

***THE DRUGS RULES, 1945¹**

[21st December, 1945]

In exercise of the powers conferred by ¹[sections 6(2), 12, 33 and 33(N)] of the Drugs ²[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 ³[***] Rules, 1945.

(2) They extend to the whole of India ³[***].

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;

⁶[(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;] ⁷[(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;

⁸[(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

(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.]

²[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 licence⁵⁴ [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 by⁵⁵ [a fee of rupees two hundred and fifty]:

⁵[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 be⁴ [rupees two hundred and fifty plus an additional fee at the rate of rupees fifty per month or part thereof].]

⁶[(3) If the original licence is either defaced, damaged or lost, a duplicate copy thereof may be issued on payment of⁵⁶ [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 licence³ [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:

⁸[Provided that no licence shall be required for exhibiting the drugs for promotional activities in any fair.]

67D. 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 licence shall be obtained in respect of each place.

67E. Duration of licences.—An original licence or a renewed licence unless it is sooner suspended or cancelled shall be ⁷[valid for a period of five years on and from the date on which] it is granted or renewed:

⁵[Provided that if the application for renewal of a 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 and the licence shall be deemed to have expired if application for its renewal is not made within six months after its expiry]

¹[**67EE. Certificate of renewal.**—The certificate of renewal of a sale licence in Forms 20C and 20D shall be issued in Form 20E.]

67F. Conditions to be satisfied before a licence in Form 20C or Form 20D is granted.—(1) A licence in Form 20C or Form 20D ²[to sell, stock exhibit or offer for sale or distribute] Homoeopathic medicines shall not be granted to any person unless the authority empowered to grant the licence is satisfied that the premises in respect of which the licence is to be granted are clean and in the case of a licence in form 20C the sale premises is in charge of a person who is or has been dealing in Homoeopathic medicines and

³[who is having,—

- (a) degree in Homoeopathy from a recognised University; or
- (b) degree in Pharmacy from a recognised University; or
- (c) Bachelor's degree from a recognised University with one year experience of dealing in Homoeopathic medicines in the clinic of a registered Homoeopathic Medical Practitioner or with the holder of licence in Form 20C or Form 20D; or

(d) diploma in Homeopathic Pharmacy; or

(e) diploma in Homeopathy Medicine and Surgery:]

⁴[Provided that the person already registered with the State Licensing Authority as competent person for the purposes of grant of license in Form 20C or Form 20D or both prior to the coming into force of the Drugs and Cosmetics (11th Amendment) Rules, 2017, shall continue to be considered as a competent person for the said purposes:

Provided further that no registered Homeopathic medical practitioner who is practising Homeopathy in the premises where Homeopathic medicines are sold shall deal in Homeopathic 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.

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

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

¹ [(2) In the case of licence in Form 20C the Homeopathic medicines shall be sold,—

(i) under the supervision of a person having qualifications referred to in sub-rule (1) of rule 67F; and

(ii) in manufacturer's sealed packing only except dispensing of medicines in globules, water or milk sugar or as per prescription of a Homeopathic Medical Practitioner.]

(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 20D shall maintain records of purchase and sale of Homoeopathic medicines containing alcohol together with names and addresses of parties to whom sold.

²[(5) The licensee in Form 20C shall maintain records of purchase and sale of Homoeopathic medicines containing alcohol. No records of sale in respect of Homoeopathic potentised preparations 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.]

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

⁴[**67GG. 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 or 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.]

67H. 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, 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 made thereunder:

¹ [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, 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 licence or the provisions of the Act or the rules thereunder were observed.]

²[(2) A licensee whose licence 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.]]

³[MANUFACTURE FOR SALE OR FOR DISTRIBUTION] OF DRUGS OTHER THAN HOMOEOPATHIC MEDICINES

68. Manufacture on more than one set of premises. —If drugs are manufactured on more than one set of premises a separate application shall be made and a separate licence shall be issued in respect of each such set of premises.

⁴[68A. Grant ⁵[*] of Licences by the Central Licence Approving Authority.** —(1) Notwithstanding anything contained in this Part, on and from the commencement of the Drugs and Cosmetics (9th Amendment) Rules, [*vide* G.S.R 923 (E), dated 14th December, 1992], a licence for the manufacture for sale or distribution of drugs as specified from time to time by the Central Government by notification in the Official Gazette, for the purpose of