Service Name: Wholesale Drug License

The purpose of the drug license for wholesale is to grant permission to allow enterprises or individuals to engage in businesses related to drugs and Medical Device. Regulation governing manufacture & sale of drugs are given in the Drugs and Cosmetics Act, 1940 and Rules framed by Government of India. Any person/entity who intends to carry out wholesale of drugs must obtain a wholesale license. Wholesale means the sale of the drug to a another wholesaler/retailer of drugs /Registered Medical Practitioner/hospital. This license is issued by the Department of Food & Drug Administration (DFDA), under the provisions of the Drugs and Cosmetics act, 1940 & Rules thereunder.

Sr No	Particulars	Details
1.	**Competent Authority**	Directorate of Food & Drug Administration, Government of Goa
2.	**URL/s**	Goa-DFDA: https://dfda.goa.gov.in/ ONDLS: https://statedrugs.gov.in
3.	**Type of service**	Pre-Operations
4.	**Act / Rule**	THE DRUGS AND COSMETICS ACT, 1940 https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/ THE DRUG RULES 1945 https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Drugs-Rules/
5.	**Service mode:**	Online through ONDLS
6.	**Online mode notification**	Mandate dtd 25/10/2023 (Pls see the section below)
7.	**Timeline for approval**	30 days. Pls see the timeline section below.
8.	**Validity of approval**	Valid perpetually with retention of licence every 5 years by paying retention fee
9.	**Provision of Deemed Approval:**	Not Applicable
10.	**Auto Renewal**	Not Applicable
11.	**Auto Renewal – URL**	Not Applicable

Step by Step Procedure for approval with timeline

#	Action by User Type	Stages/Steps	Time taken for approval
1.	User / Investor	Registers on ONDLS portal and logins into ONDLS with the login id and password	Not Applicable
2.		From the dashboard, fill in the site facility details and then click on fresh application and application submission page will appear.	
3.		Now applicant selects retail drug license and technical member and reviews the application form.	
4.		Once the application form details are filled in, then proceeds for document upload.	
5.		The applicant must pay the requisite fee in the Goa e-challan portal and submit the payment details in ONDLS.	
6.		The applicant then uploads the legal form and submits the application for processing by the department.	
7.	ONDLS	Once the application is submitted, the system will display the file number & the user/investor will get SMS / email form the ONDLS system.	Real time
8.	Department (FDA)	Once fresh application for retail sale/wholesale of drugs is received in ONDLS portal the nodal officer allots the file to the Drugs Officers (Reviewing officer) online.	NA
9.		The hard copy of application inwarded by the applicant is forwarded by entry clerk to Accounts section of the Department for verification of amount paid through challan**.**	1 day
10.		The Accounts Section after verification of amount forwards the file to concerned dealing hand in Technical section**.**	2 days
11.		The dealing hand registers the application, generates the file number, and puts up to the respective Drug Inspector**.**	2 days
12.		Drugs Inspector scrutinises the online application and once documents are found satisfactory, inspects the premises.	21 days
13.		In case there are any discrepancies in the documents' submitted query is raised online and application is put up to Licensing Authority. Once the query is approved by the Licensing Authority the application is reverted to applicant in ONDLS. Once the query is responded by applicant the application is reverted to Drugs Officer.	Not applicable

#	Action by User Type	Stages/Steps	Time taken for approval
14.		Once the documents submitted are found satisfactory and inspection of the premises Drugs Inspector put up the inspection report along with observations and recommendation online to the Licensing Authority	Not applicable
15.		The offline application is put up to supervisory level ie Asst Drugs Controller/Deputy Director for comments.	2 days
16.		ADC/DD peruses the report and forwards the file to LA(Director) with their comments and recommendations	Not applicable
17.		LA agrees/rejects to grant the licenses and if agreed license is generated by the LA online. The e-signed license is uploaded on ONDLS.	2 days
18.	ONDLS	System triggers and email and SMS to the user / investor for downloading the certificate.	Real time
19.	User / Investor	User / Investor logs in to download the Certificate from ONDLS portal.	Not Applicable

Document Checklist

Checklist of documents: Following documents are required to avail the wholesale license.

