

# \*THE DRUGS RULES, 1945<sup>1</sup>

[21st December, 1945]

In exercise of the powers conferred by <sup>1</sup>[sections 6(2), 12, 33 and 33(N)] of the Drugs <sup>2</sup>[and Cosmetics] Act, 1940 (23 of 1940), the Central Government is pleased to make the following Rules:—

## PART I PRELIMINARY

1. **Short title, extent and commencement.**—(1) These Rules may be called the Drugs <sup>3</sup>[\*\*\*] Rules, 1945.

(2) They extend to the whole of India <sup>3</sup>[\*\*\*].

2. **Definitions.**—In these Rules, unless there is anything repugnant in the subject or context—

(a) "the Act" means the Drugs and Cosmetics Act, 1940 (23 of 1940), as amended from time to time;

<sup>6</sup>[(aa) "biopharmaceutical classification system" means a system used to classify drugs on the basis of solubility and permeability, classified as category I-high solubility and high permeability, category II-low solubility and high permeability, category III-high solubility and low permeability, and category IV-low solubility and low permeability;] <sup>7</sup>[(b) "Central Licence Approving Authority" means the Drugs Controller, India, or the Joint Drugs Controller (India) or the Deputy Drugs Controller (India) appointed by the Central Government;]

(c) "Director" means the Director of the Central Drugs Laboratory;

(d) "Form" means a Form set forth in Schedule A;

<sup>8</sup>[(dd) "Homoeopathic medicines" include any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature of India and abroad and which is prepared according to the techniques of Homoeopathic pharmacy and covers combination of ingredients of such

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 Cosmetics (1st Amendment) Rules, 1997.]

<sup>6</sup>[(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.]

**65. Condition of licences.**—Licences in <sup>44</sup> [Forms 20, 20A, 20B, 20F, 20G, 21 and 21B] shall be subject to the conditions stated therein and to the following general conditions:—

<sup>1</sup>[(1) Any drug shall, if compounded or made on the licensee's premises, be compounded or made by or under the direction and personal supervision of a <sup>45</sup> [registered pharmacist],

(2) The supply, otherwise than by way of wholesale dealing <sup>46</sup> [\*\*\*] of any drug supplied on the prescription of a Registered Medical Practitioner shall be effected only by or under the personal supervision of a <sup>2</sup> [registered pharmacist].

<sup>4</sup>[(3) (1) The supply of any drug <sup>3</sup> [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 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

<sup>5</sup>[(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 <sup>47</sup>[Schedule H and Schedule HI]] the name of manufacturer of the drug, its batch number and the date of expiry of potency, if any,

(g) the signature of the <sup>2</sup>[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 case or credit memo books, 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 Employees State Insurance Scheme if all the above particulars are given in that prescription, and

(ii) any drugs other than that specified in <sup>48</sup>[Schedule C or <sup>2</sup>[Schedule H and Schedule HI]] 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.

<sup>3</sup>[(h) the supply of a drug specified in Schedule HI shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.]

(2) The option to maintain a prescription register or a cash or credi 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 <sup>49</sup>[\*\*\*] of the licence 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.]

<sup>5</sup>[(4) (1) The supply by retail, otherwise than on a prescription of a drug specified in Schedule C <sup>50</sup>[\*\*\*] 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 cash or credit memo book shall be made in writing to the Licensing Authority at the time of application for the grant<sup>1</sup>[\*\*\*] of a licence 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 or credit memo book are not legible.

(3) (i) The supply by retail of any drug shall be made against a cash or credit memo which shall contain the following particulars: —

(a) name, address and sale licence number of the dealer,

<sup>2</sup>[(b) serial number of the cash or credit memo,]

<sup>3</sup>[(c)] the name and quantity of the drug supplied.

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

<sup>4</sup>[(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 licence 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 memos shall be serially numbered by the licensee and maintained by him in a chronological order.]]

<sup>5</sup>[(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 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 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,

<sup>1</sup> [(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.

<sup>2</sup>[(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 relevant licence 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 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.

