

## **Control of Narcotic Substances (Regulation of Drugs of Abuse, Controlled Chemicals, Equipment and Materials) Rules, 2001**

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**S. R. O. 808 (I)/2000 dated 26-11-2001.**---In exercise of the powers conferred by section 77 of the Control of Narcotics Substances Act, 1997 (XXV of 1997), read with sections 4, 6, sub-section (2) of section 7 and 10 thereof, the Federal Government is pleased to make the following rules, namely:--

### **Comments**

*Ephedrine was a controlled chemical/narcotic substance. Approvers had fulfilled all the codal formalities as provided in S.337, Cr. P. C.; as such their statements would have evidentiary value and would be material and relevant for consideration. Elements of mala fide could not be attached with the officials of investigation agency, as they would not have been benefited by replacing the accused from his candidature of Prime Minister. Pre-arrest bail could only be granted if the proposed arrest was for ulterior motives such as humiliation and unjustified harassment by a prosecuting agency, motivation for which was to cause irreparable injury to reputation and liberty of the accused person. Said elements were missing in the present case rather had not been raised by accused and co-accused. Prima facie, accused and co-accused had misused their status and by their unauthorized and illegal acts the commission of alleged offence was made possible. Purpose of effective and meaningful investigation into the case could not be achieved by putting accused and co-accused at large. Accused and co-accused were denied bail, in circumstances.<sup>1</sup>*

*Percentage of morphine present in poppy capsules or poppy straw not to be necessarily proved by prosecution. Control of Narcotic Substances (Regulation of Drugs of Abuse, Controlled Chemical, Equipment and Materials) Rules, 2001, had been framed to regulate cultivation, acquisition and supply under a licence. If any person had acquired possession of poppy straw or poppy capsules after mowing without a licence issued, by the competent Authority; his possession would be culpable under S. 6 of the Control of Narcotic Substances Act, 1997, punishable under the clauses (a), (b) and (c) of S.9 in accordance with weight of such stuff in respective of percentage of morphine, because sub-clause (iii) of S.2(t) of the said Act related to the mixture proposed, with or without natural material; of any of the form of opium defined in sub-clauses (i) and (ii) which is an independent clause not affecting definition of 'opium' as contained in clauses (i) and (ii) therefore it is not essential for the prosecution to prove*

*percentage of morphine present in poppy capsules or poppy straw.<sup>1</sup>*

*Licence holder of opium quota cannot claim release of his full quota of opium after enactment of Rules/2001. His licence for opium would have no validity after the enactment of Rules/2001. Single Judge would be right in dismissing writ petition filed by licence holder for release of his full quota on ground that case was covered by the Rules/2001. Division Bench upholding judgment of Single Judge and dismissing intra-Court appeal filed to challenge it.<sup>2</sup>*

### **Chapter 1.---PRELIMINARY**

**1. Short title and Commencement.**---(1) These rules may be called the Control of Narcotic Substances (Regulation of Drugs of Abuse, Controlled Chemicals, Equipment and Materials) Rules, 2001.

(2) These rules shall come into force at once.

**2. Definitions.**---(1) In these rules unless there is anything repugnant in the subject or context:--

(i) "Act" means Control of Narcotics Substances Act, 1997 (XXV of 1997);

(ii) "analogue" means any substance not listed in any Schedule of these rules whose chemical structure is substantially similar to any drug of abuse whose psychoactive effect it simulates;

(iii) "animal" includes fish, birds, invertebrates or other fauna;

(iv) "Competent Authority" means the authority notified in the official Gazette by the Federal Government to discharge various functions including registration, licensing and import, export or transit permit authorisation, etc., under these rules;

(v) "controlled chemical" means a substance listed in Schedule V and includes a controlled chemical preparation;

(vi) "controlled equipment" means anything listed as such in Schedule VI;

(vii) "controlled material" means anything listed as such in Schedule VI;

- (viii) "Convention State" means a State which is a party to the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic substances, 1988;
- (ix) "cultivate" includes planting, sowing, scattering the seed, growing, nurturing, tending or harvesting, and also includes the separating of opium, coca leaves, cannabis and cannabis resin from the plants from which they are obtained;
- (x) "data" means representations, in any form, of information or concepts;
- (xi) "dentist" means any person who is registered under the Medical and Dental Council Ordinance, 1962 (XXXII of 1962), and entitled to practice the profession of dentistry;
- (xii) "drug dependent person", in relation to a drug of abuse or analogue, means any person who has such a condition that:-
- (a) administration of the drug to him or her results in the person demonstrating impaired control in relation to the use of that drug, or drug-seeking behaviour suggesting such impaired control; or
  - (b) cessation of the administration of the drug is likely to result in the person experiencing symptoms of mental or physical distress or disorder;
- (xiii) "drug of abuse" means a prohibited drug, a high-risk drug, or a risk drug, and includes a preparation;
- (xiv) "Encapsulating machine" means any device which may be used to fill shells, capsules or other containers with a drug of abuse or analogue in whatever physical form;
- (xv) "foreign State" means:--
- (a) any country other than Pakistan; and
  - (b) every constituent part of such country, including a territory, dependency or protectorate, which administers its own laws relating to drugs of abuse, analogues, controlled equipment and controlled materials;

- (xvi) "high-risk drug" means a substance listed in Schedule II;
- (xvii) "Inspector" means any person appointed under rule 44;
- (xviii) "institution" means a hospital, nursing home or other institution used for the accommodation, treatment and care of persons suffering from physical or mental conditions;
- (xix) "International Drug Control Conventions" means:--
  - (a) The Single Convention on Narcotic Drugs done at New York on the 30th March, 1961, as amended by the 1972 Protocol amending the Single Convention done at Geneva on the 25th March 1972;
  - (b) The Convention Against Phychotropic substances done at Vienna on the 21st February, 1971;
  - (c) The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances done at Vienna on the 20th December 1988; and
  - (d) Any other international convention to which Pakistan may become party after the commencement of these rules relating in whole or in part to the control of drugs of abuse, controlled chemicals or controlled equipment;
- (xx) "medical practitioner" means any person who is registered under the Medical and Dental Council Ordinance, 1962 (XXXII of 1962), and entitled to practice the profession of medicine;
- (xxi) "open individual authorization" means an authorization permitting an operator to export from Pakistan such quantities of such controlled chemicals, equipment or materials to such countries or regions during such periods as may be specified in the authorization;
- (xxii) "operator" means any person who carries on a business of the manufacture, acquisition or supply of:--
  - (a) a drug of abuse, intended for medical, scientific use or other lawful use; and

- (b) a controlled chemical or any item of controlled equipment or controlled material, intended for lawful use;
- (xxiii) "permit" means a permit of the kind referred to in rules 12, 13, 14 or 15 of the rules, as the case may be;
- (xxiv) "person" means any natural or legal person;
- (xxv) "pharmacist" means any person who is registered under the Pharmacy Act, 1967 (XI of 1967) and entitled to practise the profession of pharmacy;
- (xxvi) "place" includes any land (whether vacant enclosed or built upon, or not), and any premises;
- (xxvii) "practitioner" means:--
  - (a) a dentist, medical practitioner or veterinary surgeon;
  - (b) any person who is entitled under the laws of Pakistan to practice any other profession whose members may lawfully prescribe, dispense or administer any drug of abuse;
- (xxviii) "premises" includes the whole or any part of a structure, building, aircraft, or vessel;
- (xxix) "prescription" means a written direction by a practitioner that a stated amount of a drug of abuse be dispensed for the person named therein;
- (xxx) "preparation" means a solution or mixture, in whatever physical state, containing:--
  - (a) a drug of abuse; or
  - (b) a controlled chemical ;
- (xxxi) "prohibited drug" means a substance specified in Schedule I;
- (xxxii) "record" means any material on which data are recorded or marked and which is capable of being read or understood by a person, computer system or other device;

- (xxxiii) "risk drug" means a substance specified in Schedule III;
- (xxxiv) "Schedule" means a Schedule to these rules;
- (xxxv) "supply" includes sale, consignment, despatch, transport, delivery, distribution, dispensing, as well as offer to supply;
- (xxxvi) "tableting machine means any device which may be used to compact of mould a drug of abuse or analogue into a solid tablet;
- (xxxvii) "toxic chemical inhalant" means a substance specified in Schedule IV.;
- (xxxviii) "transit" means the physical transfer of any drug of abuse, analogue, controlled chemical or controlled material into, and out of, the territory of Pakistan:--
- (a) without it passing through Pakistan Customs; and
  - (b) where Pakistan is neither its country of origin nor destination
- (xxxix) "veterinary surgeon" means any person who is registered under the Pakistan Veterinary Medical Council Act, 1962 (III of 1996), and entitled to practise the profession of veterinary medicine; and

(2) The words and expressions used but not defined in these rules shall have the same meaning as are respectively assigned to them under the Act.

