## The Gazette



## of Pakistan

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## ISLAMABAD, FRIDAY, APRIL 22, 2022

### 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 22nd April, 2022

S.R.O. 546(I)/2022.— In exercise of the powers conferred by section 24 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Authority, with the approval of the Policy Board, is pleased to make the following further amendments in the Drug Regulatory Authority of Pakistan Employees Service Regulations, 2015, namely:—

In the aforesaid Regulations,—

- (1) in chapter-1, in regulation 2, sub-regulation (b) shall be substituted with the following, namely,—
  - "Appointing Authority" means the Authority as defined in Schedule-I of these regulations.";

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- (2) in chapter-2,—
  - (I) in regulation 3,—
    - (a) in sub-regulation (1),—
      - (i) in clause (c), the words "or transfer" shall be omitted;
      - (ii) after clause (c), the following new clauses (d), (e) and (f) shall be inserted, namely,—
        - "(d) Henceforth, all Initial appointment made by the Appointing Authority on the recommendations of the Selection Authority as detailed in Schedule-I shall be on contract basis for a period of three years which is extendable subject to satisfactory performance and approval of Appointing Authority. All contract employment shall be governed under terms and conditions given at Schedule-VII.
        - (e) Contingent appointment shall be made for RO-1 to RO-4 under terms and conditions given in Schedule-VIII.
        - (f) The deputationists shall be entitled to remuneration of their own pay at parent department along with deputation allowance as per rate prescribed by the Federal Government.";
    - (b) sub-regulation (3) shall be substituted with the following, namely,—
      - "(3) The posts to be filled by the direct appointment in DRAP shall be filled on merit basis in accordance with Schedule-II(B) and Schedule-III on contract basis.";
    - (c) sub-regulation (8) shall be substituted with the following, namely,—
      - "(8) DRAP employees may be transferred on any post in DRAP as per need or requirement.";

- (II) in regulation 4,—
  - (a) sub-regulation (2) shall be substituted with the following, namely,—
    - "(2) A regular employee shall be considered for promotion if he fulfills the criteria and specified requirements for promotion prescribed in Schedule-II(B) and Schedule-III.":
  - (b) sub-regulation (4) shall be substituted with the following, namely,—
    - "(4) Previous service of employees who opted for absorption in DRAP under section 15(5)(a) of the DRAP Act, 2012 shall be counted as experience in corresponding RO Scales.";
  - (c) after sub-regulation (4), the following new sub-regulation (5) shall be inserted, namely,—
    - "(5) Ratio reserved for initial appointment shall be as specified in Schedule-II(B) and Schedule-III.";
- (III) in regulation 5, sub-regulation (1) shall be substituted with the following, namely,—
  - "(1) A person on promotion shall be on probation for a period of **one year** or till probation period is terminated by a specific order by the Appointing Authority.";
- (IV) regulation 6 shall be substituted with the following, namely,—
  - "6. Seniority.—(1) The appointing authority shall, by Office Order, determine the seniority list of employees of each Service, cadre or post. There shall be two separate service structures for officers and officials serving in DRAP namely Civil Servants in BPS Scales and DRAP Employees in RO Scales. Seniority of DRAP Employees shall be further sub-divided into following five (05) Cadres;
  - (i) Technical Cadre,—comprising of Pharmaceutical Evaluation & Registration Division, Drug Licensing Division, Biological Evaluation & Registration Division, Controlled Drugs Division, Pharmacy Services Division, Medical Devices & Medicated Cosmetics Division, Health & OTC Products (Non-Drugs) Division, Quality Assurance & Laboratory Testing Division.

