परिशिष्ट
85 के प्रश्नांश 'ग' का परिशिष्ट
वि.स. अतारांकित प्रश्न क्र - 6215 प्रश्नकर्ता-श्री शिवराज सिंह, माननीय विधायक

[1]Provided that if the application for renewal of licence in force is made before its expiry or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired if application for its renewal is not made within six months after its expiry.

[2]**63A**.*Certificate of renewal of a sale licence*.— The certificate of renewal of a sale licence in Forms 20, 20-A, 20-B,[3][20-F, 20-G], 21, 21-A and 21-B shall be issued in Form 21-C.

[4]**63B.** *Certificate of renewal of licence*.— A certificate of renewal of a licence in Form 20BB or Form 21BB shall be issued in Form 21-CC.;

[5]**64.***Conditions to be satisfied before a licence in Form*[3][*20, 20-B, 20-F,20-G 21 or 21-B*] *is granted .—(1)*A licence in Form [3][20, 20-B, 20-F,20-G, 21 or 21-B] [6][to sell, stock, exhibit or offer for sale or distribute]drugs shall not be [7][granted or renewed] to any person unless the authority empowered to grant the licence is satisfied that the premise in respect of which the licence is to be [7][granted or renewed] are adequate, equipped with proper storage accommodation for preserving the properties of the drugs to which the licence applies and are in charge of a person competent in the opinion of the licensing authority to supervise and control the sale, distribution and preservation of drugs :

Provided that in the case of a pharmacy a licence in Form 20 or 21 shall not be [7][granted or renewed] unless the licensing authority is satisfied that the requirements prescribed for a pharmacy in Schedule N have been complied with.

[3][Provided further that licence in Form 20-F shall be [7][granted or renewed] only to a pharmacy and in areas where a pharmacy is not operating, such licence may be [7][granted or renewed] to a chemist and druggist]

Explanation.— For the purpose of this rule the term 'Pharmacy' shall be held to mean to include every store or shop or other place : (1) where drugs are dispensed, that is, measured or weighed or mode up and supplied : or (2), where prescriptions are compounded; or (3) where drugs are prepared; or (4) which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "Pharmacy", "Pharmacist," "Dispensing Chemist" or "Pharmaceutical Chemist"; or (5) which, by sign, symbol or indication within or.

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[1]Amended by S. O. No. 2139, dated 12th August, 1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).
[2]Added under Government of India Notification No. F. 1-10/62-D, dated 10th April, 1964.
[3]Inserted by Notification No. G.S.R 462(E) dated 22-6-1982
[4]Added by Govt. of India Notification No. X11013/7/76—DGHS dated the 25th January 1979.
[5]Amended by Government of India Notification No. F. 1-16/57-D, dated 15th June 1957 and No. F. 1-19/59-D, dated 13th June, 1961
[6]Amended by G.O.I. Notification No. G.S.R 778(E) dated 10-10-1985
[7]Amended by G.O.I. Notification No. G.S.R 681(E) dated 6-6-1988

upon it gives the impression that the operations mentioned at (1), (2) and (3) are carried out in the premises; or (6) which is advertised in terms referred to in (4) above

*(2)*In granting a licence under sub-rule *(1)* the authority empowered to grant it shall have regard—

[1]*(i)*to the average number of licences granted during the period of 3 years immediately preceding, and

*(ii)*to the occupation, trade or business ordinarily carried on by such applicant during the period aforesaid :

Provided that the licensing authority may refuse to grant or renew a licence to any applicant or licensee in respect of whom it is satisfied that by reason of his conviction of an offence under the Act or these Rules, or the previous cancellation or suspension of any licence granted thereunder, he is not a fit person to whom a licence should be granted under this rule. Every such order shall be communicated to the licensee as soon as possible.

[2][Provided further that in respect of an application for the grant of a licence in form 20-B or form 21-B or both, the licensing authority shall satisfy himself that the premises in respect of which a wholesale licence is to be granted are:--

(i) of an area of not less than ten square meters; and]

[3][*(ii)* in the charge of a competent person, who—

(a) is a Registered Pharmacist, or,

(b) has passed the matriculation examination or its equivalent examination from a recognised Board with the four years experience in dealing with sale of drugs, or;

(c) holds a degree of a recognised University with one year's experience in dealing with drugs]

[4][Provided also that,--

(i) in respect of an application for the grant of a licence in Form 20 or Form 21 or both, the licensing authority shall satisfy itself that [5][the premises are of an area] of not less than 10 square meters, and

(ii) in respect of an application for the grant of a licence--

*(A)*In Form 20 or Form 21 or both, and

*(B)*In Form 20 B or Form 21B or both,

the licensing authority shall satisfy itself that the premises are of an area not less than 15 square meter;

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[1]Amended by Government of India Notification No. F. 1-19/59-D, dated 13th June, 1961

[2] Ins. by G.O.I. Notification No. G.S.R 681(E) dated 5-12-1980

[3]Amended by G.O.I. Notification No. G.S.R 351(E) dated 26-4-2000

[4] Ins. by G.O.I.Notification No. G.S.R 91(E) dated 25-2-1997

[5]Amended by Corrigendum G.S.R. 121 (E) dated 5-3-1998

Provided also that the provisions of the preceding proviso shall not apply to the premises for which licences have been issued by the licensing authority before the commencement of the Drugs and Cosmetic (1st Amendment) Rules, 1997]

[6][(3) Any person who is aggrieved by the order passed by the licensing authority in sub-rule (1) may, within 30 days from the date of receipt of such order, appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, make such an order in relation thereto as it thinks fit.]

65. *Condition of licences.* — Licences in [1][Form 20, 20-A, 20-B, 20-F, 20-C, 21, and 21-B] shall be subject to the conditions stated therein and to the following general conditions—

[1][*(1)* Any drug shall, if compounded or made on the licensee's premises be compounded or made 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].

[4]*(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 the entry in the register 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,

[5]*(d)* 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 drug or preparation and the quantity or in the case of a 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 the manufacturer 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.

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[1]Subs. by G.O.I. Notification No. G.S.R 462(E) dated 22-6-1982

[2]Subs. by G.O.I.Notification No. G.S.R 676(E) dated 06-09-1994

[3]Omitted by G.O.I.Notification No. G.S.R 462(E) dated 22-6-1982

[4]Amended by S. O. No. 2139, dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972.)

[5]Amended by GSR No. 926 dated 16-7-1977, (Govt. of India Notification No. X. 11014/6/76-D & M.S. dated 24-6-77).

6Amended by G.O.I. Notification No. F.1-9/60-D dated 3rd July,1961.