OFFICE OF THE STATE DRUGS CONTROLLER
DRUGS & FOOD CONTROL ORGANIZATION
PATOLI MANGOTRIAN J&K (JAMMU)

Regd. Post / Email / WAP

Sub: Adoption of "Online National Drug Licensing System" for Manufacturing & Sales Licensing in the UT of J&K – Regarding.

ORDER No. DFO of 119, 2021
Dated : 02 - 12 - 2021

Whereas , XLN Online Module for Licensing System (Sales) was adopted by this UT on 13.08.2018 in terms of Notification bearing No. HD/Drugs/69/2017 , dt: 13.08.2018 ;

Whereas , Apex Drug Authority of the Country viz Central Drugs Standard Control Organization , New Delhi **(herein referred to as CDSCO)** in collaboration with Centre for Development of Advanced Computing , Noida **(herein referred to as CDAC)** has developed a PAN India Portal under the banner **"Online National Drug Licensing System (ONDLS)"** for all states which shall extend to all regulatory clearances related to Manufacturing ; Blood Centers , Retail Sale & Wholesale under the provisions of Chapter IV of Drugs & Cosmetics Act, 1940 ;

Whereas , in order to ensure smooth transition , XLN Module was shut down vide this office Order No. DFO 105 of 2021 dt : 10.11.2021 ;

Whereas , the procedural trial / validation of ONDLS Module has been completed by the CDAC Authorities ;

Whereas , the said portal / module bearing URL as https://statedrugs.gov.in has been launched on 30th November, 2021 ;

Whereas, under **XLN Module** , Wholesale Licensing (Fresh) were disposed off as per ***"Guidance Manual for issuance of Drug Sale Licenses on Form 20B &21B"*** issued vide this office Communication No. DFO/D-845/7418-20 , dt: 04.02.2019 ;

Whereas, **XLN Module** & Newly adopted Module **(ONDLS)** are different in operation design & therefore necessary amendment is required in the existing Guidance Manual ;

Now , therefore in light of the contents explained herein above , all the statutory authorities appointed by the Government of J&K to carryout statutory duties under the provisions of the Drugs & Cosmetics Act, 1940 & Drugs Rules 1945 thereunder are hereby ordered to adopt Online Module viz **"Online National Drug Licensing System" (ONDLS)** with immediate effect for regulatory clearances under the said Act & Rules.

2/12.

No. DFO/D-936/ 4193-4242
Dt: 02-12-2021

(Lotika Khajuria)
State Drugs Controller
Drugs & Food Control Organization
J&K (Jammu)

Copy To :

1. The Additional Chief Secretary to Government , H&ME Department, Civil Secretariat (J&K) for favor of information.
2. Drugs Controller General (I) , CDSCO (HQ) , FDA Bhawan , Kotla Road , New Delhi for favor of information.
3. Commissioner, FDA (J&K) –Drugs & Food Control Organization J&K for favor of information.
4. Jt. Director Planning (H&ME) Department , Civil Secretariat , J&K for information. Process of integration of Portal with UT specific SWC System has been already taken up with concerned quarters for necessary action at an earliest convenience.
5. SIO-NIC (J&K) for information.
6. Dy. Controller –Drugs & Food Control Organization Jammu / Kashmir for information & necessary action with the request to ensure implementation of revised guidelines in letter & spirit. The revised Guidance Manual is attached herewith as Annexure A.
7. All Assistant Controller Drugs / All Licensing Authorities for necessary compliance.
8. Assistant Controller Drugs (I), CDSCO Sub Zone Jammu for information.
9. Mr. Rahul Gautam –CDAC , Noida for information.
10. ***All Drug Control Officers (Enforcement) for strict compliance.***
11. Mr. Surinder C/o M/s Saytechnologies , Jammu with the request to upload the document on our official website by today only.

Revised Guidelines for evaluation of Competent Person for Wholesale Licensing :

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.

1A. The working principle for official users on the portal is based on Registration of Officials (email & mobile number based) , Creation of Zones & Mapping of Registered Officials with created Zones. The Module also provides nomenclature for various level of functionaries & this UT has been customised to three tier level of officers on the portal as under :

A) Reviewing Officers (RO) : Drugs Control Officer
B) Nodal Officers (NO) : Receives applications submitted by applicants – DDC/ACD/LA
C) Licensing Authority (LA) : Approval & Signing of Licenses.
Note : DDC/ADC have two functions (NO & LA) in matters related to Retail / Wholesale Licensing. Switch Over option provided in the portal.

24 Zones have been created as on date on the portal as per below details :

A) One District - One Retail Zone except District Jammu for which two zones have been created (Total 21)
B) Ten Districts of each Division – One Wholesale Zone (Total 2)
C) 20 Districts of J&K – One Manufacturing Zone (Total 1) .

The Registered officials are mapped as under :

Zone Type	District	LA / NO	RO
Retail	Concerned District	Concerned LA	All concerned DCO's of the District
Wholesale	Concerned Division	Concerned LA	All concerned DCO's of the Division
Manufacturing	Whole UT	Concerned LA/NO	DCO's Mfg & HQ (J&K)

The application submitted by the applicant will be received on the dash board of Nodal Officer concerned Retail / Wholesale. The Nodal Officer has to send the file to concerned RO. The RO after scrutiny of Documents & uploading of Inspection Report has the option to send the file to RO / LA with recommendations. Based on recommendations , the LA can approve or reject the application. The Permission / Licence approved by LA requires to be downloaded & then uploaded after signatures along with uploading of Cover Letter separately.

