

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

**Most Urgent / Time Bound
Out By Email / WAP**

NOTICE

Sub:- Online National Drug Licensing System (ONDLS) – Regarding

Jammu & Kashmir became the first State / UT in the country to adopt PAN India online Portal (ONDLS) for disposal of various regulatory clearances. The portal has now completed one year of its operation & has attained stability to a larger extent.

In the First Phase , online application submission related to Sales Licensing & Fresh Manufacturing Licensing for Drugs / Cosmetics & Product Endorsement were released over the portal. Additional Online Services / features were developed & provided over the portal from to time in a staggered manner for use of stakeholders. As on date , following online services / features are now available over the portal w.r.t **Existing Manufacturers of Drugs & Cosmetics (Own Licensee / Loan Licensee).**

- 1. Uploading of data by existing manufacturers of Drugs & Cosmetics & submission of data thereof for review at official end.**
- 2. Review & Approval / Rejection of submitted data of existing manufacturers at the official end.**
- 3. Submission of Retention Applications.**
- 4. Additional Product Endorsement.**
- 5. Change in Technical Staff.**

The Department of Drug & Food Control Organization is in constant touch with National Drug Regulatory Authority & CDAC , Noida in making the ONDLS Portal robust , Industry Compatible & user friendly. The guidance manuals are available on homepage of the said portal. A handholding session for existing manufacturers was also conducted successfully by the Department in the recent past.

In light of the foregoing paras, all existing manufacturers of Drugs / Cosmetics **(Own Licensee / Loan Licensee) are instructed to comply as follows :**



1. Registration of Corporate Office / Firm (Site Address) over ONDLS Portal.
2. Registration of Technical Staff (Individual Basis) as per Licenses , Hiring & Mapping with Licenses thereof.
3. After successful Registration , uploading of existing License & Product Approvals data through License Management tab.
4. Submission of uploaded data.
5. After review of uploaded data at official end , online application submission for below regulatory clearances :
 - a) Retention of Licenses & Product Approvals if due for Retention.
 - b) Additional Product Endorsement
 - c) Change in Technical Staff

The Process of Registration & Existing Data Uploading followed by submission of data shall be completed by or before 30th April , 2023 by all the manufacturers of Drugs / Cosmetics. The Data so submitted shall be reviewed & approved / rejected at official end instantly on first come first serve basis & expected to be completed by 30th of May , 2023.

It may be noted that no offline application for aforementioned available online services shall be entertained by this office beyond the cut –off date i.e 01st , June , 2023.

Note : a) Loan Licensee shall be able to Register / upload data over the portal only after Principal Manufacturer has completed Registration / Data Uploading.

b) The existing Cosmetic Manufacturers who have not obtained Licenses as per new Licensing Regime i.e Cosmetic Rules, 2020 shall not upload data but shall apply afresh as per Cosmetics Rules, 2020.

The CDAC has also informed that 5 types of certifications are likely to be released over the portal in a short span of time & information regarding the same shall be disseminated accordingly.

A briefly summarised guidance manual is enclosed herewith as Annexure A & handholding Power Point Presentation as Annexure B.





For any further assistance / guidance if required , please contact below officers :

1. Mr. Sanjay Bhat , Drugs Control Officer (Mfg) – Jammu Based Manufacturers (9906136659 / 7006672824)
2. Mr. Shabir Ahmad , Drugs Control Officer (Mfg) – Kashmir Based Manufacturers (7006042831)

No. DFO/ D-936/ 6649-6698

Dt: 24-03-2023


24/3
(Lotika Khajuria)
State Drugs Controller
Drugs & Food Control Organization
J&K (Jammu)


Copy To:

1. The Secretary to Govt. H&ME , Civil Secretariat (J&K) for favor of information.
2. Drugs Contyroller General (India) , CDSCO (HQ) , Kotla Road, FDA Bhawan , New Delhi for favour of information.
3. Mr. Sanjeev Kumar – Dy. Drugs Controller (I) , CDSCO (HQ) , FDA Bhawan Kotla Road , New Delhi for information.
4. Drugs Control Officer (Mfg) Jammu / Kashmir for information & necessary follow up at Manufacturers level.
5. Mr. Uttam Kumar – CDAC (Noida) for information.
6. President J&K Pharmaceutical Manufacturers Association for information.
7. All Existing Manufacturing Units of Drugs / Cosmetics in J&K for necessary compliance.
8. Website

Brief Guidance Manual

1. Registration over ONDLS Portal :

- a) The Process of Registration over ONDLS Portal is based on receipt of OTP on given Mobile No. & email id.
- b) The Registration is further based on PAN or CIN or LLPIN (whichever applicable)
- c) If Registered Corporate office address & Firm site address are different , then Corporate & Firm are to be registered separately with different credentials of Mobile & Email. It is advised to Register Corporate First . The firm (Site) shall then use PAN or CIN or LLPIN as used by corporate & details will be extracted accordingly. Moreover , it shall be noted that answer to question during Registration process i.e “whether firm & corporate address are same” shall be “NO”. Approval Link will be sent from Firm (Site) to Corporate. Once the Corporate grants approval to firm request , then only Registration of firm will be completed.
- d) If Firm & Corporate address are same , then answer to question during Registration i.e “whether firm & corporate address are same” shall be “Yes”. Only one account will be created with Corporate & Firm as switch over roles in the same account.

2. Existing Data Uploading.

After successful Registration , existing Licenses data & Product Approvals data shall be uploaded through Firm Account. After login through firm account , License Management Tab shall be used for uploading of Licenses & Product Approvals.

- 3. For Retention of Licenses & Products :**
Firm shall be able to apply for retention individually for respective Form (25/28 etc) , once data uploaded through License Management Tab is submitted & same stands approved at official end.
- 4. For Additional Product Endorsement :**
Firm shall use Product Management Tab available in dash board of Firm account outside the License Management Tab Once the uploaded data is approved at official end.
- 5. For Change in Technical person :**
Firm shall apply through Post Approval Submission Tab available in dash board of Firm account in Application Processing Tab.

For further assistance & information please refer to PPT (Annexure B).



Online National Drug Licensing System (ONDLS)

Mir Tariq Masroor
Drugs Control Officer (HQ) J&K
Drugs & Food Control Organization

Brief Overview

- Designed & developed by CDSCO in collaboration with Centre for Development of Advanced Computing (CDAC)
- PAN India Portal
- J&K became the first State / UT in the country to adopt the portal & turned live over URL : <https://statedrugs.gov.in> on 30.11.2021
- Initially some technical hiccups were confronted but as on date has gained a large level of adoption & acquaintance especially in Fresh Licensing.

Services available as on date :

Sales	Manufacturing
Fresh Licenses	Fresh Licensing of Drugs / Cosmetics
Retentions	Retentions
Change in Technical Staff	Additional Product Endorsement
Change in premises	Change in Technical Staff

