
*Your Well-being, Our Priority.*

# FOOD AND DRUGS AUTHORITY

## GUIDELINES AND APPLICATION FORM 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.

Table of Contents

## 1.0. INTRODUCTION

These guidelines describe the data requirements for the exportation or importation of pathology material(s).

Virulent /pathogenic specimens may only be exported or imported by **Specific Import/Export Permit for Hazardous Pathological Material(s)** 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, tissues and cells.
- Materials derived from human Embryos, Foetal tissue, Zygotes, Gametes, Human blood
- Any other 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 for;

- Research
- Diagnosis of a medical condition
- Therapeutic purposes
- 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 APPLICATION FORM FOR A PERMIT TO IMPORT / EXPORT PATHOLOGICAL MATERIALS

Cover letter addressed to:

The Chief Executive Officer
Food and Drugs Authority
P. O. Box CT 2783
Cantonments-Accra
Ghana.

Please use block letters to complete the form

| **2.1 APPLICANTS DETAILS** | |
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| Full name of applicant: | |
| Applicant's main business (e.g., clinic, hospital, fractionation unit, exporting agent, broker, etc.): | |
| Street or physical address (applicant): | |
| E-mail (applicant): | |
| Telephone number(applicant): | |
| HeFRA Certificate or any other certifacates(if applicable): | |
| Name of contact person: | |
| Signature of contact person: | |
| Name of Medical Superintendent / Director: | |
| Ghana Medical and Dental Council Certificate: | |
| Signature of Medical Superintendent / Director: | |
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| **2.2 IMPORT OF PATHOLOGICAL MATERIALS** | |
| Source of pathological material(s) to be imported: | |

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| Identity of pathological material(s) to be imported: | |
| Filled and signed donor consent form (if applicable). | |
| Quantity of pathological material(s) to be imported (must be expressed in mass, volume or unit, whichever is most appropriate): | |
| Storage condition of pathological material(s) to be imported: | |
| Statement about the degree of infectivity of the sample/specimen: | |
| A protocol and report for a 'dummy shipment' detailing sample handling and storage conditions. | |
| Facility's capacity for storing the pathological material(s) to be imported: | |
| Reason for request (Specific purpose(s) for which the pathological material(s) is (are) to be used must be clearly stated): | |
| Name of overseas company the pathological material is to be imported from | |
| Location address of overseas company the pathological material is to be imported from | |
| Email address of overseas company the pathological material is to be imported from | |
| Contact number of overseas company the pathological material is to be imported from | |
| Overseas company's license certificates that mandates the company to export the pathological material(s) | |
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| **2.3 EXPORT OF PATHOLOGICAL MATERIALS** | |
| Source of pathological material(s) to be exported: | |
| Identity of pathological material(s) to be exported: | |
| Filled and signed donor consent form (if applicable). | |
| Quantity of pathological material(s) to be exported (must be expressed in mass, volume or unit, whichever is most appropriate): | |
| Storage condition of pathological material(s) to be exported: | |

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| Statement about the degree of infectivity of the sample/specimen: | |
| A protocol and report for a 'dummy shipment' detailing sample handling and storage conditions. | |
| Reason for request (specific purpose(s) for which the pathological material(s) is (are) to be used must be clearly stated): | |
| Recipient Company: | |
| Name of overseas company the pathological material (s) is/ are to be exported to: | |
| Location address of overseas company the pathological material(s) is/ are to be exported to: | |
| Email address of overseas company the pathological material(s) is/ are to be exported to: | |
| Contact number of overseas company the pathological material(s) is/ are to be exported to: | |
| Overseas company's license certificates that mandates the company to import the pathological material(s) | |
| List of test(s) to be carried out overseas: | |
| Courier service to be used to export: | |

## 3.0 OTHER REQUIREMENTS

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

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).