65 Conditions of Licences. – Licences in [1][Forms 20, 20-A, 20-B, 20-F, 20-G, 21 and 21-B] shall be subject to the conditions stated therein and to the following general conditions –

(1) [1]Any drugs shall, if compounded or made on the licensee, premises be compounded or made by or under the direct and personal supervision of a [2][registered Pharmacist].

(2) The supply, otherwise than by way of wholesale dealing [3][***] of any drug supplied on the prescription of a Registered Medical practitioner shall be effected only by or under the personal supervision of a [2][registered Pharmacist].

(3) (1) The supply of any drug [1][Other than those specified in Schedule X] on a prescription of a registered medical practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of entry in this regard shall be entered on the prescription. The following particulars shall be entered in the register –

(a) serial number of the entry,

(b) the date of supply,

(c) the name and address of the prescriber,

(d) [5][the name and address of the patient, or the name and address of the owner of the animal if the drug supplied is for veterinary use.]

(e) the name of the drugs or preparation and the quantity or in the case of medicine made up by the licensee, the ingredients and quantities thereof.

(f) in the case of a drug specified in [1][Schedule C or Schedule H] the name of manufacture of the drug, its batch number and the date of expiry of potency, if any.

(g) the signature of the [2][registered Pharmacist] by or under whose supervision the medicine was made up or supplied :-

Provided that in the case of drugs which are not compounded in the premises and which are supplied from or in the original containers the particulars specified in items (a) to (g) above may be entered in a cash or credit memo book, serially numbered and specially maintained for this purpose :

Provided further that if the medicine is supplied on a prescription on which the medicine has been supplied on previous occasion and entries made in the prescription register, it shall be sufficient if the new entry in the register includes a serial number , the date of supply , the quantity supplied and a sufficient reference to an entry in the register recording the dispensing of the medicine on the previous occasion :

Provided further that it shall not be necessary to record the above details in the register or in the cash or credit memo particulars in respect of-

(i) any drugs supplied against prescription under the Employee State Insurance Scheme if all the above particulars are given in that prescription, and

(ii) any drugs other than that specified in [1][Schedule C or Schedule H) if it is supplied in the original unopened container of the manufacturer and if the prescription is duly stamped at the time of supply with the name of the supplier and the date on which the supply was made and on condition that the provisions of sub-rule (4)(3) of this rule are complied with.

(2) The option to maintain a prescription register or a cash or credit memo book in respect of drugs and medicines which are supplied from or in the original container, shall be made in writing to the Licensing Authority at the time of application for the grant or renewal of the licence to sell by retail :

Provided that the Licensing Authority may require records to be maintained only in prescription register if is satisfied that the entries in the carbon copy of the cash or credit memo book are not legible.

(4) (1) The supply by retail, otherwise than on a prescription of a drug specified in Schedule C shall be recorded at the time of supply either –

(i) In a register a specially maintained for the purpose in which the following particulars shall be entered –

(a) Serial number of the entry.

(b) The date of Supply

(c) The name and address of the purchaser.

(d) The name of the drug and the quantity thereof.

(e) In the case of a drug specified in Schedule C, the name of the manufacture, the batch number and the date of expiry of potency.

(f) The signature of the person under whose supervision the sale was effected , or

(ii) In a cash or credit memo book, serially numbered containing all the particulars specified in items (b) to (f) of sub-clause (I) above.

Note – The entries in the carbon copy of the cash or credit memo which is retained by the licensee shall be maintained in a legible manner.

(2) The option to maintain a register or cash or credit memo book shall be made in writing to the Licensing Authority at the time of application for the grant or renewal of licence to sell by retail :

Provided that the licensing Authority may require records to be maintained in register if it is satisfied that the entries in the carbon copy of the cash/credit memo book are not legible.

(1) (1) The supply by retail of any drug shall be made against a cash/credit memo which shall contain the following particulars :-

(a) Name, address and sale licence number of the dealers.

(b) Serial number of the cash/credit number.

(c) The name and quantity of the drug supplied.

(2) Carbon copies of cash/credit memo shall be maintained by the licensee as record.

(4) (I) Records of purchase of drugs intended for sale or sold by retail shall be maintained by the licensee and such records, shall show the following particulars, namely :-

(a) The date of purchases.

(b) The name and address of the person from whom purchased and the number of the relevant licence held by him.

(c) The name of the drug, the quantity and the batch number, and

(d) The name of the manufacture of the drugs.

(ii) Purchases bills including cash or credit memos shall be serially numbered by the licensee and maintained by him in a chronological order.

(5) (1) Subject to the other provisions of these rules the supply of a drugs by wholesale shall be made against a cash or credit memo bearing the name and address of the licensee and his licence number under the Drugs and Cosmetics Act in which the following particulars shall be entered -

(a) The date of sale

(b) The name, address of the licensee to whom sold and his sale licence number. In case of sale to an authority purchasing on behalf of Government, or to a hospital, medical, educational or research institution or to a registered medical partcitioner for the purpose of supply to his patients the name and address of the authority institutions or the registered medical parctitioner as the case may be,

(c) The name of the drug, the quantity and the batch number.

