FOOD AND DRUGS AUTHORITY

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Technical Advisory Committee on Safety of Medicines

Guideline on Registration of Orphan Drugs

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This guideline replaces the Guideline for Registration of Orphan Drug (FDA/DRI/DER/GL-INP/2019/16).

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Document Revision History

Date of Revision	Version Number	Changes made and/or reasons for revision
15th March 2019	01	Initial Issue
8th January 2024	02	General review of the Guideline in line with the current structure.

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Executive Summary

This guideline specifies the criteria for classifying a drug as an orphan drug and the requirements for market authorization in Ghana.

1. Introduction

The Food and Drugs Authority recognizes the need for granting special status to a drug to treat a rare disease or condition upon request of an applicant.

1.1 Legal Basis

This guideline applies to Marketing Authorization Applications for human medicinal products submitted in accordance with the Public Health Act 851 of 2012.

1.2 Scope

These guidelines apply to the category of products classified as orphan drugs, documentation to be submitted, and timelines.

2. Definitions and abbreviations

An Orphan drug is:

(a) A pharmaceutical product that remains commercially undeveloped due to low commercial returns, or

(b) A drug intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders, or

(c) Drugs intended to treat rare diseases that the sponsors are reluctant to develop them under usual marketing conditions.

"A Rare Disease" means a disease condition which occurs in a small percentage of the population

3. Requirements

The following should be submitted for the registration of Orphan Drugs

1. A cover letter from the local representative

2. A completed FDA application form for the registration of allopathic medicines (please refer to the FDA website www.fdaghana.gov.gh).

3. Samples of the product as per the FDA's sample schedule.

4. Pay the requisite application fee (Please refer to the FDA website www.fdaghana.gov.gh)

4. Criteria For Orphan Drug Classification

1. The drug should fall under conditions in the above definition.

2. If a product is registered through the normal registration, an application for orphan drug status by another applicant will be considered if the applicant is able to prove nonavailability and meet orphan drug criteria.

5. Timelines For Registration

Applications under this category shall have a decision made within three (3) months of submission.