## **CHAPTER 2.---CLASSIFICATION AND SCHEDULING OF DRUGS OF ABUSE AND CONTROLLED CHEMICALS**

**3. Classification of Drugs of abuse and controlled chemicals.--**(1) Each of the drugs of abuse to which these rules apply is classified by the Schedule in which it appears under its international non-proprietary name or, lacking such a name, under its scientific name.

(2) Different measures of control are specified in these rules for different drugs of abuse according to the classification so adopted, with the strictest measures being applied in relation to drugs of abuse specified in Schedule I, less strict measures in relation to those specified in Schedule II, and the least strict in relation to those specified in Schedule III.

(3) Each of the controlled chemicals to which these rules apply is classified by the divisions of Schedule V in which it is specified.

(4) Different measures of control are provided for in these rules for different controlled chemicals, according to the classification so adopted in that pre-export notification of the competent authority of exports of controlled chemicals, is required for those controlled chemicals specified in Division I of Schedule V, measures of control relating to registration or licensing as provided in rules 5, 6, and 7; reporting of material changes as provided in rule 19, suspicious transactions as provided in rule 21 and loss or theft as provided in rules 41 and 43 ; documentation and labeling, record-keeping as provided in rules 26, 27, 28, 29, 30, 34 and 35 generally apply in respect of all such chemicals, equipment and materials, and any supplementary control measures provided for in the rules for the regulatory oversight of lawful trade in controlled chemicals, controlled equipment and controlled materials (open individual authorization) as provided in rule 16, or import, export, transit or re-direction permits as provided in rules 7, 11 and 13 shall apply only if the competent authority so determines under sub-rule (1) of rule 5.

**4. Preparations.**---(1) Preparations shall be subject to the same measures of control, under these rules, as the drugs of abuse or controlled chemicals they contain, and where any preparation contains two or more constituent drugs of abuse, it shall be subject to the measures governing the most strictly controlled constituent.

(2) The competent Authority may, by order in writing, exempt any preparation containing:--

(a) a drug of abuse specified in Schedule II or III from such measure of control provided in these rules, when the Competent Authority is satisfied that:--

(i) the preparation is compounded in such a way as to present no or negligible risk of abuse; and

(ii) The drug of abuse cannot be readily recovered from it in a quantity liable to present such a risk; and

(b) a controlled chemical, when the Competent Authority is satisfied that it is in such a state that the chemical cannot easily be used for the illicit manufacture of a drug of abuse.

(3) The Competent Authority shall not exempt any preparation, under sub-rule (2):--

- (a) In so far as it relates to the manufacture, import or export of preparations containing high risk drugs or risks drugs, or the making and keeping of records relating to such activities; and
- (b) otherwise, except to the extent if any to which it may be exempted under any international drug control convention applicable to the particular preparation or class of preparation.

(4) The Competent Authority shall maintain a register of the preparation exempted under this section, specifying in relation to each such preparation each control measure from which it is exempted.

### **CHAPTER 3.---REGISTRATION, LICENSING AND PERMIT SYSTEM**

**4. Requirement for registration, licensing etc., of controlled chemical, equipment and materials operators.---**(1) To help and ensure that there is no significant risk that controlled chemicals, equipment and materials may be diverted from lawful use to the unlawful manufacture of any drug of abuse in Pakistan or elsewhere, the Competent Authority, by notice published in the official Gazette, may determine in relation to any operator or class of operators which control measures, or combination of measures specified in sub-rule (2), shall apply for the purposes of this Chapter.

(2) The following control measures, or combination of control measures, which the Competent Authority may determine, shall apply for the purposes of sub-rule(1) namely.--

- (a) registration, under rule 6;
- (b) the grant of a licence, under rule 9, or
- (c) in the case of import and export activities registration or licensing, and:--
  - (i) an open individual authorization issued to the operator by Competent Authority under rule 16 for all such activities:

Provided that the Competent Authority may, by written notice, restrict the open authorization temporarily or indefinitely, to one of such activities, involving such chemicals, equipment or materials or countries as the Competent Authority may specify in the notice;

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- (ii) a permit for each intended import or export transaction, or for each transit or redirection, issued under rules 12 or 13;
- (iii) an export permit for each intended export transaction, conditional on the prior receipt of an import certificate issued by the competent authorities of the country of intended import; or
- (iv) a pre-export notification made by the operator to the Competent Authority in accordance with the prescribed form in Annexure II, within a prescribed period before each export transaction.

(3) In determining, which control measure shall apply in cases under such rule (2), the competent authority shall consider:

- (a) the likely quantities and ultimate use (lawful or unlawful) of the controlled chemicals, equipment or materials involved;
- (b) in the case of transit or export, the countries or regions to which any such chemicals, equipment or materials are likely to be destined, particularly if they are ones in which drugs of abuse or the raw materials for making them are believed to be illicitly produced;
- (c) the commercial experience and integrity of operators and their staff, including their experience in dealing with the chemicals, equipment or materials concerned; and
- (d) any other relevant matter.

(4) No operator shall manufacture, import, export, acquire, supply or possess any controlled chemical or item of controlled equipment or materials except in pursuance of, and in accordance with, the relevant control measure determined by the Competent Authority under sub-rule (2).

(5) The Competent Authority may, by notification in the official Gazette, add such terms and conditions to any control measures as it thinks fit, including the those which limit or prohibit imports or exports of specified chemicals or specified quantities thereof, whether to or from specified countries, persons or classes of persons, or during specified periods.

(6) The Competent Authority, by notice published in the official Gazette, may exempt any operator or class of operator other than those whose business include the manufacture, import or export of any controlled

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chemical, controlled equipment or controlled material from the operation of these rules, if satisfied, that such exemption would not give rise to any significant risk of unlawful diversion.

(7) This rule does not apply to the following classes of persons in relation to the following activities, except to the extent if any to which their activities include the import or export of any controlled chemical, controlled equipment or controlled material namely:---

- (a) a pharmacist, acting in accordance with the norms and standards of the pharmacy profession, in the ordinary course of compounding and dispensing preparation containing a drug of abuse for medical, scientific or related purposes;
- (b) any person who holds a license issued under these rules to manufacture a preparation containing a drug of abuse of which a controlled substance is an essential ingredient, in the ordinary course of such manufacture; and
- (c) any person engaged in the conduct of scientific education or research in a laboratory which is attached to a university or hospital, and whose activities are recognized by the Competent Authority, in the ordinary course of such education or research.

**6. Registration of controlled chemical, equipment and material operators.**---An Operator, who is required to be registered for the purposes of these rules in respect of the manufacture, import, export, acquisition supply or possession of any controlled chemical or item of controlled equipment or controlled material shall, before undertaking any such activity within ten working days from the day on which these rules come into force, intimate the Competent Authority in writing with the following particulars, namely:--

- (a) the full name, private and business address of the operator;
- (b) the activity for which registration is sought;
- (c) if the operator is a company, the full name and residential address of each director and of the company secretary;
- (d) if the operator will engage in the activity, under a business name, that name;
- (e) each controlled chemical or item of controlled equipment or material for which registration is sought;

- (f) the address of each place where the controlled chemical or item of controlled equipment or material is to be stored;
- (g) whether the person or if a company, any director or secretary of the company, has ever been convicted in Pakistan or elsewhere of an offence under Chapter II of the Act or any offence however described relating to trafficking in drugs, controlled chemicals, controlled equipment or controlled material; and
- (h) such other particulars as the Competent Authority may require.

(2) Subject to sub-rule (3), on receipt of a notification made in accordance with sub-rule (1), the Competent Authority shall register the operator, include particulars of the notification in the register, and give notice of registration to the operator.

(3) The Competent Authority may refuse to register any operator and in case of a company, any director or secretary of the company as the case may be, who has ever been convicted of any offence referred to in clause (g) of sub-rule (1).

**7. Requirements of licences and permits for drugs of abuse operators.---**Subject to sub-rule (2), no operator shall:--

- (a) cultivate any cannabis plant coca bush or opium poppy or;
- (b) manufacture, acquire or supply any drug of abuse, except pursuant to, and in accordance with, the terms and conditions of a licence granted by the Competent Authority under rule 9.

(2) Sub-rule (1) does not apply to professional supply by authorized persons pursuant to such-rule (1) of rule 23.

(3) No operator shall import, export, bring into Pakistan in transit, or redirect from Pakistan while in transit, any drug of abuse, except pursuant to, and in accordance, with any terms and conditions of:--

- (a) a license issued by the Competent Authority under rules 9 authorizing the applicant to carry out such activities in general; and
- (b) a separate import permit, export permit, transit permit or redirection permit, as the case may be, authorizing the

applicant to carry out the specific transaction the subject of the permit application.

