ORDINANCE NO. I OF 2012

AN

ORDINANCE

to provide for the establishment of Drug Regulatory Agency of Pakistan

WHEREAS it is expedient to establish a Drug Regulatory Agency of Pakistan to provide for effective coordination and enforcement of Drugs Act, 1976 (XXXI of 1976) and to bring harmony in inter-provincial trade and commerce of Drugs and therapeutic goods;

AND WHEREAS that is expedient to regulate, manufacture, import, export, storage, distribution and sale of therapeutic good and medical devices;

AND WHEREAS the Provincial Assemblies of Khyber Paktunkhwa, Punjab and Sindh have passed resolution under Article 144 of the Constitution of the Islamic Republic of Pakistan to the effect that Majlis-e-Shoora (Parliament) may by Law regulate the issue;

AND WHEREAS the Senate and the National Assembly are not in session and the President of Islamic Republic of Pakistan is satisfied that circumstances exist which render it necessary to take immediate action;

NOW, THEREFORE, in exercise of the powers conferred by clause (1) of Article 89 of the Constitution of the Islamic Republic of Pakistan, the President is pleased to make and promulgate the following Ordinance:—

CHAPTER-I

PRELIMINARY

1. Short title, extent and commencement.—(1) This Ordinance may be called the Drug Regulatory Agency of Pakistan Ordinance, 2012.

(2) It extends to the whole of Pakistan.

(3) It shall come into force at once.

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

(a) "Act" means the Drugs Act, 1976 (XXXI of 1976);

(b) "Agency" means the Drug Regulatory Agency of Pakistan established under Section 3;

(c) "Board" means the Policy Board of the Agency constituted under Section 11;

(d) "CEO" means the Chief Executive Officer of the Agency appointed under Section 5;

(e) "Chairperson" means the Chairperson of the Board;

(f) "Civil servant" means a civil servant as defined in the Civil Servants Act, 1973 (LXXI of 1973);

(g) "Decision" includes an order, determination or direction of the Agency or the Board made in accordance with laws, rules and regulations;

(h) "Drug" means drug as defined in Schedule-I;

(i) "Fee" means fee prescribed by the Board for any service;

(j) "Fund" means the Drug Regulatory Agency of Pakistan Fund created under Section 19;

(k) "Inspectors" means the Inspector appointed under the Act;

(l) "Medical device" includes—

(i) instruments, medical equipment, implants, disposables and software, used mainly for the purpose of diagnosis, monitoring and treatment of disease; or

(ii) any other item which the Federal Government may, by notification in the official Gazette, declare as medical device;

(m) "Member" means a Member of the Board;

(n) "Therapeutic goods" includes drug or medicine or medical device or biologicals or other related thins as may be notified by the Agency;

(o) "Penalty" means penalty as specified in Schedule II;

(p) "Person" includes means any individual or any legal entity;

(q) "Pharmaceutical field" means regulation, manufacturing, quality control and pharmacy services in drugs.

(r) "Pharmacy Services" means services rendered by pharmacist in pharmaceutical care, selection, posology, counseling, dispensing, use, administration, prescription monitoring, pharmacoepidemiology, therapeutic goods information and poison control, pharmacovigillance, pharmacoeconomics, storage, sales, procurement, forecasting, supply chain management, drug utilization evaluation, drug utilization review, formulary based drug utilization and managing therapeutic goods at all levels including pharmacy, clinic, medical store, hospital or medical institution;

(s) "Prescribed" means prescribed by rules or regulations under this Ordinance;

(t) "Prohibitions" means prohibitions as specified in Schedule III;

(u) "Regulation" means the regulations made under this Ordinance;

(v) "Rules" means the rules made under this Ordinance;

(w) "Secretary" means Secretary of the Board; and

(x) "Schedule" means Schedule to this Ordinance;

CHAPTER-II

AGENCY AND BOARD

3. Establishment of the Agency.—(1) As soon as may be, after the commencement of this Ordinance, the Federal Government shall establish an Agency to be known as the Drug Regulatory Agency of Pakistan to carry out the purposes of this Ordinance.

(2) The Agency shall be a body corporate having perpetual succession and a common seal with powers, subject to the provisions of this Ordinance, to acquire, purchase, hold and dispose of property both movable and immovable and shall by its name sue and be sued.

