**AZAD GOVT. OF THE STATE OF JAMMU & KASHMIR,LAW AND PARLIAMENTARY AFFAIRS SECRETARIAT, MUZAFFARABAD.**

Muzaffarabad dated July, 1977.

The following Act of the Assembly received the assent of the President on the 18th of July, 1977, and is hereby published for general information:-

**(ACT VI of 1977)**

AN ACT to regulate the manufacture, storage, distribution and sale of drugs.

**WHEREAS** it is expedient to regulate the manufacture, storage, distribution and sale of drugs, in the manner hereinafter appearing;

It is hereby enacted as follows:-

CHAPTER-1

**INTRODUCTORY**

1. **Short title, extent and commencement**:- (1) This Act may be called the Azad Jammu and Kashmir Drugs Act, 1977.

(2) It extends to the whole of AzadJammu and KashmirTerritory.

(3) It shall come into force at once.

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

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

(a) "Adulterated drug" mean a drug-

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

(ii) which has been manufactured, packed, or

held under unsanitary conditions whereby it may have been contaminated with dirt, filth or any other foreign matter or where by it may have been rendered injurious to health; or

(iii) the container of which releases any poisonous or deleterious substance which may a 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 an reviewed;

(e) "Licensing Board" means a Board set up under section 4;

(f) "Counterfeit drug" means a drugs the label oar 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 substance that it 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 there of in human beings or animals or the restoration, correction, or modification of organic function 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, gelatins capsules and antiseptic solution;

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

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

(v) any substance mentioned as monograph or as a preparation in Pakistan Pharmacopoeia or the Pakistan National Formulary or the international pharmacopoeia or the British pharmacopoeia or the British Pharmaceutera codex or the or the United States Pharmacopoeia or the National Formulary of United States, whether alone or in combination with any substance exclusively used in the Unani, ayurvedic, homeopathic or bio-chemic 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 Government may, by notification in the official gazette, declare to be '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 experience in the relevant field;

(j) 'generic name' means the non-properietary, scientific or official name of a drug as approved by the Federal Government of Pakistan;

(k) 'Government Analyst' means the Analyst appointed under section 15;

(l) 'Inspector' means an inspector appointed under section 16;

(m) 'Label' means a display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of a drug package;

(n) 'Labeling' means all labels and other written, printed or graphic matter accompanying any drug;

(o) 'Licensing authority' means any such authority as may be prescribed;

(p) 'manufacture' in relation to a drug, means all operations involved in the production of the drug, including processing, compounding, formulating, filling, packing, repacking, or ornamenting, finishing and labeling with a view to its storage, sale and distribution, but does not include the compounding and dispensing onthe package of any Drug in the ordinary course of retail business or on a prescription of registered medical practitioner or dentist or of a veterinarian and to 'manufacture'

shall be construed accordingly;

(q) 'misbranded drug'means a drug---

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

(ii) on the label or labelling of which any word, statement, or other matter or information required by the rules to appear on the label or labeling is not prominently placed with such conspicuousness (as compared with other words, statements, designs, or devices on the label or labeling 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 danger 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 any thing 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;

(r) 'prescribed' means prescribed by rules;

(s) 'Quality Control Board' means a Board set up under section (10);

(t) 'Registration Board' means a Board set up under section (6);

(u) 'Registered drug' means any drug registered under section 6;

(v) 'rule' means rules made under this Act;

(w) 'Drug Court' means a Court established under Section 29;

(x) 'specifications' when applied to drug mean---

(i) such specification as may be prescribed; or

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

(1) the Pakistanpharmacopoeia;

(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 publications as may be prescribed.

Provided that, if the specifications do not appear inthe 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 specifications approved for the purpose ofregistration under this Act;

(y) 'sell'means sell offer for sale, expose for sale,have the possession for sale and distributionand to 'sell' 'sold' or 'sale' shall be construed accordingly;

(z) 'spurious drug' means a drug-

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

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

(iii) which is 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 individualor company purporting to be its manufacturer orproducer which individual or company is fictitious ordoes not exist;

(aa) 'storage'means storage for sale and 'to store'or 'stored' shall be construed accordingly; and

(ab) 'substandard drug'means a drug which is not of specifications.