(4) Nothing in sub-rule (2) shall apply in relation to any drug of abuse in transit by post or forming part of the medical stores of any ship or aircraft.

**8. Application for operators licence.---**(1) An operator who is required by these rules to be licenced shall apply in writing to the Competent Authority for the grant of a licence and shall state:--

- (a) the full name, private and business address of the applicant;
- (b) each activity to which the application relates;
- (c) if the applicant is a company, the full name and residential address of each director and secretary of the company;
- (d) if the applicant proposes to engage in the activity under a business name, that name;
- (e) the drug of abuse, controlled chemical or item of controlled equipment or controlled material to which the application relates;
- (f) the address of each:
  - (i) place where the proposed activity would be carried out ; and
  - (ii) premises where the drug of abuse, controlled chemical or item of controlled equipment or controlled material would be stored;
- (g) the security arrangements that would be implemented at each address;
- (h) the name, residential address and qualification of each person under whose supervision the activity would be carried out; and
- (i) such other particulars as may be prescribed (eg volume estimates in the forthcoming year, and volume statistics for the past year ; in the case of cultivation, eg the geographical location, land surface area, as well as the storage location and ultimate destination of the harvest ;

and in the case of manufacture, the extraction, manufacturing and denaturing procedure to be used, name and quantities of the substances and raw materials to be used, estimates relating to each drug of abuse and preparation produced, etc.).

(2). An application for licence shall be accompanied by :--

- (a) a plan of each of the relevant premises, indicating where the drug of abuse, controlled chemical or item of controlled equipment or controlled material would be stored, and the location and nature of any security devices; and
- (b) the prescribed fee.

**9. Grant of licence.**---Where an application has been made in accordance with rule 8, the Competent Authority may grant a licence if it is satisfied that:--

- (a) the applicant and, if a company, each director and secretary of the company:--
  - (i) has never been convicted in Pakistan or elsewhere of any serious offence, or any offence, relating to a drug of abuse, controlled chemical or item of controlled equipment or controlled material; and
  - (ii) is otherwise a fit and proper person to hold a licence;
- (b) the applicant proposes to engage in the activity;
- (c) all places and premises at or in which the activity is to be undertaken are in fit condition and appropriate;
- (d) the security arrangements and devices proposed at each relevant place and premises are appropriate and sufficient;
- (e) the activity shall at all times be carried out under the supervision of a person who is a fit and proper person to carry out that supervision; and
- (f) where the activity relates to a drug of abuse, the activity shall be carried out exclusively for medical or scientific purposes.

**10. Contents and conditions of licences.**---(1) A licence issued by the Competent Authority under rules 9 shall specify:--

- (a) the full name and address of the licensee;
- (b) each activity to which the licence relates;
- (c) the drug of abuse, controlled chemical or item of controlled equipment or controlled material to which the licence relates;
- (d) the address of each place and premises at which:--
  - (i) the licensed activity is to be carried out; and
  - (ii) the drug of abuse, controlled chemical or item of controlled equipment, controlled materials is to be stored;
- (e) such terms and conditions as are necessary and reasonable for ensuring the proper:--
  - (i) carrying out and supervision of the licensed activity;
  - (ii) establishment, maintenance and preservation of record relating to that activity;
  - (iii) reporting to the Competent Authority in relation to the carrying out of that activity;
  - (iv) maintenance and security of all places and premises at or in which the licensed activity will be carried out;
- (f) in the case of any licence to import, export or bring to Pakistan in transit a drug of abuse, controlled chemical or item of controlled equipment of controlled material, the condition that a separate import, export or transit permit be first obtained in relation to any such transaction before it takes place; and
- (g) such other particulars as the Competent Authority may, by order in writing, require.

**11. Applications for import, export or transit permits.**---

(1) An application for an import, export or transit permit shall be made in writing to the Competent Authority specifying therein:--

- (a) the full name and address of the importer, exporter, carrier, consignee and, if known, of any ultimate consignee;
- (b) in the case of a proposed import, export or transit of a drug of abuse:
  - (i) its international non-proprietary name or failing this, its name as listed in Schedule II or III, together with its trade name, if it has one; and
  - (ii) its pharmaceutical form;
- (c) in the case of proposed import, export or transit of a controlled chemical, the name as specified in Schedule V and trade name;
- (d) in the case of a proposed export of a drug of abuse, the intended point of entry in the foreign State of intended import;
- (e) the quantity, mass and volume or percent in mixture of any drug of abuse, controlled, chemical or controlled material that is the subject of the proposed operation;
- (f) a description quantity and type of any controlled equipment that is the subject operation;
- (g) the date, or period within which, the planned import, export or transit is to take place;
- (h) the planned transport route, if known, including the planned point of entry or exit from Pakistan; and
- (i) in the case of a proposed import of a drug of abuse to a bonded warehouse, the identity and address of the warehouse.

(2) In the case of proposed export of a drug of abuse, the import permit, by whatever name described, issued by the Government of the foreign State of intended import shall be attached to the application for export permit.

**12. Grant of import, export or transit permits.**---(1) The Competent Authority may, on written application made in accordance with rule 11 by a registered or licensed importer or licensed exporter, grant an import permit, export permit, or transit permit as the case may be, in

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relation to a specified import or export transaction involving a drug of abuse, controlled chemical or item of controlled equipment or controlled material.

(2) An import permit, export permit or transit permit granted under sub-rule (1) may allow import, export or transit in more than one consignment.

(3) The Competent Authority shall not grant an export permit in relation to any consignment of a drug of abuse to a bonded warehouse in a foreign State, unless the competent authority of that State has certified on the import permit referred to in sub-rule (2) of rule 11 that it has approved the import to a bonded warehouse.

(4) An import permit, export permit or transit permit shall specify:--

(a) the full name and address of the registered or licensed operator to whom it is granted;

(b) the name, including any international non-proprietary name and trade name, quantity and form of any drug of abuse, controlled chemical or item of controlled equipment or controlled material for which it is granted;

(c) in the case of an import permit:--

(i) the name and address of the exporter; and

(ii) whether the import is to be effected in a single consignment or more than one consignment.

(d) in the case of an export permit:--

(j) the name and address of the immediate consignee, and if known, of the ultimate consignee;

(ii) the number and date of any required import permit, affirming that the import of the drug of abuse or preparation has been authorized;

(iii) the intend point of entry in the foreign State of import; and

(iv) if the export consignment is intended for a bonded warehouse and is not prohibited under sub-rule (3), that the consignment is to be so exported;



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relation to a specified import or export transaction involving a drug of abuse, controlled chemical or item of controlled equipment or controlled material.

(2) An import permit, export permit or transit permit granted under sub-rule (1) may allow import, export or transit in more than one consignment.

(3) The Competent Authority shall not grant an export permit in relation to any consignment of a drug of abuse to a bonded warehouse in a foreign State, unless the competent authority of that State has certified on the import permit referred to in sub-rule (2) of rule 11 that it has approved the import to a bonded warehouse.

(4) An import permit, export permit or transit permit shall specify:--

(a) the full name and address of the registered or licensed operator to whom it is granted;

(b) the name, including any international non-proprietary name and trade name, quantity and form of any drug of abuse, controlled chemical or item of controlled equipment or controlled material for which it is granted;

(c) in the case of an import permit:--

(i) the name and address of the exporter; and

(ii) whether the import is to be effected in a single consignment or more than one consignment.

(d) in the case of an export permit:--

(j) the name and address of the immediate consignee, and if known, of the ultimate consignee;

(ii) the number and date of any required import permit, affirming that the import of the drug of abuse or preparation has been authorized;

(iii) the intend point of entry in the foreign State of import; and

(iv) if the export consignment is intended for a bonded warehouse and is not prohibited under sub-rule (3), that the consignment is to be so exported;

- (e) the period during which import or export is to be made;
- (f) in the case of an intended import to a bonded warehouse, a term that:--
  - (i) any subsequent withdrawal from the bonded warehouse shall require a permit from the Competent Authority; and
  - (ii) if the withdrawal is intended for a foreign destination, a separate export permit shall be first obtained prior to export;
- (g) such terms and conditions as the Competent Authority may consider necessary and reasonable; and
- (h) such other particulars as the Competent Authority may, by order in writing, require.

**13. Redirection permits.**---(1) The Competent Authority may, on production by a licensed operator of a valid import authorization issued by an authority in the foreign State to which it is proposed to redirect a drug of abuse or controlled chemical, issue a redirection permit in respect of the drug of abuse or controlled chemical in transit.