The Agency shall be an autonomous body under the administrative control of the Federal Government.

(4) The Headquarters of the Agency shall be at Islamabad.

(5) The Agency may set up its establishments including sub-offices and laboratories at provincial Capitals and such other places, as it may deem necessary from time to time. The existing Federal Drugs Control Administration and the sub-offices set up in all Provinces and laboratories called the Central Drugs Laboratory, Karachi, the National Control Laboratory for Biologicals, Islamabad and the Surveillance Laboratory, Islamabad shall, upon the commencement of this Ordinance, become part of the Agency, subject to sub-section (2) of Section 14.

4. Composition of the Agency.—The Agency shall consist of a Chief Executive Officer (CEO) and seven full time Members to be appointed by the Federal Government whose qualifications, terms and conditions shall be such as may be prescribed. The members shall be designated as:

(a) Member Registration;

(b) Member Alternative Medicines/Traditional Drugs (Ayurvedic, Unani and Homeopathy);

(c) Member Biologicals and Medical devices;

(d) Member Licensing and Quality Control;

(e) Member Pharmacy Services;

(f) Member Pricing; and

(g) Member Administration, Human Resources and Legal Affairs:

Provided that the Federal Government, on the recommendations of the Board, may increase the number of Members and prescribe the qualifications, terms, mode and manner of their appointment.

5. Chief Executive Officer.—(1) The Federal Government may appoint a person as CEO who has a post graduate degree in pharmacy, public health, or medicine with a minimum of twenty years experience, in pharmacy services, public health, management or regulatory affairs from either public or private sector. The term of appointment shall be for a period of three years and extendable for one similar term only.

(2) The CEO shall be the head of the Agency and shall discharge such duties and perform such functions as are assigned to him by or under this Ordinance or as may be prescribed.

6. Meetings of the Agency.—(1) Save as hereinafter provided, the Agency shall regulate the procedure for its meetings.

(2) The meetings of the Agency shall be convened by and under the directions of the CEO any time on any matter requiring decision by the Agency.

7. Powers and functions of the Agency.—The powers and functions of the Agency shall be to,—

(a) administer the laws specified in the Schedule VI that apply to Federal Government, and advise the Provincial Governments for the laws that are applicable to the Provinces;

(b) monitor the enforcement of laws specified in the Schedule VI and collect relevant data and information;

(c) issue guidelines for,—

(i) licensing of therapeutic goods;

(ii) registration of therapeutic goods;

(iii) specifications and laboratory practices;

(iv) prosecution and appeals under this Ordinance relating to Federal subjects;

(v) regulation and allocation of quota of narcotics and psycholropic drugs and precursor substances;

(vi) regulation for pricing and mechanism for fixation of prices;

(vii) determining standards for biological manufacturing and testing;

(viii) current good manufacturing practices;

(ix) inspections, investigations and other like functions and; and

(x) any other function under this Ordinance which the Agency may deem fit;

(d) promote Pharmacy Services;

(e) coordinate, monitor or engage, in conjunction with other organizations, Provincial Governments and international agencies, in training, study or project related to therapeutic goods. The Agency may engage any individual or counsel to advise or work for managing national and international opportunities for training, education, seminars, conferences etc; with a view to improve capacity building;

(f) facilitate the up gradation of industry to meet international standards and also to promote export of therapeutic goods;

(g) coordinate at policy level and provide policy guidance to the Provincial Governments in the performance of their functions with a purpose to bring uniformity;

(h) facilitate the procurement and implementation of foreign aided technical assistance on therapeutic goods where such expertise does not exist but its existence would promote public good;

(i) take steps for development and promotion of pharmacy services;

(j) to advise the Federal Government on issues related to obligations and commitments related to therapeutic goods;

(k) appoint such employees, consultants and experts as deemed necessary on prescribed terms and conditions including their salaries and remunerations with consultation and approval of the Board. Such recruitment, continuation and remuneration to be based on merit and productivity;

(l) prescribe rules for seniority, promotion, code of conduct and terms and condition of its employees;

(m) levy such charges or fees as may be prescribed for services and facilities provided by the Agency and its offices;

(n) carry out such other works or activities as may be deemed necessary by the Agency to carry out the purposes of this Ordinance;

(o) enter into contract for the supply of materials or for the execution of works as may be necessary for the discharge of any of its duties and functions;

(p) prepare annual budget to be approved by the Board;

(q) to monitor and regulate the marketing practices, so as to ensure rational use of drugs, and ethical criteria for promotion of therapeutic goods in line with international practices;

(r) develop working manuals, guidelines, references, materials and procedures in order to improve the working environment of offices etc, set up under the Agency;

(s) prescribe, regulate or implement measures and standards on matters related or connected with the Agency; and

(t) perform and carry out any other act, duty or function as may be assigned to it by the Federal Government.

8. Delegation of powers.—The Agency may, by general or special order in writing subject to such conditions or limitations, delegate any of its powers and functions to any of its officers as it may deem appropriate.

9. Policy Board.—(1) There shall be a Policy Board of the agency consisting of the following, namely:—

(a) Secretary, of the concerned Divisions. *Chairperson*

(b) CEO *Member*

(c) representative of Ministry of Law and Justice not below BPS-20. *Member*

(d) Secretary, of the concerned Department, Government of the Punjab. *Member*

(e) Secretary, of the concerned Department, Government of the Sindh. *Member*

(f) Secretary, of the concerned Department, Government of the Khyber Pakhtunkhwa. *Member*

(g) Secretary, of the concerned Department, Government of the Balochistan. *Member*

(h) Secretary, of the concerned Department, Government of Gilgit Baltistan. *Member*

(i) Representative from Federally Administered Tribal Area. *Member; and*

(j) Six experts from the public and private sector with equal representation. *Member*

(2) The CEO shall also be the Secretary of the Boards.

(3) The Federal Government shall, by notification in the official Gazette, appoint six expert Members, with representation from the Provinces, under clause (j) of sub-section (1) preferably one from each province having specialty in the fields of drug manufacturing industry, quality control, regulation, public health, pharmacy services, finance and health economics and management:

Provided that the expert member shall be appointed for a period of three years and shall be eligible for one more similar term only:

Provided further that the expert Member shall himself attend, the netting and shall not send a representative.

(4) No act or proceeding of the Board shall be invalid by reason only if the existence of a vacancy in the constitution of the board.

(5) Notwithstanding the composition of the Federal Government constituted under sub-section (1) and (2), the board may increase or decrease the number of its members and prescribe the qualifications and procedure for their appointment.

10. Meeting of the Board.—(1) Save as hereinafter provided, the Board shall make regulations for the conduct of its business.

(2) The meetings of the Board shall be convened by the Secretary with the prior approval of the Chairperson. In case of absence of the Chairperson, the members present may elect the Chairperson for that meeting.

(3) The meetings of the Board shall be held at least twice a year. A special meeting may also be called at any time to deal with any urgent business.

(4) A simple majority of the total membership shall constitute the quorum for a meeting of the Board and in case of equality of votes, the Chairperson or the person presiding over the meeting shall have a casting vote.

(5) All decisions, determinations taken by the Board shall be recorded in writing.

11. Functions of the Board.—(1) The Board shall have the following functions, namely:—

(a) to frame the policy and provide guidelines to the Agency and monitor the implementation and performance of the guidelines and of the functions of the Agency;

(b) approval of the Budget of the Agency;

(c) the Board determines the fees.

(2) The Federal Government, as and when it considers necessary, may issue policy directives in accordance with law to the Agency in respect of its activities and the compliance whereof shall be binding on the Agency, within a stipulated time.

(3) Notwithstanding anything contained in sub-section (2) if there is any difficulty in implementation of the directions and guidelines of the Board, the Agency shall refer the case back to the Board for its review specifying reasons for non-implementation, within the stipulated time.

12. Committees of the Board.—(1) The Board may constitute committees of experts as it considers necessary or expedient to assist it in the performance of its functions under this Ordinance.

(2) A committee constituted under sub-section (1) shall act in accordance with the regulations made by the Board.

13. Invitation by Board.—The Board may invite any person to attend its meeting or deliberations including any meeting of the committees for the purpose of advising it on any matter under discussion but such person shall have no right to vote at the meeting or deliberation.

14. Appointment of officers and employees etc., of the Agency.—(1) The Agency, with approval of the Board, may create posts and appoint such officers, employees, experts and consultants, as it may consider necessary, for the performance of its functions in the prescribed manner.

