THE FOOD AND DRUGS AUTHORITY BLOOD REGULATION FRAMEWORK

The legislative basis for blood regulation rest with the Food and Drugs Authority (FDA) of Ghana. Whole blood, Blood components and Blood products are regulated as Biological Products in accordance with Act 851 of the Parliament of the Republic of Ghana entitled Public Health Act, 2012.

The FDA is responsible for licensing blood facilities, component listing and surveillance activities that apply to blood facilities and sites, including Hospital Blood banks and sites where blood donors are screened and blood is collected, tested, components are prepared, stored, released and distributed for either transfusion or further manufacture.

All owners or operators of blood facilities that prepare blood components shall be required to license their facility with FDA pursuant to the Public Health Act, Act 851, unless they are exempted. A list of every blood component prepared, or processed for distribution shall be declared by the blood facility, and subsequently listed by the FDA.

You are considered a Blood Facility, and you need to hold a Blood Facility license to operate if you:

- conduct donor assessment and selection ○ collect whole blood and blood components ○ prepare blood components
- conduct specific serological and nucleic-acid-based tests for various infectious disease pathogens, such as human

immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) and syphilis to reduce Transfusion-Transmitted Infections (TTI's) ○ label

whole blood and blood components

- ○ store whole blood, blood components and blood product ○ release and distribute blood, blood component and blood products
- ○ conduct compatibility testing on blood and blood components exclusively for use in hospital facilities, including hospital-based transfusion activities
- ○ carry out secondary processing of blood components such as;
  - ▪ Irradiation/Cell wash/Pack splitting ○ collect blood and/or blood components for pre-deposit autologous transfusion
- ○ import blood from abroad

A facility that receives Blood and Blood Components (BBC) from another facility for direct transfusion, *i.e.* without conducting compatibility testing or engaging in transit storage at the site of transfusion will not be designated a Blood facility. Such a facility will not be assessed for compliance with Good Preparation Practices and/or Good Distribution

Practices as long as a service level agreement or a similar arrangement exist that demonstrates that the facility receive BBC's from specified and accredited facilities that are licensed to operate as Blood Facilities.

The classes of blood facilities and their permitted scope of operation is presented in the table below:

CLASS	BLOOD FACILITY	PERMITTED ACTIVITIES / PROCESSES
I	HOSPITAL BLOOD BANK	STORAGE,COMPATIBILITY TESTING AND ISSUE FOR TRANSFUSION
II	COLLECTION SITE	DONOR MANAGEMENT, COLLECTION OF WHOLE BLOOD
III	AREA SUB-CENTRE	DONOR MANAGEMENT, COLLECTION OF WHOLE BLOOD, TESTING, PROCESSING, STORAGE, RELEASE/ISSUE TO HOSPITAL BLOOD BANK
IV	AREA BLOOD CENTRE	DONOR MANAGEMENT, COLLECTION OF WHOLE BLOOD, APHERESIS, TESTING, PROCESSING, STORAGE, RELEASE/ISSUE, DISTRIBUTION FOR FURTHER MANUFACTURE
V	PLASMA FRACTIONATION CENTRE	RECEIPT OF BLOOD COMPONENT FOR FURTHER MANUFACTURE

If you are not sure which one you are, please contact the FDA by emailing: fda@fdaghana.gov.gh; Telephone: (+233 –302)233200, 235100 or Fax: (+233-302)229794, 225502.

BLOOD FACILITY (BF)

To operate as a blood facility you must;

- have a blood facility license;
- be audited by the FDA at least once every year
- have a system for reporting any Serious Adverse Blood Reactions or Events (SABRE)to FDA; Specifically, Safety Monitoring Department –Haemovigilance
- have a system to report diagnostic/medical device failures to the FDA
- have a system to submit an annual compliance report
- pay a facility licensing and component listing fee at the time of first licensure, and a license renewal fee every three years

BLOOD FACILITY AUDIT AND COMPLIANCE

The blood facility will be audited by the FDA when you first apply for Blood facility license and at least once every year to maintain the facility license. Following each audit, the applicant (operator/owner) will be sent an official communication with the observations documented at the time of the audit. The observations will be presented with corresponding recommendations to facilitate implementation of corrective actions.

Once fully implemented, the Blood facility will be adjudged as compliant with Good Preparation Practices, Good Storage Practices and Good Distribution Practice. Such a facility shall be recommended for licensure. To maintain the facility licence, it shall be audited once every year for compliance with GPP.