## CHAPTER II

## ADMINISTRATION AND ENFORCEMENT

4. **Regulation of manufacture of drug**:- (1) The grant of licenses to manufacture drugs shall be regulated inaccordance with suchconditions and procedure as may be prescribed, by a licensingBoardto be set up by the Government and consisting of such representatives of the Government as may be prescribed.

(2) The members of the Licensing Board shall exercise such powers including the powers of am Inspector, as may

be prescribed.

(3) The Licensing Board shall make regulations to regulate theconduct of its business.

(4) Any member of the Licensing Board may, at any time by writingunder his hand addressed to the Government, resign his officeor shall vacat his office if the Government, being of the opinion that in the public interest it is necessaryso to do, so directs.

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

5. **Regulation of sale of drugs**:- The Government shall regularte the sale of drugs in the prescribed and may for that purpose make such orders, and issue such directions to the manufacturers, stockistist, retailers or other dealers of drugs, as it may deem fit.

6. **Registration of drugs**:- (1) TheGovernment shall cause all drugs to be registered in accordance with such conditions and procedure as be prescribed and for that purpose set up a Registration Board, consisting of suchmember of persons, possessing such qualifications, as may be prescribed.

**Explanation**:- In this section,'drug' 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 make regulations toregulate the conduct of its business.

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

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

(6) The Government shall, by notification in the official

Gazette, fix the date after which nodrug which is not registered shall be allowed to be 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 evolution of the drug.

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

**Explanation**:- In this sub-section:-

(a) 'Single-ingredient drug' means drugscontaining oneactive ingredient;

(b) 'compound drugs' means drugs containing more than ingredient.

(9) The registration of a drug shall be subject to suchconditionsif any, as the Registration Board may specify at the time of its registration.

(10) Where the Registration Board registers a drug, it shall inform the person applying for itsregistration,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 exists; or

(c) there has been a volition of the conditions, subject towhich a drug was registered; or

(d) it is necessary in the public interest soto do, theregistration 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 accordingly.

(12) The Government shall take all such steps as may be necessaryto ensure compliance with the conditions subject to which a drug is registered ant 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.

7. **National formulary**:- National Formulary compiled, reviewedor modified from time to time by the Federal Government of Pakistan comprising all drugs allowed to be imported, manufactured or sold, shall be the National Formulary of Azad Jammu andKashmir.

8. **Appellate board**:- (1) The Government shall in accordance withthe rules constitute an Appellate Board for the disposal of appeals preferred by persons aggrievedby any decision of the Licensing Board or the Registration Board or the Licensing authority or a Board or Authority to which the powers of the Government under Section 11 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 Government, including a Chairman as the Government may from time to time, appoint.

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

(4) The Chairman or any other member of the Appellate Board may,bywriting under his hand addressed to the Government,resign his office or shall vacate his office if the Government, being of opinion that inthe 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 purpose of detailed study of any specific matter before it.

(7) The Appellate Board shall make regulations to regulate the conduct of its business.

**9. Expert committees:-** (1) The Government may constitute Committeeof experts on Drugs Evaluation, 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 consistof such member Government may from time to time such member shall hold office during the pleasure of the Government.

**10. Quality control board**:- (1) The Government shall set upa Quality Control Board consisting of such members including a Chairman, as the Government may appoint from time to time.

(2) The Chairman and other members of the Quality Control Board shallhold office during the pleasure of the Government, onsuch terms andconditions as the Government may determine.

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

(4) The Quality Control Board shall make regulations to regulate the conduct of its business.

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

(a) to Inspect any premises where any drug is being, or is to be,manufactured or soldandto recommend the appropriate authority the cancellation or suspension of the license or 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 Inspectors in respect of

contraventions of this Act and reports of the Government analysis in respect of drugs sent to them by Inspectors for test and analysis and issue instructions to the inspectors as to the action to be taken on such reports:

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

(c) to exercise all the powers of an inspector underthis Act and the rules, and

(d) to advise the Government on ways andmeans to ensure quality control of drugs manufactured in Azad Jammu and Kashmir.

