FOOD AND DRUGS AUTHORITY

GUIDELINES AND APPLICATION FORM TO IMPORT AN UNREGISTERED BIOLOGICAL PRODUCT FOR A NAMED PATIENT

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FOREWORD

The Ghana Public Health Act 851 of 2012 requires that biological medicinal products, including vaccines intended to be marketed in Ghana meet the acceptable standards of quality, safety and efficacy and at the same time be assessed to have been produced in facilities that comply with current Good Manufacturing Practices (cGMP).

This document is intended to provide guidance to applicants in situations where the therapeutic needs of a patient are not adequately met by registered and available treatment options.

This guideline outlines the requirements for approval to import limited quantities of an unregistered biological product including vaccines into Ghana, for the use of an individual named patient.

Scope

The limits of application for approval to import an unregistered biological product or vaccine are as follows:

1. Permission to import a medicinal product without a license may be granted to a doctor for the purpose of administering the medicinal product to his/her patient

2. The permission to import an unregistered medicinal product is granted on a consignment basis. Each application is specific to a single product (i.e. one product per application)

3. Each application form may be used for the request of no more than one doctor at a time, and applicable for the use of no more than one patient at a time.

4. Permission may be granted for a quantity not exceeding 3 months' supply of the unregistered medicinal product, at the discretion of the Food and Drugs Authority. The validity of the permit shall be 6 months from the date of issuance or expires upon the grant of a product license to the medicinal product to which the permit relates, whichever is earlier.

5. All products must be supplied in packaging written in English language, including the package inserts and product labels. For a first-time product application, these documents must be submitted for review.

6. Sections A and B of the application form must be completed and duly signed by the person importing the unregistered biological product. The information in the application form must be printed or written in a legible manner. Incomplete application will not be accepted.

7. Section D must be completed and duly signed by the doctor seeking permission for importation of an unregistered medicinal product for the purpose of administering the medicinal product to a patient under his/her care. By completing section D, the doctor is fully aware that the product has not been evaluated for quality, safety and efficacy by the Food and Drugs Authority and he/she takes full responsibility for the use of this product on the patient.

APPLICATION FOR PERMISSION TO IMPORT UNREGISTERED MEDICINAL PRODUCT FOR A NAMED PATIENT	FOOD AND DRUGS AUTHORITY FDA GHANA Your Well-being, Our Priority.

Please refer to the guideline above before completing this form

Section A-product details (To be completed by importer)

Product Name (including dosage form & strength):	Importing Quantity :
Name & Strength Of Active Ingredient(s):	Pack Size:
	Route of Administration:
Name & Country of Manufacture:	

Section B- Particulars of Importer (To be completed by Importer)

<table>
<tr><td rowspan="2">Name and Address of Importing Company /Hospital/Clinic:</td><td colspan="2">Name of Applicant:</td></tr>
<tr><td colspan="2">Designation:</td></tr>
<tr><td rowspan="3">Declaration
1. I undertake to maintain proper records on the import and supply.
2. I undertake to comply with the applicable registration requirements pertaining to the registration of a biological product.

…… …….
…….
Signature of Applicant
Date</td><td colspan="2">Name of country where product is sourced :</td></tr>
<tr><td colspan="2">Email Address:</td></tr>
<tr><td>Tel No:</td><td>Fax No:</td></tr>
</table>

Section C- Permit (To be completed by licensing Authority)

<table>
<tr><td>Permit No.:</td><td>Date:</td></tr>
<tr><td colspan="2">Permission is hereby granted for the import of one consignment of the product to be imported within 6 months from the date of approval subject to the following conditions:
1. Import and supply is made by the company/hospital/ clinic stated in this application on behalf of the doctor stated in Section D of this application form and the medicinal product is supplied directly to the requesting doctor.
2. Records of the import and supply must be made readily available for inspection by the Food and Drugs Authority.
3. Product must be properly labeled, with product insert and all label and insert information must be in English language.
The validity of this permit will cease once a product License has been granted to the medicinal product to which this permit relates.
……
For Food and Drugs Authority</td></tr>
</table>

Section D-Importation of unregistered medicinal product (To be completed by the requesting doctor)

Purpose (Tick appropriate box)	☐For Named -Patient ☐As Buffer Stock ……
Full Name of Product	
Unit Quantity Required	
Dosage Regimen	
Indication	
Reason for not using registered product(s)	

Doctor's Particulars & Declaration	Name: MDC Reg No: Email Address: Name of Hospital/Clinic:: Address of Hospital/Clinic: Tel No.: Fax No.: Declaration: 1. I am fully aware that the above medicinal product has not been evaluated for the required quantity, safety and efficacy standards for supply in Ghana. The importation is requested for the purpose of administering product to a patient under my care and I undertake to assume full responsibility for its use on the patient under my care.. 2. I undertake to maintain records of the name, patient ID number and contact details of the patient who received the above medicinal product under my care. Signature: …… Date: ……

*MDC Reg No – Medical and Dental Council Registration Number