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

Process Description:

Name of Process	Drug Product Registration (Local Manufacturing / Finished Product Import - Biologicals) for human use
Name of Business process	Application for registration of drug product for local manufacturing or finished product import (biologicals) for human 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 drug product registration process of biological is as follows: - **1. Registration Board is the relevant forum for consideration of registration applications** 2. Applicant shall submit drug product registration application form as per Rules 26 of Drugs (Licensing, Registering &Advertising) Rules, 1976 according to product type, as follows: - **For Human Use:** • Form 5F–For all types of human drug products* (*Common Technical Document (CTD) (Form 5F) is applicable with effect from 07-Mar-2019 for all human pharmaceutical and biological product including local manufacturing, imported finished drug products, new drug formulation, etc.) 3. Applicant (manufacturer / importer) shall support drug product registration application with requisite documents and fee. 4. Applicant submits the application to DRAP. 5. DRAP receives the application(s) which along with details is/are entered in the database of received applications after its categorization (routine/priority). 6. 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. 7. After rectification of shortcomings, Biological Evaluation & Research Division of DRAP prepare the summary for consideration of Registration Board.

	8. 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. 9. For imported drugs, GMP inspection of foreign manufacturer is carried out prior to grant of registration. However, pharmaceutical / biological products approved by United States Food and Drug Administration (USFDA), World Health Organization (WHO), European Medicine Agency (EMA) or regulatory bodies of Japan, Australia, Canada, or any of regulatory authority of erstwhile Western Europe (United Kingdom, Germany, France, Switzerland, Netherlands, Austria, Belgium, Denmark, Finland, Sweden, Italy, Ireland, Luxemburg, Norway, Scotland and Spain) or three stringent regulatory bodies of erstwhile Eastern Europe are exempted from inspection. 10. Registration Board take the final decision. 11. If the Registration Board rejected the application, BE&R Division informs the applicant (manufacturer /importer) for rejection of application. 12. If MRP is already fixed by Federal Government, Biological Evaluation & Research Division of DRAP issues Certificate of Registration of approved drug product to the applicant (manufacturer / importer). 13. 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. 14. 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