(d) The name of the manufacturer.

(2) Carbon copies of cash or credit memo specified in clause (I) shall be preserved as records for a period of three years from the date of the sale of the drug.

(3) (1) Records of purchase of a drug intended for resale or sold by wholesale shall be maintained by the licensee and such records shall show the following particulars, namely :-

(a) The date of purchase.

(b) The name, address and the number of relevant licence held by the person from whom purchased.

(c) The name of the drugs, the quantity and the batch number and

(d) The name of the manufacturer of drug.

(2) Purchase bill including cash or credit memos shall be serially numbered by the licensee and maintained by him in a chronological order.

(6) Purchase bills including for inspection by an Inspector appointed under the Act on demand all registers and recrods maintained under these Rules, and shall supply to the Inspector such information as he may required for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.

(7) Except where otherwise provided in these Rules, all registers and recordes maintained under these Rules shall be preserved for a period of not less than two years from the date of the last entry therein.

(8) Notwithstanding anything contained in this Rule it shall be not be necessary to record any particulars in a register specially maintained for the purpose if the particulars are recorded in any other register specially maintained under any other law for the time being in force.

(9) (a) Substances specified in Schedule H or Schedule X shall not be sold by retail except on and in accordance with the prescription of a Registered Medical Practioner and in the case of substances specified in Schedule X,

the prescription shall be in duplicate one copy of which shall be retained by the licensee for a period of two years.

(b) The supply of drugs specified in Schedule H or Schedule X to Registered Medical Practitioners, Hospitals, Dispensaries and Nursing Homes shall be made only against the signed order in writing wich shall be preserved by the licensee for period of two years.

(10) For the purposes of clause (9) a prosecution shall –

(a) Be in writing and be signed by the person giving it with his usual signature and be dated by him.

(b) Specify the name and address of the person for whose treatment it is given, or the name and address of the owner of the animal if the drug is mean for veterinary use ;

(c) Indicate the total amount of the medicine to be supplied and the does to be taken.

(11) The person dispensing a prescription containing a drug specified in Schedule H [And schedule X] shall comply with the following requirements in addition to other requirement of these.

Rules -

(a) The prescription must not be dispensed more than once, unless the prescriber has stated thereon that it may be dispensed more than once.

(b) If the prescription contains a direction that it may be dispensed a stated number of times or a t stated intervals it must not be dispensed otherwise than in accordance with the directions :

(c) At the time of dispensing there must be noted on the prescription above the signature of the prescribe the name and address if the seller and the date on which the prescription is dispensed.

11-A No person dispensing a prescription containing substances specified in [Schedule H or Schedule X], may supply and other preparation, whether containing the same substance or not in lieu thereof.

12 Substances specified in shcedule X kept in retail shop or premises used in connection therewith shall be stored –

(a) Under lock and key in cupboard or drawer reserved solely for the storage of these substances ; or

(b) In a part of the premises separated from the remainder of the premises and to which only responsible person have access.

13. [* * * *]

14. [* * * *]

15. (a) The description " Drugstore" shall be displayed by such licensees who do not require the services of a qualified person.

(b) The description "Chemists and Druggists" shall be displayed by such licensees who employ the services of a "Qualified person" but who do not maintain a "Pharmacy" for compounding against prescriptions.

(C) The description "Pharmacy" Pharmacist", "Dispensing Chemist" or "Pharmaceutical Chemist" shall be displayed by such licensees who employ the servies of a "Qaulified person" and maintain a "Pharmacy" for compounding against prescriptions.

Examples – For the purpose of this rule –

(i) [* * *]

(ii) Qualified person means a person who –

(a) holds a diploma or degree in pharmacy or pharmaceutical chemistry of an institute approved by the licensing authority ' or

(b) is a registered pharmacist as defined in the Pharmacy Act, 1948 :

(Provided that in those states (including Union territores)

Where the first register of Pharmacists under Section 29 of the said Act has not been prepared, a person possessing

qualifications to have his name entered in that register shall be deemed to be a qualified person till such time as that register is prepared : or

(c) has not less than four years practical experience of dispensing which is in the opinion of the licensing authority adequate and has been approved by that authority as a 'qualified person' on or before [the 31 st December, 1979]

(iii) Date of expiry of potency means the date that is recorded on the container, label or wrapper as the date up to which the substance may be expected to retain potency not less than or not o acqure toxicity greater than that required or permitted by the prescribed test.

(16) The licensee shall maintain an Inspection Book [in Form} to enable an Inspector to record his impressions and the defects noticed.

