

[TO BE INTRODUCED IN THE NATIONAL ASSEMBLY]

A

BILL

to regulate the manufacture, import, export, storage, distribution and sale of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal and any other non-Allopathic medicine;

WHEREAS it is expedient to regulate the manufacture, import, export, storage, distribution and sale of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal and any other non-Allopathic medicine;

It is hereby enacted as follows: —

1. **Short title, extent and commencement.**—(1) This Act may be called the Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal and other non-Allopathic Medicine Act, 2008

(2) It extends to the whole of Pakistan.

(3) It shall come into force after six months on a date to be notified by the Federal Government in the official Gazette.

CHAPTER I

INTRODUCTORY

2. **Provisions of this Act in addition to and not in derogation of other laws.**—The provisions of this Act, shall be in a addition to, and not in derogation of the Unani, Ayurvedic and Homoeopathic Practitioners Act, 1965 (II of 1965), the Drugs Act, 1976 (XXXI of 1976), the Customs Act, 1969 (IV of 1969), the Control of Narcotic Substances Act, 1997 (XXV of 1997) or any other law for the time being in force:

Provided that where there is inconsistency between any provision of this Act and any other law for the time being in force, the provision of this Act shall prevail.

3. **Definitions.**—(1) In this Act, unless there is anything repugnant in the subject or context:—

- (a) “adulterated Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine” means:—
 - (i) which consists, in whole or in part, of any filthy or putrid substance; or
 - (ii) which has been prepared, packed or stored under unhygienic or insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
 - (iii) the container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
 - (iv) which bears or contains, for the purpose of coloring only, a color other than one which is prescribed; or
 - (v) which contains any harmful or toxic substance which may render it injurious to health; or
 - (vi) any substance which has been mixed therewith so as to reduce its quality or strength;
- (b) “Appellate Authority” means the Authority constituted under section 7;
- (c) “Board” means Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal and other non-Allopathic medicine Board constituted under section 4;
- (d) “counterfeit Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine” means if it is an imitation of, or resembles in a manner likely to deceive or bears upon it or upon its label or container the name of another Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine or a drug defined in the Drugs Act, 1976, or bear a name which closely resembles to that of another manufacturer with a view to deceiving the public, provided that if the name is included in any authoritative books as prescribed under the rules;

- (e) “expert” means a person with relevant university education or relevant education from a recognized institution with at least fifteen years experience in the related field;
- (f) “export” with its grammatical variations and cognate expressions means to take out of Pakistan by sea, land or air;
- (g) “Federal Government” means the Ministry of Health;
- (h) “Government Analyst” means a Government Analyst appointed under section-11;
- (i) “Hakim”, “Tabib”, “Vaid” or “Homoeopathic Doctor”, as the case may be, means a practitioner registered under the Unani, Ayurvedic and Homoeopathic Practitioners Act, 1965;
- (j) “Import” with its grammatical variations and cognate expressions means to bring into Pakistan by sea, land or air;
- (k) “Inspector” means Inspector appointed under section-12;
- (l) “label” means a display of a written, printed or graphic matter upon the immediate container or the outside container or wrapper of a Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine package and includes, where provided, packaging inserts;
- (m) “manufacture” in relation to Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine in finished form, ready for use, means all operations involved in the production, including processing, compounding, formulating, filling, packing repacking and labeling with a view to storage, sale and distribution, but, does not include the compounding, dispensing, packing and labeling of any such medicine in the ordinary course of practice in the Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic system of medicine by a practitioner registered under the Unani, Ayurvedic and Homoeopathic Practitioners Act 1965;
- (n) “misbranded Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine” means if it is not labeled in the prescribed manner, or if its label or container or any thing accompanying it bears any statement, design or device which makes any false claim or which is false or misleading in any particular information;

