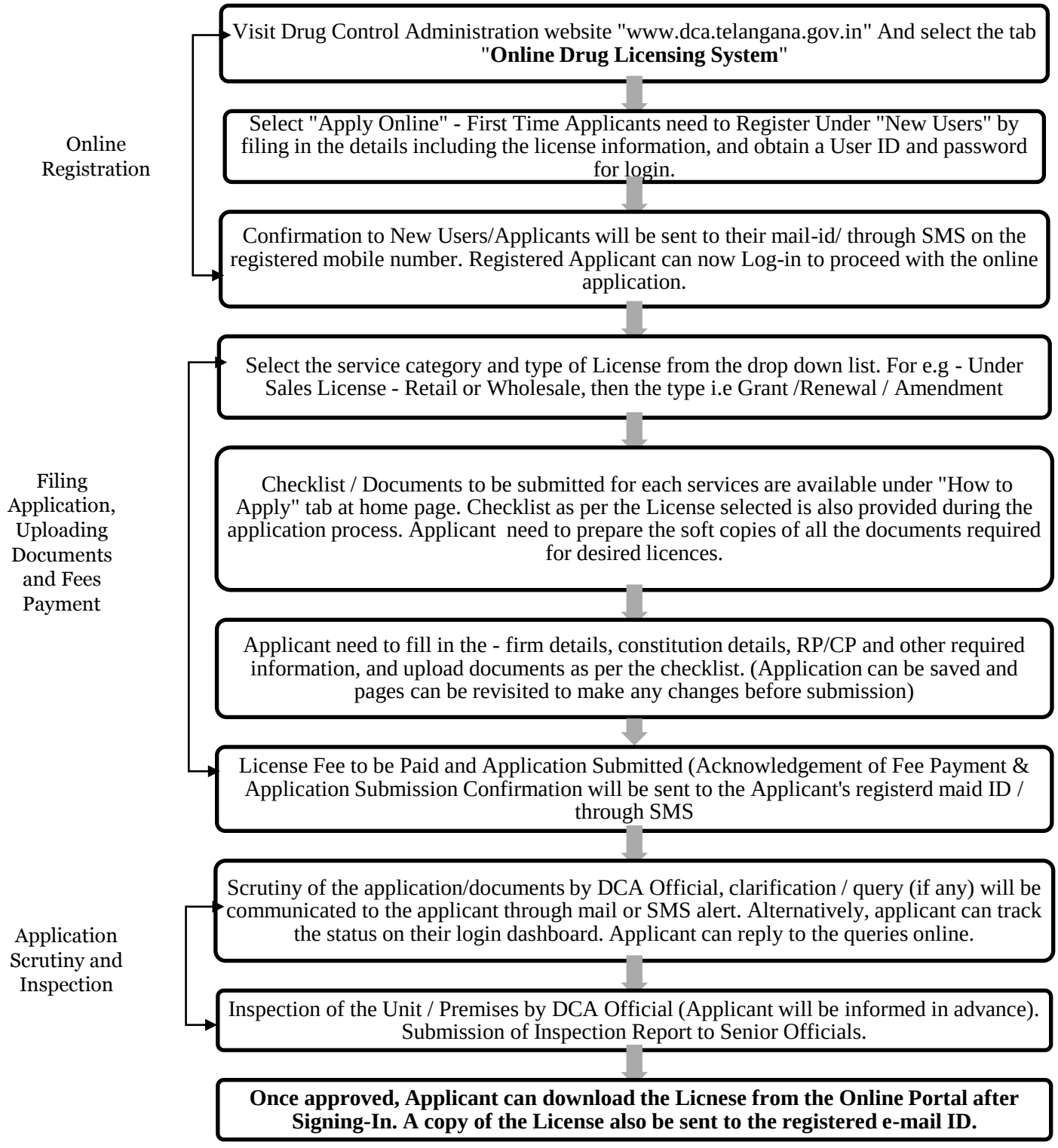
Online Application Procedure



Inspection Procedure for Manufacturing & Sales License's Application

a) The inspector shall verify the following aspects at the time of inspection of the facility for ***grant/ renewal of manufacturing licences:***

- Production area of the facility to verify the uni-flow of various operations carried out in the respective modules.
- Design of the facility for proper segregation of areas meant for various activities.
- Installation of the required equipment along with the qualification status.
- Purified water generation and distribution system and the status of validation.
- Air Handling Units validations along with the zoning classification (air classification), pressure differentials in various areas of the production modules.
- Material movement and men movement in the production areas to ensure regarding the no chance of cross contamination/ mix up.
- Quality Control laboratory to verify the instruments & calibration status (analytical capabilities of firm).
- Warehousing facilities of the firm for raw materials and finished products.
- Required capabilities of Technical Staff for manufacturing and testing.
- To verify the compliance of the facility with the provisions of Good Manufacturing Practices as per Schedule M (general requirements and specific requirements) and Good Laboratory Practices as per Schedule L-1 of Drugs and Cosmetics Act 1940 and Rules made thereunder.

b) The inspector shall verify the following aspects at the time of inspection of the outlet/premises for ***grant/ renewal of sales licences*** as per Rule 64 of Drugs and Cosmetics Act 1940 and Rules made thereunder:

- Area of the outlet to verify the compliance with the statutory limits.
- Capabilities to provide good storage conditions for the drugs stocked in the premises such as racks, refrigerator (for cold storage drugs) etc.