(2) Selection, recruitment, appointment of all officers, employees, experts and consultants including the officers and employees of the Federal Drug Control Administration, the sub-offices or laboratories as referred in sub-section (5) of Section 3 shall be based on merit. The criteria for recruitment selection of employees officers to be determined by the Board according to the rules as prescribed.

15. Integration of Federal Drugs Control Administration its sub-offices and Laboratories.—Upon the commencement of this Ordinance, the Drugs Control Administration, its sub-offices, its Laboratories hereinafter referred to as the said offices shall become part of the Agency, and,—

(a) All assets, rights, powers, authorities and privileges and all properties, movable and immovable, cash and bank balance, reserve funds, investment and all other interest and rights in, or arising out of such properties and all debts, liabilities and obligations of whatever kind of the said offices subsisting immediately before their integration shall stand transferred to and vest in the Agency;

(b) all debts and obligations incurred or contracts entered into or rights acquired and all matters and things engaged to be done by, with or for the said offices before their integration, shall be deemed to have been incurred, entered into, acquired or engaged to be done by or for the Agency; and

(c) all suits and other legal proceedings instituted by or against the said offices before their integration shall be deemed to be suits and proceedings by or against the Agency and may be proceeded or otherwise dealt with accordingly.

(d) Notwithstanding anything contained in any contract or agreement or in the conditions of services, —

(i) every employee of the said offices under the Federal Government immediately before the commencement of this Ordinance shall be required to exercise an irrevocable option either to continue in the

present pay and service structure or to opt absorption form in the agency within a period of thirty days from the date of promulgation of this Ordinance.

(ii) all employees to be included in this Scheme shall be governed by this Ordinance and the terms and conditions prescribed; and

(iii) no health personnel who opts to be governed under the Ordinance shall be entitled to any compensation because of such transfer.

16. Experts, consultants and advisers not to be civil servants.—The experts, consultants, employees or advisers employed by the Agency shall be governed by the terms and conditions of their appointment and shall not be deemed to be Civil Servant.

17. CEO and officers etc., to be public servants.—The CEO, officers, employees, experts and consultants of the Agency shall, when acting or purporting to act in pursuance of any of the provisions of this Ordinance, be deemed to be public servants within the meaning of Section 21 of the Pakistan Penal Code (Act XLV of 1860).

18. Conflict of interest.—(1) No person shall be appointed as CEO, Member consultant, advisor, officer or employee of the Agency if he or she has any financial or professional conflict of interest.

(2) No person shall be member of the Board if he has immediate family members (parent, child, sibling or spouse) as senior officials or owner of pharmaceutical companies.

CHAPTER-III

FUND, BUDGET AND ACCOUNTS

19. Drug Regulatory Agency Fund.—(1) There shall be a fund to be known as the Drug Regulatory Agency of Pakistan Fund which shall vest in the Agency and shall be utilized by the Agency to meet its expenses and charges properly incurred in connection with the carrying out of its functions and duties assigned or transferred to it under this Ordinance, including but not limited to the payment of salaries and other remuneration to the CEO, Members, employees, experts, consultants and advisers of the Agency.

(2) The Drug Regulatory Agency Fund shall be financed from the following sources namely:—

(a) initial Grant to be provided by the Federal Government;

(b) grants and loans by the Federal Government or a Provincial Government;

(c) loans and grants from the national or international agencies received by the Federal Government to finance the function of the Agency;

(d) charges and fees collected by the Agency to recover the costs of regulated activities under this Ordinance;

(e) proceeds of any investments made by the Agency which are not required for immediate use. All investments to be made by the Agency shall be with the approval of the Board; and

(f) proceeds from any other service rendered by the Agency, including Inspection Services, foreign or local, or sale of any publication.

20. Fees and other charges to be levied by the Agency.—The Agency shall levy and collect such fees, in respect of any of its functions at such rates as may be determined, from time to time by the Agency, with the approval of the Board, in accordance with rules.

21. Budget.—The Agency shall, in respect of each financial year prepare on such date as may be prescribed, a statement of the estimated receipts and expenditure, including the budgets and requirements of foreign exchange for the next financial year for consideration and approval of the Board. Any foreign exchange requirements within the overall annual approved budget by the Board shall be sent to Ministry of Finance in the Federal Government for appropriate provision and allocation.

