropriate fees opposite the appropriate item specified in the first column of the **First Schedule**.

(2) The fees specified in terms of these regulations shall not be payable by any person or institution that has been exempted, in writing, by the Authority.

Offences and penalties

33. Any person who contravenes or fails to comply with any provision of these regulations shall be guilty of an offence and liable on conviction to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

Objections and Appeals

34. Any person who is aggrieved by the decision made in terms of these Regulations may appeal in terms of section 62 of the Act.

Exemptions

35. These regulations shall apply to any person or any blood establishment except those exempted by the Authority in writing.

FIRST SCHEDULE (Sections 8, 9, 11, 16, 24, and 29 of the Medicines and Allied Substances (and Blood Components) Regulations

FEES

1. Application for licensing of a blood establishment -
2. Application for licensing of a responsible person
3. Application for approval of a substantial change -
4. Application for renewal of a person's licence -
5. Application for renewal of a premises licence –
6. Application for authorisation to import or import blood and blood components-
7. Verification fee of any consignment - 1% of value of the consignment -

SECOND SCHEDULE
FORMS

FORM BB1 APPLICATION FOR ISSUE OF A LICENCE FOR A BLOOD ESTABLISHMENT

FORM BB 2 APPLICATION FOR ISSUE OF A LICENCE FOR A RESPONSIBLE PERSON

FORM BB 3 APPLICATION FOR RENEWAL OF A LICENCE FOR A BLOOD ESTABLISHMENT

FORM BB 4 APPLICATION FOR RENEWAL OF A LICENCE FOR A RESPONSIBLE PERSON

FORM BB 5 LICENCE A BLOOD ESTABLISHMENT

FORM BB 6 LICENCE FOR A RESPONSIBLE PERSON

Form B.B.1

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

APPLICATION FOR ISSUE OF A LICENCE FOR A BLOOD ESTABLISHMENT

This form is submitted in terms of Section *8* of the Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20xx

Part A *(To be completed by all applicants)*

1. Name of blood establishment .....
Physical address .....
Registered Office .....
Telephone number ……
Cellphone number ……
Email address ……

2. State shareholders or distribution of shares or nominees.....

Particulars of Directors:

Full Names	**Physical Address**	**Citizenship**
….…….	……	……..
……..	……	…….
……..	……	…….

3. If any director is registered with the Health Professions Authority state the registration number

……

4. Name and address of applicant, in full
……..……
……

5. Position of applicant in the blood establishment .....…….

6. Name under which business is conducted
.....…… ……
Address .....……..

7. Physical address of premises to be licensed
.....……..……..

8. Purposes for which premises to be licensed (Please detail below premises activity, for clarity please write 'Yes' or 'No' against each proposed activity type):

SITE ACTIVITY		
	YES	**NO**
Collecting blood		
Testing blood		
Storing blood		
Distributing blood		
Processing blood into blood components		
Storage of blood components		
Distribution of blood components (refer to Section 10)		
Compatibility testing		

9. 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:		
Red cells		
Platelets		

Granulocytes		
Fresh frozen plasma		
Recovered plasma (for discard)		
Cryoprecipitate		
Cryoprecipitate depleted plasma		
Buffy coats		
Other (please specify):		
Components Processed into:		
Methylene blue treated plasma		
Irradiated components		
Washed components		
Splitting into small volume packs		
Pooling cryoprecipitate		
Manipulation of haematocrit		
Other (please specify):		

10. Has any application made by you for a licence been refused or cancelled? YES/NO*
    If YES give details .....
11. Particulars and date of any trading or other licence held by the applicant or business……..……
12. State the name of the responsible person under whose personal supervision the premises will be for the purposes of section 55(1)(b) of the Act and the registration number of that person with the Health Professions Authority and the practising certificate number thereof.

Name **Numbers**

…….
……..

…….
……..

13. Are the directors of the company or a majority thereof citizens or ordinarily resident in Zimbabwe? YES/NO*

If YES, supply proof thereof.

If NO, has the company been exempted by the Minister in terms of the proviso to paragraph (a) of subsection (1) of section 38 of the Act? YES/NO*

If YES supply proof thereof.

