Government of Pakistan Drug Regulatory Authority of Pakistan Ministry of National Health Services, Regulations & Coordination

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EXPRESSIONS OF INTEREST (EOI)

FOR SHORTLISTING OF EXPERT MEMBERS OF CENTRAL LICENSING BOARD OF DRAP

1. INTRODUCTION:

Drug Regulatory Authority of Pakistan (hereinafter referred to as the Authority or DRAP) is an autonomous body of the Federal Government established under the DRAP Act, 2012. The Authority is responsible for effective coordination and enforcement of Drugs Act, 1976 and to bring harmony in interprovincial trade and commerce of drugs and therapeutic goods.

The Central Licensing Board of DRAP (hereinafter referred to as the CLB) is mandated with the statutory functions of licensing of drug manufacturing facilities and to perform other functions connected therewith. The CLB comprises of thirteen members including Director (Drugs Licensing Division), DRAP as its ex-officio Chairman, Seven (07) ex-officio members and Six (06) expert members from the given fields, who are jointly responsible to regulate the grant of licenses for the manufacture of pharmaceuticals in the country. The details of expert members of CLB are as under:

- i. Two expert members in the field of Pharmaceutical Drugs Production.
- ii. Two expert members in the field of Pharmaceutical Quality Control of Drugs.
- iii. Two Professors of Pharmacy from Public or Private University in Pakistan.
- 3. As per directive of Prime Minister of Pakistan vide U. No. 7-1/2024-Coord dated 11th July, 2024 to ensure at least 33% representation of women on the Board and to comply with the Women Empowerment Package-2024, appointment of remaining 01-woman member is mandatory in Central Licensing Board of DRAP. In order to frame nominations to the Policy Board of DRAP and Federal Government for appointment of one (01) woman expert member of CLB, the Authority invites expressions of interest from qualified woman experts fulfilling the prescribed eligibility criteria for their nomination/appointment as Expert Member of the CLB for three years' tenure. Details of eligibility criteria, instructions for filing applications and qualification criteria are given in this EOI document.

2. SCOPE OF SERVICES OF EXPERT MEMBERS OF CLB:

The powers, functions and responsibilities of the members of CLB as outlined in the DRAP Act, 2012, the Drugs Act, 1976 and the Drugs (Licensing, Registering and Advertising) Rules, 1976 are summarized hereunder:

i. POWER OF DRUG INSPECTOR

The members of the CLB shall exercise all the powers of an inspector without restrictions as to area and shall have the powers of a provincial inspector in relation

to Section 30 of the Drugs Act, 1976 as provided in Rule 9(1) of Drugs (Licensing, Registering and Advertising) Rules 1976.

ii. STRENGTHENING OF QUALITY ASSURANCE AND LICENSING

The Expert Member of CLB shall be required to advise the CLB to strengthen existing Licensing, Quality Assurance and Laboratory Testing (QA<) system with special focus on inspection, enforcement & compliance. He shall propose a work plan with timeline to improve the system in line with the International Standards.

iii. DEVELOPMENT OF KNOWLEDGE BASE

The members are expected to have upto date knowledge of current Good Manufacturing Practices, global standards and benchmarking, regulatory requirements and guidelines and to stay informed about the emerging technologies and trends in pharmaceutical manufacturing.

iv. ENSURANCE OF GMP COMPLIANCE

The members shall be required to participate in inspections and audits of pharmaceutical manufacturing facilities to ensure compliance to the good manufacturing practices (GMP) and other quality standards.

v. ADVISORY FUNCTION

To advise the CLB on manufacturing-related matters.

vi. MISCELLENOUS TASKS

The members may perform any other assignment/function entrusted by the CLB.

3. OUALIFICATION AND EXPERIENCE FOR EXPERT MEMBER OF THE CLB:

The Expert Member serves as an integral part of the CLB. The expert member is required to fulfill the following eligibility criteria and the qualification and experience duly supported by documentary evidences:

A. Eligibility Criteria:

- i. Must be a woman citizen of Pakistan (Copy of CNIC be provided):
- ii. The applicant has never been terminated from service during her entire career for any breach of law and trust. Moreover, the applicant must have an active filer status with FBR and should have never been included in ECL and/or convicted by any Court including NAB and FIA in Pakistan (An affidavit to this effect on stamp paper along with NTN certificate be provided);
- ii. No person shall be member of the Board or Director if she has immediate family members (parent, child, sibling or spouse) as senior officials or owners of concerns dealing in therapeutic goods as provided in Section 18(2) of DRAP Act, 2012 (an affidavit on stamp for non-existence of conflict of interest be provided).

B. Qualification & Experience

- i. The expert member must have basic Degree in Pharmacy or Chemistry (wherever applicable) with excellent academic achievements (Copy of HEC attested degree be provided).
- ii. The expert member must have at least fifteen years' experience in Quality Control of Drugs (wherever applicable) in reputable and national / international manufacturing facility (copies of experience letters be provided).
- iii. The applicant intending to be part of CLB as expert member is expected to have an updated knowledge of pharmaceutical drug manufacturing / Quality Control / Policy at international level (applicant's detailed CV/ Profile be provided).
- iv. The record of any outstanding achievement / scientific merit or impact of the applicant's work (research article / report etc.) in terms of changing policy and practices will be given preference.
- v. An applicant with high H-index on Scopus and citations shall be given preference.