#	Document	Mandatory / Non-Mandatory
1.	Covering letter mentioning the complete details of documents submitted.	Mandatory
2.	Application in respective Form- 19, 19B, 19C dully filled and signed	Mandatory
3.	Self-declaration by proprietor regarding sale of drugs in presence of whole time Registered Pharmacist/Competent Person only.	Mandatory
4.	Undertaking form duly filled & signed by the Registered Pharmacist/Competent person.	Mandatory
5.	e - Challan receipt paid (Head of Accounts- Demand No.53) for Rs. 3000/- (additional fees Rs. 250/- for homoeopathic license and Rs. 500/- for schedule X license, if requested)	Mandatory
6.	Blueprint plan of the premises drawn to scale & Site plan of the premise.	Mandatory
7.	Ownership documents (House tax/ certified copy agreement for leave and licenses & ownership document of shop owner/sale deed)	Mandatory
8.	Certified copy of Partnership Deed (if in partnership firm)	Mandatory
9.	NOC from Panchayat / Municipality (attested copy)	Mandatory
10.	Certified copy of Qualification certificates/ Registration Certificate issued by GSPC/ Experience certificates of Registered Pharmacist/Competent Person	Mandatory
11.	Resignation/Relieving letter of the Registered Pharmacist/Competent Person from the Previous employer	Mandatory
12.	Appointment letter & Acceptance letter issued to the Registered Pharmacist/Competent Person	Mandatory
13.	Request for option letter to maintain carbon copies of cash/credit memos in lieu of prescription Register book. (in case of retail sale)	Mandatory
14.	Certified copy of power of attorney of applicant if applicable.	Mandatory
15.	ID card (Pan Card/Aadhar Card) copy of Proprietor/ Partners/ Directors/ Registered Pharmacists/competent persons	Mandatory
16.	Additional information data form dully filled and signed.	Non-Mandatory
17.	Biodata of the applicant mentioning the details of DOB, experience, and details of Occupation for previous five years.	Non-Mandatory
18.	Description of the premises, with area and height of the premises and other details.	Non-Mandatory
19.	Copy of Invoice of refrigerator & digital display thermometer (if no invoice than letter to DFDA w.r.t make, capacity and working condition of refrigerator)	Non -Mandatory

The above can be seen through this link: ONDLS|CDSCO (statedrugs.gov.in)

Fee Applicable

An amount of Rs 3000/- & additional fees Rs. 250/- for homoeopathic licence and Rs. 500/- for schedule X licence as applicable must be paid to the Head of Accounts- Demand No.53. This is same for fresh application and retention/renewal of license.

In case of retention of licence; if application is made after due date licensee to pay licence retention fee along with a late fee calculated at the rate of two per cent of the licence fee for every month or part thereof up to six months,

The payment of fee should be made online through the link given below:

https://egov.goa.nic.in/echallanpg/mainpage.aspx

Timeline

The timeline for the service is given below:

K- Directorate of Food and Drugs Administration				
71	Grant of Drugs Retail Licence	Dy. Director of Food and Drugs Administration	Thirty days	Director of Food and Drugs Administration.
[3][71 A	Grant of Drugs Wholesale License	Dy. Director of Food and Drugs Administration	30 days	Director of Food and Drugs Administration].
72	Grant of Goods Manufacturing Practices Certificate.	Dy. Director of Food and Drugs Administration	Seven days	Director of Food and Drugs Administration.
73	Grant of No Conviction Certificate	Dy. Director of Food and Drugs Administration	Seven days	Director of Food and Drugs Administration.
74	Grant of Free Sales Certificate	Dy. Director Food and Drugs Administration	Seven days	Director of Food and Drugs Administration.

