

THE DRUGS AND COSMETICS RULES, 1945

PART VI

SALE OF DRUGS OTHER THAN HOMOEOPATHIC MEDICINES

59. (1) The State Government shall appoint Licensing Authorities for the purpose of this Part for such areas as may be specified.

(2) Applications for the grant or renewal of a license to sell, stock, exhibit or offer for sale or distribute drugs, other than those included in Schedule X, shall be made in Form 19 accompanied by a fee of rupees one thousand and five hundred or Form 19-A accompanied by a fee of rupees five hundred, as the case may be, or in the case of drugs included in Schedule X shall be made in Form 19-C accompanied by a fee of rupees five hundred, to the licensing authority:

Provided that in the case of an itinerant vendor or an applicant who desires to establish a shop in a village or town having population of 5,000 or less, the application in Form 19-A shall be accompanied by a fee of rupees ten .

(3) A fee of rupees one hundred and fifty shall be paid for a duplicate copy of a license to sell, stock, exhibit or offer for sale or distribute drugs, other than those included in Schedule X, or for a license to sell, stock, exhibit or offer for sale or distribute drugs, included in Schedule X, if the original is defaced, damaged or lost:

Provided that in the case of itinerant vendor or an applicant who desires to establish a shop in a village or town having a population of 5,000 or less, the fee for a duplicate copy of a license if the original is defaced, damaged or lost, shall be rupees two.

(4) Application for renewal of a license to sell, stock, exhibit or offer for sale or distribute drugs, after its expiry but within six months of such expiry shall be accompanied by a fee of rupees one thousand and five hundred plus an additional fee at the rate of rupees five hundred per month or part thereof in Form 19, rupees five hundred plus an additional fee at the rate of rupees two hundred and fifty per month or part thereof in Form 19-A and rupees five hundred plus an additional fee at the rate of rupees two hundred and fifty per month or part thereof in Form 19-C:

Provided that in the case of an itinerant vendor or an applicant desiring to open a shop in a village or town having a population of 5,000 or less the application for such renewal shall be accompanied by a fee of rupees ten, plus an additional fee at the rate of rupees eight per month or part thereof.

60. A licensing authority may with the approval of the State Government by an order in writing delegate the power to sign licenses and such other powers as may be specified in the order to any other person under his control.

61. *Forms of licenses to sell drugs.* — (1) a license to sell, stock, exhibit or offer for sale or distribute drugs other than those specified in Schedules C, C (1) and X and by retail on restricted license or by wholesale, shall be issued in Form 20, Form 20-A or Form 20 –B, as the case may be:

Provided that a license in Form 20-A shall be valid for only such drugs as are specified in the license.

(2) A license to sell, stock, exhibit or offer for sale or distribute drugs specified in Schedule C and C (1) excluding those specified in Schedule X, by retail on restricted license or by wholesale shall be issued in Form 21, Form 21-A or Form 21-B, as the case may be:

Provided that a license in Form 21-A shall not be granted for drugs specified in Schedules C and shall be valid for only such Schedule C (1) drugs as are specified in the license.

(3)A license to sell, stock, exhibit or offer for sale or distribute] drugs specified in Schedule X by retail or by wholesale shall be issued in Form 20-F or Form 20-G as the case may be.

62. Sale at more than one place.- If drugs are sold or stocked for sale at more than one place, separate application shall be made, and a separate license shall be issued, in respect of each such place:

Provided that this shall not apply to itinerant vendors who have no specified place of business and who will be licensed to conduct business in a particular area within the jurisdiction of the licensing authority.

62A. Restricted licenses in Forms 20-A and 21-A. — (a) Restricted licenses in Forms 20-A and 21-A shall be issued subject to the discretion of the Licensing Authority, to dealers or persons in respect of drugs whose sale does not require the supervision of a qualified person.

(b) Licenses to itinerant vendors shall be issued only in exceptional circumstances for *bona fide* travelling agents of firms dealing in drugs or for a vendor who purchases drugs from a licensed dealer for distribution in sparsely populated rural areas where other channels of distribution of drugs are not available.