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

**11. Power to fix maximum prices of drugs:-** (1) The 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 manufactured 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 Government may require a manufacturer stockiest, retailer or other dealer in drugs to furnish such relevant information as may be necessary.

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

12. **Drugs testing laboratory**:- The Government shall, as soon as may be set up a Drug Testing Laboratory for such purposes as may be prescribed:

Provided that, till the said laboratory is set up any

Drug Testing Laboratory Pakistan may be declared by notification in the official Gazette to be the Drug Testing laboratory for such purposes as may be prescribed.

13. **Government analysts:-** The Government may by notification in the official Gazette appoint such persons as it thinks fit, having the prescribed qualifications, to be the Government Analysts, for suchareas and in respect of such drugs or classes of drugs as may be specified in the notifications:

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

14. **Inspectors:-** Government may by notification in the officialGazette appoint such persons as it thinks fit, having the prescribed qualifications, to be the inspectors for the purposes of this Act within such local limits as it may assign to them:

Provided that no person who has any financial interest in the manufacture or sale of drug shall be so appointed.

15. **Power of inspectors**:- (1) Subject to the provisions of section 16and of any rules made in this behalf, an Inspector may within the local limitfor which he is appointed,and in any other area with the permission of the licensing authority,-

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

(b) inspect any premises whereinany drug is sold or is stocked orexhibited 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

heconsiders necessary,any building vessel or place, in which he has reason to believe that an offence under this Act or rules has been or is being committed or continue to be committed;

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

(f) seizure such drug and all materials used in the manufacturethereof and any other articles, including registers, cash-memo, invoices and bills, which hehas reason to believe may furnishevidence of the commission of an offence punishable under this Act or any rules;

(g) require any person to appear before him at any reasonabletime and place to give statement, assistance or informationrelating to or in connection with the of anoffence under this Act or the rules:

Provided that the exemptions under section 132 and 133 of the Code of Civil Procedure, 1908 (Act V of 1908), shallbe applicable to requisitions for attendance under this clause.

(h) look 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 four weeks or such further period,which shall not be more than three months, as the Inspector may, with the approval of the Quality Control Board, the 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 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 thisAct or rules:

Provided that the powers under clauses (f) to (j) shall be exercisable only by an inspector specifically authorised in this behalf, by an order in writing, by the government,subject to such conditions as may be specified in such order:

Provided further that the powers under clause (h) may be exercised by an inspector not authorised as aforesaid where the contravention is of a provision which requires a license to be obtained for the manufacture, storage or sale of a drugs.

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

16. **Procedure for inspectors**:- (1) Where an inspector seizures drug or any other article under section 15, he shall tender a receipt therefor in the prescribed form.

(2) where an inspector takes a sample of a drug for the purpose oftest or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in presence of such person unless he willfully absents him, shall divide the sample into four portions and effectively seal and suitably mark the same andpermit such person to add his own seal, if any, and mark all or any of the portions so sealed and marked:

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

Provided further that, where the drug is made up in containersof 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 marketing 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 whom he takes itand shall retain the reminder and dispose of the same within seven days as follows:-

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

(ii) the second he shall send to the Chairman Quality Control Board or the Licensing Board or the Registration Board, as the case may be; and

(iii) the third, where taken, he shall send to the warrantor, if any, named under the proviso to sub-section (3)of section 29;

(4) Where an inspector seizes any drug containing any filthyor putrid substance, vermin, worm, rodent, insect or any foreignmatter which is visible to the naked eye and the sample issuch that it cannot or need not be divided, he shalleffectively seal and suitably mark the same and permit the personfrom whom he seizes the drug to add his own seal if any, andmark to it and shall produce the same before the Drug Court of theLicensing Board or the Registration Board, as the case may be,before which proceedings are instituted or action is initiated inrespect of the drug.

(5) Where an Inspector takes any action under Section 15,

(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 contravenes, 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 samplestaken, under intimation to the Board

concerned;

(b) if he seizes the stock of the drug, heshall, as soon as may be, inform the Board concerned and take its order as to the custody thereof.

