PROCEDURE FOR REGISTRATION OF DRUGS

1. Drugs Act, 1976 regulates the import, export, manufacture, storage, distribution and sale of the drugs. Drugs are registered under section 7 of the Drugs Act, 1976. Registration Board is authority for registration of drugs.

2. The Registration Board has been setup under section 7 of the Drugs Act, 1976. The Registration Board is comprised of 17 highly technical, professional and experienced members from Medical, Pharmaceutical, Biologicals, Pharmacy, Veterinary, Law (from Law & Justice Division), Drug testing, relevant Directors of DRAP and representative of Intellectual Proprietary Organization. Representatives of stake holder's i.e. Pakistan Pharmaceuticals Manufacturer Association, Pharma Bureau and Pakistan Veterinary Manufacturer Association are included in the Drugs Registration Board as observers. Composition of Registration Board is laid down under rule 24 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 framed under the Drugs Act, 1976.

2. Rule 26 & 29 of Drugs (Licensing, Registering and Advertising) Rules, 1976 prescribe procedure for grant of registration as follows:-

(i) An application for registration of a drug shall be made in Form 5 (for local manufacture), 5-A (for imported drugs), 5-D (for new molecule) or Form-E (for Patent Drugs) accompanied by fee in duplicate to the Registration Board addressed to its Secretary, and separate application shall be made for each drug.

(ii) The applicant shall furnish such further information and material as may be required by the Registration Board for proper evaluation of the drug.

(iii) The Registration Board may, if it considers necessary, cause the application for registration and the information and material supplied to it to be evaluated by a Committee on Drugs Evaluation consisting of experts related to the aspect of the drug (Expert Committee on Biological Drugs for biological drugs and Veterinary Expert Committee for veterinary drugs constituted under Section 10 of the Drugs Act, 1976) to be evaluated and obtain its report.

(iv) The Registration Board may, before issuing a registration, cause the premises in which the manufacture is proposed to be conducted to be inspected by itself or by its sub-

committee or by a panel of Inspectors or experts appointed by it for the purpose, which may examine all portions of the premises and the plant and appliances, inspect the process of manufacture intended to be employed and the means to be employed for standardizing, if necessary, and testing the substances to be manufactured and enquire into the professional qualifications of the technical staff employed. Where inspection is carried out by a Sub-Committee or panel of experts or Inspectors appointed, it shall forward to the Registration Board a detailed report of the result of the inspection.

(v) The Registration Board shall, before registering a new drug for which the research work has been conducted in other countries and its efficacy, safety and quality has been established therein, require the investigation on such pharmaceutical, pharmacological and other aspects, to be conducted and clinical trials to be made as are necessary to establish its quality and, where applicable, the biological, availability, and its safety and efficacy to be established under the local conditions: Provided that under special circumstances to be recorded in writing, the Registration Board may register a drug and require such investigations and clinical trials to be conducted after its registration.

(vi) A new drug, where new method of manufacture is contemplated or a change is proposed in source, standard or specification of the active ingredient or the finished product may not require full investigations and clinical trials except in so far as they are necessary for the purpose of establishing bio-equivalence, absorption, acceptability or other such features.

(vii) For imported drugs, GMP inspection of foreign manufacturer is also carried out prior to grant of registration. Experts in the relevant field inspect the foreign manufacturer to ensure that manufacturer fulfills the current Good Manufacturing Practices. 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, Health Canada, Switzerland any of the regulatory bodies of erstwhile Western Europe or three stringent regulatory bodies of erstwhile Eastern Europe shall be exempted from the inspection of the manufacturing unit abroad**.**

(viii) If the Registration Board, after such further enquiry, if any, as it may consider necessary, is satisfied of its safety, efficacy, quality and economical value or where the public interest so requires, it may register the drug and issue a certificate of registration in Form 6, subject to such specific conditions as it may specify.

(ix) Where it is necessary in the public interest so to do, the Registration Board may register a drug on its own motion without having received any application for registration.

(x) If the Registration Board is not satisfied as to the safety, efficacy, quality or economic value of a drug, or where the public interest so requires it may reject the application for registration and inform the applicant of the reasons for such rejection in writing.

(xi) The Drugs Registration Fee vide S.R.O 1117(I)/2012 is as follows:

		Fee (Rs.)	Renewal Fee (Rs.)
(a)	New drug or molecule / drug not manufactured locally	50,000/-	20000/-
(b)	Any other drug for import	100,000/-	20,000/-
(c)	Drug for local manufacture	20,000/-	10,000/-
(d)	Drug for import	---	40,000/-
(e)	Drug for local manufacture	---	20,000/-
(f)	Variance to registration application i.e. changes in inactive raw materials, method of manufacture, testing methods or quality specifications, product specification, packing materials including changes of labeling specification etc.	5,000/-	---

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