

Renewal of Registration Process:

Process Description:

Name of Process	Renewal of Registration (For all kind of Drug Registration).
Name of Business process	Application for renewal of registered drug product
Related Laws, Rules and regulations	<ul style="list-style-type: none"> • Drug Regulatory Authority of Pakistan Act, 2012. • Drugs Act, 1976 • The Drugs (Labeling & Packing) Rules, 1986 • The Drugs (Licensing, Registering & Advertising) Rules, 1976. • The Drugs (Specification) Rules, 1978.
Input & Criteria to enter/begin the business process	<ul style="list-style-type: none"> • A valid Drug Manufacturing License (Form 2) • For Finished product Import; A valid Drug Sale License and Sole Agency Agreement • A valid Certificate of Registration or within one year after expiry of certificate of Registration. (If the applicant applies within time for renewal of registration, the registration of drug will be considered valid until an explicit decision is taken by Registration Board.)
Activities and associated documentary requirements	<p>Initiation of renewal of registration of pharmaceutical / biological (drug) product:</p> <ol style="list-style-type: none"> 1. Applicant shall submit renewal application (Form 5B) for all categories of registered Drugs with requisite documents and fee. 2. DRAP receives, scrutinizes and evaluate the renewal applications and requisite documents as per SOP approved by Registration Board on FIFO basis. <ul style="list-style-type: none"> • If the application is in-complete, DRAP informs the applicant with observation note. One reminder is issued in case applicant fails to reply in stipulated time period. 3. After rectification of shortcomings by applicant, Pharmaceutical Evaluation & Registration Division / Biological Evaluation & Research Division DRAP prepares summary and present it before the Registration Board. 4. Registration Board review the summary and take final decision. 5. DRAP issues renewal of drug registration letter to the applicant. 6. In case Registration Board rejects the renewal of registration application, due process of cancellation of registration will be initiated after issuance of show cause letter to the applicant and opportunity of personal hearing. 7. In case of rejection of application by RB, applicant has the right of appeal within 60 days before the Appellate Board.
Output Criteria to exit the	<ul style="list-style-type: none"> • Renewal of Registration of Drug letter from DRAP office.

business process	<ul style="list-style-type: none"> • Validity for 5 years (unless earlier cancelled or suspended by the Registration Board). • Legal Reference: Drug Regulatory Authority of Pakistan Act, and The Drug Licensing, Registering & Advertising) Rules, 1976
Time required to exit the business process	<ul style="list-style-type: none"> • Minimum: 01 months • Maximum: 03 months
Fee*	<ul style="list-style-type: none"> • PKR 10,000/- Fee for renewal of registration of locally manufactured drugs (in-time submission; before expiry of registration certificate) • PKR 20,000/- Fee for renewal of registration of locally manufactured drugs after expiry of registration certificate but within 60 days, afterwards an additional fee equivalent to applicable renewal fee for each delayed month shall be deposited if the renewal application is submitted after 60 days but within 01 year after expiry of registration. • PKR 20,000/- Fee for renewal of registration of new drug/molecule • PKR 20,000/- Fee for renewal of registration of any other drug for import (in-time submission; before expiry of registration certificate) • PKR 40,000/- Fee for renewal of registration of any other drug for import after expiry of registration certificate but within 60 days, afterwards additional fee equivalent to applicable renewal fee for each delayed month shall be deposited if the renewal application is submitted after 60 days but within 01 year after expiry of registration. • An *(Fee are prescribed in schedule F of The Drug (Licensing, Registering & Advertising) Rules, 1976 as amended Vide SRO 1117 dated 12th September, 2012.)