DRUG REGULATORY AUTHORITY
OF PAKISTAN

The Drugs Act, 1976

THE DRUGS ACT, 1976

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Part II THE GAZETTE OF PAKISTAN EXTRA, MAY 18, 1976
[ACT NO. XXXI OF 1976

(As amended vide Ordinance No. CXXVIII, dated 15th November, 2002)
These amendments are in blue color

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

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

It is hereby enacted as follows:-

CHAPTER-I: INTRODUCTORY

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

(2) It extends to the whole of Pakistan.

(3) It shall come into force at once.

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

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

(a) **"adulterated drugs"** means a drug-

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

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

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

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

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

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

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

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

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

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

(g) **"drug"** includes-

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

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

(iii) 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;

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

(v) 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 (i), (ii) and (iii); and

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

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

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

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

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

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

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

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

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

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

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

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

(s) **"misbranded drug"** means a drug-

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

(ii) on the label or labelling of which any word, statement or other matter or information required by the rules to appear on the label or labelling is not prominently placed with such conspicuousness (as compared with other words, statements, designs, or devices on the label or labelling) and in such terms as may render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; or

(iii) which is not labelled with such directions for use and such warnings against use in indications where its use may be dangerous to health, or against unsafe dosage or duration of administration or application, in such manner and form as are necessary for the protection of users or as may be prescribed; or

(iv) the label or container of which, or anything accompanying which, bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular; or

(v) which is so coloured, coated, powdered or polished that damage is concealed, or which is made to appear of better or greater therapeutic value than it really is; or

(vi) which is manufactured according to the specifications of a particular pharmacopoeia or any other document as may be prescribed and the label does not bear the name of that pharmacopoeia or document;

(t) **"prescribed"** means prescribed by rules;

(u) **"Provincial Quality Control Board"** means a Board set up under section 11;

(v) **"Registration Board"** means a Board set up under section 7;

(w) **"registered drug"** means any drug registered under section 7;

(x) **"rules'** means rules made under this Act;

(y) **"Drug Court"** means a Court established under section 31;

(z) "**specifications**" when applied to a drug mean-

(i) such specifications as may be prescribed; or

(ii) when the specifications are not prescribed, the specifications as contained in the most recent edition of any of the following publications, namely:-

(1) the Pakistan Pharmacopoeia;
(2) the International Pharmacopoeia;
(3) the European Pharmacopoeia;
(4) the United States Pharmacopoeia;
(5) the British Pharmacopoeia;
(6) the British Pharmaceutical Codex;
(7) the United States National Formulary; and
(8) such other publication as may be prescribed:

Provided that, if the specifications do not appear in the most recent edition of any such publication, the specifications appearing in the next preceding edition of such publication in which the specifications appear shall apply; or

(iii) if no specifications are either prescribed or contained in any of the publications referred to in sub-clause (ii), the specification approved for the purpose of registration under this Act;

(za) "**sell**" means sell, offer for sale, expose for sale, have in possession for sale and distribution and "to sell", "sold" or "sale" shall be construed accordingly;

(zb) "**spurious drug**" means a drug-

(i) which purports to be a drug but does not contain the active ingredient of that drug; or

(ii) which purports to be the product of a manufacturer, place or country of whom or of which it is not truly a product; or

(iii) which is imported or exported or sold or offered or exposed for sale under a particular name while actually it is another drug; or

(iv) the label of which bears the name of an individual or company purporting to be its manufacturer or producer which individual or company is fictitious or does not exist;

(zc) "**storage**" means storage for sale and "to store" or "stored" shall be construed accordingly; and

(zz) **"sub-standard drug"** means a drug which is not of specifications.

CHAPTER II: ADMINISTRATION AND ENFORCEMENT

4. Regulation and prohibition of import, etc., of drugs.- (1) The Federal Government shall regulate the import and export of drugs in the prescribed manner and for that purpose may make such orders and issue such directions to the importers and exporters as it may deem fit.

(2) If in the opinion of the Federal Government the public interest so requires, the Federal Government may, by notification in the official Gazette,-

(a) direct that a drug or a class of drugs specified in the notification, or drugs generally, shall not be imported or exported otherwise than under the authority of a license issued under this Act or except by an importer or exporter or through an indentor registered in accordance with the rules;

(b) direct that a drug or class of drugs specified in the notification shall not be imported except by an agency of Government so specified; or

(c) prohibit the import or export of any drug or class of drugs specified in the notification.

