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

Islamabad, the 21st February, 2023.

NOTIFICATION

The following draft of further amendments in the Drugs (Research) Rules, 1978, which are 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 be sent to the Drug Regulatory Authority of Pakistan within fourteen days of the publication of this Notification.

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 Drug Regulatory Authority of Pakistan.

DRAFT AMENDMENTS

In the aforesaid Rules,—

(1) in rule 2,—

(a) the following new clauses shall be inserted, namely.—

"**(a) 'Act'** means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012);";

"**(b) 'Authority'** means the Drug Regulatory Authority of Pakistan established under section 3 of the Act;"; and

"**(c) 'Clinical trial or clinical study'** means any investigation in human subjects intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of an investigational product or to identify any adverse reactions to any investigational product or to study absorption, distribution, metabolism and excretion of an investigational product with the subject of ascertaining its safety and efficacy;";

(b) after insertion of aforesaid new clauses, the remaining clauses shall be re-numbered accordingly.;

(2) rule 3 shall be substituted with the following, namely.—

"**3. Utilization of Fund.—** (1) The Authority may utilize the Fund for conducting basic and operational research subject to such conditions as may be specified by the Committee of Experts on Drug Research.

(2) The Authority may utilize the Fund for establishment and operation of its laboratories, offices, pharmacovigilance centre, antimicrobial consumption surveillance cell, drug information and poison control centre, unit for reference standards as per pharmacopeial monograph, databases and data centers including digitization of record of therapeutic goods and related activities for international accreditations. The Authority may facilitate provinces for upgradation of provincial drug testing laboratories and pharmacovigilance centres in accordance with the guidelines issued by the Authority.

(3) Notwithstanding sub-rule (1) and (2), the Authority may also utilize the Fund in accordance with section 19 of the Act.

(4) The Authority shall utilize the Fund through a Committee to be constituted for the purposes of sub-rule (2) and (3).

(5) The utilization of Fund shall be in accordance with the Accounting Procedures of Authority and the same may be monitored by a committee constituted by the Authority if deemed appropriate.";

(3) rule 4 shall be substituted with the following, namely.—

"**4. Research in drugs.—** The research in drugs shall be conducted at such place(s) and by such person(s) as may be approved by the Committee of Experts on Drug Research and shall be categorized as under:

(i) clinical trials;
(ii) other than clinical trials; and
(iii) any other category with the approval of Authority.";

(4) in rule 5, the words "for research in drugs" shall be inserted after the expression "Application for grant of aid" in the title.;

(5) in rule 6.—

(a) the word "of" appearing in the title shall be omitted; and

(b) sub-rule (4) shall be substituted with the following, namely.—

"(4) The recipient shall allow an expert or a panel of experts authorized by the Authority to visit the premises at which the research is being conducted and to see that the Fund is being utilized in accordance with the approved project.";

(6) in rule 7, sub-rule (1) shall be substituted with the following, namely.—

"(1) In addition to the conditions laid down in rule 6, research in drugs in respect of the clinical trials shall be conducted as per the guidelines approved by the Authority including but not inconsistent with the ICH guidelines:

Provided that the Authority may alter the requirements in exceptional circumstances to be recorded therein.";

(7) in rule 8.—

(a) sub-rule (1) shall be substituted with the following, namely.—

"(1) The Authority shall constitute a Committee of Experts to advise it on the utilization of the Fund for grant of aid on applications received under rule 5."; and

(b) sub-rule (2) shall be substituted with the following, namely.—

"(2) The Committee shall consist of the following members, namely:—

(a) The Director, Pharmacy Services who shall be its ex-officio Chairman;

(b) Additional/ Deputy Director, Pharmacy Services nominated by the Director Pharmacy Services, who shall be ex-officio member/Secretary of the Committee;

(c) Four Professors from the discipline of pharmacy, pharmacology, biotechnology, medicine with equal representation of the Provinces to be nominated by the Authority having relevant experience of 15 years; and

(d) Co-opted expert in the field related to a specialty case before the Committee to be nominated by the Chairman of the Committee of Experts on Drug Research.";

(8) in rule 9.—

(a) in clause (vi), the expression "Federal Government" shall be substituted with the word "Authority"; and

(b) in the proviso, the expression "Federal Government" shall be substituted with the word "Authority".; and

(9) in Form 'B', in paragraph (5), in sub-paragraph (iv), the expression "Federal Government" shall be substituted with the word "Authority".

No. F.13-1/2022-DD(LA)/DRAP

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