To be published in the extra ordinary Gazette of Pakistan, Part-II

Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
*****

Islamabad, the 10th June, 2022.

NOTIFICATION

S.R.O. 778 **(I)/2022.**— The following draft of further amendments in the Drugs (Licensing, Registering and Advertising) Rules, 1976, which is proposed to be made by the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, in exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with clause (a) of section 7 thereof and 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, as required by sub-section (3) of section 43 of the said Act (XXXI of 1976), notice is hereby given that objections or suggestions thereon, if any, may, for consideration of the Federal Government, be sent within fourteen days of the publication of this Notification in the official Gazette.

Any objections or suggestions which may be received from any person in respect of the said draft before expiry of the aforesaid period shall be taken into consideration by the Federal Government, namely:-

DRAFT AMENDMENTS

In the aforesaid Rules,--

(1) in rule 16.—

(i) in clause (a), for the expression "Schedule B", the expression "Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, as updated from time to time" shall be substituted;

(ii) in clause (b), for the expression "Schedule B-I", the expression "Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, as updated from time to time" shall be substituted;

(iii) in clause (bb), for the expression "in addition to the conditions specified in Schedule B and Schedule B-1 comply with the conditions specified in Schedule B-IA", the expression "comply with the conditions specified in Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, as updated from time to time" shall be substituted; and

(iv) after clause (bb), amended as aforesaid, the following two provisos shall be inserted, namely:-

"Provided that the amendments in clause (a), (b) and (bb) shall take effect from the 1st July, 2022:

Provided further that the matters not explicitly covered in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, the guidelines of the World Health Organization shall be followed.";

(2) in rule 20.—

(i) in clauses (a) and (c), for the expression "Schedule B-III", the expression "Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, as updated from time to time" shall be substituted;

(ii) in clause (b), for the expression "Schedule B-III", the expression "in a manner as specified in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, as updated from time to time" shall be substituted; and

(iii) in clause (c), for full stop at the end, a colon shall be substituted and thereafter the following provisos shall be inserted, namely:-

"Provided that the amendments in clause (a), (b) and (c) shall take effect from the 1st July, 2022:

Provided further that the matters not explicitly covered in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, the guidelines of the World Health Organization shall be followed.";

(3) in Schedule-B, clause 1.3 shall be omitted; and

(4) Schedule B, B-1, and B-1A, B-II and B-III shall be omitted with effect from the 1st July, 2022.".

[No. F.10-9/2021-Lic/DRAP]

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