(3) Subject to sub-section (1) and (2), only such drugs shall be imported which are on sale in the market of any of the Western European countries, USA, Japan, Australia or any other country as may be prescribed.

5. Regulation of manufacture of drugs.- (1) The grant of licenses to manufacture drugs shall be regulated in accordance with such conditions and procedure as may be prescribed, by a Central Licensing Board to be set up by the Federal Government and consisting of such representatives of the Federal Government and the Provincial Governments as may be prescribed.

(2) The members of the Central Licensing Board shall exercise such powers, including the powers of an Inspector, as may be prescribed.

(3) The Central Licensing Board shall, with the approval of the Federal Government and by notification in the official Gazette, make regulations to regulate the conduct of its business.

(4) Any member of the Central Licensing Board may, at any time, by writing under his hand addressed to the Federal Government, resign his office or shall vacate his office if the Federal Government, being of opinion that in the public interest it is necessary so to do, so directs.

(5) Subject to sub-section (4), a member of the Central Licensing Board shall hold office for the prescribed period.

6. Regulation of sale of drugs.-The Provincial Governments shall regulate the sale of drugs in the prescribed manner and may for that purpose make such orders, and

issue such directions to the importers, manufacturers, stockists, retailers or other dealers of drugs, as they may deem fit.

7. Registration of drugs.- (1) The Federal Government shall cause all drugs to be registered in accordance with such conditions and procedure as may be prescribed and for that purpose set up a Registration Board, consisting of such number of persons, possessing such qualifications, as may be prescribed.

Explanation.- In this section, "drugs" means drugs which are in the finished form ready for use.

(2) The members of the Registration Board shall exercise such powers, including the powers of an Inspector, as may be prescribed.

(3) The Registration Board shall, with the approval of the Federal Government, and by notification in the official Gazette, make regulations to regulate the conduct of its business.

(4) Any member of the Registration Board may, at any time, by writing under his hand addressed to the Federal Government, resign his office or shall vacate his office if the Federal Government, being of opinion that in the public interest it is necessary so to do, so directs.

(5) Subject to sub-section (4), the members of the Registration Board shall hold office for the prescribed period.

(6) The Federal Government shall, by notification in the official Gazette, fix the date after which no drug which is not registered shall be allowed to be exported, imported, manufactured, stored, distributed or sold.

(7) A person applying for the registration of a drug shall furnish such information in respect of the drug as may be prescribed, including information relating to its efficacy, safety, and quality, or as may be required by the Registration Board for the purpose of the evaluation of the drug.

(8) Single-ingredient drugs shall be registered generally by their generic names while compound drugs shall be registered generally by their proprietary names.

Explanation.- In this sub-section,-

(a) "single-ingredient drugs" means drugs containing one active ingredient;

(b) "compound drugs" means drugs containing more than one active ingredient.

(9) The registration of a drug shall be subject to such conditions as may be prescribed.

(10) Where the Registration Board registers a drug, it shall inform the person applying for its registration and the Provincial Governments of its having done so and of the conditions subject to which it has been registered.

(11) If the Registration Board, on the basis of information received or an inquiry conducted by it, is of opinion that -

(a) the registration of a drug was procured by fraud or misrepresentation; or

(b) the circumstances in which a drug was registered no longer exist; or

(c) there has been a violation of the conditions subject to which a drug was registered; or

(d) it is necessary in the public interest so to do;

the Registration Board may, after affording to the person on whose application the drug was registered an opportunity of showing cause against the action proposed to be taken, cancel or suspend the registration or specify any further conditions to which the registration shall be subject and inform such person and the Provincial Governments accordingly.

(12) The Provincial Governments shall take all such steps as may be necessary to ensure compliance with the conditions subject to which a drug is registered and to prevent the manufacture or sale of a drug-

(a) which has not been registered; or

(b) the registration of which has been cancelled or stands suspended.

8. Pakistan National Formulary.-The Federal Government shall compile and publish in the official Gazette Pakistan National Formulary comprising all drugs allowed to be imported, manufactured or sold and such Formulary may be reviewed and modified from time to time.

9. Appellate Board.-(1) The: Federal Government shall, in accordance with the rules, constitute an Appellate Board for the disposal of appeals preferred by persons aggrieved by any decision of the Central Licensing Board or the Registration Board or the Licensing Authority or a Board or Authority to which the powers of the Federal Government under section 12 have been delegated under sub-section (3) of that section and for revision of any such decision on its own motion.

