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THE DRUG REGULATORY AUTHORITY OF PAKISTAN ACT, 2012
ACT NO.XXI OF 2012
[12 November, 2018]
An Act to provide for the establishment of Drug Regulatory Authority of Pakistan
WHEREAS it is expedient to establish a Drug Regulatory Authority of Pakistan to provide for effective co-ordination and enforcement of The Drugs Act, 1976 (XXXI of 1976) and to bring

harmony in inter-provincial trade and commerce of therapeutic goods;

AND WHEREAS it is expedient to regulate, manufacture, import, export, storage, distribution and sale of therapeutic goods;

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;

It is hereby enacted as follows:

CHAPTER-I
PRELIMINARY

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

(2) It extends to the whole of Pakistan.
(3) It shall come into force at once.
2. Definitions. —In this Act, unless there is anything repugnant in the subject or context,—
(i) “Act” means the Drugs Act, 1976 (XXXI of 1976);
(ii) “Alternative Medicine” means a product used exclusively in Homeopathic, Unani, Ayurvedic, Biochemic, Chinese or other traditional system of treatment;
(iii) | “Appellate Board” means an Appellate Board constituted under Section 12 for the disposal of appeals against the decisions of the

Licensing Board or the Registration Board or Pricing Committee;

(iv) “Authority” means the Drugs Regulatory Authority of Pakistan established under Section 3;

(v) “Biologicals” means biological drugs as defined in Schedule-I;

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“Board” means the Policy Board of the Authority constituted under Section 9;

“CEO” means the Chief Executive Officer of the Authority appointed under Section 5;

“Chairperson” means the Chairperson of the Board;

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

“decision” includes an order, determination or direction of the Authority or the Board made in accordance with laws, rules and regulations;

“Director” means director of a department of the Authority;

“drug” means drug as defined in Schedule-I;

“fee” means fee prescribed by the Board for any service;

“Fund” means the Drug Regulatory Authority of Pakistan Fund created under Section 19;

“health and OTC Products (non-drugs)” include probiotics and disinfectant, nutritional products, food supplements, baby milk and foods, medicated cosmetics, medicated soaps and medicated

shampoos;

“Inspector” means the Inspector appointed under the Act as specified in Schedule-V;

“Licensing Board” means a Licensing Board constituted under Section 7 sub-section (u) of this Act to regulate the grant of licenses for the manufacture of therapeutic goods;

“Medical Device” means medical devices as specified in Schedule-I;

“Medicated Cosmetics” means cosmetics containing drugs as specified in Schedule-1;

“Member” means a member of the Board;
“OTC” mean over-the-counter non-prescription products;
“penalty” means penalty as specified in Schedule III;

“person” means any individual or any legal entity;

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“Pension Endowment Fund” means an endowment fund separate from the Fund of the Authority dedicated only for the payment of pension benefits of Authority's employees;

“pharmaceutical field” means regulation, manufacturing, quality control, quality assurance, research, academia, import, export, and pharmacy services in drugs;

“pharmacy services” means services rendered by a 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, distribution, 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;

(xxvii) “pharmaceutical evaluation” means the assessment of a detailed

pharmaceutical dossier submitted for the registration of a therapeutic good;

(xxviil) “pharmaceutical dossier” means a set of documents, as specified in

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Schedule-I;
“prescribed” means prescribed by rules or regulations under this Act;
“Prohibitions” means Prohibitions as specified in Schedule-I;

“regulation” means the regulations made under this Act;

(xxxil) “Registration Board” means a Registration Board constituted under

Section 7 sub-section (u) of this Act to regulate the grant of registration to therapeutic goods;

(xxxiil) “rules” means the rules made under this Act;

(xxxiv) “Secretary” means Secretary of the Board;

(xxxv) “Schedule” means Schedule to this Act; and

(xxxvi) “Therapeutic goods” includes drugs or alternative medicine or medical

devices or biologicals or other related products as may be notified by the Authority.

CHAPTER-II

AUTHORITY AND BOARD

3. Establishment of the Authority. — (1) As soon as may be, after the commencement of this Act, the Federal Government shall, by notification in the official Gazette, establish an Authority to be known as the Drug Regulatory Authority of Pakistan, to carry out the purposes of this Act.

(2) The Authority shall be a body corporate having perpetual succession and a common seal, and may sue and be sued in its own name and, subject to and for the purposes of this Act, may enter into contracts and may acquire, purchase, take, hold and enjoy moveable and immovable property of every description and may convey, assign, surrender, yield up, charge, mortgage, demise, reassign, transfer or otherwise dispose of or deal with, any moveable or immovable property or any interest vested in it.

(3) The Authority shall be an autonomous body under the administrative control of the Federal Government with its headquarters at Islamabad.