(17) No drug shall be sold or stocked by the licensee after the date of expiration of potency recorded on its container, lable or wrapper, or in violation of any statement or direction recorded on such container, label or wrapper :

Provided that any such drugs in respect of which the licensee has taken

steps with the manufaturer of his representative for the withdrawal, reimbursement of disposal of the same, may be stocked after the date of expiration of potency pedning such withdrawal, remursement or disposal, as the case may be, subject to the condition that the same shall be stored separately from the trade stocks [and all such drugs shall be ketp in packages or cartons, the top of which shall disply prominely, the words 'Not for Sale']

(18) No drug intended for distribution to the medical profession as free sample which bears a label on the container as specified in clause (viii) of sub rule (1) of Rule 96, and no drug meant for consumption by the Employees, State Insurance Coprortation, the Stores Depots, the Armed Forces Medical

stores or other Government institutions, which bears a distinguishing mark or any inscription on the drug or no the label affixed to the container thereof indicating the purpose shall be sold or stocked by the licensee on his premises :

Provided that this sub-rule shall not be applicable to licensees who have

been appointed chemists, by State Government in writing, under the employees' State Insurance Scheme for drugs meant for consumption under that Scheme.

(19) The supply by retail of any drug in a container other than the one in which the manufacturer has marketed the drugs, shall be made only dealers who employ the services of a qualified person and such supply shall be made under the drect supervision of the 'qualified person' in an envelope of other suitable wrapper or container showing the following particulars on the label –

(a) name of the drug.

(b) The quantity supplied.

(c) The name and address of the dealer.

(20) The medicine for tratement of animals kept in a retail shop or premises shall be labeled with the words " Not for human use _____ for treatment of animals only" and shall be stored –

(a) in a cupboard or drawer reserved solely for the storage of veterinary drug, or

(b) in a part of the premises separated from the remainder of the premises to which customers are not permitted to have access.

(21) (a) The supply of drugs specified in Schedule X shall be recorded at the time of supply in a register (bound and sereially page numbered) specially maintained for the purpose and separate pages shall be allotted for each drug.

(b) The following particulars shall be entered in the said register namely-

(i) Date of transition.

(ii) Quantity received if any, the name and address of the supplier and the number of the relevant licence held by the supplier :

(iii) Name of drug

(iv) Quantity supplied

(v) Manufacture's Name

(vi) Batch No. or Lot No. :

(vii) Name and address of the patient/ purchaser

(viii) Reference number of the prescription against which supplies were made :

(ix) Bill No. and date in respect of purchases and supplies made by him

(x) Signature of the person under whose supervision the drugs have been supplied.

COMMENTARY

Scope – Rule 65 (9) is restricted to the substnaces specified in Schedules H and L and prepartions contianing such substances medicines which do not fall within the description of substances specified in Schedule H and L and which are not prepartions containing these substances can be sold by a chemist even without a prescriptions registered medical practitioner. Prakash Cahndra V. State, AIE 1976 MP 50.

Expired date medicine – There is nothing in the rules to make obligatory upon a licensee to destory or throw away the stocks as soon as it crosses the date of expiry. If for claiming rebate from income tax departments the licensee keeps expreid date medicne in his stock with the due precaution everybody should know that the same were not intended for sale then he cannot be said to have committed any offence. Aftab v. Ahmad v. State Cri LJ 1333.

Stocked Meaning of – The workd "stocked' in sub-rule (17) means stocked for sale and stocking drugs. Labelled as 'Physicians's sample not for sale"

which are not meant tonbe sold is violation of the rule with section 18 (a) (Cri) of the Act. Public Persecutor v. Mahaveer Prasad Crl LJ 1546 (AP).

Registered medical practitioner- The expression " registered medical practitioner" does not include a Homeopathic and Bilochemic practitioners registered under the Homeopathic and Biochemis Practitioners ACT, Madhya pradesh. Prakash Chandra v. State AIR 1976 MP 50.

65. Additional information to be furnished by an applicant for licence or a licensee to the licensing authority.

The applicant for the grant of a licence or any person granted a licence under this part shall on demand, furnish to the licensing authority, before the grant of the licence or during the period the licence is in force, as the case may be documentary evidence in respect of the ownership or occupation on rental or other basis of the premises, specified in the application for licence or in the licence granted for the purpose of verifying the correctness of the statements made by the applicant or the licensee while applying for or after obtaining the licence, as the case may be.

1. *Subs. By GSR 462 (E), dt. 22.6.1982 (w.e.f . 22.6.1982)*
2. *Subs. For "qualified person" by GSR 676(E), dt. 6.9.1994 (w.e.f. 6.9.1994)*
3. *Omitted by GSR 462 (E), dt. 22.6.1982 (w.e.f . 22.6.1982)*
4. *Subs. By S.O. 2139, dt. 5.6.1972 (w.e.f. 12.8.1972)*
5. *Subs. By GSR 926 (E), dt. 24.6.1977 (w.e.f. 16.7.1977)*