(2) The Appellate Board shall consist of such representatives of the Federal Governments and the Provincial Governments, including a Chairman, as the Federal Government may from time to time appoint.

(3) Subject to sub-section (4), the Chairman and other members of the Appellate.- Board shall hold office for the prescribed period.

(4) The Chairman or any other member of the Appellate Board may, by writing under his hand addressed to the Federal Government, resign his office or shall vacate his office if the Federal Government, being of opinion that in the public interest it is necessary so to do, so directs.

(5) The members of the Appellate Board shall exercise such powers, including the powers of an Inspector, as may be prescribed.

(6) The Appellate Board may appoint experts for the purposes of detailed study of any specific matter before it.

(7) The Appellate Board shall, with the approval of the Federal Government and by notification in the official Gazette, make regulations to regulate the conduct of its business.

(8) The Appellate Board shall meet at least every month and shall decide any appeal preferred to it within sixty days of receipt of appeal unless the Board is prevented from doing so for sufficient cause to be recorded.

9A. Appeal to the Provincial Appellate Authority.- (1) Any person aggrieved by any decision of the licensing authority may prefer appeal to the Provincial Appellate Authority.

(2) The Provincial Government shall constitute a Provincial Appellate Authority for the disposal of appeal preferred under sub-section (1) as may be prescribed.

10. Expert Committees.-(1) The Federal Government may constitute committees of experts on Drugs Evaluation, on Pakistan Pharmacopoeia, on Advertising and on such other matters as may be necessary for the purposes of this Act.

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

11. Provincial Quality Control Board.-(1) Each Provincial Government shall set up a Provincial Quality Control Board consisting of such members, including a Chairman, as that Government may appoint from time to time.

(2) The Chairman and other members of the Provincial Quality Control Board shall hold office during the pleasure of the Provincial Government, on such terms and conditions as that Government may determine.

(3) The Provincial Government shall appoint a person to be the Secretary of the Provincial Quality Control Board and provide the Board with such staff as the Provincial Government may consider necessary.

(4) The Provincial Quality Board shall, with the approval of the Provincial Government and by notification in the official Gazette, make regulations to regulate the conduct of its business.

(5) The following shall be the powers and functions of the Provincial Quality Control Board, namely:-

(a) to inspect any premises where any drug is being, or is to be, manufactured or sold and to recommend to the appropriate authority the cancellation or suspension of the licence to manufacture or sell drugs granted to any person who is found to be contravening, or to have contravened, any of the provisions of this Act, or the rules;

(b) to scrutinize the reports of Provincial Inspectors in respect of contraventions of this Act and reports of the Government Analysts in respect of drugs sent to them by the Provincial Inspectors for test and analysis and issue instructions to the Inspectors as to the action to be taken on such reports;

Provided that the Provincial Quality Control Board may specify the class of cases in which a Provincial Inspector may make a complaint to the Drug Court, or take any other action, without the specific instructions of the Board;

(c) to exercise all the powers of an Inspector under this Act and the rules;

(d) to advise the Provincial Government on ways and means to ensure quality control of drugs manufactured in the Province;

(e) to ascertain the names of such directors, partners and employees of the company, corporation, firm or institution who are *prima facie* responsible for the commission of any offence under this Act or the rules and allow an Inspector to institute prosecution only against such person;

(f) to conduct annual validation of all instruments in the provincial drug testing laboratories and to recommend measures to upgrade such laboratories, if required;

(g) identify and accredit on payment of fee other laboratories in the Province with suitable facilities and expertise;

(h) to conduct training programs to update Government Analysts and for improving their knowledge according to latest analytical method and technology; and

(i) to submit a monthly report of decisions and activities to the Federal Government.

(6) The Provincial Quality Control Board may entrust any of its powers or functions under sub-section (5) to any one or more of its members.

11A. Conflict of interest.- No person who is a member of the Appellate Board, Central Licensing Board, a Provincial Quality Control Board, the Registration Board or a

member of Expert Committee shall be a members of the any other board or committee of which he is a member to avoid any conflict of interest.

12. Power to fix maximum prices of drug, etc.- (1) The Federal Government may, by notification in the official Gazette,-

(a) fix the maximum price at which any drug specified in the notification is to be sold; and

(b) specify a certain percentage of the profits of manufacturers of drugs which shall be utilized, in accordance with the rules for purposes of research in drugs.

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

(3) The Federal Government may, by notification in the official Gazette, delegate any of its powers under this section to any Board or other authority.