(4) The Authority 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 Federal Drug Surveillance Laboratory, Islamabad shall, upon the commencement of this Act, become part of the Authority.

(5) The common seal of the Authority shall be kept in the custody of the Chief Executive Officer or such other person as may be prescribed by regulations and documents required or permitted to be executed under the common seal shall be specified and authenticated in such manner as may be prescribed by regulations.

4. Composition of the Authority. — (1) The Authority shall consist of a full time Chief Executive Officer (CEO) and thirteen Directors who shall be appointed by the Federal Government on the recommendation of Board, whose qualifications, terms and conditions shall be such as may be prescribed. The Directors shall be designated as: —

(a) Director Pharmaceutical Evaluations and Registration.—He shall be incharge of the Division of Pharmaceutical Evaluations and Registration which shall be responsible for the evaluation, assessment and registration of Pharmaceuticals drugs for human beings, animals and to perform other functions connected therewith and assigned by the Board;

(b) Director Drug Licensing.—He shall be the incharge of the Division of Drug Licensing which shall be responsible for the licensing of the drugs manufacturing facilities and to perform other functions connected therewith;

(c) Director Quality Assurance and Laboratory testing.—He shall be incharge of the Division of Quality Assurance and Laboratory testing which shall be responsible for enforcement of current Good Manufacturing Practices under the Act, and for testing or research of drugs and to perform other functions

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connected therewith. The Division will also perform the functions related to post marketing surveillance and shall be responsible for the evaluation, co-ordination and monitoring of safety, efficacy and quality of registered drugs and inactive materials including the clinical and toxicological study, drug recalls and with drawls, and to perform other functions connected therewith;

Director Medical Devices and Medicated Cosmetics.—He shall be incharge of the Division of Medical Devices and Medicated Cosmetics which shall be responsible for the assessment, enlistment or registration of medical devices and medicated cosmetics, medicated shampoos and medicated soaps for human beings, animals and to perform other functions connected therewith;

Director Biological Drugs.—He shall be incharge of the Division of Biological Evaluation and Research which shall be responsible for the evaluation, assessment, registration and licensing of Biologicals for human beings, animals and to perform other functions connected therewith including all the functions of national control authority for biologicals as required for the prequalification by World Health Organizations of locally manufactured human biological drugs;

Director Controlled Drugs.— He shall be incharge of the Division of Controlled Drugs which shall in consultation with the Federal Government be responsible for regulation and allocation of quota of narcotic drugs, psychotropic substances and precursor chemicals and to perform other functions connected therewith;

Director Pharmacy Services.— He shall be incharge of the Division of Pharmacy Services which shall be responsible for the development and promotion of pharmacy services and to perform other functions connected therewith;

Director Health and OTC Products (non-drugs).— He shall be incharge of the Division of Health and OTC Products (non-drugs) which shall be responsible for the assessment, licensing and registration of Alternative Medicines such as Ayurvedic, Chinese, Unani and Homeopathy, enlistment or registration of nutritional products and food supplements for human beings, animals and to perform other functions connected therewith;

Director Costing and Pricing.—He shall be incharge of the Division of Costing and Pricing which shall be responsible for the costing and pricing of therapeutic goods and to perform other functions connected therewith;

Director Budget and Accounts.—He shall be incharge of the Division for

Budget and Accounts which shall be responsible for budgetary and financial aspects of the Authority and other daily accounting matters connected therewith or ancillary thereto;

Director Administration, Human Resource and Logistics.—He shall be incharge of the Division for Administration, Human Resource and Logistics

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which shall be responsible for administration, recruitment, appointment, capacity building and development for the Authority and other matters connected therewith and ancillary there to;

Director Legal Affairs—He shall be incharge of the Division for Legal Affairs which shall be responsible for legal aspects of the Authority and other matters connected with Drug Court and other Court cases therewith or ancillary thereto; and

Director Management Information Services.—He shall be in charge of the Division for Management Information Services which shall be responsible for development of automation of functions using information technology for the Authority and other matters connected therewith and ancillary there to;

(2) The Federal Government, on the recommendations of the Board may increase or decrease the number of Divisions or Director and prescribe their functions and the relevant experience, qualification, terms, mode and manner of appointment of Directors and related staff in each Division.