- (ii) Budget & Accounts and Costing & Pricing Cadre,—comprising of Budget & Accounts Division and Costing & Pricing Division,
- (iii) Legal Affairs Cadre,—comprising of Legal Affairs Division only,
- (iv) Management Information Systems Cadre,—comprising of Management Information Systems Division only,
- (v) Admin, Human Resource & Logistics Cadre,—comprising of Admin, Human Resource & Logistics Division only.
- (2) Seniority of DRAP staff comprising RO-1 to RO-10 shall be maintained post wise separately for Head Office, Field Office and Laboratories whereas, seniority of posts of Superintendent (RO-11) and Assistant Private Secretary (RO-11) shall be maintained as combined seniority of head office, field offices and laboratories for each post.
- (3) For determination of *inter-se seniority* of each service, cadre or post, the general provisions of Civil Servants (Seniority) Rules, 1993 shall be followed.
- (4) The services of employees who opted for absorption under the Authority under section 15(5)(a) of the DRAP Act, 2012 shall be protected for the purposes of seniority, promotion and experience equivalent to RO pay scale as per schedule-VI.
- (5) The cadre wise seniority of the DRAP employees who opt to be included in the Authority shall be counted after closing of the date for exercising the option, maintaining their previous *inter se seniority* or from the date of initial appointment for direct recruitment, as the case may be, and the seniority list shall be determined through Office Order.
- (6) Civil Servants who have not opted for DRAP service shall be governed in accordance with Civil Servants Act, 1973 and rules framed thereunder.";
- (3) in chapter-3,—
  - (I) regulation 8 shall be substituted with the following, namely,—
    - **"8. Retirement benefits of DRAP employees,—(1)** Employees appointed on contract basis shall be eligible for gratuity upon leaving the Authority or on completion or

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termination of contract as specified in their terms and conditions of employment.

- (2) Existing regular DRAP employees shall be entitled for Contributory Provident (CP) Fund upon retirement or leaving organization in accordance with regulations prescribed by the Policy Board.
- (3) Retirement benefits of those employees who opted for absorption in the DRAP for period served as civil servant shall be dealt as per applicable rules and procedures.
- (4) Insurance of regular employees of Authority shall be made in the manner as determined by the Authority.";

## (II) in regulation 9,—

- (a) sub-regulation (1) shall be substituted with the following, namely,—
  - "(1) An employee of the DRAP may resign from his post by submitting resignation under his signature by giving prior notice. The employee shall continue performing his duty till such time the Appointing Authority accepts the resignation and shall not absent himself from his duties without prior permission. Notice period shall be thirty days for CEO and all employees. Appointing Authority may waive the notice period if so desired.";
- (b) in sub-regulation (2), the words "the salary" shall be substituted with the words "one month pay".;

## (III) in regulation 10,-

- (a) in sub-regulation (1), the words "ninety days" shall be substituted with the words "thirty days".;
- (b) in sub-regulation (2), the words "ninety days" shall be substituted with the words "thirty days".;
- (c) in sub-regulation (5), the words "or termination of the service" shall be substituted with the words "from service".;
- (4) in chapter-4, regulation 16 shall be substituted with the following, namely,—
  - **"16. Nomenclature.**—The nomenclature for posts in DRAP shall be as mentioned in Schedule-VI and this shall be applicable to all employees of DRAP including Civil Servants working in DRAP.

Their equivalence with the corresponding post in BPS shall be as mentioned therein.";

- (5) in chapter-5, the existing regulation 18 shall be numbered as sub-regulation (1) of the said regulation and thereafter the following new sub-regulation (2) shall be inserted, namely,—
  - "(2) For grant of study leave to the regular DRAP employees, the Study Leave Rules as approved by the president of Pakistan shall be followed for the time being in-force.";
- (6) in chapter-7,—
  - (I) in regulation 20,—
    - (a) in sub-regulation (1), the words "be converted to DRAP posts" shall be substituted with the words "be abolished".;
    - (b) sub-regulation (2) shall be substituted with the following, namely,—
      - "(2) Civil servants working in DRAP shall be under administrative control of the Authority and they may be transferred at any post in DRAP as per need or requirement.";
    - (c) sub-regulation (3) shall be omitted.;
- (7) in chapter-8,—
  - (I) the existing regulation 22 shall be numbered as sub-regulation (1) of the said regulation and thereafter the following new sub-regulation (2) shall be inserted, namely,—
    - "(2) For right of appeal of regular DRAP Employees, the procedure prescribed in Civil Servants (Appeal) Rules, 1977 as amended from time to time shall be followed.";
  - (II) regulation 23 shall be substituted with the following, namely,—
    - **"23. Right of Reversion.** There shall be no right of reversion for confirmed DRAP employees who, on their own accord, join some other service, post or cadre, after being selected through a regular selection process.";
- (8) in Schedule-I, in column 4, at serial No. 3, 4, 5 and 6, the words "Departmental Selection Committee to be approved by Policy Board" shall be substituted with words "Departmental Selection Committee approved by Policy Board".;
- (9) Schedule-II shall be substituted with the following, namely,—

