The Drugs (Labeling and Packing) Rules, 1986

1. Short title and commencement : (1) These rules may be called the Drugs (Labeling and Packing) Rules. 1986.

2. They shall come into force on the expiration of the period of one year beginning with their publication in the official Gazette.

3. Definitions :- In these rules, unless there is anything repugnant in the subject or context;

(a) International non-proprietary name means the name of drug as recommended by the World Health Organization or such other name as may be notified by the federal Government in the official gazette;

(b) Pharmacopoeial means a publication mentioned in sub-clause (ii) of clause (2) of section (3) of drugs Act, 1976 (XXXI of 1976).

(c) Pharmacopoeial name "means the name of a drug as mentioned in the pharmacopoeia".

(d) "Schedule" means a schedule to these rules; and

(e) "Registered Medical Practitioners" means a Medical Practitioner registered or provincially registered under the medical and Dental Council Ordinance, 1962(XXXII of 1962).

(3) Manner of Labeling : The following particulars shall appear either in print or in writing in inedible ink in a conspicuous manner on a label of the innermost container of drug and also on the in which such container is packed namely :-

(a) The registered name of the drug;

(b) If the registered name is a proprietary name, then immediately following the registered name, the international non-proprietary name, and if no such non-proprietary name is known the Pharmacopoeial name or any other name, if any, approved by the registration board for this purpose in conspicuous manner;

(c) The international non-proprietary name of the pharmacopoeial name of the generic name, and if no such name is known the chemical name of each active ingredient of a drug with weight.

Added by SRC 1122 (i) 86 dated 23-12-1986

Or measures in metric system, or the number of units of activity as the cause may be, expressed :-

(i) In the case of oral liquid preparations in terms of contents per specified volume, the volume being indicated in militaries;

(ii) In the case of liquid parenteral preparations ready for administration in terms of militaries or percentage by volume or dose.

Provided that in the case of a preparation contained in ampoule, it shall be sufficient if the ingredients are shown on the label or wrapper affixed to any package in which such ampoule is issued for sale.

(iii) In the case of drugs in solid form intended for parenteral administration in terms of weight or unitage per milligram or gram or per container.

(iv) In the case of tablets, capsules pill or other units as the case may be; and

(v) In the case of other preparations in terms of percentage by weight or volume or unitage per gram or milliliter as the case may be;

(d) The name and principal place of business of the manufacturer

(e) The drug manufacturing license number.

(f) The drug registration number.

(g) The date of expiry.

(h) Urdu version of the following namely;

(i) Name of drug

(ii) dosage; and

(iii) Instructions;

(i) The distinctive batch number date of manufacture and the maximum retail price;

Provided that in the case of a drug packed in a strip of paper or blister or foil or contained in an ampoule of a capacity of not more that two milliliter or in an ampoule containing a sterile suture or ligature and such strip foil blister or ampoule is placed in other package and also in the case of printed collapsible tubes it shall be sufficient to give the information on the outer packing containing such strips, foils, blister or ampoule.

Provided further that the registration board may allow relaxation of any of these conditions.

4. **Labelling of Drugs for internal use :-** The label of container of a drug meant for internal use, except a Drug contained in a strip or foil or blister or collapsible tube shall in

additions to the particulars required to be given under rule 3, bear in a conspicuous manner.

(i) If it contains a substance specified in the schedule the words "to be sold on prescription of a registered medical practitioner only" and ;

(ii) If it contains not less then three percent by volume and alcohol a statement giving the quantity of alcohol in terms of average percentage by volume of absolute alcohol in the finished product.

5. Labelling of Drugs of external use only :-The label of a container of ointment, cream, liniment, lotion, antiseptic or any drug for external application shall in addition to the particular required to be given under rule 3, bear in a conspicuous manner :-

(i) The words "For external use only " and;

6. Labelling of physician's sample :- The label of a container of every drug intended for distribution to the medical profession as free sample shall in addition to the particulars required to be given under these rules bear the words "Physician sample not for Sale" which shall be over printed or stamped.