5. Chief Executive Officer — (1) The Federal Government may, on the recommendations of the Board appoint a person as Chief Executive Officer who, —

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has a post graduate degree in Pharmacy or medicine with an age not less than

45 years or more than 56 years, with a minimum of twenty years experience in management or pharmaceutical field or regulatory affairs, in public sector, or if no such person of aforesaid qualifications is available in the public sector, then a person possessing above qualifications and experience from the private sector;

the tenure of appointment of CEO shall be for a period of three years, extendable on the recommendation of the Board for one year only; and

the CEO shall exercise general Control and supervision over the affairs of the Authority and shall ensure the provisions of the Act, the rules, and that the regulations, policies and directions of the Board are properly executed;

(2) The CEO shall discharge such duties and perform such functions as are assigned to him by or under this Act or as may be prescribed by the Board and in particular shall,—

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keep in custody the records and seal of the Authority;

submit plan of work and budget estimates of the Authority for approval of the Board; and

submit to the Board, in accordance with the rules and regulations reports on the activities of the Authority.

(3) The CEO shall also have the power to, —

(a) supervise the activities connected with the execution of programs for training, research, institutional consultancies, and other services;

(b) authorize expenditure provided for in the budget in accordance with the rules and regulations;

(c) re-appropriate funds within the approved budget;

(d) delegate his powers to appropriate levels of management subject to such conditions as he may deem fit;

(e) issue notices of meetings of the Board and Appellate Board and to maintain proper record of the minutes and proceedings thereof;

(f) execute deeds and documents on behalf of the Board; and
(g) perform any other duty assigned to him by the Board.

(4) The CEO shall not, except with the prior approval of the Board in each case or unless already approved in the budget duly itemized, allow expenditure on items of civil works, or capital expenditure on office or laboratory equipment or automobiles,

(5) The CEO may tender his resignation under his own hand.

(6) In case of occurrence of vacancy of CEO the Federal Government is authorised to appoint any person having prescribed qualification as CEO for a period of three months or till the

appointment of CEO, whichever is earlier.

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

(2) The meetings of the Authority shall be convened by the CEO at any time on his own or as directed by the Policy Board on any matter requiring decision by the Authority.

7. Powers and functions of the Authority. —The powers and functions of the Authority 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 and monitor the enforcement of, —
(i) licensing of the manufacture of therapeutic goods;

(ii) registration of therapeutic goods;

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(iii) —_ regulation for the advertisement;
(iv) drug specifications and laboratory practices;

(v) prosecution and appeals under this Act and the Drugs Act, 1976 (XXXI of 1976) relating to Federal subject;

(vi) regulation and allocation of quota of narcotic drugs, psychotropic substances and precursor substances (chemicals) in consultation with Federal Government;

(vii) regulation for pricing and mechanism for fixation of prices of various therapeutic goods under its ambit;

(viii) determining standards for biological manufacturing and testing;

(ix) implementation of internationally recognized standards such as good laboratory practices, current good manufacturing practices, good distribution practices, cold chain management, bioequivalence studies, stability studies, anti-spurious codes, clinical trials, biosimilar evaluations, and endorsement and systematic implementation of World Health Organization, International Conference on Harmonizations and Food and Drug Administration guidelines etc.;

(x) regulation, enforcement and monitoring of advertisement rule and ban on false advertisement;

(xi) manufacturing of active pharmaceutical ingredients in all its forms; and

(xii) use of central research fund.

co-ordinate, monitor or engage, in conjunction with other organizations, Provincial Governments and international agencies, in training, study or project related to therapeutic goods. The Authority 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;

facilitate advancement and up gradation of the sector to meet international standards and also to promote manufacture and export of active pharmaceutical ingredients and therapeutic goods;

coordinate at policy level and provide policy guidance to the Provincial

Government in the performance of their functions with a purpose to bring uniformity;

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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;

take steps for development and promotion of pharmacy services;

undertake awareness campaigns regarding prevention of diseases, patients! rights, healthcare privileges etc., through media, seminars, publications, and other available means of information technology;

issue guidelines and monitor proceedings and funding and accounts of health seminars, workshops and conferences;

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

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 shall be based on merit and productivity;

prescribe rules for seniority, promotion, code of conduct and terms and condition of service of its employees;

levy such charges or fees as may be prescribed for services and facilities provided by the Authority and its offices;

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;

prepare annual budget to be approved by the Board;

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;

develop working manuals, guidelines, references, materials and procedures in order to improve the working environment of offices etc., set up under the

Authority;

prescribe, regulate or implement measures and standards on matters related or connected with the Authority;

develop, issue, adopt, and enforce the standards and guidelines to ensure safety, efficacy, and quality of therapeutic goods with rational use at

reasonable price;

perform licensing, registration, pricing and appellate function thereof;

(v) coordinate with Provincial Governments and International agencies for smooth implementation of laws, capacity building and training of the regulatory staff;

(w) develop standard operating procedures, manuals, guidelines for transparent working of offices and conduct quality audits for conformance of the same;

(x) establish system of cost recovery to ensure financial autonomy and efficient functioning of the authority without becoming burden on the Government; and

(y) perform and carry out any other act, duty or function as may be assigned to it by the Policy Board and the Federal Government for furthering the provisions of this Act.