13. Directions to Provincial Governments.- The Federal Government may give such directions to a Provincial Government as may appear to the Federal Government to be necessary for carrying into execution in the Province of any of the provisions of this Act or of any rule or order made thereunder or for maintaining supplies of drugs of standard quality at reasonable prices or for the achievement of uniformity in respect of any matter in different parts of Pakistan.

14. Federal Drugs Laboratory and institutes, etc.- The Federal Government shall, as soon as may be, establish a Federal Drug Laboratory and may also set up such other institutes and drugs testing and research laboratories for the purposes of this Act as may be prescribed.

15. Provincial Drugs Testing Laboratory.- Each Provincial Government shall, as soon as may be, set up a Provincial Drugs Testing Laboratory for such purposes as may be prescribed.

16. Government Analysts.- The Federal Government or a Provincial Government may, by notification in the official Gazette, appoint such persons it thinks fit, having the prescribed qualifications, to be the Federal Government Analysts or, as the case may be, Provincial Government Analysts, for such areas and in respect of such drugs or classes of drugs as may be specified in the notification:

Provided that no person who has any financial interest in the manufacture, import, export or sale of drugs shall be so appointed:

Provided further that a person serving under the Federal Government or another Provincial Government shall not be so appointed without the previous consent of that Government.

17. Inspectors.- The Federal Government or a Provincial Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Federal Inspectors or, as the case may be, Provincial Inspectors for the purposes of this Act within such local limits as it may assign to them respectively:

Provided that no person who has any financial interest in the manufacture, import, export or sale of any drug shall be appointed:

Provided further that a person serving under the Federal Government or another Provincial Government shall not be so appointed without the previous consent of such Government.

18. Powers of Inspectors.- (1) Subject to the provisions of section 19 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 with 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 standardising 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 Act 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 Act or any rules:

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

(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 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 clause;

(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 Act or the rules;

(i) forbid for a reasonable period, not exceeding two 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 Act or the rules; and

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

Provided that the powers under causes (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.

[Second proviso omitted]

(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 Act, shall apply to searches and seizures made under this Act.

19. Procedure for Inspectors.- (1) Where an Inspector seizes any drug or any other article under section 18, 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 five 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, sealing them:

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

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

(i) one portion of sample he shall send to the Government Analyst concerned for test and analysis;

(ii) 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;

(iii) the third, where taken, he shall send to the warrantor, if any, named under the proviso to sub-section (3) of section 32; and

(iv) the fourth, where taken, he shall send to the person purporting to be its manufacturer or importer, as the case may be.

(4) Where an Inspector seizes any drug 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 18,-

(a) he shall, as soon as practicable ascertain whether or not the drug contravenes any of the provisions of this Act and, if 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 drug, 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 Inspectors is not competent to take action under section 30, 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.

(6) The Provincial Inspector on finding any contravention of this 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 Act for which he is authorised 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.

20. Persons bound to disclose place where drugs are manufactured or kept.- Every person for the time being in charge of any premises whereon any drug is being manufactured or is kept for sale or distribution shall, on being required by an Inspector so to do, disclose to the Inspector the place where the drug is being manufactured or is kept, as the case may be.

21. Disclosure of the name of the manufacturer.- Every person, not being the manufacturer of a drug or his agent for the distribution thereof, shall if so required by an Inspector, disclose to him the name, address and other particulars of the manufacturer or other person from whom he acquired the drug.

22. Reports of Government Analysts.- (1) The Government Analyst to whom a sample of any drug has been submitted for test and analysis under sub-section (3) of section 19 shall deliver to the Inspector submitting it a signed report in quadruplicate in the prescribed form and forward one copy thereof to the authority as may be prescribed.

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

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

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

(b) forward one copy to the warrantor, if any, named under the proviso to sub-section (3) of section 32;

(c) forward one copy to the Central Licensing Board or, as the case may be, the Registration Board or the Provincial Quality Control Board for its directions as to the action to be taken on the report; and

(d) retain the fourth copy for use in any prosecution or for any other purpose.

