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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 29th December, 2017

S.R.O. 1336(I)/2017.-- The following draft of certain further amendments in the Drugs (Specification) Rules, 1986, which is proposed to be made in exercise of 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 as required under sub-section (3) of said section 43, and notice is hereby given that objections or suggestions thereon, if any, may be sent to the Federal Government within seven days of the publication of this notification in the official Gazette.

Any objection or suggestion which may be received from any person in respect of the said draft, and before the expiry of the aforesaid period, will be considered by the Drug Regulatory Authority of Pakistan.

DRAFT AMENDMENTS

In the aforesaid Rules,--

(a) rule 1A shall be omitted; and
(b) in rule 2, for the existing Schedule, the following shall be substituted, namely:-

"SCHEDULE
Specifications for Drugs

	Class of drugs	**Specifications to be complied with**
(1)	(2)	(3)
(i)	Human drugs	Specifications shall be complied in following order.- (a) The United States Pharmacopoeia or The British Pharmacopoeia or The European Pharmacopoeia;

		(b) Pharmacopoeia of reference regulatory countries as approved by Registration Board; (c) If specifications are not present in any of above pharmacopoeias, then specification of innovator product shall be followed till such time it appears in pharmacopeias in above order. In case of non-availability of innovator's specifications, the specification of same drug of the comparator company under license from the innovator and in case of non-availability of such under license comparator then specifications of any other comparator as approved by Registration Board for this purpose shall be followed. Those specification parameters should be considered which are prescribed in general chapters of pharmacopoeias of reference regulatory countries as approved by Registration Board; and (d) Specifications as approved by Registration Board for such purpose.
(ii)	Veterinary drugs	Specifications shall be complied in following order:- (a) The United States Pharmacopoeia or The British Pharmacopoeia or The European Pharmacopoeia; (b) Pharmacopoeia of reference regulatory countries as approved by Registration Board; (c) If specifications are not present in any of above pharmacopoeias, then specification of innovator product shall be followed till such time it appears in pharmacopeias in above order. In case of non-availability of innovator's specifications, the specification of same drug of the comparator company under license from the innovator and in case of non-availability of such under license comparator then specifications of any other comparator as approved by Registration Board for this purpose shall be followed. Those specification parameters should be considered which are prescribed in general chapters of pharmacopoeias of reference regulatory countries as approved by Registration Board; and (d) Specifications as approved by Registration Board for such purpose."

[File No. 1-11/2017/Addl-Dir(PE&R)]

AAMAR LATIF,
Deputy Director (Legal Affairs).