8. Delegation of powers. — The Authority may with the approval of the Board, 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) The general direction, administration and monitoring of the Authority shall vest in the Policy Board which shall consist of fifteen members, namely:—

(a) Secretary of the concerned Division (Federal Secretary BS- Chair
22) person

(b) CEO Member

(c) Representative of Ministry of Law and Justice not below Member
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(d) Secretary of the concerned Department, Government of the Member
Balochistan

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

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

(g) Secretary of the concerned Department, Government of the Member
Punjab

(h) Secretary of the concerned Department, Government of the Member
Gilgil-Bultistan

(i) Representative from Federally Administered Tribal Area Member

Gj) Six experts from the public and private sector with equal Member

representation from each Province, these members shall be
from different specialties as defined in sub-section (3)
below.

(2) The CEO shall also be the Secretary of the Board. The Board shall look after and be responsible for the affairs of the Authority.

(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, quality control, drug

regulation, public health, pharmacy services, health finance, health economics, health management, pharmacology, or biotechnology:

Provided that unless earlier removed by the Federal Government the term of the expert member shall be two years and shall be eligible for one more similar term only. The expert member

may resign his office by writing under his hand addressed to the Federal Government:

Provided further that the expert member shall himself attend the meeting 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 Board constituted by the Federal Government under sub-section (1), the Board may increase or decrease the number of its members and prescribe the qualifications and procedure for their appointment.

10. Meeting of the Policy Board. — (1) The meetings of the Board shall be convened by the Secretary of the Board with the prior approval of the Chairperson. In case of absence of the

Chairperson, the members present may elect the Chairperson for that meeting.

(2) The meetings of the Board shall be held at twice a year or more as and when required. A special meeting may also be called at any time to deal with any urgent business.

(3) Save as hereinafter provided, the Board shall make regulations for the conduct of its 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 or determinations taken by the Board shall be recorded in writing.

(6) The Board meeting shall be called by giving an advance notice of at least seven days.

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

(a) frame the policy and provide guidelines based on global and regional trends to the Authority and monitor the implementation and performance of the guidelines and of the functions of the Authority ensuring good governance and accountability;

(b) monitor and supervise all the functions of the Authority;

(c) approve the Budget of the Authority; and

(d) determine all fees and levies.

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

(2) A Board and 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 Appellate Board or its Committees constituted under Section 12, 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 Authority. —(1) The Authority, 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. The criteria for recruitment and selection of employees and officers will be determined by the Board according to the rules as prescribed.

(2) The age of superannuation for each employee shall be sixty years.

(3) No person shall be appointed as the CEO or Director of the Authority unless he is a citizen of Pakistan.

15. Integration of Federal Drugs Control Administration its sub-offices and Laboratories. — (1) Upon the commencement of this Act the Drugs Control Administration, its sub-offices and its Laboratories hereinafter referred to as the said offices as referred in sub-section (4) of Section 3 shall become part of the Authority.

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

(3) All debts and obligation 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 for the Authority.

(4) 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 Authority and may be proceeded or otherwise dealt with accordingly.

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

(a) every employee of the said offices under the Federal Government

immediately after the commencement of this Act shall be required to exercise an irrevocable option either to continue in the present pay and service structure

as a civil servant or to opt for absorption in the Authority within a period of thirty days from the date of commencement of this Act;

(b) all employees who opt to be included in the Authority under its rules shall be governed by this Act and the terms and conditions so prescribed;

(c) no health personnel who opts to be governed under this Act shall be entitled to any compensation because of such transfer; and

(d) the terms and conditions of service of all officers and staff employed in the Drug Regulatory Agency of Pakistan under Ordinance I of (2012) before the commencement of this Act shall not be varied to their disadvantage under the Authority.

16. Experts, consultants and advisers not to be civil servants. — The experts, consultants, employees or advisers employed by the Authority shall be governed by the terms and conditions of their appointment and shall not be deemed to be civil servant within the meaning of Civil Servants Act, 1973 (LXXI of 1973).

17. CEO and officers etc., to be public servants. —The CEO. officers, employees, experts and consultant of the Authority shall, when acting or purporting to act in pursuance of any of the provisions of this Act, 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, Director, consultant, advisor, officer or employee of the Authority if he or she has any financial or professional conflict of interest.

(2) No person shall be member of the Board or Director if he has immediate family members (parent, child, sibling or spouse) as senior officials or owners of concerns dealing in therapeutic goods.

