

1. (ई-फार्मैसी का नाम व पता) को एतद्वारा, औषधि और प्रसाधन सामग्री नियम, 1945 की अनुसूची X में विनिर्दिष्ट ट्रेड्किलाइज़र और स्वापक औषधि और मनःप्रभावी पदार्थ अधिनियम, 1985 (1985 का 61) के स्वापक तथा मनःप्रभावी वर्गों के अंतर्गत शामिल औषधियों से भिन्न औषधि वर्गों के वितरण, विक्रय भंडारण या खुदरा प्रदर्शन या प्रस्ताव अथवा थोक व्यापार के द्वारा विक्रय हेतु और नीचे निर्दिष्ट शर्तों तथा औषधि एवं सौंदर्य प्रसाधन अधिनियम, 1940 एवं उसके अंतर्गत बनाए गए नियमों के अधीन ई-फार्मैसी प्रचालन के लिए पंजीकृत किया जाता है।
2. पंजीकरण दिनांक से तक प्रभावी रहेगा।
3. ई-फार्मैसी (यूआरएल/मोबाइल अनुप्रयोग/ई-फार्मैसी पद्धति के माध्यम से प्रचालित की जाएगी।
4. पंजीकृत प्रभारी फार्मासिस्ट का नाम एवं पंजीकरण संख्या

केंद्रीय लाइसेंसदाता प्राधिकारी

(हस्ताक्षर)

(नाम एवं पदनाम)

पंजीकरण की शर्त

पंजीकरण धारक औषधि और सौन्दर्य प्रसाधन अधिनियम, 1940 के प्रावधानों और समय-समय पर संशोधन के तहत बने नियमों का अनुपालन करेगा।

[फा. सं. X.11035/1010/2016-डीआरएस-पार्ट-I]

सुधीर कुमार, संयुक्त सचिव

नोट : मूल नियम अधिसूचना सं. एफ.28-10/45-एच (1), तारीख 21 दिसंबर, 1945 के तहत भारत के राजपत्र में प्रकाशित किए गए थे और अंतिम संशोधन अधिसूचना सं. सा.का.नि. (अ) तारीख के माध्यम से किया गया था।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 28th August, 2018

G.S.R. 817(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by Section 12 and Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby, and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of forty-five days from the date on which copies of the Gazette of India containing these draft rules are made available to the public.

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

Draft Rules

1. (1) These rules may be called the Drugs and Cosmetics (_____ Amendment) Rules, 2018.
(2) It shall come in to force after their final publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945 (hereinafter to be referred as said rules) after rule 67H and before Part VII the following PART VIB shall be inserted, namely,-

“PART VIB**SALE OF DRUGS BY E-PHARMACY****67-I. Definitions.- In this PART unless the context otherwise requires,-**

- (a) “e-pharmacy” means business of distribution or sale, stock, exhibit or offer for sale of drugs through web portal or any other electronic mode;
- (b) “e-pharmacy portal” means a web or electronic portal or any other electronic mode established and maintained by the e-pharmacy registration holder to conduct business of e-pharmacy;
- (c) “Central Licensing Authority” for the purposes of this PART, the Central Licensing Authority means licensing authority appointed by the Central Government under clause (b) of rule 21 of the Drugs and Cosmetics Rules, 1945;
- (d) “prescription” means an instruction from a Registered Medical Practitioner to a patient, written by hand or in any electronic mode duly signed, to dispense a drug and quantity of drug to a patient;
- (e) “sale by way of e-pharmacy” means a sale whether to a hospital, or dispensary, or a medical, educational or research institute or to any other person through e-pharmacy by way of retail sale;”
- (f) The words and expressions used herein and not defined in this PART but defined in the Drugs and Cosmetics Act, 1940 and rules made thereunder shall have the same meaning assigned to them in that Act or rules, respectively.

67J.Registration of - e-pharmacy- (1) With effect from the commencement of PART VIB of these rules, no person shall distribute or sell, stock, exhibit or offer for sale of drugs through e-pharmacy portal unless registered under rule 67N.

- (2) The e-pharmacy registration holder shall receive the orders for retail sale through e-pharmacy portal.
- (3) e-pharmacy registration holder shall arrange or provide the drugs, as per the prescription received from the customer, within the period specified by the e-pharmacy registration holder at the time of placement of the order through e-pharmacy portal.
- (4) The e-pharmacy registration holder shall have a facility for customer support and grievance redressal of all stakeholders which shall run not less than twelve hours for all seven days of a week:

Provided, that the facility for customer support shall have registered pharmacist in place to answer the queries of customers through such customer helpline.

