MINISTERIAL PROVISIONS CONCERNING TO TURKISH PHARMACEUTICALS

MINISTRY OF HEALTH
AND SOCIAL ASSISTANCE

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REPUBLIC OF TURKEY

MINISTRY OF HEALTH AND SOCIAL ASSISTANCE

Directorate of Pharmaceuticals

ANKARA — 1986

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PREFACE

During the past two years, General Directorate of Pharmaceuticals of the Ministry of Health and Social Assistance has made genuine progressive developments in the production and consumption of pharmaceutical and medical products and cosmetics. The purpose of those guiding progressive studies was initially, to achieve the assurance of the quality of products and ultimately, the safety, well-being and protection of the consumer.

Greater care and responsibilities are required in the process of manufacturing the pharmaceutical and medical products, in view of the current large - scale use of such products in health therapy and the possible risks resulting from their increased potency. For this reason, new criteria were adopted and new legislations were enacted on the production, registration and importation of herbal and synthetic drugs, medical, dental and surgical materials and medical gases.

In order to well-inform the public and also the related authorities, about the new measures taken, symposiums were organised and documents were published.

This booklet is prepared to collect all new regulations in the field that General Directorate is responsible for. We hope that it will meet the demands of the interested readers.

REGULATION CONCERNING PHARMACEUTICALS AND MEDICAL PREPARATIONS' MANUFACTURING PREMISES

(G.M.P.)

Official Gazette
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REGULATION CONCERNING PHARMACEUTICALS AND MEDICAL PREPARATIONS' MANUFACTURING PREMISES

Object

Article 1 — The purpose of this regulation is to rule the manufacturing practices of high quality drugs, pharmaceuticals, medical preparations, substances, materials and compositions and the establishment, business practices and control of relevant manufacturing premises.

Scope

Article 2 — This regulation rules on the production premises, related conditions, controlling and the responsibilities of personnel for the herein mentioned good manufacturing practices of pharmaceuticals and medical preparations, substances, materials and compositions necessary to save life, to preserve or to restore public health.

Descriptions

Article 3 — For the purposes of this regulation, the following descriptions are adopted :

a) Ministry : Ministry of Health and Social Assistance

b) Law : Law No. 1262 on pharmaceutical and medical preparations as revised by Law 6243.

c) Drug : Pharmaceuticals and medical preparations.

d) Manufacturing : All operations involved in the production of a drug, including processing, compounding, formulating, filling, packaging and labelling.

e) Manufacturing premises : Factory of pharmaceuticals and medical preparations.

f) Starting materials : All substances, whether active or inactive or whether they remain unchanged or become altered, that are employed in the manufacture of drugs.

g) Batch : A quantity of any drug produced during a given cycle of manufacture. The essence of a manufacturing batch is its homogeneity.

h) Batch number: A designation (in numbers and/or letters) that identifies the batch and that permits the production history of the batch, including all stages of manufacture and control to be traced and reviewed.

ı) Quarantine : The status of a material that is set apart and that is not available for use until released.

j) Quality control : All measures designed to ensure the output of uniform batches that conform to established spesifications of identity, quantity purity and other characteristics.

k) «Half finished» product: Any material or mixture of materials that must undergo further manufacture.

Application to establish manufacturing premises

Article 4 — The conformity to conditions herein mentioned by this Regulation concerning drug manufacturing premises subject to establishment should be documented and these documents in turn submitted to Ministry by means of the highest local governing authority.

— In this application following documents should be included :

a) Petition,

b) Diploma of responsible director, approved copies of specialisation certificates, if there be any, and documents of good conduct,

c) Implicit address of the manufacturing premises subject to establishment and its location within the city plan, if such a plan is drawn,

d) Internal layout of manufacturing premises (equipments included).

Personnel

Article 5 — Personnel of manufacturing premises should have the following qualifications :

a) Responsible Director : Should have one of the professions envisaged by the law and be subject to employment preference in the case of acquirement of expert certificate on drug manufacturing, quality control and pharmacology.

b) Responsible Technical Personnel: Satisfying number of personnel competent to handle manufacturing processing of drugs in accordance with determined specifications and having high level relevant training, should be employed. Ministry may increase the number of personnel when deemed necessary.

Personnel should undergo job commencement training and again professional training to be arranged by the real persons or legal entities as whoever the employer may be.

Personnel responsible for manufacturing and quality control should have the same qualifications as the responsible director.

Authority and Responsibilities

Article 6 — The authorities and responsibilities of the manufacturing expert and the quality control expert are defined in writing by the responsible director. The responsibility for quality control and manufacturing can not be placed at the person of one expert. The responsible director and the personnel responsible for quality control and manufacturing can not resume other job engagements except those endowed by elections at professional societies.

The responsible director, along with the experts responsible for manufacturing and quality control are obliged to be ready at manufacturing premises during working hours and have to actively participate at work. In the case when they can not be present at premises, they should nominate their representatives of the same qualifications to carry on their duties. The responsible director have to issue the permission of local health authority for his absence to be prolonged longer than three days.

Buildings

Article 7 — Manufacturing premises consist of the following necessary departments:

a) Administrative department,
b) Manufacturing department,
c) Control department,
d) Packaging department.

— Drugs should be manufactured, packaged and controlled in premises suitable for these purposes as given below:

A — General : In determining the suitability of premises regard should be paid to :

a) The compatibility of other manufacturing operations that may be carried out in the same or adjacent premises.

b) The adequacy of the working space, which should allow orderly and logical placement of equipment and materials so as to minimize the risk of confusion between different drugs or their components, control the possibility of cross-contamination by other drugs or substances and minimize the risk of omission of any manufacturing or control step.

c) Those physical aspects of the premises that could affect the quality and safety of products, buildings should be so designed and constructed as to prevent the entry of animals and insects; interior surfaces, walls, floors and ceilings should be smooth and free from cracks, should not shed particulate matter and should permit easy cleaning and if necessary disinfection.

d) Lighting, heating and ventilation and if necessary, air conditioning required to maintain a satisfactory temperature and relative humidity that will not adversely affect the drug during manufacture and storage, nor the accuracy and functioning of laboratory instruments.

B — Storage areas : The storage areas should be satisfactory for the need and arranged in observing the following principles :

a) Storage areas should provide adequate space, suitable lighting and should be arranged and equipped to allow dry, clean and orderly placement of stored materials and products, whenever necessary under controlled conditions of temperature and humidity.

b) Such areas should provide for suitable and effective separation of quarantined and starting materials.

c) Special segregated areas should be available for storage of :

1. Substances presenting special risk of fire and explosion.

2. Highly toxic, narcotic and other dangerous drugs (these areas should be adequately protected against theft).

3. Rejected and recalled starting materials and drugs.

C — Special areas : For special purposes, such as the manufacture of drugs that are intended to be sterile but cannot be sterilized in