(c) The licensing authority may issue a license in Form 21-A to a travelling agent of a firm but to no other class of itinerant vendors for the specific purpose of distribution to medical practitioners or dealers, samples of biological and other special products specified in Schedule C:

Provided that travelling agents of licensed manufacturers, agents, of such manufacturers and importers of drugs shall be exempted from taking out license for the free distribution of samples of medicines among members of the medical profession, hospitals, dispensaries and the medical institution or research institutions.

62-B. Conditions to be satisfied before a license in Form 20-A or Form 21-A is granted. — (1) A license in Form 20-A or Form 21-A shall not be granted to any person, unless the authority empowered to grant the license is satisfied that the premises in respect of which the license is to be granted are adequate and equipped with proper storage accommodation for preserving the properties of drugs to which the license applies:

Provided that this condition shall not apply in the case of license granted to itinerant vendors.

(2) In granting a license under Rule 62-A the authority empowered to grant it shall have regard to : —

(i) the number of licenses granted in the locality during one year immediately preceding; and

(ii) the occupation, trade or business carried on by such applicant :

Provided that the licensing authority may refuse to grant or renew a license 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 license granted thereunder, he is not a fit person to whom a license should be granted under this Rule.

(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 the 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 order in relation thereto as it thinks fit.

62C. *Application for license to sell drugs by wholesale or to distribute the same from a motor vehicle.*—(1) Application for the grant or renewal of a license to sell by wholesale or to distribute from a motor vehicle shall be made to the Licensing Authority in Form 19-AA and shall be accompanied by a fee of rupees five hundred:

Provided that if the applicant applies for the renewal of a license after its expiry but within six months of such expiry , the fee payable for renewal of such license shall be rupees five hundred plus an additional fee at the rate of rupees two hundred and fifty per month or part thereof.

(2) A fee of rupees one hundred and fifty shall be paid for a duplicate copy of a license issued under this rule, if the original is defaced, damaged or lost.

62D. *Form of licenses to sell drugs by wholesale or distribute drugs from a motor vehicle.*—A license shall be issued for sale by wholesale or for distribution from a motor vehicle of drugs other than those specified in Schedule and Schedule C(1) in Form 20BB and of drugs specified in Schedule C and Schedule C(1) in Form 21BB :

Provided that such a license shall not be required in a case where a public carrier or a hired vehicle is used for transportation or distribution of drug.

63. *Duration of license.*— An original license or a renewed license to sell drugs, unless sooner suspended or cancelled, shall be valid for a period of five years on and from the date on which it is granted or renewed:

Provided that if the application for renewal of license 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 license shall continue to be in force until orders are passed on the application. The license shall be deemed to have expired if application for its renewal is not made within six months after its expiry.

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

63B. *Certificate of renewal of license.*— A certificate of renewal of a license in Form 20BB or Form 21BB shall be issued in Form 21-CC.

64. *Conditions to be satisfied before a license in Form 20, 20-B, 20-F, 20-G, 21 or 21-B is granted .*—(1)A license in Form 20, 20-B, 20-F, 20-G, 21 or 21-B to sell, stock, exhibit or offer for sale or distribute drugs shall not be granted or renewed to any

person unless the authority empowered to grant the license is satisfied that the premises in respect of which the license is to be granted or renewed are adequate, equipped with proper storage accommodation for preserving the properties of the drugs to which the license 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 license in Form 20 or 21 shall not be granted or renewed unless the licensing authority is satisfied that the requirements prescribed for a pharmacy in Schedule N have been complied with:

Provided further that license in Form 20-F shall be granted or renewed only to a pharmacy and in areas where a pharmacy is not operating, such license may be 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 made 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 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 or renewing a license under sub-rule (1) the authority empowered to grant it shall have regard—

(i) to the average number of licenses 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 license 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 license granted thereunder, he is not a fit person to whom a license should be granted under this rule. Every such order shall be communicated to the licensee as soon as possible:

Provided further that in respect of an application for the grant of a license 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 license is to be granted are:-

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

(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 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:

Provided also that,

(i) in respect of an application for the grant of a license in Form 20 or Form 21 or both, the licensing authority shall satisfy itself that 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 license

(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 meters:

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

(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 licenses. — Licenses in 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) Any drug shall, if compounded or made on the licensee's premises be compounded or made by or under the direct and personal supervision of a registered Pharmacist.