CHAPTER-II

FUND, BUDGET AND ACCOUNTS

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

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

(a) grant-in-aid in terms of salaries and retirement benefits of the existing staff to be provided by the Federal Government;

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

(d) loans and grants from the national and international agencies received by the Federal Government and Provincial Governments to finance the function of the Authority;

(e) charges and fees collected by the Authority to recover the costs of regulated activities under this Act;

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

(g) proceeds from any other service rendered by the Authority, including Inspection Services, foreign or local, or sale of any publication; and

(h) Central Research Fund collected from the pharmaceutical industry.

(3) At the end of each financial year, the balance sheet shall be prepared and any un-spent remaining amount and all other collections including Central Research Fund shall be securely invested only in Government schemes in order to achieve self-sufficiency of the Authority.

(4) A separate pension endowment fund shall be established for the payment of pensions of employees recruited in the Authority.

20. Fees and other charges to be levied by the Authority. — (1) The Authority 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 Authority, with the approval of the Policy Board, in accordance with rules.

(2) The Central Research Fund fee shall be deposited in the non-lapsable sub-account of the Authority to be utilized as per existing rules.

(3) The existing Central Research Fund kept with the Federal Government shall be transferred to the Authority immediately after the notification of establishment of the Authority.

21. Budget. — (1) The Authority 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 revised and estimated budgets, requirements of grant-in-aid from Federal Government, and 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 Federal Government for appropriate provision and allocation.

(2) It shall not be necessary for the Authority to take prior approval from the Government to

spend money from its own generated funds, and shall practice financial freedom as the Board deem fit for furtherance of its functions.

22. Accounting and Audit. — (1) The Authority may open its accounts with any scheduled Bank or financial institution within the framework of the prescribed rules. The Authority may approach the Government, for the grant of initial funds in this respect.

(2) The accounts of the Authority shall be maintained as a double entry system and in the manner prescribed by the Controller General of Accounts.

(3) The Authority 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 Act, 1961 (X of 1961).

(4) Notwithstanding the audit provided by in sub-section (3) the Auditor General shall have the power to audit or cause to be audited the accounts of the Authority.

(5) A copy of the audit report shall be sent to the Federal Government along with the comments of the Authority.

(6) The Authority 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 Authority may, with the approval of the Federal Government, by notification in the official Gazette, make rules for carrying out the purposes of this Act.

24. Power to make regulations. — The Authority may, by notification in the official Gazette, with the approval of the Board, make regulations, for its internal working and terms and condition of employees not inconsistent with the provisions of the Act or the rules, for the carrying out of its functions under this Act.

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

(2) The Federal Government may require the Authority to furnish: —

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

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

(c) a copy of any document in the custody of the Authority;
(3) The Authority shall expeditiously comply with such directions.

26. Power to call for information.—The Authority 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 Act. The person so called upon to provide such information shall do so within the period prescribed by the Authority 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-IIL

(2) The prohibition specified in Schedule-II shall be punished in accordance with Schedule-Il.

28. Offences by companies etc.—Where the person guilty of an offence under this Act or the Drugs Act, 1976 (XXXI of 1976), 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-IV.

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

(2) The Authority 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 Authority may, on completion of investigation, take any action as may be prescribed under this Act or as the case may be subject to the provisions of any law specified in the Schedule-VI.

(3) Appeals against the decisions of the Authority shall be referred to the Board, which shall formulate an Appellate Board from among its members, who shall decide the case on merit.

31. 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 Act 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 Act.

(2) A person who knowingly receives records or information obtained under this Act 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.

32. Act not to override other laws. — (1) The provisions of this Act 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 Act and any other law for the time being in force, the provisions of this Act shall prevail.

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

34. 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.

35. 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 on the recommendation of the Board.

36. 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 Act, for the purpose of removing the difficulty.

37. Employment under the Authority to be employment under the Federal Government.— Every employment under the Authority shall, for the purpose of Pakistan Essential Services (Maintenance) Act, 1952 (LIII of 1952), be deemed to be employment under Federal Government and the said Act shall have effect accordingly.

38. Act X of 2012 not to apply to the Authority. — Nothing contained in the Industrial Relation Act (X of 2012), shall apply to or in relation to the Authority or any of the officers and employees of the Institute.

39. Co-operation with international organizations. — The Authority may, subject to the prior approval of the Federal Government, co-operate with any foreign authority or international organization in the field of health on the terms and conditions of any program or agreement for co-operation to which such authority or organization is a party, or pursuant to any other international agreement made or after the commencement of this Act.

40. Repeal and Savings. — (1) The Drug Regulatory Agency of Pakistan Ordinance, 2012 (Ordinance I of 2012) is hereby repealed.