(4) Notwithstanding anything contained in any other law for the time being in force, any document purporting to be a report signed by a Government Analyst shall be admissible as evidence of the facts stated therein without formal proof and such evidence shall be conclusive unless the person from whom the sample was taken or the said warrantor has, within thirty days of the receipt of a copy of the report notified in writing to the Inspector or the Provincial Quality Control Board or, as the case may be, the Central Licensing Board or the Registration Board or the Drug Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(5) Where a person has, under sub-section (4), notified his intention of adducing evidence in controversion of a Government Analyst's report, the Provincial Quality Control Board or, as the case may be, the Central Licensing Board or the Registration Board or the Drug Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug lying with the Board concerned under sub-section (3) of section 19 to be sent for test or analysis to the Federal Drug Laboratory or any other laboratory specified for the purpose by the Federal Government which shall make the test or analysis and report in writing signed by, or under the authority of, the person for the time being incharge of the Federal Drug Laboratory, or, as the case may be, such other laboratory, the result thereof and such report shall be conclusive evidence of the facts stated therein.

(6) The cost of a test or analysis made by the Federal Drug Laboratory or other laboratory under sub-section (5) shall be paid by the complainant or accused as the Drug Court or the Board concerned shall direct.

CHAPTER III: PROHIBITIONS

23. 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;
(iii) 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 labelling thereof; or

(x) any drug in contravention of any of the provisions of this Act or any rule;

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

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

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

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

(f) supply an incorrect, incomplete or misleading information, when required to furnish any information under this Act 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 drug 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 authorised 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 drug.

(2) Nothing in sub-section (1) shall apply to the manufacture or import, subject to prescribed conditions, of small quantities of any drug for the purpose of clinical trial, examination, test, analysis or personal use;

24. 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,-

(i) any drug;

(ii) 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 be prescribed;

(iii) any remedy, treatment or offer of a treatment for any disease.

Explanation.-In this section, "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.

25. 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.

26. Control of printing of labeling.- No person shall print any labelling in respect of any drug 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 or for a person who does not possess a licence under this Act to manufacture that drug.

CHAPTER IV: OFFENCES, PENALTIES AND PROCEDURE

27. Penalties.-(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 licence; or
(c) imports without licence any drug for the import of which a licence 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—

(a) imports, manufactures for sale or sells any counterfeit drug; or

(b) 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 section 23 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

(c) 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 sub-section (1), sub-section (2) and sub-section (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 fifty thousand rupees, or with both.

28. Penalty for subsequent offence.-(1) Whoever having been convicted of an offence under sub-section (1) of section 27 is convicted for a subsequent offence under that sub-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 two lakh rupees.

(2) Whoever having been convicted of an offence under sub-section (2) of section 27 is convicted for a subsequent offence under that sub-section shall be punishable with imprisonment for a term which shall not be less than two years or more than ten years, or with fine which may extend to two lakh rupees, or with both.

(3) Whoever having been convicted of an offence under sub-section (4) of section 27 is convicted for a subsequent offence under that sub-section 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.

29. Forfeiture.-(1) Where any person has been convicted under this Act, for contravening any such provisions of this Act or any rule as may be prescribed in this behalf, the Drug Court may order that the stock of drug or substance by means of or in relation to which the offence was committed or anything of a similar nature belonging to or in the possession of the accused or found with such drug or substance, and if such contravention is punishable under sub-section (1) of section 27, any implements used in manufacture or sale of such drug and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances, used in carrying such drug, be forfeited to the Federal Government or, as the case may be, the Provincial Government and, upon such order being made, such drug, substance,

implements, receptacles, packages or coverings, animals, vehicles, vessels or conveyance may be disposed of as that Government may direct.

(2) Without prejudice to the provisions of sub-section (1), where the Drug Court is satisfied, on the application of an Inspector or otherwise, and after such inquiry as may be necessary, that a drug contravenes the provisions of this Act, the Drug Court may order that such drug be forfeited to the Federal Government or, as the case may be, the Provincial Government and, upon such order being made, such drug may be destroyed or otherwise disposed of as that Government may direct.

(3) An Inspector shall release any drug or article seized by him under this Act when he is satisfied that all the provisions of this Act and the rules with respect there to have been complied with.

30. Cognizance of offences.- (1) Subject to the provisions of section 19, 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 sub-section (1) of section 23 or section 24 or any of the provisions of this Act 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 licence 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 Federal Government, institute a prosecution for a contravention of any other provision of this Act.

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

(a) an offence punishable under this Chapter other than an offence mentioned in sub-section (1) of section 27, shall be non-cognizable, and

(b) no court other than a Drug Court shall try an offence punishable under this Chapter.

(3) Nothing contained in this Chapter 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 Chapter 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.

