**The Drugs (Labelling and Packing) Rules, 1986**

1. Short title and commencement: (1) These rules may be called the Drugs (Labelling 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.
2. Definitions: In these rules, unless there is anything repugnant in the subject. or context; (a) "international non-proprietary name" means the name of a 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) "pharmacopoeia" means a publication mentioned in sub-clause (ii) of clause (z) of Section 3 of the 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 practitioner" means a medical practitioner registered or provisionally registered under the Medical and Dental Council Ordinance, 1962 (XXXII of 1962).
3. Manner of labelling: The following particulars shall appear either in print or in writing in inedible ink in a conspicuous manner on the label of the innermost container of a drug and also on the covering 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 generic name or other name, if any, approved by the Registration Board, for this purpose small be printed within breakets with at least equal prominence as that of the brand name;
(c) the international non-proprietary name or the pharmacopoeial name or the generic name, and if no such name is known, the chemical name, of each active ingredient of a drug with weight or measure in metric system, or the number of units of activity, as the case may be, expressed,--
(i) in the case of oral liquid preparations, in terms of contents per specified volume,, the volume being indicated in millilitres;
(ii) in the case of liquid parenteral preparations ready for administration, in terms of millilitres 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 warpper 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, pills and the like, in terms of the contents per tablets, capsule, pill or other unit, as the case may be; and
(v) in the case of other preparations, in terms of percentage by weigh or volume or unitage, per gram or millilitre, as the case may be;
(d) the name and principle place of business of the manufacturer;
(e) the drug manufacturing licence number;
(f) the drug registration number;
(g) the date of expiry;
(h) Urdu version of the following namely:-
(i) registered name of drug.
(ii) dosage (numerals in English shall be sufficient ): 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 than two millilitres or in an ampoule containing a sterile suture or ligature, and such strip, foil. blister, or ampoule is placed in another package, and also in the case of printed collapsible tubes, it shall be sufficient to give the information on the outer packing containing such strip, foil, 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 addition 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 prescriptions of a registered medical practitioner only"; and
(ii) if it contains not less than three per cent by volume an 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 for external use only: The label of a container of ointment, cream, liniment, lotion, liquid, antiseptic or any other drug for external application shall, in addition to the particulars required to be given under rule 3, bear in a conspicuous manner,--
(i) the words "For external use only"; and
(ii) if the drug contains a substance specified in the Schedule, the words "Poison; for external use only".
6. Labelling of physician's samples: 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's sample: Not for sale" which shall be overprinted 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 millilitres or in a collapsible tube, it shall be sufficient to label the outer packing only with the said words.
7. Labelling of drugs for Government supply: The 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, preferably in red ink the words for veterinary use only.
9. Outer transparent wrapper not to require labelling: Nothing in these rules shall be deemed to require the labelling 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 on 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 operation upon human body unless properly sterilized".
11. Use of letter to indicate specifications: If a drug is included in the recent edition of any publication specified in the rules, the name of relevant publication in conventional abbreviations (B.P., U.S.P., etc.) shall be printed in indelible ink, on the label to indicate that the drug conforms to the specifications set out in that publication.
12. Packing of finished drugs: Each finished drug ready of use-shall be packed in containers intended for retail sale to a hospital, .dispensary, clinic or any other such institution.
13. Labelling of drugs manufactured for export or experimental purposes: (1) Nothing contained in rules 3 to 12 shall apply to a drug manufactured for experimental purposes which shall be labelled in accordance with rule 23 of the Drugs (Licensing, Registering and Advertising) Rules. 1976.
(2) Labelling of drugs manufactured for export shall, in addition to meeting specific requirements of the importers, bear following particulars printed in indelible ink, on the inner most container and other packings of such drugs,--
(i) name of drugs ;
(ii) name and address of manufacturer; and
(iii) batch number and dates of manufacture and expiry date of the drug:
Provided that in case of a drug packed in a strip of paper, foil or blister or contained in an ampoule of a capacity of not more than two millilitres or in a printed collapsible tube or in an ampoule containing a sterile suture or ligature and that such strip, foil, blister or ampoule is placed in another package, then it shall be sufficient to give name, date of expiry and batch number of the drug, name and address of the manufacturer on the inner-most container or its label, while full particulars shall be given on outer packing containing such strip, foil, blister, ampoule or tube.
14. Exemption: These rules shall 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 of a registered medical practitioner.
Provided that the label bears the following particulars, namely :--
(i) the ham e and 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 contain a substance specified in the Schedule' the words "For external use only"; and
(vi) if the 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 PRACTITIONER
1. C.N.S. stimulants.
2. Drugs affecting uterine motility.
3, Drugs inhibiting hormonal production.
3. 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 mentioned as per Convention on Psychotropic Substances, 1971.