The facility will be required to complete a Blood Facility compliance report before a notified audit or unless it is triggered by an audit. Guidelines document uploaded on the FDA website to provide guidance on how to submit the compliance report to the FDA.

The responsible officer for signing the compliance report and completing the declaration form must ensure that all the questions are completed, and the completed answers are true and accurate. The blood facility shall submit Blood facility Compliance Report and Declaration Form to the FDA. The form should be prepared by the responsible officer for Quality Assurance (QA), and signed by either the QA or an officer with a higher rank authorized to sign.

BLOOD FACILITY VARIATION

Blood facilities shall not make any substantial change to the prescribed activities for which it has been licensed to perform without prior written approval by the FDA. Should the licence holder decide to change/alter any activity contained in their licensure, the blood facility shall submit an application to the FDA to vary the licensure. All applications shall be

submitted to the FDA for consideration prior to implementation by the blood facility. Variations to blood facility licenses shall be classified as either **Administrative** – requiring a limited amount of assessment by the FDA or **Technical** – requiring significant assessment by the FDA with possible scheduling of a site audit.

Note: If the operation of the Blood facility goes through any major change which will alter the approved activities, sites or personnel, the Blood facility shall apply for a variation to the licensure before making the change. See variation forms for Blood Facility licensure at www.fdaghana.gov.gh .

APPLY FOR A BLOOD FACILITY LICENSURE

The Blood facility shall complete a Blood Facility Licensure and product listing application forms (FDA/BPU/A-LBF/2015/01 - Application form for Licensing Blood Facilities in Ghana) and (FDA/BPU/A-LBBP/2015/01 -Application form for listing Blood and Blood Products in Ghana), and pay an application fee to the FDA. The application forms and supporting guidance documents shall be downloaded from the FDA's website, www.fdaghana.gov.gh. The completed form shall be sent (one hard copy and one soft copy) to the FDA, and addressed to the Chief Executive Officer (CEO) (see section 2 of the form for guidance). Alternatively, the completed form shall be sent to the FDA- addressed to the CEO- via fda@fdaghana.gov.gh.

The submission shall trigger an audit of the Blood facility. Upon successful audit of the facility and demonstration of compliance, the facility will be issued a licence and the products prepared in the facility listed. A blood facility shall receive its licensure within 160 days of receipt.

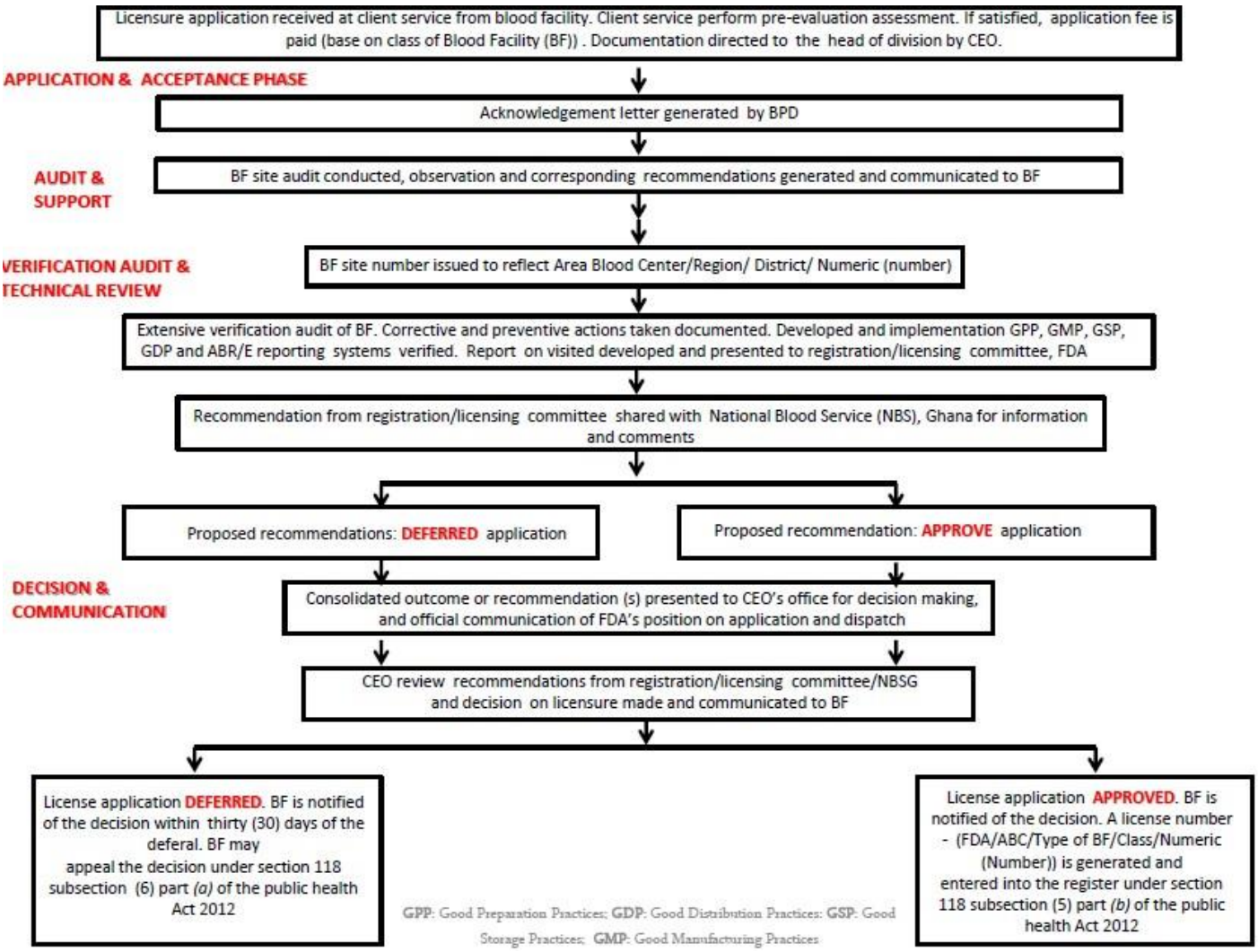
To maintain your licensure, you will be inspected at least once every year to ensure that the facility remain in compliance with the requirements of the legislation.

