Guidance Document for Manufacturers (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 as mandated under provisions of Chapter IV of Drugs & Cosmetics Act, 1940.

2. Applicant Stakeholders :

The module is based on the principle of self – registration on the portal by :

- i) Firm
- ii) Technical Person
- iii) Firm & Technical Person
- iv) Blood Centre.

3. Accessibility to the module :

- The individual / firm intending to register on the portal shall visit <u>https://statedrugs.gov.in</u>
- On the Homepage of the Module at top right corner , click on Sing in /up.
- Enter Mobile No. & OPT will be sent on Mobile Number. Enter OTP within 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 Technical Person Firm & Technical Person
 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 / Corporate , Tile "Firm" is required to be selected.

- b) If user is an individual & intends to register as a Technical Person, Tile "Technical person" is required to be selected.
- c) If Firm & Technical Person is one entity (usually in case of Retailer & Wholesaler) i.e Proprietor & Q.P/C.P is the same person , Tile "Firm & Technical Person " is required to be selected. 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 gets displayed. Login Password for given Email ID is sent at the email after successful registration.
- > The user can then login again with given credentials either through **Mobile based OTP** or **Email based login**.

4. <u>**Concept of Technical Person</u> Tile** : The module provides a common pool of all technical persons required for Sales & Manufacturing Licensing.</u>

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

A) Academic Qualification B) Professional ExperienceC) Technical Registration.

The Portal accepts below documentary evidence as valid eligibility : Pharmacy Council of India **or** State Pharmacy Council **or** State Licensing Authority. After completing the above process, System generated Technical Registration Number is allotted to Technical Person which is available in the profile option.

Note : The module provides option of hiring of technical person by the firm. The Technical has to share his system person generated Technical Registration Number with the firm. The firm feeds the number in the "Adding **Technical** Member" tile. 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.

3. Application Submission :

After successful registration of the firm on the portal , a dashboard with following Tiles is displayed :



In the tile "Add Dosage Form" firm has to update details of dosage forms being manufactured or proposed to be manufactured.

In "Submit Forms" Tile, user has to proceed as

- select License type viz Test License or Manufacturing License etc & relevant Form.
- Authorised Signatory

- Select "Fresh" or "Endorsement on old (offline) Licence" or "Retention / Renewal / Revalidation" as per intended regulatory clearance required.
- > The applicant shall then proceed further accordingly.