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

NOTIFICATION

Islamabad, the 1st August, 2025.

S.R.O. 1400(I)/2025. – In exercise of the powers conferred by section 36 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government, being of the opinion that the public interest so requires, is pleased to exempt, the anticancer drugs, cardiac drugs and any essential lifesaving drugs so considered by the licensing authority imported for use in hospital and institutions, from the provisions of sub-clause (vii) of clause (a) of sub-section (1) of section 23 of the said Act, for a period of five years w.e.f. the 22nd January, 2025, subject to the following conditions, namely:

(a) the imports shall be made with prior approval of the licensing authority under rule 9 of the Drugs (Import and Export) Rules, 1976;

(b) the drug shall not be sold or distributed in the market;

(c) the drug shall be on free sale in the country of origin except for life saving vaccines and anti-sera for human use only, where pre-qualification by WHO or approval of any regulatory authorities as defined by the Registration Board is provided;

(d) the drug shall be used for therapeutic purpose in the hospital or institutions only and not for the purpose of clinical trial, examination, test or analysis;

(e) clearance certificate must be obtained from Assistant Director concerned, at the time of arrival of shipment, before customs clearance. Consumption or utilization record must be maintained by the importer, under the supervision of qualified person; and

(f) the drug is not registered or available in Pakistan.

Provided that condition mentioned at serial No. (c) shall not apply to medicine(s) and vaccine(s) used in treatment and prevention of COVID-19.

[No. F. 1-1/2025-IE(QA&LT)]

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