(2) Notwithstanding the repeal of the Drug Regulatory Agency of Pakistan Ordinance, 2012 (Ordinance I of 2012) by sub-section (1),—

(a) any license to manufacture or any registration or maximum retail price fixed for sale issued thereunder to any person, or for the revalidation of an license or registration issued earlier under the Act, for which an application has been made to the Licensing Board, Registration Board, and Drug Pricing Committee as the case may be within the specified time, shall continue to be valid;

(b) any license for import or export or sale of drugs issued thereunder to any person, shall, unless it expires earlier under the terms thereof, continue to be

valid for such periods as the Federal Government, may by notification in the official Gazette, specify in this behalf.

(3) All such actions of the Federal Government as mentioned in sub-section (2) since 20th April, 2010 shall be deemed to have validly made under this Act.

41. Policy Directive of Federal Government. — (1) The Federal Government may issue policy directives in accordance with the law and Constitution to the Board in respect of any of its activities, powers and functions and whose compliance shall be binding on the Authority, within a stipulated time.

(2) Notwithstanding anything contained in sub-section (1) if there is any difficulty in implementation of the directions and guidelines of the Policy Board or the Federal Government, the Authority shall refer the case back to the Federal Government for its review specifying reasons for non-implementation, within the stipulated time, whose decision in this respect shall be final.

42. Winding up of Authority. — No provision of any law relating to winding up of bodies

corporate shall apply to the Authority. The Authority shall only be wound up by the law to be enacted by the Parliament for winding up of the Authority.

SCHEDULE-I
[See Section 2 (Vv, xii, xvili, xix, & Xxviii)]
1. BIOLOGICALS includes, —
(1) Biological drugs produced by biological systems and which require standardization by biological assays according to the relevant and updated recommendations of the World Health Organization published in Technical Report Series and Biological Standardization Report and

includes—

(a) blood products including Plasma, Albumin, Clotting Factors, Factors VIII, [X, Mixed Clotting Factors Tractions, Fibrinogens, Immunoglobulins:

(b) immunological products including Antisera, Antitoxins, specific Immunoglobulins;

(c) in vivo diagnostics including Tuberculins, Lepronin, Histoplasmin, Coccidioidin, Allergens, Allergens Extracts, Antibodies conjugated with isotopes for imaging studies;

(d) antigens, cytokines/antibodies/cells injected to elicit a biological response;

(e) vaccines, including: —

(i) bacterial vaccines including live, killed whole cell, protein sub-unit, polysacchrid or glyco-conjugate, toxin derivatives, and rDNA biotechnology developed.

(ii) viral vaccines including live, inactivated, sub-unit, (DNA, conjugated;

(iii) polyvalent combinations of vaccines containing combination of vaccines defined in e (i) and d(ii).

(f) toxins and venoms including snake venoms, scorpion venoms etc;

(g) immunostimulants of biological origin including BCG vaccine for immunothcrapy;

(h) biotechnology products which are primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques.

(i) human interferons, natural hormones, recombinant antibodies, monoclonal antibodies and derivatives gene therapy products;

(2) “Biological Drugs (Finished form)”, are Biological Drugs that are defined in sub-section (1) above and are manufactured, packed by the manufacturer under his responsibility of quality assurance and is further released by the National Control Authority or the National Control Laboratory of the country of origin under the World Health Organization's Lot Release system of evaluation.

(3) “Biological Drugs (Ready-to-fill form)”, are Biological Drugs that are defined in sub-section (1) above but are manufactured at one site in the form of a “Ready-to-fill Bulk” but are transferred to another site for final filling, labeling, packaging and quality control of the finished form. No further formulation or dilution of the Ready-to-fill bulk is allowed in this case of manufacture. The final product is released by the Pakistan's National Control Laboratory for Biologicals under the World Health Organization's Lot Release system of evaluation.

(4) “Biological Drugs (Concentrated form)”, are Biological Drugs that are defined in sub-section (1) above that are manufactured at one site but are stored in the form of Concentrated-Bulk of the active ingredient at controlled temperatures. Such Concentrated-Bulk may be transferred to any other site under temperature controlled conditions for further dilution, stabilization, filling and packaging. The diluted and stabilized bulk requires its own set of quality control test and the final finished form of such Biological Drugs under go another set of complete quality control tests. The final product is released by the Pakistan's National Control Laboratory for Biologicals under the World Health Organization's Lot Release system of evaluation.

(5) ''Biological Drugs (Naked vials)”, are Biologicals Drugs that are defined in sub-section (1) above that are manufactured and filled at one site but the final containers are neither labeled nor packed in cartons. These drugs are imported in unlabeled vials and are labeled and packed in carton locally. In such cases at least an identity test is required to confirm the positive identification of the required antigen. The final product is released by the Pakistan's National Control Laboratory for Biologicals under the World Health Organization's Lot Release system of evaluation.

