RENEWAL OF DRUGS MANUFACTURING LICENSE

Process Description

Name of Process	Renewal of Drug Manufacturing License
Name of a business process	Apply for the renewal of license to manufacture drugs
Related laws, rules, and regulations	Drug Regulatory Authority of Pakistan Act, 2012 Drugs Act, 1976 The Drugs (Licensing, Registration & Advertising) Rules, 1976
Process participant	Manufacturer DRAP
Input and criteria to enter/ begin the business process	• Manufacturer is a registered company as per SECP regulations/Registrar of Firms/Sole Proprietor • Manufacturing site area is minimum 2000 sq. yards. • A valid DML holder. (If the applicant applies within time for renewal of DML, the DML will be considered valid until an explicit decision is taken by Central Licensing Board.)
Activities and associated documentary requirements	Initiate process for renewal of drug license 1. Manufacturer fills the application form (Form 1A) for renewal of drug manufacturing license. • Applicant attaches supporting documents required as per the checklist mentioned in the application form. 2. Manufacturer submits fee through a bank challan. 3. Manufacturer submits application to DRAP office. 4. DRAP office receives the application form, challan copy and supporting documents. 5. DRAP office scrutinizes and evaluates the application form and supporting documents as per the checklist. • If the application is in-complete, DRAP informs the applicant with observation note. 6. DRAP forms a panel to assess the case of renewal of DML. 7. DRAP inspection team inspects and prepares the inspection report and submits to the DRAP. 8. DRAP Central Licensing Board review and finalize the case for renewal of the drug manufacturing license. 9. If case Central Licensing Board rejects the DML, due process of cancellation of license will be initiated after issuance of show cause letter to the applicant and opportunity of personal hearing and DRAP informs the manufacturer for application rejection. 10. If approved, DRAP issues renewed Drug Manufacturing License (Form 2) to the manufacturer. 11. Manufacturer collects the Form 2 from DRAP office 12. In case of rejection of application by CLB, applicant has the right of appeal within 60 days before the Appellate Board.

Output criteria to exit the business process	Drug Manufacturing License (Form 2) from DRAP office. Form 2 Validity: 5 years Legal Reference: Drug Regulatory Authority of Pakistan Act, 2012, The Drug Act, 1976 and The Drugs (Licensing, Registering & Advertising) Rules, 1976.
Time required to complete this business process	Minimum = 6 months Maximum = 9 months
Fee	The updated fee structure of regulatory functions can be accessed on https://www.dra.gov.pk/publications/regulatory-fees/.