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

NOTIFICATION

Islamabad, the 25th August, 2025.

S.R.O. 1587(I)/2025. – In exercise of the power conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with clause (a) and clause (t) of section 7 thereof and section 43 of the Drugs Act 1976 (XXXI of 1976), the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, is pleased to direct that in the Drugs (Licensing, Registering, and Advertising) Rules, 1976, the following further amendments which shall take effect six months after commencement of this Notification shall be made, which as required by sub-section (3) of the said section 43 were previously published *vide* Notification No. S.R.O. 778(I)/2022, dated the 10th June, 2022, namely:-

In the aforesaid Rules,--

(1) in rule 16, –

(i) in clause (a), for the words "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-1", the expression "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 PIC/S GMP guidelines, as updated from time to time" shall be substituted; and

(iv) for full stop at the end a colon shall be substituted and thereafter the following proviso shall be added, namely:-

"Provided that without prejudice to anything contained in the Act, the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) and rules made thereunder,-

(i) for the matters not explicitly covered in the PIC/S GMP guidelines, the guidelines of the World Health Organization shall be followed; and

(ii) the Central Licensing Board may, if it deems appropriate, at any time, by order in writing, exempt any specific condition of PIC/S GMP guidelines, subject to such conditions, if any, and for such period, as may be specified in the order.";

(2) in rule 20, –

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

(iii) in clause (c), for the expression "Schedule B-III", the expression "PIC/S GMP guidelines, as updated from time to time" shall be substituted; and

(iv) in clause (c), amended as aforesaid, for the full stop at the end a colon shall be substituted and thereafter the following proviso shall be added, namely:-

"Provided that without prejudice to anything contained in the Act, the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) and rules made thereunder,-

(i) for the matters not explicitly covered in the PIC/S GMP guidelines, the guidelines of the World Health Organization shall be followed; and

(ii) the Central Licensing Board may, if it deems appropriate, at any time, by order in writing, exempt any specific condition of PIC/S GMP guidelines, subject to such conditions, if any, and for such period, as may be specified in the order."; and

(3) Schedule B, B-1, B-1A, B-II and B-III shall be omitted.

[No. F.10-9/2012-Lic.]

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