<sup>1</sup>[(9) (a) Substances specified in <sup>51</sup>[Schedule H and Schedule HI] 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 <sup>2</sup>[Schedule H and Schedule HI] 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;

<sup>3</sup>[(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 <sup>2</sup>[Schedule H and Schedule HI] <sup>52</sup>[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.

<sup>5</sup>[(11A) No person dispensing a prescription containing substances specified in <sup>1</sup>[<sup>2</sup>[Schedule H and Schedule HI] or X] may supply any other preparation, whether containing the same substances or not in lieu thereof.]

<sup>1</sup>[(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.]

<sup>1</sup>[\*\*\*]

<sup>2</sup>[(15) (a) The description "Drugstore" shall be displayed by such licensees who do not require the services of a <sup>53</sup>[Registered Pharmacist].

(b) The description "Chemists and Druggists" shall be displayed by such licensees who employ the services of a <sup>3</sup>[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 <sup>3</sup>[Registered Pharmacist] and maintain a "Pharmacy" for compounding against prescriptions.

<sup>3</sup>[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 (8 of 1948):

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

(ii) "Date of Expiry of Potency" means the date that is recorded on the container label or wrapper as the date upto which the substance may be expected to retain a potency nor less than or not to acquire a toxicity greater than that required or permitted by the prescribed test.]]

<sup>4</sup>[(16) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.]

<sup>5</sup>[(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 tradestocks '[and all such drugs shall be kept in packages or cartons, the top of which shall display prominently, the words "Not for sale"'.]

<sup>2</sup>[(18) No drug intended for distribution to the medical profession as free sample which bears a label on the container as specified in clause <sup>3</sup>[(ix)] 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:]

<sup>4</sup>[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 Employee's 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 <sup>5</sup>[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.]

<sup>6</sup>[(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 <sup>7</sup>[Registered Pharmacist] and such supply shall be made under the direct supervision of the <sup>7</sup>[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.]

<sup>8</sup>[(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 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.]

<sup>1</sup>[(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 licence 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.]

<sup>2</sup>**[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 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, 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 which applying for or after obtaining the licence, as the case may be.]

<sup>3</sup>**[65B. Inspection for verification of compliance.]**—The licensing authority shall cause inspection, by the Inspector appointed under the Act, of each premises licensed under this Part, to verify the compliance with the conditions of licence and the provisions of the Act and these rules, not less than once in three years or as needed as per risk based approach.]

**66. Cancellation and suspension of licences.**—(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 therefore, cancel a licence 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 licence or with any provisions of the Act or rules thereunder:

<sup>1</sup>[Provided that, where such failure or contravention is the consequence of an Act or omission on the part of an agent or employee, the licence 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 licence or the provisions of the Act or the rules thereunder were observed.]

<sup>2</sup>[(2) A licensee whose licence 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.]

<sup>3</sup>[**66A. Procedure for disposal of drugs in the event of cancellation of licence.** — (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 licence 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 licence 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.]

## <sup>2</sup>[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 licence <sup>54</sup>[to sell, stock, exhibit or offer for sale or distribute] Homoeopathic medicines shall be made in Form 19B to the licensing authority and shall be accompanied by <sup>55</sup>[a fee of rupees two hundred and fifty]:

<sup>5</sup>[Provided that if the applicant applied for renewal of licence after its expiry but within six months of such expiry the fee payable for renewal of such licence shall be <sup>4</sup>[rupees two hundred and fifty plus an additional fee at the rate of rupees fifty per month or part thereof].]

<sup>6</sup>[(3) If the original licence is either defaced, damaged or lost, a duplicate copy thereof may be issued on payment of <sup>56</sup>[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 licences and such other powers, as may be specified, to any other person under this control.

**67C. Form of licences to sell drugs.**—(1) A licence <sup>3</sup>[to sell, stock, exhibit or offer for sale or distribute] Homoeopathic medicines by retail or by wholesale shall be issued in Form 20C or Form 20D as the case may be: