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PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN

Ministry of National Health Services, Regulations and Coordination
Drug Regulatory Authority of Pakistan

NOTIFICATION

Islamabad, the 5th October, 2017

S.R.O. 1012(I)/2017. – In exercise of the powers conferred by sub-section (2) of section 12 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Policy Board is pleased to make the following regulations, namely:-

1. **Short title and commencement.--** (1) These regulations may be called the GMP Inspection Committee (Appeal) Regulations, 2017.

(2) These shall come into force at once.

2. Definitions.– (1) In these Regulations, unless there is anything repugnant in the subject or context,-

(a) "Act" means the Drug Regulatory Authority of Pakistan (DRAP) Act, 2012 (XXI of 2012);

(b) "Committee" means an Appellate Inspection Committee constituted by the Policy Board under section 12 of the Act; and

(c) "Licensee" means any legal entity (person or firm of company), enlistment holder, proprietor, owner of a company of firm, establishment involved in manufacturing, import, export, storage, distribution or sale of therapeutic goods for the purpose of these regulations.

(2) The words and expressions used but not defined herein shall have the same meanings as are assigned to them under the Act the Drugs Act, 1976 (XXXI of 1976).

3. **Appellate Inspection Committee.--** The Policy Board shall constitute an Appellate Inspection Committee consisting of following members, namely:-

(a) the Chief Executive Officer, DRAP, Chairman;
(b) the Director (Legal Affairs), DRAP, Secretary; and
(c) any Director of the Authority as a member, co-opted by the CEO, DRAP.

4. **Procedure of Appeal.--** (1) Any licensee aggrieved of the any of the order of the Federal Inspector of Drugs during the course of inspection or in an inspection report may prefer an appeal in writing to the Chief Executive Officer of the Authority, within thirty days of inspection or writing such report on the authorized inspection book by the Federal Inspector challenging the authenticity or correctness of the report for getting the premises re-inspected for GMP compliance.

(2) The memorandum of the appeal shall include the following.-

(i) a detailed counter report, duly signed by the company's authorized representative, the Production Incharge and the Quality Control Incharge approved for the purpose of the license, enlistment or establishment license, stating therein the acts of omission and commission of the Federal Inspector leading to the appeal, along with the evidence, and justification whatsoever; and

(ii) the appeal in triplicate; one original and two copies, along with a fee of twenty five thousand rupees, duly paid in the Authority's Bank account.

(3) The Chief Executive Officer of the Authority on receipt of the appeal shall cause it to be examined by the Committee constituted by the Board of the Authority. The Committee in the process of examination of the appeal may give an opportunity of personal hearing to both the parties, that is the appellant and the Federal Inspector whose report is challenged.

(4) The Committee shall conclude examination and investigation of the appeal within ten days exclusive of the period for which the appellant seeks any adjournment and such adjournment shall be allowed only once up to seven days in the entire proceedings.

(5) The Chief Executive Officer may on the recommendation by the committee constitute a three member panel of experts to re-inspect the licensed, enlisted or establishment licensed premises for GMP compliance within fifteen days and the report of this panel of experts shall be final and admissible for any action under Act and the Drugs Act, 1976, and the rules made thereunder, as the case may be.

(6) The Appellant shall also be liable to pay to the Authority such estimated re-inspection expenditure of the panel of experts, as may be determined by the Authority, at least three working days in advance and before Appellate Inspection.

(7) If the Federal Inspector is found guilty on the grounds that the report was malicious, a disciplinary action shall be initiated by the Directorate of Administration, under the respective administrative laws, rules and regulations.

5. **Panel of experts.** The panel of experts shall be constituted out of a pool of experts in the manufacture and quality control of therapeutic goods as approved by the Board.

[No. F.12-5/2015/DD(LA)]

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