31. Drug Courts.-(1) The Federal Government may, by notification in the official Gazette, establish as many Drug Courts as it considers necessary and, where it establishes more than one Drug Court, shall specify in the notification the territorial limits within

which, or the class of cases in respect of which, each one of them shall exercise jurisdiction under this Act.

(2) A Drug Court shall consist of a person who is, or has been, or is qualified for appointment as, a Judge of a High Court, who shall be the Chairman, and two members being persons who, in the opinion of the Federal Government, are experts in the medical or pharmaceutical fields:

Provided that for deciding applications of bail the Chairman and any one member shall constitute full quorum of a Drug Court.

(3) A Drug Court shall sit at such place or places as the Federal Government may direct.

(4) A Drug Court shall have all the powers conferred by the Code of Criminal Procedure, 1898 (Act V of 1898), on a Court of Session exercising original jurisdiction.

(5) A Drug Court shall not, merely by reason of a change in its composition, be bound to recall and rehear any witness who has given evidence, and may act on the evidence already recorded by or produced before it.

(6) A Drug Court shall, in all matters with respect to which no procedure has been prescribed by this Act, follow the procedure prescribed by the Code of Criminal Procedure, 1898 (Act V of 1898), for the trial of summons cases by Magistrates.

(7) A person sentenced by a Drug Court may prefer an appeal to a Bench of the High Court consisting of not less than two Judges within thirty days of the judgment.

(8) The provisions of sections 5 and 12 of the Limitation Act, 1908 (IX of 1908), shall be applicable to an appeal referred to in sub-section (7).

32. Pleas.- (1) Save as hereafter provided in this section, it shall be no defence in a prosecution under this Act to prove merely that the accused was ignorant of the nature, substance or quality of the drug in respect of which the offence has been committed or of the circumstances of its manufacture or import, or that a purchaser, having bought only for the purpose of test or analysis, has not been prejudiced by the sale.

(2) A drug shall not be deemed to be misbranded or adulterated or sub-standard only by reason of the fact that there has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the drug fit for carriage or consumption and not to increase the bulk, weight or measure of the drug or to conceal its inferior quality or other defect or there is a decomposed substance which is the result of a natural process of decomposition:

Provided that such decomposition is not due to any negligence on the part of the manufacturer of the drug or the dealer thereof and that it does not render the drug injurious to health or does not make it substandard.

(3) A person, not being the manufacturer of a drug or his agent for the distribution thereof, shall not be liable for a contravention of section 23 if he proves—

(a) that he did not know, and could not with reasonable diligence have ascertained, that the drug in any way contravened the provision of this Act and that the drug while in his possession remained in the same state as when he acquired it; and

(b) that he acquired the drug from a duly licensed manufacturer or his authorised agent or an importer or an indentor resident in Pakistan under a written warrant, in the prescribed form stating, in particular, the batch number of the drug and signed by such person that the drug does not in any way contravene the provisions of Section 23 and that the drug while in his possession was properly stored and remained in the same state as when he acquired it and that the drug has been manufactured by a manufacturer holding a valid licence to manufacture drugs and permission to manufacture that drug:

Provided that a defence under clause (b) shall be open to a person only-

(i) if he has, within seven days of the service on him of the summons, sent to the Inspector a copy of the warranty with a written notice statings that he intends to rely upon it and giving the name and address of the warrantor, and
(ii) if he proves that he has, within the same period, sent written notice of such intention to the said warrantor.

33. Application of law relating to customs and powers of officers of customs.- (1) The law for the time being in force relating to customs and to goods the import of which is prohibited by or under the Customs Act, 1969 (IV of 1969), shall, subject to the provisions of section 27 of this Act, apply in respect of drugs the import of which is prohibited under this Act, and officers of customs and officers to whom any of the functions of an officer of customs have been entrusted under the said Act shall have the same powers in respect of such drugs as they have for the time being in respect of such goods as aforesaid.

(2) Without prejudice to the provisions of sub-section (1), an officer of customs or a Federal Inspector or any other person as may be authorized by the Federal Government in this behalf may detain any imported package which he suspects to contain any drug the import of which is prohibited under this Act, and shall forthwith report such detention to the licensing authority and, if required by it, forward the package or samples of any suspected drug found therein to a laboratory specified by it.

34. Offences by companies, etc.-Where the person guilty of an offence under this 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.

35. Publication of offender's name.-(1) If any person is convicted of an offence under this Act, it shall be lawful for the Drug Court to cause the offender's name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the Court may direct.

(2) The expenses of such publication shall be recoverable in the same manner as a fine is recoverable.