14. Has the company or any of the directors to the company within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in any activities related to blood and blood components supply, or of an offence involving dishonesty?.YES/NO*

If YES state details.....

Date ....

Signature of applicant

** Delete inapplicable*

NOTE:

1. The site master file in accordance with Part III, the appropriate fee, proof of citizenship, residency or an exemption by the Minister etc., are required to be attached to the application. Copies of original documents must be properly certified.
   If any plan, document or fee required to be attached is not attached, the application cannot be accepted.
2. If insufficient space is provided in the application, attach a sheet of paper with the additional information

Form B.B. 2

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

APPLICATION FOR ISSUE OF A LICENCE FOR A RESPONSIBLE PERSON OF A BLOOD ESTABLISHMENT

This form is submitted in terms of Section 11 of the Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20xx

1. Full names ……
2. Date and place of birth ……

3. Qualifications ……

4. Registration Certificate Number with the Health Professions Authority……

   Practising Certificate Number with the Health Professions Council ……

5. Address (Home) ……

   ……...

   (Business)
   ……

   ……...

6. Telephone number (Home) ……(Business) ……...

7. Cellphone number ……

8. Email address ……

9. Present place of employment ……

   ……

10. Position of applicant at place of employment (e.g. medical director, manager, etc) ……

11. Qualifications of applicant……

    ……

12. Experience of applicant (details of applicant's practical post-graduate experience relevant to the to the responsibilities of a responsible person) ……

13. Are you a citizen of, or ordinary resident in Zimbabwe? YES/NO*

    If YES, supply proof thereof.

    If NO, have you been exempted by the Minister in terms of the proviso to paragraph (a) of subsection (2) of section 59 of the Act?

14. Have you within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of medicines, or of an offence involving dishonesty?

YES/NO*

If YES state details

……

……

Date ……..... *Signature of applicant*

……

**Delete the inapplicable*

Form B. B. 3

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

APPLICATION FOR THE RENEWAL OF A LICENCE FOR A BLOOD ESTABLISHMENT

This form is submitted in terms of Section *13* of the Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20xx

1. Name of blood establishment .....……

Physical address .....……

Registered Office .....……

State shareholders or distribution of shares or nominees .....……

Telephone number(s)…….

Email address……

Cellphone number(s)……..

Particulars of Directors:

Full Names	**Physical Address**	**Citizenship**
….……	……	……..….
……	……	……
……	……	……..…

2. Name and address of applicant, in full
……..

……

3. Position of applicant in the blood establishment .....……

4. Name under which the business is conducted ……

Address ……

……

5. Name of person(s) under whose supervision the premises will be for the purposes of section 55 of the Act

Name	**Licence No.**
……	…….....
……	……..

6. Have any particulars contained in the original application for the licence changed? YES/NO*

If YES give details ……

7. (a) Are the directors of the company or a majority thereof citizens or ordinarily resident in Zimbabwe?

……..

If YES supply proof thereof.

If NO has the company been exempted by the Minister in terms of the proviso to paragraph (a) of subsection 59 of the Act" YES/NO*

If YES supply proof thereof.

(b) Has the company or any of the directors to the company within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in dealing in or supply or possession of medicines, or of an offence involving dishonesty? YES/NO*

If YES state details ……

Date ……..... …….

Signature of applicant

**Delete the inapplicable*

Form B. B. 4

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

APPLICATION FOR THE RENEWAL OF A LICENCE FOR A RESPONSIBLE PERSON OF A BLOOD ESTABLISHMENT

This form is submitted in terms of Section *13* of the Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20xx

1. Name and address of applicant, in full
   ……..

   Telephone number……Cellphone number……Email address ……..……

2. Number of licence……

3. Name and address of employer ……

   ……

4. Location of place of employment……

   ……

5. State whether any particulars contained in the original application for the issue of the licence or the application for the last renewal of the licence have changed……

6. Are you a citizen of, or ordinarily resident in Zimbabwe? YES/NO*

   If YES supply proof thereof.

   If NO, have you been exempted by the Minister in terms of the proviso to paragraph (a) of subsection (2) of section 59 of the Act? YES/NO

   If YES, supply proof thereof.