4. TENURE OF THE EXPERT MEMBERS:

The members of the Central Licensing Board, other than its ex officio members, shall hold office for a period of three years from the date of notification and shall be eligible for renomination by the Authority.

5. HONORARIUM / DAILY ALLOWANCE / TRAVELING ALLOWANCE AND OTHER BENEFITS TO MEMBERS

The expert members shall be entitled for the following remuneration and benefits in connection with their services rendered to DRAP:

- i. Travelling allowance @ Rs.20/- per KM for traveling by own car/ vehicle.
- ii. Traveling allowance @ Rs.20/- per km for traveling to and from airport.
- iii. ½ Daily Allowance i.e. Rs.2000/- will be granted if the member travels on the same day for meeting.
- iv. Full daily allowance i.e. Rs.4000/- will be granted if the member travels on the next day for meeting along with equal amount to the number of nights stays at venue i.e. Rs.4000/- per night stay.

- v. Hotel bill amount will be Rs.12,000/- per night. Extra night stay in the bill will be subject to return air ticket and/ or justified reasons or as meetings go on.
- vi. Honorarium for members per sitting would be Rs.10,000/- (as approved in 46th Meeting of Policy Board).

5. INELIGIBILITY/ DISQUALIFICATION OF APPLICANTS:

- Applicants who submitted incomplete or conditional applications shall be rejected.
- ii. Applications received after the closing date and time.
- iii. The applicants who did not fulfill the prescribed eligibility/ qualification/ experience.

6. SUBMISSION OF APPLICATION:

- 6.1. The proposal(s) shall be prepared and submitted along with requisite supporting documents so as to reach the undersigned by the closing date and time as mentioned in the EOI advertisement published in daily newspapers. Last date and time for submission of proposals is mentioned in advertisement. Late submissions will not be entertained. Applicants will be required to fill up online form through the following link which is also available on DRAP's website (https://www.dra.gov.pk/news_updates/careers/induction-of-licensing-board-members/). Following information must be clearly marked on the envelope that will be forwarded to DRAP: -
 - 1. Proposal for Nomination of Expert Member of CLB
 - 2. Name of field: Pharmaceutical Quality Control of Drugs.
 - 3. Name of the Applicant (expert member)

Address: Deputy Director (HR/Officers)
Drug Regulatory Authority of Pakistan,
Prime Minister's National Health Complex,
Park Road, near NIH, Islamabad.

- 6.2. Photocopies of following documents must be provided / attached with EOI Proposal:
 - i. Copy of CNIC
 - ii. Affidavit to the effect that applicant has never been terminated from service during his entire career for any breach of law and trust. Moreover, that applicant has never been included in ECL and/or convicted by any Court including NAB and FIA in Pakistan
 - iii. Affidavit to the effect that applicant has no conflict of interest to become a member of CLB as required under Section 18(2) of DRAP Act, 2012.
 - iv. Copy of HEC attested degree i.e. degree in bachelors in Pharmacy / M. Phil / PhD
 - v. Proof of experience i.e. experience letters issued by the employers.
 - vi. Copy of CV/ Profile of the applicant.
 - vii. Copy of tax registration certificate/ NTN issued by FBR.
 - viii. NOC from the parent organization in case the applicant is an employee of a public sector organization of Federal/ Provincial Governments.

7. PROCURING AGENCY RIGHTS

DRAP reserves full rights to accept or reject any or all applications without assigning any reason. Submission of applications and/ or fulfilling the eligibility/ qualification criteria does not confer any right on the applicant to claim his nomination as member of CLB. All the nominations shall be subject to legal due diligence and clearance of applicants by the concerned departments/ security agencies. The nominations will be submitted to the appointing authority as per prescribed procedure and law.

8. EVALUATION/ QUANTIFICATION OF EOI PROPOSALS

EOI proposals complying with the eligibility parameters will be evaluated on the basis of the following qualification criteria. Minimum threshold of 60 marks shall be mandatory for all applicants to become eligible for nomination as member of CLB. Applicants failing to secure the minimum threshold of 60 marks as per below mentioned criteria will not be considered.

Sr.	Description	Maximum Marks	Marks Allocated	Remarks
1.	Qualification of the Expert Member [Bachelor Degree in Pharmacy = 10 marks] [Master degree in pharmacy = 10 Marks] [Ph.D in Pharmacy = 10 Marks]	30 Marks		
2.	Experience [15 Years relevant experience = 30 Marks] [20 Years relevant experience = 35 Marks] [More than 20 Years relevant experience = 40 Marks]	40 Marks		
3.	Research & Publications For each H-index point, 1 mark will be given up to a maximum of 20.	20 Marks	5) 1/1	W
4.	[Experience with a reputed International regulatory organization in similar capacity	10 Marks	3.55	

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