- (2) A redirection permit shall specify:--
  - (a) the full name and address of the registered or licensed operator to whom it is granted;
  - (b) the name, including any international non-proprietary name and trade name, quantity and form of any drug of abuse, controlled chemical or item of controlled equipment or controlled material for which it is granted;
  - (c) the name and address of the immediate consignee, and if known, of the ultimate consignee;
  - (d) the number and date of any required import permit affirming that the import of the drug of abuse or controlled chemical or item of controlled equipment or controlled material has been authorized;
  - (e) the intended point of entry, in the foreign State of import;

- (e) the period during which import or export is to be made;
- (f) in the case of an intended import to a bonded warehouse, a term that:--
  - (i) any subsequent withdrawal from the bonded warehouse shall require a permit from the Competent Authority; and
  - (ii) if the withdrawal is intended for a foreign destination, a separate export permit shall be first obtained prior to export;
- (g) such terms and conditions as the Competent Authority may consider necessary and reasonable; and
- (h) such other particulars as the Competent Authority may, by order in writing, require.

**13. Redirection permits.**---(1) The Competent Authority may, on production by a licensed operator of a valid import authorization issued by an authority in the foreign State to which it is proposed to redirect a drug of abuse or controlled chemical, issue a redirection permit in respect of the drug of abuse or controlled chemical in transit.

- (2) A redirection permit shall specify:--
  - (a) the full name and address of the registered or licensed operator to whom it is granted;
  - (b) the name, including any international non-proprietary name and trade name, quantity and form of any drug of abuse, controlled chemical or item of controlled equipment or controlled material for which it is granted;
  - (c) the name and address of the immediate consignee, and if known, of the ultimate consignee;
  - (d) the number and date of any required import permit affirming that the import of the drug of abuse or controlled chemical or item of controlled equipment or controlled material has been authorized;
  - (e) the intended point of entry, in the foreign State of import;

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- (f) if the export consignment is intended for a bonded warehouse and is not prohibited under sub-rule (3), that the consignment is to be so exported;
- (g) the period during which import or export is to be made;
- (h) in the case of an intended import to a bonded warehouse, a term that:--
  - (i) any subsequent withdrawal from the bonded warehouse shall require a permit from the Competent Authority; and
  - (ii) if the withdrawal is intended for a foreign destination, a separate export permit shall be first obtained prior to export;
- (i) such terms and conditions as the Competent Authority may consider necessary and reasonable; and
- (j) such other particulars as may be prescribed.

(3) The Competent Authority shall not issue a redirection permit under sub-rule (1) unless it is satisfied that the drug of abuse or controlled chemical is to be sent to the new country of destination in a lawful manner and for a proper purpose.

**14. Permits in relation to first-aid kits.---**(1) The Competent Authority may, on written application made in the prescribed form, grant a permit to include a drug of abuse in a first-aid kit for medical use during international flights or voyages.

- (2) A permit to include a drug of abuse in a first-aid kit shall specify:--
- (a) the full name and address of the authorized person;
  - (b) the name and maximum quantity of the drug of abuse that may be kept in the first aid kit at any one time;
  - (c) such terms and conditions as are necessary and reasonable to ensure the proper use and safe keeping of the drug of abuse; and
  - (d) such other particulars as may be prescribed.

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- (f) if the export consignment is intended for a bonded warehouse and is not prohibited under sub-rule (3), that the consignment is to be so exported;
  - (g) the period during which import or export is to be made;
  - (h) in the case of an intended import to a bonded warehouse, a term that:--
    - (i) any subsequent withdrawal from the bonded warehouse shall require a permit from the Competent Authority; and
    - (ii) if the withdrawal is intended for a foreign destination, a separate export permit shall be first obtained prior to export;
  - (i) such terms and conditions as the Competent Authority may consider necessary and reasonable; and
  - (j) such other particulars as may be prescribed.
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  - (d) such other particulars as may be prescribed.

**15. Permits in relation to programmes for medical and scientific purposes.**---(1) The Competent Authority may, on written application made in the prescribed form by a person, grant a permit to conduct a programme for scientific or strictly limited medical purposes that would require cultivation of:--

(a) a drug of abuse, or

(b) an analogue;

(2) An application to conduct such a programme shall specify:-

(a) the full name, address, academic, professional or other relevant qualifications of the applicant;

(b) the drug of abuse or analogue in relation to which the permit is sought;

(c) the strength and form in which the drug of abuse or analogue is to be used;

(d) the maximum quantity of the drug of abuse or analogue to be possessed at any one time, and the total quantity to be possessed during the period of the programme;

(e) details of the manner in which the drug of abuse or analogue would be used;

(f) the name and address of the place where the programme is to be conducted;

(g) the name and academic, professional or other relevant qualifications of any person other than the applicant, under whose supervision the programme would be conducted; and

(h) the security arrangements that would be undertaken while the drug of abuse or analogue is possessed, used or disposed of.

(3) An application to conduct such a programme shall be accompanied by:--

(a) a written description of the programme, including its estimated duration;

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(a) a drug of abuse, or

(b) an analogue;

(2) An application to conduct such a programme shall specify:--

(a) the full name, address, academic, professional or other relevant qualifications of the applicant;

(b) the drug of abuse or analogue in relation to which the permit is sought;

(c) the strength and form in which the drug of abuse or analogue is to be used;

(d) the maximum quantity of the drug of abuse or analogue to be possessed at any one time, and the total quantity to be possessed during the period of the programme;

(e) details of the manner in which the drug of abuse or analogue would be used;

(f) the name and address of the place where the programme is to be conducted;

(g) the name and academic, professional or other relevant qualifications of any person other than the applicant, under whose supervision the programme would be conducted; and

(h) the security arrangements that would be undertaken while the drug of abuse or analogue is possessed, used or disposed of.

(3) An application to conduct such a programme shall be accompanied by:--

(a) a written description of the programme, including its estimated duration;

- (b) in the case of a programme of research, a research protocol;
- (c) in the case of a clinical trial, a clinical trial protocol; and
- (d) a written statement approving the programme, signed by the person Incharge of the institution.

(4) The Competent Authority may authorize such a programme if satisfied that:--

- (a) the programme cannot be carried out satisfactorily without the use of the specified drug of abuse or analogue;
- (b) the programme is scientifically viable having regard to any relevant protocol;
- (c) the applicant is a fit and proper person to conduct the programme;
- (d) the programme will be adequately supervised; and
- (e) the programme is to be conducted at, or under the auspices of, a recognized institution.

(5) A permit shall specify:--

- (a) the full name and address of the authorized person;
- (b) the drug of abuse or analogue to which the permit relates;
- (c) the strength and form in which the drug of abuse or analogue may be used;
- (d) the maximum quantity of the drug of abuse or analogue that may be possessed at any one time, and the total quantity that may be possessed during the period of the programme;
- (e) the purpose for which the permit is granted;
- (f) the institution in relation to which the permit is granted;



- (g) such conditions as are necessary and reasonable for ensuring:
  - (i) the proper use and safe-keeping of the drug of abuse or analogue; and
  - (ii) that proper records are kept concerning its receipt, use and disposal;
- (h) the condition that such reports, as the Competent Authority may specify, are sent to him or her on the use of the drug of abuse or analogue in the programme, including particulars of the quantities acquired, used, disposed of and still hold; and
- (i) such other particulars as may be prescribed.

**16. Open individual authorization for certain exports of controlled chemicals, etc.**---(1) Where an operator is required under rule 5 sub-rule (1) to hold an open individual authorization issued by the Competent Authority, the operator shall, before undertaking any activity for which the authorization is required/within ten days from the day on which these rules come into force, intimate the Competent Authority in writing of, stating therein:--

- (a) the full name, private and business address of the operator;
- (b) the activity for which authorization is sought;
- (c) if the operator is a company, the full name and residential address of each director and secretary of the company;
- (d) if the operator engage in the activity under a business name, that name;
- (e) each controlled chemical or item of controlled equipment or material for which authorization is sought;
- (f) details of the operator's commercial experience relevant to the controlled chemicals, equipment of materials concerned, and of each person under whose supervision the activity will be carried out;
- (g) details in summary form of export transactions in the relevant chemicals, equipment of materials during the preceding twelve months, specifying the country of export

in relation to each chemical or item of equipment or material exported, the total quantities and total number of transactions involved; and

(h) such other particulars as may be prescribed.

(2) Subject to sub-rule (3), on receipt of an application made in accordance with sub-rule (1), the Competent Authority may:--

(a) grant an open individual authorization; and

(b) subject the authorization to such terms and conditions as it thinks fit.