# "SCHEDULE-II(A) [See regulations 2(1) (b), 4(2)]

Maximum Age Limit	9	56 years	•	1			
 Minimum Age Limit	У <b></b>	45 years					
Qualification and Experience	7	ficer Market based salary as As per Section-5 (1) (a) (b) of the	DRAP Act, 2012	•			
Pay Scale	3	Market based salary as	approved by the Federal DRAP Act, 2012	Government on	recommendations of the	Policy Board.	
Name of Post	2	Chief Executive Officer			· · ·	•	
	1.	-					

# SCHEDULE-II(B) [See regulations 2(1) (b), 4(2)]

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Š.	Name of Post	RO S	Method of Appointment	pointment ,	Condition for Initial Appointment	intment	Condition	Conditions for Promotion	_
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╢╌	TECHNICAL CADRE	2			•		0		_
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					Pharmaceutical Sciences		in technical	years service in RO-13	
			-		(Pharmaceutics,		cadre.	and above for initial	
			•		Pharmacology,		•	recruits in RO-13 or 5	
		•			Pharmaceutical Chemistry,			years service in RO-14	
					Pharmacy Practice,			for initial recruits in	
					osy)			RO-14.	
					years related experience in				-,-
					pharmaceutical field or				
					Master / M. Phil in				
					Pharmacy or in related field				
	•				of Pharmaceutical Sciences				
_	1		•		(Pharmaceutics,				
					Pharmacology,				<u>.                                    </u>

	12 years service in RO- 12 and above or 07 years service in RO-13 and above for initial recruits in RO-13.		5 years service in RO-	
	Deputy Director (RO-13) in technical cadre		Assistant Director (RO-12) in technical cadre.	
	42 years		35 years	
Pharmaceutical Chemistry, Pharmacognosy) with 13 years related experience in Pharmaceutical field. ii. Having basic qualification iii. Pharmacy	Ph. D. in Pharmacy or in related field of Pharmaceutical Sciences (Pharmaceutics, Pharmacoulics, Pharmacorops, Pharmacorops, with 7 years	related experience in pharmaceutical field or Master /-M. Phil in Pharmacy or in related field of Pharmaceutical Sciences (Pharmaceutical Chemistry, Pharmacy Practice, Pharmacognosy) with 10 years related experience in Pharmaceutical field.	Having basic qualification in Pharmacy.  Ph.D in Pharmacy or in related field of Pharmaceutical Sciences (Pharmaceutics,	Pharmacology, Pharmaceutical Chemistry, Pharmacy Practice, Pharmacy Practice, Pharmacognosy) with 02 years related experience in Pharmaceutical field or Master / M. Phil in Pharmacy or in related field of Pharmaceutical Sciences (Pharmaceutical Chemistry, Pharmacylics, Pharmacylics, Pharmacylics, Pharmacylics, Pharmacylics, Pharmacylics, Pharmacylics,
	70 %		10%	
<b></b>			×	
	30 <i>%</i>		30%	
	14 30 %			
			30%	