- (o) “prescribed” means prescribed by rules;
- (p) “raw material” means any substance used in the manufacture of Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic Medicine, not being a raw material used in the drugs under the Drugs Act, 1976 or a packaging material;
- (q) “rules” means rules made under this Act;
- (r) “sell” means sell, offer for sale, exhibit for sale, have in possession for sale or distribution and “to sell”, “sold” or “sale” shall be construed accordingly;
- (s) “spurious Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine” means if:
 - (i) it is imported or manufactured under a name which belongs to a drug as defined in the Drugs Act, 1976; or
 - (ii) its label or container bears the name of an individual or a company purporting to be the manufacturer, which individual or company is fictitious or does not exist; or
 - (iii) it purports to be the product of a manufacturer of whom it is not truly a product; or
 - (iv) it has been mixed wholly or in part with a drug as defined in the Drugs Act, 1976 unless such a drug is excluded or exempted from section 3 (g) of the Drugs Act, 1976; or
 - (v) it purports to be a Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine but does not contain the active ingredient of that medicine;
- (t) “storage” means storage for sale, to “store”, or “stored” shall be construed accordingly; and
- (u) “Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine” means: —
 - (i) any substance or mixture of substances, product, or preparations intended for external or internal use in human beings or animals for the treatment, mitigation, or prevention of disease, an abnormal physical state or the symptoms thereof, or for restorations, correction or

modification of organic functions of human beings or animals, that are manufactured, sold, stored, or offered for sale exclusively in accordance with the ingredients or formula prescribed in the authoritative books of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic system of medicine as prescribed under the rules, or manufactured in accordance with Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic system of medicine, not being a drug as defined in the Drugs Act, 1976 excluding any Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine included in any of the Pharmacopoeia of Allopathic medicines;

- (ii) any substance or material or mixtures thereof as may be prescribed or notified in the official gazette by the Federal Government;

CHAPTER II

ADMINISTRATION AND ENFORCEMENT

4. **Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine Board.**— (1) The Federal Government shall by notification in the official Gazette and with effect from such date as may be specified therein, constitute a Board to be called “Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic Medicine Board” consisting of the following members, namely:—

- (a) the Director General Health, Ministry of Health, Government of Pakistan, who shall be its *ex-officio*, Chairman;
- (b) the Secretary Health of each Provincial Government, who shall be its *ex-officio* member, or his nominee being an expert in the subject;
- (c) the Chairman, Quality Control, Ministry of Health, who shall be its *ex-officio* member;
- (d) a representative of National Institute of Health from Drugs Control and Traditional Medicine Division to be nominated by the Federal Government;
- (e) four experts one each from the field of Tibb-e-Unani, Ayurvedic, Homeopathic and Herbal Medicine, to be nominated by the Federal

Government in consultation with Provincial Governments having at least fifteen years of experience in the related field;

- (f) President of National Council for Tibb;
- (g) President of National Council for Homoeopathy;
- (h) An expert in the field of Pharmacognosy or a Phytochemist, to be nominated by the Federal Government;
- (i) a Pharmacologist to be nominated by the Federal Government;
- (j) a Pharmacist to be nominated by the Federal Government;
- (k) a practicing Physician, with at least fifteen years experience as such to be nominated by the Federal Government;
- (l) a representative, not below the status of an officer of BPS-19 from the Ministry of Finance, to be nominated by the Federal Government;
- (m) an expert from Tibb-e-Unani industry, to be nominated by the Federal Government;
- (n) an expert from Homoeopathic industry, to be nominated by the Federal Government;

(2) For the purposes of this Act, the Board may, from time to time, employ such officers and staff, or appoint such experts or consultants, or form committees, as it may consider necessary for assistance in the performance of its functions, on such terms and conditions as may be prescribed.

(3) The members of the Board shall hold office for a period of three years and shall be eligible for re-nomination.

(4) A member, other than an *ex-officio* member may, by giving in writing to the Federal Government, a notice of not less than sixty days, resign his office.

(5) Any vacancy on the Board or a defect in its composition shall not prevent the Board from execution of its functions.

(6) The Federal Government shall appoint a person to be the Secretary of the Board.

- (7) The following shall be the functions of the Board:—
- (a) To act as Licensing Authority for import, export and manufacture of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine and shall exercise the following powers:—
- (i) to grant license for import, export and manufacture of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine in accordance with such conditions and procedure as may be prescribed, including requirements for compliance to good manufacturing practices, and may require enlisting of medicines followed by notification, registration and approval as may deemed fit;
 - (ii) to classify Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine in different categories for the purpose of their regulation as well as to prescribe measures to ensure their safety, efficacy and access in the manner as may be prescribed;
 - (iii) to exercise such powers, including the powers by the members, of an Inspector under this Act and such other powers as may be prescribed;
 - (iv) to make regulations with the prior approval of the Federal Government for the conduct of its business;
- (b) to identify therapeutic claims which can not be made for a Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine unless the claim is sub-stantiated in a manner as may be prescribed;
- (c) to propose measures for ensuring safety of public health from any untoward action or use of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine;
- (d) to advise the Federal Government on matters pertaining to regulation of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic system of medicine;
- (e) to appropriate funds for research and development of the Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic system of medicine as may be prescribed; and

(f) any other function as may be assigned to it by the Federal Government for the purposes of this Act.

