

Subject: - Amended Drug Policy 2019, for Grant / Retention of Wholesale and Retailsale Drug Licenses in urban & rural areas.

The earlier policy for the purpose of uniform grant / renewal of drugs sale licences was introduced on 24-4-2010 and the same was made effective in the whole of the State w.e.f. 1-5-2010. During implementation of the above said policy and with the passage of more than 8 years of time, the department has experienced that more clarity is required for uniform & transparent implementation of the policy. The existing policy / guidelines have been revisited and certain amendments in the existing policy have been made. The amended policy is as under and will be effective from 1-4-2019.

Eligibility Criteria for grant of Wholesale / Retailsale drugs licence in the Urban & Rural Areas: -

1. No wholesale licence shall be granted in urban & rural area, except C&FA / Company depot with the title of Drugs Manufacturing Company and will be non transferable.
2. The applicant shall approach the Zonal Licensing Authority of the area to know that whether the fresh 5 retailsale licenses have been issued in the area, where the applicant intends to obtain the wholesale drugs license. In case the fresh 5 retailsale licenses have been granted in the proposed area, the applicant shall obtain an eligibility certificate from ZLA and after that shall upload an application for grant of wholesale license in the ratio of 5:1 alongwith eligibility certificate. Such wholesale license shall be granted on first come first serve basis within timeline fixed for grant of license.
- (3) (i) That once a firm is dissolved or split or ceased to exist, then the individual partner will have no claim for grant of wholesale licenses except the parent firm.
- (ii) The change in constitution with regard to major share will not be permitted, i.e. a partner / share holder, who is having the major share / controlling share will not be allowed to be substituted by the minor partners except the family members. The share holder who are in minority can be substituted, however this will not be applicable in the event of death of partner(s), he or she will be substituted with the legal heir of the deceased partner. The intention of the Government is very clear that the licenses shall not be sold in the name of others. Similarly, the inter district relocation of the premises of wholesale licenses will not be permitted. Similarly, if the partner of the dissolved firm wishes to obtain the wholesale license, the continuing partner needs to apply afresh for grant

of licenses as per criteria fixed by the Government & within 3 months from the date of change in constitution affected.

4. The Drugs Control Officer should verify the experience certificate with respect to appointment letter, attendance record, salary record with minimum wages slabs paid to the proposed competent person. Salary must have been paid to the experience holder through cheque payment/ any other approved source like RTGS, NEFT etc.
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 - (i) One fresh retailsale drugs license shall be issued in the urban / Township area on a population of 5000 and the existing licenses shall be taken into account.
 - (ii) The retailsale license so granted would be non transferable except in cases of death where it would be permissible for transfer of licenses to the legal heir only.
 - (iii) The retailsale licences applied under Pardhan Mantri Bhartiya Jan Aushadhi Yojna will be exempted from the purview of this policy.
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 - (i) That a retailsale license may be granted at the periphery of urban area, which is newly developed having a minimum population of 5000. With the addition of another 5000 population, the additional retailsale license may be granted at a distance of minimum 500 meters from the existing chemist shop(s).
 - (ii) A retailsale license may be granted inside or just outside the Hospital / Nursing Home having multispecialty facility.
 - (iii) A retail sale drugs license may be granted in rural / village area with the population of not less than 2500, for every addition of 2500 population 01 additional license shall be considered for grant.
 - (iv) In the Village having a PHC, not more than 03 retail sale licenses or in a village / town having CHC, not more than 05 retail sale drugs licences should be granted, depending upon the population of the local area where the PHC/CHC is situated. Existing licenses shall be taken into account by the DCO & ZLA.
 - (v) In the considered opinion of ZLA, if the number of existing licenses are adequate to cater the needs of the rural / village area, the ZLA may refuse to grant a retail sale license in such area.
 - (vi) The Licensing Authority should impose the specific conditions on the face of license prohibiting the possession of identified six habit forming drugs.
 - (vii) The retailsale license so granted would be non-transferable except in cases of death, where it would be permissible for transfer of licenses to the legal heir only. However the retail sale license would not be allowed to sold or relocated.

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- (i) A committee headed by Joint Commissioner (Drugs) / Assistant Commissioner (Drugs) and ZLA of the concerned area shall make the scrutiny of application to determine the eligibility for grant of retail sale license in the urban area as per fixed criteria.
 - (ii) That once a firm is dissolved or split or ceased to exist, then the individual partner will have no claim for grant of retail sale licenses except the continuing partner.
 - (iii) The change in constitution with regard to major share will not be permitted, i.e. a partner / share holder, who is having the major share / controlling share will not be allowed to be substituted by the minor partners except the family members.
 - (iv) The share holder who are in minority can be substituted, however this will not be applicable in the event of death of partner(s), he or she will be substituted with the legal heir of the deceased partner/proprietor. The intention of the Government is very clear that the licenses shall not be sold in the name of others. Similarly, the relocation of the premises of retail sale licenses will not be permitted out of district, if any firm intends to relocate, he has to apply in fresh, similarly if the partner of the dissolved firm wish to obtain the retail sale license need to apply afresh for grant of licenses as per criteria fixed by the Government & within 3 months from the date of change in constitution affected.
- 8 The Wholesale & Retail sale licenses of a firm/person whose licenses has been cancelled previously on account of his/her indulgence in unethical trade of habit forming drugs, such person/firm or his blood relation should not be granted a license.

Eligibility Criteria for retention of Wholesale & Retail sale drugs licence: -

- (i) The drugs licenses of the firm shall be cancelled in the event, the conviction of the firm and its proprietor / partner(s) / director(s) under Drugs & Cosmetics Act is upheld by the Hon'ble High Court.
- (ii) Due consideration be given at the time of renewal/ retention whether any irregularity was detected and the firm was not in compliance of the provisions of Drugs & Cosmetics Rules.

Common conditions to be observed by the wholesale / retail sale licensee: -

- (i) The non-maintenance of records and daily register of Schedule 'H1' drugs and such records maintained without the signature of Qualified person shall invite action under Rule 66 of Drugs and Cosmetics Rules, 1945 against the licensee and will lead to suspension of registration of qualified person on repeated contraventions.

- (ii) The Licenses shall not be retained if the application is made after 6 months from the date of expiry of licences held by the firm.
- (iii) The proprietor / partner of the firm shall display the registration certificate with photograph of the registered pharmacist / qualified person at the prominent place. It would be mandatory for proprietor / partner of the firm to install biometric attendance system and daily attendance of qualified person would be uploaded on the website of the department. The qualified person shall be paid salary either by cheque or salary shall be transferred in his / her bank account.

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