THE DRUGS ACT, 1976

CONTENTS

SECTIONS:

THE DRUGS ACT, 1976

[1]ACT No. XXXI OF 1976

[*11th May, 1976*]

An Act to regulate the import, export, manufacture, storage, distribution and sale of drugs.

WHEREAS it is expedient to regulate the import, export, manufacture, storage, distribution and sale of drugs ;

It is hereby enacted as follows :-

CHAPTER I

INTRODUCTORY

1. Short title, extent and commencement.—(1) This Act may be called the Drugs Act, 1976.

(2) It extends to the whole of Pakistan.

(3) It shall come into force at once.

2. Application of other laws not barred. The provisions of this Act, shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930 (II of 1930), and any other law for the time being in force.

3. Definitions. In this Act, unless there is anything repugnant in the subject or context,—

(a) "adulterated drug" means a drug—

(i) which consists in whole or in part of any filthy, putrid or decomposed substance or which contains any foreign matter, vermin, worm, rodent or insect ; or

(ii) which has been manufactured, packed, or held under unsanitary conditions whereby it [2][has] been contaminated with dirt, filth or any other foreign matter or whereby it may have been rendered injurious to health ; or

(iii) the container of which releases any poisonous or deleterious substance which may render the contents injurious to health ; or

---

[1]*For Statement of Objects and Reasons, see Gaz., of P., 1976, Ext., Pt. III, p. 250.*
An offence punishable under the Drugs Act, 1976, will be tried and punished by a Military Court, see Notification No. 57/1(1)1943/AJAG/CMLA/82, dated, see Gaz. of P., Ext., Pt. I, p. 153.
[1]*Applied to FATA & PATA of NWFP vide S.R.O. 668(1)/91, dated 15-07-91,& NWFP, Gaz-Ext. dated 10-09-91, P. 264.*
[2]*Subs by Ord. 128 of 02, s. 2.*

(iv) which bears or contains as an ingredient a substance other than the prescribed substance ; or

(v) with which any substance has been mixed or packed so as to reduce its quality or strength or for which any substance has been substituted wholly or in part ;

(b) "Appellate Board" means the Board constituted under section 9 ;

(c) "batch" means a quantity of any drug produced during a given cycle of manufacture ;

(d) "batch number" means a designation printed on the label of a drug that identifies the batch and permits the production history of the batch, including all stages of manufacture and control, to be traced and reviewed ;

(e) "Central Licensing Board" means a Board set up under section 5 ;

(f) "counterfeit drug" means a drug the label or outer-packing of which is an imitation of, or resembles or so nearly resembles as to be calculated to deceive, the label or outer-packing of a drug of another manufacturer ;

(g) "drug" includes—

(i) any substance or mixture of substances that is manufactured, sold, stored, offered for sale or represented for internal or external use in the treatment, mitigation, prevention or diagnosis of disease, an abnormal physical state, or the symptoms thereof in human beings or animals, or the restoration, correction, or modification of organic functions in human beings or animals, not being a substance exclusively used or prepared for use in accordance with the ayurvedic, unani, homoeopathic or biochemic system of treatment except those substances and in accordance with such conditions as may be prescribed ;

(ii) abortive and contraceptive substances, agents and devices, surgical ligatures, sutures, bandages, absorbent cotton, disinfectants, bacteriophages, adhesive plasters, gelatine capsules and antiseptic solutions ;

(iii) such substances intended to be used for the destruction or repulsion of such vermin, insects, rodents and other organisms as cause, carry or transmit disease in human beings or animals or for disinfection in residential areas or in premises in which food is manufactured, prepared or kept or stored ;

(iv) such pesticides as may cause health hazard to the public ;

(v) any substance mentioned as monopraph or as a preparation in the Pakistan Pharmacopoeia or the Pakistan National Formulary or the International Pharmacopeia or the British Pharmacopoeia or the British Pharmaccutial Codex or the United States Pharmacopoeia or the National Formulary of the United States, whether alone or in combination with any substance exclusively used in the unani,

ayurvedic, homoeopathic or biochemic system of treatment, and intended to be used for any of the purposes mentioned in sub-clauses (i), (ii) and (iii) ; and

(vi) any other substance which the Federal Government may, by notification in the official Gazette, declare to be a "drug" for the purposes of this Act;

(h) "expiry date" means the date stated on the label of a drug after which the drug is not expected to retain its claimed efficacy, safety, quality or potency or after which it is not permissible to sell the drug ;

(i) "expert" means a specialist through university education and experience in the relevant field ;

(j) "export", with its grammatical variations and cognate expressions, means to take out of Pakistan by sea, land or air ;

(k) "generic name" means the non-proprietary, scientific or official name of a drug as approved by the Federal Government ;

(l) "Government Analyst" means a Federal Government Analyst or a Provincial Government Analyst appointed under section 16 ;

(m) "import", with its grammatical variations and cognate expressions, means to bring into Pakistan by sea, land or air ;

(n) "Inspector" means a Federal Inspector or a Provincial Inspector appointed under section 17 ;

(o) "label" means a display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of a drug package;

(p) "labelling" means all labels and other written, printed or graphic matter accompanying any drug;

(q) "licensing authority" means such authority as may be prescribed;

(r) "manufacture", in relation to a drug, means all operations involved in the production of the drug, including processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labelling with a view to its storage, sale and distribution, but does not include the compounding and dispensing or the packing of any drug in the ordinary course of retail business or on a prescription of a registered medical practitioner or dentist or of a veterinarian and "to manufacture" shall be construed accordingly;

(s) "misbranded drug" means a drug—

(i) which is not labelled in the prescribed manner; or

(ii) on the label or labelling of which any word, statement, or other matter or information required by the rules to appear on the label or labeling is not