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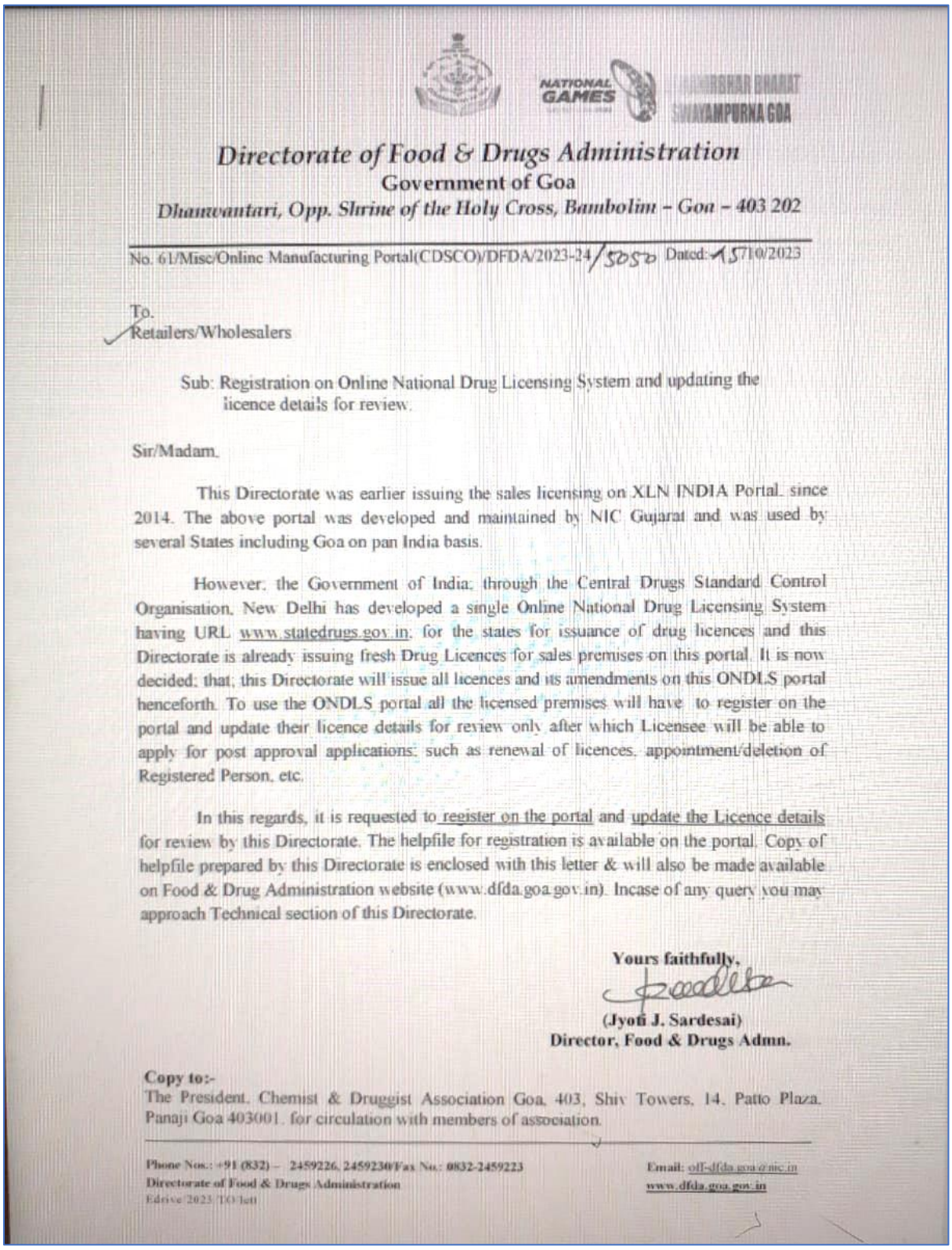
URL: Sr. II No. 31 Extraordinary No. 3 (LOW RESO) (goa.gov.in)

Risk-based classification

Risk Classification is not applicable.

