

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

Sub:- Temporary suspension of grant of Fresh Wholesale Licensing across UT of Jammu & Kashmir – Revocation thereof.

ORDER No. DFO of 124 of 2023
Dated : 23-12-2023

Ref: - ORDER No. DFO of 98 of 2023 , Dated: 04.11.2023

Whereas, Fresh Application Submission for all output Forms of Wholesale Licensing was temporarily suspended / blocked vide this office under reference order ; &

Whereas , the suspension was effected amidst challenges of Drug Abuse as also the Department contemplating to rationalize Wholesale Units in the Union Territory of Jammu & Kashmir ; &

Whereas, virtual meeting was conducted by the undersigned with Dy. Drugs Controllers (Licensing Authorities) to review the status of identification of non-functional / non –existing firms who were issued Licenses by the competent authorities ; &

Whereas, Dy. Drugs Controllers (Licensing Authorities) have informed that inspectorate staff has identified 476 & 136 number of non-operational / non-existing firms in Kashmir & Jammu Divisions respectively; &

Whereas, Regulatory Challenges demand a review of under reference Order in the interest of Healthcare.

Now therefore , the undersigned hereby revokes the temporary suspension of Wholesale Licensing Applications with immediate effect *subject to below conditions :*

- 1. Fresh Applications for grant of Licenses shall be considered strictly for the intended premises at District Headquarters.*
- 2. The Experience Certificate uploaded by the Sole Proprietor / Partners cum Competent Person shall also be supported with Salary Records for the period of experience gained which shall be duly vetted by Chartered Accountant (CA) . It may be noted that no application with experience based on honorary basis shall be entertained.*

3. *The Licensing Authority shall secure due diligence with Rule 65A to Drugs Rules, 1945. The Inspecting Authority shall make a special mention against the Recommendations Note / Para / Inspection Note that the Experience Certificate as uploaded by the applicant in ONDLS Application has been verified & found genuine.*
4. *The applicant shall upload an affidavit to the extent that the Drugs shall be procured from original manufacturing firm or authorized C&F / Depo/ Super Stockiest / Authorized Stockiest of the Company(ies). The applicant shall further undertake, that no drug that is available in the authorized supply chain within the borders of Union Territory of J&K shall be procured for supply, sale, distribution from outside UT Borders.*
5. *All Licenses (Existing / Fresh) shall submit annual returns for all Drug Molecules falling under the purview of Sch. H1 & X to Drugs Rules, 1945 to the Licensing Authority (concerned) by or before 31st March of every Financial Year.*
6. *The Fresh Licenses shall be considered for grant only after securing due diligence by the inspecting authority that the intending firm has installed CCTV cameras & established Computerized Billing System.*
7. *Wholesale Licensing Application for License on Form 20 G to Drugs Rules, 1945 (Sch. X Drugs) shall not be considered for grant unless the Inspector of Drugs (concerned) furnishes an undertaking in writing to the Licensing Authority that the applicant firm has Good Market Standing & no untoward attempt / incidence has been reported against the firm especially w.r.t drug molecules which are likely to get misused.*
8. *The applicants shall upload Stockiest Authorization Letter obtained from Original Manufacturer / Super Stockiest in favor of the firm seeking grant of Licenses.*
9. *The exercise of identification of non-operational firms shall be continued & status thereof provided by respective Licensing Authorities to the Controlling cum State Licensing Authority on fortnightly basis.*

No. DFO/D-936/ 4527-4545
Dt: 23-12-2023


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

Copy for Distribution as :

1. Drugs Controller General (I), CDSCO (HQ), New Delhi.
2. Joint Director Information (J&K) with the request to publish this order in leading daily locals of the UT.
3. Dy. Drugs Controller cum Licensing Authority -Drugs & Food Control Organization Jammu / Kashmir for necessary action with the request to devise Format for affidavit content as mentioned at condition No. 04.
4. All Assistant Controller Drugs cum Licensing Authorities (Retail for information & compliance in respect of condition No. 9.
5. Pvt. Secretary to Secretary to Govt. (H&ME) Department for information of the worthy Secretary.
6. Pvt. Secretary to Commissioner (FDA), Civil Secretariat (J&K) for information of the worthy Commissioner.
7. Mr. Uttam Kumar (CDAC) with the request to release Fresh Application submission over the portal
8. Mr. Surinder C/o M/s Say technologies, Jammu with the request to upload the document on our official website.
9. Email / WAP.