



## 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"> <li>• Drug Regulatory Authority of Pakistan Act, 2012.</li> <li>• Drugs Act, 1976</li> <li>• The Drugs (Labeling &amp; Packing) Rules, 1986</li> <li>• The Drugs (Licensing, Registering &amp; Advertising) Rules, 1976.</li> <li>• The Drugs (Specification) Rules, 1978.</li> </ul>
Input & Criteria to enter/begin the business process	<ul style="list-style-type: none"> <li>• A valid Drug Manufacturing License (Form 2)</li> <li>• For Finished product Import; A valid Drug Sale License and Sole Agency Agreement</li> <li>• 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.)</li> </ul>
Activities and associated documentary requirements	<p>Initiation of renewal of registration of pharmaceutical / biological (drug) product:</p> <ol style="list-style-type: none"> <li>1. Applicant shall submit renewal application (<a href="#">Form 5B</a>) for all categories of registered biologicals with requisite documents and fee.</li> <li>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"> <li>• 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.</li> </ul> </li> <li>3. After rectification of shortcomings by applicant, Biological Evaluation &amp; Research Division DRAP prepares summary and present it before the Registration Board.</li> <li>4. Registration Board reviews the summary and take final decision.</li> <li>5. DRAP issues renewal of drug registration letter to the applicant.</li> <li>6. In case Registration Board rejects the renewal of registration application, due process of cancellation of registration will be initiated.</li> <li>7. In case of rejection of application by RB, applicant has the right of appeal within 60 days before the Appellate Board.</li> </ol>
Output Criteria to exit the business process	<ul style="list-style-type: none"> <li>• Renewal of Registration of Drug letter from DRAP office.</li> <li>• Validity for 5 years (unless earlier cancelled or suspended by the Registration Board).</li> </ul>



*Process Description for Grant of Renewal of Drug Registration  
(Biologicals)*

Doc #

BE&R/SOP/RB/005

Ver

02

	<ul style="list-style-type: none"><li>• Legal Reference: Drug Regulatory Authority of Pakistan Act, 2012 and The Drug Licensing, Registering &amp; Advertising) Rules, 1976</li></ul>
Time required to exit the business process	<ul style="list-style-type: none"><li>• Minimum: 01 months</li><li>• Maximum: 03 months</li></ul>
Fee*	The updated fee structure of regulatory functions can be accessed on <a href="https://www.dra.gov.pk/publications/regulatory-fees/">https://www.dra.gov.pk/publications/regulatory-fees/</a> .