Provided that if the drug is packed in a strip of paper or blister or foil or contained in an ampoule of a capacity of not more than three milliliters or in a collapsible tube, it shall be to label the outer packing only with the said words.

7. Labelling of Drugs for Government supply :- T he label of a container of every drug intended for the supply to any Government agency including an autonomous body or a semi-Government Agency shall. While complying with the other labelling requirements of these rules, bear the words or mark reading "Government supply" or such other words or mark as may be required by the agency concerned.

8. Labelling of Drugs for Veterinary use:- The label of a container of drug for veterinary use shall bear in a conspicuous manner the words " For veterinary use only"

9. Outer transparent wrapper not to require labeling :- Nothing in these rules shall be deemed to require the labeling of any transport cover, wrapper, case, or other covering used solely for the purpose of packing, transport or delivery of a drug.

10. Labelling of Non-Sterile Surgical ligature and suture :- Every container of and every wrapper enclosing a surgical ligature or suture, other than a ligature or suture certified to be sterile and fit for surgical use without further sterilization., shall bear a label or which shall be printed or written in a conspicuous manner in indelible red ink the word " Non-Sterile Surgical ligature/suture, Not to be used for operations upon human body unless properly sterilized".

11. Use of letters to indicate specifications :- Subject to these rules the letters "P.P", "Ph.I", "Eur.P", "B.P", "B.P.C" and "U.S.N.F". shall be printed or written in indelible ink on the label to indicate so that the drug is manufactured in accordance with the specifications set out in

the Pakistan Pharmacopoeia, international Pharmacopoeia, European Pharmacopoeia, United States Pharmacopoeia, British Pharmacopoeia, British Pharmaceuticals Codex or the United States National Formulary, as the case may be.

12. **Packing of finished drugs :**- Each finished drugs ready for use shall be packed in containers intended for retail sale to a hospital dispensary, clinic, or any other such institutions.

13. **Labelling of Drugs manufactured for export :**- Noting contained in rules 3 to 12 shall apply to a drug manufactured for export the label on the package or container of which has

has bee adopted to meet the specific requirements of the country to which the drug is exported. The label on the package or container of such drug shall bear the following particulars at a conspicuous place on the innermost container in which the container is packed namely :-

(i) The Name of the drug
(ii) The name and principle place of business of the manufacturer and ;
(iii) Batch number of the drug date of manufacture and the date of expiry.

Provided that in the case of a drug packed in strips of paper or foils or blister or contained in ampoules of a capacity of not more than two milliliters or in printed collapsible tubes, except for expiry date it shall be sufficient if these particulars are given on the outer packing containing such strips, foil, blister, ampoules or tubes.

14. Exemption :- These rules should not be applicable in respect of a drug made up ready for treatment, whether after or without dilution and is supplied by a person licensed to sell drugs on the prescription a registered medical practitioner.

Provided that the label bears the following particulars namely :-

(i) The name and the address of the suppliers of the drug;
(ii) The name of the patient;
(iii) The number representing the serial number of the entries in the prescription register.
(iv) If the drug is for internal use the dosage
(v) If the drug is for external use and does not contains a substance specified in the schedule the words, “For external use only” and;
(vi) If he drug is for external use and contains a substance specified in the schedule the words “Poison for external use only”

THE SCHEDULE

TO BE SOLD BY A RETAILER ON THE PRESCRIPTION OF

REGISTERED MEDICAL PRACTITIONERS.

1. C.N.C. stimulants
2. Drugs affecting Uterine motility.
3. Drugs inhibiting hormonal production.
4. Hormones and other steroidal preparation excluding preparations for external and topical use.
5. Narcotic drugs as per single convention on Narcotic drugs 1961.
6. Psychotropic substances, 1971.