22. Accounts and audit.—(1) The Agency may open its accounts with any scheduled Bank or financial institution within the framework of the prescribed rules with the initial grant by the Federal Government, in the amount, as may be determined by the Federal Government.

(2) The accounts of the Agency shall be maintained in the manner prescribed by the Controller General of Accounts.

(3) The Agency shall cause to be carried out audit of its accounts by one or more auditors registered as chartered accountants within the meaning of the Chartered Accountants Ordinance, 1961 (X of 1961).

(4) Notwithstanding the audit provided by in sub-section (2) the Auditor-General shall have the power to audit or cause to be audited the accounts of the Agency.

(5) A copy of the audit report shall be sent to the Federal Government alongwith the comments of the Agency.

(6) The Agency shall take the requisite steps for the rectification of any objection raised by the Auditor-General of Pakistan.

CHAPTER-IV

RULES AND REGULATIONS

23. Power to make rules.—The Federal Government, by notification in the official Gazette and in consultation with the Agency, may make rules for carrying out the purposes of this Ordinance.

24. Power to make regulations.—The Agency may, by notification in the official Gazette, with the approval of the Board, make regulations, for its internal marking and terms

and condition of employees not inconsistent with the provisions of this Ordinance or the rules, for the carrying out of its functions under this Ordinance.

CHAPTER-V

MISCELLANEOUS

25. Submission of annual reports and returns.—(1) Within three months of the conclusion of each financial year, the Agency shall submit an annual report to the Federal Government in respect of the activities of the Agency including the status of its existing programmes, projects and further plans formulated in furtherance of its aims and objectives.

(2) The Federal Government may require the Agency to furnish,—

(a) any return, statement, estimate, statistics or other information regarding any matter under the control of the Agency;

(b) a report on any subject related to the Agency; and

(c) a copy of any document in the custody of the Agency.

(3) The Agency shall expeditiously comply with such directions.

26. Power to call for information.—The Agency may call for any person, involved directly or indirectly, and reasonably believed to having such information in his control or possession which is required for carrying out the purposes of this Ordinance. The person so called upon to provide such information shall do so within the period prescribed by the Agency and in case of failure to do so he shall be punished by imposition of such penalty which may not exceed one hundred thousand rupees.

27. Offences, penalties etc.—(1) The offences shall be such as specified in Schedule-III of this Ordinance.

(2) the prohibition specified in Schedule-II shall be punished in accordance with Schedule-III.

28. Offences by companies etc.—Where the person guilty of an offence under this Ordinance or the Act is a company, corporation, firm or institution, every director, partner and employee of the company, corporation, firm or institution with whose knowledge or consent the offence was committed shall be guilty of the offence.

29. Cognizance of offences.—Cognizance of offences shall be taken by the Inspector in the manner specified in Schedule-V. Cong.

30. Complaints.—(1) Any aggrieved person may file a written complaint with the Agency against contravention of any provision of this Ordinance or any law specified in the Schedule-VI.

(2) The Agency shall, on receipt of a complaint cause it to be investigated as may be prescribed and provide an opportunity to the complainant as well as the person against whom

such complaints has been made. The Agency may, on completion of investigation, take any action as may be prescribed under this Ordinance or as the case may be subject to the provisions of any law specified in the Schedule.

31. Existing agreements.—If on the commencement of this Ordinance there exists an agreement in respect of, or dealing with, a regulated activity to which the Federal Government is a party, in the event of any inconsistency between the provisions of this Ordinance, the rules or the regulations, the provisions of the agreement shall prevail to the extent of the inconsistency.

32. Confidential information.—(1) Except as provided under the regulations, no person shall communicate, or allow to be communicated, any record or information obtained under this Ordinance to a person not legally entitled to that record or information or allows any person not legally entitled to that record or information to have access to any record obtained under this Ordinance.

(2) A person who knowingly receives records or information obtained under this Ordinance shall hold the record or information subject to the same restrictions under sub-section (1) as apply to the person from who the records or information were received.

33. Ordinance not to override other laws.—(1) The provisions of this Ordinance shall be in addition to and not in derogation of the provisions made in the Drugs Act, 1976 (XXXI of 1976) and any other law for the time being in force.

