FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE CANCELLATION/ SUSPENSION OF A REGISTERED DRUG

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1. INTRODUCTION

1.1 Scope

In pursuance of section 119 of the Public Health Act 2012, Act 851, this guideline is hereby made to provide guidance on the cancellation or suspension of the Marketing Authorization of Allopathic drugs for Human Use, Veterinary drugs, Vaccines, Biological Products, Herbal Medicines, Food supplements and Homeopathic medicines

Applicants are encouraged to familiarize themselves with this document and the above law before completing the registration/application form.

2. GLOSSARY

In this guideline, unless the context otherwise states: -

"**Applicant**" means the product owner or license holder. Representatives of license holders may not hold themselves as applicants unless they own the product

"**Authority**" means Food and Drugs Authority

"**Drug**" means

a. a substance referred to in a publication mentioned in the Fourth Schedule,
b. a substance or mixture of substances prepared, sold or represented for use in the:
    - diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it, in man or animal, or
    - restoring, correcting or modifying organic functions in man or animal, and c. nutritional supplements;

"Local agent' means locally appointed representative

3. GENERAL REQUIREMENTS

3.1 Cancellation of a Marketing Authorization by an Applicant

An applicant may cancel the marketing authorization of a product by addressing the following;

1. By submitting a letter addressed to the Chief Executive Officer of the Authority giving reason(s) for the cancellation of marketing authorization of the Allopathic drugs for Human Use, Veterinary drugs, Vaccines, Biological Products, Herbal Medicines, Nutritional supplements and Homeopathic medicines

2. The Authority shall act on this request and amend its records accordingly where applicable.

3. An applicant may at any time after suspension/cancellation of a registration resubmit new information on the drug in line with current requirements for registration.

3.2 Cancellation/Suspension of A Marketing Authorization by the Authority

1. The Authority shall cancel/suspend the marketing authorization of a drug based on a new national policy.

2. The Authority shall cancel the marketing authorization of a product based on recommendations by the FDA's Technical Advisory Committee for Safety for Medicines and Vaccines and Biologics.

3. The Authority shall cancel an approval in respect of a registration of a product if the product is not made available on the market after one year of registration.

4. The Authority shall cancel/ suspend the registration of a drug if:

    a) The grounds on which it was registered is later found to be false; or

    b) The circumstances under which it was registered no longer exist; or

c) Any of the provisions under which it was registered has been contravened; or

d) The standard of quality, safety and efficacy, as prescribed in the documentation for registration is not being complied with; or

e) The premises, in which the product or part thereof is manufactured, packaged or stored by or on behalf of the holder of the certificate of registration is unsuitable for the manufacturing, packaging or storing of the product.

5. The Authority shall cause the suspension/cancellation of a drug for any other sufficient reason determined by the Authority from time to time.

6. Where the registration of a product is suspended/cancelled based on safety or quality issues, the Authority shall cause the withdrawal from circulation of that product from the market.