	elevant qualifications like	17 years service in RQ-12 and above or 12 years service in RQ-13 and above for initial recruits in RQ-14. For initial recruits in RQ-14. Having basic qualification in Accountancy, Cost and Management, CA, MBA. (Finance) and M.Com.	12 years service in RO- 12 and above or 7 years service in RO-13 and above for initial recruits in RO-13. Having basic qualification in
	professionals with r sciences / engineeri	Additional Director (RO-14) in C&P and B&A Divisions	Deputy Director (RO-13) in C&P and B&A Divisions
	30 years filled by other y, bio-medical	47 years	42 years
years related experience in Pharmaceutical field or Pharm-D, B- Pharmacy, with 06 years related experience in Pharmaceutical field. Having basic qualification in Pharmacy.	Pharm. D or B. Pharmacy. Relevant pharmaceutical experience will be preferred. Is of direct recruitment shall be cular biology, clinical pharmac	i. Ph.D in Accountancy with 10 years related experience; Cost and Management Accountant with post membership with 13 years related experience preferably in analysis of pricing / costing of pharmaceutical and health care products or MBA (Finance) / M.Com, with 15 years experience preferably in analysis of pricing / costing of pricing / costing of pricing / costing of pharmaceuticals and health care products  Note: Qualification in Pharmacy qualification in Pharmacy would be preferable.	PhD in Accountancy with 07 years related experience, Cost and Management Accountant or Chartered Accountant with post membership with 10 years experience
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	100 % elds a maximum o microbiology, bio	40 % %	%; (C)
	12 in different fi al chemistry, he Authority)	<b>5</b>	<b>*</b>
	A Assistant Director 12 100% Relevant pharmacy 30 years Relevant pharmaccutical Relevant pharmaccutical parmaccutical experience will be preferred.  * To ensure availability of expertise in different fields a maximum of 20% of positions of direct recruitment shall be filled by other professionals with relevant qualifications like medical, organic chemistry, analytical chemistry, microbiology, biotechnology, molecular biology, clinical pharmacy, bio-medical sciences / engineering, statistics, engineering, BHMS and BEMS as determined by the Authority).	Director 15 40% 66	2 Additional Director

Accountancy, Cost and Management, CA, MBA (Finance) and M.Com.		5 years service in RO- 12. Having basic qualification in Accountancy, Cost and Management, CA, MBA (Finance) and M.Com.	17 years service in RO- 12 and above or 12 years service in RO-13 and
		Assistant Director (RO-12) in C&P and B&A Divisions	Additional Director (RO-14)
		35 years	30 years
preferably in analysis of pricing / costing of health care products or MBA (Finance)/M.Com, with 12 years experience in analysis of pricing / costing of Pharma health care products with subject experience.	und ation i	Cost and Management Accountant / Chartered Accountant with post membership with 3 years experience in analysis of pricing / costing of health care products or MBA (Finance) or MCom, with 7 years experience in analysis of pricing / costing of health care products with subject experience. Qualification background with basic qualification in Pharmacy would be preferable.	Cost and Management Accountant (Chartered Accountant, MBA (Finance) or M.Com or Management (MRM) Management (MRM) Management (MRM)
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	4 1 1 1	3 Deputy Director	Assista Director

12 years service in RO- 12 and above or 7years service in RO-13 and above for initial recruits in RO-13. Having qualification in Human Resource management and Administration.	5 years service in RO-12. Having
Deputy Director (RO-13) in Admn, HR & Log Division	Assistant
42 years	35 years
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30 %	30%
<b>±</b>	13
Additional Director	
	30% 70% 'i. Ph. Distribution Resource 42 years Deputy Director 12 years service in Management (HRM), Administration or equivalent with 07 years related experience or Management, Public (HRM), Management, Public Administration or equivalent with 10 years related experience or Masser (16 year education) in Public Administration or Management with 12 years related experience in Human Resource Management and Public Administration in Human Resource Management and Public Administration.

