FOOD AND DRUGS AUTHORITY

GUIDELINES FOR REGISTRATION OF UK GENERICS

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INTRODUCTION

SCOPE

This Guideline is developed in pursuance of Section 118 of the Public Health Act, 2012, Act 851.

This Guideline applies only to allopathic medicines and prescribes the minimum information required for submission of documentation. It provides recommendations for applicants preparing applications for registration of UK Generics* for submission to the Food and Drugs Authority.

FORMAT

LANGUAGE

Application and supporting documents shall be in English and legible. Where material is not originally in English, a copy in the original language and a full translation should be submitted, the accuracy of the translation is the responsibility of the applicant. Authentication of the translation has to be done at the nearest Ghana Embassy or by the National Drug Regulatory Authority of the country from where the document originates. Reports submitted only in a language other than English will not be accepted.

DATA PRESENTATION

All information, data, attachments must be legible of font size 12 or more and shall be presented on in soft copy on CD-ROM. All pages shall be numbered sequentially with the format page numbered as ***page x of y***. Before submitting the completed form, check that you have provided all requested information. Acronyms and abbreviations should be defined the first time they are used in each part.

SUBMISSION OF APPLICATION

- An application for the registration of UK Generics, shall be made in writing via a cover letter.
- The application shall be submitted through the authorized local agent by the regulatory contact person to the following address:

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

GLOSSARY

The definitions provided below apply to the words and phrases used in these guidelines. Although an effort has been made to use standard definitions as far as possible, they may have different meanings in other contexts and documents. The following definitions are provided to facilitate interpretation of the guidelines.

Applicant*:* Company paying the application fee.

The Authority: The Food and Drugs Authority, Ghana

New Chemical Entity: A chemically Active Pharmaceutical Ingredient (API) that has not previously been registered as an ingredient of any pharmaceutical product.

New Drug: means a generic copy of an innovator product that has not been previously registered as a pharmaceutical product in Ghana, or which has been marketed in Ghana for a period of not less than ten (10) years or any other period to be determined by the Authority from time to time, for public health reasons.

Non-pharmacopoeia products- products for which no monograph exist as outlined in Fourth Schedule of the Public Health Act, 2012 (Act 851).

UK Generics*: means medicines originating from United Kingdom (UK) onto the Ghanaian market, not branded but labelled as the international non-proprietary name (INN) and manufactured in accordance with standards (British Pharmacopeia, United States Pharmacopeia, International Pharmacopoeia, Extra Pharmacopoeia and any other work of reference adopted and approved by The Authority) as stated in the Fourth Schedule; Section 112 of the Public Health Act, 2012 (Act 851)

REQUIREMENTS

1. Completed Application Form.
2. Samples as per the FDA sample schedule.
3. Prescribed application fee of $3600.
4. Dated and signed specification(s) of active pharmaceutical ingredient(s) (APIs).
5. Certificate(s) of analysis (COA) of active pharmaceutical ingredient(s) (APIs).
6. Declaration by the finished pharmaceutical product (FPP) manufacturer of the API source.
7. Dated and signed release specification of the FPP.
8. Certificates of analysis for at least three (3) batches of FPP.
9. GMP certificate of the manufacturer of the FPP.
10. Shelf life of imported medicines should be in accordance with existing Guidelines on Importation of Allopathic Medicines.

N/B.

- For products which applicant can submit evidence of approval from Medicines and Healthcare products Regulatory Agency (MHRA), UK, only requirements 1, 2, 3 and 10 will apply. Additionally, a declaration of sameness of the product to Ghana to that approved by MHRA should be submitted by the FPP manufacturer.

- Imported consignments of registered UK generic products would be sampled periodically at the port of entry at a frequency that will be determined by FDA.

This Guideline is **not applicable** to the following;

- Products with non-pharmacopoeia standards/monographs.

- Sterile products.

- Program medicines (malaria, tuberculosis, HIV/AIDS, reproductive health, neglected tropical diseases)- medicines intended for treatment, cure or prevention of malaria, tuberculosis, HIV/AIDS, reproductive health, neglected tropical diseases.

- New drugs and new chemical entities