67K. Disclosure of information generated through e-pharmacy portal. - (1) The information received by the e-pharmacy registration holder from the customer by way of prescription or in any other manner shall not be disclosed by the e-pharmacy registration holder for any other purposes nor shall same be disclosed to any other person.

- (2) The e-pharmacy registration holder shall be duty bound to provide such information to the Central Government or the State Government, as the case may be, as and when required for public health purposes.
- (3) The e-pharmacy portal shall be established in India through which they are conducting the business of e-pharmacy and shall keep the data generated localised:

Provided, that in no case the data generated or mirrored through e-pharmacy portal shall be sent or stored, by any means, outside the India.

67L. Application for registration of e-pharmacy. - (1) Any person who intends to conduct business of e-pharmacy shall apply for the grant of registration to the Central Licensing Authority in Form 18AA through the online portal of the Central Government.

(2) The information furnished above shall be supported by the duly notarised affidavit from the applicant.

(3) Any application for the grant of e-pharmacy registration of e-pharmacy made in Form 18AA to the Central Licensing Authority shall be accompanied with a fee of fifty thousand rupees and the information and documents as specified in Form 18AA.

67M. Conditions of registration of e-pharmacy. -

(1) An e-pharmacy registration holder shall comply with provisions of Information Technology Act, 2000 (21 of 2000) and rules made thereunder.

(2) The details of patient shall be kept confidential and shall not be disclosed to any person other than the Central Government or the State Government concerned, as the case may be.

(3) The supply of any drug shall be made against a cash or credit memo generated through the e-pharmacy portal and such memos shall be maintained by the e-pharmacy registration holder as record which shall contain the following particulars: -

(i) name, address and sale licence number of the licensee who is dispensing the drugs mentioned in prescription uploaded on the e-pharmacy portal;

(ii) serial number and date of the cash/credit memo; and

(iii) the name of the drug, quantity, batch number or lot number, date of expiry and name of the manufacturer;

(iv) name and address of e-pharmacy registration holder with Registration Number along with signature/ digital signature of Registered Pharmacist in-charge.

(4) The e-pharmacy registration holder shall inform the Central Licensing Authority in writing in the event of any change in the constitution of the firm operating under the registration. Where any change in the constitution of the firm takes place, the current registration shall be deemed to be valid for a maximum period of three months from the date on which change takes place unless, in the meantime, a fresh registration has been taken from Licencing Authority in the name of the firm with the changed constitution.

(5) The e-pharmacy registration holder shall not carry out e-pharmacy with respect to the drugs covered under the categories of the Narcotic and psychotropic as referred to in the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), tranquilizers and the drugs as specified in the Schedule X of Drugs and Cosmetics Rules, 1945.

(6) The e-pharmacy shall mention the following details on its e-pharmacy portal, -

(i) registration issued in Form 21AA;

(ii) constitution of the firm including details of the Directors, partners or persons having ownership of the E-pharmacy;

(iii) official logo of the e-pharmacy portal, if any.

(iv) details of the logistic service provider;

(v) return policy of dispensed drugs;

(vi) name of the registered pharmacist, with the Regd. No. and name of Pharmacy Council where the pharmacist has been registered, who validates the prescription prior to forward it to dispense the drugs;

(vii) contact details of e-pharmacy including telephone number, mobile number, e-mail, address;

(viii) procedure for lodging grievances, complaints etc. on the e-pharmacy portal and complaint redressal mechanism.

67N. Grant of registration of e-pharmacy. - (1) The Central Licencing Authority, may, after scrutiny of the information and documents furnished with the application in Form 18AA and such further enquiry, if any, as may be considered necessary, -

- (i) if satisfied, that the provisions of this Part have been complied with, shall grant registration to the applicant in Form 21AA.
- (ii) if not, reject the application, for reasons to be recorded in writing, within a period of thirty days, from the date the application made under rule 67L;
- (iii) in case, where the Licencing Authority considers that there are some deficiencies in the application and the same can be rectified, the Central Licencing Authority shall inform the applicant of the deficiencies within a period of thirty days;
- (iv) the applicant may, after being informed under clause (iii), rectify the deficiencies within a reasonable period specified by the Licencing Authority;
- (v) in case where the applicant rectifies the deficiency, within the period referred to in clause (iv) and provides required information and documents, the Licencing Authority shall scrutinise the application again and if satisfied that the provisions of this Part have been complied with, shall grant registration to the applicant in Form 21AA or if not satisfied, reject the application within a period of thirty days reckoned from the day when the required information and documents furnished.
- (vi) the Central Licencing Authority after registration of any e-pharmacy, shall list all the registered e-pharmacy on its website from time to time for information to all stakeholders.

