FOOD AND DRUGS AUTHORITY

GUIDELINES FOR IMPORT AND EXPORT OF PATHOLOGICAL MATERIALS

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FOREWORD

The Ghana Public Health Act 851 of 2012 requires that pathological specimens to be exported from Ghana are packaged and transported safely and responsibly in order that the integrity of the specimen is preserved and the specimen does not become a danger to any person or persons that come into contact with it.

To that end virulent /pathogenic specimens MAY NOT be exported from or imported into Ghana unless by **Specific Import/Export Permit for Hazardous Pathological Material,** from the Food and Drugs Authority. Such hazardous Biological specimens are outside the scope of this guideline.

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1.0. INTRODUCTION

These guidelines describe the data requirements for the exportation or importation of pathology and research sample(s)/specimen(s).

Virulent /pathogenic specimens may only be exported or imported by **Specific Import/Export Permit for Hazardous Pathological Material** from the Food and Drugs Authority. Such hazardous Biological specimens are outside the scope of this guideline.

1.1. Scope

This document is intended to provide guidance on export or import of pathology and research sample(s)/specimen(s) Items that may require permission include, but are not limited to;

- Human body fluids, organs and other tissues
- Including a part or constituent of human body fluids, organs and tissues
- if the internal volume of the primary container exceeds 0.5 ml
- Materials derived from human Embryos
- Foetal tissue
- Zygotes
- Gametes
- Human blood
- Any substance derived from human blood (blood fractions, immunoglobulin)

1.2. Definition of Terms

In these guidelines, unless the context otherwise states:

'Biological Specimen/Sample' organic material derived from living organisms (biological fluids, tissues and cells derived from animal or human sources) or containing living organisms that are used to;

- Research
- Diagnosis of a medical condition
- Manufacture of a biological product
- Research and Development of a biological product

'Donor' a person or animal providing blood, an organ, bone marrow cells, or other biological tissue for transfusion or transplantation: sperm donor; organ donor.

'Human Body Fluid' any natural bodily fluid or secretion of fluid such as blood, semen, or saliva.

'Organ' a distinct part of an organism that performs one or more specialized functions. Examples of organs are the eyes, ears, lungs, and heart.

'Tissue' an ensemble of cells, not necessarily identical, but from the same origin, that together carry out a specific function. Examples are connective tissue, nervous tissue, mammary tissue.

'Embryo' a multicellular diploid eukaryote in its earliest stage of development, from the time of first cell division until about eight weeks after fertilization ,from then it is instead called a foetus.

'Foetus' the period from eight weeks after conception until birth. Foetal tissue is derived from legal/therapeutic or spontaneous abortions and may be used for the purpose of conducting lifesaving scientific experiments. Fetal tissue transplantation research uses fetal tissue to study potential treatment of life-threatening diseases.

'Zygote' the product of the fusion of an egg and a sperm. It contains two copies of each chromosome, one from each parent. The zygote develops into an embryo.

'Gamete' a mature male or female reproductive cell usually possessing a haploid chromosome set and capable of initiating formation of a new diploid individual by fusion with a gamete of the opposite sex. Human examples are the sperm cell and ovum respectively.

'Human Blood' the fluid that circulates in the principal vascular system of human beings consisting of plasma in which the red blood cells, white blood cells, and platelets are suspended.

'Blood Fraction' the components of blood plasma that are separated by electrophoresis or a similar analytical technique.

'Immunoglobulin' any of a group of large glycoproteins secreted by plasma cells that function as antibodies in the immune response by binding to specific antigens.

'Applicant' the importer or the exporter of the biological/pathological sample or specimen. This individual is personally responsible for the packaging, transportation and safety of the specimen or sample.

2.0. REQUIREMENTS

- Detach and complete form (REQUEST FOR APPROVAL TO EXPORT BIOLOGICS, page 8)

2.1. Other requirements

- Cover letter addressed to the Chief Executive (CE).
- Statement about the degree of infectivity of the sample/specimen.
- A protocol and report for a 'dummy shipment' which will be used to evaluate sample handling and storage conditions.
- Filled and signed donor consent form if applicable.

2.2. Explanatory notes

- Applicant's main business must be provided, e.g., clinic, hospital, fractionation unit, exporting agent, broker, etc.
- Quantity of sample/specimen must be expressed in mass, volume or unit, whichever is most appropriate
- Although detail is not required, the specific purpose(s) for which the samples(s) is (are) to be used must be clearly stated

If import or export has been done to and from Ghana on behalf of the authorized institution by another organization or person, an authority letter (signed, stamped and dated) to that effect must be submitted.

3.0 FORM-REQUEST FOR APPROVAL TO EXPORT BIOLOGICS

(*Public Health Act, 2012, (Act 851), Section 148*)

Permission may be required to export or import pathology and research sample(s)/specimen. Items that may require permission may include, but not limited to;

1) Human body fluids, organs and other tissues
   a) Including a part or constituent of that material of that kind, if the internal volume of the immediate container in which the material is packed exceeds 0.5 mL; and
   b) Including materials derived from human Embryos, Foetal tissue, Zygotes and Gametes
2) A substance derived from human blood

Item 2 refer to products such as blood fractions, immunoglobulins, etc, which are manufactured from human blood

Please use block letters to complete the form

Name of Applicant	
Applicant's designation/ Rank/Position	
Applicant's main business	
Applicant's business address (Physical and Postal)	

Applicant's telephone number	
Applicant's facsimile	
Applicant's e-mail	
Source of sample/specimen	
Identity of samples(s) to be exported*	
Quantity of sample(s) to be exported*	
Volume of individual container(s) and total shipment	
Storage condition (Packaging and temperature)	
Reason for request**	
Name of overseas recipient***	
Overseas recipient address***	
Overseas testing facility address	
Test(s) to be carried-out overseas	
Flight/courier details	
Applicant's Name and signature	

*for plasma/fraction products, specify the source of plasma and batch number for the plasma source as well as the item number and batch number for the finished products For whole blood/tissue/organ related materials provide information about the donor (including sex and age).

**please specify whether this sample/specimen will be used to for clinical use, for research purpose etc.

***if the sample/specimen is obtained from a Ghanaian donor (blood/tissue products) or from the Ghanaian donor whole blood/plasma pool (plasma/fraction products) and is intended to be used on a non-Ghanaian citizen, a formal indemnity statement from the government in the home country of the patient must be provided.