7. Have you within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongfully dealing in or supply or possession of medicines, or of an offence involving dishonesty? YES/NO*

If YES state details ……

……

I enclose the fee of ……

Date ……..... *Signature of applicant*
……

**Delete the inapplicable*

Form B.B.5

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

LICENCE FOR BLOOD ESTABLISHMENTS

This form is submitted in terms of Section *14* of the Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20xx

Licence Number……

1. Licensee

……..……

2 Names of Directors

……..……

……..……

……..……

3 Location of premises

……..…….

……

4 Activities to be carried out at premises

……..…….

……

……

……

5 Processes to be conducted at premises

……..…….

……

……

6 Conditions of issue/renewal* imposed by the Authority

……..…….

……

……

7 The premises shall, for the purposes of section 55 of the Act, be under the personal supervision of the following person(s) –

Name	**Licence Number**
…….	……..
…….	……..

8 Date of issue/renewal* of licence

……

9.Date of Expiry of licence

…….

……

Director-General

**Delete the inapplicable*

Form B.B.6

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

LICENCE FOR ARESPONSIBLE PERSON OF A BLOOD ESTABLISHMENT

This form is submitted in terms of Section *14* of the Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20xx

Licence Number……

1 Licensee

……..……..…

2 Place of employment

……..……

……..……

……..……

3 Conditions of issue/renewal* imposed by the Authority

……..……..

……..…

……..…

4 Date of issue/renewal* of licence

……

5 Date of Expiry of licence

…….

……

Director-General

**Delete the inapplicable*

THIRD SCHEDULE (Section 8(2) **of the Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20xx**

MINIMUM REQUIREMENTS FOR BLOOD ESTABLISHMENTS

An applicant for a blood establishment license shall comply with the requirements set out in the current standards and current Good Manufacturing Practices (cGMP) as published by the World Health Organisation and adopted by the Authority from time to time, and any other requirements as may be required by the Authority.

(1) A blood establishment shall –

(a) ensure that the personnel directly involved in the collection, testing, processing, storage and distribution of human blood and blood components 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 management system for blood establishments based on the principles of good practice;

(c) ensure that all testing and processes of the blood establishment which are referred to in Sections 2 to 5 of this Schedule are validated;

(d) maintain documentation on standard operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection under Section 22 of the Regulations;

(e) notify the Authority as soon as possible but within a maximum of fifteen days of first knowledge of—

(i) any serious adverse events related to the collection, testing, processing, storage and distribution of blood and blood components 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 components collected, tested, processed, stored or distributed by the blood establishment; and

(f) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any notification referred to in subsection (e).

(g) notify the Authority of any case of transmission of infectious agents by blood and blood components as soon as known.

(h) submit an annual report to the Authority after the end of each year, which shall include –

(i) a declaration that the blood establishment has in place appropriate systems to ensure compliance with the requirements of these Regulations; and

(ii) details of the systems which it has in place to ensure such compliance.

(iii) a listing of all adverse reactions and events which have occurred over this period

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

(a) give all prospective donors of blood or blood components information in accordance with Part (a) of the Sixth Schedule;

(b) obtain from all persons who are willing to provide blood or blood components, information in accordance with Part (b) of the Sixth Schedule;;

(c) put and keep in place procedures for the evaluation, selection and qualification of donors;

(d) apply eligibility criteria for all donors of blood and blood components in accordance with Part (c) of the Sixth 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 components,

(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; and

(g) encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components 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) A blood establishment shall ensure that, in relation to the blood and blood components which it collects, processes, stores or distributes—

(a) each donation of blood and blood components is tested in conformity with –

(i) the basic testing requirements for whole blood and apheresis donations, specified in Section (7), and

(ii) any additional tests which may be necessary for specific components, types of donors or epidemiological situations, or as specified by the Authority;

(b) the storage, transport and distribution conditions of blood and blood components comply with the requirements of Section 4 of this Schedule; and

(c) quality and safety requirements for blood and blood components meet the standards specified in Section 5 of this Schedule.