36. Powers to exempt.- Notwithstanding anything contained in this Act, the Federal Government may, if it is of opinion that the public interest so requires, at any time, of its own motion or on a representation made to it, by notification in the official Gazette, exempt any drug or class of drugs from the operation of any of the provisions of this Act, subject to such conditions, if any, and for such period, as may be specified in the notification.

37. Inspectors to be public servants.- Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Pakistan Penal Code (Act XLV of 1860), and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

38. Indemnity.- Except as otherwise expressly provided in this Act, no suit, prosecution or other legal proceeding shall lie against Government or any other authority or person for anything which is in good faith done or intended to be done under this Act or any rule.

39. Finality of order, etc.- Save as otherwise expressly provided in this Act, every order passed or decision given by any Board, a Drug Court or any other authority under this Act shall be final and shall not be called in question by or before any Court or other authority.

40. Publication of result of test or analysis, etc.- (1) It shall be lawful for the Federal Government to publish, in such manner as it may deem fit, the result of any test or analysis of any drug for public information and to pass such orders relating to the withdrawal of such drug from sale and its disposal as it may consider necessary.

(2) The Federal Government may, if it considers it necessary in the public interest so to do, publish for public information, in such manner as it may deem fit, any information relating to a drug or to the use of a drug in specified circumstances.

41. Cancellation or suspension of licences.- Where any person has been found to have contravened any of the provisions of this Act, or the rules in respect of any drug and the contravention is of such a nature that the import, export, manufacture or sale of any drug by such person is, in the opinion of the licensing authority or the Central Licensing Board, likely to endanger public health, that authority may, after giving such person an opportunity of being heard, cancel the licence to import, export, manufacture or sell drugs issued to such person or suspend such licence for a specified period.

42. Cancellation or suspension of registration of registered drugs.- Where any person has been found to have contravened any of the provisions of this Act, or the rules in respect of any registered drug, the Registration Board may, after giving such person an opportunity of being heard, cancel the registration of such drug or suspend such registration for a specified period.

CHAPTER V: MISCELLANEOUS

43. Power of Federal Government to make rules.- (1) Subject to section 44, the Federal Government may, by notification in the official Gazette, make rules for carrying out the purposes of this Act.

(2) In particular and without prejudice to the generality of the foregoing provision, such rules may-

(a) prescribe the functions of the Federal Drug Laboratory and any other laboratory set up under section 14 or specified under section 22 or section 33 and the procedure for the submission to any such laboratory of samples of drugs for analysis or test, the forms of the laboratory's reports thereon and the fees payable in. respect of such reports; and such other matters as may be necessary for any such laboratory to perform its functions;

(b) prescribe specifications, including the strength, potency, purity, quality or other property, of any drug, and the methods of test or analysis to be employed in determining whether a drug is of required specifications;

(c) prescribe the maximum proportion of any poisonous or other substance which may be added to or contained in any drug, or extracted or omitted therefrom; prohibit the import, manufacture, sale or stocking or exhibition for sale or distribution of any drug in which that proportion is exceeded and specify substances which shall be deemed to be poisonous;

(d) specify the drugs or classes of drugs for the import or export of which a licence is required, the testing of such drugs, and prescribe the form and conditions of such licences, the authority empowered to issue the same, and the fees payable therefor;

(e) prescribe the places at which any specific drug or drugs may be imported, prohibit their import at any other place, and control their import through any specified agency;

(f) prescribe the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of drugs sought to be imported, the procedure of officers, of customs in dealing with such evidence and the manner of storage at places of import of drugs detained pending admission;

(g) prescribe the forms of licences for the manufacture for sale of drugs or any specified drugs or class of drugs, the form of application for such licences, the conditions subject to which such licence may be issued, the person under whose signature the same be issued and the fees payable therefor;

(h) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label and container of any specified drug or class of drugs and prohibit the sale, stocking or exhibition for sale or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry date and prescribe the manner of disposal of such drug or class of drugs;

(i) prescribe the conditions to be observed in the packing in bottles, packages and other containers of drugs and prohibit the sale, stocking or exhibition for sale or distribution of drugs packed in contravention of such conditions;

(j) regulate the mode of packing and packaging, including its size, dimensions, fill and other specifications, the material used therefor and mode of labelling packed drugs and prescribe the matters which shall or shall not be included in such labels or on the leaflets accompanying the drugs;