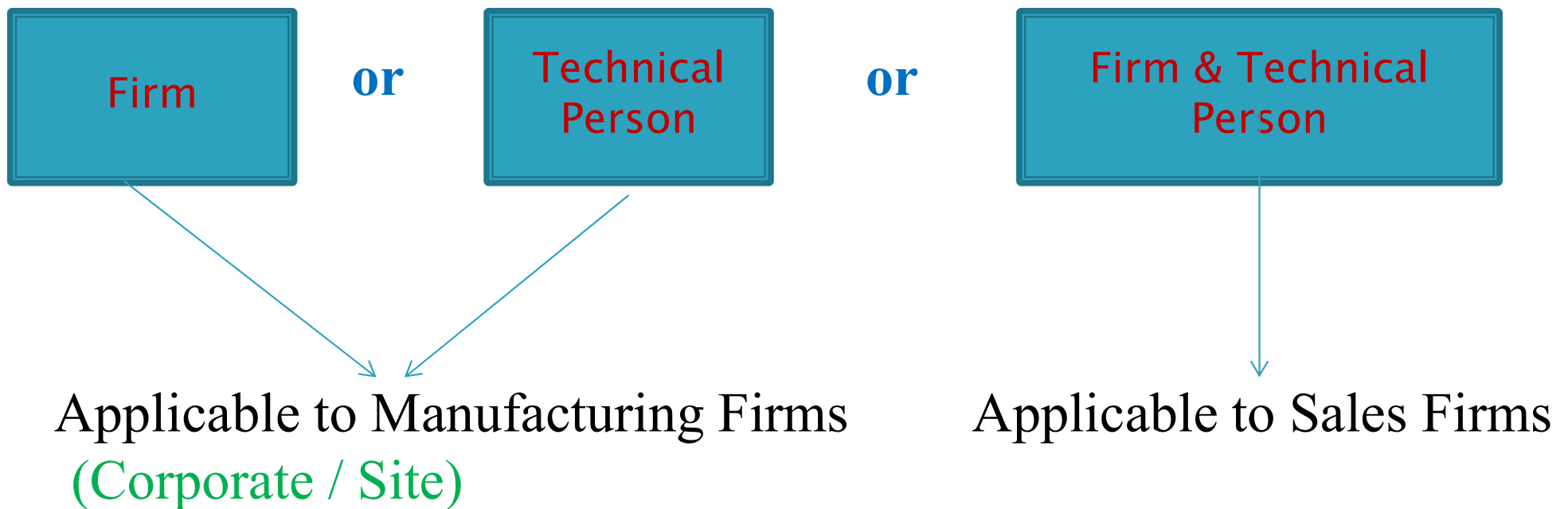
Salient Features :

- Online Application Submission
 - Track Status of Application
 - Downloading of Final Certificate by applicant
 - Data Preservation & Integrity (For all stakeholders)
 - Third Party Verification System.
 - Auto Alerts (to be provided later)
- 

Basic Concept & User Manuals

Registration : Common for all - Fresh Applicant / Existing Licensee

The portal has been designed using the concept of Self- Registration System based on Mobile Number & Email ID followed by selection of User Account Type as :



Note : Complete User manuals available over portal & www.dfcojk.org

REGISTRATION STEPS.

- ▶ Open the link : <https://www.statedrugs.gov.in>
- ▶ Click on Sign in / Up.
- ▶ Existing User can login through Mobile based OTP or email based Password.
- ▶ **New User has to initiate process of registration as follows :**
 - 1.1 Enter Mobile No. Click on Get OTP & then enter OTP (60 sec).
 - 1.2 After completing step 1.1 new page will be redirected. Enter email ID , Click on Get OTP , OTP will be received on given email ID & enter (60 sec).

REGISTRATION STEPS..

2.1 User Account Type Selected as

Firm

After selecting firm , below details to be filled so as to decided future course :

2.1.1 Whether the firm corporate/Registered address and site address is same

2.1.2 Account type

2.1.3 Site type

If answer to 2.1.1 is yes , then Account Type to be filled as Both Corporate / Registered and Site & Site Type to be filled as Manufacture of Drugs / Cosmetics & click on save & proceed.

Note : (Three type validation system of Firms provided over portal)

a) CIN No. b) PAN No. c) LLPIN : Firms can register on the basis of one of the No. as applicable

REGISTRATION STEPS...

2.2 Fill Firm Details & Save & Proceed

2.3 Fill Personal Details & save & proceed

2.4 Registration Completed successfully & click on go to homepage for login afresh.

2.5 Switch over feature between Corporate & Site provided in Profile. Login & switch over to Corporate. Will be redirected to add director & members page & fill all the details & click on add record. (pdf only allowed)

Note: Separate Dashboards provided for Corporate / Site.

REGISTRATION STEPS....

User Account Type Selected as

Firm

After selecting firm , below details to be filled so as to decided future course :

- 3.1 Whether the firm corporate/Registered address and site address is same
- 3.2 Account type
- 3.3 Site Type

If answer to 3.1 is No , then **Account Type** to be filled as :

3.2.1 Corporate / Registered . Site Type (Not Applicable). Fill Firm details , Personal Details & Proceed.

Registration Successful as Corporate & login afresh & update Director / Member Details. Approval to be granted to site(s).

REGISTRATION STEPS.....

User Account Type Selected as

Firm

After selecting firm , below details to be filled so as to decided future course :

- 4.1 Whether the firm corporate/Registered address and site address is same
- 4.2 Account type
- 4.3 Site Type

If answer to 3.1 is No , then **Account Type** to be filled as :

3.2.1 Site . Site Type (to be selected).

Fill the corporate office details (CIN or PAN or LLPIN as used by Corporate) then click on Get details. After getting your corporate details click on save and proceed.

Now you will get directed to a page where you have to select whether your Firm is Own or Loan Site. After selecting firm site type, you will get directed to the firm details , fill & proceed. Add Personal Details & save & proceed. Registration as site completed.

REGISTRATION STEPS.....(TP)

User Account Type Selected as **Technical Person**

After selecting Technical person , fill personal details & save & proceed. Registration as Technical Person completed. Login afresh & complete his / her dashboard viz,

- Experience Tab
- Education Qualification Tab
- Technical registration Tab. (Approved as Mfg Chemist , Analytical Chemist , Microbiologist).

10 digit System generated Number allotted to Registered Technical Person & available in Profile. Need to Share with firm for Hiring.

IMPORTANT POINTS

- Fresh applicant has to initiate Registration Process & hiring of Technical Staff & updating of details of intended products through Product Management Tab & Mapping of Products through . Has to Draft a fresh Application , Map products & Technical Staff with such application & submit.
- Existing Manufacturers have to initiate Registration of Firm (Corporate + Site ; Corporate ; Site) as per requirement. The approved technical person have to initiate registration using their own credentials.
- Complete Process of Hiring of Technical Staff.
- Upload basic License data through License Management Tab. Upload Products through Product management Tab . Submit for review.
- Official review will be taken (Double Review System) . Data approved & then only existing manufacturer becomes eligible for online services

IMPORTANT POINTS

- Fresh applicant has to initiate Registration Process & hiring of Technical Staff & updating of details of intended products through “**Product Management Tab**” & “**Product Endorsement Tab**”. Has to Draft a fresh Application , Map products & Technical Staff with such application & submit.
- Existing Manufacturers have to initiate Registration of Firm (Corporate + Site ; Corporate ; Site) as per requirement. The approved technical person have to initiate registration using their own credentials.
- Complete Process of Hiring of Technical Staff.
- Upload basic License data through License Management Tab. Products through SUB-TAB of “**License Product Draft Management**” . Submit for review. (Existing Product Uploading depends upon Retention Period).
- Official review will be taken (Double Review System) . Data approved & then only existing manufacturer becomes eligible for online services