(4) A blood establishment shall, in relation to the activities specified in Section 3 for which it is responsible, maintain records, for a minimum period of 10 years, of –

(a) the information specified in Sections (5) and (6),

(b) the conduct of the tests referred to in Section (3)(a).

(5) The information specified in this subsection is –

(a) the total number of donors who give blood and blood components;

(b) the total number of donations;

(c) an updated list of the hospital blood banks which it supplies;

(d) the total number of whole donations not used;

(e) the number of each component produced and distributed;

(f) the incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood components;

(g) the number of product recalls; and

(h) the number of serious adverse events and serious reactions reported, including the investigation reports;

(6) The information specified in this Section is –

(a) information provided to donors by the blood establishment in accordance with Section (2)(a);

(b) information obtained from donors by the blood establishment in accordance with subsection (2)(b); and

(c) information relating to the suitability of blood and plasma donors in accordance with the eligibility criteria specified in Part 3 of this Schedule.

(7) The basic testing requirements with which blood establishments must ensure compliance pursuant to subsection (3)(a)(i) are –

(a) testing to establish ABO Group, except in respect of plasma intended only for fractionation;

(b) testing to establish Rh D Group, except in respect of plasma intended only for fractionation; and

(c) testing for the following infections of donors –

(i) Hepatitis B (HBs-Ag);

(ii) Hepatitis C (Anti-HCV);
(iii) HIV 1 and 2 (Anti-HIV 1 and 2).
(iv) Syphilis (Treponema pallidum).

(d) testing for high alloglutinin titres in all Group O donations

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

(8) The Authority may issue guidance, based on the best scientific and technological evidence, as to the additional tests referred to in Section (3)(a)(ii) which are necessary in relation to specific components, types of donor or epidemiological situations and blood establishments shall have regard to such guidance.

(9) As soon as practicable after the end of the reporting year, each blood establishment shall provide to the Authority a report specifying –

(a) the information referred to in Section (3) for that year; and

(b) details of the steps it has taken during that year to comply with Section (2)(g).

FOURTH SCHEDULE (Section 8 **of the Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20xx**

REQUIREMENTS OF PLANS ACCOMPANYING APPLICATIONS TO AUTHORITY

A. Every plan or set of plans of premises proposed to be licensed shall—

(a) show the premises floor plan;

(b) be to a scale of 1:100 (metric);

(c) have figures thereon the sizes of rooms, passages and stairways (if any), the position and types of windows, and the means of external and internal communications;

(d) have indicated thereon the use to which rooms are to be put, with particular reference to store rooms showing in details the types and positions of fittings and equipment;

(e) be amplified by notes explaining the systems of ventilation and lighting, and the finishing of roofs, ceilings, walls and floors, and any other relevant information;

(f) have indicated thereon the layout of the premises, including the designation of areas for use (e.g. donor area, processing or production area, storage areas, laboratories etc.);

(g) have indicated thereon security of the premises against entry and theft (e.g. burglar bars, alarms, etc.).

B. Every site of premises proposed to be licensed as a manufacturing facility shall be shown clearly on a plan to a scale of not less the 1:500 (metric), which plan shall also show—

(a) the north point;

(b) the area, in square meters, of the site;

(c) the development on the site, including, particularly, the position of every existing building and of any proposed new building and the use to which such buildings are being, or are proposed to be put;

(d) the drainage arrangements, sewerage-disposal system and the nature and situation of the water-supply;

(e) the developments, particularly buildings, on all neighboring sites which abut the site of the premises to be licensed;

(f) the surrounding streets in urban areas, or the roads in rural areas (indicating the places to which they lead and the relevant road distances therefrom), and the position and form of access from such streets or roads to the premises proposed to be licensed.

FIFTH SCHEDULE (section 8 **of the Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20xx**

Standards for blood donation

A blood establishment shall comply with the current standards for blood donation as published from time to time by the Minister, and any other requirements as may be required by the Authority.

(1) No blood establishment shall provide or promise to provide any monetary compensation, benefits or any other interests to a blood donor.

(2) No blood establishment shall discriminate blood donor on the basis of race, gender, creed, nationality, religion or any other ethnicity.

(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.