REPORT A SERIOUS ADVERSE EVENT OR REACTION RELATED TO BLOOD TRANSFUSION AND REPORTING A DIAGNOSTIC FAILURE

A licensed Blood facility shall report all Serious Adverse Event and Reactions (SABRE) related to blood to FDA using the documented procedures for reporting SABRE. Similarly, all diagnostic failures, including false positives and false negatives shall be reported to the FDA through the standard procedure for reporting.

If you have questions about SABRE or diagnostic failures, please send an email to: drug.safety@fdaghana.gov.gh

LICENSING PATHWAY FOR BLOOD FACILITIES



PLASMA DERIVED MEDICINAL PRODUCTS (PDMPS) AND MANUFACTURERS

Marketing authorization holders located outside of Ghana that import or offer for import blood products into Ghana are required to register as importers of Biological Products and subsequently register their product with the FDA pursuant to section 118 of the Public Health Act 2012 Act 851. Applicants shall provide the name of the local agent for Ghana, and the name of each local distributor, and any other entity or person who imports or offers for import these blood products.

A guidance document that provides the regulatory requirements for the registration of human plasma – derived medicinal products have been published on the FDA's website - Guideline for the Registration of Human Plasma-Derived Medicinal Products (PDMPS).

The guideline is applicable to all plasma-derived medicinal products either manufactured in-country or imported into Ghana, and containing an active or inactive ingredient that is derived from human blood either sourced from a local Blood facility or abroad. Due to the associated risk of transmitting infectious agents, the safety of these products is assured through the requirements as described in the published guidelines.