(3) The Competent Authority may refuse to grant the open individual authorization, if the operator, or if a company, any director or secretary of the company has ever:--

(a) failed to comply with a provision of these rules or any other law in Pakistan relating to any drug abuse, controlled chemical or item of controlled equipment or material; or

(b) been convicted in Pakistan or elsewhere of any serious offence of any offence relating to trafficking in drugs, or controlled chemicals, equipment or material.

**17. Extended Authorization for Related Activities.---**

Where a person is registered or licenced, or holds a permit or authorization under these rules in relation to any activity, the person shall, subject to these rules and to any terms and conditions of the licence, permit or authorization, be deemed to be entitled to possess the relevant drug of abuse, analogue, controlled chemical or item of controlled equipment or material for the purpose of that activity.

**18. Duration of registration, licences, permits and open individual authorizations.---**

(1) A registration or licence shall remain in force for a period of one year, unless earlier surrendered, suspended or revoked, and may successively renewed for a period of one year on application in writing, signed by the applicant and accompanied with the prescribed fee.

(2) A permit or open individual authorization shall only remain in force for such period as may be specified in it, which in the case of an import permit, export permit or transit permit shall not exceed six months.

**19. Duty of authorized persons to notify material changes, etc.**-(1) Where, in relation to any licence or permit granted to any person under these rules, a material change occurs in the:--

- (a) name or address of the person, or in the case of a company, of any director or secretary of the company;
- (b) address of the place or premises where:--
  - (i) the licensed or permitted activity is carried out; or
  - (ii) any drug of abuse, controlled chemical or item of controlled equipment or material is stored;
- (c) raw materials, or manufacturing or denaturing processes used in the licenced manufacture of any drug of abuse;
- (d) security arrangements implemented at any relevant address;
- (e) identity of persons under whose supervision the licensed activity is carried out; or
- (f) planned transport route, including the planned point of entry or exit from Pakistan or any import, export or transit consignment for which a permit has been granted under sub-rule (1) of rule 12;

the person shall, within fourteen days of its occurrence, furnish the Competent Authority with a written notice containing full particulars of the change, and shall return to the Competent Authority any licence or permit issued under these rules.

(2) Where, in relation to any registration or open individual authorization granted to any person under these rules, a material change occurs in the:--

- (a) name or address of the person, or in the case of a company, of any director or secretary of the company; or
- (b) address of the place or premises where:--
  - (i) the registered or authorized activity is carried out; or

- (ii) the controlled chemical, or item of controlled material or equipment is stored,

the person shall, within fourteen days of its occurrence, furnish with the Competent Authority with a written notice containing full particulars of the change.

**20. Variation, suspension or revocation of registration, licences, permits or authorizations.**---(1) If, at any time after the grant of a licence, permit, registration or open individual authorization, it appears to the Competent Authority that:--

- (a) it was granted on the basis of information that was false or misleading in a material particular;
- (b) a material change of circumstances referred to in rule 19 has occurred since it was granted, whether notified under that rule or not;
- (c) a condition to which it was subject has not been complied with; or
- (d) the person has been charged or convicted of an offence against the rules, or of a serious offence,

the Competent Authority may, as it thinks necessary and reasonable in all the circumstances to prevent the risk of unlawful diversion:--

- (i) impose conditions, or vary any existing conditions specified in the licence, permit or authorization, within twenty-eight days of the date of issue of a notice of variation;
- (ii) suspend the registration, licence, permit or authorization for such period as the Competent Authority deems fit; or
- (iii) revoke the registration, licence; permit or authorization.

(2) Any person whose licence, permit or authorization is suspended or revoked under sub-rule (1) shall return it to the Competent Authority within two days after the Competent Authority notifies the person in writing of the revocation or suspension.

**21. Duty of operators to check and notify suspicious orders and transactions.**---(1) Whenever an operator:--

- (a) is registered, licenced, permitted or authorized under these rules;
- (b) receives an order or becomes party to a transaction involving a drug of abuse, controlled chemical or item of controlled equipment or materials; and
- (c) has reasonable grounds to suspect that information, which is concerning the order or transaction may be relevant to an offence provided in Chapter II of the Act, the operator shall, immediately after forming that suspicion, communicate to the Competent Authority the particulars of the suspicion, the basis of it, and such other information, if requested, as the person has in relation to the order or transaction.

**22. Power to limit licensee's stocks.**---(1) On or before the 31st day of December each year, the Competent Authority shall, in the light of the prevailing market conditions determine the maximum quantities, if any, of each drug of abuse, controlled chemical, that each operator licenced under Chapter 1 of these rules may manufacture or stock for the normal conduct of its business during the following year.

(2) The Competent Authority may, at any time amend any quota determined under sub-rule (1), and shall promptly intimate each licensee in writing of the amended quota.

(3) The Competent Authority may, if satisfied that a person authorized to stock a drug of abuse holds a quantity in excess, of the annual quota as revised in accordance with sub-rule (2), it may requisition the surplus quantity upon payment of an amount not less than the amount paid by the person to acquire it.

#### **CHAPTER 4. – PROFESSIONAL SUPPLY OF DRUGS OF ABUSE**

**23 Persons authorized to engage in professional supply of drugs of abuse.**---(1) No person shall engage in conduct that constitutes professional supply of any drug of abuse except:--

- (a) a pharmacist, acting in accordance with the norms and standards of the pharmacy profession, who supplies to another person on prescription or on requisition, in the ordinary course of a pharmacy business;
- (b) a person licenced under clause (b) of sub-rule (1) of rule 7, provided that such supply at all times takes place under the immediate supervision of a pharmacist;

(c) a practitioner who, in accordance with the norms and standards of his or her profession:--

(i) administers the drug directly to a patient or animal in the ordinary course of treatment; or

(ii) supplies the drug to a patient or for an animal in the ordinary course of treatment from a place more than ten kilometers from the place of business of a pharmacist.

(2) Notwithstanding anything contained in sub-rule (1), where access to a practitioner is not reasonably possible by virtue of distance, the Competent Authority may authorize a licensed retail distributor to supply a drug of abuse without prescription, in exceptional cases for use by individuals in small quantities for exclusively medical purposes.

**24. Prescriptions.**---No person shall prescribe a drug of abuse, unless that person is:--

(a) a medical practitioner, who prescribes the drug of abuse in the ordinary course of treatment of another person's physical or mental condition;

(b) a dentist, who prescribes the drug of abuse in the ordinary course of treatment of another person's mental condition;

(c) a veterinary surgeon, who prescribes the drug of abuse in the ordinary course of treatment of an animal; or

(d) a person or class of persons which the Competent Authority may authorize, from time to time, for the purposes of this rules to prescribe certain drugs of abuse in places where access to a practitioner is not reasonably possible.

(2) A person referred to in sub-rule (1) shall not, except in:--

(a) a medical emergency; or

(b) in the ordinary course of treatment,

prescribe a drug of abuse to a person who, he has reason to believe, may be a drug dependent person, without the prior written approval of the Competent Authority.

(3) Subject to sub-rule (4), a prescription for a drug of abuse shall:--

- (a) be on a form prescribed by the Competent Authority;
- (b) be legible;
- (c) be written in terms and symbols used in ordinary professional practice;
- (d) specify the name, address, qualifications and registration number of the prescribing practitioner;
- (e) specify the date on which it is issued if different from the date on which it was signed, and the period during which it may be filled;
- (f) specify the name and address of the patient, or the owner of the animal being treated, as the case may be;
- (g) specify the name, quantity, form and strength of the drug of abuse;
- (h) specify the number of times up to a maximum of the three times, the drug of abuse may be refilled and, if more than once, the interval to elapse between dispensing;
- (i) if the prescription is for an unusual or dangerous dose, it shall bear the initials of the prescribing practitioner beside an underlined reference to the dose;
- (j) if the prescription is issued by a veterinary surgeon:--
  - (i) be endorsed as being for the treatment of an animal;
  - (ii) specify the name and address of the owner or caretaker of the animal;
  - (iii) specify the species of animal;
  - (iv) specify means of identifying the animal; and
- (k) be signed with date by the prescribing practitioner.

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(4) Where the need for treatment is urgent, a prescription may be given orally and acted upon, provided that is confirmed by a written prescription within twenty-four hours.

**25. Requisitions in an institution for purpose of treatment.--**(1) No person shall issue a requisition for a drug of abuse unless the person is:--

- (a) a pharmacist in a dispensary in an institution;
- (b) a practitioner practicing in an institution; or
- (c) a person in charge of a ward in an institution.

(2) A person shall not supply a drug of abuse against a requisition, except to a person referred to in sub-rule (1), at an institution for the treatment of a person therein.