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

(3) (1) The supply of any drug 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,

(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 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 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 a 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 also 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 Employees State Insurance Scheme if all the above particulars are given in that prescription, and

(ii) any drug other than that specified in 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 license to sell by retail:

Provided that the Licensing Authority may require records to be maintained only in prescription register if it 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 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 manufacturer, 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 a 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 a license to sell by retail:

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

(3)(i) 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 license number of the dealer,

(b) Serial number of the cash/credit memo,

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

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

(4)(i) Records of purchase of a drug 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 purchase,

(b) the name and address of the person from whom purchased and the number of the relevant license held by him,

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

(d) the name of the manufacturer of the drug.

(ii) Purchase bills including cash or credit memo 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 drug by wholesale shall be made against a cash or credit memo bearing the name and address of the licensee and his license 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 license 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 Practitioner for the purpose of supply to his patients the name and address of the authority, institution or the Registered Medical Practitioner as the case may be,

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

(d) the name of the manufacturer,

(e) the signature of the competent person under whose supervision the sale was effected.

(2) Carbon copies of cash or credit memos specified in clause (1) shall be preserved as records for a period of three years from the date of the sale of the drug.

(3) (i) 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 the relevant license held by the person from whom purchased,

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

(d) the name of the manufacturer of the drug.

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

(6) The licensee shall produce for inspection by an Inspector appointed under the Act on demand all registers and records maintained under these Rules, and shall supply to the Inspector such information as he may require 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 records 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 not be necessary to record 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 Practitioner and in the case of substances specified in Schedule X, the prescriptions 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 which shall be preserved by the licensee for a period of two years.

(10) For the purposes of clause (9) a prescription 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 meant for veterinary use;

(c) indicate the total amount of the medicine to be supplied and the dose 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 requirements 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 at 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 prescriber the name and address of 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 X, may supply any other preparation, whether containing the same substance or not, in lieu thereof.

(12) Substances specified in Schedule 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 persons have access;]

(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 “registered Pharmacist” 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 services of a “registered Pharmacist” and maintain a “Pharmacy” for compounding against prescriptions:

Explanation:- For the purpose of this rule,-

(i) “registered Pharmacist” means a person who is a registered Pharmacist as defined in clause (i) of section (2) of the Pharmacy Act, 1948 (Act No. 8 of 1948):

Provided that the provisions of sub-clause (i) shall not apply to those persons who are already approved as “qualified person” by the Licensing authority on or before 31st December, 1969:

(ii) “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 a potency not less than or not to acquire a toxicity greater than that required or permitted by the prescribed test.

(16) The licensee shall maintain an Inspection Book in Form 35 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, label 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 manufacturer or his representative for the withdrawal, reimbursement or disposal of the same, may be stocked after the date of expiration of potency pending such withdrawal, reimbursement 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 kept in packages or cartons, the top of which shall display prominently, 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 Corporation, the Central Government Health Scheme, the Government Medical Stores Depots, the Armed Forces Medical Stores or other Government institutions, which bears a distinguishing mark or any inscription on the drug or on the label affixed to the container thereof indicating this 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 as approved chemists, by the State Government in writing, under the employees' State Insurance Scheme, or have been appointed as authorised agent or distributor, by the manufacturer in writing, for drugs meant for consumption under the Central Government Health Scheme, the Government Medical Stores Depots, the Armed Forces Medical Stores or other Government Institutions for drugs meant for consumption under those schemes or have been appointed as authorised Depots or Carrying and Forwarding agent by the manufacturer in writing, for storing free samples meant for distribution to medical profession subject to the conditions that the stock shall be stored separately from the trade stocks and shall maintain separate records of the stocks received and distributed by them.

