

Grant of NOC for import of unregistered finished drugs by Hospital and Institutional use

Process Description

Name of Process	Grant of NOC for import of unregistered finished drugs by Hospital and Institutional use
Name of a business process	Apply for grant of NOC for import of unregistered finished drugs by Hospital and Institutional use
Related laws, rules, and regulations	The Drug Regulatory Authority of Pakistan Act, 2012 The Drugs Act, 1976 The Drugs (Import & Export) Rules, 1976 SRO 142(I)/2018 as renewed from time to time.
Process participant	Importer (Hospital / institution) DRAP
Input and criteria to enter/begin the business process	Importer is a registered hospital / institution (private / public). (Documentary evidence for applicants applying for 1 st time.)
Activities and associated documentary requirements	<p>Process for grant of NOC for import of unregistered drugs by Hospital and Institutional use</p> <ol style="list-style-type: none"> 1. Applicant applies for grant of NOC to import by Hospital and Institutional use on its letter head. Applicant also attaches supporting documents required as per the checklist. 2. Applicant submits the application to DRAP. (If consignment is less than 100 doses, application for NOC will be processed by respective field offices of DRAP. In case of more than 100 doses, application will be forwarded by respective field office to DRAP HQ for further processing.) 3. DRAP receives and scrutinizes the application with supporting documents as per checklist. <ul style="list-style-type: none"> • If application is not compliant, DRAP communicate the observations to applicant. 4. After completion of application, DRAP analyze the request for NOC issuance decision. <ul style="list-style-type: none"> • If request is rejected, DRAP informs the applicant. 5. If request is approved, DRAP issues NOC for import by Hospital and Institutional use. 6. Applicant receives the NOC from DRAP. 7. After arrival of consignment at custom, the applicant is required to obtain clearance certificate from respective field office / DRAP HQ as per following procedure: <ol style="list-style-type: none"> i. Importer prepares the application form (on Form 1). Importer attaches supporting documents required as per the checklist. ii. Importer submits the application to respective field office. iii. DRAP receives and scrutinizes the application form and supporting documents as per checklist. <ul style="list-style-type: none"> • If application is not compliant; DRAP communicates observation notes to applicant. iv. If application is compliant, DRAP verifies the documents. v. If verification is successful, DRAP takes final decision and endorses/stamps the invoice.

	<p>vi. Applicant receives the stamped invoice from DRAP.</p> <p>vii. If case is not approved, DRAP rejects the application and informs the applicant.</p>
Output criteria to exit the business process	<ul style="list-style-type: none"> • NOC for import by Hospital and Institutional use • Endorsed / stamped invoice <p>Validity: For particular consignment (one time)</p> <p>Legal Reference: Drug Regulatory Authority of Pakistan Act, 2012, The Drugs Act, 1976 & The Drugs (Import & Export) Rules, 1976, SRO 142(I)/2018 as renewed from time to time.</p>
Time required to complete this business process	<p>Minimum = 10 days</p> <p>Maximum = 30 days</p>
Fee	No fee