

Grant of License to Import Drug(s) for Clinical Trials, Examination, Test, or Analysis

Process Description

Name of Process	Grant of License to Import Drug(s) for Clinical Trials, Examination, Test, or Analysis
Name of a business process	Apply for grant of import license to import drug(s) for Clinical Trials, Examination, Test, or Analysis
Related laws, rules, and regulations	The 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)
Activities and associated documentary requirements	<p>Initiate process for grant of import license to import drug(s) for Clinical Trials, Examination, Test, or Analysis</p> <ol style="list-style-type: none"> 1. Importer prepares the application form (on Form 4). 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 officer 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 verify the DML status of importer. 6. DRAP verify the status of GMP Certificate & API mfg. License of exporter (of manufacture) 7. If application is approved, DRAP issues the Drugs Import License (Form 6). 8. Importer receives the Drug(s) Import License (Form 6) from DRAP office. 9. If application is not approved, DRAP informs the importer for DIL case rejection.
Output criteria to exit the business process	<p>Importer collects the Drug(s) Import License (Form 6) from DRAP office.</p> <p>Validity: 2 Years</p> <p>Legal Reference: Drug Regulatory Authority of Pakistan Act, 2012 , The Drugs Act, 1976 & The Drugs (Import & Export) Rules, 1976</p>
Time required to complete this business process	<p>Minimum = 3 days</p> <p>Maximum = 5 days</p>
Fee	PKR 5,000