Service Mode:

The circular from Goa-DFDA mandating the same is given below:



Directorate of Food & Drugs Administration
Government of Goa
Dhanvantari, Opp. Shrine of the Holy Cross, Bambolim – Goa – 403 202

No. 61/Misc/Online Manufacturing Portal(CDSCO)/DFDA/2023-24/5052 Dated: 15/10/2023

To,
Retailers/Wholesalers

Sub: Registration on Online National Drug Licensing System and updating the licence details for review.

Sir/Madam,

This Directorate was earlier issuing the sales licensing on XLN INDIA Portal since 2014. The above portal was developed and maintained by NIC Gujarat and was used by several States including Goa on pan India basis.

However, the Government of India, through the Central Drugs Standard Control Organisation, New Delhi has developed a single Online National Drug Licensing System having URL www.statedrugs.gov.in, for the states for issuance of drug licences and this Directorate is already issuing fresh Drug Licences for sales premises on this portal. It is now decided, that, this Directorate will issue all licences and its amendments on this ONDLS portal henceforth. To use the ONDLS portal all the licensed premises will have to register on the portal and update their licence details for review only after which Licensee will be able to apply for post approval applications, such as renewal of licences, appointment/deletion of Registered Person, etc.

In this regards, it is requested to register on the portal and update the Licence details for review by this Directorate. The helpfile for registration is available on the portal. Copy of helpfile prepared by this Directorate is enclosed with this letter & will also be made available on Food & Drug Administration website (www.dfda.goa.gov.in). Incase of any query you may approach Technical section of this Directorate.

Yours faithfully,

(Jyoti J. Sardesai)
Director, Food & Drugs Admn.

Copy to:-
The President, Chemist & Druggist Association Goa, 403, Shiv Towers, 14, Patto Plaza, Panaji Goa 403001, for circulation with members of association.

Phone Nos.: +91 (832) – 2459226, 2459230/Fax No.: 0832-2459223
Directorate of Food & Drugs Administration
Email: otf-dfda.goa@nic.in
www.dfda.goa.gov.in

The circular issued by the Goa Investment Promotion and Facilitation Board (Goa-IPB) is given below:

GOA@60

GOA INVESTMENT PROMOTION AND FACILITATION BOARD (GOA-IPB)
1ST FLOOR, SPACES, EDC PATTO PLAZA, PANAJI, GOA – 403 001
Email: ceo-ipb.goa@gov.in / ipb.goa@gmail.com

No. 15/2019/Goa-IPB/EoDB/515 Dated: 25/01/2021

MEMORANDUM

In furtherance of the notification No.3/02/2015-IND/64 dated 25/01/2021issued by the Department of Industries, Government of Goa, the Goa Investment Promotion and Facilitation Board (Goa-IPB), State's implementation agency for Ease of Doing Business, hereby issues the following mandates as outlined below:-

1) Further to point 3 of the above mentioned notification, the online system for Public Consultation has been implemented in the State to ensure the following for all proposed regulations in the State:

i. Legal basis
ii. Necessity
iii. Business friendly policies
iv. The drafts of proposed acts, rules or regulations should be made available for a minimum period of 30 days

All departments of the State Government are to note the above four points while drafting and proposing any legislation, rules or regulations.

2) Furthermore, the online single window system and all online services should have the following features:

i. End-to-end online application and submission
ii. Online payment and document submission
iii. Online status tracking and department comments
iv. Online certificate issuance and download
v. Facility for online verification of certificates/ licenses/ permits by third parties

All Departments of the State Government and their IT vendors concerned should make sure that any service made online should have above mentioned features for the online systems used and developed by them.

Vandana Rao
(Vandana Rao, IAS) 25.01.21
Chief Executive Officer,
Goa Investment Promotion &
Facilitation Board

Page 1 of 2

URL: Notification_2.PDF (goaonline.gov.in)

Additional Remarks: The procedural steps indicated above is uniform for all types of establishments, irrespective of risk category, size of firm, business location or type of investor (Foreign or Domestic).