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FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE REGISTRATION OF PARALLEL IMPORTED DRUGS OR HERBAL MEDICINAL PRODUCTS

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1.0 SCOPE

In pursuance of section 122 of the Public Health Act 2012, Act 851 of this guideline is hereby made to provide guidance on the procedure for registering parallel imported drugs or herbal medicinal products. Applicants are encouraged to familiarize themselves with this document and the above law before completing the registration form.

2.0 DEFINITION OF TERMS

Parallel importation means importing a drug without authorization of the drug registration holder from another country where it is legitimately placed. The Food and Drugs Authority may in the public interest authorize parallel importation of drugs or herbal medicinal products in pursuant to section 122 subsection 2 of the Public Health Act, 2012.

3.0 OBJECTIVES

The main objective of the Food and Drugs Authority's consideration for parallel import registration is to establish whether the required identity exists between the medicinal product already registered and the medicinal product for which an application for a parallel import registration has been submitted.

4.0 REQUIREMENTS AND CONDITIONS FOR PARALLEL IMPORTATION

4.1 Conditions for Parallel Import

The following requirements must be met in order for the Food and Drugs Authority to issue registration for a parallel importation of medicinal product(s):

1. The registered product in relation to which an application for parallel import has been submitted must have a valid registration in Ghana. Moreover, the two medicinal products must contain the same active substance and have the same pharmaceutical form.
2. The parallel imported medicinal product can be imported from any country of the world.
3. The parallel imported medicinal product must be covered by an existing valid registration from the exporting country.
4. The parallel imported medicinal product must have justification of shelf life based on stability studies under WHO zone IV b conditions.
5. There must not be any differences in therapeutic significance between the parallel imported product and the registered medicinal product.
6. An application must be submitted for registration of parallel import from each individual exporting country.
7. It is the responsibility of the parallel importer to notify the registration license holder of the registered product about their intention of parallel importation of the medicinal product in question.

4.2 Biological Medicinal Products

Due to the special nature of biological medicinal products, the FDA will make a concrete assessment of each individual case for patient safety by requesting for special documentation such as same Drug Master File and Plasma Master File as the case may be.

Furthermore it is a requirement that the parallel importer must ensure traceability of the product.

4.3 Scope of the Parallel Import Registration

Parallel import registration shall be valid for 3years from the time when the first registration for parallel import is issued. Renewal applications must be submitted not later than 3months before the registration expires for all of the products pharmaceutical forms and strengths under the same name.

When registration for parallel import is issued, so is a summary of product characteristics, which is identical with the summary of the product characteristics that applies to the registered product in relation to which the parallel import takes place.

4.4 Withdrawal of Registration for a Parallel imported Medicinal Product If the registration of a medicinal product is withdrawn for safety reasons, any parallel import registration will be withdrawn at the same time.

If the registration of a medicinal product is withdrawn for reasons not related to safety, the parallel import registration will not be withdrawn unless for reasons of protecting public health.

4.5 Changes to a Parallel Imported Medicinal Product

The parallel importer is obliged to keep the Food and Drugs Authority updated on any changes to the parallel imported product. Changes to the parallel imported product composition, appearance, primary packing, manufacturer, registration license holder in the exporting country etc. in relation to what was applied for at the time parallel importation registration was issued must be approved by the FDA before permit to import the product can be allowed.

The parallel importer must ensure that records of minor changes to the approved product is communicated to the FDA to aid in the Authority's programme of controlling substandard, spurious, falsely labeled, falsified, counterfeit medicinal products.

4.6 Company Authorization

A parallel importer must have a license to import medicinal products. Parallel importers who wish to engage in additional labeling or repackaging etc. must in addition to having an importers license also hold a manufacturing license.

Parallel importers must observe current good distribution and good manufacturing practices for medicinal products.

4.7 Fees

Registration fees for parallel imported medicinal products shall be the same as the registration fees for the product relative to which parallel import is granted.

4.8 Product Name

Parallel imported medicinal products can be marketed under the same name as the registered product in relation to which the parallel imported product is being registered.

If the parallel importer decides to market the parallel imported medicinal product under a generic name, the generic name may be followed by the name or logo of the holder of the registration in relation to which the parallel import is bought.

If parallel importers wish to change the name of a parallel imported medicinal product after issuance of their registration, they can apply for another name by submitting a variation application.

4.9 Labeling and Package Leaflets

Labeling and package leaflets of parallel imported medicinal products must not deviate from that of the product in relation to which the parallel import is granted. Parallel imported medicinal products labeling and package leaflets must conform to the FDA labeling guidelines.

4.10 Reporting of Adverse Reactions

Parallel importers are subject to the same condition on reporting of adverse drug reactions as importers of the products in relation to which the parallel import is granted as explained in the FDA guideline on safety monitoring based on section 125 of the Public Health Act, 2012.

Parallel importers are however exempted from the submission of Periodic Safety Update Reports (PSURs).