The Gazette of Pakistan

EXTRAORDINARY
PUBLISHED BY AUTHORITY

ISLAMABAD, WEDNESDAY, NOVEMBER 8, 2017

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 31st October, 2017

S.R.O. 1163(I)/2017. – The following draft of certain further amendments in the Drugs (Licensing, Registering and Advertising) Rules, 1976, which the Federal Government proposes to be make in exercise of the powers conferred by section 23 and clause (a) of section 7 of the Drugs Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with section 43 of the Drugs Act, 1976 (XXXI of 1976), is hereby published for the information of all persons likely to be affected thereby, and notice is hereby given that the amendments shall be taken into consideration after fifteen days of its publication in the official Gazette.

Any objection or suggestion, which may be received from any person, before the expiry of the aforesaid period, shall be considered by the Federal Government.

DRAFT AMENDMENTS

In the aforesaid Rules,-

(1) in rule 8, in sub-rule (1), in clause (h), for the words "Deputy Director General", the words "Additional Director" shall be substituted;

(2) in rule 15, in sub-rule(1),-
  (a) in clause (c), for the word "ten", the word "eight" shall be substituted; and
  (b) in clause (e), for the word "ten", the word "eight" shall be substituted.

(3) in rule 16,-
  (a) in clause (c),-
    (i) in sub-clause (i), for the word "ten", the word "six" shall be substituted;

(ii) sub-clause (ii) shall be omitted;
(iii) in sub-clause (iii), the words "or sub-clause (ii)" shall be omitted; and
(iv) in sub-clause (iii), in the first proviso, for the word "medicine", the words "pharmacy or microbiology or biotechnology" shall be substituted.

(b) for clause (e), the following shall be substituted, namely:-

"(e) The Quality Control Department shall be independent of the manufacturing unit and its incharge shall be a whole time employee of the manufacturer and shall possess a degree in pharmacy and shall have minimum six years experience in testing of types of drugs intended to be manufactured, or a master degree in science with chemistry and shall have minimum ten years experience in testing of types of drugs intended to be manufactured:

Provided that for pharmacological testing, there shall be an additional employee who shall possess a degree in pharmacy or a master degree in pharmacology and shall have minimum six years experience in testing of types of drugs intended to be manufactured, and for microbiological testing there shall be an additional employee who shall possess a degree in pharmacy or a master degree in microbiology and shall have minimum six years experience in testing of types of drugs intended to be manufactured:

Provided further that in the case of drugs specified in Schedule C, the Central Licensing Board may allow the applicant to make arrangements with some other institution approved by the Central Licensing Board for such tests to be regularly carried out on his behalf by that institution:

Provided also that there shall be an independent Head of Quality Assurance for the quality assurance of the drugs being manufactured who shall possess a degree in pharmacy with seven years experience having minimum five years experience in Quality Control and testing of drugs.".

[Dy. 1096-Dir (Drug Lic]

SHAIKH FAQEER MUHAMMAD,
Director (Drug Licensing).