Product Management

**Fresh Application
Submission**

Save As Draft

Submitted

Approved

Query Raised

Add Technical Member

**Request For Surrender /
Withdrawn**

Cancelled Licence

**Hired Technical Member
Pool**

Licence Managment

Product Endorsement

Licence Management

Draft Licence

Licence Under Review

Licence under Rectification

Approved Licence

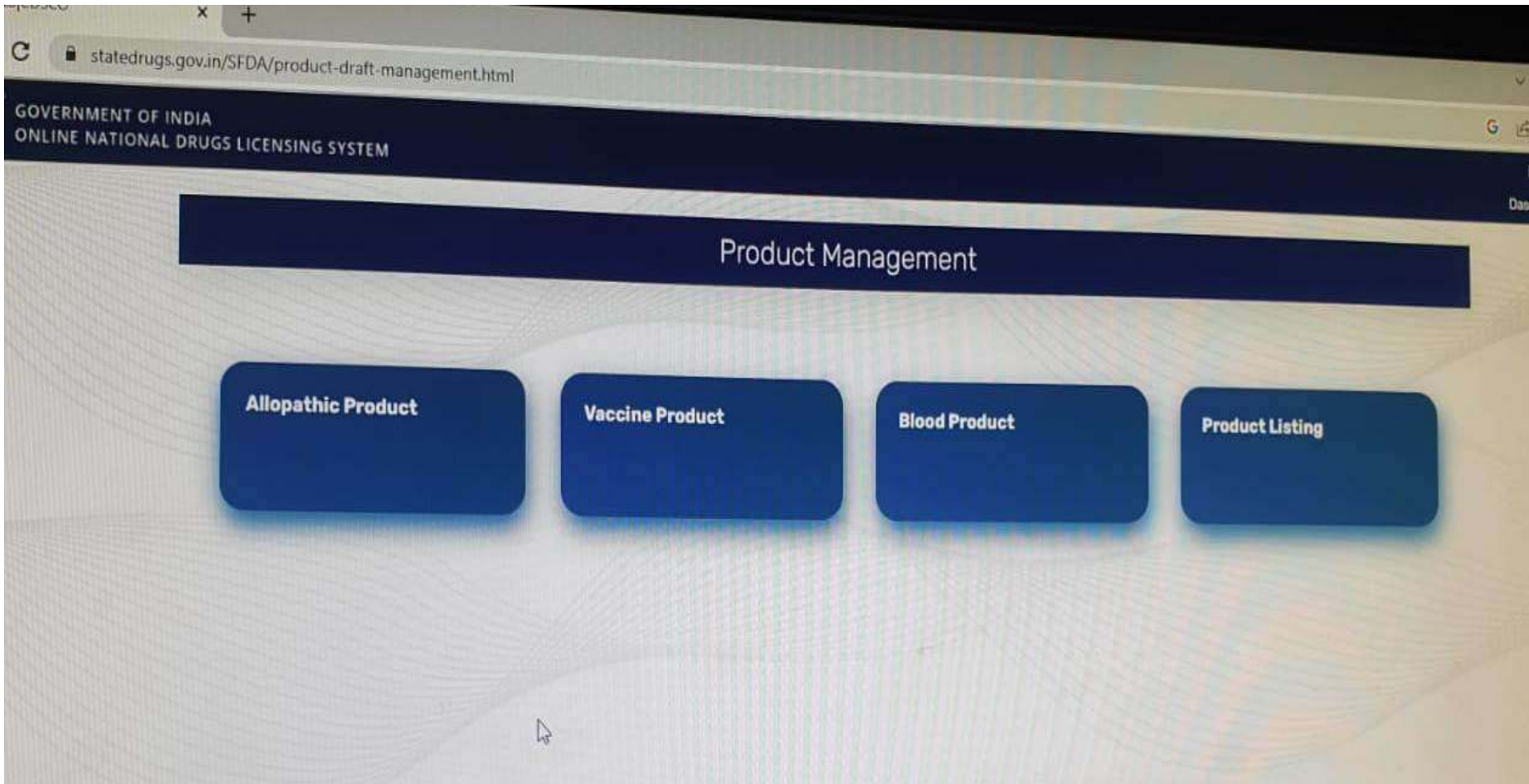
Rejected Licence

**Licence Product Draft
Management**

Apply Rentention/Renewal

Retained/Renewed Licence





QUESTIONS / SUGGESTIONS / CLARIFICATIONS
IF ANY

Email: mirmasroortariq@gmail.com



Thank you

