Product Registration Process (Local Manufacturing / Finished Product Import of Biologicals) for veterinary use

Process Description:

Name of Process	Drug Product Registration for Local Manufacturing / Finished Product Import-Biologicals) for veterinary use
Name of Business process	Application for registration of drug product for local manufacturing or finished product import (Biologicals) for 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 • For Finished product Import; A valid Drug Sale License and Sole Agency Agreement
Activities and associated documentary requirements	Outline for biological product registration process for veterinary use is as follows: - **1. <u>Registration Board is the relevant forum for consideration of registration applications</u>** 2. Applicant shall submit product registration application form as per Rules 26 of Drugs (Licensing, Registering &Advertising) Rules, 1976 according to product type, as follows: - **For Veterinary Use:** • Form 5- Local Manufacturing, • Form 5A – Imported Drugs, • Form 5D New Drug Molecules, • Form 5E, Patent Drugs 3. Applicant (manufacturer / importer) shall support product registration application with requisite documents and fee. 4. Pre-Screening of application is performed by designated officer of DRAP and if application is incomplete, applicant is being informed. 5. In case of complete application, applicant submits the application to DRAP. 6. DRAP receives the application(s) which alongwith details is/are entered in the database of received applications after its categorization (routine/priority). 7. These applications are scrutinized and evaluated on FIFO basis as per checklist approved by Registration Board. • 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.

	8. After rectification of shortcomings, Biological Evaluation & Research (BE&R) of DRAP prepare the summary for consideration of Registration Board. 9. For locally manufactured drugs, Registration Board may cause the premises of drug manufacturer to be inspected by a panel of experts and detail report shall be presented before the Registration Board. 10. For imported drugs, GMP inspection of foreign manufacturer is carried out prior to grant of registration as per the policy on inspection of manufacturers abroad. 11. Registration Board takes the final decision. 12. If the Registration Board rejects the application, BE&R Division informs the applicant (manufacturer /importer) for rejection of application. 13. If MRP is already fixed by Federal Government, Pharmaceutical Evaluation & Registration, Division of DRAP issues Certificate of Registration of approved drug product to the applicant (manufacturer / importer). 14. In case, the MRP is not fixed, matter is referred to Costing & Pricing Division for fixation of price by the Federal Government under the Drug Pricing Policy. The certificate of registration will be issued after price fixation by Federal Government. 15. In case rejection of application by Registration Board, applicant has the right of appeal within 60 days before the Appellate Board.
Output Criteria to exit the business process	• Certificate of Registration (Form 6) of drug product 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 exit the business process	• Minimum: 03 months • Maximum: 18 months
Fee	The updated fee structure of regulatory functions can be accessed on https://www.dra.gov.pk/publications/regulatory-fees/.