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

NOTIFICATION

Islamabad, the 18th February, 2025.

S.R.O. 168(I)/2025. – In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with section 43 of the Drugs Act, 1976 (XXXI of 1976), the Drug Regulatory Authority of Pakistan, with the prior approval of the Federal Government, is pleased to direct that in the Drugs (Research) Rules, 1978, the following further amendments shall be made, the same having been previously published *vide* Notification, dated the 21st day of February, 2023, as required by sub-section (3) of the said section 43, namely:-

In the aforesaid Rules,—

(1) in rule 2, in sub-rule (1),—

(A) the existing clauses (a) and (aa) shall be re-numbered as (ac) and (ae), respectively;

(B) before clause (ae), re-numbered as aforesaid, the following new clauses shall be inserted, namely:—

"(a) "Act" shall have the same meaning as assigned thereto in the DRAP Act;

(aa) "Authority" shall have the same meaning as assigned thereto in the DRAP Act;

(ab) "clinical trial" or "clinical study" means any investigation in human subjects intended to discover or verify the clinical, pharmacological or other pharmacodynamics 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 a view of ascertaining its safety and efficacy;"; and

(C) after clause (ac), inserted as aforesaid, the following new clause (ad) shall be inserted, namely:—

"(ad) "DRAP Act" means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012);"; and

(D) in clause (b), for the word "Fund", occurring for the first time, the words "Central Research Fund" shall be substituted;

(2) for the word "Fund", wherever occurring, except clause (b) of sub-rule (1) of rule 2, the words "Central Research Fund" shall be substituted;

(3) for rule 3, the following shall be substituted, namely:—

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

(2) The Authority may, subject to section 19 of the DRAP Act, utilize the Fund for operation and upgradation of its laboratories, pharmacovigilance centers, antimicrobial consumption surveillance cell, drug information and poison control center, unit for reference standards as per pharmacopeial monograph, databases and data centers including digitization of record thereof in respect 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 under clause (c) of section 7 of the DRAP Act.

(4) for rule 4, the following shall be substituted, namely:

"**4. Research in drugs.—** The research in drugs shall be conducted at such places and by such persons as may be approved by the Committee and shall be categorized as under:

(a) clinical trials;
(b) other than clinical trials; and
(c) any other category determined with the approval of the Authority.";

(5) in rule 5,—

(A) in the marginal heading, after the word "aid", the words "for research in drugs" shall be inserted; and

(B) after sub-rule (4), the following new sub-rule (5) shall be added, namely:—

"(5) The applications for grant of aid for research in drugs shall be processed through the Committee on Drugs Research whereas remaining demands for allocation of funds from the Central Research Fund shall be directly considered by the Authority or a committee constituted by it for the said purpose.";

(6) in rule 6,—

(A) in the marginal heading, after the word "of", the word "drug" shall be inserted; and

(B) for sub-rule (4), the following shall be substituted, namely:—

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

(7) in rule 7, for sub-rule (1), the following shall be substituted, namely:—

"(1) Subject to rule 6, research in drugs in respect of the clinical trials shall be conducted as per the guidelines approved by the Authority, under sub-clause (xii) of clause (c) of section 7 of the DRAP Act, including but not inconsistent with the current version of International Conference on Harmonization – Good Clinical Practices (ICH-GCP) guidelines:

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

(8) for rule 8, the following shall be substituted, namely:—

"**8. Committee of Experts on Drug Research.**— (1) The Authority shall constitute a Committee of Experts on Drug Research to scrutinize, assess and decide research proposals and recommend to the Authority on the utilization of the Central Research Fund for grant of aid on applications received under rule 5.

(2) The Committee under sub-rule (1) shall consist of the following, namely:—

(a)	Five professors or scientists from the discipline of pharmacy, pharmacology, biotechnology, chemistry or medicine from renowned national and international organizations or universities with equal representation of the Provinces and Islamabad Capital Territory (ICT) to be nominated by the administrative division or department of provinces and ICT, as the case may be.	*Members*
(b)	Any expert to be co-opted by the Chairperson	*Member*
(c)	Director, Pharmacy Services of the Authority.	*Convener-cum-Secretary*
(d)	One nominee each from Pharma Bureau and Pakistan Pharmaceutical Manufacturers' Association having no right to vote.	*Observers*

Provided that unless earlier removed by the Authority the term of the member shall be five years. The member may resign from his office by writing under his hand addressed to the Authority.

(3) No act or proceeding of the Committee shall be invalid by reason only if the existence of a vacancy in the constitution of the Committee.

(4) The Chairperson of the Committee shall be appointed on rotation and on yearly basis from amongst members. The first Chairperson of the Committee shall be the member from the ICT and thereafter from amongst provinces in alphabetical order. In case a member from ICT or Provinces has not been nominated by the respective administrative division or department or existence of a vacancy in the constitution of the Committee due to any circumstances, the Chairman shall be appointed from the next available member in alphabetical order:

Provided that leftover quota due to non-availability of eligible person to be nominated, shall be carried forward.

(5) The meetings of the Committee shall be convened by the Convener-cum-Secretary. In case of absence of the Chairperson, the members present may elect the Chairperson for that meeting.

(6) A simple majority of the total membership shall constitute the quorum for a meeting of the Committee and in case of equality of votes, the Chairperson or the person presiding over the meeting shall have a casting vote.

(7) All decisions or determinations taken by the Committee shall be recorded in writing.

(8) The utilization of Central Research Fund shall, subject to Articles 169 and 170 of the Constitution, be in accordance with the accounting procedure of the Authority and the same may be monitored by a sub-committee of the Authority comprising the Director (Pharmacy Services), Director (Budget and Accounts) and Director (Administration).

(9) The sub-committee of the Authority constituted in sub-rule (8) shall have the following functions, namely:—

(a) to oversee the implementation of approved projects as per the approval of the Committee; and

(b) to forward its recommendations to the committee for its decision in case of non-compliance.;

(10) The Committee may suspend or cancel any ongoing research after having recommendation of the sub-committee constituted under sub-rule (8) or on receiving any information or complaint after investigation and recommendation by the aforementioned sub-committee.

(11) Within three months of the conclusion of each financial year, the Committee shall submit an annual report to the Federal Government in respect of the activities of the Committee including the status of utilization of Central Research Fund.

(9) in rule 9,—

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

(B) in the proviso, for the expression "Federal Government", the word "Authority" shall be substituted; and

(10) in Form 'B', in paragraph (5), in clause (iv), for the expression "Federal Government", the word "Authority" shall be substituted.

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AAMAR LATIF,
Additional Director (Legal Affairs).

The Manager,
Printing Corporation of Pakistan Press,
Islamabad.