(8) The Board shall comply with such policy directions as the Federal Government may issue from time to time.

5. **Funds of the Board.**—(1) A non-lapsable fund shall be maintained vesting in the Board known as “Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine Board Fund”, hereinafter referred to as the ‘Fund’, to be utilized by the Board in the manner prescribed by the Federal Government, to meet its operational expenses in connection with its functions under this Act, including the payment of salaries and other remunerations and allowances to the persons engaged and employed for assistance in the performance of its functions.

(2) The Fund shall be kept in a scheduled bank and shall be strictly operated according to rules and regulations of the Federal Government.

(3) To the credit of the Fund shall be placed all funds received by the Board and the Fund shall consist of:

- (a) grants made by the Federal Government;
- (b) income from all the fees collected under this Act including for grant of licenses, registration, enlisting, inspections and such other services as may be carried out under this Act;
- (c) funds provided by the Federal Government, foreign aids, grants and loans negotiated and raised by the Board with the prior approval of the Federal Government;
- (d) any other sum received by the Board, such as renewal fees, etc.

6. **Accounts of the Board.**—(1) The Board shall maintain complete and accurate books of accounts of its actual expenses and receipts in such manner as the Federal Government may determine in consultation with the Accountant General of Pakistan.

(2) The Auditor General of Pakistan shall audit the accounts of the Board annually.

7. **Appellate Authority.**—(1) The Appellate Authority shall consist of the following members, namely: —

- (a) Secretary, Ministry of Health, Government of Pakistan, who shall be its *ex-officio* Chairman;
- (b) Drugs Controller, Ministry of Health, who shall be its *ex-officio* member;
- (c) Chief, Drugs Control and Traditional Medicines Division of National Institute of Health, Islamabad who shall be its *ex-officio* member;
- (d) One expert each in the field of Tibb-e-Unani and Homoeopathy to be nominated by the Federal Government; and
- (e) One practicing Physician of Allopathic medicine with at least fifteen years experience as such, to be nominated by the Federal Government.

(2) Any person aggrieved by a decision of the Board may, within sixty days of receipt of such decision, prefer an appeal in the prescribed manner to the Appellate Authority.

(3) An appeal under sub-sections (2) shall be in triplicate and be accompanied by a copy of the decision appealed against, and shall contain all material statements and arguments relied upon by the appellant.

(4) The Appellate Authority shall transmit a copy of the appeal referred to in sub-section (3) to the Board and the Board shall, on demand, produce before the Appellate Authority the record of the case leading to the decision.

(5) The Appellate Authority shall, after giving the appellant an opportunity of being heard, pass such order as it thinks fit and such order shall be final.

(6) The Appellate Authority may, of its own motion at any time, call for the record of any case for the purpose of satisfying itself as to the correctness, legality or propriety of such order and may pass such order in relation thereto as it deems fit.

8. **Expert Committees.**—(1) The Federal Government may constitute committees of experts on evaluation of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or for any other non-Allopathic medicine, for preparations of pharmacopoeias, on advertising and on such other matters as may be necessary for the purposes of this Act.

(2) Each committee constituted under sub-section (1) shall consist of such members as the Federal Government may appoint from time to time and each such member shall hold office during the pleasure of the Federal Government.

9. **Withdrawal from sale of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine for Public safety.**—(1) The Federal Government may on the basis of evidence available and in consultation with the Board notify such preparations or type of products, which could pose a serious threat to the public health and may after providing on opportunity of hearing to the concerned manufacturer or importer, as the case may be, order their withdrawal from sale, storage and distribution in a manner as may be prescribed.

(2) The Provincial Government may also order such withdrawal referred to in sub-section (1) subject to prior approval of the Federal Government.

10. **Directions to Provincial Governments.**—The Federal Government may give such directions to a Provincial Government as may appear to the Federal Government to be necessary for carrying into execution in the Provincial of any of the provisions of this Act, or of any rule or order made there under or for maintaining supplies of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine of standard quality, or for the achievement of uniformity in respect of any matter in different parts of Pakistan.