(5) A blood establishment shall ensure that-

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

(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) carefully observe whether a side effect from blood collection occurs, take necessary measures to prevent any side effects from blood collection and report any reactions to the Authority as provided for in Section 20 of these Regulations.

Standards for blood transfusion

A blood establishment shall comply with the current standards for blood transfusion as published from time to time by the Minister, and any other requirements as may be required by the Authority.

1. A blood establishment shall ensure that-

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

(b) patients are afforded the right to accept or refuse transfusion, in the event that the patient has refused or unable to give informed consent, the basis of treatment by transfusion must be in the best interests of the patient;

(c) as far as practicable, patients should receive only those components, packed Red Blood Cells, plasma, platelets and cryoprecipitates that are clinically appropriate and afford optimal safety;

(d) patients are transfused blood based on transfusion triggers; and

(e) blood transfusion committees are created and operationalized based on guidelines promulgated by the Minister.

SIXTH SCHEDULE (Section 20 **of the Medicines and Allied Substances Control (Blood and Blood Components) Regulations, 20xx**

Information requirements for blood donors

Part (a) – Information to be provided to prospective donors of blood or blood *components*

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

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

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

4. For autologous donations, the possibility of deferral and the reasons why the donation procedure would not take place 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, of information concerning the donor's health, and of the results of the tests performed, other than in accordance with the requirements of these Regulations.

6. The reasons why individuals are not to 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 process and their respective associated risks. For autologous donations, the possibility that the autologous blood and blood components may not suffice for the intended transfusion requirements.

8. Information on the possibility 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 any undue embarrassment or discomfort.

9. The reasons why it is important that donors inform the blood establishment of any subsequent event that may render any 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 of 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, Syphilis 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.

Part (b) – Information to be obtained from donors by blood establishments at every donation

Identification of the donor

14. Personal data uniquely, and without any risk of mistaken identity, distinguishing the donor, as well as contact details.

Health and medical history of the donor

15. Health and medical history, provided on a questionnaire and through a personal interview performed by a qualified health professional, that includes relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or health risks to themselves.

Informed Donor Consent

16. Every blood donor shall, by way of their signature (in writing), on the donor questionnaire, countersigned by the qualified health professional responsible for obtaining the health history, confirm that the donor has—

(a) read and understood the educational materials provided;

(b) had an opportunity to ask questions;

(c) been provided with satisfactory responses to any questions asked;

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

(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

(f) acknowledged that all the information provided by the donor is true to the best of his/her knowledge.

Part (c) – Eligibility criteria for donors of whole blood and blood components

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

Under exceptional circumstances, individual donations from donors who do not comply with following criteria may be authorized by the responsible person in the blood establishment. All such cases must be clearly documented.

[4]The criteria in this subsection do not apply to autologous donations.

Parameter	Acceptable limits	Comments
Age	16 to 65 years	
	>65 years	The maximum age of donation can be extended to 70 years on the recommendation of the medical director.
Body weight	≥50 kg	Unexplained weight loss of a significant degree (at least 4,5 kg) shall be a reason for exclusion.
Haemoglobin	≥12,5 g/dl(125g/l) for females and not less than ≥13,5g/dl(135g/l) for males.	Applicable to allogeneic donors of whole blood and cellular components
Donation Interval	≥56 days	unless authorised by a medical director
	≥28 days	for apheresis platelet donors
Volume of Donation	≤10.5mL/kg donor weight	There shall be a mechanism to indicate that this volume has been reached so that collection is stopped forthwith.

2. Deferral criteria for donors of whole blood and blood components

a) [5] Permanent deferral criteria for donors of allogeneic donations

Condition	Comments
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,	Prospective donors with serious active, chronic, or relapsing disease

[4] These need to be extended based on stakeholder consultation. These are based on the current NBSZ requirements published in the National Standards for Blood Transfusion in Zimbabwe