(2) Notwithstanding anything contained in these rules, Licencing Authority may refuse to grant registration to any applicant in respect of whom it is satisfied that by reason of his conviction of an offence under the Act or this Part, 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.

(3) An applicant who is aggrieved by the decision of the Central Licencing Authority under sub-rule (1), may file an appeal within forty-five days from the date of receipt of such rejection before the Central Government in the Ministry of Health and Family Welfare, which may after such enquiry and after giving an opportunity of being heard to the appellant, dispose of the appeal within a period of sixty days.

67-O. Periodic Inspection of e-pharmacy, - The premises from where the e-pharmacy business is conducted shall be inspected, every two years, by a team of officers authorised by the Central Licencing Authority, with or without the experts in the relevant field or the officers authorised by the concerned State Licencing Authority.

67P. Procedure for distribution or sale, of drugs through e-Pharmacy, - (1) On receipt of prescription, through e-pharmacy portal, the registered pharmacist on behalf of the e-pharmacy registration holder shall verify the details of the patient, Registered Medical Practitioner and arrange for the dispense of the drugs as per the instructions of the Registered Medical Practitioner, if not already found dispensed;

(2) The e-pharmacy registration holder who has received prescription in sub-rule (1) shall dispense and made arrangement for supply of drugs from any retail or wholesale licenced premises under the Drugs and Cosmetics Act, 1940 and rules made thereunder;

(3) The details of the drugs dispensed including the patient details shall be maintained on the e-pharmacy portal.

(4) In case of e-prescription, the prescription shall be uploaded on the e-pharmacy portal and shall be kept in record by the dispenser.

67Q. Validity of registration of e-pharmacy, - A registration issued to any person in Form 21AA shall remain valid for a period a three years from the date of its issue.

67R. Renewal of Registration of e-pharmacy.- An e-pharmacy registration holder of e-pharmacy who intend to renew the registration issued under rule 67N in Form 21AA, shall make an application in

Form 18AA along with the a fee of fifty thousand rupees and the documents as specified in Form 18AA:

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

67S. Prohibition of advertisement of drugs through e-pharmacy, - No e-pharmacy shall advertise any drug on radio or television or internet or print or any other media for any purpose.

67T. Suspension or cancellation of registration. - (1) Where the e-pharmacy registration holder contravenes any provision of the Drugs and Cosmetics Act, 1940 and this Part, the Central Licensing Authority, shall, after giving the e-pharmacy registration holder an opportunity to show cause as to why such an order should not be passed, shall, by an order and for reasons to be recorded in writing, suspend it for such period as it considers necessary or cancel the registration.

(2) An e-pharmacy registration holder whose registration has been suspended or cancelled by the Central Licensing Authority, under sub-rule (1), may within forty-five days of the receipt of a copy of the order by such authority, prefer an appeal to the Central Government in the Ministry of Health and Family Welfare, and that Government, shall after giving the appellant an opportunity of being heard, confirm, reverse or modify such order.

(3) Where the licence of any e-pharmacy registration holder, as provided in the Proviso to sub-rule(2) of rule 67P, is cancelled by two or more States, the e-pharmacy registration granted by the Central Licencing Authority under rule 67N shall deemed to have been cancelled for all purposes.

67U. Complaint Redressal mechanism, - (1) In the event of suspicion of supply of a Not of Standard Quality or adulterated or misbranded or spurious drug through e-pharmacy to any customer, that customer may file a complaint in writing to the concerned State Drugs Controller, by whatever name called, in that State Licensing Authority, as the case may be.

(2) On receipt of the complaint as referred in sub-rule (1), that State Drugs Controller or whatever name called, shall take action as per the procedure specified in the Drugs and Cosmetics Act, 1940 and Rules made thereunder to decide the complaint of the customer.