(19) The supply by retail of any drug in a container other than the one in which the manufacturer has marketed the drug, shall be made only by dealers who employ the services of a registered Pharmacist and such supply shall be made under the direct supervision of the registered Pharmacist in an envelope or 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 medicines for treatment of animals kept in a retail shop or premises shall be labelled 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 drugs, 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 serially 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 transaction;

- (ii) Quantity received, if any, the name and address of the supplier and the number of the relevant license held by the supplier;
- (iii) Name of the drug;
- (iv) Quantity supplied;
- (v) Manufacturer'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.

65A. *Additional information to be furnished by an applicant for licence or a licensee to the Licensing Authority.* —The applicant for the grant of a license or any person granted a license under this Part shall, on demand, furnish to the licensing authority, before the grant of the license or during the period the license is in force, as the case may be, documentary evidence in respect of the ownership of occupation or rental or other basis of the premises, specified in the application for license or in the license granted, constitution of the firm, or any other relevant matter which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the license, as the case may be.

66. *Cancellation and suspension of licenses.* — (1) The Licensing Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed by an order in writing stating the reasons therefor, cancel a license issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the license or with any provisions of the Act or Rules thereunder:

Provided that, where such failure or contravention is the consequence of an act or omission on the part of an agent or employee, the license shall not be cancelled or suspended if the licensee proves to the satisfaction of the licensing authority—

(a) that the act or omission was not instigated or connived at by him or, if the licensee is a firm or company, by a partner of the firm or a director of the company, or

(b) that he or his agent or employee had not been guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place, or where his agent or employee had been guilty of any such act or omission the licensee had not or could not reasonably have had, knowledge of that previous act or omission, or

(c) if the act or omission was a continuing act or omission, he had not or could not reasonably have had knowledge of that previous act or omission, or

(d) that he had used due diligence to ensure that the conditions of the license or the provisions of the Act or the Rules thereunder were observed.

(2) A licensee whose license has been suspended or cancelled may, within three months of the date of order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.

66A. *Procedure for disposal of drugs in the event of cancellation of license.*—(1) In case a licensee, whose license has been cancelled, desires to dispose of the drugs he has in his possession in the premises in respect of which the license has been cancelled, he shall apply in writing to the licensing authority for this purpose, giving the following particulars, namely:—

(a) the name and address of the person to whom the drugs are proposed to be sold or supplied together with the number of the license for sale or manufacture, as the case may be, held by him,

(b) the names of drugs together with their quantities, batch numbers, the names and addresses of their manufacturers and the dates of their expiry, if any, proposed to be sold to the person mentioned in clause (a).

(2) The licensing authority may, after examination of the particulars referred to in sub-rule (1) and, if necessary, after inspection by an Inspector of the premises where the drugs are stocked, grant the necessary permission for their disposal.]

PART VIA

SALE OF HOMOEOPATHIC MEDICINES

67A. (1) The State Government shall appoint Licensing Authorities for the purpose of this Part for such areas as may be specified.

(2) Application for the grant or renewal of a license to sell, stock or exhibit or offer for sale or distribute Homoeopathic medicines shall be made in Form 19-B to the Licensing Authority and shall be accompanied by a fee of rupees two hundred and fifty:

Provided that if the applicant applies for renewal of license after its expiry but within six months of such expiry the fee payable for renewal of such license shall be rupees two hundred and fifty plus an additional fee at the rate of rupees fifty or part thereof.

(3) If the original license is either defaced, damaged or lost, a duplicate copy thereof may be issued on payment of a fee of rupees fifty.

67B. A Licensing Authority may, with the approval of the State Government, by an order in writing, delegate the power to sign licenses and such other powers, as may be specified, to any other person under his control.

67C. *Forms of licenses to sell drugs.*— (1) A license to sell, stock or exhibit or offer for sale or distribute Homoeopathic medicines by retail or by wholesale shall be issued in Form 20-C or 20-D as the case may be.