(6) The Inspector on finding any contravention ofthis Act for which he is authorised shall, unless otherwise,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.

17. **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.

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

19. **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 16 shall deliver to the Inspector submitting it a signed report in quadruplicatein the prescribed form and forward one copy thereof to the authority as may be prescribed.

(2) The government Analyst, as for as may be, shallsubmit 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 isnot able to do so for reasons beyond his control, shall communicate the reasons to the Inspector in writing and shall endorse its copy to the Board concerned who shall have the sample tested from the same or any other Government Analyst or a Government Drug Testing Laboratory or anyother 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 29;

(c) forward, one copy to the Board concerned forits directions as to the action to be taken on the reports; and

(d) retain the fourth copy for use in anyprosecution or for any other purposes.

(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 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 Drug Court or, as the case may be, the Licensing Board or the Registration Boardbefore which may proceedings in respect of the sample are pending that he intends toAdduce evidence in contravention, of the report.

(5) Where a person has,under subsection (4), notified his intention of adducing evidence in contravention of a Government Analystreport, the Drug Court or the Board concerned 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 16 to be sent for test or analysis to the Drug Testing Laboratory or any other Laboratory specified for the purpose by the 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 Drug Testing 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 Drug Testing Laboratory or other Laboratory under subsection (5) shall be paid by the complainant or accused as the DrugCourt or the Board concerned shall direct.

**CHAPTER III – PROHIBITIONS**

20. **Manufacture and sale of drugs.-**(1) No person shall himself or by any other person on hisbehalf.

(a) manufacture for sale or sell –

(i) any spurious drug;

(ii) any counterfeit drug;

(iii) any misbranded drug;

(iv) any adulterated drug;

(v) easy substandard drug;

(vi) any drag after its expiry date;

(vii) any drug which is not registeredor is not in accordance with theconditions of registration;

(viii) any drug which, by means of any statement, design or device accompanyingit or by any other means, purportsor claims to cure or mitigate anysuch disease or ailment, or to have any such other effect, as 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 labelingthereof; or

(x) anydrug in contravention of any of theprovisions of this Act or any rule;

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

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

(d) supply an incorrect, incomplete or misleading information when requires to furnishinformation under this Act or the rules;

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

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

(g) sell drug without having a warranty in the prescribed form bearing the name and batch number of the drug, manufactured in Azad Jammu and Kashmir, by the manufacturerholding a valid license to manufacture drugs and permission to manufacture that drug or by his authorised agent;

(h) apply an incorrect batch number to a drug;

(2) nothing in subsection (1) shall apply to the manufacture or subject to prescribed conditions, of small quantities of any drug for the purpose of clinical trial, examination, test, analysis or personal use.

21. **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 ayurvedic, unani, homeopathic 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 substances 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.

22. **Control of sampling**:- No person shall distribute or cause to be distributed any drug as a sample except in accordance with such conditions as may be prescribed.

23. **Control of printing of labelling**:- No person shall print any labeling 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 Government under sub-section(6) of section 6 or for a person who does not possess a license under this Act to manufacture that drug.

## CHAPTER IV-

## OFFENCES, PENALTIES AND PROCEDURE

24. **Penalties**.- Whoever himself or by any other person on his behalf .

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

(b) manufactures for sale any drug without a license; shall be punishable with imprisonment for a term which shall not be less than three years of more than ten years and with fine which may extend to one lakh rupees:

Provided that the Drug Court may, for air 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) 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 20 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 permit 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) manufactures for sale or sells any drug under a name other than he registered name; or

(e) 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, and with fine which may extend to one lakh rupees.

(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.

25. **Penalty for subsequent offence**.- (1) Whoever having been convicted of an offence under sub-section (1) of Section 24 is again convicted of an offence under that sub-section shall be punishable with imprisonment which shall not be less 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 24 is again convicted of an 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 24 is again convicted of an offence under that sub-section shall be punishable with imprisonment for a term which may extend to sever years, of with fine which may extend to one lakh rupees, or with both.

26. **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 24, 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 Government and, upon such order being made, such drug, substance, implements, receptacles, packages or coverings, animals, vehicles, vessels or conveyances may be disposed of as the Government may direct.

