**Appeal No. PPRA/AP-04/2025**
Government of Pakistan
**Public Procurement Regulatory Authority**
(Appeal & Review Petition Secretariat)
1st Floor, FBC Building, G-5/2, Islamabad
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# ORDER

M/s Lab Diagnostic Systems (Pvt.) Limited

***...the "Appellant"***

*Vs.*

Ministry of National Health Services Regulations and Coordination (NHSRC)

***...the "Respondent"***

| **Date of Hearing(s)** | |
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| **24.03.2025**<br>**11.03.2025** | Mr. Muhammad Zeeshan Akhtar, Advocate, Mr. Muhammad Usman, Advocate, Mr. Muhammad Iqbal, Ms. Mehak, Mr. M. Wajid Shahid<br>***(On behalf of Appellant)***<br>Dr. Shabana Saleem, DG (Health), Dr. Hafiz Athar Abbas, Mr. Mohsin<br>***(On behalf of Respondent)***<br>Dr. Obaidullah, CEO (DRAP), Director (DRAP) |

**APPEAL UNDER RULE 48(7) OF THE PUBLIC PROCUREMENT RULES, 2004**

The above mentioned learned counsel(s) and representative(s) of the parties tendered appearance before the Appellate Committee and furnished their arguments at length.

2. At the outset of the hearing, learned counsel of the appellant i.e., M/s Lab Diagnostic Systems (Pvt.) Limited

submitted that Ministry of National Health Services Regulations and Coordination (NHSR&C) (the Respondent / the procuring agency) floated bidding documents which required WHO Approved / Prequalified certification from the local manufacturer to oust local manufacturer and to favor importers in Pakistan. Further, such requirement in prequalification is only for importers and not for manufacturers in Pakistan and it not only violates Rule 4, 10, & 32 of the Public procurement Rules, 2004 but also R.24 of Medical Devices Rules, 2017 including infringing fundamental rights of the appellant as envisaged under Article 18 & 25 of the Constitution of Pakistan 1973.

3. The counsel of the appellant also submitted that being aggrieved of the said clause in Punjab also filed a representation before Managing Director Punjab Procurement Regulatory Authority (PPRA) being the first line regulator. Upon which MD-PPRA after hearing contentions of the parties issued an Advice/Order NO. L&M(PPRA)375/2024/com, Dated 03.10.2024 which is reproduced as under:

> *Above in view, complaints in hand are hereby accepted and Procuring Agencies are advised to formulate evaluation criteria in conformity with PPRA legal Framework and all other applicable laws/ rules in a manner that is should not discriminate amongst the bidders in any manner whatsoever and also avoid any undue/unjust exclusion of local manufacturer.*

4. The counsel of the appellant further submitted that the advice issued by Managing Director PPRA is in conformity with the principles of natural justice and fairness as inclusion of such clause in bidding document is discriminatory, unjust and against the rule of fair competition and liable to be set aside from the standard bidding documents. Moreover, the respondent under the legal frame work of this Authority also included the same clause in its prequalification bidding document. The appellant agitated the same before the procuring agency under Rule 48 of PP Rules, 2004 and submitted its grievance but same is turned down by the respondent strictly in derogation to the said Rules.

5. The counsel of the appellant further argues that the Honorable Lahore High Court, Lahore in Writ Petition No.71814/2024 also directed the respondents i.e. PPRA Punjab and Health authorities to implement the order of the Honorable PPRA Punjab on all the procuring agencies. Further submitted that, in the light of above said advice issued by the Punjab Procurement Regulatory Authority (PPRA), keeping in view the mandate of Drug Regulatory Authority of Pakistan (DRAP) and also having regard to the principles of natural justice and fair competition in public procurement the Appellant seeks to challenge the illegal and unlawful clause requiring the WHO Approved / Prequalified certifications from the local manufacturer of medical devices

in the public procurement documents/ bid documents, hence filed the instant appeal.

6. On the other hand learned representative of the respondent i.e., Ministry of National Health Services Regulations and Coordination (NHSRC) submitted that a meeting of the Grievances Redressal Committee regarding the said issue under the chairmanship of Special Secretary, M/o NHSR & C was held in his office on 14.02.2025 to review the bidder / appellant complaints regarding an alleged violation of Rule 32 of Public Procurement Rules, 2004, in the pre-qualification of Rapid Diagnostic Testing Kits for Financial Year 2024-25 to 2026-27 for the project titled "Prime Minister's Program for Elimination of Hepatitis C Infection.