(2) In case of inconsistency between the provisions of this Ordinance and any other law for the time being in force, the provisions of this Ordinance shall prevail.

34. Recovery of arrears.—All amounts due to the Agency may be recovered as arrears of land revenue.

35. Indemnity.—No suit prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act or any rules or regulations made there under.

36. Power to amend Schedule.—The Federal Government may, by notification in the official Gazette amend the Schedule so as to add any entry thereto or modify or omit any entry therefrom.

37. Removal of difficulties.—If any difficulty arises in giving effect to any of the provisions of this Act, the Federal Government may make such Order by notification in the official Gazette, not inconsistent with the provisions of this Ordinance, for the purpose of removing the difficulty.

SCHEDULE-I

[See Section 2(1)]

"Drug" includes,—(a) 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 diseases, 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, including substance 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;

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

(c) such substances intended to be used for the destruction or repulsion of such vermin, insects, rodents and other organism 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;

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

(e) any substance mentioned as monograph or as a preparation in the Pakistan Pharmacopoeia or the Pakistan National Formulary or the International Pharmacopoeia or the British Pharmacopoeia or the British Pharmaceutical 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 (a), (b) and (c); and

(f) 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;

SCHEDULE-II

[See Section 27]

PROHIBITIONS

A. Import, manufacture and sale of drug:

(1) No person shall himself or by any other person on his behalf—

(a) export, import or manufacture for sale or sell.—

(i) any spurious drug;

(ii) any counterfeit drug any misbranded drug;

(iv) any adulterated drug;

(v) any substandard drug;

(vi) any drug after its expiry date;

(vii) any drug which is not registered or is not in accordance with the conditions of registration;

(viii) any drug which, by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

(ix) any drug if it is dangerous to health when used in the dosage or with the frequency, or, for the duration specified, recommended or suggested in the labeling thereof; or

(x) any drug in contravention of any of the provisions of this Ordinance or rules made thereunder;

(b) manufacture for sale any drug except under, and in accordance with the conditions of, a license issued under this Ordinance;

(c) sell any drug except under, and in accordance with the conditions of, a license issued under this Ordinance;

(d) import or export any drug the import or export of which is prohibited by or under this Ordinance;

(e) import or export any therapeutic good drug for the import or export of which a license is required, except under, and in accordance with the conditions of, such license;

(f) supply an incorrect, incomplete or misleading information, when required to furnish any information under this Ordinance or the rules;

(g) peddle, hawk or offer for sale any drug in a park or public street or on a highway, footpath or public transport or conveyance;

(h) import, manufacture for sale, or sell any substance, or mixture of substances, which is not a drug but is presented in a form or a manner which is intended or likely to cause the public to believe it to be a drug;

(i) sell any drug without having a warranty in the prescribed form bearing the name and batch number of the therapeutic good issued;

(i) in the case of a drug manufactured in Pakistan, by the manufacturer holding a valid licence to manufacture drugs and permission to manufacture that drug or by his authorized agent;

(ii) in the case of an imported drug, by the manufacturer or importer of that drug or, if the drug is imported through an indentor by such indentor; and

(j) apply an incorrect batch number to a therapeutic good.

(2) Nothing in Paragraph (1) shall apply to the manufacture of small quantities of any therapeutic good for the purpose of clinical trial examination, test, analysis or personal use in small quantities.

B. Control of advertisement:

No person shall himself or by any other person on his behalf advertise, except in accordance with such conditions as may be prescribed;

(a) any therapeutic good;

(b) any substance used or prepared for use in accordance with the ayurvedic, unani, homoeopathic or biochemic system of treatment or any other substance or mixture of substances as may he prescribed;

(c) any remedy, treatment or offer of a treatment for any disease:

Explanation: For the purposes of this entry "advertise" means to make any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of a drug, a substance or a mixture of substances, a remedy or a treatment except the display of sign boards for a clinic, a dispensary or a hospital or such other institution offering treatment.

C. Control of samplings:

No person shall distribute or cause to be distributed any drug as a sample except in accordance with such conditions as may be prescribed.