qualification in Human Resource Management or Public Administration.											5 years service as	Superintendent in /RO-								
(RO-12) in Admn, HR & Log Division			,								Superintendent					•			7	
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years experience   (RO-12) in Legal   Affairs Division   Preferably   In Pharmaceutical field.   Affairs Division   Pharmaceutical field.   LL.   Wh membership of Bar   30 years   Superintendent   In Preferably   Assistant Director   Assistant Director   Assistant Director   Assistant Director   In Preferably   In						Bar Association, with 07		Director	12. Having basic	
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1. Ph.D. in Management Information Systems, Computer Science, Bioinformatics or M.Phill in Management Information Systems, Computer Sciences, or M.Phill in Management Information System, Computer Sciences or Master in pharmaceutical related fields or Master in Management Information System, Computer Sciences or Bioinformatics, with 15 years experience prefrably in Management information System, Computer Sciences or Bioinformatics, with 15 years experience prefrably in Management Information Systems, Computer Sciences or Bioinformatics.  1. Having basic qualification in Management Information Systems, Computer Sciences or Bioinformatics or Bioinformatics or Bioinformatics or equivalent, with 07 years experience or M.Phill in Management Information Systems, Computer Science, Sc
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(10) Schedule-IV shall be substituted with the following, namely,—

## "SCHEDULE IV

[See Regulation 3(1)(b)]

## Composition of Departmental Selection Boards of DRAP

For the Posts of	Composition	
Director (RO-15)	Secretary NHSR&C / Chairman Policy Board.     CEO DRAP     Additional Secretary NHSP & C.	Chairman Member
	Additional Secretary, NHSR&C     Director (Admin, HR & Log), DRAP	Member Member / Secretary
Additional Director	1. CEO DRAP	Chairman
(RO-14)	Joint Secretary (Admn), NHSR&C.     Director of the concerned Division of DRAP or any Director nominated by CEO in case of technical cadre	Member Member
	4. Director (Admin, HR & Log) DRAP	Member / Secretary
Deputy Director (RO-13) / Assistant Director	Director (Admin, HR & Log)     Deputy Secretary, NHSR&C     Director of the concerned Division of DRAP or any Director	Chairman Member Member
(RO-12)	nominated by CEO in case of technical cadre.  4. Additional Director (Admn, HR & Log), DRAP	Member / Secretary
Post from (RO 1-11)	Additional Director (Admn, HR & Log)     Additional Director as nominated by the CEO DRAP.     Assistant Director (Admn, HR & Log), DRAP	Chairman Member Member /
1	1 A	Secretary

In case of conflict of interest of any member of Departmental Selection Boards, the said member shall not attend the meeting during relevant case. In case of promotions to Director (RO-15), in above situation or in case of non-availability of any of the member, the Chairman, Policy Board shall nominate a suitable replacement in DSB whereas, CEO, DRAP shall nominate suitable replacement in DSB for all other cases."

(11) after Schedule-VI, a new Schedule-VII shall be inserted, namely,-

## "SCHEDULE-VII

[See Regulation 3 (1)(d)]

## Terms and Conditions of Contract Employment in DRAP

- 1. Pay Shall be equal to minimum of relevant RO pay scale. Maximum of three advance increments can be given with the approval of Policy Board in case of higher qualifications and experience.
- 2. Annual increment after completion of one year of service as per relevant pay scale.

- 3. All allowances, if applicable for DRAP RO Pay Scales.
- 4. The employee shall earn 2 days paid leave for each completed month of service. The employee will be eligible for 24 days paid leave in a calendar year. Leave shall not be carried forward into next year.
- 5. TA/DA as per DRAP Service Regulations 2015.
- 6. Medical facility at par with regular employees of DRAP.
- 7. Contract Period: Initial contract shall be offered for a period of three years which can be extended on yearly basis subject to satisfactory performance and approval of the appointing authority. The contract shall stand automatically terminated on the expiry of the contract period unless otherwise extended further.
- 8. One month notice or one month pay in lieu of notice period shall be required from either party for termination of employment.
- 9. Equal opportunity of training will be provided to the contract employees.
- 10. Contract employees shall not contribute to C.P Fund and shall not be entitled to any retirement benefits except gratuity equal to 50% of their last pay against each completed year of service subject to minimum continuous service of three years.
- 11. Contract appointments (RO-01 to RO-15) shall be made on the recommendations of Departmental Selection Committee (DSC) approved by the Policy Board and as specified in Schedule-I DRAP employees service regulations 2015 amended from time to time. All contract appointments shall be subject to submission of the following documents, at the time of joining, namely:
  - (i) Verified degrees/certificates from respective Board/ Authority / Organization;
  - (ii) Undertaking / affidavit of non-existence of any financial and professional interest under section 18 of the Act;
  - (iii) Duly filled 'character and antecedents' proforma; and
  - (iv) An undertaking on Judicial stamp paper not less than Rs, 20 that he/she has read all terms and conditions of the contract and he/she has read, understood and willingly signed the contract agreement and will not claim regular employment in DRAP on the basis of this offer of appointment in future.