(3) Subject to sub-rule (4), a requisition for a drug of abuse shall:--

- (a) be legible;
- (b) specify the name of the person issuing it and the capacity in which he or she issues it;
- (c) specify the name, quantity, form and strength of the drug of abuse;
- (d) specify the ward or dispensary where the drug is required;
- (e) be signed with date by the person issuing it; and
- (f) be countersigned by either the pharmacist who is to supply the drug of abuse, or a medical practitioner.

(4) Where the need for the drug of abuse is urgent, a requisition may be given orally and acted upon, provided that, it is confirmed by a written requisition within twenty four hours.

**CHAPTER 5. -- COMMERCIAL DOCUMENTATION AND LABELLING, RECORDS AND SECURITY**

**26. Commercial documents.---**Any commercial document, such as an invoice, cargo manifest or a customs, transport and other shipping document, relating to any transaction by an operator involving a



drug of abuse, controlled chemical or item of controlled equipment, shall include:--

- (a) the name and quantity of the drug of abuse, controlled chemical or item of controlled equipment as specified in the relevant Schedule; and
- (b) in the case of any import or export, the name and address of the exporter, the importer and, where known, the consignee.

**27. Forwarding of import permit in advance to proposed foreign exporter.**---Where the Competent Authority issues an import permit under these rules to an operator, the operator shall, as soon as possible but no later than five working days after its receipt forward the permit to the exporter named in the permit.

**28. Export permits to be attached to consignments.**---Where the Competent Authority issues an export permit under these rules to an operator, the operator shall attach an authenticated copy of the permit to each consignment on export.

**29. Endorsement and return of export permits following import.**---After an imported consignment has entered Pakistan or when the period stipulated in the import permit expires, the Competent Authority shall cause the export permit issued by the competent authority of the exporting country or territory to be returned to that authority, with an endorsement specifying the quantity of each drug of abuse or controlled chemical, equipment or material actually imported.

**30. Forwarding of redirection permits, etc.**---(1) Where a redirection permit is issued under sub-rule (1) of rule 13:--

- (a) one copy shall accompany the drug of abuse or controlled chemical when it is exported from Pakistan; and
- (b) the Competent Authority shall cause another copy of the redirection permit to be sent forthwith, upon issue, to the authority in the foreign country to which the consignment has been redirected.

(2) Upon the issue of a redirection permit, any person holding the export permit or redirection permit accompanying the drug or chemical, on its arrival in Pakistan shall remit it to the Competent Authority who shall return it to the competent authority issuing it, together with:--

**34. Disposal of export authorisation issued by foreign authority.**---When the importation of a drug of abuse, or controlled chemicals, equipment and material has been effected or when the period fixed for importation has expired, the importer shall submit to the Competent Authority the export authorisation, on the basis of which the import permit was granted to him, and thereon the Competent Authority shall return the authorisation with endorsement to the effect that the quantity of the drug as specified in the endorsement has actually been imported, or, as the case may be, that the said period has expired.

**35. Quantity actually exported.**---If a lesser quantity, than that specified in an export permit, is actually exported, the quantity actually exported shall be stated by the Customs authorities on the export permit and on any official copy thereof.

**36. Trans-shipment.**---(1) Subject to the provisions of section 72 of the Act and these rules, no drug of abuse, or controlled chemicals, equipment and material, as specified in the schedules of these rules, shall be trans-shipped at any port save with the permission of the Collector of Customs.

(2) The Collector of Customs shall not grant the permission, referred to in sub-rule (1), save under the special order in writing of the Competent Authority in each case, unless:

- (a) the country from which the drugs or substances have been shifted and country to which the drugs or the substances are consigned are signatories to and have ratified the UN Conventions of 1961, 1971, and 1988, on Narcotics Drugs/Psychotropic Substances; and
- (b) the drug are covered by an export authorisation or a diversion certificate granted in accordance with Article 31 of the Single Convention on Narcotics Drugs, 1961, by or under the authority of the Government of the country from which they have been shipped and such authorisation or certificate is produced for inspection of the Collector of Customs in accordance with the said Article 31.

**37. Processing or alteration or packing.**---No consignment of drug of abuse, or controlled chemicals, equipment and material while in transit or while stored in a bounded warehouse, shall be subjected to any process which would change the nature of the drugs, nor shall the packing of any such consignment be altered without the permission, in writing, of the Competent Authority.

- (a) a notice of the name of the foreign country to which the consignment has been redirected; and
- (b) an endorsement specifying the quantity of each drug of abuse or controlled chemical, equipment or material actually imported.

**31. Liability to forfeiture of improperly or undocumented consignments.**---(1) A consignment of a drug of abuse or controlled chemical, equipment or material is liable to forfeiture if:--

- (a) it is accompanied by an export permit or redirection permit, and there are reasonable grounds to believe that the permit is false, or has been obtained by fraud or wilful misrepresentation of a material particular;
- (b) there are reasonable grounds to believe that any import permit relating to it is false; or
- (c) in the case of a consignment of a drug of abuse, it is not accompanied by any export or redirection permit.

(2) Where the Competent Authority is satisfied that any consignment referred to in sub-rule (1) is legitimate, the consignment shall be released forthwith to the person lawfully entitled to it.

**32. Restriction for further import permit.**--- If an import permit has already been issued, to an operator for a specific drug of abuse, controlled chemical, equipment and material, no further import permit for the same shall be issued to the same person unless the items covered by the earlier permit have been actually imported and report regarding its import has been sent to the Competent Authority.

**33. Importation or exportation by post.**---(1) All permits issued under these rules shall, save where import or export is authorised by post, be prominently marked "NOT AVAILABLE BY POSTS".

(2) Save as provided in sub-rule (3), the medium of the post office shall not be used for import into, or export from, Pakistan by sea or by land, of any drug of abuse, or controlled chemicals, equipment and material.

(3) Where any drug of abuse, or controlled chemicals, equipment and material is to be imported or exported in accordance with these rules by air for urgent reasons, the import or export permit may be marked "AVAILABLE BY PARCLE BY AIR".

**38. Drugs of abuse registers.**---(1) The following persons shall keep, or cause to be kept, at a place where any drug of abuse is kept, a register in the manner determined, from time to time, by the Competent Authority namely:--

- (a) any person granted registration, or a licence or a permit under these rules in relation to any drug of abuse;
- (b) any person authorized under these rules to issue a prescription or requisition for a drug of abuse, or to supply such a drug by retail;
- (c) any pharmacist, including a pharmacist responsible for the supervision of all other pharmacists employed in a hospital or other institution for medical treatment or care; and
- (d) any duly qualified person, for the time being, in-charge of ward or other area of an institution in which any drug of abuse is administered.

(2) A person required by sub-rule (1) to keep, or cause to be kept, a register in relation to any drug of abuse, shall within twenty-four hours of any import, export, manufacture, administration, supply, acquisition, disposal or return of such drug enter or cause to be entered in the register:--

- (a) the date of the import, export, manufacture, administration, supply, acquisition, disposal or return;
- (b) the name, quantity, dosage, form and strength of the drug, imported, exported, manufactured, administered, supplied, acquired, disposed of or returned;
- (c) the name and occupational or business address of the person to or from whom the drug was imported, exported, supplied or acquired;
- (d) in case of export or supply, the quantity of the drug, if any, still kept;
- (e) in case of supply on prescription for the purpose of treatment, or of administration of a drug of abuse for that purpose:--
  - (i) the name and address of the person who prescribed the drug or ordered its administration;

- (ii) the name and residential address of the person for whom or to whom the drug was supplied or administered, or where prescribed or administered to an animal, the name of the person having custody of the animal at the time;
  - (iii) the name and residential address of the patient to whom the drug was prescribed, if different from the person referred to in sub-clause (ii); and
  - (iv) where applicable, the name and address of any person other than the treating practitioner who administered the drug, the time of administration, and particulars sufficient to identify any animal for whose treatment the drug was administered prescribed or supplied on prescription;
- (f) in the case of supply on requisition in an institution, details of the dispensary, ward or other place to which the drug was supplied;
- (g) in the case of return, the name of the person to whom the drug was returned; and
- (h) in the case of disposal:--
- (i) the method of disposal; and
  - (ii) the signature, name and designation of the person responsible for the disposal, and of at least one witness to the disposal.

(3) A person who makes an entry in a drugs register shall sign the entry, with date.

(4) A person may, in the presence of a witness, correct, by notation, a mistake in an entry in a drugs register, provided the person making the correction makes, signs and dates the notation, and the witness countersigns the notation.

(5) Any person who:--

- (a) delivers a drug of abuse to a ward or other area of an institution; or

- (b) in the ordinary course of duties in a medical, dental or veterinary practice, or in a ward or other area of an institution, witnesses the administration of that drug,

shall countersign the relevant entry in the drugs register.

