G U I D E L I N E S

ON THE REQUIREMENTS

FOR THE REGISTRATION OF

PHARMACEUTICAL MANUFACTURERS

PART III

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INTRODUCTION

Experience in the past has shown that there is wide variation in technological competence of pharmaceutical manufacturers. This difference has been evidenced by variations in the quality of products supplied to the country.

The situation has thus created a necessity to develop a system for the evaluation and registration of pharmaceutical manufacturers.

Consequently, the Drug Administration and Control Authority of has prepared a guideline for the registration of pharmaceutical manufacturers with the purpose of ensuring the safety, quality and efficacy of pharmaceutical products that are imported into the country.

The guideline consists of two sections:

Section I dealing with legalized documents; and
Section II dealing with company profile.

All manufacturers intending to export their pharmaceutical product (both raw material as well finished products) to Ethiopia are, therefore, required to be registered with the Drug Administration and Control Authority .

Definitions

For the purpose of this guideline, the following have the meanings hereby assigned to them:

1. Pharmaceutical product- refers to drugs and medical supplies.

2. Medical supply- refers to surgical dressings, Ligatures and sutures.

SECTION I LEGALIZED DOCUMENTS

This section deals with certificates and legalized document(s) to be submitted by applicants.

1. **Certificate of pharmaceutical products**

1.1. The certificate to be submitted for the registration of manufacturers of Drug products (both raw materials and Finished products) should be the WHO-type certificate of pharmaceutical products issued by the National Competent Authority communicated in the "WHO certification scheme on the quality of pharmaceutical products moving in the International commerce" (sample of the certificate is annexed to the guideline for the registration of drugs for human use (part I of the consolidated guidelines)

1.2 The certificates of Good Manufacturing practice (GMP) and product certificate (which could be combined in one certificate) to be submitted for the registration of manufacturers of medical supplies must be as indicated in the "Guidelines on the Requirements for the Registration of Medical supplies" (part II of the consolidated guidelines).

1.3. All certificates should be authenticated by the Ethiopian Embassy in the country of origin.

1.4. The certificates should be original and current.

2. **Agency Agreement**

2.1. An agency agreement should be made between the manufacturer and the agent responsible to act on behalf of the manufacturer.

2.2. The agreement should specify that the representative is the sole agent in Ethiopia.

2.3. The agreement should be signed by both parties.

2.4. The agent representing the manufacturer should hold a license issued by the Ministry of Trade.

SECTION II COMPANY PROFILE

This section deals with documents to be supplied by the manufacturer.

1. **Back ground information**

The manufacturer should submit background information about the company indicating the following major points.

1.1. Year of establishment,
1.2. Development since establishment,
1.3. Capital,
1.4. Organogram
1.5. Total working force,
1.6. Ownership,
1.7. Subsidiaries (if any)

2. **Production Unit**

A. The manufacturer should submit information on the production unit indicating the following.

A.2.1. Production layout
A.2.2. Major production equipment
A.2.3. Qualification and experience of production personnel
A.2.4. The source of production technology
A.2.5. Major suppliers of raw materials and packaging materials.

B. The information on production unit should also indicate whether the company has the following;

B.2.1. GMP procedure
B.2.2. Master file and batch production record system
B.2.3. Product specifications
B.2.4. Standard operation manual
B.2.5. Special procedures for production of penicillin's (if it formulates penicillin's
B.2.6. List of pharmaceuticals produced by the manufacturer (specify those which are the manufacturer's innovation).
B.2.7. Other relevant informations

3 Quality Control Unit

The manufacturer should state:
A. Whether it performs the following:

A.3.1. Raw and packaging materials Q.C.
A.3.2. In-process Q.C.
A.3.3. Finished product Q.C.

B. The types of Q.C. tests performed (where they are applicable)
B.3.1 Physicochemical tests
B.3.2. Sterility test
B.3.3. Pyrogen test
B.3.4. Acute toxicity test
B.3.5. Biological assay
B.3.6. Microbiological assay etc.

C. Whether it has Good laboratory Practice (GLP) Procedure.
D. The major Q.C. Instruments available (where they are applicable)
D.3.1. IR spectrophotometer
D.3.2. UV visible spectrophotometer
D.3.3. Gas chromatography
D.3.4. Refractometer
D.3.5. PH-meter (with electrodes)
D.3.6. Melting point apparatus,
D.3.7. Disintegration test
D.3.8. Dissolution test apparatus
D.3.9. Karl-Fisher titrator
D.3.10 HPLC, etc.

E. Qualification and experience of Q.C. personnel

4. **Supply system**
The manufacturer should give information on its supply system indicating whether it has at least the following (where they are applicable).

4.1. Cold storage facilities
4.2. Separate stores for raw materials, packaging materials, labels etc.
4.3. Separate room for weighing raw materials
4.4. Quarantine for raw materials, finished products, etc,
4.5. procedure for supplies control.

5. Research and Development Unit (R and D)

The manufacturer should give detailed information on at least the following major points.

5.1. The year R and D was initiated.
5.2. Qualification of the personnel engaged in R and D activities
5.3. Major research areas and achievements attained.
5.4. Affiliation with other institutes (if there is any)

6. Product Registration and marketing Experience of the manufacturer

The manufacturer should submit full information on its marketing experience and registration status of its products indicating:

6.1. List of countries to which it exports most of its products.

6.2. List of countries in which its products are registered

6.3. List of countries where its product9s) has have been withdrawn from the market.

Annex I

APPLICATION FORM FOR THE REGISTRATION Of PHARMACEUTICAL MANUFACTURERS

FORM M.pha/R

TO: _____
_____

1. Date of application: _____
2. Name and address of the manufacturer:
_____
_____
3. License number of the manufacturer in the country of origin
_____

4. The type of products manufactured by the factory:

Medical supplies ☐

Drug raw material ☐

Finished drug products ☐

5. Documents attached:
Certificate of Good manufacturing Practice

Product certificate
Agency agreement
Company profile
Consent form
Others (Please specify below)

Name and official./designation of the applicant (person(s) representing the manufacturer).
_____
_____

Signature ----------
Date _____

ANNEX 11

CONSENT FORM

We, ……assure you that the legalized documents, the company profile, and other documents that we have submitted are true and correct.

We agree to inform the Drug Administration and Control Authority, of Ethiopia, about any change or modification made on the information given in the documents submitted.

We also agree to allow officials from the Drug Administration and Control Authority ,of Ethiopia, to visit and have first-hand information about the industry at any time

We recognize and accept the right of the Drug Administration and Control Authority of Ethiopia, to suspend or to revoke the registration certificate that is already issued to us if any fraud or anything contradictory to our registration documents is discovered.

Signed by:

Person authorized to
Sign on behalf of the manufacturer

Date:

(Manufacturer's full name and address)