11. **Government Analyst.**—(1) The Federal Government or a Provincial Government shall, by notification in the official gazette, appoint such persons as it thinks fit, having the prescribed qualifications and experience in testing of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine, to be Government Analyst for such areas or classes of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine as may be assigned to them in the notification.

(2) No person who has any financial interest in the manufacture or sale of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine shall be appointed as Government Analyst.

12. **Inspectors.**—(1) The Federal Government or a Provincial Government shall by notification in the official gazette appoint such persons as it thinks fit. Having the prescribed qualifications and experience in the field of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine, to be Inspectors for such local limits as may be assigned to them respectively.

(2) No person who has any financial interest in the manufacture or sale of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine shall be appointed as an Inspector.

(3) Every inspector shall be deemed to be a public servant within the meaning of section 21 of the Pakistan Penal Code (Act XLV of 1860) and shall be subordinate to such authority as the appointing Government may specify in this behalf.

13. **Powers of Inspectors.**—(1) Subject to the provisions of section 12 and of any rules made in this behalf, and Inspector may, within the local limits for which he is appointed:

- (a) inspect any premises wherein any Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine is manufactured, the plant and process of manufacture, or, stored for sale, and storage conditions;
- (b) take samples of any Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine which is being manufactured or imported or being sold or is stored or exhibited for sale or is being distributed;
- (c) enter and search, with such assistance, if any, as he considers necessary any building vessel or place, in which he has reason to believe that an offence under this Act or any rules has been or is being committed or may continue to be committed;
- (d) call any respectable person of the locality to be present as witness in the course of sampling, search or seizure or in connection with any other matter where the presence of witnesses is necessary;
- (e) seize such Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine and all materials used in the manufacture or sale thereof and any other articles, including register, cash memos, invoices and bills, which he has reason to believe may furnish evidence of the commission of an offence punishable under this Act or any rules:

Provided that where the contravention is such, which can be remedied, the stocks shall not be seized upon undertaking in writing of the person not to sell the stocks without remedying the defect;

- (f) require, in writing, any relevant person to appear before him at any reasonable time and place to give statement, assistance or

information relating to or in connection with the investigation of an offence under this Act or the rules:

Provided that the exemptions under sections 132 and 133 of the Code of Civil Procedure, 1908 (Act of 1908) shall be applicable to requisitions for attendance under these clauses;

- (g) lock and seal any premises, or a part thereof, where any Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine is or is being manufactured for sale without a license issue under this Act;
- (h) forbid for a reasonable period, not exceeding two weeks or such further period, which shall not be more than six weeks with the approval of the Board, as the case may be, specify any person in charge of the premises from removing or dispensing of any Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine, article or other thing likely to be used in evidence of the commission of an offence under this Act or the rules.

(2) The provision of the Code of Criminal Procedure, 1898 (Act V of 1898) in so far as they are not inconsistent with the provisions of this Act, shall apply to sampling, searches and seizures made under this Act.

14. **Procedure for Inspector.**—(1) Where an Inspector seizes any Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine or any other article, under section 13, he shall tender a receipt thereof, in the prescribed form to the person from whom such seizure is made.

(2) where an Inspector takes a sample of a Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person, unless he willfully absent himself, shall divide the sample into five portions and effectively seal and suitably mark the same and permit such person to add his own seal, if any, and mark to all or any of the portion so sealed and marked:

Provided that, where the sample is taken from premises whereon the Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal or any other non-Allopathic medicine is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that, where the Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine is made up in containers of small

volume, instead of dividing a sample as aforesaid, the Inspector may and if the Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine be such that it is likely to deteriorates or be otherwise damaged by exposure shall take three or four, as the case may be, of the said containers after suitably marking the same and where necessary sealing them:

Provided further that if the contents of one container are insufficient for the laboratory test and analysis, the Inspector may increase the number of the containers in order to make the sample sufficient for this purpose.

(3) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same within seven days as follows:—

- (a) one portion of sample he shall send to the Government Analyst concerned for test and analysis;
- (b) the second he shall send to the Chairman Board for purposes of second testing, where needed;
- (c) the third, where taken, he shall send to the warrantor, if any, and
- (d) the fourth, where taken, he shall send to the individual or company purporting to be its manufacturer;

*Explanation:—*For the purpose of this sub-section warrantor means the manufacturer, importer, indenter, distributor, wholesaler or a person authorized in writing by the manufacturer or importer, who has sold the Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine to the person from whom sample is taken under a valid invoice, stating in particular the name and batch number of the Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine and give a warranty to the effect that the Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal medicine does not contravene in any respect the provisions o this Act or the rules. Ayurvedic, Homeopathic, Herbal medicine does not contravene in any respect the provisions of this Act or the rules.