(6) Originator Biological Drugs means a biological drug which has been licensed by the national regulatory authorities on the basis of a full registration dossier; i.e. the approved indication(s) for use were granted on the basis of full quality, efficacy and safety data:

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reference biotherapeutic product (RBP) means an originator biological drug product that was licensed on the basis of a full registration dossier. It does not refer to measurement standards such as international, pharmacopoeial, or national standards or reference standards;

biosimilar biological drugs mean Similar Biotherapeutic Product (SBP) which is similar in terms of quality, safety and efficacy to an already licensed

reference biotherapeutic product;

similarity means absence of a relevant difference in the parameter of interest.

(7) No human biological drug is allowed sale and use until a “Lot Release Certificate” from the Federal Government Analyst of the National Control Laboratory for Biologicals, Islamabad has

been obtained.

(8) Pharmaceutical dossier includes a set of documents submitted by a Person for the registration of a therapeutic good, containing complete information about:

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master formula;

all ingredients both active pharmaceutical ingredients and inactive excipients added with their safety profile data;

complete manufacturing procedure of the drug, biological or medical device;

quality control steps and procedures at each level of raw material selection, in-process testing, finished drug testing, and stability testing;

clinical trial data and published reports about the safety and efficacy of the

drug;

complete details of manufacturing plant and equipment, quality control laboratories and equipment;

ware-houses capacities and facilities; details of human resources available and the latest cGMP report shall also be part of this document set;

any other information required by the registration board for establishing the safety, efficacy, bioavailability, bioequivalence, or biosimilarity of the drug.

2. 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

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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, Chinese or biochemic system of treatment except those substances and in accordance with such conditions as may be prescribed;

abortive and contraceptive substances, agents and devices, surgical ligatures, sutures, bandages, absorbent cotton, disinfectants, bacteriophages, adhesive plasters, gelatin capsules and antiseptic solution;

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;

such pesticides as may cause health hazard to the public;

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, Chinese or Biochemic system of treatment, and intended to be used for any of the purposes mentioned in sub-Clauses (a), (b) and (c); and

any other substance which the Federal Government may by notification in the official Gazette, declare to be a drug for the purpose of this Act.

3. MEDICAL DEVICES include, —

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

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

4. MEDICATED COSMETICS include, —Cosmetics containing drugs and are defined as articles containing active drug ingredients intended to be rubbed, poured, sprinkled, or sprayed on, or introduced into, or otherwise applied to human body or part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of

any such articles; except that such term shall not include soap.

SCHEDULE-II
[See Section 2(xxx)]

PROHIBITIONS

A. Import, manufacture and sale of therapeutic goods:

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

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Export, import or manufacture for sale or sell, —

(i) any spurious therapeutic good;

(ii) any counterfeit therapeutic good;

(iii) any misbranded therapeutic good;

(iv) any adulterated therapeutic good;

(v) any substandard therapeutic good;

(vi) any therapeutic good after its expiry date;

(vii) | any therapeutic good which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceutical evaluation;

(viii) any therapeutic good 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 therapeutic good in contravention of any of the provisions of this Act or rules made thereunder;

manufacture for sale any therapeutic good except under, and in accordance with the condition of a license issued under this Act;

sell any therapeutic good except under, and in accordance with the conditions of a license issued under this Act;

import or export any therapeutic good the import or export of which is prohibited by or under this Act;

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;

supply an incorrect, incomplete or misleading information, when required to furnish any information under this Act or the rules;

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peddle, hawk or offer for sale any therapeutic good in a park, or public street or on a highway footpath or public transport or conveyance;

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

sell any therapeutic good without having warranty in the prescribed form bearing the name and batch number of the therapeutic good issued;

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

(ii) in the case of an imported drug, by the manufacture or importer of that therapeutic good or if the therapeutic good is imported through an

indenter by such indenter; and

(iii) 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,—

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any therapeutic good;

any substance used or prepared for use in accordance with the Ayurvedic, Unani, Homoeopathic, Chinese or Biochemic system of treatment or any other substance or mixture of substances as may he prescribed;

any remedy, treatment or offer of a treatment for any disease.

Explanation.--For the purpose 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 therapeutic good, 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 therapeutic good as a sample except in accordance with such conditions as may be prescribed.