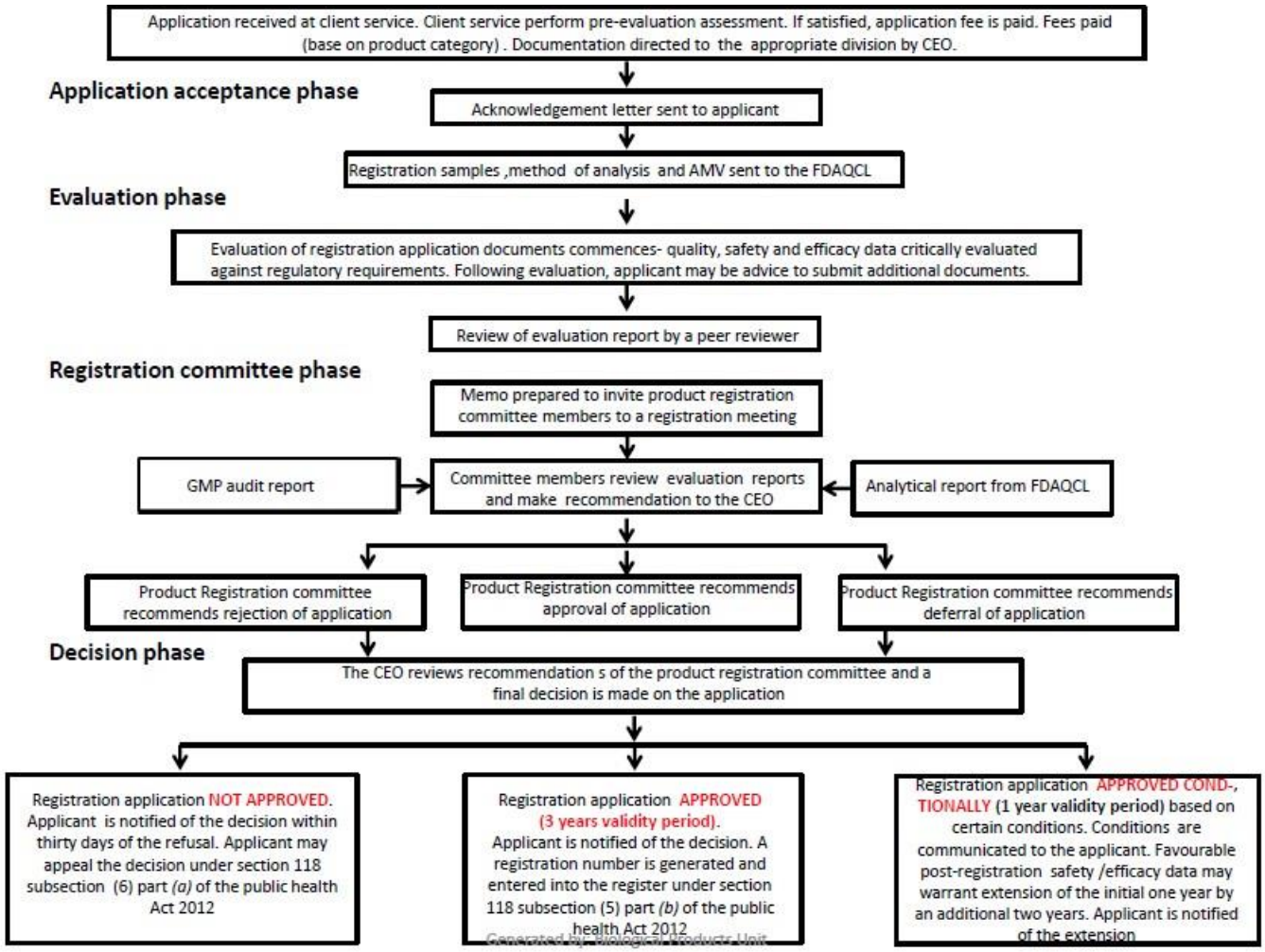
Applications for human plasma-derived medicinal products will be evaluated based on the products' Quality, Safety and Efficacy submissions. The published guideline outlines the requirements for the Plasma Master File (PMF) and the

specific quality documentation required to support registration of these products.

Documents pertaining to the collection and control of source materials should be provided as a standalone PMF. Two sets of the application, including the product dossier and the PMF shall be submitted in softcopy in a CD/DVD (do not submit in hardcopy) together with the appropriate product registration fee for the registration of the human plasma-derived medicinal product. The classify factor VIII concentrate, factor IX complex concentrate (coagulation factors II, VII, IX and X) and human normal immunoglobulin as PDMPs. Anti-D, anti-rabies, anti-tetanus and antisnake are treated. Note that reference to the relevant PMF/s may be made in the sections in the dossier provided below:

a) CTD section 3.2.S.2.3, if the PMF relates to a drug substance; or
b) CTD section 3.2.R.1 (ICH CTD) or 3.2.Q.1 (ACTD), if the PMF relates to an excipient.

REGISTRATION PATHWAY FOR BLOOD PRODUCTS



GUIDELINES AND APPLICATION FORMS

- Application form for licensing blood facilities in Ghana
- Application form for blood facility products listing in Ghana
- Guidelines for licensing blood facilities and blood products listing
- Guidance document for blood facility licensure application form
- Guidelines for reporting adverse reaction
- Guidelines for safety monitoring of medicinal products

- Guidelines for qualified person for pharmacovigilance