67-D. *Sale at more than one place.*— If drugs are sold or stocked for sale at more than one place, a separate application shall be made and a separate license shall be obtained in respect of each place.

67-E. *Duration of licenses.*— An original license or a renewed license unless it is sooner suspended or cancelled shall be ¹ [valid for a period of five years on and from the date on which] it is granted or renewed :

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

67-EE. Certificate of renewal.— The certificate of renewal of a sale license in Forms 20-C and 20-D shall be issued in Form 20-E.

67-F. Condition to be satisfied before a license in Form 20-C or Form 20-D is granted.—(1) A license in Form 20-C or Form 20-D to ⁴ [to sell, stock or exhibit or offer for sale or distribute] Homoeopathic medicines shall not be granted to any person unless the authority empowered to grant the license is satisfied that the premises in respect of which the license is to be granted are clean and in the case of a license in Form 20-C the sale premises is in charge of a person who is or has been dealing in Homoeopathic medicines and who is in the opinion of the Licensing Authority competent to deal in Homoeopathic medicines:

Provided that no registered Homoeopathic medical practitioner who is practising Homoeopathy in the premises where Homoeopathic medicines are sold shall deal in Homoeopathic medicines.

(2) Any person who is aggrieved by the order passed by the Licensing Authority under sub-rule (1) may within 30 days from the date of the 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 case, make such order in relation thereto as it thinks fit.

67-G. Conditions of license.— License in Form 20-C or 20-D shall be subject to the conditions stated therein and to the following further conditions, namely:—

(1) The premises where the Homoeopathic medicines are stocked for sale or sold are maintained in a clean condition.

(2) The sale of Homoeopathic medicines shall be conducted under the supervision of a person, competent to deal in Homoeopathic medicines.

(3) The licensee shall permit an Inspector to inspect the premises and furnish such information as he may require for ascertaining whether the provisions of the Act and the Rules made thereunder have been observed.

(4) The licensee in Form 20-D shall maintain records of purchase and sale of Homoeopathic medicines containing alcohol together with names and addresses of parties to whom sold.

(5) The licensee in Form 20-C shall maintain records of purchase and sale of Homoeopathic medicines containing alcohol. No records of sale in respect of Homoeopathic potentised preparation in containers of 30 ml. or lower capacity and in respect of mother tinctures made up in quantities up to 60 ml. need be maintained.

(6) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

67-GG. Additional information to be furnished by an applicant for license or a licensee to the Licensing Authority.— The applicant for the grant of a license or any person granted a license under this Part shall, on demand furnish to the Licensing Authority, before the grant of the license or during the period the license is in force as

the case may be, documentary evidence in respect of the ownership or occupation or rental or other basis of the premises, specified in the application for license or in the license granted, constitution of the firm, or any other relevant matter, which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the license, as the case may be.

67-H. Cancellation and suspension of licenses.—(1) The Licensing Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed by an order in writing stating the reasons therefor, cancel a license issued under this Part or suspend it for such period as he thinks fit, if in his opinion, the licensee has failed to comply with any of the conditions of the license or with any provisions of the Act or Rules made thereunder :

Provided that, where such failure or contravention is the consequence of an act or omission on the part of an agent or employee, the license shall not be cancelled or suspended if the licensee proves to the satisfaction of the Licensing Authority—

(a) that the act or omission was not instigated or connived at by him or, if the licensee is a firm or company, by a partner of the firm or a director of the company, or

(b) that he or his agent or employee had not been guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place, or where his agent or employee had been guilty of any such act or omission, the licensee had not or could not reasonably have had, knowledge of that previous act or omission, or

(c) if the act or omission was a continuing act or omission that he had not or could not reasonably have had knowledge of that previous act or omission, or

(d) that he had used due diligence to ensure that the conditions of the license or the provisions of the Act or the Rules thereunder were observed.]

(2) A licensee whose license has been suspended or cancelled may, within three months of the date of the order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.