Export Registration of Biologicals of Human /Veterinary use:

Process Description:

Name of Process	Grant of Registration exclusively for export purpose for Biological Drug Product
Name of Business process	Apply for export registration of Biological product of Human / veterinary use.
Related Laws, Rules and regulations	• 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	• For local manufacturer; A valid Drug Manufacturing License (Form 2) by DRAP
Activities and associated documentary requirements	Outline for registration of biological drug product exclusively for export purpose: 1. DRAP has established an Export Facilitation Desk to provide guidance and assistance to the manufacturers regarding documentation and approval process of export registration. 2. Applicant shall submit the drug product registration application form for export purpose as per Rules 26 of Drugs (L,R&A) Rules, 1976 according to product type, as follows: • Form 5 – Generic drugs • Form 5D New molecules 3. DRAP scrutinizes the application form and requisite documents as per checklist. • 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. 4. After rectification of shortcomings, BE&R Division DRAP prepares the summary. 5. For Generic drug products or formulations approved by reference regulatory authorities, Chairman Registration Board is authorized to decide regarding registration application for export purpose 6. For products not falling in above category, cases are submitted to Registration Board for decision 7. BE&R Divisions DRAP issues Certificate of Export Registration of approved drug products.
Output Criteria to exit the business process	• Export Registration Certificate from DRAP office. • Validity for 5 years (unless earlier cancelled or suspended by the Registration Board). • Legal Reference: Drug Regulatory Authority of Pakistan Act, 2012 and The (Drug Licensing, Registering & Advertising) Rules, 1976
Time required to	• Minimum: 05 Days

exit the business process	• Maximum: 45 Days
Fee	The updated fee structure of regulatory functions can be accessed on https://www.dra.gov.pk/publications/regulatory-fees/.