(k) require that the non-proprietary or chemical or accepted scientific name or the proprietary name of any specified drug or any ingredient thereof shall be displayed in the prescribed manner;

(l) prescribe the requirements and conditions in respect of good practices in the manufacture and quality control of drugs;

(m) prescribe conditions for distribution of samples for sales promotion of drugs;

(n) prescribe the procedure for introduction in Pakistan of a new drug;

(o) prescribe terms and conditions of members of the Central Licensing Board and the Registration Board;

(p) prescribe types of registration of drugs, the form of application for such registration, the conditions subject to which such registration may be granted, the manner of registration and post-registration surveillance and deregistration of registered drugs and the fees payable therefor;

(q) prescribe conditions for registration of indentors, importers, wholesalers and distributors within Pakistan and any establishment within any foreign country engaged in the manufacture for export of a drug and prescribe conditions providing effective and adequate means, by arrangement with the Government of such foreign country or otherwise, to enable the licensing authority or the Registration Board to determine from time to time whether drugs manufactured in such establishment, if imported or offered for import into Pakistan, shall be refused admission where the public interest so requires;

(r) prescribe the form of warranty for manufactured drugs;

(s) specify offences in relation to which the stock of drugs, articles or things shall be liable to forfeiture under this Act;

(t) prescribe the qualifications, and regulate the procedure for exercise of powers and performance of functions, of Federal Inspectors;

(u) prescribe the laboratories to which the Federal Inspectors shall submit samples of drugs taken for the purpose of test and analysis and the form and procedure for submitting the report of such test and analysis and the fee payable therefor, where so required;

(v) prescribe measures for securing and maintaining supplies of drugs at reasonable prices, conditions to be met in respect of manufacture, production, pricing, keeping, movement and disposal of drugs and to fix prices, commissions, discount of the manufacturer, wholesaler, distributor, retailer or any other dealer of drugs, to control giving of bonus in cash or kind or in any other manner to any of the said parties and for collecting or calling for any information, statistics, records or books with a view to regulating the matters aforesaid;

(w) specify drugs which may be advertised and the conditions subject to which such drugs may be advertised;

(x) prescribe conditions subject to which small quantities of drugs may be imported or manufactured or exported for the purpose of examination, test or analysis, clinical trial or personal use; and

(y) prescribe any other matter which is to be, or may be, prescribed by the Federal Government.

(3) The power to make rules conferred by this section shall, except on the first occasion of the exercise thereof, be subject to the condition of previous publication.

44. Power of the Provincial Government to make rules.-(1) The Provincial Government may by notification in the official Gazette, make rules in respect of the following matters, namely :-

(a) the establishment of laboratories for testing and analysing drugs;

(b) the qualifications and the procedure, for exercise of powers and performance of functions of Provincial Inspectors;

(c) the forms of reports to be given by Government Analysts and the manner of application for test or analysis and the fees payable therefor;

(d) the conditions to regulate sale or storage or distribution of drugs or any specific drug or class of drugs;

(e) the offences against this Act or any rule in relation to which the stock of drugs shall be liable to confiscation and destruction under this Act;

(f) the forms of licences for the sale or distribution of drugs or any specified drug or class of drugs, the authority empowered to issue the same, the form of applications for such licences, the fees payable therefor and the condition subject to which such licences may be issued;

(g) the procedure to be followed by the Provincial Quality Control Board; and

(h) any other matter which is to be or may be, prescribed by the Provincial Government.

(2) The power to make rules conferred by this section shall, except on the first occasion of the exercise thereof, be subject to the condition of previous publication.

45. Repeal and savings.- (1) The Drugs Act, 1940 (XXIII of 1940), the Drugs (Generic Names) Act, 1972 (XXIV of 1972), and the Drugs Ordinance, 1976 (IV of 1976), are hereby repealed.

(2) Notwithstanding the repeal of the Drugs Act, 1940 (XXIII of 1940), by sub-section (1),-

(a) any licence to manufacture for sale issued thereunder to any person, for the revalidation of which an application has already been made to the Central Licensing Board within the date specified by the Federal Government shall continue to be valid until orders are passed by the said Board in this behalf;

(b) any licence 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, or as the case may be, the Provincial Government may by notification in the official Gazette, specify in this behalf:

Provided that in case of drugs to be imported or exported licences may continue to be issued under the rules framed under the Drugs Act, 1940, till the rules under this Act are framed or as the case may be, a date is fixed under sub-section (6) of section 7 in respect of drugs in the finished form ready for use.

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