D. Control of printing of labelling:

No person shall print any labeling in respect of any drug which is required to be registered under this Ordinance but is not so registered after the date fixed by the Federal Government under sub-section (6) of Section 7 of the Act or for a person who does not possess a license under that Act to manufacture that drug.

SCHEDULE-III

[See Section 27]

OFFENCES

(1) Whoever himself or by any other person on his behalf—

(a) exports, imports, manufactures for sale or sells any spurious drug or any drug which is not registered;

(b) manufactures for sale any drug without a license; or

(c) imports without license any drug for the import of which a license is required;

shall be punishable with imprisonment for a term which shall not be less than three years or more than ten years and with fine which may extend to one lakh rupees:

Provided that the Drug Court may, for any special reasons to be recorded , award a sentence of imprisonment for a term of less than three years.

(2) Whoever himself or by any other person on his behalf—

Imports, manufactures for sale or sells any counterfeit drug; or

(a) gives to the purchaser a false warranty in respect of any drug sold by him that the drug does not in any way contravene the provisions of Schedule (II) and is not able to prove that, when he gave the warranty, he had good and sufficient reason to believe the same to be true; or

(b) applies or permits to be applied to any drug sold, or stocked or exhibited for sale, by him, whether on the container or a label or in any other manner, a warranty given in respect of any other drug; or

(d) imports, manufactures for sales or sells any drug under a name other than the registered name; or

(e) exports, imports, manufactures for sale or sells any drug with which any substance, which should not actually be its component, has been mixed or packed so as to reduce its quality or strength or for which any such substance has been substituted wholly or in part;

shall be punishable with imprisonment for a term which may extend to seven years, or with fine which may extend to one lakh rupees or with both.

(3) Whoever obstructs an Inspector in the exercise of any power conferred upon him by or under this Act, or disobeys the lawful authority of any Inspector, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees, or with both.

(4) Subject to the provisions of Paragraph (1), (2) and (3), whoever himself or by any other person on his behalf contravenes any of the provisions of this Ordinance or any rule shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to fifty thousand rupees, or with both.

2. Penalty for subsequent offence.—(1) Whoever having been convicted of an offence under entry (1) shall be punishable with imprisonment for life or with imprisonment which shall not be less than five years and with fine which may extend to two hundred thousand rupees.

3. Penalty for violating the Prohibitions.—Whoever himself or by any other person on his behalf violates any prohibations specified in Schedule-II shall be punished with imprisonment for a term upto five years and with fine upto two lakh rupees.

SCHEDULE-IV

[See Section 29]

COGNIZANCE OF OFFENCES

(1) Subject to the provisions of Schedule-V, no prosecution shall be instituted under this Chapter except.

(a) by a Federal Inspector, where the prosecution is in respect of a contravention of clause (h) of Paragraph (1) of hereby A of Schedule-I or any of the provisions of this Ordinance or the rules relating to the import or export of drugs or the manufacture for sale, or sale, of a drug which is not for the time being registered or for the manufacture for sale of which a license is not for the lime being in force; or

(b) by a Provincial Inspector:

Provided that, where the public interest so requires, the Federal Inspector may, with the prior permission of the Federal Government, institute a prosecution for a contravention of any other provision of the Act and Ordinance.

(2) Notwithstanding anything contained in the Code of Criminal Procedure, 1898 (Act V of 1898).

(a) an offence punishable under Schedule-III other than an offence mentioned in Paragraph (1) of Schedule shall be non-cognizable, and

(b) no Court other than a Drug Court established under the Act shall try an offence punishable under Schedule-VI. Nothing contained in this Schedule shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence punishable under the Act or Ordinance or to require the transfer to a Drug Court of any case which may be pending in any Court immediately before the establishment of the Drug Court.