(6) Any person required by these rules to keep a drugs of abuse register shall, subject to any written direction to the said person by the Competent Authority, retain possession of the register and all prescriptions, requisitions and commercial documents relating to entries therein for three years after the date of the last entry in the register.

**39. Controlled chemicals, equipment and materials registers.**---(1) Any person granted registration, licence, permit or open individual authorization under these rules in relation to any controlled chemical or item of controlled equipment or material shall keep, or cause to be kept, at a place where any such chemical or item is kept by that person, a register in accordance with the form prescribed from time to time by the Competent Authority.

(2) Any person required under sub-rule (1) to keep and maintain a register, in relation to any controlled chemical or item of controlled equipment or material, shall, within twenty-four hours of any import, export, manufacture, supply, acquisition or disposal by that person of any such chemical or item, enter or cause to be entered in such register:-

- (a) the date of the import, export, manufacture, supply, acquisition or disposal;
- (b) the name of the chemical equipment or material, and the quantity involved;
- (c) in the case of a controlled chemical, its form and strength;
- (d) in the case of disposal, the method of disposal; and
- (e) in the case of import, export, acquisition or supply, the name and occupational or business address of the person to, or from whom the chemical has been acquired, documents shall be kept for at least three years after the end of the calendar year of the last entry in the register.

(3) Any register required to be kept under sub-rule (1), and all commercial documents relating to entries therein such as orders, invoices, dispatch notes, cargo manifests or customs or other shipping documents shall be kept for at least three years after the end of the calendar year of the last entry in the register.

**40. False or misleading entries in registers and records.-**

Any person required to keep a register or other record under these rules shall not:--

- (a) make, or cause or permit to be made, an entry which is, to the knowledge of that person a false or misleading in any material particular; or
- (b) cancel, obliterate or alter any entry, except to correct an error in accordance with sub-rule (4) of rule 38.

**41. Duty to report and record loss, destruction or discrepancies in registers.---**Any person, required to keep a register under these rules, shall forthwith:--

- (a) report the loss or destruction of the register, or of the whole or any part of the contents of the register; or
- (b) record any discrepancy in the register, other than a mistaken entry and shall report to the Competent Authority in writing accordingly.

**42. Safe keeping of drugs of abuse.---**(1) Any person authorized:--

- (a) to import, export, manufacture, administer, supply or acquire a drug of abuse or controlled chemical in accordance with these rules; or

- (b) to engage in professional supply in accordance with rule 23, shall, while the drug or chemical is in the person's custody or control, keep it or cause it to be kept in vault, safe or other prescribed secure storage;

(2) A person, referred to in sub-rule (1), shall take such measures as the Competent Authority may direct, in writing, to ensure that no unauthorized person has:--

- (a) access to the combination, key or other means of access to any secure receptacle containing a drug of abuse or controlled chemical; or
- (b) the drug or chemical contained therein.

**43. Duties where there is loss or theft of a drug of abuse or controlled chemical.**---Any person authorized:--

- (a) to import, export, manufacture, administer, supply or acquire a drug of abuse or controlled chemical in accordance with these rules; or
- (b) to engage in professional supply in accordance with rules 23;

shall, immediately upon becoming aware of the loss or theft of any quantity of the drug or chemical in the person's custody or control shall:--

- (i) if the person believes on reasonable grounds that the drug or chemical has been stolen, he shall immediately inform an Inspector and an authorized officer orally, and report the matter in writing within twenty-four hours;
- (ii) in the case of loss, give a written report of the circumstances of the loss to an inspector; and
- (iii) record relevant particulars of the loss of theft in the register.

#### **CHAPTER 6.-- INSPECTION FOR COMPLIANCE**

**44. Appointment of Inspectors.**---(1) The Competent Authority may, by notification in the official Gazette, appoint any person to be an Inspector for the purposes of the rules.

(2) An Inspector shall perform such duties for the purposes of the rules as the Competent Authority may direct.

(3) The Competent Authority shall cause to be issued to an Inspector an identity card which states the name and appointment of the Inspector and on which shall appear a recent photograph of the Inspector.

**45. Inspection of authorized premises and operations.**--- A person who is registered, or holds a licence or permit issued under these rules shall, when required to do so in writing by an Inspector, provide the Inspector with a statement in writing, signed and dated by the person, accounting for each drug of abuse, controlled chemical or item of controlled equipment or material in possession of the authorized person at any time since the grant of the registration, licence, or permit, as the case may be.

**46. Powers of Inspectors.**---(1) A person appointed as an Inspector by the Competent Authority pursuant to rule 44 may, at any time during ordinary business or professional hours, with such assistance and by



such force as is necessary and reasonable, enter any premises or place at which any activity is carried out by any person who has been:--

- (a) granted a registration, licence or permit under these rules, or
- (b) authorized in accordance with rule 23 to engage in professional supply.

(2) Subject to rule 47, an inspector who enters any premises or place pursuant to sub-rule (1) may:--

- (a) require the occupier of the premises to supply his or her name and address;
- (b) inspect the premises or place in order to ascertain whether or not the rules or terms or conditions of any licence or permit granted pursuant to the rules has been or is being complied with;
- (c) examine any label, advertising material, register, record, book, electronic data or other document therein relating to any drug of abuse, controlled chemical or item of controlled equipment or material;
- (d) make an extract therefrom or take a copy thereof, and require from any person an explanation of an entry in any such register, record or document;
- (e) open and examine any receptacle or package found in that place in which a drug of abuse, analogue, controlled chemical or item of controlled equipment may be found;
- (f) examine any thing found in that place that is used or may be capable of being used for the manufacture, packaging or storage of a drug of abuse, analogue, controlled chemical or item of controlled equipment or material;
- (g) use or cause to be used any computer system at that place to examine any electronic data referred to in clause (c) or (f), and reproduce any document from any such data or cause it to be reproduced in the form of a print out or other output;
- (h) take anything referred to in clause (c) or (f) for examination or copying;
- (i) use or cause to be used any copying equipment at that place to make copies of any document;

- (j) examine any substance found in that place and take, for the purpose of analysis, such samples thereof as are reasonably required;
- (k) seize and detain anything, which in the opinion of the inspector, is connected with, or may provide proof of a contravention of the rules or a term or condition of any licence or permit granted under the rules and which the Inspector believes on reasonable grounds is necessary for the purpose of ensuring compliance with the rules or the regulations.

(3) Where an Inspector seizes and detains any substance suspected to be a drug of abuse, analogue, controlled chemical or item of controlled equipment or material, he may, at his discretion, be kept or stored at the place from where it was seized or be removed to any other proper place.

(4) Where an Inspector determines that for the purpose of ensuring compliance with these rules, it is no longer necessary to detain a substance suspected to be a drug of abuse, controlled chemical or item of controlled equipment or material under clauses (j), (k) of sub-rule (2), the Inspector shall notify in writing to the owner or other person in charge of the place where it was detained of that determination and, on being issued a receipt therefor shall return the substance to that person.

(5) Where in the ordinary course of duty, an Inspector becomes aware of a possible offence against the Act, he or she shall immediately report that fact to the Anti Narcotics Force and provide such further lawful assistance as may be reasonable or necessary for the purpose of any investigation or proceeding relating to that possible offence.

**47. Inspectors to produce authority.**---(1) An Inspector exercising any powers conferred under rules 46 shall produce his or her identity card issued under sub-rule (3) of rule 44 to the person in charge of any place in which the Inspector entered in pursuance of the rules for the purposes of inspection.

(2) An Inspector who enters premises in accordance with these rules is not authorized to remain on the premises, if, on request by or on behalf of the occupier of the premises, the Inspector does not produce the identity card issued under sub-rule (3) of rule 44, any person on the premises is not obliged to comply with that order of the Inspector.

**48. Obstruction of inspectors, etc.**---No person shall, without reasonable excuse, by an act or omission:--

- (a) obstruct or hinder an inspector in the exercise of the powers or performance of the duties of the inspector under these rules or regulations; or
- (b) refuse or fail to comply with a reasonable request of an inspector who has entered any premises in accordance with these rules.

#### **CHAPTER 7.-- MISCELLANEOUS**

**49. Repeal and savings.**---(1) The Dangerous Drugs (Import, Export and Trans-shipment) Rules, 1967, are hereby repealed.

(2) The repeal of the rules referred to in sub-rule (1) shall not affect anything done or action taken or penalty incurred under the said rule or any investigation or legal proceeding in respect of such penalty; and any such investigation or legal proceeding may be instituted, continued or enforced and any such penalty may be imposed as if these rules had not been made.