(2) Without prejudice to this 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 may be forfeited to the Government and, upon such order being made, such drug may be destroyed or otherwise disposed of as the 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

thereto have been complied with.

27. **Cognizance of offences**.- (1) Subject to the provisions of section 16, no prosecution shall be instituted under this Chapter except, by an Inspector, where the prosecution is in respect of a contravention of clause (h) of sub-section (1) of Section 20 or section 21 or any of the provisions of this Act or the rules relating to the manufacture of drugs for sale, or sale of a drug which is not for the time being registered or for the manufacture for sale of which a license is not for the time being in force:

Provided that, where the public interest so requires, the inspector may with the prior permission of the 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 of section 24, shall be non-cognizable; and

(b) no Court other than a Drag 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.

28. **Drug courts**.- (1) The 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 Government are experts in the medical or pharmaceutical fields.

(3) A Drug Court shall sit at such place or places as the 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 theevidence 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 Magistrate.

(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 section 5 and 12 of the Limitation Act, 1908 (IX of 1908) as adapted in Azad Jammu and Kashmir, shall be applicable to an appeal referred, to in sub-section (7).

29. **Please**.- (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 or the drug in respect of which the offence has been committed or of the circumstances of its manufacture, or that a purchaser, having brought 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 substandard 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 manufacture 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 20 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 provisions of this Act and that the drug while in his possession remained in the same state as when he acquired it; and

(b) that acquired the drug from a duly licensed manufacturer or his authorised agent or an importer or an indenter resident in Azad Jammu and Kashmir/Pakistan under a written warranty in the prescribed form stating , in a particular the batch number of the drug and signed by such person that the drug does in any way contravene the provisions of section 20 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 license to manufacture drug and permission to manufacture that drug; provided that a defence under clause (b) shall be opened 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 stating 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 period, sent written notice of such intention to the said warrantor.

30. **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 shall unless he proves that the offence was committed without his knowledge or consent, be guilty of the offence.

31. **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 or residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expenses 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.

32. **Powers to exempt**.- Notwithstanding anything contained in this Act the 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 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.

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

34. **Indemnity**.- Except as otherwise expressly provided in this Act, no suit, prosecution or other legal proceedings 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.

35. **Finality of orders 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, be final and shall not be called in question by or before any Court or other authority.

36. **Publication of result of test or analysis, etc**.- (1) It shall be lawful for the 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 Government may, if it considers it necessary in the public interest so to do, publish 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.

(3) The Government may, if it consider it necessary in the public interest so to do, publish for public information and to pass such orders relating to a drug or to the use of a drug in specified circumstances.

37. **Cancellation or suspention of licence.-** 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 nature that the manufacture or sale of any drug by such person is, in the opinion of the licensing authority or the Licensing Board, likely to endanger public health, the authority may after giving such person an opportunity of being heard, cancel the license to manufacture or sell drugs issued to such person or suspend the license for a specific period.

38. **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 drugs or suspend such registration for a specified period.

## CHAPTER V

## MISCELLANEOUS

39. **Power of the government to make rules.-** (1) The 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 the drugs;

(b) The qualifications and the procedure, for exercise or powers and performance of functions of the inspector;

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

(d) The conditions to regulate sale or storage or distribution of drugs or any specified drugs 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 licenses for the sale or distribution of drugs, or any specified drugs or clause of drugs, the authority empowered to issue the same and form of applications for such licenses, the fee payable therefor and the conditions subject to which such licenses may be issued;

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

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

40. **Removal of difficulties.-** If any difficulty arises in giving effect to any provision of this Act, the Government may make such orders or issue such directives not inconsistent with the provisions of this Act, as may appear to it to be necessary or expedient for the purpose of removing the difficulty.

41. **Repeal.-** The Azad Jammu and Kashmir Drugs Ordinance (No. IV of 1977) is hereby repealed.

Sd/-
(Muhammad Idbrahim Khan)
President
Azad Jammu and Kashmir

Sd/-
(Sardar Aftab Ahmed Khan)
Secretary,
Law and Parliamentary Affairs,
Azad Govt. of the State of J&K