

Procedure for obtaining renewal of Retail / Wholesale Drug Licences

For obtaining Retail/Wholesale drug Licences from this Directorate the applicant should follow procedure given below. The renewal certificates are issued online by the Department.

1. To obtain renewal certificates in Form 21C (for Allopathic Drugs/ Schedule X Drugs), 20-E (for Homoeopathic drugs) applicant should fill form 19,19B and19C respectively and form for Additional information data. The application forms may be downloaded from link below:

Drug Forms

2. Applicant should pay the necessary fees vide E-challan. The fee of Rs. 3000/- with additional fee of Rs 250/- for Homoeopathic Licence and Rs. 500/- for Schedule X licence needs to be paid to Head of accounts, Demand No. 53; 201 Medical and Public Health, 04 Public Health, 104 Fees and Fines, 01 Fines. Fee structure can also be downloaded from link below:

Fee Structure

3. Using Firms login ID and Password provided, Licensee have to login to <http://www.xlnindia.gov.in> and create new application by clicking on “**New Inward**” and upload the required documents as per the **sales guidelines**; which will be available once the applicant logs in to xlnindia web application; and e-send the application.
4. After generating full application, take print out of software generated applications i.e. Form 19/19B/19C. For future reference; note down the inward ID that is generated on the system which will be generated only when full application is completed. The **Inward ID generated** is required to be mentioned on the covering letter while submitting hard copies of the application.
5. Submit hard copy of all documents, along with **original copy of e-challan** paid towards the fees to the entry clerk in the inward Section within 72 hours of e-send of application.

File movement once it is submitted in entry section is as under:

1. Hard copy of application received in the inward Entry section.
2. Entry clerk forwards the file to Accounts section of the Department for verification of amount paid through challan.
3. The Accounts Section after verification of amount forwards the file to concerned dealing hand.
4. The dealing hand places the application in the file of the licensee maintained in the department and scrutinises all the documents and puts up to the Director for allotting to the Drugs Inspector/ADC.
5. The Director peruses the application and marks it to any Drugs Inspector/Asst. Drugs Controller for further processing; online. The hard copy also moves; as the online application moves.

6. Drugs Inspector/ADC will scrutinise the documents and accordingly inspect the premises. Drugs Inspector/ADC will propose for grant of renewal certificate if relevant documents are submitted and the premises were found satisfactory on inspection.
7. Depending on the observations during inspection, Drugs Inspector/ADC will propose
 - a) Grant of renewal certificate.
 - b) Issue of Show cause letter.
 - c) Issue corrective letter.and forwards the file to Assistant Drugs Controller /Deputy Director.
8. Assistant Drugs Controller /Deputy Director will put recommendations and forward the file to the Director.
9. In case of 7(a) the final Renewal Certificate are granted by the Director ie. Licensing Authority. And file is sent to the Dispatch Clerk.
10. In case of 7(b) Licensee gives clarification offline as a hard copy to the entry Clerk as well as online.
11. Application is handed over to the Dealing Hand by the Entry Clerk.
12. Dealing Hand files the clarification and forwards the file to the Drugs Inspector.
13. If Licensee gives **a)** satisfactory clarification/reply, then the Drugs Inspector will propose for grant of renewal licences and put up the file to concerned Assistant Drug Controller/Dy. Director, which is also recorded online.
b) If clarification found not satisfactory; then the Drugs Inspector will propose for personal hearing by the Director and forward the file to Assistant Drugs Controller /Deputy Director.
14. Assistant Drug Controller/Dy. Director will put up the file for Director with his comments.
15. In case of (a), Director will grant the Renewal Certificate to the Licensee, final certificate is issued by the Director online. In case of (b), Licensee is called for personal hearing.
16. In continuation of 13(a) the e-signed licence is printed and forwarded to Dispatch clerk. In case of 13(b) after personal hearing Warning/Suspension is issued to the Licensee.
17. Licensee shall collect the Renewal Certificate from Technical Section of Directorate of Food & Drugs Administration.

Note: 1) Validity of renewal certificate - valid upto 5 years from issue of licence subject to the conditions specified in the licence & to the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder.