

Grant of Drug(s) Import License to import drugs (other than finished drugs)/Raw Materials

(Form 5)

Process Description

Name of Process	Grant of Drug(s) Import License to import drugs (other than finished drugs) /raw materials for manufacturing
Name of a business process	Apply for grant of import license to import drugs (other than finished drugs) /raw materials for manufacturing
Related laws, rules, and regulations	Drug Regulatory Authority of Pakistan Act, 2012 The Drugs Act, 1976 The Drugs (Import & Export) Rules, 1976
Process participant	Importer DRAP
Input and criteria to enter/begin the business process	Importer is licensed with DRAP (DML) Product is registered with DRAP.
Activities and associated documentary requirements	<p>Initiate Process for import license of drugs (other than finished drugs)/raw materials</p> <ol style="list-style-type: none"> 1. Importer prepares the application form (on Form 2). Importer attaches supporting documents required as per the checklist. 2. Importer submits the challan fee to designated bank. 3. Importer submits the application to DRAP office. 4. DRAP receives and scrutinizes the application form and supporting documents as per checklist. <ul style="list-style-type: none"> • If applicant is not compliant, DRAP informs the Importer with observation notes. 5. If application is complete, DRAP verifies the DML and registration status of importer. 6. DRAP verifies the status of GMP Certificate & API mfg. License of exporter (of manufacture) 7. If application is approved, DRAP issues the Drugs Import License (Form 5). 8. Importer receives the Drug(s) Import License (Form 5) from DRAP office. 9. If application is not approved, DRAP informs the importer for DIL case rejection.
Output criteria to exit the business process	Importer collects the Drug(s) Import License (Form 5) from DRAP office. Validity: 2 Years Legal Reference: Drug Regulatory Authority of Pakistan Act, 2012 , The Drugs Act, 1976 & The Drugs (Import & Export) Rules, 1976
Time required to complete this business process	Minimum = 3 days Maximum = 5 days
Fee	PKR 5,000