(3) Without prejudice to sub-rule (2), the customer shall have a right to seek relief under the Consumer Protection Act, 1986 and rules made thereunder.

67V. Monitoring of e-pharmacy, - (1) The e-pharmacy registration holder shall maintain and update, from time to time, the information regarding the drugs availability, types of drugs offered for sale, supply channels or vendor lists, details of registered pharmacists, registered medical practitioner (if any) and any other requirements of the Drugs and Cosmetics Act and rules thereunder, on the e-pharmacy portal.

(2) The Central Licensing Authority and the State Licensing Authority shall monitor the data or information as referred to in sub-rule (1), periodically to ensure compliance with the provisions of the Drugs and Cosmetics Act, 1940 and Rules thereunder.

(3) without prejudice to anything contained in these rules, the Central Licencing Authority or State Licencing Authority, as the case may be, at any time, may direct any e-pharmacy registration holder to provide prescription on the basis of which the drugs have been dispensed for the purpose of transaction audit.

Explanation: For the purpose of this rule, "transaction audit" means audit of the received prescription by the e-pharmacy registration holder and the drugs dispensed on that basis for the risk based data samples or system generated random data samples.

67W. Mode of payment of fee. — The fee prescribed under this Part, payable to the Central Government, shall be paid through challan or by electronic mode, in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch of Bank of Baroda, or any other bank, notified by the Ministry of Health and Family Welfare in the Central Government, to be credited under the Head of Account "0210- Medical and Public Health, 04-Public Health, 104-Fees and Fines."

3. In the said rules, after Form 18A, the following Forms shall be inserted, namely, -

“FORM 18AA

[See rule 67L, 67N and 67R]

Application for grant of Registration or Renewal to distribute and sell, stock or exhibit or offer for sale, drugs through e-pharmacy

1. I/We of hereby apply for a registration or renewal to distribute or sale of drugs other than those specified under the categories of the Narcotic and Psychotropic as referred to in the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), tranquilizers and the drugs as specified in the Schedule X of Drugs and Cosmetics Rules, 1945.
2. Whether applicant is Individual or HUF or Company or Partnership or Limited liability partnership or public sector or any other entity details may be given along with proof.
3. Address of the e-pharmacy owner (Specify the Name, location, premises number, etc.)
4. Name of the Pharmacist In-charge of the e-pharmacy.....
5. URL/Mobile application/mode of e-pharmacy and mode of customer care
6. Fee paid on Rs..... receipt/challan/transaction id
7. I undertake to comply with all the conditions required to obtain registration as specified in PART VIB of the Drugs and Cosmetics Rules, 1945.

Place: _____

Date: _____

Signature
(Name & Designation)
Seal/Stamp of authorized/
Signature/Digital signature

Documents or Information to be enclosed by the applicant:

- (i) A copy of identity and address proof of the applicant, any one of the followings:
valid passport, voter ID card, valid permanent driving license, adhaar card;
- (ii) Constitution details of the applicant; whether proprietorship or partnership or limited liability partnership or company;
Details of mode of helpline facility for counselling the patient or his representative with respect to drug usage, its method of administration, warnings, contra-indications and any other information relating to the drugs sold through e-pharmacy;
- (iii) any other relevant information which may be required for the purpose of verifying the correctness of the statements made by the applicant, if any;”

4. In the said rules, after Form 21A, the following Forms shall be inserted, namely,-

“FORM 21AA

[See rule 67M, 67N, 67Q and 67R]

Registration to distribute and sell, stock or exhibit or offer for sale, drugs through e-pharmacy

Registration No: _____

Date:

1. having situated at is hereby registered to distribute or sell, stock or exhibit or offer for sale by retail dealing for the categories of drugs, other than those specified under the categories of the Narcotic and Psychotropic as referred to in the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), tranquilizers and the drugs as specified in the Schedule X of Drugs and Cosmetics Rules, 1945 and to operate a e-pharmacy subject to the conditions specified below to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.
2. The registration shall be in force from to.....
3. The e-pharmacy shall operate through (URL/Mobile application/mode of e-pharmacy).
4. Name and registration number of registered pharmacist in-charge:

Central Licensing Authority

Signature

(Name and designation)

Condition of Registration

The registration holder shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder amended from time to time.

[F.No.X.11035/1010/2016-DRS-Vol-I]

SUDHIR KUMAR, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification No. F. 28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. dated

RAKESH
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