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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 7th February, 2018*

**S.R.O. 142(I)/2018.** – In exercise of the powers conferred by section 36 of the Drugs Act, 1976 (XXXI of 1976), and in supersession of its Notification No. S.R.O. 28(I)/2013 dated the 22<sup>nd</sup> January, 2013, the Federal Government, being of the opinion that the public interest so requires, is pleased to exempt, the anti-cancer drugs, cardiac drugs and any essential life saving 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 two years w.e.f. 22<sup>nd</sup> January, 2018, subject to following conditions, namely:--

- (a) the imports shall be made with the 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.

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[No. F.3-4/2017-I&E/QA&LT]

AAMAR LATIF,  
*Deputy Director (Legal Affairs).*