SCHEDULE-V

[See Section 29]

Powers of Inspectors

(1) Subject to the provisions of this Schedule and of any rules made in this behalf, an Inspector may, within the local limits for which he is appointed, and in any other area within the permission of the licensing authority,—

(a) inspect any premises-wherein any drug is manufactured, the plant and process of manufacture, the means employed for standardizing and testing the drugs and all relevant records and registers;

(b) inspect any premises wherein any drug is sold or is stocked or exhibited for sale or is distributed, the storage arrangements and all relevant records and registers;

(c) take samples of any drug which is being manufactured, or being sold or is stocked or exhibited for sale or is being distributed;

(d) 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 Ordinance or any rules has been or is being committed or may continue to be committed;

(e) call any person to be present as witness in the course of search or seizure or in connection with any other matter where the presence of witnesses is necessary;

(f) seize such drug and all materials used in the manufacture thereof and any other articles, including registers, cash memos., invoices and bills, which he has reason to believe may furnish evidence of the commission of an offence punishable under this Ordinance or any rules;

(g) require any 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 Ordinance, the Act or the rules:

Provided that the exemptions under Sections 132 and 133 of the Code of Civil Procedure, 1908 (Act V of 1908), shall be applicable to requisitions for attendance under this Schedule;

(h) lock and seal any factory, laboratory, shop, building, store-house or godown, or a part thereof, where any drug is or is being manufactured, stored, sold or exhibited for sale in contravention of any of the provisions of this Ordinance or the rules;

(i) forbid for a reasonable period, not exceeding four weeks or such further period, which shall not be more than three months, as the Inspector may, with the approval of the Provincial Quality Control Board, the Central Licensing Board, the Registration Board, or the licensing authority, as the case may be, specify, any person in charge of any premises from removing or dispensing of any drug, article or other thing likely to be used in evidence of the commission of an offence under this Ordinance or the rules; and

(j) exercise such other powers as may be necessary for carrying out the purposes of this Ordinance or any rules:

Provided that the powers under Paragraph (f) to (j) shall be exercisable only by an Inspector specifically authorized in this behalf, by an order in writing, by the Government appointing him, subject to such conditions as may be specified in such order:

Provided further that the power under Paragraph (h) may be exercised by an Inspector not authorized as aforesaid where the contravention is of a provision which requires a license to be obtained for the manufacture, storage or sale of a drug.

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

PROCEDURE FOR INSPECTORS

(1) Where an Inspector seizes any drug or any other article under this schedule he shall tender a receipt therefore in the prescribed form.

(2) Where an Inspector takes a sample of a drug 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 absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such persons to add his own seal, if any, and mark to all or any of the portions so sealed and marked:

Provided that, where the sample is taken from premises whereon the drug is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that, where the drug is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug be such that it is likely to deteriorate 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, scaling them:

Provided also 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, Provincial Quality Control Board or the Central Licensing Board or the Registration Board, as the case may be; and

(c) the third, where taken, he shall send to the warrantor, if any, named under the proviso to sub-section (3) of Section 32 of the Act.

(4) Where an Inspector seizes any therapeutic good containing any filthy or putrid substance, vermin, worm, rodent, insect or any foreign matter which is visible to the naked eye, and the sample is such that it cannot or need not be divided, he shall effectively seal and suitably mark the same and permit the person from whom he seizes the drug to add his own seal, if any, and mark to it and shall produce the same before the Drug Court or the Central Licensing Board or the Registration Board, as the case may be, before which proceedings are instituted or action is initiated in respect of the drug.

(5) Where an Inspector takes any action under section this Schedule.

(a) he shall as soon as practicable ascertain whether or not the drug contravenes any of the provisions of this Ordinance and, it is ascertained that the drug does not so contravene, he shall forthwith revoke the order passed under the said section or, as the case may be, take such action as may be necessary for the return of the stock seized and payment for the samples taken, under intimation to the Board concerned;

(b) if he seizes the stock of the therapeutic good he shall, as soon as may be inform the Board concerned and take its order as to the custody thereof:

Provided that where a Federal Inspector is not competent to take action under Schedule-IV, he shall as soon as may be, report the matter and hand over the stock, if any, to the Provincial Inspector for further action under this Ordinance or act.

(6) The Provincial Inspector on Finding any contravention of this Ordinance or Act shall, unless the Board otherwise directs, always refer the case to the Provincial Quality Control Board and seek orders as to the action to be taken in respect of such contravention.

(7) The Federal Inspector on finding any contravention of this Ordinance or the Act for which he authorized shall unless otherwise directed, always refer the case to the Central Licensing Board or the Registration Board or any other authority as may be specified for the purpose and seek any further orders as to the action to be taken in respect of such contravention.

SCHEDULE-VI

[See Section 30(1)]

1. The Drugs Act, 1976 (XXXI of 1976)

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