7. The representative of the respondent also submitted that in the said GRC meeting the appellant expressed their concerns that the mandatory WHO pre-qualification requirement in the prequalification process restricts or discourages local manufacturers from participating in violations of Rule 32 of the Public Procurement Rules, 2004. The appellant argued that this limits competition and may hinder the growth of the local industry. Additionally, the appellant questioned, why WHO Pre-qualification was not required for PCR kits and medicines. The appellant cited cases from the Lahore High Court and PPRA on similar procurement issues and objected to the absence of virologists

and pathologists in the technical committee. Finally, the appellant requested a review of the clause to ensure a level playing field for all manufacturers, including local suppliers.

8. The representative of the respondent further submitted that the Grievances Redressal Committee reviewed the appellant concerns regarding the requirement for WHO prequalification for the Rapid Diagnostic Testing (RDT) kits under the "Prime Minister's Program for Elimination of Hepatitis C Infection" project. The appellant's concern was that the mandatory WHO prequalification requirement limits local manufacturers participation, possibly hindering competition and growth. However, the committee of the respondent's GRC emphasized that this requirement was based on feedback from the technical committee, which assessed the global standards necessary for such medical supplies due to quality variability and associated public health risks. Further, the representative of the respondent added that the inclusion of WHO Prequalification does not exclude local manufacturers but ensures a uniform quality benchmark for all suppliers. Furthermore, the respondent upheld that RDT kits require such a standard to ensure safety, unlike PCR kits and medicines, which follow different regulatory standards. Therefore, the respondent decided not to modify or remove this clause, upholding the decision of the procurement committee from the pre-bid meeting.

9. The representative of the respondent further argued that as far as the objection / concerns raised the appellant regarding the competition, the respondent recognized that five bids were received, which indicates that the process was competitive and did not restrict participation. The decision aligns with the project's need to adhere to international quality standards while ensuring transparency and fairness.

10. On the other side, since the procurement process called in question is a very technical and sensitive in nature, which also involves the public health and safety, therefore, an expert opinion was also sought from the Drug Regulatory Authority (DRAP) on the said matter. In this regard, the CEO of DRAP appeared before the Appellate Committee on the date of hearing i.e., 24.03.2025 and apprised the Committee on the subject issue.

11. After hearing the arguments made by both the parties and after perusal of all the relevant record, the Committee observed that the Respondent / the procuring agency floated bidding documents for "Pre-Qualification of Rapid Diagnostic Testing Kits", which required WHO Approved / Prequalified certification from the local manufacturer. Further, the Committee also observed that the World Health Organization (WHO) has already issued instructions regarding such Diagnostic Kits that it must be approved by WHO or Stringent Regulatory Authority (SRA) for

the purpose of medical diagnostics to ensure best quality products which assessed the global standards necessary for such medical supplies due to quality, variability and associated public health risks. Moreover, the inclusion of requirement of WHO Approved / Prequalified certification is aligned with international quality standards and necessary for the assurance of public health safety in procurement of diagnostic kits. Furthermore, WHO and other global health bodies mandate such certifications to ensure reliability and consistency of diagnostic outcomes.

12. The Committee is of the view that, it is the prerogative of the procuring agency to define appropriate evaluation criteria as per their need / requirement and all procuring agencies are bound to comply with the mandatory requirements of Procurement Laws and Legal Framework and to follow the guidelines and policies of government and international organizations as well for such type of complex medical procurements which involves public health and safety. Further, the procuring agency is required to process and evaluate the bids in accordance with the pre-defined evaluation criteria, terms and conditions and other information required in the bidding documents. Moreover, in the instant appeal, no evidence has been provided by the appellant which could prove that the impugned clause regarding WHO Approved / Prequalified certification was

inserted by the respondent to unfairly exclude local manufacturers or to favor specific bidders.

13. In the light of above, the Committee is of the view that the clause (WHO Approved / Prequalified certification) inserted / included by the respondent is not discriminatory in nature and has been incorporated just to meet the international standards, hence, the ground raised by the appellant is baseless. Therefore, the appeal filed by M/s Lab Diagnostic Systems (Pvt.) Limited is hereby **dismissed** being devoid of merit and disposed of accordingly.

**(Dr. Muhammad Aslam Waseem)**
Director General (Legal)
(Member)

**(Sheikh Afzaal Raza)**
Director (M&E)
(Member)

**(Hasnat Ahmed Qureshi)**
Managing Director (PPRA)
(Chairman of the Committee)

*Each page of the order has been signed by all members of the Appellate Committee. The order comprises of eight (08) pages.*