D. Control of printing of labeling: —

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

SCHEDULE-III
[See Section 27]

OFFENCE

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

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exports, imports, manufactures for sale or sells any spurious therapeutic good or any therapeutic good which is not registered;

manufactures for sale any therapeutic good without a license;

imports without license any therapeutic good 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 ten 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, —

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imports, manufactures for sale or sells any counterfeit therapeutic good; or

gives to the purchaser a false warranty in respect of any therapeutic good sold by him that the therapeutic good 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

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

imports, manufactures for sales or sells any therapeutic good under a name other than the registered name; or

exports, imports, manufactures for sale or sells any therapeutic good with which any substance, which should not actually be its component, or has been mixed or packed it 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 five lakh rupees or with both.

(3) Obstruction of Inspector.— 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 one lakh rupees, or with both.

(4) Contravention of rules.— Subject to the provisions of Clauses (1), (2) and (3), whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or any rule shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to one lakh rupees, or with both.

(5) Penalty for subsequent offence Whoever having been convicted of an offence under Clause (1) of Schedule-Ill is convicted for a subsequent offence under that section 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 five hundred thousand rupees.

(6) Penalty for violating the prohibitions. —Whoever himself or by any other person on his behalf violates any prohibitions specified in Schedule-II shall be punished with imprisonment for a term up to five years and with fine up to five hundred thousand rupees.

SCHEDULE-IV

[See Section 29]
COGNIZANCE OF OFFENCES

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

(a) by a Federal Inspector, where the prosecution is in respect of a contravention of Clause (h) of Paragraph (1) of heading A of Schedule-II or any of the provisions of this Act or the rules relating to the import or export of therapeutic goods or the manufacture for sale, or sale, of a therapeutic good which is not for the time being registered or for the manufacture for sale of which a license is not for the time 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 Registration Board or Licensing Board as the case may be, institute a prosecution for a contravention of any other provision of this Act and The Drugs Act, 1976 (XXXII of 1976).

(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 Clause (1) of that Schedule shall be non-cognizable, and

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no Court other than a Drug Court established under The Drugs Act, 1976, (XXXI of 1976) shall try an offence punishable under this Act and Drugs Act, 1976 (XXXI of 1976);

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 this Act or The Drugs Act, 1976 (XXXI of 1976) or to require the transfer to a drug Court of any case which may be pending in any Court immediately before the establishment of Drug Court.

SCHEDULE-V
[See Section 2(xvi)]

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 or Licensing Board as the case may be,—

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inspect any premises where in any therapeutic good is manufactured, the plant and process of manufacture, the means employed, for standardizing and testing the therapeutic goods and all relevant records and registers;

inspect any premises wherein any therapeutic good is sold or is stocked or exhibited for sale or is distributed, the storage arrangements and all relevant records and registers;

take samples of any therapeutic good which is being manufactured, or being sold or is stocked or exhibited for sale or is being distributed;

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;

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;

seize such therapeutic good 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 Act or any rules;

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

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investigation of any offence under this Act and the Drugs Act, 1976 (XXXI of 1976) or the rules:

Provided that the exemption 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;

lock and seal any factory, laboratory, shop, building, store-hose or godown, or

a part thereof, where any therapeutic good is or is being manufactured, stored, sold or exhibited for sale in contravention of any of the provisions of this Act, the Drugs Act, 1976 or the rules;

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 Licensing Board, the Registration Board, as the case may be, specify, any person in charge of any premises from removing or dispensing of any therapeutic good, article or other thing likely to be used in evidence of the commission of an offence under this Act or the rules; and

exercise such other powers as may be necessary for carrying out the purposes of this Act 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 drug.

(2) The provisions of the Code of Criminal Procedure, 1898 (Act V of 1898), insofar as they are not inconsistent with the provisions of this Act and The Drugs Act, (XXXI of 1976), shall apply to searches and seizures made under this Act.

PROCEDURE FOR INSPECTORS

(1) Where an Inspector seizes any therapeutic good 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 therapeutic good 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 divided the sample into four portions and effectively seal and suitable 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 therapeutic good is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the therapeutic good 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, sealing 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 return 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, namely, —

(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 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 proviso to sub-section (3) of Section 32 of The Drugs Act, 1976 (XXXI of 1976).

(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 therapeutic good to add his own seal, if any, and mark to it and shall produce the same before the Drug Court, or the Provincial Quality Control Board, or the 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 therapeutic good contravenes any of the provisions of this Act 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 Act or The Drugs Act, 1976.

(6) The Provincial Inspector on finding any contravention of this Act or the Drugs Act, 1976 (XXXI of 1976) 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 contraventions.

(7) The Federal Inspector on finding any contravention of this Act or the Drugs Act, 1976 (XXXI of 1976) for which he is authorized shall unless otherwise directed, always refer the case to

the 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 2(1)]
(1) The Drugs Act, 1976 (XXXI of 1976).

(2) Rules made under the Drugs Act, 1976 (XXXI of 1976).