Guidance Document for Stakeholders for ONDLS Portal

1. Introduction to Online National Drug Licensing System :

The National Drug Authority of the Country viz CDSCO has designed & developed an Online Module/Portal in collaboration with Centre for Development of Advanced Computing , Noida. The said portal is extended to all types of Regulatory Clearances in terms of Licensing / Certifications for Manufacturing , Blood Centres & Sales.

2. Guidance for Applicant Stakeholders:

The module is based on the principle of self – registration on the portal by Firm / Blood Centre & Technical Person.

2A. Accessibility to the module :

- The individual / firm intending to register on the portal may logon at <u>https://statedrugs.gov.in</u>
- On the Homepage of the Module at top right corner , click on Sing on /up.
- Enter Mobile No. & OPT will be sent on Mobile Number. Enter OTP with 60 seconds.
- Enter email ID. OTP will be sent on email ID. Enter OTP within 60 seconds.
- New Page will open up which provides below tiles :
 Firm O Technical Person O Firm & Technical Person
 O Blood Centre
- The Firm / Individual has to select one tile as per requirement. The selection of tiles is simplified as below :
 - a) If user is a Firm or Corporate , Tile "Firm" is required to be selected & proceed accordingly.
 - b) If user is an individual & intends to register as a Technical Person, Tile "Technical person" is required to be selected & proceed accordingly.
 - c) If Firm & Technical Person is one entity (in case of Retailer & Wholesaler) i.e Proprietor & Q.P/C.P is one person only, Tile "Firm & Technical Person " is required

to be selected & proceed accordingly. In case Proprietor & Q.P / C.P are two different persons (Technical Person on arrangement basis), then firm & technical person are to be registered on the portal by selecting relevant tile respectively.

- d) Blood Bank applicants have to select Tile "Blood Bank"& Technical Persons are to be registered separately by selecting "Technical Person" Tile.
- After selecting a requisite tile , certain basic details are to be updated as per provided proforma. After submission of details , process of Registration gets completed & message is displayed for the same & Login Password for given Email ID is sent at the email.
- > The user can then login again with given credentials either through **Mobile based OTP** or **Email based login**.

2B. Submission of Application by Firm / Uploading of Details by Technical Person :

(i) A person who has registered himself / herself as technical person has to update below details along with uploading of relevant documents.

A) Add Academic Qualification B) Add Proffessional Experience C) Add Technical Registration.

After completing the details , System generated Technical Registration Number is allotted to Technical Person which is available in the profile option.

(ii) Application submission by Firm / Blood Centre

- The user has to click on Fresh Application & update basic details about the premises , add technical person details & selection of License Forms.
- Proceed to checklist of documents related to type of License Form(s) selected.

- Upload documents against the checklist & proceed.
- > Fill Payment details form.
- Download Legal Form viz Form 19 in case of Retailer / Wholesaler
- ➢ Sign the legal form & proceed to upload.
- Submit the application & message will be displayed that your application has been submitted successfully. Kindly note your File No._____for future correspondence.

Note : The module provides option of hiring of technical person by the firm. The Technical person has to share his system generated Technical Registration Number with the firm. The firm searches this number in the Hiring of Technical Staff option. After completion of offer & acceptance by & between firm & technical person, the hiring process is complete & the services of such hired person can be utilised as Competent Technical Staff on Licenses if fulfilling eligibility criteria for same.

However, in case of registration as "Firm & Technical person" auto-hiring & switch role option as Firm or Technical Person are provided.

Further , the applicants intending to seek Fresh Wholesale License(s) on the basis of Experience are impressed upon to obtain Technical Registration Document at first instance from the Divisional Level Empowered Committee of the Department. After obtaining such Document , the applicant becomes eligible for online submission of the application through online portal. Procedure to obtain Technical registration Document by a proposed competent person is as below :

The Technical Person (Competent Person) intending to obtain Technical Registration Document shall have to furnish the details on a prescribed Form (A1- Annexed herewith) along with supportive documents as mentioned in the prescribed form & submit to Dy. Drugs Controller of respective Division at dedicated Email / Registered Post.

3. Guidance for Official Stakeholders :

The working principle for official users is based on Mobile Number & Email ID based Registration of Officials on the portal , Creation of Application Type Zones, & Mapping of registered Officials with Created Zones.

Three tier hierarchy system is customised for UT of J&K.

(a) Reviewing Officer (Drug Inspector) (b) Nodal Officer (c) Licensing Authority.

- The applications submitted by the stakeholders are received on the dashboard of Nodal Officer.
- Nodal Officer assigns the application to concerned Reviwing Officer.
- Reviewing Officer after scrutiny of uploaded documents & uploading of Inspection Report forwards the application to Licensing Authority with specific recommendation.
- Based on recommendations, Licensing Authority shall dispose off the application. The approved application is downloaded & uploaded along with Cover Letter.
- The applicant can download the final certificate from his /her user Id credentials.

Annexure A1

FORM A1

(Divisional Level Empowered Committee for Wholesale Licensing)

1. Name	
2. Father's	Dhotograph
Name	
3.	
Age	
4. Sex	
5. Resident of	

6. Academic Qualification

S.No	Class / Degree	Year of Passing
01	10 th	
02	12 th	
03	Graduation / Post Graduation	

Note : Self attested Photocopy of Higher Qualification to be attached.

7. Experience Details :

S.No	Name & Address of	Licence Numbers of	Period of Experience
	the Employer Firm	Employer Firm	(w.e.fto)
01			
02			
04			

Note : Duly stamped & signed Experience Certificate to be attached.

Date:

Place:

Signature of Applicant

General Instruction: The applicant shall carry 3 No. Passport Size Photographs at the time of evaluation / interview & handover to the evaluation committee.