15. **Reports of the Government Analyst.**—(1) The Government Analyst to whom a sample of any drug has been submitted for test and analysis under sub-section (3) of section 14 shall deliver to the Inspector submitting it a signed report in quadruplicate in the prescribed form and forward one copy thereof to the authority as may be prescribed.

(2) The Government Analyst, as far as may be, shall submit the report referred to in sub-section (1) within thirty days of the receipt by him of the sample of the medicine and, if he is not able to do so for reasons beyond his control, shall communicate the reasons to the Inspector in writing and shall endorse its copy to the Board who shall have the sample tested from the same or any other Government Analyst, or any other laboratory and shall ensure the receipt of results of such test and analysis within a further period as may be prescribed and shall make the test report available to the Inspector for further action.

(3) On receipt of the report, the Inspector shall:—

deliver one copy thereof to the person from whom the sample was taken;

forward one copy to the warrantor, if any, named under the proviso to sub-section (3) of section 14;

forward one copy to the Board for its directions as to the action to be taken on the report; and

retain the fourth copy for use in any prosecution or for any other purpose;

(4) Notwithstanding anything contained in any other law for the time being in force, any document purporting to be a report signed by a Government Analyst shall be admissible as evidence of the facts stated therein without formal proof and such evidence shall be conclusive unless the person from whom the sample was taken or the said warrantor has, within thirty days of the receipt of a copy of the report notified in writing to the Inspector or Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal and any other non-Allopathic medicine Board or the Drug Court before which any proceeding in respect of the sample are pending that he intends to adduce evidence in contravention of the report.

(5) Where a person has, under sub-section (4), notified his intention of adducing evidence in contravention of a Government Analyst's report, the Board or the Drug Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug lying with the Board concerned under sub-section (3) of section 14 to be sent for test or analysis to the Drugs Control and Traditional Medicines Division of National Institute of Health, Islamabad which shall act as an Appellate Laboratory for second testing in terms of clause (b) of sub-section (3) of section 14 in the manner as may be prescribed, which shall make the test or analysis and report in writing signed by, or under the authority of, the person for the time being in charge of the Drugs Control and Traditional Medicines Division of National

Institute of Health, Islamabad, the result thereof and such report shall be conclusive evidence of the facts stated therein.

(6) The cost of a test or analysis made by Drugs Control and Traditional Medicines Division of National Institute of Health, Islamabad under sub-section (5) shall be paid by the complainant or accused, as the Drug Court or the Board concerned shall direct.

16. **Prohibition for import, export, manufacturer and sale.**—(1) From such date or dates as may be fixed by the Federal Government by notification in official Gazette in this behalf, no person shall himself or by any other person on his behalf:—

- (a) manufacture or import or export Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine without obtaining license from the Board;
- (b) manufacture Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine except under the prescribed conditions of good manufacturing practices;
- (c) manufacture Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine except under the supervision of a person having the qualifications as may be prescribed;
- (d) manufacture or import or export Tibb-e-Unani, Ayurvedic, Homeopathic or Herbal or any other non-Allopathic medicine except under and in accordance with the conditions of a license issued for such purpose;
- (e) manufacture or import or export Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine unless the raw materials used in the preparation of such medicine are in conformity with any authoritative book as may be prescribed or in accordance with such standards, if any, as may be prescribed in relation to that medicine;
- (f) manufacture or import or export or sell Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine in contravention of any of the provisions of this Act or any rule made there under:

Provided that nothing in clause (c), (e) and (f) shall apply to the manufacturer of small quantities of any such medicine for the purpose of trials, research and development,

examination test or analysis, subject to conditions as may be prescribed.

- (2) No person shall himself or by any other person on his behalf:—
- (a) manufacture or import or export or sell Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine containing a synthesized chemical, biochemical, biotechnological or microbiological component for the therapeutic activity or any other substance which falls under the definition of drug under the Drugs Act, 1976, except those substances allowed by the Ministry of Health to be used in the manufacture of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine and not be a drug under the said Act;
 - (b) manufacture, import or export or sell any spurious or adulterated or misbranded or counterfeit Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine;
 - (c) manufacture, import or export or sell Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine other than the notified or approved Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine:

Provided that, subject to the prescribed conditions, nothing in this section shall prohibit the manufacture solely for the purpose of the export of a Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine, which is made in accordance with the requirement of importer abroad.

17. **Advertisement.**—(No person shall himself or by any other person on his behalf advertise, except in accordance with such conditions and manner as may be prescribed, any Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine or treatment or offer of a treatment of any disease specified in the official Gazette, or display of sign boards for a clinic, or a Mattab or a hospital or such other Institutions offering treatment of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic system of medicine.

Explanation:—In this section “advertise” means to make any representation direct to general public by any means whatsoever, for the purpose

of promoting directly or indirectly the sale or disposal of a Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine but does include a representation wherein claims or indications for such Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine are not indicated.

18. **Offences, penalties and procedure.**—Notwithstanding anything contained in any other law for the time being in force, whoever himself or by any other person on his behalf:—

- (a) contravenes the provisions of clause (a) of sub section (1) of section 16, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to fifty thousand rupees, or with both;
- (b) contravenes the provisions of clause (b) to (f) of sub-section (1) of section 16, shall be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to fifty thousand rupees, or with both;
- (c) contravenes the provisions of sub-section (2) of section 16, shall be punishable with fine which may extend to one hundred thousand rupees;
- (d) contravenes the provisions of section 17, shall be punishable with fine which may extend to fifty thousand rupees;

19. **Penalty for subsequent offences.**—(1) Whoever having been convicted of an offence under clause (a) or clause (b) of section 18 is convicted for a subsequent offence under that provision shall be punishable with imprisonment which may extend to three years or with fine which may extend to rupees one hundred thousand or with both;

(2) Whoever having been convicted of an offence under clause (c) of section 17 is convicted for a subsequent offence under that provision shall be punishable with imprisonment which may extend to six months, or with fine which may extend to two hundred thousand rupees, or with both;

(3) Whoever having been convicted of an offence under clause (d) of section 18 is convicted for a subsequent offence under that provision shall be punishable with fine which may extend to one hundred thousand rupees.

(4) Where any person has been convicted under this Chapter, the court of law may order that the stock of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine in respect of which the offence was committed be forfeited to the Federal Government or as the case may be to the Provincial Government.

20. **Application of provisions to government department.**—(1) The provisions of this chapter shall apply in relation to the import, export or manufacture for sale or distribution of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine by any department of government as they apply in relation to the import, export or manufacture for sale, or distribution of such Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine by any other person.

21. **Cognizance of offences.**—(1) Subject to the prior approval of Board, no prosecution under this Chapter shall be instituted except by an Inspector appointed under section 12.

(2) No Court other than a Drug Court established under the Drugs Act 1976, shall try an offence punishable under this chapter:

Provided that when trying offences under this Act, the Drug Court shall consist of the Chairman and two members, one being expert in Tibb-e-Unani and the other in Homoeopathy.

(3) The respective Court shall have all the powers conferred by the Code of Criminal Procedure, 1898, (Act V of 1898) on a Court of Sessions exercising original jurisdiction.

(4) The respective Court shall, in all matters regarding which no procedure has been prescribed in this Act, follow the procedure prescribed by the Code of Criminal Procedure, 1898 (Act V of 1898).

(5) A person sentenced by a court under this Act may prefer an appeal to the High Court within thirty days of the judgment.

(6) The provisions of sections 5 and 12 of the Limitation Act, 1908 (IX of 1908), shall be applicable to an appeal referred to in sub-section (5).

22. **Offences by companies, etc.**—(1) Where a person guilty of an offence under this Act is a company, corporation, firm or institution the person who at the time the offence was committed, was in charge of and was responsible to the company for the conduct of the business of the company, corporation, firm or institution, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

(2) Notwithstanding anything contained in any other law for the time being in force, where Drug Court issues process for appearance of such accused, it may dispense with personal attendance of the accused and allow him to appear by his pleader or authorized agent.