- 12. A contract employee can be placed at any post as per need and requirement.
- 13. The individuals appointed in DRAP on contract basis shall not have any right / claim for regular appointment against any post in DRAP.
- 14. Any other condition as determined by the Authority from time to time."; and
- (12) after Schedule-VII, a new Schedule-VIII shall be inserted, namely,—

## "SCHEDULE-VIII

[See Regulation 3(1)(e)]

## Policy / SOPs for Hiring Contingent Staff in DRAP.

- 1. To cope up with the shortage of skeleton staff (R0-1 to RO-4) of Drug Regulatory Authority of Pakistan and for quick and efficient disposal of official business, Drug Regulatory Authority of Pakistan may hire the services of individuals on contingency basis against the sanctioned vacant posts.
- 2. <u>Mode of appointment</u>: Appointment on contingent basis would be purely on temporary basis, against those vacant posts of skeleton staff in RO-01 to RO-04 that are to be filled through initial appointment for a fixed term and on a fixed remuneration.
- 3. Method of appointment: Individuals would be appointed on contingency basis on purely need basis without any advertisement. However, appointment would be made against the vacant posts of DRAP strictly in accordance with the DRAP Employees Service Regulations, 2015 and as amended from time to time, with the approval of the Appointing Authority for the concerned post after recommendations of the interview / selection committee for hiring contingent staff comprising of the following members:—

Sr. No.	Designation	Status
1.	Additional Director (Admn, HR & Log)	Chairman
2.	Deputy Director (Admn)	Member
3.	Assistant Director (Admn-I)	Member/ Secretary

In case of unavailability of any officer, Director Administration, HR and Logistics may nominate any alternative.

4. <u>Eligibility criteria</u>: Eligibility criteria in respect of contingent staff would strictly be observed in accordance with the criteria set in Schedule-III of DRAP Employees Service Regulations, 2015 as amended for the posts against

1

which a person has to be appointed except age limit which will be superannuation age as per Federal Government.

5. <u>Remuneration</u>: Contingent staff would be hired on fixed remuneration per month as mentioned below:—

RO Scale	Fixed Remuneration @ Rs. p/m		
RO-01	20,000		
RO-02	25,000		
RO-03	30,000		
RO-04	 35,000		

Authority may from time to time revise the fixed remuneration for contingent staff considering the inflation rate and other related factors.

- 6. **Tenure**: The contingent staff would be hired for a period of 89 days.
- 7. Entitlement of benefits as admissible to regular employees of DRAP: The individuals appointed in DRAP on contingent basis would not be entitled to any benefit (Financial / Non-Financial) as admissible to the regular and contract employees of DRAP apart from the fixed remuneration per month.
- 8. <u>Regularization of services</u>: The individuals appointed in DRAP on contingent basis shall not have any right / claim for regular appointment against any post in DRAP.
- 9. <u>Admissibility of leave</u>: The individuals appointed in DRAP on contingent basis would be entitled for five (05) days leave during their 89 days period only in emergency cases, without any deduction of remuneration. However, for the leave beyond five (05) days deduction would be made from their monthly remuneration.
- 10. <u>Termination of services</u>: The services of a contingent staff may be terminated at any time without notice and without assigning any reason, with the approval of the Appointing Authority.

[No.F.2-26/2014-Admin-I.]

HAFIZ BILAL BIN AKBAR, Assistant Director (Legal Affairs).