[5] This is just an example based on the UK regulations. A more customized list should be developed in consultation with key stakeholders including NBSZ (looking at the current criteria)

immunological, metabolic, renal, or respiratory system diseases	
Diabetes	If being treated with insulin
Infectious diseases	Hepatitis B
	Hepatitis C
	HIV – 1 and 2
	HTLV I/II
	Syphilis
Malignant diseases	Except in situ cancer with complete recovery
Intravenous (IV) or intramuscular (IM) drug use	Any history of non-prescribed IV or IM drug use, including body-building steroids or hormones
Xenotransplant recipients	
Sexual behavior	Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood

b) Temporary deferral criteria for donors of allogeneic donations

i. Infections

Duration of deferral period

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

However, the following deferral periods shall apply for the infections[6] listed in the table:

Infection	Deferral period	Comments
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	
Toxoplasmosis	6 months 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	
Flu-like illness	1 month after cessation of symptoms	
Malaria (*)	6 months	

[6] These serve as examples based on the UK regulations. A more customized list should be developed in consultation with key stakeholders including NBSZ

Travel history in a malaria area	3 months	

ii. Exposure to risk of acquiring a transfusion-transmissible infection

Risk factor	Deferral period	Comments
- transfusion of blood components, - tissue or cell transplant of human origin, - major surgery, - tattoo or body piercing, - acupuncture unless performed by a qualified - persons at risk due to close household contact with Hepatitis B	Defer 6 months	
Persons whose **behavior** or activity places them at risk of acquiring infectious diseases that may be transmitted by blood.	Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests.	

iii. Vaccination

Risk factor	Deferral period	Comments
Attenuated viruses or bacteria	4 weeks	
Inactivated/killed viruses, bacteria or rickettsiae	No deferral if the donor well	
Toxoids	No deferral if the donor well	
Hepatitis A or hepatitis B vaccines	No deferral if the donor well and if no exposure	
Rabies	If vaccination is given following exposure defer for one year	
Tick-borne encephalitis vaccines	No deferral if the donor well and if no exposure	

iii. Other temporary deferrals

Risk factor	Deferral period	Comments
Pregnancy	6 months after delivery or termination	
Minor surgery	1 week	Or at the discretion of the physician
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	A registered nurse or medical practitioner must evaluate prospective donors who are taking medications to determine their suitability to donate blood.

3. Deferral criteria for donors of autologous donations

Risk factor	Deferral period	Comments
Serious cardiac disease	Depending on the clinical setting of the blood collection	
Active bacterial infection		Or at the discretion of the physician

Part 4: Storage, transport and distribution conditions for blood and blood *components*

1. **Storage**[7]

a. Liquid storage

[7] These are based on the current standards published in the National Standards for Blood Transfusion in Zimbabwe

Product	**Storage temperature**	**Maximum storage time**
Whole blood for transfusion	+2 to +6°C	35 days after collection if CPDA-1 anticoagulant solution used. 21 days if ACD-A, CPD or CP2D anticoagulant solution used.
Plasma Reduced Red-cell concentrates (including paediatric)	+2 to +6°C	35 days after collection if a closed system is used for separation. If additive solution is used, the expiry date may be extended in accordance with the blood container manufacturer's recommendations. If an open system is used with aseptic technique, the expiry date shall be 24 hours after separation. If aseptic technique is not used, the expiry time shall be 6 hours after separation.
Red-cell concentrate, leucocyte-poor (filtered)	+2 to +6°C	If a closed system is used, each product shall have the same expiry date as the original donation from which it was prepared. If an open system is used, the expiry time shall be 24 hours.
Red-cell concentrate, washed	+2 to +6°C	When prepared in an open system, washed red cells shall be used within 24 hours.
Platelet concentrates	+20 to +24°C	3-5 days after blood collection, depending on the nature of the plastic bag used, except if an open system has been used then the unit shall be used within 6 hours.
ACD-A is acid citrate dextrose solution. ***CPD is citrate phosphate dextrose solution.*** ***CP2D is citrate phosphate dextrose-dextrose solution CPDA-1 is citrate phosphate dextrose solution with adenine.***		

b. Cryopreservation

Product	Storage temperature	Maximum storage time
Red blood cells	−65 °C to −196 °C.	10 years from date of freezing. Once thawed and washed, the product shall be used within 24 hours.
Fresh Frozen Plasma (FFP)	≤−18 °C OR ≤−25°C	12 months if stored at minus 18 °C or below. 24 months if stored at minus 25 °C or below. FFP must be reconstituted by thawing at a temperature not use of a purpose-made plasma-thawing device is recommended. After thawing, the product shall be transfused as soon as possible or stored at +1 °C to +6°C for up to 24 hours.
Cryoprecipitate	≤−25°C	12 months if stored between minus 18 °C and minus 25 °C OR 24 months if stored at minus 25 °C or below.