23. **Penalty for vexatious search or seizure.**—Any Inspector exercising powers under this Act or the rules made thereunder, who;

- (a) vexatiously and otherwise than in good faith seizes any Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine or any substance or article, or any record, register, document or other material object; or
- (b) commits as such Inspector, any other act, to the injury of any person without having reason to believe that such act is required for the execution of this duty;

shall be punishable with imprisonment for a term which may extend to six months or fine which may extend to fifty thousand rupees or with both:

Provided that no prosecution under this section shall be initiated without prior approval of the Federal Government or a Provincial Government, as the case may be.

24. **Power to fix maximum prices of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine.**—(1) The Federal Government, after consideration of the recommendations of the Board, may be notification in the official gazette.

- (a) fix the maximum price at which any Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine is to be sold; and
- (b) specify a certain percentage of the profits of manufacturers of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine which shall be utilized, in accordance with the rules, for the purposes of research in Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine.

(2) For the purpose of the exercise of its powers under sub-section (1), the Federal Government may require a manufacturer, stockist, importer, exporter, retailer or other dealer in medicines to furnish such information as may be necessary.

CHAPTER III

MISCELLANEOUS

25. **Powers of Federal Government to make rules.**—(1) The Federal Government may on the recommendation of the Board and subject to

condition of previous publication, by notification in the official gazette, make rules for the purpose of giving effect to the provisions of this Act.

(2) Without prejudice to the generality of the foregoing powers such rules may:—

- (a) provide notification of laboratories and Government Analyst for testing and analyzing Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine;
- (b) prescribe the qualifications and duties of Government Analyst and the qualifications of the Inspectors;
- (c) prescribe methods of test or analysis to be employed for determining whether Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine contain ingredients in accordance with the labeled claim;
- (d) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any remedy, prohibit the import or manufacture or sale of any Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine in which that proportion is exceeded and specify the substances which shall be deemed to be poisonous;
- (e) prescribe the forms of licenses for the manufacture and import of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine, the form of application for such licenses, the conditions subject to which such licenses may be issued and the fee payable thereof;
- (f) regulate the mode of labeling, packing of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine and prescribe the matters which shall or shall not be included in such labels;
- (g) prescribe fee as necessary in relation to application for licensing, inspection for the grant of license or renewal of license or listing, notifications and registration of the products;
- (h) to compile Pharmacopoeia and National Formulary of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine for the publication in the official gazette of Pakistan;

- (i) prescribe the authoritative books for the purpose of this Act;
- (j) prescribe the conditions subject to which, small quantities of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine, the manufacture or import of which is otherwise prohibited under this Act, may be manufactured or imported for the purpose of test and analysis, examination, research and development.
- (k) prescribe under section 3 (a) (iv), the colour or colours which a Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine may bear or contain for the purposes of coloring;
- (l) prescribe the standards for Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine under section-16 (1) (e);
- (m) prescribe the priority areas for research and development and specify the rules and regulations government research by considering the recommendations of the Board.
- (n) prescribe the manner to regulate sale, conditions for storage, sale and warranty to regulate the sale of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine.
- (3) any other matter that is or may be prescribed under this Act.

26. **Power to exempt.**—Notwithstanding anything contained in this Act, the Federal Government may, if it is of opinion that the public interest so requires, at any time, of its own motion or on a representation made to it, by notification in the official Gazette, exempt any Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine or class of Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal or any other non-Allopathic medicine from the operation any of the provisions of this Act, subject to such conditions, if any, and for such period as may be specified in the notification.

STATEMENT OF OBJECTS AND REASONS

Traditional Medicines have been in use worldwide for prevention and treatment of many ailments. In Pakistan, Tibb-e-Unani and Homoeopathy systems are in vogue since long. Parliament enacted a law *i.e.* Unani, Ayurvedic and Homoeopathic Practitioners Act, 1965, to promote the Unani, Ayurvedic and Homoeopathic Systems of medicine regulate education and research in and provide for the registration of practitioners of those systems of medicine. However, that Act did not include the matter of regulation of manufacture, quality, sale, import or export of such drugs.

2. Many companies are manufacturing Tibb-e-Unani, Ayurvedic, Homeopathic and Herbal Medicine in the country on industrial scale. There is a need to regulate the manufacture, import, export, storage, distribution and sale of these medicines. In Pakistan more than 400 manufacturers are producing Unani medicines and likewise some 300 companies are manufacturing homoeopathic medicines. There are over 50,000 Hakims and 100,000 Homoeopaths in the country. A proper regulatory regime is long overdue.

3. Bill seeks to achieve the above-said object.

Sd/-

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