**50. Supply of data to Anti Narcotics Force.**---The Competent Authorities designated under these rules shall arrange to supply on regular basis all relevant data on the registration/licensing of various operators, issuance of import / export / transit / redirection and other relevant permits under these rules to the Anti Narcotics Force, in order to meet Federal Government's obligations under UN Conventions of 1961, 1971 and 1988 on Narcotics Drug and Psychotropic substances regarding supply of relevant data to the international agencies like INCB, UNDCP and Interpol.

#### **SCHEDULE -I** **[see clause (XXX) of rule-21]** **PROHIBITED**

This Schedule includes:--

- (i) the following substances, designated by their international nonproprietary names or the names used in the international conventions in force;
- (ii) their isomers, unless specifically excepted, whenever the existence/ of/such isomers is possible within the specific chemical/designation.
- (iii) their esters and ethers, unless specifically excepted, whenever/the/ existences of such esters and ethers is possible;

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- (iv) their salts, including the salts of esters, ethers and isomers/whenever the existence of such salts is possible;
- (v) preparations of these substances, unless exempted by law.

**(FROM SCHEDULE IV OF THE CONVENTION ON NARCOTIC DRUGS, 1961)**

Acetorphine	Acetyl- $\alpha$ -methyl-	Methyl-3fentanyl
Cannabis and	fentanyl	Methyl-3-thio
Cannabis resin	Alphacetylmethadol	fentanyl
Desomorphine	Alpha-methylfentanyl	MPPP
Etorphine	Beta-hydroxyfentanyl	Para-fluorofentanyl
Heroin	Beta-hydroxy-methyl-3-	PEPAP
Ketobemidone	fentanyl	Thiofentanyl

**(FROM SCHEDULE I OF THE CONVENTION ON PSYCHOTROPIC SUBSTANCES, 1971)**

Brolamphetamine	Etryptamine	Parahexyl
Cathinone	(+)-Lysergide	PMA
DET	MDA	Psilocine, psilotsin
DMA	Mescaline	Psilocybine
DMHP	Methcathinone	Rolicyclidine
DMT	Methyl-4 aminorex	STP, DOM
DOET	MMDA	Tenamphetamine
Eticyclidine	MDMA	Tenocyclidine
	N-ethyl MDA	Tetrahydrocannabmol
	N-hydroxy MDA	TMA

**SCHEDULE -II**

[see clause (XVI) of rule 2]

**HIGH RISK DRUGS OF ABUSE**

**(From Schedule I of the Convention on Narcotic Drugs, 1961)**

Acetylmethadol	Ethylmethyl-	Normorphine
Alfentanil	thiambutene	Norpipanone

Allylprodune	Etonitazene	Opium
Alphameprodine	Etoxidine	Oxycodone
Alphamethadol	Fentanyl	Oxymorphone
Alphamethylthio- fentanyl	Furethidine	Pethidine
Alphaprodine	Hydrocodone	Pethidine
Anileridine	Hydromorhinol	intermediate A
Benzethidine	Hydromorphone	(4-cyano-1-methyl- 4-phenyl-piperidine)
Benzylmorphine	Hydroxypethidine	Pethidine
Betacetylmethadol	Isomethadone	intermediate B
Betameprodine	Levomethorphan	(4-phenylpiperidine-4- carboxylic acid
Betamethadol	Levomoramide	ethyl ester)
Betaprodine	Levophenacymorphan	Pethidine
Bezitramide	Levorphanol	intermediate C
Clonitazene	Metazocine	(1-methyl-4- phenylpiperidine
Coca (leaf)	Methadone	4-carboxylic acid)
Cocaine	Methadone intermediate	Phenadoxone
Codoxime	(4-cyano-2-dimethyl- amino-4,4-diphenyl butane)	Phenampromide
Concentrate of poppy straw	Methyldesorphine	Phenazocine
Dextromoramide	Methyldihydromorphine	Phenomorphane
Diampromide	Metopon	Phenoperidine
Diethylthinambutene	Moramide	Piritramide
Difenoxin	Morphine	Piritramide
Dihydromorphine	Morphine	Proheptazine
Dimenoxadol	Morphine methobromide	Properidine
Dimepheptanol	and other pentavalent nitrogen morphine	Racemethorphan
Dimethylthiambutene	derivatives	Racemoramide
Dioxaphetyl butyrate	Morphine-N-oxide	Racemorphan
Diphenoxylate	Mkyrophine	Sufentanil
Dipipanone	Nicomorphine	Thebacon
Drotebanol	Noracymethadol	Thebaine
Ecgonine	Norlevorphanol	Tilidine
its esters and		

derivatives                      Normethadone                      Trimeperidine

**(from Schedule II of the Convention on Narcotic Drugs, 1961)**

Acetyldihydrocodeine	Ethylmorphine	Pholcodine
Codeine	Nicodicodine	Propiram
Dextropropoxyphene	Nicocodine	
Dihydrocodeine	Norcodeine	

**(from Schedule II of the Convention of Psychotropic Substances, 1971)**

Amphetamine	Methamphetamine	Phenmetrazine
Dexamphetamine	Methamphetamine racemate	Secobarbital
Fenetylline	Methaqualone	Zipeprol
Levamphetamine	Methylphenidate	
Mecloqualone	Phencyclidine	

**SCHEDULE -III**

[see clause (XXXIII) of rule 2]

**RISK DRUGS OF ABUSE**

**SCHEDULE III**

**of the Convention of Psychotropic Substances, 1971**

Amobarbital	Cathine	Pentazocine
Buprenorphine	Cyclobarbital	Pentobarbital
Butalbital	Glutethimide	Flunitrazepam

**SCHEDULE-IV**

**of the Convention on Psychotropic Substances, 1971**

Allobarbital		Methylprylon
Alprazolam	Ethinamate	Midazolam
Aminorex	Ethyl loflazepate	Nimetazepam
Amphepramone	Etilamphetamine	Nitrazepam
Barbital	Fencamfamin	Nordazepam
Benzphetamine	Fenproporex	Oxazepam

Bromazepam	Fludiazepam	Oxazolam
Brotizolam	Flurazepam	Pemoline
Butobarbital	Halazepam	Phendimetrazine
Camazepam	Haloxazolam	Phenobarbital
Chlordiazepoxide	Ketazolam	Phentermine
Clobazam	Lefetamine	Pinazepam
Clorazepam	Loprazolam	Piptadrol
Clorazepate	Lorazepam	Prazepam
Clotiazepam	Lormetazepam	Pyrovalerone
Cloxazolam	Mazindol	Secbutabarbital
Delorazepam	Meazepam Mefenorex	Temazepam
Diazepam	Meprobamate	Tetrazepam
Estazolam	Mesocarb	Triazolam
Ethchlorvynol	Methylpheno-barbital	Vinylbital

**SCHEDULE -IV**  
[see clause (XXXVII) of rule 2]

**TOXIC CHEMICAL INHALANTS**

**SCHEDULE V – CONTROLLED CHEMICALS**

This schedule includes:--

- (i) the following substances, designated by their international non-proprietary names or the names used in the international conventions in force;
- (ii) the salts of these substances, whenever the existence of such salts is possible, with the exception of sulphuric acid and hydrochloric acid.

**DIVISION I**

(Table I of 1988 Convention)

Ephdrine	N-acetylanthranilic acid
Ergometrine	Isosafrole
Ergotamine	3,4 methylenedioxyphenyl
Lysergic Acid	2 Propanone

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4-Phenyl-2-Propanone

Piperonal

Pseudoephedrine

Safrole

**DIVISION II**

**(Table II of the 1988 Convention)**

Acetic anhydride

Hydrochloric acid

Acetone

Methyl ethyl

Anthranilic acid

Ketone

Ethyl ether

Potassium permanganate

phenylacetic acid

Sulphuric acid

Piperidine

Toluene

**SCHEDULE -VI**

**[see clause (VI) and (VII) of rule 2]**

**DIVISION 1 - CONTROLLED EQUIPMENT**

- 1 Encapsulating machines
- 2 Tableting machines
- 3 Rotary evaporators
- 4 Laboratory equipment with a capacity for large volume production (eg round bottom flasks of 25 liters or above and related condensers, separating funnels and heating apparatus) 5 6

**DIVISION 2 - CONTROLLED MATERIAL**

Gelatin capsules

[eg glucose, lactose, phenolphthalein]

[prescribed bulking agents e.g magnesium stearate, calcium oxide ("talc")]

[colouring materials or food dyes]

Annexure - I

Annexure - II

Annexure - III

Annexure - IV

Annexure - V

Annexure - VI

Annexure - VII

Annexure - VIII

Annexure - IX

**Note:** For Annexure please see Gazette of Pakistan, Extraordinary, Part II, Page No. 2775 to 2797, dated 28-11-2001