2. **Transport and distribution**

Transport and distribution of blood and blood components at all stages of the transfusion chain must be under conditions that maintain the integrity of the product. The 30-minute[8] rule shall be observed at all times.

3. **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.

In addition to the labelling requirements outlined for allogenic blood under Section 10 of the Regulations, the following information shall appear on a label attached to the blood containers: NAME, DATE OF BIRTH, REFERRING PHYSICIAN and the warning “FOR AUTOLOGOUS TRANSFUSION ONLY”.

Part 5: Quality control requirements for blood and blood components

[8] The "30 minute rule" is the customary limit accepted in most jurisdictions, and currently in Zimbabwe (based on the current standards) as the time allowed out of controlled storage, which if not exceeded, can allow the unit to be replaced back into controlled storage for re-use. (Transfusion. 1990 Jan;30(1):58-62.)Transfusion. 1990 Jan;30(1):58-62.)

Product	Technical Information	Quality requirements/measures	Acceptable limits/results
Whole blood	A unit of blood collected into a pack with anticoagulant and contains 450mL of blood and 63mL of anticoagulant.	Volume Haemoglobin Haemolysis Haematocrit	420 -520mL Approximately 12g/100mL < 0.8% of red cell mass at end of shelf life. 35 – 45%.
Plasma Reduced Red-cell concentrates	Red cell components prepared by removing a portion of plasma from whole blood and resuspending the red cells in an approved additive solution (e.g. SAG-M).	Volume Haemoglobin Haemolysis Haematocrit	150 – 200mL Approximately 20g/mL. < 0.8% of red cell mass at end of shelf life. 55 – 75%
		Haemoglobin (*)	0.6 l/l ± 0.1
Fresh Frozen Plasma (FFP)	Plasma obtained from whole blood or by aphaeresis and frozen within 6	Volume: Random FFP Aphaeresis Factor VIII:C	 200 – 300mL 200 – 210mL >0.70 IU/mL

	hours of collection.	Platelets Total Protein Residual Cellular contents: RBC WBC Platelets	30 x 109 /L > 50g/L <6.0X10^9/L <0.1X10^9/L <50X10^9/L
Platelets (PLT)	Could either be obtained from single donor preparation or collected by aphaeresis	Volume: Random Aphaeresis Count: Random Aphaeresis pH Residual Cell Content: RBC WBC	 50 - 60mL 150 – 300mL ≥55 x 10^9 /L 150 – 500 x 10^9 /L 6.4 – 7.4 <1.2X10^9/L <0.12X10^9/L
Cryoprecipitate (CRP)	The component represents a source of concentrated Factor VIII:C, von	Volume Factor VIII:C Fibrinogen Residual cellular content:	10 – 20 ml 8 – 120 IU/unit 150 – 300 IU/unit

	Willebrand factor, fibrinogen, Factor XIII and fibronectin prepared from a unit of freshly collected plasma.	RBC WBC PLT	<0.3X10^9/L <0.3X10^9/L <0.3X10^9/L
Washed Red Blood Cells	A red cell component washed with 0.9% w/v NaCl for injection and should be used as soon as possible.	Volume Haemoglobin Protein WBC Haemolysis Haematocrit	220 -320mL ≥ 40g/unit <0.5g/L <1X10^9/L <0.8% of red cell mass at end of shelf life. 55 – 65%[9]

1. Blood and blood components must comply with the following technical quality requirements and meet the acceptable results.
2. Appropriate bacteriological control of the collection and manufacturing process must be performed at all times.
3. For autologous donations, the requirements marked with an asterisk (*) serve as recommendations only.

[9] Based on the Standards For Blood Transfusion In Zimbabwe