PROCEDURE FOR GRANT OF DRUGS MANUFACTURING LICENSE

The Drugs Act, 1976 regulates the import, export, manufacture, storage, distribution and sale drugs.

2. The grant of licenses to manufacture drugs is regulated by Central Licensing Board (CLB) setup under section 5 of the Drugs Act, 1976. The C.L.B. consists of highly technical, professional and experienced persons from pharmaceutical field, including the representatives of renowned Pharmacy institutions, representatives of all Provincial Health Departments and a law expert (representative of Law & Justice Division) etc. The nominees of stake holders i.e. Pakistan Pharmaceutical Manufacturers Association (PPMA), Pharma Bureau (representative body of multinational companies), Pakistan Chemists and Druggists Association (PCDA) etc may also attend the meeting of C.L.B. The composition of C.L.B. is laid down under rule 8 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 framed under the Drugs Act, 1976.

3. The Central Licensing Board (CLB) at present comprisies of 14 members including experts from the fields of Manufacturing and Quality Control of Pharmaceuticals, Professors of renowned universities, representatives of Health Departments Government of Punjab, Sindh, Khyber Pakhtun Khwa, Balochistan and a Law expert.

4. As provided under rule 3 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 framed under the Drugs Act, 1976, following five (5) types of licenses are issued depending upon the nature of the activity of Pharmaceutical Manufacture: -

a) License to manufacture by way of Formulation
b) License to manufacture by way of Basic Manufacture
c) License to manufacture by way of Semi Basic Manufacture
d) License to manufacture by way of Repacking
e) License to manufacture by way of Experimental purpose.

A pharmaceutical unit (facility) can possess more than one licenses depending upon the nature of activity being under taken by the manufacturer / licensee.

5. The salient features of the procedure for grant of a license by way of formulation / basic/ semi basic/ re-packing are as under: -

i) When an application is made to the Central Licensing Board for establishment of a Pharmaceutical unit, the same is examined and scrutinized in the light of required documents and after the fulfillment of pre-requisites **the proposed site is got inspected for site verification** by the Area FID / Field Officer of Drug Regulatory Authority of Pakistan (DRAP). If the proposed site is recommended for establishment of pharmaceutical unit in the light of requirements laid down under Schedule B of the Drugs (Licensing, Registering and Advertising) Rules, 1976 framed under the Drugs Act, 1976, the case is processed for approval of the site by the competent authority. Afterward the site approval is communicated to the applicant if it is in conformity to the provisions of the rules otherwise the same is rejected by the competent authority, if the site does not meet the laid down criteria under the aforesaid rules and so reported by the field officer/FID concerned.

ii) **In case the site is approved, the applicant is then required to furnish layout plan, drawn inline with current Good Manufacturing Practices (cGMP) requirements, for construction of the proposed unit**. The guidelines to this effect (cGMP requirements) are given in Schedule B-1 of the above referred rules. **Once the layout plan is found in order as per cGMP requirement**, the same is processed for the approval of competent authority. **The approval is communicated to the applicant for construction of the facility.**

iii) **The applicant after completing the construction of the unit submits application for grant of Drug Manufacturing License (DML) on the prescribed Form-I along with the necessary documents / information.** The application is examined and scrutinized and if all codal

formalities have been fulfilled, a panel is constituted for inspection of the unit. **The panel of experts / inspectors including a member of C.L.B. inspects the premises to evaluate the facilities provided for production and Quality Control of drugs to be manufactured** and submits its report accordingly. The inspection report is placed before the CLB in its meeting for consideration and decision in the light of recommendations of the panel and provisions of the relevant law / rules.

iv) The CLB which meets after every six to eight weeks, passes its orders on the recommendations of the panel as mentioned in the report. If a case for grant of DML is approved by the CLB a license is issued on prescribed Form-2 for a period of five years after which it is renewable for another such period on an application made by the applicant on prescribed Form-IA alongwith all requisites documents. Once an application for renewal of DML has been made in time, the license continues to be enforced till the decision / orders on the application for renewal are passed by the CLB.

v) A license may be suspended or cancelled or renewal denied if the licensee fails to comply with the conditions of license or cGMP as provided under the Drugs (Licensing, Registering and Advertising) Rules, 1976 framed under the Drugs Act, 1976.

6. The procedural requirements for other types of Drug Manufacturing Licenses are similar as that of the Formulation, with some variations of conditions depending upon the type of the license.

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