1B. The working principle for applicants / stakeholders is based on access to the Module by logging in on the URL & signing in through Mobile Number & Email after verification of OTP's received on the Mobile Number & Email ID respectively. After verification of OTP's , the Module provides below tiles :

1) Firm 2) Technical Person 3). Firm & technical Person 4) Blood Centre :

The applicant has to choose tile as per his requirement. In case of Retail & Wholesale Licensing , if sole Proprietor & Q.P is one entity, then Tile No. 3 will suffice his purpose. If Proprietor & Q.P are two different entities (Arrangement system) , the proprietor will select Tile No. 1 & Q.P has to login & signon as explained above separately in Tile No. 2.

After selecting requisite tile , basic details are to be submitted & after submission of requisite information , login password is provided on the given email ID.

The applicant has then the option to login with Mobile Number on the basis of OTP obtained or alternatively email through login password.

Note : The firm has the option to hire services of competent technical persons subject to the condition that such CTP is registered themselves on the portal. In case Proprietor & Approved Technical Person is the same , the applicant shall use Tile No. 3

For registration of CTP following documents are required.

1. Qualification Details
2. Professional Experience
3. Technical Registration.

The Portal accepts below documents as valid eligibility : Pharmacy Council of India **or** State Pharmacy Council **or** State Licensing Authority.

The Technical Registration Document for Competent Person for Wholesale Licensing requires to be approved by Licensing Authority after evaluation of technical expertise of the intending personnel & thereby making him eligible for submission of online application. Therefore , for this purpose guidelines have been revised.

The D & C Act, 1940 & Rules there under provide following requirements of eligibility for issuance of a Wholesale Drug License on Form 20B & 21B

a) is a Registered Pharmacist , or;

b) has passed the matriculation examination or its equivalent examination from a recognised Board with the four years' experience in dealing with sale of drugs, or ;

c) holds a degree of a recognised University with one year's experience in dealing with drugs ;

So far as category (a) applicants are concerned , the qualification shall be treated as valid. However, w.r.t category (b) & (c) applicants , **the revised guidelines / Road map has been revised as follows & shall be followed.**

2. Revised Guidelines :

2A. Application Submission by Technical Person :

- The Technical Person (Competent Person) intending to obtain Technical Registration Document shall have to furnish the details on a prescribed Form **(annexed to this guideline as Annexure A1)** along with supportive documents as mentioned in the prescribed form & submit the same before Dy. Drugs Controller of respective Division through a dedicated Email to be generated by them.
  Note : In case the name of technical person is already endorsed on a Wholesale License granted on Forms 20B & 21B) , the applicant shall submit the prescribed Form through email along with photocopy of such License. The concerned Licensing Authority shall issue a Approval certificate in favour of such applicant. The said document shall be treated as valid document for purpose of claiming the eligibility of such applicant.

2B. Functioning of Divisional Level Empowered Committee :

- The Constitution of Divisional Level Empowered Committee shall remain unchanged. However, Committee may co-opt services of Drugs Control Officer Divisional (HQ) to facilitate the documentation process.
- The said committee shall create their dedicated email id & share the same with this office for mentioning in the guidance document to be uploaded on the official website of the Department.
- The said committee shall ensure that the applications so received through the dedicated email id are disposed off on First—In-First–Out basis.

- The committee shall be responsible to inform the applicant about his personal appearance for evaluation of his technical expertise within 10 days of receipt of such mail. The final list of approved persons shall be furnished in the WhatsApp group for receiving recommendation at Drug Control Officer Level in respect of Experience Verification. The DCO shall furnish his recommendation to the said committee in week's time & committee shall therefore ensure final disposal of the application within a period of 21 days from the date of receipt of email.
- The Committee shall assign a unique Technical Registration Number to the approved competent Person. The Kashmir based Committee shall assign first number as DDCK/01/100001 & proceed in an ascending Order to the 6 Digit Number.

  The Jammu based Committee shall assign first number as DDCJ/02/200001 & proceed in an ascending Order to the 6 Digit Number. (**Note :** This Technical Registration Number / Document shall be purely as an internal mechanism / procedure & is required by the firm to be uploaded in the tile of "Add Technical Registration". The system generates its own Technical registration Number which is available in profile of the applicant & that number only is to be used for hiring by the firm.
- The committee shall maintain a dedicated offline Register for entering details of approved Competent Person. The details shall include Name of the Person ; Parentage & Residence ; Receipt date of application Form ; Period of Experience ; Experience Obtained from ; DCO Remarks regarding Experience Verification ; Higher Academic Qualification ; email ID ; **Technical Registration Number** & Signature of Chairperson of the Committee.
- The approved Technical Registered Document as per devised format **(annexed to this guideline as Annexure A2)** shall be shared with the applicant at his given email ID.

Annexure A-1

FORM A1

(Divisional Level Empowered Committee for Wholesale Licensing)

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

Photograph

6. Academic Qualification

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

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

7. Experience Details :

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

Note : Duly stamped & signed Experience Certificate issued by the employer to be attached.

Date:

Place: **Signature of Applicant**

General Instruction: The applicant shall carry 3 No. Passport Size Photographs at the time of evaluation. However, a digital photograph shall also be provided on the email along with this form.

Annexure A2

OFFICE OF THE Dy. Drugs CONTROLLER
DRUGS & FOOD CONTROL ORGANIZATION
MUTHI JAMMU / BEMINA SRINAGAR (J&K)

Technical Person Registration Certificate
(See Rule 64(2) clause (b) / (c) 2nd Provisio)

Mr._____

S/o_____

R/o _____

Photograph

Please refer your Form A1 , Dated : regarding approval of Technical Person. In this connection, it is to inform that you have been approved as a technical person as per below details :

Name & Parentage	Higher Qualification	Extent of approval	Official Technical Registration Number
		Competent Person for Wholesale Licensing	

(Chairperson)
Empowered Committee for Wholesale Licensing
Drugs & Food Control Organization
(Jammu / Kashmir Division)